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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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
04/30/2014	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. 10/500,354	Applicant(s) HIGASHIYAMA, MASAYO	
	Examiner BARBARA FRAZIER	Art Unit 1611	AIA (First Inventor to File) Status No

-- 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* MONTHS 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 *28 February 2014*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ 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*

5)☒ Claim(s) *1,3,5-9 and 12-15* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☒ Claim(s) *14* is/are allowed.

7)☒ Claim(s) *1,3,5-9,12,13 and 15* is/are rejected.

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

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

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

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

11)☐ 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).

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).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

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) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)

3) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. *4/24/14*.

DETAILED ACTION

1. The present application is being examined under the pre-AIA first to invent provisions.

Examiner's Remarks

2. The Examiner notes that the proper status of claim 14 was inadvertently omitted from the previous Office action mailed 23 April 2014. The Office action mailed 23 April 2014 is hereby vacated; a corrected Office action follows.

Status of Claims

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

Claim Rejections - 35 USC § 103

4. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. **Claims 1, 3, 5-9, 12, 13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lehmussaari et al. ("Lehmussaari", US Patent 5,795,913, previously cited) in view of Kita et al. ("Kita", US Patent 6,307,052, previously cited) and optionally further in view of Araki et al. ("Araki", WO 01/80858).** US

2003/0139436 is the national stage entry of WO 01/80858, and thus serves as an English translation of WO 01/80858; accordingly, relevant passages will be taken from the US '436 reference.

Regarding claims 1 and 13, Lehmussaari teaches an ophthalmic composition in the form of a topical aqueous solution consisting essentially of an ophthalmologically active agent containing basic groups, an ion sensitive hydrophilic polymer containing acidic groups, and at least one salt selected from the group of inorganic salts and buffers in a total amount of from 0.01 to 2.0% by weight (abstract). The ophthalmologically active agent may be an antiallergic agent containing basic groups, including basic heterocycles, such as pyridine and piperidine (col. 4, lines 2-9). The salt/buffer functions as a viscosity reducing agent; choices of salts include sodium chloride and potassium chloride (col. 3, lines 45-50 and claim 5). Sodium chloride is exemplified in an amount of 0.9% w/v (Example 2), and therefore the skilled artisan would be sufficiently motivated to prepare the aqueous solution with sodium chloride, with a reasonable expectation of forming the ophthalmic composition. The composition is prepared by dissolving active ingredient(s) and inorganic salt(s) in sterile water, followed by mixing with a dispersion of the polymer in sterile water, to form a homogeneous solution (col. 5, lines 1-11). The composition is administered as a liquid and obtains a desired beneficial effect of the active agent in the eye, while simultaneously reducing any discomfort in the patient's eye, as compared to the administration of a composition in gel form. The composition also provides for an

additional wetting effect while providing for a better contact and thus a controlled absorption of active agent into the eye (col. 2, lines 10-18).

While Lehmussaari teaches the steps of preparing an aqueous preparation comprising an ophthalmic agent and sodium chloride, and teaches the ophthalmically active agent may be an antiallergic agent containing basic groups, including basic heterocycles, such as pyridine and piperidine, Lehmussaari does not specifically teach that the antiallergic agent is bepotastine. Lehmussaari also does not specifically teach that the amount of sodium chloride is a light-stabilizing effective amount (claim 1), or that the antiallergic agent is light-stabilized (claim 13).

Kita teaches 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. Kita et al also teach that its present invention relates to a medical composition containing the compound as an effective ingredient (see col. 1, lines 10-22).

Araki teaches a stabilized liquid preparation having improved light stability, comprising an aqueous solution containing sitafloxacin and sodium chloride (abstract). The light stabilizing effect is enhanced with an increase of the sodium chloride concentration; a particularly high stabilizing effect is obtained at a sodium chloride concentration of 0.1% or higher (paragraph [0055]). The liquid preparation is suitable

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