

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

BOW RIVER LLC,

Plaintiff,

v.

ALEMBIC PHARMACEUTICALS
LTD and ALEMBIC
PHARMACEUTICALS, INC.,

Defendants.

C.A. No. 25-1017-CFC
ANDA CASE

**ALEMBIC PHARMACEUTICALS LIMITED AND ALEMBIC
PHARMACEUTICALS, INC.’S ANSWER, DEFENSES, AND
COUNTERCLAIMS TO PLAINTIFF’S
COMPLAINT FOR PATENT INFRINGEMENT**

Defendants Alembic Pharmaceuticals Limited (“APL”) and Alembic Pharmaceuticals, Inc. (“API”) (APL and API are collectively referred to herein as “Defendants” or “Alembic”) hereby respond to Plaintiff Bow River LLC’s (“Bow River” or “Plaintiff”) Complaint for Patent Infringement (“Complaint”) as follows:

1. Alembic admits that the Complaint purports to allege a civil action for patent infringement of United States Patent Nos. 11,337,967 (the “’967 Patent”); and 11,974,998 (the “’998 Patent”) (collectively, the “Asserted Patents” or the “Patents-in-Suit”), arising under the patent laws of the United States, Title 35, United States Code.

2. Alembic admits that it notified Plaintiff that it had submitted ANDA No. 220639 to FDA (“Alembic’s Notice Letter”). Alembic further admits that the

purpose of this submission was to seek approval to market Alembic's ANDA Products (as defined herein) prior to the expiration of the Patents-in-Suit. Alembic states that Alembic's Notice Letter speaks for itself, and denies any allegations to the extent they deviate from or otherwise do not accurately reflect or describe Alembic's Notice Letter. Alembic denies the remaining allegations in Paragraph 2.

3. Alembic denies any infringement. Alembic further denies that Plaintiff is entitled to any of the relief requested in the Complaint.

PARTIES

4. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 4, and therefore denies them.

5. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 5, and therefore denies them.

6. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 6, and therefore denies them.

7. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 7, and therefore denies them.

8. Admitted.

9. Admitted.

10. The allegations in Paragraph 10 state legal conclusions to which no response is required. To the extent a response is required, Alembic denies the allegations in Paragraph 10.

11. The allegations in Paragraph 11 state legal conclusions to which no response is required. To the extent a response is required, Alembic admits that Alembic is in the business of development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. Alembic denies the remaining allegations in Paragraph 11.

12. The allegations in Paragraph 12 state legal conclusions to which no response is required. To the extent a response is required, Alembic denies the allegations in Paragraph 12.

13. Alembic states that APL submitted ANDA No. 220639 for Alembic's ANDA Products to FDA for approval to market Alembic's ANDA Products in the United States. The remaining allegations in Paragraph 13 state legal conclusions to which no response is required. To the extent a response is required, Alembic denies the remaining allegations in Paragraph 13.

JURISDICTION AND VENUE

14. The allegations in Paragraph 14 state legal conclusions to which no response is required. To the extent a response is required, Alembic does not

dispute subject matter jurisdiction under 35 U.S.C. § 1 *et seq.* for the purposes of this action only.

15. The allegations in Paragraph 15 state legal conclusions to which no response is required. To the extent a response is required, Alembic does not dispute subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a) for the purposes of this action only. Alembic denies that Plaintiff is entitled to any of the relief requested in the Complaint.

16. Alembic admits that APL was or is a named defendant in the following District of Delaware action: *Galderma Lab 'ys L.P. et al. v. Alembic Pharms. Limited et al.*, C.A. No. 22-1312-SB (D.I. 18) (D. Del. Dec. 7, 2022). The remaining allegations in Paragraph 16 state legal conclusions to which no response is required. To the extent any further response is required, API does not dispute personal jurisdiction for the purposes of this action only.

17. Alembic admits that APL was or is a named defendant in the following District of Delaware action: *Galderma Lab 'ys L.P. et al. v. Alembic Pharms. Limited et al.*, C.A. No. 22-1312-SB (D.I. 18) (D. Del. Dec. 7, 2022). The remaining allegations in Paragraph 17 state legal conclusions to which no response is required. To the extent any further response is required, APL does not dispute personal jurisdiction for the purposes of this action only. Alembic denies the remaining allegations in Paragraph 17.

18. The allegations in Paragraph 18 state legal conclusions to which no response is required. To the extent a response is required, Alembic admits that Alembic manufactures generic drugs for sale throughout the United States, including in the State of Delaware. To the extent any further response is required, APL does not dispute personal jurisdiction for the purposes of this action only. Alembic denies the remaining allegations in Paragraph 18.

19. The allegations in Paragraph 19 state legal conclusions to which no response is required. To the extent a response is required, Alembic does not dispute venue for the purposes of this action only.

THE VITRAKVI® PRODUCTS

20. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 20, and therefore denies them.

21. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 21, and therefore denies them.

22. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 22, and therefore denies them.

23. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 23, and therefore denies them.

24. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 24, and therefore denies them.

25. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 25, and therefore denies them.

26. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 26, and therefore denies them.

ASSERTED PATENTS

27. Alembic admits that the face of the '967 Patent indicates that it is entitled "Methods of Treatment," that it was issued on May 24, 2022, from U.S. Patent Application No. 17/332,600. Alembic admits that a purported copy of the '967 Patent is attached to the Complaint as Exhibit A. Alembic denies that the '967 Patent was duly and legally issued.

28. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 28. To the extent a response is required, Alembic admits that the face of the '967 Patent lists Sundar Srinivasan and Christina Chow as purported inventors and Bow River LLC as the assignee.

29. The allegations in Paragraph 29 state legal conclusions to which no response is required. To the extent a response is required, Alembic admits the '967 Patent is listed in the Orange Book in connection with VITRAKVI® Capsules. To the extent any further response is required, Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 29, and therefore denies them.

30. Alembic admits that the face of the '998 Patent indicates that it is entitled "Methods of Treatment," that it was issued on May 7, 2024, from U.S. Patent Application No. 18/366,060. Alembic admits that a purported copy of the '998 Patent is attached to the Complaint as Exhibit B. Alembic denies that the '998 Patent was duly and legally issued.

31. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 31. To the extent a response is required, Alembic admits that the face of the '998 Patent lists Sundar Srinivasan and Christina Chow Wallen as purported inventors and Bow River LLC as the assignee.

32. The allegations in Paragraph 32 state legal conclusions to which no response is required. To the extent a response is required, Alembic admits the '998 Patent is listed in the Orange Book in connection with VITRAKVI® Capsules. To the extent any further response is required, Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 32, and therefore denies them.

ALLEGED INFRINGEMENT BY ALEMBIC

33. Alembic admits that APL notified Plaintiff that it had submitted its ANDA No. 220639 to FDA under Section 505(j)(2)(B) of the FDCA (21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95). Alembic further admits that the purpose of this submission was to obtain approval to market Alembic's ANDA

Products prior to the expiration of the Asserted Patents. Alembic denies any remaining allegations in Paragraph 33.

34. Alembic admits that it intends to market Alembic's ANDA Products upon approval of Alembic's ANDA. Alembic denies any remaining allegations in Paragraph 34.

35. Alembic avers that the active ingredient, strength, and dosage form of its ANDA Products are Larotrectinib 25 mg and 100 mg, capsules. The remaining allegations in Paragraph 35 state legal conclusions to which no response is required. To the extent a response is required, Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 35, and therefore denies them.

36. The allegations in Paragraph 36 state legal conclusions to which no response is required. To the extent a response is required, Alembic's Notice Letter and the proposed labeling for Alembic's ANDA Products speak for themselves. Alembic denies any remaining allegations in Paragraph 36.

37. The allegations in Paragraph 37 state legal conclusions to which no response is required. To the extent a response is required, Alembic states that the proposed labeling for Alembic's ANDA Products speaks for itself. To the extent any further response is required, Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 37, and therefore denies them.

38. Alembic admits that Alembic's Notice Letter included an Offer of Confidential Access to portions of ANDA No. 220639 and requested that Bow River accept the Offer of Confidential Access before accessing ANDA No. 220639.

39. Denied.

40. Admitted.

FIRST COUNT¹
Infringement of the '967 Patent Under 35 U.S.C. § 271 (e)(2)(A)

41. Insofar as Plaintiff repeats and realleges the allegations of the preceding paragraphs of the Complaint, Alembic repeats, realleges, and incorporates by reference as if fully set forth herein Alembic's responses thereto.

42. Alembic admits that it submitted ANDA No. 220639 to FDA under section 505(j) of the FDCA with a Paragraph IV Certification seeking approval to market the products that are the subject of ANDA No. 220639 in the United States prior to the expiration of the '967 Patent. The remaining allegations in Paragraph 42 state legal conclusions to which no response is required. To the extent a response is required, Alembic specifically denies that it has infringed, is infringing, or will infringe the '967 Patent, either literally or under the doctrine of equivalents. Alembic denies any remaining allegations in Paragraph 42.

¹ Recitation of headings from the Complaint are for organizational purposes and not an admission by Alembic.

43. The allegations in Paragraph 43 state legal conclusions to which no response is required. To the extent a response is required, Alembic specifically denies that it has infringed, is infringing, will infringe, or will induce infringement of the '967 Patent, either literally or under the doctrine of equivalents. Alembic denies any remaining allegations in Paragraph 43.

44. The allegations in Paragraph 44 state legal conclusions to which no response is required. To the extent a response is required, Alembic specifically denies that it has infringed, is infringing, will infringe, or will induce infringement of the '967 Patent, either literally or under the doctrine of equivalents. Alembic further states the proposed labeling for Alembic's ANDA Products speaks for itself. Alembic denies any remaining allegations in Paragraph 44.

45. The allegations in Paragraph 45 state legal conclusions to which no response is required. To the extent a response is required, Alembic specifically denies that it has infringed, is infringing, will infringe, or will induce infringement of the '967 Patent, either literally or under the doctrine of equivalents. Alembic denies any remaining allegations in Paragraph 45.

46. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 46, and therefore denies them.

SECOND COUNT

Infringement of the '998 Patent Under 35 U.S.C. § 271(e)(2)(A)

47. Insofar as Plaintiff repeats and realleges the allegations of the preceding paragraphs of the Complaint, Alembic repeats, realleges, and incorporates by reference as if fully set forth herein Alembic's responses thereto.

48. Alembic admits that it submitted ANDA No. 220639 to FDA under section 505(j) of the FDCA with a Paragraph IV Certification seeking approval to market the products that are the subject of ANDA No. 220639 in the United States prior to the expiration of the '998 Patent. The remaining allegations in Paragraph 48 state legal conclusions to which no response is required. To the extent a response is required, Alembic specifically denies that it has infringed, is infringing, or will infringe the '998 Patent, either literally or under the doctrine of equivalents. Alembic denies any remaining allegations in Paragraph 48.

49. The allegations in Paragraph 49 state legal conclusions to which no response is required. To the extent a response is required, Alembic specifically denies that it has infringed, is infringing, will infringe, or will induce infringement of the '998 Patent, either literally or under the doctrine of equivalents. Alembic denies any remaining allegations in Paragraph 49.

50. The allegations in Paragraph 50 state legal conclusions to which no response is required. To the extent a response is required, Alembic specifically denies that it has infringed, is infringing, will infringe, or will induce infringement

of the '998 Patent, either literally or under the doctrine of equivalents. Alembic further states the proposed labeling for Alembic's ANDA Products speaks for itself. Alembic denies any remaining allegations in Paragraph 50.

51. The allegations in Paragraph 51 state legal conclusions to which no response is required. To the extent a response is required, Alembic specifically denies that it has infringed, is infringing, will infringe, or will induce infringement of the '998 Patent, either literally or under the doctrine of equivalents. Alembic denies any remaining allegations in Paragraph 51.

52. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 52, and therefore denies them.

PRAYER FOR RELIEF

Alembic denies that Plaintiff is entitled to any of the relief requested in the Complaint.

DEFENSES TO PLAINTIFF'S COMPLAINT

53. Without any admissions as to the burdens of proof, or as to any of the allegations in the Complaint, Alembic states the following:

FIRST SEPARATE DEFENSE **(Non-Infringement of the '967 Patent)**

54. The submission of Alembic's ANDA and the importation, manufacture, use, offer for sale, or sale of the products that are the subject of Alembic's ANDA will not directly, indirectly, contributorily, and/or by

inducement infringe, either literally or under the doctrine of equivalents, any valid claim of the '967 Patent under any section of 35 U.S.C. § 271.

SECOND SEPARATE DEFENSE
(Invalidity of the '967 Patent)

55. To the extent any of the claims of the '967 Patent would otherwise cover the submission of Alembic's ANDA or the importation, manufacture, use, offer for sale or sale of the products that are the subject of Alembic's ANDA, the claims of the '967 Patent are invalid for failure to meet one or more requirements of 35 U.S.C. § 100 et seq., including but not limited to §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

THIRD SEPARATE DEFENSE
(Non-Infringement of the '998 Patent)

56. The submission of Alembic's ANDA and the importation, manufacture, use, offer for sale, or sale of the products that are the subject of Alembic's ANDA will not directly, indirectly, contributorily, and/or by inducement infringe, either literally or under the doctrine of equivalents, any valid claim of the '998 Patent under any section of 35 U.S.C. § 271.

FOURTH SEPARATE DEFENSE
(Invalidity of the '998 Patent)

57. To the extent any of the claims of the '998 Patent would otherwise cover the submission of Alembic's ANDA or the importation, manufacture, use, offer for sale or sale of the products that are the subject of Alembic's ANDA, the claims of the '998 Patent are invalid for failure to meet one or more requirements

of 35 U.S.C. § 100 et seq., including but not limited to §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

FIFTH SEPARATE DEFENSE
(No Relief Available)

58. Alembic repeats and realleges its responses in Paragraphs 1-57 as set forth herein.

59. Plaintiffs have not suffered any damages.

60. Plaintiffs are not suffering an irreparable injury.

61. Plaintiffs are barred from obtaining relief pursuant to one or more provisions of 35 U.S.C. § 1 et seq., including, but not limited to, §§ 286 and 287.

SIXTH SEPARATE DEFENSE
(Failure to State a Claim)

62. The Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

RESERVATION OF DEFENSES

63. Alembic's investigation of its defenses is continuing, and Alembic expressly reserves the right to allege and assert any additional defenses. Alembic has not knowingly or intentionally waived any applicable affirmative or other defenses and reserve the right to assert and rely upon such other affirmative and other defenses as may become available or apparent during discovery proceedings. Alembic further reserves the right to amend this Answer and/or affirmative defenses accordingly.

RESERVATION OF RIGHTS

64. Alembic reserves the right to assert such other defenses and damages that may appear as discovery proceeds in this case.

ALEMBIC'S COUNTERCLAIMS

Alembic Pharmaceuticals Limited (“APL”) and Alembic Pharmaceuticals, Inc. (“API”) (APL and API are collectively referred to herein as “Alembic”) for their counterclaims against Counterclaim Defendant Bow River LLC (“Bow River” or “Counterclaim Defendant”), allege as follows:

THE PARTIES

1. APL is a corporation organized and existing under the laws of India, with a principal place of business at Alembic Road, Vadodara 390003, Gujarat, India.

2. API is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 550 Hills Drive, Suite 104B, Bedminster, New Jersey 07921.

3. On information and belief, based on its allegations, Bow River is a limited liability company organized and existing under the laws of the State of Wyoming with a principal place of business at 23 Corporate Plaza Drive, Suite 150, Newport Beach, CA 92660.

NATURE OF THE ACTION

4. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and under the patent laws of the United States, 35 U.S.C. § 1 et seq.

5. Alembic seeks a declaration that Alembic has not infringed, is not infringing, and will not infringe, or contribute to or induce infringement of any valid and enforceable claim of U.S. Patent No. 11,337,967 (the “’967 Patent”); and 11,974,998 (the “’998 Patent”), literally or under the doctrine of equivalents. Together, these patents are referred to herein as the “Patents-in-Suit.”

6. As a consequence of Counterclaim Defendant’s Complaint against Alembic, and based on Alembic’s denials in its Answer, there exists an actual, continuing, and substantial case or controversy between Alembic and Counterclaim Defendant having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the alleged infringement and validity of the Patents-In-Suit.

JURISDICTION AND VENUE

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

8. Counterclaim Defendant has submitted to this Court’s personal jurisdiction by suing Alembic in this District. On information and belief,

Counterclaim Defendant sells products in this District, including the Vitrakvi product at issue in this case, and conducts substantial business in, and has regular and systemic contacts with this District.

9. This Court is the proper venue under 28 U.S.C. §§ 1391(b) and 1400(b).

BACKGROUND

10. On information and belief, based on Counterclaim Defendant's allegations, Counterclaim Defendant is the owner of the Patents-in-Suit.

11. The face of the '967 Patent, titled "Methods of Treatment," indicates that it was issued on May 24, 2022.

12. The face of the '998 Patent, titled "Methods of Treatment," indicates that it was issued on May 7, 2024.

13. The '967 Patent is listed in the Orange Book for Vitrakvi.

14. The '998 Patent is listed in the Orange Book for Vitrakvi.

15. APL submitted ANDA No. 220639 ("Alembic's ANDA") to FDA seeking approval to market larotrectinib capsules, 25 mg and 100 mg ("Alembic's ANDA Products") before the purported expiration of the Patents-in-Suit.

16. APL has certified under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the claims of the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by Alembic's ANDA Products.

17. On August 13, 2025, Counterclaim Defendant filed its Complaint in this Court alleging that APL's act of submitting ANDA No. 220639 infringes the Patents-in-Suit.

18. Alembic denies that it infringes or will infringe any valid and enforceable claim of the Patents-in-Suit.

19. This suit by Counterclaim Defendant impairs Alembic's ability to obtain approval of its ANDA No. 220639 and market Alembic's ANDA Products.

20. Unless enjoined, Counterclaim Defendant will continue to assert that Alembic infringes the claims of the Patents-in-Suit. Alembic believes this will continue to interfere with Alembic's business with respect to Alembic's ANDA Products.

21. Alembic will be irreparably harmed if Counterclaim Defendant is not enjoined from asserting the Patents-in-Suit against Alembic.

FIRST CLAIM FOR RELIEF
(Declaratory Judgment of Non-Infringement of the '967 Patent)

22. Alembic repeats, realleges, and incorporates by reference, as if fully set forth herein, the preceding paragraphs of Alembic's Answer and Counterclaims.

23. Alembic's submission of ANDA No. 220639 seeking approval to market Alembic's ANDA Products that are the subject of ANDA No. 220639 prior to the expiration of the '967 Patent does not directly or indirectly infringe any valid

and/or enforceable claim of the '967 Patent, either literally or under the doctrine of equivalents.

24. Alembic's manufacture, sale, use, offer for sale, and/or importation of Alembic's ANDA Products that are the subject of ANDA No. 220639 will not infringe, either directly or indirectly, any valid and enforceable claim of the '967 Patent, either literally or under the doctrine of equivalents.

25. Because Alembic has not infringed the '967 Patent, and will not infringe any valid and enforceable claim of the '967 Patent, Counterclaim Defendant is not entitled to any damages or any other relief from or against Alembic.

26. Alembic is entitled to a declaratory judgment that Alembic's ANDA Products that are the subject of ANDA No. 220639 have not infringed, do not infringe, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '967 Patent, either literally or under the doctrine of equivalents.

SECOND CLAIM FOR RELIEF
(Declaratory Judgment of Invalidity of the '967 Patent)

27. Alembic repeats, realleges, and incorporates by reference, as if fully set forth herein, the preceding paragraphs of Alembic's Answer and Counterclaims.

28. The claims of the '967 Patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

29. Because one or more claims of the '967 Patent are invalid, Counterclaim Defendant is not entitled to any damages or other relief from or against Alembic.

30. Alembic is entitled to a declaratory judgment that the claims of the '967 Patent are invalid.

THIRD CLAIM FOR RELIEF
(Declaratory Judgment of Non-Infringement of the '998 Patent)

31. Alembic repeats, realleges, and incorporates by reference, as if fully set forth herein, the preceding paragraphs of Alembic's Answer and Counterclaims.

32. Alembic's submission of ANDA No. 220639 seeking approval to market Alembic's ANDA Products that are the subject of ANDA No. 220639 prior to the expiration of the '998 Patent does not directly or indirectly infringe any valid and/or enforceable claim of the '998 Patent, either literally or under the doctrine of equivalents.

33. Alembic's manufacture, sale, use, offer for sale, and/or importation of Alembic's ANDA Products that are the subject of ANDA No. 220639 will not

infringe, either directly or indirectly, any valid and enforceable claim of the '998 Patent, either literally or under the doctrine of equivalents.

34. Because Alembic has not infringed the '998 Patent, and will not infringe any valid and enforceable claim of the '998 Patent, Counterclaim Defendant is not entitled to any damages or any other relief from or against Alembic.

35. Alembic is entitled to a declaratory judgment that Alembic's ANDA Products that are the subject of ANDA No. 220639 have not infringed, do not infringe, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '998 Patent, either literally or under the doctrine of equivalents.

FOURTH CLAIM FOR RELIEF
(Declaratory Judgment of Invalidity of the '998 Patent)

36. Alembic repeats, realleges, and incorporates by reference, as if fully set forth herein, the preceding paragraphs of Alembic's Answer and Counterclaims.

37. The claims of the '998 Patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

38. Because one or more claims of the '998 Patent are invalid, Counterclaim Defendant is not entitled to any damages or other relief from or against Alembic.

39. Alembic is entitled to a declaratory judgment that the claims of the '998 Patent are invalid.

DEMAND FOR JUDGMENT

WHEREFORE, Alembic respectfully prays that this Court enter judgment in its favor and grant the following relief:

- A. A judgment dismissing the Complaint against Alembic with prejudice;
- B. A judgment denying Counterclaim Defendant any of the relief it has requested in the Complaint against Alembic;
- C. A judgment declaring that the claims of the Patents-in-Suit are invalid;
- D. A judgment declaring that APL's submission of ANDA No. 220639 seeking approval to market Alembic's ANDA Products that are the subject of ANDA No. 220639 prior to the expiration of the Patents-in-Suit does not directly or indirectly infringe any valid and enforceable claim of the Patents-in-Suit either literally or under the doctrine of equivalents;

E. A judgment declaring that Alembic has not infringed, either directly or indirectly, any valid and enforceable claim of the Patents-in-Suit, either literally or under the doctrine of equivalents, and that Alembic's manufacture, sale, offer for sale, and/or importation of Alembic's ANDA Products that are the subject of ANDA No. 220639 would not infringe, either directly or indirectly, any valid and enforceable claim of the Patents-in-Suit, either literally or under the doctrine of equivalents;

F. A judgment declaring that Counterclaim Defendant is entitled to no damages, interest, costs, or other relief (including injunctive relief) from or against Alembic for infringement of the Patents-in-Suit;

G. A judgment declaring this to be an exceptional case under 35 U.S.C. § 285 in Alembic's favor, and awarding Alembic its reasonable attorneys' fees, costs, and expenses in defending this action under 35 U.S.C. § 285 and all other applicable statutes and rules in common law that would be appropriate, with pre-and post-judgment interest thereon;

H. Alembic's costs and expenses for defending this action; and

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

OF COUNSEL:

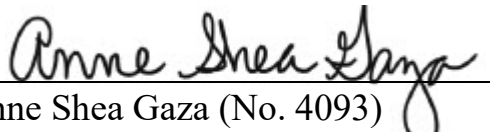
Aziz Burgy
AXINN, VELTROP &
HARKRIDER LLP
1901 L Street NW
Washington, DC 20036
(202) 912-4700
aburgy@axinn.com

Ricardo S. Camposanto
AXINN, VELTROP &
HARKRIDER LLP
55 Second Street
San Francisco, CA 94105
(415) 490-2000
rcamposanto@axinn.com

Ross E. Blau
AXINN, VELTROP &
HARKRIDER LLP
45 Rockefeller Plaza
New York, NY 10111
212.784.5431
rblau@axinn.com

Dated: October 20, 2025

YOUNG CONAWAY STARGATT
& TAYLOR, LLP

/s/ 
Anne Shea Gaza (No. 4093)
Daniel G. Mackrides (No. 7230)
Rodney Square
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
agaza@ycst.com
dmackrides@ycst.com

*Attorneys for Defendants Alembic
Pharmaceuticals Limited and Alembic
Pharmaceuticals, Inc.*

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on October 20, 2025, a copy of the foregoing document was served on the counsel listed below in the manner indicated:

BY EMAIL

Rodger D. Smith II Derek J. Fahnestock MORRIS, NICHOLS, ARSHT & TUNNELL LLP 1201 North Market Street Wilmington, DE 19899 rsmith@morrisnichols.com dfahnestock@morrisnichols.com	
---	--

Attorneys for Plaintiff Array Biopharma Inc.

YOUNG CONAWAY STARGATT
& TAYLOR, LLP

/s/ Anne Shea Gaza
Anne Shea Gaza (No. 4093)
Daniel G. Mackrides (No. 7230)
Rodney Square
1000 North King Street
Wilmington, Delaware 19801
(302) 571-6600
agaza@ycst.com
dmackrides@ycst.com

*Attorneys for Alembic Pharmaceuticals
Limited and Alembic Pharmaceuticals,
Inc.,*

Dated: October 20, 2025