Unified Patent Court
Einheitliches Patentgericht
Juridiction unifiée du brevet

Central Division

Paris Seat

DECISION
of the Court of First Instance of the Unified Patent Court
Central division - Paris seat
issued on 21 July 2025
in the revocation action No. ACT_27463/2024
UPC_CFI_231/2024

HEADNOTES: 1. Lack of novelty and lack of an inventive step are separate grounds for revoking a patent and cannot be absorbed when asserted against the same prior art document. Simply indicating in general terms that a prior art document will be used to challenge the patent's novelty and/or inventive step, providing a detailed analysis of the document only with respect to inventive step, is insufficient to establish that the document is being used to challenge the patent's novelty.

2. Although the dependent claims are subordinated to the independent claims, the grounds for their revocation must be stated at the outset, as the latter form part of the overall challenge to the patent in its entirety.

3. In accordance with the principle of flexibility and efficiency set out in paragraph 4 of the Preamble to the Rules of Procedure, Rule 75(3) 'RoP' must be interpreted as not applying when a counterclaim for revocation concerning the same patent is brought in a subsequent infringement action before a local division of the UPC, provided that the oral hearing in an earlier revocation action before a central division has already taken place.

KEYWORDS: revocation; novelty; inventive step; late filed arguments; Rule 75(3) 'RoP'

CLAIMANT:

Sibio Technology Limited
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represented by Dr. Thomas Gniadek, Simmons & Simmons LLP
contributing: Fritz Lahtz, Oscar Lamme, Florian Laus, Dr. Diptanil DebBarma

DEFENDANT:

Abbott Diabetes Care Inc.

1360 South Loop Road, CA 94502, Alameda, US

represented by Wim Maas, Taylor Wessing N.V. and François Pochart and Mehdi Mahammedi-Bouzina, August Debouzy
contributing: Christian Dekoninck, Faziel Abdul, Christopher Thornham, Nigel Stoate, Geert Theuws, Taylor Wessing N.V

PATENT AT ISSUE

European patent **EP 3 831 283 B1,** hereafter referred to as "EP'283" or as "the Patent".

DECIDING JUDGES

Panel 2 of the Central Division (Paris Seat)

Paolo Catallozzi	Presiding judge
Tatyana Zhilova	Legally qualified judge and judge-rapporteur
Renaud Fulconis	Technically qualified judge

DATE OF THE ORAL HEARING

4 June 2025

LANGUAGE OF THE PROCEEDINGS

English

SUMMARY OF FACTS AND PARTIES' REQUESTS

1. On 15 May 2024 Sibio Technology Limited (hereafter, the Claimant or Sibio) filed a revocation action against Abbott Diabetes Care Inc. (hereafter the Defendant or Abbott) concerning the patent at issue (EP'283) before the Paris Central Division, registered as No. ACT_27463/2024 UPC_CFI_231/2023.

2. Abbott is the registered proprietor of EP'283. The Patent is titled "Analyte Sensor Devices, Connections, and Methods" and relates to an *in vivo* analyte monitoring device and method.

3. The patent was filed on 11 December 2012 and claims the priority of US 201161569287 from 11 December 2011. The grant of the Patent was published and mentioned on 26 April 2023. According to the Claimant and undisputed by the Defendant, EP'283 at the time of filing the statement of claim was valid in the following contracting member states of the UPCA: Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, The Netherlands and Sweden. An opt-out from the exclusive jurisdiction of the UPC had been declared and withdrawn on 15 March 2024.

4. The Claimant challenges the validity of the patent on the grounds of added subject matter and lack of novelty and inventive step. The Defendant contests the alleged grounds for revocation. Alternatively, if the Court finds that the grounds for revocation are justified, the Defendant submits six auxiliary requests to amend the patent and overcome the invalidity of the claims as granted.

5. The Claimant requests the following decision in merit:

(1) European patent EP'283 to be revoked in its entirety for all Member States of the UPC that the Patent is validated in.

(2) The Defendant's alternative requests to maintain the patent based on any of Defendant's proposed amendments of the claims of the patent to be dismissed.

(3) Defendant to be ordered to bear the legal costs of the proceedings.

6. The Defendant requests the following decision in merit.

(1) The revocation action be dismissed;

(2) The Patent be maintained:

a) as granted;

or

b) in the alternative based on one of the proposed amendments of the claims of the Patent.

(3) Claimant to be ordered to bear the legal costs of the proceedings.

7. By Order of the judge-rapporteur, issued on 14. April 2025 following the interim conference held on 9 April 2025, the value of the proceedings was set for the purpose of applying the scale of ceilings for recoverable costs for this case to be EUR 2,500,000.00.

8. Following the oral hearing, the Claimant filed a counterclaim for revocation relating to the same patent in the infringement action pending before The Hague LD (ACT_12915/2025, UPC_CFI-230/2025 and CC_32605/2025). As the counterclaim was filed after all procedural activities in the present case had been completed – specifically, after the oral hearing and the subsequent deliberation on the merits – there were no further pending proceedings involving the parties. Therefore, in accordance with the principle of flexibility and efficiency set out in paragraph 4 of the Preamble to the Rules of Procedure, Rule 75(3) 'RoP' does not apply.

GROUNDS FOR THE DECISION

A. Procedural issues

I. Late filed arguments

9. In the Statement for revocation the Claimant states that all cited prior art documents "will be used to argue against novelty/inventive step of the Patent" (p. 17 of the Statement for revocation). Further, the novelty of the Patent is challenged in respect to independent claims 1 and 15 only over prior art documents US 2008/0255440 A1 (Exhibit D1, hereafter US'440 or D1) and WO 2011/077893 A1 (Exhibit D3, hereafter WO'893 or D3) by means of detailed arguments. In the Reply to the Defence to revocation the Claimant argues that the Patent is also not novel over the prior art document WO 2011/119896 A1 (Exhibit D2, hereafter WO'896 or D2) which has only been used in combination with other prior art documents in details to attack the inventive step of claim 1 so far.

10. In the Statement for revocation, the allegation of added matter is made only with regard to the independent claims 1 and 15 and the validity of the dependent claims is challenged only on the grounds of lack of novelty and inventive step. In the Reply to the Defence to revocation, the Claimant argues that also the subject-matters of the dependent claims comprise added matter.

11. The Defendant objects to the newly raised arguments on the grounds for revocation that they were filed too late.

12. As a rule, the parties are obliged to present their complete case as early as possible (Preamble to the RoP, para. 7, last sentence).

13. Rule 44 'RoP' states that the statement for revocation shall contain "… (e) one or more grounds for revocation, which shall as far as possible be supported by arguments of law, and where appropriate an explanation of the claimant's proposed claim construction; (f) an indication of the facts relied on; (g) the evidence relied on, where available, and an indication of any further evidence which will be offered in support …".

14. This provision must also be interpreted in the light of the principle of proportionality, as set out in the Preamble of the 'RoP', which requires that the parties should not be burdened with tasks that are unnecessary to achieve the stated objective. However, it must be noted that Rule 44 'RoP' requires an "indication" of the facts relied on and this seems to support an interpretation of the relevant provisions contrary to an overly strict application of the 'front loaded' procedural system.

15. Additionally, it can be considered that a document may be introduced into the proceedings at a later stage if it becomes available to the party during the proceedings, given the principle of fairness which protects a party that has acted in a diligent way.

16. Therefore, it can be concluded that the claimant in revocation proceedings must specify the grounds for invalidating the contested patent in detail, as well as the prior art documents used to support any allegations of a lack of novelty or inventive step. This defines the subject matter of the dispute, enabling the defendant to understand the allegations made against them and prepare an adequate defence. It also allows the court to determine the scope of its jurisdiction in relation to the claim.

17. Consequently, the claimant cannot introduce new grounds of invalidity of the attacked patent or introduce new documents considered novelty destroying or prejudicial to inventive step in subsequent written acts.

18. However, it should be noted that in certain situations, following the defence raised by the defendant, the claimant may need to allege new facts, insofar as they are considered capable of supporting the main facts already timely alleged and disputed by the defendant. In this case, the need to respond to the defendant's defence, the terms of which cannot be foreseen ex ante by the claimant, justifies the introduction of such new facts in the reply to defence to revocation.

19. Likewise, the need to produce new evidence may arise from the defendant's defence which disputes the facts alleged by the claimant or the probative value of the evidence already filed in Court.

20. This is consistent with the principles set by the Court of Appeal (order issued on 21 November 2024, UPC_CoA_456/2024) according to which, while the parties are required to set out their case as early as possible in the proceedings, nevertheless specific new arguments may be admitted into the proceedings in consideration of specific circumstances of the case.

21. Applying these principles to the present case, it must be concluded that the newly raised arguments for lack of novelty of the independent claims and added subject-matter in the dependent claims are inadmissible. The burden is on the claimant to convince the Court that, even with due care, it was not possible for it to include the (further) attacks on novelty and added subject-matter contained in the Reply to the defence for revocation and that admitting these further attacks would not put the defendant at an unreasonable disadvantage when exercising its rights (see, LD Düsseldorf, UPC_CFI_11/2024, decision of 8 May 2025). In the present case, the newly raised arguments do not follow the defence and there are no objective obstacles to their earlier presentation. Indicating in general terms that D2 will be used to challenge the patent's novelty or inventive step without providing a detailed analysis of the document with respect to novelty is insufficient to establish that this document is being used to challenge the patent's novelty. Although the dependent claims are subordinated to the independent claims, the grounds for their revocation must be stated at the outset, as the latter form part of the overall challenge to the patent in its entirety.

22. For these reasons, the Court will not discuss these arguments on the merits.

II. Admissibility of the auxiliary requests

23. In its Defence to revocation on 2 October 2024, the Defendant filed an application to amend the patent based on six auxiliary requests (ARs). The defence was filed in accordance with Rule 4 'RoP' in electronic form. At the time of filing the defence, the Case Management System ('CMS') offered a special electronic form for applications to amend the patent. Although all of the formal requirements for lodging an application to amend the patent were met, a separate workflow was not opened.

24. The Claimant filed its Reply to the defence to revocation on 2 December 2024, which also contained a Defence to the Application to amend the Patent.

25. Further, on 16 January 2025, the Claimant filed the same ARs in a separate workflow (App_2749/2024).

26. On 14 February 2025, the Court of Appeal issued the decision in case UPC_CoA_382/2024, APL_39664/2024 concerning the proceedings on application for provisional measures between the same parties in the matter of EP'283 before The Hague LD (UPC_CFI_131/2024, ACT_14945/2024). The Hague LD denied Abbott's request for provisional measures as the patent was held to be likely invalid due to added matter (order of 19 June 2024). The Court of Appeal overturned this order and held the patent likely valid and infringed.

27. On 17 February 2025, the Claimant filed a Rule 9 'RoP' application registered as No. App_7973/2025 for rejection of the ARs filed in the main proceedings with the Defence to revocation as inadmissible because they were not filed in the proper workflow. In this application, the Claimant commented as well on the Court of Appeal's order.

28. The admissibility of the ARs was discussed at the interim conference held by the judge-rapporteur. In view of the Claimant, the ARs are inadmissible, because they were not filed in the correct form under Rule 30 'RoP' which provides for a specific inter omnes transparency mechanism. The Court of Appeal was unaware of the Application to amend the patent, precisely because it was not filed in the Rule 30 workflow and there was no notification from the 'CMS'. This seriously harmed Claimant's interests, because if the

Court of Appeal had known about the Application to amend the patent, it might have taken a different decision. The parallel workflow is contrary to the principle of efficiency of the procedure and leads to additional costs of representation, as the representatives have to react again.

29. In view of the Defendant, the ARs are admissible as they were filed in accordance to the 'RoP'. It cannot be said with certainty that the Application to amend the patent would have had any effect on the decision of the Court of Appeal. In the latter, the objections of added matter were rejected solely on the basis of the patent as granted. It is not true that the parallel workflow causes additional costs because the Claimant has already filed its pleading against the ARs in the main proceedings. By order No. ORD_8542/2025 in App_7973/2025, the judge-rapporteur referred the Application to the full panel.

30. The Defendant is right. The right to request an amendment to a patent is an essential part of the right to defend against a revocation action or counterclaim. This substantive right, which affects the scope of protection of the patent, is established in Article 138(2) of the European Patent Convention ('EPC') and Article 65(3) of the 'UPCA'. The procedural requirements for exercising this right are set out in Rule 30 'RoP'. According to this rule, a request to amend the patent may be included in the Defence to revocation. On the other hand, when filing their pleadings and applications with the 'CMS', the parties must use the official electronic form pursuant to Rule 4 'RoP'. However, failure to comply with the requirement of Rule 4 'RoP' cannot result in the inadmissibility of the Application to amend the patent included in the Defence to revocation. Given the existence of two competing provisions in the 'RoP', giving greater weight to the electronic form than to the substantive content would violate the principles of proportionality and fair trial, particularly since electronic forms can be easily modified by any change to the electronic filing system or the introduction of a new one.

31. The arguments put forward by the Claimant regarding the Court of Appeal's order are unfounded. Firstly, the provision of Article 76(2) of the 'UPCA' must be taken into account, according to which decisions on the merits may only be based on grounds, facts and evidence submitted by the parties or included in the proceedings by an order of the Court, on which the parties have had an opportunity to comment. There is no provision under which the Court is required to consider an application to amend a patent filed in other proceedings, even if submitted in a separate electronic form (workflow). Rule 30(3) 'RoP' requires the claimant to inform the Court before other proceedings concerning the same patent are pending of the application to amend the patent in suit filed in the revocation proceedings. The purpose of this requirement is to enable the other Court to assess the impact that amending the patent would have on the resolution of the pending dispute. In the present case, there is no evidence that the Claimant took advantage of this possibility, even though it became aware of the filed request for amendment of the patent in the revocation action during the proceedings before the Court of Appeal. Secondly, there is no reason to assume that the Court of Appeal's order would have been different had it taken the request to amend the patent into account. The objection that the claimant was unfairly burdened by additional costs is unconvincing, irrelevant to these proceedings and should not be discussed.

32. For these reasons, the claimant's request to dismiss the ARs is to be rejected.

B. Issues on merit

I. Legal framework

33. The Court of Appeal of the UPC has laid down the following legal framework for the interpretation of patent claims (order dated 26 February 2024, UPC_CoA_335/2023, paras. 26-27; see also order dated 13 May 2024, UPC_CoA_1/2024).

34. In accordance with Art. 69 'EPC' and the Protocol on its interpretation, a patent claim is not only the starting point, but the decisive basis for determining the scope of protection of a European patent. The interpretation of a patent claim does not depend solely on the strict, literal meaning of the wording used. Rather, the description and the drawings must always be used as explanatory aids for the interpretation of the patent claim and not only to resolve any ambiguities in the patent claim. However, this does not mean that the patent claim merely serves as a guideline and that its subject-matter also extends to what, after examination of the description and drawings, appears to be the subject-matter for which the patent proprietor seeks protection.

35. A feature in a patent claim is always to be interpreted in the light of the claim as a whole (see Court of Appeal, order issued on 13 May 2024, UPC_CoA_1/2024, para. 29). From the function of the individual features in the context of the patent claim as a whole, it must be deduced which technical function these features actually have individually and as a whole. The description and the drawings may show that the patent specification defines terms independently and, in this respect, may represent a patent´s own lexicon. Even if terms used in the patent deviate from general usage, it may therefore be that ultimately the meaning of the terms resulting from the patent specification is authoritative. In applying these principles, the aim is to combine adequate protection for the patent proprietor with sufficient legal certainty for third parties.

36. The relevant point in time for interpreting a patent claim for the assessment of validity is the filing (or priority) date of the application that led to the Patent.

37. The patent claims are to be interpreted and assessed from the point of view of a person skilled in the art.

II. The concept of person skilled in the art and the common general knowledge

38. The identification of the person skilled in the art and the common general knowledge ('CGK') can conveniently be done in one go.

39. The person skilled in the art (skilled person) is a legal fiction which, in the interests of legal certainty, forms a standardized basis for the assessment of the legal concepts of 'prior art', 'novelty', 'inventive step' and 'sufficiency of disclosure'. The skilled person stands for the average expert who is typically active in the technical field of the invention, has had the usual prior training and has acquired average knowledge, skills and practical experience for routine work, but does not have inventive imagination, thinking and skills. When interpreting a patent claim, the person skilled in the art does not apply a philological understanding but determines the technical meaning of the terms used with the aid of the description and the drawings.

40. When interpreting the claims and determining the profile of the skilled person, the following must be borne in mind: conventional techniques for conducting biological indicator studies are *in vitro* techniques, whereby the studies are conducted on biological material, such as cells, tissue or fluid, separated from the organism under laboratory

conditions. These techniques are conducted entirely outside the organism's natural biological environment. *In vivo* techniques also involve analysing biological material, but it is not separated from the organism under laboratory conditions. These techniques are carried out directly on the living organism in its natural environment by special devices. Usually, it is necessary to implant an electronic sensor in the organism to analyse biological samples, transmit data and store it.

41. Parties completely agree on the qualification of the skilled person who should be 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* techniques. The court accepts this profile of the skilled person, emphasising professional and practical experience in the field of electronic devices for *in vivo* analysis.

42. The 'CGK', in general, is information which has been commonly known to the skilled person from written sources or from practical experience in the relevant technical field. A familiar source of information typically is a source to which a skilled person regularly turns for guidance on standard design solutions that are generally applicable, such as standard textbooks, encyclopaedias, manuals, handbooks, dictionaries and databases which the skilled person knows and can use as a suitable and reliable source for the respective information in the respective technical field or other closely related technical field.

43. In any case, the 'CGK' is subject of evidence. Pursuant to Art. 54 of the UPCA, the burden of proving the existence of the 'CGK' lies with the party invoking it. Without bearing the burden of proof, the opposing party may present evidence to establish the 'CGK', including evidence to the contrary.

III. Technical field and prior art discussed in the patent at suit

44. The Patent relates to an on-body device and method for in vivo monitoring of blood glucose levels titled "Analyte Sensor Devices, Connections, And Methods" (para. [0001] of EP'283).

45. The vast and uncontrolled fluctuations in blood glucose levels in people suffering from diabetes cause long-term, serious complications. Accordingly, one important and universal strategy in managing diabetes is to control blood glucose levels (para. [0003] of EP'283).

46. The prior art is described in para. [0005] of EP'283: "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".

47. The patentee states in para. [0006] of EP'283 that the systems described in the prior art do have a number of advantages, but there is still opportunity for improvement, particularly to make the applicator systems configured to handle insertion, as well as

packaging and user interface issues easy-to-use, reliable and minimizing both user inconvenience and pain.

IV. The invention

48. Given this background, the object of the Patent is to provide improved *in vivo* application systems for glucose level monitoring.

49. The problem to be solved by the invention, as defined in [0006] of EP'283, is how to provide an easy-to-use and reliable on-body device and minimize both user inconvenience and pain.

50. The patented invention is defined by claim 1 of EP '283, having 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 within the enclosure, the sensor electronics comprising a processor (4804), and a communications facility,
Feature 1.4	wherein the base portion of the enclosure comprises a recess (3704, 4710) in a bottom exterior surface, the recess (3704, 4710) comprising a distal-facing opening,
Feature 1.5	wherein the connector support (3604, 4706) is received through the distal-facing opening and into the recess (3704, 4710), and
Feature 1.6	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).

51. Fig. 3 of EP'283 illustrates an assembly view of an applicator or inserter. Fig. 4 is an assembly view of a sensor container or loader.

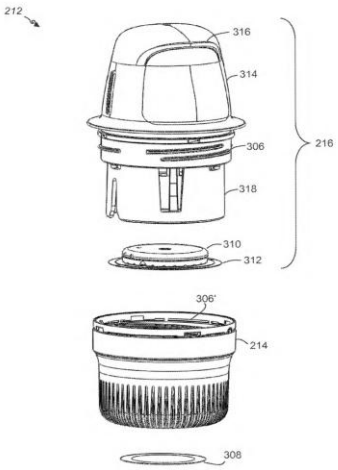


FIG. 3

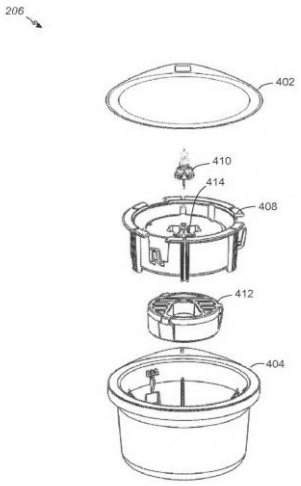


FIG. 4

52. Fig. 47A and 47B of EP'283 show two different views of an on-body device including an integrated connector for the sensor assembly.

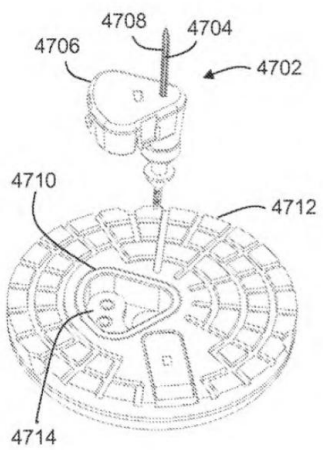


FIG. 47A

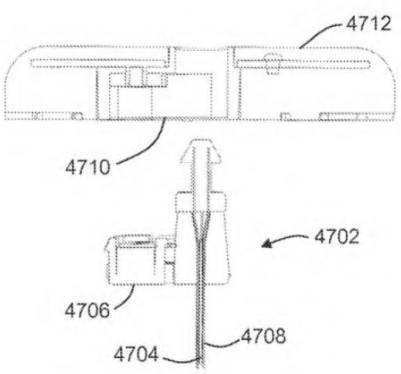


FIG. 47B

53. Furthermore, the patent comprises 13 dependent claims (claims 2 to 14) establishing different embodiments of the device of claim 1.

54. Claim 15 relates to a method for assembling an on-body device. The features of claim 15, therefore, mostly correspond to those of claim 1. Claim 15 can be broken down as follows:

Feature 15.0	A method for assembling an on-body device comprising
Feature 15.0.1	a glucose sensor assembly (3702, 4702),
Feature 15.0.2	an enclosure, and
Feature 15.0.3	sensor electronics,
Feature 15.1	wherein the glucose sensor assembly (3702, 4702) comprises a proximal section comprising a connector support

Feature 15.1.1 coupled with a proximal portion (3310) of a glucose sensor (3300, 4704), and

Feature 15.1.2 a distal tail section comprising a distal portion (3302) of the glucose sensor (3300, 4704)

Feature 15.1.2.a configured to be positioned under a skin surface and in contact with a bodily fluid of a subject,

Feature 15.2 wherein the enclosure comprises a top portion (5002) and a base portion (5004),

Feature 15.3 wherein the base portion (5004) comprises a recess (3704, 4710) in a bottom exterior surface, and

Feature 15.4 wherein the recess (3704, 4710) comprises a distal-facing opening,

Feature 15.5 the method comprising: positioning the sensor electronics within the enclosure of the on-body device,

Feature 15.6 wherein the sensor electronics comprise a processor (4804), a communications facility;

Feature 15.7 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),

Feature 15.7.1 causing the glucose sensor (3300, 4704) to electrically couple with the sensor electronics.

55. Furthermore, the patent comprises 11 dependent claims (claims 16 to 26) establishing different embodiments of the method of claim 15.

V. Claim interpretation

56. Claim 1 of EP'283 requires interpretation of some terms regarding its features debated between the parties.

57. Feature 1.1.1 in conjunction with features 1.4, 1.5 and 1.6 with regard to the term 'a connector support' needs interpretation in the light of Fig. 34A-34D and Fig. 36-38 of the Patent. According to the Claimant's view, the term 'a connector support' does not include a separate connector to provide electrical connectivity between the glucose sensor and the sensor electronics – respectively, the embodiments in Fig. 34A-34D (paras. [0084] and [0085]) which are referred to as an alternative connector arrangement for connecting a circuit board to a sensor 3300 and which have not a recess do not fall in the scope of protection of feature 1.1.1. and feature 1.4. Claimant's arguments are not convincing for the following reasons:

I. Features 1.1.1 and 1.1.2 define the general structure of the glucose sensor assembly of proximal and distal sections and a connector support shown in Fig. 36 -38. The connector support creates the reliable connection between the glucose sensor and

the sensor electronics. To the skilled person's understanding, the term 'a connector support' is not limited to only one connector or to a support comprising only one element. Any other types of connecting elements may be used when needed.

II. Fig. 34A-34D disclose an embodiment with an additional separate connector which may be used for electrical connectivity and, thus, it falls under the scope of claim 1, feature 1.1.1 in the meaning given above. Para. [0088] of the Patent makes a link between Fig. 34A-34D and Fig. 36-38.

III. It is true that the recess is not shown in Fig. 34A-34D. However, the skilled person would clearly understand from para. [0088] and Fig. 38 of the Patent that the connector support shown in Fig. 34A-34D is intended to be received into a recess.

58. Feature 1.2.2 'a base portion (5004) configured to be adhered to the skin surface by an adhesive patch' must be understood to mean ''a base portion suitable for being adhered to the skin surface by an adhesive patch'. In the above-cited decision on provisional measures concerning the patent on suit, the Court of Appeal laid down the general principle of interpretation whereby means-plus-function features must be understood as any feature suitable for carrying out the function.

VI. The added matter attack

59. The Claimant argues that the patent as granted has extended the subject-matter of the claims beyond that of the earlier application as filed and raises several arguments in support of this allegation. With respect to claim 1 of the patent, the Claimant presents the following objections:
- The combination of features of claim 1 is not based on a single embodiment of the earlier application as filed. Instead, the Defendant has artificially combined various features selected from unrelated passages of the application as filed – what is sometimes referred to as "cherry picking" features from an original disclosure.
- The features of claim 1 were only originally disclosed in combination with other features, and in particular in combination with an elastomeric sealing member. By omitting to recite such elastomeric sealing member in claim 1, an unallowable intermediate generalization was made.
- The features of claim 1 were only originally disclosed in combination with the notion that the on-body device is arrangeable in position by way of a specific apparatus. By omitting to recite that the on-body device of claim 1 is arrangeable in this manner, an unallowable intermediate generalization was made.
- There is no direct and unambiguous disclosure of the sensor electronics positioned within the enclosure.
- There was a change in wording in claim 1 relative to the disclosure of the earlier application as filed.

60. The patent in suit is a second generation divisional based on the European patent application having the publication number EP 3300658, which itself is based on the European patent application having the publication number EP 2713879 (and originally published as PCT application No. WO 2013/090215). By "earlier application as filed" is meant the content of EP 3300658 as originally filed. The Court understands that the Claimant's added matter objections are equally applicable based on the application as filed itself and on the earlier application as filed as their contents are similar.

61. The Court will address the Claimant's five objections in turn.

62. For independent claim 15, the Claimant merely states that the reasoning on alleged added matter is the same as for claim 1.

63. In addition, the Claimant also raises added matter objections against the dependent claims. However, these further objections are not admitted into the proceedings for the reasons presented above (para. 20).

64. It must first be observed that, as already mentioned, the Defendant sought a preliminary injunction and other interim measures against the Claimant due to direct infringement of the patent in question. In those proceedings, the Claimant defended itself by pleading the invalidity of the Patent on grounds substantially identical to those raised herein.

65. The request for interim measures was denied at first instance, as the Court deemed it more probable than not that the patent was invalid due to added matter. However, this decision was overturned on appeal. The Court of Appeal, expressing contrary evaluations regarding the added matter issue and thus deeming it more probable than not that the patent was valid, granted the original application, ordering the preliminary injunction and other requested provisional measures.

66. This latter order and its underlying reasoning, while not binding on the present proceedings given the summary nature of the assessment conducted, cannot, however, be disregarded, considering the authority of the issuing body.

67. As set out in the Court of Appeal's order (para. 52), there is added matter if the patent, and in particular the claims, contain subject-matter that extends beyond the content of the original application documents. In order to ascertain whether there is added matter, the question to be answered is whether the claimed subject-matter would be directly and unambiguously derivable from the whole of the application as filed by the skilled person, taking into account common general knowledge as well as subject-matter which is implicitly disclosed, i.e. which is a clear and unambiguous consequence of what is explicitly mentioned. Where, as here, the patent is a divisional application, this requirement applies to the application as filed as well as to each earlier application.

68. The legal principle of direct and unambiguous disclosure is commonly referred to as the "gold standard", especially in the case law of the Boards of appeal of the European patent office. Both parties agreed that the Court should indeed apply this gold standard.

69. The Court would like to emphasise that strict compliance with the requirements of the gold standard in the context of the appraisal of added matter is of paramount importance for legal certainty. A patent proprietor should not be allowed to benefit from an unwarranted advantage by adding subject-matter not directly and unambiguously disclosed in the (earlier) application as filed, as third parties could then be confronted with claims extending beyond what they could legitimately expect when reviewing the original application.

Alleged undisclosed combination of features

70. The Claimant argues that the combination of features recited in claim 1 as granted cannot be found in an original claim, or in an original claim-like clause, or more generally in a single passage of the earlier application as filed. On the contrary, different parts of the

earlier application as filed need to be combined, and there is no pointer to such combination in the earlier application as filed.

71. The Court is of the opinion that, when a plurality of features taken from unrelated embodiments or from various lists of features in an original disclosure need to be combined to arrive at a claimed subject-matter, there may be added matter, in the absence of a clear pointer to the specific combination in the original disclosure. Indeed, the content of a patent application must not be considered to be a reservoir from which features pertaining to separate embodiments of the application can be combined at will in any possible way in order to create *ex post* a practically unlimited number of new claims. However, in the present case, it does not appear that claim 1 at stake is the result of an artificial combination from distinct embodiments.

72. In terms of proposed support for claim 1, the Defendant mostly relies on claim-like clause 32 on p. 8 of the earlier application in combination with the embodiment of Fig. 36-38 and with the embodiment of Fig. 47A-47C, including the corresponding description, in particular paragraphs [0145] and [0150]. These three passages, which are the most important ones for the present assessment, are reproduced below:

"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 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 FIG. 34A-34D and 35A-35D is presented in FIG. 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".

"*[0150] Turning now to FIG. 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 FIG. 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".

73. Clause 32 discloses the general architecture of the on-body device in very generic terms. In this clause 32, the on-body device is in particular said to comprise an enclosure which contains sensor electronics including a processor and a communications facility, as well as a sensor assembly.

74. The skilled person reading the earlier application as filed would understand the embodiment of Fig. 36-38 (which is presented as a variation of the embodiment of Fig. 34A-34D) and the embodiment of Fig. 47A-47C as being specific examples of the on-body device generically defined in clause 32. These two embodiments contain many more details than clause 32 but do not include any characteristic which is incompatible with clause 32. Therefore, the skilled person would indeed read the description of these two embodiments in connection with the generic disclosure of clause 32.

75. Each of these two embodiments discloses the further features now recited in claim 1 as granted, and most critically the presence of a recess in a bottom exterior surface of the base portion of the enclosure, wherein the recess comprises a distal-facing opening, such that a connector support of the sensor assembly is received through the distal-facing opening and into the recess and the sensor is electrically coupled with the sensor electronics by the connector support when the connector support is received into the recess.

76. The Claimant has not shown that the combination of clause 32 with either the embodiment of Fig. 36-38 or the embodiment of Fig. 47A-47C is not enough for the skilled person to arrive at the combination of features recited in claim 1, and that a further combination with other, unrelated passages of the earlier application as filed would be necessary. For the sake of completeness, the fact that the sensor in clause 32 and in these two embodiments is a glucose sensor is clear from the overall context of the earlier application as filed, including para. [0008].

77. In this context, the differences between the embodiments of Fig. 34A-34D and Fig. 47A-47C, noted by the Claimant in its Reply to Defence to Revocation, do not appear to be of relevance for the issue to be decided.

78. In its Request to dismiss the submitted auxiliary requests of 17 February 2025, the Claimant comments on the Court of Appeal's order in the proceedings for provisional measures and argues that the embodiment of Fig. 36-38 does not disclose features 1.3 and 1.6 and that the embodiment of Fig. 47A-47C does not disclose features 1.2.2, 1.3 and 1.6.

79. The fact that the base portion is configured to be adhered to the skin surface of the subject by an adhesive patch (feature 1.2.2) is disclosed in combination with the embodiment of Fig. 36-38 as was not contested by the Claimant, and the skilled person would understand that the same mode of attachment is necessarily used in the embodiment of Fig. 47A-47C. Feature 1.3 recites that the sensor electronics are positioned within the enclosure and comprise a processor and a communications facility. This feature is already disclosed in the generic statement of clause 32 and therefore also applies to the embodiments of Fig. 36-38 and Fig. 47A-47C even if this is not explicitly repeated. Finally, feature 1.6 recites that the glucose sensor is electrically coupled with the sensor electronics by the connector support when the connector support is received into the recess. Paragraphs [0145] and [0150] of the earlier application as filed explicitly

refer to a connector support, and the skilled person reading these paragraphs would understand without any doubt that there is indeed an electrical coupling between the glucose sensor and the sensor electronics by the connector support in the recess.

80. Therefore, the Court cannot accept that there was 'cherry picking' of features from distinct embodiments or from unrelated passages of the earlier application as filed without a pointer – which indeed could have been a reason to find that there is added matter. On the contrary, the skilled person would directly and unambiguously read the generic statement of clause 32 in combination with the embodiment of either Fig. 36-38 or Fig. 47A-47C (which are implementations of this generic statement) and thus would be presented with the combination of features of claim 1.

Alleged unallowable intermediate generalisation based on the embodiments of Fig. 36-38 and Fig. 47A-47C

81. There is a so-called intermediate generalisation when a claimed subject-matter is obtained by importing one or more features from a certain embodiment in the original disclosure 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. An intermediate generalisation can be allowable or unallowable – in view of the prohibition of added matter – depending on the circumstances of the case.

82. The Court considers that an intermediate generalisation is justified only in the absence of any clearly recognisable functional or structural relationship among the (imported and omitted) features of the specific combination.

83. In the present case, the Claimant argues that a number of features of the embodiments of Fig. 36-38 or Fig. 47A-47C were originally disclosed and omitted from claim 1. This is correct but, in order for such intermediate generalisation to be held unallowable, it would have been necessary for the Claimant to demonstrate that there was a clearly recognisable functional or structural relationship between the omitted features and the features imported into claim 1. The Claimant has failed to provide such demonstration.

84. The main omitted feature which was discussed at length between the parties is the presence of an elastomeric seal ("elastomeric […] seal backing" and "second elastomeric unit" in paragraph [0145], "elastomeric sealing member" in paragraph [0150]). The question which then arises is whether there is a clearly recognisable functional or structural relationship between the features of claim 1 which were imported from the two embodiments (namely, in summary, the recess on the base portion of the enclosure having a distal-facing opening for receiving a connector support of the sensor assembly) and the contested omitted feature, namely the presence of some kind of elastomeric seal.

85. A mere allegation that there is a functional or structural relationship is not enough for the Court to conclude that there is an unallowable intermediate generalisation. On the contrary, a concrete explanation of an alleged functional or structural relationship, based on the content of the original disclosure, would be necessary.

86. The parties disagree as to whether the elastomeric seal is necessary for the object of the invention or not. The Defendant argues that the elastomeric seal may be necessary for the general functioning of the on-body device, but not specifically for the object of the invention, which is to provide for an on-body device which is meant to form part of an

applicator system configured to handle insertion of an in vivo analyte monitoring system, which is easy-to-use, reliable and minimizes both user inconvenience and pain, as noted by the Court of Appeal in paragraph 76 of its order of 14 February 2025. The Claimant counters that the elastomeric seal is necessary for the reliability of the device, and thus indeed is relevant to the object of the invention.

87. The Court accepts that it may sometimes be difficult or even artificial to clearly distinguish between features which are relevant to the object of the invention and features which are merely relevant to the general functioning of the device, as the definition of the object of the invention may be complex and involve various aspects. However, there is no need to decide on this particular point, as the key issue remains the presence or absence of the alleged functional or structural relationship between the elastomeric seal and, in summary, the recess in the enclosure or, as the Defendant puts it its pleadings, the "plug and socket" configuration from the bottom of the on-body device.

88. In this respect, the Defendant points to several passages of the earlier application as filed which disclose other methods of sealing than by using an elastomeric seal. In particular, paragraph [0102] mentions that "mating snap features on the sensor assembly 410 and the electronics assembly 310 can be used to compel the components to remain locked and compressed together to insure (sic) a sealed, reliable connection". Reference is also made to paragraphs [0128] and [0153].

89. These passages suggest that sealing may be performed in different manners. Whether, specifically in the case of a plug-and-socket arrangement on the bottom of the enclosure, the particular arrangement involving an elastomeric seal is required, has not been demonstrated by the Claimant.

90. The Claimant has also not identified any other specific feature of the embodiments of Fig. 36-38 and 47A-47C, apart from the elastomeric seal, which would be omitted from claim 1 and which would be functionally or structurally linked to the features imported from these embodiments into claim 1.

91. Therefore, the Court must conclude that no unallowable intermediate generalisation has been established.

Alleged unallowable intermediate generalisation relating to the fact that the on-body device is arrangeable in position by way of a specific apparatus

92. As a reminder, clause 32 is relied upon by the Defendant as the main basis for claim 1 as granted. This clause is directed to "an on-body device, arrangeable in position by way of the apparatus according to any of the preceding clause (sic)". The Claimant argues that, by not reciting in claim 1 that the device is arrangeable in position by way of the apparatus described in clauses 1-31, an unallowable intermediate generalisation has been made.

93. However, a prerequisite for any finding of added matter is that new technical information is presented to the skilled person. In this case, the first question is then whether adding or not adding the contested feature "arrangeable in position by way of the apparatus according to any of the preceding clauses" would change anything in terms of the nature of the on-body device. The Claimant states that it would change something, without however explaining exactly what it would change in practical terms.

94. Clause 1 (to which clause 32 refers) defines an apparatus in extremely broad terms:

> *"An apparatus for arranging in position a sensor for an analyte, the apparatus comprising:*
> *a first assembly including a first portion of an on-body device;*
> *a second assembly including a second portion of the on-body device,*
> *an applicator assembly releasably coupled to the first assembly,*
> *wherein the apparatus is configured such that on arranging in position of the sensor, the first and second portions are coupled together".*

95. The Claimant has not identified any concrete technical feature which (1) would be explicitly or implicitly required for an on-body device to be arrangeable in position by way of this broadly defined apparatus, and which (2) would not already be explicitly or implicitly present in the subject-matter of claim 1. Therefore, the omission of the part of clause 32 reading "arrangeable in position by way of the apparatus according to any of the preceding clause (sic)" has no impact on the definition of the claimed subject-matter and does not add matter.

Alleged absence of disclosure of the sensor electronics positioned within the enclosure

96. The Claimant argues that clause 32 discloses "an enclosure surrounding the sensor electronics" which is different from the corresponding feature in claim 1 as granted, namely "sensor electronics positioned within the enclosure".

97. The Defendant replies that the two features have the same technical meaning.

98. The Court notes that the Claimant has not clearly explained how the difference in wording could possibly translate into a difference in technical meaning. The Claimant mentions "different conceptual focuses", a wording which "emphasizes the enclosure's role and could imply various configurations of sensor electronics, without specifying their arrangement or orientation" or which conversely "implies that the positioning of the sensor electronics is a critical aspect of the invention, potentially influencing functionality, performance, or manufacturability" (Reply to Defence to revocation, p. 28). These generic statements do not provide the Court with a comprehensible argument that the meaning is different on the technical standpoint. And if the technical meaning is the same, there can be no added matter.

Change in wording

99. The Claimant notes that several terms of claim 1 cannot be found in the earlier application as filed, in particular the "glucose sensor assembly", the "proximal section" and "distal tail section" of the glucose sensor assembly, the "distal-facing opening", the "top portion", the "base portion" the "bottom exterior surface" of the enclosure.

100. The Defendant replies that, under the 'EPC' and the 'UPCA', there is no requirement for literal support in the earlier application as filed, and that all of the above features are directly and unambiguously derivable from the content of the earlier application as filed; even if the wording has been slightly modified, the technical meaning remains the same.

101. The Court agrees with the Defendant.

102. As to the "glucose sensor assembly", a "sensor assembly" is in fact disclosed in paragraph [0145] (in connection with Fig. 36-38) and in paragraph [0150] (in connection with Fig. 47A-47C). As already mentioned above, the fact that the sensor is a glucose sensor is

clear from the overall context of the earlier application as filed, including paragraph [0008].

103. "Proximal" and "distal" have their ordinary meaning of relatively close to or relatively distant from the point of origin. A proximal section and a distal tail section of the glucose sensor assembly can readily be seen in Fig. 36-38 and Fig. 47A-47C and are disclosed in a generic manner in paragraph [0126] of the earlier application as filed.

104. The presence of the "distal-facing opening" is derivable at least from the expression "recess 4710 formed directly in the enclosure of the electronics assembly 4712" (paragraph [0150]) and is directly and unambiguously disclosed on the drawings of Fig. 38 and 47A-47C. Additional reference was also made by the Defendant to paragraph [0102] mentioning "an opening in the electronics assembly 310 which couples the sensor to the electronics". It is also clear from these passages that the recess and its distal-facing opening are on a bottom exterior surface.

105. Finally, the "top portion" and "base portion" merely and self-evidently designate two portions of the enclosure. The Claimant has not disputed that the earlier application as filed discloses a surface of the enclosure which is intended to be adhered to the skin by an adhesive patch. Designating the corresponding portion of the enclosure as a base portion and another portion of the enclosure as a top portion does not add any technical information. Additional reference is also made by the Defendant to paragraph [0153] in connection with Fig. 50A mentioning a "top shell" and a "mounting base".

106. In conclusion, the Court considers that the Defendant's added matter objections against claim 1 must fail. The same necessarily applies to claim 15.

VII. The novelty attack

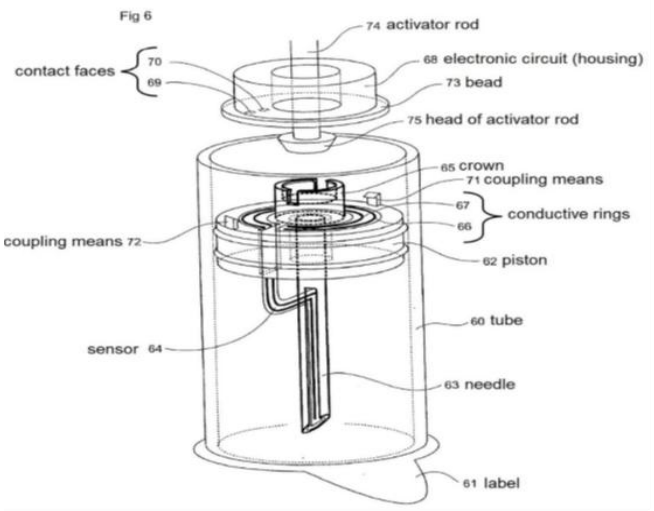
107. The Claimant argues that claims 1 and 15 are not valid for lack of novelty over:

- US 2008/0255440 A1 (D1), published on 16 October 2008;
- WO 2011/077893, published on 30 June 30 2011 in Japanese language. WO'893 was also published in English with the same content in a Canadian patent application CA 2 785 009 A1 which was used by both parties as an English language equivalent (D3) .

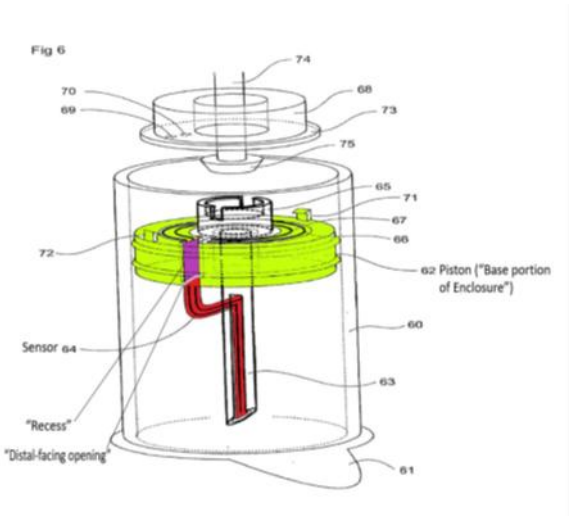
108. The late filed arguments concerning the lack of novelty over WO'896 (D2) are not admitted into proceedings (see, previously, para. 22)

Novelty over US'440 (D1)

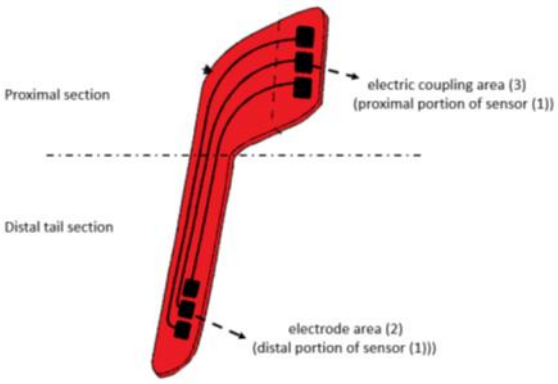
109. US'440 relates to a sensor package comprising an implantable sensor. The Claimant's objection is primarily based on the embodiment of Fig. 6, which is reproduced below with the Claimant's own annotations:



110. The Claimant argues that the sensor 64 in US'440 corresponds to the claimed glucose sensor assembly, that the electronic circuit housing 68 corresponds to the claimed top portion of the enclosure, and that the piston 62 corresponds to the claimed base portion of the enclosure. The Claimant further argues that a recess in a bottom exterior surface of said base portion must be present to couple the sensor 64 within the piston 62, as shown in their annotated version of Fig. 6 below:



111. As far as the structure of the glucose sensor assembly is concerned, the Claimant makes reference to Fig. 1 of US'440 showing a distal tail portion and a proximal section. According to the Claimant, "the upper part of the thin film layer that covers the electric coupling areas 3 of sensor 1 is the connector support, as it provides support for the electric coupling areas 3, i.e., the connection area" (Statement for revocation, p. 40). Again, a version of Fig. 1 annotated by the Claimant is reproduced below:



112. The Defendant replies that the Claimant's objection is based on a combination of unrelated embodiments of US'440, namely the embodiment of Fig. 1 and the embodiment of Fig. 6, which is not permitted in a novelty assessment. The Defendant further disagrees with the Claimant's claim mapping and argues that Fig. 1 only shows a sensor, not a sensor assembly; that only the electronic circuit housing 68, not the piston

62, can be considered as forming the enclosure of feature 1.2 and that this enclosure lacks many of the requirements of claim 1, in particular the configuration to be adhered to the skin via an adhesive patch. The Defendant adds that the sensor 64 and the piston 62 form an integrated part so that the sensor 64 is not inserted into a recess of the piston 62. As a result, the Defendant challenges the presence of (inter alia) features 1.1.1, 1.2, 1.2.2, 1.4, 1.5 and 1.6.

113. The Court is indeed not convinced that the embodiments of Fig. 1 and Fig. 6 are disclosed in combination in US'440, at least not in a direct and unambiguous manner. The general purpose of US'440 is to facilitate sterilisation and handling of sensor devices by providing an electrode area contained in a shielding packaging, and an electric contact area extending outside of the shielding packaging (see notably para. [0013]-[0016]). In this context, the embodiment of Fig. 1 shows a sensor together with a base packaging 4 and a supplementary packaging 5 (para. [0036]). In contrast, in the embodiment of Fig. 6, "the shielding consists of a tube 60 being at the bottom closed by means of a tear-off label 61 and at the top being able to receive a piston 62 provided with O-rings" (para. [0052]). These two embodiments therefore appear to relate to distinct, unrelated technical solutions.

114. Furthermore, even if the sensor of the embodiment of Fig. 6 was as depicted in Fig. 1, it does not seem reasonable to consider the upper part of the thin film layer as a connector support as per feature 1.1.1. The claimed connector support must be a distinct element coupled with the proximal section of the glucose sensor and adapted to ensure the electrical coupling with the sensor electronics as characterised in features 1.5 and 1.6. There is no disclosure in US'440 that the upper part of the thin film layer is configured in this manner.

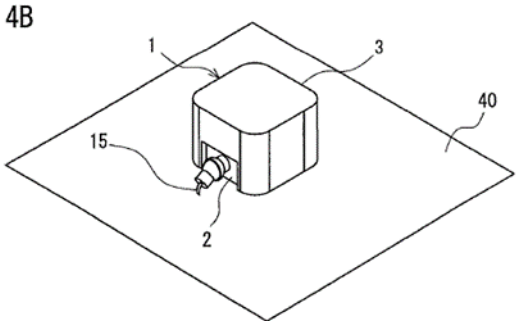
115. Still additionally, US'440 explicitly recites that "the piston 62 constitutes a part of the sensor" (paragraph [0052]). It therefore seems unreasonable to consider that this piston 62 constitutes a part of the enclosure, together with an entirely different element, namely the electronic circuit housing 68. It rather appears that a sensor assembly in US'440 is provided by the sensor 64 integrated with the piston 62.

116. For at least the above reasons, claim 1 is novel over US'440. For similar reasons, claim 15 is novel over US'440.

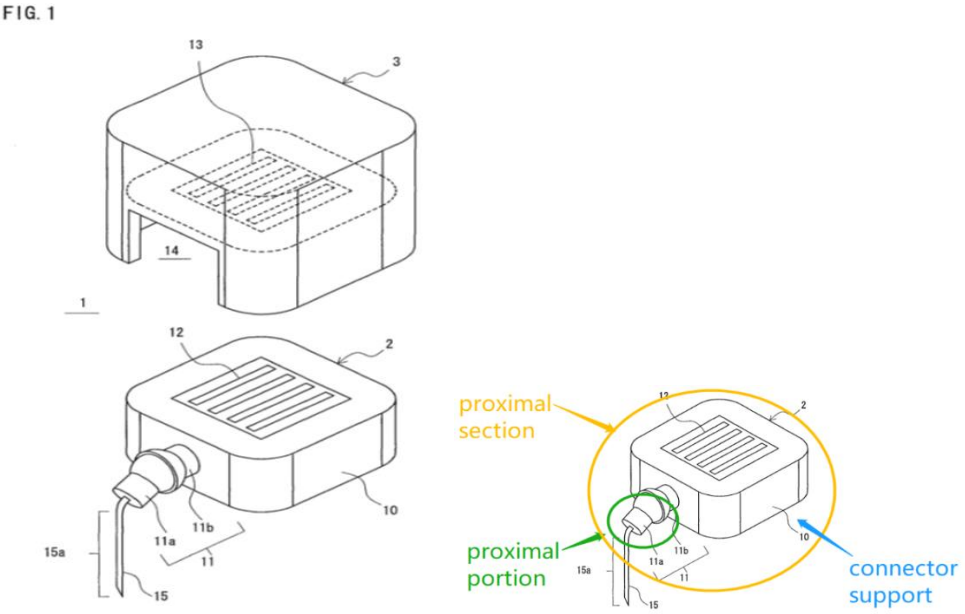
Novelty over WO'893-CA'009 (D3)

117. D3 discloses an on-body device (the measuring apparatus 1) that measures glucose levels in a body. The on-body device comprises a sensor unit 2 and a control unit 3 as shown in Fig. 4B below:

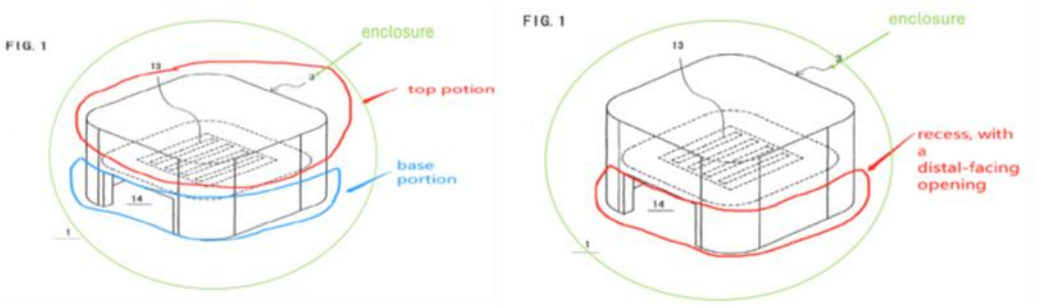
FIG. 4B



118. According to the Claimant, the sensor unit 2, illustrated in Fig. 1, corresponds to the glucose sensor assembly of claim 1 at stake, while the control unit 3 corresponds to the enclosure of claim 1 at stake.



119. The Claimant further considers that the enclosure / control unit 3 comprises a top portion and a base portion, as well as a recess with a distal-facing opening on the base portion, as illustrated in the figures below, annotated by the Claimant:



120. In the Defence to revocation, the Defendant disputes that features 1.2 and 1.2.2 are disclosed by WO'893-CA'009, as the control unit 3 is in fact a cover and not an enclosure, and as the base portion identified by the Claimant is not configured to be adhered to the skin surface of the subject by an adhesive patch. In the context of the inventive step discussion, the Defendant adds that also features 1.1, 1.1.2, 1.4, 1.5 and 1.6 are not disclosed by WO'893-CA'009.

121. The Court considers that a claim only lacks novelty over a prior art document if all claimed features are directly and unambiguously disclosed in combination in said prior art document (taking into account common general knowledge as well as subject-matter which is implicitly disclosed, i.e. which is a clear and unambiguous consequence of what is explicitly mentioned).

122. One of the main points of contention between the parties is whether the base portion, which according to the Claimant is assumed to be the lower part of the control unit 3, is directly and unambiguously disclosed by D3 as being "configured to be adhered to the skin surface of the subject by an adhesive patch" as per feature 1.2.2.

123. First of all, it does not seem to be contested that D3 does not explicitly disclose that the base portion is configured to be adhered to the skin surface by an adhesive patch.

124. Second of all, the Court does not consider that D3 implicitly discloses that the base portion is configured to be adhered to the skin surface by an adhesive patch either.

125. Even if the adhesive patch is not recited as being necessarily part of the on-body device of claim 1, there is a functional requirement in the claim that the base portion must be able to cooperate with an adhesive patch to ensure effective attachment to the skin surface. The Court also understands that this functional requirement is closely linked with the structural requirements of feature 1.2 (an "enclosure") and feature 1.4 (presence of a "distal-facing opening" in a "bottom exterior surface" of the base portion of the enclosure).

126. The fact that there is an actual enclosure, with a bottom exterior surface contributing to enclosing the sensor electronics, also makes it possible for the base portion to be configured to be adhered to the skin surface of the subject by an adhesive patch.

127. As shown in Fig. 1 and 4b of WO'893-CA'009 reproduced above, the sensor unit 2 comprises a base 10 having a large contact surface against the skin. According to paragraph [0064], "the control unit 3 is then attached onto the sensor unit 2 disposed on the skin 40, as shown in FIG. 4B." This suggests that the sensor unit 2 may be configured to be adhered to the skin surface by an adhesive patch.

128. On the other hand, the same cannot be said of the control unit 3, which was designated by the Claimant as the enclosure of claim 1. The exact shape of the bottom of the control unit 3 is not known, as only the top and the lateral walls of the control unit 3 are depicted, and then only schematically. In fact, it is not even clearly taught in WO'893-CA'009 whether any portion of the control unit 3, when attached to the sensor unit 2, is in contact with the skin, let alone whether it would have a surface area and shape compatible with an adhesive patch. Accordingly, the Court is not convinced that the base portion identified by the Claimant is configured to be adhered to the skin surface of the subject by an adhesive patch.

129. The Court is in fact not convinced either that the control unit 3 can be reasonably considered as an "enclosure" (feature 1.2). The control unit 3 encloses the sensor electronics, on the top and laterally, but does not enclose the sensor electronics from below. Feature 1.2, as properly interpreted in view of the claim as a whole and in view of the description and drawings, requires that the enclosure should also comprise a portion (the "base portion" of feature 1.2.2, having a "bottom exterior surface" as per feature 1.4) which (partly) encloses the sensor electronics from below, thus providing the function of adhesion to the skin via an adhesive patch.

130. Therefore, claim 1 is novel over WO'893-CA'009 at least because it fails to disclose features 1.2 and 1.2.2. Since claim 15 also calls for an enclosure similarly to claim 1, claim 15 is also novel over WO'893-CA'009.

VIII. The inventive step attack

131. The Claimant argues that claims 1 and 15 are not valid for lack of inventive step based on two different starting points:
- starting from WO'893-CA'009 (D3) as the closest prior art itself and in combination with any of the prior art documents D1, D2, EP 2 236 077 A1 (Exhibit D4, hereafter EP'077 or D4), US 2004/0002682 A1 (Exhibit D6, hereafter US'682 or D6) and US 2011/0021889 A1 (Exhibit D7, hereafter US'889 or D7);
- starting from WO'896 A1 (D2) as the closest prior art itself and in combination with US '440 A1 (D1).

132. For the inventive step attack against the dependent claims, the Claimant refers to different combinations between D1, D2, D3 and US 2011/288574 A1 (Exhibit D5, hereafter US'574 or D5).

133. The assessment of inventive step must be carried out in accordance with Article 56 'EPC', which states that "[a]n invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art". Hence, it is necessary to determine whether, given the state of the art, a person skilled in the art would have arrived at the technical solution claimed by the patent using its technical knowledge and carrying out simple operations. Inventive step is assessed in terms of the specific problem encountered by the person skilled in the art (see Paris LD, decision issued on 3 July 2024, UPC_CFI_230/2023).

134. In order to assess whether or not a claimed invention is obvious to a person skilled in the art, it is first necessary to determine one or more teachings in the prior art that would have been of interest to a person skilled in the art who, at the priority date of the patent in suit, was seeking to develop an invention or process similar to that disclosed in the prior art. Then, it must be assessed whether it would have been obvious for the skilled person to arrive at the claimed solution of the underlying technical problem on the basis of a realistic disclosure of the selected prior art documents (see, Munich CD, decision issued on 17 October 2024, UPC_CFI_252/2023; Dusseldorf LD, decision issued on 10 October 2024, UPC_CFI_363/2023). This panel considers that an assessment based on two different starting points as suggested by the Claimant is indeed appropriate.

WO'893-CA'009 (D3) as starting point for the assessment of inventive step

135. The Claimant identifies feature 1.2.2 as the sole distinguishing feature over WO'893-CA'009, namely the fact that the base portion of the enclosure is configured to be adhered to the skin surface of the subject by an adhesive patch. As a reminder, for the Claimant, this base portion of the enclosure is constituted by the bottom lateral walls of the control unit 3. The Claimant argues that the technical problem to be solved by the claimed subject-matter can be seen in providing a way of fixating the on-body device to the user. The solution to this problem would be obvious in view of common general knowledge and in view of a number of secondary references, namely US'440, WO'896, EP'077, US'682, or US'889.

136. The Defendant replies that WO'893-CA'009 cannot be considered as the closest prior art, that there are a large number of distinguishing features between claim 1 and WO'893-CA'009, including features 1.1, 1.1.2, 1.2.2, 1.4, 1.5 and 1.6, that the technical problem should be formulated as how to enable an on-body device to be applied to a skin surface of a subject in a single action, and that the secondary references do not address the technical problem, do not disclose the distinguishing features and relate to devices and applicators which are completely different from the teaching of the starting point.

137. The Court has no doubt that WO'893-CA'009 can be a valid starting point for an inventive step reasoning, as it relates to an on-body device for glucose monitoring, like the claimed invention.

138. As discussed above, claim 1 differs from the teaching of WO'893-CA'009 at least because WO'893-CA'009 fails to disclose features 1.2 and 1.2.2. The control unit 3 in WO'893-CA'009 cannot be considered as an actual enclosure having a base portion (including a

bottom exterior surface as per feature 1.4) wherein the base portion is configured to be adhered to the skin surface of the subject by an adhesive patch.

139. Regardless of the formulation of the technical problem, the Claimant has not identified a clear incentive in the prior art for the skilled person to modify the device disclosed in WO'893-CA'009 to achieve the claimed invention. The various secondary references cited by the Claimant disclose attaching various devices to the skin by adhesive patches. It can thus be accepted that the skilled person would contemplate attaching the device disclosed in WO'893-CA'009 to the skin by an adhesive patch. However, there would be *prima facie* no motivation for the skilled person to add an adhesive patch to the control unit 3 of WO'893-CA'009. It would make much more sense to add an adhesive patch to the base 10 of the sensor unit 2, since the shape of the base 10 appears to already be adapted for this purpose, and since the base 10 is placed on the skin before the control unit 3 is attached to the sensor unit 2.

140. Besides, starting from WO'893-CA'009, the skilled person must redesign the whole structure of the device in a manner which was not commonly and generally known. In order to arrive at the claimed invention, the skilled person would need to modify the shape of the control unit 3. The Claimant has not convincingly explained why the skilled person would make such a modification, how exactly they would make this modification, and whether the modified device would still be suitable for the purposes of WO'893-CA'009. In summary, modifying WO'893-CA'009 in combination with 'CGK' and the cited prior art documents is a step taken in hindsight by the Claimant, therefore features 1.2, 1.2.2 are not obvious.

141. As a result, claim 1 involves an inventive step over WO'893-CA'009. The same applies to claim 15 for similar reasons.

WO'896 (D2) as starting point for the assessment of inventive step

142. The Court decides not to admit the Claimant's objection regarding a lack of novelty over WO'896, which was raised late, into the proceedings (see previous para. 22).

143. However, since WO'896 is relied upon as a starting point for an inventive step objection which was raised by the Claimant in due time in the Statement for revocation, it is appropriate to nevertheless review the teaching of WO'896 and identify the differences between claim 1 and said teaching.

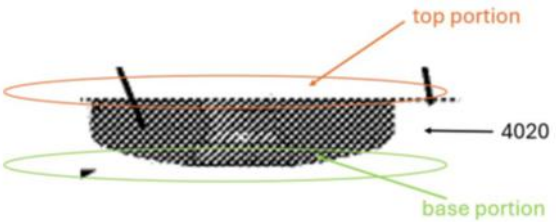
144. WO'896 discloses various embodiments of medical device inserters for use with on-body electronics. The on-body electronics are applied to the skin of a user using an inserter device which positions both the on-body electronics on the skin surface as well as a portion of an analyte sensor through the skin surface (paras. [00112] and [00113] of WO'896).

145. Making in particular reference to the embodiment of Fig. 150-158, which is the main embodiment relied upon by the Claimant, two parts of an on-body unit are provided separately and combined by the user to form the complete on-body unit. An inserter/insertion device can be used by the user for inserting the part of the sensor subcutaneously, while the on-body electronics is adhered to the skin surface. The two parts of the on-body unit that are provided separately are a housing unit 4020 that includes a mount and on-body electronics, and a sensor hub 4022 where the sensor is located. Fig. 152-154 are reproduced below, with the Claimant's annotations.

146. The sensor hub 4022 corresponds to the glucose sensor assembly of claim 1 at stake, while the housing unit 4020 corresponds to the enclosure of claim 1 at stake. The Defendant identifies features 1.4 and 1.5 as distinguishing features between the subject-matter of claim 1 and WO'896, namely the fact that the base portion of the enclosure of the claimed invention comprises a recess in a bottom exterior surface, the recess comprising a distal-facing opening, so that the connector support is received through the distal-facing opening and into the recess.

147. The Court agrees with this analysis. In WO'896, it is the top portion of the enclosure, not the base portion, which comprises a recess with an opening adapted to receive the sensor hub (and thus the connector support). As shown in Fig. 152-154 reproduced above, the sensor hub is introduced from above the housing unit, whereas in view of features 1.4 and 1.5 of claim 1 at stake, the glucose sensor assembly must be introduced from below the enclosure.

148. In its late and inadmissible lack of novelty objection, the Claimant looks at the housing unit 4020 upside down, and decides to label the actual bottom as the "top portion" and the actual top as the "base portion", as shown in their drawing below:



Enlarged component 4020 from Fig. 152 of WO'896

149. This claim mapping cannot be accepted. When claim 1 is properly interpreted, already based on its literal wording and as confirmed by the description and drawings of the patent in suit, the "top portion" must be above the "base portion" when viewed relative to the skin on which the on-body device is to be applied, and the "distal-facing opening" must face the skin. For the sake of completeness, even if one were to accept this claim mapping (quod non), then the base portion identified by the Claimant, which appears to have a convex shape, would not be configured to be adhered to the skin surface of the subject by an adhesive patch (as required by feature 1.2.2), as it is in fact the opposite (flat) portion of the housing unit which is configured to be adhered to the skin surface.

150. These distinguishing features 1.4 and 1.5 do not, however, disqualify WO'896 as a starting point, but must be considered as distinguishing elements within the assessment of the inventive step, namely these are the features whose obviousness must be assessed.

151. The Claimant raises two distinct lines of argumentation concerning the alleged lack of inventive step when starting from WO'896 as the closest prior art.

152. In the first line of argumentation presented in the Statement for revocation, the Claimant accepts that claim 1 differs from the teaching of WO'896 in that the recess is in a bottom exterior surface (feature 1.4) and the connect support is received through the distal-facing opening into the recess (feature 1.5).

153. In the second line of argumentation set out for the first time in the Reply to Defence to revocation, which was presented as an auxiliary reasoning based on the late objection of lack of novelty, the Claimant considers that the bottom of the housing unit 4020 is the "top portion" and that the top of the housing unit 4020 is the "base portion", and that the sole distinguishing feature is the fact that the thus identified base portion is configured to be adhered to the skin surface of the subject by an adhesive patch (feature 1.2.2).

154. The Defendant objects to the admissibility of this second line of argumentation. The Court concurs that this second line of argumentation is inadmissible for the same reasons as the lack of novelty objection over WO'896. For the sake of completeness, this second line of argumentation is not convincing anyway, since the claim mapping proposed by the Claimant is unreasonable (see above) and since, even if this claim mapping were accepted, there would be no reason for the skilled person to render the upper surface of the housing unit 4020 configured to be adhered to the skin surface of the subject by an adhesive patch as this upper surface is not intended to be in contact with the skin.

155. Turning now to the first line of argumentation, the Claimant argues that the technical problem when starting from WO'896 would be to provide an alternative arrangement for the glucose sensor assembly and sensor electronics connection and that the skilled person faced with this technical problem would arrive at the subject-matter of claim 1 in view of US'440, which discloses a glucose sensor assembly introduced through a bottom surface of an enclosure.

156. The Defendant replies that the technical problem would be how to enable an on-body device to be movable to different locations until being applied to the skin of a user, that the skilled person would not find any solution to this problem in US'440, and that anyway US'440 does not disclose the distinguishing features 1.4 and 1.5.

157. The Court is of the opinion that, regardless of how the technical problem is formulated, US'440 would provide no incentive for the skilled person to arrive at the claimed invention. Arriving at the on-body device of claim 1 starting from WO'896 would require a dramatic design change, not only of the on-body device itself, but also of the way it is assembled and therefore of the applicator.

158. The Claimant has not identified any pointer in US'440 which would motivate the skilled person to endeavour to carry out this dramatic design change, let alone which would teach them how to carry it out in practice. US'440 does in fact not disclose the introduction of a glucose sensor assembly through a distal-facing opening in a bottom exterior surface of an enclosure, for the reasons already discussed above.

159. Therefore, claim 1 involves an inventive step over WO'896 as the closest prior art. The same applies to claim 15 for similar reasons.

IX. Conclusion

160. The alleged grounds for invalidity of claims 1 and 15 of EP'283 are not proven.

161. This leads to the conclusion that also the grounds for invalidity based on lack of novelty and inventive step of the dependent claims 2-14 and 16-26 are unfounded. As mentioned above, the added matter objections against the dependent claims are inadmissible (see previous para. 22).

162. The revocation action should be dismissed, and the patent should be maintained as granted.

163. The auxiliary requests to amend the patent are admissible but there is no need to discuss them.

C. Costs

164. The costs of the Court and of the Defendant shall be borne by the Claimant, as the unsuccessful party in accordance with Art. 69(1) 'UPCA'.

DECISION:

Based on the foregoing, the Paris Central Division of the UPC rules as follows:

1.The revocation action filed by Sibio Technology Limited against Abbott Diabetes Care Inc. concerning the European patent EP 3 831 283 B1 is dismissed.

2. European patent EP 3 831 283 B1 is maintained as granted.

3. The costs of the proceedings shall be borne by the Claimant.

Paolo Catallozzi Presiding judge	Paolo Catallozzi Firmato digitalmente da Paolo Catallozzi Data: 2025.07.21 16:38:06 +02'00'
Tatyana Zhilova Legally qualified judge and judge-rapporteur	Tatyana Zhilova Signature numérique de Tatyana Zhilova Date : 2025.07.21 16:27:52 +02'00'
Renaud Fulconis Technically qualified judge	Renaud, Patrick, Raymond Fulconis 2025.07.21 16:52:09 +02'00'
Margaux Grondein Clerk	Unified Patent Court Einheitliches Patentgericht Juridiction unifiée du brevet Signature numérique de MARGAUX MARIE-ANGE GRONDEIN

Information about appeal

An appeal against the present Decision may be lodged at the Court of Appeal, by the unsuccessful party within two months of the date of its notification (Art. 73(1) 'UPCA', R. 220.1(a), 224.1(a) 'RoP').

Decision details

Order no. ORD_69322/2024 in ACTION NUMBER: ACT_27463/2024
UPC number: UPC_CFI_231/2024
Action type: Revocation Action