

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

PFIZER INC., WARNER-LAMBERT)	
COMPANY LLC, PF PRISM C.V., PFIZER)	
MANUFACTURING HOLDINGS LLC and)	
PFIZER PFE IRELAND PHARMACEUTICALS)	C.A. No. 19-745-CFC
HOLDING 1 B.V.,)	
)	
Plaintiffs,)	
)	
v.)	
)	
ALEMBIC PHARMACEUTICALS, INC. and)	
ALEMBIC PHARMACEUTICALS, LTD.,)	
)	
Defendants.)	

DEFENDANTS' ANSWER AND DEFENSES

Defendants Alembic Pharmaceuticals, Ltd. and Alembic Pharmaceuticals, Inc. (collectively “Alembic” or “Defendants”), by its counsel, hereby answers the allegations set forth in Plaintiffs Pfizer Inc., Warner-Lambert Company LLC, PF PRISM C.V., Pfizer Manufacturing Holdings LLC, and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. (collectively “Pfizer” or “Plaintiffs”) Complaint for patent infringement against Alembic under 35 U.S.C. § 271 for alleged infringement of United States Patent Nos. 6,936,612 (“the ‘612 patent”), as follows:

1. The allegations in paragraph 1 are legal conclusions to which no answer is required. To the extent an answer is required, Alembic admits that Pfizer’s Complaint purports to be a civil action for alleged patent infringement arising under the Patent Laws of the United States, Title 35 of the United States Code, arising from Alembic’s submission of an Abbreviated New Drug Application (“ANDA”) to the Food and Drug Administration (“FDA”) seeking approval to manufacture and sell generic versions of Plaintiffs’ IBRANCE® (palbociclib) tablets.

2. Admitted.

THE PARTIES¹

3. Alembic lacks sufficient information or knowledge to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

4. Alembic lacks sufficient information or knowledge to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

5. Alembic lacks sufficient information or knowledge to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

6. Alembic lacks sufficient information or knowledge to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

7. This paragraph contains allegations to which no answer is required. To the extent that an answer may be required, Alembic admits that Alembic Pharmaceuticals, Ltd. is a corporation organized under the laws of the Republic of India having a principal place of business at Alembic Road, Vadodara 390003, Gujarat, India.

8. This paragraph contains allegations to which no answer is required. To the extent that an answer may be required, Alembic admits that Alembic Pharmaceuticals, Inc. is a Delaware corporation having a principal place of business at 750 Highway 202, Bridgewater, New Jersey 08807.

9. Alembic admits that Alembic Pharmaceuticals, Inc. is a wholly owned subsidiary of Alembic Pharmaceuticals Ltd. The remainder of this paragraph contains no allegations to which a response is required. To the extent an answer may be required, Alembic acknowledges

¹ For convenience, certain section headings used by Plaintiffs in their Complaint are repeated herein. The copying of certain section headings for convenience from Plaintiffs' Complaint does not constitute an admission as to the substance or contents of any such section headings.

that Pfizer does refer to Alembic Pharmaceuticals Ltd. and Alembic Pharmaceuticals, Inc. collectively as “Alembic.”

10. This paragraph contains legal conclusions and allegations to which no answer is required. To the extent that an answer may be required, Alembic admits that Alembic Pharmaceuticals Ltd. contributed to the preparation and submission of ANDA No. 213128 (“Alembic’s ANDA”) for Alembic Pharmaceuticals Ltd.’s 75 mg, 100 mg, and 125 mg palbociclib tablets (“Alembic’s ANDA Product”).

11. This paragraph contains legal conclusions to which no answer is required. To the extent an answer may be required, Alembic admits that it is seeking FDA approval to market its ANDA Product. Alembic denies any remaining allegations in this paragraph.

12. This paragraph contains legal conclusions to which no answer is required. To the extent an answer may be required, Alembic admits that it is seeking FDA approval to market its ANDA Product. Alembic denies any remaining allegations in this paragraph.

JURISDICTION AND VENUE

13. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, for the limited purposes of this action only, Alembic does not contest subject matter jurisdiction in this Court. Otherwise Alembic denies all remaining allegations of this paragraph.

14. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Alembic admits that Alembic Pharmaceuticals, Ltd. develops, and/or manufactures generic drug products that are distributed by another party for sale within the United States. Alembic Pharmaceuticals, Ltd. denies that it is subject to personal jurisdiction

in this District, but does not contest jurisdiction in this District for the limited purpose of this case. Alembic denies any remaining allegations or conclusions of law in this paragraph.

15. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Alembic admits that Alembic Pharmaceuticals, Inc. is incorporated under the laws of the State of Delaware, and Alembic admits that Alembic Pharmaceuticals, Inc. participates in the sale of generic drug products that are distributed within the United States. For the limited purposes of this action only, Alembic Pharmaceuticals, Inc. does not contest personal jurisdiction in this District. Alembic denies any remaining allegations or conclusions of law in this paragraph.

16. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Alembic admits that it has previously challenged pharmaceutical patents by filing a certification as set forth in 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter, and engaging in patent litigation. Alembic denies any remaining allegations or conclusions of law in this paragraph.

17. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Alembic admits that it sent Alembic's Notice Letter to Pfizer, and alleged that the '612 patent is invalid. Alembic denies any remaining allegations or conclusions of law in this paragraph.

18. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Alembic admits that it has been a litigant in connection with other infringement actions under the Hatch-Waxman Act. Alembic denies any remaining allegations or conclusions of law in this paragraph.

19. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Alembic admits that Alembic Pharmaceuticals, Ltd. develops, and/or manufactures generic drug products that are distributed by another party for sale within the United States. Alembic Pharmaceuticals, Ltd. denies that it is subject to personal jurisdiction in this District, but does not contest jurisdiction in this District for the limited purpose of this case. Alembic denies any remaining allegations or conclusions of law in this paragraph.

20. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Alembic admits that Alembic Pharmaceuticals, Ltd. develops, and/or manufactures generic drug products that are distributed by another party for sale within the United States. Alembic Pharmaceuticals, Ltd. denies that it is subject to personal jurisdiction in this District, but does not contest jurisdiction in this District for the limited purpose of this case. Alembic denies any remaining allegations or conclusions of law in this paragraph.

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

22. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Alembic admits that Alembic Pharmaceuticals, Inc. is organized and existing under the laws of the State of Delaware. For the limited purposes of this action only, Alembic Pharmaceuticals, Inc. does not contest personal jurisdiction or venue in this

District for the limited purposes of this action only. Alembic denies any remaining allegations or conclusions of law in this paragraph.

COUNT I – ALLEGED INFRINGEMENT OF THE ‘612 PATENT

23. Alembic incorporates its answers to Paragraphs 1-22 as if fully set forth herein.

24. Alembic lacks sufficient information or knowledge to form a belief as to the truth of the allegations of this paragraph, but admits that the face of the ‘612 patent names the following inventors: Mark Barvian, Richard John Booth, John Quin III, Joseph Thomas Repine, Derek J. Sheehan, Peter Laurence Toogood, Scott Norman Venderwel, and Hairong Zhou.

25. This paragraph contains legal conclusions and allegations to which no answer is required. To the extent that an answer may be required, Alembic admits that the title of the ‘612 patent is “2-(Pyridin-2-ylamino)-pyrido[2,3-d]pyrimidin-7-ones,” and that the ‘612 patent was issued on August 30, 2005. Alembic denies any remaining allegations in this paragraph.

26. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Alembic states that the face of the patent indicates that Warner Lambert Company, LLC is the assignee of the ‘612 patent, but Alembic is not aware of any assignment recorded on the database of patent assignments maintained by the United States Patent and Trademark Office. Alembic lacks sufficient information or knowledge to form a belief as to the truth of the remaining allegations of this paragraph, and therefore denies them.

27. Admitted.

28. Admitted.

29. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Alembic lacks sufficient information or knowledge to form a belief as to the truth of the allegations of this paragraph, but admits that the ‘612 patent has been listed

in connection with IBRANCE® in the FDA's Orange Book. Alembic denies any remaining allegations in this paragraph.

30. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Alembic admits that it notified Pfizer of the submission of Alembic's ANDA to the FDA, and that Alembic's ANDA to the FDA included a certification that the '612 patent was invalid, unenforceable and/or will not be infringed by the manufacture use, offer for sale, sale, and/or importation of Alembic's ANDA Product. Alembic denies any remaining allegations or conclusions of law in this paragraph.

31. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Alembic admits that it notified Pfizer of the submission of Alembic's ANDA to the FDA, and that Alembic's ANDA to the FDA included a certification that the '612 patent was invalid, unenforceable and/or will not be infringed by the manufacture use, offer for sale, sale, and/or importation of Alembic's ANDA Product. Alembic denies any remaining allegations or conclusions of law in this paragraph.

32. Alembic denies that its ANDA Product and the use of Alembic's ANDA Product are covered by any valid claim of the '612 patent.

33. Alembic denies that its ANDA Product and the use of Alembic's ANDA Product are covered by any valid claim of the '612 patent.

34. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Alembic denies that Alembic's ANDA Product and the use of Alembic's ANDA Product infringe any valid claim of the '612 patent.

35. Denied.

36. Denied.

37. Denied.

38. Denied.

39. Denied.

40. Denied.

41. Denied.

42. Denied.

43. Denied.

44. Denied.

COUNT II – DECLARATORY JUDGMENT
OF ALLEGED INFRINGEMENT OF THE ‘612 PATENT

45. Alembic incorporates by reference its responses to the foregoing paragraphs 1-44 as if fully set forth herein.

46. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Alembic denies that it infringes any valid claim of the ‘612 patent.

47. Admitted.

48. Admitted.

49. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Alembic admits that it notified Pfizer of the submission of Alembic’s ANDA to the FDA, and that Alembic’s ANDA to the FDA included a certification that the ‘612 patent was invalid, unenforceable and/or will not be infringed by the manufacture use, offer for sale, sale, and/or importation of Alembic’s ANDA Product. Alembic denies any remaining allegations or conclusions of law in this paragraph.

50. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Alembic admits that it notified Pfizer of the submission of

Alembic's ANDA to the FDA, and that Alembic's ANDA to the FDA included a certification that the '612 patent was invalid, unenforceable and/or will not be infringed by the manufacture use, offer for sale, sale, and/or importation of Alembic's ANDA Product. Alembic denies any remaining allegations or conclusions of law in this paragraph.

51. Alembic denies that its ANDA Product and the use of Alembic's ANDA Product infringe any valid claim of the '612 patent.

52. Alembic denies that its ANDA Product and the use of Alembic's ANDA Product infringe any valid claim of the '612 patent.

53. Denied.

54. Denied.

55. Denied.

56. Denied.

57. Denied.

58. Denied.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

PRAYER FOR RELIEF

Alembic denies that Plaintiffs are entitled to any of the relief sought in their 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 Plaintiffs' 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 any admissions as to the burden of proof, burden of persuasion, or the truth of any allegations in Plaintiffs' Complaint, Alembic states the following defenses:

FIRST DEFENSE

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

SECOND DEFENSE

The claims of the '612 patent 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, and/or 116.

THIRD DEFENSE

Defendants have not infringed and are not infringing, either literally or under the doctrine of equivalents, any valid and enforceable claim of the Patents-in-Suit. Defendants have not contributed to and are not contributing to any infringement of any valid and enforceable claim of the Patents-in-Suit. Defendants have not induced and are not inducing infringement of any valid and enforceable claim of the Patents-in-Suit.

FOURTH DEFENSE

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

FIFTH DEFENSE

Defendants have not intentionally, willfully, or deliberately infringed any valid claim of the '612 patent.

SIXTH DEFENSE

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

SEVENTH DEFENSE

Plaintiffs' infringement claims against Defendants regarding the Patents-in-Suit are barred and the '612 patent is unenforceable against Defendants under the equitable doctrines of laches, waiver, estoppel, and/or acquiescence.

RESERVATION OF ADDITIONAL DEFENSES

Defendants hereby reserve the right to assert additional defenses if such defenses or are discovered during the course of this litigation.

PRAYER FOR RELIEF

WHEREFORE, Alembic respectfully requests that the Court enter judgment for Alembic and against Plaintiffs, and decree:

- A. That the Complaint be dismissed with prejudice;
- B. That the claims of the '612 patent are not infringed by Alembic;
- C. That the claims of the '612 patent are invalid;
- D. That this is an exceptional case under 35 U.S.C. § 285 and 15 U.S.C. § 117(a);

E. That the effective date of any FDA approval of Alembic's ANDA Procut 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), nor 7.5 years from the date of the initial approval of Plaintiffs palbociclib product, in accordance with 21 U.S.C. § 355(j)(5)(F)(ii); and

F. 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

OF COUNSEL:

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

Dated: July 8, 2019
6302057 / 49171

By: /s/ Bindu A. Palapura
Bindu A. Palapura (#5370)
Alan R. Silverstein (#5066)
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
Tel: (302) 984-6000
bpalapura@potteranderson.com
asilverstein@potteranderson.com

*Attorneys for Defendants Alembic
Pharmaceuticals, Inc. and Alembic
Pharmaceuticals, Ltd.*