

**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.)
MUSTAFA NEVZAT İLAÇ SANAYII A.Ş.)
(a.k.a. MN PHARMACEUTICALS),)
PAR PHARMACEUTICAL COMPANIES, INC.,)
PAR PHARMACEUTICAL, INC.)
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 Mustafa Nevzat İlaç Sanayii A.Ş. (a.k.a. and hereinafter referred to as "MN Pharmaceuticals"), Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, 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 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, MN Pharmaceuticals is a Turkish limited liability company, conducting business from a facility at Pak Is Merkezi Prof. Dr. Bülent Tarcan Sok. No. 5/1 34349 Gayrettepe, Istanbul, Turkey.

5. On information and belief, Par Pharmaceutical Companies, Inc. is a Delaware corporation, conducting business from facilities at 300 Tice Boulevard, Woodcliff Lake, New Jersey.

6. On information and belief, Par Pharmaceutical, Inc. is a Delaware corporation, conducting business from facilities at 300 Tice Boulevard, Woodcliff Lake, New Jersey.

7. On information and belief, MN Pharmaceuticals is in the business of manufacturing generic pharmaceutical products.

8. On information and belief, Par Pharmaceutical Companies, Inc. is a holding company that operates principally through its wholly-owned subsidiary, Par Pharmaceutical, Inc. and is engaged in the business of developing, manufacturing, and distributing pharmaceutical products.

9. On information and belief, Par Pharmaceutical, Inc. is in the business of developing, manufacturing, and distributing pharmaceutical products. Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. are hereinafter referred to collectively as "Par."

10. On information and belief, MN Pharmaceuticals has entered into a strategic partnership with Par.

11. On information and belief, the strategic partnership is, *inter alia*, for the purpose of developing and marketing injectable generic pharmaceutical products in the United States.

12. On information and belief, MN Pharmaceuticals currently sells pharmaceutical products to the United States as a whole either directly or through Par.

13. On information and belief, MN Pharmaceuticals, acting in concert with Par, 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. 78-816 concerning a proposed drug product, oxaliplatin injection, 5 mg/ml, 10ml and 20ml vials.

JURISDICTION AND VENUE

14. 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).

15. Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. are subject to jurisdiction in New Jersey because both have established and continuing places of business in New Jersey.

16. MN Pharmaceuticals is subject to jurisdiction in New Jersey through its partnership, joint venture, or other relationship with Par.

17. Alternatively, MN Pharmaceuticals 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). MN Pharmaceuticals has contacts with the United States as a whole by, *inter alia*, its having filed an ANDA with the FDA and through its sales of pharmaceutical products to the United States.

18. 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

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

20. 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.

21. 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.

22. On information and belief, MN Pharmaceuticals and Par submitted ANDA No. 78-816 to the FDA 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.

23. On information and belief, MN Pharmaceuticals and Par submitted ANDA No. 78-816 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of generic oxaliplatin formulations before the expiration of the ‘874 patent.

24. On information and belief, MN Pharmaceuticals and Par made, and included in ANDA No. 78-816, a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in their opinion and to the best of their knowledge, the ‘874 patent is unenforceable and not infringed. On May 24, 2007, MN Pharmaceuticals and Par sent Plaintiffs notice of that certification pursuant to 21 U.S.C. § 355(j)(2)(B).

25. By filing ANDA No. 78-816 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of proposed drug products before the expiration of the ‘874 patent, MN Pharmaceuticals and Par committed an act of infringement under 35 U.S.C. § 271(e)(2).

26. Further, MN Pharmaceuticals’ and Par’s commercial manufacture, use, offer for sale, sale and/or importation of the generic oxaliplatin products for which MN Pharmaceuticals and Par seek approval in ANDA No. 78-816 will infringe one or more claims of the ‘874 patent under 35 U.S.C. § 271.

27. 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. 78-816

relating to MN Pharmaceuticals' and Par'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

28. Plaintiffs repeat and reallege paragraphs 1-27 above as if fully set forth herein.

29. 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.

30. On information and belief, MN Pharmaceuticals and Par submitted ANDA No. 78-816 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of generic oxaliplatin formulations before the expiration of the '988 patent.

31. On information and belief, MN Pharmaceuticals and Par made, and included in ANDA No. 78-816, a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in their opinion and to the best of their knowledge, the '988 patent is invalid and that certain claims were not infringed. On May 24, 2007, MN Pharmaceuticals and Par sent Plaintiffs a notice of that certification pursuant to 21 U.S.C. § 355(j)(2)(B).

32. By filing its ANDA No. 78-816 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of proposed drug products before the expiration of the '988 patent, MN Pharmaceuticals and Par committed an act of infringement under 35 U.S.C. § 271(e)(2).

33. Further, MN Pharmaceuticals' and Par's commercial manufacture, use, offer for sale, sale and/or importation of the generic oxaliplatin products for which MN

Pharmaceuticals and Par seek approval in ANDA No. 78-816 will also infringe one or more claims of the '988 patent under 35 U.S.C. § 271.

34. 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. 78-816 relating to MN Pharmaceuticals' and Par'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 MN Pharmaceuticals, Par Pharmaceutical Companies, Inc., and Par Pharmaceutical, Inc. have infringed one or more claims of the '874 and '988 patents by filing ANDA No. 78-816 relating to MN Pharmaceuticals' and Par's generic oxaliplatin products;

B. A permanent injunction restraining and enjoining MN Pharmaceuticals, Par Pharmaceutical Companies, Inc., and Par Pharmaceutical, Inc. and their respective officers, agents, attorneys and employees, and those acting in privity or concert with those parties, 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. 78-816 relating to MN Pharmaceuticals' and Par'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: July 6, 2007

Respectfully submitted,

By: William S. O'Shaughnessy

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