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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVO NORDISK INC. and NOVO NORDISK A/S, Plaintiffs, v. CIPLA LTD. and CIPLA USA, INC., Defendants.	C.A. No. _____ **(Filed Electronically)**

COMPLAINT FOR PATENT INFRINGEMENT

1. Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk"), by their undersigned attorneys, for their Complaint against Defendants Cipla Ltd. and Cipla USA, Inc. (collectively, "Cipla"), allege:

NATURE OF THE ACTION

2. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Cipla's submission of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA"), by which

Cipla seeks approval to market a generic version of Novo Nordisk's pharmaceutical product Ozempic® in dosage strengths of 2 mg/3 ml (0.68 mg/ml), 4 mg/3 ml (1.34 mg/ml), and 8 mg/3 ml (2.68 mg/ml) prior to the expiration of United States Patent Nos. 8,129,343 (the "'343 patent"), 10,335,462 (the "'462 patent"), 12,295,988 (the "'988 patent"), and 12,569,543 (the "'543 patent"), which cover, *inter alia*, Ozempic® and/or its use.

THE PARTIES

3. 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.

4. 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.

5. On information and belief, Defendant Cipla Ltd. is a corporation organized and existing under the laws of the Republic of India and has its principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai Maharashtra 400013, India. On information and belief, Cipla Ltd. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of New Jersey and throughout the United States.

6. On information and belief, Defendant Cipla USA, Inc. ("Cipla USA") is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 10 Independence Boulevard, Suite 300, Warren, NJ 07059. On information and belief, Cipla USA is in the business of making and selling generic pharmaceutical products, which it distributes in the State of New Jersey and throughout the United States.

7. On information and belief, Defendant Cipla USA is an indirect, wholly owned subsidiary of Defendant Cipla Ltd. and is controlled and/or dominated by Cipla Ltd.

8. On information and belief, Defendants Cipla Ltd. and Cipla USA acted in concert to prepare and submit ANDA No. 219719 ("Cipla's ANDA") to the FDA.

9. On information and belief, following any FDA approval of Cipla's ANDA, Defendant Cipla Ltd. will distribute and sell generic versions of semaglutide injection, 2 mg/3 ml (0.68 mg/ml), 4 mg/3 ml (1.34 mg/ml), and 8 mg/3 ml (2.68 mg/ml) (collectively, "Cipla's Product") and will act in concert with Cipla USA to distribute and sell Cipla's Product throughout the United States, including within New Jersey.

JURISDICTION AND VENUE

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

11. This Court has personal jurisdiction over Defendant Cipla USA because, upon information and belief, it has a physical presence in New Jersey; it conducts business in New Jersey; it derives revenue from conducting business in New Jersey; and it has engaged in systematic and continuous contacts with the State of New Jersey, either directly or through its affiliates and/or agents, including by marketing and/or selling pharmaceutical products in New Jersey, including in this Judicial District.

12. This Court has personal jurisdiction over Defendant Cipla Ltd. by virtue of, *inter alia*, its presence in New Jersey, its having conducted business in New Jersey; its having derived revenue from conducting business in New Jersey; its previously consenting to personal jurisdiction in this Court (*see, e.g.*, *ARS Pharms. Ops., Inc. v. Cipla Ltd.*, C.A. No. 26-03796 (D.N.J. Apr. 10, 2026)); and its having taken advantage of the rights and protections provided by this Court, including its having asserted counterclaims in this jurisdiction (*see, e.g.*, *ARS Pharms. Ops., Inc.*

v. Cipla Ltd., C.A. No. 26-03796 (D.N.J. Apr. 10, 2026); *American Regent, Inc. v. Cipla USA, Inc.*, C.A. No. 25-16422 (D.N.J. Oct. 9, 2025)).

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

14. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b). Venue is proper as to Defendant Cipla USA because Cipla USA has a regular and established place of business in New Jersey and, on information and belief, prepared and submitted Cipla's ANDA from its New Jersey headquarters. *See* 28 U.S.C. § 1400(b). Venue is proper as to Defendant Cipla Ltd. because, as "a defendant not resident in the United States," venue is proper in "any judicial district" under 28 U.S.C. § 1391(c)(3).

THE PATENTS-IN-SUIT

15. 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.

16. 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.

17. On May 13, 2025, the United States Patent and Trademark Office issued the '988 patent, entitled "Semaglutide in Medical Therapy," a copy of which is attached to this Complaint as Exhibit C. NNAS is the owner of all right, title, and interest in the '988 patent.

18. On March 10, 2026, the United States Patent and Trademark Office issued the '543 patent, entitled "Semaglutide in Cardiovascular Conditions," a copy of which is attached to this Complaint as Exhibit D. NNAS is the owner of all right, title, and interest in the '543 patent.

OZEMPIC®

19. NNI holds approved New Drug Application No. 209637 (the "Ozempic® NDA") for Ozempic® (semaglutide) subcutaneous solution, 2 mg/3 ml (0.68 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®. Ozempic® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, to reduce the risk of major cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease, and to reduce the risk of sustained eGFR decline, end-stage kidney and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney disease.

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

21. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '343, '462, and '543 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Ozempic® in dosage strengths of 2 mg/3 ml (0.68 mg/ml) and 4 mg/3 ml (1.34 mg/ml).

22. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '343, '988, and '543 patents are listed in the Orange Book with respect to Ozempic® in dosage strength 8 mg/3 ml (2.68 mg/ml).

CIPLA'S ANDA

23. On information and belief, Cipla submitted Cipla's ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market Cipla's Product, a generic version of semaglutide injection, 2 mg/3 ml (0.68 mg/ml), 4 mg/3 ml (1.34 mg/ml), and 8 mg/3 ml (2.68 mg/ml), as an

adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, to reduce the risk of major cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease, and to reduce the risk of sustained eGFR decline, end-stage kidney and cardiovascular death in adults with type 2 diabetes mellitus and chronic kidney disease.

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

25. By letter to NNI and NNAS, dated June 5, 2026 (the "Notice Letter"), Cipla stated that Cipla's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '343, '462, '988, and '543 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Cipla's Product (the "Paragraph IV Certification"). Cipla 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

26. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-25 of this Complaint.

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

28. Claims 1-2 and 4-5 of the '343 patent encompass semaglutide and pharmaceutical compositions comprising semaglutide. Claims 3 and 6 encompass a method of treating type 2 diabetes comprising administering to a patient an effective amount of semaglutide. Cipla's manufacture, use, offer for sale, or sale of Cipla's Product within the United States, or importation

of Cipla's Product into the United States, during the term of the '343 patent would infringe claims 1-6 of the '343 patent under 35 U.S.C. § 271(a).

29. Upon information and belief, Cipla's sale or offer for sale of Cipla's Product within the United States, or importation of Cipla's Product into the United States, or commercial marketing of Cipla's Product in the United States, during the term of and with knowledge of the '343 patent, would intentionally induce others to use Cipla's Product in the United States, thus inducing infringement of claims 3 and 6 of the '343 patent under 35 U.S.C. § 271(b).

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

31. Novo Nordisk has no adequate remedy at law.

32. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4)(A), including an order that the effective date of any FDA approval of Cipla's ANDA be a date that is not earlier than the expiration of the '343 patent or any later expiration of extensions, adjustments, and exclusivities for the '343 patent to which Novo Nordisk becomes entitled.

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

33. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-32 of this Complaint.

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

35. Claims 1-10 of the '462 patent are directed to methods of treating type 2 diabetes by administering a semaglutide solution. Cipla's manufacture, use, offer for sale, or sale of Cipla's Product within the United States, or importation of Cipla's Product into the United States, during

the term of the ’462 patent would infringe claims 1-10 of the ’462 patent under 35 U.S.C. § 271(a). Additionally, the use of Cipla’s Product by healthcare professionals and patients during the term of the ’462 patent would infringe claims 1-10 of the ’462 patent under 35 U.S.C. § 271(a).

36. Upon information and belief, Cipla’s sale or offer for sale of Cipla’s Product within the United States, or importation of Cipla’s Product into the United States, or commercial marketing of Cipla’s Product in the United States, during the term of and with knowledge of the ’462 patent, would intentionally induce others to use Cipla’s Product in the United States, thus inducing infringement of claims 1-10 of the ’462 patent under 35 U.S.C. § 271(b).

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

38. Novo Nordisk has no adequate remedy at law.

39. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4)(A), including an order that the effective date of any FDA approval of Cipla’s ANDA be a date that is not earlier than the expiration of the ’462 patent or any later expiration of extensions, adjustments, and exclusivities for the ’462 patent to which Novo Nordisk becomes entitled.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 12,295,988

40. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-39 of this Complaint.

41. Cipla has infringed the ’988 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Cipla’s ANDA, by which Cipla seeks approval from the FDA to manufacture, use, offer to sell, and sell Cipla’s Product prior to the expiration of the ’988 patent.

42. Claim 1 of the ’988 patent is directed to a method of treating type 2 diabetes by administering semaglutide subcutaneously. Cipla’s manufacture, use, offer for sale, or sale of

Cipla's Product within the United States, or importation of Cipla's Product into the United States, during the term of the '988 patent would infringe claim 1 of the '988 patent under 35 U.S.C. § 271(a). Additionally, the use of Cipla's Product by healthcare professionals and patients during the term of the '988 patent would infringe claim 1 of the '988 patent under 35 U.S.C. § 271(a).

43. Upon information and belief, Cipla's sale or offer for sale of Cipla's Product within the United States, or importation of Cipla's Product into the United States, or commercial marketing of Cipla's Product in the United States, during the term of and with knowledge of the '988 patent, would intentionally induce others to use Cipla's Product in the United States, thus inducing infringement of claim 1 of the '988 patent under 35 U.S.C. § 271(b).

44. Novo Nordisk will be harmed substantially and irreparably if Cipla is not enjoined from infringing the '988 patent and/or if the FDA is not enjoined from approving Cipla's ANDA before the '988 patent expires.

45. Novo Nordisk has no adequate remedy at law.

46. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4)(A), including an order that the effective date of any FDA approval of Cipla's ANDA be a date that is not earlier than the expiration of the '988 patent or any later expiration of extensions, adjustments, and exclusivities for the '988 patent to which Novo Nordisk becomes entitled.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 12,569,543

47. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-46 of this Complaint.

48. Cipla has infringed the '543 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Cipla's ANDA, by which Cipla seeks approval from the FDA to manufacture, use, offer to sell, and sell Cipla's Product prior to the expiration of the '543 patent.

49. Claims 1-13 of the ’543 patent are directed to methods of reducing the risk of a major adverse cardiovascular event in a patient having type 2 diabetes and cardiovascular disease by administering semaglutide by subcutaneous injection. Cipla’s manufacture, use, offer for sale, or sale of Cipla’s Product within the United States, or importation of Cipla’s Product into the United States, during the term of the ’543 patent would infringe claims 1-13 of the ’543 patent under 35 U.S.C. § 271(a). Additionally, the use of Cipla’s Product by healthcare professionals and patients during the term of the ’543 patent would infringe claims 1-13 of the ’543 patent under 35 U.S.C. § 271(a).

50. Upon information and belief, Cipla’s sale or offer for sale of Cipla’s Product within the United States, or importation of Cipla’s Product into the United States, or commercial marketing of Cipla’s Product in the United States, during the term of and with knowledge of the ’543 patent, would intentionally induce others to use Cipla’s Product in the United States, thus inducing infringement of claims 1-13 of the ’543 patent under 35 U.S.C. § 271(b).

51. Novo Nordisk will be harmed substantially and irreparably if Cipla is not enjoined from infringing the ’543 patent and/or if the FDA is not enjoined from approving Cipla’s ANDA before the ’543 patent expires.

52. Novo Nordisk has no adequate remedy at law.

53. Novo Nordisk seeks an order pursuant to 35 U.S.C. § 271(e)(4)(A), including an order that the effective date of any FDA approval of Cipla’s ANDA be a date that is not earlier than the expiration of the ’543 patent or any later expiration of extensions, adjustments, and exclusivities for the ’543 patent to which Novo Nordisk becomes entitled.

PRAYER FOR RELIEF

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

A. A judgment that Cipla has infringed the ’343 patent;

B. A judgment that Cipla has infringed the ’462 patent;

C. A judgment that Cipla has infringed the ’988 patent;

D. A judgment that Cipla has infringed the ’543 patent;

E. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Cipla’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, ’462, ’988, and ’543 patents, including any extensions, adjustments, and exclusivities;

F. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Cipla, 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 Cipla’s Product within the United States, or importing Cipla’s Product into the United States, prior to the expiration of the ’343, ’462, ’988, and ’543 patents, including any extensions, adjustments, and exclusivities;

G. If Cipla commercially manufactures, uses, offers to sell, or sells Cipla’s Product within the United States, or imports Cipla’s Product into the United States, prior to the expiration of the ’343, ’462, ’988, and ’543 patents, including any extensions, adjustments, and exclusivities, a judgment awarding Novo Nordisk monetary relief, together with interest;

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

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

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

Dated: July 17, 2026

By: s/ Charles M. Lizza

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LOCAL CIVIL RULES 11.2 AND 40.1 CERTIFICATION

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that this matter is related to *Novo Nordisk Inc. et al. v. Apotex Inc.*, 1:24-cv-9729 (RMB) (AMD) (D.N.J.) because it involves the same plaintiffs and involved one of the same patents.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: July 17, 2026

By: s/ Charles M. Lizza

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