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. _____
ACCORD HEALTHCARE, INC. and INTAS PHARMACEUTICALS LIMITED,	)	
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 Accord Healthcare, Inc. (a/k/a Accord Healthcare, Inc. USA) and Intas Pharmaceuticals Limited (collectively, "Accord" or "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 1900 Powell Street, Suite 750, Emeryville, California 94608.

4. Upon information and belief, Defendant Accord Healthcare, Inc. is a North Carolina corporation having a principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703. Upon information and belief, Defendant Accord Healthcare, Inc. is a wholly owned subsidiary of Intas Pharmaceuticals Limited. Upon information and belief, Defendant Accord Healthcare, Inc. distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including as an agent of Intas Pharmaceuticals Limited.

5. Upon information and belief, Defendant Intas Pharmaceuticals Limited is a corporation organized and existing under the laws of India, having its principal place of business at Chinubhai Centre, Off. Nehru Bridge, Ashram Road, Ahmedabad 380009, Gujarat, India. Upon information and belief, Defendant Intas Pharmaceuticals Limited (referred to herein, together with Accord Healthcare, Inc., as "Accord") 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 Accord Healthcare, Inc.

NATURE OF THE ACTION

6. This is a civil action for the infringement of the following patents by Accord: 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 ("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 Accord Healthcare, Inc. by virtue of, *inter alia*, its systematic and continuous contacts with Delaware. On information and belief, Defendant Accord Healthcare, Inc. is amenable to litigating in this forum based on Defendant Accord Healthcare, Inc.'s conduct in multiple prior litigations in this District. In particular, Defendant Accord Healthcare, Inc. did not contest jurisdiction in at least: (1) Civil Action No. 15-272 (D.I. 11); (2) Civil Action No. 15-178 (D.I. 17); (3) Civil Action No. 14-932 (D.I. 11); (4) Civil Action No. 13-2095 (D.I. 32); (5) Civil Action No. 13-1206 (D.I. 9); (6) Civil Action No. 13-1155 (D.I. 9); (7) Civil Action No. 12-1490 (D.I. 10); (8) Civil Action No. 11-1253 (D.I. 12); and (9) Civil Action No. 11-18 (D.I. 8).

10. This Court has personal jurisdiction over Defendant Intas Pharmaceutical Limited by virtue of, *inter alia,* its systematic and continuous contacts with Delaware, including through its subsidiary and agent Defendant Accord Healthcare, Inc., including the marketing, distribution, and/or sale of generic pharmaceutical drugs to Delaware residents through Accord Healthcare, Inc. Upon information and belief, Defendant Intas Pharmaceutical Limited currently manufactures over 30 pharmaceutical drug products for marketing, distribution, and/or sale to Delaware residents through Accord Healthcare, Inc. (*See, e.g.*, http://www.accord-healthcare.com/productsearch.php?gid=2&cid=1 (package inserts with manufacturing

information).) Upon information and belief, Defendant Intas Pharmaceutical Limited financially benefits from the sale of these pharmaceutical drugs to Delaware residents. Upon information and belief, Defendant Intas Pharmaceuticals Limited is amenable to litigating in this forum based on Defendant Intas Pharmaceuticals Limited's conduct in multiple prior litigations in this District. In particular, Defendant Intas Pharmaceuticals Limited did not contest jurisdiction in at least: (1) Civil Action No. 15-178 (D.I. 17); (2) Civil Action No. 13-2095 (D.I. 32); and (3) Civil Action No. 11-1253 (D.I. 37, ¶ 1).

11. Venue is proper in this judicial district as to each Defendant 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 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 "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 the United States. A copy of the '379 patent 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, 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®.

ACTS GIVING RISE TO THIS ACTION

20. Upon information and belief, on or before August 26, 2015, Accord submitted ANDA No. 207688 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. 207688 seeks FDA approval for the commercial manufacture, use, and sale of generic extended release tablet products containing 7, 14, 21, and 28 milligrams of memantine hydrochloride as the active ingredient ("the Accord Generic Products"). ANDA No. 207688 specifically seeks FDA approval to market the Accord 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.

21. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 207688 alleges 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 and/or will not be

infringed by the manufacture, use, or sale of the Accord Generic Products. Plaintiffs received written notification of ANDA No. 207688 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 September 1, 2015.

22. Accord's submission of ANDA No. 207688 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, 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 Accord commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the Accord 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/or 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 Accord Generic Products or any other generic extended release memantine hydrochloride product that contains memantine hydrochloride as the sole active ingredient.

23. Upon information and belief, each of Accord Healthcare, Inc. and Intas Pharmaceutical Limited 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/or the '233 patent in connection with the preparation and submission of ANDA No. 207688 to the FDA 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/or the '233 patent once the Accord Generic Products are manufactured, used, offered for sale, or sold in the United States, or imported into the United States. Each of Accord

Healthcare, Inc. and Intas Pharmaceutical Limited 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/or the '233 patent.

24. Accord was aware 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 filing ANDA No. 207688, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to those patents.

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

26. Plaintiffs will be irreparably harmed by Accord'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 Accord 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 ANDA No. 207688 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 Accord, 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 Accord 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, or 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 Accord commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, the Accord 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, or 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.

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