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: AMENDMENT**

SUPPLEMENTAL AMENDMENT

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

Sir:

In further response to the final Office Action of November 30, 2011, the Advisory Action of May 2, 2012, and in view of the personal interview with the Examiner held June 26, 2012, please amend the above-identified application as follows:

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AMENDMENTS TO THE CLAIMS

1. (Previously presented) 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, 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.

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10. (Currently amended) An aqueous eye drop ~~comprising~~consisting essentially of, 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. (Previously presented) 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, 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.

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REMARKS

Claims 1, 3, 5-10 and 12-14 are pending in this application.

Claim 10 has been amended to recite "consisting essentially of" in order to be consistent with claims 1 and 13.

I. Personal Interview

Applicant appreciates the courtesies extended to Applicant's attorneys by Examiner Frazier and Supervisory Examiner Blanchard during the personal interview held June 26, 2012.

Applicant's attorneys traversed the outstanding prior art rejection based upon the arguments presented in the Amendment After Final Rejection filed April 24, 2012, and presented new arguments to traverse the Examiner's arguments presented in the Advisory Action dated May 2, 2012 (discussed below).

Examiner Frazier maintained the rejection, and asserted that even though there is a showing of unexpected results in Example 1 of the specification, and claims 1 and 13 recite "consisting essentially of" language to exclude Carbopol, the *prima facie* case of obviousness has not been overcome.

In addition, Examiner Frazier stated that she has performed another prior art search, and found that US 2003/0139436 teaches to use a water-soluble metal chloride for light-stabilizing effects.

New claim 14 was also discussed. Examiner Frazier stated that she has not fully examined this claim to determine whether it is patentable over the art, but it appears allowable over the references of record.

Applicant greatly appreciates the Examiners' comments, and has considered these comments in preparing this Supplemental 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.

A. The Examiner's Position

The Examiner has asserted that Kita et al. disclose (+)-(S)-4-[4-[(4-chlorophenyl)(2-pyridyl)methoxy]piperidino] butyric acid or a benzenesulfonic acid salt thereof (hereinafter, "bepotastine"), but do not disclose how a composition comprising bepotastine is formulated and

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do not disclose a composition comprising bepotastine and a water-soluble metal chloride in a light-stabilizing effective amount of 0.2 w/v% to 1.2 w/v%. The Examiner applies Lehmussaari et al. for disclosing sodium chloride and potassium chloride in an amount of 0.01 to 2.0% by weight. See final Office Action, pages 2-3.

B. Carbopol

Claims 1, 10 and 13 each recite the transitional phrase "consisting essentially of", which limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic(s) of the claimed invention (see MPEP 2111.03).

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).

Carbopol is degraded by light. This is clear from the Chemical Abstract reference dated January 3, 1972 enclosed with the Amendment filed April 24, 2012, and the enclosed Declaration under 37 CFR 1.132. As requested by the Examiner, the Chemical Abstract reference is submitted again herewith in an Information Disclosure Statement.

As discussed in the Declaration, the reference states "CARBOXYVINYL POLYMERS of the type Carbopol 940…and 941 were degraded by light, type 941 presenting the highest DEGRADATION" (emphasis in original). This clearly teaches that it was known that Carbopol is degraded by light well-prior to the U.S. filing date of the present application (2003).

Using an ion sensitive, hydrophilic polymer, such as Carbopol, in the aqueous liquid preparation of claim 1 and the eye drops of claims 10 and 13 would materially affect the basic and novel characteristics of the claimed compositions, because it would introduce a component that degrades in light into a composition that is designed to be "light-stabilized" by a water-soluble metal chloride.

As a result, an ion sensitive, hydrophilic polymer is **excluded** from the aqueous liquid preparation of claim 1 and the eye drops of claims 10 and 13. Therefore, a person of ordinary skill in the art could not have arrived at the presently claimed invention from the combination of Kita et al., disclosing bepotastine, and Lehmussaari et al., disclosing a metal chloride in a composition with Carbopol, with any reasonable expectation of success.

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