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*Attorneys for Plaintiffs Novo Nordisk Inc.
and Novo Nordisk FemCare AG*

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

NOVO NORDISK INC. and
NOVO NORDISK FEMCARE AG,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS, LLC and
AMNEAL PHARMACEUTICALS OF NEW
YORK, LLC

Defendants.

Civil Action No. _____

COMPLAINT

Plaintiffs Novo Nordisk, Inc. and Novo Nordisk FemCare AG (collectively, “Novo Nordisk”), by their undersigned attorneys, for their Complaint against Defendants Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC (collectively, “Defendants” or “Amneal”) 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 Amneal’s filing of an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”), by which Amneal 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 FemCare AG (“NNFCAG”) 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, Amneal Pharmaceuticals, LLC (“Amneal Pharma”) is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 440 US Highway 22 East, Suite 104, Bridgewater, New Jersey, 08807. On information and belief, Amneal Pharma 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. On further information and belief, Amneal Pharma maintains its principal place of business in this District.

5. On information and belief, Amneal Pharmaceuticals of New York, LLC (“Amneal NY”) is a corporation organized under the laws of the State of Delaware and a subsidiary of Amneal Pharma, having its principal place of business at 85 Adams Avenue, Hauppauge, New York, 11788.

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 Amneal Pharma by virtue of, inter alia, Amneal Pharma’s presence in New Jersey, having conducted business in New Jersey and having derived substantial revenue therefrom, and having engaged in systematic and continuous contacts with the State of New Jersey.

8. This Court has personal jurisdiction over Amneal NY by virtue of, inter alia, Amneal NY having conducted business in New Jersey and having derived substantial revenue therefrom, and having engaged in systematic and continuous contacts with the State of New Jersey.

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

THE PATENT-IN-SUIT

10. On March 28, 2006, the United States Patent and Trademark Office issued the ‘992 patent,¹ entitled “Hormone Composition,” a copy of which is attached to this Complaint

¹ On October 24, 2012, NNFCAG filed a reissue application which is pending as United States Application No. 13/659,605.

as Exhibit A. At the time of its issue, the '992 patent was assigned to Novo Nordisk A/S. NNFCAG currently is the owner of all right, title, and interest in and to the '992 patent. NNI and NNFCAG are indirect, wholly owned subsidiaries of Novo Nordisk A/S.

VAGIFEM®

11. 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®.

12. 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®.

AMNEAL’S ANDA

13. On information and belief, Amneal has submitted ANDA No. 205256 (“Amneal’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 (“Amneal’s Product”).

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

15. By letter to NNI and NNFCAG, dated July 8, 2013, Amneal stated that Amneal’s ANDA contained a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '992 patent is invalid or will not be infringed by the commercial manufacture, use, or sale of Amneal’s Product (the “Paragraph IV Certification”). Amneal attached a memorandum to its July 8, 2013 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

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

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

18. Defendants' sale, offer for sale, use, or commercial manufacture, of Amneal's Product within the United States, or importation of Amneal'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).

19. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '992 patent.

20. Plaintiffs have no adequate remedy at law.

21. 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, Plaintiffs pray for a judgment in their favor and against Defendants and respectfully request the following relief:

A. A judgment that Defendants have infringed the '992 patent under 35 U.S.C. § 271(e)(2)(A);

B. A judgment that the manufacture, use, sale, or offer for sale of Amneal's Product will infringe the '992 patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

C. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Defendants, their 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 Amneal's Product within the United States, or importing Amneal's Product into the United States, prior to the expiration of the '992 patent, including any extensions;

D. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 205256, 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;

E. If Defendants commercially manufacture, use, offer to sell, or sell Amneal's Product within the United States, or import Amneal's Product into the United States, prior to the expiration of the '992 patent, including any extensions, a judgment awarding Novo Nordisk monetary relief, together with interest;

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

G. Costs and expenses in this action; and

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

Dated: August 14, 2013
Newark, New Jersey

Respectfully submitted,

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