

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

**ALLERGAN, INC.,**

**Plaintiff,**

**v.**

**TWI PHARMACEUTICALS, INC. and TWI  
PHARMACEUTICALS USA, INC.,**

**Defendants.**

**Civil Action No. \_\_\_\_\_**

**JURY TRIAL DEMANDED**

**ALLERGAN, INC.'S COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Allergan, Inc. (“Allergan” or “Plaintiff”), for its Complaint against Defendants TWi Pharmaceuticals, Inc. (“TWi-Taiwan”) and TWi Pharmaceuticals USA, Inc. (“TWi-USA”) (collectively, “TWi”), 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. On information and belief, Defendant TWi-Taiwan is a corporation organized and existing under the laws of Taiwan, having a principal place of business at 3F., No. 41, Lane 221, Gangqian Road, Neihu District, Tai Pei 114, Taiwan.

5. On information and belief, Defendant TWi-USA is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 115 West Century Road, Suite 180, Paramus, New Jersey 07652. On information and belief, TWi-USA is a wholly-owned subsidiary of TWi-Taiwan. On information and belief, TWi-USA acts at the direction, under the control, and for the benefit of TWi-Taiwan.

**Venue and Jurisdiction**

6. 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.

7. This Court has personal jurisdiction over TWi-USA and TWi-Taiwan by virtue of their systematic and continuous contact with this jurisdiction, as alleged herein.

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

9. On information and belief, TWi-Taiwan submitted ANDA No. 209064 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.

10. On information and belief, TWi is in the business of researching, developing, seeking regulatory approval for, commercializing, producing, and manufacturing generic drug products.

11. On information and belief, TWi-USA is incorporated in Delaware and has therefore availed itself of the rights, benefits, and privileges of Delaware's laws.

12. On information and belief, TWi-USA has a registered agent in the State of Delaware, located at 4550 New Linden Hill Road, Suite 201, Wilmington, Delaware 19808.

13. On information and belief, TWi-USA is actively registered with the Delaware Secretary of State to conduct business in Delaware.

14. On information and belief, TWi-Taiwan and TWi-USA are agents of each other and/or work in concert with each other to develop, seek regulatory approval for, commercialize, produce, manufacture, market, export, import, distribute, transfer, offer to sell, and sell drug products in the United States, including in the State of Delaware.

15. On information and belief, based on its systematic contact with Delaware, TWi knows and intends that its proposed Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 209064 will be distributed and sold in Delaware.

16. On information and belief, TWi knows and intends that sales of its proposed Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 209064 will displace sales of Allergan's RESTASIS® product causing injury to Allergan in Delaware.

17. 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**

18. 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 1.

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

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

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

22. 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**

23. 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 2.

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

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

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

27. 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**

28. 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 3.

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

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

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

32. 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**

33. 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 4.

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

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

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

37. 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**

38. 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 5.

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

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

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

42. 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**

43. 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 6.

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

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

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

47. 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**

48. On information and belief, TWi submitted ANDA No. 209064 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.

49. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the FDCA, TWi included with its ANDA No. 209064 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 TWi's Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064. Plaintiff received written notification of ANDA No. 209064 and its § 505(j)(2)(A)(vii)(IV) allegations with respect to the '111, '162, '556, '048, '930, and '191 patents on or about June 10, 2016.

50. On information and belief, the FDA has not yet approved TWi's ANDA No. 209064.

51. On information and belief, TWi 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.

52. On information and belief, TWi continues to seek approval of ANDA No. 209064 from the FDA and intends to continue in the commercial manufacture, marketing, and sale of its proposed generic version of Allergan's RESTASIS® product.

53. On information and belief, following FDA approval of its ANDA No. 209064, TWi will sell the approved generic version of Allergan's RESTASIS® product throughout the United States, including in Delaware.

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

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

55. TWi submitted ANDA No. 209064 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, TWi has committed an act of infringement of the '111 Patent under 35 U.S.C. § 271(e)(2)(A).

56. The commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 will constitute an act of direct infringement of the '111 Patent.

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

58. On information and belief, TWi knows or should know that the commercial offer for sale and sale of TWi's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064, will constitute an act of induced infringement and will contribute to actual infringement of the '111 Patent.

59. On information and belief, TWi knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 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. 209064 will actively contribute to the actual infringement of the '111 Patent.

60. The commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 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 TWi)**

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

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

63. 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.

64. The commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 will constitute an act of direct infringement of one or more claims of the '111 Patent.

65. On information and belief, TWi will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 immediately and imminently upon approval of ANDA No. 209064.

66. The foregoing actions by TWi will constitute infringement of the '111 Patent.

67. TWi will commit those acts of infringement without license or authorization.

68. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 by TWi will infringe the '111 Patent.

69. Unless TWi 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 TWi's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)**

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

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

72. 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.

73. TWi has actual knowledge of the '111 Patent.

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

75. On information and belief, TWi 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.

76. The commercial manufacture, use, sale, offer for sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 will induce the actual infringement of the '111 Patent.

77. On information and belief, TWi 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. 209064 will actively induce the actual infringement of the '111 Patent.

78. On information and belief, TWi 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. 209064, which is covered by certain claims of the '111 Patent.

79. TWi's acts of infringement will be done with knowledge of the '111 Patent and with the intent to encourage infringement.

80. The foregoing actions by TWi will constitute active inducement of infringement of the '111 Patent.

81. On information and belief, TWi knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 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.

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

83. On information and belief, TWi 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. 209064 will contribute to the actual infringement of the '111 Patent.

84. The foregoing actions by TWi will constitute contributory infringement of the '111 Patent.

85. On information and belief, TWi intends to, and will, actively induce and contribute to the infringement of the '111 Patent when ANDA No. 209064 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

86. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 by TWi will induce and/or contribute to the infringement of the '111 Patent.

87. The commercial manufacture, use, offer for sale, sale and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064, 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.

88. Unless TWi 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.

89. On information and belief, despite having actual notice of the '111 Patent, TWi 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 TWi's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)**

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

91. TWi submitted ANDA No. 209064 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, TWi has committed an act of infringement of the '162 Patent under 35 U.S.C. § 271(e)(2)(A).

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

93. On information and belief, TWi knows or should know that the commercial offer for sale and sale of TWi's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064, will constitute an act of induced infringement and will contribute to actual infringement of the '162 Patent.

94. On information and belief, TWi knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 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. 209064 will actively contribute to the actual infringement of the '162 Patent.

95. The commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 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 TWi's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)**

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

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

98. 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.

99. TWi has actual knowledge of the '162 Patent.

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

101. On information and belief, TWi 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.

102. The commercial manufacture, use, sale, offer for sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 will induce the actual infringement of the '162 Patent.

103. On information and belief, TWi 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. 209064 will actively induce the actual infringement of the '162 Patent.

104. On information and belief, TWi 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. 209064, which is covered by certain claims of the '162 Patent.

105. TWi's acts of infringement will be done with knowledge of the '162 Patent and with the intent to encourage infringement.

106. The foregoing actions by TWi will constitute active inducement of infringement of the '162 Patent.

107. On information and belief, TWi knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 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.

108. The commercial manufacture, use, sale, offer for sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 will contribute to the actual infringement of the '162 Patent.

109. On information and belief, TWi 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. 209064 will contribute to the actual infringement of the '162 Patent.

110. The foregoing actions by TWi will constitute contributory infringement of the '162 Patent.

111. On information and belief, TWi intends to, and will, actively induce and contribute to the infringement of the '162 Patent when ANDA No. 209064 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

112. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 by TWi will induce and/or contribute to the infringement of the '162 Patent.

113. The commercial manufacture, use, offer for sale, sale and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064, 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.

114. Unless TWi 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.

115. On information and belief, despite having actual notice of the '162 Patent, TWi 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 Twi's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)**

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



117. TWi submitted ANDA No. 209064 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, TWi has committed an act of infringement of the '556 Patent under 35 U.S.C. § 271(e)(2)(A).

118. The commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 will constitute an act of direct infringement of the '556 Patent.

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

120. On information and belief, TWi knows or should know that the commercial offer for sale and sale of TWi's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064, will constitute an act of induced infringement and will contribute to actual infringement of the '556 Patent.

121. On information and belief, TWi knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 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. 209064 will actively contribute to the actual infringement of the '556 Patent.

122. The commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA

No. 209064 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 TWi)**

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

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

125. 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.

126. The commercial manufacture, use, offer for sale, sale, and/or importation of TWi'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.

127. On information and belief, TWi will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 immediately and imminently upon approval of ANDA No. 209064.

128. The foregoing actions by TWi will constitute infringement of the '556 Patent.

129. TWi will commit those acts of infringement without license or authorization.

130. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 by TWi will infringe the '556 Patent.

131. Unless TWi 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 TWi's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)**

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

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

134. 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.

135. TWi has actual knowledge of the '556 Patent.

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

137. On information and belief, TWi 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.

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

139. On information and belief, TWi 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. 209064 will actively induce the actual infringement of the '556 Patent.

140. On information and belief, TWi 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. 209064, which is covered by certain claims of the '556 Patent.

141. TWi's acts of infringement will be done with knowledge of the '556 Patent and with the intent to encourage infringement.

142. The foregoing actions by TWi will constitute active inducement of infringement of the '556 Patent.

143. On information and belief, TWi knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 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.

144. The commercial manufacture, use, sale, offer for sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 will contribute to the actual infringement of the '556 Patent.

145. On information and belief, TWi 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. 209064 will contribute to the actual infringement of the '556 Patent.

146. The foregoing actions by TWi will constitute contributory infringement of the '556 Patent.

147. On information and belief, TWi intends to, and will, actively induce and contribute to the infringement of the '556 Patent when ANDA No. 209064 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

148. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 by TWi will induce and/or contribute to the infringement of the '556 Patent.

149. The commercial manufacture, use, offer for sale, sale and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064, 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.

150. Unless TWi 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.

151. On information and belief, despite having actual notice of the '556 Patent, TWi 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 TWi's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)**

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

153. TWi submitted ANDA No. 209064 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, TWi has committed an act of infringement of the '048 Patent under 35 U.S.C. § 271(e)(2)(A).

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

155. On information and belief, TWi knows or should know that the commercial offer for sale and sale of TWi's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064, will constitute an act of induced infringement and will contribute to actual infringement of the '048 Patent.

156. On information and belief, TWi 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. 209064 will actively contribute to the actual infringement of the '048 Patent.

157. The commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 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 TWi's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)**

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

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

160. 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.

161. TWi has actual knowledge of the '048 Patent.

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

163. On information and belief, TWi 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.

164. The commercial manufacture, use, sale, offer for sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 will induce the actual infringement of the '048 Patent.

165. On information and belief, TWi 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. 209064 will actively induce the actual infringement of the '048 Patent.

166. On information and belief, TWi 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. 209064, which is covered by certain claims of the '048 Patent.

167. TWi's acts of infringement will be done with knowledge of the '048 Patent and with the intent to encourage infringement.

168. The foregoing actions by TWi will constitute active inducement of infringement of the '048 Patent.

169. On information and belief, TWi knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 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.

170. The commercial manufacture, use, sale, offer for sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 will contribute to the actual infringement of the '048 Patent.

171. On information and belief, TWi 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. 209064 will contribute to the actual infringement of the '048 Patent.

172. The foregoing actions by TWi will constitute contributory infringement of the '048 Patent.

173. On information and belief, TWi intends to, and will, actively induce and contribute to the infringement of the '048 Patent when ANDA No. 209064 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

174. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 by TWi will induce and/or contribute to the infringement of the '048 Patent.



175. The commercial manufacture, use, offer for sale, sale and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064, 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.

176. Unless TWi 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.

177. On information and belief, despite having actual notice of the '048 Patent, TWi 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 TWi's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)**

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

179. TWi submitted ANDA No. 209064 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, TWi has committed an act of infringement of the '930 Patent under 35 U.S.C. § 271(e)(2)(A).

180. The commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 will constitute an act of direct infringement of the '930 Patent.

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

182. On information and belief, TWi knows or should know that the commercial offer for sale and sale of TWi's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064, will constitute an act of induced infringement and will contribute to actual infringement of the '930 Patent.

183. On information and belief, TWi knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 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. 209064 will actively contribute to the actual infringement of the '930 Patent.

184. The commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 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 TWi)**

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

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

187. 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.

188. The commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 will constitute an act of direct infringement of one or more claims of the '930 Patent.

189. On information and belief, TWi will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 immediately and imminently upon approval of ANDA No. 209064.

190. The foregoing actions by TWi will constitute infringement of the '930 Patent.

191. TWi will commit those acts of infringement without license or authorization.

192. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 by TWi will infringe the '930 Patent.

193. Unless TWi 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 TWi's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)**

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

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

196. 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.

197. TWi has actual knowledge of the '930 Patent.

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

199. On information and belief, TWi 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.

200. The commercial manufacture, use, sale, offer for sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 will induce the actual infringement of the '930 Patent.

201. On information and belief, TWi 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. 209064 will actively induce the actual infringement of the '930 Patent.

202. On information and belief, TWi 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. 209064, which is covered by certain claims of the '930 Patent.

203. TWi's acts of infringement will be done with knowledge of the '930 Patent and with the intent to encourage infringement.

204. The foregoing actions by TWi will constitute active inducement of infringement of the '930 Patent.

205. On information and belief, TWi knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 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.

206. The commercial manufacture, use, sale, offer for sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 will contribute to the actual infringement of the '930 Patent.

207. On information and belief, TWi 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. 209064 will contribute to the actual infringement of the '930 Patent.

208. The foregoing actions by TWi will constitute contributory infringement of the '930 Patent.

209. On information and belief, TWi intends to, and will, actively induce and contribute to the infringement of the '930 Patent when ANDA No. 209064 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

210. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 by TWi will induce and/or contribute to the infringement of the '930 Patent.

211. The commercial manufacture, use, offer for sale, sale and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No.

209064, 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.

212. Unless TWi 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.

213. On information and belief, despite having actual notice of the '930 Patent, TWi 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 TWi's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)**

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

215. TWi submitted ANDA No. 209064 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, TWi has committed an act of infringement of the '191 Patent under 35 U.S.C. § 271(e)(2)(A).

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

217. On information and belief, TWi knows or should know that the commercial offer for sale and sale of TWi's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product

described in ANDA No. 209064, will constitute an act of induced infringement and will contribute to actual infringement of the '191 Patent.

218. On information and belief, TWi knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 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. 209064 will actively contribute to the actual infringement of the '191 Patent.

219. The commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

**Count XV**

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

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

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

222. 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.

223. TWi has actual knowledge of the '191 Patent.

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

225. On information and belief, TWi 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.

226. The commercial manufacture, use, sale, offer for sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 will induce the actual infringement of the '191 Patent.

227. On information and belief, TWi 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. 209064 will actively induce the actual infringement of the '191 Patent.

228. On information and belief, TWi 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. 209064, which is covered by certain claims of the '191 Patent.

229. TWi's acts of infringement will be done with knowledge of the '191 Patent and with the intent to encourage infringement.

230. The foregoing actions by TWi will constitute active inducement of infringement of the '191 Patent.

231. On information and belief, TWi knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 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.

232. The commercial manufacture, use, sale, offer for sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 will contribute to the actual infringement of the '191 Patent.

233. On information and belief, TWi 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. 209064 will contribute to the actual infringement of the '191 Patent.

234. The foregoing actions by TWi will constitute contributory infringement of the '191 Patent.

235. On information and belief, TWi intends to, and will, actively induce and contribute to the infringement of the '191 Patent when ANDA No. 209064 is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

236. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064 by TWi will induce and/or contribute to the infringement of the '191 Patent.

237. The commercial manufacture, use, offer for sale, sale and/or importation of TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064, 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.

238. Unless TWi 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.

239. On information and belief, despite having actual notice of the '191 Patent, TWi 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 TWi 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 TWi, 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 TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No.

209064, 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 TWi, 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 TWi's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 209064, 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 TWi'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 TWi, 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 TWi attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of TWi'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 TWi attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of TWi'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: July 20, 2016

Respectfully submitted,

FISH & RICHARDSON P.C.

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