

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 40

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RICHARD D. SONTHEIMER, TSU-SAN LIEU,
DANIEL P. McCAULIFFE and J. DONALD CAPRA

Appeal No. 1995-2785
Application No. 07/576,423¹

ON BRIEF

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

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 17 through 19, 21 through 23, 26, and 30. Claims 7 and 25 stand allowed. Claims 20, 24, and 27 through

¹ Application for patent filed May 24, 1991.

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29, which are the only other claims remaining in the application, stand "objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form." See the Second Supplemental Examiner's Answer (Paper No. 31), page 1.

REPRESENTATIVE CLAIMS

Claims 17, 21, and 26, which are illustrative of the subject matter on appeal, read as follows:

17. A purified nucleic acid segment that corresponds to, or is complementary to, from a 14 to 1890 nucleotide long region of the DNA sequence of Figure 2 of the drawings, said segment being capable of forming a hybrid with the nucleotide sequence of Figure 2 under conditions that include 6 x SSC at 42EC.

21. A method for identifying the presence of a nucleic acid molecule having a sequence in accordance with claim 17 in a biological sample suspected of containing such a molecule, the method comprising the steps of:

- (a) incubating nucleic acids from the biological sample with a DNA segment as defined by any one of claims 17 through 19 under conditions appropriate for the formation of specific hybrids; and
- (b) detecting the formation of specific hybrids between the nucleic acids and the segment by means of a detectable label, the formation of such hybrids being indicative of the presence of such a nucleic acid sequence in the biological sample.

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26. A recombinant vector comprising a nucleic acid segment of that:

- (a) encodes an amino acid sequence as set forth in Figure 2 of the drawing;
- (b) encodes the amino acid sequence phe-lys-glu-gln-phe-leu-asp-gly-asp-gly-trp-thr-asp-arg;
- (c) encodes the amino acid sequence lys-glu-gln-phe-leu-asp-gly-asp-gly-trp-thr-asp-arg-trp-ile-glu-ser; or
- (d) that corresponds to, or is complementary to, from a 14 to 1890 nucleotide long region of the DNA sequence of Figure 2 of the drawings, said segment being capable of forming a hybrid with the nucleotide sequence of Figure 2 under conditions that include 6 x SSC at 42°C.

THE REJECTIONS

In the Examiner's Answer (Paper No. 24), the examiner entered a new ground of rejection of claims 7, 26, and 27 under 35 U.S.C. § 112, first paragraph. That rejection was withdrawn in the Supplemental Examiner's Answer (Paper No. 28), page 1, in view of the amendment filed September 12, 1994.

The issues remaining for review are: (1) whether the examiner erred in rejecting claims 17 through 19, 21 through 23, 26, and 30 under 35 U.S.C. § 112, first paragraph, "as failing to adequately teach how to make and/or use the

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invention"; and (2) whether the examiner erred in rejecting claims 17 through 19, 26, and 30 under 35 U.S.C. § 112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." See the Examiner's Answer (Paper No. 24), pages 3 and 4.

In setting forth these rejections, the examiner does not rely on any prior art references.

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DISCUSSION

On consideration of the record, we shall not sustain the examiner's rejections under 35 U.S.C. § 112, first and second paragraphs.

Claims 17 through 19, 21 through 23, 26, and 30 stand rejected under 35 U.S.C. § 112, first paragraph, as based on a specification which does not adequately teach how to make or how to use the claimed invention. In view of its brevity, we here reproduce the entire statement of rejection from the Examiner's Answer (Paper No. 24), paragraph bridging pages 3 and 4:

Enablement is not commensurate in scope with any \$14, \$18, or \$22-nucleotide long region of the DNA sequence of Figure 2 as claimed in claims 17, 18 and 19, respectively. The specification as filed teaches how to use such fragments in those cases where the fragments encode epitopic portions of protein. However, the scope of the claims is such as to include all possible DNA fragments from either the coding or the non-coding strands of the molecule, which fragments exceed a minimum stated length. The current specification as filed does not teach how to make and use all such possible fragments. Specifically, only a limited number of such fragments will encode epitopic regions of the Ro antigen, and applicants have failed to present teachings commensurate in scope with claims to nucleic acids which do not encode epitopic regions.

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Having carefully reviewed the examiner's statement, we find no fact-based analysis of the specification and the relevant prior art which would support a conclusion of non-enablement. Apparently, the examiner expresses concern that appellants' claims "read on" some unspecified inoperative embodiments. However, as stated in Atlas Powder Co. v. E.I. Du Pont Demours & Co., 750 F.2d 1569, 1576-77, 224 USPQ 409, 414 (Fed. Cir. 1984):

Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. "It is not a function of the claims to specifically exclude . . . possible inoperative substances. . . ." Of course, if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid. . . . That, however, has not been shown to be the case here. [Citations omitted].

On this record, the examiner has not established that the number of inoperative embodiments encompassed by claims 17 through 19, 21 through 23, 26, and 30 is significant or "in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention." The examiner's conclusion of non-enablement is not adequately supported by facts and cannot stand.

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The rejection of claims 17 through 19, 21 through 23, 26, and 30 under 35 U.S.C. § 112, first paragraph, as based on a specification which does not adequately teach how to make or how to use the claimed invention is reversed.

Claims 17 through 19, 26, and 30 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Again, in view of its brevity, we reproduce the entire statement of rejection from the Examiner's Answer (Paper No. 24), page 4, lines 8 through 15:

Claims 17-19, 26 and 30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's inclusion of the language "under conditions that include 6x SSC at 42E C" fails to adequately specify hybridization conditions, as such are incomplete; the stringency of hybridization is dependent upon numerous other factors, such as the amount of formamide and/or other chemicals present. Therefore it is not clear from the claims what the hybridization conditions are, and therefore what the metes and bounds of the claims are.

The examiner expresses concern that appellants' claim language "fails to adequately specify hybridization conditions" and that "it is not clear from the claims what the hybridization conditions are." However, as stated in Ex parte Jackson,

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217 USPQ 804, 806 (PTO Bd. App. 1982):

It is by now well established that it is the function of the descriptive portion of the specification and not that of the claims to set forth operable proportions and similar process parameters and that claims are not rendered indefinite by the absence of the recitation of such limitations. [Citations omitted].

Furthermore, as stated in In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971):

This first inquiry [under 35 U.S.C. § 112, second paragraph] is merely to determine whether the claims do, in fact, set out and circumscribe a particular area with a reasonable degree of precision and particularity. It is here where the definiteness of the language employed must be analyzed-not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art. [Footnote omitted].

Having carefully reviewed the statement of rejection, we find no indication that the examiner analyzed appellants' claim language in light of the teachings of the prior art and of the instant specification as it would be interpreted by a person having ordinary skill in the art. Accordingly, the rejection under 35 U.S.C. § 112, second paragraph, must fall.

The rejection of claims 17 through 19, 26, and 30 under 35 U.S.C. § 112, second paragraph, as indefinite is reversed.

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The examiner's decision is reversed.

REVERSED

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

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