

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte THOMAS CACECI,
THOMAS E. TOTH
and MARIA B.W. SZUMANSKI

Appeal No. 95-2041
Application 07/814,220¹

ON BRIEF

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

WEIMAR, Administrative Patent Judge.

DECISION ON APPEAL

¹ Application for patent filed December 23, 1991. According to applicants, the application is a continuation of Application 07/588,437, filed September 25, 1990, now abandoned.

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This is an appeal from the examiner's decision finally rejecting claims 6, 11, 17-21, and 32-47. Appealed claims 48 and 49 were canceled by appellants in Paper No. 20, an amendment filed subsequent to the Examiner's Answer on February 2, 1994. Note that on this amendment "Please enter" is marked in the left margin, however, claims 48 and 49, which appear in Paper No. 14, an amendment filed April 1, 1993, have not been properly marked as canceled.

Claims 6, 17, 21, and 43 are illustrative of the subject matter of the claims on appeal and read as follows:

6. A synthetic DNA sequence having a sequence of nucleotides coding for an antifreeze polypeptide modeled after the antifreeze polypeptide found in winter flounder having greater than five repeats of an eleven amino acid sequence where the first and fourth amino acids in said eleven amino acid sequence are selected from the group consisting of threonine, asparagine, glutamine, glutamic acid, serine and aspartic acid and the second, third and fifth through eleventh amino acids in said eleven amino acid sequence are selected from the group consisting of alanine, glycine, lysine, isoleucine, valine, serine and leucine.

17. A gene having a deoxyribonucleic acid sequence as shown in Figure 4.

21. A bacterial host having the characteristics of ATCC deposit No. 68425.

43. A synthetic DNA sequence having a sequence of nucleotides coding for an antifreeze polypeptide modeled after the antifreeze polypeptide found in winter flounder comprising

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Willson et al., "A Simple Method For Constructing Directly Repeated Multimeric DNA Segments," Gene Anal. Techn., Vol. 2, pages 77-82 (1985).

The rejection of claims 17, 18, 48 and 49 under 35 U.S.C. § 112, second paragraph, presented in the Examiner's Answer, mailed December 6, 1993, has been obviated, as indicated in the Supplemental Examiner's Answer, mailed February 9, 1994.

Claims 6, 11 and 32-39 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a disclosure which fails to provide a written description which would have enabled any person skilled in the art to which it pertains to practice the claimed invention throughout the full scope of the claims without undue experimentation.

Claims 6, 11, 17-21 and 32-47 stand rejected under 35 U.S.C. § 103 over a combination of all of the above listed references.

We vacate the examiner's rejections with respect to claims 6, 11, 21 and 32-47, make new grounds of rejection with respect to these claims under the provisions of 37 CFR § 1.196(b); and reverse the examiner's rejection with respect to claims 17-20.

BACKGROUND

Antifreeze polypeptides are known in the art. These polypeptides have been found in fish which live in arctic waters. The polypeptides prevent the formation of ice in the body fluids of these fish. See the specification at page 3, lines 8-22. The specification describes a specific protein, shown in Figure 4 of the application, which is a variant of an antifreeze polypeptide found in winter flounder. Figure 4 also indicates a specific DNA sequence encoding this variant antifreeze polypeptide. The prior art describes an antifreeze polypeptide found in winter flounder and its production by bacteria that have been transformed with DNA which encodes the polypeptide. See pages 3 through 6 of the specification.

Discussion

Having considered the entire record in this appeal, we have determined that some of the claims presented are indefinite under 35 U.S.C. § 112, second paragraph. Accordingly, we institute a new ground of rejection of claims 6, 11, 21 and 32-47 under this statute *infra*. Since the metes and bounds of claims 6, 11, 21 and 32-47 cannot be readily ascertained,

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consideration of the issues raised under the enablement requirement of 35 U.S.C. § 112, first paragraph, and obviousness under 35 U.S.C. § 103 would be premature with respect to these claims. ***In re Moore***, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971)(One is not in position to determine whether a claim is enabled under the first paragraph of 35 U.S.C. § 112 until the metes and bounds of that claim are determined under the second paragraph of this section of the statute.). ***In re Steele***, 305 F.2d 859, 862, 134 USPQ 292, 295 (CCPA 1962)(Analyzing claims based on "speculation as to meaning of the terms employed and assumptions as to the scope of such claims" is legal error.).

With respect to claims 17-20 we will reach the merits of the examiner's rejection under 35 U.S.C. § 103. We note these claims had been rejected under 35 U.S.C. § 112, first paragraph in the Final Rejection, mailed June 24, 1993, Paper No. 17. However, the Examiner's Answer, mailed December 6, 1995, Paper No. 19, presents the claims that are rejected under 35 U.S.C. § 112, first paragraph, as limited to "claims 6, 11, and 32-39." See page 11 of the Examiner's Answer, the

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second complete paragraph. Thus, claims 17-20 are not presently rejected under 35 U.S.C. § 112, first paragraph.

New Ground of Rejection Under 37 CFR § 1.196(b)

Claims 6, 11, 21 and 32-47 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 applicants regard as their invention.

1. "modeled after"

Claims 6, 11 and 32-47 recite, either expressly or via dependence on a claim that recites, a DNA sequence "coding for an antifreeze polypeptide modeled after the antifreeze polypeptide found in winter flounder." The metes and bounds of this language are not apparent, nor is there a specific definition in the specification that would provide a structural and/or functional limitation of the claimed DNA compounds. Does the winter flounder possess more than one gene which encodes a protein which has an activity such that it can be classified as an "antifreeze polypeptide?" How close to which protein produced by a winter flounder must a compound be in order to be considered as "modeled after" the

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protein? We note that the as-filed specification states, in pertinent part, from line 23 of page 3 to line 5 of page 4, that:

Figure 1 shows the primary amino acid sequence of a native AFP isolated from the winter flounder.... This is a class 1 or alanine rich AFP. There are 38 amino acids (SEQ ID NO:1)... The AFP of SEQ ID NO:1 is but one example of a wide variety of AFPs.

It is not clear what degree of ice suppression activity, if any, a protein encoded by the claimed DNA compounds must have before falling within the scope of the indicated claims.

Claims 6, 11, 32, 33, and 36-42 each recite, or is dependent on a claim which recites, the presence of codons in the DNA compound which encode multiples of an eleven amino acid sequence and limit the choices of those eleven amino acids by the following language:

where the first and fourth amino acids in said eleven amino acid sequence are selected from the group consisting of threonine, asparagine, glutamine, glutamic acid, serine and aspartic acid and the second, third and fifth through eleventh amino acids in said eleven amino acid sequence are selected from the group consisting of alanine, glycine, lysine, isoleucine, valine, serine and leucine.

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Within the genus of possible eleven amino acid sequences claimed thus, is the species consisting of eleven serines. In addition, the language in the claims includes multiple eleven amino acid sequences which are devoid of alanine. The protein from winter flounder described in Figure 1 contains only one serine and contains 26 alanines of the 38 amino acids. This disparity exemplifies the breadth of the indicated proteins that are to be encoded by the claimed genus of DNA compounds and the protein that they are to be "modeled after".

We note that the words "modeled after the antifreeze polypeptide found in winter flounder" were added to the claims for the first time via an amendment filed December 23, 1991, Paper No. 10. On page 10 of this submission, at line 4 applicants state, "This addition was suggested by the Examiner...." Applicants then refer to a declaration of one of the inventors (Caceci), previously submitted in the course of prosecution, and a publication by Kao et al., for a discussion of the differences between winter flounder, ocean pout and sea raven AFPs. However, such does not remove the statutory requirement that the claims particularly point out and distinctly claim the subject matter which applicants

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regard as their invention, nor substitute for the requirement under 35 U.S.C. § 112, first paragraph, that the invention be described in the as-filed specification.

2. "host having the characteristics of"

Claim 21 is indefinite in that it recites:

A bacterial host having the characteristics
of ATCC deposit No. 68425.

In pertinent part, the specification at page 26, lines 1-4
recites:

Therefore, a deposit has been made with the
American Type Culture Collection (ATCC) of
Rockville, Maryland, of the plasmid PgX28L
in the E. coli strain DH5" and has ATCC
number 68425.²

The scope of the claimed products is not clear. Which
characteristics of the deposited culture are limitations on
the claimed products? Does the claim include a bacterial host
which has been transformed with plasmid PgX28L but which is
incapable of expressing any of the DNA contained in the

² We note that the number 68425 has not actually been inserted into page 26, line 4, of the specification, however the direction to do so is contained in a partially entered amendment, "Amendment A", filed January 15, 1991, Paper #2, in parent Application No. 07/588,437.

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plasmid? Does the claim include bacterial cultures other than E. coli? It is not ascertainable which cells, beyond the cells in the culture held at the ATCC, are within the metes and bounds of claim 21.

3."an amino acid sequence defined by blocks...of Figure 4"

Claims 43-47 refer to the blocks of Figure 4. Claims 43-46 commonly recite: "A synthetic DNA sequence ... comprising a sequence of nucleotides coding for a protein which has an amino acid sequence defined by blocks ... of Figure 4." The only variation in these four claims is that a specific segment of "blocks" from Figure 4 is recited in each one of claims 43-46. Claim 47 recites that the claimed DNA encodes "a protein which has an amino acid sequence with greater than five of the eight blocks shown in Figure 4." The specification refers to the blocks of Figure 4 at page 10, lines 4-16. The blocks are indicated in Figure 4 by two-directional arrows. Blocks 1-8 are contiguous in Figure 4. The specification also contemplates adding segments which are 11 amino acids in length at the PST1 site shown in block 7 of Figure 4. Such an addition would result in a non-contiguous association of

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multiple segments (see the specification from page 14, line 15, through page 16, line 1). It is not clear whether the language "defined by blocks ... of Figure 4" or "with greater than five of the eight blocks shown in Figure 4" is inclusive of the additional segments discussed on pages 14-16 of the specification.

Claim Interpretation

In contrast to the above-noted ambiguity, when referring to Figure 4, claims 17-20 recite "as shown in Figure 4." Page 8 of the specification at lines 22-25, describes Figure 4 as "a base pair sequence ... and a synthesized amino acid sequence for an AFP polypeptide WF8R wherein the gene wf8r codes for the AFP WF8R" (emphasis added). Page 9 of the specification at lines 20-25, refers to Figure 4, stating:

Referring now to the drawings, and more particularly to Figure 4, there is shown a synthetic AFP peptide (SEQ ID NO:2) and a synthetic gene (comprised of DNA SEQ ID NO:3 and DNA SEQ ID NO:4) coding for the AFP peptide having SEQ ID NO:2.(emphasis added)

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Thus, we hold that claims 17-20 recite the DNA and amino acid sequences of Figure 4 as they are shown in Figure 4, i.e. uninterrupted by any additional DNA or amino acids. The "having" and "has" recitations of these claims result in opening the claims to sequences which are inclusive of the sequences of Figure 4, but which contain additional nucleotides or amino acids on either end of the corresponding Figure 4 sequence.

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

We vacate the examiner's rejection of claims 6, 11, and 32-39 under 35 U.S.C. § 112, first paragraph. In doing so, we emphasize that we have not decided the merits of the issues raised by the examiner therein. If prosecution is continued on this subject matter and claims are presented which meet the requirements of 35 U.S.C. § 112, second paragraph, the examiner should revisit these issues.

The examiner's rejection under 35 U.S.C. § 103

We vacate the examiner's rejection of claims 6, 11, 21, and 32-47 under 35 U.S.C. § 103. In doing so, we emphasize

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that we have not decided the merits of the issues raised by the examiner therein. If prosecution is continued on this subject matter, and claims are presented which meet the requirements of 35 U.S.C. § 112, second paragraph, the examiner should revisit these issues.

Claims 17-20 stand rejected under 35 U.S.C. § 103 over Gourlie and Peters in view of Chakrabarty, Houghten and Scott and further in view of any one of Williams, Ferrari, Shen, Doel, Kempe or Willson.

We reverse this rejection. A prima facie case of obviousness has not been presented by the Examiner.

The combined prior art teachings do not provide a reasonable basis for increasing the number of 11 amino acid sequence repeats in the antifreeze polypeptide of winter flounder to establish that the claimed genes and transformed hosts which produce such polypeptides would have been obvious to a person having ordinary skill in the art at the time of the invention. The reasoning presented in the rejection is stated in the Examiner's Answer, beginning on the last line of page 13 and continuing through lines 1-14, of page 14, as:

It would have been further obvious to enhance the antifreeze properties of the protein by adding additional repeat sequences as suggested by Chakrabartty or by amino acid substitution as suggested by Scott, since these references as cited above indicate that the number of ice contact points is the limiting factor in antifreeze activity. Thus, increasing the number of ice contact points by the addition of AFP repeat sequences (note the same conclusion was admitted by appellants from a review of Chakrabartty (19) and Scott, see page 12, last paragraph, ending on page 13 of the specification), or adding ice contact points via amino acid substitution, or using like amino acids instead of the naturally occurring ones were all suggested by the prior art to enhance AFP activity and provide both the motivation and a reasonable expectation of enhanced AFPs.

We do not agree that "adding additional repeat sequences" is reasonably "suggested by Chakrabartty", nor that Chakrabartty and Scott "indicate that the number of ice contact points is the limiting factor in antifreeze activity." The examiner argues that Chakrabartty teaches length variation in the right hand column of page 11315. See the sentence bridging pages 10 and 11 of the Final Rejection. We find that Chakrabartty there refers to "analogs which vary in length" in the context of "repeating the experiment." Chakrabartty's work involves analogs of 1 repeat, 2 repeats and 3 repeats. See Table 1 of Chakrabartty on page 11314. The reference does

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not teach lengthening the polypeptide by adding more than three repeats. The genes and hosts of claims 17-20, encode and produce, respectively, polypeptides which contain the eight specified 11-amino acid sequence "repeats" of Figure 4. Polypeptides of this length with this number of repeats are neither taught by nor reasonably suggested by the teachings of Chakrabartty. Nor is a finding that the limiting factor in antifreeze activity is the "number of ice contact points" reasonably supported by the Chakrabartty and Scott teachings. These references note the significance of the number of ice contact points, but they do not lessen the significance of other factors, including the known number of contiguous repeats in known antifreeze polypeptides.

We disagree with the statement in the above-quoted section of the Examiner's Answer (page 14, 7-9) which reads "(note the same conclusion was admitted by appellants from a review of Chakrabartty (19) and Scott, see page 12 last paragraph, ending on page 13 of the specification)." The cited section of the specification is not an admission of a "conclusion...from a review of Chakrabartty and Scott." Rather, the section of pages 12 and 13 of the specification to

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which the examiner refers, notes the teaching in the Chakrabartty that "a minimum of three repeats of the basic sequence are required for ice suppression activity." Then in the following sentence the inventors, not Chakrabartty, conclude "Hence, larger molecules with a greater number of repeating sequences which can form a larger amount of hydrogen bonds should be more effective in preventing ice crystal growth (emphasis added)." This sentence is not an admission that the prior art had drawn the stated generic conclusion.

Hindsight shall not form the basis of a conclusion of obviousness under 35 U.S.C. § 103. "Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." In re Dow Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). The prior art of record does not denominate the critical features of appellants' invention; i.e. genes and hosts corresponding to the production of proteins containing the eight-repeat sequences required by claims 17-20. As the Federal Circuit stated in Sensonics, Inc. v. Aerosonic Corp., 81 F.3d 1566, 1570, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996):

To draw on hindsight knowledge of the

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patented invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction - an illogical and inappropriate process by which to determine patentability. . . . The invention must be viewed not after the blueprint has been drawn by the inventor, but as it would have been perceived in the state of the art that existed at the time the invention was made. [citations omitted]

Thus, we hold that claims 17-20 define genes and hosts which would not have been obvious in view of the prior art cited by the examiner.

CONCLUSION

We reverse the rejection of claims 17-20 under 35 U.S.C. § 103.

We vacate the rejection of claims 6, 11, and 32-39 under 35 U.S.C. § 112, first paragraph.

We vacate the rejection of claims 6, 11, 21, and 32-47 under 35 U.S.C. § 103.

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We newly reject claims 6, 11, 21, and 32-47 under 35 U.S.C. § 112, second paragraph, and the provisions of 37 CFR § 1.196(b).

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REVERSED-IN-PART; VACATED-IN-PART; 37 CFR § 1.196(b)

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REVERSED-IN-PART
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37 CFR 1.196(b)

Corrections: