**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| NOVARTIS PHARMACEUTICALS CORPORATION,<br><br>Plaintiff,<br><br>v.<br><br>HETERO USA INC., HETERO LABS LIMITED, HETERO LABS LIMITED UNIT III,<br><br>Defendants. | ) | C.A. No. _____ |

**COMPLAINT AGAINST**
**HETERO USA INC., HETERO LABS LIMITED AND**
**HETERO LABS LIMITED UNIT III**

Plaintiff Novartis Pharmaceuticals Corporation (hereinafter "Plaintiff" or "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 an Abbreviated New Drug Application ("ANDA") 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 Plaintiff's ENTRESTO® tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg, prior to the expiration of U.S. Patent No. 11,058,667 (the "'667 patent").

## PARTIES

2. Plaintiff Novartis is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at One Health Plaza, East Hanover, New Jersey 07936.

3. On information and belief, Hetero USA Inc. is a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854. Hetero USA Inc. has a registered agent for the service of process at W/K Incorporating Services, Inc., 3500 South Dupont Highway, Dover, Delaware 19901 and has also identified that John Thallemer, Esq. of Hetero USA Inc. at 1035 Centennial Avenue, Piscataway, NJ 08854 as being authorized to accept service of process for any patent infringement complaint that results from Hetero's November 1, 2021 Letter to Novartis ("Hetero Notice Letter"). 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.

4. 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.

5. 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.

6. 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.

7. 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.

8. 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.

9. By the November 1, 2021 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 '667 patent, and that (ii) ANDA No. 213668 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '667 patent.

10. 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 '667 patent, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

11. On information and belief, 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 '667 patent.

12. 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 '667 patent.

13. 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 '667 patent.

14. 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.

15. 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.

16. 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.

17. 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.

18. Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III each availed itself of the legal protections of the State of Delaware, by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Novartis Pharmaceuticals Corp. v. Dr. Reddy's Labs., Inc. et*

*al.*, C.A. No. 1:19-cv-2053; *Gilead Sciences, Inc. v. Apotex, Inc. et al.*, C.A. No: 1:20-cv-00189; *Amgen Inc. et al. v. Annora Pharma Private Limited et al.*, C.A. No. 1:20-cv-00122; *Biogen Int'l. GmbH et al. v. Amneal Pharmaceuticals LLC et al.*, C.A. No. 1:17-cv-00823.

## JURISDICTION AND VENUE

19. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

20. 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.

21. 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 '667 patent.

22. 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.

23. This Court also has personal jurisdiction over Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III. because each has availed itself of the legal protections of the State of Delaware, by admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

24. 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. 213688 in Delaware and not to contest personal jurisdiction or venue in Delaware in such an action. This is an action concerning ANDA No. 213688.

25. 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.

26. 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).

## THE PATENT-IN-SUIT AND ENTRESTO®

27. The ’667 patent, titled “Sacubitril-Valsartan Dosage Regimen for Treating Heart Failure,” was duly and legally issued on July 13, 2021. A true and correct copy of the ’667 patent is attached hereto as Exhibit A.

28. Novartis owns the ’667 patent.

29. The ’667 patent claims, *inter alia*, a regimen for treating chronic heart failure with reduced ejection fraction, comprising administering to a human patient in need thereof a twice-daily target dose of 200 mg of (i) sacubitril or a pharmaceutically acceptable salt thereof with (ii) valsartan or a pharmaceutically acceptable salt thereof; wherein (i) and (ii) are provided in a 1:1 molar ratio and wherein the twice daily target dose of 200 mg is reached after a titration with a twice daily starting dose of 50 mg of (i) and (ii) in a 1:1 molar ratio for a specified period of time followed by a twice daily dose of 100 mg of (i) and (ii) in a 1:1 molar ratio for a specified period of time and wherein the human patient is not taking an ACE inhibitor or an ARB or is taking a low dose of an ACE inhibitor or an ARB before initiating treatment with (i) and (ii).

30. 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.

31. The ENTRESTO® label provides specific instructions for titration for human patients who are not taking an ACE inhibitor or an ARB or taking a low dose of an ACE inhibitor or an ARB before treatment with ENTRESTO® is initiated.

32. One or more claims of the '667 patent cover the use of ENTRESTO®.

33. The FDA's official publication of approved drugs (the "Orange Book") lists the '667 patent in connection with ENTRESTO®.

**INFRINGEMENT BY HETERO OF THE PATENT-IN-SUIT**

34. Plaintiff incorporates paragraphs 1 – 33 as if fully set forth herein.

35. On information and belief, Hetero USA Inc., Hetero Labs Limited, and/or 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 '667 patent.

36. 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 '667 patent, Hetero USA Inc., Hetero Labs Limited, and/or Hetero Labs Limited Unit III have committed an act of infringement under 35 U.S.C. § 271(e)(2).

37. This action was commenced within 45 days of Plaintiff's receipt of the Hetero Notice Letter.

38. On information and belief, the use of the Hetero ANDA Products in the United States in accordance with and as directed by Hetero's labeling for those products, if approved, will directly infringe one or more claims of the '667 patent.

39. On information and belief, the Hetero ANDA Products, to be approved, must contain instructions for practicing a regimen for the treatment of chronic heart failure with reduced ejection faction comprising administering to a human patient in need thereof a twice-daily target dose of 200 mg of (i) sacubitril or a pharmaceutically acceptable salt thereof with (ii) valsartan or a pharmaceutically acceptable salt thereof; wherein (i) and (ii) are provided in a 1:1 molar ratio and wherein the twice daily target dose of 200 mg is reached after a titration with a twice daily starting dose of 50 mg of (i) and (ii) in a 1:1 molar ratio for a specified period of time followed by a twice daily dose of 100 mg of (i) and (ii) in a 1:1 molar ratio for a specified period of time and wherein the human patient is not taking an ACE inhibitor or an ARB or is taking a low dose of an ACE inhibitor or an ARB before initiating treatment with (i) and (ii), which administration will constitute direct infringement of one or more claims of the ’667 patent. On information and belief, if the Hetero ANDA Products are approved, physicians, other medical providers, caregivers and/or patients following said instructions will directly infringe one or more claims of the ’667 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 ’667 patent, and with knowledge and intent that their acts will induce infringement of one or more claims of the ’667 patent.

40. 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 must be specifically labeled for use in a regimen for the treatment of chronic heart failure with reduced ejection fraction comprising administering to a human patient in need thereof a twice-daily target dose of 200 mg

of (i) sacubitril or a pharmaceutically acceptable salt thereof with (ii) valsartan or a pharmaceutically acceptable salt thereof; wherein (i) and (ii) are provided in a 1:1 molar ratio and wherein the twice daily target dose of 200 mg is reached after a titration with a twice daily starting dose of 50 mg of (i) and (ii) in a 1:1 molar ratio for a specified period of time followed by a twice daily dose of 100 mg of (i) and (ii) in a 1:1 molar ratio for a specified period of time and wherein the human patient is taking neither an ACE inhibitor nor an ARB or is taking a low dose of an ACE inhibitor or an ARB before initiating treatment with (i) and (ii), as recited in one or more claims of the ’667 patent. On information and belief, if the Hetero ANDA Products are approved, those products will constitute a material part of a regimen for the treatment of chronic heart failure with reduced ejection fraction comprising administering to a human patient in need thereof a twice-daily target dose of 200 mg of (i) sacubitril or a pharmaceutically acceptable salt thereof with (ii) valsartan or a pharmaceutically acceptable salt thereof; wherein (i) and (ii) are provided in a 1:1 molar ratio and wherein the twice daily target dose of 200 mg is reached after a titration with a twice daily starting dose of 50 mg of (i) and (ii) in a 1:1 molar ratio for a specified period of time followed by a twice daily dose of 100 mg of (i) and (ii) in a 1:1 molar ratio for a specified period of time and wherein the human patient is not taking an ACE inhibitor or an ARB or is taking a low dose of an ACE inhibitor or an ARB before initiating treatment with (i) and (ii), as recited in one or more claims of the ’667 patent. On information and belief, if the Hetero ANDA Products are approved, physicians, caregivers and/or patients following the approved instructions in the Hetero ANDA Products will directly infringe one or more claims of the ’667 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 ’667 patent and will do so with knowledge of the ’667 patent, and that

the Hetero ANDA Products are especially made or especially adapted for use in infringing one or more claims of the ’667 patent and are not suitable for substantial non-infringing use.

41. Plaintiff will be substantially and irreparably damaged by Hetero USA Inc.’s, Hetero Labs Limited’s, and/or Hetero Labs Limited Unit III’s infringement of the ’667 patent.

42. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 283, 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 May 9, 2036, the expiration of the ’667 patent, or a date no earlier than the expiry of any other patent extension or exclusivity to which Plaintiff 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/or Hetero Labs Limited Unit III with respect to the subject matter claimed in the ’667 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

43. On information and belief, Hetero USA Inc., Hetero Labs Limited, and/or Hetero Labs Limited Unit III has taken and continues 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.

44. There is a substantial and immediate controversy between Plaintiff and Hetero USA Inc., Hetero Labs Limited, and/or Hetero Labs Limited Unit III concerning the ’667 patent. Plaintiff is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that the use of the Hetero ANDA Products will directly infringe one or more claims of the ’667 patent and Defendants will induce infringement of and/or contributorily infringe one or more claims of the ’667 patent.

## PRAYER FOR RELIEF

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

45. Judgment that defendants Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit III have infringed one or more claims of the '667 patent by filing ANDA No. 213668;

46. 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 '667 patent, inclusive of any extensions and additional periods of exclusivity;

47. An order that the effective date of any approval of ANDA No. 213668 be a date that is not earlier than the expiration date of the '667 patent, inclusive of any extensions and additional periods of exclusivity;

48. Declaratory judgment that the use of the Hetero ANDA Products will directly infringe one or more claims of the '667 patent;

49. Declaratory judgment that the commercial manufacture, sale, offer for sale, and/or importation of the Hetero ANDA Products will induce infringement of and/or contributorily infringe one or more claims of the '667 patent;

50. 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 '667 patent;

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

52. Plaintiff's costs and expenses in this action; and

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

Dated: December 16, 2021

MCCARTER & ENGLISH, LLP

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