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

ALLERGAN, INC., **Plaintiff,** **v.** **APOTEX, INC., APOTEX CORP.,** **Defendants.**	**Civil Action No. 1:14-cv-1028** **JURY TRIAL DEMANDED**

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Allergan, Inc. ("Allergan") claims relief from Defendants Apotex, Inc. and Apotex Corp. (together, "Apotex"), as follows:

NATURE OF THE ACTION

1. This is an action for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202 of claims 8, 23, and 26 of United States Patent No. 8,926,953 ("the '953 patent") issued to Allergan.

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, Apotex Inc. is a corporation organized and existing under the laws of Canada, with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

4. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce

Parkway, Suite 400, Weston, Florida, 33326, and a registered agent at 150 Fayetteville St., Box 1011, Raleigh, NC 27601.

5. On information and belief, Apotex Corp. is a subsidiary of Apotex, Inc.

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, based on an actual controversy between Allergan, on the one hand, and Apotex, on the other hand, for claims under the Patent Laws of the United States of America, 35 U.S.C. § 1 *et seq.* Plaintiff is seeking relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

7. On information and belief, in 2010 Apotex submitted ANDA No. 201894 under section 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j) ("FDCA"), seeking FDA 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.

8. On information and belief, FDA approved Apotex's ANDA No. 201894 on or about December 1, 2014.

9. This Court has personal jurisdiction over Apotex by virtue of its systematic and continuous contacts with this jurisdiction, as alleged herein, as well as because of the injury to Plaintiff in this forum arising from Apotex's ANDA filing and Apotex's receipt of FDA approval for its ANDA, and the causes of action Plaintiff has raised, as alleged herein.

10. Specifically, this Court has personal jurisdiction over Defendants Apotex Inc. and Apotex Corp. because they, either directly or through an agent, including each other, regularly do

or solicit business in this jurisdiction, engage in other persistent courses of conduct in this jurisdiction, and/or derive substantial revenue from services or things used or consumed in this jurisdiction.

11. On information and belief, Apotex, Inc. and Apotex Corp. are agents of each other and/or work in active concert with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products, including the generic Bimatoprost Topical Solution, 0.03% described in ANDA No. 201894 (defined below).

12. On information and belief, Apotex Corp. and Apotex Inc. are in the business of developing, manufacturing, and/or marketing pharmaceutical products in the United States, including in this district.

13. On information and belief, Apotex Corp. is a licensed drug wholesaler in North Carolina.

14. On information and belief, Apotex Corp. is on the list of Active Drug Rebate Labelers issued by the North Carolina Department of Health and Human Services.

15. On information and belief, Apotex, Inc.'s drug products are listed on relevant North Carolina formulary(ies).

16. On information and belief, Apotex Corp. sells numerous generic drugs, manufactured and supplied by Apotex, Inc., throughout the United States, including in this judicial district.

17. On information and belief, since 2013 Apotex Corp. has sold over $551 million worth of Apotex, Inc.'s products in North Carolina, over $11 million of which were sold in this district.

18. On information and belief, Defendant Apotex Inc. has brought lawsuits in this judicial district against other drug manufacturers.

19. On information and belief, Apotex knows and intends that its proposed Bimatoprost Topical Solution, 0.03% will be distributed and sold in North Carolina, including this district, and will displace sales of Latisse® causing injury to Plaintiff in North Carolina, including this district. On information and belief, Apotex also intends to take advantage of its established channels of distribution in North Carolina for the sale of its proposed Bimatoprost Topical Solution, 0.03%.

20. Apotex has previously been sued in this judicial district concerning ANDA No. 201894 without objecting on the basis of lack of personal jurisdiction, and Apotex has availed itself to this judicial district through the assertion of counterclaims in those suits: Case Nos. 1:10-CV-681, 1:12-CV-247, and 1:13-CV-16.

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

THE PATENT-IN-SUIT

22. On January 6, 2015, the ’953 patent, entitled “Method of Enhancing Hair Growth,” issued to Allergan. A copy of the ’953 patent is attached to this Complaint as Exhibit A.

23. Allergan, as assignee, owns the entire right, title, and interest in the ’953 patent.

24. 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.

25. Latisse® is indicated to treat hypotrichosis of the eyelashes by increasing their growth including length, thickness and darkness.

26. Latisse® has been a commercially successful product for Allergan, resulting in net sales for Allergan of over $70 million annually since its launch in 2009.

27. Latisse® is covered by at least claims 8, 23, and 26 of the ’953 patent.

ACTS GIVING RISE TO THIS ACTION FOR APOTEX’S INFRINGEMENT OF THE PATENT-IN-SUIT

28. On information and belief, in 2010 Apotex submitted ANDA No. 201894 under section 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j) (“FDCA”), seeking FDA 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.

29. On information and belief, FDA approved Apotex’s ANDA No. 201894 on or about December 1, 2014.

30. On information and belief, Apotex has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import its FDA-approved generic Bimatoprost Topical Solution, 0.03% before the expiration of the ’953 patent.

31. On information and belief, Apotex has manufactured exhibit batches of its generic Bimatoprost Topical Solution, 0.03% product. On information and belief, a launch of Apotex’s FDA-approved generic Bimatoprost Topical Solution, 0.03% throughout the United States, including in North Carolina and this district, is imminent.

32. On information and belief, Apotex intends to take advantage of its established channels of distribution in North Carolina for the launch of its Bimatoprost Topical Solution, 0.03%.

33. On information and belief, the launch of Apotex's FDA-approved generic Bimatoprost Topical Solution, 0.03% will negatively decrease Allergan's net revenue of Latisse® sales throughout the United States, including in North Carolina.

34. On information and belief, Apotex monitors the status of patent applications prosecuted by Allergan that relate to methods of using bimatoprost to treat hair loss or promote hair growth.

35. On information and belief, Apotex became aware of the '953 patent no later than when it was issued by the United States Patent Office on January 6, 2015.

COUNT I

(Declaratory Judgment of Infringement claims 8, 23, and 26 of the '953 Patent Under 35 U.S.C. §§ 271(c) by Apotex's FDA-Approved Generic Bimatoprost Topical Solution, 0.03%)

36. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

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

38. 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.

39. Apotex 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 Apotex's FDA-approved generic Bimatoprost Topical Solution, 0.03% product.

40. Apotex's actions, including, but not limited to, the filing of ANDA No. 201894, manufacturing exhibit batches of its Bimatoprost Topical Solution, 0.03% product, engaging in litigation to manufacture, offer to sell, sell and/or import a Bimatoprost Topical Solution, 0.03%

product before expiration of the patents listed by Allergan in the Orange Book as covering the Latisse® product, and obtaining FDA approval of its Bimatoprost Topical Solution, 0.03% product indicate a refusal to change the course of its actions.

41. On information and belief, Apotex will include within the packaging of its FDA-approved Bimatoprost Topical Solution, 0.03%, or will otherwise make available to prospective patients, a label and/or instructions for use that instruct patients to perform one or more of the methods claimed in claims 8, 23, and 26 of the ’953 patent.

42. A patient’s use of Apotex’s FDA-approved Bimatoprost Topical Solution, 0.03% product according to the instructions included in the label and/or instructions for use of that product will constitute an act of direct infringement of one or more of the methods claimed in claims 8, 23, and 26 of the ’953 patent.

43. Apotex’s FDA-approved Bimatoprost Topical Solution, 0.03% product is a material part of one or more of the methods claimed in claims 8, 23, and 26 of the ’953 patent.

44. Apotex’s FDA-approved Bimatoprost Topical Solution, 0.03% product has no substantial uses that do not constitute infringement of one or more of the methods claimed in claims 8, 23, and 26 of the ’953 patent.

45. On information and belief, Apotex became aware of the ’953 patent no later than when it was issued by the Patent Office on January 6, 2015.

46. On information and belief, Apotex knew of the potential for infringement of claims 8, 23, and 26 of the ’953 patent when the ’953 patent issued on January 6, 2015.

47. Any commercial distribution, marketing, sale, offer for sale, and/or importation of Apotex’s FDA-approved Bimatoprost Topical Solution, 0.03% product before patent expiration will constitute contributory infringement of claims 8, 23, and 26 of the ’953 patent.

48. Plaintiff is entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's FDA-approved Bimatoprost Topical Solution, 0.03% product by Apotex before patent expiration will constitute contributory infringement of claims 8, 23, and 26 of the '953 patent.

COUNT II

(Declaratory Judgment of Infringement of claims 8, 23, and 26 of the '953 Patent Under 35 U.S.C. §§ 271(b) by Apotex's FDA-Approved Generic Bimatoprost Topical Solution, 0.03%)

49. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

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

51. 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.

52. Apotex 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 Apotex's FDA-approved generic Bimatoprost Topical Solution, 0.03% product.

53. Apotex's actions, including, but not limited to, the filing of ANDA No. 201894, manufacturing exhibit batches of its Bimatoprost Topical Solution, 0.03% product, and engaging in litigation to manufacture, offer to sell, sell and/or import a Bimatoprost Topical Solution, 0.03% product before expiration of the patents listed by Allergan in the Orange Book as covering the Latisse® product, and obtaining FDA approval of its Bimatoprost Topical Solution, 0.03% product indicate a refusal to change the course of its actions.

54. On information and belief, Apotex will include within the packaging of its FDA-approved Bimatoprost Topical Solution, 0.03%, or will otherwise make available to prospective patients, a label and/or instructions for use that instruct patients to perform one or more of the methods claimed in claims 8, 23, and 26 of the ’953 patent.

55. A patient’s use of Apotex’s FDA-approved Bimatoprost Topical Solution, 0.03% product according to the instructions included in the label and/or instructions for use of that product will constitute an act of direct infringement of one or more of the methods claimed in claims 8, 23, and 26 of the ’953 patent.

56. On information and belief, Apotex became aware of the ’953 patent no later than when it was issued by the Patent Office on January 6, 2015.

57. On information and belief, Apotex either actually knew of the potential for infringement of claims 8, 23, and 26 of the ’953 patent, or was willfully blind as to the potential for that infringement, when the ’953 patent issued on January 6, 2015, at least because of the prior adjudication that Apotex had induced infringement of similar methods of use claimed in U.S. Patent No. 7,388,029 by filing ANDA No. 201894, or because the label and/or instructions for use instruct patients to perform one or more of the methods claimed in claims 8, 23, and 26 of the ’953 patent.

58. Any commercial distribution, marketing, offer for sale, sale and/or importation of the Apotex’s FDA-approved Bimatoprost Topical Solution, 0.03% product before patent expiration will constitute active inducement of infringement of claims 8, 23, and 26 of the ’953 patent.

59. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Apotex’s FDA-approved Bimatoprost Topical

Solution, 0.03% product by Apotex before patent expiration will constitute active inducement of infringement of claims 8, 23, and 26 of the ’953 patent.

JURY TRIAL DEMAND

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

PRAYER FOR RELIEF

Plaintiff respectfully prays for the following relief:

a. That a declaration be issued pursuant to 28 U.S.C. § 2201 that, if Apotex, 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, distribution, marketing, offer for sale, sale, and/or importation of Apotex’s FDA-approved generic Bimatoprost Topical Solution 0.03% prior to patent expiration, it will constitute an act of infringement of claims 8, 23, and 26 of the ’953 patent;

b. That Apotex, and 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, either directly or indirectly, be permanently enjoined from infringing claims 8, 23, and 26 of the ’953 patent;

c. That, if Apotex sells its FDA-approved generic Bimatoprost Topical Solution 0.03% product, Apotex pay to Plaintiff damages in amounts sufficient to compensate them for Apotex’s infringement of claims 8, 23, and 26 of the ’953 patent, together with pre-judgment and post-judgment interest and costs, pursuant to 35 U.S.C. § 284;

d. That Apotex be ordered to account for, and pay, Plaintiff's additional damages for any and all periods of infringement not included in the damages awarded by the Court or jury, including specifically any time periods between any order or verdict awarding damages and final entry of judgment;

e. That this is an exceptional case pursuant to 35 U.S.C. § 285, and that Plaintiff be awarded reasonable attorneys' fees and costs; and

f. That this Court award such other and further equitable or legal relief as It may deem just and proper.

Dated: May 22, 2015

/s/ *Larry McDevitt*

Larry McDevitt
N.C. State Bar No. 5032
David Wilkerson
N.C. State Bar No. 35742
Heather Whitaker Goldstein
N.C. State Bar No. 26194
THE VAN WINKLE LAW FIRM
11 North Market Street
Asheville, NC 28801
Telephone: (828) 258-2991
Facsimile: (828) 257-2767
E-mail: lmcdevitt@vwlawfirm.com;
dwilkerson@vwlawfirm.com;
hgoldstein@vwlawfirm.com

COUNSEL FOR PLAINTIFF
ALLERGAN, INC.

OF COUNSEL:

Jonathan E. Singer
Deanna J. Reichel
FISH & RICHARDSON P.C.
60 South Sixth St., Suite 3200
Minneapolis, MN 55402
Telephone: (612) 335-5070
Email: singer@fr.com; reichel@fr.com

Juanita R. Brooks
FISH & RICHARDSON P.C.
12390 El Camino Real
San Diego, CA 92130
Telephone: (858) 678-5070
Email: brooks@fr.com

Douglas E. McCann
Elizabeth M. Flanagan
FISH & RICHARDSON P.C.
222 Delaware Avenue, 17th Floor
P.O. Box 1114
Wilmington, DE 19899-1114
Telephone: 302-652-5070
Email: dmccann@fr.com; eflanagan@fr.com

Counsel for Plaintiff Allergan, Inc.

CERTIFICATE OF SERVICE

I hereby certify that I have this day served the foregoing document with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all attorneys of record in this matter.

Dated: May 22, 2015

/s/ Larry McDevitt
Larry McDevitt