IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Entresto (Sacubitril/Valsartan) Patent Litigation	)	C.A. No. 20-md-2930-LPS
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., HETERO USA INC., HETERO LABS LIMITED, HETERO LABS LIMITED UNIT III, MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, MSN LIFE SCIENCES PRIVATE LIMITED, NOVUGEN PHARMA (MALAYSIA) SDN. BHD., ZYDUS PHARMACEUTICALS (USA) INC., CADILA HEALTHCARE LTD., Defendants.	)	C.A. No. 19-2053-LPS

AMENDED COMPLAINT

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

NATURE OF THE ACTION

1. This is a patent infringement action arising under Title 35 of the United States Code and concerning Abbreviated New Drug Applications ("ANDAs") submitted to the United States Food and Drug Administration ("FDA") by the above-named defendants seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of

sacubitril/valsartan tablets, generic versions of Novartis's ENTRESTO® tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg, prior to the expiration of U.S. Patents Nos. 8,101,659 (the "'659 patent"), 8,796,331 (the "'331 patent"), 8,877,938 (the "'938 patent"), and 9,388,134 (the "'134 patent").

PARTIES

A. Novartis

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

B. Defendants

a. Dr. Reddy's Laboratories, Inc.; Dr. Reddy's Laboratories, Ltd. (ANDA No. 213627)

3. On information and belief, Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540. On information and belief, Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories, Ltd.

4. On information and belief, Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 8-2-337 Road No. 3, Banjara Hills, Hyderabad, 500034, India.

5. On information and belief, Dr. Reddy's Laboratories, 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.

6. On information and belief, Dr. Reddy's Laboratories, 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.

7. By a letter dated September 18, 2019 ("Dr. Reddy's Notice Letter"), Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. notified Novartis that (i) Dr. Reddy's Laboratories, Inc., on behalf of Dr. Reddy's Laboratories, Ltd., had submitted to the FDA ANDA No. 213627 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Dr. Reddy's ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Dr. Reddy's 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. 213627 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '659, '331, '938, and '134 patents.

8. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. have committed an act of infringement in this judicial district by filing ANDA No. 213627 with the intent to make, use, sell, offer for sale, and/or import the Dr. Reddy's 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.

9. On information and belief, Dr. Reddy's Laboratories, Inc. acted in concert with and under the direction of Dr. Reddy's Laboratories, Ltd. in the preparation and submission of ANDA No. 213627, and, if the ANDA is approved, will act in concert with and under the direction of Dr. Reddy's Laboratories, Ltd. to engage in the commercial manufacture, use, sale,

offer for sale, and/or importation of the Dr. Reddy's ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659, '331, '938, and '134 patents.

10. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories Ltd. have taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Dr. Reddy's ANDA Products, that will be purposefully directed at Delaware and elsewhere.

11. On information and belief, Dr. Reddy's Laboratories, Inc. has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware either directly or indirectly through subsidiaries, agents, or affiliates; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

12. On information and belief, Dr. Reddy's Laboratories, 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 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.

13. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, 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., Boehringer Ingelheim Pharms. Inc. et al. v. Dr. Reddy's Labs., Ltd. et al.*, C.A. No. 19-1495 (D. Del.).

14. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd., the entities identified in the Dr. Reddy's Notice Letter as having submitted ANDA No. 213627, have agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213627 in the District of Delaware, and have agreed, only for the purposes of such action(s), not to challenge personal jurisdiction and venue in the District of Delaware.

b. Hetero USA Inc.; Hetero Labs Limited; Hetero Labs Limited Unit III (ANDA No. 213668)

15. On information and belief, Hetero 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 W/K Incorporating Services, Inc., 3500 South Dupont Highway, Dover, Delaware 19901, and having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854. On information and belief, Hetero USA Inc. is a partially owned subsidiary of Hetero Labs Limited and a United States regulatory agent of Hetero Labs Limited Unit III.

16. On information and belief, Hetero Labs Limited is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2 Hetero Corporate Industrial Estates Sanath Nagar, Hyderabad, Telangana 500018, India.

17. On information and belief, Hetero Labs Limited Unit III is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2 Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad, Telangana 500018, India. On information and belief, Hetero Labs Limited Unit III is a division of Hetero Labs Limited.

18. On information and belief, Hetero 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.

19. On information and belief, Hetero 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.

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

21. By a letter dated September 18, 2019 ("Hetero Notice Letter"), Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III notified Novartis that (i) Hetero USA Inc., Hetero Labs Limited, and/or Hetero Labs Limited Unit III had submitted to the FDA ANDA No. 213668 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Hetero ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Hetero 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. 213668 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '659, '331, '938, and '134 patents.

22. Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III have committed an act of infringement in this judicial district by filing ANDA No. 213668 with the intent to make, use, sell, offer for sale, and/or import the Hetero 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.

23. On information and belief, Hetero USA Inc. acted in concert with and under the direction of Hetero Labs Limited and/or Hetero Labs Limited Unit III in the preparation and

submission of ANDA No. 213668, and, if the ANDA is approved, will act in concert with and under the direction of Hetero Labs Limited and/or Hetero Labs Limited Unit III to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Hetero ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659, '938, '331 and '134 patents.

24. On information and belief, Hetero Labs Limited acted in concert with and directed Hetero USA Inc. and/or Hetero Labs Limited Unit III in the preparation and submission of ANDA No. 213668, and, if the ANDA is approved, will act in concert with and direct Hetero USA Inc. and/or Hetero Labs Limited Unit III to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Hetero ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659, '938, '331 and '134 patents.

25. On information and belief, Hetero Labs Limited Unit III acted in concert with and under the direction of Hetero Labs Limited, and acted in concert with and directed Hetero USA Inc., in the preparation and submission of ANDA No. 213668, and, if the ANDA is approved, will act in concert with and under the direction of Hetero Labs Limited, and will act in concert with and direct Hetero USA, Inc., to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Hetero ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659, '938, '331 and '134 patents.

26. Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III have taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Hetero ANDA Products, that will be purposefully directed at Delaware and elsewhere.

27. On information and belief, Hetero 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 Hetero 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.

28. On information and belief, Hetero Labs Limited Unit III 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 Hetero 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.

29. Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III, the entities identified in the Hetero Notice Letter as having submitted ANDA No. 213668, have agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213668 in the District of Delaware, and have agreed, only for the purposes of such action(s), not to challenge personal jurisdiction and venue in the District of Delaware.

c. MSN Pharmaceuticals Inc.; MSN Laboratories Private Limited; MSN Life Sciences Private Limited (ANDA No. 213748)

30. On information and belief, MSN 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 United States Corporation Agents, Inc., 300 Delaware Avenue, Suite 210-A, Wilmington, Delaware 19801, and having a principal place of business at 20 Duke Road,

Piscataway, New Jersey 08854. On information and belief, MSN Pharmaceuticals Inc. is a wholly owned subsidiary of and U.S. agent for MSN Laboratories Private Limited.

31. On information and belief, MSN Laboratories Private Limited is a corporation organized and existing under the laws of India, having a principal place of business at MSN House, C-24, Sanathnagar Industrial Estate, Hyderabad, 500018, Telangana, India.

32. On information and belief, MSN Life Sciences Private Limited is a corporation organized and existing under the laws of India, having a principal place of business at Sy No - 21/A & 21AA, Mambapur (Village), Gummadidala (Mandal), Sangareddy (District) - 502313, Telangana, India. On information and belief, MSN Life Sciences Private Limited is a wholly owned subsidiary of MSN Laboratories Private Limited.

33. On information and belief, MSN 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.

34. On information and belief, MSN Laboratories Private 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.

35. On information and belief, MSN Life Sciences Private 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.

36. By a letter dated September 17, 2019 ("MSN Notice Letter"), MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited notified Novartis that (i) MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited had submitted to the FDA ANDA No. 213748 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg

("MSN ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the MSN 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. 213748 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '659, '331, '938, and '134 patents.

37. MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited have committed an act of infringement in this judicial district by filing ANDA No. 213748 with the intent to make, use, sell, offer for sale, and/or import the MSN 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.

38. On information and belief, MSN Pharmaceuticals Inc. acted in concert with and under the direction of MSN Laboratories Private Limited, and acted in concert with MSN Life Sciences Private Limited, in the preparation and submission of ANDA No. 213748, and, if the ANDA is approved, will act in concert with and under the direction of MSN Laboratories Private Limited, and will act in concert with MSN Life Sciences Private Limited, to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the MSN ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659, '331, '938, and '134 patents.

39. On information and belief, MSN Life Sciences Private Limited acted in concert with and under the direction of MSN Laboratories Private Limited, and acted in concert with MSN Pharmaceuticals Inc., in the preparation and submission of ANDA No. 213748, and, if the ANDA is approved, will act in concert with and under the direction of MSN Laboratories Private

Limited, and will act in concert with MSN Pharmaceuticals Inc., to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the MSN ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659, '331, '938, and '134 patents.

40. MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited, by themselves or together with MSN Life Sciences Private Limited, have taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the MSN ANDA Products, that will be purposefully directed at Delaware and elsewhere.

41. On information and belief, MSN Laboratories Private 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 MSN 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.

42. On information and belief, MSN Life Sciences Private 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 MSN 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.

43. MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited have availed themselves of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g., Vanda Pharms. v. MSN Pharms. Inc. et al.*, C.A. No. 19-926 (D. Del.).

44. MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited, the entities identified in the MSN Notice Letter as having submitted ANDA No. 213748, have agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213748 in the District of Delaware, and have agreed, only for the purposes of such action(s), not to challenge personal jurisdiction and venue in the District of Delaware.

d. Novugen Pharma (Malaysia) Sdn. Bhd. (ANDA No. 213611)

45. On information and belief, Novugen Pharma (Malaysia) Sdn. Bhd. ("Novugen") is a corporation organized and existing under the laws of Malaysia, having a principal place of business at 3, Jalan Jururancang U1/21, Hicom-glenmarie Industrial Park, Shah Alam, 40150, Malaysia.

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

47. By a letter dated September 16, 2019 ("Novugen Notice Letter"), Novugen notified Novartis that (i) Novugen had submitted to the FDA ANDA No. 213611 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Novugen ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Novugen 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. 213611 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the ’659, ’331, ’938, and ’134 patents.

48. Novugen has committed an act of infringement in this judicial district by filing ANDA No. 213611 with the intent to make, use, sell, offer for sale, and/or import the Novugen ANDA Products in or into this judicial district, prior to the expiration of the ’659, ’331, ’938, and ’134 patents, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

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

50. On information and belief, Novugen 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.

51. Novugen, the entity identified in the Novugen Notice Letter as having submitted ANDA No. 213611, has agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213611 in the District of Delaware, and has agreed, only for the purposes of such action(s), not to challenge personal jurisdiction and venue in the District of Delaware.

e. Zydus Pharmaceuticals (USA) Inc.; Cadila Healthcare Ltd. (ANDA No. 213719)

52. On information and belief, Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. On information and belief, Zydus Pharmaceuticals (USA) Inc. is a wholly owned subsidiary of Cadila Healthcare Ltd.

53. On information and belief, Cadila Healthcare Ltd. is a corporation organized and existing under the laws of India, with a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015, Gujarat, India.

54. On information and belief, Zydus 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.

55. On information and belief, Cadila Healthcare 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.

56. By a letter dated September 18, 2019 ("Zydus Notice Letter"), Zydus Pharmaceuticals (USA) Inc. notified Novartis that (i) Zydus Pharmaceuticals (USA) Inc. had submitted to the FDA ANDA No. 213719 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Zydus ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Zydus 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. 213719 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '659, '331, '938, and '134 patents.

57. Zydus Pharmaceuticals (USA) Inc. has committed an act of infringement in this judicial district by filing ANDA No. 213719 with the intent to make, use, sell, offer for sale,

and/or import the Zydus 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.

58. On information and belief, Cadila Healthcare Ltd. acted in concert with and directed Zydus Pharmaceuticals (USA) Inc. in the preparation and submission of ANDA No. 213719, and, if the ANDA is approved, will act in concert with and direct Zydus Pharmaceuticals (USA) Inc. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Zydus ANDA Products in or into the United States, including Delaware, prior to the expiration of the ’659, ’331, ’938, and ’134 patents.

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

60. On information and belief, Zydus Pharmaceuticals (USA) Inc. 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.

61. On information and belief, Cadila Healthcare 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; has

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

62. Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. 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., Boehringer Ingelheim Pharms. Inc. et al. v. Zydus Pharms. (USA) Inc. et al.*, C.A. No. 19-1501 (D. Del.).

63. Zydus Pharmaceuticals (USA) Inc., the entity identified in the Zydus Notice Letter as having submitted ANDA No. 213719, has agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213719 in the District of Delaware, and has agreed, only for the purposes of such action(s), not to challenge personal jurisdiction and venue in the District of Delaware.

JURISDICTION AND VENUE

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

a. Dr. Reddy's Laboratories, Inc.; Dr. Reddy's Laboratories, Ltd. (ANDA No. 213627)

65. This Court has personal jurisdiction over Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, 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. 213627 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.

66. This Court also has personal jurisdiction over Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. because, on information and belief, each such Defendant, upon approval of ANDA No. 213627, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213627 that will be purposefully directed at Delaware, including the marketing of the Dr. Reddy's ANDA Products in Delaware, prior to the expiration of the '659, '331, '938, and '134 patents.

67. This Court also has personal jurisdiction over Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. because, on information and belief, each such Defendant's affiliations with the State of Delaware are sufficiently continuous and systematic as to render each such Defendant essentially at home in this forum.

68. This Court also has personal jurisdiction over Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. because each such Defendant has availed itself of the legal protections of the State of Delaware, by admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

69. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd., the entities identified in the Dr. Reddy's Notice Letter as having submitted ANDA No. 213627, have agreed with Novartis to litigate this action in Delaware and not to contest personal jurisdiction or venue in Delaware in this action.

70. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd.

71. Venue is proper in this Court because Dr. Reddy's Laboratories, Inc. has consented to venue in Delaware for purposes of this action and because Dr. Reddy's

Laboratories, 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).

b. Hetero USA Inc.; Hetero Labs Limited; Hetero Labs Limited Unit III (ANDA No. 213668)

72. This Court has personal jurisdiction over Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III 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. 213668 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.

73. This Court also has personal jurisdiction over Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III because, on information and belief, each such Defendant, upon approval of ANDA No. 213668, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213668 that will be purposefully directed at Delaware, including the marketing of the Hetero ANDA Products in Delaware, prior to the expiration of the ’659, ’938, ’331, and ’134 patents.

74. This Court also has personal jurisdiction over Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III because, on information and belief, each such Defendant’s affiliations with the State of Delaware, including Hetero USA Inc.’s incorporation in Delaware, Hetero Labs Limited’s ownership of and actions in concert with Hetero USA Inc., and Hetero Labs Limited Unit III’s actions in concert with Hetero USA Inc. in filing ANDA No. 213668 and in regard to future tortious acts of patent infringement permitted under ANDA No.

213668, are sufficiently continuous and systematic as to render each such Defendant essentially at home in this forum.

75. Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III, the entities identified in the Hetero Notice Letter as having submitted ANDA No. 213668, have agreed with Novartis to litigate this action in Delaware and not to contest personal jurisdiction or venue in Delaware in this action.

76. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III.

77. Venue is proper in this Court because Hetero USA Inc. is incorporated in the State of Delaware and therefore resides in this judicial district, and because Hetero Labs Limited and Hetero Labs Limited Unit III 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).

c. MSN Pharmaceuticals Inc.; MSN Laboratories Private Limited; MSN Life Sciences Private Limited (ANDA No. 213748)

78. This Court has personal jurisdiction over MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited 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. 213748 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.

79. This Court also has personal jurisdiction over MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited because, on information

and belief, each such Defendant, upon approval of ANDA No. 213748, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213748 that will be purposefully directed at Delaware, including the marketing of the MSN ANDA Products in Delaware, prior to the expiration of the '659, '331, '938, and '134 patents.

80. This Court also has personal jurisdiction over MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited because each such Defendant's affiliations with the State of Delaware, including MSN Pharmaceuticals Inc.'s incorporation in Delaware, MSN Laboratories Private Limited's ownership of and actions in concert with MSN Pharmaceuticals Inc., and MSN Life Sciences Private Limited's actions in concert with MSN Pharmaceuticals Inc. are sufficiently continuous and systematic as to render each such Defendant essentially at home in this forum.

81. This Court also has personal jurisdiction over MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited because each such Defendant has availed itself of the legal protections of the State of Delaware, by admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

82. MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited, the entities identified in the MSN Notice Letter as having submitted ANDA No. 213748, have agreed with Novartis to litigate this action in Delaware and not to contest personal jurisdiction or venue in Delaware in this action.

83. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited.

84. Venue is proper in this Court because MSN Pharmaceuticals Inc. is incorporated in the State of Delaware and therefore resides in this judicial district, and because MSN Laboratories Private Limited and MSN Life Sciences Private Limited are foreign entities who may be sued in any judicial district, including Delaware. 28 U.S.C. § 1400(b); 28 U.S.C. § 1391(c)(3).

d. Novugen Pharma (Malaysia) Sdn. Bhd. (ANDA No. 213611)

85. This Court has personal jurisdiction over Novugen because Novugen has committed tortious acts of patent infringement in preparing and submitting ANDA No. 213611 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.

86. This Court also has personal jurisdiction over Novugen because, on information and belief, Novugen, upon approval of ANDA No. 213611, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213611 that will be purposefully directed at Delaware, including the marketing of the Novugen ANDA Products in Delaware, prior to the expiration of the ’659, ’331, ’938, and ’134 patents.

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

88. Novugen, the entity identified in the Novugen Notice Letter as having submitted ANDA No. 213611, has agreed with Novartis to litigate this action in Delaware and not to contest personal jurisdiction or venue in Delaware in this action.

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

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

e. Zydus Pharmaceuticals (USA) Inc.; Cadila Healthcare Ltd. (ANDA No. 213719)

91. This Court has personal jurisdiction over Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare 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. 213719 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.

92. This Court also has personal jurisdiction over Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. because, on information and belief, each such Defendant, upon approval of ANDA No. 213719, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213719 that will be purposefully directed at Delaware, including the marketing of the Zydus ANDA Products in Delaware, prior to the expiration of the ’659, ’331, ’938, and ’134 patents.

93. This Court also has personal jurisdiction over Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. because, on information and belief, each such Defendant’s affiliations with the State of Delaware are sufficiently continuous and systematic as to render each such Defendant essentially at home in this forum.

94. This Court also has personal jurisdiction over Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. because each such Defendant has availed itself of the legal

protections of the State of Delaware, by admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

95. Zydus Pharmaceuticals (USA) Inc., the entity identified in the Zydus Notice Letter as having submitted ANDA No. 213719, has agreed with Novartis to litigate this action in Delaware and not to contest personal jurisdiction or venue in Delaware in this action.

96. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd.

97. Venue is proper in this Court because Zydus Pharmaceuticals (USA) Inc. has consented to venue in Delaware for the purposes of this action and because Cadila Healthcare Ltd. is a foreign entity who may be sued in any judicial district, including Delaware. 28 U.S.C. § 1400(b); 28 U.S.C. § 1391(c)(3).

THE PATENTS-IN-SUIT AND ENTRESTO®

98. 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.

99. 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.

100. 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.

101. 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.

102. 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.

103. 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.

104. 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.

105. 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.

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

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

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

INFRINGEMENT BY EACH DEFENDANT OF THE PATENTS-IN-SUIT

109. Novartis incorporates paragraphs 1 – 63 and 98 – 108 as if fully set forth herein.

a. Dr. Reddy's Laboratories, Inc.; Dr. Reddy's Laboratories, Ltd. (ANDA No. 213627)

110. 129. On information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. submitted to the FDA ANDA No. 213627 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 Dr. Reddy's ANDA Products prior to the expiration of the '659, '331, '938, and '134 patents.

111. This action was commenced within 45 days of Novartis's receipt of the Dr. Reddy's Notice Letter.

112. By filing their 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 Dr. Reddy's ANDA Products in or into the United States prior to the expiration of the '659, '331, '938, and '134 patents, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. have committed an act of infringement under 35 U.S.C. § 271(e)(2).

113. On information and belief, when Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. filed ANDA No. 213627, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, 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.

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

115. The Dr. Reddy's Notice Letter does not deny that the Dr. Reddy's ANDA products would infringe claims 1-4 of the '659 patent, and that the use of the Dr. Reddy's ANDA Products would infringe claims 1, 2, and 4-8 of the '331 patent.

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

117. On information and belief, the Dr. Reddy's ANDA Products, if approved, will contain instructions for preparing, from the Dr. Reddy's ANDA Products, a pharmaceutical composition in the form of an aqueous oral suspension comprising (i) valsartan or a pharmaceutically acceptable salt thereof, (ii) sacubitril or a pharmaceutically acceptable salt thereof, and (iii) a pharmaceutically acceptable carrier, wherein components (i) and (ii) are administered in combination in about a 1:1 ratio. On information and belief, if the Dr. Reddy's

ANDA Products are approved, physicians, medical professionals, pharmacists, caregivers and/or patients following said instructions will directly infringe one or more claims of the ’659 patent. On information and belief, if the Dr. Reddy’s ANDA Products are approved, Dr. Reddy’s Laboratories, Inc. and/or Dr. Reddy’s Laboratories, Ltd. will actively encourage, recommend, or promote this infringement with knowledge of the ’659 patent, and with knowledge and intent that their acts will induce infringement of one or more claims of the ’659 patent.

118. On information and belief, if the Dr. Reddy’s ANDA Products are approved, Dr. Reddy’s Laboratories, Inc. and/or Dr. Reddy’s Laboratories, Ltd. will commercially manufacture, sell, offer for sale, and/or import those products, which will be specifically labeled with instructions for preparing, from the Dr. Reddy’s ANDA Products, a pharmaceutical composition in the form of an aqueous oral suspension comprising (i) valsartan or a pharmaceutically acceptable salt thereof, (ii) sacubitril or a pharmaceutically acceptable salt thereof, and (iii) a pharmaceutically acceptable carrier, wherein components (i) and (ii) are administered in combination in about a 1:1 ratio. On information and belief, if the Dr. Reddy’s ANDA Products are approved, those products will constitute a material part of a pharmaceutical composition comprising (i) valsartan or a pharmaceutically acceptable salt thereof, (ii) sacubitril or a pharmaceutically acceptable salt thereof, and (iii) a pharmaceutically acceptable carrier, wherein components (i) and (ii) are administered in combination in about a 1:1 ratio. On information and belief, if the Dr. Reddy’s ANDA Products are approved, physicians, medical professionals, pharmacists, caregivers and/or patients following the instructions in the Dr. Reddy’s ANDA Products will directly infringe one or more claims of the ’659 patent. On information and belief, if the Dr. Reddy’s ANDA Products are approved, Dr. Reddy’s Laboratories, Inc. and/or Dr. Reddy’s Laboratories, Ltd. will contributorily infringe one or more

claims of the ’659 patent, and will do so with knowledge of the ’659 patent, and that the Dr. Reddy’s ANDA Products are especially made or especially adapted for use in infringing one or more claims of the ’659 patent, and are not suitable for a substantial noninfringing use.

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

120. On information and belief, the Dr. Reddy’s 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 Dr. Reddy’s 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 Dr. Reddy’s ANDA Products are approved, Dr. Reddy’s Laboratories, Inc. and/or Dr. Reddy’s Laboratories, 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.

121. On information and belief, if the Dr. Reddy’s ANDA Products are approved, Dr. Reddy’s Laboratories, Inc. and/or Dr. Reddy’s Laboratories, 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 Dr. Reddy's 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 Dr. Reddy's ANDA Products are approved, physicians and/or patients following the instructions in the Dr. Reddy's ANDA Products will directly infringe one or more claims of the '331 patent. On information and belief, if the Dr. Reddy's ANDA Products are approved, Dr. Reddy's Laboratories, Inc. and/or Dr. Reddy's Laboratories, 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 Dr. Reddy's 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.

122. On information and belief, the Dr. Reddy's 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 Dr. Reddy's 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 Dr. Reddy's ANDA Products are approved, Dr. Reddy's Laboratories, Inc. and/or Dr. Reddy's Laboratories, 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.

123. On information and belief, if the Dr. Reddy's ANDA Products are approved, Dr. Reddy's Laboratories, Inc. and/or Dr. Reddy's Laboratories, 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 Dr. Reddy's 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 Dr. Reddy's ANDA Products are approved, physicians and/or patients following the instructions in the Dr. Reddy's ANDA Products will directly infringe one or more claims of the '134 patent. On information and belief, if the Dr. Reddy's ANDA Products are approved, Dr. Reddy's Laboratories, Inc. and/or Dr. Reddy's Laboratories, 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 Dr. Reddy's 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.

124. Novartis will be substantially and irreparably damaged by Dr. Reddy's Laboratories, Inc.'s and/or Dr. Reddy's Laboratories, Ltd.'s infringement of the '659, '331, '938, and '134 patents.

125. 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. 213627 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 Dr. Reddy’s ANDA Products and any act committed by Dr. Reddy’s Laboratories, Inc. and Dr. Reddy’s Laboratories, 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).

126. On information and belief, Dr. Reddy’s Laboratories, Inc. and Dr. Reddy’s Laboratories, Ltd. have taken and continue to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Dr. Reddy’s ANDA Products, including seeking approval of those products under ANDA No. 213627.

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

b. Hetero USA Inc.; Hetero Labs Limited; Hetero Labs Limited Unit III (ANDA No. 213668)

128. On information and belief, Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III submitted to the FDA ANDA No. 213668 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 Hetero ANDA Products prior to the expiration of the ’659, ’331, ’938, and ’134 patents.

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

130. By filing their 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 Hetero ANDA Products in or into the United States prior to the expiration of the ’659, ’331, ’938, and ’134 patents, Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III have committed an act of infringement under 35 U.S.C. § 271(e)(2).

131. On information and belief, when Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III filed ANDA No. 213668, Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III 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.

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

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

134. On information and belief, the Hetero ANDA Products, if approved, will contain instructions for preparing, from the Hetero ANDA Products, a pharmaceutical composition in the form of an aqueous oral suspension comprising (i) valsartan or a pharmaceutically acceptable

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

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

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

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

137. On information and belief, the Hetero 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 Hetero 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 Hetero ANDA Products are approved, Hetero USA Inc., Hetero Labs Limited, and/or Hetero Labs Limited Unit III 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.

138. On information and belief, if the Hetero ANDA Products are approved, Hetero USA Inc., Hetero Labs Limited, and/or Hetero Labs Limited Unit III 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 Hetero 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 Hetero ANDA Products are approved, physicians and/or patients following the instructions in the Hetero ANDA Products will directly infringe one or more claims of the ’331 patent. On information and belief, if the Hetero ANDA Products are approved, Hetero USA Inc., Hetero Labs Limited, and/or Hetero Labs Limited Unit III will contributorily infringe one or more claims of the ’331 patent, and will do so with knowledge of the ’331 patent, and that the Hetero 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.

139. On information and belief, the Hetero 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 Hetero 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 Hetero ANDA Products are approved, Hetero USA Inc., Hetero Labs Limited, and/or Hetero Labs Limited Unit III 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.

140. On information and belief, if the Hetero ANDA Products are approved, Hetero USA Inc., Hetero Labs Limited, and/or Hetero Labs Limited Unit III 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 Hetero 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 Hetero ANDA Products are approved, physicians and/or patients following the instructions in the Hetero ANDA Products will directly infringe one or more claims of the ’134 patent. On information and belief, if the Hetero ANDA Products are approved, Hetero USA Inc., Hetero Labs Limited, and/or Hetero Labs Limited Unit III will contributorily infringe one or more claims of the ’134 patent, and will do so with knowledge of the ’134 patent, and that the Hetero 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.

141. Novartis will be substantially and irreparably damaged by Hetero USA Inc.’s, Hetero Labs Limited’s, and Hetero Labs Limited Unit III’s infringement of the ’659, ’331, ’938, and ’134 patents.

142. 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. 213668 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 Hetero ANDA Products and any act committed by Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III 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).

143. On information and belief, Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III have taken and continue to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Hetero ANDA Products, including seeking approval of those products under ANDA No. 213668.

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

c. MSN Pharmaceuticals Inc.; MSN Laboratories Private Limited; MSN Life Sciences Private Limited (ANDA No. 213748)

145. On information and belief, MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited, by themselves or in concert with MSN Life Sciences Private Limited, submitted to the FDA ANDA No. 213748 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 MSN ANDA Products prior to the expiration of the ’659, ’331, ’938, and ’134 patents.

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

147. By filing their 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 MSN ANDA Products in or into the United States prior to the expiration of the ’659, ’331, ’938, and ’134 patents, MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited, and, on information and belief, MSN Life Sciences Private Limited, have committed an act of infringement under 35 U.S.C. § 271(e)(2).

148. On information and belief, when MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited filed ANDA No. 213748, MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited 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.

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

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

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

152. On information and belief, the MSN ANDA Products, if approved, will contain instructions for preparing, from the MSN ANDA Products, a pharmaceutical composition in the form of an aqueous oral suspension comprising (i) valsartan or a pharmaceutically acceptable salt thereof, (ii) sacubitril or a pharmaceutically acceptable salt thereof, and (iii) a pharmaceutically acceptable carrier, wherein components (i) and (ii) are administered in combination in about a 1:1 ratio. On information and belief, if the MSN ANDA Products are approved, physicians, medical professionals, pharmacists, caregivers and/or patients following said instructions will directly infringe one or more claims of the ’659 patent. On information and belief, if the MSN ANDA Products are approved, MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and/or MSN Life Sciences Private Limited will actively encourage, recommend, or promote this infringement with knowledge of the ’659 patent, and with knowledge and intent that their acts will induce infringement of one or more claims of the ’659 patent.

153. On information and belief, if the MSN ANDA Products are approved, MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and/or MSN Life Sciences Private Limited will commercially manufacture, sell, offer for sale, and/or import those products, which will be specifically labeled with instructions for preparing, from the MSN ANDA Products, a pharmaceutical composition in the form of an aqueous oral suspension comprising (i) valsartan

or a pharmaceutically acceptable salt thereof, (ii) sacubitril or a pharmaceutically acceptable salt thereof, and (iii) a pharmaceutically acceptable carrier, wherein components (i) and (ii) are administered in combination in about a 1:1 ratio. On information and belief, if the MSN ANDA Products are approved, those products will constitute a material part of a pharmaceutical composition comprising (i) valsartan or a pharmaceutically acceptable salt thereof, (ii) sacubitril or a pharmaceutically acceptable salt thereof, and (iii) a pharmaceutically acceptable carrier, wherein components (i) and (ii) are administered in combination in about a 1:1 ratio. On information and belief, if the MSN ANDA Products are approved, physicians, medical professionals, pharmacists, caregivers and/or patients following the instructions in the MSN ANDA Products will directly infringe one or more claims of the ’659 patent. On information and belief, if the MSN ANDA Products are approved, MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and/or MSN Life Sciences Private Limited will contributorily infringe one or more claims of the ’659 patent, and will do so with knowledge of the ’659 patent, and that the MSN ANDA Products are especially made or especially adapted for use in infringing one or more claims of the ’659 patent, and are not suitable for a substantial noninfringing use.

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

155. On information and belief, the MSN 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 MSN 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 MSN ANDA Products are approved, MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and/or MSN Life Sciences Private Limited 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.

156. On information and belief, if the MSN ANDA Products are approved, MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and/or MSN Life Sciences Private Limited 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 MSN 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 MSN ANDA Products are approved, physicians and/or patients following the instructions in the MSN ANDA Products will directly infringe one or more claims of the ’331 patent. On information and belief, if the MSN ANDA Products are approved, MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and/or MSN Life Sciences Private Limited will contributorily infringe one or more claims of the ’331 patent, and will do so with knowledge of the ’331 patent, and that the MSN 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.

157. On information and belief, the MSN 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 MSN 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 MSN ANDA Products are approved, MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and/or MSN Life Sciences Private Limited 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.

158. On information and belief, if the MSN ANDA Products are approved, MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and/or MSN Life Sciences Private Limited 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 MSN 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 MSN ANDA Products are approved, physicians and/or patients following the instructions in the MSN ANDA Products will directly infringe one or more claims of the ’134 patent. On information and belief, if the MSN ANDA Products are approved, MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and/or MSN Life Sciences Private Limited will contributorily infringe one or more claims of the ’134 patent, and will do so with knowledge of the ’134 patent, and that the MSN 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.

159. Novartis will be substantially and irreparably damaged by MSN Pharmaceuticals Inc.’s, MSN Laboratories Private Limited’s, and MSN Life Sciences Private Limited’s infringement of the ’659, ’331, ’938, and ’134 patents.

160. 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. 213748 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 MSN ANDA Products and any act committed by MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited 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).

161. On information and belief, MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited have taken and continue to take active steps

towards the commercial manufacture, use, sale, offer for sale, and/or importation of the MSN ANDA Products, including seeking approval of those products under ANDA No. 213748.

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

d. Novugen Pharma (Malaysia) Sdn. Bhd. (ANDA No. 213611)

163. On information and belief, Novugen submitted to the FDA ANDA No. 213611 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 Novugen ANDA Products prior to the expiration of the '659, '331, '938, and '134 patents.

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

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

166. On information and belief, when Novugen filed ANDA No. 213611, Novugen was aware of the '659, '331, '938, and '134 patents and that the filing of the ANDA with the

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

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

168. The Novugen Notice Letter does not deny that use of the Novugen 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.

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

170. On information and belief, the Novugen ANDA Products, if approved, will contain instructions for preparing, from the Novugen ANDA Products, a pharmaceutical composition in the form of an aqueous oral suspension comprising (i) valsartan or a pharmaceutically acceptable salt thereof, (ii) sacubitril or a pharmaceutically acceptable salt thereof, and (iii) a pharmaceutically acceptable carrier, wherein components (i) and (ii) are administered in combination in about a 1:1 ratio. On information and belief, if the Novugen ANDA Products are approved, physicians, medical professionals, pharmacists, caregivers and/or patients following said instructions will directly infringe one or more claims of the ’659 patent. On information and belief, if the Novugen ANDA Products are approved, Novugen will actively encourage, recommend, or promote this infringement with knowledge of the ’659 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the ’659 patent.

171. On information and belief, if the Novugen ANDA Products are approved, Novugen will commercially manufacture, sell, offer for sale, and/or import those products, which will be specifically labeled with instructions for preparing, from the Novugen ANDA Products, a pharmaceutical composition in the form of an aqueous oral suspension comprising (i) valsartan or a pharmaceutically acceptable salt thereof, (ii) sacubitril or a pharmaceutically acceptable salt thereof, and (iii) a pharmaceutically acceptable carrier, wherein components (i) and (ii) are administered in combination in about a 1:1 ratio. On information and belief, if the Novugen ANDA Products are approved, those products will constitute a material part of a pharmaceutical composition comprising (i) valsartan or a pharmaceutically acceptable salt thereof, (ii) sacubitril or a pharmaceutically acceptable salt thereof, and (iii) a pharmaceutically acceptable carrier, wherein components (i) and (ii) are administered in combination in about a 1:1 ratio. On information and belief, if the Novugen ANDA Products are approved, physicians, medical professionals, pharmacists, caregivers and/or patients following the instructions in the Novugen ANDA Products will directly infringe one or more claims of the ’659 patent. On information and belief, if the Novugen ANDA Products are approved, Novugen will contributorily infringe one or more claims of the ’659 patent, and will do so with knowledge of the ’659 patent, and that the Novugen ANDA Products are especially made or especially adapted for use in infringing one or more claims of the ’659 patent, and are not suitable for a substantial noninfringing use.

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

173. On information and belief, the Novugen 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 Novugen 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 Novugen ANDA Products are approved, Novugen 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.

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

Novugen 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.

175. On information and belief, the Novugen 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 Novugen 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 Novugen ANDA Products are approved, Novugen 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.

176. On information and belief, if the Novugen ANDA Products are approved, Novugen 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 Novugen 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 Novugen ANDA Products are approved, physicians and/or patients following the instructions in the Novugen ANDA Products will directly infringe

one or more claims of the ’134 patent. On information and belief, if the Novugen ANDA Products are approved, Novugen will contributorily infringe one or more claims of the ’134 patent, and will do so with knowledge of the ’134 patent, and that the Novugen 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.

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

178. 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. 213611 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 Novugen ANDA Products and any act committed by Novugen 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).

179. On information and belief, Novugen has taken and continues to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Novugen ANDA Products, including seeking approval of those products under ANDA No. 213611.

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

e. Zydus Pharmaceuticals (USA) Inc.; Cadila Healthcare Ltd. (ANDA No. 213719)

181. On information and belief, Zydus Pharmaceuticals (USA) Inc., by itself or in concert with Cadila Healthcare Ltd., submitted to the FDA ANDA No. 213719 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 Zydus ANDA Products prior to the expiration of the '659, '331, '938, and '134 patents.

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

183. By filing their 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 Zydus ANDA Products in or into the United States prior to the expiration of the '659, '331, '938, and '134 patents, Zydus Pharmaceuticals (USA) Inc., and, on information and belief, Cadila Healthcare Ltd., have committed an act of infringement under 35 U.S.C. § 271(e)(2).

184. On information and belief, when Zydus Pharmaceuticals (USA) Inc. filed ANDA No. 213719, Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare 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.

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

186. The Zydus Notice Letter does not deny that use of the Zydus 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.

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

188. On information and belief, the Zydus ANDA Products, if approved, will contain instructions for preparing, from the Zydus ANDA Products, a pharmaceutical composition in the form of an aqueous oral suspension comprising (i) valsartan or a pharmaceutically acceptable salt thereof, (ii) sacubitril or a pharmaceutically acceptable salt thereof, and (iii) a pharmaceutically acceptable carrier, wherein components (i) and (ii) are administered in combination in about a 1:1 ratio. On information and belief, if the Zydus ANDA Products are approved, physicians, medical professionals, pharmacists, caregivers and/or patients following said instructions will directly infringe one or more claims of the ’659 patent. On information and belief, if the Zydus ANDA Products are approved, Zydus Pharmaceuticals (USA) Inc. and/or Cadila Healthcare Ltd. will actively encourage, recommend, or promote this infringement with knowledge of the ’659 patent, and with knowledge and intent that their acts will induce infringement of one or more claims of the ’659 patent.

189. On information and belief, if the Zydus ANDA Products are approved, Zydus Pharmaceuticals (USA) Inc. and/or Cadila Healthcare Ltd. will commercially manufacture, sell, offer for sale, and/or import those products, which will be specifically labeled with instructions for preparing, from the Zydus ANDA Products, a pharmaceutical composition in the form of an aqueous oral suspension comprising (i) valsartan or a pharmaceutically acceptable salt thereof,

(ii) sacubitril or a pharmaceutically acceptable salt thereof, and (iii) a pharmaceutically acceptable carrier, wherein components (i) and (ii) are administered in combination in about a 1:1 ratio. On information and belief, if the Zydus ANDA Products are approved, those products will constitute a material part of a pharmaceutical composition comprising (i) valsartan or a pharmaceutically acceptable salt thereof, (ii) sacubitril or a pharmaceutically acceptable salt thereof, and (iii) a pharmaceutically acceptable carrier, wherein components (i) and (ii) are administered in combination in about a 1:1 ratio. On information and belief, if the Zydus ANDA Products are approved, physicians, medical professionals, pharmacists, caregivers and/or patients following the instructions in the Zydus ANDA Products will directly infringe one or more claims of the ’659 patent. On information and belief, if the Zydus ANDA Products are approved, Zydus Pharmaceuticals (USA) Inc. and/or Cadila Healthcare Ltd. will contributorily infringe one or more claims of the ’659 patent, and will do so with knowledge of the ’659 patent, and that the Zydus ANDA Products are especially made or especially adapted for use in infringing one or more claims of the ’659 patent, and are not suitable for a substantial noninfringing use.

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

191. On information and belief, the Zydus 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 Zydus 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 Zydus ANDA Products are approved, Zydus Pharmaceuticals (USA) Inc. and/or Cadila Healthcare 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.

192. On information and belief, if the Zydus ANDA Products are approved, Zydus Pharmaceuticals (USA) Inc. and/or Cadila Healthcare 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 Zydus 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 Zydus ANDA Products are approved, physicians and/or patients following the instructions in the Zydus ANDA Products will directly infringe one or more claims of the ’331 patent. On information and belief, if the Zydus ANDA Products are approved, Zydus Pharmaceuticals (USA) Inc. and/or Cadila Healthcare 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 Zydus 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.

193. On information and belief, the Zydus 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 Zydus 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 Zydus ANDA Products are approved, Zydus Pharmaceuticals (USA) Inc. and/or Cadila Healthcare 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.

194. On information and belief, if the Zydus ANDA Products are approved, Zydus Pharmaceuticals (USA) Inc. and/or Cadila Healthcare 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 Zydus 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 Zydus ANDA Products are approved, physicians and/or patients following the instructions in the Zydus ANDA Products will directly infringe one or more claims of the '134

patent. On information and belief, if the Zydus ANDA Products are approved, Zydus Pharmaceuticals (USA) Inc. and/or Cadila Healthcare 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 Zydus 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.

195. Novartis will be substantially and irreparably damaged by Zydus Pharmaceuticals (USA) Inc.’s and Cadila Healthcare Ltd.’s infringement of the ’659, ’331, ’938, and ’134 patents.

196. 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. 213719 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 Zydus ANDA Products and any act committed by Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare 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).

197. On information and belief, Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. have taken and continue to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Zydus ANDA Products, including seeking approval of those products under ANDA No. 213719.

198. There is a substantial and immediate controversy between Novartis and Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. concerning the ’659, ’331, ’938, and

’134 patents. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. will infringe, induce infringement of, and/or contributorily infringe one or more claims of the ’659, ’331, ’938, and ’134 patents.

PRAYER FOR RELIEF

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

a. Dr. Reddy’s Laboratories, Inc.; Dr. Reddy’s Laboratories, Ltd. (ANDA No. 213627)

199. Judgment that defendants Dr. Reddy’s Laboratories, Inc. and Dr. Reddy’s Laboratories, Ltd. have infringed one or more claims of the ’659, ’331, ’938, and ’134 patents by filing ANDA No. 213627;

200. A permanent injunction restraining and enjoining defendants Dr. Reddy’s Laboratories, Inc. and Dr. Reddy’s Laboratories, Ltd., Inc. and their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Dr. Reddy’s ANDA Products prior to the expiration of the ’659, ’331, ’938, and ’134 patents, inclusive of any extensions and additional periods of exclusivity;

201. An order that the effective date of any approval of ANDA No. 213627 be a date that is not earlier than the expiration dates of the ’659, ’331, ’938, and ’134 patents, inclusive of any extensions and additional periods of exclusivity;

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

203. Damages or other monetary relief from defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. for the infringement, inducement of infringement, and contributory infringement of the '659, '331, '938, and '134 patents;

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

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

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

b. Hetero USA Inc.; Hetero Labs Limited; Hetero Labs Limited Unit III (ANDA No. 213668)

207. Judgment that defendants Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III have infringed one or more claims of the '659, '331, '938, and '134 patents by filing ANDA No. 213668;

208. A permanent injunction restraining and enjoining defendants Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III, and their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Hetero ANDA Products prior to the expiration of the '659, '331, '938, and '134 patents, inclusive of any extensions and additional periods of exclusivity;

209. An order that the effective date of any approval of ANDA No. 213668 be a date that is not earlier than the expiration dates of the '659, '331, '938, and '134 patents, inclusive of any extensions and additional periods of exclusivity;

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

211. Damages or other monetary relief from defendants Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III for the infringement, inducement of infringement, and contributory infringement of the '659, '331, '938, and '134 patents;

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

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

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

c. MSN Pharmaceuticals Inc.; MSN Laboratories Private Limited; MSN Life Sciences Private Limited (ANDA No. 213748)

215. Judgment that defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited have infringed one or more claims of the '659, '331, '938, and '134 patents by filing ANDA No. 213748;

216. A permanent injunction restraining and enjoining defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited, and their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale or offer for sale in the United States, or importation into the United States, of the MSN ANDA Products prior to the expiration of the '659, '331, '938, and '134 patents, inclusive of any extensions and additional periods of exclusivity;

217. An order that the effective date of any approval of ANDA No. 213748 be a date that is not earlier than the expiration dates of the '659, '331, '938, and '134 patents, inclusive of any extensions and additional periods of exclusivity;

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

219. Damages or other monetary relief from defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited for the infringement, inducement of infringement, and contributory infringement of the ’659, ’331, ’938, and ’134 patents;

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

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

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

d. Novugen Pharma (Malaysia) Sdn. Bhd. (ANDA No. 213611)

223. Judgment that defendant Novugen has infringed one or more claims of the ’659, ’331, ’938, and ’134 patents by filing ANDA No. 213611;

224. A permanent injunction restraining and enjoining defendant Novugen, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale or offer for sale in the United States, or importation into the United States, of the Novugen ANDA Products prior to the expiration of the ’659, ’331, ’938, and ’134 patents, inclusive of any extensions and additional periods of exclusivity;

225. An order that the effective date of any approval of ANDA No. 213611 be a date that is not earlier than the expiration dates of the ’659, ’331, ’938, and ’134 patents, inclusive of any extensions and additional periods of exclusivity;

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

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

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

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

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

e. Zydus Pharmaceuticals (USA) Inc.; Cadila Healthcare Ltd. (ANDA No. 213719)

231. Judgment that defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. have infringed one or more claims of the ’659, ’331, ’938, and ’134 patents by filing ANDA No. 213719;

232. A permanent injunction restraining and enjoining defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd., and their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale or offer for sale in the United States, or importation into the United States, of the Zydus ANDA Products prior to the expiration of the ’659, ’331, ’938, and ’134 patents, inclusive of any extensions and additional periods of exclusivity;

233. An order that the effective date of any approval of ANDA No. 213719 be a date that is not earlier than the expiration dates of the ’659, ’331, ’938, and ’134 patents, inclusive of any extensions and additional periods of exclusivity;

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

235. Damages or other monetary relief from defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. for the infringement, inducement of infringement, and contributory infringement of the ’659, ’331, ’938, and ’134 patents;

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

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

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

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