IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. ALKEM LABORATORIES LTD., S&B PHARMA, INC., 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., TEVA PHARMACEUTICAL INDUSTRIES LTD., TORRENT PHARMA INC., TORRENT PHARMACEUTICALS LTD., Defendants.	:	Civil Action No. 1:19-cv-01979-LPS

DEFENDANT CRYSTAL PHARMACEUTICAL (SUZHOU) CO., LTD.'S
ANSWER TO PLAINTIFF NOVARTIS' ORIGINAL COMPLAINT

Defendant Crystal Pharmaceutical (Suzhou) Co., Ltd. ("Crystal" or "Defendant"), by and through its attorneys, answers the Complaint for Patent Infringement (the "Complaint") filed by Novartis Pharmaceuticals Corporation ("Novartis" or "Plaintiff") as follows:

NATURE OF 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").

ANSWER

Defendant admits that the Complaint purports to assert an action for patent infringement pursuant to the patent laws of the United States. Defendant admits that it has submitted an ANDA seeking approval to market sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg (hereinafter "Crystal's ANDA Product") before expiration of the '659, '331, '938, and '134 patents. Defendant denies the remaining allegations in Paragraph 1.

THE 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.

ANSWER

Defendant is without knowledge or information sufficient to admit or deny the allegations of Paragraph 2 of the Complaint, and therefore denies same.

B. Defendants

a. Alkem Laboratories Ltd.; S&B Pharma, Inc. (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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 3 and therefore denies the same.

4. On information and belief, S&B Pharma, Inc. ("S&B") 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 405 South Motor Avenue, Azusa, California 91702. On information and belief, S&B is a wholly owned subsidiary of Alkem.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 4 and therefore denies the same.

5. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 5 and therefore denies the same.

6. On information and belief, S&B 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 6 and therefore denies the same.

7. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 7 and therefore denies the same.

8. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 8 and therefore denies the same.

9. On information and belief, S&B acted in concert with and under the direction of Alkem in the preparation and submission of ANDA No. 213764, and, if the ANDA is approved, will act in concert with and under the direction of Alkem 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 9 and therefore denies the same.

10. Alkem, by itself or together with S&B, 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 10 and therefore denies the same.

11. 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, including S&B; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 11 and therefore denies the same.

12. Alkem and S&B 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.*, *Biogen Int'l GMBH et al. v. Alkem Labs. Ltd. et al.*, C.A. No. 17-850 (D. Del.).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 12 and therefore denies the same.

13. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 13 and therefore denies the same.

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

14. On information and belief, Aurobindo Pharma USA Inc.[1] 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 14 and therefore denies the same.

15. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 15 and therefore denies the same.

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

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 16 and therefore denies the same.

[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."

17. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 17 and therefore denies the same.

18. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 18 and therefore denies the same.

19. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 19 and therefore denies the same.

20. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 20 and therefore denies the same.

21. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 21 and therefore denies the same.

22. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 22 and therefore denies the same.

23. 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.).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 23 and therefore denies the same.

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

24. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 24 and therefore denies the same.

25. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 25 and therefore denies the same.

26. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 26 and therefore denies the same.

27. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 27 and therefore denies the same.

28. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 28 and therefore denies the same.

29. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 29 and therefore denies the same.

30. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 30 and therefore denies the same.

31. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 31 and therefore denies the same.

32. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 32 and therefore denies the same.

33. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 33 and therefore denies the same.

34. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 34 and therefore denies the same.

35. 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 doingbusiness in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 35 and therefore denies the same.

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

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 36 and therefore denies the same.

37. 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.).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 37 and therefore denies the same.

38. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 38 and therefore denies the same.

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

39. 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 B4-301, Biobay, 218 Xinghu Street, Suzhou Industrial Park, China, 215123.

ANSWER

Admitted.

40. 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.

ANSWER

Defendant admits that it develops drugs for distribution in the United States. Defendant denies the remaining allegations in Paragraph 40.

41. 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.

ANSWER

Defendant admits that it notified Novartis through the Crystal Notice Letter that it had filed ANDA No. 213605 seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Crystal ANDA Products, with the certification provided for in 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Defendant denies the remaining allegations in Paragraph 41.

42. 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.

ANSWER

Denied. Paragraph 42 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations in Paragraph 42.

43. 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.

ANSWER

Denied.

44. 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.

ANSWER

Denied.

45. 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.

ANSWER

Defendant admits that it does not contest personal jurisdiction or venue in this District for the limited purpose of this action only.

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

46. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 46 and therefore denies the same.

47. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 47 and therefore denies the same.

48. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 48 and therefore denies the same.

49. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 49 and therefore denies the same.

50. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 50 and therefore denies the same.

51. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 51 and therefore denies the same.

52. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 52 and therefore denies the same.

53. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 53 and therefore denies the same.

54. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 54 and therefore denies the same.

55. 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.).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 55 and therefore denies the same.

56. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 56 and therefore denies the same.

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

57. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 57 and therefore denies the same.

58. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 58 and therefore denies the same.

59. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 59 and therefore denies the same.

60. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 60 and therefore denies the same.

61. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 61 and therefore denies the same.

62. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 62 and therefore denies the same.

63. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 63 and therefore denies the same.

64. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 64 and therefore denies the same.

65. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 65 and therefore denies the same.

66. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 66 and therefore denies the same.

67. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 67 and therefore denies the same.

68. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 68 and therefore denies the same.

69. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 69 and therefore denies the same.

70. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 70 and therefore denies the same.

71. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 71 and therefore denies the same.

72. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 72 and therefore denies the same.

73. 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.).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 73 and therefore denies the same.

74. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 74 and therefore denies the same.

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

75. Novartis incorporates paragraphs 57 – 64 as if fully set forth herein.

ANSWER

Defendant repeats and incorporates by reference the responses to each of the foregoing paragraphs of the Complaint as if fully set forth herein.

76. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 76 and therefore denies the same.

77. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 77 and therefore denies the same.

78. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 78 and therefore denies the same.

79. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 79 and therefore denies the same.

80. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 80 and therefore denies the same.

81. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 81 and therefore denies the same.

82. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 82 and therefore denies the same.

83. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 83 and therefore denies the same.

84. 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.).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 84 and therefore denies the same.

85. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 85 and therefore denies the same.

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

86. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 86 and therefore denies the same.

87. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 87 and therefore denies the same.

88. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 88 and therefore denies the same.

89. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 89 and therefore denies the same.

90. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 90 and therefore denies the same.

91. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 91 and therefore denies the same.

92. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 92 and therefore denies the same.

i. Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries Ltd. (ANDA No. 213577)

93. On information and belief, Teva Pharmaceuticals 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 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. On information and belief, Teva Pharmaceuticals USA, Inc. is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 93 and therefore denies the same.

94. On information and belief, Teva Pharmaceutical Industries Ltd. is a corporation organized and existing under the laws of Israel, having a principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva, 49131, Israel.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 94 and therefore denies the same.

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

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 95 and therefore denies the same.

96. On information and belief, Teva Pharmaceutical Industries Ltd., 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 96 and therefore denies the same.

97. By a letter dated September 4, 2019 ("Teva Notice Letter"), Teva Pharmaceuticals USA, Inc. notified Novartis that (i) Teva Pharmaceuticals USA, Inc. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 97 and therefore denies the same.

98. Teva Pharmaceuticals USA, Inc. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 98 and therefore denies the same.

99. On information and belief, Teva Pharmaceutical Industries Ltd. acted in concert with and directed Teva Pharmaceuticals USA, Inc. in the preparation and submission of ANDA No. 213577, and, if the ANDA is approved, will act in concert with and direct Teva Pharmaceuticals USA, Inc. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 99 and therefore denies the same.

100. Teva Pharmaceuticals USA, Inc., by itself or together with Teva Pharmaceutical Industries Ltd., 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 100 and therefore denies the same.

101. On information and belief, Teva Pharmaceutical Industries 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 Teva Pharmaceuticals 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 101 and therefore denies the same.

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

102. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 102 and therefore denies the same.

103. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 103 and therefore denies the same.

104. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 104 and therefore denies the same.

105. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 105 and therefore denies the same.

106. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 106 and therefore denies the same.

107. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 107 and therefore denies the same.

108. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 108 and therefore denies the same.

109. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 109 and therefore denies the same.

110. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 110 and therefore denies the same.

111. 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.).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 111 and therefore denies the same.

112. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 112 and therefore denies the same.

JURISDICTION AND VENUE

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

ANSWER

Paragraph 113 of the Complaint states legal conclusions to which no response is required. To the extent any response is required, Defendant does not contest subject matter jurisdiction in this District for the limited purpose of this action only.

a. Alkem Laboratories Ltd.; S&B Pharma, Inc. (ANDA No. 213764)

114. This Court has personal jurisdiction over Alkem and S&B 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. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 114 and therefore denies the same.

115. This Court also has personal jurisdiction over Alkem and S&B because, on information and belief, each such Defendant, 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 115 and therefore denies the same.

116. This Court also has personal jurisdiction over Alkem and S&B because, on information and belief, each such Defendant's affiliations with the State of Delaware, including S&B's incorporation in Delaware, and Alkem's ownership of and actions in concert with S&B, are sufficiently continuous and systematic as to render each such Defendant essentially at home in this forum.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 116 and therefore denies the same.

117. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 117 and therefore denies the same.

118. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 118 and therefore denies the same.

119. 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 and S&B.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 119 and therefore denies the same.

120. Venue is proper in this Court because S&B is incorporated in the State of Delaware and therefore resides in this judicial district, and because Alkem 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 120 and therefore denies the same.

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

121. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 121 and therefore denies the same.

122. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 122 and therefore denies the same.

123. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 123 and therefore denies the same.

124. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 124 and therefore denies the same.

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 Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 125 and therefore denies the same.

126. 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 126 and therefore denies the same.

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

127. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 127 and therefore denies the same.

128. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 128 and therefore denies the same.

129. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 129 and therefore denies the same.

130. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 130 and therefore denies the same.

131. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 131 and therefore denies the same.

132. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 132 and therefore denies the same.

133. 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 133 and therefore denies the same.

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

134. 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.

ANSWER

Denied. Defendant denies that its preparation and submission of ANDA No. 213605 to FDA will lead to foreseeable harm to Novartis and that foreseeability of harm is a basis for establishing jurisdiction. By way of further answer, Paragraph 134 of the Complaint states legal conclusions to which no response is required. Nevertheless, to the extent a response is required, Defendant does not contest personal jurisdiction in this District for the limited purpose of this action only. Defendant denies the remaining allegations in Paragraph 134.

135. 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.

ANSWER

Denied. Defendant denies that jurisdiction can be based on alleged future actions. By way of further answer, Paragraph 135 of the Complaint states legal conclusions to which no response is required. Nevertheless, to the extent a response is required, Defendant does not contest personal jurisdiction in this District for the limited purpose of this action only. Defendant denies the remaining allegations in Paragraph 135.

136. 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.

ANSWER

Denied.

137. 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.

ANSWER

Defendant admits that it does not contest personal jurisdiction or venue in this District for the limited purpose of this action only.

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 Crystal.

ANSWER

Denied. Paragraph 138 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Defendant does not contest personal jurisdiction in this District for the limited purpose of this action only. Defendant denies the remaining allegations in Paragraph 138.

139. 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).

ANSWER

Paragraph 139 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Defendant does not contest venue in this District for the limited purpose of this action only. Defendant denies the remaining allegations in Paragraph 139.

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

140. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 140 and therefore denies the same.

141. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 141 and therefore denies the same.

142. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 142 and therefore denies the same.

143. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 143 and therefore denies the same.

144. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 144 and therefore denies the same.

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 Laurus Labs Limited and Laurus Generics Inc.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 145 and therefore denies the same.

146. 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 146 and therefore denies the same.

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

147. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 147 and therefore denies the same.

148. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 148 and therefore denies the same.

149. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 149 and therefore denies the same.

150. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 150 and therefore denies the same.

151. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 151 and therefore denies the same.

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

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 152 and therefore denies the same.

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 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 153 and therefore denies the same.

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

154. This Court has personal jurisdiction over Lupin Limited, Lupin Atlantis Holdings, S.A., Lupin Inc., and Lupin Pharmaceuticals, Inc. because, on information and belief, each such Defendant has committed or has aided, abetted, contributed to, or participated in the commission of tortious acts of patent infringement in preparing and submitting ANDA No. 213809 with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which acts have led to foreseeable harm and injury to Novartis, a Delaware corporation.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 154 and therefore denies the same.

155. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 155 and therefore denies the same.

156. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 156 and therefore denies the same.

157. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 157 and therefore denies the same.

158. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 158 and therefore denies the same.

159. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 159 and therefore denies the same.

160. 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 160 and therefore denies the same.

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

161. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 161 and therefore denies the same.

162. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 162 and therefore denies the same.

163. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 163 and therefore denies the same.

164. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 164 and therefore denies the same.

165. 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.

ANSWER

Denied. Upon information and belief, Plaintiff intended to direct this allegation to a defendant (Noratech) other than Crystal. Therefore, Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 165 and denies same. By way of further answer, Paragraph 165 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Defendant does not contest personal jurisdiction in this District for the limited purpose of this action only. Defendant denies the remaining allegations in Paragraph 165.

166. 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 166 and therefore denies the same.

i. Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries Ltd. (ANDA No. 213577)

167. This Court has personal jurisdiction over Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries 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. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 167 and therefore denies the same.

168. This Court also has personal jurisdiction over Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. because, on information and belief, each such Defendant, 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 168 and therefore denies the same.

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

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 169 and therefore denies the same.

170. 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 Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 170 and therefore denies the same.

171. Venue is proper in this Court over Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. because Teva Pharmaceuticals USA, Inc. is incorporated in the State of Delaware and therefore resides in this judicial district, and Teva Pharmaceutical Industries 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 171 and therefore denies the same.

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

172. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 172 and therefore denies the same.

173. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 173 and therefore denies the same.

174. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 174 and therefore denies the same.

175. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 175 and therefore denies the same.

176. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 176 and therefore denies the same.

177. 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 177 and therefore denies the same.

THE PATENTS-IN-SUIT AND ENTRESTO®

178. 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.

ANSWER

Defendant admits that Novartis AG is the assignee listed on the face of the '659 Patent. Defendant admits that the '659 Patent is entitled "Methods of treatment and pharmaceutical composition." Defendant denies that the '659 Patent was duly and legally issued. Defendant admits that what purports to be a true and correct copy of the '659 Patent is attached as Exhibit A.

179. 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.

ANSWER

Defendant neither admits nor denies the allegations that refer to a written document, the terms of which speak for itself, except to state that the allegations inconsistent with the express terms of that document are denied.

180. 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.

ANSWER

Defendant admits that Novartis AG is the assignee listed on the face of the '331 Patent. Defendant admits that the '331 Patent is entitled "Methods of treatment and pharmaceutical

composition." Defendant denies that the '331 Patent was duly and legally issued. Defendant admits that what purports to be a true and correct copy of the '331 Patent is attached as Exhibit B.

181. 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.

ANSWER

Defendant neither admits nor denies the allegations that refer to a written document, the terms of which speak for itself, except to state that the allegations inconsistent with the express terms of that document are denied.

182. 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.

ANSWER

Defendant admits that Novartis Pharmaceuticals Corporation is the assignee listed on the face of the '938 Patent. Defendant admits that the '938 Patent is entitled "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." Defendant denies that the '938 Patent was duly and legally issued. Defendant admits that what purports to be a true and correct copy of the '938 is attached as Exhibit C.

183. 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.

ANSWER

Defendant neither admits nor denies the allegations that refer to a written document, the terms of which speak for itself, except to state that the allegations inconsistent with the express terms of that document are denied.

184. 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.

ANSWER

Defendant admits that Novartis, AG is the assignee listed on the face of the ’134 Patent. Defendant admits that the ’134 Patent is entitled “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.” Defendant denies that the ’134 Patent was duly and legally issued. Defendant admits that what purports to be a true and correct copy of the ’134 Patent is attached as Exhibit D.

185. 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.

ANSWER

Defendant neither admits nor denies the allegations that refer to a written document, the terms of which speak for itself, except to state that the allegations inconsistent with the express terms of that document are denied.

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

ANSWER

Defendant admits that, according to the FDA website Drugs@FDA, Novartis is the holder of NDA 207620, which is sold under the trade name ENTRESTO®. Defendant admits that ENTRESTO® currently is indicated (i) to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction, and (ii) for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older.

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

ANSWER

Denied.

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

ANSWER

Defendant admits that the '659, '331, '938, and '134 patents are listed in the Orange Book for ENTRESTO®. Plaintiffs caused these patents to be listed in the Orange Book, and Defendant denies that they were properly listed.

INFRINGEMENT BY EACH DEFENDANT OF THE PATENTS-IN-SUIT

189. Novartis incorporates paragraphs 1 – 112 and 178 – 188 as if fully set forth herein.

ANSWER

Defendant repeats and incorporates by reference the responses to each of the foregoing paragraphs of the Complaint as if fully set forth herein.

a. Alkem Laboratories Ltd.; S&B Pharma, Inc. (ANDA No. 213764)

190. On information and belief, Alkem, by itself or in concert with S&B, 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 190 and therefore denies the same.

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

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 191 and therefore denies the same.

192. 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, and, on information and belief, S&B, have committed an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 192 and therefore denies the same.

193. On information and belief, when Alkem filed ANDA No. 213764, Alkem and S&B 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 193 and therefore denies the same.

194. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 194 and therefore denies the same.

195. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 195 and therefore denies the same.

196. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 196 and therefore denies the same.

197. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 197 and therefore denies the same.

198. 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 and/or S&B 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 198 and therefore denies the same.

199. On information and belief, if the Alkem ANDA Products are approved, Alkem and/or S&B 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 and/or S&B 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 199 and therefore denies the same.

200. 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 and/or S&B 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 200 and therefore denies the same.

201. On information and belief, if the Alkem ANDA Products are approved, Alkem and/or S&B 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 and/or S&B 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 201 and therefore denies the same.

202. Novartis will be substantially and irreparably damaged by Alkem’s and/or S&B’s infringement of the ’659, ’331, ’938, and ’134 patents.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 202 and therefore denies the same.

203. 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 and/or S&B 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 203 and therefore denies the same.

204. On information and belief, Alkem and S&B have taken and continue 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 204 and therefore denies the same.

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

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 205 and therefore denies the same.

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

206. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 206 and therefore denies the same.

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

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 207 and therefore denies the same.

208. 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 208 and therefore denies the same.

209. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 209 and therefore denies the same.

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 infringe one or more claims of the '659, '331, '938, and '134 patents.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 210 and therefore denies the same.

211. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 211 and therefore denies the same.

212. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 212 and therefore denies the same.

213. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 213 and therefore denies the same.

214. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 214 and therefore denies the same.

215. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 215 and therefore denies the same.

216. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 216 and therefore denies the same.

217. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 217 and therefore denies the same.

218. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 218 and therefore denies the same.

219. 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 219 and therefore denies the same.

220. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 220 and therefore denies the same.

221. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 221 and therefore denies the same.

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

222. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 222 and therefore denies the same.

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

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 223 and therefore denies the same.

224. 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 224 and therefore denies the same.

225. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 225 and therefore denies the same.

226. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 226 and therefore denies the same.

227. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 227 and therefore denies the same.

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 or more claims of the '659 patent.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 228 and therefore denies the same.

229. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 229 and therefore denies the same.

230. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 230 and therefore denies the same.

231. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 231 and therefore denies the same.

232. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 232 and therefore denies the same.

233. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 233 and therefore denies the same.

234. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 234 and therefore denies the same.

235. 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 235 and therefore denies the same.

236. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 236 and therefore denies the same.

237. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 237 and therefore denies the same.

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

238. 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.

ANSWER

Defendant admits that it submitted ANDA No. 213605 to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to manufacture, use, sale, offer for sale, or import the Crystal ANDA Products prior to the expiration of the '659, '331, '938, and '134 patents.

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

ANSWER

Admitted.

240. 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).

ANSWER

Denied.

241. 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.

ANSWER

Defendant admits that it was aware of the '659, '331, '938, and '134 patents at the time of filing its ANDA. Defendant denies the remaining allegations in Paragraph 241.

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 infringe one or more claims of the '659, '331, '938, and '134 patents.

ANSWER

Denied.

243. 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.

ANSWER

Denied.

244. 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.

ANSWER

Denied.

245. 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.

ANSWER

Denied.

246. 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.

ANSWER

Denied.

247. 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.

ANSWER

Denied.

248. 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.

ANSWER

Denied.

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

ANSWER

Denied.

250. 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).

ANSWER

Denied.

251. 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.

ANSWER

Denied.

252. 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.

ANSWER

Denied.

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

253. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 253 and therefore denies the same.

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

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 254 and therefore denies the same.

255. 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 255 and therefore denies the same.

256. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 256 and therefore denies the same.

257. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 257 and therefore denies the same.

258. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 258 and therefore denies the same.

259. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 259 and therefore denies the same.

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 more claims of the ’938 patent.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 260 and therefore denies the same.

261. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 261 and therefore denies the same.

262. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 262 and therefore denies the same.

263. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 263 and therefore denies the same.

264. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 264 and therefore denies the same.

265. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 265 and therefore denies the same.

266. 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 266 and therefore denies the same.

267. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 267 and therefore denies the same.

268. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 268 and therefore denies the same.

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

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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 269 and therefore denies the same.

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

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 270 and therefore denies the same.

271. 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 271 and therefore denies the same.

272. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 272 and therefore denies the same.

273. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 273 and therefore denies the same.

274. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 274 and therefore denies the same.

275. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 275 and therefore denies the same.

276. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 276 and therefore denies the same.

277. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 277 and therefore denies the same.

278. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 278 and therefore denies the same.

279. 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 279 and therefore denies the same.

280. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 280 and therefore denies the same.

281. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 281 and therefore denies the same.

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

282. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 282 and therefore denies the same.

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

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 283 and therefore denies the same.

284. 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 284 and therefore denies the same.

285. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 285 and therefore denies the same.

286. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 286 and therefore denies the same.

287. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 287 and therefore denies the same.

288. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 288 and therefore denies the same.

289. 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 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 289 and therefore denies the same.

290. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 290 and therefore denies the same.

291. 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 291 and therefore denies the same.

292. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 292 and therefore denies the same.

293. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 293 and therefore denies the same.

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

294. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 294 and therefore denies the same.

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

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 295 and therefore denies the same.

296. 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 296 and therefore denies the same.

297. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 297 and therefore denies the same.

298. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 298 and therefore denies the same.

299. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 299 and therefore denies the same.

300. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 300 and therefore denies the same.

301. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 301 and therefore denies the same.

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

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 302 and therefore denies the same.

303. 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 303 and therefore denies the same.

304. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 304 and therefore denies the same.

305. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 305 and therefore denies the same.

i. Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries Ltd. (ANDA No. 213577)

306. On information and belief, Teva Pharmaceuticals USA, Inc., by itself or in concert with Teva Pharmaceutical Industries Ltd., 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 306 and therefore denies the same.

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

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 307 and therefore denies the same.

308. 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 Pharmaceuticals USA, Inc., and, on information and belief, Teva Pharmaceutical Industries Ltd., have committed an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 308 and therefore denies the same.

309. On information and belief, when Teva Pharmaceuticals USA, Inc. filed ANDA No. 213577, Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 309 and therefore denies the same.

310. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 310 and therefore denies the same.

311. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 311 and therefore denies the same.

312. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 312 and therefore denies the same.

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 directly infringe one more claims of the '938 patent.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 313 and therefore denies the same.

314. 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 Pharmaceuticals USA, Inc. and/or Teva Pharmaceutical Industries 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 314 and therefore denies the same.

315. On information and belief, if the Teva ANDA Products are approved, Teva Pharmaceuticals USA, Inc. and/or Teva Pharmaceutical Industries 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 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 Pharmaceuticals USA, Inc. and/or Teva Pharmaceutical Industries 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 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 315 and therefore denies the same.

316. 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 Pharmaceuticals USA, Inc. and/or Teva Pharmaceutical Industries 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 316 and therefore denies the same.

317. On information and belief, if the Teva ANDA Products are approved, Teva Pharmaceuticals USA, Inc. and/or Teva Pharmaceutical Industries 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 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 Pharmaceuticals USA, Inc. and/or Teva Pharmaceutical Industries 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 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 317 and therefore denies the same.

318. Novartis will be substantially and irreparably damaged by Teva Pharmaceuticals USA, Inc.’s and/or Teva Pharmaceutical Industries Ltd.’s infringement of the ’659, ’331, ’938, and ’134 patents.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 318 and therefore denies the same.

319. 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 Pharmaceuticals USA, Inc. and/or Teva Pharmaceutical Industries 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 319 and therefore denies the same.

320. On information and belief, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. have taken and continue 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 320 and therefore denies the same.

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

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 321 and therefore denies the same.

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

322. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 322 and therefore denies the same.

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

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 323 and therefore denies the same.

324. 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 324 and therefore denies the same.

325. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 325 and therefore denies the same.

326. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 326 and therefore denies the same.

327. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 327 and therefore denies the same.

328. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 328 and therefore denies the same.

329. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 329 and therefore denies the same.

330. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 330 and therefore denies the same.

331. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 331 and therefore denies the same.

332. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 332 and therefore denies the same.

333. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 333 and therefore denies the same.

334. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 334 and therefore denies the same.

335. 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).

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 335 and therefore denies the same.

336. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 336 and therefore denies the same.

337. 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.

ANSWER

Defendant Crystal lacks knowledge or information sufficient to confirm or deny the allegations in Paragraph 337 and therefore denies the same.

PRAYER FOR RELIEF

Defendant denies that Plaintiff is entitled to the judgment or other relief prayed for in subparagraphs 362-369 under the heading "Prayer for Relief" in the Complaint.

DEFENDANT'S AFFIRMATIVE DEFENSES

Pursuant to Fed. R. Civ. P. 8(b) and (c), without assuming any burden that they would not otherwise bear, without reducing or removing Plaintiff's burdens of proof on its affirmative claims against Defendant Crystal Pharmaceutical (Suzhou) Co., Ltd., and reserving its rights to assert additional defenses, Defendant assert the following defenses to the Complaint.

FIRST AFFIRMATIVE DEFENSE

Plaintiff fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

Plaintiff fails to state any facts to support any claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

Each asserted claim of the ’659, ’331, ’938, and ’134 Patents are invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103 and/or 112, as well as judicially created conditions for patentability, including obviousness-type double patenting.

FOURTH AFFIRMATIVE DEFENSE

Defendant has not infringed, induced infringement, or contributed to the infringement, and Defendant will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, any valid and enforceable asserted claim of the ’659, ’331, ’938, and ’134 Patents.

FIFTH AFFIRMATIVE DEFENSE

Plaintiff is not entitled to seek injunctive relief against Defendant because the alleged harm is not immediate or irreparable, and therefore Plaintiff has an adequate remedy at law.

SIXTH AFFIRMATIVE DEFENSE

Plaintiff is not entitled to attorney’s fees against Defendant because Plaintiff has not sufficiently alleged, and cannot prove, that this is an exceptional case under 35 U.S.C. § 285.

SEVENTH AFFIRMATIVE DEFENSE

35 U.S.C. § 288 prevents Plaintiff from recovering any costs associated with this action.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's admission in Paragraphs 41, 134, and 238 above that Defendant Crystal followed the requirements of 21 U.S.C. §355(j) preempts Plaintiff's claim for exceptional damages under 35 U.S.C. §285.

NINTH AFFIRMATIVE DEFENSE

Any additional affirmative defenses that discovery may reveal.

COUNTERCLAIMS

Counterclaim Plaintiff Crystal Pharmaceutical (Suzhou) Co., Ltd. ("Counterclaim Plaintiff" or "Crystal"), for its Counterclaims against Counterclaim Defendant Novartis Pharmaceuticals Corporation ("Counterclaim Defendant" or "Novartis"), allege and aver as follows:

THE PARTIES

1. Counterclaim Plaintiff Crystal is a corporation organized and existing under the laws of China, having a principal place of business at B4-301, Biobay, 218 Xinghu Street, Suzhou Industrial Park, China, 215123.

2. Upon information and belief, Counterclaim Defendant Novartis 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.

JURISDICTION AND VENUE

3. This is an action for a declaratory judgment, together with such further relief based thereon as may be necessary or proper, pursuant to the Federal Declaratory Judgment Act 28 U.S.C. §§ 2201 and 2202.

4. There is an actual controversy between Counterclaim Plaintiff and Counterclaim Defendant arising under the United States Patent Laws, Title 35 of the United States Code.

5. This Court has subject matter jurisdiction over the action based on 28 U.S.C. §§ 1331 and 1338.

6. This Court has personal jurisdiction over Counterclaim Defendant, at least because they voluntarily filed the Complaint asserting claims to which these Counterclaims are directed in this Court.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400.

FACTUAL BACKGROUND

8. Counterclaim Plaintiff hereby incorporates each response to each of the foregoing paragraphs of the Complaint, and the foregoing Paragraphs 1-7 of the Counterclaims, as if fully stated herein.

9. Counterclaim Defendant filed the Complaint in this Court against Counterclaim Plaintiff alleging that the filing of Crystal's ANDA No. 213605 infringed the '659, '331, '938, and '134 Patents, and that any commercial manufacture, use, offer to sell, sale or import of the products which are the subject of that ANDA would infringe the '659, '331, '938, and '134 Patents.

10. An actual and justiciable controversy exists regarding the '659, '331, '938, and '134 Patents by virtue of the filing of the Complaint by Counterclaim Defendant and as admitted by Counterclaim Defendant in the Complaint.

11. Counterclaim Plaintiff requires an immediate declaration of their rights vis-à-vis the Counterclaim Defendant with respect to the products which are the subject of Crystal's ANDA No. 213605 and the '659, '331, '938, and '134 Patents.

FIRST COUNTERCLAIM

12. Counterclaim Plaintiff repeats and realleges the allegations contained in Paragraphs 1-11 of the Counterclaims as if fully set forth herein.

13. Each and every asserted claim of the ’659 Patent is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103 and/or 112, as well as judicially created conditions for patentability.

14. Counterclaim Plaintiff is entitled to a judicial declaration that the asserted claims of the ’659 are invalid.

SECOND COUNTERCLAIM

15. Counterclaim Plaintiff repeats and realleges the allegations contained in Paragraphs 1-14 of the Counterclaims as if fully set forth herein.

16. Counterclaim Plaintiff has not infringed, induced infringement, or contributed to the infringement, and Defendant will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of the ’659 Patent.

17. Counterclaim Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of the product that is the subject of Crystal’s ANDA No. 213605 has not infringed, does not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the ’659 Patent.

THIRD COUNTERCLAIM

18. Counterclaim Plaintiff repeats and realleges the allegations contained in Paragraphs 1-17 of the Counterclaims as if fully set forth herein.

19. Each and every asserted claim of the ’331 Patent is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103 and/or 112, as well as judicially created conditions for patentability.

20. Counterclaim Plaintiff is entitled to a judicial declaration that the asserted claims of the ’331 Patent are invalid.

FOURTH COUNTERCLAIM

21. Counterclaim Plaintiff repeats and realleges the allegations contained in Paragraphs 1-20 of the Counterclaims as if fully set forth herein.

22. Counterclaim Plaintiff has not infringed, induced infringement, or contributed to the infringement, and Defendant will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of the ’331 Patent.

23. Counterclaim Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of the product that is the subject of Crystal’s ANDA No. 213605 has not infringed, does not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the ’331 Patent.

FIFTH COUNTERCLAIM

24. Counterclaim Plaintiff repeats and realleges the allegations contained in Paragraphs 1-23 of the Counterclaims as if fully set forth herein.

25. Each and every asserted claim of the ’938 Patent is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103 and/or 112, as well as judicially created conditions for patentability.

26. Counterclaim Plaintiff is entitled to a judicial declaration that the asserted claims of the’938 Patent are invalid.

SIXTH COUNTERCLAIM

27. Counterclaim Plaintiff repeats and realleges the allegations contained in Paragraphs 1-126 of the Counterclaims as if fully set forth herein.

28. Counterclaim Plaintiff has not infringed, induced infringement, or contributed to the infringement, and Defendant will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of the ’938 Patent.

29. Counterclaim Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of the product that is the subject of Crystal’s ANDA No. 213605 has not infringed, does not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the ’938 Patent.

SEVENTH COUNTERCLAIM

30. Counterclaim Plaintiff repeats and realleges the allegations contained in Paragraphs 1-29 of the Counterclaims as if fully set forth herein.

31. Each and every asserted claim of the ’134 Patent is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103 and/or 112, as well as judicially created conditions for patentability.

32. Counterclaim Plaintiff is entitled to a judicial declaration that the claims of the’134 Patent are invalid.

EIGHTH COUNTERCLAIM

33. Counterclaim Plaintiff repeats and realleges the allegations contained in Paragraphs 1-32 of the Counterclaims as if fully set forth herein.

34. Counterclaim Plaintiff has not infringed, induced infringement, or contributed to the infringement, and Defendant will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of the ’134 Patent.

35. Counterclaim Plaintiff is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of the product that is the subject of Crystal’s ANDA No. 213605 has not infringed, does not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the ’134 Patent.

COUNTERCLAIM PLAINTIFF’S REQUEST FOR RELIEF

WHEREFORE, Counterclaim Plaintiff respectfully requests that:

(a) Judgment be entered that the Complaint against Crystal is dismissed with prejudice and that Novartis take nothing thereby;

(b) Judgment be entered that the commercial manufacture, use, offer to sell, sale or import of the products which are the subject of Crystal’s ANDA No. 213605 do not and will not infringe any valid asserted claim of United States Patent 8,101,659;

(c) Judgment be entered that each asserted claim of United States Patent 8,101,659 is invalid;

(d) The Court permanently enjoin Novartis or any of their assigns or successors from asserting that the commercial manufacture, use, offer to sell, sale or import of the products which are the subject of Crystal’s ANDA No. 213605 infringes or will infringe any claim of United States Patent 8,101,659;

(e) Judgment be entered that the commercial manufacture, use, offer to sell, sale or import of the products which are the subject of Crystal's ANDA No. 213605 do not and will not infringe any valid asserted claim of United States Patent 8,796,331;

(f) Judgment be entered that each asserted claim of United States Patent 8,796,331 is invalid;

(g) The Court permanently enjoin Novartis or any of their assigns or successors from asserting that the commercial manufacture, use, offer to sell, sale or import of the products which are the subject of Crystal's ANDA No. 213605 infringes or will infringe any claim of United States Patent 8,796,331;

(h) Judgment be entered that the commercial manufacture, use, offer to sell, sale or import of the products which are the subject of Crystal's ANDA No. 213605 do not and will not infringe any valid asserted claim of United States Patent 8,877,938;

(i) Judgment be entered that each asserted claim of United States Patent 8,877,938 is invalid;

(j) The Court permanently enjoin Novartis or any of their assigns or successors from asserting that the commercial manufacture, use, offer to sell, sale or import of the products which are the subject of Crystal's ANDA No. 213605 infringes or will infringe any claim of United States Patent 8,877,938;

(k) Judgment be entered that the commercial manufacture, use, offer to sell, sale or import of the products which are the subject of Crystal's ANDA No.

213605 do not and will not infringe any valid asserted claim of United States Patent 9,388,134;

(l) Judgment be entered that each asserted claim of United States Patent 9,388,134 is invalid;

(m) The Court permanently enjoin Novartis or any of their assigns or successors from asserting that the commercial manufacture, use, offer to sell, sale or import of the products which are the subject of Crystal's ANDA No. 213605 infringes or will infringe any claim of United States Patent 9,388,134;

(n) This case be deemed an exceptional case within the meaning of 35 U.S.C. § 285;

(o) Crystal be awarded its attorney's fees and costs; and

(p) The Court award Crystal such other and further relief as this Court may deem necessary, just and proper.

Dated: January 7, 2020

Respectfully submitted,

/s/ Adam V. Orlacchio

BLANK ROME LLP
Adam V. Orlacchio (ID No. 5520)
1201 N. Market Street, Suite 800
Wilmington, Delaware 19801
Telephone: (302) 425-6431
Orlacchio@BlankRome.com

Jay P. Lessler, Esq.
(pro hac vice)
1271 Avenue of the Americas
New York, NY 10020
Telephone: (212) 885-5176
Facsimile: (917) 332-3773
JLessler@BlankRome.com

ATTORNEYS FOR DEFENDANT CRYSTAL PHARMACEUTICAL (SUZHOU) CO., LTD.