

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

ABBVIE INC. and GENENTECH, INC.,

*Plaintiffs/
Counterclaim Defendants,*

v.

ALEMBIC PHARMACEUTICALS LTD.,
ALEMBIC PHARMACEUTICALS, INC.,
and ALEMBIC GLOBAL HOLDING SA,

*Defendants/
Counterclaim Plaintiffs.*

C.A. No. 20-1009-LPS

**DEFENDANTS' ANSWER, DEFENSES, AND COUNTERCLAIMS
TO PLAINTIFFS' FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Defendants Alembic Pharmaceuticals Ltd. (“APL”), Alembic Pharmaceuticals, Inc. (“API”), and Alembic Global Holding SA (“AGH”) (collectively, “Defendants” or “Alembic”), hereby answer the First Amended Complaint (“First Amended Complaint”) brought by Plaintiffs AbbVie Inc. (“AbbVie”) and Genentech, Inc. (“Genentech”) (collectively, “Plaintiffs”). Additionally, Defendants hereby assert counterclaims for declaratory judgment of non-infringement and invalidity of U.S. Patent Nos. 8,722,657 (“the ‘657 patent”) and 10,730,873 (“the ‘873 patent”) (collectively, “the Patents-in-Suit”).

Alembic denies all allegations in Plaintiffs’ First Amended Complaint except for those specifically admitted below. With respect to the allegations made in the First Amended Complaint, upon knowledge with respect to Defendants’ own acts, and upon information and belief as to other matters, Defendants respond and 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 No. 8,722,657 ("the '657 Patent") and U.S. Patent No. 10,730,873 ("the '873 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"), the '657 Patent, and the '873 Patent.

ANSWER: Alembic admits that the above-captioned action purports to be an action for patent infringement arising under Patent Laws of the United States, Title 35 of the United States Code, respectively, in response to Alembic's submission of ANDA No. 214747 ("Alembic's ANDA") to the United States Food and Drug Administration ("FDA"). Alembic further admits that the First Amended Complaint purports to relate to the '657 patent and the '873 patent. Alembic admits that it participated in the submission of Alembic's ANDA with the FDA seeking approval to market a generic venetoclax product. Alembic lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations or legal conclusions in Paragraph 1, and therefore denies them.

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").

ANSWER: Alembic lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2, and therefore denies them.

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.

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

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.

ANSWER: Paragraph 4 contains legal conclusions to which no response is required. To the extent a response is required, Alembic admits that the FDA approved NDA No. 208573 on April 11, 2016, and that the FDA publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (“Orange Book”) lists VENCLEXTA® (venetoclax) Tablets in 10 mg, 50 mg, or 100 mg dosage forms. Alembic denies any remaining allegations or legal conclusions in Paragraph 4.

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.

ANSWER: Alembic admits that venetoclax is the active ingredient in VENCLEXTA® Tablets, and that the current label for VENCLEXTA® provides the current approved uses and indications for VENCLEXTA® and speaks for itself. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 5.

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.

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

7. The FDA has recognized the innovative nature of VENCLEXTA® in granting it five 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; and (5) venetoclax in combination with obinutuzumab for the treatment of adult patients with CLL. 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.

ANSWER: Paragraph 7 contains legal conclusions to which no response is required. To the extent a response is required, Alembic admits that venetoclax is the active ingredient in VENCLEXTA® Tablets. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 7.

8. VENCLEXTA® has one of the most robust clinical oncology development programs for a single molecule in the industry, with approximately 195 ongoing clinical trials (including 15 Phase 3 trials).

ANSWER: Alembic lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 8, and therefore denies them.

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.

ANSWER: Alembic lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 9, and therefore denies them.

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.

ANSWER: Alembic lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 10, and therefore denies them.

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 exclusive licensee of the Patents-in-suit.

ANSWER: Alembic lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 11, and therefore denies them.

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.

ANSWER: Alembic admits the allegations in Paragraph 12.

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.

ANSWER: Alembic admits the allegations in Paragraph 13.

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.

ANSWER: Alembic admits the allegations in Paragraph 14.

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

ANSWER: Paragraph 15 contains legal conclusions to which no response is required.

Alembic denies any remaining allegations or legal conclusions contained in Paragraph 15.

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.

ANSWER: Paragraph 16 contains legal conclusions to which no response is required. To the extent a response is required, Alembic admits that API is a wholly owned subsidiary of AGH, and in turn, that AGH is a wholly owned subsidiary of APL. Alembic denies the remaining allegations in Paragraph 16.

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

ANSWER: Alembic admits the allegations in Paragraph 17.

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.

ANSWER: Alembic admits only that APL develops and manufactures pharmaceuticals in India and that API imports, markets, and sells pharmaceutical products in the United States. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 18.

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.

ANSWER: Alembic admits only that APL develops and manufactures pharmaceuticals in India and that API imports, markets, and sells pharmaceutical products in the United States. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 19.

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.

ANSWER: Alembic admits only that APL develops and manufactures pharmaceuticals in India and that API imports, markets, and sells pharmaceutical products in the United States. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 20.

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

ANSWER: Alembic admits the allegations in Paragraph 21.

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") and September 4, 2020 ("Alembic's September 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.

ANSWER: Alembic admits that it provided Plaintiffs with written notification of Alembic's ANDA by way of a notice letter dated June 15, 2020 and a notice letter dated September 3, 2020 ("Alembic's Notice Letters"). Alembic further admits that it participated in the submission of Alembic's ANDA seeking approval from the FDA to offer to sell, sell, and/or import generic venetoclax tablets. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 22.

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.

ANSWER: Paragraph 23 contains legal conclusions to which no response is required. To the extent a response is required, Alembic admits that it participated in the submission of Alembic's ANDA seeking approval from the FDA to offer to sell, sell, and/or import Alembic's Generic Version. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 23.

JURISDICTION AND 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.

ANSWER: Alembic admits that the above-captioned action purports to be an action arising under the Patent Laws and Food and Drug Laws of the United States, Titles 35 and 21 of the United States Code, respectively. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 24.

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

ANSWER: Paragraph 25 contains conclusions of law to which no response is required. To the extent that a response is required, Alembic admits that this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). Alembic denies any remaining allegations or legal conclusions contained in Paragraph 25.

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).

ANSWER: Alembic admits that in Defendants' Answer, Defenses, and Counterclaims to Plaintiffs' Complaint for Patent Infringement, D.I. 10, Alembic answered that it "does not contest personal jurisdiction over it in this Court for purposes of this action only." See ¶¶ 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 to residents of the State of Delaware, including Alembic's Generic Version. Accordingly, Alembic should reasonably anticipate being hauled into court in this Judicial District.

ANSWER: Paragraph 27 contains conclusions of law to which no response is required. To the extent a response is required, Alembic does not contest personal jurisdiction over it in this

Court for purposes of this action only. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 27.

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

ANSWER: Paragraph 28 contains legal conclusions to which no response is required. To the extent a response is required, Alembic does not contest personal jurisdiction over it in this Court for purposes of this action only. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 28.

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.

ANSWER: Paragraph 29 contains legal conclusions to which no response is required. To the extent a response is required, Alembic does not contest personal jurisdiction over it in this Court for purposes of this action only. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 29.

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

ANSWER: Paragraph 30 contains legal conclusions to which no response is required. To the extent a response is required, Alembic does not contest personal jurisdiction over it in this Court for purposes of this action only. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 30.

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.

ANSWER: Paragraph 31 contains legal conclusions to which no response is required. To the extent a response is required, Alembic does not contest personal jurisdiction over it in this Court for purposes of this action only. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 31.

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.

ANSWER: Paragraph 32 contains legal conclusions to which no response is required. To the extent a response is required, Alembic does not contest personal jurisdiction over it in this Court for purposes of this action only. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 32.

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

ANSWER: Paragraph 33 contains legal conclusions to which no response is required. To the extent a response is required, Alembic does not contest personal jurisdiction over it in this Court for purposes of this action only. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 33.

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.

ANSWER: Paragraph 34 contains legal conclusions to which no response is required. To the extent a response is required, Alembic does not contest personal jurisdiction over it in this

Court for purposes of this action only. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 34.

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).

ANSWER: Alembic admits that in Defendants' Answer, Defenses, and Counterclaims to Plaintiffs' Complaint for Patent Infringement, D.I. 10, Alembic answered that it "does not contest venue over it in this Court for purposes of this action only." See ¶¶ 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.

ANSWER: Paragraph 36 contains legal conclusions to which no response is required. To the extent a response is required, Alembic does not contest venue over it in this Court for purposes of this action only. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 36.

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.

ANSWER: Paragraph 37 contains legal conclusions to which no response is required. To the extent a response is required, Alembic does not contest venue over it in this Court for

purposes of this action only. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 37.

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.

ANSWER: Paragraph 38 contains legal conclusions to which no response is required. To the extent a response is required, Alembic does not contest venue over it in this Court for purposes of this action only. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 38.

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.

ANSWER: Paragraph 39 contains legal conclusions to which no response is required. To the extent a response is required, Alembic does not contest venue over it in this Court for purposes of this action only. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 39.

THE ASSERTED PATENTS

40. The '657 Patent, titled "Salts and Crystalline Forms of an Apoptosis-Inducing Agent," was duly and legally issued by the USPTO on May 13, 2014. A true and correct copy of the '657 Patent is attached as Exhibit A.

ANSWER: Alembic admits that on its face the '657 patent states that it issued on May 13, 2014. Alembic further admits that on its face the '657 patent is titled "Salts and Crystalline Forms of an Apoptosis-Inducing Agent." Alembic admits that what purports to be a copy of the '657 patent was attached to the First Amended Complaint as Exhibit A. Alembic is without

knowledge or information sufficient to form a belief as to any remaining allegations contained in Paragraph 40, and on that basis denies those allegations.

41. The '657 Patent is assigned to AbbVie and exclusively licensed to Genentech.

ANSWER: Paragraph 41 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, Alembic admits that on its face the '657 patent is assigned to AbbVie Inc. Alembic is without knowledge or information sufficient to form a belief as to any remaining allegations contained in Paragraph 41, and on that basis denies those allegations.

42. The '873 Patent, titled "Salts and Crystalline Forms of an Apoptosis-Inducing Agent," was duly and legally issued by the USPTO on August 4, 2020. A true and correct copy of the '873 Patent is attached as Exhibit B.

ANSWER: Alembic admits that on its face the '873 patent states that it issued on August 4, 2020. Alembic further admits that on its face the '873 patent is titled "Salts and Crystalline Forms of an Apoptosis-Inducing Agent." Alembic admits that what purports to be a copy of the '873 patent was attached to the First Amended Complaint as Exhibit B. Alembic is without knowledge or information sufficient to form a belief as to any remaining allegations contained in Paragraph 42, and on that basis denies those allegations.

43. The '873 Patent is assigned to AbbVie and exclusively licensed to Genentech.

ANSWER: Paragraph 43 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, Alembic admits that on its face the '873 patent is assigned to AbbVie Inc. Alembic is without knowledge or information sufficient to form a belief as to any remaining allegations contained in Paragraph 43, and on that basis denies those allegations.

ALEMBIC'S ANDA

44. 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).

ANSWER: Alembic admits the allegations contained in Paragraph 44.

45. 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.

ANSWER: Alembic admits the allegations contained in Paragraph 45.

46. On information and belief, the FDA has not approved Alembic's ANDA.

ANSWER: Alembic admits only that the FDA has not yet approved Alembic's ANDA.

Alembic denies any remaining allegations or legal conclusions contained in Paragraph 46.

47. 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.”

ANSWER: Admitted.

48. Alembic's 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.”

ANSWER: Admitted.

49. VENCLEXTA®’s Prescribing Information (“VENCLEXTA® PI”) states that “VENCLEXTA® tablets for oral administration . . . contain 10, 50, or 100 mg venetoclax as the active ingredient.”

ANSWER: Alembic admits the allegations contained in Paragraph 49.

50. 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®.

ANSWER: Alembic admits that it provided Plaintiffs with Alembic’s Notice Letters dated June 15, 2020 and September 3, 2020. Alembic further admits that it participated in the submission of Alembic’s ANDA seeking approval from FDA to market a generic venetoclax product, and that Alembic complied with all statutory and regulatory requirements for filing an ANDA. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 50.

51. On information and belief, Alembic’s Notice Letters represent that Alembic certified in Alembic’s ANDA that the claims of the Patents-in-suit would not be infringed by the commercial manufacture, use, sale, or offer for sale of Alembic’s Generic Version.

ANSWER: Alembic admits the allegations contained in Paragraph 51.

52. 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.

ANSWER: Paragraph 52 of the First Amended Complaint contains legal conclusions to which no response is required.

53. For at least one claim of the ’657 Patent, Alembic’s June Notice Letter failed to allege any invalidity argument.

ANSWER: Alembic admits that it provided Plaintiffs with Alembic's June Notice Letter dated June 15, 2020, which provides notice that the '657 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Alembic's Generic Version. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 53.

54. For at least one claim of the '657 Patent, Alembic's June Notice Letter failed to certify that Alembic actually analyzed Alembic's Generic Version to determine whether the claimed polymorphic form of the '657 Patent was not present in its finished drug product.

ANSWER: Alembic admits that it provided Plaintiffs with Alembic's June Notice Letter dated June 15, 2020, which provides notice that the '657 Patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Alembic's Generic Version. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 54.

55. For at least one claim of the '873 Patent, Alembic's September Notice Letter failed to allege any invalidity argument.

ANSWER: Alembic admits that it provided Plaintiffs with Alembic's September Notice Letter dated September 3, 2020, which provides notice that the '873 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Alembic's Generic Version. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 55.

56. For at least one claim of the '873 Patent, Alembic's September Notice Letter failed to certify that Alembic actually analyzed Alembic's Generic Version to determine whether the claimed polymorphic forms of the '873 Patent were not present in its finished drug product.

ANSWER: Alembic admits that it provided Plaintiffs with Alembic's September Notice Letter dated September 3, 2020, which provides notice that the '873 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Alembic's

Generic Version. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 56.

57. Alembic's Notice Letters failed to address the '399 Patent, '982 Patent, and '251 Patent, which are listed in the Orange Book for VENCLEXTA®.

ANSWER: Alembic admits that pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), Alembic included with its ANDA certifications that Alembic does not seek approval of its ANDA Product prior to the expiration of the '399 Patent and '982 Patent. Alembic further admits that it included a section viii statement with respect to the '251 Patent pursuant to 21 U.S.C. § 505 (j)(2)(A)(viii). Alembic denies any remaining allegations or legal conclusions contained in Paragraph 57.

58. 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).

ANSWER: Paragraph 58 of the First Amended Complaint contains legal conclusions to which no response is required.

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

ANSWER: Paragraph 59 of the First Amended Complaint contains legal conclusions to which no response is required.

60. 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 have not as of the filing of this Amended Complaint.

ANSWER: Alembic admits that it provided Plaintiffs with Alembic's June Notice Letter dated June 15, 2020, which contains an Offer of Confidential Access ("OCA") to certain confidential information regarding Alembic's ANDA and Alembic's Generic Version. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 60.

61. To date, Alembic has not provided Plaintiffs with any portion of Alembic's ANDA nor any information regarding Alembic's Generic Version, beyond the information in Alembic's Notice Letters.

ANSWER: Alembic admits that it provided Plaintiffs with Alembic's Notice Letters dated June 15, 2020 and September 3, 2020, which provide notice that the '657 patent and the '873 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Alembic's Generic Version. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 61.

62. To date, Alembic has not provided Plaintiffs with samples of Alembic's Generic Version embodied by Alembic's ANDA or the active pharmaceutical ingredient.

ANSWER: Alembic admits that it provided Plaintiffs with Alembic's Notice Letter dated June 15, 2020 and September 3, 2020, which provide notice that the '657 patent and the '873 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Alembic's Generic Version. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 62.

63. 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 Patents-in-suit.

ANSWER: Paragraph 63 of the Complaint contains legal conclusions to which no response is required. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 63.

64. The original Complaint in this action claimed infringement of the '657 Patent and was filed within 45 days of Plaintiffs' receipt on June 16, 2020 of Alembic's June Notice Letter, pursuant to 21 U.S.C. § 355(c)(3)(C). This First Amended Complaint includes the same claim of infringement concerning the '657 Patent and thus relates back to the original Complaint. Accordingly, Plaintiffs remain entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and U.S.C. § 355(j)(5)(F)(ii).

ANSWER: Paragraph 64 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, Alembic admits that Plaintiffs filed the original Complaint on July 28, 2020 and the First Amended Complaint on September 17, 2020. Alembic denies any remaining allegations or legal conclusions contained in Paragraph 64.

CLAIM FOR RELIEF
COUNT 1: INFRINGEMENT OF THE '657 PATENT BY ALEMBIC

65. Plaintiffs restate, re-allege, and incorporate by reference paragraphs 1-64 as if fully set forth herein.

ANSWER: Alembic repeats, re-alleges, and incorporates its Answers to Paragraphs 1-64 of the First Amended Complaint as if fully set forth herein.

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

ANSWER: Alembic admits only that it participated in the submission of Alembic's ANDA seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, or importation of Alembic's Generic Version. Alembic denies any remaining allegations contained in Paragraph 66.

67. On information and belief, Alembic's Generic Version infringes one or more claims of the '657 Patent.

ANSWER: Denied.

68. Alembic has infringed one or more claims of the '657 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Alembic's ANDA with Paragraph IV certification and thereby seeking FDA approval of a generic version of VENCLEXTA®, prior to the expiration of the '657 Patent.

ANSWER: Denied.

69. On information and belief, the importation, manufacture, sale, offer for sale, or use of Alembic's Generic Version prior to the expiration of the '657 Patent would infringe one or more claims of the '657 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 '657 Patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER: Denied.

70. Alembic had actual and constructive notice of the '657 Patent prior to filing Alembic's ANDA, and was aware that the filing of Alembic's ANDA with the request for FDA approval prior to the expiration of the '657 Patent would constitute an act of infringement of the '657 Patent.

ANSWER: Denied.

71. Alembic filed its ANDA without adequate justification for asserting that the '657 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Alembic's Generic Version.

ANSWER: Denied.

72. Plaintiffs will be irreparably harmed if Alembic is not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '657 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.

ANSWER: Denied.

CLAIM FOR RELIEF
COUNT 2: INFRINGEMENT OF THE '873 PATENT BY ALEMBIC

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

ANSWER: Alembic repeats, re-alleges, and incorporates its Answers to Paragraphs 1-72 of the First Amended Complaint as if fully set forth herein.

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

ANSWER: Alembic admits only that it participated in the submission of Alembic's ANDA seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, or importation of Alembic's Generic Version. Alembic denies any remaining allegations contained in Paragraph 74.

75. On information and belief, Alembic's Generic Version infringes one or more claims of the '873 Patent.

ANSWER: Denied.

76. Alembic has infringed one or more claims of the '873 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Alembic's ANDA with Paragraph IV certification and thereby seeking FDA approval of a generic version of VENCLEXTA®, prior to the expiration of the '873 Patent.

ANSWER: Denied.

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 '873 Patent would infringe one or more claims of the '873 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 '873 Patent under 35 U.S.C. § 271(b) and/or (c).

ANSWER: Denied.

78. Upon information and belief, Alembic had actual and constructive notice of the '873 Patent since its publication on August 4, 2020, 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 '873 Patent would constitute an act of infringement.

ANSWER: Denied.

79. Plaintiffs will be irreparably harmed if Alembic is not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '873 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.

ANSWER: Denied.

RESPONSE TO PRAYER FOR RELIEF

Alembic denies that Plaintiffs are entitled to any of the requested relief or any other relief. Each averment and/or allegation contained in Plaintiffs' First Amended Complaint that is not specifically admitted herein is hereby denied.

DEFENSES

Without prejudice to the denials set forth in its Answer to the First Amended Complaint, and without admitting any allegations of the First Amended Complaint not otherwise specifically admitted, Alembic asserts the following separate defenses to the First Amended Complaint without assuming the burden of proof on any such defenses that would otherwise rest on the Plaintiffs, and without regard to and without any prejudice regarding the applicable burden of proof.

FIRST DEFENSE

(NON-INFRINGEMENT OF THE '657 PATENT)

Alembic does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '657 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of Alembic's Generic Version does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '657 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

SECOND DEFENSE

(INVALIDITY OF THE '657 PATENT)

Each claim of the '657 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including, without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

THIRD DEFENSE

(NON-INFRINGEMENT OF THE '873 PATENT)

Alembic does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '873 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of Alembic's Generic Version does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '873 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

FOURTH DEFENSE

(INVALIDITY OF THE '873 PATENT)

Each claim of the '873 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including, without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

FIFTH DEFENSE

(NO RELIEF AVAILABLE)

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

Plaintiffs have not suffered any damages.

Plaintiffs are not suffering an irreparable injury.

SIXTH DEFENSE

(FAILURE TO STATE A CLAIM)

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

SEVENTH DEFENSE

(NO EXCEPTIONAL CASE)

Alembic's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

EIGHTH DEFENSE

(NO WILLFUL INFRINGEMENT)

Alembic has not willfully infringed any valid and enforceable claim of the Patents-in-Suit.

NINTH DEFENSE

(ESTOPPEL)

Plaintiffs are estopped from asserting infringement by the doctrine of prosecution history estoppel and/or judicial estoppel.

TENTH DEFENSE

(WAIVER)

Plaintiffs have waived any alleged defect in the way in which Alembic's Notice Letters were served.

ELEVENTH DEFENSE

(DAMAGES)

Plaintiffs' damages, if any, are limited pursuant to 35 U.S.C. §§ 286-287.

RESERVATION OF DEFENSES

Alembic reserves the right to assert additional defenses as may be warranted by discovery or further factual investigation in this action.

COUNTERCLAIMS

Defendants and Counterclaim Plaintiffs Alembic Pharmaceuticals Ltd. (“APL”), Alembic Pharmaceuticals, Inc. (“API”), and Alembic Global Holding SA (“AGH”) (collectively, “Alembic”), assert the following counterclaims against Plaintiffs and Counterclaim Defendants AbbVie Inc. (“AbbVie”) and Genentech, Inc. (“Genentech”) (collectively, “Plaintiffs”).

COUNTERCLAIM I (COUNTS I THROUGH IV)

NATURE OF THE ACTION

1. Alembic seeks declaratory judgment that one or more claims of U.S. Patent Nos. 8,722,657 (“the ’657 patent”) and 10,730,873 (“the ’873 patent”) are invalid, unenforceable, and/or not infringed.

2. The case arises under the Hatch-Waxman Act, which governs the U.S. Food & Drug Administration’s (“FDA”) approval of both new and generic drugs. See 21 U.S.C. § 355; 35 U.S.C. §§ 156, 271(e).

3. Alembic participated in the submission of ANDA No. 214747 (“Alembic’s ANDA”) to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, or importation of venetoclax tablets, 10 mg, 50 mg, and 100 mg, described therein (“Alembic’s Generic Version”). Plaintiffs’/Counterclaim-Defendants’ VENCLEXTA® is the Reference Listed Drug (“RLD”) relied upon in Alembic’s ANDA.

4. Upon information and belief, Plaintiffs/Counterclaim-Defendants caused U.S. Patent Nos. 8,546,399 (“the ’399 patent”), 9,174,982 (“the ’982 patent”), 9,539,251 (“the ’251 patent”), the ’657 patent, and the ’873 patent to be listed in the FDA’s publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly referred to as the “Orange Book”) as allegedly covering VENCLEXTA® Tablets.

5. Under the Hatch-Waxman Act, Alembic was required to submit patent certifications regarding the ’873, ’657, ’399, ’982, and ’251 patents.

6. Alembic’s ANDA contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV certification”) that the ’657 patent and the ’873 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Alembic’s Generic Version.

7. Alembic’s ANDA contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(III) that Alembic does not seek approval of its ANDA Product prior to the expiration of the ’399 patent and ’982 patent.

8. Alembic’s ANDA contains a section viii statement with respect to the ’251 patent pursuant to 21 U.S.C. § 505 (j)(2)(A)(viii).

9. On June 15, 2020, in accordance with 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Alembic sent notice to AbbVie Inc. of Alembic’s Paragraph IV certification regarding the ’657 patent (“Alembic’s June Notice Letter”). Alembic’s Notice Letter asserted that the claims of

the '657 patent are invalid, unenforceable, and/or will not be infringed by Alembic's ANDA or the products or activities described therein. Alembic's Notice Letter also expressly reserves the right to raise additional defenses and arguments.

10. On September 3, 2020, in accordance with 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Alembic sent notice to AbbVie Inc. of Alembic's Paragraph IV certification regarding the '873 patent ("Alembic's September Notice Letter"). Alembic's September Notice Letter asserted that the claims of the '873 patent are invalid, unenforceable, and/or will not be infringed by Alembic's ANDA or the products or activities described therein. Alembic's September Notice Letter also expressly reserves the right to raise additional defenses and arguments.

11. Alembic's June Notice Letter and Alembic's September Notice Letter ("Alembic's Notice Letters") each included a detailed statement of the legal and factual bases for the Paragraph IV certifications included in Alembic's ANDA pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c)(7).

12. Upon information and belief, Plaintiffs/Counterclaim-Defendants received Alembic's Notice Letters shortly after they were sent.

13. On July 28, 2020, Plaintiffs/Counterclaim-Defendants filed a Complaint (D.I. 1) against Alembic in the above-captioned action, alleging infringement of the '657 patent.

14. On September 17, 2020, Plaintiffs/Counterclaim-Defendants filed a First Amended Complaint (D.I. 13) against Alembic in the above-captioned action, alleging infringement of the '873 patent.

15. Alembic's declaratory judgment action is necessary to remove the '657 patent and the '873 patent as a barrier to Alembic's market entry. The current listing in the Orange Book of

the '657 patent and the '873 patent delay final approval of Alembic's ANDA. But for these patents being listed in the Orange Book, the FDA could grant final approval of Alembic's ANDA.

16. Alembic therefore seeks a declaration that the '657 patent and the '873 patent are invalid and/or not infringed by Alembic's Generic Version.

THE PARTIES

17. APL is a corporation organized under the laws of India and its principal place of business is located at Alembic Road, Vadodara - 390 003, Gujarat, India.

18. API is a corporation organized under the laws of the State of Delaware and its principal place of business is located at 750 Highway 202, Bridgewater, New Jersey 08807.

19. AGH is a corporation organized under the laws of Switzerland, with a principal place of business at Rue Fritz-Courvoisier 40, 2300 La Chaux-de-Fonds, Switzerland.

20. Upon information and belief, Counterclaim Defendant AbbVie Inc. 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.

21. Upon information and belief, Counterclaim Defendant Genentech, Inc. is a corporation organized and existing 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 an exclusive licensee of the '657 patent and the '873 patent.

JURISDICTION AND VENUE

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

23. This Court has subject matter jurisdiction based on 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and 21 U.S.C. § 355(j)(5)(C).

24. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because Plaintiffs/Counterclaim-Defendants consented to jurisdiction by suing Alembic in this District.

25. Venue is legally proper in this District under 28 U.S.C. § 1391, § 1400(b), 21 U.S.C. § 355(j)(5)(C)(i)(II), and/or by Plaintiffs/Counterclaim-Defendants' choice of forum.

LEGAL FRAMEWORK AND BACKGROUND

26. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act. See 21 U.S.C. § 355; 35 U.S.C. §§ 156, 271(e). The Hatch-Waxman Act was intended to encourage generic-drug competition while leaving intact incentives for research and development of new drugs by pioneering, *i.e.*, “branded,” drug companies. *See H.R. Rep. No. 98-857, pt. 1, at 14-15 (1984)*, reprinted in U.S.C.C.A.N. 2647, 2648.

27. To accomplish this goal, the Hatch-Waxman Act established a framework with four elements that are pertinent here.

28. First, a company seeking FDA approval of a new drug must submit a New Drug Application (“NDA”) to the FDA. *See 21 U.S.C. § 355*. A brand-name drug sponsor must also inform the FDA of every patent that claims the “drug” or “method of using [the] drug” for which a claim of patent infringement could reasonably be asserted against unlicensed manufacture, use, or sale of that drug product. *See 21 U.S.C. § 355(b)(1); 21 U.S.C. § 355(c)(2); 21 C.F.R. § 314.53(b), 314.53(c)(2)*. Upon approval of the NDA, the FDA publishes a listing of patent information for the approved drug in the Orange Book. *See 21 U.S.C. § 355(b)(1)*. The new FDA-approved drug is known as the “reference-listed drug” or “RLD.”

29. Second, the Hatch-Waxman Act provides a streamlined process for approving generic drugs. Before marketing a generic version of an FDA-approved drug, a generic-drug

manufacturer must submit an ANDA to the FDA. An ANDA is “abbreviated” because it is generally not required to include the extensive preclinical and clinical data that must be included in an NDA for a brand-name drug. Instead, the ANDA can rely on the NDA’s preclinical and clinical data if the proposed generic product is “bioequivalent” to the corresponding reference-listed drug. *See* 21 U.S.C. § 355(j)(4)(F).

30. An ANDA must also contain one of four certifications for each patent listed in the Orange Book: (i) that there are no patents listed in the Orange Book; (ii) that any listed patent has expired; (iii) that the patent will expire before the generic manufacturer is seeking to market its generic product; or (iv) that the patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV); 21 C.F.R. § 314.94(a)(12). The last of these is commonly referred to as a “Paragraph IV certification.”

31. An applicant submitting an ANDA containing a Paragraph IV certification must notify both the patent holder and the NDA holder of its Paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(i).

32. Third, the Hatch-Waxman Act encourages prompt resolution of patent disputes by authorizing a patent owner to sue an ANDA applicant for patent infringement if the ANDA applicant makes a Paragraph IV certification. *See* 35 U.S.C. § 271(e)(2). By statute, if the patent owner brings suit within 45 days of receiving notice of the Paragraph IV certification, the suit will trigger an automatic statutory 30-month stay of approval by the FDA of the ANDA to allow the parties time to adjudicate the merits of the infringement action before the generic company launches its product. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

33. Fourth, to encourage prompt generic-market entry, the Hatch-Waxman Act grants the first generic applicant to file a substantially complete ANDA containing a Paragraph IV certification on an Orange Book-listed patent a 180-day period of marketing exclusivity that begins on the earlier of (1) the date it begins commercial marketing of its generic-drug product, or (2) the date of a court decision finding the listed patent(s) invalid, unenforceable, or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv); *see also* 21 C.F.R. § 314.107(c)(1).

THE '657 PATENT AND THE '873 PATENT

34. Upon information and belief, AbbVie holds approved NDA No. 208573 for VENCLEXTA® (venetoclax) Tablets in 10 mg, 50 mg, 100 mg dosage forms (“VENCLEXTA® Tablets”).

35. On its face, the '657 patent, titled “Salts and Crystalline Forms of an Apoptosis-Inducing Agent,” issued on May 13, 2014.

36. On its face, the '873 patent, titled “Salts and Crystalline Forms of an Apoptosis-Inducing Agent,” issued on August 4, 2020.

37. Under 21 U.S.C. § 355(b)(1), an NDA holder must provide to the FDA the patent number and expiration date of any patent(s) that it believes “claims the drug for which the applicant submitted the application or which claims a method of using such drug.” The FDA publishes these patents in the Orange Book.

38. Upon information and belief, the '657 patent and the '873 patent remain listed in the Orange Book for NDA No. 208573 for VENCLEXTA® (venetoclax) Tablets.

FIRST COUNTERCLAIM

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '657 PATENT

39. Counterclaimant Alembic repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

40. Alembic filed ANDA No. 214747 with a Paragraph IV certification stating that the '657 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of Alembic's Generic Version.

41. Plaintiffs/Counterclaim-Defendants have alleged in this action that Alembic has infringed an Orange Book patent, the '657 Patent, under 35 U.S.C. § 271(e)(2) by filing ANDA No. 214747, and that the manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of Alembic's Generic Version would directly infringe, induce others' direct infringement of, and contribute to infringement of the '657 Patent in violation of 35 U.S.C. § 271(a), (b), and/or (c).

42. Plaintiffs/Counterclaim-Defendants' conduct has created reasonable apprehension that it will maintain an action against Alembic alleging infringement of the '657 patent, an Orange Book patent, thereby impeding Alembic's ability to manufacture, use, offer to sell, sell, and/or import into the United States its non-infringing goods without a cloud of uncertainty.

43. There is a present, genuine, and justiciable controversy between the parties regarding whether the filing of Alembic's ANDA No. 214747 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Alembic's Generic Version infringes, has infringed, and/or will infringe any valid and enforceable claim of the '657 patent.

44. Alembic is entitled to a declaration by this Court that the manufacture, use, offer for sale, sale, and/or importation of Alembic's Generic Version, as described in ANDA No. 214747, has not infringed, does not infringe, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid and enforceable claim of the '657 patent, either directly, contributorily, or by inducement and is not liable for any such alleged infringement.

45. Alembic is entitled to further necessary or proper relief based on this Court's declaratory judgment or decree.

SECOND COUNTERCLAIM

DECLARATORY JUDGMENT OF INVALIDITY OF THE '657 PATENT

46. Counterclaimant Alembic repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

47. The '657 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

48. There is a present, genuine, and justiciable controversy between the parties.

49. Alembic is entitled to a declaration by this Court that one or more of the claims of the '657 patent is invalid.

50. Alembic is entitled to further necessary or proper relief based on this Court's declaratory judgment or decree.

THIRD COUNTERCLAIM

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '873 PATENT

51. Counterclaimant Alembic repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

52. Alembic filed ANDA No. 214747 with a Paragraph IV certification stating that the '873 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of Alembic's Generic Version.

53. Plaintiffs/Counterclaim-Defendants have alleged in this action that Alembic has infringed an Orange Book patent, the '873 patent, under 35 U.S.C. § 271(e)(2) by filing ANDA No. 214747, and that the manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of Alembic's Generic Version would directly infringe, induce others' direct infringement of, and contribute to infringement of the '873 patent in violation of 35 U.S.C. § 271(a), (b), and/or (c).

54. Plaintiffs/Counterclaim-Defendants' conduct has created reasonable apprehension that it will maintain an action against Alembic alleging infringement of the '873 patent, an Orange Book patent, thereby impeding Alembic's ability to manufacture, use, offer to sell, sell, and/or import into the United States its non-infringing goods without a cloud of uncertainty.

55. There is a present, genuine, and justiciable controversy between the parties regarding whether the filing of Alembic's ANDA No. 214747 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Alembic's Generic Version infringes, has infringed, and/or will infringe any valid and enforceable claim of the '873 patent.

56. Alembic is entitled to a declaration by this Court that the manufacture, use, offer for sale, sale, and/or importation of Alembic's Generic Version, as described in ANDA No. 214747, has not infringed, does not infringe, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid and enforceable claim of the '873 patent, either directly, contributorily, or by inducement and is not liable for any such alleged infringement.

57. Alembic is entitled to further necessary or proper relief based on this Court's declaratory judgment or decree.

FOURTH COUNTERCLAIM

DECLARATORY JUDGMENT OF INVALIDITY OF THE '873 PATENT

58. Counterclaimant Alembic repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

59. The '873 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, and/or other judicially created bases for invalidation.

60. There is a present, genuine, and justiciable controversy between the parties.

61. Alembic is entitled to a declaration by this Court that one or more of the claims of the '873 patent is invalid.

62. Alembic is entitled to further necessary or proper relief based on this Court's declaratory judgment or decree.

PRAAYER FOR RELIEF FOR COUNTERCLAIM I (COUNTS I THROUGH IV)

WHEREFORE, Alembic requests that the Court enter judgment in its favor and against Plaintiffs/Counterclaim-Defendants as follows:

(a) Declaring that the filing of Alembic's ANDA No. 214747 has not infringed, does not infringe, and will not infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '657 patent and the '873 patent;

(b) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Alembic's Generic Version does not, and will not, infringe, either directly, contributorily, or by inducement, any valid and enforceable claim of the '657 patent and the '873 patent;

- (c) Declaring that the claims of the '657 patent and the '873 patent are invalid and/or unenforceable;
- (d) Awarding Alembic its costs and expenses in this action under all applicable statutes and rules in common law that would be appropriate;
- (e) If the facts demonstrate that the case is exceptional within the meaning of 35 U.S.C. § 285, awarding Alembic its reasonable attorney fees and costs reasonably incurred in prosecuting this action;
- (f) Granting Alembic such other and further relief as the Court deems just and appropriate; and
- (g) Ordering that the Plaintiffs/Counterclaim Defendants' First Amended Complaint be dismissed with prejudice and judgment be entered in favor of Alembic.

Of Counsel:

Dennies Varughese, Pharm.D.
Robert W. Stout
STERNE, KESSLER, GOLDSTEIN
& FOX, P.L.L.C.
1100 New York Avenue, N.W., Suite 600
Washington, D.C. 20005
(202) 371-2600
dvarughese@sternekessler.com
rstout@sternekessler.com

Date: October 1, 2020

YOUNG CONAWAY STARGATT
& TAYLOR, LLP

/s/ Anne Shea Gaza

Anne Shea Gaza (No. 4093)
Samantha G. Wilson (No. 5816)
Rodney Square
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
agaza@ycst.com
swilson@ycst.com

*Attorneys for Defendants/Counterclaim Plaintiffs
Alembic Pharmaceuticals Ltd., Alembic
Pharmaceuticals, Inc., and Alembic Global
Holding SA*

CERTIFICATE OF SERVICE

I, Anne Shea Gaza, Esquire hereby certify that on October 1, 2020, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to all registered participants.

I further certify that on October 1, 2020, I caused the foregoing document to be served by e-mail on the following counsel of record:

James D. Taylor, Jr.
Jessica M. Jones
Charles E. Davis
SAUL EWING ARNSTEIN & LEHR LLP
1201 N. Market Street, Suite 2300
P.O. Box 1266
Wilmington, Delaware 19899
James.Taylor@saul.com
Jessica.Jones@saul.com
Chad.Davis@saul.com

Chad J. Peterman
Eric W. Dittmann
Bruce M. Wexler
Ashley N. Mays-Williams
Katherine A. Daniel
Krystina L. Ho
PAUL HASTINGS LLP
200 Park Avenue
New York, New York 10166
chadpeterman@paulhastings.com
ericdittmann@paulhastings.com
brucewexler@paulhastings.com
ashleymayswilliams@paulhastings.com
katherinedaniel@paulhastings.com
krystinaho@paulhastings.com

*Attorneys for Plaintiffs AbbVie Inc. and
Genentech, Inc.*

Dated: October 1, 2020

YOUNG CONAWAY STARGATT
& TAYLOR, LLP

/s/ Anne Shea Gaza

Anne Shea Gaza (No. 4093)

Samantha G. Wilson (No. 5816)

Rodney Square

1000 North King Street

Wilmington, Delaware 19801

(302) 571-6600

agaza@ycst.com

swilson@ycst.com

*Attorneys for Defendants/Counterclaim
Plaintiffs Alembic Pharmaceuticals Ltd.,
Alembic Pharmaceuticals, Inc., and Alembic
Global Holding SA*