IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

NOVO NORDISK INC. and NOVO NORDISK A/S, Plaintiffs, v. VIATRIS INC. and MYLAN PHARMACEUTICALS INC. Defendants.	C.A. No. 1:23-cv-00013-TSK

PLAINTIFFS' ANSWER TO COUNTERCLAIMS

Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Plaintiffs"), by their undersigned attorneys, for their Answer to the counterclaims of Mylan Pharmaceuticals Inc. ("MPI") (together with Viatris Inc., the "Defendants") allege:

PARTIES

1. Plaintiffs admit, upon information and belief, based on facts alleged in MPI's Counterclaims, that MPI purports to have a principal place of business at 3711 Collins Ferry Road, Morgantown, West Virginia 26505.

2. Plaintiffs admit that, by letter to Novo Nordisk Inc. and Novo Nordisk A/S dated December 16, 2022, MPI stated that it was the owner of ANDA No. 27705 ("Defendants' ANDA"), which MPI submitted to the FDA seeking approval for semaglutide injection, 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, 1.7 mg/0.75 mL, and 2.4 mg/0.75 mL single-dose prefilled pens ("Defendants' Proposed ANDA Product"). Plaintiffs otherwise lack knowledge or

information sufficient to form a belief as to the truth of the allegations of Paragraph 2 of the counterclaims and therefore deny those allegations.

3. Plaintiffs admit the allegations of Paragraph 3.

4. Plaintiffs admit the allegations of Paragraph 4.

NATURE OF THE ACTION

5. Paragraph 5 contains conclusions of law to which no answer is required. To the extent an answer is required, Plaintiffs admit that MPI purports to seek a declaratory judgement under the patent laws, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. § 2201 et seq., that United States Patent Nos. 8,129,343 ("'343 patent"), 8,536,122 ("'122 patent"), 9,764,003 ("'003 patent"), 10,888,605 ("'605 patent"), and 11,318,191 ("'191 patent") (collectively, the "patents-in-suit") are invalid and/or not infringed. Plaintiffs deny the remaining allegations of Paragraph 5.

JURISDICTION AND VENUE

6. Paragraph 6 contains conclusions of law to which no answer is required. To the extent an answer is required, Plaintiffs do not contest that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. Paragraph 7 contains conclusions of law to which no answer is required. To the extent an answer is required, Plaintiffs do not contest that this Court has personal jurisdiction in this judicial district for the limited purpose of this action only.

8. Paragraph 8 contains conclusions of law to which no answer is required. To the extent an answer is required, Plaintiffs do not contest venue in this judicial district for the limited purpose of this action only.

9. Plaintiffs admit that an actual and justiciable controversy currently exists between Plaintiffs and Defendants as to the infringement and validity of the patents-in-suit.

BACKGROUND

10. Plaintiffs admit, on information and belief, that MPI (as an agent or alter ego of Viatris), submitted Abbreviated New Drug Application ("ANDA") No. 217705 ("Defendants' ANDA") seeking to obtain FDA approval for semaglutide injection, 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, 1.7 mg/0.75 mL, and 2.4 mg/0.75 mL single-dose prefilled pens ("Defendants' Proposed ANDA Product"). Plaintiffs otherwise lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 10 of the counterclaims and therefore denies those allegations.

11. Plaintiffs admit that NNI holds approved New Drug Application ("NDA") No. 215256 for WEGOVY® (semaglutide) injection, for subcutaneous use, administered with 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, 1.7 mg/0.75 mL and 2.4 mg/0.75 mL Pre-filled Single-dose Pens under Section 505(b) of the Federal Food Drug and Cosmetic Act ("FFDCA").

12. Plaintiffs admit that the patents in suit are listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") in connection with WEGOVY® and the related NDA No. 215256 and claim at least the drug listed in NDA No. 215256, a method of using, or a kit containing that drug.

13. Plaintiffs admit the allegations of Paragraph 13.

14. Plaintiffs admit the allegations of Paragraph 14.

15. Plaintiffs admit the allegations of Paragraph 15.

16. Plaintiffs admit the allegations of Paragraph 16.

17. Plaintiffs admit the allegations of Paragraph 17.

18. Plaintiffs admit the allegations of Paragraph 18.

19. Plaintiffs admit that Defendants' ANDA purports to provide "Paragraph IV" certifications under 21 U.S.C. §505(j)(2)(A)(vii)(IV) that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Defendants' Proposed ANDA Product. Plaintiffs deny that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Defendants' Proposed ANDA Product. Plaintiffs deny the remaining allegations of Paragraph 19.

20. Plaintiffs admit that, on December 16, 2022, MPI sent Plaintiffs a letter titled "Notice of Paragraph IV Certification Regarding U.S. Patent Nos.: 8,129,343; 8,536,122; 9,764,003; 10,888,605; and 1,318,191" ("MPI's Notice Letter") that purported to provide Plaintiffs written notice of MPI's Paragraph IV Certifications, pursuant to 21 U.S.C. § 355(j)(2)(B) and asserted that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by Defendants' ANDA or the products or activities described therein. Plaintiffs deny that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by Defendants' ANDA or the products or activities described therein. Plaintiffs deny the remaining allegations of Paragraph 20.

21. Plaintiffs admit that MPI's Notice Letter purported to include legal and factual bases for the Paragraph IV certifications included in Defendants' ANDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6). Plaintiffs deny the remaining allegations of Paragraph 21.

22. Plaintiffs admit they filed the present lawsuit alleging infringement of the patents-in-suit on January 27, 2023. The remaining allegations in Paragraph 22 contain conclusions of

law to which no answer is required. To the extent an answer is required, Plaintiffs admit that, as of the submission of Defendants' ANDA, an actual and justiciable controversy exists between Plaintiffs and Defendants as to the infringement of the patents-in-suit, including as to whether Defendants' Proposed ANDA Product would infringe, induce infringement, or contribute to the infringement of at least one valid and enforceable claim of the patents-in-suit. Plaintiffs deny the remaining allegations of Paragraph 22.

FIRST COUNTERCLAIM: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF U.S. PATENT NO. 8,129,343

23. Plaintiffs incorporate by reference the averments contained in Paragraphs 1-22 of this Answer to MPI's Counterclaims.

24. Plaintiffs deny the allegations of Paragraph 24.

25. Plaintiffs admit that they assert that Defendants' Proposed ANDA Product infringes the claims of the '343 patent and will continue to assert such infringement. Plaintiffs deny the remaining allegations of Paragraph 25.

26. Plaintiffs deny the allegations of Paragraph 26.

27. Plaintiffs admit that an actual and justiciable controversy exists between Plaintiffs and Defendants as to infringement of the '343 patent. Plaintiffs deny the remaining allegations of Paragraph 27.

28. The allegations in Paragraph 28 contain conclusions of law to which no answer is required. To the extent an answer is required, Plaintiffs deny that Defendants' Proposed ANDA Product does not infringe the claims of the '343 patent. Plaintiffs deny the remaining allegations of Paragraph 28.

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