RESPONSE UNDER 37 CFR § 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP 1611

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	:	Attorney Docket No. 2004_1016A
Masayo HIGASHIYAMA	:	**Confirmation No. 2612**
Serial No. 10/500,354	:	Group Art Unit 1611
Filed June 30, 2004	:	Examiner Barbara S. Frazier
AQUEOUS LIQUID PREPARATIONS AND LIGHT-STABILIZED AQUEOUS LIQUID PREPARATIONS	:	**Mail Stop: AF**

AMENDMENT AFTER FINAL REJECTION

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

Sir:

In response to the Office Action of November 30, 2011, the time for responding thereto being extended for two months in accordance with payment of an extension of time fee submitted herewith, please amend the above-identified application as follows:

AMENDMENTS TO THE CLAIMS

1. (Currently amended) An aqueous liquid preparation consisting essentially of, in an aqueous solution, an active ingredient consisting of (+)-(S)-4-[4-[(4-chlorophenyl)(2-pyridyl)methoxy]piperidino] butyric acid or a pharmacologically acceptable acid addition salt thereof, and a water-soluble metal chloride in a light-stabilizing effective amount ~~of 0.2 w/v% or more~~, wherein the metal chloride has a concentration selected from the range of a lower limit concentration of 0.2 w/v% and an upper limit concentration of 1.2 w/v%.

2. (Cancelled)

3. (Previously presented) The aqueous liquid preparation of claim 1, wherein the metal chloride is at least one kind selected from sodium chloride, potassium chloride and calcium chloride.

4. (Cancelled)

5. (Previously presented) The aqueous liquid preparation of claim 1, which is an acid addition salt of (+)-(S)-4-[4-[(4-chlorophenyl)(2-pyridyl)methoxy]piperidino]butyric acid.

6. (Original) The aqueous liquid preparation of claim 5, wherein the acid addition salt is monobenzenesulfonate.

7. (Previously presented) The aqueous liquid preparation of claim 1, wherein the aqueous liquid preparation has a pH in the range of 4-8.5.

8. (Previously presented) The aqueous liquid preparation of claim 1, which is an eye drop.

9. (Previously presented) The aqueous liquid preparation of claim 1, which is a nasal drop.

10. (Previously presented) An aqueous eye drop comprising, in an aqueous solution, (+)-(S)-4-[4-[(4-chlorophenyl)(2-pyridyl)methoxy]piperidino]butyric acid monobenzenesulfonate, as the only active ingredient, and sodium chloride at not less than 0.2 w/v% and not more than 0.8 w/v% in a light-stabilizing effective amount.

11. (Cancelled)

12. (Previously presented) The aqueous liquid preparation of claim 1, wherein the metal chloride is at least one kind selected from alkali metal chlorides and alkaline earth metal chlorides.

13. (Currently amended) An aqueous eye drop consisting essentially of an active ingredient consisting of (+)-(S)-4-[4-[(4-chlorophenyl)(2-pyridyl)methoxy]piperidino]butyric acid or a pharmacologically acceptable acid addition salt thereof, which is light-stabilized with a water-soluble metal chloride ~~at not less than 0.2 w/v%~~, wherein the metal chloride has a concentration selected from the range of a lower limit concentration of 0.2 w/v% and an upper limit concentration of 1.2 w/v%.

REMARKS

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Entry of the amendments is proper under 37 CFR §1.116, because the amendments place the application in condition for allowance and do not raise any new issue requiring further search and/or consideration. The amendments are necessary and were not earlier presented, because they are made in response to arguments raised in the final rejection. Entry of the amendments is thus respectfully requested.

Claims 1 and 13 have been amended to recite "wherein the metal chloride has a concentration selected from the range of a lower limit concentration of 0.2 w/v% and an upper limit concentration of 1.2 w/v%". Support for these amendments can be found on page 5, lines 17-21 of the specification. As a result, claims 2 and 4 have been cancelled.

I. Telephonic Interview

Applicant appreciates the courtesies extended to Applicant's attorney by Examiner Frazier during the telephonic interview held April 6, 2012.

During the interview, Applicant's attorney proposed to amend claims 1 and 13 to limit the concentration of the water-soluble metal chloride to 0.2-1.2 w/v%. The Examiner stated that these amendments would overcome the rejection in view of Experimental Example 1 of the specification (comparing Formulation 2 to Formulations 3-6 in Table 1), because this is a critical range that provides unexpected light-stabilizing effects on (+)-(S)-4-[4-[(4-chlorophenyl)(2-pyridyl)methoxy]piperidino] butyric acid (hereinafter, "bepotastine") or a salt thereof over the art.

The Examiner also agreed to enter an Amendment After Final Rejection with these claim amendments. However, she will need to update her prior art search, and did not agree to allow the claims during the interview.

In addition, Applicant's attorney presented a reference stating that Carbopol is degraded by light. The Examiner agreed that a person of ordinary skill in the art would have expected Carbopol to impair the claimed invention, because Carbopol is degraded by light. As a result, Applicant's attorney maintained the position that using an ion sensitive, hydrophilic polymer, such as Carbopol, in the aqueous liquid preparation of claim 1 and the eye drop of claim 13

would materially affect the basic and novel characteristics of the claimed compositions. Applicant's attorney also pointed out that each example of Lehmussaari et al. (US 5,795,913) includes Carbopol.

In addition, Applicant's attorney stated that (1) Applicant should only be required to demonstrate unexpected results over Kita et al. (US 6,307,052), rather than a combination of Kita et al. and Lehmussaari et al., in view of MPEP 716.02(e)III; (2) adding a water-soluble metal chloride provides unexpected light-stabilization properties to a composition containing bepotastine based upon Experimental Example 4 of the specification; (3) the compounds disclosed in Lehmussaari et al. do not share any structural similarity and do not share a common structural feature that demonstrates light-stability; (4) the problems addressed by Lehmussaari et al. are completely different from the problems addressed by the present application; and (5) the position taken by the Examiner in the paragraph bridging pages 7-8 of the Office Action is clearly based upon Applicant's own specification and is therefore impermissible hindsight.

The Examiner did not specifically comment on items (1)-(5) above, but requested Applicant to include these items in a formal response to the Office Action.

Applicant has carefully considered the Examiner's comments and suggestions in preparing this Amendment.

II. Claim Rejection Under 35 U.S.C. § 103

The Examiner has rejected claims 1-10, 12 and 13 under 35 U.S.C. § 103(a) as being unpatentable over Kita et al. (US 6,307,052) in view of Lehmussaari et al. (US 5,795,913). As applied to the amended claims, Applicant respectfully traverses the rejection.

The Concentration of the Metal Chloride

Kita et al. teach a medical composition comprising bepotastine, but the reference does not specifically teach how the composition is formulated and does not specifically teach a water-soluble metal chloride in a light-stabilizing effective amount.

As discussed above, claims 1 and 13 have been amended to recite that the concentration of the water-soluble metal chloride is 0.2-1.2 w/v%, and, as agreed during the interview, this is a critical range that provides unexpected light-stabilizing effects over the art. Moreover, claim 10 has an even narrower metal chloride concentration of 0.2-0.8 w/v%. Thus, as demonstrated by Experimental Example 1 of the specification, Formulation 2, comprising 0.1 w/v% of a metal

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