

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

**DUKE UNIVERSITY and ALLERGAN, INC.,**

**Plaintiffs,**

**v.**

**APOTEX, INC., APOTEX CORP.,**

**Defendants.**

**Civil Action No. 14-cv-1028**

**JURY TRIAL DEMANDED**

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Duke University and Allergan, Inc. (“Allergan”) (collectively, “Plaintiffs”), claim 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 of United States Patent No. 8,906,962 (“the ’962 patent”) under 28 U.S.C. §§ 2201 and 2202.

**THE PARTIES**

2. Duke University is an educational, research and healthcare institution and a North Carolina nonprofit corporation located in Durham, North Carolina.

3. 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.

4. 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.

5. 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.

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

### **JURISDICTION AND VENUE**

7. 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 Plaintiffs, 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.* Plaintiffs are seeking relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. This Court has personal jurisdiction over Apotex because of the injury to Plaintiffs in this forum arising from Apotex's ANDA filing and Apotex's receipt of FDA approval for its ANDA, and the causes of action Plaintiffs have raised, as alleged herein.

9. 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).

10. Further demonstrating the close interconnections between the two entities is the fact that both Apotex, Inc. and Apotex Corp. provided Plaintiffs with notice on or about July 27, 2010, via a single letter, that the two entities had submitted an abbreviated new drug application for Bimatoprost Topical Solution, 0.03% to the United States Food and Drug Administration ("FDA"). Apotex sent that letter to Duke University, who received it in Durham, North Carolina.

11. Apotex, Inc. sent a second letter concerning ANDA No. 201894 to Duke University in Durham, North Carolina on or about July 7, 2014.

12. 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.

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

### **THE PATENT-IN-SUIT**

14. On December 9, 2014, the '962 patent, entitled "Compositions and Methods for Treating Hair Loss Using Non-Naturally Occurring Prostaglandins," issued to Duke University. A copy of the '962 patent is attached to this Complaint as Exhibit A.

15. Duke University, as assignee, owns the entire right, title, and interest in the '962 patent.

16. In 2007, Duke University entered into a license agreement with Allergan. Under that agreement Duke University licensed certain patent rights to Allergan, including the exclusive right to practice the inventions of the '962 patent in a field of use that includes the use of treating the loss or promoting the growth of eyelashes.

17. Allergan is an exclusive field licensee of the '962 patent.

18. 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.

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

20. 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.

21. Latisse® is covered by at least one claim of the '962 patent.

22. Under the license agreement with Allergan, Duke University receives royalties from Allergan on the net sales of Latisse®, in addition to certain milestone payments.

23. Duke University uses those royalties to fund laboratories and provide research support to Duke's Trinity College of Arts and Sciences and to the Duke University School of Medicine.

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

24. 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.

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

26. 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 '962 patent.

27. On information and belief, Apotex has manufactured exhibit batches of its generic Bimatoprost Topical Solution, 0.03% product.

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

29. 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.

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

31. 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.

32. 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.

33. 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.

34. 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.

35. On information and belief, the launch of Apotex's FDA-approved generic Bimatoprost Topical Solution, 0.03% will reduce the royalties Duke University receives from the net sales revenue of Latisse®.

36. On information and belief, the launch of Apotex's FDA-approved generic Bimatoprost Topical Solution, 0.03% will reduce the amount of funding available to Duke University to fund laboratories and provide research support to Duke's Trinity College of Arts and Sciences and to the Duke University School of Medicine

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

38. On information and belief, Apotex became aware of the '962 patent no later than when it was issued by the United States Patent office on December 9, 2014.

### **COUNT I**

#### **(Declaratory Judgment of Infringement of the '962 Patent Under 35 U.S.C. §§ 271(c) by Apotex's FDA-Approved Generic Bimatoprost Topical Solution, 0.03%)**

39. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

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

41. There is an actual case or controversy such that the Court may entertain Plaintiffs' 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.

42. 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.

43. 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.

44. 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 the '962 patent.

45. 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 the '962 patent.

46. Apotex's FDA-approved Bimatoprost Topical Solution, 0.03% product is a material part of one or more of the methods claimed in the '962 patent.

47. 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 the '962 patent.

48. On information and belief, Apotex became aware of the '962 patent no later than when it was listed issued by the Patent Office on December 9, 2014.

49. On information and belief, Apotex knew of the potential for infringement of the '962 patent when the '962 patent issued on December 9, 2014.

50. 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 the '962 patent.

51. Plaintiffs are 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 will constitute contributory infringement of the '962 patent.

## COUNT II

### **(Declaratory Judgment of Infringement of the '962 Patent Under 35 U.S.C. §§ 271(b) by Apotex's FDA-Approved Generic Bimatoprost Topical Solution, 0.03%)**

52. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

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

54. There is an actual case or controversy such that the Court may entertain Plaintiffs' 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.

55. 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.

56. 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.

57. 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 the '962 patent.



58. 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 the '962 patent.

59. On information and belief, Apotex became aware of the '962 patent no later than when it was issued by the Patent Office on December 9, 2014.

60. On information and belief, Apotex either actually knew of the potential for infringement of one or more claims of the '962 patent, or was willfully blind as to the potential for that infringement, when the '962 patent issued on December 9, 2014, 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 the '962 patent.

61. 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 the '962 patent.

62. Plaintiffs are 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 prior to patent expiration will constitute active inducement of infringement of the '962 patent.

### **JURY TRIAL DEMAND**

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

**PRAYER FOR RELIEF**

Plaintiffs respectfully pray for the following relief:

a. That a declaration be issued under 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 the '962 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 the '962 patent;

c. That, if Apotex sells its FDA-approved generic Bimatoprost Topical Solution 0.03% product, Apotex pay to Plaintiffs damages in amounts sufficient to compensate them for Apotex's infringement of the '962 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, Plaintiffs 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 under 35 U.S.C. § 285, and that Plaintiffs 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: December 9, 2014

/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 PLAINTIFFS DUKE  
UNIVERSITY AND 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 Plaintiffs Duke University  
and Allergan, Inc.*