Datasheet for the decision
of 24 October 2016

Case Number: T 2105/12 - 3.2.02
Application Number: 07253502.4
Publication Number: 1897488
IPC: A61B5/00
Language of the proceedings: EN

Title of invention:
Analytical meter with display-based tutorial module

Patent Proprietor:
Lifescan Scotland Limited

Opponent:
Abbott Diabetes Care Inc.

Headword:

Relevant legal provisions:
EPC Art. 100(a), 54, 84
RPBA Art. 12(4), 13(1)
Keyword:
Public availability of user manuals of a device (yes)
Admissibility of auxiliary requests 1 to 3 (yes)
Novelty - main and auxiliary request 1 (no)
Clarity - auxiliary requests 2 and 3 (no)

Decisions cited:
T 0861/04, G 0009/91

Catchword:
Case Number: T 2105/12 - 3.2.02

DEcision  
of Technical Board of Appeal 3.2.02  
of 24 October 2016

Appellant:  
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Decision under appeal:  
Decision of the Opposition Division of the  
European Patent Office posted on 17 July 2012  
revoking European patent No. 1897488 pursuant to  
Article 101(3)(b) EPC.

Composition of the Board:  
Chairman  
E. Dufrasne  
Members:  
M. Stern  
D. Ceccarelli
Summary of Facts and Submissions

I. The patent proprietor lodged an appeal against the decision posted on 17 July 2012 revoking European patent No. 1 897 488. In the decision under appeal, the Opposition Division revoked the patent for lack of novelty in view of the following documents:


II. The following documents cited during the appeal proceedings are also relevant for the present decision:

E30: "Plug It In! New Meter Modules Receive FDA Approval", Diabetes Interview, Free Weekly E-mail Letter, September 2002, pages 63 and 66
E31: "Make Your PDA a Health Partner", Business Week Online, October 7, 2002
E32: "We’re Closing In On Diabetes", Parade Magazine, November 3, 2002, pages 13 and 14
E34: "Handheld Computers in Diabetes Management", Diabetes Self-Management, November/December 2002, pages 43 to 49
III. Notice of appeal was filed on 27 September 2012 and the fee for appeal was paid the same day. A statement setting out the grounds of appeal was received on 27 November 2012.

IV. Oral proceedings were held on 24 October 2016.

The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained as granted or, in the alternative, on the basis of one of auxiliary request 1, filed on 27 November 2012, and auxiliary requests 2 and 3, filed with letter dated 2 May 2013.

The respondent (opponent) requested that the appeal be dismissed. It withdrew its earlier requests that the appeal be held inadmissible, and the case remitted to the Opposition Division if auxiliary requests 2 and 3 were admitted into the proceedings.

V. Claim 1 of the main request (patent as granted) reads as follows:

"An analytical meter for determining an analyte in a bodily fluid sample, the analytical meter comprising:

- a display-based tutorial module with:
  - a user interface that includes a visual display;
  - a memory unit storing a tutorial
  - a microprocessor unit configured for controlling and coordinating at least the user interface and the memory unit, and characterized in that the tutorial has a plurality of chapters with each of the plurality of chapters containing at least one
tutorial image depicting use of the analytical meter; and in that
the user interface, microprocessor unit and memory unit are operatively linked and configured for
event-driven chapter-based display of the tutorial images to a user on the visual display."

Claim 1 of **auxiliary request 1** reads as follows:

"An analytical meter for determining an analyte in a
bodily fluid sample, the analytical meter comprising:
a display-based tutorial module with:
a user interface that includes a visual display;
a memory unit storing a tutorial;
a microprocessor unit configured for controlling
and coordinating at least the user interface and
the memory unit,
and characterized in that
the tutorial has a plurality of chapters with each
of the plurality of chapters containing tutorial images depicting use of the analytical meter,
the user interface, microprocessor unit and memory unit are operatively linked and configured for
event-driven chapter-based display of the tutorial images to a user on the visual display,
the display-based tutorial module includes a user-operable tutorial button and the event-driven
chapter-based display of the tutorial images is driven by an event of the user depressing the user
operable tutorial button,
the user operable tutorial button is configured
such that depression thereof increments the displayed tutorial image within a given chapter of
the tutorial."
Claim 1 of auxiliary request 2 reads as follows:

"An analytical meter for determining an analyte in a bodily fluid sample, the analytical meter comprising:

a display-based tutorial module with:

- a user interface that includes a visual display and a user-operable tutorial button;
- a memory unit storing a tutorial;
- a microprocessor unit configured for controlling and coordinating at least the user interface and the memory unit,

and characterized in that the tutorial has a plurality of chapters with each of the plurality of chapters containing at least one tutorial image depicting use of the analytical meter.

wherein the user interface, microprocessor unit and memory unit are operatively linked and configured for event-driven chapter-based display of the tutorial images to a user on the visual display, wherein the display of each tutorial chapter is driven by one or more unique events that can occur during use of the kit or analytical meter, wherein depression of the user-operable tutorial button is an event for the purposes of displaying tutorial images in an event-driven chapter based manner, and wherein the depression of the tutorial button is rendered unique by its context, so that the depression of the tutorial button drives the display of different tutorial chapters depending upon the other events that have preceded it."

Claim 1 of auxiliary request 3 reads as follows:

"An analytical meter for determining an analyte in a bodily fluid sample, the analytical meter comprising:
a display-based tutorial module with:
a user interface that includes a visual display and
a user-operable tutorial button;
a memory unit storing a tutorial;
a microprocessor unit configured for controlling
and coordinating at least the user interface and
the memory unit,
and characterized in that
the tutorial has a plurality of chapters with each
of the plurality of chapters containing at least
one tutorial image depicting use of the analytical
meter
wherein the user interface, microprocessor unit and
memory unit are operatively linked and configured
for event-driven chapter-based display of the
tutorial images to a user on the visual display,
wherein the display of each tutorial chapter is
driven by one or more unique events that can occur
during use of the kit or analytical meter, wherein
depression of the user-operable tutorial button is
an event for the purposes of displaying tutorial
images in an event-driven chapter based manner,
wherein the depression of the tutorial button is
rendered unique by its context, so that the
depression of the tutorial button drives the
display of different tutorial chapters depending
upon the other events that have preceded it, and
wherein the user operable tutorial button is also
configured such that its depression increments the
displayed tutorial image within a given chapter of
a tutorial."

VI. The arguments of the appellant relevant for the present
decision are summarised as follows:
- Public availability of documents E1 and E24

E24 was a user guide for the TheraSense "FreeStyle Tracker Diabetes Management System" which could not be deemed to be prior art. The user guide was contained in a box with the TheraSense diabetes management system and distributed as an integral part of a complete package. However, the opponent had not provided any evidence that this system was available to the public before the priority date. The copyright date of 2002 shown in the footer sections of the pages of E24 was not sufficient evidence of public disclosure. In this respect, decision T 861/04 was not applicable since the facts underlying that case were substantially different from those of the present one. It had concerned a user manual for a television produced by a well-known global manufacturer which would have been presumed to have put televisions on the market as soon as possible. The present case, in contrast, concerned a diabetes management device which was not known on the market.

For analogous reasons, the TheraSense testing guide E1 did not constitute prior art.

- Main request - Novelty

There was no disclosure in E1 or E24 as to where a tutorial might be stored. It was not stated in E1 or E24 that the memory of the test strip module contained a tutorial, nor was it stated that the PDA itself contained a tutorial. Moreover, it would be quite possible for individual images of the tutorial to be transmitted to the PDA from a remote location. The images of E1 and E24 did not even correspond to a "tutorial", since a tutorial contained instructions to the user about operating the device.
- Auxiliary request 1

Auxiliary request 1 was clearly admissible as it had been filed with the statement of grounds of appeal and was in substance identical to auxiliary request 1 underlying the impugned decision.

The subject-matter of claim 1 was not disclosed in E24. The term "increments" in claim 1 necessarily meant that the next image following on from a previous image within a given chapter had to be displayed on the occurrence of an event. The incrementing of images within a chapter was the result of depressing the user-operable tutorial button. E24 did not present a plurality of tutorial chapters, each of which comprised a plurality of tutorial images. The screens shown on page 3-19 of E24 were introductory screens which the user could use at the beginning of the operation of the meter, but not during the measurement of the bodily fluid sample. They were therefore not images of a tutorial providing instructions on how to use the meter.

- Auxiliary requests 2 and 3

These requests should be admitted under Article 13(1) RPBA. They had been filed only a few months after the statement of grounds of appeal, and after oral proceedings before the Opposition Division on a sister patent (EP-B-1 897 492) had taken place, during which very similar claims had been discussed and held to be allowable by the Opposition Division. This showed that the requests were prima facie allowable. Since the requests had been filed in the early stages of the present appeal proceedings, the respondent and the Board
had had sufficient time to consider them. By filing only two additional auxiliary requests the complexity of the case had not been unduly increased.

The meaning of "one or more unique events" was clear from the specification as a whole, in particular from paragraphs [0018], [0026] and [0039]. Moreover, paragraph [0019] of the patent explained that unique events were those which drove the chapter forward, and paragraphs [0031] and [0039] described examples of unique events. The expression was further clarified by the definition that the event of depressing the tutorial button was "rendered unique by its context". According to paragraph [0018], the context of the event was given by the events that preceded the event. This was explained in detail in the description of Figure 4.

VII. The arguments of the respondent regarding the requirements of novelty and clarity which are relevant for the present decision are essentially those on which the reasons set out below are based.

Regarding the request not to admit auxiliary request 1 under Article 12(4) RPBA it was argued that it differed from auxiliary request 1 underlying the impugned decision and that it had therefore been submitted for the first time with the patentee's grounds of appeal. It was, moreover, prima facie not allowable since it lacked clarity and contained added subject-matter. Also the Opposition Division should not have admitted the prima facie non-allowable late-filed auxiliary request 1 then on file. At oral proceedings before the Board, the respondent acknowledged that auxiliary request 1 was in substance no different from auxiliary request 1 underlying the impugned decision.
Regarding the admissibility of auxiliary requests 2 and 3, it was requested that the Board exercises its discretion under Article 13(1) RPBA not to admit these requests since they had been submitted for the first time after the grounds of appeal just because an Opposition Division had considered them to be allowable in a different case (EP-B-1 897 492, leading to T 537/13). This was no justification for admitting these late-filed requests into the present appeal proceedings. They contained, moreover, amendments which deviated significantly from the amendments submitted during the opposition proceedings. This unduly increased the complexity of the present case. Moreover, in spite of the positive decision by the Opposition Division in the other case, the requests were prima facie unallowable as they were inherently unclear and contained added matter.

**Reasons for the Decision**

1. During the oral proceedings, the respondent withdrew its earlier request that the appeal be held inadmissible. Consistent with the Board's preliminary positive assessment of the admissibility of the appeal, as communicated to the parties with the summons to oral proceedings, the Board considers that the appeal is admissible.

2. **Public availability of documents E1 and E24**

2.1 Document E24 is a user guide for the TheraSense "FreeStyle Tracker Diabetes Management System". It carries a copyright date of 2002 on the footer section of its pages which predates the earliest priority date of the patent in suit (5 September 2006) by about four
years. Document E1 is a testing guide for the same diabetes management system, also bearing a copyright date of 2002 on its last page.

2.2 The appellant argued that E1 and E24 should not be considered to be prior art as the copyright date of 2002 was not sufficient evidence of public disclosure, in particular since the respondent had not provided any evidence that the TheraSense diabetes management system was available to the public before the priority date. Since the system was not available or free to be marketed in the United States, the reasoning of decision T 861/04 relating to the copyright of television user manuals was not applicable to the present case involving the copyright of user guides for an unknown glucose tester.

The Board disagrees. The respondent provided detailed evidence proving that the TheraSense "FreeStyle Tracker Diabetes Management System" began to be marketed in the United States in 2002. E28 demonstrates that the system had been approved by the Food and Drug Administration (FDA) in June 2002 and articles E29 to E35 provide further details relating to the marketing of the system in the United States as of 2002.

In view of these facts, the present case, like that underlying decision T 861/04, concerns a device which was free to be marketed. Therefore, as in decision T 861/04 (point 2.6 of the Reasons), the Board finds it highly unlikely that the diabetes management system and its user guide E24 and testing guide E1 would have been kept in stock for about four years following FDA approval.
2.3 From the above the Board concludes that E1 and E24 were
made available to the public before the priority date
and are therefore comprised in the state of the art
according to Article 54(2) EPC.

3. Main request - Novelty

3.1 Document E1 is a blood glucose testing guide for the
TheraSense FreeStyle Tracker System for measuring blood
glucose (page 2). The analytical meter in E1 comprises
two elements, which are shown on page 12: a visor PDA
(Personal Digital Assistant) and a measurement module
insertable into the PDA. The PDA with the inserted
measurement module together form a module which equates
to what claim 1 of the granted patent defines as an
"analytical meter ... comprising a display-based
tutorial module" with a "user interface that includes a
visual display" on which instructions to the user are
presented, as illustrated on pages 13, 14 and 17 of E1.
For example, on page 13 the display presents the image
of a test strip above the insertion slot on the module.
This instructs the user to insert the test strip into
the module. Likewise, on page 14 the display shows a
calibration screen instructing the user to tap a
calibration code corresponding to the test strip. Such
instructions concerning the operation and use of the
meter constitute a "tutorial" as defined in claim 1. It
is moreover implicit that the tutorial is stored in a
"memory unit" of the "display-based tutorial module"
which has a "microprocessor unit configured for
controlling and coordinating at least the visual
display and the memory unit". Indeed, on page 7 of E1,
reference is made to the "1.2 program version" used in
the FreeStyle Tracker System, and the image of this
page depicts the PDA display carrying icons of this
program. Therefore, the Board is not convinced by the
appellant's argument that according to E1 the images of the tutorial were transmitted to the meter from a remote location.

The tutorial disclosed in E1 may be said to have a "plurality of chapters" as defined in claim 1. The notion of a "chapter" entails no specific limitative technical character so that, for example, page 13 may be considered to be a chapter about the insertion of the test strip into the meter, page 14 may be regarded as another chapter concerning the setting of the calibration code, and page 17 as yet another chapter about applying blood to the test strip. As shown in E1, each of these "chapters" contains a tutorial image, and the microprocessor unit is configured for displaying a tutorial image after an "event" has occurred. Such an "event" is considered to encompass any action related to the operation of the meter, such as the pressing of a button or the insertion of a test strip, consistent with claims 3 and 6 and paragraphs [0018] and [0026] of the contested patent. In particular, as indicated at the bottom of page 13 of E1, after the "event" of tapping the Measurement icon on the Logbook or Diary screens (pages 20 and 21), the display shows the screen next to point 1 on page 13. As indicated under point 1 on page 14, the (calibration) image on page 14 is displayed following the "event" of inserting a test strip and, as indicated at the bottom of page 14, the image of the logbook of page 20 is displayed following the "event" of pressing the Cancel icon. Hence, E1 also anticipates the feature of claim 1 according to which "the user interface, microprocessor unit and memory unit are operatively linked and configured for event-driven chapter-based display of the tutorial images to a user on the visual display".
3.2 From the above it follows the subject-matter of claim 1 of the main request (patent as granted) lacks novelty in view of document E1.

3.3 The aforementioned disclosure of pages 7, 12, 13, 14, 17, 20 and 21 of E1 is likewise given on pages 4-14 to 4-19, 4-26, 4-32 and 4-33 of document E24, a user manual for the TheraSense FreeStyle Tracker Diabetes Management System which explains the use of the meter in even greater detail. Hence, the subject-matter of claim 1 of the main request is likewise anticipated by E24 for analogous reasons.

3.4 As a consequence, the ground for opposition under Article 100(a) EPC in combination with Article 54 EPC prejudices the maintenance of the patent as granted.

4. **Auxiliary request 1 - Admissibility**

4.1 The respondent requested the Board to exercise its discretion under Article 12(4) RPBA not to admit auxiliary request 1.

4.2 Auxiliary request 1 was filed with the statement of grounds of appeal and its claim 1 is in substance identical to claim 1 of auxiliary request 1 underlying the impugned decision. Only editorial or formal amendments, such as a different two-part form, distinguish the present claim 1 from the one decided upon by the Opposition Division. At oral proceedings before the Board, the respondent actually shared this view. Moreover, the statement of grounds of appeal contains reasons for contesting the finding of the Opposition Division that the subject-matter claimed lacked novelty over E24. The Board also finds that the Opposition Division correctly exercised its discretion
to admit the late-filed auxiliary request 1 then on file, providing detailed reasons in the impugned decision (point 5) for not sharing the opponent's prima-facie assessment of non-allowability.

4.3 Consequently, the Board fails to see any valid reason for not admitting auxiliary request 1.

5. Auxiliary request 1 - Novelty

5.1 Claim 1 of auxiliary request 1 compared with that of the main request additionally requires that each of the chapters contains a plurality of tutorial images and that "the display-based tutorial module includes a user-operable tutorial button and the event-driven chapter-based display of the tutorial images is driven by an event of the user depressing the user operable tutorial button, the user operable tutorial button is configured such that depression thereof increments the displayed tutorial image within a given chapter of the tutorial" [emphasis added].

5.2 As discussed during the oral proceedings, E24 presents on page 3-19 different screens, each of which deals with a separate aspect of the use of the meter, for example a screen concerning the Preferences Menu and a screen concerning the Logbook. Thus, each of these screens provides the user with instructions about the operation and use of a specific aspect of the meter. Consequently, each of these screens may be said to be within a specific "chapter" of a "tutorial". As seen on page 3-19, each of the screens comprises, inter alia, a Next icon which, when pressed, takes the user to the next screen or "tutorial image" within that "tutorial chapter". The Next icon is thus, in the language of the claim, a "user-operable tutorial button" included in
the display-based tutorial module which, when pressed, allows the displayed tutorial image to be "incremented" to show the next tutorial image in that tutorial chapter.

5.3 The appellant argued during the oral proceedings that the screens shown on page 3-19 were introductory screens which the user would use at the beginning of the operation of the meter, but not during measurement of the bodily fluid sample. They were therefore not images of a tutorial providing instructions on how to use the meter.

The Board is not persuaded by this argument. As indicated above (point 3.1), the Board considers that a display of indications or instructions about the operation and use of the meter is a "tutorial image". The term "tutorial image" does not entail the specific restriction of being related to the physical measurement of the bodily fluid sample, as argued by the appellant. Moreover, screens of the Preferences Menu or of the Logbook clearly relate to the operation and use of the meter and are thus tutorial images.

5.4 It follows that the subject-matter of claim 1 of auxiliary request 1 lacks novelty within the meaning of Article 54 EPC.

6. **Auxiliary requests 2 and 3 - Admissibility**

6.1 The respondent requested the Board to exercise its discretion under Article 13(1) RPBA not to admit auxiliary requests 2 and 3.

6.2 The appellant filed auxiliary requests 2 and 3 with letter dated 2 May 2013, about five months after the
statement of grounds of appeal, explaining that they were being filed following oral proceedings before the Opposition Division concerning a "sister patent" (EP-B-1 897 492) during which very similar claims had been discussed and held to be allowable by the Opposition Division (giving rise to appeal T 537/13).

6.3 The Board rejects the appellant's argument that filing "similar claims" in opposition proceedings of a "sister patent" is a valid justification for admitting their late introduction into the present appeal proceedings which concern a different patent. Under Article 12(2) RPBA, a party should present its complete appeal case with the statement of grounds of appeal. Thereafter, the admissibility of any amendment to the party's case is left to the Board's discretion in accordance with Article 13(1) RPBA. This discretion must be exercised in view of, inter alia, the complexity of the new subject-matter, the current state of the proceedings and the need for procedural economy.

6.4 The respondent is in principle right in observing that auxiliary request 2 does not just restrict the subject-matter claimed in the preceding requests, but claims subject-matter going in a somewhat different direction. However, since the amended appellant's case contains a total of just three auxiliary requests of which only auxiliary request 2 "diverges" somewhat from the preceding requests, the Board considers that the case's complexity is not unduly increased. Moreover, auxiliary requests 2 and 3 were filed about five months after the statement of grounds of appeal, but still about 3.5 years before the Board issued the summons to oral proceedings, so that the respondent-opponent and the Board had sufficient time to consider the new requests. The Board was moreover unable to establish, in just a
prima-facie assessment, that they were inherently unclear and contained added subject-matter, as the respondent argued. The Board considered, instead, that the assessment of the allowability of the requests required a thorough examination and discussion of the raised objections.

6.5 As a consequence, the Board decided to admit auxiliary requests 2 and 3 in the exercise of its discretion under Article 13(1) RPBA.

7. **Auxiliary requests 2 and 3 - Clarity**

7.1 Claim 1 of auxiliary requests 2 and 3 additionally requires that "the display of each tutorial chapter is driven by **one or more unique events** that can occur during use of the kit or analytical meter, wherein depression of the user-operable tutorial button is an event for the purposes of displaying tutorial images in an event-driven chapter based manner, and wherein the depression of the tutorial button is rendered unique by its context, so that the depression of the tutorial button drives the display of different tutorial chapters depending upon the other events that have preceded it" [emphasis added].

7.2 The claims of the patent as granted contain the expressions "event-driven chapter-based display" (claim 1) and "event-driven chapter-based display driven by an event of the user depressing the user operable tutorial button" (dependent claim 3). However, the expressions highlighted above, defining "one or more unique events" and the depression of the tutorial button being "rendered unique by its context", were, instead, extracted from the description (paragraphs [0018] and [0019]). Hence, the clarity of
these expressions is to be examined (G 9/91, Reasons 19).

7.3 In the context of the analytical meter as defined in claim 1 of the granted patent, the term "event" appears to encompass any action related to the operation of the meter. As indicated under point 3.1 above, examples of such events according to the patent are, inter alia, the depression of the user-operable tutorial button (claim 3), the insertion of an analytical strip (claim 6) and the dosing of bodily fluid (claim 7).

7.4 However, the meaning of the feature of a "unique event", or, a fortiori, of a plurality of "unique events", is unclear. Firstly, the skilled person is at a loss to know which of the generally accepted meanings of the term "unique" should apply, that is, he would not know whether the event is meant to be the only one of its kind, whether a remarkable or extraordinary event is meant, etc. This uncertainty alone does not allow to precisely ascertain the subject-matter for which protection is sought.

7.5 Moreover, none of these possible meanings seems to be free of contradictions within the present technical context. In fact, if "unique" is to carry the meaning of the only one of its kind, the claimed alternative of a plurality of such events is an oxymoron. If a "unique" event is to be understood as meaning a remarkable or extraordinary event, the definition is unclear since it relies on subjective judgment to establish how remarkable or extraordinary the event needs to be in order to be considered as "unique". Furthermore, it appears contradictory that the events of depressing the tutorial button, inserting an analytical test strip and dosing of a bodily fluid,
which claims 3, 6 and 7 of the patent define as (normal) events, are described in paragraphs [0031] and [0039] of the patent as examples of "unique events". It is also noted that paragraphs [0019] and [0026] mentioned by the appellant do not even give a hint as to how the term "unique" is to be interpreted.

7.6 A further expression in the claim reciting that the event of depressing the tutorial button "is rendered unique by its context" is likewise unclear. In this expression the lack of clarity of the term "unique" is compounded by defining the uniqueness of an event in terms of its "context" without specifying what the context is.

7.7 The appellant argued that paragraph [0018] explained the meaning of this expression by stating: "an event is rendered unique by its context, i.e., by the other events that have preceded it". It was therefore clear that the "context" was given by the events that have preceded it. This was explained in detail in the description of Figure 4.

This argument does not persuade the Board. Firstly, the claim does not contain the alleged equivalence between "context" and events that preceded the event "rendered unique". What the claim defines is, instead, that the event of depressing the tutorial button "is rendered unique by its context, so that [as a consequence] the depression of the tutorial button drives the display of different tutorial chapters depending upon the other events that have preceded it" [emphasis added].

Furthermore, to say that an event is rendered unique by other events that preceded it appears to be a circular argument, since in that case every event preceded by another event would be a unique event. Finally,
contrary to the appellant's view, neither Figure 4 nor its description (paragraph [0020]) contains any further aspects which might help in understanding the terminology objected to.

7.8 The Board therefore concludes that the meaning of the features objected to remains obscure.

Hence, claim 1 of auxiliary requests 2 and 3 does not fulfil the requirement of clarity, in breach of Article 84 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated