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12/536,807	08/06/2009	Hans Wim Pieter VERMEERSCH	TIP-0033USDIV1	4088
27777	7590	09/12/2011	EXAMINER	
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			ART UNIT	PAPER NUMBER
			1625	
			NOTIFICATION DATE	DELIVERY MODE
			09/12/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No. 12/536,807	Applicant(s) VERMEERSCH ET AL.
Examiner CELIA CHANG	Art Unit 1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 October 2020.
- 2a) This action is **FINAL**.
- 2b) This action is non-final.
- 3) An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) Claim(s) 15-22 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) Claim(s) ____ is/are allowed.
- 7) Claim(s) 15-22 is/are rejected.
- 8) Claim(s) ____ is/are objected to.
- 9) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) The specification is objected to by the Examiner.
- 11) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/6/09, 10/16/09.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) Notice of Informal Patent Application
- 6) Other: ____.

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DETAILED ACTION

1. This application is a divisional of SN 10/514,352.

Claims 1-14 have been canceled.

Claims 15-22 are pending.

2. Claims 15-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear whether the product of claim 15 is the same as that of claim 16; or the composition of claim 17 is the same as that of claim 18 or the relationship among claims 19-22 and their base claims.

Please note that a crystalline form can exist as a solvate of a hydrate, thus, it is unclear what is claim 16 or 18 etc. because it is unclear whether a "solvate" of formula in claim 16 is "the" hydrate of the formula or a solvate of the formula. The same rationale also applies to claims 17, 19-22.

If they are the same product, then, it is recommended that the term "solvate" be deleted from claims 17 and 18 to be consistent of the claiming of a product.

3. Claims 19 and 21 are rejected to under 35 U. S. C. 112 4th paragraph or 37 CFR 1.75(c), as being of improper dependent form or for failing to further limit the subject matter of a previous claim. Please note that claims 19 and 21 depends on a composition for which no antecedent basis was found in the base claim. It is further questioned that since the composition comprises other than the compounds of the base claim, whether the claims are further limiting of the base scope. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

A survey of the specification as compare with the prior art has been made and the analysis is as following:

It is well known in the art that a compound per se and a salt, solvate or hydrate of the compound are not the same chemical product i.e. different chemical identity (Seddon). There is no predictability in possession of a compound per se to be in possession of any solvate, hydrate or mixed solvate/hydrate (see Braga, cited on 1449). Since it is considered that in possession of the compound per se to predict any form of solvate/hydrate is a nightmare, one can only patent the product after showing possession of such a product.

The specification, on p.23, disclosed that, form B has the characteristic as:

“Form B: a weight loss of 3.4% was observed in the temperature range 25-78°C (water) and of 5.1% in the temperature range 25-110°C (ethanol + water for T>78°C). From 110-200°C further 1.1% weight was lost (ethanol).”

There is insufficient antecedent basis to support the scope of claim 15 wherein the hydrate is a monohydrate i.e. 1:1 ratio. There is no description for the claims being hydrate of the compound (3 R,3 aS,6aR)- hexahydrofuro [2,3-b] furan-3-yl (1 S,2R)-3-[[4-aminophenyl sulfonyl] (isobutyl) amino]-1-benzyl-2- hydroxypropyl carbamaterin which the ratio of compound to water is about 1:1 because the characteristic of form B as indicated supra included loss of water and ethanol; also because there was no explicit process of how to make the 1:1 ratio hydrate (see process p.22-23 only described steps for form D). Were the 1:1 ratio hydrate made by the same steps as disclosed on p.22-23, example 2, there is no information as to how water or ethanol were included. Were the 1:1 ratio hydrate made by alternative processes, the claims would constitute claiming a new matter. Nowhere in the specification such a product was prepared or the structural formula of claim 16 or 18 be found.

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5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916), where the Supreme Court looked to whether the experimentation needed to practice an invention was undue or unreasonable. *Id.* An invention must be described so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). As stated in the MPEP 2164.01(a) “There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. The analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. *Id.* at 740, *Id.* at 1407. The factors to be considered herein are those set forth as the *In re Wands*, 8 USPQ 2nd 1400 (1988) decision.

The analysis is applied to the instant case.

Nature of invention

The claims are drawn to polymorphic crystalline forms of (3 R,3aS,6aR)- hexahydrofuro [2,3-b] furan-3-yl (1 S,2R)-3-[[4-aminophenyl)sulfonyl] (isobutyl) amino]-l-benzyl-2-hydroxypropyl carbamaterin. Polymorphic forms are highly specific chemical compounds with particular molecular packing. A hydrate or solvate of the same compound is not a polymorphic form but a different chemical entity (see Seddon)

Breadth of the claims

The claims are drawn to hydrate of (3 R,3aS,6aR)- hexahydrofuro [2,3-b] furan-3-yl (1 S,2R)-3-[[4-aminophenyl)sulfonyl] (isobutyl) amino]-l-benzyl-2- hydroxypropyl carbamaterin, wherein the compound to water is 1:1. To claim such a product, the monohydrate of the compound must be prepared.

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