

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(2) is not binding precedent of the Board.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. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JEROME S. SCHULTZ

Appeal No. 98-2792
Application 08/516,257¹

ON BRIEF

Before CALVERT, FRANKFORT and STAAB, Administrative Patent
Judges.

FRANKFORT, Administrative Patent Judge.

¹ Application for patent filed August 17, 1995. According to appellant, the application is a division of Application 07/980,027 filed November 23, 1992, abandoned.

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DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 15 through 17 and from the examiner's refusal to allow claims 1, 2, 4 through 10 and 36 through 38 as amended subsequent to the final rejection in a paper filed June 13, 1997 (Paper No. 11). Claims 24, 25, 34 and 35 stand allowed. Claims 22, 23, 26 and 39 through 55, the only other claims pending in the application, have been withdrawn from further consideration by the examiner under 37 CFR § 1.142(b). Claims 3, 11 through 14, 18 through 21 and 27 through 33 have been canceled.²

Appellant's invention relates to a system or device for measuring the concentration of certain biochemical constituents in a patient. As can be seen in Figures 1-3 of the application, the system includes a sensor unit (4) having

² Decided concurrently herewith is the appeal in appellant's co-pending application No. 08/714,830, filed September 17, 1996 (Appeal No. 99-0446).

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a single zone or processing chamber (10) therein. At least a portion of the capsule or sensor unit housing is transparent or translucent so

as to allow light (e.g., from an optical fiber (30)) to enter the processing chamber in the housing. At least a portion of the capsule or sensor unit housing is also defined by a semi-permeable membrane (8 or 50) which allows the passage of biochemical constituents of interest (i.e., analytes) into the capsule interior, while retaining within the capsule predetermined materials that cause a response. The chamber within the sensor unit housing or capsule also includes receptor material that is capable of chemically interacting with the analyte of interest. The processing chamber also contains an "analog-analyte," which is a competing substance which has properties similar to the analyte and which can bind with the receptor material.

As explained in the last paragraph on page 13 of the specification, the analog-analyte binds with a receptor to form an analog-analyte-receptor complex. When the analyte molecules are introduced into the processing chamber by diffusion through the semi-permeable membrane (8), they may then bind with a receptor to form an analyte-receptor complex. Apparently the receptor material has a higher affinity for the analyte molecule

than for the analog-analyte molecule, because the formation of an analyte-receptor complex frees a previously bound analog-analyte molecule. The analog-analyte molecules are labeled by covalent coupling with an appropriate dye (specification, page 14) so that they fluoresce in response to excitation energy sent into the processing chamber (i.e., via the optical fiber (30)). The degree of interaction of the analyte with the receptor material in the processing chamber of the sensor is

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monitored remotely by detection means (44) which measures, for example, the level of fluorescence of the freed analog-analyte molecules and converts the measured level of light emerging from the sensor (4) into the desired concentration information for the analyte of interest. One example of a use for the system disclosed by appellant (Example 1, page 22) is for determining the concentration of glucose in blood, e.g., in a patient with diabetes mellitus.

A copy of representative claims 1 and 15 is attached to this decision.

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

Schultz	4,344,438	Aug. 17, 1982
Komives et al. (Komives)	5,143,066	Sept. 1, 1992

Claims 15 and 16 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Schultz.

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Claims 1, 2, 4 through 9, 15 and 16 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Komives.

Claims 10, 17 and 36 through 38 stand rejected under 35 U.S.C. § 103 as being unpatentable over Komives in view of Schultz.³

Rather than attempt to reiterate the examiner's full commentary with regard to the above-noted rejections and the conflicting viewpoints advanced by the examiner and appellant regarding the rejections, we make reference to the examiner's answer (Paper No. 18, mailed October 1, 1997) for the examiner's reasoning in support of the rejections, and to appellant's brief (Paper No. 17, filed September 23, 1997) for appellant's arguments thereagainst.

³ The rejection of claims 2 and 4 through 8 under 35 U.S.C. § 112, second paragraph, in the final rejection (Paper No. 10) has been overcome by the amendment filed June 13, 1997 (Paper No. 11). See the advisory action mailed July 29, 1997 (Paper No. 14).

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OPINION

In reaching our decision in this appeal, we have given careful consideration to appellant's specification and claims, to the applied prior art references, and to the respective positions articulated by appellant and the examiner. As a consequence of our review, we have made the determinations which follow.

Looking first at the examiner's rejection of claims 15 and 16 under 35 U.S.C. § 102(b) as being anticipated by Schultz, we share the examiner's view that Schultz discloses (Figures 5a, 5b) a sensor unit (26) for sensing properties of a sample analyte, which unit is structured to be used with a remote light source (36) and remote detection means (41) both of which are disposed in noncontacting position with respect to the sensor unit. The sensor unit itself includes a capsule (30, 34) closed by an optical fiber (32) inserted in one end thereof. The capsule defines a single undivided processing chamber (28), a

portion (30) of which is a semi-permeable membrane that is permeable to the analyte (e.g., glucose). Receptor material (35, e.g., Con-A) is disposed within the chamber and, more particularly, is coated on the inner wall of the portion (30) thereof. The receptor material is capable of chemically interacting with the analyte. As can be seen in Figure 5b, light (40) entering the chamber (28) will not be blocked from impinging on the analyte or receptor material by a chamber dividing wall restricting passage of said light. Thus, we conclude that appellant's claims 15 and 16 on appeal are readable on the sensor unit of Schultz (Figures 5a, 5b) and that the subject matter of appellant's claims 15 and 16 is therefore anticipated by Schultz.

Appellant's argument (brief, page 6) that Schultz does not disclose a sensing unit which is adapted for use with a remote detection means, because the optical fiber (32) in Schultz is physically part of and cooperates in defining the chamber (28), is not persuasive. The sensing unit (26) of

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Schultz, which is comprised of the optical fiber (32), the hollow dialysis fiber (30) and the plug (34), is clearly "structured to be used with

remote light source means [36] and remote detection means [41] both of which are disposed in noncontacting position with respect

to the sensor unit." Note particularly, the disclosure at column 5, lines 37-44, of Schultz, wherein it is indicated that

the emitted fluorescence from the chamber (28) enters the optical fiber (32) and is transmitted "through the other end" (39), where it is then reflected by the half-silvered mirror (38) into the light detector (41) through a filter (42). While we realize that appellant's argument is specifically related to the embodiment of the invention seen in Figure 1 of the application, wherein the sensing unit or capsule (4) is implanted under the skin (6) of a patient and is physically

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separate from any optical fiber, light source, or detection means, we note that the system broadly set forth in claims 15 and 16 on appeal is not limited to that embodiment and is susceptible to the much broader interpretation which we have applied above.

Based on the foregoing, we will sustain the examiner's rejection of appellant's claims 15 and 16 under 35 U.S.C. § 102(b) relying on Schultz.

Turning next to the examiner's rejection of claims 1, 2, 4 through 9, 15 and 16 under 35 U.S.C. § 102(e) as being anticipated by Komives, we note that each of the independent claims 1 and 15 on appeal requires a sensor capsule having or defining "a single undivided processing chamber." When this recitation is read in light of appellant's disclosure and given its broadest reasonable interpretation consistent therewith, it is clear that the sensor capsule has one and only one

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(i.e., a single) processing chamber. Note particularly, Figures 1 through 3 of appellant's application which clearly show the capsule (4) with a single processing chamber (10). Like appellant, we find no disclosure in Komives of a sensor unit or system for measuring properties of an analyte that includes a sensor capsule that is formed with a single (only one) undivided processing chamber. Notwithstanding the examiner's comments regarding the light chamber (27) of Komives being an undivided chamber, we note that this reference clearly has a sensor capsule (defined by the probe housing (5) and optical fiber (9)) which includes two processing chambers (27) and (29), instead of a sensor capsule having a single processing chamber as required in the claims on appeal. For this reason, we will not sustain the

examiner's rejection of claims 1, 2, 4 through 9, 15 and 16 under 35 U.S.C. § 102(e) as being anticipated by Komives.

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In rejecting dependent claims 10, 17 and 36 through 38 under 35 U.S.C. § 103 as being unpatentable over Komives in view of Schultz, the examiner has relied upon the teachings in Schultz regarding receptor material immobilized in a gel (Fig. 6) and several binding agents or receptors being incorporated into one sensor capsule (col. 7, lines 23-30) to modify Komives. However, even if such teachings would have made it obvious to one of ordinary skill in the art to modify Komives in the manner urged by the examiner, we note that Komives (as modified) would still not have a sensor capsule having or defining only one (a single) undivided processing chamber. Thus, the examiner's rejection of claims 10, 17 and 36 through 38 under 35 U.S.C. § 103 will likewise not be sustained.

In addition to the foregoing, we find it necessary to REMAND this case to the examiner for a decision on the record as to whether or not a rejection of one or more of the claims on appeal in this case would be appropriate based on the combined

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teachings of the Meadows article applied in appellant's co-pending application No. 08/714,830 (Appeal No. 99-0446) and Komives (Figure 3), or based on Schultz (Figures 5a, 5b) in view of Komives (Figure 3). In particular, we point to our affirmance of the § 103 rejection in appellant's co-pending application (Appeal No. 99-0446) based on the Meadows article and Komives.

In view of the foregoing, the examiner's decision rejecting claims 15 and 16 under 35 U.S.C. § 102(b) as being anticipated by Schultz has been affirmed, but the decision rejecting claims 1, 2, 4 through 9, 15 and 16 under 35 U.S.C. § 102(e) relying on Komives, and the decision rejecting claims 10, 17 and 36 through 38 under 35 U.S.C. § 103 based on Komives and Schultz have been reversed. In addition, we have REMANDED this application to the examiner to consider certain designated prior art and possible rejections flowing therefrom.

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The decision of the examiner is affirmed-in-part.

In addition to affirming the examiner's rejection of one or more claims, this decision contains a remand. 37 CFR § 1.196(e) provides that

[w]henever a decision of the Board of Patent Appeals and Interferences includes or allows a remand, that decision shall not be considered a final decision. When appropriate, upon conclusion of proceedings on remand before the examiner, the Board of Patent Appeals and Interferences may enter an order otherwise making its decision final.

Regarding any affirmed rejection, 37 CFR § 1.197(b) provides:

Appellant may file a single request for rehearing within two months from the date of the original decision. . . .

The effective date of the affirmance is deferred until conclusion of the proceedings before the examiner unless, as a mere incident to the limited proceedings, the affirmed rejection is overcome. If the proceedings before the

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examiner do not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejections, including any timely request for rehearing thereof.

This application, by virtue of its "special" status, requires immediate action, see MPEP § 708.01 (Seventh Edition, July 1998).

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

AFFIRMED-IN-PART AND REMANDED

IAN A. CALVERT)
Administrative Patent Judge)
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PATENT)	BOARD OF
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APPENDIX

1. A system for measuring properties of an analyte comprising

a sensor capsule having a single undivided processing chamber defined by a wall which has a semi-permeable membrane permeable to said analyte as at least a portion thereof,

receptor material disposed within said chamber and being capable of chemically interacting with said analyte, and

at least a portion of said sensor wall being translucent, whereby light entering said processing chamber will not be blocked from impinging on the analyte or receptor material by a chamber dividing wall restricting passage of said light.

15. A sensor unit for sensing properties of a sample analyte and structured to be used with remote light source means and remote detection means both of which are disposed in non-contacting position with respect to said sensor unit, said sensor unit comprising

a capsule defining a single undivided processing chamber, at least a portion of said capsule being a semi-permeable membrane, which is permeable to said analyte, and

receptor material disposed within said chamber and capable of chemically interacting with said analyte, whereby light entering said chamber will not be blocked from impinging on the analyte or receptor material by a chamber dividing wall restricting passage of said light.