

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

NOVO NORDISK INC. and NOVO)	
NORDISK A/S,)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 1:22-cv-23-JPB
)	
MYLAN PHARMACEUTICALS INC.,)	
)	
)	
Defendant.)	

**PLAINTIFFS’ ANSWER TO MYLAN PHARMACEUTICALS INC.’S
COUNTERCLAIMS**

Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively, “Plaintiffs”), by their undersigned attorneys, for their Answer to Mylan Pharmaceuticals Inc.’s (“Mylan”) Counterclaims allege:

Paragraphs 1 through 144 of Mylan’s Answer respond to Paragraphs 1 through 144 of Plaintiffs’ Complaint and therefore do not require a response. To the extent that a response is required, Plaintiffs incorporate by reference the allegations of Paragraphs 1 through 144 of their Complaint, and deny the allegations set forth in Mylan’s First through Forty-Second Separate Defenses.

THE PARTIES

1. Plaintiffs admit, upon information and belief, based on facts alleged in Mylan’s Counterclaims, that Mylan has 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 February 4, 2022, Mylan stated that it was the owner of ANDA No. 216991 (“Mylan’s

ANDA”), which Mylan submitted to the FDA seeking approval for semaglutide injection, 2 mg/1.5 mL (1.34 mg/mL); 4 mg/3 ml (1.34 mg/ml) (“Mylan’s Proposed ANDA Product”). Plaintiffs otherwise deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 2 of the Counterclaims and on that basis deny the allegations contained therein.

3. Plaintiffs admit the allegations contained in Paragraph 3 of the Counterclaims.

4. Plaintiffs admit the allegations contained in Paragraph 4 of the Counterclaims.

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 do not contest that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 for the limited purpose of this action only. Plaintiffs deny the Court has subject matter jurisdiction under 21 U.S.C. § 355(j)(5)(C)(ii)(I).

6. Paragraph 6 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.

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

8. Plaintiffs admit that a controversy currently exists between Plaintiffs and Mylan as to the infringement and validity of United States Patent Nos. 8,114,833 (the “833 patent”), 8,129,343 (the “343 patent”), 8,536,122 (the “122 patent”), 8,684,969 (the “969

patent”), 8,920,383 (the “383 patent”), 9,108,002 (the “002 patent”), and 9,132,239 (the “239 patent”), 9,457,154 (the “154 patent”), 9,616,180 (the “180 patent”), 9,687,611 (the “611 patent”), 9,775,953 (the “953 patent”), 9,861,757 (the “757 patent”), 10,220,155 (the “155 patent”), 10,335,462 (the “462 patent”), 10,357,616 (the “616 patent”), 10,376,652 (the “652 patent”), 11,097,063 (the “063 patent”), and RE46,363 (the “363 patent”), (collectively, the “Asserted Patents”). Plaintiffs deny the remaining allegations contained in Paragraph 8 of the Counterclaims.

9. Paragraph 9 contains conclusions of law to which no answer is required. To the extent an answer is required, Plaintiffs admit that Mylan purports to seek an order under 21 U.S.C. § 355(j)(5)(C)(ii)(I). Plaintiffs deny the remaining allegations contained in Paragraph 9 of the Counterclaims.

BACKGROUND

10. Plaintiffs admit that 21 U.S.C. § 355(b)(1) states the following:

[Applicants] shall submit to the Secretary as part of the application [...] (viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that— (I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or (II) claims a method of using such drug for which approval is sought or has been granted in the application.

Plaintiffs deny the remaining allegations contained in Paragraph 10 of the Counterclaims.

11. Plaintiffs admit that 21 C.F.R. § 314.53(b)(1) states the following:

An applicant ... must submit to its NDA the required information, on the required FDA declaration form, ... for each patent that claims the drug or a method of using the drug that is the subject of the NDA or amendment or supplement to it and with respect to which a claim of patent

infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product ... such patents consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents.

Plaintiffs deny the remaining allegations contained in Paragraph 11 of the Counterclaims.

12. Paragraph 12 contains conclusions of law to which no answer is required.

To the extent an answer is required, Plaintiffs deny the allegations contained in Paragraph 12 of the Counterclaims.

13. Plaintiffs admit that the FDA publishes the patent information from NDA applicants in the FDA publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”). Plaintiffs otherwise deny knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 13 of the Counterclaims and on that basis deny the allegations contained therein.

14. Paragraph 14 contains conclusions of law to which no answer is required, to the extent an answer is required, Plaintiffs deny the allegations contained in Paragraph 14 of the Counterclaims.

15. Plaintiffs admit that Novo Nordisk Inc. submitted patent listing information in connection with NDA No. 209637. Plaintiffs deny the remaining allegations contained in Paragraph 15 of the Counterclaims.

16. Plaintiffs admit the allegations contained in Paragraph 16 of the Counterclaims.

17. Plaintiffs admit that by letter to Novo Nordisk Inc. and Novo Nordisk A/S, dated February 4, 2022 (“Mylan’s Notice Letter”), Mylan stated that its ANDA contains certifications, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Mylan’s Paragraph IV

Certifications”), that the ’833, ’343, ’122, ’969, ’383, ’002, ’239, ’154, ’180, ’611, ’953, ’757, ’155, ’462, ’616, ’652, ’063, and ’363 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Mylan’s Proposed ANDA Product. Plaintiffs deny the remaining allegations contained in Paragraph 17 of the Counterclaims.

18. Plaintiffs admit that Mylan’s Notice Letter purports to include a statement of the legal and factual basis for Mylan’s Paragraph IV Certifications. Plaintiffs deny that the positions taken in Mylan’s Paragraph IV Certifications are correct.

19. Plaintiffs admit that Plaintiffs filed this instant lawsuit alleging infringement of the ’833, ’343, ’122, ’969, ’383, ’002, ’239, ’154, ’180, ’611, ’953, ’757, ’155, ’462, ’616, ’652, ’063, and ’363 patents. The remaining allegations in Paragraph 19 contain conclusions of law to which no answer is required. To the extent an answer is required, Plaintiffs admit that a controversy currently exists between Plaintiffs and Mylan as to the infringement of the ’833, ’343, ’122, ’969, ’383, ’002, ’239, ’154, ’180, ’611, ’953, ’757, ’155, ’462, ’616, ’652, ’063, and ’363 patents. Plaintiffs deny the remaining allegations contained in Paragraph 19 of the Counterclaims.

FIRST COUNTERCLAIM

(Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,114,833)

20. Plaintiffs hereby re-allege and incorporate by reference the averments contained in Paragraphs 1-19 of this Answer.

21. Plaintiffs admit the allegations contained in Paragraph 21 of the Counterclaims.

22. Plaintiffs deny the allegations contained in Paragraph 22 of the Counterclaims.

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