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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
6449	7590	09/12/2012	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 607 14th Street, N.W. SUITE 800 WASHINGTON, DC 20005			ALLEY, GENEVIEVE S	
			ART UNIT	PAPER NUMBER
			1617	
			NOTIFICATION DATE	DELIVERY MODE
			09/12/2012	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

Office Action Summary

Application No. 12/811,737	Applicant(s) STROPPOLO ET AL.	
Examiner GENEVIEVE S. ALLEY	Art Unit 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 14 May 2012.
- 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) 1-11 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) ____ 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) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <i>search history</i> . |

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DETAILED ACTION

Claim Status

Applicants' response of May 14, 2012, to the non-final Office action dated February 14, 2012 has been entered. Claims 1-10 have been amended and claims 10 and 11 have been previously withdrawn. Accordingly, claims 1-11 are pending in the application and claims 1-9 are under current examination.

Withdrawn Claim Objection/Rejections

The objections to claims 1-9 for minor informalities are hereby withdrawn in view of the claim amendments filed on May 14, 2012.

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 1-4 and 8 remain rejected under 35 U.S.C. 102(b) as being anticipated by Martino et al. (US 2003/0180357; published: Sep. 25, 2003; of record).

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.

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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 homogeneously 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.

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

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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 1-4 and 8-9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Martino et al. (US 2003/0180357; published: Sep. 25, 2003; of record).

The teachings of Martino et al. are applied as above for claims 1-4 and 8.

Claim 9 encompasses an orally disintegrating tablet with speckled appearance comprising colored granules of a water-soluble sugar (1-30% w/w) in admixture with a pharmaceutically acceptable carrier.

Regarding the concentration of granules as specified in claim 9, MPEP 2144.05 states:

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Furthermore, Martino et al. teach that relatively large particles will tend to produce a speckled pattern having larger blocks of color than will be produced by smaller particles [0061]. The Applicants' specification provides no evidence that the selected concentration in claim 9 was not due to routine optimization and/or that the results should be considered unexpected compared to the prior art. It would have been obvious to a person of ordinary skill in the art at the time of the invention to combine

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