

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

**ALLERGAN, INC.,**

**Plaintiff,**

v.

**APOTEX INC., APOTEX CORP., SANDOZ,  
INC., and HI-TECH PHARMACAL CO., INC.,**

**Defendants.**

**Civil Action No. 1:12-cv-247**

**JURY TRIAL DEMANDED**

**COMPLAINT FOR PATENT INFRINGEMENT**

For its Complaint against Defendants Apotex Inc., Apotex Corp. (collectively “Apotex”), Sandoz, Inc. (“Sandoz”), and Hi-Tech Pharmacal Co., Inc. (“Hi-Tech”), Plaintiff Allergan, Inc. (“Allergan” or “Plaintiff”), by its attorneys, alleges as follows:

**NATURE OF THE ACTION**

1. This is an action for infringement of United States Patent Nos. 8,038,988 (“the ’988 patent”) and 8,101,161 (“the ’161 patent”) under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, including §§ 271(e)(2), 271(a), 271(b), and 271(c), and for a declaratory judgment of infringement of the ’988 and ’161 patents 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, 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.

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

6. On information and belief, Sandoz, Inc. is a corporation organized and existing under the laws of the State of Colorado, having a place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540 and a Registered Agent, Corporation Service Company, at 327 Hillsborough Street, Raleigh, NC 27603.

7. 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**

8. 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(a), 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.

#### **Personal Jurisdiction over Apotex**

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 and the causes of action Plaintiff has raised, as alleged herein.

10. Specifically, this Court has personal jurisdiction over 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. Further demonstrating the close interconnections between the two entities is the fact that both Apotex Inc. and Apotex Corp. provided Plaintiff with notice, via a single letter, that the two entities had submitted a new drug application for Bimatoprost Topical Solution, 0.03% to the United States Food and Drug Administration (“FDA”).

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, an officer of Apotex Corp. has attended multiple meetings held by the North Carolina Board of Pharmacy on behalf of Apotex Corp.

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

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

18. On information and belief, in 2009 Apotex Corp. sold over \$348 million worth of Apotex Inc.'s products in North Carolina, over \$51 million of which were sold in this judicial district.

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

20. On information and belief, Apotex Inc. filed suit against Eisai Inc. and Eisai Co., Ltd. on July 1, 2009 in this judicial district, Case No. 1:09-CV-00477.

21. On information and belief, Apotex Inc. filed suit against Glaxo Wellcome Inc. and SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, on July 6, 2009 in this judicial district, Case No. 1:09-CV-00485.

#### **Personal Jurisdiction over Sandoz**

22. This Court has personal jurisdiction over Sandoz 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.

23. Specifically, this Court has personal jurisdiction over Sandoz 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.

24. On information and belief, Sandoz is a licensed drug manufacturer in North Carolina and has a manufacturing facility located at 4700 Sandoz Drive, Wilson, North Carolina 27893.

25. On information and belief, Sandoz is a licensed drug wholesaler in North Carolina.

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

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

28. On information and belief, in 2010 Sandoz sold over \$460 million of products in North Carolina, over \$81 million of which were sold in this judicial district.

### **Personal Jurisdiction over Hi-Tech**

29. 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.

30. 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.

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

32. 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.

33. 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.

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

35. 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.

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

### **THE PATENTS-IN-SUIT**

37. On October 18, 2011, the '988 patent, entitled "Method of Enhanced Hair Growth," issued to David F. Woodward and Amanda M. VanDenburgh. A copy of the '988 patent is attached to this Complaint as Exhibit A.

38. Allergan, as assignee, owns the entire right, title, and interest in the '988 patent.

39. On January 24, 2012, the '161 patent, entitled "Methods of Enhanced Hair Growth," issued to David F. Woodward and Amanda M. VanDenburgh. A copy of the '161 patent is attached to this Complaint as Exhibit B.

40. Allergan, as assignee, owns the entire right, title, and interest in the '161 patent.

41. 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. In conjunction with NDA No. 22-369, Allergan listed with the FDA U.S. Patent Nos. 7,351,404 ("the '404 patent"), 7,388,029 ("the '029 patent") and 6,403,649 ("the '649 patent"), which cover methods of using the approved formulation of Latisse® and the composition of the active ingredient of Latisse®. Allergan subsequently listed the '988 and '161 patents with the FDA after those patents issued.

42. 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 APOTEX'S INFRINGEMENT  
OF THE PATENTS-IN-SUIT**

43. On information and belief, Apotex actively reviews pharmaceutical patents and seeks opportunities to challenge those patents.

44. On information and belief, Apotex reviewed the '404 and '029 patents and certain commercial and economic information relating to Latisse® and decided to file an Abbreviated New Drug Application (“ANDA”), seeking approval to market Bimatoprost Topical Solution, 0.03%.

45. On information and belief, Apotex submitted ANDA No. 201894 under section 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j) (“FDCA”). ANDA No. 201894 seeks 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, prior to expiration of the '404, '029, '988 and '161 patents. ANDA No. 201894 seeks FDA approval to market the Apotex proposed generic Bimatoprost Topical Solution, 0.03% prior to expiration of the '404, '029, '988 and '161 patents.

46. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, in ANDA No. 201894, Apotex alleged that the claims of 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 Apotex's proposed Bimatoprost Topical Solution, 0.03%. Plaintiff received written notification of Apotex's § 505(j)(2)(A)(vii)(IV) allegations regarding the '404 and '029 patents on or about July 27, 2010 (“Apotex Paragraph IV letter”).

47. Attached to the Apotex Paragraph IV letter was a statement of the factual and legal bases for Apotex'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 Apotex's proposed Bimatoprost Topical Solution, 0.03%.

48. In a separate action, *Allergan, Inc. v. Apotex Inc.*, C.A. 10-CV-681, Plaintiff asserted the '404 and '029 patents against Apotex.

49. The '988 and '161 patents had not issued at the time Apotex submitted its certification under section 505(j) of the FDCA.

50. On information and belief, Apotex became aware of the '988 and '161 patents no later than when they were listed in the Orange Book as patents covering the approved formulation of Latisse®.

51. Apotex 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 prior to patent expiry.

52. Apotex'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 a Paragraph IV certification, indicate a refusal to change the course of its action in the face of acts by Plaintiff.

53. On information and belief, Apotex continues to seek approval of ANDA No. 201894 from the FDA and intends to continue in the commercial manufacture, marketing, and sale of Bimatoprost Topical Solution, 0.03%.

54. On information and belief, following FDA approval of its ANDA No. 201894, Apotex will sell the approved generic version of Allergan's Latisse® product throughout the United States, including in North Carolina.

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

55. On information and belief, Sandoz actively reviews pharmaceutical patents and seeks opportunities to challenge those patents.

56. On information and belief, Sandoz reviewed the '404 and '029 patents and certain commercial and economic information relating to Latisse® and decided to file an ANDA, seeking approval to market Bimatoprost Topical Solution, 0.03%.

57. On information and belief, Sandoz submitted ANDA No. 202719 under section 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j). ANDA No. 202719 seeks 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, prior to expiration of the '404, '029, '988 and '161 patents. ANDA No. 202719 seeks FDA approval to market the Sandoz proposed generic Bimatoprost Topical Solution, 0.03% prior to expiration of the '404, '029, '988 and '161 patents.

58. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, in ANDA No. 202719, Sandoz alleged that the claims of 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 Sandoz's proposed Bimatoprost Topical Solution, 0.03%. Plaintiff received written notification of Sandoz's § 505(j)(2)(A)(vii)(IV) allegations regarding the '404 and '029 patents on or about March 3, 2011 ("Sandoz Paragraph IV letter").

59. Attached to the Sandoz Paragraph IV letter was a statement of the factual and legal bases for Sandoz'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 Sandoz's proposed Bimatoprost Topical Solution, 0.03%.

60. In a separate action, *Allergan, Inc. v. Sandoz, Inc.*, C.A. 11-CV-298, Plaintiff asserted the '404 and '029 patents against Sandoz.

61. The '988 and '161 patents had not issued at the time Sandoz submitted its certification under section 505(j) of the FDCA.

62. On information and belief, Sandoz became aware of the '988 and '161 patents no later than when they were listed in the Orange Book as patents covering the approved formulation of Latisse®.

63. Sandoz 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 prior to patent expiry.

64. Sandoz'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 a Paragraph IV certification, indicate a refusal to change the course of its action in the face of acts by Plaintiff.

65. On information and belief, Sandoz continues to seek approval of ANDA No. 202719 from the FDA and intends to continue in the commercial manufacture, marketing, and sale of Bimatoprost Topical Solution, 0.03%.

66. On information and belief, following FDA approval of its ANDA No. 202719, Sandoz will sell the approved generic version of Allergan's Latisse® product throughout the United States, including in North Carolina.

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

67. On information and belief, Hi-Tech actively reviews pharmaceutical patents and seeks opportunities to challenge those patents.

68. On information and belief, Hi-Tech reviewed the '404 and '029 patents and certain commercial and economic information relating to Latisse® and decided to file an ANDA, seeking approval to market Bimatoprost Topical Solution, 0.03%.

69. On information and belief, Hi-Tech submitted ANDA No. 203051 under section 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j). ANDA No. 203051 seeks 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, prior to expiration of the '404, '029, '988 and '161 patents. ANDA No. 203051 seeks FDA approval to market the Hi-Tech proposed generic Bimatoprost Topical Solution, 0.03% prior to expiration of the '404, '029, '988 and '161 patents.

70. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, in ANDA No. 203051, Hi-Tech alleged that the claims of 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%. 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").

71. Attached to the first Hi-Tech Paragraph IV 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%.

72. In a separate action, *Allergan, Inc. v. Hi-Tech Pharmacal Co.*, C.A. 11-CV-650, Plaintiff asserted the '404 and '029 patents against Hi-Tech.

73. 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.

74. Attached to the second Hi-Tech Paragraph IV letter was a statement of the factual and legal bases for Hi-Tech’s certifications under 21 CFR § 314.94-.95 that the ’988 patent is 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%.

75. The ’161 patent had not issued at the time Hi-Tech submitted its certification to the ’988 patent under section 505(j) of the FDCA.

76. 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®.

77. 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 prior to patent expiry.

78. 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.

79. 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%.

80. 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 '988 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's Proposed Generic Bimatoprost Topical Solution, 0.03%)**

81. Paragraphs 1 to 80 are incorporated herein as set forth above.

82. Apotex submitted ANDA No. 201894 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, Apotex has committed an act of infringement of the '988 patent under 35 U.S.C. § 271(e)(2)(A).

83. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Bimatoprost Topical Solution, 0.03% will constitute an act of direct infringement of the '988 patent.

84. On information and belief, Apotex became aware of the '988 patent no later than when it was listed in the Orange Book as one of the patents covering the approved formulation of Latisse®.

85. On information and belief, Apotex 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 '988 patent.

86. On information and belief, Apotex 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 '988 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 '988 patent.

87. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex'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 '988 Patent Under 35 U.S.C. §§ 271(a), 271(b), or 271(c) by Apotex's Proposed Generic Bimatoprost Topical Solution, 0.03%)**

88. Paragraphs 1 to 87 are incorporated herein as set forth above.

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

90. 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.

91. 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 proposed generic Bimatoprost Topical Solution, 0.03%.

92. Apotex's actions, including, but not limited to, the filing of ANDA No. 201894 and engaging in litigation to manufacture, offer to sell, sell and/or import Apotex'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.

93. Any commercial manufacture, use, offer for sale, and/or importation of the Apotex proposed Bimatoprost Topical Solution, 0.03%, prior to patent expiry will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '988 patent.

94. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed Bimatoprost Topical Solution, 0.03% prior to patent expiry by Apotex will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '988 patent.

### **COUNT III**

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

95. Paragraphs 1 to 94 are incorporated herein as set forth above.

96. Apotex submitted ANDA No. 201894 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, Apotex has committed an act of infringement of the '161 patent under 35 U.S.C. § 271(e)(2)(A).

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

98. On information and belief, Apotex 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®.

99. On information and belief, Apotex 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.

100. On information and belief, Apotex 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.

101. The commercial manufacture, use, offer for sale, sale, and/or importation of Apotex'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 IV**

#### **(Declaratory Judgment of Infringement of the '161 Patent Under 35 U.S.C. §§ 271(a), 271(b), or 271(c) by Apotex's Proposed Generic Bimatoprost Topical Solution, 0.03%)**

102. Paragraphs 1 to 101 are incorporated herein as set forth above.

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

104. 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.

105. 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 proposed generic Bimatoprost Topical Solution, 0.03%.

106. Apotex's actions, including, but not limited to, the filing of ANDA No. 201894 and engaging in litigation to manufacture, offer to sell, sell and/or import Apotex'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.

107. Any commercial manufacture, use, offer for sale, and/or importation of the Apotex proposed Bimatoprost Topical Solution, 0.03%, prior to patent expiry will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '161 patent.

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

#### **COUNT V**

#### **(Infringement of the '988 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz's Proposed Generic Bimatoprost Topical Solution, 0.03%)**

109. Paragraphs 1 to 108 are incorporated herein as set forth above.

110. Sandoz submitted ANDA No. 202719 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, Sandoz has committed an act of infringement of the '988 patent under 35 U.S.C. § 271(e)(2)(A).

111. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Topical Solution, 0.03% will constitute an act of direct infringement of the '988 patent.

112. On information and belief, Sandoz became aware of the '988 patent no later than when it was listed in the Orange Book as one of the patents covering the approved formulation of Latisse®.

113. On information and belief, Sandoz 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 '988 patent.

114. On information and belief, Sandoz 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 '988 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 '988 patent.

115. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz'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 VI**

**(Declaratory Judgment of Infringement of the '988 Patent Under 35 U.S.C. §§ 271(a), 271(b), or 271(c) by Sandoz's Proposed Generic Bimatoprost Topical Solution, 0.03%)**

116. Paragraphs 1 to 115 are incorporated herein as set forth above.

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

118. 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.

119. Sandoz 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 Sandoz's proposed generic Bimatoprost Topical Solution, 0.03%.

120. Sandoz's actions, including, but not limited to, the filing of ANDA No. 202719 and engaging in litigation to manufacture, offer to sell, sell and/or import Sandoz'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.

121. Any commercial manufacture, use, offer for sale, and/or importation of the Sandoz proposed Bimatoprost Topical Solution, 0.03%, prior to patent expiry will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '988 patent.

122. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed Bimatoprost Topical Solution, 0.03% prior to patent expiry by Sandoz will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '988 patent.

#### **COUNT VII**

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

123. Paragraphs 1 to 122 are incorporated herein as set forth above.

124. Sandoz submitted ANDA No. 202719 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, Sandoz has committed an act of infringement of the '161 patent under 35 U.S.C. § 271(e)(2)(A).

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

126. On information and belief, Sandoz 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®.

127. On information and belief, Sandoz 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.

128. On information and belief, Sandoz 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.

129. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz'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 VIII**

#### **(Declaratory Judgment of Infringement of the '161 Patent Under 35 U.S.C. §§ 271(a), 271(b), or 271(c) by Sandoz's Proposed Generic Bimatoprost Topical Solution, 0.03%)**

130. Paragraphs 1 to 129 are incorporated herein as set forth above.

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

132. 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.

133. Sandoz 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 Sandoz's proposed generic Bimatoprost Topical Solution, 0.03%.

134. Sandoz's actions, including, but not limited to, the filing of ANDA No. 202719 and engaging in litigation to manufacture, offer to sell, sell and/or import Sandoz'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.

135. Any commercial manufacture, use, offer for sale, and/or importation of the Sandoz proposed Bimatoprost Topical Solution, 0.03%, prior to patent expiry will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '161 patent.

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

### **COUNT IX**

#### **(Infringement of the '988 Patent Under 35 U.S.C. § 271(e)(2) by Hi-Tech's Proposed Generic Bimatoprost Topical Solution, 0.03%)**

137. Paragraphs 1 to 136 are incorporated herein as set forth above.

138. 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 '988 patent under 35 U.S.C. § 271(e)(2)(A).

139. 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 '988 patent.

140. On information and belief, Hi-Tech became aware of the '988 patent no later than when it was listed in the Orange Book as one of the patents covering the approved formulation of Latisse®.

141. 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 '988 patent.

142. 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 '988 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 '988 patent.

143. 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 X**

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

144. Paragraphs 1 to 143 are incorporated herein as set forth above.

145. 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).

146. 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.

147. 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®.

148. 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.

149. 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.

150. 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 XI**

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

151. Paragraphs 1 to 150 are incorporated herein as set forth above.

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

153. 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.

154. 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%.

155. 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.

156. 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 direct infringement, contributory infringement and/or active inducement of infringement of the '161 patent.

157. Plaintiff is entitled to a declaratory judgment that future 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 by Hi-Tech will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '161 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 judgment be entered that Apotex has infringed the '988 and '161 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 201894 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 Apotex's proposed generic Bimatoprost Topical Solution, 0.03% will constitute an act of infringement of the '988 and '161 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 Apotex's ANDA No. 201894 shall be a date which is not earlier than the expiration date of the '988 and '161 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 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, 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 '988 and/or '161 patents;

d. If Apotex attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Apotex's generic product disclosed in its ANDA No. 201894 prior to the expiration of the '988 and '161 patents, as extended by any applicable period of exclusivity, a preliminary injunction be entered enjoining such conduct;

e. If Apotex attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Apotex's generic product disclosed in its ANDA No. 201894 prior to the expiration of the '988 and '161 patents, 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 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, offer for sale, sale, and/or importation of Apotex's proposed generic Bimatoprost Topical Solution 0.03% prior to patent expiry, it will constitute an act of infringement of the '988 and/or '161 patents;

g. That judgment be entered that Sandoz has infringed the '988 and '161 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202719 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 Sandoz's proposed generic Bimatoprost Topical Solution, 0.03% will constitute an act of infringement of the '988 and '161 patents;

h. That an Order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Sandoz's ANDA No. 202719 shall be a date which is not earlier than the expiration date of the '988 and '161 patents, as extended by any applicable period of exclusivity;

i. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Sandoz, 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 '988 and/or '161 patents;

j. If Sandoz attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's generic product disclosed in its ANDA No. 202719 prior to the

expiration of the '988 and '161 patents, as extended by any applicable period of exclusivity, a preliminary injunction be entered enjoining such conduct;

k. If Sandoz attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's generic product disclosed in its ANDA No. 202719 prior to the expiration of the '988 and '161 patents, 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;

l. That a declaration be issued under 28 U.S.C. § 2201 that if Sandoz, 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 Sandoz's proposed generic Bimatoprost Topical Solution 0.03% prior to patent expiry, it will constitute an act of infringement of the '988 and/or '161 patents;

m. That judgment be entered that Hi-Tech has infringed the '988 and '161 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 '988 and '161 patents;

n. 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 '988 and '161 patents, as extended by any applicable period of exclusivity;

o. 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 '988 and/or '161 patents;

p. 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 '988 and '161 patents, as extended by any applicable period of exclusivity, a preliminary injunction be entered enjoining such conduct;

q. 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 '988 and '161 patents, 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;

r. 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.

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

t. An accounting for infringing sales not presented at trial and an award by the Court of additional damages for any such infringing sales; and

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

Dated: March 13, 2012

Respectfully submitted,

/s/ Bryan G. Scott

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