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10/514,352	11/12/2004	Hans Wim Pieter Vermeersch	TIP-0033 US	9009
27777	7590	01/14/2008	EXAMINER	
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			ART UNIT	PAPER NUMBER
			1625	
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**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.

Office Action Summary

10/514,352

VERMEERSCH ET AL.

Examiner

Art Unit

Celia Chang

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) [X] Responsive to communication(s) filed on 24 September 2007.
2a) [ ] This action is FINAL. 2b) [X] This action is non-final.
3) [ ] 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

- 4) [X] Claim(s) 1-13 and 15-17 is/are pending in the application.
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
5) [ ] Claim(s) \_\_\_\_\_ is/are allowed.
6) [X] Claim(s) 1-13, 15-17 is/are rejected.
7) [ ] Claim(s) \_\_\_\_\_ is/are objected to.
8) [ ] Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) [ ] The specification is objected to by the Examiner.
10) [ ] 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).
11) [ ] 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

- 12) [ ] 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) [X] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [ ] Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date \_\_\_\_\_.
4) [ ] Interview Summary (PTO-413) Paper No(s)/Mail Date. \_\_\_\_\_.
5) [ ] Notice of Informal Patent Application
6) [ ] Other: \_\_\_\_\_.

### DETAILED ACTION

1. Applicant's election of Group I, claims 9-10, with ethanolate as the elected species in the reply filed on Sept. 24, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Claim 14 has been canceled. Claims 15-17 have been added. Claims 1-13, 15-17 are pending.

2. Claims 1-11, 17 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 what subject matter was being claimed. Please note that for utility patent, the category of novel and unobvious product/material or compositions of matter can be claimed. It is unclear what is a "pseudomorph". According to skilled person in the art (see Seddon) the term "pseudomorph" is very ambiguous and does not define the chemical identity of a product. The elected species which is (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-yl (1 S,2R)-3-[[[(4-aminophenyl) sulfonyl] (isobutyl) amino]-l-benzyl-2- hydroxypropylcarbamate ethanolate 1:1, is a single chemical product (see RN 635728-49-3). The chemical identity demarcates the elected compound from the known compound (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-yl (1 S,2R)-3-[[[(4-aminophenyl) sulfonyl] (isobutyl) amino]-l-benzyl-2- hydroxypropylcarbamate. Skilled person in the chemical art does not call such a compound a pseudomorph. Seddon stated clearly that such empirical use of the term should have been corrected with the modern advancement in the art by clearly identify the products obtained using its chemical identify such as delineated by CAS.

It is unclear what is the intended scope of the claims: Are they referring to the compounds which have been obtained/possessed in the specification? Are they multiple products which are extrapolated from the compounds obtained by the specification? Or are they future products possibly obtained when solvents and (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-

3-yl (1 S,2R)-3-[[[4-aminophenyl) sulfonyl] (isobutyl) amino]-1-benzyl-2-hydroxypropylcarbamate were brought together?

According to Seddon, solvates are *chemically different* products which should be named according to its own chemical identity while forms are different packing solid material with identical chemical and molecular composition thus it created enormous confusion when claims are drawn to (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-yl (1 S,2R)-3-[[[4-aminophenyl) sulfonyl] (isobutyl) amino]-1-benzyl-2- hydroxypropylcarbamate, form A which is a product having (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-yl (1 S,2R)-3-[[[4-aminophenyl) sulfonyl] (isobutyl) amino]-1-benzyl-2- hydroxypropylcarbamate:ethanol in 1:1 ratio, further, such from A can "comprising water" in indefinite amount.

3. Claim 12 is 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 [in accordance with the statute] was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled 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). See also *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.").

In the instant case, the claim is drawn to a process of making any crystalline material with any molecular composition by contacting 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, form A which is a product having (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-yl (1 S,2R)-3-[[[4-aminophenyl) sulfonyl] (isobutyl) amino]-1-benzyl-2-hydroxypropylcarbamate with an organic solvent. 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.

Specifically, 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, the state of the art of polymorph recovery is highly unpredictable. See for example *Kirk-Othmer Encyclopedia of Chemical Technology* Copyright © 2002 by John Wiley & Sons, Inc., pp. 95-147, Article Online Posting Date: August 16, 2002. This article indicates that many uncertain factors determine morphology, and specifically that the appearance

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