IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC, FOREST LABORATORIES HOLDINGS, LTD., and ADAMAS PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
AMERIGEN PHARMACEUTICALS, INC., and AMERIGEN PHARMACEUTICALS LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Forest Laboratories, LLC (f/k/a Forest Laboratories, Inc.), Forest Laboratories Holdings, Ltd., and Adamas Pharmaceuticals, Inc. (collectively, "Plaintiffs"), for their Complaint against Defendants Amerigen Pharmaceuticals, Inc., and Amerigen Pharmaceuticals Ltd. (collectively, "Defendants"), hereby allege as follows.

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 (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 2200 Powell Street, Suite 220, Emeryville, California 94608.

4. Upon information and belief, Defendant Amerigen Pharmaceuticals, Inc. is a Delaware corporation having a principal place of business at 9 Polito Avenue, Suite 900, Lyndhurst, New Jersey, 07071. Upon information and belief, Defendant Amerigen Pharmaceuticals, Inc. manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including as an agent for Amerigen Pharmaceuticals Ltd.

5. Upon information and belief, Defendant Amerigen Pharmaceuticals Ltd. is a Cayman Islands corporation having a registered office at C/O Codan Trust Company (Cayman) Limited, Cricket Square, Hutchins Drive, P.O. Box 2681, Grand Cayman, KY1-1111 Cayman. Upon information and belief, Defendant Amerigen Pharmaceuticals Ltd. (referred to herein, together with Amerigen Pharmaceuticals, Inc. as "Amerigen") manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including through its agent Amerigen Pharmaceuticals, Inc.

NATURE OF THE ACTION

6. 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"); 8,168,209, as corrected ("the '209 patent"); 8,173,708 ("the '708 patent"); 8,283,379 as corrected ("the '379 patent"); 8,329,752 ("the '752 patent"); 8,362,085 ("the '085 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

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

8. This Court has personal jurisdiction over each of the Defendants by virtue of the

fact that, *inter alia*, each Defendant has committed, or aided, abetted, induced, contributed to, and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs in Delaware. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such personal jurisdiction is challenged.

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

10. This Court has personal jurisdiction over Defendant Amerigen Pharmaceuticals Ltd. by virtue of, *inter alia*: (1) its presence in Delaware, including through its agent Defendant Amerigen Pharmaceuticals, Inc.; and (2) its systematic and continuous contacts with Delaware, including through its agent Defendant Amerigen Pharmaceuticals, Inc. On information and belief, Amerigen Pharmaceuticals Ltd. is amenable to litigating in this forum based on Amerigen Pharmaceuticals Ltd.'s conduct in multiple prior litigations in this District. In particular, Amerigen Pharmaceuticals Ltd. did not contest jurisdiction in Civil Action No. 14-508 (D.I. 36) (related case), Civil Action No. 13-1156 (D.I. 9) or Civil Action No. 12-305 (D.I. 37).

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 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 the United States. A copy of the '209 patent, including its certificate of correction, is attached hereto as Exhibit B.

14. 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 the United States. A copy of the '708 patent is attached hereto as Exhibit C.

15. On October 9, 2012, the '379 patent, titled "Methods And 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 '379 patent on July 8, 2014. 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 the United States. A copy of the '379 patent, including its certificate of correction, is attached hereto as Exhibit D.

16. 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 the United States. A copy of the '752 patent is attached hereto as Exhibit E.

17. 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 the United States. A copy of the '085 patent is attached hereto as Exhibit F.

18. 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 the United States. A copy of the '233 patent is attached hereto as Exhibit G.

19. Forest Laboratories, Inc. (n/k/a Forest Laboratories, LLC) holds New Drug Application ("NDA") 22-525 for Namenda XR® brand memantine hydrochloride extended release capsules. The '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent are all listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Namenda XR®.

20. Forest is the exclusive distributor of Namenda XR® in the United States.

ACTS GIVING RISE TO THIS ACTION

Count I – Patent Infringement by Amerigen

21. Upon information and belief, on or before March 31, 2014, Amerigen submitted ANDA No. 205365 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)) seeking FDA approval for the commercial manufacture, use, and sale of generic extended release capsule products containing 7, 14, and 28 milligrams of memantine hydrochloride as the active ingredient ("the Amerigen Generic Products"). Upon information and belief, ANDA No. 205365 specifically seeks FDA approval to market the 7, 14, and 28 milligram dosage forms of the Amerigen Generic Products prior to the expiration of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent.

22. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 205365 includes allegations that the claims of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the 7, 14, and 28 milligram dosage forms of the Amerigen Generic Products. Plaintiffs received written notification of ANDA No. 205365 with respect to the 7, 14, and 28 milligram dosage forms of the Amerigen Generic Products and its § 505(j)(2)(A)(vii)(IV) allegations with respect to the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent on or about April 1, 2014. Plaintiffs timely brought suit against Amerigen for infringement of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent on or about April 21, 2014 in *Forest Laboratories, Inc., et al. v. Amneal Pharmaceuticals LLC, et al.*, Civil Action No. 14-508-LPS.

23. Upon information and belief, on or before July 31, 2014, Amerigen amended ANDA No. 205365 to include a 21 milligram dosage form of the Amerigen Generic Products. Upon information and belief, as amended, ANDA No. 205365 seeks FDA approval for the commercial manufacture, use, and sale of generic extended release capsule products containing 21 milligrams of memantine hydrochloride as the active ingredient. Upon information and belief, ANDA No. 205365 specifically seeks FDA approval to market the 21 milligram dosage form of the Amerigen Generic Products prior to the expiration of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent.

24. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 205365, as amended, included allegations that the claims of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the 21 milligram dosage form of the Amerigen Generic Products. Plaintiffs received written notification that Amerigen had amended ANDA No. 205365 to include a 21 milligram dosage form of the Amerigen Generic Products on or about August 6, 2014. Plaintiffs timely brought suit against Amerigen for infringement of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent on or about August 15, 2014 in *Forest Laboratories, LLC., et al. v. Lupin Limited, et al.*, Civil Action No. 14-1058-LPS.

25. On or about August 21, 2014, Amerigen sent another written notification that Amerigen had submitted ANDA No. 205365 seeking FDA approval for the commercial manufacture, use, and sale of the 7, 14, and 28 milligram dosage forms of the Amerigen Generic Products prior to the expiration of the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent. This written notification states that ANDA No. 205365

contains allegations, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, that the claims of the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the 7, 14, and 28 milligram dosage forms of the Amerigen Generic Products. Plaintiffs received this written notification on or about August 22, 2014.

26. Amerigen's submission of ANDA No. 205365 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, for the 7, 14, and 28 milligram dosage forms of the Amerigen Generic Products, constitutes infringement of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Amerigen commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the 7, 14, and 28 milligram dosage forms of the Amerigen Generic Products, or induces or contributes to any such conduct, it would further infringe the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent under 35 U.S.C. § 271(a), (b), and/or (c). For purposes of clarity, Plaintiffs state that they are not asserting Claims 6-15 of the '379 patent against the 7, 14, and 28 milligram dosage forms of the Amerigen Generic Products or any other generic extended release memantine hydrochloride product that contains memantine hydrochloride as the sole active ingredient.

27. Upon information and belief, each of Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals Ltd. has participated in, contributed to, aided, abetted, and/or induced infringement of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752

patent, the '085 patent, and the '233 patent once the 7, 14, and 28 milligram dosage forms of the Amerigen Generic Products are manufactured, used, offered for sale, or sold in the United States, or imported into the United States. Each of Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals Ltd. is jointly and severally liable for the infringement of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent.

28. Amerigen was aware of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent prior to filing ANDA No. 205365, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to those patents, and was aware of the '233 patent at least prior to making its § 505(j)(2)(A)(vii)(IV) allegation with respect to that patent.

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

30. Plaintiffs will be irreparably harmed by Amerigen's infringing activity 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 Defendant Amerigen has infringed the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendant Amerigen's ANDA No. 205365 for the 7, 14, and 28 milligram dosage forms of the Amerigen Generic Products shall not be earlier than the expiration date of the last to expire of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent, including any extensions or exclusivities;

C. That Defendant Amerigen, 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 manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, the 7, 14, and 28 milligram dosage forms of the Amerigen Generic Products, and any other product that infringes or induces or contributes to the infringement of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent, prior to the expiration date of those patents, including any extensions or exclusivities;

D. That Plaintiffs be awarded monetary relief if Defendant Amerigen commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, the 7, 14, and 28 milligram dosage forms of the Amerigen Generic Products, or any other product that infringes or induces or contributes to the infringement of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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October 3, 2014
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