

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

ARRAY BIOPHARMA INC., LOXO
ONCOLOGY, INC., BAYER
CONSUMER CARE AG, BAYER
HEALTHCARE LLC, and BAYER
HEALTHCARE
PHARMACEUTICALS INC.,

Plaintiffs,

v.

ALEMBIC PHARMACEUTICALS
LIMITED and ALEMBIC
PHARMACEUTICALS, INC.,

Defendants.

C.A. No. 25-1016
ANDA CASE

**ALEMBIC PHARMACEUTICALS LIMITED AND ALEMBIC
PHARMACEUTICALS, INC.’S ANSWER, DEFENSES, AND
COUNTERCLAIMS TO PLAINTIFFS’ COMPLAINT**

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 Plaintiffs Array Biopharma Inc. (“Array”), Loxo Oncology, Inc. (“Loxo”), Bayer Consumer Care AG (“BCC”), Bayer HealthCare LLC (“BHC”), Bayer HealthCare Pharmaceuticals Inc. (“BHCPI”) (Array, Loxo, BCC, BHC, and BHCPI are collectively referred to herein as “Plaintiffs”) Complaint as follows:

1. Alembic admits that the Complaint purports to allege a civil action for patent infringement under the patent laws of the United States, Title 35, United

States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202, in response to APL’s submission of an Abbreviated New Drug New Drug Application (“ANDA”) to the U.S. Food and Drug Administration (“FDA”) seeking approval to market larotrectinib sulfate capsules, 25 mg and 100 mg (“Alembic’s ANDA Products”), prior to the expiration of U.S. Patent No. 9,782,414 (“the ’414 patent”); U.S. Patent No. 10,172,861 (“the ’861 patent”); U.S. Patent No. 10,285,993 (“the ’993 patent”); U.S. Patent No. 10,799,505 (“the ’505 patent”); and U.S. Patent No. 10,813,936 (“the ’936 patent”) (collectively, the “Patents-in-Suit”). Alembic denies that the Complaint properly states a claim for patent infringement. Except as otherwise admitted, the allegations are denied.

2. Alembic admits that APL notified Plaintiffs that it had submitted ANDA No. 220639 (“Alembic’s ANDA”) 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.

PARTIES
PLAINTIFFS

3. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 3, and therefore denies them.

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.

DEFENDANTS

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 admits that Alembic is in the business of manufacturing generic drug products. To the extent any further response is required, Alembic admits that APL has filed ANDAs with FDA seeking approval to allow marketing of generic drugs in the United States. Alembic denies the remaining allegations in Paragraph 10.

11. 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 11 state legal conclusions to which no response is required. To the extent a response is required, 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 admits that APL develops and manufactures high-quality generic pharmaceutical products, and that API sells pharmaceutical drugs in the United States, including in the State of Delaware. To the extent any further response is required, Alembic denies the remaining allegations in Paragraph 12.

13. The allegations in Paragraph 13 state legal conclusions to which no response is required. To the extent a response is required, Alembic admits that APL develops and manufactures high-quality generic pharmaceutical products, and that API sells pharmaceutical drugs in the United States, including in the State of Delaware. Alembic denies the remaining allegations in Paragraph 13.

JURISDICTION

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 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 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 personal jurisdiction for the purposes of this action only.

16. The allegations in Paragraph 16 state legal conclusions to which no response is required. To the extent a response is required, Alembic admits that APL develops and manufactures high-quality generic pharmaceutical products, and that API sells pharmaceutical drugs in 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 16.

17. The allegations in Paragraph 17 state legal conclusions to which no response is required. To the extent a response is required, Alembic admits that API is a corporation registered to do business in the State of Delaware, and National Registered Agents, Inc. (located at 1209 Orange Street, Wilmington, DE) is the registered agent for service of process in Delaware for API. Alembic further 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, API 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 API manufactures generic drugs for sale throughout the United States, including in the State of Delaware. Alembic denies the remaining allegations in Paragraph 18.

19. Alembic states that APL is the named applicant on various ANDAs in the United States. Alembic further admits that APL develops and manufactures high-quality generic pharmaceutical products, and that API sells pharmaceutical drugs in the United States, including in the State of Delaware. The remaining allegations in Paragraph 19 state legal conclusions to which no response is required. To the extent a response is required, Alembic denies the remaining allegations in Paragraph 19.

20. The allegations in Paragraph 20 state legal conclusions to which no response is required. To the extent a response is required, Alembic admits that APL submitted ANDA No. 220639 for larotrectinib capsules 25 mg and 100 mg described in ANDA No. 220639. Alembic further admits that the purpose of this submission was to obtain approval to market Alembic's ANDA Products in the United States, including in Delaware. Alembic denies the remaining allegations in Paragraph 20.

21. The allegations in Paragraph 21 state legal conclusions to which no response is required. To the extent a response is required, Alembic denies that its ANDA Products are infringing. Alembic lacks sufficient information to form a belief as to the truth of the remaining allegations in Paragraph 21, and therefore denies them.

22. The allegations in Paragraph 22 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 remaining allegations in Paragraph 22, and therefore denies them.

23. The allegations in Paragraph 23 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 remaining allegations in Paragraph 23, and therefore denies them.

24. Alembic admits that APL has filed certifications under Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), and followed FDA's related regulations, which has resulted in patent litigation. Alembic denies the remaining allegations in Paragraph 24.

25. APL 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 ANDA. The remaining allegations in Paragraph 25

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 remaining allegations in Paragraph 25, and therefore denies them.

26. Alembic admits that Alembic was or is a named defendant in the following District of Delaware actions: *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); *AbbVie Inc. et al. v. Alembic Pharms. Ltd. et al.*, C.A. No. 20-1009-MSG, D.I. 10 (D. Del. Sept. 1, 2020); *H. Lundbeck A/S et al. v. Alembic Pharms. Limited et al.*, C.A. No. 18-113-LPS, D.I. 17 (D. Del. Apr. 13, 2018). The remaining allegations in Paragraph 26 state legal conclusions to which no response is required. To the extent any further response is required, Alembic does not dispute personal jurisdiction for the purposes of this action only.

VENUE

27. The allegations in Paragraph 27 state legal conclusions to which no response is required. To the extent a response is required, API does not dispute venue for the purposes of this action only.

28. The allegations in Paragraph 28 state legal conclusions to which no response is required. To the extent a response is required, APL does not dispute venue for the purposes of this action only.

FACTUAL BACKGROUND

29. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 29, and therefore denies them.

30. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 30, and therefore denies them.

31. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 31, and therefore denies them.

32. Admitted.

COUNT I – INFRINGEMENT OF THE '414 PATENT¹

33. Insofar as Plaintiffs repeat and reallege 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.

34. Alembic admits that the face of the '414 patent indicates that it is entitled "Crystalline form of (S)-N-((R)-2-(2,5-difluorophenyl)-pyrrolidin-1-yl)-pyrazolo[1,5-A]pyrimidin-3-yl)-3-hydroxypyrrolidine-1-carboxamide hydrogen sulfate" and that it was issued on October 10, 2017. Alembic admits that a purported copy of the '414 patent is attached to the Complaint as Exhibit A. Alembic denies that the '414 patent was duly and legally issued.

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

35. Alembic admits that the Orange Book lists the '414 patent in connection with NDA 210861.

36. Alembic states that the '414 patent speaks for itself. Alembic denies any remaining allegations in Paragraph 36.

37. Alembic states that the '414 patent speaks for itself. Alembic denies any remaining allegations in Paragraph 37.

38. Alembic admits that, APL notified Plaintiffs that it had submitted its ANDA to FDA. 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 '414 patent. Alembic denies any remaining allegations in Paragraph 38.

39. Alembic admits that in Alembic's Notice Letter, APL notified Plaintiffs that Alembic's ANDA contained a certification under Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '414 patent. Alembic further admits that APL submitted Alembic's ANDA to FDA containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '414 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Alembic's ANDA Products. Alembic denies any remaining allegations in Paragraph 39.

40. Alembic admits that in Alembic's Notice Letter, APL stated that Alembic's ANDA Products is a capsule containing larotrectinib. Alembic denies the remaining allegations in Paragraph 40.

41. The allegations in Paragraph 41 state legal conclusions to which no response is required. To the extent a response is required, the proposed labeling for Alembic's ANDA Products speaks for itself. Alembic denies any remaining allegations in Paragraph 41.

42. 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 any remaining allegations in Paragraph 42.

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, or will infringe the '414 patent. Alembic denies any remaining allegations in Paragraph 43.

44. Alembic admits that Alembic intends to market Alembic's ANDA Products upon approval of Alembic's ANDA. 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, or will infringe the '414 patent. Alembic states that the proposed labeling for Alembic's ANDA Products speaks for itself. Alembic denies any remaining allegations in Paragraph 45.

46. The allegations in Paragraph 46 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 or induce infringement of, the '414 patent. Alembic denies any remaining allegations in Paragraph 46.

47. The allegations in Paragraph 47 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 '414 patent, either directly, indirectly, or contributorily. Alembic states that the proposed labeling for Alembic's ANDA Products speaks for itself. Alembic denies any remaining allegations in Paragraph 47.

48. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 48, and therefore denies them.

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, or will infringe the '414 patent, either directly, indirectly, or contributorily. Alembic denies any remaining allegations in Paragraph 49.

50. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 50, and therefore denies them.

51. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 51, and therefore denies them.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '414 PATENT

52. Insofar as Plaintiffs repeat and reallege 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.

53. The allegations in Paragraph 53 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 53, and therefore denies them.

54. The allegations in Paragraph 54 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 54, and therefore denies them.

COUNT III – INFRINGEMENT OF THE '861 PATENT

55. Insofar as Plaintiffs repeat and reallege 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.

56. Alembic admits that the face of the '861 patent indicates that it is entitled "Crystalline form of (S)-N-((R)-2-(2,5-difluorophenyl)-pyrrolidin-1-yl)-pyrazolo[1,5-A]pyrimidin-3-yl)-3-hydroxypyrrolidine-1-carboxamide hydrogen sulfate" and that it was issued on January 8, 2019. Alembic admits that a purported copy of the '861 patent is attached to the Complaint as Exhibit B. Alembic denies that the '861 patent was duly and legally issued.

57. Alembic admits that the Orange Book lists the '861 patent in connection with NDA 210861.

58. Alembic states that the '861 patent speaks for itself. Alembic denies any remaining allegations in Paragraph 58.

59. Alembic admits that, APL notified Plaintiffs that it had submitted its ANDA to FDA. 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 '861 patent. Alembic denies any remaining allegations in Paragraph 59.

60. Alembic admits that in Alembic's Notice Letter, APL notified Plaintiffs that Alembic's ANDA contained a certification under Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '861 patent. Alembic further admits that APL submitted Alembic's ANDA to FDA containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '861 patent is invalid, unenforceable, and/or will not be infringed by the

manufacture, use, offer for sale, sale, and/or importation of Alembic's ANDA Products. Alembic denies any remaining allegations in Paragraph 60.

61. Alembic admits that in Alembic's Notice Letter, APL stated that Alembic's ANDA Products is a capsule containing larotrectinib. Alembic denies the remaining allegations in Paragraph 61.

62. The allegations in Paragraph 62 state legal conclusions to which no response is required. To the extent a response is required, the proposed labeling for Alembic's ANDA Products speaks for itself. Alembic denies any remaining allegations in Paragraph 62.

63. 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 any remaining allegations in Paragraph 63.

64. The allegations in Paragraph 64 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 '861 patent. Alembic denies any remaining allegations in Paragraph 64.

65. Alembic admits that Alembic intends to market Alembic's ANDA Products upon approval of Alembic's ANDA. Alembic denies any remaining allegations in Paragraph 65.

66. The allegations in Paragraph 66 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 '861 patent either literally or under the doctrine of equivalents. Alembic denies any remaining allegations in Paragraph 66.

67. The allegations in Paragraph 67 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 '861 patent. Alembic states that the proposed labeling for Alembic's ANDA Products speaks for itself. Alembic denies any remaining allegations in Paragraph 67.

68. The allegations in Paragraph 68 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 or induce infringement of, the '861 patent. Alembic denies any remaining allegations in Paragraph 68.

69. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 69, and therefore denies them.

70. The allegations in Paragraph 70 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 or induce infringement of, the '861 patent. Alembic denies any remaining allegations in Paragraph 70.

71. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 71, and therefore denies them.

72. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 72, and therefore denies them.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '861 PATENT

73. Insofar as Plaintiffs repeat and reallege 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.

74. The allegations in Paragraph 74 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 74, and therefore denies them.

75. The allegations in Paragraph 75 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 75, and therefore denies them.

COUNT V – INFRINGEMENT OF THE '993 PATENT

76. Insofar as Plaintiffs repeat and reallege 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.

77. Alembic admits that the face of the '993 patent indicates that it is entitled "Crystalline form of (S)-N-((R)-2-(2,5-difluorophenyl)-pyrrolidin-1-yl)-pyrazolo[1,5-a]pyrimidin-3-yl)-3-hydroxypyrrolidine-1-carboxamide hydrogen sulfate" and that it was issued on May 14, 2019. Alembic admits that a purported copy of the '993 patent is attached to the Complaint as Exhibit C. Alembic denies that the '993 patent was duly and legally issued.

78. Alembic admits that the Orange Book lists the '993 patent in connection with NDA 210861.

79. Alembic states that the '993 patent speaks for itself. Alembic denies any remaining allegations in Paragraph 79.

80. Alembic admits that, APL notified Plaintiffs that it had submitted its ANDA to FDA. 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 '993 patent. Alembic denies any remaining allegations in Paragraph 80.

81. Alembic admits that in Alembic's Notice Letter, APL notified Plaintiffs that Alembic's ANDA contained a certification under Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '993 patent. Alembic further admits that APL submitted Alembic's ANDA to FDA containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '993 patent is invalid, unenforceable, and/or will not be infringed by the

manufacture, use, offer for sale, sale, and/or importation of Alembic's ANDA Products. Alembic denies any remaining allegations in Paragraph 81.

82. Alembic admits that in Alembic's Notice Letter, APL stated that Alembic's ANDA Products is a capsule containing larotrectinib. Alembic denies the remaining allegations in Paragraph 82.

83. The allegations in Paragraph 83 state legal conclusions to which no response is required. To the extent a response is required, the proposed labeling for Alembic's ANDA Products speaks for itself. Alembic denies any remaining allegations in Paragraph 83.

84. 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 any remaining allegations in Paragraph 84.

85. The allegations in Paragraph 85 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 '993 patent. Alembic denies any remaining allegations in Paragraph 85.

86. Alembic admits that Alembic intends to market Alembic's ANDA Products upon approval of Alembic's ANDA. Alembic denies any remaining allegations in Paragraph 86.

87. The allegations in Paragraph 87 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 '993 patent. Alembic states that the proposed labeling for Alembic's ANDA Products speaks for itself. Alembic denies any remaining allegations in Paragraph 87.

88. The allegations in Paragraph 88 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 or induce infringement of, the '993 patent. Alembic denies any remaining allegations in Paragraph 88.

89. The allegations in Paragraph 89 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 '993 patent, either directly, indirectly, or contributorily. Alembic states that the proposed labeling for Alembic's ANDA Products speaks for itself. Alembic denies any remaining allegations in Paragraph 89.

90. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 90, and therefore denies them.

91. The allegations in Paragraph 91 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 or induce infringement of, the '993 patent. Alembic denies any remaining allegations in Paragraph 91.

92. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 92, and therefore denies them.

93. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 93, and therefore denies them.

**COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT OF
THE '993 PATENT**

94. Insofar as Plaintiffs repeat and reallege 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.

95. The allegations in Paragraph 95 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 95, and therefore denies them.

96. The allegations in Paragraph 96 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 96, and therefore denies them.

COUNT VII – INFRINGEMENT OF THE '505 PATENT

97. Insofar as Plaintiffs repeat and reallege 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.

98. Alembic admits that the face of the '505 patent indicates that it is entitled "Crystalline form of (S)-N-((R)-2-(2,5-difluorophenyl)-pyrrolidin-1-yl)-pyrazolo[1,5-A]pyrimidin-3-yl)-3-hydroxypyrrolidine-1-carboxamide hydrogen sulfate" and that it was issued on October 13, 2020. Alembic admits that a purported copy of the '505 patent is attached to the Complaint as Exhibit D. Alembic denies that the '505 patent was duly and legally issued.

99. Alembic admits that the Orange Book lists the '505 patent in connection with NDA 210861.

100. Alembic states that the '505 patent speaks for itself. Alembic denies any remaining allegations in Paragraph 100.

101. Alembic admits that, APL notified Plaintiffs that it had submitted its ANDA to FDA. 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 '505 patent. Alembic denies any remaining allegations in Paragraph 101.

102. Alembic admits that in Alembic's Notice Letter, APL notified Plaintiffs that Alembic's ANDA contained a certification under Section

505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '505 patent. Alembic further admits that APL submitted Alembic's ANDA to FDA containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '505 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Alembic's ANDA Products. Alembic denies any remaining allegations in Paragraph 102.

103. Alembic admits that in Alembic's Notice Letter, APL stated that Alembic's ANDA Products is a capsule containing larotrectinib. Alembic denies the remaining allegations in Paragraph 103.

104. The allegations in Paragraph 104 state legal conclusions to which no response is required. To the extent a response is required, the proposed labeling for Alembic's ANDA Products speaks for itself. Alembic denies any remaining allegations in Paragraph 104.

105. 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 any remaining allegations in Paragraph 105.

106. The allegations in Paragraph 106 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 '505 patent. Alembic denies any remaining allegations in Paragraph 106.

107. Alembic admits that Alembic intends to market Alembic's ANDA Products upon approval of Alembic's ANDA. Alembic denies any remaining allegations in Paragraph 107.

108. The allegations in Paragraph 108 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 '505 patent either literally or under the doctrine of equivalents. Alembic denies any remaining allegations in Paragraph 108.

109. The allegations in Paragraph 109 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 '505 patent. Alembic states that the proposed labeling for Alembic's ANDA Products speaks for itself. Alembic denies any remaining allegations in Paragraph 109.

110. The allegations in Paragraph 110 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 or induce infringement of, the '505 patent. Alembic denies any remaining allegations in Paragraph 110.

111. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 111, and therefore denies them.

112. The allegations in Paragraph 112 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 or induce infringement of, the '505 patent. Alembic denies any remaining allegations in Paragraph 112.

113. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 113, and therefore denies them.

114. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 114, and therefore denies them.

**COUNT VIII – DECLARATORY JUDGMENT OF INFRINGEMENT OF
THE '505 PATENT**

115. Insofar as Plaintiffs repeat and reallege 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.

116. The allegations in Paragraph 116 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 116, and therefore denies them.

117. The allegations in Paragraph 117 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 117, and therefore denies them.

COUNT IX – INFRINGEMENT OF THE '936 PATENT

118. Insofar as Plaintiffs repeat and reallege 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.

119. Alembic admits that the face of the '936 patent indicates that it is entitled "Crystalline form of (S)-N-((R)-2-(2,5-difluorophenyl)-pyrrolidin-1-yl)-pyrazolo[1,5-a]pyrimidin-3-yl)-3-hydroxypyrrolidine-1-carboxamide hydrogen sulfate" and that it was issued on October 27, 2020. Alembic admits that a purported copy of the '936 patent is attached to the Complaint as Exhibit E. Alembic denies that the '936 patent was duly and legally issued.

120. Alembic admits that the Orange Book lists the '936 patent in connection with NDA 210861.

121. Alembic states that the '936 patent speaks for itself. Alembic denies any remaining allegations in Paragraph 121.

122. Alembic admits that, APL notified Plaintiffs that it had submitted its ANDA to FDA. 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 '936 patent. Alembic denies any remaining allegations in Paragraph 122.

123. Alembic admits that in Alembic's Notice Letter, APL notified Plaintiffs that Alembic's ANDA contained a certification under Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '936 patent. Alembic further admits that APL submitted Alembic's ANDA to FDA containing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '936 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Alembic's ANDA Products. Alembic denies any remaining allegations in Paragraph 123.

124. Alembic admits that in Alembic's Notice Letter, APL stated that Alembic's ANDA Products is a capsule containing larotrectinib. Alembic denies the remaining allegations in Paragraph 124.

125. The allegations in Paragraph 125 state legal conclusions to which no response is required. To the extent a response is required, the proposed labeling for Alembic's ANDA Products speaks for itself. Alembic denies any remaining allegations in Paragraph 125.

126. 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 any remaining allegations in Paragraph 126.

127. The allegations in Paragraph 127 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 '936 patent. Alembic denies any remaining allegations in Paragraph 127.

128. Alembic admits that Alembic intends to market Alembic's ANDA Products upon approval of Alembic's ANDA. Alembic denies any remaining allegations in Paragraph 128.

129. The allegations in Paragraph 129 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 '936 patent. Alembic states that the proposed labeling for Alembic's ANDA Products speaks for itself. Alembic denies any remaining allegations in Paragraph 129.

130. The allegations in Paragraph 130 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 or induce infringement of, the '936 patent. Alembic denies any remaining allegations in Paragraph 130.

131. The allegations in Paragraph 131 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 '936 patent, either directly, indirectly, or contributorily. Alembic states that the proposed labeling for

Alembic's ANDA Products speaks for itself. Alembic denies any remaining allegations in Paragraph 131.

132. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 132, and therefore denies them.

133. The allegations in Paragraph 133 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 '936 patent, either directly, indirectly, or contributorily. Alembic denies any remaining allegations in Paragraph 133.

134. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 134, and therefore denies them.

135. Alembic lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 135, and therefore denies them.

**COUNT X – DECLARATORY JUDGMENT OF INFRINGEMENT OF
THE '936 PATENT**

136. Insofar as Plaintiffs repeat and reallege 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.

137. The allegations in Paragraph 137 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 137, and therefore denies them.

138. The allegations in Paragraph 138 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 138, and therefore denies them.

PRAYER FOR RELIEF

Alembic denies that Plaintiffs are entitled to any of the relief requested in the Complaint.

DEFENSES TO PLAINTIFFS' COMPLAINT

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 '414 Patent)**

139. 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 '414 patent under any section of 35 U.S.C. § 271.

SECOND SEPARATE DEFENSE
(Invalidity of the '414 Patent)

140. To the extent any of the claims of the '414 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 '414 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 '861 Patent)

141. 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 '861 patent under any section of 35 U.S.C. § 271.

FOURTH SEPARATE DEFENSE
(Invalidity of the '861 Patent)

142. To the extent any of the claims of the '861 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 '861 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
(Non-Infringement of the '993 Patent)

143. 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 '993 patent under any section of 35 U.S.C. § 271.

SIXTH SEPARATE DEFENSE
(Invalidity of the '993 Patent)

144. To the extent any of the claims of the '993 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 '993 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.

SEVENTH SEPARATE DEFENSE
(Non-Infringement of the '505 Patent)

145. 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 '505 patent under any section of 35 U.S.C. § 271.

EIGHTH SEPARATE DEFENSE
(Invalidity of the '505 Patent)

146. To the extent any of the claims of the '505 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 '505 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.

NINTH SEPARATE DEFENSE
(Non-Infringement of the '936 Patent)

147. 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 '936 patent under any section of 35 U.S.C. § 271.

TENTH SEPARATE DEFENSE
(Invalidity of the '936 Patent)

148. To the extent any of the claims of the '936 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 '936 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.

ELEVENTH SEPARATE DEFENSE
(No Relief Available)

149. Alembic repeats, realleges, and incorporates by reference as if fully set forth herein its responses in Paragraphs 1-148.

150. Plaintiffs have not suffered any damages.

151. Plaintiffs are not suffering an irreparable injury.

152. 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.

TWELFTH SEPARATE DEFENSE
(Failure to State a Claim)

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

RESERVATION OF DEFENSES

154. 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 reserves 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

155. 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 Defendants Array Biopharma Inc. (“Array”), Loxo Oncology, Inc. (“Loxo”), Bayer Consumer Care AG (“BCC”), Bayer HealthCare LLC (“BHC”), Bayer HealthCare Pharmaceuticals Inc. (“BHCPI”) (Array, Loxo, BCC, BHC, and BHCPI are collectively referred to herein as “Counterclaim Defendants”), 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 their allegations, Plaintiff Array is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3200 Walnut Street, Boulder, CO 80301.

4. On information and belief, based on their allegations, Plaintiff Loxo is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 281 Tresser Boulevard, Floor 9, Stamford, CT 06901.

5. On information and belief, based on their allegations, Plaintiff BCC is a Swiss corporation with its principal place of business at Peter Merian-Str. 84, Basel, Switzerland 4052.

6. On information and belief, based on their allegations, Plaintiff BHC is a limited liability company organized and existing under the laws of the State of Delaware, with a place of business at 100 Bayer Boulevard, Whippany, New Jersey.

7. On information and belief, based on their allegations, Plaintiff BHCPI is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 100 Bayer Boulevard, Whippany, New Jersey.

NATURE OF THE ACTION

8. 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.

9. 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. 9,782,414 (“the ’414 patent”); U.S. Patent No. 10,172,861 (“the ’861 patent”); U.S. Patent No. 10,285,993 (“the ’993 patent”); U.S. Patent No. 10,799,505 (“the ’505 patent”); and U.S. Patent No. 10,813,936 (“the ’936 patent”), literally or under the doctrine of equivalents. These patents are referred to collectively herein as the “Patents-in-Suit.”

10. As a consequence of Counterclaim Defendants’ 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 Defendants 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

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

12. Counterclaim Defendants have submitted to this Court’s personal jurisdiction by suing Alembic in this District. On information and belief, Counterclaim Defendants sell 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.

13. This Court is the proper venue under 28 U.S.C. §§ 1331(b) and 1400(b).

BACKGROUND

14. On information and belief, based on Counterclaim Defendants' allegations, Counterclaim Defendants are either the owner, assignee, exclusive licensee, exclusive sublicensee, or exclusive sub-sublicensee of the Patents-in-Suit.

15. The face of the '414 patent, titled "Crystalline form of (S)-N-(5-((R)-2-(2,5-difluorophenyl)-pyrrolidin-1-yl)-pyrazolo[1,5-A]pyrimidin-3-yl)-3-hydroxypyrrolidine-1-carboxamide hydrogen sulfate" indicates that it was issued on October 10, 2017.

16. The face of the '861 patent, titled "Crystalline form of (S)-N-(5-((R)-2-(2,5-difluorophenyl)-pyrrolidin-1-yl)-pyrazolo[1,5-A]pyrimidin-3-yl)-3-hydroxypyrrolidine-1-carboxamide hydrogen sulfate" indicates that it was issued on January 8, 2019.

17. The face of the '993 patent, titled "Crystalline form of (S)-N-(5-((R)-2-(2,5-difluorophenyl)-pyrrolidin-1-yl)-pyrazolo[1,5-a]pyrimidin-3-yl)-3-hydroxypyrrolidine-1-carboxamide hydrogen sulfate" indicates that it was issued on May 14, 2019.

18. The face of the '505 patent, titled "Crystalline form of (S)-N-(5-((R)-2-(2,5-difluorophenyl)-pyrrolidin-1-yl)-pyrazolo[1,5-A]pyrimidin-3-yl)-3-

hydroxypyrrolidine-1-carboxamide hydrogen sulfate” indicates that it was issued on October 13, 2020.

19. The face of the ’936 patent, titled “Crystalline form of (S)-N-((R)-2-(2,5-difluorophenyl)-pyrrolidin-1-yl)-pyrazolo[1,5-a]pyrimidin-3-yl)-3-hydroxypyrrolidine-1-carboxamide hydrogen sulfate” indicates that it was issued on October 27, 2020.

20. On information and belief, based on their allegations and based on the Orange Book, BHCPI is the holder of New Drug Application (“NDA”) No. 210861 for larotrectinib sulfate, 25 mg and 100 mg, capsules, sold in the United States as Vitrakvi.

21. 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.

22. The ’414 patent is listed in the Orange Book for Vitrakvi.

23. The ’861 patent is listed in the Orange Book for Vitrakvi.

24. The ’993 patent is listed in the Orange Book for Vitrakvi.

25. The ’505 patent is listed in the Orange Book for Vitrakvi.

26. The ’936 patent is listed in the Orange Book for Vitrakvi.

27. 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.

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

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

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

31. Unless enjoined, Counterclaim Defendants 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.

32. Alembic will be irreparably harmed if Counterclaim Defendants are not enjoined from asserting the Patents-in-Suit against Alembic.

FIRST CLAIM FOR RELIEF
(Declaratory Judgment of Non-Infringement of the '414 Patent)

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

34. Alembic's submission of ANDA No. 220639 seeking approval to market the products that are the subject of ANDA No. 220639 prior to the expiration of the '414 Patent does not directly or indirectly infringe any valid and/or enforceable claim of the '414 Patent either literally or under the doctrine of equivalents.

35. Alembic's manufacture, sale, use, offer for sale, and/or importation of the products that are the subject of ANDA No. 220639 will not infringe, either directly or indirectly, any valid and enforceable claim of the '414 Patent, either literally or under the doctrine of equivalents.

36. Because Alembic has not infringed the '414 Patent, and will not infringe any valid and enforceable claim of the '414 Patent, Counterclaim Defendants are not entitled to any damages or any other relief from or against Alembic.

37. 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 '414 Patent, either literally or under the doctrine of equivalents.

SECOND CLAIM FOR RELIEF
(Declaratory Judgment of Invalidity of the '414 Patent)

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

39. The claims of the '414 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.

40. Because one or more claims of the '414 Patent are invalid, Counterclaim Defendants are not entitled to any damages or other relief from or against Alembic.

41. Alembic is entitled to a declaratory judgment that the claims of the '414 Patent are invalid.

THIRD CLAIM FOR RELIEF
(Declaratory Judgment of Non-Infringement of the '861 Patent)

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

43. 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 '861 Patent does not directly or indirectly infringe any valid

and/or enforceable claim of the '861 Patent either literally or under the doctrine of equivalents.

44. 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 '861 Patent, either literally or under the doctrine of equivalents.

45. Because Alembic has not infringed the '861 Patent, and will not infringe any valid and enforceable claim of the '861 Patent, Counterclaim Defendants are not entitled to any damages or any other relief from or against Alembic.

46. 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 '861 Patent, either literally or under the doctrine of equivalents.

FOURTH CLAIM FOR RELIEF
(Declaratory Judgment of Invalidity of the '861 Patent)

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

48. The claims of the '861 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.

49. Because one or more claims of the '861 Patent are invalid, Counterclaim Defendants are not entitled to any damages or other relief from or against Alembic.

50. Alembic is entitled to a declaratory judgment that the claims of the '861 Patent are invalid.

FIFTH CLAIM FOR RELIEF
(Declaratory Judgment of Non-Infringement of the '993 Patent)

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

52. 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 '993 Patent does not directly or indirectly infringe any valid and/or enforceable claim of the '993 Patent either literally or under the doctrine of equivalents.

53. 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 '993 Patent, either literally or under the doctrine of equivalents.

54. Because Alembic has not infringed the '993 Patent, and will not infringe any valid and enforceable claim of the '993 Patent, Counterclaim Defendants are not entitled to any damages or any other relief from or against Alembic.

55. 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 '993 Patent, either literally or under the doctrine of equivalents.

SIXTH CLAIM FOR RELIEF
(Declaratory Judgment of Invalidity of the '993 Patent)

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

57. The claims of the '993 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.

58. Because one or more claims of the '993 Patent are invalid, Counterclaim Defendants are not entitled to any damages or other relief from or against Alembic.

59. Alembic is entitled to a declaratory judgment that the claims of the '993 Patent are invalid.

SEVENTH CLAIM FOR RELIEF
(Declaratory Judgment of Non-Infringement of the '505 Patent)

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

61. 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 '505 Patent does not directly or indirectly infringe any valid and/or enforceable claim of the '505 Patent either literally or under the doctrine of equivalents.

62. 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 '505 Patent, either literally or under the doctrine of equivalents.

63. Because Alembic has not infringed the '505 Patent, and will not infringe any valid and enforceable claim of the '505 Patent, Counterclaim

Defendants are not entitled to any damages or any other relief from or against Alembic.

64. 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 '505 Patent, either literally or under the doctrine of equivalents.

EIGHT CLAIM FOR RELIEF
(Declaratory Judgment of Invalidity of the '505 Patent)

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

66. The claims of the '505 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.

67. Because one or more claims of the '505 Patent are invalid, Counterclaim Defendants are not entitled to any damages or other relief from or against Alembic.

68. Alembic is entitled to a declaratory judgment that the claims of the '505 Patent are invalid.

NINTH CLAIM FOR RELIEF
(Declaratory Judgment of Non-Infringement of the '936 Patent)

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

70. 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 '936 Patent does not directly or indirectly infringe any valid and/or enforceable claim of the '936 Patent either literally or under the doctrine of equivalents.

71. 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 '936 Patent, either literally or under the doctrine of equivalents.

72. Because Alembic has not infringed the '936 Patent, and will not infringe any valid and enforceable claim of the '936 Patent, Counterclaim Defendants are not entitled to any damages or any other relief from or against Alembic.

73. 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 '936 Patent, either literally or under the doctrine of equivalents.

TENTH CLAIM FOR RELIEF
(Declaratory Judgment of Invalidity of the '936 Patent)

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

75. The claims of the '936 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.

76. Because one or more claims of the '936 Patent are invalid, Counterclaim Defendants are not entitled to any damages or other relief from or against Alembic.

77. Alembic is entitled to a declaratory judgment that the claims of the '936 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 Defendants any of the relief they have 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 Defendants are 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.

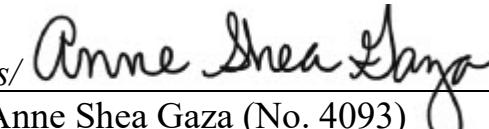
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Dated: October 20, 2025

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:

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