

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

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SANOFI-AVENTIS and DEBIOPHARM, S.A.

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SANOFI-AVENTIS U.S. LLC, )  
SANOFI-AVENTIS, )  
DEBIOPHARM, S.A., )  
) )  
Plaintiffs, )  
) )  
v. )  
) )  
MAYNE PHARMA LIMITED, )  
MAYNE PHARMA (USA) INC., )  
HOSPIRA AUSTRALIA PTY LTD. )  
HOSPIRA, INC. )  
) )  
Defendants. )

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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 Mayne Pharma Limited, Mayne Pharma (USA) Inc., Hospira Australia Pty Ltd., and Hospira, 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 company organized under the laws 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 Hospira, Inc. is a Delaware corporation with its headquarters at 275 North Field Drive, Lake Forest, Illinois.

5. On information and belief, Mayne Pharma Limited is an Australian corporation conducting business from facilities at Level 3, 390 St. Kilda Rd., Melbourne, Victoria, 3004, Australia.

6. On information and belief, Mayne Pharma Limited is now known as Hospira Australia Pty Ltd. For simplicity, Hospira Australia Pty Ltd. is referred to by its former name “Mayne Pharma Limited.”

7. On information and belief, Defendant Mayne Pharma (USA) Inc. is a Delaware corporation with its headquarters at 650 From Road, Paramus, New Jersey 07652. and continues to have a mailing address of 650 From Road, Paramus, New Jersey 07652.

8. On information and belief, Defendant Mayne Pharma (USA) Inc. is a subsidiary of Mayne Pharma Limited, and Mayne Pharma Limited and Mayne Pharma (USA) Inc. are owned and controlled by Hospira, Inc.

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

10. On information and belief, Mayne Pharma (USA) Inc. and/or Hospira Inc. are responsible for the sale and distribution of Mayne Pharma Limited's generic products in the United States.

11. On information and belief, Mayne Pharma Limited 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. 78-813, which concerns a proposed drug product, Oxaliplatin Injection (50 mg/10 ml and 100 mg/20 ml) and an amendment to ANDA No. 78-813, which concerns a proposed drug product, Oxaliplatin Injection (200 mg/40 ml)

12. On information and belief, Mayne Pharma (USA) Inc. participated in the submission of ANDA No. 78-813 or otherwise acted in concert with Mayne Pharma Limited in the submission of ANDA No. 78-813.

13. Mayne Pharma (USA) Inc. participated in the preparation of ANDA No. 78-813 or otherwise acted in concert with Mayne Pharma Limited in the preparation of ANDA No. 78-813.

14. On information and belief, Mayne Pharma Limited exercised control over Mayne Pharma (USA) Inc. during the preparation or submission of ANDA No. 78-813.

15. On information and belief, Mayne Pharma Limited conducts and/or conducted U.S. operations through Mayne Pharma (USA) Inc. and/or Hospira Inc.

16. On information and belief, if any product is approved under ANDA No. 78-813, it is the intention of Mayne Pharma Limited, Mayne Pharma (USA) Inc. and/or Hospira, Inc. that the product will be manufactured, used, marketed, sold, or distributed in the United States.

17. Defendants are referred to hereinafter, collectively, as “Mayne.”

### **JURISDICTION AND VENUE**

18. 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).

19. Mayne Pharma Limited is subject to general personal jurisdiction in New Jersey.

20. Mayne Pharma Limited has contacts with New Jersey including, *inter alia*, its business dealings with its New Jersey-based subsidiary, Mayne Pharma (USA) Inc., and/or Hospira Inc.

21. Mayne Pharma Limited has launched products in the United States through Mayne Pharma (USA) Inc. and/or through Hospira Inc.

22. Mayne Pharma Limited has distributed its products in the United States through and has sold or otherwise transferred its products to Mayne Pharma (USA) Inc. and/or Hospira Inc.

23. Mayne Pharma Limited has continuing obligations to Mayne Pharma (USA) Inc. and/or Hospira, Inc.

24. Mayne Pharma Limited is subject to specific personal jurisdiction in New Jersey.

25. The preparation or submission of Mayne Pharma Limited's ANDA No. 78-813 involved the participation of its New Jersey-based subsidiary, Mayne Pharma (USA) Inc. and/or Hospira Inc.

26. In the alternative, Mayne Pharma Limited 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). Mayne Pharma Limited has contacts with the United States by, *inter alia*, its having filed an ANDA with the FDA.

27. In the alternative, Mayne Pharma Limited is subject to general jurisdiction because, among other reasons, Mayne Pharma (USA) Inc. acted as the *alter ego* or agent of Mayne Pharma Limited during the preparation and submission of ANDA No. 78-813. Mayne Pharma Limited and Mayne Pharma (USA) Inc. also share or shared, *inter alia*, websites, officers, and responsibility for ANDA filings. Mayne Pharma Limited directed the U.S. operations of Mayne Pharma (USA) Inc. during the preparation or submission of ANDA No. 78-813.

28. Mayne Pharma (USA) Inc. is subject to specific and general personal jurisdiction in New Jersey.

29. Mayne Pharma (USA) Inc. has contacts with New Jersey including, *inter alia*, through the maintenance of a mailing address in Paramus, New Jersey.

30. Hospira, Inc. is subject to personal jurisdiction in New Jersey through, *inter alia*, its sale and distribution of products within New Jersey as well as its other contacts directly with New Jersey residents, including but not limited to the fact that Hospira, Inc. has over thirty distributors in New Jersey, including Hospira Worldwide Contracted Distribution Center in Jersey City, New Jersey, and that it has continuing obligations to Mayne Pharma (USA) Inc. or has succeeded to the obligations and liabilities of Mayne Pharma (USA) Inc.

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

**INFRINGEMENT OF U.S. PATENT NO. 5,338,874**

32. Plaintiffs repeat and reallege paragraphs 1-31 above as if fully set forth herein.

33. Sanofi-Aventis U.S. LLC holds approved New Drug Application (“NDA”) Nos. 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.

34. 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.

35. On information and belief, Mayne submitted to the FDA ANDA No. 78-813 and an amendment to ANDA No. 78-813 under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of Oxaliplatin Injection (50 mg/10 ml, 100 mg/20 ml, and 200 mg/40 ml).

36. On information and belief, Mayne submitted ANDA No. 78-813 and an amendment to ANDA No. 78-813 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.

37. On information and belief, Mayne made, and included in ANDA No. 78-813 and an amendment to ANDA No. 78-813, certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '874 patent is invalid and not infringed. On June 8, 2007, Mayne sent Plaintiffs notice of the certification filed with ANDA No. 78-813 (and pertaining to the 50 mg/10 ml and 100 mg/20 ml dosage forms) pursuant to 21 U.S.C. § 355(j)(2)(B).

38. On July 23, 2007, Plaintiffs filed suit against Mayne for patent infringement in the United States District Court for the District of New Jersey (docket no. 3:07-cv-03409-FLW-JJH).

39. On August 7, 2007, Mayne (using the name "Mayne Pharma Limited") filed with the FDA an amendment to ANDA No. 78-813 for the new dosage strength of 200 mg/40 ml, included with that amendment a new "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), and sent Plaintiffs notice of that certification pursuant to 21 U.S.C. § 35(j)(2)(B).

40. By filing its ANDA No. 78-813 and the amendment to ANDA No. 78-813 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, Mayne committed acts of infringement under 35 U.S.C. § 271(e)(2).

41. Further, the commercial manufacture, use, offer for sale, sale, and/or importation of the generic oxaliplatin products for which Mayne seeks approval in its ANDA

No. 78-813 as originally filed or as amended will infringe one or more claims of the '874 patent under 35 U.S.C. § 271.

42. 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. 78-813 and relating to Mayne'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 Defendants have infringed one or more claims of the '874 patent by filing ANDA No. 78-813 and the amendment to ANDA No. 78-813 relating to Defendants' generic oxaliplatin products;

B. A permanent injunction restraining and enjoining Defendants and their officers, agents, attorneys, and employees, and those acting in privity or concert with them, 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. 78-813 relating to Defendants' 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.

Dated: September 21, 2007

Respectfully submitted,

s/Stacey P. Rappaport  
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