

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
MARSHALL DIVISION**

ALLERGAN, INC.,

Plaintiff,

v.

SANDOZ INC.,

Defendant.

Civil Action No. 2:09-cv-97

**Jury Trial Demanded**

**ALLERGAN'S COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Allergan, Inc. ("Allergan" or "Plaintiff") by its attorneys, Ireland, Carroll & Kelley, P.C. and Fish & Richardson P.C., 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 Patents Nos. 7,030,149 ("the '149 patent") and 7,320,976 ("the '976 patent") under 35 U.S.C. § 271(e)(2).

**The Parties**

2. Allergan 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, Sandoz is a corporation incorporated under the laws of the State of Colorado, with a place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

4. On information and belief, Sandoz is in the business of manufacturing, distributing and selling generic drugs throughout the United States, including in this judicial jurisdiction.

## **Jurisdiction and Venue**

5. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq.* This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338.

6. This Court has personal jurisdiction over Defendant Sandoz by virtue of its systematic and continuous contacts with this jurisdiction.

7. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

## **Background**

8. The '149 patent, entitled "Combination of Brimonidine Timolol For Topical Ophthalmic Use," issued to Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L. Batoosingh on April 18, 2006. A copy of the '149 patent is attached to this complaint as Exhibit A.

9. Allergan, as assignee, owns the entire right, title, and interest in the '149 patent.

10. The '976 patent, entitled "Combination of Brimonidine Timolol For Topical Ophthalmic Use," issued to Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L. Batoosingh on January 22, 2008. A copy of the '976 patent is attached to this complaint as Exhibit B.

11. Allergan, as assignee, owns the entire right, title, and interest in the '976 patent.

12. Allergan is the holder of an approved New Drug Application ("NDA") No. 21-398 for brimonidine tartrate/timolol maleate ophthalmic solution 0.2%/0.5%, sold under the Combigan® trademark.

13. In conjunction with that NDA, Allergan has listed with the United States Food and Drug Administration ("FDA") two patents (the "Listed Patents") that cover the approved

formulation of Combigan®. The Listed Patents are the '149 and '976 patents. The FDA has published the Listed Patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the “Orange Book.”

14. Combigan® is covered by at least one claim of each of the Listed Patents.

15. On February 23, 2009, Allergan received a letter, dated February 20, 2009, signed on behalf of Sandoz Inc. by Alison Sherwood. The letter stated that Sandoz Inc. had filed Abbreviated New Drug Application (“ANDA”) No. 91-087 with the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) seeking approval to market a generic version of Allergan’s Combigan® product before expiration of the Listed Patents.

16. The stated purpose of the February 20, 2009 letter was to notify Allergan that Sandoz’s ANDA contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the '149 and '976 patents. The letter alleged that the claims of the Listed Patents would not be infringed by the manufacture, use, importation, sale or offer for sale of the Sandoz product.

17. Attached to the February 20, 2009 letter was a “Detailed Statement” of the factual and legal basis for Sandoz’s opinion that the Listed Patents would not be infringed by the manufacture, use, importation, sale or offer for sale of the Sandoz product. The Detailed Statement alleged that the Listed Patents were invalid and therefore not infringed by the manufacture, use, importation, sale or offer for sale of the Sandoz product.

18. In filing its ANDA, Sandoz has requested the FDA’s approval to market a generic version of Allergan’s Combigan® product throughout the United States, including in Texas.

19. On information and belief, following FDA approval of its ANDA, Sandoz will sell the approved generic version of Allergan’s Combigan® product throughout the United States, including in Texas.

### Count I

**(Infringement of the '149 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz's proposed generic Brimonidine Tartrate 0.2%, timolol maleate 0.5%, ophthalmic solution/drops)**

20. Paragraphs 1 to 19 are incorporated herein as set forth above.

21. Sandoz submitted ANDA No. 91-087 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use or sale of its proposed Brimonidine Tartrate 0.2%, timolol maleate 0.5%, ophthalmic solution/drops product throughout the United States. By submitting this application, Sandoz has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

22. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Brimonidine Tartrate 0.2%, timolol maleate 0.5%, ophthalmic solution/drops product will constitute an act of infringement of the '149 patent.

23. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Brimonidine Tartrate 0.2%, timolol maleate 0.5%, ophthalmic solution/drops product in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

### Count II

**(Infringement of the '976 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz's proposed generic Brimonidine Tartrate 0.2%, timolol maleate 0.5%, ophthalmic solution/drops)**

24. Paragraphs 1 to 19 are incorporated herein as set forth above.

25. Sandoz submitted ANDA No. 91-087 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use or sale of its proposed Brimonidine Tartrate 0.2%, timolol maleate 0.5%, ophthalmic solution/drops product throughout the United States. By submitting this application, Sandoz has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

26. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Brimonidine Tartrate 0.2%, timolol maleate 0.5%, ophthalmic solution/drops product will constitute an act of infringement of the '976 patent.

27. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Brimonidine Tartrate 0.2%, timolol maleate 0.5%, ophthalmic solution/drops product in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

### **Jury Trial Demand**

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury of all issues so triable.

### **Prayer for Relief**

Plaintiffs respectfully pray for the following relief:

a. That judgment be entered that Sandoz has infringed the '149 and '976 patents under 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed Brimonidine Tartrate 0.2%, timolol maleate 0.5%, ophthalmic solution/drops product will constitute an act of infringement of the '149 and '976 patents;

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 '149 and '976 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 to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '149 and '976 patents;

d. If Sandoz attempts to engage in the commercial manufacture, use, offer to sell, sale or importation of Sandoz's generic product disclosed in its ANDA prior to the expiration of the '149 and '976 patents, as extended by any applicable period of exclusivity, a preliminary injunction be entered enjoining such conduct;

e. If Sandoz attempts to engage in the commercial manufacture, use, offer to sell, sale or importation of Sandoz's generic product disclosed in its ANDA prior to the expiration of the '149 and '976 patents, as extended by any applicable period of exclusivity, judgment awarding Allergan damages resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

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

g. An accounting for infringing sales not presented at trial and an award by the court of additional damages for any such infringing sales; and

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

Dated: April 7, 2009

Respectfully submitted,

By: /s/ Jonathan E. Singer (by Wesley Hill)

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