IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

ALLERGAN, INC., **Plaintiff,** **v.** **HI-TECH PHARMACAL CO., INC.,** **Defendant.**	**Civil Action No. 1:12-cv-492** **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Allegan, Inc., ("Allergan") complains of Defendant Hi-Tech Pharmacal Co., Inc. ("Hi-Tech") and alleges as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 8,101,161 ("the '161 patent") under 35 U.S.C. §§ 271(e)(2), 271(b) and 271(c) and for declaratory judgment of infringement of the '161 patent under 28 U.S.C. §§ 2201 and 2202 relating to Allergan's commercially successful hypotrichosis treatment, Latisse®.

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, Hi-Tech is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 369 Bayview Avenue, Amityville, NY 11701.

JURISDICTION AND VENUE

4. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq*. including §§ 271(e)(2), 271(b), and 271(c), and 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

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

6. 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.

7. On information and belief, Hi-Tech is a licensed drug manufacturer in North Carolina.

8. On information and belief, Hi-Tech is on the list of Active Drug Rebate Labelers issued by the North Carolina Department of Health and Human Services.

9. On information and belief, E. Claiborne Robinson Company, Inc., which employs pharmaceutical sales representatives in North Carolina and has an office in North Carolina, operates as a wholly owned subsidiary of Hi-Tech.

10. On information and belief, Hi-Tech's drug products are listed on relevant North Carolina formulary(ies).

11. On information and belief, in 2010 Hi-Tech sold over $19 million of products in North Carolina, over $7 million of which were sold in this judicial district.

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

THE PATENT-IN-SUIT

13. The ’161 patent, entitled “Method of Enhancing Hair Growth,” issued to David F. Woodward and Amanda M. VanDenburgh on January 24, 2012. A copy of the ’161 patent is attached to this Complaint as Exhibit A.

14. Allergan, as assignee, owns the entire right, title, and interest in the ’161 patent.

15. Allergan is the holder of approved New Drug Application (“NDA”) No. 22-369 for bimatoprost ophthalmic solution, 0.03%, sold under the Latisse® registered trademark. In conjunction with NDA No. 22-369, Allergan has listed U.S. Patent Nos. 7,351,404 (“the ’404 patent), 7,388,029 (“the ’029 patent”), 6,403,649 (“the ’649 patent”), 8,038,988 (“the ’988 patent”) and the ’161 patent with the FDA as covering Latisse® or approved methods of using Latisse®.

16. In conjunction with that NDA, Allergan listed the ’404, ’029, ’649, ’988 and ’161 as patents that cover the approved formulation of Latisse® with the FDA and the FDA has published those patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the “Orange Book.”

17. Latisse® is covered by at least one claim of each of the ’404, ’029, ’649, ’988 and ’161 patents.

ACTS GIVING RISE TO THIS ACTION FOR HI-TECH'S INFRINGEMENT OF THE PATENT IN SUIT

18. On information and belief, Hi-Tech has submitted ANDA No. 203051 under section 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, importation, sale, or offer for sale of Bimatoprost Topical Solution, 0.03%, a generic version of Allergan’s Latisse® product.

19. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Hi-Tech included with its ANDA No. 203051 certifications for the ’404 and ’029 patents.

20. Plaintiff received written notification of Hi-Tech’s § 505(j)(2)(A)(vii)(IV) allegations regarding the ’404 and ’029 patents on or about July 5, 2011 (“First Hi-Tech Paragraph IV Letter”). The First Hi-Tech Paragraph IV Letter was dated June 29, 2011, and stated that the ’404 and ’029 patents were invalid and/or would not be infringed by the commercial manufacture, use, importation, sale or offer for sale of Hi-Tech’s proposed Bimatoprost Topical Solution, 0.03%.

21. Within 45 days of the receiving Hi-Tech’s First Paragraph IV Letter, Allergan and Duke University filed *Allergan, Inc. v. Hi-Tech Pharmacal Co.*, C.A. 1:11-CV-650, asserting the ’404 and ’029 patents against Hi-Tech.

22. Plaintiff received a second Paragraph IV letter from Hi-Tech (“Second Hi-Tech Paragraph IV Letter”) on or about January 30, 2012. The Second Hi-Tech Paragraph IV Letter was dated January 23, 2012, and stated that the ’988 patent was invalid and/or would not be infringed by the commercial manufacture, use, importation, sale, or offer for sale of Hi-Tech’s proposed Bimatoprost Topical Solution, 0.03% described in ANDA No. 203051.

23. Within 45 days of receiving Hi-Tech’s Second Paragraph IV letter, Allergan filed *Allergan, Inc. v. Hi-Tech Pharmacal Co., et. al.,* C.A. 1:12-CV-247, asserting the ’988 patent against Hi-Tech.

24. Plaintiff received a third Paragraph IV letter from Hi-Tech (“Third Hi-Tech Paragraph IV Letter”) on or about April 2, 2012. The Third Hi-Tech Paragraph IV Letter was dated March 27, 2012, and stated that the ’161 patent was invalid and/or would not be infringed

by the commercial manufacture, use, importation, sale, or offer for sale of Hi-Tech's proposed Bimatoprost Topical Solution, 0.03% described in ANDA No. 203051.

25. Hi-Tech has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import a generic version of Allergan's Latisse® product before expiration of the '161 patent.

26. Hi-Tech's actions, including, but not limited to, the development of its proposed generic Bimatoprost Topical Solution, 0.03% and the filing of an ANDA with Paragraph IV certifications, indicate a refusal to change the course of its action in the face of acts by Plaintiff.

27. On information and belief, Hi-Tech continues to seek approval of ANDA No. 203051 from the FDA and intends to continue in the commercial manufacture, marketing, and sale of Bimatoprost Topical Solution, 0.03%.

28. In filing its ANDA No. 203051, Hi-Tech has requested the FDA's approval to market a generic version of Allergan's Latisse® product throughout the United States, including in North Carolina.

29. On information and belief, following FDA approval of its ANDA No. 203051, Hi-Tech will sell the approved generic version of Allergan's Latisse® product throughout the United States, including in North Carolina.

COUNT I

(Infringement of the '161 Patent Under 35 U.S.C. § 271(e)(2) by Hi-Tech's Proposed Generic Bimatoprost Topical Solution, 0.03%)

30. Paragraphs 1 through 29 are incorporated herein as set forth above.

31. Hi-Tech submitted ANDA No. 203051 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 Topical Solution, 0.03% throughout the United

States. By submitting this application, Hi-Tech has committed an act of infringement of the '161 patent under 35 U.S.C. § 271(e)(2)(A).

32. The commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Topical Solution, 0.03% will constitute an act of direct infringement of the '161 patent.

33. On information and belief, Hi-Tech became aware of the '161 patent no later than when it was listed in the Orange Book as one of the patents covering the approved formulation of Latisse®.

34. 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 Topical Solution, 0.03% will actively induce the actual infringement of the '161 patent.

35. On information and belief, Hi-Tech knew or should have known that its proposed generic Bimatoprost Topical Solution, 0.03% will be especially made or especially adapted for use in an infringement of the '161 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 Topical Solution, 0.03% will actively contribute to the actual infringement of the '161 patent.

36. The commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech's proposed generic Bimatoprost Topical Solution, 0.03% in violation of Plaintiff's patent rights will cause harm to Plaintiff for which damages are inadequate.

COUNT II

(Declaratory Judgment of Infringement of the ’161 Patent Under 35 U.S.C. §§ 271(b) or 271(c) by Hi-Tech’s Proposed Generic Bimatoprost Topical Solution, 0.03%)

37. Paragraphs 1 through 36 are incorporated herein as set forth above.

38. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

39. There is an actual case or controversy such that the Court may entertain Plaintiff’s request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

40. Hi-Tech has made and will continue to make, substantial preparation in the United States, including the Middle District of North Carolina, to manufacture, sell, offer to sell, and/or import Hi-Tech’s proposed generic Bimatoprost Topical Solution, 0.03%.

41. Hi-Tech’s actions, including, but not limited to, the filing of ANDA No. 203051 and engaging in litigation to manufacture, offer to sell, sell and/or import Hi-Tech’s proposed Bimatoprost Topical Solution, 0.03% prior to patent expiry, indicate a refusal to change the course of its action in the face of acts by Plaintiff.

42. Any commercial manufacture, use, offer for sale, and/or importation of the Hi-Tech proposed Bimatoprost Topical Solution, 0.03%, prior to patent expiry will constitute contributory infringement and/or active inducement of infringement of the ’161 patent.

43. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech’s proposed Bimatoprost Topical Solution, 0.03% prior to patent expiry by Hi-Tech will constitute contributory infringement and/or active inducement of infringement of the ’161 patent.

JURY TRIAL DEMAND

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

PRAYER FOR RELIEF

WHEREFORE, Allergan respectfully prays the Court as follows:

a. That judgment be entered that Hi-Tech has infringed the ’161 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 203051 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 Topical Solution, 0.03% will constitute an act of infringement of the ’161 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. 203051 shall be a date which is not earlier than the expiration date of the ’161 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 ’161 patent;

d. That 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. 203051 prior

to the expiration of the ’161 patent, as extended by any applicable period of exclusivity, a preliminary injunction be entered enjoining such conduct;

e. That 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. 203051 prior to the expiration of the ’161 patent, as extended by any applicable period of exclusivity, judgment awarding Plaintiff damages or other monetary relief 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 a declaration be issued under 28 U.S.C. § 2201 that if 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, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hi-Tech’s proposed generic Bimatoprost Topical Solution 0.03% prior to patent expiry, it will constitute an act of infringement of the ’161 patent;

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

h. That there be an accounting for infringing sales not presented at trial and an award by the Court of additional damages for any such infringing sales;

i. That a jury trial be held on all triable issues; and,

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

Dated: May 16, 2012

/s/ Larry McDevitt
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