COURT OF FIRST INSTANCE
MILAN LOCAL DIVISION

UPC CFI no. 1086/2026
order
issued on 7 September 2026

HEADNOTES:

The Court considers that, in the specific circumstances of the present case, the new defence arguments submitted by the respondents for the first time in their last written submission concerning the interpretation and infringement of feature 1.6 are admissible.

For the purpose of assessing the admissibility of the new arguments raised by the respondents with regard to the interpretation and infringement of feature 1.6, the following considerations are relevant.

First, it should be emphasised that claim construction is a matter of law, on which the Court may therefore also elaborate *ex officio*. The classification of this issue as a matter of law also entails that, had this Court held the respondents' new submissions on this point to be inadmissible at first instance, the Court of Appeal could, in all likelihood and in full compliance with the adversarial principle, have taken those same arguments into consideration, with the practical consequence that one level of jurisdiction on a substantive issue in the present dispute would have been lost (for such a case, specifically related to non-infringement arguments, see UPC CoA no. 36/2026, order of 8 July 2026, para. 158 et seq.).

At the same time, it is essential and indispensable that the opposing party is always given the opportunity to be heard, in accordance with the adversarial principle and the right of defence.

The respondents introduced this new argument in their last written submission, filed one month before the oral hearing, without relying on any additional factual element or document that had not been on the case file from the outset of the proceedings.

Against that procedural background, significance must also be attached to the applicant's conduct, since the applicant merely objected to the late filing, without requesting, even in the alternative or as a subsidiary request, the grant of a short time limit to file a reply confined to that specific issue.

During the oral hearing, the applicant was in fact given an adequate opportunity to respond to that specific argument, both as regards the interpretation of the claim and as regards infringement of the patent.

All the foregoing considerations must be assessed in the specific context of proceedings for provisional measures, where there is considerable time pressure and the parties are required to organise their arguments within very short time limits.

A different conclusion would amount to an overly rigid application of the front-loaded character of UPC proceedings, at least in the specific context of proceedings for provisional measures, with an excessive and in any event disproportionate impairment of the effectiveness of the right of defence.

APPLICANT

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1360 South Loop Road, Alameda, CA 94502, United States of America

represented by

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RESPONDENTS

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2) SIBIONICS GMBH

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3) SIBIO TECHNOLOGY LIMITED

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4) SIBIO PTE LTD.

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PATENT AT ISSUE

EP 3 960 072 B1 (hereafter referred to as EP'072) entitled "*Compact on-body physiological monitoring devices and methods thereof*"

DECIDING JUDGE

This order has been issued by the Court of First Instance - Milan Local Division in the following panel:

-	Pierluigi	PERROTTI	presiding judge and judge rapporteur
-	Alima	ZANA	legally qualified judge
-	Samuel	GRANATA	legally qualified judge
-	Steen	WADSKOV-HANSEN	technically qualified judge

LANGUAGE OF PROCEEDINGS

English

SUBJECT-MATTER OF THE ORDER

Application R. 206 RoP

DATE OF THE HEARING

14 July 2026

1. Summary of facts.

On 27 March 2026, Abbott Diabetes Care Inc. (hereafter Abbott) filed an application for provisional measure against 1) Shenzhen SiSensing Co., Ltd, 2) SiBionics GmbH, 3) Sibio Technology Limited, 4) Sibio PTE Ltd. and 5) Shanghai International Holding Corp. GmbH (hereafter, jointly, "the respondents" or, individually, SiSensing - respondent 1), SiBionics - respondent 2), Sibio Technology - respondent 3), Sibio PTE - respondent 4), Shangai International - respondent 5), pursuant to Articles 62, 60(5) UPCA and R. 206.3 RoP indicating that main proceedings on the merits of the case had not yet been started before the Court.

Abbott was the proprietor of EP'072 (hereafter also "the patent"), titled "*Compact on-body physiological monitoring devices and methods thereof* ".
The patent was filed on 2 February 2010 and granted on 11 December 2024.
Two opposition proceedings were filed before the EPO, the first by [redacted] and the second by Strawman limited. The Opposition Division submitted a (non-binding) preliminary opinion on 13 April 2026, followed by the intervention of respondent 3) in the opposition proceedings on 24 June 2026 and by an addendum to the preliminary opinion on 2 July 2026.
Abbott already filed an application for provisional measure before the UPC - The Hague Local Division against MicroTech Medical (Hangzhou) Co., Ltd. and other six related parties.
The Court granted the requested provisional measures by order of 6 February 2026. No appeal was filed.

Abbott developed and was a market leader in solutions for continuous glucose monitoring ("CGM") systems for diabetes. In 2014 it launched the *FreeStyle Libre* CGM system, which revolutionized the glucose monitoring market with an easy to use, affordable and accurate CGM, which was factory calibrated, meaning the user did not have to calibrate the device using finger-pricks. Abbott has continued to innovate the *FreeStyle Libre* since, with the latest version named the *FreeStyle Libre 3 Plus*. All versions are collectively referred to as *FreeStyle Libre*.
Abbott was the main supplier of CGM products in the Contracting Member States and Spain. The applicant served over 1.3 million patients with its products and had a substantial market share.

According to the applicant, the respondents intended to manufacture, sell, import and place on the market a device named GS3-R System (hereafter also "infringing product"), that infringed on EP'072.

SiSensing was a Chinese company that manufactured the infringing products. It was involved in - at least - the manufacturing and/or importing of the GS3-R for - at least - Bulgaria, Germany, Italy, Latvia, Lithuania and Slovenia. Respondent 1) was a parent company of respondent 3).

SiBionics was a German company that imported the GS3-R. It was involved in - at least - the importing of the GS3-R System for - at least - Bulgaria, Germany, Italy, Latvia, Lithuania and Slovenia.

Respondent 2) was a wholly owned subsidiary of respondent 3).

Sibio Technology was a Hong Kong company that controlled and operated the website sibioniscgm.com (hereafter "the Website"). It was involved in - at least - the offering/selling or importing of the GS3-R System or supporting this for - at least - Bulgaria, Germany, Italy, Latvia, Lithuania and Slovenia. Respondent 3) was wholly owned by respondent 1) and also owned shares of respondent 4).

Sibio PTE was a Singaporean company that was involved in the operation of the website. It was involved in - at least - the offering/selling or importing of the GS3-R System or supporting this for - at least - Bulgaria, Germany, Italy, Latvia, Lithuania and Slovenia. Respondent 4) was a subsidiary of the respondent 3).

The German company Shangai International was the EU Authorised Representative of the GS3-R, under Regulation (EU) 2017/745. Accordingly, additionally or in the alternative, respondent 5) was an intermediary within the meaning of Art. 63(1) UPCA, which makes a decisive contribution to ensuring that the GS3-R System can be placed on the market in the Contracting Member States in which the patent is in force in an infringing manner. It was involved in the offering/selling or importing of the GS3-R and/or providing intermediary acts in relation to the acts of the respondents 1), 2), 3) and 4) for - at least - Bulgaria, Germany, Italy, Latvia, Lithuania and Slovenia.

The GS3-R product was substantially identical to another CGM system previously placed on the market in Spain by the respondents under the name GS3. The sole difference was that GS3-R was provided with a dedicated reader, as acknowledged by the respondents, and this element was not relevant for this case.

The applicant alleged infringement to the independent claim 1 and to dependent claims 2, 3, 4, 5, 6, 7, 8 and 9 of the patent.

The respondents filed their objection to the application for provisional measure on 13 May 2026.
They challenged the validity of the patent on the grounds of sufficiency of disclosure, added matter and lack of inventive step. They also disputed that the GS3-R was infringing on EP'072.

The judge-rapporteur authorised a second round of written submissions, which were filed, respectively, on 29 May 2026 by the applicant and on 12 June 2026 by the respondents.

After the expiry of the latter time limit, on 17 June 2026 Abbott filed a written submission raising an objection of inadmissibility in respect of certain new defence arguments introduced by the respondents for the first time only in their last written submission of 12 June 2026, in particular with regard to the interpretation and infringement of feature 1.6.

Subsequently, by written submission of 2 July 2026, the applicant requested authorisation to file new documents which had come into existence after the expiry of the time limits for the written procedure, namely the notice of intervention filed by respondent 3)) in the proceedings before the EPO Opposition Division and the addendum to the preliminary opinion filed by the Opposition Division.
The judge-rapporteur authorised the production of those documents by order of 3 July 2026. The respondents raised no objections. Those documents must therefore be regarded as having been finally admitted to the case file in the present proceedings.

The parties discussed the application at the oral hearing held on 14 July 2026.
During the hearing, Abbott maintained its objection that the respondents' new submissions concerning the interpretation and infringement of feature 1.6 were inadmissible and, at the same time, also addressed the substance of those submissions.

2. Requests of the parties.

Abbott requests that the Court orders the following by way of provisional measures:

(a) prohibiting the respondents, individually and jointly, on a provisional basis, from infringing the patent in any way, with immediate effect after service of the order to be rendered in this matter, in particular by offering, placing on the market, and/or using, the GS3-R System (or components thereof) as well as by importing or storing the GS3-R System for those purposes for each of the Contracting Member States in which the patent is in force (in the Contracting Member States of Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Portugal, Romania, Slovenia and Sweden) [Art. 62(1), Art. 25 UPCA];

(b) prohibiting the Fifth respondent from exercising its services as the EU Authorised Representative in respect of the GS3-R System within the meaning of the MDR in such a way that the infringing acts complained of are carried out for each of the Contracting Member States in which the patent is in force (in the Contracting Member States of Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Portugal, Romania, Slovenia and Sweden) [Art. 64(1) (2)a UPCA];

(c) declares that the GS3-R System are considered "goods suspected of infringing an intellectual property right" within the meaning of Article 2(7)(a) of Regulation (EU) No. 608/2013 [Art. 64(1) (2)(a)];

(d) orders the respondents to provide within four weeks after service, of the order rendered in this matter, to Abbott's representative a written account with the full names and address details of the origin and distribution channels of the GS3-R System, including the full names and addresses of the legal entities and any other non-consumer third person(s) that are involved in the manufacture of and trade in the GS3-R System within the territory of the Contracting Member States in which the patent is in force (in the Contracting Member States of Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Portugal, Romania, Slovenia and Sweden) [Art. 67(1) UPCA];

(e) orders the respondents to deliver up, within one week after service of this order, to a bailiff appointed by Abbott, at their own expense, of any GS3-R System in stock and / or otherwise held, owned or in the direct or indirect possession of the respondents, within the territory of the Contracting Member States in which the patent is in force (in the Contracting Member States of Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Portugal, Romania, Slovenia and Sweden) [Art. 62(3) UPCA, R. 211.1(b) RoP];

(f) orders each respondent to pay to the Court a penalty sum of up to EUR 100,000.00 for each day or part of a day that it does not comply with the injunction at (a) with a maximum of EUR 1,000,000 per respondent and a penalty of EUR 10,000 for each day or part of a day that it does not comply with the orders at (d) and (e) with a maximum of EUR 100,000 per respondent, or EUR 100 for each product with which the orders are violated (per day or per product determined by whichever leads to the higher amount); the penalties will be determined by this Local Division of the Court upon request by Abbott [Art. 63(2) UPCA, R. 354.3 RoP];

(g) orders the Fifth respondent to pay to the Court a penalty sum of up to EUR 100,000.00 for each day or part of a day that it does not comply with the injunction at (b) with a maximum of EUR 1,000,000; the penalties will be determined by this Local Division of the Court upon request by Abbott;

(h) appends an order for the enforcement to its decision, while declaring that the judgment is immediately enforceable [Art. 82(1) UPCA];

(i) orders the respondents to jointly and severally bear reasonable and proportionate legal costs and other expenses incurred by Abbott in these proceedings and orders, insofar such costs are to be determined in separate proceedings for the determination of such costs, that the respondents pay to Abbott an interim award of costs in the amount of EUR 200,000 within 14 days after service of the order in this matter [Art. 69 UPCA, R. 118.5 and 150.2 RoP].

The respondents request the Court to:

I. reject the application for provisional measures in its entirety.

II. order that the applicant bears the costs of the proceedings. In case such costs are to be set in separate proceedings as requested by the applicant, order the applicant to pay the respondents an interim award of costs in the amount of 200,000 € within 14 days after service of the order in this matter.

III. in the alternative, in case the Application is granted, to:
   a. dismiss the penalty requested by the applicant or reduce any penalty to an amount deemed appropriate by the Court.
   b. order that the provisional measures shall be revoked if the applicant fails to initiate proceedings on the merits within the prescribed timeframe.

3. Guiding principles for the assessment of an application for provisional measures.

The guiding principles for the assessment of an application for provisional measures in the RoP have been established in the case law of the UPC (UPC CFI no. 317/2024, LD Lisbon, order of

15 October 2024; UPC CFI no. 582/2024, LD Brussels, order of 21 March 2025, with reference to the relevant case law of the court of first instance and the court of appeal).
For ease of reference, these guiding principles (also taking into consideration UPC CoA no. 382/2024, order of 14 February 2024) and more specifically the conditions for granting an application for provisional measures, are set out below:

- entitlement: an applicant should provide reasonable evidence with a sufficient degree of certainty that he is entitled to initiate proceedings under Art. 47 UPCA (Art. 62(4) UPCA).
- validity and infringement: an applicant should provide reasonable evidence with a sufficient degree of certainty that the patent is valid and that its rights are being infringed, or that such infringement is imminent (Art. 62(4) UPCA and R. 211.2 RoP).
- urgency: an applicant should prove its need for early and prompt protection of its right to avoid further damage resulting from delays in resolving the case on its merits. This would not be the case if an applicant has acted negligently or hesitated in requesting provisional measures after gathering all the necessary elements for legal action (from an objective standpoint and taking into consideration factual circumstances). To assess urgency from an objective standpoint, it is necessary that the applicant provides the Court with a specific date when he became aware of the alleged infringement. (R. 211.4 RoP).
- weighing the interest of the parties: an applicant should prove that the balance of interests weighs in his advantage (Art. 62(2) UPCA, R. 209.1(b), 211.2 and 211.3 RoP); the risk of an irreparable harm - and therefore necessity of the measure - has to be considered in comparison to the interests of the counterparty.

Only a *prima facie* analysis of the facts (conditions) is required. Such *prima facie* analysis is articulated in R. 211.2 RoP by only requiring from an applicant to prove with "a sufficient degree of certainty" the made allegations. Achieving a sufficient degree of certainty requires the Court to consider it "at least more likely than not" that the conditions of mentioned rule are met: (i) the applicant is entitled to initiate proceedings, (ii) the patent is valid, and (iii) the patent is infringed.
Although the mentioned conditions already state that it is up to an applicant to provide the requested evidence (and as such bears the burden of proof), the burden of proof that the patent is not valid in respect of inter partes preliminary injunctions lies with the respondent.
The *prima facie* analysis (articulated as "a sufficient degree of certainty") does not apply for the assessment of (i) the (international or substantive) jurisdiction of the UPC and (territorial) competence of a division (which foregoes any decision or order of the Court), (ii) the requirement of urgency, and (iii) the weighing of interests.
It should be noted that the mentioned conditions are of a cumulative nature in the sense that not meeting one of these conditions implies the claims for provisional measures to be held unfounded without the necessity or obligation for the Court to further assess any other requirement. Such limited assessment is in line with the purpose of an application for provisional measures and the procedural-economy of such proceedings which should not lead to a mini-trial on the merits.

4. The patent at issue.

EP'072 has been granted with the title "*Compact on-body physiological monitoring devices and methods thereof*" by the European Patent Office on 11 December 2024.
The original application has a filing date of 2 February 2010 and claims priority of US 698424 and US69812910 of 1 February 2009 and of US149639P of 3 February 2009.
EP'072 was filed on 24 August 2021 as a divisional application of the parent application EP 3 730 044 (EP20177703.4), itself filed as a divisional application of the grandparent application EP 3 329 842 (EP17201183.5), itself filed as a divisional application of the great grandparent application EP 2 393 418 (EP10739031.2) published as WO 2010/091028.
Therefore, EP'072 is a third-generation divisional application with WO 2010/091028 as the earliest parent application.

Two opposition proceedings were filed before the EPO, the first by [redacted] the second by Strawman Limited. A notice of intervention was filed by SenEaron Healthcare Limited on 14 November 2025 and a further notice of intervention was subsequently filed by Sibio Technology Limited on 24 June 2026.
The Opposition Division issued its non-binding preliminary opinion on 13 April 2026, followed by an addendum of 2 July 2026.

The patent was initially opted out of the exclusive competence of the UPC. The opt out was withdrawn on 22 August 2025.

The patent relates to a glucose sensor insertion assembly for positioning an on-body patch device, including sensor and sensor electronics assembly.
The background of the invention acknowledges that ease of insertion, minimal user intervention, and compact on-body size are important for usability and comfort (para. [0004]).
The invention addresses this by providing an integrated on-body assembly that includes a transcutaneously positioned analyte sensor and sensor electronics in a compact, low-profile assembly coupled to an insertion device for deployment (para. [0011] of the application as filed).
The key concept is a single integrated assembly that combines the sensor and its electronics, which can be positioned on the body using an insertion device. This contrasts with earlier systems that often required a separate sensor insertion followed by the manual attachment of an electronics unit (para. [0003]).
The technical problem addressed is improving the safety, ease, and comfort of use of a continuous glucose monitoring (CGM) device. The solution is a fully integrated sensor insertion assembly where the sensor and its electronics are pre-assembled within the housing of an insertion device, allowing for a simplified, single-action deployment onto the user's skin, followed by an automatic retraction of the introducer (needle).

The insertion device and its operation can be seen, for example, in Figures 12A – 12G. This embodiment is primarily described at para. [0115] – [0119].

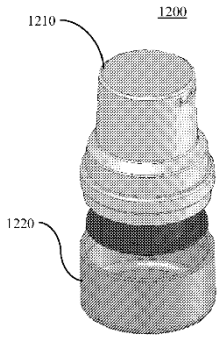


FIGURE 12A

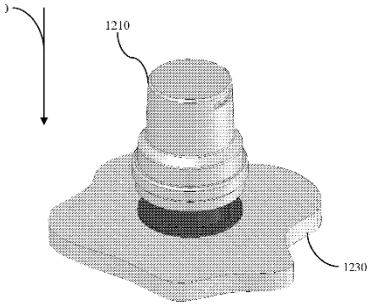


FIGURE 12B

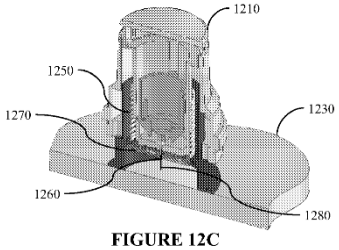


FIGURE 12C

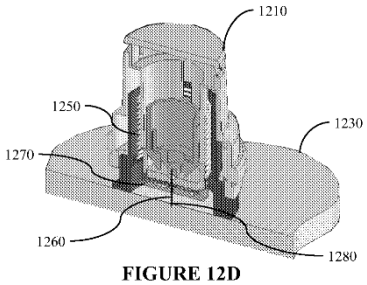


FIGURE 12D

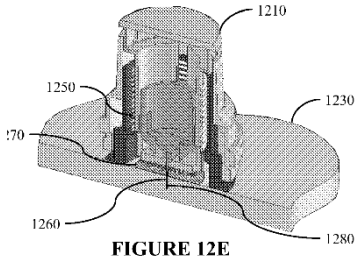


FIGURE 12E

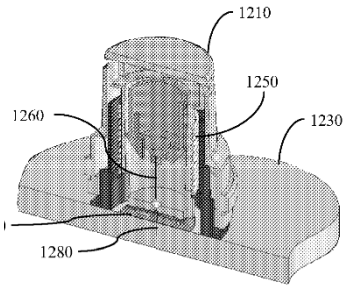


FIGURE 12F

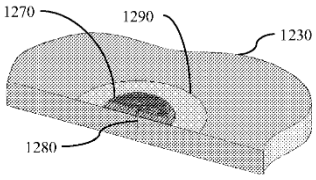


FIGURE 12G

Para. [0115] FIGS. 12A-12B illustrate pre-deployment and post insertion configurations of the insertion device for positioning the on-body patch device including sensor and sensor electronics assembly in accordance with embodiments of the present disclosure. Referring to FIG. 12A, insertion device 1200 in one embodiment includes a housing or body 1210 and a cap 1220 which is configured to provide closure or seal on the open end of the insertion device. As shown, the insertion device 1200 may be configured for sensor insertion and sensor electronics assembly positioning in a direction substantially perpendicular to the skin surface.

Para. [0116] Referring to FIG. 12B, when a force, e.g., a manual force, is applied upon the top end of the housing 1210 in the direction as shown by arrow 1240, and with the open end of the housing on the skin surface 1230, the integrated sensor and sensor electronics assembly provided within the housing (not shown) is configured to come into contact with the skin surface 1230. Furthermore, the force applied as discussed above also may be configured to

move the introducer (not shown) within the housing in the same direction as shown by arrow 1240 to pierce the skin surface 1230 and position the sensor in fluid contact with an analyte of the user.

Para. [0118] As shown in these figures, in response to the force applied on the insertion device housing 1210, the introducer 1260 is driven in a direction substantially perpendicular to the skin surface 1230, and along with the movement of the introducer 1260, the sensor 1280 and the sensor electronics assembly 1270 are moved in the same direction [...].

Para. [0119] Referring back to the Figure, it can be seen that the introducer needle 1260 is substantially and entirely retained within the insertion device housing 1210 after sensor insertion [...].

Para. [0148] Moreover, as discussed above, the insertion device in embodiments of the present disclosure includes a sharp needle or introducer for aiding the transcutaneous insertion of the sensor through the skin layer of the user. The sharp needle or the introducer may be configured to be retracted within the insertion device housing after deployment to permit movement, such as tilting or angled movement, to position the adhesive on the housing of the sensor electronics onto the skin surface of the user without the introducer interfering such movement. Also, by retaining the introducer within the insertion device housing after insertion, the disposal of the used introducer may be safer, without presenting possible biohazard concerns.

Para. [0150] In a further embodiment, the insertion device may be configured for manual deployment with spring biased or automatic retraction of the introducer. That is, sensor insertion, the user may apply a predetermined amount of pressure upon the housing of the insertion device to insert the introducer and the sensor, the applied pressure sufficient to pierce through the skin layer of the user, and the device housing configured such that the applied pressure or the distance travelled by the introducer is predetermined (for example, by the use of a stopper or a protrusion within the inner wall of the insertion device that effectively stops of blocks further downward movement of the introducer towards the skin piercing direction after the introducer has reached a predetermined distance. In one aspect, the applied pressure may be configured to also press down upon a spring or a bias mechanism provided within the housing of the insertion device such that, when the applied pressure is released, the introducer is automatically retracted to its original pre-deployment position within the housing of the insertion device, by the return force from the spring or bias mechanism.

The patent comprises 9 claims, of which claim 1 is independent.
Claim 1 of the patent reads as follows (the following features' breakdown has been accepted by all parties):

1.1 A glucose sensor insertion assembly for positioning an on-body patch device including sensor and sensor electronics assembly, the insertion assembly comprising:
1.2 an insertion device (1200) comprising:
1.3 a housing (1210),

1.4 an introducer (1260),
1.5 a bias mechanism (1250), and
1.6 a cap (1220) configured to provide a closure or seal on an open end of the insertion device (1200); and
1.7 an integrated glucose sensor (1280) and sensor electronics assembly (1270) provided within the housing (1210);
1.8 wherein the introducer (1260) is configured to pierce the skin surface (1230) of a user and position the glucose sensor in fluid contact with a body fluid of the user;
1.9 wherein the insertion device (1200) is configured to move the introducer (1260) and the integrated glucose sensor (1280) and sensor electronics assembly (1270) within the housing (1210) towards the skin surface (1230) of the user in a direction substantially perpendicular to the skin surface (1230);
1.10 wherein the bias mechanism (1250) is configured to retract the introducer (1260) from an insertion position to a retracted position in which the introducer (1260) is entirely retained within the housing (1210);
1.11 wherein the glucose sensor insertion assembly is configured such that when the insertion device (1200) is removed from the skin surface (1230), the sensor electronics assembly (1270) is retained on the skin surface (1230), while the position of the glucose sensor (1280) is maintained in fluid contact with the body fluid of the user under the skin surface (1230); and
1.12 wherein the sensor electronics assembly (1270) is configured to communicate with a reader device or receiver unit via a Bluetooth enabled communication link.

5. Admissibility of arguments related to feature 1.6.

The Court considers that, in the specific circumstances of the present case, the new defence arguments submitted by the respondents for the first time in their last written submission concerning the interpretation and infringement of feature 1.6 are admissible.

For the purpose of assessing the admissibility of the new arguments raised by the respondents with regard to the interpretation and infringement of feature 1.6, the following considerations are relevant.

First, it should be emphasised that claim construction is a matter of law, on which the Court may therefore also elaborate *ex officio*. The classification of this issue as a matter of law also entails that, had this Court held the respondents' new submissions on this point to be inadmissible at first instance, the Court of Appeal could, in all likelihood and in full compliance with the adversarial principle, have taken those same arguments into consideration, with the practical consequence that one level of jurisdiction on a substantive issue in the present dispute would have been lost (for such a case, specifically related to non-infringement arguments, see UPC CoA no. 36/2026, order of 8 July 2026, para. 158 et seq.).

At the same time, it is essential and indispensable that the opposing party is always given the opportunity to be heard, in accordance with the adversarial principle and the right of defence.

The respondents introduced this new argument in their last written submission, filed one month before the oral hearing, without relying on any additional factual element or document that had not been on the case file from the outset of the proceedings.
Against that procedural background, significance must also be attached to the applicant's conduct, since the applicant merely objected to the late filing, without requesting, even in the alternative or as a subsidiary request, the grant of a short time limit to file a reply confined to that specific issue.
During the oral hearing, the applicant was in fact given an adequate opportunity to respond to that specific argument, both as regards the interpretation of the claim and as regards infringement of the patent.

All the foregoing considerations must be assessed in the specific context of proceedings for provisional measures, where there is considerable time pressure and the parties are required to organise their arguments within very short time limits.
A different conclusion would amount to an overly rigid application of the front-loaded character of UPC proceedings, at least in the specific context of proceedings for provisional measures, with an excessive and in any event disproportionate impairment of the effectiveness of the right of defence.

6. Claim interpretation.

6.1. In general.

The applicant submits that the claim should be given a broader construction, based primarily on its wording. In the applicant's view, the claim defines the invention by reference to its function, whereas the mechanism shown in Figures 12A to 12G is merely one example of how the invention may be carried out.
In support of that position, the applicant relies on UPC case law according to which claims should not be limited to preferred embodiments.

The respondents, by contrast, argue for a narrower construction, limiting the claim to the specific embodiment shown in Figures 12A to 12G. They submit that the claimed functions, in particular movement and retraction, are enabled only by a "*movable inner housing*" — the darker shaded part shown in the drawings — which, although not expressly named or numbered, is structurally and functionally essential. On that basis, any device achieving those functions by a different mechanism would fall outside the scope of the claim.

The Court considers that the dispute essentially turns on whether the claims are to be read functionally, as submitted by Abbott, or whether they are structurally limited to the single embodiment described in the patent, as submitted by the respondents.
The preliminary opinion of the Opposition Division appears, at least implicitly, to favour a broader construction, in so far as it rejects the contention that the "*inner housing*" constitutes an essential limiting feature.

The Opposition Division observed that the "*inner housing*" is not mentioned in the text of the patent application and is merely the opponents' interpretation of a drawing, which cannot, as such, be used to limit the claim (preliminary opinion, paragraph 20).
Furthermore, according to the ordinary principles of claim interpretation applied by the UPC, the claims are the starting point, while the description and drawings must be used to interpret those claims.
Accordingly, limiting the claim to an element which is not described in the text of the patent, but is inferred only from a drawing, would appear to be difficult to reconcile with the principle that the claim wording is the starting point for interpretation. Conversely, a purely functional construction which disregards the only mechanism expressly described in the patent would also be open to objection. The most appropriate construction is therefore a balanced one, under which the functional wording of the claim is interpreted in the light of the principles disclosed in the embodiment, without being strictly confined to every structural detail of that embodiment.
On the basis of the granted patent, the application as filed, the parties' submissions and the preliminary opinion of the Opposition Division, the following construction of the disputed claim features appears to be the most appropriate. It takes account of the need for a balanced interpretation, informed by the disclosure of the patent but not limited to a single embodiment.

6.2. Feature 1.6.

"*a cap configured to provide a closure or seal on an open end to the insertion device*"

The applicant submits a broad interpretation that is based on the wording of the claim, where the sterilization functionality is not even considered, as it is mentioned only in some embodiments cited by the respondents.

According to the respondents, the cap does not enclose the components within the housing.
The claim and the patent's disclosure (e.g., EPA1 WO2010091028, [0147], [0202]) mean that the cap's function is to seal the opening of the housing, thereby protecting the components inside the housing.
The cap is an element that closes or seals an open end of the housing of the insertion device and encloses the electronics assembly and the introducer within the housing, i.e. these elements are not contained in the cap. The cap further ensures that (at least) the sensor and sensor electronics assembly are maintained in a safe and sterile environment within that housing.

The opinion of the Court is that a balanced construction lies in understanding what technical problem the cap is disclosed to solve.
The claim requires a "*cap*" that performs the function of providing a "*closure or seal*" on an "*open end*" of the insertion device's housing.
The patent's description repeatedly clarifies the purpose of this cap and seal.
Paragraph [0147] of the granted patent (EP3960072B1) states that the cap "*provides a safe and sterile environment* [...] *for the sensor provided within the insertion device*".
Paragraph [0202] further specifies that when the cap is coupled to the housing, "*the interior space of the housing is maintained in a substantially contaminant free environment*".

These passages provide a direct and unambiguous teaching that the function of the cap is not merely to cover an opening, but to effectively seal the interior of the housing from the external environment to protect the components held within it, particularly the sensor and introducer, and maintain their sterility.
The essential technical principle is the provision of a protective barrier that ensures the integrity and sterility of the pre-loaded, ready-to-use insertion assembly up to the point of deployment. A component that does not achieve this functional outcome can be argued to not embody the teaching of the patent.
The feature "*a cap configured to provide a closure or seal*" must be construed as a component that mates with the housing of the insertion device to form a barrier that is sufficient to maintain the interior space of the housing in a substantially sterile and contaminant-free environment, thereby protecting the sensor and introducer assembly located within that housing.

6.3. Movable inner housing.

features 1.9, 1.10, 1.11, in conjunction with feature 1.7

The respondents argue that EP'072 is particularly concerned with functional aspects relating to the movement of components within the claimed insertion device, resulting in the application of the on-body device ("OBD") onto the user's skin and in the retraction of the introducer.
Features 1.9, 1.10, 1.11 in conjunction with feature 1.7 provide for a specific functioning of the device, as follows:

(i) in the initial position, the OBD is within the housing;
(ii) the insertion device moves the OBD towards the skin surface of the user in a direction substantially perpendicular to the skin surface;
(iii) the bias mechanism retracts the introducer from an insertion position to a retracted position in which it is entirely retained within the housing, and
(iv) the sensor electronics assembly remains on the skin when the insertion device is removed, while the sensor remains in fluid contact under the skin.

Claim 1 covers a functional arrangement with a downward movement of the introducer and OBD, followed by a retraction of the introducer while the OBD remains on the patient.
This means that there must be a relative movement of the OBD and introducer within the housing, firstly at the insertion phase, and secondly at the retraction phase.
EP'072 contains the description of one single embodiment that achieves the claimed functional result: the coordinated movement within the housing and retraction is described with reference to the embodiment of Fig. 12A-12G and corresponding para. para. [0115] - [0119] of EP'072 as granted, that includes a second inner housing (in dark grey in the following drawing).

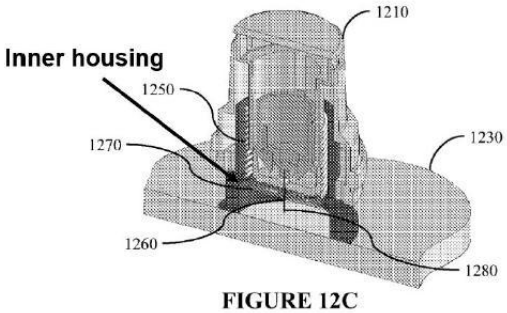


FIGURE 12C

Upon application of a force to the housing 1210, the inner housing serves as a supporting component, which produces a relative displacement between the outer housing 1210 and the inner housing. This relative motion allows the movement of "the introducer (1260) and the integrated glucose sensor (1280) and sensor electronics assembly (1270) within the [outer] housing (1210) towards the skin surface (1230) of the user in a direction substantially perpendicular to the skin surface (1230)" (feature 1.9).
In the described embodiment, the inner housing is thus the element permitting the claimed relative movement.

The applicant strongly objected to that construction, arguing that the application as filed does not require the presence of a second inner housing. In support of its position, Abbott relied both on the preliminary opinion of the EPO Opposition Division, in particular paragraph 20, and on a previous order of the UPC Court of First Instance concerning the same patent.

As already clarified by this Court (see UPC CFI no. 830/2025, LD The Hague, order of 6 February 2026, para. 4.7.4.), the skilled person would not consider the claimed system to be limited to the specific embodiment described in para. [0137] - [0141] and fig. 12A-G of the original application. This it is just an example, but other embodiments can also fall within the scope of protection.
The disclosure relied upon by the respondents does not make any mention of a movable inner housing. It mentions "a housing or body 1210", which provides support for the corresponding housing feature in the claim. The feature of a "movable inner housing" is not mentioned anywhere else in the patent application's description, in fact no distinction is made anywhere between an 'inner' and 'outer' housing.
The respondents rely only on the drawings, figure 12, for this distinction, specifically on the fact that part of the housing in figure 12 is a darker colour which they assert to be the 'inner' housing. While the dark colour of the "movable inner housing" may suggest some importance, the fact that it is not indicated with a reference number suggests the opposite, i.e. that this is not a relevant distinction. The latter suggestion is compounded because a skilled person would look in vain for any support in the description in the patent application of an 'inner housing'. The skilled person would therefore understand, not only from the disclosure in connection with Figure 12, but also from the original application as a whole, that the technical teaching of the

patent is not limited to any specific insertion/introducer or retraction mechanism, let alone a movable inner housing.
For the sake of completeness, it should be recalled that the very same considerations are also reflected in the preliminary opinion of the Opposition Division, according to which the inner housing is neither disclosed nor implied as a feature of the patent.

6.4. Feature 1.9.

"*wherein the insertion device (1200) is configured to move*"

The applicant argues that feature 1.9 requires that the insertion device is configured to cause the movement, and not that any of the claimed components of the insertion device must necessarily cause the movement.
It is not excluded by the claim language that other (non-claimed) components of the insertion device cause the movement. Those components would still be part of the insertion device which would be configured to cause the movement. Feature 1.2 reads that the insertion device "comprises" the components which are then claimed in features 1.3-1.6.
According to the well-established meaning of "comprises" in patent law (as opposed to "consisting of"), it leaves open other components to be comprised in the insertion device.
This understanding of feature 1.9 is fully in line with the description. Nowhere does the description suggest that it would be essential that the movement of the introducer, sensor and sensor electronics assembly is caused by a specifically claimed element of the insertion device such as the housing.
To the contrary, the specification of the patent makes clear that the particular insertion mechanism is not relevant. As described in paragraph [0145], the integrated sensor and sensor electronics assembly may be positioned on the skin surface of the user "using an insertion device", without specifying which particular element of the insertion device is causing the positioning of the integrated sensor and sensor electronics assembly on the user's skin surface. In fact, paragraph [0145] makes clear that different types of insertion devices may be provided to deploy the integrated glucose sensor and the sensor electronics assembly, such as automated or semi-automated, spring biased and/or manual insertion device.
What is relevant, is that the insertion device is configured to move the sensor and sensor electronics assembly together, not how or by which particular element of the insertion device.
The respondents only refer to paragraph [0118] of the description. This relates to the Figure 12 embodiment. There, the sensor and sensor electronics assembly are caused to move in response to a force applied on the housing of the insertion device, but the Figure 12 embodiment merely concerns an example of the claimed invention.
The description of the patent makes clear to the skilled person that the disclosed introducer mechanism is not limited to the embodiment of Figure 12. Paragraph [0050] refers to the introducer mechanism and explains that it will be described in more detail in connection with Figure 12, which is an embodiment of the invention (see paragraph [0010]). In the next paragraph ([0051]), the description of the patent teaches the skilled person that different types of introducer mechanisms may be employed. Like paragraph [0145], it lists several possible implementations, including fully or partially automated systems. These implementations may,

for example, include a trigger mechanism – which is what the respondents are employing in their GS3-R System.

According to the respondents, the skilled person notes that the insertion device comprises several elements, namely a housing (feature 1.3), an introducer (feature 1.4), a bias mechanism (feature 1.5), a cap (feature 1.6), and an integrated glucose sensor and sensor electronics assembly (feature 1.7). The skilled person thus understands that the expression "*the insertion device is configured to move the* […]" means that one of the claimed elements of the insertion device listed in claim 1 is responsible for such movement.
This interpretation is further supported by the description. In the embodiment of Fig. 12A-12B, the movement of the introducer, the integrated glucose sensor and sensor electronics assembly is caused by the claimed housing, in response to a force applied on the same. This results from Fig. 12A-12G as well as para. [0118]: "*Referring to FIG. 12B, when a force, e.g., a manual force, is applied upon the top end of the housing 1210 in the direction as shown by arrow 1240, and with the open end of the housing on the skin surface 1230, the integrated sensor and sensor electronics assembly provided within the housing (not shown) is configured to come into contact with the skin surface 1230. Furthermore, the force applied as discussed above also may be configured to move the introducer (not shown) within the housing in the same direction as shown by arrow 1240 to pierce the skin surface 1230 and position the sensor in fluid contact with an analyte of the user*".
Feature 1.9 should therefore be interpreted as requiring that the claimed movement of the introducer, the integrated glucose sensor and sensor electronics assembly is caused by (at least) one of the elements of the insertion device claimed in claim 1, such as the housing.
respondents had no choice but to rely on the embodiment of Fig. 12A-12G, since this is the only passage of the description disclosing the combination of claimed features. Besides, while the applicant claims that the embodiment of Fig. 12A-12G would only be an example, its own interpretation of the claims relies on the disclosure of para. [0115-0119], i.e. passages that are specifically concerned with Fig. 12A-12G.
Adopting the applicant's position would lead to a situation in which while a description provides structural details, a broad wording of the claims that covers mere functions would suffice to provide a virtually infinite scope of protection.
This is precisely why claimed features should be interpreted taking the description into account.
The term "*comprise*" does not exclude that the insertion device may include other elements, this does not solve the question of which component of the insertion device should be responsible for moving the introducer, the integrated glucose sensor and sensor electronics assembly.
In this respect, the skilled person would understand that (at least) one of the claimed elements of the insertion device, listed immediately previously in the claim, must be responsible for the function claimed in feature 1.9.

The Court observes that the phrase "*the insertion device* [...] *is configured to move*" should be construed to mean that the insertion device, as a complete assembly, is structurally and

functionally arranged to cause the downward movement of the introducer, integrated sensor, and sensor electronics assembly.
This construction is not limited to the movement being directly caused by manual force applied to the housing.
Firstly, the claim attributes the function to the "insertion device" as a whole, not to a specific component like "the housing".
Secondly, the patent explicitly contemplates various mechanisms. Paragraphs [0051] and [0145] of the granted patent (corresponding to [0073] and [0167] of the original application) state that the introducer mechanism may be "*fully or partially automated, for example with a trigger mechanism, or may be fully or partially manual*". This is a direct and unambiguous disclosure that the invention is not limited to the single, purely manual force embodiment shown in Figures 12C-12E. In other words, "*comprises*" means that there are some structural elements but not that the list of the elements is exhaustive, with no space for additional one.
Finally, the essential technical principle is the single-action deployment of an integrated on-body device from a self-contained insertion assembly. Limiting the claim to only one possible way of initiating this action (direct manual force) when the patent itself suggests others (trigger mechanisms, springs) would improperly narrow the scope of protection to just one example.
Therefore, the feature is satisfied for a device where a user action on the housing (such as pressing a button) releases stored energy (e.g., from a spring) which in turn drives the assembly downwards. The entire assembly, including the button and spring, constitutes the "insertion device" that is "configured to move" the internal components.
The case law cited by respondents (UPC CoA no. 813/2025, order of 6 March 2026; UPC CFI no. 628/2024, LD Munich, decision of 13 January 2026) does not alter this conclusion, because in the case at hand the functionality is explained in the description by various clear examples.

6.5. Feature 1.10.

"[...] *a retracted position in which the introducer is entirely retained within the housing*"

According to the applicant, feature 1.10 does not require that the retracted position corresponds to the pre-deployment position, i.e. the position of the introducer before the insertion phase starts. The literal claim language does not impose such limitations.
The respondents refer to a single paragraph in the description (paragraph [0150]). There, the patent describes that the introducer is retracted to its original pre-deployment position, but this merely concerns an example from the description to which the patent is not limited. There are numerous other places in the description disclosing a retraction of the introducer to a retracted position, without requiring it to be retracted exactly to the original pre-deployment position (paragraphs [0119], [0148], [0149]).
In light of the description, the skilled person would also understand that it is unnecessary to retract the introducer needle exactly to the original pre-deployment position. As long as the introducer is retracted within the insertion device housing after deployment, the intended purpose of the retraction is met. That purpose is described in paragraphs [0148]-[0149]. Retaining the introducer within the housing reduces the potential for perceived pain when a sharp needle is visible (see paragraph [0149]). It also allows the device to tilt or move at an angle. This enables stable application of the adhesive of the sensor electronics housing to the

skin, without interference from the introducer. In addition, retaining the introducer within the housing improves safety during disposal and it reduces or avoids biohazard risks (see paragraph [0148]).
There is no need for the retracted position to exactly correspond to the original pre-deployment position to achieve these goals.

On the other hand, the respondents' position is that with respect to feature 1.10, para. [0150] is the only disclosure providing clarification regarding the location of the claimed "retraction position".
Feature 1.10 has two components:

(i) it requires the introducer to be "*entirely retained within the housing*"; support for that feature is probably to be found in para. [0149], which states that neither the needle nor the introducer should be visible to the user before, during, or after use of the insertion device to position the sensor and the sensor electronics;

(ii) the feature also requires the introducer to be specifically in the "retracted position"; in this respect, para. [0150] teaches that: "*the introducer is automatically retracted to its original pre-deployment position*".

As this is the only support for the claim language "*retracted position*", the skilled person understands that the "*retracted position*" of feature 1.10 thus corresponds to the pre-deployment position, i.e. the position of the introducer before the insertion phase starts.

The Court considers that the term "a retracted position" should be construed as any position the introducer occupies after retraction where it is, as the claim explicitly states, entirely contained within the physical boundaries of the housing.
This construction is not limited to the introducer returning to its exact pre-deployment position. The claim provides its own definition for the required outcome: the introducer must be "entirely retained within the housing". It does not specify where within the housing.
Paragraph [0148] explains the purpose of the retraction: to make disposal safer, avoid biohazard concerns, and permit movement of the device on the skin without interference. Paragraph [0149] adds that it minimizes perceived pain by hiding the needle. These objectives are fully achieved as long as the sharp introducer is safely contained inside the housing, regardless of its precise location relative to its starting point.
The mention of the "original pre-deployment position" in paragraph [0150] is best understood as an illustrative example of one possible retracted position, not a restrictive definition of the only possible retracted position.
The feature is satisfied if, after insertion, the introducer is fully withdrawn inside the housing. A device where the introducer retracts to a position that is different from (e.g., higher than) its pre-deployment position still meets the requirements of this feature, provided the introducer does not protrude from the housing.

7. Validity.

The respondents challenged the validity of the patent on the grounds of sufficiency of disclosure, added matter and lack of inventive step. These grounds are the same as in the opposition proceedings before the EPO.

7.1. Sufficiency of disclosure.

The UPC Court of Appeal has defined the legal standard to be applied when assessing the requirement of sufficiency of disclosure (UPC CoA no. 528/2025, decision of 25 November 2025).

Sufficiency has to be examined on the basis of the patent as a whole, thus on the basis of the claims, description and drawings, from the perspective of the skilled person with his common general knowledge at the filing or priority date.

The test to be applied is whether the skilled person is able to reproduce the claimed subject matter on the basis of the patent without any inventive effort and without undue burden. An invention is sufficiently disclosed if the patent specification shows the skilled person at least one way – and in case of functional features: one technical concept, i.e., one workable technical principle – of performing the claimed invention.

Where a claim contains one or more functional features, it is not required that the disclosure includes specific instructions as to how each and every conceivable embodiment within the functional definition(s) should be obtained. A fair protection requires that variants of specifically disclosed embodiments that are equally suitable to achieve the same effect, which could not have been envisaged without the invention, should also be protected by the claim. Consequently, any non-availability of some embodiments of a functionally defined claim is immaterial to sufficiency, as long as the skilled person through the disclosure is able to obtain suitable embodiments within the scope of the claim.

At the same time, another decision of the Court of First Instance (UPC CFI no. 2255/2025, LD Hamburg, order of 7 April 2026) introduced a form of counterbalance to the general principle laid down by the Court of Appeal, in a way that had previously found similar expression in the case law of the EPO Boards of Appeal (T 500/20, T 141/21). It states that "*when the patent, including the description, discloses at least one way to carry out the invention, it is for the respondent to demonstrate that it cannot be carried out over the entire breadth of the claim*", and that this is to be regarded as a very high burden of proof.

The two decisions are complementary. In practical terms, the foregoing principles mean that the patent proprietor must disclose at least one clear way of carrying out the invention. Where the claim is broad and expressed in functional terms, insufficiency does not follow merely from the fact that certain embodiments falling within the claim may not work or are not specifically described. However, if the opponent establishes, on the basis of verifiable facts, that a substantial range of embodiments cannot be carried out without undue burden because the patent is silent on an important aspect of the claimed invention, the claim may be found to be insufficiently disclosed.

Against that legal background, the respondents submit that the breadth of the claim must be matched by a corresponding disclosure capable of supporting it.
If the "*movable inner housing*" is not considered a necessary feature of the invention, according to the broad claim construction proposed by the applicant, then the patent fails to disclose how to carry out the invention without it, thus rendering the disclosure insufficient.
On that construction, claim 1 is not limited to the only concrete deployment architecture disclosed; it covers a wider class of assemblies that must still achieve the coordinated sequence of features 1.9 to 1.11. EP'072, however, neither describes nor suggests any architecture for achieving that sequence other than the Fig. 12 arrangement.
The respondents contend that the specification does not identify which structural element provides the perpendicular guidance of the introducer if the cooperating internal housing portion is absent; it does not disclose what triggers the bias mechanism in the absence of the disclosed contact-driven release event; and it does not teach how the integrated sensor and sensor electronics assembly is retained on the skin while the introducer is retracted, if not by the cooperating retention surface depicted in Figs. 12F–12G.
To implement an insertion device that does not include the internal support, transmission and trigger relationship disclosed in Fig. 12, the skilled person needs to know how the device:
(i) moves the sensor and the electronics assembly downward to the skin surface,
(ii) moves the introducer, the sensor and the electronics assembly together without damaging the sensor,
(iii) retracts the introducer after insertion, and
(iv) leaves the electronics assembly on the skin while the introducer is fully retained within the housing.
Yet, EP'072 does not provide the skilled person with any technical information on how to implement an insertion device that does not include the internal support, transmission and trigger relationship disclosed in Fig. 12, while being able to perform the claimed functional sequence of coordinated movement and retraction without using an inner housing or other intermediate structure to that effect.
The skilled person wishing to implement an insertion device that does not include the internal support, transmission and trigger relationship disclosed in Fig. 12, bearing the introducer and the OBD, and movable within the claimed housing, will face an undue burden and would need inventive skill to overcome the issues he would face.
Without an internal moving element(s) (or any equivalent means), the force applied does not result in the claimed coordinated insertion movement. There is accordingly a claimed physical impossibility to manufacture a device according to the claim by following this route. The same problem applies with respect to the claimed coordinated retraction movement. The latter requires a trigger/release event after the insertion phase; however, without an internal moving element(s) – or any other equivalent means – no information is provided to the skilled person on how to achieve the claimed retraction.
EP'072 lacks information on an important aspect of the claimed invention, without which the skilled person cannot realize insertion devices that do not include the internal support, transmission and trigger relationship disclosed in Fig. 12 without undue burden.

In other words, the respondents submit that an embodiment without the inner housing is not a mere variant of the disclosed teaching, but a fundamentally different technical concept which is not described anywhere in the patent specification, still less in the drawings.

The applicant relies on the case law of the Court of Appeal, as recalled in the assessment of The Hague LD order (UPC CFI no. 830/2025, order of 6 February 2026) that recites as follows: "*it is undisputed that the description provides at least one detailed example and embodiment to illustrate how the invention can be put into practice*". The Court of First Instance thus confirmed that the description of the patent provides at least one detailed example and embodiment to illustrate how the invention can be put into practice, and that this is enough to satisfy the requirement of sufficiency of disclosure.
Furthermore, the Opposition Division likewise held in its preliminary opinion that the patent is sufficiently disclosed (see paragraphs 23-28).

Beyond this, the Court considers that a closer examination of the patent's disclosure provides a substantive rebuttal to the respondents' core criticism. The patent is not entirely silent on alternative mechanisms. The original application explicitly contemplates mechanisms other than direct manual force. Paragraphs [0073] (corresponding to [0051] of the granted patent) and [0167] (corresponding to [0145] of the granted patent) state that "the introducer mechanism may be fully or partially automated, for example with a trigger mechanism," or may be "spring biased". This is a direct and unambiguous disclosure that the core inventive concept—a single-action deployment of an integrated assembly—is not inextricably linked to the specific manual-force embodiment of Figures 12A-12G. It teaches the skilled person that the functional results of the claims can be achieved through different technical means, such as triggers or springs, which inherently operate differently from the direct manual force mechanism that necessitates the "inner housing". Therefore, the patent provides the skilled person not just with one specific embodiment, but with the technical principle of single-action deployment and points towards alternative, known types of mechanisms to achieve it.

Additionally, the Court notes a potential internal contradiction between the respondents' arguments on sufficiency of disclosure (Art. 100(b) EPC) and lack of inventive step (Art. 100(a) EPC), which may significantly impact at least a preliminary assessment of the question of sufficiency of disclosure.
Thus, as far as can be understood the respondents' core argument is that the patent fails to enable any embodiment that does not rely on the specific "movable inner housing" mechanism shown in Figs. 12A-12G, since implementing the claimed functions without this specific structure would require inventive skill to overcome a "physical impossibility" (Rejoinder, para. 65).
Conversely, when arguing for lack of inventive step, the respondents propose combining the teachings of e.g. Stafford (D1) and Cote (D2), and their own submissions illustrate that this specific combination would result in a functional insertion device that achieves the claimed outcome (Rejoinder, paras. 232-236, Figs. on p. 71-72). This proposed "obvious" combination

does, however, not appear to use the specific “movable inner housing” of the patent’s embodiment but rather an alternative spring-and-trigger mechanism.
The respondents have pinpointed specific, mechanical functions required by the claim (downward movement, retraction, retention) and have presented a logical, physics-based argument as to why these functions would fail without the internal support structure shown in the only detailed embodiment. This goes beyond merely stating “it might not work”. They argue a “physical impossibility” based on the explicitly disclosed components.
To the extent that this is correct, this may, thus, not simply be a case of “some non-available embodiments” being immaterial, but rather of an entire class of embodiments (those without an inner housing) being non-enabled, which might then in turn be found to constitute a “wide range” of the claim's scope.
The applicant’s response does not substantively address the specific mechanical problems raised by the respondents. Merely stating that alternative mechanisms like triggers are mentioned in the patent (e.g., EP3960072B1, [0051]) does not as such explain how such a trigger would be integrated to solve the specific mechanical challenges in an embodiment lacking the inner housing structure.
Thus, while the applicant has a positive EPO opinion in its favour, the respondents have responded with a detailed argument that purports to identify a fundamental flaw in the patent's disclosure relative to the breadth of its claims, by arguing that practicing the invention across its full scope would require overcoming a “physical impossibility” and would thus impose an “undue burden” on the skilled person.
As noted above, however, the respondents appear to argue that a solution not relying on the specific inner housing is, on one hand, so difficult to conceive that the patent is insufficient for not teaching it, while on the other hand, at least one specific solution not relying on an inner housing is so obvious from the prior art that the patent lacks an inventive step. Positions which would at face value seem mutually exclusive.
At the very least, this apparent self-contradiction weakens the respondents' assertion that they have met the "very high burden of proof" for insufficiency. The fact that the respondents themselves propose a workable alternative that does not rely on the “inner housing” must at least in preliminary proceedings as the present serve to severely undermine their claim that the patent fails to enable such alternatives without undue burden.

In conclusion, the respondents' argument on insufficiency faces two significant hurdles.
First, the patent itself discloses that the inventive concept can be implemented via alternative means such as trigger or spring mechanisms, thereby providing the skilled person with avenues beyond the single manual-force embodiment.
Second, the respondents' own inventive step argument demonstrates that a skilled person, starting from the prior art, could arrive at a workable alternative mechanism. This logically undermines their assertion that doing so would constitute an "undue burden" or face "physical impossibility." Therefore, at this preliminary stage, the Court finds it not more likely than not that the patent is invalid for lack of sufficient disclosure.

7.2. Added matter.

The respondents rely on two objections based on added matter.

The first objection proceeds on the assumption that claim 1 must be construed as requiring a movable inner housing.
For the reasons set out in section 6.3 above, the Court does not accept that construction. The movable inner housing is not a limiting feature of the claimed invention. It is therefore not necessary, for the purposes of the present preliminary assessment, to examine this added-matter objection any further.

The second added-matter objection concerns an alleged intermediate generalisation. According to the respondents, claim 1 results from the extraction of a specific set of features from a disclosure in which those features were presented only in combination with further features, in particular the application of force to the top of the insertion device in the deployment sequence shown in Figure 12. In particular, there is omission of "*force applied to the top of the insertion device*", tied to Fig. 12 deployment architecture. This argument was also raised by one of the intervener before the EPO Opposition Division.
The application as filed makes it clear that movement of the introducer, integrated sensor, and sensor electronics assembly within the housing - as required by claim 1 - results from a force (typically manual) applied on the top of the housing. Para. [0138] and Fig. 12B of the application as filed (as well as para. [0140]) indeed teach that a force, e.g. manual, is applied upon the top end of the housing to enable the introducer, the sensor and the sensor electronics assembly to move towards the skin surface, the introducer piercing the skin to position the sensor in fluid contact with an analyte of the user. Para. [0142] of the application as filed further clarifies that no further action is required from the user apart from applying a force to the housing to obtain the triggering-positioning-retraction sequence.
The "force applied to the top of the insertion device" is therefore disclosed in combination with other features present in claim 1. Moreover, this feature is structurally and functionally linked to these claimed features. It is indeed evident that the disclosed embodiment cannot function with-out applying a force on the top of the housing. In addition, this feature participates in solving the technical problem of providing ease and comfort of use of a CGM device, as applying a force to the housing is all what is needed (see para. [0142] reproduced above).

The applicant replies observing that the patent teaches, as an alternative, the use of an automatic release mechanism (para. [0072] and [0073]), in relation with the embodiment shown in Fig. 12. Therefore, it is clear that there is no inextricable link between features, as argued by the counterparties.

The Court agrees with the assessment expressed in the Addendum to the preliminary opinion of the EPO Opposition Division.
At this stage of the proceedings, it does not appear that the claimed invention is inextricably linked to the application of a force to the top of the housing. Paragraphs [0072] and [0073] of the application as filed, which are linked to the disclosure of Figures 12A to 12G, make clear that the insertion mechanism may also be automated or semi-automated. The skilled person

would therefore understand that the manual application of force to the housing is one possible way of carrying out the deployment sequence, but not an essential structural or functional feature which must necessarily be incorporated into the claim. Accordingly, on the basis of the material presently before the Court, the omission of that feature does not make it more likely than not that claim 1 contains added matter.

7.3. Lack of inventive step (Stafford + Cote).

The inventive step attack raised by the respondents is based on two prior art documents:

- D1 - US 2008/0097246 A1 ("Stafford"), titled "*method and system for providing an integrated analyte sensor insertion device and data processing unit*" and published on 24 April 2008;
- D2 - US 2005/0101932 A1 ("Cote"), titled "*subcutaneous infusion device and device for insertion of a cannula of an infusion device and method*", published on 12 May 2005.

Stafford discloses an integrated on-body device (OBD) comprising a glucose sensor and data processing unit in a single assembly. It features a manual deployment mechanism where the user pushes the device onto the skin and manually retracts the introducer needle. It is chosen by the respondents as a realistic starting point. It discloses the core concept of an integrated sensor and electronics assembly (Feature 1.7) but lacks the automated insertion and retraction mechanics of the claimed insertion device.

Cote discloses a device (1100) for inserting the cannula of a subcutaneous infusion device (referred to as a "site" 1800). It also describes an automatic insertion device with a housing (1110), a needle (1336) for insertion, and a spring (1150) that automatically retracts the needle after the cannula is placed ([0209]). The device is pre-loaded with the infusion site (1800) ([0205]). It explicitly discloses a cap (1170) that is coupled to the housing (1110). This cap is described as providing a seal to maintain a "substantially sterile environment" for the internal components (including the needle and the pre-loaded site) before use (D2 [0197]-[0198], Figs. 54-55, 79A). This appears to correspond directly to feature 2.4 of the patent-in-suit. The primary focus is on a mechanical inserter for a separate component (the "site" 1800) that remains on the patient's skin. It does not appear to disclose an integrated glucose sensor and sensor electronics assembly with communication capabilities. This is the secondary document, alleged to provide the missing features of a mechanical bias mechanism (1.5, 1.10) and an insertion device that moves the transcutaneous element (1.9).

According to the legal standard defined by the UPC Court of Appeal for the assessment of inventive step (UPC CoA no. 457/2024, decision of 25 November 2025), it first has to be established what the object of the invention is, i.e. the objective problem. This must be assessed from the perspective of the person skilled in the art, with their common general knowledge, as at the application or priority date (also referred to as the effective date) of the patent. This must be done by establishing what the invention adds to the state of the art, not by looking at the individual features of the claim, but by comparing the claim as a whole in the context of the specification and the drawings, thus also considering the inventive concept underlying the

invention (the technical teaching), which must be based on the technical effect(s) that the person skilled in the art, on the basis of the application, understands is (are) achieved with the claimed invention.
In order to avoid hindsight, the objective problem should not contain pointers to the claimed solution. The claimed solution is obvious when at the effective date the person skilled in the art, starting from a realistic starting point in the state of the art in the relevant field of technology and wishing to solve the objective problem, would (and not only "could") have arrived at the claimed solution.
The relevant field of technology is the specific field relevant to the objective problem to be solved as well as any field in which the same or similar problem arises and of which the person skilled in the art in the art of the specific field must be expected to be aware.
A starting point is realistic if the teaching thereof would have been of interest to a person skilled in the art who, at the effective date, wishes to solve the objective problem. This may for instance be the case if the relevant piece of prior art already discloses several features similar to those relevant to the invention as claimed and/or addresses the same or a similar underlying problem as that of the claimed invention. There can be more than one realistic starting point, and the claimed invention must be inventive starting from each of them.
The person skilled in the art has no inventive skills and no imagination and requires a pointer or motivation (in German: "Anlass") that, starting from a realistic starting point, directs them to implement a next step in the direction of the claimed invention. As a general rule, a claimed solution must be considered not inventive/obvious when the person skilled in the art would take the next step, prompted by the pointer or as a matter of routine, and arrive at the claimed invention.
For an inventive step to be present, it is not necessary to show improvement of the technical teaching as defined by the patent claims over the prior art. Inventive step may also be found if the patent claims disclose a non-obvious alternative to solutions known in the prior art.

The parties agree that the skilled person is an engineer involved in the design and manufacture of devices for monitoring analytes, particularly CGMs, and the components of these devices such as the insertion device and the sensor.
The parties also agree in the definition of the objective technical problem, i.e. improving the safety, ease and comfort of use of a CGM device, as introduced and explained by the patent description.
This formulation of the objective technical problem does not contain any pointer to the solution.

According to the respondents, the key functional difference between Stafford and EP'072 is that, in Stafford, the introducer is driven manually by the user, both during the insertion and retraction phases.
Stafford does not provide for an insertion device per se; therefore, Stafford does not describe a mechanical positioning of the OBD onto the patient's skin (including the insertion of the sensor), followed by a mechanically - driven retraction of the introducer. The difference between claim 1 and Stafford lies in the presence of an insertion device to mechanically position

the OBD and subsequently retract the introducer, whereas Stafford provides for a manual sequence of operations.
Stafford also addresses the same or similar underlying problem to that of the claimed invention, i.e. how to improve ease and comfort of use (para. [0005], easy to handle and accurate sensor introduction and retention mechanism for use in analyte monitoring system) as well as safety (para. 0003, the inserter is sharp and may damage other parts of the patient's skin if not properly handed ... precautions in the handling of the inserter ... sterile environment ... protect the sharp edge of the lower portion").
The differences between the claimed invention and Stafford lie in
(i) the provision of a housing conformed such that the integrated glucose sensor, the sensor electronics assembly and the introducer are provided in said housing before the deployment phase, and the introducer is separated from the OBD after the deployment phase while retaining the introducer in its retracted position within said housing, and
(ii) the presence of a bias mechanism to retract the introducer.
These various points actually result from one single conceptual difference, which lies in the fact that the deployment in Stafford is manual instead of being mechanical.
Stafford acknowledges a safety concern, which lies in the sharp end of the inserter as posing a safety risk to the patient, whose skin may be damaged. Stafford also emphasizes that the safety concern is even more severe after the insertion took place as the contamination risk is higher after exposure to the biological fluids of the patient (see e.g. para. [0003]). The risk of contamination and injury - prior, during and especially after the insertion - is considered but not fully solved. The solution is only for prior insertion risk, by a guard segment effective only before the insertion (like a protective needle guard), nothing is provided during and after the insertion. This is a pointer to a next step, i.e. increase safety.
Cote relates to an infusion device, but it is relevant in the case because of interchangeability of technologies' field. The two types of device share the same mechanical principle of subcutaneous insertion and needle retraction
Cote addresses the problem of providing an easier to use, more comfortable and safer insertion device, see para. [0005], [0234], [0236] and [0239]. Cote is thus specifically concerned with the problem raised but not solved by Stafford, which is to reduce the risk of damage from needle exposure during and after insertion. It explicitly mentions the concern of mitigating the safety problems caused by the needle during and after the insertion of the OBD and does provide a solution to this problem.

The applicant objects that Stafford is not a realistic starting point.
Firstly, many features of EP'072 are indeed missing.
More generally, Stafford is a manual device with no insertion device, the inserter requires a high level of care and manual insertion is proposed as simpler, safer and less expensive (see para. [0045]) The underlying technical problem is different from EP'072, i.e. to reduce components, costs, weight, packaging and waste.
It does not address the need to improve safety as it solved the problem by the implementation of the guard segment.

Even if this safety risk would not be solved by Stafford, this would in any event not lead the skilled person to consider developing an insertion device with a retraction mechanism with a cavity for retaining the sharp needle after deployment, when the insertion mechanism disclosed in Stafford is much more simplistic and where Stafford definitely teaches away from using an insertion device at all.
There is therefore no motivation at all for the skilled person to consider modifying the disclosed arrangement to provide an integrated glucose sensor and sensor electronics assembly within a vastly modified insertion device capable of automatic retraction.
There is no recognizable pointer in para. [0003] and [0226] of Stafford. The improve of safety does not point to a completely different architecture with the inclusion of an insertion device.
Stafford and Cote differ in their architecture. Stafford integrates insertion into the OBD and eliminates the need for a separate inserter, whereas Cote relies on a complex, standalone inserter that is fully discarded after use. If Cote were combined with Stafford, it would result in a substantial increase in the number of components, manufacturing cost, material cost, weight, packaging, waste, and overall assembly size —the very opposite of Stafford's design objective.
Cote is related to a different field, deals only with problems of the existing infusion systems, not with CGMs or other kind of sensor. The person skilled in the art would have looked at separate insertion mechanism related to sensors, not to infusions systems.
The respondents do not provide any explanation whatsoever why the skilled person would on the one hand abandon the explicit teaching of Stafford to manually deploy the sensor and electronics assembly without the use of a separate insertion device, but would on the other hand maintain such integrated assembly when turning towards mechanical deployment, when all of the known mechanical deployment systems teach a two-step approach, and thus do not disclose the application of an integrated assembly in a single step.

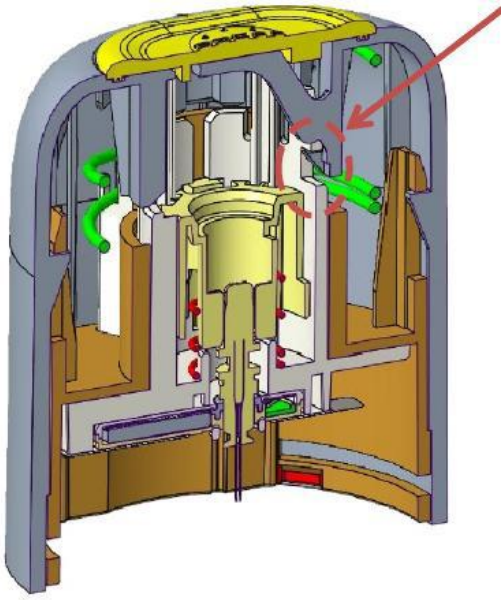
The Court considers it highly doubtful, at this stage of the proceedings, that Stafford may properly be regarded as a realistic starting point for the assessment of inventive step.
Although Stafford discloses certain features which are also present in EP'072, its overall teaching appears to pursue a different technical approach. Stafford is directed to a device of deliberately simplified mechanical construction, with the stated aim of reducing the number of components, cost, weight, packaging and waste.
Stafford's disclosure is centred on a simple, single-unit arrangement and on avoiding the need for a separate and more complex insertion mechanism. A skilled person starting from Stafford would therefore be directed towards simplification, rather than towards the incorporation of a more complex mechanical inserter of the kind disclosed in Cote. In that respect, Stafford appears to teach away from the very modification proposed by the respondents.
Even if Stafford were nevertheless accepted as a realistic starting point, the respondents have not shown, with the degree of persuasiveness required in the present proceedings, why the skilled person, without the benefit of hindsight, would have turned to the specific field of infusion-set inserters and selected the Cote device in order to solve the alleged safety problem, in particular where such a choice would run counter to Stafford's own teaching.
The proposed selection of the specific mechanism disclosed in Cote therefore appears to be driven, at least to a significant extent, by knowledge of the claimed invention.

Cote concerns a device for inserting an infusion cannula, not an integrated glucose sensor and sensor electronics assembly. On the basis of the material presently before the Court, that distinction further weakens the respondents' contention that the skilled person would have selected Cote as an obvious source of the missing teaching.
The parties have extensively debated whether the technical fields of CGM insertion devices and infusion-set inserters were interchangeable at the relevant date. For the purposes of the present preliminary assessment, however, the Court does not consider it necessary to reach a definitive conclusion on that issue.
It is sufficient to note that, if such interchangeability were as straightforward as the respondents submit, one would have expected a more natural inventive-step attack to start from Cote, which already discloses the complex mechanical insertion architecture relied upon by the respondents, and then to consider whether the skilled person would have incorporated the integrated sensor and electronics assembly known from Stafford.

7.4. Conclusion on validity.
In the light of the foregoing considerations concerning sufficiency of disclosure, added matter and inventive step, the Court considers, on the basis of the preliminary assessment required in proceedings for provisional measures, that it is more likely than not that the patent in suit is valid.

8. Infringement.
It is common ground between the parties that the GS3 device, which has been distributed in Spain, and the GS3-R system, which is intended to be placed on the market in the Contracting Member States concerned, are substantially identical. The manuals and user guides published on the sibionicsserver.com website support that conclusion, as they do not disclose any relevant difference between the two models and appear to be the same for both devices (Annex B2).
This conclusion is further supported by the information contained in the EUDAMED registration (EUDAMED is the IT system established by Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on in vitro diagnosis medical devices).

Based on the parties' submissions, these devices use a button on the top of the housing. When pressed, the button releases a pre-compressed spring, which then drives the introducer and the integrated sensor/electronics assembly towards the skin.



drawing of GS3 provided by the respondents

The GS3 comprises an outer housing (dark grey), an inner housing (brown), an OBD carrier (light grey), and a needle carrier (yellow). It also comprises two types of springs. The first spring (green) retains the OBD carrier (supporting the needle carrier) thanks to a hook (identified by the red arrow) of the outer housing; upon release of the hook, the first spring positions the OBD onto the skin. The second spring (in red) is positioned around the needle carrier and is used for its retraction. The GS3 also comprises a button (yellow) located on the upper part of the device
When the GS3 is activated, the hook of the outer housing is released from the OBD carrier. The green spring then expands, driving the OBD carrier downwards along with the needle carrier. Importantly, the inner and outer housings remain fixed together, i.e. there is no relative movement between them.
At the end of the retraction phase, the needle carrier of the GS3 rises above its initial position to reach the top of the product, propelled upwards by the action of the red spring.

The parties are discussing the inclusion of features 1.6, 1.9 and 1.10 in the GS3-R.

a) feature 1.6 (cap)
The applicant submits that, on the proper construction of the claim, sterility is not a limiting feature of claim 1 and, in particular, is not part of the scope of protection conferred by feature 1.6.

According to the applicant, the fact that, in the GS3-R, the introducer needle and the sensor tip may be partially located within the cap is not decisive.
The claims do not specify the position of those elements in relation to the cap. What is required is only that the introducer and the integrated sensor and sensor electronics assembly are provided within the housing, as set out in feature 1.7, and that the cap is configured to provide a closure or seal on an open end of the insertion device.

The respondents rely on visual evidence, in particular X-ray images, which, in their submission, show that in the GS3 product the introducer needle and the sensor tip extend into the physical volume of the component identified by them as the cap, rather than being enclosed by that component within the main housing (Rejoinder, para. 225, Fig. 39). On that basis, they argue that, if the components which the cap is intended to protect are located within the cap itself, the cap cannot be regarded as performing the function of sealing the housing so as to protect the components located inside it. In that configuration, the cap would form part of the container, rather than merely constituting a closure or lid for it.
The respondents further submit that, in the GS3 device, the sterile barrier is provided at the upper end of the cap and not at the interface between the cap and the housing. In their view, the interior space of the housing is therefore not maintained in a substantially contaminant-free environment by the cap in the sense taught by the patent (Rejoinder, paras. 227-229). That argument proceeds on the premise that the patent links the function of the cap to the protection, in a sterile environment, of the components located within the insertion device. If the sterile barrier is provided elsewhere, and if no effective seal is formed at the cap-housing interface, the respondents submit that the cap does not perform the function required by feature 1.6.

In the Court's view, the non-infringement argument related to feature 1.6 may be argued not to be a mere semantic debate, as it points to a potential structural and functional difference between the role of the cap as explicitly thought in the patent and the role of the corresponding part in the accused device. Feature 1.6 does, however, not literally require that the cap should "enclose" the components within the housing but rather refers to an open end of the insertion device. Likewise feature 1.6 does not literally exclude that the introducer needle and/or sensor tip could extend into the physical volume of the component of the cap. What feature 1.6 of claim 1 requires is that the cap mates with the housing of the insertion device to form a barrier that is sufficient to maintain the interior space of the housing in a substantially sterile and contaminant-free environment, thereby protecting in particular the sensor and introducer assembly of the insertion device.
In light of the above, this feature appears to be more likely than not to be implemented in the alleged infringing device.

b) feature 1.9 (movement by insertion device)
The applicant assumes that the button and spring are components of the insertion device. Therefore, the insertion device is "configured to move" the assembly, even if indirectly. The claim does not require the force to be directly applied by the user's hand to the moving parts.

According to the respondents, the movement is caused by a spring, a second bias mechanism other than the one intended to be used for the retraction, not by the "insertion device" itself (which they construe as the housing). Pressing the button only triggers the spring; it doesn't directly cause the movement.

The opinion of the Court is that the proposed balanced claim construction is not limited to movement directly caused by manual force on the housing but encompasses arrangements where a user action on the device triggers the movement, such as through a spring mechanism. The accused product's button-and-spring system is part of the overall insertion device. Therefore, the device is "configured to move" the internal components as claimed. The respondents' argument for non-infringement, which requires a narrower, purely structural interpretation, is likely to fail in light of the patent's broader functional language and disclosure of "trigger mechanisms".

c) feature 1.10 (retracted position):
The applicant position is that the claim only requires the introducer to be "entirely retained within the housing". It does not specify that it must return to the original pre-deployment position. The GS3 introducer is entirely retained within the housing after retraction.

Respondents argue that the "retracted position" must be the original pre-deployment position, as this is the only position described in detail (para. [0150]). In the GS3, the introducer retracts to a position above its initial pre-deployment position.

The Court reiterates here the opinion that a correct claim interpretation requires only that the introducer be "entirely retained within the housing" after retraction. Limiting this to the original pre-deployment position would be an undue restriction based on a single example from the description, contrary to established principles of claim construction. The accused product's introducer is fully contained within its housing post-retraction, even if not at its exact starting point. It therefore appears to meet this claim limitation.

In the light of the foregoing considerations, and on the basis of the preliminary assessment required at this stage of the proceedings, the Court considers it more likely than not that, applying the balanced claim construction set out above, the accused GS3-R product literally infringes the patent in suit.

9. Acts of infringement.
The factual framework advanced by the applicant, including the conduct attributed to and the respective roles of each respondent, is substantially undisputed.
In particular, none of the respondents has meaningfully disputed the material facts relied upon by the applicant concerning their involvement in the manufacture, importation, regulatory approval, marketing and intended commercialisation of the GS3-R System within the territory of the UPC Contracting Member States.

The Court should therefore take those facts into account as established pursuant to R. 171.2 RoP.

respondent 1) - SiSensing

Respondent 1) is identified as the manufacturer of the GS3-R System in multiple official sources, including EUDAMED (Annex C5), the HMV Directory of Assistive Devices in Germany (Annex C7), and the EU Declaration of Conformity issued for the GS3-R System pursuant to Regulation (EU) 2017/745 on medical devices ("MDR"), a copy of which was provided by the SiBionics parties' legal representatives with their letter dated 12 February 2026 (Annex D1, pp. 23-24).

Under Articles 2(43), 10(6) and 19 MDR, the EU Declaration of Conformity and the affixing of the CE marking constitute formal acts by which the manufacturer declares that the device complies with the applicable requirements of Union law and may be placed on the Union market.

The EUDAMED entries relating to the GS3-R System expressly identify, inter alia, Germany, Italy, Romania and Slovenia as countries in which the device is intended to be made available (Annex C5). Respondent 1) therefore expressly contemplates and targets the marketing of the GS3-R System within several UPC Contracting Member States.

Respondent 1) further took the steps required for the commercialisation of the GS3-R System within the European Union by designating respondent 5) as its authorised representative in accordance with Article 11 MDR. Pursuant to Article 11(1) MDR, a manufacturer established outside the Union may place a device on the Union market only if it designates a sole authorised representative established within the Union. Under Article 11(2) MDR, such designation must be accepted in writing by the authorised representative and thereby constitutes a valid mandate. The appointment of respondent 5) was therefore a deliberate and necessary measure adopted by respondent 1) for the purpose of placing the GS3-R System on the Union market. Together with the issuance of the EU Declaration of Conformity and the affixing of the CE marking, this demonstrates respondent 1)'s intention to commercialise the GS3-R System throughout the European Union, including within the territory of the UPC Contracting Member States.

Absent the actions undertaken by respondent 1), including the issuance of the EU Declaration of Conformity and the designation of an authorised representative within the Union, the GS3-R System could not lawfully be placed on the European market. These acts therefore establish respondent 1)'s direct and substantial involvement in the marketing and commercialisation of the accused product within the territory covered by the patent and the UPC Agreement.

respondent 2) - SiBionics

Respondent 2) is identified as the importer of the GS3-R. In the letter dated 12 February 2026 from the SiBionics parties' legal representatives, it is expressly stated that: *"The products at stake [GS3-R] will be manufactured and/or imported into Europe by SiSensing Co., Ltd, Shanghai International Holding Corp. GmbH, and Sibionics GmbH..."* (Annex D1, pp. 21-22). Respondent 2) therefore expressly identifies itself as an entity involved in the importation of the GS3-R System into the European market and is directly engaged in the commercialisation of the accused products within the territory of the Contracting Member States.

respondent 3) - Sibio Technology
respondent 4) - Sibio PTE
Respondent 3) controls and operates the Website through which the GS3-R System is promoted and offered to customers in Europe (Annex C2). Respondent 3) is therefore actively involved in the marketing and commercialisation of the GS3-R System within the territory covered by the patent and the UPC Agreement.
Respondent 4) is involved in the operation of the Website (Annex C2).
In particular, when the Website is accessed from at least the Contracting Member State of Italy, the website footer identifies respondent 4) as the relevant operating entity (Figure 55).
The involvement of respondent 4) has been expressly acknowledged by the SiBionics parties themselves. In their letter dated 28 February 2026, their legal representatives stated:
"We would like to further indicate that Sibio Technology Limited and Sibio PTE Ltd. might also be involved in the aforementioned activities in respect of the GS3-R device" (Annex D1, pp. 28-29).
The evidence therefore demonstrates that respondent 4) is involved in the activities relating to the promotion, offering and commercialisation of the GS3-R System and forms part of the group of entities responsible for the acts complained of in these proceedings.

respondent 5) - Shanghai International
Respondent 5) is identified as the EU Authorised Representative for the GS3-R System both in the Declaration of Conformity supplied by the SiBionics parties through their legal representatives by letter dated 12 February 2026 (Annex D1, pp. 23-24) and in the EUDAMED database (Annex C5).
Pursuant to Article 2(32) MDR, an "authorised representative" is any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer established outside the Union to act on that manufacturer's behalf in relation to specified tasks concerning the manufacturer's obligations under the Regulation.
As already set out above, the designation of an EU Authorised Representative constitutes a prerequisite for a manufacturer established outside the EU/EEA to place medical devices on the Union market. Such designation requires a positive and express act by both the manufacturer and the authorised representative, as confirmed by Article 11(1) and (2) MDR.
The role of the EU Authorised Representative is not merely formal. The EU legislature has expressly provided that authorised representatives may incur liability in relation to non-compliant medical devices placed on the Union market and are, in certain circumstances, jointly and severally liable together with the manufacturer and the importer[1]. This reflects the central

[1] MDR, Recital 35 "*For manufacturers who are not established in the Union, the authorised representative plays a pivotal role in ensuring the compliance of the devices produced by those manufacturers and in serving as their contact person established in the Union. Given that pivotal role, for the purposes of enforcement it is appropriate to make the authorised representative legally liable for defective devices in the event that a manufacturer established outside the Union has not complied with its general obligations.*").
Article 11(5) MDR: "*Without prejudice to paragraph 4 of this Article, where the manufacturer is not established in a Member State and has not complied with the obligations laid down in Article 10, the authorised representative shall be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer*").

function attributed to authorised representatives within the regulatory framework governing the placing of medical devices on the Union market and supports the conclusion that respondent 5) is directly involved in, and bears responsibility for, the commercialisation of the GS3-R System within the European Union (for the liability of the authorised representative see UPC CFI no. 213/2025, LD Düsseldorf, order of 10 July 2025, para. 89 "[...] *By making itself available as authorised representative, the respondent makes a decisive contribution to the fact that the attacked embodiment can be placed on the market in the European Union and thus also in the relevant Contracting Member States in violation of the law.*", machine translation)
As held by the Court of Appeal in Philips v Belkin (UPC CoA no. 534/2024, decision of 2 October 2025, Headnote 3), the concept of an "infringer" is not limited to a person who personally performs the acts referred to in Article 25 UPCA. Rather, it also encompasses persons to whom the infringing acts of a third party are attributable because they acted as an instigator, co-perpetrator or accessory: "*An 'infringer' within the meaning of Art. 63 UPCA in conjunction with Art. 25 UPCA is also a person who does not personally carry out the acts referred to in Art. 25 UPCA but to whom the acts of a third party are attributable because they are an instigator, co-perpetrator or accessory. Who qualifies as an instigator, co-perpetrator or accessory in this sense is determined on the basis of an autonomous interpretation of Art. 63 UPCA and Art. 25 UPCA.*"
Respondent 5) acted as the authorised representative of the manufacturer within the European Union pursuant to Article 11 MDR. In that capacity, respondent 5) accepted a written mandate to act on behalf of the non-EU manufacturer in relation to its regulatory obligations and thereby enabled the placing of the GS3-R System on the Union market. The appointment and acceptance of an authorised representative constitute a necessary legal precondition for a non-EU manufacturer to market medical devices within the Union.
In these circumstances, respondent 5) cannot be regarded as a mere passive intermediary. By assuming and performing the role of authorised representative for the GS3-R System, respondent 5) made a material and legally relevant contribution to the placing and marketing of the allegedly infringing products within the territory covered by the UPCA. Accordingly, the infringing acts are attributable to respondent 5), which therefore qualifies as an infringer within the meaning of Articles 25 and 63 UPCA.

It is undisputed that the respondents, each acting in the respective capacities described above, have undertaken and continue to undertake activities directed at the making, offering, placing on the market and importing of a product falling within the scope of protection of the patent. Such conduct constitutes an infringement of the patent pursuant to Article 25 UPCA, which confers on the patent proprietor the right to prevent third parties, without its consent, from making, offering, placing on the market, using, or importing for those purposes a patented product.
Furthermore, the correspondence referred to above was exchanged pursuant to specific agreements between the parties, under which the respondents undertook to provide advance notice of any launch of the GS3-R System within the territories of the UPC Contracting Member

States. In compliance with those arrangements, the respondents informed the applicant by letters dated 11 and 12 February 2026 of their intention to launch the product within the UPC territory with two months' prior notice.
Those communications constitute a further acknowledgment by the respondents of their planned and imminent commercialisation of the GS3-R System within the UPC territory and confirm their direct involvement in the acts complained of in these proceedings.
Finally, in the course of the hearing the applicant clarified that imminent launch in all the UPC members States was expected by the end of August. This factual circumstance was not disputed by the respondents.

10. No delay in filing the application.

Prior to the filing of the present application, the applicant engaged in extensive correspondence with the SiBionics parties and their legal representatives concerning the intended marketing of the GS3 and GS3-R systems within the territory covered by the UPCA.
By letter dated 30 June 2025, the applicant first contacted SiBionics regarding its CGM products. In response, SiBionics undertook to provide two months' advance notice before launching its products in UPC Contracting Member States.
SiBionics subsequently launched the GS3 System in Spain. Thereafter, by letter dated 11 February 2026, SiBionics notified the applicant of its intention to launch the GS3 System within the UPC territory two months later. By a further letter dated 12 February 2026, SiBionics provided notice in respect of the GS3-R System, indicating that the planned launch would be limited to Bulgaria, Germany, Italy, Latvia, Lithuania and Slovenia. On 11 March 2026, SiBionics' newly appointed legal representatives confirmed that the notice provided concerned only the GS3-R System.
The cited evidence shows that SiBionics intended to launch the GS3-R System on 11 April 2026. Its legal representatives, Clifford Chance, expressly stated that they had been instructed to accept service only until that date.
Despite repeated requests, the respondents did not provide samples of either the GS3 System or the GS3-R System. As set out above, the evidence establishes that the GS3 System and the GS3-R System differ only in that the latter is supplied with a dedicated reader.
By letter dated 24 March 2026, the applicant informed SiBionics of its intention to commence the present proceedings. In that correspondence, the applicant identified the patent in suit and referred to the order issued by the Hague Local Division on 6 February 2026 against MicroTech concerning the same patent.
The present application under Rule 206 RoP was filed on 27 March 2026.
On the basis of this chronology, which is supported by contemporaneous documentary evidence and has not been materially disputed by the respondents, the Court is satisfied that the applicant acted promptly and diligently and that no unreasonable delay occurred in the commencement of these proceedings.
In the circumstances of the case, a period of approximately six weeks between receipt of the launch notices and the filing of the application constitutes a reasonable period for the preparation of the application, the collection and assessment of evidence, and the completion of the technical and legal analyses necessary before commencing proceedings.

This is particularly so given the need to determine whether the GS3 device, already marketed in Spain and known to the applicant, was identical to, or technically equivalent in all relevant respects to, the GS3-R device, in relation to which the applicant first received notice of the intended launch by letters dated 11 and 12 February 2026.
The Court therefore concludes that the applicant acted with the requisite diligence upon becoming aware of the imminent launch of the GS3-R System within the UPC territory and that the present Application was filed without undue delay, pursuant to R. 211.4 RoP.

11. Weighing of interests of the parties.

With regard to the balancing of interests, the Court of Appeal has defined the applicable legal framework as follows (UPC CoA No. 540/2024, Order of 24 February 2025):
"*19. Pursuant to Art. 62(2) UPCA and R. 211.3 RoP, the Court shall have the discretion to weigh up the interests of the parties and, in particular, to take into account the potential harm for either of the parties resulting from the granting or the refusal of the injunction. In view of the considerations given above, this means that Court must not merely take into account the harm for either of the parties, but also the time factor. More specifically, the Court must assess whether it is possible to await proceedings on the merits, or whether provisional measures are necessary.*
20. Accordingly, R. 206.2(c) RoP requires that the applicant in its application for provisional measures set out the reasons why provisional measures are necessary to prevent a threatened infringement, to forbid the continuation of an alleged infringement or to make such continuation subject to the lodging of guarantees. The Court of Appeal clarified that this is not a formal requirement. It concerns the merits of the application for provisional measures and must be considered by the judge when issuing an order under R. 211 RoP (UPC CoA no. 335/2023– NanoString vs. 10x, p .21).
21. Provisional measures will be necessary, for instance, where any delay would cause irreparable harm to the patent proprietor. Irreparable harm is, however, not a necessary condition for the ordering of provisional measures (UPC CoA no. 182/2024, order of 25 September 2024, para. 237).
22. This understanding of Art. 62 UPCA and R. 211 RoP is consistent with the Enforcement Directive. Art. 9 of the Enforcement Directive requires that the Member States ensure that the judicial authorities may, at the request of the applicant, issue interlocutory injunctions. According to recital 22 of the Enforcement Directive, it is essential to provide such provisional measures for the immediate termination of infringements, without awaiting a decision on the substance of the case, while observing the rights of the defence, ensuring the proportionality of the provisional measures as appropriate to the characteristics of the case in question. As indicated there, provisional measures are particularly justified where any delay would cause irreparable harm to the holder of an intellectual property right. The Court of Justice of the European Union (hereinafter: "CJEU") clarified that, in accordance with Article 9(1)(a) of the Enforcement Directive, read in conjunction with recital 22 thereof, the provisional measures must enable the infringement of an intellectual property right to be immediately terminated, without awaiting a decision on the merits, and that those measures are particularly justified where any delay would cause irreparable harm to the holder of such a right. The CJEU

emphasized that, thus, the 'time' factor is of particular importance for the purposes of effective enforcement of intellectual property rights (CJEU, judgment of 28 April 2022, C-44/21, ECLI:EU:C:2022:309, Phoenix Contact/Harting, para. 32). Accordingly, Art. 62 UPCA provides for provisional measures that can be relied on to terminate infringements immediately. The procedure can be used where necessary for the effective enforcement of patents, having regard to the time factor".

The applicant advanced detailed submissions in support of a finding that the balance of interests weighs in its favour.
In particular, it distinguished between two separate market segments existing across the relevant national markets: the reimbursement segment, accounting for approximately 95% of sales, and the cash segment, representing the remaining 5%. The applicant provided specific observations relating to a number of national markets, in particular Italy and Germany.
As regards Italy, the applicant submitted that the reimbursement segment operates through public procurement procedures, with device procurement being conducted through tender processes organised by central, regional or aggregated purchasing authorities, subject only to prior notification of the product to the Ministry of Health. According to the applicant, the Italian tender-based system is particularly sensitive to the entry of lower-priced competitors, and the resulting price erosion may persist even if the competitor subsequently exits the market.
With regard to Germany, the applicant explained that the reimbursement system is based on mandatory public or private health insurance schemes, under which suppliers negotiate directly with insurers. Although no evidence had yet been produced showing that contracts had already been concluded by the respondents, the applicant submitted that it was reasonable to expect that they would seek to compete through lower-priced offers, resulting in price erosion to the detriment of Abbott. Such contracts generally remain in force for a period of two years, after which it would be extremely difficult to restore previous pricing levels.
The applicant further argued that, within the cash segment, the effects of price erosion would materialise even more rapidly, owing to the possibility of direct placement of products on the market at discounted prices. This would create an imminent risk of erosion of sales volumes and prices, the effects of which would be difficult, if not impossible, to reverse, while also causing significant disruption to patients purchasing products through that channel.
By way of example, the applicant pointed out that, in Spain, Abbott markets the FreeStyle Libre system at a price of 64,19 EUR (Annex C3), whereas SiBionics launched its product at 69,00 EUR but subsequently applied extensive discount policies, including promotions of 10% (62,10 EUR) and subscription models providing discounts of 15% (58,65 EUR).

The respondents, on the other hand, contend that there is no genuine risk of price erosion.
First, they submit that prices are not determined by public authorities but by market forces and market participants.
Second, they argue that the structure of the relevant market does not support any expectation of price erosion. In their view, there is no evidence of systematic price undercutting. The applicant does not hold a monopoly position in the market for CGM devices, which already accommodates several competing suppliers. The respondents further observe that the applicant

has failed to address adequately the situation in Spain, where the GS3 product has been marketed for almost one year. According to the respondents, had the applicant's theory of price erosion been correct, concrete evidence of such effects should already have emerged in that market. To the contrary, the respondents' products have been offered in Spain at prices broadly comparable to those of the applicant.

The risk invoked by the applicant has already been examined in detail by the Court of Appeal in a highly comparable case concerning the marketing of CGM devices (UPC CoA No. 382/2024, order of 14 February 2025, paras. 153-157), where the Court held as follows:
"*153. Sibionics is presently active on the so-called 'cash-pay' segment of the CGM market. Although the 'base' price of the GS1 product is comparable, Sibionics offers promotions and discounts that undercut Abbott's market price. These discounts are of a structural repeated nature and incomparable to Abbott's offer of a first free test set. This will lead to a negative price spiral which, especially in this type of market, is very difficult to reverse, thus causing irreparable harm to Abbott.*
154. There is also a risk that Sibionics will try to enter the reimbursement segment of the CGM market by participating in tender procedures, offering its product for lower prices, also resulting in price erosion. Since these contracts are entered into for a substantial period of time, typically two years, price recovery will be even more difficult. The Court of Appeal rejects Sibionics argument that there will be no price erosion in the reimbursement segment. Even though it is true that the insurers set the price, they do so, among other factors, also on the basis of prices offered in tender procedures.
155. Sibionics' market entry with infringing products is not something Abbott has to accept as 'just a matter of competition', and 'required to be allowed as a driver for further innovation', as Sibionics contends. Obviously, competing with infringing products cannot be accepted as fair. Being able to prevent that is at the core of the exclusive right a patent offers. Also, further innovation does not justify patent infringement.
156. As Sibionics is based in China with no apparent assets within UPC territory, there is uncertainty whether any damages suffered by Abbott due to the infringing acts could be recovered.
157. The interest of Sibionics to be able to enter and stay on the market during proceedings on the merits do not outweigh the interests of Abbott by an immediate injunction. The damages of Sibionics due to later market entry should the injunction be lifted in proceedings on the merit will be easier to quantify, whereas Abbott's damages due to the long term effect of price erosion is difficult to quantify, also in view of its influence on the price of similar devices marketed by third parties and on the prices set by insurers".
In the case at hand, the Court notes that, in Spain, where the parties' products have coexisted on the market for approximately one year, there has so far been no significant evidence of price erosion within the cash segment. The respondents have marketed their device at a price level broadly equivalent to that of the applicant, save for limited promotional discounts corresponding to reductions of approximately 3% to 8% compared with Abbott's price.

The Court also accepts that the issuance of an injunction may seriously and, to some extent, irreversibly affect the respondents' market entry strategy, without prejudice to their right to challenge the present order on appeal.
However, it is common ground and undisputed that the vast majority of the relevant market is linked to reimbursement systems based either on public tender procedures, as is the case in Italy, or insurance-driven schemes, as in Germany. In relation to those market structures, the Court finds it entirely plausible that mechanisms of price erosion may arise, the effects of which are particularly difficult to reverse, for the reasons clearly identified by the Court of Appeal in the above-mentioned decision.
Furthermore, the possibility for patients to switch to an alternative and fully substitutable device offered at a lower price exposes the applicant to a concrete risk of losing a significant part of its customer base, with only limited prospects of recovering those patients within a short period of time.
Accordingly, after weighing the competing interests of the parties, the Court concludes that the balance of interests favours the applicant. The measures set out in detail in the following section 12 shall therefore be granted.
As the GS3-R system has not yet been placed on the market, there is no need to consider the interests of patients in that regard, since they have not had any actual opportunity to commence using that product.

12. Measures.

For the reasons set out above, the Court finds that the requested injunction concerning the GS3-R system is proportionate. The injunction shall therefore be granted in favour of the applicant for the entire territory of the UPC in the concerned Contracting Member States. The respondents' regulatory and commercial preparations demonstrate an intention to market the GS3-R throughout the UPC territory and therefore justify UPC-wide relief.
The specific request directed to the respondent 5) as EU authorised representative is dismissed as it appears to be unnecessary in light of the general injunction.

The applicant's request for a declaration that the infringing products constitute goods suspected of infringing an intellectual property right within the meaning of Article 2(7) of Regulation (EU) No 608/2013 is inadmissible, as such relief cannot be granted in proceedings for provisional measures (see UPC CFI No. 830/2025, LD The Hague, order of 6 February 2026, para. 4.12.3).

The Court further grants the applicant's request for an order for the provision of information. Information concerning the distribution channels of the products at issue and their further origin is considered both urgent and necessary in order to enable the applicant effectively to prevent and pursue possible further acts of infringement by third parties.

Having regard to the specific circumstances of the present case, the Court finds that the injunction granted is sufficient and proportionate to provide the applicant with adequate and effective protection. The request for an additional order for delivery up may be assessed in the

proceedings on the merits, where the parties will have the opportunity to fully address, in an adversarial setting, all factual and legal issues potentially relevant to the adoption of such a measure, including, *inter alia*, the applicable law, the duration of the measure, the allocation of the related costs, and the ultimate disposition of the delivered goods in a manner consistent with the outcome of the proceedings on the merits.

Finally, the Court considers it appropriate to impose recurring penalty payments in the event of non-compliance. Such penalty payments shall, however, be limited and capped as specified in the operative part of this order.

13. Value of the case.

Abbott has declared a value of the case of 4.000.000 EUR.
Respondents did not dispute such declaration.
The Court considers that there is no factual reason, at this stage, to deviate from such undisputed declaration. Therefore, the value of the case is set at 4.000.000 EUR.

14. Interim award of costs.

Pursuant to R. 211.1(d) RoP, the Court may order an interim award of costs in favour of the applicant.
In proceedings for provisional measures, there will often be grounds for granting the successful party an interim award of costs. Such an award enables the successful party to recover, on an interim basis, at least part of the costs incurred from the unsuccessful party, pending the commencement and final determination of separate cost proceedings under R. 150 et seq. RoP (see UPC CoA Nos. 317/2025 and 376/2025, order of 28 November 2025; see also UPC CFI No. 587/2025, LD The Hague, order of 22 October 2025).
As regards the amount of the interim award, the Court of Appeal has held that an award of up to 50% of the applicable ceiling for recoverable representation costs will generally be appropriate, unless there are clear indications that the successful party has in fact incurred lower representation costs or that such amount would be unreasonable or disproportionate in the particular circumstances of the case. At the same time, prior to the conclusion of the cost proceedings, the Court cannot assume that the successful party is entitled to recover more than 50% of the applicable ceiling (UPC CoA No. 19/2026, order of 18 February 2026).
In the present case, the Court considers that the pre-litigation conduct of the respondents justifies a moderation of the interim award. In particular, the respondents complied with their undertaking to notify the applicant, at least two months in advance, of their intention effectively to enter the market with the infringing product. By doing so, they enabled the applicant to make a fully informed decision as to whether and when to initiate the present application for provisional measures.
The Court considers that this conduct should be taken into account when determining the amount of the interim award and justifies a reduction from the level that would otherwise be granted. Accordingly, the Court finds it appropriate to award the applicant interim costs corresponding to the reduced percentage of 30% of the applicable ceiling.

Under the scale of ceilings for recoverable costs adopted by the Administrative Committee on 24 April 2023 pursuant to R. 152.2 RoP, the maximum recoverable representation costs for proceedings with a value of up to and including 4.000.000 EUR amount to 400.000 EUR.
Applying the principles set out above, the Court awards Abbott an interim sum for costs of 120.000 EUR, without prejudice to the final determination of recoverable costs in the proceedings on the merits.

ORDER

The Unified Patent Court, Court of First Instance, Milan Local Division:

a) prohibits the respondents, individually and jointly, on a provisional basis, from infringing the patent in any way, with immediate effect after service of the order to be rendered in this matter, in particular by offering, placing on the market, and/or using, the GS3-R System (or components thereof) as well as by importing or storing the GS3-R System for those purposes for each of the Contracting Member States in which the patent is in force (Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Portugal, Romania, Slovenia and Sweden);

b) orders the respondents to provide within four weeks after service, of the order rendered in this matter, to Abbott's representative a written account with the full names and address details of the origin and distribution channels of the GS3-R System, including the full names and addresses of the legal entities and any other non-consumer third persons that are involved in the manufacture of and trade in the GS3-R System within the territory of the Contracting Member States in which the patent is in force (Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Portugal, Romania, Slovenia and Sweden);

c) orders each respondent to pay to the Court a penalty sum of up to 100.000 EUR for each day or part of a day that it does not comply with the injunction at a) with a maximum of 1.000.000 EUR per respondent and a penalty of 10.000 EUR for each day or part of a day that it does not comply with the order at b) with a maximum of 100.000 EUR per respondent, or 100 EUR for each product with which the orders are violated (per day or per product determined by whichever leads to the higher amount); the penalties will be determined by this Local Division of the Court upon request by Abbott;

d) orders the respondents to jointly and severally pay Abbott an interim award of costs in the amount of 120.000 EUR within 14 days after service of the order in this matter;

e) declares that the order is immediately enforceable;

f) dismiss the application in all other the respects;

g) set the value of the case at 4.000.000 EUR;

h) orders that the proceedings on the merits be instituted within 31 calendar days or 20 working days from the date of service of this order to the respondents, noting that the order will be revoked or otherwise become ineffective, at the request of the respondents, if the applicant does not initiate proceedings on the merits before the Unified Patent Court within that period;

i) holds that the costs of the proceedings will be settled in the proceedings on the merits.

Parties may lodge an appeal within fifteen days of being served with this order pursuant to Article 73(2)(a) UPCA and R. 220.1(c) and 224.2(b) RoP.

Milan, 7 September 2026.

Pierluigi Perrotti presiding judge and judge rapporteur	Digitally signed Perrotti Pierluigi 2026-09-04 10:36:36 +0200 Unified Patent Court Einheitliches Patentgericht Juridiction unifiée du brevet
Alima Zana legally qualified judge	ALIMA ZANA MINISTERO DELLA GIUSTIZIA 01.09.2026 09:51:19 GMT+00:00
Samuel Granata legally qualified judge	Samuel Rocco M Granata Digitally signed by Samuel Rocco M Granata Date: 2026.09.01 10:34:19 +02'00'
Steen Wadskov-Hansen technically qualified judge	Wadskov-Hansen Steen Lyders Lerche Digitalt signeret af Wadskov-Hansen Steen Lyders Lerche Dato: 2026.09.01 11:10:57 +02'00'
for the Deputy Registrar	Digitally signed [redacted] 2026-09-04 10:32:46 +0200 Unified Patent Court Einheitliches Patentgericht Juridiction unifiée du brevet