IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Atty. Docket 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 FINAL OFFICE ACTION MAILED FEBRUARY 25, 2009

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

Dear Sir:

Please consider the following amendments and remarks in response to the final Office Action mailed February 25, 2009. 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.

CERTIFICATE OF TRANSMISSION (37 C.F.R. 1.8)
I hereby certify that this correspondence is being transmitted to the USPTO via the USPTO EFS on April 24, 2009.

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) levocetirizine or a pharmaceutically acceptable salt of levocetirizine, and (ii) at least one preservative, wherein the preservative is 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~~1 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 1, wherein the amount of the p-hydroxybenzoate esters is in the range of 0.0001 and ~~1.5~~1 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 (Withdrawn) The liquid pharmaceutical composition according to claim 1, wherein the pharmaceutical composition contains an amount of thimerosal in the range of 0.0001 and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 (Withdrawn) The liquid pharmaceutical composition according to claim 1, wherein the pharmaceutical composition contains an amount of chlorhexidine acetate in the range of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 (Withdrawn) The liquid pharmaceutical composition according to claim 1, wherein the pharmaceutical composition contains an amount of benzylalcohol in the range of 0.0001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-currently amended) 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~~ 1 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, claim objection, and rejection of claims 1-2, 5, 12, and 17 under 35 USC § 112, second paragraph

Claims 1 and 5 were amended to recited an upper limit on the amount of p-hydroxybenzoate esters of 1 mg/ml. Support for these amendments is found on p. 4, ll. 25-30, of the application.

The claims were objected to and rejected as indefinite for the recitation of "p-hydroxybenzoate esters" in claim 5, the Office alleging that the recitation of this term in dependent claim 5 was seen as broadening the scope of the claim beyond that of independent claim 1 from which claim 5 depends. While the applicants respectfully traverse, in order to clarify claim 5 and expedite prosecution, claim 5 has been amended by inserting the definite article "the" before the recitation of "p-hydroxybenzoate esters." This amendment clarifies that the "p-hydroxybenzoate esters" referred to in claim 5 are the methyl parahydroxybenzoate and propyl parahydroxybenzoate recited in claim 1. It is respectfully submitted that this amendment merely clarifies claim 5 and does not narrow its scope.

In view of the foregoing, the applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection of claims 1-2, five, 12, and 17 under 35 USC 103

Claims 1-2, 5, 12, and 17 were rejected as obvious over DeLongueville et al. (WO 02/47689 A2) and Doron et al. The Office relied on DeLongueville for its teaching of cetirizine or an optical isomer (levocetirizine being identified as an optical isomer of cetirizine), liquid pharmaceutical compositions containing them, and a syrup containing cetirizine and methyl- and propylparaben. The Office notes that DeLongueville does not specifically teach an embodiment comprising levocetirizine and a mixture of methyl- and propylparaben nor the total amount of parabens or their ratios. The office relies on Doron for its teachings of the antibacterial effects of methylparaben (MP) and propylparaben (PP) with concentration ratios of [MP]:[PP] up to 8.33:1 and the synergistic antibacterial effects of combinations of parabens. For the following reasons, the applicants respectfully traverse.

The presently amended claims recite liquid levocetirizine compositions comprising [MP]:[PP] = 9:1 with a total urban concentration of [MP] + [PP] < 1 mg/ml. The lowest total

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.