

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.
13/687,242	11/28/2012	Shirou SAWA	2012_5420	1577
513 7590 08/01/2013 WENDEROTH, LIND & PONACK, L.L.P. 1030 15th Street, N.W., Suite 400 East			EXAMINER	
			SOROUSH, LAYLA	
Washington, DC 20005-1503			ART UNIT	PAPER NUMBER
			1627	
			NOTIFICATION DATE	DELIVERY MODE
			08/01/2013	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):

ddalecki@wenderoth.com eoa@wenderoth.com



	Application No. 13/687,242		Applicant(s) SAWA ET AL.	
Office Action Summary	Examiner LAYLA SOROUSH	<b>Art Unit</b> 1627	AIA (First Inventor to File) Status No	
The MAILING DATE of this communication a Period for Reply	ppears on the cover sheet w	ith the corresponden		
A SHORTENED STATUTORY PERIOD FOR REF WHICHEVER IS LONGER, FROM THE MAILING  - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory perions for reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNION of the community	CATION. reply be timely filed NTHS from the mailing date of BANDONED (35 U.S.C. § 13	this communication.	
Status				
1) Responsive to communication(s) filed on 9 A  A declaration(s)/affidavit(s) under 37 CFR	-			
. ,	nis action is non-final.	<del></del>		
3) An election was made by the applicant in res		rement set forth durir	na the interview on	
; the restriction requirement and electi  4) Since this application is in condition for allow closed in accordance with the practice under	on have been incorporated vance except for formal mat	into this action. ters, prosecution as t		
Disposition of Claims				
5) Claim(s) 29-48 is/are pending in the applicat 5a) Of the above claim(s) is/are withdo 6) Claim(s) is/are allowed. 7) Claim(s) 29-48 is/are rejected. 8) Claim(s) is/are objected to. 9) Claim(s) are subject to restriction and of the striction and allowable, you may be participating intellectual property office for the corresponding antip://www.uspto.gov/patents/init_events/pph/index.jsp or se  Application Papers 10) The specification is objected to by the Exami 11) The drawing(s) filed on is/are: a) and antiparticip	rawn from consideration.  I/or election requirement.  eligible to benefit from the <b>Pat</b> grapplication. For more informate and an inquiry to <u>PPHfeedbacks</u> ner.	tion, please see <u>@uspto.gov</u> .	<b>way</b> program at a	
Applicant may not request that any objection to the Replacement drawing sheet(s) including the corresponding to th	ne drawing(s) be held in abeyar	nce. See 37 CFR 1.85	` '	
Priority under 35 U.S.C. § 119  12) Acknowledgment is made of a claim for foreign Certified copies:  a) All b) Some * c) None of the:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the papplication from the International Burent * See the attached detailed Office action for a list	ents have been received. ents have been received in a riority documents have been eau (PCT Rule 17.2(a)).	Application No n received in this Nat		
Attachment(s)    X Notice of References Cited (PTO-892)   X Information Disclosure Statement(s) (PTO/SR/08)	• ——	Summary (PTO-413) s)/Mail Date		



Application/Control Number: 13/687,242 Page 2

Art Unit: 1627

#### **DETAILED ACTION**

The Office Action is in response to the Applicant's reply filed April 9, 2013 to the restriction requirement made on March 25, 2013.

Applicant's election of benzalkonium chloride as the species of quarternary ammonium salts is hereby acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 19-48 read on the elected species.

The requirement is still deemed proper and is therefore made **FINAL**.

### Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph: 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 44-48 rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA),

second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention. Applicant has claimed the preservative efficacy standard is satisfied by EP-criteria B of the European Pharmacopoeia. Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a



Application/Control Number: 13/687,242 Page 3

Art Unit: 1627

necessity doctrine, not for applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted).

## Claim Rejections - 35 USC § 103

The following is a quotation of 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.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).



Application/Control Number: 13/687,242 Page 4

Art Unit: 1627

Claims 19, 21-24, 26, 28-30, 32, 34-36, 38, 40-42, and 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gamache, et al. (WO 01/15677 A2; 03/2001).

Gamache teaches compositions for otic and intranasal use (p.6, lines 5-6) that contain a combination of a 5-HT agonist and an anti-inflammatory agent (p. 6, lines 1-4; p. 12 lines 9-10) or alternatively sequential or concurrent dosing of separate compositions that contain the 5-HT antagonist in one composition and the antiinflammatory agent in a second composition (p. 12, lines 9-11); specifically claimed is the anti-inflammatory specie bromfenac (2-amino-3-(4-bromobenzoyl)phenylacetic acid). Typical concentrations of anti-inflammatory agents, such as bromfenac, are taught in the range 0.01-1.0% (w/v) (overlapping with 0.01-0.5; p. 13, lines 6-8); aqueous formulations are preferred (p. 10, lines 11-14); tyloxapol is taught in a concentration of 0.05 % (w/v) (p. 16, line 30). The salt form of bromfenac in solution will be the same when the acid is dissolved in a solution followed by adjustment to the desired pH with NaOH/HCI (Gamache, p. 15, line 33) as when the sodium salt is dissolved in solution adjusted to the same pH; in this case Gamache also teaches the sodium salt limitation of instant claim 21. The concentration range of 0.01-1.0% overlaps and encompasses the claimed concentration range of the sodium salt of bromfenac instantly claimed.

Although, the reference does not exemplify an aqueous liquid preparation comprising the first component and second component, it would have been obvious



# DOCKET

# 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.

