IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. NANJING NORATECH PHARMACEUTICAL CO., LIMITED, Defendant.	C.A. No. _____

COMPLAINT

Plaintiff 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 an Abbreviated New Drug Application ("ANDA") submitted to the United States Food and Drug Administration ("FDA") by Defendant Nanjing Noratech Pharmaceutical Co., Limited ("Noratech") 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. Patent No. 8,101,659 ("the '659 patent") and U.S. Patent No. 11,058,667 ("the '667 Patent").

PARTIES

2. Plaintiff 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.

3. On information and belief, Defendant Nanjing Noratech Pharmaceutical Co., Limited ("Noratech") is a corporation organized and existing under the laws of China, having a principal place of business at 6/F, Building F6, No. 9 Weidi Road, Jiangsu Life Science and Technology Innovation Park, Qixia District, Nanjing, China.

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

5. On April 6, 2023, Noratech informed Novartis that, by a letter purportedly dated June 10, 2022 ("Noratech Notice Letter"), Noratech previously had notified Novartis that (i) Noratech had submitted to the FDA ANDA No. 213671 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("the Noratech ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Noratech ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659 and '667 patents, and that (ii) ANDA No. 213671 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") against the '659 and '667 patents.

6. On information and belief, Noratech has submitted to the FDA ANDA No. 213671, including amendments thereto, for the Noratech ANDA Products, seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of

the Noratech ANDA Products in or into the United States, including Delaware, prior to the expiration of the '659 and '667 patents.

7. Noratech has committed an act of infringement in this judicial district by filing ANDA No. 213671, including amendments thereto, with the intent to make, use, sell, offer for sale, and/or import the Noratech ANDA Products in or into this judicial district, prior to the expiration of the '659 and '667 patents, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

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

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

10. Noratech, the entity that, on information and belief, submitted ANDA No. 213671, has agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213671 in the District of Delaware, and has agreed, only for the purposes of such action(s), not to challenge personal jurisdiction and venue in the District of Delaware.

JURISDICTION AND VENUE

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

12. This Court has personal jurisdiction over Noratech because Noratech has committed tortious acts of patent infringement in preparing and submitting ANDA No. 213671, including amendments thereto, 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.

13. This Court also has personal jurisdiction over Noratech because, on information and belief, Noratech, upon approval of ANDA No. 213671, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213671 that will be purposefully directed at Delaware, including the marketing of the Noratech ANDA Products in Delaware, prior to the expiration of the '659 and '667 patents.

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

15. Noratech, the entity that, on information and belief, submitted ANDA No. 213671, has agreed with Novartis to litigate any patent action(s) concerning ANDA No. 213671 in the District of Delaware, and has agreed, only for the purposes of such action(s), not to challenge personal jurisdiction and venue in the District of Delaware.

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

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

THE PATENTS-IN-SUIT AND ENTRESTO®

18. 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.

19. 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.

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

21. 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).

22. 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.

23. One or more of the claims of the ’659 patent cover ENTRESTO®.

24. One or more of the claims of the ’667 patent cover the use of ENTRESTO®.

25. The FDA’s official publication of approved drugs (the “Orange Book”) lists the ’659 and ’667 patents in connection with ENTRESTO®.

INFRINGEMENT BY NORATECH OF THE PATENTS-IN-SUIT

26. Novartis incorporates paragraphs 1–25 as if fully set forth herein.

27. On information and belief, Noratech submitted to the FDA ANDA No. 213671, including amendments thereto, under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Noratech ANDA Products prior to the expiration of the ’659 and ’667 patents.

28. By filing its ANDA under 21 U.S.C. § 355(j), including amendments thereto, for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Noratech ANDA Products in or into the United States prior to the expiration of the ’659 and ’667 patents, Noratech has committed an act of infringement under 35 U.S.C. § 271(e)(2).

29. On information and belief, when Noratech filed an amended ANDA No. 213671 containing Paragraph IV Certifications for the ’659 and ’667 patents, Noratech was aware of the ’659 and ’667 patents and that the filing of the ANDA with the request for its approval prior to the expiration of the ’659 and ’667 patents was an act of infringement of those patents.

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

31. On information and belief, the Noratech ANDA Products, if approved, will be pharmaceutical compositions comprising (i) valsartan or a pharmaceutically acceptable salt thereof; (ii) sacubitril 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, such that the commercial manufacture, use, sale, offer for sale, and/or importation of the Noratech ANDA Products in or into the United States will infringe one or more claims of the ’659 patent.

32. The Noratech Notice Letter does not dispute that the Noratech ANDA Products are pharmaceutical compositions comprising (i) valsartan or a pharmaceutically acceptable salt thereof; (ii) sacubitril 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.

33. On information and belief, and pursuant to the District Court for the District of Delaware’s June 27, 2022 Memorandum Order, 20-md-2930, D.I. 661, Noratech has represented that the Noratech ANDA Products, if approved, will be pharmaceutical compositions comprising physically separate valsartan or a pharmaceutically acceptable salt thereof and physically separate sacubitril or a pharmaceutically acceptable salt thereof.

34. Novartis will be substantially and irreparably damaged by Noratech’s infringement of the ’659 patent.

35. Novartis 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. 213671 be a date that is no earlier than July 15, 2025, the expiration of the pediatric exclusivity

for the ’659 patent and an award of damages for any commercial sale or use of the Noratech ANDA Products and any act committed by Noratech with respect to the subject matter claimed in the ’659 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1). Novartis also is entitled to the relief provided by Fed. R. Civ. P. 65, including a preliminary injunction to enjoin any “at risk” commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Noratech ANDA Products, and any act committed by Noratech with respect to the subject matter claimed in the ’659 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1), prior to the resolution of this action.

36. On information and belief, the use of the Noratech 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.

37. On information and belief, the Noratech 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 Noratech 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 Noratech ANDA Products are approved, Noratech will actively encourage, recommend, or promote this infringement with knowledge of the '667 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the '667 patent.

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

39. The Noratech Notice Letter does not dispute that the use of the Noratech ANDA Products, if approved, by physicians, caregivers and/or patients following the approved instructions in the Noratech ANDA Products will directly infringe at least claims 1 and 7 of the '667 patent. The Noratech Notice Letter does not dispute that if the Noratech ANDA Products are approved, Noratech will actively encourage, recommend, or promote this infringement with knowledge of the '667 patent, and with knowledge and intent that its acts will induce infringement of one or more claims of the '667 patent.

40. Novartis will be substantially and irreparably damaged by Noratech's infringement of the '667 patent.

41. Novartis 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.

213671 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 Novartis is entitled, and an award of damages for any commercial sale or use of the Noratech ANDA Products and any act committed by Noratech with respect to the subject matter claimed in the ’667 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1). Novartis also is entitled to the relief provided by Fed. R. Civ. P. 65, including a preliminary injunction to enjoin any “at risk” commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Noratech ANDA Products, and any act committed by Noratech 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), prior to the resolution of this action.

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

43. There is a substantial and immediate controversy between Novartis and Noratech concerning the ’659 and ’667 patents. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that the Noratech ANDA Products will directly infringe one or more claims of the ’659 patent; that the use of the Noratech ANDA Products will directly infringe one or more claims of ’667 patent; and that Noratech will induce infringement of and/or contributorily infringe one or more claims of the ’667 patent.

PRAYER FOR RELIEF

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

44. Judgment that Noratech has infringed one or more claims of the ’659 and ’667 patents by filing ANDA No. 213671, including amendments thereto;

45. A preliminary injunction to enjoin any "at risk" commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Noratech ANDA Products, and any act committed by Noratech with respect to the subject matter claimed in the '659 and '667 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1), prior to the resolution of this action;

46. A permanent injunction restraining and enjoining Noratech, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Noratech ANDA Products prior to the expiration of the '659 and '667 patents, inclusive of any extensions and additional periods of exclusivity;

47. An order that the effective date of any approval of ANDA No. 213671 be a date that is not earlier than the expiration dates of the '659 and '667 patents, inclusive of any extensions and additional periods of exclusivity;

48. Declaratory judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of the Noratech ANDA Products will directly infringe, induce infringement of, and/or contributorily infringe one or more claims of the '659 and '667 patents;

49. Damages or other monetary relief from Noratech for the infringement, inducement of infringement and contributory infringement of the '659 and 667 patents;

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

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

Dated: April 10, 2023

MCCARTER & ENGLISH, LLP

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