

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

Paper No. 14

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CLAIR L. HICKS

Appeal No. 1997-4381
Application 08/440,734

HEARD: November 30, 2000

Before WILLIAM F. SMITH, SCHEINER, and MILLS, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 1-17, which are all of the claims pending in this application.

We reverse.

Claims 1 and 9 are illustrative of the claims on appeal and read as follows:

1. A method of controlling bacteriophage attack on cheese making bacteria used in a cheese making process, comprising:

treating a blocker peptide precursor selected from a group consisting of a source of immunoglobulins, bacteriophages to which cheese making bacteria are sensitive, bacteriophage parts to which cheese making bacteria are sensitive and mixtures thereof with a protease enzyme that hydrolyzes the blocker peptide precursor;

collecting blocker peptides produced by hydrolysis of the blocker peptide precursor;

formulating a starter media with the blocker peptides and heat treating the formulated started media;

growing bulk cultures of cheese making bacteria used in the cheese making process in the formulated starter media; and

adding cheese making bacteria grown in the formulated starter media to a fermentation medium for producing cheese.

9. A method of making cheese with bacteriophage resistant cheese making bacteria, comprising:

formulating a starter media with peptides that block bacteriophage attachment sites on the cheese making bacteria;

growing bulk cultures of the cheese making bacteria in the formulated starter media;

adding the cheese making bacteria grown in the formulated starter media to a fermentation media for producing cheese whereby a curd is formed; and

cutting the curd.

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The prior art references relied upon by the examiner are:

Hettinga et al. (Hettinga)	4,379,170	Apr. 5, 1983
Payne et al. (Payne)	5,172,193	Dec. 15, 1992

Nordstrom et al. (Nordstrom), "Prevention of Bacteriophage Adsorption to Staphylococcus aureus by Immunoglobulin G," Journal of Virology, Vol. 14, No. 2, pp. 203-206 (1974)

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims, to the applied prior art references, and to the respective positions articulated by the appellant and the examiner.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellant regarding the above-noted rejection, we make reference to the examiner's Answer (Paper No. 10, April 1, 1997) for the examiner's complete reasoning in support of the rejection, and to the appellant's Brief (Paper No. 9, January 6, 1997) for the appellant's arguments thereagainst. As a consequence of our review, we make the determinations which follow.

DECISION ON APPEAL

Grounds of Rejection

1. Claims 1-17 stand rejected under 35 U.S.C. § 112, first paragraph, as unpatentable for lack of enablement.

2. Claims 9-12 and 15-16 stand rejected under 35 U.S.C. § 103 as unpatentable for obviousness over Payne or Hettinga in view of Nordstrom.

35 U.S.C. § 112, first paragraph

Claims 1-17 stand rejected under 35 U.S.C. §112, first paragraph, as unpatentable for lack of enablement.

It is the examiner's position that the specification does not describe the nature and characteristics of the claimed blocking peptides. The examiner argues that the specification only demonstrates that whey hydrolyzate with components of a molecular weight lower than 10,000 Daltons will prevent lysis of two specific strains of bacteria by two distinct phages. It is further alleged that appellant presents no data to demonstrate that the hydrolyzate consists of immunoglobulin peptides. Answer, page 4. The examiner contends, similarly, that appellant has not demonstrated the usefulness of using digested bacteriophages to block phage infection of bacteria used in the cheese making process, such as lactic acid bacteria. Answer, page 5.

The examiner supports the rejection of lack of enablement with argument but not evidence that 1) virology is a highly unpredictable art, 2) that the site of phage attachment is unknown and varies from phage to phage and bacteria to bacteria, 3) that the

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specification does not provide sufficient examples, and 4) that there is no predictable way for the skilled artisan to determine what peptides will block phage attachment/infection without undue experimentation.

In order to establish a prima facie case of non-enablement, the examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure. See In re Wright, 999 F.2d 1557, 1561-562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). A disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. See In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). As stated by the court,

it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.

The threshold step in resolving this issue is to determine whether the examiner has met his burden of proof by advancing acceptable reasoning inconsistent with enablement. In re Morehouse, 545 F.2d 162, 165, 192 USPQ 29, 32 (CCPA 1976). Further, even a broad allegation that the disclosure is speculative, coupled with a recitation of various difficulties which might be encountered in practice, is not sufficient basis for requiring proof of operability. In re Chilowsky, 229 F.2d 457, 462, 108 USPQ 321, 325 (CCPA 1956).

In the present case, we find that the examiner has not provided acceptable evidence that the claimed invention is inconsistent with enablement. At best, we find the examiner has made broad allegations that the disclosure is speculative and recited various difficulties which might be encountered in practice of the invention. This is not a sufficient evidentiary basis for requiring proof of enablement and a shifting of the burden of proof to appellant.

In addition, contrary to the examiner's contention, we find that the specification provides guidance to one of ordinary skill in the art as to how to determine what peptides will block phage attachment/infection without undue experimentation. The specification, page 12, lines 28-31, provides that "the blocker peptides of the invention bind and block binding sites/determinates on the bacteria thereby providing a competition inhibition to subsequent phage attack." Thus, it would reasonably appear that one of ordinary skill in the art can determine blocker peptides within the scope of the invention by their ability to

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bind and block binding sites/determinates on the bacteria and their ability to competitively inhibit subsequent phage attack. In this regard, the following passage from PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996) is instructive here.

In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim. See, e.g., In re Goodman, 11 F.3d 1046, 1050-52, 29 USPQ2d 2010, 2013-15 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1212-14, 18 USPQ2d 1016, 1026-28 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991); In re Vaeck, 947 F.2d at 496, 20 USPQ2d at 1445. Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made, based on the disclosure in the specification, without undue experimentation. But the question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation “must not be unduly extensive.” Atlas Powder Co., v. E.I. DuPont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). The Patent and Trademark Office Board of Appeals summarized the point well when it stated:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.

Ex parte Jackson, 217 USPQ 804, 807 (1982).

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In the present case, even if a considerable amount of experimentation is required to determine blocker peptides within the scope of the invention by their ability to bind and block binding sites/determinates on the bacteria and their ability to competitively inhibit subsequent phage attack, such experimentation would appear to be routine to those of ordinary skill in the relevant art.

Nor are we concerned that the claims may include inoperable embodiments, as is it not a function of the claims to specifically exclude possible inoperative embodiments.

Atlas Powder Co. v. E.I. DuPont de Nemours & Co., 750 F.2d 1569, 1576-77, 224 USPQ 409, 414 (Fed. Cir. 1984); In re Geerdes, 491 F.2d 1260, 1265, 180 USPQ 789, 793

(CCPA 1974). The Federal Circuit has cautioned against limiting a claimed invention to

preferred embodiments or specific examples set forth in the specification. Texas

Instruments v. U.S. Int'l Trade Comm., 805 F.2d 1558, 1562,

231 USPQ 833, 835 (Fed. Cir 1986). Thus, we find with respect to the pending claims,

the examiner has not met the burden of proof by advancing acceptable reasoning

inconsistent with enablement. In view of the above, the rejection of the claims under 35

U.S.C. § 112, first paragraph is reversed.

35 U.S.C. § 103

Claims 9-12 and 15-16 stand rejected under 35 U.S.C. § 103 as unpatentable for

obviousness over Payne or Hettinga in view of Nordstrom.

The examiner relies on Hettinga and Payne for establishing a process of making cheese which includes fermenting a mixture with a bacterial starter culture, making a curd, cutting the curd and curing the curd. The examiner acknowledges that neither Hettinga nor Payne teach using a peptide blocker in a cheese making process or adding such a blocker peptide to a starter culture. Answer, page 6.

The examiner subsequently relies on Nordstrom as evidence of the digestion of immunoglobulins with papain to produce peptides with antiphage activity. The examiner indicates, however, that Nordstrom does not disclose using the digested immunoglobulins to prevent phage attack on bacteria used in the cheese making process. The examiner argues, however, that [Answer, page 7]

[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to use the preparation taught by Nordstrom as an additive to inhibit phages which are detrimental to the cheese making processes of Hettinga and Payne. The digested immunoglobulins are known to be antiphage and the determination of the particular phages upon which they are effective is within the purview of the ordinarily skilled artisan and would be a matter of routine experimentation. This is especially true because Nordstrom teaches that the immunoglobulin acts on the phage itself and not the target microorganism.

To establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of

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making the specific combination that was made by the applicant. See In re Dance, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998); In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). The motivation, suggestion or teaching to modify a reference may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved. See In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) In addition, the teaching, motivation or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references. See WMS Gaming, Inc. v. Int'l Game Tech., 184 F.3d 1339, 1355, 51 USPQ2d 1385, 1397 (Fed. Cir. 1999). The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art. See In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). Broad conclusory statements standing alone are not “evidence.” Dembiczak, Id.

In the present case, the examiner has failed to indicate the specific understanding or principle within the knowledge of a skilled artisan, explicit or implicit, that would have motivated one with no knowledge of appellant’s invention to make the combination in the manner claimed. In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457 (Fed. Cir. 1998). We agree with appellant that the cited references fail to provide any teaching or

suggestion of the use of anti-phage blocker peptides or digested immunoglobulins to prevent phage attack on bacteria used in a cheese making process or the addition of such blocker peptides to a starter culture. Brief, page 14. We do not find where the examiner has provided evidence or a suggestion in the cited references of making the proposed modification of adding phage blocker peptide to the cheese making bacterial starter cultures of the processes of Hettinga and Payne to solve the problem solved by appellant.

In view of the above, we find the examiner has not established on the record before us that the cited references both suggest the claimed subject matter and reveal a reasonable expectation of success to one reasonably skilled in the art. The rejection of the claims for obviousness of the claimed invention is reversed.

CONCLUSION

The rejection of claims 1-17 under 35 U.S.C. § 112, first paragraph is reversed.
The rejection of claims 9-12 and 15-16 under 35 U.S.C. § 103 is reversed.

REVERSED

William F. Smith)
Administrative Patent Judge)
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Toni R. Scheiner
Administrative Patent Judge

Demetra J. Mills
Administrative Patent Judge

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King & Schickli
Corporate Gateway
Suite 210
3070 Harrodsburg Road
Lexington, KY 40503