Internal distribution code:

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

Datasheet for the decision of 2 August 2022

Case Number: T 0724/17 - 3.2.02

Application Number: 06829789.4

Publication Number: 1965691

IPC: A61B5/00, A61M5/142, G06F19/00, G01N33/487

Language of the proceedings: EN

Title of invention:
PORTABLE ANALYTICAL DEVICE

Patent Proprietors:
Roche Diagnostics GmbH
F. Hoffmann-La Roche AG

Opponent:
Abbott Diabetes Care Inc.

Relevant legal provisions:
EPC Art. 54, 56, 123(2)
RPBA Art. 12(4)

Keyword:
Novelty - (yes)
Inventive step - (yes)
Late-filed objection - should have been submitted in first-instance proceedings (yes) - admitted (no)

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0724/17 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 2 August 2022

Appellant: (Patent Proprietor 1)	Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim (DE)
Appellant: (Patent Proprietor 2)	F. Hoffmann-La Roche AG Grenzacherstrasse 124 4070 Basel (CH)
Representative:	Altmann Stößel Dick Patentanwälte PartG mbB Theodor-Heuss-Anlage 2 68165 Mannheim (DE)
Respondent: (Opponent 1)	Abbott Diabetes Care Inc. 1360 South Loop Road Alameda, CA 94502 (US)
Representative:	Mathys & Squire The Shard 32 London Bridge Street London SE1 9SG (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 12 January 2017 revoking European patent No. 1965691 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Dennler
	Y. Podbielski

Summary of Facts and Submissions

I. The patent proprietors filed the appeal against the Opposition Division's decision to revoke the contested patent on the ground, *inter alia*, that the subject-matter of claim 1 as granted was not novel over the following document:

D6 : WO 02/078512 A2

II. The appellants (proprietors) requested that the decision under appeal be set aside and that the patent be maintained as granted, as a main request. As an auxiliary measure, they requested that the patent be maintained in amended form on the basis of one of auxiliary requests I, Ii, II, IIa, IIb, IIi, IIai and IIbi, with auxiliary requests I, II, IIa, IIb filed with the statement of grounds of appeal and auxiliary requests Ii, IIi, IIai, IIbi filed with the submission dated 14 April 2022. Oral proceedings were also requested as an auxiliary measure.

The respondent (opponent 1) requested that the appeal be dismissed. Oral proceedings were also requested as an auxiliary measure.

III. The Board summoned the parties to attend oral proceedings on 15 June 2022 and provided its preliminary opinion in its communication pursuant to Article 15(1) RPBA 2020.

By letter dated 1 June 2022, the respondent announced that it would not attend the oral proceedings.

Therefore, the Board cancelled the oral proceedings. Accordingly, the present decision is based on the parties' written submissions on appeal.

IV. The present decision also refers to the following documents:

D27 : Wikipedia entry of "*Firmware*"
D35 : definition of "*standard*" according to the Merriam-Webster dictionary

V. Claim 1 according to the main request (claim 1 as granted) reads as follows (feature numbering in bold as used by the appellants):

1a *"Portable, patient-operable analytical device (1) for analysis of a medically significant component of a body fluid for self monitoring by a patient, in particular a blood glucose measuring device (2), comprising*

1b *a device housing (3),*

1c *a measuring facility arrange* [sic] *inside the device housing (3) for carrying out the analysis on a test element (7), that is inserted through a housing opening (8) into the analytical device (1) and the measuring facility,*

1d *wherein the analytical device (1) is configured to carry out the analysis on a mutually adapted test element (7) that contains a reagent, such that when the test element (7) is contacted with a liquid sample of the body fluid the reaction between the liquid sample and the reagent leads to a change in the test element (7) that is characteristic of the analysis, wherein the analytical device (1) is adapted to analyze the change in the test element (7) when it is*

inserted through the housing opening (8) into the analytical device. [sic] *(1), and*

1e *a processor with software for processing of the measuring values determined by the measuring facility and for processing the measuring values, to yield analytical measuring data taking into account calibration values,*

characterized in that

1f *the analytical device (1) comprises a standardized, wire-based computer interface by means of which*

1g *- the analytical device (1) can be operated by a computer,*

1h *- the analytical measuring data can be transmitted from the analytical device (1) to the computer, and*

1i *- the analytical device (1) can be supplied with electrical power by the computer,*

and ***in that***

1j *it comprises a memory in which the software required for operation of the analytical device (1) is stored, and*

1k *can provide this software to be read-out by the computer via the interface of the analytical device (1) when the analytical device (1) becomes connected to the computer."*

VI. The **appellants' arguments** relating to the main request, as far as they are relevant for the present decision, can be summarised as follows.

Added subject-matter

Those parts of the decision under appeal that addressed added subject-matter issues (points 3.1 to 3.3 of the

reasons) were entirely silent about the feature "a change in the test element" on which the respondent's objection was based. In view of the purpose of the appeal proceedings being the review the first-instance decision, this objection should not be admitted into the proceedings.

Moreover, this objection was not convincing, because optical and electrical changes were merely disclosed in the application as filed as possible measurement principles. Thus, claim 1 as granted did not comprise an unallowable intermediate generalisation.

Novelty over D6

The interface described in D6 was highly specialised and manufacturer-specific. It only allowed the module to be connected to other personal digital assistants (PDAs) having the same interface. However, it was not possible to connect the module to other devices without modifying the interface. Therefore, the interface was not "standardized". As defined in D35, the term "standardized" related indeed to "something established by authority, custom or general consent", hence to universal standards rather than in-house standards. Thus, D6 did not disclose feature 1f.

From the wording of features 1j and 1k, it was clear that the software to be read out by the computer was the software required for operation of the analytical device by the computer, i.e. driver software. The "meter firmware", "firmware revision data" and other parameters transmitted by the measurement module to the PDA as well as the various "applications" disclosed in D6 could not be regarded as driver software for

operation of the analytical device by the computer. Hence, D6 did not disclose features 1j and 1k either.

At least for these reasons, the subject-matter of claim 1 as granted was novel over D6.

Inventive step starting from D6

The subject-matter of claim 1 as granted differed from the disclosure of D6 at least on account of features 1f, 1j and 1k.

As described in paragraphs [0050] and [0059] of the contested patent, these features enabled the analytical device to be carried around and connected to different non-preconfigured computers, for example to display measured data.

The objective technical problem to be solved starting from D6 was therefore to facilitate portability and universal operation of the analytical device and its interconnection with other devices, such as a computer.

Proceeding from D6, the person skilled in the art would not have arrived at the subject-matter of claim 1 in an obvious manner. The subject-matter of claim 1 as granted thus involved an inventive step over D6.

VII. The **respondent's arguments** relating to the main request, as far as they are relevant for the present decision, can be summarised as follows.

Added subject-matter

The application as originally filed on which the contested patent was based only disclosed, consistently

throughout the description, an analytical device configured to analyse a test element containing a reagent that reacted to a liquid sample, leading to an optically or electrically detectable change (see e.g. page 2, second paragraph; paragraphs bridging pages 6-7 and 7-8, respectively; page 9, first paragraph). There was no disclosure in the application as filed of the detection of any other kind of change in the test element.

By contrast, claim 1 as granted broadly defined that the analysis carried out by the analytical device was based on "a change in the test element" (feature 1d). It followed that claim 1 as granted was based on an unallowable intermediate generalisation in breach of Article 123(2) EPC.

The respondent did not comment on the admittance of this objection.

Novelty over D6

D6 disclosed an analytical device (glucose measurement module 2) that comprised all the features of claim 1 as granted.

In particular, this module had a wire-based interface for connection with a hand-held processing device, i.e. a computer, such as a PDA 4 as shown in Figure 1. Albeit being manufacturer-specific, this interface allowed the module to be connected to multiple other PDAs having the same interface. Hence, it was a "standardized, wire-based computer interface" according to feature 1f.

Moreover, the module had memory for storing a "meter firmware" (page 26, lines 16-18) and the PDA received "firmware revision data" from the module (page 29, lines 14-15). D6 also described various "applications" such as meter application 150 that operated the module (page 33, last paragraph). Thus, D6 also disclosed features 1j and 1k. In this respect, the claimed software was not limited to driver software as argued by the appellants.

Therefore, the subject-matter of claim 1 as granted was not novel over D6.

Inventive step starting from D6

If the subject-matter of claim 1 as granted were to be considered novel over D6, it would in any event not be inventive over that document.

Whatever the difference with D6, the person skilled in the art would have arrived at the subject-matter of claim 1 in an obvious way. The objective technical problem to be solved starting from D6 formulated by the appellants, to facilitate the portability and universal operation of the analytical device and its interconnection with other devices, was incorrect because it was not based on features actually claimed. Even if this problem were admitted, the person skilled in the art would have found a solution in D6 itself as the module described in D6 was portable and could be universally operated and interconnected with the disclosed PDAs.

Hence, the subject-matter of claim 1 as granted did not involve an inventive step starting from D6.

Reasons for the Decision

1. The subject-matter of the contested patent

1.1 The contested patent relates to a portable, patient-operable analytical device, such as a blood glucose measuring device (paragraph [0001]).

Unlike conventional devices that operate autonomously (paragraph [0008]), the analytical device defined in claim 1 of the patent as granted is specifically configured for use with a computer (also generally called electronic device in the description). An exemplary embodiment, provided in the design of a conventional USB stick (paragraph [0043]), is illustrated in Figure 2 reproduced below.

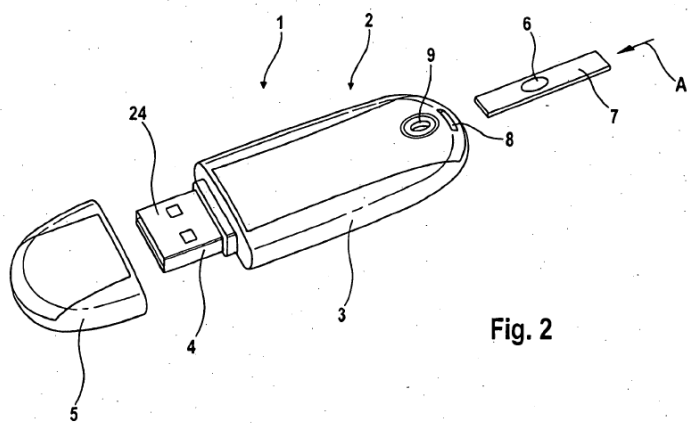

Fig. 2

1.2 In addition to a measuring facility (in the illustrated example, one which is configured to receive a test element 7 and to analyse a sample of body fluid, such as blood, deposited on it; paragraph [0044]), the analytical device also comprises a wire-based computer interface, such as a USB connector 24 (paragraph [0043]).

By means of this interface, the analytic device can be powered and operated by the computer. The analytical

measuring data measured by the measuring facility can also be transmitted to the computer, for example to be displayed to the user by the computer's own display (paragraphs [0050], [0066]).

As a result, the construction of the analytical device can be very simple and substantially limited to what is needed to carry out the analysis of the test element. For example, the analytical device may be deprived of a user interface and a display (paragraphs [0054]-[0055]).

1.3 Furthermore, the analytical device comprises a memory in which the software required for operation of the analytical device is stored. The analytical device can provide this software to be read out by a computer via the interface when the analytical device becomes connected to this computer.

Thus, a preconfiguration of the computer is not required for it to operate the analytical device. Instead, the computer can load the required software directly from the memory of the analytical device. This renders the analytical device easily and directly operable by any computer having the same interface, even non-preconfigured (paragraphs [0059], [0071]).

2. Added subject-matter

2.1 The respondent raised an objection under Article 123(2) EPC against claim 1 as granted, objecting to the fact that feature 1d broadly referred to "a change in the test element" rather than to an optically or electrically detectable change as specifically disclosed in the application as filed. This resulted,

in the respondent's view, in an unallowable intermediate generalisation.

2.2 Pursuant to Article 12(4) RPBA 2007, which applies in this case by virtue of the transitional provisions of Article 25(2) RPBA 2020, the Board has the power to hold inadmissible facts, evidence or requests which could have been presented or were not admitted in the first-instance proceedings.

2.3 As put forward by the appellants, the respondent's added subject-matter objection above has not been addressed in the decision under appeal. It appears from the file that this objection was in fact raised for the first time on appeal, in the respondent's reply to the statement of grounds of appeal.

In the Board's view, this objection, which concerns claim 1 as granted, could and should have been raised in the first-instance proceedings. The respondent has not provided any reason why it was not.

The Board therefore decides to hold the respondent's added subject-matter objection above inadmissible pursuant to Article 12(4) RPBA 2007.

In any event, this objection is prima facie not convincing. Indeed, as argued by the appellants, optically and electrically detectable changes are merely examples of changes on which a measurement can be based. This is explicitly disclosed in the description as filed (page 17, last paragraph to page 18, second paragraph).

3. Novelty over D6

3.1 It is common ground that D6 discloses (see for example Figure 9, reproduced below, and the corresponding description on page 27, lines 3-15) an analytical device (blood glucose measurement module 2) adapted to be connected to a computer (PDA 4) via a wire-based computer interface 116 (see for example the electrical pin connector 84 of this interface shown in Figure 6c and described on page 21, lines 9-11).

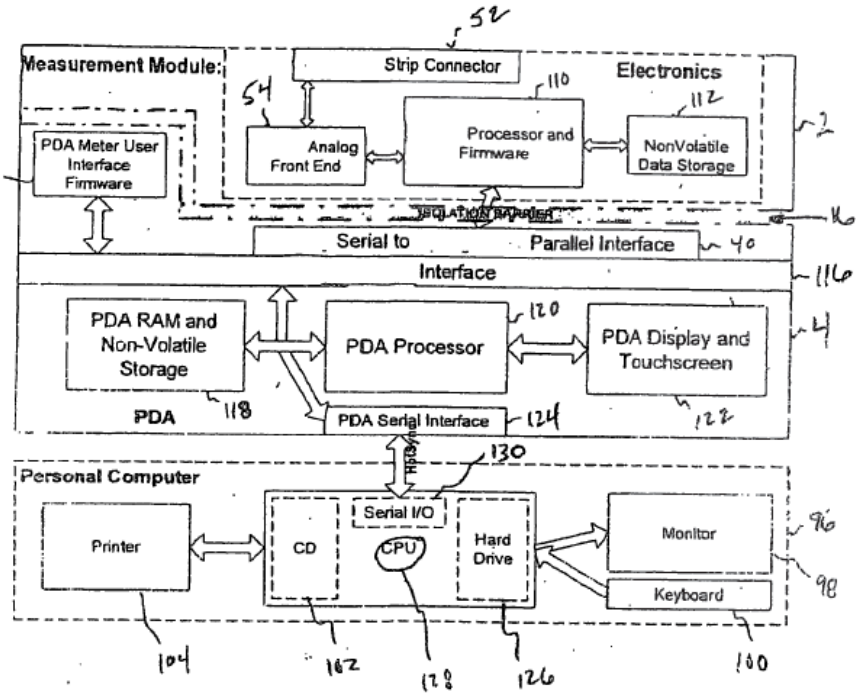

Figure 9

3.2 A first point of dispute between the parties is whether or not the computer interface 116 disclosed in D6 is "standardized" as required by feature 1f.

On a plain reading, the term "standardized" merely requires the computer interface to meet some pre-determined "standard". This enables the analytical device to be connected to any other device having a compatible interface meeting the same standard.

As the appellant conceded, the interface 116 enables the module to be connected to any other PDA compatible with this interface. For this purpose, the interface 116 has, inter alia, a specifically shaped mounting portion 80 with an electrical pin connector 84, as shown e.g. in Figures 6a-6i, which is adapted to connect to any complementary connector (page 20, third paragraph; page 21, lines 9-11). The Board concurs with the respondent's view that this is sufficient to establish a "standard" - albeit a manufacturer-specific one - and thus to qualify the interface 116 as "standardized".

Contrary to the appellants' view, it does not matter that the interface 116 may be "highly specialised", because the definition of a standard, for example as given in D35, does not involve any criterion on the level of specialisation. Moreover, this definition does not exclude that the standard be established by a manufacturer acting as an "authority". It is also irrelevant that the interface 116 may be further developed by the manufacturer. It is true that, in this case, further development could lead to a new or revised standard with which the interface 116 may not be compatible; however, this would not prevent the interface 116 from meeting the former, unrevised standard.

It follows that D6 discloses feature 1f, as the Opposition Division correctly concluded (point 4.3 of the decision under appeal, first paragraph).

3.3 A second point of dispute between the parties is whether or not D6 discloses features 1j and 1k. As explained below, the Board shares the appellants' view that D6 does not.

3.3.1 As put forward by the appellants, it follows from the wording of claim 1, especially of its characterising portion, that "the software required for operation of the analytical device" specified in feature 1j and defined in feature 1k to be ultimately read out by the computer is the software required *for operation of the analytical device by the computer*. This is not only in line with feature 1g according to which "the analytical device (1) can be operated by a computer", but also with the description of the contested patent (paragraphs [0059] and [0071]).

At least for this reason, it follows, as argued by the appellants, that the "meter firmware" stored in a memory of the measurement module of D6 (page 26, lines 16-18) cannot anticipate this software. The meter firmware runs indeed on the processor of the module (page 27, lines 6-7) and is therefore not *for operation of the module by the computer*.

3.3.2 Moreover, irrespective of this, D6 does not disclose that this firmware is "provided [by the module] to be read-out" by the PDA via the computer interface as required by feature 1k. In this respect, the respondent argued that the PDA received "firmware revision data" from the module (page 29, lines 14-15; see also the corresponding arrow labelled "Firmware Rev" on Figure 10 between block 132 "Setup" of the module 2 and block 4 representing the PDA). As argued by the appellants, transmitting "firmware revision data" to the PDA does not necessarily include providing the firmware itself to be read out by the PDA. Rather, these "firmware revision data", which are not further described in D6, could well be limited to version numbers only. The same applies, as further argued by

the appellants, to the other data transmitted by the module to the PDA, such as the parameters related to the "System Setup" (see the corresponding arrow on Figure 10). None of these parameters can be identified as "software required for operation of the analytical device", not least by the computer.

3.3.3 The respondent also pointed to the various applications, such as the meter application 150, disclosed in D6 (page 33, last paragraph).

It is true that these applications, which may run on the PDA (page 30, last paragraph), constitute "software for operation of the analytical device" by the PDA. However, D6 does not disclose that this software is stored in a memory of the measurement module and can be transmitted to the PDA via the computer interface when the module and the PDA are connected. Rather, as the appellant put forward, D6 explicitly discloses that this software must be pre-installed on the PDA from another source, for instance downloaded (first two lines of page 31).

3.3.4 The Opposition Division's reasoning concluding that features 1j and 1k are disclosed in D6 (page 11 of the decision under appeal, second and third paragraphs) does not convince the Board either.

The Opposition Division took the view that the "PDA meter user interface firmware" stored in the analytical device (page 27, lines 11-12; Figure 9) anticipated the software specified in features 1j and 1k. To arrive at this conclusion, the Opposition Division assumed ("it is thus clear") that this firmware was "used for flashing (upgrading) of the firmware of the PDA".

However, while this flashing might indeed imply some "read-out" by the PDA, there is, contrary to the Opposition Division's affirmation, no direct and unambiguous disclosure confirming this assumption. The fact that this feature "is not in contradiction to D6" as the Opposition Division argued does not mean that it is disclosed in D6, even implicitly. The definition of "firmware" in D27 is immaterial and does not contradict this conclusion. Moreover, the disclosure in D6 that "firmware revision data" are transmitted to the PDA does not represent a direct and unambiguous disclosure of a "process of updating or modifying software" as alleged by the Opposition Division (see also point 3.3.2 above in this respect).

3.4 The Board therefore concludes that the subject-matter of claim 1 is novel over D6.

4. Inventive step starting from D6

4.1 It follows from the novelty analysis above that the subject-matter of claim 1 as granted differs from the disclosure of D6 at least on account of features 1j and 1k.

4.2 The appellants based their reasoning in support of inventive step not only on these features, but additionally on feature 1f, which the Board has found to be disclosed in D6.

The Board notes, however, that the appellants' reasoning applies similarly when limited to computers having the same computer interface as, or at least compatible with, the computer interface 116 of the measurement module of D6.

Indeed, as explained in paragraphs [0059] and [0071] of the contested patent, features 1j and 1k enable the analytical device to be operated by any computer compatible with the interface, without requiring the computer to be preconfigured with the software required for operation of the analytical device. Hence, they solve the objective technical problem of facilitating portability and operation of the analytical device.

4.3 Proceeding from D6, the person skilled in the art would not have arrived at the solution defined in claim 1 as granted in an obvious way.

First, D6 does not contain any motivation in this sense. It is true, as asserted by the respondent, that the measurement module of D6 is also portable and can also be operated and interconnected with compatible PDAs. However, in contrast to the claimed solution, D6 discloses explicitly, as discussed above, that the software required for operation of the measurement module by the PDA must be separately pre-installed on the PDA by downloading it from another source, for instance from another computer, a server or another storage device (page 31, first two lines). There is no suggestion in D6 that this software could be downloaded from the measurement module itself.

Moreover, storing this software in a memory of the measurement module and configuring the latter so that it provides this software to be read out by a PDA via the interface upon connection of the module to the PDA would require substantial modifications of the measurement module. In the Board's view, these modifications are beyond the type of modifications that a person skilled in the art would have contemplated without exercising inventive skills, especially in the

absence of any incentive in D6. The respondent has not submitted any convincing counter-arguments in this respect.

4.4 The Board therefore concurs with the appellants' view that the subject-matter of claim 1 as granted involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained as granted.

The Registrar: The Chairman:

N. Schneider M. Alvazzi Delfrate

Decision electronically authenticated