

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte AMY H. CHU and MICHAEL J. WILCOX

Appeal No. 1997-0204
Application No. 08/400,786

HEARD: February 22, 2000

Before GARRIS, PAK, and WALTZ, Administrative Patent Judges.

PAK, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal from the examiner's refusal to allow claims 28 through 37, 39 through 42 and 44 which are all of the claims pending in the application. Claims 28 and 41 were amended subsequent to the final Office action dated December 18, 1995, Paper No. 15.

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Claim 28 is representative of the subject matter on appeal and reads as follows:

28. A device for detecting an analyte in a biological fluid, said device comprising:

a) a separation matrix containing an agglutinating agent and between 70 and 150 millimolar of the buffer 4-(-2-hydroxyethyl)-1-piperazine-ethanesulfonic acid (HEPES); and

b) means for detecting said analyte, which detection means is vertically adjacent to the separation matrix and substantially coincident with the matrix such that said analyte can move from the separation matrix to the means for detecting said analyte;

wherein said device has a faster endpoint detection speed due to the presence of the HEPES buffer in the separation matrix.

As evidence of obviousness, the examiner relies on the following prior art:

Cowsar et al. (Cowsar)	4,181,500	Jan. 1, 1980
Hildenbrand et al. (Hildenbrand)	5,160,436	Nov. 3, 1992
Wilk et al. (Wilk)	5,262,067	Nov. 16, 1993
Chu et al. (Chu '485) (Published European Patent Application)	0 535 485 A1	Apr. 7, 1993

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Chu et al., U.S. Patent Application 08/454,614¹ filed on
October 3, 1991.

The appealed claims stand rejected as follows:

- (1) Claims 28, 29, 31 through 35, 39, 41, 42 and 44 under 35 U.S.C. § 103 as unpatentable over Chu '485 in view of Wilk;
- (2) Claims 30 and 40 under 35 U.S.C. § 103 as unpatentable over Chu '485 in view of Wilk and Hildenbrand;
- (3) Claims 36 through 37 under 35 U.S.C. § 103 as unpatentable over Chu '485 in view of Wilk and Cowsar;
- (4) Claims 28, 29, 31 through 35, 39, 41, 42 and 44 under 35 U.S.C. 103 as unpatentable over Chu '834 in view of Wilk;
- (5) Claims 30 and 40 under 35 U.S.C. § 103 as unpatentable over Chu '834 in view of Wilk and Hildenbrand; and
- (6) Claims 36 through 37 under 35 U.S.C. § 103 as unpatentable over Chu '834 in view of Wilk and Cowsar.

¹ This application has matured into U.S. Patent 5,558,834 on September 24, 1996. Accordingly, our reference to this application in this decision is to its corresponding U.S. Patent 5,558,834 (hereinafter referred to as "Chu '834").

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We have carefully reviewed the specification, claims and applied prior art, including all of the arguments advanced by both the examiner and appellants in support of their respective positions. This review leads us to conclude that the examiner's § 103 rejections are not well founded. We reverse each of the examiner's § 103 rejections for essentially those reasons set forth in the Brief. We add the following primarily for emphasis and completeness.

The claimed subject matter is directed to a device for detecting an analyte in a biological fluid. The device includes "a separation matrix containing an agglutinating agent and between 70 and 150 millimolar of 4-(2-hydroxyethyl)-1-piperazine-ethanesulfonic acid (HEPES)" and means for detecting the analyte. See claim 28. The presence of the HEPES buffer in the separation matrix is said to provide a faster endpoint detection. *Id.*

The examiner states that both Chu '485 and '843 disclose essentially the device recited in claims 28, except that they fail to include between 70 and 150 millimolar of HEPES in their separation matrix. See Answer, pages 4, 5, 7, 8 and 9. The examiner then relies on Wilk to demonstrate that it would

have been obvious to include HEPES in the separation matrix of the type described in Chu '485 or '843.² See Answer, pages 5 and 9. The dispositive question is, therefore, whether one of ordinary skill in the art would have been led to include the claimed amount of HEPES in the separation matrix described in Chu '485 or '843. We answer this question in the negative.

As argued by appellants, Wilk teaches the importance of using polyvinyl and other materials in a separation matrix to minimize the occurrence of substantial hemolysis. See, e.g., column 3, lines 36-43 and column 4, line 60 to column 5, line 28. According to Table 1, example 2, at column 9 of Wilk, the use of a particular combination of these materials would result in preventing the occurrence of any hemolysis. Wilk mentions using HEPES in example 2 as one of the solvents useful for dissolving an agglutinating agent used in the separation matrix. See column 6, lines 8-18, together with column 8, lines 48-51. However, as urged by appellants, Wilk discloses that the solvents, including HEPES, are removed from

² The examiner does not rely on Hildenbrand and Cowsar for the purpose of establishing obviousness with respect to employing HEPES in the separation matrix of the claimed device. See Answer, pages 6, 7, 10 and 11.

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the separation matrix, prior to their use, so as not to impair the plasma separating properties of the separation matrix. See column 6, lines 8-18. Even if HEPES is not removed from the separation matrix described in Wilk as alleged by the examiner (Answer, page 13-14), Wilk's example 2 shows at best the inclusion only 10 millimolar of HEPES in the separation matrix (Wilk, column 8, lines 48-51). Thus, we agree with appellants that the applied prior art as whole would not have suggested including the claimed amount of HEPES (at least seven times more than that shown in Wilk) in the separation matrix of Chu's assaying device. Accordingly, on this record, the examiner has not established a *prima facie* case of obviousness regarding the claimed subject matter within the meaning of 35 U.S.C. § 103.

In view of the foregoing, the decision of the examiner is 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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BRADLEY R. GARRIS)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
CHUNG K. PAK)	APPEALS
Administrative Patent Judge)	AND
)	INTERFERENCES
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)	
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THOMAS A. WALTZ)	
Administrative Patent Judge)	

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APJ PAK

APJ GARRIS

APJ WALTZ

DECISION: REVERSED
Send Reference(s): Yes No
or Translation (s)
Panel Change: Yes No
Index Sheet-2901 Rejection(s):

Prepared: March 15, 2001

Draft Final

3 MEM. CONF. Y N

OB/HD GAU

PALM / ACTS 2 / BOOK
DISK (FOIA) / REPORT