IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., and ADAMAS PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	
RANBAXY INC., RANBAXY LABORATORIES LIMITED, and TEVA PHARMACEUTICALS USA, INC.,	)	C.A. No. _____
Defendants.	)	

COMPLAINT

Plaintiffs Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and Adamas Pharmaceuticals, Inc. (collectively, "Plaintiffs"), for their Complaint against Defendants Ranbaxy Inc., Ranbaxy Laboratories Limited, and Teva Pharmaceuticals USA, Inc. (collectively, "Defendants"), hereby allege as follows.

PARTIES

1. Plaintiff Forest Laboratories, Inc. is a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York 10022.

2. Plaintiff Forest Laboratories Holdings, Ltd. is an Irish corporation having a principal place of business at Columbia House, 1 Victoria Street, Hamilton HM11, Bermuda (referred to herein, together with Forest Laboratories, Inc., 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 Ranbaxy Inc. is a Delaware corporation with a principal place of business at 600 College Road East, Princeton, New Jersey 08540. Upon information and belief, Defendant Ranbaxy 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 of Ranbaxy Laboratories Limited.

5. Upon information and belief, Defendant Ranbaxy Laboratories Limited is an Indian corporation having a principal place of business at 12th Floor, Devika Towers, 6 Nehru Place, New Delhi, India. Upon information and belief, Defendant Ranbaxy Laboratories Limited (referred to herein, together with Ranbaxy Inc., as "Ranbaxy") 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 Ranbaxy Inc.

6. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva") is a Delaware corporation having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Upon information and belief, Defendant Teva 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. 8,168,209, 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

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 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.

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

11. This Court has personal jurisdiction over Defendant Ranbaxy Laboratories Limited by virtue of, *inter alia*: (1) its presence in Delaware, including through its agent Defendant Ranbaxy Inc.; and (2) its systematic and continuous contacts with Delaware, including through its agent Ranbaxy Inc. On information and belief, Ranbaxy Laboratories Limited is amenable to litigating in this forum based on Ranbaxy Laboratories Limited's conduct in multiple prior litigations in this District. In particular, Ranbaxy Laboratories Limited did not contest jurisdiction in this District in Civil Action No. 14-117 (D.I. 11), Civil Action No. 13-1607 (D.I. 14), or Civil Action No. 10-357 (D.I. 55).

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

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 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 United States Patent and Trademark Office ("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 A.

15. 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 B.

16. 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 C.

17. 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 D.

18. 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 E.

19. 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 F.

20. Forest Laboratories, Inc. holds New Drug Application ("NDA") 22-525 for Namenda XR® brand memantine hydrochloride extended release capsules. 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®.

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

ACTS GIVING RISE TO THIS ACTION

Count I – Patent Infringement by Ranbaxy

22. Upon information and belief, on or before May 6, 2014, Ranbaxy submitted ANDA No. 205929 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. 205929 seeks FDA approval for the commercial manufacture, use, and sale of generic extended release capsule products containing 7, 14, 21, and 28 milligrams of memantine hydrochloride as the active ingredient ("the Ranbaxy Generic Products"). ANDA No. 205929 specifically seeks FDA approval to market the Ranbaxy 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.

23. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 205929 alleges 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 Ranbaxy Generic Products. Plaintiffs received written notification of ANDA No. 205929 and its § 505(j)(2)(A)(vii)(IV) allegations on or about May 9, 2014.

24. Ranbaxy's submission of ANDA No. 205929 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of 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 Ranbaxy commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the Ranbaxy Generic Products, or induces or contributes to any such conduct, it would further infringe 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 Ranbaxy Generic Products or any other generic extended release memantine hydrochloride product that contains memantine hydrochloride as the sole active ingredient. Relying on the representations set out in Ranbaxy'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 Ranbaxy Generic Products infringe U.S. Patent No. 8,039,009 ("the '009 patent"). To the extent that discovery in this action demonstrates that assertion of the '009 patent against the Ranbaxy Generic Products is warranted, Plaintiffs reserve the right to assert it.

25. Upon information and belief, each of Ranbaxy Inc. and Ranbaxy Laboratories Limited has participated in, contributed to, aided, abetted, and/or induced infringement of the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and/or the '233 patent and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and/or the '233 patent once the Ranbaxy Generic Products are manufactured, used, offered for sale, or sold in the United States, or imported into the United States. Each of Ranbaxy Inc. and Ranbaxy Laboratories Limited is jointly and severally liable for the infringement of the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and/or the '233 patent.

26. Ranbaxy was aware of the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent prior to filing ANDA No. 205929, 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.

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

28. Plaintiffs will be irreparably harmed by Ranbaxy'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 Teva

29. Upon information and belief, on or before December 20, 2013, Teva submitted ANDA No. 205808 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. 205808 seeks FDA approval for the commercial manufacture, use, and sale of generic extended release capsule products containing 7, 14, 21, and 28 milligrams of memantine hydrochloride as the active ingredient ("the Teva Generic Products").

30. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 205808 previously 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 Teva Generic Products. Plaintiffs received written notification of ANDA No. 205808 and its previous § 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, and the '085 patent on or about December 21, 2013. Plaintiffs timely brought suit against Teva 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 January 31, 2014 in *Forest Laboratories, Inc., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 14-121-LPS.

31. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 205808 was recently amended to include an allegation that the claims of the '233 patent are invalid, unenforceable, and/or will not be

infringed by the manufacture, use, or sale of the Teva Generic Products. Plaintiffs received written notification of Teva's § 505(j)(2)(A)(vii)(IV) allegation with respect to the '233 patent on or about April 17, 2014.

32. Teva's submission of ANDA No. 205808 to the FDA, including its recent § 505(j)(2)(A)(vii)(IV) allegation with respect to the '233 patent, constitutes infringement of the '233 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Teva commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the Teva Generic Products, or induces or contributes to any such conduct, it would further infringe the '233 patent under 35 U.S.C. § 271(a), (b), and/or (c).

33. Teva was aware of the '233 patent prior to making its § 505(j)(2)(A)(vii)(IV) allegation with respect to that patent.

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

35. Plaintiffs will be irreparably harmed by Teva'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 Defendant Ranbaxy has infringed the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent;

B. That Defendant Teva has infringed the '233 patent;

C. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendant Ranbaxy's ANDA identified in this Complaint shall not be earlier than the expiration date of the last to expire of the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 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 Defendant Teva's ANDA identified in this Complaint shall not be earlier than at least the expiration date of the '233 patent, including any extensions or exclusivities;

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

F. That Plaintiffs be awarded monetary relief if Defendant Ranbaxy commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, the Ranbaxy Generic Products, or any other product that infringes or induces or contributes to the infringement of 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;

G. That Defendant Teva, 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 Teva Generic Products, and any other product that infringes or induces or contributes to the infringement of the '233 patent, prior to the expiration date of that patent, including any extensions or exclusivities;

H. That Plaintiffs be awarded monetary relief if Defendant Teva commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, the Teva Generic Products, or any other product that infringes or induces or contributes to the infringement of the '233 patent, prior to at least the expiration date of that patent, 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

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Peter J. Armenio, P.C.
F. Dominic Cerrito
Anne S. Toker
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
51 Madison Avenue
New York, NY 10010
(212) 849-7000

May 30, 2014