IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC. and SAINT REGIS MOHAWK TRIBE, Plaintiffs, v. SAPTALIS PHARMACEUTICALS, LLC, Defendant.	Civil Action No. _____ JURY TRIAL DEMANDED

PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Allergan, Inc. ("Allergan") and Saint Regis Mohawk Tribe ("the Tribe" and, collectively, "Plaintiffs") for their Complaint against Defendant Saptalis Pharmaceuticals, LLC ("Saptalis"), by their attorneys, allege as follows:

The Nature of the Action

1. This is an action for infringement of United States Patent Nos. 8,633,162 ("the '162 Patent") and 8,642,556 ("the '556 Patent") (collectively, "the Patents-in-Suit") 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 '556 Patent under 35 U.S.C. § 271 (a), (b), and (c), and for a declaratory judgment of infringement of the '162 Patent 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 principal place of business at 5 Giralda Farms, Madison, New Jersey 07940.

Allergan is a global, research-driven pharmaceutical company that discovers, develops, manufactures, and markets a broad range of innovative products to improve human health, including RESTASIS® (Cyclosporine Ophthalmic Emulsion, 0.05%).

4. The Tribe is a federally recognized, sovereign American Indian Tribe located in upstate New York.

5. On information and belief, Defendant Saptalis is a corporation organized and existing under the laws of Delaware, having a principal place of business at 45 Davids Drive, Hauppauge, NY 11788.

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. On information and belief, Saptalis submitted ANDA No. 211943 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.

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

9. On information and belief, Saptalis knows and intends that its proposed Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 211943 will be distributed and sold nationwide, including in this District.

10. On information and belief, Saptalis knows and intends that sales of its proposed Cyclosporine Ophthalmic Emulsion, 0.05% described in ANDA No. 211943 will displace sales of Allergan's RESTASIS® product causing injury to Plaintiffs nationwide and in this District.

11. This Court has personal jurisdiction over Saptalis because Saptalis is incorporated in the State of Delaware and is, thus, a resident of the State. Even if Saptalis was not a resident of the State of Delaware, this Court would have personal jurisdiction over Saptalis under Federal Rule of Civil Procedure 4(k)(1)(A) and 10 Del. C. § 3104 because Saptalis has submitted ANDA No. 211943 with the intention of marketing and selling its generic version in the United States, including in this District. *See Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755 (Fed. Cir. 2016). Upon information and belief, Saptalis is amenable to litigating in this forum based on Saptalis's conduct in another litigation in this District. In Civil Action No. 18-648 (MPT) (D.I. 9, D.I. 20), Saptalis withdrew or waived its objections, and/or right to object, to personal jurisdiction in this District.

12. Venue is proper in this Court under 28 U.S.C. § 1400(b). Saptalis is incorporated in Delaware, and thus it resides in this District. *TC Heartland LLC v. Kraft Foods Group Brands LLC*, 137 S. Ct. 1514 (2017); *In re Cray*, 871 F.3d 1355 (Fed. Cir. 2017). Plaintiffs note that while prior cases regarding the Patents-in-Suit have been brought against other generic manufacturers in the Eastern District of Texas, based on currently-available information, venue does not appear to lie in that jurisdiction over Saptalis. Upon information and belief, Saptalis is amenable to litigating in this forum based on Saptalis's conduct in another litigation in this District. In Civil Action No. 18-648 (MPT) (D.I. 9, D.I. 20), Saptalis withdrew or waived its objections, and/or right to object, to venue in this District.

Factual Background

A. Patents-In-Suit

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

13. 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 1.

14. The Tribe, as assignee, owns the entire right, title, and interest in the ’162 Patent.

15. Allergan holds an exclusive field-of-use license to the ’162 Patent with respect to commercializing RESTASIS®.

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

17. The ’162 Patent is listed in the Orange Book for RESTASIS®.

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

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

19. 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 2.

20. The Tribe, as assignee, owns the entire right, title, and interest in the ’556 Patent.

21. Allergan holds an exclusive field-of-use license to the ’556 Patent with respect to commercializing RESTASIS®.

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

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

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

B. Prior Litigation regarding patents related to the Patents-in-Suit

25. Allergan, Inc.[1] previously asserted in the Eastern District of Texas (the "Texas Actions") the two Patents-in-Suit along with four additional patents that cover RESTASIS®—U.S. Patent Nos. 8,629,111 ("the '111 Patent"), 8,648,048 ("the '048 Patent"), 8,685,930 ("the '930 Patent"), and 9,248,191 ("the '191 Patent). The Texas Actions stemmed from seven separate generic defendants' ("Texas Defendants") submissions of Abbreviated New Drug Applications (ANDAs) 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%, the defendants' generic copies of Allergan's RESTASIS® product. *See Allergan, Inc. v. Teva Pharm. et al.*, C.A. No. 2:15-cv-1455-WCB, Dkt. 522 (E.D. Tex. Oct. 17, 2017).

26. In the Texas Actions, Allergan narrowed its set of asserted claims against the Texas Defendants to certain claims from the '111, '048, '930, and '191 patents. Allergan elected not to take any claims of the Patents-in-Suit in this case to trial against the Texas Defendants.

27. The District Court for the Eastern District of Texas found that the filing of the Texas Defendants' ANDAs constituted contributory infringement and induced infringement of

[1] Allergan, Inc. assigned the Patents-in-Suit to the Tribe in September 2017. The Tribe was added as a co-plaintiff to the Texas Actions in October 2017.

the asserted claims of the ’111, ’048, ’930, and ’191 patents. The District Court further found that the asserted claims of the ’111, ’048, ’930, and ’191 patents were not invalid as anticipated, and that those claims met the requirements of 35 U.S.C. § 112, but also found that the asserted claims of the ’111, ’048, ’930, and ’191 patents were invalid as obvious. *See Allergan, Inc. v. Teva Pharm. et al.*, C.A. No. 2:15-cv-1455-WCB, Dkt. 522 (E.D. Tex. Oct. 17, 2017).

28. Plaintiffs appealed the district court’s judgment, and that appeal is pending before the Federal Circuit. *See Allergan, Inc. v. Teva Pharm. et al.*, No. 2018-1130, Dkt. 42 (Fed. Cir. Jan. 9, 2018). Plaintiffs have not brought suit on the ’111, ’048, ’930, and ’191 patents here, but reserve the right to amend or request that those patents be added to the case depending on the outcome of the appeal of the district court’s judgment to the Federal Circuit.

C. Acts Giving Rise to This Action

29. On information and belief, Saptalis submitted ANDA No. 211943 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.

30. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the FDCA, Saptalis included with its ANDA No. 211943 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 Saptalis’s Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 211943. Plaintiffs received written notification of ANDA No. 211943 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 27, 2018.

31. On information and belief, the FDA has not yet approved Saptalis's ANDA No. 211943.

32. On information and belief, Saptalis 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.

33. On information and belief, Saptalis continues to seek approval of ANDA No. 211943 from the FDA and intends to continue in the commercial manufacture, marketing, and sale of its proposed generic version of Allergan's RESTASIS® product.

34. On information and belief, following FDA approval of its ANDA No. 211943, Saptalis will sell the approved generic version of Allergan's RESTASIS® product throughout the United States, including this judicial district.

Count I
(Infringement of the '162 Patent Under 35 U.S.C. § 271(e)(2) by Saptalis's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

35. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

36. Saptalis submitted ANDA No. 211943 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, Saptalis has committed an act of infringement of the '162 Patent under 35 U.S.C. § 271(e)(2)(A).

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

38. On information and belief, Saptalis knows or should know that the commercial offer for sale and sale of its proposed Cyclosporine Ophthalmic Emulsion, 0.05% product

described in ANDA No. 211943, will constitute an act of induced infringement and will contribute to actual infringement of the ’162 Patent.

39. On information and belief, Saptalis knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 211943 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. 211943 will actively contribute to the actual infringement of the ’162 Patent.

40. The commercial manufacture, use, offer for sale, sale, and/or importation of Saptalis’s proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 211943 in violation of Plaintiffs’ patent rights will cause harm to Plaintiffs for which damages are inadequate.

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

41. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein

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

43. There is an actual case or controversy such that the Court may entertain Plaintiffs’ 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.

44. Saptalis has actual knowledge of the ’162 Patent.

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

46. On information and belief, Saptalis 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.

47. The commercial manufacture, use, sale, offer for sale, and/or importation of Saptalis’s proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 211943 will induce the actual infringement of the ’162 Patent.

48. On information and belief, Saptalis 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. 211943 will actively induce the actual infringement of the ’162 Patent.

49. On information and belief, Saptalis 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. 211943, which is covered by certain claims of the ’162 Patent.

50. Saptalis’s acts of infringement will be done with knowledge of the ’162 Patent and with the intent to encourage infringement.

51. The foregoing actions by Saptalis will constitute active inducement of infringement of the ’162 Patent.

52. On information and belief, Saptalis knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 211943 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.

53. The commercial manufacture, use, sale, offer for sale, and/or importation of Saptalis’s proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 211943 will contribute to the actual infringement of the ’162 Patent.

54. On information and belief, Saptalis 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. 211943 will contribute to the actual infringement of the ’162 Patent.

55. The foregoing actions by Saptalis will constitute contributory infringement of the ’162 Patent.

56. On information and belief, Saptalis intends to, and will, actively induce and contribute to the infringement of the ’162 Patent when ANDA No. 211943 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

57. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Saptalis’s proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 211943 by Saptalis will induce and/or contribute to the infringement of the ’162 Patent.

58. The commercial manufacture, use, offer for sale, sale and/or importation of Saptalis’s proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 211943, which will actively induce and/or contribute to infringement of the ’162 Patent, in violation of Plaintiffs’ patent rights, will cause harm to Plaintiffs for which damages are inadequate.

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

60. On information and belief, despite having actual notice of the '162 Patent, Saptalis continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '162 Patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

Count III
(Infringement of the '556 Patent Under 35 U.S.C. § 271(e)(2) by Saptalis's Proposed Generic Cyclosporine Ophthalmic Emulsion, 0.05%)

61. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

62. Saptalis submitted ANDA No. 211943 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, Saptalis has committed an act of infringement of the '556 Patent under 35 U.S.C. § 271(e)(2)(A).

63. The commercial manufacture, use, offer for sale, sale, and/or importation of Saptalis's proposed Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 211943 will constitute an act of direct infringement of the '556 Patent.

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

65. On information and belief, Saptalis knows or should know that the commercial offer for sale and sale of its proposed Cyclosporine Ophthalmic Emulsion, 0.05% product

described in ANDA No. 211943, will constitute an act of induced infringement and will contribute to actual infringement of the ’556 Patent.

66. On information and belief, Saptalis knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 211943 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. 211943 will actively contribute to the actual infringement of the ’556 Patent.

67. The commercial manufacture, use, offer for sale, sale, and/or importation of Saptalis’s proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 211943 in violation of Plaintiffs’ patent rights will cause harm to Plaintiffs for which damages are inadequate.

Count IV
(Declaratory Judgment of Infringement of the ’556 Patent Under 35 U.S.C. § 271(a) by Saptalis)

68. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

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

70. There is an actual case or controversy such that the Court may entertain Plaintiffs’ 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.

71. The commercial manufacture, use, offer for sale, sale, and/or importation of Saptalis'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.

72. On information and belief, Saptalis will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 211943 immediately and imminently upon approval of ANDA No. 211943.

73. The foregoing actions by Saptalis will constitute infringement of the '556 Patent.

74. Saptalis will commit those acts of infringement without license or authorization.

75. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Saptalis's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 211943 by Saptalis will infringe the '556 Patent.

76. Unless Saptalis is enjoined from infringing the '556 Patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

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

77. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

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

79. There is an actual case or controversy such that the Court may entertain Plaintiffs' 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.

80. Saptalis has actual knowledge of the ’556 Patent.

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

82. On information and belief, Saptalis 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.

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

84. On information and belief, Saptalis 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. 211943 will actively induce the actual infringement of the ’556 Patent.

85. On information and belief, Saptalis 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. 211943, which is covered by certain claims of the ’556 Patent.

86. Saptalis’s acts of infringement will be done with knowledge of the ’556 Patent and with the intent to encourage infringement.

87. The foregoing actions by Saptalis will constitute active inducement of infringement of the ’556 Patent.

88. On information and belief, Saptalis knows or should know that its proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 211943 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.

89. The commercial manufacture, use, sale, offer for sale, and/or importation of Saptalis’s proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 211943 will contribute to the actual infringement of the ’556 Patent.

90. On information and belief, Saptalis 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. 211943 will contribute to the actual infringement of the ’556 Patent.

91. The foregoing actions by Saptalis will constitute contributory infringement of the ’556 Patent.

92. On information and belief, Saptalis intends to, and will, actively induce and contribute to the infringement of the ’556 Patent when ANDA No. 211943 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

93. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Saptalis’s proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 211943 by Saptalis will induce and/or contribute to the infringement of the ’556 Patent.

94. The commercial manufacture, use, offer for sale, sale and/or importation of Saptalis’s proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 211943, which will actively induce and/or contribute to infringement of the ’556 Patent, in violation of Plaintiffs’ patent rights, will cause harm to Plaintiffs for which damages are inadequate.

95. Unless Saptalis is enjoined from actively inducing and contributing to the infringement of the ’556 Patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

96. On information and belief, despite having actual notice of the ’556 Patent, Saptalis continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the ’556 Patent in disregard of Plaintiffs’ rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

Jury Trial Demand

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

Prayer for Relief

Plaintiffs respectfully pray for the following relief:

1. A finding that the ’162 and ’556 Patents are valid and enforceable;

2. That a judgment be entered that Saptalis has infringed the ’162 and ’556 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 Saptalis, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf engage in the commercial manufacture, use, offer for sale, sale and/or importation of Saptalis’s proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 211943, it will constitute an act of infringement of the ’556 Patent under 35 U.S.C. § 271(a), (b), and (c);

4. That a declaration be issued under 28 U.S.C. § 2201 that if Saptalis, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons

acting or attempting to act in active concert or participation with it or acting on its behalf engage in the commercial manufacture, use, offer for sale, sale and/or importation of Saptalis's proposed generic Cyclosporine Ophthalmic Emulsion, 0.05% product described in ANDA No. 211943, it will constitute an act of infringement of the '162 Patent 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 Saptalis's ANDA shall be a date which is not earlier than the latest expiration date of the '162 and '556 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 Saptalis, 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 '162 and '556 Patents;

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

8. If Saptalis attempts to engage in the commercial manufacture, use, offer to sell, sale, or importation of its generic product disclosed in its ANDA prior to the expiration of the '162 and '556 Patents, including any extensions or periods of exclusivity, judgment awarding Plaintiffs 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 Plaintiffs 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.

FISH & RICHARDSON P.C.

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