IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC and FOREST LABORATORIES HOLDINGS, LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 14-1119 (SLR) (SRF)
	)	**CONSOLIDATED**
SIGMAPHARM LABORATORIES, LLC, et al.	)	
Defendants.	)	

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Forest Laboratories, LLC (f/k/a Forest Laboratories, Inc.) and Forest Laboratories Holdings, Ltd., (collectively, "Forest") file this Amended Complaint for patent infringement against Defendant Sigmapharm Laboratories, LLC ("Sigmapharm") under 35 U.S.C. §§ 271(e)(2), (a), (b), and (c). This patent action concerns the pharmaceutical drug product Saphris®. Plaintiffs hereby allege 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. Defendant Sigmapharm Laboratories, LLC, admits that it is a limited liability company organized and existing under the laws of the State of Pennsylvania, having its principal place of business at 3375 Progress Drive, Bensalem, Pennsylvania 19020. (D.I. 43 at ¶3.)

4. On information and belief, Sigmapharm has derived substantial revenue from the sale of its products in Delaware and throughout the United States.

5. This Court has personal jurisdiction over Sigmapharm by virtue of, among other things: (1) its sale and distribution of generic drugs in Delaware; and (2) its course of conduct that is designed to cause the performance of the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Plaintiff Forest Laboratories, LLC, which is a Delaware limited liability company.

6. Sigmapharm does not contest personal jurisdiction and venue in this judicial district. (*Id.* at ¶¶5-6.)

7. 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))

8. Plaintiffs reallege and incorporate by reference paragraphs 1-7.

9. 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.

10. 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.

11. 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®.

12. On information and belief, on August 13, 2013, Sigmapharm filed, or caused to be filed, ANDA No. 206107 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 sublingual asenapine maleate tablets ("Sigmapharm's Generic Asenapine Product") in the United States before the expiration of the '476 patent.

13. On information and belief, ANDA No. 206107 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 Sigmapharm's Generic Asenapine Product.

14. Sigmapharm sent, or caused to be sent, to Plaintiffs a letter dated August 7, 2014 ("Sigmapharm's 1st Notice Letter") notifying Plaintiffs that Sigmapharm had submitted ANDA No. 206107, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Sigmapharm's

1st Notice Letter alleged, *inter alia*, invalidity and noninfringement of certain claims of the '476 patent. Sigmapharm's 1st Notice Letter did not raise a noninfringement defense with regard to claim 4 of the '476 patent.

15. On April 13, 2015, Sigmapharm sent, or caused to be sent, to Plaintiffs a letter ("Sigmapharm's 2nd Notice Letter") notifying Plaintiffs that Sigmapharm amended its ANDA No. 206107 and provided information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Sigmapharm's 2nd Notice Letter alleged invalidity and noninfringement of certain claims of U.S. Patent No. 8,022,228.

16. On March 29, 2017, Sigmapharm sent, or caused to be sent, to Plaintiffs a letter ("Sigmapharm's 3rd Notice Letter") notifying Plaintiffs that Sigmapharm amended its ANDA No. 206107 and provided information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Sigmapharm's 3nd Notice Letter alleged, *inter alia*, invalidity and noninfringement of certain claims of the '476 patent.

17. Sigmpharm's 3rd Notice Letter represented that Sigmapharm had submitted to FDA a new certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("the 2017 Paragraph IV certification") for the '476 patent in connection with ANDA No. 206107. On information and belief, the 2017 Paragraph IV certification alleges that the claims of the '476 patent are invalid and/or will not be infringed by Sigmapharm's Generic Asenapine Product.

18. On information and belief, Sigmapharm seeks approval for the commercial manufacture, use, and sale of at least one formulation for Sigmapharm's Generic Asenapine Product that is claimed in the '476 patent.

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

20. Under 35 U.S.C. § 271(e)(2)(A), Sigmapharm 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—Sigmapharm's Generic Asenapine Product. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Sigmapharm'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 Sigmapharm's Generic Asenapine Product would contribute to or induce the direct infringement of one or more claims of the '476 patent by users of Sigmapharm's Generic Asenapine Product.

21. On information and belief, Sigmapharm has knowledge of the '476 patent and has filed ANDA No. 206107 seeking authorization to commercially manufacture, use, offer for sale, and sell Sigmapharm's Generic Asenapine Product in the United States. On information and belief, if the FDA approves ANDA No. 206107, physicians, health care providers, and/or patients will use Sigmapharm's Generic Asenapine Product in accordance with the instructions and/or label provided by Sigmapharm and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '476 patent.

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

23. On information and belief, if the FDA approves ANDA No. 206107, Sigmapharm 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 Sigmapharm's Generic Asenapine Product is a material part of the claimed invention, wherein Sigmapharm knows that physicians will prescribe and patients will use Sigmapharm's Generic Asenapine Product in accordance with the instructions and/or label provided by Sigmapharm 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, Sigmapharm will thus contribute to the infringement of one or more claims of the '476 patent.

24. Plaintiffs will be substantially and irreparably harmed by Sigmapharm'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))

25. Plaintiffs reallege and incorporate by reference paragraphs 1-24.

26. 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.

27. On information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Sigmapharm's Generic Asenapine Product, if approved by the FDA, will infringe literally and/or under 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.

28. On information and belief, Sigmapharm has knowledge of the '476 patent and has filed ANDA No. 206107 seeking authorization to commercially manufacture, use, offer for sale, and sell Sigmapharm's Generic Asenapine Product in the United States. On information and

belief, if the FDA approves ANDA No. 206107, physicians, health care providers, and/or patients will use Sigmapharm's Generic Asenapine Product in accordance with the instructions and/or label provided by Sigmapharm 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.

29. On information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Sigmapharm'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, under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiffs' patent rights.

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

31. On information and belief, if the FDA approves ANDA No. 206107, Sigmapharm 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 Sigmapharm's Generic Asenapine Product is a material part of the invention claimed in the '476 patent, wherein Sigmapharm knows that physicians will prescribe and patients will use Sigmapharm'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, Sigmapharm will thus contribute to the infringement of the '476 patent under 35 U.S.C. § 271(c).

32. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Sigmapharm as to liability for the infringement of the '476 patent claims. Sigmapharm's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Sigmapharm'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), Sigmapharm infringed United States Patent No. 5,763,476 by submitting ANDA No. 206107 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 Sigmapharm's Generic Asenapine Product prior to the expiration of said patents;

c) declare that Sigmapharm's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Sigmapharm'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 Sigmapharm'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 Sigmapharm, and all persons acting in concert with Sigmapharm, from seeking, obtaining, or maintaining final approval of ANDA No. 206107 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 Sigmapharm, and all persons acting in concert with Sigmapharm, from commercially manufacturing, using, offering for sale, or selling Sigmapharm's Generic Asenapine Product within the United States, or importing Sigmapharm'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 Sigmapharm, and all persons acting in concert with Sigmapharm, from commercially manufacturing, using, offering for sale, or selling Sigmapharm's Generic Asenapine Product within the United States, or importing Sigmapharm'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
Courtney B. Casp
Jorge F. Gonzalez
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000

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