

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte THOMAS J. BORODY

Appeal No. 2002-1371
Application No. 08/474,796

ON BRIEF

Before, WINTERS, SCHEINER, and ADAMS, Administrative Patent Judges.
ADAMS, Administrative Patent Judge.

VACATUR and REMAND TO THE EXAMINER

Having reviewed the record in this appeal, we have determined that the rejection under 35 U.S.C. § 112, first paragraph is not based upon the correct legal standards. Accordingly we vacate¹ the rejection under 35 U.S.C. § 112, first paragraph. In addition, there are a number of issues that need to be clarified by the examiner. Thus, we remand the application to the examiner to consider the following issues and take appropriate action.

Claim 27 is illustrative of the subject matter on appeal and is reproduced below:

¹ Lest there be any misunderstanding, the term “vacate” in this context means to set aside or to void. When the Board vacates an examiner’s rejection, the rejection is set aside and no longer exists. Therefore the issues set forth herein cannot be satisfied by a Supplemental Examiner’s Answer. See Ex parte Zambrano, 58 USPQ2d 1312, 1313 (Bd. Pat. App. & Int. 2000).

27. A method for the treatment of a chronic gastrointestinal disorder selected from the group consisting of spastic colon, mucous colitis, collagenous colitis, inflammatory bowel disease, microscopic colitis, idiopathic or simple constipation, diverticular disease, chronic idiopathic pseudo obstructive syndrome and chronic enteric infections, in an adult human host, where causative infection cannot be demonstrated due to the inability to detect infecting agents associated with such infection in the human host, which method comprises substantially completely removing the host's existing enteric microflora by a method comprising using a lavage, and the substitution of an effective amount of fresh or dried or reconstituted feces from a disease-screened human donor or the administration of an effective amount of a pharmaceutically acceptable composition comprising microorganism selected from the group consisting of Bacteroides and E. coli in liquid culture or dried viable form.

While the examiner expressly states (Answer, page 3) that “[n]o prior art is relied upon...,” at page 7 of the Answer, the examiner relies on the Merck Manual of Diagnosis and Therapy².

GROUND OF REJECTION

Claims 27-34, 36-43, 45-52, 54-61, 63-70, 72-76 and 86-89 stand rejected under 35 U.S.C. § 112, first paragraph as based on a non-enabling disclosure.

The examiner, however, has indicated that claims 77-85 and 90-92 are allowable.

² We also note that this reference does not appear to be present in the administrative file.

DISCUSSION

The examiner's statement of the rejection (Answer, page 3) is ambiguous; while the examiner begins with the phrase "while being enabling for ..." the examiner makes no statement of what the specification is not enabling for. In addition, we recognize appellant's argument (Brief, page 20):

there already has been a determination that scope of enablement is correct vis-à-vis [a] number of treatments and microorganism treating agent, from allowance of [c]laims 77-85 and 90-92.

The only motivation for taking a contrary position would be a disbelief that the invention does not work for certain conditions. This is not a proper motivation and in any event should not apply to [c]laims 27-34, 36-43, 72 and 73 since very broad coverage on chronic gastrointestinal disorder for the same treatment, has been agreed as being enabled and operative, by allowance of [c]laim 90.

While the examiner recognizes (Answer, pages 8-9) appellant's argument regarding claim 90 the examiner fails to explain the apparent inconsistency in indicating that generic claim 90 is allowable but that a species within that generic claim (e.g., claim 27) is not enabled by the specification. Accordingly, we vacate the rejection under 35 U.S.C. § 112, first paragraph, and remand the application to the examiner for further consideration.

We also recognize the questions posed by the examiner. Answer, page 7. This series of questions, however, is not the type of fact-based reasoned analysis required to support a proper conclusion of non-enablement. As set forth in In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988), the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include

the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Instead of a fact-based reasoned analysis as to why appellant's disclosure does not provide an enabling description of the claimed invention, we find only the examiner's unsupported conclusion that the specification does not enable the claimed invention. In this regard, we note the examiner's numerous references to the "state of the art" (Answer, page 5); missing however, is a citation to any reference that provides a factual basis upon which to question the predictability of appellants' claimed invention. In this regard, we remind the examiner that findings of fact and conclusions of law by the USPTO must be made in accordance with the Administrative Procedure Act, 5 U.S.C.

§ 706(A),(E), 1994. Dickinson v. Zurko, 527 US 150, 158, 119 S. Ct. 1816, 1821, 50 USPQ2d 1930, 1934 (1999). Our reviewing court has held that findings of fact must be supported by substantial evidence within the record. In re Gartside, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000) ("because our review of the board's decision is confined to the factual record compiled by the board ... the 'substantial evidence' standard is appropriate for our review of board fact findings, see 5 U.S.C. § 706(2)(E)."). See also In re Lee, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002) (a board decision denying patent must be founded on necessary findings and must provide an

administrative record showing the evidence which the findings are based; the board must assure the requisite findings are made, based on evidence of record).

We recognize appellant's argument (Brief, page 20), "the law places a burden on the PTO to come forward initially on scope of enablement. This has not been done by reference to the application as filed or by proper interpretation of extrinsic evidence and certainly not by clear and convincing evidence...." In this regard, we remind the examiner, as set forth in In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971) 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.

For the forgoing reasons, it is our opinion, that the rejection under 35 U.S.C. § 112, first paragraph is not based upon the correct legal standards. Accordingly we vacate the rejection under 35 U.S.C. § 112, first paragraph, and remand the application to provide the examiner with an opportunity to reconsider the administrative file and to take appropriate action.

We are not authorizing a Supplemental Examiner's Answer under the provisions of 37 CFR § 1.193(b)(1). Any further communication from the examiner that contains a rejection of the claims should provide appellants with a full and fair opportunity to respond.

VACATED and REMANDED

Sherman D. Winters)	
Administrative Patent Judge)	
)	
)	
)	BOARD OF PATENT
Toni R. Scheiner)	
Administrative Patent Judge)	APPEALS AND
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Donald E. Adams)	
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