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

BAUSCH HEALTH IRELAND LIMITED
and ASSERTIO THERAPEUTICS INC.,

Plaintiffs,

v.

ZYDUS PHARMACEUTICALS (USA), INC.,

Defendant.

Civil Action No. 19-10645

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. 6,488,962 (the “’962 Patent”), 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 Zydus Pharmaceuticals (USA), Inc. (“Zydus” or “Defendant”), through the filing of Abbreviated New Drug Application (“ANDA”) No. 213028 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. Upon information and belief, defendant Zydus is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 73 Route 31 N., Pennington, New Jersey 08534. On information and belief, Zydus is in the business of developing, manufacturing, and marketing and/or selling generic pharmaceutical products for the U.S. market, including in this judicial district.

NATURE OF THE ACTION

4. 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.

5. This action arises out of Zydus filing ANDA No. 213028 (“Zydus ANDA”) including their “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 or sale of Zydus’ ANDA Products.

JURISDICTION AND VENUE

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

7. This Court has personal jurisdiction over Zydus because, *inter alia*, it has purposely availed itself of the benefits and protections of New Jersey’s laws such that it should reasonably

anticipate being hauled into court here. On information and belief, Zydus has had persistent, systematic and continuous contacts with New Jersey as set forth below.

8. Upon information and belief, Zydus is a New Jersey corporation that resides in the state of New Jersey and conducts business in the State of New Jersey.

9. Upon information and belief, Zydus 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.

10. Venue is proper in this district pursuant to 28 U.S.C. §1400 because Zydus is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 73 Route 31 N., Pennington, New Jersey 08534.

THE PATENTS-IN-SUIT

11. On December 3, 2002, the '962 Patent entitled "Tablet Shapes To Enhance Gastric Retention of Swellable Controlled-Release Oral Dosage Forms" was duly and legally issued. The named inventors of the '962 Patent are Bret Berner and Jenny Louie-Helm. The FDA's Electronic Orange Book, Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") lists the expiration of the '962 Patent as June 20, 2020. (A copy of the '962 Patent is attached as Exhibit 1.)

12. 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 2.)

13. Assertio is the assignee of the '962 Patent and '340 Patent.

14. On August 4, 2010, the '987 Patent entitled "Controlled Release Dosage Forms" was dully 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 3.)

15. On December 4, 2012, the '692 Patent entitled "Controlled Release Dosage Forms" was dully 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 4.)

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

ACTS GIVING RISE TO THIS ACTION

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

18. Pursuant to 21 U.S.C. § 355(b)(1), the '962 Patent and '340 Patent are 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.

19. On information and belief, Zydus submitted the Zydus ANDA to the FDA seeking approval to engage in the commercial manufacture, use or sale of the Zydus 500 mg product and Zydus 1 gm Product, hereinafter collectively referred to as the "Zydus ANDA Products."

20. Plaintiffs received from Zydus a letter, dated March 7, 2019, (the "Zydus Notice Letter"), stating that Zydus had included a certification in the Zydus ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '962, '340, '987 and '692 Patents are invalid, or will not be infringed by the commercial manufacture, use, or sale of the Zydus ANDA Products (the "Paragraph IV Certification").

21. The Zydus ANDA refers to and relies upon the Glumetza® NDA and contains data that, according to Zydus, demonstrate the bioequivalence of the Zydus ANDA Products and Glumetza®.

22. This action was commenced by Plaintiffs within 45 days of the date of receipt of the Zydus Notice Letter.

CLAIMS FOR RELIEF

COUNT I (Infringement of the '962 Patent)

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

24. On information and belief, Zydus has infringed at least one claim of the '962 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Zydus ANDA, by which Zydus 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 Zydus ANDA Products prior to the expiration of the '962 Patent.

25. Moreover, if Zydus manufactures, uses, sells, offers for sale, or imports into the United States the Zydus' ANDA Products, or induces or contributes to any such conduct, prior to the expiration of the '962 Patent, including any applicable exclusivities or extensions, Zydus would further infringe (either literally or under the doctrine of equivalents) at least one claim of the '962 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

26. 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 Zydus ANDA be a date that is not earlier than the expiration of the term of the '962 Patent, including any extension(s) granted by the U.S. Patent and Trademark Office ("PTO") pursuant to 35 U.S.C. §§ 154 or 156, or any

late expiration of exclusivity for the '962 Patent to which Plaintiffs are or become entitled.

27. Plaintiffs will be substantially and irreparably harmed if Zydus is not enjoined from infringing the '962 Patent.

28. Plaintiffs have no adequate remedy at law.

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

COUNT II
(Infringement of the '340 Patent)

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

31. On information and belief, Zydus has infringed at least one claim of the '340 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Zydus ANDA, by which Zydus 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 Zydus ANDA Products prior to the expiration of the '340 Patent.

32. Moreover, if Zydus manufactures, uses, sells, offers for sale, or imports into the United States the Zydus ANDA Products, or induces or contributes to any such conduct, prior to the expiration of the '340 Patent, including any applicable exclusivities or extensions, Zydus 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).

33. 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 Zydus 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 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.

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

35. Plaintiffs have no adequate remedy at law.

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

COUNT III
(Infringement the '987 Patent)

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

38. On information and belief, Zydus has infringed at least one claim of the '987 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Zydus ANDA, by which Zydus 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 Zydus ANDA Products prior to the expiration of the '987 Patent.

39. Moreover, if Zydus manufactures, uses, sells, offers for sale, or imports into the United States the Zydus ANDA Products, or induces or contributes to any such conduct, prior to the expiration of the '987 Patent, including any applicable exclusivities or extensions, Zydus 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).

40. 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 Zydus 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.

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

42. Plaintiffs have no adequate remedy at law.

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

COUNT IV
(Infringement of the '692 Patent)

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

45. On information and belief, Zydus has infringed at least one claim of the '692 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Zydus ANDA, by which Zydus 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 Zydus ANDA Products prior to the expiration of the '692 Patent.

46. Moreover, if Zydus manufactures, uses, sells, offers for sale, or imports into the United States the Zydus ANDA Products, or induces or contributes to any such conduct, prior to the expiration of the '692 Patent, including any applicable exclusivities or extensions, Zydus 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).

47. 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 Zydus 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.

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

49. Plaintiffs have no adequate remedy at law.

50. 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 Zydus has infringed one or more valid claims of the '962, '340, '987 and '692 Patents by submitting or causing to be submitted the Zydus ANDA to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Zydus' 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 Zydus, 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 Zydus ANDA Products within the United States, or importing the Zydus 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 Zydus 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 Zydus, 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 Zydus 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 prosecution 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: April 22, 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: April 22, 2019
Newark, New Jersey

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