IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC, FOREST LABORATORIES HOLDINGS, LTD., and ADAMAS PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, and PAR PHARMACEUTICAL, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd., and Adamas Pharmaceuticals, Inc. (collectively, "Plaintiffs"), for their Complaint against Defendants Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC, and Par Pharmaceutical, Inc. (collectively, "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 (referred to herein, together with Forest Laboratories, LLC, as "Forest").

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

4. 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.

5. 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 (referred to herein, together with Amneal Pharmaceuticals, LLC as "Amneal") 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.

6. Upon information and belief, Defendant Par Pharmaceutical, Inc. ("Par") is a Delaware corporation having a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977. Upon information and belief, Defendant Par Pharmaceutical, Inc. manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

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. This Court has personal jurisdiction over Defendant Par Pharmaceutical, Inc. by virtue of, *inter alia*, the fact that Par Pharmaceutical, Inc. is a Delaware corporation.

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

THE PATENTS

13. 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.

14. 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.

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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.

21. 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.

22. 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.

23. 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.

24. 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.

25. 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").

26. 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.

ACTS GIVING RISE TO THIS ACTION

Count I – Patent Infringement by Amneal

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 Amneal Generic Products"). ANDA No. 208328 specifically seeks FDA approval to market the Amneal 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 Amneal 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 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(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 Amneal Generic Products, or induces or contributes to any such conduct, it would further infringe 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, Plaintiffs do not allege at this time that the Amneal Generic Products infringe the '009 patent. To the extent that discovery in this action demonstrates that assertion of the '009 patent against the Amneal Generic Products 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 '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 '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 Amneal 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 '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. Amneal was aware of 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.

32. 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 Amneal's proposed generic version

of NAMENDA XR®. That patent infringement action is ongoing and is styled *Forest Laboratories, Inc., et al. v. Amneal Pharmaceuticals LLC, et al.*, Civil Action 14-508-LPS (D. Del.).

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

34. 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.

Count II – Patent Infringement By Par

35. Upon information and belief, on or before July 28, 2015, Par submitted ANDA No. 208359 to the United States Food and Drug Administration ("FDA") under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 208359 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 Par Generic Products"). ANDA No. 208359 specifically seeks FDA approval to market the Par 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.

36. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 208359 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 Par Generic Products. Plaintiffs received

written notification of ANDA No. 203293 and its § 505(j)(2)(A)(vii)(IV) allegations on or about July 29, 2015.

37. Par's submission of ANDA No. 208359 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes 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 under 35 U.S.C. § 271(e)(2)(A). Moreover, if Par commercially makes, uses, offers to sell, or sells within the United States, or imports into the United States, the Par Generic Products, or induces or contributes to any such conduct, it would further 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 under 35 U.S.C. § 271(a), (b), and/or (c).

38. Par 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. 208359, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to those patents.

39. On February 14, 2014, Forest and Adamas filed a Complaint for patent infringement against Par asserting infringement of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent in connection with Par's proposed generic version of NAMENDA XR®. That patent infringement action was styled *Forest Laboratories, Inc., et al. v. Apotex Corp., et al.*, Civil Action 14-200-LPS (D. Del.), and was resolved by the entry of a Stipulation And Order on January 15, 2015.

40. On August 15, 2014, Forest and Adamas filed a Complaint for patent infringement against Par asserting infringement of the '233 patent in connection with Par's amended § 505(j)(2)(A)(vii)(IV) allegations regarding the '233 patent made in connection with Par's proposed generic version of NAMENDA XR®. That patent infringement action was styled *Forest Laboratories, Inc., et al. v. Lupin Ltd., et al.*, Civil Action 14-1058-LPS (D. Del.), and was resolved by entry of a Stipulation And Order on January 15, 2015.

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

42. Plaintiffs will be irreparably harmed by Par'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 '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 Par 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;

C. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of Amneal's ANDA No. 208328 shall not be earlier than the expiration date of the last to expire of 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;

D. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Par's ANDA No. 208359 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;

E. 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 Amneal Generic Products, and any other product that infringes or induces or contributes to the infringement of 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;

F. 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 Amneal Generic Products, or any other product that infringes or induces or contributes to the infringement of 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;

G. That Par, 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 Par 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;

H. That Plaintiffs be awarded monetary relief if Par commercially makes, uses, offers to sell, or sells in the United States, or imports into the United States, the Par 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;

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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