IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK INC. and NOVO NORDISK A/S,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

COMPLAINT

Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk"), by their undersigned attorneys, for their Complaint against Defendant Teva Pharmaceuticals USA, Inc. ("Teva"), 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 Teva's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA"), by which Teva 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"), 8,114,833 (the "'833 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, Teva is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania, 19454. On information and belief, Teva 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 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 B. NNAS is the owner of all right, title, and interest in the '833 patent.

7. On September 30, 2012, 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 C. NNAS is the owner of all right, title, and interest in the '618 patent.

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

9. 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 E. NNAS is the owner of all right, title, and interest in the RE '956 patent.

VICTOZA®

10. 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®.

11. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '343, '833, '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®.

TEVA'S ANDA

12. On information and belief, Teva has submitted ANDA No. 210084 ("Teva's ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market a generic version of liraglutide recombinant solution injection, 18 mg/3 ml (6 mg/ml) ("Teva's Product").

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

14. By letter to NNI, dated January 20, 2017, Teva stated that Teva's ANDA contained certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '343, '833, '618, '893, and RE '956 patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Teva's Product (the "Paragraph IV Certifications"). Teva attached a memorandum to its January 20, 2017 letter, in which it alleged factual and legal bases for its Paragraph IV Certifications.

15. Novo Nordisk attempted to negotiate confidential access to Teva's ANDA prior to filing this lawsuit, pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). Because Teva imposed unacceptable restrictions on its offer of confidential access to its ANDA, Novo Nordisk was unable to review any of Teva's ANDA before filing this action. Novo Nordisk's infringement claims are therefore based on 35 U.S.C. § 271(e)(2)(A), which makes the filing of an ANDA containing a Paragraph IV certification an act of patent infringement, as well as the information presently available to Novo Nordisk.

JURISDICTION AND VENUE

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

17. This Court has personal jurisdiction over Teva by virtue of, inter alia, its presence in Delaware, being a Delaware corporation, 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, and having engaged in systematic and continuous contacts with the State of Delaware.

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

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

19. Novo Nordisk re-alleges and incorporates by reference the allegations of paragraphs 1-18 of this Complaint.

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

21. Teva's sale, offer for sale, use, or commercial manufacture of Teva's Product within the United States, or importation of Teva'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).

22. Upon information and belief, Teva's sale or offer for sale of Teva's Product within the United States, or importation of Teva's Product into the United States, or commercial marketing of Teva's Product in the United States, during the term of and with knowledge of the '343 patent, would intentionally induce others to use Teva's Product in the United States, thus inducing infringement of claim 39 of the '343 patent.

23. Novo Nordisk will be harmed substantially and irreparably if Teva is not enjoined from infringing the '343 patent.

24. Novo Nordisk has no adequate remedy at law.

25. 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.

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

26. Novo Nordisk re-alleges and incorporates by reference the allegations of paragraphs 1-18 of this Complaint.

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

28. Teva's sale, offer for sale, use, or commercial manufacture of Teva's Product within the United States, or importation of Teva's Product into the United States, during

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