

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC.,

Plaintiff,

v.

SANDOZ, INC.

Defendant.

C.A. No. _____

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Allergan, Inc. (“Allergan” or “Plaintiff”) by its attorneys, Fish & Richardson P.C. and Gibson Dunn & Crutcher LLP, for its complaint against Defendant Sandoz, Inc. (“Sandoz” or “Defendant”) alleges as follows:

The Nature of the Action

1. This is an action for infringement of United States Patent Nos. 5,688,819 (the “819 patent”) and 6,403,649 (the “649 patent”) under 35 U.S.C. § 271(e)(2).

The Parties

2. Plaintiff Allergan, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2525 Dupont Drive, Irvine, California 92612.

3. On information and belief, Defendant Sandoz, Inc. is a corporation organized and existing under the laws of the State of Colorado, with a place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540.

4. On information and belief, Sandoz is in the business of manufacturing, distributing, and selling generic pharmaceutical products throughout the United States, including in this judicial district, and is registered to distribute drugs in the State of Delaware.

Jurisdiction and Venue

5. This is an action for infringement of the '819 and '649 patents under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq.*

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

7. This Court has personal jurisdiction over Sandoz by virtue of the fact that, *inter alia*, it has committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiff, a Delaware corporation.

8. This Court also has personal jurisdiction over Sandoz by virtue of the fact that it regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware. These activities further demonstrate that Sandoz has continuous and systematic contacts with Delaware.

9. On information and belief, Sandoz has indicated that it is subject to personal jurisdiction in any judicial district in which it conducts business.

10. On information and belief, Sandoz conducts business in the State of Delaware.

11. On information and belief, Sandoz is registered with the Delaware Board of Pharmacy as a licensed "Distributor/Manufacturer CSR" (License No. DS0131) and "Pharmacy-Wholesale" (License No. A4-0000260) pursuant to Del. C. § 2540.

12. On information and belief, Sandoz has derived substantial revenue from sales of pharmaceutical products in Delaware, including sales of over \$30.6 million in 2008.

13. On information and belief, Sandoz has entered into contracts with and/or purchased goods or services from companies located in Delaware, including at least Agilent Technologies, Inc., and LabWare, Inc.

14. On information and belief, Sandoz has previously availed itself of this forum for purposes of litigating its patent disputes. For example, Sandoz has submitted to the jurisdiction of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

Specifically, Sandoz consented to jurisdiction and filed counterclaims in *Daiichi Sankyo Co., LTD. v. Sandoz Inc.*, C.A. No. 09-898 (D. Del.); *Aventis Pharma S.A. v. Sandoz Inc.*, C.A. 09-810 (D. Del.); *Bone Care Int'l LLC v. Sandoz Inc.*, C.A. No. 09-524 (D. Del.); *Pfizer Inc. v. Sandoz Inc.*, C.A. No. 09-310 (D. Del.); *Abbott Labs. v. Sandoz Inc.*, C.A. No. 09-215 (D. Del.); *Medicis Pharms. Corp. v. Mylan Inc. et al.*, C.A. No. 09-033 (D. Del.); *Endo Pharmaceuticals Inc. v. Sandoz Inc.*, C.A. No. 08 - 534 (D. Del.); *Wyeth v. Sandoz Inc.*, C.A. No. 08 - 317 (D. Del.); and *AstraZeneca Pharmaceuticals LP v. Sandoz Inc.*, C.A. No. 07 - 807 (D. Del.).

15. As recently as December 15, 2009, in *Daiichi Sankyo Co., LTD. v. Sandoz Inc.*, C.A. No. 09-898 (D. Del.), Sandoz consented to personal jurisdiction in Delaware.

16. In these and other cases, Sandoz has engaged the services of various Delaware law firms to represent it and has repeatedly entered this District to litigate its patent disputes before this Court.

17. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

Background

18. The '819 patent, entitled "Non-Acidic Cyclopentane Heptanoic Acid, 2-Cycloalkyl or Arylalkyl Derivatives as Therapeutic Agents," issued to David F. Woodward, Steven W. Andrews, Robert M. Burk, and Michael E. Garst on November 18, 1997. A copy of the '819 patent is attached to this complaint as Exhibit A.

19. Allergan, as the assignee, owns the entire right, title, and interest in the '819 patent.

20. The '649 patent, entitled "Non-Acidic Cyclopentane Heptanoic Acid, 2-Cycloalkyl or Arylalkyl Derivatives as Therapeutic Agents," issued to David F. Woodward, Steven W. Andrews, Robert M. Burk, and Michael E. Garst on June 11, 2002. A copy of the '649 patent is attached to this complaint as Exhibit B.

21. Allergan, as the assignee, owns the entire right, title, and interest in the '649 patent.

22. Allergan is the holder of approved New Drug Application ("NDA") 02-1275 for 0.03% bimatoprost ophthalmic solution, sold under the LUMIGAN® trademark.

23. In conjunction with NDA 02-1275, Allergan listed the '819 and '649 patents with the U.S. Food and Drug Administration ("FDA") as patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1).

24. On or about December 18, 2009, Allergan received a letter, dated December 14, 2009, signed on behalf of Sandoz, Inc. The letter stated that Sandoz had filed an Abbreviated New Drug Application ("ANDA") (No. 200487) with the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j), seeking approval to market a

generic version of Allergan's LUMIGAN® product before the expiration of the '819 and '649 patents.

25. The purpose of the December 14, 2009 letter was to notify Allergan that Sandoz had filed a certification with the FDA under section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), ("Paragraph IV certification") in conjunction with its ANDA. The letter alleged (1) that no claims of the '819 patent would be infringed by Sandoz's generic version of Allergan's LUMIGAN® product and (2) that all claims of the '819 patent and the '649 patent were invalid.

Count I

(Infringement of the '819 Patent Under 35 U.S.C. § 271(e)(2))

26. Paragraphs 1 to 25 are incorporated herein as set forth above.

27. Sandoz submitted an ANDA to the FDA under section 505(j) of the FDCA, 21 U.S.C. § 355(j), to obtain approval to engage in the commercial manufacture, use, or sale of its proposed generic 0.03% bimatoprost ophthalmic solution product throughout the United States. By submitting the application, Sandoz has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

28. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic 0.03% bimatoprost ophthalmic solution product will constitute direct and/or contributory infringement of the '819 patent and/or active inducement of infringement of the '819 patent.

Count II

(Infringement of the '649 Patent Under 35 U.S.C. § 271(e)(2))

29. Paragraphs 1 to 28 are incorporated herein as set forth above.

30. Sandoz submitted an ANDA to the FDA under section 505(j) of the FDCA, 21 U.S.C. § 355(j), to obtain approval to engage in the commercial manufacture, use, or sale of its proposed generic 0.03% bimatoprost ophthalmic solution product throughout the United States. By submitting the application, Sandoz has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

31. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic 0.03% bimatoprost ophthalmic solution product will constitute direct and/or contributory infringement of the '649 patent and/or active inducement of infringement of the '649 patent.

Prayer for Relief

a. That judgment be entered that Sandoz and all those acting in concert with it have infringed the '819 and '649 patents under 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA under section 505(j) of the FDCA, 21 U.S.C. § 355(j), and that the commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic 0.03% bimatoprost ophthalmic solution product will constitute an act of infringement of the '819 and '649 patents as pled;

b. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Sandoz's ANDA shall be a date which is not earlier than the expiration date of the '819 and '649 patents and any relevant exclusivity and term extension attaching to those patents;

c. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Sandoz, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with

it or acting on its behalf, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of any drug product covered by the '819 and '649 patents;

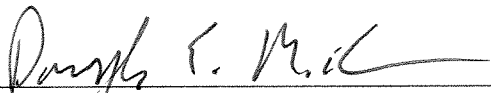
d. That damages or other monetary relief be awarded to Allergan under 35 U.S.C. § 271(e)(4)(C) as appropriate;

e. That this is an exceptional case under 35 U.S.C. § 285, and that Allergan be awarded reasonable attorneys' fees and costs; and

f. That this Court award such other and further relief as it may deem just and proper.

Demand For Jury Trial

Allergan demands a trial by jury on all issues appropriately tried to a jury.

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Dated: January 8, 2010

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