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. _____
ACCORD HEALTHCARE, INC. and INTAS PHARMACEUTICALS LIMITED,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd., Allergan USA, Inc., 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, "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 Accord Healthcare, Inc. ("Accord") is a North Carolina corporation having a principal place of business at 1099 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.

6. Upon information and belief, Defendant Intas Pharmaceuticals Limited ("Intas") 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 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.

7. Upon information and belief, Accord is a wholly owned subsidiary and alter ego of Intas and, for purposes of this action, Accord and Intas are effectively the same entity.

NATURE OF THE ACTION

8. 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

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

10. This Court has specific personal jurisdiction over the Defendants by virtue of, *inter alia*, the fact that the Defendants intend to sell the proposed generic products at issue in this litigation in this judicial district upon receiving FDA approval. Furthermore, 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.

11. This Court has personal jurisdiction over Defendant Accord Healthcare, Inc. by virtue of, *inter alia*, its systematic and continuous contacts with Delaware. Defendant Accord Healthcare, Inc. has admitted "that it is in the business of selling drug products, which Accord may import or manufacture, distribute, sell, or offer to sell throughout the United States, including in Delaware; that it derives substantial revenue from services or things used or consumed in Delaware; that as part of its ordinary business practice of engaging in U.S. patent litigation, it has regularly and routinely litigated NDA and ANDA cases without contesting jurisdiction in this judicial district." (Civil Action No. 16-79, D.I. 14 at ¶14.) Defendant Accord Healthcare, Inc. also has admitted that "it regularly does business in Delaware and has placed

goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware." (Civil Action No. 16-79, D.I. 14 at ¶15.) Furthermore, on information and belief, Defendant Accord Healthcare, Inc. is amenable to litigating in this forum based on its 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. 16-79 (D.I. 14); (2) Civil Action No. 15-903 (D.I. 8); (3) Civil Action No. 15-272 (D.I. 11); (4) Civil Action No. 15-178 (D.I. 17); (5) Civil Action No. 14-932 (D.I. 11); (6) Civil Action No. 13-2095 (D.I. 32); (7) Civil Action No. 13-1206 (D.I. 9); (8) Civil Action No. 13-1155 (D.I. 9); (9) Civil Action No. 12-1490 (D.I. 10); (10) Civil Action No. 11-1253 (D.I. 12); and (11) Civil Action No. 11-18 (D.I. 8).

12. 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. Defendant Accord Healthcare, Inc. has admitted that "that Intas [Pharmaceuticals Limited] includes Accord Healthcare, Inc." and that Intas Pharmaceuticals Limited and Accord Healthcare, Inc. "have overlapping officers and directors." (Civil Action No. 16-79, D.I. 14 at ¶15.) 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) (site last visited May 9, 2016).) 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 its 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. 15-903 (D.I. 8); (2) Civil Action No. 15-178 (D.I. 17); (3) Civil Action No. 13-2095 (D.I. 32); and (4) Civil Action No. 11-1253 (D.I. 37).

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

THE PATENTS

14. 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.

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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.

21. 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.

22. 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.

23. 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.

24. 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.

25. 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.

26. 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").

27. 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.

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

ACTS GIVING RISE TO THIS ACTION

Count I – Patent Infringement by Accord and Intas

29. Upon information and belief, on or before April 6, 2016, Accord submitted ANDA No. 209098 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 209098 seeks FDA approval for the commercial manufacture, use, and sale of generic capsule products containing 28 milligrams of extended-release memantine hydrochloride and 10 milligrams of donepezil hydrochloride or 14 milligrams of extended-release memantine hydrochloride and 10 milligrams of donepezil hydrochloride as the active ingredients ("the Generic Products"). ANDA No. 209098 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.

30. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 209098 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 Generic Products. Plaintiffs received written notification of an ANDA and § 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 April 11, 2016. The April 11, 2016 written notification, however, did not identify ANDA No. 209098 in the subject line. Plaintiffs received a written notification of ANDA No. 209098 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 May 6, 2016.

31. Accord’s submission of ANDA No. 209098 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 1-3, 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 2, 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 Defendants commercially make, use, offer to sell, or sell within the United States, or import into the United States, the Generic Products, or induce or contribute to any such conduct, Defendants will 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).

32. 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 ‘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 Accord Healthcare, Inc. and Intas Pharmaceutical Limited 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.

33. Upon information and belief, Accord and Intas have knowledge that if they were to receive approval from the FDA to market the products described in ANDA No. 209098 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, Accord and Intas have knowledge of such infringing use and also know that the products described in ANDA No. 209098 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.

34. Upon information and belief, Accord and Intas were 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. 209098, 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 Defendants’ § 505(j)(2)(A)(vii)(IV) allegations, Defendants possesses the specific intent to encourage others to infringe.

35. On or about October 9, 2015, Forest and Adamas filed a Complaint for patent infringement against Defendants 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 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, LLC, et al. v. Accord Healthcare, Inc., et al.*, Civil Action 15-903-LPS (D. Del.) and was subsequently dismissed pursuant to a January 19, 2016 stipulation of the parties. (*See* D.I. 8; Jan. 21, 2016 Order terminating case.)

36. Defendants’ actions render this an exceptional case under 35 U.S.C. § 285.

37. Plaintiffs will be irreparably harmed by Defendants’ 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 Defendants have 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. 209098 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 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 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 Intas, 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;

E. That Plaintiffs be awarded monetary relief if Defendants commercially make, use, offer to sell, or sell in the United States, or import into the United States, the 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;

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

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

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