

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Acheampong, *et al.*

Examiner: TBA

Serial No.: TBA

Group Art Unit: TBA

Filed: Herewith

Confirmation No. TBA

For: METHODS OF PROVIDING
THERAPEUTIC EFFECTS USING
CYCLOSPORIN COMPONENTS

Customer No.: 51957

PRELIMINARY AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Prior to examining the above-referenced application, please amend the specification as described on page 2 of this paper, and please amend the claims as described on pages 3-6 of this paper. Remarks follow on page 7.

Amendments to the Specification

Please replace page 1, lines 5-10 of the specification filed herewith with the following amended paragraph:

This application is a continuation of copending U.S. Application Serial No. 11/897,177, filed August 28, 2007, which is a continuation of U.S. Application Serial No. 10/927,857, filed August 27, 2004, now abandoned, which claimed the benefit of U.S. Provisional Application No. 60/503,137 filed September 15, 2003, which ~~is~~ are incorporated in ~~its~~ their entirety herein by reference.

Please replace page 4, line 25 – page 5, line 3 of the specification filed herewith with the following amended paragraph:

The present methods are useful in treating any suitable condition which is therapeutically sensitive to or treatable with cyclosporin components. Such conditions preferably are ophthalmic or ocular conditions, that is relating to or having to do with one or more parts of an eye of a human or animal. Included among such conditions are, without limitation, dry eye syndrome, phacoanaphylactic endophthalmitis, uveitis, vernal conjunctivitis, atopic keratoconjunctivitis, corneal graft rejection and the like conditions. The present invention is particularly effective in treating dry eye syndrome. Cyclosporin has been found as effective in treating immune medicated keratoconjunctivitis sicca (KCS or dry eye disease) in a patient suffering therefrom. The activity of cyclosporins is as an immunosuppressant and in the enhancement or restoring of lacrimal gland tearing. Other conditions that can be treated with cyclosporin components include an absolute or partial deficiency in aqueous tear production (keratoconjunctivitis sicca, or KCS). Topical administration to a patient's tear deficient eye can increase tear production in the eye. The treatment can further serve to correct corneal and conjunctival disorders exacerbated by tear deficiency and KCS, such as corneal scarring, corneal ulceration, inflammation of the cornea or conjunctiva, filamentary keratitis, mucopurulent discharge and vascularization of the cornea.

Amendments to the claims

The following list of claims will replace all previous versions of claims presented in this application:

1. – 36. (Canceled)

37. (New) A topical ophthalmic emulsion for treating an eye of a human having KCS, wherein the topical ophthalmic emulsion comprises cyclosporin A in an amount of about 0.05% by weight, polysorbate 80, Pemulen, water, and castor oil in an amount of about 1.25% by weight; and

wherein the topical ophthalmic emulsion is therapeutically effective in treating KCS.

38. (New) The topical ophthalmic emulsion of Claim 37, wherein the topical ophthalmic emulsion further comprises a tonicity agent or a demulcent component.

39. (New) The topical ophthalmic emulsion of Claim 38, wherein the tonicity agent or the demulcent component is glycerine.

40. (New) The topical ophthalmic emulsion of Claim 37, wherein the topical ophthalmic emulsion further comprises a buffer.

41. (New) The topical ophthalmic emulsion of Claim 40, wherein the buffer is sodium hydroxide.

42. (New) The topical ophthalmic emulsion of Claim 37, wherein the topical ophthalmic emulsion further comprises glycerine and a buffer.

43. (New) The topical ophthalmic emulsion of Claim 37, wherein the topical ophthalmic emulsion comprises polysorbate 80 in an amount of about 1.0% by weight.

44. (New) The topical ophthalmic emulsion of Claim 37, wherein the topical ophthalmic emulsion comprises Pemulen in an amount of about 0.05% by weight.
45. (New) The topical ophthalmic emulsion of Claim 37, wherein the topical ophthalmic emulsion further comprises glycerine in an amount of about 2.2% by weight, water, and a buffer.
46. (New) The topical ophthalmic emulsion of Claim 45, wherein the buffer is sodium hydroxide.
47. (New) The topical ophthalmic emulsion of Claim 37, wherein, when the topical ophthalmic emulsion is administered to an eye of a human in an effective amount in treating KCS, the blood of the human has substantially no detectable concentration of cyclosporin A.
48. (New) The topical ophthalmic emulsion of Claim 42, wherein the topical ophthalmic emulsion has a pH in the range of about 7.2 to about 7.6.
49. (New) The topical ophthalmic emulsion of Claim 37, wherein the topical ophthalmic emulsion is as substantially therapeutically effective as an emulsion comprising cyclosporin A in an amount of 0.1% by weight and castor oil in an amount of 1.25% by weight.
50. (New) The topical ophthalmic emulsion of Claim 37, wherein the topical ophthalmic emulsion achieves at least as much therapeutic effectiveness as an emulsion comprising cyclosporin A in an amount of 0.1% by weight and castor oil in an amount of 1.25% by weight.
51. (New) The topical ophthalmic emulsion of Claim 37, wherein the topical ophthalmic emulsion breaks down more quickly in the eye of a human, once administered to the eye of the human, thereby reducing vision distortion in the eye of the human as compared to an emulsion that contains only 50% as much castor oil.
52. (New) The topical ophthalmic emulsion of Claim 37, wherein the topical ophthalmic emulsion, when administered to the eye of a human, demonstrates a reduction in adverse events

in the human, relative to an emulsion comprising cyclosporin A in an amount of 0.1% by weight and castor oil in an amount of 1.25% by weight.

53. (New) The topical ophthalmic emulsion of Claim 52, wherein the adverse events include side effects.

54. (New) A topical ophthalmic emulsion for treating an eye of a human, wherein the topical ophthalmic emulsion increases tear production in the eye of a human, and wherein the topical ophthalmic emulsion comprises:

- cyclosporin A in an amount of about 0.05% by weight;
- castor oil in an amount of about 1.25% by weight;
- polysorbate 80 in an amount of about 1.0% by weight;
- Pemulen in an amount of about 0.05% by weight;
- a tonicity component or a demulcent component in an amount of about 2.2% by weight;
- a buffer; and
- water.

55. (New) The topical ophthalmic emulsion of Claim 54, wherein the buffer is sodium hydroxide.

56. (New) The topical ophthalmic emulsion of Claim 54, wherein the tonicity component or the demulcent component is glycerine.

57. (New) The topical ophthalmic emulsion of Claim 54, wherein, when the topical ophthalmic emulsion is administered to an eye of a human in an effective amount to increase tear production, the blood of the human has substantially no detectable concentration of the cyclosporin A.

58. (New) The topical ophthalmic emulsion of Claim 54, wherein the topical ophthalmic emulsion has a pH in the range of about 7.2 to about 7.6.

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