

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

ALLERGAN SALES, LLC,

Plaintiff,

v.

SANDOZ, INC.

Defendant.

Civil Action No. _____

Jury Trial Demanded

PLAINTIFF ALLERGAN, SALES, LLC'S COMPLAINT AGAINST SANDOZ, INC.

Plaintiff Allergan Sales, LLC ("Allergan" or "Plaintiff") by its attorneys, Love Law Firm, P.C. and Fish & Richardson P.C., for its complaint against Defendant Sandoz, Inc. ("Sandoz") alleges as follows:

The Nature of the Action

1. This is an action for infringement of United States Patent Nos. 7,030,149 ("the '149 patent"), 7,320,976 ("the '976 patent"), the 7,642,258 ("the '258 patent"), and the 8,748,425 ("the '425 patent") under 35 U.S.C. § 271(e)(2) and for Declaratory Judgment of infringement under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a), (b), and (c) relating to Allergan's commercially successful product, Combigan®.

The Parties

2. Allergan is a limited liability company 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 Colorado corporation with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

4. On information and belief, Sandoz is in the business of manufacturing, distributing and selling generic drugs throughout the United States, including in this judicial district.

Jurisdiction and Venue

5. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq* and the Declaratory Judgment Act. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

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

7. Allergan operates a facility in Waco, Texas where it manufactures and distributes numerous pharmaceutical products, including Combigan® (brimonidine tartrate/timolol maleate ophthalmic solution 0.2%/0.5%). Allergan's Combigan® product sold in the United States is exclusively manufactured in Allergan's Waco facility from which Allergan also coordinates the nationwide distribution of Combigan®. Allergan employs over 600 individuals in Texas, more than in any other U.S. state, except California. Were Sandoz to sell or offer to sell its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% product, Allergan will be injured specifically in Texas.

8. This Court has specific personal jurisdiction over Sandoz because the conduct complained of herein is directed at Allergan, a resident of the state of Texas, and Sandoz's conduct threatens and causes injury to Allergan through Allergan's Texas facilities and employees. In this regard, Sandoz, 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.

9. On information and belief, Sandoz is a licensed drug distributor in Texas and has established contacts with Texas wholesalers, retailers, and state agencies to further the sales of its products.

10. On information and belief, Sandoz's drug products are listed on the Texas prescription drug formulary.

11. On information and belief, Sandoz markets and sells generic drugs manufactured by Sandoz throughout Texas, including in this judicial district. On information and belief, Sandoz sold approximately \$600 million of its products in Texas in 2014 to wholesalers, which accounted for over \$1.5 billion in retail sales. On information and belief, approximately \$78 million of those sales to wholesalers were in this judicial district. Sandoz continues to achieve substantial sales in both Texas and this judicial district.

12. Sandoz knows and intends that its proposed Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will be distributed and sold in Texas and will displace sales of Allergan's Combigan® product causing injury to Allergan in Texas. Sandoz also intends to take advantage of its established channels of distribution in Texas for the sale of its proposed Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%. These channels of distribution were arranged by Sandoz to take advantage of the Texas market, the second-largest market for prescription drugs in the United States.

13. On information and belief, Sandoz previously availed itself of this forum for purposes of litigating patent disputes regarding its ANDA products, including regarding its ANDA No. 91-087 for generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution,

0.2%/0.5%, the product at issue here. In particular, Sandoz submitted to the jurisdiction of this Court and filed counterclaims in prior disputes over the product at issue in this litigation, *Allergan, Inc. v. Sandoz Inc. et al.*, 2:09-cv-00097-TJW, D.I. 83 at 17-25 (E.D. Tex.); *Allergan, Inc. v. Sandoz Inc. et al.*, 2:12-cv-00207-JRG, D.I. 92 at 51-62 (E.D. Tex.). Moreover, C.A. No. 2:09-cv-0097-TJW involved three of the four patents at issue in this litigation, the '149, '976, and '258 patents.

14. This Court has previously found a generic pharmaceutical manufacturer was subject to specific personal jurisdiction in an action with facts similar to those present here. *Allergan, Inc. v. Actavis, Inc.*, C.A. No. 2:14-cv-638, 2014 WL 7336692 (E.D. Tex. Dec. 23, 2014).

15. This Court further has personal jurisdiction over Sandoz by virtue of its systematic and continuous contacts with this jurisdiction, as alleged herein.

Background

16. The '149 patent, entitled "Combination of Brimonidine Timolol For Topical Ophthalmic Use," issued to Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L. Batoosingh on April 18, 2006. A copy of the '149 patent is attached to this complaint as Exhibit A.

17. Allergan, as assignee, owns the entire right, title, and interest in the '149 patent.

18. The '976 patent, entitled "Combination of Brimonidine And Timolol For Topical Ophthalmic Use," issued to Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L. Batoosingh on January 22, 2008. A copy of the '976 patent is attached to this complaint as Exhibit B.

19. Allergan, as assignee, owns the entire right, title, and interest in the '976 patent.

20. The '258 patent, entitled "Combination of Brimonidine And Timolol For Topical Ophthalmic Use," issued to Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L. Batoosingh on January 5, 2010. A copy of the '258 patent is attached to this complaint as Exhibit C.

21. Allergan, as assignee, owns the entire right, title, and interest in the '258 patent.

22. The '425 patent, entitled "Combination of Brimonidine And Timolol For Topical Ophthalmic Use," issued to Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L. Batoosingh on June 10, 2014. A copy of the '425 patent is attached to this complaint as Exhibit D.

23. Allergan, as assignee, owns the entire right, title, and interest in the '425 patent.

24. Allergan is the holder of an approved New Drug Application ("NDA") No. 21-398 for brimonidine tartrate/timolol maleate ophthalmic solution 0.2%/0.5%, sold under the Combigan® trademark.

25. In conjunction with that NDA, Allergan has listed with the United States Food and Drug Administration ("FDA") six patents that cover the approved formulation or methods of using the approved formulation of Combigan®. The listed patents are the '149 patent, the '976 patent, the '258 patent, the '425 patent, and U.S. Patent Nos. 8,133,890 and 8,354,409 (collectively, "the Listed Patents"). The FDA has published these six patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book."

26. Combigan® or approved methods of using Combigan® are covered by at least one claim of each of the Listed Patents, including the '149, '976, '258, and '425 patents.

27. On November 20, 2008, Sandoz submitted its ANDA No. 91-087 to the FDA, seeking approval to commercially manufacture, use, offer for sale, or sell a generic version of Combigan®. Sandoz's ANDA No. 91-087 received tentative approval from the FDA on May 11, 2011.

28. In an August 22, 2011 opinion, the District Court for the Eastern District of Texas found that Sandoz's proposed generic version of Combigan® infringed U.S. Patent Nos. 7,030,149, 7,320,976, 7,323,463, and 7,642,258, and that those patents were not invalid. The Court entered an injunction order on August 25, 2011 stating that Sandoz is enjoined from manufacturing its proposed generic version of Combigan® until the latest of the expiration dates of U.S. Patent Nos. 7,030,149, 7,320,976, 7,323,463, and 7,642,258.

29. On appeal, in a May 1, 2013 opinion, the Federal Circuit held that claim 4 of the '149 patent is not invalid, declined to rule on the validity of the '976 and '258 patents, and ruled that the claims of the '463 patent are invalid. In addition, the opinion affirmed the factual findings of this Court's August 22, 2011 opinion. Thereafter, Sandoz filed a petition for rehearing and rehearing *en banc*, which was denied on September 9, 2013, and a petition for a writ of certiorari to the Supreme Court which was denied on March 31, 2014.

30. In its petitions for rehearing and rehearing *en banc*, and in its petition for writ of certiorari, Sandoz asserted that it had amended its ANDA in an effort to avoid infringement of the '149 patent (the "Amendment"). Despite these new assertions, Sandoz did not provide a revised notice of Paragraph IV certification to Allergan at any time during the pendency of those petitions.

31. After the Federal Circuit denied Sandoz's rehearing petitions, Sandoz filed a motion for relief from this Court's judgment under Federal Rule of Civil Procedure 60 on

September 17, 2013. That filing again referenced the Amendment. This Court denied that motion on December 3, 2013, and the Federal Circuit affirmed the judgment of this Court on December 11, 2014. Sandoz filed a petition for rehearing and rehearing *en banc* on February 11, 2015 at the Federal Circuit, which has not yet been decided.

32. At no time during the proceedings over its Rule 60 motion did Sandoz provide a revised notice of Paragraph IV certification to Allergan notifying Allergan of Sandoz's Amendment to its ANDA and its arguments regarding non-infringement of the '149 patent.¹

33. On or about January 26, 2015, Allergan received a letter dated January 23, 2015, signed on behalf of Sandoz by Jean Domenico.

34. The January 23, 2015 letter states in part that "Sandoz has now amended its ANDA to include an additional certification under 21 U.S.C. §355(j)(2)(A)(vii)(IV) to U.S. Patent No. 8,748,425." The letter alleges that "the claims of the '425 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Sandoz Product."

35. The letter also formally notified Allergan for the first time of Sandoz's Amendment referenced in paragraph 30 above. Based on the Amendment, in the January 23, 2015 letter, Sandoz also avers that claim 4 of the '149 patent is not infringed by the Sandoz Product reflected in the amended ANDA. The January 23, 2015 letter also states that Sandoz maintains and repeats its prior assertions that the '976 and '258 patents are invalid.

¹ On April 13, 2012, Allergan filed suit against Sandoz in this Court in C.A. No. 2:12-cv-207, asserting infringement initially of U.S. Patent No. 8,133,890 and later also of U.S. Patent No. 8,354,409. On December 18, 2013, the Court ordered that the case be stayed. The Court continued that stay in an order dated January 22, 2015.

36. Included in the January 23, 2015 letter is a “Detailed Statement” of the factual and legal basis for Sandoz’s opinion that the claims of the ’149 patent, ’258 patent, ’976 patent, and ’425 patent are invalid and/or will not be infringed by the manufacture, use or sale of the Sandoz Product. The letter includes a statement that if Allergan does not sue Sandoz for infringement of the ’149, ’976, ’258, and ’425 patents, Sandoz would file a declaratory judgment action on those patents.

37. Sandoz’s letter does not reference prior findings and conclusions by this Court that were resolved against it that were affirmed by the Federal Circuit. Under the doctrines of collateral estoppel, law of the case, and other legal finality doctrines, Sandoz is precluded from re-litigating issues that were finally decided against it in other litigations involving the subject matter that is at issue here.

38. Because Sandoz has submitted a new paragraph IV certification, however, and has amended its ANDA, Allergan files this suit to preserve its rights under the Hatch-Waxman Act, including its rights to a 30-month stay on approval of Sandoz’s now amended ANDA. By filing this suit, Allergan does not intend to waive any rights that Sandoz may be precluded from re-litigating issues relevant to the infringement and/or validity of the previously adjudicated ’149, ’976, and ’258 patents.

39. In filing its ANDA, and submitting the Amendment, Sandoz has requested the FDA’s approval to market a generic version of Allergan’s Combigan® product throughout the United States, including in Texas.

40. On information and belief, following FDA approval of ANDA Nos. 91-087, Sandoz will sell the approved generic version of Allergan’s Combigan® product throughout the United States, including in Texas.

Count I

(Infringement of Claim 4 of the '149 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%)

41. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

42. Sandoz submitted ANDA No. 91-087 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use or sale of its proposed Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% throughout the United States. By submitting that application and notifying Allergan, Sandoz has committed an act of infringement of claim 4 of the '149 patent under 35 U.S.C. § 271(e)(2)(A). Further, by submitting its Amendment and notifying Allergan, Sandoz has committed an act of infringement of claim 4 of the '149 patent under 35 U.S.C. § 271(e)(2)(A).

43. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will constitute an act of infringement of claim 4 of the '149 patent.

44. On information and belief, Sandoz became aware of the '149 patent no later than the date on which that patent was listed in the Orange Book.

45. On information and belief, Sandoz knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively induce and contribute to the actual infringement of claim 4 of the '149 patent.

46. On information and belief, Sandoz knows or should know that its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will be especially made for or especially adapted for use in an infringement of claim 4 of the '149

patent, and is 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 Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively contribute to the actual infringement of claim 4 of the '149 patent.

47. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count II

(Declaratory Judgment of Infringement of Claim 4 of the '149 Patent under 35 U.S.C. § 271(b) and (c) by Sandoz's Proposed Generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%)

48. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

49. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

50. There is an actual case or controversy such that the Court may entertain Allergan'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.

51. Sandoz has actual knowledge of the '149 patent.

52. On information and belief, Sandoz became aware of the '149 patent no later than the date on which that patent was listed in the Orange Book.

53. On information and belief, Sandoz has acted with full knowledge of claim 4 of the '149 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of claim 4 of the '149 patent.

54. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will induce the actual infringement of claim 4 of the '149 patent.

55. On information and belief, Sandoz knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively induce the actual infringement of claim 4 of the '149 patent.

56. On information and belief, Sandoz will encourage another's infringement of the '149 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%, which is covered by claim 4 of the '149 patent.

57. Sandoz's acts of infringement will be done with knowledge of claim 4 of the '149 patent and with the intent to encourage infringement.

58. The foregoing actions by Sandoz will constitute active inducement of infringement of claim 4 of the '149 patent.

59. On information and belief, Sandoz knows or should know that its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will be especially made or especially adapted for use in an infringement of claim 4 of the '149 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

60. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will contribute to the actual infringement of claim 4 of the '149 patent.

61. On information and belief, Sandoz knows or should know that its offer for sale, sale and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will contribute to the actual infringement of claim 4 of the '149 patent.

62. The foregoing actions by Sandoz will constitute contributory infringement of claim 4 of the '149 patent.

63. On information and belief, Sandoz intends to, and will, actively induce and contribute to the infringement of claim 4 of the '149 patent when ANDA No. 91-087 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

64. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% by Sandoz will induce and/or contribute to infringement of claim 4 of the '149 patent.

65. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%, which will actively induce and/or contribute to infringement of claim 4 of the '149 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

66. Unless Sandoz is enjoined from actively inducing and contributing to the infringement of claim 4 of the '149 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

67. On information and belief, despite having actual notice of claim 4 of the '149 patent, Sandoz continues to willfully, wantonly, and deliberately prepare to actively induce

and/or contribute to infringement of claim 4 of the '149 patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count III

(Infringement of the '976 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%)

68. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

69. Sandoz submitted ANDA No. 91-087 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use or sale of its proposed Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% throughout the United States. By submitting that application and notifying Allergan, Sandoz has committed an act of infringement of the '976 patent under 35 U.S.C. § 271(e)(2)(A). Further, by submitting its Amendment and notifying Allergan, Sandoz has committed an act of infringement of the '976 patent under 35 U.S.C. § 271(e)(2)(A).

70. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will constitute an act of infringement of the '976 patent.

71. On information and belief, Sandoz became aware of the '976 patent no later than the date on which that patent was listed in the Orange Book.

72. On information and belief, Sandoz knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively induce and contribute to the actual infringement of the '976 patent.

73. On information and belief, Sandoz knows or should know that its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will be especially made for or especially adapted for use in an infringement of the '976 patent, and is 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 Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively contribute to the actual infringement of the '976 patent.

74. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count IV

(Declaratory Judgment of Infringement of the '976 Patent under 35 U.S.C. § 271(b) and (c) by Sandoz's Proposed Generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%)

75. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

76. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

77. There is an actual case or controversy such that the Court may entertain Allergan'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.

78. Sandoz has actual knowledge of the '976 patent.

79. On information and belief, Sandoz became aware of the '976 patent no later than the date on which that patent was listed in the Orange Book.

80. On information and belief, Sandoz has acted with full knowledge of the '976 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '976 patent.

81. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will induce the actual infringement of the '976 patent.

82. On information and belief, Sandoz knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively induce the actual infringement of the '976 patent.

83. On information and belief, Sandoz will encourage another's infringement of the '976 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%, which is covered by the '976 patent.

84. Sandoz's acts of infringement will be done with knowledge of the '976 patent and with the intent to encourage infringement.

85. The foregoing actions by Sandoz will constitute active inducement of infringement of the '976 patent.

86. On information and belief, Sandoz knows or should know that its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will be especially made or especially adapted for use in an infringement of the '976 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

87. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will contribute to the actual infringement of the '976 patent.

88. On information and belief, Sandoz knows or should know that its offer for sale, sale and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will contribute to the actual infringement of the '976 patent.

89. The foregoing actions by Sandoz will constitute contributory infringement of the '976 patent.

90. On information and belief, Sandoz intends to, and will, actively induce and contribute to the infringement of the '976 patent when ANDA No. 91-087 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

91. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% by Sandoz will induce and/or contribute to infringement of the '976 patent.

92. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%, which will actively induce and/or contribute to infringement of the '976 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

93. Unless Sandoz is enjoined from actively inducing and contributing to the infringement of the '976 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

94. On information and belief, despite having actual notice of the '976 patent, Sandoz continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '976 patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count V

(Infringement of the '258 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%)

95. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

96. Sandoz submitted ANDA No. 91-087 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use or sale of its proposed Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% throughout the United States. By submitting that application and notifying Allergan, Sandoz has committed an act of infringement of the '258 patent under 35 U.S.C. § 271(e)(2)(A). Further, by submitting its Amendment and notifying Allergan, Sandoz has committed an act of infringement of the '258 patent under 35 U.S.C. § 271(e)(2)(A).

97. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will constitute an act of infringement of the '258 patent.

98. On information and belief, Sandoz became aware of the '258 patent no later than the date on which that patent was listed in the Orange Book.

99. On information and belief, Sandoz knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively induce the actual infringement of the '258 patent.

100. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count VI

(Declaratory Judgment of Infringement of the '258 Patent Under 35 U.S.C. § 271(a) by Sandoz)

101. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

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

103. There is an actual case or controversy such that the Court may entertain Allergan'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.

104. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will constitute an act of direct infringement of one or more claims of the '258 patent.

105. On information and belief, Sandoz will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% immediately and imminently upon approval of ANDA No. 91-087.

106. The foregoing actions by Sandoz will constitute infringement of the '258 patent.

107. Sandoz will commit those acts of infringement without license or authorization.

108. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic

Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% by Sandoz will infringe the '258 patent.

109. Unless Sandoz is enjoined from infringing the '258 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

110. On information and belief, Sandoz became aware of the '258 patent no later than the date on which that patent was listed in the Orange Book.

111. On information and belief, Sandoz has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%.

112. Sandoz's actions indicate a refusal to change the course of its actions in the face of acts by Allergan.

113. On information and belief, Sandoz has acted, and will continue to act, with full knowledge of the '258 patent and without a reasonable basis for believing that it would not be liable for infringing the '258 patent.

114. On information and belief, despite having actual notice of the '258 patent, Sandoz continues to willfully, wantonly, and deliberately prepare to infringe the '258 patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count VII

(Declaratory Judgment of Infringement of the '258 Patent under 35 U.S.C. § 271(b) and (c) by Sandoz's Proposed Generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%)

115. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

116. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

117. There is an actual case or controversy such that the Court may entertain Allergan'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.

118. Sandoz has actual knowledge of the '258 patent.

119. On information and belief, Sandoz became aware of the '258 patent no later than the date on which that patent was listed in the Orange Book.

120. On information and belief, Sandoz has acted with full knowledge of the '258 patent and without a reasonable basis for believing that it would not be liable for actively inducing the infringement of the '258 patent.

121. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will induce the actual infringement of the '258 patent.

122. On information and belief, Sandoz knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively induce the actual infringement of the '258 patent.

123. On information and belief, Sandoz will encourage another's infringement of the '258 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%, which is covered by certain claims of the '258 patent.

124. Sandoz's acts of infringement will be done with knowledge of the '258 patent and with the intent to encourage infringement.

125. The foregoing actions by Sandoz will constitute active inducement of infringement of the '258 patent.

126. On information and belief, Sandoz knows or should know that its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will be especially made or especially adapted for use in an infringement of the '258 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

127. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will contribute to the actual infringement of the '258 patent.

128. On information and belief, Sandoz knows or should know that its offer for sale, sale and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will contribute to the actual infringement of the '258 patent.

129. The foregoing actions by Sandoz will constitute contributory infringement of the '258 patent.

130. On information and belief, Sandoz intends to, and will, actively induce and contribute to the infringement of the '258 patent when ANDA No. 91-087 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

131. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% by Sandoz will induce and/or contribute to infringement of the '258 patent.

132. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution,

0.2%/0.5%, which will actively induce and/or contribute to infringement of the '258 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

133. Unless Sandoz is enjoined from actively inducing and contributing to the infringement of the '258 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

134. On information and belief, despite having actual notice of the '258 patent, Sandoz continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '258 patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count VIII

(Infringement of the '425 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%)

135. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

136. Sandoz submitted ANDA No. 91-087 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use or sale of its proposed Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% throughout the United States. By submitting that application and notifying Allergan, Sandoz has committed an act of infringement of the '425 patent under 35 U.S.C. § 271(e)(2)(A). Further, by submitting its Amendment and notifying Allergan, Sandoz has committed an act of infringement of the '425 patent under 35 U.S.C. § 271(e)(2)(A).

137. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will constitute an act of infringement of the '425 patent.

138. On information and belief, Sandoz became aware of the '425 patent no later than the date on which that patent was listed in the Orange Book.

139. On information and belief, Sandoz knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively induce and contribute to the actual infringement of the '425 patent.

140. On information and belief, Sandoz knows or should know that its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will be especially made for or especially adapted for use in an infringement of the '425 patent, and is 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 Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively contribute to the actual infringement of the '425 patent.

141. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count IX

(Declaratory Judgment of Infringement of the '425 Patent under 35 U.S.C. § 271(b) and (c) by Sandoz's Proposed Generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%)

142. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

143. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

144. There is an actual case or controversy such that the Court may entertain Allergan'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.

145. Sandoz has actual knowledge of the '425 patent.

146. On information and belief, Sandoz became aware of the '425 patent no later than the date on which that patent was listed in the Orange Book.

147. On information and belief, Sandoz has acted with full knowledge of the '425 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '425 patent.

148. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will induce the actual infringement of the '425 patent.

149. On information and belief, Sandoz knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will actively induce the actual infringement of the '425 patent.

150. On information and belief, Sandoz will encourage another's infringement of the '425 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%, which is covered by certain claims of the '425 patent.

151. Sandoz's acts of infringement will be done with knowledge of the '425 patent and with the intent to encourage infringement.

152. The foregoing actions by Sandoz will constitute active inducement of infringement of the '425 patent.

153. On information and belief, Sandoz knows or should know that its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will be especially made or especially adapted for use in an infringement of the '425 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

154. The commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will contribute to the actual infringement of the '425 patent.

155. On information and belief, Sandoz knows or should know that its offer for sale, sale and/or importation of its proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% will contribute to the actual infringement of the '425 patent.

156. The foregoing actions by Sandoz will constitute contributory infringement of the '425 patent.

157. On information and belief, Sandoz intends to, and will, actively induce and contribute to the infringement of the '425 patent when ANDA No. 91-087 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

158. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% by Sandoz will induce and/or contribute to infringement of the '425 patent.

159. The commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution,

0.2%/0.5%, which will actively induce and/or contribute to infringement of the '425 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

160. Unless Sandoz is enjoined from actively inducing and contributing to the infringement of the '425 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

161. On information and belief, despite having actual notice of the '425 patent, Sandoz continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '425 patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Jury Trial Demand

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

Prayer for Relief

Plaintiffs respectfully pray for the following relief:

- a. That judgment be entered that Sandoz has infringed the '149, '976, '258, and '425 patents under 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's proposed Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% product will constitute an act of infringement of the '149, '976, '258, and '425 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 Sandoz's ANDA shall be a date which is not earlier than the expiration

date of the '149, '976, '258, and '425 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 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 '149, '976, '258, and '425 patents;

d. 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 prior to the expiration of the '149, '976, '258, and '425 patents, as extended by any applicable period of exclusivity, a preliminary injunction be entered enjoining such conduct;

e. 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 prior to the expiration of the '149, '976, '258, and '425 patents, as extended by any applicable period of exclusivity, judgment awarding Allergan damages resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

f. That 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 them or acting on their behalf engage in the commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's

proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%, it will constitute an act of infringement of the '149, '976, '258, and '425 patents;

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

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

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

Dated: March 9, 2015

Respectfully submitted,

By: /s/ Gregory P. Love

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