

**Decision in an action for infringement
with counterclaim for revocation**

UPC_CFI_230/2023
Decision on the merits
of the Court of First Instance of the Unified Patent Court
delivered on *04/07/2024*
concerning *EP3435866*

HEADNOTES

The scope of the dispute brought before the Court is incontestably governed by the principle that the parties define the subject-matter of the dispute, a general principle of law which is reiterated in Art. 76(1) of the UPC Agreement and which, moreover, allows the claimant in the main action to exclude certain acts of infringement in order to avoid the inconvenience of parallel jurisdictions between the UPC and national courts during the transitional period provided for in Art. 83 of the Agreement ("carve out"). However, this principle cannot restrict a defendant in its challenge to the validity of the European patent which is being asserted against it since no legal text that is binding upon UPC law expressly states such a restriction.

It is not necessary to apply Art. 71c for the UPC to be governed by the Brussels Ibis. Art. 29 to 30 of the Brussels Ibis are directly applicable to the UPC. Moreover, Art. 31 of the UPC Agreement governing its international jurisdiction clearly states: "The international jurisdiction of the Court shall be established in accordance with Regulation (EU) No 1215/2012".

KEYWORDS

Infringement action with counterclaim for revocation, jurisdiction on revocation request by counterclaim, parallel jurisdiction and related actions, invention related to analyte monitoring system, principles for claim interpretation, novelty (yes), inventiveness (no), auxiliary request, added subject-matter (no).

CLAIMANT

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PATENT AT ISSUE

Patent no. *Proprietor*

EP3435866 DexCom, Inc.

DECIDING JUDGES

COMPOSITION OF PANEL

Presiding judge and Judge-rapporteur	Camille Lignières
Legally qualified judge	Rute Lopes
Legally qualified judge	Carine Gillet
Technically qualified judge	Alain Dumont

LANGUAGE OF PROCEEDINGS: English

SUBJECT-MATTER OF THE PROCEEDINGS: Infringement action and Counterclaim for revocation

DATE OF THE ORAL HEARING: 24 May 2024

THE PARTIES

DEXCOM Inc. (hereinafter: DEXCOM) is a US company founded in 1999 and headquartered in San Diego, California, which positions itself as a world leader in the development, manufacture and marketing of innovative Continuous Glucose Monitoring ("CGM") systems for persons with diabetes.

All the defendants (hereinafter: ABBOTT entities or ABBOTT) are part of a global healthcare group headquartered in Chicago, USA.

The ABBOTT entities develop and distribute diagnostic, medical and nutritional products and software, notably the products sold under the "FreeStyle Libre" trademarks (including "Freestyle Libre 2"), which constitute a glucose monitoring system and are the subject of the present infringement action.

Defendant 1, Abbott Laboratories, is the US parent company of the Abbott group.

Defendant 2 is Abbott Diabetes Care Inc, a US subsidiary of the First Defendant which develops the "FreeStyle Libre 2 system".

Defendants 3 through 10 ensure distribution of the FreeStyle Libre 2 products at their respective locations in the EU in France, Belgium, the Netherlands, Italy and Sweden.

1. FACTS AND PROCEEDINGS

- 1.1. This dispute is part of ongoing global litigation between DEXCOM and the ABBOTT entities, notably relating to the European patent EP 3 435 866 B1 (hereinafter "EP 866"). This litigation is taking place in Germany before the Mannheim Regional Court for an infringement action and before the German Federal Patent Court for a revocation action of the German national part, as well as in the UK before the High Court of England and Wales, which has rendered a consent order revoking the UK designation of EP 866. (DEXCOM Exhibits C048, C049, C051, C054).

- 1.2. On 7 July 2023, DEXCOM lodged an infringement action against the ABBOTT entities before the UPC Paris Local Division, seeking remedies against the acts of infringement of European Patent No. EP 3 435 866 committed by the Defendants within the territories of the states that have ratified the UPCA at the time of the hearing before this Court, including Germany, with the exception of the acts committed by the Defendants 1, 2 and 8, which are already the subject of infringement proceedings pending before a German court.
- No preliminary objection pursuant to R. 19 RoP was raised: jurisdiction, competence and language were not challenged at this time.
- A counterclaim for revocation with the Statement of Defence was filed by the ABBOTT entities on 13 November 2023.
- An order establishing a confidentiality club was issued on 19 December 2023.
- In its reply to the defence and the counterclaim, DEXCOM rejected the arguments for revocation of its patent and filed auxiliary requests to amend the patent in question.

2. THE REQUESTS

- 2.1. In its written statements of 7 July 2023, 15 January 2024 and 15 April 2024, DEXCOM seeks, in summary:
- permanent injunctions to prevent direct and indirect infringement of claims 1, 2, 3, 4, 5 and 7 of the patent at issue within the territory of UPC Member States, except in Germany for Defendants 1, 2 and 8 or, in the alternative, within the territory comprising Belgium, France, the Netherlands, Italy, Sweden and Germany, with the exception of the acts committed by Defendant 1, 2 and 8, under penalty of law;
 - corrective measures (recall from distribution channels, destruction of infringing products) and communication of information;
 - an interim award of damages of EUR 500,000;
 - a cost decision;
 - publication of the Court's decision in full or in part, on its website;
 - an order dismissing all the Defendants' requests in the counterclaim for revocation, declining jurisdiction and rejecting as inadmissible the Defendants' counterclaims for revocation of the German part of the patent at issue, and transferring jurisdiction to the German Federal Patent Court.
- 2.2. In support of its written statements, DEXCOM maintains that independent claim 1 and its dependent claims are valid and that none of the grounds raised, nor any of the patents opposed by the Defendants, are relevant with regard to lack of novelty, lack of inventive step or added subject-matter.
- As a precaution, it has submitted two auxiliary requests to amend the patent, providing indications regarding their respective validity.
- With respect to the acts of infringement, DEXCOM contends that the FreeStyle Libre 2 monitoring system reproduces all the features of Claims 1 to 5 and Claim 7, and affirms that the Defendants 3 through 7 (local distributors), Defendant 8 (which imports the infringing products), Defendants 9 and 10 (which provide logistics services for the distribution of the products), Defendant 2 (which develops the accused products and the related software application, FreeStyle LibreLink) and Defendant 1 (which controls and manages the activities of the other Defendants), have all committed direct and indirect acts of infringement in the relevant territory.
- As a result of these acts of infringement, DEXCOM is seeking a permanent injunction to prevent these acts, as well as corrective measures such as the recall of the products and the destruction of the allegedly infringing products at the Defendants' expense. DEXCOM also requests the sum of EUR 500,000.00 as a provision for damages, as well as the communication of information and the

publication of the decision, with the Defendants being required to bear the legal costs of the proceedings.

In its defence to the counterclaim for revocation, DEXCOM primarily argues that the Court does not have jurisdiction to hear the Defendants' claim for revocation of the German part of the patent.

- 2.3. In their statement of defence and counterclaim for revocation, lodged on 13 November 2023, as well as in their rejoinder to the reply and their reply to the defence to the counterclaim dated 15 March 2024, the ABBOTT entities request the Court to:

In the main proceedings:

- dismiss the infringement action in its entirety;
- order the Claimant to pay the costs of the proceedings incurred by the Defendants, to be determined in separate proceedings, with an interim award of costs of EUR 100,000 to be paid within 14 days after service of the judgment,

In the alternative, if it is assumed that the infringement is established:

- grant the Defendants a grace period of 18 months before the enforcement of corrective measures,
- order the Claimant to provide security for costs in the amount of EUR 100 million,
- order the protection of confidential information;

In the counterclaim proceedings:

- revoke the patent in its entirety,
- order the Claimant to bear the costs of the proceedings incurred by the Defendants, to be determined in separate proceedings, with an interim award of costs of EUR 100,000 to be paid within 14 days after service of the judgment,
- declare the order immediately enforceable.

In their reply to the defence to the application to amend the patent, on 15 May 2024, ABBOTT makes the same requests as above, adding the revocation of the patent as amended.

- 2.4. To support their written statements, the Defendants contend, in summary, that the "FreeStyle Libre 2" product does not reproduce the features of the patent EP 866 and that the Claimant must bear all the costs (legal costs and other expenses).

Alternatively, if the Court estimates that there is an infringement, the Defendants request a grace period of 18 months after the decision to enforce the corrective measures.

With respect to the revocation action, the Defendants argue that Patent EP 866 is not novel, not inventive, and contains added matter, specifically in relation to D1 (Berman), D2 (Cole), D3 (Bernstein), D4 (Ferro), and D10, and that the two auxiliary requests to amend the patent are not valid.

On the issue of jurisdiction, the Defendants argue that all Defendants are fully entitled to request the revocation of the patent, on the grounds that Art.71c Brussels Regulation does not apply. Furthermore, they claim that, under Art.33 §2 UPCA, there are no related actions pending before the UPC Local Division Paris or the German Court.

3. THE PATENT AT ISSUE

- 3.1. DEXCOM is the registered proprietor of the European patent EP 3 435 866 (hereinafter "EP 866"). The Patent in suit, titled "Analyte Monitoring System", was filed with the European Patent Office on 28 March 2017, claiming US priority dated 31 March 2016.

Mention of the grant of the patent at issue was published on 18 November 2020 (DEXCOM Exhibit C020).

Defendant 2 filed an opposition against EP 866 and Defendant 8 intervened in the opposition proceedings (DEXCOM Exhibits, C040 and C041). However, the EPO opposition division rejected the opposition by a decision dated 20 April 2023 (DEXCOM Exhibit C047).

The patent is in force notably in the following EU Member States: Belgium, France, Italy, the Netherlands, Sweden, Germany, Spain, and Ireland.

3.2. EP 866 relates generally to systems and methods for communication between a sensor electronics unit and a display device of an analyte monitoring system (DEXCOM Exhibit C020, patent in suit, [0001]).

In some cases, persons with diabetes *mellitus* (also known as diabetes) can use an analyte monitor in order to measure their level of glucose in the blood (patent in suit, [0003]).

A variety of analyte monitoring systems are being developed for continuously detecting blood glucose values and transmitting processed data to remote devices (patent in suit, [0005]).

3.3. According to the description, the technical problems to be solved in the systems existing in the state of the art are as follows:

- data transmission between sensor electronics and display devices consumes too much energy and processing capacity, due to, notably, the use of resource-intensive communication protocols (patent in suit, [0041]);

- under certain circumstances, it is possible for a transmission to be compromised by third parties, and there is a need to improve security in data communication. (DEXCOM Exhibit C020, [0046]).

3.4. The patent at issue presents an invention providing an analyte monitoring system, as set out in claim 1, to solve these problems (patent at issue, [0008]).

EP 866 comprises a set of 9 claims, of which claim 1 is the only independent claim.

3.5. Claim 1 reads as follows (the "feature breakdown" presentation by DEXCOM (C021) is not contested by the Defendants):

1. *An analyte monitoring system, comprising*

1.1 *a sensor configured to take measurements indicative of analyte levels;*

1.2 *a sensor electronics unit communicatively coupled to the sensor, wherein the sensor electronics unit is configured to:*

1.2.1 *receive the analyte measurement data indicative of analyte levels from the sensor;*

1.2.2 *transmit a first portion of the analyte measurement data indicative of analyte levels using a first communication protocol that is Bluetooth or Bluetooth Low Energy, BLE;*

1.2.3 *receive a data request command using a second communication protocol that is near field communication, NFC, or radio-frequency identification, RFID; and*

1.2.4 *in response to the data request command, transmit a second portion of the analyte measurement data indicative of analyte levels using the second communication protocol,*

1.3 *a display device configured to:*

- 1.3.1 receive the first portion of the analyte measurement data indicative of analyte levels using the first communication protocol;
- 1.3.2 transmit the data request command to the sensor electronics unit using the second communication protocol; and
- 1.3.3 receive the second portion of the analyte measurement data indicative of analyte levels using the second communication protocol in response to the data request command.

3.6. According to DEXCOM, the patent proposes a system with a sensor coupled to a sensor electronics unit and a display device, and analyte measurement data can be transmitted from the sensor electronics unit to the display device using two different communication protocols. A first portion of the measurement data is transmitted by Bluetooth or Bluetooth Low Energy (“BLE”), and a second portion is transmitted by RFID technology (“Radio Frequency Identification”) or NFC (“Near Field Communication”).

This allows data communication between the sensor electronics unit and also enables the display device to benefit from:

- the advantages of Bluetooth/BLE radio technology, for example its relatively high communication range (several meters), which allows the transmission of a first portion of data autonomously, and,
- the advantages of the RFID or NFC technology, for example its very low power consumption which allows the transmission of a second portion of data upon request, a low risk of unauthorized access to data by a third party and enhanced medical security due to its limited transmission range (a few cms).

3.7. Figure 1A of the patent at issue illustrates an example of a continuous analyte monitoring system having a sensor electronics unit (6), a sensor (8) and a plurality of display devices (20a to 20e) that can be connected to the sensor electronics unit.

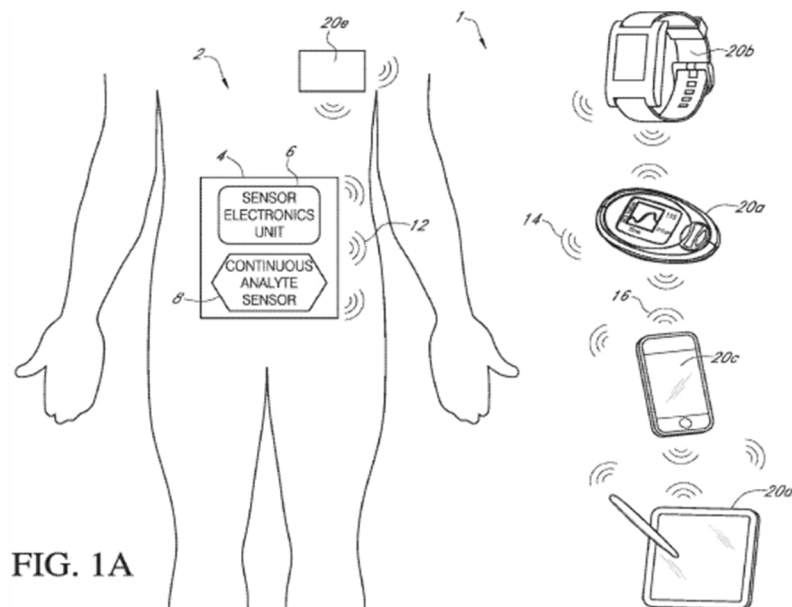


FIG. 1A

EP 3 435 868 B1

GROUNDS FOR THE DECISION

4. CLAIM INTERPRETATION

4.1. The skilled person

In the present case, the Court considers that the skilled person is a group of persons, comprising persons skilled in the field of (physiological) analyte monitoring systems (such as Continuous Glucose Monitoring (CGM)) and persons skilled in the art of designing portable electronic systems, who are also familiar with the communication techniques involved in such systems. In other words, for the purposes of Art. 56 EPC, the field of electronic data communication is not a technical field remote from the field of analyte monitoring systems.

4.2. Principles for claim interpretation

In accordance with Art. 69 of the Convention on the Grant of European Patents (EPC) and the Protocol on its Interpretation, the present panel adopts the standard for the interpretation of patents set by the UPC Court of Appeal in two recent orders (UPC_CoA_335/2023 and UPC_CoA 1/2024), as follows:

- 1) The patent claim is not only the starting point, but the decisive basis for determining the protective scope of the European patent.
- 2) 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.
- 3) However, this does not mean that the patent claim serves only as a guideline and that its subject-matter may extend to what, from a consideration of the description and drawings, the patent proprietor has contemplated.
- 4) The patent claim is to be interpreted from the point of view of a person skilled in the art.
- 5) In applying these principles, the aim is to combine adequate protection for the patent proprietor with sufficient legal certainty for third parties.

4.3. These principles for the interpretation of a patent claim apply equally to the assessment of the infringement and the validity of a European patent. This follows from the function of patent claims, which under the European Patent Convention serve to define the scope of protection of the patent under Art. 69 EPC and thus the rights of the patent proprietor in the designated Contracting States under Art. 64 EPC, while considering the conditions for patentability under Art. 52 to 57 EPC.

4.4. The subject-matter and the scope of protection

As regards claim 1, the points of contention are the meaning of “analyte measurement data” and the interpretation of “first” and “second” portions of analyte measurement data.

Applying the principles for claim interpretation mentioned above, the Court notes that the description distinguishes between analyte measurements and raw sensor measurements ([0005] and [0020] in the patent in suit). It follows that analyte measurement data closely reflect the raw

measurements indicative of physiological analyte levels taken by the sensor, as is sufficiently clear from the wording of claim 1. That data could be used as a basis for further processing, for example to calculate “transformed” data (see e.g. [0040] in the patent in suit) such as estimated analyte values (see also claims 6 and 7 in the patent in suit).

Claim 1 further defines first and second portions of analyte measurement data, the meaning of which is contentious among the parties. These features require interpretation, relying on the standard meaning of the terms and in the light of the description.

- 4.5. According to DEXCOM, Claim 1 of the Patent at issue discloses an analyte monitoring system in which the sensor electronics unit transmits both¹ a first portion of analyte measurement data using a first communication protocol that is Bluetooth or Bluetooth Low Energy and a second portion of analyte measurement data using a second communication protocol that is NFC or RFID in response to a data request command that is transmitted to the sensor electronics unit using the second communication protocol.
- 4.6. ABBOTT argues that during the opposition proceedings, DEXCOM adopted a narrow construction of the term “portion” in claim 1 of the Patent. According to this narrow construction, the wording of claim 1 has two requirements: (1) the transmission of two distinct portions of analyte measurement data indicative of analyte levels using two different communication protocols and (2) neither of the two portions can contain all of the data. ABBOTT adds that DEXCOM adopts a broader interpretation in seeking remedies in its infringement action against the accused product “Freestyle Libre 2”. The reason for this broader interpretation adopted by DEXCOM is that ABBOTT’s products use two communication protocols for transmission of analyte measurement data, however in Libre 2 the same analyte measurement data is transmitted using both communications protocols (BLE and NFC) with all of the data being transmitted via each protocol, resulting in a total overlap (pages 13-15 of ABBOTT’s Statement of Defence and Counterclaim).
- 4.7. In the Court’s view, portions of data are not comparable to parts of a book or portions of a cake (see ABBOTT’s pleadings during the oral hearing), since it is technically possible to include the same piece of data in different portions for transmission, meaning that the portions may overlap. However, contrary to DEXCOM’s arguments, the portions cannot be identical, since this would contradict the usual distinction between a first and a second portion, as well as the description (Patent at issue, paragraph [0018]: “*a portion of the analyte data or values may be communicated using the first communication protocol, and another portion of the analyte data or values may be communicated using a different communication protocol*”). Moreover, at least once piece of data must be present in each portion to avoid defeating the purpose of the present invention. Lastly, the Court considers that one portion cannot be construed as meaning “all” measurement data stored at a given point in time in the sensor electronics unit. This corresponds to the usual meaning of a “portion” and is in line with the description of the patent in suit, which distinguishes a portion from all data (Patent at issue, paragraph [0020]: “*send a portion or all of the stored data*”).

5. VALIDITY OF THE PATENT AT ISSUE

- 5.1. ABBOTT seeks the revocation of the patent at issue on various grounds: added subject-matter, lack of novelty, and lack of inventive step.

¹ For the sake of clarity, certain terms have been highlighted by the Court using bold and underlined font.

5.2. As a preliminary point, there is an issue related to the jurisdiction of the present Court in relation to the revocation request. DEXCOM requested that the Court decline jurisdiction in relation to the German part of the European patent at issue, while ABBOTT requested a revocation of the patent in its entirety.

6. Jurisdiction of the UPC for the counterclaim for revocation of the German part of EP 866

6.1. DEXCOM argues in its statement filed on 15 January 2024 (Reply to the Statement of Claim and to the counterclaim, page 7) that the UPC has no jurisdiction to hear the counterclaim for revocation against the German part of EP 866:

- for Defendants 1, 2 and 8, lack of jurisdiction already follows from the fact that Claimant has not asserted the German national part against them so there is no possibility of a counterclaim under Art. 33(3) UPCA regarding the German national part for those Defendants;
- for Defendant 8, pursuant to Art. 31 UPCA, and Art. 71c(2), Art. 29(3) of 1215/2012 EU Regulation, lack of jurisdiction additionally results from the fact that this Defendant has already brought a nullity action before the German Federal Patent Court against the German national part of EP 866 (C051, C051-EN), as stated in the Statement of Claim, § 32.
- for the remaining Defendants, lack of jurisdiction results from Art. 31 UPCA, and Art. 71c(2), Art. 30(2) of 1215/2012 EU Regulation.

6.2. From ABBOTT's perspective, (Rejoinder to the reply and Reply to the defence to the counterclaim, pages 27 to 30):

- concerning arguments based on Art. 33(3) UPCA, even if the Court decides that Defendants 1, 2 and 8 cannot bring a counterclaim for revocation pursuant to Art. 33(3) UPCA, the counterclaims for revocation of the other Defendants are not affected given the fact that the revocation of the Patent would in any event have *erga omnes* effect.
- concerning arguments based on Art. 29 and 30 Regulation 1215/2012 (Brussels I recast Regulation): it is unclear whether the jurisdictional rules as provided for in Art. 29 and 30 of Regulation 1215/2012 are applicable in a situation wherein national proceedings were initiated before the entry into force of the transitional period with regard to Art. 71c Brussels Ibis Regulation and Art. 83 UPCA.
- the counterclaim of the other Defendants cannot be considered as a related action within the meaning of Art. 30 Regulation 1215/2012, since the German national action and the action before the UPC involve completely different parties. Even if the Court were to consider the counterclaim of the other defendants to be related, it is not obliged to decline jurisdiction.

7. *Legal framework*

7.1. *Articles of the Agreement on a Unified Patent Court (UPCA)*

Art. 31 UPCA: "The international jurisdiction of the Court shall be established in accordance with Regulation (EU) No 1215/2012 or, where applicable, on the basis of the Convention on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (Lugano Convention)."

Art. 32(1) UPCA: "(1) The Court shall have exclusive competence in respect of:
(a) actions for actual or threatened infringements of patents and supplementary protection certificates and related defences, including counterclaims concerning licences;".

Art. 83 UPCA: "(1) During a transitional period of seven years after the date of entry into force of this Agreement, an action for infringement or for revocation of a European patent or an action for infringement or for declaration of invalidity of a supplementary protection certificate issued for a product protected by a European patent may still be brought before national courts or other competent national authorities."

7.2. *Articles of the Regulation EU N° 1215/2012 Brussels I recast (Brussels Ibis):*

Art. 29 Brussels Ibis:

"(1) Without prejudice to Article 31(2), where proceedings involving the same cause of action and between the same parties are brought in the courts of different Member States, any court other than the court first seised shall of its own motion stay its proceedings until such time as the jurisdiction of the court first seised is established.

(2) In cases referred to in Paragraph 1, upon request by a court seised of the dispute, any other court seised shall without delay inform the former court of the date when it was seised in accordance with Article 32.

(3) Where the jurisdiction of the court first seised is established, any court other than the court first seised shall decline jurisdiction in favour of that court."

Art. 30 Brussels Ibis:

"(1) Where related actions are pending in the courts of different Member States, any court other than the court first seised may stay its proceedings.

(2) Where the action in the court first seised is pending at first instance, any other court may also, on the application of one of the parties, decline jurisdiction if the court first seised has jurisdiction over the actions in question and its law permits the consolidation thereof.

(3) For the purposes of this Article, actions are deemed to be related where they are so closely connected that it is expedient to hear and determine them together to avoid the risk of irreconcilable judgments resulting from separate proceedings."

Art. 71a Brussels Ibis:

(1) For the purposes of this Regulation, a court common to several Member States as specified in Paragraph 2 (a 'common court') shall be deemed to be a court of a Member State when, pursuant to the instrument establishing it, such a common court exercises jurisdiction in matters falling within the scope of this Regulation.

(2) For the purposes of this Regulation, each of the following courts shall be a common court:

(a) the Unified Patent Court established by the Agreement on a Unified Patent Court signed on 19 February 2013 (the 'UPC Agreement'); (...)"

Art. 71c Brussels Ibis:

"(2) Articles 29 to 32 shall apply where, during the transitional period referred to in Article 83 of the UPC Agreement, proceedings are brought in the Unified Patent Court and in a court of a Member State party to the UPC Agreement."

8. *Grounds for the jurisdiction issues*

In its infringement action, DEXCOM requests the exclusion of the infringement acts that are the subject-matter of an action initiated before the Mannheim Regional Court, which is based on the German part of the same patent (DEXCOM Exhibits C048 and C049). This action is still pending against Defendants 1, 2 and 8. In addition, Defendant 8 (ABBOTT GmbH) has previously initiated a revocation action concerning the German part of EP 866 dated 9 May 2023 before the German Federal Patent Court (DEXCOM Exhibit C051/C051-EN).

9. Concerning the scope of Paris Local Division's jurisdiction to revoke the Patent:

According to DEXCOM, in the present case, the scope of the counterclaim for revocation of the patent should be identical to the scope of the infringement claim, from which certain acts of infringement that are already pending before a national court with parallel jurisdiction are excluded for certain defendants.

9.1. The Court finds this argument irrelevant in the present case for two reasons.

First, as ABBOTT rightly pointed out, the application for revocation is also supported by defendants other than Defendants 1, 2 and 8 which are involved in the parallel national proceedings. These additional defendants are accused of infringement in all territories where the European patent is in force and in particular in Germany. It would be contrary to the principle of a fair trial to deprive these defendants of the right to defend themselves by means of a counterclaim for revocation of the entire European patent.

9.2. Furthermore, this revocation of the entire patent will have an "erga omnes" effect. Under French law practice, it is accepted that the scope of a counterclaim for revocation is limited to what is asserted in the main infringement claim, through a very strict interpretation of the sufficient link that must exist between the main claim and the counterclaim based on Art. 70 of the French Code of Civil Procedure. However, there is no provision in the UPC Rules of Procedure that limits the party bringing a counterclaim to the parts of the patent asserted against it by the claimant in the infringement action, and no requirement that such party limit its action for revocation to what is asserted against it in the main infringement action. Only Art. 33(3) UPCA governing the internal jurisdiction of the UPC divisions provides that "(3) [a] counterclaim for revocation as referred to in Article 32(1)(e) may be brought in the case of an action for infringement as referred to in Article 32(1)(a)".

9.3. Consequently, the fact that DEXCOM has chosen to exclude certain acts of infringement from its claim against some of the defendants is irrelevant in the present case.

9.4. The scope of the dispute brought before the Court is incontestably governed by the principle that the parties define the subject matter of the dispute, a general principle of law which is reiterated in Art. 76(1) of the UPC Agreement and which, moreover, allows the claimant in the main action to exclude certain acts of infringement in order to avoid the inconvenience of parallel jurisdictions between the UPC and national courts during the transitional period provided for in Art. 83 of the Agreement ("carve out"). However, this principle cannot restrict a defendant in its challenge to the validity of the European patent which is being asserted against it since no legal text that is binding upon UPC law expressly states such a restriction.

10. Concerning parallel jurisdiction with the German court first seized:

According to ABBOTT, it is under Art. 71c of the Brussels Ibis that Art. 29 and 30 on *lis pendens* cases can be applied to disputes in which the UPC has jurisdiction in parallel with a national court. Art. 71c only governs the transitional period defined by Art. 83 of the Agreement. In the present case, the German court was seized before 1 June 2023, the date on which the UPC entered into force, and consequently the conditions for applying Art. 71c are not met in the present case, and Articles 29 and 30 of Brussels Ibis are not applicable.

- 10.1. The Court does not accept the above reasoning, as it is not necessary to apply Art. 71(c) for the UPC to be governed by the Brussels Ibis. In fact, Art. 71(a) states that the UPC is a "common court" which "shall be deemed to be a court of a Member State". This means that the UPC is subject to the "Member State courts" regime in this matter. Art. 29 and 30 of the Brussels Ibis are therefore directly applicable to the UPC. Moreover, Article 31 of the UPC Agreement, which governs the UPC's international jurisdiction clearly states: "The international jurisdiction of the Court shall be established in accordance with Regulation (EU) No 1215/2012".
- 10.2. Art. 29 and 30 of the Brussels Ibis address *lis pendens* and *related actions*. In the present case, the revocation action brought by Defendant 8 (ABBOTT GmbH) before the German Federal Patent Court was filed on 9 May 2023, prior to the counterclaim for revocation in the present case, which was filed on 14 November 2023. DEXCOM infers therefrom that this present Court must decline jurisdiction in favour of the German court.
- 10.3. ABBOTT disputes that the present case involves a *lis pendens* situation. The Court considers that the present case does not constitute a situation of identity of parties and subject-matter, as the parties are different given that the revocation action in Germany concerns only the German part of the patent, and Defendant 8 is the sole claimant. The Court is therefore not obliged to decline jurisdiction in favour of the first court seized (Art. 29(3) Brussels Ibis).
- 10.4. Notwithstanding the above, the two parallel actions must be considered "related actions" insofar as they both concern patent EP 866 and involve two of the same parties in the present action (DEXCOM and Defendant 8). Thus, the situation falls under Art. 30(2), which specifies that, in this case, it is at the discretion of the court seized second to decide whether to decline its jurisdiction in favour of the court first seized. In the case at hand, the German Federal Patent Court delivered its Preliminary opinion on 26 March 2024 and scheduled an oral hearing for 29 January 2025 (ABBOTT Exhibit: Annex C7).
- 10.5. In this context, it is clear that the German national Court will not give its final decision until after the present decision has been rendered on 4 July 2024. In light of the principles of efficiency and expeditious decisions set out in points 4 and 7 of the Preamble and Recital (6) of the Agreement, the Court considers that, in the present situation, it is not in the interests of the proper administration of justice either to decline jurisdiction in favour of the German national court or to stay proceedings pending the decision of the national court.
- 10.6. For these reasons, the Court decides to maintain jurisdiction to rule on the validity of the entire European patent EP 866, including its German part.

11. Added subject-matter

11.1. Art.138(1)(c) EPC provides that a European patent may be revoked with effect for a Contracting State on the grounds that "the subject-matter of the European patent extends beyond the content of the application as filed".

11.2. ABBOTT contends that the subject-matter of claim 1 of the European patent extends beyond the content of the application as filed, arguing that the application as filed (ABBOTT Exhibit, Annex A3) discloses the transmission of a portion of data by two different protocols *only in response to a data request command sent by NFC/RFID*. According to ABBOTT, there is no basis in the application as filed for sending a portion of data by either of the two protocols *unless* it occurs in response to the same data request command sent by NFC/RFID.

11.3. The Court notes that, as DEXCOM rightly pointed out, the claim as originally filed that is closest to claim 1 as granted is claim 22.

Original claim 22 reads (ABBOTT Exhibit, A3):

"An analyte monitoring system, comprising:

a sensor configured to take measurements indicative of analyte levels

a sensor electronics unit communicatively coupled to the sensor, wherein the sensor electronics unit is configured to:

receive the measurements indicative of analyte levels from the sensor and calculate estimated analyte values,

transmit the estimated data indicative of analyte levels using a first communication protocol, and receive commands using a second communication protocol;

and a display device configured to:

receive data indicative of analyte levels using the first communication protocol, and

transmit a data request command to the sensor electronics unit using the second communication protocol, wherein the sensor electronics unit sends a portion of the data indicative of analyte levels using the first communication protocol and another portion of the data indicative of analyte levels using the second communication protocol in response to the data request command."

11.4. A disclosure regarding the concrete implementation of the first and second protocols as Bluetooth/BLE and NFC/RFID, respectively, is not contested. In the Court's view, the last feature of claim 22 as originally filed does not imply that both portions of data must be transmitted in response to the (same) data request command. There is no embodiment of the invention described that would cause transmission of the two portions in response to the same command. Moreover, transmission can occur autonomously from device 6 to device 20, and only in some cases, e.g. at the initiative of the user, can data be transmitted in response to commands and/or requests sent over the second protocol, i.e. NFC or RFID (see paragraph [0235] in the description of the application as originally filed).

11.5. A difference from claim 1 as granted is that features related to estimated analyte values were omitted in claim 1 as granted. This omission is allowable because the skilled person understands that the steps of calculating and transmitting estimated analyte values are distinct from receiving and sending portions of the data indicative of analyte levels. They are also presented as optional in the description as originally filed (see paragraph [0184]: "... *In some cases, a conversion function can be used to convert measured unprocessed data into processed data, such as estimated glucose values*").

11.6. In conclusion, the subject-matter of claim 1 of the patent in suit does not extend beyond the content of the application as filed.

12. Novelty

12.1. Art. 54 EPC states the following: "(1) An invention shall be considered to be new if it does not form part of the state of the art.

(2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

(3) Additionally, the content of European patent applications as filed, the dates of filing of which are prior to the date referred to in paragraph 2 and which were published on or after that date, shall be considered as comprised in the state of the art. (...)"

12.2. In order to be considered part of the state of the art, an invention must be found integrally, directly and unambiguously in one single piece of prior art and in its existing form it must be identical with its constitutive elements, in the same form, with the same arrangement and the same features.

12.3. In support of its application for a declaration of invalidity on the grounds of lack of novelty, ABBOTT relies on three prior art documents: US 2015/0205947- "Berman" (Annex D1; Berman), US 2015/0038818 A1- "Cole" (Annex D2; Cole) and US 2011/0213225 A1- "Bernstein" (Annex D3; Bernstein).

13. Novelty over D1 (Berman):

The ABBOTT entities contest the novelty of the subject-matter of the claims of the patent in suit *inter alia* on the basis of document US 2015/0205947 (D1; Berman). Berman was published on 23 July 2015 and thus constitutes prior art in accordance with Art. 54(2) EPC. This is not contested. ABBOTT argues that Berman anticipates all the features of claim 1 of the Patent in a manner detrimental to novelty. In particular, Berman discloses the transmission of different data portions via Bluetooth/BLE on the one hand and via NFC/RFID on the other hand in an analyte monitoring system.

DEXCOM contests the alleged lack of novelty over D1.

13.1. D1, Figure 1:

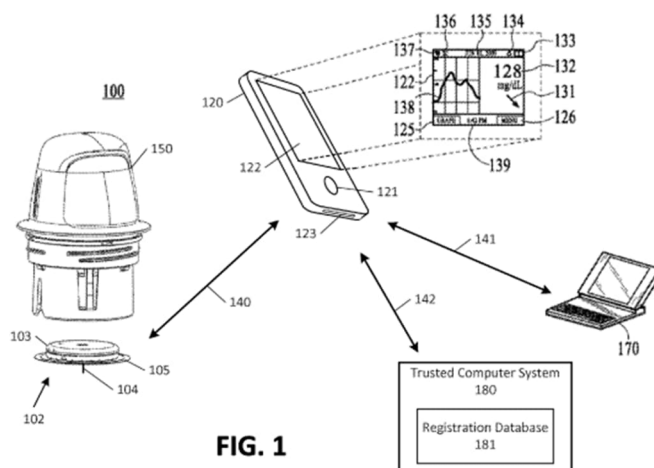


FIG. 1

Figure 1 (D1) shows an analyte monitoring system, comprising:

- a sensor (104) configured to take measurements indicative of analyte levels;
- a sensor electronics unit (sensor control device 102) communicatively coupled to the sensor and configured to receive the analyte measurement data indicative of analyte levels from the sensor and transmit the analyte measurement data indicative of analyte levels;
- a display device (reader device 120) configured to receive analyte measurement data indicative of analyte levels from the sensor electronics unit.

13.2. According to DEXCOM, D1 only discloses the use of a single communication protocol on a single communication path (see arrow 140 in Fig.1) for the transmission of analyte data; moreover, D1 teaches the use of two transmission techniques (on-demand and broadcast) for the transmission of analyte data, but not the use of two communication protocols.

13.3. By contrast, ABBOTT considers that D1 teaches all the features of Claim 1 of the patent at issue, in particular feature 1.3.3. ABBOTT argues that D1 discloses receiving a first portion of analyte measurement data by the reader via Bluetooth or BLE ([0100], [0104]) and, in the following paragraph and in the same embodiment, receiving a second portion of analyte measurement data by the reader via NFC ([0101], [0104]).

14. In light of its comparative analysis between EP 688 (claim 1) and D1, the Court notes the following.

15. *The protocols*

In cases where data transmission is wireless, D1 mentions that a near-field communication (NFC) protocol, RFID protocol, Bluetooth or Bluetooth Low Energy protocol, or Wi-Fi protocol can be used between a device 102 and a device 120 that communicate with each other over a local communication path (see paragraph [0064]).

DEXCOM submits that a wireless data communication referred to in document D1, paragraphs [0100] and [0101] through a “connection” (see paragraph [0102]) must not be confused with a protocol. However, in the Court’s view, the skilled person would understand such a connection as implying the use of the corresponding protocol, i.e. for instance a BLE connection would be implemented using the BLE protocol, at least absent any indication to the contrary. The patent specification does not hint at a departure from this assumption.

As a result, this argument is not convincing and, hereinafter, any mention of a wireless data transmission or connection, such as BLE, implies the use of the corresponding protocol, e.g. the BLE protocol.

16. *The two schemes*

16.1. D1 discloses that data may be transmitted from device 102 to device 120 at the initiative of either device 102 or device 120, i.e. according to two schemes:

- First scheme (see paragraph [0100]): data transfer at the initiative of device 102: device 102 may communicate data periodically in a broadcast-type fashion, such that an eligible reader device 120 can receive the communicated data (e.g. sensed analyte data). This is at the initiative of device 102 because device 120 does not have to send a request that would prompt device 102 to communicate. Bluetooth or BLE (BTLE being the acronym designating Bluetooth Low Energy in D1) are expressly listed as alternatives for a first communication protocol.
- Second scheme (see paragraph [0101]): data transfer at the initiative of device 120: device 120 sends a transmission that prompts device 102 to communicate its data to device 120.

An on-demand data transfer can be initiated based on a schedule stored in the memory of device 120, or at the behest of the user via device 120. For example, if the user wishes to check his or her analyte level, the user could perform a scan of device 102 using an NFC, Bluetooth, BTLE, or WiFi connection.

- 16.2. The units (102, 120) are configured to support both schemes combined into a single system, as is clear and unambiguous from the final sentence of paragraph [0101]: *"Data exchange can be accomplished using broadcasts only, on demand transfers only, or any combination thereof."*
- 16.3. DEXCOM submits that document D1 teaches sending all analyte measurement data using only a single communication protocol on a single communication path, thereby deterring the skilled person from using two protocols. The Court notes that the description of D1 never uses the word "single" associated with the schemes listed above. Moreover:
- Figure 1 is a schematic presentation of the system. Depicting the path (140) as a single line between the devices (102, 120) does not imply any restriction on the number of protocols actually used in successive data transmissions along that path.
 - Paragraph [0038], lines 1-4 and paragraph [0042], lines 1-5 disclose that *"an RF transceiver [is] adapted to receive data from an in vivo analyte sensor"*. These paragraphs are irrelevant for the protocol used for data transmission.
 - Paragraph [0064] discloses that *"[i]n embodiments where path 140 is wireless, a near field communication (NFC) protocol, RFID protocol, Bluetooth or Bluetooth Low Energy protocol, Wi-Fi protocol, proprietary protocol, or the like can be used."* Contrary to DEXCOM's submissions, the use of the coordinating conjunction "or" does not mean that the "or" is exclusive, i.e. that only one of the listed protocol could be used to the exclusion of the others.
 - Paragraph [0088] relates to an embodiment where two separate applications (sensor interface application 232 and user interface application 234) are each executed for processing and display on different devices (devices 102 and 120, respectively) and communicate over communication path 140. The paragraph is irrelevant to the protocol used for data transmission.
 - Paragraph [0101], last sentence, discloses that *"[d]ata exchange can be accomplished using broadcasts only, on demand transfers only, or any combination thereof."* DEXCOM's submission that the possibility of combining schemes does not imply combining the protocols expressly associated with these schemes (e.g. in paragraph [0064]) is not convincing.
 - Figure 2A is a block diagram depicting an example embodiment of a reader device configured as a smartphone, more specifically *"an abbreviated representation of the typical hardware and functionality that resides within a smartphone, but other hardware and functionality (e.g., codecs, drivers, glue logic, etc.) can also be included here."*, as recited in the last sentence of paragraph [0084]. The skilled person would understand that this example and the related explanations do not limit the protocols to a single one.
- 16.4. The Court agrees with DEXCOM that implementing two protocols might result in issues such as hardware integration problems, an increased footprint, increased power requirements and costs for the on-body electronics unit, compared to using a single protocol. However, the system described in D1 expressly envisages the use of two protocols and the skilled person would not perceive any insuperable issues that would deter them from implementing the system of D1. The Court further observes that the invention described in the patent in suit does not provide any specific technical feature to resolve or mitigate the aforementioned potential issues.

16.5. As a result, the skilled person would interpret D1 as disclosing the use of two protocols for data transmission.

17. *The data request command*

17.1. Near-field communication (e.g. NFC) requires that the unit (120) be close enough to the on-body unit (102). The system of D1 initiates on-demand communication with a technique working near-field, i.e. NFC (see paragraph [0103]: *"In certain embodiments, positioning sensor control device 102 and reader device 120 within a predetermined distance (e.g., close proximity) relative to each other initiates one or more software routines of reader device 120 to generate and transmit a request, command..."*).

17.2. From the above, it follows that D1 discloses a system with:

- a sensor electronics unit configured to receive a data request command using a second communication protocol, that is near field communication, NFC; and
- a display device configured to transmit a data request command to the sensor electronics unit using the second communication protocol, as set out in claim 1.

18. *The portions*

18.1. Different amounts of analyte measurement data may be transmitted in each mode (see paragraph [0104] in D1: *"Different types and/or forms and/or amounts of information may be sent as part of each on-demand or broadcast transmission including, but not limited to, one or more of current analyte level information (i.e., real time or the most recently obtained analyte level information temporally corresponding to the time the reading is initiated)"*). The "amounts" indicated in D1 correspond to the portions specified in claim 1, and the system according to D1 is configured to transmit the first and second portions of the analyte measurement data indicative of analyte levels, as outlined in claim 1.

18.2. From the above, it follows that D1 discloses a system with:

- a sensor electronics unit configured to:
transmit a first portion of the analyte measurement data indicative of analyte levels using a first communication protocol, that is Bluetooth or Bluetooth Low Energy, BLE;
in response to the data request command, transmit a second portion of the analyte measurement data indicative of analyte levels;
- a display device configured to:
receive the first portion of the analyte measurement data indicative of analyte levels using the first communication protocol;
receive the second portion of the analyte measurement data indicative of analyte levels in response to the data request command.

19. *The differences*

Paragraph [0101] of D1 lists various candidates for the protocols available for transmitting the second portion of the analyte measurement data, namely NFC, Bluetooth, BLE, and WiFi. However, D1 does not expressly disclose NFC as the protocol selected.

20. In conclusion, the subject-matter of claim 1 is novel over the system disclosed in D1 and differs in that:

- the sensor electronics unit is configured to:

transmit a second portion of the analyte measurement data indicative of analyte levels using the second communication protocol;

- the display device is configured to:
receive the second portion of the analyte measurement data indicative of analyte levels using the second communication protocol.

Therefore, the subject-matter of claim 1 is novel over D1.

21. Novelty over D2 (Cole):

Cole (Annex D2) was published on 5 February 2015 and thus constitutes pre-published prior art in accordance with Art.54 (2) EPC. This is not contested.

21.1. According to ABBOTT, Cole anticipates the subject-matter of claim 1 of the Patent at issue, while DEXCOM argues that D2 fails to anticipate claim 1. Specifically DEXCOM points out that while D2 discloses multiple different embodiments, none of the embodiments comprises an analyte monitoring system in which the sensor electronics unit transmits both a first portion of analyte measurement data using a first communication protocol that is Bluetooth or Bluetooth Low Energy and a second portion of analyte measurement data using a second communication protocol that is NFC or RFID in response to a data request command that is transmitted to the sensor electronics unit using the second communication protocol.

21.2. On the contrary, DEXCOM considers in particular that there is no disclosure of the transmission and reception of a first portion of analyte measurement data indicative of analyte levels using a first communication protocol such as Bluetooth or BLE and that the Defendants wrongly interpret “analyte data indicative of analyte levels” in their analysis of the teaching of D2.

21.3. The Court observes that Cole is primarily concerned with sending a notification (“*notification data*”) by a sensor unit to a display device (120) in case an adverse condition (e.g. an excessive glucose rate of change) is detected. Notification data “*can be a single data bit representative of an adverse condition alert*” (see [0025]) and is therefore clearly distinct from measurement data. The sensor unit initiates transmission of the notification data via RF communication, e.g. Bluetooth or BLE.

21.4 . This is combined with normal transmission of measurement (glucose) data (“*data packets*”) in response to a request from the display device via RFID (see [0030], [0031]), upon interrogation/request from the display device (120).

21.5. The question arises as to whether Cole also describes the transmission of a first portion of measurement data as in claim 1 of the patent in suit, when interpreted in the light of the description. In particular one sentence in paragraph [0042] (“*In addition to the notification data, stored and current glucose data... may be transmitted using the RF communication link*”) must be correctly understood. The notification data is prioritised over measurement data and transmitted with higher power levels to increase reliability, i.e. an increased transmission range when compared with the range during normal operation (see [0033], [0034]). By contrast, according to the patent in suit, both portions are transmitted as part of normal operation, i.e. the first portion is not transmitted in the event of an adverse condition along with notification data.

21.6. Thus, the Court considers that it was not sufficiently demonstrated that Cole discloses the transmission of two portions of measurement data according to two different protocols within the meaning of the patent in suit.

Therefore, the subject-matter of claim 1 is novel over the system disclosed in D2, and D2 is considered less relevant than D1.

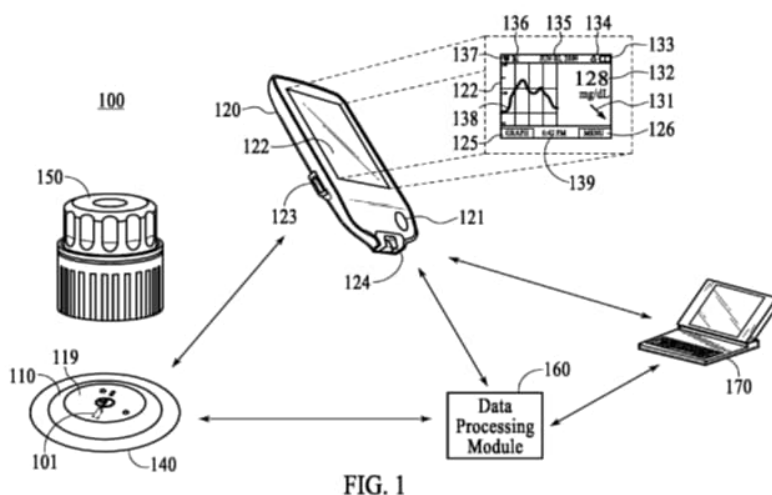
22. Novelty over D3 (Bernstein):

Application US 2011/0213225 A1 ("Bernstein") was published on 1 September 2011 and thus constitutes prior art in accordance with Art. 54(2) EPC. This is not contested.

22.1. According to ABBOTT, Bernstein anticipates all features of the claim 1 of the Patent in a manner detrimental to novelty.

22.2. DEXCOM rejects this argument, arguing that in particular D3 fails to disclose an analyte monitoring system in which the sensor electronics unit transmits both a first portion of analyte measurement data using a first communication protocol that is Bluetooth or Bluetooth Low Energy and a second portion of analyte measurement data using a second communication protocol that is NFC or RFID in response to a data request command that is transmitted to the sensor electronics unit using the second communication protocol.

22.3. Figure 1 (D3) shows:



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22.4. The Court notes that Bernstein discloses a monitoring system with an analyte sensor (101), an on-body electronics unit (110) configured to store monitored analyte-related data received from the analyte sensor and a display device (120).

Device 120 sends a request and receives measurement data, using near-field communication protocols such as RFID (see [0096], [0196], [0278]). D3 stresses the importance of power aspects in the sensor electronic unit (see [0181], [0185]). The Bluetooth protocol might also be used, for example, in conjunction with an optional module (160) that communicates with units (110, 120) (see [0099]).

Although it lists RFID and Bluetooth, Bernstein does not disclose a system configured to transmit two portions of measurement data using these two protocols as set out in claim 1 of the patent in suit.

For these reasons, the subject-matter of claim 1 is novel over the system disclosed in D3, and D3 is less relevant than D1.

23. Lack of inventive step

23.1. Art. 56 EPC 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.”

23.2. In order to assess inventiveness, it is necessary to determine whether, given the state of the art, a person skilled in the art would have obtained the technical solution claimed by the patent using their technical knowledge and carrying out simple operations. Inventive step is defined in terms of the specific problem encountered by the person skilled in the art.

23.3. ABBOTT argues that Berman:

- discloses different protocols that can be used for each transmission type. For the broadcast communication, Berman teaches the use of Wi-Fi, Bluetooth or BLE ([0100]). For the on-demand communication, Berman teaches the use of NFC, Wi-Fi, Bluetooth or BLE ([0101]).

- teaches the skilled person that "*Data exchange can be accomplished using broadcasts only, on-demand transfers only, or any combination thereof.*" ([0101]).

- and instructs the skilled person that the different types of data transmission (on-demand and broadcast) may be used to transmit different portions of analyte measurement data ([0104]).

ABBOTT adds that, even if one considers, in line with the decision by the EPO Opposition Division (Annex C1: OD views), that Berman discloses the combined use of two different communication types, namely "on-demand" data transmission on the one hand, and "broadcast" data transmission on the other hand, but does not disclose the combined use of two different communication protocols (Bluetooth or BLE on the one hand and NFC or RFID on the other hand), nonetheless the system of claim 1 would have been obvious to the skilled person reading Berman at the Priority Date.

23.4. DEXCOM contends that:

- ABBOTT's argument is based on an incorrect assumption about the disclosure,

- ABBOTT's argument regarding multi-functional circuitry 212 is incorrect,

- in any event, there is no motivation to select Bluetooth or BLE for the "broadcast technique" and NFC for the "on-demand" technique.

In summary, DEXCOM concurs with the conclusion reached by the Opposition Division (C047, p.19): there is nothing in D1, or in common general knowledge, that would motivate the skilled person to modify the system of D1 to arrive at the claimed system.

23.5. As explained above, the Court considers that the claimed invention differs from the system described in Berman solely in that Berman does not expressly disclose the protocol used for transmitting the second portion of the analyte measurement data from device 102 to device 120 in the second, on-demand, scheme.

23.6. Confronted with the task of carrying out the system of D1, the skilled person would have to select one protocol. The technical problem can be defined as choosing a protocol for transmitting the second portion of the analyte measurement data.

D1 expressly lists four candidates, namely NFC, Bluetooth, BLE and WiFi (see paragraph [0101]).

The advantages and disadvantages of each protocol are common general knowledge, such as considerations of energy efficiency and security. The patent in suit does not ascribe any particular

or surprising effect to choosing NFC (or RFID), beyond the well-known advantages of low power consumption and security due to the low range.

D1 expressly discloses that the device 120 already uses NFC for the request command initiating the transmission of the second portion, meaning that the user has already brought the device 120 into close proximity with the device 102.

It would therefore be obvious for the skilled person to continue using the same protocol, namely the second near-field communication protocol NFC, to transmit the data and achieve the effects commonly ascribed to this protocol.

23.7. For all the reasons above, the Court concludes that the invention set out in claim 1 of the patent in suit does not involve an inventive step when considered in view of D1 combined with common general knowledge.

23.8. Furthermore, the Court notes that the Preliminary Opinion issued by the German Federal Patent Court on the German part of EP 866, dated 26 March 2024, states in its § 6: "since an NFC connection is already established anyway due to the NFC scan, it should have been obvious for the person skilled in the art to use this NFC connection, a data transmission protocol, to transmit the on-demand analysis data. In paragraph [0059], sentence 2 of D1, there is also an explicit reference to the basic interchangeability of components of different embodiments, functions or components mentioned in the citation (see D1, paragraph [0059], sentence 2: "if a certain feature, element, function or step is described with respect to only one embodiment, then it should be understood that the feature, element, component, function or step can be used with every other embodiment described herein unless explicitly stated otherwise")." (ABBOTT Exhibit C097, English translation).

24. Auxiliary requests

Pursuant to Rule 30 RoP, DEXCOM has filed two auxiliary requests (DEXCOM Exhibits C129 and C130) to amend claim 1 in the patent in suit.

ABBOTT contends that both proposed amendments are not allowable, arguing that Auxiliary request 1 is neither new nor at least inventive and that Auxiliary request 2 consists of unlawful added matter and is not inventive.

25. Auxiliary Request 1

The amendment of Claim 1 concerns more specifically feature 1.2.2 in two ways, namely by deleting "Bluetooth" and by adding that a data connection is established between the sensor electronics unit and the display device.

Claim 1 has been amended to specify that the sensor electronics unit is configured to:

- "establish a data connection with a display device and transmit to the connected display device a first portion of the analyte measurement data indicative of analyte levels using a first communication protocol that is Bluetooth Low Energy, BLE"

Support for the added feature can be found e.g. in paragraph [0094] and paragraphs [0128]-[0133] of the application as originally filed. The Court is satisfied that the amendments comply with Article 138(1) (c) and (d) EPC.

25.1. Novelty of the amended claim under Auxiliary request 1 over D1, D2, D3

The Court has already explained above why the system of claim 1 as granted is novel over the systems known from D1, D2 or D3. The subject-matter of claim 1 according to Auxiliary request 1 is a fortiori also novel, as it further limits the first protocol to BLE and sets out an additional feature (establishing a data connection).

Therefore, the subject-matter of the amended claim according to Auxiliary request 1 is novel.

25.2. Inventiveness of the amended claim under Auxiliary request 1 over D1 (Berman)

D1 expressly discloses the use of BLE as the first protocol, as explained above with respect to claim 1 of the patent in suit.

The Court considers that the establishment of a data connection, as set out in the amended claim 1, does not contribute to an inventive step for the following reasons:

Establishing a data connection can be achieved by the electronics unit sending advertisements and the display unit responding and acknowledging the advertisement. After completion of the connection process, the sensor electronics unit and the now-connected display device can engage in a data communication according to the first protocol, i.e. BLE.

25.3. DEXCOM submits that D1 discloses a broadcast transmission expressly referred to as a "broadcast mode" in the Bluetooth or BLE specification, which is a connectionless unidirectional transmission mode, meaning no connection is established prior to transmitting data.

A data connection may increase security, improve reliability and reduce power consumption, since the sensor electronics unit would send data only when a target display unit is within range.

25.4. The Court acknowledges the potential advantages of a data connection compared to a mere connectionless "broadcast mode" according to the BLE specification.

However, the Court does not agree that D1 would deter the skilled person from establishing a data connection, for the following reasons.

- D1 makes no express reference to the "broadcast mode" according to the Bluetooth specification: when it refers to broadcast for the first protocol in paragraphs [0100] and [0101], D1 mentions a "broadcast-type fashion", a "broadcast fashion" or "broadcast(s)" without providing further details.
- In paragraph [0100], last sentence ("*Further, broadcasts can occur in a repeated fashion regardless of whether each broadcast is actually received by a reader device 120*"), D1 hints at connectionless data transmission. However, in paragraph [0100], second sentence ("*... in some example embodiments sensor control device 102 can communicate data periodically in a broadcast-type fashion, such that an eligible reader device 120, if in range and in a listening state, can receive the communicated data*"), D1 suggests another possibility, which implies a data connection to ascertain that device 120 is "eligible", (i.e. authorised to receive sensitive analyte measurement data), "in range" and "in listening state". Mentioning this possibility would make no sense if the disclosure of D1 was limited to the connectionless "broadcast mode" of the Bluetooth specification, as submitted by DEXCOM.

25.5. Thus, there is no reason for the skilled person to interpret the disclosure of D1 in the restrictive manner suggested by DEXCOM.

Starting from D1, the problem to be solved can be formulated as improving the system of D1.

Security is a constant concern in the transmission of highly sensitive data such as physiological data. Reliability and power savings are also constant priorities in the design of wearable systems. The skilled person would therefore seek a solution, particularly for the data transmission using BLE, which is relatively power-hungry compared to the second protocols.

As is apparent from the patent in suit itself (see for examples paragraphs [0178], [0179] and [0180]), Tap-to-Initiate or more generally Out-of-Band pairing are integral parts of the Bluetooth/BLE specification. This is not contested, and the Court additionally refers to the Bluetooth specification Version 4.0 (ABBOTT Exhibit D14.1, section 5.1.4.3 on page 88 of 140; *"The user's experience differs a bit depending on the Out of Band mechanism. As an example, with a Near Field Communication (NFC) solution, the user(s) will initially touch the two devices together, and is given the option to pair the first device with the other device."*). This mechanism is used to discover devices within range and establish a data connection using the NFC protocol, thereby improving security and saving energy in the pairing process.

25.6. As a result, using such a pairing mechanism to establish a data connection is a solution the skilled person would readily envisage, to ascertain for instance that a target display unit is available for data transmission (*"an eligible reader device... if in range and in a listening state"* in D1, paragraph [0100]) and to achieve the known advantageous effects.

The above solution relates to initiating the transmission of the first portion. It is independent of the solution to the problem to be solved concerning the choice of protocol for the transmission of the second portion, and, therefore, no synergetic or surprising effect is achieved by juxtaposing the two features.

In conclusion, the invention set out in claim 1 according to the Auxiliary request 1 does not involve an inventive step over D1, when complemented with common general knowledge.

26. Auxiliary request 2

ABBOTT, first of all, argues that the amended claim 1 under auxiliary request 2 is not allowable on the grounds of added subject-matter.

26.1. *On the grounds of added subject-matter:*

Compared to claim 1 under Auxiliary request 1, Claim 1 under Auxiliary request 2 adds the feature that the display device (20) is *"configured to use the second communication protocol to facilitate pairing of the display device (20) and the sensor electronics unit (6) for communication of the first portion of the analyte measurement data indicative of analyte levels using the first communication protocol."*

26.2. DEXCOM submits that the addition is based on the description of Figure 8, namely paragraphs [0200] to [0206] in the description as originally filed.

According to paragraph [0200], Figure 8 illustrates an example flow chart showing how one communication protocol can be used to facilitate pairing for communication using another communication protocol. The concept of facilitating pairing is further presented in paragraphs [0203] and [0206]. From all the embodiments described in connection with Figure 8, the skilled person understands that facilitating pairing is the consequence or the beneficial effect achieved by using NFC or RFID for sending commands or information from one device to another, as shown in steps 802 and 804. However, there is no basis for a broadening or a generalisation to any use of the second protocol that would be suitable for achieving the effect of facilitating pairing.

26.3. DEXCOM refers to the decision by the Enlarged Board of Appeal of the EPO G 2/10, OJ 2012, 376, point 4.5.1. However, that decision pertains to disclaimers, which is a different situation to introducing subject-matter into a claim from described embodiments of the invention.

26.4. Therefore, Auxiliary request 2 extends the subject-matter of the European patent beyond the content of the application as filed (Art. 138(1)(c) EPC).

27. The dependent claims (2 to 9 of the Patent at issue)

27.1. The ABBOTT entities have requested revocation of the patent in its entirety and have provided concrete reasons to challenge dependent claims 2 to 9 in the statement of counterclaim for revocation of 13 November 2023.

27.2. DEXCOM has defended the dependent claims by stating that "*[t]he dependent claims 2 to 9 contain the features of claim 1 through their dependencies and are therefore novel and inventive for at least the same reasons as explained above in relation to claim 1*" (see page 54, Reply to the Statement of Defence and Counterclaim). However, the parties must provide reasons in support of their claims, but DEXCOM has not presented specific arguments to that effect.

27.3. It is therefore not for the Court to provide reasons why any of the grounds for revocation referred to in Art. 65(2) UPCA, as presented by ABBOTT, would not apply to dependent claims 2 to 9.

27.4. DEXCOM has also not limited the patent by amending the claims to correspond to the subject-matter of one of the dependent claims, in accordance with Art. 65(3) UPCA and Art. 138(2) EPC.

27.5. Instead, DEXCOM has made a conditional application to amend the patent in accordance with Rule 30.1 RoP, by filing replacement claim 1 under a first and a second auxiliary request. These claims have been addressed above and found to be invalid.

28. CONCLUSION

28.1. Given this, the European patent EP 3435866 B1 is not valid, neither as granted, nor as amended by Auxiliary requests 1 and 2, and it must be entirely revoked in accordance with Art. 138(1) EPC and Art. 65(2) UPCA.

28.2. Consequently, the infringement action brought by DEXCOM has no legal basis and all related requests must be dismissed.

28.3. With regard to costs, as mentioned in the Interim conference Order, both parties have requested separate proceedings.

Pursuant to Rule 118. 5 RoP, the Court decides in principle that DEXCOM, as the unsuccessful party, is required to bear legal costs in accordance with Art. 69 of the Agreement.

ABBOTT requests in its statements an interim award of costs of 100.000 Euros, without however submitting any further argument as to this requested amount. The Court considers that the interim award request is not sufficiently justified, consequently the amount covering the costs of the successful party shall be determined by the Court in separate proceedings, upon request by a party for cost decision pursuant to Rule 151 RoP. Therefore, the request made by ABBOTT for an interim award of costs of 100.000 Euros must be dismissed.

DECISION

The Court orders that:

1. The European patent EP 3 435 866 B1 is entirely revoked with effect in the territories of the Contracting Member States for which the European patent had effect at the date of the counterclaim for revocation and as specified by ABBOTT's requests, namely Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Portugal, Slovenia, Sweden,
2. the Registry shall send a copy of this decision to the European Patent Office and to the national patent office of any Contracting Member States concerned, in accordance with Article 65(5) UPCA, after the deadline for appeal has passed,
3. All of DEXCOM's infringement claims based on the patent in suit are dismissed,
4. DEXCOM is required to bear the costs of the proceedings in the action CFI_230/2023 and ABBOTT's request for an interim award of costs of 100.000 Euros is dismissed.

Delivered in Paris, 4 July 2024.

Camille Lignières, Presiding judge and Judge-rapporteur

Carine Gillet, Legally qualified judge

Rute Lopes, Legally qualified judge

Alain Dumont, Technically qualified judge

Alain Marie J Dumont	Signed by: Alain Marie J Dumont Date: 2024-07-03 17:45:17 CEST
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Charlotte Ferhat, Clerk

Information about appeal

An appeal against the present Decision may be lodged at the Court of Appeal, by any party which has been unsuccessful, in whole or in part, in its submissions, within two months of the date of its notification (Art. 73(1) UPCA, R. 220.1(a), 224.1(a) RoP).

Information about enforcement (Art. 82 UPCA, Art. Art. 37(2) UPCS, R. 118.8, 158.2, 354, 355.4 RoP) An authentic copy of the enforceable decision or order will be issued by the Deputy-Registrar upon request of the enforcing party, R. 69 RegR.

DECISION DETAILS

Decision no. 37297/2024 in ACTION NUMBER: ACT_546446/2023

UPC number: UPC_CFI_230/2023

Action type: Infringement Action and Counterclaim for Revocation