IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SERVIER PHARMACEUTICALS LLC,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 22-1420-GBW
v.	)	
	)	
ALEMBIC PHARMACEUTICALS LIMITED,	)	
	)	
Defendants.	)	

DEFENDANT ALEMBIC PHARMACEUTICALS LIMITED'S ANSWER AND COUNTERCLAIMS TO PLAINTIFF SERVIER PHARMACEUTICAL LLC'S COMPLAINT FOR PATENT INFRINGEMENT

Defendant Alembic Pharmaceuticals Limited ("Alembic" or "Defendant"), by its counsel, hereby answer the allegations set forth in Plaintiff Servier Pharmaceuticals LLC's ("Servier" or "Plaintiff") Complaint for patent infringement against Alembic, as follows:

NATURE OF THE ACTION[1]

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and in particular under 35 U.S.C. § 271. This action relates to Abbreviated New Drug Application ("ANDA") No. 217768, filed by and for the benefit of Alembic with the United States Food and Drug Administration ("FDA"). Through ANDA No. 217768, Alembic seek approval to market generic versions of TIBSOVO® (ivosidenib tablets) 250 mg tablets (the "Proposed ANDA Product"), prior to the expiration of U.S. Patent Nos. 9,968,595 ("the '595 Patent"), 10,449,184 ("the '184 Patent"), 10,799,490 ("the '490 Patent"), and 10,980,788 ("the '788 Patent") (collectively, "the Patents-in-Suit").

ANSWER: Alembic admits that Plaintiff's Complaint purports to bring an action alleging infringement of U.S. Patent Nos. 9,968,595 ("the '595 Patent"), 10,449,184 ("the '184 Patent"), 10,799,490 ("the '490 Patent"), and 10,980,788 ("the '788 Patent") (collectively, "the Patents-in-Suit"), and that Plaintiff's cause of action purportedly arises under 35 U.S.C. § 1, *et*

[1] For convenience, certain section headings used by Plaintiff in its Complaint are repeated herein.

seq., including 35 U.S.C. § 271. Alembic further admits that it seeks FDA approval of the ivosidenib (250 mg) tablet product described in Abbreviated New Drug Application ("ANDA") No. 217768 (the "Proposed ANDA Product") before the expiration of the Patents-in-Suit, but deny that Alemic's Proposed ANDA Product has infringed or will infringe any valid and enforceable claim of the Patents-in-Suit. Alembic denies the remaining allegations of Paragraph 1.

THE PARTIES

2. Plaintiff Servier Pharmaceuticals LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 200 Pier Four Boulevard, Boston, MA 02210.

ANSWER: Alembic lack sufficient information or knowledge to form a belief as to the truth of the allegations of this paragraph, and therefore deny them.

3. On information and belief, Defendant Alembic Pharmaceuticals Limited is a corporation organized and existing under the laws of the Republic of India, having a principal place of business at Alembic Road, Vadodara 390003, Gujarat, India.

ANSWER: Admitted.

JURISDICTION AND VENUE

4. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of the submission of Alembic ANDA No. 217768 to the FDA.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Alembic admits that Plaintiff's Complaint purports to be an action under Title 35 of the United States Code. Alembic denies any remaining allegations in this paragraph.

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and 35 U.S.C. § 1 et seq.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Alembic admits that Plaintiff's Complaint purports to be an action under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. Alembic denies any remaining allegations in this paragraph.

6. This Court has personal jurisdiction over Alembic because, inter alia, it has maintained continuous and systematic contacts with this District and availed itself of the privilege of doing business in this District. On information and belief, Alembic has (1) filed ANDA No. 217768 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product in the United States, including in this District; (2) regularly and continuously transacted business within this District, including by selling pharmaceutical products in this District either on its own or through its affiliates; and (3) derived substantial revenue from the sale of those products in this District. Alternatively, this Court has personal jurisdiction over Alembic pursuant to Federal Rule of Civil Procedure 4(k)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Alembic denies that Alembic is subject to personal jurisdiction in this District, but does not contest personal jurisdiction for the limited purposes of this action only. Alembic denies any remaining allegations in this paragraph.

7. On information and belief, if ANDA No. 217768 is approved, the Proposed ANDA Product charged with infringing the Patents-in-Suit will be marketed, distributed, offered for sale, and/or sold in this District, prescribed by physicians practicing in this District, dispensed by pharmacies located within this District, and/or used by patients in this District, all of which would have a substantial effect on this District.

ANSWER: The allegations of this paragraph are wholly speculative, as ANDA No. 215238 does not yet have approval from the Federal Food and Drug Administration ("FDA"). To the extent an answer is required, Alembic admits that ANDA No. 217768 was filed with the FDA and seeks FDA approval for the Proposed ANDA Product. For the purposes of this action only, Alembic does not contest personal jurisdiction or venue in this District for the limited purposes of this action only. Alembic denies any remaining allegations in this paragraph.

8. This Court also has personal jurisdiction over Alembic because they have affirmatively availed themselves of the jurisdiction of this Court through the assertion of counterclaims

in suits brought in this District and/or by being sued in this District without challenging personal jurisdiction. *See, e.g.*, *Pfizer Inc., et al. v. Alembic Pharmaceuticals, Inc., et al.*, Civil Action No. 20-1392 (D. Del.); *Boehringer Ingelheim Pharmaceuticals Inc., et al. v. Mankind Pharma Ltd., et al.*, Civil Action No. 18-1689 (D. Del.); *H. Lundbeck A/S, et al. v. Alembic Pharmaceuticals Limited, et al.*, Civil Action No. 18-0113 (D. Del.); *Adverio Pharma GmbH, et al. v. MSN Laboratories Private Limited, et al.*, Civil Action No. 18-0073 (D. Del.).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Alembic admits that in certain prior matters it has not contested personal jurisdiction in this District for the limited purposes of specific cases, and that Alembic has filed counterclaims in litigations in this District. Further answering, Alembic does not contest personal jurisdiction or venue in this District for the limited purposes of this action only. Alembic denies any remaining allegations in this paragraph.

9. For the reasons set forth above, and for additional reasons which will be supplied if Alembic challenges personal jurisdiction in this action, Alembic is subject to personal jurisdiction in this District.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Alembic does not contest personal jurisdiction or venue in this District for the limited purposes of this action only. Alembic denies any remaining allegations in this paragraph.

10. Venue is proper in this District for Alembic pursuant to 28 U.S.C. § 1391(c) because, inter alia, Alembic is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this District.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Alembic admits that Alembic is a corporation organized and existing under the laws of the Republic of India. Alembic does not contest personal jurisdiction or venue in this District for the limited purposes of this action only. Alembic denies any remaining allegations in this paragraph.

THE PATENTS-IN-SUIT

11. The Patents-in-Suit are assigned to Servier.

ANSWER: Alembic lacks knowledge or information sufficient to form a belief about the allegations of this paragraph, and on that basis deny said allegations.

12. The '595 Patent, entitled "Pharmaceutical compositions of therapeutically active compounds," was duly and legally issued on May 15, 2018. A copy of the '595 Patent is attached as Exhibit A.

ANSWER: Alembic admits that the '595 Patent is entitled "Pharmaceutical compositions of therapeutically active compounds," and that the '595 Patent issued on or about May 15, 2018. Alembic further admits that what appears to be an uncertified copy of the '595 Patent was attached to Plaintiff's Complaint (D.I. 1) as Exhibit A. Alembic denies any remaining allegations in this paragraph.

13. The '184 Patent, entitled "Pharmaceutical compositions of therapeutically active compounds," was duly and legally issued on October 22, 2019. A copy of the '184 Patent is attached as Exhibit B.

ANSWER: Alembic admits that the '184 Patent is entitled "Pharmaceutical compositions of therapeutically active compounds," and that the '184 Patent issued on or about October 22, 2019. Alembic further admits that what appears to be an uncertified copy of the '595 Patent was attached to Plaintiff's Complaint (D.I. 1) as Exhibit B. Alembic denies any remaining allegations in this paragraph.

14. The '490 Patent, entitled "Pharmaceutical compositions of therapeutically active compounds," was duly and legally issued on October 13, 2020. A copy of the '490 Patent is attached as Exhibit C.

ANSWER: Alembic admits that the '490 Patent is entitled "Pharmaceutical compositions of therapeutically active compounds," and that the '490 Patent issued on or about October 13, 2020. Alembic further admits that what appears to be an uncertified copy of the '490 Patent was

attached to Plaintiff's Complaint (D.I. 1) as Exhibit C. Alembic denies any remaining allegations in this paragraph.

15. The '788 Patent, entitled "Therapy for treating malignancies," was duly and legally issued on April 20, 2021. A copy of the '788 Patent is attached as Exhibit D.

ANSWER: Alembic admits that the '788 Patent is entitled "Pharmaceutical compositions of therapeutically active compounds," and that the '788 Patent issued on or about April 20, 2021. Alembic further admits that what appears to be an uncertified copy of the '788 Patent was attached to Plaintiff's Complaint (D.I. 1) as Exhibit D. Alembic denies any remaining allegations in this paragraph.

FACTUAL BACKGROUND

TIBSOVO® (ivosidenib tablets)

16. TIBSOVO® (ivosidenib tablets) is a drug used to treat newly-diagnosed and relapsed or refractory acute myeloid leukemia and locally advanced or metastatic cholangiocarcinoma.

ANSWER: Alembic admits that the current prescribing information for TIBSOVO® lists three indications: treatment of newly-diagnosed acute myeloid leukemia, relapsed or refractory acute myeloid leukemia, and locally advanced or metastatic cholangiocarcinoma. Alembic denies any remaining allegations in this paragraph

17. Servier is the holder of approved New Drug Application ("NDA") No. 211192 for TIBSOVO® (ivosidenib tablets). Pursuant to NDA No. 211192, Servier markets and distributes TIBSOVO® (ivosidenib tablets) 250 mg tablets in the United States.

ANSWER: Alembic admits that according to FDA's electronic publication "*Approved Drug Products with Therapeutic Equivalence Evaluations*" (the "Orange Book") Servier is the holder of New Drug Application ("NDA") No. 211192 for TIBSOVO® (ivosidenib tablets) 250 mg tablets. Alembic lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph, and on that basis denies these allegations.

18. The Patents-in-Suit have been listed for NDA No. 211192 in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is also known as the "Orange Book."

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Alembic admits that Plaintiff has chosen to list the Patents-in-Suit in FDA's *Orange Book* in association with NDA No. 211192. Alembic denies any remaining allegations in this paragraph.

Alembic's ANDA No. 217768

19. In a letter dated September 14, 2022 (the "Notice Letter"), Alembic stated that it had submitted ANDA No. 217768 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product prior to the expiration of the Patents-in-Suit. The Notice Letter further stated that ANDA No. 217768 contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed ANDA Product.

ANSWER: Alembic admits that it sent a letter dated September 14, 2022 to Plaintiff pursuant to 21 U.S.C. § 355(j)(2)(B)(iv), the content of which speaks for itself. Alembic denies any remaining allegations in this paragraph.

20. Alembic was aware of the Patents-in-Suit when it submitted ANDA No. 217768 with a Paragraph IV Certification.

ANSWER: Admitted.

21. On information and belief, ivosidenib is the active ingredient in the Proposed ANDA Product.

ANSWER: Admitted.

22. On information and belief, ANDA No. 217768 refers to and relies upon the NDA for TIBSOVO® (ivosidenib tablets) 250 mg tablets and contains data that, according to Alembic, demonstrates the bioequivalence of the Proposed ANDA Product and TIBSOVO® (ivosidenib tablets) 250 mg tablets. See 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

ANSWER: Alembic admits that ANDA No. 217768 refers to NDA No. 21192. Alembic further admits that ANDA No. 217768 complies with the statutory requirements of 21 U.S.C. § 355(j) *et seq*. and the FDA's regulations under 21 C.F.R. § 314 *et seq*. Alembic denies any remaining allegations of this paragraph.

23. On information and belief, Alembic intend [sic] to have healthcare providers use the Proposed ANDA Product, if approved, as set forth in the Proposed ANDA Product label. On information and belief, Alembic's Proposed ANDA Product label will instruct healthcare providers to prescribe the Proposed ANDA Product in the manner set forth in the label.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, the content of ANDA No. 217768, including the proposed labeling information, is intended to and upon information and belief does comply with FDA regulatory requirements. Further the FDA has not yet finally approved ANDA No. 217768, and the label for which Alembic seeks FDA approval may change during the course of FDA review. The allegations of this paragraph are speculative and except as expressly admitted, Alembic denies any remaining allegations of this paragraph.

24. On information and belief, the FDA has not yet approved ANDA No. 217768.

ANSWER: Admitted.

25. Plaintiff commenced this action within 45 days of receipt of the Notice Letter.

ANSWER: Admitted.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 9,968,595

26. Plaintiff hereby realleges and incorporates the allegations of paragraphs 1 – 25 of this Complaint.

ANSWER: Alembic incorporates and reallege each of its responses to the foregoing paragraphs 1-25 as if fully set forth herein.

27. On information and belief, the Proposed ANDA Product infringes at least claims 1 and 4 of the '595 Patent, either literally or under the doctrine of equivalents, by the use and/or

presence in the Proposed ANDA Product of an ivosidenib crystalline form as covered by at least claims 1 and 4 of the '595 Patent.

ANSWER: Denied.

28. Alembic's submission of ANDA No. 217768 to the FDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product before the expiration of the '595 Patent constitutes infringement of the '595 Patent under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

29. On information and belief, Alembic plans to, intends to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product immediately upon approval of ANDA No. 217768 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, the content of ANDA No. 217768, including the proposed labeling information, is intended to and upon information and belief does comply with FDA regulatory requirements. Further the FDA has not yet finally approved ANDA No. 217768, and the label for which Alembic seeks FDA approval may change during the course of FDA review. As Alembic has not yet received final FDA approval of ANDA No. 217768, it has not yet determined or finalized its plans to commercialize the Proposed ANDA Product. The allegations of this paragraph are speculative and except as expressly admitted, Alembic denies any remaining allegations of this paragraph.

30. On information and belief, upon FDA approval of ANDA No. 217768, Alembic will infringe the '595 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

ANSWER: Denied.

31. On information and belief, Alembic had knowledge of the '595 Patent when it submitted ANDA No. 217768 to the FDA, Alembic knew or should have known that it will induce or contribute to another's direct infringement of the '595 Patent, and Alembic acted with the specific intent to induce or contribute to another's direct infringement of the '595 Patent.

ANSWER: Denied.

32. Plaintiff will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

ANSWER: Denied.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 10,449,184

33. Plaintiff hereby realleges and incorporates the allegations of paragraphs 1 – 32 of this Complaint.

ANSWER: Alembic incorporates and reallege each of its responses to the foregoing paragraphs 1-32 as if fully set forth herein.

34. On information and belief, the Proposed ANDA Product infringes at least claim 1 of the '184 Patent, either literally or under the doctrine of equivalents, by the use and/or presence in the Proposed ANDA Product of a composition comprising ivosidenib as covered by at least claim 1 of the '184 Patent.

ANSWER: Denied.

35. Alembic's submission of ANDA No. 217768 to the FDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product before the expiration of the '184 Patent constitutes infringement of the '184 Patent under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

36. On information and belief, Alembic plans to, intends to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product immediately upon approval of ANDA No. 217768 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, the content of ANDA No. 217768, including the proposed labeling information, is intended to comply with FDA regulatory requirements. Further the FDA has not yet finally approved ANDA No. 217768, and the label for which Alembic seeks FDA approval may change during the course of FDA review. As Alembic has not yet received final FDA approval of ANDA No. 217768, it has not yet determined or finalized its plans to

commercialize the Proposed ANDA Product. The allegations of this paragraph are speculative and except as expressly admitted, Alembic denies any remaining allegations of this paragraph.

37. On information and belief, upon FDA approval of ANDA No. 217768, Alembic will infringe the '184 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

ANSWER: Denied.

38. On information and belief, Alembic had knowledge of the '184 Patent when it submitted ANDA No. 217768 to the FDA, Alembic knew or should have known that it will induce or contribute to another's direct infringement of the '184 Patent, and Alembic acted with the specific intent to induce or contribute to another's direct infringement of the '184 Patent.

ANSWER: Denied.

39. Plaintiff will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

ANSWER: Denied.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 10,799,490

40. Plaintiff hereby realleges and incorporates the allegations of paragraphs 1 – 39 of this Complaint.

ANSWER: Alembic incorporates and reallege each of its responses to the foregoing paragraphs 1-39 as if fully set forth herein.

41. On information and belief, the Proposed ANDA Product infringes at least claim 1 of the '490 Patent, either literally or under the doctrine of equivalents, by the use and/or presence in the Proposed ANDA Product of a composition comprising ivosidenib as covered by at least claim 1 of the '490 Patent.

ANSWER: Denied.

42. Alembic's submission of ANDA No. 217768 to the FDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product before the expiration of the '490 Patent constitutes infringement of the '490 Patent under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

43. On information and belief, Alembic plans to, intends to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product immediately upon approval of ANDA No. 217768 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, the content of ANDA No. 217768, including the proposed labeling information, is intended to comply with FDA regulatory requirements. Further the FDA has not yet finally approved ANDA No. 217768, and the label for which Alembic seeks FDA approval may change during the course of FDA review. As Alembic has not yet received final FDA approval of ANDA No. 217768, it has not yet determined or finalized its plans to commercialize the Proposed ANDA Product. The allegations of this paragraph are speculative and except as expressly admitted, Alembic denies any remaining allegations of this paragraph.

44. On information and belief, upon FDA approval of ANDA No. 217768, Alembic will infringe the '490 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

ANSWER: Denied

45. On information and belief, Alembic had knowledge of the '490 Patent when it submitted ANDA No. 217768 to the FDA, Alembic knew or should have known that it will induce or contribute to another's direct infringement of the '490 Patent, and Alembic acted with the specific intent to induce or contribute to another's direct infringement of the '490 Patent.

ANSWER: Denied.

46. Plaintiff will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

ANSWER: Denied.

COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 10,980,788

47. Plaintiff hereby realleges and incorporates the allegations of paragraphs 1 – 46 of this Complaint.

ANSWER: Alembic incorporates and reallege each of its responses to the foregoing paragraphs 1-46 as if fully set forth herein.

48. On information and belief, the Proposed ANDA Product infringes at least claim 1 of the '788 Patent, either literally or under the doctrine of equivalents, by the use and/or presence in the Proposed ANDA Product of ivosidenib as covered by at least claim 1 of the '788 Patent.

ANSWER: Denied.

49. Alembic's submission of ANDA No. 217768 to the FDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product before the expiration of the '788 Patent constitutes infringement of the '788 Patent under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

50. On information and belief, Alembic plans to, intends to, and will commercially manufacture, use, offer for sale, sell, and/or import the Proposed ANDA Product immediately upon approval of ANDA No. 217768 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, the content of ANDA No. 217768, including the proposed labeling information, is intended to comply with FDA regulatory requirements. Further the FDA has not yet finally approved ANDA No. 217768, and the label for which Alembic seeks FDA approval may change during the course of FDA review. As Alembic has not yet received final FDA approval of ANDA No. 217768, it has not yet determined or finalized its plans to commercialize the Proposed ANDA Product. The allegations of this paragraph are speculative and except as expressly admitted, Alembic denies any remaining allegations of this paragraph.

51. On information and belief, upon FDA approval of ANDA No. 217768, Alembic will infringe the '788 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

ANSWER: Denied.

52. On information and belief, Alembic had knowledge of the '788 Patent when it submitted ANDA No. 217768 to the FDA, Alembic knew or should have known that it will induce or contribute to another's direct infringement of the '788 Patent, and Alembic acted with the specific intent to induce or contribute to another's direct infringement of the '788 Patent.

ANSWER: Denied.

53. Plaintiff will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

ANSWER: Denied.

PRAYER FOR RELIEF

Alembic denies that Plaintiff is entitled to any of the relief sought in its Prayer for Relief, including the relief sought in Paragraphs a) through g) thereof, and/or any other relief. Alembic lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations contained in Paragraphs a) through g) of Plaintiff's Prayer for Relief, and on that basis, denies them.

DEFENSES

Alembic reserves all defenses under Rule 8(c) of the Federal Rules of Civil Procedure and any other defense at law or at equity that may now exist or in the future be available based on discovery and further factual investigation in this case, whether or not expressly stated herein. Without prejudice to the denials set forth in its Answer and without any admissions as to the burden of proof, burden of persuasion, or the truth of any allegations not expressly admitted in Plaintiff's Complaint, Alembic states the following defenses:

FIRST DEFENSE

The allegations set forth in Plaintiff's Complaint fail to state a claim for which relief can be granted.

SECOND DEFENSE

The claims of the Patents-in-Suit are invalid and/or unenforceable for failure to satisfy or comply with the requirements of Title 35 of the United States Code, including, without limitation one or more of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120, non-statutory (obviousness-type) double patenting, the defenses recognized in 34 U.S.C. § 282(b) and/or any other judicially created bases for invalidity.

THIRD DEFENSE

Alembic has not infringed, is not infringing, and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the Patents-in-Suit. Alembic has not contributed to, is not contributing to, and will not contribute to any infringement of any valid and enforceable claim of the Patents-in-Suit. Alembic has not induced, is not inducing, and will not induce infringement of any valid and enforceable claim of the Patents-in-Suit.

FOURTH DEFENSE

Plaintiff is not entitled to injunctive relief because any injury to Plaintiff is not immediate or irreparable, because any such injunction would be against the public interest, and because Plaintiff has an adequate remedy at law.

FIFTH DEFENSE

Alembic has not intentionally, willfully, or deliberately infringed any valid claim of the Patents-in-Suit.

SIXTH DEFENSE

Plaintiff's case is not exceptional under 35 U.S.C. § 285.

SEVENTH DEFENSE

Plaintiff's infringement claims against Alembic regarding the Patents-in-Suit are barred and the Patents-in-Suit are unenforceable against Alembic under the equitable doctrines of laches, waiver, estoppel, and/or acquiescence.

RESERVATION OF ADDITIONAL DEFENSES

Alembic hereby reserves the right to assert additional defenses and/or counterclaims if such defenses or counterclaims are discovered during the course of this litigation.

COUNTERCLAIMS

Without admitting any of the allegations in the Complaint, other than those allegations expressly admitted in the Answer *Supra* and without prejudice to Alembic's right to plead additional counterclaims as the facts of the matter warrant, the Defendant/Plaintiff-In-Counterclaim, Alembic Pharmaceuticals Limited ("Alembic" or "Counterclaim Plaintiff"), and, for its Counterclaims against Plaintiff Servier Pharmaceuticals LLC ("Servier" or "Counterclaim Defendant"), hereby alleges as follows:

1. Counterclaim Plaintiff repeats and incorporates by reference each of the foregoing paragraphs of Alembic's Answer and Defenses to the Complaint.

2. This is a counterclaim for declaratory judgment of non-infringement and/or invalidity of one or more claims of U.S. Patent Nos. 9,968,595 ("the '595 Patent"), 10,449,184 ("the '184 Patent"), 10,799,490 ("the '490 Patent"), and 10,980,788 ("the '788 Patent") (collectively, "the Patents-in-Suit") under 28 U.S.C. §§ 2201 and 2202. On information and belief, true and correct uncertified copies of the Patents-in-Suit were attached to Counterclaim Defendant's Complaint (D.I. 1) as Exhibits A-D, respectively.

THE PARTIES

3. Counterclaim Plaintiff Alembic Pharmaceuticals Limited is a corporation organized and existing under the laws of the Republic of India, having its corporate office at Alembic Road, Vadodara 390003, Gujarat, India.

4. On information and belief, Counterclaim Defendant Servier Pharmaceuticals LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 200 Pier Four Boulevard, Boston, MA 02210.

JURISDICTION AND VENUE

5. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. §100, et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

6. There is an actual and justiciable controversy between the parties as to whether the ivosidenib tablet products described in Alembic's ANDA No. 2017768 infringe any valid and enforceable claim of the Patents-in-Suit.

7. Personal jurisdiction over the Plaintiff/Counterclaim Defendant exists because the Plaintiff/Counterclaim Defendant has voluntarily submitted itself to the personal jurisdiction of the Court by filing its Complaint here and because Counterclaim Defendant does business in this jurisdiction.

8. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400.

FACTUAL BACKGROUND

The Patents-in-Suit

9. On October 26, 2022, Plaintiff/Counterclaim Defendant filed a Complaint alleging, inter alia, infringement of the '595, '184, '490, and'788 Patents.

10. Prior to the filing of this action, upon information and belief, Plaintiff/Counterclaim Defendant listed and caused to be listed the ’595, ’184, ’490, and’788 Patents in the publication of the Federal Food and Drug Administration (“FDA”) entitled “Approved Drug Products for Therapeutic Equivalents Evaluations” (commonly known and the “Orange Book”) for NDA No. 211192.

11. The ’595 Patent is entitled, “Pharmaceutical compositions of therapeutically active compounds,” and indicates on its face that it issued on May 15, 2018.

12. The ’184 Patent is entitled, “Pharmaceutical compositions of therapeutically active compounds,” and indicates on its face of that it issued on October 22, 2019.

13. The ’490 Patent is entitled, “Pharmaceutical compositions of therapeutically active compounds,” and indicates on its face that it issued on October 13, 2020.

14. The ’788 Patent is entitled, “Pharmaceutical compositions of therapeutically active compounds,” and indicates on its face that it issued on April 20, 2021.

15. Plaintiff/Counterclaim Defendant alleges that it is the current assignee of each of the Patents-in-Suit, and has asserted each of these patents in the current action.

Alembic’s Notice Letter and Servier’s Suit

16. Alembic has filed with the FDA an Abbreviated New Drug Application (“ANDA”) bearing No. 217768, seeking to obtain approval to engage in the commercial manufacture, use, sale, or importation of a proposed ivosidenib table product (“Alembic’s ANDA Product”).

17. Pursuant to 21 U.S.C. § 355(j)(2)(A)(iv), Alembic’s ANDA No. 217768 contains a “Paragraph IV” certification stating that each of the ’595, ’184, ’490, and’788 Patents are invalid or will not be infringed by the manufacturing, use, sale, offer to sell, or importation into

the United States of the proposed drug product which is the subject of Alembic's ANDA No. 217768.

18. Pursuant to the applicable statutes, rules, and regulations, Alembic notified Plaintiff/Counterclaim Defendant that it had submitted ANDA No. 217768 to the FDA for Alembic's ANDA Product by letter dated September 14, 2022 ("Alembic's Notice Letter").

19. Pursuant to 21 U.S.C. § 355(c)(3)(C), Plaintiff/Counterclaim Defendant had 45 days from receipt of Alembic's Notice Letter to file the Complaint ("the 45-day period").

20. Plaintiff/Counterclaim Defendant filed their Complaint within the 45-day period following receipt of Alembic's Notice Letter.

21. Pursuant to 21 U.S.C. § 355(c)(3)(C), Plaintiff/Counterclaim Defendant's act of filing the Complaint within the 45-day period prohibits the FDA from approving Alembic's ANDA Product for a period of thirty months following Plaintiff/Counterclaim Defendant's receipt of Alembic's Notice Letter ("the thirty-month stay").

22. During the pendency of the thirty-month stay, Alembic is prohibited from selling Alembic's ANDA Product in the United States.

23. By virtue of Plaintiff/Counterclaim Defendant having listed '595, '184, '490, and'788 Patents in the Orange Book, by virtue of Alembic's submission of a "Paragraph IV" certification regarding these patents and providing Plaintiff/Counterclaim Defendant with notice and the basis for such certification, and by virtue of the Complaint filed herein, an actual case and controversy exists between Alembic and Plaintiff/Counterclaim Defendant as to the infringement and validity of the '595, '184, '490, and'788 Patents.

24. Alembic does not infringe any valid and enforceable claim of the Patents-in-Suit, either directly or indirectly.

25. An actual and justiciable controversy therefore exists between Plaintiff/Counterclaim Defendant and Alembic relating to, inter alia, the Patents-in-Suit.

COUNT I

(Declaratory Judgment of Noninfringement – U.S. Patent No. 9,968,595)

26. Alembic repeats and realleges each of the foregoing paragraphs of the counterclaims as if fully set forth herein.

27. There is an actual, substantial, and continuing justiciable case or controversy between Alembic and Servier regarding non-infringement of the ’595 Patent.

28. Alembic’ manufacture, use, offer for sale, sale, and/or importation into the United States of Alembic’s ANDA Product upon FDA approval to do so pursuant to ANDA No. 217768 has not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’595 patent, either literally or under the doctrine of equivalents, including for at least the reasons set forth in the detailed statement included with Alembic’s Notice Letter.

29. Alembic will not commit, is not committing, and has not committed any acts in violation of 35 U.S.C. § 271.

30. Alembic is entitled to a declaratory judgment that its manufacture, use, offer for sale, sale, and/or importation into the United States of Alembic’s ANDA Product pursuant to ANDA No. 217768 has not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’595 patent, either literally or under the doctrine of equivalents.

COUNT II

(Declaratory Judgment of Noninfringement – U.S. Patent No. 10,449,184)

31. Alembic repeats and realleges each of the foregoing paragraphs of the counterclaims as if fully set forth herein.

32. There is an actual, substantial, and continuing justiciable case or controversy between Alembic and Servier regarding non-infringement of the ’184 Patent.

33. Alembic’s manufacture, use, offer for sale, sale, and/or importation into the United States of Alembic’s ANDA Product upon FDA approval to do so pursuant to ANDA No. 217768 has not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’184 patent, either literally or under the doctrine of equivalents, including for at least the reasons set forth in the detailed statement included with Alembic’s Notice Letter.

34. Alembic will not commit, is not committing, and has not committed any acts in violation of 35 U.S.C. § 271.

35. Alembic is entitled to a declaratory judgment that its manufacture, use, offer for sale, sale, and/or importation into the United States of Alembic’s ANDA Product pursuant to ANDA No. 217768 has not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’184 patent, either literally or under the doctrine of equivalents.

COUNT III

(Declaratory Judgment of Noninfringement – U.S. Patent No. 10,799,490)

36. Alembic repeats and realleges each of the foregoing paragraphs of the counterclaims as if fully set forth herein.

37. There is an actual, substantial, and continuing justiciable case or controversy between Alembic and Servier regarding non-infringement of the ’490 Patent.

38. Alembic’s manufacture, use, offer for sale, sale, and/or importation into the United States of Alembic’s ANDA Product upon FDA approval to do so pursuant to ANDA No. 217768 has not and will not infringe, directly or indirectly, any valid and enforceable claim of

the ’490 patent, either literally or under the doctrine of equivalents, including for at least the reasons set forth in the detailed statement included with Alembic’s Notice Letter.

39. Alembic will not commit, is not committing, and has not committed any acts in violation of 35 U.S.C. § 271.

40. Alembic is entitled to a declaratory judgment that its manufacture, use, offer for sale, sale, and/or importation into the United States of Alembic’s ANDA Product pursuant to ANDA No. 217768 has not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’490 patent, either literally or under the doctrine of equivalents.

COUNT IV

(Declaratory Judgment of Noninfringement – U.S. Patent No. 10,980,788)

41. Alembic repeat and reallege each of the foregoing paragraphs of the counterclaims as if fully set forth herein.

42. There is an actual, substantial, and continuing justiciable case or controversy between Alembic and Servier regarding non-infringement of the ’788 Patent.

43. Alembic’s manufacture, use, offer for sale, sale, and/or importation into the United States of Alembic’s ANDA Product upon FDA approval to do so pursuant to ANDA No. 217768 has not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’788 patent, either literally or under the doctrine of equivalents, including for at least the reasons set forth in the detailed statement included with Alembic’s Notice Letter.

44. Alembic will not commit, is not committing, and has not committed any acts in violation of 35 U.S.C. § 271.

45. Alembic is entitled to a declaratory judgment that its manufacture, use, offer for sale, sale, and/or importation into the United States of Alembic’s ANDA Product pursuant to

ANDA No. 217768 has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '788 patent, either literally or under the doctrine of equivalents.

COUNT V

(Declaratory Judgment of Invalidity – U.S. Patent No. 10,980,788)

46. Alembic repeats and realleges each of the foregoing paragraphs of the counterclaims as if fully set forth herein.

47. There is an actual, substantial, and continuing justiciable case or controversy between Alembic and Servier regarding the invalidity of the '788 patent.

48. The '788 Patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, *et seq*., including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 116, 120, non-statutory (obviousness-type) double patenting, the defenses recognized in 34 U.S.C. § 282(b) and/or any other judicially created bases for invalidity.

49. The '788 patent is invalid at least for the reasons set forth in the detailed statement included in Alembic's Notice Letter.

50. Alembic incorporates by reference Alembic's Notice Letter, which contains exemplary and nonlimiting explanations for why the '778 Patent is invalid.

51. Alembic is entitled to a declaratory judgment that the claims of the '788 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Alembic respectfully requests that the Court enter judgment for Alembic, and against Plaintiff/Counterclaim Defendant, and decree:

A. That the Complaint be dismissed with prejudice and that each and every prayer for relief contained therein be denied;

B. That the manufacture, use, sale, offer for sale, or importation of the product that is the subject of Alembic's ANDA No. 217768 has not infringed, does not infringe, would not infringe, would not contributorily infringe and would not induce the infringement of any valid and enforceable claim of the '595, '184, '490, and '788 Patents, either literally or under the doctrine of equivalents;

C. That the claims of the'788 Patent is invalid and/or unenforceable;

D. That this case is exceptional and awarding Alembic its reasonable attorneys' fees, costs, and expenses in this action, pursuant to 35 U.S.C. § 285 and/or other applicable laws;

E. That Alembic be awarded its fees, costs, and expenses in this action;

F. That the effective date of any FDA approval of Alembic's ANDA Product shall not be stayed thirty months from the date of the Notice Letter, in accordance with 21 U.S.C. § 355(j)(5)(B)(iii); and

G. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

By: */s/ Bindu A. Palapura*

David E. Moore (#3983)
Bindu A. Palapura (#5370)
Elizabeth R. Schlecker (#6913)
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
Tel: (302) 984-6000
dmoore@potteranderson.com
bpalapura@potteranderson.com
eschlecker@potteranderson.com

Attorneys for Defendant Alembic Pharmaceuticals Limited

OF COUNSEL:

Steven M. Coyle
Nicholas Geiger
CANTOR COLBURN LLP
20 Church Street, 22nd Floor
Hartford, CT 06103-3207
Tel: (860) 286-2929

Dated: January 6, 2023
10533200 / 22666.00001