IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

GLENMARK GENERICS LTD. and **GLENMARK GENERICS INC., USA** *Plaintiffs*, v. **SANOFI-AVENTIS U.S. LLC** and **FERRING B.V.** *Defendants*.	)	Civil Action No. _____

PLAINTIFFS GLENMARK GENERICS LTD. AND GLENMARK GENERICS INC., USA'S COMPLAINT FOR DECLARATORY JUDGMENTS OF PATENT NONINFRINGEMENT AND INVALIDITY

Plaintiffs Glenmark Generics Ltd. (individually, "Glenmark Ltd.") and Glenmark Generics Inc., USA (individually, "Glenmark USA") (collectively, "Glenmark") bring this action against Defendants Sanofi-Aventis U.S. LLC (individually, "Sanofi-Aventis U.S.") and Ferring B.V. (together, "Defendants") for a declaration that Glenmark has not infringed, does not infringe, and will not infringe any valid and enforceable claim of U.S. Patent No. 7,022,340 ("the '340 patent").

THE NATURE OF THE ACTION

1. This action is based on the patent laws of the United States, Title 35 of the United States Code. Defendants have asserted rights under the '340 patent based on Glenmark USA's filing of an Abbreviated New Drug Application ("ANDA") No. 201-831 with the United States Food and Drug Administration for approval to market generic versions of Defendants' DDAVP® Tablets (desmopressin acetate) drug product. In conjunction with the ANDA filing, Glenmark USA filed Paragraph IV Certification with respect to the '340 patent, which was and

currently is listed in the "Orange Book" with respect to Defendants' DDAVP® Tablets. FDA has tentatively approved Glenmark's ANDA product, but Glenmark cannot obtain final approval until it obtains a court decision that its product does not infringe the '340 patent or that the '340 patent is invalid or unenforceable. Glenmark is entitled by law to bring and maintain this action for declaratory judgment of patent non-infringement, unenforceability and/or invalidity under the Declaratory Judgment Act and the MMA[1] where, as here, Defendants did not sue Glenmark within 45 days of receipt of Glenmark's notice of Paragraph IV Certification as to the '340 patent, and Glenmark provided Defendants an Offer of Confidential Access to Glenmark's ANDA for its generic desmopressin acetate tablets.

THE PARTIES

2. Glenmark Ltd. is an Indian company having its principal place of business at Glenmark House, HDO-Corporate Building, Wing -A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099, Maharashtra, India. Glenmark Ltd. develops and manufactures prescription pharmaceutical drugs, including affordable, high-quality generic medicines.

3. Glenmark USA is a Delaware corporation with its principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. Glenmark USA develops and manufactures prescription pharmaceutical drugs, including affordable, high-quality generic medicines. Glenmark USA is the North American division of Glenmark Ltd.

[1] "MMA," or the "Medicare Modernization Act," refers to parts of the Hatch-Waxman Act amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), as amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2006 (2003); *see also Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278 (Fed. Cir. 2008).

4. Based on publicly available information, Sanofi-Aventis U.S. LLC is a Delaware corporation with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. On information and belief, Sanofi-Aventis U.S. LLC manufactures and sells pharmaceutical products throughout the United States, including within the State of New Jersey.

5. Based on publicly available information, Ferring B.V. is a corporation organized and existing under the laws of the Netherlands with its corporate headquarters at Polaris Avenue 144, 2132 JX Hoofddorp, The Netherlands. On information and belief, Ferring B.V. is engaged in the research, development, manufacture, and sale of pharmaceutical products.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action involves substantial claims arising under the United States Patent Act (35 U.S.C. §§ 1 *et seq.*), the Declaratory Judgment Act (28 U.S.C. §§ 2201 and 2202), and the MMA (21 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5)).

8. This Court has general personal jurisdiction over Sanofi-Aventis U.S. because it has its principal place of business in Bridgewater, New Jersey. The Court also has personal jurisdiction over Sanofi-Aventis U.S. because it regularly conducts business in, has availed itself of the rights and benefits of the laws of, and has regular and systematic contact with, the State of New Jersey. Sanofi-Aventis U.S. also has previously submitted to and availed itself of the jurisdiction of this Court by filing lawsuits in the United States District Court for the District of New Jersey. *See, e.g.*, 3:07-cv-03143, 3:07-cv-03163, 1:13-cv-06827, and 1:12-cv-04709.

9. This Court has personal jurisdiction over Ferring B.V. On information and belief, Ferring B.V. has previously submitted to the jurisdiction of this Court and availed itself of the

jurisdiction of this Court by filing lawsuits in the United States District Court for the District of New Jersey, including in cases involving the same DDAVP® (desmopressin) product at issue here. *See, e.g.*, 3:05-cv-04083 and 3:03-cv-03860. This Court also has personal jurisdiction over Ferring B.V. because it has a registered agent authorized to accept service of process in this state, located at 4 Gatehall Drive, Parsippany, NJ 07054-4518.

10. Venue is appropriate in this District under 28 U.S.C. § 1391.

THE HATCH-WAXMAN REGULATORY FRAMEWORK

11. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 217(e)).

12. Under the Hatch-Waxman Act, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by FDA. *See* 21 U.S.C. § 355. An NDA must include, *inter alia*, any patents that claim the "drug" or "method of using [the] drug" for which a claim of patent infringement could reasonably be asserted against unlicensed manufacture, use, or sale of that drug product. *See* 21 U.S.C. § 355(b)(1); *see also* 21 U.S.C. § 355(c)(2); 21 C.F.R. §§ 314.53(b), 314.53(c)(2). Upon approval of the NDA, FDA publishes a listing of patent information for the approved drug in the Orange Book. *See* 21 U.S.C. § 355(j)(7)(A)(iii).

13. Generic drugs are versions of brand-name drugs that typically contain the same active ingredients, but not necessarily the same inactive ingredients, as the brand-name original. An ANDA application for a generic drug is "abbreviated" because it is generally not required to include preclinical and clinical data, but must show, *inter alia*, that the generic drug is "bioequivalent" to the listed reference drug. *See* 21 U.S.C. § 355 (j)(4)(F).

14. An ANDA must also contain a certification to each patent listed in the Orange Book for the brand-name drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12). One such certification, a "paragraph IV" certification, asserts that the listed patent is invalid, unenforceable, or will not be infringed and, on that basis, seeks FDA approval of the generic-drug product prior to expiration of the listed patent. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

15. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and the NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(i). If the NDA holder/patent owner files an infringement suit within 45 days of receiving notice of the paragraph IV certification, FDA is not permitted to issue final approval of the generic applicant's ANDA for a period of 30 months, absent certain exceptions. *See* 21 U.S.C. § 355(j)(5)(B)(iii); *see also* 35 U.S.C. § 271(c)(2)(A).

16. The Hatch-Waxman Act provides that the first applicant to file a substantially complete ANDA containing a paragraph IV certification to an Orange Book listed patent will be eligible for a 180-day period of marketing exclusivity beginning either from the date it begins commercial marketing of its generic-drug product, or from the date of a court decision finding the listed patent invalid, unenforceable, or not infringed, whichever date is first. 21 U.S.C. § 355(j)(5)(B)(iv).

17. Either of these two events—first commercial marketing or a court decision finding the patent invalid, unenforceable, or not infringed—will trigger the beginning of the 180-day exclusivity. Conversely, if the first-filer does not begin commercial marketing of the generic drug and there is no court decision on an Orange Book-listed patent, there will be prolonged or indefinite delays in the beginning of the first applicant's 180-day exclusivity period, colloquially referred to as "bottlenecking."

18. Until an eligible first ANDA filer's 180-day exclusivity period has been triggered and expired, FDA may not approve any subsequently submitted ANDAs for the same drug, even if the subsequent ANDAs are otherwise ready for approval, a subsequent applicant is willing to begin marketing its generic-drug product immediately, and the generic-drug product does not infringe any valid and enforceable Orange Book-listed patent for the brand-name drug product.

19. To address such bottlenecking, an ANDA applicant who has filed a paragraph IV certification is statutorily entitled to institute and maintain a declaratory-judgment action against an NDA-holder/patent owner if: (1) the 45-day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor the NDA-holder brought an action for infringement of the patent within the 45-day period; and (3) the notice of paragraph IV certification contains an Offer of Confidential Access to the ANDA. 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa)-(cc); *see also Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278 (Fed. Cir. 2008).

20. By specifically allowing declaratory-judgment actions under these circumstances, Congress intended that full generic competition would not be delayed indefinitely, or blocked, by the first ANDA filer's 180-day exclusivity. A declaratory-judgment action by a subsequent ANDA applicant can result in a court decision that would trigger the first-filer's 180-day exclusivity, thereby clearing the way for approval of the subsequent-filers' bottlenecked ANDAs.

FACTUAL BACKGROUND

Defendants' DDAVP® Tablets (Desmopressin Acetate)

21. According to publicly available FDA records, Sanofi-Aventis U.S. holds the approved NDA No. 19-955 for DDAVP® Tablets.

22. DDAVP® Tablets (desmopressin acetate) are a synthetic analogue of the natural pituitary hormone 8-arginine vasopressin (ADH), an antidiuretic hormone affecting renal water conservation.

23. Defendants market and sell DDAVP® Tablets throughout the United States, including within New Jersey.

The Patent-in-Suit

24. The '340 patent issued on April 4, 2006, and is entitled "Pharmaceutical Composition as Solid Dosage Form and Method for Manufacturing Thereof." The patent will expire on April 20, 2023. A copy of the '340 patent as it is issued is attached to this Complaint as Exhibit 1.

25. USPTO records show that Ferring B.V. is the assignee of the '340 patent.

26. The '340 patent is listed in FDA's Orange Book for NDA 19-995. As a consequence of this Orange Book listing, Sanofi-Aventis U.S. has maintained and affirmatively represented to the world that the '340 patent claims the approved drug DDAVP® Tablets, or a method of using that drug, and that a claim for patent infringement could reasonably be asserted against any generic ANDA applicant, including Glenmark, that attempts to market a generic version of the DDAVP® Tablets before expiration of the '340 patent.

Glenmark's Desmopressin Acetate Tablets

27. Glenmark seeks to market a generic version of the DDAVP® Tablets before expiration of the '340 patent. Therefore, as required by the FFDCA, Glenmark USA has submitted an ANDA and certified to FDA that its ANDA product will not infringe any claim of the '340 patent and/or that this patent is invalid or unenforceable, and has further notified Sanofi-Aventis U.S. of the legal and factual basis for that certification. Glenmark's submission of the

Paragraph IV Certification to the '340 patent constitutes an artificial act of patent infringement putting Glenmark at considerable risk of being sued by Defendants both before and after Glenmark's market entry.

28. Glenmark has satisfied all substantive requirements for approval of its ANDA and is prepared to begin commercial marketing of its competing tablet formulation of desmopressin acetate promptly and well prior to the expiration of the '340 patent. However, Glenmark is being excluded from selling its Desmopressin Acetate Tablets, notwithstanding that its product does not infringe any valid or enforceable claim of the '340 patent, because Glenmark's final approval is being blocked by the eligibility to 180-day market exclusivity pursuant to 21 U.S.C. § 355(j)(5)(B)(iv) held by another, unknown ANDA applicant who was the first to submit an ANDA containing a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '340 patent.

29. A declaratory judgment from this Court as to the validity, enforceability, and/or non-infringement of the '340 patent will alleviate Glenmark's harm by allowing Glenmark to obtain final approval of its ANDA product and compete in the market for desmopressin acetate tablets.

30. Moreover, unless Glenmark obtains a court order finding the '340 patent invalid, unenforceable, or not infringed, Glenmark will be unable to market its generic product prior to patent expiration without fear of suit. Only a declaratory judgment from this Court can alleviate this harm and allow Glenmark to obtain final approval of its ANDA product and compete in the market for desmopressin acetate tablets free from such potential liability.

31. Were it not for the 180-day exclusivity bottleneck, which prevents Glenmark from obtaining final approval, Defendants would likely have sought to assert its patent rights against

Glenmark. Glenmark should be able to avoid any potential liability for infringement by obtaining a declaratory judgment of non-infringement or invalidity and thus reach the market free from such potential liability.

32. Glenmark is entitled by law to bring and maintain this action for declaratory judgment of patent non-infringement, unenforceability, and/or invalidity under the Declaratory Judgment Act and the MMA where, as here, Defendants did not sue Glenmark within 45 days of receipt of Glenmark's notice of Paragraph IV Certification as to the '340 patent, and Glenmark provided Defendants an Offer of Confidential Access to Glenmark's ANDA for its generic desmopressin acetate tablets pursuant to 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa)-(cc). Glenmark sent Defendants notice of its Paragraph IV Certification as to the '340 patent on June 8, 2010, and the notice letter included an Offer of Confidential Access to Glenmark's ANDA. Defendants did not sue Glenmark within the 45-day period following receipt of Glenmark's Paragraph IV Certification.

33. Glenmark is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of Glenmark's Desmopressin Acetate Tablets does not and will not infringe any valid or enforceable claim of the '340 patent.

34. Absent the exercise of jurisdiction by this Court and such declaratory relief, Glenmark and the American public will be irreparably harmed by the substantial delay in the market entry and availability of lower-priced DDAVP® Tablets.

35. The harm to Glenmark in this instance is compounded by the fact that a number of generic companies are already marketing desmopressin acetate tablets in the United States. This scenario, where Glenmark is blocked while other generics have received final approval, is a unique situation arising under the pre-MMA version of the Hatch Waxman act. In pertinent part,

the pre-MMA Hatch Waxman Act awards eligibility for 180-day exclusivity on a patent-by-patent basis. The first ANDA applicant to file a Paragraph IV certification against a patent receives 180-day market exclusivity based on certification to that particular patent. When more than one patent was listed in the Orange Book, a situation could arise where one ANDA filer holds 180-day exclusivity for a drug based on certification to one patent and another ANDA filer holds a separate 180-day exclusivity for the same drug based on certification to another patent. Further, where a new patent is listed in the Orange Book after a first ANDA filer has filed, received final approval, and begun marketing its generic, a subsequent filer can submit a Paragraph IV certification against the newly listed patent and block all subsequent ANDA filers from receiving final approval based on its exclusivity.[2]

36. That is exactly what has happened here. The '340 patent was listed in the Orange Book after several generic companies had already received final approval and begun marketing their desmopressin acetate tablets. An unknown ANDA filer then submitted a Paragraph IV certification against the '340 patent, receiving 180-day marketing exclusivity with respect to that patent. But the unknown filer apparently has not commenced commercial marketing and no court decision on the '340 patent has been obtained to trigger the running of the 180-day exclusivity. Thus Glenmark and subsequent ANDA filers are blocked from obtaining final approval. Only a declaratory judgment from this Court can alleviate this harm, triggering the 180-day exclusivity

[2] The 2003 MMA corrected this by providing 180-exclusivity on a product-by-product basis instead of patent-by-patent basis. But the MMA contained a grandfather provision specifying that the exclusivity amendments do not apply to Paragraph IV ANDAs filed before the date of enactment of the MMA, so-called "pre-MMA" ANDAs. *See* MMA § 1102(b). The amendments also do not apply if another generic drug company had filed a Paragraph IV ANDA for the same listed drug before the date of enactment of the MMA. *Id.* In this case, a generic drug company, Barr, filed a Paragraph IV ANDA before the December 2003 enactment of the MMA. Thus, the MMA exclusivity amendments are inapplicable to this case.

of the unknown ANDA filer, and allowing Glenmark to obtain final approval of its ANDA product and compete in the market for desmopressin acetate tablets.

37. Accordingly, there is an actual, substantial, and continuing justiciable case and controversy between Glenmark and Defendants regarding the validity, enforceability, and infringement of the '340 patent over which this Court can and should exercise jurisdiction and declare the rights of the parties. *See Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278 (Fed. Cir. 2008).

FIRST CLAIM FOR RELIEF

(Declaratory Judgment of Non-Infringement of the '340 Patent)

38. Glenmark realleges and incorporates by reference paragraphs 1 through 37, inclusive, as though fully set forth in this paragraph.

39. There is an actual, substantial, and continuing justiciable case or controversy between Defendants and Glenmark regarding the non-infringement of the '340 patent.

40. The manufacture, use, sale, offer for sale, or importation of Glenmark's Desmopressin Acetate Tablets, which is the subject of ANDA No. 201-831, has not infringed, does not infringe, and will not infringe any valid and/or enforceable claim of the '340 patent.

41. Glenmark is entitled to a declaratory judgment that it does not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '340 patent, either literally or under the doctrine of equivalents.

SECOND CLAIM FOR RELIEF

(Declaratory Judgment of Invalidity of the '340 Patent)

42. Glenmark realleges and incorporates by reference paragraphs 1 through 41, inclusive, as though fully set forth in this paragraph.

43. There is an actual, substantial, and continuing justiciable case or controversy between Defendants and Glenmark regarding the invalidity of the '340 patent.

44. The claims of the '340 patent are invalid at least for failure to comply with the requirements for patentability of Title 35 of the U.S. Code, including one or more of 35 U.S.C. §§ 101, 102, 103, and 112.

45. Glenmark is entitled to a declaratory judgment that the claims of the '340 Patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Glenmark asks this Court to enter judgment against Defendants:

A. Declaring that Glenmark Generics Ltd. does not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '340 patent, either literally or under the doctrine of equivalents;

B. Declaring that Glenmark Generics Inc., USA does not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '340 patent, either literally or under the doctrine of equivalents;

C. Declaring that all claims of the '340 patent are invalid; and

D. Awarding Glenmark such other relief as this Court deems just and proper.

Dated: April 11, 2014

By: /s/Robert J. Fettweis

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LOCAL RULE 11.2 CERTIFICATION

Plaintiffs Glenmark Generics Ltd. and Glenmark Generics Inc., USA, through their attorneys, certify that the matter in controversy is not the subject of any other action pending in any court, or any pending arbitration or administrative proceeding.

Dated: April 11, 2014

By: /s/Robert J. Fettweis

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