

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA**

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

Plaintiffs,

vs.

SYNTHON PHARMACEUTICALS, INC.,  
SYNTHON HOLDING B.V., SYNTHON  
B.V., and SYNTHON LABORATORIES,  
INC.,

Defendants.

Civil Action No. \_\_\_\_\_

**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 Synthon Pharmaceuticals, Inc., Synthon Holding B.V., Synthon B.V., and Synthon Laboratories, Inc. (collectively "Defendants") hereby allege as follows:

**PARTIES**

1. Plaintiff Forest Laboratories, Inc. ("Forest Labs") 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 Milner House, 18 Parliament Street, Hamilton JM11, 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 Synthon Pharmaceuticals, Inc. ("Synthon Pharma") is a North Carolina corporation having a principal place of business at 9000 Development Drive, P.O. Box 110487, Research Triangle Park, North Carolina 27709. Upon information and belief, Defendant Synthon Pharma, itself and on behalf of its parent Defendant Synthon Holding and its sister companies Defendants Synthon and Synthon Labs, develops, manufactures, and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district. Upon information and belief, Synthon Pharma also prepares and/or aids in the preparation and submission of Abbreviated New Drug Applications ("ANDA") to the United States Food and Drug Administration ("FDA").

6. Upon information and belief, Defendant Synthon Holding B.V. ("Synthon Holding") is a Dutch entity having a principal place of business at Microweg 22, 6545 CM Nijmegen, Netherlands. Upon information and belief, Defendant Synthon Holding is the ultimate parent of Defendants Synthon Pharma, Synthon B.V., and Synthon Laboratories, Inc.

7. Upon information and belief, Defendant Synthon B.V. ("Synthon") is a Dutch entity having a principal place of business at Microweg 22, P.O. Box 7071, 6503 GN Nijmegen, Netherlands. Upon information and belief, Defendant Synthon develops numerous generic drugs for sale and use throughout the United States, including in this judicial district. Upon information and belief, Synthon also aids its sister companies and agents Defendants Synthon Pharma and Synthon Laboratories, Inc. in the manufacture and distribution of numerous generic drugs throughout the United States, including in this judicial district. Upon information and belief, Synthon also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

8. Upon information and belief, Defendant Synthon Laboratories, Inc. ("Synthon Labs") is a Virginia corporation having a principal place of business at 7130 Heritage Village Plaza, Suite 201, Gainesville, Virginia 20155. Upon information and belief, Defendant Synthon Labs, itself and on behalf of its parent Defendant Synthon Holding and its sister companies Defendants Synthon Pharma and Synthon, submits ANDAs to the FDA. Upon information and belief, Defendant Synthon Labs, through its parent Defendant Synthon Holding and its sister companies Defendants Synthon Pharma and Synthon, manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

#### **NATURE OF THE ACTION**

9. This is a civil action for infringement of United States Patent No. 5,061,703 ("the '703 patent") (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

## JURISDICTION AND VENUE

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

11. 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, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including a corporation, Plaintiff Forest Labs, which manufactures numerous drugs for sale and use throughout the United States, including in this judicial district. 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 jurisdiction is challenged.

12. This Court has personal jurisdiction over Defendant Synthon Pharma by virtue of, *inter alia*: (1) its presence in North Carolina at its principal place of business; and (2) the fact that it is a North Carolina corporation.

13. This Court has personal jurisdiction over Defendant Synthon Holding by virtue of, *inter alia*: (1) its presence in North Carolina through its subsidiary and agent Synthon Pharma; and (2) its systematic and continuous contacts with North Carolina, including through its subsidiaries and agents Synthon Pharma, Synthon, and Synthon Labs.

14. This Court has personal jurisdiction over Defendant Synthon by virtue of, *inter alia*: (1) its presence in North Carolina through its sister company and agent Synthon Pharma; and (2) its systematic and continuous contacts with North Carolina, including through its sister companies and agents Synthon Pharma and Synthon Labs.

15. This Court has personal jurisdiction over Defendant Synthon Labs by virtue of, *inter alia*: (1) the fact that it is an alter ego or agent of Synthon Pharma, a corporation

present in North Carolina; (2) its systematic and continuous contacts with North Carolina, including through its alter ego or agent Synthon Pharma; and (3) its systematic and continuous contacts with North Carolina, including through its sister company Synthon.

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

### **THE PATENT-IN-SUIT**

17. 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 ("PTO"). Merz has been, and continues to be, the sole assignee of the '703 patent since its issuance.

18. Forest is the exclusive licensee of the '703 patent in the United States. Forest holds New Drug Application ("NDA") No. 21-487 for Namenda<sup>®</sup> brand memantine hydrochloride tablets. The '703 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Namenda<sup>®</sup>.

19. Forest is the exclusive distributor of Namenda<sup>®</sup> in the United States.

20. On August 18, 2004, Merz submitted a request to the PTO for reexamination of the '703 patent. The PTO issued a reexamination certificate (Exhibit B) for the '703 patent on November 7, 2006.

### **ACTS GIVING RISE TO THIS ACTION**

#### **Count I – Infringement Of The '703 Patent By Defendants Synthon Holding, Synthon, Synthon Labs, and Synthon Pharma**

21. Upon information and belief, Defendant Synthon Labs, on behalf of its parent Synthon Holding and its sister companies Synthon Pharma and Synthon, submitted ANDA No. 90-047 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act

(21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use and sale of a generic tablet product containing 5 milligrams of memantine hydrochloride ("the Synthron Generic Product"). ANDA No. 90-047 specifically seeks FDA approval to market the Synthron Generic Product prior to the expiration of the '703 patent.

22. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Synthron Labs alleged in ANDA No. 90-047 that the claims of the '703 patent are invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of the Synthron Generic Product. Plaintiffs received written notification of ANDA No. 90-047 and its § 505(j)(2)(A)(vii)(IV) allegation on or about February 5, 2008.

23. Synthron Labs' submission of ANDA No. 90-047 to the FDA, on behalf of its parent Synthron Holding and its sister companies Synthron Pharma and Synthron, 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 Synthron Labs commercially manufactures, uses, offers to sell, sells, or imports any of the Synthron 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).

24. Synthron Pharma is jointly and severally liable for any infringement of the '703 patent. Upon information and belief, Synthron Pharma participated in, contributed to, aided, abetted and/or induced Synthron Labs' submission of ANDA No. 90-047 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

25. Synthron Pharma's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 90-047 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Synthron Pharma commercially manufactures, uses, offers to sell, sells, or imports any of the

Synthon 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).

26. Synthon Holding is jointly and severally liable for any infringement of the '703 patent. Upon information and belief, Synthon Holding participated in, contributed to, aided, abetted and/or induced Synthon Labs' submission of ANDA No. 90-047 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

27. Synthon Holding's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 90-047 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Synthon Holding commercially manufactures, uses, offers to sell, sells, or imports any of the Synthon 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).

28. Synthon is jointly and severally liable for any infringement of the '703 patent. Upon information and belief, Synthon participated in, contributed to, aided, abetted and/or induced Synthon Labs' submission of ANDA No. 90-047 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

29. Synthon's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 90-047 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Synthon commercially manufactures, uses, offers to sell, sells, or imports any of the Synthon 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).

30. Defendants were aware of the '703 patent prior to filing ANDA No. 90-047.

31. Defendants' actions render this an exceptional case under 35 U.S.C. § 285.

32. 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.

33. Plaintiffs have sought to enjoin acts of infringement of the '703 patent by numerous other parties in an action filed by Plaintiffs in the District of Delaware on January 25, 2008, Civil Action No. 1:08-CV-00052. An amended complaint which added Defendants as parties to that case was filed on February 13, 2008. Defendants are properly subject to personal jurisdiction in the District of Delaware, and judicial economy would be promoted if all of Plaintiffs' claims for infringement of the '703 patent are addressed in the District of Delaware.

34. On March 12, 2008, Defendants filed a Motion to Dismiss the action against them in the District of Delaware, pursuant to Rules 12(b)(2), 12(b)(3), and 12(b)(5), Fed. R. Civ. P. Given the possible consequences if Defendants succeeded with such unjustified action, Plaintiffs had no choice but to file this Complaint. In the event that Defendants are unsuccessful in any such challenge in the District of Delaware, Plaintiffs will dismiss this action.

**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs pray for judgment as follows:

- A. That all Defendants have infringed the '703 patent;
- B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants' ANDA identified in this Complaint shall not be earlier than the expiration date of the '703 patent, including any extensions;
- C. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, selling, or importing any of the proposed generic versions of Plaintiffs' Namenda<sup>®</sup> brand product identified in this Complaint and any other product that infringes or induces or contributes to the infringement of the '703 patent, prior to the expiration of the '703 patent, including any extensions;
- D. That this case is exceptional under 35 U.S.C. § 285;
- E. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and
- F. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

Dated: March 20, 2008

Respectfully submitted,

**WOMBLE CARLYLE SANDRIDGE & RICE, PLLC**

/s/W. Andrew Copenhaver

W. Andrew Copenhaver (State Bar # 944)

One West Fourth Street

Winston-Salem, NC 27101

Telephone: (336) 721-3633

E-mail: acopenhaver@wcsr.com

*Attorney for Plaintiffs*

*Of Counsel:*

John Desmarais

Gerald J. Flattmann, Jr.

Melanie R. Rupert

KIRKLAND & ELLIS LLP

Citigroup Center

153 East 53rd Street

New York, NY 10022

Tel: (212) 446-4800

F. Dominic Cerrito

Daniel L. Malone

Eric C. Stops

JONES DAY

222 East 41st Street

New York, NY 10017

Tel: (212) 326-3939