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10/500,354	06/30/2004	Masayo Higashiyama	2004_1016A	2612

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EXAMINER	
FRAZIER, BARBARA S	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
04/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/500,354	HIGASHIYAMA, MASAYO	
	Examiner	Art Unit	
	BARBARA FRAZIER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other:

DETAILED ACTION

Status of Claims

1. Claims 1-10, 12, and 13 are pending in this application. Claim 11 stands canceled.

2. Addition of new claims 12 and 13 is acknowledged.

3. Claims 1-10, 12, and 13 are examined.

Claim Rejections - 35 USC § 112

4. The rejection of claims 1-10 under 35 U.S.C. 112, first paragraph is withdrawn in view of Applicant's amendment to claim 1.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. The previous rejection of claims 1-10 under 35 U.S.C. 103(a) as being unpatentable over Kita et (US Patent 6,307,052), Stevenson (US Patent 4,053,628) is modified as follows:

7. Claims 1-10, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevenson (US Patent 4,053,628) in view of Kita et al (US Patent 6,307,052).

The claimed invention is drawn to an aqueous liquid preparation comprising, in an aqueous solution, (+)-(S)-4-[4-[(4-chlorophenyl)(2-pyridyl)methoxy]piperidino]butyric acid (i.e., bepotastine) 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 (see claim 1).

Stevenson et al teach substantially clear, sterile aqueous solutions indicated for the treatment of conditions of the eye and the nose (abstract). The compositions may contain conventional excipients, such as sodium chloride (col. 2, lines 61-62) in amounts preferably less than 5% w/v (col. 3, lines 4-6); amounts of sodium chloride of 0.56% w/v and 0.42% w/v are exemplified (col.s 5 and 6, Examples 1 and 3). The compositions may also contain additional therapeutically useful compounds, such as antihistamine (col. 3, lines 7-13).

Stevenson et al do not specifically teach that the antihistamine may be bepotastine.

Kita et al teach that the benzenesulfonic acid salt or benzoic acid salt of (S)-4-[4-[(4-chlorophenyl)(2-pyridyl)methoxy]piperidino]butanoic acid (i.e., bepotastine) is excellent in antihistaminic activity and antiallergic activity, has little hygroscopicity and excellent in physicochemical stability, so that it is particularly suitable compound as a medicine (col. 1, lines 10-22).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to select bepotastine as the antihistamine in the composition of Stevenson et al; thus arriving at the claimed invention. One skilled in the art would be

motivated to do so, with a reasonable expectation of success, because bepotastine provides the benefits of having excellent antihistaminic activity, little hygroscopicity, and excellent physicochemical stability, as taught by Kita et al.

Regarding the limitations, “a water-soluble metal chloride in a light-stabilizing effective amount of 0.2 w/v% or more” (claim 1), “sodium chloride at not less than 0.2 w/v% and not more than 0.8 w/v% in a light-stabilizing effective amount” (claim 10), and “light-stabilized with a water-soluble metal chloride at not less than 0.2 w/v% (claim 13), Stevenson et al exemplify amounts of sodium chloride of 0.56% w/v and 0.42% w/v (col.s 5 and 6, Examples 1 and 3). These amounts would necessarily be a light-stabilizing effective amount, as evidenced by Applicant’s specification. Since concentrations of sodium chloride of 0.56% and 0.42%, as taught by the Stevenson et al, overlaps with the amount of sodium chloride disclosed by applicant as being a "light-stabilizing effective amount (specification, page 8, lines 6-15, including Table 1), one would reasonably expect that the sodium chloride component of the aqueous liquid preparations encompassed by the prior art, wherein said sodium chloride is present in an amount of 0.2% or more (e.g. 0.56%) would also be a light-stabilizing effective amount, absent objective evidence to the contrary.

Regarding claims 2, 3, and 12, Stevenson et al exemplify sodium chloride as an excipient present in the composition, in amounts of 0.56% w/v and 0.42% w/v (col.s 5 and 6, Examples 1 and 3), which are within Applicant’s range.

Regarding claim 4, Stevenson et al teach that amounts of additional compounds may be present at a concentration of from about 0.05 to 0.6% w/v (col. 3, lines 32-34).

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