

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC and)
FOREST LABORATORIES HOLDINGS,)
LTD.,)
)
Plaintiffs,)
)
v.) C.A. No. _____
)
AMNEAL PHARMACEUTICALS, LLC,)
AMNEAL PHARMACEUTICALS OF NEW)
YORK, LLC and AMNEAL)
PHARMACEUTICALS CO. INDIA PVT.)
LTD.,)
)
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 Amneal Pharmaceuticals, LLC (“Amneal Pharma”), Amneal Pharmaceuticals of New York, LLC (“Amneal NY”), and Amneal Pharmaceuticals Co. India Pvt. Ltd. (“Amneal India”) (collectively, “Amneal” or “Defendants”) under 35 U.S.C. §§ 271(e)(2), (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, Amneal Pharma is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807-2863.

4. On information and belief, Amneal Pharma is a generic pharmaceutical company in the business of marketing and distributing generic drug products. On information and belief, Amneal Pharma directly and through its affiliates markets and sells drug products in the State of Delaware and throughout the United States. Amneal Pharma is also qualified to do business in Delaware and has appointed a registered agent for service of process in Delaware.

5. Amneal Pharma is subject to personal jurisdiction in this district because, *inter alia*, Amneal Pharma has 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.

6. This Court also has personal jurisdiction over Amneal Pharma because Amneal Pharma has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Amneal Pharma regularly and continuously transacts business within the State of Delaware.

7. On information and belief, Amneal Pharma derives substantial revenue from the sale of its products in Delaware and throughout the United States.

8. This Court also has personal jurisdiction over Amneal Pharma because Amneal Pharma has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this district, and has previously been sued in this district and has not challenged personal jurisdiction. *See, e.g., Forest Laboratories, Inc. v. Amneal Pharmaceuticals, LLC*, 1:13-cv-01737-SLR (D. Del.) (consolidated with 1:13-cv-1602-SLR); *Endo Pharmaceuticals Inc. v. Amneal*

Pharmaceuticals, LLC, 1:14-cv-1382-RGA (D. Del.); *UCB, Inc. v. Amneal Pharmaceuticals, LLC*, 1:13-cv-1208-LPS (D. Del.); *Forest Laboratories, Inc. v. Amneal Pharmaceuticals, LLC*, 1:14-cv-508-LPS (D. Del.); *Abbott Laboratories v. Amneal Pharmaceuticals, LLC*, 1:12-cv-235-SLR (D. Del.).

9. This Court has personal jurisdiction over Amneal Pharma by virtue of, among other things: (1) its incorporation in Delaware; (2) its registration to do business in Delaware, including appointment of a registered agent; (3) its sale and distribution of generic drugs in Delaware; (4) 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 corporation; (5) its purposeful availment of this forum previously for the purpose of litigating a patent dispute; and (6) its admission that it is subject to the Court's jurisdiction in other patent litigations.

10. On information and belief, Amneal NY is a Delaware limited liability company with a principal place of business at 85 Adams Avenue, Hauppauge, New York 11788.

11. On information and belief, Amneal NY is a pharmaceutical company that directly or indirectly through its affiliates and agents, including Amneal Pharma and Amneal India, formulates, manufactures, packages and markets generic drug products for distribution in the District of Delaware and throughout the United States. Amneal NY is also qualified to do business in Delaware and has appointed a registered agent for service of process in Delaware.

12. On information and belief, Amneal NY is a subsidiary of Amneal India, a subsidiary of Amneal Pharma, and Amneal NY acts as an agent for Amneal India in connection with Amneal Pharma in the sale of pharmaceutical products in the United States, including the State of Delaware.

13. This Court also has personal jurisdiction over Amneal NY because Amneal NY has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this district, and has previously been sued in this district and has not challenged personal jurisdiction. *See, e.g., Forest Laboratories, Inc. v. Amneal Pharmaceuticals, LLC*, 1:13-cv-01737-SLR (D. Del.) (consolidated with 1:13-cv-1602-SLR); *Endo Pharmaceuticals Inc. v. Amneal Pharmaceuticals, LLC*, 1:14-cv-1382-RGA (D. Del.); *UCB, Inc. v. Amneal Pharmaceuticals, LLC*, 1:13-cv-1208-LPS (D. Del.); *Forest Laboratories, Inc. v. Amneal Pharmaceuticals, LLC*, 1:14-cv-508-LPS (D. Del.).

14. This Court has personal jurisdiction over Amneal NY by virtue of, among other things: (1) its incorporation in Delaware; (2) its registration to do business in Delaware, including appointment of a registered agent; (3) its sale and distribution of generic drugs in Delaware; (4) 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 corporation; (5) its purposeful availment of this forum previously for the purpose of litigating a patent dispute; and (6) its admission that it is subject to the Court's jurisdiction in other patent litigations.

15. On information and belief, Amneal India is a corporation organized and existing under the laws of India, having a principal place of business at 882/1-871, Nr. Hotel Kankavati, Sarkhej Bavla Highway, Village - Rajoda, Bavla, Ahmedabad-382220, Gujarat, India.

16. On information and belief, Amneal India is a pharmaceutical company that conducts its North American operations, in part, through Amneal Pharma and together they collaborate in formulating, manufacturing, packaging and marketing generic drug products for distribution in the District of Delaware and throughout the United States.

17. On information and belief, Amneal India is a wholly-owned subsidiary of Amneal Pharma, and Amneal India, in connection with its subsidiary Amneal NY, acts as an agent for Amneal Pharma in the sale of pharmaceutical products in the United States, including the State of Delaware.

18. On information and belief, Amneal Pharma and Amneal India hold themselves out as a unitary entity for purposes of research and development of generic products. For example, Amneal maintains a website, www.amneal.in/operation/research.php, where it represents that Amneal India's Research & Development Centre "develops over a dozen FDA ANDAs from this Centre annually across all dosage forms—all of which are to be filed from our US facilities."

19. On information and belief, based in part on representations on their website, Amneal Pharma and Amneal India worked collaboratively on the preparation and submission of ANDA No. 207307.

20. On information and belief, Amneal India does business in the State of Delaware and has derived substantial revenue from sales of pharmaceutical products in Delaware.

21. This Court also has personal jurisdiction over Amneal India because Amneal India has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this district, and has previously been sued in this district and has not challenged personal jurisdiction. *See, e.g., Forest Laboratories, Inc. v. Amneal Pharmaceuticals, LLC*, 1:13-cv-01737-SLR (D. Del.) (consolidated with 1:13-cv-1602-SLR); *Abbott Laboratories v. Amneal Pharmaceuticals, LLC*, 1:12-cv-235-SLR (D. Del.).

22. This Court has personal jurisdiction over Amneal India by virtue of, among other things: (1) its presence in Delaware, including through Amneal Pharma; (2) its sale and distribution of generic drugs in Delaware; (3) 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 corporation; (4) its purposeful availment of this forum previously for the purpose of litigating a patent dispute; and (5) its admission that it is subject to the Court's jurisdiction in other patent litigations.

23. 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))

24. Plaintiffs reallege and incorporate by reference paragraphs 1-23.

25. 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, with pediatric exclusivity through December 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.

26. 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.

27. 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[®].

28. On information and belief, Amneal filed, or caused to be filed, ANDA No. 207307 with the FDA under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of asenapine maleate tablets (“Amneal’s Generic Asenapine Product”) in the United States before the expiration of the ’476 patent.

29. On information and belief, ANDA No. 207307 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 Amneal’s Generic Asenapine Product.

30. Amneal sent, or caused to be sent, to Plaintiffs a letter dated April 13, 2015, (“Amneal’s Notice Letter”) notifying Plaintiffs that Amneal had submitted ANDA No. 207307, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Amneal’s Notice Letter alleges invalidity and noninfringement of certain claims of the ’476 patent. Amneal’s Notice Letter does not raise a noninfringement defense with regard to claims 1, 2, 5, and 6 of the ’476 patent.

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

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

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

34. On information and belief, Amneal has knowledge of the '476 patent and has filed ANDA No. 207307 seeking authorization to commercially manufacture, use, offer for sale, and sell Amneal's Generic Asenapine Product in the United States. On information and belief, if the FDA approves ANDA No. 207307, physicians, health care providers, and/or patients will use Amneal's Generic Asenapine Product in accordance with the instructions and/or label provided by Amneal and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '476 patent.

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

36. On information and belief, if the FDA approves ANDA No. 207307, Amneal 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 Amneal's Generic Asenapine Product is a material part of the claimed invention, wherein Amneal knows that physicians will prescribe and patients will use Amneal's Generic Asenapine Product in accordance with the instructions and/or label provided by Amneal 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, Amneal will thus contribute to the infringement of one or more claims of the '476 patent.

37. Plaintiffs will be substantially and irreparably harmed by Amneal'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))

38. Plaintiffs reallege and incorporate by reference paragraphs 1-37.

39. 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.

40. On information and belief, and based on information provided by Amneal, if the FDA approves Amneal's Generic Asenapine Product for use and sale in the United States, Amneal 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 Amneal's Generic Asenapine Product for use and sale within the United States.

41. On information and belief, Amneal has knowledge of the '476 patent and has filed ANDA No. 207307 seeking authorization to commercially manufacture, use, offer for sale, and sell Amneal's Generic Asenapine Product in the United States. On information and belief, if the FDA approves ANDA No. 207307, physicians, health care providers, and/or patients will use Amneal's Generic Asenapine Product in accordance with the instructions and/or label provided by Amneal 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.

42. On information and belief, the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Amneal'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.

43. On information and belief, Amneal knows and intends that physicians, health care providers, and/or patients will use Amneal'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).

44. On information and belief, if the FDA approves ANDA No. 207307, Amneal 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 Amneal's Generic Asenapine Product is a material part of the invention claimed in the '476 patent, wherein Amneal knows that physicians will prescribe and patients will use Amneal'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, Amneal will thus contribute to the infringement of the '476 patent under 35 U.S.C. § 271(c).

45. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Amneal as to liability for the infringement of the '476 patent claims. Amneal's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Amneal'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), Amneal infringed United States Patent No. 5,763,476 by submitting ANDA No. 207307 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 Amneal's Generic Asenapine Product prior to the expiration of said patent;
- c) declare that Amneal's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Amneal'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 Amneal'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 Amneal, and all persons acting in concert with Amneal, from seeking, obtaining, or maintaining final approval of ANDA No. 207307 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 Amneal, and all persons acting in concert with Amneal, from commercially manufacturing, using, offering for sale, or selling Amneal's Generic Asenapine Product within the United States, or importing Amneal'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 Amneal, and all persons acting in concert with Amneal, from commercially manufacturing, using, offering for sale, or selling Amneal's Generic Asenapine Product within the United States, or importing Amneal'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

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