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.

1:24-CV-67 (Kleeh)

C.A. No. _____

COMPLAINT

Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk"), by their undersigned attorneys, for their Complaint against Defendant Mylan Pharmaceuticals Inc. ("Mylan"), 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 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. 8,129,343 (the "'343 patent") and 10,335,462 (the "'462 patent"), which cover *inter alia*, Ozempic® 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, 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 3711 Collins Ferry 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.

JURISDICTION AND VENUE

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

6. This Court has personal jurisdiction over Mylan 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.*, *Abraxis Bioscience, LLC v. Mylan Pharmaceuticals Inc.*, C.A. No. 23-cv-00033 (N.D. W. Va. Apr. 6, 2023); *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, C.A. No. 22-cv-00061 (N.D. W. Va. Aug. 2, 2022)).

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.

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

THE PATENTS-IN-SUIT

9. 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 A. NNAS is the owner of all right, title, and interest in the '343 patent.

10. On July 2, 2019, the United States Patent and Trademark Office issued the '462 patent, entitled "Use of Long-Acting GLP-1 Peptides," a copy of which is attached to this Complaint as Exhibit B. NNAS is the owner of all right, title, and interest in the '462 patent.

OZEMPIC®

11. NNI holds approved New Drug Application No. 209637 (the "Ozempic® NDA") for Ozempic® (semaglutide) subcutaneous solution, 2 mg/3 ml (0.68 mg/ml), 2 mg/1.5 ml (1.34 mg/ml), 4 mg/3 ml (1.34 mg/ml), and 8 mg/3 ml (2.68 mg/ml), which NNI sells under the trade name Ozempic®.

12. The claims of the patents-in-suit cover, *inter alia*, Ozempic® and/or its use.

13. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '343 and '462 patents, among others, are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Ozempic®.

MYLAN'S ANDA

14. On information and belief, Mylan submitted ANDA No. 219255 ("Mylan's ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market a generic version of semaglutide injection, 2 mg/3 mL (0.68 mg/mL) ("Mylan's Product").

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

16. By letter to NNI and NNAS, dated May 22, 2024 (the "Notice Letter"), Mylan stated that Mylan's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '343 and '462 patents, in addition to the '833, '969, '383, '002, '239, '154, '180, '611, '953, '757, '155, '616, '652, '063, '679, '443, and '363 patents, are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Mylan's Product (the "Paragraph IV Certification"). Mylan attached a memorandum to the Notice Letter in which it purported to allege factual and legal bases for its Paragraph IV Certification. NNI and NNAS file this suit within 45 days of receipt of the Notice Letter.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,129,343

17. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-16 of this Complaint.

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

19. Claims 1-2 and 4-5 of the '343 patent encompass semaglutide and pharmaceutical compositions comprising semaglutide. Claims 3 and 6 encompass methods of treating type 2 diabetes comprising administering to a patient an effective amount of semaglutide. Mylan's manufacture, use, offer for sale or sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, during the term of the '343 patent would infringe claims 1-6 of the '343 patent.

20. Upon information and belief, Mylan's sale or offer for sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, or commercial marketing of Mylan's Product in the United States, during the term of and with knowledge of the '343 patent, would intentionally induce others to use Mylan's Product in the United States, thus inducing infringement of claims 3 and 6 of the '343 patent.

21. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '343 patent and/or if the FDA is not enjoined from approving Mylan's ANDA before the '343 patent expires.

22. Novo Nordisk has no adequate remedy at law.

23. Mylan was aware of the '343 patent when it submitted its ANDA. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorney's fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 10,335,462

24. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-23 of this Complaint.

25. Mylan has infringed the '462 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Mylan's ANDA, by which Mylan seeks approval from the FDA to manufacture, use, offer to sell, and sell Mylan's Product prior to the expiration of the '462 patent.

26. Claims 1-10 of the '462 patent are directed to a method of treating type 2 diabetes comprising administering semaglutide to a subject in need thereof. Mylan's manufacture, use, offer for sale or sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, during the term of the '462 patent would infringe claims 1-10 of the '462 patent.

27. Upon information and belief, Mylan's sale or offer for sale of Mylan's Product within the United States, or importation of Mylan's Product into the United States, or commercial marketing of Mylan's Product in the United States, during the term of and with knowledge of the '462 patent, would intentionally induce others to use Mylan's Product in the United States, thus inducing infringement of claims 1-10 of the '462 patent.

28. Novo Nordisk will be harmed substantially and irreparably if Mylan is not enjoined from infringing the '462 patent and/or if the FDA is not enjoined from approving Mylan's ANDA before the '462 patent expires.

29. Novo Nordisk has no adequate remedy at law.

30. Mylan was aware of the '462 patent when it submitted its ANDA. 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.

PRAYER FOR RELIEF

WHEREFORE, Novo Nordisk prays for a judgment in its favor and against Mylan and respectfully requests the following relief:

A. A judgment that Mylan has infringed the '343 patent;

B. A judgment that Mylan has infringed the '462 patent;

C. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Mylan's ANDA, under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), shall not be earlier than the expiration of the '343 and '462 patents, including any extensions, adjustments, and exclusivities;

D. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Mylan, its officers, agents, servants, and employees, and those persons in active concert

or participation with any of them, from manufacturing, using, offering to sell, or selling Mylan's Product within the United States, or importing Mylan's Product into the United States, prior to the expiration of the '343 and '462 patents, including any extensions, adjustments, and exclusivities;

E. If Mylan commercially manufactures, uses, offers to sell, or sells Mylan's Product within the United States, or imports Mylan's Product into the United States, prior to the expiration of the '343 and '462 patents, including any extensions, adjustments, and exclusivities, a judgment awarding Novo Nordisk monetary relief, together with interest;

F. An award of attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

G. An award of costs and expenses in this action; and

H. Such other relief as the Court deems just and proper.

SCHRADER COMPANION DUFF & LAW, PLLC

/s/ James F. Companion
James F. Companion (#790)
Sandra K. Law (#6071)
401 Main Street
Wheeling, WV 26003
(304) 233-3390
jfc@schraderlaw.com

Attorneys for Novo Nordisk Inc. and Novo Nordisk A/S

OF COUNSEL:

Jeffrey J. Oelke
Ryan P. Johnson
Robert E. Counihan
Laura T. Moran
Vanessa Park-Thompson
Erica R. Sutter
Olivia L. Wheeling
FENWICK & WEST LLP
902 Broadway, Suite 18
New York, NY 10010-6035
(212) 430-2600

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