



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,354	06/30/2004	Masayo Higashiyama	2004_1016A	2612

513 7590 02/08/2008
WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER

RAE, CHARLESWORTH E

ART UNIT	PAPER NUMBER
----------	--------------

1611

MAIL DATE	DELIVERY MODE
-----------	---------------

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.

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 Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.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Claim 11 is withdrawn for being directed to non-elected subject matter.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

Art Unit: 1611

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

Art Unit: 1611

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:

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.