Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Action n°: UPC 48305/2024
Case UPC_CFI_497/2024
Action: Revocation
Action n°: UPC 54050/2024
Case UPC_CFI_571/2024
Action: Counterclaim for Revocation

DECISION

of the Court of First Instance of the Unified Patent Court
Central Division Milan
delivered on 23 October 2025
concerning EP 3 756 767 B1

HEADNOTES:

1. An assessment based on a maximum of different documents to challenge the novelty and to argue for non-inventiveness is indeed appropriate. The attacks not identified by the party challenging the patent as (most) promising will not be discussed on the merits because, when the party submits a number of attacks that appear to be unmanageable by the Court in accordance with the principles of proportionality (point 3 of the preamble) and speed (point 7 of the preamble), and the same party is unable to re-module some of the attacks in such a way as to allow the Court to organise its time for the efficient management of the proceedings, it must be assumed that if the (most) promising attacks, after assessment of the Court, do not affect the validity of the claim(s), the others wouldn't have done so either.
2. The agreed amount of the legal costs will not be kept confidential, because that amount does not (simply) say anything about the company's financial capacity, its commercial strategy, or the importance of the patent as a corporate asset.

KEYWORDS: amendments of patent, auxiliary request, added subject-matter, novelty, inventive step, sufficiency of disclosure, costs, confidentiality

CLAIMANT/RESPONDENT:

ACT_48305/2024 (UPC_CFI_497/2024):

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CC_54050/2024 (UPC_CFI_571/2024):

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DEFENDANT/APPLICANT:

Labrador Diagnostics LLC Represented by Christof Höhne
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PATENT AT ISSUE

European patent with unitary effect no. EP 3 756 767 B1 of Labrador Diagnostics LLC.

PANEL/DIVISION

Panel of the Central Division Milan

LANGUAGE OF PROCEEDINGS: English

DECIDING JUDGES OR: DECIDING JUDGE:

This decision has been delivered by:

the Presiding Judge Andrea Postiglione,
the Legally Qualified Judge and Judge-Rapporteur ('JR') Marije Knijff and
the Technically Qualified Judge Michel Abello.

PROCEDURAL BACKGROUND AND THE PROCEEDINGS BEFORE THE CENTRAL DIVISION OF MILAN

Case UPC_CFI_497/2024 (ACT_48305/2024)

1. On 30 August 2024, bioMérieux UK Limited (the 'Claimant') brought the present revocation action (the 'Revocation Case') in the Central Division (Section Milan) (the 'Central Division' or the 'Court') against Labrador Diagnostics LLC (the 'Defendant').

Case UPC_CFI_571/2024 (CC_54050/2024)

2. On 30 September 2024, in their Statement of Defence to the infringement action that had been brought by Labrador Diagnostics LLC in the Local Division Düsseldorf against bioMérieux SA, bioMérieux Deutschland GmbH, bioMérieux Italia S.p.A., bioMérieux Austria GmbH, bioMérieux Portugal, Lda. and bioMérieux Benelux B.V. (ACT_35332/2024), all – just as bioMérieux UK Limited – being part of the same group of bioMérieux companies, those companies of the bioMérieux group (the 'Applicant') brought the present counterclaim for revocation in the Local Division Düsseldorf against Labrador Diagnostics LLC (the 'Respondent').

3. The Applicant's request to refer the counterclaim for revocation (the 'Counterclaim for Revocation Case') to the Central Division, for consolidation with the Revocation Case, has been allowed.

Both cases

4. Claimant and Applicant will hereinafter be jointly referred to as bioMérieux, and Defendant, also Respondent, will hereinafter be denoted as Labrador.

5. In both the Revocation Case as the Counterclaim for Revocation Case, after closure of the written procedure, an online interim conference was held on 14 July 2025 by the Central Division. In answer to the questions raised by the Court, as laid down in the procedural order issued on 18 July 2025:

a. bioMérieux has indicated that, in respect of the novelty and inventive step attacks, she will focus the discussion during the oral hearing on the following attacks:

> • the VIDAS® instrument (as described in the 'VIDAS® Instrument User's Manual Ref. 99762 Version A 03/2005', CR-Rev 7, 'the VIDAS® Manual', and in the 'VIDAS® Instrument User's Manual Ref 99762 Version B 12/2005', CR-Rev 8, 'the VIDAS® Manual B', supported by the Affidavit of Dominique Decaux (CR-Rev 30)) including a discussion on the similarities with the prior art document 'Rogers' (an article from the American Clinical Laboratory Journal, dated May 1989, 35-37, CR-Rev 9, 'Rogers') (Lack of Novelty) and then combined with the common general knowledge (the 'CGK') on automation illustrated by the document 'Chapman' (an

article by Chapman, T. titled '*Lab automation and robotics: Automation on the move.'* from Nature 421, 661–663 (2003), 'Chapman') (Lack of Inventive step);

• the prior art document 'Tsuruta' (an article in Elsevier's Journal of Immunological Methods 183 (1995), p. 221-229, called '*An automated ELISA system using a pipette tip as solid phase and a pH-sensitive field effect transistor as a* detector', CR-Rev 11, 'Tsuruta') combined with the prior art document 'Tominaga' (European Patent Application EP 0 889 328 A1 for an '*Automated Immunological Analyzer*', published on 7 January 1999, CR-Rev 20, 'Tominaga') (Lack of Inventive step);

• the prior art document 'Clark' (Lack of Novelty) (International application WO 95/08774, published on 30 March 1995, CR-Rev 6, 'Clark') and Clark combined with the prior art document 'Coassin' (US Patent application US 2005/0271552 A1, published on 8 December 2005, CR-Rev 13, 'Coassin') (Lack of Inventive step).

b. bioMérieux confirmed that in respect of the exhibits which relate to the validity attacks that she has chosen to focus on during the oral hearing, there are no material differences between the validity attacks in the Revocation Case and the Counterclaim for Revocation Case.

6. Finally, the oral hearing was held in person in Milan on 12 September 2025. The Court reserved to issue the final decision within 6 weeks.

SUMMARY OF FACTS (THE PATENT)

1. EP 3 756 767 B1 entitled '*Modular Point-Of-Care Devices and Uses Thereof*' or simply EP 767 was filed on 2 October 2008 (the 'Patent').

The Patent derives from a third-generation application (European Patent application 20187805.5), ultimately deriving from the international patent application PCT/US2008/078636, with the international publication number WO2009/046227 A1 (the 'Mother Application'). The Patent claims priority to US 99746007 P of 2 October 2007. The registered owner of the Patent is Labrador.

2. The Patent is registered with unitary effect.

3. According to the description of the Patent:

> ***[0001]*** *The discovery of a vast number of disease bookmarkers and the establishment of miniaturized medical systems have opened up new avenues for the prediction, diagnosis and monitoring of treatment of diseases in a point-of-care setting. Point-of-care systems can rapidly deliver test results to medical personnel, other medical professionals and patients. Early diagnosis of a disease or disease progression can allow medical personnel to begin or modify therapy in a timely manner.*
>
> ***[0003]*** *In a Point-of-Care (POC) device, the number of assays that can be performed in parallel is often limited by the size of the device and the volume of sample to be*

analyzed. In many POC devices, the number assays is performed is about 2 to 10. A POC capable of performing multiplexed assays on a small sample would be desirable.

[0007] *Thus there remains an unmet need for alternative designs of POC devices. A desirable design provides modular capture surfaces and assay incubation elements. Furthermore, modular capture surfaces and assay incubation elements need to be integrated into POC disposables suited for just-in-time (JIT) manufacturing methods. It would be desirable to provide customizable POC device at a practical cost to user and the manufacturer. The present invention is defined in accordance with the appended claims.*

[0021] *In an aspect, a method is provided to automated detection of a plurality of analytes in a bodily fluid sample, comprising: providing the bodily fluid sample to a fluid device, wherein the fluidic device comprises: a sample collection unit configured to contain the bodily fluid sample; an array of assay units, wherein an individual assay unit of said array of assay units is configured to run a chemical reaction that yields a signal indicative of an individual analyte of said plurality of analytes being detected; and an array of reagent units, wherein an individual reagent unit of said array of reagent units contains a reagent; engaging the individual assay unit using a fluid transfer device; transferring the bodily fluid sample from the sample collection unit to the individual assay unit using the fluid transfer device; and transferring the reagent from the individual reagent unit to the individual assay unit, thereby reacting the reagent with the bodily fluid sample to yield the signal indicative of the individual analyte of the plurality of analytes being detected.*

[0087] *Cartridges, devices and systems as described herein can offer many features that are not available in existing POC systems or integrated analysis systems. For example, many POC cartridges rely on a closed fluidic system or loop to handle small volumes of liquid in an efficient manner. That cartridges and fluidic devices described herein can have open fluid movement between units of the cartridge. For example, a reagent can be stored in a unit, a sample in a sample collection unit, a diluent in a diluent unit, and the capture surface can be in an assay unit, wherein in one state of cartridge, none of the units are in fluid communication with any of the other units. Using a fluid transfer device or system as described herein, the units do not have to be in fluid communication with each other in a state. The units can be movable relative to each other in order to bring some units into fluid communication. For example, a fluid transfer device can comprise a head that engages an assay unit and moves the assay unit into fluidic communication with a reagent unit.*

[0092] *In some instances, wherein the units of the cartridge are separate, devices and systems provide flexibility in construction of the systems described herein. For example, a cartridge can be configured to run 8 assays using an array of assay units and an array of reagent units. Due to the features of the cartridge as described herein, the same housing, or a housing of the same design can be used to manufacture a cartridge with up to 8 different assays than the previous cartridge. This flexibility is difficult to achieve in many current POC device designs because of the closed systems*

and fluid channels, and therefore the devices may not be modular or easy to assemble as described.

[0099] *In another example, a system and/or fluid transfer device as described herein provides a great deal of flexibility. For example, the fluid transfer device can be automated to move an assay unit, an assay tip, or an empty pipette from one unit of the device to a separate unit of the device, not in fluid communication with each other. In some instances, this can avoid cross-contamination of the units of a device as described. In other instances, it allows for the flexibility of moving several fluids within a device as described into contact with each other according to a protocol or instructions. (…)*

4. The Patent includes 17 claims. Claims 9 and 14 of the Patent as granted read:

9. An instrument for detecting a biological analyte, comprising:

first means for receiving a device comprising an array of reagent units, each reagent unit of the array of reagent units for containing a reagent for an assay to detect the biological analyte;
second means configured to, with the device received by the first means:

move at least one of a first tip comprising sample or a reagent unit of the array of reagent units relative to the other of the first tip or the reagent unit, for transfer of sample from a sample unit to the reagent unit, and move at least one of the reagent unit or a second tip relative to the other of the reagent unit or the second tip, for transfer of sample from the reagent unit to the second tip, the second tip comprising a surface configured to bind with the biological analyte,

a detection assembly for detecting a signal indicative of the presence, absence or concentration of the biological analyte bound to the surface configured to bind with the biological analyte.

14. A method of detecting a biological analyte, comprising:

receiving by first means of an instrument, a device comprising an array of reagent units, each reagent unit of the array of reagent units for containing a reagent for an assay to detect the biological analyte;

moving, using second means of the instrument, at least one of a first tip comprising sample or a reagent unit of the array of reagent units relative to the other of the first tip or the reagent unit, to transfer sample from the sample unit to the reagent unit,
moving, using the second means, at least one of the reagent unit or a second tip relative to the other of the reagent unit or the second tip, to transfer sample from the reagent unit to the second tip, the second tip comprising a surface configured to bind with the biological analyte, and

detecting, using a detection assembly of the instrument, a signal indicative of the presence, absence or concentration of the biological analyte bound to the surface configured to bind with the biological analyte.

5. BioMérieux France filed an opposition against the Patent on 31 January 2025. Labrador has now replied to the opposition and both parties are awaiting further instructions in that procedure.

INDICATION OF THE PARTIES' REQUESTS

1. BioMérieux argues that the Patent is invalid because its subject matter is not patentable within the terms of Arts. 52 to 57 EPC[1] (Art. 65(1), (2) UPCA[2] in combination with Art. 138(1)(a) EPC), since it lacks novelty (Art. 54 EPC) and is not based on an inventive step (Art. 56 EPC); the Patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Art. 65(1), (2) UPCA in combination with Art. 138(1)(b) EPC); and the Patent extends beyond the content of the Mother Application as filed (Art. 65(1), (2) UPCA in combination with Art. 138(1)(c) EPC).

2. On these grounds, bioMérieux requests in both the Revocation Case and the Counterclaim for Revocation Case:

- to revoke the Patent in its entirety (amended in accordance with the Main Request) with effect in the territory of the member states of the UPCA for which the Patent has effect; and
- that the Auxiliary Requests 1-7 are not admitted into the proceedings, and should (any of) those requests be admitted, to reject those Auxiliary Requests;
- to order Labrador to pay the costs of the proceedings (Art. 69(1) UPCA).

3. Labrador has put forward various defences, but only against bioMérieux's argument that claims 9 and 14 of the Patent as granted are invalid, in fact, together with her Defence to Revocation in the Revocation Case of 26 November 2024, and with her Reply to the Statement of Defence in the Counterclaim for Revocation Case of 29 January 2025, Labrador lodged an (unconditional) application to amend the Patent (R. 30.1 RoP[3]) in the form of a Main Request (to maintain claims 9 and 14 as granted, in a later stage of these proceedings renumbered to claims 1 and 2 in the amended version). At the same time, Labrador lodged a (conditional) application to amend the claims of the Main Request in the form of Auxiliary Requests 1-7.

[1] Convention on the Grant of European Patents of 5 October 1973 (European Patent Convention) including any subsequent amendments
[2] Agreement on a Unified Patent Court of 19 February 2013 (OJ 175, 20.6.2013, p. 1) including any subsequent amendments
[3] Rules of Procedure of the Unified Patent Court as adopted by decision of the Administrative Committee on 8 July 2022, including any subsequent amendments

4. The Auxiliary Requests 1 and 2 read (which claims are renumbered to claims 1 and 2 in the amended version) as follows, where Auxiliary Request 3 is the combination of the first and the second Auxiliary Requests:

Auxiliary Request 1

1. An instrument for detecting a biological analyte, comprising:

*first means for receiving a device**, inserted into the instrument,** comprising*

*an array of reagent units, each reagent unit of the array of reagent units for containing a reagent for an assay to detect the biological analyte **and a sample unit comprising a sample applied by a user;***

second means configured to, with the device received by the first means:

*move at least one of a first tip comprising sample or a reagent unit of the array of reagent units relative to the other of the first tip or the reagent unit, for transfer of sample from **the** sample unit to the reagent unit, and*
move at least one of the reagent unit or a second tip relative to the other of the reagent unit or the second tip, for transfer of sample from the reagent unit to the second tip, the second tip comprising a surface configured to bind with the biological analyte,

a detection assembly for detecting a signal indicative of the presence, absence or concentration of the biological analyte bound to the surface configured to bind with the biological analyte.

2. A method of detecting a biological analyte, comprising:

*receiving by first means of an instrument, a device**, inserted into the instrument,** comprising*

*an array of reagent units, each reagent unit of the array of reagent units for containing a reagent for an assay to detect the biological analyte **and a sample unit comprising a sample applied by a user;***

moving, using second means of the instrument, at least one of a first tip comprising sample or a reagent unit of the array of reagent units relative to the other of the first tip or the reagent unit, to transfer sample from the sample unit to the reagent unit,

moving, using the second means, at least one of the reagent unit or a second tip relative to the other of the reagent unit or the second tip, to transfer sample

from the reagent unit to the second tip, the second tip comprising a surface configured to bind with the biological analyte, and

detecting, using a detection assembly of the instrument, a signal indicative of the presence, absence or concentration of the biological analyte bound to the surface configured to bind with the biological analyte.

Auxiliary Request 2

1. An instrument for detecting a biological analyte, comprising:

first means for receiving a device comprising an array of reagent units, each reagent unit of the array of reagent units for containing a reagent for an assay to detect the biological analyte;

second means configured to, with the device received by the first means:

*move at least one of a first **pipette** tip comprising sample or a reagent unit of the array of reagent units relative to the other of the first **pipette** tip or the reagent unit, for transfer of sample from a sample unit to the reagent unit, and*

*move at least one of the reagent unit or a second **pipette** tip relative to the other of the reagent unit or the second **pipette** tip, for transfer of sample from the reagent unit to the second **pipette** tip, the second **pipette** tip comprising a **capture** surface configured to bind with the biological analyte,*

*a detection assembly for detecting a signal indicative of the presence, absence or concentration of the biological analyte bound to the **capture** surface configured to bind with the biological analyte.*

2. A method of detecting a biological analyte, comprising:

receiving by first means of an instrument, a device comprising an array of reagent units, each reagent unit of the array of reagent units for containing a reagent for an assay to detect the biological analyte;

*moving, using second means of the instrument, at least one of a first **pipette** tip comprising sample or a reagent unit of the array of reagent units relative to the other of the first **pipette** tip or the reagent unit, to transfer sample from the sample unit to the reagent unit,*
*moving, using the second means, at least one of the reagent unit or a second **pipette** tip relative to the other of the reagent unit or the second **pipette** tip, to transfer sample from the reagent unit to the second **pipette** tip, the second **pipette** tip comprising a **capture** surface configured to bind with the biological analyte, and*

detecting, using a detection assembly of the instrument, a signal indicative of the presence, absence or concentration of the biological analyte bound to the surface configured to bind with the biological analyte.

5. Labrador requests in both the Revocation Case and the Counterclaim for Revocation Case:

- that the revocation action is dismissed insofar as it relates to claims 9 and 14 of the Patent, and the Patent is maintained in the form of the Main Request;
- in the alternative, if the Court considers the claims of the Patent in the form of the Main Request invalid, that the application to amend the Patent submitted as Auxiliary Request 1 (and further subsidiary as Auxiliary Requests 2-7) is admitted and allowed and the Patent is maintained accordingly;
- to order bioMérieux to pay the costs of the proceedings.

6. The parties agree that the value of the action in accordance with R. 370.6 RoP should be set at € 5 million, but they disagree on how that value should be applied to the Claim for revocation action and the Counterclaim for revocation action.

7. The parties agreed at the OH that the reasonable and proportionate legal costs amount to EUR 600.000. Labrador has requested the Central Division to order this amount as confidential pursuant to Art. 58 UPCA in conjunction with R. 262.2 RoP.

8. The grounds and defences brought forward by the parties will, to the extent relevant for this decision, be discussed in detail below.

GROUNDS FOR THE DECISION

1. Summary of the Outcome

1.1 Since Labrador is not defending the revocation action insofar as it relates to the claims 1-8, 10-13 and 15-17 as granted, the Patent can at best be upheld in accordance with the Main Request or (subsidiary) one of the Auxiliary Requests.

1.2 BioMérieux filed a significant number of attacks: about 50 invalidity attacks, more than 12 added matter attacks, 3 novelty attacks, 1 insufficiency attack, and 6 different starting points for 30 inventive steps attacks:

- Clark (combined with VIDAS/Rogers or Coassin or Miles),
- VIDAS/Rogers (combined with Chapman, Clark or Coassin, Hayashi, Ashihara, Miles, Johnson, Tominaga, Frankel, and Hewett) and CGK,
- Coassin (combined with Frankel or Hewett),
- Hewett (combined with VIDAS/Rogers, Coassin or Mil

- Tsuruta (combined with Clark or Coassin, Hayashi, Ashihara, Miles, Johnson, Tominaga, Frankel, and Hewett)
- and Sato (combined with Clark or Frankel, or Hewett).
  Among which several attacks of the type D1+D2 and the reverse attack D2+D1 (see Coassin + Hewett and Hewett + Coassin, Clark + VIDAS/Rogers and VIDAS/Rogers + Clark, VIDAS/Rogers + Hewett and Hewett + VIDAS/Rogers).

1.3 The Court therefore asked the plaintiff to limit the number of arguments. BioMérieux requested that the Court indicate which arguments should be retained and which should be discarded. Instead, the Court asked the plaintiff to rank its arguments in order of importance. Subsequent, bioMérieux has indicated that, in respect of the novelty and inventive step attacks, she will focus the discussion during the oral hearing on the attacks as mentioned under 5. of the 'Procedural background and the proceedings before the Central Division of Milan'.

1.4 The Court reached the conclusion that the Main Request and the first Auxiliary Request lack novelty because the claimed subject matter is disclosed directly and unambiguously in the prior art document Clark.

1.5 The Court also maintains that the second and the third Auxiliary Requests are novel over Clark, but the subject matter of the second Auxiliary Request (not of the third Auxiliary Request) extends beyond the content of the Mother Application.

1.6 The Court further stipulates that, like Clark, the VIDAS® instrument does not impede the novelty of the third Auxiliary Request and the skilled person would, whether that person starts from Clark (in combination with Coassin), the VIDAS® instrument (in combination with the CGK, being Chapman) or the prior art document Tsuruta (in combination with Tominaga), not have arrived in an obvious manner at the subject matter of the third Auxiliary Request. The skilled person is also able to carry out the claimed invention according to the third Auxiliary Request.

1.7 Finally the Court holds that the attacks not identified by bioMérieux as (most) promising do not warrant further investigation on the merits because, when the party submits a number of attacks that appear to be unmanageable by the Court in accordance with the principles of proportionality (point 3 of the preamble) and speed (point 7 of the preamble), and the same party is unable to re-module some of the attacks in such a way as to allow the Court to organise its time for the efficient management of the proceedings, it must be considered that if the (most) promising attacks, after assessment of the Court, do not affect the validity of the claim(s), the others wouldn't have done so either.

1.8 Pursuant to R. 44(e) RoP, the party seeking revocation of a patent must state the grounds for revocation related to in Art. 138(1) EPC. Conversely, patent attacks as such cannot be interpreted as 'grounds for revocation' but rather constitute legal pleadings based on a combination of facts (R. 44(f)), evidence supporting those facts (R. 44(g)), and arguments of law (Rule 44(e)), which start from the claimant's own interpretation of the patent and aim to show the existence of the conditions referred to in Art. 138 EPC.

1.9 Under R. 104 RoP, the JR is entitled to ask the parties to limit the attacks and the auxiliary request to make their assessment more manageable, or, alternatively, to list them in a logical order, to establish a schedule for the further progress of the proceedings and to clarify the position of the parties as regards the facts in dispute (letters c, a and b). At the end of the written procedure, the claimant and defendant must, therefore, consider all arguments and documents put forward by the other party, possibly reshaping their procedural defences based on the opposing party's arguments, to ensure the interim conference swiftly progresses towards the oral hearing. A particular feature of the interim conference is therefore the selection of relevant issues and therein all parties are required to contribute to the smooth management of the process so that the UPC's decisions are issued within a limited time frame and meet the highest quality standards.

1.10 If the number of arguments proves unmanageable or overly complex for the panel, the party that filed them must, if not reduce them, at least arrange the legal pleadings in order of importance and likelihood of success.
Each legal team is therefore called upon to cooperate with the Court by limiting attacks and auxiliary requests, facilitating the Court's work in accordance with the principles of proportionality and fairness set out in the preamble.
However, given the judge's impartiality, it is not the Court's role to indicate which attacks it considers to be the most promising or likely to be successful.
Consequently, the Court may ask the party to arrange their legal defence in order of likelihood of success and argue that if the attacks the party considers most promising are unsuccessful, the others will be too.

1.11 Therefore, the Patent will be maintained in the form of the third Auxiliary Request.

2. Admissibility of the requests to amend the Patent

2.1 BioMérieux argues that the application of Labrador to amend the Patent in accordance with Auxiliary Requests 1-7 should be denied since several objections are not addressed by the amendments of these requests. The Court will, however, admit the Auxiliary Requests 1-3 in the proceedings, since bioMérieux has not sufficiently substantiated that, and if so why, Labrador did not meet the conditions for admitting these requests in the proceedings. In the opinion of the Court, Labrador has met the conditions set out in R.

30(1)(a), (b) and (c) RoP. Labrador also included in her application an explanation as to why she believes these amendments satisfy the requirements of Arts. 84 and 123(2), (3) EPC and why she believes the proposed amended claims are valid. Also the number of amendments appears to this Court reasonable and acceptable.

2.2 In the opinion of the Court the features added in the Auxiliary Requests 1-3 to the Main Request are also clear enough to define the matter for which (conditionally) protection is sought by Labrador, especially if it is taken into account that the skilled person should try, with synthetical propensity, i.e. building up rather than tearing down, to arrive at an interpretation of the claim which is technically sensible and takes into account the whole disclosure of the Patent. The Patent must be construed by a 'mind willing to understand, not a mind desirous of misunderstanding'. Claim features must always be interpreted in the light of the claim as a whole (UPC Court of Appeal, 13 May 2024 UPC_CoA_1/2024 para. 29 - Hanshow). The person skilled in the art will not only consider the literal meaning of a certain word used in the patent claim but will also claim the technical function of a certain part addressed in the patent claim (cf. Local Division Düsseldorf, ACT 58084/2023, decision of 31 October 2024)

2.3 Whether and in what way the Auxiliary Requests actually satisfy the requirements of Arts. 84 and 123(2), (3) EPC and whether these requests actually are valid, will be assessed below.

3. Claim Features

3.1 Since claim 2 of the Main Request claims a method corresponding to the instrument claimed in claim 1, claim 2 shares the fate of claim 1. The Court will therefore assess the validity of the (amended) claims 1 and 2 on the basis of claim 1.

3.2 Claim 1 of the Main Request, wherein the Court added the features of the Auxiliary Requests (the 'AR') 1 and 2 (combined Auxiliary Request 3), can be divided into the following features:

1. An instrument for detecting a biological analyte, comprising:

1.1 first means for receiving a device ***[inserted into the instrument, AR 1]*** *comprising*

1.1.1 an array of reagent units, each reagent unit of the array of reagent units for containing a reagent for an assay to detect the biological analyte; ***[and***

1.1.2 a sample unit comprising a sample applied by the user; AR 1]

1.2 second means configured to, with the device received by the first means:

1.2.1 move at least one of a first ***[pipette, AR 2]*** *tip comprising sample or a reagent unit of the array of reagent units relative to the other of the first* ***[pipette, AR 2]*** *tip or*

*the reagent unit, for transfer of sample from a **[/the, AR 1]** sample unit to the reagent unit, and*
*1.2.2 move at least one of the reagent unit or a second **[pipette, AR 2]** tip relative to the other of the reagent unit or the second **[pipette, AR 2]** tip, for transfer of sample from the reagent unit to the second **[pipette, AR 2]** tip,*
*1.2.2.1 the second **[pipette, AR 2]** tip comprising a **[capture, AR 2]** surface configured to bind with the biological analyte,*

*1.3 a detection assembly for detecting a signal indicative of the presence, absence or concentration of the biological analyte bound to the **[capture, AR 2]** surface configured to bind with the biological analyte.*

4. Claim Interpretation from the point of view of the skilled person

4.1 Some features of claim 1 as amended by Labrador require interpretation.

4.2 The Court of Appeal of the UPC has laid down the following legal framework for the interpretation of patent claims (CoA, 26.02.2024 – UPC_CoA_335/2023, APL_576355/2023, p. 26-27 of the original German language version – NanoString v 10x Genomics, also see CoA, 13.05.2024 – UPC_CoA_1/2024, APL_8/2024 – VusionGroup v Hanshow).

4.3 In accordance with Art. 69 EPC and the Protocol on its interpretation, a patent claim is not only the starting point, but the decisive basis for determining the scope of protection of a European patent. The interpretation of a patent claim does not depend solely on the strict, literal meaning of the wording used. Rather, the description and the drawings must always be used as explanatory aids for the interpretation of the patent claim and not only as a mean to resolve any ambiguities in the patent claim. However, this does not mean that the patent claim merely serves as a guideline and that its subject-matter also extends to what, after examination of the description and drawings, appears to be the subject-matter for which the patent proprietor seeks protection.

4.4 The patent claim is to be interpreted from the point of view of a person skilled in the art. When interpreting a patent claim, the person skilled in the art does not apply a philological understanding but determines the technical meaning of the terms used with the aid of the description and the drawings (UPC_CFI 1/2023 LD Munich). A feature in a patent claim is always to be interpreted in light of the claim as a whole (CoA, 13.05.2024 – UPC_CoA_1/2024, APL_8/2024, para. 29 – Vusion Group v Hanshow). From the function of the individual features in the context of the patent claim as a whole, it must be deduced which technical function these features actually have, both individually and as a whole. The description and the drawings may show that the patent specification defines terms independently and, in this respect, may represent a patent's own lexicon, also taking into account that 'when identical terms are used in a claim, they generally have the same

meaning. However, 'claim language' does not forbid the use of different words for identical parts of a tool. It is only for certain parts of a device addressed in the claim that different terms are used' (see Milan CD UPC_CFI 513/2024 Decision by Default of the Court of First Instance of the Unified Patent Court delivered on 08 July 2025**)**

4.5 In applying these principles, the aim is to combine adequate protection for the patent proprietor with sufficient legal certainty for third parties.

4.6 The person skilled in the art (the 'skilled person') is a legal fiction which, in the interests of legal certainty, forms a standardized basis for the assessment of the legal concepts of e.g. "novelty", "inventive step" and "enablement". The skilled person represents the average expert who is typically active in the technical field of the invention, has had the usual prior training and has acquired average knowledge, skills and practical experience. The skilled person is assumed to have had access to the entire publicly available art on a relevant date (when assessing inventive step) and to have in the specific technical domain, an average general knowledge.

4.7 With regard to the skilled person, there is no substantial disagreement between the parties. The relevant person skilled in the art is a team, including someone having a university degree in biological sciences (or biochemistry), (post-doctoral) experience in the field of assays for measurement of disease biomarkers and an engineer (a systems engineer, biomedical engineer or electrical engineer). The Court agrees with this definition, bearing in mind that also the definition of the person skilled in the art is a legal definition which cannot be left to the mutual agreement of the parties.

4.8 Both from the written briefs and from the debate at the oral hearing, it follows that the following features can be considered as key features when it comes to the claim interpretation:

- First means (feature 1.1) and second means (feature 1.2);
- Reagent unit (features 1.1.1 and 1.2.1), sample unit (features 1.1.2 and 1.2.1) and the claimed path of the sample (features 1.2.1 and 1.2.2);
- First and second tips (features 1.2.1-1.2.2.1).

These features are discussed below.

4.9 For a good understanding of this, the relevant figures are included here with (where relevant) the explanation thereof from the description of the Patent (to be read in conjunction with the previously included paragraphs of the description):

4.9.1 The figures:

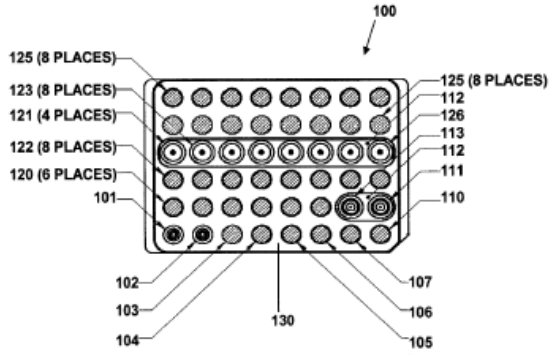


FIGURE 1

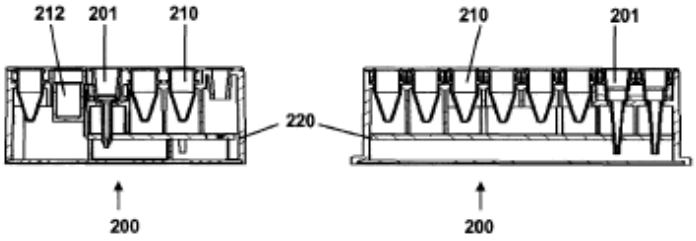


FIGURE 2

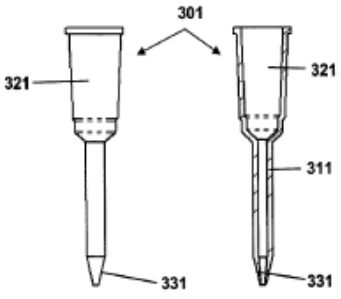


FIGURE 3A

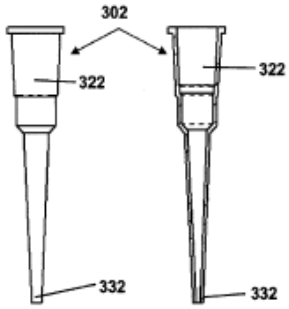


FIGURE 3B

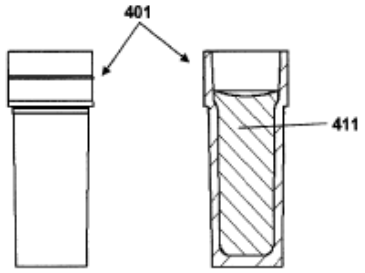


FIGURE 4A

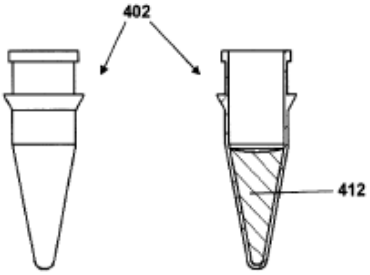


FIGURE 4B

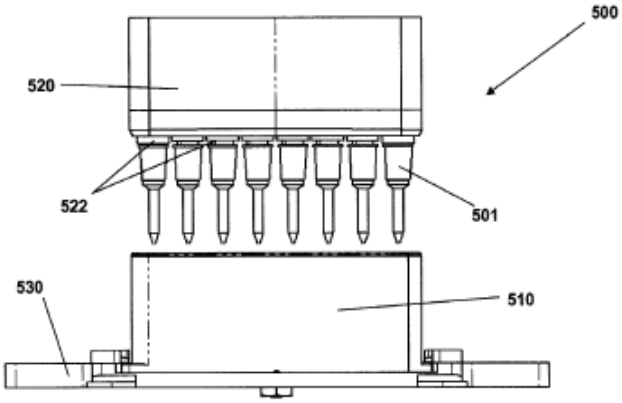


FIGURE 5

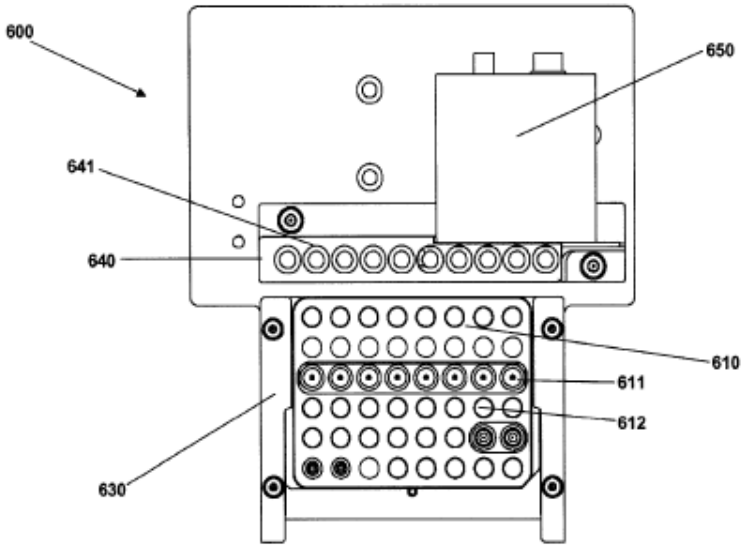


FIGURE 6

4.9.2 The description:

BRIEF DESCRIPTION OF THE DRAWINGS

[0029]
Figure 1 illustrates an exemplary device of the invention comprising assay units, reagent units, and other module components of the device.
Figure 2 illustrates two side-cut away views of the exemplary device of Figure 1 comprising cavities in the housing of the device shaped to accommodate an assay unit, a reagent unit, and a sample tip.
Figure 3A demonstrates an exemplary assay unit that comprises a small tip or tubular formation.
Figure 3B demonstrates an example of a sample tip as described herein.
Figures 4A and 4B illustrate two examples of a reagent unit comprising a cup.
Figure 5 demonstrates an example of a system comprising a device and a fluid transfer device.
Figure 6 illustrates an exemplary system of the invention comprising a heating block for temperature control and a detector.

DETAILED DESCRIPTION

Devices

[0032] In another aspect of the invention, a device for automated detection of an analyte in a bodily fluid sample comprises an array of assay units configured to run a chemical reaction that yields a detectable signal indicative of the presence of the analyte, and an array of reagent units containing reagents for running the chemical reaction, wherein at least one of the assay units and at least one of the reagent units are movable relative to each other within the device such that reagents for running the chemical reaction are automatically brought in contact with the bodily fluid sample in the assay unit.

[0037] A bodily fluid may be drawn from a patient and provided to a device in a variety of ways, including but not limited to lancing, injection, or pipetting. (…) The collected fluid can be placed in the sample collection unit within the device. (…)

[0040] A sample of bodily fluid can be collected from a subject and delivered to a device of the invention as described hereinafter.

[0041] In an embodiment, the arrays of assay and reagent units are configured to be a set of mix-and-match components. The assay units can comprise at least one capture surface capable of reacting with an analyte from the sample or bodily fluid. The assay unit may be a tubular tip with a capture surface within the tip. Examples of tips of the invention are described herein. A reagent unit typically stores liquid or solid reagents necessary for conducting an assay that detect a give analyte. Each individual assay and reagent unit can be configured for assay

function independently. To assemble a device, the units can be assembled in a just-in-time fashion for use in integrated cartridges.

[0042] Separate components, both liquids and solid phase, can be made and then be tested for performance and stored. In an embodiment, the assembly of the device is carried out in on-demand fashion at a manufacturing location. The device can be modular and include components such as a housing that is generic for all assays, assay units, such as tips, and reagent units, such as a variety of frangible or instrument operable containers that encapsulate liquid reagents. (…)

[0046] An exemplary device as described herein is illustrated in Figure 1. The device **100** is also sometimes referred to herein as a cartridge **100**. The device **100** comprises a housing **130** with locations to accommodate assay units **121** and reagent units **103**, **122**, **124**, **125**. In the exemplary embodiment of Figure 1, assay units **121** occupy a center row of the housing **130** of the device **100**. The assay units **121** can optionally include at least one calibration unit **126**. In an example, the assay units **121** are similar to pipette tips and referred to as assay tips **121** and the calibration units **126** are referred to as calibration tips **126** herein, however, the assay units **121** can be of any shape and size as are accommodated broadly by device **100** as described herein. The assay units **121** in Figure 1 can comprise a capture surface and are capable, for example, of performing a chemical reaction such as nucleic acid assays and immunoassays. The assay units **121** can be assembled into the housing according instructions or the assays that a user wishes to perform on a sample.

[0047] As shown in Figure 1, the housing of the device **100** can comprise a sample collection unit **110** configured to contain a sample. A sample, such as a blood sample, can be placed into the sample collection unit **110**. A sample tip **111** (for example, a pipette tip that couples to a fluid transfer device as described more in detail herein) can occupy another portion of the housing **130**. When an assay is to be run the sample tip **111** can distribute the sample to pretreatment reagent units or pretreatment units **103**, **104**, **105**, **106**, **107**, or assay units **121**. Exemplary pretreatment units **103**, **104**, **105**, **106**, **107** include but are not limited to: mixing units **107**, diluent or dilution units **103**, **104**, and, if the sample is a blood sample, plasma removal or retrieval units **105**, **106**. The pretreatment units **103**, **104**, **105**, **106**, **107** can be the same type of unit or different types of units. Other pretreatment units **103**, **104**, **105**, **106**, **107** as are necessary to run a chemical reaction can be incorporated into device **100** as would be obvious for one skilled in the art with knowledge of this disclosure. The units **103**, **104**, **105**, **106**, **107** can contain various amounts of reagents or diluents, flexible to whatever is needed to run the assay on the current cartridge **100**.

[0048] Often, the assay units **121** can be manufactured separately from the housing **130** and then inserted into the housing **130** with pick-and -place methods. The assay units can fit snugly into the housing **130** or can fit loosely into the housing **130**. (…)

[0049] A device, such as the example shown in Figure 1, can also comprise other features as may be needed to run a chemical reaction. For example, if the assay units **121** are assay tips **121** as described herein, the device can comprise tip touch-off pads **112** to remove excess sample or reagent from an assay tip **121** or a sample tip **111** after fluid transfer, for example, by a system as described herein. The housing **130** can also comprise units or areas **101**, **102** within the device **100** for placing a used tip or unit, for example, in order to avoid cross-contamination of a sample tip **111** or assay unit **121**. In Figure 1, the device **100** comprises a sample tip **111** for transferring a sample between units of the device **100**. The device **100** as illustrated in Figure 1 also comprises a pretreatment tip **113** for transferring a sample that has been pretreated in a unit of the device **100** to other units of a device **100** to perform a chemical reaction. For example, the sample tip **111** can be used to remove a blood sample from the sample collection unit **110** and transfer the blood sample to pretreatment units **103**, **104**, **105**, **106**, **107** as described. Red cells can be removed from the blood sample in the pretreatment units **103**, **104**, **105**, **106**, **107** and the pretreatment tip **113** can then be used to collect the blood plasma from the pretreatment units **103**, **104**, **105**, **106**, **107** and/or to at least one assay unit **121**. In an embodiment, a sample tip **111** is the sample collection unit **110**. In another embodiment, the sample collection unit **110** is similar to a well and is configured to contain sample as received by a user.

[0051] Two side cut-away views of the exemplary device **200** of Figure 1 are illustrated in Figures 2A and 2B. A cavity can be shaped in a housing **220** of a device to accommodate assay units (for example, assay tips) **201** in a vertical orientation (housing horizontal) with their bosses toward the top of the device **200**. As shown in Figure 2, a cavity can also be shaped to accommodate a reagent unit **210**, **212** or a sample collection unit or tip **202**. There may be features in the housing **220** to capture the units precisely and hold them securely. Such features can also be designed to operate with a mechanism for moving the tips, such as tip pick-up and drop-off. (…)

[0055] An individual reagent unit can be configured to receive a movable assay unit. In some embodiments, the individual assay unit comprises an open end hollow cylindrical element comprising a capture surface and a reaction cuvette. A cylindrical assay unit can be referred to as an assay tip herein. In some embodiments, the individual assay unit is configured to run an immunoassay. An assay unit **301** that comprises a small tip or tubular formation is shown in Figure 3A. In some instances, the tip **301** is configured to provide an interior cylindrical capture surface **311** and a boss **321** capable of engaging with the housing of device. In some instances, the boss **321** and the tip **301** is configured to engage with a mechanism of moving the tip **301** such as a system as described herein or for example, a fluid transfer device. An assay tip **301** as shown in Figure 3A can comprise an opening **331** at the bottom of the tip. The opening **331** can be utilized for transferring fluids or reagents in and out of an assay unit **301**. In an embodiment, an assay unit **301** as described is or is similar to a pipette tip with the improvement that the assay unit **301** comprises a capture surface **311** configured to detect an analyte in a sample.

[0057] Figure 3B demonstrates an exemplary sample collection unit **302** comprising a sample tip **302**. The sample tip **302** as shown in Figure 3B can also be separate form a sample collection unit **302** and used to transfer sample from the sample collection unit to other units on a device as described herein. The sample tip as shown in Figure 3B comprises a boss **322** as described herein to couple the tip **302** with a housing of a device and a fluid transfer device. The sample tip **302** also comprises an opening **332** to allow the transfer of fluids or samples in and out of the sample tip. In some embodiments, the sample tip **302** is of the same shape as an assay tip **301**. In other embodiments (such as those shown in Figures 3A and 3B) the sample tip **302** is a different shape than the assay tip **301**.

[0058] In an embodiment, one function of a tip is to enable samples and liquid reagents to be brought into contact with the capture surface of the assay unit. The movement can occur by a variety of means including, but not limited to, capillary action, aspiration, and controlled pumping. (…)

[0062] A capture surface (also referred to herein as a reaction site) can be formed by a binding antibody or other capture reagents bound covalently or by adsorption to the assay unit. The surface can then dried and maintained in dry condition until used in an assay. In an embodiment, there is a reaction site for each analyte to be measured.

[0063] In an embodiment, the assay unit can be moved into fluid communication with the reagent unit and/or sample collection unit, such that a reagent or sample can interact with a reaction site where bound probes can detect an analyte of interest in the bodily fluid sample. A reaction site can then provide a signal indicative of the presence or concentration of the analyte of interest, which can then be detected by a detection device described herein.

[0071] In an embodiment, an assay unit can be operably coupled with a fluid transfer device. The fluid transfer device can be operated under automatic control without human interaction. In assay units comprising tips, the control of the installed height of a disposable liquid tip relies on the tapered interference attachment of the tip to the liquid dispenser. A fluid transfer device can engage the tip. (…) The modular device and fluid transfer device can enable many assays to be performed in parallel.

[0072] The reagent units of a device can store reagents that are required to perform a give chemical reaction for detecting a given analyte of interest. (…) Two examples of reagent unit **401**, **402** comprising a cup are shown in Figures 4A and 4B. Where desired, the units **401**, **402** fit snugly unto cavities in a housing of a device. (…) A unit can be of any shape as is necessary to contain a reagent. For example, a cylindrical shaped reagent unit **401** is shown in Figure 4A, and the reagent unit contains a liquid reagent **411**. A different shaped reagent unit **402** is illustrated in Figure 4B also contain a liquid reagent **412**. Both exemplary reagent

units **401**, **402** comprise optional slight modifications near the top surface that allow the units **401**, **402** to fit snugly into a housing of a device described herein.

[0075] Reagents according to the present invention include without limitation wash buffers, enzyme substrates, dilution buffers, conjugates, enzyme-labeled conjugates, DNA amplifiers, sample diluents, wash solutions, sample pre-treatment reagents including additives such as detergents, polymers, chelating agents, albumin-binding reagents, enzyme inhibitors, enzymes, anticoagulants, red-cell agglutinating agents, antibodies, or other materials necessary to run an assay on a device. (…) In general, reagents, especially those that are relatively unstable when mixed with liquid, are confined separately in a defined region (for example, a reagent unit) within the device.

Systems

[0080] In an aspect, a system of the invention comprises a device comprising assay units and reagent units comprising reagents (both liquid and solid phase reagents). In some embodiments, at least one of the whole device, an assay unit, a reagent unit, or a combination thereof is disposable. In a system of the invention, the detection of an analyte with device is operated by an instrument. In most embodiment, the instrument, device, and method offer an automated detection system. (…)

[0082] In an embodiment, the user applies a sample (for example, a measured or an unmeasured blood sample) to the device and inserts the device into the instrument. (…)

[0099] In another example, a system and/or fluid transfer device as described herein provides a great deal of flexibility. For example, the fluid transfer device can be automated to move an assay unit, an assay tip or an empty pipette from one unit of the device to a separate unit of the device, not in fluid communication with each other. (…)

[0110] An individual head of a fluid transfer device can be configured to adhere to the individual assay unit. The fluid transfer device can be a pipette, such as an air-displacement pipette. The fluid transfer device can be automated. For example, a fluid transfer device can further comprise a motor in communication with a programmable processor and the motor can move the plurality of heads based on a protocol from the programmable processor. As described, an individual assay unit can be a pipette tip, for example, a pipette tip with a capture surface or reaction site.

[0113] As described, the systems and devices herein can enable many features of the flexibility of laboratory setting in a POC environment. For example, samples can be collected and manipulated automatically in a table top size or smaller service or system. A common issue in POC devices is achieving different dilution ranges when conducting a plurality of assays, wherein the assays may have

significantly different sensitivity or specificity. For example, there may be two analytes in a sample, but only one analyte has a high concentration in the sample and the other analyte has a very low concentration. As provided, the systems and devices herein can dilute the sample to significantly different levels in order to detect both analytes. For example, if the analyte is in a high concentration, a sample can be serially diluted to the appropriate detection range and provided to a capture surface for detection. In the same system or device, a sample with an analyte in a low concentration may not need to be diluted. In this manner, the assay range of the POC devices and systems provided herein can be expanded from many of the current POC devices.

[0120] Figure 5 demonstrates an example of a fluid transfer device **520** and system **500** as described herein. The fluid transfer device system can move eight different or identical volumes of liquid simultaneously using eight different heads **522**. For example, the cartridge (or device as described herein) **510** comprises eight assay units **501**. Individual assay units **501** are configured according to the type of assay to be run within the unit **501**. Individual assay units **501** may require a certain volume of sample. An individual head **522** can be used to distribute a proper amount of sample to an individual assay unit **501**. In this example, each head **522** corresponds to an addressed individual assay unit **501**.

[0121] The fluid transfer device mechanism **520** can also be used to distribute reagents from the reagent units. Different types of reagents include a conjugate solution, a wash solution, and a substrate solution. In an automated system, the stage **530** on which the device **510** sits can be moved to move the device **510** relative to the positioning of the assay units **501** and heads **522** and according to the steps necessary to complete an assay demonstrated in Figure 5. Alternatively, the heads **522** and tips **501** or the fluid transfer device **520** can be moved relative to the position of the device **510**.

[0126] An exemplary system **600** as described herein is demonstrated in Figure 6, The system **600** comprises a translational stage **630** onto which a device **610** (or cartridge in this example) is placed either manually or automatically or a combination of both. The system **600** also comprises a heating block **640** that can be aligned with the assay units **611** of the device **610**. As shown in Figure 6, the device **610** comprises a series of 8 assay units **611** and multiple corresponding reagent units **612**, and the heating block **640** also comprises an area **641** for at least 8 units to be heated simultaneously. (…) The system **600** also comprises a detector (such as a photomultiplier tube) **650** for detection of a signal from an assay unit **611** representative of the detection of an analyte in a sample.

[0132] A device and system may, after manufacturing, be shipped to the end user, together or individually. The device or system of the invention can be packaged with a user manual or instructions for use. In an embodiment, the system of the invention is generic to the type of assays run on different devices. Because components of the device can be modular, a user may only need one system and a variety of devices or assay units or reagent units to run a multitude of assays in

a point-of-care environment. In this context, a system can be repeatedly used with multiple devices (…)

Methods

[0178] In embodiments, a sample containing an analyte for detection can be moved from a first location to a second location by aspiration-, syringe- or pipette-type action. The sample can be drawn into the reaction tip by capillary action or reduced atmospheric pressure. In some embodiments, the sample is moved to many locations, including an array of assay units of a device of the invention and different wells in the housing of a device of the invention. The process of moving sample can be automated by a system of the invention as described herein.

First means (feature 1.1) and second means (feature 1.2)

4.10 The instrument of claim 1 of the Main Request consists of three distinguishable parts: first means, second means, and a detection assembly. In patent claims the labels 'first' and 'second' (here: means) are frequently used to clearly distinguish between features that generally fall under the same heading but differ in number or functionally from each other.

4.11 According to the literal wording of claim 1 of the Main Request, the first means of the instrument are intended 'for receiving a device'. This wording leaves open the possibility that the device is not part of the instrument (but the first means are simply adapted to allow the device to be part of the instrument). Since the device is an essential part of the instrument, so that the device can be used, there is a need to claim the device as such. As Labrador does so explicitly in her third Auxiliary Request (by referring to a device inserted into the instrument), in what form the Patent will be maintained (as explained below), further considerations on this point need not be considered. The first means thus have the function of receiving and do receive the device.

4.12 Referring to paragraph [0132] of the description ([0155] of the Mother Application) Labrador has argued that 'device' is nothing more than a collective term for components, such as a sample unit and a reagent unit, being brought together. As can be read in paragraph [0041] ([0065] of the Mother Application), according to Labrador, a housing is optional. However, the Court agrees with bioMérieux that the skilled person will perceive the device of feature 1.1 as a construct (like a housing) in which different units are or can be held together. This already follows from the literal wording of features 1.1-1.1.2, which claims a device that comprises an array of reagent units and (in the third Auxiliary Request) a sample unit, but is also confirmed by paragraph [0021] of the description of the patent, which describes which different units a (fluidic) device comprises. It is unimaginable how an array of reagent units can be contained in a device without any construct or housing. It is also that device (as a whole) that can be received by the first

means and is to be inserted into the instrument. Figure 1 with the descriptive paragraphs [0046]-[0048] illustrates this.

4.13 The means by which the device is received are shown in Figures 5 and 6 of the description of the Patent and described as 'the stage **530** on which the device **510** sits' in paragraph [0121] and as 'a translational stage **630** onto which a device **610** (or cartridge in this example) is placed' in paragraph [0126]. In the opinion of the Court, the skilled person would therefore interpret the 'first means for receiving a device inserted in the instrument' as a stage on which the device sits (or onto which the device is placed). The term 'stage' in the Patent does not add any specific technical teaching with respect to the term 'means' and 'receiving' is to be interpreted by the skilled person as a synonymous function to 'sitting on' or placing onto' in the context of the Patent. The interpretation of the device as being monolithic or not is not relevant to the present nullity actions, so that the Panel does not consider necessary to address this issue.

4.14 The second means have a different function than the first means, namely (as claim 1 of the Main Requests says) moving tips and a reagent unit relative to the other for transfer of (bodily fluid) sample. The means by which (bodily fluid) sample is transferred according to the description of the Patent is a fluid transfer device (see Figure 5, and paragraphs [0120] and [0121]). The skilled person will therefore understand that the claimed second means refer to that fluid transfer device.

<u>Reagent unit (features 1.1.1 and 1.2.1), sample unit (features 1.2.1 and 1.1.2) and the claimed path of the sample (features 1.2.1 and 1.2.2)</u>

4.15 According to features 1.1 and 1.1.1, the device, as received by the stage (first means), comprises an array of reagent units, each reagent unit for containing a reagent for an assay to detect the biological analyte. By the second means (bodily fluid) sample is to be transferred from a sample unit to such a reagent unit (as claimed by feature 1.2.1), and from this reagent unit, the (bodily fluid) sample is to be transferred to a second tip (as claimed by feature 1.2.2). This means that the skilled person will understand that the reagent unit will either contain a reagent without sample (before the transfer of the sample to the reagent unit) or a mixture of sample and reagent (as a diluent or not), but never just the sample (as a reagent, as Labrador argues). Feature 1.1.1 does not state "reagent unit (…) containing a reagent" but "reagent unit (…) **for** containing a reagent" which means for the skilled person that the reagent unit has to contain at one point the reagent and covers both pre-filled reagent units (Figures 1, 4A and 4B), and units which are filled during the operation of the instrument (Figures 2 and 6). The reagent unit as claimed, cannot only contain the sample. After all, an assay to detect a biological analyte cannot be run in the second tip (see below) if a sample is mixed to another sample as a reagent or a sample mixed with nothing is just transferred to the second tip. A substance used in chemical reactions (reagent) is needed to test the presence of the biological

analyte. The sample does not react with itself and cannot be used to test the analyte within itself. That there are passages in the description from which it follows that sample can also be diluted (paragraph [0113], also paragraph [0136] of the Mother Application) or pretreated (paragraph [0154], also paragraph [0177] of the Mother Application) in a device according to the Patent, as Labrador puts forward, does not change this. This Court notes that a patent has its own lexicon. However, patent terms should be interpreted following a straightforward reading of the claims in light of the description and drawings, without looking, result-oriented, for a way out of a possible adjustment of the claim domain. Thus, the terms of the patent must be interpreted according to their principal functional meaning, bearing in mind the language used in the patent itself (see also UPC_CFI_355/2023 Fujifilm v Kodak Decision issued on 28.02.2025 page 27: 'As a rule, if a patentee wishes to argue for a narrow scope of a claim, this should be on the basis of the wording of said claim, and not on the basis of something appearing only in the description, as the patentee has the possibility of restricting the scope of the claim by means of claim amendment. A narrowing interpretation of the claims which deviates from the broader general understanding of the terms used therein by a skilled person can therefore only be permitted if there are convincing reasons based on the circumstances of the individual case in question. Art. 69 EPC and its Protocol do not provide a justification for excluding what is literally covered by the terms of the claims by a narrowing claim construction based on the description or drawings').

4.16 In claim 1 of the Main Request, according to the literal wording, the device does not contain a sample unit. A sample unit is not, like the (array of) reagent unit(s) is, included under feature 1.1 of the Main Request and in feature 1.2.1 a sample unit is only referred to in relation to the transfer of sample to a reagent unit. Labrador puts forward that the sample (collection) unit is implicitly part of the device, since manual sample handling, with a user applying a sample to the claimed device, is disclosed in paragraph [0082] of the description of the Patent. Concerning the inclusion of an implicit function in claim construction, the Court sees eye to eye with the decision of the Düsseldorf Regional Court in the case Kodak/Agfa UPC_CFI 355/2023: 'the interpretation of a claim beyond its straightforward literal or functional meaning cannot be used as a means of circumventing an amendment to the claim'. And paragraph [0082] indeed states that in an embodiment of the invention, the user applies a sample (for example, a measured or an unmeasured blood sample) to the device, but this paragraph does not say anything about a sample unit. In the wording of claim 1 of the Main Request the user (of the device) can add the sample into a sample unit outside the device (such as a tube), from which it is included in the first tip (feature 1.2.1, see below) for transfer of the sample to a reagent unit (part) of the device. Paragraph [0051] cannot help Labrador, because – as Labrador argues elsewhere – that paragraph only describes figures 1 and 2, which show an example of a device, so that a different design, with more or fewer units, remains possible. With feature 1.1.2 of the first Auxiliary Request Labrador still adds the sample unit as part of the device.

First and second tips (features 1.2.1-1.2.2.1)

4.17 To transfer the sample as described above by the fluid transfer device (second means), claim 1 of the Main Request claims the use and the – relative – movement of a 'first tip comprising sample' and a 'second tip comprising a surface configured to bind with the biological analyte'.

4.18 The Court follows bioMérieux in her argument that the skilled person will not interpret the first and second tips restrictively as being pipette tips. According to the description of the Patent, a pipette tip is an example of a tip (see paragraph [0047] '*A sample tip **111** (for example, a pipette tip that couples to a fluid transfer device as described more in detail herein) (…)*') and Figure 3B also demonstrates an example of a sample tip as described. In addition, paragraph [0055] of the description states that an individual (movable) assay unit in some embodiments comprises an open-end hollow cylindrical element (a structure similar to a cuvette) and can be referred to as an assay tip. Nothing is said here about a pipette. Paragraph [0057] then states that '*In some embodiments, the sample tip **302** is of the same shape as an assay tip **301'.*** For the functions of the tips, it is not without further ado necessary that the tips have the shape of a pipette.

4.19 The first tip comprises a (bodily fluid) sample and is involved in the transfer of the sample from the sample unit to the reagent unit (feature 1.2.1). In the light of the description, it is clear to the skilled person that a sample from the sample unit is pumped, aspirated or by capillarity or pipette-type action is taken into the first tip (then containing sample) and ejected from the first tip into the reagent unit. This follows from paragraphs [0047], [0049], [0057], [0058] and [0178] stating that sample can be distributed to other units in the device of the invention, such as (pretreatment) reagent units, that this can be done using a tip and that the sample can be moved by aspiration-, syringe-, capillary- or pipette-type action. The sample must be introduced into the reagent unit to enable the transfer of the sample from the reagent unit to the second tip (the step of feature 1.2.2). For the skilled person, there is therefore no difference between the wording 'to' or 'into', which distinction is not made in the description of the Patent either.

4.20 The wording of feature 1.2.2 is not the same as the wording of feature 1.2.1, in that sense that, with regard to the second tip, it is not mentioned that it contains sample (or any other fluid). This means that the skilled person will interpret feature 1.2.2 in such a way that it is only required that a (bodily fluid) sample (mixed with reagent) is transferred from the reagent unit to the second tip, for which transfer the reagent unit and the second tip move relative to each other. Now the second tip is thus not necessarily involved in the transfer of the fluid itself, but only serves as a final destination of the sample (mixed with the reagent), and that tip comprises a surface configured to bind with the biological analyte (feature 1.2.2.1), the skilled person will label the second tip as an assay tip, meant

for detection of the biological analyte only. Having the surface configured to bind with the biological analyte, the second tip, after all, is configured to run a chemical reaction that yields a detectable signal indicative of the presence of the analyte, which signal will be detected by the claimed detection assembly. The second tip thus complies with what in the description of the Patent is described as an assay unit (see for example paragraphs [0041], [0051], [0055]) and [0063]). According to the description, an assay unit may also comprise other features, such as a reaction cuvette (paragraph [0055]), but these features are optional.

4.21 Labrador seems to argue that the first tip must be construed differently from the second tip, since they are labelled as a 'first' and 'second' tip, so that the first tip, unlike the second tip, cannot comprise a surface configured to bind with a biological analyte. The Court disagrees with this argument. 'First' and 'second' in this regard mean nothing more than that there must be at least two tips, and not a single tip, involved in both steps of the transfer of the sample. As Labrador states herself, the skilled person understands that an all-purpose assay tip (comprising a surface to bind with a biological analyte, as the second tip does), can (also) be used for more general sample transfer (as the first tip does).

5. Main Request and Auxiliary Request 2: Added Matter

5.1 An amendment is regarded as introducing subject-matter which extends beyond the content of the application as filed, and therefore unallowable, if the overall change in the content of the application (whether by way of addition, alteration or excision) results in the skilled person being presented with information which is not directly and unambiguously derivable from that previously presented by the application, even when account is taken of matter which is implicit to a person skilled in the art. Any amendment can only be made within the limits of what a skilled person would directly and unambiguously derive, using common general knowledge, and seen objectively and relative to the date of filing (or the priority date, where appropriate), from the whole of the documents as filed: the so-called 'golden standard' (LD The Hague, UPC_CFI_131/2024 ACT_14945/2024; order of 19 June 2024; page 12, mn 3.4).

5.2 Given that the Patent derives from a third-generation application (European Patent application 20187805.5), ultimately deriving from the Mother Application (patent application PCT/US2008/078636, with the international publication number WO2009/046227 A1), a (claim of a) Patent is to be revoked if it extends beyond the content of the Mother Application.

5.3 As already considered above the sample unit according to the precise wording of claim 1 of the Main Request is not simply part of the device. Labrador admits that the sample unit

must be part of the device. The Mother Application describes after all that 'the fluidic device comprises (not optionally): a sample collection unit configured to contain the bodily fluid sample (…)' (paragraph [0022] of the Mother Application). The Main Request (and also Auxiliary Request 2) contains therefore added matter and cannot be considered valid.

5.4 Since the Court considers the claims of the Patent in the form of the Main Request invalid and feature 1.1.2 is included in Auxiliary Request 1 (and 3), which means Auxiliary Request(s) 1 (and 3) (unlike the Main Request) do(es) not contain added matter in relation to the sample unit, the Court will consider Auxiliary Request 1 (and 3) further.

6. Auxiliary Request 1: Novelty (Clark)

6.1 For the purposes of Art. 54 EPC, an invention shall be considered to be novel if it does not form part of the state of the art. The state of the art, in accordance with Art. 54(2) EPC shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application (or when applicable the priority date).

6.2 The assessment of novelty within the meaning of Art. 54(1) EPC requires the determination of the whole content of the prior art publication. It is decisive whether the subject matter of the claim with all its features is directly and unambiguously disclosed in the prior art citation (see UPC CoA, Order of 25 September 2024, UPC_CoA_182/2024, App 21143/2024, *Mammut/Ortovox*, par. 123).

6.3 Applying the above standard to the first (and third) Auxiliary Request of the case at hand, leads to the following.

6.4 The prior art document Clark is a patent application, published on 30 March 1995, and thus a prior art publication, that describes an automated analytical system and method for the analysis of liquid test samples (page 2, lines 15-17). The system apparatus is shown in figure 1. It has an exposed a front-end carousel 4 which is served by a first transfer pipette mechanism 6 for kitting scheduled tests along with samples into a reaction vessel. Figure 4A shows the top plan view of the automated analytical system with component covers removed to show the system in detail.

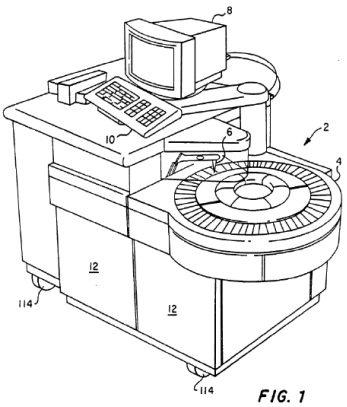


FIG. 1

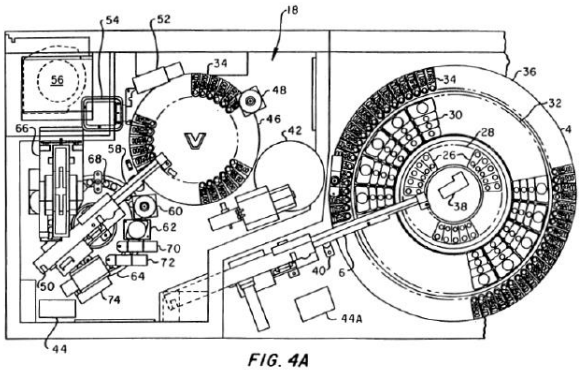


FIG. 4A

6.5 BioMérieux provided Figure 4A with colours, to allow for a better comparison with the Patent.

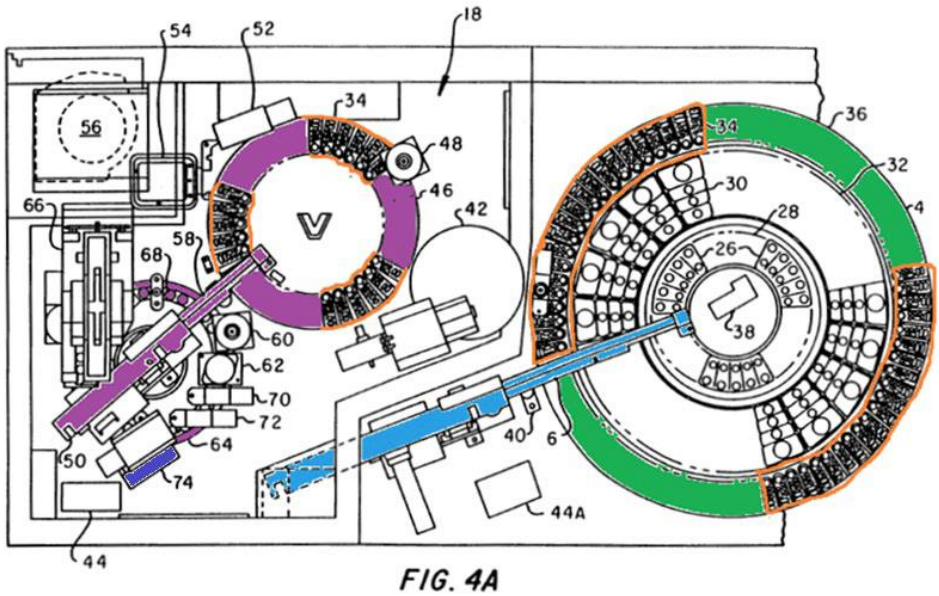


FIG. 4A

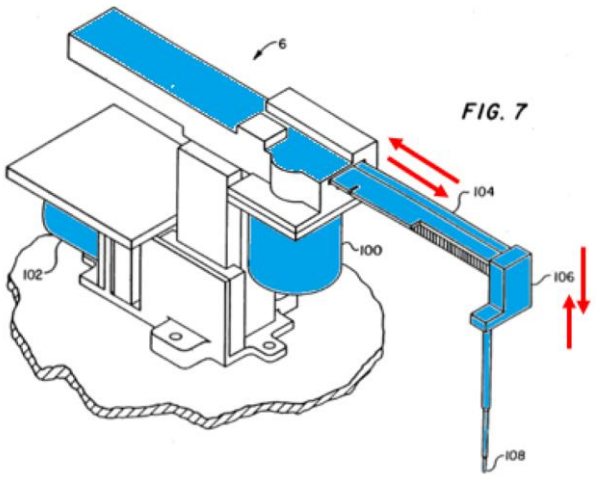
- Feature 9.1 – green
- Feature 9.1.1 – orange
- Feature 9.2.1 – blue
- Feature 9.2.2 – purple
- Feature 9.3 – dark blue

6.6 Both parties agree (at least bioMérieux states and Labrador does not deny) that Clark herewith discloses directly and unambiguously an instrument for detecting a biological analyte (feature 1), comprising first means for receiving a device inserted into the instrument (feature 1.1), the device comprising an array of reagent units, each reagent unit of the array of reagent units for containing a reagent for an assay to detect the biological analyte (feature 1.1.1) and a sample unit comprising a sample applied by a user

(feature 1.1.2), and (the instrument also) comprising second means configured to, with the device received by the first means (feature 1.2), move at least one of a first pipette tip comprising sample or reagent unit of the array of reagent units relative to the other of the first tip or the reagent unit, for transfer of sample from a sample unit into a reagent unit (feature 1.2.1). The Court can follow parties in this, provided that the Court considers the front end carousel 4 as the first means, and considers that the device comprises three carousels, namely sample cup carousel 28 (with sample cups 26 mounted thereon for holding blood collection tubes, being a sample unit), reagent pack carousel 32 and reaction vessel carousel 36 (which carries reaction vessels 34 as wells, being the array of reagent units).

6.7 Parties also agree, and the Court sees no reason to judge otherwise, that the second means of Clark are configured to move at least one reagent unit or a part called the MEIA cartridge 68 relative to the other of the reagent unit or the MEIA cartridge 68, for transfer of sample from the reagent unit to the MEIA cartridge 68 (feature 1.2.2), which cartridge comprises (undisputed during the written procedure) a surface configured to bind with the biological analyte (feature 9.2.2.1). It is also not in dispute that the instrument of Clark can comprise a detection assembly (MEIA reader 74) as claimed by feature 9.3. The parties are divided on whether the MEIA cartridge can be considered a second tip within the meaning of claim 1 of Auxiliary Request 1.

6.8 Clark describes that a '*first transfer pipette mechanism 6 is utilized in kitting the various reagent pack liquid materials and sample into a reaction vessel 34*' (page 62, lines 2-4), and that '*the first transfer pipette mechanism 6 (…) includes a transfer pipette Z axis motor 102 which moves the probe arm 104, probe 106 and probe tip 108 in a vertical direction while transfer pipette R axis motor 100 drives the probe arm 104, probe adjustment means 106 and probe tip 108 in a horizontal motion*' (page 73, lines 1-7). This is visible in more detail in Figure 7 (colouring and arrows added by bioMérieux):



6.9 In addition to this mechanism with probe tip 108, there is a second transfer mechanism. A second transfer pipette 50 is utilized for moving a pipette probe and pipetting the mixture of sample and reagent (reagent mixture) contained in the reagent vessel 34 on the process carousel and transferring said mixture to the MEIA cartridge 68 on the auxiliary carousel 64 (page 63, lines 14-17). Clark describes that '*The MEIA reagent mixed sample is transferred to the MEIA cartridge 68 by the second transfer pipette 50. The second transfer pipette 50 moves the pipette probe between the wells in the reaction vessel 34 on the process carousel 46 to the MEIA cartridge 68 on the auxiliary carousel 64*.' and that '*The auxiliary carousel 64 moves the MEIA cartridge 68 between various stations including the second transfer pipettor mechanism pipette point*' (page 63, line 22 to page 64, line 11, and see also page 228, step 4). This is also visible in Figure 4A of Clark (see above).

6.10 The MEIA cartridge 68 including a fibrous matrix is shown in Figure 55 and is further described in Clark as follows (page 48, lines 3-15): "*The MEIA cartridge which is employed by the automated analytical system of the present invention comprises a reaction well for retaining and immobilizing microparticle-analyte complexes. The reaction well has an entrance port for holding a quantity of sample and assay reaction mixtures positioned over a fibrous matrix which retains and immobilizes microparticle-analyte complexes as described above*".

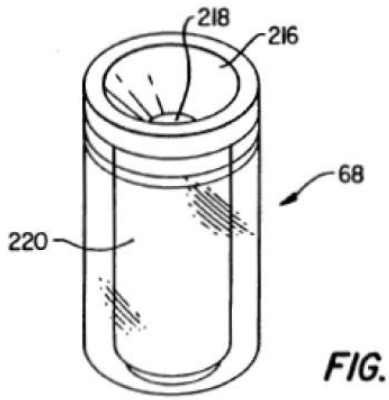


FIG. 55

6.11 Now, from the claim interpretation as explained above it follows that the second tip is not necessarily involved in the transfer of the fluid itself, but only serves as a final destination of the sample, as the MEIA cartridge 68 does, and the skilled person will not interpret the second tip restrictively as being a pipette tip, but that tip also may be a cuvette as illustrated in Figure 55, the MEIA cartridge 68 anticipates the second tip of claim 1 of the Auxiliary Request 1.

6.12 This leads to Clark being novelty-damaging for Claim 1 of Auxiliary Request 1. Because it is undisputed that the MEIA cartridge 68 is not a pipette tip and in the third Auxiliary

Request the second tip is claimed as such, claim 1 of the third Auxiliary Request is novel compared to Clark. The validity of Auxiliary Request 3 will now be discussed further.

7. Auxiliary Request 3: Further assessment validity

7.1 In her written submissions, bioMérieux put about 50 different attacks on the table to argue against the lack of validity of the Patent. As written above this number is not compatible with the resources available to the Court, which is required to deliver a high-quality decision within a year. This is particularly pertinent when considering the need to address several disputes simultaneously. Such a high number of undifferentiated attacks suggests a lack of strategy, and the Court is not required to remedy this by choosing one that suggests greater or lesser success of the attack. Nor is the Court required to establish a hierarchical or conceptual order in the parties' defences. The UPC's proceedings are based on the principle of allegation and require the Court to have a clear and sustainable procedural strategy in terms of resource deployment.

7.2 If the party refuses to limit its attacks and does not show a straightforward procedural strategy, the Court may require it to indicate which attacks it considers most promising. This would limit the examination and discussion at the oral hearing to these alone, based on the assumption that if the attacks the party considers most likely to succeed fail, those considered less effective would also fail

7.3 During the interim conference bioMérieux then agreed to indicate which novelty and inventive step attacks were, in their opinion, the most promising, without waiving in part her legal claims under R. 263 RoP. This panel considers that an assessment based on (a maximum of) two different documents to challenge the novelty and three different starting points to argue for non-inventiveness, as suggested by bioMérieux was indeed appropriate. Now that bioMérieux has identified the attacks to be discussed below as the most promising and those attacks do not affect the validity of Auxiliary Request 3, it will be assumed that the other, less promising, attacks on the validity of the third Auxiliary Request, do not do so either. Those attacks will therefore not be discussed on the merits.

8. Auxiliary Request 3: Added Matter

8.1 Due to the claim interpretation already discussed above, a number of added matter objections from bioMérieux automatically fail. It concerns the objections that:

- the first means of feature 1.1 introduce subject-matter extending beyond the content of the Mother Application (that is 'the stage **530** on which the device **510** sits' in paragraph [0144] of the Mother Application and 'a translational stage **630** onto which a device **610** is placed' in paragraph [0149] of the Mother Application),

- the second means of features 1.2 and 1.2.1 introduce subject-matter extending beyond the content of the Mother Application (that is the fluid transfer device), and
- the second tip if feature 1.2.2 is an impermissible generalization of the term assay tip/unit (the second tip is to be interpreted as an assay tip/unit).

8.2 A number of added matter objections from bioMérieux no longer applies to Auxiliary Request 3 which is limited to a device inserted into the instrument (feature 1.1) and comprising a sample unit (feature 1.1.2) and to a second pipette tip comprising a capture surface (feature 1.2.2.1).

8.3 The added matter objections of bioMérieux, insofar as she has made clear that she would like to maintain them after Labrador submitted the Main and Auxiliary Requests, will be discussed below.

Is the 'biological anallyte' cherry picked from a list?

8.4 According to bioMérieux, the 'biological analyte' of claim 1 has been selected from an extensive list of options of different sorts of analytes, listed in paragraph [0252] of the Mother Application, and combined with the other claimed features, which leads to the introduction of subject-matter extending beyond the content of the Mother Application. This objection fails. To the skilled person, it is common general knowledge that a biological analyte is (as any other analyte) an analyte where the instrument may apply to.

Does the sample path provide new technical information?

8.5 Another added matter argument brought forward by bioMérieux is that the specific path of the sample as claimed (from a sample unit to a reagent unit and from said reagent unit to a second tip) is not disclosed in the Mother Application. In bioMérieux's eyes, instead of this path, the Mother Application only describes the transfer of the sample from the sample unit to the assay unit directly, namely in paragraph [0022], confirmed in paragraph [0130]. But the Court agrees with Labrador that the direct path of the sample from the sample unit to the assay unit is not the only revealed option in the Mother Application for transferring the sample to the claimed second tip to run an assay. The path as claimed is described in the paragraphs [0070], [0072], [0080] (same text as paragraphs [0047], [0049] and [0057] of the description of the Patent) when it comes to the transfer of the sample to a pretreatment reagent unit and from the pretreatment reagent unit to an assay tip/unit. The fact that various paths for transfer of the sample are possible is also consistent with the flexibility of the instrument/system as described in the Mother Application, see for example paragraph [0122] (paragraph [0099] of the Patent). A pretreatment reagent unit is also labelled as a reagent unit (both indicated by the reference number 103). There is, therefore, no question of added matter on this point.

Is an assay unit missing?

8.6 As an added matter objection, bioMérieux has argued during the written procedure that an assay unit, which is an essential part to the functionality of the claimed instrument, is not claimed as an entity as such. As follows from the considerations on the claim interpretation, the Court is of the opinion that the skilled person will label the second tip as an assay unit. The added matter objection can therefore be passed.

8.7 For the first time during the oral hearing, to the question from the panel whether the second tip should be received by (or should be part of) the device, and only in a second instance, bioMérieux came up with the argument that, if the second tip is to be interpreted as an assay unit and therefore claimed as an entity as such, then there is an added matter problem, because the Mother Application only discloses the assay unit as part of (accommodated by) the device, while the second tip is not claimed as part of the device. Labrador has objected to this newly raised argument on the grounds that it was raised too late, and if it were admitted, she should be given the opportunity to submit a new Auxiliary Request.

8.8 As a rule, the parties are obliged to present their complete case as early as possible (Preamble to the RoP, para. 7, last sentence). R. 44 RoP states that the statement for revocation shall contain "… (e) one or more grounds for revocation, which shall as far as possible be supported by arguments of law, and where appropriate an explanation of the claimant's proposed claim construction; (f) an indication of the facts relied on; (g) the evidence relied on, where available, and an indication of any further evidence which will be offered in support …". This provision requires an "indication" of the facts relied on and this seems to support an interpretation of the relevant provisions contrary to an overly strict application of the 'front loaded' procedural system, but at the same time the principle of fairness must be taken into account.

8.9 This Court has already observed (Order no. ORD_17190/2025 in ACT_56003/2024 UPC_CFI_597/2024) that 'whenever a party proposes to bring an action before the UPC, it must take care to collect in advance the documents supporting the claim. The procedure before the UPC is in fact a front-loaded procedure, where the written procedure allows the parties to confront with replies and rejoinders based on a wealth of knowledge and documents that are supposed to be stable and consolidated from the very moment the claim is filed. In general, the parties are obliged to present their complete case as early as possible (RoP Preamble, para. 7, last sentence).

8.10 Therefore, it can be concluded that the claimant in revocation proceedings must specify the grounds for invalidating the contested patent in detail, as well as the prior art documents used to support any allegations of a lack of novelty or inventive step. This

defines the subject matter of the dispute, enabling the defendant to understand the allegations made against them and prepare an adequate defence. It also allows the court to determine the scope of its jurisdiction in relation to the claim.

8.11 Consequently, bioMérieux cannot introduce new grounds of added matter for the first time during the oral hearing. The Court agrees with Labrador that this newly raised attack is brought up too late to be taken in consideration in this procedure. Labrador only had the opportunity to respond to this argument in her final reply at the oral hearing, while there were no (known) objective obstacles for bioMérieux to present this added matter attack earlier, during the written procedure. Now that the attack is inadmissible, the Court will not discuss this argument on the merits.

Does detection of concentration lack basis?

8.12 BioMérieux refers to paragraph [0014] of the Mother Application which does not disclose a signal indicative of the concentration. However, Labrador rightly points to paragraph [0086] (corresponding to [0063] of the Patent reproduced above) which recites "A reaction site can then provide a signal indicative of the presence or concentration of the analyte of interest, which can then be detected by a detection device described herein".

9. Auxiliary Request 3: Clarity

9.1 In the decision Fujifilm v Kodak (LD Düsseldorf, UPC_CFI_355/2023, 28 January 2025), page 45, section 3, second paragraph the Court stated that *"Clarity and conciseness can only be examined by the UPC with regard to those amendments which were not already part of the granted claims. Any unclarity already present in the granted claims must be "lived with". This principle is also to be applied when a granted dependent claim is integrated into an independent claim (here: granted claim 6 into claim 1), provided this does not create a hitherto inexistent clarity issue"*.

9.2 Here, Labrador added to granted claim 9 (now new amended claim 1) of Auxiliary Request 3, the feature 1.1.2 "*a sample unit comprising a sample applied by a user*". This wording being based on paragraphs [0070], [0072] and [0105] of the Mother Application, according to Labrador, and not comprised in granted claims, it must comply with Article 84 EPC (R. 30.1(b) RoP).

9.3 BioMérieux objected clarity of this wording in Auxiliary Request 1 (in its rejoinder to the Reply to the Defence to the Application to amend the patent at paragraph 2.6) which is incorporated in Auxiliary Request 3, on the grounds that "*it is unclear if the 'user' is the user of the device, or the patient providing the sample*" and also "*it is unclear if it is*

required that the sample be applied directly from the patient, or whether the sample is to be 'applied' by pipetting or the like from a sample source, such as a sample cup".

9.4 However, paragraph [0105] recites that "*the user applies a sample (for example, a measured or an unmeasured blood sample) to the device and inserts the device into the instrument*" (also [0072]) and [0070] recites "*a patient can simply provide a bodily fluid to the device, as for example, could occur with a saliva sample. The collected fluid can be placed in the sample collection unit within the device*". Consequently, it is clear for the skilled person that "*a sample unit comprising a sample applied by a user*" refers to any user or patient and to any type of application by the user.

10. Auxiliary Request 3: Novelty (VIDAS®)

10.1 Besides Clark. bioMérieux has also brought up the VIDAS® instrument as novelty-destroying to claim 1 of the third Auxiliary Request.

10.2 The VIDAS® Legacy system is an immunoassay system that was launched by bioMérieux in 1991. The first version of the system was sold until 2002. The second version has been sold since 1 January 2004 and is still on the market. Together with the instrument is included the VIDAS® Manual from March 2005. This Manual describes the system that is still sold today. The VIDAS® Manual and a later version of the VIDAS® Manual (VIDAS® Manual B), which incorporates the content of the VIDAS® Manual, was provided with the VIDAS® Instrument from 2005.

10.3 Parties are discussing in these proceedings whether the VIDAS® Legacy system and the VIDAS® manual(s) were made available to the public before the priority date. The Court leaves that discussion open, because, assuming that the VIDAS® Legacy system and the VIDAS® manual(s) were made available to the public before the priority date, they do not impede the novelty and inventiveness of claim 1 of Auxiliary Request 3, as further explained below.

10.4 The VIDAS® manual describes the VIDAS® instrument as a compact automated multiparametric immunoanalyzer, which contains an analytical module divided into independent sections, each containing six assays. In the workflow disclosed by the VIDAS® manual, a sample is manually pipetted into the sample well on a reagent strip, and then the reagent strip is placed in the reagent strip tray of the instrument, with six channels into which reagent strips can be inserted. Up to six reagent strips or three dual reagent strips can be inserted at one time. A reagent strip contains ten wells, including the sample well, eight wells containing reagents, and an optical cuvette in which fluorescence of the substrate is measured. Such a reagent strip looks like the following picture taken from the acts:

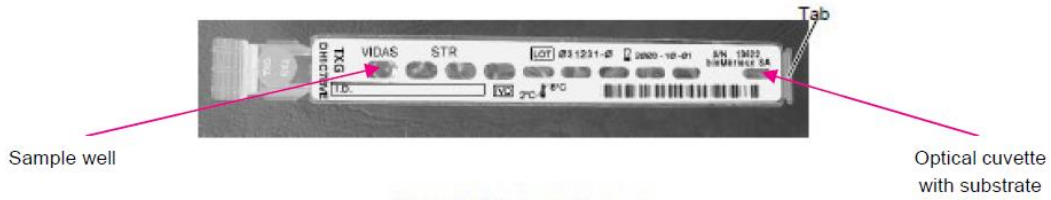
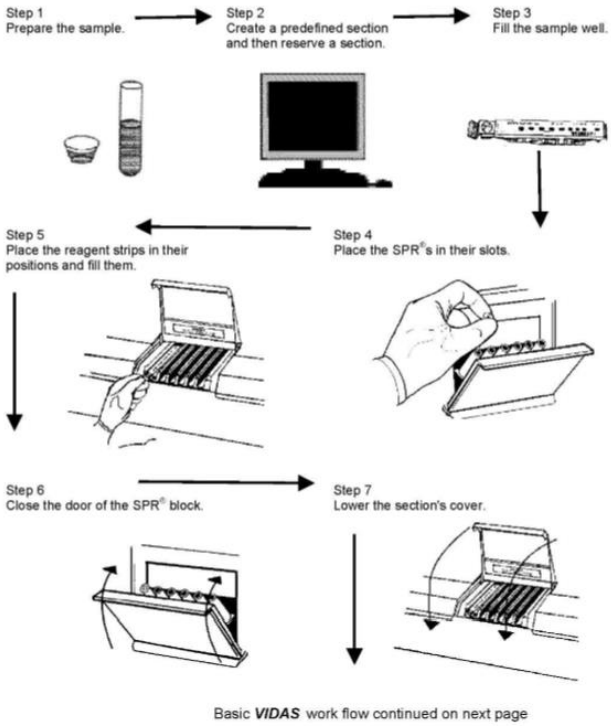


Fig. 2-10: Single reagent strip

10.5 The instrument also features a SPR® block, with six slots to receive SPR®'s, pipette-tip shaped plastic (polypropylene or polystyrene) devices capable of capturing soluble proteins, viruses and bacteria. A SPR® is coated on its inside surface at time of manufacture with antibody or antigen or other treatments allowing it to capture the target.



Basic ***VIDAS*** work flow continued on next page

Fig. 5-1: Basic *VIDAS* work flow

Fig. 2-14: SPR®

10.6 In the instrument, the reagent strip slides to position the required well under the SPR®. Each SPR® has a corresponding reagent strip. In the instrument, the SPR® is first brought into contact with the sample. The SPR® then moves up and down to perforate the foil seals on the reagent strips and pipette the required reagents. The reagent is cycled in and out of each SPR® by a piston-driven system. The instrument makes a background fluorescent reading of the substrate and a final fluorescent reading of the optical cuvette on the reagent strip. The final fluorescent reading measures the intensity of the final reaction. The results of the assays are then printed.

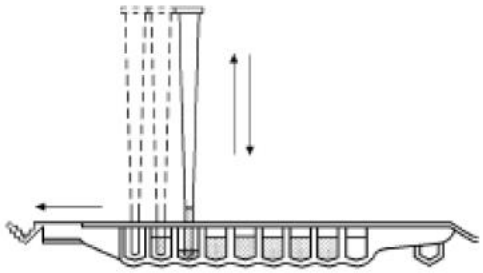


Fig. 2-15: Dynamic reactions

10.7 BioMérieux takes the position that the manual pipetting of the sample in a well on the reagent strip is within the scope of feature 1.2.1 of claim 1 of the third Auxiliary Request (the – relative – movement of the first tip to transfer sample from a sample unit to a reagent unit) and identifies the SPR®'s as assay units (second tip) (feature 1.2.2 and 1.2.2.1), where the SPR® block represent the second means of the instrument (feature 1.2). This reasoning cannot be followed, in that sense that features 1.2-1.2.2 require second means, being a fluid transfer device, configured to move two different tips and a reagent unit relative to the other unit for transfer of a (bodily fluid) sample. Manual pipetting cannot be equated with a fluid transfer device (second means) within the meaning of claim 1 of the Auxiliary Request 3. The skilled person will understand that "*a second means configured to (…) move*" a pipette tip or a reagent unit refers to a system which implements an automated action and excludes any manual operation. Only technical means may be patented, manual operations being out of the scope of patentability. Additionally, unlike a part of an instrument, a hand is not configured to produce a specific movement, and the hand does not add the sample to the well of the reagent strip in the instrument, but before the reagent strip is placed in the instrument. This means that the VIDAS® Legacy system uses a single tip, namely the SPR®, and not two different tips as claimed by claim 1 of the Auxiliary Request 3. The VIDAS® instrument, therefore, does not hinder the novelty of that claim.

10.8 This does not change when the VIDAS® instrument uses the dual reagent strip. As the VIDAS® manual describes, in that case, a portion of the same sample is manually pipetted in the sample well on both reagent strips, and the two reagent strips are placed side by side in the reagent strip tray of the instrument. The one reagent strip serves as a reference strip, and the other as the sample test strip. Both strips are operated by their own SPR®, a reference SPR® serves the reference reagent strip, and the test SPR® serves the sample test reagent strip. Contrary to what bioMérieux argues, this does not mean that in this mode two different (a first and a second) tips, as claimed by claim 1 of the Auxiliary Request 3, can be identified. In both reagent strips, the corresponding SPR® functions still as an assay unit (second tip), so that the same SPR® cannot also be regarded as the first tip (distinguishable from the second tip). And if the reference SPR® belonging to the

reference reagent strip would be considered the first tip (to transfer sample from the sample well of the reference reagent strip to a reference reagent unit), then the test SPR® cannot be considered the second tip, because it does not pipette that reference reagent unit, and therefore does not receive the sample as transferred by the first tip.

11. Auxiliary Request 3: Inventive step (in general)

11.1 The assessment of inventive step must be carried out in accordance with Art. 56 EPC, which states that "[a]n invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art". An objective approach must be taken to the assessment of inventive step. The subjective ideas of the applicant or inventor are irrelevant. Inventive step is to be assessed from the point of view of the skilled person on the basis of the state of the art as a whole, including the skilled person´s common general knowledge. The skilled person is assumed to have had access to the entire publicly available art on the relevant date. The decisive factor is whether the claimed subject matter follows from the prior art in such a way that the skilled person would have found it on the basis of that person's knowledge and skills, for example by obvious modifications of what was already known. In order to assess whether or not a claimed invention was obvious to a skilled person, the court can follow the problem and solution approach (PSA) as also used by the EPO, as a tool to assess obviousness, but nothing prevents the Court from following a different approach. Any approach in fact would render the same result in this case, as follows from the below.

12. Auxiliary Request 3: Inventive step (Clark in combination with Coassin)

12.1 BioMérieux, in line with the previously discussed novelty of Auxiliary Request (1 and) 3 based on Clark, identifies the features 1.2.2 and 1.2.2.1 as the sole distinguishing features of claim 1 of the third Auxiliary Request over Clark, namely that the MEIA cartridge 68 is not a second pipette tip having a capture surface (but a cuvette). BioMérieux argues that the technical effect of the second tip being a pipette tip having a capture surface is that the process may be more efficient, because additional steps of transferring/dispensing the sample for combination with reagents may be avoided. The second pipette tip, having a capture surface, performs both a transfer function and an assay unit function. Hence, a problem solved by the features 1.2.2 and 1.2.2.1 of claim 1 of Auxiliary Request 3 is, according to bioMérieux, how to improve the efficiency of the process performed by the instrument of Clark. Faced with this problem, the skilled person would readily consider implementing a pipette tip with a capture surface. Such a pipette tip is disclosed in Coassin, thus still bioMérieux.

12.2 Labrador replies that whichever problem is used, the skilled person would not be motivated to combine the teachings of Coassin with Clark in an attempt to provide a more

flexible method/instrument in accordance with claims 1/2, because of fundamental differences of the Coassin and Clark teachings with respect to using multiple or single pipette tips and because the object of Coassin is to have a "*minimal number of liquid transfers*" (see Coassin [0009] 2nd sentence). To that effect, Coassin teaches the use of a single all-purpose assay tip 29: Coassin assay uses a pipette adapter, or a pipette tip (see e.g. Figure 4) with a substrate to bind with target biomolecules and then uses a bioarray to detect the number of immobilized biomolecule complexes [0010]

12.3 Coassin relates to a system for detecting the presence of target biomolecules within samples with robotic assistance for a sample holder carrying an array of reactants. Coassin contains the following paragraphs and figures:

[0009] *It is an object to the present invention to provide apparatus and methods for rapidly and automatically determining the presence of multiple target biomolecules in a single sample. It is another object of the present invention to provide analytical methods which require minimal sample volume and a minimal number of liquid transfers. It is a further object of the present invention to provide a device and system for rapid assessment of samples for target biomolecules which is readily adaptable to a variety of chemical and other detection schemes.*

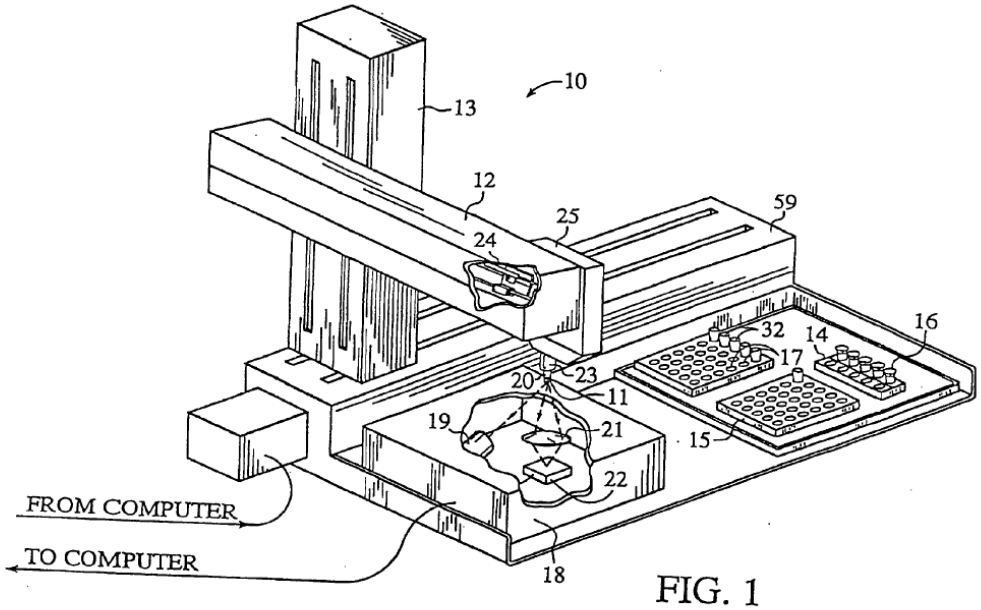


FIG. 1

[0010] *The present invention achieves the above objects by providing an analytical biochemistry system for automated analysis of samples for the presence of target biomolecules. The system includes a solid substrate which is supported by a holder and carried by a manipulator, such as a robotic arm. Immobilized on the solid substrate surface at discrete, site-specific locations are reactants in an array which are capable of binding with target biomolecules in specific binding reactions to form immobilized biomolecule complexes. Such an array is termed a "bioarray". The presence of target biomolecules in*

the sample is determined by detecting immobilized biomolecule complexes on the bioarray with some kind of probe, e.g. a fluorescence detector. In operation, the manipulator moves the bioarray to contact the substrate surface with a volume of sample. Then the manipulator moves the contacted bioarray to a detection station to detect the absence or presence of immobilized biomolecule complexes. In alternative embodiments the bioarray is stationary and a sample manipulator moves samples to the holder. In the preferred embodiment, the bioarray is mobile, being carried by a manipulator. A detection station is located near the sample to probe the substrate after interaction between the reactants and sample or samples has occurred.

[0011] *Distinct reactants specific to different target biomolecules are immobilized on a preferably flat, non-porous substrate. These reactants form a plurality of active sites on the substrate at known locations. The substrate may be a planar strip with lineary-arranged reactants forming separate spots or bands, or may be a planar sheet having an area-wide arrangement of reactants, forming spots or dots in a two-dimensional array, or may be a fiber or rod with substrate disposed on a manner similar to a strip.*

[0012] *The holder supports the bioarray and is carried by the manipulator which transports the substrate to the location of the fixed sample, and then to the location of the detection assembly. As stated, the substrate could be fixed and the sample transported. One example of a holder is a pipette or a pipette tip, within which a bioarray is affixed. The sample is drawn up into the pipette tip, as with aspiration from a bulb or vacuum pump, or withdrawal of a plunger. The sample is thus placed in contact with the substrate, allowing any target molecules which may be present within the sample to interact with the appropriate reactive sites on the substrate. After the appropriate incubation or reaction period, the sample may be removed from the pipette tip, as by air or positive displacement with a plunger.*

[0014] *The method for detecting target biomolecules within a sample includes the steps of treating a substrate with a plurality of distinct reactants to form reagents immobilized on the substrate at fixed, known positions defining an array, i.e. a bioarray. The reactants are selected to bind one or more target molecules to form a complex having a detectable and identifiable character-istic such as a fluorescence signature. The bioarray is supported in the holder. In turn, the holder has a shape which can be picked up by a manipulator which moves the substrate for contact with the fixed sample, and then removes and possibly rinses the substrate at another location to remove unbound biomolecules. Then the manipulator moves the substrate to a probing station, such as an optical inspection location for probing the active sites of the substrate with a beam for determining complementation of the target biomolecules by detecting the optically detectable characteristics.*

[0015] *Inspection may include detection of fluorescence, light scattering, absorbance, reflectance, chemiluminescence, radioactive emission, conductivity or electronic property. Depending on the nature of the substrate, detection of transmitted light is also possible.*

[0016] *(…) Optical inspection of the substrate within the pipette tip is possible by use of an optical surface on the pipette tip. (…) A manipulator in the form of a robotic arm*

gripping the pipette tip (…) may place the bioarray in contact with the sample, and subsequently transfer the substrate to a detection assembly. Multiple sample transfers are this eliminated. (…)

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] ***FIG. 2*** *is a plan view of a lineary-arranged substrate for use in the system of* ***FIG. 1****.*

[0019] ***FIG. 3*** *is a plan view of a two-dimensional arranged substrate for use in the system of* ***FIG. 1****.*

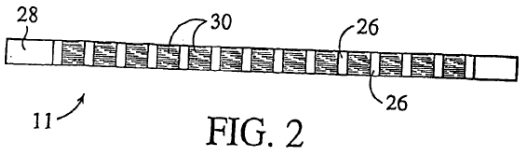


FIG. 2

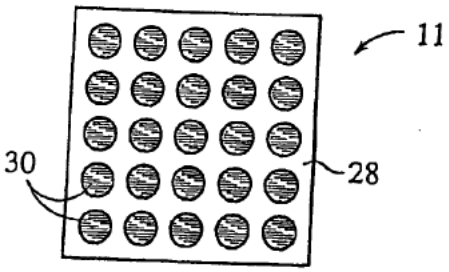


FIG. 3

[0020] ***FIG. 4*** *is a plan view of a pipette tip having a substrate for use in the system of* ***FIG. 1****.*

[0021] ***FIG. 5*** *is a plan view of a plunger-type pipette tip having a substrate for use in the system of* ***FIG. 1****.*

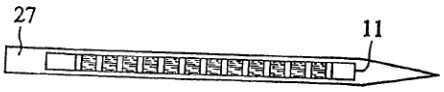


FIG. 4

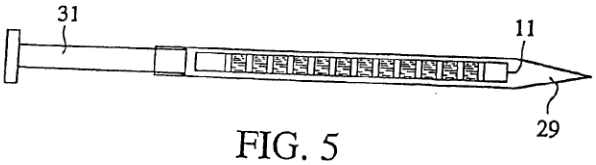


FIG. 5

[0030] ***FIG. 14*** *is a perspective view of the elements of an optical detection station for use in the system of* ***FIG. 1****.*

[0031] ***FIG. 15*** *is a plan view of an alternate embodiment of the detection station for use in the system of* ***FIG. 1****.*

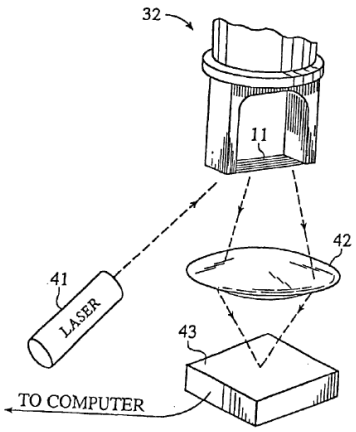


FIG. 14

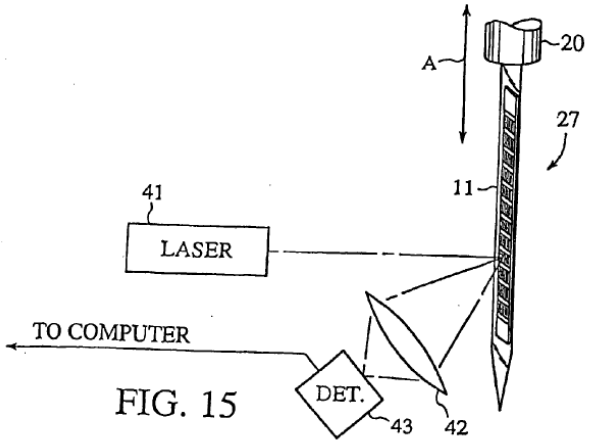


FIG. 15

[0037] ***FIG. 21*** *is a perspective view of a jet head-type reagent deposition apparatus for creating a substrate in accord with the present invention.*

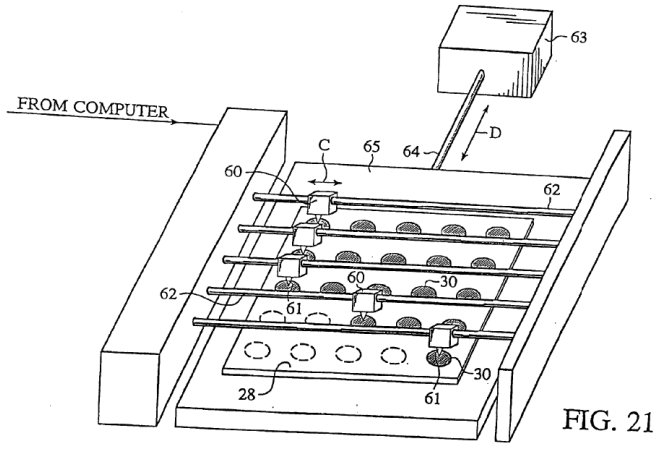


FIG. 21

12.4 The object of Coassin is to have a "minimal number of liquid transfers" (at paragraph [0009] reproduced above). According to Labrador, to that effect Coassin teaches the use of a single all-purpose assay tip 29; Coassin assay uses a pipette adapter, or a pipette tip (see e.g. Figure 4) with a substrate to bind with target biomolecules and then uses a

bioarray to detect the number of immobilized biomolecule complexes (see paragraph [0010] reproduced above).

12.5 Looking at this, Coassin indeed discloses a pipette tip (29) with a capture surface (having a substrate), but the skilled person would not be motivated to replace the MEIA Cartridge of Clark with Coassin's pipette tip. The Plunger-type pipette tip 29 of Coassin implements all transfer and assay functions, so that the skilled person would find no motivation to use it to replace the cuvette MEIA cartridge 68 of Clark only. In any case, this will not improve the efficiency of the process performed by the instrument of Clark.

12.6 As Clark describes, the system has a first transfer pipette mechanism utilized in kitting various reagent pack liquid materials and sample into a reaction vessel 34. The kitted reaction vessel 34 is positioned by reaction vessel carrousel 36 into the proper position for transfer to the transfer station 42. The reaction vessel 34 is transferred to the transfer station 42 through transfer means, wherein the transfer station 42 is then rotated to move the reaction vessel onto process carousel 46. The process carousel 46 is driven by a stepper motor 48 and is serviced by a second transfer pipette mechanism 50 (p. 62, l. 2-19). In the MEAI process, the second transfer pipette mechanism 50 is utilized for transferring the reagent mixture (by pipetting) to the MEIA cartridges 68, which are mounted on the auxiliary carousel 64, also referred to as the cartridge wheel carousel (p. 63, l. 18-22). The MEAI cartridges comprise a reaction well for retaining and immobilizing microparticle-analyte complexes. The reaction well has an entrance port and means for holding a quantity of sample and assay reaction mixtures positioned over a fibrous matrix which retains and immobilizes microparticle-analyte complexes (p. 48, l. 3-11). The MEIA reagent mixed sample is transferred to the MEIA cartridge by the second transfer pipette mechanism 50. The second transfer pipette mechanism 50 moves the pipette probe between the wells in the reaction vessel 34 on the process carousel 46 to the MEIA cartridge 68 on the auxiliary carousel 64 (p. 63, l. 18-p. 64, l. 2). The auxiliary carousel 64 holds, for example, 32 MEIA cartridges 68. The carousel moves the MEIA cartridges 68 between various stations including the second transfer pipettor mechanism pipette point and the MEIA reader 74 (p. 64, l. 7-14).

12.7 From the foregoing, and taking also into account figure 55 of Clark, as included above, it is clear to the skilled person that the MEIA reagent mixed sample is by pipette-type action taken into the pipette probe of the second transfer pipette mechanism 50 (then containing that MEIA reagent mixed sample) and (at the second transfer pipettor mechanism pipette point) ejected from that pipette probe into the MEIA cartridge. On the other hand, plunger-type pipette tip 29 of Coassin implements all transfer and assay functions, so that the skilled person would find no motivation to use it to replace the cuvette MEIA cartridge 68 of Clark only.

12.8 Even if the complete pipetting system of Coassin replaces the cuvette MEIA cartridge 68, the auxiliary carousel 64 and the second transfer pipette system 50 of Clark, the efficiency of the process is still not improved with respect to fluid transfer, since two tips are still used instead of only one, with many fluid transfers from sample cup carousel vessel 28 to first transfer pipette system 6, then to reaction vessel carousel 36, then to transfer station 42, then to process carousel 46, and finally to second transfer pipette system 50.

12.9 Much more efficient, as Labrador argues, for the skilled person who wishes to apply the main teaching of Coassin system, by using the single all-purpose pipette tip with the substrate for all transfer and assay functions, would be to apply it to the first transfer pipette mechanism 6 - thus eliminating the entire second carousel system of Clark including transfer station 42, process carousel 46, second transfer pipette system 50, MEIA cartridge 68 and auxiliary carousel 64.

12.10 In other words, at best, the skilled person would be incited to replace the probe 106 of first transfer pipette mechanism 6 of Clark by the pipette 29 of Coassin, and to get rid of the entire second carousel system of Clark, so that the combination would lead to use a single all-purpose pipette tip, instead of 2 pipette tips as claimed.

12.11 The Court therefore does not consider the argument of bioMérieux, as brought forward during the oral hearing, that the pipette tip of Coassin brings more efficiency, because the pipette tips of Clark need to be washed (to make sure that it is free from contamination) (p. 216, l. 12), which is not necessary with the pipette tip of Coassin, so that tip provides minimum fluid loss and minimum fluid transfer.

12.12 Claim 1 of Auxiliary Request 3 is thus inventive over Clark in combination with Coassin.

13. Auxiliary Request 3: inventive step (VIDAS in combination with the CGK as disclosed by Chapman)

13.1 As follows from the novelty of claim 1 of the third Auxiliary Request as discussed above, feature 1.2.1 is the distinguishing feature over the VIDAS® instrument, namely that in the VIDAS® instrument, a first pipette tip is missing. In the eyes of bioMérieux, to obtain the claimed instrument starting from the VIDAS® instrument, nothing more is needed than to automate the manual pipetting step (of transferring the sample into the reagent strip). According to bioMérieux, Chapman, setting out the state of automation of testing devices in 2003, shows that automating a manual step in a device was common practice (CGK) for the skilled person at the priority date, in particular in this field: "*Benchtop automated liquid handling and sample-dispensing systems are now routine in most life-science laboratories. Such systems will become even more ubiquitous with the introduction*

of a new wave of lower-cost modular devices with much the same functionality as the systems used by big-pharma labs.". And using a pipette to that effect was also CGK: ""*Xiril (…) specialists in robotic liquid-handling, has a range of pipetting robots. Allegro's latest range of pipetting systems uses electromagnetically controlled valves (…) Beckman Coulter in Fullerton, California, and has also put the pipettes into its own robotic system*." (p. 663, first column).

13.2 This may all be true, but even if the step of manually pipetting of the sample into the sample well of the reagent strip before placing the strip into the VIDAS® instrument were automated, then feature 1.2.1, the first pipette tip for transferring the sample from the sample unit to the reagent unit, would still be missing. What would then be automated is the step (feature 1.1.2) that is also done manually according to claim 1 of the third Auxiliary Request; applying sample to a sample unit (the sample well of the reagent strip). The second means of the VIDAS® instrument (the SPR® block being the fluid transfer device) would still be configured to move only one pipette tip (the SPR® as second tip and assay unit). The combination of the VIDAS® instrument and the CGK in the form of Chapman cannot therefore affect the inventiveness of claim 1 of the Auxiliary Request 3.

14. Auxiliary Request 3: Inventive step (Tsuruta in combination with Tominaga)

14.1 Tsuruta describes a fully automated enzyme-linked immunosorbent assay (Acronym: E.L.I.S.A) system for detecting various biological analytes (including antigens).

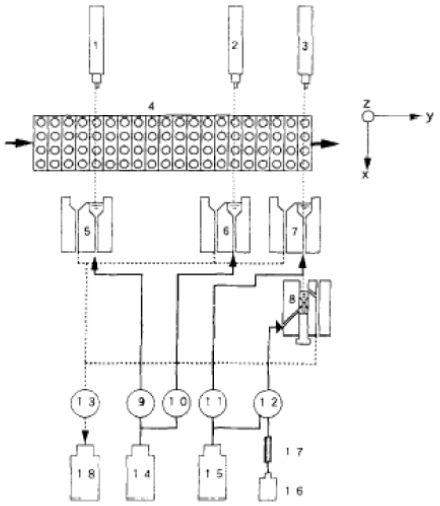


Fig. 1. Basic structure of the present ELISA system: 1, 2, and 3, two-dimensional pipetters; 4, reagent cartridge; 5 and 6, PBS solution cells; 7, ammonium chloride solution cell; 8, pH-measuring cell; 9–12, feeding pumps; 13, wasting pump; 14, 100 mM PBS (pH 7.8); 15, 10 mM ammonium chloride + 154 mM sodium chloride + 0.01% chloramphenycol; 16, 1 M urea; 17, ion exchange column; 18, wasted solution.

14.2 The article discloses a 'cartridge mover' (the first means) which pushes a 'reagent cartridge' (a device) forward, which cartridge has four cups (A, B, C and D). Cup A is for sample serum (1). Cup B and C are for sample dilution (2) and the first immunoreaction

(3) respectively, wherein cup C contains a solid-phase pipette tip (7), coated with capturing material. Cup D is for the second immunoreaction (4), and freeze-dried conjugate is deposited at the bottom of the cup. BioMérieux sees cups B, C and D as the reagent units of the device. The reagent cartridge is depicted in Tsuruta as follows:

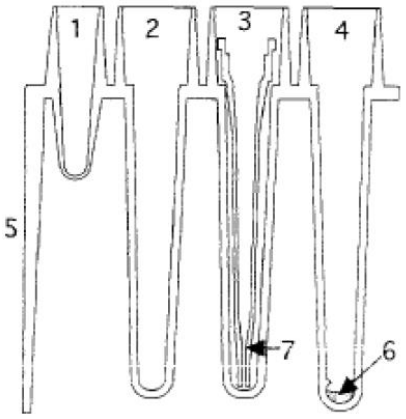


Fig. 4. The reagent cartridge for the present ELISA system: 1, cup A for serum sample; 2, cup B for serum dilution; 3, cup C for the 1st immunoreaction; 4, cup D for the 2nd immunoreaction and also as a container of freeze-dried conjugate; 5, stick board for a bar-cord label; 6, freeze-dried conjugate; 7, pipette tip as a solid phase.

14.3 The pipetter part of the instrument (the second means) is composed of three pipetter probes. The first pipetter probe is used for sample dilution and for starting the first immunoreaction. The second one is for washing the tip after the first immunoreaction and for starting the second immunoreaction. The third one is for washing the tip after the second immunoreaction and for measuring urease activity. Each pipetter moves in the xz plane shown by the dotted lines in figure 1. The solid phase tip in cup C is held by the first pipetter probe (number 1 in figure 1) and serum in cup A is transferred to cup C. When dilution is necessary, a desired amount of solution is also pipetted from a PBS solution cell (numbers 5 and 6 in figure 1) into cup C. The solid phase tip can also be received in cup B if dilution is needed. The solid-phase tip after the first immunoreaction is held by the second pipetter probe (number 2 in figure 1) and then the tip is dropped into cup D to carry out the second immunoreaction.

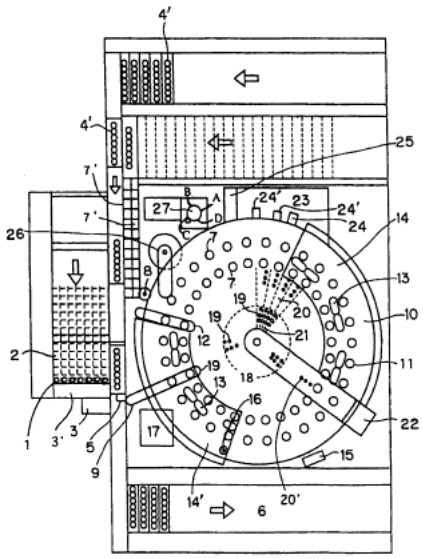
14.4 Now that the immunoreactions are carried out in the solid-phase tip, bioMérieux identifies that tip as the assay unit (second tip), engaged by the pipetter part that is configured to move the tip relative to the reagent cartridge for (at least) cup C thereof to receive the solid-phase tip. But is also that same solid-phase tip that is used for the transfer of serum from cup A (the sample unit) to cup C (a reagent unit). This means that, just like in the VIDAS® instrument, in the instrument as described by Tsuruta, a single tip is used for both the transfer of the sample from the sample unit to the reagent unit as from the reagent unit to the assay unit, and not two different tips as claimed by claim 1 of the Auxiliary Request 3. Therefore (at least) feature 1.2.1 is the distinguishing feature

over the Tsuruta instrument, namely that in the Tsuruta instrument a first pipette tip is missing.

14.5 BioMérieux has put forward that Tominaga discloses that missing feature of a first pipette tip for transferring sample from a sample unit to a reagent unit before that sample is transferred to a second pipette tip. Even assuming that the skilled person would see reason to combine the teaching of Tominaga with the teaching of Tsuruta, which is being disputed by Labrador, the skilled person would not arrive at the in Auxiliary Request 3 claimed instrument without further non-routine steps and creative adaptations. That can be explained as follows.

14.6 Tominaga discloses an automatic immunoassay device that makes use of magnets. In the example the following instrument is further explained:

Fig. 1



14.7 In the device there is a sample rack 2 which holds a large number of sample tips 1, for supplying sample from sample units 4 to a test tube 7 on the turret 10. A drive mechanism of the sample apportioning means 9 of a three axis (X, Y, Z) robot 3 (which comprises an arm that can move up and down, longitudinally and laterally, is operated to pick up the sample tips and move them to pick up sample 4 and apportion the sample into the test tubes 7. After apportioning the sample, the sample tip 1 is discarded.

14.8 As a reaction vessel, the inner wall of test tube 7 serves as a solid phase to capture the antigens and antibodies (columns 1 and 2 of the description). Sample dilution can also be diluted in test tube 7 by an automated dilution system.

14.9 Then reagent apportioning means can move and convey a reagent pipette 22 along two axes (X, Y) and pick up a reagent tip 19, held in reagent tip accommodating part 21, to transfer reagent from the reagent unit 20 to the test tube 7 on the turret 10. After tip 19 has been used, it is returned to and accommodated in its original position in the tip rack. The apportioning process involves using an exclusive-use tip for each reagent by means of an attachment/removal mechanism on reagent pipette 22, ensuring no cross-contamination between reagents.

14.10 A detector 27 detects the dose of luminescence in the test tube 7, which depends on the amount of a specific antigen is assayed.

14.11 If the skilled person would now be motivated to learn lessons from Tominaga, for example to improve Tsuruta's transfer system of liquid so that cross-contamination and/or washing steps can be reduced, he/she sees in Tominaga the use of two different tips, one (disposable) tip for transfer of sample from a sample unit to the assay unit (test tube 7) and one (reusable) tip for the transfer of reagent to the assay unit (test tube 7). If the skilled person would consider to apply those tips into the instrument of Tsuruta, he/she would realize that the two tips of Tominaga cannot replace the solid-phase tip 7 of Tsuruta, since neither tip of Tominaga comprises a capture surface configured to bind with an analyte. In addition, two tips (one disposable and one reusable) cannot be added to the instrument of Tsuruta without further modifications to the instrument. As can be seen in Tominaga a three axis (X, Y, Z) robot 3 (which comprises an arm that can move up and down, longitudinally and laterally, is used to pick up, move and discard the (disposable) sample tips one and the second pipetter system 22 cooperates with the rotating turret 10 to pick up and put back (after use) the reagent tips 19 form and into a reagent tip accommodating part 21.

14.12 Without further explanation, which bioMérieux has not given, it cannot be seen how simple two axis (X, Z) movable pipetter probes cooperating a single tip carried by a Y-axis movable device in Tsuruta, could be easily adapted to accommodate the complex arrangement of Tominaga, comprising a plurality of (disposable) first sample tips 1, a plurality of reagent tips 19, a three axis robot to move the first sample tips and a reagent tip accommodating part 21, wherein the reusable reagent tips can be received and kept until next use. In fact (see UPC_CFI 505/2023 LD Düsseldorf Decision issued on 13 May 2025): 'In terms of inventive step, the subject matter of the claim may be obvious if the skilled person would have been motivated to implement it as the next step in the view of the problem. A motivation to implement may be absent or negated if the skilled person is faced with many uncertainties or expected difficulties.

14.13 As a conclusion, claim 1 of Auxiliary Request 3 involves an inventive step over Tsuruta in combination with Tominaga.

15. Auxiliary Request 3: Insufficient disclosure

15.1 Pursuant Art. 138(1) (b) EPC in conjunction with Art. 83 EPC, applicable according to Art. 65(2) UPCA, a patent shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. The disclosure shall be in the patent itself, encompassing the claims, description and drawings.

15.2 BioMérieux argues that the teaching of the Patent in suit does not enable the skilled person to carry out the whole subject-matter defined in claim 1 of the Auxiliary Request 3 without undue burden. BioMérieux states that, according to the description, the Patent encompasses an option whereby the 'first means' and the 'second means' correspond to one and the same means (namely the translational stage), while those means are presented as separate means in the claim (features 1.1 and 1.2). BioMérieux points to paragraph [0121] of the description (corresponding with paragraph [0144] of the Mother Application) ('the stage 530 on which the device 510 sits can be moved to move the device 510 relative to the positioning of the assay units 501 and heads 522') and figure 5 (reference number 530).

15.3 The Court considers that it appears that bioMérieux confuses the means for receiving the device (the 'first means', being the stage 530 on which the device 510 sits or onto which the device is placed) with the means for moving the first means with the device (the 'second means', being the fluid transfer device 520, which means move the stage 530 in translation, for instance thanks to a motor as stated at paragraph [0017]). Claim 1 of Auxiliary Request 3, wherein the first and second means indeed are presented as separate means, both having a different function, corresponds in that respect with paragraph [0121] and figure 5 of the description.

15.4 Now, several paragraphs and the embodiments of figure 5 of the Patent provide teaching on the first and second means being different means, both having a different function; this teaching should be clear to the skilled person and enable him/her to produce embodiments as claimed by claim 1 of the third Auxiliary Request. Hence, the Patent fulfils the sufficiency requirements under Art. 83 EPC.

16. Conclusion

16.1 The conclusion of all this is that claim 1 of Auxiliary Request 3 will be considered valid. Since claim 2 claims a method corresponding to the instrument claimed in claim 1 and claim 2 thus shares the fate of claim 1, claim 2 of Auxiliary Request 3 will also be considered valid.

16.2 In line with this reasoning, the Court will uphold the Patent in the form of claims 1 and 2 of Auxiliary Request 3.

17. Costs

17.1 Both parties agree that the value of the proceedings in accordance with R. 370.6 RoP should be set at EUR 5 million, but they disagree on how that value should be applied to the Claim for revocation action and the Counterclaim for revocation action.

17.2 Labrador is of the opinion that this single amount applies to the combined actions (so this value should be shared between the Claim for revocation and the Counterclaim for revocation), because in fact there is one single (revocation) action. She takes legal basis for that opinion from two portions of the Administrative Committee's Guidelines for the determination of the court fees of the ceiling of recoverable costs. The first one is the principles section, where according to Labrador is stated that the valuation should relate to the summed values of the main remedies claimed. In the claim for revocation and the counterclaim for revocation there is obviously only one single possible remedy (revocation). The second section where Labrador refers to is section 2 for the valuation of a claim for revocation and a counterclaim for revocation, from which follows that the value of the counterclaim for revocation or a claim for revocation should be determined by the patent to be revoked. According to Labrador it is thus about the patent: in this case only one patent. According to Labrador it is not legally right, only because there are two procedures (two approached angles), and especially where the parties are related, to double the value.

17.3 BioMérieux brought forward that she sees no rule where the opinion of Labrador is based on. BioMérieux's previous experience in the UPC in a case where a Counterclaim for revocation was joined with a Claim for revocation (in case UPC_CFI_001/2023) is that the two ceilings of recoverable costs were added together (so there were two actions, two separate values and two ceilings). BioMérieux is of the opinion that a Revocation action is a different action from a Counterclaim for revocation. If Labrador had not asked for the Counterclaim for revocation to be referred to the Milan Central Division, the situation would still be that the parties had an agreement that the value of the claim for revocation would be set at EUR 5 million and at the Local Division of Düsseldorf would still have the infringement case together with the Counterclaim for revocation. So basically that means, according to bioMérieux, that by asking to move the Counterclaim for revocation over to the Milan Central Division, the party that attacked the patent of Labrador, is asking to pay less costs if they lose. That would be an incorrect consequence. BioMérieux believes that for that reason, in case UPC_CFI_001/2023 was decided that there were two actions, two values and two ceilings.

17.4 In reply of this, Labrador stated that the outcome in case UPC_CFI_001/2023 was the result of an agreement of the parties to which the Court had no objection, which bioMérieux has contradicted. Labrador also stated in reply that if the Counterclaim for revocation had not been referred, she would still be arguing for a non-duplication of the value of the action.

17.5 The Court considers that Art. 1.3 of the Decision on scale of ceilings (Scale of ceiling for recoverable costs of the Administrative Committee of 24/04/2023 in AC/10/24042023) provides that 'the ceiling shall be applied to each instance of the Court proceedings regardless of the number of parties, claims or patents concerned'. Taking also into account that in the Revocation Case and the Counterclaim for Revocation Case there are the same (group of) parties and it concerns the same (invalidity) attacks against one patent, the value of the proceedings together should be set at EUR 5 million, and the ceiling of recoverable costs, therefore, applies to both the Revocation Case and the Counterclaim for Revocation Case. The combined value of EUR 5 million results in a ceiling for recoverable costs of EUR 600,000.

17.6 The parties reached an agreement on the legal costs of the successful party to be borne by the unsuccessful party. The Court will follow this agreed amount of EUR 600.000 as undisputed.

17.7 Labrador has requested the Central Division to order this amount as confidential pursuant to Art. 58 UPCA in conjunction with R. 262.2 RoP.

17.8 Referring to an earlier decision of the Milan Central Division (UPC_CFI_477/2025 of 5 June 2025), in principle, the costs of the proceedings are not covered by confidentiality unless they are specifically indicative of the company's financial capacity, its commercial strategy, or the importance of the patent as a corporate asset. Since the agreement on the amount of the legal costs between parties, does not (simply) say anything about the company's financial capacity, its commercial strategy, or the importance of the patent as a corporate asset, the request of Labrador to order the agreed amount as confidential will be dismissed.

17.9 During the oral hearing the parties clarified that it is up to the Court to decide on who is the successful party and what success means. In accordance with Art. 69 UPCA and R. 118.5 RoP, the Court considers Labrador as the most successful party in these proceedings, as the Patent will be maintained in the form of Auxiliary Request 3. But since bioMérieux has initiated the (counterclaim for) revocation action against the patent as granted, and the patent as such, as well as the Main Request, Auxiliary Request 1 and Auxiliary Request 2, do not lead to a valid patent, the Court will order that the legal costs be apportioned equitably, in that sense that bioMérieux, as the most unsuccessful party,

has to bear two third of the legal costs of Labrador. The amount to be awarded to Labrador is therefore set at EUR 400.000.

DECISION

Based on the foregoing, the Milan Central Division of the UPC rules as follows:

1.The (counterclaim for) revocation action filed by BioMérieux against Labrador concerning the European patent EP 3 756 767 B1 is rejected, in that sense that European Patent EP 3 756 767 B1 is maintained as amended by Auxiliary Request 3 (AR 3), as attached in the Annex to this decision.

2. The value of the combined proceedings (Revocation Case and Counterclaim for Revocation Case) is set at EUR 5 million, and the ceiling of recoverable costs is therefore set at EUR 600.000;

3. BioMérieux shall pay the legal costs incurred by Labrador to an amount of EUR 400.000;

4. Labrador's request to order the agreed amount of legal costs as confidential is dismissed.

Done and delivered on 23 October 2025

NAMES AND SIGNATURES	
Judges Andrea Postiglione Presiding judge ANDREA POSTIGLIONE Firmato digitalmente da ANDREA POSTIGLIONE Data: 2025.10.22 21:55:57 +02'00' Marije Knijff Legally qualified judge and judge-rapporteur Marije Knijff Digitaal ondertekend door Marije Knijff Datum: 2025.10.23 10:38:10 +02'00' Michel Abello Technically qualified judge Michel, Robert, Gérard Abello Signature numérique de Michel, Robert, Gérard Abello Date : 2025.10.22 20:36:00 +02'00'	**Deputy-Registrar** Firmato digitalmente da MOLINARI VALERIA Data: 2025.10.23 14:05:51 +02'00'

Information about the appeal

An appeal against the present Decision may be lodged at the Court of Appeal, by any party which has been unsuccessful, in whole or in part, in its submissions, within two months of the date of its notification (Art. 73(1) UPCA, R. 220.1(a), 224.1(a) RoP).

Information about enforcement (Art. 82 UPCA, Art. Art. 37(2) UPCS, R. 118.8, 158.2, 354, 355.4 RoP)

An authentic copy of the enforceable decision will be issued by the Deputy Registrar upon request of the enforcing party, R. 69 RegR.

Art. 65.5 UPCA: Where the Court, in a final decision, revokes a patent, either entirely or partly, it shall send a copy of the decision to the European Patent Office and, with respect to a European patent, to the national patent office of any Contracting Member State concerned.

ANNEX

AUXILIARY REQUEST 3 - Clean

1. An instrument for detecting a biological analyte, comprising:

first means for receiving a device inserted into the instrument, the device comprising:

an array of reagent units, each reagent unit of the array of reagent units for containing a reagent for an assay to detect the biological analyte, and

a sample unit comprising a sample applied by a user;

second means configured to, with the device received by the first means:

move at least one of a first pipette tip comprising sample or a reagent unit of the array of reagent units relative to the other of the first pipette tip or the reagent unit, for transfer of sample from the sample unit to the reagent unit; and

move at least one of the reagent unit or a second pipette tip relative to the other of the reagent unit or the second pipette tip, for transfer of sample from the reagent unit to the second pipette tip, the second pipette tip comprising a capture surface configured to bind with the biological analyte,

a detection assembly for detecting a signal indicative of the presence, absence or concentration of the biological analyte bound to the capture surface configured to bind with the biological analyte.

2. A method of detecting a biological analyte, comprising:

receiving, by first means of an instrument, a device inserted into the instrument, the device comprising:

an array of reagent units, each reagent unit of the array of reagent units for containing a reagent for an assay to detect the biological analyte, and

a sample unit comprising a sample applied by a user;

moving, using second means of the instrument, at least one of a first pipette tip comprising sample or a reagent unit of the array of reagent units relative to the other of the first pipette tip or the reagent unit, to transfer sample from the sample unit to the reagent unit;

moving, using the second means, at least one of the reagent unit or a second pipette tip relative to the other of the reagent unit or the second pipette tip, to transfer sample from the reagent unit to the second pipette tip, the second pipette tip comprising a capture surface configured to bind with the biological analyte; and

detecting, using a detection assembly of the instrument, a signal indicative of the presence, absence or concentration of the biological analyte bound to the capture surface configured to bind with the biological analyte.