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*December 11, 2020*

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OF:

APPLICATION NUMBER: 15/208,537

FILING DATE: *July 12, 2016*

PATENT NUMBER: 9770447

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Certified by

*Andrew Laven*

Under Secretary of Commerce  
for Intellectual Property  
and Director of the United States  
Patent and Trademark Office

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application:

Inventor: Gregory I. Ostrow et al.

Application No.: 15/208,537

Filed: July 12, 2016

Title: **OPHTHALMIC COMPOSITION**

Confirmation No.: 1009

Examiner: To Be Assigned

Group Art Unit: To Be Assigned

M/S Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**PRELIMINARY AMENDMENT AND**  
**RESPONSE TO NOTICE TO FILE MISSING PARTS DATED JULY 28, 2016**

Commissioner:

This paper responds to the Notice to File Missing Parts dated July 28, 2016, setting forth an initial due date of September 28, 2016. Accordingly, this response is timely submitted. Entry of the following Preliminary Amendment is respectfully requested.

**Amendments to the Claims** begin on page 2 of this paper.

**Remarks** begin on page 5 of this paper.

### **AMENDMENTS TO THE CLAIMS**

The following listing of claims replaces all prior listings of claims in this application.

#### **CLAIM LISTING:**

- 1-30. (Cancelled).
31. (New) An ophthalmic composition, consisting essentially of from about 0.001 wt% to about 0.03 wt% of a muscarinic antagonist and deuterated water, at a pD of from about 4.2 to about 7.9, wherein the muscarinic antagonist is atropine, or atropine sulfate.
32. (New) The ophthalmic composition of claim 31, wherein the ophthalmic composition has a pD of one of: less than about 7.3, less than about 7.2, less than about 7.1, less than about 7, less than about 6.8, less than about 6.5, less than about 6.4, less than about 6.3, less than about 6.2, less than about 6.1, less than about 6, less than about 5.9, less than about 5.8, less than about 5.2, or less than about 4.8 after extended period of time under storage condition.
33. (New) The ophthalmic composition of claim 31, wherein the muscarinic antagonist is present in the composition at a concentration of one of: from about 0.001 wt% to about 0.025 wt%, from about 0.001 wt% to about 0.02 wt%, from about 0.001 wt% to about 0.01 wt%, from about 0.001 wt% to about 0.008 wt%, or from about 0.001 wt% to about 0.005 wt%.
34. (New) The ophthalmic composition of claim 31, wherein the ophthalmic composition further comprises an osmolarity adjusting agent.
35. (New) The ophthalmic composition of claim 34, wherein the osmolarity adjusting agent is sodium chloride.
36. (New) The ophthalmic composition of claim 31, wherein the ophthalmic composition further comprises a preservative.

37. (New) The ophthalmic composition of claim 36, wherein the preservative is selected from benzalkonium chloride, cetrimonium, sodium perborate, stabilized oxychloro complex, SofZia, polyquaternium-1, chlorobutanol, edetate disodium, polyhexamethylene biguanide, or combinations thereof.
38. (New) The ophthalmic composition of claim 31, wherein the ophthalmic composition further comprises a buffer agent.
39. (New) The ophthalmic composition of claim 38, wherein the buffer agent is selected from borates, borate-polyol complexes, phosphate buffering agents, citrate buffering agents, acetate buffering agents, carbonate buffering agents, organic buffering agents, amino acid buffering agents, or combinations thereof.
40. (New) The ophthalmic composition of claim 31, wherein the ophthalmic composition is essentially free of procaine and benactyzine, or pharmaceutically acceptable salts thereof.
41. (New) The ophthalmic composition of claim 31, wherein the ophthalmic composition further comprises a pD adjusting agent.
42. (New) The ophthalmic composition of claim 41, wherein the pD adjusting agent comprises deuterated hydrochloric acid, deuterated sodium hydroxide, deuterated acetic acid, or deuterated citric acid.
43. (New) The ophthalmic composition of claim 31, wherein the ophthalmic composition comprises one of: less than 5% of H<sub>2</sub>O, less than 4% of H<sub>2</sub>O, less than 3% of H<sub>2</sub>O, less than 2% of H<sub>2</sub>O, less than 1% of H<sub>2</sub>O, less than 0.5% of H<sub>2</sub>O, less than 0.1% of H<sub>2</sub>O, or 0% of H<sub>2</sub>O.
44. (New) The ophthalmic composition of claim 31, wherein the ophthalmic composition is not formulated as an injectable formulation.

45. (New) An ophthalmic solution, consisting essentially of from about 0.001 wt% to about 0.03 wt% of a muscarinic antagonist and deuterated water, at a pD of from about 4.2 to about 7.9, wherein the muscarinic antagonist is atropine, or atropine sulfate.
46. (New) The ophthalmic solution of claim 45, wherein the ophthalmic solution has a pD of one of: less than about 7.3, less than about 7.2, less than about 7.1, less than about 7, less than about 6.8, less than about 6.5, less than about 6.4, less than about 6.3, less than about 6.2, less than about 6.1, less than about 6, less than about 5.9, less than about 5.8, less than about 5.2, or less than about 4.8 after extended period of time under storage condition.
47. (New) The ophthalmic solution of claim 45, wherein the ophthalmic solution comprises one of: less than 5% of H<sub>2</sub>O, less than 4% of H<sub>2</sub>O, less than 3% of H<sub>2</sub>O, less than 2% of H<sub>2</sub>O, less than 1% of H<sub>2</sub>O, less than 0.5% of H<sub>2</sub>O, less than 0.1% of H<sub>2</sub>O, or 0% of H<sub>2</sub>O.
48. (New) A method of arresting myopia progression, comprising administering to an eye of an individual in need thereof an effective amount of an ophthalmic composition consisting essentially of from about 0.001 wt% to about 0.03 wt% of a muscarinic antagonist and deuterated water, at a pD of from about 4.2 to about 7.9, wherein the muscarinic antagonist is atropine, or atropine sulfate.
49. (New) The method of claim 48, wherein the ophthalmic composition is stored at between about 2 °C to about 10 °C prior to first use.
50. (New) The method of claim 48, wherein the ophthalmic composition is stored at between about 16 °C to about 26 °C after first use.

### **REMARKS**

This response is filed to preliminarily amend the claims. Examination on their merits is respectfully requested.

### **Claims**

Claims 1-30 are cancelled. Claims 31-50 are submitted herein. Support for the amendment to the claims can be found in the originally filed application. No new matter has been added.

### **Fees**

As amended, the application has not more than three independent claims, and no more than 20 claims in total. As such, no additional claim fee is due. Other missing fees are submitted herewith.

### **Allowance of Parent Application 14/726,139**

Applicant notes that the parent application (US14/726,139) has been examined by the USPTO with issuance of Notice of Allowance on June 13, 2016. As stated in the Notice of Allowance (the paragraph bridging pages 2-3):

The following is an examiner's statement of reasons for allowance: the amendments set forth in the examiner's amendment and the data presented to the advantages of the combination of atropine and deuterated water in comparison to the combination of atropine and water has placed the application in condition for allowance.

The amended claims presented herein are prepared in light of the Examiner's Reasons for Allowance above. Favorable consideration and allowance of the pending claims are respectfully

requested. Should the Examiner have any questions, Applicant encourages the Examiner to contact the undersigned attorney at 858-350-2339.

### **FEE AUTHORIZATION**

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. **23-2415**, referencing Attorney Docket No. 46682-701.301.

Respectfully submitted,

Date: August 3, 2016

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