

Internal distribution code:

- (A) Publication in OJ
(B) To Chairmen and Members
(C) To Chairmen
(D) No distribution

D E C I S I O N
of 12 October 2005

Case Number: T 0716/03 - 3.2.02

Application Number: 00911792.0

Publication Number: 1135052

IPC: A61B 5/00

Language of the proceedings: EN

Title of invention:

Devices and methods for frequent measurement of an analyte present in a biological system

Applicant:

CYGNUS, INC.

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 52(1), 56

Keyword:

"Inventive step (no) "

Decisions cited:

-

Catchword:

-



Case Number: T 0716/03 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 12 October 2005

Appellant: CYGNUS, INC.
400 Penobscot Drive
Redwood City, CA 94063 (US)

Representative: Hallybone, Huw George
Carpmaels and Ransford
43 Bloomsbury Square
London WC1A 2RA (GB)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 30 January 2003
refusing European application No. 00911792.0
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: S. Chowdhury
A. Pignatelli

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 30 January 2003 to refuse European patent application No. 00 911 792.0.

The application was refused on the grounds that claim 1 of the main and auxiliary requests did not meet the inventive step requirement of Articles 52(1) and 56 EPC.

The following documents cited during the examination procedure are of interest in the appeal procedure:

D1: WO-A-95/288 78

D2: WO-A-96/00 110

D3: EP-A-0 680 727 (and its family member D3': US-A-5 507 288).

II. On 24 February 2003 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee on the same day. On 2 June 2003 a statement of grounds of appeal was filed.

III. Oral proceedings requested by the appellant were scheduled for 12 October 2005.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 17 of the main request or on the basis of the first auxiliary request filed, both received on 2 June 2003, or on the basis of claims 1 to 17 of the second auxiliary request filed by letter dated 12 September 2005.

On 7 October 2005 the appellant withdrew its request for oral proceedings and requested that the Board takes a decision on the matter on the basis of the written procedure. Nevertheless, in accordance with Rule 71(2) EPC the Board held the oral proceedings in the absence of the appellant's representative.

IV. Claim 1 of the main request reads as follows:

"A monitoring system for frequently measuring glucose present in a subject and providing to said subject self-monitoring of said glucose, said monitoring system comprising:

(A) a first component to be placed in contact with a skin or mucosal surface of said subject, comprising:

(i) an iontophoretic sampling mechanism for extracting the glucose from the subject, wherein said sampling mechanism is adapted for extracting the glucose across the skin or mucosal surface of said subject;

(ii) a sensing mechanism in operative contact with the glucose extracted by the sampling mechanism, wherein said sensing mechanism obtains a signal from the extracted glucose by detecting electrochemical signals produced at a biosensor electrode surface and said signal is specifically related to the glucose amount or concentration; and

(iii) a first mechanism for providing operative communication with a second component of the monitoring system, wherein said operative communication comprises

wireless communication technology that employs electromagnetic waves; and

(B) a second component separated from the first component and adapted to be worn by the subject, comprising:

(i) a user interface;

(ii) a second mechanism for providing operative communication with the first component, wherein said operative communication comprises wireless communication technology that employs electromagnetic waves, and wherein the second component (a) receives the signal from the first component, and (b) is capable of communicating with a third component remote from the subject being monitored, and

(iii) a computing mechanism that converts the signal from the extracted glucose to an output indicative of the amount or concentration of glucose extracted by the sampling mechanism, wherein the second component displays said output and provides an alarm to the subject when the amount or concentration of glucose is above or below threshold values."

Claim 1 of the first auxiliary request includes the further features that the iontophoretic sampling mechanism in part A(i) of the claim is adapted to be connected to a power source within the first component, the sensing mechanism in part A(ii) of the claim is adapted to be connected to a power source within the first component, and the second component is adapted to

be connected to a power source disposed within the second component.

Claim 1 of the second auxiliary request is identical to claim 1 of the main request, except that according to the second auxiliary request the second component is adapted to be carried by the subject instead of being worn by the subject.

V. The appellant argued as follows in the written submissions:

The feature of a second component being adapted to be worn by the subject was not disclosed in the prior art and it solved the problem of how to ensure that the first and second components continually remained in operative communication whilst being separated from each other, so that glucose swings could be monitored continually by the subject. The solution could not be provided by D3 since the central unit of D3, although portable, would not always be in close enough proximity to the sensor unit to allow continual monitoring of the glucose level.

In D2 the first and second components did not correspond to the first and second components of claim 1 since separation of the two components of D2 by removing the wires connecting them would result in a non-functional device. The wireless communication technology of claim 1 could not be equated with a wireless power supply sufficient to drive iontophoretic extraction.

It was unclear how the collection reservoir portion of D2 could be separated from the power and control portion since D2 did not have the features of the iontophoretic sampling mechanism and the sensing mechanism being adapted to be connected to a power source within the first component, and the computing mechanism being adapted to be connected to a power source disposed within the second component. Moreover, D3 did not show the central stationary unit as having a power supply.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. *Novelty*

Novelty has not been at issue during the examining procedure and the Board has no reason to question the novelty of the claimed subject-matter.

3. *Inventive step*

The Board considers the closest prior art document to be document D1 which describes a monitoring system for frequently measuring glucose present in a subject and providing to said subject self-monitoring of said glucose, said monitoring system comprising:

(A) a first component (16) having

(i) means (20) for measuring the glucose concentration in a patient,

(ii) a sensing mechanism in operative contact with the subject's glucose, wherein said sensing mechanism obtains a signal by detecting electrochemical signals produced at a biosensor electrode surface and said signal is specifically related to the glucose amount or concentration; and

(iii) a first mechanism (26) for providing operative communication with a second component (28) of the monitoring system, wherein said operative communication comprises wireless communication technology that employs electromagnetic waves; wherein

(B) the second component (28) is separated from the first component and is adapted to be worn by the subject and displays the glucose concentration, and comprises:

(i) a user interface;

(ii) a second mechanism for providing operative communication with the first component, wherein said operative communication comprises wireless communication technology that employs electromagnetic waves, and wherein the second component (a) receives the signal from the first component, and (b) is capable of communicating with a third component (14), and

- (iii) a computing mechanism that converts the signal from the extracted glucose to an output indicative of the amount or concentration of glucose extracted by the sampling mechanism, wherein the second component displays said output.
- 3.1 The monitoring system of claim 1 differs from the system of D1 by the following features:
- (a) The claimed system measures the glucose concentration using electrodes to be placed in contact with a skin or mucosal surface of said subject and an iontophoretic sampling mechanism for extracting the glucose from the subject, wherein said sampling mechanism is adapted for extracting the glucose across the skin or mucosal surface of said subject,
 - (b) the third component is remote from the subject being monitored, and
 - (c) the second component provides an alarm to the subject when the amount or concentration of glucose is above or below threshold values.
- 3.2 Each of the features (a), (b), and (c) is technically independent of the other of the features (a), (b), and (c), so each one may be examined independently for inventive step.
- 3.3 The difference (a) does not involve an inventive step since iontophoretic sensing systems became known since the date of D1, e.g. from D2, and would be employed as an alternative, the two systems being equivalent, as

indicated by the paragraph linking pages 16 and 17 of the application, and there is no special effect in using an iontophoretic system in the present context.

Each of the sampling systems mentioned in the above paragraph of D2 has its own advantages, including iontophoretic sampling devices (see D2, page 3, last paragraph), and these would be employed in a given circumstance and according to a particular need.

3.4 The third component defined in claim 1 is not clearly a feature of the claimed device since part B(ii)(b) of the claim says only that the second component is capable of communication with the third component.

Moreover, in D1 the second component (28) is capable of communicating with the third component (14), and if this were outside the body, for example for testing, then it would be remote from the subject. Therefore, even if the third component to be considered a feature of the claimed apparatus, it is not clearly a distinguishing feature.

Moreover, assuming that the third component is clearly a feature of the device of claim 1, this feature does not involve an inventive step since D3' teaches that in some cases it may be of advantage to provide data to a third component.

D3' discloses a first component (sensor unit 2 for monitoring blood glucose) connected by wireless data transmission to a second unit (central unit 3), which in turn may communicate with a third component remote from the subject (D3', column 8, lines 25 to 28). The

provision of feature (b) does not involve an inventive step, accordingly.

3.5 Feature (c) also does not involve an inventive step since this is well known in the context, see, for example, D2, page 30, lines 23 and 24, and D3, column 8, lines 35 to 39, and its use in the present context brings no new technical effect.

3.6 Therefore, none of the features (a), (b), and (c) involves an inventive step, and claim 1 as a whole is devoid of inventive step. Therefore, the main request is not allowable.

4. *First auxiliary request*

The additional features of the first auxiliary request, that the different components include respective power supplies, are trivial in the context. Power sources are compulsory components of electronic components, and to provide a power source locally in each part of a multi-part electronic system does not involve an inventive step.

5. *Second auxiliary request*

The technical effect of carrying the second component, as against wearing it, is not clear, it would appear merely to be a matter of convenience. In order to continually monitor the blood sugar of a subject a wrist monitor worn by the subject as shown in D1 would appear to be a convenient device, but it may also take other forms as suggested by D1 (page 7, lines 9 to 12) and alternative convenient devices that could be

carried would occur to the person skilled in the art.
Claim 1 of this request also does not involve an
inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

T. K. H. Kriner