

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

Paper No. 24

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SIEGFRIED R. KRUTZIK

Appeal No. 1999-1423
Application 08/261,639

ON BRIEF

Before ROBINSON, 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 48-61, which are all of the claims pending in this application.

We reverse.

Claim 48 is illustrative of the claims on appeal and read as follows:

48. A device for detecting the presence or amount of HIV-1 or HIV-2 antibody in a biological sample, comprising:

a sample absorber pad for application of said sample;

a first matrix, said first matrix being in fluid communication with said sample absorber pad, said first matrix being impregnated with a first glycoprotein covalently linked to bovine serum albumin, said first glycoprotein being selected from the group consisting of HIV-1 glycoprotein 41 and HIV-2 glycoprotein 36, said glycoprotein covalently linked to bovine serum albumin being conjugated to gold particles having a diameter of between about 5 nm and about 50 nm; and

a second matrix in fluid communication with the first matrix, said second matrix having immobilized thereon a point spatially separated from the first matrix a second glycoprotein covalently linked to bovine serum albumin, said second glycoprotein being HIV-1 glycoprotein 41 when said first glycoprotein is HIV-1 glycoprotein 41 and being HIV-2 glycoprotein 36 when said first glycoprotein is HIV-2 glycoprotein 36, said second glycoprotein being immobilized on the second matrix;

wherein said first glycoprotein is capable of moving from the first matrix to the second matrix and to said point spatially separated from the first matrix after application of the sample to the first zone.

The prior art references relied upon by the examiner are:

Kondo et al. (Kondo)	4,256,693	Mar. 17, 1981
Weng et al. (Weng)	4,740,468	Apr. 26, 1988
Tzeng et al (Tzeng)	WO 92/22797	Dec. 23, 1992

Berry et al. (Berry), "A comparison of four enzyme immunoassays for the simultaneous detection of HIV-1- and HIV-2-specific antibody, Journal of Virological Methods, Vol. 34, pp. 91-100 (1991)

Appeal No. 1999-1423
Application 08/261,639

Brief and Reply Brief for the appellant's arguments thereagainst. As a consequence of our review, we make the determinations which follow.

Claim Interpretation

Our appellate reviewing court stated in Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1567-1568, 1 USPQ2d 1593, 1597 (Fed. Cir.), cert denied, 481 U.S. 1052 (1987):

Analysis begins with a key legal question -- what is the invention claimed? Courts are required to view the claimed invention as a whole. 35 U.S.C. 103. Claim interpretation, in light of the specification, claim language, other claims and prosecution history, is a matter of law and will normally control the remainder of the decisional process. [Footnote omitted.]

To that end, we note that during ex parte prosecution, claims are to be given their broadest reasonable interpretation consistent with the description of the invention in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). In the present case we interpret claim 48 as including several critical claim elements which include a “first glycoprotein being selected from the group consisting of HIV-1 glycoprotein 41 and HIV-2 glycoprotein 36,” and that the “first glycoprotein is capable of moving from the first matrix to the second matrix and to said point spatially separated from the first matrix after application of the sample to the first zone”.

35 U.S.C. § 103

Claims 48, and 50-60 stand rejected under 35 U.S.C. § 103 over Tzeng and Berry.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art. In re Bell, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993). An obviousness analysis requires that the prior art both suggest the claimed subject matter and reveal a reasonable expectation of success to one reasonably skilled in the art. In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). With this as background, we analyze the prior art applied by the examiner in the rejection of the claims on appeal.

The examiner suggests that Tzeng teaches the basic concept of the present invention. According to the Examiner, Tzeng describes the second antigen as being the same as the first antigen and is to be fixed at a second location to capture the mobile antigen and analyte antibodies. Tzeng, also, teaches one how to conjugate BSA and metal sols to the antigen and that such techniques are well known in the art. Tzeng describes a device that is not only subdivided into reactive regions, but that

suitable materials including nitrocellulose and glass fiber compositions are known.

Answer, page 5.

The examiner suggests that “it would be within the skill of the artisan to arrange the components as would be useful and convenient to performing the assay.” Id. Tzeng is indicated by the examiner to provide for a control region downstream from the reactive zones of the device. While the examiner suggests that “Tzeng teach that the method can be adapted to testing for anti-HIV antibodies”, the examiner has not provided a specific reference to, and we do not find such a specific statement in Tzeng regarding the adaptability of the assay and device of Tzeng for testing HIV-antibodies.

Berry is relied on by the examiner for the disclosure of numerous assays that test for HIV-1, HIV-2, or both. For this reason, the examiner finds (Answer, page 6) that, “It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the assay device and method disclosed by Tzeng et al and modify it to test for antibodies reactive against HIV-1, HIV-2, or both.”

The conclusion that the claimed subject matter is prima facie obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Rejections based on § 103 must rest on a factual basis with these facts being

interpreted without hindsight reconstruction of the invention from the prior art. All the claims under appeal require specific glycoproteins selected from the group consisting of HIV-1 glycoprotein 41 and HIV-2 glycoprotein 36. However, these claim elements are not suggested by the applied prior art or specifically addressed by the examiner in the statement of rejection. In this regard, while Tzeng does appear to generally teach the use of “any antigen having specific reactivity with the particular antibody of interest” in its described assay and device (specification, page 13), there is no specific mention of the use of HIV antigens or the detection of antibodies to HIV-1 or HIV-2, in particular glycoproteins selected from the group consisting of HIV-1 glycoprotein 41 and HIV-2 glycoprotein 36.

To supply these omissions in the teachings of the applied prior art, the examiner made determinations that these differences would have been obvious to an artisan or that they are commercially available. Answer, page 5. However, we find these determinations have not been supported by evidence of commercial availability or any evidence that would have led an artisan to arrive at the claimed invention.

Appellant, similarly, argues that the disclosure of Tzeng makes no mention of the detection of HIV antibodies using the specific antigens employed by the Appellant, and that the Examiner’s broad conclusion can only be supported by the luxury of hindsight, a legally improper way to conduct an obviousness determination. Brief, page 13. We agree.

In view of the above, we find the examiner has failed to established a prima facie case of obviousness, and the rejection of claims 48, and 50-60 under 35 U.S.C. § 103 over Tzeng and Berry is reversed.

35 U.S.C. § 103

The rejections of claims 48 and 49 under 35 U.S.C. § 103 over Tzeng and Berry in further view of admissions in the specification; of claims 48 and 57 under 35 U.S.C. § 103 over Tzeng and Berry in further view of Weng; and of claims 48, 59 and 61 under 35 U.S.C. § 103 over Tzeng and Berry in further view of Kondo are also reversed.

All of these additional rejections rely on the primary combination of references, Tzeng and Berry. The examiner relies on admissions in the specification to establish that the use of albumin, and variations on it, were known in the art and were readily available from commercial suppliers. Answer, page 6. Weng is relied on by the examiner for the disclosure of poly(vinyl) butyrate support material. Id. Kondo is relied on for the disclosure of the use of a prefilter device in immunoassays. Answer, page 7.

The additional cited references fail to overcome the deficiencies of the primary combination of Tzeng and Berry and the failure to describe specific glycoproteins selected from the group consisting of HIV-1 glycoprotein 41 and HIV-2 glycoprotein 36.

After evidence or arguments are submitted by the appellant in response to a rejection based on obviousness, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of the argument. On balance, we believe that the totality of the evidence presented by the examiner and appellant weighs in favor of finding the claimed invention to be nonobvious in view of the cited references. We find the examiner has failed to establish, 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 rejections of the remaining claims for obviousness are reversed.

Other Issue

The above rejections of record are reversed because the examiner failed to provide objective evidence of knowledge in the prior art of the either of the specific glycoproteins HIV-1 glycoprotein 41 or HIV-2 glycoprotein 36, as required by the claims. Upon return of the application to the examiner, the examiner should consider fully the disclosure of Chin with respect to its teachings of the use of a monoclonal antibody to HIV-2 gp36 antigen in kits and knowledge in the art of a murine antibody specific for HIV-1 gp 41 (columns 1-2 and 14). Chin states that the monoclonal antibody to HIV-2 gp36 specifically binds to HIV-2 and does not significantly bind to HIV-1. Column 1.

In considering the propriety of a possible rejection of the claims under 35 U.S.C. § 103 in view of Tzeng and Chin, the examiner should note that the appellant raises an argument in the Brief that Tzeng teaches that it is possible that the complex formed by the labeled antigen and the analyte antibody may be insoluble. Thus, one of skill in the art would not have a reasonable expectation of success that the claimed glycoprotein antibody complex would migrate properly. Brief, page 16. If the examiner should decide a rejection of the claims over Tzeng in view of Chin is appropriate, the examiner should address the question of whether there is a reasonable expectation of success provided by the references that the “first glycoprotein is capable of moving from the first matrix to the second matrix and to said point spatially separated from the first matrix after application of the sample to the first zone”, in view of the disclosure of Tzeng. The examiner should consider whether Tzeng merely discloses a possibility of insolubility and agglutination problems and whether Tzeng additionally discloses methods of addressing these problems. See, for example, Tzeng, page 18, lines 24-30.

CONCLUSION

The rejections of Claims 48 and 50-60 under 35 U.S.C. § 103 over Tzeng and Berry; Claims 48 and 49 under 35 U.S.C. § 103 over Tzeng and Berry in further view of

Appeal No. 1999-1423
Application 08/261,639

admissions in the specification; and Claims 48 and 57 under 35 U.S.C. § 103 over Tzeng and Berry in further view of Weng are reversed.

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

REVERSED

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Douglas W. Robinson)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
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Administrative Patent Judge)	APPEALS AND
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Appeal No. 1999-1423
Application 08/261,639

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