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,	)	C.A. No. _____
v.	)	
ALEMBIC PHARMACEUTICALS LIMITED and ALEMBIC PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT

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") file this Complaint for patent infringement against Alembic Pharmaceuticals Limited ("APL") and Alembic Pharmaceuticals, Inc. ("API") (APL and API are collectively referred to herein as "Defendants" or "Alembic") and by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an 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, that arises out of APL's submission of an Abbreviated New Drug New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import 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"). These patents are referred to collectively herein as the "Patents-in-Suit."

2. APL notified Plaintiffs by letter dated June 30, 2025 ("Alembic's Notice Letter") that it had submitted to FDA ANDA No. 220639 ("Alembic's ANDA"), seeking approval from FDA to engage in the commercial manufacture, use and/or sale of Alembic's ANDA Products prior to the expiration of the Patents-in-Suit. According to Alembic's Notice Letter, "[t]he established name of Alembic's proposed drug product is: Larotrectinib Capsules, 25 mg and 100 mg."

PARTIES

Plaintiffs

3. 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. Array is the owner and assignee of the Patents-in-Suit.

4. 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. Loxo is an exclusive licensee under the Patents-in-Suit.

5. Plaintiff BCC is a Swiss corporation with its principal place of business at Peter Merian-Str. 84, Basel, Switzerland 4052. BCC is an exclusive sublicensee under the Patents-in-Suit.

6. 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. BHC is an exclusive sub-sublicensee under the Patents-in-Suit.

7. 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. BHCPI is the holder of New Drug Application ("NDA") No. 210861 for VITRAKVI® (larotrectinib sulfate) capsules.

Defendants

8. Upon information and belief, defendant APL is a company organized and existing under the laws of the Republic of India, with a place of business at Alembic Road, Vadodara 390 003, Gujarat, India.

9. Upon information and belief, defendant 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.

10. Upon information and belief, APL is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market. As a part of this business, on information and belief, APL, acting in concert with API, files ANDAs with FDA seeking approval to engage in, and engages in, the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products prior to the expiration of United States patents that cover such products.

11. Upon information and belief, and consistent with their practice with respect to other generic products, APL and API acted in concert to prepare and submit ANDA No. 220639

for Alembic's ANDA Products, which was done at the direction of, under the control of, and for the direct benefit of APL.

12. Upon information and belief, APL and API are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Alembic's ANDA Products, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products thought the United States, including into Delaware, and including with respect to Alembic's ANDA Products at issue. Upon information and belief, API participated in, assisted, and cooperated with APL in the acts complained of herein.

13. Upon information and belief, following any FDA approval of Alembic's ANDA, APL and API will act in concert to distribute and sell Alembic's ANDA Products throughout the United States, including within Delaware.

JURISDICTION

14. Jurisdiction is proper in this Court pursuant to 28 U.S.C. §§ 1331, 1338(a). Declaratory judgment relief is authorized under 28 U.S.C. §§ 2201 and 2202.

15. This Court has personal jurisdiction over each of APL and API.

16. APL is subject to personal jurisdiction in Delaware because, among other things, APL, itself and through its subsidiary API, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, APL, itself and through its subsidiary API, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of

Delaware. In addition, APL is subject to personal jurisdiction in Delaware because, upon information and belief, it controls API and therefore the activities of API in this jurisdiction are attributed to APL.

17. API is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. API is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware (National Registered Agents, Inc., 1209 Orange Street, Wilmington, DE) to accept service of process. It therefore has consented to general jurisdiction in Delaware. In addition, upon information and belief, API develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

18. On information and belief, API is responsible for marketing, distributing, offering for sale, and/or selling generic copies of branded pharmaceutical products for the U.S. market, including in Delaware, and relies on contributions from APL to do so.

19. On information and belief, API, acting as the agent of APL, markets, distributes, offers for sale, and/or sells in Delaware and elsewhere in the United States generic pharmaceutical products that are manufactured by APL or for which APL is the named applicant on approved ANDAs.

20. In addition, this Court has personal jurisdiction over APL and API because, among other things, on information and belief, APL, acting in concert with API, has filed ANDA

No. 220639 for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the larotrectinib sulfate capsules 25 mg and 100 mg described in ANDA No. 220639 in the United States, including in Delaware.

21. In addition, on information and belief, Alembic's ANDA Products, which are charged with infringing the Patents-in-Suit, will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

22. In addition, APL is subject to personal jurisdiction in Delaware because, on information and belief, APL derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and that are manufactured by API and/or for which APL is the named applicant on approved ANDAs. On information and belief, various products for which APL is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

23. Alternatively, if APL's connections with Delaware, including its connections with API, are found to be insufficient to confer personal jurisdiction, then on information and belief, APL is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over APL in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

24. APL and API have previously used the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

25. Upon information and belief, APL, with knowledge of the Hatch-Waxman Act process, directed Alembic's Notice Letter to BHCPI, an entity incorporated in Delaware. Upon information and belief, APL knew when it did so that it was triggering the forty-five-day period for BHCPI to bring an action for patent infringement under the Hatch-Waxman Act. Because BHCPI is incorporated in Delaware, BHCPI suffers injury and consequences from APL's filing of Alembic's ANDA, in Delaware.

26. Further, this Court has personal jurisdiction over APL and API because they regularly engage in patent litigation concerning FDA approved branded drug products in this district, have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of their ANDAs, and/or they have filed counterclaims in such cases. *See, e.g.*, *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).

VENUE

27. Venue is proper in this district as to API pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, API is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

28. Venue is proper in this district as to APL pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, APL is a company organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

29. VITRAKVI® (active ingredient larotrectinib sulfate) is a tropomyosin receptor kinase (TRK) inhibitor that is used to treat adults and children with solid tumors (cancer) that:

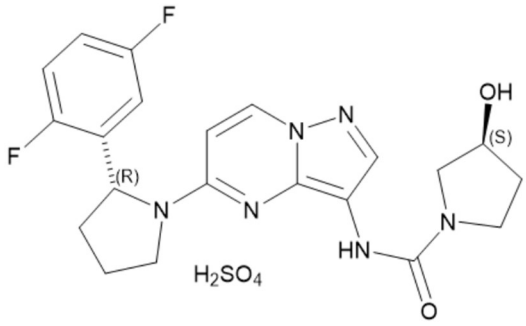
a. have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation

b. are metastatic or where surgical resection is likely to result in severe morbidity, and

c. have no satisfactory alternative treatments or that have progressed following treatment.

30. In adults and pediatric patients with a body surface area of 1 meter-squared or greater, the recommended dosage of VITRAKVI® is 100 mg orally twice daily. In pediatric patients with a body surface area of less than 1 meter-squared, the recommended dosage of VITRAKVI® is 100 mg/m^2 orally twice daily.

31. VITRAKVI® is available in a capsule formulation containing 25 mg or 100 mg larotrectinib. VITRAKVI® contains larotrectinib in the form of the sulfate salt, which has the following chemical structure:



32. Plaintiffs are filing this Complaint within forty-five days of receipt of Alembic's Notice Letter.

COUNT I – INFRINGEMENT OF THE '414 PATENT

33. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

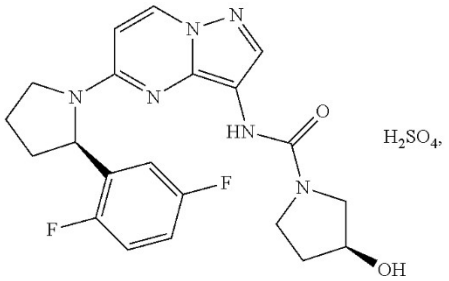
34. The '414 patent, entitled "Crystalline form of (S)-N-(5-((R)-2-(2,5-difluorophenyl)-pyrrolidin-1-yl)-pyrazolo[1,5-A]pyrimidin-3-yl)-3-hydroxypyrrolidine-1-carboxamide hydrogen sulfate" (attached as Exhibit A), was duly and legally issued on October 10, 2017.

35. The '414 patent has been listed in connection with NDA 210861 in the FDA's Orange Book.

36. Claim 1 of the '414 patent recites:

> A method of treating cancer in a pediatric patient in need thereof, the method comprising:
>
> a) detecting a cancer in a pediatric patient that exhibits a dysregulation of a NTRK gene, a Trk protein, or expression or level of the same; and
>
> b) administering to the pediatric patient a therapeutically effective amount of a dosage form comprising a crystalline form (I-HS) having the formula

I-HS

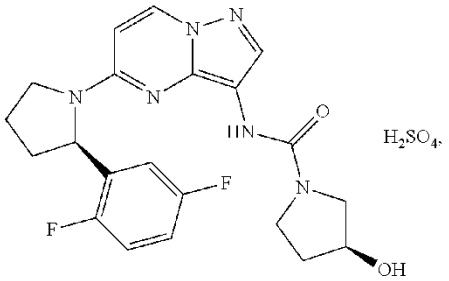


wherein the crystalline form has an X-ray powder diffraction pattern comprising peaks at °2θ values of 18.4±0.2, 20.7±0.2, 23.1±0.2, and 24.0±0.2.

37. Claim 21 of the ’414 patent recites:

A method of treating a cancer that exhibits a dysregulation of a NTRK gene, a Trk protein, or expression or level of the same in a pediatric patient in need thereof, the method comprising administering to the pediatric patient a therapeutically effective amount of a dosage form comprising a crystalline form (I-HS) having the formula

I-HS



wherein the crystalline form has an X-ray powder diffraction pattern comprising peaks at °2θ values of 18.4±0.2, 20.7±0.2, 23.1±0.2, and 24.0±0.2.

38. In Alembic’s Notice Letter, APL notified Plaintiffs of the submission of Alembic’s ANDA to FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Alembic’s ANDA Product prior to the expiration of the ’414 patent.

39. In Alembic’s Notice Letter, APL also notified Plaintiffs that, as part of Alembic’s ANDA, APL filed certifications of the type described in Section 505(j)(2)(B)(iv) of the

FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '414 patent. On information and belief, APL submitted Alembic's ANDA to FDA containing certifications pursuant to 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 Product.

40. According to Alembic's Notice Letter, Alembic's ANDA Product is a capsule containing larotrectinib sulfate. On information and belief, the use of Alembic's ANDA Product in accordance with its proposed labeling meets the other limitations of at least claims 1 and 21 of the '414 patent.

41. On information and belief, the use of Alembic's ANDA Product in accordance with its proposed labeling are covered by at least claims 1 and 21 of the '414 patent.

42. In Alembic's Notice Letter, Alembic did not contest the infringement of claims 1-10 and 21-25 of the '414 patent.

43. Alembic's submission of Alembic's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alembic's ANDA Product before the expiration of the '414 patent was an act of infringement of the '414 patent under 35 U.S.C. § 271(e)(2)(A).

44. On information and belief, Alembic will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product, including with its proposed labeling, immediately and imminently upon approval of Alembic's ANDA.

45. On information and belief, the manufacture, use, sale, offer for sale, or importation of Alembic's ANDA Product in accordance with, and as directed by, its proposed

labeling would infringe one or more claims of the '414 patent, including at least claims 1 and 21 of the '414 patent.

46. On information and belief, Alembic plans and intends to, and will, actively induce infringement of the '414 patent when Alembic's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Alembic's activities will be done with knowledge of the '414 patent and specific intent to infringe that patent.

47. On information and belief, Alembic knows that Alembic's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '414 patent, that Alembic's ANDA Product is not a staple article or commodity of commerce, and that Alembic's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Alembic plans and intends to, and will, contribute to infringement of the '414 patent immediately and imminently upon approval of Alembic's ANDA.

48. Notwithstanding Alembic's knowledge of the claims of the '414 patent, Alembic has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Alembic's ANDA Product with its proposed labeling following FDA approval of Alembic's ANDA prior to the expiration of the '414 patent.

49. The foregoing actions by Alembic constitute and/or will constitute infringement of the '414 patent; active inducement of infringement of the '414 patent; and contribution to the infringement by others of the '414 patent.

50. Plaintiffs will be substantially and irreparably damaged by infringement of the '414 patent.

51. Unless Alembic is enjoined from infringing the '414 patent, actively inducing infringement of the '414 patent, and contributing to the infringement by others of the '414 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

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

52. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

53. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Alembic on the other regarding Alembic's infringement, active inducement of infringement, and contribution to the infringement by others of the '414 patent.

54. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Alembic's ANDA Product with its proposed labeling will infringe, induce the infringement of, and contribute to the infringement by others of the '414 patent.

COUNT III – INFRINGEMENT OF THE '861 PATENT

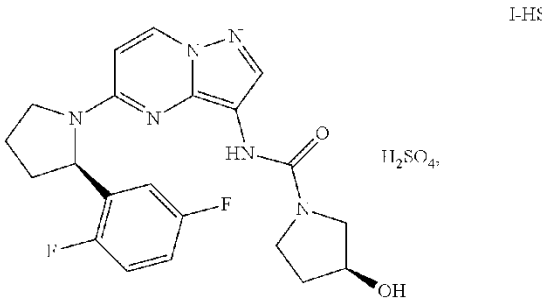
55. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

56. The '861 patent, entitled, "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" (attached as Exhibit B), was duly and legally issued on January 8, 2019.

57. The '861 patent has been listed in connection with NDA 210861 in FDA's Orange Book.

58. Claim 1 of the ’861 patent recites:

A crystalline form (I-HS) having the formula



wherein the crystalline form is characterized by having an X-ray powder diffraction (XRPD) pattern comprising peaks at °2θ values of 18.4±0.2, 20.7±0.2, 23.1±0.2, and 24.0±0.2.

59. In Alembic’s Notice Letter, APL notified Plaintiffs of the submission of Alembic’s ANDA to FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Alembic’s ANDA Product prior to the expiration of the ’861 patent.

60. In Alembic’s Notice Letter, APL also notified Plaintiffs that, as part of Alembic’s ANDA, APL filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the ’861 patent. On information and belief, APL submitted Alembic’s ANDA to FDA containing certifications pursuant to 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 Product.

61. According to Alembic’s Notice Letter, Alembic’s ANDA Product is a capsule containing larotrectinib sulfate. On information and belief, Alembic’s ANDA Product meets the other limitations of at least claim 1 of the ’861 patent.

62. On information and belief, Alembic's ANDA Product and the use of Alembic's ANDA Product in accordance with its proposed labeling are covered by at least claim 1 of the '861 patent.

63. In Alembic's Notice Letter, Alembic did not contest the infringement of claims 1-9 of the '861 patent.

64. Alembic's submission of Alembic's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alembic's ANDA Product before the expiration of the '861 patent was an act of infringement of the '861 patent under 35 U.S.C. § 271(e)(2)(A).

65. On information and belief, Alembic will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product immediately and imminently upon approval of Alembic's ANDA.

66. On information and belief, the manufacture, use, sale, offer for sale, or importation of Alembic's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '861 patent, including at least claim 1 of the '861 patent.

67. On information and belief, the manufacture, use, sale, offer for sale, or importation of Alembic's ANDA Product in accordance with, and as directed by, its proposed labeling would infringe one or more claims of the '861 patent, including at least claim 1 of the '861 patent.

68. On information and belief, Alembic plans and intends to, and will, actively induce infringement of the '861 patent when Alembic's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Alembic's activities will be done with knowledge of the '861 patent and specific intent to infringe that patent.

69. Notwithstanding Alembic's knowledge of the claims of the '861 patent, Alembic has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Alembic's ANDA Product with its proposed labeling following FDA approval of Alembic's ANDA prior to the expiration of the '861 patent.

70. The foregoing actions by Alembic constitute and/or will constitute infringement of the '861 patent and active inducement of infringement of the '861 patent.

71. Plaintiffs will be substantially and irreparably damaged by infringement of the '861 patent.

72. Unless Alembic is enjoined from infringing the '861 patent and actively inducing infringement of the '861 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

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

73. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

74. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Alembic on the other regarding Alembic's infringement and active inducement of infringement of the '861 patent.

75. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Alembic's ANDA Product, including with its proposed labeling, will infringe and induce the infringement of the '861 patent.

COUNT V – INFRINGEMENT OF THE '993 PATENT

76. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

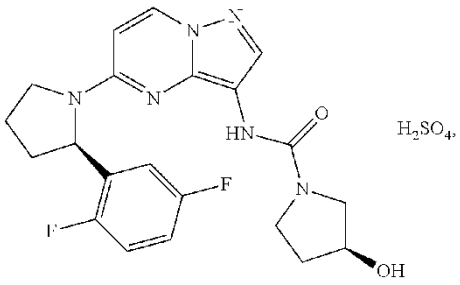
77. The '993 patent, entitled "Crystalline form of (S)-N-(5-((R)-2-(2,5-difluorophenyl)-pyrrolidin-1-yl)-pyrazolo[1,5-a]pyrimidin-3-yl)-3-hydroxypyrrolidine-1-carboxamide hydrogen sulfate" (attached as Exhibit C), was duly and legally issued on May 14, 2019.

78. The '993 patent has been listed in connection with NDA 210861 in the FDA's Orange Book.

79. Claim 1 of the '993 patent recites:

> A method of treating a cancer mediated by a Trk kinase in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of a crystalline form (I-HS) having the formula:

I-HS



> wherein the crystalline form is characterized by having XRPD diffraction peaks (2θ degrees) at 18.4±0.2, 20.7±0.2, 23.1±0.2, and 24.0±0.2.

80. In Alembic's Notice Letter, APL notified Plaintiffs of the submission of Alembic's ANDA to FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Alembic's ANDA Product prior to the expiration of the '993 patent.

81. In Alembic's Notice Letter, APL also notified Plaintiffs that, as part of Alembic's ANDA, APL filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '993 patent. On information and belief, APL submitted Alembic's ANDA to FDA containing certifications pursuant to 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 Product.

82. According to Alembic's Notice Letter, Alembic's ANDA Product is a capsule containing larotrectinib sulfate. On information and belief, the use of Alembic's ANDA Product in accordance with its proposed labeling meets the other limitations of at least claim 1 of the '993 patent.

83. On information and belief, the use of Alembic's ANDA Product in accordance with its proposed labeling are covered by at least claim 1 of the '993 patent.

84. In Alembic's Notice Letter, Alembic did not contest the infringement of any claim of the '993 patent.

85. Alembic's submission of Alembic's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alembic's ANDA Product before the expiration of the '993 patent was an act of infringement of the '993 patent under 35 U.S.C. § 271(e)(2)(A).

86. On information and belief, Alembic will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product, including with its proposed labeling, immediately and imminently upon approval of Alembic's ANDA.

87. On information and belief, the manufacture, use, sale, offer for sale, or importation of Alembic's ANDA Product in accordance with, and as directed by, its proposed labeling would infringe one or more claims of the '861 patent, including at least claim 1 of the '993 patent.

88. On information and belief, Alembic plans and intends to, and will, actively induce infringement of the '993 patent when Alembic's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Alembic's activities will be done with knowledge of the '993 patent and specific intent to infringe that patent.

89. On information and belief, Alembic knows that Alembic's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '993 patent, that Alembic's ANDA Product is not a staple article or commodity of commerce, and that Alembic's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Alembic plans and intends to, and will, contribute to infringement of the '993 patent immediately and imminently upon approval of Alembic's ANDA.

90. Notwithstanding Alembic's knowledge of the claims of the '993 patent, Alembic has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Alembic's ANDA Product with its proposed labeling following FDA approval of Alembic's ANDA prior to the expiration of the '861 patent.

91. The foregoing actions by Alembic constitute and/or will constitute infringement of the '993 patent; active inducement of infringement of the '993 patent; and contribution to the infringement by others of the '993 patent.

92. Plaintiffs will be substantially and irreparably damaged by infringement of the '993 patent.

93. Unless Alembic is enjoined from infringing the '993 patent, actively inducing infringement of the '993 patent, and contributing to the infringement by others of the '993 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

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

94. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

95. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Alembic on the other regarding Alembic's infringement, active inducement of infringement, and contribution to the infringement by others of the '993 patent.

96. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Alembic's ANDA Product with its proposed labeling will infringe, induce the infringement of, and contribute to the infringement by others of the '993 patent.

COUNT VII – INFRINGEMENT OF THE '505 PATENT

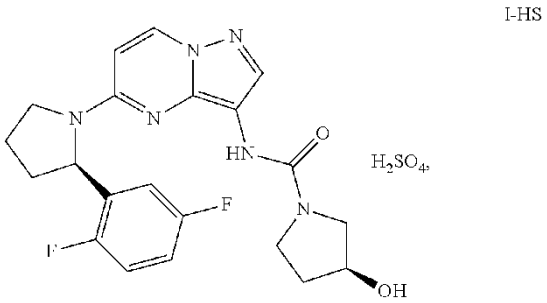
97. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

98. The '505 patent, entitled, "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" (attached as Exhibit D), was duly and legally issued on October 13, 2020.

99. The '505 patent has been listed in connection with NDA 210861 in FDA's Orange Book.

100. Claim 1 of the '505 patent recites:

A crystalline form (I-HS) having the formula:



wherein the crystalline form is substantially free of the amorphous form.

101. In Alembic's Notice Letter, APL notified Plaintiffs of the submission of Alembic's ANDA to FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Alembic's ANDA Product prior to the expiration of the '505 patent.

102. In Alembic's Notice Letter, APL also notified Plaintiffs that, as part of Alembic's ANDA, APL filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '505 patent. On information and belief, APL submitted Alembic's ANDA to FDA containing certifications pursuant to 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 Product.

103. According to Alembic's Notice Letter, Alembic's ANDA Product is a capsule containing larotrectinib sulfate. On information and belief, Alembic's ANDA Product meets the other limitations of at least claim 1 of the '505 patent.

104. On information and belief, Alembic's ANDA Product and the use of Alembic's ANDA Product in accordance with its proposed labeling are covered by at least claim 1 of the '505 patent.

105. In Alembic's Notice Letter, Alembic did not contest the infringement of claims 1-12 of the '505 patent.

106. Alembic's submission of Alembic's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alembic's ANDA Product before the expiration of the '505 patent was an act of infringement of the '505 patent under 35 U.S.C. § 271(e)(2)(A).

107. On information and belief, Alembic will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product immediately and imminently upon approval of Alembic's ANDA.

108. On information and belief, the manufacture, use, sale, offer for sale, or importation of Alembic's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '505 patent, including at least claim 1 of the '505 patent.

109. On information and belief, the manufacture, use, sale, offer for sale, or importation of Alembic's ANDA Product in accordance with, and as directed by, its proposed labeling would infringe one or more claims of the '505 patent, including at least claim 1 of the '505 patent.

110. On information and belief, Alembic plans and intends to, and will, actively induce infringement of the '505 patent when Alembic's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Alembic's activities will be done with knowledge of the '505 patent and specific intent to infringe that patent.

111. Notwithstanding Alembic's knowledge of the claims of the '505 patent, Alembic has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Alembic's ANDA Product with its proposed labeling following FDA approval of Alembic's ANDA prior to the expiration of the '505 patent.

112. The foregoing actions by Alembic constitute and/or will constitute infringement of the '505 patent and active inducement of infringement of the '505 patent.

113. Plaintiffs will be substantially and irreparably damaged by infringement of the '505 patent.

114. Unless Alembic is enjoined from infringing the '505 patent and actively inducing infringement of the '505 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

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

115. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

116. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Alembic on the other regarding Alembic's infringement and active inducement of infringement of the '505 patent.

117. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Alembic's ANDA Product, including with its proposed labeling, will infringe and induce the infringement of the '505 patent.

COUNT IX – INFRINGEMENT OF THE '936 PATENT

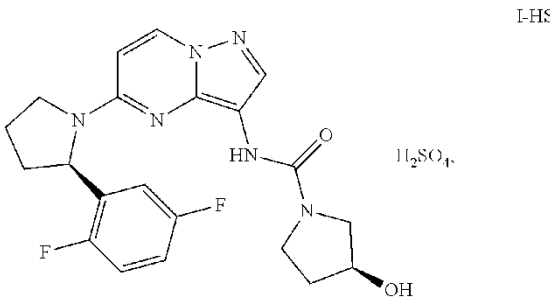
118. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

119. The '936 patent, entitled "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" (attached as Exhibit E), was duly and legally issued on October 27, 2020.

120. The '936 patent has been listed in connection with NDA 210861 in the FDA's Orange Book.

121. Claim 1 of the '936 patent recites:

> A method of treating a cancer in a patient in need thereof, wherein the cancer exhibits one or more chromosome translocations or inversions resulting in one or more NTRK1, NTRK2, or NTRK3 gene fusions, the method comprising administering to the patient a therapeutically effective amount of a crystalline form (I—HS) having the formula



> wherein the crystalline form is characterized by having an X-ray powder diffraction pattern comprising peaks at ° 20 values of 18.4±0.2, 20.7±0.2, 23.1±0.2, and 24.0±0.2,
>
> wherein the cancer is selected from the group consisting of: lung cancer, undifferentiated sarcoma, acute myeloid leukemia, and colorectal cancer.

122. In Alembic's Notice Letter, APL notified Plaintiffs of the submission of Alembic's ANDA to FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Alembic's ANDA Product prior to the expiration of the '936 patent.

123. In Alembic's Notice Letter, APL also notified Plaintiffs that, as part of Alembic's ANDA, APL filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355 (j)(2)(B)(iv), with respect to the '936 patent. On information and belief, APL submitted Alembic's ANDA to FDA containing certifications pursuant to 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 Product.

124. According to Alembic's Notice Letter, Alembic's ANDA Product is a capsule containing larotrectinib sulfate. On information and belief, the use of Alembic's ANDA Product in accordance with its proposed labeling meets the other limitations of at least claim 1 of the '936 patent.

125. On information and belief, the use of Alembic's ANDA Product in accordance with its proposed labeling are covered by at least claim 1 of the '936 patent.

126. In Alembic's Notice Letter, Alembic did not contest the infringement of any claim of the '936 patent.

127. Alembic's submission of Alembic's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alembic's ANDA Product before the expiration of the '936 patent was an act of infringement of the '936 patent under 35 U.S.C. § 271(e)(2)(A).

128. On information and belief, Alembic will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product, including with its proposed labeling, immediately and imminently upon approval of Alembic's ANDA.

129. On information and belief, the manufacture, use, sale, offer for sale, or importation of Alembic's ANDA Product in accordance with, and as directed by, its proposed labeling would infringe one or more claims of the '861 patent, including at least claim 1 of the '936 patent.

130. On information and belief, Alembic plans and intends to, and will, actively induce infringement of the '936 patent when Alembic's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Alembic's activities will be done with knowledge of the '936 patent and specific intent to infringe that patent.

131. On information and belief, Alembic knows that Alembic's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '936 patent, that Alembic's ANDA Product is not a staple article or commodity of commerce, and that Alembic's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Alembic plans and intends to, and will, contribute to infringement of the '936 patent immediately and imminently upon approval of Alembic's ANDA.

132. Notwithstanding Alembic's knowledge of the claims of the '936 patent, Alembic has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Alembic's ANDA Product with its proposed labeling following FDA approval of Alembic's ANDA prior to the expiration of the '861 patent.

133. The foregoing actions by Alembic constitute and/or will constitute infringement of the '936 patent; active inducement of infringement of the '936 patent; and contribution to the infringement by others of the '936 patent.

134. Plaintiffs will be substantially and irreparably damaged by infringement of the '936 patent.

135. Unless Alembic is enjoined from infringing the '936 patent, actively inducing infringement of the '936 patent, and contributing to the infringement by others of the '936 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

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

136. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

137. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Alembic on the other regarding Alembic's infringement, active inducement of infringement, and contribution to the infringement by others of the '936 patent.

138. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Alembic's ANDA Product with its proposed labeling will infringe, induce the infringement of, and contribute to the infringement by others of the '936 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

a) A judgment that each of the Patents-in-Suit has been infringed under 35 U.S.C. § 271(e)(2) by Alembic's submission to FDA of Alembic's ANDA;

b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Alembic's ANDA Product, or any other drug product that infringes or the use of which infringes one or more of the Patents-in-Suit, be not earlier than the latest of the expiration dates of the Patents-in-Suit for which liability for infringement is found, inclusive of any extension(s) and additional period(s) of exclusivity;

c) A preliminary and permanent injunction enjoining Alembic, and all persons acting in concert with Alembic, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Alembic's ANDA Product, or any other drug product covered by or whose use is covered by one or more of the Patents-in-Suit, prior to the latest of the expiration dates of the Patents-in-Suit for which liability for infringement is found, inclusive of any extension(s) and additional period(s) of exclusivity;

d) A judgment declaring that the commercial manufacture, use, sale, offer for sale, or importation of Alembic's ANDA Product, or any other drug product which is covered by or whose use is covered by one or more of the Patents-in-Suit, will infringe, induce the infringement of, and/or contribute to the infringement by others of, each of the corresponding Patents-in-Suit;

e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

f) Costs and expenses in this action; and

g) Such further and other relief as this Court may deem just and proper.

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