IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC, FOREST LABORATORIES HOLDINGS, LTD., ALLERGAN USA, INC., and ADAMAS PHARMACEUTICALS, INC., Plaintiffs, v. AMNEAL PHARMACEUTICALS LLC and AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, Defendants.	Civil Action No. 15-756-LPS

AMENDED COMPLAINT

Plaintiffs Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd., Allergan USA, Inc., and Adamas Pharmaceuticals, Inc. (collectively, "Plaintiffs"), for their Amended Complaint against Defendants Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (collectively, "Amneal" or "Defendants"), hereby allege as follows.

PARTIES

1. Plaintiff Forest Laboratories, LLC 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. Plaintiff Allergan USA, Inc. is a Delaware corporation having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054 (referred to herein, together with Forest Laboratories, LLC and Forest Laboratories Holdings, Ltd., as "Forest").

4. Plaintiff Adamas Pharmaceuticals, Inc. ("Adamas") is a Delaware corporation having a principal place of business at 1900 Powell Street, Suite 750, Emeryville, California 94608.

5. Upon information and belief, Defendant Amneal Pharmaceuticals LLC is a Delaware limited liability company having a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807. Upon information and belief, Defendant Amneal Pharmaceuticals, LLC manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including through its subsidiary and agent Amneal Pharmaceuticals of New York, LLC.

6. Upon information and belief, Defendant Amneal Pharmaceuticals of New York, LLC is a Delaware limited liability company having a principal place of business at 85 Adams Avenue, Hauppage, New York 11788. Upon information and belief, Defendant Amneal Pharmaceuticals of New York, LLC is a wholly owned subsidiary of Amneal Pharmaceuticals, LLC. Upon information and belief, Defendant Amneal Pharmaceuticals of New York, LLC manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including as a subsidiary and agent of Amneal Pharmaceuticals, LLC.

NATURE OF THE ACTION

7. This is a civil action for the infringement of one or more of the following patents

by each of the Defendants: United States Patent Nos. 8,039,009 ("the '009 patent"); 8,058,291 ("the '291 patent"); 8,168,209, as corrected ("the '209 patent"); 8,173,708 ("the '708 patent"); 8,283,379 ("the '379 patent"); 8,293,794 ("the '794 patent"); 8,329,752 ("the '752 patent"); 8,338,485 ("the '485 patent"); 8,338,486 ("the '486 patent"); 8,362,085 ("the '085 patent"); 8,580,858, as corrected ("the '858 patent"); and 8,598,233 ("the '233 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Defendant Amneal Pharmaceuticals LLC by virtue of, *inter alia*, the fact that Amneal Pharmaceuticals LLC is a Delaware limited liability company.

10. This Court has personal jurisdiction over Defendant Amneal Pharmaceuticals of New York, LLC by virtue of, *inter alia*, the fact that Amneal Pharmaceuticals of New York, LLC is a Delaware limited liability company.

11. Venue is proper in this judicial district as to all Defendants pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS

12. On October 18, 2011, the '009 patent, titled "Modified Release Formulations Of Memantine Oral Dosage Forms," was duly and legally issued by the United States Patent and Trademark Office ("USPTO"). Since the issuance of the '009 patent, Forest Laboratories Holdings, Ltd. has been, and continues to be, the '009 patent's sole owner. A copy of the '009 patent is attached hereto as Exhibit A.

13. On November 15, 2011, the '291 patent, titled "Methods And Compositions For The Treatment Of CNS-Related Conditions," was duly and legally issued by the USPTO. Since January 26, 2012, Adamas has been, and continues to be, the '291 patent's sole owner. Forest is the exclusive licensee of the '291 patent with respect to commercializing pharmaceutical products containing memantine in combination with donepezil in the United States. A copy of the '291 patent is attached hereto as Exhibit B.

14. On May 1, 2012, the '209 patent, titled "Method And Composition For Administering An NMDA Receptor Antagonist To A Subject," was duly and legally issued by the USPTO. The USPTO issued a certificate of correction for the '209 patent on June 26, 2012. Since the issuance of the '209 patent, Adamas has been, and continues to be, the '209 patent's sole owner. Forest is the exclusive licensee of the '209 patent with respect to commercializing pharmaceutical products containing memantine in combination with donepezil in the United States. A copy of the '209 patent, including its certificate of correction, is attached hereto as Exhibit C.

15. On May 8, 2012, the '708 patent, titled "Method And Composition For Administering An NMDA Receptor Antagonist To A Subject," was duly and legally issued by the USPTO. Since the issuance of the '708 patent, Adamas has been, and continues to be, the '708 patent's sole owner. Forest is the exclusive licensee of the '708 patent with respect to commercializing pharmaceutical products containing memantine in combination with donepezil in the United States. A copy of the '708 patent is attached hereto as Exhibit D.

16. On October 9, 2012, the '379 patent, titled "Method And Compositions For The Treatment Of CNS-Related Conditions," was duly and legally issued by the USPTO. Since the issuance of the '379 patent, Adamas has been, and continues to be, the '379 patent's sole owner.

Forest is the exclusive licensee of the '379 patent with respect to commercializing pharmaceutical products containing memantine in combination with donepezil in the United States. A copy of the '379 patent is attached hereto as Exhibit E.

17. On October 23, 2012, the '794 patent, titled "Methods And Compositions For The Treatment Of CNS-Related Conditions," was duly and legally issued by the USPTO. Since the issuance of the '794 patent, Adamas has been, and continues to be, the '794 patent's sole owner. Forest is the exclusive licensee of the '794 patent with respect to commercializing pharmaceutical products containing memantine in combination with donepezil in the United States. A copy of the '794 patent is attached hereto as Exhibit F.

18. On December 11, 2012, the '752 patent, titled "Composition For Administering An NMDA Receptor Antagonist To A Subject," was duly and legally issued by the USPTO. Since the issuance of the '752 patent, Adamas has been, and continues to be, the '752 patent's sole owner. Forest is the exclusive licensee of the '752 patent with respect to commercializing pharmaceutical products containing memantine in combination with donepezil in the United States. A copy of the '752 patent is attached hereto as Exhibit G.

19. On December 25, 2012, the '485 patent, titled "Compositions For The Treatment of CNS-Related Conditions," was duly and legally issued by the USPTO. Since the issuance of the '485 patent, Adamas has been, and continues to be, the '485 patent's sole owner. Forest is the exclusive licensee of the '485 patent with respect to commercializing pharmaceutical products containing memantine in combination with donepezil in the United States. A copy of the '485 patent is attached hereto as Exhibit H.

20. On December 25, 2012, the '486 patent, titled "Methods For The Treatment of CNS-Related Conditions," was duly and legally issued by the USPTO. Since the issuance of the

'486 patent, Adamas has been, and continues to be, the '486 patent's sole owner. Forest is the exclusive licensee of the '486 patent with respect to commercializing pharmaceutical products containing memantine in combination with donepezil in the United States. A copy of the '486 patent is attached hereto as Exhibit I.

21. On January 29, 2013, the '085 patent, titled "Method For Administering An NMDA Receptor Antagonist To A Subject," was duly and legally issued by the USPTO. Since the issuance of the '085 patent, Adamas has been, and continues to be, the '085 patent's sole owner. Forest is the exclusive licensee of the '085 patent with respect to commercializing pharmaceutical products containing memantine in combination with donepezil in the United States. A copy of the '085 patent is attached hereto as Exhibit J.

22. On November 12, 2013, the '858 patent, titled "Compositions For the Treatment Of CNS-Related Conditions," was duly and legally issued by the USPTO. The USPTO issued a certificate of correction for the '858 patent on October 14, 2014. Since the issuance of the '858 patent, Adamas has been, and continues to be, the '858 patent's sole owner. Forest is the exclusive licensee of the '858 patent with respect to commercializing pharmaceutical products containing memantine in combination with donepezil in the United States. A copy of the '858 patent, including its certificate of correction, is attached hereto as Exhibit K.

23. On December 3, 2013, the '233 patent, titled "Method For Administering An NMDA Receptor Antagonist To A Subject," was duly and legally issued by the USPTO. Since the issuance of the '233 patent, Adamas has been, and continues to be, the '233 patent's sole owner. Forest is the exclusive licensee of the '233 patent with respect to commercializing pharmaceutical products containing memantine in combination with donepezil in the United States. A copy of the '233 patent is attached hereto as Exhibit L.

24. Forest Laboratories, LLC holds New Drug Application ("NDA") 206439 for NAMZARIC® brand memantine hydrochloride extended-release and donepezil hydrochloride capsules. The '009 patent, the '291 patent, the '209 patent, the '708 patent, the '379 patent, the '794 patent, the '752 patent, the '485 patent, the '486 patent, the '085 patent, the '858 patent, and the '233 patent are all listed for NAMZARIC® in the United States Food and Drug Administration ("FDA") publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book").

25. NAMZARIC® is manufactured by Forest Laboratories Ireland Ltd. for Forest Pharmaceuticals, Inc., a subsidiary of Forest Laboratories, LLC, for subsequent sale in the United States.

26. Allergan USA, Inc. is the exclusive distributor of NAMZARIC® in the United States.

ACTS GIVING RISE TO THIS ACTION

27. Upon information and belief, on or before July 13, 2015, Amneal submitted ANDA No. 208328 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 208328 seeks FDA approval for the commercial manufacture, use, and sale of generic capsule products containing 14 or 28 milligrams of extended-release memantine hydrochloride and 10 milligrams of donepezil hydrochloride as the active ingredients ("the Generic Products"). ANDA No. 208328 specifically seeks FDA approval to market the Generic Products prior to the expiration of the '009 patent, the '291 patent, the '209 patent, the '708 patent, the '379 patent, the '794 patent, the '752 patent, the '485 patent, the '486 patent, the '085 patent, the '858 patent, and the '233 patent.

28. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act,

ANDA No. 208328 alleges that the claims of the '009 patent, the '291 patent, the '209 patent, the '708 patent, the '379 patent, the '794 patent, the '752 patent, the '485 patent, the '486 patent, the '085 patent, the '858 patent, and the '233 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Generic Products. Plaintiffs received written notification of ANDA No. 208328 and its § 505(j)(2)(A)(vii)(IV) allegations with respect to the '009 patent, the '291 patent, the '209 patent, the '708 patent, the '379 patent, the '794 patent, the '752 patent, the '485 patent, the '486 patent, the '085 patent, the '858 patent, and the '233 patent on or about July 15, 2015.

29. Amneal's submission of ANDA No. 208328 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of at least Claims 1, 2 and 21-23 of the '009 patent, Claims 3, 19, 20, 22, 37, 41, 48, 49, 50 and 53-57 of the '291 patent, Claims 1 and 10-14 of the '209 patent, Claims 12 and 16 of the '708 patent, Claims 2, 9, 11 and 12 of the '379 patent, Claims 1-3, 9, 10, 14-16, 23, 24 and 28 of the '794 patent, Claims 1 and 9 of the '752 patent, Claims 1, 3, 9 and 11 of the '485 patent, Claims 1, 3, 7 and 9 of the '486 patent, Claims 1 and 7 of the '085 patent, Claims 1, 2, 4 and 10 of the '858 patent, and Claims 1 and 4 of the '233 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Amneal commercially makes, uses, offers to sell, or sells within the United States, or imports into the United States, the Generic Products, or induces or contributes to any such conduct, it would further infringe these claims of the '009 patent, the '291 patent, the '209 patent, the '708 patent, the '379 patent, the '794 patent, the '752 patent, the '485 patent, the '486 patent, the '085 patent, the '858 patent, and the '233 patent under 35 U.S.C. § 271(a), (b), and/or (c). Relying on the representations set out in Amneal's notice of Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95, and fact discovery regarding the Amneal Generic Products to date, including production of Amneal's

core technical documents pursuant to Paragraph 4(b) of the Default Standard for Discovery, Plaintiffs do not allege at this time that the 14 mg/10 mg dosage form of the Amneal Generic Product infringes the '009 patent. To the extent that discovery in this action demonstrates that assertion of the '009 patent against the 14 mg/10 mg dosage form of the Amneal Generic Product is warranted, Plaintiffs reserve the right to assert it.

30. Upon information and belief, each of Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC has participated in, contributed to, aided, abetted, and/or induced infringement of the '009 patent, the '291 patent, the '209 patent, the '708 patent, the '379 patent, the '794 patent, the '752 patent, the '485 patent, the '486 patent, the '085 patent, the '858 patent, and the '233 patent and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '009 patent, the '291 patent, the '209 patent, the '708 patent, the '379 patent, the '794 patent, the '752 patent, the '485 patent, the '486 patent, the '085 patent, the '858 patent, and the '233 patent once the Generic Products are commercially made, used, offered for sale, or sold in the United States, or imported into the United States. Each of Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC is jointly and severally liable for the infringement of the '009 patent, the '291 patent, the '209 patent, the '708 patent, the '379 patent, the '794 patent, the '752 patent, the '485 patent, the '486 patent, the '085 patent, the '858 patent, and the '233 patent.

31. Upon information and belief, each of Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC have knowledge that if they were to receive approval from the FDA to market the products described in ANDA No. 208328 and made said products available for sale and/or use during the proposed shelf life of the products before expiration of the '009 patent, the '291 patent, the '209 patent, the '708 patent, the '379 patent, the '794 patent,

the '752 patent, the '485 patent, the '486 patent, the '085 patent, the '858 patent, and/or the '233 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. Upon information and belief, Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC have knowledge of such infringing use and also know that the products described in ANDA No. 208328 are not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather are especially made and/or adapted for use in the direct infringement of the '009 patent, the '291 patent, the '209 patent, the '708 patent, the '379 patent, the '794 patent, the '752 patent, the '485 patent, the '486 patent, the '085 patent, the '858 patent, and/or the '233 patent.

32. Amneal was aware of the '009 patent, the '291 patent, the '209 patent, the '708 patent, the '379 patent, the '794 patent, the '752 patent, the '485 patent, the '486 patent, the '085 patent, the '858 patent, and the '233 patent prior to filing ANDA No. 208328, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to those patents. Upon information and belief, the proposed label for the Generic Products induces others to infringe the '009 patent, the '291 patent, the '209 patent, the '708 patent, the '379 patent, the '794 patent, the '752 patent, the '485 patent, the '486 patent, the '085 patent, the '858 patent, and the '233 patent, and based on Amneal's § 505(j)(2)(A)(vii)(IV) allegations, Amneal possesses the specific intent to encourage others to infringe.

33. On April 21, 2014, Forest and Adamas filed a Complaint for patent infringement against Amneal asserting infringement of the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent in connection with the 7, 14, 21, and 28 milligram dosage forms of a proposed generic version of Namenda XR®. That patent infringement action was styled *Forest Laboratories, Inc., et al. v. Amneal Pharmaceuticals LLC, et al.*, Civil Action

14-508-LPS (D. Del.) and was subsequently dismissed pursuant to a September 10, 2015 stipulation of the parties. (*See* D.I. 208; Sept. 11, 2015 Order terminating case.)

34. Amneal's actions render this an exceptional case under 35 U.S.C. § 285.

35. Plaintiffs will be irreparably harmed by Amneal's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Amneal has infringed the '009 patent, the '291 patent, the '209 patent, the '708 patent, the '379 patent, the '794 patent, the '752 patent, the '485 patent, the '486 patent, the '085 patent, the '858 patent, and the '233 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of ANDA No. 208328 shall not be earlier than the expiration date of the last to expire of the '009 patent, the '291 patent, the '209 patent, the '708 patent, the '379 patent, the '794 patent, the '752 patent, the '485 patent, the '486 patent, the '085 patent, the '858 patent, and the '233 patent, including any extensions or exclusivities;

C. That Amneal, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially making, using, offering to sell, or selling in the United States, or importing into the United States, the Generic Products, and any other product that infringes or induces or contributes to the infringement of the '009 patent, the '291 patent, the '209 patent, the '708 patent, the '379 patent, the '794 patent, the '752 patent, the '485 patent, the '486 patent, the '085 patent, the '858 patent, and the '233 patent, prior to the expiration date of the last to expire of those patents, including any extensions or exclusivities;

D. That Plaintiffs be awarded monetary relief if Amneal commercially makes, uses, offers to sell, or sells in the United States, or imports into the United States, the Generic Products, or any other product that infringes or induces or contributes to the infringement of the '009 patent, the "291 patent, the '209 patent, the '708 patent, the '379 patent, the '794 patent, the '752 patent, the '485 patent, the '486 patent, the '085 patent, the '858 patent, and the '233 patent, prior to the expiration of the last to expire of those patents, including any extensions or exclusivities, and that such monetary relief be awarded to Plaintiffs with prejudgment interest;

E. That Plaintiffs be awarded the attorney fees, costs, and expenses that they incur prosecuting this action under 35 U.S.C. § 285; and

F. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

/s/ Maryellen Noreika

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Attorneys for Adamas Pharmaceuticals, Inc.

July 19, 2016

CERTIFICATE OF SERVICE

I hereby certify that on July 19, 2016, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on July 19, 2016, upon the following in the manner indicated:

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