

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 36

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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

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Ex parte ROBERT R. BRUBAKER,  
VLADIMIR L. MOTIN, and  
GEORGE B. SMIRNOV

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Appeal No. 2002-2281  
Application No. 08/302,423

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ON BRIEF

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Before ADAMS, MILLS, and GRIMES, 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 10-13, which are all the claims pending in the application.

Claim 10 is illustrative of the subject matter on appeal and is reproduced below:

10. A method of controlling Y. pestis in a mammal comprising the steps of:
  - a) providing a vaccine comprised of an antigen protein encoded by a plasmid prepared by recombinant techniques having the construct shown in Figure 1; and
  - b) treating a mammal with an immunologically effective amount of the vaccine.

The references relied upon by the examiner are:

Lawton et al. (Lawton), "Biosynthesis and Purification of V and W Antigen in Pasteurella Pestis," J. Immunology, Vol. 91, No. 2, pp. 179-84 (1963)

Une et al. (Une), "Roles of V Antigen in Promoting Virulence and Immunity in Yersinia," J. Immunology, Vol. 133, No. 4, pp. 2226-30 (1984)

Nilsson et al. (Nilsson), "Immobilization and Purification of Enzymes with Staphylococcal Protein A Gene Fusion Vectors," EMBO J., Vol. 4, No. 4, pp. 1075-80 (1985)

Brubaker et al. (Brubaker), "Proteolysis of V Antigen from Yersinia pestis," Microbial. Pathogenesis, Vol. 2, pp. 49-62 (1987)

Sato et al. (Sato), "Preparation of Monoclonal Antibody to V Antigen from Yersinia pestis," Contrib. Microbiol. Immunol., Vol. 12, pp. 225-29 (1991)

#### GROUND OF REJECTION

Claims 10-13 stand rejected under 35 U.S.C. § 103 as obvious over any one of Sato, Une, or Lawton in view of Brubaker and Nilsson.

#### DISCUSSION

According to the examiner (Answer, page 4), Sato, Une, and Lawton "teach a method of immunizing and the same antigen as recited in the claims, however, the antigen was not produced by the plasmid construct of Figure 1." To make up for this deficiency, the examiner relies (Answer, page 5) on Brubaker to teach "the V antigen is a potentially labile molecule and that appropriate methods of stabilization may have to be developed in order to define its function." In addition, the examiner relies (id.) on Nilsson to teach "a method of stabilizing recombinant proteins to allow purification in a one-step procedure

by using two plasmid vectors....” Based on this evidence, the examiner concludes (id.):

Although none of the references teach the recombinant plasmid construct of Figure 1, the references disclose the V antigen and a method of immunizing. The production of a protein by a particular process does not impart novelty or unobviousness to a protein when the same protein is taught by the prior art, absent evidence to the contrary or unexpected results. This is particularly true when the properties of the protein are not changed by the process in an unexpected manner.

As appellants explain (Brief, page 2), the construct of Figure 1, as referred to in the claims, “was constructed so as to encode a fusion of lcrV ... and the structural gene for staphylococcal protein A with the exception of the first 67 N-terminal amino acids of the antigen and the signal sequence plus immunoglobulin (IgG) binding domains....” In addition, as defined in the specification (page 10), “[a]s a consequence of this fusion, lcrV lost 201 bp which thus deleted the first 67 amino acids comprising the N-terminal portion of V antigen.”

As the examiner admits, “none of the references teach the recombinant plasmid construct of Figure 1....” Answer, page 5. To the extent that the examiner would argue (Answer, page 6), that the phrase “a vaccine (or composition) comprised of an antigen protein” allows for the inclusion of additional amino acids at the N-terminal portion of the V antigen, and thereby the claim reads on the full length V antigen, we disagree. In our opinion, the transitional phrase “comprised of” modifies the vaccine or composition, and not the antigenic protein encoded by the construct illustrated in Figure 1. Therefore, while the vaccine or composition may contain additional antigenic proteins, even

the full length V antigen, the vaccine or composition must contain the antigen encoded by the construct illustrated in Figure 1.

Upon review of the Answer, and the references relied upon by the examiner, we are unable to identify any suggestion to utilize a truncated Y. pestis antigen, one that is missing 67 amino acids of the N-terminal end. See also, Brief, pages 5 and 6. While the examiner believes that “the burden is upon [a]pplicant to demonstrate that the resulting peptide produces a materially, functionally and structurally different protein,” for the forgoing reasons we believe that this evidence is already of record.

What is not of record, is any evidence suggesting that a person of ordinary skill in the art at the time the invention was made would have been motivated to utilize a truncated antigenic protein, having the characteristics of the one encoded by the construct illustrated in appellants' Figure 1 as is required by the claimed invention. Prima facie obviousness based on a combination of references requires that the prior art provide “a reason, suggestion, or motivation to lead an inventor to combine those references.” Pro-Mold and Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996).

[E]vidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. . . . The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular.

In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999)

(citations omitted). The suggestion to combine prior art references must come

from the cited references, not from the application's disclosure. See In re Dow Chem. Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

On reflection it is our opinion that the examiner failed to meet her burden of providing the evidence necessary to establish a prima facie case of obviousness. Accordingly, we reverse the rejection of claim 10-13 under 35 U.S.C. § 103 as obvious over any one of Sato, Une or Lawton in view of Brubaker and Nilsson.

REVERSED

Donald E. Adams )  
Administrative Patent Judge )  
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) BOARD OF PATENT  
Demetra J. Mills )  
Administrative Patent Judge ) APPEALS AND  
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) INTERFERENCES  
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Eric Grimes )  
Administrative Patent Judge )

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William J. Schramm  
Reising, Ethington, Barnard & Perry  
P.O. Box 4390  
Troy, MI 48099-4390

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