UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

SANOFI-AVENTIS U.S. LLC, SANOFI-AVENTIS, DEBIOPHARM, S.A., Plaintiffs, v. EBEWE PHARMA GES.M.B.H. NFG.KG 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 EBEWE Pharma Ges.m.b.H. Nfg.KG allege as follows:

JURISDICTION AND VENUE

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, EBEWE Pharma Ges.m.b.H. Nfg.KG (“EBEWE”) is an Austrian company, conducting business from facilities at Mondseestrasse 11, 4866 Unterach, Austria.

5. On information and belief, EBEWE 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.

6. On information and belief, EBEWE caused to be assembled and filed with the United States Food and Drug Administration (“FDA”), pursuant to 21 U.S.C. § 355(j), Abbreviated New Drug Application (“ANDA”) No. 78-812 concerning a proposed drug product, oxaliplatin injection, 5mg/mL, 10mL and 20mL vials.

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. EBEWE is subject to the jurisdiction of this Court by virtue of, *inter alia*, its contacts and sales within this district, including those with its subsidiary, Ebewe Parenta Pharmaceuticals, Inc.

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

ALLEGATIONS

FOR A FIRST CAUSE OF ACTION
(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 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.

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, EBEWE submitted to the FDA ANDA No. 78-812 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, EBEWE submitted ANDA No. 78-812 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.

15. On information and belief, EBEWE made, and included in ANDA No. 78-812, 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 May 25, 2007, EBEWE sent Plaintiffs notice of that certification pursuant to 21 U.S.C. § 355(j)(2)(B).

16. By filing its ANDA No. 78-812 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, EBEWE committed acts 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 EBEWE seeks approval in its ANDA No. 78-812 will 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 ANDA No. 78-812 relating to EBEWE'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.

FOR A SECOND CAUSE OF ACTION
(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, EBEWE submitted ANDA No. 78-812 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. EBEWE made, and included in its ANDA No. 78-812, 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.

23. By filing its ANDA No. 78-812 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, EBEWE 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 EBEWE seeks approval in its ANDA No. 78-812 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 ANDA No. 78-812 relating to EBEWE'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 EBEWE has infringed one or more claims of the '874 and '988 patents by filing ANDA No. 78-812 relating to EBEWE's generic oxaliplatin products;

B. A permanent injunction restraining and enjoining EBEWE 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 No. 78-812 relating to EBEWE'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.

Respectfully submitted,

s/ Susan L. Maupin
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