

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC, FOREST)
LABORATORIES HOLDINGS, LTD.,)
MERCK KGaA and MERCK PATENT)
GESELLSCHAFT MIT BESCHRÄNKTER)
HAFTUNG,)

Plaintiffs,)

v.)

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

Defendants.)

C.A. No. _____

COMPLAINT

Plaintiffs Forest Laboratories, LLC and Forest Laboratories Holdings, Ltd. (collectively, “Forest”), and Merck KGaA and Merck Patent Gesellschaft mit beschränkter Haftung (“Merck Patent GmbH”) (collectively, “Merck”), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by Defendant Alembic Pharmaceuticals Ltd. of Abbreviated New Drug Application (“ANDA”) No. 208202 with the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture and sell a generic version of Forest’s Viibryd® product prior to the expiration of U.S. Patent Nos. 7,834,020; 8,193,195; 8,236,804; and 8,673,921.

PARTIES

2. Plaintiff Forest Laboratories, LLC (f/k/a Forest Laboratories, Inc.) is a Delaware limited liability company having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

3. Plaintiff Forest Laboratories Holdings, Ltd. is an Irish corporation having a principal place of business at Cumberland House, 1 Victoria Street, Hamilton HM11, Bermuda.

4. Plaintiff Merck KGaA is a German corporation having a principal place of business at Frankfurter Str. 250, 64293 Darmstadt Hessen, Germany.

5. Plaintiff Merck Patent GmbH is a German corporation having a principal place of business at Frankfurter Str. 250, 64293 Darmstadt Hessen, Germany.

6. On information and belief, Defendant Alembic Pharmaceuticals Ltd. (“Alembic Ltd.”) is a corporation organized and existing under the laws of India, having a principal place of business at Alembic Road, Vadodara 39003, Gujarat, India.

7. On information and belief, Defendant Alembic Global Holding SA (“Alembic Global”) is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Rue Fritz-Courvoisier 40, 2300 La Chaux-de-Fonds, Switzerland.

8. On information and belief, Defendant Alembic Pharmaceuticals Inc. (“Alembic Inc.”) is a Delaware corporation, having its principal place of business at 116 Village Boulevard, Suite 200, Princeton, New Jersey 08650.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, and this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, and 1338(a).

10. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

11. This Court has personal jurisdiction over Alembic Ltd., Alembic Global, and Alembic Inc. (collectively, “Alembic”) because they have engaged in continuous and systematic contacts with the State of Delaware and/or purposefully availed themselves of this forum by, among other things, making, marketing, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in Delaware, and deriving substantial revenue from such activities.

12. This Court has personal jurisdiction over Alembic Inc. because, *inter alia*, it is a corporation organized and existing under the laws of the State of Delaware.

13. On information and belief, Defendants Alembic Ltd., Alembic Global, and Alembic Inc. are in the business of formulating, developing, manufacturing, marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, including in the State of Delaware.

14. On information and belief, Alembic Global is a wholly-owned subsidiary of Defendant Alembic Ltd. Alembic Global’s website states, “The basic objective of forming a wholly owned overseas subsidiary is to expand business globally aiming at purchase, sale, packaging, manufacturing, research and development of pharmaceutical products, intermediates and raw materials as well as acquisition and management of Intellectual property. Alembic Global is the headquarters for all the overseas business in countries like USA, Europe, UAE, Australia and other developed markets.”

15. On information and belief, Alembic Inc. is the United States subsidiary of Alembic Global. Alembic Inc.’s website states, “The basic objective of forming a wholly owned overseas subsidiary in USA is to establish a globally recognized organization in USA. Alembic

aims at creating a strong US presence. Alembic has filed 57 ANDAs, received approval for 24 and has commercialized 15 of the approved filings.”

16. On information and belief, Alembic Inc. is the agent of Alembic Ltd. and Alembic Global, and it acts in concert with them to manufacture, market, distribute, and sell Alembic’s generic pharmaceutical products within the United States, including the State of Delaware. On information and belief, the acts of Defendants Alembic Ltd. and Alembic Global enumerated in this Complaint were done at the direction of, with the authorization of, with the cooperation, participation, and/or assistance of, and, in part, for the benefit of Alembic Inc.

17. On information and belief, Alembic Inc., itself and on behalf of Alembic Ltd. and Alembic Global, has purposefully conducted business in the State of Delaware, continues to conduct business in Delaware, and Delaware is a likely destination of Alembic’s products, including its proposed generic version of Viibryd® that is at issue in this action.

18. On information and belief, upon approval of Abbreviated New Drug Application (“ANDA”) No. 208202, Alembic Inc., itself and on behalf of Alembic Ltd. and Alembic Global, will market and sell vilazodone (10, 20, and 40 mg) tablets (the “Alembic ANDA Product”) in Delaware and throughout the United States and will derive substantial revenue therefrom.

19. On information and belief, upon approval of ANDA No. 208202, Alembic Ltd., Alembic Global, and Alembic Inc. will place the Alembic ANDA Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will be purchased and used by consumers in Delaware and throughout the United States.

20. On information and belief, as a result of its submission of ANDA No. 208202, Alembic has committed a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has

led and/or will lead to foreseeable harm and injury to Plaintiff Forest Laboratories, LLC, a Delaware company.

21. Alembic Ltd. has previously availed itself of this forum, for example, by asserting counterclaims in other civil actions initiated in this jurisdiction. *See Sanofi v. Alembic Pharm. Ltd.*, C.A. No. 14-424-RGA (D. Del.); *Teijin Ltd. v. Alembic Pharm. Ltd.*, C.A. No. 13-1939-SLR (D. Del.); *Pfizer Inc. v. Breckenridge Pharm., Inc.*, C.A. No. 12-810-SLR (D. Del.). On information and belief, Alembic Ltd. has been a defendant in at least nine ANDA suits in the District of Delaware, and it has not challenged this Court's exercise of personal jurisdiction over it in any of those prior actions.

22. Alembic Global and Alembic Inc. have both waived objections to personal jurisdiction in the District of Delaware. *See Forest Laboratories, LLC v. Alembic Pharm. Ltd.*, C.A. No. 15-158-SLR (D. Del.).

23. The Court has personal jurisdiction over Alembic Ltd., Alembic Global, and Alembic Inc. by virtue of, *inter alia*, the above-mentioned facts.

24. In the alternative, this Court may exercise personal jurisdiction over Alembic Ltd. and Alembic Global pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Alembic Ltd. and Alembic Global are foreign companies not subject to personal jurisdiction in the courts of any state; and (c) Alembic Ltd. and Alembic Global have sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Alembic Ltd. and Alembic Global satisfies due process.

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