

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 18

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CHANDRA CHOUDHURY

Appeal No. 1996-3170
Application No. 08/180,371

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and ROBINSON, Administrative Patent Judges.

ROBINSON, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 45-48. Claims 1-13, 26-31, 33-44 and 50 stand withdrawn from consideration by the examiner and are not presented on appeal.

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Claims 45 - 48 read as follows:

45. A purified and isolated protein having a peptide sequence consisting of amino acids 6 through 75 as shown in SEQ ID NO. 6.

46. A pharmaceutical composition consisting essentially of the protein according to claim 45 in a pharmaceutically-acceptable carrier.

47. The protein according to claim 45 further consisting of a label.

48. The protein according to claim 45 attached to a support.

GROUND OF REJECTION

Claims 45 - 48 stand rejected under 35 U.S.C. § 112, first paragraph, as being non-enabled by the specification.

We reverse.

BACKGROUND

The applicant describes the invention, as presently claimed, at page 2 of the specification as being directed to an isolated polypeptide which is a T cell-derived colony stimulating factor (TC-CSF) having biological or immunological activity.

DISCUSSION

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

Claims 45 - 48 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a non-enabling disclosure. The issue, as framed by the examiner, is whether appellant's "specification teaches how to use the invention now claimed in the manner

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required by § 112, first paragraph." (Answer, page 3). The first paragraph of 35 U.S.C. § 112 requires that the specification contain a written description of the claimed invention and the manner and process of making and using that invention in such full, clear, concise, and exact terms as to enable any person skilled in the art to which that invention pertains to make and use that invention. In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

On this record, the examiner has acknowledged that the disclosure in support of the presently claimed invention is sufficient to meet the "written description", "how to make", and "best mode" requirements of 35 U.S.C. § 112, first paragraph. (Answer, page 8). In addition, the examiner does not dispute that "a protein having CSF activity would indeed be 'useful.'" (Id.)

In explaining the basis for this rejection, the examiner states (Answer, page 3-4):

The specification provides confusing and conflicting teachings about "TC-CSFs" generally, and the structural relationship of the peptide fragment now claimed to the various other species disclosed is so insubstantial that no conclusions regarding its functional properties may properly be drawn from comparisons with other "TC-CSFs".

The examiner concludes (Answer, page 7):

In summary, the data presented in the disclosure are not credible, and the attempts to reconcile fundamental differences between conflicting results are not logically consistent. In view of the evident lack of any evolutionary relationship between the human "TC-CSF" and the other proteins characterized in the specification and the confusing teachings relative to the claimed peptide *per se*, it cannot reasonably be predicted that the "TC-CSF

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fragment of SEQ. ID NO: 6 will have any of the functional properties alleged for the invention. If the claimed peptide does not have any activity described in the disclosure, the artisan cannot use the peptide, a composition comprising it, or a labeled or immobilized peptide for any purpose.

Having reviewed the examiner's statements and reasoning in support of this rejection, (Answer, pages 3-7), it reasonably appears that the examiner is, in fact, questioning whether the disclosure in support of the claimed invention sufficiently establishes that the claimed peptide fragment would be expected to be useful in the manner described in the disclosure and as noted by the appellant (Principal Brief, page 4, and the paragraph bridging pages 8-9). The reasoning proffered by the examiner questions whether appellant has demonstrated that the claimed peptide is useful for the disclosed uses which is an issue properly raised under 35 U.S.C. § 101 or 35 U.S.C. § 112, first paragraph.¹ However, the rejection before us is based on the "how to use" requirement of 35 U.S.C. § 112, first paragraph and the issue of lack of utility has not been briefed by either the examiner or the appellant.

The rejection presented in this appeal is predicated on the premise that the disclosure does not provide an enabling disclosure which would permit those skilled in this art to use the invention for the stated use without undue experimentation.

The examiner bears the initial burden of providing reasons for doubting the

¹ We are cognizant that the examiner may reject a claim under 35 U.S.C. § 112, first paragraph, as being non-enabled where the claimed invention is not useful. See In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995).

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objective truth of the statements made by applicant as to the scope of enablement. In re Marzocchi, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971). On the record before us, we find that the examiner's statements, in support of this rejection, fall short of the requirement set forth above and fail to provide adequate evidence or reasons why one skilled in the art would doubt the statements relating to the use the claimed polypeptide. The lack of a structural relationship or similarity between the claimed polypeptide fragment to other polypeptides which are known to have CSF activity is insufficient, standing alone, to establish that one skilled in this art would doubt the objective truth of appellant's disclosure or that it would not be possible to use the invention without undue experimentation. The examiner has acknowledged that the claims meet the requirements of 35 U.S.C. § 112, first paragraph with regard to written description and how to make. More is required in order to establish a prima facie case of unpatentability of a claimed invention under 35 U.S.C. § 112, first paragraph, as to whether the disclosure in support of the claimed invention would enable those skilled in the art to practice the invention without undue experimentation. See In re Wands, 858 F.2d 731, 8 USPQ2d 1400, (Fed. Cir. 1988).

Thus, to the extent that we understand the examiner's position in this rejection, the examiner has failed to make those factual findings which must be made before a conclusion of "lack of enablement" may properly be reached. Having failed to establish a reasonable basis for questioning the sufficiency of the supporting specification as it relates

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to how to use the claimed subject matter, the rejection of claims 45-48 is improper.
Therefore, the rejection of claims 45-48 under 35 U.S.C. § 112, first paragraph, is reversed.

CONCLUSION

The examiner's rejection of claims 45-48 under 35 U.S.C. § 112, first paragraph, is reversed.

REVERSED

SHERMAN D. WINTERS)	
Administrative Patent Judge)	
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WILLIAM F. SMITH)	BOARD OF PATENT
Administrative Patent Judge)	APPEALS AND
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DOUGLAS W. ROBINSON))	
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