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.	)	C.A. No. _____
AMERIGEN PHARMACEUTICALS, INC. and AMERIGEN PHARMACEUTICALS LTD.	)	
Defendants.	)	

COMPLAINT

Plaintiffs Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd., Allergan USA, Inc., and Adamas Pharmaceuticals, Inc. (collectively, "Plaintiffs"), for their Complaint against Defendants Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals Ltd. (collectively, "Amerigen"), 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 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, 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.

6. 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, 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

7. This is a civil action for the infringement 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 the Defendants by virtue of the fact that the Defendants have 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 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.

10. 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.

11. This Court has personal jurisdiction over Defendant Amerigen Pharmaceuticals Ltd. by virtue of, *inter alia*: (1) its presence in Delaware, including through its agent Amerigen Pharmaceuticals, Inc.; and (2) its systematic and continuous contacts with Delaware, including through its agent 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. 15-966 (D.I. 8), Civil Action No. 14-1508 (D.I. 24), Civil Action No. 14-508 (D.I. 36), Civil Action No. 13-1156 (D.I. 9), and Civil Action No. 12-305 (D.I. 37).

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.

27. Allergan USA, Inc. is the exclusive distributor of Namzaric® in the United States.

ACTS GIVING RISE TO THIS ACTION

28. Upon information and belief, on or before September 10, 2015, Amerigen submitted ANDA No. 208237 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 208237, as originally submitted, 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. As originally, submitted, ANDA No. 208237

specifically seeks FDA approval to market Amerigen's generic capsule products containing 14 or 28 milligrams of extended-release memantine hydrochloride and 10 milligrams of donepezil hydrochloride 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.

29. On or about October 23, 2015, Forest and Adamas filed a Complaint for patent infringement against Amerigen asserting 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 in connection with Amerigen's proposed generic versions of Namzaric® containing 14 or 28 milligrams of extended-release memantine hydrochloride and 10 milligrams of donepezil hydrochloride as the active ingredients. That ongoing patent infringement action is styled *Forest Laboratories, LLC, et al. v. Amerigen Pharmaceuticals, Inc., et al*., Civil Action No. 15-966-LPS (D. Del.). Plaintiffs filed an Amended Complaint against Amerigen on or about July 22, 2016. (D.I. 39.)

30. Subsequently, upon information and belief, on or before September 23, 2016, Amerigen amended ANDA No. 208237 to seek FDA approval for the commercial manufacture, use, and sale of additional generic capsule products containing 21 milligrams of extended-release memantine hydrochloride and 10 milligrams of donepezil hydrochloride as the active ingredients.

31. Upon information and belief, on or before September 26, 2016, Amerigen amended ANDA No. 208237 again to seek FDA approval for the commercial manufacture, use, and sale of additional generic capsule products containing 7 milligrams of extended-release

memantine hydrochloride and 10 milligrams of donepezil hydrochloride as the active ingredients.

32. As a result of the amendments of ANDA No. 208237 that, upon information and belief, Amerigen made in September 2016, ANDA No. 208237 now seeks, *inter alia*, FDA approval to market generic capsule products containing 21 or 7 milligrams of extended-release memantine hydrochloride and 10 milligrams of donepezil hydrochloride as the active ingredients ("the Additional Amerigen 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.

33. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, amended ANDA No. 208237 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 and/or will not be infringed by the manufacture, use, or sale of the Additional Amerigen Generic Products. With respect to Amerigen's generic capsule products containing 21 milligrams of extended-release memantine hydrochloride and 10 milligrams of donepezil hydrochloride, the earliest that any of the Plaintiffs received written notification of amended ANDA No. 208237 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 was September 26, 2016. With respect to Amerigen's generic capsule products containing 7 milligrams of extended-release memantine hydrochloride and 10 milligrams of donepezil hydrochloride, the earliest that any of the Plaintiffs received written notification of amended ANDA No. 208237 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 was September 28, 2016.

34. Amerigen's submission of its amendments to ANDA No. 208237 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 1, 3, 19, 20, 22, 37, 41, 48, 49, 50 and 53-57 of the '291 patent, Claims 1-3, 9, 10, 14-16, 23, 24 and 28 of the '794 patent, Claims 1, 3, 9 and 11 of the '485 patent, Claims 1, 3, 7 and 9 of the '486 patent, Claims 1, 2, 4 and 10 of the '858 patent, Claims 1 and 10-14 of the '209 patent, Claims 12 and 16 of the '708 patent, Claims 7, 9, 11 and 12 of the '379 patent, Claims 1 and 9 of the '752 patent, Claims 1 and 7 of the '085 patent, and Claims 1 and 4 the '233 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Amerigen commercially makes, uses, offers to sell, or sells within the United States, or imports into the United States, the Additional Amerigen 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).

35. Upon information and belief, each of Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals Ltd. has participated in, contributed to, aided, abetted, and/or induced the amendments of ANDA No. 208237 and resulting 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 Additional Amerigen Generic Products are commercially made, used, offered for sale, or sold in the United States, or imported into the United States. Each of Amerigen Pharmaceuticals, Inc. LLC and Amerigen Pharmaceuticals Ltd. 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 alleged in this Complaint.

36. Upon information and belief, each of Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals Ltd. has knowledge that if it were to receive approval from the FDA to market the products described in ANDA No. 208237 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, Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals Ltd. each have knowledge of such infringing use and also know that the products described in ANDA No. 208237 are not a staple article or commodity of commerce suitable for substantial non-infringing 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.

37. Amerigen 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 its amendments to ANDA No. 208327, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to those patents.

38. On or about October 23, 2015, Forest and Adamas filed a Complaint for patent infringement against Amerigen asserting 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 in connection with Amerigen's proposed generic versions of Namzaric® containing 14 or 28 milligrams of extended-release memantine hydrochloride and 10 milligrams of donepezil hydrochloride as the active ingredients. That ongoing patent infringement action is styled *Forest Laboratories, LLC, et al. v. Amerigen Pharmaceuticals, Inc., et al*., Civil Action No. 15-966-LPS (D. Del.). Plaintiffs filed an Amended Complaint against Amerigen on or about July 22, 2016. (D.I. 39.)

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

40. Plaintiffs will be irreparably harmed by Amerigen'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 Amerigen 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 in connection with the Additional Amerigen Generic Products;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of Amerigen's ANDA No. 208327 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 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 making, using, offering to sell, or selling in the United States, or importing into the United States, the Additional Amerigen 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 Amerigen commercially makes, uses, offers to sell, or sells in the United States, or imports into the United States, any of the Additional Amerigen Generic Products, or any other product that infringes or induces or contributes to the infringement of the ‘009 patent, ‘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; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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