

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

## UNITED STATES PATENT AND TRADEMARK OFFICE

---

### BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

---

Ex parte MONTY KRIEGER, and HELENA E. MIETTINEN

---

Appeal No. 2006-0730  
Application No. 10/164,863

---

ON BRIEF

---

Before SCHEINER, ADAMS, and MILLS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

#### DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-9 and 11-16, which are all the claims pending in the application.

Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

1. A method for treating reproductive disorders involving abnormal levels of lipids in a female mammal mediated by SR-BI activity comprising administering an effective amount of a compound altering directly or indirectly the transfer of cholesterol or cholestryl ester from high density lipoprotein or other lipoproteins via SR-BI to liver or steroidogenic tissues to normalize the abnormal levels of lipids and thereby treat one or more symptoms of the reproductive disorder resulting from the abnormal levels of lipids.

The examiner relies on the following reference<sup>1</sup>:

Merriam-Webster dictionary, <http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=symptom&x=13&y=14>.

### GROUNDS OF REJECTION

Claims 1-9 and 11-16 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written descriptive support.

Claims 1-9 and 11-16 stand rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification does not enable those skilled in the art to practice the full scope of the claimed method without undue experimentation.

We reverse.

### BACKGROUND

According to appellants (Brief, page 5), “the fertility of SR-BI KO females . . . can be restored in the absence of ovarian and/or extraovarian SR-BI expression by manipulations that modify the structure, composition and/or abundance of their abnormal plasma lipoproteins.” Accord, specification, page 28. According to appellants (*id.*), “[t]hese manipulations included inactivation of the apolipoprotein A-I gene and administration of the cholesterol-lowering drug PROBUCOL™.”

---

<sup>1</sup> It appears that the examiner made a typographical error in not listing the Dictionary in the “Evidence Relied Upon” section (Section No. 8) of the Answer.

## DISCUSSION

### Written Description:

According to the examiner (Answer, page 2), appellants have not identified a portion of their specification wherein the phrase “treat one or more of the symptoms of the reproductive disorder,” as it appears in claim 1, can be found. With reference to the Merriam-Webster dictionary<sup>2</sup> the examiner finds (Answer, bridging sentence, pages 2-3, emphasis removed), “a symptom is ‘1a: subjective evidence of disease or physical disturbance.’” From this the examiner concludes (Answer, page 3, emphasis removed), “[a]pplicants’ specification is focused on the objective signs of a disease (i.e. infertile), not the subjective sensations of an individual.” We disagree.

Initially, we note that the examiner has relied on a very limited reading of the definition as it appears in the online version of the Merriam-Webster dictionary. For clarity, we reproduce the entire Merriam-Webster dictionary definition for symptom below.

### Symptom:

1 a : subjective evidence of disease or physical disturbance;  
broadly : something that indicates the presence of bodily disorder  
    b : an evident reaction by a plant to a pathogen

2 a : something that indicates the existence of something else  
<symptoms of an inner turmoil> b : a slight indication : TRACE

---

<sup>2</sup> According to the examiner (Answer, page 2), the online version of the Merriam-Webster dictionary was relied upon and the content was retrieved February 16, 2004, “from the internet: URL:<http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=symptom&x=13&y=14>.”

Notwithstanding the examiner's limited reading of the definition, we find the examiner skewed the definition of the term when he applied it in the rejection of record. Specifically, the definition relied upon by the examiner states that a symptom is "subjective evidence of disease or physical disturbance." As applied by the examiner, the "subjective evidence of disease . . ." becomes, "the subjective sensations of an individual." The latter is not what the definition states – "sensations of an individual" are simply not part of the definition relied upon.

Further, the examiner finds that appellants' specification focuses on "objective signs of a disease (i.e. infertil[ity]) . . ." There is no doubt that appellants' specification mentions infertility. Appellants' claims, however, are drawn to "[a] method for treating reproductive disorders involving abnormal levels of lipids in a female mammal mediated by SR-BI activity. . ." See e.g., claim 1. The claim makes no mention of "infertility." As we understand it, the claim language falls directly into the second definition of the term "symptom" as it appears on the online version of the Merriam-Webster's dictionary as cited by the examiner on page 2 of the Answer. Specifically, the definition of symptom as being "something that indicates the existence of something else", e.g., abnormal levels of lipids in a female mammal mediated by SR-BI activity, indicating the existence of a reproductive disorder.

"In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide in haec verba support for the claimed subject matter at issue." Purdue Pharma L.P. v. Faulding, Inc., 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000). Adequate written description

requires only a disclosure that conveys with reasonable clarity to those skilled in the art that the inventor was in possession of the invention. See id.

In this case, the examiner has not adequately explained why the description provided by the specification would not be considered sufficient by those skilled in the art. We therefore reverse the rejection based on the written description provision of 35 U.S.C. § 112, first paragraph.

Enablement:

According to the examiner (Answer, page 3), appellants' specification provides an enabling disclosure of "altering fertility in female mice by knocking out the SR-BI gene. . . ." The examiner finds, however, appellants' specification fails to enable "any method of treating infertility or treating any and all reproductive disorders by altering lipoprotein, LDL, or HDL transfer, or cholesterol levels in a mammal." Id. According to the examiner (id.), appellants "provided no guidance and working examples of any compounds which act via SR-BI to alter fertility . . . other than those in knockout infertile female mice." In response, appellants assert (Brief, page 11), "[a]s demonstrated by the examples at page 10, administering probucol to female mice that are deficient in SR-BI, and characterized by abnormal lipid levels restores their fertility. As discussed at page 28 of the application, the results prove that it is the abnormal lipid levels that cause the infertility." The examiner provides no response to these arguments. As we understand the examiner's arguments, it appears that the examiner's basis for maintaining the rejection is his unsupported premise that

SR-BI knockout mice are not a representative animal model for evaluating “[a] method of treating reproductive disorders involving abnormal levels of lipids in a female mammal mediated by SR-BI activity.” See e.g., claim 1.

“When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.” In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). “[It] is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.” In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). Upon consideration of the record, we find no evidence to support the examiner’s arguments.

In our opinion, the examiner fail to meet his burden of providing the evidence necessary to support his position. The examiner also asserts (Answer, page 4), “[t]here is no evidence [on this record] that altering SR-BI levels in a fertile female with normal SR-BI levels and no reproductive disorders will have

the desired effect of the claimed method.” Apparently, the examiner is misapprehends appellants’ claimed invention. The claimed invention is not a method of treating normal females with no reproductive disorders.<sup>3</sup> To the contrary, the claimed method is drawn to “[a] method of treating reproductive disorders involving abnormal levels of lipids in a female mammal mediated by SR-BI activity. . . .” See e.g., claim 1. Accordingly we are not persuaded by the examiner’s argument.<sup>4</sup>

In addition, we recognize the examiner’s assertion (Answer, page 4, emphasis removed) that it would “be unpredictable to one of ordinary skill in the art how [sic] to alter fertility or treat any and all reproductive disorders simply by altering lipoprotein, HDL, LDL, or cholesterol levels in a mammal, especially since fertility and reproductive disorders all have a separate mechanism of action. . . .” We do not find this argument persuasive. Contrary to the examiner’s assertion, appellants are not claiming the treatment of “any and all reproductive disorders.” Instead, appellants are claiming “[a] method for treating reproductive disorders involving abnormal levels of lipids in a female mammal mediated by SR-BI activity.” In our opinion, the examiner provides no reasonable basis to conclude that treating the reproductive disorders set forth in

---

<sup>3</sup> See e.g., Brief, page 11, wherein appellants assert “[i]f an individual has completely normal cholesterol and lipoprotein levels, there would be no reason based on this application to treat the individual with a drug to normalize their cholesterol or lipoprotein.”

<sup>4</sup> We are also not persuaded by the examiner’s unsupported assertion that “it would generally be expected that numerous females who have reproductive disorders would also suffer from high cholesterol” or the conclusions he would have us draw from this unsupported assertion. Answer, page 6.

appellants' claimed invention could not be practiced without undue experimentation based on appellants' disclosure.

For the foregoing reasons, we find the examiner failed to meet his burden of setting forth a prima facie case of lack of enablement. Accordingly, we reverse the rejection based on the enablement provision of 35 U.S.C. § 112, first paragraph.

### SUMMARY

We reverse the rejection of claims 1-9 and 11-16 under the written description provision of 35 U.S.C. § 112, first paragraph.

We reverse the rejection of claims 1-9 and 11-16 under the enablement provision 35 U.S.C. § 112, first paragraph.

### REVERSED

)  
Toni R. Scheiner )  
Administrative Patent Judge )  
)  
) BOARD OF PATENT  
)  
Donald E. Adams )  
Administrative Patent Judge )  
) APPEALS AND  
)  
) INTERFERENCES  
)  
)  
Demetra J. Mills )  
Administrative Patent Judge )

PATREA L. PABST  
PABST PATENT GROUP LLP  
400 COLONY SQUARE  
SUITE 1200  
ATLANTA, GA 30361