

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC.,
ARBOR PHARMACEUTICALS, LLC and
TAKEDA PHARMACEUTICAL
COMPANY LIMITED,

Plaintiffs,

v.

SABA ILAC SANAYI VE TICARET AS,

Defendant.

C.A. No. 25-814-MN

**DEFENDANT SABA ILAC SANAYII VE TICARET AS'S ANSWER AND
COUNTERCLAIMS TO THE COMPLAINT**

Defendant Saba Ilac Sanayii Ve Ticaret As (“Saba”), by its counsel, hereby responds to the allegations in the Complaint set forth by the Plaintiffs Azurity Pharmaceuticals, Inc. (“Azurity”), Arbor Pharmaceuticals, LLC (“Arbor”) and Takeda Pharmaceutical Company Limited (“Takeda”) (collectively, “Plaintiffs”) against Saba. This response is based on Saba’s current knowledge as to its own activities, and on information and belief as to the activities of others. If not specifically admitted herein, the allegations of the Complaint are denied. The headings in Plaintiffs’ Complaint are copied herein for convenience only, and any allegations in such headings are denied.

THE PARTIES

1. Saba is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 1 of the Complaint and therefore denies them.
2. Saba is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2 of the Complaint and therefore denies them.
3. Saba is without knowledge or information sufficient to form a belief as to the truth

of the allegations of paragraph 3 of the Complaint and therefore denies them.

4. Saba admits that it is a corporation organized and existing under the laws of Turkey, having a principal place of business at Merkez Mah. Basın Ekspres Cad. No: 1, Kucukcekmece, Istanbul, Turkey, 34303. Saba denies any remaining allegations in this paragraph.

5. Paragraph 5 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, denied.

NATURE OF THE ACTION

6. Saba admits that this action purports to arise under the Patent Laws of the United States, United States Code, Title 35. Saba further admits that Plaintiffs purport to seek relief from alleged infringement by Saba of U.S. Patent Nos. 9,066,936 (“the ’936 patent”), 9,169,238 (“the ’238 patent”) and 9,387,249 (“the ’249 patent) (collectively “the Patents-in-Suit”).

JURISDICTION & VENUE

7. Paragraph 7 of the Complaint states a legal conclusion to which no response is required. Saba will not contest subject matter jurisdiction in this Court solely for the purposes of Plaintiffs’ Complaint in this case and solely as applied to Saba’s proposed ANDA product described in ANDA No. 217111.

8. Paragraph 8 of the Complaint states a legal conclusion to which no response is required. Saba will not contest subject matter jurisdiction in this Court solely for the purposes of Plaintiffs’ Complaint in this case and solely as applied to Saba’s proposed ANDA product described in ANDA No. 217111.

9. Paragraph 9 of the Complaint states a legal conclusion to which no response is required. Saba will not contest personal jurisdiction for the limited purpose of this action only. Saba denies any remaining allegations in this paragraph.

10. Paragraph 10 of the Complaint states a legal conclusion to which no response is required. Saba will not contest personal jurisdiction for the limited purpose of this action only. Saba denies any remaining allegations in this paragraph.

11. Paragraph 11 of the Complaint states a legal conclusion to which no response is required. Saba admits that it filed ANDA No. 216699 Saba will not contest personal jurisdiction for the limited purpose of this action only. Saba denies any remaining allegations in this paragraph.

12. Paragraph 12 of the Complaint states a legal conclusion to which no response is required. Saba will not contest venue for the limited purpose of this action only. Saba denies any remaining allegations in this paragraph.

THE PATENTS-IN-SUIT

13. Saba admits that the copy of what purports to be the '936 patent in Ex. A to the Complaint is titled "Solid Pharmaceutical Composition Comprising a Benzimidazole-7-Carboxylate Derivative and a pH Control Agent" and that the listed date of the patent is June 30, 2015. Saba is without knowledge or information sufficient to form a belief as to the truth of the allegations that Ex. A is a "copy of the '936 patent." Saba denies that the '936 patent was "duly and legally issued." Saba denies any remaining allegations in paragraph 13.

14. Saba admits that the copy of what purports to be the '936 patent in Ex. A to the Complaint lists Takeda as the assignee. Saba is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 14 of the Complaint and therefore denies them.

15. Saba is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 15 of the Complaint and therefore denies them.

16. Saba admits that the copy of what purports to be the '238 patent in Ex. B to the

Complaint is titled “Solid Pharmaceutical Composition,” and that the listed date of the patent is October 27, 2015. Saba is without knowledge or information sufficient to form a belief as to the truth of the allegations that Ex. B is a “copy of the ’238 patent.” Saba denies that the ’238 patent was “duly and legally issued.” Saba denies any remaining allegations in paragraph 16.

17. Saba admits that the copy of what purports to be the ’238 patent in Ex. B to the Complaint lists Takeda as the assignee. Saba is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 13 of the Complaint and therefore denies them.

18. Saba is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 18 of the Complaint and therefore denies them.

19. Saba admits that the copy of what purports to be the ’249 patent in Ex. C to the Complaint is titled “Methods of Treating Hypertension with at Least One Angiotensin II Receptor Blocker and Chlorthalidone” and that the listed date of the patent is July 12, 2016. Saba is without knowledge or information sufficient to form a belief as to the truth of the allegations that Ex. C is a “copy of the ’249 patent.” Saba denies that the ’249 patent was “duly and legally issued.” Saba denies any remaining allegations in paragraph 19.

20. Saba admits that the copy of what purports to be the ’249 patent in Ex. C to the Complaint lists Takeda as the assignee. Saba is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 20 of the Complaint and therefore denies them.

21. Saba is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 21 of the Complaint and therefore denies them.

ACTS GIVING RISE TO THIS ACTION

22. Saba admits that the proprietary name for the drug listed in NDA 202331 is “EDARBYCLOR”, and that the dosage form is oral tablet. Saba is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 22 of the Complaint and therefore denies them.

23. Paragraph 23 of the Complaint states a legal conclusion to which no response is required. To the extent that a response is required, Saba admits that in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”), the patents presently listed in association with EDARBYCLOR are the Patents-in-Suit. Saba is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 23 of the Complaint and therefore denies them.

24. Admitted.

25. Paragraph 25 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, denied.

26. Admitted.

27. Admitted.

28. Admitted.

29. Saba’s Notice Letter contained an Offer of Confidential Access with reasonable protections for Saba’s confidential information. Plaintiffs rejected this OCA. Saba disagrees with Plaintiffs’ characterization of what occurred and therefore denies the remainder of this paragraph.

30. Saba’s Notice Letter contained an Offer of Confidential Access with reasonable protections for Saba’s confidential information. Plaintiffs rejected this OCA. Saba disagrees with Plaintiffs’ characterization of what occurred and therefore denies the remainder of this paragraph.

31. Saba's Notice Letter contained an Offer of Confidential Access with reasonable protections for Saba's confidential information. Plaintiffs rejected this OCA. Saba disagrees with Plaintiffs' characterization of what occurred and therefore denies the remainder of this paragraph.

32. Saba's Notice Letter in 2022 contained an Offer of Confidential Access with reasonable protections for Saba's confidential information. Plaintiffs rejected this OCA. Saba disagrees with Plaintiffs' characterization of what occurred and therefore denies the remainder of this paragraph.

33. Defendant admits that in the cited litigation the parties agreed to a Stipulated Order protecting each party's confidential information. Any remaining allegations or characterizations are denied.

34. Denied.

35. Denied.

36. Saba admits that attached to Saba's Notice Letter was a statement of the factual and legal bases for Saba's positions, of which Saba was aware as of the date of Saba's Notice Letter, having not yet conducted any discovery in this litigation, that the Patents-in-Suit are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, sale, or offer for sale of Saba's proposed ANDA product described in ANDA No. 216699. Saba denies any remaining allegations in paragraph 36.

37. Admitted.

COUNT I

38. Saba re-alleges paragraphs 1-37 as if fully set forth herein.

39. Saba admits that Saba submitted ANDA No. 217111 to the FDA, which included § 505(j)(2)(A)(vii)(IV) certification. Saba denies any remaining allegations in this paragraph.

40. Denied.

41. Saba admits that it became aware of the '936 patent no later than when Saba submitted a paragraph IV certification to the FDA with respect to the '936 patent regarding ANDA No. 217111. Saba denies any remaining allegations in this paragraph.

42. Denied.

43. Denied.

44. Denied.

45. Denied.

COUNT II

46. Saba re-alleges paragraphs 1-45 as if fully set forth herein.

47. Saba admits that Saba submitted ANDA No. 217111 to the FDA, which included § 505(j)(2)(A)(vii)(IV) certification. Saba denies any remaining allegations in this paragraph.

48. Denied.

49. Saba admits that it became aware of the '238 patent no later than when Saba submitted a paragraph IV certification to the FDA with respect to the '238 patent regarding ANDA No. 217111. Saba denies any remaining allegations in this paragraph.

50. Denied.

51. Denied.

52. Denied.

53. Denied.

COUNT III

54. Saba re-alleges paragraphs 1-54 as if fully set forth herein.

55. Saba admits that Saba submitted ANDA No. 217111 to the FDA, which included §

505(j)(2)(A)(vii)(IV) certification. Saba denies any remaining allegations in this paragraph.

56. Denied.

57. Saba admits that it became aware of the '249 patent no later than when Saba submitted a paragraph IV certification to the FDA with respect to the '249 patent regarding ANDA No. 217111. Saba denies any remaining allegations in this paragraph.

58. Denied.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

PLAINTIFFS' PRAYER FOR RELIEF

Saba denies all allegations not specifically admitted herein, and further denies that Plaintiffs are entitled to any of the relief sought in their Prayer for Relief.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its responses to paragraphs 1 through 45 of the Complaint, and without undertaking any of the burdens imposed by law on the Plaintiffs, Saba asserts the following separate defenses to the Complaint.

FIRST AFFIRMATIVE DEFENSE

(Non-Infringement)

The manufacture, use, sale, offer for sale, and/or importation of Saba's ANDA Products do not and will not infringe, neither literally nor under the doctrine of equivalents, directly, or indirectly, neither by inducement nor contributorily, any valid, enforceable claim of the Patents-

in-Suit.

SECOND AFFIRMATIVE DEFENSE

(Invalidity or Unenforceability)

The claims of the Patents-in-Suit are invalid and/or unenforceable for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, one or more of 35 U.S.C. § 101, 102, 103, 112, and 116 and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patents and/or defenses recognized in 35 U.S.C. § 282.

THIRD AFFIRMATIVE DEFENSE

(Failure to State a Claim)

Plaintiff's Complaint fails to state a claim upon which relief can be granted.

FOURTH AFFIRMATIVE DEFENSE

(Failure to State a Claim for Exceptional Case)

To the extend the Complaint purports to seek an "exceptional case" determination, the Complaint fails to state a claim for exceptional case under 35 U.S.C. § 285 and/or 35 U.S.C. § 271(e)(4). Moreover, Saba's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

FIFTH AFFIRMATIVE DEFENSE

(Additional Defenses)

Saba reserves the right to present any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Defendant/Counterclaimant Saba Ilac Sanayii Ve Ticaret As ("Saba") brings the following

Counterclaims against Plaintiffs/Counterdefendants Azurity Pharmaceuticals, Inc. (“Azurity”), Arbor Pharmaceuticals, LLC (“Arbor”) and Takeda Pharmaceutical Company Limited (“Takeda”) (collectively, “Plaintiffs”) for a declaratory judgment that U.S. Patent Nos. 9,066,936 (“the ’936 patent”), 9,169,238 (“the ’238 patent”) and 9,387,249 (“the ’249 patent) (collectively “the Patents-in-Suit”) are invalid and/or not infringed by the manufacture, use, sale, offer for sale, or importation of Saba’s ANDA Products.

PARTIES

1. Saba is a corporation organized and existing under the laws of Turkey, having a registered office at Merkez Mah. Basin Ekspres Cad. No: 1, Kucukcekmece, Istanbul, Turkey, 34303.

2. On information and belief, and based on Counterdefendants’ allegations, Plaintiff/Counterdefendant Azurity is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 8 Cabot Road, Suite 2000, Woburn, MA 01801

3. On information and belief, and based on Counterdefendants’ allegations, Plaintiff/Counterdefendant Arbor is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 6 Concourse Parkway, Suite 1800, Atlanta, GA 30328.

4. On information and belief, and based on Counterdefendants’ allegations, Plaintiff/Counterdefendant Takeda is a corporation organized and existing under the laws of Japan, having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan.

JURISDICTION AND VENUE

5. Saba seeks a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

6. The Court has jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and 35 U.S.C. § 271(e)(2).

7. Venue is proper under 28 U.S.C. § 1391 and 1400(b), and by Counterdefendants' choice of forum.

8. This is an action based upon an actual controversy between the parties concerning the invalidity and/or non-infringement of the Patents-in-Suit and Saba's right to continue to seek approval of ANDA No. 217111 ("Saba's ANDA") for oral azilsartan/chlorthalidone tablets ("Saba's ANDA Products").

9. Saba has been and presently is engaged in the submission of documents to the FDA, and those documents seek approval to engage in the commercial manufacture, importation, use, offer for sale, or sale of Saba's ANDA Products. Counterdefendants have alleged that the submission of Saba's ANDA infringes, will infringe, will induce infringement, or will contribute to infringement of one or more claims of the Patents-in-Suit.

10. Counterdefendants have filed in this Court an infringement action to enforce the Patents-in-Suit against Saba.

11. On information and belief, and according to Counterdefendants' allegations, Takeda is the owner of the '936 patent, the '238 patent, and the '249 patent.

12. On information and belief, and according to Counterdefendants' allegations, Arbor holds the New Drug Application ("NDA") No. 202331 for EDARBYCLOR (oral azilsartan/chlorthalidone tablets).

13. Saba has denied that it has, continues to, or will infringe, induce infringement of, and/or contribute to the infringement of, any valid and enforceable claim of the Patents-in-Suit.

14. Saba has further asserted that the Patents-in-Suit are invalid for failure to satisfy

one or more of the provisions of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent, and the defenses recognized in 35 U.S.C. § 282.

15. The '936 patent, the '238 patent, and the '249 patent are listed in the electronic Orange Book with respect to EDARBYCLOR.

16. In view of the foregoing, a conflict of asserted rights has arisen between Saba and the Counterdefendants with respect to the non-infringement and invalidity of the relevant claims of the Patents-in-Suit, and as to Saba's right to obtain FDA approval to engage in the commercial manufacture, importation, use, offer for sale, or sale of Saba's ANDA Products. An actual controversy therefore exists between the Counterdefendants and Saba.

FIRST COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT

(U.S. Patent No. 9,066,936)

17. Saba realleges Paragraphs 1-16 as though fully set forth herein.

18. The manufacture, use, sale, offer for sale, and/or importation of Saba's ANDA Products do not and will not infringe, neither literally nor under the doctrine of equivalents), directly or indirectly, neither by inducement or contributorily, any valid, enforceable claim of the '936 patent.

19. Saba is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Saba's ANDA Products do not, and would not if marketed, infringe any valid and enforceable claim of the '936 patent, at least because Saba's ANDA Products do not meet at least one limitation recited in the claims of the '936 patent.

SECOND COUNTERCLAIM – DECLARATION OF INVALIDITY

(U.S. Patent No. 9,066,936)

20. Saba realleges Paragraphs 1-19 as through fully set forth herein.
21. The claims of the '936 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. § 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. § 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

22. Saba is entitled to a judicial declaration that the claims of the '936 patent are invalid.

THIRD COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT

(U.S. Patent No. 9,169,238)

23. Saba realleges Paragraphs 1-22 as though fully set forth herein.
24. The manufacture, use, sale, offer for sale, and/or importation of Saba's ANDA Products do not and will not infringe, neither literally nor under the doctrine of equivalents), directly or indirectly, neither by inducement or contributorily, any valid, enforceable claim of the '238 patent

25. Saba is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Saba's ANDA Products do not, and would not if marketed, infringe any valid and enforceable claim of the '238 patent, at least because Saba's ANDA Products do not meet at least one limitation recited the claims of the '238 patent.

FOURTH COUNTERCLAIM – DECLARATION OF INVALIDITY

(U.S. Patent No. 9,169,238)

26. Saba realleges Paragraphs 1-25 as through fully set forth herein.

27. The claims of the '238 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. § 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. § 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

28. Saba is entitled to a judicial declaration that the claims of the '238 patent are invalid.

FIFTH COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT

(U.S. Patent No. 9,387,249)

29. Saba realleges Paragraphs 1-28 as though fully set forth herein.

30. The manufacture, use, sale, offer for sale, and/or importation of Saba's ANDA Products do not and will not infringe, neither literally nor under the doctrine of equivalents), directly or indirectly, neither by inducement or contributorily, any valid, enforceable claim of the '249 patent

31. Saba is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Saba's ANDA Products do not, and would not if marketed, infringe any valid and enforceable claim of the '249 patent, at least because Saba's ANDA Products do not meet at least one limitation recited in the claims of the '249 patent.

SIXTH COUNTERCLAIM – DECLARATION OF INVALIDITY

(U.S. Patent No. 9,387,249)

32. Saba realleges Paragraphs 1-31 as through fully set forth herein.

33. The claims of the '249 patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. § 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. § 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or

any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

34. Saba is entitled to a judicial declaration that the claims of the '249 patent are invalid.

SABA'S PRAYER FOR RELIEF

Wherefore, Saba prays for the following relief:

- A. That the Court order the Complaint dismissed with prejudice and judgment be entered in favor of Saba;
- B. That a judgment be entered declaring that the manufacture, import, use, sale, and/or offer to sell Saba's ANDA Products has not infringed, does not, and will not infringe, neither literally nor under the doctrine of equivalents, directly or indirectly, neither by inducement nor contributorily, any valid, enforceable claim of the Patents-in-Suit;
- C. That a judgment be entered declaring the claims of U.S. Patent Nos. 9,066,936, 9,169,238, and 9,387,249 invalid;
- D. That the Court declare that Saba has the lawful right to manufacture, import, use, sell, and/or offer to sell Saba's ANDA Products in the United States once the products are approved by the FDA;
- E. That the Plaintiffs/Counterdefendants and their agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice thereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Saba or any of its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Saba, or charging any of them either orally or in writing with infringement of U.S. Patent Nos 9,066,936, 9,169,238, and 9,387,249;
- F. That a judgment be entered, declaring that this action is an exceptional case within

the meaning of 35 U.S.C. § 285 and that Saba is therefore entitled to recover its reasonable attorneys' fees upon prevailing in this action;

G. That Saba be awarded costs, attorneys' fees, and other relief, both legal and equitable, to which it may be justly entitled; and

H. That Saba be awarded such other and further relief as is just and proper.

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