IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| FOREST LABORATORIES, LLC and FOREST LABORATORIES HOLDINGS, LTD., | ) | |
| Plaintiffs, | ) | |
| v. | ) | C.A. No. _____ |
| ALEMBIC PHARMACEUTICALS LTD., ALEMBIC GLOBAL HOLDING SA, and ALEMBIC PHARMACEUTICALS, INC., | ) | |
| Defendants. | ) | |

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Forest Laboratories, LLC (f/k/a Forest Laboratories, Inc.) and Forest Laboratories Holdings, Ltd. (collectively, "Forest") file this Complaint for patent infringement against Defendants Alembic Pharmaceuticals Ltd., Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. under 35 U.S.C. §§ 271(e)(2) and (a), (b), and (c). This patent action concerns the pharmaceutical drug product Saphris®. Forest hereby alleges as follows:

**JURISDICTION AND PARTIES**

1. 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.

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

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

4. 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. On information and belief, Alembic Global is a wholly-owned subsidiary of Defendant Alembic Limited.

5. On information and belief, Defendants Alembic Limited and Alembic Global are in the business of developing and manufacturing generic drugs throughout the world. 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 headquarter for all the overseas business in countries like USA, Europe, UAE, Australia and other developed markets." Alembic Global's website identifies Alembic Pharmaceuticals, Inc. as the United States subsidiary of Alembic Global.

6. 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. According to its website, Alembic Inc. "is the 100 % subsidiary of the Alembic Global Holding SA." Further, 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."

7. Defendants Alembic Limited and Alembic Global are subject to personal jurisdiction in this district because, inter alia, alone and/or together with their agent Alembic Inc.,

Defendants Alembic Limited and Alembic Global have committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement against Plaintiffs, including Plaintiff Forest Laboratories, LLC, which is a Delaware limited liability company.

8. This Court also has personal jurisdiction over Defendants Alembic Limited and Alembic Global because, alone and/or together with their agent Alembic Inc. (a Delaware corporation), Defendants Alembic Limited and Alembic Global have, inter alia, purposefully availed themselves of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. On information and belief, Defendants Alembic Limited and Alembic Global, together with Alembic Inc., regularly and continuously transact business within the State of Delaware. On information and belief, Defendant Alembic Limited has previously admitted that "it is 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." *See* Answer, *Sanofi v. Alembic Pharm. Ltd.*, 14-424-RGA (D. Del.).

9. This Court also has personal jurisdiction over Defendant Alembic Limited because Alembic Limited has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this district, and has been previously been sued in this district and has not challenged personal jurisdiction. *See, e.g.*, *Pfizer Inc. v. Breckenridge Pharm., Inc.*, 1:12-cv-810-SLR (consolidated with 1:12-cv-808) (D. Del.); *UCB, Inc. v. Alembic Pharm. Ltd.*, 13-1207-LPS (D. Del.); *Teijin Ltd. v. Alembic Pharm. Ltd.*, 13-1939-SLR (D. Del.).

10. In the alternative, and to the extent either Defendant Alembic Limited or Alembic Global contest jurisdiction in this forum, this Court has personal jurisdiction over Defendants Alembic Limited and Alembic Global under Fed. R. Civ. P. 4(k)(2).

11. Alembic Inc. is subject to personal jurisdiction in this district because it is a Delaware corporation and, on information and belief, it regularly and continuously transacts business within the State of Delaware, including, but not limited to, the regular sale of pharmaceutical products within the State of Delaware.

12. On information and belief, Alembic Inc. is further subject to jurisdiction in this Court because it is the agent, affiliate, representative, and/or alter ego of and/or acts in concert with Defendants Alembic Limited and Alembic Global for purposes of manufacturing, marketing, distributing, and selling generic pharmaceutical products within the United States, including the State of Delaware. On information and belief, the acts of Defendants Alembic Limited and Alembic Global complained of herein 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.

13. This patent infringement action arises under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2). This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

**COUNT I FOR PATENT INFRINGEMENT**
(Infringement of the ’476 Patent Under 35 U.S.C. § 271(e)(2))

14. Plaintiffs reallege and incorporate by reference paragraphs 1-13.

15. United States Patent No. 5,763,476 (“the ’476 patent”), titled “Sublingual or Buccal Pharmaceutical Composition,” was duly and legally issued to inventors Leonardus Petrus

Carla Delbressine and Johannes Hubertus Wieringa by the United States Patent and Trademark Office ("PTO") on June 9, 1998. The PTO issued a certificate of correction for the '476 patent on November 24, 1998. The '476 patent is currently assigned to Plaintiff Forest Laboratories Holdings, Ltd. and expires on June 9, 2020. This expiration date includes a 5-year patent term extension granted by the PTO pursuant to 35 U.S.C. § 156. A true and correct copy of the '476 patent, including its certificate of correction, is attached as Exhibit A. A true and correct copy of the Certificate Extending Patent Term is attached as Exhibit B.

16. Forest Laboratories, Inc. (n/k/a Forest Laboratories, LLC) holds New Drug Application ("NDA") No. 22117, which is directed to the use of Saphris® in the treatment of schizophrenia and bipolar disorder. The FDA approved NDA No. 22117 on August 13, 2009. The '476 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for NDA No. 22117.

17. Plaintiff Forest Laboratories Holdings, Ltd. is the assignee of the '476 patent. Plaintiffs manufacture and sell 5 mg and 10 mg dosage strengths of sublingual tablets containing the active ingredient asenapine maleate in the United States under the brand name Saphris®.

18. On information and belief, Defendants Alembic Limited, Alembic Global, and Alembic Inc. (collectively referred to hereafter as "Alembic") filed, or caused to be filed, ANDA No. 206098 with the FDA under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of 5 mg and 10 mg asenapine maleate tablets ("Alembic's Generic Asenapine Product") in the United States before the expiration of the '476 patent.

19. On information and belief, ANDA No. 206098 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") alleging that the claims of the '476 patent are invalid and/or will not be infringed by Alembic's Generic Asenapine Product.

20. Alembic sent, or caused to be sent, to Plaintiffs a letter dated January 3, 2015 ("Alembic's Notice Letter") notifying Plaintiffs that Alembic had submitted ANDA No. 206098, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Alembic's Notice Letter alleges invalidity of claims 1-6 and 8-13 of the '476 patent. Alembic's Notice Letter alleges noninfringement of claims 3, 7, 8, 11, and 12 of the '476 patent.

21. On information and belief, Alembic seeks approval for the commercial manufacture, use, and sale of at least one formulation for Alembic's Generic Asenapine Product that, if approved, would infringe one or more claims of the '476 patent.

22. On information and belief, Alembic seeks approval of at least one indication for Alembic's Generic Asenapine Product that is claimed in the '476 patent.

23. Under 35 U.S.C. § 271(e)(2)(A), Alembic infringed one or more claims of the '476 patent, in violation of Plaintiffs' patent rights, by submitting to the FDA an ANDA that seeks approval to commercially market—before the expiration date of the '476 patent—Alembic's Generic Asenapine Product. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Alembic's Generic Asenapine Product would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '476 patent. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Alembic's Generic Asenapine Product would contribute to or induce the direct infringement of one or more claims of the '476 patent by users of Alembic's Generic Asenapine Product.

24. On information and belief, Alembic has knowledge of the '476 patent and has filed ANDA No. 206098 seeking authorization to commercially manufacture, use, offer for sale, and sell Alembic's Generic Asenapine Product in the United States. On information and belief,

if the FDA approves ANDA No. 206098, physicians, health care providers, and/or patients will use Alembic's Generic Asenapine Product in accordance with the instructions and/or label provided by Alembic and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '476 patent.

25. On information and belief, Alembic knows and intends that physicians, health care providers, and/or patients will use Alembic's Generic Asenapine Product in accordance with the instructions and/or label provided by Alembic, and will therefore induce infringement of one or more claims of the '476 patent, with the requisite intent.

26. On information and belief, if the FDA approves ANDA No. 206098, Alembic will sell or offer to sell its Generic Asenapine Product specifically labeled for use in practicing one or more claims of the '476 patent, wherein Alembic's Generic Asenapine Product is a material part of the claimed invention, wherein Alembic knows that physicians will prescribe and patients will use Alembic's Generic Asenapine Product in accordance with the instructions and/or label provided by Alembic in practicing one or more claims of the '476 patent, and wherein asenapine is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Alembic will thus contribute to the infringement of one or more claims of the '476 patent.

27. Plaintiffs will be substantially and irreparably harmed by Alembic's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

**COUNT II FOR DECLARATORY JUDGMENT**
(Declaratory Judgment of Patent Infringement of the '476 Patent Under 35 U.S.C. § 271 (a), (b), and/or (c))

28. Plaintiffs reallege and incorporate by reference paragraphs 1-27.

29. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

30. On information and belief, and based on information provided by Alembic, if the FDA approves Alembic's Generic Asenapine Product for use and sale in the United States, Alembic would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '476 patent under 35 U.S.C. § 271(a), in violation of Plaintiffs' patent rights by making, using, offering to sell, selling, and/or importing Alembic's Generic Asenapine Product for use and sale within the United States.

31. On information and belief, Alembic has knowledge of the '476 patent and has filed ANDA No. 206098 seeking authorization to commercially manufacture, use, offer for sale, and sell Alembic's Generic Asenapine Product in the United States. On information and belief, if the FDA approves ANDA No. 206098, physicians, health care providers, and/or patients will use Alembic's Generic Asenapine Product in accordance with the instructions and/or label provided by Alembic and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '476 patent under 35 U.S.C. § 271(a), in violation of Plaintiffs' patent rights.

32. On information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Alembic's Generic Asenapine Product so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the '476 patent, including at least claim 4, under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiffs' patent rights.

33. On information and belief, Alembic knows and intends that physicians, health care providers, and/or patients will use Alembic's Generic Asenapine Product in accordance with the instructions and/or label provided by Alembic and will therefore induce infringement of one or more claims of the '476 patent with the requisite intent under 35 U.S.C. § 271(b).

34. On information and belief, if the FDA approves ANDA No. 206098, Alembic will sell or offer to sell its Generic Asenapine Product specifically labeled for use in practicing one or more claims of the '476 patent, including at least claim 4, wherein Alembic's Generic Asenapine Product is a material part of the invention claimed in the '476 patent, wherein Alembic knows that physicians will prescribe and patients will use Alembic's Generic Asenapine Product for practicing one or more claims in the '476 patent, and wherein asenapine is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Alembic will thus contribute to the infringement of the '476 patent under 35 U.S.C. § 271(c).

35. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Alembic as to liability for the infringement of the '476 patent claims. Alembic's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Alembic's threatened imminent actions.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor as follows:

a) declare that United States Patent No. 5,763,476 is valid;

b) declare that, under 35 U.S.C. § 271(e)(2)(A), Alembic infringed United States Patent No. 5,763,476 by submitting ANDA No. 206098 to the FDA to obtain approval to

commercially manufacture, use, offer for sale, or sell within the United States, or import into the United States Alembic's Generic Asenapine Product prior to the expiration of said patent;

c) declare that Alembic's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Alembic's Generic Asenapine Product prior to the expiration of United States Patent No. 5,763,476 constitutes infringement of one or more claims of said patent under 35 U.S.C. §§ 271 (a), (b), and/or (c);

d) order that the effective date of any FDA approval of Alembic's Generic Asenapine Product shall be no earlier than the expiration date of United States Patent No. 5,763,476, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(A);

e) enjoin Alembic, and all persons acting in concert with Alembic, from seeking, obtaining, or maintaining final approval of ANDA No. 206098 until the expiration of United States Patent No. 5,763,476, including any exclusivities or extensions to which Plaintiffs are or become entitled;

f) enjoin Alembic, and all persons acting in concert with Alembic, from commercially manufacturing, using, offering for sale, or selling Alembic's Generic Asenapine Product within the United States, or importing Alembic's Generic Asenapine Product into the United States, until the expiration of United States Patent No. 5,763,476, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(B);

g) enjoin Alembic, and all persons acting in concert with Alembic, from commercially manufacturing, using, offering for sale, or selling Alembic's Generic Asenapine Product within the United States, or importing Alembic's Generic Asenapine Product into the

United States, until the expiration of United States Patent No. 5,763,476, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 283;

h) declare this to be an exceptional case and award Plaintiffs their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4); and

i) grant Plaintiffs such further and additional relief that this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Maryellen Noreika*

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

*Attorneys for Plaintiffs*

OF COUNSEL:

Charles E. Lipsey
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
Two Freedom Square
11955 Freedom Drive.
Reston, VA 20190-5675
(571) 203-2700

Howard W. Levine
Sanya Sukduang
Jonathan R. Davies
Seth R. Ogden
Aaron V. Gleaton
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000

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