

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

NOVARTIS PHARMACEUTICALS)
CORPORATION and NOVARTIS AG,)
)
Plaintiffs,) C.A. No.: _____
)
v.)
)
ZENARA PHARMA PRIVATE LIMITED)
and BIOPHORE INDIA)
PHARMACEUTICALS PRIVATE)
LIMITED,)
)
Defendants.

COMPLAINT

Novartis Pharmaceuticals Corporation (“NPC”) and Novartis AG (collectively “Novartis”), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendants Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited (collectively, “Zenara” or “Defendants”). This action relates to Abbreviated New Drug Application (“ANDA”) No. 220033 (the “Zenara ANDA”) filed by Defendants with the United States Food and Drug Administration (“FDA”), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of eltrombopag tablets (12.5 mg, 25 mg, 50 mg, and 75 mg), generic versions of Novartis’s PROMACTA® (eltrombopag olamine) tablets (collectively, the “ANDA Product”), prior to the expiration of U.S. Patent No. 8,828,430 (“the ’430 patent” or “the Asserted Patent”).

PARTIES

A. Novartis

2. Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

3. Novartis AG is a company organized and existing under the laws of Switzerland, having a principal place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland.

B. Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited

4. Upon information and belief, Defendant Zenara Pharma Private Limited is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 83/B, 84, 87 to 96, Phase III, IDA Cherlapally, Hyderabad, Telangana, 500051, India.

5. Upon information and belief, Defendant Biophore India Pharmaceuticals Private Limited is a corporation organized and existing under the laws of India, having a principal place of business at Plot 92, 1-98/2/92, Kavuri Hills, Phase II, Jubilee Hills, Hyderabad, Telangana, 500033, India.

6. Upon information and belief, Defendant Zenara Pharma Private Limited is a wholly owned subsidiary of Biophore India Pharmaceuticals Private Limited. *See, e.g., Astellas Pharma Inc. v. Cipla Limited*, C.A. No. 24-1333-GBW (D. Del. Mar. 24, 2025) (D.I. 32 at 6).

7. Upon information and belief, Defendants are agents of each other with respect to the development, regulatory approval, marketing, sale, and/or distribution of generic products within the United States. Upon information and belief, the acts of Defendants complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of, each other.

8. Upon information and belief, Zenara is a generic pharmaceutical organization that works to develop, manufacture, market, and distribute generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

DEFENDANTS' INFRINGING ACTS

9. In a letter dated April 10, 2025 (the "Zenara Notice Letter"), Zenara Pharma Private Limited notified Novartis (i) that Zenara Pharma Private Limited submitted to the FDA ANDA No. 220033, seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of eltrombopag tablets (12.5 mg, 25 mg, 50 mg, and 75 mg) in or into the United States, including Delaware, prior to the expiration of the '430 patent and (ii) that ANDA No. 220033 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '430 patent.

10. Defendants have committed an act of infringement in this judicial district by filing the Zenara ANDA with the intent to make, use, sell, offer for sale, and/or import the ANDA Product in or into this judicial district prior to the expiration of the Asserted Patent.

11. Upon information and belief, Biophore India Pharmaceuticals Private Limited acted in concert with and/or directed Zenara Pharma Private Limited in the preparation and submission of the Zenara ANDA and, if the Zenara ANDA is approved, will act in concert with and direct Zenara Pharma Private Limited to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the ANDA Product in or into the United States, including Delaware, prior to the expiration of the Asserted Patent.

12. Upon information and belief, Zenara Pharma Private 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 Biophore India Pharmaceuticals Private Limited; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

13. Upon information and belief, Biophore India Pharmaceuticals Private 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 Zenara Pharma Private Limited; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

14. Zenara Pharma Private Limited has availed itself of the legal protections of the State of Delaware by, among other things, conceding jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g., Astellas Pharma Inc. v. Cipla Limited*, C.A. No. 24-1333-GBW; *SK Biopharmaceuticals Co., Ltd. v. Aurobindo Pharma Limited*, C.A. No. 24-718-JLH; *Harmony Biosciences, LLC v. AET Pharma US, Inc.*, C.A. No. 23-1340-JLH.

15. Biophore India Pharmaceuticals Private Limited has availed itself of the legal protections of the State of Delaware by, among other things, conceding jurisdiction in the United States District Court for the District of Delaware. *See, e.g., Astellas Pharma Inc. v. Cipla Limited*, C.A. No. 24-1333-GBW; *Harmony Biosciences, LLC v. AET Pharma US, Inc.*, C.A. No. 23-1340-JLH.

JURISDICTION AND VENUE

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

17. This Court has personal jurisdiction over Zenara Pharma Private Limited under Federal Rule of Civil Procedure 4(k)(2) because, upon information and belief, Zenara Pharma Private Limited is organized under the laws of India and the exercise of personal jurisdiction over Zenara Pharma Private Limited in any judicial district is consistent with the United States Constitution and laws.

18. This Court has personal jurisdiction over Biophore India Pharmaceuticals Private Limited under Federal Rule of Civil Procedure 4(k)(2) because, upon information and belief, Biophore India Pharmaceuticals Private Limited is organized under the laws of India and the exercise of personal jurisdiction over Biophore India Pharmaceuticals Private Limited in any judicial district is consistent with the United States Constitution and laws.

19. This Court also has personal jurisdiction over Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited because, upon information and belief, Defendants have committed or aided, abetted, contributed to, or participated in the commission of tortious acts of patent infringement in preparing and submitting the Zenara ANDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

20. Upon information and belief, the effort to seek approval for the Zenara ANDA and to manufacture, import, market, and/or sell Defendants' ANDA Product upon approval has been a cooperative and joint enterprise and venture between Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited.

21. This Court also has personal jurisdiction over Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited because, upon information and belief, Defendants will, upon approval of the Zenara ANDA, market, distribute, offer for sale, and/or sell Defendants'

ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of the ANDA Product in the State of Delaware.

22. This Court also has personal jurisdiction over Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited because, upon information and belief, Defendants' ANDA Product, upon approval of the Zenara ANDA, will be marketed, distributed, offered for sale, and/or sold in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which will have a substantial effect on Delaware.

23. This Court also has personal jurisdiction over Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited because, upon information and belief, Defendants' affiliations with the State of Delaware, including Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited's availing themselves of the legal protections of the State of Delaware, and Zenara Pharma Private Limited's actions in concert with Biophore India Pharmaceuticals Private Limited are sufficiently continuous and systematic as to render Defendants at home in this forum.

24. Upon information and belief, Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited operate as an integrated business with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products, including the ANDA Product, throughout the United States including in this judicial district.

25. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited.

26. Venue is proper in this Court because Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited are foreign entities who may be sued in any judicial district, including Delaware. 28 U.S.C. §§ 1391(c)(3), 1400(b). Defendants have also previously conceded that venue is proper in Delaware for at least the cases listed above and have conceded that venue is proper in Delaware for purposes of the counterclaims filed in those cases.

THE PATENT-IN-SUIT AND PROMACTA®

27. Novartis AG is the owner of the '430 patent, titled “3’-[(2Z)-[1-(3,4-dimethylphenyl)-1,5-dihydro-3-methyl-5-oxo-4H-pyrazol-4-ylidene]hydrazino]-2’-hydroxy-[1,1’-biphenyl]-3-carboxylic acid bis-(monoethanolamine).” The '430 patent was duly and legally issued on September 9, 2014. A true and correct copy of the '430 patent is attached hereto as Exhibit A. The '430 patent expires on August 1, 2027, excluding any pediatric exclusivity.

28. Novartis is the holder of New Drug Application (“NDA”) No. 022291 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of PROMACTA® (eltrombopag) tablets. PROMACTA® is currently indicated (i) for the treatment of thrombocytopenia in adult and pediatric patients 1 year and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy, (ii) for the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy, (iii) in combination with standard immunosuppressive therapy for the first-line treatment of adult and pediatric patients 2 years and older with severe aplastic anemia, and (iv) for the treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

29. One or more claims of the Asserted Patent cover PROMACTA®.

30. The FDA's official publication of approved drugs (the "Orange Book") lists the Asserted Patent in connection with PROMACTA®.

INFRINGEMENT OF THE ASSERTED PATENT

FIRST COUNT FOR PATENT INFRINGEMENT ('430 PATENT)

31. Novartis realleges, and incorporates in full herein, each preceding paragraph.

32. Novartis received the Zenara Notice Letter dated April 10, 2025, purporting to include a Notice of Certification for ANDA No. 220033 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '430 patent.

33. The '430 patent claims, *inter alia*, a pharmaceutical tablet consisting of 3'-(2Z)-[1-(3,4-dimethylphenyl)-1,5-dihydro-3-methyl-5-oxo-4H-pyrazol-4-ylidene]hydrazino]-2'-hydroxy-[1,1'-biphenyl]-3-carboxylic acid bis-(monoethanolamine) ("eltrombopag olamine").

34. Claim 1 recites: A pharmaceutical tablet consisting essentially of:

(a) 3'-(2Z)-[1-(3,4-dimethylphenyl)-1,5-dihydro-3-methyl-5-oxo-4H-pyrazol-4-ylidene]hydrazino]-2'-hydroxy-[1,1'-biphenyl]-3-carboxylic acid bis-(monoethanolamine);

wherein,

(b) about 90% of the compound particles have a particle size of greater than 10 micron but less than 90 micron;

(c) the tablet contains from about 25% to about 89% by weight of one or more excipients selected from the group consisting of microcrystalline cellulose, powdered cellulose, pregelatinized starch, starch, lactitol, mannitol, sorbitol and maltodextrin;

(d) the tablet is film coated;

- (e) the tablet contains a disintegrant in an amount equal to or greater than 4% by weight;
- (f) the tablet optionally contains a binder in an amount up to about 8% by weight; and
- (g) the tablet optionally contains a lubricant in an amount up to about 2% by weight.

35. At least one claim, including claim 1, of the '430 patent covers FDA-approved PROMACTA®.

36. Upon information and belief, Defendants submitted ANDA No. 220033 to the FDA, under Section 505(j) of the Act, and 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic eltrombopag tablets, 12.5 mg, 25 mg, 50 mg, and 75 mg eltrombopag olamine in or into the United States, including Delaware.

37. Upon information and belief, Defendants' proposed generic eltrombopag tablets that are the subject of ANDA No. 220033 contain eltrombopag olamine, the core and coating materials, the excipients, and compound particles according to claim 1 of the '430 patent. Defendants' generic eltrombopag tablets will therefore directly infringe at least claim 1 of the '430 patent.

38. Upon information and belief, Defendants' generic eltrombopag tablets, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim, including claim 1, of the '430 patent under 35 U.S.C. § 271(a).

39. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim, including claim 1, of the '430 patent by submitting, or causing to be

submitted to the FDA, ANDA No. 220033 seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic eltrombopag tablets before the expiration date of the '430 patent. Upon information and belief, the eltrombopag tablets described in ANDA No. 220033 would infringe, either literally or under the doctrine of equivalents, at least one claim, including claim 1, of the '430 patent under 35 U.S.C. § 271(e)(2)(A).

40. Upon information and belief, Defendants had actual knowledge of the '430 patent prior to the submission of ANDA No. 220033 to the FDA.

41. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 220033 complained of herein were done by and for the benefit of Defendants.

42. If Defendants' marketing and sale of generic eltrombopag tablets prior to the expiration of the '430 patent and all other relevant activities are not enjoined, Novartis will suffer substantial and irreparable harm for which there is no adequate remedy at law.

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

PRAYER FOR RELIEF

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

44. Judgment that Defendants Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited have infringed one or more claims of the Asserted Patent by filing ANDA No. 220033;

45. A permanent injunction restraining and enjoining Defendants, and their affiliates, subsidiaries, and each of 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 ANDA Product until the expiration of the Asserted Patent, inclusive of any extensions and additional periods of exclusivity;

46. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 220033 shall be a date that is not earlier than the expiration of the Asserted Patent, inclusive of any extensions and additional periods of exclusivity;

47. Declaratory judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of the ANDA Product will directly infringe, induce infringement of, and/or contributorily infringe one or more claims of the Asserted Patent;

48. Damages or other monetary relief from Defendants for the infringement, inducement of infringement, and/or contributory infringement of the Asserted Patent if one or both of the Defendants engage in the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the ANDA Product prior to the expiration date of the Asserted Patent, inclusive of any extensions and additional periods of exclusivity;

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

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

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

Dated: May 23, 2025

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