

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

NOVARTIS PHARMACEUTICALS  
CORPORATION,

Plaintiff,

V.

C.A. No. \_\_\_\_\_

BIOCON PHARMA LIMITED, BIOCON  
LIMITED, BIOCON PHARMA, INC.

Defendants.

**COMPLAINT AGAINST  
BIOCON PHARMA LIMITED, BIOCON LIMITED AND BIOCON PHARMA, INC.**

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

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

5. On information and belief, Biocon Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a registered agent for the service of process at Harvard Business Services, Inc., 16192 Costal Highway, Lewes, Delaware 19958, and having a principal place of business at 485 US Highway 1 S B305, Iselin, New Jersey 08830. On information and belief, Biocon Pharma, Inc. is a wholly owned subsidiary of Biocon Pharma Limited.

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

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

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

9. By a letter dated April 18, 2022 (“Biocon Notice Letter”), Biocon Pharma Limited notified Novartis that (i) Biocon Pharma Limited had submitted to the FDA ANDA No. 213680 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg (“Biocon ANDA Products”), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Biocon ANDA Products in or into the United States, including Delaware, prior to the expiration of the ’667 patent, and that (ii) ANDA No. 213680 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the ’667 patent.

10. Biocon Pharma Limited has committed an act of infringement in this judicial district by filing ANDA No. 213680 with the intent to make, use, sell, offer for sale, and/or import the Biocon ANDA Products in or into this judicial district, prior to the expiration of the ’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, Biocon Limited acted in concert with and directed Biocon Pharma Limited and/or Biocon Pharma, Inc., in the preparation and submission of ANDA No. 213680, and, if the ANDA is approved, will act in concert with and direct Biocon Pharma Limited and/or Biocon Pharma, Inc. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Biocon ANDA Products in or into the United States, including Delaware, prior to the expiration of the ’667 patent.

12. On information and belief, Biocon Pharma, Inc. acted in concert with and under the direction of Biocon Pharma Limited and/or Biocon Limited in the preparation and

submission of ANDA No. 213680, and, if the ANDA is approved, will act in concert with and under the direction of Biocon Pharma Limited and/or Biocon Limited to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Biocon ANDA Products in or into the United States, including Delaware, prior to the expiration of the '667 patent.

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

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

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

16. Biocon Limited, Biocon Pharma Limited, and Biocon Pharma, Inc. have availed themselves of the legal protections of the State of Delaware by, among other things, admitting or

waiving objections to jurisdiction and/or asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g., Novartis Pharms. Corp. v. Alkem Labs. Ltd. et al.*, C.A. No. 19-1979 (D. Del.); *Sanofi-Aventis U.S. LLC et al. v. Biocon Ltd.*, C.A. No. 17-3 (D. Del.); *Novartis Pharms. Corp. v. Accord Healthcare Inc.*, C.A. No. 18-1043 (D. Del.); *Teva Pharms. USA, Inc., et al. v. Biocon Ltd. and Apotex Corp.*, C.A. No. 16-278 (D. Del.).

17. Biocon Pharma Limited, the entity identified in the Biocon Notice Letter as having submitted ANDA No. 213680, has agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213680 in the District of Delaware, and has agreed, only for the purposes of such action(s), not to contest personal jurisdiction and venue in the District of Delaware.

#### **JURISDICTION AND VENUE**

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

19. This Court has personal jurisdiction over Biocon Pharma Limited, Biocon Limited, and Biocon Pharma, Inc. because, on information and belief, each such Defendant has committed or has aided, abetted, contributed to, or participated in the commission of tortious acts of patent infringement in preparing and submitting ANDA No. 213680 with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which acts have led to foreseeable harm and injury to Novartis, a Delaware corporation.

20. This Court also has personal jurisdiction over Biocon Pharma Limited, Biocon Limited, and Biocon Pharma, Inc. because, on information and belief, each such Defendant, upon approval of ANDA No. 213680, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213680 that will be

purposefully directed at Delaware, including the marketing of the Biocon ANDA Products in Delaware, prior to the expiration of the '667 patent.

21. This Court also has personal jurisdiction over Biocon Pharma Limited, Biocon Limited, and Biocon Pharma, Inc. because, on information and belief, each such Defendant's affiliations with the State of Delaware, including Biocon Pharma, Inc.'s incorporation in Delaware, and Biocon Pharma Limited's and Biocon Limited's ownership of and actions in concert with Biocon Pharma, Inc., are sufficiently continuous and systematic as to render each such Defendant essentially at home in this forum. On information and belief, each such Defendant 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 and/or has engaged in systematic and continuous business contacts within the State of Delaware. Upon information and belief, each such Defendant regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, such generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, the Biocon ANDA Products will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware.

22. This Court also has personal jurisdiction over Biocon Pharma Limited, Biocon Limited and Biocon Pharma, Inc. because each such Defendant has availed itself of the legal protections of the State of Delaware, by admitting or waiving objections to jurisdiction and/or asserting counterclaims in lawsuits filed in the United States District Court for the District of

Delaware. *See, e.g., Novartis Pharms. Corp. v. Alkem Labs. Ltd. et al.*, C.A. No. 19-1979 (D. Del.); *Sanofi-Aventis U.S. LLC et al. v. Biocon Ltd.*, C.A. No. 17-3 (D. Del.); *Novartis Pharms. Corp. v. Accord Healthcare Inc.*, C.A. No. 18-1043 (D. Del.); *Teva Pharms. USA, Inc., et al. v. Biocon Ltd. and Apotex Corp.*, C.A. No. 16-278 (D. Del.).

23. Biocon Pharma Limited, the entity identified in the Biocon Notice Letter as having submitted ANDA No. 213680, has agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213680 in the District of Delaware, and has agreed, only for the purposes of such action(s), not to contest personal jurisdiction and venue in the District of Delaware.

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

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

#### **THE PATENT-IN-SUIT AND ENTRESTO®**

26. 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.

27. Novartis owns the '667 patent.

28. 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).

29. 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<sup>®</sup> (sacubitril and valsartan) tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg. ENTRESTO<sup>®</sup> 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.

30. The ENTRESTO<sup>®</sup> 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<sup>®</sup> is initiated.

31. One or more claims of the ’667 patent cover the use of ENTRESTO<sup>®</sup>.

32. The FDA’s official publication of approved drugs (the “Orange Book”) lists the ’667 patent in connection with ENTRESTO<sup>®</sup>.

### **INFRINGEMENT OF THE PATENT-IN-SUIT**

33. Plaintiff incorporates paragraphs 1 – 32 as if fully set forth herein.

34. On information and belief, Biocon Pharma Limited, by itself or in concert with Biocon Limited and Biocon Pharma, Inc., submitted to the FDA ANDA No. 213680 under the



provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Biocon ANDA Products prior to the expiration of the '667 patent.

35. 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 Biocon ANDA Products in or into the United States prior to the expiration of the '667 patent, Biocon Pharma Limited, and, on information and belief, Biocon Limited and Biocon Pharma, Inc., have committed an act of infringement under 35 U.S.C. § 271(e)(2).

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

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

38. On information and belief, the Biocon ANDA Products, to be approved, must contain instructions for practicing 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), which

administration will constitute direct infringement of one or more claims of the '667 patent. On information and belief, if the Biocon 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 Biocon ANDA Products are approved, Biocon Pharma Limited, Biocon Limited, and/or Biocon Pharma, Inc. will actively encourage, recommend, or promote this infringement with knowledge of the '667 patent, and with knowledge and intent that their acts will induce infringement of one or more claims of the '667 patent.

39. On information and belief, if the Biocon ANDA Products are approved, Biocon Pharma Limited, Biocon Limited, and/or Biocon Pharma, Inc. will commercially manufacture, sell, offer for sale, and/or import those products, which 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 Biocon 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 Biocon ANDA Products are approved, physicians, caregivers and/or patients following the approved instructions in the Biocon ANDA Products will directly infringe one or more claims of the '667 patent. On information and belief, if the Biocon ANDA Products are approved, Biocon Pharma Limited, Biocon Limited, and/or Biocon Pharma, Inc. will contributorily infringe one or more claims of the '667 patent and will do so with knowledge of the '667 patent, and that the Biocon 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.

40. Plaintiff will be substantially and irreparably damaged by Biocon Pharma Limited, Biocon Limited, and/or Biocon Pharma, Inc.'s infringement of the '667 patent.

41. 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. 213680 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 Biocon ANDA Products and any act committed by Biocon Pharma Limited, Biocon Limited, and/or Biocon Pharma, Inc.

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).

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

43. There is a substantial and immediate controversy between Plaintiff and Biocon Pharma Limited, Biocon Limited, and/or Biocon Pharma, Inc. concerning the '667 patent. Plaintiff is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that the use of the Biocon ANDA Products will directly infringe one or more claims of the '667 patent and Biocon Pharma Limited, Biocon Limited, and/or Biocon Pharma, Inc. 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:

44. Judgment that defendants Biocon Pharma Limited, Biocon Limited, and/or Biocon Pharma, Inc. have infringed one or more claims of the '667 patent by filing ANDA No. 213680;

45. A permanent injunction restraining and enjoining defendants Biocon Pharma Limited, Biocon Limited, and/or Biocon Pharma, Inc. and their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Biocon ANDA Products prior to the expiration of the '667 patent, inclusive of any extensions and additional periods of exclusivity;

46. An order that the effective date of any approval of ANDA No. 213680 be a date that is not earlier than the expiration date of the '667 patent, inclusive of any extensions and additional periods of exclusivity;

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

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

49. Damages or other monetary relief from defendants Biocon Pharma Limited, Biocon Limited, and/or Biocon Pharma, Inc. for the infringement, inducement of infringement and contributory infringement of the '667 patent;

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

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

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

Dated: June 2, 2022

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*

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*