

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opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.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 JAN E. LILJA and SVEN-ERIK L. NILSSON

Appeal No. 95-0635
Application 07/768,255¹

ON BRIEF

Before WINTERS, JOHN D. SMITH and GRON, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 1, 3, 4, 7, 8 and 12, which are all of the claims remaining in the application.

Claims 1 and 8 are representative:

¹ Application for patent filed October 16, 1991.

1. A method for determining the glucose content in whole blood, in which a sample of undiluted whole blood is contacted with a dye-containing reagent system which undergoes chemical reaction with the glucose in the whole blood sample, the method consisting essentially of the steps of:

introducing the undiluted whole blood sample in a microcuvette having at least one cavity for receiving the sample, said cavity being internally pretreated with the reagent in a dry form and said chemical reaction then taking place in said cavity,

the reagent being comprised of a hemolyzing agent and agents used in the glucose dehydrogenase method, said agents being comprised of glucose dehydrogenase and a redox indicator dye, the hemolyzing agent exposing the glucose contained in the blood cells of the whole blood sample permitting a quantitative total glucose determination in a whole blood hemolysate, the agents which participate in the chemical reaction ensure that a dye concentration change takes place in a wavelength range above 650 nm and,

performing an absorption measurement at said wavelength range directly on the sample in the cuvette, and further conducting a secondary absorption measurement to compensate for background interference in a wavelength range above 700 nm.

8. A disposable cuvette for carrying out a determination of the glucose content of undiluted whole blood where a sample of undiluted whole blood is contacted with a dye-containing reagent system undergoes chemical reaction with the glucose in the undiluted whole blood sample, the cuvette being comprised of at least one cavity for receiving the undiluted whole blood sample, said cavity being internally pretreated with a reagent in dry form and said chemical reaction occurring in said cavity after introduction of the sample in undiluted form, the reagent being comprised of a hemolyzing agent and agents used in the glucose dehydrogenase method, said agents being comprised of glucose dehydrogenase and a redox indicator dye, the hemolyzing agent exposing the glucose contained in the blood cells of the whole blood sample permitting a quantitative total glucose determination in a whole blood hemolysate, the agents which participate in the chemical reaction ensure that the dye concentration change takes place in a wavelength range above 650 nm and that the cuvette is at least partly transparent for

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permitting an absorption measurement directly on the sample in the cavity of the cuvette in said wavelength range.

The prior art references relied on by the examiner are:

Banauch et al. (Banauch)	3,964,974	June 22, 1976
Lilja et al. (Lilja)	4,088,448	May 9, 1978
Pierre et al. (Pierre)	4,120,755	Oct. 17, 1978
Draeger et al. (Draeger)	4,551,427	Nov. 5, 1985
Tanaka et al. (Tanaka)	4,990,457	Feb. 5, 1991

(filed Apr. 4, 1989)

Claim 8 stands rejected under 35 U.S.C. § 102(b) as described by or, in the alternative, under 35 U.S.C. § 103 as unpatentable over Lilja. Claims 1, 3, 4, 7 and 12 stand rejected under 35 U.S.C. § 103 as unpatentable over Pierre, Banauch, Draeger, or Tanaka, either of those references considered alone or further considered in view of Lilja. We shall reverse these rejections.

DISCUSSION

The examiner's finding, that Lilja describes the disposable cuvette of claim 8, is clearly erroneous. We summarily reverse the rejection of claim 8 under 35 U.S.C. § 102(b) as described by Lilja.

With respect to the rejection of claim 8 under 35 U.S.C. § 103 as unpatentable over Lilja, the examiner bears the initial burden of presenting a prima facie case of unpatentability. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed.

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Cir. 1992). This the examiner has not done. The examiner does not provide an adequate evidentiary basis to sustain a prior art rejection of claim 8 drawn to a cuvette having at least one cavity,

said cavity being internally pretreated with a reagent in dry form . . . the reagent being comprised of a hemolyzing agent and agents used in the glucose dehydrogenase method, said agents being comprised of glucose dehydrogenase and a redox indicator dye.

In an effort to reach the hemolyzing agent and other "agents used in the glucose dehydrogenase method," recited in claim 8, the examiner refers to "references" and to "reagents . . . taught by the prior art" and to acknowledged prior art. See the Examiner's Answer, page 5, lines 11 through 23. However, the rejection before the Board is predicated on 35 U.S.C. § 103, and the only evidence included in the statement of that rejection is Lilja. In the statement of rejection, the examiner does not include any other prior art references or acknowledged prior art. As stated in In re Hoch, 428 F.2d 1341, 1342 n.3, 166 USPQ 406, 407 n.3 (CCPA 1970):

Where a reference is relied on to support a rejection, whether or not in a "minor capacity," there would appear to be no excuse for not positively including the reference in the statement of rejection.

In conclusion, the Lilja patent alone is insufficient to support a conclusion of obviousness of claim 8 which includes the

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above-quoted limitations. Accordingly, we reverse the rejection of claim 8 under 35 U.S.C. § 103 as unpatentable over Lilja.

Independent method claims 1 and 12 recite a reagent containing more than conventional agents used in the glucose dehydrogenase method for determining the glucose content of blood. Each of those claims additionally requires a "hemolyzing agent" in the reagent. Furthermore, claim 1 recites the steps of (1) "performing an absorption measurement at said wavelength range [above 650 nm] directly on the sample in the cuvette;" and (2) "further conducting a secondary absorption measurement to compensate for background interference in a wavelength range above 700 nm." By the same token, claim 12 recites the steps of (1) "determining by transmission photometry the concentration change of the dye at a wavelength that is in an absorption range above 650 nm., the dye being selected so that the dye concentration change takes place at least in a wavelength range above 650 nm. which is outside the absorption range of the blood hemoglobin;" and (2) "further conducting a secondary absorption measurement to compensate for background interference in a wavelength range above 700 nm."

Manifestly, the examiner has not established a prima facie case of obviousness of claims containing those limitations. We have carefully reviewed the examiner's discussion of Pierre,

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Banauch, Draeger, Tanaka and Lilja (Answer, pages 6 through 11). In our judgment, however, the examiner does not adequately explain how the cited prior art would have led a person having ordinary skill from "here to there," i.e., from the disclosures of the cited references to appellants' claimed method containing the limitations outlined above. Ex parte Tanksley, 37 USPQ2d 1382, 1386 (Bd. Pat. App. & Int. 1994). We therefore reverse the rejection of claims 1, 3, 4, 7 and 12 under 35 U.S.C. § 103 as unpatentable over Pierre, Banauch, Draeger or Tanaka, either of those references considered alone or further considered in view of Lilja.

The examiner's prior art rejections are reversed.

REVERSED

SHERMAN D. WINTERS)	
Administrative Patent Judge)	
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JOHN D. SMITH)	BOARD OF PATENT
Administrative Patent Judge)	APPEALS AND
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