Neutral Citation Number: [2025] EWCA Civ 1633

Case No: CA-2025-000284

IN THE COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE HIGH COURT OF JUSTICE, BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES, INTELLECTUAL PROPERTY LIST (ChD), PATENTS COURT
Mr Justice Mellor
[2024] EWHC 1664 (Pat)

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 18 December 2025

Before :

LORD JUSTICE LEWISON
LORD JUSTICE ARNOLD
and
LORD JUSTICE COBB

- -

Between :

(1) ABBOTT DIABETES CARE INC. **(2) ABBOTT LABORATORIES VASCULAR ENTERPRISES LP** **(3) ABBOTT IRELAND** **(4) ABBOTT DIABETES CARE LIMITED** **(5) ABBOTT DIAGNOSTICS GMBH** **(6) ABBOTT LABORATORIES LIMITED**	**Claimants/ Appellants**
- and -	
(1) DEXCOM INCORPORATED **(2) DEXCOM INTERNATIONAL LIMITED** **(3) DEXCOM OPERATING LIMITED** **(4) DEXCOM (UK) DISTRIBUTION LIMITED**	**Defendants/ Respondents**

- -
- -

Tom Mitcheson KC and Tim Austen (instructed by **Taylor Wessing LLP**) for the **Appellants**
Stuart Baran (instructed by **Government Legal Department**) for the **Comptroller General of Patents, Designs and Trade Marks**

Hearing date : 11 December 2025

- -

Approved Judgment

This judgment was handed down remotely at 10.30am on 18 December 2025 by circulation to the parties or their representatives by e-mail and by release to the National Archives.

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Lord Justice Arnold:

Introduction

1. This is an appeal by the Claimants ("Abbott") against paragraph 5 of an order made by Mellor J on 13 January 2025, which revoked European Patent (UK) No. 3 730 044 entitled "Compact on-body physiological monitoring device" ("the Patent") for the reasons given by the judge in his judgment dated 28 June 2024 [2024] EWHC 1664 (Pat). The priority date of the Patent is 3 February 2009. The judge held that the claims of the Patent were all obvious in the light of United States Patent Application No. 2003/01000821 ("Heller"), although he rejected a number of other attacks on the validity of the Patent advanced by the Defendants ("Dexcom"). Abbott have settled their dispute with Dexcom, but nevertheless wish to overturn the order for revocation of the Patent. This Court has been assisted by counsel instructed by the Comptroller-General of Patents, Designs and Trade Marks ("the Comptroller") as explained in more detail below.

2. The invention described and claimed in the Patent has application particularly in the field of continuous glucose monitoring ("CGM") systems used by people with diabetes. As explained in more detail below, CGM systems were well known by 2009. The three leading systems on the market at that time comprised four main components: a sensor, a sensor electronics unit, an applicator or insertion device and a reader. In each system, the sensor was inserted into the patient's skin using the insertion device. Once the sensor had been inserted, the user then connected a separate sensor electronics unit to the sensor. Blood glucose readings were taken from the sensor electronics unit by the reader which displayed the readings to the user. The sensor electronics unit was only connected to the sensor after its insertion because sensors were disposable with a short life (3-7 days), whereas sensor electronics units had a much longer life (potentially up to a year depending on battery life) and were much more costly.

3. At trial these prior art systems were described as "two-part" or "non-integrated" systems. By contrast, the Patent describes and claims an integrated system in which the sensor and the sensor electronics unit are connected together before the sensor is inserted into the patient's skin. As explained in more detail below, the claims also include an insertion device for inserting the sensor.

The skilled team

4. There was a dispute at trial as to the precise composition of the team of persons skilled in the art to whom the Patent is directed. It was common ground that the skilled team would have had, or would have included persons who had, expertise in each of the fields of (i) electronic engineering and (ii) mechanical engineering, and in particular mechanical design. There was nevertheless a dispute which essentially concerned the extent to which the team would be led by a project leader with experience in CGM.

5. The judge found that the Patent was addressed specifically to a design engineer and an electronic engineer working within a wider CGM team. The wider team would require a leader of some description, but the design engineer and the electronic engineer would each play their role in the development of a new CGM system. The design engineer and the electronic engineer did not require prior experience in developing CGM systems, and would have knowledge of non-CGM devices.

The expert witnesses

6. Abbott called a single expert witness, Dr Michael Schoemaker. Dr Schoemaker had considerable experience leading multi-disciplinary teams developing CGM systems both before and after 2009. The judge found, however, that Dr Schoemaker's expertise in mechanical and electronic engineering was limited to aspects he had absorbed from engineers in his teams. He did not have a working knowledge of the toolkit of concepts available to either a mechanical engineer or an electronic engineer. The judge also found that Dr Schoemaker's evidence was influenced in certain respects by his experience while employed by Roche which was not representative of the experience of the skilled team. The judge also found that Dr Schoemaker was unable to adopt the viewpoint of the mechanical engineer in the skilled team when considering what was obvious. Overall, the judge agreed with Dexcom that Abbott's choice of Dr Schoemaker as their sole expert witness was a strange one.

7. Dexcom called two expert witnesses, Professor Pantelis Georgiou and Andrew Varde, neither of whom had been involved in the development of CGM systems before the priority date. Prof Georgiou gave evidence about electronic engineering. His evidence was largely uncontroversial. The judge rejected some criticisms made by Abbott of his oral evidence.

8. Mr Varde gave evidence about mechanical engineering. Abbott submitted that Mr Varde had failed to adopt the mindset of a member of the skilled team and had been affected by hindsight. The judge considered these points when assessing obviousness as explained below. Reading the judgment as a whole, it is clear that the judge largely, but not entirely, accepted Mr Varde's evidence.

9. Abbott also criticised the way in which Dexcom's experts had been instructed, and in particular the fact that they had been kept separate from each other and had not even been permitted to read each other's reports. The judge thought that there was some force in this criticism, but that it was overdone. Although it would have been better if Prof Georgiou and Mr Varde had been able at least to see what the other was saying, this had not in the end had any detrimental effect on the force of their reasoning.

Agreed common general knowledge

10. The judge set out at [51]-[74] an agreed summary of the skilled team's common general knowledge. I reproduce this below in slightly abbreviated form and with one addition (see paragraph 28 below).

Diabetes

11. Diabetes is a metabolic disorder in which an individual's blood glucose levels are too high. In effect, the glucose that is broken down from carbohydrates is not absorbed by the user (or is absorbed insufficiently), meaning it cannot be stored or metabolised to later generate energy. There are two main types of diabetes. Type 1 diabetes occurs when the pancreas is unable to produce insulin. Insulin is a hormone released by the pancreas which acts to reduce the levels of glucose in the blood by increasing the rate of conversion of blood glucose and larger molecules (such as carbohydrates) stored in bodily tissue. Type 2 diabetes, on the other hand, occurs when, although some insulin is made, it is insufficient or does not work effectively. Both types of diabetes can lead

to chronic high blood sugar, which can in turn result in a number of symptoms including an increased need to urinate, fatigue, thirst, weight loss, blurred vision and slow-healing wounds. It can also cause significant complications for the eyes, heart, feet and/or kidneys. If left untreated, diabetes is a life-threatening condition.

Blood glucose monitoring

12. By 2009, it was well known that individuals diagnosed with diabetes could (and generally would) manage their condition by monitoring their own blood glucose levels. This allowed them to keep their levels within an acceptable range. Traditionally, and certainly prior to the advent of CGM systems, this was done by way of blood glucose monitoring ("BGM") devices. In short, blood glucose measurements would be taken by the user who would prick their finger in order to obtain a blood sample. They would then apply the sample to the end of a disposable test strip which was inserted into a reader device to obtain a precise blood glucose measurement. Notwithstanding the advent of CGM, BGM devices remain in widespread use, particularly for patients with Type 2 diabetes.

13. It was well known that BGM testing had advantages and disadvantages. An advantage was its accuracy, but a significant disadvantage was the discomfort or pain caused to users, particularly those who were required to check their blood glucose levels on various occasions throughout the day. Another disadvantage was that finger-prick testing provided only a handful of discrete data points throughout the day, so users did not know how their blood glucose levels fluctuated between measurements. Finger-prick testing also placed the responsibility on the user to adhere to a strict testing schedule (which, for those with Type 1 diabetes, would be a lifelong commitment). For those reasons, finger-prick testing was rarely ever performed as often as would ideally be necessary, and therefore was seldom used to its fullest potential.

14. As a result, several players in the industry had shifted their focus towards developing a technology which would reduce (or ideally replace) the need for finger-prick testing. The aim was to create a system which continuously monitored blood glucose levels, but was less painful and required minimal effort from users.

CGM at the priority date

15. CGM systems had been available on the market since 1999 in various forms, but remained at a relatively early stage of development. Anyone interested in developing a new CGM would have made it a priority to learn about the features of these systems.

16. Three devices would have been of particular interest to the skilled team at the priority date since they had emerged as the main CGM devices in the market, and other devices had been withdrawn, were commercially unsuccessful and/or had significant technical shortcomings:

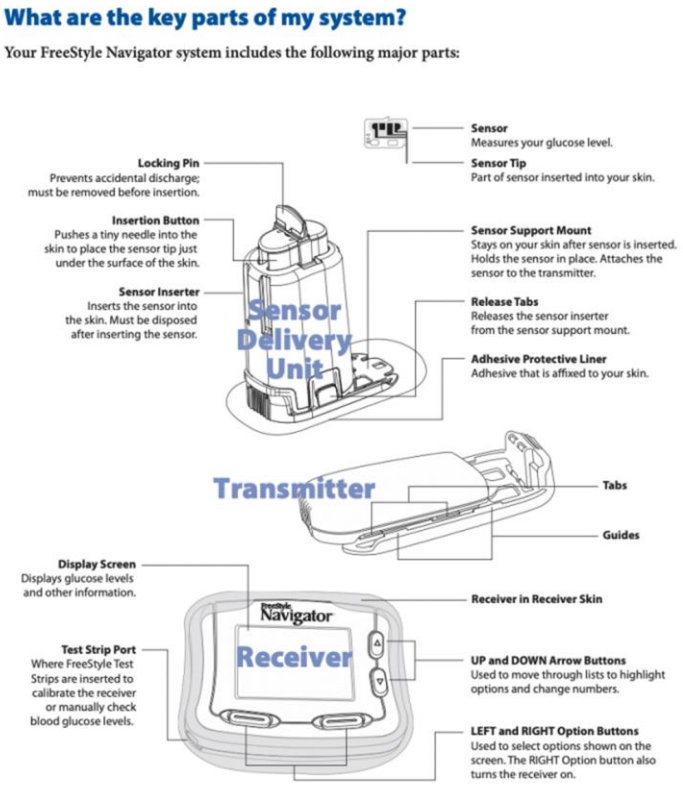
    i) Abbott Freestyle Navigator I;

    ii) Dexcom STS-7; and

    iii) Medtronic Guardian Realtime.

17. These three systems had important differences, but in terms of general design were broadly similar. Each system comprised a transcutaneous electrochemical sensor, a sensor electronics unit, an applicator or insertion device and a reader device that would receive and display glucose data. The systems also shared a common architecture, whereby the sensor would be inserted into the skin with the applicator/insertion device, and a separate sensor electronics unit would be manually connected as an additional step for the user. As noted above, these systems were referred to at trial as "two-part" or "non-integrated" systems.

18. An image depicting these four components (and how they interacted) in the Freestyle Navigator, by way of example, is reproduced here.



19. None of the CGM systems available at the priority date were considered accurate or reliable enough to receive regulatory approval to be a replacement for BGM through finger-prick testing. In fact, prior to the priority date, all of the CGM devices on the market were authorised for adjunctive use only, meaning their glucose measurement had to be confirmed by a finger-prick test before any therapeutic decision (e.g., the administration of insulin) could be taken. In addition, all known CGM systems required calibration through finger-prick measurements, which the user would have to do once upon insertion (following an initial "warm up" period), and then periodically thereafter.

Glucose sensors

20. The skilled team would have been able to understand how the sensor worked from a teardown of the commercially available CGM devices. The Freestyle Navigator, the STS-7 and the Guardian Realtime all used transcutaneous electrochemical sensors. At the priority date, these were considered the most reliable form of CGM sensor, although they had a very limited lifespan (three days for the Guardian Realtime, five days for the Freestyle Navigator and seven days for the Dexcom STS-7).

21. The transcutaneous electrochemical sensors worked by electrolysis. They comprised two (sometimes three) electrodes covered by coating(s) and were inserted into the skin so that they came into contact with the interstitial fluid at one end. Once a potential difference was applied to the sensor, the electrodes generated the electrochemical reaction necessary to detect glucose levels. The sensor did not need to engage with the user's bloodstream because the glucose concentration in the interstitial fluid broadly reflected overall blood glucose concentration. Creation of the sensor involved deposition of a delicate enzyme layer. Known methods for doing so included screen-printing onto a flat substrate, and dip coating.

22. It was also well known that sensors would need to be sterilised. At the priority date, known methods of medical sterilisation included ethylene oxide ("ETO"), steam, gamma ray and electron beam (or e-beam). The skilled team would have recognised that some of these techniques might not be compatible with the sensor chemistry and/or electronics.

Sensor electronics

23. The sensor electronics served to process the analogue signal received from the sensor into a digital form. The electrical current reading obtained was an analogue signal that would need to be converted into digital readings before they could be further processed and transmitted wirelessly. The digital signals could be filtered to reduce noise, translated into accurate glucose concentration values or transmitted as raw data. It was therefore well known that at least some processing would be required within the sensor electronics to enable wireless transmission.

24. The sensor electronics unit generally contained a power supply (to power the sensor), one or more component(s) for processing the sensor signal, and a transmitter for wireless transmission to the reader device. The skilled team would have sought to understand the power requirements necessary for processing, the size and type of battery required and therefore the dimensions of the on-body unit. Each of three main CGM systems used a battery as the form of power supply, but did so in different ways:

    i) The Abbott Freestyle Navigator I used a non-rechargeable battery that lasted for 30 days and needed to be replaced by the user at the end of its lifetime.

    ii) The Dexcom STS-7 used a non-replaceable, non-rechargeable battery which was integrated into the sensor electronics. At the end of the battery's lifetime (around three months), both the battery and the sensor electronics would be disposed of together.

iii) The Medtronic Guardian Real-Time used a non-replaceable but rechargeable battery which was also integrated into the sensor electronics. Similar to the STS-7, both the battery and the sensor electronics would be disposed of at the end of the battery's lifetime (around 14 days per charge, rechargeable on average for one year).

25. At the priority date, all CGM systems with a transcutaneous sensor (including the Freestyle Navigator, the STS-7 and the Guardian Real-Time) used an assembly whereby the sensor electronics unit and the sensor would be provided to the user as separate components. The user would, in effect, have manually to connect the sensor electronics unit to the sensor after the sensor had already been inserted. The reasons for this would have been well known to the skilled person. As noted above, the sensor had a much shorter lifetime compared to the sensor electronics unit. It therefore needed to be replaced more frequently. However, the electronic components were significantly more expensive than the sensor. As such, it made both practical and commercial sense for the non-integrated systems to use disposable sensors and reusable electronics, to avoid the costs associated with disposing of expensive electronics every 3-7 days.

26. In general companies did not yet invest in bespoke sensor electronics components, such as an ASIC, due to significant upfront costs. Instead, companies typically relied on sourcing electronic components off-the-shelf. This contributed to the manufacturing costs of the sensor electronics units being several times that of the sensor. This was also partly due to the fact that CGM devices were not yet in wide use in the market, even though the potential market was acknowledged to be huge.

Insertion devices and mechanisms

27. An applicator was used to insert the sensor into the body. At the priority date, the design and functionality of the insertion devices varied, but they typically had the same basic components, including a housing, a needle, some sort of insertion mechanism and a retraction mechanism. The insertion device could insert and retract the needle either manually or automatically. The three main CGM devices varied in this respect:

i) The Abbott Freestyle Navigator I used an automatic insertion and removal process which was activated by a single push button.

ii) The Dexcom STS-7 used a manual insertion and removal process.

iii) The Medtronic Guardian Real-Time used an automatic insertion which was activated by a single push button, and a manual removal process.

28. As counsel for Abbott pointed out in this Court, none of the prior art devices employed manual insertion and automatic retraction.

29. Both the Abbott Freestyle Navigator and Dexcom STS-7 insertion devices also made use of a mounting unit onto which the sensor electronics unit was attached. The unit would be adhered to the user's skin and allowed the sensor electronics unit to be coupled to the sensor as precisely as possible whilst minimising trauma to the tissue. Nevertheless, the user still needed to manually attach the sensor electronics unit to the mounting unit after insertion to connect it to the sensor.

30. Medtronic did not make use of a mounting unit. Instead, the user would couple the sensor electronics to the sensor through a connector on the sensor base (which contained an adhesive).

Disputed common general knowledge

31. There were a number of disputes between the parties at trial concerning common general knowledge. Some of these related to the composition of the skilled team and/or the evidence of the expert witnesses. One is no longer relevant. Two were addressed by the judge in the context of his assessment of obviousness, and I will mention them below.

32. That leaves the judge's finding that the agreed statement of common general knowledge omitted some very important knowledge and practical skills which the mechanical engineer in particular would bring to the skilled team. As Dexcom pointed out, the Patent is entirely silent on a number of matters critical to the making of the claimed device, and thus assumes that they are common general knowledge. The judge found at [89] that these include:

> "i) How to make a working sensor. The Patent contains no teaching of the deposition of enzyme layers or any information about electrochemistry, or any information about sterilisation of the device and the possible effects of sterilisation on the sensor materials.
>
> ii) Needle design, or how it is to be enabled to be engaged with the sensor.
>
> iii) Many of the features of the insertion and retraction mechanisms. [The Patent] discloses the existence of a spring but no details of how it is engaged or activated and leaves it entirely to the mechanical engineer on the Team to design a working spring-loaded retraction system.
>
> iv) How to implement various types of activation switch."

The Patent

33. The specification of the Patent is a moderately lengthy document which is replete with detail, but is not very clearly drafted. Unhelpfully, the specification states at [0005] that subject matter that is disclosed in the specification, but not covered by the claims, is not part of the invention. Furthermore, there are no consistory clauses corresponding to the claims. Claim 1 appears to be based on an embodiment described towards the end of the document at [0190]-[191], but the wording of claim 1 is not identical to those paragraphs. Still further, the claim is not very clearly drafted either. This does not make it easy to understand precisely what the claimed invention consists of.

34. It may therefore be helpful to explain before turning to the specification that the claim is directed to an "integrated analyte monitoring assembly" which comprises (i) "a sensor electronics assembly" and (ii) "an insertion device" which is used to deploy the "sensor electronics assembly" onto and under the patient's skin. In the claim, the

"sensor electronics assembly" includes "an analyte sensor" and "sensor electronics", but the specification frequently refers to the "sensor and sensor electronics assembly".

35. The relevant disclosure of the Patent may be summarised, using the headings in the specification, as follows.

Background

36. The specification begins by reciting the requirement which certain individuals have to detect glucose or other analytes in their bodies, and by referring to the development of devices for continuous monitoring of analytes such as glucose. After acknowledging a prior art disclosure, the specification states at [0004]:

> "Ease of insertion and use, including minimal user intervention and on-body size and height (or thickness) of such transcutaneous or percutaneous medical devices that are worn on the body are important in usability, wearability, and comfort during the device usage. …"

Summary

37. This section of the specification draws attention to various features of the disclosure. It states in [0005]:

> "… Examples of the subject disclosure include devices and methods and kits for providing sensor electronics assembly including an analyte sensor for monitoring of analyte levels such as glucose levels over a sensing time period. …"

38. It also states in [0008]:

> "Embodiments also include real time discrete glucose measurement data acquisition on-demand, as desired by the user or upon request, based on, for example, RFID data communication techniques for data transmission and acquisition from the analyte sensor/electronics assembly or the on-body patch device including the analyte sensor and the data processing and communication components provided in a compact, low profile housing and placed on the skin surface of the user. …"

Brief description of the drawings

39. The specification introduces the figures at [0010]. Figures 1-7 are schematic diagrams of a data monitoring and management system and its components. Figures 8A-11C show an "on-body patch device including an [sic] sensor and sensor electronics assembly". Figures 12A-12G show an "insertion device for deploying the on-body patch device". Figures 13-18 are concerned with various power supply switch mechanisms, which are not relevant for the purposes of the appeal.

Detailed description

40. The specification states in [0011]:

> "… Embodiments include an on-body assembly including a transcutaneously positioned analyte sensor and sensor electronics in a compact, low profile integrated assembly and coupled to an insertion device for deployment."

41. It goes on by reference to Figure 1 in [0033]:

> "… In aspects of the present disclosure, the sensor 101 and the data processing unit (sensor electronics) 102 may be configured as a single integrated assembly 110. In certain embodiments, the integrated sensor and sensor electronics assembly (110) may be configured as an on-body patch device. …"

42. It continues by reference to Figure 2:

> "[0050] … the on-body patch device 211 including sensor electronics coupled to an analyte sensor 250 is positioned on a skin surface 210 of a patient or a user. In one aspect, an introducer mechanism may be provided, as discussed in further detail below in conjunction with FIGS. 12A-12G, for the transcutaneous placement of the analyte sensor 250 such that when the on-body patch device 211 is positioned on the skin surface, a portion of sensor 250 is inserted through the skin surface and in fluid contact with a body fluid of the patient or the user under the skin later 210.
>
> [0051] The introducer mechanism may be fully or partially automated, for example with a trigger mechanism, or may be fully or partially manual such that the sensor 250 is positioned transcutaneously by a manual operation of the user. That is, in one aspect, the on-body patch device 211 may include a introducer needle … which may guide the sensor 250 during the insertion process through the skin layer 210. In a further aspect, the placement of the on-body patch device 211 on the skin layer 210 includes the initial piercing of the skin layer 210 with a force applied on the on-body patch device 211 in conjunction with the on-body patch device 211 placement on the skin layer 210, effectively driving the sensor 250 (and/or the introducer) through the skin layer 210. Within the scope of the present disclosure, a mechanism (such as a spring for example) may be provided within the on-body patch device 211 or alternatively, in the introducer in cooperation with the on-body patch device 211, to withdraw the introducer needle after the sensor 250 has been positioned in fluid contact with the body fluid. …"

43. Further on, the specification states in [0089]:

> "… certain embodiments described below include configurations of the on-body patch device to provide for a compact configuration which is configured remain adhered to the skin surface for a predetermined wear time period

> comfortably and without detaching from the skin surface. For example, in one embodiment the on-body patch device may include a single integrated housing or body assembly that includes the analyte sensor, electronics and an adhesive patch. Such configuration provides for fewer parts that require manipulation by the patient or user, leading to improved ease of use, and further, with an over-molded assembly, may be configured to provide the desired water tight seal during the course of the wear, preventing moisture or other contaminants from entering into the on-body patch device housing. Such single body configurations may additionally provide ease of manufacturing with the fewer components that require assembly."

44. Figures 10A and 10B are reproduced below.

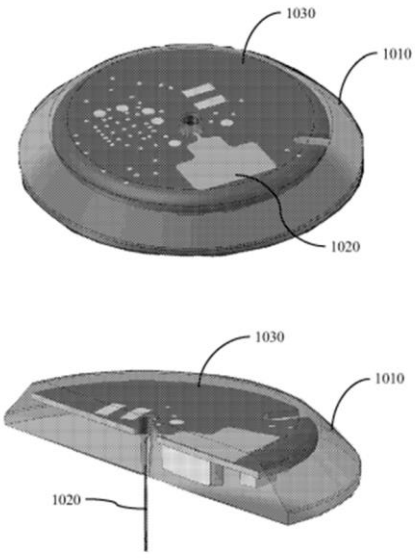


FIGURE 10A

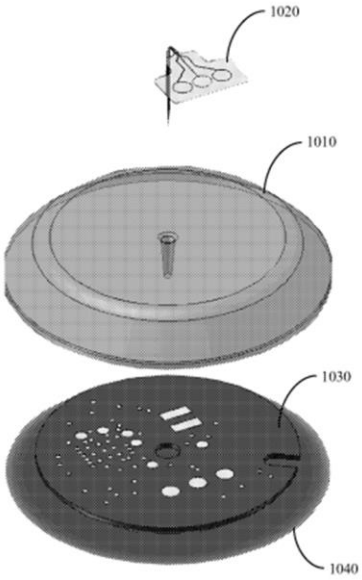


FIGURE 10B

45. Figure 10A shows a cross-sectional and perspective view of the on-body patch device including sensor and sensor electronics assembly, whereas Fig 10B is a somewhat exploded view. The sensor is labelled 1020 and comprises a thin needle attached to what appears to be a small circuit board carrying three connectors. The sensor electronics are labelled 1030. The device includes a housing 1010.

46. The specification explains at [0110]:

> "Referring back to FIG. 10A, in one embodiment, the analyte sensor 1020 is assembled (e.g., provided to the user) with the sensor electronics 1030 and provided within the housing 1010. Furthermore an adhesive (single sided or two sided) layer 1040 (FIG. 10C) may be provided on a lower surface of the housing 1010 to provide secure positioning of the housing 1010 on the skin surface during and after sensor deployment. As discussed in further detail below, the integrated sensor and sensor electronics

> assembly/on-body patch device 110 may be positioned (e.g., during manufacture to provide to the user) within the housing of an insertion device, avoiding the need for a user to align, position, or otherwise connect or couple the sensor and sensor electronics to the insertion device prior to the insertion of the sensor and turning on the sensor electronics. Accordingly, potential misuse, misalignment of the sensor relative to the introducer of the insertion device, or errors and difficulties in use of the integrated assembly by the user may be avoided."

47. Figures 12A-12G are reproduced below.

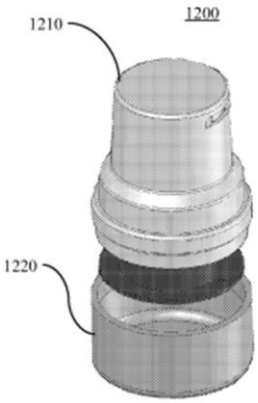


FIGURE 12A

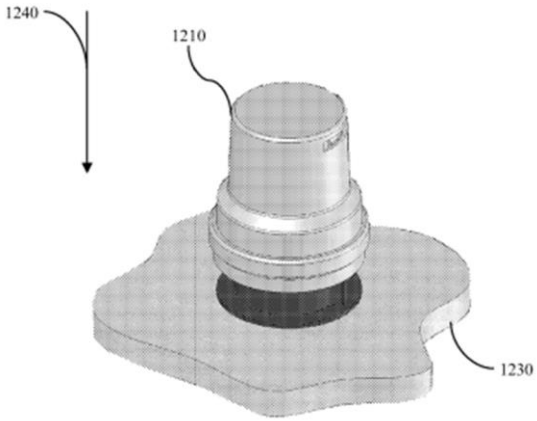


FIGURE 12B

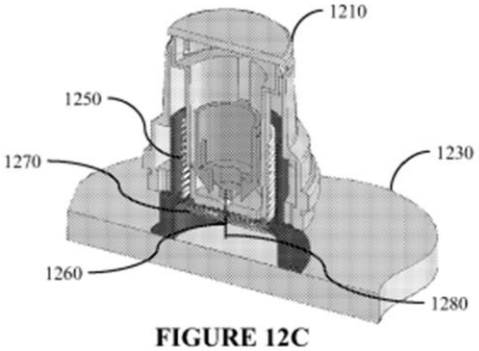


FIGURE 12C

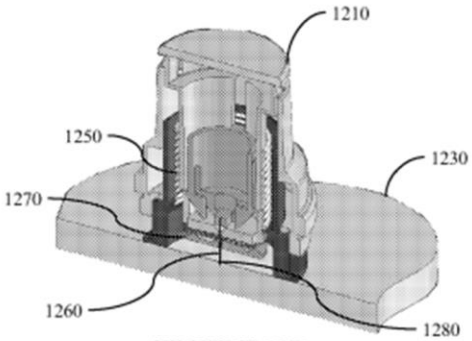


FIGURE 12D

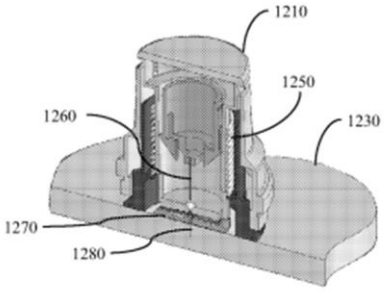


FIGURE 12F

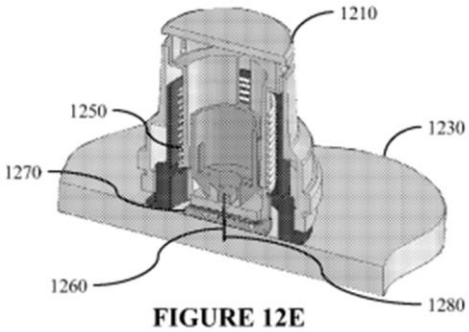


FIGURE 12E

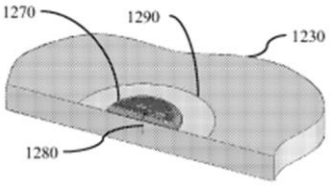


FIGURE 12G

48. As the judge explained, in these figures:

i) 1200 is the insertion device.

ii) 1210 is the housing of the insertion device. It can be seen that the figures show relative movement between the light-coloured upper part and the dark-coloured lower portion which is placed on the user's skin.

iii) 1220 is the cap in Figure 12A which is removed before the insertion device is placed on the skin 1230 of the user in Figure 12B.

iv) The arrow 1240 in Figure 12B shows the direction of a force applied to the top end of the housing which brings the integrated sensor and sensor electronics assembly within the housing into contact with the skin surface 1230.

v) Figures 12C-12F show cross-sectional perspectives of the operation of the insertion device, and Figure 12G shows the integrated sensor and sensor electronics assembly in place on the user's skin.

vi) 1250 is a bias spring.

vii) 1260 is the introducer needle.

viii) 1270 is the sensor electronics assembly.

ix) 1280 is the sensor.

x) Not labelled is the cylindrical internal component with a conical shape at its base which drives the introducer needle 1260 into the skin and then retracts back into the housing in Figure 12F, carrying the introducer needle with it.

49. The way this embodiment works is explained as follows:

"[0117] Referring to FIG. 12B, a force, e.g. a manual force, is applied upon the top end of the housing 1210 in the direction as shown by arrow 1240, and with the open end of the housing on the skin surface 1230, the integrated sensor and sensor electronics assembly provided within the housing (not shown) is configured to come into contact with the skin surface 1230. Furthermore, the force applied as discussed above also may be configured to move the introducer (not shown) within the housing in the same direction as shown by arrow 1240 to pierce the skin surface 1230 and position the sensor in fluid contact with an analyte of the user.

…

[0119] As shown in these figures, in response to the force applied on the insertion device housing 1210, the introducer 1260 is driven in a direction substantially perpendicular to the skin surface 1230, and along with the movement of the introducer 1260, the sensor 1280 and the sensor electronics assembly 1270 are moved in the same direction. When the bottom surface of the sensor electronics assembly 1270 comes into contact with the skin surface 1230, the bottom surface is maintained in an adhered relationship with the skin surface 1230 by, for example, the adhesive layer 1290 (FIG. 12G). Moreover, also shown in the Figures is a bias spring 1250 which, in one embodiment, is configured to retract the introducer needle from the insertion position to a retracted position which is an opposite direction from the direction indicated by arrow 1240 (FIG. 12B).

[0120] Referring back to the Figure, it can be seen that the introducer needle 1260 is substantially and entirely retained within the insertion device housing 1210 after sensor insertion, and thereafter, when the insertion device 1200 is removed from the

> skin surface 1230, the sensor electronics assembly 1270 is retained on the skin surface 1230, while the position of the sensor 1280 is maintained in fluid contact with the analyte of the user under the skin layer 1230."

50. The judge said at [126](ii) that it was "not immediately clear whether the designation 'the housing' comprises just the light coloured part at the top or whether it also includes the dark coloured portion lower down". Despite this, he went on to say at [163] that, in the context of Figure 12, "it is clear that the housing is the upper light-coloured part (to which the force is applied) and not the darker lower part which is placed on the skin".

51. Leaving aside the contradiction between these two statements, Abbott submit that the second statement is wrong because it is clear from [0117], and in particular the reference to "the open end of the housing on the skin surface 1230", that, as Mr Varde accepted in cross-examination, the housing includes the dark-coloured portion. I agree, but in itself this error is insignificant.

52. More importantly, the judge explained:

> "129. These figures are not particularly clear. As Dr S[c]hoemaker agreed in cross-examination, in these figures the bias spring 1250 is not shown as moving i.e. either being compressed or expanding, even though it can be seen that the upper part of the housing moves down over most of the darker lower part as the introducer needle 1260 and the sensor 1280 moves down and then into the skin. Furthermore, even when the introducer needle has been retracted into the housing and out of the skin, leaving the sensor 1280 in place in the subcutaneous tissue in the skin, in Fig 12F the upper lighter part of the housing is still shown in the same lowest position as in Fig 12E. This implies (to the mechanical engineer) that the relative movement between the upper light-coloured housing and the dark lower part compresses the spring which then must disconnect from the upper light-coloured housing in order to drive the retraction of the needle carriage back into the upper light-coloured housing. In this regard, the Skilled Addressee of the Patent would understand these figures as schematic and not purporting to show the precise retraction mechanism which is (as [0119] explains) powered by the bias spring.
>
> 130. As Mr Varde pointed out, Figures 12C to 12G make clear that the act of the user applying a force during the insertion process causes a spring within the insertion device housing to compress. This is the bias spring 1250. This process is described more explicitly in [0151] which I set out below."

53. The specification goes on (emphases added):

> "[0146] In accordance with embodiments of the present disclosure, the integrated sensor and sensor electronics assembly may be positioned on the skin surface of the user using an insertion

> device. *For example, [an] automated or semi-automated, spring biased and/or manual insertion device may be provided to deploy the sensor and the sensor electronics* such that the implantable portion of the sensor is positioned in fluid contact with the analyte of the user such as the interstitial fluid, while the housing of the sensor electronics is securely positioned and adhered to the skin surface. In embodiments of the present disclosure, the sensor electronics device (for example, a transmitter unit of an analyte monitoring system) may be switched to an operational state or condition (from an inactive, shelf mode) upon deployment of the integrated assembly by the insertion device.
>
> …
>
> [0151] In a further embodiment, *the insertion device may be configured for manual deployment with spring biased or automatic retraction of the introducer*. That is, sensor insertion, the user may apply a predetermined amount of pressure upon the housing of the insertion device to insert the introducer and the sensor, the applied pressure sufficient to pierce through the skin layer of the user, and the device housing configured such that the applied pressure or the distance traveled by the introducer is predetermined (for example, by the use of a stopper or a protrusion within the inner wall of the insertion device that effectively stops of blocks further downward movement of the introducer towards the skin piercing direction after the introducer has reached a predetermined distance. In one aspect, the applied pressure may be configured to also press down upon a spring or a bias mechanism provided within the housing of the insertion device such that, when the applied pressure is released, the introducer is automatically retracted to its original predeployment position within the housing of the insertion device, by the return force from the spring or bias mechanism.
>
> [0152] In this manner, consistent and repeatable insertion depth for the placement of the analyte sensor may be achieved. Furthermore, the insertion device housing (for example, a plastic or a combination of plastic and metal housing) may not be under the stress of spring tension since the bias spring provided for retraction of the introducer is, in the predeployment state, unbiased and in a relaxed state."

54. The only other point which it is necessary to note is that the specification explains at [0148]:

> "In one aspect, the integrated sensor and sensor electronics assembly and the insertion device may be sterilized and packaged as one single device and provided to the user. … In addition, the inserter [sic] device may include an end cap that is

> rotatably coupled to the insertion device body, and provides a safe and sterile environment … for the sensor provided within the insertion device along with the integrated assembly. …"

The claims

55. The only claims which remain in issue on the appeal are claims 1, 2 and 3.

56. At trial the parties agreed a breakdown of claim 1 into integers as follows:

> "[1] An integrated analyte monitoring assembly, comprising:
>
> [1.1] a sensor electronics assembly including:
>
> [1.2] an analyte sensor; and
>
> [1.3] sensor electronics including a power supply and comprising:
>
> [1.4] an activation switch operatively coupled to the power supply and the analyte sensor; and
>
> [1.5] a controller unit having one or more programming instructions stored therein for execution,
>
> [1.6] the controller unit in electrical contact with the analyte sensor and the activation switch and configured to process one or more signals received from the analyte sensor when the activation switch is triggered; and
>
> [1.7] an insertion device including:
>
> [1.8] a housing;
>
> [1.9] an introducer needle coupled to the housing configured to move between a first position and a second position; and
>
> [1.10] a bias mechanism operatively coupled to the housing and configured to automatically retract the introducer needle from the second position to a retracted position entirely within the insertion device housing,
>
> [1.11] wherein the sensor electronics assembly is configured for communication with a remote device
>
> [1.12] and is retained entirely within the housing of the insertion device prior to the introducer needle movement from the first position to the second position."

57. Claim 2 is as follows:

> "The integrated analyte monitoring assembly of claim 1, further comprising a cap configured to mate with an open end of the

> housing of the insertion device, to seal the sensor electronics assembly therein, optionally wherein the cap is configured to rotatably couple to the end of the housing."

58. Claim 3 is as follows:

> "The integrated analyte monitoring assembly of claim 2, wherein when the cap is coupled to the housing prior to deployment, the interior space of the housing is maintained in a substantially contaminant free and/or sterile environment."

Interpretation of the claims

59. The judge had to resolve a number of issues of interpretation of claim 1. The most contentious issue was the interpretation of "coupled to the housing" in integer 1.9, particularly bearing in mind the presence of the words "operatively coupled to the housing" in integer 1.10. At trial Abbott argued for a broad construction of "coupled to the housing", whereas Dexcom argued for a narrower construction.

60. The judge considered this issue at [150]-[182]. The judge agreed with the construction he understood Dexcom to have advanced, with the consequence that Dexcom's G7 product was held not to infringe the Patent. Since there is no challenge by Abbott to the judge's conclusion on interpretation, it is not necessary to consider his reasoning in detail. Since the judge's construction forms a key plank of Abbott's appeal, however, it is important to explain how he interpreted this feature of the claim. It is also relevant, for reasons that will appear, to consider his understanding of Dexcom's construction.

61. When summarising the parties' arguments, the judge correctly noted at [153] that Mr Varde had given evidence in his first report (at paragraph 9.44) that he understood the words "coupled to the housing" in integer 1.9 to refer to an "insertion process ... in which the movement of the needle is driven by a manual force applied to the housing". This meant that the claim was limited to manual insertion as shown in Figure 12. The judge said that Dexcom had advanced the same interpretation in their opening skeleton argument, but as counsel for Abbott pointed out to this Court what Dexcom actually said was this (emphases added):

> "83. … there is *no restriction as to how the force is imparted* to push the housing/needle configuration as it moves from the first to the second position.
>
> 84. For the purposes of infringement it is necessary for Abbott to construe the claim as including the use of *non-manual (eg spring loaded)* insertion forces in circumstances where the only actual discussion of any insertion mechanism concern the manual mechanisms of figs 12A-12G and [0151]. … "

Dexcom went on to argue that such a construction would give rise to a squeeze between obviousness and insufficiency.

62. The judge went on at [155]-[156] to say that in closing submissions Dexcom had put their argument "slightly differently" although "the end result – a narrow construction –

was the same". He quoted the following paragraphs from Dexcom's written closing submissions (emphases added):

> "59. … The drawings at Fig. 12 explain and illustrate the contrasting wording. The first movement is achieved by the coupling between housing and introducer needle so that they move together. This means that a force (*whether manual or not*) pushing the housing downwards also pushes the needle downwards. But the second movement is automated. The operative coupling of the spring to the housing (in which its potential energy is built up and stored by being pushed against the shoulder of the housing, in a manner not shown in the drawings) is what causes the automatic retraction of the introducer needle back into the housing.
>
> 60. The whole point of the contrasting wording is to explain the distinct movements and how they are achieved. By coupling the housing to the needle the patentee enables the downward movement of the needle to be achieved by the application of downward force to the housing (*whether manual or automated* - see [0151]) so that one will carry the other downwards towards the skin. The patentee conceives of this occurring by using a two-part housing, but it could equally be achieved by a one-part housing."

63. As counsel for Abbott pointed out, the words I have italicised make it clear that Dexcom's construction of the claim did not restrict it to manual insertion. (I would add that it appears that the cross-reference in paragraph 60 should have been to [0146] of the Patent: see paragraph 53 above. [0151] concerns the Figure 12 embodiment.)

64. The judge reasoned that the claim draws a contrast between "coupled to the housing" for the step of inserting the introducer needle in integer 1.9 and "operatively coupled to the housing" for the retraction step in integer 1.10. The insertion step in integer 1.9 requires the needle to be "coupled to the housing configured to move" (i.e. so that it moves) between a first position and a second position. The judge considered that this suggests (a) no relative movement between needle and housing, and (b) that it is the movement of the housing which causes insertion of the needle (and the sensor).

65. Integer 1.10 is explicit in requiring automatic retraction of the needle, and this occurs by the configuration of the bias mechanism being "operatively coupled" to the housing. Automatic retraction means there must be relative movement between the needle and the housing, and this relative movement is caused by the bias mechanism. Although the bias mechanism is not explicitly limited to a spring, a spring is a convenient way to envisage the bias mechanism. For the retraction to be automatic, that implies the use of the potential energy in a compressed spring, which causes the needle to be retracted to the "retracted position entirely within the insertion device housing". Thus the judge considered that, in the context of claim 1, "operatively coupled" means that the bias mechanism need only be coupled to the housing in order to be able to operate i.e. to perform its function of causing the retraction of the needle.

66. The judge concluded at [170] that (judge's emphasis in italics, my emphasis in underlining):

> "… although the specification *describes* embodiments with automatic (and semi-automatic) insertion of the needle, those are not *claimed*. Accordingly, I agree with Dexcom that claim 1 is limited to manual insertion in which the force on, and movement of, the housing is the cause of the insertion of the needle."

Heller

67. Heller is a long document, with considerable detail that is not relevant to the issues in this case. Although the invention is stated generally as being directed to devices and methods for the *in vivo* monitoring of an analyte, the monitoring of glucose is the main focus, using a subcutaneously implantable sensor.

68. Under the heading "summary of the invention", Heller states in [0007]:

> " … One embodiment is a sensor control unit having a housing adapted for placement on skin. The housing is also adapted to receive a portion of an electrochemical sensor. The sensor control unit includes two or more conductive contacts disposed on the housing and configured for coupling to two or more contact pads on the sensor. A transmitter is disposed in the housing and coupled to the plurality of conduct conductive contacts for transmitting data obtained using the sensor. The sensor control unit may also include a variety of optional components, such as, for example, adhesive for adhering to the skin, a mounting unit, a receiver, a processing circuit, a power supply (e.g., a battery) …"

69. It goes on at [0008]:

> "Another embodiment of the invention is a sensor assembly that includes the sensor control unit described above. The sensor assembly also includes a sensor having at least one working electrode and at least one contact pad coupled to the working electrode or electrodes. The sensor may also include optional components, such as, for example, a counter electrode, a counter/reference electrode, a reference electrode, and a temperature probe. Other components and options for the sensor are described below."

70. It also states at [0010]:

> "Yet another embodiment of the invention is an insertion kit for inserting an electrochemical sensor into a patient. The insertion kit includes an inserter. A portion of the inserter has a sharp, rigid, planer structure adapted to support the sensor during insertion of the electrochemical sensor. The insertion kit also includes an insertion gun having a port configured to accept the

> electrochemical sensor and the inserter. The insertion gun has a driving mechanism for driving the inserter and electrochemical sensor into the patient, and a retraction mechanism for removing the inserter while leaving the sensor within the patient."

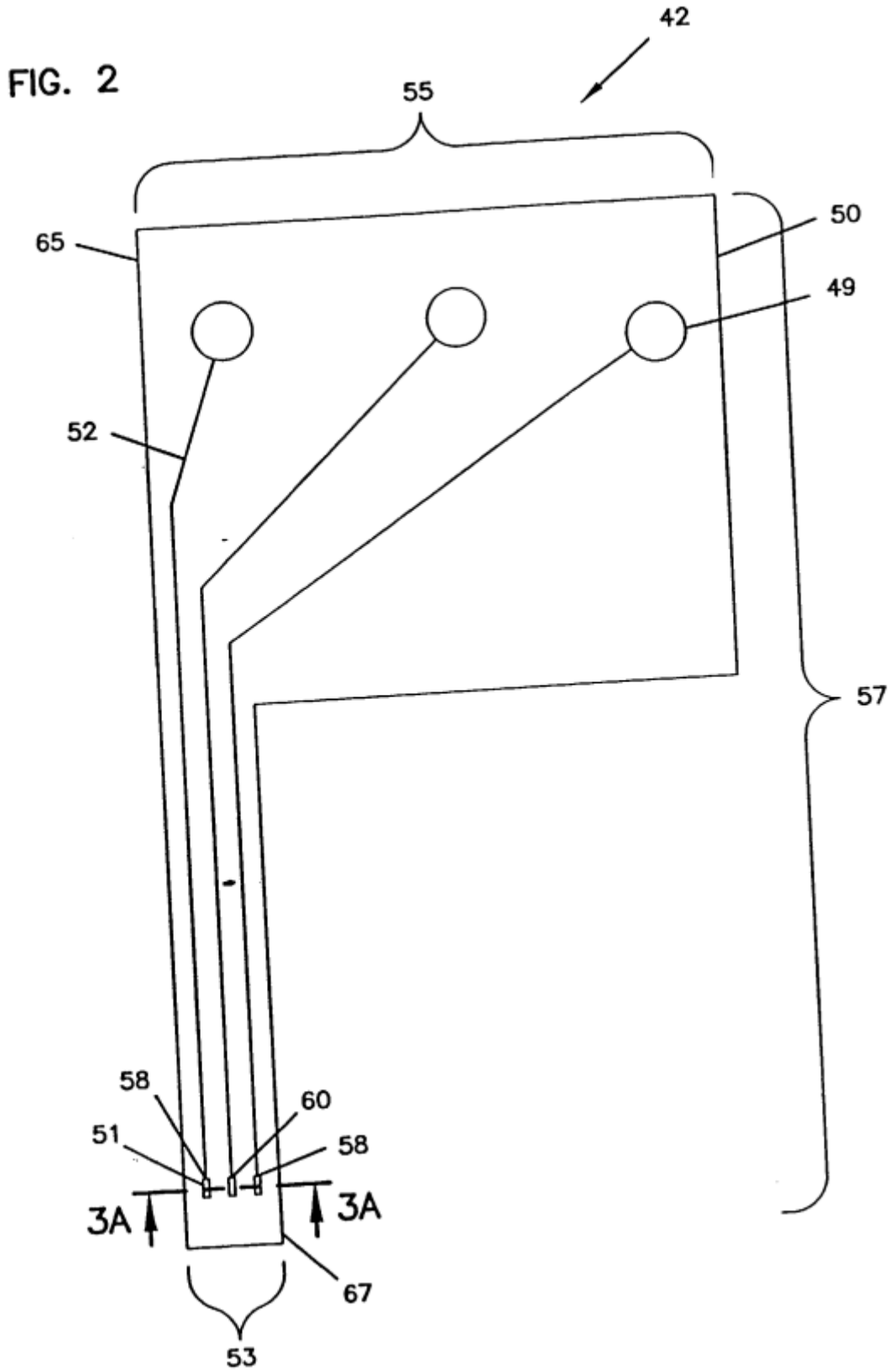
71. It was common ground at trial that Heller describes two configurations of analyte monitoring system, which were referred to as "the Main Configuration" and "the Fig. 32 Configuration". The Main Configuration is a two-part system, whereas the Fig. 32 Configuration is a system with integrated sensor and sensor electronics. As the judge noted at [204]:

> "… Dexcom's case involves the Skilled Team deciding to take forward something of a combination of the two whereas Abbott submitted that these were 'two mutually incompatible configurations'. Therefore it is important to be precise about what would be disclosed to relevant members of the Skilled Team by Heller when the document was read with the CGK in mind."

The Main Configuration

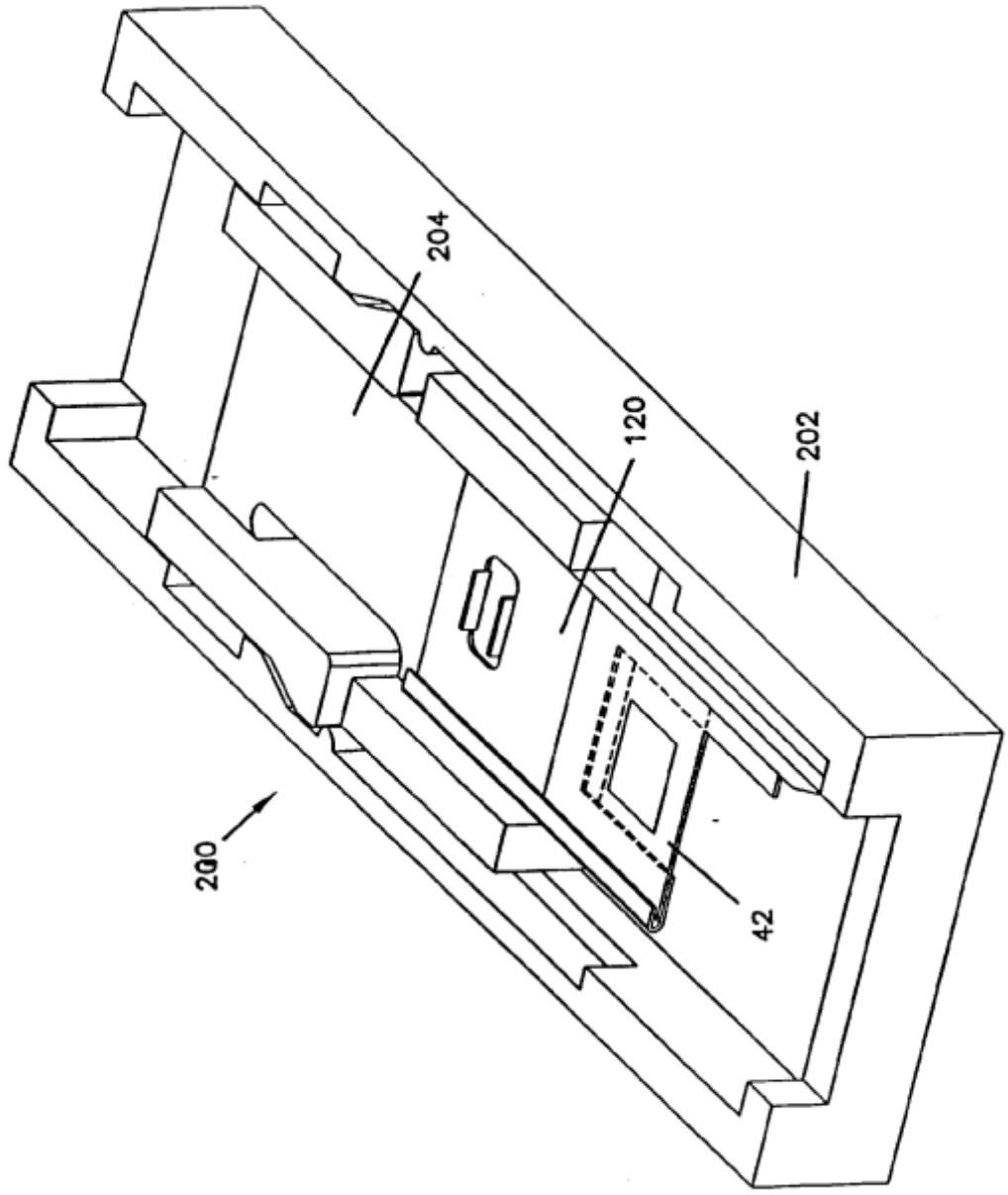
72. The Main Configuration has a number of components, some optional, which are described in turn, with a considerable number of embodiments. The general arrangement is shown schematically in Figure 1 and described in [0075]. It comprises a subcutaneously implantable sensor 42 coupled to a sensor control unit 44 which is typically attached to the skin of a patient. The sensor control unit may transmit signals to one or more receiver/display units 46, 48 for evaluation.

73. The sensor 42 is shown schematically in Figure 2, which is reproduced below, and described at [0076]-[0080].



74. The sensor 42 includes working electrodes 58 and a counter electrode 60 formed of conductive traces 52 disposed on a substrate 50. It also includes contact pads 49. As explained at [0090], the distal end 67 of the sensor has a relatively narrow width 53 to facilitate implantation into the subcutaneous tissue.

75. An "insertion device" 120 (i.e. a needle) used to insert the sensor 42 is shown schematically in Figures 12-13C, and described at [0201]-[0211]. This section of Heller also discloses an "insertion gun" 200 shown schematically in Figure 26, which is reproduced below.



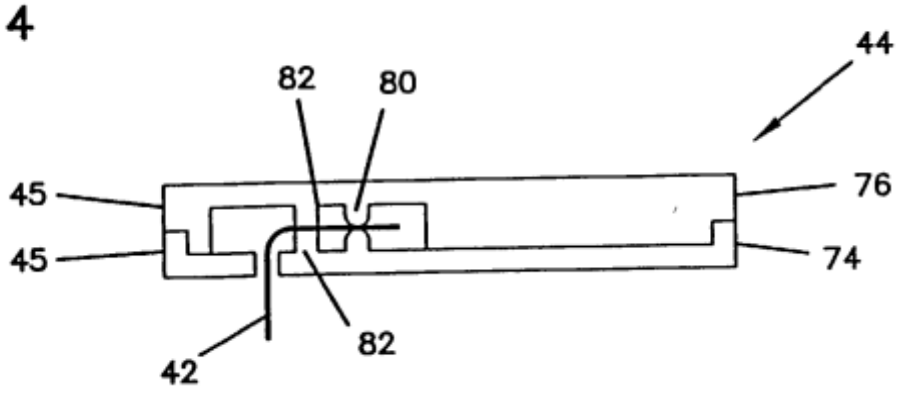
76. Heller explains (emphasis added):

> "[0206] The force applied to the insertion device 120 and/or the sensor 42 may be applied *manually or mechanically*. Preferably, the sensor 42 is reproducibly inserted through the skin of the patient. In one embodiment, an insertion gun is used to insert the sensor. One example of an insertion gun 200 for inserting a sensor 42 is shown in Figure 26. The carrier 204 drives the sensor 42 and, optionally, the insertion device 120 into the skin of the patient using, for example, a cocked or wound spring, a burst of compressed gas, an electromagnet repelled by a second magnet,

> or the like, within the insertion gun 200. In some instances, for example, when using a spring, the carrier 204 and insertion device may be moved, cocked, or otherwise prepared to be directed towards the skin of the patient.
>
> [0207] After the sensor 42 is inserted, the insertion gun 200 may contain a mechanism which pulls the insertion device 120 out of the skin of the patient. Such a mechanism may use a spring, electromagnet, or the like to remove the insertion device 120.
>
> [0208] The insertion gun may be reusable. The insertion device 120 is often disposable to avoid the possibility of contamination. …"

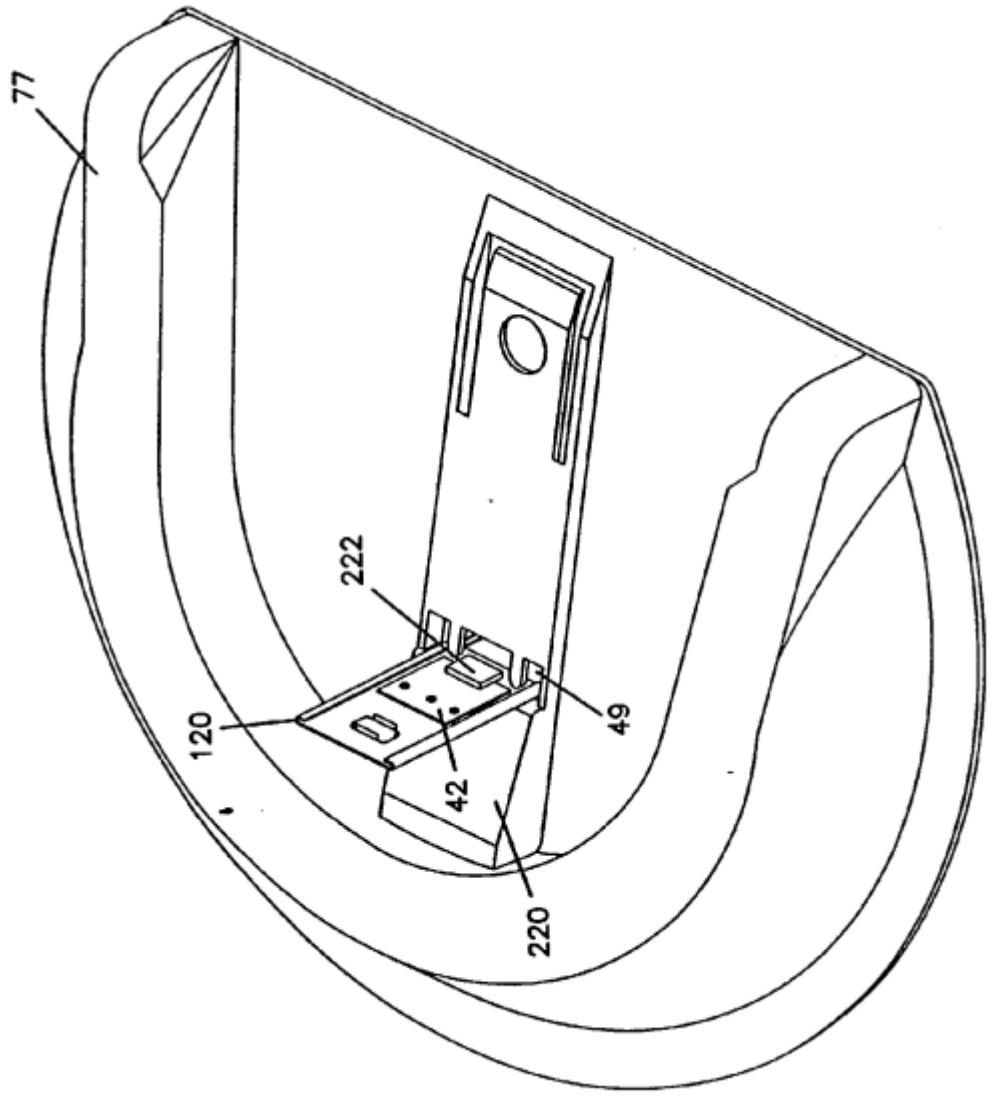
77. The "on-skin sensor control unit" 44 is described at [0212]-[0256]. Certain embodiments are described by reference by Figures 14-16. Figure 14 is reproduced below.

FIG. 14



78. This shows an on-skin sensor control unit 44 with a housing 45 formed in two portions, namely a base 74 and a cover 76, but Heller explains at [0219] that the housing 45 may be a single piece.

79. Heller also explains at [0225]-[0227] that the on-skin sensor control unit 44 may be directly adhered to the patient's skin or using a mounting unit 77. The latter arrangement is described in more detail at [0235]-[0237] by reference to Figures 27A-28D. Figure 28B is reproduced below.



80. As Heller explains at [0237]:

> "…. The mounting unit 77 typically includes an opening 49 through which a sensor 42 is disposed, as shown in FIG. 28B. The opening 49 may optionally be configured to allow insertion of the sensor 42 through the opening 49 using an insertion device 120 or insertion gun 200 (see FIG. 26). The housing 45 of the on-skin sensor control unit 44 has a base 74 and a cover 76, as illustrated in FIG. 28C. A bottom view of the housing 45, as shown in FIG. 28D, illustrates ports 230 through which conductive contacts (not shown) extend to connect with contact pads on the sensor 42. …"

81. The section of Heller that discusses the on-skin sensor control unit also describes an "insertion kit" by reference to Figure 33, which is reproduced below.

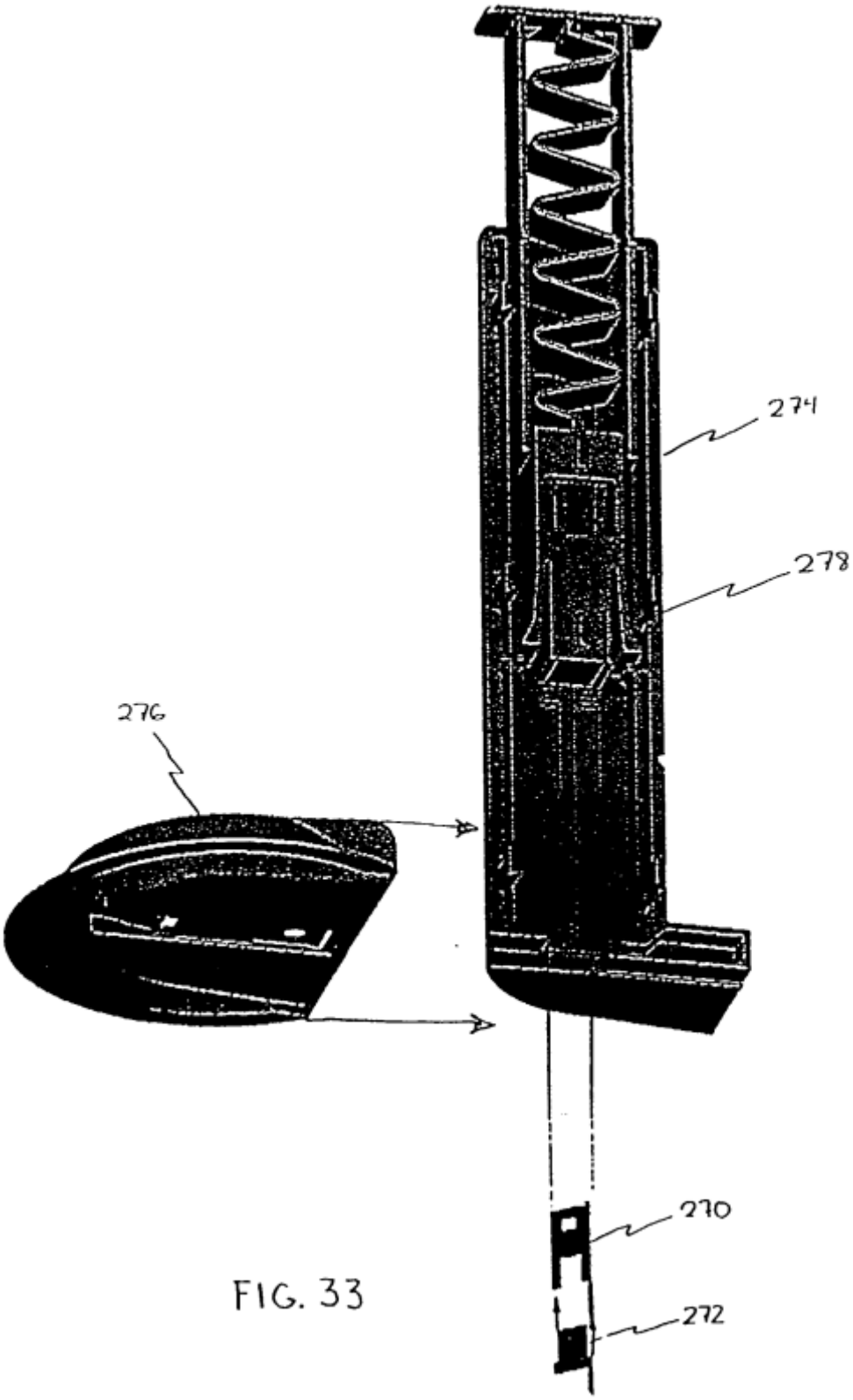


FIG. 33

82. The insertion kit is described as follows:

> "[0255] The insertion device, sensor, insertion gun and mounting unit can be manufactured, marketed, or sold as a unit. For example, FIG. 33 depicts an insertion device 270, sensor 272, insertion

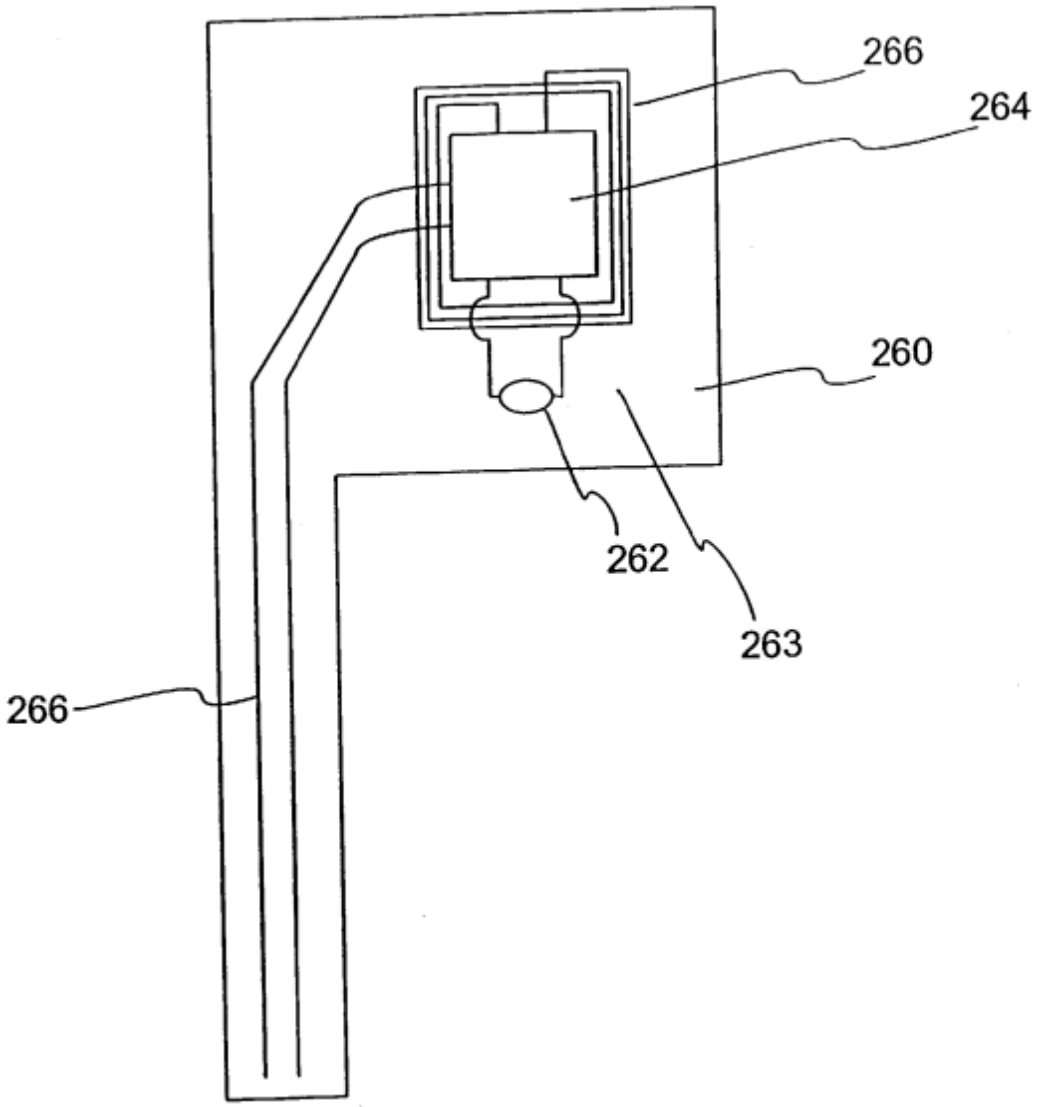
> gun 274 and mounting unit 276, which can be assembled (as indicated by the arrows) and sold together in an insertion kit. In Such an embodiment of an insertion kit, the insertion gun 274 can be packaged in a pre-loaded fashion, with an insertion device 270 and sensor 272 mated or otherwise coupled, the mated sensor 272 and insertion device 270 loaded upon the carrier 278 of the insertion gun, and with a mounting unit 276 already mated with the end of the insertion gun 274.
>
> [0256] In one embodiment, the insertion gun 274 is packaged in a state where it is ready to thrust the sensor 272 (and perhaps insertion device 270) into subcutaneous tissue. For example, the insertion gun 274 can be packaged in a 'cocked' state, such that the thrusting force used to introduce the sensor 272 into the subcutaneous tissue is stored in the device as potential energy (in the case of the embodiment depicted in FIG. 33, the insertion gun 274 would be 'cocked' by compressing its spring 280, thus storing potential energy in the coils of the spring). Preferably, an insertion gun 274 packaged in such a manner employs a 'safety', a barrier to prevent the release of the stored potential energy. The barrier is removed in order to permit the potential energy to be released. Within the context of the embodiment presented in FIG. 33, an example of a safety is a pin (not pictured) that impedes the spring from expanding when compressed. Thus, an insertion kit so embodied can be obtained at a place of purchase, removed from its package, and used after removal of the safety, without necessitating additional steps. Alternatively, the insertion gun 274 can be packaged in the above-described pre-loaded configuration, but without being 'cocked'. Thus, an insertion kit with an 'uncocked' insertion gun 274 can be obtained at a place of purchase, removed from its package, cocked, and used. To facilitate the insertion kit being ready to use with minimal user-exercised steps, the insertion kit can be sterilized prior to packaging. …"

83. No component in Figure 33 is labelled 280, but it is common ground that the spring referred to is the component visible in an expanded state near the top.

84. Heller describes the on-skin control electronics in more detail at [0257]-[0326] and the receiver/display unit in more detail at [0327]-[0362], but it is not necessary to refer to these sections.

The Fig. 32 Configuration

85. Figure 32 is reproduced below.



86. It was common ground at trial that Figure 32 contains a typographical error: the conductive traces on the sensor which are labelled 266 on the left of the figure should be labelled 268.

87. The Fig. 32 Configuration is introduced and described as follows:

> "[0229] An alternate embodiment of the invention allows for the transmitter 98 to be disposed upon the sensor substrate 50. In this embodiment, the transmitter 98 is electrically coupled to at least one conductive trace disposed upon the substrate 50, so that the transmitter 98 is provided with a signal that is representative of an analyte level of bodily fluid. This arrangement provides the advantage of relieving the user of the analyte monitoring device from having to electrically connect the transmitter 98 to the sensor 42. This is advantageous because the mechanics involved in forming the aforementioned electrical connection may be difficult for a user to accomplish. Furthermore, if the user connects the sensor 42 to the transmitter, then the region of

> electrical connectivity would likely be designed for protection from moisture and contamination, causing the housing 45 to be more important to the operation of the device.
>
> [0230] FIG. 32 depicts one possible embodiment of a transmitter 263 disposed upon a substrate 260. As can be seen from FIG. 32, substrate 260 has a conductive trace 268 disposed upon it, a portion of which is chemically enabled to form an electrochemical sensor. The substrate 260 may be flexible, thereby enhancing patient comfort. Such flexibility also reduces the risk of the substrate 260 shattering upon impact, potentially embedding a shard of the substrate within the user. Thus, flexibility enhances user safety. The transmitter 263 is comprised of an integrated circuit 264 designed to generate a transmission signal representative of the analyte level of the bodily fluid. … Integrated circuit 264 is powered by a battery 262 disposed upon substrate 260. The integrated circuit 264 is electrically coupled to conductive trace 268, to provide the integrated circuit 264 with a signal representative of an analyte level of a bodily fluid. The output of the integrated circuit 264 is a transmission signal, which is provided to an antenna 266 for transmission into the region of space surrounding the antenna 266. …
>
> [0231] It is important that transmitter 263 is protected from corrosive or contaminating influences. To this end, in one embodiment, transmitter 263 is encapsulated in a protective non-conductive coating, such as an epoxy.
>
> [0232] A patient using the aforementioned embodiment wherein the transmitter 263 is disposed upon the substrate 260, may make use of the device by simply inserting the implantable portion of the sensor transcutaneously and fixing the unit to the skin. The sensor need not be connected by the patient to an on-skin sensor control unit (such as on-skin sensor control unit 44 in FIG. 17). Thus, the entire device becomes disposable, meaning that a user of the device is able to purchase the device as a single unit and dispose of it as such, after a period of use that may range from one to fourteen days, or more.
>
> [0233] Other embodiments of the invention depicted in FIG. 32 exist. For example, although the battery 262 is shown as being mounted upon the substrate 260, the battery 262 may be a separate unit from the single-unit transmitter 263/substrate 260. …"

The law as to obviousness

88. The judge set out the applicable legal principles at [267]-[291]. There is no challenge to the accuracy of that account. For the purposes of the appeal it is sufficient to note

four points, all drawn from the judgment of Lord Hodge in *Actavis Group PTC EHF v ICOS Corp* [2019] UKSC 15, [2019] Bus LR 1318.

89. First, as Lord Hodge noted at [58]-[59], section 3 of the Patents Act 1977 provides that:

> "An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art …"

The notional skilled person has no inventive capacity.

90. Secondly, as Lord Hodge noted at [60], it is common for courts to adopt the structured approach to the assessment of obviousness described by Jacob LJ in *Pozzoli SPA v BDMO SA* [2007] EWCA Civ 588, [2007] FSR 37 at [23]:

> "(1) (a) Identify the notional 'person skilled in the art'; (b) Identify the relevant common general knowledge of that person;
>
> (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
>
> (3) Identify what, if any, differences exist between the matter cited as forming part of the 'state of the art' and the inventive concept of the claim or the claim as construed;
>
> (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?"

This approach is not mandatory, however.

91. Thirdly, as Lord Hodge said at [63]:

> "In *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc* [2008] 4 All ER 621, para 42, Lord Hoffmann endorsed the fact-specific approach which Kitchin J set out in *Generics (UK) Ltd v H Lundbeck* [2007] RPC 32, para 72 where he stated:
>
> > 'The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success.'
>
> Kitchin J's list of factors is illustrative and not exhaustive. …"

92. Fourthly, as Lord Hodge said at [72]:

> "… the courts have repeatedly emphasised that one must not use hindsight, which includes knowledge of the invention, in addressing the statutory question of obviousness. That is expressly stated in the fourth of the *Windsurfing*/ *Pozzoli* questions. … The obvious danger of a step-by-step analysis is that the combination of steps by which the inventor arrived at his invention is ascertained by hindsight knowledge of a successful invention. … "

Mr Varde's evidence as to obviousness over Heller

93. Mr Varde gave evidence in his first report that claim 1 of the Patent was obvious in the light of Heller. For present purposes his reasoning can be summarised as follows. First, he considered Heller and how it would be taken forward in section 8 of his report. He said in paragraph 8.57 (emphasis added):

> "… The Design Engineer would consider [Figure 33] as an exemplary configuration for an insertion device that provides *automatic* insertion and a reduction in user steps compared to other possible configurations contemplated earlier in Heller. The Design Engineer would be aware from earlier in Heller (in particular [0010], and the ideas expressed in [0201] to [0211]), as well as from his or her CGK that automatic retraction would be preferable."

94. Mr Varde went on in paragraphs 8.66 and 8.67 to note that Heller disclosed two insertion guns, those shown in Figure 26 and in Figure 33, and to say that the latter would be "attractive to the Design Engineer because of its focus on safety and few user steps". He then reasoned as follows (emphasis added):

> "8.69 The Figure 33 embodiment therefore provides a good starting point for the design of the mechanical aspects of a CGM system based on the Figure 32 embodiment in a housing. ….
>
> 8.70 I think therefore that the obvious thing for the Design Engineer to do would be to use the concept disclosed in Figure 33 and its description, modified in order that the 'insertion device 270' that is part of the inner workings of the gun was configured to fit with the housing of the integrated sensor/transmitter based on Figure 32 and allow for its release after insertion. …
>
> 8.71 The mounting unit could be dispensed with. This would allow a sterile barrier, such as a foil, to be applied so that the end was not left open. …
>
> 8.72 The Design Engineer would consider how to make the insertion needle retract: elsewhere in Heller (e.g. in [0010] and in the passage from [0201] to [0211]) reinforces the Design Engineer's CGK that this is desirable but does not explicitly say that the needle in the Figure 33 embodiment does retract, or if so, how. Earlier in Heller, at paragraph [0207], a spring or electromagnet

> is proposed for retraction. *Insertion and retraction mechanisms using springs are known in the CGK (both in CGM devices and lancing devices).* The Design Engineer knows how to achieve this. [He then suggested two methods: using the spring in Figure 33 and using a second spring.]"

95. Secondly, Mr Varde compared Heller with the claims of the Patent in section 10 of his report. He began at paragraph 10.6 by saying:

> "For the reasons I have given at paragraphs 8.60 to 8.73 above, in my opinion of what the Design Engineer's reaction to Heller would be, the Design Engineer would in particular look to take forward or improve upon the embodiment shown in Figure 32 and described in [0229] to [0232], contained within a housing (such as that shown in Figure 14 – the flexible sensor of Figure 32 could be arranged with its electronics fitted within) for protection during wear and insertion, inserted using the insertion gun of the embodiment shown in Figure 33 modified to accommodate that wearable with an automatic retraction as proposed e.g. in paragraphs [0010] and [0201] to [0211]."

96. Mr Varde proceeded to consider each of the integers of claim 1. In relation to integer 1.9, he said this:

> "10.13 The 'insertion device' (270) of Figure 33 includes a needle. While the Design Engineer needs to adapt the insertion needle to accommodate the shape of the housing of the sensor and electronics, the insertion needle is a fundamental component of the insertion device, used for inserting the flexible sensor. (I also note that a penetrating needle is also a common feature in all insertion devices in the on-market devices.) The Design Engineer would use an introducer needle.
>
> 10.14 In use, the insertion needle moves from one position, inside the housing, to an insertion position outside the housing where it penetrates the skin during operation of the insertion mechanism."

97. Two points should be noted about these paragraphs. The first is that they refer to two different housings without making this clear. Paragraph 10.13 refers to the housing of the sensor electronics assembly, whereas paragraph 10.14 refers to the housing of the insertion device. The second is that, as will appear, the judge understood this evidence to be describing automatic insertion. Counsel for Abbott submitted that the judge was correct to do so given that it was based on the mechanism of Figure 33, and counsel for the Comptroller did not dissent from this.

<u>The judge's judgment on obviousness over Heller</u>

98. The judge began his assessment of obviousness by considering some general points at [298]-[318]. Having considered obviousness over two other items of prior art, the judge

considered obviousness over Heller at [335]-[392]. His reasoning may be summarised as follows.

The context for the assessment

99. The judge began by observing at [298]:

> " It is helpful to set the scene. The Skilled Team, comprising a collection of unimaginative individuals who have the CGK relating to their discipline, is interested in designing and developing a new CGM system and device. They have regard to the existing CGK devices on the market. So, *per* Pozzoli, I have identified the Skilled Team and their CGK and it is now necessary to identify the differences between what each piece of prior art discloses and the invention and then to ask *Pozzoli* question 4."

Obviousness over common general knowledge

100. Abbott characterised Dexcom's case as being, in reality, an unpleaded one of obviousness over common general knowledge. The judge did not in terms reject this contention, but he set out the points which Abbott relied on in support of it at [300]-[309] and it is clear that he had them well in mind.

Mindset issues

101. Abbott advanced two arguments concerning the "mindset" of the skilled team. The first was that CGM system developers were particularly motivated to improve the accuracy and signal stability of the sensor. The second was that the skilled team would consider two-part systems to be the "established architecture". The judge said at [316] that he was "inclined to give both these factors relatively little weight". It was clear that companies were continuing to develop CGM systems without waiting for sensor accuracy to be improved. The commercial reasons for the two-part architecture "did not render the idea of an integrated unit inventive from a technical standpoint".

Why was it not done before?

102. Abbott posed a rhetorical question: if the Patent was obvious, why had Dexcom not launched an integrated system long before they released the G7 in 2022? The judge held at [318] that there were two answers to this question. First, the costs of the electronics had come down by 2022. Secondly, Dexcom had their previous system on the market. (I would add that Abbott's argument assumed that Dexcom were aware of Heller, but not of the Patent, which seems unlikely.)

Mechanical cases

103. In the context of his rejection of Dexcom's case based on another item of prior art, the judge made a point at [334] which Abbott endorse and rely upon with respect to Heller:

> "I should also mention that I have not reached these conclusions based on Dr Schoemaker's analysis which, as I have indicated, was not based on what a Skilled Mechanical Engineer would

> derive from the prior art or on what he or she would implement in a design based on it. Instead, and this is a point which has particular force in mechanical cases, it is, in my view, necessary for the party saying a claim is obvious to present an obviousness case which provides the Court with a clear idea of what is said to be the end result of the process."

Dexcom's case on Heller

104. The judge summarised Dexcom's case on Heller as follows (evidence references omitted, emphases added):

> "336. Dexcom's case in closing was simple: Heller discloses all the features of claim 1, with various options for putting them together. A device with all those features in combination is a natural result of following the teaching of Heller and could readily have been achieved at the priority date by the Skilled Team necessary to implement the Patent. Thus, on Dexcom's case, no substantial changes were required which meant there was ample motivation for the Skilled Team to take Heller forward.
>
> 337. Dexcom submitted that Heller describes with precision and detail a CGK Navigator-type insertion device, including details of the needle, the preferred shape for the sensor, the electronics, an insertion and retraction mechanism with *spring loaded insertion and retraction* etc., and automated activation or the use of an activation switch. It also discloses that the sensor (whilst keeping the same general shape and configuration) can be combined with the electronics unit including the transmitter and the battery in the manufacturing process on the same substrate. It should be noted that the disclosure of the use of an integrated sensor and electronics unit is not simply a passing reference in Heller. It is in fact the subject of the invention which is actually claimed.
>
> 338. Dexcom acknowledged that Heller does not explicitly teach the use of the disclosed *spring loaded CGK-type insertion mechanism* with the integrated sensor/electronics assembly (simply referring in [0232] to 'insertion' by the patient) but submitted it was common ground between the experts that the Skilled Team would expect to use that mechanism, adapted as necessary …. Similarly for activation, Dexcom submitted it was common ground that in an integrated device an activation switch was necessary …, and that either of the activation mechanisms specifically disclosed in Heller in relation to the 2-part device could readily be used for the integrated device …."

Abbott's case on Heller

105. The judge summarised Abbott's case on Heller as follows:

> "339. Abbott's principal point was that Dexcom's case on Heller was classic ex post facto hindsight, involving multiple redesign steps which involved moving away from the teaching of Heller in material ways. Abbott submitted that, cumulatively, all the steps constituted a significant research project that the Skilled Team would either not be motivated to embark upon in the first place or, if embarked upon, it was not clear that the Skilled Team would end up within the claims of the Patent.
>
> 340. Abbott managed to develop no less than 12 steps which they said Dexcom's case required to get from Heller to claim 1, although there were alternative choices on two of the 12 steps."

In fact, the twelfth step involved getting to claim 2, but that is a minor point.

Issues with manufacture and sterilisation

106. Dr Schoemaker suggested two potential problems of implementation in making the Figure 32 sensor and sensor electronics for a CGM device: manufacture and sterilisation. The judge considered these issues at [342]-[355].

107. So far as manufacturing was concerned, the judge accepted the evidence of Dexcom's experts which he summarised at [345]:

> "Prof. Georgiou had two answers to this in reply. He pointed out that encapsulating the electronics would protect them during the dip-coating process, and he posited an obvious alternative whereby the sensor and transmitter are manufactured on separate substrates, which are then stuck together back-to-back. Mr Varde also relied on the 'back-to-back' approach, noting that the Design Engineer was not attracted to the [0229] embodiment by the single *substrate* disclosure, but rather by the idea of the single integrated unit and the advantages that flowed from it, as taught by Heller."

108. As for sterilisation, the judge accepted Dexcom's submission that Dr Schoemaker's evidence taken as a whole was that the skilled team would at the priority date have had the ability and resources to sterilise a combined sensor/electronics assembly with ETO and a reasonable expectation of success in doing so. The judge also gave two further answers to this point, the second of which was the problem would not arise with the back-to-back manufacturing method.

Abbott's 12 steps

109. Before turning to consider each of Abbott's 12 steps, the judge commented:

> "357. … I have not found it necessary to set out the lengthy submissions made by Abbott in relation to each of these steps. The allegation of hindsight was made repeatedly, but, in view of what Heller actually disclosed, it is an allegation which has very little force.

> 358. As is sometimes the case, the patentee greatly exaggerated the number of steps required. Furthermore, the identification of all these steps indicates to me that Abbott did not approach matters from the correct viewpoint - that of the unimaginative skilled design engineer fulfilling their role in the Skilled Team. Nonetheless, I analyse each suggested step and, importantly, whether it was obvious to take forward the combination of all of them."

110. The judge discussed each of the 12 steps at [359]-[387]. For reasons that will appear, it is only necessary to set out his assessment of the first five, tenth and twelfth steps.

111. *Step 1A - Decide to take forward the Figure 32 embodiment*. Dexcom disputed this was a step at all since Figure 32 was what was disclosed. Although he did not say so in terms, the judge appears to have accepted this, since he held that the skilled team would have the necessary skills to make the Fig. 32 Configuration. It follows that it is not necessary for the purposes of the appeal to discuss step 1B, which was an alternative to step 1A.

112. *Step 2 - putting Figure 32 in a housing*. The judge said at [362]:

> "… How to enclose the Fig 32-type sensor and electronics was routine design."

113. *Step 3A - Modifying Fig 14 to house Fig 32 - and Step 3B - Make a new housing for Figure 32 with only part of the sensor exposed*. The judge commented at [363]:

> "These alternatives illustrate, in my judgment, Abbott's impractical approach. The skilled mechanical engineer would understand the figures in Heller are schematic. Any implementation would require that engineer to make real-life practical routine design choices, which include these supposed 'steps'."

114. *Step 4 - Decide to use Figure 33 as the starting point for the new insertion device*. The judge commented at [364]:

> "I do not consider this to be a step at all. It is a choice from what Heller actually discloses, by way of insertion device. In this regard, in my judgment, it would be clear to the Skilled Team, and the mechanical engineer in that Team, that Heller presents them with a series of options from which they can make their selection without requiring any inventive capacity."

115. *Step 5 - Change the dimensions of Figure 33 to accommodate Figure 32*. The judge began by commenting at [365]:

> "This is routine development and a further illustration of Abbott's deeply impractical and overly literal approach."

116. The judge first considered Mr Varde's evidence and then Dr Schoemaker's evidence. In relation to the latter, the judge said (evidence references omitted, emphases added):

> "368. … Dr Schoemaker's cross-examination began with the Fig.2 embodiment. He accepted that the Skilled Team would use the Fig.2 sensor with one of the Fig. 12/13 needles, in the insertion gun of [0206] with *spring-loaded insertion and retraction*, aided by a mounting unit and a cover …. He considered that all this was within the Skilled Team's CGK, and they would have no difficulty implementing any of it.
>
> 369. Moving onto the Fig. 33 embodiment, he agreed that this was of a similar shape to the Fig. 2 sensor, but with an additional depth of a few millimetres, and with a protective *housing* (e.g. the encapsulating coating of [0231]) *over the electronics*. He agreed that the starting point for *insertion and retraction* would be to use the same *spring mechanisms* applicable to Fig.2. …
>
> 370. He also agreed that any changes to the size of the Fig.33 device were obvious to make …. However, he suggested in XX that having the *housing over the electronics* would lead to difficulties in engaging the sensor with (and disengaging it from) the insertion needle.
>
> 371. As the cross-examination proceeded …, it became apparent that Dr Schoemaker had in mind a *housing that enveloped the entire end of the substrate containing the electronics*, which would accordingly interfere with the needle that was engaged with the sensor down the 'flagpole' …
>
> 372. With a housing built in this way, it would interfere with the insertion needle engaging with the 'flagpole'. However, Dr Schoemaker was then asked to consider a smaller *housing surrounding only the electronic components* shown in Fig. 32, with some space around it, which he accepted would lack aesthetic appeal but would work …"

It is common ground that [369] contains a typographical error: the reference to Fig. 33 should be to Fig. 32. The source of this typographical error is explained below.

117. The judge concluded at [374] (emphases added):

> "As Dexcom submitted, both Mr Varde and Dr Schoemaker therefore arrived at the same place - a modified version of the Fig.33 device that would *automatically* insert the Fig.32 *integrated sensor/transmitter unit with a housing*. The unit could be adhered to the skin using the housing with or without using a mounting unit. It satisfied integers 1.7-1.10 of claim 1."

118. *Step 10 - Decide to implement automatic retraction in the new insertion device*. The judge said at [379]:

> "Again, an option disclosed in Heller and the choice of it was routine."

119. *Step 12 - Adding a cap*. The judge said:

> "384. I agree that this is a step. Heller describes packaging of the insertion kit in general terms, along with sterilisation, although it does describe a safety or barrier to prevent a cocked insertion spring being released (and the insertion needle being driven out) before it is intended to be used.
>
> …
>
> 386. Although the sterilised state of the insertion device and sensor could be maintained by placing a film over the device, I consider that an equally obvious alternative would be to add a cap which would have the added advantage of preventing anyone being stuck with any inadvertent release of the insertion device/needle.
>
> 387. As regards the additional integers in claims 3, 4, 5 & 7, I did not understand Abbott to contend that any of these conferred inventiveness if I concluded that claims 1 and 2 were obvious. In any event, I find that it was obvious to have the cap attached prior to deployment (claim 3) i.e. attached during manufacture …"

Conclusions regarding Heller

120. Having considered all 12 steps, the judge concluded as follows:

> "388. I can now revert to the rival submissions regarding Heller. Stepping back from the detail, many of the arguments made by Abbott on obviousness as a matter of generality had little force when it came to Heller because, as Dexcom submitted, Heller disclosed not just the idea of an integrated device but considered details of how to implement and deliver such a device.
>
> 389. Similarly, Abbott's accusations that the whole obviousness analysis was driven by hindsight and that Mr Varde was constantly in problem-solving mode have, in my judgment, very little force in relation to Heller. …. in the light of the disclosure of Heller, I acquit Mr Varde of the use of hindsight. In my judgment he was properly focussed on how the unimaginative skilled mechanical engineer would implement what Heller disclosed.
>
> 390. In this regard, it is relevant that Abbott characterised *any* change from what was shown in a schematic (and literally interpreted) figure as driven by and indicative of hindsight. This was unrealistic. I acknowledge Abbott's point (see [295] above, that hindsight can be a particular problem in mechanical cases. I also acknowledge Abbott's point on the passage from Mr Varde's cross-examination to which they drew particular attention ….

> 391. As appears from my analysis of the 'steps' which Abbott said were required to get from Heller to claim 1, most of them were not 'steps' at all, but were inevitable in any practical implementation of the Fig 32/Fig 33 teaching in Heller. In these circumstances, the differences between Heller and claim 1 were minimal and merely required some necessary but routine design implementation choices."

The judge's judgment on insufficiency

121. The judge addressed this topic at [393] as follows (emphases added):

> " At various points there were three insufficiency squeezes identified. They concerned (a) *automatic insertion*, (b) the activation switch and (c) sterilisation of a combined sensor and sensor electronics unit. *(a) does not arise due to my decision on construction*. So far as (b) and (c) are concerned, the squeezes have done their job, albeit largely because the Patent assumes that the Skilled Team has the ability to implement both from their CGK. In these circumstances, there is no reason to discuss these any further."

Grounds of appeal

122. Abbott appeal with permission granted by myself on seven grounds. Ground 1 is that the judge erred by taking as the starting point for the purposes of the assessment of obviousness a hybrid of the two configurations disclosed by Heller. Ground 2 is that the judge erred in treating the Fig. 32 Configuration as a general teaching of the idea of a single integrated on-body unit in which the electronics were integrated with the sensor in any configuration. Ground 3 is that the judge failed to distinguish between the housing of the insertion device of claim 1 and the housing of the sensor electronics assembly. Ground 4 is that the judge failed to consider whether Heller disclosed or made obvious an introducer needle "coupled to the housing" as he had interpreted that feature of claim 1. Ground 5 is that the judge failed properly to assess the obviousness of claims 2 and 3 because of his error with respect to the housing. Ground 6 is that the judge wrongly adopted Dexcom's written closing submissions as to obviousness over Heller. Ground 7 is that the judge unduly delayed in giving his judgment.

123. Before turning to consider these grounds of appeal, it is important in fairness to the judge to note three points. The first is that the judge was faced with a considerable number of issues which do not arise on the appeal. These included the issues as to the composition of the skilled team and the common general knowledge which I have touched on above, infringement and the validity attacks which the judge rejected.

124. The second is that it is clear from the judgment that the judge was not assisted by many aspects of Abbott's case. I have already mentioned his assessment that Dr Schoemaker was a strange choice of expert. It can be seen from his reasoning on obviousness that the judge was equally unimpressed by Abbott's points concerning the mindset of the skilled team, why was it not done before, manufacturing and sterilisation or by the 12 steps postulated by Abbott as being required to get from Heller to the claims.

125. The third and most important point is that, before the judge, Abbott argued for a broad interpretation of claim 1 for the purposes of their infringement claim, which made it more difficult for them to argue that the claim was not obvious over Heller. Although Dexcom argued for a narrower interpretation of claim 1, Dexcom's fundamental position was that the Patent could not be both valid and infringed by Dexcom's G7 device. In this Court Abbott accept the judge's narrow interpretation of claim 1, which inevitably puts a different complexion on the issue of obviousness.

The role of the Comptroller

126. In *Halliburton Energy Services Inc's Patent* [2006] EWCA Civ 185, [2006] RPC 26 this Court held that, normally, the Court would not restore a patent which had been held invalid by the court below unless that decision was shown to be wrong. Faced with the difficulty posed by an appeal by the patentee which was not resisted by the defendant because of a settlement, the Court concluded that the Comptroller should be invited to intervene to assist the Court on terms that the Comptroller's costs would (subject to assessment) be paid by the appellant patentee in any event. Jacob LJ noted at [8] that "in the nature of things [the Comptroller] could not provide a full-blooded opposition to the appeal".

127. Subsequently, in *Aerotel Ltd v Telco Holdings Ltd* [2006] EWCA Civ 1371, [2006] RPC 7 there was a settlement in the first of the two cases which the Court of Appeal was due to hear together shortly before the hearing. As Jacob LJ explained at [4]:

> "Mr Birss, in addition to appearing in the Macrossan appeal, then took on the job of acting as an amicus curiae in the Aerotel appeal, moving from a neutral position prior to the settlement to take on the burden of defending the judgment below in accordance with the procedure indicated in *Halliburton*. As would be expected of counsel for the Comptroller, Mr Birss presented matters objectively and in a non-partisan manner."

128. Practice Direction 52D paragraph 14.1 now provides:

> "(1) This paragraph applies where an appeal lies to the Court of Appeal from an order for the revocation of a patent.
>
> (2) The appellant must serve the appellant's notice on the Comptroller-General of Patents, Designs and Trade Marks (the 'Comptroller') in addition to the persons to be served under rule 52.12(3) and in accordance with that rule.
>
> (3) Where, before the appeal hearing, the respondent decides not to oppose the appeal or not to attend the appeal hearing, the respondent must immediately serve notice of that decision on –
>
> (a) the Comptroller; and
>
> (b) the appellant.

(4) Where the respondent serves a notice in accordance with sub-paragraph (3), copies of the following documents must also be served on the Comptroller with that notice –

(a) the petition;

(b) any statements of claim;

(c) any written evidence filed in the claim.

(5) Within 14 days after receiving the notice in accordance with sub-paragraph (3), the Comptroller must serve on the appellant a notice stating an intention to attend the appeal hearing or otherwise.

(6) The Comptroller may attend the appeal hearing and oppose the appeal –

(a) in any case where notice has been given under paragraph (5) of the intention to attend; and

(b) in any other case (including, in particular, a case where the respondent withdraws his opposition to the appeal during the hearing) if the Court of Appeal so directs or permits."

129. I would comment that this provision would merit reconsideration. Paragraph 14.1(4)(a) is inapposite given that petitions were abolished long ago: the reference should be to the claim form or counterclaim as the case may be. Furthermore, the Comptroller needs the transcripts of the oral evidence and submissions, the skeleton arguments and the written closing submissions in addition to the items listed.

130. It can be seen from paragraph 14.1(6) that the Comptroller may attend the hearing of an appeal either of his own volition or if permitted or directed to do so by this Court. The usual practice of this Court since *Halliburton* has not been to direct the Comptroller to attend, but to request him to do so. So far as I am aware, that request has almost always been accepted. (In one case the request for assistance was passed on to the Attorney General.)

131. In the present case Abbott had settled with Dexcom by the time that they sought permission to appeal from this Court. When granting permission to appeal, I directed:

> "The Comptroller may attend the appeal pursuant to PD52D para 14.1(6)(b) and is requested to do so."

132. The Comptroller accepted that request and instructed counsel. As can be seen from *Halliburton* and *Aerotel*, the task of counsel for the Comptroller is to defend the judgment, but to do so in an objective and non-partisan manner. This is because the Comptroller's role is to safeguard the public interest, which requires both that invalid patents be revoked and that patents that are not invalid as alleged be upheld. In the present case counsel for the Comptroller discharged this task admirably. We are grateful for his assistance.

133. As will appear, counsel for the Comptroller accepted that two of Abbott's grounds of appeal, grounds 3 and 4, had merit. Accordingly, he identified arguments which he considered that a properly-advised respondent might advance by way of a respondent's notice raising additional or alternative grounds for the decision made below. Counsel for Abbott was content to address these arguments on their merits and took no procedural objection. The Comptroller's stance nevertheless gave rise to a debate as to whether the Comptroller has power in a case such as this to serve a respondent's notice. Counsel for Abbott pointed out that the Comptroller (then represented by himself) had served a respondent's notice in *Apimed Medical Honey Ltd v Brightwake Ltd* [2012] EWCA Civ 5, [2012] RPC 17, but the Comptroller's power to do so was not considered in that case.

134. As counsel for the Comptroller pointed out, a respondent's notice can only be served by a respondent to an appeal: see CPR rule 52.13(1). Rule 52.1(3)(e) defines "respondent" to mean:

> "(i) a person other than the appellant who was a party to the proceedings in the lower court and who is affected by the appeal; and
>
> (ii) a person who is permitted by the appeal court to be a party to the appeal".

135. In a case such as this the Comptroller is not within either of these categories: he was not a party below and PD54 paragraph 14.6 does not make him a party to the appeal. It follows that the Comptroller cannot serve a respondent's notice. (It would be different if the Comptroller applied to be joined as a party.) As a matter of good practice, however, the Comptroller should notify the appellant of any respondent's notice-type grounds sufficiently in advance of the hearing to enable the appellant to deal with them. This was duly done by counsel for the Comptroller in the present case by means by his skeleton argument for the appeal.

Standard of review on appeal

136. Since the assessment of obviousness involves a multi-factorial evaluation by the judge, this Court is only entitled to intervene if the judge erred in law or principle: see *Actavis v ICOS* at [78]-[81]. See also *Lifestyle Equities CV v Amazon UK Services Ltd* [2024] UKSC 8, [2024] Bus LR 532 at [46]-[50] (Lord Briggs and Lord Kitchin) and *Iconix Luxembourg Holdings SARL v Dream Pairs Europe Inc* [2025] UKSC 25, [2025] Bus LR 1391 at [94]-[95] (Lord Briggs and Lord Stephens).

Ground 7: delay

137. The judge heard the trial from 24 April to 5 May 2023. Judgment was delivered on 28 June 2024, nearly 14 months later. The general rule is that judgments should be delivered within three months of a hearing even in long and complex cases (*Bank St Petersburg PJSC v Arkhangelsky* [2020] EWCA Civ 408, [2020] 4 WLR 55 at [78] and [84] (Sir Geoffrey Vos MR)), although this is not an inviolable rule (*Phones 4U Ltd v EE Ltd* [2025] EWCA Civ 869 at [323] (Falk LJ)). Delay in producing a judgment is not in itself a sufficient ground to impugn a judgment, but where there is a serious delay the appellate court must exercise special care in reviewing the evidence, the judge's

treatment of that evidence, his findings of fact and his reasoning (*NatWest Markets plc v Bilta (UK) Ltd* [2021] EWCA Civ 680 at [45] (Asplin, Andrews and Birss LJJ)).

138. In the present case the delay in producing the judgment was inordinate. Although the judge had the benefit of transcripts of the evidence and submissions, which it is evident from the judgment he carefully reviewed, it is clear from the authorities that this is not sufficient to avoid the risks caused by such delay. One particular risk that is exacerbated by a prolonged period of judgment writing, although it is present with any lengthy judgment no matter how quickly it is produced, is that of internal inconsistency. Counsel for Abbott did not in the end need to invoke the need for this Court to review the judgment with special care. Rather, he relied upon the delay as going some way to explain the errors he identified in the judgment, and in particular those which are subject of grounds 3 and 4.

Ground 6: adoption of Dexcom's submissions

139. Abbott complain that the judgment at [336]-[338], [342]-[356], [366]-[374] and [380]-[383] tracks Dexcom's written closing submissions at paragraphs 77-79, 97-109, 116-124 and 110-113 respectively almost verbatim with a certain amount of re-formatting and a few added words here and there. Abbott point out that in *Crinion v IG Markets Ltd* [2013] EWCA Civ 587, [2013] CP Rep 41 this Court was highly critical of a judge almost all of whose judgment was taken from one party's closing submissions with only minor changes, although the Court nevertheless dismissed the appeal. Counsel for Abbott did not press this ground of appeal, and rightly so. There is no comparison between this case and *Crinion*. The passages in question are only a small part of a long judgment. They are not even the whole of the section of the judgment which deals with obviousness over Heller. Furthermore, although the judge used material from Dexcom's closing submissions, he re-organised it: whereas these paragraphs of Dexcom's closing submissions apart from the introductory summary were structured by reference to the features of claim 1, the judge structured the other material by reference to the first five and eleventh of the 12 steps proposed by Abbott as being required to get from Heller to the claims. (Step 11 concerned the activation switch of integers 1.4 and 1.6.)

140. On the other hand, it is possible that this again helps to explain the errors which are the subject of grounds 3 and 4. Thus it is notable that [374] (paragraph 117 above) was copied almost verbatim from paragraph 124 of Dexcom's closing submissions with the addition of the words "As Dexcom submitted".

Ground 1: conflation of the two configurations in Heller

141. Abbott contend that the judge erred in principle by taking as the starting point for the purposes of the assessment a hybrid of the Main Configuration and the Fig. 32 Configuration, which are two distinct configurations. I do not consider that this is an accurate description of the judge's reasoning or that he made any error of principle. It can be seen from the judgment, in particular at [339] (paragraph 105 above), that the judge took the Fig. 32 Configuration of sensor and sensor electronics as the starting point. It can also be seen, in particular from [364] (paragraph 114 above), that he considered it would be obvious to the skilled team to combine the Fig. 32 Configuration of sensor and sensor electronics with the insertion gun shown in Figure 33. He did not take some hybrid of the Fig. 32 Configuration and the Main Configuration as the

starting point. His assessment that it would be obvious to the skilled team to combine the Fig. 32 Configuration of sensor and sensor electronics with the insertion gun shown in Figure 33 was open to him given that, as he said, Heller presents the reader with a series of options from which to choose. Abbott argued at trial that the insertion gun of Figure 33 was incompatible with the Fig. 32 Configuration of sensor and sensor electronics, but the judge rejected that argument on the expert evidence.

142. I would nevertheless note that, although the judge stated at [298] that "it is now necessary to identify the differences between what each piece of prior art discloses and the invention and then to ask *Pozzoli* question 4", he did not explicitly carry out that exercise in relation to Heller. The reason for this appears to be that he accepted Dexcom's case that the Fig. 32 Configuration combined with the insertion gun of Figure 33 disclosed every feature of claim 1, albeit that some routine modification would be required in order to combine the two: see [391] (paragraph 120 above). As I will explain, error might have been avoided if the judge had checked this combination against the integers of claim 1 as he had construed it.

Ground 2: treating the Fig. 32 Configuration as a general teaching

143. Abbott contend that the judge erred in principle by treating the Fig. 32 Configuration as a general teaching of the idea of a single integrated on-body unit in which the electronics were integrated with the sensor in any configuration. Again, I do not consider that that this is an accurate description of the judge's reasoning or that he made any error of principle. Rather, his reasoning involved starting from the Fig. 32 Configuration of sensor and sensor electronics and making what the judge assessed to be routine modifications in order to combine it with the insertion gun of Figure 33. Furthermore, as counsel for the Comptroller pointed out, Abbott's arguments in support of this ground involved an attempt to resurrect the evidence of Dr Schoemaker, when the judge considered that Dr Schoemaker was not properly qualified to assist the court, and to deprecate the evidence of Mr Varde, which the judge considered persuasive.

Ground 3: the housing

144. Integer 1.8 of claim 1 is "a housing". Integer 1.7 specifies that the housing is part of the insertion device. Integer 1.9 requires that the introducer needle be "coupled to the housing". As Abbott submit, it follows that it is important accurately to identify the housing when considering whether an obvious development or modification of Heller would fall within the claim.

145. Abbott point out that steps 2 and 3 in their 12 steps involved putting the Fig. 32 Configuration in a housing, but that housing was a housing for the sensor electronics assembly (integer 1.1). (It will be appreciated that claim 1 does not require the sensor electronics assembly to include a housing, but Abbott's case was that a practical implementation of the Fig. 32 Configuration which could be combined with the insertion gun of Figure 33 would require one.) Similarly, when discussing step 5, the evidence of Dr Schoemaker which the judge considered at [368]-[372] (paragraph 116 above) was concerned with a housing for the sensor electronics assembly, as can be seen from the passages I have italicised. So too the judge's conclusion at [374] (paragraph 117 above) refers to "the Fig.32 integrated sensor/transmitter unit with a housing". This is not the housing required by integer 1.8.

146. Abbott submit that it follows that the judge's bald statement at the end of [374] that the device he postulated "satisfied integers 1.7-1.10 of claim 1" lacks foundation. The housing referred to by the judge in this paragraph is the wrong housing, and there is no reference to the housing of the insertion device.

147. Counsel for the Comptroller did not contest this submission. As both counsel agreed, the error appears to be attributable to the fact that Dexcom made the same error in their closing submissions, and as noted above these paragraphs in the judgment were essentially copied from Dexcom's submissions.

148. As counsel for the Comptroller submitted, this error would not in itself necessarily undermine the judge's conclusion. A properly-advised respondent would be able to argue that the insertion device of Figure 33 includes a housing, and that the judge's reasoning would stand up if reference were made to that housing instead of the housing of the sensor electronics assembly. As counsel for the Comptroller acknowledged, however, this error is linked to the next one.

Ground 4: coupled to the housing

149. Integer 1.9 of claim 1 requires that the introducer needle be "coupled to the housing". As discussed in paragraphs 59-66 above, the judge interpreted this feature of the claim as limiting the claim to *manual* insertion. As Abbott point out, however, the judge held in [374] that a system that *automatically* inserted the integrated sensor and sensor electronics "satisfied integers 1.7-1.10 of claim 1". Abbott submit that this conclusion is flatly inconsistent with the judge's construction of the claim. Furthermore, it is also flatly inconsistent with the judge's resolution of the first insufficiency squeeze advanced by Dexcom at [393] (paragraph 121 above).

150. Again, counsel for the Comptroller did not contest this submission. As both counsel agreed, the judge's error again appears to be attributable to his adoption of Dexcom's closing submissions on this point, this time without noticing that they were inconsistent with his construction of the claim. As I have explained, it was sufficient for Dexcom's purposes to establish that a claim which embraced automatic insertion would be obvious over Heller. That was how Dexcom put their case in the summary at paragraphs 77-79 of their closing submissions, which the judge transposed into [336]-[338] of the judgment (paragraph 104 above). Dexcom did not need to establish that a claim limited to manual insertion would be obvious over Heller, because such a claim would not be infringed by the G7.

151. Counsel for the Comptroller explored the possibility that a properly-advised respondent might nevertheless attempt to maintain the judge's order for revocation by advancing an argument that it would be obvious to combine the Fig. 32 Configuration with Figure 33, but with the latter modified so as to substitute a manual insertion mechanism for the automatic insertion mechanism disclosed in Figure 33. As he acknowledged, however, the difficulty such a respondent would face is that Dexcom neither advanced such a case at trial, nor adduced any evidence which would support it. It can be seen from paragraphs 93-97 above that, as the judge correctly understood, Mr Varde's evidence focussed on automatic insertion. The best that counsel for the Comptroller could do was to point out that Heller does contemplate manual insertion in the first sentence of [0206] (paragraph 76 above), but that is when introducing the insertion gun of Figure 26. Not only is it evident that the insertion gun is intended to represent an improvement, but

also Mr Varde's evidence was that the mechanical engineer would consider the insertion gun of Figure 33 to be superior to that of Figure 26. As Lewison LJ observed during the course of argument, an argument that it would be obvious to dispense with a key feature of Figure 33 would have to confront the question of what motivation the skilled team would have for taking such an apparently retrograde step, particularly when none of the prior art devices employed manual insertion and automatic retraction. As counsel for the Comptroller accepted, there is no evidence which provides an answer to that question.

152. I therefore conclude that the judge's conclusion on obviousness cannot stand because it is inconsistent with his interpretation of the claim and there is no evidence to support a finding of obviousness of claim 1 on that interpretation.

Ground 5: claims 2 and 3

153. It follows that it is unnecessary to consider ground 5.

Conclusion

154. For the reasons given above I would allow the appeal and set aside paragraph 5 of the judge's order. I would emphasise, however, that this conclusion is based on (i) the judge's construction of claim 1 of the Patent, and in particular integer 1.9, and (ii) the evidence adduced by Dexcom as to obviousness over Heller.

Lord Justice Cobb:

155. I agree.

Lord Justice Lewison:

156. I also agree.