

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, INC., FOREST	)	
LABORATORIES HOLDINGS, LTD. and	)	
ADAMAS PHARMACEUTICALS, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 14-686 (LPS)
	)	
RANBAXY INC., RANBAXY	)	
LABORATORIES LIMITED and TEVA	)	
PHARMACEUTICALS USA, INC.,	)	
	)	
Defendants.	)	

**STIPULATION AND ORDER**

The Court, upon the consent and request of Plaintiffs Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and Adamas Pharmaceuticals, Inc. (collectively, “Plaintiffs”) and Defendants Ranbaxy Inc. and Sun Pharmaceuticals Industries, Ltd. (formerly Ranbaxy Laboratories Limited) (collectively, “Ranbaxy”), hereby acknowledges the following Stipulation and issues the following Order.

**STIPULATION**

1. This Court has subject matter jurisdiction over this patent infringement action (the “Action”). Ranbaxy consents to personal jurisdiction in this Court for purposes of this Stipulation and Order, and any proceedings relating thereto. Venue is proper in this Court as to Plaintiffs and Ranbaxy for this action.

2. In this Action, Plaintiffs have charged Ranbaxy with infringement of U.S. Patent Nos. 8,168,209 (“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”) in connection with Ranbaxy’s submission of Abbreviated New Drug Application

(“ANDA”) 205929 directed to generic extended release capsule products containing 7 milligrams, 14 milligrams, 21 milligrams, and 28 milligrams of memantine hydrochloride per capsule to the U.S. Food and Drug Administration (“FDA”).

3. In response to Plaintiffs’ charges of patent infringement, Ranbaxy has alleged certain defenses and counterclaims, including that U.S. Patent No. 8,039,009 (“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 not infringed by the filing of ANDA 205929 with the FDA and/or any making, using, selling, or offering to sell within the United States, or importing into the United States, of the generic extended release capsule products containing 7 milligrams, 14 milligrams, 21 milligrams, and 28 milligrams of memantine hydrochloride that are the subject of ANDA 205929. To date, no decision has been obtained from this Court regarding Plaintiffs’ charges of infringement or Ranbaxy’s defenses and counterclaims.

4. Ranbaxy admits that the submission of ANDA 205929 to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use, and/or sale of the generic extended release capsule products containing 7 milligrams, 14 milligrams, 21 milligrams, and 28 milligrams of memantine hydrochloride per capsule within the United States before the expiration of the ‘209 Patent, the ‘708 Patent, the ‘379 Patent, the ‘752 Patent, the ‘085 Patent, and the ‘233 Patent was a technical act of infringement of each of those patents under 35 U.S.C. § 271(e)(2)(A). This admission is without prejudice to Ranbaxy’s defenses and counterclaims in the Action that 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 not infringed by any making, using, selling, or offering to sell within the United States, or importing into the United States, of the generic products described by ANDA 205929. This admission is further

without prejudice to any claim, defense, or counterclaim in any possible future action between Ranbaxy and any of the Plaintiffs regarding the '009 Patent, the '209 Patent, the '708 Patent, the '379 Patent, the '752 Patent, the '085 Patent, and/or the '233 Patent and a generic memantine hydrochloride product other than the generic products that are the subject of ANDA 205929.

5. Both parties agree that all other claims, defenses, and counterclaims set forth in Plaintiffs' and Ranbaxy's pleadings against each other, including the allegations and averments contained therein, should be dismissed, without prejudice.

### **ORDER**

Accordingly, pursuant to the above Stipulation, and upon the consent and request of Plaintiffs and Ranbaxy, **IT IS HEREBY ORDERED, ADJUDGED AND DECREED THAT:**

1. The filing of ANDA 205929 was a technical act of 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). No decision of the Court has been obtained by either party regarding the presumptive validity of the '209 Patent, the '708 Patent, the '379 Patent, the '752 Patent, the '085 Patent, and the '233 Patent and/or whether any making, using, selling, or offering to sell within the United States, or importing into the United States, of the products described by ANDA 205929 would infringe those patents.

2. All other claims, defenses, and counterclaims set forth in Plaintiffs' and Ranbaxy's pleadings against each other, including the allegations and averments contained therein, are hereby dismissed, without prejudice.

3. Ranbaxy, its officers, agents, servants, employees, and attorneys, and all other persons in active concert or participation with any of them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering

to sell, or selling within the United States, or importing into the United States, the generic extended release capsule products containing 7 milligrams, 14 milligrams, 21 milligrams, and 28 milligrams of memantine hydrochloride per capsule that are the subject of ANDA 205929 during the life of the '209 Patent, the '708 Patent, the '379 Patent, the '752 Patent, the '085 Patent, and the '233 Patent, including any extensions and pediatric exclusivities, absent a license agreement or other authorization by Plaintiffs, unless all of the claims of the '209 Patent, the '708 Patent, the '379 Patent, the '752 Patent, the '085 Patent, and the '233 Patent are found invalid or unenforceable by a court decision from which no appeal has been or can be taken, other than a petition for a writ of certiorari to the U.S. Supreme Court.

4. Plaintiffs and Ranbaxy each expressly waive any right to appeal or otherwise move for relief from this Stipulation And Order.

5. This Court retains jurisdiction over Plaintiffs and Ranbaxy for purposes of enforcing this Stipulation And Order.

6. This Stipulation And Order shall finally resolve this Action between Plaintiffs and Ranbaxy.

7. This Stipulation And Order is without prejudice to any claim, defense, or counterclaim in any possible future action between Ranbaxy and any of the Plaintiffs regarding the '209 Patent, the '708 Patent, the '379 Patent, the '752 Patent, the '085 Patent, and/or the '233 Patent and a product other than the generic extended release capsule products containing 7 milligrams, 14 milligrams, 21 milligrams, and 28 milligrams of memantine hydrochloride per capsule that are the subject of ANDA 205929.

8. The Clerk of the Court is directed to enter this Stipulation And Order forthwith.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

RICHARDS, LAYTON & FINGER, P.A.

*/s/ Maryellen Noreika*

*/s/ Travis S. Hunter*

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Laboratories Limited*

SO ORDERED this \_\_\_\_\_ day of May 2015

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HONORABLE LEONARD P. STARK  
UNITED STATES DISTRICT JUDGE