William P. Deni, Jr.
Charles H. Chevalier
J. Brugh Lower
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Tel: (973) 596-4500
Fax: (973) 596-0545

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH HEALTH IRELAND LIMITED and ASSERTIO THERAPEUTICS INC., Plaintiffs, v. GLENMARK PHARMACEUTICALS LIMITED, Defendant.	Civil Action No. 19-12045 *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 Glenmark Pharmaceuticals Limited ("Glenmark" or "Defendant"), through the filing of Abbreviated New Drug Application ("ANDA") No. 212969 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 Glenmark is a corporation organized and existing under the laws of India with its principal place of business at Glenmark Pharmaceuticals Limited, B/2, Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai, India – 400 026.

4. On information and belief, Glenmark together with its subsidiaries, develops, manufactures, and markets pharmaceutical products in India, the United States, Latin America, 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 action arises out of Glenmark filing ANDA No. 212969 ("Glenmark 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 the Glenmark ANDA Products.

JURISDICTION AND VENUE

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

8. This Court has personal jurisdiction over Glenmark 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.

9. This Court has personal jurisdiction over Glenmark for the further reasons that, *inter alia*, Glenmark (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.

10. Upon information and belief Glenmark Generics Inc., USA ("GGI") (formerly known as Glenmark Pharmaceuticals Inc., USA), is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430.

11. Upon information and belief GGI is the North American division of Glenmark Generics Ltd., which is a wholly-owned subsidiary of Glenmark.

12. Glenmark through its subsidiaries and various agents (for example GGI) 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.

13. Upon information and belief, this Court has personal jurisdiction over Glenmark because, on information and belief, Glenmark will collaborate with GGI for the purposes of marketing and selling the Glenmark ANDA Products once approved by the FDA. Upon information and belief, Glenmark conducts business through and with GGI and Glenmark Generics

Ltd., its wholly-owned subsidiaries. Glenmark has purposefully directed activities at the State of New Jersey and this litigation relates to or arises out of those activities. Glenmark directly or through its affiliates and agents develops, formulates, synthesizes, manufactures, markets, imports, offers to sell, and/or sells pharmaceutical drug products including the Glenmark ANDA Products.

14. In the alternative, Plaintiffs are further informed and believe, and on that basis allege, that this Court has personal jurisdiction over Glenmark pursuant to Federal Rule of Civil Procedure 4(k)(2) because Glenmark 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 Glenmark is consistent with the laws of the United States and the United States Constitution.

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

THE PATENTS-IN-SUIT

16. 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.)

17. On April 20, 2004, the ’340 Patent entitled “Optimal Polymer Mixtures for Gastric Retentive Tablets” was dully 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.)

18. Assertio is the assignee of the ’962 Patent and ’340 Patent.

19. 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.)

20. 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.)

21. Bausch Ireland is the assignee of the ‘987 Patent and the ’692 Patent.

ACTS GIVING RISE TO THIS ACTION

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

23. 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.

24. On information and belief, Glenmark submitted the Glenmark ANDA to the FDA seeking approval to engage in the commercial manufacture, use or sale of the Glenmark 500 mg product and Glenmark 1000 mg Product, herein collectively referred to as the “Glenmark ANDA Products.”

25. Plaintiffs received from Glenmark a letter, dated March 18, 2019, (the “Glenmark Notice Letter”), stating that Glenmark had included a certification in the Glenmark 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 Glenmark ANDA Products (the "Paragraph IV Certification").

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

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

CLAIMS FOR RELIEF

COUNT I
(Infringement of the '962 Patent)

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

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

30. Moreover, if Glenmark manufactures, uses, sells, offers for sale, or imports into the United States, the Glenmark ANDA Products, or induces or contributes to any such conduct, prior to the expiration of the '962 Patent, including any applicable exclusivities or extensions, Glenmark 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).

31. 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 Glenmark 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.

32. Plaintiffs will be substantially and irreparably harmed if Glenmark is not enjoined from infringing the ’962 Patent.

33. Plaintiffs have no adequate remedy at law.

34. 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)

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

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

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

38. 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 Glenmark 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.

39. Plaintiffs will be substantially and irreparably harmed if Glenmark is not enjoined from infringing the ’340 Patent.

40. Plaintiffs have no adequate remedy at law.

41. 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)

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

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

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

45. 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 Glenmark 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.

46. Plaintiffs will be substantially and irreparably harmed if Glenmark is not enjoined from infringing the ’987 Patent.

47. Plaintiffs have no adequate remedy at law.

48. 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)

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

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

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

52. 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 Glenmark 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.

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

54. Plaintiffs have no adequate remedy at law.

55. 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 Glenmark has infringed one or more valid claims of the '962, '340, '987 and '692 Patents by submitting or causing to be submitted the Glenmark 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 Glenmark 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 Glenmark, 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 Glenmark ANDA Products within the United States, or importing the Glenmark 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 Glenmark 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 Glenmark, 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 Glenmark 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: May 1, 2019
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

William P. Deni, Jr.
Charles H. Chevalier
J. Brugh Lower
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Tel: (973) 596-4500
Fax: (973) 596-0545
wdeni@gibbonslaw.com
cchevalier@gibbonslaw.com
jlower@gibbonslaw.com

Attorneys for Plaintiffs

OF COUNSEL:

Thomas P. Steindler (*pro hac vice* to be submitted)
MCDERMOTT WILL & EMERY LLP
500 North Capitol Street N.W.
Washington, D.C. 20001
(202) 756-8000

Sami Sedghani (*pro hac vice* to be submitted)
MCDERMOTT WILL & EMERY LLP
415 Mission Street, Suite 5600
San Francisco, CA 94105-2533
(628) 218-3908

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: May 1, 2019
Newark, New Jersey

s/ William P. Deni, Jr.
William P. Deni, Jr.
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Tel: (973) 596-4500
Fax: (973) 596-0545
wdeni@gibbonslaw.com

Attorneys for Plaintiffs