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Datasheet for the decision of 20 April 2020

Case Number: T 0275/15 - 3.2.02

Application Number: 01950550.2

Publication Number: 1296587

IPC: A61B1/00, A61B5/00, A61B5/15

Language of the proceedings: EN

Title of invention:
ANALYTE MONITOR

Patent Proprietor:
Intuity Medical, Inc.

Opponent:
Roche Diagnostics GmbH

Headword:

Relevant legal provisions:
EPC Art. 54, 100(a), 111(1)
RPBA 2020 Art. 11, 12(2)

Keyword:

Decisions cited:
T 1966/16, T 0547/14

Catchword:

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European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0275/15 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 20 April 2020

Appellant: (Patent Proprietor)	Intuity Medical, Inc. 526 Almanor Avenue Sunnyvale, CA 94085 (US)
Representative:	Cooley (UK) LLP Dashwood 69 Old Broad Street London EC2M 1QS (GB)
Appellant: (Opponent)	Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim (DE)
Representative:	Altmann Stößel Dick Patentanwälte PartG mbB Dudenstrasse 46 68167 Mannheim (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 2 December 2014 concerning maintenance of the European Patent No. 1296587 in amended form.**

Composition of the Board:

Chairman	P. L. P. Weber
Members:	S. Böttcher
	C. Schmidt

Summary of Facts and Submissions

I. Both the patent proprietor (with letter dated 12 February 2015) and the opponent (with letter dated 4 February 2015) filed a notice of appeal against the interlocutory decision of the Opposition Division, dispatched on 2 December 2014, that, account being taken of the amendments according to the auxiliary request valid at that time, European patent No. EP 1 296 587 and the invention to which it related met the requirements of the EPC. The main request was considered to lack novelty in view of E12.

II. The opponent withdrew its appeal with letter dated 25 February 2015.

III. The patent proprietor filed a statement setting out the grounds of appeal with letter dated 13 April 2015.

IV. The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or that the patent be maintained in the form allowed by the Opposition Division (auxiliary request).

With letters dated 22 January 2020 and 27 January 2020 the appellant requested republication of the patent specification.

V. The respondent did not file a reply to the statement of grounds of appeal.

VI. By a communication under Rule 100(2) EPC dated 28 November 2019 the parties were informed that the

Board intends to set aside the decision and to remit the case to the department of first instance.

VII. The respondent did not file any observations in reply to this communication within the set time period of two months.

VIII. On 3 April 2020 the registrar of the Board contacted the representative of the respondent who confirmed that no reply to the above communication had been delivered to a recognised postal service provider in due time before expiry of the period. Hence, there are no requests of the respondent on file.

IX. The following document is cited in the present decision:

E12: US 5 035 704

X. Claim 1 of the patent as granted reads as follows (Text as annexed to the communication under Rule 71(3) EPC):

"An analyte monitoring device (60) having a housing, the device comprising:

a. a plurality of needles (53), each configured to pierce the skin and draw fluid for analysis, having a retracted position and a position wherein it is extended from the housing a distance adapted to pierce skin;

b. an electrically or spring powered needle pushing apparatus (87,37) to move each needle (53) from the retracted position to the extended position;

c. an energy source located within the housing;

d. a plurality of analysis sites (50) comprising an analysis preparation, each adapted to receive liquid drawn from a respective needle to wet the analysis preparation;

e. one or more light sources (64) adapted to direct light at the analysis sites;

f. one or more light detectors (64) adapted to receive light from the analysis sites; and

g. a processor (65);

wherein elements a and d can be replaceably inserted into the analyte monitoring device as part of a cassette."

XI. The arguments of the appellant in relation to the objection of lack of novelty, which are relevant for the present decision, are as follows:

E12 failed to disclose the feature of an "energy source located within the housing". It could not be derived that the device of E12 was portable. Therefore, the assertion that the device of E12 implicitly included an energy source was not correct. Furthermore, it could not be derived that an energy source was provided within the housing since it could be provided outside the housing.

Reasons for the Decision

1. The appeal is admissible.

2. The invention

The invention as defined in claim 1 of the patent as granted relates to an analyte monitoring device having a plurality of needles, a needle pushing apparatus, an energy source, a plurality of analysis sites (chambers 50) adapted to receive liquid drawn from one of the needles, one or more light sources and detectors, and a processor. The needles and the analysis sites are part of a cassette that can be replaceably inserted into the device.

As shown in Figure 1, the respective needles and chambers are arranged on a ring. The light source and the detector are positioned on a platform inside the ring that can be brought into alignment with one of the chambers by rotation.

Upon activation of the needle pushing apparatus, a needle pierces the skin of a patient, and fluid (e.g. blood) is drawn from the needle to the respective chamber. The detector, operated by the controller, monitors the amount of analyte (e.g. glucose) in the sample.

According to the description, a reliable and essentially pain-free glucose monitoring can be achieved by the invention.

3. Novelty in view of E12

3.1 The present analysis is based on the wording of claim 1 according to the text annexed to the communication under Rule 71(3) EPC. The published version contained several mistakes.

3.2 E12 relates to a blood sampling device including a housing (10) in which a plurality of test pads (50) contained in a magazine (40) are inserted (Figure 1). From the lower part of the magazine, individual test pads are sequentially fed to a loading/testing station (60), transferred (by means of a pivotally mounted transfer arm 91) to a blood sampling station (100) and returned to the loading/testing station for testing by a testing, calibrating and discriminating means (80) (Figures 2 and 3). Each test pad carries a resilient dermis piercing member (295) having a pointed end (291) directed toward a wicking membrane (285). The wicking membrane contacts a test strip (305) (Figures 7 to 10). When the test pad is at the blood test station (100), a hammer (180) deflects the piercing member to drive the pointed end into the dermis causing blood to be "wicked" through the wicking membrane and into the test strip which is then optically analysed at the loading/ testing station by the testing means (80).

3.3 Hence, E12 discloses an analyte monitoring device having a housing (10), the device comprising:

a spring powered pushing apparatus (spring 175 pushes hammer 180) to move each piercing member from the retracted position to the extended position (column 8, lines 63 to 65);

an energy source located within the housing

(implicitly);

a plurality of analysis sites (test strips 305) comprising an analysis preparation (column 16, lines 22 to 31), each adapted to receive liquid to wet the analysis preparation;

one light source (implicitly, since the test strips are analysed through optical scanning (column 10, lines 42 to 45));

one light detector (implicitly, since the test strips are analysed through optical scanning (column 10, lines 42 to 45)); and

a processor (column 16, lines 37 to 41);

wherein the analysis sites can be replaceably inserted into the analyte monitoring device as part of a cassette (40) (column 4, lines 21 to 27) (It is not mentioned explicitly that the magazine 40 is replaceable. However, from the statement that each magazine has to be provided with a code number of the production batch (column 4, lines 57 to 62), it can be derived that one magazine can be replaced with another one).

3.4 E12 does not disclose a plurality of needles, each configured to draw fluid for analysis.

The pointed end of the piercing member cannot be regarded as a needle that can draw fluid. The Opposition Division referred to the passage "Thus, the blood is drawn from the area of the pointed end along and through the wicking membrane..." (column 13, lines 12 to 15). However, in the Board's view, this means

that blood is drawn from the area where the pointed end of the piercing member has pierced the skin. It is mentioned further down in E12 that the pointed end is withdrawn virtually immediately after penetration, and that blood flows freely from the pierced skin to wet the wicking membrane (column 13, lines 29 to 39). Hence, in E12 the blood is drawn by the wicking membrane to the test strip.

It is further mentioned in column 12, line 60, to column 13, line 12, that the deflection of the ring-like portion 294 of the piercing member 295, which drives the pointed end into the skin, also (i.e. simultaneously) drives the wicking portion 287 of the wicking membrane 285 against the skin. This also indicates that it is the wicking membrane that draws the blood to the test strip.

Furthermore, in the present invention the needles are hollow since they have an inner diameter (column 9, lines 30 to 39), and blood is drawn through the needle either by capillary action or by a vacuum. In either case, the needle is retracted only after the blood has been drawn.

In contrast, in E12 the piercing members are solid and retracted immediately after piercing the skin. Although it might be possible that blood is drawn by capillary forces on the outside of a solid piercing member, this is not possible in the device of E12, since the pointed end is withdrawn immediately. Hence, in the specific arrangement of the device of E12 the pointed end of the piercing member is not configured to draw blood.

3.5 Accordingly, in E12 the analysis sites are not adapted to receive liquid drawn from a respective needle.

3.6 Furthermore, E12 does not disclose that the one or more light sources are adapted to direct light at the analysis sites.

In the device of E12, the light source is always directed to the same position, namely, to the blood testing station. The test pad has to be brought to this position. It is not possible to direct light at several different sites, i.e. to move the light source from one analysis site to the next.

3.7 Accordingly, the detector of E12 is also not adapted to receive light from the different analysis sites.

3.8 The appellant contests that E12 discloses an energy source located within the housing.

The Board notes that E12 discloses a testing, calibrating and discriminating means 80 for optically testing the blood sample. This testing means is arranged in the housing 10 (shown only schematically in Figure 1) and energised by opening the door 18 (column 11, lines 4 to 8). Power is cut off by closing the door (col. 14, lines 23 to 25). Hence, the Board considers that there is a battery in the housing for powering the testing means, and a switch that is connected to the door of the housing and operated by opening or closing the door.

Therefore, the Board agrees with the Opposition Division that an (electric) energy source is implicitly disclosed.

Moreover, in view of the definition of a spring given in the patent (column 15, lines 50 to 53), also one of the springs of the device of E12, which are clearly located inside the housing, can be regarded as a (mechanical) energy source.

3.9 Consequently, the subject-matter of claim 1 is novel over E12.

4. Remittal to the department of first instance

4.1 As said before, the subject-matter of present claim 1 is novel. However, the claims of the main request have not been examined with regard to inventive step by the Opposition Division.

4.2 Under Article 111(1) EPC, the Board may in the present case either proceed further with the examination of the application, in particular with respect to Article 56 EPC, or remit the case to the examining division for further prosecution. Since the present appeal was pending on 1 January 2020, the revised version of the RPBA applies (OJ EPO 2019, A63), subject to the transitional provisions set out in Article 25 of said RPBA. In particular Article 11 RPBA 2020 is applicable.

4.3 Article 11 RPBA 2020 provides that the Board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so. However, this provision has to be read in conjunction with Article 12(2) RPBA 2020, which provides that it is the primary object of the appeal proceedings to review the decision under appeal in a judicial manner (see also T 1966/16 from 20 January 2020, point 2.2 of the reasons and T 0547/14 from 29 January 2020, point 7.1 and 7.2 of the

reasons).

4.4 This principle would not be respected if the Board were to conduct a complete examination of the application. Consequently, in the present case, Article 11 RPBA 2020 does not entail that the Board should carry out a full examination of the application for compliance with the requirements of Article 56 EPC for which no decision of the first instance exists yet.

4.5 Consequently, the Board considers it appropriate to exercise its discretion under Article 111(1) EPC to remit the case to the department of first instance for further prosecution.

5. Request for republication of the patent specification

The request for republication of the patent specification must be considered once the definitive version of claim 1 is established.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution.

The Registrar: The Chairman:

D. Hampe P. L. P. Weber

Decision electronically authenticated