IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Entresto (Sacubitril/Valsartan) Patent Litigation	MDL No. 20-2930-LPS
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. MYLAN PHARMACEUTICALS INC., Defendant.	C.A. No. 20-445-LPS W.V.N.D. C.A. No. 1:19-201-IMK

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 Mylan Pharmaceuticals Inc. 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").

2. This is an amendment to a complaint that Novartis originally filed against Mylan Pharmaceuticals Inc. on October 30, 2019 in the Northern District of West Virginia in W.V.N.D. C.A. No. 1:19-201-IMK. By order dated March 27, 2020 in MDL No. 2930, the West Virginia complaint was transferred under 28 U.S.C. § 1407 to the District of Delaware in D. Del. C.A. No. 20-445-LPS. The October 30, 2019 West Virginia complaint appears in its original form at D. Del. C.A. No. 20-445-LPS, D.I. 1. The allegations concerning personal jurisdiction and venue in this amended complaint remain directed to West Virginia. Novartis makes those allegations without prejudice to Novartis's ability to litigate this dispute against Mylan Pharmaceuticals Inc. in the District of Delaware to the full extent permitted under 28 U.S.C. § 1407.

PARTIES

3. 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.

4. On information and belief, defendant Mylan Pharmaceuticals Inc. ("Mylan") is a corporation organized under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

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

6. By a letter dated September 16, 2019 ("Mylan Notice Letter"), Mylan notified Novartis that (i) Mylan had submitted to the FDA ANDA No. 213646 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg ("Mylan ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or

importation of the Mylan ANDA Products in or into the United States, including West Virginia, prior to the expiration of the '659, '331, '938, and '134 patents, and that (ii) ANDA No. 213646 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '659, '331, '938, and '134 patents.

7. Mylan has committed an act of infringement in this judicial district by filing ANDA No. 213646 with the intent to make, use, sell, offer for sale, and/or import the Mylan 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 in West Virginia.

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

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

JURISDICTION AND VENUE

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

11. This Court has personal jurisdiction over Mylan because, on information and belief, Mylan 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. 213646 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 in West Virginia.

12. This Court also has personal jurisdiction over Mylan because, on information and belief, Mylan, upon approval of ANDA No. 213646, will commit or will aid, abet, contribute to, or participate in future tortious acts of patent infringement permitted under ANDA No. 213646 that will be purposefully directed at West Virginia, including the marketing of the Mylan ANDA Products in West Virginia, prior to the expiration of the '659, '331, '938, and '134 patents.

13. This Court also has personal jurisdiction over Mylan because, on information and belief, Mylan's affiliations with the State of West Virginia, including Mylan incorporation in West Virginia, are sufficiently continuous and systematic as to render Mylan essentially at home in this forum.

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

15. Venue is proper in this Court because Mylan is incorporated in the State of West Virginia and therefore resides in this judicial district. 28 U.S.C. § 1400(b).

THE PATENTS-IN-SUIT AND ENTRESTO®

16. 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.

17. 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.

18. 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.

19. 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.

20. 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.

21. 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”) in crystalline form.

22. 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.

23. 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 sacubitril/valsartan trisodium hemipentahydrate.

24. 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.

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

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

INFRINGEMENT OF THE PATENTS-IN-SUIT

27. Novartis incorporates paragraphs 1 — 9 and 16 — 26 as if fully set forth herein.

28. On information and belief, Mylan submitted to the FDA ANDA No. 213646 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 Mylan ANDA Products prior to the expiration of the '659, '331, '938, and '134 patents.

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

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

31. On information and belief, when Mylan filed ANDA No. 213646, Mylan 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.

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

33. The Mylan Notice Letter does not deny that the Mylan ANDA Products would infringe claims 1-4 of the '659 patent, and that the use of the Mylan ANDA Products would infringe claims 1, 2 and 5-8 of the '331 patent.

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

35. On information and belief, the Mylan ANDA Products, if approved, will contain instructions for preparing, from the Mylan 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 Mylan 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 Mylan ANDA Products are approved, Mylan 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.

36. On information and belief, if the Mylan ANDA Products are approved, Mylan will commercially manufacture, sell, offer for sale, and/or import those products, which will be specifically labeled with instructions for preparing, from the Mylan 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 Mylan 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 Mylan ANDA Products are approved, physicians, medical professionals, pharmacists, caregivers and/or patients following the instructions in the Mylan ANDA Products will directly infringe one or more claims of the '659 patent. On information and belief, if the Mylan ANDA Products are approved, Mylan will contributorily infringe one or

more claims of the ’659 patent, and will do so with knowledge of the ’659 patent, and that the Mylan 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.

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

38. On information and belief, the Mylan 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 Mylan 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 Mylan ANDA Products are approved, Mylan 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.

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

40. On information and belief, the Mylan 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 Mylan 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 Mylan ANDA Products are approved, Mylan 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.

41. On information and belief, if the Mylan ANDA Products are approved, Mylan 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 Mylan 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 Mylan ANDA Products are approved, physicians and/or patients following the instructions in the Mylan ANDA Products will directly infringe one or more claims of the ’134 patent. On information and belief, if the Mylan ANDA Products are approved, Mylan will contributorily infringe one or more claims of the '134 patent, and will do so with knowledge of the ’134 patent, and that the Mylan 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.

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

43. 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. 213646 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 Mylan ANDA Products and any act committed by Mylan 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).

44. On information and belief, Mylan has taken and continues to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Mylan ANDA Products, including seeking approval of those products under ANDA No. 213646.

45. There is a substantial and immediate controversy between Novartis and Mylan concerning the '659, '331, '938, and '134 patents. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Mylan 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:

46. Judgment that defendant Mylan has infringed one or more claims of the '659, '331, '938, and '134 patents by filing ANDA No. 213646;

47. A permanent injunction restraining and enjoining defendant Mylan, 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 Mylan ANDA Products prior to the expiration of the '659, '331, '938, and '134 patents, inclusive of any extensions and additional periods of exclusivity;

48. An order that the effective date of any approval of ANDA No. 213646 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;

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

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

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

53. 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*