



Local Division Munich

**UPC\_CFI\_233/2023**

**Decision on the merits**  
**of the Court of First Instance of the Unified Patent Court**  
**delivered on July 31<sup>st</sup> 2024**

## CLAIMANT

**DexCom, Inc.**, represented by its CEO Kevin Sayer, 6340 Sequence Drive,  
92121 - San Diego, CA – USA,

Represented by:

Quinn Emanuel Urquhart & Sullivan, LLP, Hermann-Sack-Straße 3, 80331  
Munich

## DEFENDANTS

1. **Abbott Laboratories**, represented by its board of directors which is represented by the CEO Robert Ford, 100 Abbott Park Road, Abbott Park, Illinois 60064-6400, USA
2. **Abbott Diabetes Care Inc.**, represented by its president Jared Watkin, 1360 South Loop Road, Alameda, California 94502, USA
3. **Abbott GmbH**, represented by its managing directors Christian Grapow, Robert Funck, and Varlas Konstantinos, Max-Planck-Ring 2, 65205 Wiesbaden, Germany
4. **Abbott Diagnostics GmbH**, represented by its managing directors Christian Grapow, Robert Funck, and Varlas Konstantinos, Max-Planck-Ring 2, 65205 Wiesbaden, Germany
5. **Abbott Logistics B.V.**, represented by its director Hendrikus Lueb, Meeuwenlaan 4, 8011BZ Zwolle, The Netherlands
6. **Abbott (S.A./N.V.)**, represented by its directors Hendrikus Lueb, Hasna Nadir, and Bradley Slater, Avenue Einstein 14, 1300 Wavre, Belgium
7. **Abbott s.r.l.**, represented by the chairman of its boards of directors Massimiliano Bindi, Viale Giorgio Ribotta 9, 00144 Rome, Italy
8. **Abbott B.V.**, represented by its directors Hendrikus Lueb and Bradley Slater, Wegalaan 9, 2132 JD Hoofddorp, The Netherlands
9. **Abbott Scandinavia Aktiebolag**, represented by its board of directors which is represented by the chair of the board Karl Almroth, Hemvärnsgatan 9, 171 54 Solna, Sweden

**10. Abbott France (S.A.S.)**, represented by its president Philippe Emery, 40/48 rue d'Arcueil, 94593 Rungis, France

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PATENT AT ISSUE

***Patent no.***                      *Patent proprietor*

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**EP 3 797 685**                      DexCom, Inc.

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DECIDING JUDGES

Presiding judge	<b>Matthias Zigann</b>
Judge-rapporteur	<b>Tobias Pichlmaier</b>
Legally qualified judge	<b>Tatyana Zhilova</b>
Technically qualified judge	<b>Alain Dumont</b>

LANGUAGE OF THE PROCEEDINGS: English

ORAL HEARING OF: JUNE 6<sup>th</sup> 2024

DECISION ISSUED ON: July 31<sup>st</sup> 2024

## **Facts and submissions of the parties**

The claimant alleges that the defendants have infringed EP 3 797 685 B1 (“patent at issue”).

The patent at issue was filed under the title

“Communication systems between a sensor electronics unit  
and a display device of an analyte monitoring system”

as a divisional application of the earlier application EP 17776465.1 (publication number EP 3 435 866 A1) filed on 28 March 2017, claiming the priority from US provisional application No. 62/315,976 dated 31 March 2016 ("priority date"). The grant of the patent was published on 4 May 2022.

Claim 1 of the patent at issue reads:

An analyte monitoring system, comprising: a sensor configured to take measurements indicative of analyte levels; a sensor electronics unit communicatively coupled to the sensor and configured to: receive the measurements indicative of analyte levels, process the received measurements, and transmit data indicative of the analyte levels using a first communication protocol that is Bluetooth or Bluetooth Low Energy, BLE, at predefined times; and a display device configured to send a transmission to the sensor electronics unit utilizing a second communication protocol that is near field communication, NFC, or radio-frequency identification, RFID, to start a sensor session, wherein the sensor electronics unit is configured to start sensor measurements in response to the transmission, wherein the display device is configured to: receive the data indicative of the analyte levels sent by the sensor electronics unit using the first communication protocol, and use the second communication protocol to retrieve data indicative of analyte levels from the sensor electronics unit between the predefined times by sending a command using the second communication protocol to the sensor electronics unit to cause the sensor electronics unit to send data indicative of analyte levels to the display device using the second communication protocol; wherein the sensor electronics unit is further configured to send data indicative of analyte levels to the display device using the second communication protocol in response to the command.

Claimant is the registered proprietor of the patent at issue. An opt-out from the exclusive jurisdiction of the UPC had indeed been declared (App\_461036/2023, lodged 1 June 2023) which, however, was withdrawn on 3 July 2023 (App\_544162/2023) which has been registered on 3 July 2023.

The patent at issue is a divisional application for EP 3 435 866 (“EP ‘866”). EP ‘866 was upheld by the Opposition Division of the European Patent Office as granted in a decision dated 20 April 2023. Defendant 3) filed a nullity action against the German part of EP ‘866 on 9 May 2023, which is pending before the German Federal Patent Court (6 Ni 20/23). In its qualified note dated 26 March 2024, the German Federal Patent Court sets out its preliminary view that EP ‘866 is invalid. By decision of 4 July 2024 in an action for infringement with counterclaim for revocation, the Paris Local Division (UPC\_CFI\_230/2023) revoked EP ‘866 in its entirety with effect in the territories of the contracting member states for which the European patent had effect at the time of the counterclaim for revocation.

Defendant 1) is a US corporation and the parent company of the Abbott Group, which manufactures and distributes diagnostic, medical, and nutritional products and software, including glucose monitoring products. Defendant 2) is a US corporation and a subsidiary of Defendant 1). Defendants 3) to 10) are European subsidiaries of Defendant 1).

Subject of the present infringement action are glucose monitoring systems, in particular the “FreeStyle Libre 2” glucose monitoring system.

The claimant alleges that the defendants develop, offer and sell infringing products.

**The claimant therefore requests the Court to rule as follows:**

- I. European Patent No. 3 797 685 has been infringed by the Defendants.
- II. The Defendants are ordered
  1. to cease and desist from
    - a) making, offering, placing on the market, using or importing or storing for these purposes, analyte monitoring systems (in particular the "FreeStyle Libre 2" glucose monitoring system), in the territory of the Contracting Member States in which EP 3 797 685 has effect, which comprise:
      - a sensor configured to take measurements indicative of analyte levels;
      - a sensor electronics unit communicatively coupled to the sensor and configured to:
        - receive the measurements indicative of analyte levels,
        - process the received measurements, and
        - transmit data indicative of the analyte levels using a first communication protocol that is Bluetooth or Bluetooth Low Energy, BLE, at predefined times; and
      - a display device configured to
        - send a transmission to the sensor electronics unit utilizing a second communication protocol that is near field communication, NFC, or radio-frequency identification, RFID, to start a sensor session, wherein the sensor electronics unit is configured to start sensor measurements in response to the transmission;
      - wherein the display device is configured to:
        - receive the data indicative of the analyte levels sent by the sensor electronics unit using the first communication protocol, and

- use the second communication protocol to retrieve data indicative of analyte levels from the sensor electronics unit between the predefined times by sending a command using the second communication protocol to the sensor electronics unit to cause the sensor electronics unit to send data indicative of analyte levels to the display device using the second communication protocol;
- wherein the sensor electronics unit is further configured to send data indicative of analyte levels to the display device using the second communication protocol in response to the command;

(EP 3 797 685 – claim 1, direct infringement)

especially if

- the display device is configured to display the data indicative of the analyte levels received from the sensor electronics unit;

(EP 3 797 685 – claim 2, direct infringement)

and/or

- the display device is configured for alarming based on the data indicative of the analyte levels received from the sensor electronics unit;

(EP 3 797 685 – claim 3, direct infringement)

and/or

- the display device is a medical receiver or a mobile phone

(EP 3 797 685 – claim 4, direct infringement)

and/or

- the display device is further configured to calculate estimated analyte values based at least in part on the data indicative of the analyte level;

(EP 3 797 685 – claim 6, direct infringement)



and/or

- the display device is configured to query a sensor electronics unit database stored in a memory of the sensor electronics unit for data indicative of analyte levels;

(EP 3 797 685 – claim 10, direct infringement)

and/or

- the analyte is glucose and the sensor is configured to take as the measurements, measurements that are indicative of glucose levels;

(EP 3 797 685 – claim 11, direct infringement)

and/or

- the display device is configured for:
  - alarming based on sensor information transmitted by the sensor electronics unit using the first communication protocol; and
  - collecting past data from the sensor electronics unit using the second communication protocol;

(EP 3 797 685 – claim 13, direct infringement)

b) offering to supply and/or supplying sensor units (in particular the "FreeStyle Libre 2" sensors) in the territory of the Contracting Member States in which EP 3 797 685 has effect, to any person other than those entitled to exploit the patented invention, comprising:

- a sensor configured to take measurements indicative of analyte levels;
- a sensor electronics unit communicatively coupled to the sensor and configured to:
  - receive the measurements indicative of analyte levels,
  - process the received measurements, and

- transmit data indicative of the analyte levels using a first communication protocol that is Bluetooth or Bluetooth Low Energy, BLE, at predefined times;

and

wherein the sensor electronics unit is further configured to send data indicative of analyte levels to the display device using the second communication protocol in response to the command;

and which are suitable to form, together with a display device, an analyte monitoring system according to II. 1. a);

(EP 3 797 685 – claim 1, indirect infringement)

especially if

- the display device is configured to display the data indicative of the analyte levels received from the sensor electronics unit;

(EP 3 797 685 – claim 2, indirect infringement)

and/or

- the display device is configured for alarming based on the data indicative of the analyte levels received from the sensor electronics unit;

(EP 3 797 685 – claim 3, indirect infringement)

and/or

- the display device is a medical receiver or a mobile phone

(EP 3 797 685 – claim 4, indirect infringement)

and/or

- the display device is further configured to calculate estimated analyte values based at least in part on the data indicative of the analyte level;

(EP 3 797 685 – claim 6, direct infringement)

and/or

- the display device is configured to query a sensor electronics unit database stored in a memory of the sensor electronics unit for data indicative of analyte levels;

(EP 3 797 685 – claim 10, indirect infringement)

and/or

- the analyte is glucose and the sensor is configured to take as the measurements, measurements that are indicative of glucose levels;

(EP 3 797 685 – claim 11, indirect infringement)

and/or

- the display device is configured for:
  - alarming based on sensor information transmitted by the sensor electronics unit using the first communication protocol; and
  - collecting past data from the sensor electronics unit using the second communication protocol;

(EP 3 797 685 – claim 13, indirect infringement)

c) offering to supply and/or supplying display devices (in particular the “FreeStyle Libre 2” reader) and/or application software intended for mobile phones for creating such display devices (in particular the “FreeStyle LibreLink” application), in the territory of the Contracting Member States in which EP 3 797 685 has effect, to any person other than those entitled to exploit the patented invention, which are configured to:

- send a transmission to the sensor electronics unit utilizing a second communication protocol that is near field communication, NFC, or radio-frequency identification, RFID, to start a sensor session, wherein the sensor electronics unit

is configured to start sensor measurements in response to the transmission;

- wherein the display device is configured to:
  - receive the data indicative of the analyte levels sent by the sensor electronics unit using the first communication protocol, and
  - use the second communication protocol to retrieve data indicative of analyte levels from the sensor electronics unit between the predefined times by sending a command using the second communication protocol to the sensor electronics unit to cause the sensor electronics unit to send data indicative of analyte levels to the display device using the second communication protocol;

and which are suitable to form, together with a sensor and a sensor electronics unit, an analyte monitoring system according to II. 1. a);

(EP 3 797 685 – claim 1, indirect infringement)

especially if

- the display device is configured to display the data indicative of the analyte levels received from the sensor electronics unit;

(EP 3 797 685 – claim 2, indirect infringement)

and/or

- the display device is configured for alarming based on the data indicative of the analyte levels received from the sensor electronics unit;

(EP 3 797 685 – claim 3, indirect infringement)

and/or

- the display device is a medical receiver or a mobile phone

(EP 3 797 685 – claim 4, indirect infringement)

and/or

- the display device is further configured to calculate estimated analyte values based at least in part on the data indicative of the analyte level;

(EP 3 797 685 – claim 6, direct infringement)

and/or

- the display device is configured to query a sensor electronics unit database stored in a memory of the sensor electronics unit for data indicative of analyte levels;

(EP 3 797 685 – claim 10, indirect infringement)

and/or

- the analyte is glucose and the sensor is configured to take as the measurements, measurements that are indicative of glucose levels;

(EP 3 797 685 – claim 11, indirect infringement)

and/or

- the display device is configured for:
  - alarming based on sensor information transmitted by the sensor electronics unit using the first communication protocol; and
  - collecting past data from the sensor electronics unit using the second communication protocol;

(EP 3 797 685 – claim 13, indirect infringement)

2. to inform the Claimant on the extent to which the Defendants have committed the acts referred to under II. 1. since May 4, 2022, stating in each case:

- a) the origin and distribution channels of the infringing products;

- b) the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the infringing products; and
    - c) the identity of any third person involved in the production or distribution of the infringing products;
  - 3. to destroy at their own expense the products in their direct and/or indirect possession and/or owned by Defendants in the Contracting Member States referred to in under II. 1. and to furnish proof of destruction to the Claimant, without being requested to do so, or, at their option, to hand them over to a bailiff to be appointed by the Claimant for the purpose of destruction at the Defendant's expenses;
  - 4. to recall from the channels of commerce the products referred to under II. 1. which were supplied to the channels of commerce since May 4, 2022 and which are in the possession of third parties, by seriously requesting those third parties in writing who have been supplied with the products by the Defendants or with their consent, with reference to the fact that this Court has found an infringement of the EP 685 in the present decision, to return the products to the Defendants and to assure the third parties, in the event of the return of the products, a refund of the purchase price already paid, if any, as well as bearing of the costs of the return, and to remove them definitively from the channels of commerce by the Defendants taking back these products or arranging for the destruction of the same by the respective owner, whereby the Defendants are to send the Claimant the recall letters in digital copy and to provide evidence of the destruction of products without being requested to do so.
- III. Any failure to comply with the cease and desist order(s) referred to under II. will render the Defendants liable to pay to the Court a penalty in an amount to be determined in the discretion of the Court.
- IV. The Defendants are liable for all damages resulting from the patent infringement referred to under II. 1. that occurred since June 4, 2022.

- V. The Defendants are ordered to pay to the Claimant as an interim award of damages EUR 500,000.00.
- VI. The Defendants are to bear the legal costs of the proceedings.

Defendants do not dispute that the contested products make use of the patent at issue. However, Defendants contend that the patent at issue lacks novelty because Bernstein (D11), Berman (D12) and Cole (D13) each directly and unambiguously disclose the combination of features of claim 1 of the patent at issue in a novelty-destroying manner. At least these documents would render it obvious in combination with common general knowledge, and at least in combination with Miller (see D14), and/or Bhavaraju (see D15).

**The defendants ask the Court to rule as follows:**

- I. The action is dismissed.
- II. Claimant bears the costs of the proceedings including adequate reimbursement of the Defendants' costs.

In the alternative in case the Court should order an injunction, information, destruction and/or recall and removal

- III. The Defendants are granted a grace period of 18 months after the announcement of the decision, before an injunction (II.1), destruction (II.3) and/or recall and removal (II.4) are enforced.
- IV. The enforcement of any injunction, destruction or recall and removal is conditional upon a financial security provided by the Claimant in the amount of EUR 100 million.
- V. An order against the Defendants to provide information under motion II.2 of the Complaint is made conditional upon a confidentiality order against the Claimant to the effect that (a) the access to the information is restricted to Claimant's outside counsels and two representatives of Claimant who are named to the Defendants in advance and (b) the information may be used only for the purposes of calculating potential damage and compensation claims against the Defendants and for identifying other parties involved in

the supply or distribution of the accused products for the purpose of asserting claims for alleged patent infringement against them.

**With their counterclaims for revocation defendants request to rule as follows:**

- VI. EP 3 797 685 B1 is revoked in its entirety for all Contracting Member States in which EP 3 797 685 B1 has effect.
- VII. The court sends a copy of the decision to the European Patent Office and to the national patent office of any Contracting Member State concerned in accordance with UPCA, Article 65(5).
- VIII. Claimant bears the costs of the counterclaim for revocation including adequate reimbursement of the Defendants' costs.

Claimant considers the counterclaims for revocation to be unfounded; in the alternative, the claimant seeks conditional amendment of the patent as follows (amendments underlined):

Auxiliary request 1:

An analyte monitoring system, comprising: a sensor configured to take measurements indicative of analyte levels; a sensor electronics unit communicatively coupled to the sensor and configured to: receive the measurements indicative of analyte levels, process the received measurements, and establish a data connection with a display device and transmit to the connected display device data indicative of the analyte levels using a first communication protocol that is ~~Bluetooth or~~ Bluetooth Low Energy, BLE, at predefined times; and a the display device configured to send a transmission to the sensor electronics unit utilizing a second communication protocol that is near field communication, NFC, or radio-frequency identification, RFID, to start a sensor session, wherein the sensor electronics unit is configured to start sensor measurements in response to the transmission, wherein the display device is configured to: receive the data indicative of the analyte levels sent by the sensor electronics unit using the first communication protocol, and use the second communication protocol to retrieve data indicative of analyte levels from the sensor electronics unit between the predefined times by sending a command using the second communication protocol to the sensor



electronics unit to cause the sensor electronics unit to send data indicative of analyte levels to the display device using the second communication protocol; wherein the sensor electronics unit is further configured to send data indicative of analyte levels to the display device using the second communication protocol in response to the command.

Auxiliary request 2:

An analyte monitoring system, comprising: a sensor configured to take measurements indicative of analyte levels; a sensor electronics unit communicatively coupled to the sensor and configured to: receive the measurements indicative of analyte levels, process the received measurements, and establish a data connection with a display device and transmit to the connected display device data indicative of the analyte levels using a first communication protocol that is ~~Bluetooth or~~ Bluetooth Low Energy, BLE, at predefined times; and a the display device configured to send a transmission to the sensor electronics unit utilizing a second communication protocol that is near field communication, NFC, or radio-frequency identification, RFID, to start a sensor session, wherein the sensor electronics unit is configured to start sensor measurements in response to the transmission, wherein the display device is configured to: use the second communication protocol to facilitate pairing of the display device and the sensor electronics unit for the transmission of the data indicative of the analyte levels using the first communication protocol; receive the data indicative of the analyte levels sent by the sensor electronics unit using the first communication protocol, and use the second communication protocol to retrieve data indicative of analyte levels from the sensor electronics unit between the predefined times by sending a command using the second communication protocol to the sensor electronics unit to cause the sensor electronics unit to send data indicative of analyte levels to the display device using the second communication protocol; wherein the sensor electronics unit is further configured to send data indicative of analyte levels to the display device using the second communication protocol in response to the command.

For further details of the parties' arguments, reference is made to their written pleadings and to their submissions at the hearing.

## Reasons for the decision

### A.

The subject-matter of the proceedings is, on the one hand, the alleged infringement of the patent at issue and, on the other hand, the invalidity of the patent at issue as alleged in the counterclaims.

#### I. Person skilled in the art

In order to assess the legal situation in the present case, it is first necessary to determine the person skilled in the relevant art.

The Local Division leaves open whether the person skilled in the art is to be defined as a single person (according to the Federal Patent Court, 6 Ni 20/23 (EP)) or as a group of persons (according to LD Paris, UPC\_CFI\_230/2023). However, the Local Division, like the German Federal Patent Court and the LD Paris, considers that the skilled person must have knowledge in the field of (physiological) analyte monitoring systems (such as continuous glucose monitoring (CGM)) as well as knowledge in the art of designing portable electronic systems, so that the skilled person is familiar with the communication techniques, including the relevant connection protocols, such as NFC or Bluetooth, involved in such systems.

This panel is staffed with a technically qualified judge with the necessary knowledge.

#### II. Subject matter of the patent at issue

According to the understanding of the person skilled in the art the patent at issue relates to communication within an analyte monitoring system, which is used in particular for the continuous monitoring of glucose levels in patients with diabetes mellitus (“diabetes”) which consists of a sensor, sensor electronics and a display device.

In order to ensure continuous monitoring of glucose levels and to avoid the inconvenience of repeated finger pricking, sensors for continuous glucose

monitoring ("CGM") have been developed in recent years that can be applied to the skin and remain there for a certain period of time. When applied to the skin, these sensors use a thin needle to pierce the subcutaneous fat tissue, where they continuously measure the interstitial glucose concentration from which the blood glucose level is determined.

The patent at issue criticizes that in the CGM systems known in the prior art data links between the sensor electronics and the display devices consume too much power and processor functionality, in particular due to resource-intensive communication protocols and repetitive pairing procedures (para. [0043]).

Thus, the object of the patent at issue is to provide improved data communication for an analyte monitoring system that allows users to continuously check their glucose levels. This addresses the inherent limitations of wearable sensors by making more effective use of power and processor functions (para. [0043]).

## 1. Patent claim 1

In order to achieve this objective, the patent at issue proposes an analyte monitoring system comprising the following features according to claim 1 (with the numbering of the features added by the Local Division):

An analyte monitoring system (1), comprising:

- 1.1 a sensor configured to take measurements indicative of analyte levels;
- 1.2 a sensor electronics unit (6) communicatively coupled to the sensor and configured to:
  - 1.2.1 receive the measurements indicative of analyte levels,
  - 1.2.2 process the received measurements, and
  - 1.2.3 transmit data indicative of the analyte levels using a first communication protocol that is Bluetooth or Bluetooth Low Energy, BLE, at predefined times; and
- 1.3 a display device (20) configured to
  - 1.3.1 send a transmission to the sensor electronics unit (6) utilizing a second communication protocol that is near field communication,

NFC, or radio-frequency identification, RFID, to start a sensor session, wherein the sensor electronics unit (6) is configured to start sensor measurements in response to the transmission,

wherein the display device (20) is configured to:

- 1.3.2 receive the data indicative of the analyte levels sent by the sensor electronics unit (6) using the first communication protocol, and
  - 1.3.3 use the second communication protocol to retrieve data indicative of analyte levels from the sensor electronics unit between the predefined times by sending a command using the second communication protocol to the sensor electronics unit (6) to cause the sensor electronics unit to send data indicative of analyte levels to the display device using the second communication protocol;
- 1.4 wherein the sensor electronics unit (6) is further configured to send data indicative of analyte levels to the display device using the second communication protocol in response to the command.

## 2. Claim construction

The essence of the patent at issue is to enable the transmission of measurement data from the sensor electronics unit to the display device using two different communication protocols. According to claim 1 of the patent at issue measurement data is transmitted

- at predefined times via Bluetooth or Bluetooth Low Energy (“BLE”) being referred to as a “first communication protocol” on the one hand and
- between the predefined times by Radio Frequency Identification (“RFID”) or Near Field Communication (“NFC”) upon request of the display device, being referred to as a “second communication protocol” on the other hand.

Some features and terms need to be explained in more detail:

Claim 1 of the patent at issue identifies two different **communication protocols** (“...a first communication protocol that is.../ „... a second communication protocol that is...”). In the language of the patent at issue, a specific *communication protocol* is synonymous (“...that is...”) with various transmission

technologies and transmission standards mentioned in the patent (i.e. Bluetooth, Wi-Fi, RFID, etc.; para [0063]: "...using a communication protocol, such as, without limitation, Bluetooth..."). The first communication protocol covered by the patent at issue is Bluetooth and Bluetooth Low Energy (BLE). The second communication protocol covered by the patent at issue is NFC and RFID. Bluetooth, Bluetooth Low Energy (BLE), NFC and RFID are different transmission standards, all of which were known at the priority date. Neither these standards – which the patent at issue apparently presumes to be known – nor the term *communication protocol* used in this context are further explained in the patent at issue.

The communication protocols mentioned in claim 1 (first and second communication protocol) must not be identical protocols. This is clear from the claim wording itself in features 1.2.3 and 1.3.1. The claimant confirms and emphasizes with reference to the decision of the Opposition Division of the European Patent Office (Exhibit C 18, section 4.5.2) that there are two *distinct* communication protocols according to the patent at issue.

### III. Validity of the patent at issue

The defendants base their counterclaim for revocation on lack of novelty and lack of inventive step.

#### 1. Novelty of the patent at issue

In order to be considered part of the state of the art (Art. 54 (1) EPC), an invention must be found clearly integrally, directly and unambiguously in one single piece of prior art and in its existing form, it must be identical in its constitutive elements, in the same form, with the same arrangement and the same features.

For lack of novelty to be found, the subject-matter of the invention must be derived directly and unambiguously from the prior art. This applies to all claim features. The standard for the disclosure content of a publication is what can and may be expected from the knowledge and understanding of an average person skilled in the relevant art.

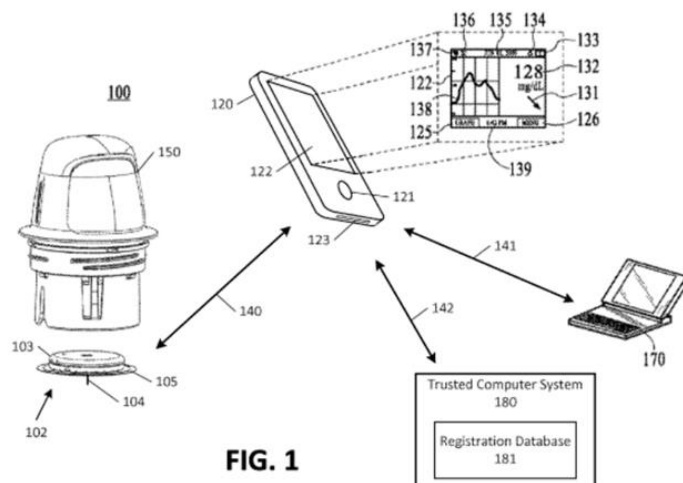
Based on this standard of review, the following must be stated here:

- a. **Defendants** argue, inter alia, that *Berman* (D12; US 2015/0205947 A1) anticipates all features of claim 1 of the patent at issue. *Berman* was published on 23 July 2015 and thus constitutes prior art under Art. 54 (2) EPC.

The **Claimant** rejects this argument, arguing that *Berman* does not disclose features 1.2.3 and 1.3.2 in combination with features 1.3.3 and 1.4 as well as feature 1.3.1.

Figure 1 of *Berman* 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 to transmit the analyte measurement data indicative of analyte levels; and
- a display device (reader device 120) configured to receive analyte measurement data indicative of analyte levels from the sensor electronics unit.



The **Local Division** considers that *Berman* also discloses the following features of claim 1:

*Berman* discloses feature 1.2.2 (see e.g. paragraph [0080], first sentence; paragraph [0087]), which is not disputed by the claimant.

In feature 1.3.1, claim 1 sets out the step of sending a transmission to the sensor electronics unit to start a sensor session, wherein the sensor electronics unit is configured to start sensor measurements in response to the transmission. This step relates to an interaction between the sensor and the sensor electronics unit (see paragraph [0025] of the patent at issue) and it is distinct from the transmission of data indicative of (already measured) analyte levels between the sensor electronics unit and the display device. *Berman* also discloses that an interface application may request the electronics unit to initiate an analyte measurement, which is distinct from a request to communicate already measured data (see *Berman* paragraph [0087]: "... The sensor interface application 232 can be programmed to initiate communications with sensor control device 102 (e.g, a request for an analyte measurement to be performed, a request for already measured data to be communicated to reader device 120, and others) and process data received from sensor control device 102...").

- b. According to **Claimant**, *Berman* discloses only the use of a *single communication protocol on a single communication path* for the transmission of analyte data; moreover, in the view of Claimant, *Berman* 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. Claimant argues that also the EPO Opposition Division in the case of EP '866 did not see in *Berman* a data transmission based on two different communication protocols.

**Defendants** argue that *Berman* discloses receiving analyte measurement data by the reader via Bluetooth or BLE ([0100]) and, in the following paragraph and in the same embodiment, receiving analyte measurement data by the reader via NFC ([0101]). In their view the specification of a communication path between two components is not a specification of *how* the communication takes place. The communication path therefore only describes *whether* data can be exchanged

between two components. *How* data can be exchanged is described by the communication protocols.

The **Local Division** is of the opinion that the skilled person would understand that a data transfer using any of the techniques mentioned in paragraphs [0100] and [0101] implies the use of the corresponding protocol, i.e. for instance a BTLE data transfer would be implemented using the corresponding BTLE protocol, as explicitly mentioned in *Berman* (paragraph [0064], last sentence). There is no indication to the contrary in *Berman*.

*Berman* explicitly mentions that both techniques can be combined in a single system (paragraph [0101], last sentence).

Furthermore, *Berman's* use of the term *communication path* does not lead to the conclusion that only a single communication protocol is used. *Berman* explains in paragraph [0100] of the description that data can be communicated periodically (i.e. at predefined times) to the display device at the initiative of the sensor control device in a broadcast type fashion using Bluetooth or BLE. Paragraph [0101] then describes that data transfer can also take place as an on-demand data transfer, with the request coming from the reader using an NFC connection. Thus, *Berman* discloses the step of retrieving data indicative of analyte levels from the sensor electronics unit between the predefined times by sending a command to the sensor electronics unit to cause the sensor electronics unit to send data indicative of analyte levels to the display device, wherein the sensor electronics unit is further configured to send data indicative of analyte levels to the display device in response to the command (parts of features 1.3.3 and 1.4 in claim 1).

However, since Bluetooth and BTLE are mentioned as possible transmission technologies in paragraph [0100], which describes periodic data transfer, and in paragraph [0101], which describes “on-demand” data transfer, it is not integrally, directly and unambiguously disclosed in *Berman* that there *must* be two distinct communication protocols, i.e. Bluetooth or BLE on the one hand and RFID or NFC on the other hand (decision of the EPO Opposition Division, Exhibit C18, point 4.6.2; preliminary opinion of the German Federal Patent Court, Exhibit C 26, point 6. p. 1313 - 6). Although in *Berman* the same protocol can thus be used



for both data transmissions, the skilled person would understand that *Berman* does not limit the protocols to a single one.

According to paragraph [0101] of *Berman*, periodic data transfer via broadcast (i.e. using Bluetooth or BTLE) can be combined with on-demand data transfer (i.e. using NFC) (“...any combination thereof.”), so that the use of different protocols for the two transmissions described in *Berman* (paragraphs [0100] and [0101]) is at least possible. However, there is no clear disclosure that two different protocols are *essential*. *Berman* merely discloses that the use of two different protocols is just as possible as the use of the same single communication protocol for both types of data transfer, e.g. Bluetooth or BTLE.

In other words, *Berman* discloses features 1.2.3 and 1.3.2 in full, but does not disclose the need of a second communication protocol different from a first communication protocol. Paragraph [0101] of *Berman* lists various candidates for the protocols available for transmitting data as “on demand” data transfer, but *Berman* does not explicitly disclose NFC as the protocol chosen for this purpose (see also LD Paris, decision UPC\_CFI\_230/2023, page 19).

The subject matter of claim 1 of the patent at issue is therefore not anticipated by *Berman*.

## 2. Inventive step

According to Article 56 EPC, an invention is considered to involve an inventive step if it is not obvious to a person skilled in the art from the prior art.

- a. The **defendants** contend that claim 1 of the patent at issue lacks an inventive step in the light of *Berman* in combination with the common general knowledge of the skilled person.

In their view *Berman* discloses that different protocols can be used for different types of data transmission. For the broadcast communication, *Berman* teaches using either Wi-Fi, Bluetooth or BLE (see paragraph [0100]); for the “on-demand” communication, *Berman* teaches using either NFC, Wi-Fi, Bluetooth or BLE (see paragraph [0101]).

Reading the patent at issue (paragraph [0043] to [0045]), the objective technical problem can be formulated as how to optimize the energy consumption and other resources of a CGM system. The skilled person would appreciate that energy consumption is a very important consideration in the field of wearable glucose sensor devices since the sensor control device needs to be replaced when its battery runs out. The skilled person would also know that, among the possible combinations of *Berman*, BLE/Bluetooth for broadcast transmissions and NFC (or RFID) for on-demand transmissions is the most energy efficient combination of protocols from the perspective of the sensor control device. In fact, of the proposed protocols for broadcast transmissions, Wi-Fi is about ten times more energy consuming than Bluetooth, which is also more energy consuming than BLE. In addition, NFC/RFID does not consume power from the sensor control device for on-demand transmission, but can only be used for “on-demand” transmission and not for broadcasting, as the reader device can be configured to provide an appropriate power signal so that the battery of the sensor control device is not required for on-demand transmission at all. These advantages of the various communication protocols were common general knowledge at the priority date of the patent at issue. Therefore, it would be obvious in the light of the direct teaching of *Berman* to implement the system in such a way that broadcast data is transmitted via Bluetooth or BLE and “on-demand” data is transmitted via NFC or RFID.

It would not have been inventive to select from the prior art one of three named well-known and widely used broadcast alternatives, let alone if, as in this case, two of three named alternatives were selected. Similarly, if additional guidance is sought as to the best protocol for implementing the "on-demand" type of data transmission, NFC would be the most obvious option, especially since NFC/RFID technology has significantly lower power requirements than other protocols.

- b. According to the **Claimant**, the correctly formulated objective technical problem is how to provide a more reliable analyte monitoring system while at the same time maintaining the usability of the analyte monitoring system (Reply to the Statement of Defence, p. 82). The Statement of Claim states that, in the CGM systems known in the prior art, the data links between the sensor electronics and

the display devices consume too much power and processor functionality, in particular due to resource-intensive communication protocols and repetitive pairing procedures; accordingly, there is a need for improved communications that effectively use power, processor functionality, and/or other resources of CGM systems (paragraph [0043]).

From the point of view of the Claimant, *Berman* does not disclose the use of a first and a second communication protocol. On the contrary, *Berman* teaches the use of a single communication path with a single communication protocol to perform either or both broadcast transmissions and on-demand transmissions. This use of a single communication path with a single communication protocol is *Berman's* modus operandi. Therefore, in order to achieve the claimed features, the skilled person would therefore have to abandon *Berman's* modus operandi. This in itself is inventive because there is nothing in *Berman* that would lead the skilled person to make such a drastic change. The skilled person would be aware of the challenges and practical disadvantages (hardware integration problems, increased footprint of the on-body sensor control device, increased power requirements, increased costs) associated with redesigning *Berman's* analyte monitoring device to implement two separate communication paths using two different communication protocols.

In addition, *Berman* also fails to disclose feature 1.3.1, which requires the display device to send a transmission to the sensor electronic unit using NFC or RFID to initiate a sensor session. Even if the skilled person were to consider the use of two separate communication protocols, *Berman* provides no motivation for selecting Bluetooth or BLE for the "broadcast" technique, and selecting NFC for the "on-demand" technique. The fact that all known systems at the priority date used only a single communication protocol to transmit analyte data and none of the known systems at the priority date implemented the parallel use of Bluetooth/BLE and NFC to send analyte data, is evidence that the features of claim 1 are inventive. The skilled person would be aware of the range, bandwidth and versatility of Wi-Fi and the advantages of using Wi-Fi to implement the "broadcast" technique and the "on-demand" technique.

- c. In its qualified note of 26 March 2024 on EP '866, the **German Federal Patent Court** held that the subject-matter of the granted patent (claim 1) should have been obvious to a person skilled in the art from *Berman* in combination with common general knowledge. In its reasoning, it stated that an NFC connection (data transfer protocol) had already been established anyway by the NFC scan. In view of this, it would have been obvious to a skilled person to use this connection to transfer the on-demand analysis data. Furthermore, paragraph [0059] of *Berman* explicitly states that the various components are interchangeable.
- d. In contrast, the **Opposition Division of the EPO** in its decision of 3 May 2023 concerning EP '866 found that *Berman* discloses the possible use of two types of transfers (broadcasts and on-demand transfers), but not two types of communication protocols (NFC/RFID and Bluetooth/BLE). According to the Opposition Division, the skilled person might find in *Berman* an incentive to add a broadcast functionality to the system (paragraph [0101]), but would not therefore find Bluetooth or BLE as required by claim 1 of EP '866. Paragraph [0100] discloses that broadcasts can be performed using an active WiFi, Bluetooth or BTLE connection. However, *Berman* does not indicate any preferred ones which might assist the skilled person in deciding which one to select. Rather, paragraph [0082] explains that the reader device is a Wi-Fi or Internet enabled device, so that this functionality is de facto already present. Therefore the skilled person would not be prompted to select Bluetooth or BTLE as communication protocol. Rather, the skilled person would consider using a single protocol that is capable of doing both types of transmission.
- e. The Local Division takes the following view:

Based on the case law of the CoA (UPC\_CoA\_335/2023; App\_576355/2023), it must first be determined whether *Berman* would have been of interest to a person skilled in the art who, at the priority date of the patent at issue, was seeking to optimize the energy consumption and other resources of a CGM system. In this respect, the underlying problem here differs from the problem on which the Opposition Division appears to have based its decision (point 5.1.1: "...how to

provide enhanced capabilities for the transmission of analyte data to the reader device.”).

*Berman* would have been of interest to a person skilled in the art, because *Berman* deals with CGM systems using two types of data transfers and describes the possible use of different communication protocols in this context. Contrary to the EPO decision (section 5.1.2), *Berman* also teaches the *possible* use of different types of communication protocols for these data transfers (WiFi, Bluetooth, BTLE for broadcasts; NFC, Bluetooth, BTLE or WiFi for on-demand data transfer). As explained above, contrary to claim 1 of the patent at issue, *Berman* does not teach that two different communication protocols must (necessarily) be used for the two types of data transfer. However, it is clear from *Berman* (paragraphs [0100] and [0101]) that different protocols *can* be used for the two types of transfer.

Thus, on the basis of *Berman*, the skilled person is faced with the task of selecting a communication protocol for on-demand data transfer from the list disclosed in *Berman*, after having selected, for example, BLE as the communication protocol for broadcasts. In doing so, the skilled person will consider all the advantages and disadvantages attributed to the respective protocols, which are common general knowledge. In short, it is well known that near-field communication protocols (e.g. NFC) are more reliable due to their limited range, which also makes them more energy efficient. The technical problems formulated by the parties, although seemingly different, are complementary ways of looking at aspects that the skilled person would take into account when implementing the system known by *Berman*.

In order to optimize the energy consumption and other resources of a CGM system, the skilled person receives from *Berman* the suggestion to use a near-field communication protocol to generate and transmit a request in order to initiate an on-demand data transfer (see paragraph [0103] last sentence), which he knows to be significantly less energy-intensive than any of the other protocols (Bluetooth or Wi-Fi) listed for periodic data transfer.

Nor does *Berman* teach against combining different communication protocols. On the contrary, *Berman* teaches that a combination is possible. In doing so, the skilled person would also be aware of possible disadvantages or limitations of using NFC (or RFID) as the second protocol, which requires the electronic unit and the display device to be in close proximity, which may reduce usability. In the relevant technical field, the skilled person is aware of the trade-offs to be made between various aspects (range, energy efficiency, reliability) and finding the right balance is simply a matter of design choice depending on the specific case, which does not involve an inventive step. The choice made in the system according to claim 1 also has no particular or surprising effect.

This choice would not require drastic changes to the system known from *Berman*, in which the display device can typically be a smartphone (see paragraph [0082]) already supporting various communication protocols, such as Wi-Fi, Bluetooth, BLE and NFC. As to any practical drawbacks to be overcome, neither claim 1 nor, more generally, the patent at issue discloses any technical details as to the concrete implementation that would improve hardware integration, address power requirements or costs in the on-body sensor control device.

With respect to feature 1.3.1, the skilled person would choose a communication protocol for starting a sensor session according to the same principles. There is also no particular effect mentioned in the description associated with the particular choice of the second communication protocol.

3. It can be left open whether the analyte monitoring system described in the patent at issue was already disclosed in the prior art by D11 or D13 as novelty-destroying. In any case, based on *Berman*, this system is not based on an inventive step.

#### IV. Application to amend the patent at issue

In response to the counterclaim for revocation, the claimant has filed two applications under RoP 30.

##### 1. Amendment 1

Auxiliary request 1 conditionally amends granted claim 1 of the patent in two aspects: First, claim 1 as granted is amended to delete the feature that the first communication protocol may be Bluetooth, so that amended claim 1 requires the first communication protocol to be Bluetooth Low Energy, BLE. Secondly, claim 1 as granted is further amended to recite that the transmission of the data indicative of the analyte levels using the first communication protocol is performed by establishing a data connection with the display device and transmitting the data to the connected display device.

In the view of claimant, D12 (*Berman*) does not disclose or suggest, with respect to this amendment, that the sensor electronics unit transmits data indicative of analyte levels to a display device using BLE by establishing a BLE data connection with the display device and transmitting the data to the connected display device. Instead, D12 directs the skilled person away from implementing such a modification by teaching, in paragraphs [0100] and [0101], that data periodically sent by the sensor control device 102 via BLE is a broadcast transmission according to the Bluetooth specification, i.e. a connectionless data transmission.

##### 2. Amendment 2

Auxiliary Request 2 further amends claim 1 of Auxiliary Request 1 to recite that the display device is configured to use the second communication protocol to facilitate pairing of the display device and the sensor electronics unit for the transmission of the data indicative of the analyte levels using the first communication protocol.

In the claimant's view, D12 does not disclose or propose, in relation to this amendment, a display device which uses the second communication protocol (i.e.

NFC or RFID) to facilitate the pairing of the display device and the sensor electronics unit for the transmission of the data indicative of the analyte levels using the first communication protocol (i.e. BLE). Faced with the objective technical problem of how to improve the reliability of the analyte monitoring system in D12, claimant contends that there is nothing in D12 or any other cited document that would motivate the skilled person to implement the features of Auxiliary Request 2. Instead, D12 would dissuade the skilled person from implementing the features of Auxiliary Request 2 because D12 teaches the skilled person to perform BLE transmissions by broadcast and the Bluetooth specification explains that a device operating in the BLE broadcast mode is excluded from performing pairing.

3. The opinion of the Local Division on Amendments 1 and 2

The Local Division has already explained above why the system of claim 1 as granted is novel compared to the system known from *Berman*. The subject-matter of claim 1 according to auxiliary requests 1 and 2 is *a fortiori* also novel, since it further restricts the first protocol to BLE and specifies additional features.

Auxiliary request 2 further restricts auxiliary request 1 by specifying that a data connection is achieved by (facilitating) pairing using the second communication protocol. The subject matter of both claims will be discussed together in the following.

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

*Berman* does not explicitly refer to the “broadcast mode” according to the Bluetooth specification: when referring to broadcast for the first protocol (paragraphs [0100] and [0101]), *Berman* mentions a “broadcast-type fashion”, a “broadcast fashion” or “broadcast(s)” without giving further details. In paragraph [0100], last sentence, *Berman* hints at connectionless data transmission. However, in paragraph [0100], second sentence, *Berman* suggests another possibility, which implies a data connection to determine that the display device 120 is “eligible”, (i.e. authorised to receive sensitive analyte level measurement



data), “in range” and “in listening state”. Mentioning this possibility would be meaningless if *Berman*’s disclosure were limited to the connectionless “broadcast mode” of the Bluetooth specification, as presented by the claimant. In addition, *Berman* mentions the possibility of pairing with authentication and encryption (e.g. in paragraphs [0110], [0111]).

Security is a constant concern in the transmission of highly sensitive data such as physiological data. The skilled person would therefore seek a solution that avoids unsecure and/or useless data transmission, particularly when using BLE, which is a relatively power-hungry protocol.

As is clear from the patent at issue itself (see, for example, paragraphs [0028], [0179] to [0181]), tap-to-initiate or, more generally, out-of-band pairing using NFC is an integral part of the Bluetooth/BLE specification. It is well known that the pairing process saves energy. This is not disputed by the Claimant.

*Berman* does not explicitly describe how a pairing is carried out. However, the skilled person knows that the pairing of different devices can be carried out in a secure manner by using NFC-assisted pairing as can be seen, for example, from the document “Bluetooth Secure Simple Pairing Using NFC” (Exhibit D22) published on 9 January 2014 by the groups responsible for the development of the Bluetooth and NFC specifications, namely the Bluetooth Special Interest Group and the NFC Forum. This document is considered to be common general knowledge in its field.

Thus, the skilled person wishing to establish a secure data connection, more specifically to ensure secure pairing of devices, will certainly take into account the NFC-assisted pairing routines part of the Bluetooth/BLE specification and thus arrive at the subject-matter of claim 1 of auxiliary requests 1 and 2 without any inventive activity.

In conclusion, the invention set out in claim 1 according to auxiliary requests 1 and 2 does not involve an inventive step over *Berman* when supplemented with common general knowledge.

## V. Outcome of the counterclaim for revocation and the application to amend the patent

In view of the above, the patent at issue is not valid, neither as granted, nor as amended by auxiliary requests 1 and 2, and must be revoked in its entirety pursuant to Art. 138 (1) EPC and Art. 65 (2) UPCA.

Claimant has defended the dependent claims by stating that the “dependent claims 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.” Claimant has not provided any specific arguments as to why any of the grounds for revocation relating to claim 1 would not apply to the dependent claims. The dependent claims are therefore also not valid.

## VI. Consequences for the Infringement action

Due to the invalidity of the patent at issue, the infringement action has no legal basis and all related requests must be dismissed.

### B.

With regard to costs, the Court decides in principle that the claimant, as the unsuccessful party, shall bear the costs of the proceedings in accordance with Art. 69 of the Agreement.

On the basis of the foregoing, the Munich Local Division of the UPC, composed of the presiding judge Dr. Zigann, the legally qualified judges Pichlmaier and Zhilova and the technically qualified judge Dumont, rules as follows

## Decision

1. EP 3 797 685 B1 is entirely revoked with effect in the territories of the Contracting Member States for which the European Patent had effect at the time of the counterclaim for revocation, namely Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Portugal, Slovenia and Sweden.
2. The auxiliary requests are dismissed.
3. 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 this decision has become *res iudicata* effect.
4. All infringement claims are dismissed.
5. Claimant is required to bear the costs of all proceedings in the action CFI\_233/2023.

Delivered in Munich, July 31<sup>st</sup> 2024.

Dr. Zigann Presiding Judge	
Pichlmaier Judge-Rapporteur	
Zhilova Legally qualified judge	
Dumont Technically qualified judge	
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

Infringement Action                      ACT\_547520/2023

Counterclaim for Revocation            CC\_586829/2023, CC\_586841/2023, CC\_586858/2023,  
CC\_586859/2023, CC\_586860/2023, CC\_586867/2023,  
CC\_586900/2023. CC\_587048/2023, CC\_587056/2023,  
CC\_587077/2023

Application to amend the patent    App\_2178/2024