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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: VERMEERSCH, Hans Wim Pieter et al. **Art Unit:** 1625
Serial No.: 10/514,352 **Examiner:** CHANG, Celia C.
Filed: November 12, 2004 **Confirmation Number:** 9009
For : PSEUDOPOLYMORPHIC FORMS OF A HIV PROTEASE INHIBITOR

Mail Stop: Patent Application (Response)
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

RESPONSE & AMENDMENT

Dear Sir:

This is a response to the Office communication dated January 14, 2008, response to which is due, with a 3-month extension, on July 14, 2008. Appropriate extension of time request is contained herein.

☐ Amendments to the Specification begin on page of this paper.

☒ Amendments to the claims are reflected in the listing of the claims that begins on page 2 of this paper.

☐ Amendments to the Drawings begin on page of this paper and include an attached replacement sheet.

☒ Remarks begin on 4 of this paper.

EXTENSION OF TIME

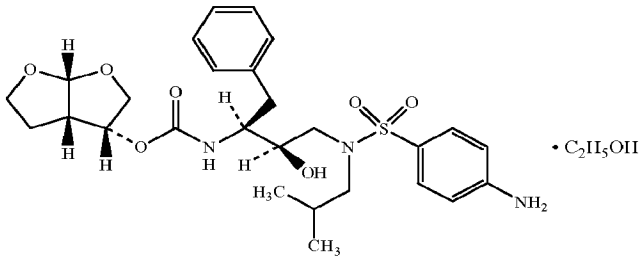
It is requested that the period for filing a response to the present office action be extended three months to July 14, 2008. The Commissioner is hereby authorized to charge the extension fee of $1,050.00 and any other fees that may be required by this paper to Deposit Account 10-0750/TIP0033USPCT/AGK.

Listing of Claims:

This listing of claims replaces all prior versions, and listings, of claims in the captioned application.

Claims 1-18 (cancelled)

19. (New) An ethanolate solvate of the compound (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-yl (1 S,2R)-3-[[(4-aminophenyl) sulfonyl] (isobutyl) amino]-l-benzyl-2-hydroxypropylcarbamate.
20. (New) A solvate according to claim 19, in which the ratio of compound to ethanol ranges between (5:1) and (1:5).
21. (New) A solvate according to claim 19, in which the ratio of compound to ethanol is about 1:1.
22. (New) A solvate according to claim 21, additionally comprising water molecules.
23. (New) A solvate having the formula:



24. (New) A process for preparing an ethanolate solvate according to claim 19 comprising the steps of combining (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-yl (1S,2R)-3-[[(4-aminophenyl) sulfonyl] (isobutyl) amino]-1-benzyl- 2-hydroxypropylcarbamate with ethanol, and inducing crystallization.
25. (New) A process for preparing an ethanolate solvate according to claim 22 comprising the steps of combining (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-yl (1S,2R)-3-[[(4-aminophenyl) sulfonyl] (isobutyl) amino]-l-benzyl- 2-hydroxypropylcarbamate with ethanol, or mixtures of water and ethanol, and inducing crystallization.
26. (New) Pharmaceutical composition comprising a solvate according to claim 19 and a pharmaceutically acceptable carrier or diluent.
27. (New) Pharmaceutical composition comprising a solvate according to claim 22 and a pharmaceutically acceptable carrier or diluent.
28. (New) A solvate according to claim 23, additionally comprising water molecules.
29. (New) The pharmaceutical composition of claim 26, comprising a solid dosage form.

30. (New) The pharmaceutical composition of claim 26, comprising a solid dosage form.

31. (New) The pharmaceutical composition of claim 29, wherein the solid dosage form is a tablet or capsule.

32. (New) The pharmaceutical composition of claim 30, wherein the solid dosage form is a tablet or capsule.

REMARKS

The claims in the case are 19-32 newly added. These relate to the ethanolate solvate of the compound (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-yl (1 S,2R)-3-[[(4-aminophenyl) sulfonyl] (isobutyl) amino]-l-benzyl-2- hydroxypropylcarbamate. This ethanolate solvate can be partially replaced by water. The newly added claims are supported by the specification.

Claim 19 is to the preferred species of Form A. Claims 20 and 21, are directed to the ratio of compound to ethanol, supported by the specification at p. 7, lines 16-37 as well as original claims 9 and 10. Claim 22 is directed to the ethanolate solvate in which some of the ethanol solvent is replaced by water, supported by the specification at p. 7, lines 27-37.

Claims 23 and 28 are directed to the preferred species by structure. This claim is supported by the specification, Figure 4, wherein the structure is depicted as a 3-dimensional molecule. Claims 29-32 are directed to solid dosage forms. These claims are supported by the specification at page21.

Claims 24 and 25 correspond to original claims Claim 12; and Claims 26 and 27 correspond to original Claim 13, respectively.

In regard to the restriction requirement and the election as summarized by the Examiner, Applicants have the following comments. The line of distinction drawn between the solvates and the hydrates failed to account for an important aspect of applicants' invention: that is, an ethanolate solvate form in which a *portion* of the ethanol is replaced by water. This is a different invention from those outlined within the restriction requirement. The mixture of an ethanolate solvate form with a partial replacement by water is not purely a solvate nor is it purely a hydrate. However, it is *primarily* an ethanolate solvate form, and as such should be considered part of a single invention, and examined together in the instant application. The Examiner had assumed the purity of either solvate or hydrate forms, and the response to the restriction requirement operated under the same assumption. Upon review of the invention and revision of the claims to cover the preferred product candidate, Applicants' attorney has come to the realization that the partial replacement of the ethanolate solvate with some water more correctly is part of a single invention, and should correctly be examined together as a seamless part of the elected invention.

To the extent that the grounds of rejection apply to the newly added claims, Applicants provide the following comments.

Rejection of Claims 1-11, 17 under 35 U.S.C. § 112, Second Paragraph

Claims 1-11 and 17 are rejected under 35 U.S.C. § 112, Second Paragraph, as being indefinite (Office Action at page 2). Specifically, the Office Action states: "It is unclear what is a 'pseudomorph'" (Office Action at page 2). Applicant respectfully points out that the term used in the instant application is "pseudopolymorph" and not "pseudomorph".

Applicant respectfully disagrees with the Examiner's assertion that the term "pseudopolymorph" is unclear. However, in the interest of expediting allowance, Applicant has amended the claims at issue to replace the term "pseudopolymorph" with "solvate". Support for the amendment is found in the Specification generally and at page 3. Applicant notes that the "one skilled in the art" cited by the Examiner, Kenneth R. Seddon, a chemistry professor at Queen's University, Belfast, suggests that the term "solvate" be used in place of the term "pseudopolymorph":

> So let us be clear. The term pseudopolymorph is now commonly being applied to mean the solvate, or (in the specific case of water) hydrate, of a material. We gain no new understanding by introducing the term "pseudopolymorphs", and indeed it is pedagogically misleading. It has been introduced into the literature, but I believe it should be expunged; editors should insist that it is removed from manuscripts in which it is used prior to publication. The term "solvate" has been around for centuries, is universally understood, and is a perfect descriptor for these materials. Why introduce unnecessary and misleading jargon?

(Crystal Growth & Design, 4 (6), 1087 –1087, **2004**).

Accordingly, Applicant requests withdrawal of the rejection, insofar as it could apply to the newly added claims in the application, under 35 U.S.C. § 112, Second Paragraph.

Rejection of Claims 1-11, 16-17 and 12 under 35 U.S.C. § 112, First Paragraph

Claims 1-11, 16-17 and 12 are rejected under 35 U.S.C. § 112, First Paragraph, as failing to comply with the enablement requirement (Office Action at pages 3-6). This rejection is moot, as the claims presently in the application relate to the ethanolate solvate form of the compound (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-yl (1S,2R)-3-[[(4-aminophenyl) sulfonyl] (isobutyl) amino]-1-benzyl-2-hydroxypropylcarbamate , clearly enabled within the

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