IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOW RIVER LLC, Plaintiff, v. ALEMBIC PHARMACEUTICALS LTD and ALEMBIC PHARMACEUTICALS, INC., Defendants.	)	C.A. No.

COMPLAINT FOR PATENT INFRINGEMENT

For its Complaint against Defendants Alembic Pharmaceuticals Limited ("Alembic Ltd.") and Alembic Pharmaceuticals, Inc. ("Alembic Inc.") (collectively, "Alembic"), Plaintiff Bow River LLC ("Bow River" or "Plaintiff"), by and through its attorneys, alleges as follows:

THE NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent Nos. 11,337,967 (the "'967 Patent"); and 11,974,998 (the "'998 Patent") (collectively, the "Asserted Patents"), arising under the patent laws of the United States, Title 35, United States Code.

2. By letter dated June 30, 2025 (the "Notice Letter"), Alembic notified Bow River that it had submitted Abbreviated New Drug Application ("ANDA") No. 220639 to the U.S. Food and Drug Administration ("FDA") under § 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act ("FDCA") (21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1)) seeking approval to engage in the commercial manufacture, use, and sale of a generic version of the VITRAKVI® capsule products (25 mg and 100 mg) (the "Alembic ANDA Products") before the expiration of the Asserted Patents.

3. Bow River seeks all available relief under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and other applicable laws for Alembic's infringement of the Asserted Patents.

THE PARTIES

4. Bow River LLC is a limited liability company organized and existing under the laws of the State of Wyoming with a principal place of business at 23 Corporate Plaza Drive, Suite 150, Newport Beach, CA 92660.

5. Bow River owns the '967 and '998 Patents.

6. Bow River supports independent research on pharmaceutical safety, including research into serious adverse events associated with pharmaceuticals. One type of such serious adverse events is drug-drug interactions ("DDIs"). DDIs are a significant source of danger for patients in the United States and can have deadly consequences.

7. Bow River supports high quality research to investigate and characterize DDIs and their serious consequences. The result of that research provides invaluable guidance to medical professionals on how to safely administer critical medications. The result is more benefit to patients with lower risk. Examples of such guidance are reflected in the claimed methods of the Asserted Patents.

8. On information and belief, Alembic Ltd. is a company organized and existing under the laws of India, having a principal place of business at Alembic Road, Vadodara 390 003, Gujarat, India.

9. On information and belief, Alembic Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 550 Hills Drive,

Suite 104B, Bedminster, NJ 07921. On information and belief, Alembic Inc. is a wholly-owned subsidiary of Alembic Ltd.

10. On information and belief, Alembic Inc. is a U.S. agent for Alembic Ltd.

11. On information and belief, Alembic Inc. and Alembic Ltd. collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products.

12. On information and belief, Alembic Inc. and Alembic Ltd. are agents of each other and/or operate in concert as integrated parts of the same business group.

13. On information and belief, Alembic Inc. and Alembic Ltd. acted in concert to prepare and submit ANDA No. 220639 for Alembic's ANDA Products.

JURISDICTION AND VENUE

14. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1, *et seq*. and from Alembic's submission of ANDA No. 220639.

15. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338(a) (patent infringement). Relief is sought under 35 U.S.C. § 271(e)(2).

16. On information and belief, this Court has personal jurisdiction over Alembic Inc. because, among other things, Alembic Inc. is a corporation incorporated and existing under Delaware law, such that Alembic Inc. is rendered essentially at home in this District. Alembic Inc. has also regularly engaged in patent litigation concerning FDA-approved products in this judicial district, has not contested personal jurisdiction in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *E.g., Galderma Labs, L.P. v. Alembic Pharma Ltd.*, C.A. No. 22-1312 (D.I. 18) (D. Del. December 7, 2022).

17. On information and belief, this Court has personal jurisdiction over Alembic Ltd. because of, among other things, Alembic Ltd.'s persistent and continuous contacts with Delaware. Alembic Ltd. has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Alembic Ltd. regularly and continuously transacts business in Delaware, including by, directly or indirectly, through one or more agents (including but not limited to Alembic Inc.), developing, manufacturing, marketing, and selling generic pharmaceutical products in Delaware. On information and belief, Alembic Ltd. derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware. Alembic Ltd. has regularly engaged in patent litigation concerning FDA-approved products in this judicial district, has not contested personal jurisdiction in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *E.g.*, *Galderma Labs, L.P. v. Alembic Pharma Ltd.*, C.A. No. 22-1312 (D.I. 18) (D. Del. December 7, 2022).

18. In the alternative, this Court has personal jurisdiction over Alembic Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Bow River's claims arise under federal law; (b) Alembic Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Alembic Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to FDA and/or manufacturing, importing, offering to sell, or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Alembic Ltd. satisfies due process.

19. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

THE VITRAKVI® PRODUCTS

20. VITRAKVI® is a first-in-class cancer drug available in both capsule and oral solution form. The VITRAKVI® capsule products are available in both 25 mg and 100 mg dosage strengths (collectively, the "VITRAKVI® Capsules").

21. VITRAKVI® is approved by FDA for the treatment of adult and pediatric patients with solid tumors that: have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation; are metastatic or where surgical resection is likely to result in severe morbidity; and have no satisfactory alternative treatments or that have progressed following treatment.

22. The active ingredient in the VITRAKVI® Capsules is larotrectinib. The active ingredient in any generic version of the VITRAKVI® Capsules will be the same. 21 U.S.C. § 355(j)(2)(A)(ii)(I).

23. Patients prescribed VITRAKVI® are often prescribed other drugs as well. For instance, patients prescribed VITRAKVI® are often immunocompromised and are often prescribed an antifungal agent, such as posaconazole.

24. When larotrectinib is administered with certain other drugs, the result can be dangerous for the patient. Specifically, when larotrectinib is administered to a patient that is already receiving a strong CYP3A inhibitor, such as posaconazole, the larotrectinib will not be metabolized at the same rate as it is in the absence of the CYP3A inhibitor, which can lead to life-threatening consequences.

25. Through years of clinical and analytical research into the interactions between posaconazole and CYP3A4 substrate drugs like larotrectinib, the inventors of the Asserted Patents solved this problem. Specifically, the inventors of the Asserted Patents pioneered a

method of administering larotrectinib such that the interaction with posaconazole could be avoided. As a result of this novel method, the patient receives the proper dosage of larotrectinib.

26. Consistent with FDA's requirement that drug labeling must contain a summary of the essential scientific information needed for the safe and effective use of the drug, the claimed method has been deemed so essential to the proper administration of CYP3A4 substrate drugs that it must be included on the label for larotrectinib products, including the label for the VITRAKVI® Capsules.

ASSERTED PATENTS

27. The '967 Patent, entitled "Methods of Treatment," was duly and legally issued on May 24, 2022, from U.S. Patent Application No. 17/332,600. A true and correct copy of the '967 Patent is attached to this Complaint as Exhibit A.

28. The face of the '967 Patent names Sundar Srinivasan and Christina Chow as inventors and Bow River LLC as the assignee.

29. Pursuant to 21 U.S.C. § 355, the '967 Patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with the VITRAKVI® Capsules. Certain uses of the VITRAKVI® Capsules are covered by at least one claim of the '967 Patent. The prescribing information for the VITRAKVI® Capsules instructs performance of methods that are covered by at least one claim of the '967 Patent.

30. The '998 Patent, entitled "Methods of Treatment," was duly and legally issued on May 7, 2024, from U.S. Patent Application No. 18/366,060. A true and correct copy of the '998 Patent is attached to this Complaint as Exhibit B.

31. The face of the '998 Patent names Sundar Srinivasan and Christina Chow Wallen as inventors and Bow River LLC as the assignee.

32. Pursuant to 21 U.S.C. § 355, the ’998 Patent is listed in the Orange Book in connection with the VITRAKVI® product. Certain uses of the VITRAKVI® product is covered by at least one claim of the ’998 Patent. The prescribing information for the VITRAKVI® Capsules instructs performance of methods that are covered by at least one claim of the ’998 Patent.

INFRINGEMENT BY ALEMBIC

33. By the Notice Letter, Alembic Ltd. notified Bow River that it had submitted ANDA No. 220639 to FDA under Section 505(j)(2)(B) of the FDCA (21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1)) seeking approval to engage in the commercial manufacture, use, and sale of the Alembic ANDA Products before the expiration of the Asserted Patents.

34. On information and belief, Alembic intends to engage in commercial manufacture, use, and sale of the Alembic ANDA Products promptly upon receiving FDA approval to do so.

35. By filing ANDA No. 220639, Alembic has necessarily represented to FDA that the Alembic ANDA Products have the same active ingredients as the VITRAKVI® Capsules, have the same route of administration, dosage form, use, and strength as VITRAKVI® Capsules, and are bioequivalent to the VITRAKVI® Capsules.

36. The Notice Letter did not contend the proposed prescribing information for the Alembic ANDA Products differs in any way from the prescribing information for VITRAKVI® Capsules. For example, the Notice Letter did not include a statement pursuant to 21 U.S.C. § 355(j)(2)(A)(viii).

37. On information and belief, the proposed prescribing information for the Alembic ANDA Products is substantially identical to the prescribing information for VITRAKVI® Capsules with the exception of the names of the respective drug products. 21 U.S.C. § 355(j)(2)(A)(v).

38. In the Notice Letter, Alembic offered confidential access to portions of ANDA No. 220639 on the terms and conditions set forth in the Notice Letter (the "Offer"). Alembic requested that Bow River accept the Offer before receiving access to any portion of ANDA No. 220639.

39. The Offer contained unreasonable restrictions that differ materially from standard terms of protective orders entered in this jurisdiction. *Avion Pharms., LLC v. Granules Pharms., Inc.*, C.A. No. 20-898-LPS, 2021 WL 1785580, at *3 (D. Del. May 5, 2021) (finding proposed prosecution bar was "overbroad" and ordering it be limited, among other aspects, to specific subject matter) (quoting 21 U.S.C. § 355(j)(5)(C)(i)(III)). For example, the Offer limited access to portions of ANDA No. 220639 to outside counsel only and required any person that accessed the unspecified ANDA information to "not engage in any patent prosecution for Bow River" for all time and with respect to any subject matter. *In re Deutsche Bank Tr. Co. Ams.*, 605 F.3d 1373, 1381 (Fed. Cir. 2010) ("We therefore hold that a party seeking imposition of a patent prosecution bar must show that the information designated to trigger the bar, ***the scope of activities prohibited by the bar***, ***the duration of the bar***, and the subject matter covered by the bar reasonably reflect the risk presented by the disclosure of proprietary competitive information.") (emphasis added).

40. Bow River commenced this action within 45 days of the date of receipt of the Notice Letter.

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

41. Bow River incorporates each of the preceding paragraphs as if fully set forth herein.

42. Alembic submitted ANDA No. 220639 to FDA under section 505(j) of the FDCA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Alembic ANDA Products throughout the United States prior to the expiration of the ’967 Patent. By submitting this ANDA, Alembic has committed an act of infringement of the ’967 Patent under 35 U.S.C. § 271(e)(2)(A) either literally or under the doctrine of equivalents.

43. On information and belief, the Alembic ANDA Products, if approved by FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Alembic or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in Alembic’s proposed prescribing information, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the ’967 Patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the Alembic ANDA Products will occur with Alembic’s specific intent to encourage infringement. On information and belief, Alembic will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Bow River’s rights under the ’967 Patent.

44. On information and belief, if ANDA No. 220639 is approved by FDA, the commercial manufacture, use (in accordance with and as directed by Alembic’s proposed labeling for the Alembic ANDA Products), offer to sell, or sale within the United States, and/or

importation into the United States of the Alembic ANDA Products will constitute acts of infringement, either literally or under the doctrine of equivalents, of the ’967 Patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

45. On information and belief, Alembic had actual and constructive knowledge of the ’967 Patent prior to filing ANDA No. 220639 and was aware that filing this ANDA with FDA constituted an act of infringement of the ’967 Patent. In addition, on information and belief, Alembic had specific intent to infringe the ’967 Patent when it filed ANDA No. 220639. Moreover, there are no substantial non-infringing uses for the Alembic ANDA Products other than in the methods claimed in the ’967 Patent.

46. The commercial manufacture, use, offer for sale, sale, and/or importation of the Alembic ANDA Products in violation of Bow River’s patent rights will cause irreparable harm to Bow River for which damages are inadequate.

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

47. Bow River incorporates each of the preceding paragraphs as if fully set forth herein.

48. Alembic submitted ANDA No. 220639 to FDA under section 505(j) of the FDCA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Alembic ANDA Products throughout the United States prior to the expiration of the ’998 Patent. By submitting this ANDA, Alembic has committed an act of infringement of the ’998 Patent under 35 U.S.C. § 271(e)(2)(A) either literally or under the doctrine of equivalents.

49. On information and belief, the Alembic ANDA Products, if approved by FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by

Alembic or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in Alembic's proposed prescribing information, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '998 Patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the Alembic ANDA Products will occur with Alembic's specific intent to encourage infringement to occur. On information and belief, Alembic will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Bow River's rights under the '998 patent.

50. On information and belief, if ANDA No. 220639 is approved by FDA, the commercial manufacture, use (in accordance with and as directed by Alembic's proposed labeling for the Alembic ANDA Products), offer to sell, or sale within the United States, and/or importation into the United States of the Alembic ANDA Products will constitute acts of infringement, either literally or under the doctrine of equivalents, of the '998 Patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

51. On information and belief, Alembic had actual and constructive knowledge of the '998 Patent prior to filing ANDA No. 220639 and was aware that filing this ANDA with FDA constituted an act of infringement of the '998 Patent. In addition, on information and belief, Alembic had specific intent to infringe the '998 Patent when it filed ANDA No. 220639. Moreover, there are no substantial non-infringing uses for the Alembic ANDA Products other than in the methods claimed in the '998 Patent.

52. The commercial manufacture, use, offer for sale, sale, and/or importation of the Alembic ANDA Products in violation of Bow River's patent rights will cause irreparable harm to Bow River for which damages are inadequate.

PRAYER FOR RELIEF

Bow River respectfully requests the following relief:

a) A judgment that Alembic has infringed at least one claim of the '967 and '998 Patents either literally or under the doctrine of equivalents;

b) A judgment ordering that the effective date of any FDA approval of ANDA No. 220639 shall be a date which is not earlier than the latest expiration date of any of the '967 and '998 Patents, as extended by any applicable periods of exclusivity;

c) A preliminary and permanent injunction enjoining Alembic, its subsidiaries, parents, officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or importation into the United States, of any drug product covered by, or any drug product for which the use of the drug product is covered by the '967 or '998 Patents, including the Alembic ANDA Products;

d) A judgment that the '967 and '998 Patents are valid and enforceable;

e) A finding that this is an exceptional case under 35 U.S.C. § 285, and that Bow River be awarded reasonable attorneys' fees and costs; and

f) An award of any such other and further relief as the Court may deem just and proper.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

By: */s/ David E. Moore*

David E. Moore (#3983)
Bindu A. Palapura (#5370)
Andrew M. Moshos (#6685)
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
Tel: (302) 984-6000
dmoore@potteranderson.com
bpalapura@potteranderson.com
amoshos@potteranderson.com

Attorneys for Plaintiff Bow River LLC

OF COUNSEL:

Wendy L. Devine
WILSON SONSINI GOODRICH & ROSATI
One Market Plaza
Spear Tower, Suite 3300
San Francisco, CA 94105
Tel: (415) 947-2000

Nicholas Halkowski
WILSON SONSINI GOODRICH & ROSATI
1700 K Street, NW
Washington, DC 20006
Tel: (202) 920-8711

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