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SANOFI-AVENTIS, and
SANOFI-AVENTIS U.S. LLC

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS, SANOFI-AVENTIS U.S. LLC, Plaintiffs, v. MUTUAL PHARMACEUTICAL COMPANY, INC., UNITED RESEARCH LABORATORIES, INC. and PHARMACEUTICAL HOLDINGS CORP. Defendants.	Civil Action No. **COMPLAINT**

Plaintiffs Sanofi-Aventis and Sanofi-Aventis U.S. LLC (hereinafter "Plaintiffs"), by way of Complaint against Defendants Mutual Pharmaceutical Company, Inc., United Research Laboratories, Inc. and Pharmaceutical Holdings Corp. say:

PARTIES

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 limited liability company formed under the laws of the state of Delaware, having commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. On information and belief, Defendant Mutual Pharmaceutical Company, Inc. is a corporation incorporated under the laws of the State of Pennsylvania, having its principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania 19124.

4. On information and belief, Defendant United Research Laboratories, Inc. is a corporation incorporated under the laws of the State of Pennsylvania, having its principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania 19124.

5. On information and belief, Defendant Pharmaceutical Holdings Corp. is a corporation incorporated under the laws of the State of Delaware, having its principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania 19124.

6. On information and belief, Mutual Pharmaceutical Company, Inc. is a wholly-owned subsidiary of Pharmaceutical Holdings Corp. and has common officers and directors.

7. On information and belief, United Research Laboratories, Inc. is a wholly-owned subsidiary of Pharmaceutical Holdings Corp. and has common officers and directors.

8. United Research Laboratories, Inc. is registered with the State of New Jersey to conduct business in New Jersey.

9. On information and belief, Mutual Pharmaceutical Company, 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 ("ANDA") No. 78-716, concerning a proposed drug product, zolpidem tartrate extended-release tablets in 6.25 mg and 12.5 mg dosage strengths.

10. On information and belief, Mutual Pharmaceutical Company, Inc., United Research Laboratories, Inc. and Pharmaceutical Holdings Corp., or all or part of the foregoing, acting alone or in concert, caused, actively encouraged and/or directed Mutual Pharmaceutical Company, Inc. to file ANDA No. 78-716 with the FDA, and/or participated in the work related to the submission of ANDA No. 78-716.

11. Mutual Pharmaceutical Company, Inc., United Research Laboratories, Inc. and Pharmaceutical Holdings Corp. are at times referred to hereinafter collectively as "Mutual."

JURISDICTION AND VENUE

12. 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).

13. Mutual conducts business within the district and sells various products throughout the United States, including within this district.

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

CLAIM FOR PATENT INFRINGEMENT

15. 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.

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

17. 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.

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

19. On information and belief, Mutual 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.

20. Mutual'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.

21. On information and belief, Mutual submitted its ANDA No. 78-716 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.

22. 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, Mutual 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 Mutual seeks approval in its ANDA will also infringe one or more claims of the '531 patent.

23. On information and belief, Mutual 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 and/or not infringed by Mutual's zolpidem tartrate extended release tablets.

24. 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 Mutual's generic zolpidem tartrate extended release products be a date which is not earlier than the date of expiration of the '531 patent plus any pediatric exclusivity.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request judgment against Defendants as follows:

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

B. A permanent injunction restraining and enjoining Mutual 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 Mutual's generic zolpidem tartrate extended release products be a date which is not earlier than the date of expiration of the '531 patent plus any pediatric exclusivity;

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.

McCARTER & ENGLISH, LLP
Attorneys for Plaintiffs

By: William O'Shaughnessy
WILLIAM J. O'SHAUGHNESSY

Dated: May 11, 2007

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