

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

ALLERGAN, INC.,

Plaintiff,

v.

HI-TECH PHARMACAL CO.,

Defendant.

Civil Action No. 6:12-cv-43

Jury Trial Demanded

ALLERGAN'S COMPLAINT FOR PATENT INFRINGEMENT

For its Complaint against Defendant Hi-Tech Pharmacal Co. ("Hi-Tech" or "Defendant"), Plaintiff Allergan, Inc. ("Allergan" or "Plaintiff"), by its attorneys, alleges as follows:

The Nature of the Action

1. This is an action for infringement of United States Patent No. 7,851,504 B2 ("the '504 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. Allergan operates a facility in Waco, Texas where it manufactures and distributes numerous pharmaceutical products, including Lumigan®. Allergan employs approximately 600 individuals in Texas, more than in any other U.S. state except California.

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

5. On information and belief, Hi-Tech is in the business of manufacturing, distributing and selling generic drugs throughout the United States, including in this judicial district.

Jurisdiction and Venue

6. 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.

7. This Court has personal jurisdiction over Defendant Hi-Tech by virtue of its systematic and continuous contacts with this jurisdiction, as alleged herein.

8. Specifically, this Court has personal jurisdiction over Hi-Tech because it, either directly or through an agent, regularly does or solicits business in this jurisdiction, engages in other persistent courses of conduct in this jurisdiction, and/or derives substantial revenue from services or things used or consumed in this jurisdiction.

9. 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 it offers those products to customers in this judicial district.

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

11. On information and belief, Hi-Tech is a licensed wholesale distributor of prescription drugs in Texas, and sells over 80 products in Texas.

12. On information and belief, in 2011 Hi-Tech sold over \$76 million of products in Texas, over \$3.5 million of which were sold in this judicial district. On information and belief,

Hi-Tech's sales in Texas over this period were higher than any other state in the United States except California.

13. On information and belief, from 2009-2011 Hi-Tech sold over \$176 million of products in Texas, over \$9 million of which were sold in this judicial district.

14. On information and belief, Hi-Tech has entered into contracts with the Texas Department of State Health Service to sell prescription drugs in Texas.

15. On information and belief, Hi-Tech's products appear on the Preferred Drug List for the Texas Medicaid program, and are available to the millions of Texans in this judicial district and throughout the State who participate in the Texas Medicaid program.

16. On information and belief, as a Medicaid participant, Hi-Tech is required to sell products to Veterans Administration ("VA") and Public Health Services ("PHS") facilities, of which there are over 200 in Texas. The Department of Veteran Affairs formulary lists Hi-Tech products as being available to its participants.

17. On information and belief, Hi-Tech has entered into arrangements with Texas entities to have its products appear on the formulary lists of Blue Cross Blue Shield of Texas and Scott and White, two major managed care and health plan companies in Texas.

18. On information and belief, Hi-Tech lists AmeriSource Bergen Co. ("ABC"), Cardinal, and McKesson as three of its customers in its SEC filings, all of which distribute products throughout Texas. One of ABC's largest distribution centers is located in the Eastern District in Roanoke, TX.

19. On information and belief, Hi-Tech previously admitted that it markets and sells products in Texas in *Coria Labs, Ltd. v. Hi-Tech Pharmacal Co., Inc.*, Case No. 07-ca-0734 (W.D. Tex.).

20. On information and belief, Hi-Tech has previously availed itself of this forum for purposes of litigating its patent disputes regarding its ANDA products. For example, Hi-Tech has submitted to the jurisdiction of this Court and filed counterclaims in *Allergan, Inc. v. Sandoz Inc. and Hi-Tech Pharmacal Co., Inc.*, Case No. 09-cv-00182 (E.D. Tex.).

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

Background

22. The '504 patent, entitled "Enhanced Bimatoprost Ophthalmic Solution," issued to Chin-Ming Chang, James N. Chang, Rhett M. Schiffman, R. Scott Jordan, and Joan-En Chang-Lin on December 14, 2010. A copy of the '504 patent is attached to this complaint as Exhibit A.

23. Allergan, as assignee, owns the entire right, title, and interest in the '504 patent.

24. Allegan is the holder of an approved New Drug Application ("NDA") No. 22-184 for bimatoprost ophthalmic solution 0.01% sold under the Lumigan® trademark.

25. In conjunction with that NDA, Allergan has listed with the United States Food and Drug Administration ("FDA") four patents (the "Listed Patents") that cover the approved 0.01% formulation of Lumigan®. The Listed Patents are the '504 patent, U.S. Patent No. 5,688,819 ("the '819 patent"), U.S. Patent No. 6,403,649 ("the '649 patent"), and U.S. Patent No. 8,017,655 ("the '655 patent"). The FDA has published the Listed Patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book."

26. Lumigan® 0.01% is covered by at least one claim of each of the Listed Patents.

27. On or about January 3, 2012, Plaintiff received a letter, dated December 23, 2011, signed on behalf of Hi-Tech by Joanne Curri, Director of Regulatory Affairs.

28. The December 23, 2011 letter stated that Hi-Tech had submitted an Abbreviated New Drug Application (“ANDA”) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (“FDCA”), seeking approval to engage in the commercial manufacture, use, importation, sale or offer for sale of Bimatoprost Ophthalmic Solution, 0.01%, a generic version of Allergan’s Lumigan® 0.01% product, prior to expiration of the ’504 patent. The ANDA Number for Hi-Tech’s application is 203604.

29. The December 23, 2011 letter stated that the ’504 patent is invalid and/or will not be infringed by the commercial manufacture, use, importation, sale or offer for sale of Hi-Tech’s proposed Bimatoprost Ophthalmic Solution, 0.01%. The December 23, 2011 letter did not discuss the ’649 patent, the ’819 patent, or the ’655 patent.

30. Attached to the December 23, 2011 letter was a statement of the factual and legal bases for Hi-Tech’s certifications under 21 CFR § 314.95 that the ’504 patent is invalid, or will not be infringed by the manufacture, use, importation, sale or offer for sale of Hi-Tech’s proposed Bimatoprost Ophthalmic Solution, 0.01%. No such statement was attached to the December 23, 2011 letter regarding the ’819 patent, the ’649 patent, or the ’655 patent.

31. On or around January 25, 2012, Hi-Tech sent a letter to Allergan counsel confirming that Hi-Tech filed a paragraph IV certification only as to the ’504 patent and not as to the ’649 patent, the ’819 patent, and the ’655 patent. Hi-Tech confirmed in this letter that Hi-Tech has no present intention of selling a product made under ANDA No. 203604 prior to the expiration of the ’649, ’819, and ’655 patents.

32. In filing its ANDA No. 203604, Hi-Tech has requested the FDA’s approval to market a generic version of Allergan’s Lumigan® 0.01% product throughout the United States, including in Texas.

33. On information and belief, following FDA approval of its ANDA No. 203604, Hi-Tech will sell the approved generic version of Allergan's Lumigan® 0.01% product throughout the United States, including in Texas.

Count I

(Infringement of the '504 Patent Under 35 U.S.C. § 271(e)(2) by Hi-Tech's Proposed Generic Bimatoprost Ophthalmic Solution, 0.01%)

34. Paragraphs 1 to 30 are incorporated herein as set forth above.

35. Hi-Tech submitted ANDA No. 203604 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% throughout the United States. By submitting this application, Hi-Tech has committed an act of infringement of the '504 patent under 35 U.S.C. § 271(e)(2)(A).

36. The commercial manufacture, use, offer for sale, sale and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of direct infringement of the '504 patent.

37. On information and belief, Hi-Tech became aware of the '504 patent no later than when it submitted ANDA No. 203604 to the FDA, in which it identified the '504 patent as one of the patents covering the approved 0.01% formulation of Lumigan®.

38. On information and belief, Hi-Tech knew or should have known that its commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively induce the actual infringement of the '504 patent.

39. On information and belief, Hi-Tech knew or should have known that its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will be especially made or especially adapted

for use in an infringement of the '504 patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Bimatoprost Ophthalmic Solution, 0.01% will actively contribute to the actual infringement of the '504 patent.

40. The commercial manufacture, use, offer for sale, sale and/or importation of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% 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), Plaintiff hereby demands a trial by jury of all issues so triable.

Prayer for Relief

Allergan respectfully prays for the following relief:

a. That judgment be entered that Hi-Tech has infringed the '504 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 203604 under section 505(j) of the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Hi-Tech's proposed generic Bimatoprost Ophthalmic Solution, 0.01% will constitute an act of infringement of the '504 patent;

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 No. 203604 shall be a date which is not earlier than the expiration date of the '504 patent, as extended by any applicable period of exclusivity;

c. That 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 '504 patent;

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 No. 203604 prior to the expiration of the '504 patent, 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 No. 203604 prior to the expiration of the '504 patent, 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: January 27, 2012

Respectfully submitted,

By: Wesley Hill (by permission of lead attorney)

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