IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	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/Madam:

In response to the Office Action of April 30, 2014, 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~~ thereof; a water-soluble metal chloride in a light-stabilizing effective ~~amount,~~ amount; water; and optionally at least one material selected from the group consisting of a buffer, a preservative, a chelating agent, and a flavor; 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.

10-11. (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~~ of: (a) 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~~ ; (b) a water-soluble metal ~~chloride,~~ chloride; (c) sodium dihydrogen phosphate buffer; (d) a preservative; (e) water; and optionally (f) disodium edetate; 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%.

14. (Previously Presented) An aqueous liquid preparation consisting 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, a water-soluble metal chloride in a light-stabilizing effective amount, 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%, benzalkonium chloride, sodium dihydrogenphosphate dihydrate, sodium hydroxide and water.

15. (Currently Amended) The aqueous eye drop of claim 13, wherein:

~~(a)~~ (i) the (+)-(S)-4-[4-[(4-chlorophenyl)(2-pyridyl)methoxy]piperidino]butyric acid or the pharmacologically acceptable acid addition salt thereof is (+)-(S)-4-[4-[(4-chlorophenyl)(2-pyridyl)methoxy]piperidino]butyric acid monobenzenesufonate;

~~(b)~~ (ii) the water-soluble metal chloride is sodium chloride; and

~~(c)~~ (iii) the sodium chloride has a concentration selected from the range of a lower limit concentration of 0.2 w/v% and an upper limit concentration of 0.8 w/v%.

REMARKS

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

I. Claim Amendments

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. In addition, the amendments are submitted with a request under AFCP 2.0. Entry of the amendments is thus respectfully requested.

Claims 1, 3, 5-9 and 12-15 are pending in this application.

Claim 14 has been allowed.

Claims 1 and 13 have been amended to replace "consisting essentially of" with "consisting of".

Claim 1 has also been amended to include one or more "optional" materials selected from the group consisting of "a buffer, a preservative, a chelating agent, and a flavor". Support for these optional materials can be found on page 6, lines 4-18 of the specification.

Claim 13 has also been amended to include "sodium dihydrogen phosphate buffer", "a preservative", "water", and, optionally, "disodium edetate". Support for these amendments can be found on page 6, lines 4-16, Tables 2 and 3, and Examples 1-3 and 8-12.

Claim 15 has been amended to make minor editorial changes in view of the amendments to claim 13.

II. Telephone Interviews

Applicant appreciates the courtesies extended to Applicant's attorney by Examiner Frazier during the telephone interviews held April 25, 2014, May 6, 2014 and May 22, 2014.

During the first interview, Applicant's attorney pointed out that the Office Action issued April 23, 2014 does not list claim 14 as allowed. The Examiner agreed to issue the new outstanding Office Action to confirm that claim 14 has been allowed.

During the second interview, Applicant's attorney presented the amendments to claims 1, 13 and 15 mentioned above, and explained that changing "consisting essentially of" to "consisting of" should overcome the rejection under 35 U.S.C. § 103(a). Further, Applicant's attorney pointed out that claim 14, which recites "consisting of", has been allowed. Examiner Frazier provisionally agreed that the amendments over the rejection, but stated that further consideration and/or search are necessary before she could confirm allowance of the claims. The Examiner also requested Applicant submit the amendments under AFCP 2.0.

During the third telephone interview, the Examiner confirmed that her Supervisor agrees that the amendments appear to overcome the rejection.

Accordingly, Applicant has amended claims 1, 13 and 15 as discussed during the interview, and submits the amendments under AFCP 2.0.

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

The Examiner has rejected claims 1, 3, 5-9, 12, 13 and 15 under 35 U.S.C. § 103(a) as being unpatentable over Lehmussaari et al. (US 5,795,913) in view of Kita et al. (US 6,307,052), and optionally further in view of Araki et al. (WO 01/80858; US 2003/0139436). As applied to the amended claims, Applicant respectfully traverses the rejection.

Claims 1 and 13 has been amended to recite the transitional phrase "consisting of". The transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim (see MPEP 2111.03, citing *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931)).

The composition of Lehmussaari et al. requires the inclusion of an ion sensitive, hydrophilic polymer having viscosity, such as Carbopol, to control the formation of the polymer film on the cornea of the eye, and each of the reference's examples contain Carbopol (please see col. 2, line 57 to col. 3, line 6, and the Examples).

However, claims 1 and 13 do not recite "Carbopol". As a result, this ingredient is excluded from the aqueous liquid preparation of claim 1 and the eye drop of claim 13.

The references fail to disclose or suggest the aqueous liquid preparation of claim 1 or the eye drop of claim 13, consisting of the ingredients recited therein.

Therefore, as agreed during the interview, claims 1 and 13 would not have been obvious over the combination of references.

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