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12/536,807	08/06/2009	Hans Wim Pieter VERMEERSCH	TIP-0033USDIV1	4088
45511	7590	05/22/2012	EXAMINER	
WOODCOCK WASHBURN LLP CIRA CENTRE, 12TH FLOOR 2929 ARCH STREET PHILADELPHIA, PA 19104-2891			CHANG, CELIA C	
			ART UNIT	PAPER NUMBER
			1625	
			NOTIFICATION DATE	DELIVERY MODE
			05/22/2012	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):

eofficemonitor@woodcock.com

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 10 April 2012.
- 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) 15-17, 20, 21 and 23-36 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5a) Of the above claim(s) _____ is/are withdrawn from consideration.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) 15-17, 20-21, 23-36 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 11/9/11, 4/10/12.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

Art Unit: 1625

DETAILED ACTION

1. Amendment and response filed by applicants dated Mar. 12, 2012 have been entered and considered carefully.

Claims 1-14, 18-19, 22 have been canceled. Claims 23-36 have been added. Claims 15-17, 20-21, 23-36 are pending.

2. The rejection of claims 15-22 (now 15-17, 20-21, 23-36) 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.

The current amendment in claim 15 drawn to “A hydrate” having ratio 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 to water to be about 1:0.5 to 1:3 is confusing. Initially, it is unclear is there one hydrate, many hydrates or how many hydrates.

Claims 16 makes claim 15 confusing because claim 16 is monohydrate yet claim 15 is a range and normally, the range is a continuous value. Claims 23-35 are unclear for the same reason that they are discrete compounds which chemically does not form a continuous range as its antecedent basis in the base claim 15.

Since hydrates are known as hemihydrate, monohydrate, di-, tri-...etc. if the claims are a group discrete compounds, the Markush elements are hemi-, mono, di- and tri-hydrate not a range of water content.

3. The rejection of claims 19 and 21 under 35 U. S. C. 112 4th paragraph or 37 CFR 1.75(c), as being of improper dependent form is dropped in view of cancellation of claim 19 and change of dependency of claim 21.

4. The rejection of claims 15-22 (now applicable to claims 15-17, 20-21, 23-36) under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reason of record and claims 16, 23-35 are rejected also for containing new matter.

Applicants pointed to table 10 as the antecedent basis for the claimed products.

Art Unit: 1625

[0117] Table 10 shows approximate expected mass losses for different Forms in thermogravimetric (TG) experiments.

Mass loss in % ($M_{t+T}/M_{t=100\%}$)

Pseudopolymorph	BP[° C.]	Hemi-solvate	Mono-solvate	Di-solvate	Tri-solvate
Form D	56	5.0	9.6	17.5	24.1
Form H	152	9.0	16.5	28.3	37.2
Form E	46	7.2	13.4	23.7	31.8
Form G	119	7.6	14.1	24.8	33.1
Form F	76	7.4	13.9	24.3	32.6
Form A	78	4.0	7.8	14.4	20.2
Form B	106	1.6	3.2	6.2	9.0
Form C	65	2.8	5.5	10.5	14.9
Form I	66	6.2	11.6	20.8	28.3

It is clearly described that table 10 is “expected mass losses” that is it is a calculated loss if such mass was found in thermogravimetric experiments. The experimental results for example were:

[0116] The following TG data were obtained:

Form A: a weight loss of 4.2% was observed in the temperature range of 25-138° C. (ethanol+little water) and of 6.9% (ethanol+CO₂) in the temperature range of 25-200° C. Ethanol loss rate was maximal at 120° C. CO₂ loss was due to chemical degradation and was visible at around 190° C.

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).

The specification has not provided any product that showed water loss corresponding to the above table or to the claims i.e. a *continuous range* between 0.5-3 molecules of water per molecule of the compound. This is further evidenced by the structural delineation of the products of the instant application being indexed by CAS wherein a 1:1 ratio ethanolate was indexed with other solvate/hydrate being of *indefinite* ratio (see CA140).

Therefore, the explicit compounds having 1:0.5m 1:2, 1:3 etc. are new matter for which no antecedent basis of possession was found.

Art Unit: 1625

5. The rejection of claims 15-22 (now applicable to claims 15-17, 20-21, 23-36) under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reason of record.

The Wands analysis in the record is as following:

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.

The state of the art and predictability

The standard of the amount of guidance or direction needed to enable an invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling. In the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles. Most often, additional factors, such as the teachings in pertinent references, will be available to substantiate any doubts that the asserted scope of objective enablement is in fact commensurate with the scope of protection sought and to support any demands based thereon for proof."

In the instant case, specific crystal preparation requires very limited and specific process to obtain consistent single crystalline forms. Based on the level of skill as stated in the state of the art reference *Kirk-Othmer Encyclopedia of Chemical Technology* Copyright © 2002 by John Wiley & Sons, Inc., pp. 95-147, Article Online Posting Date: August 16, 2002, the amount of guidance in the specification, the disclosure does not contain sufficient information to enable one skilled in the pertinent art for recovery of such a product as claimed.

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