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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG, Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	)	Civil Action No.:

COMPLAINT

Novartis Pharmaceuticals Corporation ("NPC") and Novartis AG (collectively "Novartis"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL" or "Defendants"). This action relates to Abbreviated New Drug Application ("ANDA") No. 218393 (the "DRL ANDA") filed by Defendants with the United States Food and Drug Administration ("FDA"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of siponimod tablets (0.25 mg, 1 mg, and 2 mg), generic versions of Novartis's MAYZENT® (siponimod) tablets[1] (collectively, the "ANDA Product"), prior to the expiration of U.S. Patent Nos. 8,492,441 ("the '441 patent") and 11,944,602 ("the '602 patent") (collectively, "the Asserted Patents").

PARTIES

A. Novartis

2. Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

3. Novartis AG is a company organized and existing under the laws of Switzerland, having a principal place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland.

[1] Novartis's MAYZENT® (siponimod) tablets are referred to as EQ 0.25 mg base, EQ 1 mg base, and EQ 2 mg base in the FDA's official publication of approved drugs (the "Orange Book"). For purposes of this complaint, Novartis will assume that DRL considers these dosages to be equivalent and will adopt DRL's nomenclature.

B. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.

4. Upon information and belief, Defendant Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500 034, India.

5. Upon information and belief, Defendant Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 107 College Road East, Princeton, NJ 08540. Upon information and belief, Defendant Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories, Ltd. *See, e.g., Impax Lab'ys, LLC v. Dr. Reddy's Lab'ys Ltd.*, C.A. No. 3:24-7875-SRC-LDW (Nov. 18, 2024) (D.I. 9 at 3).

6. Upon information and belief, the DRL Defendants are agents of each other with respect to the development, regulatory approval, marketing, sale, and/or distribution of generic products within the United States. Upon information and belief, the acts of the DRL Defendants complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of, each other.

7. Upon information and belief, DRL is a generic pharmaceutical organization that works to develop, manufacture, market, and distribute generic pharmaceutical products for sale in the State of New Jersey and throughout the United States.

DEFENDANTS' INFRINGING ACTS

8. In letter dated May 18, 2023 (the "First DRL Notice Letter"), Defendants notified Novartis (i) that Dr. Reddy's Laboratories, Inc. submitted to the FDA ANDA No. 218393, seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or

importation of siponimod tablets (0.25 mg, 1 mg, and 2 mg) in or into the United States, including New Jersey, prior to the expiration of the '441 patent and (ii) that ANDA No. 218393 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '441 patent.

9. In a letter dated March 27, 2025 (the "Second DRL Notice Letter"), Defendants notified Novartis (i) that Dr. Reddy's Laboratories, Inc. submitted to the FDA ANDA No. 218393, seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of siponimod tablets (0.25 mg, 1 mg, and 2 mg) in or into the United States, including New Jersey, prior to the expiration of the '602 patent and (ii) that ANDA No. 218393 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '602 patent.

10. Defendants have committed an act of infringement in this judicial district by filing the DRL ANDA with the intent to make, use, sell, offer for sale, and/or import the ANDA Product in or into this judicial district prior to the expiration of the Asserted Patents, an act of infringement that has led and will lead to foreseeable harm and injury to NPC, a corporation with its principal place of business in New Jersey.

11. Upon information and belief, Dr. Reddy's Laboratories, Ltd. acted in concert with and/or directed Dr. Reddy's Laboratories, Inc. in the preparation and submission of the DRL ANDA and, if the DRL ANDA is approved, will act in concert with and direct Dr. Reddy's Laboratories, Inc. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the ANDA Product in or into the United States, including New Jersey, prior to the expiration of the Asserted Patents.

12. Upon information and belief, Dr. Reddy's Laboratories, Ltd. has systematic and continuous contacts with New Jersey; has established distribution channels for drug products in

New Jersey; regularly and continuously conducts business in New Jersey, including by selling drug products in New Jersey, either directly or indirectly through its subsidiaries, agents, or affiliates, including Dr. Reddy's Laboratories, Inc.; has purposefully availed itself of the privilege of doing business in New Jersey; and derives substantial revenue from the sale of drug products in New Jersey.

13. Upon information and belief, Dr. Reddy's Laboratories, Inc. has systematic and continuous contacts with New Jersey; has established distribution channels for drug products in New Jersey; regularly and continuously conducts business in New Jersey, including by selling drug products in New Jersey, either directly or indirectly through its subsidiaries, agents, or affiliates, including Dr. Reddy's Laboratories, Ltd.; has purposefully availed itself of the privilege of doing business in New Jersey; and derives substantial revenue from the sale of drug products in New Jersey.

14. Dr. Reddy's Laboratories, Ltd. has availed itself of the legal protections of the State of New Jersey by, among other things, conceding jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey. *See, e.g.*, *Impax Lab'ys, LLC v. Dr. Reddy's Lab'ys, Ltd.*, C.A. No. 3:24-7875-SRC-LDW; *In re Selenious Acid Litigation*, C.A. No. 2:24-7791-BRM-CLW; *Vifor (Int'l) AG v. Dr. Reddy's Lab'ys, Ltd.*, C.A. No. 3:24-6833-GC-JBD.

15. Dr. Reddy's Laboratories, Inc. has availed itself of the legal protections of the State of New Jersey by, among other things, conceding jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey. *See, e.g.*, *Impax Lab'ys, LLC v. Dr. Reddy's Lab'ys, Ltd.*, C.A. No. 3:24-7875-SRC-LDW ; *In re Selenious Acid*

Litigation, C.A. No. 2:24-7791-BRM-CLW; *Vifor (Int'l) AG v. Dr. Reddy's Lab'ys, Ltd.*, C.A. No. 3:24-6833-GC-JBD.

JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

17. This Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. under Federal Rule of Civil Procedure 4(k)(2) because, upon information and belief, Dr. Reddy's Laboratories, Ltd. is organized under the laws of India and the exercise of personal jurisdiction over Dr. Reddy's Laboratories, Ltd. in any judicial district is consistent with the United States Constitution and laws.

18. This Court has personal jurisdiction over Dr. Reddy's Laboratories, Inc. because Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under New Jersey law.

19. This Court also has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. because, upon information and belief, Defendants have committed or aided, abetted, contributed to, or participated in the commission of tortious acts of patent infringement in preparing and submitting the DRL ANDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which acts will lead to foreseeable harm and injury to NPC, a corporation with its principal place of business in New Jersey.

20. Upon information and belief, the effort to seek approval for the DRL ANDA and to manufacture, import, market, and/or sell Defendants' ANDA Product upon approval has been a cooperative and joint enterprise and venture between Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.

21. This Court also has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. because, upon information and belief, Defendants will, upon approval of the DRL ANDA, market, distribute, offer for sale, and/or sell Defendants' ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of the ANDA Product in the State of New Jersey.

22. This Court also has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. because, upon information and belief, Defendants' ANDA Product, upon approval of the DRL ANDA, will be marketed, distributed, offered for sale, and/or sold in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which will have a substantial effect on New Jersey.

23. This Court also has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. because, upon information and belief, Defendants' affiliations with the State of New Jersey, including Dr. Reddy's Laboratories, Inc.'s organization or incorporation in New Jersey, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.'s availing themselves of the legal protections of the State of New Jersey, and Dr. Reddy's Laboratories, Ltd.'s ownership of and actions in concert with Dr. Reddy's Laboratories, Inc. are sufficiently continuous and systematic as to render Defendants at home in this forum.

24. Upon information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. operate as an integrated business with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products, including the ANDA Product, throughout the United States including in this judicial district.

25. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.

26. Venue is proper in this Court because Dr. Reddy's Laboratories, Inc. is organized under the laws of the State of New Jersey and therefore resides in this judicial district, and Dr. Reddy's Laboratories, Ltd. is a foreign entity who may be sued in any judicial district, including New Jersey. 28 U.S.C. §§ 1391(c)(3), 1400(b). Defendants have also previously conceded that venue is proper in New Jersey for at least the cases listed above and have conceded that venue is proper in New Jersey for purposes of the counterclaims filed in those cases.

THE PATENTS-IN-SUIT AND MAYZENT®

27. NPC is the owner of the '441 patent, titled "Dosage Regimen of an S1P Receptor Agonist." The '441 patent was duly and legally issued on July 23, 2013. A true and correct copy of the '441 patent is attached hereto as Exhibit A. The '441 patent expires on November 30, 2030, excluding any pediatric exclusivity.

28. Novartis AG is the owner of the '602 patent, titled "Treatment of Autoimmune Disease in a Patient Receiving Additionally a Beta-Blocker." The '602 patent was duly and legally issued on April 2, 2024. A true and correct copy of the '602 patent is attached hereto as Exhibit B. The '602 patent expires on July 24, 2036, excluding any pediatric exclusivity.

29. NPC is the holder of New Drug Application ("NDA") No. 209884 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of MAYZENT® (siponimod) tablets. MAYZENT® is currently indicated for the treatment of

relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

30. One or more claims of each of the Asserted Patents cover MAYZENT® and/or its use.

31. The FDA's official publication of approved drugs (the "Orange Book") lists the Asserted Patents in connection with MAYZENT®.

INFRINGEMENT OF THE ASSERTED PATENTS

FIRST COUNT FOR PATENT INFRINGEMENT ('441 PATENT)

32. Novartis realleges, and incorporates in full herein, each preceding paragraph.

33. Novartis received the First DRL Notice Letter dated May 18, 2023, purporting to include a Notice of Certification for ANDA No. 218393 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '441 patent.

34. The '441 patent claims, *inter alia*, a method of administering to a subject in need thereof a medication comprising a S1P receptor agonist, whereby said S1P receptor modulator or agonist is given at a dosage lower than the standard daily dosage of said S1P receptor modulator or agonist during the initial period of treatment and then the dosage is increased, up to the standard daily dosage of said S1P receptor agonist.

35. At least one claim, including claim 1, of the '441 patent covers FDA-approved methods of administering MAYZENT®.

36. Upon information and belief, Defendants submitted ANDA No. 218393 to the FDA, under Section 505(j) of the Act, and 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic siponimod

tablets containing 0.25 mg, 1 mg, and 2 mg siponimod tablets in or into the United States, including New Jersey. Upon information and belief, if the FDA approves ANDA No. 218393, physicians, health care providers, and/or patients will use Defendants' generic siponimod tablets according to Defendants' provided instructions and/or label and will directly infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claim 1, of the '441 patent.

37. Upon information and belief, if the FDA approves ANDA No. 218393, Defendants know and intend that physicians, health care providers, and/or patients will prescribe, administer, and/or use Defendants' generic siponimod tablets according to Defendants' provided instructions and/or label in an infringing manner, and will therefore induce infringement of at least one claim, including claim 1, of the '441 patent with the requisite intent under 35 U.S.C. § 271(b).

38. Upon information and belief, if the FDA approves ANDA No. 218393, Defendants will sell or offer to sell their generic siponimod tablets with provided instructions and/or label in an infringing manner, wherein Defendants' generic siponimod tablets are a material part of the claimed invention, wherein Defendants know that physicians will prescribe, health care providers will administer, and/or patients will use Defendants' generic siponimod tablets in accordance with Defendants' provided instructions and/or label, wherein such use will directly infringe at least one claim, including claim 1, of the '441 patent, and wherein generic siponimod tablets are not staple articles or commodities of commerce suitable for substantial noninfringing use. Upon information and belief, Defendants will thus contribute to the infringement of at least one claim, including claim 1, of the '441 patent under 35 U.S.C. § 271(c).

39. Novartis received the First DRL Notice Letter dated May 18, 2023, purporting to include a Notice of Certification for ANDA No. 218393 under 21 U.S.C. § 355(j)(2)(B) and 21

C.F.R. § 314.95 as to the ’441 patent. The First DRL Notice Letter did not allege non-infringement as to at least claim 1 of the ’441 patent.

40. Upon information and belief, Defendants had actual knowledge of the ’441 patent prior to the submission of ANDA No. 218393 to the FDA.

41. Upon information and belief, Defendants’ actions relating to Defendants’ ANDA No. 218393 complained of herein were done by and for the benefit of Defendants.

42. If Defendants’ marketing and sale of generic siponimod tablets prior to the expiration of the ’441 patent and all other relevant activities are not enjoined, Novartis will suffer substantial and irreparable harm for which there is no adequate remedy at law.

SECOND COUNT FOR PATENT INFRINGEMENT (’602 PATENT)

43. Novartis realleges, and incorporates in full herein, each preceding paragraph.

44. Novartis received the Second DRL Notice Letter dated March 27, 2025, purporting to include a Notice of Certification for ANDA No. 218393 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the ’602 patent.

45. The ’602 patent claims, *inter alia*, a method of treating an autoimmune disease in a patient comprising a) administering to said patient an initial titration regimen of siponimod; b) administering to said patient 1-15 mg siponimod daily as a maintenance regimen; and c) introducing in said patient a beta-blocker treatment the earliest at the first day when said patient is receiving the dosage of the maintenance regimen; wherein said initial titration regimen comprises administering siponimod at a dosage lower than the dosage of the maintenance regimen and then increasing the dosage stepwise up to the dosage of the maintenance regimen.

46. At least one claim, including claim 1, of the ’602 patent covers FDA-approved methods of treatment using MAYZENT®.

47. Upon information and belief, Defendants submitted ANDA No. 218393 to the FDA, under Section 505(j) of the Act, and 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic siponimod tablets containing 0.25 mg, 1 mg, and 2 mg siponimod in or into the United States, including New Jersey. Upon information and belief, if the FDA approves ANDA No. 218393, physicians, health care providers, and/or patients will use Defendants’ generic siponimod tablets according to Defendants’ provided instructions and/or label and will directly infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claim 1, of the ’602 patent.

48. Upon information and belief, if the FDA approves ANDA No. 218393, Defendants know and intend that physicians, health care providers, and/or patients will prescribe, administer, and/or use Defendants’ generic siponimod tablets according to Defendants’ provided instructions and/or label in an infringing manner, and will therefore induce infringement of at least one claim, including claim 1, of the ’602 patent with the requisite intent under 35 U.S.C. § 271(b).

49. Upon information and belief, if the FDA approves ANDA No. 218393, Defendants will sell or offer to sell their generic siponimod tablets with provided instructions and/or label in an infringing manner, wherein Defendants’ generic siponimod tablets are a material part of the claimed invention, wherein Defendants know that physicians will prescribe, health care providers will administer, and/or patients will use Defendants’ generic siponimod tablets in accordance with Defendants’ provided instructions and/or label, wherein such use will directly infringe at least one claim, including claim 1, of the ’602 patent, and wherein generic siponimod tablets are not staple

articles or commodities of commerce suitable for substantial noninfringing use. Upon information and belief, Defendants will thus contribute to the infringement of at least one claim, including claim 1, of the ’602 patent under 35 U.S.C. § 271(c).

50. Novartis received the Second DRL Notice Letter dated March 27, 2025, purporting to include a Notice of Certification for ANDA No. 218393 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the ’602 patent.

51. Upon information and belief, Defendants’ actions relating to Defendants’ ANDA No. 218393 complained of herein were done by and for the benefit of Defendants.

52. If Defendants’ marketing and sale of generic siponimod tablets prior to the expiration of the ’602 patent and all other relevant activities are not enjoined, Novartis will suffer substantial and irreparable harm for which there is no adequate remedy at law.

53. This action was commenced within 45 days of Novartis’s receipt of the Second DRL Notice Letter.

PRAYER FOR RELIEF

WHEREFORE, Novartis prays that this Court grant the following relief:

54. Judgment that Defendants Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories, Inc. have infringed one or more claims of each of the Asserted Patents by filing ANDA No. 218393;

55. A permanent injunction restraining and enjoining Defendants, and their affiliates, subsidiaries, and each of their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale, or offer for sale in

the United States, or importation into the United States, of the ANDA Product until the expiration of the Asserted Patents, inclusive of any extensions and additional periods of exclusivity;

56. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 218393 shall be a date that is not earlier than the latest to expire of the '441 and '602 patents, inclusive of any extensions and additional periods of exclusivity;

57. Declaratory judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of the ANDA Product will directly infringe, induce infringement of, and/or contributorily infringe one or more claims of each of the Asserted Patents;

58. Damages or other monetary relief from Defendants for the infringement, inducement of infringement, and/or contributory infringement of each of the Asserted Patents if one or both of the Defendants engage in the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the ANDA Product prior to the latest expiration date of the '441 and '602 patents, inclusive of any extensions and additional periods of exclusivity;

59. A declaration that this case is an exceptional case pursuant to 35 U.S.C. § 285 and an award of attorney's fees;

60. Novartis's costs and expenses in this action; and

61. Such other and further relief as the Court may deem just and proper.

Dated: May 14, 2025

MCCARTER & ENGLISH, LLP

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LOCAL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy involves the same drug and patents that are at issue in the following actions currently pending in the District of Delaware:

- *Novartis Pharmaceuticals Corporation et al v. Lupin Limited et al.*, Civil Action No. 25-578, concerning infringement of U.S. Patent No. 8,492,441 and U.S. Patent No. 11,944,602.
- *Novartis Pharmaceuticals Corporation et al v. Cipla Limited et al.*, Civil Action No. 25-186, concerning infringement of U.S. Patent No. 8,492,441 and U.S. Patent No. 11,944,602.

The Defendants in this matter are not involved in these cases.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: May 14, 2025

MCCARTER & ENGLISH, LLP

/s/ Cynthia S. Betz

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