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.

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

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.

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

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.

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

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.

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

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;

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.