Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

UPC Court of Appeal
UPC_CoA_382/2024
APL_39664/2024

ORDER
of the Court of Appeal of the Unified Patent Court
issued on 14 February 2025
concerning a request for provisional measures

HEADNOTE:

- As a general principle of claim interpretation, means-plus-function features must be understood as any feature suitable for carrying out the function.

- A general injunction may be justified even if it is not shown that a patent is infringed by all possible infringing acts. One type of (likely) infringement suffices as a basis for a general preliminary injunction, which includes all possible ways of infringing.

- The measures mentioned in Art. 67 UPCA may also be ordered in the framework of provisional measure proceedings, always provided that there is an urgent interest and such measures are proportionate.

KEYWORDS:

- Claim construction, added matter, infringement, urgency, balance of interests, general injunction, order to provide information

APPELLANT / APPLICANT IN THE MAIN PROCEEDINGS BEFORE THE COURT OF FIRST INSTANCE

Abbott Diabetes Care Inc., Alameda, California, USA,
hereinafter also referred to as "Abbott"
represented by: Wim Maas, Eelco Bergsma, Geert Theuws, David Mulder, and Iris van der Heijdt, attorneys at law, Taylor Wessing, Eindhoven and Amsterdam, The Netherlands, and Peter Haartsen, Raimon Haan and Teun van Berkel, patent attorneys, AOMB, Eindhoven, The Netherlands

RESPONDENTS / DEFENDANTS IN THE MAIN PROCEEDINGS BEFORE THE COURT OF FIRST INSTANCE

1. **Sibio Technology Limited**, Kowloon, Hong Kong, Special Administrative Region of the People's Republic of China
2. **Umedwings Netherlands B.V.**, Rijswijk, The Netherlands

hereinafter also jointly referred to as "Sibionics" (in singular)

both represented by: Thomas Gniadek, Sebastian Horleman, attorneys at law, and Dr Fritz Lahrtz and Diptanil Debbarma, patent attorneys, Simmons & Simmons LLP, Munich, Germany

LANGUAGE OF THE PROCEEDINGS
English

PATENT AT ISSUE
EP 3 831 283

PANEL AND DECIDING JUDGES

This order was adopted by Panel 2, consisting of:
Rian Kalden, presiding judge and judge-rapporteur
Ingeborg Simonsson, legally qualified judge
Patricia Rombach, legally qualified judge
Patrik Rydman, technically qualified judge
Marc van der Burg, technically qualified judge

IMPUGNED ORDER OF THE COURT OF FIRST INSTANCE

- Date: 19 June 2024; ORD_30431/2024 in the proceedings concerning provisional measures ACT_14945/2024
- Action number attributed by the Court of First Instance, Local Division The Hague: UPC_CFI_131/2024

POINTS AT ISSUE

Claim construction, infringement, validity (added matter, novelty, inventive step).

SUMMARY OF THE DISPUTE

Patent at issue

1. Abbott is the proprietor of the patent at issue. The patent was filed as a second generation divisional application (the application), stemming from a parent application (published as EP 3 300 658 A1, the parent application), itself originating from a PCT application published as WO 2013/090215 A2 (the original application). The filing date of the application is the filing date of the original PCT application, namely 11 December 2012 and it has a priority date of 11 December 2011. The application was published on 9 June 2021 and the mention of the grant of the patent was published on 26 April 2023. No opposition was filed against the patent within the statutory time limit. The patent is in force in UPCA (the Agreement on a Unified Patent Court) Contracting Member States Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, The Netherlands, and Sweden. It is also in force in other countries, including the UK, Ireland and Spain. The patent was opted-out of the UPC competence, but this opt-out was withdrawn by Abbott on 14 March 2024.

2. The patent has two independent claims. Claim 1 claims an on-body device and claim 15 claims a method for assembling an on-body device. Claim 1 of the patent at issue reads as follows:

> **1.** An on-body device, comprising:
>
> (1) a glucose sensor assembly (3702, 4702) comprising:
>
> a proximal section comprising a connector support (3604, 4706) coupled with a proximal portion (3310) of a glucose sensor

(3300, 4704);
a distal tail section comprising a distal portion (3302) of the glucose sensor (3300, 4704) configured to be positioned under a skin surface and in contact with a bodily fluid of a subject;

(2) an enclosure comprising:

a top portion (5002); and
a base portion (5004) configured to be adhered to the skin surface of the subject by an adhesive patch (3802, 5104); and

(3) sensor electronics positioned within the enclosure, the sensor electronics comprising a processor (4804), and a communications facility,

wherein the base portion of the enclosure comprises a recess (3704, 4710) in a bottom exterior surface, the recess (3704, 4710) comprising a distal-facing opening,
wherein the connector support (3604, 4706) is received through the distal-facing opening and into the recess (3704, 4710), and
wherein the glucose sensor (3300, 4704) is electrically coupled with the sensor electronics by the connector support when the connector support is received into the recess (3704, 4710).

3. The parties and the CFI have referred to the separate features of claim 1 as follows:

Feature 1.0	An on-body device, comprising:
Feature 1.1	(1) a glucose sensor assembly (3702, 4702) comprising:
Feature 1.1.1	a proximal section comprising a connector support (3604, 4706) coupled with a proximal portion (3310) of a glucose sensor (3300, 4704);
Feature 1.1.2	a distal tail section comprising a distal portion (3302) of the glucose sensor (3300, 4704) configured to be positioned under a skin surface and in contact with a bodily fluid of a subject;
Feature 1.2	(2) an enclosure comprising:
Feature 1.2.1	a top portion (5002); and
Feature 1.2.2	a base portion (5004) configured to be adhered to the skin surface of the subject by an adhesive patch (3802, 5104); and
Feature 1.3	(3) sensor electronics positioned with the enclosure, the sensor electronics comprising a processor (4804), and a communications facility,
Feature 1.4	wherein the base portion of the enclosure comprises a recess (3704, 4710) in a bottom exterior surface, the recess (3704, 4710) comprising a distal-facing opening,
Feature 1.5	wherein the connector support (3604, 4706) is received through the distal-facing opening and into the recess (3704, 4710), and

Feature 1.6 where the glucose sensor (3300, 4704) is electrically coupled with the sensor electronics by the connector support when the connector support is received into the recess (3704, 4710).

The contested embodiment

4. Sibionics has offered a continuous glucose monitoring device, also referred to as the 'GS1 CGM product', for sale on its sibionicsshop.com website in the packaging and with the product parts as shown below:

Procedural background and the impugned order

5. On 20 March 2024, Abbott filed an Application for a preliminary injunction and other provisional measures (ACT_14945/2024) with the UPC Local Division The Hague, arguing that Sibionics' GS1 CGM product was infringing its patent at issue (hereinafter also: the patent).
6. The Court of First Instance denied that Application by Order no. ORD_30431/2024. The CFI found that, on the balance of probabilities, it was more likely than not that claim 1 and (consequently) the asserted dependent claims 6, 7, 9, 11, 12, 13, 14 and 26 of the patent will be held to contain added matter relative to the original application as filed and relative to the parent application (EP 3 300 658 A1) as filed and to the application as filed, due to the omission of an elastomeric sealing member or a second elastomeric unit in the wording of the claim.
7. Subsequently, Abbott lodged an appeal against this Order.
8. The oral hearing was held on 27 November 2024.

SUMMARY OF THE PARTIES' REQUESTS

9. In the Statement of appeal, Abbott requests that the impugned order be set aside and that the requests as stated in the Application for provisional measures, submitted at the UPC Local Division The Hague, be granted. Thus, Abbott requests that the Court of Appeal, for the Contracting Member States in which the patent is in force:
   (a) set aside the impugned order;
   (b) grant a preliminary injunction for direct infringement of the patent by prohibiting Sibionics, individually and jointly, from infringing the patent in any way, with immediate effect after service of the order to be rendered in this matter, in particular by making, offering and / or placing on the market the GS1 Device, or importing or storing the GS1 Device for those purposes (Art. 63(1) and 25(a) UPCA);
   (c) order Sibionics to provide counsel for Abbott, within 4 weeks after service of the order rendered in this matter, with a written statement, substantiated with appropriate documentation of:
      (i) the origin and distribution channels of GS1 Devices in the Contracting Member States in which the patent is in force (including the full names and addresses of the legal entities that are involved);
      (ii) the quantities delivered, received or ordered, as well as the price obtained for GS1 Devices in the Contracting Member States in which the patent is in force; and

(iii) the identity of any third party involved in the production or distribution of GS1 Devices in the Contracting Member States in which the patent is in force (including the full names and addresses of the legal entities that are involved);

(Art. 62(1) and 67 UPCA; and R. 211 RoP)

(d) order Sibionics to deliver up to a bailiff appointed by Abbott, at their own expense, or alternatively order the seizure, of any GS1 Device in stock and / or otherwise held, owned or in the direct or indirect possession of Sibionics in the Contracting Member States in which the patent is in force, within 1 week after service of the order to be rendered in this matter, and to provide counsel for Abbott with proper evidence of the full and timely compliance with this order within 10 days after the delivery up to the bailiff or seizure (Art. 62(3) UPCA; and R. 211(1) RoP);

(e) order Sibionics to comply with the orders under 1.1(a) – 1.1(c) above, subject to a recurring penalty payment of up to EUR 250,000.00 or another amount as the Court of Appeal may order, to the Court of Appeal for each violation of, or non-compliance with, the order(s), plus up to EUR 100,000.00 for each day, or part of a day counting as an entire day, that the violation or non-compliance continues, or another amount as determined by this Court in the proper administration of justice (Art. 62(2) UPCA; and R. 354.3 RoP);

(f) append an order for the enforcement to its decision, while declaring that the order is immediately enforceable (Art. 82(1) UPCA);

(g) order Sibionics to jointly and severally bear reasonable and proportionate legal costs and other expenses incurred by Abbott in the proceedings at first instance and on appeal and order, insofar such costs are to be determined in separate proceedings for the determination of such costs, that Sibionics pay to Abbott by means of an interim award of costs of the sum of EUR 11,000.00 or another amount as the Court may order (Art. 69 UPCA; and R. 118.5 and R. 150.2 RoP).

10. Abbott also requests that the amount of security, if any, be fixed separately for each enforceable part of the Court's decision.
11. On appeal Abbott also requests leave to change the claim (*inter alia*) by adding the following wording to the request under (b):

    Or in the discretion of the Court of Appeal, in the alternative,
    grants a preliminary injunction for infringement of the Patent by prohibiting the Respondents, individually and jointly, from infringing the Patent, with immediate effect after service of the order to be rendered in this matter, by making, offering and/or placing on the market the GS1 Device, or importing or storing the GS1 Device for those purposes (Articles 62(1) and 25 and 26 of the UPCA);

    and:

    order Sibionics, jointly and severally, to repay to Abbott all costs that were paid by Abbott to Sibionics in execution of the Order of the Court of First Instance (R. 242.1 RoP).

12. Abbott also filed an application for leave to change its claims, submitting four "exemplary auxiliary requests" for the situation where the Court of Appeal considers the Patent not valid in its granted form due to added matter.
13. Sibionics requests to reject the appeal, to order that Abbott must bear the costs of the proceedings, to set the value-in-dispute to EUR 4,000,000, to reject Abbott's request to amend the claim with regard to the requested provisional measures for Ireland, in the alternative to disregard Abbott's argument with regard to the requested provisional measures for Ireland, and in the further alternative to deny jurisdiction for Ireland, to disregard Abbott´s auxiliary requests submitted as Annexes G3 to G6 and corresponding arguments and to disregard Abbott´s arguments with regard to infringement and validity of claim 10.
14. As an auxiliary request, Sibionics requests that Abbott be ordered to provide an appropriate security for enforcement.

SUMMARY OF THE PARTIES' SUBMISSIONS

15. Abbott argues that the CFI was wrong to find that claim 1 contains added matter. It contends that its patent is valid and independent claim 1 as well as dependent claims 6, 7, 9, 11, 12, 13, 14 and 26 of the patent are (threatened to be) infringed by Sibionics, among others by the offering for sale of its so-called GS1 Devices through Sibionics' website sibionicsshop.com. On appeal Abbott relies on four auxiliary requests, in case the Court of Appeal would agree with the CFI that the claims as granted contain added matter.
16. Sibionics contends that the Application is inadmissible because the requirements of R. 211.2 RoP in conjunction with Art. 62(4) UPCA are not met. Sibionics disagrees with Abbott that the patent is infringed. It further asserts that the patent is (likely) invalid because of added matter, lack of novelty and lack of inventive step. Additionally, it contends that the Application was brought with unreasonable delay and that Abbott lacks sufficient interest in the current Application because it will not suffer irreparable harm. When weighing up the interests of the parties, the interest of Sibionics clearly prevails. Sibionics further asserts Abbott should bear the costs in relation to the request in relation to Ireland. . Sibionics disputes that auxiliary requests can be relied on in proceedings for provisional measures and argues that they would still lead to an invalid patent.

GROUNDS FOR THE ORDER

Admissibility

17. Sibionics argues that Abbott´s arguments with regard to infringement and validity insofar as they do not relate to the express ground of appeal in relation to added matter are to be disregarded, as Abbott did not refer to its other arguments – such as those on infringement, validity, urgency – as a basis for its appeal. This must be rejected. Abbott has explicitly referred to its submissions and evidence relied upon in first instance as a basis for its maintained request for an injunction and other provisional measures (par. 132 Statement of appeal). Such a general reference to submissions made at first instance is sufficient if and to the extent that the impugned decision does not address them (see R. 226 RoP).

The patent at issue

18. As reference for the reader of this decision, the Court of Appeal will begin with a summary of those parts of the patent description that are relevant for its subsequent analysis.

19. Par. [0002] – [0006] of the description sets out the background of the invention. It states that the 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 (par. [0003]).

20. Next to the use of conventional *in vitro* techniques (described in par. [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, through 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 (par. [0005]).
21. The invention provides an applicator system configured to handle insertion, as well as packaging and user interface issues, that is easy-to-use, reliable and minimizes both user inconvenience and pain (par. [0006]).
22. Par. [0007] – [0012] contains a summary of the invention.
23. Par. [0010] states that the on-body device may include sensor electronics and other adaptation to communicate with a monitoring device.
24. Par. [0011] states: In accordance with the present invention, there is provided an on-body device as claimed in claim 1 or a method for assembling an on-body device as claimed in claim 15.

25. Par. [0011] goes on to say: "*In some embodiments, methods are provided for assembling the on-body device including assembling the sensor assembly to the electronics assembly, which enables inserting a portion of the sensor under the skin of a user. Thus, the sensor assembly includes a sensor that has a distal portion for operative contact with a fluid of the user. The on-body device also includes an electronics assembly including a housing defining a distal surface adapted for attachment to the skin of the user and a circuit coupleable to the sensor for detecting electrical signals from the sensor*."

26. Par. [0013] contains a brief description of the drawings (fig. 1 to 51C) and par. [0014] – [0098] contain a detailed description.

27. The on-body device and different embodiments thereof are described in more detail in par. [0068] – [0093], headed "*Electrical Connection Details*" and in par. [0094] – [0098], headed "*On-body Device Construction Details*".

28. Par. [0068] states: "*The selection of various hardware options from the above alternative embodiments will depend, at least in part, on the sensor assembly configuration. Sensor assembly configuration, in turn, depends on the mechanism selected for establishing electrical contact between the sensor assembly and the electronics assembly, as well as the method used to seal the contacts. A number of advantageous alternative embodiments are illustrated in FIGS. 22 through 48*."

29. Fig. 33A – 33G provide views of a sensor configuration. Fig. 33A and 33B are shown below:

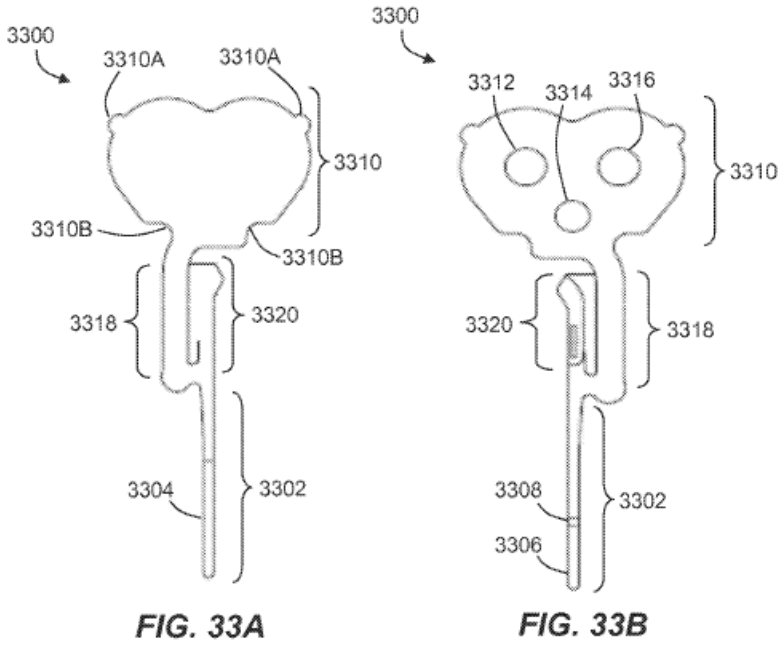


FIG. 33A FIG. 33B

30. Par. [0077] describes this sensor configuration as follows: *FIGS. 33A-33G depict a low-profile multilayer sensor configuration with the electrical contacts all on one side and some details of its construction. FIGS. 33A and 33B illustrate the two sides of this embodiment of a sensor 3300 and its overall shape. The example sensor 3300 includes a tail portion 3302 that is initially supported by a sharp and then disposed within the user's interstitial fluid or dermal space below the skin upon application of the on-body device. The tail portion 3302 includes electrodes 3304, 3306, 3308 that are used to contact the interstitial fluid and to sense (e.g., transmit and receive) the electrical signals used to measure the analyte concentration within the interstitial fluid. The sensor 3300 also includes an electrical contacts portion 3310 which includes electrical contacts 3312, 3314, 3316 that are disposed all on one side of the sensor 3300 and are in electrical communication with the electrodes 3304, 3306, 3308 via conductive traces (not visible in FIGS. 33A and 33B but see FIG. 33F). Note also that the electrical contacts portion 3310 is shaped to facilitate being securely held and sealed into a connector support that will be described below*.

31. The embodiment shown in fig. 34A – 34D and described in par. [0084] – [0085] is referred to as an alternative connector arrangement for connecting a circuit board to a sensor 3300:

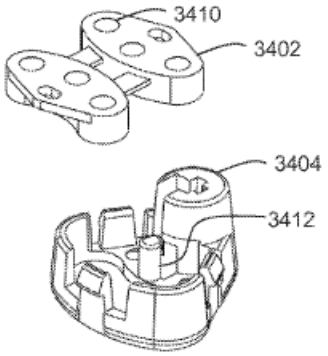


FIG. 34A

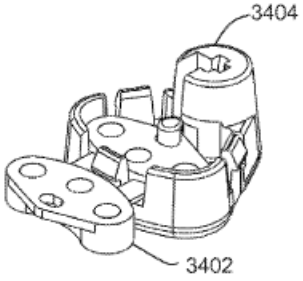


FIG. 34B

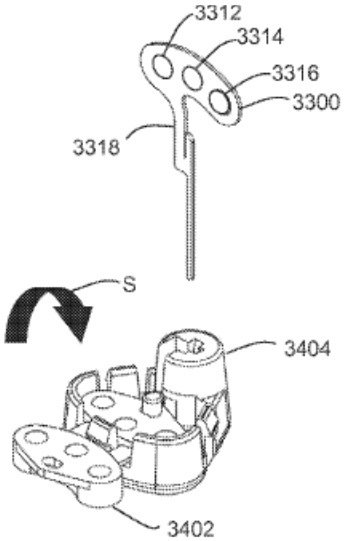


FIG. 34C

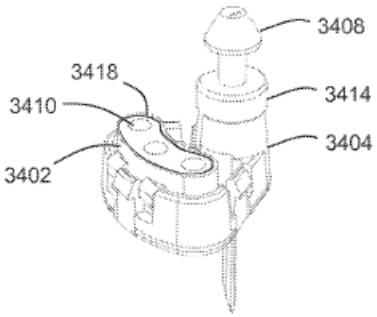


FIG. 34D

[0084] Turning now to FIGS. 34A-35D, an alternative connector arrangement for connecting a circuit board to a sensor 3300 such as depicted in FIGS. 33A, 33B, and 33J is described. As shown in FIG. 34A, a flexible onepiece seal or connector 3402 is molded in silicone or other practicable elastic material. Separate doped silicone conductive elements are set therein which provide electrical contacts 3410 for connection to a circuit board. In some embodiments, the conductive elements can alternatively be over molded or insert-molded into place. The result is a generally malleable/flexible hybrid connection and sealing unit or connector 3402 incorporating a living hinge joining two (as-shown) symmetrical sections. Alternatively, a two-piece design is possible. Yet, with the unitary design, the arrangement can be neatly secured using a single catch boss or post 3412 opposite the hinged section. In some embodiments, two or more posts can be used to secure the connector 3402 folded around and sealing both sides of the contacts portion of the sensor 3300. Thus, even if a dielectric coating on the sensor 3300 fails (e.g., pinhole leaks), the connector 3402 insures that the sensor contacts 3312, 3314, 3316 are protected from moisture or any contaminants. The one-piece design also facilitates assembly as illustrated, in which the flexible connector 3402 is set in a rigid or semi-rigid housing or connector support 3404 with one side located on the post 3412. Then a sensor 3300 is inserted, and bent approximately ninety degrees at the bendable portion 3318 of the sensor 3300. Once bent, the sensor 3300 is then captured with the upper part of the connector 3402 by folding over the connector 3402 as indicated by arrow S in FIG. 34C (…)..

[0085] As shown in FIG. 34D, in some embodiments, the top surface of the connector 3402 includes a raised lip 3418 disposed at the top surface edge of the connector 3402 that encircles the electrical contacts 3410 of the connector 3402. The raised lip 3418 can be integrally formed in the elastomeric material that forms the connector 3402 and is thus compressible when the sensor assembly is inserted into the electronics assembly. Alternatively, the raised lip can be embodied as gasket or o-ring on the top surface of the connector 3402. The raised lip 3418 functions to ensure that a seal is formed around the electrical contacts 3410 of the connector 3402 and the electrical contacts of the PCB before any electrical

connectivity between the sensor and the electronics assembly is established. Thus, the raised lip 3418 provides a failsafe against a short by insuring the order of assembly includes creating a seal and then creating electrical connectivity as the sensor assembly is mated with the electronics assembly.

32. The embodiment of fig. 36 – 38 described in par. [0088] is called a 'related arrangement' to that of fig. 34A – 34D:

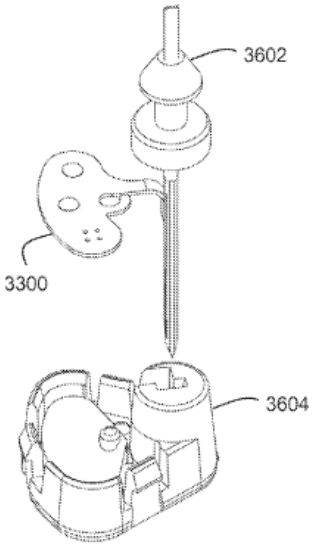


FIG. 36

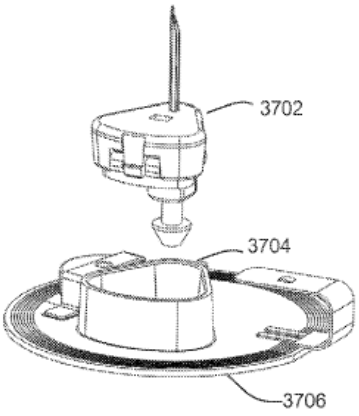


FIG. 37

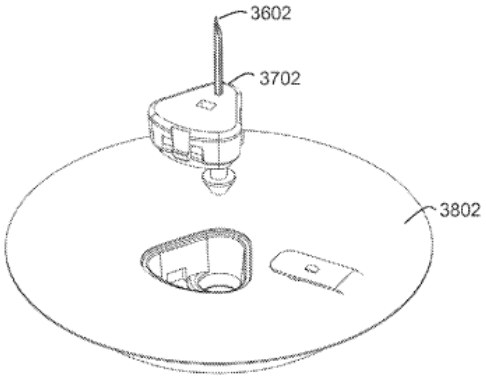


FIG. 38

[0088] A related arrangement to that described in connection with FIGS. 34A-34D and 35A-35D is presented in FIGS. 36 to 38. In FIG. 36, a sensor 3300 with all electrical contacts on the same side is shown with a sharp 3602 for insertion in a connector support 3604. The connector support 3604 includes an elastomeric (e.g., silicone) seal backing. Once such a sensor assembly set is in a container (or alternatively in an applicator), the sensor assembly can be coupled to the sensor electronics to form an on-body device 222. As shown in FIG. 37, 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 3704. Note that in FIG. 37, the enclosure of the electronics assembly is not shown so that the socket can be more clearly displayed. The socket 3704 is affixed to a circuit board 3706 via any practicable method. The socket 3704 and/or the connector support 3604 can include various coupling features (e.g., a snap fit lip and hook arrangement) to ensure that the electrical contacts are pressed tightly together and sealed within the socket 3704 and sensor assembly 3702. Once the sensor assembly 3702 is received within the socket 3704, the on-body device (e.g., with the complete over-mold enclosure around the circuit board 3706 and adhesive patch 3802 as shown in FIG. 38) is ready for use.

33. Par. [0093] illustrates in fig. 47A to 47C, an 'alternative sensor assembly / electronics assembly connection approach' is illustrated. The figures as well as par. [0093] is shown below.

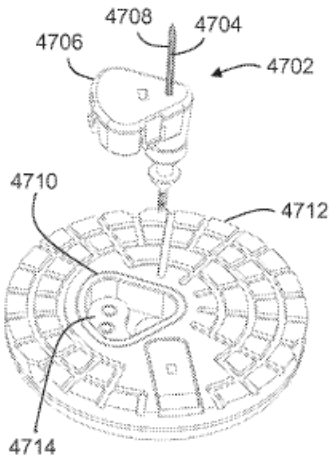


FIG. 47A

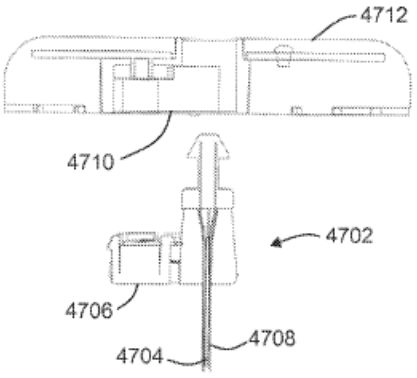


FIG. 47B

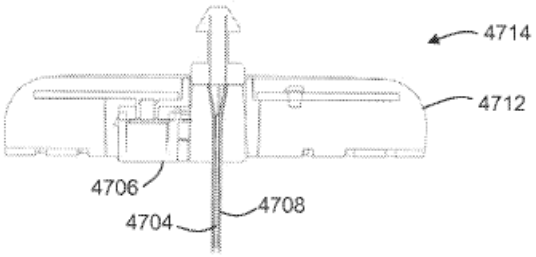


FIG. 47C

[0093] Turning now to FIGS. 47A to 47C, an alternative sensor assembly/electronics assembly connection approach is illustrated. As shown, the sensor assembly 4702 includes sensor 4704, connector support 4706, and sharp 4708. 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). Instead, a recess 4710 formed directly in the enclosure of the electronics assembly 4712 includes an elastomeric sealing member 4714 (including conductive material coupled to the circuit board and aligned with the electrical contacts of the sensor 4704). Thus, when the sensor assembly 4702 is snap fit or otherwise adhered to the electronics assembly 4712 by driving the sensor assembly 4702 into the integrally formed recess 4710 in the electronics assembly 4712, the on-body device 4714 depicted in FIG. 47C is formed. This embodiment provides an integrated connector for the sensor assembly 4702 within the electronics assembly 4712.

34. Under the heading "*On-body Device Construction Details*" par. [0094] – [0098] then describe the on-body device referring to fig. 48 – 51, explicitly stating that "*any or all of the above electrical connection configurations*" may be applied. Par. [0096] states: "*An enclosure including a top shell 5002 and a mounting base 5004 can be used to sealably enclose and protect the circuit board 4800*." Reference is made to fig. 50A – 50B:

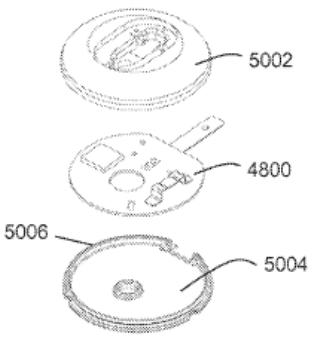


FIG. 50A

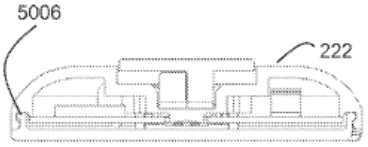


FIG. 50B

Skilled person

35. Sibionics has uncontested stated that the person skilled in the art is an engineer with an academic degree such as a M.Sc. and several years of professional experience in the field of medical devices, specifically glucose sensor devices performing in vivo technics.

The object of the invention

36. The skilled person understands from the description that the object of the invention is to provide for an on-body device, which is meant to form part of an applicator system configured to handle insertion of an *in vivo* analyte monitoring system, which is easy-to-use, reliable and minimizes both user inconvenience and pain (par. [0005] – [0011], see par. 20 – 25 above). In particular, as follows from par. [0022], which states that "*Advantageously, an adhesive of the on-body device does not contact the skin of the user until the application operation is performed*", the object is to provide for an on-body device that is configured such that it allows the applicator containing the on-body device to be moved freely over the skin to find the right position before the on-body device is subsequently adhered to the skin in a single step. This latter aspect requires that the adhesive of the on-body device does not contact the skin of the user until the application operation is performed.

Claim construction

37. The principles applicable to claim construction have been set out by this Court in its final order in UPC_CoA_335/2023 (NanoString v 10x Genomics, Headnote 2, as rectified). The 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.

38. Claim 1 does not specify the precise configuration of the on-body device. Instead, many features are described in a functional way. There is dispute on the interpretation of claim 1, in particular some of its features. These are discussed below.

Feature 1.1.

39. The term 'glucose sensor assembly' according to feature 1.1. is not expressly defined in the description, as Sibionics noted. However, from the overall context of the description, the skilled person will understand that this is an assembly of a monitoring system used to sensor blood glucose levels (see par. [0005] cited in par. 20 above; par. [0008] of the description also mentions that certain embodiments include e.g. a glucose sensor).

Features 1.1.1 and 1.6

40. Sibionics argues that the term 'connector support' in features 1.1.1 and 1.6 must be interpreted as a connector support 'which does not include a separate connector to provide electrical connectivity between the glucose sensor and the sensor electronics'. According to Sibionics it is in line with the technical teaching of claim 1, more in particular feature 1.6, that solely the connector support, i.e. without a separate connector, achieves the technical effect of providing connectivity between the glucose sensor and the sensor electronics.

41. Sibionics in this respect refers to the embodiment of fig. 34A – 34D (see par. 31 above), which has an additional / separate connector which, according to Sibionics, is also used to provide for electrical connectivity, in addition to the connector support. The Court of Appeal rejects this argument.

42. Claim 1 does not specify whether the connector support, which provides for electrical connectivity, must contain only one element. This does not follow from the description. Even if the connector in fig. 34A-34D provides electrical connectivity between the glucose sensor and the sensor electronics, that would only confirm that such an embodiment is covered by the claim.

43. The understanding of features 1.1.1 and 1.6 as suggested by Sibionics is therefore rejected.

Features 1.1.1 and 1.1.2

44. The words 'proximal' and 'distal' have an ordinary meaning. There is no doubt that the skilled person understands the proximal section of a glucose sensor assembly containing the connector region to be situated nearer to the enclosure to which it is to be coupled. Where it discusses validity, Sibionics also interprets 'proximal' to mean 'close to the device' (p. 26 Objection). Consequently, the distal tail section comprising the distal portion of the glucose sensor configured to be positioned under the skin is on the opposite side, so close to / facing the skin.

Features 1.2.1 and 1.2.2

45. In accordance therewith, the skilled person understands the feature of a base portion of the enclosure comprising a recess, comprising a 'distal-facing opening' to mean that the opening is at the bottom side of the enclosure and directed towards the skin.

46. The words 'top portion' and 'base portion' also have an ordinary meaning. In the context of the patent description these will be understood by the skilled person to have the same meaning as the top shell 5002 and mounting base 5004 mentioned in par. [0096] and shown in fig. 50A (see par. 34 above), together forming the enclosure, with the recess in the base portion comprising the distal-facing opening.

Feature 1.2.2

47. As to feature 1.2.2, requiring *a base portion (5004) configured to be adhered to the skin surface of the subject by an adhesive patch (3802, 5104)*, Sibionics is right in saying that the words 'configured to' must be understood to mean 'suitable for'. As a general principle of interpretation, means-plus-function features must be understood as any feature suitable for carrying out the function. Abbott wrongly refers to Part F-IV-3.9.1(ii) of the Guidelines which relates to claims directed to computer-implemented inventions. As an exception to the mentioned general principle, where the function is carried out by a computer or similar apparatus, the means-plus-function features are interpreted as means *adapted to* carry out the respective steps/functions. This does not apply here.

Feature 1.4

48. The words 'bottom exterior surface' also has an ordinary meaning. The skilled person will derive from the patent description that the surface of the bottom exterior is the outside part on the bottom of the base portion of the enclosure, where the adhesive patch is meant to be attached in order to adhere the bottom side of the enclosure to the skin surface of a subject. This can be seen in fig. 38 and 47A (see par. 32 and 33 above).

49. From feature 1.4, in connection with feature 1.6, the skilled person understands that the on-body device of claim 1 must be configured such that the sensor assembly is received in the enclosure *from beneath*. Such a configuration allows that both assemblies are coupled within the applicator before either of them is adhered to the skin. Only then the applicator may be moved freely over the skin before the on-body device is adhered to the skin in a single step, because the adhesive of the on-body device does not contact the skin of the user until the application operation is performed.

Feature 1.6

50. Taking the above objective and interpretation into account, the skilled person understands from the requirement of a connector support in feature 1.6, which requires that this connector support is used to electrically couple the glucose sensor with the sensor electronics by receiving the connector support in the recess of the enclosure, that the configuration according to claim 1 must have sensor and electronics assemblies with aligned electrical contacts that will mate once coupled in a directional manner (see [0093] cited in par. 33 above).

<u>Added matter</u>

51. The Court of Appeal shall now consider the main ground for Abbott's appeal, i.e. whether the CFI was right in finding that on the balance of probabilities it was more likely than not that the patent will be held invalid due to added matter.

52. There is added matter if the claim as granted contains subject-matter that extends beyond the content of the application as filed. In order to ascertain whether there is added matter, the Court must thus first ascertain

what the skilled person would derive directly and unambiguously using his common general knowledge and seen objectively and relative to the date of filing, from the whole of the application as filed, whereby implicitly disclosed subject-matter, i.e. matter that is a clear and unambiguous consequence of what is explicitly mentioned, shall also be considered as part of its content. Where, as here, the patent is a divisional application, this requirement applies to each earlier application.

53. The Court of Appeal notes that the assessment of added matter cannot be restricted to only those parts of the original application which the patent proprietor indicated as a basis for an amended claim during the examination proceedings at the EPO, since a proper understanding of these parts also requires an assessment of their content in the context of the disclosure of the application as a whole.

54. The Court of Appeal is of the opinion that, when applying this standard, it is not more likely than not that the patent at issue contains added matter relative to the original application as filed, to the parent application and the application. This will be explained below.

55. It is undisputed that the original application, the parent application and the application have an identical content. Below, they shall jointly be referred to as the original application.

56. The only difference between the patent description and the original application is that the description also contains the wording of par. [0011] that is cited in par. 24 above, which the original application does not have. The original application contains in its par. [0013] 43 Clauses (claims), which are not present in the description of the patent at issue. The paragraph numbers of both documents differ as from their par. [0013] since the (grouped) figures listed under the heading 'brief description of the drawings' are given separate paragraph numbers in the original application.

57. Clause 32 of the original application reads:

> *An on-body device, arrangeable in position by way of the apparatus according to any of the preceding clause, the on-body device comprising:*
>
> *a first assembly including a first portion of the on-body device, the first portion preferably being an electronics assembly including sensor electronics and preferably further comprising an enclosure surrounding the sensor electronics, the sensor electronics including a processor and a communications facility; and*
>
> *a second assembly including a second portion of the on-body device, the second portion preferably being a sensor assembly including a sensor and preferably further comprising a sharp supporting the sensor, a support structure and a connector coupled to the sensor and coupleable to the sensor electronics, the support structure supporting the connector and sensor, and releasably supporting the sharp."*

58. Clause 32 in the original application does not convey any information that is not already conveyed to the skilled person when reading the rest of the original application as a whole and is also consistent therewith. Also, the wording added to par. [0011] in the description of the patent, does not cause it to have a content different from the original application. This leads to the conclusion that the original application and the patent description have the same content and thus also the same objective.

No basis for the combination of features of claim 1

59. The Court of Appeal rejects Sibionics' argument that claim 1 is the result of 'cherry picking' features from the application that were not disclosed in combination.

60. It follows from the objective of the invention as disclosed in the original application, that the skilled person understands the configurations of fig. 34A – 34D, 36 – 38, and 47A – 47C (see par. 31 – 33 above) to be all embodiments with which the objective of the invention may be accomplished. Even though the focus of the drawings and related paragraphs in the description with respect to each of these embodiments may be on different elements of the on-body device, it is apparent to the skilled person that each of these are meant to be part of an on-body device for use in an applicator system as envisaged by the invention.

61. In relation to the embodiment of fig. 36 – 38 the description ([par.0088] cited in par. 32 above) mentions explicitly that it may be used in an on-body device and that it makes use of sensor 3300. Given the context and given that this embodiment is related to the arrangement of fig. 34A – 34D, described as *an alternative connector arrangement for connecting a circuit board to sensor 3300* (see par. [0084] cited in par. 31 above),

the skilled person would derive directly and unambiguously from the description that the embodiment of fig. 34A – 34D is meant for use in an on-body device as well.

62. Sibionics' argument that the embodiment of fig. 34A – 34D does not have a recess fails. This does not follow from [0093], where it says "*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). Instead, a recess 4710 formed directly in the enclosure of the electronics assembly 4712 includes an elastomeric sealing member 4714 (including conductive material coupled to the circuit board and aligned with the electrical contacts of the sensor 4704)*." as Sibionics suggests. The word 'instead' does not relate to the presence of a recess, but to the presence of an elastomeric sealing member 4714 which is positioned *in* the recess. Neither can it be deduced from fig. 34A – 34D (see par. 31 above), which only show the glucose sensor assembly and not the enclosure where the recess is situated. Rather, the skilled person understands that also in this embodiment the connector support – shown in those figures – is to be received in a recess in the base portion of an enclosure containing a circuit board (sensor electronics), as is described and shown for the embodiments of fig. 36 – 38 and 47A – 47C and par. [0088] and [0093] (see par. 32 and 33 above).

63. The Court of Appeal rejects Sibionics' argument that no recess is disclosed in which the embodiment of fig. 34A – 34D fits. Sibionics argues that this embodiment has a separate connector / seal which makes that it does not fit in the socket / recess 3704 disclosed in relation to the embodiment of fig. 36 – 38 since that includes a second elastomeric unit with electrical contacts in the elastomer body of the socket. It also does not fit the recess disclosed in relation to the embodiment of fig. 47A – 47D either, because that includes an elastomeric sealing member 4714 (including conductive material coupled to the circuit board and aligned with the electrical contacts of the sensor 4704), so Sibionics contends.

64. This is, however, not how the skilled person would understand the disclosure of the original application. Firstly, he would not consider the presence of a connector / seal of the 34A – 34D embodiment to rule out a further sealing member, especially since the embodiment of fig. 36 – 38 is an embodiment related to the 34A – 34D embodiment and refers to a *second* elastomeric unit. Secondly, he would primarily consider relevant that the choice of configuration of the on-body device allows the object of the invention to be achieved. The manner of sealing can then be chosen to suit that configuration. As such, he would consider a fitting recess as disclosed in relation to the embodiments of fig. 36 – 38 and fig. 47A – 47C to be essential and would understand that the enclosure of the on-body device of which the sensor assembly of fig. 34A – 34D is to form part, also has such a 'formed to fit' recess.

65. Further, the skilled person learns from par. [0089] where it says: "*The electrical contacts/connector approaches described above are "directional"* that in the embodiments of fig. 34A – 34D and of fig. 36 – 38 discussed (and shown in par. 31 and 32) above (which are referred to in par. [0089] as "*electrical contacts/connector approaches described above*"), the sensor assembly is mated with the electronics assembly in a directional way, meaning that the electrical contacts of the sensor (assembly) and the electronics (assembly) of these three embodiments are aligned relative to each other both longitudinally and rotationally, so that when these are connected in a predetermined manner, these electrical contacts are pressed together thus allowing electrical current to flow between them.

66. The skilled person will understand that the same applies to the embodiment of fig. 47A – 47C (shown in par. 33 above). Even though the sensor is not explicitly described in relation to this embodiment, the skilled person will appreciate that a sensor of the same shape as that of sensor 3300 is shown in the figures, with respect to which the description (par. [0077]) mentions: "*Note also that the electrical contacts portion 3310 is shaped to facilitate being securely held and sealed into a connector support that will be described below*." Fig. 47A – 47C show and describe such a shaped to fit connector support.

67. To conclude, the Court of Appeal is of the opinion that the combination of features of claim 1 has sufficient basis in the original application.

Added matter due to different claim wording

68. Sibionics' argument that claim 1 has no basis in the original application because the claim wording used cannot be found in the original application must be rejected. It is not required that a claim uses the exact same wording as used in the original application, as long as the skilled person would derive the combination of features from the whole application. It follows from what is discussed above that the Court of Appeal is of

the opinion that this requirement is met here.

Added matter due to intermediate generalisations

69. Sibionics further argues that claim 1 contains added matter because it omits certain features that are disclosed in combination with the features of claim 1, thus resulting in an unallowable intermediate generalization. This is discussed below, whereby, although only the original application is relevant, reference is also made to the paragraph numbers of the description (between brackets) cited above, as an indication of the identical wording of the relevant paragraph of the original application.

Omission of use of an elastomeric or elastic material

70. As Sibionics rightly pointed out, the embodiments of fig. 34A – 34D, of fig. 36 – 38 and of fig. 47A – 47C (see par. 31-33 above) all make use of an elastomeric or elastic material for sealing the coupling between the sensor and the electronics. This is clear for fig. 34A – 34D from par. [(0084)/0141] ("*a flexible one-piece seal or connector 3402 is molded in silicone or other practicable elastic material*") and from par. [(0085)/0142]: "*The raised lip 3418 can be integrally formed in the elastomeric material that forms the connector 3402" and "The raised lip 3418 functions to ensure that a seal is formed around the electrical contacts 3410 of the connector 3402 and the electrical contacts of the PCB before any electrical connectivity between the sensor and the electronics assembly is established*." For fig. 36 – 38 par. [(0088)/0145] states: "*The connector support 3604 includes an elastomeric (e.g., silicone) seal backing*." and "*As shown in FIG. 37, 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 3704*." In par. [0093/0150] it is stated in relation to fig. 47A – 47C: "*a recess 4710 formed directly in the enclosure of the electronics assembly 4712 includes an elastomeric sealing member 4714 (including conductive material coupled to the circuit board and aligned with the electrical contacts of the sensor 4704)*."

71. Sibionics is also right in saying that claim 1 does not explicitly require the existence of an elastomeric or elastic sealing member. Sibionics' argument that for this reason claim 1 is an unallowable intermediate generalization and contains added matter, must however be rejected. In the opinion of the Court of Appeal the subject-matter of claim 1 does not extend beyond the content of the original application as filed by omitting the use of elastomeric or elastic material as a sealing member, for the following reasons.

72. It is clear from the description (see e.g. par. [0084] and [0085]) that sealing is considered important to ensure that contacts on the sensor assembly and the contacts on the electronics assembly are protected from moisture or any contaminants and thus to prevent a short, which would disturb the functioning of the device.

73. The original application discloses various ways to achieve sealing of the contacts, also other than by the use of elastomeric and elastic material, such as in par. [(0069)/0126]:

> "*When inserted in a housing 2210, the sensor 2202 and the connector 2204 are advantageously sealed, encased or potted with an adhesive. Epoxy, a UV cure or <u>another type of dielectric (non-conductive)</u> (emphasized by the Court) compound may be used. Generally, the compound selected is of such viscosity that it is able to flow around features and fully seal the sensor 2202 within its housing 2210 to avoid leakage. Such an approach avoids contamination and/or current leakage due to fluid intrusion*".

74. Also, par. [0072] discusses "*another advantageous sensor"* which can be used in embodiments of the invention, i.e. that may be received into a recess in a bottom surface exterior of the enclosure of the sensor electronics. It is mentioned that "*potting 2810 (e.g. UV potting)* [is] *used to seal the electrical contacts"*.

75. From all of this, it is clear to the skilled person that there is a need for sealing of the contacts for the reasons set out in the original application. As to the specific method of sealing, the original application does not provide any particular guidance in terms of specific advantages or disadvantages of the various methods of sealing, neither in general, nor in relation to specific configurations of the sensor assembly. In particular, there is no described advantage or function of the use of elastomeric or plastic material, other than that it provides sealing. The skilled person understands therefrom that the exact method of sealing does not contribute to, and is thus not relevant for, the technical teaching of the invention as disclosed in the original application. In other words, the skilled person would not consider the use of elastomeric sealing necessary for achieving the overall aim and effect of the invention.

76. Likewise, the original application provides various detailed examples of how the sensor assembly and the electronics assembly may be configured. However, in view of the object of the invention – which he understands from the original application to be to provide for an on-body device, which is meant to form part of an applicator system configured to handle insertion of an *in vivo* analyte monitoring system, which is easy-to-use, reliable and minimizes both user inconvenience and pain (par. [0005] – [0012], see par. 20 – 25 above) and, as follows from the advantage mentioned in par. [(0022)/0079] (cited in par. 36 above), configured such that it allows the applicator containing the on-body-device to be moved freely over the skin to find the right position before the on-body device is subsequently adhered to the skin in a single step – the skilled person would not consider the exact configuration of the assemblies to be relevant for the invention, as long as a configuration of the on-body device is chosen that allows this objective to be achieved.

77. Nothing else follows from par. [(0068)/0125] (see par. 28 above), which makes the skilled person aware of the importance of sealing the contacts and that the sensor assembly configuration depends on the method used to seal the contacts. It merely stresses the need for sealing as such and that the assembly configuration must match (be suitable for) the method of sealing that is chosen, and vice versa, without prescribing any specific method of sealing or configuration or combination thereof.

78. Sibionics has not substantiated why the skilled person would consider the method of sealing for the embodiments that Abbott relies on as a basis for claim 1, as the only possible match. To the contrary, in view of the disclosure as stated above, in particular the various ways of sealing mentioned in the original application, without any specific connection to any specific configuration, the skilled person does not discern a functional or structural relationship between the use of an elastomeric seal and the other features of these embodiments. Failing an inextricable link with the features of these embodiments, not including the use of elastomeric sealing in claim 1 cannot be considered as an intermediate generalization.

79. For all of these reasons, the Court of Appeal is of the opinion that the skilled person would derive directly and unambiguously from the original application, that an embodiment with the configuration of fig. 34A – 34D, fig. 36 – 38 and fig. 47A – 47C – or any other embodiment configured as prescribed by claim 1 – but using another manner of sealing than the use of elastomeric or elastic material, would still be covered by the disclosure of the original application as filed.

80. In view of this understanding of the original application, the subject-matter of claim 1 does not extend beyond the content of the original application due to the omission of the use of an elastomeric or elastic sealing member, as argued by Sibionics.

Omission of a sharp

81. Sibionics' further argument, that claim 1 contains added matter for failure to comprise a sharp, fails as well. For the reasons set out above, the skilled person understands from the original application that the on-body device of the invention disclosed in the original application is to form part of and be used in an applicator system configured to handle insertion of an *in vivo* analyte monitoring system. He understands from the original application, e.g. par. [0005] of the background section (see par. 20 above) and par. [0009] of the summary, which states "*such a monitoring system includes (…) and an insertion sharp"* and that refers for "*Exemplary form-factors or configurations (e.g. for associated use with an insertion sharp)"* to several patent publications, that by necessity such applicator system, more in particular the sensor assembly of the on-body device, contains a sharp in order to position the sensor under the skin, but that the details of the sharp and its configuration as part of the sensor assembly are not relevant to the invention. This already follows from the original clause 32 (see par. 57 above) where the sensor assembly is only "*preferably further comprising a sharp supporting the sensor*".

82. The fact that a sharp is not explicitly comprised in claim 1 does not lead the skilled person to think a sensor could be positioned under the skin without one; rather the skilled person understands from the functional language of feature 1.1.2 (*a distal tail section comprising a distal portion (3302) of the glucose sensor (3300, 4704) configured to be positioned under a skin surface and in contact with a bodily fluid of a subject*) read in context of the description, that a sharp – however configured – shall be used to position the sensor under the skin. Sibionics acknowledges this in its Objection (p. 13) lodged in the proceedings at first instance, where under the heading of 'The teaching of claim 1' it says in relation to feature 1.1.2: "*Technically, this features [sic] ensures that the glucose sensor is in contact with a bodily fluid of a subject. This is achieved by providing a distal portion of the glucose sensor configured to be positioned under a skin surface of a subject. For that*

purpose a sharp can be used (the Patent, [0093])".

83. It follows that the fact that claim 1 does not explicitly require a sharp does not extend the subject-matter of claim 1 beyond the disclosure of the original application.

Omission of enclosure 'surrounding' the sensor electronics; omission of 'shell' and 'mounting'

84. The Court of Appeal also rejects Sibionics' argument that the claim contains added matter for not requiring that the enclosure *surrounds* the sensor electronics. Other than as argued by Sibionics, the Court of Appeal fails to see, and Sibionics has not substantiated, why the skilled person would understand this to be substantially different from 'the sensor electronics are *positioned within the enclosure*' as required by claim 1.

85. Sibionics also without success complains that "the technical expressions 'shell' (in the sense of surrounding component) and 'mounting' (in the sense of fixation) exhibit technical content which has been left out from the wording of claim 1". Claim 1 specifies an enclosure comprising a top shell and a base portion configured to be adhered to the skin surface of the subject by an adhesive patch. Both a surrounding component and fixation are thus part of claim 1.

Omission of the on-body device is 'arrangeable in position by way of the apparatus'

86. Sibionics argues that not including the language from clause 32 "arrangeable in position by way of the apparatus according to any of the preceding clauses" in claim 1 constitutes added matter, because this omission would entail technical content, i.e. an interrelation between the on-body device and its positioning means, so Sibionics argues. This argument fails. For the skilled person it is clear that the features of the claim result in an on-body device that may be brought into position by moving the applicator over the skin before the on-body device is adhered thereto. The cited language from clause 32 is therewith implicit in claim 1 and the Court of Appeal fails to see, and Sibionics has not further substantiated, what information has been added.

Omission of recess in combination with a sealing member including electrical contacts.

87. Sibionics' last added matter argument is that in fig. 36 – 38 and fig. 47A – 47C of the original application (see par. 32 and 33 above) the recess is disclosed in combination with a sealing member *including electrical contacts*, while the electrical contacts are missing from claim 1. Sibionics has not explained why this omission would convey new information to the skilled person. The Court of Appeal fails to see it does. In view of the description the skilled person understands that the whole purpose of mating the sensor assembly with the electronics assembly as prescribed in claim 1 is to connect the electrical contacts of both assemblies. This allows that the information collected by the sensor is received by a monitoring device, which is the purpose of the in-vivo analyte monitory system in the first place. The skilled person will not assume it could function without electrical contacts. Omitting them from the claim language thus does not convey new information to the skilled person and does not constitute added matter.

88. To conclude, the Court of Appeal rejects all added matter arguments brought forward by Sibionics.

Auxiliary requests

89. As the Court of Appeal is of the opinion that it is not more likely than not that it will be held that claim 1 of the patent at issue contains added matter, there is no need to decide whether the auxiliary requests lodged by Abbot in these preliminary injunction proceedings for the first time on appeal are admissible.

Novelty

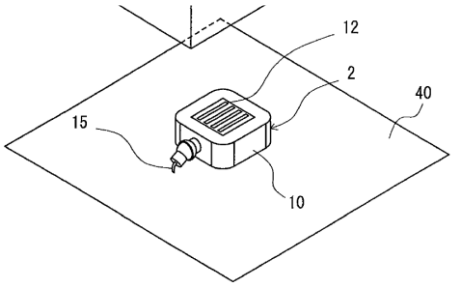
90. Sibionics argues that the patent lacks novelty over the prior art documents WO 2011/077893 A1 (WO893) and CA 2 785 009 A1 (CA009) with the same content in English (both also referred to as D3) and US 2008/0255440 A1 (US440, also referred to as D1).

91. The Court of Appeal is not convinced that it is more likely than not that the patent is invalid for lack of novelty. This will be explained below.

WO893 / CA009 – D3

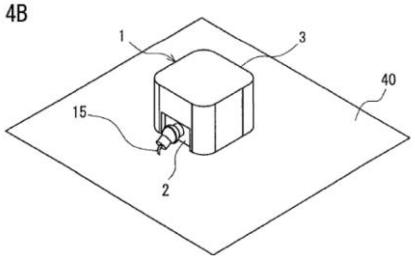
92. As a first novelty attack Sibionics refers to WO893 and CA009. Hereafter reference shall be made to CA009.

93. CA009 discloses a measuring apparatus 1, provided with a sensor unit 2 as shown in fig. 4A (shown insofar as relevant):

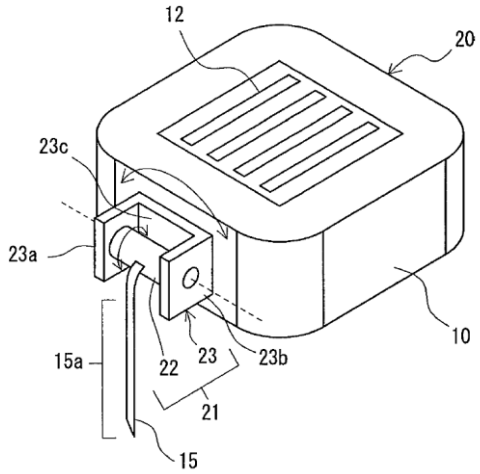


And a control unit 3, shown in fig. 4B:

FIG. 4B



and the more detailed fig. 6 showing the sensor unit:



94. Paragraphs [0034] to [0037] of CA009 read as follows:

[0034] The sensor unit 2 is provided with a base 10, a variable mechanism 11, and a sensor 15. Of these, the sensor 15 is placed partially under the skin, in order to execute CGM (see FIG. 4A and FIG. 4B discussed below). The sensor unit 2 will also function as a sensor placement apparatus for placing the sensor 15. Also, the sensor 15 generates a signal according to the state of a substance in interstitial fluid or blood.

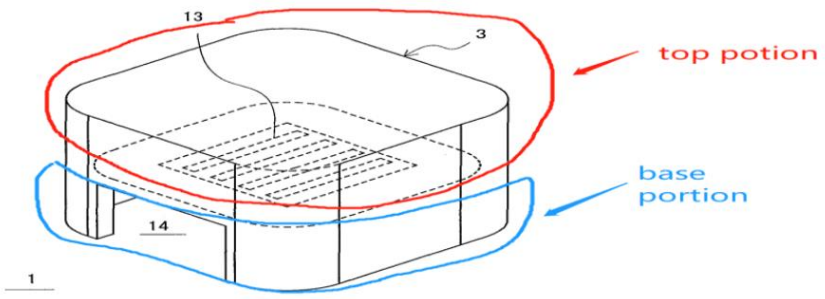
[0035] The base 10 is disposed on the skin of the patient who is being measured and holds the sensor 15. The variable mechanism 11 is attached to the base 10, and interposes between the base 10 and the sensor 15. Also, the variable mechanism 11 enables at least one of a position and an orientation of the sensor 15 to be changed based on the base 10. Note that the position and the orientation of the sensor 15 based on the base 10 denotes the relative position and relative orientation of the sensor to the base.

[0036] The control unit 3 receives the signal generated by the sensor 15 via an external terminal 12, and executes processing based on the received signal. Also, the control unit 3 is formed so as to be attachable to the base 10.

[0037] In the present Embodiment 1, the sensor 15 is thus held by the base 10 via the variable mechanism 11. Therefore, even if the control unit 3 is attached in a state where the sensor 15 is partially embedded and the base 10 moves at that time, the external force generated thereby is absorbed by the variable mechanism 11, preventing the sensor 15 itself from moving.

95. Sibionics argues that the sensor unit 2 is the glucose sensor assembly of feature 1.1, that base 10 is the connector support which, together with the variable mechanism 11 and the sensor 15, constitute the proximal section. Features 1.2, requiring "an enclosure comprising a top portion 5002; and a base portion 5004 configured to be adhered to the skin surface of the subject by an adhesive patch (3802, 5104)", would according to Sibionics be disclosed in fig. 1 as follows:

FIG. 1



whereby the "top portion and a base portion are mere arbitrary divisions of the component [the control unit 3) into two portions" and whereby it would be sufficient that the base portion is suitable for being adhered to the skin surface by using a patch.

96. As Abbott rightly points out, feature 1.2 of claim 1 is not clearly and unambiguously disclosed by control unit 3 in CA009, as Sibionics contends. The skilled person will understand from [0035] and [0036] of CA009 that it is the base 10 of the sensor unit 2, which clearly has a large surface in the horizontal plane on the bottom side of base 10, that is adhered to the skin surface ("disposed on the skin of the patient"). This is also clear from par. [0055] – [0056] of CA009 setting out how the sensor is placed onto the skin:

[0055] First, as shown in FIG. 3A, the sensor unit 2 to which the sensor 15 is attached is set in an implanting device 41. The implanting device 41 is disposed on the patient's skin 40. The implanting device 41 is provided with the function of driving out the sensor unit 2 and the sensor 15 attached thereto toward the skin 40 together with a puncture needle (not shown), using an elastic body such as a spring.

[0056] Next, as shown in FIG. 3B, the sensor 15 attached to the base 10 is driven out toward the skin 40 by the implanting device 41 together with the puncture needle (not shown). At this time, the base 10 is also simultaneously sent toward the skin 40. The portion 15a at the tip end of the sensor 15 is thereby embedded in the skin 40 together with the puncture needle, and, at the same time, the base 10 is disposed on the skin 40.

97. The control unit 3 is intended to slide over the sensor unit 2. This is described in par. [0064] of CA009:

[0064] Next, the implanting device 41 is removed, as shown in FIG. 4A. The control unit 3 is then attached onto the sensor unit 2 disposed on the skin 40, as shown in FIG. 4B. The external terminal 12 provided in the base 10 and the terminal 13 of the control unit 3 (see FIG. 1) are thereby electrically connected, enabling measurement by the sensor 15. At this time, even if external force is exerted on the base 10, the external force is absorbed by the variable mechanism 11, making it extremely unlikely that the sensor 15 will move inadvertently.

98. It is clear from fig. 1 that the control unit 3, which is described as "formed so as to be detachable to the base 10" ([0036]), only contains relatively thin walls intended to slide over base 10. There is no clear disclosure that the bottom side thereof actually contacts the skin. Contrary to Sibionics' suggestion, this is not apparent from fig. 4B. Even if there were such a disclosure, there is no disclosure that these walls are designed to be adhered to the skin. There is no indication that the surrounding walls have a flat surface underneath, as Sibionics contends. The skilled person would not think that the relatively small area underneath the walls of the control unit would be suitable to be adhered to the skin surface by an adhesive patch, as required by feature 1.2.2, especially considering that the invention is to solve the technical problem underlying CA009, that the on-body device is subject to mechanical stress due to physical activity when the patient is wearing the sensor, as Sibionics submits (p. 48 Objection). Rather, in view of the disclosure with respect to sensor unit 2 and base 10 thereof, as set out above, in particular "the control unit 3 is then attached onto the sensor unit 2 disposed on the skin" in par. [0064], he would consider that this function is performed by base 10 of the sensor unit 2, prior to unit 3 being attached thereto. This reading is also reinforced by the fact that the senor unit 2 is meant to be disposable, while the control unit is intended for re-use.

99. Feature 1.2.2, requiring that the base portion of the enclosure – and not the sensor assembly – fulfills the function of being adhered to the skin, this feature is missing.

100. As the skilled person understands base 10 to fulfil the function of being suitable to be adhered to the skin, there is no disclosure of a connector support as a distinct feature, as required by claim 1, according to which the function of being suitable to be adhered to the skin and the function of connector support are fulfilled by distinct features, each being an element of a different assembly. Further, as the control unit 3 of CA009 cannot be seen as a base portion configured to be adhered to the skin surface, it consequently cannot not be seen as the base portion of feature 1.4 referring to the same base portion. The sensor unit 2 of CA009 lacks a recess in its bottom exterior surface. Features 1.1.1, 1.4, 1.5 and 1.6 can therefore not be considered to be disclosed in CA009 either.

101. The Court of Appeal concludes that it is more likely than not that CA009 (D3) is not a novelty destroying prior art publication.

US440 (D1)

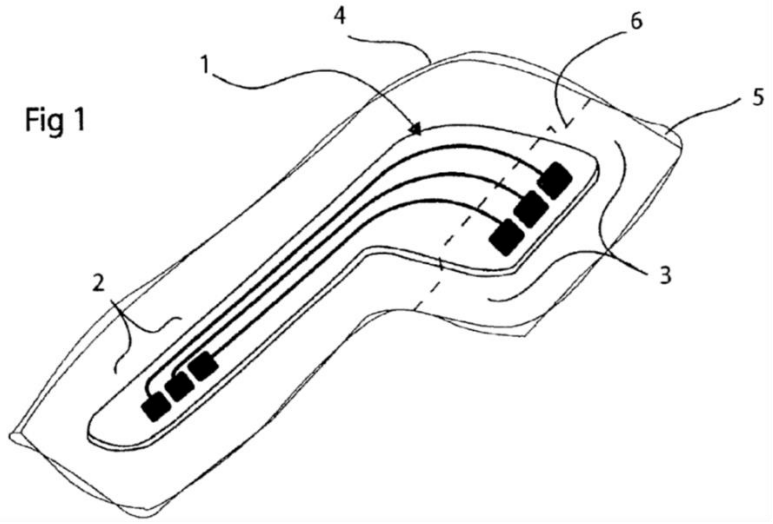
102. The novelty attack based on US440 is also more likely to fail than not to fail.

103. US440, with the title 'Method of forming sterilized sensor package and a sterilized sensor package' relates to a method of sterilising an electrochemical sensor comprising an electrode area and an electric contact area, in particular to sterilisation of integrated sensor assemblies employing transcutaneous electrochemical sensors suitable for in vivo measurement of metabolites (par. [0001]).

104. It discusses the problem of sterilization of sensor assemblies, which comprise parts for which radiation is the only viable strategy, as well as parts that are sensitive to radiation sterilisation. It is the object of the invention to provide a method that, on the one hand, facilitates sterilisation of a disposable assembly comprising sensor and electronics and, on the other, increases the handling reliability of disposable sensors to be coupled to multiple-use electronics by the users themselves. This object is accomplished in that at least the electrode area is enclosed in a shielding packaging that is impermeable to micro-organisms, in such a manner that the electric contact area extends outside the shielding packaging; and that the part of the sensor which is situated outside the shielding packaging is sterilised (par. [0009] – [0014]).

105. US440 discloses various types of sensor packages. Fig. 1 of US440 (see below) shows a sensor 1, including an electrode area 2 and electric coupling areas 3. The sensor 1 is sterile when supplied and is therefore shielded from the surroundings by means of a housing or a bag of a material which is sealed hermetically at least against micro-organisms. In fig. 1, two shielded bags are shown, viz a so-called base packaging 4 and a supplementary packaging 5. The base packaging 4 is closely connected to the sensor 1 along the broken line 6, both on its top face and on its bottom face, thus readily enabling coupling of an electronic unit to the electric coupling areas 3, while simultaneously the remainder of the sensor—in particular the part that is to be implanted in the body—continues to be sterile (par. [0036]). Par. [0040] states that the advantages of the invention rely on the fact that the sensor area is sterilised and separated from the electric coupling area of the sensor by means of a shielding packaging or housing that protects the electrodes of the sensor by being destroyed when the electronics are sterilized or when the user is to mount his multiple-use electronics.

Fig 1

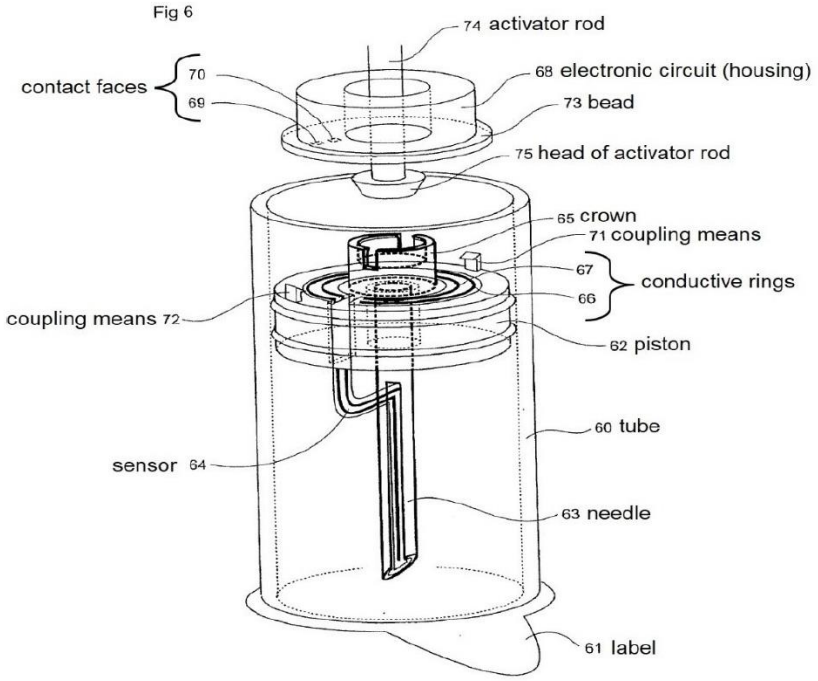


106. The sensor may alternatively be packaged in a tube. This is described in par. [0028] and [0029]:

[0028] By a further embodiment which is suitable both for producing sensor assemblies and for being used by a user in combination with multiple-use electronics, the base packaging comprises a tube which is closed at the one end and the other end of which is configured for receiving a part of the sensor which is configured as a piston. The piston can slide in the tube and does not at least in its initial position allow micro-organisms to enter the tube. This embodiment accomplish a very simple sterile packaging, while simultaneously the use enables many other advantages—see below.

[0029] The tube can be closed by a tear-off label, and the piston may serve as support for a sensor either configured as a needle or in any other manner configured for inserting a flexible sensor. In this manner embodiments are enabled that are, from a production point of view, very similar to each other and wherein the one is suitable for further (subsequent) production-line mounting, whereas the other is suitable for being mounted by a user.

107. Fig. 6 (with some of the references added by Sibionics, see p. 36 Objection) shows such an embodiment of US440.



108. This embodiment is described in par. [0052] to [0054]:

[0052] By this embodiment the shielding consists of a tube **60** being at the bottom closed by means of a tear-off label **61** and at the top being able to receive a piston **62** provided with O-rings, whereby it ensures sealing in a micro-organism-impermeable manner to the interior side of the tube **60**, while

simultaneously the piston **62** is displaceable within the tube **60**. The piston **62** constitutes a part of the sensor which is, in FIGS. **6** and **7**, of the flexible type, ie wherein a slit needle **63** or some other means of insertion is provided for introducing the sensor **64**. The needle is slit only for some length for receiving the electrode area of the sensor and is otherwise solid or the like to pass by the piston **62** in a sealing manner that does not allow passage of micro-organisms; and on the other side of the piston the needle **63** is secured to an activator crown. By this embodiment it is very easy to ensure micro-organism-impermeable closure around the needle, since—compared to the embodiments described earlier—the sensor is conveyed around the needle and through piston, where the electric contact areas are situated in the form of conductive, concentric rings **66**, **67**.

[0053] The reference numeral **68** designates a housing for an electronic circuit and having has contact faces **69**, **70**, whose radial distances match those of the conductive rings **66**, **67**, whereby the electronic circuit **68** can be arranged in any rotational position in relation to the piston **62**. The piston is provided with coupling means **71**, **72** for cooperating with a bead **73** on the housing, and centrally both parts feature a cut-out for receiving an activator rod **74** with coupling head **75**.

[0054] When the sensor shown in FIG. **6** is used in connection with multiple-use electronics **68**, the circuit **68** may first be conveyed down into the tube **60**, and by coupling of the head **75** to the crown **65** it is possible to hold back the piston, while the circuit **68** is pressed down to the effect that the bead **73** cooperates with the coupling means **71** and **72**. Then the label **61** is pulled off and by means of the rod **74** the needle with sensor is pressed into the body. By holding on to the rod **74**, the tube **60** can be withdrawn and finally the needle **63** can be withdrawn by means of the rod **74**.

109. According to Sibionics, the sensor 64 of fig. 6 is also shown as sensor 1 in fig. 1. The Court of Appeal does not agree. The skilled person will understand from the description that fig. 1 and 6 show distinct embodiments of the invention disclosed in US440. These can therefore not be combined. This is also clear from par. [0052] which describes the embodiment of fig. 6 and states that the piston constitutes part of the sensor and that the piston contains the electric contact areas in the form of the conductive rings. A piston is clearly absent in the embodiment of fig. 1. Nothing else follows from the fact that both sensors are of the flexible type, as Sibionics noted, since there is nothing to indicate that choice of material determines configuration. Neither is relevant that par. [0056] mentions that it is possible to apply a further shielding packaging around the sensor assembly as explained in the context of fig. 1. Therewith, reference is clearly made to the packaging shown in fig. 1, not to the sensor configuration.

110. Sibionics has not explained and it is also not apparent where the connector support coupled with a proximal portion of the glucose sensor of the embodiment of fig. 6 is disclosed. Feature 1.1.1 is thus not disclosed.

111. Sibionics further argues that electronic circuit housing 68 forms the top portion of the enclosure and that piston 62 forms the base portion of the enclosure. That cannot be accepted. The piston is clearly described as part of the sensor and therewith part of the glucose sensor assembly of feature 1.1. Even if parts of the

sensor assembly are attachable / detachable, as Sibionics argues, the piston cannot (also) be the base portion of the enclosure as required by feature 1.2.2. If anything, the skilled person will consider the electronic housing 68 to be the enclosure, but the base portion thereof is not meant to be adhered to the skin, but shall be coupled to the piston as described in par. [0053]. The Court of Appeal agrees with Sibionics that the piston is to be adhered to the skin, but therewith feature 1.2.2. which requires the base portion of the enclosure to be adhere to the skin is not disclosed.

112. This also means that feature 1.4, which requires that the base portion of the enclosure comprises a recess in a bottom exterior surface, the recess comprising a distal-facing opening, is also not disclosed. By consequence, features 1.5 and 1.6 are also lacking.

113. The Court of Appeal concludes that it is more likely than not that US440 (D1) is not a novelty destroying prior art publication.

Inventive step

114. Sibionics contends that the patent is not inventive over the prior art document D3 in combination with any one of D1, WO 2011/119896 (WO 896 or D2), EP 2 236 077 A1 (EP077 or D4), US 2004/0002682 A1 (US 682 or D6), or US 2011/0021889 A1 (US889 or D7). Alternatively, Sibionics argues that the patent lacks inventive step if WO896 (D2) would be taken as a starting point and combined with US440 (D1).

115. The Court of Appeal is also not convinced that it is more likely than not that the patent is invalid for lack of inventive step.

116. As Abbott rightly pointed out, the invention seeks to provide an applicator system that is easy-to-use, reliable and minimizes both user inconvenience and pain. The solution is found in a configuration as prescribed by claim 1. According to claim 1, in particular features 1.4 to 1.6, the separate sensor and electronics assemblies are coupled by receiving the sensor assembly into the distal-facing opening of a recess in the bottom surface of the base portion of the enclosure, thus from beneath. This process may take place within the applicator, with the enclosure already sitting in the applicator before the sensor assembly is received, and allows that the applicator can still be moved freely over the skin before the on-body device is subsequently adhered to the skin in a single step.

117. The inventive concept is thus that the on-body device is configured in a way that it allows an application operation whereby the on-body device is adhered to the skin of the patient in a single action.

CA009 (D3) as a starting point

118. The argumentation of Sibionics based on CA009 as the starting point, assumes the omission of feature 1.2.2. However, as considered above, base 10 of sensor unit 2 must be considered to be the base portion of the enclosure according to feature 1.2.2. of claim 1 of the patent. Consequently, CA009 does not disclose features 1.1.1, 1.4, 1.5 and 1.6.

119. In CA009 the on-body device is adhered to the skin in two steps. As is clear from e.g. par. [0064], first the sensor unit 2 is applied to the skin. Then the applicator is removed. Only thereafter the control unit 3 is attached onto the sensor unit 2 disposed on the skin.

WO893 / CA009 (D3) in combination with US440 (D1)

120. From the above considerations in relation to novelty, it is clear that the exact same features that are missing from CA009 are also missing from US440. Sibionics has not substantiated and it is not otherwise apparent why (which pointers) and how the skilled person, even if combining CA009 with US440, would arrive at claim 1 of the patent, without using inventive skills.

WO893 / CA009 (D3) in combination with WO896 (D2)

121. The obviousness argument based on this combination is based on the embodiments shown in fig. 150 – 158 of WO896. In these embodiments the sensor assembly with the connector support (sensor hub 4022) is coupled with the enclosure (housing unit 4020) through an opening in the upper portion of the enclosure. As such, WO896 does not disclose features 1.4 and 1.5 which are also missing from CA009.

122. Moreover, as is clear from fig. 152 and 153 shown below, in these embodiments the sensor assembly is contained in the applicator. The enclosure 4020 is already adhered to the skin before it receives the sensor assembly 4022 in the top portion. This configuration makes it impossible to receive the sensor assembly from

beneath in a recess in the base portion of the enclosure. Also, due to this configuration, the application of the on-body device to the skin is necessarily a two-step process.

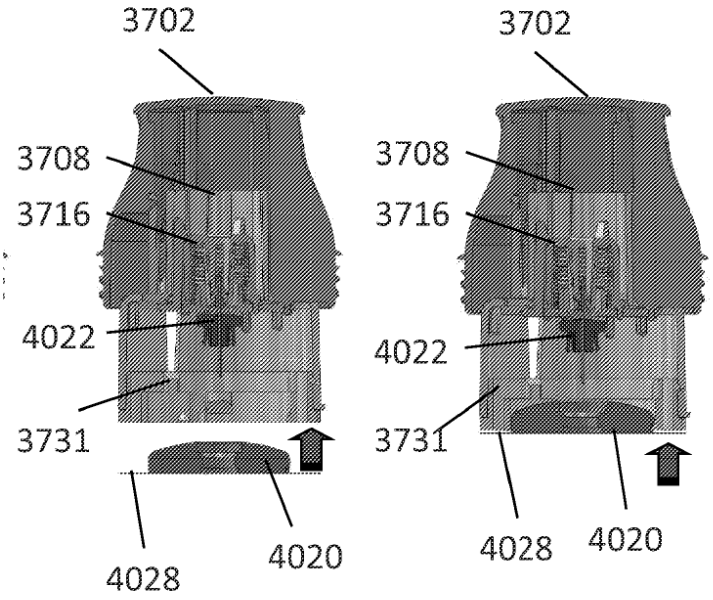


FIG. 152

FIG. 153

123. Taking this into account, Sibionics failed to explain why (which pointers) and how the skilled person, without taking any inventive steps, starting from CA009 and combining with WO896, would arrive at the solution of claim 1 resulting in the possibility of a one-step application of the on-body device to the skin.

WO893 / CA009 (D3) in combination with EP077 (D4)

124. Fig. 2 of EP077 depicted below, shows a cross-sectional view of an embodiment of an analyte concentration measurement system according to the invention with body access unit and processing unit separated.

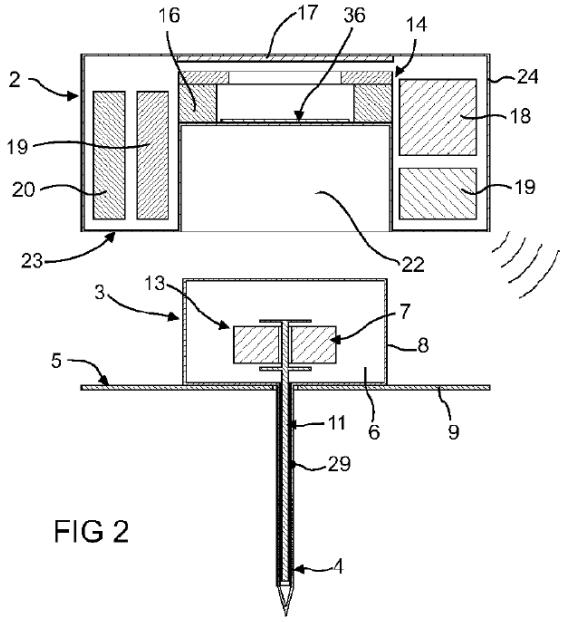


FIG 2

125. Paragraph [0064] of the description reads:

> **[0064]** The functional connection between the processing unit 2 and the body access unit 3 is preferably achieved by magnetic or electromagnetic fields to avoid a direct electrical connection between the two units.

126. In view thereof, Abbott rightly pointed out that EP077 does not disclose feature 1.6, which requires the glucose sensor to be electrically coupled by mating the electrical contacts of the sensor electronics and the connector support. Since feature 1.6 is also missing from CA009, it cannot, without further substantiation, which lacks, be accepted that it would be obvious for the skilled person, if combining these documents, to arrive at the solution of claim 1 of the patent.

127. The Court of Appeal is also of the opinion that Abbott is right in saying that EP077 discloses such a different way of measuring, that the skilled person would have no incentive to combine it with CA009, which Sibionics did not sufficiently contest.

WO893 / CA009 (D3) in combination with US682 (D6)

128. US682 relates generally to an insertion device for automatic placement of an insertion set through the skin of a patient, and in particular embodiments to a compact and easily operated insertion device for placement of an insertion needle of a subcutaneous insertion set or the like through the skin of a patient with a controlled force and insertion speed by the patient (par. [0002]).

129. US682 does not disclose feature 1.6 either, as Abbott noted and Sibionics subsequently did not dispute. Thus, it cannot, without further substantiation, which lacks, be accepted that it would be obvious for the skilled person, if combining these documents, to arrive at the solution of claim 1 of the patent.

WO893 / CA009 (D3) in combination with US889 (D7)

130. US889 discloses a continuous analyte measurement system. As is clear from fig. 10A-10F, shown below, the base 904 (enclosure) is first attached to the skin and subsequently the sensor assembly is inserted in and through that base into the skin. Features 1.4 to 1.6 are missing. If there is a recess to receive the sensor assembly, it is not situated in a bottom exterior surface of the base portion of the enclosure and the connector support of the sensor assembly is not received through a distal facing opening (but instead a proximal facing opening). Since features 1.4 to 1.6 are also missing from CA009, it is not apparent, and Sibionics failed to substantiate, that it would be obvious for the skilled person, if combining these documents, to arrive at the solution of claim 1 of the patent.

WO896 (D2) as a starting point, in combination with US440 (D1) or CA009

131. As explained above, in the embodiments disclosed in fig. 150-158 of WO896 that Sibionics relies on, the enclosure is already adhered to the skin of the patient before the sensor assembly is coupled therewith from above.

132. It follows from the considerations above relating to US440 that, like WO896, this document also lacks disclosure of features 1.4 to 1.6. As such, failing a sufficient substantiation, identifying a pointer in that direction, the Court of Appeal cannot see that a skilled person starting from WO896 and considering US440, would without inventive efforts arrive at the solution of claim 1, that allows the application of the on-body device in a single step.

133. The same applies to the combination of WO896 with CA009, which also does not disclose features 1.4 to 1.6.

<u>Conclusion on validity; dependent claims</u>

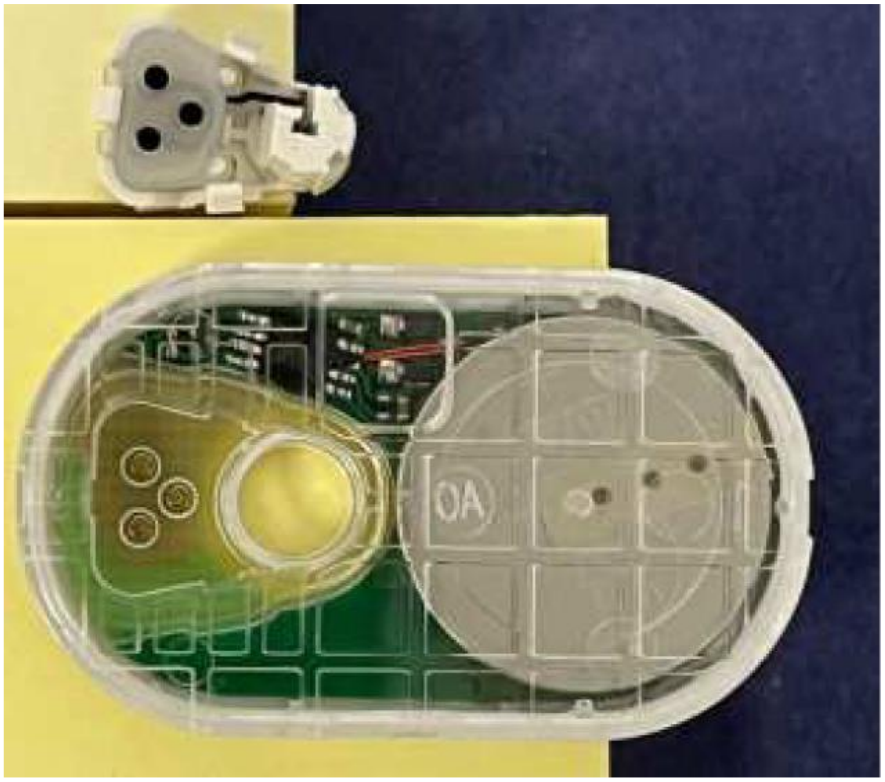
134. As the Court of Appeal on the balance of probabilities considers it not more likely than not that claim 1 of the patent will be held invalid, there is no need to consider the validity of any of the dependent claims.

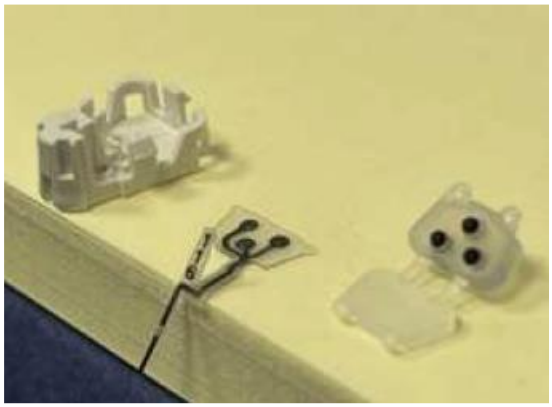
<u>Infringement</u>

135. The sibionicsshop.com website where Sibionics offered its GS1 CGM product for sale was undisputedly also directed to consumers in the European market, including UPC territory. The website could be set to English, Bulgarian, Danish, French, Italian, Swedish, German and Dutch language and mentions “Available at all European Countries”. For sales in Germany, Italy and The Netherlands, GS1 devices were also offered via Amazon websites, with respondent 1 being the seller. Respondent 2 is mentioned as the EU importer of the

GS1 product at the bottom of the last page of the GS1 App User Guide and the final page of the GS1 Product Insert. It is also named as EU importer of the EU Medical Devices database EUDAMED.

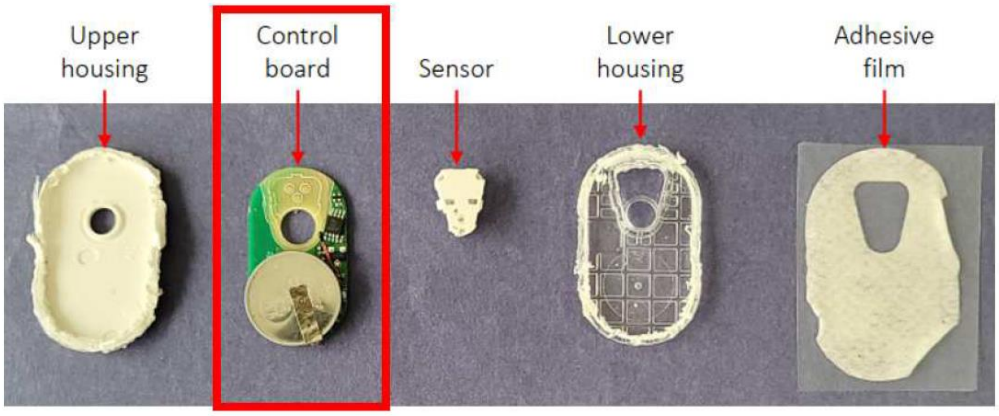
136. The pictures below show the distal-facing view of the on-body device (without adhesive layer) with the sensor assembly removed and the disassembled sensor assembly, with the separate connector at the far right.





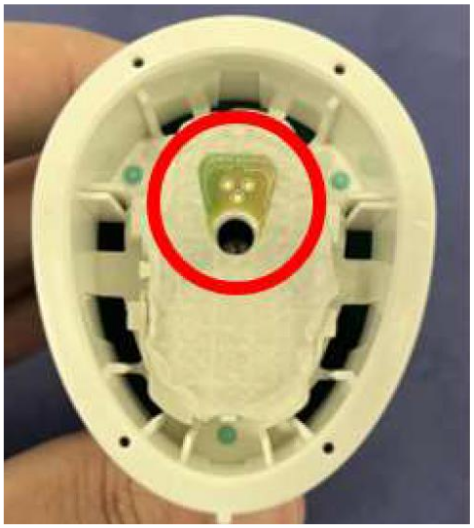
137. The X-ray image below shows the on-body device with the sharp held in the applicator prior to deployment.

138. Below is a picture of the separate components of the enclosure of the GS1 CGM product.



139. Contrary to the opinion of Sibioncis, features 1.1.1 and 1.6 are realised even if the attacked embodiment contains a separate connector, as already explained above (par. 40-42).

140. Insofar as Sibionics argues that the embodiment of fig. 34A -34 D of the description of the patent at issue does not disclose a recess, then it would only mean that Sibionics' product is not similar to the embodiment of fig. 34A – 34D. That doesn't prevent it from being an infringing product. It is not contested and it is also clear from the evidence provided by Abbott that Sibionics' GS1 CGM product has a recess in the bottom exterior surface of the base portion of the enclosure as required by claim 1. This is shown in the above picture of the separate components of the enclosure and in the picture below of the applicator, holding the enclosure, which clearly shows the distal facing opening of the recess. It is not contested that the remaining features of claim 1 are also embodied by the GS1 CGM product.



141. It follows that the Court of Appeal is of the opinion that on the balance of probabilities it is more likely than not that Sibionics' GS1 CGM product infringes claim 1 the patent.

142. Sibionics argues that there is a discrepancy between the request and grounds of application in that Abbott requests a general injunction, whereas in its Application it does not allege infringement by making the attacked embodiment, but only by offering, placing on the market, importing and/or storing the attacked embodiment. In relation to Respondent under 2 only importing of infringing products is alleged, so Sibionics states. Insofar as Sibionics argues that a general injunction can only be issued if Abbott shows that Sibionics infringes or threatens to infringe the patent in all possible ways (including producing infringing products), this must be rejected. Abbott has sufficiently substantiated that Respondent under 1 has offered infringing products and placed them on the market within the UPC territory. The imminent threat of importing the GS1 CGM product by respondent 2 is clear from its position as an importer for the EU territory. This suffices as a basis for a general preliminary injunction, which includes all possible ways of infringing.

Urgent interest

143. 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 also that it is more likely than not that the patent is infringed. Sibionics argues that an injunction should nevertheless not follow, as Abbott has not been sufficiently expedient in filing its Application.

144. According to Sibionics, Abbott's Application lacks urgency, because Abbott was already aware of the attacked embodiment when it was presented at the fair trades EASD in October 2023 in Hamburg and Medica in November 2023, which Abbott attended.

145. This argument is rejected. As Sibionics itself noted during the oral hearing, it would have required that Abbott signed a non-disclosure agreement in order for it to be shown Sibionics' product at these trade fairs. It goes without saying that it cannot be expected that Abbott had done so, since the purpose of obtaining the product was to prepare and possibly start legal proceedings, which the NDA would possibly have made it impossible to do. In addition, the assembled product would not have given Abbott sufficient information on its exact configuration required to assess whether it should be considered to be infringing, as Sibionics admits.

146. Abbott brings forward that it ordered GS1 products once available on the Website during Sibionics' pre-sale campaign and received samples and phones with the Sibionics app on 18 and 21 December 2023 and in January 2024. These were sent for inspection to third party providers in California, USA. Due to the holiday season, inspection began on 15 January 2024 and was completed on 14 February 2024. Inspection included not only disassembly and traditional photography, but also functionality checks as well as X-rays to identify the internal structures and workings of the commercial CE marked GS1 Device. The Application was subsequently filed on 20 March 2024.

147. Sibionics does not dispute this, but asserts that Abbott unreasonably delayed filing the Application, as it was not necessary for Abbott to have X-ray images made there and send the product to the US for that purpose. Abbott points out that the housing of the GS1 device is not transparent and that X-ray images are relied on to show the internal components, also in view of infringement of dependent claims, and their operation in use. Shipping to the US did not cost more time and overall saved time as in California the required expertise was present, which would not have been the case in any of Abbott's European locations, so Abbott contends.

148. Abbott also points out that it has asserted various patents against Sibionics, both before the UPC as well as national courts, which seven actions in total had to be coordinated, thus requiring more time than the filing of just one action.

149. Even though the Court of Appeal agrees that in hindsight the X-rays do not contribute much to the evidence of infringement of claim 1, this can only be concluded in hindsight and Abbott cannot reasonably be denied an injunction for being cautious not to accuse Sibionics of infringing acts prior to having done a thorough investigation by an independent third party, whereby in view of possible validity attacks it also anticipated the possibility that it might have to rely on more limited dependent claims,.

150. It cannot be concluded from the line of events together with Abbott's explanation that Abbott 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.

Weighing of interests

151. The Court of Appeal is convinced that Abbott has an (urgent) interest that Sibionics is injuncted from bringing its infringing products on the market.

152. The Parties are competitors in the field of Continuous Glucose Monitoring ("CGM") techniques. Abbott has been a developer, manufacturer and marketer of continuous glucose monitoring ("CGM") devices since 2007. Its 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. According to Abbott, this technology utilizes the invention disclosed in the patent. Abbott is the main supplier of CGM products in the Contracting Member States. In Europe, Abbott serves over 1.3 million patients with its FreeStyle Libre products and has a market share of approximately 80%. Respondent 1 also manufactures CGM systems and it has been marketing a CGM device in China since 2021. And at the end of 2023 it entered

the European market with its GS1 device.

153. Sibionics is presently active on the so-called 'cash-pay' segment of the CGM market. Although the 'base' price of the GS1 product is comparable, Sibionics offers promotions and discounts that undercut Abbott's market price. These discounts are of a structural repeated nature and incomparable to Abbott's offer of a first free test set. This will lead to a negative price spiral which, especially in this type of market, is very difficult to reverse, thus causing irreparable harm to Abbott.

154. There is also a risk that Sibionics will try to enter the reimbursement segment of the CGM market by participating in tender procedures, offering its product for lower prices, also resulting in price erosion. Since these contracts are entered into for a substantial period of time, typically two years, price recovery will be even more difficult. The Court of Appeal rejects Sibionics argument that there will be no price erosion in the reimbursement segment. Even though it is true that the insurers set the price, they do so, among other factors, also on the basis of prices offered in tender procedures.

155. Sibionics' market entry with infringing products is not something Abbott has to accept as 'just a matter of competition', and 'required to be allowed as a driver for further innovation', as Sibionics contends. Obviously, competing with infringing products cannot be accepted as fair. Being able to prevent that is at the core of the exclusive right a patent offers. Also, further innovation does not justify patent infringement.

156. As Sibionics is based in China with no apparent assets within UPC territory, there is uncertainty whether any damages suffered by Abbott due to the infringing acts could be recovered.

157. The interest of Sibionics to be able to enter and stay on the market during proceedings on the merits do not outweigh the interests of Abbott by an immediate injunction. The damages of Sibionics due to later market entry should the injunction be lifted in proceedings on the merit will be easier to quantify, whereas Abbott's damages due to the long term effect of price erosion is difficult to quantify, also in view of its influence on the price of similar devices marketed by third parties and on the prices set by insurers.

Change of claim; possibility of an injunction in general terms

158. Abbott has requested leave to change the claim in case the Court of Appeal would consider a request to issue an injunction in general terms to be inadmissible. Other than in its separately filed request, in its Statement of appeal Abbott seems to make the request dependent on the situation where an auxiliary request must be relied on. Even if the request is to be considered unrelated to the auxiliary requests, as Abbott suggested at the oral hearing, there is no need to decide on this request. There is no need to rely on an auxiliary request and contrary to Sibionics' argument, Abbott's request for a general injunction is admissible. The need for a limitation of the issued injunction to the specific infringing products cannot be inferred from Art. 62(1) UPCA. The scope of the general injunction requested by Abbott – which always has to be interpreted in the light of the reasoning underlying the order whereby the injunction is issued – is sufficiently clear, and not too broad. There is also no need to decide whether Abbott was allowed to add a request for repayment, since – as will be explained below – this request must be rejected.

Scope of the injunction – Ireland

159. Abbott requested an injunction in relation to Contracting Member States where the patent is in force and also explicitly stated it did not seek an injunction covering the territory of Ireland (par. 5.45 Reply). Insofar as Abbott wishes to extend its claim on appeal to also cover the territory of Ireland, the Court of Appeal disregards this. Such a request could reasonably have been made during the proceedings before the CFI, but Abbott explicitly chose not to do so. In view of the issues it raises as to the jurisdiction of the UPC, since Ireland is not a Contracting Member State (see Order dated 19 August in UPC_CoA_388/2024), there is no justification to allow the request to be extended to Ireland for the first time on appeal. Such justification cannot be found in the fact that the CFI – wrongly – considered Ireland to be a Contracting Member State and issued an injunction covering that territory in another action.

Other requested measures

160. The Court of Appeal rejects Sibionics' argument that the UPC can only issue preliminary measures that are explicitly stated in Art. 62 UPCA and R. 211.1 RoP. In the opinion of the Court of Appeal, Art. 67 UPCA applies to proceedings for provisional measures as well. This is apparent from the use of the term 'applicant' in this Article. If it were exclusively applicable to proceedings on the merits, it would have used the term 'claimant'.

The fact that Art. 67 UPCA refers to 'infringer' rather than 'alleged infringer' as in Art. 62 UPCA, is explained by the fact that Art. 62 UPCA applies solely to provisional measure proceedings, whereas Art. 67 UPCA applies to both proceedings for provisional measures and to proceedings on the merits.

161. A further clear indication that Art. 67 UPCA also applies to provisional measures is to be found in the Rules of procedure. R.211.1 RoP sets out that the Court may 'in particular' order the provisional measures that are mentioned under (a) to (d), thus leaving open the possibilities that other measures may be ordered as well.

162. In addition, R.220.1 RoP, with the heading 'appealable decisions' distinguishes between on the one hand decisions (under (a) and (b)) to which an appeal period of two months applies (R. 224.1(a) RoP) and on the other hand orders (under (c)) to which an appeal period of 15 days applies (R. 224.1(b) RoP). R. 220.1(c) RoP specifically mentions 'orders referred to in (…) Art. 62 or 67 of the Agreement. This is a clear indication that the measures mentioned in Art. 67 UPCA may also be ordered in the framework of provisional measure proceedings, always provided that there is an urgent interest and such measures are proportionate.

163. In view thereof, the Court of Appeal is of the opinion that Abbott has a sufficient and urgent interest to receive the requested information with respect to the origin and distribution channels of GS1 Devices in the Contracting Member States in which the patent is in force (including the full names and addresses of the legal entities that are involved) and the identity of any third party involved in the production or distribution of GS1 Devices in the Contracting Member States in which the patent is in force (including the full names and addresses of the legal entities that are involved). This information will allow Abbott to take appropriate action to prevent any further infringements within UPC territory.

164. Abbott has not sufficiently indicated why it has an urgent interest to obtain the requested information in relation to the price obtained for GS1 Devices in the Contracting Member States in which the patent is in force. This information is primarily relevant in relation to the calculation of damages. Abbott has not substantiated that this information is relevant prior to a decision on the merits being rendered. This request shall therefore be denied.

165. The requested delivery up (R. 212.1 (b) RoP) shall also be ordered, since this also prevents that further infringing products enter the market.

166. The Court of Appeal shall order that penalty payments shall be paid in case of any violation of the orders. The Court considers a penalty payment of EUR 10,000 for each product with which the orders are violated or alternatively, at Abbott's choice, a penalty sum of EUR 100,000.00 for each day, a part of a day counting as an entire day, that the orders are violated, reasonable.

167. Since this order ends the action, the Court of Appeal shall render a cost decision. Sibionics is the unsuccessful party and shall be ordered to pay the costs of the proceedings at first instance. Where the request in relation to Ireland is concerned, there is no reason to decide otherwise for the costs of the first instance proceedings, since – as Sibionics itself states (p. 63 Response) – Ireland has never been the subject-matter of Abbott's Application before the CFI. On appeal, the costs in relation to the request for suspensive effect and Abbott's request to extend the Application to the territory of Ireland shall be borne by Abbott. All other costs of the appeal proceedings shall be borne by Sibionics.

168. In addition, Sibionics shall be ordered to pay an amount of EUR 11,000 as an interim award of costs, equal to the fees paid by Abbott on appeal.

169. The requested repayment of anything paid by Abbott in execution of the impugned order is rejected. Abbott has not substantiated that any payment has actually been made. The Order does not require Abbott to make any payment and the costs of proceedings are to be established in a separate cost proceeding once the proceedings on the merits have come to an end.

Security for enforcement

170. Sibionics' request for a security for enforcement shall be rejected. It has not substantiated why serious difficulties would be expected in connection with the recovery of any possible damages from Abbott, which is a US based listed company with several subsidiaries in Europe and undisputed global sales of US$ 43.7 billion in 2022. Sibionics poses the hypothesis that it might have to file for bankruptcy if the injunction is issued without such a security, however without any substantiation. There is therefore insufficient ground for such an order.

Conclusion

171. It follows from the above that the impugned order must be set aside. The request shall be allowed as set out in the order below.

ORDER

The Court of Appeal:

(a) sets aside the impugned order;

(b) orders Sibionics, individually and jointly to refrain from any infringing acts as set forth in Art. 25(a) UPCA with any product according to claim 1 of the patent at issue (EP 3 831 283), in particular with the GS1 Device in the Contracting Member States in which the patent is in force, namely Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, The Netherlands, and Sweden;

(c) orders Sibionics to provide counsel for Abbott, within 4 weeks after service of this order, with a written statement, substantiated with appropriate documentation of:

(i) the origin and distribution channels of GS1 Devices in the Contracting Member States in which the patent is in force (including the full names and addresses of the legal entities that are involved); and

(ii) the quantities delivered, received or ordered, of GS1 Devices in the Contracting Member States in which the patent is in force; and

(iii) the identity of any third party involved in the production or distribution of GS1 Devices in the Contracting Member States in which the patent is in force (including the full names and addresses of the legal entities that are involved);

(d) orders Sibionics to deliver up to a bailiff appointed by Abbott, at their own expense, any GS1 Device in stock and / or otherwise held, owned or in the direct or indirect possession of Sibionics in the Contracting Member States in which the patent is in force, within one week after service of the order to be rendered in this matter, and to provide counsel for Abbott with proper evidence of the full and timely compliance with this order within 10 days after the delivery up to the bailiff;

(e) orders Sibionics to comply with the orders under (b) – (d) above, subject to a recurring penalty payment of up to EUR 10,000.00 for each violation of, or non-compliance with, the order(s), plus EUR 100,000.00 for each day, or part of a day counting as an entire day, that the violation or non-compliance continues;

(f) orders Sibionics to jointly and severally bear the reasonable and proportionate legal costs and other expenses incurred by Abbott in the proceedings at first instance and on appeal, except for the costs in relation to the request for suspensive effect and Abbott's request in the appeal proceedings to extend the Application to the territory of Ireland, which costs shall be borne by Abbott;

(g) orders Sibionics jointly and severally to pay to Abbott an amount of EUR 11,000.00 as an interim award of costs;

(h) specifies the date as referred to in R. 213 RoP at 31 calendar days after service of this order;

(i) declares the order to be immediately enforceable;

(j) rejects any further requests made by Abbott or Sibionics.

Issued on 14 February 2025

Rian Kalden

Date: 2025.02.14 14:23:58 +01'00'

Rian Kalden, presiding judge and judge-rapporteur

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Date: 2025.02.14 14:42:00 +01'00'

Ingeborg Simonsson, legally qualified judge

Patricia Ursula Rombach

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MARC WILLEM DIRK Van der Burg

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Marc van der Burg, technically qualified judge

Anna Monika Ławrynowicz-Drewek

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The Registry