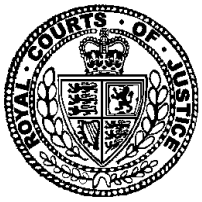

Neutral Citation Number: [2023] EWHC 2591 (Ch)

Case No: HP-2021-000025

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT

Rolls Building
Fetter Lane
London, EC4A 1NL

18 October 2023

Before:

MR JUSTICE RICHARDS

Between:

ABBOTT DIABETES CARE INCORPORATED and others
Claimants

- and –

DEXCOM INCORPORATED and others
Defendants

Daniel Alexander KC, James Whyte, Jennifer Dixon (instructed by **Taylor Wessing LLP**) for the **Claimants**

Iain Purvis KC and David Ivison (instructed by **Bird & Bird LLP)** for the **Defendants**

Hearing dates: 6,7 July (reading days); 10-14 July; 20-21 July 2023

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Approved Judgment

This judgment was handed down remotely at 10.30am on 18 October 2023 by circulation to the parties or their representatives by e-mail and by release to the National Archives.

Mr Justice Richards:

1. This is the third trial in a series of UK patent infringement/validity trials concerning continuous glucose monitoring ("CGM") systems. CGM technology enables people with diabetes to monitor the level of glucose in their blood. This is achieved by inserting beneath the skin a tiny sensor which forms part of a wearable unit which is adhered to the skin (often on the arm). The sensor measures the concentration of glucose in surrounding tissue and transmits information to a receiver (often a smartphone) so that the user can see at a glance whether their blood glucose is within a normal range.

2. The Claimants ("Abbott" unless it is necessary to refer to a particular Claimant individually) own European Patent (UK) No. 2 549 918 (the "Patent"). The Patent has a priority date of 24 March 2010 (the "Priority Date") and relates to designs for an "inserter": a device which positions CGM components into or onto the user, including by inserting the sensor beneath the skin. Abbott asserts that the Patent is infringed by a "G7 Applicator" sold by the Defendants ("Dexcom") and sues Dexcom for infringement. Dexcom counterclaims for declarations that the Patent is invalid. Abbott has, in turn, proposed various Conditional Amendments ("CA1", "CA2" etc) to the Patent to take effect if any of the claims in the Patent are held to be invalid.

THE ISSUES

3. I need to determine the following issues:

    i) the construction of various claims within the Patent;

    ii) whether the G7 Applicator infringes Claim 1 or Claim 7 of the Patent as properly construed, it being common ground that the Conditional Amendments raise no different issues relevant to infringement from those of the unamended claims;

    iii) whether the Patent's claims should be declared invalid because of the presence of "added matter";

    iv) a squeeze argument as to whether the Patent is anticipated by, or obvious over, three aspects of the prior art namely:

        a) US/2009/0124979 A1 ("Raymond")

        b) US/2005/0101912 A1 ("Faust")

        c) US/2010/00049129 A1 ("Yokoi")

    v) a squeeze argument as to whether the Patent is insufficient in the "*Biogen* sense" namely that it teaches a reader to perform the claimed invention to some extent, but not to the full extent of the claims.

THE WITNESSES

4. I had no witness evidence of fact. Both sides rely only on expert evidence. Abbott relies on expert evidence of Mr Douglas Jennings, a design engineer, and Dr Michael Schoemaker, a chemist and biochemist by training who has experience working on the development of CGM systems. Dexcom relies on expert evidence of Mr Andrew Varde,

an engineer who has worked on the development of medical devices, and of Professor Pantelis Georgiou, who is Professor of Biomedical Electronics at Imperial College, London. Mr Jennings, Mr Varde and Dr Schoemaker were cross-examined, but Professor Georgiou was not.

5. I do not need to provide a detailed review of each expert's evidence since neither side suggested that any expert lacked expertise or was failing to comply with duties imposed by CPR 35. I regarded all of the experts' reports as fair. Both sides had taken care to ensure that their experts' evidence was untainted by hindsight by asking them first about common general knowledge ("CGK"), then showing them the prior art and only then showing them the patent in suit. I can, therefore, deal relatively briefly with some specific criticisms that were made of aspects of the experts' evidence.

Mr Varde

6. Abbott does not challenge Mr Varde's expertise in matters of mechanical engineering. However, it does suggest that, since he is not an expert in CGM systems specifically or in CGM device design, he is not able to assist on the question of the general knowledge of a skilled team in the field of CGM specifically as at the Priority Date. I do not accept that criticism. Mr Varde has worked on the design of needle-deploying medical devices for approximately half of his career. While doing so, he has obtained an understanding of spring-driven mechanisms, triggers, needles and user "cues" to promote the correct use of such devices. Mr Jennings had no greater experience of CGM systems specifically than did Mr Varde. Dr Schoemaker is a CGM specialist, but his specialism is on the chemistry of the sensors that such devices employ.

7. I do not, therefore, accept Abbott's implicit point that somehow its team of experts was better able to approximate the "skilled team" than was Dexcom's team. As Jacob LJ explained in *Technip France SA's Patent* [2004] RPC 46, the primary function of expert witnesses in patent trials is to educate the Court in the technology. Their secondary function is, by providing opinions on evaluative factual questions such as "obviousness", to assist the Court in reaching its own conclusion on those questions with the reasons for those opinions, rather than the opinions themselves being of most assistance. I have concluded that all the experts put forward have been able to provide valuable assistance and I would not categorise the assistance provided by one expert team as being any less than that provided by the other.

8. Abbott suggested that there were instances in which Mr Varde's opinions were unduly affected by hindsight. I have, of course, sought to avoid deploying hindsight in my own conclusions on the question of "obviousness". However, I do not consider that Mr Varde's opinions, or those of other experts, have been so tainted by hindsight as to prevent them being of use in my own evaluation. A specific criticism of the way in which Mr Varde dealt with (non-existent) data on complaints concerning CGM inserters is dealt with in paragraph 49 below.

Mr Jennings

9. Dexcom placed some emphasis on corrections that Mr Jennings made to one of his expert reports after the parties had exchanged skeleton arguments. I understand why Dexcom did so and I deal with the point in paragraph 89 below. I find nothing improper in the amendments that Mr Jennings made but have concluded that the opinion he expressed in his unamended report is of greater weight.

Dr Schoemaker

10. Dexcom suggests that much of the evidence of Dr Schoemaker, who has no background in mechanical engineering, was simply irrelevant. I do not agree. While I have rejected any suggestion that his specific background in CGM devices gives his opinion evidence any greater weight, not least given that he is a chemist rather than a mechanical engineer, I have benefited from his evidence on CGM products specifically.

THE SKILLED TEAM AS AT THE PRIORITY DATE

11. The characteristics of a notional team "skilled in the art" are of direct relevance to a number of the issues that arise for determination. As Jacob LJ put it in *Technip France SA's Patent* [2004] EWCA Civ 381:

> *The 'man skilled in the art' is invoked at many critical points of patent law. The claims of a patent must be understood as if read by that notional man—in the hackneyed but convenient phrase the 'court must don the mantle of the skilled man.' Likewise many questions of validity (obviousness, and sufficiency for instance) depend upon trying to view matters as he would see them. He indeed has statutory recognition—Arts 56, 83 and 100 of the EPC expressly refer to 'the person skilled in the art'.*

12. The parties prepared an agreed statement of the common general knowledge (the "Joint CGK Statement"). From that statement, together with the fact that Dexcom expressed no significant disagreement with the articulation of the characteristics of the skilled team that Abbott set out in closing, I have concluded that the following matters were common ground. I have also borne in mind the more lengthy description of the skilled team set out in the Joint CGK Statement:

    i) The Patent (both as granted and as proposed to be amended by the Conditional Amendments) is addressed primarily to persons having expertise in the fields of mechanical engineering and having some expertise as a product designer.

    ii) That mechanical engineer would be working within a larger team in the field of medical device design and development. That larger team (the "Skilled Team") would have expertise across various disciplines such as manufacturing and production engineers, biologists and chemists, clinicians and medics, regulatory and quality departments and electronics and software engineers.

    iii) As regards the claims of the Patents that are relevant to the present proceedings (including those claims as proposed to be amended by the Conditional Amendments) the Skilled Team would be involved in the design and development of an inserter for a medical device. As regards Claim 7 of the Patent, the Skilled Team would be looking at the design and development of an inserter for an analyte sensor specifically. Although the claims of the Patent (including as amended by the Conditional Amendments) are not limited to inserters for CGM systems specifically, the intended addressees of the Patent would be involved in the design and development of an inserter specifically for a CGM system.

    iv) The Skilled Team would be led by a project leader with overall responsibility for developing the CGM system as a whole. The project leader would have specific CGM experience including at least 3 to 5 years working on CGM systems and would be familiar with all relevant aspects of CGM system design.

COMMON GENERAL KNOWLEDGE AS AT THE PRIORITY DATE

13. Although there were some differences between the parties as to matters that were part of the "common general knowledge" (the "CGK") as at the Priority Date, there was no disagreement as to why, conceptually, CGK is important. Abbott put the matter neatly in its written closing submissions saying:

> *…the CGK consists of information that is generally known to the Skilled Team at the Priority Date and is generally regarded as a good basis for further action by the bulk of those engaged in the relevant field. The CGK includes information that the Skilled Team would know existed and would know where to find as a matter of course, even if they could not quote that information off-hand. It also includes information that would be acquired by the Skilled Team as a matter of routine.*

Agreed aspects of CGK

14. The parties' Joint CGK Statement set out those aspects of CGK on which they were agreed. I will not quote that statement in its entirety in the interests of brevity. However, I have kept in mind all of the agreed aspects of CGK that it contains.

15. The CGK included matters relevant to diabetes generally. Diabetes is a metabolic disorder that involves a person's glucose levels being naturally too high. People diagnosed with diabetes benefit from monitoring their blood glucose levels which allows them to manage their blood sugar levels better by means of insulin injections. From the early 1980s, the principal way of taking a blood glucose measurement (a "BGM") involved patients pricking their finger to take a sample of blood and then applying that blood to the end of a disposable strip inserted into a reader device.

16. Taking blood from the finger in this way involved a sharp sterile lancet being used to penetrate the skin of the finger and by March 2010, the lancet was typically housed in some form of device which deployed the lancet out of the device and retracted it using, for example, a spring-loaded mechanism.

17. The Skilled Team would be aware of the advantages and disadvantages of the fingerstick method. One advantage was that it was highly accurate. However, a disadvantage was that the process of drawing blood from the fingertip could cause a patient discomfort or pain which was exacerbated by the need for frequent testing. Moreover, it placed responsibility for adherence to the testing schedule on the patient. That was a not immaterial burden as doctors would typically advise patients to conduct around seven fingerstick tests per day. Tests were generally required on a fixed schedule at points that might include upon waking, before and after meals, before sleep, and during the night. The combination of these factors meant that fingerstick testing was linked with imperfect compliance, with tests being forgotten or otherwise missed causing poor self-management of the condition.

18. By the Priority Date, CGM had become established as an alternative method to BGM, although one that was still undergoing considerable development and which required BGM testing to be performed alongside, but less frequently. Whereas fingerstick or BGM devices enable users to obtain a single measurement at a single time, the purpose of CGM devices was to provide a user's blood glucose level regularly with minimal intervention from the user.

19. While there were a small number of early CGMs that were operated by physicians, a key benefit of many CGMs was that, like BGMs, they were operable by patients. Patients would be responsible for commencing a period of sensing with their device, including positioning the device on their body and operating any electronic controls.

20. In the years before the Priority Date, a small number of different CGM devices were made commercially available or were known to be under development. Each of these devices had particular advantages or disadvantages. Anybody interested in building a new CGM device would make it a priority to learn about the features of the devices that were already available on the market (if they did not already know about them) including their known advantages and disadvantages.

21. By the Priority Date, CGM devices had been produced by a number of manufacturers for some time and these would be studied by the Skilled Team concerned with the aspects of design to which the Patent relates.

22. The Skilled Team would be aware of the following three CGM systems that were being used by the Priority Date ("Existing CGM Systems"):

    i) The Abbott Freestyle Navigator;

    ii) The Dexcom STS-7; and

    iii) The Medtronic Guardian Realtime.

23. The Existing CGM Systems had a transcutaneous electrochemical sensor and sensor electronics unit which the user attached to the sensor after sensor insertion, an applicator device (or inserter) and a reader device that received and displayed glucose data. The associated inserters all performed the same key function but had some different characteristics.

24. The Existing CGM Systems used an assembly where a reusable sensor electronics unit and a disposable sensor were provided to the user as separate components. The sensor was placed into the skin using an applicator and the sensor electronics unit was manually coupled to the sensor by the user after the insertion of the sensor into the skin. The lifetime of the sensor was less than that of the sensor electronics and the sensor electronics were re-usable in that they were removed from an expired sensor and connected to a new sensor (after insertion) a number of times before their disposal.

25. The Skilled Team would be aware that medical devices that are placed under the skin, including CGM devices and cannulas, use an insertion device which can help to ensure correct placement with minimal pain to the user. Insertion devices may be described as "manual" or "automatic", depending on the amount of control that the user has in the insertion process once initiated.

26. Although not specifically mentioned in the Joint CGK Statement, I have concluded that it was CGK at the Priority Date that a CGM inserter that gave a user a high degree of control over the insertion process once initiated (for example, a purely manual inserter) had a potential problem. A user of such an inserter, on starting to feel the tip of the needle against their skin, might stop the insertion process or not insert the sensor into the intended position under the skin. Relatedly, users might struggle with a manual insertion system, for example, if they have dexterity problems. Users of a manual inserter may insert the needle to the incorrect depth, use too much force or, if they become nervous during the attempts to insert, may abandon the process altogether. Like the parties during

the trial, I will refer to these known problems compendiously as the "hesitant user problem".

27. I also conclude that it was CGK at the Priority Date that it would be desirable for an inserter for a CGM device to have some protection against "unintended actuation" by which I mean actuation of the device before it is positioned correctly against the skin to enable the sensor to be inserted correctly.

28. The Existing CGM Systems had the following characteristics:

    i) The Dexcom STS-7 used a manual insertion and a manual removal process. The user inserted the needle by pushing down a plunger and retracted it using a collar. Insertion took place at 45 degrees to the skin.

    ii) The Medtronic Guardian Realtime used an automatic insertion process activated by a push button. The insertion needle was removed by the user first removing the insertion device from the sensor component and then removing the needle from the skin with their fingers leaving the sensor behind. The Guardian Realtime also inserted the needle at an angle of 45 degrees.

    iii) The Abbott Freestyle Navigator used an automatic insertion and removal process activated by a single push button. It inserted the needle at a 90 degree angle to the skin.

29. All of the Existing CGM Systems involved "non-integrated" assemblies. This meant that, once the sensor had been inserted under a user's skin the user needed to take a separate step in order to connect electronics to that sensor. The Abbott Freestyle Navigator and Dexcom STS-7 insertion devices made use of a mounting unit adhered to the user's skin to which the sensor was attached when the sensor was inserted. The mounting unit provided a mount onto which the sensor electronics unit was connected. The sensor in the Medtronic Guardian Realtime was adhered to the skin directly without the use of a mounting unit.

30. Although not specifically mentioned in the Joint CGK Statement, I have concluded, as Mr Jennings said in paragraph 5.12 of his First Report, that mechanical engineers within the Skilled Team would have a good understanding of mechanical design, engineering principles and manufacturability with particular useful experience in the use and design of compression spring release mechanisms. In addition, those mechanical engineers would have good mechanism design layout and problem-solving skills. For example, they would be able to design and layout complex mechanisms where components engage and interact with others in tight geometric constraints. In paragraph 2.5 of his Fourth Report, Mr Varde expressed no disagreement with Mr Jennings on this issue.

Disputed issues on "mindset"

31. The Joint CGK Statement set out some areas on which the parties did not agree. By the time of the parties' closing submissions, Abbott was seeking findings on the "mindset" of the Skilled Team in three areas. Dexcom did not request any additional findings on CGK and so I focus on the areas Abbott mentioned.

32. Abbott seeks findings on "mindset" in support of its case on the issue of "obviousness". As Floyd LJ held at [188] of his judgment in *Koninklijke Philips NV v Asustek Computer Corp* [2019] EWCA Civ 2230 "mindset" (in that case a "commercially driven mindset") can be a relevant aspect of a skilled person or team's common general knowledge in the

sense that what the skilled person does in the light of a given prior disclosure must be decided in light of that mindset.

33. Dexcom does not accept that the Skilled Team would have the "mindset" that Abbott suggests and it is that factual dispute that I address in the remainder of this section. The question of what, if any, impact the mindset of the Skilled Team has on questions of "obviousness" will be considered later in this judgment.

The likely focus of the Skilled Team as at the Priority Date

34. I accept the opinion evidence of Dr Schoemaker that the main focus at the Priority Date of the Skilled Team would be on improving the accuracy of the sensor used in a CGM device. CGM systems that were available at the Priority Date were not considered accurate or reliable enough to receive a regulatory approval to serve as a replacement for a fingerstick test when making a therapeutic decision. The Skilled Team would wish to overcome that problem so that they could claim in advertising materials for the CGM product under development that it eliminated the need for a fingerstick test for the purposes of confirmation before therapeutic decision making. For his part, Mr Varde accepted that improving sensor accuracy would be a very important area of focus for the Skilled Team at the Priority Date.

35. Abbott invites me to go further and conclude that, at the Priority Date, the Skilled Team would not be focusing on anything other than sensor accuracy. I will not go that far since Dr Schoemaker did not go that far in his own expert report. His opinion was that the "main focus" of the Skilled Team was on sensor development and specifically sensor accuracy. That does not exclude the possibility of the Skilled Team having other, subsidiary, areas of focus.

36. Mr Varde was cross-examined on two academic papers that he had exhibited to his expert report. One such paper entitled "Realistic Expectations and Practical Use of Continuous Glucose Monitoring for the Endocrinologist", prepared in 2009, contained a status report on early experiences with CGM technology. Mr Varde accepted, as he had to, that the paper focused on accuracy. It did not, for example, suggest that improvements in inserter design were necessary or that an integrated device offered advantages over devices that required a user to connect electronics to the sensor separately. However, papers such as these simply emphasise Dr Schoemaker's opinion that accuracy was the main focus. They do not exclude the possibility of other focuses.

37. Abbott also points to the fact that Dexcom itself made a few changes to its inserter between 2010 and 2017 when it launched the G6 Applicator (the predecessor to the G7). In 2017, Dexcom's then CEO, Mr Kevin Sayer, briefed investors on the ability of Dexcom's products to compete with the Abbott Freestyle Libre product which had just received FDA approval. Mr Sayer was upbeat, pointing to advantages that he considered Dexcom's products to have over Abbott's. He also signalled that Dexcom would be pursuing more innovation saying:

> *We haven't had anything new to push in the United States for quite a while other than connectivity, but that applicator looks the same way it did in 2006. It works lovely, but it's kind of scary and if you read the blogs and the patients' comments it's "Man, I got my new Dexcom, but I don't know if I want to push that plunger". That problem's gone when we launch G6. It's pushing a button.*

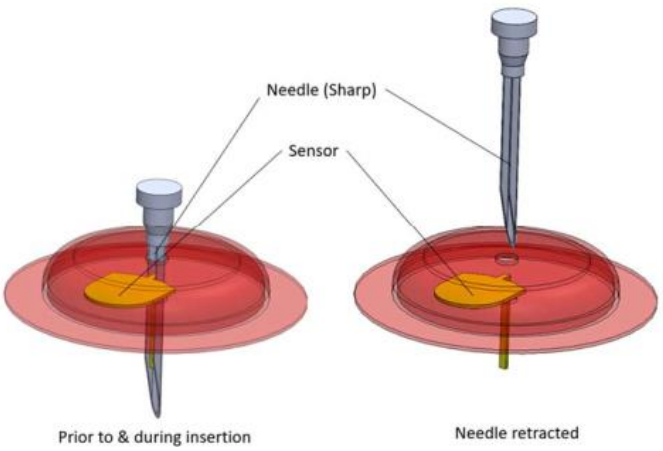
38. I do not consider that this statement bears the weight that Abbott seek to put on it. The fact that Dexcom did not have anything "new to push" other than connectivity does not demonstrate that the Skilled Team had a "mindset" at the Priority Date that was resistant to focusing on any issue other than sensor accuracy. Mr Sayer's comments are just as consistent with sensor accuracy being a main, but not a sole, priority. The fact that Dexcom chose not to update its inserter between 2006 and 2017 no doubt speaks to Dexcom's priorities over that period but similarly does not demonstrate any "mindset" to the effect that the Skilled Team at the Priority Date would not even have considered making changes to its inserter.

The relevance of infusion set design to the design of inserters for CGM

39. I accept Mr Jennings's opinion evidence to the effect that the Skilled Team, at the Priority Date, would be aware that different design considerations applied to an insertion device for an infusion set as opposed to an insertion device for a CGM system generally. Some of the more material differences are as follows:

    i) An important design goal when developing a CGM inserter would be to minimise any injury that could be caused by insertion of the CGM sensor. That is because inflammation or tissue trauma at the insertion site of a CGM sensor could lead to "biofouling" of the sensor and a loss of sensor function. An inserter for an infusion set would be designed to insert a flexible cannula into a user's body that could then be attached to an external infusion pump via tubing. Of course it would be desirable for an inserter for an infusion set to minimise pain or discomfort for the user. However, by contrast with an inserter for a CGM sensor, an inserter of an infusion set would not need to consider the possibility of a component being adversely affected by inflammation or tissue trauma.

    ii) In an infusion set inserter, the cannula, both prior to and during insertion, is located concentrically outside the sharp. By contrast in a CGM inserter, illustrated below, the position is the exact opposite. The sensor electrodes and contacts that are to be left under the user's skin sit inside the sharp prior to and during insertion. Thus, the sharp in a CGM inserter is not a complete hoop as the sensor electrodes and contacts must remain intact and under the skin while allowing retraction of the sharp as illustrated in the figure below. That design difference also has implications for the manufacture of the CGM insertion needle and may involve a non-standard grinding method.



iii) In a CGM inserter, there must be clearance between the electrode surfaces of the sensor and the sharp during insertion and retraction to avoid damage to the electrodes. By contrast, there is no similar need to avoid contact between an infusion set insertion needle and the inside of the inserted cannula during the retraction process since such contact would be unlikely to cause damage to the cannula.

40. I also conclude that the Skilled Team at the Priority Date would not regard designs for inserters for non-CGM products as part of its CGK for the purposes of designing inserters for CGM products. That was Mr Jennings's opinion and Mr Varde agreed during his cross-examination that, because he had no background in CGM products specifically, he was not in a position to assert that inserters for non-CGM products were part of the relevant CGK.

41. Nor was it CGK at the Priority Date that the Skilled Team seeking to design an inserter for a CGM device should use designs for inserters of an infusion set as a starting-point. I accept the evidence of Mr Jennings to that effect during his cross-examination. Abbott invites me to go further and conclude positively that, not only was it not CGK, but the Skilled Team at the Priority Date would not even have considered Raymond, Faust or Yokoi which relate to the design for inserters of infusion sets. It seems to me that making a finding such as this at this stage would risk trespassing on the question of "obviousness" which I address below. I will therefore return to this question later in the judgment.

42. I also find that a Skilled Team in 2010 that was seeking to develop an inserter for a CGM device would start by obtaining a detailed understanding of the Existing CGM Systems. Obtaining that understanding would include obtaining those devices and "tearing them down" so as to understand the inner workings of the inserter in detail. That emerged clearly from Mr Varde's evidence in paragraph 6.18 of his Third Report. The reasons for that are partly general, namely a wish to avoid "reinventing the wheel" and to understand problems present with those existing devices so that they could be remedied in a new product. Some of the reasons are more specific to the nature of inserter devices. Since they permit users to inject needles into their own skin, there is an obvious focus on safety and by starting with a device already on the market, the Skilled Team would have reassurance that it was starting from a safe place and, moreover, one that regulators accepted.

43. The Skilled Team's focus on the products that would have been on the market at the Priority Date has consequences for the way in which it would have approached the task of designing a new inserter for a CGM device:

i) Both the Dexcom STS-7 product and the Medtronic Guardian Realtime product inserted the needle at a 45 degree angle to the skin. By contrast, the Abbott Freestyle Navigator inserted the needle at a 90 degree angle. The Skilled Team would have to decide for itself which angle of insertion was to be preferred. There was no CGK to the effect that one approach was to be preferred to the other.

ii) The Existing CGM Systems all involved non-integrated CGM devices. As I have noted, all three of those devices required the user to take a separate step in order to connect electronics to the sensor. If a Skilled Team was motivated to develop an inserter for an integrated assembly, it would need to address additional considerations that did not arise in connection with inserters for the Existing CGM Systems. For example, additional regulatory approval procedures applied to electronic medical devices. The Skilled Team would also have to consider which

materials to use for the additional features and how the integrated device could be sterilised: sterilisation using ethylene oxide would be incompatible with the chemistry of the sensor whereas sterilisation by irradiation would not be readily compatible with the electronics of the transmitter. The Skilled Team would also need to consider issues such as how sensor electrodes would be kept dry in a humidity-controlled environment prior to insertion. There would also be additional considerations as to how to fit an integrated CGM device within the inserter.

CGK and thinking with respect of sensor and electronics/transmitter design

44. Abbott seeks findings in this area as part of its case, arising in relation to CA1, to the effect that it was not obvious at the Priority Date to fashion an inserter for an integrated in vivo analyte sensor on-body electronics assembly.

45. I will make the following findings and later in this section will explain my reasons:

    i) The CGK in the field of CGM systems at the Priority Date involved an accepted architecture of a two-part, "non-integrated" design, by which I mean a design which involved a CGM sensor being inserted under the skin separately from associated electronics. The user would then need to take a separate step that consisted of attaching the sensor to those electronics.

    ii) The Skilled Team would have understood as a matter of CGK that this established architecture was adopted primarily because of considerations of cost. A CGM sensor would have a life of just a few days. By contrast, the associated electronics could be expected to last much longer and were more expensive to manufacture than the sensor. Accordingly, a "two-part" architecture saved costs as the expensive electronic components could be reused even while sensors were being discarded.

    iii) It was not CGK at the Priority Date that the two-part architecture involved any specific drawbacks beyond the general drawback that, when designing an inserter for a CGM system, it was always preferable for the insertion process to involve as few steps as practicable.

46. In describing the two-part architecture as "accepted" in paragraph 45.i), I am not concluding that the Skilled Team would have refused to countenance any possible deviation from that architecture at the Priority Date. Mr Varde spoke convincingly in his oral evidence about the motivation that the Skilled Team would have to make life better for people diagnosed with diabetes. That motivation meant that the Skilled Team would be receptive to suggestions for improvement to CGM systems. However, the two-part architecture was "accepted" in the sense that it was recognised to be the way things were done at the time, primarily for the reasons of cost that I have summarised in paragraph 45.ii). I did not detect any great dispute between the parties on that proposition.

47. Abbott invites me to go further than the findings set out in paragraph 45.ii) by concluding another reason for the two-part architecture being "accepted" was because moving to a one-part architecture would, as Abbott put it, "entail a significant, risky, redesign". I will not go as far as that. I accept the evidence that Mr Jennings gave in paragraph 3.7 of his Second Report, that if the Skilled Team at the Priority Date moved away from the two-part architecture, some redesign would be necessary. Moreover, additional difficulties would need to be overcome, for example those that Dr Schoemaker mentioned set out in paragraph 43.ii). I also accept Mr Jennings's evidence that undertaking such a redesign would carry risk and would require significant development. However, I am not satisfied

that issues associated with such a redesign would be technically difficult although it would be inconvenient and costly for the Skilled Team to address the issues raised by using a one-part architecture and the Skilled Team would need to monitor risk closely to ensure that the redesign did not have unwelcome consequences. In short, I have concluded that both Mr Jennings and Dr Schoemaker were referring to technical "issues" rather than significant technical "problems", I will not go as far as describing the issues identified as being, of themselves, a barrier in the way that the considerations of cost were.

48. Abbott also suggested in closing that safety considerations caused the two-part architecture to be "accepted". I do not accept that. Of course, two-part non-integrated systems were considered "safe" as they had obtained regulatory approval to be sold. However, I do not conclude from the expert evidence that, at the Priority Date, it was CGK that an integrated system would be "unsafe" although it would, of course, be necessary to persuade regulators that any particular integrated system met applicable safety requirements.

49. In its closing submissions, Abbott was critical of passages in Mr Varde's Third Report that identified the two-part architecture of the Existing CGM Systems as a disadvantage of them. Abbott submitted that that assertion was unsupported by any contemporaneous evidence that identified the two-part architecture as a disadvantage despite an apparent extensive search by Dexcom and its solicitors that extended to trying to track down complaints on the databases of the FDA and European regulators. I considered that criticism to be misplaced. Mr Varde was not identifying the disadvantage as an "overarching" problem with the accepted two-part architecture that was perceived as such at the Priority Date and so provided an impetus for moving away from that architecture. Rather, he was making the more measured point that, as a purely general proposition, the fewer steps a user had to take in relation to a CGM device, the better. Therefore, "two-part" systems, which required a user to connect electronics to the sensor, necessarily had a "disadvantage" consisting of a requirement that the user take an additional step with the consequential risk of user error that could result in damage to the sensor or the sensor not being located in the right place.

50. I conclude that this disadvantage would have been appreciated by the Skilled Team as part of the CGK at the Priority Date. However, the considerations of cost that I have mentioned in paragraph 45.ii) above would have led the Skilled Team to conclude that not much could be done about this disadvantage at the Priority Date.

THE PATENT

51. The Patent was granted by the European Patent Office on 29 June 2016 as EP 2 549 918 B1 ("B1"). It was amended following the initial application and I will deal with the amendments when considering Dexcom's "added matter" challenge later in this judgment. Dexcom brought opposition proceedings after B1 was granted. Those proceedings concluded with the Technical Board of Appeal (the "TBA") of the European Patent Office ("EPO") upholding the Patent, in its amended form.

52. The Patent discloses, and claims in its broadest claims, an apparatus for inserting medical devices of any kind into the skin of a subject. However, its focus is on the insertion of on-body glucose or analyte monitoring devices (see [0003] to [0005] of the Patent). Although the claims in the Patent relate to an apparatus for inserting a medical device into the skin of a subject, there is significant disclosure in the Patent that relates to the

nature of the medical device inserted. For example, some of the embodiments in the Patent refer specifically to in vivo analyte sensors and the interface between that sensor and the user by which information obtained through the sensor is shared with the user. It is common ground between both parties' experts that embodiments 200, 300, 400 and 2400 shown in the Patent are not covered by its claims.

53. Recognising that the claims of the Patent are perfectly capable of extending beyond particular embodiments, Embodiment 2700, shown in figures 91 to 108 and discussed at [0175] to [0187] gives a good example of the nature of the invention with figure 100 being reproduced below. Throughout the Patent, the terms "proximal" and "distal" are used in a slightly unusual sense with "proximal" tending to mean "away from the user's skin" and "distal" tending to mean "towards the user's skin". I adopt the same usage throughout this judgment.

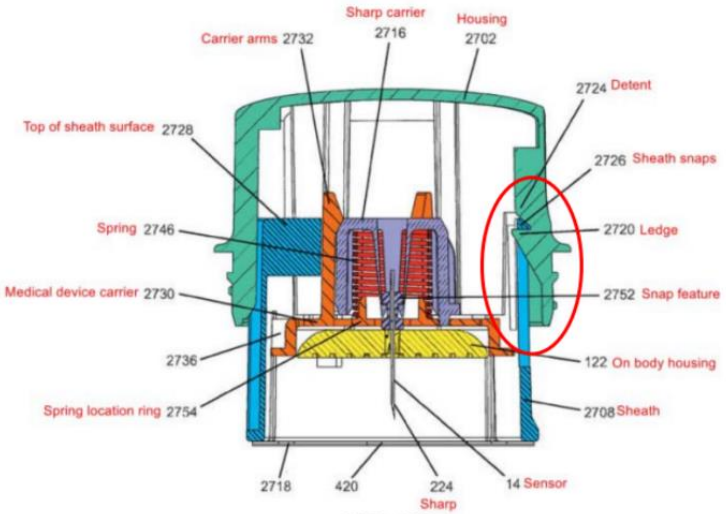


FIG. 100

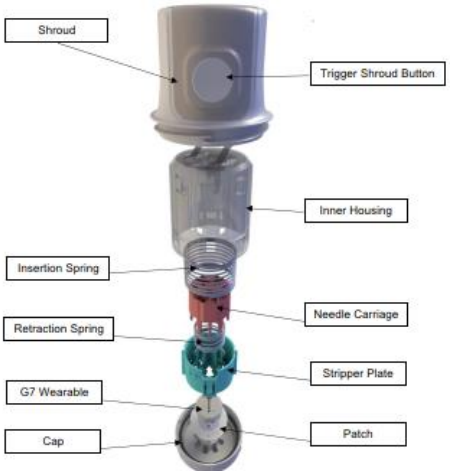
54. This embodiment shows an inserter that is to be placed against the skin and used to insert a sensor (14) into the user's skin. The handle (green) is initially kept axially distant from the top of a sheath (shown in blue as 2708). When the user presses the handle, the pushing motion is resisted by the sheath snap (2726). Only the application of a sufficient minimum force causes the sheath snap (2726) to ride upwards and advance past the angled surface of the detent (2724). The amount of that minimum force is determined by, among other variables, the angle of the detent. Once that sufficient minimum force has been applied, the medical device carrier and sharp are free to move from the proximal position to the distal position. Ultimately that results in the sharp inserting the sensor into the skin.

55. In the Appendix to this judgment, I set out Claims 1 and 7 of the Patent broken down, as is customary, to various "integers" that formed the battleground for the parties' arguments on construction and infringement. I remind myself that breaking down the claims of the Patent into integers in this way is simply a convenient way of structuring those claims and ordering discussion of the parties' arguments. Ultimately the claims of the Patent have to be construed as a whole and accordingly, by breaking those claims into integers, I do not signal that I am following a compartmentalised approach to their construction.

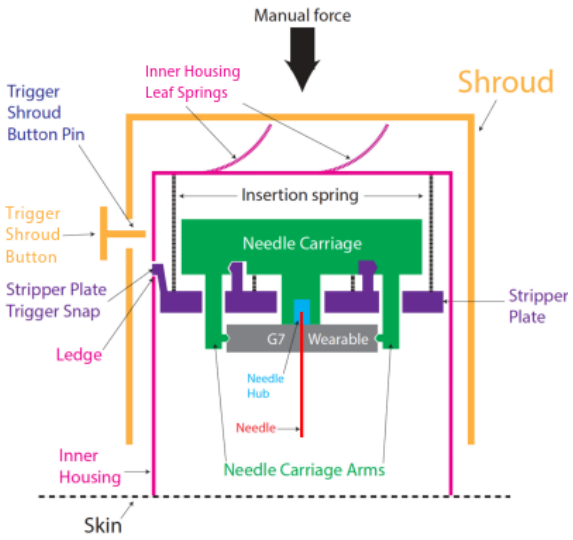
OPERATION OF THE G7 APPLICATOR

56. The operation of the G7 Applicator is set out in a Product and Process Description (the "PPD") that Dexcom prepared in lieu of disclosure. The factual accuracy of the PPD is not challenged.

57. An exploded diagram of the G7 Applicator showing some of the key components is reproduced below

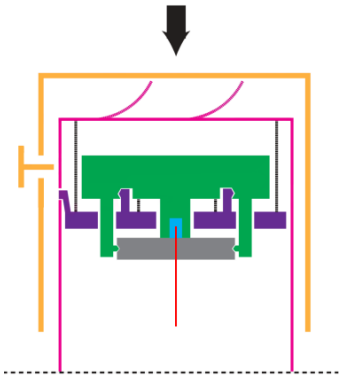


58. The operation of the G7 Applicator is appropriately explained by some schematics that Dexcom's legal team prepared which, subject to certain amendments, Abbott agreed set out a high level overview of the G7 Applicator's operation. I will use those schematics, but will bear well in mind that they set out an overview only and the detailed evidence as to the operation of the device is set out in the PPD. The following diagram shows a cross-section of the device together with some additional internal components.

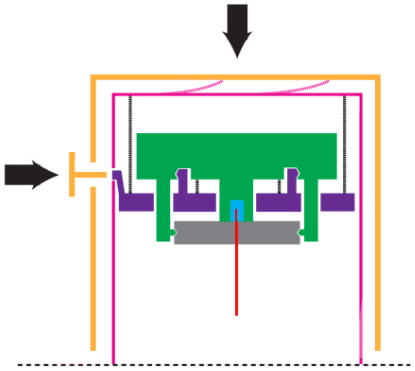


59. The G7 Applicator will not actuate unless and until the Trigger Shroud Button is depressed. The process leading up to the depression of that button, and the events that follow it are set out in the following diagrams showing the G7 Applicator at various positions.

60. In Position 1, the G7 Applicator has been placed in contact with the user's skin in the place where the sensor is to be inserted and surrounded by the G7 Wearable. The Leaf Springs attached to the top of the Inner Housing are keeping the Trigger Shroud Button in a position where pressing it has no effect. In Position 2, a downward force has been applied to the Shroud. This has moved the Shroud into the position where the Trigger Shroud Button Pin is lined up with the aperture in the Inner Housing that will enable it to contact the Stripper Plate Trigger Snap.

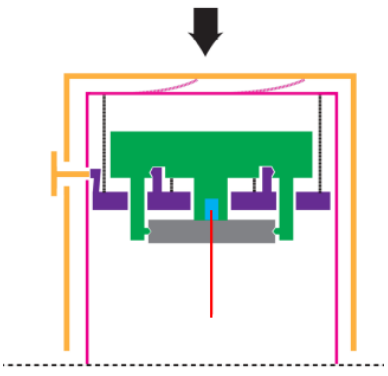


Position 1

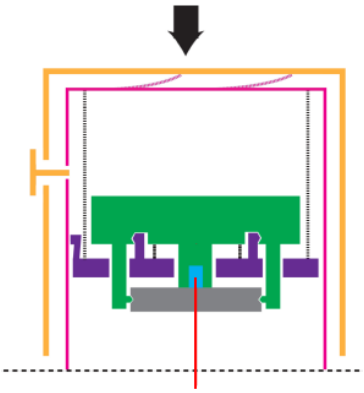


Position 2

61. At Position 3, the Trigger Shroud Button has been pressed inwards (at right angles to the direction in which the Shroud has moved). The Trigger Shroud Button Pin has pushed the Stripper Plate Trigger Snap off the Ledge of the Inner Housing. The Insertion Spring expands because there is nothing to stop it from doing so and the Needle Carriage is driven distally. Since the Stripper Plate is engaged to the Needle Carriage at the Stripper Plate Retraction Arms, the Needle Carriage, Needle and G7 Wearable all move distally. Position 4 shows the position where insertion has begun. The Insertion Spring has expanded and (perhaps together with the manual force that continues to be applied to the Shroud, a point I address further below) has forced the Stripper Plate (and with it, the Needle Carriage, Needle and G7 Wearable) towards the skin.

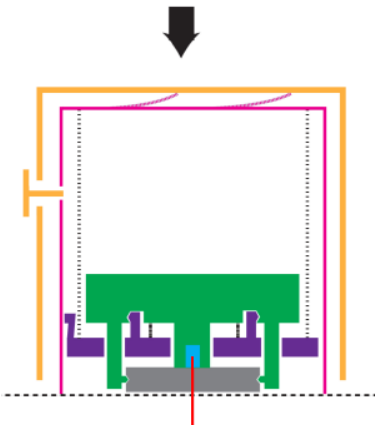


Position 3

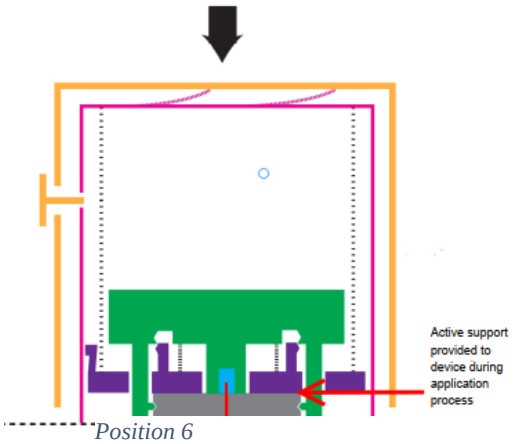


Position 4

62. At Position 5, the G7 Wearable has contacted the skin and can move no further but the Stripper Plate continues to move towards the skin. The continued movement of the Stripper Plate towards the skin causes the Needle Carriage and the Stripper Plate to disengage. At Position 6 the Stripper Plate has become disengaged from the Needle Carriage. There is now nothing stopping the Retraction Spring from expanding and so it expands.



Position 5

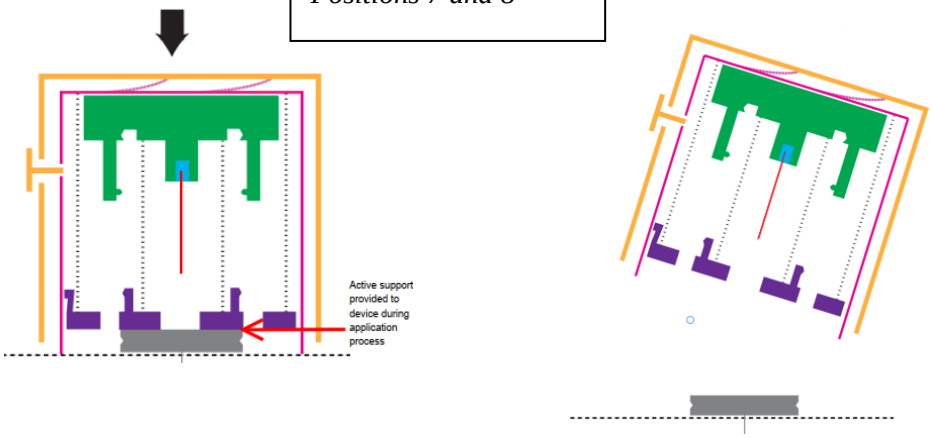


Position 6

63. Throughout Positions 1 to 5, the G7 Wearable has been held in position by a reaction force between the G7 Wearable and the arms of the Needle Carriage. However, this changes at Position 6. At this position, the Needle Carriage is starting to move upwards under the force of the Retraction Spring. Accordingly, at that point, the arms of the Needle Carriage exert a force on the G7 Wearable in the proximal direction. Against that, the G7 Wearable has an adhesive patch and so an adhesive force is exerted in the distal direction. In addition, the continued movement of the Stripper Plate towards the skin exerts a force on the G7 Wearable in the distal direction. The forces on the G7 Wearable that operate in the distal direction exceed those in the proximal direction and so the G7 Wearable remains in position on the skin. This is the "active support" that is shown in the diagram for Position 6.

64. At Position 7 the Retraction Spring has expanded moving the Needle Carriage away from the skin and withdrawing the needle, leaving the sensor under the skin. Position 8 shows the user removing the G7 Applicator from contact with the skin leaving the G7 Wearable in place.

Positions 7 and 8



65. It will be seen that all of the diagrams for Positions 1 to 7 have a downward arrow at the top that represents a force being applied downwards on the Shroud. This is deliberate. Even though the force that directly results in the Needle being inserted into the user's skin comes from the Insertion Spring (see paragraph 61 above), Mr Varde accepted in

cross-examination that the G7 Applicator will not function unless that downward force is applied to the Shroud, essentially to hold the device in contact with the skin.

CONSTRUCTION/INFRINGEMENT ISSUES

66. There is no significant dispute between the parties as to how the G7 Applicator works. Rather, the dispute on infringement concerns whether the G7 Applicator contains all integers of the claims of the Patent that are said to be infringed. It is unnecessary to get unduly caught up in the extent to which this is a dispute about construction (i.e. what the claims of the Patent mean) or a question of whether the features of the G7 Applicator answer to the various integers of the Patent's claims once those claims have been properly construed. As Jacob LJ said in *Technip France SA's Patent* [2004] RPC 46, in infringement proceedings it is sensible to identify the areas of dispute in relation to construction by reference to the alleged infringement:

> *Although it has often been said that the question of construction does not depend on the alleged infringement ('as if we had to construe it before the defendant was born' per Lord Esher MR in* Nobel v Anderson *(1894) 11 RPC 519 at 523), questions of construction seldom arise in the abstract. That is why in most sensible discussions of the meaning of language run on the general lines 'does it mean this, or that, or the other?' rather than the open-ended 'what does it mean?'*

67. With that approach in mind, the parties at my request helpfully prepared a "Construction Schedule" that set out their respective positions on questions of construction of the Patent, formulated by reference to relevant features of the G7 Applicator and the prior art. Determining those questions of construction is a necessary step in determining the question of infringement and also in the prior art based challenges. I will, therefore, determine the questions of construction set out in the Construction Schedule, by reference to the parties' labelling of those issues as Points A to J, although I will not necessarily deal with them in the order set out in the Construction Schedule.

The law on the construction of patent claims

68. As a general matter, the Court's task is to construe the claims objectively through the eyes of the skilled person and using their common general knowledge. I will apply the following principles applicable to the construction of claims in patents that were set out by the Court of Appeal in *Saab Seaeye Limited v Atlas Elektronik GmbH and another* [2017] EWCA Civ 2175:

> *18. There was no dispute about the principles which apply to the construction of patent claims. Both parties relied, as did the judge, on the summary in this court's judgment in* Virgin Atlantic v Premium Aircraft *[2010] RPC 8 at [5]:*
>
> > *"(i) The first overarching principle is that contained in Article 69 of the European Patent Convention.*
> >
> > *(ii) Article 69 says that the extent of protection is determined by the claims. It goes on to say that the description and drawings shall be used to interpret the claims. In short the claims are to be construed in context.*

> *(iii) It follows that the claims are to be construed purposively – the inventor's purpose being ascertained from the description and drawings.*
>
> *(iv) It further follows that the claims must not be construed as if they stood alone – the drawings and description only being used to resolve any ambiguity. Purpose is vital to the construction of claims.*
>
> *(v) When ascertaining the inventor's purpose, it must be remembered that he may have several purposes depending on the level of generality of his invention. Typically, for instance, an inventor may have one, generally more than one, specific embodiment as well as a generalised concept. But there is no presumption that the patentee necessarily intended the widest possible meaning consistent with his purpose be given to the words that he used: purpose and meaning are different.*
>
> *(vi) Thus purpose is not the be-all and end-all. One is still at the end of the day concerned with the meaning of the language used. Hence the other extreme of the Protocol – a mere guideline – is also ruled out by Article 69 itself. It is the terms of the claims which delineate the patentee's territory.*
>
> *(vii) It follows that if the patentee has included what is obviously a deliberate limitation in his claims, it must have a meaning. One cannot disregard obviously intentional elements.*
>
> *(viii) It also follows that where a patentee has used a word or phrase which, acontextually, might have a particular meaning (narrow or wide) it does not necessarily have that meaning in context.*
>
> *(ix) It further follows that there is no general 'doctrine of equivalents.'*
>
> *(x) On the other hand purposive construction can lead to the conclusion that a technically trivial or minor difference between an element of a claim and the corresponding element of the alleged infringement nonetheless falls within the meaning of the element when read purposively. This is not because there is a doctrine of equivalents: it is because that is the fair way to read the claim in context.*
>
> *(xi) Finally purposive construction leads one to eschew the kind of meticulous verbal analysis which lawyers are too often tempted by their training to indulge."*

Sub-paragraph (ix) must now be read in the light of the Supreme Court's judgment in Actavis v Lilly *[2017] UKSC 48, which explains that, at least when considering the scope of protection, there is now a second question, to be asked after the patent claim has been interpreted, which is designed to take account of equivalents….*

69. Since the question of "equivalents" does not arise given the way that Abbott puts its case, I say nothing further on that matter. I do not consider that any great amplification of these principles is necessary in order to determine the dispute that is before me. I therefore simply note that:

i) The Protocol to Article 69 of the European Patent Convention referred to in the quotation above requires that the extent of protection confirmed by a European patent is to be interpreted in a manner "which combines a fair protection for the patentee with a reasonable degree of certainty for third parties".

ii) Where a patentee has used general language in a claim, but has described the invention by reference to a specific embodiment, it is not normally legitimate to write limitations into the claim corresponding to details of the specific embodiment if the patentee has chosen not to do so. That would amount to rewriting the claims rather than construing them. (See [41] of the judgment of Floyd J (as he then was) in *Nokia v IPCom* [2009] EWHC 3842 (Pat).) That said, the colour taken from the specification of a patent can sometimes narrow the acontextual meaning which the claim would bear out when read alone (a process described by Lord Hoffmann in his speech in *Kirin Amgen and others v Hoescht* [2004] UKHL 46 as being analogous to a recognition that in particular contexts, "the City" can mean the City of London specifically).

iii) The construction of a patent claim is a matter solely for the Court. Expert evidence as to the meaning of language is not admissible except where a term is a "term of art". That said, expert evidence can shed some light on the meaning of a claim: for example expert evidence might establish that it is only if a particular construction of a claim is adopted, that general technical statements made in the body of the patent about what the invention achieves will hold good. That can serve as a guide as to the true construction of the claim (see [10] of the judgment of Floyd J, as he then was, in *Qualcomm v Nokia* [2008] EWHC 329).

The "purpose" of the Patent

70. Considerations of "purpose" feature prominently in the principles set out in *Saab* which I have set out in paragraph 68 above. Both Abbott and Dexcom submitted that some light could be shed on the various points of construction that are in dispute by having regard to the purpose of the invention disclosed in the Patent as a whole. Both parties placed at the heart of their submissions on overall purpose the requirement of Integer 1.6b for a minimum force to be applied to the handle to overcome a biased retention feature to allow distal movement of the handle relative to the sheath.

71. Abbott characterises the main aspect of Claims 1 and 7 of the Patent (as unamended) as to provide a design which produces a two-stage insertion process so that the user has to place the device on the skin where the sensor is to be inserted and push the handle towards the skin, initially to overcome a force which is in the direction away from the skin, before the device can be actuated at all. Actuation requires the user then to maintain a force on the handle to effect insertion after that initial force is overcome. Abbott therefore characterises the primary aspect of Claims 1 and 7 (as unamended) as being to provide protection against unintended actuation. Abbott supports that conclusion by references to the following extract from the decision of the TBA that discusses integer 1.6b:

> *This feature has the technical effect that, to enable actuation of the apparatus, a certain initial force applied by the biased retention feature has to be overcome…*
>
> *Providing a dedicated biased retention feature makes it possible to set the initial force to be overcome to enable actuation independently of the force needed for advancing the sharp support. Hence the distinguishing feature*

addresses the objective technical problem of better preventing unwanted actuation.

72. Dexcom articulates the purpose of the Patent's invention differently. It argues that the point of the invention of the Patent is to take the benefits of a "one spring" system whilst avoiding some of the problems which come with manual insertion, in particular not being able to control the amount of force applied by the user which leads to the "hesitant user problem". To achieve this, a predetermined resistance must be overcome as the handle is forced down towards the skin, taking the device and needle with it. That establishes a predetermined force to ensure that the user is firmly pushing the device into the skin.

73. Understandably, Abbott places some emphasis on the TBA's conclusions as to the overall purpose of the invention. However, quite rightly, Abbott does not suggest that the TBA's conclusion is binding on me. In *Human Genome Sciences v Eli Lilly* [2012] RPC 6, Lord Neuberger emphasised, at [83] to [85] of his judgment, the importance of UK patent law aligning itself, so far as possible with the jurisprudence of the EPO. However, he emphasised the statement of Lord Walker at [35] of his judgment in *Generics* [2009] R.P.C 13 to the effect that national courts may reach different conclusions as to the evaluation of the evidence in the light of relevant principles even though the principles themselves should be the same, stemming as they do from the European Patent Convention. Accordingly, the EPO and a national court may come to different conclusions because they have had different evidence or arguments or because they assess the same competing arguments and factual expert evidence differently.

74. I consider that the arguments that were before the TBA were materially different from those that are now before me. That can be seen from the fact that, at least in some respects, both parties were taking positions that were the diametric opposite of those that they now take. Before the TBA, Dexcom was arguing that the term "biased retention feature" should be interpreted broadly to cover any biased feature that has a retaining function. Dexcom argues for a more restricted interpretation of the term "biased retention feature" in the present proceedings. Dexcom's contrary position in proceedings before the TBA is explained by the fact that those proceedings concerned the validity of the Patent and it was in Dexcom's interest to advance a broad construction of the Patent to increase the risk to the Patent posed by the prior art. In a similar vein, Abbott argued before the TBA that the shuttle in Raymond that moved under the force of an insertion spring was not within the scope of the claims in the Patent since anything that moved under the force of an insertion spring was not being moved by means of a force applied to the handle for the purposes of Integer 1.7 of Claim 1. That argument, which is the opposite of the argument that Abbott is advancing in the present proceedings, was explicable by the fact that, in proceedings before the TBA concerning validity, it was in Abbott's interest as patentee to argue for a narrow scope of the claims so as to avoid the prior art.

75. In those circumstances, since the TBA's conclusion was not as to the correct application of any aspect of EPO jurisprudence, but rather was a factual or evaluative conclusion, I consider it to be of relatively little assistance in determining whether the invention in the Patent has any overall purpose. Abbott argues that, before the TBA, both parties were agreed as to the Patent's overall purpose, but I consider that to be of little significance as well. Even if the parties were agreed, the dynamic that I have outlined in paragraph 74 above demonstrates that it can suit parties to take positions in validity proceedings that are completely different from those taken in infringement proceedings. Accordingly, even if the parties happened to be aligned on considerations of overall purpose before the TBA, that does not compel the conclusion that the purpose on which they were agreed in those proceedings is correct for the purposes of the proceedings before me.

76. For my part, I see relatively little to be gained from a high-level analysis of the "overall purpose" of the invention disclosed in the Patent. That is simply because, in my judgment, the invention has multiple purposes. It certainly results in safeguards against unintended actuation. However, it also has the benefit that Dexcom emphasises of overcoming the "hesitant user problem". I therefore regard Abbott's formulation of the overall purpose of the Patent as being at best incomplete since it gives insufficient prominence to the purpose of dealing with the "hesitant user problem".

77. If it were necessary (which I do not consider it is) to choose between the competing formulations of overall purpose, I would prefer that advanced by Dexcom for the essential reason that both Mr Varde and Mr Jennings seemed to be largely agreed on that formulation. In cross-examination, Mr Jennings expressed agreement with Mr Varde's opinion that the point of the invention was to get over the hesitant user problem. Mr Jennings provided his own neat summary of what he saw as the point of the invention:

> *The way I always look at it, is actually what it is doing is making a manual insertion device into an automatic insertion device because the user has to push down on the top. They have to overcome the minimum force at which point you have wound up the spring in the arm and you are going to push that into the skin…. What they have done in this one, they have made an automatic device but with the user applying the insertion forces rather than adding a separate spring*

The meaning of "biased retention feature" and the concept of "overcoming" that biased retention feature to allow distal movement of the handle relative to the sheath

The parties' respective positions in overview

78. These questions of construction were Points G and H in the Construction Table. The relevant concepts appear in Integers 1.6a and 1.6b of Claim 1 as follows (ignoring for present purposes numerical references to particular embodiments):

    i) Integer 1.6a requires that the "sheath … has at least one biased retention feature".

    ii) Integer 1.6b is oddly worded but, as it appears in the Patent, requires that "advancing the handle… from the proximal position to the distal position comprises applying a minimum force to the handle overcome the at least one biased retention feature to allow distal movement of the handle relative to the sheath".

79. The debate on the meaning of "biased retention feature" is illustrated by reference to the Leaf Springs in the G7 Applicator. Mr Varde explained that a mechanical engineer would consider a component to be "biased" if it is placed in its natural resting position but may be moved or flexed into an unnatural position, thereby applying a force as it seeks to return back to its natural position. The Leaf Springs appear in the G7 Applicator in their natural (uncompressed) state. Pressing down on the Shroud involves the Leaf Springs being compressed and exerting a force that resists compression. It is common ground that this is a "biased" feature. However, the parties do not agree as to whether the Leaf Springs are a "biased retention feature".

80. The parties' respective positions on the concept of "retention feature" are as follows:

    i) Abbott's position is that the Leaf Springs are a retention feature as they retain the spatial relationship between the Shroud and the Inner Housing until they are "overcome" by a force.

ii) Dexcom's position, by contrast, is that a component or components constitute a "retention feature" only if they secure elements together or prevent one thing from falling out of another. A "biased retention feature" must, therefore, "retain" the sheath by securing it in the handle. Since the Leaf Springs only maintain, temporarily, the relative positions of the Shroud and the Inner Housing and do not secure the Inner Housing within the device, they do not constitute a "retention feature".

81. The parties' positions on the question of "overcoming" are as follows:

i) Abbott argues that the biased retention feature is "overcome" when a certain initial force is provided by the user to enable actuation. The requirement is satisfied in relation to the G7 Applicator since, in order to actuate the device, a user must push down on the Leaf Springs and compress them so that the Trigger Shroud Button Pin lines up with the Stripper Plate Trigger Snap. That action, Abbott submits, satisfies the "overcoming" requirement of Integer 1.7.

ii) Dexcom argues that Abbott's interpretation, which focuses on the word "overcome" overlooks important components of Integer 1.7. There can only be an "overcoming" of a biased retention feature if a threshold minimum force has to be applied to the handle which results in the retention feature ceasing to provide resistance against distal movement of the handle so that only after that threshold minimum force is applied is there any meaningful distal movement of the handle relative to the sheath. On that interpretation, Dexcom argues that Integer 1.7 is not present in the G7 Applicator.

Conclusion on Points G and H

82. It is common ground that the concept of a "retention feature" or a "biased retention feature" is not a term of art.

83. Abbott does not dispute Dexcom's closing submission to the effect that the only time the description of the Patent uses the term "retention feature" is in reference to the 3700 embodiment. In that context, [0193] of the Patent describes aspects of embodiment 3700 as follows:

> *The sheath 3708 is secured to the housing 3702 via retention features 3726, which can be configured, e.g., as a snap.*

84. Figure 126 illustrates the components referred to in this description. The "retention features 3726" are shown as snap features that secure the sheath temporarily to the housing in such a way that, only if the handle is depressed with a certain minimum force, will the snap feature be decoupled from a detent in the housing.

85. Other instances where the word "retention" is used in the Patent are as follows:

i) At [0125] of the Patent in a discussion of Figure 30, the Patent describes how "retention portions" prevent the carriage from falling out of the inserter.

ii) At [0164] of the Patent, there is a description of a "retention member" that prevents an item of on-body housing from falling out of the inserter.

86. These uses of the word "retention" within the Patent support Dexcom's position namely that a "biased retention feature" must secure two components together (albeit in a way

that can be "overcome") and not merely maintain temporarily the relative position of two components. Significantly, given the requirement to construe the Patent through the eyes of the Skilled Team, that was also Mr Jennings's initial reaction to the phrase "biased retention member". Up to the point at which the parties exchanged skeleton arguments, Mr Jennings said in paragraph 8.11(a) of his First Report that:

> *[the biased retention feature] maintains the relationship between the sheath and the handle… This prevents the sheath from coming out of the insertion device, and protects the medical device and protects the user from potential needlestick injury.*

87. Mr Jennings expressed that view from a review of the Patent that he performed before he considered specific features of the G7 Applicator. That is a common approach for experts to take so as to reduce the risk of another party to the litigation asserting that their response to the words used in the patent have been unduly affected by their knowledge of the allegedly infringing product. Mr Jennings's initial response to the Patent was, accordingly, of some significance given that it was expressed without a detailed knowledge of the G7 Applicator.

88. In its opening skeleton argument served on 5 July 2023, Dexcom placed some emphasis on the extract from Mr Jennings's expert report that I have quoted. On 7 July 2023, Abbott's solicitors wrote to Dexcom's solicitors to explain that Mr Jennings wished to correct paragraph 8.11(a) so as to read:

> *[the biased retention feature] maintains the relationship between the sheath and the handle… In addition, it may also prevent the sheath from coming out of the insertion device and protect the medical device and protect the user from potential needlestick injury.*

89. The difference in emphasis is clear. I will not find that Mr Jennings has improperly changed his opinion so as to fit better with the case that Abbott is advancing. However, I do consider that the understanding that he expressed without knowledge of either the G7 Applicator or the parties' respective positions on infringement is of greater weight than the opinion he expressed subsequently.

90. Abbott correctly observes that as a matter of construction, the scope of the claims of the Patent is not limited to any particular embodiment. However, I do not understand Dexcom to be arguing otherwise: its position is simply that the way the concept of "retention" is used throughout the Patent supports its interpretation of the meaning of a "biased retention feature".

91. I also consider that the meaning of the term "biased retention feature" is informed by an analysis of what is necessary for that feature to be "overcome": the debate between the parties that is summarised in paragraph 81 above.

92. I agree with Dexcom that Integer 1.6b of Claim 1 requires that the application of a minimum force to the handle must overcome the biased retention feature itself so as to allow distal movement of the handle relative to the sheath. Abbott's interpretation is that the biased retention feature is "overcome" when it no longer maintains the spatial relationship between the handle and the sheath in its original position so that the device is in an "actuation-ready" state. However, that interpretation overlooks the centrality of the requirement for the application of a minimum force to allow distal movement of the handle relative to the sheath. On Abbott's interpretation, and using G7 Applicator as an example, the biased retention feature has been "overcome" when the Leaf Springs have

been sufficiently depressed to put the device into an actuation-ready state. However, there is a contradiction in that interpretation. Once the G7 Applicator has been put into that actuation ready state, there is no further distal movement of the Shroud (handle) relative to the Inner Housing (sheath). As Dexcom correctly points out, this is the opposite of what Integer 1.6b requires namely that the distal movement is made possible by the "overcoming".

93. I have also considered an alternative formulation of the argument set out in paragraph 92 above, namely whether the biased retention feature in the G7 Applicator could be said to be "overcome" at some point between the initial compression of the Leaf Springs and the Shroud moving to a point at which the Trigger Shroud Button can be depressed. However, I agree with Dexcom that this interpretation would be inconsistent both with the concept of "overcoming" and with the requirement that the "overcoming" results from the application of a "minimum force" to the handle. At no point prior to full compression of the Leaf Springs, can it be said that the biased retention feature has been "overcome" to allow distal movement of the handle relative to the sheath since (i) the handle is already moving relative to the sheath at that point and (ii) there is still to be further distal movement of the handle relative to the sheath. Moreover, such an interpretation would give no sensible meaning to the concept of the "minimum force" since, at any point before the Leaf Springs are fully compressed, the user needs to supply more force to achieve further compression. I agree with Dexcom that, read purposively, the "minimum force" referred to in Integer 1.6b must be some predetermined force ([0194] of the Patent suggests that it may range from about 0.5 lbf to about 5 lbf) and not some minimal force below which nothing happens at all.

94. Abbott's principal arguments in support of its interpretation of "biased retention feature" and the "overcoming" issue are rooted in its arguments about the overall purpose of the invention in the Patent as being to prevent unintended actuation. Essentially, it argues that a biased feature that retains the spatial relationship between sheath and handle which can only be "overcome" by the application of sufficient force to put the device in an actuation-ready state, serves the purpose of preventing unintended actuation. Accordingly, it argues that such a feature constitutes a "biased retention feature" construed purposively. However, in my judgment, that argument pays insufficient attention to the way that the word "retention" is used in the Patent. It also pays insufficient attention to the true extent of the "overcoming" requirement set out in paragraph 92. It also relies on an assertion of the overall purpose of the Patent that I consider to be at best incomplete (see paragraph 76 above).

95. In conclusion, I prefer the construction that Dexcom advances on both Point G and Point H and the consequential conclusion that neither Integer 1.6a nor Integer 1.6b is present in the G7 Applicator. I will not seek to delineate the precise scope of the term "biased retention feature" any further than necessary to determine the points of construction that are in dispute between the parties. However, it does not follow from my conclusion that a "biased retention feature" can only comprise the kind of snap and detent feature that is set out in embodiment 3700.

The handle and the force applied to it – Points E, I and J

The positions of the parties

96. These questions of construction arise in the following contexts:

i) Integer 1.4 requires that the apparatus of Claim 1 must have a "handle". That handle must be "movable between a proximal position and a distal position relative to the sheath".

ii) Integer 1.4 also requires that the handle must be "adapted to urge the device support and the sharp support from the proximal position to the distal position to insert the sharp under the skin surface".

iii) Integer 1.7 requires that "a force applied to the handle moves the sheath into the handle and moves the medical device from the proximal position to the distal position and inserts the sharp under the skin surface".

97. Abbott argues that these requirements are met in relation to the G7 Applicator because:

i) The Shroud is the "handle" and the Trigger Shroud Button, being an integral part of the Shroud, is also part of the "handle". The Shroud is movable from a proximal to a distal position relative to the Inner Housing which serves as the "sheath".

ii) The Shroud is "adapted to urge" the device support (whose identity is considered below) and the "sharp support" (the Needle Carriage). That is because these components are not able to move distally until a force is applied by the user onto the top of the Shroud. Only once the necessary force has been applied can the user press the Trigger Shroud Button, thereby, releasing the Insertion Spring that moves the medical device from the proximal to the distal position. Abbott acknowledges that the "urging" which results from pressing the Shroud is indirect rather than direct. However, it argues that nothing in Integer 1.4 requires the "urging" to be direct. In any event, as noted in paragraph 65 above, the maintenance of a user force on the Shroud is an integral part of the insertion process.

iii) Integer 1.7 is satisfied if a force applied to the handle moves the sheath into the handle and a force (not necessarily the same) is maintained so as to allow subsequent movement of the medical device and insert the sharp. That is the case with the G7 Applicator. The force that the user applies to the Shroud moves the Inner Housing (the sheath) into the Shroud (the handle). Application of that force enables the user to push the Trigger Shroud Button which releases the Insertion Spring which, together with a continued user force that is applied to the Shroud, enables the medical device to move from the proximal position to the distal position and the Needle to be inserted under the skin surface of the user.

98. Dexcom's position is as follows:

i) Integer 1.7 requires that the force that moves the sheath into the handle must be the same as the force that moves the medical device from the proximal to the distal position and inserts the sharp under the user's skin. It follows that Integer 1.7 is not present if, as with the G7 Applicator, the handle is compressed manually, but the medical device moves distally under the force applied by a spring.

ii) Integer 1.4 requires that the handle must be able to push or force the device support and sharp support from the proximal to the distal position in which the sharp is under the skin.

iii) While Dexcom accepts that the Shroud is able to move a short distance relative to the Inner Housing, it does so only as part of a "safety catch" mechanism to

prevent the Trigger Shroud Button from being pressed before the user is ready. Once the initial movement of the Shroud has taken place (by Position 2 set out in the diagram in paragraph 60 above) no further movement of the Shroud occurs.

iv) It follows that the movement of the Shroud is unconnected, both literally and conceptually, to the movement of the Stripper Plate or Needle Carriage. It is the force generated by the Insertion Spring (and not any force applied to the Shroud) that causes the Stripper Plate and Needle Carriage to move distally. Moreover, while those components are moving distally and while the Needle is being inserted, the Shroud and the Inner Housing remain stationary both in absolute and relative terms. In those circumstances, the Shroud provides no "urging" of those components towards the distal position and Integer 1.4 is not present either.

Conclusion

99. There is a strong linguistic indication in Integer 1.7 that it is the same force which both (i) moves the sheath into the handle and (ii) moves the medical device from the proximal position to the distal position. Abbott's counter argument, that it is sufficient for a force applied to the handle to be "maintained" so as to allow subsequent movement of the medical device or that a force applied to the handle is "required" for movement of the medical device involves, in my judgment, placing a gloss on the ordinary meaning of the words that are used.

100. The natural meaning of Integer 1.7 that I have set out in paragraph 99 is reinforced by Integer 1.4. That specifies a key feature of the handle, namely that it is movable from a proximal to a distal position relative to the sheath. It also requires that the handle must be "adapted to urge" the device support and the sharp support from the proximal position to the distal position. In my judgment, and in agreement with Dexcom, the combination of Integers 1.4 and 1.7 describe a device which has a handle that starts in a proximal position. When the user applies a force to that handle, the handle moves distally. By its movement from its proximal to its distal position, the moving handle urges the device support and sharp support from proximal to distal positions moving the medical device towards the skin, whilst the sheath moves into the handle, and inserting the sharp.

101. Abbott argues that its contrary interpretation (summarised in paragraph 97.iii)) is supported by considerations of the invention set out in the Patent namely an inserter with protection against unintended actuation. However, I consider that to be a weak guide to the interpretation of Integer 1.7. First, Dexcom's interpretation of Integer 1.7 also results in an invention that guards against unintended actuation. Second, I consider Abbott's articulation of "overall purpose" to be at best incomplete for the reasons I have given in 76. Finally, I do not consider that general assertions of overall purpose can alter the clear meaning of the words used.

102. Abbott has referred to [0091] of the Patent. That mentions the possibility that "a driver may be provided for advancing the sharp and/or the analyte sensor/support structure towards the skin of the patient". However, while of relevance to the construction of the claims of the Patent, I consider that it provides a relatively weak indication of meaning. [0091] starts with statements about inserters generally. I regard these statements as general scene-setting which may simply be describing matters known in the prior art without linking the "driver" that is mentioned to any of the embodiments of the invention. It is only after the "driver" is mentioned that [0091] embarks on a discussion of particular embodiments. In any event, Mr Varde and Mr Jennings are agreed that some of the embodiments described in the Patent are not covered by the specific claims. Accordingly,

the fact that a "driver" is mentioned in [0091] has in my judgment relatively little to say about the correct construction of Integers 1.4 and 1.7.

103. The features set out in paragraph 100 are absent from the G7 Applicator. Crucially, the Needle Carriage and the Stripper Plate (which, on Abbott's interpretation functions as a "device support") only move distally once the Trigger Shroud Button has been depressed and the Insertion Spring released. While these components are moving distally, the Shroud and the Inner Housing (the "handle" and "sheath" respectively) remain completely stationary both in absolute and relative terms. In its opening submissions, there was a suggestion that Abbott attached significance to the averred fact that a user of the G7 Applicator needs to continue to apply a force to the Trigger Shroud during actuation so as to counteract a recoil force generated when the Insertion Spring expands. However, the point was not pursued in Abbott's closing submissions, no doubt because, in cross-examination, Mr Varde accepted that he was in no position to provide an opinion on the magnitude of the recoil force generated.

104. I prefer Dexcom's interpretation of Points E, I and J of the Construction Schedule and conclude that Integers 1.4 and 1.7 are not present in the G7 Applicator.

"Sheath" points – Points B and F

The respective positions of the parties

105. These points concern the characteristics of the "sheath" that features in a number of the integers of Claim 1. They also concern the nature of the relationship between the "sheath" and the "biased retention feature" that is set out in the requirement of Integer 1.6a to the effect that the "sheath… has at least one biased retention feature".

106. Abbott's position on these issues is as follows:

    i) The "sheath" is the single physical component that defines the distal surface referred to in Integer 1.1. The entirety of that component, and not part only of it, constitutes the "sheath". Accordingly, the entirety of the Inner Housing of the G7 Applicator is a "sheath".

    ii) The requirement of Integer 1.6a that the sheath "has" a biased retention feature requires only that at least one such feature is part of the same physical component that is the sheath. In the context of the G7 Applicator, the sheath is the Inner Housing. The Leaf Springs are affixed to the top of the Inner Housing and so are a "biased retention feature" of the sheath.

107. Dexcom's contrary position is as follows:

    i) The "sheath defining a distal surface" describes the element of a device which closely surrounds the working parts and serves to define a surface placed on the skin. Accordingly, the cylindrical walls of the Inner Housing of the G7 Applicator answer to the definition of a "sheath". However, the top part of the Inner Housing, even though it is not a separate removable cap, is not capable of forming part of the "sheath" for the purposes of any of the claim integers as it plays no part in defining the distal surface.

    ii) In order for a sheath to "have" at least one biased retention feature for the purposes of Integer 1.6a, the biased retention feature must fairly be regarded as a feature of the sheath. That does not require the biased retention feature to form part of the

> same unitary component as the sheath just as a lace is a feature of a shoe even though it is physically distinct from the leather upper and sole.

Conclusion

108. On Point B, I prefer Abbott's interpretation of the term "sheath". Once a component is identified that defines a distal surface for placement of the apparatus on a user's skin, that answers to the definition of a "sheath". The Patent does not suggest that part only of a unitary component is capable of constituting a "sheath". Still less does it specify which part of a "sheath -like" unitary component constitutes a "sheath" and which part does not. It is significant that the figures in the Patent relating to particular embodiments label the whole of a component as a "sheath" and not part only (see, for example Figures 115 and 116).

109. I agree with Dexcom that in the 2700 and 3700 embodiments, figures representing the sheath (Figures 94, 95, 115 and 116) depict the sheath as cylindrical and open at both the proximal and distal ends. At [0117] of the Patent, a sheath is described as having an "annular configuration" which is also consistent with a sheath that is open at both the proximal and distal ends. However, [0179] and [0194] of the Patent on which Dexcom also relies are more nuanced. Those paragraphs describe the sheath as being "generally cylindrical" and "generally formed as a unitary tubular member". While perhaps a "tube" might generally be understood as a component that is open at both ends, it seems to me that a "cylinder" is capable of being open or closed at either end.

110. Dexcom counters that the "sheath" is defined by its function (namely to define a distal surface for placement on the skin and to guide components from their proximal to distal positions). It argues that the "walls" of the component in question fulfil that function, but the top of the component, whether it takes the form of a removable cap or not does not fulfil the function and so is not part of the "sheath". However, there are two fundamental difficulties with this argument. First, the Patent contains no mechanism to determine which part of a single unitary component is a "sheath" and which part is not. Second, Dexcom's formulation of the function of the sheath being to "guide components" represents a gloss on the claims of the Patent. Integer 1.1 of the Patent simply refers to the need for the sheath to define a distal surface. Certainly the base of the sheath does that, but if Dexcom's argument is correct it is not clear why the entirety of the side walls of the sheath do. If Dexcom's interpretation is correct, a reader of the Patent would be left uncertain as to which part of the side walls (for example the bottom half or the bottom third) form part of the sheath and which do not.

111. I also prefer Abbott's interpretation on Point F of the Construction Schedule set out in paragraph 106.ii) above. I see little support for Dexcom's interpretation of the requirement of the sheath to "have" a biased retention feature and its interpretation strikes me as introducing uncertainty since different readers of the Patent may have different perceptions as to what can "fairly be regarded" as a feature of the sheath. I am reassured to note that the TBA also preferred Abbott's interpretation, saying in their decision that:

> *As the Opposition Division correctly noted in the impugned decision, the expression "the sheath has" in claims 1 and 8 of the main request implies that the biased retention feature is a part of the sheath. This is the normal technical meaning of such an expression, and is in accordance with the detailed description of the embodiments of the invention in the patent.*

112. I also consider that Abbott's interpretation is more consistent with my conclusion on Point G. I have concluded that, to be a "biased retention feature", a feature must secure

the sheath within the handle until it is "overcome" by the application of a minimum force. That is consistent with the biased retention feature being a part of the same component as the sheath.

113. I therefore prefer Abbott's interpretation on Points B and F.

"Device support" points – Points C and D

The parties' positions

114. These points involve the question of the characteristics that the "device support" and "second engagement member" mentioned in Integer 1.2 and 1.6 must have. Also at issue is what it means for the sharp to be extending through a portion of the device support as required by Integer 1.3.

115. Abbott's position on these issues is as follows:

i) The purpose of the "device support" is to support the medical device during the insertion/application process. Integer 1.2 can be satisfied if different components function as "device supports" at different times.

ii) The G7 Wearable (the medical device) is supported by different components at different times for the purposes of Integer 1.2. At Positions 1 to 5 described in paragraphs 60 to 62 above, the G7 Wearable is supported by the arms of the Needle Carriage which function as the "device support".

iii) At Position 6, the lower surface of the Stripper Plate takes over the function of device support because at that point the Stripper Plate "supports" the G7 Wearable by applying a force to it so as to prevent it from losing contact with the skin (see paragraph 63 above).

iv) The Needle (the sharp) extends through a portion of the Stripper Plate (the device support) because, among other reasons, the Needle extends into the Needle Carriage (so that the Needle has sufficient rigidity to penetrate the skin).

116. Dexcom's contrary position is as follows:

i) A component only satisfies the definition of a "device support" if it supports the medical device as it moves from the proximal to the distal position. Accordingly, the Stripper Plate does not answer to the definition of "device support" as it simply imposes a force on the medical device after it is inserted into the skin. Moreover, the Stripper Plate does not have a "second engagement member… for engaging the medical device". The only "members" that engage the medical device (the G7 Wearable) are the arms to be found on the Needle Carriage.

ii) The sharp is what extends from the sharp support and is inserted into the skin. In order to meet the requirement of Integer 1.3, the sharp must extend right through some part of the device support. A temporary overlap between the sharp and the device support only at a point during insertion or retraction is insufficient. Moreover, the requirement of Integer 1.3 is not satisfied by reference to a portion of the Needle that extends "backwards" into the Needle Carriage (i.e. away from the skin).

Conclusion

117. I can take these points briefly since, given my conclusions on the other points of construction at issue, I have already determined that the G7 Applicator does not infringe Claim 1 or Claim 7 of the Patent. Moreover, these points of construction have no implications for Dexcom's challenges to validity based on the prior art.

118. Dexcom is correct to emphasise that the "device support" of Claim 1 has the following characteristics:

    i) It is "movable between a proximal and a distal position" (Integer 1.2).

    ii) It is "adapted to support a medical device" (Integer 1.2).

    iii) It includes a "first engagement member for releasably coupling the device support to the sharp support" (Integer 1.6).

    iv) It includes a "second engagement member for engaging the medical device" (Integer 1.6).

119. The whole focus of these references is on the role of the "device support" throughout its movement from the proximal to the distal position. Throughout that movement, the device support is "supporting" the medical device (see paragraphs 118.i) to 118.iii)). However, at the end of the movement, once the device support has become decoupled from the sharp support, the function of the device support changes with the second engagement member that is included within the device support, playing a role in "engaging" the medical device. Abbott's construction does not pay sufficient regard to the need for the device support to fulfil its various roles over a continuum of time. It impermissibly focuses on the end of the insertion process and, by means of an unduly literal interpretation of the claim seeks to derive the conclusion that the under part of the Stripper Plate plays that role for a brief moment in time.

120. I therefore prefer Dexcom's interpretation of Point C. I will not address Point D because it proceeds from the assumption (which I concluded to be incorrect) that the Stripper Plate, or part of it, is capable of functioning as a "device support".

Conclusion on infringement issues

121. The Construction Schedule also included, as Point A, a question as to whether Claim 1 of the Patent is limited to a device that effects manual insertion of the sharp into the skin (as distinct from a device like the G7 Applicator which involves the sharp being propelled distally by the force of a spring). However, both parties were agreed that Claim 1 is not limited to a device that effects a purely manual insertion. Their points of difference related to the role of the force applied to the handle in moving it, together with the medical device and sharp, distally. Those points have already been addressed in the construction issues set out above and, accordingly, I do not consider that Point A requires separate determination.

122. My conclusion on the question of infringement is that the G7 Applicator does not infringe Claim 1 or Claim 7 of the Patent as those claims are properly construed. It was common ground that the Conditional Amendments gave rise to no different or additional questions relevant to infringement and so the G7 Applicator does not infringe the Claim 1 or Claim 7 as conditionally amended either.

Point K

123. I address Point K on the Construction Schedule last of all because it does not raise an issue of construction that has any bearing on the question of infringement. Rather it arises as a consequence of Dexcom's objection to CA1. By CA1, Abbott seeks to replace the various references in Claim 1 and Claim 7 to a "medical device" with references to "an integrated in vivo analyte sensor on-body electronics assembly".

124. Dexcom's objection is based on the proposition that, as a matter of pure construction, if Claim 1 or Claim 7 are invalid, whether for insufficiency, anticipation, or obviousness, CA1 cannot alter the position and so should be refused for that reason. Dexcom's argument proceeds by reference to the following chain of reasoning:

    i) The claims of the Patent as unamended relate to an apparatus "for" inserting a medical device (Claim 1) or an analyte sensor (Claim 7).

    ii) In general, the word "for" when used in a claim for an apparatus is to be construed as meaning "suitable for".

    iii) Integer 1 of CA1 claims an apparatus "for" (i.e. "suitable for") inserting an integrated in vivo analyte sensor on-body electronics assembly. However, that fell within the scope of unamended Claim 1 and Claim 7 since an apparatus suitable for inserting a medical device or an analyte sensor would be just as suitable for inserting an integrated in vivo analyte sensor.

    iv) Therefore, if Claim 1 or Claim 7 is invalid, so would the claims of the Patent as amended by CA1.

125. While I agree that the word "for" is often construed in an apparatus claim as meaning "suitable for" (see for example *Coflexip v Stolt* [2000] EWCA Civ 242 at [24] to [27]), this is not an invariable rule of construction. As Birss LJ said at [19] of *Optis Cellular Technology LLC and others v Apple Retail UK Limited and others* [2023] EWCA Civ 758:

> Coflexip *is illustrative but cannot be taken too far. That is because in the end the issue is always and only a matter for the true construction of the patent in question.*

126. Reading Claim 1, as conditionally amended, as a whole makes clear that what is claimed is not just an apparatus that is "suitable for" inserting an integrated in vivo analyte sensor, but an apparatus that actually inserts such a device. Integer 1 is not the only element of the claim. Integer 1.2 requires that the apparatus must contain a device support that is adapted to support an integrated in vivo analyte sensor. If the apparatus does not actually contain such a sensor, Integer 1.2 is not present. The same point can be made of Integers 1.3, 1.6 and 1.7.

127. Dexcom submits that the integers I have referred to can appropriately be read as referring to an integrated in vivo analyte sensor if one is present in the apparatus. However, I regard that interpretation as being at odds with any natural reading of the words used. For example, if a device contains no integrated in vivo analyte sensor, it is not clear how it could be tested against Integer 1.7 (as conditionally amended) which asks about movement of the integrated in vivo analyte sensor. Moreover, the Patent itself contains a good quantity of disclosure extending beyond the inserter to the nature of the device to be inserted. Some embodiments specifically envisage that the device to be inserted is an

integrated assembly (see, for example, Figure 122). Given this linkage, read in context, CA1 should not be read as referring only to an integrated assembly if present. I am reinforced in that conclusion by the evidence of Mr Varde to the effect that the Skilled Team would realise that CGM inserters tend to be designed to insert specific CGM devices and so the prospects of some of the claimed invention sometimes containing an integrated in vivo analyte sensor and sometimes not are slender.

128. I accept that, in different contexts, it might well be appropriate to read a claim for an apparatus "for" a particular purpose as referring to an apparatus that is "suitable for" that purpose. Such an interpretation can have the desirable effect of rendering unnecessary any examination of a person's subjective purpose in making or selling an allegedly infringing device. However, in my judgment, a rejection of Dexcom's interpretation on Point K does not open the door to any questions of subjective intention when deciding whether an apparatus falls within the conditionally amended claim. I reject the construction of CA1 that Dexcom advances.

INVALIDITY BY VIRTUE OF "ADDED MATTER"

129. Unlike Dexcom's other challenges to the validity of the patent based on insufficiency and anticipation/obviousness in the light of the prior art, Dexcom pursues its "added matter" challenge as a free-standing challenge to the validity of the Patent rather than as a squeeze argument. Dexcom's argument is that the Patent should be revoked under s72(1)(d) because matter was added after the application for the Patent was filed in relation to the "biased retention feature". In essence, Dexcom's argument is that, in its application for the Patent, the invention disclosed involved the use of a "biased retention feature" (although it was not described in that way in the application) that interacted with a detent in the housing. However, subsequently, Claim 1 of the Patent was extended so as to include integers involving biased retention features that did not interact with a detent. That, argues Dexcom, is a case of "intermediate generalisation": elements of the invention that were taught in the application for the Patent as essential are no longer required in the claims of the Patent as granted.

Comparison between the application for the Patent and the Patent as granted

130. In *Bonzel v Intervention Ltd (No 3)* [1991] RPC 553 at p574, Aldous LJ said that the task of the Court when faced with an added matter objection such as this is threefold:

> *(1) To ascertain through the eyes of the skilled addressee what is disclosed, both explicitly and implicitly in the application.*
>
> *(2) To do the same in respect of the patent is granted.*
>
> *(3) To compare the two disclosures and decide whether any subject matter relevant to the invention has been added whether by deletion or addition. The comparison is strict in the sense that subject matter will be added unless such matter is clearly and unambiguously disclosed in the application either explicitly or implicitly.*

131. Abbott's application for the Patent (the "PCT Application") was made as PCT Application WO 2011/119896 A1.

132. The PCT Application discusses the use of detent-type retention features in a few places. For example:

i) At [00217] of the PCT Application, it is said that "Detent 2440 provides a minimum force threshold to overcome before on body housing 122 can continue on its downward distal movement". The embodiment referred to in that paragraph is set out in Figure 61 and shows the inner housing of the device, prior to actuation, being held in place by a ledge-like detent (2440). A certain minimum force must be applied to the handle in order to push the needle carriage off the ledge.

ii) At [00254] of the PCT Application, in a discussion of an embodiment set out in Figures 109 to 134, it is stated that:

> *The sheath 3708 is secured to the housing 3702 via retention features 3726, which can be configured, e.g., as a snap. Retention feature 3726 snaps into the housing detent 3724 (In some embodiments, it is pinched between ledge 3720 and detent 3724, thus controlling its height relative to the housing 3702). In some embodiments, the surfaces of the housing ledges 3720, 3722, 3724 and retention features 3726 are configured to engage in a single point of contact or a plurality of discrete points of contact…*

iii) The "retention features 3726" and the "detent 3724" are similar to the snap and detent features that are set out in the diagram I have included in paragraph 53 above.

133. The PCT Application uses the expression "biased retention feature" only in Claim 20. That claim follows a similar architecture to Claim 1 of the Patent as granted and reads, so far as material, as follows with the added emphasis being my own since Dexcom argues that it is significant:

> *20. A medical device insertion system comprising:*
>
> > *a sheath defining a distal surface for placement on the skin of the subject, the sheath having at least one biased retention feature…*
>
> *wherein advancing the handle distally comprises applying a minimum force to overcome the at least one biased retention feature to allow distal movement of the* ***handle relative to the detent***

134. In the B1 Publication, the language used in Claim 20 of the PCT Application was changed. Instead of allowing distal movement of the "handle relative to the detent", claim 12 of the B1 Publication specified that the application of the minimum force overcoming a biased retention feature allowed "distal movement of the handle relative to the sheath". That language became Claim 1 of the Patent as upheld by the TBA.

135. Dexcom argues that these changes made after the PCT Application was submitted amounts to impermissible "intermediate generalisation". It argues that the changes introduced into the Patent for the first time the idea that a mechanism could have (and distal movement of the handle could overcome) a "biased retention feature of the sheath" which has no corresponding detent in the handle.

136. Before considering that approach through the eyes of the Skilled Team, I note that it is necessary to draw a distinction between two situations. In the first situation, a patentee may disclose any invention by reference to a number of embodiments. The claims of the patent, whose function is to delimit the area of the patentee's monopoly, may use phrases that generalise the claims beyond the description of the invention set out in particular embodiments. In that situation, provided that the generalised wording does not teach anything new about the invention, there is no added matter and instead the situation is

one of "the kind of broadening of coverage without any new teaching which is lawful" as Birss J (as he then was) put it at [330] of *Varian Medical Systems International AG v Elektra Limited* [2017] EWHC 712 (Pat).

137. In a second situation, as Kitchin LJ put at [56] of *Nokia v IPCom* [2013] RPC 5:

> *a feature is taken from a specific embodiment, stripped of its context and then introduced into the claim in circumstances where it would not be apparent to the skilled person that it has any general applicability to the invention.*

138. The second situation results in the claim being invalid, but the first situation does not. The key difference between the two situations is that in the second, the effect of the generalisation is to teach the skilled person to whom the patent is addressed something new about the invention, whereas in the first situation the skilled person is taught nothing new.

139. Dexcom emphasises, by reference to Section 1.9 of the *Case Law of the Boards of Appeal of the European Patent Office* (10th edition), that the concept of an intermediate generalisation is applied strictly and is justified only in the absence of any clearly recognisable functional or structural relationship among the features of the specific combination or if the extracted feature is not inextricably linked with those features. Dexcom points out decisions of the TBA in which an intermediate generalisation was admissible only if the skilled person could recognise without any doubt from the application as filed that the characteristics extracted were not closely related to the other characteristics of the working example. Dexcom argues that there is a clear "functional or structural relationship" between the kind of snap and detent feature disclosed at [00254] and [00255] of the PCT Application such that the amendment to refer to a "biased retention feature" necessarily added matter.

140. Given that I have accepted Dexcom's approach to Point G on the Construction Schedule summarised in paragraph 80.ii) above, I have concluded that this is not a case of intermediate generalisation. Rather, I conclude that it falls into the first category, of permitted generalisation, that is set out in paragraph 136 above.

141. The "snap" and "retention features" described at [00254] and [00255] of the PCT Application describe the key aspects of the "biased retention feature" described in what became Claim 1 of the Patent. The "retention" aspect is disclosed in [00254] as "The sheath 3708 is secured to the housing 3702 via retention features 3726, which can be configured, e.g. as a snap". The "biasing" element is disclosed at [00255] as "Sheath 3708 can include retention members 3726, e.g. detent snaps, which are biased into detent 3724 of housing 3702 to create a minimum force that must be overcome in order to advance sharp 324 into the subject's skin". What ultimately became Claim 1 in the Patent was simply a generalisation of this concept beyond the snaps and detents referred to in particular embodiments. In my judgment, given my conclusion on Point G on the Construction Schedule, the amendment teaches nothing new.

142. Perhaps if I had reached a different conclusion on the construction of the term "biased retention feature" as extending to features that do not "retain" the sheath within the handle, the added matter objection might have had more force. In that case, perhaps it could be said that what became Claim 1 of the Patent was teaching something new as compared with [00254] and [00255] of the PCT Application since the skilled reader might see that the necessary "bias" in a "biased retention member" could be produced otherwise than by means of an interaction between that member and the handle that held components in place. However, as I have explained, the concept of "retention" is integral

to the understanding of the term "biased retention feature". It requires some interaction between the "biased retention feature" and other components to achieve the necessary "retention" of the sheath within the handle. Given my conclusion on Point G, the skilled reader of the Patent is not taught anything new on learning that the "biased retention feature" could consist of something other than a snap and detent.

143. For those reasons, Dexcom's challenge to the validity of the Patent on "added matter" grounds fails.

INVALIDITY ON THE GROUNDS OF INSUFFICIENCY

144. Dexcom makes an argument as to the insufficiency of the disclosure in the Patent as a "squeeze" against Abbott's arguments on construction. Dexcom's argument proceeds as follows:

    i) In order to bring the G7 Applicator within the scope of the Patent's claims, Abbott has to say that they cover embodiments in which the movement of the medical device and the insertion of the sharp are not achieved by engaging them with the handle and forcing the handle past the point of resistance (a biased retention feature on the sheath interacting with a detent in the handle).

    ii) Rather, Abbott has to say that the claims in the Patent extend to a completely different mechanism in which the handle is pushed down to enable a button to be pressed which then actuates an internal insertion spring within the sheath.

    iii) There is no teaching in the Patent as to how to move the medical device in the way set out in paragraph 144.ii). It follows that the disclosure in the Patent is insufficient.

145. I have, by accepting Dexcom's position on Points E, G, H, I and J on the Construction Schedule, rejected the construction of the Patent summarised in paragraph 144.ii). It follows that Dexcom's argument based on insufficiency does not need to be addressed. However, in case I am wrong on those points of construction, I will make findings sufficient to enable the insufficiency argument to be dealt with if necessary.

146. The parties are broadly agreed on the following propositions of law:

    i) Section 72(1)(c) of the Patents Act 1977 provides that a patent can be revoked if "the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art". That reflects a fundamental ingredient of the "patent bargain" namely that a patentee obtains a monopoly for an invention only by laying out in the patent document all the information necessary to equip the uninventive person skilled in the art to perform it by means of an application of CGK.

    ii) The simplest kind of insufficiency is where a patent simply fails to inform the skilled person how to perform the invention. For example, explanation may be missing or inadequate or incorrect. Alternatively, the patent may impose an "undue burden" by requiring the skilled person to carry out experiments, trials or investigations in order to discover how actually the invention can be performed. That is not the allegation of insufficiency that is made in this case and so I deal with it no further.

iii) A more subtle kind of insufficiency is known as "claim breadth insufficiency" or "*Biogen* insufficiency" (named after the judgment of the House of Lords in *Biogen v Medeva* [1997] RPC 1). That involves situations where a skilled reader is enabled by the patent to perform the claimed invention to some extent but not to the full extent of the claims. There is in the common shorthand, a failure to enable a claim "across its scope". In *Kymab v Regeneron* [2018] UKSC 27, Lord Briggs explained the requirement in the following way:

> *The disclosure required of the patentee is such as will, coupled with the common general knowledge existing as at the priority date, be sufficient to enable the skilled person to make substantially all the types or embodiments of products within the scope of the claim. That is what, in the context of a product claim, enablement means.*

147. Had it been necessary to consider the point, I would have rejected Dexcom's assertion of "claim breadth insufficiency". The core of that argument is that the Patent's disclosure focuses on a biased retention feature in the form of a "snap" on the sheath that engages with a detent in the handle but the scope of the claimed monopoly goes further than that. However, I conclude that the aspects in which the claimed monopoly does go further simply involve an application of the CGK described in paragraph 30 above. In short, if I were wrong in my conclusions on Points E, G, H, I and J in the Construction Schedule I would agree with Abbott that, to bridge the gap between the snap and detent features disclosed in the Patent and the relevant features of the G7 Applicator including the Leaf Springs and actuation by means of depressing a button, the Skilled Team would need only to put together an arrangement of standard components with that arrangement being within its CGK.

PRIOR ART CHALLENGES

148. In its closing submissions, Dexcom confirmed that all of its prior art challenges to the Patent are being advanced as squeeze arguments. If the G7 Applicator is found not to infringe the Patent, Dexcom will accept in the UK proceedings that the claims of the Patent are not invalid in the light of the cited prior art. Since I have found that the G7 Applicator does not infringe the Patent, it is strictly not necessary for me to make any determinations as regards Dexcom's prior art challenges. However, my findings on infringement have to a significant extent been informed by my conclusions on the correct construction of the claims of the Patent. I will, therefore, address the prior art challenges in case my conclusions on construction are incorrect.

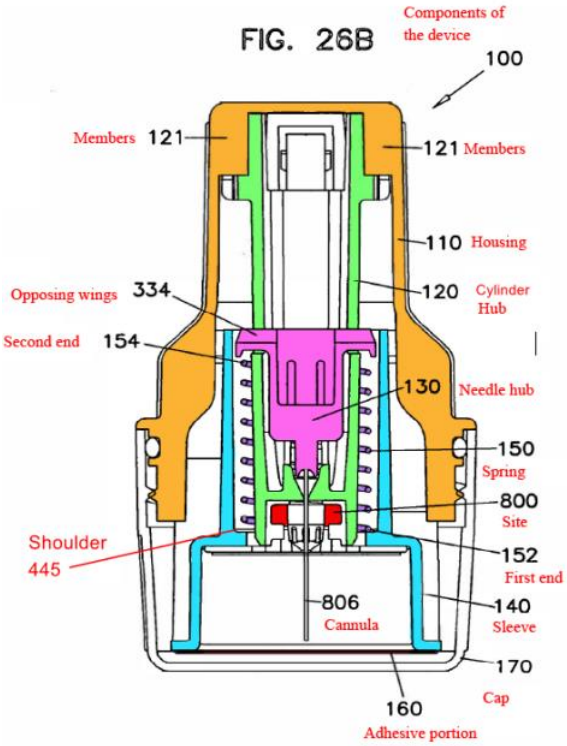
149. It was common ground between the parties that all integers of Claim 1 of the Patent are present in embodiments of the prior art patents that are discussed below with the exception of the presence of a "biased retention feature" (whose construction was Point G on the Construction Schedule) and the requirement that the sheath "has" that biased retention feature (whose construction was Point F on that schedule).

150. If my conclusion on Point G is correct, then the G7 Applicator does not infringe the Patent (as it would contain no biased retention feature as I construe that term). Since Dexcom does not rely on prior art challenges if the G7 Applicator does not infringe, I will therefore approach all of the prior art challenges on the footing (the "Contrary Interpretation") that my conclusion on Point G is incorrect.

Findings as to the cited prior art

Faust

151. Faust is a US patent application entitled "Device and Method for Insertion of a Cannula of an Infusion Device". It was published on 12 May 2005. Much of the debate surrounding obviousness and anticipation related to the first embodiment of Faust, which consists of a device (100) shown in the figure below:

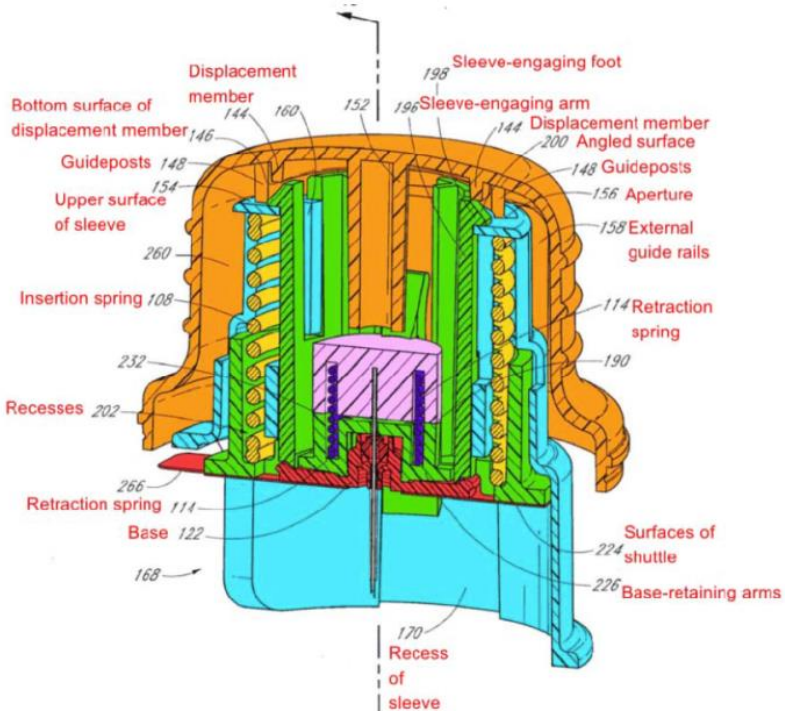


152. That embodiment is a cannula inserter with a single, wholly manual, insertion phase. The user places the device on the skin and pushes down on the top of the orange housing. That makes the orange housing slide relative to the blue sleeve, compressing the spring (150). The green cylinder hub is held rigidly in the orange housing and is engaged with the purple needle hub. Distal movement of the orange housing therefore results in distal movement of the purple needle hub and insertion of the cannula as the spring is compressed. Retraction takes place automatically following the decompression of a retraction spring.

153. On my interpretation of Point G above, the spring (150) does not constitute a "biased retention feature". However, under the Contrary Interpretation, it does. On the basis of my conclusion on Point F, the sheath does not "have" that biased retention feature since it is not physically connected to the blue sleeve but rather sits on "shoulder 445" and is compressed between it and the opposing wings of the Needle Hub. However, if I am wrong on Point F, the sheath does "have" that biased retention feature.

Raymond

154. Raymond is a US patent application, entitled "Inserter Devices for Infusion Devices", filed on 10 September 2008 and published on 14 May 2009. The debate between the parties on Raymond centres on its first embodiment which describes an insertion device (100) for an infusion set which can be understood by reference to the following colour-coded figure that Mr Jennings prepared and which is based on Figure 15 of Raymond itself:



155. The device has a rotational unlocking safety mechanism which is unlocked prior to positioning the insertion device on the skin. Once unlocked, guideposts are in a position where they can access the yellow spring contained within the sleeve through apertures in the upper surface (156). In the pre-actuation state, that yellow spring is partially compressed. It is therefore exerting a force against the top inside surface of the sleeve and down against the carriage. The downward force is transmitted through the sleeve engaging arms back onto the top of the sleeve.

156. When the hollow blue sleeve is depressed, the yellow spring resists further compression and so resists the downward motion of the actuator. When the user has pressed far enough, the displacement members (144) will, by pressing on the angled surface on top of the sleeve engaging arm, shunt the sleeve-engaging arms off the upper surface of the sleeve. This frees the shuttle from the sleeve and allows it to be moved distally under force of the insertion spring. The green shuttle, which functions as a device support within the meaning of Claim 1 of the Patent, has sleeve engaging arms which extend up and sit on top of the upper surface of the sleeve.

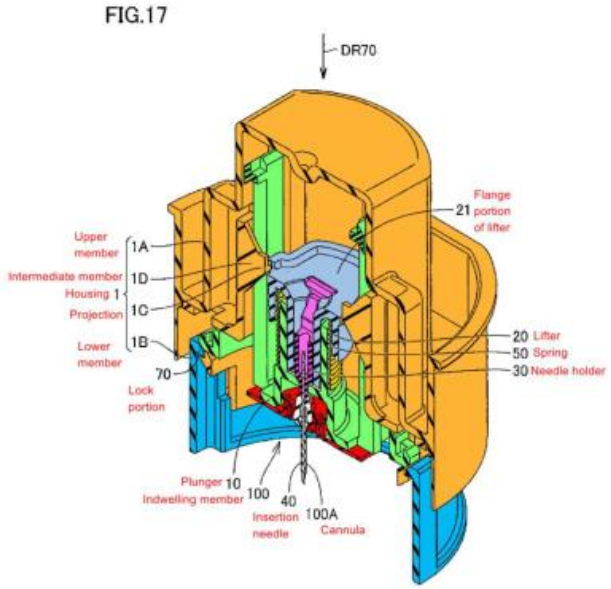
157. Therefore, at a high level, there is a similarity between this embodiment of Raymond and the G7 Applicator. Both involve the application of a downward force against an opposing spring-generated force before the release of a mechanism to trigger spring-powered insertion. The yellow spring is not a "biased retention feature" applying my interpretation of Point G. However, applying the Contrary Interpretation, the yellow spring would be a biased retention feature. Applying my interpretation of Point F, the blue sleeve (which

functions as the "sheath" for the purposes of Claim 1) does not "have" that biased retention feature since the yellow spring is not part of the "sheath". However, if I am wrong in my approach to Point F, it does.

Yokoi

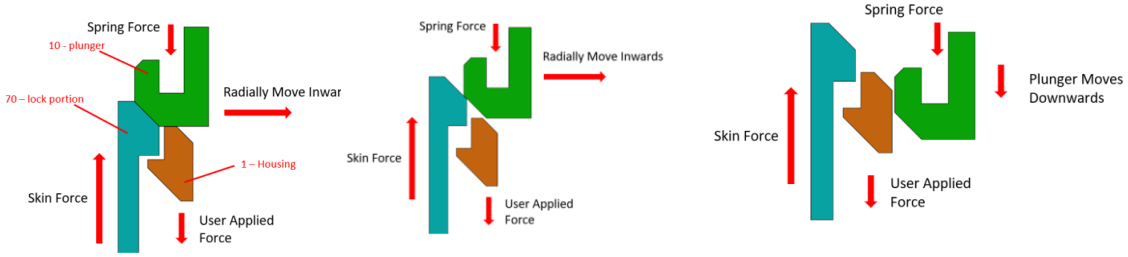
158. Yokoi is a patent application dated 25 February 2010. It relates to an inserter for automatically inserting a cannula of an indwelling member of an infusion device into the body of a user. Yokoi contains two embodiments. The first occupies the bulk of the description and the figures and can fairly be described as the "principal embodiment". The second is dealt with in less detail and I describe it as the "second embodiment".

159. Mr Jennings provided his own coloured version of Figure 17 contained in Yokoi that describes the second embodiment:



160. In its initial state, the plunger (10) of this embodiment is locked by lock portion (70) formed at the lower housing member (1B). When the user presses the upper member of the housing (1A), in the direction of the arrow shown as DR70 with a certain minimum force, the lock portion becomes unlocked which releases a spring that propels the insertion needle distally.

161. I took the parties to be agreed that the lock feature in Yokoi included "a biased retention feature" on the Contrary Interpretation. There was also a broad agreement as to how lock portion (70) worked that can be illustrated by reference to the following diagrams from Mr Jennings's expert report:



162. The diagram on the left shows the device in its "locked" state. The middle diagram shows the position as a downward force is applied as a result of the user's compression of housing (1) that functions as a handle for the purposes of Claim 1 of the Patent. The green "J-shaped" portion of the plunger is starting to slide past the part of the housing shown in brown. In the diagram on the right, the plunger has moved past the brown housing and is free to move further downwards under the force of the insertion spring (50), together (as Mr Varde concludes) with force applied to the plunger so as to insert the needle under the patient's skin.

163. However, although Mr Varde and Mr Jennings broadly agreed on how the embodiment worked, and that it involved the overcoming of a bias, they did not agree as to precisely which parts of that configuration were "biased".

164. Mr Varde seemed to suggest in cross-examination that it was possible that components that were physically attached to the blue sheath deformed as part of the unlocking process (which was of potential significance to the question of whether the blue sheath "has" a biased retention feature). By contrast, Mr Jennings concluded that the only parts of the unlocking mechanism that deformed, and so were biased, were not physically attached to the blue sheath.

165. I preferred the conclusion of Mr Jennings, namely that the only parts of the unlocking mechanism in Yokoi's second embodiment that were "biased" were parts that were not physically attached to the blue "sheath". I have reached that conclusion because:

    i) Mr Jennings provided a clear exposition in his first and second reports as to how the unlocking mechanism in Yokoi functioned that was entirely consistent with the biased components not forming part of the blue sheath.

    ii) Mr Varde's expert reports indicated broad agreement with Mr Jennings' conclusions. Mr Varde's fourth report did indicate some possible disagreement with Mr Jennings about how the unlocking mechanism works precisely. However, while he did suggest that it might involve outward radial movement of a protrusion of the orange housing which Mr Jennings had not suggested in his own explanation, Mr Varde did not suggest that the blue lock portion, that formed part of the "sheath", might deform outwards.

    iii) In cross-examination, Mr Jennings was clear in his opinion that the blue lock portion would not flex during the unlocking process. Mr Varde's opinion that it was possible that components attached to the blue sheath were biased came up largely in cross-examination, as distinct from his written expert reports, and was more nuanced, namely that it was not possible to be "absolutely definitive" that the blue lock component was rigid.

166. Given the parties' common position referred to in paragraph 161, on the Contrary Interpretation, the second embodiment of Yokoi contains a "biased retention feature". However, given my conclusion on Point F and findings I have made in paragraph 165, the sheath does not "have" that biased retention feature although it would do so if my approach on Point F is incorrect.

Anticipation

Claim 1

167. As I have noted, in considering all of the challenges based on the prior art, I proceed on the basis of the Contrary Interpretation. On that interpretation, the referenced embodiments of Raymond, Faust and Yokoi have a "biased retention feature".

168. The position on anticipation is therefore reasonably straightforward applying the Contrary Interpretation. Given my findings on the prior art set out above, Claim 1 of the Patent is not anticipated by any of Yokoi, Raymond and Faust if my conclusion on Point F is correct (since the biased retention feature does not form part of the sheath). By contrast, applying the Contrary Interpretation, if my conclusion on Point F is incorrect, then Claim 1 of the Patent is anticipated by all of Raymond, Faust and Yokoi (since the biased retention feature could fairly be regarded as being a feature of the sheath in the same way as a lace is a feature of a shoe even though physically distinct from the leather upper and sole).

Other claims

169. Dexcom does not argue that any of the other claims are anticipated by the prior art, even on constructions of those claims that are contrary to those that I have determined. Dexcom accepts that Claim 7 is not anticipated because none of the prior art relates to an inserter for an analyte sensor specifically. The same is true of Conditional Amendments 1, 2, 4 and 5.

Obviousness – Claim 7

170. As I understood the closing submissions on behalf of Dexcom, Dexcom does not invite the Court to make any finding of obviousness in relation to Claim 1 if Dexcom loses on infringement. Its case in that scenario is that Claim 1 is anticipated by the prior art.

171. In any event, it does not seem to me that an "obviousness" challenge under Claim 1 would be any different from the challenge that is advanced in relation to Claim 7. Although Claim 1 relates to an apparatus for inserting any medical device, whereas Claim 7 relates only to an inserter for an analyte sensor, this distinction is of little significance in the present proceedings. That is because both parties are agreed that the Patent is addressed to a Skilled Team involved in the design of CGM inserter specifically (see paragraph 12.iii) above). Since that Skilled Team has that focus, the distinction between any "medical device" in Claim 1 and an "analyte sensor" in Claim 7 would be of little significance.

The law on obviousness

172. The applicable statute law is set out in s3 of the Patents Act 1977:

> *[a]n 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 burden is on Dexcom to establish "obviousness".

173. It is relevant to have regard to the purpose behind the concept of obviousness. As Laddie J explained in *Brugger & anr v Medic-Aid Ltd* [1996] RPC 635 at 653:

> *A trader must be free to adopt a product, process or design which is the, or one of the, obvious modifications over what has gone before without the need to look over his shoulder to consider whether it is protected by patent. Obviousness is tested against the mental and developmental norm of a notional uninventive person skilled in the art. In doing that the law is protecting not only established businesses which may wish to adopt new products, processes or designs or modify existing ones but also the new entrant who has employed persons skilled in the art to help him get into the market. Each of those categories of trader must be free to adopt what is obvious. Therefore it is legitimate to approach the prior art as if it had been collected and put on the desk of the new entrant at the priority date.*

174. The parties were agreed that it was appropriate to assess obviousness using the structured approach set out by the Court of Appeal in *Pozzoli v BDMO SA* [2007] RPC 37 at [23] and as amplified by the judgment of the Supreme Court in *Actavis Group PTC EHF & others v ICOS Corporation and another* [2019] UKSC 15, namely:

    i) Identify:

        a) the notional "person skilled in the art";

        b) the relevant CGK of that person

    ii) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it.

    iii) 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.

    iv) Viewed without any knowledge of alleged invention as claimed, determine whether those differences constitute steps which would have been obvious to the person skilled in the art or whether they would have required any degree of invention.

175. Clearly it is at step iv) of *Pozzoli* that the ultimate conclusion on obviousness emerges and for that reason the parties directed a good proportion of their submissions on the approach to be taken at that step. I concluded that the following principles were uncontroversial:

    i) It is important for the Court to "don the mantle" of the Skilled Team at the Priority Date. Expert evidence plays an important part in enabling the Court to do this for a number of reasons, including the fact that expert evidence can help the Court to assess what would have been in the mind of the Skilled Team at the Priority Date (see, for example, *Panduit Corp v Band-IT Co Ltd* [2002] EWCA Civ 465).

    ii) Once an invention has been made it is often easy to see, with hindsight, how it was arrived at. However, hindsight is to be avoided. The question is whether it would have been obvious to the Skilled Team to make the invention at the Priority Date (see, for example, *British Westinghouse v Braulik* (1910) 27 RPC 2009).

    iii) The Skilled Team is assumed to read all the prior art properly and, in that sense, with "interest". However, that does not mean that the Skilled Team assumes that the prior art will provide it with any assistance in solving the problem confronting it. In some cases, the Skilled Team may conclude that prior art is not a useful

starting point for development (see [102] of the judgment of Arnold J as he then was in *Jarden Consumer Solutions v SEB SA* [2014] EWHC 445 (Pat)). Having read a particular piece of prior art with interest, the way in which the Skilled Team responds to it is a question of fact to be determined in the light of all relevant circumstances. One possibility is that the Skilled Team will say, "I have read it with interest, but I'm not interested" (see *Vernacare Ltd v Environmental Pulp Products Ltd* [2012] EWPCC 41).

176. As will be seen, Abbott's position in these proceedings is that the inventions set out in the Patent (including the Patent as conditionally amended) were not obvious in the light of the prior art because, in part, of the "mindset" of the Skilled Team at the Priority Date. The detail of that argument will be explored later in this judgment, but I will apply the following propositions of law when evaluating this aspect of Abbott's case:

    i) Questions of "mindset" are of potential relevance when addressing a question of obviousness. That is simply because obviousness has to be considered on the facts of each case and so involves a multi-factorial evaluation. Relevant factors may, therefore, include matters such as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research and the effort involved in pursuing them and expectations of success (see the statement of Kitchin J in *Generics (UK) Ltd v H Lundbeck* [2007] RPC 32 at [72]).

    ii) It can, therefore, be relevant to explore whether there are potential barriers that mean that, although the Skilled Team "could" have arrived at the claimed invention without inventive effort, it "would" not in fact have done so. However, care needs to be taken to ensure that the application of a "would" test is not misleading. For example, the application of a "would" test does not make it permissible to consider whether it would be worthwhile commercialising an otherwise technically obvious product. Nor does it require it to be shown that the Skilled Team would go ahead and implement a particular invention commercially. In a similar vein, the application of a "would" test could produce an incorrect outcome if, for example, the prior art reveals a range of obvious possibilities making it statistically unlikely that any particular one of them would be chosen (see [15] and [16] of the judgment of Floyd LJ in *Hospira UK Limited v Genentech, Inc* [2016] EWCA Civ 780).

    iii) Undue focus on whether the Skilled Team "would" have alighted on a particular claim can also lead to a different type of incorrect outcome. The purpose of the concept of "obviousness" is to define what is inventive. It follows that, even if the Skilled Team "would not" alight on a particular claim, because, for example, it is purely arbitrary and non-technical, it does not follow that the claim is protected from an obviousness challenge. In *Actavis UK Ltd v Novartis AG* [2010] EWCA Civ 82, Jacob LJ illustrates the idea by reference to a hypothetical patentee who claims a patent for a 5¼ inch plate in circumstances where there is no reference in the prior art to a plate having that precise diameter. Even though no skilled person would alight on the idea of a plate with that particular diameter, the alleged invention remains obvious as the 5¼ inch limitation is purely arbitrary and non-technical, solves no problem and does not advance the art at all.

    iv) That said, it is not necessarily wrong to ask whether the Skilled Team "would" have taken a particular step. Analysing that question can shed a light on relevant questions of motivation and, as the Supreme Court makes clear at [70] of *Actavis v ICOS* "the absence of a motive to take the allegedly inventive step makes an argument of obviousness more difficult".

v) The question whether the Skilled Team "could" have arrived at the claimed invention without inventive effort is a minimum condition that must be satisfied before obviousness case can be established (see the judgment of Slade LJ in *Hallen Co. v Brabantia (UK) Ltd.* [1991] RPC 195 at page 212).

"Obviousness" of Claim 7 - discussion

177. I have made findings above on Stage i) of the *Pozzoli* structured analysis. As regards Stage ii), while both parties rightly stressed the centrality of the claim integers as drafted in the Patent, they were broadly agreed that at a very high level the inventive concept of Claim 1 and 7 is the inclusion of a feature which ensures that the inserted device is only activated when the user has pressed sufficiently hard on the housing towards the skin to overcome the minimum force required to start the movement of the handle, mechanical device and needle.

178. I have already noted that I am proceeding on the basis of the Contrary Interpretation, namely that my approach to Point G is wrong. In the remainder of the discussion I will also proceed on the basis that my interpretation of Point F is correct since that results in the widest possible difference between the Patent and the prior art for the purposes of making evaluative findings as to obviousness.

179. On that basis, all of the cited prior art contains a "biased retention feature" (the springs in Raymond and Faust and the lock mechanism in Yokoi), but the sheath does not "have" that biased retention feature since, in each item of cited prior art, the biased retention feature is located otherwise than on the sheath. It follows that, at *Pozzoli* Stage (iii), the only difference between the cited embodiments of Raymond, Faust and Yokoi and the invention as claimed by Claim 7 are: (i) that Claim 7 of the Patent is for an inserter for an analyte sensor (whereas, in Raymond, Yokoi and Faust it was for an infusion set or cannula) and (ii) as to the location of the biased retention feature.

180. Abbott argues that the difference (i) that I have set out in paragraph 179 above is crucial. It relies heavily on my finding in paragraph 40 that it was not part of the CGK for the Skilled Team to adapt designs for infusion set inserters for use as CGM inserters. It points to the evidence of Dr Schoemaker and Mr Jennings, reflected in my findings in paragraph 39 as to the differences between considerations applicable to designs for infusion set inserters and those applicable to CGM inserters. Abbott acknowledges that the Skilled Team on reading the prior art at the Priority Date could have adapted it for use when designing a CGM inserter. However, it submits that critically the Skilled Team would not have done so. It places emphasis on Mr Varde's acceptance in cross-examination that he could not say that the Skilled Team, on being given the cited prior art, would have used concepts from that prior art when designing a CGM device.

181. In my judgment, Abbott over-emphasises the significance of the fact that it was not CGK to adapt infusion set inserters for use as CGM inserters. That finding might well suggest that the Skilled Team would not positively have sought out the prior art when designing an inserter for a CGM device. However, the question of obviousness is not just concerned with whether the Skilled Team would have sought out the prior art. Rather, it invites a consideration of how the Skilled Team would have reacted if the prior art had landed on its desk and the Skilled Team then proceeded to read it with the kind of interest that I have described in paragraph 175.iii). Accordingly, the question is whether the Skilled Team, having read the prior art with the requisite degree of interest, would still say "we are not interested".

182. The experts disagreed on that issue. Mr Varde's opinion was that a design engineer on the Skilled Team would understand the mechanical aspects disclosed in each of Faust (see 9.42 of his Third Report), Raymond (see 9.87 of his Third Report) and Yokoi (see 9.118 to 9.119 of his Third Report) would be directly applicable to the design of a CGM inserter with only minor modifications that could be made by reference to the engineer's CGK. Mr Jennings referred in paragraph 9.46 of his First Report to the "different considerations" that applied to an insertion device for an analyte sensor as compared to an infusion device which I have summarised in paragraph 39 to support his opinion that it would not be obvious to use the devices set out in the cited prior art as the starting point for the design of an inserter for an analyte sensor.

183. On balance, I prefer Mr Varde's opinion. In my judgment, his opinion evidence was more closely directed at the question that the Court needs to answer on "obviousness". By contrast, Mr Jennings's opinion, by focusing on the "different considerations" that he identified was focusing unduly on whether the Skilled Team would actually implement the knowledge that they gleaned from the prior art rather than whether Claim 7 would be obvious in the light of that prior art. Moreover, the different considerations that Mr Jennings stressed related largely to reconfigurations of the sharp that would be necessary if the prior art was to be adapted for use as an analyte sensor. When pressed on that issue in cross-examination, Mr Jennings accepted that the "fundamental principles" that governed the design of an inserter for an infusion set were also applicable to an inserter for a CGM device. Although he thought that the "detailed bits that need to change might be quite significant", he did not identify any inventions that would be necessary for the prior art to be adapted into the design of a CGM inserter.

184. I quite acknowledge that overcoming a "mindset", even a commercial mindset, is capable of constituting sufficient invention to overcome an obviousness challenge. For example, in *Dyson v Hoover* [2002] RPC 22 the notional skilled person would have had a strong prejudice against the viability of purifying dirt-laden air from a vacuum cleaning operation other than by using a bag. That prejudice arose because the industry at the time attached significance to generating revenue by the sale of vacuum cleaner bags. Sedley LJ said:

> *It is entirely in accordance with what we know about innovation that this commercial mindset will have played a part in setting the notional skilled addressee's mental horizon, making a true inventor of the individual who was able to lift his eyes above the horizon and see a bag-free machine…*

185. My task, of course, is not to make an impressionistic comparison between the facts of this case and the facts of *Dyson v Hoover*. However, Sedley LJ's statement quoted above brings out an aspect of this case that is significant. Having heard the differing views of both parties' experts as tested in cross-examination, I have concluded that the "mindset" on which Abbott relies was less fixed than it suggested. The Skilled Team would certainly have been conservative and wished to proceed by reference to inserters for the Existing CGM Systems partly because those inserters were known to work and had been approved by regulators from a safety perspective. However, I have concluded that the Skilled Team, having read Raymond, Faust and Yokoi with appropriate interest would, on the Contrary Interpretation, have seen that it contained the very "biased retention feature" that is at the heart of the inventive concept of the Patent. I prefer Mr Varde's conclusion that the Skilled Team would have realised that there was a good degree of work to do (although not invention) in adapting the prior art for use in a CGM inserter. However, they would not have said that they were simply uninterested in what the prior art had to teach them.

186. I have paused to consider Abbott's contrary argument that, for the Skilled Team even to consider adapting the cited prior art for use as a CGM inserter would involve a significant departure from the CGK which was to take existing CGM products as the starting point for the design of new CGM inserters. However, I regard the force of that indication as being of less weight than the point I make in paragraph 183 above. The work needed to reconfigure the inserters shown in the prior art might well have been fiddly and time-consuming. Moreover, a regulator would need to be persuaded that the end-result was safe. However, the necessary work fell within the scope of the Skilled Team's CGK summarised in paragraph 30. There is support for that conclusion in the terms of the Patent itself which, at [0087] suggests a read-across between the design of inserters for infusion sets and CGM devices by stating that the invention disclosed by the Patent can be configured to insert various medical devices such as, for example, an analyte sensor, an infusion set or a cannula.

187. I turn now to the second difference between the prior art and the invention of Claim 7 identified in paragraph 179, namely the location of the biased retention feature. I have concluded that the precise location of the biased retention feature, whether physically attached to the sheath or not, has very little impact on the overall inventive concept of Claim 7. What matters for the purpose of the invention is not where the biased retention feature is situated, but the function that it performs. I therefore conclude that moving the biased retention features shown in the prior art to a different location in the apparatus to which Claim 7 relates would be an arbitrary and non-technical step of the kind Jacob LJ was discussing in his example of the 5¼ inch plate. I accept Abbott's point that some element of redesign might be necessary to move the biased retention features shown in the prior art. However, in my judgment, doing so would involve no invention and would be within the CGK of the Skilled Team (see paragraph 30 above).

188. Having considered the relevant differences between the prior art and Claim 7 identified at *Pozzoli* Step (iii), my overall conclusion at Step (iv) is that, on the Contrary Interpretation, Claim 7 of the Patent would be invalid on the grounds of obviousness.

Obviousness – CA1

189. The key inventive concept of the invention claimed by CA1 remains essentially the same as that described in paragraph 177 above except that the CA1 invention is an inserter for, specifically, an integrated analyte sensor. At *Pozzoli* Step (iii), the differences between the prior art and the key inventive concept were that (i) the prior art relates to inserters for infusion sets whereas CA1 makes a claim relating to an inserter for an integrated analyte sensor and (ii) the location of the biased retention feature.

190. I have already explained why I do not consider that difference (ii) set out in paragraph 189 protects against a finding of obviousness. Therefore, the key issue relates to difference (i).

191. Abbott's position is that the claims as amended by CA1 are far from obvious. It points to the absence of any CGK suggesting that the Skilled Team should be designing inserters for use with integrated assemblies resulting from the fact that integrated assemblies themselves were not part of the CGK. Abbott goes further, arguing that CGK at the time pointed firmly away from using integrated CGM sensors so that a Skilled Team that sought to design an inserter for an integrated assembly would be acting positively contrary to CGK. It would, submits Abbott, be a still further significant departure from CGK to use the prior art, that related to inserters for infusion sets, as a basis for designing an inserter for integrated CGM devices.

192. Abbott also observes that Dexcom itself was not proposing designs for an integrated CGM sensor until 2017, more than seven years after the Priority Date. That was well after Abbott had designed a system with that feature. It argues that Dexcom's case on the obviousness of an inserter for an integrated CGM sensor was affected by hindsight and seemed to involve the Skilled Team being more inventive than Dexcom itself.

193. Dexcom argues that the concept of an integrated CGM device was completely obvious at the Priority Date. That concept involved nothing more complicated than supplying users with a sensor that was already connected to the necessary electronics rather than requiring users to make the necessary connections themselves. The only considerations that were holding a Skilled Team back from developing an integrated CGM device at the Priority Date were the considerations of cost that I have identified in paragraph 45 above.

194. I prefer the analysis of Dexcom on this issue. I acknowledge that CGK at the Priority Date was that the two-part architecture was "accepted". However, that was only because of considerations of cost. I do not consider that there is any inventive step involved in taking the prior art and adapting it for use as an inserter for an integrated CGM device.

195. Dr Schoemaker set out in his Third Report, certain issues, other than those related to cost, that would need to be addressed if a Skilled Team at the Priority Date was considering moving beyond the CGK and designing an inserter for an integrated CGM device. He mentioned the need for different means of sterilising the sensor and transmitter parts of an integrated device. However, I am not satisfied that any invention would be needed in order to do this. What Dr Schoemaker was describing was simply a process under which different parts of the component are sterilised in different ways. He also mentioned the need for an additional mechanism or method for disengaging the sharp from the electronics assembly after sensor insertion. However, he accepted in cross-examination that he was not referring to an aspect of the inserter device. The needle retraction mechanism of an inserter for a CGM device did not need to be any different simply because the device was integrated rather than two-part. Rather, his point about disengaging the sharp related to aspects of the on-body housing of the medical device. Nor did he specify the nature of any inventions that would be necessary to enable the sharp to be disengaged appropriately.

196. In its closing submissions, Abbott argued that the Court should be careful about finding that the one-part architecture was obvious in the light of CGK alone. It pointed to the cautionary statements made by Floyd J as he then was in *Ratiopharm v Napp* [2008] EWHC 3070 at [154] to [159]. However, in my judgment those statements were directed at a different situation from the present one. Dexcom is not arguing that the Skilled Team could have come up with the entirety of the invention disclosed in CA1 simply by reference to CGK. Rather, its point is that (i) the prior art knew of inserters for medical devices; (ii) on the Contrary Interpretation, the only material point of distinction between the prior art and the claims of the Patent as amended by CA1 was that the latter dealt with an inserter for an integrated CGM device; (iii) the concept of an integrated CGM device was obvious at the Priority Date and it was only considerations of cost that prevented such a device from being implemented and (iv) no inventive step was necessary to take the prior art and adapt it for use as an inserter for an integrated CGM device.

197. On detailed analysis, Abbott's case on obviousness highlights some of the difficulties that can arise if the question is analysed as whether the Skilled Team "would" have arrived at the claimed invention from the prior art. I am quite prepared to accept that the Skilled Team, on reading the prior art with the necessary interest, would have been unlikely to proceed to develop an inserter for an integrated CGM device on the Priority

Date. However, that would be because the Skilled Team would have concluded that an integrated CGM device would be too expensive because it required costly electronic components to be discarded every few days. Since an integrated CGM device would not have been commercially viable at the Priority Date, the Skilled Team would not have pressed ahead with the design of an inserter for such a device.

198. As noted in my analysis of Claim 7, there can be invention in a process that involves "lifting one's eyes above the horizon" to see possibilities that others have not seen. However, as Pumfrey J explained in *Cipla v Glaxo Group* [2004] RPC 43 at [30]:

> *Such a prejudice may be a merely commercial one ('this device won't sell') or it may be a technical one ('this won't work and it is not worth bothering with'). A 20-year monopoly is conferred for overcoming a prejudice of the second kind, but not for overcoming a commercial prejudice (see* Hallen Co v Brabantia (UK) Ltd *[1989] R.P.C. 307 (Aldous J.))*

199. In my judgment, this case falls within Pumfrey J's first category and on the Contrary Interpretation, the invention disclosed in the claims of the Patent as modified by CA1 would remain obvious in the light of the prior art. The absence of a need for inventive steps to adapt the prior art for use as an inserter for an integrated CGM device means that Dexcom's arguments on obviousness are to be preferred, having regard to the purpose of the enquiry into obviousness that I have set out in paragraph 173 above.

200. I am reassured in this conclusion by the analysis that I have already undertaken on the obviousness of Claim 7. If I am wrong in that conclusion, then there is no need to consider CA1. However, if I am right, and Claim 7 would, on the Contrary Interpretation, be obvious, the claims as amended by CA1 involve no greater degree of invention, as compared with the prior art, than would the unamended claim.

201. My conclusion is that, on the Contrary Interpretation, the claims as amended by CA1 would be obvious over the cited prior art.

CONDITIONAL AMENDMENTS 2 AND 4

Conditional Amendment 4

202. I do not consider that I need to make any further factual or evaluative determinations in connection with CA4.

203. I therefore simply record my conclusion that, if I am wrong in my approach to the obviousness of Claims 1 and 7 (including as amended by CA1), then CA4 does not need to be addressed. If, by contrast, I am correct in my approach to the obviousness of those Claims, then I do not consider that the additional amendments of CA4, which consist primarily of relatively minor drafting changes, together with changes to the precise location of the "biased retention feature" could save the claims, as amended by CA1, from invalidity.

Conditional Amendment 2

204. By paragraph 4 of his order of 20 June 2023, made after the Pre-Trial Review, Mellor J required Abbott to notify Dexcom by 4pm on 26 June 2023, those claims of the Patent "as allowed by the EPO and/or as proposed to be amended… whose validity they will defend at trial". Abbott did not specify that CA2 was to be defended at trial by this

deadline and, accordingly, until skeleton arguments were exchanged Abbott did not suggest that there were any points on CA2 that required determination.

205. However, in its skeleton, Dexcom raised what became Point K on the parties' Construction Schedule. Abbott characterised this as a new point and so sought to put CA2 on the agenda to deal with the possibility that (i) Dexcom's interpretation on Point K was accepted and (ii) the Court also held that, as a factual matter, the invention disclosed in the Patent (as unamended) was "suitable for" insertion of an integrated sensor. Something of a snowball effect resulted with both parties making, and responding to each other's, detailed arguments on CA2.

206. Both sides were critical of each other's approach. Abbott criticised Dexcom for raising a "new" point of construction (Point K). Dexcom criticised Abbott for seeking to resurrect CA2, having failed to give the notice that Mellor J had required in his order of 20 June 2023. Ultimately, however, both parties accepted that CA2 could be dealt with if necessary on the basis of the evidence that was already before the Court and the additional submissions that were made in closing.

207. Abbott relies only on CA2 as a hedge against Dexcom's Point K and associated factual argument succeeding (see paragraph 205 above). It states expressly that, for the purposes of this trial, it does not rely on the "activation" feature that constitutes Integer 1.8 of the amended claim as setting out any additional invention. In those circumstances, I do not consider that CA2 needs to be addressed for the following reasons:

    i) Dexcom does not invite the Court to uphold its challenges based on the prior art given that it has succeeded on the issue of infringement.

    ii) I have nevertheless considered prior art based challenges to CA1 on the Contrary Interpretation. The claims as amended by CA1 would, on the Contrary Interpretation, be invalid not because of Dexcom's approach to Point K, which I have rejected, but rather because of the "obviousness" of those claims as amended.

    iii) Given my conclusion in paragraph 207.ii), CA2 could not produce any different outcome in circumstances where Abbott accepts that those amendments involve no additional inventive step as compared with CA1.

DISPOSITION

208. Abbott's claim against Dexcom for infringement of the Patent is dismissed.

209. Dexcom's counterclaim for a declaration that the Patent is invalid for "added matter" is dismissed.

210. Given the way in which Dexcom put its prior art challenges (based on obviousness and anticipation) and its challenge to validity of the Patent based on insufficiency, it is not necessary to determine those matters. I have nevertheless sought to make findings relevant to their determination throughout this judgment.

211. Since I have made no finding that any of the claims in the Patent are invalid, it is not necessary to consider Abbott's application to amend those claims conditionally. Again, however, I have tried to make relevant findings both on factual matters and on construction should those applications need to be considered.

APPENDIX 1 – INTEGERS OF THE CLAIMS AND CONDITIONAL AMENDMENTS

Unamended	**As amended by CA1 (red), CA2 (red and green) and CA4 (red and blue)**
1 An apparatus (200) (300) (400) (2400) (2500) (2700) (3700) for inserting a medical device (14) into the skin of a subject, which comprises:	An apparatus (200) (300) (400) (2400) (2500) (2700) (3700) for inserting an ~~medical device~~ integrated in vivo analyte sensor on-body electronics assembly (14) into the skin of a subject, which comprises:
1.1 a sheath (242) (342) (442) (2512) (2708) (3708) defining a distal surface for placement on a skin surface;	
1.2 a device support (430) (3702) movable between a proximal position and a distal position that is closer to the skin surface, and adapted to support a medical device;	a device support (430) (3702) movable between a proximal position and a distal position that is closer to the skin surface, and adapted to support an ~~medical device~~ integrated in vivo analyte sensor on-body electronics assembly;
1.3 a sharp support movable between the proximal position and the distal position that is closer to the skin surface and adapted to support a sharp (224) (324) (424) (2404) (2550) for inserting the medical device under the skin surface and extending through a portion of the device support;	a sharp support movable between the proximal position and the distal position that is closer to the skin surface and adapted to support a sharp (224) (324) (424) (2404) (2550) for inserting a portion of the ~~medical device~~ integrated in vivo analyte sensor on-body electronics assembly under the skin surface and extending through a portion of the device support;
1.4 a handle (302) (402) (2502) (2702) (3702) movable between a proximal position and a distal position relative to the sheath and adapted to urge the device support and the sharp support from the proximal position to the distal position to insert the sharp under the skin surface; and	
1.5 a driver (246) (346) (446) (2406) (2544) for advancing the sharp support towards the proximal position when the sharp support reaches the distal position;	
1.6 wherein the device support (430) (3702) includes a first engagement member (474) (475) for releasably coupling the device support to the sharp support (428) (434) (436) and a second engagement member (3727) (3732) for engaging the medical device; and further characterised in that	wherein the device support (430) (3702) includes a first engagement member (474) (475) for releasably coupling the device support to the sharp support (428) (434) (436) and a second engagement member (3727) (3732) for engaging the ~~medical device~~ integrated in vivo analyte sensor on-body electronics assembly; ~~and further characterised in that~~
1.6a the sheath (242) (342) (442) (2512) (2708) (3708) has at least one biased retention feature (2440) (2518) (2726) (3726); and	wherein: the sheath (242) (342) (442) (2512) (2708) (3708) has at least one biased retention feature (2440) (2518) (2726) (3726) that is a part of the sheath and that is biased against the handle and that is configured to prevent the handle from moving

	relative to the sheath until a minimum force has been applied in a distal direction to the handle; and
1.6b advancing the handle (302) (402) (2502) (2702) (3702) from the proximal position to the distal position comprises applying a minimum force to the handle overcome the at least one biased retention feature to allow distal movement of the handle relative to the sheath; and	advancing the handle (302) (402) (2502) (2702) (3702) from the proximal position to the distal position comprises applying ~~a~~ the minimum force to the handle overcome the at least one biased retention feature to allow distal movement of the handle relative to the sheath; and
1.7 a force applied to the handle moves the sheath into the handle and moves the medical device from the proximal position to the distal position and inserts the sharp under the skin surface.	a force applied to the handle moves the sheath into the handle and moves the ~~medical device~~ integrated in vivo analyte sensor on-body electronics assembly from the proximal position to the distal position and inserts the sharp and the portion of the in vivo analyte sensor under the skin surface; and
	1.8 the apparatus is configured to activate the on-body electronics of the integrated in vivo analyte sensor on-body electronics assembly
7 The apparatus of any of the preceding claims,	
7.1 wherein the medical device (14) is an analyte sensor	