

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 32

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CORNELUS G.M. JANSSEN, ALFONSUS G. KNAEPS,
LUDO E.J. KENNIS, and JAN VANDERBERK

Appeal No. 1998-1488
Application No. 08/100,907

ON BRIEF

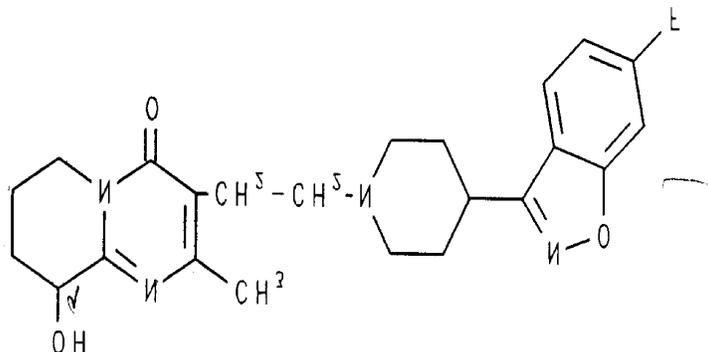
Before WINTERS, ROBINSON, and MILLS, Administrative Patent Judges.
ROBINSON, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 20, 22, 23, and 26 - 28, which are all of the claims pending in the application.

Claim 20 is illustrative of the subject matter on appeal and reads as follows:

20. A process for preparing an enantiomeric form of the compound having the formula:



or a pharmaceutically acceptable acid addition salt thereof,

wherein said process comprises the steps of:

(a) reacting a racemic mixture of said compound with chiral 4, 5-dihydro-1H-2-benzopyran-2-carboxylic acid or the acid chloride thereof, to form a mixture of diastereomeric esters;

(b) physically separating said mixture of diastereomeric esters by chromatography;
and

(c) converting said separated diastereomeric salts or esters into the corresponding enantiomeric forms of said compound by hydrolysis in an acidic or basic aqueous medium.

The examiner has relied on no references in rejecting the claimed subject matter.

Ground of Rejection

Claims 20, 22, 23, and 26 - 28 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a disclosure which fails to teach how to use.

We reverse.

Discussion

The rejection under 35 U.S.C. § 112, first paragraph

The claims on appeal are directed to a process of separating the enantiomeric forms of the structurally defined 9-OH-risperidone. (Claim 20). The examiner urges that "[t]he specification fails to teach how to use the process." (Answer, page 3). The examiner states that "[i]t is entirely possible that there is some usefulness in separating the (+) from the (-), and in separating the (-) from the (+), but the specification does not teach what that usefulness is." (*Id.*) The examiner, further, states that it "is not necessarily enough to show how the process itself is to be used." (*Id.*) The examiner states that no rejection is made under 35 U.S.C. § 101. (Answer, page 4). Therefore, the issue raised by the appeal is whether appellants' disclosure would have enabled one skilled in the art to make and use the claimed invention throughout its scope without undue experimentation.

The Patent and Trademark Office (PTO) bears the initial burden of providing reasons for doubting the objective truth of the statements made by applicants as to the

scope of enablement. Only when the PTO meets this burden, does the burden shift to applicants to provide suitable evidence indicating that the specification is enabling in a manner commensurate in scope with the protection sought by the claims. In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971).

On the record before us, there appears to be no dispute that the disclosure in support of the claimed invention provides sufficient information to permit those skilled in this art to carry out or practice the claimed process without undue experimentation. Further, the examiner does not dispute that both of the enantiomeric forms of 9-OH-risperidone, resulting from the claimed process, are active and useful as pharmaceutical agents in the treatment of psychotic diseases in the manner described in the specification. However, the examiner questions whether the process of isolating the enantiomeric forms of 9-OH-risperidone has any usefulness. It would appear that the examiner is not questioning whether one could practice the invention as claimed, but is questioning the lack of disclosure as to why one should use the claimed process to arrive at the enantiomeric forms of 9-OH-risperidone. The examiner cites no authority to support the reliance on this proposition as a basis for refusing patentability of a claimed process under 35 U.S.C. § 112, first paragraph.

Thus, we agree with appellants that the disclosure presented in support of the claimed invention is sufficient to comply with the requirements of both 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph. (Brief, pages 6 and 8). Therefore, it is our opinion that the examiner has failed to provide a reasonable basis for questioning the sufficiency of the

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disclosure in support of the claimed invention. We, therefore, reverse the rejection under 35 U.S.C. § 112, first paragraph, as failing to teach how to use.

Summary

The rejection of claims 20, 22, 23, and 26 - 28 under 35 U.S.C. § 112, first paragraph is reversed.

REVERSED

Sherman D. Winters)	
Administrative Patent Judge)	
)	
)	
)	BOARD OF PATENT
Douglas W. Robinson)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
)	
Demetra J. Mills)	
Administrative Patent Judge)	

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