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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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WASHINGTON, DC 20006-1021

EXAMINER

RAE, CHARLESWORTH E

ART UNIT	PAPER NUMBER
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1611

MAIL DATE	DELIVERY MODE
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02/08/2008

PAPER

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.

Office Action Summary	Application No. 10/500,354	Applicant(s) HIGASHIYAMA, MASAYO	
	Examiner Charleswort Rae	Art Unit 1614	

-- 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 11/13/07.
- 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) 1-11 is/are pending in the application.
4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10 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)

- | | |
|--|--|
| <ul style="list-style-type: none"> 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | <ul style="list-style-type: none"> 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date _____ 5) <input type="checkbox"/> Notice of Informal Patent Application 6) <input type="checkbox"/> Other: _____ |
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DETAILED ACTION

Applicant's arguments/amendment, filed 10/9/07, and supplemental response/amendment, filed 11/13/07, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

Entry of the amendment to the specification, filed 10/09/07, is hereby granted. No new matter is deemed to have been introduced by the said amendment (see amendment).

Applicant's statement that Formulation 7 discloses monobenzenesulfonate as "bepotastine besilate (Table 2 and specification at page 1, lines 25-27) is acknowledged.

This action is made final.

Status of the Claims

Claims 1-11 are currently pending in this application.

Claim 11 is withdrawn for being directed to non-elected subject matter.

Claims 1-10 are under examination.

Claim of Priority

Receipt of a non-English certified copy of the Foreign Priority application received 6/30/04 is acknowledged and made of record. The effective filing date of the instant application is considered to be July 30, 2003, which is the filing date of the international application PCT/JP03/09713. Applicant is invited to submit

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an English translation of the priority document in support of the claimed benefit to the filing date of the foreign priority document (i.e. July 31, 2002).

Declaration

The declaration of Dr. Higasiyama, filed 11/13/07, under CFR 1.32 is acknowledged. The experimental data provided showing the light-stabilizing effect of water-soluble metal chloride bepotastine besilate aqueous solutions as disclosed in Examples 1-4 are appreciated. Dr. Higasiyama's conclusion statement that the "results indicate that water-soluble metal chloride improves light-stability of bepotastine besilate and that isotonic agents such as glycerin, saccharides and the light do not improve light-stability of bepotastine besilate" is found to be applicable only to non-metal chloride isotonic agents such as glycerin and saccharides. The data fail to reasonably address the fact that, unlike the non-ionizable non-alkali metal isotonic agents (e.g. glycerin) disclosed by Dr. Higasiyama, the isotonic property of the claimed ionizable alkali metal chlorides (e.g. sodium chloride) when employed in pharmaceutical aqueous solutions e.g. eye/nasal solutions, is coextensive with the purported claimed light-stabilizing property of said metal chlorides. To the extent that the instant claims encompass metal chloride isotonic agents, as oppose to glycerin/saccharide isotonic agents, the declaratory evidence is not commensurate in scope with the instant claims. Thus, the declaration is found to be insufficient to overcome the rejection of record.

Response to applicant's arguments/remarks

Objection

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The objection to the specification is withdrawn in view of the amendment to the specification filed 10/09/07.

Rejection under 103(a)

Applicant asserts that this rejection should be withdrawn for the following reasons:

1) Koida et al. and Kita et al. do not disclose or suggest an aqueous solution containing a pharmacologically acceptable acid addition salt of bepotastine, and metal chloride, and a light-stabilization method of an aqueous solution containing bepotastine.

2) Remington/s teach calcium chloride, potassium chloride or sodium chloride are generally used for isotonization, but do not teach the use of these agents to light stabilize a drug in aqueous solution as claimed in the instant application.

3) The comparative test results employing the isotonic agents, glycerin, glucose, and mannitol, clearly show that the light stabilizing effect of the present invention is not an effect accompanying isotonization. The finding of the metal chloride light-stabilizing effect was an unexpected finding and therefore the combination of references do not render the instant claimed invention obvious.

In response, the rejection is maintained as applicant's arguments are not found to be persuasive for the reasons previously made of record in the Office action mailed 7/9/07 and for the additional following reasons:

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