

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, Sandoz Inc. (“Sandoz”) is registered with the State of New Jersey to conduct business in New Jersey, and has its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

4. On information and belief, Sandoz is in the business of developing, manufacturing, marketing, and distributing generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

5. On information and belief, Sandoz 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. 90-107, concerning zolpidem tartrate extended release tablets.

JURISDICTION AND VENUE

6. 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).

7. Sandoz is subject to personal jurisdiction in New Jersey because it regularly and systematically conducts business within New Jersey, has an office within New Jersey, and sells various products throughout the United States, including within New Jersey.

8. 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

9. 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.

10. Ambien CR[®] is a controlled release formulation of zolpidem tartrate.

11. 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.

12. Ambien CR[®] is an embodiment of the ’531 Patent.

13. On information and belief, Sandoz submitted to the FDA its ANDA No. 90-107 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.

14. Sandoz’s ANDA No. 90-107 seeks approval to manufacture and sell zolpidem tartrate extended release tablets that are covered by one or more claims of the ’531 patent.

15. On information and belief, Sandoz submitted its ANDA No. 90-107 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.

16. 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 zolpidem tartrate extended release tablets before the expiration of the '531 patent, Sandoz 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 tablets made under that ANDA will also infringe one or more claims of the '531 patent.

17. On information and belief, Sandoz 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 Sandoz's zolpidem tartrate extended release tablets.

18. 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 Sandoz's generic zolpidem tartrate extended release tablets 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 Defendant as follows:

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

B. A permanent injunction restraining and enjoining Sandoz 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 tablets as claimed in the '531 patent;

C. An order that the effective date of any approval of the aforementioned ANDA relating to Sandoz's generic zolpidem tartrate extended release tablets 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.

Respectfully Submitted,

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