David E. De Lorenzi
Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Telephone: (973) 596-4500
Facsimile: (973) 596-0545

Jeffrey J. Oelke
Alison Hanstead
Laura T. Moran
WHITE & CASE LLP
1221 Avenue of the Americas
New York, New York 10020
Telephone: (212) 819-8200
Facsimile: (212) 354-8113

Attorneys for Plaintiffs Novo Nordisk Inc.
and Novo Nordisk Healthcare AG

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVO NORDISK INC. and NOVO NORDISK HEALTHCARE AG, Plaintiffs, v. GLENMARK PHARMACEUTICALS LIMITED and GLENMARK PHARMACEUTICALS INC., USA, Defendants.	Civil Action No. _____

COMPLAINT

Plaintiffs Novo Nordisk Inc. and Novo Nordisk Healthcare AG (collectively, "Plaintiffs" or "Novo Nordisk"), by their undersigned attorneys, for their Complaint against Defendants Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA (collectively, "Defendants" or "Glenmark") allege:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Glenmark's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA"), by which Glenmark seeks approval to market a generic version of Novo Nordisk's pharmaceutical product, Vagifem®, prior to the expiration of United States Patent No. 7,018,992 ("the '992 patent"), which covers, inter alia, a method for administering Vagifem®.

THE PARTIES

2. Plaintiff Novo Nordisk Inc. ("NNI") is a corporation organized and existing under the laws of Delaware, and maintains its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey, 08536.

3. Plaintiff Novo Nordisk Healthcare AG ("NNHCAG") is an entity organized and existing under the laws of Switzerland, having a place of business at Thurgauerstrasse 36-38, Zurich, Switzerland.

4. On information and belief, Glenmark Pharmaceuticals Limited ("Glenmark Ltd.") is a corporation organized and existing under the laws of India, having a principal place of business at Glenmark House, HDO-Corporate Building, Wing-A, B D Sawant Marg, Chakala, Off Western Express Highway, Andheri (E), Mumbai, Maharashtra 400099,

India. On information and belief, Glenmark Ltd. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of New Jersey and throughout the United States.

5. On information and belief, Defendant Glenmark Pharmaceuticals, Inc. USA ("Glenmark USA"), a wholly owned subsidiary and agent of Glenmark Ltd., is a corporation organized and existing under the laws of Delaware, having a principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. On information and belief, Glenmark USA is in the business of making and selling generic pharmaceutical products, which it distributes in the State of New Jersey and throughout the United States.

JURISDICTION AND VENUE

6. This 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 Glenmark by virtue of, inter alia, Glenmark's presence in New Jersey, having conducted business in New Jersey, having derived revenue from conducting business in New Jersey, previously consenting to personal jurisdiction in this Court, having filed counterclaims in this Court, and having engaged in systematic and continuous contacts with the State of New Jersey.

8. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT-IN-SUIT

9. On March 28, 2006, the United States Patent and Trademark Office issued the '992 patent, entitled "Hormone Composition," a copy of which is attached to this Complaint as Exhibit A. At the time of its issue, the '992 patent was assigned to Novo Nordisk A/S.

NNHCAG currently is the owner of all right, title, and interest in and to the '992 patent. NNI and NNHCAG are indirect, wholly owned subsidiaries of Novo Nordisk A/S.

VAGIFEM®

10. NNI holds approved New Drug Application No. 20908 ("the Vagifem® NDA") for estradiol vaginal tablets, in a 10 mcg dosage strength, which NNI sells under the trade name Vagifem®.

11. Pursuant to 21 U.S.C. §§ 355(b)(1) and 355(c)(2), and attendant FDA regulations, the '992 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Vagifem®.

GLENMARK'S ANDA

12. On information and belief, Glenmark has submitted ANDA No. 210264 ("Glenmark's ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to sell, offer to sell, use, and/or engage in the commercial manufacture of generic estradiol vaginal tablets in a 10 mcg dosage strength ("Glenmark's Product").

13. On information and belief, Glenmark's ANDA refers to and relies upon the Vagifem® NDA and contains data that, according to Glenmark, demonstrate the bioequivalence of Glenmark's Product and Vagifem®.

14. By letter to NNI and NNHCAG, dated March 31, 2017, Glenmark stated that Glenmark's ANDA contained a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '992 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Glenmark's Product (the "Paragraph IV Certification"). Glenmark attached a memorandum to its March 31, 2017 letter, in which it alleged factual and legal bases for its Paragraph IV Certification.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 7,018,992

15. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-14 of this Complaint.

16. Glenmark has infringed the '992 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Glenmark's ANDA, by which Glenmark seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Glenmark's Product prior to the expiration of the '992 patent.

17. Glenmark's sale, offer for sale, use, or commercial manufacture, of Glenmark's Product within the United States, or importation of Glenmark's Product into the United States, during the term of the '992 patent would infringe at least claims 7, 8, 9, 11, and 12 of the '992 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

18. Plaintiffs will be harmed substantially and irreparably if Glenmark is not enjoined from infringing the '992 patent.

19. Plaintiffs have no adequate remedy at law.

20. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Novo Nordisk prays for a judgment in its favor and against Glenmark and respectfully requests the following relief:

A. A judgment that Glenmark has infringed the '992 patent;

B. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Glenmark, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling

Glenmark's Product within the United States, or importing Glenmark's Product into the United States, prior to the expiration of the '992 patent, including any extensions, adjustments, and exclusivities;

C. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 210264, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), shall not be earlier than the expiration of the '992 patent, including any extensions, adjustments, and exclusivities;

D. If Glenmark commercially manufactures, uses, offers to sell, or sells Glenmark's Product within the United States, or imports Glenmark's Product into the United States, prior to the expiration of the '992 patent, including any extensions, adjustments, and exclusivities, a judgment awarding Novo Nordisk monetary relief, together with interest;

E. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such other relief as the Court deems just and proper.

Dated: May 11, 2017
Newark, New Jersey

Respectfully submitted,

By: s/ David E. De Lorenzi

David E. De Lorenzi
Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Telephone: (973) 596-4500
Facsimile: (973) 596-0545

Attorneys for Plaintiffs Novo Nordisk Inc. and Novo Nordisk Healthcare AG

OF COUNSEL:

Jeffrey J. Oelke
Alison Hanstead
Laura T. Moran
WHITE & CASE LLP
1221 Avenue of the Americas
New York, New York 10020
Telephone: (212) 819-8200
Facsimile: (212) 354-8113