

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Hans Wim Pieter Vermeersch

Confirmation No.: **4088**

Serial 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 Appeal-Brief Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

APPELLANT'S BRIEF PURSUANT TO 37 C.F.R. § 41.37

This brief is being filed in support of Appellant's appeal from the rejections of claims 15-17, 20, 21, and 23-36 dated May 22, 2012. A Notice of Appeal was filed on September 17, 2012.

1. REAL PARTY IN INTEREST

The real party in interest is Janssen R&D Ireland (formerly known as Tibotec Pharmaceuticals Ltd.), to which the inventors have assigned their rights and which is a subsidiary of Johnson & Johnson.

2. RELATED APPEALS AND INTERFERENCES

None.

3. STATUS OF CLAIMS

Rejected: 15-17, 20, 21, and 23-36

Allowed: None

Withdrawn: None

Objected to: None

Cancelled: 1-14, 18, 19, 22

Appealed: 15-17, 20, 21, and 23-36

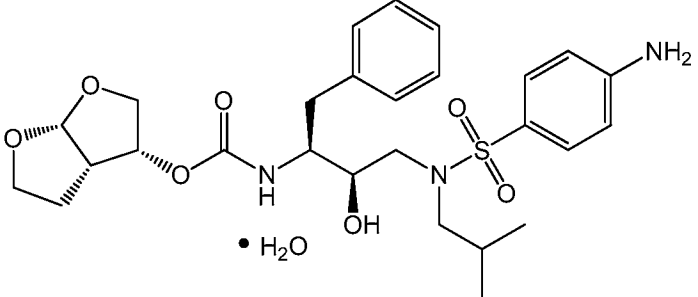
4. STATUS OF AMENDMENTS

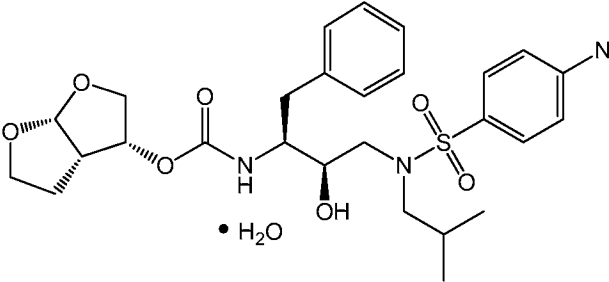
The amendments made in the March 12, 2012, Response to the September 12, 2011, Non-Final Office Action have been entered. No further amendments have been made.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is directed to hydrated, polymorphic forms 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, as well as compositions comprising those forms.

The following summary is for the purpose of complying with the provisions of 37 C.F.R. § 41.37(c)(1)(v). The entire disclosure should be reviewed to obtain a complete understanding of the claim language.

| Claim Language | Citation to Specification |
|--|---|
| 15. 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. | Page 6, lines 5-7; Page 6, lines 16-18; Page 7, lines 10-11. |
| 16. A hydrate having the formula: <div style="text-align: center;">  </div> | Page 6, lines 5-7; Page 6, lines 16-18; Page 7, lines 10-11; Page 25, line 1 et seq. |

| Claim Language | Citation to Specification |
|---|---|
| <p>17. A composition comprising 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 compound to water is about 1:0.5 to about 1:3, and an inert carrier.</p> | <p>Page 6, lines 5-7; Page 6, lines 16-18; Page 7, lines 10-11; lines 16-37; Page 20, lines 8-10; Page 25, line 1 et seq.</p> |
| <p>23. A composition comprising a hydrate having the formula:</p>  <p>and an inert carrier.</p> | <p>Page 6, lines 16-18; Page 7, lines 10-11; lines 16-37; Page 20, lines 8-10.</p> |

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 15-17, 20, 21, and 23-36 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Claims 15-17, 20, 21, and 23-36 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description and enablement.

7. ARGUMENT

The Examiner erred by failing to identify any reason why a person skilled in the art would have found the claims indefinite. The Examiner also erred by failing to identify any reason why such a person would have questioned Applicants' possession of the claimed inventions, or any reason why such a person would have been unable to practice those inventions. Because the Examiner has failed to establish that the claims do not comply with 35 U.S.C. § 112, the rejections of record must be overturned.

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

The Examiner erred by failing to identify any aspect of the pending claims that those skilled in the art would have found indefinite.

“The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification. If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 [second paragraph] demands no more.” *Miles Laboratories, Inc. v. Shandon Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993). If a skilled artisan can determine whether a particular chemical compound is or is not within the scope of a claim, the requirement of § 112, second paragraph has been fulfilled. *In re Miller*, 441 F.2d 689, 692 (C.C.P.A. 1971). Even a claim that reads on numerous chemical compounds is not rendered indefinite by its breadth, so long as the boundaries of patent protection sought are clearly set forth. *In re Barr*, 444 F.2d 588, (595 C.C.P.A. 1971). “The examiner’s focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available.” *In re Swinehart*, 439 F.2d 210 (C.C.P.A. 1971); M.P.E.P. § 2173.02 (emphasis added).

The Examiner has not come forward with any credible evidence or reasoning demonstrating that those skilled in the art would not understand the bounds of the instant claims. Claim 15 stands rejected under 35 U.S.C. § 112, second paragraph, due to an alleged inconsistency between the fact it is directed to “[a] hydrate” yet embraces multiple hydrates that each include the specified proportions of water and recited compound. 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 and *Baldwin Graphic Sys. v. Siebert, Inc.*, 512 F.3d 1338, 1342-43 (Fed. Cir. 2008)). The Examiner 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 "unclear" (May 22, 2012 Final Office Action at page 2).

Claims 16 and 23-25 have been rejected because they allegedly make claim 15 "confusing." (*id.*), but this rejection also lacks basis. None of claims 16 or 23-25 depend from claim 15, nor does claim 15 depend from them. The Examiner has failed to identify any legal basis for rejecting a claim because it renders another, non-interdependent claim "confusing." Even if one of claims 16 and 23-25 did depend from claim 15, there would be no confusion. Claim 16, for example, 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.

Because the Examiner has not supported her rejections for alleged indefiniteness with evidence or reasoning, the rejection should be overturned.

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

Although the Examiner contends that claims 15-17, 20, 21, and 23-36 do not comply with 35 U.S.C. § 112, first paragraph, she has failed to come forward with any evidence or reasoning indicating that those skilled in the art would have questioned Applicants' possession of the claimed subject matter.

To determine whether a specification contains adequate written description, the critical question is not whether it provides a literal description of the claimed subject matter 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 M.P.E.P. §2163.04).

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