

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 21

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ROBERT L. DOW

Appeal No. 1997-1856
Application 08/142,284

ON BRIEF

Before WINTERS, ROBINSON, and ADAMS, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 1 through 4, which are all of the claims in the application.

Claim 1, which is illustrative of the subject matter on appeal, is attached as an appendix to this opinion.

Appeal No. 1997-1856
Application 08/142,284

In rejecting the appealed claims on non-prior art grounds, the examiner relies on the following references:

Kruse et al. (Kruse), "Synthesis and Evaluation of Multisubstrate Inhibitors of an Oncogene-Encoded Tyrosine-Specific Protein Kinase," J. Med. Chem., Vol. 31, No. 9, pp. 1768-772 (1988)

Levitzki, "Tyrphostins: tyrosine Kinase blockers as novel antiproliferative agents and dissectors of signal transduction," The FASEB Journal, Vol. 6, pp. 3275-282 (Nov. 1992)

The issues presented for review are: (1) whether the examiner erred in rejecting claims 1 through 4 under 35 U.S.C. § 112, first paragraph, as based on a non-enabling disclosure; and (2) whether the examiner erred in rejecting claims 1 through 4 under 35 U.S.C. § 112, second paragraph, as indefinite.

On consideration of the record, we reverse the examiner's rejection under 35 U.S.C. § 112, first paragraph. We remand this application to the examiner for clarification and further proceedings respecting the rejection under 35 U.S.C. § 112, second paragraph.

35 U.S.C. § 112, FIRST PARAGRAPH

The examiner acknowledges that appellant's specification enables any person skilled in the art to make the instantly claimed compounds (Examiner's Answer, page 4, lines 4 and 5). The examiner argues, however, that the specification does not enable any person skilled in the art to use the claimed compounds (Examiner's Answer, page 4, lines

6 and 7). Thus, the issue before us centers on the “how to use” requirement of 35 U.S.C. § 112, first paragraph.

Appellant expressly states that the compounds of his invention “are all readily adapted to therapeutic use as tyrosine kinase inhibitors for the control of tyrosine kinase dependent diseases in mammals” (specification, page 16, line 30 through page 17, line 1). Appellant amplifies on the meaning of tyrosine kinase dependent diseases, and provides examples of those diseases (specification, page 17, lines 1 through 7).

Further, appellant sets forth an in vitro assay, useful for demonstrating the tyrosine kinase inhibitory activity of the present compounds (specification, page 17, lines 8 through 29). With respect to the specifics of “how to use” his compounds, appellant describes specific modes of administration, dosages, and dosage forms (specification, page 17, line 30 through page 18, line 14). Furthermore, appellant elaborates on the preparation of tablets, capsules, and aqueous suspensions and/or elixirs for the purposes of oral administration (specification, page 18, line 15 through page 19, line 5). Likewise, appellant describes the preparation of solutions useful for parenteral or topical administration (specification, page 19, lines 6 through 24). Finally, appellant provides guidelines for preparing a pharmaceutical composition comprising, as active ingredient, a claimed compound or pharmaceutically acceptable salt thereof (specification, page 19, lines 15 through 32).

Appeal No. 1997-1856
Application 08/142,284

All in all, we believe that the specification imparts ample information enabling any person skilled in the art to use the claimed compounds throughout their scope without undue experimentation. Therefore, we disagree with the examiner's conclusion that the specification does not satisfy the "how to use" requirement of 35 U.S.C. § 112, first paragraph.

We have carefully reviewed the Examiner's Answer (Paper No. 16) and Supplemental Answer (Paper No. 18). In our judgment, however, the examiner does not adequately explain why she doubts the truth or accuracy of any statement in appellant's supporting disclosure. Nor does the examiner back up assertions of her own with acceptable evidence or reasoning inconsistent with the contested statement. See In re Marzocchi, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971). In this regard, we find that the examiner's reliance on Kruse and Levitzki is misplaced. Those references relate to compounds structurally distinct from and not analogous to the instantly claimed compounds. In our judgment, therefore, the discussion of tyrosine kinase inhibiting activity in Kruse or Levitzki does not constitute reason to doubt the objective truth of statements in the specification which are relied on by appellant for enabling support. In re Marzocchi, 439 F.2d at 223, 169 USPQ at 369 (CCPA 1971).

To the extent that the examiner would find working examples of "how to use" the claimed compounds desirable, we agree. As the court cautioned in In re Strahilevitz,

Appeal No. 1997-1856
Application 08/142,284

668 F.2d 1229, 1232, 212 USPQ 561, 563 (CCPA 1982), however, working examples are not required to satisfy section 112, first paragraph.

The rejection of claims 1 through 4 under 35 U.S.C. § 112, first paragraph, is reversed.

35 U.S.C. § 112, SECOND PARAGRAPH

In the Examiner's Answer, section (10), the examiner entered a new ground of rejection of claims 1 through 4 under 35 U.S.C. § 112, second paragraph, as indefinite. According to the examiner, claims 1 through 4 are indefinite in view of the recitation “[a] compound ... and the pharmaceutically-acceptable cationic salts and prodrugs thereof” (emphasis added). The examiner argued that it is unclear whether these claims “read on” a combination of a compound and its pharmaceutically acceptable cationic salts and prodrugs. To resolve this issue, the examiner recommended that the claims be amended using the language “a compound ... or a pharmaceutically-acceptable cationic salt or a prodrug thereof” (Examiner's Answer, page 7, section (10)).

In the Reply Brief (Paper No. 17), appellant proffered an amendment designed to overcome the examiner's new ground of rejection. In the Supplemental Examiner's Answer (Paper No. 18), however, the examiner does not indicate whether the proffered amendment has been entered; nor does the examiner repeat or refer to the rejection under

Appeal No. 1997-1856
Application 08/142,284

35 U.S.C. § 112, second paragraph. This is confusing, and leads us to conclude that the rejection for indefiniteness is not ready for review.

Under these circumstances, we remand this application to the examiner to clarify the status of the rejection under 35 U.S.C. § 112, second paragraph. On return of this application to the examining corps, the examiner should review appellant's Reply Brief and expressly state whether the proffered amendment, designed to overcome the new ground of rejection, has been entered. Assuming that the amendment has not been entered, and further assuming that the examiner adheres to the rejection, we would recommend to both appellant and the examiner that every effort be made to resolve this issue at the examining group level.

Accordingly, this application is remanded to afford appellant and the examiner the opportunity to review and resolve the issue arising under 35 U.S.C. § 112, second paragraph.

Appeal No. 1997-1856
Application 08/142,284

This application, by virtue of its "special" status, requires an immediate action.

Manual of Patent Examining Procedure (MPEP) § 708.01(d)(7th ed., July 1998).

REVERSED and REMANDED

Sherman D. Winters)	
Administrative Patent Judge)	
)	
)	
)	BOARD OF PATENT
Douglas W. Robinson)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
)	
Donald E. Adams)	
Administrative Patent Judge)	

Appeal No. 1997-1856
Application 08/142,284

Gregg C. Benson
Pfizer Inc.
Eastern Point Road
Groton, CT 06340

SDW/cam