IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 06-796)

In the Application of:	)	
	)	
Fanara et al.	)	
	)	Examiner: Timothy P. Thomas
Serial No. 10/599,451	)	
	)	Art Unit: 1614
Filing Date: September 28, 2006	)	
	)	Confirmation No.: 9142
For: Pharmaceutical Composition of Piperazine Derivatives	)	

RESPONSE TO THE OFFICE ACTION MAILED SEPTEMBER 25, 2008

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

Dear Sir:

Please consider the following amendments and remarks in response to the Office communication mailed September 25, 2008. No fees are believed to be due, but the Office is nevertheless authorized to charge any fees necessary to maintain the pendency of this application to Deposit Account, No. 13-2490.

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 will replace all prior versions and listings of claims in the application.

Listing of Claims:

1. (Currently Amended) A liquid pharmaceutical composition comprising (i) ~~cetirizine,~~ levocetirizine~~, efletirizine,~~ or a pharmaceutically acceptable salt of ~~cetirizine~~, levocetirizine~~, or efletirizine~~, and (ii) at least one preservative, wherein the preservative is ~~(a) a parahydroxybenzoate ester that is present in an amount of more than 0 and less than 1.5 mg/ml of the composition, or (b) a preservative other than a parahydroxybenzoate ester that is present in an amount having the same bactericidal effect on the composition as a parahydroxybenzoate ester of concentration of more than 0 and less than 1.5 mg/ml.~~ a mixture of methyl parahydroxybenzoate and propyl parahydroxybenzoate in a ratio of 9/1 expressed in weight, said mixture being present in an amount of more than 0 and less than 1.5 mg/ml of the composition.

2. (Previously presented) The liquid pharmaceutical composition according to claim 1, wherein the composition is aqueous.

3. (Canceled)

4. (Canceled)

5. (Currently amended) The liquid pharmaceutical composition according to claim [[4]] 1, wherein the amount of p-hydroxybenzoate esters is in the range of 0.0001 and [[1.4]] 1.5 mg/ml of the composition.

6. (Withdrawn) The liquid pharmaceutical composition according to claim 1, wherein the pharmaceutical composition contains an amount of thimerosal in the range of 0.0001 and 0.05 mg/ml of the composition.

7. (Withdrawn) The liquid pharmaceutical composition according to claim 1, wherein the pharmaceutical composition contains an amount of chlorhexidine acetate in the range of 0.0001 and 0.05 mg/ml of the composition.

8. (Withdrawn) The liquid pharmaceutical composition according to claim 1, wherein the pharmaceutical composition contains an amount of benzylalcohol in the range of 0.0001 and 10 mg/ml of the composition.

9. (Withdrawn) The liquid pharmaceutical composition according to claim 1, wherein the pharmaceutical composition contains an amount of benzalkonium chloride in the range of 0.0001 and 0.05 mg/ml of the composition.

10. (Withdrawn) The liquid pharmaceutical composition according to claim 1, wherein the active substance is cetirizine.

11. (Canceled)

12. (Previously presented) The liquid pharmaceutical composition according to claim 1, wherein the composition is in the form of oral solutions, nasal drops, eye drops or ear drops.

13. (Canceled)

14. (Previously Presented) The liquid pharmaceutical composition according to claim 13, wherein the pharmaceutically acceptable salt of levocetirizine is a hydrochloride salt.

15. (Previously Presented) The liquid pharmaceutical composition according to claim 14, wherein the hydrochloride salt of levocetirizine is present in amount of 0.5 mg/ml and the mixture of methyl p-hydroxybenzoate and propyl p-hydroxybenzoate is present in amount of 0.75 mg/ml.

16. (Canceled)

17. (Previously presented) The liquid pharmaceutical composition according to claim 1, which composition comprises levocetirizine or a pharmaceutically acceptable salt that is at least 95% by weight of the levorotatory enantiomer of cetirizine.

18. (Withdrawn) A method of making a liquid pharmaceutical composition according to claim 1 comprising combining,

a) cetirizine, levocetirizine, efletirizine, or a pharmaceutically acceptable salt of cetirizine, levocetirizine, or efletirizine, and

b) parahydroxybenzoate ester in an amount of more than 0 and less than 1.5 mg/ml of the composition.

19. (Withdrawn) The method according to claim 18, comprising mixing levocetirizine or a pharmaceutically acceptable salt thereof with a mixture of methyl p-hydroxybenzoate and propyl p-hydroxybenzoate.

20. (Withdrawn) The method according to claim 19, comprising mixing a pharmaceutically acceptable salt of levocetirizine with a mixture of methyl p-hydroxybenzoate and propyl p-hydroxybenzoate, wherein the methyl p-hydroxybenzoate and propyl p-hydroxybenzoate are present in a ratio of 9:1.

21. (Withdrawn) The method according to claim 20, wherein the pharmaceutically acceptable salt of levocetirizine is a hydrochloride salt.

22. (Withdrawn) In a method of treating a patient with cetirizine, levocetirizine, efletirizine, or a pharmaceutically acceptable salt of cetirizine, levocetirizine, or efletirizine, the improvement comprising administering a liquid composition according to claim 1.

23. (Withdrawn) The method according to claim 23, wherein the liquid composition comprises levocetirizine or a pharmaceutically acceptable salt thereof and a mixture of methyl p-hydroxybenzoate and propyl p-hydroxybenzoate.

24. (Withdrawn) The method according to claim 23, wherein the pharmaceutically acceptable salt of levocetirizine is a hydrochloride salt.

25. (Withdrawn) The method according to claim 24, wherein the hydrochloride salt of levocetirizine is present in amount of 0.5 mg/ml and the mixture of methyl p-hydroxybenzoate and propyl p-hydroxybenzoate is present in amount of 0.75 mg/ml.

26. (Withdrawn) The method according to claim 25, wherein the methyl p-hydroxybenzoate and propyl p-hydroxybenzoate are present in a ratio of 9:1 by weight.

REMARKS

Claims 1-26 are pending in this case. Claims 18-26 are withdrawn as directed to the non-elected Group II and Group III inventions. Claims 6-10 are withdrawn as directed to non-elected species.

The limitations of claims 4 and 11 have been incorporated into claim 1, and claims 4 and 11 have been canceled accordingly. Claims 3, 13, and 16 have been canceled as redundant in view of the amendment to claim 1. Claim 5 has been amended to depend from claim 1, and to correct a typographical error. Support for this amendment is found in the specification as originally filed at page 4, line 25-28. The claims remaining under consideration are 1, 2, 5, 12, 14, 15, and 17. In the prior response, it was stated that the elected species was covered by claims 1-5 and 11. As the elected species is also covered by claims 12, 14, 15, and 17, it is requested that those claims also be considered at this time.

Oath/Declaration

The examiner's objection to the Declaration submitted in this application is respectfully not understood. The Declaration has two alterations on the second page, one to inventor Claire Poulain's citizenship and the other to her address. In both cases, the inventor's dated signature appears immediately adjacent to the alterations. Thus, the date "28 June 07" and her signature "C Poulain" appear three times on that page: once in the space for the Inventor's signature, once next to the corrected citizenship, and once next to the corrected address. Applicants respectfully request the Examiner to explain what else, if anything, is required.

Claim rejection -- 35 USC 112

The claims were rejected as indefinite with respect to the use of "or" in two separate instances in claim 1. This language has been deleted from amended claim 1, thereby overcoming this ground of rejection.

Claim rejection -- 35 USC 103

The present invention is generally directed to a liquid pharmaceutical composition comprising an active ingredient and a preservative. Pursuant to the amendments herein, the

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