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ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			ALLEY, GENEVIEVE S	
			ART UNIT	PAPER NUMBER
			1617	
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**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.

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Claims 10-11 are hereby withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking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

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