

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, INC., FOREST)
LABORATORIES HOLDINGS, LTD.,)
MERZ PHARMA GMBH & CO. KGAA, and)
MERZ PHARMACEUTICALS GMBH,)

Plaintiffs,)

v.)

C.A. No. _____

AUROBINDO PHARMA USA INC. and)
AUROBINDO PHARMA LTD.,)

Defendants.)

COMPLAINT

Plaintiffs Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH (collectively, "Plaintiffs"), for their Complaint against Defendants Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd. (collectively, "Aurobindo"), 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 Merz Pharma GmbH & Co. KGaA is a German corporation having a principal place of business at Eckenheimer Landstraße 100, D-60318 Frankfurt am Main, Germany.

4. Plaintiff Merz Pharmaceuticals GmbH is a German corporation having a principal place of business at Eckenheimer Landstraße 100, D-60318 Frankfurt am Main, Germany (referred to herein, together with Merz Pharma GmbH & Co. KGaA, as “Merz”).

5. Upon information and belief, Defendant Aurobindo Pharma USA Inc. is a Delaware corporation having a principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810. Upon information and belief, Defendant Aurobindo Pharma USA Inc. is a wholly owned subsidiary of Aurobindo Pharma Ltd. Upon information and belief, Defendant Aurobindo Pharma USA Inc. manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including as a subsidiary and agent of Aurobindo Pharma Ltd.

6. Upon information and belief, Defendant Aurobindo Pharma Ltd. is an Indian corporation having a principal place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andhra Pradesh, India. Upon information and belief, Defendant Aurobindo Pharma Ltd. manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including through its subsidiary and agent Aurobindo Pharma USA Inc.

NATURE OF THE ACTION

7. This is a civil action for the infringement of United States Patent No. 5,061,703, as corrected and reexamined (“the ‘703 patent”), by Aurobindo. 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 Aurobindo Pharma USA Inc. by virtue of, *inter alia*, the fact that Aurobindo Pharma USA Inc. is a Delaware corporation.

11. This Court has personal jurisdiction over Defendant Aurobindo Pharma Ltd. by virtue of, *inter alia*: (1) its presence in Delaware, including through its subsidiary and agent Defendant Aurobindo Pharma USA Inc.; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Defendant Aurobindo Pharma USA, Inc. On information and belief, Aurobindo Pharma Ltd. is amenable to litigating in this forum based on Aurobindo Pharma Ltd.'s conduct in multiple prior litigations in this District. In particular, Aurobindo Pharma Ltd. did not contest jurisdiction in this District in Civil Action No. 13-688 (D.I. 19) or Civil Action No. 13-1210 (D.I. 14).

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 29, 1991, the '703 patent, titled "Adamantane Derivatives In The Prevention And Treatment Of Cerebral Ischemia," was duly and legally issued by the United States Patent and Trademark Office ("USPTO"). The USPTO issued a certificate of correction for the '703 patent on June 5, 2007. Merz + Co. GmbH & Co. was the original assignee of the

'703 patent and assigned the '703 patent to Merz Pharma GmbH & Co. KGaA in 2002. Since that time, Merz Pharma GmbH & Co. KGaA has been, and continues to be, the sole owner of the '703 patent. Forest is the exclusive licensee of the '703 patent in the United States. A copy of the '703 patent, including its certificate of correction, is attached hereto as Exhibit A.

14. On August 18, 2004, Merz submitted a request to the USPTO for reexamination of the '703 patent. The USPTO issued a reexamination certificate for the '703 patent on November 7, 2006. A copy of the reexamination certificate for the '703 patent is attached hereto as Exhibit B.

15. Forest Laboratories, Inc. holds New Drug Application ("NDA") 21-487 for Namenda[®] brand memantine hydrochloride tablets. The '703 patent is listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Namenda[®]. The United States Food and Drug Administration ("FDA") has granted pediatric exclusivity for Namenda[®].

16. Forest is the exclusive distributor of Namenda[®] in the United States.

ACTS GIVING RISE TO THIS ACTION

Count I – Patent Infringement by Aurobindo

17. Upon information and belief, on or before May 16, 2014, Aurobindo submitted ANDA No. 203175 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 203175 seeks FDA approval for the commercial manufacture, use, and sale of generic tablet products containing 5 and 10 milligrams of memantine hydrochloride as the active ingredient ("the Aurobindo Generic Products"). ANDA No. 203175 specifically seeks FDA approval to market the Aurobindo Generic Products prior to the expiration of the '703 patent.

18. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 203175 alleges that the claims of the '703 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Aurobindo Generic Products. Plaintiffs received written notification of ANDA No. 203175 and its § 505(j)(2)(A)(vii)(IV) allegations on or about May 19, 2014.

19. Aurobindo's submission of ANDA No. 203175 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Aurobindo commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the Aurobindo Generic Products, or induces or contributes to any such conduct, it would further infringe the '703 patent under 35 U.S.C. § 271(a), (b), and/or (c).

20. Upon information and belief, each of Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd. has participated in, contributed to, aided, abetted, and/or induced infringement of the '703 patent and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '703 patent once the Aurobindo Generic Products are manufactured, used, offered for sale, or sold in the United States, or imported into the United States. Each of Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd. is jointly and severally liable for the infringement of the '703 patent.

21. Aurobindo was aware of the '703 patent prior to filing ANDA No. 203175, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to that patent.

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

23. Plaintiffs will be irreparably harmed by Aurobindo'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 Aurobindo has infringed the '703 patent;
- B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendant Aurobindo's ANDA identified in this Complaint shall not be earlier than the expiration date of the '703 patent, including any extensions or exclusivities;
- C. That Defendant Aurobindo, 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 Aurobindo Generic Products, and any other product that infringes or induces or contributes to the infringement of the '703 patent, prior to the expiration date of that patent, including any extensions or exclusivities;
- D. That Plaintiffs be awarded monetary relief if Defendant Aurobindo commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, the Aurobindo Generic Products, or any other product that infringes or induces or contributes to the infringement of the '703 patent, prior to the expiration of that patent, 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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