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 ADVISORY ACTION

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

Dear Sir:

In further response to the Final Office Action dated 22 August 2013 and in response to the Advisory Action dated 18 October 2013, please further amend this application as follows.

Amendments to the Claims begin on page 2 of this paper. The amendments to the claims include those made in the Amendment and Response filed on 26 September 2013.

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

Exhibit 1013

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 consisting essentially of:

(1) a tablet core ~~comprising~~ consisting essentially of:

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

b) a macroscopically homogeneous composition comprising at least one lipophilic excipient, at least one amphiphilic excipient, and 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~~ consisting essentially of 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. (Currently Amended) A controlled release oral pharmaceutical composition according to claim 1, wherein said gastro-resistant film ~~comprises~~ consists essentially of 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

Status of Claims

Claims 1, 3, 5, 6, and 9-13, as amended, are currently pending and under examination. Claims 2, 4, 7 and 8 were previously canceled. Claims 1 and 5 are currently amended. Support for the amendments can be found throughout the specification, for example, at paragraphs [0047], [0051], [0052], [0080], and [0082] in the substitute Specification. Applicants note that the amendment to claim 5 and the amendment to the tablet core language in claim 1 are newly made in the paper. Applicants submit that these amendments do not constitute new matter, raise new issues, or require further searching. Thus, their entry and allowance are requested.

Examiner Interview

The undersigned thanks the Examiner for the courtesies shown during the telephone interview held on 18 October 2013. During the interview, the undersigned discussed the possibility of amending claim 5 to change the language to "consisting essentially of" in order to overcome the continued rejection of the claims. The Examiner indicated that this amendment might overcome the rejection as made with respect to the coating, but she would need to review the references. The Examiner then raised a further issue with the claims in the context of the outstanding rejections. This issue concerned the language "comprising" as used with respect to the tablet core. The Examiner said that she believes that this language does not exclude a coating. As a basis for this belief, the Examiner explained that there are many types of tablet cores including those made by coating a particle, such as with a drug layer and with further layers. Thus, she believes that this comprising language for the tablet core allows other layers, such as a coating layer of Lerner.

Rejection under 35 U.S.C. § 102(a) over Lerner

The Examiner has rejected claims 1, 5 and 6, as allegedly anticipated by U.S. Patent No. 5,840,332 to Lerner et al. ("Lerner"). Final Office Action at 2-3.

Claim 1 as amended is patentable over Lerner. Claim 1 specifies a controlled release oral pharmaceutical composition that consists essentially of a table core and a coating. The table core

consists essentially of budesonide and a macroscopically homogeneous composition. This macroscopically homogeneous composition comprises (i) at least one lipophilic excipient, (ii) at least one amphiphilic excipient and (iii) at least one hydrogel-forming hydrophilic excipient other than a gum. The budesonide is dispersed in the macroscopically homogeneous composition.

According to the Examiner,

> Lerner teaches a gastrointestinal drug delivery system comprising an active core surround by a coating. See abstract. Core in a form of a matrix tablet comprises drug and combinations of pectin, calcium pectinate, hydroxypropylmethyl cellulose, microcrystalline cellulose, lactose, starch, calcium phosphate, and polyvinylpyrrolidone (column 6, lines 9-10; and column 8, lines 35-64). Coating comprises methacrylic acid. See column 9, lines 28-65. Drug includes budesonide suitable for irritable bowel syndrome and the like (column 6, lines 44-57; and column 12, line 43).

Final Office Action at 3.

Applicant submits that Lerner does not teach a tablet core that consists essentially of a macroscopically homogeneous composition comprising "(i) at least one lipophilic excipient, (ii) at least one amphiphilic excipient and (iii) at least one hydrogel-forming hydrophilic excipient other than a gum." Thus, Lerner does not describe all of the elements of the macroscopically homogeneous composition and hence does not describe all of the elements of the tablet core. Therefore, Lerner does not anticipate the subject matter of amended claim 1. For these reasons alone, the rejection under 35 U.S.C. § 102(a) in view of Lerner should be withdrawn.

Furthermore, Applicants have amended claim 1 to recite the transitional phrase "consisting essentially of" in part (2) with respect to the coating. That is, part (2) now recites "a coating on said tablet core, said coating **consisting essentially of** a gastro-resistant film." In addition, Applicants have amended claim 5 to recite the transitional phrase "consisting essentially of" with respect to the gastro-resistant film in order to make the language consistent with the language of amended claim 1. It will not be in dispute that "consisting essentially of" is used to exclude from the claim that which affects the basic and novel characteristics of the claimed invention. *See* MPEP 2163(II)(A)(1). The amendment to claim 5 makes it clear that the

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