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RECEIPT NUMBER

560032

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

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

Plaintiffs,

v.

SUN PHARMACEUTICAL INDUSTRIES,
LTD. and CARACO PHARMACEUTICAL
LABORATORIES, LTD.,

Defendants.

Case: 2:07-cv-13107
Assigned To: Cox, Sean F
Referral Judge: Whalen, R. Steven
Filed: 07-24-2007 At 03:38 PM
CMP SANOFI AVENTIS ET AL V. SUN PHA
RMACEUTICAL IND ET AL (DA)

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

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi-Aventis U.S. LLC, Sanofi-Aventis and Debiopharm, S.A. (hereinafter "Plaintiffs"), by way of Complaint against Sun Pharmaceutical Industries Ltd. and Caraco Pharmaceutical Laboratories, 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 oncology, 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 corporation incorporated 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, Sun Pharmaceutical Industries Ltd. ("Sun India") is a corporation organized under the laws of India, having its place of business at Acme Plaza, Andheri Kurla Road, Mumbai, India 400059.

5. On information and belief, Sun India conducts business through and with its subsidiary, Sun Pharmaceutical Industries, Inc. ("Sun USA"), which is incorporated under the laws of the state of Michigan and maintains a registered office at 29714 Orion Court, Farmington Hills, MI 48334.

6. On information and belief, Caraco Pharmaceutical Laboratories, Ltd. (“Caraco”) is a corporation organized under the laws of the state of Michigan, having a place of business at 1150 Elijah McCoy Drive, Detroit, MI 48202.

7. On information and belief, Sun India owns a majority interest in Caraco.

8. On information and belief, Sun India is in the business of manufacturing generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies, and which include a generic version of Sanofi-Aventis’s injectable oxaliplatin products.

9. On information and belief, Sun India assembled and caused to be filed with the United States Food and Drug Administration (“FDA”), pursuant to 21 U.S.C. § 355(j), Abbreviated New Drug Application (“ANDA”) No. 78-818 concerning a proposed drug product, oxaliplatin for injection, containing 50 mg/vial and 100 mg/vial.

10. On information and belief, Caraco actively encouraged Sun India to file ANDA No. 78-818 with the FDA, and/or participated in the work related to submission of ANDA No. 78-818.

11. On information and belief, if ANDA No. 78-818 is approved, it is the intention of Sun India and Caraco that the product will be distributed in the United States by or through Caraco.

12. Sun India and Caraco are referred to hereinafter, collectively, as “Sun”.

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. Sun India is subject to personal jurisdiction in the Eastern District of Michigan because Sun India consented to jurisdiction in this district. Sun India has conducted and continues to conduct business, directly, or through its subsidiaries, including Caraco and Sun USA, in this judicial district. On information and belief, Sun India, directly, or through its subsidiaries, manufactures, markets and sells generic drugs throughout the United States, including within Michigan.

15. Caraco is subject to personal jurisdiction in the Eastern District of Michigan because it is incorporated in Michigan and maintains a place of business in Michigan.

16. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 (b), (c), (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 new drug applications (“NDA”) 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. On information and belief, Sun submitted to the FDA ANDA No. 78-818 under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use and sale of injectable oxaliplatin formulations.

21. On information and belief, Sun submitted ANDA No. 78-818 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of its generic oxaliplatin formulations before the expiration of the '874 patent.

22. On information and belief, Sun made, and included in ANDA No. 78-818, 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 '874 patent is invalid and not infringed. On June 8, 2007, Sun sent Plaintiffs notice of that certification pursuant to 21 U.S.C. § 355(j)(2)(B).

23. By filing its ANDA No. 78-818 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 '874 patent, Sun committed acts 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 Sun seeks approval in its ANDA No. 78-818 will 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(c)(4), including an order of this Court that the effective date of any approval of ANDA No. 78-818 relating to Sun'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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request:

A. Judgment that Sun India and Caraco have infringed one or more claims of the '874 patent by filing ANDA No. 78-818 relating to Sun's generic oxaliplatin products;

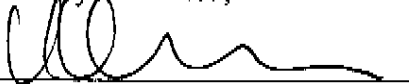
B. A permanent injunction restraining and enjoining Sun and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of generic oxaliplatin products as claimed in the '874 patent;

C. A declaration that the effective date of any approval of ANDA No. 78-818 relating to Sun's generic oxaliplatin formulations 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;

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.

Respectfully submitted,

By: 

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Dated: July 24, 2007

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