

DOCKET NO.: TIBO-0063
Application No.: 12/536,807
Actions Dated: May 22, 2012 and July 27, 2012

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Hans Wim Pieter 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 AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicants respectfully request a pre-appeal brief conference for review and reconsideration of the final rejection of claims 15-17, 20, 21, and 23-36 (the only pending claims) dated May 22, 2012, in the above-identified patent application.

This request is being filed together with a notice of appeal, no amendments are being filed with this request, and no more than five sheets of remarks.

REMARKS

Claims 15-17, 20, 21, and 23-36 are pending in this patent application. The Examiner alleges that these claims are indefinite under 35 U.S.C. § 112, second paragraph. The Examiner also alleges that all the claims lack both written description and enablement under 35 U.S.C. § 112, first paragraph.

The Examiner Has Not Identified Any Respect In Which Those Skilled In The Art Would Have Found The Claims Indefinite

Claims 15-17, 20, 21, and 23-36 stand rejected under 35 U.S.C. § 112, second paragraph, due to an alleged inconsistency between the fact that claim 15 is directed to “A hydrate” yet embraces *multiple* hydrates that each include the specified proportions of water and recited compound. However, it is well established that an applicant may present a patent claim that (as in claim 15) uses the definite article “a” to embrace each of multiple embodiments of an invention (*see, e.g.*, U.S. Patent No. 7,553,974). The Office Action also alleges that it is unclear “how many hydrates” are within the scope of claim 15 (May 22, 2012 Final Office Action at page 2), but there is no requirement under the patent laws for a claim to specify how many embodiments it includes. Accordingly, there is no basis for the Examiner’s assertions regarding alleged indefiniteness.

There is similarly no basis for the Examiner’s assertion that the term “hydrate” is indefinite. The instant specification expressly defines “hydrates” as “substances that are formed by adding water molecules.” (Specification at page 6, lines 6-7). This clear definition refutes the Examiner's assertion that those skilled in the art would have found Applicants’ claim language to have been “confusing” (May 22, 2012 Final Office Action at page 2).

Claim 16 has been alleged to make claim 15 confusing, but this rejection also lacks basis. Claim 16 specifies that the ratio of compound to water be 1:1, which is well within the range (*i.e.*, 1:0.5 to about 1:3) that is recited in claim 15.

Accordingly, Applicants request that the rejection for alleged indefiniteness be withdrawn.

The Examiner Has Failed To Identify Any Respect In Which Those Skilled In The Art Would Have Questioned Applicants' Possession Of The Claimed Methods

Claims 15-17, 20, 21, and 23-36 stand rejected under 35 U.S.C. § 112, first paragraph, because Applicants' disclosure allegedly does not provide adequate support for the ratios that are recited in claim 15. Applicants request withdrawal of this rejection because their disclosure reasonably conveys to those skilled in the art that Applicants were in possession of the claimed subject matter.

To determine whether a specification contains adequate written description of the claimed subject matter, the critical question is not whether literal description of the claimed subject matter is present in the specification but, rather, whether review of the specification would convey the claimed subject matter to those having skill in the art. *In re Edwards*, 568 F.2d 1349, 1351-1352 (C.C.P.A. 1978). In rejecting a claim for lack of written description, the examiner carries the burden of providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed (*see* MPEP §2163.04).

Here, the Examiner has failed to make any such showing. The Examiner contends that Applicants were not in possession of "hydrates" at the time of filing because the instant specification describes compounds that are not only hydrated (by virtue of their inclusion of water) but also include ethanol. (May 22, 2012 Final Office Action at page 32). However, there is no basis for the Examiner's restrictive definition of the term "hydrate." As noted above, for example, the Specification clearly defines "hydrates," in a non-limiting way, as "substances that are formed by adding water molecules." The presence, or absence, of ethanol is, per this definition, irrelevant in determining whether a substance of interest is a "hydrate."

The Examiner also appears to contend that the pending claims lack written description because they recite a "continuous range" of water molecules per molecule of compound, whereas hydrates include discrete ratios of these components (*id.* at page 3). Applicants' use of a continuous range, however, does not demonstrate any lack of written description. Indeed, those skilled in the art frequently use "continuous" ranges to describe phenomena that are known to occur in fixed intervals. For example, the term "C₁₋₁₀ alkyl group" is widely

used to describe chemical substituent groups, even in instances in which the substituent does not include a non-integer number of carbon atoms, *e.g.*, 3.5 carbon atoms. (*see, e.g.*, U.S. Patent No. 8,227,506). The Examiner thus has failed to identify any basis for questioning Applicants' possession of the claimed subject matter.

The Examiner Has Failed To Establish That Those Skilled In The Art Would Not Be Able To Practice The Claimed Methods

Claims 15-17, 20, 21, and 23-36 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled. According to the Office Action, "the disclosure does not contain sufficient information to enable one skilled in the pertinent art for recovery of [specific crystal preparations]." (May 22, 2012 Final Office Action at page 4). Applicants request withdrawal of this rejection because the evidence of record indicates that Applicants' disclosure would have enabled those skilled in the art to practice the claimed inventions.

Enablement must be evaluated against the claimed subject matter. MPEP 2164.08. "Accordingly, the first analytical step requires that the examiner determine exactly what subject matter is encompassed by the claims." *Id.* The pending claims are directed to, among other things, hydrates of the claimed compound. As defined in the specification, "hydrates" are "substances that are formed by adding water molecules." (Specification at page 6, lines 6-7).¹

The Examiner has failed to identify any respect in which those skilled in the art would have been unable to practice the claimed methods and prepare compositions wherein water molecules have been added to the recited compound. The specification sets forth several examples describing the claimed compound and water. As noted above, Example 2 describes the preparation of a mixture of Form D (acetate) and Form B. As stated in Example 2, the starting compound was stirred in acetone and heated until the compound dissolved. Water was then added and the solution was cooled. The resulting crystals were a mixture of the acetate (Form D) and the hydrate (Form B). Various Form B hydrates were also formed by

¹ The Examiner, rather than interpreting the claims in light of the specification, has alleged that the claims "are drawn to polymorphic crystalline forms of" the claimed compound (May 22, 2012 Office Action at page 4). The claims must be interpreted in light of the specification which, as originally filed, clearly establishes that the Applicants had possession of water molecules added to the claimed compound.

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subjecting Form A to adsorption/desorption tests, as described at Example 7. Form B hydrates were also formed by subjecting a sample of Form B to adsorption/desorption. *See, e.g.,* Example 12.

Because there is no evidence indicating that this disclosure would have been insufficient for those skilled in the art to make the claimed hydrates (*i.e.* substances formed by adding water molecules to the claimed compound) the rejection for alleged lack of enablement should be withdrawn.

The Examiner contends that the claims are not enabled because some of Applicants' experimental examples produce hydrates that include ethanol or amorphous material (May 22, 2012 Final Office Action at pages 6-7), but this fact is irrelevant in assessing enablement because, as noted above, such hydrates are within the scope of Applicants' claims. Because the Examiner's arguments are based upon a restrictive definition of "hydrate" that is at odds with the definition that Applicants provide in their specification, such arguments fail to support rejection of the instant claims for alleged lack of enablement.

Conclusion

The pending claims are in condition for allowance. An early and favorable notice to that effect is, therefore, earnestly solicited.

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