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

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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| SANOFI-AVENTIS,<br>SANOFI-AVENTIS U.S. LLC,<br><br>Plaintiffs,<br><br>v.<br><br>WATSON PHARMACEUTICALS, INC., and<br>WATSON LABORATORIES, INC.,<br><br>Defendants. | Civil Action No.<br><br>**COMPLAINT** |

Plaintiffs Sanofi-Aventis and Sanofi-Aventis U.S. LLC (hereinafter "Plaintiffs"), by way of Complaint against defendants Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc., 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 Watson Pharmaceuticals, Inc. is a corporation incorporated under the laws of the State of Nevada, having an office and conducting business at 360 Mt. Kemble Avenue, Morristown, NJ 07962.

4. On information and belief, Defendant Watson Laboratories, Inc. is a corporation incorporated under the laws of the State of Nevada, having an office and conducting business at 360 Mount Kemble Avenue, Morristown, New Jersey 07962.

5. On information and belief, Watson Laboratories, Inc. is a wholly owned subsidiary of Watson Pharmaceuticals, Inc., and the two have common officers and directors.

6. On information and belief, the acts of Watson Laboratories, Inc. complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of and at least in part, for the benefit of Watson Pharmaceuticals, Inc.

7. Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. are referred to hereinafter, collectively, as "Watson."

## JURISDICTION AND VENUE

8. 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).

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

10. 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

11. 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.

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

13. 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.

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

15. On information and belief, Watson 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.

16. Watson'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.

17. On information and belief, Watson submitted its ANDA No. 78-456 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.

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

19. On information and belief, Watson 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 Watson's zolpidem tartrate extended release tablets.

20. 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 Watson's generic zolpidem tartrate extended release products be a date which is not earlier than the June 1, 2020 expiration date of the '531 patent.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully requests judgment against Defendants as follows:

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

B. A permanent injunction restraining and enjoining Watson 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 Watson'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.

CARELLA, BYRNE, BAIN, GILFILLAN,
CECCHI, STEWART & OLSTEIN
Attorneys for Plaintiffs

By: /s/ James E. Cecchi
JAMES E. CECCHI

Dated: January 26, 2007