MAIL STOP AFTER FINAL
EXPEDITED PROCESSING

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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 AND RESPONSE TO OFFICE ACTION

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In response to the Office Action[1] dated May 16 2013, please further amend this application as follows. No additional fee is believed to be due. In the event that a fee is required in connection with the filing of this Amendment and Response, the Commissioner for Patents is authorized to charge the amount of such fee to Rothwell, Figg, Ernst and Manbeck PC Deposit Account No. 02-2135.

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 4 of this paper immediately after the Amendments to the Claims.

[1] During the interview with the Examiner on May 29, 2013, the Examiner indicated that the outstanding Office Action should be a final Office Action, and the non-Final Office Action shown in the Official communication resulted from clerical error.

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~~ consisting essentially of:

(1) a tablet core comprising:

a) budesonide in an amount effective to treat intestinal inflammatory disease[[,]]; and

b) a macroscopically homogeneous composition comprising at least one lipophilic excipient[[;]],

[[c)]] at least one amphiphilic excipient[[;]], and

[[d)]] at least one hydrogel-forming hydrophilic excipient other than a gum, wherein said budesonide is dispersed in said macroscopically homogeneous composition; and

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

2. (Canceled)

3. (Previously Presented) A controlled release oral pharmaceutical composition according to claim 1, wherein said at least one hydrogel-forming hydrophilic excipient comprises at least one hydroxyalkyl cellulose.

4. (Canceled)

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

6. (Previously Presented) A controlled release oral pharmaceutical composition according to claim 5, wherein said at least one hydrogel-forming hydrophilic excipient comprises at least one hydroxyalkyl cellulose.

7-8. (Canceled)

9. (Previously Presented) A controlled release oral pharmaceutical composition according to claim 1, wherein said at least one lipophilic excipient comprises stearic acid or magnesium stearate.

10. (Previously Presented) A controlled release oral pharmaceutical composition according to claim 9, wherein said at least one hydrogel-forming hydrophilic excipient comprises at least one hydroxyalkyl cellulose.

11. (Previously Presented) A controlled release oral pharmaceutical composition according to claim 1, wherein said at least one amphiphilic excipient comprises lecithin.

12. (Previously Presented) A controlled release oral pharmaceutical composition according to claim 11, wherein said at least one hydrogel-forming hydrophilic excipient comprises at least one hydroxyalkyl cellulose.

13. (Previously Presented) A controlled release oral pharmaceutical composition according to claim 11, wherein said at least one lipophilic excipient comprises stearic acid or magnesium stearate.

REMARKS

Applicants thank Examiner Tran and Supervisory Primary Examiner Wax for the many courtesies shown during the personal interview with Applicants' representatives on May 29, 2013, and greatly appreciate the Office's effort to agree on allowable subject matter. [2] Applicants respectfully disagree with the Office's summary of the interview. Hence, Applicants respectfully do not adopt the Examiner's Statements as Applicants' substance of the interview. Applicants will provide immediately hereafter their view of the interview.[3]

Interview Summary

The Office issued an Interview Summary on June 3, 2013, stating:

> Applicants pointed out that the Savastano reference teaches tablet core containing active agent coated with layers of matrix materials, while the present invention is directed to tablet core composes of active agent homogeneously dispersed in the multi-matrix system. During the interview, the Faour et al. reference was also discussed. Applicants proposed to amend the claims to: 1) include budesonide homogeneously dispersed, in the matrix system to overcome the Savastano reference; and 2), recite the transitional phrase "consisting of" to preclude the coating layers taught in Faour. The proposed Amendment appears to place the application in condition for allowance, hence, the Examiner suggested that the Amendment will be reviewed, and the patentability will be determined.

Interview Summary.

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[2] Due to unavoidable circumstances, Examiner Tran was unable to arrive at the USPTO at the hour appointed for the interview. Until she came, Applicants' representatives were graciously received by Supervisory Primary Examiner Wax and informal discussion ensued. But the undersigned understands that the informal discussion with Supervisory Examiner Wax was subsumed in and superseded by the interview with Examiner Tran reported herein. Hence, no separate summary of the discussion with Mr. Wax is deemed necessary.

[3] Of course, no transcript is generated during an interview and Applicants interviewed another five applications at the same time. No doubt, then, that reasonable people can differ in their recollection of this particular interview.

Substance of Interview

MPEP § 713.04 provides eight items (A-H) that should be addressed in Applicants' submission of the substance of the interview. Applicants make the following submissions regarding each of those items:

(A) The following draft claim formed at least part of the basis for the discussion:

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

(1) a tablet core comprising:

a) budesonide in an amount effective to treat intestinal inflammatory disease, and

b) a matrix comprising:

i) at least one lipophilic excipient;

[[c]]ii) at least one amphiphilic excipient;

[[d]]iii) at least one hydrogel-forming hydrophilic excipient other than a gum; and

(2) further wherein said controlled release pharmaceutical composition comprises a coating on said tablet core, said coating comprising a gastro-resistant film.

In addition, the following illustrations were shown at the interview:

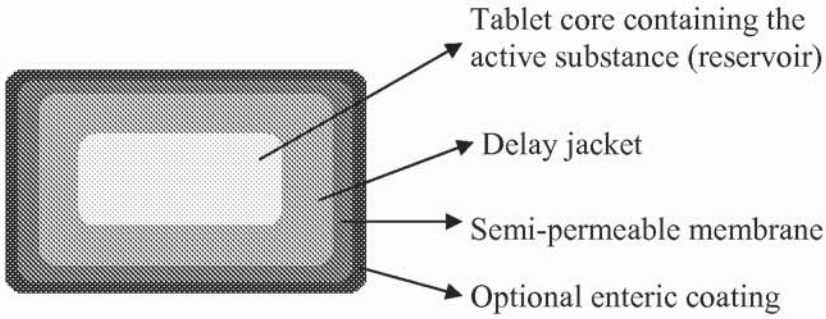

Figure 1. Structure of Savastano's drug delivery device.

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