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. ALKEM LABORATORIES LTD., AUROBINDO PHARMA USA INC., AUROBINDO PHARMA LTD., BIOCON PHARMA LIMITED, BIOCON LIMITED, BIOCON PHARMA, INC., CRYSTAL PHARMACEUTICAL (SUZHOU) CO., LTD., LAURUS LABS LIMITED, LAURUS GENERICS INC., LUPIN ATLANTIS HOLDINGS, S.A., LUPIN LIMITED, LUPIN INC., LUPIN PHARMACEUTICALS, INC., NANJING NORATECH PHARMACEUTICAL CO., LIMITED, TEVA PHARMACEUTICALS USA, INC., TORRENT PHARMA INC., TORRENT PHARMACEUTICALS LTD., Defendants.	C.A. No. 19-1979-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 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. Alkem Laboratories Ltd. (ANDA No. 213764)

3. On information and belief, Alkem Laboratories Ltd. ("Alkem") is a corporation organized and existing under the laws of India, having a principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, India 400 013.

4. On information and belief, Alkem 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.

5. By a letter dated September 9, 2019 ("Alkem Notice Letter"), Alkem notified Novartis that (i) Alkem had submitted to the FDA ANDA No. 213764 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Alkem ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or

importation of the Alkem 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. 213764 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '659, '331, '938, and '134 patents.

6. Alkem has committed an act of infringement in this judicial district by filing ANDA No. 213764 with the intent to make, use, sell, offer for sale, and/or import the Alkem 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.

7. Alkem has taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Alkem ANDA Products, that will be purposefully directed at Delaware and elsewhere.

8. On information and belief, Alkem 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; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

9. Alkem has availed itself 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., Biogen Int'l GMBH et al. v. Alkem Labs. Ltd. et al.,* C.A. No. 17-850 (D. Del.).

10. Alkem, the entity identified in the Alkem Notice Letter as having submitted ANDA No. 213764, has agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213764 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. Aurobindo Pharma USA Inc.; Aurobindo Pharma Ltd. (ANDA No. 213631)

11. On information and belief, Aurobindo 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 Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808, and having a principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520. On information and belief, Aurobindo Pharma USA Inc. is a wholly owned subsidiary of Aurobindo Pharma Ltd.

12. On information and belief, Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andhra Pradesh, India.

13. On information and belief, Aurobindo Pharma USA Inc.[1] develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including Delaware, either directly or indirectly.

14. On information and belief, Aurobindo Pharma 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.

[1] The Aurobindo Notice Letter identifies the sender and ANDA filer as "Aurobindo Pharma USA Inc" and states that it is a Delaware corporation. The Delaware Department of State identifies this entity as "Aurobindo Pharma U.S.A., Inc."

15. By a letter dated September 6, 2019 ("Aurobindo Notice Letter"), Aurobindo Pharma USA Inc. notified Novartis that (i) Aurobindo Pharma USA Inc. had submitted to the FDA ANDA No. 213631 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Aurobindo ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Aurobindo 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. 213631 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '659, '331, '938, and '134 patents.

16. Aurobindo Pharma USA Inc. has committed an act of infringement in this judicial district by filing ANDA No. 213631 with the intent to make, use, sell, offer for sale, and/or import the Aurobindo 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.

17. On information and belief, Aurobindo Pharma Ltd. acted in concert with and directed Aurobindo Pharma USA Inc. in the preparation and submission of ANDA No. 213631, and, if the ANDA is approved, will act in concert with and direct Aurobindo Pharma USA Inc. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Aurobindo ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659, '331, '938, and '134 patents.

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

19. On information and belief, Aurobindo Pharma 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 Aurobindo 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.

20. Aurobindo Pharma Ltd. has availed itself 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., Allergan Sales, LLC et al. v. Aurobindo Pharma USA Inc. et al.*, C.A. No. 18-118 (D. Del.); *Novartis Pharms. Corp. v. Accord Healthcare Inc.*, C.A. No. 18-1043 (D. Del.); *Millennium Pharms., Inc. v. Aurobindo Pharma USA Inc. et al.*, C.A. No. 19-471 (D. Del.).

c. Biocon Pharma Limited; Biocon Limited; Biocon Pharma, Inc. (ANDA No. 213680)

21. On information and belief, Biocon Pharma Limited is a corporation organized and existing under the laws of India, having a principal place of business at 20th KM, Hosur Road, Electronic City, Bangalore, 560100, India. On information and belief, Biocon Pharma Limited is a wholly owned subsidiary of Biocon Limited.

22. On information and belief, Biocon Limited is a corporation organized and existing under the laws of India, having a principal place of business at 20th KM, Hosur Road, Electronic City, Bangalore, 560100, India.

23. On information and belief, Biocon 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 Harvard Business Services, Inc., 16192 Costal Highway, Lewes, Delaware 19958, and

having a principal place of business at 485 US Highway 1 S B305, Iselin, New Jersey 08830. On information and belief, Biocon Pharma, Inc. is a wholly owned subsidiary of Biocon Pharma Limited.

24. On information and belief, Biocon 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.

25. On information and belief, Biocon 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.

26. On information and belief, Biocon 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.

27. By a letter dated September 3, 2019 ("Biocon Notice Letter"), Biocon Pharma Limited notified Novartis that (i) Biocon Pharma Limited had submitted to the FDA ANDA No. 213680 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Biocon ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Biocon 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. 213680 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '659, '331, '938, and '134 patents.

28. Biocon Pharma Limited has committed an act of infringement in this judicial district by filing ANDA No. 213680 with the intent to make, use, sell, offer for sale, and/or import the Biocon 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.

29. On information and belief, Biocon Limited acted in concert with and directed Biocon Pharma Limited and/or Biocon Pharma, Inc. in the preparation and submission of ANDA No. 213680, and, if the ANDA is approved, will act in concert with and direct Biocon Pharma Limited and/or Biocon Pharma, Inc. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Biocon ANDA Products in or into in the United States, including Delaware, prior to the expiration of the ’659, ’331, ’938, and ’134 patents.

30. On information and belief, Biocon Pharma, Inc. acted in concert with and under the direction of Biocon Pharma Limited and/or Biocon Limited in the preparation and submission of ANDA No. 213680, and, if the ANDA is approved, will act in concert with and under the direction of Biocon Pharma Limited and/or Biocon Limited to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Biocon ANDA Products in or into the United States, including Delaware, prior to the expiration of the ’659, ’331, ’938, and ’134 patents.

31. Biocon Pharma Limited, by itself or together with Biocon Limited and/or Biocon 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 Biocon ANDA Products, that will be purposefully directed at Delaware and elsewhere.

32. On information and belief, Biocon 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

Biocon 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.

33. On information and belief, Biocon 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 Biocon 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.

34. Biocon Limited and Biocon Pharma, 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., Sanofi-Aventis U.S. LLC et al. v. Biocon Ltd.,* C.A. No. 17-3 (D. Del.); *Novartis Pharmaceuticals Corp. v. Accord Healthcare Inc.,* C.A. No. 18-1043 (D. Del.).

35. Biocon Pharma Limited, the entity identified in the Biocon Notice Letter as having submitted ANDA No. 213680, has agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213680 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.

d. Crystal Pharmaceutical (Suzhou) Co., Ltd. (ANDA No. 213605)

36. On information and belief, Crystal Pharmaceutical (Suzhou) Co., Ltd. ("Crystal") is a corporation organized and existing under the laws of China, having a principal place of business at B4-101, Biological Nano Park, No. 218, Xinghu Street, Suzhou Industrial Park, China.

37. On information and belief, Crystal develops, manufactures, distributes, sells, and/or imports drugs for the entire United States market and does business in every state including Delaware, either directly or indirectly.

38. By a letter dated September 4, 2019 ("Crystal Notice Letter"), Crystal notified Novartis that (i) Crystal had submitted to the FDA ANDA No. 213605 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Crystal ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Crystal 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. 213605 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '659, '331, '938, and '134 patents.

39. Crystal has committed an act of infringement in this judicial district by filing ANDA No. 213605 with the intent to make, use, sell, offer for sale, and/or import the Crystal 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.

40. Crystal has taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Crystal ANDA Products, that will be purposefully directed at Delaware and elsewhere.

41. On information and belief, Crystal 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; has purposefully availed

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

42. Crystal, the entity identified in the Crystal Notice Letter as having submitted ANDA No. 213605, has agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213605 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.

e. Laurus Labs Limited; Laurus Generics Inc. (ANDA No. 213676)

43. On information and belief, Laurus Labs Limited is a corporation organized and existing under the laws of India, having a principal place of business at Serene Chambers, Road No. 7, Banjara Hills, Hyderabad-500 034, India.

44. On information and belief, Laurus Generics 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 Intertrust Corporate Services Delaware Ltd., 200 Bellvue Parkway Suite 210, Wilmington, Delaware 19809, and having a principal place of business at 400 Connell Drive, Suite 5200, Berkeley Heights, New Jersey 07922. On information and belief, Laurus Generics Inc. is a wholly owned subsidiary of Laurus Labs Limited.

45. On information and belief, Laurus Labs 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.

46. On information and belief, Laurus Generics 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.

47. By a letter dated September 6, 2019 ("Laurus Notice Letter"), Laurus Labs Limited notified Novartis that (i) Laurus Labs Limited had submitted to the FDA ANDA No. 213676 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Laurus ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Laurus 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. 213676 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '659, '331, '938, and '134 patents.

48. Laurus Labs Limited has committed an act of infringement in this judicial district by filing ANDA No. 213676 with the intent to make, use, sell, offer for sale, and/or import the Laurus 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.

49. On information and belief, Laurus Generics Inc. acted in concert with and under the direction of Laurus Labs Limited in the preparation and submission of ANDA No. 213676, and, if the ANDA is approved, will act in concert with and under the direction of Laurus Labs Limited to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Laurus ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659, '331, '938, and '134 patents.

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

51. On information and belief, Laurus Labs 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 Laurus Generics 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.

52. Laurus Labs Limited and Laurus Generics 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., Genentech, Inc. v. Laurus Labs Ltd. et al.*, C.A. No. 19-104 (D. Del.); *Boehringer Ingelheim Pharms. Inc. v. Laurus Labs Ltd. et al.*, C.A. No. 19-1596 (D. Del.).

53. Laurus Labs Limited, the entity identified in the Laurus Notice Letter as having submitted ANDA No. 213676, has agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213676 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.

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

54. 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, Zug, Switzerland 6300. On information and belief, Lupin Atlantis Holdings, S.A. is a wholly owned subsidiary of Lupin Limited.

55. 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 B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India.

56. 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.

57. 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.

58. 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.

59. 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.

60. 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.

61. 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.

62. By a letter dated September 3, 2019 ("Lupin Atlantis 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.

63. Lupin Atlantis Holdings, S.A. has committed an act of infringement in this judicial district by filing ANDA No. 213808 with the intent to make, use, sell, offer for sale, and/or import the Lupin Atlantis 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.

64. On information and belief, Lupin Limited acted in concert with and directed Lupin Atlantis Holdings, S.A. in the preparation and submission of ANDA No. 213808, and, if the ANDA is approved, will act in concert with and direct Lupin 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 ’938 and ’134 patents.

65. 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 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 ’938 and ’134 patents.

66. 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 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 ’938 and ’134 patents.

67. 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.

68. 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.

69. 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.

70. 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 Pharms. Inc. et al. v. Lupin Inc. et al.*, C.A. No. 19-913 (D. Del.); *Boehringer Ingelheim Pharms. Inc. v. Lupin Ltd. et al.*, C.A. No. 19-1497 (D. Del.).

71. Lupin Atlantis Holdings, S.A., the entity identified in the Lupin Atlantis Notice Letter 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.

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

72. Novartis incorporates paragraphs 54 – 61 as if fully set forth herein.

73. By a letter dated September 3, 2019 ("Lupin Limited 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.

74. 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 '938 and '134 patents, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

75. 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 '938 and '134 patents.

76. 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 '938 and '134 patents.

77. 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 '938 and '134 patents.

78. 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.

79. 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.

80. 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.

81. 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 Pharms. Inc. et al. v. Lupin Inc. et al.*, C.A. No. 19-913 (D. Del.); *Boehringer Ingelheim Pharms. Inc. v. Lupin Ltd. et al.*, C.A. No. 19-1497 (D. Del.).

82. Lupin Limited, the entity identified in the Lupin Limited Notice Letter 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.

h. Nanjing Noratech Pharmaceutical Co., Limited (ANDA No. 213671)

83. On information and belief, Nanjing Noratech Pharmaceutical Co., Limited ("Noratech") is a corporation organized and existing under the laws of China, having a principal

place of business at 6/F, Building F6, No. 9 Weidi Road, Jiangsu Life Science and Technology Innovation Park, Qixia District, Nanjing, China.

84. On information and belief, Noratech 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.

85. By a letter dated September 3, 2019 ("Noratech Notice Letter"), Noratech notified Novartis that (i) Noratech had submitted to the FDA ANDA No. 213671 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Noratech ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Noratech 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. 213671 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '938 and '134 patents.

86. Noratech has committed an act of infringement in this judicial district by filing ANDA No. 213671 with the intent to make, use, sell, offer for sale, and/or import the Noratech 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.

87. Noratech has taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Noratech ANDA Products, that will be purposefully directed at Delaware and elsewhere.

88. On information and belief, Noratech 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; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

89. Noratech, the entity identified in the Noratech Notice Letter as having submitted ANDA No. 213671, has agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213671 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.

i. Teva Pharmaceuticals USA, Inc. (ANDA No. 213577)

90. On information and belief, Teva Pharmaceuticals USA, Inc. ("Teva") is a corporation organized and existing under the laws of the State of Delaware, having a registered agent for the service of process at Corporate Creations Network Inc., 3411 Silverside Road, Tatnall Building Suite 104, Wilmington, Delaware 19810, and having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

91. On information and belief, Teva 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.

92. By a letter dated September 4, 2019 ("Teva Notice Letter"), Teva notified Novartis that (i) Teva had submitted to the FDA ANDA No. 213577 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Teva ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Teva 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. 213577 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '659, '331, '938, and '134 patents.

93. Teva has committed an act of infringement in this judicial district by filing ANDA No. 213577 with the intent to make, use, sell, offer for sale, and/or import the Teva 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.

94. Teva has taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Teva ANDA Products, that will be purposefully directed at Delaware and elsewhere.

j. Torrent Pharma Inc.; Torrent Pharmaceuticals Ltd. (ANDA No. 213604)

95. On information and belief, Torrent 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 Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808, and having a principal place of business at 150 Allen Road, Suite 102, Basking Ridge, New Jersey 07920. On information and belief, Torrent Pharma Inc. is a wholly-owned subsidiary of Torrent Pharmaceuticals Ltd.

96. On information and belief, Torrent Pharmaceuticals Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Off. Ashram Road, Ahmedabad – 380 009, Gujarat, India.

97. On information and belief, Torrent 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.

98. On information and belief, Torrent 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.

99. By a letter dated September 1, 2019 ("Torrent Notice Letter"), Torrent Pharma Inc. notified Novartis that (i) Torrent Pharma Inc., on behalf of Torrent Pharmaceuticals Ltd., had submitted to the FDA ANDA No. 213604 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Torrent ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Torrent 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. 213604 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '659, '331, '938, and '134 patents.

100. Torrent Pharma Inc. has committed an act of infringement in this judicial district by filing ANDA No. 213604 with the intent to make, use, sell, offer for sale, and/or import the Torrent 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.

101. On information and belief, Torrent Pharmaceuticals Ltd. acted in concert with and directed Torrent Pharma Inc. in the preparation and submission of ANDA No. 213604, and, if the ANDA is approved, will direct and act in concert with Torrent Pharma Inc. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Torrent ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659, '331, '938, and '134 patents.

102. Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. have taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Torrent ANDA Products, that will be purposefully directed at Delaware and elsewhere.

103. On information and belief, Torrent 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 Torrent 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.

104. Torrent Pharmaceuticals Ltd. and Torrent Pharma 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., Bial-Portela & Ca., et al. v. Torrent Pharms. Ltd., et al.*, 18-279 (D. Del.); *H. Lundbeck A/S, et al. v. Torrent Pharms. Ltd., et al.*, 18-672 (D. Del.).

105. Both Torrent Pharmaceuticals Ltd., the entity identified in the Torrent Notice Letter as having submitted ANDA No. 213604 through Torrent Pharma Inc., and Torrent Pharma Inc. have agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213604 in the District of Delaware, and have agreed, only for the purposes of such action(s), not to challenge personal jurisdiction or venue in the District of Delaware.

JURISDICTION AND VENUE

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

a. Alkem Laboratories Ltd. (ANDA No. 213764)

107. This Court has personal jurisdiction over Alkem because, on information and belief, Alkem 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. 213764 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.

108. This Court also has personal jurisdiction over Alkem because, on information and belief, Alkem, upon approval of ANDA No. 213764, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213764 that will be purposefully directed at Delaware, including the marketing of the Alkem ANDA Products in Delaware, prior to the expiration of the '659, '331, '938, and '134 patents.

109. This Court also has personal jurisdiction over Alkem because, on information and belief, Alkem's affiliations with the State of Delaware are sufficiently continuous and systematic as to render Alkem essentially at home in this forum.

110. This Court also has personal jurisdiction over Alkem because Alkem 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.

111. Alkem, the entity identified in the Alkem Notice Letter as having submitted ANDA No. 213764, has agreed with Novartis to litigate this action in Delaware and not to contest personal jurisdiction or venue in Delaware in this action.

112. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Alkem.

113. Venue is proper in this Court because Alkem is a foreign entity who may be sued in any judicial district, including Delaware. 28 U.S.C. § 1391(c)(3).

b. Aurobindo Pharma USA Inc.; Aurobindo Pharma Ltd. (ANDA No. 213631)

114. This Court has personal jurisdiction over Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd. 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. 213631 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.

115. This Court also has personal jurisdiction over Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd. because, on information and belief, each such Defendant, upon approval of ANDA No. 213631, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213631 that will be purposefully directed at Delaware, including the marketing of the Aurobindo ANDA Products in Delaware, prior to the expiration of the ’659, ’331, ’938, and ’134 patents.

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

117. This Court also has personal jurisdiction over Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd. because Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd. 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.

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

119. Venue is proper in this Court because Aurobindo Pharma USA Inc. is incorporated in the State of Delaware and therefore resides in this judicial district, and Aurobindo Pharma 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. Biocon Pharma Limited; Biocon Limited; Biocon Pharma, Inc. (ANDA No. 213680)

120. This Court has personal jurisdiction over Biocon Pharma Limited, Biocon Limited, and Biocon 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. 213680 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.

121. This Court also has personal jurisdiction over Biocon Pharma Limited, Biocon Limited, and Biocon Pharma, Inc. because, on information on belief, each such Defendant, upon approval of ANDA No. 213680, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213680 that will be purposefully directed at Delaware, including the marketing of the Biocon ANDA Products in Delaware, prior to the expiration of the ’659, ’331, ’938, and ’134 patents.

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

123. This Court also has personal jurisdiction over Biocon Limited and Biocon Pharma, Inc. because Biocon Limited and Biocon Pharma, 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.

124. Biocon Pharma Limited, the entity identified in the Biocon Notice Letter as having submitted ANDA No. 213680, has agreed with Novartis to litigate this action in Delaware and not to contest personal jurisdiction or venue in Delaware in this action.

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

126. Venue is proper in this Court because Biocon Pharma, Inc. is incorporated in the State of Delaware and therefore resides in this judicial district, and Biocon Pharma Limited and Biocon 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).

d. Crystal Pharmaceutical (Suzhou) Co., Ltd. (ANDA No. 213605)

127. This Court has personal jurisdiction over Crystal because Crystal has committed tortious acts of patent infringement in preparing and submitting ANDA No. 213605 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.

128. This Court also has personal jurisdiction over Crystal because, on information and belief, Crystal, upon approval of ANDA No. 213605, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213605 that will be purposefully directed at Delaware, including the marketing of the Crystal ANDA Products in Delaware, prior to the expiration of the '659, '331, '938, and '134 patents.

129. This Court also has personal jurisdiction over Crystal because, on information and belief, Crystal's affiliations with the State of Delaware are sufficiently continuous and systematic as to render Crystal essentially at home in this forum.

130. Crystal, the entity identified in the Crystal Notice Letter as having submitted ANDA No. 213605, has agreed with Novartis to litigate this action in Delaware and not to contest personal jurisdiction or venue in Delaware in this action.

131. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Crystal.

132. Venue is proper in this Court because Crystal is a foreign entity who may be sued in any judicial district, including Delaware. 28 U.S.C. § 1391(c)(3).

e. Laurus Labs Limited; Laurus Generics Inc. (ANDA No. 213676)

133. This Court has personal jurisdiction over Laurus Labs Limited and Laurus Generics 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. 213676 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.

134. This Court also has personal jurisdiction over Laurus Labs Limited and Laurus Generics Inc. because, on information and belief, each such Defendant, upon approval of ANDA No. 213676, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213676 that will be purposefully directed at Delaware, including the marketing of the Laurus ANDA Products in Delaware, prior to the expiration of the '659, '331, '938, and '134 patents.

135. This Court also has personal jurisdiction over Laurus Labs Limited and Laurus Generics Inc. because, on information and belief, each such Defendant's affiliations with the State of Delaware, including Laurus Generics Inc.'s incorporation in Delaware, and Laurus Labs Limited's ownership of and actions in concert with Laurus Generics Inc., are sufficiently continuous and systematic as to render each such Defendant essentially at home in this forum.

136. This Court also has personal jurisdiction over Laurus Labs Limited and Laurus Generics Inc. because Laurus Labs Limited and Laurus Generics 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.

137. Laurus Labs Limited, the entity identified in the Laurus Notice Letter as having submitted ANDA No. 213676, has agreed with Novartis to litigate this action in Delaware and not to contest personal jurisdiction or venue in Delaware in this action.

138. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Laurus Labs Limited and Laurus Generics Inc.

139. Venue is proper in this Court over Laurus Labs Limited and Laurus Generics Inc. because Laurus Generics Inc. is incorporated in the State of Delaware and therefore resides in this judicial district, and Laurus Labs 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).

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

140. 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 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.

141. 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 ANDA No. 213808, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213808 that will be purposefully directed at Delaware, including the marketing of the Lupin Atlantis ANDA Products in Delaware, prior to the expiration of the ’938 and ’134 patents.

142. 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.

143. 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.

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

145. 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.

146. 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).

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

147. 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

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.

148. 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 '938 and '134 patents.

149. 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.

150. 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.

151. Lupin Limited, the entity identified in the Lupin Limited Notice Letter as having submitted ANDA No. 213809, has agreed with Novartis to litigate this action in Delaware and not to contest personal jurisdiction or venue in Delaware in this action.

152. 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.

153. 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).

h. Nanjing Noratech Pharmaceutical Co., Limited (ANDA No. 213671)

154. This Court has personal jurisdiction over Noratech because Noratech has committed tortious acts of patent infringement in preparing and submitting ANDA No. 213671 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.

155. This Court also has personal jurisdiction over Noratech because, on information and belief, Noratech, upon approval of ANDA No. 213671, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213671 that will be purposefully directed at Delaware, including the marketing of the Noratech ANDA Products in Delaware, prior to the expiration of the ’938 and ’134 patents.

156. This Court also has personal jurisdiction over Noratech because, on information and belief, Noratech’s affiliations with the State of Delaware are sufficiently continuous and systematic as to render Noratech essentially at home in this forum.

157. Noratech, the entity identified in the Noratech Notice Letter as having submitted ANDA No. 213671, has agreed with Novartis to litigate this action in Delaware and not to contest personal jurisdiction or venue in Delaware in this action.

158. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Crystal.

159. Venue is proper in this Court because Noratech is a foreign entity who may be sued in any judicial district, including Delaware. 28 U.S.C. § 1391(c)(3).

i. Teva Pharmaceuticals USA, Inc. (ANDA No. 213577)

160. This Court has personal jurisdiction over Teva because, on information and belief, Teva 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. 213577 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.

161. This Court also has personal jurisdiction over Teva because, on information and belief, Teva, upon approval of ANDA No. 213577, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213577 that will be purposefully directed at Delaware, including the marketing of the Teva ANDA Products in Delaware, prior to the expiration of the ’659, ’331, ’938, and ’134 patents.

162. This Court also has personal jurisdiction over Teva because, on information and belief, Teva’s affiliations with the State of Delaware, including Teva’s incorporation in Delaware, are sufficiently continuous and systematic as to render Teva essentially at home in this forum.

163. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Teva.

164. Venue is proper in this Court over Teva because Teva is incorporated in the State of Delaware and therefore resides in this judicial district. 28 U.S.C. § 1400(b).

j. Torrent Pharma Inc.; Torrent Pharmaceuticals Ltd. (ANDA No. 213604)

165. This Court has personal jurisdiction over Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. because 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. 213604 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.

166. This Court also has personal jurisdiction over Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. because, on information and belief, each such Defendant, upon approval of ANDA No. 213604, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213604 that will be purposefully directed at Delaware, including the marketing of the Torrent ANDA Products in Delaware, prior to the expiration of the ’659, ’331, ’938, and ’134 patents.

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

168. Both Torrent Pharmaceuticals Ltd., the entity identified in the Torrent Notice Letter as having submitted ANDA No. 213604 in concert with Torrent Pharma Inc., and Torrent Pharma Inc. have agreed with Novartis to litigate this action in Delaware and not to contest personal jurisdiction or venue in Delaware in this action.

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

170. Venue is proper in this Court over Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. because Torrent Pharma Inc. is incorporated in the State of Delaware and therefore resides in this judicial district, and Torrent 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).

THE PATENTS-IN-SUIT AND ENTRESTO®

171. 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.

172. 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.

173. 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.

174. 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.

175. 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.

176. 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.

177. 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.

178. 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.

179. 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.

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

181. 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

182. Novartis incorporates paragraphs 1 – 105 and 171 – 181 as if fully set forth herein.

a. Alkem Laboratories Ltd.
(ANDA No. 213764)

183. On information and belief, Alkem submitted to the FDA ANDA No. 213764 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 Alkem ANDA Products prior to the expiration of the ’659, ’331, ’938, and ’134 patents.

184. This action was commenced within 45 days of Novartis’s receipt of the Alkem Notice Letter.

185. 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 Alkem ANDA Products in or into the United States prior to the expiration of the ’659, ’331, ’938, and ’134 patents, Alkem has committed an act of infringement under 35 U.S.C. § 271(e)(2).

186. On information and belief, when Alkem filed ANDA No. 213764, Alkem was 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.

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

188. The Alkem Notice Letter does not deny that the Alkem ANDA Products would infringe claims 1-4 of the ’659 patent, on any basis other than the alleged invalidity of those claims.

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

190. On information and belief, the Alkem ANDA Products, if approved, will contain instructions for preparing, from the Alkem 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 Alkem 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 Alkem ANDA Products are approved, Alkem will actively encourage, recommend,

or promote this infringement with knowledge of the ’659 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the ’659 patent.

191. On information and belief, if the Alkem ANDA Products are approved, Alkem will commercially manufacture, sell, offer for sale, and/or import those products, which will be specifically labeled with instructions for preparing, from the Alkem 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 Alkem 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 Alkem ANDA Products are approved, physicians, medical professionals, pharmacists, caregivers and/or patients following the instructions in the Alkem ANDA Products will directly infringe one or more claims of the ’659 patent. On information and belief, if the Alkem ANDA Products are approved, Alkem will contributorily infringe one or more claims of the ’659 patent, and will do so with knowledge of the ’659 patent, and that the Alkem 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.

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

193. On information and belief, the Alkem 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 Alkem 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 Alkem ANDA Products are approved, Alkem will actively encourage, recommend, or promote this infringement with knowledge of the ’331 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the ’331 patent.

194. On information and belief, if the Alkem ANDA Products are approved, Alkem 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 Alkem 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, as recited in one or more claims of the ’331 patent. On information and belief, if the Alkem ANDA Products are approved, physicians and/or patients following the instructions in the Alkem ANDA Products will directly infringe one or more claims of the ’331 patent. On information and belief, if the Alkem ANDA Products are approved, Alkem will contributorily infringe one or more claims of the ’331 patent, and will do so with knowledge of

the ’331 patent, and that the Alkem 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.

195. On information and belief, the Alkem 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 Alkem 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 Alkem ANDA Products are approved, Alkem will actively encourage, recommend, or promote this infringement with knowledge of the ’134 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the ’134 patent.

196. On information and belief, if the Alkem ANDA Products are approved, Alkem 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 Alkem 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 Alkem ANDA Products are approved, physicians

and/or patients following the instructions in the Alkem ANDA Products will directly infringe one or more claims of the ’134 patent. On information and belief, if the Alkem ANDA Products are approved, Alkem will contributorily infringe one or more claims of the ’134 patent, and will do so with knowledge of the ’134 patent, and that the Alkem 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.

197. Novartis will be substantially and irreparably damaged by Alkem’s infringement of the ’659, ’331, ’938, and ’134 patents.

198. 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. 213764 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, 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 Alkem ANDA Products and any act committed by Alkem 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).

199. On information and belief, Alkem has taken and continues to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Alkem ANDA Products, including seeking approval of those products under ANDA No. 213764.

200. There is a substantial and immediate controversy between Novartis and Alkem concerning the ’659, ’331, ’938, and ’134 patents. Novartis is entitled to declaratory judgment

under 28 U.S.C. §§ 2201 and 2202 that Alkem will infringe, induce infringement of, and/or contributorily infringe one or more claims of the '659, '331, '938, and '134 patents.

b. Aurobindo Pharma USA Inc.; Aurobindo Pharma Ltd. (ANDA No. 213631)

201. On information and belief, Aurobindo Pharma USA Inc., by itself or in concert with Aurobindo Pharma Ltd., submitted to the FDA ANDA No. 213631 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 Aurobindo ANDA Products prior to the expiration of the '659, '331, '938, and '134 patents.

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

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

204. On information and belief, when Aurobindo Pharma USA Inc. filed ANDA No. 213631, Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd. 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.

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

206. The Aurobindo Notice Letter does not deny that the Aurobindo ANDA Products would infringe claims 1-4 of the ’659 patent, and that the use of the Aurobindo 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.

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

208. On information and belief, the Aurobindo ANDA Products, if approved, will contain instructions for preparing, from the Aurobindo 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 Aurobindo 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 Aurobindo ANDA Products are approved, Aurobindo Pharma USA Inc. and/or Aurobindo Pharma Ltd. 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.

209. On information and belief, if the Aurobindo ANDA Products are approved, Aurobindo Pharma USA Inc. and/or Aurobindo Pharma Ltd. will commercially manufacture, sell, offer for sale, and/or import those products, which will be specifically labeled with instructions for preparing, from the Aurobindo 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 Aurobindo 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 Aurobindo ANDA Products are approved, physicians, medical professionals, pharmacists, caregivers and/or patients following the instructions in the Aurobindo ANDA Products will directly infringe one or more claims of the ’659 patent. On information and belief, if the Aurobindo ANDA Products are approved, Aurobindo Pharma USA Inc. and/or Aurobindo Pharma Ltd. will contributorily infringe one or more claims of the ’659 patent, and will do so with knowledge of the ’659 patent, and that the Aurobindo 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.

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

211. On information and belief, the Aurobindo 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 Aurobindo 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 Aurobindo ANDA Products are approved, Aurobindo Pharma USA Inc. and/or Aurobindo Pharma Ltd. 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.

212. On information and belief, if the Aurobindo ANDA Products are approved, Aurobindo Pharma USA Inc. and/or Aurobindo Pharma Ltd. 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 Aurobindo 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 Aurobindo ANDA Products are approved, physicians and/or patients following the instructions in the Aurobindo ANDA Products will directly infringe one or more claims of the ’331 patent. On information and belief, if the Aurobindo ANDA Products are approved, Aurobindo Pharma USA Inc. and/or Aurobindo Pharma Ltd. will contributorily infringe one or more claims of the ’331 patent, and will do so with knowledge of the ’331 patent, and that the Aurobindo 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.

213. On information and belief, the Aurobindo 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 Aurobindo 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 Aurobindo ANDA Products are approved, Aurobindo Pharma USA Inc. and/or Aurobindo Pharma Ltd. 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.

214. On information and belief, if the Aurobindo ANDA Products are approved, Aurobindo Pharma USA Inc. and/or Aurobindo Pharma Ltd. 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 Aurobindo 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 Aurobindo ANDA Products are approved, physicians and/or patients following the instructions in the Aurobindo ANDA Products will directly infringe one or more claims of the ’134 patent. On information and belief, if the Aurobindo ANDA Products are approved, Aurobindo Pharma USA Inc. and/or Aurobindo Pharma Ltd. will contributorily infringe one or more claims of the ’134 patent, and will do so with knowledge of the ’134 patent, and that the Aurobindo 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.

215. Novartis will be substantially and irreparably damaged by Aurobindo Pharma USA Inc.’s and/or Aurobindo Pharma Ltd.’s infringement of the ’659, ’331, ’938, and ’134 patents.

216. 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. 213631 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 Aurobindo ANDA Products and any act committed by Aurobindo Pharma USA Inc. and/or Aurobindo Pharma Ltd. 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).

217. On information and belief, Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd. have taken and continue to take active steps towards the commercial manufacture, use, sale,

offer for sale, and/or importation of the Aurobindo ANDA Products, including seeking approval of those products under ANDA No. 213631.

218. There is a substantial and immediate controversy between Novartis and Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd. concerning the '659, '331, '938, and '134 patents. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd. will infringe, induce infringement of, and/or contributorily infringe one or more claims of the '659, '331, '938, and '134 patents.

c. Biocon Pharma Limited; Biocon Limited; Biocon Pharma, Inc. (ANDA No. 213680)

219. On information and belief, Biocon Pharma Limited, by itself or in concert with Biocon Limited and Biocon Pharma, Inc., submitted to the FDA ANDA No. 213680 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 Biocon ANDA Products prior to the expiration of the '659, '331, '938, and '134 patents.

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

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

222. On information and belief, when Biocon Pharma Limited filed ANDA No. 213680, Biocon Pharma Limited, Biocon Limited, and Biocon 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.

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

224. The Biocon Notice Letter does not deny that use of the Biocon ANDA Products would infringe claims 1, 2, and 5-8 of the ’331 patent, on any basis other than the alleged invalidity of those claims.

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

226. On information and belief, the Biocon ANDA Products, if approved, will contain instructions for preparing, from the Biocon 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 Biocon 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 Biocon ANDA Products are approved, Biocon Pharma Limited, Biocon Limited, and/or Biocon Pharma, 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.

227. On information and belief, if the Biocon ANDA Products are approved, Biocon Pharma Limited, Biocon Limited, and/or Biocon Pharma, Inc. will commercially manufacture, sell, offer for sale, and/or import those products, which will be specifically labeled with instructions for preparing, from the Biocon 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 Biocon 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 Biocon ANDA Products are approved, physicians, medical professionals, pharmacists, caregivers and/or patients following the instructions in the Biocon ANDA Products will directly infringe one or more claims of the ’659 patent. On information and belief, if the Biocon ANDA Products are approved, Biocon Pharma Limited, Biocon Limited, and/or Biocon Pharma, 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 Biocon 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.

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

229. On information and belief, the Biocon 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 Biocon 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 Biocon ANDA Products are approved, Biocon Pharma Limited, Biocon Limited, and/or Biocon 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.

230. On information and belief, if the Biocon ANDA Products are approved, Biocon Pharma Limited, Biocon Limited, and/or Biocon 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 Biocon 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 Biocon ANDA Products are approved, physicians and/or patients following the instructions in the Biocon ANDA Products will directly infringe one or more claims of the ’331 patent. On information and belief,

if the Biocon ANDA Products are approved, Biocon Pharma Limited, Biocon Limited, and/or Biocon 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 Biocon 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.

231. On information and belief, the Biocon 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 Biocon 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 Biocon ANDA Products are approved, Biocon Pharma Limited, Biocon Limited, and/or Biocon 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.

232. On information and belief, if the Biocon ANDA Products are approved, Biocon Pharma Limited, Biocon Limited, and/or Biocon 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 Biocon 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 Biocon ANDA Products are approved, physicians and/or patients following the instructions in the Biocon ANDA Products will directly infringe one or more claims of the '134 patent. On information and belief, if the Biocon ANDA Products are approved, Biocon Pharma Limited, Biocon Limited, and/or Biocon 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 Biocon 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.

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

234. 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. 213680 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 Biocon ANDA Products and any act committed by Biocon Pharma Limited, Biocon Limited, and Biocon 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).

235. On information and belief, Biocon Pharma Limited, Biocon Limited, and Biocon Pharma, Inc. have taken and continue to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Biocon ANDA Products, including seeking approval of those products under ANDA No. 213680.

236. There is a substantial and immediate controversy between Novartis and Biocon Pharma Limited, Biocon Limited, and Biocon 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 Biocon Pharma Limited, Biocon Limited, and Biocon Pharma, Inc. will infringe, induce infringement of, and/or contributorily infringe one or more claims of the '659, '331, '938, and '134 patents.

d. Crystal Pharmaceutical (Suzhou) Co., Ltd. (ANDA No. 213605)

237. On information and belief, Crystal submitted to the FDA ANDA No. 213605 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 Crystal ANDA Products prior to the expiration of the '659, '331, '938, and '134 patents.

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

239. 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 Crystal ANDA Products in or into the United States prior to the expiration of the '659, '331, '938, and '134 patents, Crystal has committed an act of infringement under 35 U.S.C. § 271(e)(2).

240. On information and belief, when Crystal filed its ANDA, it was aware of the '659, '331, '938, and '134 patents and that the filing of its 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.

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

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

243. On information and belief, the Crystal ANDA Products, if approved, will contain instructions for preparing, from the Crystal 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 Crystal 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 Crystal ANDA Products are approved, Crystal will actively encourage, recommend, or promote this infringement with knowledge of the '659 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the '659 patent.

244. On information and belief, if the Crystal ANDA Products are approved, Crystal will commercially manufacture, sell, offer for sale, and/or import those products, which will be

specifically labeled with instructions for preparing, from the Crystal 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 Crystal 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 Crystal ANDA Products are approved, physicians, medical professionals, pharmacists, caregivers and/or patients following the instructions in the Crystal ANDA Products will directly infringe one or more claims of the ’659 patent. On information and belief, if the Crystal ANDA Products are approved, Crystal will contributorily infringe one or more claims of the ’659 patent, and will do so with knowledge of the ’659 patent, and that the Crystal 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.

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

246. On information and belief, the Crystal 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 Crystal 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 Crystal ANDA Products are approved, Crystal will actively encourage, recommend, or promote this infringement with knowledge of the ’331 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the ’331 patent.

247. On information and belief, if the Crystal ANDA Products are approved, Crystal 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 Crystal 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 Crystal ANDA Products are approved, physicians and/or patients following the instructions in the Crystal ANDA Products will directly infringe one or more claims of the ’331 patent. On information and belief, if the Crystal ANDA Products are approved, Crystal will contributorily infringe one or more claims of the ’331 patent, and will do so with knowledge of the ’331 patent, and that the Crystal 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.

248. On information and belief, the Crystal 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 Crystal 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 Crystal ANDA Products are approved, Crystal will actively encourage, recommend, or promote this infringement with knowledge of the '134 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the '134 patent.

249. On information and belief, if the Crystal ANDA Products are approved, Crystal 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 Crystal 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 Crystal ANDA Products are approved, physicians and/or patients following the instructions in the Crystal ANDA Products will directly infringe one or more claims of the '134 patent. On information and belief, if the Crystal ANDA Products are approved, Crystal will contributorily infringe one or more claims of the '134 patent, and will

do so with knowledge of the ’134 patent, and that the Crystal 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.

250. Novartis will be substantially and irreparably damaged by Crystal’s infringement of the ’659, ’331, ’938, and ’134 patents.

251. 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. 213605 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 Crystal ANDA Products and any act committed by Crystal 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).

252. On information and belief, Crystal has taken and continues to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Crystal ANDA Products, including seeking approval of those products under ANDA No. 213605.

253. There is a substantial and immediate controversy between Novartis and Crystal concerning the ’659, ’331, ’938, and ’134 patents. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Crystal will infringe, induce infringement of, and/or contributorily infringe one or more claims of the ’659, ’331, ’938, and ’134 patents.

e. Laurus Labs Limited; Laurus Generics Inc. (ANDA No. 213676)

254. On information and belief, Laurus Labs Limited, by itself or in concert with Laurus Generics Inc., submitted to the FDA ANDA No. 213680 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 Laurus ANDA Products prior to the expiration of the '659, '331, '938, and '134 patents.

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

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

257. On information and belief, when Laurus Labs Limited filed ANDA No. 213676, Laurus Labs Limited and Laurus Generics 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.

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

259. The Laurus Notice Letter does not deny that the Laurus ANDA Products would infringe claims 1 and 2 of the '659 patent, and that the use of the Laurus ANDA Products would infringe claims 1, 2 and 5-8 of the '331 patent.

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

261. On information and belief, the Laurus ANDA Products, if approved, will contain instructions for preparing, from the Laurus 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 Laurus 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 Laurus ANDA Products are approved, Laurus Labs Limited and/or Laurus Generics 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.

262. On information and belief, if the Laurus ANDA Products are approved, Laurus will commercially manufacture, sell, offer for sale, and/or import those products, which will be specifically labeled with instructions for preparing, from the Laurus 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 Laurus 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 Laurus ANDA Products are approved, physicians, medical professionals, pharmacists, caregivers and/or patients following the instructions in the Laurus ANDA Products will directly infringe one or more claims of the ’659 patent. On information and belief, if the Laurus ANDA Products are approved, Laurus Labs Limited and/or Laurus Generics 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 Laurus 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.

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

264. On information and belief, the Laurus 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 Laurus 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 Laurus ANDA Products are approved, Laurus Labs Limited and/or Laurus Generics 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.

265. On information and belief, if the Laurus ANDA Products are approved, Laurus Labs Limited and/or Laurus Generics 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 Laurus 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 Laurus ANDA Products are approved, physicians and/or patients following the instructions in the Laurus ANDA Products will directly infringe one or more claims of the ’331 patent. On information and belief, if the Laurus ANDA Products are approved, Laurus Labs Limited and/or Laurus Generics 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 Laurus 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.

266. On information and belief, the Laurus 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 Laurus 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 Laurus ANDA Products are approved, Laurus Labs Limited and/or Laurus Generics 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.

267. On information and belief, if the Laurus ANDA Products are approved, Laurus Labs Limited and/or Laurus Generics 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 Laurus 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 Laurus ANDA Products are approved, physicians and/or patients following the instructions in the Laurus ANDA Products will directly infringe one or more claims of the ’134 patent. On information and belief, if the Laurus ANDA Products are approved, Laurus Labs Limited and/or Laurus Generics 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 Laurus 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.

268. Novartis will be substantially and irreparably damaged by Laurus Labs Limited’s, and/or Laurus Generics Inc.’s infringement of the ’659, ’331, ’938, and ’134 patents.

269. 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. 213676 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 Laurus ANDA Products and any act committed by Laurus Labs Limited and Laurus Generics 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).

270. On information and belief, Laurus Labs Limited and Laurus Generics Inc. have taken and continue to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Laurus ANDA Products, including seeking approval of those products under ANDA No. 213676.

271. There is a substantial and immediate controversy between Novartis and Laurus Labs Limited and Laurus Generics Inc. concerning the ’659, ’331, ’938, and ’134 patents. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Laurus Labs Limited and Laurus Generics Inc. will infringe, induce infringement of, and/or contributorily infringe one or more claims of the ’659, ’331, ’938, and ’134 patents.

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

272. 269. 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 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 prior to the expiration of the ’938 and ’134 patents.

273. This action was commenced within 45 days of Novartis’s receipt of the Lupin Atlantis Notice Letter.

274. 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 ’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).

275. On information and belief, when Lupin Atlantis filed ANDA No. 213808, Lupin Atlantis, Lupin Limited, Lupin Inc., and Lupin 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.

276. 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 ’938 and ’134 patents.

277. The Lupin Atlantis 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.

278. 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.

279. 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.

280. 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 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.

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

282. 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. 213808 be a date that is no earlier than 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 Atlantis 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 ’938 and ’134 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

283. 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, including seeking approval of those products under ANDA No. 213808.

284. 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 ’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 ’938 and ’134 patents.

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

285. 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 prior to the expiration of the ’938 and ’134 patents.

286. This action was commenced within 45 days of Novartis’s receipt of the Lupin Limited Notice Letter.

287. 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 ’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).

288. 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 ’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.

289. 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 ’938 and ’134 patents.

290. 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.

291. 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.

292. 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 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.

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

294. 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 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 ’938 and ’134 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

295. 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, including seeking approval of those products under ANDA No. 213809.

296. 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 ’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 ’938 and ’134 patents.

h. Nanjing Noratech Pharmaceutical Co., Limited (ANDA No. 213671)

297. On information and belief, Noratech submitted to the FDA ANDA No. 213671 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 Noratech ANDA Products prior to the expiration of the ’938 and ’134 patents.

298. This action was commenced within 45 days of Novartis’s receipt of the Noratech Notice Letter.

299. 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 Noratech ANDA Products in or into the United States prior to the expiration of the ’938 and ’134 patents, Noratech has committed an act of infringement under 35 U.S.C. § 271(e)(2).

300. On information and belief, when Noratech filed its ANDA, it was aware of the ’938 and ’134 patents and that the filing of its 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.

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

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

303. On information and belief, the Noratech 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 Noratech 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 Noratech ANDA Products are approved, Noratech will actively encourage, recommend, or promote this infringement with knowledge of the ’134 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the ’134 patent.

304. On information and belief, if the Noratech ANDA Products are approved, Noratech 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 Noratech 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 Noratech ANDA Products are approved, physicians and/or patients following the instructions in the Noratech ANDA Products will directly infringe one or more claims of the ’134 patent. On information and belief, if the Noratech ANDA Products are approved, Noratech will contributorily infringe one or more claims of the ’134 patent, and will do so with knowledge of the ’134 patent, and that the Noratech 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.

305. Novartis will be substantially and irreparably damaged by Noratech’s infringement of the ’938 and ’134 patents.

306. 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. 213671 be a date that is no earlier than 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 Noratech ANDA Products and any act committed by Noratech 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).

307. On information and belief, Noratech has taken and continues to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Noratech ANDA Products, including seeking approval of those products under ANDA No. 213671.

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

i. Teva Pharmaceuticals USA, Inc. (ANDA No. 213577)

309. On information and belief, Teva submitted to the FDA ANDA No. 213577 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 Teva ANDA Products prior to the expiration of the ’659, ’331, ’938, and ’134 patents.

310. This action was commenced within 45 days of Novartis’s receipt of the Teva Notice Letter.

311. 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 Teva ANDA Products in or into the United States prior to the expiration of the ’659, ’331, ’938, and ’134 patents, Teva has committed an act of infringement under 35 U.S.C. § 271(e)(2).

312. On information and belief, when Teva filed ANDA No. 213577, Teva was 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.

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

314. The Teva Notice Letter does not deny that the Teva ANDA Products would infringe claims 1-4 of the ’659 patent, and that the use of the Teva ANDA Products would infringe claims 1, 2 and 5-8 of the ’331 patent, on any basis other than the alleged invalidity of those claims.

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

316. On information and belief, the Teva ANDA Products, if approved, will contain instructions for preparing, from the Teva 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 Teva 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 Teva ANDA Products are approved, Teva will actively encourage, recommend, or promote this infringement with knowledge of the ’659 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the ’659 patent.

317. On information and belief, if the Teva ANDA Products are approved, Teva will commercially manufacture, sell, offer for sale, and/or import those products, which will be specifically labeled with instructions for preparing, from the Teva 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 Teva 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 Teva ANDA Products are approved, physicians, medical professionals, pharmacists, caregivers and/or patients following the instructions in the Teva ANDA Products will directly infringe one or more claims of the ’659 patent. On information and belief, if the Teva ANDA Products are approved, Teva will contributorily infringe one or more claims of the ’659 patent, and will do so with knowledge of the ’659 patent, and that the Teva

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.

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

319. On information and belief, the Teva 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 Teva 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 Teva ANDA Products are approved, Teva will actively encourage, recommend, or promote this infringement with knowledge of the ’331 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the ’331 patent.

320. On information and belief, if the Teva ANDA Products are approved, Teva 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 Teva 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 Teva ANDA Products are approved, physicians and/or patients following the instructions in the Teva ANDA Products will directly infringe one or more claims of the ’331 patent. On information and belief, if the Teva ANDA Products are approved, Teva will contributorily infringe one or more claims of the ’331 patent, and will do so with knowledge of the ’331 patent, and that the Teva 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.

321. On information and belief, the Teva 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 Teva 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 Teva ANDA Products are approved, Teva will actively encourage, recommend, or promote this infringement with knowledge of the ’134 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the ’134 patent.

322. On information and belief, if the Teva ANDA Products are approved, Teva 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 Teva 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 Teva ANDA Products are approved, physicians and/or patients following the instructions in the Teva ANDA Products will directly infringe one or more claims of the ’134 patent. On information and belief, if the Teva ANDA Products are approved, Teva will contributorily infringe one or more claims of the ’134 patent, and will do so with knowledge of the ’134 patent, and that the Teva 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.

323. Novartis will be substantially and irreparably damaged by Teva’s infringement of the ’659, ’331, ’938, and ’134 patents.

324. 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. 213577 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 Teva ANDA Products and any act committed by Teva 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).

325. On information and belief, Teva has taken and continues to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Products, including seeking approval of those products under ANDA No. 213577.

326. There is a substantial and immediate controversy between Novartis and Teva concerning the ’659, ’331, ’938, and ’134 patents. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Teva will infringe, induce infringement of, and/or contributorily infringe one or more claims of the ’659, ’331, ’938, and ’134 patents.

j. Torrent Pharma Inc.; Torrent Pharmaceuticals Ltd. (ANDA No. 213604)

327. On information and belief, Torrent Pharma Inc., on behalf of Torrent Pharmaceuticals Ltd., submitted to the FDA ANDA No. 213604 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 Torrent ANDA Products prior to the expiration of the ’659, ’331, ’938, and ’134 patents.

328. This action was commenced within 45 days of Novartis’s receipt of the Torrent Notice Letter.

329. 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 Torrent ANDA Products in or into the United States prior to the expiration of the ’659, ’331, ’938, and ’134 patents, Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. have committed an act of infringement under 35 U.S.C. § 271(e)(2).

330. On information and belief, when Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. filed ANDA No. 213604, they were aware of the ’659, ’331, ’938, and

’134 patents and that the filing of their 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.

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

332. The Torrent Notice Letter does not deny that the Torrent ANDA Products would infringe claims 1-4 of the ’659 patent, and that the use of the Torrent ANDA Products would infringe claims 1-10 of the ’331 patent.

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

334. On information and belief, the Torrent ANDA Products, if approved, will contain instructions for preparing, from the Torrent 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 Torrent 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 Torrent ANDA Products are approved, Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. 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.

335. On information and belief, if the Torrent ANDA Products are approved, Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. will commercially manufacture, sell, offer for sale, and/or import those products, which will be specifically labeled with instructions for preparing, from the Torrent 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 Torrent 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 Torrent ANDA Products are approved, physicians, medical professionals, pharmacists, caregivers and/or patients following the instructions in the Torrent ANDA Products will directly infringe one or more claims of the ’659 patent. On information and belief, if the Torrent ANDA Products are approved, Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. will contributorily infringe one or more claims of the ’659 patent, and will do so with knowledge of the ’659 patent, and that the Torrent 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.

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

337. On information and belief, the Torrent 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 Torrent 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 Torrent ANDA Products are approved, Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. 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.

338. On information and belief, if the Torrent ANDA Products are approved, Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. 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 Torrent 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 Torrent ANDA Products are approved, physicians and/or patients following the instructions in the Torrent ANDA Products will directly infringe one or more claims of the ’331 patent. On information and belief, if the Torrent ANDA

Products are approved, Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. will contributorily infringe one or more claims of the ’331 patent, and will do so with knowledge of the ’331 patent, and that the Torrent 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.

339. On information and belief, the Torrent 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 Torrent 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 Torrent ANDA Products are approved, Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. 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.

340. On information and belief, if the Torrent ANDA Products are approved, Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. 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 Torrent 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 Torrent ANDA Products are approved, physicians and/or patients following the instructions in the Torrent ANDA Products will directly infringe one or more claims of the ’134 patent. On information and belief, if the Torrent ANDA Products are approved, Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. will contributorily infringe one or more claims of the ’134 patent, and will do so with knowledge of the ’134 patent, and that the Torrent 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.

341. Novartis will be substantially and irreparably damaged by Torrent Pharma Inc.’s and Torrent Pharmaceuticals Ltd.’s infringement of the ’659, ’331, ’938, and ’134 patents.

342. 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. 213604 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 Torrent ANDA Products and any act committed by Torrent Pharma Inc. and/or Torrent Pharmaceuticals Ltd. 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).

343. On information and belief, Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. have taken and continue to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Torrent ANDA Products, including seeking approval of those products under ANDA No. 213604.

344. There is a substantial and immediate controversy between Novartis and Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. concerning the ’659, ’331, ’938, and ’134 patents. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. 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. Alkem Laboratories Ltd.
(ANDA No. 213764)

345. Judgment that defendant Alkem has infringed one or more claims of the ’659, ’331, ’938, and ’134 patents by filing ANDA No. 213764;

346. A permanent injunction restraining and enjoining defendant Alkem, and its 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 Alkem ANDA Products prior to the expiration of the ’659, ’331, ’938, and ’134 patents, inclusive of any extensions and additional periods of exclusivity;

347. An order that the effective date of any approval of ANDA No. 213764 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;

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

349. Damages or other monetary relief from defendant Alkem for the infringement, inducement of infringement and contributory infringement of the ’659, ’331, ’938, and ’134 patents;

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

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

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

b. Aurobindo Pharma USA Inc.; Aurobindo Pharma Ltd. (ANDA No. 213631)

353. Judgment that defendants Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd. have infringed one or more claims of the ’659, ’331, ’938, and ’134 patents by filing ANDA No. 213631;

354. A permanent injunction restraining and enjoining defendants Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd., 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 Aurobindo ANDA Products prior to the expiration of the ’659, ’331, ’938, and ’134 patents, inclusive of any extensions and additional periods of exclusivity;

355. An order that the effective date of any approval of ANDA No. 213631 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;

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

357. Damages or other monetary relief from defendants Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd. for the infringement, inducement of infringement and contributory infringement of the ’659, ’331, ’938, and ’134 patents;

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

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

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

c. Biocon Pharma Limited; Biocon Limited; Biocon Pharma, Inc. (ANDA No. 213680)

361. Judgment that defendants Biocon Pharma Limited, Biocon Limited, and Biocon Pharma, Inc. have infringed one or more claims of the ’659, ’331, ’938, and ’134 patents by filing ANDA No. 213680;

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

363. An order that the effective date of any approval of ANDA No. 213680 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;

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

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

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

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

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

d. Crystal Pharmaceutical (Suzhou) Co., Ltd. (ANDA No. 213605)

369. Judgment that defendant Crystal has infringed one or more claims of the ’659, ’331, ’938, and ’134 patents by filing ANDA No. 213605;

370. A permanent injunction restraining and enjoining defendant Crystal and its 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 Crystal ANDA Products prior to the expiration of the ’659, ’331, ’938, and ’134 patents, inclusive of any extensions and additional periods of exclusivity;

371. An order that the effective date of any approval of ANDA No. 213605 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;

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

373. Damages or other monetary relief from defendant Crystal for the infringement, inducement of infringement and contributory infringement of the ’659, ’331, ’938, and ’134 patents;

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

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

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

e. Laurus Labs Limited; Laurus Generics Inc. (ANDA No. 213676)

377. Judgment that defendants Laurus Labs Limited and Laurus Generics Inc. have infringed one or more claims of the ’659, ’331, ’938, and ’134 patents by filing ANDA No. 213676;

378. A permanent injunction restraining and enjoining defendants Laurus Labs Limited and Laurus Generics 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 Laurus ANDA Products prior to the expiration of the ’659, ’331, ’938, and ’134 patents, inclusive of any extensions and additional periods of exclusivity;

379. An order that the effective date of any approval of ANDA No. 213676 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;

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

381. Damages or other monetary relief from defendants Laurus Labs Limited and Laurus Generics Inc. for the infringement, inducement of infringement and contributory infringement of the ’659, ’331, ’938, and ’134 patents;

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

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

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

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

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

386. 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 ’938 and ’134 patents, inclusive of any extensions and additional periods of exclusivity;

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

388. 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 ’938 and ’134 patents;

389. 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 ’938 and ’134 patents;

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

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

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

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

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

394. 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 ’938 and ’134 patents, inclusive of any extensions and additional periods of exclusivity;

395. 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 ’938 and ’134 patents, inclusive of any extensions and additional periods of exclusivity;

396. 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 ’938 and ’134 patents;

397. 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 ’938 and ’134 patents;

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

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

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

h. Nanjing Noratech Pharmaceutical Co., Limited (ANDA No. 213671)

401. Judgment that defendant Noratech has infringed one or more claims of the ’938 and ’134 patents by filing ANDA No. 213671;

402. A permanent injunction restraining and enjoining defendant Noratech and its 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 Noratech ANDA Products prior to the expiration of the ’938 and ’134 patents, inclusive of any extensions and additional periods of exclusivity;

403. An order that the effective date of any approval of ANDA No. 213671 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;

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

405. Damages or other monetary relief from defendant Noratech for the infringement, inducement of infringement and contributory infringement of the ’938 and ’134 patents;

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

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

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

i. Teva Pharmaceuticals USA, Inc. (ANDA No. 213577)

409. Judgment that defendant Teva has infringed one or more claims of the ’659, ’331, ’938, and ’134 patents by filing ANDA No. 213577;

410. A permanent injunction restraining and enjoining defendant Teva, and its 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 Teva ANDA Products prior to the expiration of the ’659, ’331, ’938, and ’134 patents, inclusive of any extensions and additional periods of exclusivity;

411. An order that the effective date of any approval of ANDA No. 213577 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;

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

413. Damages or other monetary relief from defendant Teva for the infringement, inducement of infringement and contributory infringement of the ’659, ’331, ’938, and ’134 patents;

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

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

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

j. Torrent Pharma Inc.; Torrent Pharmaceuticals Ltd. (ANDA No. 213604)

417. Judgment that defendants Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. have infringed one or more claims of the ’659, ’331, ’938, and ’134 patents by filing ANDA No. 213604;

418. A permanent injunction restraining and enjoining defendants Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd., 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 Torrent ANDA Products prior to the expiration of the ’659, ’331, ’938, and ’134 patents, inclusive of any extensions and additional periods of exclusivity;

419. An order that the effective date of any approval of ANDA No. 213604 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;

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

421. Damages or other monetary relief from defendants Torrent Pharma Inc. and Torrent Pharmaceuticals Ltd. for the infringement, inducement of infringement and contributory infringement of the '659, '331, '938, and '134 patents;

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

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

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

Dated: June 9, 2021 OF COUNSEL: Nicholas N. Kallas Christina Schwarz Christopher E. Loh Susanne L. Flanders Jared L. Stringham Shannon K. Clark Laura K. Fishwick Gregory J. Manas VENABLE LLP 1290 Avenue of the Americas New York, New York 10104 (212) 218-2100 *nkallas@venable.com* *cschwarz@venable.com* *cloh@venable.com* *slflanders@venable.com* *jlstringham@venable.com* *skclark@venable.com* *lfishwick@venable.com* *gjmanas@venable.com*	MCCARTER & ENGLISH, LLP By: */s/ Daniel M. Silver* Daniel M. Silver (#4758) Alexandra M. Joyce (#6423) Renaissance Centre 405 N. King Street, 8th Floor Wilmington, Delaware 19801 (302) 984-6300 *dsilver@mccarter.com* *ajoyce@mccarter.com* *Attorneys for Plaintiff Novartis Pharmaceuticals Corporation*