IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. LUPIN INC., LUPIN ATLANTIS HOLDINGS, S.A., LUPIN LIMITED, LUPIN PHARMACEUTICALS, INC., Defendants.	)	C.A. No. _____

COMPLAINT

Novartis Pharmaceuticals Corporation ("Novartis"), by its attorneys, hereby alleges as follows:

NATURE OF THE ACTION

1. This is a patent infringement action arising under Title 35 of the United States Code and concerning an Abbreviated New Drug Application ("ANDA") submitted to the United States Food and Drug Administration ("FDA") by the above-named defendants Lupin Inc., Lupin Atlantis Holdings, S.A., Lupin Limited, and Lupin Pharmaceuticals, Inc. ("collectively, Lupin") seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of sacubitril/valsartan tablets, generic versions of Novartis's ENTRESTO® tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg, prior to the expiration of U.S. Patent Nos. 8,101,659 ("the '659 patent") and 11,096,918 ("the '918 patent") ("Lupin ANDA Products").

2. This is the fourth complaint Novartis has filed against Lupin in connection with ANDA No. 213808. The three prior cases, filed in response to notice letters sent by Lupin to

Novartis in 2019, 2020, and 2021, were dismissed as to Lupin pursuant to a stipulation between the parties, so ordered on February 9, 2022. 19-1979, D.I. 376; 20-415, D.I. 119; 21-229, D.I. 39. In that stipulation, Lupin stipulated that its ANDA Products, if approved, would infringe the '659 patent, including during the extension of its patent term pursuant to 35 U.S.C. § 156. Novartis and Lupin also agreed to be bound by any judgment concerning the validity of the '659 patent entered by the United States Court of Appeals for the Federal Circuit. Novartis's and Lupin's claims and counterclaims were dismissed without prejudice.

3. This fourth complaint is being filed in response to a notice letter dated August 5, 2024 ("August 5, 2024 Lupin Notice Letter"). The August 5, 2024 Lupin Notice Letter represents that Lupin Inc. filed a Paragraph IV certification against the '659 patent in connection with ANDA No. 213808.

4. This fourth complaint alleges infringement by Lupin of the '659 and '918 patents by seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of sacubitril/valsartan tablets, generic versions of Novartis's ENTRESTO® tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg, prior to the expiration of the '659 and '918 patents.

PARTIES

A. Novartis

5. Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business in East Hanover, New Jersey.

B. Lupin Defendants

6. On information and belief, Lupin Inc. is a corporation organized and existing under the laws of the State of Delaware, having a registered agent for the service of process at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801, and having a principal place of business at 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. On information and belief, Lupin Inc. is a wholly owned subsidiary of Lupin Atlantis Holdings, S.A.

7. On information and belief, Lupin Atlantis Holdings, S.A. is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Landis+Gyr-Strasse 1, 6300 Zug, Switzerland. On information and belief, Lupin Atlantis Holdings, S.A. is a wholly owned subsidiary of Lupin Limited.

8. On information and belief, Lupin Limited is a corporation organized and existing under the laws of India, having a principal place of business at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India.

9. On information and belief, Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a registered agent for the service of process at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801, and having a principal place of business at 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. On information and belief, Lupin Pharmaceuticals, Inc. is a subsidiary owned jointly by Lupin Inc. and Lupin Limited.

10. On information and belief, Lupin Inc. develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

11. On information and belief, Lupin Atlantis Holdings, S.A. develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

12. On information and belief, Lupin Limited develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

13. On information and belief, Lupin Pharmaceuticals, Inc. develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

14. On information and belief, ANDA No. 213808 was originally filed by Lupin Atlantis Holdings, S.A.

15. On information and belief, on February 22, 2023, Lupin Inc. replaced Lupin Atlantis Holdings, S.A. as the applicant for ANDA No. 213808.

16. Lupin Inc. has committed an act of infringement in this judicial district by filing ANDA No. 213808 with the intent to make, use, sell, offer for sale, and/or import the Lupin ANDA Products in or into this judicial district, prior to the expiration of the ’659 and ’918 patents, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

17. Lupin Atlantis Holdings, S.A. has committed an act of infringement in this judicial district by filing ANDA No. 213808 with the intent to make, use, sell, offer for sale, and/or import the Lupin ANDA Products in or into this judicial district, prior to the expiration of the ’659 and ’918 patents, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

18. On information and belief, Lupin Limited acted in concert with and directed Lupin Inc. and/or Lupin Atlantis Holdings, S.A. in the preparation and submission of ANDA No. 213808, and, if the ANDA is approved, will act in concert with and direct Lupin Inc. and/or Lupin Atlantis Holdings, S.A. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659 and '918 patents.

19. On information and belief, Lupin Pharmaceuticals, Inc. acted in concert with and under the direction of Lupin Inc., Lupin Atlantis Holdings, S.A., and/or Lupin Limited in the preparation and submission of ANDA No. 213808, and, if the ANDA is approved, will act in concert with and under the direction of Lupin Inc., Lupin Atlantis Holdings, S.A., and/or Lupin Limited to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659 and '918 patents.

20. Lupin Inc. and/or Lupin Atlantis Holdings, S.A., by itself or together with Lupin Limited, and/or Lupin Pharmaceuticals, Inc., has taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Lupin ANDA Products, that will be purposefully directed at Delaware and elsewhere.

21. On information and belief, Lupin Atlantis Holdings, S.A. has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates, including Lupin Inc. and Lupin Pharmaceuticals, Inc.; has purposefully availed itself of the

privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

22. On information and belief, Lupin Limited has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates, including Lupin Inc., Lupin Atlantis Holdings, S.A., and Lupin Pharmaceuticals, Inc.; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

23. Lupin Inc., Lupin Atlantis Holdings, S.A., and Lupin Limited have availed themselves of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Keryx Biopharmaceuticals, Inc. v. Lupin Ltd.*, C.A. No. 18-1968 (D. Del.); *Ferring Pharm. Inc. v. Lupin Inc.*, C.A. No. 19-913 (D. Del.); *Boehringer Ingelheim Pharm. Inc. v. Lupin Ltd.*, C.A. No. 19-1497 (D. Del.); *Novartis Pharm. Corp. v. Alkem Labs. Ltd.*, C.A. No. 19-1979 (D. Del.); *Novartis Pharmaceuticals Corporation v. Lupin Atlantis Holdings, S.A.*, C.A. No. 20-415 (D. Del.); and *Novartis Pharmaceuticals Corporation v. Lupin Atlantis Holdings, S.A.*, C.A. No. 21-229 (D. Del.).

24. Lupin Atlantis Holdings, S.A., the entity identified in the August 5, 2024 Lupin Notice Letter as having originally submitted ANDA No. 213808, has agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213808 in the District of Delaware, and has agreed, only for the purposes of such action(s), not to challenge personal jurisdiction and venue in the District of Delaware.

JURISDICTION AND VENUE

25. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

26. This Court has personal jurisdiction over Lupin Inc., Lupin Atlantis Holdings, S.A., Lupin Limited, and Lupin Pharmaceuticals, Inc. because, on information and belief, each such Defendant has committed or has aided, abetted, contributed to, or participated in the commission of tortious acts of patent infringement in preparing and submitting ANDA No. 213808 with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which acts have led to foreseeable harm and injury to Novartis, a Delaware corporation.

27. This Court also has personal jurisdiction over Lupin Inc., Lupin Atlantis Holdings, S.A., Lupin Limited, and Lupin Pharmaceuticals, Inc. because, on information and belief, each such Defendant, upon approval of ANDA No. 213808, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213808 that will be purposefully directed at Delaware, including the marketing of the Lupin ANDA Products in Delaware, prior to the expiration of the ’659 and ’918 patents.

28. This Court also has personal jurisdiction over Lupin Inc., Lupin Atlantis Holdings, S.A., Lupin Limited, and Lupin Pharmaceuticals, Inc. because, on information and belief, each such Defendant’s affiliations with the State of Delaware, including Lupin Inc.’s and Lupin Pharmaceuticals, Inc.’s incorporation in Delaware, Lupin Atlantis Holdings, S.A.’s ownership of and actions in concert with Lupin Inc., and Lupin Limited’s and Lupin Inc.’s ownership of and actions in concert with Lupin Pharmaceuticals, Inc., are sufficiently continuous and systematic as to render each such Defendant essentially at home in this forum.

29. This Court also has personal jurisdiction over Lupin Inc., Lupin Atlantis Holdings, S.A., and Lupin Limited, because each has availed itself of the legal protections of the State of Delaware, by admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Keryx Biopharmaceuticals, Inc. v. Lupin Ltd.*, C.A. No. 18-1968 (D. Del.); *Ferring Pharm. Inc. v. Lupin Inc.*, C.A. No. 19-913 (D. Del.); *Boehringer Ingelheim Pharm. Inc. v. Lupin Ltd.*, C.A. No. 19-1497 (D. Del.); *Novartis Pharm. Corp. v. Alkem Labs. Ltd.*, C.A. No. 19-1979 (D. Del.); *Novartis Pharmaceuticals Corporation v. Lupin Atlantis Holdings, S.A.*, C.A. No. 20-415 (D. Del.); and *Novartis Pharmaceuticals Corporation v. Lupin Atlantis Holdings, S.A.*, C.A. No. 21-229 (D. Del.).

30. Lupin Atlantis Holdings, S.A., the entity identified in the August 5, 2024 Lupin Notice Letter as having originally submitted ANDA No. 213808, has agreed with Novartis to litigate this action in the District of Delaware and not to contest personal jurisdiction or venue in the District of Delaware in this action.

31. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Lupin Inc., Lupin Atlantis Holdings, S.A., Lupin Limited, and Lupin Pharmaceuticals, Inc.

32. Venue is proper in this Court because Lupin Inc. and Lupin Pharmaceuticals, Inc. are incorporated in the State of Delaware and therefore reside in this judicial district, and Lupin Atlantis Holdings, S.A. and Lupin Limited are foreign entities who may be sued in any judicial district, including Delaware. 28 U.S.C. § 1400(b); 28 U.S.C. § 1391(c)(3).

THE PATENTS-IN-SUIT AND ENTRESTO®

33. Novartis is the owner of the '659 patent, titled "Methods of treatment and pharmaceutical composition." The '659 patent was duly and legally issued on January 24, 2012. A true and correct copy of the '659 patent is attached hereto as Exhibit A.

34. The '659 patent claims, *inter alia*, a pharmaceutical composition comprising (i) valsartan or a pharmaceutically acceptable salt thereof; (ii) sacubitril or sacubitrilat or a pharmaceutically acceptable salt thereof; and (iii) a pharmaceutically acceptable carrier; wherein (i) and (ii) are administered in combination in about a 1:1 ratio.

35. Novartis is the owner of the '918 patent, titled "Amorphous solid form of compounds containing S-N-valeryl-N-{[2′-(1H-tetrazole-5-yl)-biphenyl-4-yl]-methyl}-valine and (2R,4S)-5-biphenyl-4-yl-4-(3-carboxy-propionylamino)-2-methyl-pentanoic acid ethyl ester moieties and sodium cations." The '918 patent was duly and legally issued on August 24, 2021. A true and correct copy of the '918 patent is attached hereto as Exhibit B.

36. The '918 patent claims, *inter alia*, an amorphous solid form of a compound comprising anionic valsartan, anionic sacubitril, and sodium cations in a 1:1:3 molar ratio.

37. Novartis is the holder of New Drug Application ("NDA") No. 207620 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of ENTRESTO® (sacubitril and valsartan) tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg. ENTRESTO® currently is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart and for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older.

38. One or more claims of the '659 patent cover ENTRESTO® and/or the use thereof.

39. The FDA's official publication of approved drugs (the "Orange Book") lists the '659 patent in connection with ENTRESTO®.

INFRINGEMENT OF THE PATENTS-IN-SUIT

40. Novartis incorporates paragraphs 1–39 as if fully set forth herein.

41. On information and belief, Lupin Inc. and/or Lupin Atlantis Holdings, S.A., by itself or in concert with Lupin Limited and/or Lupin Pharmaceuticals, Inc., submitted to the FDA ANDA No. 213808 under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin ANDA Products in or into the United States prior to the expiration of the '659 and '918 patents.

42. This action was commenced within 45 days of Novartis's receipt of the August 5, 2024 Lupin Notice Letter.

43. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin ANDA Products in or into the United States prior to the expiration of the '659 and '918 patents, Lupin Inc. and Lupin Atlantis Holdings, S.A., and, on information and belief, Lupin Limited and/or Lupin Pharmaceuticals, Inc., have committed an act of infringement under 35 U.S.C. § 271(e)(2).

44. On information and belief, when Lupin Inc. and/or Lupin Atlantis Holdings, S.A. filed ANDA No. 213808, Lupin Inc., Lupin Atlantis Holdings, S.A., Lupin Limited, and Lupin Pharmaceuticals, Inc. were aware of the '659 patent and that the filing of the ANDA with the request for its approval prior to the expiration of the '659 patent was an act of infringement of the '659 patent.

45. Lupin Inc., Lupin Atlantis Holdings, S.A., Lupin Limited, and Lupin Pharmaceuticals, Inc. previously stipulated that the filing of ANDA No. 213808, including any amendments or supplements thereto, infringes claims 1-4 of the ’659 patent including during the extension of its patent term pursuant to 35 U.S.C. § 156. 19-1979, D.I. 376; 20-415, D.I. 119; 21-229, D.I. 39.

46. The August 5, 2024 Lupin Notice Letter does not deny that the ANDA Products of ANDA No. 213808 would infringe claims 1-4 of the ’659 patent.

47. On information and belief, Lupin’s ANDA Products are a pharmaceutical composition in the form of a tablet comprising an amorphous solid form of a compound comprising (i) anionic valsartan, (ii) anionic sacubitril, and (iii) sodium cations in a 1:1:3 molar ratio.

48. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin ANDA Products in or into the United States will directly infringe one or more claims of the ’659 patent.

49. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin ANDA Products in or into the United States will directly infringe one or more claims of the ’918 patent.

50. Novartis will be substantially and irreparably damaged by Lupin Inc.’s, Lupin Atlantis Holdings, S.A.’s, Lupin Limited’s, and/or Lupin Pharmaceuticals, Inc.’s infringement of the ’659 and ’918 patents.

51. Novartis is entitled to the relief provided by 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 283, including an order of this Court that the effective date of any approval of ANDA No. 213808 be a date that is no earlier than July 15, 2025, the expiration date of the ’659 patent’s

pediatric exclusivity, and no earlier than November 8, 2026, the expiration date of the '918 patent, or a date no earlier than the expiry of any other patent extension or exclusivity to which Novartis is entitled, and an award of damages for any commercial sale or use of the Lupin ANDA Products and any act committed by Lupin Inc., Lupin Atlantis Holdings, S.A., Lupin Limited, and/or Lupin Pharmaceuticals, Inc. with respect to the subject matter claimed in the '659 and '918 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

52. On information and belief, Lupin Inc., Lupin Atlantis Holdings, S.A., Lupin Limited, and Lupin Pharmaceuticals, Inc. have taken and continue to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin ANDA Products in or into the United States, including seeking approval of those products under ANDA No. 213808.

53. There is a substantial and immediate controversy between Novartis and Lupin Inc., Lupin Atlantis Holdings, S.A., Lupin Limited, and Lupin Pharmaceuticals, Inc. concerning the '659 and '918 patents. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Lupin Inc., Lupin Atlantis Holdings, S.A., Lupin Limited, and Lupin Pharmaceuticals, Inc. will infringe one or more claims of each of the '659 and '918 patents. Novartis acknowledges that the District Court has determined that the '659 patent is invalid, but that decision has been appealed to the U.S. Court of Appeals for the Federal Circuit.

PRAYER FOR RELIEF

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

54. Judgment that defendants Lupin Inc., Lupin Atlantis Holdings, S.A., Lupin Limited, and Lupin Pharmaceuticals, Inc. have infringed one or more claims of each of the '659 and '918 patents by filing ANDA No. 213808;

55. A permanent injunction restraining and enjoining defendants Lupin Inc., Lupin Atlantis Holdings, S.A., Lupin Limited, and Lupin Pharmaceuticals, Inc., and 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 Lupin ANDA Products prior to the expiration of the '659 and '918 patents, inclusive of any extensions and additional periods of exclusivity;

56. An order that the effective date of any approval of ANDA No. 213808 be a date that is not earlier than the expiration dates of the '659 and '918 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 Lupin ANDA Products will directly infringe one or more claims of each of the '659 and '918 patents;

58. Damages or other monetary relief from defendants Lupin Inc., Lupin Atlantis Holdings, S.A., Lupin Limited, and Lupin Pharmaceuticals, Inc. for the infringement of the '659 and '918 patents;

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: September 18, 2024

MCCARTER & ENGLISH, LLP

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