

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte GERALD W. FISCHER

Appeal No. 2001-1576
Application No. 08/460,622

ON BRIEF

Before ADAMS, MILLS 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 17 and 23, which are all the claims pending in the application.

Claim 17 is illustrative of the subject matter on appeal and is reproduced below:

17. A method of preparing a Directed Human Immune Globulin having opsonophagocytic bactericidal activity against Staphylococcus epidermidis for the prevention or treatment of Staphylococcus epidermidis infections comprising the steps of:
 - (a) immunizing plasma donors with an S. epidermis vaccine comprising antigens in the TCA extractions of whole cell S. epidermidis; and
 - (b) removing plasma from said donors for Directed Human Immune Globulins.

The references relied upon by the examiner are:

(Sutherland) Separation and purification of bacterial antigens in HANDBOOK OF EXPERIMENTAL IMMUNOLOGY pp. 2.11-12 (D.M. Weir, ed., 3rd ed., Blackwell Scientific Publications, Oxford 1978)

Ichiman et al. (Ichiman), "Protective antibodies in human sera against encapsulated strains of Staphylococcus epidermidis," J. Applied Bacteriology, Vol. 63, pp. 165-69 (1987)

Fischer, "Therapeutic Uses of Intravenous Gammaglobulin for Pediatric Infections," New Topics in Pediatric Infectious Disease, Vol. 35, No. 3, pp. 517-33 (1988)

Etzioni et al. (Etzioni), "Effect of an Intravenous Gammaglobulin Preparation on the Opsonophagocytic Activity of Preterm Serum against Coagulase-Negative Staphylococci," Acta Paediatrica Scandinavica, Vol. 79, pp. 156-61 (1990)

GROUND OF REJECTION

Claim 17 and 23 stand rejected under 35 U.S.C. § 103 as obvious over Fischer in view of Etzioni and Sutherland.

Claim 17 and 23 stand rejected under 35 U.S.C. § 103 as obvious over Ichiman in view of Sutherland.

We reverse.

BACKGROUND

According to appellant, Directed Human Immune Globulin is different from standard human immune globulin preparations in that it has high levels of human anti-staphylococcal antibodies that react with surface antigens of S. epidermidis and enhance phagocytosis and killing of S. epidermidis in vitro, (opsonophagocytic bactericidal activity greater than 80%). Specification, page 8.

DISCUSSION

Fischer in view of Etzioni and Sutherland:

According to the examiner (Answer, page 4), “Fischer discloses that a directed GBS [Group B Streptococcus]-specific immunoglobulin preparation was prepared from pooled plasma obtained from volunteers immunized with a pentavalent GBS vaccine (Sandoglobulin, GBS-IVIG) which had consistent high titers of antibody to each GBS serotype (p. 522).” We note that in contrast to the claimed invention that requires immunizing plasma donors with a Staphylococcus epidermidis vaccine (claim 1, step (a)), Sandoglobulin is a directed group B Streptococcus specific immunoglobulin preparation. Nevertheless, the examiner finds (Answer, page 5), with reference to Etzioni, “that Sandoglobulin contains antibodies against two different Staphylococcus epidermidis strains (page 160, third full paragraph).”

The examiner also finds (Answer, page 4, emphasis removed), “Fischer further teaches the preparation and selection of specific donors necessary to produce highly active IGIV preparations which can be analyzed for functional activity against staphylococci (p. 529).” We, however, are unable to find such an affirmative statement in Fischer. Instead, as we read the reference, Fischer provides nothing more than an invitation to experiment. According to Fischer (bridging paragraph, pages 528-529, footnotes omitted), “[d]irected immunoglobulin preparations could be produced by selecting plasma donors with high levels of pathogen-specific antibody or by immunizing donors prior to plasmapheresis. ... Analysis of IVIG in vitro has shown functional activity for

staphylococci, streptococci, and E. coli, Serratia, and Pseudomonas organisms. Ultimate success will depend on well-characterized and standardized IVIG products.” In other words, it would have been obvious to explore this general approach that seems to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.

Therefore, we cannot agree with the examiner’s statement (Answer, page 5) that in view of the combination of Fischer with Etzioni “one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success in producing a directed human immune globulin for treatment of S. epidermidis infections....” As discussed above, it is our opinion that Fischer does not provide a person of ordinary skill in the art with the guidance necessary to establish a reasonable expectation of success. Instead, Fischer simply invites others to experiment with directed IVIG against staphylococcus and other bacteria. Stated differently, based on the teachings of Fischer it would have been obvious-to-try to prepare a directed human immune globulin having opsonophagocytic bactericidal activity against Staphylococcus epidermidis; “obvious to try,” however, is not the standard of obviousness. In re O’Farrell, 853 F.2d 894, 903-04, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

Furthermore, given the emphasis the examiner placed on Etzioni, and her statement (Answer, page 5) that a person of ordinary skill in the art would have had a reasonable expectation of success using a commercially available product, such as Sandoglobulin, we are unable to identify any motivation for one of

ordinary skill in the art at the time the invention was made to prepare a different directed human immune globulin against Staphylococcus epidermidis, having opsonophagocytic bactericidal activity as is required by the claimed invention.

We are also unable to identify from the evidence of record, any motivation for the use of TCA extracted antigens. As the examiner points out (Answer, page 6), “neither reference particularly discloses a method where [sic] the S. epidermidis antigens are obtained by TCA extraction.” While the examiner asserts (id.), Sutherland teaches “that teichoic acids of Gram-negative bacteria are antigenic determinants and have great immunological importance,” the examiner failed to identify any evidence suggesting that TCA extracts of S. epidermidis would be useful in preparing a directed human immune globulin having opsonophagocytic bactericidal activity against Staphylococcus epidermidis 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

Chemical Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

For the forgoing reasons it is our opinion that the examiner failed to meet her burden¹ of providing the evidence necessary to establish a prima facie case of obviousness. Accordingly we reverse the rejection of claims 17 and 23 under 35 U.S.C. § 103 as obvious over Fischer in view of Etzioni and Sutherland.

Ichiman in view of Sutherland:

According to the examiner (Answer, page 8), “Ichiman et al[.] prepare the IVIG in a method that is essentially the same as that which is instantly claimed, i.e., injecting S.[]epidermidis antigens into subjects and removing plasma for Directed Human Immune globulin.”

In our opinion, the examiner has misapprehended the Ichiman reference. As appellants point out (Brief, page 29);

[t]here is no suggestion in Ichiman for any method of making Directed Human Immune Globulin by immunizing donors with an S. epidermidis vaccine and later withdrawing plasma containing anti-S. epidermidis antibodies. Instead, Ichiman’s study assessed whether or not normal human sera had sufficient antibody in it to passively protect mice against challenge by S. epidermidis.

We agree with appellants. Sutherland relied upon by the examiner to teach TCA extraction does not make up for the deficiency of Ichiman.

Accordingly we reverse the rejection of claims 17 and 23 under 35 U.S.C. § 103 as obvious over Ichiman in view of Sutherland.

¹ The initial burden of presenting a prima facie case of obviousness rests on the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

Having determined that the examiner has not established a prima facie case of obviousness, we find it unnecessary to discuss the Declarations and evidence of non-obviousness, relied on by appellants to rebut any such prima facie case.

REVERSED

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Donald E. Adams)	
Administrative Patent Judge)	
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