

DOCKET NO.: TIBO-0063
Application No.: 12/536,807
Office Action Dated: September 12, 2011

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Hans Wim Peter Vermeersch

Confirmation No.: **4088**

Application No.: **12/536,807**

Group Art Unit: **1625**

Filing Date: **August 6, 2009**

Examiner: **Celia C. Chang**

For: **PSEUDOPOLYMORPHIC FORMS OF A HIV PROTEASE INHIBITOR**

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY PURSUANT TO 37 CFR § 1.111

In response to the Official Action dated **September 12, 2011**, reconsideration is respectfully requested in view of the amendments and/or remarks as indicated below:

- Amendments to the Specification** begin on page of this paper.
- Amendments to the Claims** are reflected in the listing of the claims which 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 page 5 of this paper.
- The Commissioner is hereby authorized to charge any fee deficiency, charge any additional fees, or credit any overpayment of fees, associated with this application in connection with this filing, or any future filing, submitted to the U.S. Patent and Trademark Office during the pendency of this application, to Deposit Account No. 23-3050.

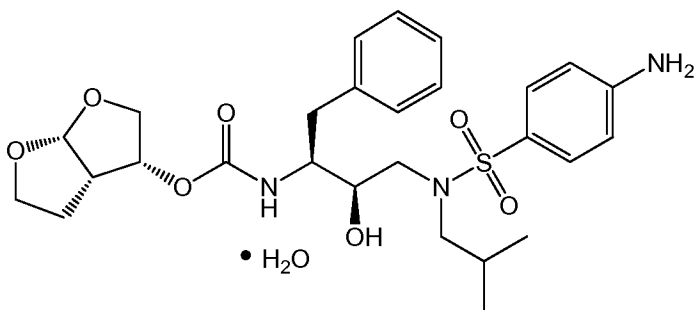
This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claims 1- 14 Cancelled

15. (Currently Amended) A hydrate 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 in which the ratio of the compound to water is about 1:0.5 to about 1:34:1.

16. (Currently Amended) A ~~hydrate~~ solvate having the formula:



17. (Currently Amended) A composition comprising a ~~an~~ hydrate 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, in which the ratio of compound to water is about 1:0.5 to about 1:34:1, and an inert carrier.

18. (Canceled)

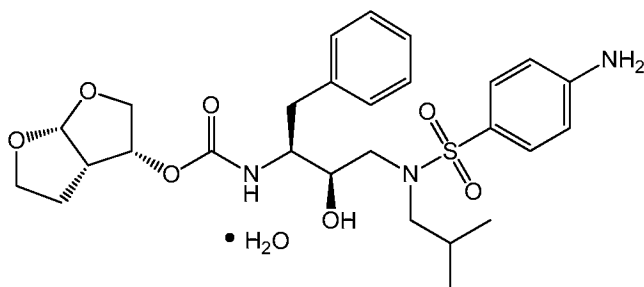
19. (Canceled)

20. (Previously Presented) The composition of claim 17 wherein the inert carrier is a pharmaceutically acceptable carrier.

21. (Currently Amended) The composition of claim ~~[[19]]~~ 20 wherein the pharmaceutically acceptable carrier is a solid inert carrier.

22. (Canceled)

23. (New) A composition comprising a hydrate having the formula:



and an inert carrier.

24. (New) The composition of claim 23 wherein the inert carrier is a pharmaceutically acceptable carrier.

25. (New) The composition of claim 24 wherein the pharmaceutically acceptable carrier is a solid inert carrier.

26. (New) The hydrate of claim 15 wherein the ratio of the compound to water is about 1:1 to about 1:2.

27. (New) The hydrate of claim 15 wherein the ratio of the compound to water is about 1:0.5.

28. (New) The hydrate of claim 15 wherein the ratio of the compound to water is about 1:1.

29. (New) The hydrate of claim 15 wherein the ratio of the compound to water is about 1:2.

30. (New) The hydrate of claim 15 wherein the ratio of the compound to water is about 1:3.

31. (New) The composition of claim 17 wherein the ratio of the compound to water is about 1:1 to about 1:2.

32. (New) The composition of claim 17 wherein the ratio of the compound to water is about 1:0.5.

33. (New) The composition of claim 17 wherein the ratio of the compound to water is about 1:1.

34. (New) The composition of claim 17 wherein the ratio of the compound to water is about 1:2.

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35. (New) The composition of claim 17 wherein the ratio of the compound to water is about 1:3.
36. (New) The composition of claim 17 further comprising amorphous (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-yl (1 S,2R)-3-[[(4-aminophenyl) sulfonyl] (isobutyl) amino]-l-benzyl-2-hydroxypropylcarbamate.

REMARKS

Claims 15 and 17 have been amended to correct minor typographical errors and to recite that the ratio of compound to water is from about 1:0.5 to about 1:3. Support for the amendments can be found throughout the specification, for example, at Example 4, Table 10, Example 11, Table 18, and Example 12.

Claim 16 has been amended to recite a hydrate having the claimed formula

Claims 23-36 are new. Claim 23 recites a composition comprising a hydrate and an inert carrier. Claims 24 and 25 depend from claim 23. Applicants note that claims 23 and 24 include subject matter from claims 18 and 19, now canceled. Claims 26-30 depend from claim 15 and recite a ratio of compound to water. Similarly, claims 31-36 depend from claim 17 and recited a ratio of compound to water.

No new matter has been added.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 15-22 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. The Office alleges that it is unclear whether the product of claim 15 is the same as that of claim 16, but it is clear that claim 16 is of narrower scope than claim 15. Claim 15 recites a hydrate of the compound (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-yl (1 S,2R)-3-[[[(4-aminophenyl) sulfonyl] (isobutyl) amino]-1-benzyl-2- hydroxypropylcarbamate in which the ratio of the compound to water is about 1:0.5 to about 1:3. Claim 16, however, recites a hydrate in which there is a 1:1 ratio of (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-yl (1 S,2R)-3-[[[(4-aminophenyl) sulfonyl] (isobutyl) amino]-1-benzyl-2- hydroxypropylcarbamate and water. Thus, the relative scope of these claims is clear.

The Office also alleges that it is unclear whether the composition of claim 17 is the same as that of claim 18. Amended claim 17 is directed to a composition in which the ratio of the recited compound to water is about 1:0.5 to about 1:3. Claim 23, which replaces claim 18, recites a chemical formula depicting a 1:1 ratio of the compound and water, and an inert carrier. Thus, claim 23 clearly is narrower than claim 17.

Applicants accordingly request withdrawal of these rejections.

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