IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
Civil Action No. _____

Attorneys for Plaintiffs,
SANOFI-AVENTIS, and
SANOFI-AVENTIS U.S. LLC

SANOFI-AVENTIS, SANOFI-AVENTIS U.S. LLC, Plaintiffs, v. SYNTHON HOLDING BV, SYNTHON BV, SYNTHON PHARMACEUTICALS, INC., SYNTHON LABORATORIES, INC., Defendants.	)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi-Aventis and Sanofi-Aventis U.S. LLC (hereinafter "Plaintiffs"), by way of Complaint against defendants Synthon Holding BV, Synthon BV, Synthon Pharmaceuticals, Inc., and Synthon Laboratories, Inc. allege as follows:

1. Sanofi-Aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 Avenue de France, Paris, France. Sanofi-Aventis is a global healthcare company whose core therapeutic areas are cardiovascular disease and thrombosis, diseases of the central nervous system, cancer, and internal medicine.

2. Sanofi-Aventis U.S. LLC is the U.S. subsidiary of Sanofi-Aventis, and is a corporation incorporated under the laws of the state of Delaware, having commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. On information and belief, Synthon Holding BV and Synthon BV are related Netherlands companies with their headquarters at P.O. Box 7071, 6503 GN Nijmegen, Netherlands, and are the ultimate parent and parent of the other Synthon entities in this suit.

4. On information and belief, Synthon Pharmaceuticals, Inc. is incorporated under the laws of the State of North Carolina, having an office and conducting business at 9000 Development Drive, P.O. Box 110487, Research Triangle Park, North Carolina, 27709.

5. On information and belief, Synthon Pharmaceuticals, Inc. is a subsidiary, affiliate, or division of Synthon Holding BV, Synthon BV, and/or Synthon Laboratories, Inc. and is in the business of developing, manufacturing, marketing, and distributing pharmaceutical products, and is the main United States subsidiary or division of Synthon.

6. On information and belief, Synthon Laboratories, Inc. is incorporated under the laws of the Commonwealth of Virginia, having an office and conducting business at 7130 Heritage Village Plaza, Suite 201, Gainesville, Virginia 20155, and is an affiliate, subsidiary, or division of Synthon Pharmaceuticals, Inc. or Synthon BV.

7. On information and belief, Synthon Laboratories, Inc. assembled and caused to be filed with the United States Food and Drug Administration (the "FDA"), pursuant to 21 U.S.C. § 355(j)(2), Abbreviated New Drug Application No. 78-483, concerning a proposed drug product, zolpidem tartrate extended release tablets in 6.25mg and 12.5mg dosage strengths.

8. On information and belief, Synthon Holding BV, Synthon BV, or Synthon Pharmaceuticals, Inc., or all or part of the foregoing, acting alone or in concert, caused, actively

encouraged and/or directed Synthon Laboratories, Inc. to file ANDA No. 78-483 with the FDA, and/or participated in the work related to the submission of ANDA No. 78-483.

9. Synthon Holding BV, Synthon BV, Synthon Pharmaceuticals, Inc., and Synthon Laboratories, Inc. are referred to hereinafter, collectively, as "Synthon."

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

11. Synthon is subject to personal jurisdiction within this district because it conducts business within this district, its agents and alter egos are present within this district, and it sells various products throughout the United States, including within this district.

12. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), (c) and (d), and 28 U.S.C. § 1400(b).

CLAIM FOR PATENT INFRINGEMENT

13. Sanofi-Aventis U.S. LLC holds approved new drug application ("NDA") 21-774 for Ambien CR®, the active ingredient of which is zolpidem tartrate. Ambien CR® was approved by the FDA on September 2, 2005, and is approved for the treatment of insomnia.

14. Ambien CR® is a controlled release formulation of zolpidem tartrate.

15. Sanofi-Aventis is the owner of United States Patent No. 6,514,531 ("the '531 Patent") (attached as Exhibit A), which discloses and claims, among other things, a pharmaceutical controlled-release dosage form adapted to release zolpidem or a salt thereof over a predetermined time period.

16. Ambien CR® is an embodiment of the '531 Patent.

17. On information and belief, Synthon submitted to the FDA an abbreviated new drug application ("ANDA") under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use and sale of generic zolpidem tartrate extended release tablets.

18. Synthon's ANDA seeks approval to manufacture and sell pharmaceutical formulations containing zolpidem tartrate extended release tablets, which are covered by one or more claims of the '531 patent.

19. On information and belief, Synthon submitted its ANDA No. 78-483 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of its generic zolpidem tartrate extended release tablets before the expiration of the '531 patent.

20. By filing the ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of its proposed drug products before the expiration of the '531 patent, Synthon has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, the commercial manufacture, use, offer for sale, sale and/or importation of the generic zolpidem tartrate extended release products for which Synthon seeks approval in its ANDA will also infringe one or more claims of the '531 patent.

21. On information and belief, Synthon made, and included in its ANDA, a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, the '531 patent is invalid.

22. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of the aforementioned

ANDA relating to Synthon's generic zolpidem tartrate extended release products be a date which is not earlier than the expiration date of the '531 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Synthon has infringed one or more claims of the '531 patent by filing the aforesaid ANDA relating to Synthon's generic zolpidem tartrate extended release products;

B. A permanent injunction restraining and enjoining Synthon and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of generic zolpidem tartrate extended release products as claimed in the '531 patent;

C. An order that the effective date of any approval of the aforementioned ANDA relating to Synthon's generic zolpidem tartrate extended release products be a date which is not earlier than the expiration date of the '531 patent;

D. Monetary damages for any acts of infringement beyond those specified in 35 U.S.C. §271(e)(1).

E. The costs and disbursements of this action; and

F. Such other and further relief as the Court may deem just and proper.

Dated: February 5, 2007 Respectfully submitted,

/s/ W. Andrew Copenhaver
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