Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

UPC Court of Appeal
UPC-CoA-884/2025

DECISION

of the Court of Appeal of the Unified Patent Court
issued on 13 August 2026
concerning EP 3 831 283

HEADNOTES

1) One situation where added matter may arise is when claimed subject-matter is obtained by importing one or more features from a certain embodiment in the application into a claim, while omitting one or more other features of this embodiment which were presented in combination with the imported feature(s) in the disclosure of this embodiment. This is referred to as an 'intermediate generalisation'. This is generally considered to be unallowable if there is a clearly recognisable functional or structural relationship among the omitted feature(s) and the claim features, also referred to 'an extricable link' between the omitted feature(s) and the claim features.

2) The technical effect that the invention aims to achieve, and whether an omitted feature contributes thereto, is relevant for the assessment of added matter. It is relevant when considering whether the skilled person would understand from the disclosure of the application as a whole that there is a structural or functional relationship between the omitted feature and the other features of the claimed embodiment or, in other words, when considering whether there is an inextricable link with such other features or, yet differently worded, whether such omitted feature is essential to the invention.

KEYWORDS

Added matter, intermediate generalisation, relevance of the technical affect for the assessment of added matter

APPELLANT (AND CLAIMANT BEFORE THE COURT OF FIRST INSTANCE)

Sibio Technology Limited, Kowloon, Hong Kong

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(hereinafter 'Sibio')

RESPONDENT (AND DEFENDANT BEFORE THE COURT OF FIRST INSTANCE)

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represented by Dr. Wim Maas, attorney at law, Taylor Wessing N.V., Amsterdam, The Netherlands

(hereinafter 'Abbott')

PATENT AT ISSUE

EP 3 831 283

LANGUAGE OF THE PROCEEDINGS

English

PANEL AND DECIDING JUDGES

Panel 2:
Rian Kalden, legally qualified judge and judge-rapporteur
Patricia Rombach, legally qualified judge
Ingeborg Simonsson, legally qualified judge
Marc van der Burg, technically qualified judge
Patrik Rydman, technically qualified judge

IMPUGNED DECISION OF THE COURT OF FIRST INSTANCE

Decision of 21 July 2025, issued by the Paris Central Division in the revocation action UPC_CFI_231/2024

ORAL HEARING

22 June 2026

SUMMARY OF THE FACTS

Procedural background and the impugned decision

1. In the impugned decision, the Paris Central Division (PCD) dismissed the revocation action filed by Sibio against Abbott concerning the patent at issue (hereinafter also 'the Patent'), maintained the Patent as granted, and ordered that the costs be borne by Sibio.

2. On 22 September 2025, Sibio lodged an appeal pursuant to R. 220.1 (a) RoP before the Court of Appeal.

3. Sibio filed its Statement of appeal and grounds of appeal on 21 November 2025, and Abbott filed its Statement of response on 24 February 2026.

4. On appeal in preliminary injunction proceedings between Abbott and (among other) Sibio, where Sibio disputed the validity of the Patent, the Court of Appeal held that the Patent is more likely than not valid (decision of 14 February 2024 in UPC-CoA-382/2024, *Abbott v Sibionics*)

SUMMARY OF THE PARTIES' SUBMISSIONS AND REQUESTS ON APPEAL

5. On appeal, Sibio requests that the impugned decision be overturned, that the Patent be revoked in its entirety for all Contracting Member States in which the Patent is validated and that Abbott be ordered to bear the costs of the proceedings at first instance and on appeal. Sibio argues that the Patent is invalid because the subject matter of independent claims 1 and 15 of the Patent extends beyond the disclosure of the original application (added matter) and for lack of inventive step of all claims in view of WO 2011/119896 A1 (D2 or WO'896) in combination with US 2008/255440 A1 (D1 or US'440).

6. Abbott defends the validity of the Patent and concludes (para. 184-185 SoR) that the subject-matter of the Patent does not contain added matter and is inventive and that therefore the request for revocation is unsound. Abbott has defended both independent claims 1 and 15 and all claims dependent thereon. If

claim 1 and 15 were considered to comprise added matter, Abbott relies on the dependent claims 2 to 14 and 16-25 (SoR para. 101-103) and in the further alternative Abbott relies on the auxiliary requests AR1 to AR6 presented in its application to amend the Patent at first instance and which were held to be admissible in the impugned decision (SoR para. 104-116).

THE PATENT

7. Abbott is the registered proprietor of the Patent. The Patent was filed as a second generation divisional application (the original application), stemming from a parent application (published as EP 3 300 658 A1, the earlier application), itself originating from a PCT application published as WO 2013/090215 A2 (the earliest application). The filing date of the original application is the filing date of the earliest application, namely 11 December 2012 and it has a priority date of 11 December 2011. The original 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 has been validated for UPCA 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 Ireland, Spain and the UK. The Patent was opted-out of the UPC competence, but this opt-out was withdrawn by Abbott on 14 March 2024.

The patent claims

8. 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. Claims 1 and 15 of the Patent read 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).

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.

9. The Court of Appeal, like the PCD and the parties, shall refer to the separate features of claim 1 as follows:

1.0	An on-body device, comprising:
1.1	(1) a glucose sensor assembly (3702, 4702) comprising:
1.1.1	a proximal section comprising a connector support (3604, 4706) coupled with a proximal portion (3310) of a glucose sensor (3300, 4704);
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;
1.2	(2) an enclosure comprising:
1.2.1	a top portion (5002); and
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
1.3	(3) sensor electronics positioned with the enclosure, the sensor electronics comprising a processor (4804), and a communications facility,
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,
1.5	wherein the connector support (3604, 4706) is received through the distal-facing opening and into the recess (3704, 4710), and
1.6	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).

The patent description

10. The Patent is titled “analyte sensor devices, connections, and methods” and relates to an on-body device for an *in vivo* analyte monitoring device.

11. The vast and uncontrolled fluctuations in blood glucose levels in people suffering from diabetes cause long-term, serious complications. An important and universal strategy in managing diabetes is to control blood glucose levels (para. [0003]).

12. Next to the use of conventional *in vitro* techniques (described in para. [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 (para. [0005]).

13. 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 (para. [0006]).

14. The on-body device may include sensor electronics and other adaptation to communicate with a monitoring device (para. [0010]).

15. 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 bodily 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 (para. [0011]).

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

17. Para. [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."

18. Figs. 33A-33G provide views of a sensor configuration. Figs. 33A and 33B are shown below:

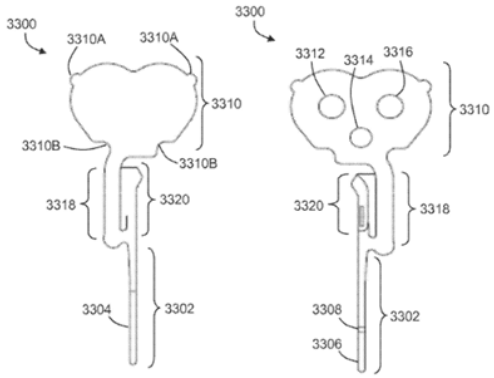


FIG. 33A FIG. 33B

19. In para. [0088] the embodiment shown in Figs. 36-38 is described as follows:

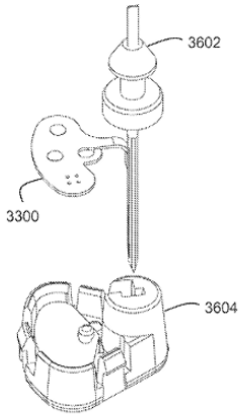


FIG. 36

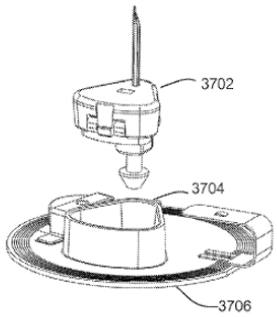


FIG. 37

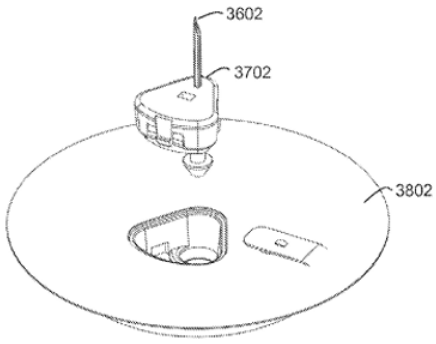


FIG. 38

"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."

20. Para. [0093] and Figs. 47A-47C illustrate an 'alternative sensor assembly / electronics assembly connection approach'. The figures are reproduced below.

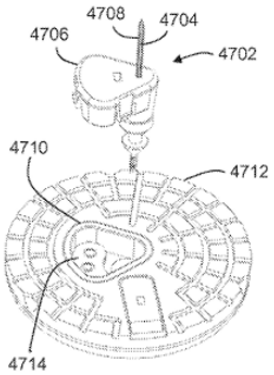


FIG. 47A

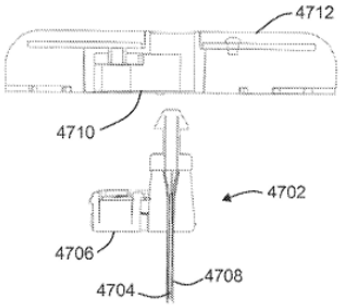


FIG. 47B

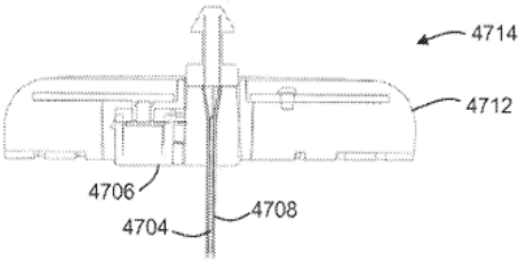


FIG. 47C

Para. [0093] states: "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."

Technical effect and core of the invention

21. The skilled person understands from the description that the glucose sensor assembly and the enclosure that houses the sensor electronics are preferably kept separate until their application to the skin, because of different sterilisation methods (para. [0029]: "The container 206 and the applicator 212 may be sterilized by different sterilization approaches. (...) The utility of a two-piece separable but combinable system (i.e., the container 206 and the applicator 212) enables the respective sterilization of the two pieces and sterility maintenance before the two are connected together for use."

22. The skilled person also understands that the on-body device is meant to form part of an applicator system configured to handle application of the on-body device to the skin – including insertion of the sensor assembly into the skin – which is easy-to-use, reliable and minimizes both user inconvenience and pain (para. [0005]-[0011]).

23. In particular, the skilled person understands from para. [0022], which states that "Advantageously, an adhesive of the on-body device does not contact the user until the application operation (108) is performed", that the on-body device must be configured such that it allows the applicator containing the assembled 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.

24. In view thereof, the skilled person appreciates that these aims are achieved by the configuration of an on-body device for *in vivo* glucose monitoring of claim 1, that is assembled immediately prior to its application by electrically coupling the glucose sensor assembly and the sensor electronics through receipt of the glucose sensor assembly in a recess formed in the *bottom* exterior surface of the enclosure (containing the sensor electronics), thus from beneath. This coupling causes the electrical contacts of the glucose sensor to be mated with the electrical contacts of the sensor electronics. Such a configuration allows free movement of the assembled on-body device sitting in the applicator before its application to the skin in one step by pushing on the applicator (as shown in Figs. 11A-11F), which facilitates easy use and minimises inconvenience and pain.

25. The core of the invention is thus that the configuration of claim 1 allows the enclosure (which houses the electronics assembly) to be first included in the applicator, and allows the subsequent coupling with the sensor assembly (containing the sensor electronics) – by insertion of the connector support (which is coupled with the sensor electronics) in the recess formed in the *bottom* exterior surface of the enclosure, thus *from beneath*, so that the applicator containing the thus assembled on-body device can move freely over the skin surface before it is applied to the skin in one step.

26. Abbott has adequately referred to the configuration of an-body device according to claim 1 as a "plug-and-socket from beneath" configuration (para. 13 SoR). The Court of Appeal notes that Figs. 37, 38 and 47A shown above must be seen reversed, with the needle in downward direction (as in Figs. 36, 47B and 47C), rather than upwards as shown.

GROUNDS FOR THE DECISION

Skilled person

27. It is uncontested that the person skilled in the art is an engineer with a university 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.

Claim construction

28. The claim construction by the PCD is uncontested on appeal. The Court of Appeal refers to that decision to avoid unnecessary repetition.

Added matter

29. On appeal, Sibio maintained one ground for revocation pursuant to Art. 65(2) UPCA based on Art. 138(1)(c) EPC. It argues that including features 1.4 to 1.6 relating to the recess, without including the elastomeric sealing in the recess of the enclosure of the electronics assembly in claim 1, constitutes added matter, either because this amounts to an intermediate generalization (para. 27 SoGA) or because this omitted feature is an element essential to the invention.

30. There is added matter if the subject-matter of the patent extends beyond the content of the application as filed. In order to ascertain whether there is added matter, the Court must 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 (UPC-CoA-382/2024, 14 February 2025, *Abbott v Sibionics*). This test is the same as the so-called 'gold standard' established by the Enlarged Board of Appeal of the European Patent Office in G2/10.

31. Where, as here, the patent is a divisional application, this requirement applies to each earlier application. It is not in dispute that the original application is identical to the earlier application, which in turn is identical to the content of the earliest application (Exh. CC03), with the exception of the claims of that earliest application being presented as clauses in the original application and the earlier application. Below, these will be jointly referred to as 'the application'. Reference will be made to the paragraph numbers of the earliest application (Exh. CC03).

Claim 1

32. It is thus relevant to establish whether not having an elastomeric sealing in the recess of the enclosure of the electronics assembly in claim 1 causes the subject matter of this claim to extend beyond 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. In other words, whether claim 1 without this feature presents new technical information.

33. One situation where added matter may arise is when claimed subject-matter is obtained by importing one or more features from a certain embodiment in the application into a claim, while omitting one or more other features of this embodiment which were presented in combination with the imported feature(s) in the disclosure of this embodiment. This is referred to as an 'intermediate generalisation'. This is generally considered to be unallowable if there is a clearly recognisable functional or structural relationship among the omitted feature(s) and the claim features, also referred to 'an extricable link' between the omitted feature(s) and the claim features.

34. On appeal, Sibio has presented 'the omission of an essential element' as a separate category of added matter, whereby it considers the elastomeric sealing in the recess of the enclosure of the electronics assembly to be an essential feature in view of the function it performs and the technical effect to be achieved. Abbott has objected to this argument, because it would be argued for the first time on appeal (para. 87–91 SoR). This is rejected. The only relevant test is whether claim 1 as a consequence of the omission of the elastomeric sealing covers subject-matter that extends beyond the content of the application. It is irrelevant whether the European Patent Office would categorise this as an 'intermediate generalisation' or as 'omitting an essential element'. In addition, R. 222.2 RoP does not apply to legal arguments which, as here, are based on the same facts and evidence.

35. Contrary to Sibio's argument (para. 30 SoGA), the technical effect that the invention aims to achieve, and whether an omitted feature contributes thereto, is relevant for the assessment of added matter. It matters when considering whether the skilled person would understand from the disclosure of the application as a whole that there is a structural or functional relationship between the omitted feature and the other features of the claimed embodiment or, in other words, when considering whether there is an inextricable link with such other features or, yet differently worded, whether such omitted feature is essential to the invention.

36. As will be explained below, the skilled person would not consider the omitted feature of an elastomeric sealing in the recess of the enclosure of the electronics assembly as necessary for achieving the technical effect of claim 1.

37. On-body devices for *in vivo* glucose monitoring were well known in the art at the priority date. As follows from what has been considered above (para. 21-25), claim 1 protects an embodiment with a *specific configuration* for a fully assembled on-body device – whereby the sensor assembly and the electronics assembly are thus already coupled – which configuration makes it possible that the applicator that is used for its installation can move freely over the skin surface before the on-body device contained therein is applied in one single step.

38. The sealing of the (components of the) on-body device, more specifically the use of an elastomeric sealing in the recess of the enclosure of the electronics assembly, is not functionally related to the features of claim 1 and the technical effect achieved thereby.

39. The electrical connection between the sensor assembly and the electronics assembly is achieved by the mating of the electrical contacts of the assemblies when the recess of the enclosure receives the connector support which is 'shaped to fit' the recess. Contrary to Sibio's argument (para. 51, 55, 64 SoGA), the elastomeric sealing member does not have a function in creating an electrical connection between the two assemblies, but serves another function. Sealing (only) serves the function of protecting the electrical connection between the contacts of both assemblies by enclosing it without interrupting it. That is a common characteristic of all types of sealing mentioned in relation to any embodiment referred to in the application.

40. Sibio also unsuccessfully argues (para. 71 SoGA) that the skilled person would at least understand that either a separate connector as recited in para. [0007] *or* an elastomeric sealing member as described in para. [0150] of the application would be necessary to create the electrical connection between the assemblies, because without such an element, the electrical connection 'by the connector support' cannot be created. This argument does not support Sibio's added matter attack, to the contrary. The skilled person will understand the 'connector for coupling the sensor to the electronics assembly' referred to in para. [0007] to refer to the connector support of features 1.1.1, 1.5 and 1.6. The connector support is coupled with the proximal portion (3310) of the sensor assembly that contains the sensor electronics (feature 1.1.1, see Fig. 33B). The connector support is used for coupling the assemblies as described in features 1.5 and 1.6, whereby the connector support with its shaped to fit design is received in the recess in the bottom exterior surface of the enclosure, allowing the electrical contacts of both assemblies to mate. The connector support indeed 'supports' the electrical coupling of the assemblies. In accordance with Sibio's argument, at least the connector as recited in para. [0007] is indeed included in claim 1.

41. The sealing of the (components of the) on-body device, more specifically the use of an elastomeric sealing in the recess of the enclosure of the electronics assembly, is also not structurally related to the features of claim 1.

42. Sibio unsuccessfully argues that the recess of the enclosure of claim 1 is only disclosed in combination with an elastomeric sealing disposed in the recess (para. 44 SoGA). For a recess in the disclosure, the application does not indicate the use of one particular type of sealing. This follows from para. [0102], [0128] and [0150], which all concern coupling the sensor assembly with the electronics assembly by bringing the sensor assembly into a recess in the enclosure containing the electronics assembly. Only para. [0150] discloses the use of an elastomeric sealing member in the recess of the enclosure.

43. Sibio's argument that the skilled person would not consider paragraphs [0102] and [0128] and the embodiments described therein because these do not pertain to embodiments presenting a recess according to features 1.4 to 1.6 (para. 31, 33 et seq. SoGA) must be rejected.

44. The skilled person understands para. [0102] to describe the coupling of the assemblies according to claim 1 within the applicator, as Abbott has asserted and not disputed by Sibio at the oral hearing. Para. [0102] relates to (among other) Fig. 10F which together with Figs. 10A-10N generally describes the mechanics of preparing the applicator for use. In view of the first sentence "Second, as the electronics assembly 310 descends further along the longitudinal axis Z (FIG. 10F), the sensor assembly 410 is forced into an opening in the electronics assembly 310 which couples the sensor to the electronics and completes assembly of the on-body device 222 (FIG. 2F)." (underlining added). The skilled person would therefore take note of it.

45. Para. [0102] teaches the skilled person that "to compel the components to remain locked and compressed together to insure a sealed, reliable connection", "mating snap features on the sensor assembly 410 and the electronics assembly 310 can be used". Para. [0102] furthermore mentions that "As an alternative to mating snap features, in some embodiments, the sensor assembly 410 and the electronics assembly 310 may be coupled by a light press fit or other connection method". As the snap features and the alternative are disclosed as achieving a *sealed* connection, the skilled person understands this to be a possible type of sealing as referred to in para. [0125]. The impugned decision thus did not confuse means intended to press parts together and sealing members, as Sibio suggests (para. 69-70 SoGA). The fact that para. [0145] in relation to the embodiment of Figs. 47A-47C discloses both an elastomeric sealing member as well as coupling features does not alter that. The coupling features disclosed there also function as (additional) sealing members, namely "to ensure that the electrical contacts are pressed tightly together and sealed within the socket 3704 and sensor assembly 3702" (underlining added).

46. In addition, when considering whether a claim as granted contains added matter, the application as a whole must be considered. Contrary to Sibio's view, the assessment shall not be restricted to the description of the embodiments that fall within the scope of claim 1. A proper understanding of the claimed embodiments requires an assessment in the context of the disclosure of the application as a whole. Also passages of the application that do not directly relate to the claimed embodiment may be relevant for the skilled person's understanding (of certain aspects) thereof.

47. In particular, in order to understand whether an elastomeric sealing in the recess of the enclosure is essential to the invention, the skilled person will also pay attention to other embodiments containing a recess. The skilled person shall appreciate that for the purposes of sealing a recess, it does not matter in which direction the mating of the electrical contacts takes place, either from above or from beneath. He shall therefore also pay attention to the embodiments where the sensor assembly is received in the recess of the enclosure from above (embodiments with a "plug-and-socket from above" configuration), thus to the embodiments shown in Figs. 25A, 25B and 26 and described in para. [0128] of the application. This teaches the skilled person that "it may be desirable to include a seal or gasket" that "advantageously includes discrete ring/rim elements to compress and ensure sealing in critical areas, including around each circuit connection/nubbin".

48. Sibio's argument that para. [0102] and [0128] do not disclose the creation of an electrical connection between the assemblies and therefore the sealing in those embodiments serves a different function than the elastomeric sealing in the embodiment of Figs. 47A-47C must be dismissed. First, as considered above, the elastomeric sealing does not serve the function of creating the electrical connection between the assemblies, but serves to seal (isolate) it. Second, both para. [0102] and [0128] also teach the creation of the connection between the assemblies as such, as well as the sealing thereof - by different methods. Para. [0102] mentions that the assemblies are coupled and the assembly of the on-body-device is completed thereby, and that the mating snap features – like an elastomeric sealing – can be used to compel the components to remain 'locked' and to 'insure a sealed, reliable connection'. The same applies to para. [0128] which mentions that a completed on-body device is provided once fitted with a

complementary sensor assembly, as shown in Figs. 25A and 25B which depict the receipt of the connector support in the recess, and also mentions that a seal or gasket may be included.

49. The application therefore in para. [0102] and [0128] already teaches the skilled person various ways of achieving sealing of the electrical contacts of the assemblies as an alternative for the use of an elastomeric sealing member in the recess of the enclosure as mentioned in para. [0150] disclosed in connection with the embodiment shown in Figs. 47A-47C. It is therefore irrelevant whether or not the claimed embodiment of Figs. 36-38 shows a sealing method similar to (as Sibio contends, para. 39-41, 45 SoGA) or different from (as Abbott argues, para. 73-75 SoR) the elastomeric sealing member disclosed in connection with the embodiment of Figs. 47A-47C.

50. Since the application also discloses a recess in the enclosure which has the function of receiving the shaped to fit connector support to achieve electrical coupling of both assemblies in combination with other sealing methods, the skilled person does not discern any structural relationship between the recess and an elastomeric sealing member.

51. The use of an elastomeric sealing in the recess of the enclosure is not a feature that the skilled person would consider essential to the invention of claim 1 and the effects to be achieved thereby. The skilled person would consider the claimed embodiment to also work with another type of sealing.

52. The skilled person knows as part of his common general knowledge that electrical contacts require sealing in order to lock them off from outside influence of dirt and moisture, which could cause a short and would disturb the functioning of the on-body device, as asserted by Abbott (para. 19 SoR) and not contested by Sibio at the oral hearing.

53. This also follows from para. [0125] of the application. This paragraph 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. It rather leaves it to the common general knowledge of the skilled person which type of sealing he uses for any particular configuration.

54. The application contains various examples of sealing, without prioritising one over the other. The skilled person does not discern in the original application any prescribed or even advantageous or rather disadvantageous type of sealing for use in connection with any particular type of configuration. There is no indication in the application – and Sibio has not advanced – that and why the skilled person would consider any type of sealing as mentioned in the application to be unsuitable for the embodiment of the invention. Specifically for the sealing of the recess, in para. [0102] and [0128] the application teaches the skilled person that a specific type of sealing – in particular the use of an elastomeric sealing member – is not necessary to achieve the technical teaching of the invention and that a recess as claimed may be implemented without also implementing an elastomeric sealing member. Or, in other words, the skilled person would not understand that the invention would only work with an elastomeric sealing in the recess of the enclosure.

55. Omitting an elastomeric sealing in the recess of the enclosure – or any other type of sealing – from the claim does not convey new technical information. The skilled person would not think no sealing is required. Based on the teaching of the application and his common general knowledge the skilled person would consider sealing of the electrical contacts essential to prevent a short (see e.g. para. [0142]) and thus to ensure the proper functioning of an on-body device generally. As instructed by para. [0125] he will apply sealing using any of the known methods as he deems fit for the particular configuration chosen, based on his common general knowledge. There is no indication in the application or otherwise that the

skilled person would consider *only* an elastomeric sealing to be appropriate for that purpose in relation to the configuration of claim 1.

56. Sibio's argument that it is essential to have an elastic conductive component between the glucose sensor and the sensor electronics due to relative movement from each due to wear or other reasons (para. 52, 65-66 SoGA) cannot be accepted to be the skilled person's understanding. Sibio failed to show where this alleged problem of relative movement was mentioned in the application that could lead to an understanding that only an elastomeric sealing in the recess of the enclosure could be an appropriate sealing method. Sibio has rightly mentioned that the application mentions that the electrical contact needs to be reliable, but this is a general requirement (see para. [0006]) and not specific to the claimed embodiment. Furthermore, the application describes the sensor connector as 'shaped to fit', while the skilled person appreciates when looking at the figures that the electrical contacts are relatively large, so that complete dis-alignment is unlikely to happen.

57. Also para. [0125], referred to by Sibio, does not specifically refer to an elastomeric sealing member. Sibio's explanation (para. 66 SoGA), that this is because the paragraph relates to all described embodiments and the electrical connection and its sealing can be established through a different (separate) element than an elastomeric sealing member in configurations not comprising a recess, does not hold. The application also discloses embodiments *with* a recess in combination with other sealing methods in para. [0102] and [0128] (discussed above). Neither has Sibio substantiated that a skilled person would understand that an elastomeric sealing member was essential based on its common general knowledge.

58. It follows from the above considerations that the application does not teach the skilled person that there is a structural or functional relationship / an inextricable link between any particular type of sealing, including an elastomeric sealing in the recess of the enclosure, and other features of claim 1, or – differently worded – that the use of any particular type of sealing, in particular an elastomeric sealing in the recess of the enclosure, is essential for achieving the technical effects of the invention as described above (para. 21-25).

Claim 15

59. The above considerations apply equally to claim 15.

Conclusion on added matter

60. To conclude, neither claim 1 nor claim 15 can be considered to contain an unallowable extension of subject matter compared to the disclosure of the original application or any of the earlier applications. As a consequence, there is no need to consider the auxiliary requests. Sibio's arguments that the dependent claims contain added matter are not part of the appeal proceedings, since the PCD disregarded these due to late filing (para. 21 of the impugned decision) and Sibio has not raised any substantiated objection in relation thereto in its Statement of grounds of appeal.

<u>Inventive step</u>

61. The principles for assessing inventive step have been set out by this Court in its decision of 25 November 2025 (UPC-CoA-528 and 529/2024 *Amgen v Sanofi & Regeneron*, para. 123-138). The object of the invention, i.e. the objective problem must be assessed from the perspective of the skilled person, with its common general knowledge, as at the application or priority date (also referred to as the relevant date). This must be done by establishing what the invention adds to the state of the art, not by looking at the individual features of the claim, but by comparing the claim as a whole in context of the description and the drawings, thus also considering the inventive concept underlying the invention (the technical

teaching), which must be based on the technical effect(s) that the skilled person on the basis of the patent description and drawings understands to be achieved with the claimed invention.

62. The parties agree that the problem to be solved is to provide a device that allows the on-body device to be freely moveable to different locations until being applied to the skin of the user (para. 81, 82 SoGA, para. 136 SoR). Since the on-body device is the assembled device, this means that the sensor and electronics assemblies are applied simultaneously.

63. There is only one inventive step attack maintained on appeal, which is based on D2 (WO'896) in combination with D1 (US'440).

64. Sibio relies on the embodiment shown in Figures 150-158 of WO'896 as a starting point. Figs. 150-156 are reproduced below (para. 76 SoGA).

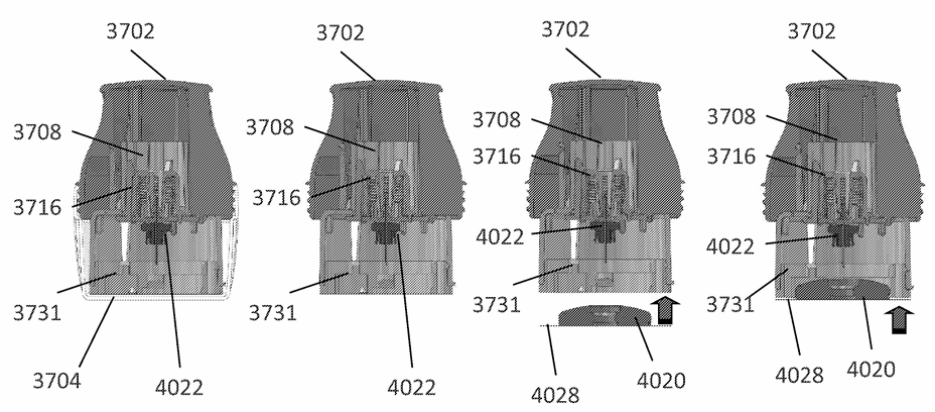


FIG. 150 FIG. 151 FIG. 152 FIG. 153

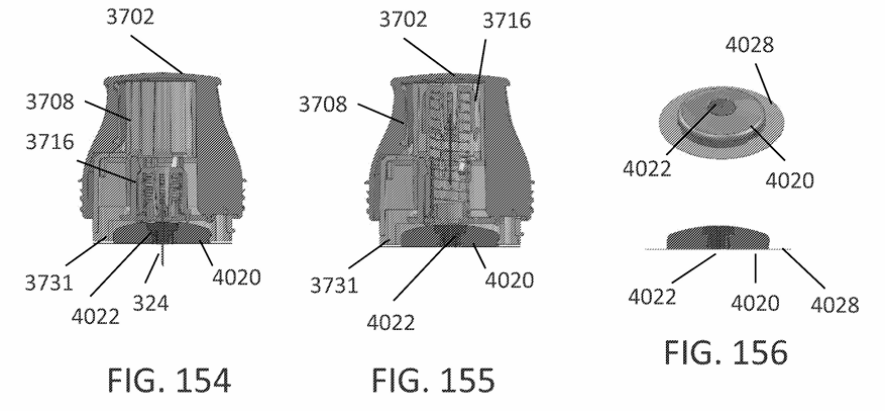


FIG. 154 FIG. 155 FIG. 156

65. In para. [00273]-[00275] of WO'896 this embodiment is described as follows:

> [00273] In some embodiments, the on-body housing is assembled on a surface (such as a tabletop) prior to insertion into the user. For example, as illustrated in FIGURES 150-156, the on-body housing may be comprised of a housing unit 4020 and an sensor hub 4022. The housing unit 4020 may include a mount and on-body electronics 14. In some embodiments, the sensor is at least partially positioned within the sensor hub 4022 and the distal insertion portion extends out of the sensor hub 4022. The sensor hub 4022 is contained in the inserter, and the housing unit 4020 is positioned in the inserter 3700. Electrical contact is made between the housing unit 4020 and the sensor in order to transfer the analyte readings from the sensor to the housing unit 4020. The inserter, similar to inserter 3700

described herein, is used to advance the distal portion of the sensor into the skin of the subject and to adhere the housing unit 4020 to the skin of the user.

[00274] As illustrated in FIGURE 150, the inserter 3700 is initially arranged with the cap 3704 attached to the housing 3702. The sensor hub 4022 is supported by the sharp carrier 3716, with the sharp 324 extending distally in a surrounding position about the sensor. FIGURES 151-155 illustrate the sequence of inserting the sensor into the skin of the user and the attachment of the housing unit 4020 to the skin of the user. In FIGURE 151, the cap 3704 is removed. In FIGURES 152-153, the housing unit 4020 is positioned in the housing support 3731, for example, by use of adhesive patch 4028. In FIGURE 154, the sharp carrier 3716 is advanced distally, thereby advancing the sensor hub 4022 distally and into engagement with the housing unit 4020. In FIGURE 155, the sharp carrier 3716 is released, thereby allowing the sharp carrier 3716 to move proximally. The inserter 3700 is removed, leaving the sensor hub 4022 coupled to the housing unit 4020, as illustrated in FIGURE 156.

[00275] In some embodiments, the housing unit 4020 and the adhesive patch 4028 are stored in a sealed compartment 4100 as shown in FIGURE 157. The compartment 4100 includes a lower cap portion 4104 and a cover portion 4102, manufactured from a flexible material such as metal foil or plastic. As shown in FIGURE 158, the lower cap portion 4104 stores the sterilized housing unit 4020 and adhesive patch 4028 therein until ready for use. In some embodiments, the adhesive patch 4028 includes adhesive on both sides."

66. Figures 150-158 thus relate to an embodiment where the 'sensor hub' 4022 holding the sensor is already contained in the inserter (Figs. 150-152) before the housing unit (containing the electrics assembly) is picked up from a flat surface (Figs. 152-153). The still separated assemblies are then applied to the skin by pushing the inserter, which advances the sensor hub distally and into engagement with the housing unit. Thus, the sensor assembly is coupled with the electronics assembly from above (a plug-and-socket from above configuration).

67. Sibio argues (para. 83/84 SoGA) that, considering the objective problem, the skilled person would first search in WO'896 for a relevant teaching and would find it in para. [00150]. This paragraph appears under the heading of "insertion assembly". An insertion assembly includes an inserter, the sensor and on-body electronics. Para. [00150] generally mentions that the body electronics (the electronics assembly) may be installed simultaneously with the sensor, after or before installation of the sensor. As such it mentions all thinkable possibilities and does not convey a particular teaching as to the order of installation of both assemblies.

68. According to Sibio, para. [00150] would teach the skilled person that the analyte sensor may first be installed by the inserter, and the on-body electronics may be subsequently installed. However, Sibio failed to explain why the skilled person would then nevertheless select the embodiment of Figs. 150-156 as a starting point to solve his problem, since that is not an embodiment according to that teaching, but a "plug-and-socket from above" configuration, whereby electronics assembly is first applied to the skin and the sensor assembly is subsequently received therein from above.

69. Since the analyte sensor (sensor assembly) is already contained in the inserter (Figs. 150-151) before the on-body electronics (electronics assembly) is picked up in the mouth of the inserter (Figs. 152) the analyte sensor assembly cannot be first installed by the inserter. Changing the order of installation of the respective assemblies in the inserter so that the analyte sensor may be installed first would require a re-design of the entire configuration of inserter, analyte sensor and on-body electronics. Failing an indication how that may be achieved, this would not be obvious to the skilled person.

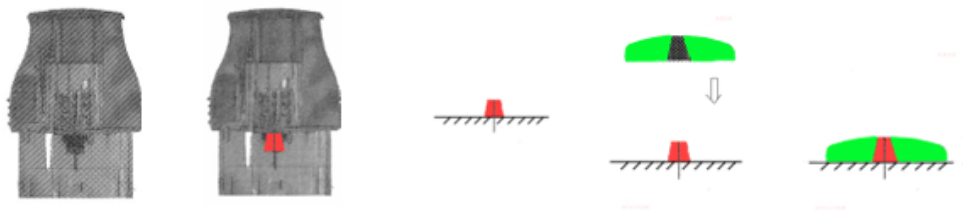
70. Furthermore, in the configuration of the embodiment of Figs. 150-158, once the on-body electronics has been picked up by the inserter (Fig. 153) it is impossible to freely move the inserter over the skin surface before the application of the on-body device to the skin, since the skilled person understands that prior

to the step of Fig. 154 (when the inserter is used to advance the distal portion of the sensor into the skin and *adhere* the housing unit to the skin, cf. para. [00273] final sentence) the protective liner of the adhesive patch on the bottom part of the on-body electronics (4028 in Fig. 156) needs to be removed in order to allow the on-body electronics to adhere to the skin. There is no assembly of the on-body device in the inserter prior to that application step, as is clear from Fig. 153 where the sensor hub 4022 and housing 4020 are not yet coupled. Freely moving the inserter can only be done prior to picking up the on-body electronics, but then it is no longer the assembled on-body device that is freely movable. Also, first applying the analyte sensor and subsequently placing the on-body electronics on top of it would lead to a two-step application, while the object is to provide a device where the sensor assembly and sensor electronics are applied in one step (namely as an already assembled device).

71. Since the embodiment of Figs. 150-158 of WO'896 thus does not teach that it can be used to solve its problem, contrary to what Sibio argues (para. 93 SoGA), the skilled person would not consider this embodiment as a reasonable starting point to solve its problem. The inventive step attack by Sibio already fails for this reason.

72. Even if this embodiment were chosen as a starting point, it would not lead the skilled person to the invention.

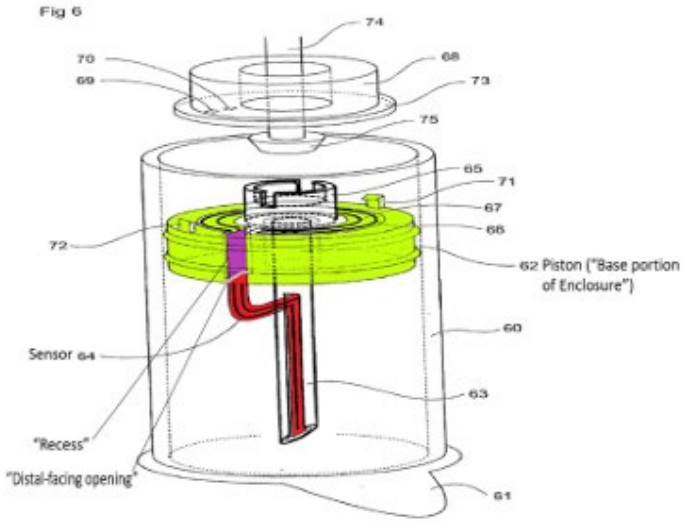
73. According to Sibio, implementing the teaching of para. [00150], the skilled person would start with the inserter with the sensor assembly at the stage of Fig 151 (step 1), change the shape of the sensor assembly (step 2), and then apply it to the skin (step 3). The skilled person would realise that after installing the analyte sensor, the on-body electronics would need to be modified to be able to install it onto the analyte sensor. The skilled person would consult US'440 for that purpose, which would teach it that this can be achieved by 'bottom-mounting', redesign and install the body electronics onto the sensor analyte (step 4-5), so Sibio argues (para. 85-93 SoGA).



(1)	(2)	(3)	(4)	(5)
The drawing 151 is the starting point	*Slightly adjust the shape of the analyte sensor*	*Install the analyte sensor*	*Add the body electronics subsequently*	*The combination results in an on-body device as claimed*

74. The skilled person would not have an incentive to combine Fig. 6 of US'440 that Sibio relies on with WO'896 because with the resulting configuration as suggested by Sibio (see above), the object of the invention would not be achieved. It would not allow the applicator containing the *fully assembled* on-body device (which contains both the sensor assembly and the electronics assembly) to freely move over the skin surface before its application *in one step*, as Sibio argues (para. 86 SoGA). Rather, as mentioned above, only the inserter with included analyte sensor may be freely moveable, while the on-body electronics are applied separately in a second step. As a result, it also does not achieve the technical effect of avoiding inconvenience and pain, because of the risk that the user touches the analyte sensor with the adhesive patch at the bottom part of the on-body electronics (4028 in Fig. 156) when it is mounted on the sensor assembly. Also for this reason Sibio's inventive attack fails.

75. In addition, even if the skilled person would consider combining the embodiment disclosed in US'440 with WO'896, it cannot lead to the invention of claim 1.



76. In Fig. 6 of US'440 above (coloured by Sibio), according to Sibio, the 'recess' of features 1.4 and 1.5, having a distal facing opening and extending from the bottom exterior surface of the piston 62, is shown in purple. The sensor 64 is shown in red. The piston 62 (in green) represents the 'base portion of the enclosure'. The sensor would be conveyed through the distal facing opening of the recess in the piston / base portion of the enclosure into the recess (para. 90 SoGA), so Sibio asserts. This cannot be accepted. When considering Fig. 6, together with the disclosure of US'440, the skilled person would identify the upper part (with reference numbers 68-70 and 73-75) as the enclosure containing the sensor electronics, and the lower part (with reference numbers 60-67 and 71,72) as the sensor assembly. The piston 62 is therefore part of the sensor assembly and cannot be considered to represent the base portion of the enclosure having a recess. Thus, feature 1.4 is not disclosed. It follows that feature 1.5 is not disclosed either. Since Sibio's obviousness argument proceeds on the basis that the embodiment of Figs. 150-158 of WO'896 does not disclose these features either (para. 80 SoGA), the combination with US'440 would not lead to the invention of claim 1.

77. Sibio asserted that the lack of disclosure of features 1.5 and 1.6 in US'440 is not relevant, because it would teach that "bottom-mounting" is possible (para. 90 in fine SoGA). That is rejected. In US'440, the enclosure (with electronics assembly) is mounted on the sensor assembly from above, in downward direction (which Sibio calls 'top-mounting' (para. 89 SoGA)), rather than that the sensor assembly is received in a recess of the on-body electronics from beneath, in upward direction, as implied by claim 1. The general teaching therefore also cannot lead to the invention according to claim 1. This is also clear from the configuration that Sibio asserts would be achieved by the skilled person (see para. 73 above). In steps 4-5, assembly of the on-body device occurs by placing the on-body electronics over the analyte sensor from above (downwards), rather than by receiving the analyte sensor (through the connector support) into the recess in the bottom exterior of the on-body electronics from beneath (upwards), as implied by features 1.4 and 1.5 of claim 1.

Conclusion on inventive step

78. To conclude, the inventive step attack based on a combination of WO'896 as a starting point, combined with US'440 must be rejected.

Conclusion

79. Since the added matter attack as well as the inventive step attack fail, Sibio's request for revocation of the Patent must be dismissed. As the unsuccessful party, Sibio will be ordered to bear Abbott's costs and other expenses of the proceedings.

DECISION

The Court of Appeal:

- dismisses Sibio's appeal;
- orders Sibio to bear Abbott's costs and other expenses of the appeal proceedings.

Issued on 14 August 2026

Rian Kalden Date: 2026.08.14 16:08:04 +02'00'

Rian Kalden, legally qualified judge and judge-rapporteur

Patricia Ursula Rombach Digitally signed by Patricia Ursula Rombach Date: 2026.08.14 11:08:29 +02'00'

Patricia Rombach, legally qualified judge

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Ingeborg Simonsson, legally qualified judge

MARC WILLEM DIRK Van der Burg Digitaal ondertekend door MARC WILLEM DIRK Van der Burg Datum: 2026.08.14 13:45:20 +02'00'

Marc van der Burg, technically qualified judge

Digitally signed Rydman Jonas Patrik 2026-08-14 11:43:02 +0200

Unified Patent Court Einheitliches Patentgericht Juridiction unifiée du brevet

Patrik Rydman, technically qualified judge