IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MYLAN PHARMACEUTICALS INC., Plaintiff, v. NOVO NORDISK INC. and NOVO NORDISK A/S, Defendants.	C.A. No. _____

COMPLAINT

Plaintiff Mylan Pharmaceuticals Inc. ("Mylan") brings this Complaint for declaratory judgment against Novo Nordisk Inc. ("NNI") and Novo Nordisk A/S ("NNAS") (NNI and NNAS, collectively, "Novo Nordisk") and alleges as follows:

INTRODUCTION

1. This is a declaratory judgment action seeking declarations of noninfringement and invalidity of U.S. Patent No. 12,551,536 ("the '536 patent").

2. This declaratory judgment action is related to the litigation between the parties in *Novo Nordisk Inc., et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 23-101-CFC (D. Del.).

3. Novo Nordisk caused the '536 patent to be listed with the Food and Drug Administration ("FDA") in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for Wegovy® (semaglutide) injection, 2.4 mg/0.75 mL prefilled single-dose pens in connection with New Drug Application ("NDA") No. 215256.

4. By listing the ’536 patent in the Orange Book, Novo Nordisk has represented that the ’536 patent is a patent that could “reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of” a generic version of Wegovy® (semaglutide) injection, 2.4 mg/0.75 mL prefilled single-dose pens.

5. Mylan has filed Abbreviated New Drug Application (“ANDA”) No. 217705 (“Mylan’s ANDA”) with the FDA, seeking approval to market semaglutide prefilled single-dose pens having semaglutide concentrations of 2.4 mg/0.75 mL, 1.7 mg/0.75 mL, 1.0 mg/0.5 mL, 0.5 mg/0.5 mL, and 0.25 mg/0.5 mL (“Mylan’s Proposed ANDA Products”).

6. Mylan has filed a Paragraph IV certification with the FDA stating that it believes no valid claim of the ’536 patent will be infringed by the making, using, selling, offering for sale, or importing into the United States of Mylan’s Proposed ANDA Products, and/or that the ’536 patent is invalid.

7. Because the ’536 patent is listed in the Orange Book, Novo Nordisk’s failure to initiate litigation concerning the ’536 patent within 45 days of receiving Mylan’s notice of Paragraph IV certification may impair Mylan’s ability to market Mylan’s Proposed ANDA Products upon receipt of FDA approval. Mylan thus seeks a declaratory judgment that the filing of Mylan’s ANDA did not and does not infringe the ’536 patent, that the making, using, selling, offering for sale, or importing of Mylan’s Proposed ANDA Products, upon receipt of FDA approval, would not infringe the ’536 patent, and that the ’536 patent is invalid.

PARTIES

8. Plaintiff Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia with a place of business at 3711 Collins Ferry Road, Morgantown, WV 26505.

9. On information and belief, Defendant NNI is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

10. On information and belief, Defendant NNAS is an entity organized and existing under the laws of the Kingdom of Denmark, having its principal place of business at Novo Allé, 2880 Bagsvaerd, Denmark. NNI is an indirect, wholly-owned subsidiary of NNAS.

11. On information and belief, NNI is the holder of NDA No. 215256 for Wegovy® (semaglutide) injection, for subcutaneous use, which NNI sells under the trade name Wegovy®. Under NDA No. 215256, Wegovy® is sold in at least five different prefilled single-dose pens, with semaglutide concentrations of 2.4 mg/0.75 mL, 1.7 mg/0.75 mL, 1.0 mg/0.5 mL, 0.5 mg/0.5 mL, and 0.25 mg/0.5 mL. Exhibit A (Wegovy label).

12. On information and belief, NNAS is the owner of the ’536 patent.

13. On information and belief, NNAS, itself and/or in cooperation with NNI, develops, imports, markets, sells, and distributes Wegovy® throughout the United States, including in this judicial district.

14. On information and belief, NNI, itself and/or in cooperation with NNAS, develops, imports, markets, sells, and distributes Wegovy® throughout the United States, including in this judicial district.

15. NNI, itself and/or in cooperation with NNAS, caused the ’536 patent to be listed in the Orange Book for Wegovy®.

JURISDICTION AND VENUE

16. This Complaint arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, the Federal Food, Drug and

Cosmetic Act, 21 U.S.C. § 301 *et seq.* as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355) (the Hatch-Waxman Act), and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

17. There is an actual and justiciable controversy between the parties regarding whether the filing of Mylan's ANDA constituted an act of infringement of the '536 patent and whether Mylan is free, upon approval by the FDA, to make, use, sell, offer to sell, and/or import Mylan's Proposed ANDA Products as described in Mylan's ANDA.

18. There is an actual and justiciable controversy between the parties regarding whether the '536 patent is valid.

19. This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331 and 1338(a).

20. Under 35 U.S.C. § 271(e)(5), this Court has subject matter jurisdiction under 28 U.S.C. § 2201 for a declaratory judgment that an unasserted Orange Book patent is invalid or not infringed.

21. This Court has personal jurisdiction over NNI because it is a corporation organized and existing under the laws of Delaware and maintains a registered agent for service of process in Delaware.

22. This Court has personal jurisdiction over NNI because it, upon information and belief, directly or indirectly markets and sells pharmaceutical products, including Wegovy®, throughout the United States and in this judicial district. Upon information and belief, NNI purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a destination of NNI's pharmaceutical products, including Wegovy®.

23. NNI has previously submitted to the jurisdiction of this Court and has previously availed itself of this Court by filing suit in this jurisdiction, including in co-pending action *Novo Nordisk Inc., et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 23-101-CFC (D. Del.) involving assertions of patent infringement based on the same ANDA that is the subject of this Complaint. NNI has also availed itself of this Court by filing the following suits in this jurisdiction: *Novo Nordisk Inc., et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 22-1040 (D. Del.); *Novo Nordisk Inc., et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 24-50 (D. Del.); and *Novo Nordisk Inc. et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 24-1013 (D. Del.).

24. This Court has personal jurisdiction over NNAS in this action under Fed. R. Civ. P. 4(k)(2) because, on information and belief, NNAS is organized under the laws of the Kingdom of Denmark and is not subject to any state's courts of general jurisdiction, and exercising jurisdiction over NNAS is consistent with the Constitution and laws of the United States.

25. This Court has personal jurisdiction over NNAS because, upon information and belief, NNAS is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products and directly, or through its affiliates, manufactures, markets, and sells pharmaceutical drug products, including Wegovy®, throughout the United States and in this judicial district. Upon information and belief, NNAS purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a destination of NNAS's pharmaceutical products, including Wegovy®.

26. NNAS has previously submitted to the jurisdiction of this Court and has previously availed itself of this Court by filing suit in this jurisdiction, including in co-pending action *Novo Nordisk Inc., et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 23-101-CFC (D. Del.) involving assertions of patent infringement based on the same ANDA that is the subject of this Complaint.

NNAS has also availed itself of this Court by filing the following suits in this jurisdiction: *Novo Nordisk Inc., et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 22-1040 (D. Del.); *Novo Nordisk Inc., et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 24-50 (D. Del.); and *Novo Nordisk Inc. et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 24-1013 (D. Del.).

27. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c), 1400(b), and/or 21 U.S.C. § 355.

THE ’536 PATENT

28. On its face, the ’536 patent, titled “Semaglutide in Medical Therapy,” indicates it was issued by the United States Patent and Trademark Office on February 17, 2026. A true and correct copy of the ’536 patent is attached hereto as Exhibit B.

29. On information and belief, NNAS is the owner of the ’536 patent. The ’536 patent names Maria Kabisch and Thomas Hansen as inventors. NNAS is the assignee identified on the face of the ’536 patent.

30. The ’536 patent is a continuation of application No. 18/820,792, filed on August 30, 2024, now U.S. Patent No. 12,295,988, which is a continuation of application No. 18/736,608, filed on June 7, 2024, now abandoned, which is a continuation of application No. 16/844,552, filed on April 9, 2020, now U.S. Patent No. 12,029,779 (“the ’779 patent”), which is a continuation of international application No. PCT/EP2018/077654, filed on October 10, 2018.

31. Independent claim 1 of the ’536 patent recites a method for reducing body weight of a subject in need thereof, comprising administering semaglutide subcutaneously to the subject in an amount of 2.0-10.0 mg weekly.

32. The ’536 patent is listed in the FDA’s Orange Book in connection with Wegovy® (semaglutide) injection, 2.4 mg/0.75 mL prefilled single-dose pens marketed pursuant to NDA

No. 215256. Exhibit C. The '536 patent is not listed in the Orange Book for the 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, or 1.7 mg/0.75 mL Wegovy® (semaglutide) injection prefilled single-dose pens, which Mylan's ANDA No. 217705 also seeks approval for.

33. The '536 patent is in the same patent family as the '779 patent, which is asserted by Novo Nordisk against Mylan in co-pending litigation *Novo Nordisk Inc., et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 23-101-CFC (D. Del.). The claims of the '536 patent are similar to the claims of the '779 patent, except that the '779 patent claims recite methods that include a specific 2.4 mg once-weekly dose of semaglutide and a once-weekly semaglutide dose of "about 2.4 mg," whereas the '536 patent recites a method that includes a once-weekly semaglutide dose range of 2.0-10.0 mg.

34. Although the '779 patent claims a semaglutide dose of "about 2.4 mg weekly," in *Novo Nordisk Inc., et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 23-101-CFC (D. Del.) Novo Nordisk has alleged that each concentration of Mylan's Proposed ANDA Products (2.4 mg/0.75 mL, 1.7 mg/0.75 mL, 1.0 mg/0.5 mL, 0.5 mg/0.5 mL, and 0.25 mg/0.5 mL) infringe the claims of the '779 patent. Proposed Joint Pretrial Order at 5, 12, *Novo Nordisk Inc. v. Mylan Pharms. Inc.*, C.A. No. 23-101-CFC (D. Del.), ECF No. 355. Novo Nordisk's assertions in *Novo Nordisk Inc., et al. v. Mylan Pharmaceuticals Inc.*, C.A. No. 23-101-CFC (D. Del.) reinforce that there is an actual and justiciable controversy between the parties.

BACKGROUND

35. In December 2003, Congress passed the Medicare Modernization Act of 2003. Title XI of that act, titled "Access to Affordable Pharmaceuticals," includes a provision allowing an ANDA applicant to bring a declaratory judgment action for invalidity or noninfringement of an

Orange Book-listed patent if the NDA holder does not sue within 45 days of receiving notice of a Paragraph IV certification. 21 U.S.C. § 355(j)(5)(C).

36. Under 21 U.S.C. § 355(j)(5)(C)(i)(I), no action may be brought under 28 U.S.C. § 2201 by an ANDA applicant for a declaratory judgment with respect to a patent which is the subject of a Paragraph IV certification unless: (aa) the 45-day period has expired; (bb) neither the owner of such patent nor the holder of the approved NDA brought a civil action against the applicant for infringement of the patent before the expiration of such period; and (cc) in any case in which the notice relates to noninfringement, the notice was accompanied by a document providing an offer of confidential access to the ANDA. Each of these prerequisites for seeking a declaratory judgment is met here.

37. Mylan submitted ANDA No. 217705 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act seeking approval for Mylan's Proposed ANDA Products. On November 30, 2022, Mylan received from the FDA a Paragraph IV Acknowledgment Letter for ANDA No. 217705.

38. On June 17, 2026, Mylan certified to the FDA that no valid claim of the '536 patent will be infringed by the making, use, sale, offer for sale, or importation into the United States of Mylan's Proposed ANDA Products described in ANDA No. 217705, and/or that the '536 patent is invalid.

39. On June 17, 2026, Mylan sent notice ("Mylan's Notice Letter") to NNI and NNAS of its Paragraph IV certification regarding the '536 patent, in accordance with 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. §§ 314.94 and 314.95.

40. Mylan's Notice Letter was sent via Federal Express to: (a) Novo Nordisk Inc. and Novo Nordisk A/S, Intellectual Property Dept., P.O. Box 846, 800 Scudders Mill Road,

Plainsboro, NJ 08536; (b) Novo Nordisk Inc., 800 Scudders Mill Road, Plainsboro, NJ 08536; and (c) Novo Nordisk A/S, Intellectual Property Dept., Novo Alle 1, Bagsvaerd, DK, 2880.

41. Mylan's Notice Letter included notice of its Paragraph IV certification that the '536 patent would not be infringed by the making, use, sale, offer for sale, or importation into the United States of Mylan's Proposed ANDA Products, and/or that the '536 patent is invalid.

42. Mylan's Notice Letter included a detailed statement of the factual and legal bases for Mylan's contention that the '536 patent is invalid and not infringed.

43. Mylan's Notice Letter included an offer of confidential access to the ANDA in accordance with 21 U.S.C. § 355(j)(5)(C)(i)(III).

44. Mylan's Notice Letter was delivered to Novo Nordisk Inc. at 800 Scudders Mill Road, Plainsboro, NJ 08536, on June 18, 2026, as confirmed by Federal Express proofs of delivery (tracking numbers 873217424967 and 873217734120 (Exhibits D and E)), each signed for by an individual at that Novo Nordisk location. Mylan's Notice Letter was delivered to Novo Nordisk A/S in Denmark at Intellectual Property Dept., Novo Alle 1, Bagsvaerd, DK, 2880, on June 19, 2026, as confirmed by Federal Express proof of delivery (tracking number 873218047779 (Exhibit F)) and was signed for by an individual at that Novo Nordisk location.

45. More than 45 days have elapsed since the delivery of Mylan's Notice Letter. Neither NNI nor NNAS, nor any other party, has brought a civil action against Mylan for infringement of the '536 patent within 45 days of receiving Mylan's Notice Letter.

46. Because Novo Nordisk caused the FDA to list the '536 patent in the Orange Book, Mylan has a reasonable apprehension that Novo Nordisk will sue Mylan for infringement of the '536 patent.

47. An actual, justiciable controversy exists between the parties as to the infringement and invalidity of the ’536 patent.

48. To avoid legal uncertainty and to protect its substantial investment (and anticipated future investment) in Mylan’s Proposed ANDA Products, Mylan has brought this declaratory judgment action regarding the ’536 patent.

COUNT ONE:
DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE ’536 PATENT

49. Mylan repeats and realleges each and every allegation set forth in the foregoing paragraphs as though fully set forth herein.

50. A justiciable case or controversy exists between Mylan and Novo Nordisk concerning the noninfringement of the ’536 patent, which requires a declaration of rights by this Court.

51. Mylan has satisfied all the requirements to bring a declaratory judgment action of noninfringement required by 21 U.S.C. § 355 as set forth above.

52. Mylan’s Proposed ANDA Products do not and would not infringe any valid or enforceable claim of the ’536 patent.

53. Mylan is entitled to a declaratory judgment that filing of Mylan’s ANDA did not and does not constitute an act of infringement of any valid or enforceable claim of the ’536 patent under 35 U.S.C. § 271(e)(2).

54. Mylan is entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale, or importation of Mylan’s Proposed ANDA Products would not infringe any valid or enforceable claim of the ’536 patent under 35 U.S.C. § 271.

COUNT TWO:
DECLARATORY JUDGMENT OF INVALIDITY OF THE '536 PATENT

55. Mylan repeats and realleges each and every allegation set forth in the foregoing paragraphs as though fully set forth herein.

56. A justiciable case or controversy exists between Mylan and Novo Nordisk concerning the invalidity of the '536 patent, which requires a declaration of rights by this Court.

57. Mylan has satisfied all the requirements to bring a declaratory judgment action of invalidity required by 21 U.S.C. 355, as set forth above.

58. The '536 patent is invalid for failure to meet the requirements of patentability under 35 U.S.C. § 101, *et seq.*, including without limitation 35 U.S.C. §§ 102, 103, and/or 112.

59. Mylan is entitled to a declaratory judgment that the '536 patent is invalid, including for at least the reasons set forth in Mylan's Notice Letter.

PRAYER FOR RELIEF

WHEREFORE, Mylan respectfully requests the Court to enter judgment as follows:

A. Declaring that the claims of the '536 patent are invalid;

B. Declaring that the claims of the '536 patent have not been infringed by the filing of Mylan's ANDA No. 217705;

C. Declaring that the making, using, offering for sale, sale, and/or importation of the products that are the subject of Mylan's ANDA No. 217705 have not infringed, do not infringe, and would not, if marketed, infringe or induce or contribute to the infringement by others of any claims of the '536 patent;

D. Awarding Mylan its costs, expenses, and reasonable attorney fees under 35 U.S.C. § 285; and

E. Awarding Mylan such other relief that the Court deems just and proper under the circumstances.

Dated: September 23, 2026

Respectfully submitted,

/s/ Stamatios Stamoulis

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