

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.)
)
)
ACTAVIS TOTOWA LLC,)
ACTAVIS, INC.,)
ACTAVIS GROUP HF,)
)
)
Defendants.)

CIVIL ACTION NO.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Debiopharm, S.A., Sanofi-Aventis and Sanofi-Aventis U.S. LLC (hereinafter "Plaintiffs"), by way of Complaint against Actavis Totowa LLC, Actavis, Inc. and Actavis Group hf 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 cancers, 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 Actavis Group hf ("Actavis Group") is a corporation, organized and existing under the laws of Iceland, and having a principal place of business at Dalshraun 1, 220 Hafnarfjordur, Iceland.

5. On information and belief, Defendant Actavis, Inc. is a corporation, incorporated and existing under the laws of the State of Delaware, and conducting business from facilities at 14 Commerce Dr., Suite 301, Cranford, New Jersey 07016.

6. On information and belief, Actavis, Inc. is a subsidiary, affiliate or division of Actavis Group.

7. On information and belief, Defendant Actavis Totowa LLC (“Actavis Totowa”) is a corporation, incorporated and existing under the laws of the State of Delaware, and having a principal place of business at 990 Riverview Drive, Totowa, New Jersey 07512.

8. On information and belief, Actavis Totowa is a subsidiary, affiliate or division of Actavis Group.

9. On information and belief, Actavis Totowa is an affiliate of Actavis, Inc.

10. On information and belief, Actavis Totowa is in the business of developing, manufacturing, marketing, and distributing generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

11. On information and belief, Actavis Totowa 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. 78-803, concerning a proposed generic drug product, oxaliplatin for injection in 50 mg and 100 mg vials.

12. On information and belief, Actavis Group and Actavis, Inc., acting alone or in concert, actively encouraged and/or directed Actavis Totowa to file ANDA No. 78-803 with the FDA, and/or participated in the work related to the submission of ANDA No. 78-803.

13. Actavis Group, Actavis, Inc. and Actavis Totowa are referred to hereinafter, collectively, as “Actavis.”

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. Actavis Totowa and Actavis, Inc. are subject to personal jurisdiction in New Jersey because they regularly and systematically conduct business within New Jersey and have offices within New Jersey.

16. Actavis Group is subject to personal jurisdiction in New Jersey because it manufactures pharmaceuticals and pharmaceutical products that are sold and used, including by Actavis Totowa, throughout the United States, including within New Jersey.

17. In the alternative, Actavis Group 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). Actavis Group has contacts with the United States by, *inter alia*, its having filed an ANDA with the FDA.

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).

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”) 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.

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. Pursuant to 21 U.S.C. § 355(j)(2)(B), Actavis sent a notice of certification to Plaintiffs regarding Abbreviated New Drug Application (“ANDA”) No. 78-803.

23. Actavis submitted to the FDA ANDA No. 78-803 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.

24. On information and belief, Actavis submitted its ANDA No. 78-803 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 '874 patent.

25. On information and belief, Actavis made, and included in its ANDA, 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 24, 2007, Actavis sent Plaintiffs notice of that certification pursuant to 21 U.S.C. § 355(j).

26. By filing its ANDA No. 78-803 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, Actavis committed an act of infringement under 35 U.S.C. § 271(e)(2).

27. Further, the commercial manufacture, use, offer for sale, sale and/or importation of the generic oxaliplatin products for which Actavis seeks approval in its ANDA will also infringe one or more claims of the '874 patent under 35 U.S.C. § 271.

28. 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 the aforementioned ANDA relating to Actavis' 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 Actavis has infringed one or more claims of the '874 patent by filing the aforesaid ANDA relating to Actavis' generic oxaliplatin products;

B. A permanent injunction restraining and enjoining Actavis 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 the aforementioned ANDA relating to Actavis' 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: July 6, 2007

Respectfully submitted,

By: William J. O'Shaughnessy

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