IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Entresto (Sacubitril/Valsartan) Patent Litigation	C.A. No. 20-md-2930-LPS
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. LUPIN ATLANTIS HOLDINGS, S.A., LUPIN LIMITED, LUPIN INC., LUPIN PHARMACEUTICALS, INC., Defendants.	C.A. No. 20-415-LPS

AMENDED 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 Abbreviated New Drug Applications ("ANDAs") submitted to the United States Food and Drug Administration ("FDA") by the above-named defendants Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and Lupin Pharmaceuticals, Inc. 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. Patents Nos. 8,101,659

(the"'659 patent"), 8,796,331 (the "'331 patent"), 8,877,938 (the "'938 patent"), and/or 9,388,134(the "'134 patent").

2. This is an amendment to the second complaint Novartis has filed against Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and Lupin Pharmaceuticals, Inc. in connection with ANDA No. 213808. The first complaint, C.A. No. 19-1979-LPS (D. Del., filed October 17, 2019), alleged infringement by Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and Lupin Pharmaceuticals, Inc. of the '938 and '134 patents in response to a September 3, 2019 notice letter ("Lupin Atlantis First Notice Letter"). The Lupin Atlantis First Notice Letter represented that ANDA No. 213808 included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") against the '938 and '134 patents. The second complaint, C.A. No. 20-415-LPS (D. Del., filed March 24, 2020), additionally alleges infringement by Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and Lupin Pharmaceuticals, Inc. of the '659 and '331 patents, and was filed in response to a later, February 12, 2020 notice letter ("Lupin Atlantis Second Notice Letter"). The Lupin Atlantis Second Notice Letter represents that a second Paragraph IV certification against the '659 and '331 patents was filed in connection with ANDA No. 213808. The Lupin Atlantis Second Notice Letter also represents that Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and Lupin Pharmaceuticals, Inc. continue to rely on the Lupin Atlantis First Notice Letter including the previously expressed positions against the '938 and '134 patents. Novartis included in the second complaint allegations addressing the '938 and '134 patents, as well as the '659 and '331 patents.

3. This is an amendment to the second complaint Novartis has filed against Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., and Lupin Pharmaceuticals, Inc. in connection with ANDA No. 213809. The first complaint, C.A. No. 19-1979-LPS (D. Del., filed

October 17, 2019), alleged infringement by Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., and Lupin Pharmaceuticals, Inc. of the ’938 and ’134 patents in response to a September 3, 2019 notice letter (“Lupin Limited First Notice Letter”). The Lupin Limited First Notice Letter represented that ANDA No. 213809 included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV certification”) against the ’938 and ’134 patents. The second complaint, C.A. No. 20-415-LPS (D. Del., filed March 24, 2020), additionally alleges infringement by Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., and Lupin Pharmaceuticals, Inc. of the ’659 and ’331 patents, and was filed in response to a later, February 12, 2020 notice letter (“Lupin Limited Second Notice Letter”). The Lupin Limited Second Notice Letter represents that a second Paragraph IV certification against the ’659 and ’331 patents was filed in connection with ANDA No. 213809. The Lupin Limited Second Notice Letter also represents that Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., and Lupin Pharmaceuticals, Inc. continue to rely on the Lupin Limited First Notice Letter including the previously expressed positions against the ’938 and ’134 patents. Novartis included in the second complaint allegations addressing the ’938 and ’134 patents, as well as the ’659 and ’331 patents.

4. Novartis filed a third complaint, C.A. No. 21-229-LPS (D. Del., filed February 18, 2021) alleging infringement by Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and Lupin Pharmaceuticals, Inc. of the ’659, ’331, ’938, and ’134 patents, and was filed in response to a January 5, 2021 notice letter (“Lupin Atlantis Third Notice Letter”). The Lupin Atlantis Third Notice Letter represents that “Lupin Atlantis’s ANDA No. 213808, has been amended … to merge ANDA No. 213809 into Lupin Atlantis’s ANDA No. 213808” (“amended ANDA No. 213808”), and includes a Paragraph IV certification against the ’659, ’331, ’938, and ’134 patents. The Lupin Atlantis Third Notice Letter also represents that Lupin Limited, Lupin

Atlantis Holdings, S.A., Lupin Inc., and Lupin Pharmaceuticals, Inc. continue to rely on the Lupin Atlantis First Notice Letter and Lupin Atlantis Second Notice Letter, including the previously expressed positions against the ’659, ’331, ’938, and ’134 patents. Novartis included in the third complaint allegations addressing the ’659, ’331, ’938, and ’134 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. Defendants

a. Lupin Atlantis Holdings, S.A.; Lupin Limited; Lupin Inc.; Lupin Pharmaceuticals, Inc. (Amended ANDA No. 213808)

6. 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.

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

8. 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.

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 Limited and Lupin Inc.

10. 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.

11. 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.

12. 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.

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. In the Lupin Atlantis First Notice Letter, Lupin Atlantis Holdings, S.A. notified Novartis that (i) Lupin Atlantis Holdings, S.A. had submitted to the FDA ANDA No. 213808 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Lupin Atlantis

ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin Atlantis ANDA Products in or into the United States, including Delaware, prior to the expiration of the '938 and '134 patents, and that (ii) ANDA No. 213808 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '938 and '134 patents.

15. In the Lupin Atlantis Second Notice Letter, Lupin Atlantis Holdings, S.A. notified Novartis that a second Paragraph IV certification, against the '659 and '331 patents, was filed in connection with ANDA No. 213808. The Lupin Atlantis Second Notice Letter represents that Lupin continues to rely on the Lupin Atlantis First Notice Letter including Lupin's previously expressed positions against the '938 and '134 patents.

16. In the Lupin Atlantis Third Notice Letter, Lupin Atlantis Holdings, S.A. notified Novartis that "Lupin Atlantis's ANDA No. 213808, has been amended … to merge ANDA No. 213809 into Lupin Atlantis's ANDA No. 213808" and includes a Paragraph IV certification against the '659, '331, '938, and '134 patents. The Lupin Atlantis Third Notice Letter also represents that Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., and Lupin Pharmaceuticals, Inc. continue to rely on the Lupin Atlantis First Notice Letter and Lupin Atlantis Second Notice Letter, including the previously expressed positions against the '659, '331, '938, and '134 patents. On information and belief, amended ANDA No. 213808 presently includes the original Lupin Atlantis ANDA Products and sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg described in ANDA No. 213809 ("Lupin Limited ANDA Products").

17. Lupin Atlantis Holdings, S.A. has committed an act of infringement in this judicial district by filing amended ANDA No. 213808 (or by filing an amendment to merge

ANDA No. 213809 with ANDA No. 213808) with the intent to make, use, sell, offer for sale, and/or import the Lupin Atlantis ANDA Products in or into this judicial district, prior to the expiration of the '659, '331, '938, and '134 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 Atlantis Holdings, S.A. in the preparation and submission of amended ANDA No. 213808, and, if the ANDA is approved, will act in concert with and direct Lupin Atlantis Holdings, S.A. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin Atlantis ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659, '331, '938, and '134 patents.

19. On information and belief, Lupin Inc. acted in concert with and under the direction of Lupin Atlantis Holdings, S.A. and/or Lupin Limited in the preparation and submission of amended ANDA No. 213808, and, if the ANDA is approved, will act in concert with and under the direction of 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 Atlantis ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659, '331, '938, and '134 patents.

20. On information and belief, Lupin Pharmaceuticals, Inc. acted in concert with and under the direction of Lupin Atlantis Holdings, S.A., Lupin Limited, and/or Lupin Inc. in the preparation and submission of amended ANDA No. 213808, and, if the ANDA is approved, will act in concert with and under the direction of Lupin Atlantis Holdings, S.A., Lupin Limited, and/or Lupin Inc. to engage in the commercial manufacture, use, sale, offer for sale, and/or

importation of the Lupin Atlantis ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659, '331, '938, and '134 patents.

21. Lupin Atlantis Holdings, S.A., by itself or together with Lupin Limited, Lupin Inc., 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 Atlantis ANDA Products, that will be purposefully directed at Delaware and elsewhere.

22. 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.

23. 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 Atlantis Holdings, S.A., 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.

24. Lupin Atlantis Holdings, S.A., Lupin Limited, and Lupin Inc. 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.).

25. Lupin Atlantis Holdings, S.A., the entity identified in the Lupin Atlantis First and Second Notice Letters as having 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.

b. Lupin Limited; Lupin Atlantis Holdings, S.A.; Lupin Inc.; Lupin Pharmaceuticals, Inc. (ANDA No. 213809)

26. Novartis incorporates paragraphs 6 – 13 as if fully set forth herein.

27. In the Lupin Limited First Notice Letter, Lupin Limited notified Novartis that (i) Lupin Limited had submitted to the FDA ANDA No. 213809 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Lupin Limited ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin Limited ANDA Products in or into the United States, including Delaware, prior to the expiration of the '938 and '134 patents, and that (ii) ANDA No. 213809 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '938 and '134 patents.

28. In the Lupin Limited Second Notice Letter, Lupin Limited notified Novartis that a second Paragraph IV certification, against the '659 and '331 patents, was filed in connection with ANDA No. 213809. The Lupin Limited Second Notice Letter represents that Lupin

continues to rely on the Lupin Limited First Notice Letter including Lupin's previously expressed positions against the '938 and '134 patents.

29. Lupin Limited has committed an act of infringement in this judicial district by filing ANDA No. 213809 with the intent to make, use, sell, offer for sale, and/or import the Lupin Limited ANDA Products in or into this judicial district, prior to the expiration of the '659, '331, '938, and '134 patents, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

30. On information and belief, Lupin Atlantis Holdings, S.A. acted in concert with and under the direction of Lupin Limited in the preparation and submission of ANDA No. 213809, and, if the ANDA is approved, will act in concert with and under the direction of Lupin Limited to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin Limited ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659, '331, '938, and '134 patents.

31. On information and belief, Lupin Inc. acted in concert with and under the direction of Lupin Limited and/or Lupin Atlantis Holdings, S.A. in the preparation and submission of ANDA No. 213809, and, if the ANDA is approved, will act in concert with and under the direction of Lupin Limited and/or Lupin Atlantis Holdings, S.A. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin Limited ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659, '331, '938, and '134 patents.

32. On information and belief, Lupin Pharmaceuticals, Inc. acted in concert with and under the direction of Lupin Limited, Lupin Atlantis Holdings, S.A., and/or Lupin Inc. in the preparation and submission of ANDA No. 213809, and, if the ANDA is approved, will act in

concert with and under the direction Lupin Limited, Lupin Atlantis Holdings, S.A., and/or Lupin Inc. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin Limited ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659, '331, '938, and '134 patents.

33. Lupin Limited, by itself or together with Lupin Atlantis Holdings, S.A., Lupin Inc., 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 Limited ANDA Products, that will be purposefully directed at Delaware and elsewhere.

34. 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 Pharmaceuticals, Inc., and Lupin Atlantis Holdings, S.A.; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

35. 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.

36. Lupin Limited, Lupin Atlantis Holdings, S.A. and Lupin Inc. 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.).

37. Lupin Limited, the entity identified in the Lupin Limited First and Second Notice Letters as having submitted ANDA No. 213809, has agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213809 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

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

a. Lupin Atlantis Holdings, S.A.; Lupin Limited; Lupin Inc.; Lupin Pharmaceuticals, Inc. (Amended ANDA No. 213808)

39. This Court has personal jurisdiction over Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., 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 amended 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.

40. This Court also has personal jurisdiction over Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and Lupin Pharmaceuticals, Inc. because, on information and belief, each such Defendant, upon approval of amended ANDA No. 213808, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under amended ANDA No. 213808 that will be purposefully directed at Delaware, including the marketing of the Lupin Atlantis ANDA Products in Delaware, prior to the expiration of the '659, '331, '938, and '134 patents.

41. This Court also has personal jurisdiction over Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., 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.

42. This Court also has personal jurisdiction over Lupin Atlantis Holdings, S.A., Lupin Limited, and Lupin Inc. 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.).

43. Lupin Atlantis Holdings, S.A., the entity identified in the Lupin Atlantis First and Second Notice Letters as having 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.

44. 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 Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and Lupin Pharmaceuticals, Inc.

45. 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).

b. Lupin Limited; Lupin Atlantis Holdings, S.A.; Lupin Inc.; Lupin Pharmaceuticals, Inc. (ANDA No. 213809)

46. This Court has personal jurisdiction over Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., 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. 213809 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.

47. This Court also has personal jurisdiction over Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., and Lupin Pharmaceuticals, Inc. because, on information and belief, each such Defendant, upon approval of ANDA No. 213809, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213809 that will be purposefully directed at Delaware, including the marketing of the Lupin

Limited ANDA Products in Delaware, prior to the expiration of the '659, '331, '938, and '134 patents.

48. This Court also has personal jurisdiction over Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., 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.

49. This Court also has personal jurisdiction over Lupin Limited, Lupin Atlantis Holdings, S.A., and Lupin Inc. 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.).

50. Lupin Limited, the entity identified in the Lupin Limited First and Second Notice Letters as having submitted ANDA No. 213809, 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.

51. 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 Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., and Lupin Pharmaceuticals, Inc.

52. 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 Limited and Lupin Atlantis Holdings, S.A. 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®

53. 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.

54. 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.

55. Novartis is the owner of the ’331 patent, titled “Methods of treatment and pharmaceutical composition.” The ’331 patent was duly and legally issued on August 5, 2014. A true and correct copy of the ’331 patent is attached hereto as Exhibit B.

56. The ’331 patent claims, *inter alia*, a method for the treatment of heart failure or hypertension, comprising administering to a patient in need thereof a therapeutically effective amount of the combination of (i) valsartan or a pharmaceutically acceptable salt thereof; and (ii) sacubitril or sacubitrilat or a pharmaceutically acceptable salt thereof; wherein (i) and (ii) are administered in one unit dose form or in two separate unit dose forms.

57. Novartis is the owner of the ’938 patent, titled “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 cations.” The ’938

patent was duly and legally issued on November 4, 2014. A true and correct copy of the '938 patent is attached hereto as Exhibit C.

58. The '938 patent claims, *inter alia*, trisodium [3-((1S,3R)-1-biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butylcarbamoyl)propionate-(S)-3′-methyl-2′-(pentanoyl{2″-(tetrazol-5-ylate)biphenyl-4′-ylmethyl}amino)butyrate] hemipentahydrate ("sacubitril/valsartan trisodium hemipentahydrate complex") in crystalline form.

59. Novartis is the owner of the '134 patent, titled "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 cations." The '134 patent was duly and legally issued on July 12, 2016. A true and correct copy of the '134 patent is attached hereto as Exhibit D.

60. The '134 patent claims, *inter alia*, a method for the treatment of heart failure or hypertension, in a patient in need thereof comprising administering to the patient a therapeutically effective amount of a sacubitril/valsartan trisodium hemipentahydrate complex.

61. 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 failure, and for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older.

62. One or more claims of each of the '659, '331, '938, and '134 patents cover ENTRESTO® and/or the use thereof.

63. The FDA's official publication of approved drugs (the "Orange Book") lists the '659, '331, '938, and '134 patents in connection with ENTRESTO®.

INFRINGEMENT BY EACH DEFENDANT OF THE PATENTS-IN-SUIT

64. Novartis incorporates paragraphs 1 – 37 and 53 – 63 as if fully set forth herein.

a. Lupin Atlantis Holdings, S.A.; Lupin Limited; Lupin Inc.; Lupin Pharmaceuticals, Inc. (Amended ANDA No. 213808)

65. On information and belief, Lupin Atlantis Holdings, S.A., by itself or in concert with Lupin Limited, Lupin Inc., and/or Lupin Pharmaceuticals, Inc., submitted to the FDA amended 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 Atlantis ANDA Products in or into the United States prior to the expiration of the '659, '331, '938, and '134 patents.

66. This action was commenced within 45 days of Novartis's receipt of the Lupin Atlantis Second Notice Letter.

67. 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 Atlantis ANDA Products in or into the United States prior to the expiration of the '659, '331, '938, and '134 patents, Lupin Atlantis Holdings, S.A., and, on information and belief, Lupin Limited, Lupin Inc., and/or Lupin Pharmaceuticals, Inc., have committed an act of infringement under 35 U.S.C. § 271(e)(2).

68. On information and belief, when Lupin Atlantis Holdings, S.A. filed amended ANDA No. 213808, Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and Lupin Pharmaceuticals, Inc. were aware of the '659, '331, '938, and '134 patents and that the filing of

the ANDA with the request for its approval prior to the expiration of the ’659, ’331, ’938, and ’134 patents was an act of infringement of those patents.

69. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin Atlantis ANDA Products in or into the United States will infringe one or more claims of the ’659, ’331, ’938, and ’134 patents.

70. The Lupin Atlantis First Notice Letter does not deny that the Lupin Atlantis ANDA Products would infringe claims 1-11 of the ’938 patent and claims 1-15 of the ’134 patent.

71. The Lupin Atlantis Second Notice Letter does not deny that the Lupin Atlantis ANDA Products would infringe claims 1-4 of the ’659 patent and claims 1, 2, and 5-8 of the ’331 patent.

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

73. On information and belief, the Lupin Atlantis ANDA Products, if approved, will contain instructions for preparing, from the Lupin Atlantis ANDA Products, a pharmaceutical composition in the form of an aqueous oral suspension comprising (i) valsartan or a pharmaceutically acceptable salt thereof, (ii) sacubitril or a pharmaceutically acceptable salt thereof, and (iii) a pharmaceutically acceptable carrier, wherein components (i) and (ii) are administered in combination in about a 1:1 ratio. On information and belief, if the Lupin Atlantis ANDA Products are approved, physicians, medical professionals, pharmacists, caregivers and/or patients following said instructions will directly infringe one or more claims of the ’659 patent. On information and belief, if the Lupin Atlantis ANDA Products are approved, Lupin Atlantis

Holdings, S.A., Lupin Limited, Lupin Inc., and/or Lupin Pharmaceuticals, Inc. will actively encourage, recommend, or promote this infringement with knowledge of the ’659 patent, and with knowledge and intent that their acts will induce infringement of one or more claims of the ’659 patent.

74. On information and belief, if the Lupin Atlantis ANDA Products are approved, Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and/or Lupin Pharmaceuticals, Inc. will commercially manufacture, sell, offer for sale, and/or import those products, which will be specifically labeled with instructions for preparing, from the Lupin Atlantis ANDA Products, a pharmaceutical composition in the form of an aqueous oral suspension comprising (i) valsartan or a pharmaceutically acceptable salt thereof, (ii) sacubitril or a pharmaceutically acceptable salt thereof, and (iii) a pharmaceutically acceptable carrier, wherein components (i) and (ii) are administered in combination in about a 1:1 ratio. On information and belief, if the Lupin Atlantis ANDA Products are approved, those products will constitute a material part of a pharmaceutical composition comprising (i) valsartan or a pharmaceutically acceptable salt thereof, (ii) sacubitril or a pharmaceutically acceptable salt thereof, and (iii) a pharmaceutically acceptable carrier, wherein components (i) and (ii) are administered in combination in about a 1:1 ratio. On information and belief, if the Lupin Atlantis ANDA Products are approved, physicians, medical professionals, pharmacists, caregivers and/or patients following the instructions in the Lupin Atlantis ANDA Products will directly infringe one or more claims of the ’659 patent. On information and belief, if the Lupin Atlantis ANDA Products are approved, Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and/or Lupin Pharmaceuticals, Inc. will contributorily infringe one or more claims of the ’659 patent, and will do so with knowledge of the ’659 patent, and that the Lupin Atlantis ANDA Products are especially made or especially adapted for use in

infringing one or more claims of the ’659 patent, and are not suitable for a substantial noninfringing use.

75. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin Atlantis ANDA Products in or into the United States will directly infringe one or more claims of the ’938 patent.

76. On information and belief, the Lupin Atlantis ANDA Products, if approved, will contain instructions for practicing a method for the treatment of heart failure comprising administering to a patient in need thereof a therapeutically effective amount of sacubitril/valsartan or their pharmaceutically acceptable salts, which administration will constitute direct infringement of one or more claims of the ’331 patent. On information and belief, if the Lupin Atlantis ANDA Products are approved, physicians and/or patients following said instructions will directly infringe one or more claims of the ’331 patent. On information and belief, if the Lupin Atlantis ANDA Products are approved, Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and/or Lupin Pharmaceuticals, Inc. will actively encourage, recommend, or promote this infringement with knowledge of the ’331 patent, and with knowledge and intent that their acts will induce infringement of one or more claims of the ’331 patent.

77. On information and belief, if the Lupin Atlantis ANDA Products are approved, Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and/or Lupin Pharmaceuticals, Inc. will commercially manufacture, sell, offer for sale, and/or import in or into the United States those products, which will be specifically labeled for use in a method for the treatment of heart failure comprising administering to a patient in need thereof a therapeutically effective amount of sacubitril/valsartan or their pharmaceutically acceptable salts, as recited in one or more claims of the ’331 patent. On information and belief, if the Lupin Atlantis ANDA Products are

approved, those products will constitute a material part of a method for the treatment of heart failure comprising administering to a patient in need thereof a therapeutically effective amount of sacubitril/valsartan or their pharmaceutically acceptable salts, as recited in one or more claims of the ’331 patent. On information and belief, if the Lupin Atlantis ANDA Products are approved, physicians and/or patients following the instructions in the Lupin Atlantis ANDA Products will directly infringe one or more claims of the ’331 patent. On information and belief, if the Lupin Atlantis ANDA Products are approved, Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and/or Lupin Pharmaceuticals, Inc. will contributorily infringe one or more claims of the ’331 patent, and will do so with knowledge of the ’331 patent, and that the Lupin Atlantis ANDA Products are especially made or especially adapted for use in infringing one or more claims of the ’331 patent and are not suitable for a substantial noninfringing use.

78. On information and belief, the Lupin Atlantis ANDA Products, if approved, will contain instructions for practicing a method for the treatment of heart failure in a patient in need thereof comprising administering to the patient a therapeutically effective amount of a sacubitril/valsartan trisodium hemipentahydrate complex, which administration will constitute direct infringement of one or more claims of the ’134 patent. On information and belief, if the Lupin Atlantis ANDA Products are approved, physicians and/or patients following said instructions will directly infringe one or more claims of the ’134 patent. On information and belief, if the Lupin Atlantis ANDA Products are approved, Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and/or Lupin Pharmaceuticals, Inc. will actively encourage, recommend, or promote this infringement with knowledge of the ’134 patent, and with knowledge and intent that their acts will induce infringement of one or more claims of the ’134 patent.

79. On information and belief, if the Lupin Atlantis ANDA Products are approved, Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and/or Lupin Pharmaceuticals, Inc. will commercially manufacture, sell, offer for sale, and/or import in or into the United States those products, which will be specifically labeled for use in a method for the treatment of heart failure in a patient in need thereof comprising administering to the patient a therapeutically effective amount of a sacubitril/valsartan trisodium hemipentahydrate complex, as recited in one or more claims of the ’134 patent. On information and belief, if the Lupin Atlantis ANDA Products are approved, those products will constitute a material part of a method for the treatment of heart failure in a patient in need thereof comprising administering to the patient a therapeutically effective amount of a sacubitril/valsartan trisodium hemipentahydrate complex, as recited in one or more claims of the ’134 patent. On information and belief, if the Lupin Atlantis ANDA Products are approved, physicians and/or patients following the instructions in the Lupin Atlantis ANDA Products will directly infringe one or more claims of the ’134 patent. On information and belief, if the Lupin Atlantis ANDA Products are approved, Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and/or Lupin Pharmaceuticals, Inc. will contributorily infringe one or more claims of the ’134 patent, and will do so with knowledge of the ’134 patent, and that the Lupin Atlantis ANDA Products are especially made or especially adapted for use in infringing one or more claims of the ’134 patent and are not suitable for a substantial noninfringing use.

80. On information and belief, the Lupin Limited ANDA Products, if approved, will contain instructions for preparing, from the Lupin Limited ANDA Products, a pharmaceutical composition in the form of an aqueous oral suspension comprising (i) valsartan or a pharmaceutically acceptable salt thereof, (ii) sacubitril or a pharmaceutically acceptable salt

thereof, and (iii) a pharmaceutically acceptable carrier, wherein components (i) and (ii) are administered in combination in about a 1:1 ratio. On information and belief, if the Lupin Limited ANDA Products are approved, physicians, medical professionals, pharmacists, caregivers and/or patients following said instructions will directly infringe one or more claims of the '659 patent. On information and belief, if the Lupin Limited ANDA Products are approved, Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and/or Lupin Pharmaceuticals, Inc. will actively encourage, recommend, or promote this infringement with knowledge of the '659 patent, and with knowledge and intent that their acts will induce infringement of one or more claims of the '659 patent.

81. On information and belief, if the Lupin Limited ANDA Products are approved, Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. will commercially manufacture, sell, offer for sale, and/or import those products, which will be specifically labeled with instructions for preparing, from the Lupin Limited ANDA Products, a pharmaceutical composition in the form of an aqueous oral suspension comprising (i) valsartan or a pharmaceutically acceptable salt thereof, (ii) sacubitril or a pharmaceutically acceptable salt thereof, and (iii) a pharmaceutically acceptable carrier, wherein components (i) and (ii) are administered in combination in about a 1:1 ratio. On information and belief, if the Lupin Limited ANDA Products are approved, those products will constitute a material part of a pharmaceutical composition comprising (i) valsartan or a pharmaceutically acceptable salt thereof, (ii) sacubitril or a pharmaceutically acceptable salt thereof, and (iii) a pharmaceutically acceptable carrier, wherein components (i) and (ii) are administered in combination in about a 1:1 ratio. On information and belief, if the Lupin Limited ANDA Products are approved, physicians, medical professionals, pharmacists, caregivers and/or patients following the instructions in the Lupin

Limited ANDA Products will directly infringe one or more claims of the ’659 patent. On information and belief, if the Lupin Limited ANDA Products are approved, Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and/or Lupin Pharmaceuticals, Inc. will contributorily infringe one or more claims of the ’659 patent, and will do so with knowledge of the ’659 patent, and that the Lupin Limited ANDA Products are especially made or especially adapted for use in infringing one or more claims of the ’659 patent, and are not suitable for a substantial noninfringing use.

82. Novartis will be substantially and irreparably damaged by Lupin Atlantis Holdings, S.A.’s, Lupin Limited’s, Lupin Inc.’s, and/or Lupin Pharmaceuticals, Inc.’s infringement of the ’659, ’331, ’938, and ’134 patents.

83. Novartis is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of amended ANDA No. 213808 be a date that is no earlier than July 14, 2023, the expiration date of the ’659 and ’331 patents’ pediatric exclusivity, November 27, 2027, the expiration date of the ’938 patent’s pediatric exclusivity, and May 8, 2027, the expiration date of the ’134 patent’s pediatric exclusivity, 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 Atlantis ANDA Products or the Lupin Limited ANDA Products and any act committed by Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and/or Lupin Pharmaceuticals, Inc. with respect to the subject matter claimed in the ’659, ’331, ’938, and ’134 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

84. On information and belief, Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., 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 Atlantis ANDA Products or the Lupin Limited ANDA Products in or into the United States, including seeking approval of those products under amended ANDA No. 213808.

85. There is a substantial and immediate controversy between Novartis and Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and Lupin Pharmaceuticals, Inc. concerning the '659, '331, '938, and '134 patents. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and Lupin Pharmaceuticals, Inc. will infringe, induce infringement of, and/or contributorily infringe one or more claims of the '659, '331, '938, and '134 patents.

b. Lupin Limited; Lupin Atlantis Holdings, S.A.; Lupin Inc.; Lupin Pharmaceuticals, Inc. (ANDA No. 213809)

86. On information and belief, Lupin Limited, by itself or in concert with Lupin Atlantis Holdings, S.A., Lupin Inc., and/or Lupin Pharmaceuticals, Inc., submitted to the FDA ANDA No. 213809 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 Limited ANDA Products in or into the United States prior to the expiration of the '659, '331, '938, and '134 patents.

87. This action was commenced within 45 days of Novartis's receipt of the Lupin Limited Second Notice Letter.

88. 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 Limited ANDA Products in or into the United States prior to the expiration of the '659, '331, '938, and '134 patents, Lupin Limited, and, on information and belief, Lupin Atlantis

Holdings, S.A., Lupin Inc., and/or Lupin Pharmaceuticals, Inc., have committed an act of infringement under 35 U.S.C. § 271(e)(2).

89. On information and belief, when Lupin Limited filed ANDA No. 213809, Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., and Lupin Pharmaceuticals, Inc. were aware of the ’659, ’331, ’938, and ’134 patents and that the filing of the ANDA with the request for its approval prior to the expiration of the ’659, ’331, ’938, and ’134 patents was an act of infringement of those patents.

90. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin Limited ANDA Products in or into the United States will infringe one or more claims of the ’659, ’331, ’938, and ’134 patents.

91. The Lupin Limited Second Notice Letter does not deny that the Lupin Limited ANDA Products would infringe claims 1-4 of the ’659 patent and claims 1, 2, and 5-8 of the ’331 patent.

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

93. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin Limited ANDA Products in or into the United States will directly infringe one or more claims of the ’938 patent.

94. On information and belief, the Lupin Limited ANDA Products, if approved, will contain instructions for practicing a method for the treatment of heart failure comprising administering to a patient in need thereof a therapeutically effective amount of sacubitril/valsartan or their pharmaceutically acceptable salts, which administration will

constitute direct infringement of one or more claims of the ’331 patent. On information and belief, if the Lupin Limited ANDA Products are approved, physicians and/or patients following said instructions will directly infringe one or more claims of the ’331 patent. On information and belief, if the Lupin Limited ANDA Products are approved, Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. will actively encourage, recommend, or promote this infringement with knowledge of the ’331 patent, and with knowledge and intent that their acts will induce infringement of one or more claims of the ’331 patent.

95. On information and belief, if the Lupin Limited ANDA Products are approved, Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. will commercially manufacture, sell, offer for sale, and/or import in or into the United States those products, which will be specifically labeled for use in a method for the treatment of heart failure comprising administering to a patient in need thereof a therapeutically effective amount of sacubitril/valsartan or their pharmaceutically acceptable salts, as recited in one or more claims of the ’331 patent. On information and belief, if the Lupin Limited ANDA Products are approved, those products will constitute a material part of a method for the treatment of heart failure comprising administering to a patient in need thereof a therapeutically effective amount of sacubitril/valsartan or their pharmaceutically acceptable salts, as recited in one or more claims of the ’331 patent. On information and belief, if the Lupin Limited ANDA Products are approved, physicians and/or patients following the instructions in the Lupin Limited ANDA Products will directly infringe one or more claims of the ’331 patent. On information and belief, if the Lupin Limited ANDA Products are approved, Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. will contributorily infringe one or more

claims of the ’331 patent, and will do so with knowledge of the ’331 patent, and that the Lupin Limited ANDA Products are especially made or especially adapted for use in infringing one or more claims of the ’331 patent and are not suitable for a substantial noninfringing use.

96. On information and belief, the Lupin Limited ANDA Products, if approved, will contain instructions for practicing a method for the treatment of heart failure in a patient in need thereof comprising administering to the patient a therapeutically effective amount of a sacubitril/valsartan trisodium hemipentahydrate complex, which administration will constitute direct infringement of one or more claims of the ’134 patent. On information and belief, if the Lupin Limited ANDA Products are approved, physicians and/or patients following said instructions will directly infringe one or more claims of the ’134 patent. On information and belief, if the Lupin Limited ANDA Products are approved, Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. will actively encourage, recommend, or promote this infringement with knowledge of the ’134 patent, and with knowledge and intent that their acts will induce infringement of one or more claims of the ’134 patent.

97. On information and belief, if the Lupin Limited ANDA Products are approved, Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. will commercially manufacture, sell, offer for sale, and/or import in or into the United States those products, which will be specifically labeled for use in a method for the treatment of heart failure in a patient in need thereof comprising administering to the patient a therapeutically effective amount of a sacubitril/valsartan trisodium hemipentahydrate complex, as recited in one or more claims of the ’134 patent. On information and belief, if the Lupin Limited ANDA Products are approved, those products will constitute a material part of a method for the

treatment of heart failure in a patient in need thereof comprising administering to the patient a therapeutically effective amount of a sacubitril/valsartan trisodium hemipentahydrate complex, as recited in one or more claims of the ’134 patent. On information and belief, if the Lupin Limited ANDA Products are approved, physicians and/or patients following the instructions in the Lupin Limited ANDA Products will directly infringe one or more claims of the ’134 patent. On information and belief, if the Lupin Limited ANDA Products are approved, Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., and/or Lupin Pharmaceuticals, Inc. will contributorily infringe one or more claims of the ’134 patent, and will do so with knowledge of the ’134 patent, and that the Lupin Limited ANDA Products are especially made or especially adapted for use in infringing one or more claims of the ’134 patent and are not suitable for a substantial noninfringing use.

98. Novartis will be substantially and irreparably damaged by Lupin Limited’s, Lupin Atlantis Holdings, S.A.’s, Lupin Inc.’s, and/or Lupin Pharmaceuticals, Inc.’s infringement of the ’659, ’331, ’938, and ’134 patents.

99. Novartis is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of ANDA No. 213809 be a date that is no earlier than July 14, 2023, the expiration date of the ’659 and ’331 patents’ pediatric exclusivity, November 27, 2027, the expiration date of the ’938 patent’s pediatric exclusivity, and May 8, 2027, the expiration of the ’134 patent’s pediatric exclusivity, 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 Limited ANDA Products and any act committed by Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., and/or Lupin

Pharmaceuticals, Inc. with respect to the subject matter claimed in the '659, '331, '938, and '134 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

100. On information and belief, Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., 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 Limited ANDA Products in or into the United States, including seeking approval of those products under ANDA No. 213809.

101. There is a substantial and immediate controversy between Novartis and Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., and Lupin Pharmaceuticals, Inc. concerning the '659, '331, '938, and '134 patents. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., and Lupin Pharmaceuticals, Inc. will infringe, induce infringement of, and/or contributorily infringe one or more claims of the '659, '331, '938 and '134 patents.

PRAYER FOR RELIEF

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

a. Lupin Atlantis Holdings, S.A.; Lupin Limited; Lupin Inc.; Lupin Pharmaceuticals, Inc. (Amended ANDA No. 213808)

102. Judgment that defendants Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and Lupin Pharmaceuticals, Inc. have infringed one or more claims of the '659, '331, '938, and '134 patents by filing ANDA No. amended 213808;

103. A permanent injunction restraining and enjoining defendants Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., 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 Atlantis ANDA Products prior to the expiration of the ’659, ’331, ’938, and ’134 patents, inclusive of any extensions and additional periods of exclusivity;

104. A permanent injunction restraining and enjoining defendants Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., 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 Limited ANDA Products prior to the expiration of the ’659 patent, inclusive of any extensions and additional periods of exclusivity;

105. An order that the effective date of any approval of amended ANDA No. 213808 be a date that is not earlier than the expiration dates of the ’659, ’331, ’938, and ’134 patents, inclusive of any extensions and additional periods of exclusivity;

106. Declaratory judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin Atlantis ANDA Products will directly infringe, induce infringement of, and/or contributorily infringe one or more claims of the ’659, ’331, ’938, and ’134 patents;

107. Declaratory judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin Limited ANDA Products will directly infringe, induce infringement of, and/or contributorily infringe one or more claims of the ’659 patent;

108. Damages or other monetary relief from defendants Lupin Atlantis Holdings, S.A., Lupin Limited, Lupin Inc., and Lupin Pharmaceuticals, Inc. for the infringement, inducement of infringement and contributory infringement of the ’659, ’331, ’938, and ’134 patents;

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

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

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

b. Lupin Limited; Lupin Atlantis Holdings, S.A.; Lupin Inc.; Lupin Pharmaceuticals, Inc. (ANDA No. 213809)

112. Judgment that defendants Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., and Lupin Pharmaceuticals, Inc. have infringed one or more claims of the '659, '331, '938, and '134 patents by filing ANDA No. 213809;

113. A permanent injunction restraining and enjoining defendants Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., 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 Limited ANDA Products prior to the expiration of the '659, '331, '938, and '134 patents, inclusive of any extensions and additional periods of exclusivity;

114. An order that the effective date of any approval of ANDA No. 213809 be a date that is not earlier than the expiration dates of the '659, '331, '938, and '134 patents, inclusive of any extensions and additional periods of exclusivity;

115. Declaratory judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of the Lupin Limited ANDA Products will directly infringe, induce infringement of, and/or contributorily infringe one or more claims of the '659, '331, '938, and '134 patents;

116. Damages or other monetary relief from defendants Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., and Lupin Pharmaceuticals, Inc. for the infringement, inducement of infringement and contributory infringement of the ’659, ’331, ’938, and ’134 patents;

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

118. Novartis’s costs and expenses in this action; and

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

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