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

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

SANOFI-AVENTIS U.S. LLC, SANOFI-AVENTIS, DEBIOPHARM, S.A., Plaintiffs, v. TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC. and TEVA INDUSTRIES, LTD. Defendants.	CIVIL ACTION NO.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Debiopharm, S.A., Sanofi-Aventis and Sanofi-Aventis U.S. LLC (hereinafter "Plaintiffs"), by way of Complaint against Teva Parenteral Medicines, Inc., Teva Pharmaceuticals USA, Inc., and Teva Industries, Ltd. allege as follows:

THE 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 innovator healthcare company whose core therapeutic areas are cancers, diseases of the central nervous system, cardiovascular disease, and internal medicine.

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

3. Debiopharm, S.A. ("Debiopharm") is a corporation, existing under the laws of Switzerland, having its principal place of business at Forum "après-demain" Chemin Messidor 5-7, Case postale 5911, CH - 1002 Lausanne, Switzerland. Debiopharm develops innovative and life-saving pharmaceuticals.

4. On information and belief, Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation incorporated under the laws of the State of Delaware, conducting business from facilities at 18-01 River Road, Fair Lawn, New Jersey 07041, and having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

5. On information and belief, Teva Industries, Ltd. ("Teva Israel") is a corporation organized and existing under the laws of Israel, having its corporate headquarters at 5 Basel Street, P.O.B. 3190, Petach Tikva 49131, Israel.

6. On information and belief, Teva Parenteral Medicines, Inc. ("Teva Parenteral") is incorporated under the laws of the State of Delaware, having an office and conducting business at 2050 Springdale Rd., Cherry Hill, NJ 08003.

7. On information and belief, Teva Parenteral is a wholly owned subsidiary of Teva USA.

8. On information and belief, Teva Parenteral is a subsidiary, affiliate or division of Teva Israel.

9. On information and belief, Teva Parenteral 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.

10. On information and belief, Teva Parenteral assembled and caused to be filed with the United Stated Food and Drug Administration (the "FDA"), pursuant to 21 U.S.C. § 355(b), New Drug Application ("NDA") No. 21-160, concerning a proposed generic drug product, oxaliplatin injection, in a 5mg/mL formulation.

11. On information and belief, Teva USA and Teva Israel, acting alone or in concert, caused, actively encouraged and/or directed Teva Parenteral to file NDA No. 21-160 with the FDA, and/or participated in the work related to the submission of NDA No. 21-160.

12. Teva Israel, Teva Parenteral and Teva USA are referred to hereinafter, collectively, as "Teva."

JURISDICTION AND VENUE

13. 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).

14. Teva Parenteral and Teva USA are subject to personal jurisdiction in New Jersey because they regularly and systematically conducts business within New Jersey, have offices within New Jersey, and sell various products throughout the United States, including within New Jersey.

15. Teva Israel is subject to personal jurisdiction in New Jersey because it manufactures pharmaceuticals and pharmaceutical products that are sold and used, including by Teva USA, throughout the United States, including within New Jersey.

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

COUNT 1
INFRINGEMENT OF U.S. PATENT NO. 5,338,874

17. Plaintiffs repeat and reallege paragraphs 1-16 above as if fully set forth herein.

18. Sanofi-Aventis U.S. LLC holds approved NDA Nos. 21-492 and 21-759 for Eloxatin®, the active ingredient of which is oxaliplatin. Eloxatin® is approved for the treatment of colorectal cancer. There are no generic oxaliplatin products approved by the FDA for sale in the United States.

19. Debiopharm is the owner of United States Patent No. 5,338,874 ("the '874 patent") (attached as "Exhibit A"). Sanofi-Aventis is the exclusive licensee of the '874 patent.

20. Teva submitted NDA No. 21-160 to the FDA under the provisions of 21 U.S.C. § 355(b), seeking approval to engage in the commercial manufacture, use and sale of injectable oxaliplatin formulations.

21. On information and belief, Teva submitted its NDA No. 21-160 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of its generic oxaliplatin solution before the expiration of the '874 patent.

22. On information and belief, Teva made, and included in its NDA, a certification under 21 U.S.C. § 355(b) that, in its opinion and to the best of its knowledge, the '874 patent is invalid and not infringed. On May 4, 2007, Teva sent Plaintiffs notice of that certification pursuant to 21 U.S.C. § 355(b)(2)(A)(iv).

23. By filing NDA No. 21-160 under 21 U.S.C. § 355(b) 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 '874 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

24. Further, the commercial manufacture, use, offer for sale, sale and/or importation of the generic oxaliplatin products for which Teva seeks approval in its NDA will also infringe one or more claims of the '874 patent under 35 U.S.C. § 271.

25. 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 NDA relating to Teva's generic oxaliplatin products be a date which is not earlier than the expiration date of the '874 patent plus any other regulatory exclusivity to which Plaintiffs are or become entitled.

COUNT 2
INFRINGEMENT OF U.S. PATENT NO. 5,716,988

26. Plaintiffs repeat and reallege paragraphs 1-18 above as if fully set forth herein.

27. Debiopharm is the owner of United States Patent No. 5,716,988 ("the '988 patent") (attached as "Exhibit B"). Sanofi-Aventis is the exclusive licensee of the '988 patent.

28. Teva submitted its NDA No. 21-160 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of its generic oxaliplatin solution before the expiration of the '988 patent.

29. On information and belief Teva made, and included in its NDA, a certification under 21 U.S.C. § 355(b)(2)(A)(iv) that, in its opinion and to the best of its knowledge, the '988 patent is invalid and not infringed. On May 4, 2007, Teva sent notice of that certification pursuant to 21 U.S.C. § 355(b) to Plaintiffs.

30. On information and belief, by filing its NDA No. 21-160 under 21 U.S.C. § 355(b) 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 '988 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

31. On information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of the generic oxaliplatin products for which Teva seeks approval in its NDA will also infringe one or more claims of the '988 patent under 35 U.S.C. § 271.

32. 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 NDA relating to Teva's generic oxaliplatin products be a date which is not earlier than the

expiration date of the '988 patent plus any other exclusivity to which Plaintiffs are or become entitled.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request:

A. Judgment that Teva has infringed one or more claims of the '874 and '988 patents by filing the aforesaid NDA relating to Teva's generic oxaliplatin products;

B. A permanent injunction restraining and enjoining Teva 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 oxaliplatin products as claimed in the '874 and '988 patents;

C. A declaration that the effective date of any approval of the aforementioned NDA relating to Teva's generic oxaliplatin formulations be a date which is not earlier than the expiration date of the '874 and '988 patents plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

D. A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and an award of reasonable attorney fees, expenses, and disbursements of this action; and

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

Dated: June 18, 2007

Respectfully submitted,

By: William J. O'Shaughnessy

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