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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/811,737	07/06/2010	Federico Stroppolo	3504-108	1929
	12/811,737 07/06/2010 6449 7590 02/14/20.		EXAMINER	
12/811,737 07/06/2010 6449 7590 02/14/2012 ROTHWELL, FIGG, ERNST & MANBI 1425 K STREET, N.W. SUITE 800		ALLEY, GENEVIEVE S		
			ART UNIT	PAPER NUMBER
		1617		
			NOTIFICATION DATE	DELIVERY MODE
			02/14/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)				
	12/811,737	STROPPOLO ET AL.				
Office Action Summary	Examiner	Art Unit				
	GENEVIEVE S. ALLEY	1617				
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						
	s action is non-final.					
3) An election was made by the applicant in resp	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 allowa	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 E	E <i>x parte Quayle</i> , 1935 C.D. 11, 45	3 O.G. 213.				
Disposition of Claims						
 5) ☐ Claim(s) 1-11 is/are pending in the application. 5a) Of the above claim(s) 10 and 11 is/are withdrawn from consideration. 6) ☐ Claim(s) is/are allowed. 7) ☐ Claim(s) 1-9 is/are rejected. 8) ☐ Claim(s) 1-9 is/are objected to. 9) ☐ Claim(s) are subject to restriction and/or election requirement. 						
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). 12) 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						
 13) 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) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 07/06/10	Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:					



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DETAILED ACTION

This action is in response to papers filed November 10, 2011. Applicants' response to the restriction requirement of October 19, 2011 has been entered. No claims were cancelled, amended, or newly added. Currently claims 1-11 are pending in the application

Election/Restrictions

Applicants' election of Group I (claims 1-9) drawn to an orally disintegrating tablet with speckled appearance, is acknowledged.

Because Applicants 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)).

As the requirement for restriction is deemed proper, it is maintained and hereby made **FINAL**. Please note that after a final requirement for restriction, the Applicants, in addition to making any response due on the remainder of the action, may petition the Commissioner to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested. (See § 1.181.).

Claims 10-11 are hereby withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. The instant claims have been examined



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commensurate with the scope of the elected invention. Applicants timely responded to the restriction requirement in the reply filed November 10, 2011.

Accordingly, claims 1-9 are under current examination.

Claim Objections

[Claims 1-9 are objected to because of the following informalities: The independent claim lacks the article "A" and the dependent claims lack the article "The" at the beginning of each claim. See MPEP 608.01(n)(IV).] Claim 1 recites tablets and thus reciting "A" would be grammatically incorrect. The claim is fine.

Claim 9 is objected to because of the following informalities: incomplete unit.

Claim 9 recites "...wherein the colored granules are present in an amount from about 0.1 w/w to about 30% w/w." The claim objection can be obviated by amending the claim to recite "...wherein the colored granules are present in an amount from about 0.1 w/w to about 30% w/w per tablet." Appropriate correction is required.

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.



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Claims 1-4 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Martino et al. (US 2003/0180357).

Claims 1-4 and 8 encompass an orally disintegrating tablet with speckled appearance comprising colored granules of a water-soluble sugar (e.g., mannitol in 0.1-50% w/w) in admixture with a pharmaceutically acceptable carrier.

Martino et al. teach a pharmaceutical tablet suitable for peroral or intraoral administration, for example for delivery of a drug contained in the core of the tablet to a subject (oral limitation of claim 1; Abstract). Martino et al. disclose that the tablet has a speckled appearance that renders the tablet readily identifiable (limitation of claim 1; Abstract). In [0011], Martino et al. state that the intraoral route refers to administration by placement of the tablet in the mouth of the subject, where the tablet disintegrates and/or dissolves, so that absorption of the drug typically occurs at least in part via the oral mucosa (limitation of claim 1). These tablets comprise a water-soluble sugar such as mannitol (granular) in 50-90% by weight and a magnesium stearate carrier (limitations of claims 1-4 and 8; [0060] and [0071]). In a particular embodiment, granular mannitol and dye (cherry shade #1632, Crompton and Knowles) were blended in a high shear mixer for 2 minutes or until homogenously mixed prior to adding other ingredients and forming the tablet (color limitation of claim 1; [0085]). Martino et al. teach that this method produced a tablet that had an attractive high gloss appearance with cherry red speckles [0092].

Therefore, by teaching all the limitations of claims 1-4 and 8, Martino et al. anticipate the instant invention as claimed.



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