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**Datasheet for the decision
of 3 May 2021**

Case Number: T 2793/18 - 3.4.02

Application Number: 07710306.7

Publication Number: 1984724

IPC: G01N21/64, G01N15/14, B01L7/00

Language of the proceedings: EN

Title of invention:
DEVICE AND METHODS FOR QUANTIFYING ANALYTES

Applicant:
Life Technologies Corporation

Headword:

Relevant legal provisions:
EPC 1973 Art. 56

Keyword:
Inventive step - (no)

Decisions cited:

Catchword:



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Case Number: T 2793/18 - 3.4.02

D E C I S I O N
of Technical Board of Appeal 3.4.02
of 3 May 2021

Appellant: Life Technologies Corporation
(Applicant) 5823 Newton Drive
Carlsbad, CA 92008 (US)

Representative: HGF
1 City Walk
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 10 July 2018
refusing European patent application
No. 07710306.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman R. Bekkering
Members: C. Kallinger
G. Decker

Summary of Facts and Submissions

- I. The appellant lodged an appeal against the decision of the examining division refusing European patent application No. 07 710 306.7.
- II. With the notice of appeal, the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the claims according to the main request or, in the alternative, according to an auxiliary request, both claim sets filed with a letter dated 11 May 2018 during the first-instance proceedings.
- III. In a communication pursuant to Article 15(1) RPBA 2020, the board gave its preliminary opinion on certain aspects of the appeal.
- IV. In a letter dated 1 April 2021 the appellant filed observations in regard of the board's preliminary opinion and two sets of amended claims forming the basis of two further auxiliary requests.
- V. Oral proceedings were held on 3 May 2021.
- VI. The appellant's final requests were that the decision under appeal be set aside and that a patent be granted on the basis of the claims according to the main request filed with the letter dated 11 May 2018, or, alternatively, on the basis of the claims according to the first auxiliary request filed with the letter dated 1 April 2021, or the second auxiliary request filed as "auxiliary request" with the letter dated 11 May 2018, or the third auxiliary request filed with the letter dated 1 April 2021. Should the claims be in

order for allowance but the application not yet ready for grant, it requested to remit the case to the examining division for further prosecution.

VII. In this decision reference is made to the following document:

D1 US 2002/0109844 A1

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

"A device that is a fluorometer for measuring the quantity of one or more predetermined analytes, wherein the device is an integrated unit which comprises

a receptacle (101, 205) for holding a sample container (306) having an analyte, a photodetector (113, 209, 217), a plurality of distinct and operably linked analyte sensing elements (ASEs), a computer processing unit (105) with machine executable instructions, wherein each of the ASEs comprises:

a) an energy source (107, 201, 211) for exciting the sample, wherein the energy source is configured to emit a predetermined peak wavelength of light;

b) an excitation filter (109, 203, 213), wherein the excitation filter is configured to isolate a predetermined range of wavelengths of light from the energy source;

c) an emission filter (111, 207, 215), wherein the emission filter is configured to isolate a predetermined range of wavelengths of light emitted from the excited sample; and

wherein each of the ASEs is configured to measure the quantity of the predetermined analyte;

characterized in that the device further comprises a user interface configured to allow a user to select the analyte for measurement and in that the machine executable instructions are configured to select the proper ASE corresponding to the analyte to be measured."

IX. In comparison to the main request, in the first auxiliary request previous dependent claims 4 and 12 have been deleted.

X. Claim 1 of the second auxiliary request reads as follows (amendments with respect to the main request marked by the board):

"A device that is a fluorometer for measuring the quantity of one or more predetermined analytes, wherein the device is an integrated unit which comprises

a receptacle (101, 205) for holding a sample container (306) having an analyte, a photodetector (113, 209, 217), a plurality of distinct and operably linked analyte sensing elements (ASEs), a computer processing unit (105) with machine executable instructions, wherein each of the ASEs comprises:

a) an energy source (107, 201, 211) for exciting the sample, wherein the energy source is configured to emit a predetermined peak wavelength of light;

b) an excitation filter (109, 203, 213), wherein the excitation filter is configured to isolate a

predetermined range of wavelengths of light from the energy source;

c) an emission filter (111, 207, 215), wherein the emission filter is configured to isolate a predetermined range of wavelengths of light emitted from the excited sample; and

wherein each of the ASEs is configured for the device to measure the quantity of one of the predetermined analyte, and wherein the computer processing unit controls the operation of the device and also provides control of various functionalities of the device;

characterized in that the device further comprises a user interface configured to allow a user to select the analyte for measurement and in that the machine executable instructions are configured to select the proper ASE corresponding to the analyte to be measured."

- XI. In comparison to the second auxiliary request, in the third auxiliary request previous dependent claims 4 and 12 have been deleted.

Reasons for the Decision

1. Main request - Inventive step

The board is of the opinion that the subject-matter of claim 1 of the main request does not meet the requirements of Article 56 EPC 1973.

1.1 Closest prior art

1.1.1 The examining division considered document D1 to represent the closest prior art.

1.1.2 The applicant argued that nothing in D1 related to the technical problem of how to increase the flexibility of performing optical measurements. Instead, D1 was directed to solving the problem of how to provide real-time detection of multiple analytes in a reaction mixture. As D1 did not solve a similar technical problem as the application, it did not represent a suitable starting point for assessment of inventive step.

1.1.3 The appellant's arguments are not convincing.

According to established case law (see Case Law of the Boards of Appeal, 9th Edition, July 2019 ("Case Law 2019"), I.D.3.2) the closest prior art for assessing inventive step is normally a prior art document directed to the same purpose as the claimed invention. Both D1 (see paragraph [0003] and claim 1) and the application (see paragraph [0003] and claim 1) relate to multi-channel optical detection systems for analytes in a sample and therefore to the same purpose.

Furthermore, a document serving as the starting point for evaluating the inventive merits of an invention should relate at least to the same or a closely related technical field as the patent (application) in suit (see Case Law 2019, I.D.3.3). As just discussed, both D1 and the application relate to the field of optical measurement of analytes in samples. The closest prior art does not have to disclose the objective technical problem, which is only determined in the second step of the problem and solution approach on the basis of the technical effect provided by those features distinguishing the invention as claimed from the closest prior art. D1 as closest prior art allows the formulation of a relevant technical problem without inappropriate hindsight (see point 1.3 below). Therefore, the decision T 835/00 (cited by the appellant as "T 935/00") is not relevant in the present case.

In conclusion, the board is of the opinion that D1 represents the closest prior art and is a suitable starting point for assessing the presence of an inventive step.

D1 (see paragraphs [0143] to [0150] and Figures 6, 12 and 13) discloses an optical interrogation device (i.e. a fluorometer for measuring the quantity of one or more predetermined analytes) with a receptacle for holding a sample container, a computer processing unit and four primary optical detection channels which are considered to represent four ASEs as claimed. The device is configured to utilise all optical detection channels sequentially.

1.2 Differences

- 1.2.1 The appellant argued that there were the following differences between the fluorometer of claim 1 and the device disclosed in D1.

Firstly, claim 1 (see preamble) related to an integrated fluorometer, e.g. a fluorometer in form of a stand-alone device. In contrast to this, D1 disclosed the optical detection unit (including e.g. LEDs 100 and detectors 102) as part of a bigger device, in particular as part of the heat exchange module (see Figure 13 and paragraphs [0119] to [0123]) which then "acted as a fluorometer". Therefore, the fluorometer of D1 was not integrated as required by claim 1.

Secondly, the device of claim 1 differed from the fluorometer disclosed in D1 in the features of the characterising portion, i.e. in that *"... the device further comprises a user interface configured to allow a user to select the analyte for measurement and in that the machine executable instructions are configured to select the proper ASE corresponding to the analyte to be measured."* Not only did D1 fail to disclose a user selection of the optical detection channels, but there was in addition no automatic selection of the corresponding optical detection channel either.

- 1.2.2 With respect to the first difference (integrated device) the board is not convinced by the appellant's arguments. Document D1 (see paragraph [0175]) discloses that *"the optics assemblies may also be used alone to optically interrogate a reaction mixture. For example, in one alternative embodiment, the optics assemblies are incorporated in a hand-held apparatus having a slot for receiving a reaction vessel."* The board is of the

opinion that this passage of D1 explicitly discloses that the optics assemblies, i.e. the four channel fluorometer, can be realised as an integrated device. Claim 1 contains no further restriction in this respect and the skilled person needs no further information in order to realise an integrated device.

With respect to the second difference (user selection of an analyte and selection of the proper ASE) the board agrees that D1 fails to disclose that the user interface is *"configured to allow a user to select the analyte for measurement"*. However, as each of the four channels is dedicated to one specific analyte, D1 does also disclose that the device (and therefore necessarily the underlying machine executable instructions) is configured to automatically select the proper ASE corresponding to the analyte to be measured in a certain step.

The board is therefore of the opinion that the only remaining difference is that D1 fails to disclose that the user interface is configured to allow a user to select the analyte for measurement.

1.3 Technical effect and problem to be solved

The appellant identified the technical effect as providing a more flexible approach to and an improved efficiency of the optical measurement of an analyte.

Therefore, the problem to be solved was to increase flexibility and efficiency of performing the optical measurements.

The board agrees with this assessment.

1.4 Obviousness

The examining division concluded that the claimed solution was obvious because it was within the routine work of the skilled person to provide a user selection instead of the automated sequential selection of each optical interrogation channel as used in D1.

- 1.4.1 The appellant argued that D1 was directed at monitoring multiple analytes in parallel (see paragraph [0003]) and that therefore the skilled person had no reason to consider addressing the problem of how to increase the flexibility and efficiency of optical measurements.

This argument is not convincing, because according to the "problem and solution approach" the technical problem to be solved is established from the technical effect achieved by the claimed invention when compared with the "closest state of the art". The technical difference and the problem to be solved are therefore formulated as discussed above.

- 1.4.2 The appellant further argued that D1 did not provide any teaching as to how to adapt the disclosed device to allow a user to select a given analyte via the user interface, with machine executable instructions then configured to select the proper ASE corresponding to the analyte to be measured. Actually, document D1 solved a different problem.

This argument is not convincing, because for the assessment of inventive step D1 does not have to provide the solution in itself. This would rather be a question of novelty.

1.4.3 The appellant further argued that the examining division's conclusion was based on an unreasonable assessment of what constituted routine work and involved the use of impermissible hindsight.

In particular, the examining division's assertion that it was a matter of routine work to increase the flexibility of measurement in an automated system by providing for manual intervention appeared unreasonable as the way to do this for any given type of instrument was hardly a matter of routine work and it was not even clear that providing manual intervention would of necessity increase the flexibility of the measurement.

Furthermore, according to D1 the operation of all of the ASEs in any given experiment was fully automated. Therefore, the device was not set up so that a routine modification would increase the flexibility of ASE operation, e.g. so that, via the user interface, a user could provide a device where a predetermined analyte was selected, so the device was then configured to only use the ASE relevant to said predetermined analyte.

Furthermore, the case law related to automation was not relevant, because the present invention lied neither in the "mere automation" nor in the provision of "less automation".

Finally, the appellant argued with reference to T 0535/98 that the present invention could not consist in the mere "removal of automation" of the functions performed by the device of D1, as the function of selecting the proper ASE for a particular analyte was not present or contemplated in D1. Thus, the present invention did not lie merely in the "abandonment of full automation" to provide flexibility but included

also the automatic selection of the appropriate optical detection channel which allowed also an unskilled user to select the analyte for measurement without any knowledge about the ASE for a particular analyte.

The board finds these arguments not convincing and is of the opinion that the provision of a user intervention in the automated system of D1 does not involve an inventive step.

D1 discloses that the optical measurements involve an automated procedure under computer control in which the adjustable current source 104 is used to activate the LEDs 100A, 100B, 100C and 100D sequentially one after the other so as to excite in sequence the fluorescently labelled analytes (see paragraphs [0095] to [0098], [0119], [0143] to [0150] and Figures 6 and 13). For a skilled person in the technical field of optical fluorescent measurements on samples in containers it is a matter of routine work that a system which performs measurements in an automated manner can have its flexibility and efficiency increased by providing for manual intervention by a user of the device. This is especially true for devices such as that used in D1 where the operation of the device already involves manual intervention via the disclosed user interface (see Figure 14, 152).

The examining division's argument with respect to automation is convincing in the sense that when "mere automation" is obvious, then the reversed process, i.e. user input instead of an automated process, is also obvious. The board agrees, even without further proof, that it is a generally known fact that the implementation of a user selection instead of an automated and therefore unchangeable process provides

increased flexibility. In addition, the possibility for the user to choose only a single channel in cases where only a single analyte has to be measured also increases the efficiency (e.g. in terms of time and power consumption) of the overall measurement as no unnecessary measurements are performed. Both advantages are linked to the abandonment of full automation in favour of a user selection. In the board's view this is well known and neither unexpected nor surprising.

Furthermore, also the fact that D1 is a fully automated system does not hinder the skilled person to implement a user selection when an improved flexibility can be expected from this change. The adaptation of the device of D1 from the therein disclosed automated (i.e. via machine executable instructions) sequential measurements of predetermined analytes (see paragraph [0147]) to the claimed selection of a proper analyte sensing element (ASE) based on a user input is a straightforward modification of the device's programming. It merely requires the inclusion of a user selection step ("measure analyte Y") instead of a preprogrammed sequence of analytes ("measure analytes X, Y and then Z"). The claim does not contain any further restrictions as to how the user selection is implemented.

Finally, as already discussed above (see point 1.2.2), D1 discloses that the device of D1 is adapted to select the proper ASE corresponding to the analyte to be measured. This feature therefore cannot contribute to the presence of an inventive step.

In conclusion, the subject-matter of claim 1 of the main request does not involve an inventive step with

respect to document D1 in combination with the routine work of the skilled person.

2. First auxiliary request

Claim 1 of the first auxiliary request is identical to claim 1 of the main request.

Therefore, for the same reasons as set out above for the main request, the subject-matter of claim 1 of the first auxiliary request does not involve an inventive step with respect to document D1 in combination with the routine work of the skilled person.

The subject-matter of claim 1 of the first auxiliary request therefore does not meet the requirements of Article 56 EPC 1973.

3. Second and third auxiliary request

In comparison to claim 1 of the main request, claim 1 of the second and third auxiliary request has been amended as follows (amendments marked in underlining):

"... wherein each of the ASEs is configured for the device to measure the quantity of one of the predetermined analyte, and wherein the computer processing unit controls the operation of the device and also provides control of various functionalities of the device; ..."

- 3.1 The appellant argued that claim 1 of the second and third auxiliary request were inventive for at least the reasons set out for the main request.

The added features further clarified the differences between the claimed fluorometer and the disclosure of D1.

Furthermore, D1 failed to disclose the "*control of various functionalities of the device*" as claimed, because D1 related to a fully pre--configured device and the control was limited to triggering the individual measuring channels.

- 3.2 The board is not convinced by the appellant's arguments because the amendments do not distinguish the claimed subject-matter claim 1 beyond the difference as identified above for the main request (see point 1.2.2):

With respect to the amendment "*one of*", D1 discloses a plurality of labelled analytes (see e.g. paragraphs [0023] and [00143] to [0150]).

With respect to the amendment relating to the control of the device and various functionalities of the device, the device of D1 comprises processing electronics (see e.g. Figures 12 and 13 and paragraph [0022]) for controlling the operation of the device and also for controlling "*various functionalities*" (such as operation of light sources, detector read-outs and control of thermal cycling).

In conclusion, D1 already discloses the added features, which therefore cannot contribute to the presence of an inventive step.

Therefore, with respect to inventive step the same reasoning as given above for the main request applies,

i.e. the subject-matter of claim 1 of the second and third auxiliary request does not involve an inventive step with respect to document D1 in combination with the routine work of the skilled person.

The subject-matter of claim 1 of the second and third auxiliary request therefore does not meet the requirements of Article 56 EPC 1973.

4. Remittal

As none of the requests is allowable, the appellant's request to remit the case to the examining division for further prosecution is moot and thus refused.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



H. Jenney

R. Bekkering

Decision electronically authenticated