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

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

MYLAN PHARMACEUTICALS INC.'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO COMPLAINT

Mylan Pharmaceuticals Inc. ("MPI") by its undersigned attorneys, answers and responds to the Complaint for Patent Infringement of plaintiffs Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk"), as follows:

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 Mylan's submission of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA"), by which Mylan seeks approval to market a generic version of Novo Nordisk's pharmaceutical product Ozempic® prior to the expiration 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"), 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") which cover *inter alia*, Ozempic® and/or its use.

ANSWER: Paragraph 1 states a legal conclusion to which no answer is required. To the extent a response is required, MPI admits that Plaintiffs' complaint purports to bring an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq. To the extent any further answer is required, MPI admits it submitted an Abbreviated New Drug Application

("ANDA") seeking approval by the United States Food and Drug Administration ("FDA") for semaglutide injection 2 mg/1.5 mL (1.34 mg/mL); 4 mg/3 mL (1.34 mg/mL). MPI admits its ANDA was filed with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '833 patent, the '343 patent, the '122 patent, the '969 patent, the '383 patent, the '002 patent, the '239 patent, the '154 patent, the '180 patent, the '611 patent, the '953 patent, the '757 patent, the '155 patent, the '462 patent, the '616 patent, the '652 patent, the '063 patent, and the '363 patent. MPI is without knowledge or information sufficient to form a belief as to any remaining allegations set forth in paragraph 1 and, therefore, denies those allegations.

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.

ANSWER: MPI is without knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 2 and, therefore, denies those allegations.

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.

ANSWER: MPI is without knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 3 and, therefore, denies those allegations.

4. On information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. On information and belief, Mylan Pharmaceuticals Inc. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of West Virginia and throughout the United States.

ANSWER: MPI admits that it is a corporation organized and existing under the laws of the State of West Virginia. MPI admits that it develops and manufactures pharmaceutical products. MPI denies the remaining allegations set forth in paragraph 4.

JURISDICTION AND VENUE

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

ANSWER: Paragraph 5 states a legal conclusion to which no answer is required. To the extent an answer is required, MPI admits that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1131 and 1338(a).

6. This Court has personal jurisdiction over Defendant Mylan Pharmaceuticals Inc. by virtue of, *inter alia*, its presence in West Virginia, being a West Virginia corporation; and having engaged in systematic and continuous contacts with the State of West Virginia; previously consenting to personal jurisdiction in this Court; and having taken advantage of the rights and protections provided by this Court, including having asserted counterclaims in this jurisdiction (*see e.g.*, *Merck Sharp & Dohme BV v. Mylan Pharmaceuticals Inc.*, C.A. No. 20-00061 (N.D. W. Va. Apr. 2, 2020); *Celgene Corp. v. Mylan Pharmaceuticals Inc.*, C.A. No. 20-00003 (N.D. W. Va. Jan. 3, 2020)).

ANSWER: Paragraph 6 states a legal conclusion to which no answer is required. To the extent an answer is required, MPI admits that it is a corporation organized and existing under the laws of West Virginia, MPI has a principal place of business in West Virginia, and MPI does not contest personal jurisdiction in this action. MPI denies the remaining allegations set forth in paragraph 6.

7. On information and belief, Mylan intends to sell, offer to sell, use, and/or engage in the commercial manufacture of Mylan's Product, directly or indirectly, throughout the United States and in this District. Mylan's filing of Mylan's ANDA confirms this intention and further subjects Mylan to the specific personal jurisdiction of this Court.

ANSWER: Paragraph 7 states a legal conclusion to which no answer in required. To the extent an answer is required, MPI does not contest personal jurisdiction in this action. MPI denies the remaining allegations set forth in paragraph 7.

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

ANSWER: Paragraph 8 states a legal conclusion to which no answer is required. To the extent and answer is required, MPI does not contest venue in this action. MPI denies the remaining allegations set forth in paragraph 8.

THE PATENTS-IN-SUIT

9. 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.

ANSWER: MPI admits that the '833 patent is entitled "Propylene Glycol-Containing Peptide Formulations Which Are Optimal for Production and for Use in Injection Devices." MPI acknowledges that what purports to be a copy of the '833 patent was attached as Exhibit A to the Complaint. MPI is without knowledge or information sufficient to form a belief as to the remaining allegations set forth in paragraph 9 and, therefore, denies those allegations.

10. On March 6, 2012, the United States Patent and Trademark Office issued the '343 patent, entitled "Acylated GLP-1 Compounds," a copy of which is attached to this Complaint as Exhibit B. NNAS is the owner of all right, title, and interest in the '343 patent.

ANSWER: MPI admits that the '343 patent is entitled "Acylated GLP-1 Compounds." MPI acknowledges that what purports to be a copy of the '343 patent was attached as Exhibit B to the Complaint. MPI is without knowledge or information sufficient to form a belief as to the remaining allegations set forth in paragraph 10 and, therefore, denies those allegations.

11. On September 17, 2013, the United States Patent and Trademark Office issued the '122 patent, entitled "Acylated GLP-1 Compounds," a copy of which is attached to this Complaint as Exhibit C. NNAS is the owner of all right, title, and interest in the '122 patent.

ANSWER: MPI admits that the '122 patent is entitled "Acylated GLP-1 Compounds." MPI acknowledges that what purports to be a copy of the '122 patent was attached as Exhibit C to the Complaint. MPI is without knowledge or information sufficient to form a belief as to the remaining allegations set forth in paragraph 11 and, therefore, denies those allegations.

12. On April 1, 2014, the United States Patent and Trademark Office issued the '969 patent, entitled "Injection Device with Torsion Spring and Rotatable Display," a copy of which is attached to this Complaint as Exhibit D. NNAS is the owner of all right, title, and interest in the '969 patent.

ANSWER: MPI admits that the '969 patent is entitled "Injection Device with Torsion Spring and Rotatable Display." MPI acknowledges that what purports to be a copy of the '969 patent was attached as Exhibit D to the Complaint. MPI is without knowledge or information sufficient to form a belief as to the remaining allegations set forth in paragraph 12 and, therefore, denies those allegations.

13. On December 30, 2014, the United States Patent and Trademark Office issued the '383 patent, entitled "Dose Mechanism for an Injection Device for Limiting a Dose Setting Corresponding to the Amount of Medicament Left," a copy of which is attached to this Complaint as Exhibit E. NNAS is the owner of all right, title, and interest in the '383 patent.

ANSWER: MPI admits that the '383 patent is entitled "Dose Mechanism for an Injection Device for Limiting a Dose Setting Corresponding to the Amount of Medicament Left." MPI acknowledges that what purports to be a copy of the '383 patent was attached as Exhibit E to the Complaint. MPI is without knowledge or information sufficient to form a belief as to the remaining allegations set forth in paragraph 13 and, therefore, denies those allegations.

14. On August 18, 2015, the United States Patent and Trademark Office issued the '002 patent, entitled "Automatic Injection Device with a Top Release Mechanism," a copy of which is attached to this Complaint as Exhibit F. NNAS is the owner of all right, title, and interest in the '002 patent.

ANSWER: MPI admits that the '002 patent is entitled "Automatic Injection Device with a Top Release Mechanism." MPI acknowledges that what purports to be a copy of the '002 patent was attached as Exhibit F to the Complaint. MPI is without knowledge or information sufficient to form a belief as to the remaining allegations set forth in paragraph 14 and, therefore, denies those allegations.

15. On September 15, 2015, the United States Patent and Trademark Office issued the '239 patent, entitled "Dial-Down Mechanism for Wind-Up Pen," a copy of which is attached to this Complaint as Exhibit G. NNAS is the owner of all right, title, and interest in the '239 patent.

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