IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK INC. and NOVO NORDISK A/S,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
MYLAN INSTITUTIONAL LLC,	)	
Defendant.	)	

COMPLAINT

Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk"), by their undersigned attorneys, for their Complaint against Defendant Mylan Institutional LLC ("Mylan"), 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 Mylan's submission of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA"), by which Mylan seeks approval to market a generic version of Novo Nordisk's pharmaceutical product Victoza® prior to the expiration of United States Patent Nos. 6,268,343 (the "'343 patent"), 7,762,994 (the "'994 patent"), 8,114,833 (the "'833 patent"), 8,579,869 (the "'869 patent"), 8,846,618 (the "'618 patent"), 9,265,893 (the "'893 patent"), and RE41,956 (the "RE '956 patent"), which cover inter alia, Victoza® and/or its use.

THE PARTIES

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

3. Plaintiff Novo Nordisk A/S ("NNAS") is an entity organized and existing under the laws of the Kingdom of Denmark, and has its principal place of business at Novo Allé, 2880 Bagsværd, Denmark. NNI is an indirect, wholly-owned subsidiary of NNAS.

4. On information and belief, Defendant Mylan Institutional LLC is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 4901 Hiawatha Drive, Rockford, Illinois 61103. On information and belief, Mylan Institutional LLC is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

THE PATENTS-IN-SUIT

5. On July 31, 2001, the United States Patent and Trademark Office issued the '343 patent, entitled "Derivatives of GLP-1 Analogs," a copy of which is attached to this Complaint as Exhibit A. NNAS is the owner of all right, title, and interest in the '343 patent.

6. On July 27, 2010, the United States Patent and Trademark Office issued the '994 patent, entitled "Needle Mounting System and a Method for Mounting a Needle Assembly," a copy of which is attached to this Complaint as Exhibit B. NNAS is the owner of all right, title, and interest in the '994 patent.

7. On February 14, 2012, the United States Patent and Trademark Office issued the '833 patent, entitled "Propylene Glycol-Containing Peptide Formulations Which Are Optimal for Production and For Use in Injection Devices," a copy of which is attached to this Complaint as Exhibit C. NNAS is the owner of all right, title, and interest in the '833 patent.

8. On November 12, 2013, the United States Patent and Trademark Office issued the '869 patent, entitled "Needle Mounting System and a Method for Mounting a Needle

Assembly," a copy of which is attached to this Complaint as Exhibit D. NNAS is the owner of all right, title, and interest in the '869 patent.

9. On September 30, 2014, the United States Patent and Trademark Office issued the '618 patent, entitled "Stable Formulation of Modified GLP-1," a copy of which is attached to this Complaint as Exhibit E. NNAS is the owner of all right, title, and interest in the '618 patent.

10. On February 23, 2016, the United States Patent and Trademark Office issued the '893 patent, entitled "Injection Button," a copy of which is attached to this Complaint as Exhibit F. NNAS is the owner of all right, title, and interest in the '893 patent.

11. On November 23, 2010, the United States Patent and Trademark Office issued the RE '956 patent, entitled "Dose Setting Limiter," a copy of which is attached to this Complaint as Exhibit G. NNAS is the owner of all right, title, and interest in the RE '956 patent.

VICTOZA®

12. NNI holds approved New Drug Application No. 022341 (the "Victoza® NDA") for Liraglutide Recombinant Solution Injection, 18 mg/3 ml (6 mg/ml), which NNI sells under the trade name Victoza®.

13. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '343, '994, '833, '869, '618, '893, and RE '956 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Victoza®.

MYLAN'S ANDA

14. On information and belief, Mylan submitted ANDA No. 213155 ("Mylan's ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market a generic version of liraglutide injection solution, 18 mg/3 ml (6 mg/ml) ("Mylan's Product").

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

16. By letter to NNI and NNAS, dated July 8, 2019 for next day delivery on July 9, 2019 (the "Notice Letter"), Mylan stated that Mylan's ANDA contained certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '343, '994, '833, '869, '618, '893, and RE '956 patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Mylan's Product (the "Paragraph IV Certifications"). Mylan attached a memorandum to the Notice Letter in which it purported to allege factual and legal bases for its Paragraph IV Certifications. NNI and NNAS file this suit within 45 days of receipt of the Notice Letter.

JURISDICTION AND VENUE

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

18. This Court has personal jurisdiction over Mylan by virtue of, inter alia, it being organized as a Delaware limited liability company; having conducted business in Delaware; being registered to do business in Delaware; having derived revenue from conducting business in Delaware; previously consenting to personal jurisdiction in this Court; having taken advantage of the rights and protections provided by this Court, including having asserted counterclaims in this jurisdiction (*see, e.g.*, *Helsinn Healthcare S.A. v. Mylan, Inc. et al*, No. 14-709 (D. Del.); *Spectrum Pharms., Inc. v. InnoPharma, Inc. et al*, No. 12-260 (D. Del.)); and having engaged in systematic and continuous contacts with the State of Delaware.

19. On information and belief, Mylan intends to sell, offer to sell, use, and/or engage in the commercial manufacture of Mylan's Product, directly or indirectly, throughout the United

States and in this District. Mylan's filing of Mylan's ANDA confirms this intention and subjects Mylan to the specific personal jurisdiction of this Court. *See Acorda Therapeutics, Inc. v. Mylan Pharms., Inc.*, 817 F.3d 755, 759-60 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 625 (2017).

20. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b). On information and belief, Mylan is an entity organized and existing under the laws of the State of Delaware. *See TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1517 (2017).

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,268,343

21. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-20 of this Complaint.

22. Mylan has infringed the '343 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Mylan's Product prior to the expiration of the '343 patent.

23. Claims 1-3 and 14 of the '343 patent encompass liraglutide; claims 28, 29, 31, 32 and 33 of the '343 patent encompass pharmaceutical compositions comprising liraglutide; and claim 39 of the '343 patent encompasses a method of treating diabetes comprising administering to a patient a therapeutically effective amount of liraglutide. In the Notice Letter, Mylan has not contested its infringement of claims 1-2, 14 or 28-40 of the '343 patent. Mylan's sale, offer for sale, use, or commercial manufacture of Mylan's Product within the United States or importation of Mylan's Product into the United States, during the term of the '343 patent would infringe at least claims 1-3, 14, 28, 29, 31, 32, 33, and 39 of the '343 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

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