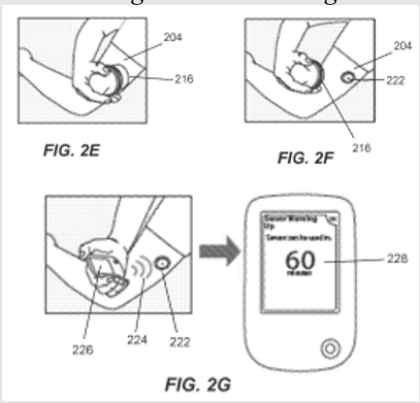
UPC CFI, Local Division The Hague, 19 June 2024, Abbott v Sibio – EP283

Revoked in appeal:
- **IPPT20250214, UPC CoA, Abbott v Sibio**
- **IPPT20240726, UPC CoA, Abbott v Sibio**

continuous glucose monitoring device



PATENT LAW – PROCEDURAL LAW

Preliminary measures denied. No sufficient degree of certainty that patent is valid (Article 62(4) UPCA; Rule 211(2) RoP). Added matter under the so-called "gold standard" disclosure test of the Boards of Appeal of the EPO for added matter (article 138(1)(c) EPC)

International jurisdiction UPC (Article 31 UPCA)
- **After Sibio c.s.' defence, Abbott indicated that it did not mean to include Ireland, so there is no need to decide on competence with regard thereto.**

Sufficient degree of certainty that the patent is valid (Rule 211(2) RoP)
- **is lacking if the court considers it on the balance of probabilities to be more likely than not that the patent is not valid.**
- **the burden of presentation and proof with regard to the facts from which the lack of validity of the patent is derived and other circumstances favourable to the invalidity or revocation lies with the opponent (Art. 54 UPCA).**[*]

The Court applies the so-called "gold standard" disclosure test of the Boards of Appeal of the EPO for added matter (article 138(1)(c) EPC)
- **which is also the standard used in many Contracting Member States of the UPC.**[♦]

Hence, any amendment to the parts of a European patent application or of a European patent relating to the disclosure (the description, claims and drawings) can therefore, irrespective of the context of the amendment made, only be made within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the application(s) as filed.[♣] After the amendment, the skilled person may not be presented with new technical information.

3.5. It is not sufficient if the claimed subject-matter is "obvious" to the skilled person in view of the original application in order to comply with the added matter provision. It is necessary that the claimed subject-matter be directly and unambiguously derivable from the original application (including any information which is implicit for the skilled person), and this is a stricter test.[♠]

3.6. This is a matter of legal certainty for third parties relying on the content of the original application and is necessary to ensure that patent proprietors do not benefit from an unwarranted advantage.[▽]

4. Following from these principles, the original application cannot be treated by the patent proprietor as a reservoir of features, from which he can pick and choose features to assemble them as he wishes to draft new claims. There must be a pointer towards the combination of features selected by the proprietor.[♥]

Claim 1 appears to be the result of an unallowable intermediate generalization,
- **at least relating to the omission of the presence of an elastomeric seal in the recess of the base portion of the enclosure (in feature 1.4).**
- **For intermediate generalization to be considered allowable (in the sense that it does not result in added matter), it should be (clearly) established that there is no structural and functional relationship between the omitted feature and the other features incorporated into the claim.**[ɣ]

Abbott ordered to bear reasonable and proportionate legal costs and other expenses incurred by Defendants in these proceedings, up to the applicable ceiling (Art. 69 UPCA; and R. 118.5 and R. 150.2 RoP);
- **Even if the applicant were to be successful in the proceedings on the merits, it will still have to bear the costs of these proceedings as the unsuccessful party.**
- **The applicant must therefore reimburse the defendant for the costs of the proceedings at first instance. For the purpose of the cost proceedings, the court sets the value of the action at EUR 4,000,000, as proposed by Abbott. Sibio c.s. did not object to this amount.**

Source: **Unified Patent Court**

[*] See **UPC CoA 26 February 2024, 10X and Harvard/Nanostring, UPC_CoA_335/2023 App_576355/2023**, page 2
[♦] See Case Law of the Boards of Appeal (hereinafter also "CLBA"), 10th edition 2022, II.E.1.1 and i.a. **G2/10**
[♣] **G 3/89, OJ 1993, 117**; **G 11/91, OJ 1993, 125**
[♠] CLBA, II.E.1.3.4.a
[▽] CLBA II.E.1.1, **G1/93**
[♥] CLBA, II.E.1.6.1.
[ɣ] CLBA, II.E.1.9.1, especially 4th and 5th paragraphs

UPC Court of First Instance,
Local Division The Hague, 19 June 2024
(Brinkman, Rinkinen, Kokke, Fulconis)
UPC_CFI_131/2024
ACT_14945/2024
Order
of the Court of First Instance of the Unified Patent Court Local Division The Hague
issued on 19/06/2024
concerning: provisional measures in the matter of EP3831283

HEADNOTE:
Application for provisional measures denied. On the balance of probabilities patent will more likely than not be held to be invalid in proceedings on the merits, due to added matter.

KEYWORDS:
provisional measures; validity; added matter
REFERENCE CODE ECLI: Not provided

CLAIMANT
1) Abbott Diabetes Care Inc.
(Applicant) - 1360 South Loop Road - CA 94502 - Alameda - US Represented by Eelco Bergsma

DEFENDANTS
1) Sibio Technology Limited (Defendant) - 6/F., Manulife Place, 348 Kwun Tong Road - - - Kowloon - HK
Represented by Thomas Gniadek
2) Umedwings Netherlands B.V.
(Defendant) - Treubstraat 1 - 2288 EG - Rijswijk - NL
Represented by Thomas Gniadek

PATENT AT ISSUE

Patent no.	Proprietor
EP3831283	Abbott Diabetes Care Inc.

COMPOSITION OF PANEL – FULL PANEL
Presiding judge and judge-rapporteur Edger Brinkman
Legally qualified judge Petri Rinkinen
Legally qualified judge Margot Kokke
Technically qualified judge Renaud Fulconis

LANGUAGE OF PROCEEDINGS: English

SUBJECT-MATTER OF THE PROCEEDINGS
Application for a preliminary injunction and other provisional measures filed on 20 March 2024 (R. 206 Rules of Procedure (RoP)).

FACTS
The facts presented below are mostly based on the application as they were not opposed by the defendants. The patent Applicant (hereinafter also referred to as "Abbott") is the proprietor of European patent number EP 3 831 283[1] ("the patent") with the following claims 1-26:

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).
2. The on-body device of claim 1, wherein the enclosure comprises a single integral unit.
3. The on-body device of claim 2, wherein the top portion (5002) and the base portion (5004) form a single over-molded unit comprising a thermoplastic material, and wherein the single over-molded unit seals the sensor electronics within the enclosure.
4. The on-body device of claim 1, wherein the top portion (5002) and the base portion (5004) are coupled by a snap-fit mechanism (5006) such that the sensor electronics are sealed within the enclosure.
5. The on-body device of claim 1, wherein the top portion (5002) and the base portion (5004) are welded together such that the sensor electronics are sealed within the enclosure.
6. The on-body device of claim 1, wherein the top portion (5002) and the base portion (5004) are adhered together such that the sensor electronics are sealed within the enclosure.
7. The on-body device of claim 1, further comprising the adhesive patch (3802, 5104) coupled with the base portion, wherein the adhesive patch comprises a window (5110) aligned with the distal-facing opening.
8. The on-body device of claim 1, wherein the sensor electronics comprise a first set of mating features coupled with a second set of mating features of the glucose sensor assembly (3702, 4702).
9. The on-body device of claim 1, wherein the recess (3704, 4710) of the base portion (5004) contains a first set of mating features coupled with a second set of mating features of the glucose sensor assembly (3702, 4702).
10. The on-body device of claim 1, further comprising an elastomeric sealing member (4714) disposed within the recess (4710), wherein the elastomeric sealing member (4714) is in contact with the connector support

[1] To be found in the EPO Espacenet register at: https://worldwide.espacenet.com/patent/search/family/047891854/publication/EP3831283B1?q=EP3831283B1

(4706) while the connector support (4706) is disposed in the recess (4710).
11. The on-body device of claim 1, wherein the recess is configured to receive the connector support (3604, 4706) after the sensor electronics are positioned in the enclosure.
12. The on-body device of claim 1, wherein the connector support (3604, 4706) is electrically coupled with the sensor electronics via an interface that is external to the enclosure, and wherein the interface between the connector support (3604, 4706) and the sensor electronics is disposed within the recess (3704, 4710).
13. The on-body device of claim 1, wherein the on-body device is configured to be received within a housing of an applicator.
14. The on-body device of claim 13, wherein the on-body device is further configured to be advanced from a first position within the housing of the applicator to a second position, wherein the base portion of the on-body device housing is adhered to the skin surface of the subject when the on-body device is in the second position.
15. A method for assembling an on-body device comprising a glucose sensor assembly (3702, 4702), an enclosure, and sensor electronics,
wherein the glucose sensor assembly (3702, 4702) comprises a proximal section comprising a connector support coupled with a proximal portion (3310) of a glucose sensor (3300, 4704), and 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,
wherein the enclosure comprises a top portion (5002) and a base portion (5004), wherein the base portion (5004) comprises a recess (3704, 4710) in a bottom exterior surface, and wherein the recess (3704, 4710) comprises a distal-facing opening, the method comprising:
positioning the sensor electronics within the enclosure of the on-body device, wherein the sensor electronics comprise a processor (4804), a communications facility;
after positioning the sensor electronics within the enclosure, inserting the connector support (3604, 4706) through the distal-facing opening of the recess (3704, 4710) in the bottom exterior surface of the base portion (5004) and into the recess (3704, 4710), causing the glucose sensor (3300, 4704) to electrically couple with the sensor electronics.
16. The method of claim 15, wherein positioning the sensor electronics within the enclosure comprises injecting a thermoplastic material into a mold (4902, 4904) to form a single integral unit configured to seal the sensor electronics within the enclosure.
17. The method of claim 16, wherein the mold is a two-piece mold comprising a first mold piece (4902) corresponding with the top portion of the housing and a second mold piece (4904) corresponding with the base portion of the housing.
18. The method of claim 15, wherein positioning the sensor electronics within the enclosure comprises coupling the top portion (5002) with the base portion (5004) by a snap-fit mechanism (5006) such that the sensor electronics are sealed within the enclosure.
19. The method of claim 15, wherein positioning the sensor electronics within the enclosure comprises welding the top portion (5002) and the base portion (5004) together such that the sensor electronics are sealed within the enclosure.
20. The method of claim 15, wherein positioning the sensor electronics within the enclosure comprises coupling the top portion (5002) with the base portion (5004) using an adhesive such that the sensor electronics are sealed within the enclosure.
21. The method of claim 15, further comprising applying an adhesive patch (3802, 5104) to the base portion, wherein the adhesive patch (3802, 5104) comprises a window aligned with the distal-facing opening.
22. The method of claim 15, further comprising causing a first set of mating features of the sensor electronics to couple with a second set of mating features of the glucose sensor assembly (3702, 4702) when the connector support is inserted into the recess (3704, 4710).
23. The method of claim 15, further comprising causing a first set of mating features contained in the recess (3704, 4710) to couple with a second set of mating features of the glucose sensor assembly (3702, 4702) when the connector support is inserted into the recess (3704, 4710).
24. The method of claim 15, further comprising causing the connector support (3604, 4706) to come into contact with an elastomeric sealing member (4714) while the connector support (3604, 4706) is disposed in the recess (3704, 4710).
25. The method of claim 15, wherein causing the glucose sensor (3300, 4704) to electrically couple with the sensor electronics comprises causing the connector support (3604, 4706) to electrically couple with the sensor electronics, wherein the connector support (3604, 4706) is electrically coupled with the sensor electronics via an interface that is external to the enclosure, and wherein the interface between the connector support (3604, 4706)and the sensor electronics is disposed within the recess (3704, 4710).
26. The on-body device of claim 1 or the method of claim 15, wherein the glucose sensor assembly (3702, 4702) further comprises a bent section (3318) between the proximal section and the distal tail section, wherein the proximal section and the distal tail section are approximately perpendicular to each other

The patent was filed as a second generation divisional application (the "application"), stemming from a parent application (published as EP 3 300 658, the "parent application"), itself originating from a Euro-PCT application originally published as WO 2013/090215 (the "original application"). The filing date of the patent is the filing date of the original Euro-PCT application, namely 11 December 2012 and it has an earliest 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, Ireland, Italy, Latvia, Lithuania, Luxembourg, The Netherlands, and Sweden. It is also in force in other countries, including the UK and Spain. The patent was opted-out of the UPC competence, but this opt-out was withdrawn by Abbott on 14 March 2024.

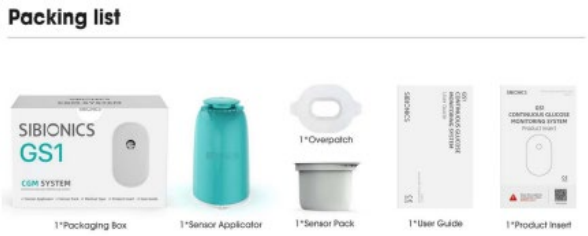
Market situation

Abbott is a developer, manufacturer and marketer of continuous glucose monitoring ("CGM") devices since 2007. The series of its 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.

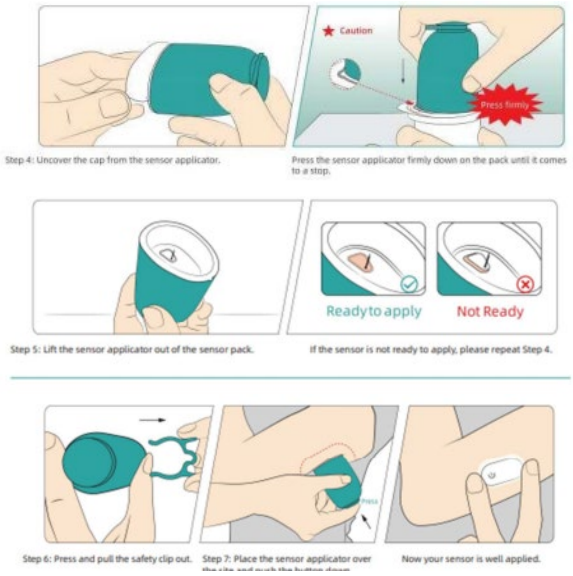
Abbott is the main supplier of CGM products in the Contracting Member States. In Europe, Abbott serves over 1.3 million patients with its FreeStyle Libre products and has a market share of approximately 80%.

Defendant 1 ("Sibio") also manufactures CGM systems. Since 2021, Sibio has been on the market in China with a CGM device. Recently, end of 2023, Sibio entered the market in Europe with its CGM device, called GS1. Defendant 2 ("Umedwings" and together with Sibio "Sibio c.s." or "Defendants") is named in the documentation for the GS1 device as an EU importer.

The packing list of the GS1 is depicted below:



The GS1 Quick Start Guide contains the following steps 1-7:



Technical background and subject of the patent

Diabetes Mellitus is an incurable chronic disease in which the body does not produce or properly utilize insulin. Insulin is a hormone produced by the pancreas that regulates blood sugar (glucose). In particular, when blood sugar levels rise, e.g., after a meal, insulin lowers the blood sugar levels by facilitating blood glucose to move from the blood into the body cells. Thus, when the pancreas does not produce sufficient insulin (a condition known as Type 1 Diabetes) or does not properly utilize insulin (a condition known as Type II Diabetes), the blood glucose remains in the blood resulting in hyperglycemia or abnormally high blood sugar levels (patent, para. [0002]).

The vast and uncontrolled fluctuations in blood glucose levels in people suffering from diabetes cause long-term, serious complications. Some of these complications include blindness, kidney failure, and nerve damage. Additionally, it is known that diabetes is a factor in accelerating cardiovascular diseases such as atherosclerosis (hardening of the arteries), leading to stroke, coronary heart disease, and other diseases. Accordingly, one important and universal strategy in managing diabetes is to control blood glucose levels (patent, para [0003]).

One element of managing blood glucose levels is the monitoring of blood glucose levels. Conventional in vitro techniques exist, such as drawing blood samples, applying the blood to a test strip, and determining the blood glucose level using colorimetric, electrochemical, or photometric tests. The patent is concerned with in vivo analyte monitoring systems, which measure and store sensor data representative of glucose levels automatically over time (patent, para [0004]).

Unlike conventional in vitro blood glucose monitoring approaches, in vivo analyte monitoring systems use an insertable or implantable in vivo sensor that is positioned to be in contact with interstitial fluid of a user for a period of time to detect and monitor glucose levels. Prior to use of an in vivo sensor, at least a portion of the sensor is positioned under the skin. An applicator assembly can be employed to insert the sensor into the body of the

user. For insertion of the sensor, a sharp engaged with the sensor, pierces the skin of the user, and is then removed from the body of the user leaving the sensor in place. The in vivo-positioned sensor can be connected to other system components such as sensor electronics contained in a unit that can be held onto the skin (patent, para [0005]).

To realize fully the advantages associated with such in vivo systems, what is needed are applicator systems configured to handle insertion, as well as packaging and user interface issues, that are easy-to-use, reliable and minimize both user inconvenience and pain. The invention of the patent provides such solutions and additional or alternative advantages (patent, para [0006]).

SUBMISSIONS

Abbott lodged the Application for preliminary injunction and other provisional measures on 20 March 2024 in the UPC Local Division The Hague.

As per the instructions of the Judge-Rapporteur, the Defendants lodged an Objection to the application for provisional measures on 23 April 2024.

Again, as instructed by the Judge-Rapporteur, on 8 May 2024 Abbott lodged a Reply to the Objection to the application for provisional measures.

The Defendants lodged a Rejoinder to this Reply on 15 May 2024, equally as stipulated by the Judge-Rapporteur.

An oral hearing was held in the matter on 22 May 2024 in the Local Division of The Hague. The hearing was recorded. Abbott and Sibio c.s. submitted notes of their pleadings.

The following attorneys attended the oral hearing of 22 May 2024:

On behalf of Abbott

Wim Maas (Taylor Wessing, lawyer)
Eelco Bergsma (Taylor Wessing, lawyer)
David Mulder (Taylor Wessing, lawyer)
Faziel Abdul (Taylor Wessing, lawyer)
Iris van der Heijdt (Taylor Wessing, lawyer)
Peter Haartsen (AOMB - patent attorney)
Raimond Haan (AOMB – patent attorney)

On behalf of Sibio c.s.

Dr Thomas Gniadek, Simmons & Simmons LLP
Dr Fritz Lahrtz, Simmons & Simmons LLP
Oscar Lamme, Simmons & Simmons LLP
Diptanil Debbarma, Simmons & Simmons LLP

ORDER SOUGHT

Abbott 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 the Defendants, among others by the offering for sale of the GS1 Devices through Sibio's website sibionicsshop.com directed at Europe. It therefore requests that the Court, for the Contracting Member States in which the patent is in force[2]:

(a) grant a preliminary injunction for direct infringement of the patent by prohibiting the Defendants, 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**);

(b) order the Defendants 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)**

(c) order the Defendants to deliver up to a bailiff appointed by Abbott, at their own expense, or alternatively orders the seizure, of any GS1 Device in stock and / or otherwise held, owned or in the direct or indirect possession of the Defendants 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**);

(d) order the Defendants 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 may order, to the Court 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. 63(2) UPCA**; and **R. 354.3 RoP**);

(e) append an order for the enforcement to its decision, while declaring that the order is immediately enforceable (**Article 82(1)** of the UPCA);

(f) order the Defendants to jointly and severally bear reasonable and proportionate legal costs and other expenses incurred by Abbott in these proceedings and orders, insofar such costs are to be determined in separate proceedings for the determination of such costs, that the Defendants 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**).

[2] Abbott made clear in its Reply to the Objection that their request does not extend to Ireland.

Abbott also requests that the amount of security, if any, be fixed separately for each enforceable part of the Court's decision.

DEFENCE

Sibio c.s. argue that this court is not competent for Ireland. In addition, they disagree with Abbott that the patent is infringed. They further assert that the patent is (likely) invalid owing to concerns regarding added matter, lack of novelty and lack of inventive step. Additionally, they contend that the application was brought with unreasonable delay and that Abbott lacks sufficient interest in the current application. Sibio c.s. further request that the court impose on Abbott an obligation to pay for the fees and costs since Abbott did not send a warning letter before initiating these proceedings and hence unnecessary costs were incurred. They finally also wish for the court to make any measure granted subject to a security pursuant to R.211.5 RoP.

GROUNDS FOR THE ORDER

Competence

1. According to Art. 31 UPCA (which provides that the international competence of the court is established in accordance with Brussels Regulation 1215/2012 as amended by EU Regulation 542/2014, "BR"), and Art. 26, 35 and 71, 71a and 71b BR, this court is competent to hear the case for the Contracting Member-States. After Sibio c.s.' defence, Abbott indicated that it did not mean to include Ireland, so there is no need to decide on competence with regard thereto. This local division is undisputedly competent to hear the case as the alleged (threatened) infringement has occurred (inter alia) in the Netherlands (Art. 33 UPCA).

Validity of the patent

2. R. 211.2 RoP, in conjunction with Art. 62(4) UPCA (see also Art. 9(3) Directive 2004/48/EC), provides that the court may invite the applicant for provisional measures to provide reasonable evidence to satisfy the court to a sufficient degree of certainty that the applicant is entitled to institute proceedings under Art. 47 UPCA, that the patent is valid and that his right is being infringed, or that such infringement is imminent.

2.1. Such a sufficient degree of certainty requires that the court considers it at least more likely than not that the Applicant is entitled to initiate proceedings and that the patent is infringed. A sufficient degree of certainty is lacking if the court considers it on the balance of probabilities to be more likely than not that the patent is not valid.

2.2. The burden of presentation and proof for facts allegedly establishing the entitlement to initiate proceedings and the infringement or imminent infringement of the patent, as well as for all other circumstances allegedly supporting the Applicant's request, lies with the Applicant, whereas, unless the subject-matter of the decision is the ordering of measures without hearing the defendant pursuant to Art. 60(5) in conjunction with Art. 62(5) UPCA, the burden of presentation and proof for facts concerning the lack of validity of the patent and other circumstances allegedly supporting the Defendant's position lies with the Defendant.

2.3. The aforementioned allocation of the burden of presentation and proof in summary proceedings is in line with the allocation of the burden of presentation and proof in proceedings on the merits, in which facts giving rise to the entitlement to initiate proceedings and the infringement or imminent infringement of the patent, as well as other circumstances favorable to the infringement action, are to be presented and proven by the right holder (Art. 54, 63, 64 and 68 UPCA, R. 13.1(f) and (l)-(n) RoP), whereas the burden of presentation and proof with regard to the facts from which the lack of validity of the patent is derived and other circumstances favourable to the invalidity or revocation lies with the opponent (Art. 54 and 65(1) UPCA, Rules 44(e)-(g), 25.1(b)-(d) RoP).[3]

Added matter

3. This court finds that, on the balance of probabilities, it is more likely than not that claim 1 as well as (consequently) asserted dependent claims 6, 7, 9, 11, 12, 13, 14 and 26 of the patent (i.e., the claims asserted by Abbott in the Application) 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, as argued by Sibio c.s. The reasons for this are explained below.

3.1. Claim 1 can be divided into the following features:

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)

[3] See UPC CoA 26 February 2024, 10X and Harvard/Nanostring, UPC_CoA_335/2023 App_576355/2023, page 2

	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).

3.2. According to **Art. 138(1) (c)** European Patent Convention (EPC), a European patent may be revoked with effect (for a EPC Contracting State) if the subject-matter of the European patent extends beyond the content of the application as filed or, if the patent was granted on a divisional application or on a new application filed under **Art. 61 EPC**, beyond the content of the earlier application as filed. This follows from the provisions that a (divisional) European patent application or European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the (original) application as filed (**Art. 76(1)** and **123(2) EPC**). Such unallowable extension of subject-matter is also more simply referred to hereinafter as "added matter".

3.3. In the present case, there are three relevant patent applications, as set out above. Abbott has stated that the original application is identical to the parent and to the application. This has not been disputed by Sibio c.s. Therefore, the reasoning is the same when considering either the original application, the parent application or the application. Hereinafter reference will be made to the original application only.

3.4. Both parties relied on the case law of the (Technical and Enlarged) Boards of Appeal of the European Patent Office (EPO) to substantiate their arguments regarding added matter. They did not indicate whether – and if so in which way – the court should apply a different standard. This court will also apply that long-standing case law, and the court will therefore in particular apply the so-called "gold standard" disclosure test in this context, which is also the standard used in many Contracting Member States of the UPC.[4] Hence, any amendment to the parts of a European patent application or of a European patent relating to the disclosure (the description, claims and drawings) can therefore, irrespective of the context of the amendment made, only be made within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the application(s) as filed.[5] After the amendment, the skilled person may not be presented with new technical information.

3.5. It is not sufficient if the claimed subject-matter is "obvious" to the skilled person in view of the original application in order to comply with the added matter provision. It is necessary that the claimed subject-matter be directly and unambiguously derivable from the original application (including any information which is implicit for the skilled person), and this is a stricter test.[6]

3.6. This is a matter of legal certainty for third parties relying on the content of the original application and is necessary to ensure that patent proprietors do not benefit from an unwarranted advantage.[7]

4. Following from these principles, the original application cannot be treated by the patent proprietor as a reservoir of features, from which he can pick and choose features to assemble them as he wishes to draft new claims. There must be a pointer towards the combination of features selected by the proprietor.[8]

4.1. Applying this test to the present case amounts to the following: the court notes in the first place that claim 1 was not drafted based on a combination of original claims or claim-like clauses in the description. Claim 1 was entirely redrafted from scratch. Abbott is correct in stating that a granted claim does not necessarily need to be based on an original claim. It can also be partly or entirely based on the original description and drawings. Abbott is also correct in that literal support is not required. However, in a case such as this, where the patent proprietor relies on several different passages of the description, on several embodiments and on various drawings of the original application as a support for claim 1, and where the patent proprietor has introduced wording in the claim which is not even present in the original application as filed, a careful assessment is necessary.

4.2. The original application discloses many features and many embodiments (with many drawings).

4.3. During the examining phase of the patent, Abbott presented to the examiner of the EPO (by letter of 9 May 2022, Sibio c.s.' Exhibit S3), to overcome an added matter objection, that the main basis for claim 1 in the original application is clause 32 in combination with
(a) The embodiment of Fig. 36-38 as well as
(b) The embodiment of Fig. 47A-C and
(c) The embodiment of Fig. 51A-C. (and corresponding paragraph) This argument was accepted, and the patent was granted.

4.4. The court understands that Abbott maintains that position in these proceedings, except for the embodiment of Fig. 51A-C as it no longer referred to this in these proceedings as providing basis. For ease of reference, the embodiments according to Fig. 36-38 and 47A-C relevant here are quoted below, together with the parts of the description where the figures are described (paragraph [0145] for embodiment (a) and paragraph [0150] for embodiment (b)):

Clause 32. 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

[4] See Case Law of the Boards of Appeal (hereinafter also "CLBA"), 10th edition 2022, II.E.1.1 and i.a. **G2/10**
[5] **G 3/89, OJ 1993, 117**; **G 11/91, OJ 1993, 125**
[6] CLBA, II.E.1.3.4.a
[7] CLBA II.E.1.1, **G1/93**
[8] CLBA, II.E.1.6.1.

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.
[0145] A related arrangement to that described in connection with FIGS. 34A-34D and 35A35D 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.

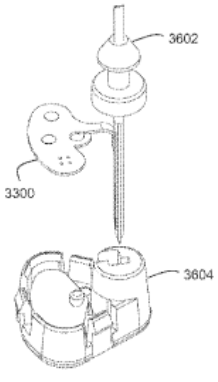


FIG. 36

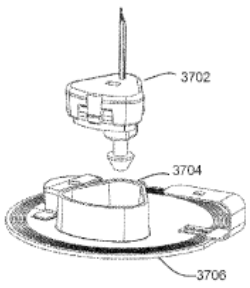


FIG. 37

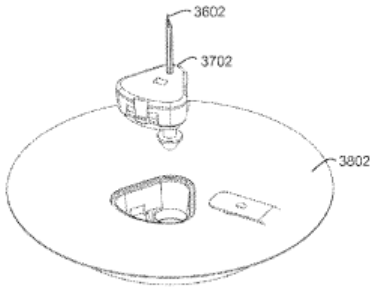


FIG. 38

[0150] 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.

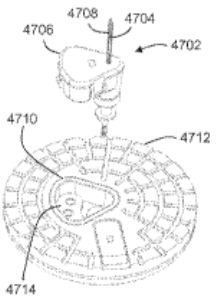


FIG. 47A

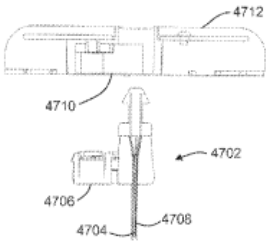


FIG. 47B

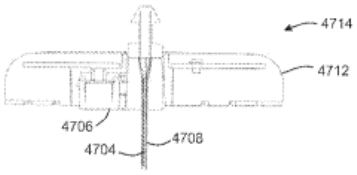


FIG. 47C

5. Sibio c.s. have convincingly argued that claim 1 appears to be the result of an unallowable intermediate generalization, at least relating to the omission of the

presence of an elastomeric seal in the recess of the base portion of the enclosure (in feature 1.4).

5.1. This feature, relating to the base portion of the enclosure comprising a recess in a bottom exterior surface, is not disclosed in clause 32. It is however disclosed in Fig. 36-38 (and paragraph [0145] (embodiment (a)) as well as in Fig. 47A-C (and paragraph [0150] (embodiment (b)). Abbott has explained that the "socket 3704" shown in Fig. 37-38 should be considered similar to/to represent the "recess 4710" shown in Fig. 47A.

5.2. In both passages describing the embodiments (a) and (b), the recess is disclosed in combination with a(n elastomeric) seal (designated as a "second elastomeric unit" in paragraph [0145] and as an "elastomeric sealing member" in paragraph [0150]). Abbott's (counter)argument that Fig. 36-38 do not show such a seal, and therefore these features are not linked, is not convincing since the drawings are schematic in nature and do not necessarily show all the elements which are present. More importantly, the presence of the "second elastomeric unit" is clearly mentioned in corresponding paragraph [0145]. The seal is not part of (feature 1.4 of) claim 1 as granted. This is an intermediate generalization.

5.3. For the intermediate generalization to be considered allowable (in the sense that it does not result in added matter), it should be (clearly) established that there is no structural and functional relationship between the omitted feature and the other features incorporated into the claim.[9]

5.4. In this case, Abbott has failed to demonstrate the absence of a structural and functional link between the seal and the recess. On the contrary, the elastomeric seal would appear to be important for the proper functioning of the device as illustrated in Fig. 36-38 and Fig. 47A-C, and more particularly to ensure a sealed connection (keeping out moisture) as the device is assembled by the end-user.

6. In support of its position that there is no structural and functional link between seal and recess, Abbott has pointed to the embodiment of Fig. 34A-D, where an embodiment where allegedly no seal in the recess is disclosed, emphasizing that Fig. 36-38 are said to be directed to "a related arrangement to that described in connection with FIGS. 34A-34D and 35A-35D" (paragraph [0145]). Figure 34A-D and explanatory paragraph [0141] are as follows:

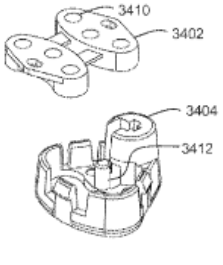


FIG. 34A

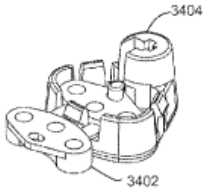


FIG. 34B

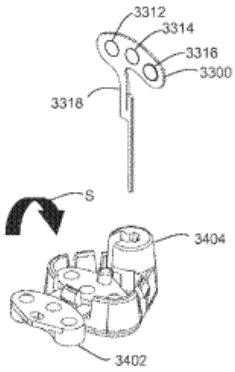


FIG. 34C

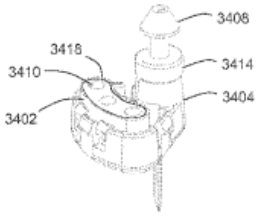


FIG. 34D

[0141] 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 one-piece 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 insures10 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. The connector 3402 is illustrated as bilaterally symmetrical, however, the connector 3402 can be formed in a direction-specific orientation because in some embodiments, certain of the electrical contacts 3410 may not be necessary. In some embodiments, all the sensor's electrical contacts 3312, 3314, 3316 can be provided on a single side of the sensor 3300 or, in other embodiments, both sides of the sensor 3300.

6.1. The court notes that the enclosure is not discussed at all in the context of Fig. 34A-D, while the layout of that enclosure with recess and distal-facing opening in the bottom portion (feature 1.4) are precisely the features

[9] CLBA, II.E.1.9.1, especially 4th and 5th paragraphs

of claim 1 which have been disclosed in conjunction with a seal in the recess in the embodiments of Fig. 36-38 (paragraph [0145]) as well as Fig. 47A-C (paragraph [0150]). Admittedly, the third and fourth sentences in paragraph [0150] could be taken to suggest that the seal in the recess may not be necessary when there is a connector in addition to the connector support, as shown in Fig. 34A-D. However, this is because this connector acts as a seal itself as mentioned in paragraph [0141] (see the second sentence: "a flexible one-piece seal or connector 3402"). Therefore, the embodiment of Fig.34A-34D, at best, would be interpreted by the skilled person as disclosing that another type of seal than the one disclosed in paragraph [0145] can be used, more particularly a connector seal, but not as implying that a generalization to an onbody device not comprising any (elastomeric) seal at all is contemplated.

7. During the hearing, Abbott further drew the attention of this court to Fig. 29 (in fact 29A-D) and paragraph [0130] (of the original application) as showing an embodiment wherein the seal in the recess is not mentioned:

[0130] An alternative embodiment is contemplated in connection with the sensor approach illustrated in FIGS. 29A-29D. Using a sensor 2902 with a vertically disposed "flag" connector portion that is supported by coupling 2904, coupling 2904 is configured to snap into connector block 2908 which is attached to PCB 2914. Connector block 2908 includes a connector socket 2910 to receive the contacts portion of the sensor 2902. Connector block 2908 also includes a coupling feature 2912 to receive snap-fit tab 2906 on the coupling 2904 which retains the sensor 2902 in the connector socket 2910.

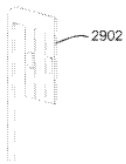


FIG. 29A

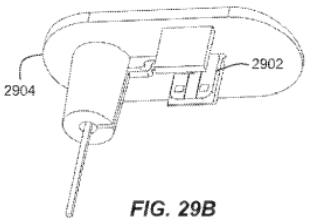


FIG. 29B

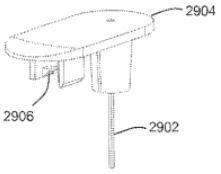


FIG. 29C

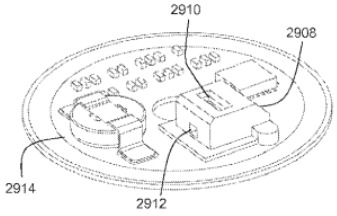


FIG. 29D

8. This however relates to yet another embodiment, which the skilled person would have to combine with the other passages (and figures) without any pointer to do so in the application. Additionally, this reference is not relevant for claim 1 as Fig. 29 does not show a recess in the bottom portion of the enclosure as required by feature 1.4, and this is not discussed in the very short paragraph [0130] either. Conversely, it appears to this panel that this embodiment in fact works in a reverse way to claim 1: the connector support is not received "through the distal-facing opening and into the recess" (as recited in claim 1), i.e., from below the bottom portion), but from above (in the claim terminology: the proximal side). This is even more salient as the distinction between these two different coupling directions is the very argument Abbott uses to assert the patent to be inventive over prior art document WO 2011/119896 (Abbott's Reply to the Objection, para. 4.179 and, more extensively, submissions made during the oral hearing). Moreover, there is no mention in this passage that the sealing means mentioned earlier may be dispensed with. The absence in this paragraph of an explicit mention of a feature discussed elsewhere does not imply that the feature can be dispensed with in the context of Fig. 36-38 and Fig. 47AC.

Conclusion

9. In view of the above, there is no need to look into the other issues brought forward by Sibio c.s. and Abbott, as the above-mentioned issues regarding added matter led to the conclusion that it is more likely than not that claim 1 of the patent will be held to be invalid. All dependent claims relied on by Abbott suffer from the same problem. For the sake of clarity: claim 10 (which recites "an elastomeric sealing member (4714) disposed within the recess (4710)") was not invoked by Abbott.

10. Consequently, the provisional measures are to be denied. Since the applicant did not prevail with its application, the present order terminates these proceedings, which means that there is no basis for a provisional reimbursement of costs as requested by Abbott. Even if the applicant were to be successful in the proceedings on the merits, it will still have to bear the costs of these proceedings as the unsuccessful party. The applicant must therefore reimburse the defendant for the costs of the proceedings at first instance. For the purpose of the cost proceedings, the court sets the value of the action at EUR 4,000,000, as proposed by Abbott. Sibio c.s. did not object to this amount.

ORDER

The court:

(a) denies the application for preliminary measures;

(b) orders the Applicant to bear reasonable and proportionate legal costs and other expenses incurred by Defendants in these proceedings, up to the applicable ceiling (Art. 69 UPCA; and R. 118.5 and R. 150.2 RoP);

(c) sets the value of the dispute at EUR 4,000,000.

INFORMATION ABOUT APPEAL

An appeal to this order may be brought in accordance with Art. 73 UPCA and R. 220.1 within 15 calendar days of the notification of this order.

E.F. Brinkman Presiding judge

M. Kokke Legally qualified judge

P. Rinkinen Legally qualified judge

R. Fulconis Technically qualified judge

ORDER DETAILS

Order no. ORD_30431/2024 in ACTION NUMBER: Not provided UPC number: UPC_CFI_131/2024 Action type: Not provided Related proceeding no. Application No.: 14945/2024 Application Type: Application for provisional measures

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