IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK INC. and NOVO NORDISK A/S,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
MEITHEAL PHARMACEUTICALS, INC. and NANJING KING-FRIEND BIOCHEMICAL PHARMACEUTICAL CO., LTD.,	)	
Defendants.	)	

COMPLAINT

Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk"), by their undersigned attorneys, for their Complaint against Defendants Meitheal Pharmaceuticals, Inc. and Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd. (collectively, "Meitheal"), 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 Meitheal's submission of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA"), by which Meitheal seeks approval to market a generic version of Novo Nordisk's pharmaceutical product Victoza® prior to the expiration of United States Patent Nos. 8,114,833 (the "'833 patent") and 9,265,893 (the "'893 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 Meitheal Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 8700 W. Bryn Mawr Avenue, Suite 600S, Chicago, IL 60631. On information and belief, Meitheal Pharmaceuticals, Inc. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

5. On information and belief, Defendant Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of China, having its principal place of business at No. 1/16, Xuefu Road, Nanjing High-Tech Zone, Nanjing, 210061, China. On information and belief, Nanjing King-Friend Biochemical Pharmaceuticals Co., Ltd. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware 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 Defendant Meitheal Pharmaceuticals, Inc. by virtue of, *inter alia*, its having conducted business in Delaware; having derived revenue from conducting business in Delaware by marketing, selling, and/or distributing generic pharmaceutical drug products to residents of Delaware; having engaged in systematic and continuous contacts with the State of Delaware; having previously consented to personal jurisdiction in this Court (*see,*

e.g., *Astellas US LLC et al. v. Meitheal Pharmaceuticals, Inc*. C.A. No. 20-01182 (D. Del. Sept. 25, 2020)); and having taken advantage of the rights and protections provided by this Court, including having asserted counterclaims in this jurisdiction (*see, e.g.*, *id.*).

8. This Court has personal jurisdiction over Defendant Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd. by virtue of, *inter alia*, its having conducted business in Delaware; having derived revenue from conducting business in Delaware by marketing, selling, and/or distributing generic pharmaceutical drug products to residents of Delaware; having engaged in systematic and continuous contacts with the State of Delaware, either directly or through its affiliates and/or agents, including by marketing and/or selling pharmaceutical products in Delaware, including in this Judicial District.

9. On information and belief, Meitheal develops, manufactures, imports, markets, offers to sell, sells, and/or distributes generic pharmaceutical products throughout the United States and in this District. On information and belief, Meitheal intends to sell, offer to sell, use, and/or engage in the commercial manufacture of Meitheal's Product, directly or indirectly, throughout the United States and in this District. Meitheal's filing of ANDA No. 218115 ("Meitheal's ANDA") confirms this intention and further subjects Meitheal to the specific personal jurisdiction of this Court.

10. If Defendant Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd.'s connections with Delaware are found to be insufficient to confer personal jurisdiction, then, on information and belief, Defendant Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction and exercising jurisdiction over Defendant Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd. in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

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

THE PATENTS-IN-SUIT

12. 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 A. NNAS is the owner of all right, title, and interest in the '833 patent.

13. 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 B. NNAS is the owner of all right, title, and interest in the '893 patent.

VICTOZA®

14. 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®.

15. The claims of the patents-in-suit cover, *inter alia*, Victoza® and/or its use.

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

MEITHEAL'S ANDA

17. On information and belief, Meitheal submitted ANDA No. 218115 ("Meitheal'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) ("Meitheal's Product").

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

19. By letter to NNI and NNAS, dated September 7, 2023 (the "Notice Letter"), Meitheal stated that Meitheal's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '833 and '893 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Meitheal's Product (the "Paragraph IV Certification"). Meitheal attached a memorandum to the Notice Letter in which it purported to allege factual and legal bases for its Paragraph IV Certification. NNI and NNAS file this suit within 45 days of receipt of the Notice Letter.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,114,833

20. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-19 of this Complaint.

21. Meitheal has infringed the '833 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Meitheal's ANDA, by which Meitheal seeks approval from the FDA to manufacture, use, offer to sell, and sell Meitheal's Product prior to the expiration of the '833 patent.

22. Claims 1-15 of the '833 patent are directed to GLP-1 formulations. Claims 16-31 are directed to methods for preparing such formulations or methods of reducing deposits or reducing clogging by replacing the isotonicity agent in a formulation with propylene glycol. Meitheal's manufacture, use, offer for sale or sale of Meitheal's Product within the United States, or importation of Meitheal's Product into the United States, during the term of the '833 patent would infringe claims 1-31 of the '833 patent.

23. Novo Nordisk will be harmed substantially and irreparably if Meitheal is not enjoined from infringing the '833 patent and/or if the FDA is not enjoined from approving Meitheal's ANDA before the '833 patent expires.

24. Novo Nordisk has no adequate remedy at law.

25. Meitheal was aware of the '833 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorney's fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,265,893

26. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-25 of this Complaint.

27. Meitheal has infringed the '893 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Meitheal's ANDA, by which Meitheal seeks approval from the FDA to manufacture, use, offer to sell, and sell Meitheal's Product prior to the expiration of the '893 patent.

28. Claims 1-6 of the '893 patent are directed to a push button connection for an injection device. Meitheal's manufacture, use, offer for sale or sale of Meitheal's Product within the United States, or importation of Meitheal's Product into the United States, during the term of the '893 patent would infringe claims 1-6 of the '893 patent.

29. Novo Nordisk will be harmed substantially and irreparably if Meitheal is not enjoined from infringing the '893 patent and/or if the FDA is not enjoined from approving Meitheal's ANDA before the '893 patent expires.

30. Novo Nordisk has no adequate remedy at law.

31. Meitheal was aware of the '893 patent when it submitted its ANDA. Novo Nordisk is 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 Meitheal and respectfully requests the following relief:

A. A judgment that Meitheal has infringed the ’833 patent;

B. A judgment that Meitheal has infringed the ’893 patent;

C. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Meitheal’s ANDA, 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 ’833 and ’893 patents, including any extensions, adjustments, and exclusivities;

D. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Meitheal, 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 Meitheal’s Product within the United States, or importing Meitheal’s Product into the United States, prior to the expiration of the ’833 and ’893 patents, including any extensions, adjustments, and exclusivities;

E. If Meitheal commercially manufactures, uses, offers to sell, or sells Meitheal’s Product within the United States, or imports Meitheal’s Product into the United States, prior to the expiration of the ’833 and ’893 patents, including any extensions, adjustments, and exclusivities, a judgment awarding Novo Nordisk monetary relief, together with interest;

F. An award of attorneys’ fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

G. An award of costs and expenses in this action; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Brian P. Egan

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