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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 46

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

_____

Ex parte KIRK FRY,
JAMES LARRICK,
and ALBERT TAM

_____

Appeal No. 94-1695
Application 07/742,088[1]

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ON BRIEF

_____

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

WILLIAM F. SMITH, Administrative Patent Judge.

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[1] Application for patent filed August 2, 1991. According to appellants, the application is a continuation of Application 07/224,961, filed July 26, 1988, now abandoned.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 2, 5, 7 through 10, and 12 through 22, all the claims in the application.

Claims 14 and 22 are illustrative of the subject matter on appeal and read as follows:

14. A method of amplifying a mixture of different-sequence double-stranded DNA fragments, comprising

treating the DNA fragments with terminal deoxynucleotide transferase and a selected deoxynucleotide triphosphate, to add a homopolymeric sequence to the 3N ends of both DNA fragment strands,

mixing the DNA fragments containing the homopolymeric sequence with (I) a homopolymer primer that is complementary to said homopolymeric sequence, (ii) heat-stable DNA polymerase and (iii) all four deoxynucleotide triphosphates,

heat denaturing the DNA fragment strands,

annealing the mixture under conditions to form DNA fragment/primer duplexes,

reacting the mixture under conditions in which the DNA fragment/primer duplexes are converted to double-stranded DNA molecules,

repeating said denaturing, annealing, and reacting steps until a desired degree of fragment amplification has been achieved.

22. A method of preparing a mixture of single-stranded RNA fragments for cloning in a cloning vector, comprising

transcribing the RNA fragments to an RNA/DNA complex using an RNA-strand primer, where said RNA-strand primer (I) has a sequence complementary to a 3N

sequence of the RNA fragments and (ii) is effective to produce in the resulting RNA/DNA duplex DNA fragment strands having a selected common 5N -end sequence,

treating the DNA fragment strands with terminal deoxynucleotide transferase in the presence of a selected deoxynucleotide, to form a homopolymeric sequence at the 3N -end of the DNA fragment strands,

mixing the DNA fragment strands containing the homopolymeric sequence with (I) a homopolymer primer having a binding sequence which is complementary to the 3N-end homopolymeric sequence of the DNA fragment strands, (ii) a common-sequence primer which has the same sequence as said selected common 5N -end sequence, (iii) a heat-stable DNA polymerase and (iv) all four deoxynucleotide triphosphates,

heat denaturing the mixture to yield single-stranded DNA fragments,

annealing the mixture under conditions to form DNA fragment stand/primer duplexes,

reacting the mixture under conditions in which the DNA fragment strand/primer duplexes are converted to double-stranded DNA molecules,

repeating said denaturing, annealing, and reacting steps until a desired degree of fragments amplification has been achieved.

There are two narrow issues under 35 U.S.C. § 112, first paragraph, presented for decision on this appeal. They are whether the original disclosure of this application provides (1) written descriptive support and (2) enabling support for that portion of the claimed subject matter which requires the use of a “heat-stable DNA polymerase.” We decide both of these issues in favor of appellants. Accordingly, we reverse the examiner’s rejections under 35 U.S.C. § 112, first paragraph.

Written Description

When this case was filed, the claims only required the use of a DNA polymerase without reference to its heat stability property. During prosecution of the application, appellants amended the claims to require that the DNA polymerase be "heat-stable." The examiner determined that the original disclosure of this application does not provide written descriptive support for the phrase "heat-stable DNA polymerase" as required by 35 U.S.C. § 112, first paragraph. As explained in the paragraph bridging pages 3-4 of the Examiner's Answer, the examiner believes that the original disclosure would support the phrase "DNA polymerase" or "Taq polymerase," which the examiner admits is a "heat-stable DNA polymerase" but "no where in the disclosure as filed is there a citation of the phrase 'heat-stable DNA polymerase'."

The examiner's consideration of this issue has apparently been based upon a misunderstanding as to the correct legal standard for determining whether the original disclosure of a patent application provides written descriptive support for later added language. It appears that the examiner is of the opinion that the original disclosure must contain the exact language later added by amendment. This is incorrect. As set forth in Vas-Cath, Inc. v. Mahukar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), "the original disclosure of the application need only convey the concept now claimed in order for the written description requirement of 35 U.S.C. § 112, first paragraph,

to be satisfied." Here, the original disclosure of the application describes the specific DNA polymerase used, Taq DNA polymerase, as "heat-stable." See, e.g., page 12, lines 8-15, of the present specification. Thus, appellants, in describing their invention in the specification, conveyed the concept that the present invention involves the use of a "heat-stable DNA polymerase." That is all this section of the statute requires.

The rejection under 35 U.S.C. § 112, first paragraph, written description, is reversed.[2]

Enablement

As understood from a review of the paragraph bridging pages 2-3 of the Examiner's Answer, the examiner's concern in regard to the enablement requirement of 35 U.S.C. § 112, first paragraph, is that the description and use in the specification of a single "heat-stable DNA polymerase" does not enable one skilled in the art to make and use the claimed invention. In response, appellants rely, inter alia, upon the declaration filed under 37 CFR § 1.132 of co-appellant Kirk Fry executed on September 4, 1992. Therein Dr. Fry cites several references which indicate that thermostable polymerases other than Taq

[2] The examiner's concern that the specification contain the exact wording of the claims is better addressed by enforcement of the provisions of 37 CFR § 1.75(d). Any time a claim is amended using language that does not literally appear in the specification of the application, this rule requires that applicant amend the specification to include the amendatory language.

DNA polymerase had been isolated from thermophilic bacteria prior to the effective filing date of this application. Dr. Fry concludes that one skilled in this art would expect that those heat-stable polymerases would be active under the temperature conditions used in the claimed method.

The examiner acknowledges in the paragraph bridging pages 6-7 of the Examiner's Answer that other heat-stable DNA polymerases are known in the art as well as the citation of the references in Dr. Fry's declaration. However, the examiner appears to dismiss this prior art knowledge on the basis that appellants did not refer to this prior art knowledge in the specification of this application.

Again, the examiner's rejection appears to be based upon a misunderstanding of the correct legal standard for determining whether a supporting specification provides enabling support for a claimed invention as well as the avenues available to an applicant to respond to an enablement rejection. As set forth in In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369-70 (CCPA 1971), an applicant may rebut a prima facie case of non-enablement by relying upon "teachings in pertinent references." Thus, an examiner may not dismiss out of hand, as apparently occurred here, appellants' reliance upon prior art references in responding to a non-enablement rejection merely because those references were not cited in the specification. Absent a clearer, fact based, legally sound explanation

of the examiner's position, we do not find that the examiner has properly established that the specification is nonenabling

We reverse the rejection under 35 U.S.C. § 112, first paragraph, enablement.

Other Issues

The examiner has raised in a backhanded manner a question as to whether the claims on appeal comply with a definiteness requirement of 35 U.S.C. § 112, second paragraph. See, e.g., page 5 of the Examiner's Answer ("[I]f appellants wish to claim 'heat-stable DNA polymerase' by inference, guidance directed to the metes and bounds of 'heat-stable' is also required.") See also the paragraph bridging pages 1-2 of the Supplement Examiner's Answer ("[V]agueness and indefiniteness are added thereby due to a lack of definition of the metes and bounds of 'heat-stable' other than summarizing the heat stability of Taq DNA polymerase.") Despite raising these questions in the Examiner's Answer and Supplemental Examiner's Answer, the examiner has not seen fit to reject the claims under 35 U.S.C. § 112, second paragraph. Upon return of the application, the examiner should clarify the matter by determining whether the claims pending in this application meet the requirements of 35 U.S.C. § 112, second paragraph. If the examiner determines that the claims are indefinite, an appropriate rejection using the proper legal standards should be made. If the examiner determines that the claims are in compliance

with the requirements of 35 U.S.C. § 112, second paragraph, an explicit statement to that effect should be made.

REVERSED

Sherman D. Winters	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
William F. Smith	)	APPEALS AND
Administrative Patent Judge	)	INTERFERENCES
	)	
	)	
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Elizabeth C. Weimar	)	
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