Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

UPC Court of Appeal
UPC_CoA_899/2025

ORDER

of the Court of Appeal of the Unified Patent Court
issued on 30 March 2026
concerning a request for provisional measures

HEADNOTES

1. By not contesting the jurisdiction and competence of the Court in First Instance, the Appellant (Defendant in first instance) has in principle foregone this opportunity on appeal and cannot raise the alleged lack of jurisdiction and competence as a ground for overturning the impugned order (Art. 26(1) Brussels I Recast and R. 19.7 RoP).

2. By manufacturing, preparing and selling allegedly infringing products intended for the Contracting Member States of the UPC, there is a likelihood of damage occurring in the UPC territory arising from the possibility of third parties obtaining these products in the Contracting Member States, even if the acts causing the damage are performed by the Defendant outside the Contracting Member States. This provides basis for jurisdiction of the UPC pursuant to Art. 71b(2) in conjunction with Art. 7(2) Brussels I Recast.

3. Appellants must demonstrate that any alleged procedural or substantive errors by the Court of First Instance, such as those in relation to the procedural schedule applied in first instance, have resulted in an incorrect decision by the Court of First Instance. In the absence of such a showing, the alleged errors cannot result in setting aside the impugned order.

KEYWORDS

Jurisdiction – Claim construction – Infringement – Validity (added matter, sufficiency, novelty and inventive step) – Urgency, necessity and balance of interests

APPELLANTS (AND DEFENDANTS BEFORE THE COURT OF FIRST INSTANCE)

1. **Sinocare Inc.**, No. 265, Guyan Road, Hi-Tech Zone, Changsha, Hunan Provence 410205, China
(hereinafter referred to as "Appellant 1")

represented by Tjibbe Douma, attorney at law, Bird & Bird (Netherlands) LLP, Amsterdam, The Netherlands

2. **A. Menarini Diagnostics s.r.l.**, Via Sette Santi 3, 50131 Firenze, Italy
(hereinafter referred to as "Appellant 2")

represented by Edoardo Barbera, attorney at law, Bird & Bird Società tra Avvocati S.r.l., Milan, Italy

RESPONDENT (AND APPLICANT BEFORE THE COURT OF FIRST INSTANCE)

Abbott Diabetes Care Inc., 1360 South Loop Road, Alameda, CA 94502, United States of America (hereinafter referred to as "Respondent")

represented by Christian Dekoninck, attorney at law, Taylor Wessing N.V., Brussels, Belgium

PATENT AT ISSUE

EP 4 344 633

PANEL AND DECIDING JUDGES

Panel 3:
Ulrike Voß, presiding judge
Bart van den Broek, legally qualified judge and judge-rapporteur
Nathalie Sabotier, legally qualified judge
Dorothea Hofer, technically qualified judge
Gérard Myon, technically qualified judge

IMPUGNED ORDER OF THE COURT OF FIRST INSTANCE

Order of the Local Division The Hague, 17 October 2025, issued in the application for provisional measures UPC_CFI_624/2025

LANGUAGE OF THE PROCEEDINGS

English

DATE OF THE ORAL HEARING

9 February 2026

FACTS AND REQUESTS OF THE PARTIES

The patent at issue

1. The Respondent is the proprietor of the patent at issue ("the patent"). The patent was filed as a second generation divisional application ("the application") (Exhibit BB19), stemming from EP2713879 and EP3300658. EP2713879 is the ultimate parent application ("the parent application") which itself originated from a PCT application published as WO 2013/090215 A2 ("the PCT application") (Exhibit BB18). The filing date of the application is the filing date of the PCT application, namely 11 December 2012, and the patent claims a priority date of 11 December 2011. The mention of the grant of the patent was published on 4 June 2025 and the patent was registered for unitary patent protection on 18 June 2025. The patent is in force in all Member States of the Agreement on a Unified Patent Court ("UPCA").

2. Independent claim 1 of the patent relates to a sensor assembly. Claim 15 relates to a kit comprising the sensor assembly according to any one of claim 1 and its dependent claims, and a further specified on-body device. Claims 1 and 15 of the patent read as follows:

1. A sensor assembly (3702) comprising:

a sensor (3300) having a tail portion (3302), a contacts portion (3310), and a bendable portion (3318);
a seal (3402) including electrical contacts (3410) disposed to align with the contacts portion of the sensor and to allow electrical signals to pass through the seal;
a support (3404) including a distal surface and features for sealably coupling to an electronics assembly; and
a sharp (3408) including a channel for supporting the tail portion of the sensor and a hub (3414) for gripping the sharp during retraction, wherein the seal is shaped to enclose the contacts portion of the sensor within the support.

15. A kit comprising:

the sensor assembly (3702) of any of the preceding Claims, and
an on-body device (222) comprising:

an adhesive patch (3802) for adhering the on-body device to the skin of the user; and
an electronics assembly including:

sensor electronics;
an enclosure surrounding the sensor electronics, the sensor electronics including a circuit board, a processor and a communications facility, and
a socket (3704);

wherein the socket of the electronics assembly of the on-body device is configured to receive the sensor assembly (3702), and wherein the sensor assembly (3702) is shaped to fit within the socket (3704).

The parties

3. Respondent is established in the United States and is part of the Abbott group of companies. Respondent develops and distributes, *inter alia*, continuous glucose monitoring ("CGM") systems for diabetes patients.

4. Appellant 1 was established in 2002 and is headquartered in Changsha, China. Appellant 1 manufactures and distributes CGM systems internationally and is the largest manufacturer of glucose monitoring devices in Asia.

5. Appellant 2 is a pharmaceutical and diagnostics company established in Italy. Appellant 2 is part of the Menarini pharmaceutical group of companies and is involved in the development, manufacture and distribution of blood glucose self-testing systems for diabetes patients.

The contested embodiment

6. Respondent accuses Appellants of infringing its patent with the GlucoMen iCan product. The Appellants refer to this product in their Statement of appeal and Statement of grounds of appeal ("Statement of Appeal") as the "GlucoMen iCan o3". In line with the impugned order ("Order") and the parties in first instance, the Court of Appeal will refer to this product as the "GlucoMen iCan". Pictures of the GlucoMen iCan are inserted below:

7. The GlucoMen iCan is a continuous glucose monitoring system for diabetes patients. It includes a sensor assembly and an on-body device with an adhesive patch for adhering the device to the skin of the user. The sensor assembly contains a sensor and a sharp for inserting the sensor under the user's skin. Furthermore, the sensor assembly contains a support and a seal with electrical contacts to allow electrical signals to pass from the sensor to the electronics assembly in the on-body device. In use, the sensor assembly is fitted into the socket of the electronics assembly of the on-body device. The glucose information can be read out using a mobile application, the iCan app.

8. Prior to the introduction of the GlucoMen iCan, Appellant 1 was already on the market in Europe with a product named the Sinocare iCan i3 CGM System ("Sinocare iCan i3"). According to the Appellants, the Sinocare iCan i3 is technically the same as the GlucoMen iCan. The Sinocare iCan i3 will be discussed below in the context of the scope of the injunction.

The procedural background and the impugned order

9. On 4 July 2025, the Respondent filed an Application for a preliminary injunction and other provisional measures ("Application") with the UPC Local Division The Hague ("LD" or "LD The Hague"), arguing that the GlucoMen iCan manufactured and sold by Appellants in Europe was infringing its patent.

10. In the Order, the LD The Hague held that it had jurisdiction and competence to hear the case against both Appellants and that the Application had been filed in a timely manner, satisfying the requirements of urgency. The LD further found, after hearing the parties' arguments on infringement and validity of the patent, that it was more likely than not that the GlucoMen iCan infringes claims 1 and 15 of the patent and that the grounds for revocation raised by the Appellants were not expected to affect the validity of the patent in main proceedings. On that basis, after weighing the parties' interests, the LD granted an immediately enforceable preliminary injunction prohibiting direct infringement of the patent in the UPC territory, in particular by making, marketing, placing on the market, and/or using, supplying or offering to supply the GlucoMen iCan (or components thereof), as well as by importing or storing the GlucoMen iCan for those purposes.

11. In addition, the Appellants were ordered to disclose information on the origin and distribution channels of the GlucoMen iCan and to deliver up any GlucoMen iCan products held or owned by the Appellants in the UPC territory, all subject to penalty payments for non-compliance. The LD rejected the Appellants' request to make the injunction subject to security and ordered the Appellants to pay to the Respondent an interim award of costs of € 11,000.

12. Subsequently, the Appellants lodged an appeal against the Order.

The requests of the parties

13. In the Statement of Appeal, Appellants request that the Order be set aside and that the Application be rejected, and:

    In the alternative to

    - dismiss as inadmissible Respondent's request in first instance to declare that GlucoMen iCan o3 is considered "goods suspected of infringing an intellectual property right" within the meaning of article 2(7)(a) of Regulation (EU) No 608/2013;
    - dismiss the preliminary injunction and/or the corrective measures for recall claimed against the Defendants in first instance as being disproportionate;
    - dismiss the request for communication of information made by Respondent in first instance as inadmissible, at least with respect to the Defendants' sales volumes, selling price, internal costs and purchasing costs, and gross/net profits;
    - order that any preliminary injunction and/or corrective measure against the Defendants be strictly limited to the GlucoMen iCan o3;

    In the further alternative, to:

    - order that any preliminary injunction and/or corrective measure against the Defendants be strictly limited to the GlucoMen iCan o3 in the reimbursement market of the Contracting Member States where the patent is in force;
    - dismiss Respondent's claim in first instance seeking that the recalled products be placed under seal under bailiff supervision;
    - order that penalty payments associated with the preliminary injunction shall enter into force only one month after the service of the decision and shall be mitigated as follows:
        - EUR 10,000 for each violation and EUR 1,000 for each day the violation continues, or
        - EUR 100 for each product found in violation.
    - order that the data and information to be communicated in the context of the provision of information under Art. 67(1) UPCA be qualified as trade secrets, treated as strictly confidential, and may not be used or disclosed outside of the present legal dispute, even after its conclusion, and that Respondent may only disclose the information to those representatives and to an independent economic expert designated by the parties;
    - order Respondent to provide a security bond of EUR 400,000 for enforcement of the decision.

    In any event, to

    - order Respondent to reimburse the Appellants for the reasonable and proportionate legal costs incurred both at the Court First Instance and the Court of Appeal;
    - order Respondent to reimburse the Appellants for the injury caused by the enforcement of the provisional measures pursuant to R. 213 and R. 354(2) RoP.

14. In its Statement of response, the Respondent requests the Court of Appeal to:
    (a) dismiss Appellants' appeal against the impugned order;
    (b) order the Appellants, jointly and severally, to bear reasonable and proportionate legal costs and other expenses incurred by Respondent in these proceedings, and to order such costs to be determined in separate proceedings;
    (c) order the Appellants to pay Respondent, by means of an interim award of costs, the amount of EUR 400.000 or another amount as the Court may determine within 14 days after service of the order in this matter.

Summary of the parties' submissions

15. Appellants argue that the LD was wrong to accept jurisdiction regarding Appellant 1, established in China, and to decide that the patent was more likely than not valid and infringed. In addition, the Appellants argue that the LD was wrong to decide that the matter was urgent and that the LD did not properly consider the necessity requirement and the need to weigh the parties' interests. Appellants further argue that the Order should be set aside as it is based on a number of manifest procedural and substantive errors. Finally, Appellants argue that the LD was wrong to issue a broadly worded injunction that not only covers the GlucoMen iCan, but also the Sinocare iCan i3, which has been on the market in Europe since October 2023.

16. Respondent argues that the LD correctly concluded that it had jurisdiction and competence to hear the case against both Appellants and that the GlucoMen iCan is literally covered by claims 1 and 15 of the patent. The Respondent disagrees with the Appellants that these claims are likely invalid. Furthermore, the Respondent argues that the LD was correct to decide that the matter was urgent and that the interests of both parties were properly weighed. During the oral hearing, the Respondent indicated that the Sinocare iCan i3 was not meant to be covered by the Application and should therefore be considered to be excluded from the issued preliminary injunction. Besides this, the Respondent argues that the LD was correct to grant a generally worded injunction.

GROUNDS FOR THE ORDER

17. The appeal against the Order of the LD The Hague is admissible but unfounded.

I. Jurisdiction

18. In the Order, the LD has accepted jurisdiction and competence to hear the case, both with respect to Appellant 1 (established in China) and with respect to Appellant 2 (established in Italy). With respect to both Appellants, the LD based its international jurisdiction on Art. 71b(1)/(2) and Art. 7(2) of Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgements in civil and commercial matters (recast) as amended by Regulation (EU) No 542/2014 of the European Parliament and Council of 15 May 2014 ("BR"), and its internal competence on Art. 33(1)(a) of the UPCA.

Appellant 2

19. In first instance, Appellant 2 did not contest the jurisdiction and competence of the LD The Hague. In the Objection dated 18 August 2025 ("Objection"), the jurisdiction and competence of the LD The Hague were only contested with respect to Appellant 1.

20. Appellant 2 did argue that the Respondent had not shown any infringing activities by Appellant 2 in The Netherlands. This was repeated in the Statement of Appeal, adding that the LD The Hague had ignored Appellant 2's "*substantiated defence*" that none of the evidence produced by the Respondent would show that Appellant 2 was involved in infringing activities in The Netherlands "*which was the only ground for accepting internal competence for the LD The Hague pursuant to Art. 33(1)(a) UPCA*".

21. To the extent that, with these statements, Appellant 2 intends to appeal the decision of the LD The Hague to accept jurisdiction and competence with respect to Appellant 2, this is rejected. By not contesting the jurisdiction and competence of the LD The Hague in first instance, Appellant 2 has in principle foregone this opportunity on appeal and cannot now raise the alleged lack of jurisdiction and competence as a ground for overturning the Order. This follows from Art. 26(1) BR and R. 19.7 RoP. The exception according to Art. 26(1), second sentence, BR, namely that another court has exclusive jurisdiction pursuant to Art. 24 BR, does not apply in this case.

22. Leaving this aside, also on substantive grounds, the Court of Appeal rejects Appellant 2's argument

that no infringing activities have been shown in The Netherlands. Even if it would be accepted, as argued by Appellant 2, that the GlucoMen iCan was sold in The Netherlands solely by Menarini Benelux and its third party customers (which are not parties to these proceedings), the Respondent has shown in its Application that Appellant 2 offered the GlucoMen iCan via its website https://glucomenican.com. This website was accessible to consumers throughout Europe, including in the Netherlands.

23. As a result, there was a likelihood of damage occurring in the Contracting Member States of the UPC, including in the Netherlands. As this Court decided in UPC_CoA_188/2024 (3 September 2024, Aylo v. Dish), in the case of damages allegedly caused via the internet, the likelihood of such damage may arise from the possibility of obtaining products and/or using services from an internet site accessible within the territory of the Contracting Member State(s) where the European patent has effect.

24. The LD The Hague was therefore correct to accept jurisdiction and competence regarding Appellant 2 pursuant to Art. 71b(1) in conjunction with Art. 7(2) BR and Art. 33(1)(a) UPCA, respectively.

Appellant 1

25. The LD The Hague was also correct to accept jurisdiction and competence with respect to Appellant 1 based on Art. 71b(2) in conjunction with Art. 7(2) BR and Article 33(1)(a) UPCA, respectively.

26. As the Respondent stated in the Application, Appellant 1 is the manufacturer of the GlucoMen iCan and is named as such on the packaging of the products and in the entry for the GlucoMen ican in the European EUDAMED database. Furthermore, as Respondent stated in the Application, Appellant 1 was responsible for obtaining the CE certification for the GlucoMen iCan and for affixing the CE marking to these products to bring these onto the European market, including in the Netherlands.

27. In order to sell its products in Europe, Appellant 1 entered into a strategic partnership with Appellant 2. Reference is made, for example, to Appellant 1's announcement of 4 December 2024 that was published on its website and was submitted by Respondent as Exhibit BB12:

Global Market Expansion: Sinocare's CGM Products Enter the European Market

Release time : 2024-12-04 View count : 5935

Strategic Partnership with A. Menarini Diagnostics to Launch iCan CGM in Europe

Sinocare, a leading healthcare China company, has announced a strategic partnership and signed an exclusive distribution agreement with A. Menarini Diagnostics. The agreement marks a significant milestone as Sinocare's Continuous Glucose Monitoring (CGM) products will enter over 20 jurisdictions in Europe under a co-branded label. A. Menarini Diagnostics will register, promote, distribute, and market Sinocare CGM products within reimbursed markets.

28. As part of this strategic partnership, the allegedly infringing products were "co-branded" using a combination of the brands of both partners, i.e. the brand "GlucoMen" of Appellant 2 and the brand "iCan" of Appellant 1. Appellant 1's iCan brand is shown in the below pictures (Objection, page 13):

29. The co-brand of both partners is included on the product packaging and in the advertising materials used in connection with the marketing of the GlucoMen products in Europe. Reference is made, for example, to the aforementioned website and to the GlucoMen iCan brochure that was made available to European users via this website (Exhibit BB06). In addition, Appellant 1 is specifically mentioned as the copyright owner in the user guide of the GlucoMen iCan (Exhibit C1):

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30. The user guide for the GlucoMen iCan was made available to European users via the aforementioned website accessible in the Contracting Member States and was (also) provided in the Dutch language.

31. Based on the foregoing, it is clear that the role of Appellant 1 was not merely that of a China based manufacturer having a "*standard supplier-distributor relationship*" with Appellant 2 without any involvement in Europe. As stated by the Respondent, Appellant 1 was responsible for the manufacture and preparation of the GlucoMen iCan products for sale on the European market and was closely involved in the promotion of these products in Europe, including through advertising and instruction materials in relation to the GlucoMen iCan products marketed throughout Europe, including the Netherlands.

32. As a result of these acts by Appellant 1 there was a likelihood of damage to occur, or at least threatened to occur, in the Contracting Member States where the patent is in force, including in the Netherlands, for which Appellant 1 is responsible. Even if Appellants' argument would be followed that Appellant 1 itself did not perform any acts in relation to the GlucoMen iCan in Europe, by manufacturing, preparing and selling its GlucoMen iCan products intended for the European market, the likelihood of damage arose from the possibility of third parties obtaining these products in the Contracting Member States, including in the Netherlands.

33. This provides basis for accepting jurisdiction pursuant to Art. 71(b)(2) and Art. 7(2) BR (cf. CJEU 3 October 2013, C-170/12, ECLI:EU:C:2013:635, Pickney v. KDG Mediatech and UPC_CoA_188/2024**,** 3 September 2024, Aylo v. Dish). For the same reason, the LD The Hague was correct to accept internal competence pursuant to Art. 33(1)(a) UPCA. As this Court decided in UPC_CoA_188/2024, the place "*where the actual or threatened infringement has occurred or may occur*" as referred to in Art. 33(1)(a) UPCA must be interpreted the same way as the place "*where the harmful event occurred or may occur*" of Art. 7(2) BR is interpreted in relation to alleged patent infringements (cf. UPC_CoA_317/2025, 28 November 2025, Barco v Yealink).

II. Alleged violations of due process and manifest errors

34. In the Statement of Appeal, Appellants list a number of alleged procedural violations and manifest

substantive errors by the LD The Hague and request the Court of Appeal to set aside the Order on one or more of these grounds. None of these asserted grounds justifies overturning the Order.

35. First of all, the Appellants have not shown that any of the alleged procedural errors resulted in an incorrect decision by the LD. This is for the Appellants to demonstrate and already for this reason, the alleged procedural errors cannot result in setting aside the Order.

36. Furthermore, the procedural objections are unfounded. The LD The Hague provided the Appellants sufficient time to file an objection against the Application. This resulted in Appellants' Objection of no less than 98 pages with 41 exhibits, raising a multitude of procedural and substantive defences. The Court of Appeal also disagrees with the Appellants that the LD violated the rules regarding the distribution of the burden of proof. In its Application, Respondent explained in detail why and how the Appellants' product infringed which claims of the patent, and why it considered the requested relief to be timely, necessary and proportionate. The LD correctly assumed that the Respondent thus provided sufficient detail to prove its infringement allegations.

37. The Court of Appeal neither sees merit in Appellants' complaints relating to the alleged substantive "manifest errors". These will be discussed below to the extent relevant. None of these justify overturning the Order.

III. The patent at issue

38. Paragraphs [0002] – [0006] of the description set out the background of the invention. It is explained that vast and uncontrolled fluctuations in blood glucose levels in people suffering from diabetes cause long-term, serious complications and that an important and universal strategy in managing diabetes is to control blood glucose levels (paragraph [0002]).

39. Next to the use of conventional *in vitro* techniques (described in paragraph [0004]), glucose levels in blood may be monitored automatically over time, using an *in vivo* analyte monitoring system. Such a system uses an *in vivo* sensor that is positioned under the skin to be in contact with interstitial fluid of a user for a period of time to detect and monitor glucose levels. Such a system employs an applicator assembly to insert the sensor into the body of the user using a sharp engaged with the sensor. The sensor can be connected to other system components, such as sensor electronics contained in a unit that can be held onto the skin (paragraph [0004]).

40. According to paragraph [0006] "*what is needed are applicator systems configured to handle insertion, as well as packaging and user interface issues, that are easy to use, reliable and minimize both user inconvenience and pain*."

41. In light of this, claim 1 of the patent protects a specific sensor assembly and claim 15 protects a kit containing this sensor assembly and a specific on-body device. The parties and the Court of First Instance ("CFI") have referred to the separate features of claims 1 and 15 as follows, to which the Court of Appeal agrees:

Claim 1

Feature 1.1	A sensor assembly (3702) comprising:
Feature 1.2	a sensor (3300) having a tail portion (3302), a contacts portion (3310), and a bendable portion (3318);
Feature 1.3	a seal (3402) including electrical contacts (3410) disposed to align with the contacts portion of the sensor and to allow electrical signals to pass through the seal;
Feature 1.4	a support (3404) including a distal surface and features for sealably coupling to an electronics assembly; and

Feature 1.5	a sharp (3408) including a channel for supporting the tail portion of the sensor and a hub (3414) for gripping the sharp during retraction,
Feature 1.6	wherein the seal is shaped to enclose the contacts portion of the sensor within the support.

Claim 15

Feature 15.1	A kit comprising:
Feature 15.2	the sensor assembly (3702) of any of the preceding Claims, and
Feature 15.3	an on-body device (222) comprising: an adhesive patch (3802) for adhering the on-body device to the skin of the user; and
Feature 15.4	an electronics assembly including:
Feature 15.4.1	sensor electronics;
Feature 15.4.2	an enclosure surrounding the sensor electronics, the sensor electronics including a circuit board, a processor and a communications facility, and
Feature 15.4.3	a socket (3704);
Feature 15.5	wherein the socket of the electronics assembly of the on-body device is configured to receive the sensor assembly (3702),
Feature 15.6	and wherein the sensor assembly (3702) is shaped to fit within the socket (3704).

42. In the patented invention, a sensor system is provided that is to be assembled from mainly two pre-assembled units, i.e. a sensor assembly and an on-body device which is configured to receive the sensor assembly prior to using the (integrated) on-body device (paragraph [0007]). The sensor assembly is specified in claim 1. According to claim 15, this sensor assembly is provided in a kit together with the on-body device, which contains an electronics assembly with a socket to receive the sensor assembly, and an adhesive patch for adhering the on-body device to the skin of the user.

43. The sensor assembly according to claim 1 contains a sensor and a sharp. In addition, it contains a support and a seal with electrical contacts to allow electrical signals to pass from the sensor to the electronics assembly in the on-body device. The seal of the sensor assembly is shaped to enclose the contacts portion of the sensor within the support. In turn, the support is equipped with means for sealably coupling the sensor assembly to the sensor electronics in the on-body device.

44. Figures 34A – 34D show an embodiment of the sensor assembly according to claim 1 of the patent:

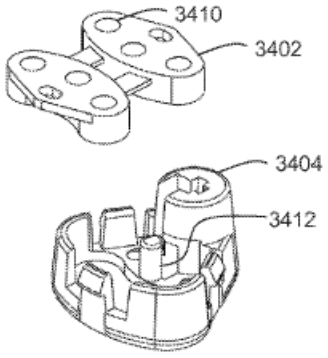


FIG. 34A

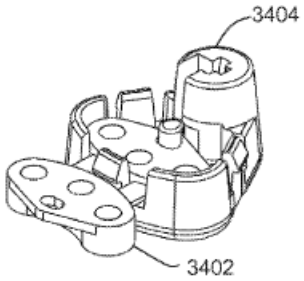


FIG. 34B

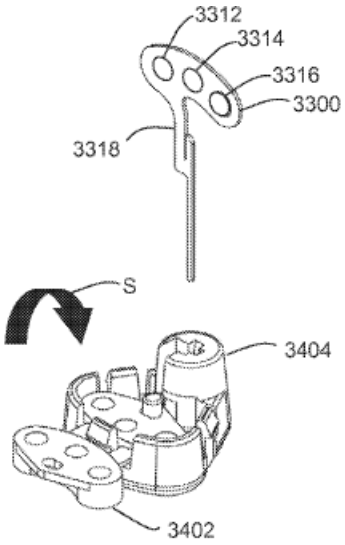


FIG. 34C

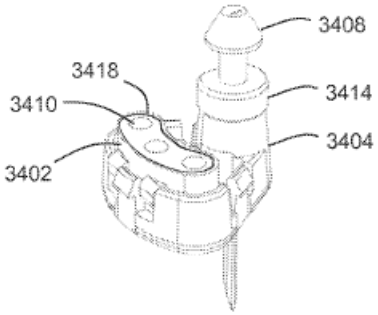


FIG. 34D

IV. Skilled person

45. The LD The Hague has defined the skilled person as a mechanical engineer with several years of experience in the design of CGM systems.

46. The Appellants argue that the LD was wrong to state that the parties did not define the skilled person, as the Appellants had defined a skilled person. According to the Appellants, because this definition was not contested by the Respondent, the LD was bound by Appellants' definition as an uncontested statement of fact (R. 171.2 RoP). By providing its own definition of the skilled person, the LD has made a manifest error, according to the Appellants. The Respondent contests this and responds that this issue is immaterial anyway, as the definition used by the LD corresponds to the definition of the Appellants.

47. The Court of Appeal rejects the Appellants' arguments.

48. First of all, the Court of Appeal notes that the definition of a skilled person is a question of law, not a statement of fact. The skilled person is a legal fiction representing a hypothetical, average practitioner in a specific field (CoA UPC_CoA_768/2024, 30 April 2025, Insulet/EOFlow). This legal fiction is used to determine the meaning and scope of the patent and the prior art, and to assess whether the patent is valid and infringed. These are all questions of law, and so is the definition of the skilled person. The LD was therefore entitled to come up with its own definition of the skilled person, irrespective of whether the Respondent had contested the Appellants' definition or not.

49. In addition, the Court of Appeal agrees with the Respondent that the definition of the skilled person by the LD does not materially differ from the definition of the Appellants. In both definitions, the skilled person has several years of experience in the design of CGM systems. For reasons of clarity, the Court of Appeal adds that the 'mechanical engineer' in the definition of the LD is an interdisciplinary *team* of engineers with several years of practical experience in the field of mechanical engineering *and* electronic engineering, in particular in the design of CGM systems.

V. Claim construction

50. The principles applicable to claim construction have been set out by this Court in its final order in UPC_CoA_335/2023 (26 February 2024, NanoString v 10x Genomics, as rectified; see also CoA UPC_CoA_1/2024, 13 May 2024, VusionGroup v Hanshow; UPC_CoA_768/2024, 30 April 2025, Insulet v. EOFlow). A patent claim is not only the starting point but the decisive basis for determining the protective scope of a European patent under Art. 69 EPC in conjunction with the Protocol on the Interpretation of Art. 69 EPC. The interpretation of a patent claim does not depend solely on the

strict, literal meaning of the wording used. Rather the description and the drawings must always be used as explanatory aids for the interpretation of the patent claim and not only to resolve any ambiguities in the patent claim. A patent claim must always be interpreted from the perspective of a person skilled in the art. The skilled person interprets the features of a claim always in the light of the claims as a whole (UPC_CoA_1/2024, 13 May 2024, VusionGroup v Hanshow; UPC_CoA_768/2024, 30 April 2025, Insulet v EOFlow, UPC_CoA_646/2024, 25 November 2025, Meril v Edwards). These principles for interpreting a patent claim apply both to the question of patent infringement and to the question of validity (NanoString v 10x Genomics, u.a.).

51. There is dispute between the parties on the interpretation of a number of the features of claims 1 and 15. These features are discussed below.

Feature 1.1.

52. Feature 1.1 relates to a "sensor assembly". The LD The Hague considered the "sensor assembly" of claim 1 to be a pre-assembled unit comprising the elements specified in the claim, i.e. a support, a seal, a sensor and a sharp.

53. Appellants criticize this interpretation and argue that the word "assembly" in feature 1.1 should be interpreted according to its ordinary meaning as a "*group of parts capable of working together but not necessarily completed into a unit*". In this context, the Appellants refer to the fact that the LD considered the embodiment of Figures 36-38 to be covered by claim 1. According to the Appellants, this would be in conflict with the interpretation of the sensor assembly of feature 1.1 as a pre-assembled unit, because the sealing in the embodiment of Figures 36-38 is not achieved by the sensor assembly itself, but by using an elastomeric member in the socket of the electronics unit of the on-body device to which the sensor assembly is coupled during use. The Appellants argue that if the embodiment of Figures 36-38 is considered to be covered by claim 1, then the sensor assembly of claim 1 cannot be a pre-assembled unit.

54. Respondent generally agrees with the LD and interprets "sensor assembly" as a "*separate part*" that comprises a sensor, a seal, a support and a sharp, and refers in this context to multiple disclosures in the description and the figures of the patent to support this interpretation.

55. The Court of Appeal agrees with the Respondent and interprets the sensor assembly as a separate part or unit.

56. First of all, this follows from the wording and structure of the claim. Claim 1 does not merely mention some individual components that must be able to work together. Instead, the claim refers to a sensor assembly that "comprises" the specified components (sensor, sharp, support and seal).

57. This is supported by the description. Reference is made, for example, to the general description in paragraph [0007] ("*The approaches variously involve the use of unique sensor and unique ancillary element arrangements to facilitate assembly of <u>separate</u> on-body devices and sensor assembly units*.."), paragraph [0009] ("..*a sensor assembly <u>coupled to</u> the electronics assembly to form an on-body device* ..") and paragraph [0011] ("..*<u>assembling</u> the sensor assembly <u>to</u> the electronics assembly*.."). In addition, paragraph [0021] explains with reference to Figure 1: "..*the applicator is inserted into the container <u>to merge or connect</u> the sensor assembly and the electronics assembly together to form an on-body device*".

58. It thus follows from these passages that the sensor assembly and the electronics assembly are separate units that are merged together to form the integrated on-body device which is applied by the user.

59. Equally, in all examples discussed in the patent description, the sensor assembly is shown as a separate unit, including the sensor and a sharp. Reference is made, for example, to Figure 4 (sensor assembly 410), Figure 6 (sensor assembly 608), Figure 19A (sensor assembly 1902), Figure 21A

(sensor assembly 2104), Figure 23B (sensor assembly 2300), Figure 34D, Figure 35B, Figures 37 and 38 (sensor assembly 3702), Figure 41A (sensor assembly 4100), and Fig. 47A (sensor assembly 4702).

60. According to the Court of Appeal, the squeeze raised by the Appellants does not exist.

61. The Court of Appeal agrees with the Appellants that the embodiment of Figures 36-38 is not covered by claim 1 and the Respondent does not seem to contest this. According to claim 1 (features 1.3 and 1.6), a seal with electrical contacts must be part of the sensor assembly and must therefore be present in this pre-assembled unit. In the embodiment of Figure 36, the sensor 3300 is positioned on an elastomeric seal backing of the support of the sensor assembly 3702 with its electrical contacts exposed (in the embodiment of Figures 36-38, sensor 3300 has all electrical contacts on one (i.e., the exposed) side; paragraph [0088]). Figures 37 and 38 show the on-body device with a socket for receiving the sensor assembly 3702. Paragraph [0088] states in this context that "*the sensor assembly 3702 is shaped to fit within a socket 3704 that includes a second elastomeric unit with electrical contacts in the elastomer body of the socket*". It follows from this passage that the seal with the electrical contacts is not part of the sensor assembly but is present in the socket of the on-body device. The embodiment of Figures 36-38 is therefore not covered by claim 1, which requires a seal with its electrical contacts to be part of the sensor assembly. Figures 36-38 are therefore not relevant for the interpretation of the sensor assembly of claim 1 and do not conflict with the above interpretation of the sensor assembly as a separate pre-assembled unit.

Feature 1.4

62. Feature 1.4 states that the support of the sensor assembly has "a distal surface".

63. The Appellants argue that the skilled person will understand this feature to require the support to have "*a surface that is facing towards and placed on the patient's skin when the on-body device is applied*". The Appellants refer in this respect to paragraph [0011] of the description and to the embodiments in the patent (e.g. Figure 37), in which the sensor assembly is inserted into the on-body device from below and therefore rests with its lower surface on the user's skin when in use. The Appellants further argue that they presented this interpretation already in their Objection and that the Respondent had not contested this interpretation. The LD would therefore be bound by Appellants' interpretation as a statement of fact pursuant to R. 171.2 RoP. Finally, the Appellants argue that the distal surface of the support must be uninterrupted and cannot have an opening.

64. Respondent interprets the term "distal surface" as a relative term, indicating "*the direction that the surface faces"*. Respondent's interpretation is generally in line with the interpretation by the LD in its Order: "*.."distal" more generally means "away", i.e. .. away from the hand of the user handling the applicator."*

65. The Court of Appeal rejects the arguments raised by the Appellants.

66. First of all, the Appellants' argument is incorrect that the LD has violated R. 171.2 RoP. Claim construction is a matter of law, not a matter of fact (UPC_CoA_768/2024, 30 April 2025, Insulet/EOFlow; UPC_CoA_405/2024, 19 June 2025, Alexion/Amgen). R. 171.2 RoP is therefore not applicable here.

67. Claim 1 refers in feature 1.4 to the "distal surface" of the support, without specifying that this surface needs to be placed on the user's skin or be adapted for this purpose. In accordance with its ordinary meaning, a skilled person would understand the word "distal" in the claim as a relative term opposite to "proximal" and referring to the lower surface of the support.

68. This is supported by the description. The Court of Appeal notes that the description does not specifically mention the distal surface of the support of the sensor assembly, but the word "distal" does appear in a number of other contexts.

69. First, the term "distal" is used in relation to the sensor, referring to the "distal tail portion" of the

sensor. Reference is made to paragraph [0011] ("*sensor that has a distal tail portion*"), paragraph [0022] ("*the applicator is driven to insert the distal end of the sensor through the user's skin*"), paragraph [0069] ("*the distal portion of the tail is to be inserted through the skin surface guided by a sharp*") and paragraph [0079] ("*FIG. 33D provides a magnified side view of the distal most part of the tail portion 3302 of the sensor 3300*").

70. Secondly, the term "distal" is used in relation to the electronics assembly, referring to the distal surface of its housing which is "*adapted for attachment to the skin of the user*". Reference is made to paragraph [0011] ("*the on-body device may also include an electronics assembly including a housing defining a distal surface adapted for attachment to the skin of the user*").

71. Thirdly, the term "distal" is used in relation to the applicator assembly, referring to a sleeve within the applicator having a distal surface "*for placement on the skin of the subject*". Reference is made to paragraph [0011] ("*in some embodiments, the system also includes an applicator assembly that has a sleeve defining a distal surface for placement on the skin of the subject*").

72. Finally, the term "distal" is used in relation to the needle guard having a "distal interface feature" that ensures that the needle guard stays in the container when the on-body device is used. Reference is made to paragraph [0064] ("*FIGS. 19A and 19B show a sensor assembly 1902 in association with a needle guard 1904. In use, a distal interface feature (e.g., a barb) of the needle guard 1904 is captured by a complimentary split ring or other feature in the container during the assembly of the on-body device. Then, when the applicator is separated from the container, the needle guard 1904 is retained in the container and the sharp is unsheathed.*").

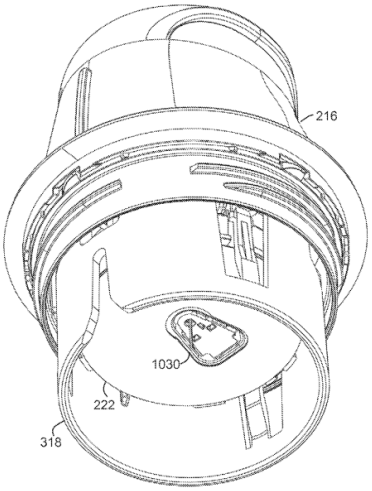
73. With respect to the first context (the sensor), the skilled person understands the "distal tail portion" as a relative term, referring to the lower end of the sensor. This is confirmed by paragraph [0069] which indicates that the sensor also has a proximal portion: "*A first example is presented in FIG. 22. Here a sensor 2202 is provided with an elongate "tail" section. The distal portion of the tail is to be inserted through the skin surface guided by a sharp. The proximal portion of the sensor 2202 includes a "flag" type connector region*." Thus, "distal" is the opposite of "proximal".

74. While the first context, as well as the second context (electronics assembly) and the third context (applicator assembly), **also** support a meaning (as *explicitly* indicated in the text) that the term "distal" can be associated with a surface that is close to/facing the patient's skin, the fourth context (needle guard) makes clear that the word "distal" is **not generally** meant to be "close to/facing the patient's skin", as the Appellants argue. The needle guard with its "distal interface feature" remains in the container and is thus neither close to nor facing the patient's skin. On the other hand, also in this context, the term "distal" may well be understood as a relative term being further away from the user's hand that places the applicator on the container to assemble the sensor assembly with the electronics assembly.

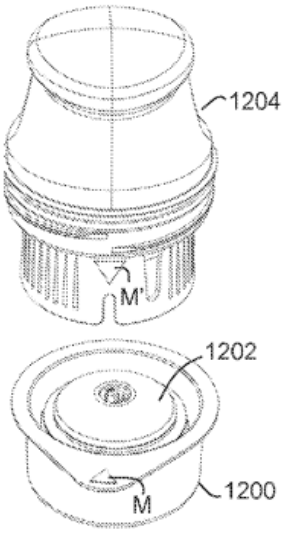
75. The patent description thus uses the word "distal" in its ordinary meaning as a relative term and does not require that the distal surface of the support is placed on the user's skin or be close to it.

76. The term "distal surface" can neither be seen as a reference to the mode of application of the sensor assembly to the on-body device, i.e. insertion from below, rather than from above. The patent description discusses both options at equal footing and the claim covers both.

77. In some embodiments, the sensor assembly is provided in a container and the on-body device is provided in a separate applicator (see e.g. Figures 3 and 4 and Figures 10A-10N). In these embodiments, the sensor assembly and the on-body device are assembled by inserting the sensor assembly into the on-body device from below. See, for example, Figure 10N of the patent:



78. In other embodiments, the sensor assembly is provided in the applicator and the on-body device is provided in a separate container. In these embodiments, the sensor assembly and the on-body device are assembled by inserting the sensor assembly into the on-body device from above. See, for example, paragraph [0057] and Figure 12A:



79. Claim 1 of the patent does not contain any limitation in this respect. As shown, for example, in Figure 21A, when the sensor assembly is inserted into the on-body device from above, the distal surface of the support is in the direction of the user's skin but is not placed on the skin, as argued by the Appellants:

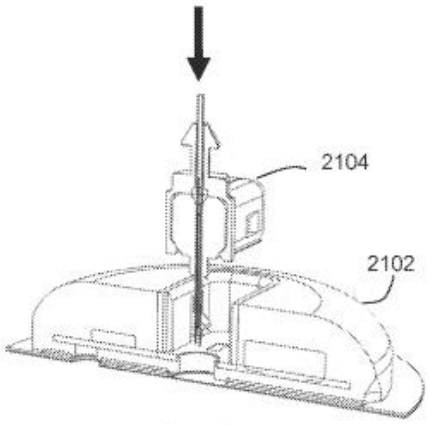


FIG. 21A

80. Finally, there is no indication in the claim or in the description that the distal surface of the support must be uninterrupted.

81. To conclude, the Court of Appeal interprets the "distal surface" of the support according to feature 1.4 as the surface away from a user's hand in the direction of the patient's skin, but not necessarily configured to be placed on the patient's skin. It may well be that other parts of the sensor assembly also have a distal surface according to that meaning and that the distinctive nature of this feature is therefore limited, as Appellants argue, but this does not justify reading limitations into this feature which are not supported by the patent.

Feature 1.6

82. Feature 1.6 specifies that the sensor assembly has a seal that is shaped to enclose the contacts portion of the sensor within the support.

83. According to the Appellants this feature requires the seal to "surround" the contacts portion on both sides of the sensor, also when the sensor has all its electrical contacts only on one side. In particular, the Appellants argue that the seal of feature 1.6 is limited to the seal shown in Figures 34-35 of the patent and described in paragraphs [0084] and [0085], as this would be the only embodiment which complies with the wording of claim 1. This would be further evidenced, according to Appellants, by the addition to paragraph [0084] of the words "*according to embodiments of the present invention as claimed in claim 1*" during prosecution. This would imply that the words "shaped to enclose" in feature 1.6 must refer to the seal of Figure 34, i.e. "*a seal that has two halves that fold around the contacts portion, thereby enclosing the contacts portion of the sensor*".

84. With respect to the words "within the support" in feature 1.6, the Appellants argue that these mean that the electrical contacts of the sensor are sealed within the support. This would imply, according to the Appellants, that the seal cannot extend to outside the support, and that the seal must perform its sealing function within the support "*and not only when the sensor assembly is mated with the electronics assembly*".

85. Respondent argues that feature 1.6 is not limited to the embodiment in Figures 34-35 and that the limitation "sealing both sides" of the contacts portion is not part of the claim. According to the Respondent, feature 1.6 should be interpreted to mean that the electrical contacts of the sensor must be "fenced off". If these electrical contacts are only present on one side of the contacts portion, it is sufficient that the seal encloses that side of the contacts portion of the sensor ("*the contact portion of the sensor can also be enclosed on one side, i.e. by fencing off the sensor contacts disposed on a side of the contacts portion*").

86. In addition, according to the Respondent, the words "within the support" merely refer to the location where the enclosure of the contacts portion of the sensor occurs and does not exclude that the seal extends to outside the support or that the actual sealing takes place after the sensor assembly is coupled to the on-body device.

87. The Court of Appeal rejects the interpretation of feature 1.6 followed by the Appellants.

The seal is shaped to enclose the contacts portion

88. To better understand the meaning of feature 1.6, reference is first made to feature 1.3 of claim 1.

89. Feature 1.3 requires that the sensor assembly comprises a seal "*including electrical contacts disposed to align with the contacts portion of the sensor and to allow electrical signals to pass through the seal*". This feature thus specifies the function of the seal as a **connector** to allow electrical signals to pass between the contacts portion of the sensor and an electronics assembly (to which the support of the sensor assembly is sealably coupled according to feature 1.4). In line with this connector function, the words "seal" and "connector" are interchangeably used in the patent description (see, for example, column 26, line 47: "*one-piece seal or connector 3402*").

90. To perform its function as a connector, the seal of feature 1.3 is equipped with electrical contacts "*disposed to align with the contacts portion of the sensor*". In view of this wording and given the seal's function as a connector, the skilled person will understand the term "contacts portion" in feature 1.3 to refer to the electrical contacts of the sensor. As a result of the alignment of the electrical contacts of the seal with that portion of the sensor, the seal can perform its connector function and pass the electrical signals from the sensor to the electronics assembly.

91. In the exemplary embodiment of Figures 33A-33G of the patent, the contacts portion 3310 includes more than just the electrical contacts. It also includes, for example, securement features to facilitate the contacts portion to be held and sealed into the connector support (column 24, line 54-column 25, line 5). These additional elements are optional and are not relevant for the seal's connector function prescribed in feature 1.3. These features will therefore be understood by the skilled person to be outside of the realm of feature 1.3.

92. Feature 1.6 builds on feature 1.3 and specifies the **sealing** configuration of the seal of feature 1.3. In this context, feature 1.6 refers to the contacts portion of feature 1.3 and specifies that the seal is shaped to enclose this portion of the sensor. Given its interrelation with feature 1.3, the skilled person will understand the reference to the contacts portion in feature 1.6 to mean the electrical contacts of the sensor with which the electrical contacts of the seal are disposed to align according to feature 1.3. According to feature 1.6, the seal must be shaped "to enclose" these electrical contacts.

93. The Court of Appeal agrees with the Respondent that the word "enclose" has a broader meaning than "surround" and may also be interpreted as "fence off" or "inclose". The skilled person therefore understands feature 1.6 to mean that the electrical contacts of the sensor are "fenced off" or "inclosed" by the seal to protect the electrical contacts of the sensor, for example, against moisture and contaminants. The seal according to feature 1.6 thereby ensures that it can optimally perform its connector function and contributes to provide a reliable glucose monitoring system in accordance with one of the stated goals of the invention (cf. paragraph [0006] of the patent).

94. In line with the wording of the claim, the importance of protecting the electrical contacts of the sensor is specifically mentioned in a number of passages in the patent description. Reference is made, for example, to column 23, lines 7-9 and 28-31 of the patent, column 24, lines 28-30, column 27, lines 4-8 and column 30, lines 17-21 ("*Notably, sensor assembly 4702 does not include a separate connector or seal* ***to enclose the sensor's connectors*** *within the connector support 4706 as in the embodiment depicted in FIGS. 34A to 34D (i.e. no seal 3402)*.").

95. The above implies that feature 1.6 does not require the seal to be shaped to enclose the contacts portion "on both sides" as the Appellants argue. The claim does not prescribe this and leaves open the possibility that the sensor only has electrical contacts on one side of the contacts portion. This is shown, for example, in Figures 33A and 33B and is specifically mentioned in column 24, lines 36-38, column 27, lines 21-24 and in dependent claim 14. In such a case, the skilled person will understand that the seal of feature 1.6 will only be required to enclose the electrical contacts on the side of the contacts portion where they are located.

96. The Court of Appeal disagrees with the Appellants that in this interpretation, feature 1.6 would not add anything to feature 1.3. The seal according to features 1.3 and 1.6 has a dual function: it functions as a connector between the electrical contacts of the sensor and the electronics assembly to allow electrical signals to pass (feature 1.3) and it seals the electrical contacts of the sensor to safeguard the connector function of the seal and provide a reliable glucose monitoring device (feature 1.6). Feature 1.6 therefore adds the sealing function to the seal of feature 1.3 and this function is achieved by enclosing the electrical contacts of the sensor.

97. Appellants' reference to the embodiment shown in Figures 34-35 and discussed in paragraphs [0084] and [0085] of the description does not alter this.

98. In general, a claim is not limited to the embodiments described in the patent. Embodiments are included in the patent description to explain and clarify the claimed invention, not to limit the claim to the specifics of the described embodiment (UPC_CoA_335/2023, 26 February 2024, NanoString v 10x Genomics; UPC_CoA_1/2024, 13 May 2024, Vusion-Group v Hanshow; UPC_CoA_523/2024, 3 March 2025, Sumi Agro Europe v Syngenta).

99. That is also the case here. Claim 1 of the patent is generally worded and there is no reason to limit the claim to the embodiment described in paragraphs [0084] and [0085]. It is true that paragraph [0084] states that Figures 34-35 show an embodiment of the invention as claimed in claim 1, but this is not necessarily the *only* embodiment protected by the claim.

100. According to paragraph [0084], the seal ("connector 3402") shown in Figures 34-35 "*insures that the sensor contacts 3312, 3314, 3316 are protected from moisture or any contaminants*." As discussed above in paragraph 94, a similar statement is made in paragraph [0093] of the patent at column 30, lines 17-21. It can thus be derived from these passages that the seal is intended to protect the electrical contacts of the sensor.

101. In the embodiment of Figures 34A-34D, the seal 3402 consists of two halves having electrical contacts 3410 on both sides of the seal to connect to the electrical contacts of the sensor. Paragraph [0084] specifically leaves open the possibility that the sensor has electrical contacts only on one side. The last sentence of paragraph [0084] reads: "*In some embodiments, all the sensor's electrical contacts 3312, 3314, 3316 can be provided on a single side of the sensor 3300 or, in other embodiments, both sides of the sensor 3300*". When the sensor 3300 has electrical contacts on only one side, the electrical contacts on the other one of the two halves of the connector 3402 are superfluous. In that case, there is nothing that prevents the skilled person from selecting a shape of the seal that only encloses the electrical contacts on the relevant side of the sensor.

102. The fact that the Respondent has decided to implement the patent in its product by also enclosing the part of the contacts portion without electrical contacts, as Appellants argue, does not mean that this would be required by the patent. For the interpretation of a patent claim, the patent is decisive, not the configuration of a subsequent product of the patent proprietor. As stated above, when feature 1.6 is read in context, in particular together with feature 1.3, it is clear that the seal must be shaped to enclose the electrical contacts of the sensor. When these are only present on one side of the sensor, the seal is required to only enclose the electrical contacts on that side of the sensor. That leaves open an implementation wherein the seal encloses more than just the electrical contacts, but this is not required by claim 1.

103. For the same reason, Appellants' reference to possible failures in the dielectric coating cannot result in requiring that both sides of the contacts portion of the sensor always need to be sealed. Paragraph [0084] refers to the failure of the dielectric coating ("*Thus, even if a dielectric coating 3300 fails (e.g. pinhole leaks), the connector 3402 insures that the sensor contacts 3312, 3314 and 3316 are protected from moisture or any contaminants*.") and such a dielectric coating may also be present on the side of the contacts portion without the electronic contacts (just as it can be present on any other part of the sensor). This does not mean, however, that the seal should always enclose both sides of the contacts portion, even if the electrical contacts are only present on one of these sides. Claim 1 does not contain such a limitation and does not refer to the use of a dielectric coating or how it would affect the configuration of the seal. The presence or absence of a dielectric coating is therefore of no relevance to the interpretation of feature 1.6.

104. Equally, Appellants' reference to statements made during prosecution cannot support its interpretation of feature 1.6. Even if these statements would be taken into account when interpreting claim 1, they do not result in limiting the claim to the embodiment of Figures 34-35 of the patent. The fact that the Respondent clarified during prosecution that the embodiment of Figures 34-35 is in accordance with the claimed invention, does not mean that the claim is *limited* to this embodiment. In addition, the fact that the Examiner regarded feature 1.6 as particularly distinctive

over the prior art does not limit the claim to the embodiment of Figures 34-35. In its communication, the Examiner merely repeated the wording of feature 1.6 without even referring to Figures 34-35 or paragraphs [0084]-[0085]. Apart from this, it is not decisive for the interpretation of a patent claim whether the claim is legally valid according to the Examiner's understanding.

105. Finally, during the oral hearing, the Appellants referred to the embodiment of Figures 36-38. Appellants argued that the sensor in that embodiment only had electrical contacts on one side of the sensor, but the sensor assembly nevertheless included an "elastomeric seal backing" to support the sensor's side without the electrical contacts (column 28, lines 20-24). That would confirm, according to the Appellants, that also in the embodiment of Figures 34-35 the side without the electrical contacts should be sealed.

106. The Court of Appeal disagrees. As stated above, the Court of Appeal is of the opinion that the embodiment of Figures 36-38 is not covered by claim 1. This embodiment can therefore not be used to interpret features 1.3 and 1.6 of claim 1 and the seal described therein.

107. For the same reason, Respondent's reference to Figures 47A-47C of the patent is rejected. According to the Respondent, these figures would show the use of a similar seal as in the GlucoMen iCan, only enclosing the side of the sensor with the electrical contacts. As stated in paragraph [0093] of the patent description, this embodiment does not show a sensor assembly with a connector according to claim 1. This embodiment is therefore also not relevant for the interpretation of features 1.3 and 1.6 of claim 1.

108. In conclusion, the Court of Appeal is of the opinion that the seal according to feature 1.6 does not need to be shaped to always enclose both sides of the contacts portion. That will depend on whether electrical contacts are present on one side or on both sides of the contacts portion. This interpretation follows from the wording of the claim and is in line with the description. It is also in line with dependent claims 4 and 5, which specify in the last half-sentence that "*both sides of the contacts portion*" are sealed. This wording would not be needed if claim 1 would already contain this limitation, as argued by Appellants.

Within the support

109. The Court of Appeal also rejects Appellants' argument that it would follow from the words "*shaped to enclose … within the support*" that the seal cannot extend to outside the support and that it must perform its sealing function in the sensor assembly without any interaction with the on-body device.

110. These words are merely meant to express that the contacts portion must be enclosed by the seal within the support. This does not mean that the seal must be entirely present in the support. Also in the embodiment of Figure 34, part of the seal 3402 extends beyond the support 3404 (cf. Figure 34D inserted above in paragraph 44, wherein seal 3402 extends to outside support 3404).

111. The words "within the support" neither require that the seal must perform its sealing function in the support without the involvement of the on-body device. Feature 1.6 is a means-plus-function feature ("*shaped to enclose .. within the support*"), which implies that the seal must be *suitable for* enclosing the contacts portion within the support. The claim does not require that the sealing effect must already occur in the sensor assembly before coupling the sensor assembly to the on-body device.

Claim 15

112. Claim 15 protects a kit comprising the sensor assembly of claim 1 and a further specified on-body device. In the Order, the LD considered the kit of claim 15 to comprise two separate parts "*one of them being the sensor assembly of claim 1 and the other the OBD* [on-body device; CoA]*. This makes even more clear that the sensor assembly and the on-body device with electronics are separate items of the kit*".

113. The Appellants argue that the LD's interpretation finds no basis in the wording of claim 15. They

understand the “kit” according to claim 15 as “*a set of multiple separate components or elements which can be combined to construe a product at the time of use*”. Appellants place particular emphasis in this context on the word “comprising“ in claim 15.

114. The Respondent generally agrees with the interpretation of the LD and points to various places in the patent which describe the interplay between the sensor assembly and the on-body device as a “plug and socket” design, wherein the sensor assembly comprises the "plug" which fits as a separate unit into the "socket" of the electronics assembly to ready the device for application and use by the user.

115. The Court of Appeal agrees with the interpretation of the LD and the Respondent that the kit according to claim 15 comprises two separate pre-assembled units, i.e. the sensor assembly and the on-body device. This clearly follows from the wording and structure of the claim.

116. Immediately at the beginning of the claim, it is stated that the kit comprises the sensor assembly of the preceding claims (including claim 1) and an on-body device. These two components are specifically named in the claim and are presented as separate units.

117. For the sensor assembly, claim 15 refers to the preceding claims. As explained above, the sensor assembly must be regarded as a separate pre-assembled unit containing the elements specified in claim 1 (sensor, sharp, support and seal). For the on-body device, claim 15 specifies its elements in features 15.3-15.6. When reading the claim, the skilled person will understand the on-body device to be a separate unit including these elements.

118. This interpretation of the sensor assembly and the on-body device as two separate units is in line with the description of the embodiments. Throughout the description, the sensor assembly and the on-body device are disclosed as two separate, pre-assembled units, i.e. as a plug and socket in the words of the Respondent. Reference is made, for example, to Figure 1 (“*User assembly: Merge sensor with electronics to form on-body device with sharp*”), Figures 2A-2G, Figures 3 and 4, Figures 21A-21C, Figure 25A, Figures 37-38, Figures 41A-41C, Figure 44 and Figures 47A-47C.

119. The skilled person will therefore understand that the kit of claim 15 comprises the sensor assembly and the on-body device as two separate units. The fact that the kit may also “comprise” more parts than these two units, does not alter the clear meaning of the claim.

VI. Validity

120. It is not more likely than not that claim 1 and claim 15 of the patent are invalid.

Added matter

Claim 1

121. In first instance, Appellants did not raise an added matter objection against claim 1 of the patent. The Appellants correctly noted that claim 1 was as such present in the PCT application (as claim 62) and in the application (as Clause 62).

122. In appeal, however, the Appellants now also raise an added matter objection against claim 1. As a justification for this change of position, Appellants refer to the “*manner in which the LD interpreted Claim 1*”. In particular, the Appellants refer to paragraph 37 of the Order, in which the LD relies on claims 4 and 5 as confirmation that feature 1.6 does not require a seal enclosing both sides of the contacts portion of the sensor. Claims 4 and 5 were not part of the (PCT) application, and therefore, according to the Appellants, the interpretation of claim 1 with reference to these claims would result in added matter.

123. Respondent objects against this new added matter argument, and, alternatively, argues that there is no added matter.

124. According to R. 222.2 RoP, requests, facts and evidence that have not been submitted by a party in first instance may be disregarded by the Court of Appeal. When exercising its discretion, the Court of Appeal can take into account the justification by the party bringing forward the new submission and the relevance of the new submission for the decision in appeal (R. 222.2(a) and (b) RoP). Applying these principles, the Appellants' new submission is refused.

125. Although the Appellants were not aware of the reasoning of the LD when preparing their Objection in first instance, they were aware of Respondent's position that claim 1 also covers a seal that encloses only one side of the contacts portion. The LD has generally accepted this view and merely refers to claims 4 and 5 as a confirmation of this interpretation. Under these circumstances, it cannot be said that the Appellants were confronted with such a new interpretation of claim 1 by the Order, that their new submission on added matter of claim 1 would be justified. The Appellants could and should have raised this added matter objection in first instance.

126. Moreover, the new submission raised by the Appellants does not appear to result in added matter of claim 1. As discussed in the foregoing, a skilled person would understand from the claim, the description and the drawings that feature 1.6 relates to a seal that protects the electrical contacts of the sensor against moisture and contaminants, possibly enclosing only one side of the contacts portion when all electrical contacts are on that side. These same disclosures are also present in the original applications. The fact that claims 4 and 5 were as such not included in the applications, is not relevant. Their subject matter is, *inter alia*, disclosed in paragraph [00141] (which corresponds to paragraph [0084] of the patent), and as the LD correctly noted, these claims merely serve as a confirmation of the interpretation which is already clear and unambiguous from the invoked claim, the description and the drawings which are included in the original applications.

Claim 15

127. In the Statement of Appeal, the Appellants also supplemented their added matter objection against claim 15. Whereas in first instance, the Appellants only argued that claim 15 contained added matter to the extent that this claim was dependent on other claims than claim 1, the Appellants now raise an extensive, independent added matter attack against claim 15. This is not justified in view of R. 222 RoP.

128. Although also in this context, the Appellants refer to the decision by the LD as a justification for their new submission, their argumentation is unrelated to the reasoning of the LD and mainly deals with arguments raised by the Respondent already during prosecution of the patent. These new added matter arguments could and should have been raised in first instance (R. 222(1) and (2) RoP). The Court of Appeal therefore accepts the objection raised by the Respondent and disregards the new added matter argumentation raised by the Appellants against claim 15 of the patent.

129. The Court of Appeal does note in this context that, as discussed above in relation to claim 15, the description and drawings consistently show the combination of the sensor assembly and the on-body device as meant in claim 15. These same descriptions and drawings are also present in the original applications.

130. As the Court of Appeal considers claims 1 and 15 valid on the balance of probabilities (see below), there is no need to rely on any other claims to establish infringement. As acknowledged by Appellants in first instance, the combination of claims 15 and 1 does not contain added matter.

<u>Sufficiency of disclosure</u>

131. The Appellants further argue that the subject matter of claim 1 and claim 15 is insufficiently disclosed, because the patent, and in particular paragraph [0084] and Figures 34A to 34D, would not disclose a seal that is "*shaped to enclose … within the support*" other than the one-piece seal of Figure 34 consisting of two halves connected by a hinge. According to the Appellants, the sensor assembly of claim 1 should therefore be interpreted as being limited to the embodiment shown in Figures 34-

35, or would otherwise not be sufficiently disclosed.

132. The Court of Appeal disagrees with the Appellants.

133. Art. 138(1)(b) of the European Patent Convention ("EPC") requires that the patent must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Sufficiency has to be examined on the basis of the patent as a whole, thus on the basis of the claims, the description and the 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 – of performing the claimed invention (UPC_CoA_528/2024 and UPC_CoA_529/2024, 25 November 2025, Amgen v Sanofi/Regeneron).

134. The embodiment of Figures 34A-34D, discussed in paragraphs [0084] and [0085], discloses at least one way of performing the invention, in particular concerning feature 1.6. The skilled person who is defined as an interdisciplinary team of engineers with several years of practical experience in the field of mechanical engineering and electronical engineering, in particular in the design of CGM systems, is able to carry out the invention without undue burden, also if the contacts portion of the sensor has electrical contacts on only one side. This lies within the expertise of the skilled person. Thus, in accordance with the principles set out by this Court in UPC_CoA_528/2024 and UPC_CoA_529/2024 (Amgen v Sanofi/Regeneron), the skilled person is able to reproduce the claimed subject matter.

135. Moreover, as indicated by this Court in UPC_CoA_528/2024 and UPC_CoA_529/2024 (Amgen v Sanofi/Regeneron), the burden of presentation and proof lies with the party invoking invalidity of the patent. Appellants did not deliver sufficient proof that the claimed invention is not sufficiently disclosed.

Novelty

US833

136. Appellants further argue that the patent lacks novelty in view of the patent applications and patents in the "Dexcom patent family". The LD has focused on US 7,905,833 B2 ("US833"). This is also the member of the Dexcom patent family that Appellants discuss in this appeal. Likewise, the Court of Appeal will refer below to US833. As will be discussed below, the Court of Appeal is not convinced that it is more likely than not that the patent is invalid for lack of novelty in view of US833.

137. According to Art. 54(1) EPC, an invention is considered new if it does not form part of the state of the art. A technical teaching does not form part of the state of the art if it differs in at least one of its known features from what is already known in the state of the art. Only that which is immediately and unambiguously apparent to a person skilled in the art from the relevant publication or prior use is considered to be anticipated by the prior art (UPC_CoA_182/2024, 25 September 2024, Mammut v Ortovox; UPC_CoA_382/2024, 14 February 2025, Abbott v Sibio).

Claim 1

138. US833 discloses a transcutaneous analyte sensor system 10 having an applicator 12, a mounting unit 14 and an electronics unit 16. As shown in Figure 1, parts 12, 14 and 16 are different structural units:

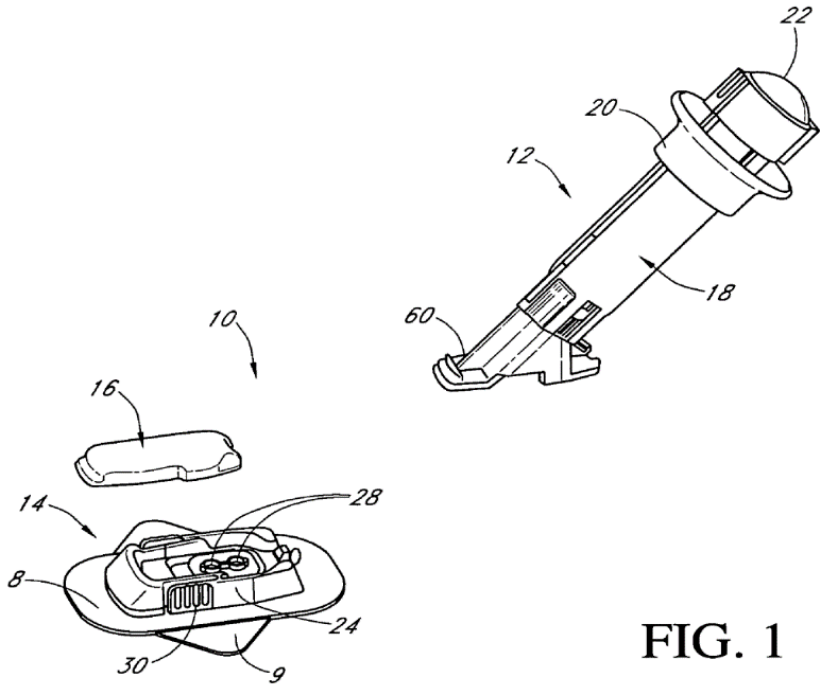


FIG. 1

139. The mounting device 14 is shown in more detail in Figure 3 of US833:

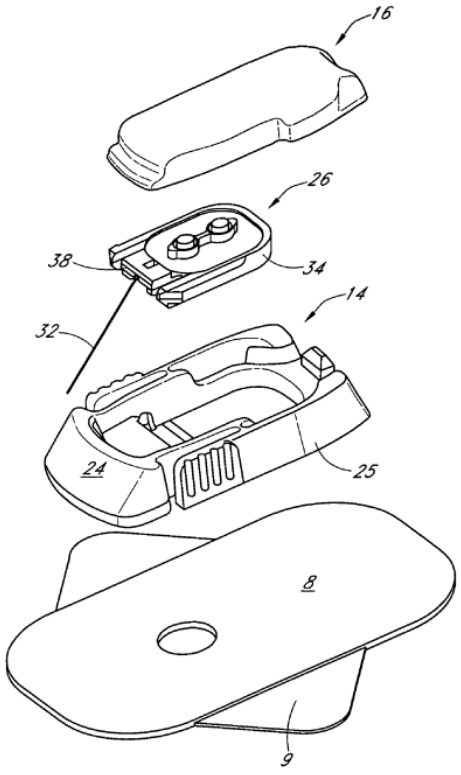


FIG. 3

140. As shown in Figure 3, the mounting device contains:

- a base portion 24, which is provided with an adhesive patch 8, and

- a contact subassembly 26 included in the base portion, which is to be connected to electronics unit 16.

141. Figure 4A is an exploded view of the contact subassembly 26:

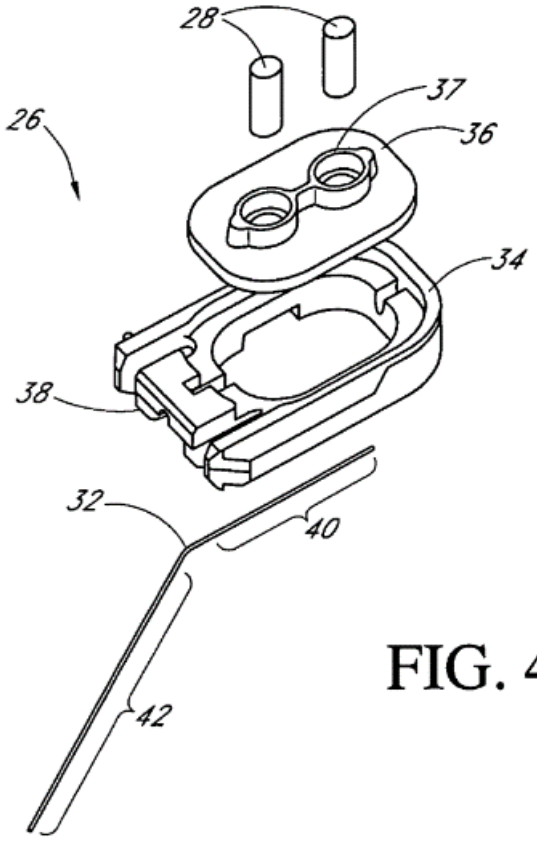


FIG. 4A

142. Figure 4A shows that the contact subassembly 26 contains, amongst others:

- contacts 28 configured to provide electrical contact between the sensor and the electronics unit 16,
- a contact holder 34 configured to fit within the base portion 24 of the mounting unit 14, and
- a sealing member 36 fitted within the contact holder 34. According to the last paragraph of column 13 (lines 59-67) of US833, the sealing member provides a watertight seal configured to surround the electrical connection of the electrode terminals of the sensor (32) within the mounting device to protect the electrodes from damage due to moisture, humidity, dirt and other external environmental factors

143. Although sensor 32 is also included in Figure 4A, it is not part of the contact subassembly 26. The sensor is encompassed in the applicator 12, in particular in needle subassembly 68. See below Figure 6:

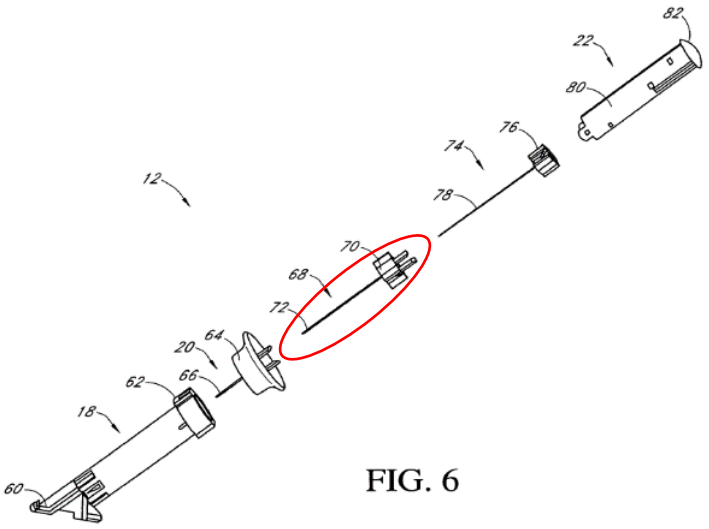


FIG. 6

144. Needle subassembly 68 includes a needle 72 and a needle carrier 70. The needle can encompass the sensor 32 and aids in its insertion into the host (column 32, lines 38-40). In the terminology of the patent, the needle can be regarded as a “sharp” for carrying the sensor.

145. In operation, the applicator is connected to the mounting device 14, and the needle 72 with sensor 32 is then pushed by the applicator through the contact subassembly 26 into and subsequently out of the host, as depicted in Figures 7A-7D. Figure 7A shows the situation before the applicator inserts the needle 72 and the sensor 32 into the host, Figure 7B shows the situation after the sensor has been inserted under the skin of the host and Figures 7C and 7D show the needle retraction after the positioning of the sensor into the host:

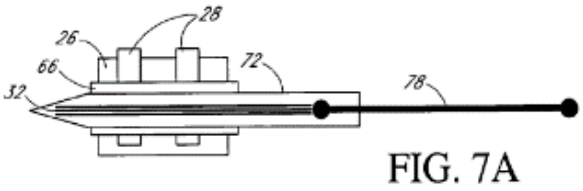


FIG. 7A

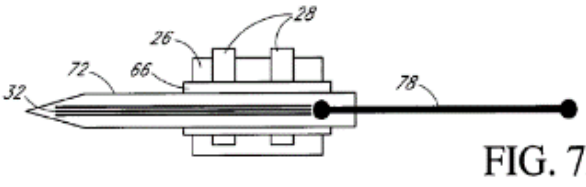


FIG. 7B

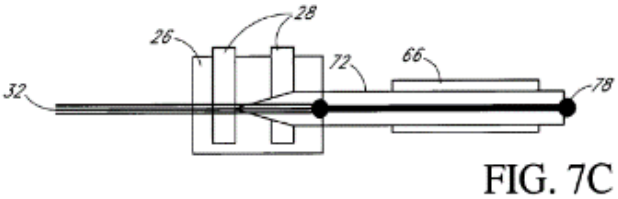


FIG. 7C

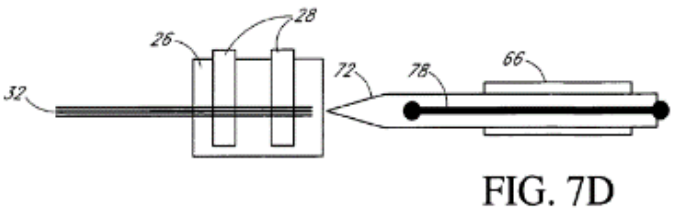


FIG. 7D

146. Figures 8A-8G show the corresponding positioning of the mounting device and the applicator during the operation depicted in Figures 7A to 7D. Figure 8C shows the positioning of the mounting device and the applicator after insertion of the sensor into the host (corresponding to Figure 7B):

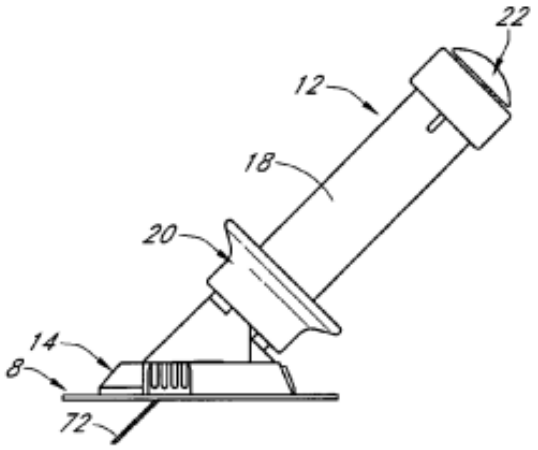


FIG. 8C

147. Figures 10A and 10B show the mounting unit attached to the user's skin immediately following sensor insertion and release of the applicator from the mounting unit:

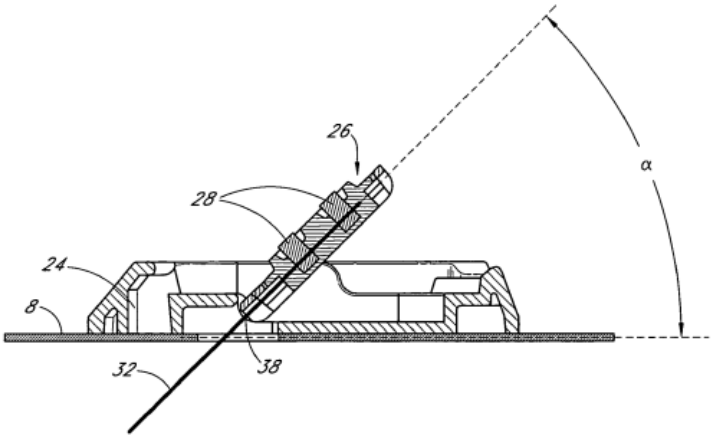


FIG. 10B

148. Figure 12B shows the mounting device 14 with the electronics unit 12 attached to it. The coloring and labels in the figure below have been included by the Appellants:

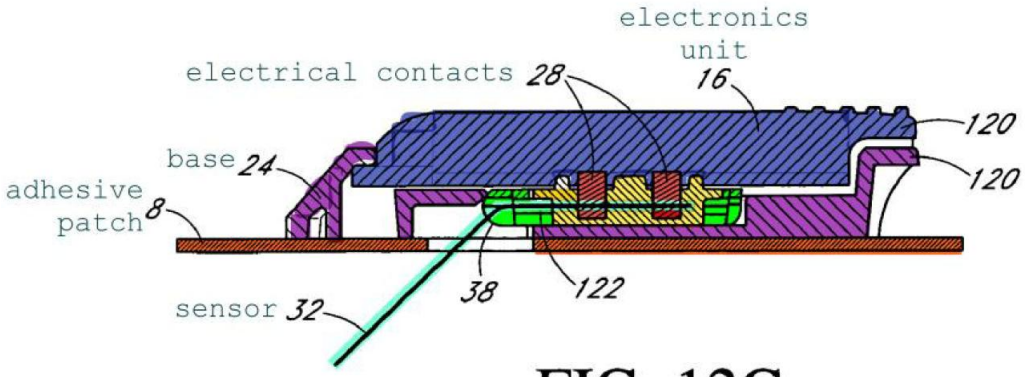


FIG. 12C

149. The Appellants consider the contact subassembly 26 shown in Figure 4A to be the sensor assembly of claim 1 (feature 1.1). Appellants consider the contact holder 34 (depicted above in green) to be

the support of the sensor assembly (feature 1.4) and the seal member 36 (depicted above in yellow) with the contacts 28 (depicted below in brown) to be the seal according to features 1.3 and 1.6.

150. According to the LD, US833 does not disclose a sensor assembly according to claim 1 (at least) because the contact subassembly 26 (the sensor assembly according to the Appellants) does not contain a sensor (feature 1.2) and a sharp (feature 1.5). These components are part of applicator 12, and not of mounting device 14 or contact subassembly 26. The needle and sensor are coupled to the contact subassembly 26 only when the applicator is connected to the mounting device during the short time interval of inserting the sensor into the host. According to the LD, this temporary configuration cannot be considered as a sensor assembly according to claim 1, because this feature requires a pre-assembled unit containing all elements specified in features 1.2-1.6, including the sharp and the sensor.

151. The Court of Appeal agrees with the reasoning and conclusions drawn by the LD, and rejects the arguments raised by the Appellants.

152. First of all, the Appellants argue that a sensor assembly according to claim 1 is also present when the assembly is "only temporary" configured (i.e. when in use) "in a transitory configuration". The Court of Appeal disagrees. As noted above, feature 1.1 requires the sensor assembly to be a pre-assembled unit containing all specified elements. US 833 discloses a substantially different sensor system.

153. Appellants further argue that the sensor assembly of claim 1 may consist of different subassemblies, such as the contact subassembly 26 and the needle subassembly 68. The Respondent argues that this would be an unallowed change of position by the Appellants, but the Court of Appeal rejects this objection. Appellants' argumentation is merely a reaction to the statements made by the LD, and the Appellants are allowed to do so.

154. In their argumentation, Appellants ignore that both subassemblies in US833 are part of distinct pre-assembled units. The contact subassembly 26 is part of the mounting device 14, whereas the needle subassembly 68 is part of the applicator 12. The temporary coupling of these subassemblies during use does not make them into a pre-assembled sensor assembly as required by feature 1.1. As discussed below (paragraph 200), this is neither disclosed in column 36, lines 2-6 of US833.

155. In view of the foregoing, also the squeeze argument raised by Appellants is rejected. Unlike in US833, all elements of claim 1 (the seal, the support, the sensor and the sharp) are part of the pre-assembled sensor unit of the GlucoMen iCan (see below).

156. In addition to these distinctions, Respondent has argued in first instance that US833 neither discloses a support including features for sealably coupling the support to an electronics assembly (feature 1.4). Respondent has repeated this argument in appeal. This feature allows the sensor assembly to be electrically connected to the on-body device when the two assemblies are coupled for use by the user. The Appellants never responded to this argument. They regard the contact holder 34 to be the support of feature 1.4 but have failed to indicate where in that contact holder the features for sealably coupling the support to the electronics unit 16 can be found. In connection with claim 10, which provides further details of the coupling features of feature 1.4, the Appellants refer to features of the mounting device 14 for coupling to the electronics unit 16. In the interpretation of the Appellants, the mounting device 14 is, however, not the support of the sensor assembly, but the on-body device as meant in claim 15. Also in their Statement of Appeal, the Appellants have failed to indicate where this element of feature 1.4 is disclosed in US833.

157. For the above reasons, the Court of Appeal does not consider it more likely than not that claim 1 will be held invalid for lack of novelty in view of US833.

Claim 15

158. The Court of Appeal also considers Claim 15 not to be anticipated by US833.

159. First of all, the kit of claim 15 contains a sensor assembly according to claim 1. As this sensor assembly is new, the same applies to the kit of claim 15 containing the sensor assembly.

160. Secondly, the on-body device according to features 15.3-15.6 is not disclosed in US833.

161. As noted above, the on-body device is a further pre-assembled unit in the kit. According to claim 15, it comprises an electronics assembly (feature 15.4) containing sensor electronics (features 15.4.1-15.4.2) and a socket (feature 15.4.3) for receiving and fitting the sensor assembly (features 15.5-15.6). In addition, the on-body device contains an adhesive patch for adhering the on-body device to the user's skin (feature 15.3).

162. According to the Appellants, mounting device 14 should be regarded as the on-body device. As shown in Figure 3 of US833 (see above), the mounting device 14 does have an adhesive patch (feature 15.3), but all other elements of the on-body device according to claim 15 are absent. The mounting device does not have an electronics assembly containing sensor electronics (in US833 the electronics assembly is part of a separate electronics unit 16), let alone an electronics assembly with a socket (feature 15.4.3). In US833, the mounting device 14 has a socket and not electronics unit 16.

163. Also with respect to claim 15, the sensor system of US833 is substantially different, with different components having different configurations and functions.

164. The above arguments were already raised by the Respondent in first instance. They were repeated by the Respondent in appeal. Appellants did not respond to these arguments in first instance or in appeal. Instead, the Appellants maintain their position in appeal that claim 15 does not require a kit containing two separate pre-assembled units (the sensor assembly and the on-body device), but also covers a collection of separate components. As indicated above, this interpretation is incorrect.

WO896

165. In addition to US833, the Appellants also rely on WO 2011/119896 ("WO896") to argue lack of novelty. In first instance, the Appellants relied on WO896 mainly to argue that the patented invention was obvious. The Respondent objects against the current novelty attack as being too late. The Court of Appeal rejects the Respondent's objection for the following reasons.

166. In first instance, the Appellants argued that feature 1.4 was the only missing feature in WO896, assuming that their interpretation of the term "distal surface" would be followed (requiring that the distal surface of the support has to be placed on the user's skin). This feature, "correctly interpreted", would, however, be obvious according to the Appellants. In addition, Appellants argued lack of novelty if Respondent's interpretation of "distal surface" would be followed.

167. As noted above in the discussion of feature 1.4, the LD disagreed with the Appellants and gave an interpretation of the term "distal surface" which, according to the Appellants, resulted in feature 1.4 to be also disclosed in WO896. The argumentation of the Appellants with respect to the other features of claims 1 and 15 remained unchanged. As the Respondent has been aware of these arguments from the first instance, and the Appellants' position on novelty is directly linked to the decision of the LD (and was in fact already raised in first instance), the Court of Appeal allows the Appellants to raise WO896 (also) in the context of novelty.

168. The Court of Appeal is, however, not convinced that it is more likely than not that the patent is invalid for lack of novelty in view of WO896.

<u>Claim 1</u>

169. WO896 is a PCT application entitled 'Medical Device Inserters and Processes of Inserting and Using Medical Devices'. WO896 concerns apparatuses for insertion of an *in vivo* analyte sensor supported by a sharp under the skin of a user.

170. According to the Appellants, all features of claim 1 are disclosed in WO896. Appellants primarily rely in this context on Figure 164 and the description of this figure in paragraph [00281] of WO896. These are both shown below:

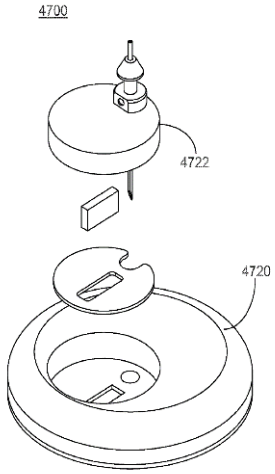


FIG. 164

[00281] In some embodiments, on body housing 4700 includes housing unit 4720 and sensor hub 4722 as illustrated in FIGURE 164. The sensor may have exposed pads on the flag and may also include a compressed anisotropic zebra, conductive elastomeric or similar. The PCB in housing unit 4720 may include exposed pads. Mechanical attachment of the housing unit and sensor hub may be accomplished by snaps. The needle guide may overmold macromelt or TPE. The housing unit 4720 may be macromelt overmold.

171. The Court of Appeal is of the opinion that not all features of claim 1 are directly and unambiguously disclosed in WO896. This concerns in particular features 1.2, 1.3 and 1.6 of the sensor assembly of claim 1.

172. The embodiment of Figure 164 is part of a series of embodiments which are described in connection with Figures 150 to 156 and paragraph [00273] of WO896. In these embodiments, the on-body device is comprised of a housing unit and a sensor hub, which may be assembled on a surface (such as a tabletop) prior to insertion into the user. In Figure 164, the housing unit is designated with reference number 4720 and the sensor hub with reference number 4722.

173. A skilled person understands from Figure 164 and the description of this figure in paragraph [00281] that WO896 discloses a sensor assembly (feature 1.1), with a sensor having a tail portion (as it has to be inserted under the user's skin) and a contacts portion ("flag with exposed pads"), and with a hub 4722 that comprises a support with a distal surface that can be mechanically attached to the housing unit 4720 by snaps (feature 1.4). Moreover, a non-referenced sharp and a non-referenced sharp hub can be seen in Figure 164 (feature 1.5).

174. Paragraph [00281] does not disclose that the sensor has a bendable portion (part of feature 1.2) and the presence of a seal (feature 1.3) or that the seal is shaped to enclose the contacts portion within the support (feature 1.6).

175. The Appellants argue that, although not explicitly shown in Figure 164, the bendable sensor shown in Figure 3 (below left) is "*clearly intended*" to be incorporated in Figure 164, as "*it is not possible to conceive of any other way in which a sensor as described in WO896 can fit within Fig. 3*". Figure 3 is included below, together with Figure 164 as modified by the Appellants:

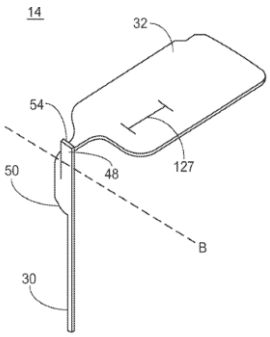


FIG. 3

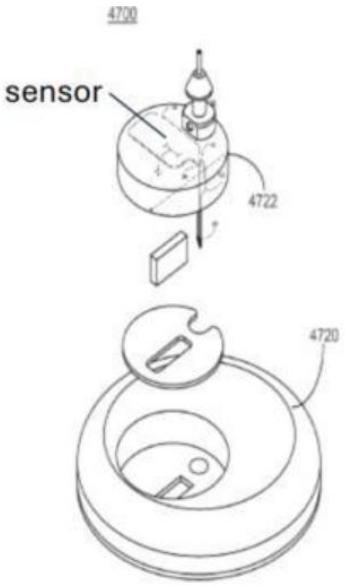


FIG. 164

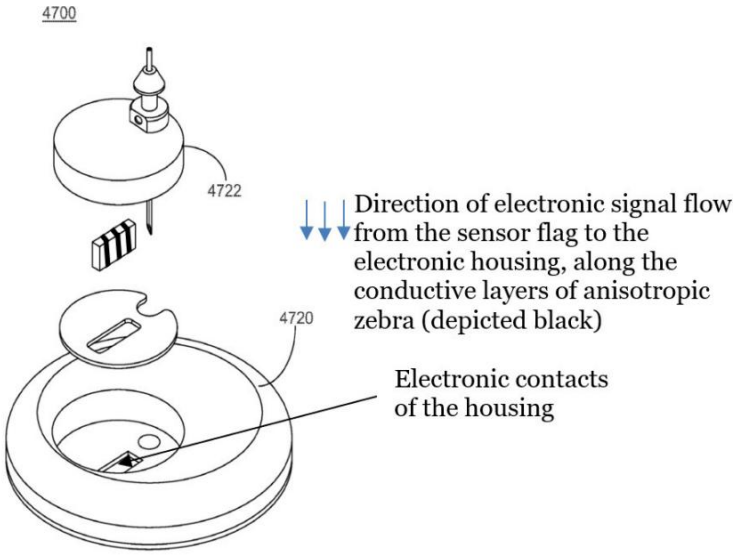
176. The Court of Appeal disagrees. There is no indication in WO896 of the sensor that is included in sensor hub 4722. The sensor of Figure 3 is only one of the possible alternatives disclosed in WO896, as is explicitly described in connection with Figures 2 and 3. Reference is made, for example, to paragraph [00140] of WO896 which states:

> *"An embodiment of the sensor 14 is illustrated in FIGURE 2. It is understood that the inserters described herein can be used with other medical devices. The shape(s) described herein are exemplary only. Other sensors are contemplated."* [underlining added; CoA]

177. One of such other possible sensors is shown, for example, in Figure 162 of WO896. This sensor does not appear to have a bendable portion.

178. It is therefore incorrect to assume that the bendable sensor of Figure 3 is the only conceivable sensor to be used in Figure 164. At most, a skilled person may consider using a sensor according to Figures 2 and 3 in the embodiment of Figure 164, but such use is not clearly and unambiguously disclosed in WO896 and does not necessarily follow from this publication.

179. In addition, features 1.3 and 1.6 are not clearly and unambiguously disclosed in WO896. The Appellants refer in this context to the "anisotropic zebra" mentioned in paragraph [00281]. They argue that a skilled person would understand the cuboid block beneath the sensor in Figure 164 to be the anisotropic zebra, and that the anisotropic zebra must have conductive layers arranged vertically to enable the electrical signals to pass from the sensor to the electronic contacts inside the housing unit 4720. Moreover, according to paragraph [00281] the anisotropic zebra is "compressed" which would imply a sealing function. Appellants' modified version of Figure 164 is shown below:



180. The Court of Appeal does not accept this reasoning.

181. WO896 is silent on the characteristics and orientation of the anisotropic zebra. There is no clear and unambiguous indication that the cuboid block depicted in Figure 164 is indeed the anisotropic zebra of paragraph [00281]. In addition, paragraph [00281] is silent on the configuration and orientation of the "flag with exposed pads" and how the anisotropic zebra is oriented and configured in relation to this flag. Appellants' modifications of Figure 164 are based on knowledge of the invention and do not necessarily follow from WO896.

182. Moreover, even if one followed Appellants' interpretation of the cuboid block in Figure 164 as the anisotropic zebra in the indicated orientation, it is still not disclosed that this element functions as a seal (feature 1.3) and that it is shaped to enclose the contacts portion of the sensor within the support (feature 1.6). WO896 is silent on the sealing function of the anisotropic zebra and also Appellants seem to agree that its primary function is to conduct electricity from one location to the other. Appellants nevertheless argue that the anisotropic zebra complies with features 1.3 and 1.6 because of the word "compressed" in paragraph [00281] ("..*a compressed anisotropic zebra, conductive elastomeric or similar*"). There is no basis for this.

183. WO896 does not provide any information on the compression level of the anisotropic zebra and whether such compression would have any sealing effect at all. Furthermore, Figure 164 does not show how the cuboid block or anisotropic zebra is connected to the contacts portion of the sensor (if any) and WO 896 provides no hint that the cuboid block or anisotropic zebra would be shaped to enclose the contacts portion within the support. The fact that the anisotropic zebra is used to conduct electrical signals does not require that it also has a sealing function, let alone that it is shaped to enclose the (non-disclosed) contacts portion of the sensor. The word "compressed" in paragraph [00281] does not imply any of this.

184. In view of the above, also the squeeze argument raised by Appellants is rejected. WO896 does not disclose a seal in accordance with features 1.3 and 1.6, let alone a seal that is comparable to the seal used in the GlucoMen iCan.

Claim 15

185. The Court of Appeal also does not consider it more likely than not that the subject matter of claim 15 will be held to be anticipated by WO896. Claim 15 requires a sensor assembly of claim 1. As claim 1 appears to be novel in view of WO896, this also applies to claim 15.

Inventive step

186. The LD The Hague considered two prior art attacks in the context of Appellants' argument that the

patented invention lacked an inventive step: the first one was based on the Dexcom patent family, in particular US833, and the second one was based on WO 896. The Appellants maintained both attacks in these appeal proceedings and the Court of Appeal will therefore deal with both attacks below.

187. The approach taken when establishing inventive step is set out by this Court in UPC_CoA_528/2024 and UPC_CoA_529/2024 (25 November 2025, Amgen v Sanofi/Regeneron, see also UPC_CoA_646/2024, 25 November 2025, Meril v Edwards). First, the object of the invention (the objective problem) must be established. This must be assessed from the perspective of the skilled person with its common general knowledge at the application or priority date of the patent. In this assessment, it should be established 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 description 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 skilled person on the basis of the patent understands is (are) achieved with the claimed invention. The claimed solution is obvious when at the relevant date, the skilled person, starting from a realistic starting point in the state of the art in the relevant field of technology, wishing to solve the objective problem, would (and not only: could) have arrived at the claimed solution (UPC_CoA_528/2024 and UPC_CoA_529/2024, 25 November 2025, Amgen v Sanofi/Regeneron).

188. The skilled person has no inventive skills and no imagination and requires a pointer or motivation that, starting from a realistic starting point, directs it 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 skilled person would take the next step prompted by the pointer or as a matter of routine, and arrive at the claimed invention.

189. Against this background, the Court of Appeal is not convinced that it is more likely than not that the patent is invalid for lack of inventive step using either US833 or WO896 as a starting point.

US833 as a starting point

190. As discussed above, the object of the invention is to provide an *in vivo* analyte monitoring system, which is easy-to-use, reliable and minimizes both user inconvenience and pain (cf. paragraphs [0005] – [0011] of the patent).

191. To achieve this objective, a sensor system is provided that is to be assembled from mainly two separate pre-assembled components, i.e. a sensor assembly and an on-body device.

192. Claim 1 protects the sensor assembly. The sensor assembly contains a specific seal to protect the electrical contacts of the sensor and a support that is equipped with means for sealably coupling the sensor assembly to the sensor electronics. This provides a reliable electrical connection between the sensor assembly and the sensor electronics. Claim 15 provides a kit which contains the sensor assembly of claim 1 and an on-body device with an electronics assembly, which contains a socket that is configured to receive the sensor assembly prior to using the (integrated) on-body device. This makes the sensor device easy to assemble and minimizes user inconvenience and pain.

193. As discussed in the context of novelty, US 833 discloses a substantially different sensor system. The system of US833 comprises an applicator 12, a mounting device 14 and an electronics unit 16. It does not disclose a pre-assembled sensor assembly having a sensor and a sharp, as well as a support with features for sealably coupling the sensor assembly to the electronics unit of the on-body device. US833 equally does not disclose an on-body device according to claim 15 comprising an adhesive patch and an electronics assembly with a socket configured to receive the (non-disclosed) sensor assembly. Instead, US833 discloses the use of a separate electronics unit 16. The skilled person had no incentive to adapt the sensor system of US833 and had no pointer to adjust this system to obtain the patented sensor system with the advantages described in the patent at issue.

Claim 1

194. Appellants maintain their (incorrect) position that the sensor assembly of claim 1 does not need to be a pre-assembled unit and argue that, in any event, it would have been obvious for a skilled person to adapt the system of US833, for example shown in Figure 8C, by attaching the sharp and the sensor to the sensor assembly present in the mounting device. According to the Appellants, the skilled person had an incentive to modify the sensor system based on US833 itself. The Court of Appeal disagrees with both points.

195. As to the incentive of the skilled person to modify the sensor system of US833, Appellants refer to the statements made in column 35, lines 48-50 of US833:

> The preferred embodiments advantageously provide a system and method for easy insertion of the sensor and subsequent retraction of the needle in a single push-pull motion. 50

and column 35, line 66 to column 36, line 2 of US833:

> force. Some prior art sensors, in contrast to the sensors of the preferred embodiments, suffer from complex, multi-step, or
>
> multi-component insertion and retraction steps to insert and remove the needle from the sensor system.

196. As Respondent correctly notes, the motivation derived by Appellants from these passages is already fulfilled by the invention disclosed in US833. There is no ground to argue that based on these passages in US833, the skilled person would be *further* motivated to modify the disclosure of US833, let alone to do so in accordance with the patented invention.

197. Even if such motivation could be derived from US833, the skilled person would not know how to modify the system of US833 to arrive at the patented invention. This would require a substantial change of the constructional details of the sensor system of US833 for which no motivation or hint is included in the cited documents.

198. In US833, the contact subassembly 26 is part of the mounting device 14, whereas the sharp and sensor are part of the needle subassembly 68 in applicator 12. In Figure 8C, referred to by the Appellants, the sensor and the needle are pushed into the mounting unit 14 (and the contact holder with the sealing member) and under the skin of the user. During this operation, the sharp and sensor are present only in the moment of pushing these through the contact holder under the skin of the user and prior to retraction.

199. There is no pointer in US833 to lift the contacts subassembly 26 out of the mounting device 14, combine it with the needle subassembly 68 into a separate pre-assembled unit and equip the contact holder 34 of contact sub-assembly 26 with features for sealably coupling the support to the electronics unit 16 (which in and of itself is constructively different from the on-body device to which the sensor assembly is sealably coupled according to claim 15). The argument of Appellants that this would be a "*straightforward modification*" is not convincing. It is not apparent how a skilled person could (let alone would) modify the system of US833 to arrive at the solution of claim 1 with the advantages described above.

200. During the oral hearing, Appellants referred in this context to column 36, lines 2-6 of US833. This passage discusses Figure 8B (showing the applicator 12 being coupled to the mounting device 14) and states that the "*sensor system can be shipped in this configuration*". This passage does not change the above. It is unclear to which "configuration" the passage refers, and whether in that configuration the needle and sensor would indeed be present in the contacts subassembly 26. The statement in the sentence before the cited passage indicating that the mounting unit and the

applicator are "*in the ready position*" suggests otherwise. Even if the needle and sensor would be in the contacts subassembly 26 in this configuration, the sensor assembly of claim 1 would still not be obtained. In this position, as shown for example in Figure 7A, the electrical contacts of the seal are not disposed to align with the contacts portion of the sensor to allow electrical signals to pass through the seal (feature 1.3). Instead, the electrical contacts of the seal are positioned against the needle 72 (and possibly the needle guide 66), so that the electrical signals can only pass after retraction of the needle. In addition, also in this configuration, the sensor assembly is not provided with features to sealably couple the support to the electronics assembly (feature 1.4).

201. To conclude, a skilled person without knowledge of the invention would have no motivation or pointer to modify the system of US 833 to obtain the patented sensor assembly.

Claim 15

202. This equally, and even *a fortiori*, applies to claim 15 of the patent.

203. In their Statement of Appeal, the Appellants refer for the alleged absence of an inventive step in claim 15, to their arguments in the Objection. In the Objection, the Appellants did not react to any of the arguments raised by the Respondent regarding the structural differences between the on-body device of claim 15 and the system of US833. The Court of Appeal discussed these differences above in the context of lack of novelty. These differences are substantial.

204. The only additional argument that the Appellants raised in this appeal, is that the kit of claim 15 could consist of a collection of separate parts. The Court of Appeal already noted above that this interpretation of claim 15 is incorrect. In addition, this argument does not respond to the multiple other structural differences between the on-body device of claim 15 and the system of US833.

205. Appellants have not explained why the kit according to claim 15 would lack an inventive step in light of US833 (even leaving aside the fact that also the sensor assembly of claim 1, which is part of the kit of claim 15, is inventive in light of US833, as discussed above).

WO896 as a starting point

206. As discussed in the context of novelty, WO896, *inter alia*, does not disclose the use of a seal as described in features 1.3 and 1.6 of claim 1 of the patent. In the Statement of Appeal, Appellants acknowledge that "*although the anisotropic zebra may be compressibly contained within the sensor hub, moisture and small particles may infiltrate inside the sensor hub, via the rectangular cut out in the base of the disc (equivalent support), affecting the contacts on the contacts portion of the senso*r." This is in line with the finding above that the anisotropic zebra cannot be regarded as a seal within the meaning of claim 1. Having regard to this, according to the Appellants, the skilled person would be motivated to develop a separate seal to enclose the contacts portion of the sensor on both sides. This approach is tainted with hindsight.

207. There is no indication in WO896 of the configuration and orientation of the sensor in the sensor hub 4722, let alone of a seal, or of the interplay between the (non-disclosed) seal and the (non-disclosed) contacts portion of the (non-disclosed) sensor and the (disclosed) anisotropic zebra that is used for conducting the electrical signals. In the approach proposed by the Appellants, the skilled person would have to come up with this themselves and do so in a way that the patented invention would be obtained, all without the presence of any pointer. Such a pointer cannot be found in paragraph [00276] of WO896, to which the Appellants refer. This paragraph indicates that sealing may be provided by an elastomeric gasket. This passage gives no hint for using a seal in the embodiment of Figure 164, or for using a seal according to features 1.3 and 1.6 of claim 1. For the same reason, also the kit of claim 15 containing the sensor assembly of claim 1, is not obvious.

Conclusion on validity

208. The Court of Appeal concludes that on the balance of probabilities it is not more likely than not that

claims 1 and 15 of the patent will be held invalid.

VII. Infringement

209. It is more likely than not that the attacked embodiment infringes claim 1 and claim 15 of the patent.

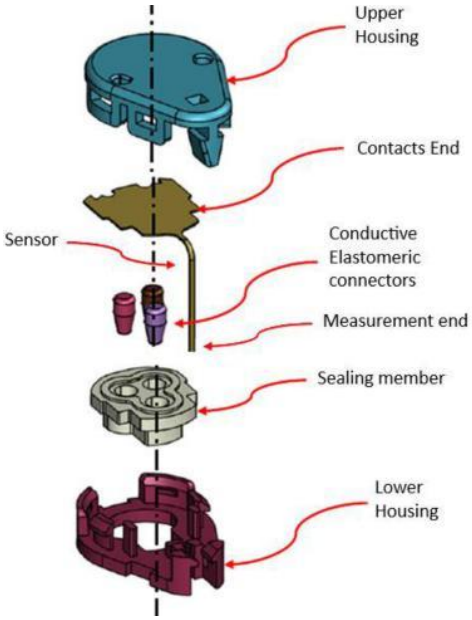
Infringing acts

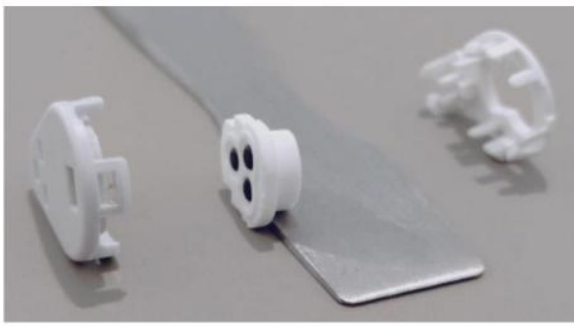
210. The requested relief is aimed at the GlucoMen iCan. Via its website (https://glucomenican.com), Appellant 2 has offered the GlucoMen iCan for sale to consumers throughout the European market, including in the UPC territory. In addition, Appellant 2 has promoted the GlucoMen iCan at various exhibitions in the UPC territory and has acted as distributor of this product in various Contracting Members States. These are all acts of direct infringement as meant in Art. 25 UPCA.

211. As the Court of Appeal noted above in the context of jurisdiction (paragraphs 25-33), Appellant 1 has also been actively involved in the marketing of the GlucoMen iCan in Europe, including in the UPC territory. The Court of Appeal further notes that an infringer within the meaning of Art. 63 UPCA in conjunction with Art. 25 UPCA is not only someone who themselves carries out the acts referred to in Art. 25 UPCA, but also someone to whom the acts of the third party are attributable, because they are an instigator, accomplice or accessory (UPC_CoA_53472024, 19/2025 and 683/2024, 3 October 2025, Philips v Belkin). For this reason, not only Appellant 1's own acts described above are to be taken into account in determining whether actual or threatened infringement has occurred, but also the acts of Appellant 2 with whom Appellant 1 has a strategic partnership pursuant to which Appellant 2 would sell the products manufactured and prepared for the European market by Appellant 1.

Infringement of claim 1

212. The pictures below, taken from the Statement of Appeal (page 53), provide a general overview of the design of the sensor assembly in the GlucoMen iCan:





213. In this overview, the sharp is omitted. It is undisputed, however, that the sharp was part of the sensor assembly in the actual product.

214. The Appellants contest the presence of features 1.1, 1.4 and 1,6 in the GlucoMen iCan.

215. Feature 1.1 would not be present, as the contacts portion of the sensor is not sealed prior to mating the sensor assembly to the electronics assembly, and accordingly the sensor assembly is not pre-assembled. Feature 1.4 would not be present, as the lower surface of the support of the GlucoMen iCan does not face the patient's skin and has an opening at the inside facing side to enable the sealing member to protrude distally, beyond the opening. Feature 1.6 would not be present as the sealing member in the GlucoMen iCan sensor assembly would not be "shaped to enclose" the contacts portion of the sensor "within the support" as it seals only one side of the contacts portion and protrudes through the opening at the bottom of the housing.

216. The Court of Appeal rejects these arguments.

Feature 1.1

217. Regarding feature 1.1, the GlucoMen iCan contains a sensor assembly that is pre-assembled. As shown in Figure 3 of the Application, the pre-assembled sensor assembly has all structural features of claim 1: a support, a seal, a sensor and a sharp with a sharp hub. Figure 3 of the Application is inserted below:

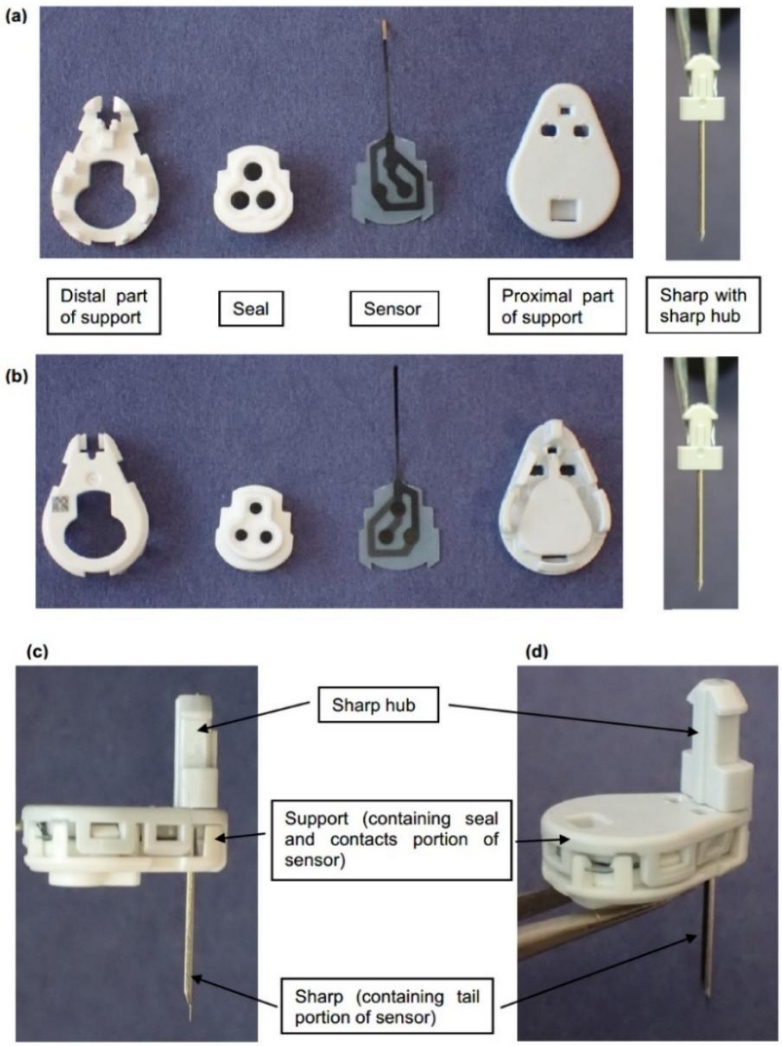


***Figure 3**: **(a)** Exploded view of GlucoMen iCan sensor assembly from the top; **(b)** exploded view of GlucoMen iCan sensor assembly from the bottom; **(c)** and **(d)** assembled GlucoMen iCan sensor assembly from two different angles*

218. Appellants' argument, that in the GlucoMen iCan the sealing takes place only when the sensor assembly is coupled to the electronics assembly (and that therefore the unit would not be pre-assembled within the meaning of feature 1.1), is rejected. Leaving aside the fact that the Respondent

contests the evidence that Appellants put forward in this respect, claim 1 does not require that the contacts portion of the sensor is already sealed in the sensor assembly prior to merging the sensor assembly with the electronics assembly.

Feature 1.4

219. Regarding feature 1.4, the support of the sensor assembly in the GlucoMen iCan has a distal surface. This is shown in the below pictures, which were taken from the Statement of response (page 44) (left picture) and the Application (page 30) (right group of pictures):

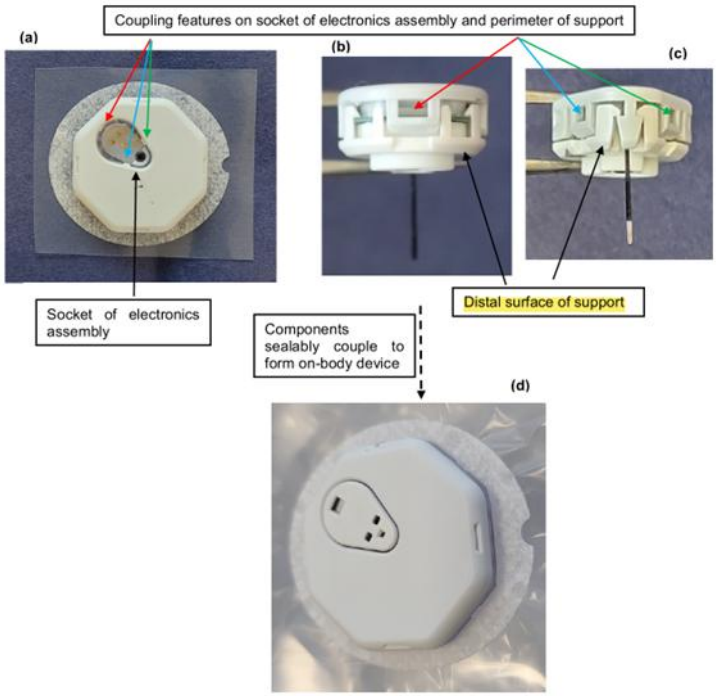


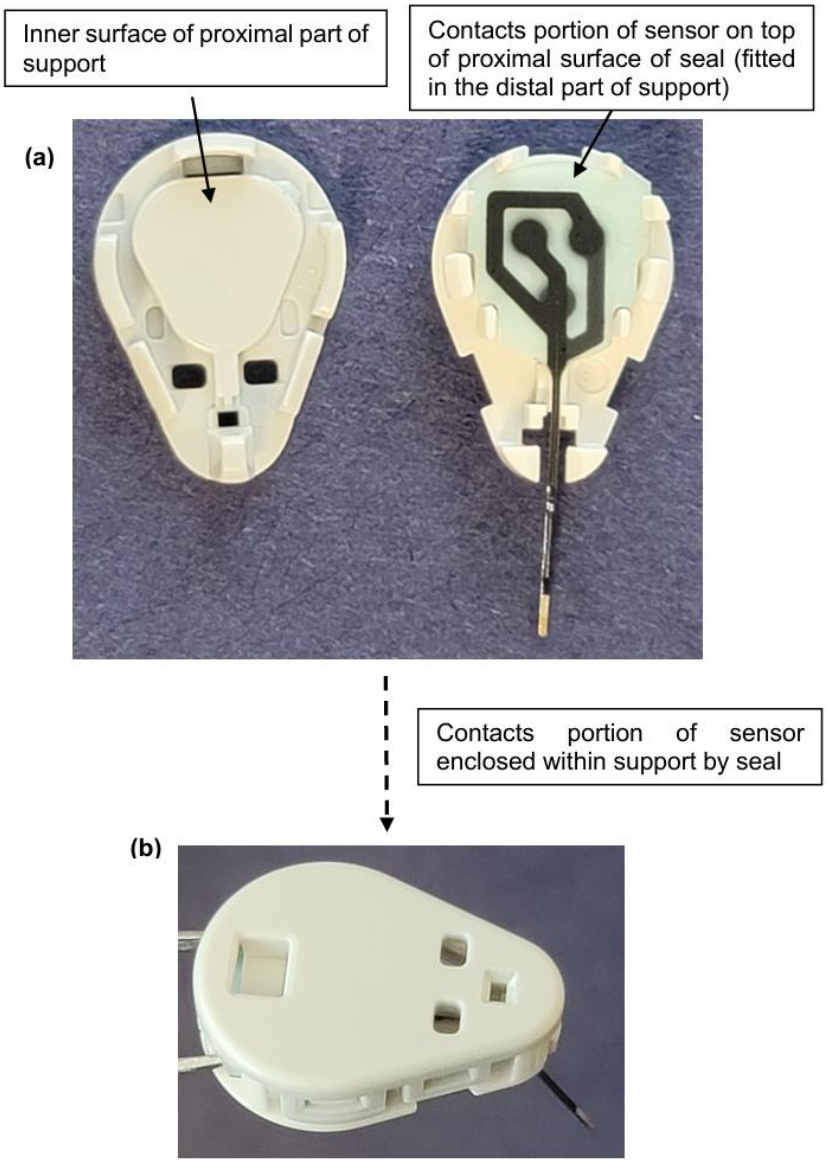
Figure 8: *(a) GlucoMen iCan electronics assembly; (b) and (c) GlucoMen iCan sensor assembly (without sharp), shown from two different angles and (d) GlucoMen iCan electronics assembly and sensor assembly when sealably coupled, i.e. GlucoMen iCan on-body device*

220. The fact that the surface of the support is not placed on the user's skin and contains an opening, as Appellants argue, does not result in non-infringement. The Court of Appeal has explained above that these additional limitations are not part of feature 1.4.

221. Furthermore, the fact that the seal in the GlucoMen iCan is closer to the user's skin than the distal surface of the support, does not mean that the support in the GlucoMen iCan does not have a distal surface. The "distal surface" in feature 1.4 is not necessarily the surface in the sensor assembly that is closest to the user's skin. The fact that the protruding part of the seal is closer to the user's skin than the distal surface of the support, is therefore irrelevant.

Feature 1.6

222. Finally, regarding feature 1.6, the seal in the sensor assembly of the GlucoMen iCan is shaped to enclose the contacts portion of the sensor within the support. This can be seen in the below pictures taken from the Application (page 32):



223. As shown above in Figure 3(b) (paragraph 217), the seal in the sensor assembly of the GlucoMen iCan fits in the opening of the lower part of the support. When the seal is in this opening, it encloses the electrical contacts of the sensor within the support.

224. The fact that the seal does not cover both sides of the contacts portion, that it partly extends to outside the support and that it would only perform its sealing function after the sensor assembly has been coupled to the electronics, as Appellants argue, does not result in non-infringement. The Court of Appeal has explained above that these additional limitations are not part of feature 1.6.

Infringement of claim 15

225. Appellants do not contest infringement of claim 15 based on any other arguments than those for claim 1. Hence, the Court of Appeal concludes that it is also more likely than not that claim 15 is infringed with the GlucoMen iCan.

VIII. Prerequisites of provisional measures and balance of interest

226. The conclusion from the above is that the Court of Appeal considers on the balance of probabilities that it is not more likely than not that the patent is invalid and that it is more likely than not that the

patent is infringed. Appellants' argument that an injunction should nevertheless not follow is rejected.

Urgency

227. When weighing up the interests of the parties, the Court must take into account any unreasonable delay in applying for provisional measures, as set out in R. 211.4 RoP in conjunction with R. 209.1(b) RoP. In case the patent proprietor's conduct shows that enforcing its rights is no longer urgent, there is no need to order provisional measures.

228. The urgency required for the order of provisional measures is only lacking if the injured party has pursued its claims so negligently and hesitantly that it can objectively be assumed that it has no interest in the rapid enforcement of its rights and it therefore does not appear appropriate to order provisional measures. In this context, it should be noted that no party can be expected to initiate proceedings without preparation. Rather, an adequate preparation of the proceedings is required. The applicant should only apply for a preliminary injunction if it has reliable knowledge of all the facts that make legal action in PI proceedings promising.

229. On this basis, the time limit within the meaning of R. 211.4 RoP is to be calculated from the date on which the applicant became aware, or should have become aware, of the infringement that would enable him, in accordance with R. 206.2 RoP, to file an application for provisional measures with a reasonable prospect of success. Thus, the decisive point in time is when the applicant has, or should have had, after exercising due diligence, the necessary facts and evidence to establish infringement within the meaning of R. 206.2(d) RoP (UPC_CoA_182/2024, 25 September 2024, Mammut v Ortovox; UPC_CoA_446/2025, 13 August 2025, Boehringer Ingelheim v Zentiva).

230. Based on these principles, the Respondent in the present case did not wait unreasonably long before filing its application for provisional measures.

231. According to the Appellants, Respondent's Application lacks urgency, because Respondent was already aware of the introduction of the attacked embodiment on 3/4 December 2024 when the Appellants announced their intended European introduction of the GlucoMen iCan and registered the GlucoMen iCan in the EU Medical Devices database EUDAMED. Appellants point out that the European introduction was confirmed in a letter dated 12 December 2024 of UK counsel of Appellant 1. Subsequently, Appellants promoted the GlucoMen iCan at various exhibitions in Europe, where also representatives of the Respondent were present. As the GlucoMen iCan was technically identical to the Sinocare iCan i3 that had already been on the market in Europe since October 2023, there was no justification, according to the Appellants, for waiting with filing the Application until 4 July 2025. The Court of Appeal disagrees.

232. The patent was granted on 4 June 2025 and obtained unitary effect on 18 June 2025. The Application was filed one month after the grant of the patent and about two weeks after obtaining unitary effect. This in and of itself already shows that the Respondent acted swiftly after obtaining (unitary) patent protection.

233. In addition, prior to the grant of the patent, Respondent had already performed substantial preparatory work for filing the Application. After the GlucoMen iCan and its user guide became available on the European market, the Respondent ordered physical samples of these products in various European countries and, following their receipt on 29 April 2025, had them analysed in the US to establish the exact configuration of the product and to determine whether it infringed its patent. The analysis report was finished on 3 June 2025 and a month later, following the grant of its patent, Respondent filed its Application.

234. The Court of Appeal agrees with the Respondent that the analysis of the GlucoMen iCan could not have been done before the products actually became available on the market. In response to the letter from Appellant 1's UK counsel of 12 December 2024, Respondent's counsel requested further

information, including samples of the product to be introduced. Appellant 1 refused to provide this information. Around this time, Respondents referred to the GlucoMen iCan in various materials as a "new" and even as a "brand new" product. It was not possible for the Respondent to determine with sufficient certainty that this "new" product actually infringed its patent, before it was able to obtain physical samples of the product by the end of April 2025. Following receipt of the physical products, the Respondent acted expediently to have these products analysed, at a time when its patent had not even been granted.

235. Appellants argue that for establishing infringement it was not necessary for Respondent to have these products analysed in the US, as evidenced by the fact that the analysis report of 3 June 2025 had not even been submitted in the proceedings. The Court of Appeal rejects this argument. Respondent cannot reasonably be blamed for being cautious not to accuse Appellants of infringing acts prior to having done a thorough investigation. The tests in the US were reasonable and useful.

236. In conclusion, it cannot be concluded from the line of events, that the Respondent behaved in such a negligent and hesitant manner in lodging the Application that, from an objective perspective, it must be concluded that it was not interested in promptly enforcing its patent against the GlucoMen iCan. The Respondent acted promptly after obtaining the patent on 4 June 2025.

Necessity of provisional measures and balance of interests

237. Under Art. 62 UPCA and R. 211.1 RoP, the Court may grant provisional measures intended to prevent any imminent infringement, and to prohibit, on a provisional basis and subject, where appropriate, to a recurring penalty payment, the continuation of the alleged infringement or to make such continuation subject to the lodging of guarantees intended to ensure the compensation of the right holder. Such provisional measures are treated by way of summary proceedings (R. 205 RoP). Compared to proceedings on the merits, these proceedings are short and fast and make it possible to bring a patent infringement to an immediate end. The expedited procedure, however, does not allow for full examination of the Applicant's entitlement to commence proceedings, of the validity of the patent and of the alleged infringement as provided for in proceedings on the merits. The expedited procedure can therefore be used only if, considering the nature of the case, proceedings on the merits cannot be awaited.

238. Pursuant to Art. 62(2) UPCA and R. 211.3 RoP, the Court has 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. The Court must in addition consider 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 (UPC_CoA_540/2024, 24 February 2025, Biolitec v Light Guide; UPC_CoA_768/2024, 20 April 2025, EOFlow v Insulet).

239. Accordingly, R. 206.2(c) RoP requires that the Applicant in its Application for provisional measures sets out the reasons why provisional measures are necessary to prevent a threatened infringement, to prohibit the continuation of an alleged infringement or to make such continuation subject to the lodging of guarantees. This is not only 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_335/2023, 26 February 2026, NanoString v 10x; UPC_CoA_540/2024, 24 February 2025, Biolitec v Light Guide).

240. Provisional measures will be necessary, for instance, where any delay would cause irreparable harm to the patent holder. Irreparable harm is, however, not a necessary condition for the ordering of provisional measures (UPC_CoA_182/2024, 25 September 2024, Mammut v Ortovox; UPC_CoA_540/2024, 24 February 2025, Biolitec v Light Guide; UPC_CoA_768/2024, 20 April 2025, EOFlow v Insulet). The necessity of provisional measures may also follow from the fact that there is direct competition between the attacked embodiment and the product of the patent holder (UPC_CoA_540/2024, 24 February 2025, Biolitec v Light Guide). In those cases, granting provisional measures may be justified if they are necessary in order to maintain the status quo that existed

immediately prior to the alleged infringement until the decision of the Court on the merits (UPC_CoA_182/2024, 25 September 2024, Mammut v Ortovox; UPC_CoA_540/2024, 24 February 2025, Biolitec v Light Guide). The necessity for provisional measures may arise in a move from a market situation where only one product is available to one where there are two such competing products. Such a move can be expected to lead not just to price pressure but to a permanent price erosion (UPC_CoA_523/2024, 3 March 2025, Sumi v Syngenta).

241. In a case, where the patented product was already marketed by the infringer before the grant of the patent, necessity may be denied because the requested provisional measures would change the status quo of the market established years before the grant of the patent (UPC_CoA_540/2024, 24 February 2025, Biolitec v Light Guide; UPC_CoA_768/2024, 20 April 2025, EOFlow v Insulet).

242. The Court of Appeal is convinced that the Respondent has an (urgent) interest that Appellants are injuncted from bringing the GlucoMen iCan on the market.

243. The parties are competitors in the field of CGM techniques. Respondent has been a developer, manufacturer and marketer of CGM devices since 2007. Its current series of devices is called FreeStyle Libre. Since 2014, these devices have comprised an applicator (i.e. an insertion device), an on-body unit consisting of an analyte sensor (for glucose) and sensor electronics as an integrated unit, and a display device (such as a reader or smartphone) with proprietary software. This technology utilizes the invention disclosed in the patent. Respondent is the main supplier of CGM products in the Contracting Member States. In Europe, Respondent serves over 1.3 million patients with its FreeStyle Libre products and has a market share of approximately 80%.

244. Appellant 1 also manufactures CGM systems and is the largest manufacturer of glucose monitoring devices in Asia. Appellant 2 markets glucose self-testing systems for people with diabetes. In the course of 2025, the Appellants entered the European market with the GlucoMen iCan, particularly aimed at the reimbursement market. The reimbursement market is by far the largest market for CGM devices. According to the parties, the cash pay segment is less than 5% of the total CGM market in each country. The remainder of the sales in this market are made in the reimbursement segment of the market. Respondent explained that it suffers harm in both segments of the CGM market.

245. According to Appellants, following the introduction of the GlucoMen iCan, the 'base' price of the GlucoMen iCan in the cash pay market was comparable to that of the Free Style Libre. Respondent referred, however, to promotions and discounts that undercut Respondent's market price. If price cutting would subsist, this would lead to a negative price spiral which, especially in this type of market, is difficult to reverse. In addition, Respondent pointed out that sales of the GlucoMen iCan prior to a decision in the main proceedings has the potential of eroding Respondent's market share (even if Appellant 2's market share would be small in the beginning) and that this would help establish the GlucoMen iCan amongst opinion leaders and users. The Court of Appeal accepts that as a result, the Respondent is likely to suffer damages caused by the continued presence of the GlucoMen iCan on the cash pay market.

246. In the absence of a preliminary injunction, there would also be a risk that Appellant 2 would extend its presence in the much larger reimbursement segment of the CGM market by participating in tender procedures, offering its product at lower prices, also resulting in price erosion. Since the contracts in the reimbursement market are entered into for a substantial period of time, typically two years, price recovery will be even more difficult than in the cash pay segment.

247. The Court of Appeal rejects Appellants' argument that there will be no price erosion in the reimbursement segment, in particular because there are already other competitors of Respondent active in the reimbursement segment. Although 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. These prices may well be influenced by a new competitor, who may try to enter the lucrative reimbursement segment of the market by offering its (very similar) products at substantially lower prices.

248. The interest of Appellants to be able to enter and stay on the market during proceedings on the merits do not outweigh the interests of the Respondent in obtaining an immediate injunction. The main argument of Appellants is that they would suffer substantial damages (loss of guarantees and damages for non-performance of contracts) as a result of having to withdraw from negotiations and concluded contracts due to the preliminary injunction, and that Appellant 2 may be "blacklisted" in Italy as a result of such withdrawal. The Appellants have failed to provide any evidence about pending negotiations and concluded contracts to show that this harm is likely to occur, and if so, to what extent. In addition, Appellants have not shown that this harm would materialize or be expected in Contracting Member States outside Italy.

249. The Court of Appeal notes in this respect that this harm would potentially be even larger when Appellant 2 would be allowed to continue its activities with the GlucoMen iCan in the reimbursement market pending the main proceedings. As stated above, the Court of Appeal considers it more likely than not that the patent will be held infringed, and therefore the chance that the negative consequences mentioned by Appellant 2 would materialize following an injunction in main proceedings, is far from hypothetical. This would not only harm the Respondent (and Appellants themselves), but also the patients and doctors using the GlucoMen iCan.

250. Finally, the damages of Appellants due to later market entry should the injunction be lifted in proceedings on the merits will be easier to quantify than Respondent's damages due to the long term effect of price erosion, also in view of the influence on the price of similar devices marketed by third parties and on the prices set by insurers.

IX. Provisional Measures

251. In view of the above, the Respondent is entitled to provisional measures. The Court of Appeal notes the following with respect to the provisional measures issued by the LD The Hague.

Scope of the preliminary injunction

252. The LD The Hague has issued a generally worded injunction. This is in line with the approach taken by this Court in previous cases (cf. e.g. UPC_CoA_382/2024, 14 February 2025, Abbott v Sibio).

253. The Appellants object against the scope of the issued injunction, because it would also cover other products than the GlucoMen iCan, in particular the Sinocare iCan i3. Appellants argue that the Sinocare iCan i3 has been on the market in Europe since October 2023 and is technically the same as the GlucoMen iCan. According to Appellants, the Respondent has never acted against this product based on its patents and has not argued the presence of urgency or necessity with respect to this product in the current proceedings for provisional relief.

254. At the oral hearing, the Respondent clarified that, despite the general wording of the requested and issued preliminary injunction, the Sinocare iCan i3 is not meant to be covered by the injunction (which was also not enforced with respect to this product). This is in line with the content of Respondent's submissions in these proceedings, both in first instance and in appeal, which are aimed at the GlucoMen iCan and are silent on the Sinocare iCan i3. In view of the Respondent's clarification, it is clear that the preliminary injunction does not cover the Sinocare iCan i3.

255. The request by the Appellants to (further) limit the injunction to the GlucoMen iCan, is rejected. Absent specific circumstances, in case infringement is held to exist with respect to a particular embodiment, a generally worded injunction may be issued (UPC_CoA_382/2024, 14 February 2025, Abbott v Sibio). This is generally justified and has the benefit that if, for example, the infringing product is slightly changed or similar products would be introduced on the market under a different name, these products are covered by the issued injunction. The assertion by the Appellants that this would result in enforcement risks in this case is rejected. With the clarification by the Respondent that the Sinocare iCan i3 is not covered by the preliminary injunction, there is no enforcement or other risk that would justify deviating from the general approach to issue a generally worded

injunction in case of patent infringement.

Other ordered measures

256. The Appellants further argue that the LD's Order under (c) for delivery up of the GlucoMen iCan products that the Appellants still had in stock or owned, is disproportionate, as the units of the GlucoMan iCan that were delivered to the bailiff will "likely expire" before a final determination on the merits. The Court of Appeal considers this interest not to outweigh the interest of the Respondent to prevent further infringing products to enter the market. In the view of the Court of Appeal, there is no disproportionality in this case and the appeal against this part of the Order will therefore be rejected.

257. On pages 121 and 122 of the Statement of Appeal, the Appellants list a number of alternative, further alternative and other ("in any event") requests, which the Appellants ask the Court of Appeal to grant. To the extent that these requests were not dealt with above, the Court of Appeal refuses these requests.

258. A number of the listed requests were already accepted by the LD The Hague (such as the dismissal of the declaration of law), while a number of other requests were specifically dealt with and rejected by the LD The Hague. With the exception of the scope of the injunction and the order for delivery up of the GlucoMen iCan products, Appellants have not substantiated their requests or explained why the decision of the LD with respect to the respective measures was wrong. These additional requests will therefore not be granted.

259. To conclude, the Court of Appeal sees no reason to set aside the provisional measures issued by the LD The Hague.

X. Costs

260. Pursuant to Art. 69(1) UPCA, reasonable and proportionate legal costs and other expenses incurred by the successful party shall, as a general rule, be borne by the unsuccessful party, unless equity requires otherwise.

261. In this case, as the unsuccessful parties, the Appellants must bear the costs of these proceedings. The fact that Respondent clarified at the oral hearing that the Sinocare iCan i3 was not meant to be covered by the requested and issued preliminary injunction, has no bearing on the division of costs between the parties. This issue was relatively minor in relation to the successful claims, and in the absence of any other information from the Appellants, the Court of Appeal considers this issue not to have caused substantial costs for the Appellants.

262. The Respondent has not substantiated why Appellants should be ordered to jointly and severally bear these costs, or why the LD was incorrect to reject the joint and several liability in first instance. This part of the request will therefore be denied.

263. The Respondent's request for an interim award of costs pursuant to R. 211.1(d) RoP in paragraph 101 under (c) of the Statement of response, is understood by the Court of Appeal to solely relate to the costs of the appeal proceedings and therefore does not constitute a cross-appeal within the meaning of Rule 237 of the RoP or require such an appeal. This request is partially justified. The Court of Appeal grants the Respondent's request for an interim award of costs in the amount of € 200,000.

264. As decided in UPC_CoA_646/2024 (25 November 2025, Meril v Edwards), the Court may assume in general that the successful party will be entitled to 50% of the applicable ceiling for recoverable costs and may order reimbursement of that amount by means of an interim award, unless there are clear indications that the successful party in fact incurred fewer representation costs or that 50% of the applicable ceiling is more than what would be reasonable or proportionate in the particular circumstances of the case. At the same time, as a general rule, the Court cannot assume that the successful party is entitled to more than 50% of the applicable ceiling before the conclusion of the

cost proceedings according to Chapter 5 of Part 1 RoP. An exception may apply if parties have submitted and discussed cost specifications during the proceedings or have agreed on the costs to be reimbursed.

265. The LD The Hague set the value of the dispute at € 4,000,000. This value was not contested by the parties in appeal. The cost-ceiling for a case with such a value is € 400,000 (cf. Decision Administrative Committee of 24 April 2023 on the "Scale of ceilings for recoverable costs", page 6). The Respondent requests the payment of this amount (or any other amount set by the Court of Appeal) by way of interim award of costs. The Appellants did not contest the requested amount (and in fact requested the same amount in first instance).

266. It follows from the above that the Respondent is entitled in this case to an interim award in the amount of € 200,000, being 50% of the applicable ceiling of representation costs. There are no indications that the Respondent in fact incurred fewer costs or that this amount is more than what would be reasonable and proportionate in the circumstances of the present case. Nor is there any reason to exceptionally reimburse more than 50% of the applicable ceiling as an interim award.

ORDER

The Court of Appeal:

1. rejects the appeal;
2. orders the Appellants to bear the costs of the appeal proceedings;
3. orders the Appellants to pay to the Respondent by way of interim award of costs in the appeal proceedings, the amount of € 200,000 within 14 days after service of this order;

This order was issued on 30 March 2026.

Ulrike Voß Digitally signed by Ulrike Voß Date: 2026.03.30 08:03:54 +02'00'

Ulrike Voß, presiding judge

Bartholomeus Johannes van den Broek Digitally signed by Bartholomeus Johannes van den Broek Date: 2026.03.30 08:08:58 +02'00'

Bart van den Broek, legally qualified judge and judge-rapporteur

Nathalie, Jeanne, Danielle SABOTIER Digitally signed by Nathalie, Jeanne, Danielle SABOTIER Date: 2026.03.30 08:16:17 +02'00'

Nathalie Sabotier, legally qualified judge

Digitally signed by DOROTHEA HOFER
Date: 2026.03.30 09:37:54 +02'00'

Dorothea Hofer, technically qualified judge

Gérard, Jean-Pierre Myon

Signature numérique de Gérard, Jean-Pierre Myon
Date : 2026.03.30 10:29:10 +02'00'

Gérard Myon, technically qualified judge