

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 16

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEVEN C. CHARLTON
and MICHAEL J. WILCOX

Appeal No. 1996-0783
Application No. 08/102,297¹

HEARD: November 15, 1999

Before PAK, WARREN, and KRATZ, Administrative Patent Judges.
KRATZ, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1 through 32, which are all of the claims pending in this application.

BACKGROUND

The appellants' invention relates to an analyte detection method and device. An understanding of the invention can be

¹ Application for patent filed August 5, 1993.

derived from a reading of exemplary claims 1, 16 and 19, which are reproduced below.

1. A device for rapidly detecting an analyte in a volume of biological fluid, wherein the volume is as low as five to ten microliters, said device comprising:

- a) means for detecting said analyte; and
- b) a separation matrix vertically adjacent, compressed to and coincident with said detection means such that analyte applied to said separation means can move from said separation matrix to said detection means, wherein said separation matrix and said detection means are under a volume compression of between 14 to 43 percent;
- c) a cover portion having an aperture, the cross-sectional area of which aperture is less than 90 percent of the cross-sectional area of said separation matrix; and
- d) a base portion containing an access means to allow detection of an analytical signal generated by the detection means.

16. A process of rapidly detecting glucose in a volume of a biological fluid, wherein said volume is as low as five to 10 microliters, said process comprising the steps of:

- a) a base portion having a transparent window;
- b) a means for detecting glucose vertically adjacent to said base portion and at least partially coincident with said window;
- c) a separation matrix vertically adjacent to, compressed to and substantially coincident with said detection means, wherein the detection means and the

separation matrix are under a volume compression of between 14 to 43 percent;² and

d) a cover portion having an aperture, the cross-sectional area of which aperture is less than 90 percent of the said separation matrix.

19. A process of rapidly detecting an analyte in a biological fluid, said process comprising the steps of:

a) providing a detection device comprising:

i) means for detecting said analyte;

ii) a separation matrix vertically adjacent to, compressed to and coincident with said detection means such that said analyte can move from said separation matrix to said detection means, wherein said detection means and said separation matrix are under a volume compression of 14 to 43 percent;

iii) a cover portion having an aperture, the cross-sectional area of which is less than 90 percent of the cross-sectional area of the said separation matrix; and

iv) a base portion containing an access means to allow detection of an analytical signal generated by the detection means;

b) applying a volume of a sample of said biological fluid, wherein the volume is as low as five to ten microliters, to said separation matrix;

c) maintaining said detection device at a temperature and for a period of time sufficient for said analyte to traverse said separation matrix, enter said

²An appropriate amendment correcting the noted typographical error should be made prior to the final disposition of this application.

detection means and interact with said means to generate a detectable signal indicative of the presence or amount of said analyte; and

d) detecting said signal.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Charlton et al. (Charlton) 1988	4,776,904	Oct. 11,
Lamos et al. (Lamos) 1991	5,037,738	Aug. 06,
Ertinghausen 1992	5,087,556	Feb. 11,
Vuorinen et al. (Vuorinen) 1993	5,213,966	May 25,

Claims 1-13, 16 and 19-32 stand rejected under 35 U.S.C. § 103 as being unpatentable over Ertinghausen. Claims 14, 15, 17, and 18 stand rejected under 35 U.S.C. § 103 as being unpatentable over Ertinghausen in view of Vuorinen. Claims 1-32 stand rejected under 35 U.S.C. § 103 as being unpatentable over Charlton alone or Charlton in view of Vuorinen or Lamos.

OPINION

We have carefully considered the respective positions advanced by the appellants and the examiner. For the reasons set forth below, we will not sustain the stated rejections.

All of the appealed apparatus and method claims require a device for detecting an analyte that includes a base portion, a cover portion, and a separation matrix that is "vertically adjacent", "compressed to" and "coincident with" a detection means (claims 1, 16, and 19). The degree of compression of the separation matrix and detection means is required to be between 14-43 percent by volume. Moreover, the appealed claims require a cover portion aperture cross-sectional area that is less than 90 percent of the separation matrix cross-sectional area.

The examiner acknowledges that neither of the relied upon primary references (Ertinghausen nor Charlton) discloses the compression and cross-sectional area limitations of the claimed subject matter (answer, pages 3-5). According to the examiner, however, it would have been obvious to utilize the claimed compression and aperture size in either of the applied Charlton or Ertinghausen references since such a modification would have been suggested as an optimization of result effective variables.

We cannot subscribe to the examiner's proposed modification since the examiner has not established that (1) the degree of compression of the separation matrix and adjacent detection means and (2) aperture size in a cover therefore relative to the separation matrix cross-sectional area were recognized in the art as result effective variables. Absent a prior art teaching of the result effectiveness of the above-noted parameters as a predicate for the proposed modification, the examiner's proposed rejections cannot be sustained. *Compare In re Antonie*, 559 F.2d 618, 620, 195 USPQ 6, 8-9 (CCPA 1977). We note that neither of the variously applied secondary references (Vuorinen nor Lamos) remedies this deficiency.

In light of the above, we cannot sustain the examiner's § 103 rejections based on this record.

CONCLUSION

To summarize, the decision of the examiner to reject claims 1-13, 16 and 19-32 under 35 U.S.C. § 103 as being unpatentable over Ertinghausen; claims 14, 15, 17, and 18 under 35 U.S.C.

§ 103 as being unpatentable over Ertinghausen in view of Vuorinen; and claims 1-32 under 35 U.S.C. § 103 as being unpatentable over Charlton alone or Charlton in view of Vuorinen or Lamos is reversed.

REVERSED

CHUNG K. PAK)	
Administrative Patent Judge)	
)	
)	
)	
)	BOARD OF PATENT
CHARLES F. WARREN)	APPEALS
Administrative Patent Judge)	AND
)	INTERFERENCES
)	
)	
)	
PETER F. KRATZ)	
Administrative Patent Judge)	

Appeal No. 1996-0783
Application No. 08/102,297

Page 8

Roger N. Coe
Miles Inc.
P.O. Box 40
Elkhart, IN 46515

APPEAL NO. - JUDGE KRATZ
APPLICATION NO. 08/102,297

APJ KRATZ

APJ PAK

APJ WARREN

DECISION: **REVERSED**

Prepared By: TINA D. LEE

DRAFT TYPED: 12 Oct 00

FINAL TYPED: