

**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.)
)
DABUR ONCOLOGY PLC.,)
DABUR PHARMA LIMITED)
)
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 Dabur Oncology Plc. and Dabur Pharma Limited 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, Defendant Dabur Oncology Plc. is a UK Public Limited Company, conducting business from facilities at Lion Court, Farnham Road, Bordon, Hampshire, GU35 0NF, United Kingdom.

5. On information and belief, Defendant Dabur Pharma Limited is a public limited company organized under the laws of India, conducting business from facilities at 3, Factory Road, Adj. Safdarjung Hospital, New Delhi, 110029 and conducting business in Europe through its wholly-owned subsidiary Dabur Oncology Plc.

6. On information and belief, Dabur Oncology Plc. is in the business of developing and manufacturing generic pharmaceutical products, including a generic version of Sanofi-Aventis's injectable oxaliplatin products.

7. On information and belief, Dabur Pharma Limited is in the business of developing and manufacturing generic pharmaceutical products, including a generic version of Sanofi-Aventis's injectable oxaliplatin products.

8. On information and belief, Dabur Oncology Plc. 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. 78-810 concerning a proposed drug product, oxaliplatin for injection 50 mg per vial and 100 mg per vial.

9. On information and belief, Dabur Oncology Plc. assembled and caused to be filed with the United States Food and Drug Administration, pursuant to 21 U.S.C. § 355(j), Abbreviated New Drug Application No. 78-811 concerning a proposed drug product, oxaliplatin injection 50 mg/10 ml and 100 mg/20 ml.

10. On information and belief, Dabur Pharma Limited exercises control over Dabur Oncology Plc. and supplies Dabur Oncology Plc. with drug substance prepared in accordance with a Drug Master File filed with the FDA.

11. On information and belief, Dabur Pharma Limited caused, actively encouraged, and/or directed Dabur Oncology Plc. to file ANDA Nos. 78-810 and 78-811 with the FDA, and/or participated in the work related to the submission of ANDA Nos. 78-810 and 78-811.

12. Dabur Oncology Plc. and Dabur Pharma Limited are referred to hereinafter, collectively, as "Dabur."

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. Dabur is subject to jurisdiction in the United States under principles of general jurisdiction, and specifically in New Jersey pursuant to Fed. R. Civ. P. 4(k)(2). Dabur has contacts with the United States by, *inter alia*, its having filed an ANDA with the FDA. On information and belief, Dabur is not subject to the jurisdiction of the courts of general jurisdiction in any state.

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

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

16. Plaintiffs repeat and reallege paragraphs 1-15 above as if fully set forth herein.

17. 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.

18. 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.

19. On information and belief, Dabur submitted to the FDA ANDA Nos. 78-810 and 78-811 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.

20. On information and belief, Dabur submitted ANDA Nos. 78-810 and 78-811 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.

21. On information and belief, Dabur made, and included in ANDA Nos. 78-810 and 78-811, certifications 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 May 10, 2007, Dabur sent Plaintiffs notice of that certification pursuant to 21 U.S.C. § 355(j)(2)(B).

22. By filing its ANDA Nos. 78-810 and 78-811 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, Dabur committed acts of infringement under 35 U.S.C. § 271(e)(2).

23. Further, the commercial manufacture, use, offer for sale, sale and/or importation of the generic oxaliplatin products for which Dabur seeks approval in its ANDA Nos. 78-810 and 78-811 will infringe one or more claims of the '874 patent under 35 U.S.C. § 271.

24. 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 Nos. 78-810 and 78-811 relating to Dabur'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

25. Plaintiffs repeat and reallege paragraphs 1-24 above as if fully set forth herein.

26. 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.

27. On information and belief, Dabur submitted ANDA No. 78-811 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.

28. Dabur made, and included in its ANDA No. 78-811, 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 a notice of that certification pursuant to 21 U.S.C. § 355(j)(2)(B) to Plaintiffs.

29. By filing its ANDA No. 78-811 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, Dabur committed an act of infringement under 35 U.S.C. § 271(e)(2).

30. Further, the commercial manufacture, use, offer for sale, sale and/or importation of the generic oxaliplatin products for which Dabur seeks approval in its ANDA No. 78-811 will also infringe one or more claims of the ‘988 patent under 35 U.S.C. § 271.

31. 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. 78-811 relating to Dabur’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 Dabur has infringed one or more claims of the '874 and '988 patents by filing ANDA Nos. 78-810 or 78-811 relating to Dabur's generic oxaliplatin products;

B. A permanent injunction restraining and enjoining Dabur 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;

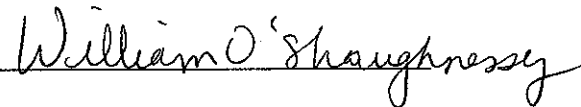
C. A declaration that the effective date of any approval of ANDA Nos. 78-810 and 78-811 relating to Dabur's generic oxaliplatin formulations be a date which is not earlier than the expiration date of the '874 and '988 patents plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

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 19, 2007

Respectfully submitted,

By: 

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