**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| Appl. No. | : 13/617,138 |
| Applicant | : Roberto VILLA *et al.* |
| Filed | : 14 September 2012 |
| TC/A.U. | : 1615 |
| Examiner | : Susan T. Tran |
| Docket No. | : 3850-125 |
| Customer No. | : 06449 |
| Confirmation No. | : 7811 |

**AMENDMENT**

MAIL STOP AMENDMENT
Director of the United States Patent
and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In response to the Office Action dated 16 November 2012, please amend this application as follows:

Amendments to the Claims begin on page 2.

**Remarks** begin on page 5.

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## AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims

1. (Currently amended) A controlled release oral pharmaceutical composition comprising:

(1) a tablet core comprising:

a) budesonide in an amount effective for treatment of inflammatory bowel disease in the gastrointestinal tract,

b) a lipophilic excipient;

c) an amphiphilic excipient;

d) a hydrogel-forming hydrophilic excipient other than a gum; and

(2) a coating on said tablet core, said coating comprising a gastro-resistant film.

2. (Currently Amended) ~~The composition of~~ A controlled release oral pharmaceutical composition according to claim 1, ~~comprising~~ wherein said controlled release oral pharmaceutical composition comprises 9 mg of budesonide.

3. (New) A controlled release oral pharmaceutical composition according to claim 1, wherein said hydrogel-forming hydrophilic excipient comprises hydroxypropyl cellulose.



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4. (New) A controlled release oral pharmaceutical composition according to claim 2, wherein said hydrogel-forming hydrophilic excipient comprises hydroxypropyl cellulose.

5. (New) A controlled release oral pharmaceutical composition according to claim 1, wherein said gastro-resistant film comprises at least one methacrylic acid polymer or copolymer.

6. (New) A controlled release oral pharmaceutical composition according to claim 5, wherein said hydrogel-forming hydrophilic excipient comprises hydroxypropyl cellulose.

7. (New) A controlled release oral pharmaceutical composition according to claim 1, wherein said lipophilic excipient and said amphiphilic excipient are present in said controlled release oral pharmaceutical composition in a ratio of about 1 to 1 by weight.

8. (New) A controlled release oral pharmaceutical composition according to claim 7, wherein said hydrogel-forming hydrophilic excipient comprises hydroxypropyl cellulose.

9. (New) A controlled release oral pharmaceutical composition according to claim 1, wherein said lipophilic excipient comprises stearic acid.

10. (New) A controlled release oral pharmaceutical composition according to claim 9, wherein said hydrogel-forming hydrophilic excipient comprises hydroxypropyl cellulose.



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11. (New) A controlled release oral pharmaceutical composition according to claim 1, wherein said amphiphilic excipient comprises lecithin.

12. (New) A controlled release oral pharmaceutical composition according to claim 11, wherein said hydrogel-forming hydrophilic excipient comprises hydroxypropyl cellulose.



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## REMARKS

*Amendments*

Claim 1 has been amended to specify that the hydrogel-forming hydrophilic excipient is not a gum. The as-filed specification discloses at paragraph 36 that the hydrophilic excipient can comprise hydrogel compounds, including natural or synthetic gums. As such, there is written description support for amending claim 1 to recite that the hydrogel-forming hydrophilic excipient comprising the presently claimed controlled release oral pharmaceutical compositions is other than a gum. *In re Johnson*, 558 F.2d 1008 (C.C.P.A. 1977).

New claims 3, 4, 6, 8, 10 and 12 have been added to specify that the hydrogel-forming hydrophilic excipient comprises hydroxypropyl cellulose. Support for these claims can be found in the as-filed specification at least in Example 1 (paragraphs [0047] to [0051]) and Example 2 (paragraphs [0052] to [0055]).

New claim 5 has been added to specify that the gastro resistant film comprises at least one methacrylic acid polymer or copolymer. Support for this claim can be found in the as-filed specification at least in Example 1 (paragraphs [0047] to [0051]) and Example 2 (paragraphs [0052] to [0055]).

New claim 7 has been added to specify that the lipophilic excipient and amphiphilic excipient are in a 1:1 ratio. Support for this claim can be found in the as-filed specification at least in Example 1 (paragraphs [0047] to [0051]) and Example 2 (paragraphs [0052] to [0055]).

New claim 9 has been added to specify that the lipophilic excipient is stearic acid. Support for this claim can be found in the as-filed specification at least in Example 1 (paragraphs [0047] to [0051]) and Example 2 (paragraphs [0052] to [0055]).



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