IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SERVIER PHARMACEUTICALS LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
ALEMBIC PHARMACEUTICALS LIMITED,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Servier Pharmaceuticals LLC ("Servier" or Plaintiff) brings this action for patent infringement against Alembic Pharmaceuticals Limited ("Alembic" or "Defendant").

NATURE OF THE ACTION

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").

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.

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.

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.

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.

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).

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.

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.).

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.

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.

THE PATENTS-IN-SUIT

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

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.

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.

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.

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.

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.

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.

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."

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.

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

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

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).

23. On information and belief, Alembic intend 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.

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

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

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.

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.

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).

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.

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).

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.

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.

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.

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.

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).

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.

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).

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.

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.

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

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.

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).

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.

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).

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.

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.

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.

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.

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).

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.

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).

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.

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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court grant the following relief:

a) Judgment that Alembic's submission of ANDA No. 217768 to the FDA was an act of infringement of one or more claims of the '595, '184, '490, and '788 Patents under 35 U.S.C. § 271(e)(2);

b) Judgment that Alembic's making, using, offering to sell, selling, or importing into the United States of the Proposed ANDA Product prior to the expiration of the '595, '184, '490, and '788 Patents, will infringe, will actively induce infringement, and/or will contribute to the infringement of one or more claims of those patents;

c) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 217768 shall be a date that is not earlier than the expiration of the '595, '184, '490, and '788 Patents plus any other exclusivity to which Plaintiff is or becomes entitled;

d) An Order permanently enjoining Alembic, Alembic's affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in concert with Alembic, from making, using, offering to sell, selling, or importing into the United States the Proposed ANDA Product until after the expiration of the '595, '184, '490, and '788 Patents plus any other exclusivity to which Plaintiff is or becomes entitled;

e) A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and an award of reasonable attorneys' fees, expenses, and disbursements of this action;

f) An award of Plaintiff's reasonable costs and expenses in this action; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

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