

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

NOVARTIS PHARMACEUTICALS
CORPORATION,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,
MYLAN INC., MYLAN LABORATORIES
LIMITED, VIATRIS INC.,

Defendants.

C.A. No. 1:21-CV-146 (Keeley)

ELECTRONICALLY
FILED
Dec 20 2021
U.S. DISTRICT COURT
Northern District of WV

COMPLAINT

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”).

2. There are multiple Hatch-Waxman patent infringement lawsuits currently pending in the United States District Court for the District of Delaware that also involve Novartis’s claims of infringement of the ‘667 patent. *Novartis Pharmaceuticals Corp. v. Aurobindo*

Pharma USA Inc., et al., C.A. No. 1:21-cv-01407; *Novartis Pharmaceuticals Corp. v. Crystal Pharmaceutical (Suzhou) Co. Ltd.*, C.A. No. 1:21-cv-01452; *Novartis Pharmaceuticals Corp. v. Hetero USA Inc., et al.*, C.A. No. 1:21-cv-01760. These pending actions share common questions of fact with the instant action including those related to the validity of the '667 patent. For the convenience of the parties and witnesses and the just and efficient conduct of these litigations, Novartis intends to move to centralize this litigation with those currently pending in the District of Delaware under 28 U.S.C. § 1407.

PARTIES

3. 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.

4. On information and belief, Mylan Pharmaceuticals Inc. 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. On information and belief, Mylan Pharmaceuticals Inc. is a wholly owned subsidiary of Mylan Inc.

5. On information and belief, Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having a principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317. On information and belief, Mylan Inc. is a wholly owned subsidiary of Viatris Inc.

6. On information and belief, Mylan Laboratories Limited is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 564/A122, Road No. 92, Jubilee Hills, Hyderabad 500034, India. On information and belief, Mylan Laboratories Limited is an indirectly wholly owned subsidiary of Mylan Inc.

7. On information and belief, Viatris Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at Robert J. Coury Global Center, 1000 Mylan Blvd., Canonsburg, Pennsylvania 15317.

8. On information and belief, Mylan Pharmaceuticals Inc. 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.

9. On information and belief, Mylan Inc. 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.

10. On information and belief, Mylan Laboratories Limited 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.

11. On information and belief, Viatris Inc. 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.

12. By a letter dated November 5, 2021 (“Mylan Notice Letter”), Mylan Pharmaceuticals Inc. notified Novartis that (i) Mylan Pharmaceuticals Inc. 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 ’667 patent, and that (ii) ANDA No. 213646 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the ’667 patent.

13. Mylan Pharmaceuticals Inc. 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 '667 patent, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis in West Virginia.

14. On information and belief, Mylan Inc. acted in concert with and directed Mylan Pharmaceuticals Inc. and/or Mylan Laboratories Limited in the preparation and submission of ANDA No. 213646, and, if the ANDA is approved, will act in concert with and direct Mylan Pharmaceuticals Inc. and/or Mylan Laboratories Limited 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 '667 patent.

15. On information and belief, Mylan Laboratories Limited acted in concert with and under the direction of Mylan Inc. and/or Viatris, and acted in concert with Mylan Pharmaceuticals Inc., in the preparation and submission of ANDA No. 213646, and, if the ANDA is approved, will act in concert with and under the direction of Mylan Inc. and/or Viatris, and will act in concert with Mylan Pharmaceuticals Inc., 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 '667 patent.

16. On information and belief, Viatris Inc. acted in concert with and directed Mylan Pharmaceuticals Inc. and/or Mylan Laboratories Limited in the preparation and submission of ANDA No. 213646, and, if the ANDA is approved, will act in concert with and direct Mylan Pharmaceuticals Inc. and/or Mylan Laboratories Limited 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 '667 patent.

17. Mylan Pharmaceuticals Inc., by itself or together with Mylan Inc., Mylan Laboratories Limited and/or Viatris Inc., 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.

18. On information and belief, Mylan Pharmaceuticals Inc. 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.

19. On information and belief, Mylan Inc. 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.

20. On information and belief, Mylan Laboratories Limited 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.

21. On information and belief, Viatris Inc. 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

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

23. This Court has personal jurisdiction over Mylan Pharmaceuticals Inc., Mylan Inc., Mylan Laboratories Limited, and Viatris Inc. because, on information and belief, each such Defendant has committed 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.

24. This Court also has personal jurisdiction over Mylan Pharmaceuticals Inc., Mylan Inc., Mylan Laboratories Limited, and Viatris Inc. because, on information and belief, each such Defendant 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 '667 patent.

25. This Court also has personal jurisdiction over Mylan Pharmaceuticals Inc., Mylan Inc., Mylan Laboratories Limited, and Viatris Inc. because, on information and belief, each such Defendant's affiliations with the State of West Virginia, including Mylan Pharmaceuticals Inc.'s incorporation in West Virginia, Mylan Inc.'s ownership of and actions in concert with Mylan Pharmaceuticals Inc., Mylan Laboratories Limited's actions in concert with Mylan Pharmaceuticals Inc., and Viatris Inc.'s ownership of Mylan Inc. and actions in concert with Mylan Pharmaceuticals Inc. are sufficiently continuous and systematic as to render each such Defendant essentially at home in this forum.

26. 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 Pharmaceuticals Inc., Mylan Inc., Mylan Laboratories Limited, and Viatris Inc.

27. Venue is proper in this Court because Mylan Pharmaceuticals Inc. is incorporated in the State of West Virginia and therefore resides in this judicial district; because, on information and belief, Mylan Inc. and Viatris Inc. have committed and/or will commit acts of infringement in this judicial district and Mylan Inc. has a regular and established place of business in this judicial district; and because Mylan Laboratories Limited is a foreign entity who may be sued in any judicial district, including the Northern District of West Virginia. 28 U.S.C. § 1400(b); 28 U.S.C. § 1391(c)(3).

THE PATENT-IN-SUIT AND ENTRESTO®

28. 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.

29. Novartis owns the '667 patent.

30. 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).

31. 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.

32. 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.

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

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

INFRINGEMENT BY MYLAN OF THE PATENT-IN-SUIT

35. Plaintiff incorporates paragraphs 1 - 34 as if fully set forth herein.

36. On information and belief, Mylan Pharmaceuticals Inc., by itself or in concert with Mylan Inc., Mylan Laboratories Limited and/or Viatris Inc., 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 '667 patent.

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

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

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

40. The Mylan Notice Letter does not deny that the use of the Mylan ANDA Products will directly infringe the claims of the '667 patent or that Mylan will induce infringement of and contributorily infringe the '667 patent.

41. On information and belief, the Mylan 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 Mylan 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 Mylan ANDA Products are approved, Mylan Pharmaceuticals Inc., Mylan Inc., Mylan Laboratories Limited, and/or Viatris 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.

42. On information and belief, if the Mylan ANDA Products are approved, Mylan Pharmaceuticals Inc., Mylan Inc., Mylan Laboratories Limited, and/or Viatris 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 Mylan 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 Mylan ANDA Products are approved, physicians, caregivers and/or patients following the approved instructions in the Mylan ANDA Products will directly infringe one or more claims of the '667 patent. On information and belief, if the Mylan ANDA Products are approved, Mylan Pharmaceuticals Inc., Mylan Inc., Mylan Laboratories Limited, and/or Viatris 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 Mylan 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.

43. Plaintiff will be substantially and irreparably damaged by Mylan Pharmaceuticals Inc.'s, Mylan Inc.'s, Mylan Laboratories Limited's, and/or Viatris Inc.'s infringement of the '667 patent.

44. 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. 213646 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 Mylan ANDA Products and any act committed by Mylan Pharmaceuticals Inc., Mylan Inc., Mylan Laboratories Limited, and/or Viatris 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).

45. On information and belief, Mylan Pharmaceuticals Inc., Mylan Inc., Mylan Laboratories Limited, and/or Viatris Inc. have taken and continue 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.

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

47. Judgment that defendants Mylan Pharmaceuticals Inc., Mylan Inc., Mylan Laboratories Limited, and Viatris Inc. have infringed one or more claims of the '667 patent by filing ANDA No. 213646;

48. A permanent injunction restraining and enjoining defendants Mylan Pharmaceuticals Inc., Mylan Inc., Mylan Laboratories Limited, and Viatris 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 Mylan ANDA Products prior to the expiration of the '667 patent, inclusive of any extensions and additional periods of exclusivity;

49. An order that the effective date of any approval of ANDA No. 213646 be a date that is not earlier than the expiration date of the '667 patent, inclusive of any extensions and additional periods of exclusivity;

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

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

52. Damages or other monetary relief from defendants Mylan Pharmaceuticals Inc., Mylan Inc., Mylan Laboratories Limited, and Viatris Inc. for the infringement, inducement of infringement and contributory infringement of the '667 patent;

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

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

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

Dated: December 20, 2021

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