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

ALLERGAN, INC.,	
Plaintiffs,	**Civil Action No. 1:14-cv-1034**
v.	
SANDOZ, INC., AKORN, INC., and HI-TECH PHARMACAL CO., INC.,	**JURY TRIAL DEMANDED**
Defendants.	

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Allergan, Inc. ("Allergan") claim relief from Defendants Sandoz, Inc. ("Sandoz"); and Akorn, Inc. and Hi-Tech Pharmacal Co., Inc. ("Hi-Tech") (together, "Akorn"), as follows:

NATURE OF THE ACTION

1. This is an action for infringement of claims 8, 23, and 26 of United States Patent No. 8,926,953 ("the '953 patent) under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, including §§ 271(e)(2), 271(b), and 271(c), and for a declaratory judgment of infringement of claims 8, 23, and 26 of the '953 patent under 28 U.S.C. §§ 2201 and 2202 relating to Allergan's commercially successful hypotrichosis treatment, Latisse®.

THE PARTIES

2. Allergan is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2525 Dupont Drive, Irvine, California 92612.

3. On information and belief, Sandoz 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 at 327 Hillsborough Street, Raleigh, NC 27603.

4. On information and belief, Akorn, Inc. is a corporation organized and existing under the laws of the state of Louisiana, with a principal place of business at 1925 West Field Court, Suite 300, Lake Forest, IL 60045-486, and a registered agent at 327 Hillsborough Street, Raleigh, North Carolina, 27603-1725.

5. 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.

6. On information and belief, Akorn, Inc. acquired Hi-Tech in April 2014, and Hi-Tech is a wholly-owned subsidiary of Akorn, 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*., including §§ 271(e)(2), 271(b), and 271(c), and 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

8. Sandoz submitted ANDA No. 202719 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.

9. Pursuant to § 505(j)(2)(A)(vii)(IV) of the FDCA, Sandoz included with its ANDA No. 202719 a Paragraph IV certification concerning patents Allergan had listed in the Orange Book as covering Latisse® at the time of its ANDA submission.

10. On or about March 3, 2011, Sandoz provided notice to Allergan, via a letter, that it had submitted ANDA No. 202719 for Bimatoprost Topical Solution, 0.03%, to the United States Food and Drug Administration ("FDA").

11. Sandoz sent a second letter concerning ANDA No. 202719 to Allergan on or about July 2, 2014 to address additional patents that Allergan had added to the Orange Book after the first letter.

12. Allergan listed the '953 patent in the Orange Book as covering Latisse® on January 6, 2015. Sandoz has not yet provided a notice letter to Allergan concerning the '953 patent.

13. Hi-Tech submitted ANDA No. 203051 under section 505(j) of the 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.

14. Pursuant to § 505(j)(2)(A)(vii)(IV) of the FDCA, Hi-Tech included with its ANDA No. 203051 a Paragraph IV certification concerning patents Allergan had listed in the Orange Book as covering Latisse® at the time of its ANDA submission.

15. On or about July 5, 2011, Hi-Tech provided notice to Allergan, via a letter, that it had submitted ANDA No. 203051 for Bimatoprost Topical Solution, 0.03%, to the FDA.

16. Allergan listed the '953 patent in the Orange Book as covering Latisse on January 6, 2015. Hi-Tech has not yet provided a notice letter to Allergan concerning the '953 patent.

Personal Jurisdiction over Sandoz

17. 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 in this forum arising from Sandoz's ANDA filing and the causes of action Plaintiff has raised, as alleged herein.

18. Specifically, this Court has personal jurisdiction over Sandoz because Sandoz 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.

19. On information and belief, Sandoz is in the business of developing, manufacturing, and/or marketing pharmaceutical products in the United States, including in this judicial district.

20. 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.

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

22. 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.

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

24. On information and belief, since 2013 Sandoz has sold over $781 million of products in North Carolina, over $358 million of which were sold in this district.

25. On information and belief, Sandoz 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, Sandoz 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%.

26. Sandoz has previously been sued in this judicial district concerning ANDA No. 202719 without objecting on the basis of lack of personal jurisdiction, and Sandoz has availed

itself to this judicial district through the assertion of counterclaims in those suits: Case Nos. 1:11-CV-298, 1:12-CV-247, and 1:13-CV-16.

Personal Jurisdiction over Akorn and Hi-Tech

27. This Court has personal jurisdiction over Akorn, Inc. and Hi-Tech by virtue of their systematic and continuous contacts with this jurisdiction, as alleged herein, and because of the injury to Plaintiff in this forum arising from Akorn's ANDA filing and the causes of action Plaintiff has raised, as alleged herein.

28. Specifically, this Court has personal jurisdiction over Akorn, Inc. and Hi-Tech because Akorn, Inc. and Hi-Tech 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.

29. On information and belief, Akorn, Inc. and Hi-Tech are in the business of developing, manufacturing, and/or marketing pharmaceutical products in the United States, including in this judicial district. On information and belief, following Akorn, Inc.'s acquisition of Hi-Tech, those entities 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 Ophthalmic Solution 0.03%, described in ANDA No. 203051.

30. On information and belief, Akorn, Inc. is a licensed drug manufacturer and wholesaler in North Carolina.

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

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

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

34. 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.

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

36. On information and belief, since 2013 Akorn has sold over $10 million of product in North Carolina, over $5 million of which were sold in this district.

37. On information and belief, Akorn 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, Akorn 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%.

38. Hi-Tech has previously been sued in this judicial district concerning ANDA No. 203051 without objecting on the basis of lack of personal jurisdiction, and Hi-Tech has availed itself to this judicial district through the assertion of counterclaims in one or more of those suits: Case Nos. 1:11-CV-650, 1:12-CV-247, 1:12-CV-492 and 1:13-CV-16.

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

THE PATENT-IN-SUIT

40. 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.

41. Allergan, as assignee, owns the entire right, title, and interest in the '953 patent.

42. 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.

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

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

45. Allergan had the '953 patent listed in the Orange Book as covering Latisse® on January 6, 2015.

46. 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.

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

47. Sandoz submitted ANDA No. 202719 under section 505(j) of the 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.

48. Pursuant to § 505(j)(2)(A)(vii)(IV) of the FDCA, Sandoz included with its ANDA No. 202719 a Paragraph IV certification concerning patents Allergan had listed in the Orange Book as covering Latisse® at the time of its ANDA submission.

49. The '953 patent had not issued or been listed in the Orange Book as covering Latisse® at the time Sandoz submitted its Paragraph IV certification under section 505(j) of the FDCA.

50. On information and belief, FDA has not yet approved ANDA No. 202719.

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

52. On information and belief, Sandoz became aware of the ’953 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latisse® on January 6, 2015.

53. 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 before expiration of the ’953 patent.

54. Sandoz’s actions, including, but not limited to, the development of its proposed generic Bimatoprost Topical Solution, 0.03% product, the filing of an ANDA with a Paragraph IV certification, the manufacture of exhibit batches of its proposed product, and engaging in litigation to manufacture, offer to sell, sell, and/or import Sandoz’s proposed Bimatoprost Topical Solution, 0.03% prior to patent expiration, indicate a refusal to change the course of its action in the face of acts by Plaintiff.

55. 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%.

56. 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 and this judicial district.

57. On information and belief, a launch of Sandoz’s proposed generic Bimatoprost Topical Solution, 0.03% product will negatively decrease Allegan’s net revenue of Latisse sales throughout the United States, including in North Carolina.

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

58. Hi-Tech submitted ANDA No. 203051 under section 505(j) of the 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.

59. Pursuant to § 505(j)(2)(A)(vii)(IV) of the FDCA, Hi-Tech included with its ANDA No. 203051 a Paragraph IV certification concerning patents Allergan had listed in the Orange Book as covering Latisse® at the time of its ANDA submission.

60. The '953 patent had not issued or been listed in the Orange Book as covering Latisse® at the time Hi-Tech submitted its Paragraph IV certification under section 505(j) of the FDCA.

61. On information and belief, FDA has not yet approved ANDA No. 203051.

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

63. On information and belief, Akorn became aware of the '953 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latisse® on January 6, 2015.

64. Akorn has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import a generic version of Allergan's Latisse® product before expiration of the '962 and '953 patents.

65. Akorn's actions, including, but not limited to, the development of its proposed generic Bimatoprost Topical Solution, 0.03%, the filing of an ANDA with a Paragraph IV certification, the manufacture of exhibit batches of Akorn's proposed product, and engaging in litigation to manufacture, offer to sell, sell and/or import Akorn's proposed Bimatoprost Topical

Solution, 0.03% prior to patent expiration, indicate a refusal to change the course of its action in the face of acts by Plaintiff.

66. On information and belief, Akorn 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%.

67. On information and belief, following FDA approval of its ANDA No. 203051, Akorn will sell the approved generic version of Allergan's Latisse® product throughout the United States, including in North Carolina and this judicial district.

68. On information and belief, a launch of Akorn's proposed generic Bimatoprost Topical Solution, 0.03% product will negatively decrease Allegan's net revenue of Latisse® sales throughout the United States, including in North Carolina.

COUNT I

(Infringement of claims 8, 23, and 26 of the '953 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz's Proposed Generic Bimatoprost Topical Solution, 0.03%)

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

70. 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 claims 8, 23, and 26 of the '953 patent under 35 U.S.C. § 271(e)(2)(A).

71. On information and belief, Sandoz will include within the packaging of its proposed generic Bimatoprost Topical Solution, 0.03% product, or will otherwise make available to prospective patients upon FDA approval, 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.

72. A patient's use of Sandoz's proposed generic 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.

73. Sandoz's proposed generic 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.

74. Sandoz's proposed generic 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.

75. On information and belief, Sandoz became aware of the '953 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book on January 6, 2015

76. On information and belief, Sandoz 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 and/or was listed in the Orange Book on January 6, 2015, at least because of the prior adjudication that Sandoz had induced infringement and contributed to the infringement of similar methods of use claimed in U.S. Patent No. 7,388,029 by filing ANDA No. 202719, 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.

77. Any commercial distribution, marketing, sale, offer for sale, sale, and/or importation of Sandoz's proposed generic Bimatoprost Topical Solution, 0.03% will constitute an act of contributory infringement and/or active inducement of infringement of claims 8, 23, and 26 of the '953 patent.

78. Any commercial distribution, marketing, 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 II

(Declaratory Judgment of Infringement of claims 8, 23, and 26 of the '953 Patent Under 35 U.S.C. §§ 271(b) and/or 271(c) by Sandoz's Proposed Generic Bimatoprost Topical Solution, 0.03%)

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

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

81. 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.

82. 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%.

83. Sandoz's actions, including, but not limited to, the development of its proposed generic Bimatoprost Topical Solution, 0.03% product, the filing of an ANDA with a Paragraph IV certification, the manufacture of exhibit batches of its proposed product, and engaging in litigation to manufacture, offer to sell, sell and/or import Sandoz's proposed Bimatoprost Topical Solution, 0.03% prior to patent expiration, indicate a refusal to change the course of its action in the face of acts by Plaintiff.

84. On information and belief, Sandoz will include within the packaging of its proposed generic Bimatoprost Topical Solution, 0.03% product, or will otherwise make available to

prospective patients upon FDA approval, 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.

85. A patient’s use of Sandoz’s proposed generic 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.

86. Sandoz’s proposed generic 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.

87. Sandoz’s proposed generic 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.

88. On information and belief, Sandoz became aware of the ’953 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book on January 6, 2015.

89. On information and belief, Sandoz 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 and/or was listed in the Orange Book on January 6, 2015, at least because of the prior adjudication that Sandoz had induced infringement and contributed to the infringement of similar methods of use claimed in U.S. Patent No. 7,388,029 by filing ANDA No. 202719, 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.

90. Any commercial distribution, marketing, sale, offer for sale, sale, and/or importation of Sandoz’s proposed generic Bimatoprost Topical Solution, 0.03% will constitute an act of

contributory infringement and/or active inducement of infringement of claims 8, 23, and 26 of the ’953 patent.

91. Any commercial distribution, marketing, 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.

92. 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% before patent expiration by Sandoz will constitute contributory infringement and/or active inducement of infringement of claims 8, 23, and 26 of the ’953 patent.

COUNT III

(Infringement of claims 8, 23, and 26 of the ’953 Patent Under 35 U.S.C. § 271(e)(2) by Akorn’s Proposed Generic Bimatoprost Topical Solution, 0.03%)

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

94. Akorn, through its now wholly-owned subsidiary 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, Akorn has committed an act of infringement of claims 8, 23, and 26 of the ’953 patent under 35 U.S.C. § 271(e)(2)(A).

95. On information and belief, Akorn will include within the packaging of its proposed generic Bimatoprost Topical Solution, 0.03% product, or will otherwise make available to prospective patients upon FDA approval, 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.

96. A patient's use of Akorn's proposed generic 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.

97. Akorn's proposed generic 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.

98. Akorn's proposed generic 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.

99. On information and belief, Akorn became aware of the '953 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book on January 6, 2015.

100. On information and belief, Akorn 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 and/or was listed in the Orange Book on January 6, 2015, at least because of the prior adjudication that Hi-Tech had induced infringement and contributed to the infringement of similar methods of use claimed in U.S. Patent No. 7,388,029 by filing ANDA No. 203051, 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.

101. Any commercial distribution, marketing, sale, offer for sale, sale, and/or importation of Akorn's proposed generic Bimatoprost Topical Solution, 0.03% will constitute an act of contributory infringement and/or active inducement of infringement of claims 8, 23, and 26 of the '953 patent.

102. Any commercial distribution, marketing, offer for sale, sale, and/or importation of Akorn'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 claims 8, 23, and 26 of the '953 Patent Under 35 U.S.C. §§ 271(b) and/or 271(c) by Akorn and Hi-Tech's Proposed Generic Bimatoprost Topical Solution, 0.03%)

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

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

105. 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.

106. Akorn 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 Akorn's proposed generic Bimatoprost Topical Solution, 0.03%.

107. Akorn's actions, including, but not limited to, the development of its proposed generic Bimatoprost Topical Solution, 0.03% product, the filing of ANDA No. 203051, the manufacture of exhibit batches of its proposed product, and engaging in litigation to manufacture, offer to sell, sell and/or import Akorn's proposed Bimatoprost Topical Solution, 0.03% prior to patent expiration, indicate a refusal to change the course of its action in the face of acts by Plaintiff.

108. On information and belief, Akorn will include within the packaging of its proposed generic Bimatoprost Topical Solution, 0.03% product, or will otherwise make available

to prospective patients upon FDA approval, 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.

109. A patient’s use of Akorn’s proposed generic 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.

110. Akorn’s proposed generic 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.

111. Akorn’s proposed generic 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.

112. On information and belief, Akorn became aware of the ’953 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book on January 6, 2015.

113. On information and belief, Akorn 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 and/or was listed in the Orange Book on January 6, 2015, at least because of the prior adjudication that Hi-Tech had induced infringement and contributed to the infringement of similar methods of use claimed in U.S. Patent No. 7,388,029 by filing ANDA No. 203051, 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.

114. Any commercial distribution, marketing, sale, offer for sale, sale, and/or importation of Akorn’s proposed generic Bimatoprost Topical Solution, 0.03% will constitute an

act of contributory infringement and/or active inducement of infringement of claims 8, 23, and 26 of the ’953 patent.

115. Any commercial distribution, marketing, offer for sale, sale, and/or importation of Akorn’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.

116. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Akorn’s proposed Bimatoprost Topical Solution, 0.03% prior to patent expiration by Akorn will constitute contributory infringement and/or 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 judgment be entered decreeing that i) Sandoz has infringed claims 8, 23, and 26 of ’953 patent 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 ii) 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%, constitutes or will constitute an infringement of claims 8, 23, and 26 of the ’953 patent;

b. That an Order be entered decreeing pursuant to 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 dates of the ’953 patent, as extended by any applicable period of exclusivity;

c. That an injunction be issued pursuant to 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 claims 8, 23, and 26 of the ’953 patent;

d. That if Sandoz engages 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 ’953 patent, as extended by any applicable period of exclusivity, a preliminary injunction and/or permanent injunction be entered enjoining such conduct pursuant to 35 U.S.C. § 283;

e. That if Sandoz engages 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 ’953 patent, as extended by any applicable period of exclusivity, Plaintiff have and recover damages or other monetary relief resulting from such infringement pursuant to 35 U.S.C. § 271(e)(4)(C);

f. That a declaration be issued pursuant to 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 expiration, it will constitute an act of infringement of claims 8, 23, and 26 of the '953 patent;

g. That judgment be entered decreeing that i) Akorn has infringed claims 8, 23, and 26 of the '953 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 203051 under section 505(j) of the Federal Food, Drug, and Cosmetic Act, and ii) that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Akorn's proposed generic Bimatoprost Topical Solution, 0.03% constitutes or will constitute an act of infringement of claims 8, 23, and 26 of the '953 patent;

h. That an Order be entered decreeing pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Akorn's ANDA No. 203051 shall be a date which is not earlier than the expiration dates of the '953 patents, as extended by any applicable period of exclusivity;

i. That an injunction be issued pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Akorn, 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, 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 claims 8, 23, and 26 of the '953 patent;

j. That if Akorn engages in the commercial manufacture, use, offer to sell, sale, or importation of Akorn's generic product disclosed in their ANDA No. 203051 prior to the expiration of the '953 patents, as extended by any applicable period of exclusivity, a preliminary and/or permanent injunction be entered enjoining such conduct pursuant to 35 U.S.C. § 283;

k. That if Akorn engages in the commercial manufacture, use, offer to sell, sale, or importation of Akorn's generic product disclosed in ANDA No. 203051 prior to the expiration of the '953 patent, as extended by any applicable period of exclusivity Plaintiff have and recover damages or other monetary relief resulting from such infringement pursuant to 35 U.S.C. § 271(e)(4)(C);

l. That a declaration be issued pursuant to 28 U.S.C. § 2201 that if Akorn, or its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Akorn's proposed 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;

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

n. That Sandoz and Akorn 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; and

o. 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

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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