IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and GENENTECH, INC.,	)	
	)	
	)	
	)	
Plaintiffs,	)	C.A. No. 20-968-MSG
	)	
	)	CONSOLIDATED
v.	)	
	)	
ALEMBIC PHARMACEUTICALS LTD.,	)	
ALEMBIC PHARMACEUTICALS, INC.,	)	
and ALEMBIC GLOBAL HOLDING SA,	)	
	)	
Defendants.	)	

FOURTH AMENDED COMPLAINT AGAINST ALEMBIC
FOR PATENT INFRINGEMENT

Plaintiffs AbbVie Inc. ("AbbVie") and Genentech, Inc. ("Genentech") (collectively, "Plaintiffs"), by their undersigned attorneys, bring this action against Defendants Alembic Pharmaceuticals Ltd. ("APL"), Alembic Pharmaceuticals, Inc. ("API"), and Alembic Global Holding SA ("AGH") (collectively, "Defendants" or "Alembic"), and hereby allege as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. §§ 1 *et seq*., arises from Alembic's submission to the United States Food and Drug Administration ("FDA") of an Abbreviated New Drug Application ("ANDA") No. 214747 ("Alembic's ANDA") seeking approval to market a generic version of Plaintiffs' highly successful pharmaceutical product VENCLEXTA®, prior to the expiration of U.S. Patent Nos. 10,993,942 ("the '942 Patent"), 11,110,087 ("the '087 Patent"), 11,369,599 ("the '599 patent"), and 11,590,128 ("the '128 Patent) (also referred to as "the Patents-in-suit"). The patents listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication

commonly known as the "Orange Book") for VENCLEXTA® are U.S. Patent Nos. 8,546,399 ("the '399 Patent"), 9,174,982 ("the '982 Patent"), 9,539,251 ("the '251 Patent"), 8,722,657 ("the '657 Patent"), 10,730,873 ("the '873 Patent"), the '942 Patent, the '087 Patent, the '599 Patent, 11,413,282 ("the '282 Patent"), and the '128 Patent.

VENCLEXTA®

2. VENCLEXTA® (venetoclax) is a ground-breaking drug which has gained widespread acceptance in the medical community. It has been used to treat over 31,000 patients in the United States and around the world who suffer from chronic lymphocytic leukemia ("CLL"), small lymphocytic lymphoma ("SLL"), and, as part of a combination therapy, acute myeloid leukemia ("AML").

3. VENCLEXTA® selectively targets and inhibits the B-cell CLL/lymphoma 2 ("BCL-2") protein and is the first FDA-approved BCL-2 inhibitor. BCL-2 prevents apoptosis, or programmed cell death, which is the process for removal of aged or damaged cells.

4. VENCLEXTA® was first approved by the FDA on April 11, 2016 pursuant to New Drug Application ("NDA") No. 208573. It is available as an oral tablet containing 10 mg, 50 mg, or 100 mg of venetoclax as the active pharmaceutical ingredient.

5. VENCLEXTA® is currently approved for use and indicated as follows: (1) for the treatment of adult patients with CLL or SLL; (2) in combination with azacitidine, or decitabine, or low-dose cytarabine for the treatment of newly-diagnosed AML in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

6. AbbVie and Genentech co-market and sell VENCLEXTA® in the United States and other parts of the world. They have invested hundreds of millions of dollars to discover

venetoclax and develop VENCLEXTA®, including investing significant resources investigating whether VENCLEXTA® alone and in combination with other drugs can treat other types of cancer.

7. The FDA has recognized the innovative nature of VENCLEXTA® in granting it six breakthrough therapy designations: (1) treatment of patients with relapsed or refractory CLL who harbor the 17p deletion mutation; (2) treatment of patients with relapsed or refractory CLL in combination with the anti-CD20 antibody rituximab (Rituxan®); (3) venetoclax in combination with hypomethylating agents for the treatment of patients with untreated (treatment-naïve) AML who are ineligible to receive standard induction therapy (high-dose chemotherapy); (4) combination of venetoclax and low-dose cytarabine for treatment-naïve patients with AML, who are ineligible for intensive chemotherapy; (5) venetoclax in combination with obinutuzumab for the treatment of adult patients with CLL; and (6) combination of venetoclax plus azacitidine as a potential systemic therapy for patients with treatment-naïve myelodysplastic syndrome whose disease is considered to be intermediate-, high-, or very high–risk. A breakthrough designation is reserved for a drug intended to treat a serious condition where preliminary clinical results indicate that the drug may demonstrate substantial improvement over available therapies.

8. VENCLEXTA® has one of the most robust clinical oncology development programs for a single molecule in the industry, with approximately 295 ongoing clinical trials (including 30 Phase 3 trials).

9. In addition to being well-received by the FDA and the medical community, VENCLEXTA® received the biomedical industry's highest accolade in 2017 when it was awarded the Prix Galien Award for Best Pharmaceutical Product.

THE PARTIES

10. Plaintiff AbbVie is a corporation organized and existing under the laws of the state of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is a global research and development-based biopharmaceutical company committed to developing innovative therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people, and unique approach to innovation to markedly improve treatments across therapeutic areas, including in oncology. AbbVie holds NDA No. 208573 for VENCLEXTA® and is an assignee of the Patents-in-suit.

11. Plaintiff Genentech is a corporation organized under the laws of the State of Delaware, with its principal place of business at 1 DNA Way, South San Francisco, California 94080. Genentech is a biotechnology company dedicated to pursuing ground-breaking science to discover and develop medicines for people with serious and life-threatening diseases. Genentech is an assignee of the '942, '087, and '128 Patents and an exclusive licensee of the '657, '873, and '599 Patents.

12. On information and belief, Defendant APL is a corporation organized and existing under the laws of India, with a principal place of business at Alembic Road, Vadodara 390 003, Gujarat, India.

13. On 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 750 Highway 202, Bridgewater, New Jersey 08807.

14. On information and belief, Defendant AGH is a corporation organized and existing under the laws of Switzerland, with a principal place of business at Rue Fritz-Courvoisier 40, 2300 La Chaux-de-Fonds, Switzerland.

15. On information and belief, Defendants are agents of one another and/or operate in concert as integrated parts of the same business group.

16. On information and belief, API is a wholly owned subsidiary of AGH and APL. On information and belief, API acts as AGH's and/or APL's authorized agent in the United States.

17. On information and belief, AGH is a wholly owned subsidiary of APL.

18. On information and belief, APL, itself and through its wholly owned subsidiaries API and/or AGH, develops, manufactures, markets, sells, and/or imports generic versions of branded pharmaceutical products throughout the United States, including in this Judicial District.

19. On information and belief, API, itself and through APL and/or AGH, is in the business of developing, manufacturing, and/or distributing generic drugs for marketing, sale, and/or use throughout the United States, including in this Judicial District.

20. On information and belief, AGH, itself and through APL and/or API, is in the business of developing, manufacturing, and/or distributing generic drugs for marketing, sale, and/or use throughout the United States, including in this Judicial District.

21. On information and belief, APL is the holder of Drug Master File 34140 for venetoclax.

22. On information and belief, and as described in APL's written notification of Alembic's ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certifications received June 16, 2020 ("Alembic's June Notice Letter"), September 4, 2020 ("Alembic's First September Notice Letter"), November 17, 2021 ("Alembic's November Notice Letter"), September 27, 2022 ("Alembic's Second September Notice Letter"), and April 18, 2023 ("Alembic's April Notice

Letter") (collectively, "Alembic's Notice Letters"), Defendants caused Alembic's ANDA to be submitted to the FDA and seek FDA approval of Alembic's ANDA prior to the expiration of the Patents-in-suit.

23. On information and belief, Alembic intends to commercially manufacture, market, offer for sale, and sell the proposed generic venetoclax tablets described in Alembic's ANDA ("Alembic's Generic Version") throughout the United States, including in the State of Delaware, in the event the FDA approves Alembic's ANDA.

JURISDICTION & VENUE

24. This civil action for patent infringement arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code.

25. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

26. In Alembic's Answer to the original Complaint in this action, Alembic stated that "Alembic does not contest personal jurisdiction over it in this Court for purposes of this action only." (D.I. 10, at ¶¶ 26-33).

27. This Court has personal jurisdiction over Alembic by virtue of, *inter alia*, on information and belief, Alembic having availed itself of the rights and benefits of the laws of the State of Delaware by engaging in substantial, continuous, and systematic contacts with the State of Delaware and because Alembic intends to indirectly or directly market, sell, and/or distribute generic drugs, including Alembic's Generic Version, to residents of the State of Delaware. Accordingly, Alembic should reasonably anticipate being hauled into court in this Judicial District.

28. On information and belief, API, APL, and/or AGH acting in concert and/or as agents of one another filed Alembic's ANDA.

29. On information and belief, API, APL, and/or AGH acting in concert and/or as agents of one another will market, distribute, and/or sell Alembic's Generic Version in the United States, including in the State of Delaware, upon approval of Alembic's ANDA, and will derive substantial revenue from the sale of Alembic's Generic Version.

30. On information and belief, Alembic's Generic Version will be used within and throughout the United States, including in the State of Delaware.

31. On information and belief, Alembic's Generic Version will be prescribed by physicians practicing in the State of Delaware, dispensed by pharmacies located within the State of Delaware, and used by patients in the State of Delaware.

32. This Court also has personal jurisdiction over Alembic by virtue of, *inter alia*, the fact that it has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led to and/or will lead to foreseeable harm and injury to Plaintiffs, with both Plaintiffs being organized under the laws of the State of Delaware.

33. This Court has jurisdiction over API because, on information and belief, *inter alia*, API is incorporated in the State of Delaware.

34. Moreover, this Court has jurisdiction over APL and/or AGH pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) APL and AGH are foreign defendants not subject to personal jurisdiction in the courts of any state; and (c) APL and AGH have sufficient contacts with the United States as a whole, including, but not limited to, submitting various ANDAs to the FDA, and manufacturing and selling pharmaceutical products

distributed throughout the United States, such that this Court's exercise of jurisdiction over APL and AGH satisfies due process.

35. In Alembic's Answer to the original Complaint in this action, Alembic stated that "Alembic does not contest venue over it in this Court for purposes of this action only." (D.I. 10, at ¶¶ 34-37).

36. Venue is proper in this Judicial District for APL pursuant to 28 U.S.C. §§ 1391 and/or 1400 because, on information and belief, *inter alia*, APL is a company organized and existing under the laws of India, and may be sued in any judicial district pursuant to 28 U.S.C. § 1391(c) and Alembic's Generic Version will be prescribed by physicians practicing in the State of Delaware, dispensed by pharmacies located within the State of Delaware, and used by patients in the State of Delaware. Each of these activities would have a substantial effect within the State of Delaware and would constitute an act of infringement of the Patents-in-suit if Alembic's Generic Version is approved before the Patents-in-suit expire.

37. Venue is proper in this Judicial District for AGH pursuant to 28 U.S.C. §§ 1391 and/or 1400 because, on information and belief, *inter alia*, AGH is a company organized and existing under the laws of Switzerland, and may be sued in any judicial district pursuant to 28 U.S.C. § 1391(c) and Alembic's Generic Version will be prescribed by physicians practicing in the State of Delaware, dispensed by pharmacies located within the State of Delaware, and used by patients in the State of Delaware. Each of these activities would have a substantial effect within Delaware and would constitute an act of infringement of the Patents-in-suit if Alembic's Generic Version is approved before the Patents-in-suit expire.

38. Venue is proper in this Judicial District for API pursuant to 28 U.S.C. § 1400 because, on information and belief, *inter alia*, API is incorporated in the State of Delaware and, therefore, resides in this Judicial District.

39. Venue is further proper against Defendants as they are the alter egos and/or agents of each other (which are all individually also subject to venue in this Judicial District) in connection with the submission of Alembic's ANDA.

THE ASSERTED PATENTS

40. The '942 Patent, titled "Combination Therapy of a Type II Anti-CD20 Antibody with a Selective BCL-2 Inhibitor," was duly and legally issued by the USPTO on May 4, 2021. A true and correct copy of the '942 Patent is attached as Exhibit A.

41. The '942 Patent is assigned to Genentech, Inc., Hoffmann-La Roche Inc., and AbbVie Inc.

42. The '087 Patent, titled "Combination Therapy of a Type II Anti-CD20 Antibody with a Selective BCL-2 Inhibitor," was duly and legally issued by the USPTO on September 7, 2021. A true and correct copy of the '087 Patent is attached as Exhibit B.

43. The '087 Patent is assigned to Genentech, Inc., Hoffmann-La Roche Inc., and AbbVie Inc.

44. The '599 Patent, titled "Melt-extruded Solid Dispersions Containing an Apoptosis-Inducing Agent," was duly and legally issued by the USPTO on June 28, 2022. A true and correct copy of the '599 Patent is attached as Exhibit C.

45. The '599 Patent is assigned to AbbVie Inc. and AbbVie Deutschland GMBH & Co. KG and exclusively licensed to Genentech, Inc.

46. The ’128 Patent, titled “Combination Therapy of a Type II Anti-CD20 Antibody with a Selective BCL-2 Inhibitor” was duly and legally issued by the USPTO on February 28, 2023. A true and correct copy of the ’128 Patent is attached as Exhibit D.

47. The ’128 Patent is assigned to Genentech, Inc., Hoffmann-La Roche Inc., and AbbVie Inc.

ALEMBIC’S ANDA

48. On information and belief, Alembic’s Notice Letters represent that Alembic submitted and continues to maintain Alembic’s ANDA to the FDA under 21 U.S.C. § 355(j).

49. On information and belief, and based on Alembic’s Notice Letters, Alembic has submitted Alembic’s ANDA to the FDA in order to obtain approval to engage in the commercial manufacture, use, or sale of venetoclax tablets as a purported generic version of VENCLEXTA® prior to the expiration of the Patents-in-suit.

50. On information and belief, the FDA has not approved Alembic’s ANDA.

51. Alembic’s June Notice Letter states that “[Alembic seeks] to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Venetoclax Tablets, 10 mg, 50 mg, and 100 mg, before the expiration of the ’657 Patent, which is listed in . . . the Orange Book in connection with NDA No. 208573” and “the active ingredient in [Alembic’s Generic Version] is venetoclax; the dose of the active ingredient in [Alembic’s Generic Version] is 10 mg, 50 mg, and 100 mg, and the dosage form of [Alembic’s Generic Version] is a tablet.”

52. Alembic’s First September Notice Letter states that “[Alembic seeks] to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Venetoclax Tablets, 10 mg, 50 mg, and 100 mg, before the expiration of the ’873 Patent, which is listed in . . . the Orange Book in connection with NDA No. 208573” and “the active ingredient

in [Alembic's Generic Version] is venetoclax; the dose of the active ingredient in [Alembic's Generic Version] is 10 mg, 50 mg, and 100 mg, and the dosage form of [Alembic's Generic Version] is a tablet."

53. Alembic's November Notice Letter states that "[Alembic seeks] to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Venetoclax Tablets, 10 mg, 50 mg, and 100 mg, before the expiration of the '087 [P]atent, which is listed in . . . the Orange Book[] in connection with NDA No. 208573" and "the active ingredient in [Alembic's Generic Version] is venetoclax; the dose of the active ingredient in [Alembic's Generic Version] is 10 mg, 50 mg, and 100 mg; and the dosage form of [Alembic's Generic Version] is a tablet."

54. Alembic's November Notice Letter also states that "Alembic's ANDA Product is indicated solely for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy, in combination with azacitidine or decitabine or low-dose cytarabine."

55. Alembic's Second September Notice Letter states that "[Alembic seeks] to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Venetoclax Tablets, 10 mg, 50 mg, and 100 mg, before the expiration of the '599 [P]atent, which is listed in . . . the Orange Book[] in connection with NDA No. 208573" and "the active ingredient in [Alembic's Generic Version] is venetoclax; the dose of the active ingredient in [Alembic's Generic Version] is 10 mg, 50 mg, and 100 mg; and the dosage form of [Alembic's Generic Version] is a tablet."

56. Alembic's Second September Notice Letter also states "Alembic is seeking approval of its ANDA Product solely for the treatment of newly-diagnosed acute myeloid leukemia

(AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy, in combination with azacitidine or decitabine or low-dose cytarabine."

57. Alembic's April Notice letter states "[Alembic seeks] to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Venetoclax Tablets, 10 mg, 50 mg, and 100 mg, before the expiration of the '128 [P]atent, which is listed in . . . the Orange Book[] in connection with NDA No. 208573" and "the active ingredient in [Alembic's Generic Version] is venetoclax; the dose of the active ingredient in [Alembic's Generic Version] is 10 mg, 50 mg, and 100 mg; and the dosage form of [Alembic's Generic Version] is a tablet."

58. Alembic's April Notice Letter also states "Alembic's [Generic Version] is indicated solely for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy, in combination with azacitidine or decitabine or low-dose cytarabine."

59. VENCLEXTA®'s Prescribing Information ("VENCLEXTA®'s PI") states that "VENCLEXTA® tablets for oral administration . . . contain 10, 50, or 100 mg venetoclax as the active ingredient" and "[v]enetoclax is described chemically as 4-(4-{[2-(4-chlorophenyl)-4,4-dimethylcyclohex-1-en-1-yl]methyl}piperazin-1-yl)-*N*-({3-nitro-4-[(tetrahydro-*2H*-pyran-4-ylmethyl)amino]phenyl}sulfonyl)-2-(1*H*-pyrrolo[2,3-*b*]pyridin-5-yloxy)benzamide)." VENCLEXTA®'s PI states that it "is indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)" and "in combination with azacitidine, or decitabine, or low-dose cytarabine for the treatment of newly diagnosed acute

myeloid leukemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy."

60. VENCLEXTA®'s PI also provides the dosing schedule for the "5-Week Ramp-up Phase for Patients with CLL/SLL" and the dosing scheduling for "3- or 4-Day Ramp-up Phase in Patients with AML."

61. On information and belief, and as supported by Alembic's Notice Letters, by filing Alembic's ANDA, Alembic has certified to the FDA that Alembic's Generic Version has the same active pharmaceutical ingredient as VENCLEXTA® and either the same or similar proposed labeling as VENCLEXTA®.

62. Alembic's Notice Letters represent that Alembic certified in Alembic's ANDA that the claims of the '657, '873, '087, '599, and '128 Patents are invalid or would not be infringed by the commercial manufacture, use, sale, or offer for sale of Alembic's Generic Version.

63. According to applicable regulations, Notice Letters such as Alembic's Notice Letters must contain a detailed statement of the factual and legal bases for the applicant's opinion that the patent is invalid, unenforceable, or not infringed, which includes a claim-by-claim analysis, describing "[f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 C.F.R. § 314.95(c)(7); *see also* 21 C.F.R. § 314.52.

64. For at least one claim of the '087 Patent, Alembic's November Notice Letter failed to allege any infringement argument.

65. For at least one claim of the '599 Patent, Alembic's August Notice Letter failed to allege any invalidity argument. For at least one claim of the '599 Patent, Alembic's

Second September Notice Letter failed to allege that Alembic's Generic Version or the proposed administration of Alembic's Generic Version would not meet the limitations of that claim.

66. For at least one claim of the '128 Patent, Alembic's April Notice Letter failed to allege that Alembic's Generic Version or the proposed administration of Alembic's Generic Version would not meet the limitations of that claim.

67. Alembic's Notice Letters failed to address the '399 Patent, the '982 Patent, and the '942 Patent, which were listed in the Orange Book for VENCLEXTA® at the time of some of the Notice Letters.

68. According to applicable regulations, foreign ANDA applicants such as APL are required to appoint an agent that maintains a place of business in the United States. 21 C.F.R. § 314.50(a)(5).

69. Alembic's June Notice Letter does not provide the identity of said agent even though APL is an Indian company.

70. Alembic's June Notice Letter contained an Offer of Confidential Access ("OCA") to certain confidential information regarding Alembic's Generic Version. Plaintiffs provided Alembic with proposed revisions to Alembic's draft OCA in an attempt to reach agreement on the terms for confidential access, but Alembic failed to respond to Plaintiffs' reasonable requests, including requests for samples of Alembic's Generic Version and active pharmaceutical ingredient. Thus, as of the filing of the original Complaint in this action, the parties had not been able to reach an agreement, and they still had not as of the filing of the First Amended Complaint.

71. The limited information relating to Alembic's Generic Version that was provided in Alembic's Notice Letters does not demonstrate that Alembic's Generic Version, which

Alembic has asked the FDA to approve for sale in the United States, will not fall within the scope of claims of the '087, '599, and '128 Patents.

72. The information relating to Alembic's Generic Version that was provided in Alembic's ANDA and discovery produced by Alembic since the filing of the original Complaint, First Amended Complaint, Second Amended Complaint, and Third Amended Complaint demonstrates infringement of the Patents-in-suit.

CLAIM FOR RELIEF
COUNT 1: INFRINGEMENT OF THE '942 PATENT BY ALEMBIC

73. Plaintiffs restate, re-allege, and incorporate by reference paragraphs 1-72 as if fully set forth herein.

74. On information and belief, Alembic submitted or caused the submission of Alembic's ANDA to the FDA, and thereby seeks FDA approval of Alembic's Generic Version.

75. Alembic's Generic Version infringes one or more claims of the '942 Patent.

76. Alembic has infringed one or more claims of the '942 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Alembic's ANDA and thereby seeking FDA approval of a generic version of VENCLEXTA®, prior to the expiration of the '942 Patent.

77. On information and belief, the importation, manufacture, sale, offer for sale, or use of Alembic's Generic Version prior to the expiration of the '942 Patent would infringe one or more claims of the '942 Patent under 35 U.S.C. § 271(a), and/or Alembic would induce or contribute to the inducement of the infringement of one or more claims of the '942 Patent under 35 USC § 271(b) and/or (c).

78. Upon information and belief, Alembic had actual and constructive notice of the '942 Patent since its publication on May 4, 2021, and nonetheless maintained Alembic's ANDA despite being aware that the importation, manufacture, sale, offer for sale, or use of

Alembic's Generic Version prior to the expiration of the '942 Patent would constitute an act of infringement.

79. Plaintiffs will be irreparably harmed if Alembic is not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '942 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Alembic, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

CLAIM FOR RELIEF
COUNT 2: INFRINGEMENT OF THE '087 PATENT BY ALEMBIC

80. Plaintiffs restate, re-allege, and incorporate by reference paragraphs 1-79 as if fully set forth herein.

81. On information and belief, Alembic submitted or caused the submission of Alembic's ANDA to the FDA, and thereby seeks FDA approval of Alembic's Generic Version.

82. Alembic's Generic Version infringes one or more claims of the '087 Patent.

83. Alembic has infringed one or more claims of the '087 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Alembic's ANDA and thereby seeking FDA approval of a generic version of VENCLEXTA®, prior to the expiration of the '087 Patent.

84. On information and belief, the importation, manufacture, sale, offer for sale, or use of Alembic's Generic Version prior to the expiration of the '087 Patent would infringe one or more claims of the '087 Patent under 35 U.S.C. § 271(a), and/or Alembic would induce or contribute to the inducement of the infringement of one or more claims of the '087 Patent under 35 USC § 271(b) and/or (c).

85. Upon information and belief, Alembic had actual and constructive notice of the '087 Patent since its publication on September 7, 2021, and nonetheless maintained Alembic's

ANDA despite being aware that the importation, manufacture, sale, offer for sale, or use of Alembic's Generic Version prior to the expiration of the '087 Patent would constitute an act of infringement.

86. Plaintiffs will be irreparably harmed if Alembic is not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '087 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Alembic, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

CLAIM FOR RELIEF
COUNT 3: INFRINGEMENT OF THE '599 PATENT BY ALEMBIC

87. Plaintiffs restate, re-allege, and incorporate by reference paragraphs 1-86 as if fully set forth herein.

88. On information and belief, Alembic submitted or caused the submission of Alembic's ANDA to the FDA, and thereby seeks FDA approval of Alembic's Generic Version.

89. Alembic's Generic Version infringes one or more claims of the '599 Patent.

90. Alembic has infringed one or more claims of the '599 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Alembic's ANDA and thereby seeking FDA approval of a generic version of VENCLEXTA®, prior to the expiration of the '599 Patent.

91. On information and belief, the importation, manufacture, sale, offer for sale, or use of Alembic's Generic Version prior to the expiration of the '599 Patent would infringe one or more claims of the '599 Patent under 35 U.S.C. § 271(a), and/or Alembic would induce or contribute to the inducement of the infringement of one or more claims of the '599 Patent under 35 USC § 271(b) and/or (c).

92. Upon information and belief, Alembic had actual and constructive notice of the '599 Patent prior to filing Alembic's ANDA, and nonetheless maintained Alembic's ANDA despite being aware that the importation, manufacture, sale, offer for sale, or use of Alembic's Generic Version prior to the expiration of the '599 Patent would constitute an act of infringement.

93. Plaintiffs will be irreparably harmed if Alembic is not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '599 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Alembic, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

CLAIM FOR RELIEF

COUNT 4: INFRINGEMENT OF THE '128 PATENT BY ALEMBIC

94. Plaintiffs restate, re-allege, and incorporate by reference paragraphs 1-93 as if fully set forth herein.

95. On information and belief, Alembic submitted or caused the submission of Alembic's ANDA to the FDA, and thereby seeks FDA approval of Alembic's Generic Version.

96. Alembic's Generic Version infringes one or more claims of the '128 Patent.

97. Alembic has infringed one or more claims of the '128 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Alembic's ANDA and thereby seeking FDA approval of a generic version of VENCLEXTA®, prior to the expiration of the '128 Patent.

98. On information and belief, the importation, manufacture, sale, offer for sale, or use of Alembic's Generic Version prior to the expiration of the '128 Patent would infringe one or more claims of the '128 Patent under 35 U.S.C. § 271(a), and/or Alembic would induce or contribute to the inducement of the infringement of one or more claims of the '128 Patent under 35 USC § 271(b) and/or (c).

99. Upon information and belief, Alembic had actual and constructive notice of the '128 Patent since its publication on February 28, 2023, and nonetheless maintained Alembic's ANDA despite being aware that the importation, manufacture, sale, offer for sale, or use of Alembic's Generic Version prior to the expiration of the '128 Patent would constitute an act of infringement.

100. Plaintiffs will be irreparably harmed if Alembic is not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '128 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Alembic, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Alembic has infringed the Patents-in-suit under 35 U.S.C. § 271(e)(2)(A);

B. A Judgment and Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Alembic's ANDA shall be no be earlier than the expiration date of the Patents-in-suit, or any later expiration of exclusivity for the Patents-in-suit, including any extensions or regulatory exclusivities;

C. A Judgment and Order that Alembic, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, are permanently enjoined from commercially manufacturing, using, offering to sell, selling, marketing, distributing, or importing Alembic's Generic Version and any other product that infringes or induces or contributes to the infringement of the Patents-in-suit, prior to the expiration

of the Patents-in-suit, including any exclusivities or extensions to which Plaintiffs are or become entitled;

D. A Judgment declaring that making, using, selling, offering to sell, or importing Alembic's Generic Version, or inducing or contributing to such conduct, would constitute infringement of the Patents-in-suit pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

E. A declaration under 28 U.S.C. § 2201 that, if Alembic, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of Alembic's Generic Version, it will constitute an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

F. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Alembic engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Alembic's Generic Version, or any product that infringes the Patents-in-suit, or induces or contributes to such conduct, prior to the expiration of the patent including any additional exclusivity period applicable to that patent;

G. A finding that this case is an exceptional case and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

H. Costs and expenses in this action; and

I. Such other and further relief as this Court deems just and proper.

Date: July 26, 2023

SAUL EWING LLP

/s/ Michelle C. Streifthau-Livizos

James D. Taylor, Jr. (#4009)
Jessica M. Jones (#6246)
Michelle C. Streifthau-Livizos (#6584)
1201 N. Market Street, Suite 2300
Wilmington, DE 19899
(302) 421-6800
james.taylor@saul.com
jessica.jones@saul.com
michelle.streifthau-livizos@saul.com

Attorneys for Plaintiffs AbbVie Inc. and Genentech, Inc.

OF COUNSEL:

Chad J. Peterman
Eric W. Dittmann
Bruce M. Wexler
Ashley N. Mays-Williams
Scott F. Peachman
Katherine A. Daniel
Krystina L. Ho
Amanda E. Hoffman
PAUL HASTINGS LLP
200 Park Avenue
New York, New York 10166
(212) 318-6000
chadpeterman@paulhastings.com
ericdittmann@paulhastings.com
brucewexler@paulhastings.com
ashleymayswilliams@paulhastings.com
scottpeachman@paulhastings.com
katherinedaniel@paulhastings.com
krystinaho@paulhastings.com
amandahoffman@paulhastings.com