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Datasheet for the decision of 27 October 2021

Case Number: T 2579/16 - 3.4.02

Application Number: 10180848.3

Publication Number: 2322914

IPC: G01N21/77, G01N21/86, G01N33/543, A61B5/00

Language of the proceedings: EN

Title of invention:
Analyte concentration detection devices and methods

Patent Proprietor:
Intuity Medical, Inc.

Opponent:
Roche Diagnostics GmbH

Headword:

Relevant legal provisions:
EPC Art. 83
RPBA Art. 12(4), 13(1)

Keyword:
Sufficiency of disclosure - (no)
Late-filed request - submitted with the statement of grounds of appeal - submitted shortly before oral proceedings - procedural economy - admitted (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Chambres de recours

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Case Number: T 2579/16 - 3.4.02

D E C I S I O N
of Technical Board of Appeal 3.4.02
of 27 October 2021

Appellant: (Patent Proprietor)	Intuity Medical, Inc. 526 Almanor Avenue Sunnyvale, CA 94085 (US)
Representative:	Cooley (UK) LLP 22 Bishopsgate London EC2N 4BQ (GB)
Appellant: (Opponent)	Roche Diagnostics GmbH Sandhoferstr. 116 68305 Mannheim (DE)
Representative:	Altmann Stößel Dick Patentanwälte PartG mbB Isartorplatz 1 80331 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 30 September 2016 concerning maintenance of the European Patent No. 2322914 in amended form.**

Composition of the Board:

Chairman	R. Bekkering
Members:	H. von Gronau
	B. Müller

Summary of Facts and Submissions

I. The opponent's appeal and the patent proprietor's appeal are directed against the interlocutory decision of the opposition division concerning maintenance of the European patent No. 2322914 in amended form. The opposition division decided that the patent in amended form according to the then auxiliary request 2 met the requirements of the EPC.

II. With the statement setting out the grounds of appeal, the appellant-patent proprietor filed a new main request (i.e. the third auxiliary request filed before the opposition division) and new first and second auxiliary requests. The claims of the second auxiliary request correspond to the claims which were considered allowable by the opposition division.

III. With the statement setting out the grounds of appeal, the appellant-opponent requested that the decision of the opposition division be set aside and the patent be revoked. In reply to the patent proprietor's appeal it requested that the first auxiliary request not be admitted because it was late filed.

IV. Both parties requested that oral proceedings be held.

V. In a communication pursuant to Article 15(1) RPBA 2020 the board expressed its provisional opinion, that inter alia the claimed invention of the main request and likewise also that of the first and second auxiliary requests were not sufficiently disclosed, contrary to the requirement of Article 83 EPC.

VI. With a letter dated 29 May 2020 the appellant-patent proprietor inter alia put forward arguments as to why the specification sufficiently described the invention so that one of skill in the art would not face an undue burden in order to be able to perform the invention. It also filed claims according to a new auxiliary request 3.

VII. With a letter dated 27 August 2020 the appellant-opponent inter alia requested that the auxiliary request 3 not be admitted into the appeal proceedings.

VIII. Oral proceedings took place on 27 October 2021.

The parties stated their final requests as follows:

The patent proprietor requested that the decision under appeal be set aside and the patent be maintained in amended form on the basis of the claims of the main request or the first auxiliary request, both filed with the statement of grounds of appeal dated 10 February 2017, or, as a second auxiliary request, that the patent be maintained in amended form as allowed by the opposition division, or that the patent be maintained in amended form on the basis of the claims of a third auxiliary request filed with a letter dated 29 May 2020.

The opponent requested that the decision under appeal be set aside and the patent be revoked.

At the end of the oral proceedings the chairman announced the board's decision.

IX. Claim 1 of the main requests reads as follows:

"An arrangement (80) constructed and arranged to detect the presence or concentration of an analyte present in bodily fluid (2108), the arrangement comprising:
a channel member (82) configured to receive a sample of the bodily fluid (2108) from a conduit (14);
an assay pad (20) in fluid communication with the open bottom of the channel member (82), the assay pad (20) containing a chemical reagent (1106);
a plurality of optical detectors (85), each detector adapted to produce a signal indicative of a reaction between the analyte and the reagent (1106);
electronics adapted for monitoring and interpreting the signals produced by the plurality of detectors to provide the following:
(i) an estimate of the volume of the sample received by the channel member (82) based at least in part on the number of detectors (85) that produce a signal indicating a reaction between the analyte and the reagent; and
(ii) information about the kinetics of the reaction between the analyte and the reagent based at least in part on the time between signals."

Claim 1 of the first auxiliary request differs from claim 1 of the main request in that after "a channel member (82)" the words "defining a known volume and" are introduced.

Claim 1 as considered for maintenance by the opposition division in the interlocutory decision (second auxiliary request) differs from claim 1 of the main request in that after "a channel member (82)" the words "having a volume directly proportional to its length and" are introduced.

Claim 1 of the third auxiliary request (auxiliary request 3) differs from claim 1 of the main request in that "a channel member (82)" is replaced by "an elongated channel member (82)".

Reasons for the Decision

1. Main request - claim 1 - sufficiency of disclosure (Article 83 EPC)

1.1 The opponent argued that the person skilled in the art did not know how the "information about the kinetics of the reaction between the analyte and the reagent based at least in part on the time between signals" could be obtained. The signals coming from the plurality of optical detectors ("each detector adapted to produce a signal") and the information about the kinetics was based on the time between these signals (see grounds of appeal, 3.2). It was not possible for a person skilled in the art to determine kinetics based on signals from several detectors without additional information. The detectors were described as binary devices which were either activated or non-activated. This was true also for the disclosure of Figure 24 where a plurality of pixel signals were shown (see reply dated 27 March 2018, 1.2).

In the oral proceedings before the board the opponent added that the wording of claim 1 was clear in that it defined a plurality of optical detectors, each detector being adapted to produce a signal indicative of a reaction between the analyte and the reagent. Thus each detector provided one signal and the information about the kinetics of the reaction was based on the time between these signals. However, the patent did not

disclose how the kinetics could be determined from the time between these signals. The cited passages on page 11 referred to readings taken by the detectors and it was clear from page 25 and Figures 24 and 25 that the detectors did not provide several signals for each detector but a binary signal indicating the presence or absence of glucose. Figure 24 did not disclose the development of a signal over time.

1.2 The patent proprietor put forward that a reaction on the assay pad developed over time and it would have been very well known by the skilled person that one detector could be used to tell how fast the reaction was proceeding (see reply dated 26 June 2017, section "Article 100(b) EPC" on pages 4 to 6). It was evident from the disclosure of the patent that the kinetics of the reaction was determined from signals of the same detector (see reply of 1 August 2019, section "Article 100(b) EPC" on pages 6 to 9).

The signals were produced by the plurality of optical detectors and each one produced multiple signals in response to the analyte reacting in the assay pad. The detectors were provided as an array of digital imaging devices. However, it was not the time between successive signals moving across the detector array that was used to obtain the kinetics information. Instead, it was the time between signals generated from an individual detector as the reaction progressed that was used to obtain the kinetics information. This was clearly defined in the specification. The means to estimate the volume of the sample were provided in the passages beginning on page 10, line 19 of the originally filed application. When the channel had the fluid sample therein, each independent detector was activated once the analyte present in the fluid reacted

with the chemicals contained in the test pad at a corresponding location of a detector. Therefore, even if the channel was not filled, the volume of the sample could be obtained as the volume of the channel was known and the relevant detector would be activated dependent on the amount of the fluid in the channel. From line 25 on page 11 it was then described that "[t]he time between the readings taken by the detectors 85 of the array 84 can also be monitored by the electronics of the arrangement". However, this did not mean that the time between the successive signals generated by different detectors along the array was assessed. It was clear from this paragraph that, once the fluid sample contacted the test pad and the analyte in the fluid sample began to react with the chemicals contained therein, the signals that were produced by each detector could be taken over time so as to provide information about the progression of the reaction. This was further clarified on page 25, line 21 to page 26 which described the algorithms applied. Figures 24 and 25 were particularly illustrative as these showed that the signals taken from the detectors were taken over time. It was well understood by the skilled person in the field of analyte monitoring that signals taken over time from a detector during the course of a reaction could be used in order to assess the kinetics of the reaction. Thus, multiple readings could be taken from one or a plurality of detectors to provide information about the rate of the reaction based on the reflectance values obtained from a detector over a defined time period. This was also confirmed by the declaration of Michael F. Tomasco, filed 22 September 2014, that explained what the skilled person in the art understood by the term "kinetics" and which was the rate of change of the reactants/reagents in the reaction (see

submission dated 29 May 2020, section "Article 83 EPC - Sufficiency").

During the oral proceedings before the board the appellant-patent proprietor referred again to passages on pages 11 and 25 of the originally filed description and to Figures 24 and 25 and emphasised that from the description it was clear that a plurality of signals were read from each of the detectors and that with these signals it was possible to determine information about the kinetics of the reaction. In particular, the passage on page 11, lines 14 to 17 referred to "the readings or data generated by each individual detector element 85 of the array 84" and the passage on page 11, lines 25 to 26 referred to the "time between the readings taken by the detectors 85 of the array 84 can also be monitored by the electronics of the arrangement". This made clear that several readings were taken by each detector to analyse the kinetics of the reaction as was disclosed on page 11, lines 27 to 31. From Figure 24 and the related portion of the description on page 25, lines 23 to 25 it was also clear that the colour read by the detectors developed in the presence of glucose which also showed that the kinetics of the reaction was identified. The definition in claim 1, section (ii) that information about the kinetics of the reaction between the analyte and the reagent was provided based on the time between signals had to be understood in this way. A person skilled in the art willing to understand could only come to the conclusion that the time between signals was the time between readings of the same detector.

1.3 The board is of the opinion that claim 1 defines clearly that each of a plurality of optical detectors is adapted to produce "a signal" indicative of a

reaction between the analyte and the reagent. According to claim 1 the information about the kinetics of the reaction is then based on the time between these signals. From the wording of the claim it is clear that the "signals" are the signals from the plurality of optical detectors of which each produces a signal. No other "signals" are defined in claim 1.

It is generally known in the art that the kinetics of the reaction is considered as the speed of reaction or the reaction over time. However, the application does not disclose that the claimed invention uses multiple signals from one detector over time as the patent-proprietor suggests. It is only disclosed that according to the invention the time between the signals of the plurality of detectors is used to determine information about the kinetics of reaction detected by the different detectors. In addition, the passages cited by the patent proprietor on page 11 do not disclose either that multiple signals from one detector are used. Page 11, lines 14 to 17 refers to "the readings or data generated by each individual detector element 85 of the array 84" which "is taken and analysed", but this portion of the originally filed description does not give a clear indication that each detector element produces multiple signals indicative of a reaction between analyte and reagent. The indicated portions on page 11 provide no indication how the readings are related to the signal indicative of a reaction. Also, Figures 24 and 25 and the related portion of the description on page 25 do not disclose that each detector produces several signals. Figure 24 shows for each pixel only a background value and one signal indicative of a reaction between analyte and reagent, i.e. a signal before glucose was delivered and a signal after glucose was delivered (see page 25,

lines 26 to 29). The signal before glucose was delivered is not "a signal indicative of a reaction between the analyte and the reagent" as defined in claim 1 so that this portion also discloses only a signal indicative of a reaction between the analyte and the reagent that each detector produces.

The application does not provide any information how these signals, clearly defined in claim 1, could be used to obtain information about the kinetics of the reaction. For a person skilled in the art it is also not generally known in the art how the kinetics can be determined from these signals of the detectors.

1.4 The board is therefore of the opinion that the claimed invention is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art in the meaning of Article 83 EPC.

2. First and third auxiliary request - admittance (Article 12(4) and 13 RPBA 2007)

2.1 The opponent requested not to admit the first auxiliary request filed with the statement setting out the grounds of appeal and the third auxiliary request filed with a letter dated 29 May 2020 because they were late filed.

2.2 The board decided, in view of procedural economy, that the first auxiliary request was taken into account pursuant to Article 12(4) RPBA 2007 and the third auxiliary request ("auxiliary request 3") was admitted to the proceedings under Article 13(1) RPBA 2007. Examining the first and third auxiliary requests is not only not detrimental to procedural economy, but, rather, suggested by procedural economy. This is

because it is a matter of prima facie impression that the Article 83 EPC objection raised for the invention of claim 1 of the main request applies likewise to the invention defined in claim 1 of all the auxiliary requests.

3. First, second and third auxiliary requests - claim 1 - sufficiency of disclosure (Article 83 EPC)

3.1 The objection under Article 83 EPC put forward with respect to the invention defined in claim 1 of the main request does apply likewise to the invention of claim 1 of the auxiliary requests because the relevant parts of claim 1 of the auxiliary requests are identical to the respective wording of claim 1 of the main request.

3.2 The patent proprietor and the opponent did not put forward any additional arguments with respect to sufficiency of disclosure.

3.3 The board is therefore of the opinion that the invention defined in claim 1 of the auxiliary requests is also not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art in the meaning of Article 83 EPC.

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:

L. Gabor R. Bekkering

Decision electronically authenticated