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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,006	03/28/2005	Shirou Sawa	2005_0232A	1756
0.00	7590 06/03/200 I, LIND & PONACK, I	EXAMINER		
1030 15th Street, N.W., Suite 400 East			JAGOE, DONNA A	
Washington, DC 20005-1503			ART UNIT	PAPER NUMBER
			1614	
			MAIL DATE	DELIVERY MODE
			06/03/2009	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.



	Application No.	Applicant(s)				
	10/525,006	SAWA ET AL.				
Office Action Summary	Examiner	Art Unit				
	Donna Jagoe	1614				
The MAILING DATE of this communication ap						
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 15 J	anuary 2009.					
	s action is non-final.					
3) Since this application is in condition for allowa	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) <u>19-29,31-34,36-51,53-56 and 58-63</u> is/are pending in the application.						
4a) Of the above claim(s) <u>39,40,61 and 62</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>19-29,31-34,36-38,41-51,53-56,58-60 and 63</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/o	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:						
<ol> <li>Certified copies of the priority documents have been received.</li> </ol>						
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) 4) Interview Summary (PTO-413) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)   Paper No(s)/Mail Date     3) Notice of Information Disclosure Statement(s) (PTO/SB/08)   Notice of Informal Patent Application						
Paper No(s)/Mail Date <u>3/11/09</u> . 6) Other:						
U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06) Office A	ction Summary	Part of Paper No./Mail Date 20090528				

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**DETAILED ACTION** 

Claims 19-29, 31-34, 36-51, 53-56 and 58-63 are pending in this application.

Claims 39, 40, 61 and 62 are withdrawn from further consideration.

Claims 19-29, 31-34, 36-38, 41-51, 53-56, 58-60 and 63 are rejected.

Applicants' arguments filed January 15, 2009 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 presently being

applied to the instant application.

Change of Examiner

The examiner assigned to the instant application has changed. The new

examiner is Donna Jagoe. Contact information is provided at the end of this Office

Action.

**Priority** 

As recited in the Office Action dated September 27, 2007, Applicant is reminded

that a certified translation has not been proved for the claim to foreign priority of

JP2003-012427, filed 1/21/2003. Since no translation has been provided, prior art

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dates have been determined with reference to the priority date for the PCT application date, PCT/JP04/00350, filed 1/16/2004.

### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-29, 31-34, 36-38, 41-51, 53-56, 58-60 and 63, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19 and 41 recite an aqueous liquid preparation comprising at least 2-amino-3-(4-bromobenzoyl)phenylacetic acid (bromfenac) and an alkyl aryl polyether alcohol type polymer or polyethylene glycol fatty acid ester "wherein said liquid preparation is in the form of an eye drop". It is unclear what is meant by "in the form of an eye drop. Is this aqueous liquid preparation in a container shaped like an eye drop? It is suggested that the claim be amended to recite "wherein said liquid preparation is formulated for ophthalmic administration".

### Claim Rejections - 35 USC § 103

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

Claims 19-29, 31-34, 36-38, 41-51, 53-56, 58-60 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hellberg et al. (US 5,998,465; 1999) and



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Nolan, et al. ("The topical anti-inflammatory and analgesic properties of bromfenac in rodents; Agents and Actions; 1988 Aug; 25(1-2):77-85; cited with previous Interview Summary).

Hellberg teaches pharmaceutical compositions of anti-inflammatory compounds (abstract); the compounds include a non-steroidal anti-inflammatory moiety (NSAIA) and an antioxidant moiety linked through an ester bond formed by the carboxylic acid moiety of the NSAIA (col. 2, lines 20-24); NSAIA moieties include bromfenac (col. 3, line 57; claim 5); examples 2 and 3 (col. 11) teach topical ophthalmic formulations useful for treating inflammation, both of these formulations include tyloxapol at 0.01-0.05 w/v %, HPMC (thickener), benzalkonium chloride (preservative), edetate disodium (chelating agent) (col. 11, Examples 2-3); the pH is adjusted to 7.4 (about 7.5; col. 11, line 64); topical formulations administered by drops (eye drops; col. 10, lines 15-18). Hellberg does not teach bromfenac (only the ester of bromfenac). Nolan teaches bromfenac (the sodium salt, sesquihydrate form) was effective as a topical analgesic at concentrations of 0.1-0.32 % in mice and more potent than the other drugs tested (abstract). It would have been obvious for one of ordinary skill in the art at the time of the invention to substitute bromfenac, taught by Nolan for the compounds of Hellberg in the example formulation giving formulations of the instant claims and to select concentrations of bromfenac sodium, sesquihydrate of 0.1, about 0.2 and about 0.32 %, in the invention of Gamache, since these values have demonstrated efficacy for topical use. It would also have been obvious to adjust the concentration of tyloxapol, to optimize the formulations for the effect would on the solubility and stability of the aqueous



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