IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

NOVO NORDISK INC. and NOVO NORDISK A/S,	)	
Plaintiffs,	)	
v.	)	C.A. No. 17-227-VAC-MPT
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

DEFENDANT TEVA PHARMACEUTICALS USA, INC.'s
ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

In response to the Complaint filed by Plaintiffs Novo Nordisk Inc. ("NNI") and Novo Nordisk A/S ("NNAS") (collectively, "Novo Nordisk"), Defendant Teva Pharmaceuticals USA, Inc., ("Teva") through its attorneys, hereby submits its Answer, Defenses, and Counterclaims.

ANSWER TO COMPLAINT

Each of the paragraphs below corresponds to the same-numbered paragraphs in the Complaint. Defendant denies all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that arguably follow from the admitted facts. Defendant denies that Plaintiffs are entitled to the relief requested or any other relief.

Defendant, through its attorneys, answers as follows:

NATURE OF THE ACTION

1. Defendant admits that the Complaint purports to state an action for patent infringement brought pursuant to the Patent Laws of the United States, Titles 35 of the United States Code arising from filing of an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of Victoza® prior to the expiration of U.S. Patent Nos. 6,268,343, 8,114,833, 8,846,618, 9,265,893, and RE41,956; Defendant denies the remaining allegations of paragraph 1.

THE PARTIES

2. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 2 and therefore denies same.

3. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 3 and therefore denies same.

4. Defendant does not contest personal jurisdiction over Teva for purposes of this action only. Teva admits that it is incorporated in the State of Delaware, and otherwise denies the allegations of paragraph 4.

THE PATENTS-IN-SUIT

5. Defendant admits that the face of the '343 patent lists the title as "Derivatives of GLP-1 Analogs," identifies the issue date as July 31, 2001, and that Exhibit A to the Complaint purports to be a copy of the '343 patent. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 5 and, therefore denies same.

6. Defendant admits that the face of the '833 patent lists the title as "Propylene Glycol-containing Peptide Formulations Which Are Optimal For Production and For Use in Injection Devices," identifies the issue date as February 14, 2012, and that Exhibit B to the

Complaint purports to be a copy of the '833 patent. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 6 and therefore denies same.

7. Defendant admits that the face of the '618 patent lists the title as "Stable Formulation of Modified GLP-1," identifies the issue date as September 30, 2012, and that Exhibit C to the Complaint purports to be a copy of the '618 patent. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 7 and therefore denies same.

8. Defendant admits that the face of the '893 patent lists the title as "Injection Button," identifies the issue date as February 23, 2016, and that Exhibit D to the Complaint purports to be a copy of the '893 patent. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 8 and therefore denies same.

9. Defendant admits that the face of the RE '956 patent lists the title as "Dose Setting Limiter," identifies the issue date as November 23, 2010, and that Exhibit E to the Complaint purports to be a copy of the RE '956 patent. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 9 and therefore denies same.

VICTOZA®

10. Defendant admits that the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") identifies NNI as the holder of NDA No. 022341 for Victoza®, Liraglutide Recombinant Solution Injection, 18 mg/3 ml (6 mg/ml). Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 10 and therefore denies same.

11. Defendant admits that the Orange Book appears to list the '343, '833, '618, '893, and RE '956 patents with respect to Victoza®. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 11 and therefore denies same.

TEVA'S ANDA

12. Admitted.

13. Admitted.

14. Defendant admits that Teva sent Plaintiffs a "Notification of Certification for US Patent Nos. 6,268,343; 8,114,833; 8,846,618; 9,265,893; and RE41,956 Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act" dated January 20, 2017 ("Notice Letter"). Defendant further admits that the Notice Letter represented that Teva had submitted to the FDA ANDA No. 210884 ("Teva's ANDA") and paragraph IV certifications, and admits that Teva attached a memorandum to its Notice Letter in which it alleged factual and legal bases for its paragraph IV certifications, and that the paragraph IV certifications allege that the '343, '833, '618, '893 and RE '956 are invalid and/or would not be infringed by the commercial manufacture, use or sale of the drug product described in Teva's ANDA, and denies the remaining allegations of paragraph 14.

15. Defendant admits that in its Notice Letter, Teva offered, pursuant to 21 U.S.C. § 355(j)(C)(i)(III) Confidential Access to Plaintiffs of certain information from Teva's ANDA, with certain restrictions, and on information and belief, Plaintiffs rejected that offer. Defendant denies the remaining allegations of paragraph 15.

JURISDICTION AND VENUE

16. Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendant admits that the Complaint purports to state claims

arising under the patent laws of the United States, and that this Court has subject matter jurisdiction over the action; Defendant denies the remaining allegations of paragraph 16.

17. Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, for purposes of this case only, Defendant does not contest jurisdiction in this Court; Defendant denies the remaining allegations of paragraph 17.

18. Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, for purposes of this case only, Defendant does not contest venue in this Court; Defendant denies the remaining allegations of paragraph 18.

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

19. Defendant repeats and incorporates here by reference its responses to paragraphs 1-18.

20. Defendant admits that Teva submitted ANDA No. 210084 to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market liraglutide recombinant solution injection, 18 mg/3 ml (6 mg/ml); Defendant denies the remaining allegations of paragraph 20.

21. Denied.

22. Denied

23. Denied.

24. Paragraph 24 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 24 and therefore denies same.

25. Denied.

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

26. Defendant repeats and incorporates here by reference its responses to paragraphs 1-25.

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