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. SUN PHARMA GLOBAL FZE, SUN PHARMACEUTICAL INDUSTRIES, INC., SUN PHARMACEUTICAL INDUSTRIES LTD., CARACO PHARMACEUTICAL LABORATORIES, LTD., Defendants.	CIVIL ACTION NO.:

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, Inc., Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE 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 Pharma Global FZE ("Sun FZE") is a corporation organized under the laws of the United Arab Emirates, having corporate offices at Office #43, Block Y, Sharjah Airport International Free Zone, P.O. Box #122304, Sharjah, United Arab Emirates.

5. On information and belief, Sun Pharmaceutical Industries Ltd. ("Sun India") is a corporation organized under the laws of India, having corporate offices at Acme Plaza, Andheri-Kurla Road, Andheri (E), Mumbai, India 400 059.

6. On information and belief, Sun India conducts business through and with its subsidiary, Sun Pharmaceutical Industries, Inc. ("Sun USA"), which maintains a offices at 270 Prospect Plains Road, Cranbury, NJ 08512.

7. On information and belief, Sun India conducts business through and with Sun FZE.

8. On information and belief, Sun FZE is an agent, affiliate or subsidiary or Sun India

9. On information and belief, Sun FZE conducts business through and with Sun USA, which maintains a offices at 270 Prospect Plains Road, Cranbury, NJ 08512.

10. On information and belief, Sun USA is an agent of Sun FZE.

11. On information and belief, Sun USA is a subsidiary of Sun FZE.

12. On information and belief, Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") is a corporation registered to do business in New Jersey and maintaining an authorized agent at 820 Bear Tavern Road, West Trenton, NJ 08628.

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

14. 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.

15. On information and belief, Sun FZE 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. 202-922 concerning a proposed drug product, oxaliplatin injection (5mg/mL), in 10 mL, 20mL and 40mL vials..

16. On information and belief, Sun India, Sun USA and/or Caraco aided, abetted and/or actively encouraged Sun FZE to file ANDA No. 202-922 with the FDA.

17. On information and belief, Sun India, Sun USA and/or Caraco participated in the work related to the submission of ANDA No. 202-922 to the FDA.

18. On information and belief, if ANDA No. 202-922 is approved, it is the intention of Sun FZE, Sun USA, Sun India and Caraco that the product will be distributed in the United States by or through Caraco and/or Sun USA.

19. Sun FZE, Sun India, Sun USA and Caraco are hereinafter referred to collectively as "Sun".

20. In settlement papers between Sun and Plaintiffs dated June 2, 2009 (the "License" or "License Agreement") and a consent order originally entered by this Court on April 22, 2010 (D.I. 661, Civil Action No. 3:07-cv-02762), Sun admitted that US. Patent Nos. 5,338,874 and 5,959,133 are not invalid and not unenforceable.

21. The License Agreement provided that Sun may market a generic oxaliplatin injection product beginning on August 9, 2012 (subject to certain acceleration provisions).

22. Sun has not stated that it will refrain from selling, marketing or distributing generic oxaliplatin products until August 9, 2012 as provided by the License Agreement.

JURISDICTION AND VENUE

23. 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, 1338(a), 2201, and 2202.

24. Sun FZE is subject to personal jurisdiction in New Jersey because Sun FZE maintains continuous and systematic contacts with this judicial district. Sun FZE has conducted and continues to conduct business, directly, or through its subsidiaries, agents and/or affiliates, including Sun USA, in this judicial district. On information and belief, Sun FZE, directly or through its agents, affiliates and/or subsidiaries, manufactures, markets and sells generic drugs throughout the United States and the District of New Jersey.

25. Sun India is subject to personal jurisdiction in New Jersey because Sun India maintains continuous and systematic contacts with this judicial 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 and the District of New Jersey. Sun has previously submitted to personal jurisdiction in New Jersey and has filed suit in New Jersey.

26. Sun USA is subject to personal jurisdiction in New Jersey because it maintains its principal place of business in New Jersey and maintains continuous and systematic contacts with this judicial district. On information and belief, Sun USA manufactures, markets and/or sells generic drugs throughout the United States and the District of New Jersey.

27. Caraco is subject to personal jurisdiction in New Jersey because it is registered to do business in New Jersey, and maintains an authorized agent in New Jersey.

28. 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

29. Plaintiffs repeat and reallege paragraphs 1-28 above as if fully set forth herein.

30. 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.

31. 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.

32. On information and belief, Sun submitted to the FDA ANDA No. 202-922 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.

33. On information and belief, Sun submitted ANDA No. 202-922 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of its generic oxaliplatin formulation prior to the effective date of its license (August 9, 2012).

34. On information and belief, Sun made, and included in ANDA No. 202-922, 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 not infringed. On May 5, 2011, Sun sent Plaintiffs notice of that certification pursuant to 21 U.S.C. § 355(j)(2)(B).

35. By filing its ANDA No. 202-922 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 effective date of Sun's License under the '874 patent (August 9, 2012), Sun committed acts of infringement under 35 U.S.C. § 271(e)(2).

36. 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. 202-922 will infringe one or more claims of the ’874 patent under 35 U.S.C. § 271.

37. 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 ANDA No. 202-922 relating to Sun ’s generic oxaliplatin products be a date which is not earlier than the date Sun is permitted to sell oxaliplatin products pursuant to its license agreement.

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

38. Plaintiffs repeat and reallege paragraphs 1-37 above as if fully set forth herein.

39. 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.

40. On information and belief, Sun submitted to the FDA ANDA No. 202-922 under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use and sale of Sun’s generic oxaliplatin formulations.

41. On information and belief, Sun submitted ANDA No. 202-922 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 ’988 patent.

42. On information and belief, Sun made, and included in ANDA No. 202-922, certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, the ’988 patent not infringed. On or about May 5, 2011 Sun sent Plaintiffs notice of those certifications pursuant to 21 U.S.C. § 355(j)(2)(B).

43. By filing its ANDA No. 202-922 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 effective date of its license (August 9, 2012), Sun committed acts of infringement under 35 U.S.C. § 271(e)(2).

44. 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. 202-922 will infringe one or more claims of the '988 patent under 35 U.S.C. § 271.

45. 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 ANDA No. 202-922 relating to Sun's generic oxaliplatin products be a date which is not earlier than the date Sun is permitted to sell oxaliplatin products pursuant to its License Agreement.

COUNT 3:
INFRINGEMENT OF U.S. PATENT NO. 5,959,133

46. Plaintiffs repeat and reallege paragraphs 1-45 above as if fully set forth herein.

47. Debiopharm is the owner of United States Patent No. 5,959,133 ("the '133 patent") (attached as "Exhibit C"). Sanofi-Aventis is the exclusive licensee of the '133 patent.

48. 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. 202-922 will infringe one or more claims of the '133 patent under 35 U.S.C. § 271.

49. Plaintiffs are entitled to a declaration of infringement against Sun and an order of this Court that Sun is enjoined from engaging in the commercial manufacturing, use,

offer for sale, sale, or importation of generic oxaliplatin products before the date Sun is permitted to sell oxaliplatin products pursuant to its License Agreement.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request:

A. Judgment that Sun FZE, Sun USA, Sun India and Caraco have infringed one or more claims of the ’874 patent and ’988 patent by filing ANDA No. 202-922 relating to Sun’s generic oxaliplatin products;

B. Judgment that Sun FZE, Sun USA, Sun India and Caraco will infringe one or more claims of the ’133 patent by engaging in the commercial manufacture, use, offer for sale, sale, or importation of generic oxaliplatin products prior to the date it is licensed to sell oxaliplatin;

C. 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, ’988 patent and/or the ’133 patent until Sun is permitted to sell generic oxaliplatin products pursuant to its License Agreement with plaintiffs;

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

Dated: June 17, 2011

Respectfully submitted,

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding. This action alleges infringement of the same patents at issue in the matter *Sanofi-Aventis US LLC, et al. v. Sun Pharmaceutical Industries., et al.*, Docket No. 07-cv-03411 (JAP-DEA), and an additional related patent.

/s/ William J. O'Shaughnessy
William J. O'Shaughnessy
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