

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

William J. O'Shaughnessy, Esq.
Nicole Corona, Esq.
McCarter & English, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
973-622-4444

Of Counsel:
Robert L. Baechtold, Esq.
William E. Solander, Esq.
Dominick Conde, Esq.
FITZPATRICK, CELLA,
HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112
(212) 218-2100

Attorneys for Plaintiffs,
SANOFI-AVENTIS U.S. LLC,
SANOFI-AVENTIS and DEBIOPHARM, S.A.

SANOFI-AVENTIS U.S. LLC,)
SANOFI-AVENTIS,)
DEBIOPHARM, S.A.,)
)
Plaintiffs,)
)
v.)
)
SANDOZ, INC.,)
)
)
Defendant.)

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 Sandoz, Inc. 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 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, Defendant Sandoz, Inc. ("Sandoz") is a corporation, incorporated and existing under the laws of the State of Colorado, and having a principal place of business at 506 Carnegie Ctr., Ste. 400, Princeton, New Jersey 08540.

5. 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.

6. On information and belief, Sandoz 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 No. 78-817, concerning a proposed generic drug product, oxaliplatin solution for injection in 50 mg vial (5 mg/ml) and 100 mg vial (5 mg/ml) formulations.

JURISDICTION AND VENUE

7. 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).

8. 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.

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

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

10. Plaintiffs repeat and reallege paragraphs 1-9 above as if fully set forth herein.

11. Sanofi-Aventis U.S. LLC holds approved new drug application (“NDA”) 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.

12. 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.

13. On information and belief, Sandoz submitted to the FDA ANDA No. 78-817 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.

14. On information and belief, Sandoz submitted its ANDA No. 78-817 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.

15. 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 '874 patent is invalid and not infringed, and sent notice of that certification pursuant to 21 U.S.C. § 355(j)(2)(B) to Plaintiffs.

16. By filing its ANDA No. 78-817 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, Sandoz committed an act of infringement under 35 U.S.C. § 271(e)(2).

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

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 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

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

20. 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.

21. On information and belief, Sandoz submitted its ANDA No. 78-817 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.

22. 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 ‘988 patent is invalid and not infringed, and sent notice of that certification pursuant to 21 U.S.C. § 355(j)(2)(B) to Plaintiffs.

23. By filing its ANDA No. 78-817 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 ‘988 patent, Sandoz 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 Sandoz seeks approval in its ANDA will also infringe one or more claims of the ‘988 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 ANDA relating to Sandoz’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 Sandoz has infringed one or more claims of the '874 and '988 patents by filing the aforesaid ANDA relating to Sandoz's generic oxaliplatin products;
- 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 oxaliplatin products as claimed in the '874 and '988 patents;
- C. A declaration that the effective date of any approval of the aforementioned ANDA relating to Sandoz'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 14, 2007

Respectfully submitted,

By: William J. O'Shaughnessy

William J. O'Shaughnessy, Esq.
Nicole Corona, Esq.
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Attorneys for Plaintiffs,
DEBIOPHARM, S.A., SANOFI-AVENTIS, and SANOFI-
AVENTIS U.S. LLC

Of Counsel:

Robert L. Baechtold, Esq.
William E. Solander, Esq.
Dominick Conde, Esq.

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, NY 10112-3801
Phone: (212) 218-2100
Facsimile: (212) 218-2200