

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.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. 13

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ERNEST J. KISER, DEBORAH P. TUOHY,
and JOHN M. DUBOWIK

Appeal No. 1999-1307
Application No. 08/442,035

ON BRIEF

Before ROBINSON, SCHEINER, and MILLS, Administrative Patent Judges.
ROBINSON, 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 1 - 17, which are all of the claims pending in the application.

Claim 1 is illustrative of the subject matter on appeal and reads as follows:

1. A test strip, for determining the concentration of an analyte in a body fluid, which comprises:

a cover sheet, having an elongated window cut through it;

a lamellar membrane adjacent to the cover sheet, extending across and into the window and containing a reagent that reacts with the analyte to produce a color change;

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a porous sheet in fluid communication with the membrane, having a porous, enlarged pillow portion and a compressed portion, the pillow portion being substantially aligned with the window; and

a backing sheet, adjoining the porous sheet and having a sample port cut through it;

whereby fluid introduced into the sample port can flow through the porous sheet to the membrane, and analyte in the fluid can react with the reagent to produce a color change visible through the window.

The reference relied upon by the examiner is:

Blatt et al. (Blatt)

4,761,381

Aug. 2, 1988

Ground of Rejection

Claims 1 - 17 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies on Blatt.

We reverse for reasons set forth herein.

Discussion

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims and to the respective positions articulated by the appellants and the examiner. We make reference to the Examiner's Answer of December 9, 1997 (Paper No. 12) for the examiner's reasoning in support of the rejection and to the appellants' Appeal Brief, filed October 9, 1997 (Paper No. 11), for the appellants' arguments thereagainst.

Background

Claim 1 is directed to a test strip for determining the concentration of an analyte in a body fluid comprising a cover sheet having an elongated window cut through it, a lamellar membrane adjacent to the cover sheet which extends across and into the window and contains the reagent which reacts with the analyte present in the sample to produce a detectable color change, a porous sheet in fluid communication with the membrane, having a porous, enlarged pillow portion and a compressed portion wherein the pillow portion is substantially aligned with the window and a backing sheet adjoining the porous sheet and having a sample port cut through it.

The rejection under 35 U.S.C. § 103

The examiner's rejection of claims 1 - 17 depends, solely, on the teachings of Blatt. While we would agree that Blatt describes a device which provides a means for dealing with the problem of excess sample so that excess liquid does not interfere with obtaining a proper reading (Answer, page 4) which, at least in part, reflects one of the benefit attributed to the present claimed invention, (Specification, page 2, second paragraph), we do not agree with the examiner's stated conclusion that (Answer, page 5):

[i]t would have been obvious to one of ordinary skill in the art at the time of the invention was made to have both a pillow portion and a compressed portion of the porous layer in the test strip of Blatt because Blatt teaches various forms of porous reagent layers and teaches an absorbent portion to absorb excess sample.

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It is sufficient for the purposes of this appeal to note that Blatt does not disclose a test strip device which has a cover sheet having an elongated window cut through it. While Blatt does describe testing devices where the cover layer may be clear and transparent (column 5, lines 21-22), we find nothing, and the examiner has pointed to no information to be found in the reference, which would suggest modifying the device explicitly disclosed by incorporating a window cut through the cover sheet. Further, the porous material described by Blatt is not described as a sheet, but is described as being in the overflow chamber (column 4, lines 21-23 and 56-59) and there is no indication that the porous material of Blatt could be in the form of a sheet or that it should have an enlarged pillow portion and a compressed portion which is spatially aligned with the window of the cover sheet.

Thus, the examiner's conclusions that it would have been obvious to have both a pillow portion and a compressed portion of the porous layer in the test strip of Blatt are not supported by any substantive evidence. We find nothing in this reference which would have reasonably led one of ordinary skill in this art to cut a window in the cover sheet or to configure the absorbent material in a manner which would correspond to that which is required by the claims.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Only if that burden is met, does the burden of

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coming forward with evidence or argument shift to the applicants. Id. In order to meet that burden the examiner must provide a reason, based on the prior art, or knowledge generally available in the art as to why it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention. Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 297, n.24, 227 USPQ 657, 667, n.24 (Fed. Cir.), cert. denied, 475 U.S. 1017 (1986).

On the record before us, the examiner has not met the initial burden of establishing why the prior art, relied on, would have led one of ordinary skill in this art to arrive at the test strip presently claimed. Blatt discloses a test strip, lacking a window in the cover sheet, which makes use of capillary channels to direct the fluid sample into the chamber where the detection reagent is located rather than a porous absorbent layer as presently claimed. The examiner has provided no facts or evidence which would reasonably be read to modify Blatt in a manner to arrive at the claimed test strip. The examiner has failed to account for the claimed elements as a whole in a manner which would reasonably support a conclusion that the claimed subject matter would have been obvious within the meaning of 35 U.S.C. § 103. In the absence of such evidence, the only suggestion to assemble a test strip of the type presently claims is provided by appellants' disclosure of the invention. However, use of this information as a basis for establishing a prima facie case of obviousness, within the meaning of 35 U.S.C. § 103, would constitute impermissible hindsight.

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Thus, the examiner has not provided those facts or evidence which would reasonably support a conclusion that the claimed subject matter would have been prima facie obvious within the meaning of 35 U.S.C. § 103. Where the examiner fails to establish a prima facie case, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir.1988). Therefore, the rejection of claims 1 -17 under 35 U.S.C. § 103 is reversed.

Summary

The rejection of claims 1 - 17 under 35 U.S.C. § 103 as unpatentable over the teachings of Blatt is reversed.

REVERSED

DOUGLAS W. ROBINSON))
Administrative Patent Judge))
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) BOARD OF PATENT)
TONI R. SCHEINER))
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