Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Düsseldorf Local Division
UPC_CFI_315/2024

Decision
of the Court of First Instance of the Unified Patent Court
delivered on 28 January 2026
concerning 3 756 767 B1

Headnotes:

1. The Local Division is bound to the new wording of the claims due to the amendment of the patent in suit by a decision of the Central Division in a bifurcated case.

2. In a bifurcated case in which the Court does not find on infringement, the question of validity is no longer decisive for the infringement action.

Keywords: Bifurcation; Central Division; amended claims

CLAIMANT:

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represented by:	Christof Höhne and all other UPC Representatives of EIP Europe LLP including, in particular, Sebastian Fuchs, Matthew Blaseby, Darren Smyth (Breite Straße 29-31, 40213 Düsseldorf, Germany and Fairfax House, 15 Fulwood Place, WC1V 6HU, London, United Kingdom)
electronic address for service:	chohne@eip.com

DEFENDANTS:

1. **bioMérieux SA,** represented by its President and CEO Alexandre Mérieux,376 Chemin de l'Orme, 69280 Marcy l'Etoile, France

2. **bioMérieux Deutschland GmbH,** represented by its Managing Director Alexandre Schneider, Weberstraße 8, 72622 Nürtingen, Germany

3. **bioMérieux Italia S.p.A.,** represented by its Directors Renato Porta, Efstathios Chorianopoulos, Alain Mérieux and Yasha Mirotti Ventura, Via di Campigliano 58, Ponte a Ema 50012 Bagno a Ripoli (FI), Italy

4. **bioMérieux Austria GmbH,** represented by its Managing Director Alexandre Schneider and Valérie Sick, Harry-Glück-Platz 2/5, A-1100 Vienna, Austria

5. **bioMérieux Portugal,** represented by its Managers Maria Antónia Ferreira Pica Nascimento, Pedro Hugo Di Rocco, Lapo Giacometti and Eric Marie Pierre Maillet,Lda., Av 25 de Abril de 1974, N°23-3, 2795-197 Linda-a-Velha, Portugal

6. **bioMérieux Benelux BV,** represented by its Directors Vincent Marciniak and Denis Monnaie, Databankweg 26 NL, 3821 AL Amersfoort, the Netherlands

represented by:	Benjamin Husband and Agathe Michel-de Cazotte, Carpmaels & Ransford LLP, One Southampton Row, London WC1B 5HA, United Kingdom
electronic address for service:	ben.husband@carpmaels.com (Defendant 1.) #CR_U010328UC@carpmaels.com (Defendants 2. to 6.)

PATENT AT ISSUE:

European patent n° 3 756 767 B1

DECIDING JUDGES:

The decision is issued by Presiding Judge Thomas, the legally qualified judge Dr Thom acting as judge-rapporteur, the legally qualified judge Bessaud and the technically qualified judge Abello.

LANGUAGE OF THE PROCEEDINGS: English

SUBJECT: Infringement action

DATE OF ORAL HEARING: 27 November 2025

SHORT SUMMARY OF FACTS:

1. The parties argue about the infringement of EP 3 756 767 B1 (exhibit KAP 1; hereinafter the patent in suit) being a patent with unitary effect. Its European patent application was filed on 24 July 2020 claiming the priority of US 99746007 of 2 October 2007. The European Patent Office published the patent grant on 1 May 2024. The patent in suit is in force Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Portugal, Slovenia and Sweden.

2 Upon request of the Claimant, the Düsseldorf Local Division bifurcated and referred the Counterclaim for Revocation (UPC_CFI_571/2024) to the Milan Central Division by Order dated 23 April 2025, where a revocation action was already pending at this time.

3. By Decision of the Milan Central Division dated 23 October 2025 (exhibit EIP 21), the patent in suit was amended in accordance with the filed auxiliary request 3. Accordingly, the patent in suit maintained only claim 1 (amended granted claim with regard to the instrument) and claim 2 (amended granted claim 14 with regard to the method).

4. On 31 January 2025, Defendant 1) filed an opposition at the EPO. The EPO issued its preliminary opinion on 13 November 2025 (exhibit CR Inf 36). The EPO proceedings are still pending.

5. Claim 1 and 2 read as follows:

Claim 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 anlayte, 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 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."

Claim 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 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

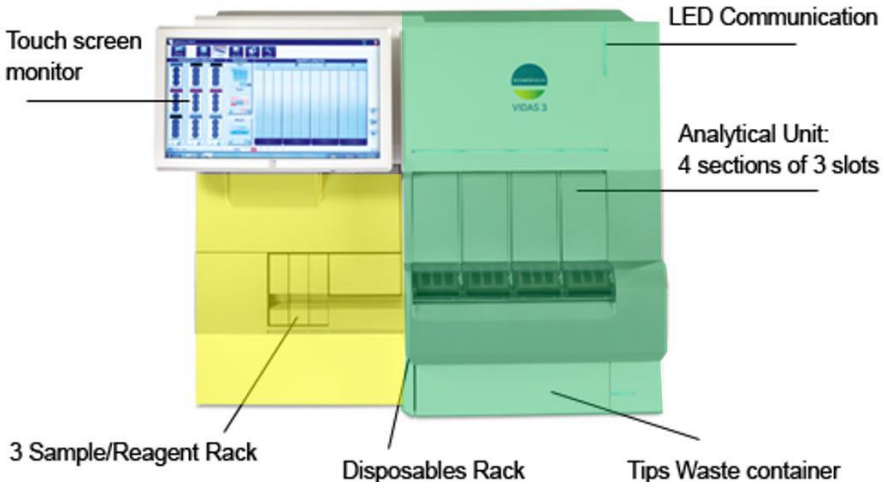
detecting, using a detection assembly of the instrument, a signal indicative of the presence, absence or concentration of the biological analyte bound to the capture surface configured to bind with the biological analyte."

6. Defendant 1) is a company having its principal place of business in France, which offers diagnostic solutions such as reagents, instruments, software and services in Europe. It also hosts a logistic hub, which is the central point from where Defendant 1) distributes its products all over the world, especially in the Unitary Patent territory.

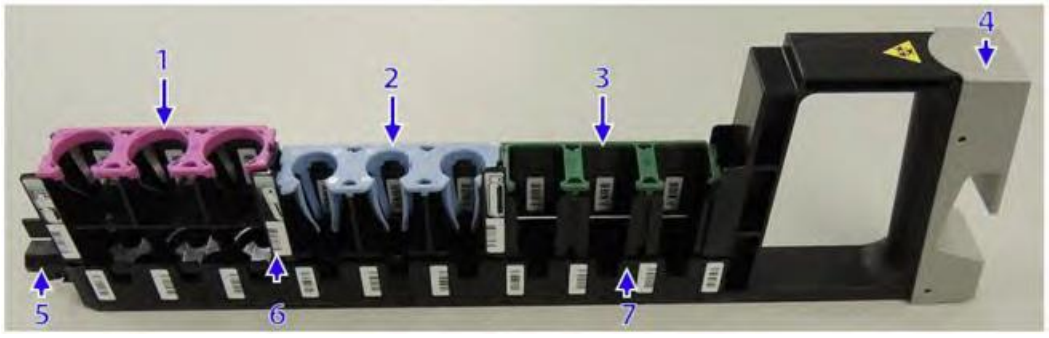
7. Defendants 2) – 6) are wholly owned subsidiaries of Defendant 1). Defendant 2) has its principal place of business in Germany. Defendant 2) is responsible for manufacturing, assembling and distribution of diagnostics, diagnostics systems and software and hardware solutions for medical and analytical testing laboratories. Defendant 3) has its principal place of business in Italy. It is responsible for the "manufacture of irradiation, electromechanical and electrotherapeutic equipment" and the "manufacture of medical and dental instruments and supplies". Defendant 3) is also listed as "manufacturer and seller of electrical and electronic equipment" as well as an "importer" of such. Defendant 4) has its principal place of business in Austria. Its business is to distribute the products of Defendant 1) and to carry out all related transactions and actions. Defendant 5) has its principal place of business in Portugal. Its business is to distribute the products of Defendant 1) and to carry out all related transactions and actions.Defendant 6) has its principal place of business in the Netherlands. It is distributing the products of Defendant 1) and carries out all related transactions and actions.

8. The Claimant challenges on the one hand the VIDAS 3, an instrument for performing immunoassay testing together with the Vidas 3-compatible reagent strips and Solid Phase Receptacles (SPR) (hereinafter challenged embodiment I) for direct and indirect infringement of the patent in suit. On the other hand, the Vidas 3-reagent strips and Solid Phase Receptacles (SPR) (hereinafter: challenged embodiment II) are challenged alone for indirect infringement of the patent in suit being disposable means which has to be refilled for using the challenged embodiment I.

9. The VIDAS 3 instrument comprises two main parts, a Pre-Analytical Unit (PAU; in yellow on the slightly reduced picture displayed below, taken from the Statement of Claim (hereinafter SoC), page 37, colouring added by the Claimant) and an Analytical Unit (AU; in green).



10. The PAU is equipped with a loading bay comprising three racks to hold “tube and vial racks to load samples and reagents”: a rack segment 1 for reagent vials (in purple) such as stimulants, a rack segment 2 for sample cups (in blue) and a rack segment 3 for reagent vials as diluents (in green) (see the picture below originating from exhibit CR-Inf 11 page 4-5).



11. The PAU also comprises one disposables rack for holding multiple (2x48) pipettor tips and multiple (2x16) dilution cups and a tips waste container/drawer for disposal of used tips which are automatically disposed there. There is an automatic pipetting unit (APU) (Exhibit EIP 8, p. 4-6) to first collect a pipettor tip from a disposables rack, then aspirate (and optionally dilute) a sample from a sample tube using a “smart pump”. The pipettor tip with the sample is then moved to a reagent strip and the sample is deposited there.

12. The AU provides for multiple slots in which reagent strips can be inserted, corresponding SPRs and reagent strips holding various reagents for a test, with a series of wells for a sample, a diluent, a washing buffer, another diluent, another washing buffer and a substrate (see SoC, pages 39 and 43):

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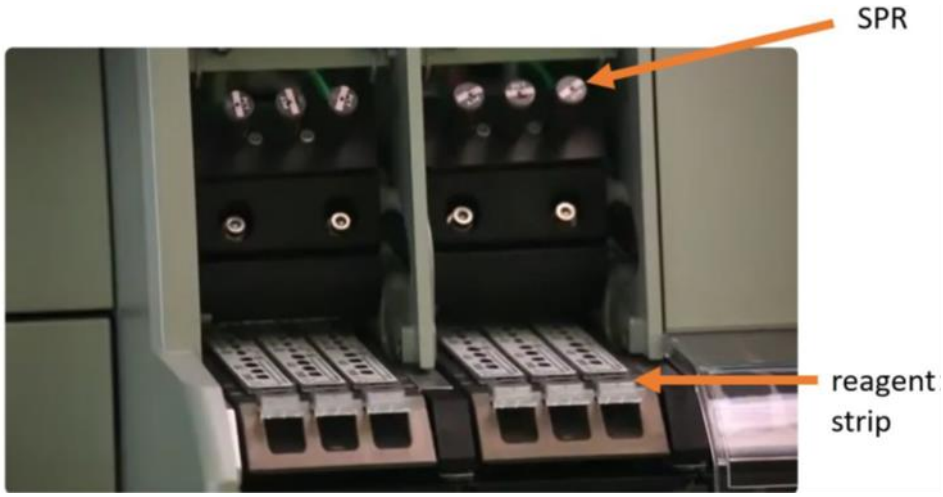
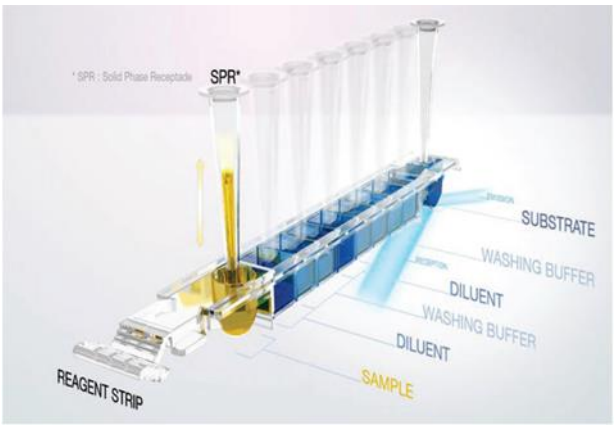




13. There are also so-called “dual reagent strips” used, where a sample is divided between the sample wells on two reagent strips.

14. An automatic pipetting system (see Exhibit EIP 8, pages 4-12) is used to automatically move an SPR relative to the reagent strip. The SPR aspirates the sample from the sample well of a reagent strip. An UV Lamp and a detector are used to perform an automated reading of emitted fluorescent light from the so-called "substrate” well carrying the fluorescent residue. The intensity of emitted fluorescent light depends on the amount of fluorescent residue in the “substrate” well. An UV Lamp and a detector are used to perform an automated reading of emitted fluorescent light from the so-called "substrate” well carrying the fluorescent residue. The intensity of emitted fluorescent light depends on the amount of fluorescent residue in the “substrate” well and this amount of fluorescent residue depends on the amount of the biological analyte bound to the inner surface of the SPR. The inner surface of the SPR has fixed antigens or antibodies to bind the antigen to be detected. The analyte to be detected then binds to the inner wall of the SPR. The SPR aspirates and/or expels various other reagents (e.g. diluents and buffers) of the reagent strip. After that the SPR outputs the fluorescent residue to be detected.

15. A standard 3 system run of the challenged embodiment I consists of the following steps (see exhibit CR-Inf 12, page 4-2):

    i. The samples (along with any controls, standards or diluents which may be required by the particular assay protocol) are loaded into the 3 sample racks on the loading bay.

ii. SPRs and reagent strips are separately loaded into section units, with SPRs loaded in the SPRs block above its corresponding reagent strip.

iii. Two sets of tips and two sets of dilution cups are loaded on the disposables rack.

iv. The X, Y, Z moving pipettor of the automatic pipetting unit picks up a disposable pipettor tip, pipettes sample fluid and, as necessary, performs any dilution process corresponding to the selected protocol (i.e. sample preparation steps). Where dilution steps are performed, each step involves the use of a fresh disposable pipettor tip. After use, the disposable pipettor tips are ejected into the disposal tray.

v. Once the pre-analytical sample preparation steps are completed, the automatic pipettor transfers the sample (which may or may not have been diluted in a dilution step) to the sample well on the appropriate reagent strip (which has been previously inserted on a horizontally movable tray of the AU).

16. The analytical protocol associated with the assay is then performed. The tower motor moves the SPR vertically and the tray motor moves the reagent trip horizontally. The SPR is moved into the sample well, with the section pump aspirating sample into the SPR. Using the tray motor, the reagent strip is moved horizontally beneath the SPR so that the SPR is moved sequentially into the reagent wells of the reagent strip, cycling reagents into and out of the SPR using an air displacement piston. A biological reaction occurs within the SPR.

17. Defendant 1) operates the website http://www.biomerieux.com. On this website under “WHO WE ARE” and “bioMérieux Worldwide”, Defendant 1) lists all countries, in which it has subsidiaries. Defendant 1) offers challenged embodiments directly to consumers in the Unitary Patent Territory, e.g. via the link https://www.biomerieux.com/corp/en/our-offer/clinical-products/vidas-3.html. Defendant 1) also lists different subsidiary entities, such as for Germany, Austria, Portugal, Italy and the Netherlands, all within the territory of the Unitary Patent (Defendants 2) to 6)).

18. Defendant 2) also offers and distributes the challenged embodiments in the territory of the Unitary Patent (particularly Germany) e.g. via https://www.biomerieux.de/klinische-diagnostik/vidasr-3 .

19. The same applies to Defendant 3) offering and distributing the challenged embodiments in the Unitary Patent territory (particularly Italian Republic). An offer is made e.g. on the website https://www.biomerieux.it/prodotto/vidasr-3. In addition to that, Defendant 3 manufactures the challenged embodiment I as it is in the VIDAS 3 Manual which reads “Made in Italy by bioMérieux Italia S.p.A. …” (Exhibit EIP 8, page 31).

20. Defendant 4) offers and distributes the challenged embodiments in the Unitary Patent territory (particularly Republic of Austria), e.g. via https://www.biomerieux.at/klinische-diagnostik/vidasr-3 (last accessed: 11 June 2024).

21. Defendant 5) offers and distributes the challenged embodiments in the Unitary Patent territory (particularly Portuguese Republic), e.g. via https://www.biomerieux.pt/produto/vidasr-3.

22. Defendant 6) offers and distributes the infringing embodiments in the Unitary Patent terri-

tory (particularly Netherlands). The website www.biomerieux.nl redirects to https://www.biomerieux.com/nl/en.html, where the Dutch entity presents itself in English language. The navigation tab reads “Netherlands, EN”: Here, customers can navigate to the website https://www.biomerieux.com/nl/en/our-offer/clinicalproducts/ vidas-3.html where the infringing embodiments are offered. In addition, users are prompted on the English-language website of Defendant 1) to contact Defendant 6). For example, in the offer of the VIDAS 3, available on the website of Defendant 1) at https://www.biomerieux.com/corp/en/our-offer/clinicalproducts/ vidas-3.html, the visitor is pointed to the “local bioMérieux representative”. With respect to the Netherlands, this “local bioMérieux representative” of Defendant 1) is Defendant 6).

REQUESTS OF THE PARTIES:

23. The Claimant requests:

I. An injunction is granted, namely an order that Defendants cease and desist in the Unitary Patent Territory from

1. making (only Defendant 3)), offering and/or placing on the market or using or importing or storing for those purposes an instrument for detecting a biological analyte, especially “VIDAS 3”, 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.

(EP 3 756 767 B1 claim 1, direct infringement)

In the alternative (under the doctrine of equivalents), should the Court conclude that the Defendants’ VIDAS 3 instrument does not literally realise the feature “device”,

an injunction is granted in respect of an instrument wherein a sample unit comprising a sample applied by a user; wherein said device is non-monolithic.

2. offering for use within the Unitary Patent Territory a process 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.

(EP 3 756 767 B1 - claim 2, direct infringement)

In the alternative (under the doctrine of equivalents), should the Court conclude that the Defendants' VIDAS 3 instrument does not literally realise the feature "device" an injunction is granted in respect of an instrument wherein

a sample unit comprising a sample applied by a user; wherein said device is non-monolithic.

3. offering to supply and/or supplying means, specifically instruments, especially "VIDAS 3", "VIDAS 3"-compatible reagent strips and "VIDAS 3"-compatible Solid Phase Receptacles (SPR) that are suitable to carry out 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.

(EP 3 756 767 B1 - claim 2, indirect infringement)

In the alternative (under the doctrine of equivalents), should the Court conclude that the Defendants' VIDAS 3 instrument does not literally realise the feature "device" an injunction is granted in respect of an instrument wherein

a sample unit comprising a sample applied by a user; wherein said device is non-monolithic.

In the alternative (warning label), should the Court consider only a warning as an adequate means in relation to non-exclusively "VIDAS 3"-compatible reagent strips and non-exclusively "VIDAS 3"- compatible Solid Phase Receptacles (SPR), the injunction requested according to I.3. shall for those products extend only to cases in which the Defendants offer to supply or supply said items

without

- in the case of offering to supply and/or supplying to commercial customers expressly and directly visibly indicating in the offer that

  the non-exclusively "VIDAS 3"-compatible reagent strips and non-exclusively "VIDAS 3"-compatible Solid Phase Receptacles (SPR) may not be used in a "VIDAS 3" instrument with the above-mentioned features without the consent of the Claimant as the owner of EP 3 756 767 B1;

- apart from that expressly and directly visibly indicating that the offered non-exclusively "VIDAS 3"-compatible reagent strips and non-exclusively "VIDAS 3"-compatible Solid Phase Receptacles (SPR) are not suitable for use in a "VIDAS 3" instrument.

II. It is found that the products VIDAS 3, "VIDAS 3"-compatible reagent strips and "VIDAS 3"-compatible Solid Phase Receptacles (SPR) infringe patent EP 3 756 767

B1 as outlined in section I.

III. The Defendants are ordered to recall the products referred to in section I.1. and I.3. which have been put on the market since 1 May 2024 vis-à-vis the commercial customers in writing with reference to the patent-infringing condition established by the court (making reference to judgement of ... dated ...) and with a binding promise to remove them from the distribution channels, whereby the Defendants must give the commercial customers a binding promise to reimburse any fees as well as to assume any necessary packaging and transport costs as well as customs and storage costs associated with the return and to take back the products, whereby the Claimant must be provided with a sample of the recall letters as well as a list of the addressees with names and postal addresses or - at the choice of the Defendants - a copy of all recall letters.

IV. The Defendants are ordered to permanently remove the products referred to in Section I. 1. from the distribution channels by requesting, referring to the fact that this Court has found the products to be infringing European Patent EP 375 676 7 B 1, third parties who are commercial customers but not end customers to cancel all orders relating to the products mentioned in Section I. 1 which are not yet delivered and to submit written proof of the measures taken to the court, within the period of 30 days after delivery of the notification with in the meaning of R. 118.8 sent. 1 RoP and, where applicable, the certified translation.

V. The Defendants are ordered to hand over, at its - each Defendant's - expense, to a bailiff to be appointed by the Claimant, for the purpose of destruction, the products referred to in section I.1. which are in its direct or indirect possession or ownership.

VI. The Defendants are ordered to provide the Claimant with information concerning

1. origin and distribution channels of the infringing products or processes,

2. the quantities produced, manufactured, delivered, received or ordered and the prices paid for the products referred to in section I, and

3. the identity of all third parties involved in the production or distribution of infringing products referred to in section I.

dating back to 1 May 2024 whereby copies of the corresponding purchase receipts (invoices, alternatively delivery notes) are to be submitted as evidence of the information and details requiring secrecy outside the data requiring information may be redacted and the information is additionally structured by way of a chronologically ordered list.

VII. The Claimant is permitted to display and publish the decision in whole or in part in public media, whereby the Defendants must reimburse the costs for a full-page publication (print) in five national daily newspapers as well as five trade media, each at the Claimant's choice.

VIII. The Defendants are ordered to pay to the court a recurring periodic penalty payment in the amount of up to EUR 250,000.00 per day for each day of infringement

by the Defendants in the event of any infringement of the order pursuant to section I.1-I.3.

IX. The Defendants are ordered – jointly and severally –,

1. to compensate the Claimant for any damage it has suffered or will suffer in the future for all past infringements pursuant to section I. since 1 June 2024.

2. to pay the Claimant EUR 50,000.00 as interim lump-sum damages.

X. The Defendants are to bear the legal costs of the proceedings.

XI. If the decision is subject to the rendering of a security, said security may also be provided in the form of a bank or savings bank guarantee. The individual parts of the operative part may be enforced individually against the provision of security in the amount of a partial amount of the total security to be determined by the court and in the form of partial security in the following amounts

- Forms of order sought I. (injunction) EUR 4,375,000.00
- Causes of action III. and IV. (recall and removal) EUR 125,000.00
- Claim V. (surrender for destruction) EUR 125,000.00
- Claim VI. (information) EUR 125,000.00
- Claim VII. (publication) EUR 125,000.00
- Claim IX.2. (provisional damages) EUR 125,000.00.

24. The Defendants request that the Court

a) dismisses the infringement action; and

b) orders that Labrador bears all legal costs and other expenses incurred by bioMérieux as per Article 69 of the Agreement on a Unified Patent Court (UPCA).

In the alternative, in the event that infringement is found, that the Court

c) dismisses the request for an injunction under I of the requested remedies and the subsequent corrective measures of recall, removal from distribution channels and destruction under III-V of the requested remedies;

d) alternatively, orders that any decision and order granted by the Court to Labrador is subject to the rendering of security by Labrador to bioMérieux in an amount no less than the value of the action as per Rule 352 of the Rules of Procedure (RoP); and

e) in any event, dismisses the request for permission to display and publish the decision in five national daily newspapers and well as five trade media at the expense of bioMérieux.

POINTS AT ISSUE:

Claim Construction

25. Claimants argue that the skilled person will understand that the device does not need not to be monolithic and can be provided in more than one part. For the functional cooperation of the first means, the device and the second means, there is no need for the sample unit and array of reagent units to be provided as a monolithic device, especially as the claim is not limited in this way. The construct required is to form an array of reagent units, and it does not extend to holding together the reagent units and the sample unit. The device is not confined to any specific embodiment, let alone a cartridge.

26. The claimed reagent unit is interpreted as any unit (e.g. a well) in the device that is suitable for containing a reagent during the operation of the instrument. The claim only requires said unit to be "for containing" a reagent; it does not specify when the reagent must be present. Thus, a reagent unit can initially be empty (or contain sample) and later receive a reagent as the assay progresses.

27. The Defendants argue that the sample unit needs to be physically attached to the array of reagent units to form a monolithic "device". Whilst it is true to say that the patent in suit stresses that the individual unit may be modular, it unequivocally discloses that these individual modular units (sample units, assay units, reagent units) be loaded into a monolithic device (i.e. a structure for accommodating and receiving those units, such as the cartridge). The skilled person would therefore understand the "device" as a single construct or housing in which the array of reagent units and the sample unit are, or can be, held. Ultimately, the "device" may be modular (or monolithic), but it certainly would not be understood by the skilled person as encompassing a mere collection of units absent any common construct (like a housing).

28. The claimed reagent unit cannot only contain sample and a sample unit comprises sample applied manually to the sample unit by a user.

Infringement

29. The Claimant states that the reagent strip of the AU together with the sample vial/tube of the PAU constitutes the claimed device. The reagent strip provides an array of reagent units held together by a construct, and the accompanying sample vial/tube containing the patient sample functions as a sample unit. Additionally, the challenged embodiment I has "first means" for receiving the device as it comprises dedicated slots and a rack to hold the reagent strip in the AU and sample vial/tube in the PAU in place for the assay. The Claimant is of the opinion that even if the sample unit would need to be physically joined with the array of reagent units in the form of a monolithic "device", the feature of the claimed "device" is realised under the doctrine of equivalents.

30. A sample well on the VIDAS 3 reagent strip qualifies as a "reagent unit for containing a reagent for an assay to detect the biological analyte" in any conceivable configuration used by the challenged embodiment I as it is designed to contain the patient sample (diluted or not), which is – as such – a substance used in an assay to detect the analyte and, thus, is a "reagent" in the meaning of the asserted claims.

31. The Defendants state that there is no infringement due to lack of the claimed device. Furthermore, the challenged embodiment is not configured to use a first tip to move sample from a sample unit of the device into a reagent unit of the device, where the device is a construct like a housing in which the sample unit and the reagent unit are held together. The tray of the section unit moving the reagent strips and the loading bays receiving the sample by a user are no first means because they do not receive the device as a whole.

32. With regard to the remaining points of dispute between the parties, reference is made to the written submissions and the minutes of the oral proceedings.

GROUNDS FOR THE DECISION:

33. The admissible infringement action is unfounded, since the challenged embodiments do not infringe the patent in suit in its form as upheld by the Milan Central Division.

A. Entitlement

34. The question of entitlement can be left open as it is not decisive due to lack of infringement (see UPC_CFI_100/2024 (LD Düsseldorf), Decision of 15 January 2026 – Ona v Google).

B. Scope of protection and prior art

35. The patent in suit relates to modular point-of-care (POC) devices and uses thereof.

36. According to the description of the patent in suit, 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 POC setting. POC 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 (para. [0001] of the patent in suit; hereinafter paragraphs without citation are those of the patent in suit).

37. In a 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 of assays being performed is about 2 to 10. A POC capable of performing multiplexed assays on a small sample would be desirable (para [0002]).

38. A shortcoming of many multiplexed POC assay devices is the high cost of manufacturing the components of the device. If the device is disposable, the high cost of the components can make the manufacturing of a POC device impractical. Further the patent in suit states that, for multiplexed POC devices that incorporate all of the necessary reagents onboard of the device, if any one of those reagents exhibit instability, an entire manufactured lot of devices may have to be discarded even if all the other reagents are still usable.

39. When a customer is interested in a customising a POC device to a particular set of analytes, manufacturers of multiplexed POC assay systems are often confronted with a need to mix-and-match the assays and reagents of the device. A multiplexed POC assay suitable to each customer can be very expensive, difficult to calibrate, and difficult to maintain quality control

(para [0005]). POC methods have proven to be very valuable in monitoring disease and therapy (for example, blood glucose systems in diabetes therapy, Prothrombin Time measurement in anticoagulant therapy using Warfarin). By measuring multiple markers, it is believed that complex diseases (such as cancer) and therapies such as multi-drug therapy for cancer can be better monitored and controlled. The patent in suit names the document US2007/0224084 relating to systems and methods of sample processing and fluid control in a fluidic system (para [0006]).

40. Thus, according to the patent in suit, 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.

41. As a solution, the patent in suit in amended form by CD´s Milan decision of 23 October 2025, provides the following product claim and the corresponding method claim (the claims were broken down into individual features by mutual agreement between the parties, in order to facilitate comparison with the allegedly infringing embodiments):

Claim 1:

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

1.1. first means for receiving a device inserted into the instrument, the device 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;
1.1.2. and a sample unit comprising a sample applied by a user;

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 tip comprising sample or 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

1.2.2. 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,

1.2.2.1. the second pipette tip comprising a capture 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 surface configured to bind with the biological analyte.

Claim 2:

2. An method for detecting a biological analyte, comprising:

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

2.1.1. 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

2.1.2. and a sample unit comprising a sample applied by a user;

2.2. moving using second means of the instrument, 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 pipette tip or the reagent unit, to transfer sample from the sample unit to the reagent unit;

2.3. moving, using 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,

2.3.1. the second pipette tip comprising a capture surface configured to bind with the biological analyte,

2.4. and detecting, using a detection assembly of an 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.

C. Claim Construction

42. The Panel agrees to the definition of the skilled person provided by CD Milan. 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).

I. Claim 1

43. With respect to the disputed issue of how the skilled person understands the terms of first means, the device and the reagent unit, claim 1 needs further interpretation.

1. First means (feature 1.1)

44. Feature 1.1. stipulates first means for receiving a device which is inserted into the instrument. According to the wording of the claim, the first means are part of the instrument. Furthermore, these construction parts of the instrument are only characterized by their function to receive a device which is inserted into the instrument. The patent in suit shows as examples of the first means, “the stage 530 on which the device 510 sits” (para. [0121], Figure 5) and “a translational stage 630 onto which a device 610 (or cartridge in this example) is placed” (para. [0126], Figure 6). As these are only preferred embodiments they naturally do

not limit the broader claim. Any other type of the reception is covered by the claim. According to the wording of the claim, the first means is a distinct element from the device, since the latter is received by the first one.

2. Device (features 1.1, 1.1.1, 1.1.2)

45. According to the wording of the claim, the device is characterized by comprising an array of reagent units (feature 1.1.1) and a sample unit (feature 1.1.2). Due to the amendment of the patent in suit by the decision of CD Milan, the sample unit now became a constructive element of the device. The Local Division is bound to this new wording of the claims.

46. The claim does not contain any strict parameters for the construction of these components of the device. In particular, it does not go so far to require that the sample unit is part of the array of the reagent units, meaning that the sample unit does not need to be physically attached to the array of reagent units or that the device is a "single construct or housing". It does not require a strict monolithic construction nor a strict modular structure. It just leaves it to the discretion of the skilled person.

47. However, the skilled person interprets the claim as a whole and will therefore take into account the context of the other features: The second means of feature group 1.2 are configured, with the device received by the first means, to move the first and the second pipette tip in a way to transfer the sample. So, the skilled person understands that regardless of the device's construction, it must allow the sample to be moved along the claimed path. Enabling this function is the most outer limit for the constructional design of the device. Notwithstanding that the device can be construed from separate (sub-) components, there must be still some form of connection or combination making the construction a device as a whole. In this context, a simple functional link is not sufficient but the sub-components have to be spatially linked to one another due to the amended wording of the claim.

48. This understanding is supported by the description of the patent in suit making clear that the device is not synonymous with a housing. In para [0046], it is said that the device (100) comprises a housing (130) and in para. [0047] it is called the housing of the device (100). Looking at Figure 1 alongside, it is self evident that the label (100) labels the device as a whole, and the label (130) labels the housing as a component of the device. Furthermore, para. [0045] explains how the (sub-) components of the device may be affixed to each other in a variety of ways, some of which will evidently result in permanent attachment (bonding, adhesives) and others in reversible attachment (friction fitting), so the patent in suit does not distinguish between these alternatives. Since the patent refers to a modular device, an assembled device, a device including components, the device is to be interpreted as not limited to a monolithic construct or housing or cartridge, but may comprise separatecomponents, such as separate cartridges which are connected somehow.

3. Reagent unit (features 1.1.1, 1.2.1, 1.2.2)

49. The panel agrees with the interpretation of CD Milan in its decision finding in paragraph 4.15:

> "*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 ([…]) if a sample is mixed to another sample as a reagent or a sample mixed with nothing is just transferred to the second tip."

50. The panel understands the decision in the way to mean that the reagent units referred to as part of the received device (feature 1.1.1) cover, on the one hand, the reagent units from where the sample is transferred to the second tip later on (features 1.2.2.) and on the other hand also pretreatment units, where the sample is pre-treated before moved.

4. Sample applied by a user (feature 1.1.2)

51. A sample applied by the user means that the user somehow sets up the sample in the sample unit. Here, the terms "sample" and "sample unit" as well es "reagent" and "reagent unit" need to be distinguished.

52. The patent in suit covers a mixture of reagent and sample as a sample. The wording of the claim in feature 1.2.2. supports this understanding as it refers to a transfer of sample from the reagent unit to the second pipette tip. A sample coming from the reagent unit naturally is a mixture of sample and reagent. Paragraphs [0012] and [0049] of the description also refer to a pre-treatment of the (bodily fluid) sample.

53. However, the sample unit only comprises the sample applied by the user. Any automatical application is not covered. The reagent unit is not subject of such limitations. It relates to any unit comprising reagent alone of a mixture of reagent and sample during the operation of the instrument.

II. Claim 2

54. Claim 2 is a method claim covering a method for detecting a biological analyte, with four method steps in distinguished order. There are no differences in the understanding of the claimed components executing the method step.

D. Infringement

55. The Court cannot find on infringement of the challenged embodiments.

I. Direct Infringement (product claim 1) by challenged embodiment I

56. Applying the claim construction outlined above the Claimant failed to show that the challenged embodiment I is an instrument with first means for receiving a device inserted into the instrument which comprises an array of reagent units and a sample unit comprising a sample applied by the user (features 1.1, 1.1.1, 1.1.2).

57. In its written submissions, the Claimant states, the reagent strip together with the sample vial/tube constitutes the claimed "device". The "first means" are the dedicated slots on the movable trays of the AU to hold the reagent strip and the sample vial/tube in place for the

assay on the PAU. As a consequence, the first means and the device are not distinct as long as they refer to the same sample vial/tube in the PAU, which does not comply with the claim wording and claim construction assessed by the Court. Indeed, the sample vial/tube can not receive itself. Feature 1.1 is not reproduced.

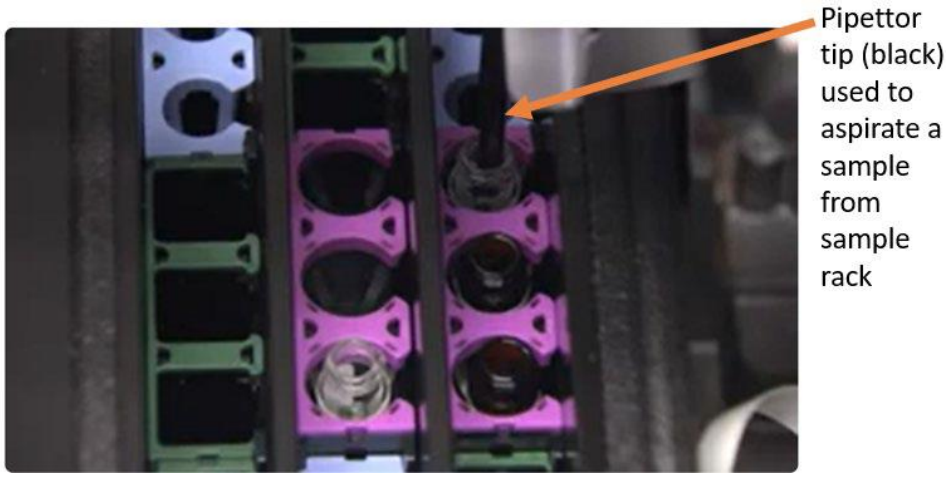
58. The Claimant reiterated at the oral hearing that the key point is that it sees the "device" not as a structural feature, but as a functional feature. And what makes the sample vial part of the device is just a conceptual linking. The Claimant went so far as to consider that the claim should be construed as if it had been drafted without reference to the device. In the Claimant's view, there is not necessarily any difference between reciting just two elements (reagent units and sample unit) and reciting a device comprising these two elements.

59. However, the Claimant is bound by the wording of claim 1. In the Court's view, it is not reasonable to construe the claim in such a way that a claimed feature can be omitted.

60. The sample vial/tube containing samples applied by the user are located in the PAU and the reagent strips which are an array of reagent units are located in the AU. Undisputedly, they are spatially separated. They are not arranged on any kind of sub-component – apart from being comprised inside the instrument – forming a connection so that the skilled person can consider the sample vials and the reagent strips as two units comprised by a device as a whole. Features 1.1, 1.1.1 and 1.1.2 in combination are not reproduced.

61. At the oral hearing, for the first time, the Claimant referred, as a subsidiary argument, to the purple sub-racks on the rack structure as part of the device to hold the sample vial/tube as being the sample unit for receiving the sample applied by the user. In such a case, the sample unit and the device are distinct elements.

62. Even if the Court were to allow this new submission, which is doubtful given the structure of the front-loaded proceedings and the fact that the parties had two further opportunities to submit written responses after the CD Milan decision was issued, this would not convince the Court of infringement. In that case, the reagent units still are in a different location without any connection to the sample units. It also raises an issue regarding the device which should then be considered as comprising the purple sub-rack on the PAU and the reagent strips on the AU, without any connection between them (see picture below taken from the SoC, page 41). Only a conceptual linking due to the set up of the challenged embodiment I is not sufficient to show the device in the meaning of the patent in suit.



II. Infringement by equivalence (product claim 1) by challenged embodiment I

63. First, the question of admissibility of the infringement by equivalence, objected by the Defendants, can be left open as it is not decisive due to lack of infringement by equivalence.

64. As even the broad interpretation does not lead to infringement, there is no room for infringement by equivalence. The alleged equivalent addresses the modular construction of the array of reagent units and the sample unit which is already covered by the literal wording of the claim. Additionally, the alleged equivalent does not perform essentially the same function as the device of claim 1, since no means distinct from the sample unit is identified by the claimant as performing the function of the device "to comprise the reagent units and a sample unit".

III. Direct Infringement (method claim 2) by challenged embodiment I

65. Beside the fact that there is no direct infringement due to the same reasons as outlined before which also apply to the method claim 2, there is also no offering, since it is not the Defendants who offer to use the method, but the users (customers/labortories) who implement the method of claim 2. The offering for use mentioned in Art. 25 (b) UPCA aims at the offering of the process implemented by third parties for who the Defendants need to sign responsibility. That is also not the case here.

IV. Indirect Infringement (method claim 2) by challenged embodiments I and II

66. Indirect infringement also fails due to the construction of the challenged embodiment I. Therefore, the challenged embodiments II are not used for a method in the meaning of claim 2.

E. Preliminary opinion of the EPO

67. In a bifurcated case in which the Court does not find on infringement, the question of validity of the patent in suit is no longer decisive for the infringement action.

F. Decision on costs and ceiling

68. According to Art. 69(1) UPCA in conjunction with R. 118.5 RoP, a decision on costs has to be made. Since the Claimant has been unsuccessful in its action for infringement, it must bear the costs in this respect.

69. Pursuant to Art. 69(1) UPCA, the costs are to be borne up to a maximum amount determined in accordance with the Rules of Procedure. With a value in dispute of € 5,000,000 for the infringement action, the table adopted by the Administrative Committee on April 24, 2023, on the basis of R. 152.2 RoP, which neither party has objected to in the oral hearing, the maximum limit for reimbursable costs is determined at € 600,000.

DECISION AND ORDER:

I. The infringement action is dismissed.

II. The costs of the infringement action shall be borne by the Claimant.

III. The value in dispute for the infringement action is set at € 5,000,000.

IV. The ceiling of recoverable representation costs is set at a total of € 600,000 for the infringement action.

Düsseldorf on 28 January 2026
NAMES AND SIGNATURES

Presiding Judge Thomas	Ronny Thomas Digital unterschrieben von Ronny Thomas Datum: 2026.01.26 18:07:37 +01'00'
Legally qualified Judge Dr Thom	Anna Bérénice Dr. THOM Digital unterschrieben von Anna Bérénice Dr. THOM Datum: 2026.01.26 17:45:43 +01'00'
Presiding Judge Thomas on behalf of Legally qualified Judge Bessaud	Ronny Thomas Digital unterschrieben von Ronny Thomas Datum: 2026.01.26 18:18:20 +01'00'
Technically qualified Judge Abello	Michel, Robert, Gérard Abello Signature numérique de Michel, Robert, Gérard Abello Date : 2026.01.26 21:01:15 +01'00'
For the sub-registrar	LAURA CHANTAL DANIEL Digital unterschrieben von LAURA CHANTAL DANIEL Datum: 2026.01.27 10:36:18 +01'00'

INFORMATION ON APPEAL:

An appeal against this decision may be brought before the Court of Appeal by any party whose claims have been unsuccessful, in whole or in part, within two months of service of the decision (Art. 73(1) UPCA, R. 220.1 (a) RoP, 224.1 (a) RoP).

INFORMATION ON ENFORCEMENT (Art. 82 UPCA, Art. 37(2) UPCS, R. 118.8, 158.2, 354, 355.4 RoP):

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

INSTRUCTION TO THE REGISTRY:

A certified copy of the decision shall be sent to the European Patent Office and the German Patent and Trade Mark office as soon as the decision on the revocation action has become legally binding.

This decision was read in open court on 28 January 2026.
Presiding Judge Thomas

Ronny Thomas

Digital unterschrieben von Ronny Thomas
Datum: 2026.01.28 09:22:45 +01'00'