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**Datasheet for the decision
of 24 October 2016**

Case Number: T 0537/13 - 3.2.02

Application Number: 07253490.2

Publication Number: 1897492

IPC: A61B5/00, A61B5/145

Language of the proceedings: EN

Title of invention:

Kit for the determination of an analyte in a bodily fluid sample that includes a meter with a display-based tutorial module

Patent Proprietor:

Lifescan Scotland Ltd

Opponent:

Abbott Diabetes Care Inc.

Headword:

Relevant legal provisions:

EPC Art. 100(a), 54, 84
RPBA Art. 13(1)

Keyword:

Public availability of user manuals of a device (yes)

Novelty - main request (no)

Clarity - auxiliary request 2 (no)

Admissibility of auxiliary request 3 (no)

Decisions cited:

T 0861/04, G 0009/91

Catchword:



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Case Number: T 0537/13 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 24 October 2016

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Decision under appeal: **Interlocutory decision of the Opposition**
Division of the European Patent Office posted on
1 February 2013 concerning maintenance of the
European Patent No. 1897492 in amended form.

Composition of the Board:

Chairman E. Dufrasne
Members: M. Stern
D. Ceccarelli

Summary of Facts and Submissions

I. Appeals were lodged by the patent proprietor and the opponent against the interlocutory decision of the Opposition Division, posted on 1 February 2013, concerning maintenance of the European Patent 1 897 492 in amended form. In the decision under appeal, the Opposition Division held, *inter alia*, that the main request did not satisfy the requirements of novelty whereas auxiliary request 2 satisfied the requirements of the EPC, in particular clarity, lack of added subject-matter, sufficiency of disclosure, novelty and inventive step having regard of the following documents:

- E1: Blood Glucose Testing Guide, FreeStyle Tracker Diabetes Management System, TheraSense, copyright 2002
- E24: User's Guide, FreeStyle Tracker Diabetes Management System, TheraSense, copyright 2002.

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

- E28: FDA 510(k) Clearance for TheraSense FreeStyle Tracker Diabetes Management System, March 15, 2002
- E29: "TheraSense Introduces the World's First Integrated Blood Glucose Meter and Personal Digital Assistant", *Diabetes Positive*, August 2002, page 32
- 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
- E33: "Take Charge Of Your Health", Parade Magazine, November 24, 2002, page 12
- E34: "Handheld Computers in Diabetes Management", Diabetes Self-Management, November/December 2002, pages 43 to 49
- E35: "TheraSense Tracker", Compu-Kiss, February 6, 2003.

III. The appellant/patent proprietor (hereinafter "the patent proprietor") filed a notice of appeal on 4 April 2013, paying the appeal fee the same day. A statement setting out the grounds of appeal was received on 11 June 2016.

IV. The appellant/opponent (hereinafter "the opponent") filed a notice of appeal on 4 March 2013 and paid the appeal fee on 27 February 2013. A statement setting out the grounds of appeal was received on 6 June 2013.

V. Oral proceedings were held on 24 October 2016.

The 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 2, filed on 11 June 2013 and auxiliary request 3, filed during the oral proceedings. Auxiliary request 1 filed with letter dated 19 March 2014 was withdrawn during the oral proceedings.

The opponent requested that the decision under appeal be set aside and that the patent be revoked. It withdrew its earlier requests that the appeal, the main request and auxiliary request 2 be held inadmissible.

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

"A kit for determining an analyte in a bodily fluid sample, the kit comprising:

an analytical meter that includes:

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

at least one analytical test strip configured for:

the application of a bodily fluid sample thereon;

and

insertion in the meter for subsequent

determination of an analyte in the bodily fluid sample;

and characterised 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 kit; 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 2** reads as follows:

"A kit for determining an analyte in a bodily fluid sample, the kit comprising:

an analytical meter that includes:

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, the tutorial having a plurality of chapters with each of the

plurality of chapters containing at least one tutorial image depicting use of the kit; and a microprocessor unit configured for controlling and coordinating at least the user interface and the memory unit, and
at least one analytical test strip configured for: the application of a bodily fluid sample thereon; and
insertion in the meter for subsequent determination of an analyte in the bodily fluid sample;

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 claim 1 of auxiliary request 2 except for the following amendment in the last paragraph:

"[...] wherein the display of each tutorial chapter is driven by one or more ~~unique~~ events [...]"

VII. The arguments of the patent proprietor 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

The images on pages 14 and 17 of E1 showed only a vial and only a test strip respectively. They were no images depicting use of the analytical kit. There was moreover 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 2

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.

- Auxiliary request 3

This request was admissible since it had been filed as a reaction to the discussion on the clarity of auxiliary request 2 during oral proceedings regarding, in particular, the objection that an event rendered unique by other events that preceded it appeared to be a circular argument.

VIII. The arguments of the opponent which are relevant for the present decision are those on which the reasons set out below are based.

Reasons for the Decision

1. During the oral proceedings the opponent withdrew its earlier request that the patent proprietor's 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 patent proprietor's appeal is admissible.

The appeal by the opponent is uncontestedly 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 opponent 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 kit formed by the analytical meter and the test strip 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 patent proprietor'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 2 - Clarity*

4.1 Auxiliary request 2 is identical to auxiliary request 2 underlying the decision under appeal which was held allowable by the Opposition Division. Claim 1 of this request 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].

4.2 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).

4.3 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).

4.4 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.

4.5 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 ambiguous since it relies on subjective judgment to establish how remarkable or extraordinary the event needs to be in order to be considered "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 patent proprietor do not even give a hint as to how the term "unique" is to be interpreted.

4.6 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.

4.7 The patent proprietor 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 patent proprietor's view, neither Figure 4 nor its description (paragraph [0020]) contains any further aspects which might help in understanding the terminology objected to.

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

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

5. *Auxiliary request 3 - Admissibility*

5.1 This request was filed at the end of the oral proceedings, after the discussion of the admissible requests filed during the appeal proceedings. According to the patent proprietor, it was filed as a reaction to the discussion on the clarity of auxiliary request 2 during the oral proceedings regarding, in particular the objection that an event rendered unique by other events that preceded it appeared to be a circular argument.

5.2 The Board notes that the opponent presented already in its statement of grounds of appeal clarity objections against the expressions mentioned above ("unique events" and the depression of the tutorial button "is rendered unique by its context"). In the communication annexed to the summons to oral proceedings, the Board remarked that these objections were of importance for the discussion at oral proceedings. The opponent addressed these objections again in its letter filed four weeks before the oral proceedings (dated 26 September 2016).

Therefore, the Board does not recognise any justification for waiting until the end of the oral proceedings to file this new auxiliary request. Moreover, far from addressing all the clarity objections raised against auxiliary request 2, claim 1 of auxiliary request 3 still includes one of the expressions objected to (defining that the depression of the tutorial button "is rendered unique by its

context"). Particularly the latter unamended expression had been considered during oral proceedings to represent a circular argument. The request is thus prima facie not allowable.

5.3 Consequently, the Board does not admit auxiliary request 3 under Article 13(1) RPBA.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated