## 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.



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## 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. 13/961,818 filed August 7, 2013, which 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.



### 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 method of treating dry eye disease, the method comprising topically administering to the eye of the human an emulsion at a frequency of twice a day, wherein the 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 effective in treating dry eye disease.

- 38. (New) The method of Claim 37, wherein the emulsion further comprises a tonicity agent or a demulcent component.
- 39. (New) The method of Claim 38, wherein the tonicity agent or the demulcent component is glycerine.
- 40. (New) The method of Claim 37, wherein the emulsion further comprises a buffer.
- 41. (New) The method of Claim 40, wherein the buffer is sodium hydroxide.
- 42. (New) The method of Claim 37, wherein the topical ophthalmic emulsion further comprises glycerine and a buffer.
- 43. (New) The method of Claim 37, wherein the emulsion comprises polysorbate 80 in an amount of about 1.0% by weight.
- 44. (New) The method of Claim 37, wherein the emulsion comprises Pemulen in an amount of about 0.05% by weight.



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45. (New) The method of Claim 37, wherein the emulsion further comprises glycerine in an amount of about 2.2% by weight and a buffer.

- 46. (New) The method of Claim 45, wherein the buffer is sodium hydroxide.
- 47. (New) The method of Claim 37, wherein, when the emulsion is administered to an eye of a human in an effective amount in treating dry eye syndrome, the blood of the human has substantially no detectable concentration of cyclosporin A.
- 48. (New) The method of Claim 42, wherein the emulsion has a pH in the range of about 7.2 to about 7.6.
- 49. (New) The method of Claim 37, wherein the 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 method of Claim 37, wherein the 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 method of Claim 37, wherein the 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 method of Claim 37, wherein the 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 method of Claim 52, wherein the adverse events include side effects.



54. (New) A method of reducing side effects in a human suffering from dry eye syndrome, the method comprising the step of topically administering to the eye of the human an emulsion at a frequency of twice a day, wherein the 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 method of Claim 54, wherein the buffer is sodium hydroxide.
- 56. (New) The method of Claim 54, wherein the tonicity component or the demulcent component is glycerine.
- 57. (New) The method of Claim 54, wherein, when the emulsion is administered to the eye of a human in an effective amount in treating dry eye syndrome, the blood of the human has substantially no detectable concentration of the cyclosporin A.
- 58. (New) The method of Claim 54, wherein the emulsion has a pH in the range of about 7.2 to about 7.6.
- 59. (New) The method of Claim 54, wherein the emulsion is effective in treating dry eye disease.
- 60. (New) A method of treating dry eye disease, the method comprising the step of topically administering to an eye of a human an emulsion, the emulsion comprising:

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;



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