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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/617,138	09/14/2012	Roberto VILLA	3850-125	7811
6449	7590	03/06/2013	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 607 14th Street, N.W. SUITE 800 WASHINGTON, DC 20005			TRAN, SUSAN T	
			ART UNIT	PAPER NUMBER
			1615	
			NOTIFICATION DATE	DELIVERY MODE
			03/06/2013	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):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	<b>Examiner</b>	<b>Art Unit</b>	
	13/617,138	VILLA ET AL.	
	SUSAN TRAN	1615	

**-- 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 15 January 2013.
- 2a)  This action is **FINAL**.                                    2b)  This action is non-final.
- 3)  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.
- 4)  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**

- 5)  Claim(s) 1-12 is/are pending in the application.  
5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6)  Claim(s) \_\_\_\_ is/are allowed.
- 7)  Claim(s) 1-12 is/are rejected.
- 8)  Claim(s) \_\_\_\_ is/are objected to.
- 9)  Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

\* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see [http://www.uspto.gov/patents/init\\_events/pph/index.jsp](http://www.uspto.gov/patents/init_events/pph/index.jsp) or send an inquiry to [PPHfeedback@uspto.gov](mailto:PPHfeedback@uspto.gov).

**Application Papers**

- 10)  The specification is objected to by the Examiner.
- 11)  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).

**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)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 3) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ . |
| 2) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/30/12</u> . | 4) <input type="checkbox"/> Other: ____.   |

## DETAILED ACTION

### *Priority*

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of 35 U.S.C. 112(a) or the first paragraph of 35 U.S.C. 112 (pre-AIA). See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications fail to provide adequate support or enablement in the manner provided by 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph for one or more claims of this application. None of the prior-filed applications appear to provide support for the limitation “hydrogel-forming hydrophilic excipient other than a gum” recites in the present claims. As such, the present application does not have priority date of the earlier filed applications.

### *Terminal Disclaimer*

The terminal disclaimer filed on 01/15/13 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of USPN 8,293,273; 8,029,823; 7,410,651; 7,431,943; and copending applications 13/249,389 and 13/462,409 has been reviewed and is accepted. The terminal disclaimer has been recorded.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

*Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Hallgren et al. US 6,239,120.*

*Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Friend et al. US 5,811,388.*

These rejections have been withdrawn in view of Applicant's Amendment filed 01/15/13.

*Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Villa et al. US 2006/0134208 A1.*

Villa teaches a controlled release and taste masking oral tablet comprising budesonide, and an inert matrix comprising of one or more hydrophilic water-swallowable excipients, an amphiphilic compound, and a lipophilic excipient. Amphiphilic compound includes lecithin. Lipophilic includes compound having melting point between 40°C to 90°C. Hydrophilic includes compound capable of molecular relaxation. See abstract; and paragraphs 0028-0031. The tablet is coated with a gastro-resistant film. (ID).

Example 2 shows a tablet having: 1) a core comprising of 9.0 mg of budesonide, stearic acid, lecithin, and cellulosic excipients; and 2) a gastro-resistant coating.

### ***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 negated by the manner in which the invention was made.

*Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friend et al. US 5,811,388 in view of Hallgren et al. US 6,239,120.*

This rejection has been withdrawn in view of Applicant's Amendment filed 01/15/13.

### ***Response to Arguments***

Applicant's arguments have been considered but are moot because the arguments do not apply to any of the references being used in the current rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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