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**
ALLERGAN, INC., **Plaintiff,** **v.** **HI-TECH PHARMACAL CO., INC.,** **Defendant.**	**Civil Action No. 2:09-cv-182** **Jury Trial Demanded**

ALLERGAN INC.'S AMENDED COMPLAINT AGAINST HI-TECH PHARMACAL CO., INC. FOR PATENT INFRINGEMENT[1]

Plaintiff Allergan, Inc. ("Allergan" or "Plaintiff") by its attorneys, Ireland, Carroll & Kelley, P.C. and Fish & Richardson P.C., for its complaint against Defendant Hi-Tech Pharmacal Co., Inc. ("Hi-Tech" 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"), 7,320,976 ("the '976 patent") and 7,323,463 ("the '463 patent") under 35 U.S.C. § 271(e)(2) relating to Allergan's commercially successful glaucoma treatment, Combigan®.

[1] Currently, this complaint against Hi-Tech Pharmacal Co., Inc. is one of two operative complaints in this consolidated action. The other operative complaint is Allergan's Amended Complaint For Patent Infringement against Sandoz Inc., which was filed on November 9, 2009.

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. Combigan® is manufactured in the state of Texas, and is distributed out of this judicial district.

3. On information and belief, Hi-Tech is a corporation incorporated under the laws of the State of Delaware, with a place of business at 369 Bayview Avenue, Amityville, NY 11701.

4. On information and belief, Hi-Tech is in the business of manufacturing, distributing and selling generic drugs and other products throughout the United States, including in this judicial jurisdiction, and it intends to sell a generic version of Combigan® in this judicial jurisdiction.

5. On information and belief, Hi-Tech markets, offers for sale, and sells products to customers, including wholesalers, retail chains, chain drugstores, distributors, mail order houses, and managed care organizations in various states throughout the United States, including Texas, and that it offers those products to customers in this judicial district.

6. On information and belief, Hi-Tech's products are available for purchase by residents of this judicial district in at least Target, CVS, Walgreens and Wal-Mart.

7. On information and belief, pharmacies in the state of Texas have purchased over $100,000,000 of Hi-Tech products over the last 5 years.

Jurisdiction and Venue

8. 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.

9. This Court has personal jurisdiction over Defendant Hi-Tech by virtue of its systematic and continuous contacts with this jurisdiction, as alleged herein, as well as because of the injury to Allergan, and the cause of action Allergan has raised, as alleged herein.

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

Background

11. 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.

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

13. The '976 patent, entitled "Combination of Brimonidine And 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.

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

15. The '463 patent, entitled "Combination of Brimonidine And Timolol For Topical Ophthalmic Use," issued to Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L. Batoosingh on January 29, 2008. A copy of the '463 patent is attached to this complaint as Exhibit C.

16. Allergan, as assignee, owns the entire right, title, and interest in the '463 patent.

17. 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.

18. In conjunction with that NDA, Allergan has listed with the United States Food and Drug Administration ("FDA") three patents (the "Listed Patents") that cover the approved formulation of Combigan®. The Listed Patents are the '149, '976 and '463 patents. The FDA has published the Listed Patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book."

19. The '463 patent was re- listed in the Orange Book after Allergan filed its original complaint against Hi-Tech.

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

21. On or about April 27, 2009, Allergan received a letter, dated April 22, 2009, signed on behalf of Hi-Tech Pharmacal Co., Inc. by Joanne Curri. The letter stated that Hi-Tech Pharmacal Co. Inc. had filed Abbreviated New Drug Application ("ANDA") No. 91-086 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 '149 and '976 patents.

22. The stated purpose of the April 22, 2009, letter was to notify Allergan that Hi-Tech's ANDA contained Paragraph IV patent certifications regarding the '149 and '976 patents.

23. Attached to the April 22, 2009 letter was a "Patent Certification Under 21 CFR §314.94 and Notice of Certification of Invalidity or Noninfringement of a Patent Under 21 CFR §341.95." The Patent Certification alleged that the '149 and '976 patents would not be infringed by the proposed Hi-Tech product and/or are invalid, and contained the factual and legal bases for Hi-Tech's opinion.

24. On November 12, 2009, Allergan received a second letter from Hi-Tech, dated November 11, 2009 and signed by Joanne Curri. The letter notified Allergan that Hi-Tech

Pharmacal Co., Inc. had filed an ANDA under section 505(j)(2)(b) of the FDCA and that the ANDA contained a Paragraph IV certification for the '463 patent.

25. Attached to the November 11, 2009 letter was a "Patent Certification Under 21 CFR §314.94 and Notice of Certification of Invalidity or Noninfringement of a Patent Under 21 CFR §341.95." The Patent Certification alleged that the '463 patent would not be infringed by the proposed Hi-Tech product and/or is invalid, and contained the factual and legal bases for Hi-Tech's opinion.

26. In filing its ANDA, Hi-Tech has requested the FDA's approval to market a generic version of Allergan's Combigan® product throughout the United States, including in Texas.

27. On information and belief, following FDA approval of its ANDA, Hi-Tech 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 Hi-Tech's proposed generic Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution, 0.2%/ 0.5% product)

28. Paragraphs 1 to 27 are incorporated herein as set forth above.

29. Hi-Tech submitted ANDA No. 91-086 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 generic Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution 0.2%/0.5% product throughout the United States. By submitting this application, Hi-Tech has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

30. The commercial manufacture, use, offer for sale, sale and/or importation of Hi-Tech's proposed generic Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution 0.2%/0.5% product will constitute an act of infringement of the '149 patent.

31. On information and belief, Hi-Tech's commercial manufacture, use, offer for sale, sale and/or importation of Hi-Tech's proposed generic Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution 0.2%/0.5% product will actively induce and/or contribute to the infringement of the '149 patent.

32. The commercial manufacture, use, offer for sale, sale and/or importation of Hi-Tech's proposed generic Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution 0.2%/0.5% 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 Hi-Tech's proposed generic Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution, 0.2%/ 0.5% product)

33. Paragraphs 1 to 27 are incorporated herein as set forth above.

34. Hi-Tech submitted ANDA No. 91-086 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 generic Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution, 0.2%/0.5% product throughout the United States. By submitting this application, Hi-Tech has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

35. The commercial manufacture, use, offer for sale, sale and/or importation of Hi-Tech's proposed generic Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution 0.2%/0.5% product will constitute an act of infringement of the '976 patent.

36. On information and belief, Hi-Tech's commercial manufacture, use, offer for sale, sale and/or importation of Hi-Tech's proposed generic Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution 0.2%/0.5% product will actively induce and/or contribute to the infringement of the '976 patent.

37. The commercial manufacture, use, offer for sale, sale and/or importation of Hi-Tech's proposed generic Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution 0.2%/0.5% product in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count III

(Infringement of the '463 Patent Under 35 U.S.C. § 271(e)(2) by Hi-Tech's proposed generic Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution, 0.2%/ 0.5% product)

38. Paragraphs 1 to 27 are incorporated herein as set forth above.

39. Hi-Tech submitted ANDA No. 91-086 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 generic Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution 0.2%/0.5% product throughout the United States. By submitting this application, Hi-Tech has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

40. The commercial manufacture, use, offer for sale, sale and/or importation of Hi-Tech's proposed generic Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution 0.2%/0.5% product will constitute an act of infringement of the '463 patent.

41. On information and belief, Hi-Tech's commercial manufacture, use, offer for sale, sale and/or importation of Hi-Tech's proposed generic Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution 0.2%/0.5% product will actively induce and/or contribute to the infringement of the '463 patent.

42. The commercial manufacture, use, offer for sale, sale and/or importation of Hi-Tech's proposed generic Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution 0.2%/0.5% 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 request 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 Hi-Tech has infringed the '149, '976 and '463 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 Hi-Tech's proposed generic Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution 0.2%/0.5% product will constitute an act of infringement of the '149, '976 and '463 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 Hi-Tech's ANDA shall be a date which is not earlier than the expiration date of the '149, '976 and '463 patents, as extended by any applicable period of exclusivity;

c. Than an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Hi-Tech, 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, ’976 and ’463 patents;

d. If Hi-Tech attempts to engage in the commercial manufacture, use, offer to sell, sale or importation of Hi-Tech’s generic product disclosed in its ANDA prior to the expiration of the ’149, ’976 and ’463 patents, as extended by any applicable period of exclusivity, a preliminary injunction be entered enjoining such conduct;

e. If Hi-Tech attempts to engage in the commercial manufacture, use, offer to sell, sale or importation of Hi-Tech’s generic product disclosed in its ANDA prior to the expiration of the ’149, ’976 and ’463 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: November 20, 2009

Respectfully submitted,

FISH & RICHARDSON P.C.

By: */s/W. Chad Shear*

Juanita Brooks – *admitted pro hac*
brooks@fr.com
12390 El Camino Real
San Diego, CA 92130
Telephone: (858) 678-5070
Facsimile: (858) 678-5099

Jonathan E. Singer – *admitted pro hac*
singer@fr.com
Deanna J. Reichel – *admitted pro hac*
reichel@fr.com
Áine M. Skow – *admitted pro hac*
skow@fr.com
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696

W. Chad Shear
Texas Bar No. 24013493
shear@fr.com
1717 Main Street, Suite 5000
Dallas, TX 75201
Telephone: (214) 747-5070
Facsimile: (214) 747-2091

Susan M. Coletti – *admitted pro hac*
coletti@fr.com
222 Delaware Avenue, 17th Floor
Wilmington, DE 19899
Telephone: (302) 652-5070
Facsimile: (302) 652-0607

IRELAND, CARROLL & KELLEY, P.C.
Otis Carroll
Texas Bar No. 03895700
otiscarroll@icklaw.com
Collin Maloney
Texas Bar No. 00794219
collinmaloney@icklaw.com
6101 South Broadway, Suite 500
Tyler, TX 75703
Telephone: (903) 561-1600
Facsimile: (903) 581-1071

Counsel for Plaintiff
ALLERGAN, INC.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing document has been served on November 20, 2009, to all counsel of record who are deemed to have consented to electronic service via the Court's CM/ECF system per Local Rule CV-5(a)(3).

/s/W. Chad Shear

60608571