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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

SANOFI-AVENTIS,
SANOFI-SYNTHELABO, INC., and
BRISTOL-MYERS SQUIBB SANOFI
PHARMACEUTICALS HOLDING
PARTNERSHIP,

Plaintiffs,

v.

WATSON PHARMACEUTICALS, INC., and
WATSON LABORATORIES, INC.,

Defendants.

CIVIL ACTION NO.:

04-4926
(WHW)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi-Aventis, Sanofi-Synthelabo, Inc., and Bristol-Myers Squibb Lowenstein Sandler PC, for their Complaint herein against defendants Watson Pharmaceuticals, Inc. and Watson 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-Synthelabo, Inc. 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 90 Park Avenue, New York, New York 10016.

3. Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership (the "Partnership") is a partnership registered in the state of Delaware, having a mailing address at P.O. Box 4000, Route 206 and Province Line Road, Princeton, New Jersey 08543. The Partnership is responsible for the marketing and sale of Plavix® in the United States and numerous countries in North America, South America, Central America, and elsewhere.

4. On information and belief, Defendant Watson Pharmaceuticals, Inc. is a corporation incorporated under the laws of the State of Nevada, having its corporate headquarters at 311 Bonnie Circle, Corona, California 92880, and an office and conducting business at 360 Mt. Kemble Avenue, Morristown, NJ 07962.

5. 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, P.O. Box 1953, Morristown, New Jersey 07962.

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

7. 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.

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

JURISDICTION AND VENUE

9. 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).

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

11. 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 RELIEF

12. Sanofi-Synthelabo, Inc. holds approved new drug application ("NDA") 20-839 for Plavix®, the active ingredient of which is clopidogrel bisulfate. Plavix® was approved by the FDA on November 17, 1997, and is indicated for the reduction of atherosclerotic events (myocardial infarction, stroke, and vascular death) in patients with atherosclerosis documented by recent stroke, recent myocardial infarction, or established peripheral arterial disease, and in patients with acute coronary syndrome.

13. Clopidogrel can be referred to by several chemical names, which refer to the same chemical structure. The chemical name referred to in Sanofi-Synthelabo Inc.'s NDA is methyl (+)-(S)-alpha-(2-chlorophenyl)-6,7-dihydrothieno(3,2-c)pyridine-5(4H)-acetate. The chemical names referred to in several Sanofi-Aventis patents are methyl (+)-(S)-alpha-(2-chlorophenyl)-4,5,6,7-tetrahydrothieno [3,2-c] pyridine-5-acetate, and (4)-(S)-alpha-(O-

chlorophenyl)-6,7-dihydrothieno[3,2-c]pyridine-5-acetate. Clopidogrel bisulfate is the hydrogen sulfate salt of clopidogrel.

14. Sanofi-Aventis is the owner of United States Patent No. 6,429,210 (“the ‘210 Patent”) (attached as Exhibit A), which discloses and claims, among other things, a novel polymorphic form of clopidogrel bisulfate, known as Form 2, and pharmaceutical compositions containing Form 2 clopidogrel bisulfate. The ‘210 Patent was duly and legally issued on August 6, 2002. The ‘210 Patent is exclusively licensed to the Partnership.

15. Plavix® is an embodiment of the ‘210 Patent.

16. 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 clopidogrel bisulfate tablets containing Form 2 clopidogrel bisulfate.

17. On information and belief, Watson submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of its generic clopidogrel bisulfate tablets before the expiration of the ‘210 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 ‘210 patent, Watson has committed an act of infringement under 35 U.S.C. § 271(c)(2). Further, the commercial manufacture, use, offer for sale, sale and/or importation of the generic clopidogrel bisulfate products for which Watson seeks approval in its ANDA will also infringe one or more claims of the ‘210 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 '210 patent is invalid.

20. On information and belief, Watson's ANDA seeks approval to manufacture and sell pharmaceutical formulations containing Form 2 clopidogrel bisulfate, which is the precise compound claimed in the '210 patent.

21. 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 clopidogrel bisulfate products be a date which is not earlier than the June 10, 2019 expiration date of the '210 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Watson has infringed one or more claims of the '210 patent by filing the aforesaid ANDA relating to Watson's generic clopidogrel bisulfate 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 clopidogrel bisulfate products as claimed in the '210 patent;

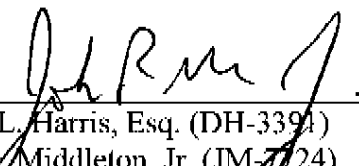
C. An order that the effective date of any approval of the aforementioned ANDA relating to Watson's generic clopidogrel bisulfate products be a date which is not earlier than the expiration date of the '210 patent;

D. The costs and disbursements of this action; and

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

Dated: October 7, 2004

Respectfully submitted,

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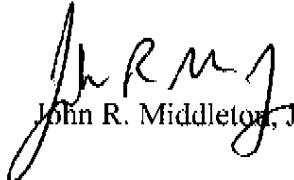
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LOCAL CIVIL RULE 11.2 CERTIFICATION

I hereby certify that the matter in controversy in this case is not the subject of any other action pending in any other court, or of any pending arbitration or administrative proceeding.

By:


John R. Middleton, Jr.

Dated: October 7, 2004

NY, Main #1615996 v1 - Plavix complaint

Exhibit A

Located in
clerk's file

US DC-Newark