

Notice of Allowability	Application No.	Applicant(s)	
	10/525,006	SAWA ET AL.	
	Examiner	Art Unit	
	LAYLA SOROUGH	1627	

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to the response to arguments submitted on September 6, 2011.
2. 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.
3. The allowed claim(s) is/are 41,43-51,53-56,58-60 and 64-68.
4. 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 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)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) hereto or 2) to Paper No./Mail Date ____.
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date ____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date ____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other ____. |

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An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Warren Cheek on December 16, 2011. This application has been amended as follows:

In claim 41, lines 3-4 after a hydrate thereof, **insert** – wherein the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate, and 3/2 hydrate -- .

In claim 64, line 2-3 after a hydrate thereof, **insert** – wherein the hydrate is at least one selected from a 1/2 hydrate, 1 hydrate, and 3/2 hydrate -- .

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

The composition as claimed are found to be patentable over the prior art because the prior art does not teach or fairly suggest an aqueous liquid preparation consisting essentially of the following two components, wherein the first component is 2-amino-3-(4- bromobenzoyl)phenylacetic acid or a pharmacologically acceptable salt thereof, and the second component is tyloxapol wherein said liquid preparation is formulated for ophthalmic administration, and wherein when a quaternary ammonium compound is included in said liquid preparation, the quaternary ammonium compound is benzalkonium chloride.

The transitional phrase “consisting essentially of” 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. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original).

The closest prior arts of record, namely Yanni et al. and Desai et al. Yanni et al. teaches a composition comprising an active agent see specifically Preparation XV (3-benzoylphenylacetic acid derivatives, salts are known) in 0.01-0.5%, polysorbate 80 in 0.01%, benzalkonium chloride, disodium EDTA, monobasic sodium phosphate, dibasic sodium phosphate, sodium chloride, pH adjustment with NaOH and/or HCl, water. Desai et al. teach an ophthalmic composition comprising bromfenac (2-amino-3-(4-bromobenzoyl)phenylacetic acid) and its ophthalmically acceptable salts, esters, amides or prodrugs thereof (column 3, lines 13-29, claims 4 and 7) and polysorbates such as tweens and tyloxapol and further comprising boric acid buffer (column 2, lines 18-44).

Applicants have found that tyloxapol is not equivalent to polysorbate 80 when combined with bromfenac. The present inventors have discovered that tyloxapol has an unexpected property in stabilizing an aqueous solution of bromfenac in comparison with polysorbate 80. Please see the description of Experimental Example 1 and Table 1 on pages 14-16 of the specification. In the Experimental Example, the stability of an aqueous solution of bromfenac was measured by storing the bromfenac solution with polysorbate 80 (see Comparison Example 1) and, separately, with tyloxapol (see A-02), under conditions of pH 7.0 at 60°C for 4 weeks. The remaining rate % of bromfenac was measured after the test. As shown in Table 1, only 51.3% of bromfenac remained in the

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aqueous solution when stored with polysorbate 80. In contrast, 73.8% of bromfenac remained in the aqueous solution when stored with tyloxapol. Thus the present inventors have found that tyloxapol has an unexpected stabilizing effect on an aqueous solution of bromfenac in comparison to polysorbate 80. Therefore the present inventors have found that tyloxapol and polysorbate 80 are not equivalent compounds. Such unequivalency, and such remarkable effects, could not have been obvious to one skilled in the art from the cited references. For the foregoing reasons, it is respectfully submitted that the teachings of the cited references do not suggest the claimed bromfenac preparation as amended, nor the unexpected properties of the preparation. Additionally, Desai et al. teach that the problems with benzalkonium chloride and other quaternary ammonium compounds can be avoided by using certain polymeric quaternary ammonium compounds in combination with boric acid. Hence, an essential component of the Desai composition is a polymeric quaternary ammonium compound. However, the instant claims as amended require that, when the claimed liquid preparation includes a quaternary ammonium compound, the quaternary ammonium compound is limited to benzalkonium chloride. Thus the polymeric quaternary ammonium compounds disclosed in Desai et al. are excluded from the amended claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on 8:30a.m.-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627

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