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

ALLERGAN, INC. and DUKE UNIVERSITY, **Plaintiffs,** **v.** **HI-TECH PHARMACAL CO., INC.,** **Defendant.**	**Civil Action No. 11-cv-650** **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

For their Complaint against Defendant Hi-Tech Pharmacal Co., Inc. ("Hi-Tech" or "Defendant"), Plaintiffs Allergan, Inc. ("Allergan") and Duke University (collectively with Allergan, "Plaintiffs"), by their attorneys, allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent Nos. 7,351,404 ("the '404 patent"), 7,388,029 ("the '029 patent"), and 6,403,649 ("the '649 patent") under 35 U.S.C. § 271(e)(2) 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. Duke University is an educational, research and healthcare institution and a North Carolina nonprofit corporation located in Durham, North Carolina.

4. 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

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 Hi-Tech by virtue of its systematic and continuous contacts with this jurisdiction, as alleged herein, as well as because of the injury to Plaintiffs, and the causes of action Plaintiffs have raised, as alleged herein.

7. 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.

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

9. 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.

10. 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.

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

12. 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.

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

BACKGROUND

14. The ’404 patent, entitled “Method of Enhanced Hair Growth,” issued to David F. Woodward and Amanda M. VanDenburgh on April 1, 2008. A copy of the ’404 patent is attached to this Complaint as Exhibit A.

15. Allergan, as assignee, owns the entire right, title, and interest in the ’404 patent.

16. The ’029 patent, entitled “Compositions and Methods for Treating Hair Loss Using Non-Naturally Occurring Prostaglandins,” issued to Mitchell Anthony DeLong, John McMillan McIver, and Robert Scott Youngquist on June 17, 2008. A copy of the ’029 patent is attached to this complaint as Exhibit B.

17. Duke University, as assignee, owns the entire right, title, and interest in the ’029 patent.

18. Allergan is an exclusive field licensee of the ’029 patent.

19. 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 C.

20. Allergan, as assignee, owns the entire right, title, and interest in the ’649 patent.

21. Allergan is the holder of an approved New Drug Application (“NDA”) No. 22-369 for bimatoprost ophthalmic solution, 0.03%, sold under the Latisse® registered trademark.

22. In conjunction with that NDA, Allergan has listed with the FDA three patents (the “Listed Patents”) that cover the approved formulation of Latisse®. The Listed Patents are the ’404,’029, and ’649 patents. The FDA has published the Listed Patents in the Approved Drug

Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book."

23. Latisse® is covered by at least one claim of each of the Listed Patents.

24. On or about July 5, 2011, Plaintiffs received a letter, dated June 29, 2011, signed on behalf of Hi-Tech by Joanne Curri, Director of Regulatory Affairs.

25. The June 29, 2011 letter stated that Hi-Tech had submitted, and the FDA had received, 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 Topical Solution, 0.03%, a generic version of Allergan's Latisse® product, prior to expiration of the '404 and '029 patents. The ANDA Number for Hi-Tech's application is 203051.

26. The June 29, 2011 letter 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%.

27. Attached to the June 29, 2011 letter was a statement of the factual and legal bases for Hi-Tech's certifications under 21 CFR § 314.94-.95 that the '404 and '029 patents are invalid, unenforceable, or will not be infringed by the manufacture, use, importation, sale or offer for sale of Hi-Tech's proposed Bimatoprost Topical Solution, 0.03%.

28. The June 29, 2011 letter did not discuss the '649 patent. Counsel for Allergan has inquired with Hi-Tech as to the reasons for omitting the '649 patent. Hi-Tech has stated that it has filed a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(III) as to the '649 patent, and has no intention of selling a product made under ANDA No. 203051 prior to the expiration of the '649 patent. The parties have not yet memorialized Hi-Tech's representation in an agreement.

29. 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.

30. 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 '029 Patent Under 35 U.S.C. § 271(e)(2) by Hi-Tech's Proposed Generic Bimatoprost Topical Solution, 0.03%)

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

32. 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 '029 patent under 35 U.S.C. § 271(e)(2)(A).

33. 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 '029 patent.

34. On information and belief, Hi-Tech became aware of the '029 patent no later than when it submitted ANDA No. 203051 to the FDA, in which it identified the '029 patent as one of the patents covering the approved formulation of Latisse®.

35. 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 ’029 patent.

36. 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 ’029 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 ’029 patent.

37. 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 Plaintiffs’ patent rights will cause harm to Plaintiffs for which damages are inadequate.

COUNT II

(Infringement of the ’404 Patent Under 35 U.S.C. § 271(e)(2) by Hi-Tech’s Proposed Generic Bimatoprost Topical Solution, 0.03%)

38. Paragraphs 1 to 37 are incorporated herein as set forth above.

39. 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 ’404 patent 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 Bimatoprost Topical Solution, 0.03% will constitute an act of direct infringement of the ’404 patent.

41. On information and belief, Hi-Tech became aware of the ’404 patent no later than when it submitted ANDA No. 203051 to the FDA, in which it identified the ’404 patent as one of the patents covering the approved formulation of Latisse®.

42. 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 ’404 patent.

43. 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 ’404 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 ’404 patent.

44. 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 Allergan’s patent rights will cause harm to Allergan for which damages are inadequate.

COUNT III

(Infringement of the ’649 Patent Under 35 U.S.C. § 271(e)(2) by Hi-Tech’s Proposed Generic Bimatoprost Topical Solution, 0.03%)

45. Paragraphs 1 to 44 are incorporated herein as set forth above.

46. 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 ’649

patent under 35 U.S.C. § 271(e)(2)(A). Hi-Tech has stated that it has filed a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(III) as to the ’649 patent, and has no intention of selling a product made under ANDA No. 203051 prior to the expiration of the ’649 patent. The parties have not memorialized that representation in a written agreement.

47. 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 ’649 patent.

48. On information and belief, Hi-Tech became aware of the ’649 patent no later than when it submitted ANDA No. 203051 to the FDA, in which it identified the ’649 patent as one of the patents covering the approved formulation of Latisse®.

49. 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 ’649 patent.

50. 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 ’649 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 ’649 patent.

51. 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 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 ’404, ’029, and the ’649 patents 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 ’404,’029, and ’649 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 No. 203051 shall be a date which is not earlier than the expiration date of the ’404,’029, and ’649 patents, 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 ’404, ’029, and/or ’649 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 No. 203051 prior to the

expiration of the ’404, ’029, and ’649 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 No. 203051 prior to the expiration of the ’404, ’029, and ’649 patents, as extended by any applicable period of exclusivity, judgment awarding Plaintiffs 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 Plaintiffs 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: August 17, 2011

Respectfully submitted,

/s/ Bryan G. Scott

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