

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 54

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte VINCENT A. FISCHETTI

Appeal No. 2001-2524
Application No. 08/369,295

Heard: June 13, 2002

Before WINTERS, ADAMS, and GREEN, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 27, 40-44, 50, 51 and 53-55, which are all the claims pending in the application.

Claim 40 is illustrative of the subject matter on appeal and is reproduced below:

40. An antigen conjugate which comprises a linkable carrier covalently bound to a polypeptide which consists of five or more amino acid residues from the conserved exposed region of the M protein of group A streptococci, wherein said antigen conjugate elicits a protective immune response to streptococcal infection in a mammal when administered mucosally.

The references relied upon by the examiner are:

Beachey et al. (Beachey) 4,695,562 Sep. 22, 1987

McKenzie et al. (McKenzie), "Cholera Toxin B subunit as a Carrier Protein to Stimulate a Mucosal Immune Response," J. Immunology, Vol. 133, No. 4, pp. 1818-1824 (1984)

Jones et al. (Jones), "Immunochemical Localization and Amino Acid Sequences of Crossreactive Epitopes Within the Group A Streptococcal M6 Protein," J. Exp. Med., Vol. 164, pp. 1226-1238 (1986)

GROUND OF REJECTION

Claims 54 and 55 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on a specification that fails to adequately describe the claimed invention.

Claims 27, 40-44, 50, 51 and 53-55 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on an insufficient disclosure to support or enable the scope of the claimed invention.

Claims 27, 40-44, 50, 51 and 53-55 stand rejected under 35 U.S.C. § 103 as being unpatentable over Jones in view of either McKenzie or Beachey.

DISCUSSION

THE REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

Written Description:

According to the examiner (Answer, page 4):

[T]he specification discloses specific peptides having selected amino acid lengths of 20, 22, 10, 21, 22 and 21.... The recitation of "more than 10 amino acids may include numerous peptides having, for example, 11, 12, 03 [sic] 13 amino acids. Furthermore, in view of the total number of amino acids of the conserved exposed region of the M protein being in the order of 130, peptides having much greater lengths are encompassed by the limitation "more

than 10”, in the absence of setting any upper limit to the number of amino acids in the peptides presently recited in the claims. By reciting “more than 10 amino acids” claims are essentially disclosing a range having only a lower limit (of 10 amino acids) but no upper limit. Peptides encompassing such a range of amino acid length[s] are not adequately supported by the specification disclosure.

In response appellant argues (Brief, page 7), “the recitation of ‘ten or more amino acid residues from the conserved exposed region’ does not admit an unlimited number of amino acids in the claimed peptide, because the conserved exposed region is approximately 130 amino acids long....” We agree. Claims 54 and 55 depend from claim 40 which requires that that antigen conjugate comprise, inter alia, “a polypeptide which consists of five or more amino acid residues from the conserved exposed region of the M protein of group A streptococci....” Therefore, contrary to the examiner’s position, since the “conserved exposed region” is approximately 130 amino acids long, there is an upper limit on the number of amino acids in the M protein polypeptide component of the conjugate.

While appellant concedes (Brief, page 7) “that neither the present specification nor the original claims specifically recite peptides of ‘ten or more’ [claim 54] or ‘10-22’ [claim 55] amino acids ... [appellant argues] the test for adequacy of the written description is not that the claimed subject matter be described literally in the specification....” According to appellant (Brief, page 6) “the present specification, on page 11, specifically exemplifies peptides of 10-22 amino acids ... [and both] [t]he specification and original claims recite peptides of at least 5 amino acids from the conserved exposed region of the M protein....”

According to appellant (Brief, page 8), the originally filed specification and claims therefore “convey with reasonable clarity to those skilled in the art” that they were in possession of what is now claimed. We agree.

On this record, appellant discloses in the originally filed specification a range of at least 5 amino acids wherein the upper limit is approximately 130 amino acids. As the examiner recognizes (Answer, page 4), the originally filed specification also provides for peptides having lengths of 10, 20, 21 and 22 amino acids. Therefore the question is whether, on these facts, the examiner has presented sufficient reason to doubt that the broader described range (at least 5 amino acids with an upper limit of approximately 130 amino acids) also describes the somewhat narrower claimed range (ten or more amino acids, as set forth in claim 54; or ten to 22 amino acids, as set forth in claim 55). We note that the examiner provides no evidence that there is a distinction between the claimed lower limit and the broader range set forth in the specification in terms of the operability of appellants’ process or of achieving the desired result, e.g., a protective immune response. Cf. In re Wertheim, 541 F.2d 257, 265, 191 USPQ 90, 98 (CCPA 1976). Therefore, in our opinion, the examiner has not provided the evidence necessary to support a finding that the broad range disclosed by appellant does not also describe the narrow range now claimed.

Accordingly, we reverse the rejection of claims 54 and 55 under 35 U.S.C. § 112, first paragraph, as being based on a specification that fails to adequately describe the claimed invention.

Enablement:

To satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, a patent application must adequately disclose the claimed invention so as to enable a person skilled in the art to practice the invention at the time the application was filed without undue experimentation. Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371-72, 52 USPQ2d 1129, 1136 (Fed. Cir. 1999). We note, however, that “nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples.” In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). As set forth in In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993):

When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.

Whether the disclosure is enabling, is a legal conclusion based on several underlying factual inquiries. See In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988). As set forth in Wands, the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

We find no analysis of the Wands factors by the examiner. Instead, we find only the examiner's unsupported conclusions as to why the specification does not enable the claimed invention. According to the examiner (Answer, page 6), "any peptides of five or more amino acids may prove to be antigenic when conjugated to a carrier protein but whether such an antigen will or will not be protective is not predictive from the fact that it is antigenic since such findings are empirical ... based on trial and experimentation...." In addition, with regard to the carrier portion of the antigen conjugate, the examiner finds (Answer, page 8), "the specification does not provide sufficient guidance as to which natural carriers would be effective in providing a conjugate that would be effectively immunogenic and/or immunoprotective." The examiner, however, failed to provide a factual basis for his concerns. In the absence of a fact-based statement of a rejection based upon the relevant legal standards, the examiner has not sustained his initial burden of establishing a prima facie case of non-enablement.

As set forth in In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971), before issues related to the patentability of the claimed subject matter can begin to be considered, the examiner must determine what is being claimed.

[T]he claims must be analyzed first in order to determine exactly what subject matter they encompass....

The first inquiry therefore 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.

See also In re Geerdes, 491 F.2d 1260, 1262, 180 USPQ 789, 791 (CCPA 1974) (“Before considering the rejections under 35 U.S.C. § ... 112, we must first decide ... [what] the claims include within their scope.”). Appellant’s claims require that the antigen conjugate elicit a protective immune response to streptococcal infection in a mammal when administered mucosally. As the examiner recognizes (Paper No. 38, page 3) appellant’s specification exemplifies the carrier cholera toxin B (CTB). The specification also discloses (page 25), “[t]hose skilled in the art will recognize that other carriers can be employed ... [including] the E. coli labile toxin B subunit or the pili from E. coli cells identified as K99 pili and 987 pili....”

While the examiner may be concerned that the claims include inoperative embodiments, as set forth in Atlas Powder Co. v. E.I. DuPont De Nemours & 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....” In re Dinh-Nguyen, 492 F.2d 856, 859-59, 181 USPQ 46, 48 (CCPA 1974)(emphasis omitted). Accord, In re Geerdes, 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974); In re Anderson, 471 F.2d 1237, 1242, 176 USPQ 331, 334-35 (CCPA 1971). 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. See e.g., In re Cook, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971).

The examiner provides no factual evidence to suggest that a person of ordinary skill in the art, following the teachings of appellant's disclosure would be forced to experiment unduly in order to practice the claimed invention.

On reflection, in our opinion, the examiner failed to provide the evidence necessary to establish a prima facie case of non-enablement. Accordingly, we reverse the rejection of claims 27, 40-44, 50, 51 and 53-55 under 35 U.S.C. § 112, first paragraph, as being based on an insufficient disclosure to support or enable the scope of the claimed invention.

THE REJECTION UNDER 35 U.S.C. § 103:

According to the examiner (Paper No. 38, page 4) Jones teach that antibodies directed toward C-terminal regions of streptococcal M protein provide better cross-reactivity to various serotyping strains of group A streptococci as compared to those directed toward the N-terminal region. The examiner relies on McKenzie and Beachey to teach mucosal carrier proteins. We note of interest the examiner's reliance on Beachey (Paper No. 38, page 4) for the disclosure "that protein carrier[s] such as tetanus toxoid are used to evoke opsonic and protective antibodies to antigenic peptides and further exemplifies 'natural' carrier proteins such as BSA and OVA."

However, as appellant points out (Brief, page 15), Jones finds (page 1236) that their antibodies were not opsonic. Jones states (id.) "[w]hether the lack of function of these antibodies is due to the location of their epitopes on the molecule or their complement fixing capabilities is currently under investigation." Jones concludes by offering a hope (id.) that the M protein epitopes they

identified and “other epitopes shared by many of the group A streptococcal M serotypes may form the basis for synthetic vaccines that can elicit crossprotective antibodies against multiple M serotype infection or that can be used as reagents for the identification of M protein-containing streptococci.” See also Brief, page 16.

In view of this evidence, appellant argues (Brief, page 17) Jones suggests “not that the disclosed peptides would be usefully combined in a therapeutic or diagnostic composition, but that the disclosed peptides were incapable of eliciting the production of opsonic antibodies and were thus non-functional.” Therefore, appellant concludes (Brief, page 18) that Jones teaches away from the present invention. We agree.

In satisfying this initial burden, “it is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art.” In re Wesslau, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965); see also In re Mercer, 515 F.2d 1161, 1165-66, 185 USPQ 774, 778 (CCPA 1975). Instead, in determining whether the claimed invention is obvious, a prior art reference must be read as a whole and consideration must be given where the reference teaches away from the claimed invention. Akzo N.V., Aramide Maatschappij v.o.f. v. United States Int’l Trade Comm’n, 808 F.2d 1471, 1481,

1 USPQ2d 1241, 1246 (Fed. Cir. 1986). In this regard we note the direction provided by In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991):

Where the subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under [35 U.S.C.] § 103 requires, inter alia, consideration of two factors (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.... Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure.

On this record, the examiner failed to establish that a person of ordinary skill in the art would have had a reasonable expectation of success in obtaining an antigen conjugate that is capable of eliciting a protective immune response to streptococcal infection when administered mucosally. In the absence of a reasonable expectation of success, one is left with only an "obvious to try" situation which is not the standard of obviousness under 35 U.S.C. § 103. See In re O'Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673, 1680. In our opinion, Jones merely provides a hope, that upon further research, a protective antibody may eventually be obtained, not a reasonable expectation of success.

Accordingly, based on the evidence presented for our review, we reverse the rejection of claims 27, 40-44, 50, 51 and 53-55 under 35 U.S.C. § 103 as being unpatentable over Jones in view of either McKenzie or Beachey.

REVERSED

Sherman D. Winters)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
Donald E. Adams)	
Administrative Patent Judge)	APPEALS AND
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Appeal No. 2001-2524
Application No. 08/369,295

Page 12

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