

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

William J. O’Shaughnessy, Esq.  
Jonathan M.H. Short, Esq.  
McCarter & English, LLP  
Four Gateway Center  
100 Mulberry Street  
Newark, New Jersey 07102  
(973) 622-4444

Of Counsel:  
Dominick A. Conde, Esq.  
William E. Solander, Esq.  
Peter D. Shapiro, Esq.  
Colleen Tracy, 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,	)	CIVIL ACTION NO.:
	)	
v.	)	
	)	
EBEWE PHARMA GES.M.B.H. NFG.KG,	)	
	)	
Defendants.	)	
_____	)	

**COMPLAINT FOR PATENT INFRINGEMENT AND CERTIFICATION PURSUANT  
TO LOCAL RULE 11.2**

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:

**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, Ebewe Pharma Ges.m.b.H. Nfg.KG ("Ebewe") is an Austrian company, conducting business from facilities at Mondseestrasse 11, 4866 Unterach, Austria and maintaining a place of business at 2125 Center Avenue, Suite 507, Fort Lee, New Jersey 07024.

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, through an agent in New Jersey,

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. 90-849 concerning a proposed drug product, Oxaliplatin For Injection, 50 mg/vial and 100 mg/vial. The supplement that is the subject of the January 26, 2009 Notice of Paragraph IV Certification presents a 200 mg/vial dosage strength of the same proposed drug product.

**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. Ebewe is subject to the jurisdiction of this Court by virtue of, *inter alia*, its continued use of an agent in New Jersey to file its ANDA and otherwise to conduct its business with the FDA, its maintenance of a place of business within New Jersey, and its contacts within this district.

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).

**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”) Nos. 21-492 and 21-759 for Eloxatin<sup>®</sup>, the active ingredient of which is oxaliplatin. Eloxatin<sup>®</sup> 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. 90-849 and a supplement to ANDA No. 90-849 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. 90-849 and a supplement to ANDA No. 90-849 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. 90-849 and in its supplement to ANDA No. 90-849 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, unenforceable, or not infringed. On January 26, 2009 Ebewe sent Plaintiffs notice of the certification regarding its supplement to ANDA No. 90-849 pursuant to 21 U.S.C. § 355(j)(2)(B).

16. By filing its ANDA No. 90-849 and supplement to ANDA No. 90-849 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. 90-849, including in its supplement to ANDA No. 90-849, 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. 90-849, including Ebewe's supplement to ANDA No. 90-849, 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.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request:

A. Judgment that Ebewe has infringed one or more claims of the '874 Patent by filing ANDA No. 90-849, including Ebewe's supplement to ANDA No. 90-849, 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 Patent;

C. A declaration that the effective date of any approval of ANDA No. 90-849, including Ebewe's supplement to ANDA No. 90-849, relating to Ebewe'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,

Dated: March 11, 2009

By: S/William J. O'Shaughnessy

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

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

Of Counsel:

Dominick A. Conde, Esq.  
William E. Solander, Esq.  
Peter D. Shapiro, Esq.  
Colleen Tracy, Esq.  
FITZPATRICK, CELLA, HARPER & SCINTO  
30 Rockefeller Plaza  
New York, New York 10112-3801  
Phone: (212) 218-2100  
Facsimile: (212) 218-2200