

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

ALLERGAN, INC.,

Plaintiff,

v.

FAMY CARE LIMITED,

Defendant.

Civil Action No. 2:16-cv-401

JURY TRIAL DEMANDED

ALLERGAN, INC.’S COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Allergan, Inc. (“Allergan” or “Plaintiff”), for its Complaint against Defendant Famy Care Limited (“Famy Care”) by its attorneys, alleges as follows:

The Nature of the Action

1. This is an action for infringement of United States Patent Nos. 8,629,111 (“the ’111 Patent”), 8,633,162 (“the ’162 Patent”), 8,642,556 (“the ’556 Patent”), 8,648,048 (“the ’048 Patent”), 8,685,930 (“the ’930 Patent”), and 9,248,191 (“the ’191 Patent”) under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, relating to Allergan’s treatment for chronic dry eye, Restasis®.

2. This is also an action under 35 U.S.C. §§ 2201-02 for a declaratory judgment of infringement of the ’111, ’556, and ’930 Patents under 35 U.S.C. § 271 (a), (b), and (c), and for a declaratory judgment of infringement of the ’162, ’048, and ’191 Patents under 35 U.S.C. § 271 (b) and (c).

The Parties

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

4. Allergan operates a facility in Waco, Texas where it manufactures and distributes numerous pharmaceutical products, including RESTASIS® (cyclosporine ophthalmic emulsion, 0.05%). Allergan coordinates the nationwide distribution of RESTASIS® from Texas. Allergan employs over 800 individuals in Texas, more than in any other state except California.

5. On information and belief, Famy Care is organized and exists under the laws of the Republic of India and has a principal place of business at 3rd Floor, Brady House, 12/14, Veer Nariman Road, Fort, Mumbai – 400 001, Maharashtra, India.

6. On its Paragraph IV Notification, Famy Care lists its attorney, William Rakoczy as its agent in the United States authorized to accept service of process. On information and belief, Famy Care has no physical location in the United States.

Venue and Jurisdiction

7. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1, *et seq.* This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338.

8. This Court has personal jurisdiction over Famy Care by virtue of its systematic and continuous contact with this jurisdiction, as alleged herein, and because of the injury to Allergan in this forum arising from Famy Care's ANDA filing and the causes of action Allergan raises, as alleged herein. *See Acorda Therapeutics Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, No. 2015-1456 (Fed. Cir. March 18, 2016).

9. Alternatively, if this Court does not have jurisdiction over Famy Care because of its contacts with this jurisdiction as described below, this Court has personal jurisdiction over Famy Care under Federal Rule of Civil Procedure 4(k)(2).

10. On information and belief, Famy Care submitted ANDA No. 208469 under section 505(j) of the FDCA, 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, importation, sale, or offer for sale of Cyclosporine Ophthalmic Emulsion, 0.05%, a generic version of Allergan's RESTASIS® product.

11. On information and belief, Famy Care is in the business of researching and developing generic drug products.

12. On information and belief, Famy Care has engaged in continuous and systematic contacts with the United States by, among other things, entering into an exclusive partnership with Mylan, Inc. that dates back to 2008 to file ANDAs for generic contraceptive products and to supply such products to customers in the United States. *See* Exhibit 1.

13. On information and belief, in the United States, Famy Care and Mylan Inc. have a portfolio of 12 approved products. As of November 2015, Famy Care and Mylan Inc. had ANDAs for 30 drugs pending the approval of the FDA. *See* Exhibit 1.

14. On information and belief, Famy Care partners with Mylan Inc. for the purposes of marketing, selling, and distributing the generic drug products that Famy Care develops throughout the United States, including in this judicial district.

15. On information, and belief, Mylan Pharmaceuticals is an agent of Mylan Inc. and works in active concert with Mylan Inc. to market, sell, and distribute pharmaceutical products.

16. On information and belief, Mylan Pharmaceuticals is a licensed drug distributor of prescription drugs sold in the State of Texas.

17. On information and belief, Mylan Pharmaceuticals is actively registered with the Texas Secretary of State to conduct business in Texas.

18. On information and belief, Mylan Pharmaceuticals has a registered agent in Texas located at 211 East 7th Street, Suite 620, Austin Texas 78701-3218.

19. On information and belief, Mylan Inc. markets and sells numerous generic drugs in Texas. On information and belief, since 2014 Mylan Inc. has sold over \$1.3 billion worth of products in Texas, over \$460 million of which were sold in this judicial district.

20. Texas is the second largest market for prescription drugs in the United States and thus a lucrative target for sale of Famy Care's proposed Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 208469.

21. In view of the lucrative Texas market for generic RESTASIS®, on information and belief, Famy Care knows and intends that its proposed Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 208469 will be distributed and sold in Texas, including through the extensive distribution networks established by Famy Care's distribution partner, Mylan Inc. and/or Mylan Pharmaceuticals.

22. On information and belief, Famy Care knows and intends that sales of its proposed Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 208469 will displace sales of Allergan's RESTASIS® product causing injury to Allergan in Texas.

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

Factual Background

A. Patents-In-Suit

1. U.S. Patent No. 8,629,111

24. On January 14, 2014, the '111 Patent, titled "Methods of Providing Therapeutic Effects Using Cyclosporin Components," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") to inventors Andrew Acheampong, Diane D. Tang-Liu, James N. Chang, and David F. Power. A true and correct copy of the '111 Patent is attached to this complaint as Exhibit 2.

25. Allergan, as assignee, owns the entire right, title, and interest in the '111 Patent.

26. Allergan is the holder of approved New Drug Application ("NDA") No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the RESTASIS® trademark.

27. The '111 Patent is listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for RESTASIS®.

28. RESTASIS® and/or methods of using RESTASIS® are covered by at least one claim of the '111 Patent.

2. U.S. Patent No. 8,633,162

29. On January 21, 2014, the '162 Patent, titled "Methods of Providing Therapeutic Effects Using Cyclosporin Components," was duly and legally issued by the USPTO to inventors Andrew Acheampong, Diane D. Tang-Liu, James N. Chang, and David F. Power. A true and correct copy of the '162 Patent is attached to this complaint as Exhibit 3.

30. Allergan, as assignee, owns the entire right, title, and interest in the '162 Patent.

31. Allergan is the holder of approved New Drug Application ("NDA") No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the RESTASIS® trademark.

32. The '162 Patent is listed in the Orange Book for RESTASIS®.

33. RESTASIS® and/or methods of using RESTASIS® are covered by at least one claim of the '162 Patent.

3. U.S. Patent No. 8,642,556

34. On February 4, 2014, the '556 Patent, titled "Methods of Providing Therapeutic Effects Using Cyclosporin Components," was duly and legally issued by the USPTO to inventors Andrew Acheampong, Diane D. Tang-Liu, James N. Chang, and David F. Power. A true and correct copy of the '556 Patent is attached to this complaint as Exhibit 4.

35. Allergan, as assignee, owns the entire right, title, and interest in the '556 Patent.

36. Allergan is the holder of approved New Drug Application ("NDA") No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the RESTASIS® trademark.

37. The '556 Patent is listed in the Orange Book for RESTASIS®.

38. RESTASIS® and/or methods of using RESTASIS® are covered by at least one claim of the '556 Patent.

4. U.S. Patent No. 8,648,048

39. On February 11, 2014, the '048 Patent, titled "Methods of Providing Therapeutic Effects Using Cyclosporin Components," was duly and legally issued by the USPTO to inventors Andrew Acheampong, Diane D. Tang-Liu, James N. Chang, and David F. Power. A true and correct copy of the '048 Patent is attached to this complaint as Exhibit 5.

40. Allergan, as assignee, owns the entire right, title, and interest in the '048 Patent.

41. Allergan is the holder of approved New Drug Application ("NDA") No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the RESTASIS® trademark.

42. The '048 Patent is listed in the Orange Book for RESTASIS®.

43. RESTASIS® and/or methods of using RESTASIS® are covered by at least one claim of the '048 Patent.

5. U.S. Patent No. 8,685,930

44. On April 1, 2014, the '930 Patent, titled "Methods of Providing Therapeutic Effects Using Cyclosporin Components," was duly and legally issued by the USPTO to inventors Andrew Acheampong, Diane D. Tang-Liu, James N. Chang, and David F. Power. A true and correct copy of the '930 Patent is attached to this complaint as Exhibit 6.

45. Allergan, as assignee, owns the entire right, title, and interest in the '930 Patent.

46. Allergan is the holder of approved New Drug Application ("NDA") No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the RESTASIS® trademark.

47. The '930 Patent is listed in the Orange Book for RESTASIS®.

48. RESTASIS® and/or methods of using RESTASIS® are covered by at least one claim of the '930 Patent.

6. U.S. Patent No. 9,248,191

49. On February 2, 2016, the '191 Patent, titled "Methods of Providing Therapeutic Effects Using Cyclosporin Components," was duly and legally issued by the USPTO to inventors Andrew Acheampong, Diane D. Tang-Liu, James N. Chang, and David F. Power. A true and correct copy of the '191 Patent is attached to this complaint as Exhibit 7.

50. Allergan, as assignee, owns the entire right, title, and interest in the '191 Patent.

51. Allergan is the holder of approved New Drug Application ("NDA") No. 50-790 for Cyclosporine Ophthalmic Emulsion, 0.05%, sold under the RESTASIS® trademark.

52. The '191 Patent is listed in the Orange Book for RESTASIS®.

53. RESTASIS® and/or methods of using RESTASIS® are covered by at least one claim of the '191 Patent.

B. Acts Giving Rise to This Action

54. On information and belief, Famy Care submitted ANDA No. 208469 to the FDA under section 505(j) of the FDCA, seeking FDA approval to engage in the commercial manufacture, use, importation, sale, or offer for sale of Cyclosporine Ophthalmic Emulsion, 0.05%, a generic version of Allergan's RESTASIS® product.

55. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the FDCA, Famy Care included with its ANDA No. 208469 a Paragraph IV certification alleging that the claims of patents listed in the Orange Book as covering RESTASIS® are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Famy Care's Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469. Plaintiff received written notification of ANDA No. 208469 and its § 505(j)(2)(A)(vii)(IV) allegations with respect to the '111, '162, '556, '048, '930, and '191 patents on or about March 1, 2016.

56. On information and belief, the FDA has not yet approved Famy Care's ANDA No. 208469.

57. On information and belief, Famy Care 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 RESTASIS® product before expiration of the patents-in-suit.

58. On information and belief, Famy Care continues to seek approval of ANDA No. 208469 from the FDA and intends to continue in the commercial manufacture, marketing, and sale of its proposed generic version of Allergan's RESTASIS® product.

59. On information and belief, following FDA approval of its ANDA No. 208469, Famy Care will sell the approved generic version of Allergan's RESTASIS® product throughout the United States, including in Texas and this judicial district.

Count I
(Infringement of the '111 Patent Under 35 U.S.C. § 271(e)(2) by Famy Care's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

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

61. Famy Care submitted ANDA No. 208469 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 Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Famy Care has committed an act of infringement of the '111 Patent under 35 U.S.C. § 271(e)(2)(A).

62. The commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will constitute an act of direct infringement of the '111 Patent.

63. On information and belief, Famy Care became aware of the '111 Patent no later than the date on which that patent was listed in the Orange Book.

64. On information and belief, Famy Care knows or should know that the commercial offer for sale and sale of Famy Care's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469, will constitute an act of induced infringement and will contribute to actual infringement of the '111 Patent.

65. On information and belief, Famy Care knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will be especially made for or especially adapted for an infringement of the '111 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 Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will actively contribute to the actual infringement of the '111 Patent.

66. The commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count II
(Declaratory Judgment of Infringement of the '111 Patent
Under 35 U.S.C. § 271(a) by Famy Care)

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

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

69. 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.

70. The commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will constitute an act of direct infringement of one or more claims of the '111 Patent.

71. On information and belief, Famy Care will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 immediately and imminently upon approval of ANDA No. 208469.

72. The foregoing actions by Famy Care will constitute infringement of the '111 Patent.

73. Famy Care will commit those acts of infringement without license or authorization.

74. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 by Famy Care will infringe the '111 Patent.

75. Unless Famy Care is enjoined from infringing the '111 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

Count III

(Declaratory Judgment of Infringement of the '111 Patent Under 35 U.S.C. § 271(b) and (c) by Famy Care's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

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

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

78. 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.

79. Famy Care has actual knowledge of the '111 Patent.

80. On information and belief, Famy Care became aware of the '111 Patent no later than the date on which that patent was listed in the Orange Book.

81. On information and belief, Famy Care has acted with full knowledge of the '111 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '111 Patent.

82. The commercial manufacture, use, sale, offer for sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will induce the actual infringement of the '111 Patent.

83. On information and belief, Famy Care knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will actively induce the actual infringement of the '111 Patent.

84. On information and belief, Famy Care will encourage another's infringement of the '111 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469, which is covered by certain claims of the '111 Patent.

85. Famy Care's acts of infringement will be done with knowledge of the '111 Patent and with the intent to encourage infringement.

86. The foregoing actions by Famy Care will constitute active inducement of infringement of the '111 Patent.

87. On information and belief, Famy Care knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will be especially made or especially adapted for use in an infringement of the '111 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

88. The commercial manufacture, use, sale, offer for sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product will contribute to the actual infringement of the '111 Patent.

89. On information and belief, Famy Care knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will contribute to the actual infringement of the '111 Patent.

90. The foregoing actions by Famy Care will constitute contributory infringement of the '111 Patent.

91. On information and belief, Famy Care intends to, and will, actively induce and contribute to the infringement of the '111 Patent when ANDA No. 208469 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

92. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 by Famy Care will induce and/or contribute to the infringement of the '111 Patent.

93. The commercial manufacture, use, offer for sale, sale and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469, which will actively induce and/or contribute to infringement of the '111 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

94. Unless Famy Care is enjoined from actively inducing and contributing to the infringement of the '111 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

95. On information and belief, despite having actual notice of the '111 Patent, Famy Care continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '111 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 IV
(Infringement of the '162 Patent Under 35 U.S.C. § 271(e)(2) by Famy Care's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

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

97. Famy Care submitted ANDA No. 208469 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 Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Famy Care has committed an act of infringement of the '162 Patent under 35 U.S.C. § 271(e)(2)(A).

98. On information and belief, Famy Care became aware of the '162 Patent no later than the date on which that patent was listed in the Orange Book.

99. On information and belief, Famy Care knows or should know that the commercial offer for sale and sale of Famy Care's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469, will constitute an act of induced infringement and will contribute to actual infringement of the '162 Patent.

100. On information and belief, Famy Care knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will

be especially made for or especially adapted for an infringement of the '162 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 Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will actively contribute to the actual infringement of the '162 Patent.

101. The commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count V

(Declaratory Judgment of Infringement of the '162 Patent Under 35 U.S.C. § 271(b) and (c) by Famy Care's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

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

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 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.

105. Famy Care has actual knowledge of the '162 Patent.

106. On information and belief, Famy Care became aware of the '162 Patent no later than the date on which that patent was listed in the Orange Book.

107. On information and belief, Famy Care has acted with full knowledge of the '162 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '162 Patent.

108. The commercial manufacture, use, sale, offer for sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will induce the actual infringement of the '162 Patent.

109. On information and belief, Famy Care knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will actively induce the actual infringement of the '162 Patent.

110. On information and belief, Famy Care will encourage another's infringement of the '162 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469, which is covered by certain claims of the '162 Patent.

111. Famy Care's acts of infringement will be done with knowledge of the '162 Patent and with the intent to encourage infringement.

112. The foregoing actions by Famy Care will constitute active inducement of infringement of the '162 Patent.

113. On information and belief, Famy Care knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will be especially made or especially adapted for use in an infringement of the '162 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

114. The commercial manufacture, use, sale, offer for sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will contribute to the actual infringement of the '162 Patent.

115. On information and belief, Famy Care knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will contribute to the actual infringement of the '162 Patent.

116. The foregoing actions by Famy Care will constitute contributory infringement of the '162 Patent.

117. On information and belief, Famy Care intends to, and will, actively induce and contribute to the infringement of the '162 Patent when ANDA No. 208469 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

118. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 by Famy Care will induce and/or contribute to the infringement of the '162 Patent.

119. The commercial manufacture, use, offer for sale, sale and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469, which will actively induce and/or contribute to infringement of the '162 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

120. Unless Famy Care is enjoined from actively inducing and contributing to the infringement of the '162 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

121. On information and belief, despite having actual notice of the '162 Patent, Famy Care continues to willfully, wantonly, and deliberately prepare to actively induce and/or

contribute to infringement of the '162 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 VI
(Infringement of the '556 Patent Under 35 U.S.C. § 271(e)(2) by InnoPharma's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

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

123. Famy Care submitted ANDA No. 208469 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 Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Famy Care has committed an act of infringement of the '556 Patent under 35 U.S.C. § 271(e)(2)(A).

124. The commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will constitute an act of direct infringement of the '556 Patent.

125. On information and belief, Famy Care became aware of the '556 Patent no later than the date on which that patent was listed in the Orange Book.

126. On information and belief, Famy Care knows or should know that the commercial offer for sale and sale of Famy Care's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469, will constitute an act of induced infringement and will contribute to actual infringement of the '556 Patent.

127. On information and belief, Famy Care knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will be especially made for or especially adapted for an infringement of the '556 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 Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will actively contribute to the actual infringement of the '556 Patent.

128. The commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count VII
**(Declaratory Judgment of Infringement of the '556 Patent
Under 35 U.S.C. § 271(a) by Famy Care)**

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

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

131. 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.

132. The commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product will constitute an act of direct infringement of one or more claims of the '556 Patent.

133. On information and belief, Famy Care will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 immediately and imminently upon approval of ANDA No. 208469.

134. The foregoing actions by Famy Care will constitute infringement of the '556 Patent.

135. Famy Care will commit those acts of infringement without license or authorization.

136. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 by Famy Care will infringe the '556 Patent.

137. Unless Famy Care is enjoined from infringing the '556 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

Count VIII

(Declaratory Judgment of Infringement of the '556 Patent Under 35 U.S.C. § 271(b) and (c) by Famy Care's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

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

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

140. 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.

141. Famy Care has actual knowledge of the '556 Patent.

142. On information and belief, Famy Care became aware of the '556 Patent no later than the date on which that patent was listed in the Orange Book.

143. On information and belief, Famy Care has acted with full knowledge of the '556 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '556 Patent.

144. The commercial manufacture, use, sale, offer for sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product will induce the actual infringement of the '556 Patent.

145. On information and belief, Famy Care knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will actively induce the actual infringement of the '556 Patent.

146. On information and belief, Famy Care will encourage another's infringement of the '556 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469, which is covered by certain claims of the '556 Patent.

147. Famy Care's acts of infringement will be done with knowledge of the '556 Patent and with the intent to encourage infringement.

148. The foregoing actions by Famy Care will constitute active inducement of infringement of the '556 Patent.

149. On information and belief, Famy Care knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will be especially made or especially adapted for use in an infringement of the '556 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

150. The commercial manufacture, use, sale, offer for sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will contribute to the actual infringement of the '556 Patent.

151. On information and belief, Famy Care knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will contribute to the actual infringement of the '556 Patent.

152. The foregoing actions by Famy Care will constitute contributory infringement of the '556 Patent.

153. On information and belief, Famy Care intends to, and will, actively induce and contribute to the infringement of the '556 Patent when ANDA No. 208469 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

154. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 by Famy Care will induce and/or contribute to the infringement of the '556 Patent.

155. The commercial manufacture, use, offer for sale, sale and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469, which will actively induce and/or contribute to infringement of the '556 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

156. Unless Famy Care is enjoined from actively inducing and contributing to the infringement of the '556 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

157. On information and belief, despite having actual notice of the '556 Patent, Famy Care continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '556 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 IX
(Infringement of the '048 Patent Under 35 U.S.C. § 271(e)(2) by Famy Care's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

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

159. Famy Care submitted ANDA No. 208469 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 Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Famy Care has committed an act of infringement of the '048 Patent under 35 U.S.C. § 271(e)(2)(A).

160. On information and belief, Famy Care became aware of the '048 Patent no later than the date on which that patent was listed in the Orange Book.

161. On information and belief, Famy Care knows or should know that the commercial offer for sale and sale of Famy Care's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469, will constitute an act of induced infringement and will contribute to actual infringement of the '048 Patent.

162. On information and belief, Famy Care knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product will be especially made for or

especially adapted for an infringement of the '048 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 Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will actively contribute to the actual infringement of the '048 Patent.

163. The commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count X

(Declaratory Judgment of Infringement of the '048 Patent Under 35 U.S.C. § 271(b) and (c) by Famy Care's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

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

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

166. 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.

167. Famy Care has actual knowledge of the '048 Patent.

168. On information and belief, Famy Care became aware of the '048 Patent no later than the date on which that patent was listed in the Orange Book.

169. On information and belief, Famy Care has acted with full knowledge of the '048 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '048 Patent.

170. The commercial manufacture, use, sale, offer for sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will induce the actual infringement of the '048 Patent.

171. On information and belief, Famy Care knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will actively induce the actual infringement of the '048 Patent.

172. On information and belief, Famy Care will encourage another's infringement of the '048 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469, which is covered by certain claims of the '048 Patent.

173. Famy Care's acts of infringement will be done with knowledge of the '048 Patent and with the intent to encourage infringement.

174. The foregoing actions by Famy Care will constitute active inducement of infringement of the '048 Patent.

175. On information and belief, Famy Care knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will be especially made or especially adapted for use in an infringement of the '048 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

176. The commercial manufacture, use, sale, offer for sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will contribute to the actual infringement of the '048 Patent.

177. On information and belief, Famy Care knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will contribute to the actual infringement of the '048 Patent.

178. The foregoing actions by Famy Care will constitute contributory infringement of the '048 Patent.

179. On information and belief, Famy Care intends to, and will, actively induce and contribute to the infringement of the '048 Patent when ANDA No. 208469 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

180. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 by Famy Care will induce and/or contribute to the infringement of the '048 Patent.

181. The commercial manufacture, use, offer for sale, sale and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469, which will actively induce and/or contribute to infringement of the '048 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

182. Unless Famy Care is enjoined from actively inducing and contributing to the infringement of the '048 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

183. On information and belief, despite having actual notice of the '048 Patent, Famy Care continues to willfully, wantonly, and deliberately prepare to actively induce and/or

contribute to infringement of the '048 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 XI
(Infringement of the '930 Patent Under 35 U.S.C. § 271(e)(2) by Famy Care's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

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

185. Famy Care submitted ANDA No. 208469 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 Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Famy Care has committed an act of infringement of the '930 Patent under 35 U.S.C. § 271(e)(2)(A).

186. The commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will constitute an act of direct infringement of the '930 Patent.

187. On information and belief, Famy Care became aware of the '930 Patent no later than the date on which that patent was listed in the Orange Book.

188. On information and belief, Famy Care knows or should know that the commercial offer for sale and sale of Famy Care's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469, will constitute an act of induced infringement and will contribute to actual infringement of the '930 Patent.

189. On information and belief, Famy Care knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will be especially made for or especially adapted for an infringement of the '930 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 Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will actively contribute to the actual infringement of the '930 Patent.

190. The commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count XII
**(Declaratory Judgment of Infringement of the '930 Patent
Under 35 U.S.C. § 271(a) by Famy Care)**

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

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

193. 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.

194. The commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will constitute an act of direct infringement of one or more claims of the '930 Patent.

195. On information and belief, Famy Care will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 immediately and imminently upon approval of ANDA No. 208469.

196. The foregoing actions by Famy Care will constitute infringement of the '930 Patent.

197. Famy Care will commit those acts of infringement without license or authorization.

198. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 by Famy Care will infringe the '930 Patent.

199. Unless Famy Care is enjoined from infringing the '930 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

Count XIII

(Declaratory Judgment of Infringement of the '930 Patent Under 35 U.S.C. § 271(b) and (c) by Famy Care's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

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

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

202. 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.

203. Famy Care has actual knowledge of the '930 Patent.

204. On information and belief, Famy Care became aware of the '930 Patent no later than the date on which that patent was listed in the Orange Book.

205. On information and belief, Famy Care has acted with full knowledge of the '930 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '930 Patent.

206. The commercial manufacture, use, sale, offer for sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will induce the actual infringement of the '930 Patent.

207. On information and belief, Famy Care knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will actively induce the actual infringement of the '930 Patent.

208. On information and belief, Famy Care will encourage another's infringement of the '930 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469, which is covered by certain claims of the '930 Patent.

209. Famy Care's acts of infringement will be done with knowledge of the '930 Patent and with the intent to encourage infringement.

210. The foregoing actions by Famy Care will constitute active inducement of infringement of the '930 Patent.

211. On information and belief, Famy Care knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will be especially made or especially adapted for use in an infringement of the '930 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

212. The commercial manufacture, use, sale, offer for sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will contribute to the actual infringement of the '930 Patent.

213. On information and belief, Famy Care knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will contribute to the actual infringement of the '930 Patent.

214. The foregoing actions by Famy Care will constitute contributory infringement of the '930 Patent.

215. On information and belief, Famy Care intends to, and will, actively induce and contribute to the infringement of the '930 Patent when ANDA No. 208469 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

216. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 by Famy Care will induce and/or contribute to the infringement of the '930 Patent.

217. The commercial manufacture, use, offer for sale, sale and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469, which will actively induce and/or contribute to infringement of the '930 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

218. Unless Famy Care is enjoined from actively inducing and contributing to the infringement of the '930 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

219. On information and belief, despite having actual notice of the '930 Patent, Famy Care continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '930 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 XIV
(Infringement of the '191 Patent Under 35 U.S.C. § 271(e)(2) by Famy Care's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

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

221. Famy Care submitted ANDA No. 208469 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 Cyclosporine Ophthalmic Emulsion, 0.05% product throughout the United States. By submitting this application, Famy Care has committed an act of infringement of the '191 Patent under 35 U.S.C. § 271(e)(2)(A).

222. On information and belief, Famy Care became aware of the '191 Patent no later than the date on which that patent was listed in the Orange Book.

223. On information and belief, Famy Care knows or should know that the commercial offer for sale and sale of Famy Care's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469, will constitute an act of induced infringement and will contribute to actual infringement of the '191 Patent.

224. On information and belief, Famy Care knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will

be especially made for or especially adapted for an infringement of the '191 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 Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will actively contribute to the actual infringement of the '191 Patent.

225. The commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

Count LIV

(Declaratory Judgment of Infringement of the '191 Patent Under 35 U.S.C. § 271(b) and (c) by Famy Care's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

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

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

228. 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.

229. Famy Care has actual knowledge of the '191 Patent.

230. On information and belief, Famy Care became aware of the '191 Patent no later than the date on which that patent was listed in the Orange Book.

231. On information and belief, Famy Care has acted with full knowledge of the '191 Patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '191 Patent.

232. The commercial manufacture, use, sale, offer for sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will induce the actual infringement of the '191 Patent.

233. On information and belief, Famy Care knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will actively induce the actual infringement of the '191 Patent.

234. On information and belief, Famy Care will encourage another's infringement of the '191 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469, which is covered by certain claims of the '191 Patent.

235. Famy Care's acts of infringement will be done with knowledge of the '191 Patent and with the intent to encourage infringement.

236. The foregoing actions by Famy Care will constitute active inducement of infringement of the '191 Patent.

237. On information and belief, Famy Care knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will be especially made or especially adapted for use in an infringement of the '191 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

238. The commercial manufacture, use, sale, offer for sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will contribute to the actual infringement of the '191 Patent.

239. On information and belief, Famy Care knows or should know that its offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 will contribute to the actual infringement of the '191 Patent.

240. The foregoing actions by Famy Care will constitute contributory infringement of the '191 Patent.

241. On information and belief, Famy Care intends to, and will, actively induce and contribute to the infringement of the '191 Patent when ANDA No. 208469 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

242. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469 by Famy Care will induce and/or contribute to the infringement of the '191 Patent.

243. The commercial manufacture, use, offer for sale, sale and/or importation of Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469, which will actively induce and/or contribute to infringement of the '191 Patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

244. Unless Famy Care is enjoined from actively inducing and contributing to the infringement of the '191 Patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

245. On information and belief, despite having actual notice of the '191 Patent, Famy Care continues to willfully, wantonly, and deliberately prepare to actively induce and/or

contribute to infringement of the '191 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

Allergan respectfully prays for the following relief:

1. A finding that the '111, '162, '556, '048, '930, and '191 Patents are valid and enforceable;
2. That a judgment be entered that Famy Care has infringed the '111, '162, '556, '048, '930, and '191 Patents under 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA under Section 505(j) of the FDCA;
3. That a declaration be issued under 28 U.S.C. § 2201 that if Famy Care, 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 Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469, it will constitute an act of infringement of the '111, '556, and '930 Patents under 35 U.S.C. § 271(a), (b), and (c);
4. That a declaration be issued under 28 U.S.C. § 2201 that if Famy Care, 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

Famy Care's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 208469, it will constitute an act of infringement of the '162, '048, and '191 Patents under 35 U.S.C. § 271(b) and (c);

5. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Famy Care's ANDA shall be a date which is not earlier than the latest expiration date of the '111, '162, '556, '048, '930, and '191 Patents, including any extensions or periods of exclusivity;

6. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Famy Care, 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 '111, '162, '556, '048, '930, and '191 Patents;

7. If Famy Care attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Famy Care's generic product disclosed in its ANDA prior to the expiration of the '111, '162, '556, '048, '930, and '191 Patents, including any extensions or periods of exclusivity, a preliminary injunction be entered enjoining such conduct;

8. If Famy Care attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of Famy Care's generic product disclosed in its ANDA prior to the expiration of the '111, '162, '556, '048, '930, and '191 Patents, including any extensions or periods 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;

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

10. A finding that this action for infringement is an exceptional case under 35 U.S.C. § 285, and that Allergan be awarded reasonable attorneys' fees and costs; and

11. An award of any such other and further relief as the Court may deem just and proper.

Dated: April 12, 2016

Respectfully submitted,

FISH & RICHARDSON P.C.

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