IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC GLOBAL HOLDING SA, ALEMBIC PHARMACEUTICALS, INC., MACLEODS PHARMACEUTICALS LTD., MACLEODS PHARMA USA, INC., NATCO PHARMA LIMITED, NATCO PHARMA, 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 Abbreviated New Drug Applications ("ANDAs") submitted to the United States Food and Drug Administration ("FDA") by the above-named defendants 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").

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 in East Hanover, New Jersey.

B. Defendants

a. Alembic Pharmaceuticals Limited; Alembic Global Holding SA; Alembic Pharmaceuticals, Inc. (ANDA No. 213682)

3. On information and belief, Alembic Pharmaceuticals Limited is a corporation organized and existing under the laws of India, having a principal place of business at Alembic Road, Vadodara, Gujarat, India 390003.

4. On information and belief, Alembic Global Holding SA is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Rue Fritz-Courvoisier 40, 2300 La Chaux-de-Fonds, Switzerland. On information and belief, Alembic Global Holding SA is a wholly owned subsidiary of Alembic Pharmaceuticals Limited.

5. On information and belief, Alembic 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 National Registered Agents, Inc., 160 Greentree Drive, Suite 101, Dover, Delaware 19904, and having a principal place of business at 750 Route 202, Bridgewater, New Jersey 08807. On information and belief, Alembic Pharmaceuticals, Inc. is a wholly owned subsidiary of Alembic Global Holding SA.

6. On information and belief, Alembic Pharmaceuticals 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.

7. On information and belief, Alembic Global Holding SA 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.

8. On information and belief, Alembic Pharmaceuticals, Inc., 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.

9. By a letter dated September 11, 2019 ("Alembic Notice Letter"), Alembic Pharmaceuticals Limited notified Novartis that (i) Alembic Pharmaceuticals Limited had submitted to the FDA ANDA No. 213682 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Alembic ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Alembic 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. 213682 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the'938 and '134 patents.

10. Alembic Pharmaceuticals Limited has committed an act of infringement in this judicial district by filing ANDA No. 213682 with the intent to make, use, sell, offer for sale, and/or import the Alembic ANDA Products in or into this judicial district, prior to the expiration of the '938 and '134 patents, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

11. On information and belief, Alembic Global Holding SA acted in concert with and under the direction of Alembic Pharmaceuticals Limited, and acted in concert with and directed Alembic Pharmaceuticals, Inc., in the preparation and submission of ANDA No. 213682, and, if the ANDA is approved, will act in concert with and under the direction of Alembic Pharmaceuticals Limited, and will act in concert with and direct Alembic Pharmaceuticals, Inc., to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Alembic ANDA Products in or into the United States, including Delaware, prior to the expiration of the '938 and '134 patents.

12. On information and belief, Alembic Pharmaceuticals, Inc. acted in concert with and under the direction of Alembic Pharmaceuticals Limited and/or Alembic Global Holding SA in the preparation and submission of ANDA No. 213682, and, if the ANDA is approved, will act in concert with and under the direction of Alembic Pharmaceuticals Limited and/or Alembic Global Holding SA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Alembic ANDA Products in or into the United States, including Delaware, prior to the expiration of the '938 and '134 patents.

13. Alembic Pharmaceuticals Limited, by itself or together with Alembic Global Holding SA and/or Alembic 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 Alembic ANDA Products, that will be purposefully directed at Delaware and elsewhere.

14. On information and belief, Alembic Pharmaceuticals 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 subsidiaries, agents, or affiliates,

including Alembic 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.

15. Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, 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.*, *Cydex Pharms. Inc. v. Alembic Global Holding SA et al.*, C.A. No. 19-956 (D. Del.).

16. Alembic Pharmaceuticals Limited, the entity identified in the Alembic Notice Letter as having submitted ANDA No. 213682, has agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213682 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. Macleods Pharmaceuticals Ltd.; Macleods Pharma USA, Inc. (ANDA No. 213728)

17. On information and belief, Macleods Pharmaceuticals Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, India 400059.

18. On information and belief, Macleods Pharma USA, 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 Incorp Services, Inc., 919 North Market Street, Suite 950, Wilmington, Delaware 19801, and having a principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, New Jersey 08536. On information and belief, Macleods Pharma USA, Inc. is a wholly owned subsidiary of Macleods Pharmaceuticals Ltd.

19. On information and belief, Macleods Pharmaceuticals Ltd. 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.

20. On information and belief, Macleods Pharma USA, 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.

21. By a letter dated September 11, 2019 ("Macleods Notice Letter"), Macleods Pharmaceuticals Ltd. notified Novartis that (i) Macleods Pharmaceuticals Ltd. had submitted to the FDA ANDA No. 213728 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Macleods ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Macleods ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659, '938, and '134 patents, and that (ii) ANDA No. 213728 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '659, '938, and '134 patents.

22. Macleods Pharmaceuticals Ltd. has committed an act of infringement in this judicial district by filing ANDA No. 213728 with the intent to make, use, sell, offer for sale, and/or import the Macleods ANDA Products in or into this judicial district, prior to the expiration of the '659, '938, and '134 patents, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

23. On information and belief, Macleods Pharma USA, Inc. acted in concert with and under the direction of Macleods Pharmaceuticals Ltd. in the preparation and submission of ANDA No. 213728, and, if the ANDA is approved, will act in concert with and under the direction of Macleods Pharmaceuticals Ltd. to engage in the commercial manufacture, use, sale,

offer for sale, and/or importation of the Macleods ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659, '938, and '134 patents.

24. Macleods Pharmaceuticals Ltd., by itself or together with Macleods Pharma USA, Inc., has taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Macleods ANDA Products, that will be purposefully directed at Delaware and elsewhere.

25. On information and belief, Macleods Pharmaceuticals Ltd. 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 Macleods Pharma USA, 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.

26. Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, 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., Merck Sharp & Dohme Corp. v. Macleods Pharms. Ltd. et al.*, C.A. No. 19-316 (D. Del.).

c. Natco Pharma Limited; Natco Pharma, Inc. (ANDA No. 213689)

27. On information and belief, Natco Pharma Limited is a corporation organized and existing under the laws of India, having a principal place of business at Natco House Road No. 2, Banjara Hills, Hyderabad 50034, India.

28. On information and belief, Natco Pharma, 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 Business Filings Incorporated, 108 West 13th Street, Wilmington, Delaware 19801, and having a principal place of business at 241 West Roseville Road, Lancaster, Pennsylvania 17601. On information and belief, Natco Pharma, Inc. is a wholly owned subsidiary of Natco Pharma Limited.

29. On information and belief, Natco Pharma 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.

30. On information and belief, Natco Pharma, 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.

31. By a letter dated September 11, 2019 ("Natco Notice Letter"), Natco Pharma Limited notified Novartis that (i) Natco Pharma Limited had submitted to the FDA ANDA No. 213689 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Natco ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Natco ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659, '331, '938, and '134 patents, and that (ii) ANDA No. 213689 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '659, '331, '938, and '134 patents.

32. Natco Pharma Limited has committed an act of infringement in this judicial district by filing ANDA No. 213689 with the intent to make, use, sell, offer for sale, and/or import the Natco 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.

33. On information and belief, Natco Pharma, Inc. acted in concert with and under the direction of Natco Pharma Limited in the preparation and submission of ANDA No. 213689, and, if the ANDA is approved, will act in concert with and under the direction of Natco Pharma Limited to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Natco ANDA Products in or into the United States, including Delaware, prior to the expiration of the ’659, ’331, ’938, and ’134 patents.

34. Natco Pharma Limited, by itself or together with Natco Pharma, Inc., has taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Natco ANDA Products, that will be purposefully directed at Delaware and elsewhere.

35. On information and belief, Natco Pharma 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 Natco Pharma, 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. Natco Pharma Limited, the entity identified in the Natco Notice Letter as having submitted ANDA No. 213689, has agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213689 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

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

a. Alembic Pharmaceuticals Limited; Alembic Global Holding SA; Alembic Pharmaceuticals, Inc. (ANDA No. 213682)

38. This Court has personal jurisdiction over Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic 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. 213682 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.

39. This Court also has personal jurisdiction over Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. because, on information and belief, each such Defendant, upon approval of ANDA No. 213682, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213682 that will be purposefully directed at Delaware, including the marketing of the Alembic ANDA Products in Delaware, prior to the expiration of the ’938 and ’134 patents.

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

41. This Court also has personal jurisdiction over Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. because each such Defendant 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.

42. Alembic Pharmaceuticals Limited, the entity identified in the Alembic Notice Letter as having submitted ANDA No. 213682, has agreed with Novartis to litigate this action in Delaware and not to contest personal jurisdiction or venue in Delaware in this action.

43. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc.

44. Venue is proper in this Court because Alembic Pharmaceuticals, Inc. is incorporated in the State of Delaware and therefore resides in this judicial district, and because Alembic Pharmaceuticals Limited and Alembic Global Holding SA 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. Macleods Pharmaceuticals Ltd.; Macleods Pharma USA, Inc. ANDA No. 213728)

45. This Court has personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, 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. 213728 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.

46. This Court also has personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. because, on information and belief, each such Defendant, upon approval of ANDA No. 213728, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213728 that will be purposefully directed at Delaware, including the marketing of the Macleods ANDA Products in Delaware, prior to the expiration of the '659, '938, and '134 patents.

47. This Court also has personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. because, on information and belief, each such Defendant's affiliations with the State of Delaware, including Macleod Pharma USA, Inc.'s incorporation in Delaware, and Macleods Pharmaceuticals Ltd.'s ownership of and actions in concert with Macleods Pharma USA, Inc., are sufficiently continuous and systematic as to render each such Defendant essentially at home in this forum.

48. This Court also has personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. because Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. have availed themselves 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.

49. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc.

50. Venue is proper in this Court because Macleods Pharma USA, Inc. is incorporated in the State of Delaware and therefore resides in this judicial district, and Macleods

Pharmaceuticals Ltd. is a foreign entity who may be sued in any judicial district, including Delaware. 28 U.S.C. § 1400(b); 28 U.S.C. § 1391(c)(3).

c. Natco Pharma Limited; Natco Pharma, Inc. (ANDA No. 213689)

51. This Court has personal jurisdiction over Natco Pharma Limited and Natco Pharma, 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. 213689 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.

52. This Court also has personal jurisdiction over Natco Pharma Limited and Natco Pharma, Inc. because, on information and belief, each such Defendant, upon approval of ANDA No. 213689, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213689 that will be purposefully directed at Delaware, including the marketing of the Natco ANDA Products in Delaware, prior to the expiration of the ’659, ’331, ’938, and ’134 patents.

53. This Court also has personal jurisdiction over Natco Pharma Limited and Natco Pharma, Inc. because each such Defendant’s affiliations with the State of Delaware, including Natco Pharma, Inc.’s incorporation in Delaware, and Natco Pharma Limited’s ownership of and actions in concert with Natco Pharma, Inc., are sufficiently continuous and systematic as to render each such Defendant essentially at home in this forum.

54. Natco Pharma Limited, the entity identified in the Natco Notice Letter as having submitted ANDA No. 213689, has agreed with Novartis to litigate this action in Delaware and not to contest personal jurisdiction or venue in Delaware in this action.

55. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Natco Pharma Limited and Natco Pharma, Inc.

56. Venue is proper in this Court because Natco Pharma, Inc. is incorporated in the State of Delaware and therefore resides in this judicial district, and Natco Pharma Limited is a foreign entity 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®

57. 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.

58. 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.

59. 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.

60. 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.

61. 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.

62. 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.

63. 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.

64. 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.

65. 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 patients with chronic heart failure (NYHA Class II-IV) and reduced ejection

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

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

67. 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

68. Novartis incorporates paragraphs 1 – 36 and 57 – 67 as if fully set forth herein.

a. Alembic Pharmaceuticals Limited; Alembic Global Holding SA; Alembic Pharmaceuticals, Inc. (ANDA No. 213682)

69. On information and belief, Alembic Pharmaceuticals Limited, by itself or in concert with Alembic Global Holding SA, and/or Alembic Pharmaceuticals, Inc., submitted to the FDA ANDA No. 213682 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 Alembic ANDA Products prior to the expiration of the '938 and '134 patents.

70. This action was commenced within 45 days of Novartis's receipt of the Alembic Notice Letter.

71. 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 Alembic ANDA Products in or into the United States prior to the expiration of the '938 and '134 patents, Alembic Pharmaceuticals Limited, and, on information and belief, Alembic Global Holding SA and Alembic Pharmaceuticals, Inc., have committed an act of infringement under 35 U.S.C. § 271(e)(2).

72. On information and belief, when Alembic Pharmaceuticals Limited filed ANDA No. 213682, Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. were aware of the ’938 and ’134 patents and that the filing of the ANDA with the request for its approval prior to the expiration of the ’938 and ’134 patents was an act of infringement of those patents.

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

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

75. On information and belief, the Alembic 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 Alembic 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 Alembic ANDA Products are approved, Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and/or Alembic 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.

76. On information and belief, if the Alembic ANDA Products are approved, Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and/or Alembic Pharmaceuticals, Inc. will commercially manufacture, sell, offer for sale, and/or import 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 Alembic 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 Alembic ANDA Products are approved, physicians and/or patients following the instructions in the Alembic ANDA Products will directly infringe one or more claims of the '134 patent. On information and belief, if the Alembic ANDA Products are approved, Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and/or Alembic 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 Alembic 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.

77. Novartis will be substantially and irreparably damaged by Alembic Pharmaceuticals Limited's, Alembic Global Holding SA's, and/or Alembic Pharmaceuticals, Inc.'s infringement of the '938 and '134 patents.

78. 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. 213682 be a date that is

no earlier than November 27, 2027, the expiration date of the ’938 patent’s pediatric exclusivity, 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 Alembic ANDA Products and any act committed by Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and/or Alembic Pharmaceuticals, Inc. with respect to the subject matter claimed in the ’938 and ’134 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

79. On information and belief, Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. have taken and continue to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Alembic ANDA Products, including seeking approval of those products under ANDA No. 213682.

80. There is a substantial and immediate controversy between Novartis and Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. concerning the ’938 and ’134 patents. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and/or Alembic Pharmaceuticals, Inc. will infringe, induce infringement of, and/or contributorily infringe one or more claims of the ’938 and ’134 patents.

b. Macleods Pharmaceuticals Ltd.; Macleods Pharma USA, Inc. (ANDA No. 213728)

81. On information and belief, Macleods Pharmaceuticals Ltd., by itself or in concert with Macleods Pharma USA, Inc., submitted to the FDA ANDA No. 213728 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 Macleods ANDA Products prior to the expiration of the ’659, ’938, and ’134 patents.

82. This action was commenced within 45 days of Novartis's receipt of the Macleods Notice Letter.

83. 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 Macleods ANDA Products in or into the United States prior to the expiration of the '659, '938, and '134 patents, Macleods Pharmaceuticals Ltd., and, on information and belief, Macleods Pharma USA, Inc., have committed an act of infringement under 35 U.S.C. § 271(e)(2).

84. On information and belief, when Macleods Pharmaceuticals Ltd. filed ANDA No. 213728, Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. were aware of the '659, '938, and '134 patents and that the filing of the ANDA with the request for its approval prior to the expiration of the '659, '938, and '134 patents was an act of infringement of those patents.

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

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

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

88. On information and belief, the Macleods 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 Macleods 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 Macleods ANDA Products are approved, Macleods Pharmaceuticals Ltd. and/or Macleods Pharma USA, 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.

89. On information and belief, if the Macleods ANDA Products are approved, Macleods Pharmaceuticals Ltd. and/or Macleods Pharma USA, Inc. will commercially manufacture, sell, offer for sale, and/or import 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 Macleods 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 Macleods ANDA Products are approved, physicians and/or patients following the instructions in the Macleods ANDA Products will directly infringe one or more claims of the

’134 patent. On information and belief, if the Macleods ANDA Products are approved, Macleods Pharmaceuticals Ltd. and/or Macleods Pharma USA, 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 Macleods 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.

90. Novartis will be substantially and irreparably damaged by Macleods Pharmaceuticals Ltd.’s and/or Macleods Pharma USA, Inc.’s infringement of the ’659, ’938, and ’134 patents.

91. 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. 213728 be a date that is no earlier than July 14, 2023, the expiration of the ’659 patent’s 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 Macleods ANDA Products and any act committed by Macleods Pharmaceuticals Ltd. and/or Macleods Pharma USA, Inc. with respect to the subject matter claimed in the ’659, ’938, and ’134 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

92. On information and belief, Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. have taken and continue to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Macleods ANDA Products, including seeking approval of those products under ANDA No. 213728.

93. There is a substantial and immediate controversy between Novartis and Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. concerning the '659, '938, and '134 patents. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. will infringe, induce infringement of, and/or contributorily infringe one or more claims of the '659, '938, and '134 patents.

c. Natco Pharma Limited; Natco Pharma, Inc. (ANDA No. 213689)

94. On information and belief, Natco Pharma Limited, by itself or in concert with Natco Pharma, Inc., submitted to the FDA ANDA No. 213689 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 Natco ANDA Products prior to the expiration of the '659, '331, '938, and '134 patents.

95. This action was commenced within 45 days of Novartis's receipt of the Natco Notice Letter.

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

97. On information and belief, when Natco Pharma Limited filed ANDA No. 213689, Natco Pharma Limited and Natco Pharma, 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.

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

99. The Natco Notice Letter does not deny that use of the Natco ANDA Products would infringe claims 1-4 of the ’659 patent, and that the use of the Natco ANDA Products would infringe claims 1, 2 and 4-8 of the ’331 patent, on any basis other than the alleged invalidity of those claims.

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

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

102. On information and belief, the Natco 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 Natco 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 Natco ANDA Products are approved, Natco Pharma Limited and/or Natco Pharma, 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.

103. On information and belief, if the Natco ANDA Products are approved, Natco Pharma Limited and/or Natco Pharma, Inc. will commercially manufacture, sell, offer for sale, and/or import 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 Natco 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 Natco ANDA Products are approved, physicians and/or patients following the instructions in the Natco ANDA Products will directly infringe one or more claims of the ’331 patent. On information and belief, if the Natco ANDA Products are approved, Natco Pharma Limited and/or Natco Pharma, 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 Natco 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.

104. On information and belief, the Natco 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 Natco 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 Natco ANDA Products are approved, Natco Pharma Limited and/or Natco Pharma, 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.

105. On information and belief, if the Natco ANDA Products are approved, Natco Pharma Limited and/or Natco Pharma, Inc. will commercially manufacture, sell, offer for sale, and/or import 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 Natco 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 Natco ANDA Products are approved, physicians and/or patients following the instructions in the Natco ANDA Products will directly infringe one or more claims of the ’134 patent. On information and belief, if the Natco ANDA Products are approved, Natco Pharma Limited and/or Natco Pharma, 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 Natco 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.

106. Novartis will be substantially and irreparably damaged by Natco Pharma Limited’s and/or Natco Pharma, Inc.’s infringement of the ’659, ’331, ’938, and ’134 patents.

107. 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. 213689 be a date that is no earlier than July 14, 2023, the expiration 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 Natco ANDA Products and any act committed by Natco Pharma Limited and Natco Pharma, 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).

108. On information and belief, Natco Pharma Limited and Natco Pharma, Inc. have taken and continue to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Natco ANDA Products, including seeking approval of those products under ANDA No. 213689.

109. There is a substantial and immediate controversy between Novartis and Natco Pharma Limited and Natco Pharma, Inc. concerning the ’659, ’331, ’938, and ’134 patents. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Natco Pharma Limited and Natco Pharma, 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. Alembic Pharmaceuticals Limited; Alembic Global Holding SA; Alembic Pharmaceuticals, Inc. (ANDA No. 213682)

110. Judgment that defendants Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. have infringed one or more claims of the '938 and '134 patents by filing ANDA No. 213682;

111. A permanent injunction restraining and enjoining defendants Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic 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 Alembic ANDA Products prior to the expiration of the '938 and '134 patents, inclusive of any extensions and additional periods of exclusivity;

112. An order that the effective date of any approval of ANDA No. 213682 be a date that is not earlier than the expiration dates of the '938 and '134 patents, inclusive of any extensions and additional periods of exclusivity;

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

114. Damages or other monetary relief from defendants Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. for the infringement, inducement of infringement and contributory infringement of the '938 and '134 patents;

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

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

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

b. Macleods Pharmaceuticals Ltd.; Macleods Pharma USA, Inc. (ANDA No. 213728)

118. Judgment that defendants Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. have infringed one or more claims of the '659, '938, and '134 patents by filing ANDA No. 213728;

119. A permanent injunction restraining and enjoining defendants Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, 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 Macleods ANDA Products prior to the expiration of the '659, '938, and '134 patents, inclusive of any extensions and additional periods of exclusivity;

120. An order that the effective date of any approval of ANDA No. 213728 be a date that is not earlier than the expiration dates of the '659, '938, and '134 patents, inclusive of any extensions and additional periods of exclusivity;

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

122. Damages or other monetary relief from defendants Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. for the infringement, inducement of infringement and contributory infringement of the '659, '938, and '134 patents;

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

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

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

c. Natco Pharma Limited; Natco Pharma, Inc. (ANDA No. 213689)

126. Judgment that defendants Natco Pharma Limited and Natco Pharma, Inc. have infringed one or more claims of the '659, '331, '938, and '134 patents by filing ANDA No. 213689;

127. A permanent injunction restraining and enjoining defendants Natco Pharma Limited and Natco Pharma, 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 Natco ANDA Products prior to the expiration of the '659, '331, '938, and '134 patents, inclusive of any extensions and additional periods of exclusivity;

128. An order that the effective date of any approval of ANDA No. 213689 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;

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

130. Damages or other monetary relief from defendants Natco Pharma Limited and Natco Pharma, Inc. for the infringement, inducement of infringement and contributory infringement of the '659, '331, '938, and '134 patents;

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

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

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

Dated: October 24, 2019

MCCARTER & ENGLISH, LLP

By: /s/ Daniel M. Silver

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