

UNITED STATES PATENT AND TRADEMARK OFFICE

---

**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

---

DEXCOM, INC.,  
Petitioner,

v.

ABBOTT DIABETES CARE INC.,  
Patent Owner.

---

Case No. IPR2023-01409

U.S. Patent No. 11,202,591

---

**DECLARATION OF KARL R. LEINSING, MSME, PE**

## **TABLE OF CONTENTS**

|       |                                                                                        |    |
|-------|----------------------------------------------------------------------------------------|----|
| I.    | INTRODUCTION .....                                                                     | 1  |
| II.   | PROFESSIONAL BACKGROUND AND QUALIFICATIONS .....                                       | 1  |
| III.  | UNDERSTANDING OF PATENT LAW STANDARDS .....                                            | 7  |
|       | A.    Person of Ordinary Skill in the Art .....                                        | 7  |
|       | B.    Claim Construction.....                                                          | 8  |
|       | C.    Obviousness.....                                                                 | 10 |
| IV.   | SUMMARY OF OPINIONS.....                                                               | 13 |
| V.    | BACKGROUND OF CONTINUOUS GLUCOSE MONITORING<br>SYSTEMS AND THE ASSERTED PRIOR ART..... | 16 |
|       | A.    Diabetes and Continuous Glucose Monitoring Systems.....                          | 16 |
|       | B.    Continuous Glucose Monitoring System Prior Art Relied Upon<br>By Dexcom.....     | 21 |
|       | 1.    U.S. Patent 6,175,752 to Say .....                                               | 21 |
|       | 2.    U.S. Publication 2007/0073129 to Shah.....                                       | 23 |
|       | 3.    WO Publication 2008/115409 to Brenneman.....                                     | 26 |
|       | 4.    U.S. Publication 2008/0097246 to Stafford.....                                   | 29 |
|       | C.    Cote’s Reorientable Infusion Set And Cannula Delivery System .....               | 33 |
| VI.   | THE 591 PATENT .....                                                                   | 38 |
| VII.  | DR. FLETCHER’S STATEMENTS REGARDING THE STATE OF<br>THE ART.....                       | 46 |
| VIII. | CLAIM CONSTRUCTION: THE TERMS AND PHRASES IN THE<br>591 PATENT .....                   | 47 |
| IX.   | ALL GROUNDS: COMBINATION OF STAFFORD AND COTE.....                                     | 48 |
|       | A.    Motivation To Combine Stafford In View Of Cote .....                             | 49 |
|       | B.    Dr. Fletcher’s Selection Of <u>Cote’s</u> Infusion Cannula Inserter .....        | 59 |
|       | C.    Reasonable Expectation Of Success .....                                          | 62 |
| X.    | GROUND 1: STAFFORD IN VIEW OF COTE (CLAIMS 1-6, 9-14,<br>16-24, 27, 29-30) .....       | 64 |

|     |                                                                                                                                                                                                           |     |
|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|
| A.  | Independent Claims 1 And 19 .....                                                                                                                                                                         | 66  |
| 1.  | The “Distal End Of The Inserter” Is <u>Not</u> “Configured To Be Positioned On The Skin...Before Advancement” And Then “Further Configured To Be Removed...After Automatic Retraction of the Sharp” ..... | 66  |
| i.  | Additional Description Of Cote’s Infusion Cannula Inserter .....                                                                                                                                          | 71  |
| ii. | “The Distal End Of [Cote’s] Inserter” Is Not “Further Configured To Be Removed From The Skin Of The User After Automatic Retraction Of The Sharp” [1.15]/[19.19] .....                                    | 80  |
| 2.  | Dr. Fletcher Has Not Shown the Claimed “Housing-Distance” Limitation [19.13] .....                                                                                                                        | 90  |
| i.  | Dr. Fletcher’s Arguments Related To Cote Fail To Establish The Limitation Is Satisfied .....                                                                                                              | 92  |
| ii. | Dr. Fletcher’s Attempts To Recreate The Limitation Based On “Knowledge” .....                                                                                                                             | 95  |
| 3.  | The Combination Does Not Teach An On-Body Unit With The Claimed Data Storage Unit [19.6]/[Claim 4] .....                                                                                                  | 103 |
| 4.  | The Combination Does Not Teach A Fully-Integrated OBU With The Claimed Height Profile [19.14]/[Claim 14] .....                                                                                            | 105 |
| B.  | Dependent Claims .....                                                                                                                                                                                    | 108 |
| 1.  | All Dependent Claims Incorporate Limitations Of Independent Claims 1 And 19.....                                                                                                                          | 108 |
| 2.  | Dependent Claims 3-6, 9-14, and 16-17 Are Not Obvious Because They Incorporate Limitations Of Claim 19 .....                                                                                              | 109 |
| 3.  | The Combination Does Not Disclose A “Second Opening Of The Top Surface” [18.1]/[21.1] .....                                                                                                               | 109 |
| i.  | Dr. Fletcher’s Arguments Related to “OBU Securing” Is Refuted by His Own Cited Art and Admissions .....                                                                                                   | 111 |
| ii. | Dr. Fletcher’s Arguments Related To “Anti-Rotation” .....                                                                                                                                                 | 116 |

|        |                                                                                                    |     |
|--------|----------------------------------------------------------------------------------------------------|-----|
| iii.   | Dr. Fletcher’s Cited “Openings” From Cote .....                                                    | 121 |
| iv.    | The Different Maximum Width Limitation.....                                                        | 122 |
| XI.    | GROUND 2: STAFFORD AND COTE IN VIEW OF SAY (CLAIMS 4, 7-8, 14-15, AND 19-30) .....                 | 123 |
| A.     | “Data Storage Unit”.....                                                                           | 125 |
| B.     | Say Does Not Teach A Fully-Integrated OBU With The Claimed “Height Profile” .....                  | 126 |
| C.     | Say Does Not Disclose The “Sleep Mode Or [] Idle Mode” Or The “Activation” Claim Limitations ..... | 127 |
| D.     | Say Does Not Disclose the “Sensor Hub” Limitations .....                                           | 134 |
| XII.   | GROUND 3: STAFFORD AND COTE IN VIEW OF BRENNEMAN (CLAIMS 18, 21-24, 27, AND 29-30) .....           | 141 |
| XIII.  | GROUND 4: STAFFORD AND COTE IN VIEW OF SHAH (CLAIMS 9, 22-24, 27 AND 29-30) .....                  | 143 |
| XIV.   | GROUND 5: STAFFORD, COTE, AND SAY IN VIEW OF BRENNEMAN (CLAIMS 21-30).....                         | 144 |
| XV.    | GROUND 6: STAFFORD, COTE, AND SAY IN VIEW OF SHAH (CLAIMS 25-26 AND 28) .....                      | 146 |
| XVI.   | GROUND 7: STAFFORD, COTE, AND BRENNEMAN IN VIEW OF SHAH (CLAIMS 22-24, 27, AND 29-30).....         | 148 |
| XVII.  | GROUND 8: STAFFORD, COTE, SAY, AND BRENNEMAN IN VIEW OF SHAH (CLAIMS 25-26, 28).....               | 149 |
| XVIII. | OBJECTIVE INDICIA OF NONOBVIOUSNESS .....                                                          | 150 |
| A.     | Abbott’s FreeStyle Libre Products.....                                                             | 152 |
| B.     | Dexcom’s CGM Products .....                                                                        | 161 |
| C.     | Long-Felt But Unresolved Needs & Failure of Others .....                                           | 165 |
| D.     | Industry Praise And Commercial Success Of Libre .....                                              | 169 |
| XIX.   | SIGNATURE.....                                                                                     | 177 |

I, Karl Leinsing, declare as follows:

## **I. INTRODUCTION**

1. As I explain further below, I have been asked to investigate the patentability of Claims 1-30 of U.S. Patent No. 11,202,591 (the “591 Patent”) on behalf of Abbott Diabetes Care Inc. (“Abbott” or “ADC”).

2. I understand that Petitioner Dexcom Inc. (“Petitioner” or “Dexcom”) filed an *inter partes* review (IPR) petition with the Patent Trial and Appeal Board (“Board”) challenging the patentability of Claims 1-30 (the “Challenged Claims”) of the 591 Patent. I further understand that the Board instituted IPR of the Challenged Claims.

3. In preparing this Declaration, I have reviewed Dexcom’s Petition for IPR and accompanying exhibits including the Declaration of Gary D. Fletcher, Ph.D. the Board’s Institution Decision, the prosecution history of the 591 Patent (Ex. 1002), and the exhibits and documents discussed in this Declaration. In forming my opinions, I relied upon my education, knowledge, and experience and considered the level of ordinary skill in the art as discussed below.

## **II. PROFESSIONAL BACKGROUND AND QUALIFICATIONS**

4. A description of my professional background and qualifications (along with my curriculum vitae) is attached to this Declaration as Appendix A. My CV provides a comprehensive description of my academic and employment history

Declaration of Karl R. Leinsing, MSME, PE

along with papers and books I have published and patents and patent applications of which I am listed as an inventor. I also have listed all of my testimony in the form of deposition, declaration, report, or testimony at trial in the last four years.

5. I earned my Bachelor of Science degree in mechanical engineering from the University of New Hampshire in 1988. In 1995, I earned a Master of Science degree in mechanical engineering from North Carolina A&T State University. I am also licensed as a Professional Engineer in the State of New Hampshire (License No. 11437).

6. I have practiced as an engineer for more than thirty years, researching, developing, designing, and/or evaluating numerous medical devices, including devices related to needle insertion, catheter insertion, intravenous infusion sets/pumps, pen injectors, and auto-injectors. Further, I have extensive experience in product design, notably research, analysis and development to create easy to use, safe, and reliable medical devices. I have lectured in the areas of medical device and manufacturing and on the science of successful product design.

7. From 1979 to 2006, I worked in a variety of engineering roles in various industries, namely in the medical device field. For example, from 1992 to 2002, I worked as a design engineer, working on the development of medical drug infusion products, including, but not limited to, disposable sets and components, syringe pumps, pump systems, valves, insulin injection systems, and catheters. This work

Declaration of Karl R. Leinsing, MSME, PE

was on the behalf of various medical device companies, including IVAC, imed, Eli Lilly, Alaris, Cardinal Health, CareFusion, and Becton Dickinson. From 2002 to 2005, I worked as a Manager of Design Engineering at ONUX Medical, focusing on the development and testing of a needlescopic Nitinol fixation device for abdominal aortic aneurysm (AAA). Further, from 2005 to 2006, I served as the Director of Biomedical Engineering at Mitralign, developing implants required for percutaneous mitral valve repair.

8. In 2006, I founded and have since served as the President of ATech Designs, Inc. ATech Designs is a seven-time award winning medical device product development, design and consulting company. We start with ideas and use thorough engineering practices to design and develop them into high quality, manufacturable, profitable products. Our approach guides us through every step in the development of each of our products, across every aspect of our business. The types of medical products ATech Designs, Inc. has developed include medical disposables, medical devices, laparoscopic devices, anastomotic connectors, catheters, intravenous (IV) devices, mitral valve repair devices, non-invasive surgical instruments, and knitted multi-pole pockets for RF endometrial ablation.

9. As part of my role as President, I have analyzed, developed, and advised on a wide variety of medical devices, including but not limited to glucose sensors including continuous glucose monitoring systems, trachea sensors/alarms, peritoneal

Declaration of Karl R. Leinsing, MSME, PE

dialysis pumps, safety syringes, disinfecting caps, auto-injectors, pen injectors, urinary catheters, insulin pumps, subcutaneous ports, and catheters.

10. I have experience in the diabetes field and have consulted in the development of various types of electrochemical analyte sensors in medical devices as well as sensor delivery systems. My work in this area has included analyzing continuous glucose monitoring systems (“CGMs”) used for patients suffering from diabetes including Abbott’s FreeStyle Libre Products, Dexcom’s CGMs including the G6 as well as Medtronic’s glucose monitoring system, and I have analyzed publications concerning CGM systems as part of other litigation between Abbott and Dexcom. I have also consulted for medical device companies, such as OptiScan, developing bedside glucose monitors, which automatically collected a blood sample and measured plasma glucose concentration levels in patients. I have consulted on the Insulet Omnipod® System. The Omnipod is an automated insulin delivery system involving an inserted infusion cannula that adjusts insulin delivery based on the current glucose levels of the patient to allow for automated management of insulin levels.

11. I also have experience in consulting and developing blood-contacting devices. For example, I am a named inventor on several patents that describe insertion devices for safely inserting catheters into the blood vessel of a patient using

Declaration of Karl R. Leinsing, MSME, PE

an insertion needle that is first extended into the skin and then retracted, leaving the catheter in position.

12. I also have experience with medical devices that use electrodes to ablate tissue for endometrial ablation, tissue sealing/cutting devices, and devices to stimulate muscles, such as pacemakers. I patented a device that makes an electrode array to ablate tissue (U.S. Patent 6,158,250) and worked on other devices (Ethicon EnSeal X1 and G2 and Covidien Sonicision) that clamp, seal (ablate), and cut tissue.

13. My experience with materials used in medical devices is also quite extensive starting with my Master's Thesis on Strength of Medical Thermoplastic Female Luers Exposed to Chemicals.

14. Over my professional career, I have received several awards and honors for my medical product designs. For example, in 2000, my design of a needle-free valve used on infants was published on the cover of LIFE Magazine. Governor James B. Hunt of North Carolina presented me the "Governors New Product" award for the design and development of this needle-free valve, which was produced using completely automated manufacturing technology. In 2000, I also received a design award from the National Society of Professional Engineers for innovative use of engineering principles and materials. In 2008, I was recognized as one of the top medical device professionals in the country by Medical Device and Diagnostic Industry ("MDDI") Magazine.

15. Over the last nearly thirty years, I have participated in numerous medical and engineering organizations. I have been a member of the American Society of Mechanical Engineers for decades. Further, since 2006, I have been on the board of Medical Development Group and the advisory board of Eureka Medical, which are organizations bringing together the best medical professionals. Since 2011, I have served on the Massachusetts Medical Device Industry Council. In 2014, I served as a chairman for the Medical Design and Manufacturing (“MD&M”) Conference.

16. I am the inventor on forty (40) U.S. patents and am currently working on two new medical device inventions. Further, I have published articles in the medical field and given lectures on medical device development and production including on “The Science of Successful Product Design.”

17. My company, ATech Designs, Inc., is being compensated for my time in connection with this matter at my standard consulting rate, which is \$550 per hour, plus reimbursement for actual expenses. My compensation is not dependent in any way upon my opinions or testimony or the outcome of this matter.

18. This Declaration is based on my own personal knowledge, skill, experience, training, and education in my field as well as information I have reviewed in connection with my retention as an expert. I reserve the right to

Declaration of Karl R. Leinsing, MSME, PE

supplement, modify, or revise my statements herein based on additional information that is provided to me in this *inter partes* review.

### **III. UNDERSTANDING OF PATENT LAW STANDARDS**

19. As I am not an attorney, I have been informed about certain aspects of patent law that relate to my opinions.

20. As a preliminary matter, I have been asked to analyze the 591 Patent and the references discussed herein from the perspective of a person of ordinary skill in the art (“POSA”) at the time of the invention. I understand that the 591 Patent claims priority to a provisional application that was filed on February 3, 2009, as well as a patent application dated February 1, 2010. My opinions are based on the perspective of a POSA in the 2009 to 2010 time-frame and do not change if the time frame is 2009 or 2010. I note that, in Paragraph 3 of his Declaration, Dr. Fletcher assumes that the time of the invention is February 2009.

#### **A. Person of Ordinary Skill in the Art**

21. I understand that a “person of ordinary skill in the art” or “POSA” is a hypothetical person who is assumed to be aware of pertinent art including knowledge in the art, thinks along conventional wisdom in the art, and uses ordinary creativity. I understand that this hypothetical person of ordinary skill in the art is considered to have the normal skills and knowledge of a person in the technical field.

22. I reviewed Dr. Fletcher’s definition of the level of ordinary skill in the art in Paragraph 28. Dr. Fletcher states that a POSA “would have had a bachelor’s degree in bioengineering, mechanical engineering, electrical engineering, or a related subject, and one or more years of experience researching, developing, and/or designing insertable medical devices, including, e.g., systems for implanting wearable medical devices such as cannulas, infusion sets, and analyte sensors, or equivalent experience. Less work experience may be compensated by a higher level of education, such as a master’s degree, and vice versa.”

23. While I do not necessarily agree with every aspect of that definition (e.g., the number of years experience and whether the POSA may be part of an interdisciplinary team with others including clinicians), I do not dispute it for purposes of this Declaration as it does not impact my opinions.

**B. Claim Construction**

24. I understand that “claim construction” is the interpretation of the meaning of patent claims. I understand that claims are generally given their ordinary and customary meaning at the time of the invention to a person of ordinary skill in the art.

25. I understand that many sources can be used to assist in understanding the meaning of a claim including the claims themselves, the specification, the

prosecution history, and extrinsic evidence concerning scientific principles, the meaning of technical terms, and the state of the art.

26. I understand that intrinsic evidence includes the claim language, language in other claims of the patent, the specification, and the prosecution history. I understand that the specification informs the proper construction of the claims and may be the most relevant source and best guide to the meaning of a term. I understand that, in some cases, the specification may include a special definition of a claim term by the patent applicant, and, in those cases, the patent applicant's special definition would govern. I further understand that, unless required by the claim language or specification, claims should not be limited to the preferred embodiment(s).

27. I understand that extrinsic evidence consists of all evidence external to the patent and prosecution history including, for example, dictionaries and treatises, or other external documents, and may also be relevant to claim construction. I also understand, however, that it cannot be used to vary the terms of the claims or otherwise contradict the intrinsic record, and that extrinsic evidence is less significant than the intrinsic record in determining the meaning of claim language.

28. In my opinion, the meaning of the claims to a POSA can be understood by referring to the language of the claims of the 591 Patent and do not need any

special redefinition. As I explain below, I apply the plain and ordinary meaning of the claim terms.

**C. Obviousness**

29. I understand that Dexcom asserts that the Challenged Claims are unpatentable as “obvious” in view of certain combinations of prior art references that I discuss herein. I understand that Dexcom does not assert that the Challenged Claims are “anticipated.” In other words, Dexcom does not contend that a single reference discloses all the limitations of the claims. I also understand that Dexcom does not contend a single reference renders the claims obvious.

30. I understand that a claim is unpatentable and invalid for obviousness if the claimed invention, as a whole, would have been obvious to a POSA at the time of the invention. I understand that obviousness is a question of law that requires underlying factual determinations of the level of ordinary skill in the relevant art; the scope and content of the prior art; and the nature of the differences (if any) between the asserted claim and the prior art.

31. I understand that “objective indicia of nonobviousness” are also to be considered when assessing obviousness. These include: the claimed invention’s commercial success; a long-felt need for the claimed invention that was not met by the prior art; evidence that others tried but failed to develop the claimed invention; copying of the invention by others; initial skepticism or disbelief that the invention

would work for its intended purpose before industry acceptance; industry recognition including articles, awards, and other public statements praising the claimed invention's merits, as well as licenses showing industry respect; and other evidence tending to show obviousness or non-obviousness.

32. I further understand that there must be a nexus or tie between the objective indicia of nonobviousness and the claimed invention.

33. I understand that a reference qualifies as prior art for obviousness when it is analogous to the claimed invention. A prior art reference is analogous if it either: (1) is from the same field of the inventor's endeavor, regardless of the problem addressed; or (2) is not from the same field of the inventor's endeavor but is reasonably pertinent to the problem addressed by the claimed invention.

34. I understand that a patent claim comprising several elements is not rendered obvious merely because each of the elements may have been independently known in the prior art. I understand that when prior art references require selective combination to render a patent obvious, there should be some reason to combine the references or modify the prior art to achieve the claimed invention as well as a reasonable expectation of success in doing so. I further understand that it is not enough to show that the prior art references *could* be combined. I understand that the motivation to combine the prior art to arrive at the claimed invention cannot be based in whole or in part on the patent in question.

35. I understand that it is impermissible to use a patent claim, or disclosure of the patent in question, as an instruction manual or template to piece together teachings of the prior art so that the patent claim is rendered obvious. In other words, it is my understanding that one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to invalidate a patent claim. As such, I understand that, even if the collective prior art discloses all the limitations of a patent claim, one should consider whether there is any evidence, other than hindsight, indicating why a POSA would combine the references in such a way as to arrive at the claimed invention.

36. I further understand that an assertion of obviousness must be supported by evidence or articulated explanation. I also understand that conclusory statements alone are insufficient, and any obviousness analysis must be supported by a reasoned explanation to support a conclusion of obviousness.

37. I understand that when determining whether a claimed combination would have been obvious to a POSA, consideration of all relevant facts is required and reasons to combine prior art references cannot be viewed in a vacuum. I understand that a prior art reference may be said to teach away when (1) a POSA would be discouraged by the teachings of one prior art reference from combining a feature or teaching from another prior art reference; (2) a POSA is led in a direction

divergent from the claimed invention that is alleged to be obvious; or (3) the proposed combination would render the result inoperable.

38. In my opinion, Claims 1 through 30 of the 591 Patent are not obvious as set forth below.

#### **IV. SUMMARY OF OPINIONS**

39. The following is a summary of my opinions regarding patentability.

40. In my opinion, Claims 1-30 are not obvious in view of the prior art as identified by Dexcom or its expert, Dr. Gary Fletcher, and no claim is rendered unpatentable based on any of the eight identified grounds of unpatentability. All of Dexcom's combinations are based on combining Stafford in view of Cote, but in my opinion a POSA would not have been motivated to make such a combination, nor has Dr. Fletcher adequately explained why success would be reasonably expected. Moreover, several limitations are missing from the cited prior art. I also disagree with much of Dr. Fletcher's analysis regarding what was "well-known" to POSAs.

41. In my opinion, the cited prior art does not disclose or suggest at least the following limitations:

- **All Claims:** "the distal end of the inserter is configured to be positioned on the skin of the user before advancement of the on-body unit and the sharp" and "the distal end of the inserter is further configured to be

- removed from the skin of the user after automatic retraction of the sharp from within the user” (limitations found in Independent Claims 1 and 19)
- **Claims 3-17 and 19-30:** the “distance between the housing when the on-body unit is in the first position and the housing when the on-body unit is in the second position is greater than a maximum height of the housing” (limitation found in Independent Claim 19 and Dependent Claim 3 (upon which Claims 4-17 depend))
  - **Claims 4 and 19-30:** on-body unit containing “sensor electronics disposed within the housing and coupled with the glucose sensor” wherein the sensor electronics include “a data storage unit” (limitation found in Claim 4 and Independent Claim 19)
  - **Claims 14 and 19-30:** on-body unit housing containing claimed sensor electronics and having “a height profile...less than or equal to approximately 10 millimeters” (limitation found in Claim 14 and Independent Claim 19)
  - **Claims 18 and 21-30:** “a second opening of the [on-body unit housing] top surface” with a maximum width less than the first opening (limitation found in Claim 18 and Claim 21 (upon which Claims 22-30 depend))

- **Claims 7 and 25:** on-body unit with sensor electronics “wherein the sensor electronics are in a sleep mode or an idle mode when the on-body unit is in the first position”
- **Claims 8 and 26:** on-body unit with sensor electronics “wherein the sensor electronics are configured to be activated when the on-body unit is at or near the second position”
- **Claims 15 and 28:** the assembly further comprising “a sensor hub” “wherein the proximal sensor portion is engaged with the sensor hub”

42. In particular, in my opinion, Claims 1-6, 9-14, 16-24, 27, and 29-30 would not have been obvious to a person of ordinary skill in the art over Stafford (Ex. 1004) in view of Cote (Ex. 1005) (Ground 1).

43. Claims 4, 7-8, 15, 19-30 would not have been obvious to a person of ordinary skill in the art over Stafford (Ex. 1004) and Cote (Ex. 1005) in further view of Say (Ex. 1008) (Ground 2).

44. Claims 18, 21-24, 27, 29-30 would not have been obvious to a person of ordinary skill in the art over Stafford (Ex. 1004) and Cote (Ex. 1005) in further view of Brenneman (Ex. 1040) (Ground 3).

45. Claims 9, 22-24, 27, 29-30 would not have been obvious to a person of ordinary skill in the art over Stafford (Ex. 1004) and Cote (Ex. 1005) in further view of Shah (Ex. 1006) (Ground 4).

46. Claims 21-30 would not have been obvious to a person of ordinary skill in the art over Stafford (Ex. 1004), Cote (Ex. 1005), and Say (Ex. 1008) in further view of Brenneman (Ex. 1040) (Ground 5).

47. Claims 25-26, 28 would not have been obvious to a person of ordinary skill in the art over Stafford (Ex. 1004), Cote (Ex. 1005), and Say (Ex. 1008) in further view of Shah (Ex. 1006) (Ground 6).

48. Claims 22-24, 27, 29-30 would not have been obvious to a person of ordinary skill in the art over Stafford (Ex. 1004), Cote (Ex. 1005), and Brenneman (Ex. 1040) in further view of Shah (Ex. 1006) (Ground 7).

49. Claims 25-26, 28 would not have been obvious to a person of ordinary skill in the art over Stafford (Ex. 1004), Cote (Ex. 1005), Say (Ex. 1008), and Brenneman (Ex. 1040) in further view of Shah (Ex. 1006) (Ground 8).

50. Additional opinions are contained in this Declaration.

## **V. BACKGROUND OF CONTINUOUS GLUCOSE MONITORING SYSTEMS AND THE ASSERTED PRIOR ART**

### **A. Diabetes and Continuous Glucose Monitoring Systems**

51. As I explained, I have experience working on medical devices involving monitoring blood glucose as well as insulin delivery. Monitoring levels of blood sugar or glucose is important for people with diabetes. It is well understood that blood glucose levels that are either too high or too low can lead to serious health issues and complications, including hyperglycemic or hypoglycemic episodes, heart

attack, stroke, kidney failure, blindness, amputation, and death. To ensure that the blood glucose levels are within their proper range, blood glucose levels are monitored, so people with diabetes or their caretakers can take appropriate action if their glucose levels are too high or too low. For example, if blood glucose levels are too high, insulin can be administered to help control glucose levels. (See, e.g., Ex. 2013, Gonzales *et al*, *The Progress of Glucose Monitoring—A Review of Invasive to Minimally and Non-Invasive Techniques, Devices and Sensors*, SENSORS 2019, vol. 19, Art. 800, pp. 1-45 (Feb. 15, 2019) (“Gonzales”), p. 1).

52. One of the traditional ways for a person with diabetes, outside of the hospital setting, to monitor their own glucose levels was to use the fingerstick method. With the fingerstick method, an individual draws blood from their fingertip using a lancet and uses a blood glucose meter and a specialized test strip to determine their blood glucose levels at that particular time. Individuals often needed to repeat this procedure several times a day. This method has several disadvantages. For example, it does not provide continuous glucose data, but rather only provides blood glucose information intermittently and single moments in time. Additionally, it requires the patient to stick their finger to extract blood several times a day, which can be painful and undesirable. This leads to individuals not measuring their blood glucose levels as frequently as they should to ensure consistent glucose control. (See, e.g, Ex. 2011, van den Boom *et al*, *Changes In the Utilization of Blood Glucose Test*

*Strips Among Patients Using Intermittent-Scanning Continuous Glucose Monitoring in Germany*, 22 DIABETES OBES. METAB. 6:922–28 (Jun. 2020), (“van den Boom”), p. 923; Ex. 2013, Gonzales, p. 1.)

53. To deal with many of these concerns, continuous glucose monitoring systems (“CGMs”) were developed. CGMs continuously and automatically detect a user’s glucose levels. Glucose levels are measured using a glucose sensor that is typically inserted into the person under the skin using a dedicated introducer or inserter (sometimes referred to as an applicator).

54. As the 591 Patent explains, glucose sensors for most CGMs are electrochemical. They include an enzyme, such as glucose oxidase, that reacts with glucose and oxygen in the interstitial fluid under the surface of the skin, causing an electrical current to develop on the sensor. (Ex. 1001 at 5:36-39, 13:6-12.) Sensor electronics sample the electrical current on the sensor and convert the current into digital data, which is then then converted into glucose concentration values via a calibration algorithm. (*Id.* at 11:53-60.) The glucose concentration values are then displayed to the user, typically using a dedicated reader or a smartphone application.

55. As I explain further below, early CGMs suffered from a number of issues. Early CGM products required users to regularly calibrate the CGM readings using frequent fingersticks and blood glucose meters. CGMs were also complex and complicated electromechanical devices. Some used costly multi-component

systems, for example, with separate sensors and transmitters where the sensor would be discarded at the end of a sensor session while the transmitter was reused with a new sensor. The CGMs also often required use of intimidating and painful inserters. CGMs were often bulky because, e.g., of the need to house numerous sensor electronic components such as a power source and wireless communication circuitry. Manufacturing designs that were cost-effective such that the CGMs could be accessible to the average individual was also a challenge. (Ex. 2012, Hermanides *et al*, *Current Application of Continuous Glucose Monitoring in the Treatment of Diabetes: Pros and Cons*, DIABETES CARE, Vol. 34 Supp. 2, S197–S201 (May 2011), (“Hermanides”), p. S199; Ex. 2013, Gonzales, p. 6.)

56. For example, the 2011 Hermanides article discusses some of the advantages and disadvantages of earlier CGM systems. (Ex. 2012 at S197-S200.) Among the disadvantages or “cons” the article identifies is that “many patients do not tolerate CGM devices” and the “cost of the CGM devices,” which is considered a “major con.” (*Id.* at S199.)

57. As I discuss further below, another challenge of designing CGMs is appropriately delivering the fragile electrochemical sensors used with them. It was therefore a challenge for POSAs to develop an inserter that could accurately and reliably position the sensor within the user without damaging the sensor or causing tissue trauma, both of which can compromise its ability to provide accurate and

consistent glucose data. (See, e.g., Ex. 2043, Gough *et al*, *Development of the Implantable Glucose Sensor – What Are the Prospects and Why Is It Taking So Long?*, *Diabetes*, Vol. 44, 1005-1009 (Sept. 1995), (“Gough”) at 1007-1008; Ex. 2044, Joseph *et al*, *Glucose Sensing in the Subcutaneous Tissue: Attempting to Correlate the Immune Response with Continuous Glucose Monitoring Accuracy*, *Diabetes, Technology, & Therapeutics*, Vol. 22, No. 5, 321-324 (2018), (“Joseph”) at 321-322.)

58. The industry worked for years on developing a CGM that provided an all-in-one smart and ultra-low profile solution that was reliable and simple enough for users while remaining cost-effective and accessible to the average person. However, despite desiring such a device, developing one that achieved these goals while simultaneously ensuring that the sensor is placed accurately (e.g., straight and without any wobble) and without causing tissue trauma to ensure sensor accuracy was challenging. Indeed, one of the main challenges that medical device engineers face is developing products that are easy-to-use and cost-effective to manufacture while maintaining effectiveness of the device. That is especially true when the medical device is for use by laypeople and not trained medical staff.

**B. Continuous Glucose Monitoring System Prior Art Relied Upon By Dexcom**

59. In this section, I generally describe each of the four main references relating to CGMs that Dexcom and Dr. Fletcher have relied upon in their grounds (Say, Shah, Brenneman, and Stafford.)

**1. U.S. Patent 6,175,752 to Say**

60. U.S. Patent Number 6,175,752 to Say (“Say”), titled “Analyte Monitoring Device and Methods of Use,” was issued on January 16, 2001, to Therasense, Inc., a predecessor of Abbott. It is my understanding that the Say patent was considered by the Patent Office during prosecution of the 591 Patent. (Ex. 1001 at 5.) As acknowledged by Dr. Fletcher, Say generally describes a “two-part” CGM system where the user separately inserts the sensor and then manually connects the electronics after insertion. (Ex. 1008 at 27:47-57, 28:44-60; Ex. 2036 at 77:3-8.) The sensor is not pre-coupled with the sensor electronics.

61. Say describes multiple embodiments of its multi-component system. In one embodiment, the user manually adheres a “mounting unit 77” to the skin. The glucose “sensor 42” is not coupled with any sensor electronics within the control unit, but is separately delivered via an “insertion gun” (e.g., 200). (*Id.* at 3:6-16, 28:44-60.) The insertion gun includes an “insertion device 120” (such as a sharp) preloaded with the sensor and delivers the sensor via an opening in the mounting unit. (*Id.* at 27:42-51, 28:44-60, 32:13-15, 32:53-59, 33:7-12, 34:5-15, 3:6-16.) An

example of the insertion gun 200 can be seen in Figure 26 of Say, reproduced and annotated below.

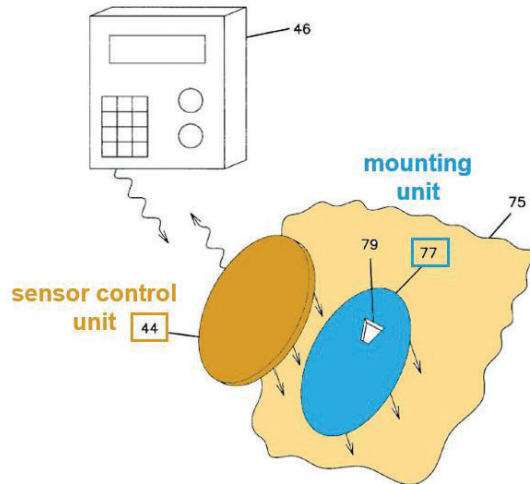
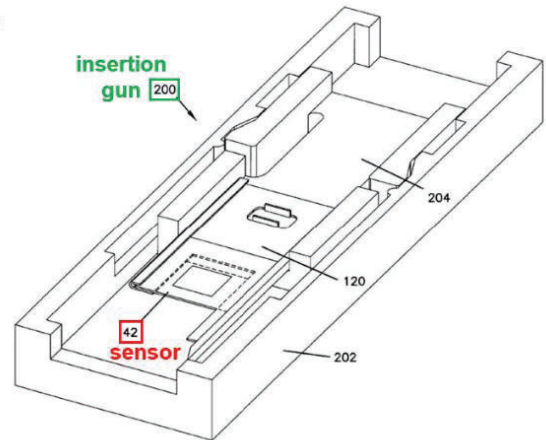


FIG. 26



62. After the sensor is implanted in the user, the user then manually attaches a “sensor control unit 44” atop the mounting unit, connecting the sensor control unit to the sensor. (*Id.* at 3:6-16, 32:6-14, 36:25-38.) This can be seen, for example, in the annotated version of Say’s Figure 17, reproduced above. Once connected, the sensor can communicate with the electronics and transmit information about the user’s glucose levels. (*Id.* at 36:41-64.) Notably, because Say’s sensor is not pre-coupled with its electronics before sensor insertion, Say offers no explanation of how to activate a sensor control unit that includes such a sensor.

**2. U.S. Publication 2007/0073129 to Shah**

63. U.S. Publication 2007/0073129 to Shah (“Shah”), titled “Flexible Sensor Apparatus,” was published on March 29, 2007. It is my understanding that Shah was considered by the Patent Office during prosecution of the 591 Patent. (Ex. 1001 at 9.) Shah describes several embodiments of a multi-component system including ones in which the sensor is delivered by an inserter into a control unit attached to the user’s skin. (Ex. 1006 at [0007].)

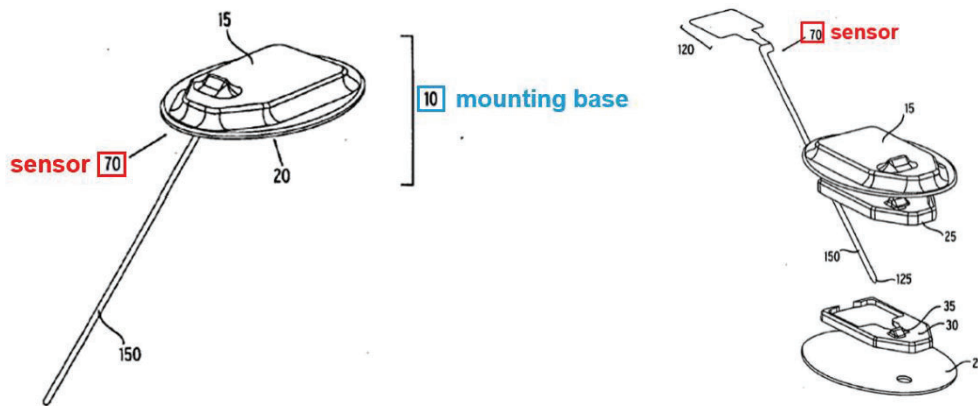
64. In discussing the field of the invention, Shah recognizes that “thin film sensors hold significant promise in patient monitoring applications,” but recognizes that such sensors “have been difficult to place transcutaneously with the sensor electrodes in direct contact with patient extracellular fluid.” (Ex. 1006 at [0005].) Shah acknowledges that, “because these sensor systems utilize a component that is positioned transcutaneously, it is very important that the [placement] site be stable.”<sup>1</sup> (*Id.* at [0006].) Shah explains that “[m]any [prior] glucose sensors generally utilize complex structures to mount and hold the sensor set in place on the patient’s skin.” (*Id.*) Shah’s solution was “an improved sensor mounting base adapted to provide quick and easy transcutaneous placement of the film sensor on a patient comfortably

---

<sup>1</sup> Unless noted, all emphasis and colored annotations to drawings herein have been added.

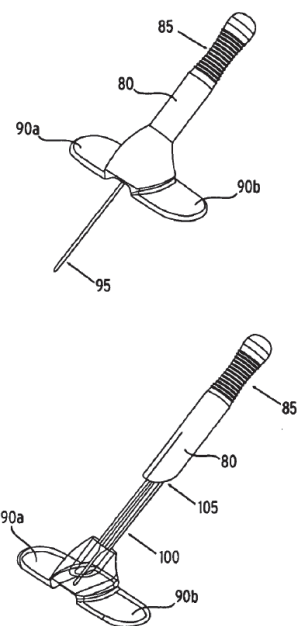
and with sufficient stability with which to hold the sensor electrodes in direct contact with patient extracellular fluid.” (*Id.* at [0007].)

65. One embodiment in Shah describes using a “subcutaneous insertion set” with a “flexible mounting base [10] for placing the sensor [70] at a selected site within the body of a patient.” (*Id.* at [0012].) The mounting base 10 is manually pressed onto the user’s skin. (*Id.* at [0013].)



66. The user employs an insertion set, which does not deliver any on-body unit, but rather includes an insertion needle (e.g., 95 in Fig. 5A), that pierces the skin and places the sensor. (*Id.*) Shah describes mechanisms to “stabilize the needle and substantially ensure[] safe, stable entry and exit for the needle.” (*Id.* at [0010], [0042]-[0043].) This includes “wings [90a, 90b]....used to hold the...needle...stable

Fig. 5A





time. To prevent these accidental sticks, Shah teaches that in some embodiments, “[w]hen the insertion needle is withdrawn, a protective sheath (not shown) contained in the flexible mounting base is dislodged and covers the needle tip as the needle is separated from the flexible mounting base.” (*Id.*).

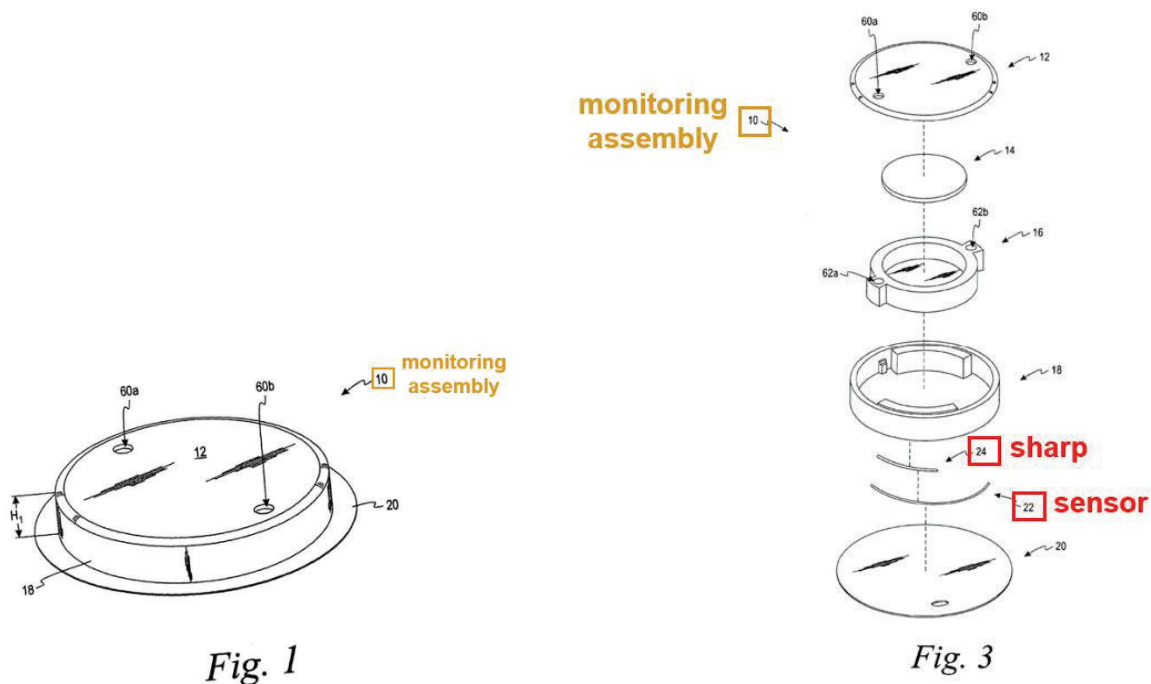
### **3. WO Publication 2008/115409 to Brenneman**

69. WIPO Publication 2008/115409 to Brenneman (“Brenneman”), titled “Continuous Analyte Monitoring Assembly and Method of Forming the Same,” was published on September 25, 2008. It is my understanding that Brenneman was considered by the Patent Office during prosecution of the 591 Patent. (Ex. 1001 at 14.) Brenneman recognizes that, despite years of development, there were still significant problems surrounding existing CGM devices. (Ex. 1040 at [003].)

70. Brenneman describes another CGM variation, focusing on “challenges” in “minimiz[ing] the number of acts to (a) attach the sensor/electronics to the skin and (b) insert the implantable sensor....” (*Id.*) Brenneman was specifically concerned with “control[ling] location (especially depth) of the sensor in the skin.” (*Id.*) Brenneman explains that controlling sensor delivery “is especially important if the user is inserting the implantable sensor at home without any assistance.” (*Id.* at [0040].)

71. Brenneman’s solution employs an inserter that uses “simple rotary motion” to deliver a “monitoring assembly 10” with a “sensor 22” and sensor

electronics. (*Id.* at [0026], [0041], [0036], [0044].) A sharp-ended “cannula 24,” which extends into a recess “formed in a bottom 18a of the disposable housing 18,” “assists in inserting the implantable sensor 22 into the body” and “in controlling the depth of the placement.” (*Id.* at [0036].) These concepts can be seen in, for example, Figures 1 and 3 from Brenneman, reproduced and annotated below.

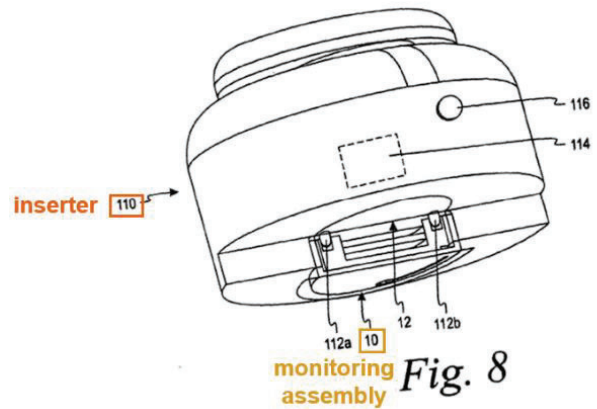


(*Id.* at Figs. 1, 3.)

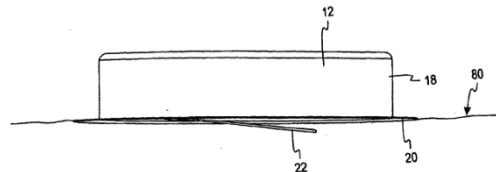
72. Brenneman’s “insertor 110” is loaded with the “monitoring assembly 10” at its distal end. (*Id.* at [0041]-[0042].) An example of the insertor 110 can be seen in Figure 8 of Brenneman, reproduced and annotated to the right. The insertor is “cocked” by rotating a plunger and then “pressed hard” against the skin. (*Id.* at [0044].) The monitoring assembly is rotated on to the skin with sufficient force such that the sensor is driven into the user at an angle. (*Id.* at [0041], [0044].) Specifically,

Declaration of Karl R. Leinsing, MSME, PE

“[t]he inserter 110 is typically spring-loaded such [that] the [continuous analyte monitoring] assembly... [is] rotated at a sufficient force to penetrate and drive the sensor 22 into the skin.” (*Id.* at [0044].) The monitoring assembly 10 is not held fully inside the inserter. It also does not advance from a retracted, or proximal, position to an advanced, or distal position. Instead, the assembly 10 remains at the distal end of the inserter, and the sensor is driven into the skin. (*Id.*)



73. Figure 7 of Brenneman, reproduced below, depicts the assembly with the “sensor 22” implanted into the skin 80.



(*Id.* at Fig. 7.)

74. Brenneman teaches that “[t]he rotary motion of the continuous analyte monitoring assembly 10 is desirable because it results in a smaller footprint for the [assembly].” (*Id.* at [0047].) Moreover, “rotary motion is desirable because an angle

Declaration of Karl R. Leinsing, MSME, PE

is used with the insertion of the sensor, which results in improved depth control in the locating of the implantable sensor.” (*Id.*)

75. As will be further discussed, Dr. Fletcher, in some of his proposed combinations, relies on Brenneman’s disclosure of “apertures 60a, 60b.” (*See, e.g.*, Ex. 1003 at ¶145.) However, Dr. Fletcher otherwise never considers Brenneman’s insertion assembly (including the disclosed “desirable” features) for his combinations though it teaches delivery of an on-body unit with a sensor.

#### **4. U.S. Publication 2008/0097246 to Stafford**

76. U.S. Publication 2008/0097246 to Stafford (“Stafford”), titled Method and System for Providing an Integrated Analyte Sensor Insertion Device and Data Processing Unit,” was published on April 24, 2008. (Ex. 1004.) The assignee is Abbott Diabetes Care, Inc. It is my understanding that Stafford was considered by the Patent Office during prosecution of the 591 Patent. (Ex. 1001 at 10.) As certain sensor delivery mechanisms became more complex, others, such as Stafford, focused on simplifying the design of the overall assembly. (*See, e.g.*, Ex. 1004 at [0005], [0045].)

77. Stafford recognizes that it was typical for “a separate deployment mechanism such as a sensor inserter or introducer” to be used to “pierce through the skin of the patient and substantially concurrently guide the sensor through the patient’s skin....” (*Id.* at [0002].) While Stafford recognizes that “it is important to

properly insert the sensor through the patient's skin and securely retain [it]," Stafford observes that the "inserter is typically used only during the sensor insertion process" and "the inserter and the introducer are [then] discarded." (*Id.* at [0004], [0003].)

78. The inventor, Gary Stafford, was aware of the availability of more complex inserters. Dr. Fletcher cites to a different Stafford publication (Ex. 1042), published one month after the Stafford publication discussed here, that describes "variable speed sensor insertion devices" that can "slow down" or "speed up" to "control the velocity" of sensor insertion. (Ex. 1003 at ¶115; Ex. 1042 at [0004].)

79. Recognizing the desire to simplify the design, Stafford's solution in the Stafford publication at issue described a "simple, easy to handle and accurate sensor introduction and retention mechanism" that "minimizes the number of components ... and which also reduces the number of required steps to properly and accurately position the analyte sensor ...." (Ex. 1004 at [0005], [0045].) Stafford's invention is thus "an integrated analyte sensor delivery and data processing unit" with an "introducer removably coupled to the housing" that "provides simple, easy to use analyte sensor placement...without a direct line of sight visual aid, and also, which may be easily performed without the use of both hands." (*Id.* at [0018], [0006].) Thus, Stafford's invention is "configured to integrate an analyte sensor, a sensor introducer mechanism, and a data processing device into a single assembly which []

may be disposable, and which allows for simple and accurate sensor deployment to the desired subcutaneous position.” (*Id.* at [0007].)

80. In Stafford’s simple design, the integrated “assembly 100” includes a “data processing unit 101,” an “introducer” 102 comprising a needle, and a “sensor 106” housed within the needle. (*Id.* at [0019], [0023].) Additionally, a removable “guard segment 104” covers the needle and protects the user from inadvertent needle sticks and maintains the lower portion of the sensor and introducer “in a substantially sterile environment prior to subcutaneous placement through the surface of the subject such as the skin of the patient.” (*Id.* at [0022].) These can be seen in Figures 1 and 2 from Stafford, reproduced to the right.

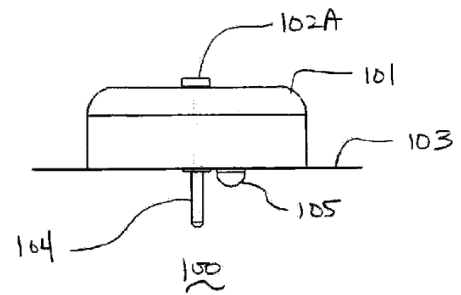


FIGURE 1

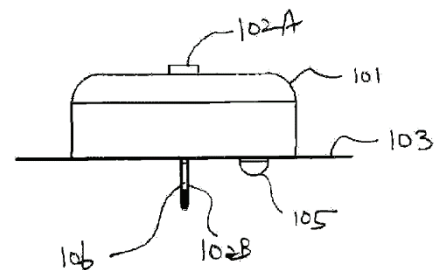


FIGURE 2

81. Stafford teaches that the user removes the needle guard 104, places the assembly on the skin, and applies force to unit 101 such that the introducer (“lower portion 102B”) pierces the skin. (*Id.* at [0024].) The user then pulls the top of the introducer (102A) away, detaching it from the unit. The unit is retained on the skin by an “adhesive patch 103” with

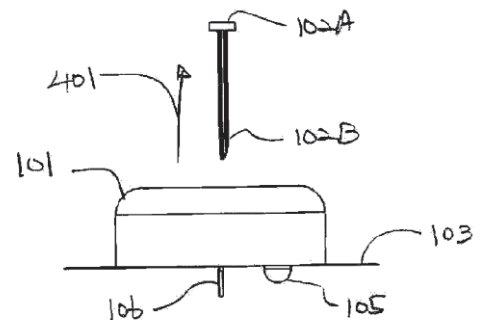


FIGURE 4A

the sensor accurately positioned under the skin. (*Id.* at [0024], [0019].) This can be seen in Figure 4A, reproduced to the right. As I discuss later, it was understood that the needle guard could be replaced back on the needle before disposal. The sensor can then sample and transmit the user's analyte levels. (*Id.* at [0036].)

82. As Stafford repeatedly states, a fundamental aspect of Stafford's design is that it is a small, one-handed, simple, and easy-to-use standalone device that is not intended to be used with a separate inserter:

[T]he integrated analyte sensor and data processing unit assembly is configured to integrate an analyte sensor, a sensor introducer mechanism, and a data processing device into a single disposable assembly which allows for simple and accurate sensor deployment to the desired subcutaneous position, and which may be used with one hand by the user or patient. Accordingly, a separate sensor introducing device such as a separate insertion gun or a separate sensor delivery mechanism is not necessary.

(*Id.* at [0044], [0028].)

83. Stafford emphasizes that its simplified design achieves numerous advantages:

Furthermore, by integrating the analyte sensor, the introducer as well as the data processing unit into a single assembly, it is possible to have a smaller profile, simpler use application with less packaging thereby achieving cost reduction in manufacturing. Indeed, by reducing the number of components needed for sensor placement, within the scope

of the present invention, other benefits such as reduction in material cost, weight, packaging, and associated handling and disposal may be achieved.

(*Id.* at [0045].)

**C. Cote’s Reorientable Infusion Set And Cannula Delivery System**

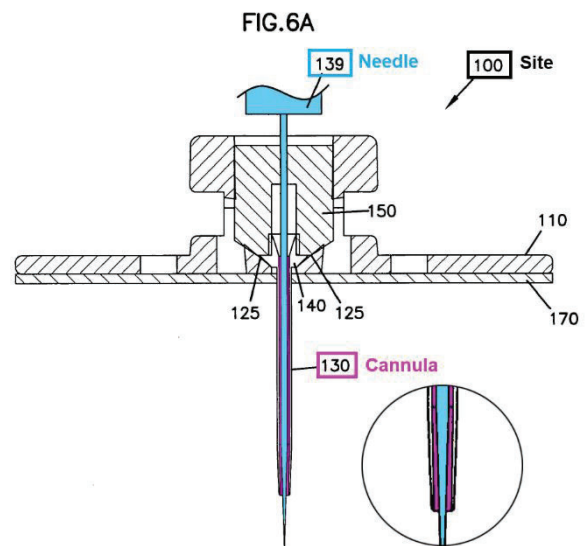
84. In addition to prior art relating to earlier CGM devices, Dr. Fletcher, in his proposed obviousness combinations, has also relied on Cote as a secondary reference for all of his grounds. U.S. Publication 2005/0101932 to Cote (“Cote”), titled “Subcutaneous Infusion Device and Device for Insertion of a Cannula of an Infusion Device and Method,” was published on May 12, 2005. It is my understanding that a counterpart of Cote was considered by the Patent Office during prosecution of the 591 Patent. (Institution Decision at 11.)

85. Cote describes a multi-component infusion system that uses a “device” to subcutaneously introduce an infusion “site” that includes an infusion cannula to a user. (Ex. 1005 at Abstract.) Once the site is placed, an infusion set is attached it and delivers medicaments through the cannula. (*Id.* at Abstract, [0001]-[0002].) Cote does not mention using its “device” to insert analyte sensors nor does it address challenges with analyte sensor delivery. (Ex. 2036 at 69:17-70:13.)

86. Instead, Cote focuses on problems with existing infusion systems. For example, Cote states that “once the infusion device is placed on the skin, there is typically no way to reorient the device...or to remove the [infusion] tubing from the

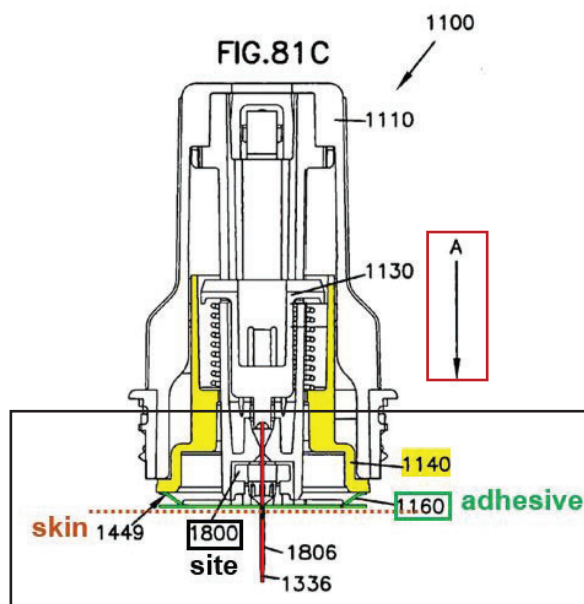
body without removing the cannula from the skin.” (*Id.* at [0003].) Cote also identifies “[o]ther issues of concern,” including that “patients may have difficulty loading the infusion device into the insertion device.” (*Id.* at [0006].) Cote’s solution is an infusion set that can “be oriented at multiple rotational orientations with respect to the [cannula] site, and can preferably be coupled and uncoupled with the site multiple times.” (*Id.* at Abstract, [0010].)

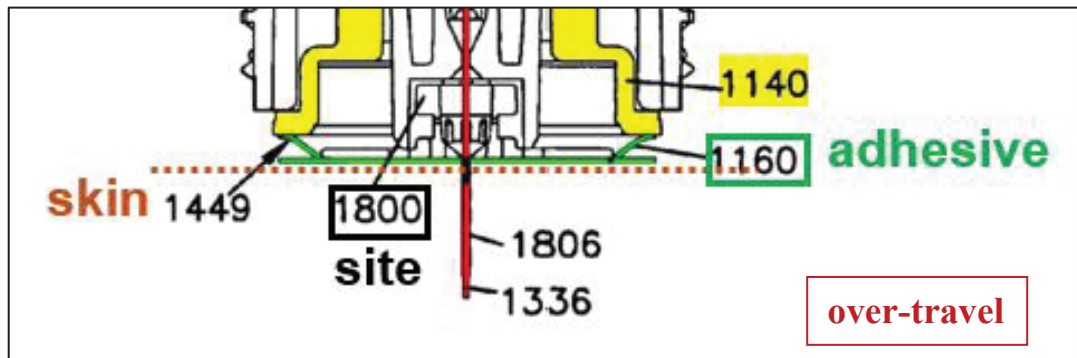
87. Specifically, Cote describes a “site 100” that includes a “cannula 130,” which surrounds a needle (e.g., 139) that facilitates the cannula’s subcutaneous delivery. (*Id.* at [0134], [0184].) Figure 6A, reproduced and annotated to the right (with an added inset), depicts the distal end of the infusion cannula (pink) surrounding the delivery needle (blue). (*Id.* at [0143].) “Diaphragm 150” functions as “a septum or seal that allows a needle to access the internal portion of the septum to deliver a substance...from an infusion device...to the cannula.” (*Id.* at [0141], [0144].) “Adhesive portion 170” is ultimately attached to the “base 110” of the site, allowing the site to adhere to skin. (*Id.* at [0134], [0150], [Fig. 79A].)



88. The patient uses a “device” (e.g., 1100), in which the “site 1800” is pre-loaded, to subcutaneously introduce the “cannula 1806.” (*Id.* at [0179], [0202], [0205]; Fig.81B, Fig.81C.) The patient manually “applies pressure” to the upper housing of the device 1100 “to move the housing 1110 and associated structures including... needle 1336 and site 1800[] in a direction A...toward the skin 1900.” (*Id.* at [0207].)

89. As will be explained in detail in Section X.A.1, unlike the sensor inserter of the claimed invention, Cote’s inserter is configured to have an “over-travel” feature that requires its distal end (sleeve 1140, colored yellow in the annotated figure below) to move away from the skin after the cannula is delivered but before its needle 1336 is retracted from within the user. The “over-travel” feature can be seen in Figure 81C, reproduced and annotated here.





90. Cote explains that “[t]his ‘over-travel’ assures that the adhesive portion 1160 [green] is properly sheared away from the... sleeve 1140 [yellow] and allows for the coupling of the site 1800 to the adhesive portion.” (*Id.* at [0209]-[0210].)

91. Importantly, the over-travel is also necessary to initiate needle retraction from within the user. *As I explain detail in Section X.A.1*, rather than having its needle retract while the distal end of its inserter is on the skin, Cote is configured so that the needle retracts from within the user while the inserter’s distal end is off the skin. (*Id.* at [0211], [0203].)

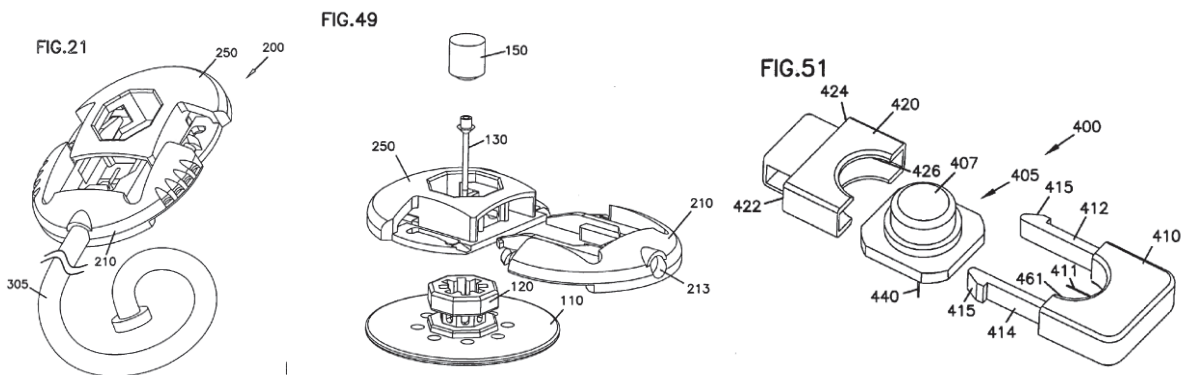
92. Once Cote’s infusion site is on the skin and the inserter has been removed, the user couples a separate infusion “set 200” to the site to allow for delivery of the desired medicament into the cannula. (*Id.* at [0153].) As discussed, a key aspect of Cote’s design are features in the site and infusion set that allow the set to be locked and unlocked from the site and reoriented in numerous positions. (*See, e.g., id.* at Abstract, [0154]-[0171].) These configurations allow the user to easily

adjust the infusion pump relative to the fixed-in-place site, which is not relevant to CGM systems.

93. For example, in one Cote embodiment, the “set 200 can be oriented and fixed in eight different positions with respect to the site 100.” (*Id.* at [0171].) In yet another embodiment, “the set can be oriented at an infinite number of rotation positions with respect to the site [] as desired...[and] can be rotated relative to the site [] without requiring that the set be completely removed from the site.” (*Id.* at [0177].)

94. This multi-orientation benefit described in Cote is relevant to systems such as infusions sets where there are two separate components that must connect and interact (like the site and infusion set in Cote). However, this feature is not relevant to glucose monitoring systems utilizing an all-in-one on-body unit where all the relevant components are integrated into a single unit.

95. Several embodiments of Cote’s reorientable infusion sets are reproduced below.



(*Id.* at Figs. 21, 49, 51.)

## **VI. THE 591 PATENT**

96. The 591 Patent is titled “Analyte Sensor and Apparatus for Insertion of the Sensor.” The 591 Patent was issued on December 21, 2021, and claims priority to a provisional patent application dated February 3, 2009, as I mentioned above. The 591 Patent is assigned to Abbott Diabetes Care Inc.

97. As I discuss below, the 591 Patent generally relates to an insertion assembly comprising an inserter designed to position and carefully but easily insert an on-body unit (“OBU”), which houses sensor electronics that are connected to a glucose sensor. (*See, e.g.*, Ex. 1001 at Claim 1.)

98. The 591 Patent recognized the long-existing “need for an easy-to-use, simple insertion assembly which is reliable, minimizes pain, and is easy to use.” (Ex. 1001 at 2:8-12.) The specification describes numerous ways to solve problems with existing CGMs resulting in a cost-effective, convenient, and reliable all-in-one solution that was accessible to the average person.

99. More specifically, the 591 Patent describes and claims “an insertion assembly,” which includes a smart and low-profile OBU that attaches to the patient’s skin as well as an “inserter” used to deliver the OBU. (*Id.* at 14:54-57, 16:30-19:40, 4:17-26, 15:1-3.) Examples of the OBU can be seen in Figures 7 and 8, reproduced to the right. The “data processing unit 12” of the OBU (e.g., 16) is designed to have

Declaration of Karl R. Leinsing, MSME, PE

a “reduced height” profile (i.e., ‘Z’-dimension) yet comprise a “sensor 14” capable of continuously monitoring the patient’s glucose levels and its related electronics (a processor, a power source, an analog interface, a data storage unit, and wireless communication circuitry configured to communicate the glucose data to an outside source). (*Id.* at 11:52-62; 14:1-27; 17:59-63.) And, unlike many prior art CGMs, users do not need to insert the sensor and then

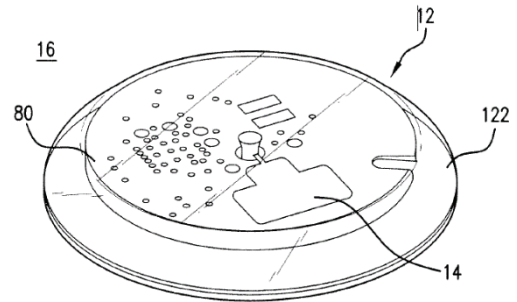


FIG. 7

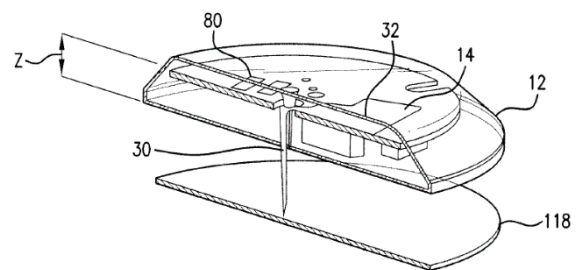


FIG. 8

manually connect the electronics; rather, the sensor electronics are disposed in the OBU housing and coupled with the glucose sensor. (*Id.* at 2:34-36, 14:28-41.)

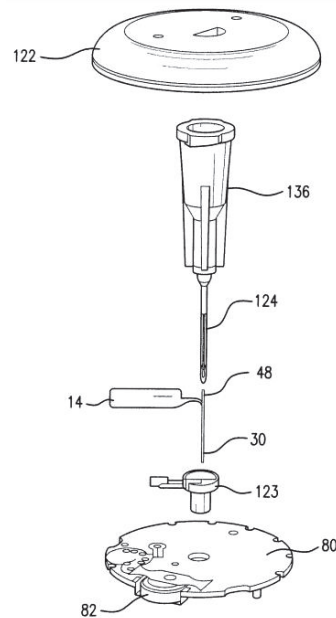
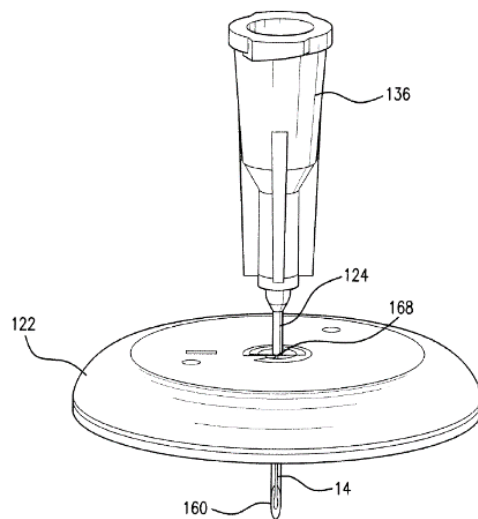
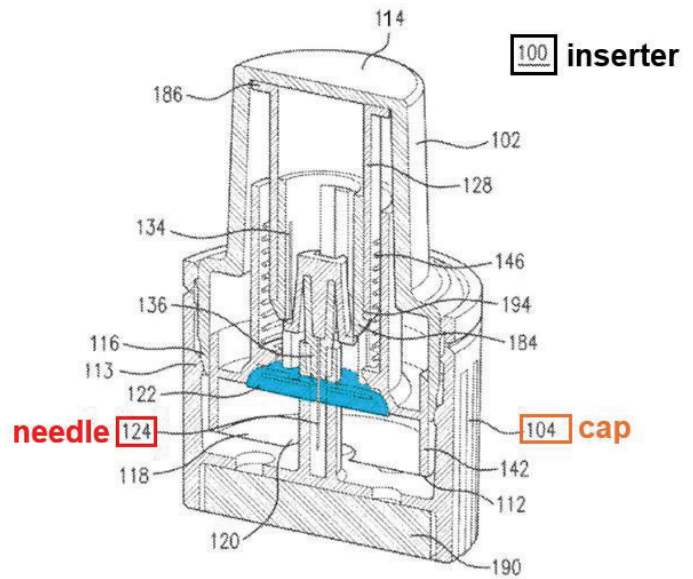
100. The 591 Patent describes several ways to construct this fully integrated, compact OBU, including descriptions on how to bend and position the sensor so that its proximal portion can be connected to the sensor electronics and positioned within the OBU. (*See, e.g., id.* at 12:34-36, 14:28-41, 17:66-18:7.)

101. Users are able to deliver the OBU using an inserter (e.g., “inserter 100”). (*Id.* at 16:30-19:40, 3:51-60, 4:17-26, 15:1-6.) The inserter is configured to include an automatically retractable sharp (e.g., “needle 124”). (*Id.* at 15:49-54, 17:20-22, 19:16-19.) A distal portion of sensor 14 is positioned within the sharp. (*Id.*

Declaration of Karl R. Leinsing, MSME, PE

at 17:54-56; 12:31-34.) As shown in, for example, Figure 10, annotated and reproduced on the right, the sharp 124 extends linearly through the OBU housing 122 (including the electronics). (*Id.* at 17:54-56, *see also* Fig. 22.)

102. Figure 22, reproduced below, depicts the sharp 124, which carries sensor 14, extending through the OBU housing 122, including an opening of the top surface of the OBU housing. Figure 23, also reproduced below, is a perspective view of these parts separated, also illustrating this concept.



103. The inserter 100 may also include a “removable distal cap 104” that serves to “maintain a sterile, contaminant-free environment for the medical device and sharp housed therein.” (*Id.* at 16:31-34, 16:60-67.) The cap 104, which can include a boss 125, will also stabilize the needle comprising the sensor and protect the user from premature exposure to the sharp. (*Id.* at 16:52-54.)

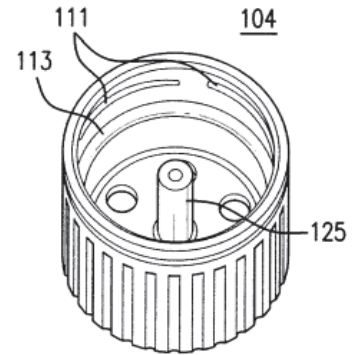
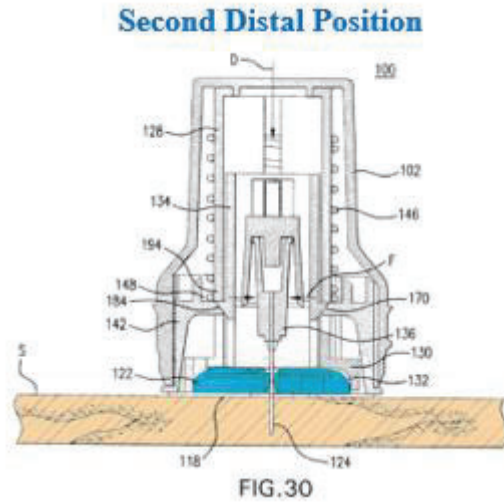
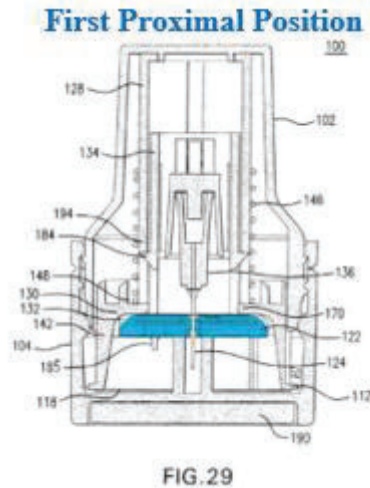


FIG. 12

104

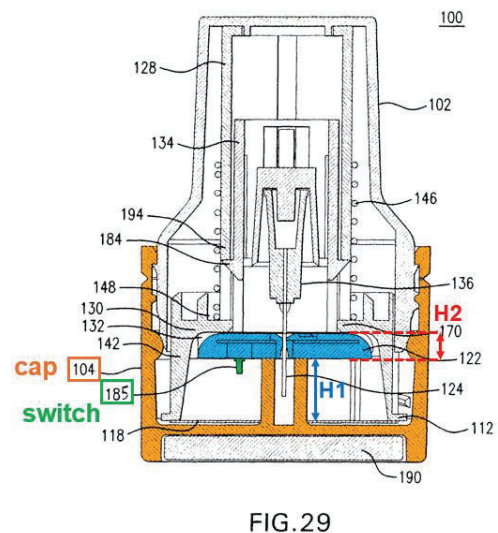
104. In use, the distal end of the inserter is positioned on the patient’s skin (S). (*Id.* at 16:37-43, 17:1-4.) As shown in the annotated figures below, the inserter is configured to advance the OBU and sharp in a linear direction from a first, proximal position within the inserter (Figure 29, where both the OBU and needle are located away from the distal end) to a second, distal position on the skin (Figure 30). (*Id.* at 16:41-43, 19:1-22.) This configuration allows the sharp to pierce the skin S and deliver and secure the OBU to the patient. (*Id.*) As discussed below (and as shown in the figures), while moving from the first to the second position, the OBU travels a distance greater than its height.



(*Id.* at Figs. 29, 30.)

105. After the OBU is advanced, the inserter then automatically retracts the sharp from within the user. (*Id.* at 15:60-16:7, 16:20-28, 19:26-33.) With the needle out of the user, the inserter can then be removed from the skin, leaving the OBU on the skin and the sensor inserted in the user. (*Id.* at 15:3-6, 19:16-33.)

106. The sensor electronic may be in in sleep or idle mode until activation, preserving battery life. (*Id.* at 19:41-57.) Many novel examples of activating the sensor electronics are discussed. (*Id.* at Figs. 32-43, 19:41-22:35.) In one example, plunger switch 185 activates the electronics when the switch engages the patient's skin when the OBU is in the second or distal position. (*Id.* at 19:58-20:14.) As discussed above (*see, e.g.*, Figure 29 to the right), the OBU and sharp are disposed entirely within



the inserter in the first position and the OBU housing travels a distance greater than its maximum height to reach the second distal position. As I discuss below, this can prevent, for example, inadvertent activation of the plunger switch or other electronics mechanisms activated upon sensor insertion. (*Id.*)

107. The **Challenged Claims** reflect the the novel all-in-one smart, precise, gentle, non-intimidating, and ultra-low profile solution that was reliable and simple enough for patients to use while remaining cost effective and accessible to the average patient.

108. The 591 Patent has two Independent Claims, Claims 1 and 19. All limitations of Claim 1 are included in Claim 19. For ease of reference, I have adopted the claim limitation numbering used by Dexcom and Dr. Fletcher.

109. **Independent Claim 19** is reproduced below and includes reference to the identical limitations in **Independent Claim 1**:

[19.1]/[1.1] An insertion assembly, comprising:

[19.2]/[1.2] **(a) an on-body unit**, comprising:

[19.3]/[1.3] a housing comprising a top surface and a bottom surface, wherein the top surface comprises an opening of the top surface, wherein the bottom surface comprises an opening of the bottom surface, and wherein a longitudinal axis extends through the opening of the top surface and the opening of the bottom surface;

[19.4]/[1.4] a glucose sensor; and

[19.5]/[1.5] sensor electronics disposed within the housing and coupled

with the glucose sensor,

[19.6] wherein the sensor electronics comprise a processor, a power source, an analog interface, a data storage unit, and wireless communication circuitry configured to communicate data indicative of a glucose level; and

[19.7]/[1.6] **(b) an inserter**, comprising:

[19.8]/[1.7] a proximal end, a distal end, and an interior; and

[19.9]/[1.8] a sharp,

[19.10]/[1.9] wherein the on-body unit and the sharp are entirely disposed in the interior of the inserter,

[19.11]/[1.10] wherein at least a portion of the glucose sensor is disposed in the sharp,

[19.12]/[1.12] wherein the inserter is configured to advance the on-body unit and the sharp in a linear direction from a[the] first position to a second position such that the sharp pierces skin of a user and the housing of the on-body unit is secured to the skin of the user in the second position,

[19.13] wherein a distance between the housing when the on-body unit is in the first position and the housing when the on-body unit is in the second position is greater than a maximum height of the housing,

[19.14] wherein a height profile of the housing is less than or equal to approximately 10 millimeters,

[19.15] wherein the sharp is configured to pierce the skin of the user at an angle substantially perpendicular to the skin of the user,

[19.16]/[1.11] wherein the sharp extends through the opening of the top surface and the opening of the bottom surface along the longitudinal axis when the on-body unit is in the[a] first position,

[19.17] / [1.13] wherein the distal end of the inserter is configured to be positioned on the skin of the user before advancement of the on-body unit and

the sharp,

[19.18]/[1.14] wherein the inserter is further configured to automatically retract the sharp entirely into the interior of the inserter and leave a part of the glucose sensor in the skin of the user, and

[19.19]/[1.15] wherein the distal end of the inserter is further configured to be removed from the skin of the user after automatic retraction of the sharp from within the user.

110. **Dependent Claims 2 through 18** depend on Claim 1. **Dependent Claims 20 through 30** depend on Claim 19. I understand this means that Claims 2-18 and Claims 20-30 have all the limitations of Claims 1 and 19, respectively, plus the additional limitations recited in those claims (including any limitations of claims from which they depend directly or indirectly).

111. **Dependent Claim 3** further recites limitation 19.3 (“wherein a distance between the housing when the on-body unit is in the first position and the housing when the on-body unit is in the second position is greater than a maximum height of the housing”). **Dependent Claims 4 through 17** each depend on Claim 3 and thus also include that limitation.

112. **Dependent Claims 4, 5, and 14** correlate with the additional limitations 19.6 (relating to sensor electronics), 19.5 (relating to the substantially perpendicular insertion angle), and 19.14 (related to the OBU housing height profile), respectively.

113. **Dependent Claims 18 and 21** further recite a second opening of the OBU housing top surface: “wherein the opening of the top surface is a first opening of the top surface, wherein the top surface further comprises a second opening of the top surface, wherein the first opening of the top surface has a first maximum width, and wherein the second opening of the top surface has a second maximum width less than the first maximum width.” **Dependent Claims 22 through 30** each further depend on Claim 21.

114. **Dependent Claims 7, 8, 25, and 26** further recite a “sleep mode or an idle mode” feature (Claims 7 and 25) or “activation” feature (Claims 8 and 26) relating to the sensor electronics. As noted above, Dependent Claims 25 and 26 include the additional requirements of Claim 21.

115. **Dependent Claims 15 and 28** state that the claimed “insertion assembly” further comprises a “sensor hub.” Claim 28 also includes the additional requirements of Claim 21.

## **VII. DR. FLETCHER’S STATEMENTS REGARDING THE STATE OF THE ART**

116. In Paragraphs 29 to 41 of his Declaration, and elsewhere in his Declaration, Dr. Fletcher makes a number of statements regarding the prior art and what he alleges is the “State of the Art.” I do not necessarily agree with Dr. Fletcher’s

statements or conclusions; however, I address some of those issues in my analysis throughout this Declaration.

117. I note that, throughout his Declaration, Dr. Fletcher repeatedly uses the claim phrase “on-body unit” to apparently refer to any type of device that is at or near a human body. For example, in Paragraph 29, Dr. Fletcher states “[i]nsetters that use automatically retractable sharps to insert part of an on-body unit (e.g., a cannula or glucose sensor) into a subject were well known before 2009” and then discusses the Cote device. I note, however, that the “on-body unit” claimed in the 591 Patent is not an infusion site cannula, but a very particular device comprising a number of electromechanical components including, among other things, a sensor coupled with sensor electronics, where the sensor electronics contain, e.g., a power source, a processor, and wireless communication circuitry that all have to work accurately during all parts of a user’s life including bathing and swimming. Dr. Fletcher’s conflation of the claimed on-body unit with any and all units that touch a patient, such as a cannula or catheter, is incorrect.

#### **VIII. CLAIM CONSTRUCTION: THE TERMS AND PHRASES IN THE 591 PATENT**

118. I discussed my understanding of claim construction principles in Section III.B above.

119. As I explained, in my opinion, the meaning of the claims to a POSA can be understood by referring to the language of the claims of the 591 Patent in view of the intrinsic evidence and do not need any special redefinition. I thus apply the plain and ordinary meaning of the claim terms with additional clarifications provided in this Declaration.

120. In Paragraphs 42 and 43 of his Declaration, Dr. Fletcher purports to use the “plain and ordinary meaning to all claim terms;” however, as I explain further below, Dr. Fletcher’s application of the prior art and fitting them to the claims demonstrate that he does not appear to be doing so. Using terms of the 591 Patent to describe features of the prior art does not necessarily mean those features are the parts and components that are claimed in the 591 Patent.

#### **IX. ALL GROUNDS: COMBINATION OF STAFFORD AND COTE**

121. All eight of the grounds of obviousness are based on the combination of Stafford in view of Cote (with or without other references). For example, in Paragraph 63, Dr. Fletcher states POSAs would have been motivated to combine “an inserter as taught by Cote integrated with Stafford’s introducer sharp and configured to advance Stafford’s data processing unit....” (Ex. 1003 at ¶63.) In Paragraph 64, Dr. Fletcher similarly states that POSAs “would have been motivated, with a reasonable expectation of success, to combine Stafford and Cote by implementing a

Cote-like inserter to deploy Stafford's on-body unit and analyte sensor...." (*Id.* at ¶64.)

122. In my opinion, the proposed combinations, all based upon Stafford and Cote, fail to disclose or suggest numerous limitations of the Challenged Claims of the 591 Patent as I discuss further below.

123. It is also my opinion that POSAs would not be motivated to combine Stafford and Cote in the manner proposed. POSAs would not be motivated to complicate Stafford's streamlined and cost-effective design by adding Cote's complex and costly infusion cannula inserter. Indeed, Stafford teaches the opposite. Additionally, Dr. Fletcher provides no explanation as to why POSAs would disregard other mechanisms of delivering glucose sensors in the CGM art but instead rely on Cote's cannula inserter.

**A. Motivation To Combine Stafford In View Of Cote**

124. In Section III.C above, I provided my understanding of the law of obviousness as it has been explained to me by counsel. It is my understanding that determining whether a combination would have been obvious requires a consideration of all the facts. I further understand that evidence suggesting reasons to combine should not be viewed in a vacuum apart from evidence suggesting reasons not to combine.

125. I disagree with Dr. Fletcher’s opinion that POSAs would have been motivated to combine Stafford and Cote. (Ex. 1003 at ¶44.) In fact, in my opinion, Stafford seems to advise against the approach urged by Dr. Fletcher.

126. In my opinion, POSAs would not be motivated to add a complex and costly “Cote-like” infusion cannula inserter to Stafford’s simple integrated analyte sensor delivery and data processing unit—particularly since Stafford explicitly states a separate inserter device is unnecessary. In fact, it is my opinion that POSAs would recognize that combining Cote and Stafford in the manner suggested by Dr. Fletcher would run contrary to the explicit purpose of Stafford and negate what Stafford describes as the advantages of his design.

127. As I explained above in Section V.B.4, Stafford teaches a self-insertable data processing unit comprising a sensor and “introducer mechanism” as a streamlined, cost-effective “single assembly.” A POSA would not have been motivated to add a complex “Cote-like inserter.”

128. As I explained, an important aspect of Stafford’s design is that it is a simple, compact, one-handed, and low-cost standalone CGM that is specifically designed to avoid the need for a separate inserter.

129. Specifically, Stafford recognized the potential wastefulness of “inserters and introducers” that are only used once and “discarded.”

The inserter is typically used only during the sensor insertion process, and once the sensor is properly and accurately positioned, the inserter and the introducer are discarded.

(Ex. 1004 at [0003].)

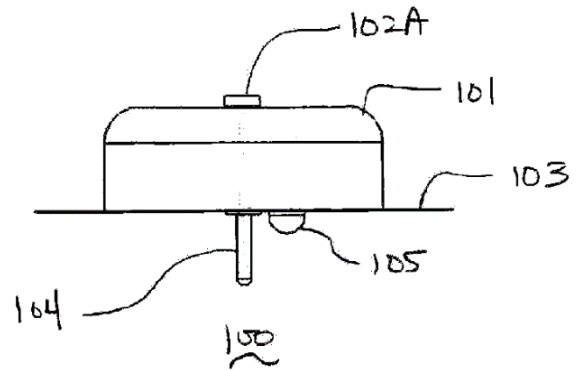


**FIGURE 1**

130. Stafford thus describes a “simple, easy to hold” system that “minimizes the number of components ... , and which also reduces the number of required steps to properly and accurately position the analyte sensor in fluid contact with the patient’s analytes” and “may be easily operated using one hand.” (*Id.* at [0005], [0007].)

131. Stafford’s simple design accomplishes this. Stafford’s specification explains how its simple design allows patients to self-deliver a glucose monitor—without a separate costly and complex sensor introducing device such as an inserter:

[T]he integrated analyte sensor and data processing unit assembly is configured to integrate an analyte sensor, a sensor introducer mechanism, and a data processing device into a single disposable assembly which allows for simple and accurate sensor deployment to the desired subcutaneous position, and which may be used with one hand by the user or patient. Accordingly, a separate sensor introducing device such as a separate insertion gun or a separate sensor delivery mechanism is not necessary.

(*Id.* at [0007], [0044].)

132. Stafford's specification further explains numerous benefits that stem from integrating the sensor, introducer mechanism, and data processing unit into a single assembly that does not need a separate inserter:

Furthermore, by integrating the analyte sensor, the introducer as well as the data processing unit into a single assembly, it is possible to have a smaller profile, simpler use application with less packaging thereby achieving cost reduction in manufacturing. Indeed, by reducing the number of components needed for sensor placement, within the scope of the present invention, other benefits such as reduction in material cost, weight, packaging, and associated handling and disposal may be achieved.

(*Id.* at [0045].)

133. In my opinion, these disclosures teach POSAs that using an inserter and other unnecessary components is disfavored.

134. Dr. Fletcher nevertheless asserts that the teachings of Cote and Stafford "complement one another" and his combination "aligns with Stafford's goal of 'a single disposable assembly' that does not require 'a *separate* sensor introducing device.'" (Ex. 1003 at ¶67 (emphasis in original).) Dr. Fletcher contrasts the insertion assembly described in Cote with the insertion gun of Say, which he states required "the user...to align with and affix to the on-body unit prior to insertion."

(*Id.*)

135. I disagree with Dr. Fletcher that Cote’s teachings align with Stafford. First, Dr. Fletcher never explains why he believes Cote’s inserter device is not a “separate” sensor introducing device. (Ex. 1003 at ¶67.) In his proposed combination, Dr. Fletcher relies on not only the Stafford on-body unit, but also the Stafford “introducer mechanism” (sensor-containing sharp). (Ex. 1003 at ¶¶61, 83-84, 89.) Dr. Fletcher adds the Cote inserter as a separate sensor introducing device on top of Stafford’s other components including its introducer mechanism. (*Id.* at ¶¶61, 80, 81.)

136. Moreover, Dr. Fletcher ignores the numerous advantages provided by Stafford’s streamlined design that I described above. For example, Dr. Fletcher’s proposed combination eliminates Stafford’s goal in achieving cost reduction and reducing components—including inserters specifically. In my opinion, Dr. Fletcher’s combination of Stafford and Cote also eliminates the numerous other advantages of Stafford’s design including: having an assembly with a “smaller profile” that uses “less packaging” and achieves “cost reduction in manufacturing” and that also reduces the “material costs, weight, packaging, and associated handling and disposal.” (*Id.* at [0045].)

137. Contrary to Stafford’s teachings, the end result of Dr. Fletcher’s combination is an assembly with a larger profile, more packaging, increased manufacturing costs, more components, increased material cost, increased weight,

increased complexity, and increased costs associated with handling and disposal. Even Dr. Fletcher agreed that this was the case. (*See, e.g.*, Ex. 2036 at 98:25-106:12.) Thus, in my opinion, a POSA would not be motivated to make the combination; indeed, Stafford suggests the opposite.

138. In Paragraph 65, Dr. Fletcher states that a POSA would be motivated to add Cote's infusion cannula inserter, with all of its additional components, to Stafford's on-body unit and introducing mechanism to "prevent accidental needle sticks when withdrawing the needle from the subject." (Ex. 1003 at ¶65.) Specifically, he states that a POSA "would be motivated to obtain the benefits of Cote's teachings on a specific inserter device that shrouds the needle both prior to and after insertion." (*Id.*) Dr. Fletcher relatedly contends that a Cote-like inserter would "minimize any pain or anxiety of the patient due to the use of a needle-implanted device such as the one described in Stafford." (*Id.* at ¶66.)

139. I disagree with Dr. Fletcher's analysis. First, Stafford already describes effective ways to prevent accidental needle sticks. As explained above, Stafford includes a "guard segment 104... [that] is configured to substantially cover the lower portion 102B of the introducer." (Ex. 1004 at [0022].) "The guard segment 104 is configured to protect the sharp edge of the lower portion 102B of the introducer from inadvertent contact

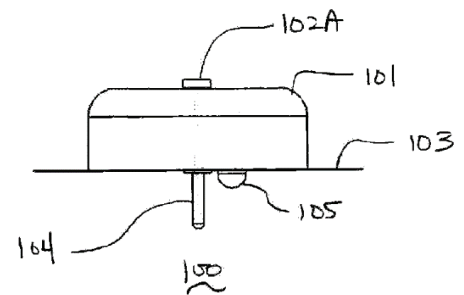


FIGURE 1

with the subject....” (*Id.*) The needle guard is discussed at length. (*Id.* at [0022]-[0025].) Therefore, in my opinion, given this disclosure, a POSA would not ignore Stafford’s deliberate teachings about minimizing components, reducing costs, and avoiding inserters in order to avoid needle sticks or any pain and anxiety caused by needles.

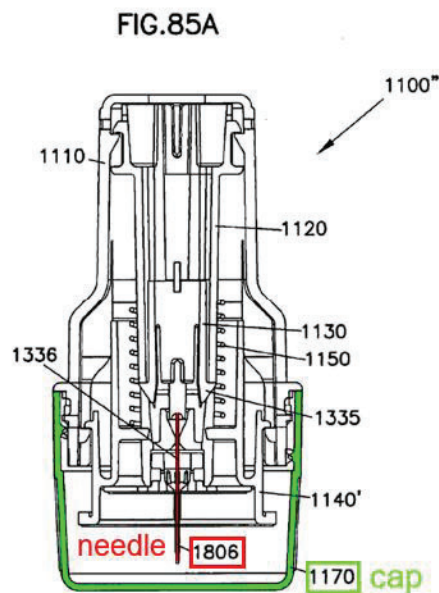
140. Dr. Fletcher does not directly address the efficacy of Stafford’s needle guard, but instead states that Stafford “lacks a way to prevent contact with the introducer’s exposed lower portion after the guard is removed....” (Ex. 1003 at ¶65.) I do not agree. The needle guard is configured to be removed right before the needle is inserted into the skin, minimizing the possibility of inadvertent contact. Additionally, it was well-known and common practice that a needle guard can be replaced after use or the needle placed in a sharp’s container. Indeed, Cote explicitly explains this. Cote states “the patient preferably reapplies the cap to the housing...to reduce the chance for further inadvertent exposure to the needle.” Ex. 1005 at [0219]; *see also* [0213] (“the cap 1170 can be replaced onto the threaded portion 1113 of the housing 1110 of the device 1100. Subsequently, the device 1100 can be discarded.”); *see also* Ex. 1006 at [0043]; Ex. 1009 at [0107] (describing “safe disposal of the needle” with and without caps).) Indeed, diabetics are familiar with sharps container to dispose of needles, so disposal of a small needle such as that described in Stafford versus a needle attached to a large plastic inserter furthered Stafford’s goals. This is

still a goal today with users complaining of disposing large amounts of plastic after only one CGM sensor/OBU insertion.

141. Dr. Fletcher also fails to explain why adding “a Cote-like inserter” would reduce “pain and anxiety” over Stafford’s existing capped design. I note that the two references that Dr. Fletcher addresses in Paragraphs 30-32 to assert “pain and anxiety” describe infusion cannula inserters (like Cote)—not sensor inserters. (Ex. 1036 at [0048] and Fig. 1; Ex. 1037 at [0070], Figs. 3-5.) In Cote’s cannula inserter, the cannula surrounds the needle (rather than the needle surrounding the sensor as in sensor inserters). (*Id.*) Thus, in such configurations, the circumference of the needle/cannula may be larger than that of a needle/sensor. This involves different considerations than the sensor-comprising sharps of the 591 Patent.

142. In any case, Dr. Fletcher’s own references demonstrate that a needle guard cover is an accepted design. For example, both Shah and Pesach (Ex. 1019) use a needle guard. (*See, e.g.*, Ex. 1006 at [0043] (“When the insertion needle is withdrawn, a protective sheath (not shown) contained in the flexible mounting base is dislodged and covers the needle tip as the needle is separated from the flexible mounting base.”); *see also* Ex. 1019 at [0083] (“In some embodiments needle cap 1231, can be removed from the needle. Then, the needle is inserted into injection site tissue, the drug injection device is operated and the drug is injected through needle into the tissue.”))

143. In fact, POSAs would understand that Cote teaches that using a needle shroud, like the guard in Stafford, is an acceptable design and does not result in pain or anxiety. As I mentioned, Cote specifically teaches embodiments where the needle is shrouded just like Stafford. For example, Figure 85A of Cote, shown below, depicts an embodiment of the Cote inserter in its “ship state” in which the needle 1336 is shrouded under a cap 1170. Cote states that, “once the cap 1170 has been removed, needle 1336 is exposed.” (Ex. 1005 at [0216].) In another embodiment of an inserter device that includes “a housing 1110’, needle 1336, and cap ... that can be threaded onto the housing 1110’,” Cote explains that after the inserter device is removed, “the patient preferably reapplies the cap to the housing 1110’ to reduce the chance for further inadvertent exposure to the needle 1336.” (*Id.* at [0219].)



144. Moreover, it is evident to POSAs that Cote does not focus on concerns with “pain or anxiety” based on needles given that, in the embodiment upon which Dr. Fletcher relies, Cote uses manual force to pierce the skin (just like Stafford). (Ex. 1005 at [0207].) Therefore, it is my opinion that POSAs would not be motivated to combine Cote and Stafford in the manner Dr. Fletcher suggests in effort to avoid needle sticks or reduce pain or anxiety.

145. In sum, it is my opinion that a POSA would not be motivated to add a costly and complex infusion cannula inserter to Stafford to address the needle “problems” identified by Dr. Fletcher—especially where these alleged problems are not acknowledged by either Stafford or Cote. Moreover, it is also my opinion that any alleged reduction in pain or anxiety does not overcome the explicit teachings and goals of Stafford to create a streamlined, simpler CGM and to eliminate components, reduce costs, reduce weight, reduce packaging, and reduce waste.

146. I further note that, in Paragraph 68, Dr. Fletcher acknowledges that Stafford—like Cote—already teaches an assembly that is “easily graspable” and “operated using one hand.” Dr. Fletcher states that this would be a motivation to combine the references. In my opinion, the opposite is true. There is no reason to complicate Stafford with a Cote device when it already includes the same benefits.

**B. Dr. Fletcher's Selection Of Cote's Infusion Cannula Inserter**

147. As explained above, POSAs analyzing Stafford would not be motivated to complicate Stafford by adding components to Stafford's assembly—particularly an inserter. Nevertheless, if a POSA did decide to ignore Stafford's teachings and add an inserter, Dr. Fletcher fails to explain why a POSA would select a Cote-like inserter used for inserting an infusion cannula rather than start with the numerous sensor inserters in the art that focus on solving sensor delivery problems.

148. Indeed, as discussed above, all of Dr. Fletcher's main CGM references (Say, Shah, Brenneman, and Stafford) all describe ways of inserting a sensor with detailed focus on the particular issues associated with delivering a sensitive and fragile electrochemical analyte sensor. For example, Brenneman, discussed above, describes a CGM that delivers an on body unit via an inserter that uses rotation to insert the sensor, improving depth control. (*See, e.g.*, Ex. 1040 at [003], [0047].) As discussed above, Shah likewise provided solutions to manage challenges with sensor delivery. (*See, e.g.*, Ex. 1006 at [0007].)

149. As I mentioned above, in Paragraph 78, Dr. Fletcher even references—and then otherwise ignores—another Stafford reference (Ex. 1042) in which Stafford describes an insertion assembly that teaches, among other things, “variable speed sensor insertion devices” that can “slow down” or “speed up” to “control the

velocity” of sensor insertion. (Ex. 1042 at [0004].) Dr. Fletcher does not explain why POSAs would not start with or consider those inserter assemblies.

150. Instead, Dr. Fletcher repeatedly disregards the sensor inserters (and their related on-body portions) from his own prior art references, while selecting other arbitrary disclosures from the references. For example, as I describe elsewhere in this Declaration, Dr. Fletcher arbitrarily relies on an alleged second opening in Brenneman (¶¶145-146) and an alleged opening in the Shah electronics (¶¶129-130) in trying to satisfy other claim limitations, while ignoring the art’s corresponding teachings on how to configure the on-body unit and mechanisms for sensor insertion.

151. Dr. Fletcher also disregards the differently-configured automatic cannula inserters described in the prior art publications that he relies upon to show needle “pain and anxiety” (Gravesen (Ex. 1036) and Thalmann (Ex. 1037)). As discussed above, both of these references describe infusion cannula inserters—not sensor inserters. (Ex. 1036 at abstract, [0004]-[0005]; Ex. 1037 at abstract, [0005].) Yet, while claiming their relevance for alleged evidence of needle “pain and anxiety,” Dr. Fletcher does not rely on their disclosures for what they teach about how to configure inserters.

152. Indeed, in Paragraphs 33 to 34 of his Declaration, Dr. Fletcher identifies seven other references that he states establishes that “various inserter designs were interchangeably used for inserting both an analyte (e.g., glucose) sensor or a cannula

or other transcutaneous device.” (Ex. 1003 at ¶¶33-34.) Yet, Dr. Fletcher relies on none of those inserters.

153. Instead, Dr. Fletcher relies on Cote’s inserter design to solve purported “needle” issues though Cote: (1) does not discuss delivering analyte sensors; (2) does not address any challenges with sensor delivery; and (3) does not address potential pain or anxiety associated with shrouded needles. Cote is instead focused on solving problems with existing infusion systems and provides embodiments that—just like Stafford—use caps to shroud the needle.

154. As Dr. Fletcher admits, the infusion cannula inserter in Cote already provides many of the same benefits as the far simpler Stafford design (which includes an “introducer mechanism”) such as being “easily graspable and operable by a single hand.” (Ex. 1003 at ¶68.) Dr. Fletcher, however, does not provide an example of any benefits the Cote inserter may provide in handling or placing a fragile glucose sensor. Nor could it, as Cote is concerned with inserting infusion cannulas, and not analyte sensors.

155. Moreover, Cote discloses embodiments with automatic needle insertion and retraction, but Dr. Fletcher does not rely on those embodiments. (*See, e.g.*, Ex. 1005 at [0220], [0236].) Indeed, Dr. Fletcher relies on a Cote embodiment that uses manual—rather than automatic—needle insertion. (*Id.* at [0207].) This suggests that

Dr. Fletcher is simply attempting to create a combination that recreates the claimed invention using hindsight—not one that minimizes “pain and anxiety.”

156. In summary, in my opinion, I do not believe POSAs would turn to Cote as a starting point for solving alleged “needle”-related “problems” while setting aside all the other prior art that offers differently-configured inserter alternatives (including ones that describe inserters for delivering sensors).

157. For all these reasons, it is my opinion that a POSA would not be motivated to combine Stafford and Cote in the manner suggested by Dr. Fletcher.

### **C. Reasonable Expectation Of Success**

158. As I discussed above, I understand that when prior art references require selective combination to render a patent claim obvious, there should be some reason to combine the references or modify the prior art to achieve the claimed invention as well as a reasonable expectation of success in doing so.

159. Dr. Fletcher states that a POSA “would have had a reasonable expectation of success in combining the teachings of Stafford and Cote.” (Ex. 1003 at ¶69.) He further states that, since “both references are directed to the deployment of transcutaneous medical devices and use of infusion devices, the teachings in these references complement one another and combining their teachings would have yielded nothing more than predictable results.” (*Id.*) However, Dr. Fletcher fails to consider that the Cote inserter is for delivering infusion cannulas and never mentions

inserting a sensor. Dr. Fletcher does not adequately explain how one could convert Cote's infusion cannula inserter into an effective inserter for analyte sensors.

160. For example, Dr. Fletcher ignores the numerous challenges associated with inserting electromechanical devices that includes an analyte sensor coupled with electronics. As discussed above (see Paragraphs 57-58), sensors are more fragile than infusion cannulas, and proper placement requires care and precision. Numerous CGM references such as Brenneman and Shah describe the challenges associated with proper sensor placement. *See also* EX2044-EX2044. There are numerous concerns with sensor insertion that are not concerns with insertion of an infusion cannula. For example, accurate sensor placement is critical to ensure that the electrochemical sensor can appropriately and correctly monitor glucose levels—an obviously critical function for a person with diabetes relying on accurate glucose readings. Relatedly, tissue trauma is not a significant concern with infusion cannula placement as it generally will not impact or affect the ability of the device to deliver medicament through the cannula. In contrast, tissue trauma can cause significant accuracy issues for electrochemical sensors. Another concern present in an on-body unit comprising a sensor and sensor electronics is ensuring that there is no ingress of contaminants or moisture into the unit as that may impair the functioning of the electromechanical device. The device also must be configured so that the sensor is

able to stay under the skin and continue to appropriately and reliably function to transmit accurate glucose information for a given period.

161. In Paragraph 34, Dr. Fletcher suggests that the “known interchangeability of inserter devices between infusion sets and analyte sensors and similar devices” is somehow established by the 591 Patent because it “states that its ‘inserter can be configured to insert various medical devices to the subject, such as for example, an analyte sensor, an infusion set, a cannula, or a lancet’ ... yet provides no meaningful guidance on how to configure or adapt the inserter for the various types of devices.” (Ex. 1003 at ¶34, citing Ex. 1001 at 14:54-59, 1:21-31, 2:13-20.) I do not agree with Dr. Fletcher’s assessment of the state of the art. Nevertheless, Dr. Fletcher ignores that, unlike Cote, the 591 Patent already describes how to address the challenges surrounding sensor placement, and the conversion from a glucose sensor inserter to an infusion cannula inserter does not present the same concerns and challenges as the reverse.

**X. GROUND 1: STAFFORD IN VIEW OF COTE (CLAIMS 1-6, 9-14, 16-24, 27, 29-30)**

162. In Ground 1, Dexcom and Dr. Fletcher assert that Claims 1-6, 9-14, 16-24, 27, and 29-30 are unpatentable as obvious over Stafford in view of Cote. (*See* Pet. at 20, Ex. 1003 at p. 31, ¶44.)

163. I disagree. In my opinion, these claims are not obvious in view of Stafford and Cote. As, a preliminary matter, as I explain in Section IX above, a POSA would not be motivated to combine Stafford and Cote nor has Dr. Fletcher explained why success would be reasonably expected from the combination. Additionally, the combined references do not disclose or suggest numerous claim limitations including:

- “the distal end of the inserter is configured to be positioned on the skin of the user before advancement of the on-body unit and the sharp” and “the distal end of the inserter is further configured to be removed from the skin of the user after automatic retraction of the sharp from within the user” (limitation 19.19/1.15, all claims)
- the “distance between the housing when the on-body unit is in the first position and the housing when the on-body unit is in the second position is greater than a maximum height of the housing” (limitation 19.13, Claims 3-17 and 19-30)
- on-body unit comprising “sensor electronics disposed within the housing and coupled with the glucose sensor” wherein the sensor electronics include “a data storage unit” (limitation 19.6, Claims 4 and 19-30)

- on-body unit housing containing claimed sensor electronics and having “a height profile...less than or equal to approximately 10 millimeters) (limitation 19.14, Claims 14 and 19-30)
- “a second opening of the [OBU housing] top surface” with a maximum width less than the first opening (Claims 18 and 21-30)

164. Therefore, Ground 1 does not render any claims of the 591 Patent unpatentable. I explain my reasons below.

**A. Independent Claims 1 And 19**

165. Even assuming Stafford could be combined with Cote, the combination proposed by Dr. Fletcher still fails to disclose or suggest many limitations of the claims, as I will describe below.

**1. The “Distal End Of The Inserter” Is Not “Configured To Be Positioned On The Skin...Before Advancement” And Then “Further Configured To Be Removed...After Automatic Retraction of the Sharp”**

166. Generally speaking, the Challenged Claims of the 591 Patent are directed to an “insertion assembly” comprising “(a) an on-body unit” and “(b) an inserter.” (Ex. 1001, Claims 1 and 19.) The inserter “is configured to advance the on-body unit and the sharp in a linear direction from the first position to a second position such that the sharp pierces skin of a user and the housing of the on-body unit is secured to the skin of the user in the second position.” (*Id.*) The claims go on to explain that the “distal end of the inserter is configured to be positioned on the

skin of the user before advancement of the on-body unit and the sharp” (limitation [1.13]/[19.17]) and that “distal end of the inserter is further configured to be removed from the skin of the user after automatic retraction of the sharp from within the user” (limitation [1.15]/[19.19]). (*Id.*)

167. A POSA would understand that the distal end is therefore configured to be positioned on the skin before advancement of the OBU and sharp and that distal end is further configured to be removed from that positioning on the skin only after the automatic retraction of the sharp from within the user.

168. The above-described operation of the claimed inserter is described throughout the 591 Patent. (*See, e.g.*, Ex. 1001 at 16:30-41, 17:1-4, 3:51-60, 15:1-6; 4:17-26; Figs. 10, 14, 28-31.) For example, the 591 Patent explains that:

An inserter 100 in accordance with an exemplary embodiment is illustrated in FIG. 10. ... Inserter 100 includes a base 142 which defines a distal, substantially planar surface 112 for placement on the skin S of a subject ....

Ex. 1001 at 16:30-41; *see also, e.g., id.* at 17:1-4 (“Base 142, as illustrated in FIGS. 10 and 14, includes ... a distal rim 112 having a substantially planar surface configuration to rest on the subject’s skin.”).

169. Figure 10 from the 591 Patent shows inserter 100, including base 142 (where the removable “distal cap 104” is still attached to the inserter):

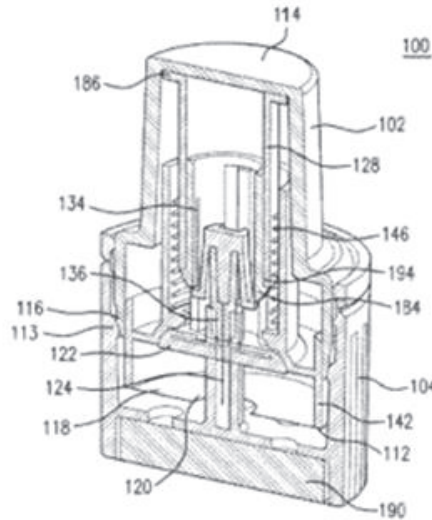


FIG. 10

(*Id.* at Fig. 10; *see also, e.g., id.* at Figs. 14, 28-31.) In use, the sample inserter 100 operates as recited in the claims. That is, the distal end of inserter 100 is first positioned on the skin before advancement of the OBU and sharp, and then remains on the skin until **after** automatic retraction of the sharp from within the user. (*See, e.g., id.* at Figs. 28-31 (Figures 28 and 29 show the initial configuration, Figure 30 shows the advanced configuration, and Figure 31 shows the retracted configuration), 15:3-6 (teaching alternative ways for securing the OBU to the skin).) In other words, the distal end of the inserter is configured to be positioned on the skin before OBU/Sharp advancement and then removed from that positioning only after automatic retraction of the sharp from within the user.<sup>2</sup>

---

<sup>2</sup> The 591 Patent nowhere discloses removing the distal end of the inserter **before** automatic retraction of the needle from within the user. Indeed, as I explain, that would be undesirable due to the numerous issues surrounding sensor placement.

170. *There are numerous advantages of the claimed configuration* in devices delivering sensors (such as those claimed in the 591 Patent). As I discussed in, e.g., Paragraphs 57, 58, and 160 above, there are many concerns and challenges facing POSAs designing on-body units comprising sensors and sensor electronics and the mechanisms that deliver them. The claimed configuration described in these limitations allows the inserter to be stabilized against the user's skin before the sharp and sensor are inserted and not removed until after the sensor has been placed and the sharp is retracted from within the user.

171. Stabilizing the distal end of the inserter on the skin before and during sensor insertion avoids tissue trauma and ensures that the fragile sensor is precisely delivered during insertion without sensor shifting or misplacement. (*See* Ex. 2043 at 1007-1008; Ex. 2044 at 321-322.) Precise sensor placement ensures users can receive accurate glucose information, which is critical for people with diabetes making treatment decisions based on readings from their CGM device. (*Id.*)

172. Maintaining the distal end of the inserter in position on the skin also helps provide stability during retraction of the sharp, which can help prevent inadvertent wobbling, tilting, bending, or angling of the sharp or sensor. Wobbling, tilting, or shifting of the inserter during sharp retraction process can cause sensor misplacement as well as pain and potential injury to the user. As I discussed, these

considerations regarding sensor placement are not present in devices for delivering infusion sites (such as Cote).

173. Dr. Fletcher agrees that the advantages of keeping the distal end of the inserter on the skin during the insertion and retraction process includes “prevent[ing] damage or misalignment of the introducer and the sensor during insertion and retraction of the introducer.” (See Ex. 2036 at 116:15-117:7.)

174. In my opinion, and as I will discuss in detail below, *the Cote inserter does not satisfy the claim limitations*. Cote’s infusion cannula inserter is not configured such that the distal end of the inserter is positioned on the skin before advancement of its infusion site/sharp and then removed from that positioning on the skin after automatic retraction of the sharp from within the user. Rather, the distal end of Cote’s inserter has the opposite configuration. It is intentionally configured so that the distal end of its inserter is removed away from its position on the skin before retraction of the sharp. The sharp is retracted while the distal end is off the skin.

175. Again, in contrast to the Cote device, in the system described in the specification and claims of the 591 Patent, the distal end of the inserter is configured to be positioned on the skin of the user before advancement of the on-body unit and the sharp and the distal end is further configured to be removed from that positioning

Declaration of Karl R. Leinsing, MSME, PE

on the skin after the automatic retraction of the sharp from within the user. See Paragraphs 168-169 above.

176. Indeed, Dr. Fletcher acknowledged that this is exactly what the claims require (Ex. 2036 at 95:15-96:2):

Q. Under claim one of the 591 patent, the distal end of the inserter is configured to be positioned on the skin before advancement of the OBU and the sharp; is that fair?

A. Yes

Q. And then under claim one of the 591 patent, the distal end of the inserter is further configured to be removed from that positioning on the skin after automatic retraction of the sharp from within the user?

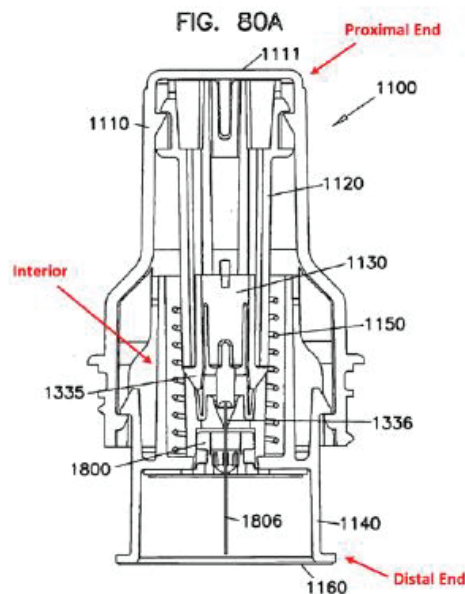
A. That's the way the claim element reads, yes.

**i. Additional Description Of Cote's Infusion Cannula Inserter**

177. As I discussed above in Section V.C, Cote teaches an inserter “device” to deliver a site comprising an infusion cannula with the cannula surrounding the sharp, wherein the site is then connected to an infusion set to deliver medicament to a user. (*See, e.g.*, Ex. 1005 at abstract, [0008]-[0009].) As I explained, an insertion device for an infusion cannula does not involve the same considerations present in a system designed to insert and place a fragile glucose sensor. And this is at least one

reason why Cote's inserter design is not transferrable to on-body units comprising a glucose sensor (and is missing the claim limitations).

178. Dr. Fletcher relies on Cote, and in particular Cote's "device 1100," to find that limitations [1.13]/[19.17] and [1.15]/[19.19] (regarding the positioning of the distal end of the inserter) are disclosed in the prior art. (Ex. 1003 at ¶¶100, 104; Ex. 2036 at 28:5-22, 29:19-30:18.) And Dr. Fletcher repeatedly identifies the distal end of Cote's sleeve 1140 as the "distal end" of the inserter. For example, Dr. Fletcher's image for limitations [1.7]/[19.8] ("distal end") is depicted below with an arrow pointing to the sleeve (see Ex. 1003 at ¶82).



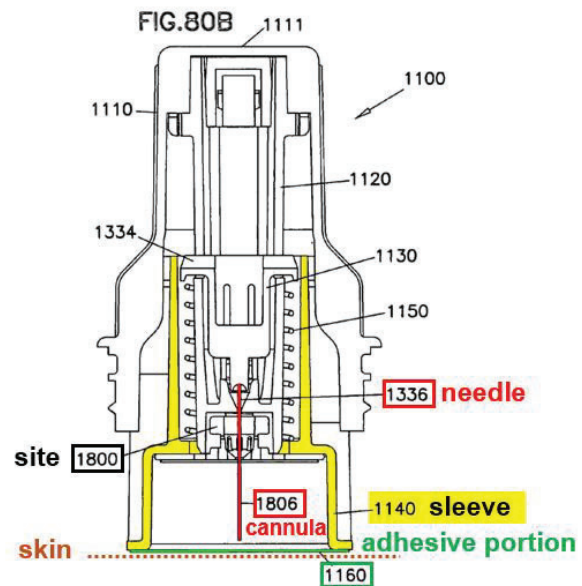
Cote, FIG. 80A (annotated)

Similarly, for limitation [1.13]/[19.17] requiring the "distal end of the inserter [be] configured to be positioned on the skin" addressed in Paragraph 100, Dr. Fletcher

quotes a portion of Cote that states that the “sleeve 1140...is positioned so that the adhesive...contacts the skin.” (*Id.* at ¶100.)

179. Below I explain details regarding the operation of Cote’s inserter relevant to Dr. Fletcher’s contentions for this limitation. Again, unlike the claimed sensor inserter, the distal end of Cote’s inserter 1100 is specifically configured to be removed away from the skin before its sharp is retracted from within the user—not after as the claims require.

180. **Delivery State.** Cote Figure 80B depicts device 1100 “in a delivery state ready to deliver the cannula of an infusion device into the skin” after the cap is removed. (Ex. 1005 at [0203].) As shown in the colorized figure here, infusion site 1800 and needle 1336 (red) are within the inserter. An adhesive portion 1160 (green) that adheres site 1800 to the skin is on the bottom of sleeve 1140 and not yet attached to the site. (*Id.* at [0180], [0190], Figs. 71-73.)

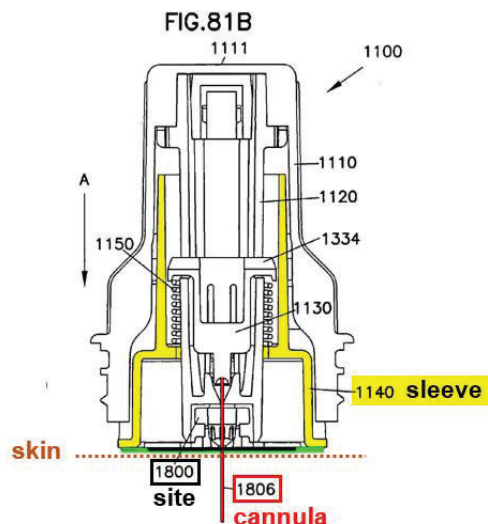


181. Cote teaches that “sleeve 1140 of the device 1100 is positioned so that the adhesive portion 1160 (i.e., [adhesive] surface 1668) contacts the skin 1900 of the patient.” (*Id.* at [0206], [0190].) This is the portion of Cote that Dr. Fletcher relies

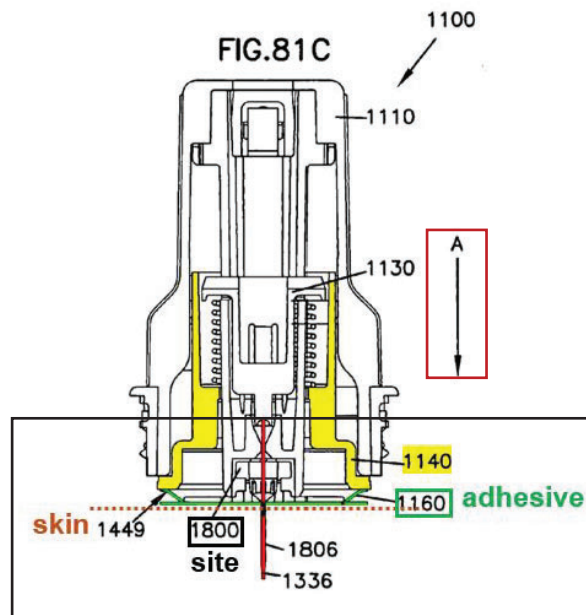
upon (see Paragraph 100) to satisfy the limitation that “the distal end of the inserter is configured to be positioned on the skin...before advancement of the on-body unit and the sharp” (limitation [1.13]/[19.17]).

182. As Dr. Fletcher acknowledges in Paragraph 100, the user “applies pressure” to the upper housing of inserter 1100 “to move the housing 1110 and associated structures including the cylinder hub 1120 and needle hub 1130 (including needle 1336 and site 1800) in a direction A with respect to the sleeve 1140 and toward the skin,” thus inserting the cannula (and the needle within it) into the skin. (*Id.* at [0207]-[0208].)

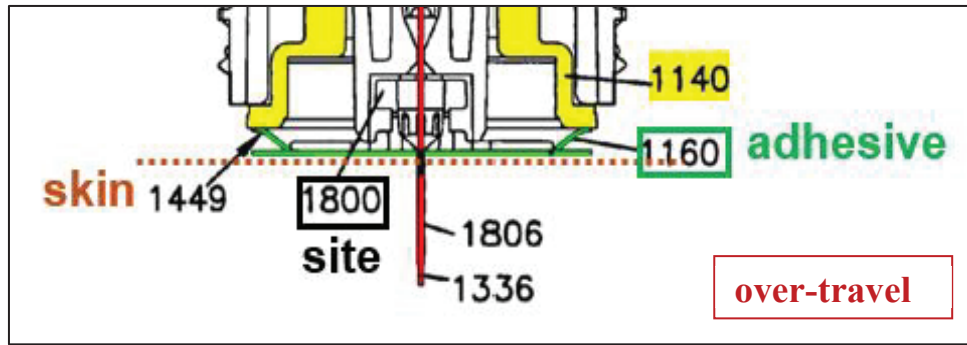
183. **Trigger State Before Retraction.** Figure 81B, reproduced below, depicts the device in a “trigger state” where “the needle 1336 and the cannula...have been fully inserted into” the skin “and the needle hub 1130 and associated needle 1336 are about to be retracted.” (*Id.* at [0203], [0208].)



184. **“Over-travel”**. Importantly, before the needle is retracted from within the user, the distal end of Cote’s infusion cannula inserter is configured to be moved away from its position on the skin in order to dislodge the adhesive from the end of the inserter. Cote explains that, “as the housing 1110...and needle hub 1130 are displaced further in the direction A” (toward the skin), the “site 1800 travels slightly beyond the second end 1442 of the sleeve 1140 as shown in Fig. 81C.” (*Id.* at [0209].) As I mentioned above, Cote refers to this feature as the site “over-travel,” which can be seen in Figure 81C, reproduced here. (*Id.* at [0209].)<sup>3</sup>



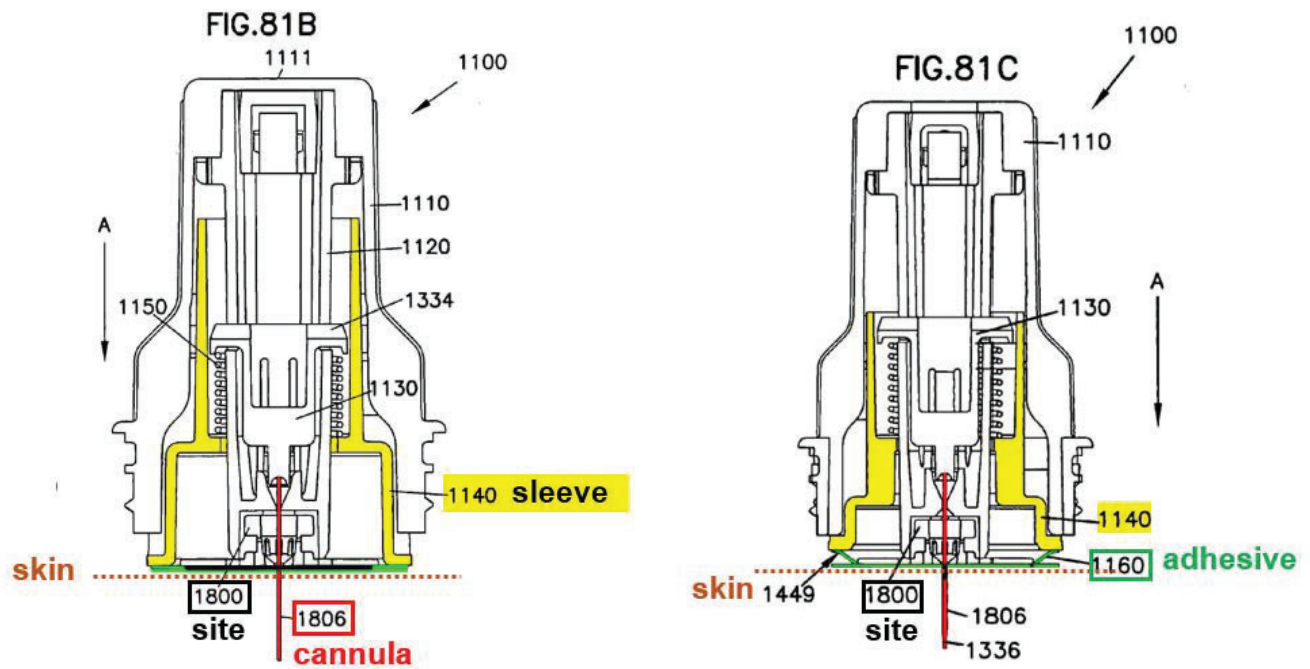
<sup>3</sup> Cote describes its “over-travel” feature in connection with device 1100 and Figure 81C uses 1100 reference number. (*Id.* at [0209]-[0211].) As Dr. Fletcher notes, while Figure 81C accurately depicts Cote’s “over-travel,” it mistakenly depicts device 1100” of Figures 85-91. (Ex. 1003 ¶110, n.6; *see also* Figs. 82A-B; Ex. 2036 at 121:16-123:15.)



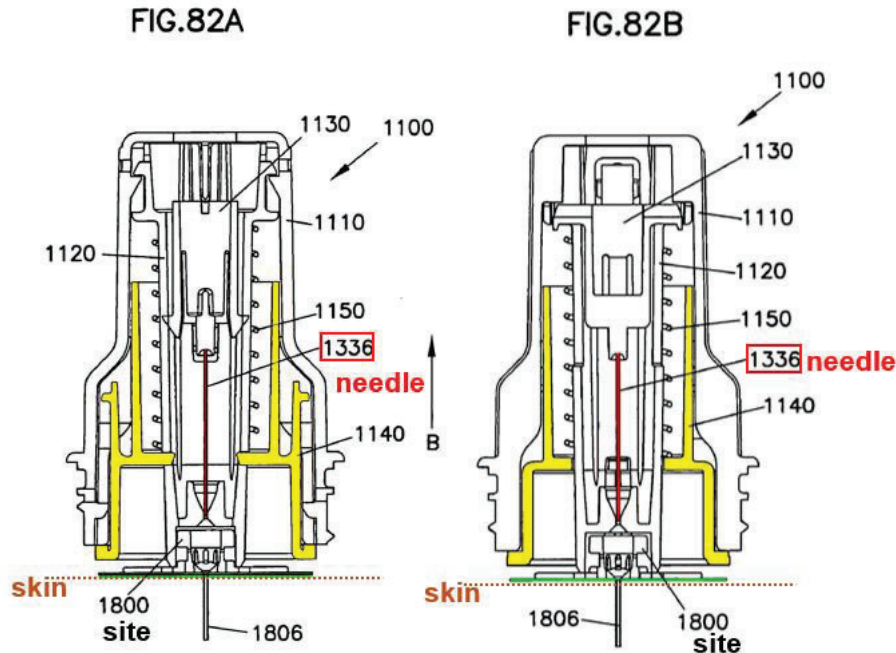
185. Cote explains that its “over-travel” feature serves a number of purposes. First, “[t]his ‘over-travel’ assures that the adhesive portion 1160 is properly sheared away from....sleeve 1140 and allows for the coupling of the site 1800 to the adhesive portion.” (*Id.* at [0209]-[0210].)

186. Second, Cote’s “over-travel” feature initiates needle retraction. Cote’s inserter is specifically configured so that the needle retracts while the distal end of the inserter is located away from the skin. (*Id.* at [0211].)

187. Specifically, Cote explains that “as the housing 1110, cylinder hub 1120, and needle hub 1130 are displaced further in the direction A as described above [i.e., over-travel], barbs holding the hub within the device are disengaged. (*Id.* at [0211] (“barbs 1335 of the needle hub 1130 are forced inwardly by the projections 1444 of the sleeve 1140, and the barbs 1335 are thereby uncoupled from engagement with the cylinder hub 1120.”). This can be seen with reference to Figures 81B and 81C.



188. **Needle Retraction.** Once the barbs are released from the needle hub, the “needle hub 1130 is free to move longitudinally within the passage 1223 of the cylinder hub 1120 in a direction B opposite to that of direction A.” (*Id.*) “[S]pring 1150, which has been compressed through the movement of the housing 1110 in the direction A, propels the needle hub 1130 and associated needle 1336 in the direction B...while the site 1800 and associated cannula 1806 are held on the skin..., as shown in Figs. 82A and 82B.” (*Id.* at [0211].)



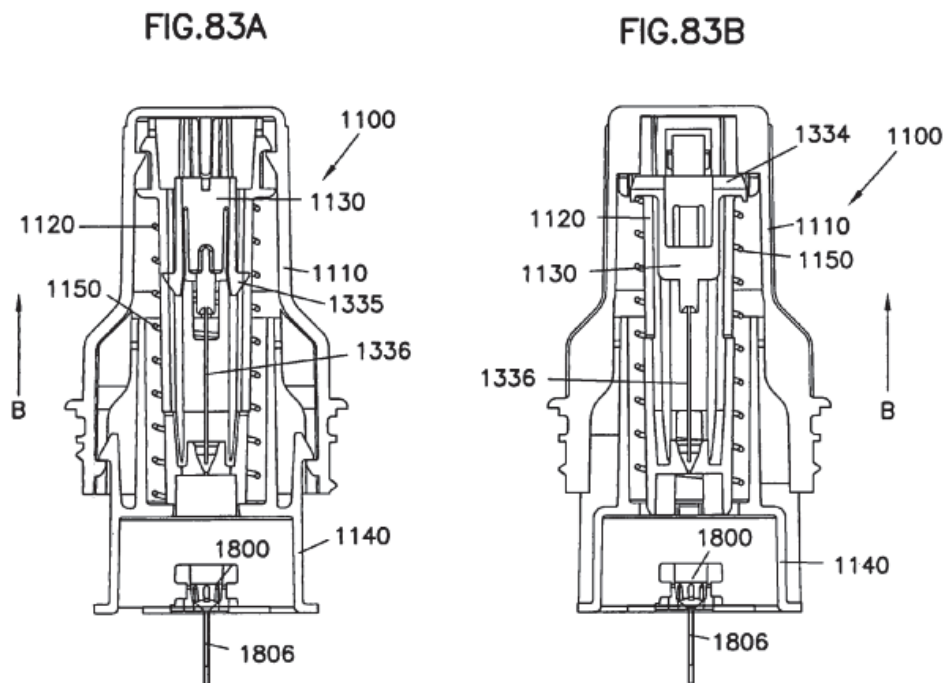
189. Simply put, the needle is retracted from within the user while the site is “over-traveling,” i.e., while the distal end is away from the skin. This is the opposite of the 591 claims. Figures 82A and 82B show Cote’s inserter device 1100 in its “retracted state with the needle hub 1130 and associated needle 1336 having been retracted into the device” and with the distal end (end of sleeve 1140) still separated from the skin. (*Id.* at [0203].)

190. In his Declaration, *Dr. Fletcher acknowledges that Cote’s over-travel feature is necessary before Cote’s needle can retract from within the user.* Dr Fletcher states:

A POSITA would understand that...[Cote’s] on-body unit [i.e., site 1800] **must** travel beyond the distal end of Cote’s inserter to enable automatic retraction of the sharp [i.e., the needle]....

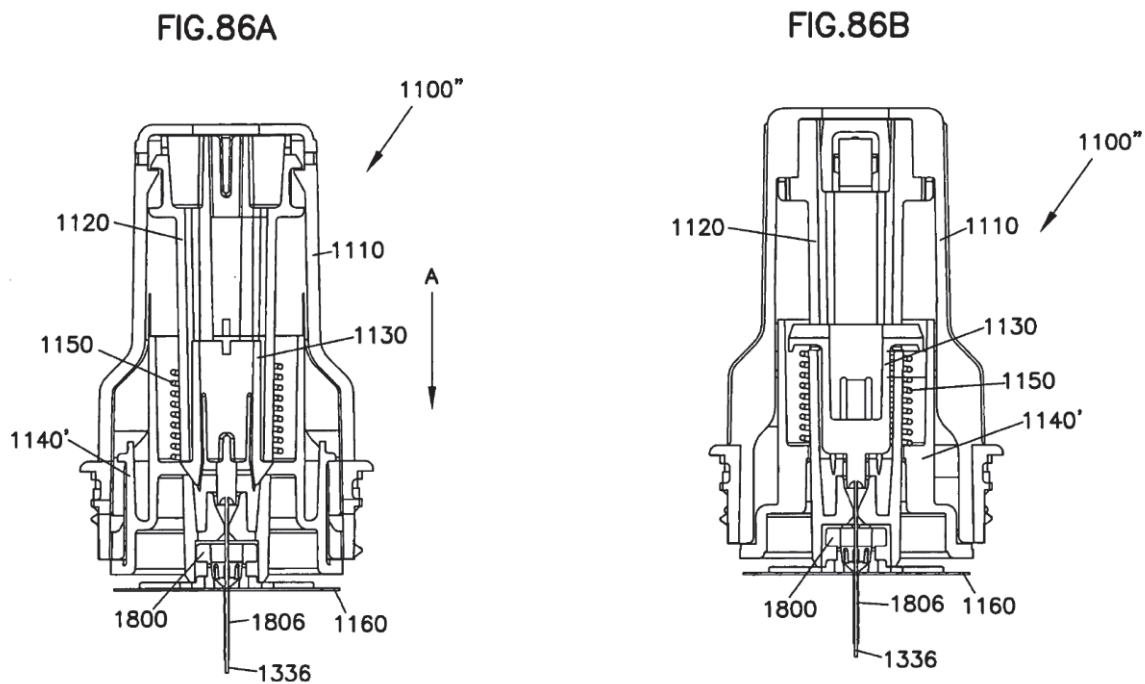
(Ex. 1003 ¶110 n.6.) I agree with this statement, as I explained above.

191. **Fully Retracted State.** The user then “removes pressure from the upper end 1111 of the housing 1110 [and] the spring 1150 causes the housing 1110 and cylinder hub 1120 to move in the direction B.” (Ex. 1005 at [0212].) The device thus moves into its “fully retracted state” as shown in Figures 83A and 83B. (*Id.* at [0212], [0203].)



192. After describing the fully retracted state, Cote states that: “[f]inally, the sleeve 1140 is removed from contact with the skin 1900, and the cap 1170 can be replaced onto the threaded portion 1113 of the housing 1110 of the device 1100.” (*Id.* at [0213].)

193. Cote also teaches alternative embodiments of its inserter device, in which there is no sleeve 1140 “to shroud the needle 1336 prior to insertion.” (*Id.* at [0215].) In this embodiment, illustrated in Figures 86A and 86B, reproduced below, the needle is not disposed within the device before use, but is “exposed” once the cap is removed. (*Id.* at [0215], [2016].) In this embodiment, a “trigger 1140” causes the needle retraction. (*Id.* at [0217].)



(*Id.* at Figs. 86A, 86B.)

ii. **“The Distal End Of [Cote’s] Inserter” Is Not “Further Configured To Be Removed From The Skin Of The User After Automatic Retraction Of The Sharp” [1.15]/[19.19]**

194. All claims require “the *distal end of the inserter* [to be] configured to be positioned on the skin...before advancement of the [OBU]....” and that “distal

end...is further configured to be removed from the skin of the user *after* automatic retraction of the sharp....” (Ex. 1001 at Claims 1, 19.) Simply put, as I discussed earlier, the distal end of the claimed inserter is configured to be positioned on the skin before OBU and sharp advancement and then removed from that positioning after automatic retraction of the sharp from within the user. As discussed above in Paragraphs 170-173, this configuration offers numerous advantages including, for example, stabilizing the sensor and sharp during insertion and retraction, minimizing effects of wobble, preventing tissue trauma, and ensuring proper sensor insertion.

195. As discussed, Dr. Fletcher relies on Cote’s device 1100, with sleeve 1140 as the distal end, for this claim limitation, but Cote has the opposite configuration. (See Sections V.C and X.A.1.i.) Again, unlike the claimed invention, Cote is configured such that, after the distal end of its inserter is purportedly positioned on the skin, that distal end is removed away from the skin before the sharp is retracted from within the user.

196. As I explained above, Cote’s device is deliberately designed this way in what Cote calls its “over-travel” feature as Dexcom and Dr. Fletcher acknowledge. (Pet. at 53-54, n.9; Ex. 1003 at ¶110, n.6.)

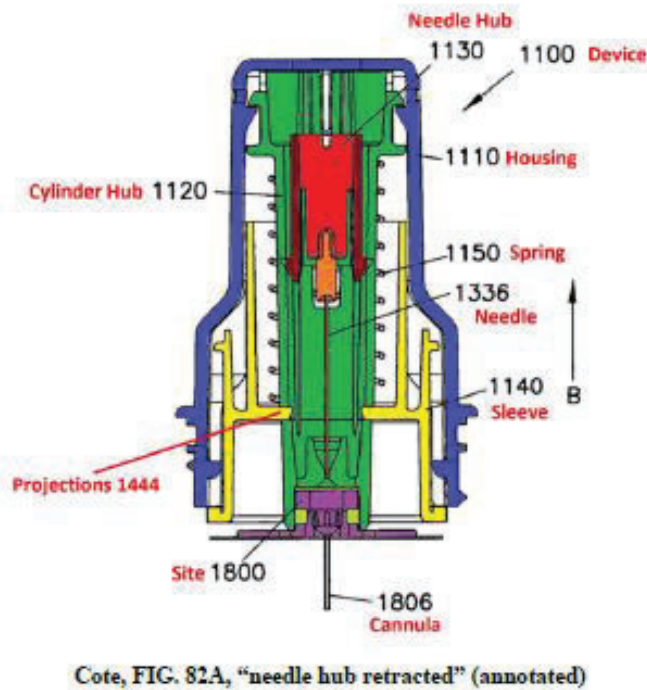
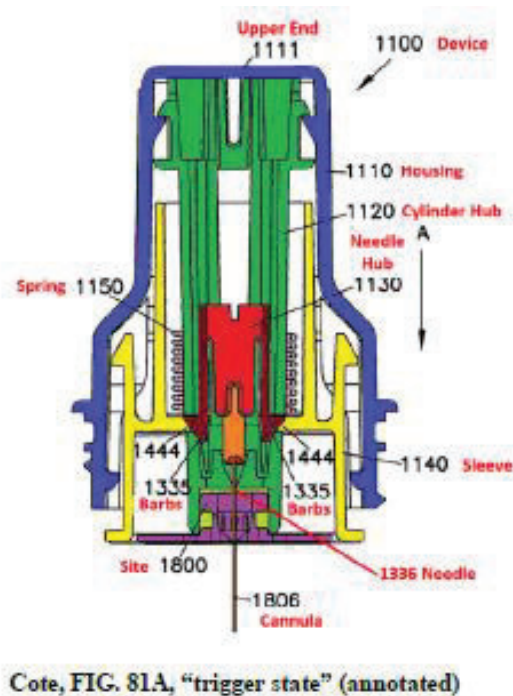
197. This can be clearly seen in Figures 81C and 82B, annotated and reproduced below. As discussed above, Figure 81C shows that the site 1800 travels beyond the end of the sleeve 1140 before automatic needle retraction (i.e., “over-

travel”). As discussed, as Dr. Fletcher admits, this over-travel is necessary to initiate needle retraction. Figure 82B shows the device in its retracted state with the needle hub 1130 and associated needle 1336 retracted into the device. In both figures, the distal end of Cote’s inserter (e.g., the distal end of sleeve 1140) is removed from (and remains away from) its position on the skin.



199. Dr. Fletcher’s own figures confirm this. For example, in Paragraphs 57 and 59, Dr. Fletcher describes the trigger state and retraction process in Cote and

employs colorized versions of Figure 81A (“trigger state”) and Figure 82A (“needle hub retracted”). Dr. Fletcher’s figures are reproduced below. They clearly depict the distal end of the inserter removed away from its positioning on the skin.



200. Therefore, it is my opinion that the “distal end of [Cote’s] inserter” is not “configured to be removed from the skin of the user after automatic retraction” of the needle, as claimed—given that it is configured to be removed from the skin before automatic retraction.

201. Importantly, Cote’s configuration and the “over-travel” feature is not an incidental feature, but it is a fundamental and necessary requirement of Cote’s design. As Dr. Fletcher recognizes, Cotes’s infusion site “must travel beyond the

distal end of Cote's inserter to enable automatic retraction of the sharp..." (Ex. 1003 at ¶110 n.6.)

202. *Dr. Fletcher's entire analysis of this limitation is a single sentence with a cite to one sentence from Cote.* (*Id.* at ¶104.) Dr. Fletcher ignores the disclosure of Cote's "over-travel" feature despite discussing it elsewhere. Instead, Dr. Fletcher quotes the following portion of Cote: "[f]inally, the sleeve 1140 is removed from contact with the skin 1900, and the cap 1170 can be replaced onto the threaded portion 1113 of the housing 1110 of the device 1100." (*Id.*)

203. The cited sentence in Cote Paragraph 213 does not support the conclusion that the distal end of Cote's insertion device is "configured to be removed from the skin...after automatic retraction of the sharp," which is required by the claim language. Specifically, the Cote sentence says nothing about how or when the automatic retraction of the sharp occurs. Rather, it simply references the "final step" of removing the device from the skin after the cannula is inserted—an act that of course must occur with any inserter after insertion regardless of the timing of automatic needle retraction.

204. In my opinion, POSAs would understand that Cote, which discloses an infusion cannula inserter that is configured such that its distal end is removed from the skin before sharp retraction, does not satisfy the limitation that requires that removal after retraction. Indeed, it is the opposite.

205. Simply put, the claims require the inserter be configured to be positioned on the skin before the OBU and sharp advance and then removed from that positioning on the skin after the sharp retracts from within the user. As I discuss throughout this Declaration, the claimed configuration, while not necessarily relevant to delivery of an infusion site with a cannula (such as Cote), results in numerous benefits for delivery of sensors including stabilizing the area, minimizing effects of wobble, and preventing tissue trauma.

206. Dr. Fletcher gave no consideration to this aspect of Cote. It was never discussed with relation to this claim limitation. But, in my opinion, to the extent that Dr. Fletcher contends that the over-travel feature can be ignored or that Cote's device, which is configured to remove the distal end of the inserter from the skin before needle retraction, could somehow satisfy the claim limitation requiring removal after needle retraction, I would disagree. This would entirely defeat the purpose of the claim language. As I mentioned repeatedly, the claimed configuration offers numerous advantages for placement of the delicate electronic sensor.

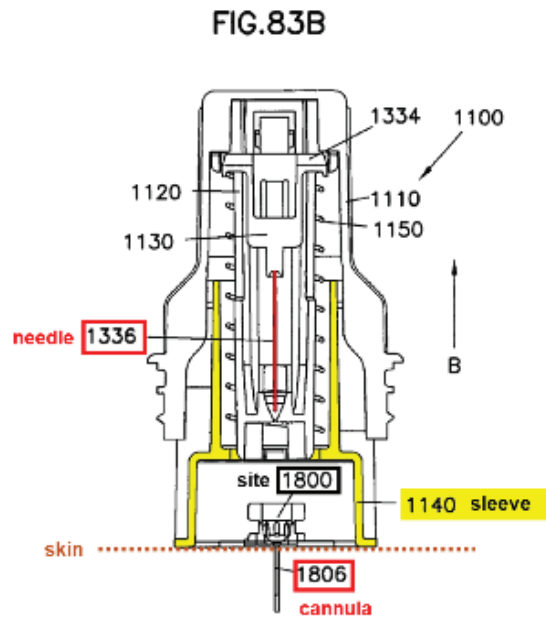
207. Furthermore, when Cote refers to removing the sleeve from the skin in Paragraph 213, it is not referring to removing it from its initial positioning on the skin as the claims require (and as Dr. Fletcher acknowledged in his deposition as I explained above, Ex. 2036 at 95:15-96:2). Instead, at best, it is referring to removing the sleeve from a later positioning on the skin that occurs after the site and needle

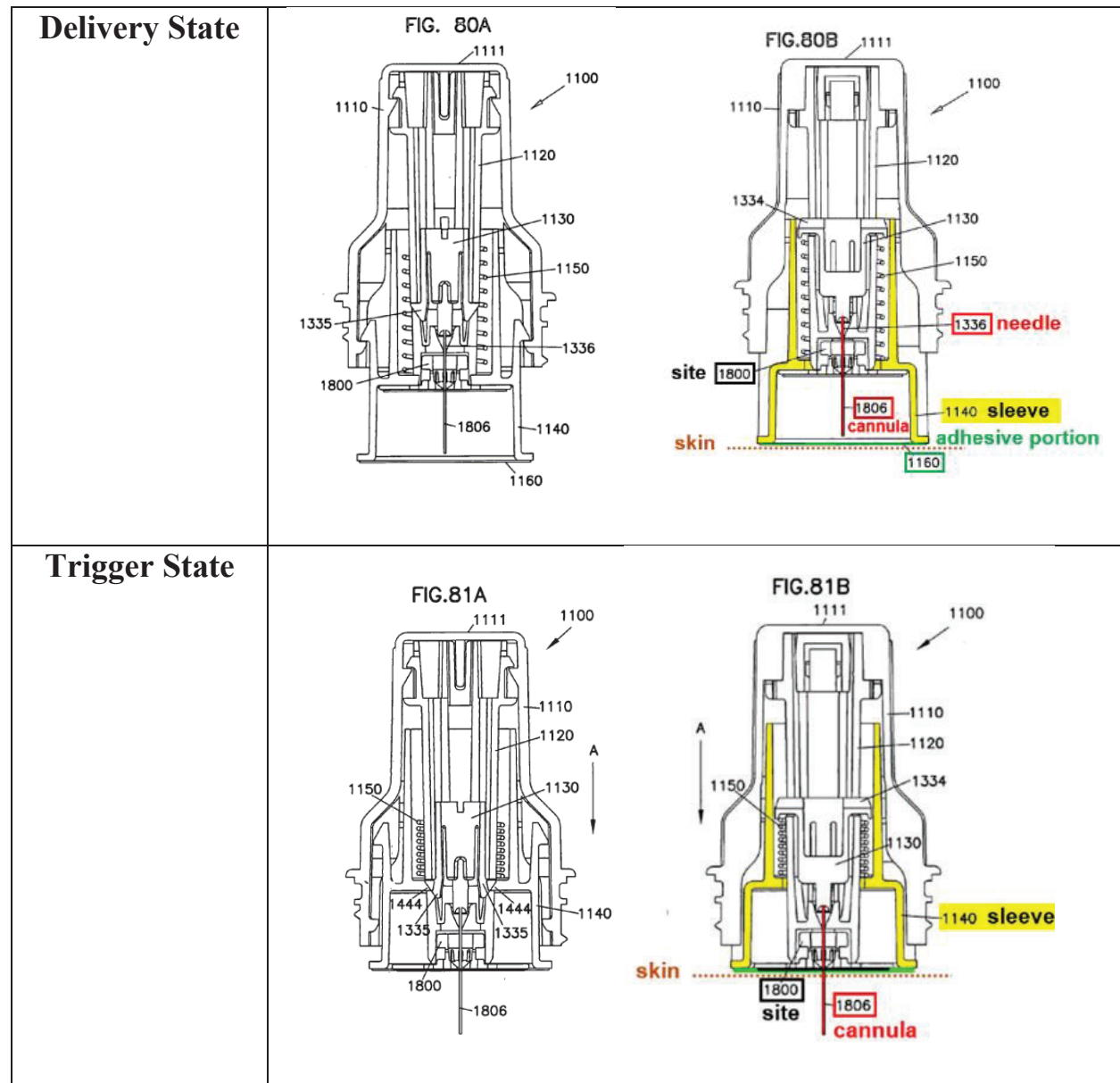
already have been advanced and after the needle has been retracted from within the user. This later positioning on the skin is shown in Figure 83B (“fully retracted state,” reproduced to the right). (Ex. 1005 at [0212].)

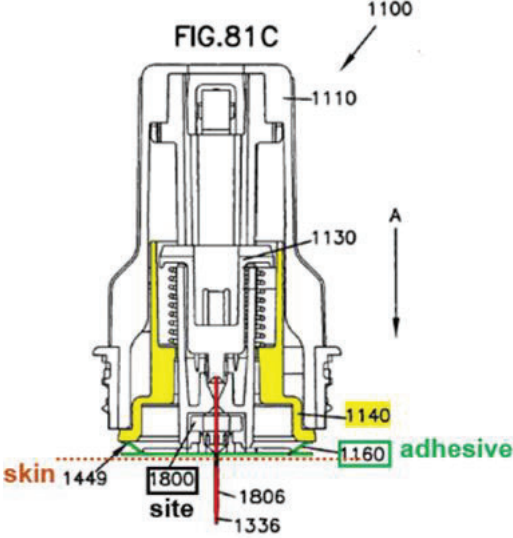
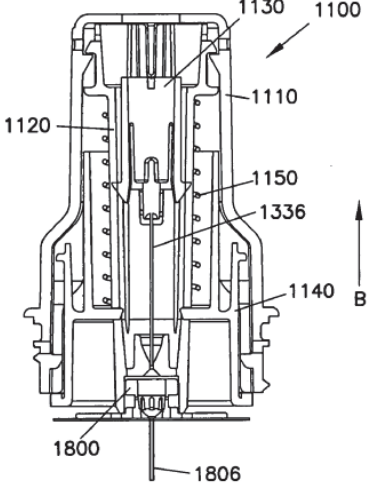
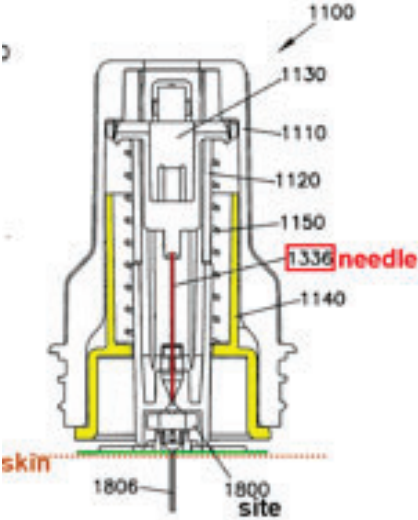
208. That “fully retracted state” occurs (1) after the distal end of the inserter (according to Dr. Fletcher, the sleeve) is positioned on the skin before the site and needle are advanced (see, e.g., [0206], Figs.

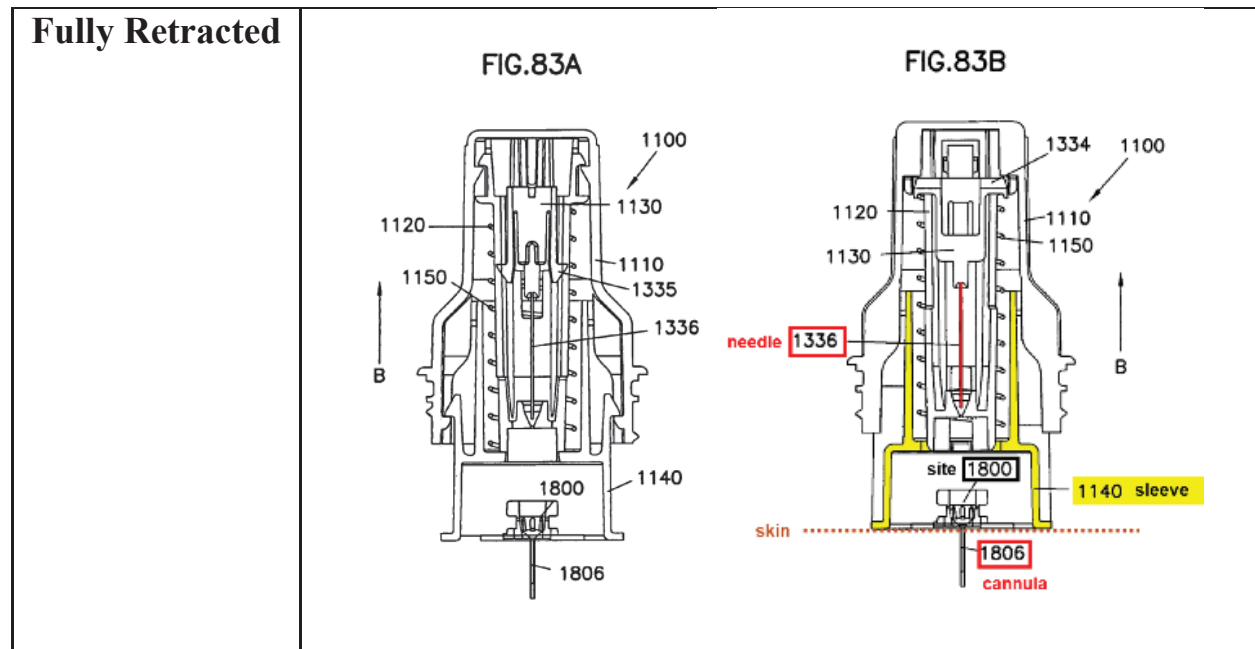
80B/81B) and also after (2) the subsequent removal of the sleeve from that positioning on the skin before needle retraction from within the user (see, e.g., [0209], Fig. 81C).

209. This can be seen in the progression (shown below) of Figures 80A/80B (delivery state, distal end positioned on skin), 81A/81B (trigger state, cannula and site delivered before sharp retraction), 81C (over-travel, distal end removed from its positioning on the skin), 82A/82B (retracted state, distal end remains off skin), and 83A/83B (fully retracted).





|                               |                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>“Over-Travel”</b></p>   | <p><b>FIG.81C</b></p>  <p>1100<br/>1110<br/>1130<br/>1140<br/>1160 adhesive<br/>skin 1449<br/>1800 site<br/>1806<br/>1336<br/>A</p>                                                                                                                                                                                                   |
| <p><b>Retracted State</b></p> | <p><b>FIG.82A</b></p>  <p>1130 1100<br/>1110<br/>1120<br/>1150<br/>1336<br/>1140<br/>1800<br/>1806<br/>B</p> <p><b>FIG.82B</b></p>  <p>1100<br/>1130<br/>1110<br/>1120<br/>1150<br/>1336 needle<br/>1140<br/>skin<br/>1806<br/>1800 site<br/>B</p> |



210. In short, in Cote, the distal end of the inserter is positioned on the skin to deliver the infusion cannula and then removed from that positioning on the skin during the over-travel to initiate needle retraction. Thus, the sentence in Paragraph 213 of Cote does not show that the distal end of Cote's inserter is configured to be positioned on the skin before site/needle advancement and then further configured to be removed from that skin positioning after automatic needle retraction from within the user as the claims require.

211. In sum, in my opinion, the cited art does not disclose or suggest the claimed limitation as Dr. Fletcher asserts.

**2. Dr. Fletcher Has Not Shown the Claimed “Housing-Distance” Limitation [19.13]**

212. All the claims require the inserter to be configured “to advance the on-body unit and the sharp in a linear direction from a first position to a second position such that the sharp pierces [the] skin of a user and the housing of the on-body unit is secured to the skin of the user in the second position.” Independent Claim 19 and Dependent Claim 3 (along with Claims 4-17 and 20-30 which depend on those claims) further require that the “distance between the housing when the on-body unit is in the first position and the housing when the on-body unit is in the second position is greater than a maximum height of the housing.” Generally speaking, the first position is a proximal position within the inserter and the second position is a distal position on the skin. For convenience, I will refer to this as the **“housing-distance” limitation**.

213. This limitation may be understood by referencing, for example, Figures 10 and 29 from the 591 Patent. These figures show the inserter with a cap 104 (orange) and an OBU (blue) in the first position. The limitation effectively requires that the OBU housing be located proximally within the inserter a particular distance (labelled by Dr. Fletcher as “H1”) that is greater than the height of the OBU housing (“H2”). (Ex. 1003 at ¶110.) I have adopted Dr. Fletcher’s H1 and H2 labelling in the images below.

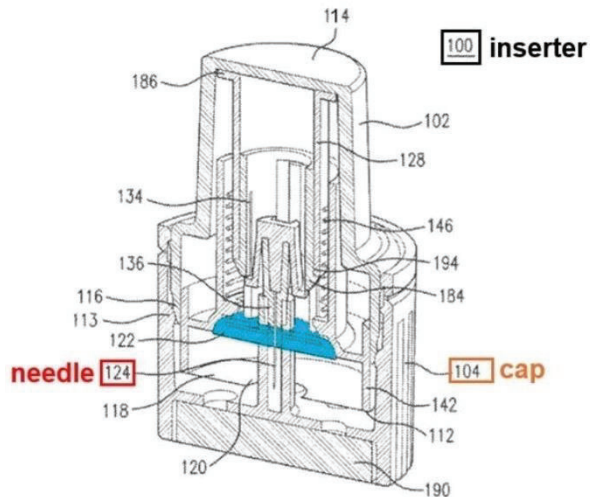


FIG. 10

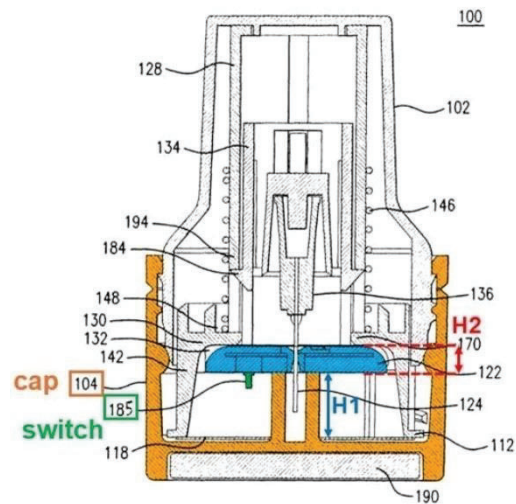


FIG. 29

(Ex. 1001 at Figs. 10 and 29.)

214. In the context of the 591 Patent, this configuration results in several benefits. For example, in one embodiment, this configuration prevents the user from accidentally or prematurely engaging a mechanism that activates the electronics disposed in the OBU housing (e.g., “plunger switch 185” shown in Figure 29 above), thus ensuring the sensor electronics remain inactive, which saves battery life until the device is ready to be used. (*Id.* at 19:58-67.)

215. Another benefit is that it allows space for the presence of a “boss 125” in “cap 104” (shown above and here in Figure 13) that surrounds and protects the sensor-containing needle, maintaining a sterile, contaminant-free environment until it is ready for use. (*Id.* at 16:30-34; 16:52-54.)

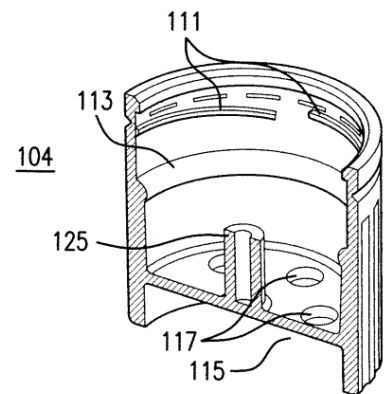


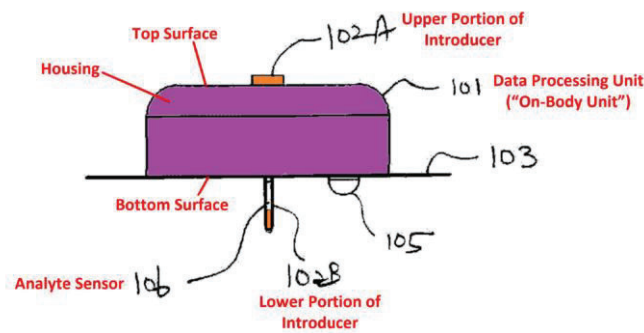
FIG. 13

216. As will be explained below, it is my opinion that Dr. Fletcher failed to establish that his proposed combination includes this limitation.

**i. Dr. Fletcher's Arguments Related To Cote Fail To Establish The Limitation Is Satisfied**

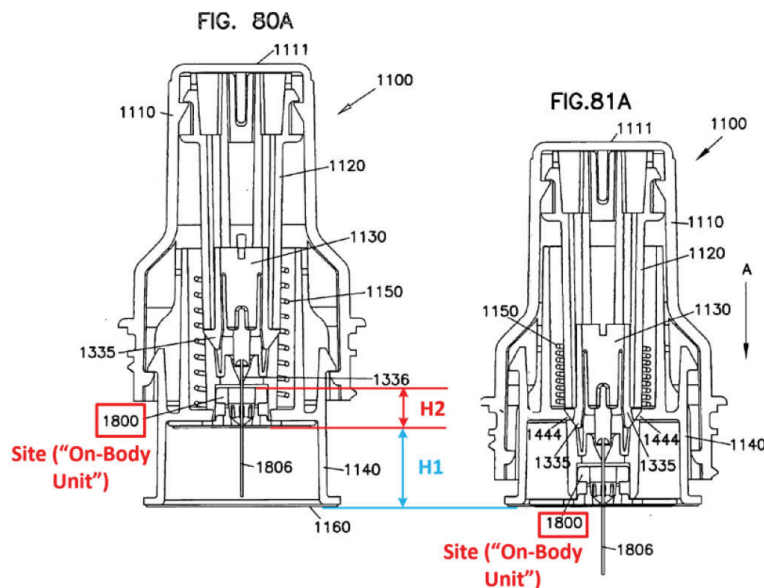
217. Throughout his analysis, Dr. Fletcher repeatedly identifies "Stafford's on-body unit" as the claimed "on-body unit" applied to the claims. For example, in Paragraph 64, Dr. Fletcher asserts that a POSA would have "implement[ed] a Cote-like inserter to deploy Stafford's on-body unit and sensor." (Ex. 1003 at ¶64.) Dr. Fletcher thereafter repeatedly relies on teachings from Stafford when discussing limitations related to the 591 Patent's "on-body unit."

218. For example, Dr. Fletcher relied on Stafford's OBU (including Stafford's "housing with openings in the top and bottom surfaces") to satisfy limitations related to the "on-body unit" of the claims. (See, e.g., *id.* at ¶¶75-76.) An image from page 51 of Dr. Fletcher's report (Paragraph 75) purportedly labelling the OBU housing components is shown below, clearly showing Dr. Fletcher's reliance on Stafford's OBU housing.



Stafford, FIG. 2 (annotated)

219. However, for the “housing distance” limitations of Claim 3 and limitation 19.13, Dr. Fletcher inconsistently relied on the height and distance dimensions associated with the “on-body unit” of Cote’s infusion “site 1800.” In Paragraph 110, for example, Dr. Fletcher states that “Cote’s figures clearly illustrate the relationship between travel distance and housing height” and thus “Cote discloses this limitation.” (Ex. 1003 at ¶110.) Dr. Fletcher then provides the following images (*see* page 74) referring to the “on-body unit” in Cote—despite having previously always relied on Stafford:



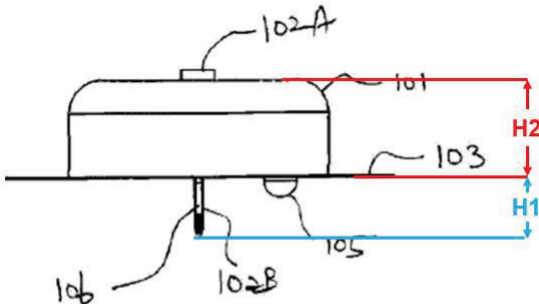
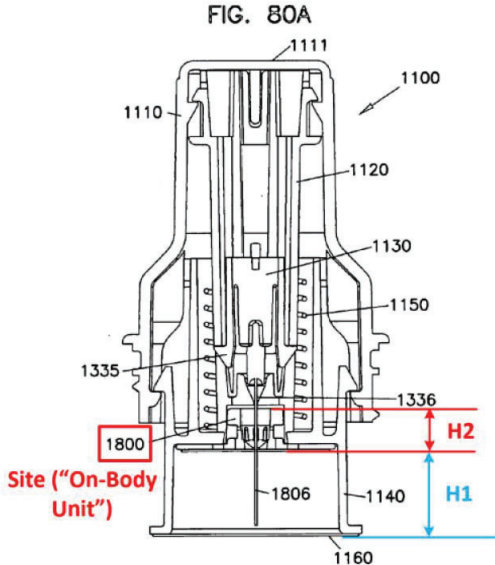
Cote, FIG. 80A (first position), FIG. 81A (second position)<sup>9</sup> (annotated)

220. Dr. Fletcher’s analysis was incorrect, and Dr. Fletcher did not show that the claim limitation was satisfied.

221. As an initial matter, it is my understanding that it is improper to switch prior art and embodiments to address a single repeated claim limitation. Yet, that is precisely what Dr. Fletcher did when he relied on Stafford's OBU for all other claim limitations relating to the OBU and its housing but then switched to Cote for this one.

222. Second, Dr. Fletcher's comparison of Cote's infusion site height to the length of the portion of Cote's infusion cannula extending below the infusion site is irrelevant. The claim limitation clearly refers to the height of the housing of the sensor-comprising OBU (which includes all the other claim limitations) and the distance relative to the first and second positions. The relative height of an infusion site compared to the length of an infusion cannula is immaterial.

223. Third, Dr. Fletcher never performed any analysis for the Stafford OBU. That is because, had Dr. Fletcher performed that analysis, the claim limitation would not be satisfied. As shown in the image below (left), the length of the needle/sensor extending below Stafford's sensor-comprising OBU (H1) is less than the height of Stafford's OBU housing (H2). In contrast, Cote's infusion site has a long infusion cannula extending below the infusion site (extending nearly double the length of the identified site housing—H1 versus H2 on the right below). Of course, as I explained above, the relative length of an infusion cannula and site is irrelevant to the claims.

| <p><b>Length Of Stafford's Needle/Sensor Extending Below Its OBU Is <i>Less Than</i> Its OBU Housing Height (<math>H1 &lt; H2</math>)</b></p> | <p><b>Length Of Cote's Needle/Cannula Extending Below Its Site Is <i>Longer Than</i> Its Site Housing Height (<math>H1 &gt; H2</math>)</b></p> |
|-----------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|
|  <p>FIGURE 2</p>                                             |  <p>FIG. 80A</p>                    |

224. Thus, if Stafford's OBU was used with Cote's inserter (as proposed by Dr. Fletcher throughout his Declaration), the "distance between the housing when the on-body unit is in the first position and...second position" [H1] would not be "greater than the maximum height of the housing [H2]" as required by the claims. Therefore, even if Dr. Fletcher appropriately considered Stafford's OBU for this limitation as he should have, the limitation is not met.

**ii. Dr. Fletcher's Attempts To Recreate The Limitation Based On "Knowledge"**

225. As I explained above, it is my opinion that Dr. Fletcher has not shown that his proposed combination of Stafford in view of Cote satisfied the "housing-distance" limitations.

226. Even though the limitation is not shown in the art, Dr. Fletcher proposes a number of ways to invent the limitation. For example, in Paragraph 113, Dr. Fletcher states that it was obvious to modify the Stafford/Cote device “such that the on-body unit’s travel distance is greater than the height of the on-body unit.” (Ex. 1003 at ¶113.) In support of this assertion, Dr. Fletcher asserts that “a POSITA would find a low-profile on-body unit desirable” and “[a] POSITA additionally would have found it desirable for the needle to extend past a distal end of the sensor to protect the tip of the sensor during insertion.” (*Id.*)

227. I disagree with Dr. Fletcher’s analysis. Whether or not these features are desirable, Dr. Fletcher does not explain how these features would lead POSAs to configure the system to meet the disputed “housing-distance” limitation. There are ways to provide for a low-profile OBU and ensure that the needle extends beyond the distal end of the sensor, which would still result in a system where the distance traveled by the OBU housing is not greater than its height. Indeed, Stafford is an example of one.

228. Moreover, Dr. Fletcher has identified nothing in Stafford or Cote that would suggest to a POSA to redesign Stafford so that the needle extending from the distal end of its OBU is longer than the OBU housing’s height. To the contrary, as I have discussed numerous times, Stafford teaches a system that “minimizes the

number of components” and materials. (Ex. 1004 at [0005].) Thus, Stafford teaches against extra components and unnecessary materials.

229. Dr. Fletcher next cites to several additional prior art references, none of which are included in his proposed Ground 1 combination of Stafford and Cote, and contends that certain “well-known” concepts would have lead to the claimed “housing-distance” limitation. It is my opinion that none of these theories or citations to background art suggest any reason why a POSA would modify Stafford as proposed nor does Dr. Fletcher provide a reason.

230. For example, in Paragraph 114, Dr. Fletcher cites to four references (none of which are part of his proposed Stafford and Cote combination), e.g., Shah (Ex. 1006), Bickoff (Ex. 1018), Eilersen (Ex. 1038), and Funderburk (Ex. 1021)) and asserts that POSAs “understood that transcutaneous devices (*e.g.*, sensors or cannulas) routinely had an *in vivo* portion that was longer than the on-body portion was tall.” (Ex. 1003 at ¶114 (citing Ex. 1006 at Fig. 1A, [0034]; Ex. 1018 at Fig. 3; Ex. 1038 at Figs. 6-11; Ex. 1021 at 8:53-55; 16:3-5; 17:11-12.)) He then concludes that it was an “obvious design choice” in the Stafford and Cote combination with no other analysis.

231. I disagree. Dr. Fletcher does not provide any explanation or description of these citations. None of these citations support Dr. Fletcher’s conclusion that a “POSITA would [] have found it at least an obvious design choice” applicable to

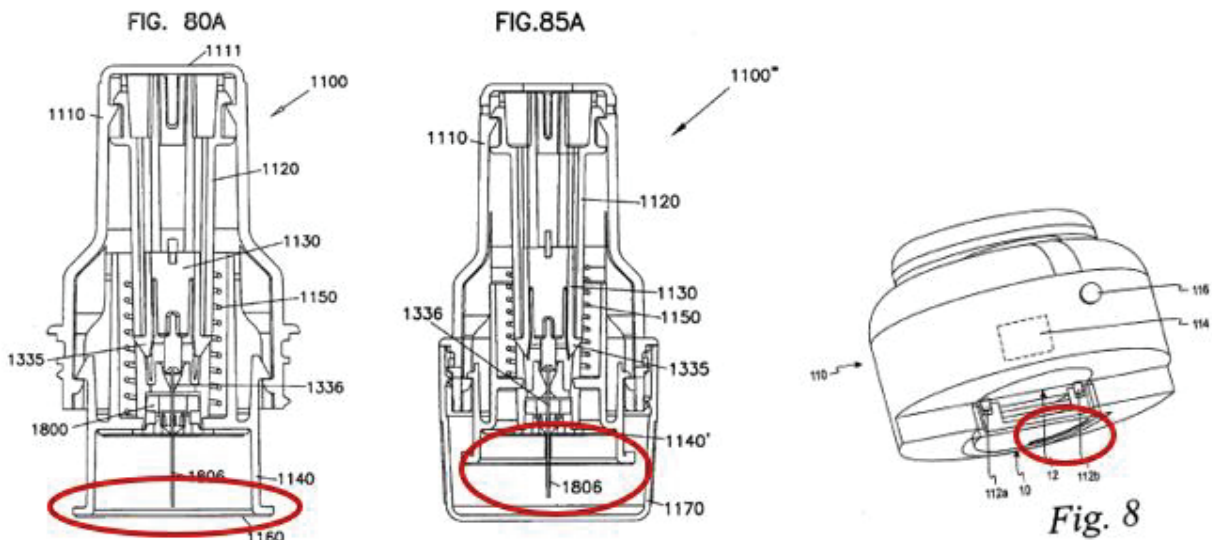
Stafford—particularly given Stafford’s emphasis on reducing unnecessary components, minimizing costs, and reducing the insertion assembly size. (Ex. 1003 at ¶114.)

232. For example, Dr. Fletcher cites Figure 1A and Paragraph [0034] of Shah, but never identifies what “*in vivo*” components are referenced and never explains why Shah is even relevant to this specific claim limitation. The on-body assembly in Shah referenced by Dr. Fletcher does not move from a proximal (or first) position to a distal (or second) position. Instead, the sensor is separately delivered to a mounting unit already on the user. (Ex. 1006, [0045]-[0046].) This is unlike the system described in the claims of the 591 Patent or even Dr. Fletcher’s proposed combination.

233. Moreover, Dr. Fletcher’s citations to transcutaneous devices that may have an *in vivo* “cannula” or “sensor” that are “longer” than various “on-body portions” does not explain why it would be “obvious” to modify the on-body unit in Stafford to include that feature. Indeed, Dr. Fletcher provides no explanation or reasoning why a POSA would arbitrarily make Stafford’s *in vivo* sensor longer than its OBU housing is tall. As such, it is my opinion that he has not adequately explained why a POSA would make his proposed modification to Stafford.

234. In Paragraph 115, Dr. Fletcher states that it was “routine and desirable to position the sharp up within the inserter device (*i.e.*, well away from the distal end

of the inserter) to avoid needle sticks,” suggesting the sharp be moved proximally. (Ex. 1003 at ¶115 (citing Cote at [0235].) However, Dr. Fletcher’s reasoning is contradicted by his own references. For example, Cote depicts the needle at or extending beyond and outside the distal end of the inserter—not “well away from” it. For example, Figure 80A from Cote depicts the sharp at the distal end of the inserter device 1100. Figure 85A depicts the sharp extending well beyond (and outside) the distal end of the inserter (note that in Fig. 85A cap 1170 is still on the device).



(Ex. 1005 at Figs. 80A, 85A; Ex. 1040 at Fig. 8.)

235. Brenneman is similar. In Brenneman Figure 8 (above), the sharp is likewise located at the distal end of the inserter.

236. In Paragraph 115, Dr. Fletcher cites to Cote Paragraph 215 to support his statement that “it would have been obvious to a POSITA to position the

Stafford+Cote sharp some distance away from the distal end of the inserter.” (Ex. 1003 at ¶115.) But this paragraph does not support his conclusion. In fact, Paragraph 215 describes the embodiment illustrated in Figure 85A where the needle clearly extends outside of the inserter and into the cap 1170. (Ex. 1005 at [0215], Fig. 85A.)

237. Dr. Fletcher also states that positioning the needle proximally in the inserter “allows the needle to accelerate prior to hitting the skin, which can be beneficial for users with higher-than-average skin thickness and/or skin density.” (Ex. 1003 at ¶115.) To support that assertion, Dr. Fletcher cites to Ex. 1042, which is an entirely different Stafford publication that generally describes “variable speed sensor insertion devices” that can “slow down” or “speed up” to “control the velocity” of sensor insertion. (Ex. 1042 at [0004].) Like the main Stafford reference used in Dr. Fletcher’s proposed combination, Ex. 1042 lists Gary Stafford as the sole inventor, and was published a month after the main Stafford reference. In my opinion, this shows that Mr. Stafford was aware of different complex inserters to use in CGM devices, but specifically chose a “simple” and cost-effective approach when disclosing his invention in the main Stafford publication at issue. (Ex. 1004 at [0044].) In any case, Dr. Fletcher does not explain why Stafford would rely on the Cote inserter instead of the differently-configured Stafford inserter instead.

238. Regardless, Dr. Fletcher has failed to provide a reason to modify Stafford or Cote in a way that results in the claimed limitation at issue. While he

asserts that recreating the claim limitation would “avoid needle sticks,” both Stafford and Cote already teach ways to avoid inadvertent needle sticks as I discussed above. Stafford uses a “protective needle guard” and Cote uses a “cap.” Thus, there is no need for the needle to be relocated further into the inserter.

239. In any case, even if a POSA did arbitrarily decide to move the needle proximally “well away from” the distal end of the inserter, Dr. Fletcher has still not provided a reason why that would necessarily result in the claimed housing-distance limitation at issue, e.g., a distance that is greater than the height of the OBU housing.

240. In Paragraph 116, Dr. Fletcher also contends that “a travel distance H1 greater than the height of the housing H2” is “well-known in the art.” (Ex. 1003 at ¶116.) Dr. Fletcher cites to three additional references in Paragraph 39 of his “background” section—Hasted (Ex. 1011), Raymond (Ex. 1009), and Kovelman (Ex. 1020). (Ex. 1003 at ¶116.) However, Dr. Fletcher provides no explanation as to why the configurations in those pieces of prior art, which are not used in any of Dr. Fletcher’s proposed combinations, have any impact on how to configure the Stafford OBU—much less how it would then operate in a Cote-like inserter. (*Id.* at ¶¶36-40.)

241. In my opinion, Dr. Fletcher has not identified any reason that would motivate a POSA to redesign Stafford’s OBU or to otherwise move Stafford’s OBU proximally within an inserter—much less to meet the claimed relative distance. Such a design modification would seemingly increase wasted space within the design,

making the overall assembly unnecessarily larger and further undermining Stafford's goal of reducing size, material, and cost.

242. After discussing the advantages of the claimed design and concluding that the claimed configuration would have been obvious due to those advantages, Dr. Fletcher finally asserts that “[n]othing...indicates that the relative dimensions are a critical aspect of the claimed invention” such that “the claimed height dimensions are not patentably distinct from the prior art.” (Ex. 1003 at ¶¶117-118.)

243. I disagree. Indeed, Dr. Fletcher's own arguments discussed above touting the benefits and advantages of the claimed configuration disprove his opinion. Moreover, as I explained above in Paragraphs 214 and 215, a POSA would understand that the claimed design provides numerous advantages in the context of the 591 Patent. That includes locating the sample on-body unit electronics activation switch away from the distal end to prevent inadvertent activation and allowing for a cap boss to stabilize the sensor and needle.

244. In sum, in my opinion, the cited art does not disclose or suggest the claimed housing-distance limitation as Dr. Fletcher asserts. Indeed, Dr. Fletcher has not identified any prior art reference—much less Stafford and Cote—where the “distance between the housing” of an OBU comprising a sensor coupled with electronics in a proximal versus distal position is “greater than...[the] height of [its]

housing.” Therefore, it is my opinion that Dr. Fletcher has failed to establish that this limitation is satisfied by the prior art.

**3. The Combination Does Not Teach An On-Body Unit With The Claimed Data Storage Unit [19.6]/[Claim 4]**

245. Independent Claims 1 and 19 (and therefore all claims) recite an OBU with “sensor electronics disposed within the [OBU] housing and coupled with the glucose sensor.” (Ex.1001 at Claims 1, 19.) Independent Claim 19 and Dependent Claim 4 further require the sensor electronics disposed within the OBU housing to comprise “a processor, a power source, an analog interface, a data storage unit, and wireless communication circuitry configured to communicate data indicative of a glucose level.” (*Id.* at Claims 4, 19.)

246. Dr. Fletcher generally relies on Stafford for these claim limitations, but concedes that Stafford does not expressly disclose the claimed “data storage unit.” (Ex. 1003 at ¶119.) Instead, he contends that a “data storage unit would be required” to “allow for [data] processing” and data transmission. (*Id.* at ¶120.) He then cites to Exhibits 1034 and 1035, two electronics textbooks that appear unrelated to CGM technology, to support his conclusion. (*Id.*) However, neither cited source establishes that there is a “requirement” for CGMs to have a data storage unit to perform the functions of processing and transmitting data. Instead, those sources describe generic data storage systems or the advantages of using digital data filters over analog ones.

Declaration of Karl R. Leinsing, MSME, PE

(Ex. 1034 at 509; Ex. 1035 at 23-25.) In my opinion, these sources do not establish that a “data storage unit” is “required” in Stafford.

247. In fact, in the next paragraph, Dr. Fletcher admits that the data storage unit is “optional” for CGMs, citing the Say reference. (Ex. 1003 at ¶121.) In discussing Say, he notes that Say “teaches that the on-skin sensor control unit electronics (‘sensor electronics’) optionally include a data storage unit.” (*Id.*)

248. Setting aside that Say is not included in Dr. Fletcher’s Ground 1 combination of Stafford and Cote, Say does not meet this claim limitation. As I discussed above in Section V.B.1, Say does not disclose an OBU comprising a glucose sensor coupled with sensor electronics as required by the claims. Rather, in Say, the sensor is separately inserted, and then the electronics are separately connected to the sensor by the user, as Dr. Fletcher acknowledged in his deposition. (*See, e.g.*, Ex. 1008 at 3:6-16; Ex. 2036 at 77:3-8.) As such, Say cannot disclose the claimed “sensor electronics disposed within the housing coupled with the glucose sensor, wherein the sensor electronics comprise...a data storage unit.” I explain why Say’s electronics are further inapposite elsewhere in this Declaration as well.

249. It is therefore my opinion that while Dr. Fletcher generically claims that the use of a data storage unit would have been an “obvious design choice,” he has not pointed to any piece of prior art that discloses the claim limitation at issue.

**4. The Combination Does Not Teach A Fully-Integrated OBU With The Claimed Height Profile [19.14]/[Claim 14]**

250. Independent Claim 19 recites an OBU housing, which includes “sensor electronics” (“processor,” “power source,” “analog interface,” “data storage unit,” and “wireless communication circuitry...”) coupled with the sensor, where “a height profile of the housing is less than or equal to approximately 10 millimeters.” (Ex. 1001 at Claim 19.) Dependent Claim 14 has the same height profile requirement. (*Id.* at Claim 14.)

251. Dr. Fletcher concedes that neither Stafford nor Cote—the only prior art explicitly relied upon in Ground 1—expressly teach this limitation. (Ex. 1003 at ¶136.) Instead, he argues that it would have been “obvious to configure the Stafford+Cote on-body unit housing to have a height profile of 10 mm or less” because both references teach a housing that “has a low height profile.” (*Id.*)

252. I disagree with Dr. Fletcher. First, the height of the housing of Cote’s infusion site is not relevant to the claim limitation at issue. This is because, as I discussed above, Cote’s infusion site (the alleged “on-body unit”) does not include any glucose sensor or sensor electronics. The height of Cote’s infusion site “housing” is simply irrelevant to this claim.

253. As for Stafford, Stafford does not include an OBU with all the claimed electronics, as Dr. Fletcher concedes that it is missing at least a “data storage unit.” (*See, e.g.*, Ex. 1003 at ¶119.) In any case, Stafford also does not disclose any OBU

housing with the claimed height profile of less than or equal to approximately ten millimeters, and Dr. Fletcher never argues that it does. (Ex. 1003 at ¶136.) While Stafford does describe having a low profile as an advantage, it never teaches the specific height profile of less than or equal to approximately ten millimeters. (Ex. 1004 at [0045].)

254. Because neither Stafford nor Cote describe the limitation, Dr. Fletcher states that “it was well-known in the art for such low height profile housings to be approximately 10 mm or less.” (Ex. 1003 at ¶136.) Dr. Fletcher cites to Section VI.B.4 of his expert declaration (Paragraph 35). In Paragraph 35, Dr. Fletcher states that the “desirability” of low-profile units was “well known” and identifies five other prior art references (which are not part of his combination) as support for his assertion that “on-body-units were known to have a height profile of 10 mm or below.” (*Id.* at ¶35.)

255. Despite citing to five additional prior art references, Dr. Fletcher has not identified any art that actually discloses the claimed limitation—much less established it is “well-known.” Specifically, none of Dr. Fletcher’s five additional references discloses an on-body unit comprising sensor electronics coupled with the sensor, wherein the height of the OBU housing is less than or equal to approximately 10 mm. (*See, e.g.*, Ex. 1012 (Brister-360) at [0155], Fig. 1 (disclosing two-part CGM where the sensor and the sensor electronics (i.e., transmitter) are manually connected

after insertion); Ex. 1013 (Brister-180) at [0267], Fig. 1 (same); Ex. 1014 (Funderburk-164) at [0009], Figs. 8, 12, 16 (disclosing unit where the sensor is not pre-coupled to electronics but coupled via port in mounting unit); Ex. 1015 (Heller) at 3:7-17, Figs. 14, 17, 33 (same); Ex. 1016 (Bonnecaze) at 31:20-35, 33:23-34:8, Figs., 14, 17 (same).) Indeed, creating an ultra-low profile OBU that includes all the claimed features was a challenge (as with other electromechanical devices).

256. Despite first asserting that low-profile on-body units are “desirable,” Dr. Fletcher next suggests the low profile does not affect “the performance of the device in any way.” (Ex. 1003 at ¶137.) However, it is my opinion that a POSA would understand that the invention of an ultra-low profile, easy to deliver OBU that included sensor electronics coupled with the glucose sensor was significant, resulting in, among other things, a device that was more tolerable and convenient for the user. (*See, e.g.* Ex. 2037 at 1; Ex. 2038 at 1.) The ultra-low profile allows for the device to be discretely and comfortably worn by users. As discussed earlier, the 591 Patent describes ways to achieve the design, including by identifying numerous ways the sensor can be configured so that the OBU housing can still be compact. (*See, e.g.*, Ex. 1001 at 17:66-18:7, 12:34-13:2, 14:28-42.)

257. Dr. Fletcher then argues in a conclusory manner that the “height profile of the housing is not a critical aspect of the claimed invention, as providing a ‘low-profile’ is well-known in the art.” (Ex. 1003 at ¶138.) However, as I explained above,

Dr. Fletcher has not established that the height profile of the claimed OBU housing (where the sensor electronics are disposed within the OBU housing and coupled with sensor electronics) was known. None of Dr. Fletcher's cited art disclosed such an OBU housing. Moreover, it is my understanding that an expert cannot just ignore certain claim limitations they perceive as "non-critical."

258. Importantly, POSAs' desire for the claimed ultra-low profile on-body unit does not establish that actually designing one was obvious. Nor does Dr. Fletcher explain why it would be. Indeed, as I discuss in Section XVIII., Dexcom for years employed multi-component systems and the ultra-low profile, all-in-one OBU used in the Abbott FreeStyle Libre products was an important innovation.

259. In sum, in my opinion, the cited art does not disclose or suggest the claimed OBU housing height profile limitation as Dr. Fletcher asserts.

## **B. Dependent Claims**

### **1. All Dependent Claims Incorporate Limitations Of Independent Claims 1 And 19**

260. Dr. Fletcher alleges in his Ground 1 combination that Dependent Claims 2-6, 9-14, 16-18, 20-24, 27, and 29-30 are also obvious based on the combination of Stafford and Cote. All of these claims depend on Independent Claims 1 or 19.

261. As I explained above, Independent Claims 1 and 19 are not rendered obvious by Dr. Fletcher's proposed combination. Therefore, these dependent claims

are also not obvious, at least for the reasons explained above with regard to Independent Claims 1 and 19.

**2. Dependent Claims 3-6, 9-14, and 16-17 Are Not Obvious Because They Incorporate Limitations Of Claim 19**

262. Dependent Claim 3, which depends on Independent Claim 1, incorporates the housing-distance limitation of Claim 19 (limitation 19.13). Therefore, it is my opinion that Claim 3 is not obvious for the reasons discussed above in Section X.A.2. Dependent Claims 4-17 each depend on Claim 3 and it is my opinion that they are not obvious at least for the same reasons.

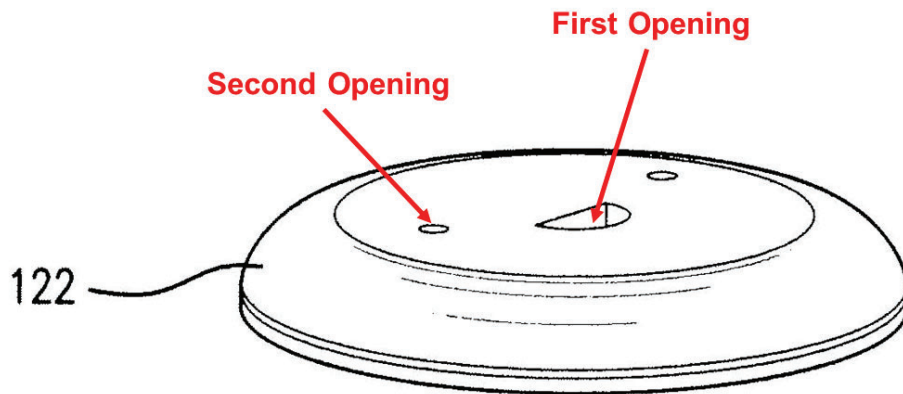
263. Dependent Claim 4 incorporates the sensor electronics limitation of Claim 19 (limitation 19.6). Therefore, it is my opinion that Claim 4 is not obvious for the reasons discussed above in Section X.A.3.

**3. The Combination Does Not Disclose A “Second Opening Of The Top Surface” [18.1]/[21.1]**

264. Independent Claims 1 and 19 recite a first “opening of the top surface” of the OBU housing, “wherein the sharp extends through the opening of the top surface... when the on-body unit is in a first position.” (Ex. 1001 at claims 1, 19.) Dependent Claim 18 (which depends on Claim 1) and Claim 21 (which depends on Claim 19) state “wherein the top surface further comprises a second opening of the top surface, wherein the first opening of the top surface has a first maximum width, and wherein the second opening of the top surface has a second maximum width less

than the first maximum width.” (*Id.* at Claims 18, 21.) Claims 22-30 of the 591 Patent depend directly or indirectly from Claim 21, and therefore also include these “second opening” limitations.

265. An example of the second opening is shown in a portion of Figure 23 of the 591 Patent, reproduced below. The second opening is also shown in Figure 22. The second opening, as well as a third, serve an alignment mechanism for the OBU during manufacturing.



266. Dr. Fletcher concedes that his primary references (Stafford and Cote) do not teach the “second opening” limitation (let alone one with a smaller maximum width). Instead, for Ground 1, Dr. Fletcher relies on “background” art (i.e., Brenneman and Turner) for this limitation. (Ex. 1003 at ¶145, n.7.) For other grounds (e.g., Ground 3), Dr. Fletcher relies on Brenneman expressly. Notably, for nearly all the “second opening” claims, Dr. Fletcher relies on at least four references (including “background” references)—and often five or more (e.g., Claim 28)—to meet the claims.

267. In my opinion, Dr. Fletcher’s arguments regarding the “second opening” are insufficient for multiple reasons. Moreover, they conflict with the teachings of his own cited references. Therefore, it is my opinion that Dr. Fletcher has failed to show that Claims 18 and 21 (and all claims that depend on Claim 21) are unpatentable.

**i. Dr. Fletcher’s Arguments Related to “OBU Securing” Is Refuted by His Own Cited Art and Admissions**

268. As his main argument based on Brenneman and Turner, Dr. Fletcher argues that a POSA would add a second opening to the top surface of Stafford’s housing “to secure the on-body unit ... to the inserter” and “to maintain the position of the on-body unit relative to the inserter.” (*Id.* at ¶41, ¶144.) Dr. Fletcher suggests that these “apertures” would “interface with corresponding protrusions on the insertion device for the aforementioned purposes.” (*Id.* at ¶144.)

269. I do not agree with Dr. Fletcher’s opinion. As Dr. Fletcher admits, Cote’s pre-existing design—without a second top-surface opening—already secures the alleged OBU to the inserter and maintains the OBU’s positioning via friction fit with the needle:

To retain the site within the opening of the cylinder hub within the inserter, an elastomeric diaphragm of the site is positioned on the needle to frictionally engage with the needle. ... Considering the inserter’s construction and the diaphragm’s structure and material properties, a POSITA reading Cote would understand that once the needle presses

through the diaphragm and the cannula, the frictional engagement between the needle and the diaphragm maintains the positioning of the site relative to the needle prior to and during delivery. ... This is similar to frictional engagement mechanisms used in other known inserter devices.

(*Id.* at ¶¶54-56; *see also id.* at ¶98 (a POSA “would have been motivated to incorporate a diaphragm-like device as taught by Cote”), ¶93; Pet. at 25-26; Ex. 1005 at [0205].) Dr. Fletcher also stated that “a POSITA would understand that the frictional engagement between the self-sealing aperture and Stafford’s sharp would be sufficient to maintain the relative vertical positioning between the on-body unit and the inserter....” (Ex. 1003 at ¶98.)

270. Dr. Fletcher cites nothing that indicates or even suggests that Cote’s “securing” method is inadequate or deficient. To the contrary, as shown above, Dr. Fletcher asserts that Cote’s securing method was commonly used in “other known inserter devices.” In my opinion, there is no reason to make Cote’s already complex assembly even more complex—and make the manufacturing process more costly—by adding a feature to achieve a function that Cote already provides. This is especially true given that Stafford emphasizes “cost reduction in manufacturing” and “reducing the number of components.” (Ex. 1004 at [0045].)

271. Adding a “second opening” is not only unnecessary, but it is inconsistent with how POSAs would view the references while also directly

conflicting with Dexcom's main references (Stafford and Cote). On the whole, it is my opinion that a POSA would avoid extra OBU housing top-surface openings—particularly ones that extend fully through the housing material (like Brenneman)—to minimize the risk of moisture or contaminant ingress into the OBU. Moisture or foreign contaminants can damage the sensitive electronics within the OBU, compromising the system's ability to function as intended. Dr. Fletcher agrees that it would be desirable to prevent moisture and other foreign contaminants from getting inside the OBU. (Ex. 2036 at 111:16-113:5.)

272. In fact, Stafford expressly teaches avoiding openings “where moisture or contaminant may compromise the functions and operations of the data processing unit 101.” (Ex. 1004 at [0027].) Cote teaches the same, stating “As the needle is removed, the closed end 154 of the diaphragm 150 reseals itself to retain the fluid-tight reservoir.” (Ex. 1005 at [0165].)

273. In his discussion of the “second opening” limitation, Dr. Fletcher also relies on Turner as background art. (Ex. 1003 at ¶¶146-148.) Setting aside that Turner is not part of any ground, Turner's cited openings (or recesses) are not used for securing an on-body unit to an inserter, as Dr. Fletcher suggests. Rather, Turner's cited openings serve a different purpose, *i.e.*, to prevent rotation between Turner's needle hub and on-body portion. (*See, e.g.*, Ex. 1007 at [0069].) Turner specifically calls them “rotation-restricting recesses” that interact with corresponding “rotation-

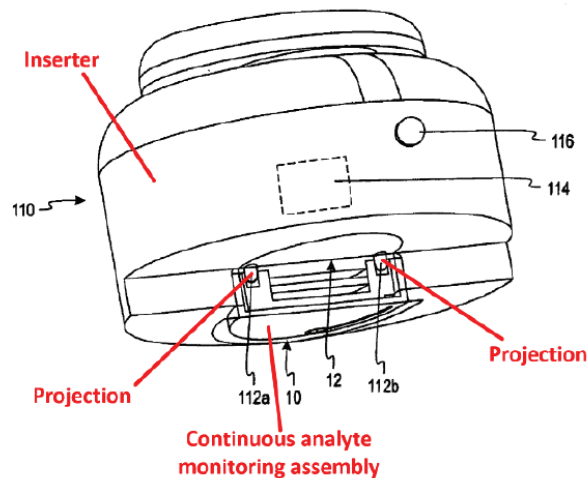
restricting protrusions” of needle hub 74. (*Id.*) Additionally, Turner teaches that its rotating-restricting recesses are optional, only further confirming that they are not responsible for “securing” the OBU. (*Id.*)

274. Notably, Turner already teaches securing its “body 20” to its needle hub-needle assembly, but not via Dr. Fletcher’s cited openings. Rather, Turner’s securing is achieved via a friction fit between the needle (coupled to the needle hub) and the “septum 40” of the “body 20”—just like Cote’s “securing” method. (*Id.* at [0099].) Accordingly, it is my opinion that if a POSA would have looked to Turner for teachings about “securing,” Turner simply would confirm that Cote’s pre-existing securing method is the way to go.

275. Dr. Fletcher also relies upon Brenneman. (Ex. 1003 at ¶¶145-147.) But the cited Brenneman openings (i.e., apertures 60a and 60b) correspond with “apertures 62a, 62b of the printed circuit board housing 16 ....” (Ex. 1040 at [0042], Fig. 3.) This is the type of openings a POSA would not want, i.e., openings that create a significant risk of moisture/contamination ingress into the electronics. The referenced Brenneman openings receive pins 112a and 112b of Brenneman’s inserter. After Brenneman’s inserter is removed after sensor insertion, the openings remain, providing a direct path for moisture/contamination. Further, Brenneman does not secure its on-body unit in a proximal position entirely within its inserter and then release it after it advances to a second position on the skin. Nor does

Brenneman teach securing its on-body unit “during shipment” as Dr. Fletcher indicates would be needed. (Ex. 1003 at ¶144.) Rather, Brenneman’s on-body unit starts at the bottom of the inserter and never moves downward (and Brenneman suggests that the user manually loads it into the inserter before applying it on the skin). (See, e.g., Ex. 1040 at [0026]-[0027] (cited Brenneman analyte monitoring assembly includes a reusable part and a disposable part and explaining how the user connects them), [0041] (describing the loading of the assembled continuous analyte monitoring assembly into the inserter), [0043] (describing the removing of the adhesive liner 20 before loading the analyte monitoring assembly into the inserter).)

276. The location of Brenneman’s monitoring assembly can be seen in Dr. Fletcher’s annotated version of Brenneman’s Figure 8, reproduced below.



Brenneman, FIG. 8 (annotated)

(Ex. 1003 at ¶145; Ex. 1040 at [0041].) Thus, even assuming a POSA would look beyond Cote's pre-existing, already-working securing design, it is my opinion that Brenneman's design would not be of interest.

277. Finally, as I explained above, it is my opinion that Dr. Fletcher's citation to Brenneman to supplement his proposed Cote and Stafford combination is inconsistent with how POSAs would view the three references. Dr. Fletcher relies on Brenneman only for the "second opening" limitation while disregarding Brenneman's disclosures about its sensor inserter. As I explained above, Brenneman generally describes a CGM assembly with an inserter that applies a monitoring assembly including a glucose sensor and sensor electronics.

278. Instead of starting with Brenneman's inserter and on-body unit design, Dr. Fletcher started with Stafford, which describes an on-body unit but specifically excludes a separate inserter, then combined that with Cote's infusion cannula inserter (that does not contemplate use with glucose sensors), and then looked to an opening from Brenneman to add a feature that solves an alleged problem that has already been addressed by Cote. It is my opinion that this is a hindsight analysis and a POSA would not follow this strained pathway.

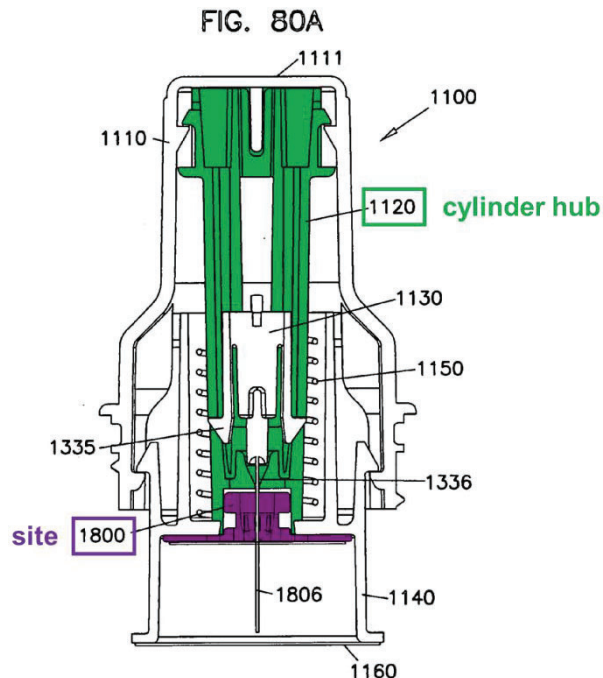
**ii. Dr. Fletcher's Arguments Related To "Anti-Rotation"**

279. Dr. Fletcher briefly suggests that a "POSITA would recognize the further benefit of the peripheral apertures taught by Brenneman, as those peripheral

apertures and associated pins would also assist in avoiding rotation of the on-body unit.” (Ex. 1003 at ¶146.) Dr. Fletcher does not expand on this cursory statement. It is my opinion that this “anti-rotation” argument likewise fails for many reasons.

280. First, Dr. Fletcher never shows that Cote’s pre-existing design does not already prevent rotation of its infusion site. In fact, he indicates the opposite, stating that Cote’s friction fit with the needle “maintains the positioning of the site relative to the needle prior to and during delivery.” (Ex. 1003 at ¶55.)

281. Further, as shown in Cote’s figures, the cylinder hub 1120 (green the annotated figure below) of Cote’s inserter pinches opposite sides of Cote’s alleged OBU (purple below), which likewise would prevent OBU rotation:



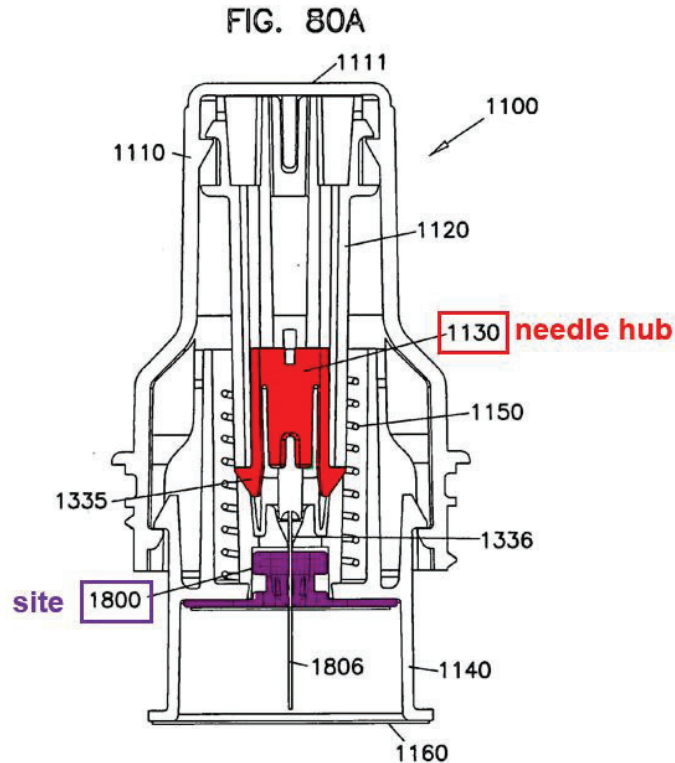
(*Id.* ¶57.) Additionally, Cote’s “adhesive portion 1160”—once coupled to Cote’s OBU (e.g., Ex. 1005 at Fig. 81A)—also would prevent OBU rotation.

282. Second, contrary to Dr. Fletcher’s assertion, Brenneman does not teach preventing OBU rotation. Brenneman actually teaches the opposite with respect to its design. Brenneman teaches that rotation of at least part of its OBU is “desirable” and necessary for its assembly to work. (*See, e.g.*, Ex. 1040 at [0047] (“The rotary motion of the continuous analyte monitoring assembly 10 [Brenneman’s OBU] is desirable because it results in a smaller footprint for the continuous analyte monitoring assembly. ... Additionally, the rotary motion is desirable because an angle is used with the insertion of the sensor, which results in improved depth control in the locating of the implantable sensor.”), [0046] (referring to “rotation of the continuous analyte monitoring assembly” during operation), [0044] (same), [007] (same).)

283. Third, Dr. Fletcher’s “background” Turner reference is also unhelpful. (Ex. 1003 at ¶¶146-148.) Turner at most teaches preventing rotation between a needle hub and an on-body device (Turner does not have a separate inserter), but Cote already does that as explained above (and as Dr. Fletcher acknowledges) (Ex. 1003 at ¶55.). POSAs starting with Stafford—which emphasizes “cost reduction in manufacturing” and “reducing the number of components”—would not want to add Turner’s merely “optional” vertical anti-rotation protrusions and recesses. (Ex. 1004

at [0045].) Further, unlike Brenneman, Turner is not part of any ground. As noted above, the reference actually cited by Dr. Fletcher in certain grounds (Brenneman) teaches that OBU rotation is desirable and necessary with its design (Dr. Fletcher's non-ground reference Turner cannot override that teaching).

284. Finally, with no independent analysis, and providing virtually no context or details, Dr. Fletcher states that he “understand[s]” that “Patent Owner” allegedly made certain Turner-related admissions in a “foreign litigation.” (Ex. 1003 at ¶148.) As an initial matter, I understand that Dr. Fletcher made this same argument in other recent IPRs filed by Dexcom and that his positions were not adopted by the Board. Second, I understand that the patent at issue in Germany is unrelated to the patent at issue here (in fact, I understand that it is not even an Abbott patent at issue there). Third, as I explained above, and as Dr. Fletcher indicates, Cote's pre-existing design appears to already prevent OBU rotation, so Dr. Fletcher's Turner-based “anti-rotation” arguments are misplaced. Finally, I understand that the cited Turner design involves needle hub protrusions directly interacting with OBU recesses. (Ex. 1007 at [0069]). Even assuming Cote does not already prevent rotation, Turner's design would not be of interest because it would not work with Cote's design because Cote's needle hub (red below) and site (purple below) are not adjacent to each other:

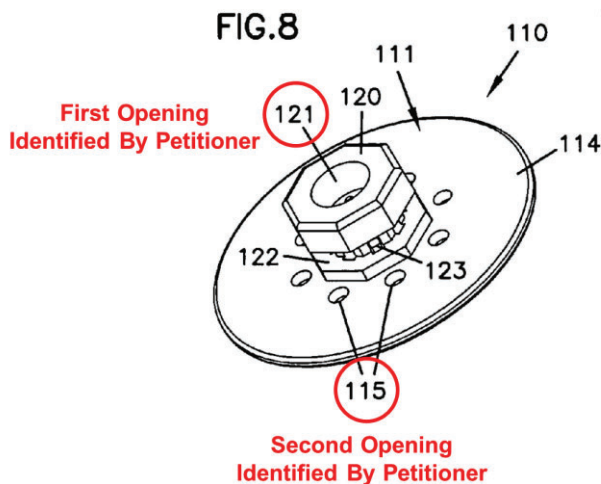


For at least these reasons, I disagree with Dr. Fletcher’s cursory alleged “admissions” argument.

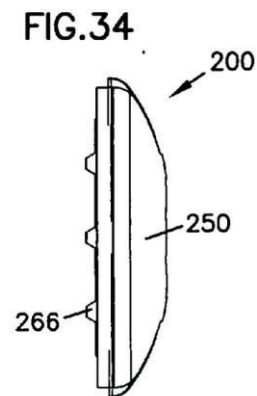
285. In sum, it is my opinion that a POSA would not seek “to add at least one peripheral aperture (or ‘second opening’) to the top surface of the Stafford+Cote on-body unit to maintain the position of the on-body unit” as Dr. Fletcher asserts. (Ex. 1003 at ¶149.) In fact, Dr. Fletcher states that Cote’s pre-existing design already maintains such positioning. (*See, e.g., id.* at ¶¶55 (“[T]he frictional engagement between [Cote’s] needle and the diaphragm maintains the positioning of the site relative to the needle prior to and during delivery.”), 93.).

**iii. Dr. Fletcher’s Cited “Openings” From Cote**

286. Dr. Fletcher also cites to certain openings in Cote. (Ex. 1003 at ¶147.) But those alleged “second openings” are located in the interior of Cote’s infusion device (specifically on a lower surface of the bottom portion). Further, Dr. Fletcher’s alleged “first opening” and “second opening” of Cote are not features of the same surface (contrary to the 591 claims).



**Bottom Portion Of  
Cote’s Infusion Device**



**Top Portion Of  
Cote’s Infusion Device**

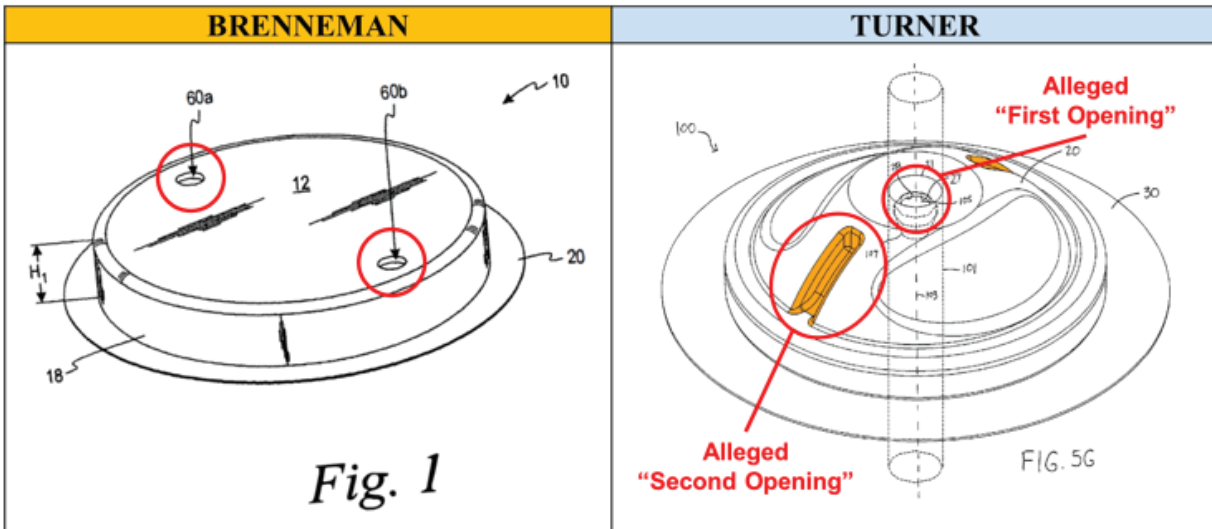
(*Id.* at Figs. 8 and 34, [0167].)

287. These alleged “second openings” are part of a male-female connection for the top portion and bottom portion of Cote’s two-piece infusion device. They are not relevant to the rest of Dr. Fletcher’s argument, so it is unclear why he references them. Dr. Fletcher admits that they are irrelevant, saying these referenced openings serve a “different purpose.” (Ex. 1003 at ¶147.) It is my opinion that these openings of Cote do not teach the claimed “second opening.”

**iv. The Different Maximum Width Limitation**

288. As discussed above, Dependent Claims 18 and 21 (and therefore, all claims that depend from them) also include a limitation stating “wherein the first opening of the top surface has a first maximum width, and wherein the second opening of the top surface has a second maximum width less than the first maximum width.” (Ex. 1001 at Claims 18, 21.) This limitation specifically requires the second opening to have a smaller maximum width than the first opening through which the needle extends. POSAs would understand that it is beneficial to have the second opening as small as possible, because the smaller opening can reduce the risk of moisture or foreign contaminants entering the OBU and potentially damaging sensitive electronics within the OBU.

289. In his declaration, Dr. Fletcher does not substantively address this limitation. Importantly, the main references Dr. Fletcher relied on to disclose the second opening, Brenneman and Turner, do not teach the claimed width limitations, and in fact teach the opposite of the claimed limitations. Brenneman’s cited openings 60a/60b are the same size and Turner teaches the opposite, i.e., its cited “second opening” has a larger maximum width than its “first opening.” This can be shown in the annotated figures below.



(Ex. 1040 at Fig. 1; Ex. 1007 at Fig. 5G.)

290. Unable to meet this limitation, Dr. Fletcher cites internal lower surface “second openings” in Cote’s infusion device (Ex. 1003 at ¶151) that are not even of the same surface as Dexcom’s identified “first opening” (as the challenged 591 claims require). Cote’s cited openings are therefore irrelevant, as explained earlier.

291. In sum, the cited art does not disclose or suggest the claimed “second opening” limitations as Dr. Fletcher asserts.

## **XI. GROUND 2: STAFFORD AND COTE IN VIEW OF SAY (CLAIMS 4, 7-8, 14-15, AND 19-30)**

292. In Ground 2, Dexcom and Dr. Fletcher assert that Claims 4, 7-8, 14-15, and 19-30 are unpatentable as obvious over Stafford and Cote in further view of Say. (See Pet. at 84, Ex. 1003 at Section IX.)

293. I disagree. In my opinion, the claims are not obvious over Stafford and Cote in further view of Say. As a preliminary matter, as I explain in Section IX

above, a POSA would not be motivated to combine Stafford and Cote nor has Dr. Fletcher explained why success would be reasonably expected from the combination. Additionally, the combined references do not disclose or suggest numerous claim limitations including the ones discussed in Ground 1.

294. Indeed, all claims challenged in Ground 2 depend on Claims 1, 3, 19, and/or 21, and are not unpatentable for at least the reasons discussed in Section X. All claims additionally depend on either Dependent Claim 3 or Independent Claim 19 (which includes the missing “housing-distance” limitation). And Claims 22-30 additionally depend on Claim 21, and therefore further include the non-obvious “second opening” limitation. Thus, numerous limitations remain missing even with Dexcom’s new proposed Say combination.

295. In addition to what was already discussed in Ground 1, the combined references of Stafford, Cote, and Say do not disclose or suggest numerous additional claim limitations, including:

- on-body unit comprising “sensor electronics disposed within the [OBU] housing and coupled with the glucose sensor” where the sensor electronics include “a data storage unit” (limitation 19.6, Claims 4 and 19-30)
- on-body unit housing with the claimed sensor electronics disposed therein and having a “height profile...less than or equal to approximately 10 millimeters” (limitation 19.14, Claims 14 and 19-30)

- on-body unit with sensor electronics disposed therein “wherein the sensor electronics are in a sleep mode or an idle mode when the on-body unit is in the first position” (Claims 7 and 25)
- on-body unit with sensor electronics disposed therein “wherein the sensor electronics are configured to be activated when the on-body unit is at or near the second position” (Claims 8 and 26)
- insertion assembly comprising “a sensor hub” (Claims 15 and 28)

296. Therefore, Ground 2 does not render any claims of the 591 Patent unpatentable. I explain additional reasons below.

**A. “Data Storage Unit”**

297. As I explained above in Section X.A.3., Dependent Claim 4 and Independent Claim 19 (as well as Dependant Claims 20-30) require that the sensor electronics comprise a “processor, a power source, an analog interface, a data storage unit, and wireless communication circuitry configured to communicate data indicative of a glucose level.” (Ex. 1001 at Claims 4, 19.) For this limitation in Ground 2, Dr. Fletcher acknowledges that neither Stafford nor Cote teach the claimed “data storage unit” and instead relies expressly on Say. (Ex. 1003 at ¶¶181-182.) However, Say still does not disclose the limitation as claimed, as I explained above in Section X.A.3.

298. Specifically, Say does not teach an on-body unit with sensor electronics disposed within the OBU housing and coupled with the glucose sensor, as required by the claims. Rather, in Say, the sensor is separately inserted, and then the electronics are separately connected to the sensor by the user as Dr. Fletcher acknowledged in his deposition. (*See, e.g.*, Ex. 1008 at 3:6-16; Ex. 2036 at 77:3-8.) As such, Say cannot disclose the claimed “sensor electronics disposed within the housing coupled with the glucose sensor, wherein the sensor electronics comprise...a data storage unit.”

299. While Dr. Fletcher generically asserts that Say describes an on-skin sensor control unit that includes a data storage unit, he has not pointed to any piece of prior art that discloses the claim limitation at issue—as claimed.

300. In sum, in my opinion, the cited art does not disclose or suggest the claimed limitation as Dr. Fletcher asserts.

**B. Say Does Not Teach A Fully-Integrated OBU With The Claimed “Height Profile”**

301. As I explained in Section X.A.4., Dependent Claim 14 and Independent Claim 19 require a housing of the claimed OBU (i.e., an OBU comprising sensor electronics disposed within the OBU housing coupled with a glucose sensor) to have a “height profile” that “is less than or equal to approximately 10 millimeters.” (Ex. 1001 at Claims 14, 19.) In his discussion of this combination, Dr. Fletcher relies solely on Say, stating that Say “teaches that the on-body unit ‘has a height of ...

preferably 0.7 cm [7 mm] or less.” (Ex. 1003 at ¶183, citing Ex. 1008 at 29:38, 29:45-47.)

302. However, like the other alleged lower-profile background references that Dr. Fletcher relied on in his Ground 1 (see Section X.A.4), the cited “on-body unit” in Say is not the OBU of the claims. The OBU does not include sensor electronics disposed within the OBU housing and coupled with a glucose sensor. As I explained previously, and as Dr. Fletcher acknowledged in his deposition, Say explicitly discloses a multi-component device where the sensor is separately inserted before a user manually connects the sensor to the electronics after sensor insertion. (*See, e.g.*, Ex. 1008, 3:6-16, 33:1-20; Ex. 2036 at 77:3-8.)

303. In sum, in my opinion, the cited art does not disclose or suggest the claimed limitation as Dr. Fletcher asserts.

**C. Say Does Not Disclose The “Sleep Mode Or [] Idle Mode” Or The “Activation” Claim Limitations**

304. Dependent Claims 7 and 25 of the 591 Patent recite that the “sensor electronics are in a sleep mode or an idle mode when the on-body unit is in the first position” within the inserter. (Ex. 1001 at Claims 7, 25.) Dependent Claims 8 and 26 require that the “sensor electronics are configured to be activated when the on-body unit is at or near the second position” on the skin. (*Id.* at claim 8, 26.)<sup>4</sup>

---

<sup>4</sup> I note that Dr. Fletcher suggests that electronics “activation” in Claims 8 and 26 is limited to activating the electronics from a no power state. (Ex. 1003 at ¶166.) The

305. The specification of the 591 Patent explains that these “sleep/idle mode” and “activation” features are important for the design of the claimed insertion assembly wherein the sensor and corresponding electronics are coupled as part of the OBU, which is initially within the inserter. For example, the specification explains that, “[w]ith a power supply such as a battery integrated within the assembly,” these features help with “cost optimization and prolonging shelf life.” (*Id.* at 19:41-51.)

306. The specification states that, in instances wherein the sensor and electronics are coupled during manufacturing, “there may be a period of time” before the product is actually in use. (*Id.* at 19:41-44.) Thus, ideally, the electronics would initially be in a sleep mode (or the like) to conserve battery power, but then activate when the OBU is on or near the skin. (*Id.* at 19:44-51.) The 591 Patent depicts and describes multiple sample novel solutions to this complex problem. (*See, e.g., id.* at Figs. 32-43, 19:41-22:35.)

---

591 claims do not include this restriction and the 591 specification expressly teaches activating the electronics from a “sleep” or “idle” mode (e.g., modes with some power) to “an active mode,” as Dr. Fletcher acknowledged during his deposition. (*See, e.g.,* Ex. 1001 at 19:41-57; Ex. 2036 at 32:21-33:3 (“Q. Now, the 591 specification teaches sensor electronics that are in a sleep [or] idle mode; is that correct? A. It certainly mentions it there, yes. Q. The 591 specification also talks about activating such electronics that are in a sleep [or] idle mode. Correct? A. That’s correct.”).) However, this distinction does not impact my analysis.

307. Dr. Fletcher's analysis is cursory. (Ex. 1003 at ¶¶164-169.) For these limitations, Dr. Fletcher relies on Say, which is evidenced by the fact that the only grounds in which he contends claims 7-8 and 25-26 are obvious include Say in the combination. (*See also* Ex. 2036 at 89:22-90:2, 90:15-20, 91:10-15.) In my opinion, Dr. Fletcher's electronics "sleep mode/activation" arguments fail for multiple reasons.

308. First, Say's and Stafford's OBUs are fundamentally different. This is especially true with respect to the electronics "sleep mode/activation" claims. That is because, as discussed earlier and as Dr. Fletcher acknowledged in his deposition, Say involves a separate electronics component that is manually connected to the sensor by the user after sensor insertion (there is no pre-coupled sensor and electronics). Say's electronics are never disposed within an inserter (pre-coupled or not), let alone advanced from a first position within an inserter with the sharp extending through an opening of the top surface of the OBU housing to a second position on the skin where the electronics are activated when the OBU is at or near the second position.

309. While Say does state that its manually-applied electronics "optionally" may be in a sleep mode prior to use, in those situations, Say's electronics are activated simply when the user manually connects the electronics to the sensor (e.g., which causes a change in resistance across the electric contacts):

The on-skin sensor control unit 44 detects that it is being used and activates itself. Detection of use may be through a number of mechanisms. These include, for example, detection of a change in resistance across the electrical contacts, actuation of a switch upon mating the on-skin sensor control unit 44 with a mounting unit 77 (see FIGS. 27A and 28A).

\*\*\*

The mating of the housing 45 and the mounting unit 77 establishes contact between the contact pads 49 (see e.g., FIG. 2) on the sensor 42 and the conductive contacts 80 on the on-skin sensor control unit 44. Optionally, this action activates the on-skin sensor control unit 44 to begin operation.

(Ex. 1008 at 31:45-53, 36:34-39.)

310. In my opinion, Say's alleged "sleep mode/activation" description could not work with Stafford. That is because, unlike Say, Stafford's sensor and electronics are already connected by the manufacturer. (*See, e.g.*, Ex. 1004 at [0018] ("In accordance with the various embodiments of the present invention, there is provided and integrated sensor delivery and data processing unit ...."), [0006], Fig. 7.) Say does not teach anything about how to maintain electronics already connected to the sensor in a sleep or idle mode (indeed, Say teaches the opposite, i.e., the electronics are activated when connected with the sensor after the sensor is already inserted in a user). Say also does not teach how to activate the electronics that are already

connected to a sensor and part of an OBU within an inserter when the OBU is on or near the skin (e.g., such that the battery is not already depleted by the time the user is ready to use the device).

311. In my opinion, these are significant achievements. For example, the 591 Patent depicts and describes multiple ways to activate electronics that are coupled with the sensor within an inserter. (See, e.g., Ex. 1001 at Figs. 32-43, 19:41-22:35, e.g., 19:58-60 (describing “automatic activation of the electronics 80”).) While a POSA may appreciate that it would be desirable to conserve battery power (Ex. 1003 at ¶169), Say does not explain how that could be done in the claimed embodiment where the sensor is pre-coupled to the electronics.

312. When addressing the electronics “activation” of Claims 8 and 26, Dr. Fletcher also quotes a partial sentence from Stafford indicating that its “data processing unit 101 may be configured to transmit the encoded sample data signals ... *after the completion of the initial power on procedure.*” (Ex. 1003 at ¶168 (emphasis in original).) But as Dr. Fletcher concedes, Stafford—including this partial sentence—does not render Claims 8 and 26 obvious as Dr. Fletcher does not include these claims in the grounds that include Stafford but not Say (i.e., grounds 1, 3, 4, and 7).

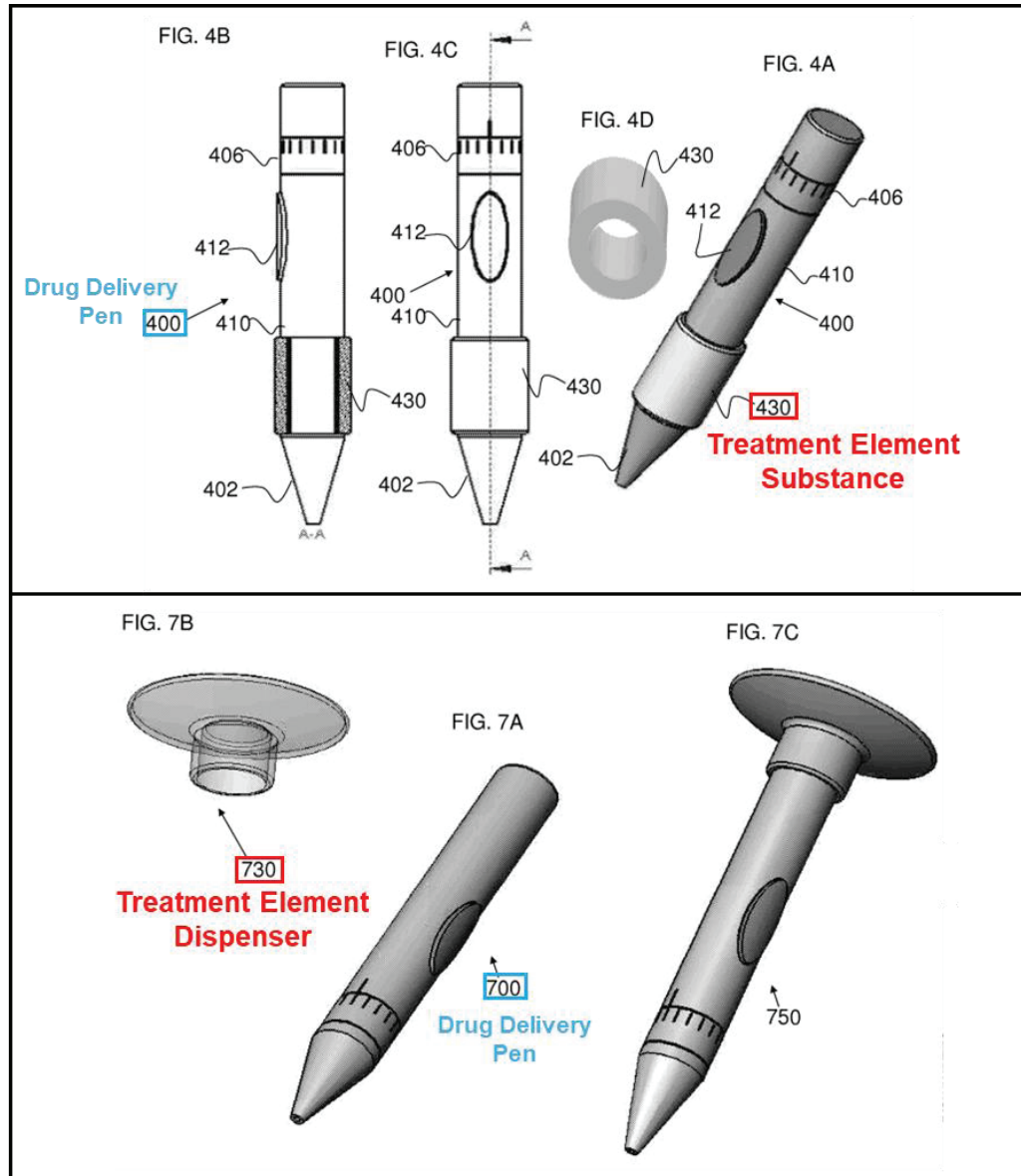
313. As discussed, Stafford does not teach activating its electronics when the OBU is at or near the second position as claimed. For example, Stafford’s OBU is

never within an inserter, so it is never in the claimed “first position” or advanced to the claimed “second position.” Moreover, Stafford’s reference to an “initial power on procedure” does not explain how or when the “power on” is initiated—much less how it could work if the OBU starts within an inserter (indeed, Stafford specifically teaches against using a separate inserter).

314. Finally, in connection with the electronics “activation” claims, Dr. Fletcher references Pesach (Ex. 1019) in a single sentence with no description or analysis. (Ex. 1003 at ¶169.) As an initial matter, Dr. Fletcher does not identify Pesach as part of any of his grounds. Further, Dr. Fletcher does not provide any explanation of (a) a motivation or reason to combine with Pesach, (b) how Pesach would be combined with the other references, or (c) any alleged reasonable expectation of success.

315. In any case, Pesach is directed to different technology. Specifically, Pesach is directed to a drug delivery device (like a drug-delivery pen) that has a “tissue treatment element” coupled to the delivery device for “improv[ing] the drug’s pharmacokinetic and/or pharmacodynamic profile.” (*See, e.g.*, Ex. 1019 at [0010], Abstract, [0048], [0018], [0082]-[0084], claims 1-3, 50.) Examples of Pesach’s “tissue treatment elements” include a heating element, radiation emitter, sound transducer, vibration device, or light emitting device. (*Id.* at [0018].)

316. Figures 4A-C and 7A-C, reproduced below, provide examples of Pesach drug delivery pens with tissue treatment elements:



(*Id.* at Figs. 4A-C, 7A-C.)

317. Even if Pesach were part of any ground, it lacks many elements relevant to the claims of the 591 Patent and any combination proposed by Dr. Fletcher. Among many other things, Pesach does not describe: an implantable glucose sensor

(let alone one coupled with sensor electronics); an OBU within an inserter (let alone one that advances from a first position within the inserter to a second position on the skin); and electronics in a sleep or idle mode.

318. Dr. Fletcher cites an embodiment where a heating “treatment element 1210” is manually pushed down on the skin to temporarily “heat the tissue around the injection site” to improve drug performance. (Ex. 1003 at ¶169; Ex. 1019 at [0082-84].) In my opinion, POSAs would not understand this to teach the claimed “activation” limitation of the 591 Patent.

319. In sum, in my opinion, the cited art does not disclose or suggest the claimed limitation as Dr. Fletcher asserts.

**D. Say Does Not Disclose the “Sensor Hub” Limitations**

320. Dependent Claims 15 and 28 of the 591 Patent recite that the claimed insertion assembly further comprises a “sensor hub” wherein “the proximal sensor portion is engaged with the sensor hub.” (Ex. 1001 at Claims 15, 28.)<sup>5</sup>

321. In discussing this limitation, Dr. Fletcher appears to assert that the claimed “sensor hub” is a separate “support structure,” used to “hold, support, and/or guide the sensor ... into the correct position,” which can also “help promote adequate

---

<sup>5</sup> Dr. Fletcher appears to suggest that the claimed “sensor hub” must be “within” the OBU housing. (Ex. 1003 at ¶¶170, 172.) But this is not required by the claims.

electrical contact between [the] proximal sensor portion and [the] sensor electronics.” (Ex. 1003 at ¶¶176-177.)

322. Dr. Fletcher concedes that Stafford, Cote, Brenneman, and Shah do not disclose the recited sensor hub, but instead relies solely on Say. (Ex. 1003 at ¶¶170-184; *see also* Ex. 2036 at 89:10-15, 90:4-14.) According to Dr. Fletcher, Say teaches a sensor hub that helps ensure a proper connection between the sensor and electronics. (*Id.* at ¶177.)

323. In my opinion, Dr. Fletcher’s “sensor hub” arguments are incorrect for multiple reasons. They are contradicted by his own cited references and positions in connection with other claims. As explained below, given Stafford’s OBU design, a POSA would not be motivated to add Say’s alleged sensor hub to Stafford’s OBU, and in fact, adding such a component would conflict with Stafford’s teachings.

324. Dr. Fletcher once again suggests that Stafford’s and Say’s OBUs are similar. (*Id.* at ¶158; *see also id.* at ¶171.) But, again, they are fundamentally different. Say does not disclose an OBU where the sensor is pre-coupled with the electronics, but as Dr. Fletcher acknowledged at his deposition, Say is directed entirely to older “two-part” CGM systems where the user first inserts the sensor into the body and thereafter manually connects separate sensor electronics to the sensor:

Once the sensor 42 is implanted in the patient, the sensor control unit 44 is placed over the sensor 42 with the conductive contacts 80 in contact with the contact pads 49 of the sensor 42.

The sensor 42 may be inserted into the subcutaneous tissue of the patient through the sensor port 78. The on-skin sensor control unit 44 may then be placed on the skin of the patient with the sensor 42 being threaded through the sensor port 78.

The insertion gun 200 is activated and a portion of the sensor 42 [is] driven through the skin .... The housing 45 of the on-skin control unit 44 is then coupled to the mounting unit 77 [which] establishes contact between the [sensor and] on-skin sensor control unit 44.

(Ex. 1008 at 31:59-62, 33:38-42, 36:25-38; (Ex. 2036 at 77:3-8 (“Q. And the Say reference is directed to two parts[] CGM systems, where the user first inserts the sensor and then manually connects the sensor electronics to the sensor after sensor insertion. Right? A. Yes, I believe that’s my understanding of the description in Say.”))

325. Because Say relies on the user to manually make the sensor-electronics connection in this manner, there is a risk of an inadequate connection. This risk can be compounded due to the fact that people with diabetes may be elderly, lack dexterity, have vision issues, etc. For example, diabetic neuropathy can cause numbness, loss of feeling, and loss of dexterity and strength in the hands and fingers and can make fine motor control difficult. Thus, it is unsurprising that Say would teach a feature to help ensure that the user achieves a proper sensor-electronics connection.

326. But, unlike Say, in Stafford, the sensor and electronics are already connected by the manufacturer. (*See, e.g.*, Ex. 1004 at [0018] (“In accordance with the various embodiments of the present invention, there is provided and integrated sensor delivery and data processing unit ....”), Fig. 7.) Dr. Fletcher notes that Stafford’s sensor has an upper portion “disposed within the housing and in electrical communication with the data processing unit” and explains that “a POSITA would understand that the upper portion of [Stafford’s] sensor physically contacts the sensor electronics....” (Ex. 1003 at ¶¶127-128.) In other words, there is no risk of an inadequate connection by the user.

327. Further, in my opinion, there is no indication (and Dr. Fletcher does not assert) that Stafford’s pre-existing sensor-electronics connection is insufficient or needs improvement. There is also no need to “guide the sensor [] into the correct position” with respect to the electronics as Dr. Fletcher asserts (*id.* at ¶176.)—this is already done for the user. In short, it is my opinion that a POSA would not be motivated to add Say’s alleged sensor hub to Stafford’s OBU, which only would add material and complexity, contrary to the teachings of Stafford.

328. Additionally, POSAs would understand that, even in Say’s context where the user must manually make the sensor-electronics connection, Say teaches that its alleged sensor hub (support structure 82) is optional. (Ex. 1008 at 34:50-52 (“The on-skin sensor control unit 44 may optionally contain a support structure 82

to hold, support, and/or guide the sensor 42 into the correct position.”), 34:59-61 (“A support 82 may be provided under the sensor 42 to promote adequate contact between the contact pads 49 on the sensor 42 and the pins 84”). Given Stafford’s pre-connected sensor and electronics—and teachings about reducing components and cost—it is my opinion that a POSA would not add this “optional” feature to Stafford’s OBU.

329. Dr. Fletcher’s own cited art—and positions in connection with other 591 claims—further refute his “sensor hub” arguments and confirm my view. Of the five main references cited in his grounds, based on his arguments, only two disclose an embodiment where the sensor electronics connection is made by the manufacturer. (*See, e.g.*, Ex. 1003 at ¶¶46, 194.) Neither teaches using a sensor hub (nor does Dr. Fletcher assert they do).

330. Dr. Fletcher cites Shah for a different limitation found in claims 9 and 22. In connection with those claims, Dr. Fletcher asserts that Shah—that does not use a sensor hub—“was at the very least the most obvious design choice ....” (Ex. 1003 at ¶130; *see also, e.g., id.* at ¶198.) If a POSA would adopt Shah’s non-sensor-hub design for Claims 9 and 22, then the same must be true for Claims 15 and 28 (the claims requiring a sensor hub). In my opinion, POSAs would not interpret the combinations in the way that Dr. Fletcher alleges.

331. Finally, Dr. Fletcher cites Bickoff (Ex. 1018) with no detailed description or analysis. (*Id.* at ¶179.) As an initial matter, Dr. Fletcher does not identify Bickoff as part of any of his grounds. Further, Dr. Fletcher does not provide any explanation of (a) a motivation or reason to combine with Bickoff, (b) how Bickoff would be combined with the other references, or (c) any alleged reasonable expectation of success.

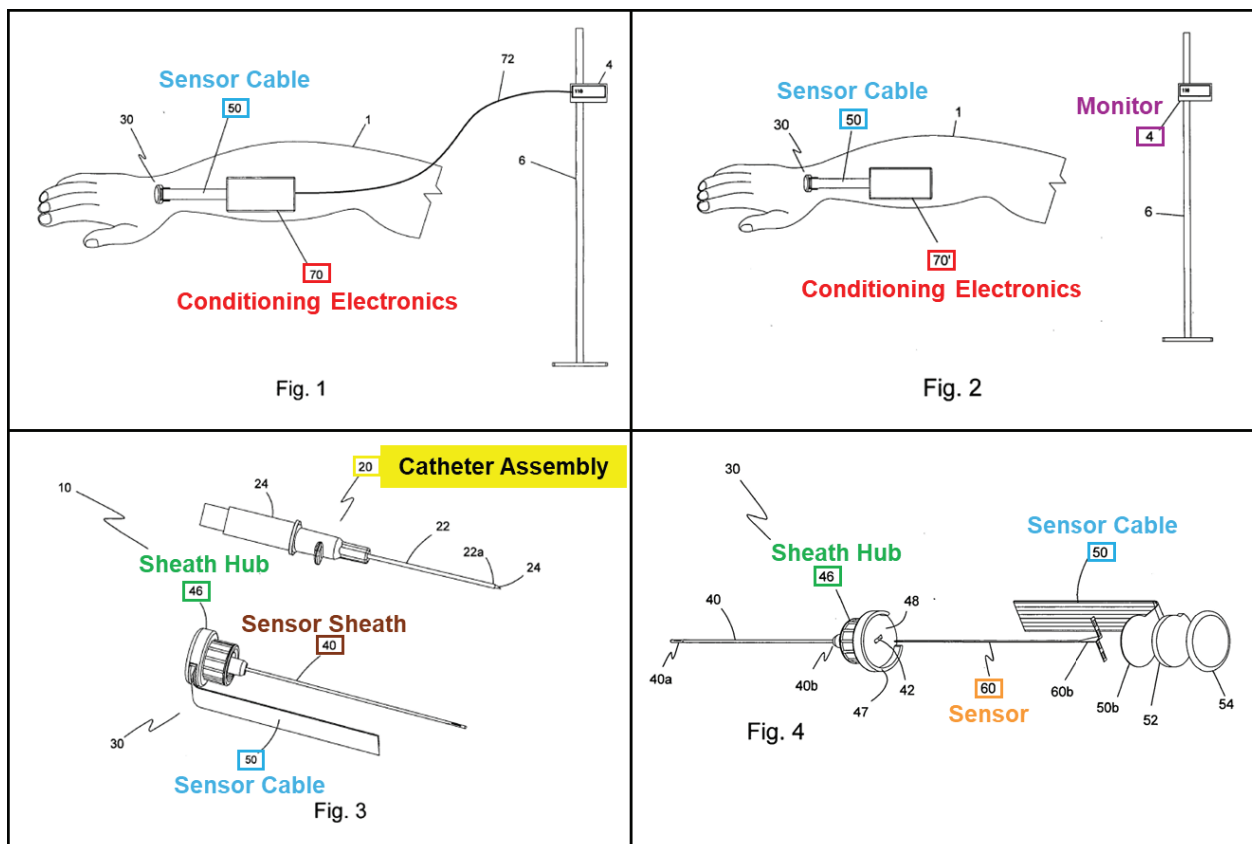
332. In any event, POSAs would not find Bickoff's complicated design relevant. Bickoff is directed to analyte measuring methods for hospitalized patients (e.g., in the ICU) using an intravenous catheter. (*See, e.g.*, Ex. 1018 at Abstract, [0004], [0009]-[0014].) Bickoff lacks an OBU comprising a glucose sensor and sensor electronics disposed within the OBU housing (let alone with the sensor contacting the electronics as in Stafford). Instead, Bickoff's sensor is surrounded by a long sheath (40). (*Id.* a Fig. 4 (below), [0012], [0034]-[0035].) The proximal end of the sensor (60b) sits within "sheath hub 46." (*Id.* at Fig. 4.)

333. According to Dr. Fletcher, Bickoff's hub "applies pressure against the sensor 60 to maintain good electrical contact" between the sensor and sensor electronics. (Ex. 1003 at ¶179.) But that is inaccurate. Bickoff's sensor never physically contacts sensor electronics (as in Stafford). Rather, Bickoff's sheath hub serves as a connection point between the proximal end of the sensor and a long cable (50). (Ex. 1018 at Figs. 3-4, [0035]-[0036].) Specifically, in use, hospital staff inserts

Declaration of Karl R. Leinsing, MSME, PE

Bickoff's sensor (within the sheath hub) into a patient using a catheter assembly (20). (*Id.* at Fig. 3, [0031], [0014].) Then, after sensor insertion, the staff manually connects that sensor cable to a separate electronics component (70) that is remote from the sensor (where that electronics component communicates with a monitor (4) on a bedside post or the like). (*Id.* at Figs. 1-4, [0032]-[0033].)

334. Below are some sample Bickoff figures:



(*Id.* at Figs. 1-4.)

335. In short, Bickoff has a fundamentally different design and purpose than the user-based designs of Stafford's OBU and Cote's inserter. It is my opinion that a POSA would not adopt Bickoff's complicated and unwieldy design meant to be

Declaration of Karl R. Leinsing, MSME, PE

used by hospital staff with an intravenous catheter, connection cable, and after-connected and remotely located electronics. Indeed, POSAs would understand that where the on-body unit already provides a direct connection between the sensor and electronics (as in Stafford), Bickoff's design makes no sense.

336. In sum, in my opinion, the cited art does not disclose or suggest the claimed "sensor hub" limitation as Dr. Fletcher asserts.

## **XII. GROUND 3: STAFFORD AND COTE IN VIEW OF BRENNEMAN (CLAIMS 18, 21-24, 27, AND 29-30)**

337. In Ground 3, Dexcom and Dr. Fletcher assert that Claims 18, 21-24, 27, and 29-30 are unpatentable as obvious over Stafford and Cote in further view of Brenneman. (*See* Pet. at 95, Ex. 1003 at Section X.)

338. I disagree. In my opinion, the claims are not obvious over Stafford and Cote in further view of Brenneman. As a preliminary matter, as I explain in Section IX above, a POSA would not be motivated to combine Stafford and Cote nor has Dr. Fletcher explained why success would be reasonably expected from the combination. Additionally, the combined references do not disclose or suggest numerous claim limitations including the ones discussed in Ground 1.

339. Indeed, all claims challenged in Ground 3 depend on Claims 1, 19, and/or 21 and are thus patentable for at least the reasons discussed in Section X.

Thus, numerous limitations remain missing even with Dexcom's and Dr. Fletcher's new proposed Brenneman combination.

340. The main basis for Dr. Fletcher's Ground 3 argument is his express contention that, to satisfy the "second opening" limitations, it would have been obvious to further modify the Stafford/Cote combination to include Brenneman "apertures." (Ex. 1003 at ¶¶187-190.) However, as explained in Section X.B.3 above, I do not agree that the combinations render the claims obvious. Indeed, as discussed in Sections IX.B and X.B.3, in my opinion, POSAs would not be motivated to combine Brenneman with Stafford and Cote in the manner that Dr. Fletcher suggests.

341. Moreover, in my opinion, POSAs would not disregard Brenneman's differently-configured sensor inserter assembly while arbitrarily selecting apertures in its housing. This Ground further demonstrates that Dr. Fletcher's combination is not based on how POSAs would view the combination of references, but rather is an attempt to recreate the claims using hindsight.

342. Therefore, Ground 3 does not render any claims of the 591 Patent unpatentable.

**XIII. GROUND 4: STAFFORD AND COTE IN VIEW OF SHAH (CLAIMS 9, 22-24, 27 AND 29-30)**

343. In Ground 4, Dexcom and Dr. Fletcher assert that Claims 9, 22-24, 27, and 29-30 are unpatentable as obvious over Stafford and Cote in further view of Shah. (*See* Pet. at 98, Ex. 1003 at Section XI.)

344. I disagree. In my opinion, the claims are not obvious over Stafford and Cote in further view of Shah. As a preliminary matter, as I explain in Section IX above, a POSA would not be motivated to combine Stafford and Cote nor has Dr. Fletcher explained why success would be reasonably expected from the combination. Additionally, the combined references do not disclose or suggest numerous claim limitations including the ones discussed in Ground 1.

345. Indeed, all claims challenged in Ground 4 depend on Claims 1, 3, 19, and/or 21 and are thus patentable for at least the reasons discussed in Section X. All claims additionally depend on either Dependent Claim 3 or Independent Claim 19 (which includes the missing “housing-distance” limitation). And Claims 22-24, 27, and 29-30 additionally depend on Claim 21, which further include the “second opening” limitation. Thus, numerous limitations remain missing even with Dexcom’s and Dr. Fletcher’s new proposed Shah combination. (*See* Sections X.A and X.B.3)

346. The main basis for Dr. Fletcher’s Ground 4 argument is his express contention that, to satisfy the additional limitations in Dependent Claims 9 and 22,

it would have been obvious to further modify the Stafford and Cote combination to additionally include an aperture in the sensor electronics based on Shah (Ex. 1003 at ¶¶201-204.) However, Dr. Fletcher does not adequately explain why POSAs would be motivated to combine Stafford and Cote with Shah.

347. In my opinion, POSAs would not be motivated to combine Shah with Stafford and Cote in the manner that Dr. Fletcher suggests. In my opinion, POSAs would not disregard Shah's differently-configured sensor inserter while arbitrarily selecting an aperture in the sensor electronics from it. This Ground further demonstrates that Dr. Fletcher's combination is not based on how POSAs would view the combination of references, but rather is an attempt to recreate the claims using hindsight.

348. Therefore, Ground 4 does not render any claims of the 591 Patent unpatentable.

#### **XIV. GROUND 5: STAFFORD, COTE, AND SAY IN VIEW OF BRENNEMAN (CLAIMS 21-30)**

349. In Ground 5, Dexcom and Dr. Fletcher assert that Claims 21-30 are unpatentable as obvious over Stafford, Cote, and Say in further view of Brenneman, essentially adding Brenneman to their Ground 2 combination and combining arguments in Grounds 1, 2, and 3. (See Pet. at 103-104, Ex. 1003 at ¶¶205-206.)

Ground 5 fails for the same reasons explained in Grounds 1, 2, and 3. (*See* Sections X, XI, and XII.)

350. Moreover, in my opinion, the claims are not obvious over Stafford, Cote, and Say in further view of Brenneman. As a preliminary matter, as I explain in Section IX above, a POSA would not be motivated to combine Stafford and Cote nor has Dr. Fletcher explained why success would be reasonably expected from the combination. Additionally, the combined references do not disclose or suggest numerous claim limitations including the ones discussed in Grounds 1, 2, and 3.

351. Indeed, all claims challenged in Ground 5 depend on Claims 19 and/or 21 and are thus patentable for at least the reasons discussed in Sections X.A and X.B.3. Moreover, as explained in Grounds 1 and 2 (Sections X and XI), Dr. Fletcher cannot establish that the combination of Stafford, Cote, and Say render any claim obvious. And, as explained in Grounds 1 and 3 (Sections IX.B., X, and XII), Dr. Fletcher's reliance on Brenneman for the "second opening" in Claim 21 is unavailing including the arbitrary selection of Brenneman's apertures while ignoring Brenneman's other disclosures. Thus, numerous limitations remain missing even with Dexcom's new proposed Ground 5 combination.

352. Further, as with all previous grounds, Dr. Fletcher has failed to explain why POSAs would have been motivated to combine all four references—Stafford, Cote, Say, and Brenneman—to achieve the claimed combinations, particularly in the

arbitrary manner proposed. Again, Dr. Fletcher ignores Say's and Brenneman's different methods of sensor insertion and instead picks and chooses among the art to recreate the invention. It is my understanding that this is a hindsight-based analysis and is not proper for a validity analysis.

353. Therefore, Ground 5 does not render any claims of the 591 Patent unpatentable.

**XV. GROUND 6: STAFFORD, COTE, AND SAY IN VIEW OF SHAH (CLAIMS 25-26 AND 28)**

354. In Ground 6, Dexcom and Dr. Fletcher assert that Claims 25-26 and 28 are unpatentable as obvious over Stafford, Cote, and Say in further view of Shah, adding Shah to their Ground 2 combination and combining arguments in Grounds 1, 2, and 4. (*See* Pet. at 103-104, Ex. 1003 at ¶¶205-206.) Ground 6 fails for the same reasons explained in Grounds 1, 2, and 4. (*See* Sections X, XI, and XIII.)

355. Moreover, in my opinion, the claims are not obvious over Stafford, Cote, and Say in further view of Shah. As a preliminary matter, as I explain in Section IX above, a POSA would not be motivated to combine Stafford and Cote nor has Dr. Fletcher explained why success would be reasonably expected from the combination. Additionally, the combined references do not disclose or suggest numerous claim limitations including the ones discussed in Grounds 1, 2, and 4.

356. Indeed, all claims challenged in Ground 6 depend on Claims 19 and 21, and are patentable for at least the reasons discussed in Sections X.A and X.B.3. For example, all claims depend on Independent Claim 19 (which includes the missing “housing-distance” limitation). Moreover, as explained in Grounds 1 and 2 (Sections X and XI), Dr. Fletcher cannot establish that the combination of Stafford, Cote, and Say renders Claim 21 or 22 (and their Dependent Claims 23-30) obvious. Thus, numerous limitations remain missing even with Dexcom’s new proposed combination.

357. Moreover, Claim 21, upon which Claims 25-26 and 28 depend, requires a “second opening” and this ground (which does not rely on Brenneman) fails to provide any evidentiary basis for that limitation. (*See* Section X.B.3.)

358. Further, Dr. Fletcher has failed to explain why POSAs would have been motivated to combine all four references—Stafford, Cote, Say, and Shah—to achieve the claimed combinations, particularly in the arbitrary manner proposed. Again, Dr. Fletcher ignores Say’s and Shah’s different methods of sensor insertion and instead picks and chooses among the art to recreate the invention. In my opinion, this Ground further demonstrates that Dr. Fletcher’s combination is not based on how POSAs would view the combination of references, but rather is an attempt to recreate the claims using hindsight.

**XVI. GROUND 7: STAFFORD, COTE, AND BRENNEMAN IN VIEW OF SHAH (CLAIMS 22-24, 27, AND 29-30)**

359. In Ground 7, Dexcom and Dr. Fletcher assert that Claims 22-24, 27 and 29-30 are unpatentable as obvious over Stafford, Cote, and Brennenman in further view of Shah, adding Shah to their Ground 3 combination and combining arguments in Grounds 1, 3, and 4. (*See* Pet. at 105, Ex. 1003 at ¶207.) Ground 7 fails for the same reasons explained in Grounds 1, 3, and 4. (*See* Sections X, XII, and XIII.)

360. Moreover, in my opinion, the claims are not obvious over Stafford, Cote, and Brennenman in further view of Shah. As a preliminary matter, as I explain in Section IX above, a POSA would not be motivated to combine Stafford and Cote nor has Dr. Fletcher explained why success would be reasonably expected from the combination. Additionally, the combined references do not disclose or suggest numerous claim limitations including the ones discussed in Grounds 1, 3, and 4.

361. Indeed, all claims challenged in Ground 7 depend on Claims 19 and 21 and are patentable for at least the reasons discussed in Sections X.A and X.B.3.

362. Moreover, as explained in Grounds 1, 3, and 4 (Sections X, XI, and XII), Dr. Fletcher cannot establish that the combination of Stafford and Cote renders Claim 21 or 22 (and their Dependent Claims 23-30) obvious. Thus, numerous limitations remain missing even with Dexcom's new combination.

363. Further, Dr. Fletcher once again has failed to explain why POSAs would have been motivated to combine all four references—Stafford, Cote,

Brenneman, and Shah—to achieve the claimed combinations, particularly in the arbitrary manner proposed. Again, Dr. Fletcher ignores Brenneman’s and Shah’s different methods of sensor insertion and instead picks and chooses among the art to recreate the invention. In my opinion, this Ground further demonstrates that Dr. Fletcher’s combination is not based on how POSAs would view the combination of references, but rather is an attempt to recreate the claims using hindsight.

364. Therefore, Ground 7 does not render any claims of the 591 Patent unpatentable.

**XVII. GROUND 8: STAFFORD, COTE, SAY, AND BRENNEMAN IN VIEW OF SHAH (CLAIMS 25-26, 28)**

365. In Ground 8, Dexcom and Dr. Fletcher assert that Claims 25-26 and 28 are unpatentable as obvious over Stafford, Cote, Say, Brenneman in further view of Shah, adding Shah to their Ground 5 combination and combining arguments in Grounds 1, 2, 3, and 5. (*See* Pet. at 105, Ex. 1003 at ¶¶210.) Ground 8 fails for the same reasons explained in Grounds 1, 2, 3, and 5. (*See* Sections X, XI, XII, and XIV.)

366. In my opinion, the claims are not obvious over Stafford, Cote, Say, Brenneman, and Shah. As a preliminary matter, as I explain in Section IX above, a POSA would not be motivated to combine Stafford and Cote nor has Dr. Fletcher explained why success would be reasonably expected from the combination.

Declaration of Karl R. Leinsing, MSME, PE

Additionally, the combined references do not disclose or suggest numerous claim limitations including the ones discussed in Ground 1.

367. Indeed, all claims challenged in Ground 8 depend on Claims 19 and 21 and are patentable for at least the reasons discussed in Sections X and XI.

368. Further, Dr. Fletcher has failed to explain why POSAs would have been motivated to combine all five references—Stafford, Cote, Say, Brenneman, and Shah—to achieve the claimed combinations, particularly in the arbitrary manner proposed. Again, Dr. Fletcher ignores Say’s, Brenneman’s, and Shah’s different methods of sensor insertion and instead picks and chooses among the art to recreate the invention. In my opinion, this Ground further demonstrates that Dr. Fletcher’s combination is not based on how POSAs would view the combination of references, but rather is an attempt to recreate the claims using hindsight.

369. Therefore, Ground 8 does not render any claims of the 591 Patent unpatentable.

#### **XVIII. OBJECTIVE INDICIA OF NONOBVIOUSNESS**

370. As I explained above, I understand that objective indicia are to be considered when assessing obviousness, if present. These include commercial success; long-felt but unresolved need; failure of others to solve the problem that the inventor solved; unexpected results; copying of the invention by others; and industry recognition. I understand that such evidence serves as independent evidence of non-

obviousness and can help prevent the error of hindsight. I further understand that there must be a nexus, i.e., a tie, between the objective indicia and the novel aspects of the claimed subject matter.

371. In Paragraph 211, Dr. Fletcher states that he is “unaware of any secondary considerations of non-obviousness that would refute the showing of obviousness....” I understand that Dr. Fletcher was not provided information about objective indicia (i.e., secondary considerations) even though it was available to Dexcom. (Ex. 2036, 58:21-59:15; Ex. 2003, Abbott Complaint.)

372. In my opinion, as I explain throughout my Declaration, there was a long-felt but unresolved need for the claimed invention and many examples of failure of others to achieve the invention. As I explain, the Abbott FreeStyle Libre 14-Day, FreeStyle Libre 2, and FreeStyle Libre 3 are covered by claims of the 591 Patent. (*See, e.g.*, my analysis below and in Appendix B.)<sup>6</sup> These products have been commercially successful and praised throughout the industry. In my opinion, the evidence that I discuss here is tied to the claimed invention of the 591 Patent. They relate to the claimed invention’s solution of providing people with diabetes an easy-

---

<sup>6</sup> For convenience and due to the non-confidential nature of these proceedings, I have focused my analysis on how the Libre products practice Independent Claims 1 and 19, as well as Dependent Claims 3, 4, and 14 (which include limitations from Independent Claim 19).

Declaration of Karl R. Leinsing, MSME, PE

to-apply, user-friendly, and cost-effective CGM with an all-in-one, ultra-low profile on-body unit that was reliable and effective.

**A. Abbott's FreeStyle Libre Products**

373. In 2014, Abbott launched the FreeStyle Libre CGM line of products, beginning with the FreeStyle Libre 14-Day, initially released in Europe. The FreeStyle Libre 2 and FreeStyle Libre 3 were launched in 2018 and 2020, respectively.

374. Exhibit 2034 is Abbott's 2023 Annual Report, available from Abbott's investor website: <https://www.abbottinvestor.com/static-files/6cb09c09-2422-40e0-a24b-6545ffcf5267>. Exhibit 2034 (p. 32) identifies Abbott as the "global leader in continuous glucose monitoring" and explains that Abbott "designed our FreeStyle Libre portfolio with access and affordability in mind from Day One, and today it's the world's most affordable and widely used continuous glucose monitoring system with more than 5 million regular users across more than 60 countries." Exhibit 2034 states that FreeStyle Libre 3 "features the world's smallest, thinnest, and most discreet sensor." (*Id.*)

375. Exhibit 2019 is an Abbott press release dated March 6, 2024, entitled "Real-World Data Show Abbott's FreeStyle Libre® Systems and GLP-1 Medicines

Work Better Together for People with Type 2 Diabetes.”<sup>7</sup> There it is reported that the “Freestyle Libre technology is the most widely used CGM system in worldwide helping more than 5.5 million people living across more than 60 countries easily monitor their glucose levels.” (Ex. 2019 at 1.)

376. Exhibit 2037 is an Abbott press release discussing the FDA approval of the FreeStyle Libre 14-day product dated July 27, 2018, and is entitled “Abbott’s Freestyle® Libre 14 Day Flash Glucose Monitoring System Now Approved In U.S.”<sup>8</sup> Upon its US release, Abbott touted the benefits of its “new innovations that minimize the daily burden of managing diabetes,” explaining how Libre “is designed to be an easier-to-use, streamlined and more affordable system compared with other available CGMs on the market.” (Ex. 2037 at 1.)

377. Exhibit 2020 is an Abbott press release regarding the FDA approval of FreeStyle Libre 2 dated June 15, 2020, and is entitled “Abbott’s FreeStyle® Libre 2 iCGM Cleared in U.S. for Adults and Children with Diabetes, Achieving Highest Level of Accuracy and Performance Standards.”<sup>9</sup> It describes how the product

---

<sup>7</sup> Printed from <https://abbott.mediaroom.com/2024-03-06-Real-World-Data-Show-Abbotts-FreeStyle-Libre-R-Systems-and-GLP-1-Medicines-Work-Better-Together-for-People-with-Type-2-Diabetes>.

<sup>8</sup> Printed from <https://abbott.mediaroom.com/2018-07-27-Abbotts-FreeStyle-R-Libre-14-Day-Flash-Glucose-Monitoring-System-Now-Approved-in-U-S>.

<sup>9</sup> Printed from <https://abbott.mediaroom.com/2020-06-15-Abbotts-FreeStyle-R-Libre-2-iCGM-Cleared-in-U-S-for-Adults-and-Children-with-Diabetes-Achieving-Highest-Level-of-Accuracy-and-Performance-Standards>.

Declaration of Karl R. Leinsing, MSME, PE

“includes a self-applied sensor (the size of two-stacked quarters) that is the easiest glucose sensor to apply...,” “a third less bulky than other CGM sensors,” and is “priced at a third of the cost of other CGM systems.” (Ex. 2020 at 1.)

378. Exhibit 2038 is an Abbott press release regarding the FDA approval of FreeStyle Libre 3 dated May 31, 2022, and is entitled “Abbott’s Freestyle Libre® 3 Receives U.S. FDA Clearance - Features World’s Smallest, Thinnest And Most Accurate 14-Day Glucose Sensor.”<sup>10</sup> Exhibit 2038 describes that that the FreeStyle Libre 3 is “the smallest and thinnest CGM sensor in the world.” Further, Exhibit 2038 describes that, “[o]ver the last year, the FreeStyle Libre 3 system has been recognized multiple times as a top health tech innovation,” listing numerous awards that the product was awarded. (Ex. 2038 at 1, 2.)

379. Libre was the first commercially-available CGM that allowed the average person to easily self-apply an all-in-one, ultra-low profile on-body unit and reliably monitor their glucose levels, making continuous glucose monitoring simple, non-intimidating, affordable, and accessible for a broad population. Indeed, as the van den Boom article recognized, the Libre “could facilitate diabetes management, support patients in their everyday life by reducing some of their burden, and help

---

<sup>10</sup> Printed from <https://abbott.mediaroom.com/2022-05-31-Abbotts-FreeStyle-Libre-R-3-Receives-U-S-FDA-Clearance-Features-Worlds-Smallest,-Thinnest-and-Most-Accurate-14-Day-Glucose-Sensor>.

them achieve and maintain good glycaemic control.” (Ex. 2011, van den Boom, pp. 923-924.)

380. As I explain in further detail in Appendix B, I have examined FreeStyle Libre 14-Day, FreeStyle Libre 2, and FreeStyle Libre 3 products. Exhibit 2007 is an in-service guide for Abbott’s FreeStyle Libre 14-Day product titled “Your FreeStyle Libre 14 day System, In-Service Guide,” dated 2021.<sup>11</sup> Exhibit 2008 is a guide for Abbott’s FreeStyle Libre 2 product titled “Get Started, Your Guide To The FreeStyle Libre 2 System,” dated 2023.<sup>12</sup> Exhibit 2009 is a guide for Abbott’s FreeStyle Libre 3 product titled “Get Started with the FreeStyle Libre 3 System,” dated 2023.<sup>13</sup> Exhibit 2010 is a user’s manual for Abbott’s FreeStyle Libre 3 product titled “FreeStyle Libre 3 Continuous Glucose Monitoring System User’s Manual,” dated

---

<sup>11</sup> Printed from <https://www.freestyleprovider.abbott/content/dam/adc/freestyleprovider/countries/us-en/4-2-page/documents/In-Service,%20FreeStyle%20Libre%2014%20Day%20System%20with%20App,%20HCP%20Sales%20New.pdf>.

<sup>12</sup> Printed from <https://www.freestyle.abbott/content/dam/adc/freestyle/countries/us-en/documents/get-started-guide.pdf>,

<sup>13</sup> Printed from [https://www.freestyleprovider.abbott/content/dam/adc/freestyleprovider/countries/us-en/4-2-page/documents/Brochure\\_FreeStyle\\_Libre3\\_Getting\\_Started\\_Guide.pdf](https://www.freestyleprovider.abbott/content/dam/adc/freestyleprovider/countries/us-en/4-2-page/documents/Brochure_FreeStyle_Libre3_Getting_Started_Guide.pdf)

2023.<sup>14</sup> Exhibit 2033 is an Abbott FAQ titled “How Big Are The Freestyle Libre Sensors? How Deeply Is It Inserted?”<sup>15</sup>

381. Abbott’s FreeStyle Libre systems (across all iterations<sup>16</sup>) include an inserter that simply and easily deploys an ultra-low profile on-body unit that includes a glucose sensor coupled with all necessary sensor electronics. (*See, e.g.*, Ex. 2007 at 7; Ex. 2008 at 6-7; Ex. 2009 at 5.) Once the sensor is inserted and the OBU are properly positioned on the user, the OBU can transmit glucose data to a dedicated reader or smartphone to provide a user glucose information.

382. The table below shows Libre’s inserter (with cap) and OBU components:

---

<sup>14</sup> Printed from [https://freestyleserver.com/payloads/ifu/2024/q2/ART49385-001\\_rev-A\\_Web.pdf](https://freestyleserver.com/payloads/ifu/2024/q2/ART49385-001_rev-A_Web.pdf).

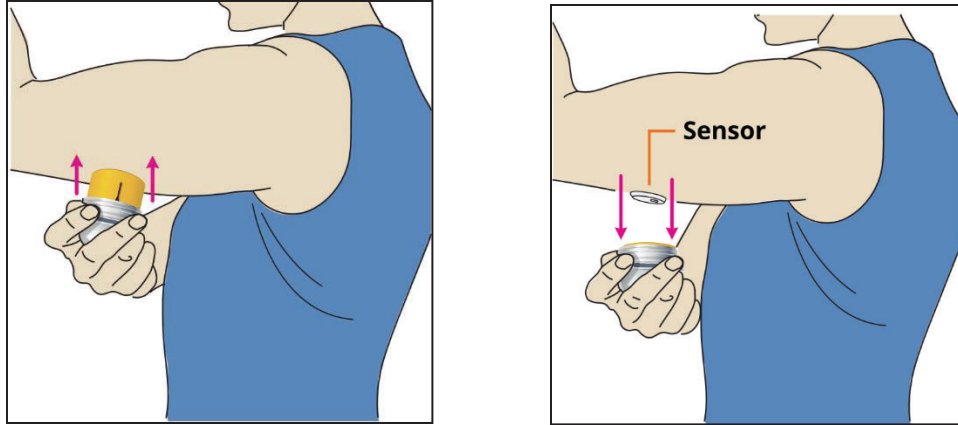
<sup>15</sup> Printed from <https://www.freestyle.abbott/uk-en/support/faq/question-answer.html?q=UKFaqquestion-55>

<sup>16</sup> As I explain further herein, the FreeStyle Libre products are covered by claims of the 591 Patent and, though there are some differences between the products, they are the same in all material respects relative to the 591 Patent claims.

|              | FreeStyle Libre                                                                   | FreeStyle Libre 2                                                                  | FreeStyle Libre 3                                                                   |
|--------------|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| Inserters    |  |  |  |
| On-Body Unit |  |  |  |

383. As described in the Libre guides (e.g., Exhibits 2007, 2008, 2009, 2010), user application of the on-body unit comprising a sensor is a simple and intuitive one-step process. A user places the inserter over a site on their body and pushes down firmly to insert the sensor under the skin and attach the OBU. (See, e.g., Ex. 2007 at 7; Ex. 2008 at 6-7; Ex. 2009 at 5, Ex. 2010 at 39.)

384. The figures below from Exhibit 2010 demonstrates how a user easily applies the OBU.



(Ex. 2010 at 39.)

385. More specifically, and as discussed in greater detail in Appendix B, the Libre products include an on-body unit and an inserter. The all-in-one on-body unit includes, among other things, a glucose sensor and sensor electronics (processor, power source, analog interface, data storage unit, wireless communication circuitry) disposed within the housing of the OBU. The sensor electronics are coupled with the glucose sensor before the inserter is positioned on the skin. The OBU is entirely disposed in the interior of the inserter, which includes a sharp. The sharp extends through openings in the top and bottom surfaces of the housing. A portion of the glucose sensor is disposed in the sharp.

386. The Libre products are configured so that the user positions the distal end of the inserter over the desired location on the skin (e.g., the back of the upper arm) and presses down on the inserter to initiate the insertion process. The inserter is configured to advance the integrated on-body unit and sharp in a linear direction from a first, proximal position to a second, distal position such that the sharp pierces

the skin of the user (at a perpendicular angle) and the housing of the OBU is secured to the skin of the user.

387. The distance between the OBU housing when the OBU is in the first position and when it is in the second position is greater than the height of the OBU housing (which is less than 10 mm).

388. Once the sharp reaches the appropriate insertion depth in the skin, a spring within the applicator is released, expanding, and thereby automatically retracting the sharp from within the user into the inserter. This leaves a part of the glucose sensor in the skin.

389. After automatic retraction of the sharp, the distal end of the inserter is removed from the skin, while the on-body unit remains adhered to the skin. The sensor can now measure glucose levels which are communicated to a receiver (typically a smart phone or dedicated receiver).

390. I explain in Appendix B how the FreeStyle Libre Products practice Claims 1, 3, 4, 14, and 19 of the 591 Patent in a claim chart. In that chart, I reference, among other things, photographs that I took of the Libre products, illustrations such as the above, as well as images from the guides for the Libre Products (Exhibits 2007, 2008, 2009, and 2010).

391. FreeStyle Libre system's use of a fully-integrated (all-in-one), yet ultra-low profile OBU that could be easily and simply applied by a user was a major

advancement in CGM technology. Earlier CGM products (including prior products sold by Dexcom) typically required users to separately insert a sensor using a multi-step procedure and then manually connect additional electrical components/CGM components (e.g., a transmitter) after sensor insertion.

392. As I discussed above, Libre's all-in-one OBU with fully-integrated sensor and electronics along with its user-friendly inserter simplified the system for users. The OBU itself is smaller, more discreet, and less obtrusive than prior devices. The Libre's inserter is also easier to use and more user-friendly, allowing for application of a sensor to the body in a simple step. (Ex. 2007 at 7; Ex. 2008 at 6-7; Ex. 2009 at 5.) Due to its innovative design and reduced components, Libre is also more affordable, often selling for a fraction of the cost of other CGMs.

393. Exhibit 2041 is an article on Healthline.com, titled "Product Review: Abbott FreeStyle Libre Flash Glucose Monitor" and dated June 1, 2021 (printed from <https://www.healthline.com/diabetesmine/abbott-freestyle-libre-review>). The article recognizes (p. 2) that, compared to other CGMs, Libre is "more affordable...because the Libre doesn't include a separate (costly) transmitter that attaches to the sensor," "more accessible, because [it]...has fewer parts needing replacement," and "fewer...complex features makes it less daunting for some people to use." It also describes (p. 4) Libre's "slimness and discreetness, simplicity of setup and use, and ease of sensor insertion."

394. Similarly, Exhibit 2042 is an article by Dr. David Ahn titled “Abbott’s Euro Approved Wearable Glucose Monitor Is Different Than Anything On The Market,” dated September 9, 2014 (printed from <https://www.imedicalapps.com/2014/09/abbotts-wearable-glucose-monitor/>). That article (p. 3-4) describes “current CGMs” that consist of multiple components (sensor, transmitter, and receiver) and recognizes (p. 4) that, “[c]ompared to existing models, the FreeStyle Libre Flash sensor is less bulky by abandoning the [separate] wireless transmitter....” (Ex. 2042 at 4.)

395. The van den Boom article likewise describes Libre as a “very easy, painless and user-friendly way of monitoring glucose values without the need for blood” and called the Libre “very discreet and fast.” (Ex. 2011, van den Boom, p. 923-924.)

396. In my opinion, the fundamental concepts embodied in the claims of the 591 Patent have contributed to these benefits. And, as I will discuss below, the Libre products have been praised worldwide and been honored with numerous industry awards.

## **B. Dexcom’s CGM Products**

397. Dexcom also manufactures and sells CGM products. For over a decade, from about 2006 until 2022, Dexcom sold multi-component and multi-step systems, requiring its users to manually attach and later remove a reusable transmitter to a

sensor pod after the sensor is inserted, and did not have a fully-integrated design. (Ex. 2014 at 20-22; Ex. 2015 at 14-16.)<sup>17</sup>

398. For example, Exhibit 2014 is a guide for Dexcom's G5 Mobile product titled "Dexcom G5 Mobile Continuous Glucose Monitoring System Quick Start Guide" dated 2020.<sup>18</sup> Exhibit 2015 is a guide for Dexcom's G6 product titled "Dexcom G6 Start Here Guide."<sup>19</sup> Dexcom's G5 and G6 products, including their multi-component units, are shown below and described in those exhibits (and further below).

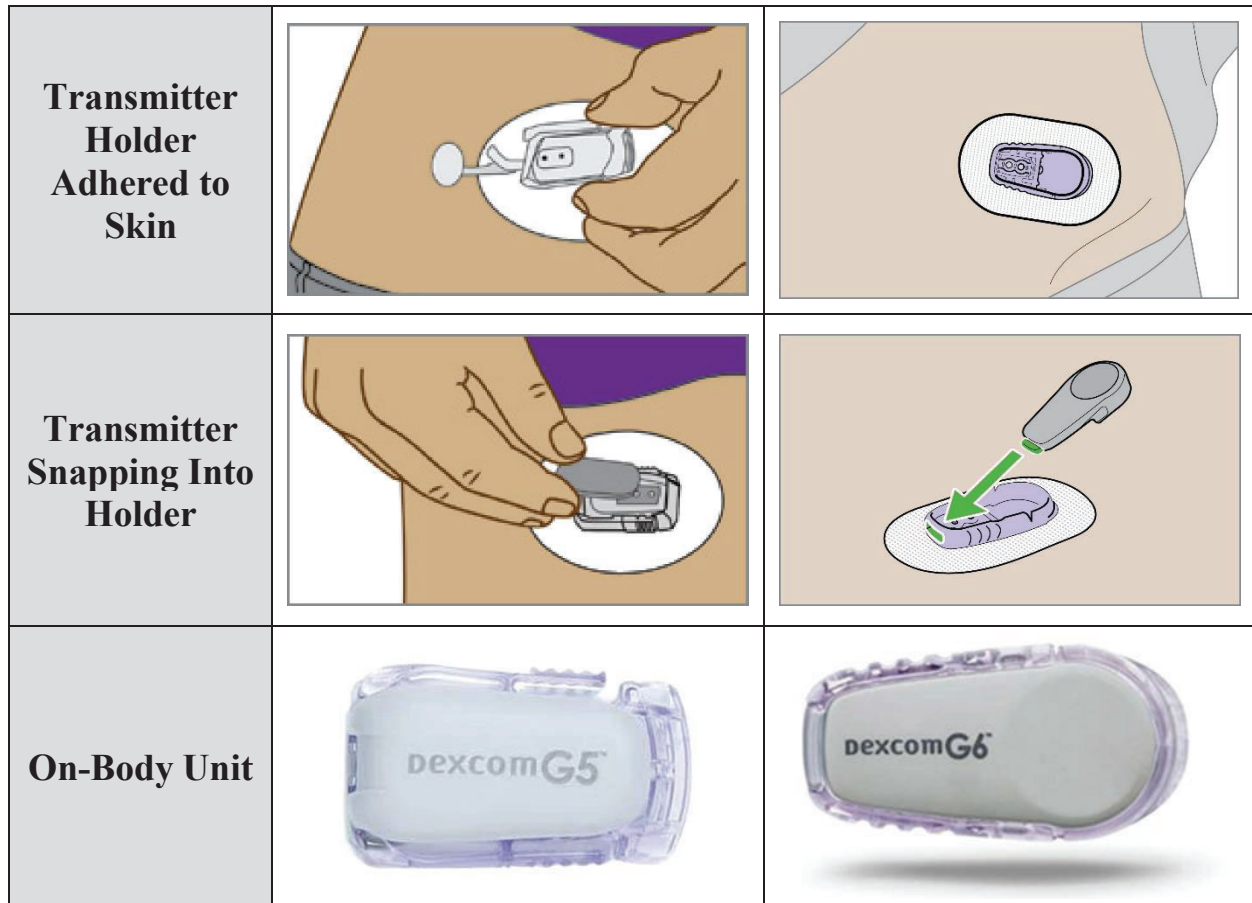
|           | Dexcom G5                                                                          | Dexcom G6                                                                            |
|-----------|------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| Inserters |  |  |

---

<sup>17</sup> Dexcom's line of products included, among other things, the Dexcom STS (2006), the Dexcom STS 7 (2007), the Dexcom Seven Plus (2009), the Dexcom G4 (2012) The Dexcom G5 (2016), and the Dexcom G6 (2018).

<sup>18</sup> Printed from <https://s3-us-west-2.amazonaws.com/dexcompdf/Downloads+and+Guides+Updates/LBL013139+G5+Mobile+CGM+QSG+OUS+Eng+mmol.pdf>,

<sup>19</sup> Printed from <https://dexcompdf.s3.us-west-2.amazonaws.com/en-us/G6-Start-Here-Guide-new.pdf>.



(Ex. 2014 at 20-22; Ex. 2015 at 14-16.)

399. Simply put, Dexcom's prior CGM products did not have a fully-integrated, all-in-one on-body unit. Rather, a user had to first apply a transmitter holder to their body using the inserter and an adhesive patch. Using the inserter, the user then had to insert the distal end of the sensor into their body (while the proximal end of the sensor coupled to the transmitter holder). The user was then required to separately connect the electronics to the sensor by snapping it into the transmitter holder. For every new sensor session, the user would have to remove the transmitter from the transmitter holder and re-use it with a newly-inserted sensor. (*See, e.g., Ex.*

2014 at 20-22; Ex. 2015 at 14-16.) This made the Dexcom products complicated and error-prone.

400. After Abbott released the Libre product, however, Dexcom developed and released a new product, the G7. Unlike its previous designs, the G7 includes a fully-integrated OBU with a sensor and sensor electronics pre-coupled as part of one disposable unit. It is also applied from the inserter in a single step—like Libre.

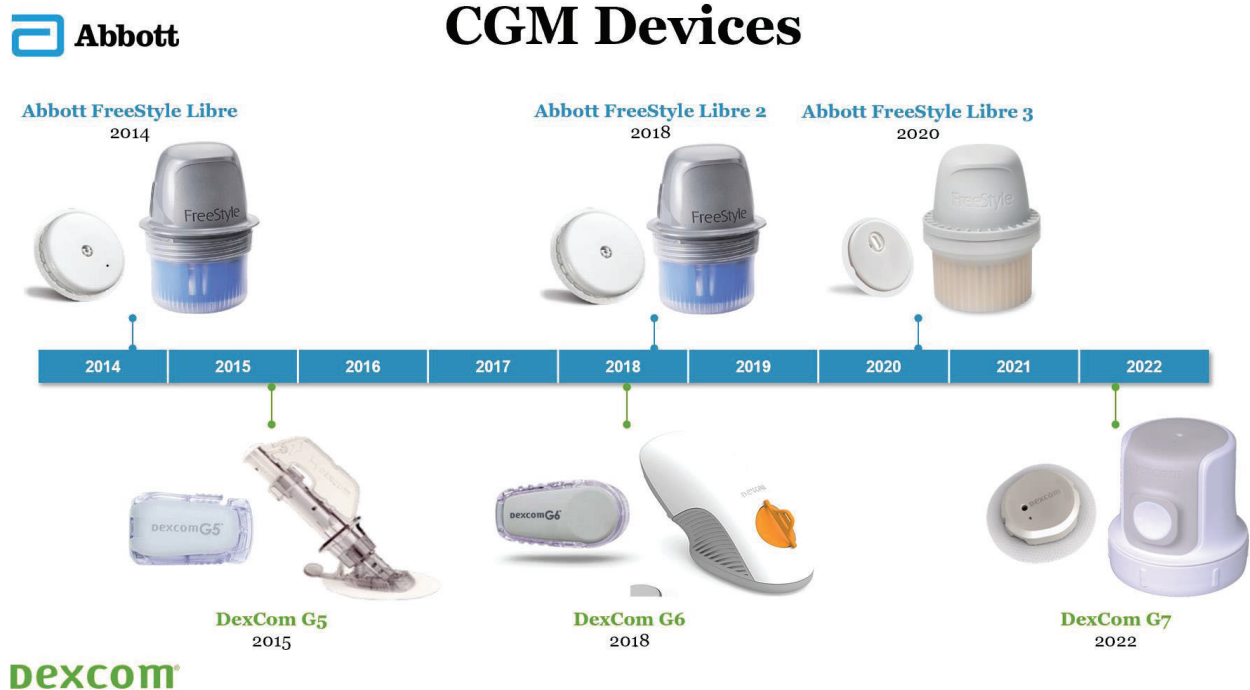
401. Dexcom's new G7 product is shown below next to the Libre product.

|              | FreeStyle Libre                                                                     | Dexcom G7                                                                             |
|--------------|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Inserters    |   |   |
| On-Body Unit |  |  |

402. Dr. Fletcher is asserting that the claimed invention was obvious by 2009; however, as shown in the timeline below, rather than using the allegedly obvious design back in 2009, Dexcom repeatedly released generation after

Declaration of Karl R. Leinsing, MSME, PE

generation of multi-component systems. Indeed, Dexcom did not launch the G7 device until 2022, well after Abbott released the Libre products.



403. I understand that Abbott has sued Dexcom in the District of Delaware, asserting that the G7 infringes the 591 Patent, among other patents. Exhibit 2003 is a copy of the Complaint in that case and includes Exhibit F, which is a claim chart alleging infringement.

### C. Long-Felt But Unresolved Needs & Failure of Others

404. As I explained above, I understand that the existence of a long-felt but unresolved need and failure of others can serve as objective indicia of non-obviousness.

405. In my opinion, there was a long-felt need for the inventions claimed in the 591 Patent. As discussed above, the industry spent years trying to satisfy the long-felt but unmet need for an easy-to-apply, intuitive, all-in-one CGM device; however, by 2009, no such solution existed. While the prior art described numerous ways for patients to self-implant glucose sensors, none provided an all-in-one solution that was reliable and simple enough for a layperson to use while remaining cost-effective and accessible to the average person with diabetes.

406. By the time of the invention, others repeatedly tried and failed to develop a solution. For example, the 591 Patent recognized the ongoing “need for an easy-to-use, simple, insertion assembly which is reliable, minimizes pain, and is easy to use.” (Ex. 1001, 2:8-12.) Stafford reinforced these concerns, itself attempting to design a device which “minimizes the number of components ..., and [] reduces the number of required steps to properly and accurately position the analyte sensor ....” (Ex. 1004, [0005].) None of the prior art described a complete solution to these problems as discussed above.

407. Indeed, the prior art recognized problems with early CGM devices. For example, Shah described how prior “glucose sensors generally utilize complex structures to mount and hold the sensor set in place on the patient’s skin.” (Ex. 1006 at [0006].) Similarly, Brenneman noted that “[o]ne of the challenges of using a continuous analyte monitoring process is to minimize the number of acts to (a) attach

Declaration of Karl R. Leinsing, MSME, PE

the sensor/electronics to the skin and (b) insert the implantable sensor that assists in determining the analyte level of a fluid (e.g., blood).” (Ex. 1040 at [003] (emphasis added).)

408. Despite Dexcom’s claims of obviousness as of 2009, Dexcom’s own previous CGMs employing multi-component, complex designs were repeatedly criticized. Indeed, it was not until 2022—more than a decade after Dr. Fletcher asserts that the prior art rendered the patented design obvious—when Dexcom finally released its G7 product, which used the simple all-in-one design.

409. Exhibit 2016 is pages from the “G7 Overview” section of Dexcom’s website describing the Dexcom G7 product, titled “Dexcom G7 CGM – Powerfully Simple Diabetes Management” (printed from <https://dexcom.com/g7-cgm-system>). Exhibit 2017 is a user’s Guide for Dexcom’s G7 product titled “Dexcom G7 User’s Guide” dated April 2024 (printed from <https://dexcompdf.s3.us-west-2.amazonaws.com/en-us/G7-CGM-Users-Guide.pdf>). Exhibit 2018 is a 510(K) Summary for the Dexcom G7 Continuous Glucose Monitoring (CGM) System, which was attached to a letter from the FDA, available on the FDA’s website at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K213919> under the link “Summary.”

410. When Dexcom finally released the G7 with its Libre-style applicator and on-body unit, Dexcom did not state it had simply implemented an “obvious”

solution known in 2009; rather, Dexcom praised its new device. Dexcom's G7 product guide (Ex. 2017, p. 2-3) touts its new "[s]treamlined all-in-one sensor with built in disposable transmitter" and "smaller sensor" as well as its new inserter that has a "smaller size" and which makes it "[f]ast and easy to insert sensor." As Dexcom explained in its 510K Summary (Ex. 2018, p. 6), the G7 "improves upon the user experience...by providing a fully enclosed miniaturized wearable with pre-connected sensor." Exhibit 2016 (p. 6-7) described G7 as Dexcom's "most comfortable and discreet sensor yet."

411. Exhibit 2040 is an article by Laura Lovett from Mobihealth News dated June 19, 2020, and titled "What's Next For Dexcom? CEO, CTO Talk G6 For Inpatient Use, Expanding CGMs For Patients Without Diabetes," (printed from <https://www.mobihealthnews.com/news/whats-next-dexcom-ceo-cto-talk-g6-inpatient-use-expanding-cgms-patients-without-diabetes>). The article (p. 5) quotes Dexcom's Chief Technology Officer describing G7 benefits: "[o]ne of the benefits of G7 is it's all-in-one CGM component. So the sensor is not separate from the electronics that measure the sensor...."

412. Others similarly recognized the benefits in the new G7. Exhibit 2039 is a web article titled "Dexcom G7: These Are The Most Exciting Features" (printed from <https://notjustapatch.com/dexcom-g7-features/>). That article states the new product is "60% smaller than its predecessor (the Dexcom G6) and about the same

size as the Libre 2. Low profile and discrete in comparison to the previous Dexcom devices.” (p. 2.) The article recognizes that G7 “is less bulky” and “is an all in 1 sensor, so the Dexcom G7 doesn’t have an external transmitter because it is built into the device (like FreeStyle Libre devices).” (*Id.*) “The all-in-one feature can help to consolidate prescriptions on multiple parts-and-pieces, as well as simply the application and removal of the wearable.” (p. 3.) The article further notes that “[i]t is a complete overhaul for Dexcom with G7. Moving in the direction of major competitor Abbott’s FreeStyle Libre with a disposable system that is an all in one transmitter and sensor.” (p. 11.) The article concludes that the G7 “catches up with the Abbott Freestyle Libre 2 low-profile offering.” (p. 12.)

#### **D. Industry Praise And Commercial Success Of Libre**

413. As I explained above, I understand that commercial success and industry praise are relevant as objective indicia of nonobviousness. I understand that there is a presumption of nexus when the objective evidence is tied to a specific product and that product is the invention disclosed and claimed in the patent.

414. As I mentioned, I explain in Appendix B to my Declaration and above how the FreeStyle Libre Products practice Claims 1, 3, 4, 14, and 19 of the 591 Patent. As I mentioned, in my opinion, the concepts embodied in the claims of the 591 Patent have contributed to Libre’s affordability, reliability, accessibility, and its simple, effective handling leading to its commercial success and industry praise.

Declaration of Karl R. Leinsing, MSME, PE

Simply put, in my opinion, there is a nexus or tie between the praise and success of the Libre products and the novel features of the claimed inventions.

415. The Libre products have been praised worldwide and have received numerous prestigious awards because of their innovative patented design.

416. For example, in 2019, Libre was awarded the prestigious Prix Galien award as the “Best Medical Technology” from the Prix Galien Foundation. The Prix Galien Awards are likened to the Nobel Prize in biopharmaceutical and medical technology research. Three years later, in 2022, the FreeStyle Libre system was named the “Best Medical Technology” of the last fifty years by the Galien Foundation at its Golden Jubilee Award Ceremony. The Golden Jubilee Awards were meant to recognize global innovations that have had the greatest impact on society since the Galien Foundation was founded in 1970.

417. Exhibit 2005 is a description of the Galien Golden Jubilee award from the Galien Foundation’s website (printed from <https://www.galienfoundation.org/galien-golden-jubilee>). It is entitled “The Galien Foundation is proud to announce the laureates of the best-of-the-best from the half century 1970-2020” and lists the recipients of the Golden Jubilee Awards.

418. Exhibit 2004 is an Abbott press release dated October 28, 2022, entitled “Abbott’s Freestyle Libre® Is Named Best Medical Technology In Last 50 Years By

Declaration of Karl R. Leinsing, MSME, PE

The Galien Foundation.”<sup>20</sup> Exhibit 2004 explains that the “Prix Galien Golden Jubilee Awards honor the global ‘best of the best’ innovations that have improved the human condition over the last 50 years.” Exhibit 2006 is an Abbott press release dated October 25, 2019, entitled “FreeStyle Libre Honored by Prix Galien” and discusses the 2019 Prix Galien award.<sup>21</sup>

419. Libre also won several Edison Awards. Exhibit 2021 is pages from the Edison Awards’ website describing the Edison Awards, titled “About the Edison Awards” (printed from <https://edisonawards.com/about.php>). The Edison Awards, named after Thomas Edison, “recognize[] and honor[] some of the most innovative products ... in the world and [are] among the most prestigious accolades honoring excellence in new product and service development, marketing, design and innovation.” (Ex. 2021 at 1.) The Edison Awards honors the “best in innovation and excellence in the development of new products and services.” (Ex. 2023 at 1.)

420. Exhibit 2022 is pages from the Edison Award’s website listing winners of the 2021 Edison Best New Product Awards (printed from <https://edisonawards.com/winners2021.php>). “Abbott’s FreeStyle Libre 2 Integrated Continuous Glucose Monitoring (iCGM) System” won gold in the category of

---

<sup>20</sup> Printed from <https://abbott.mediaroom.com/2022-10-28-Abbotts-FreeStyle-Libre-R-is-Named-Best-Medical-Technology-in-Last-50-Years-by-the-Galien-Foundation>.

<sup>21</sup> Printed from <https://www.abbott.com/corpnewsroom/strategy-and-strength/freestyle-libre-honored-by-prix-galien.html>.

“Personal Wellness Technology.” (Ex. 2022 at 14.) Exhibit 2023 is press release provided by the Edison Awards on Cision PRWeb’s website dated April 22, 2016, regarding the winners of 2016 Edison Awards.<sup>22</sup> The article recognizes that Abbott won a Gold Award in the category of “Patient Care.” (Ex. 2023 at 7.) Exhibit 2024 is pages from the Edison Award’s website listing winners of the 2022 Edison Best New Product Awards (printed from <https://edisonawards.com/2022-winners/>). “FreeStyle Libre 3 System by Abbott” won gold in the category of “Technology & Tools.” (Ex. 2024 at 41.)

421. Exhibit 2022 recognized that FreeStyle Libre is “the only integrated continuous glucose monitoring system (iCGM) that transmits glucose data every minute...It’s priced 70% lower than other iCGMS without sacrificing accuracy.” (Ex. 2022 at 14.) Exhibit 2024 recognized “FreeStyle Libre 3 is Abbott’s next-generation continuous glucose monitoring (CGM) system, featuring the world’s smallest, thinnest glucose sensor that can be worn up to 14 days to deliver continuous, real-time glucose readings....” (Ex. 2024 at 41.)

422. The FreeStyle Libre systems have won numerous other awards. For example, the 2017 Medical Design Excellence Award (MDEA) was awarded to Libre in the field of “testing and diagnostic products and systems” for

---

<sup>22</sup> Printed from [https://www.prweb.com/releases/edison\\_awards\\_announces\\_2016\\_gold\\_silver\\_and\\_bronze\\_awards\\_winners/prweb13354037.htm](https://www.prweb.com/releases/edison_awards_announces_2016_gold_silver_and_bronze_awards_winners/prweb13354037.htm).

Declaration of Karl R. Leinsing, MSME, PE

“groundbreaking work in the medical technology field.” Exhibit 2025 is a press release from UBM Americas on PR Newswire website dated June 13, 2017, regarding the 19th Annual MDEA Award Ceremony and describing Abbott’s award (p. 3). The press release is titled “27 Winners Announced at the 19<sup>th</sup> Annual Medical Design Excellence Awards (MDEA) Award Ceremony” (printed from <https://www.prnewswire.com/news-releases/27-winners-announced-at-the-19th-annual-medical-design-excellence-awards-mdea-award-ceremony-300473477.html>).

423. Libre received the “Most Innovative Product Multi-National” award at 2017 Irish Medical & Surgical Trade Association MedTech Awards. Exhibit 2026 is an Abbott press release dated September 29, 2017, and is entitled “Abbott’s FreeStyle Libre Flash Glucose Monitoring System Wins the IMSTA Most Innovative Product Multi-National Awards.”<sup>23</sup> Exhibit 2026 references Libre as a “groundbreaking monitoring system [that] allows real-time glucose readings to be taken painlessly...consist[ing] of a small, round sensor—approximately the size of a €2 coin.” (Ex. 2026 at 1.)

424. Libre also won awards in 2018 and 2021 from the Business Intelligence Group. Exhibit 2027 is a Business Intelligence Group press release dated February

---

<sup>23</sup> Printed from <https://www.ie.abbott/media-center/news/abbotts-freestyle-libre-flash-glucose-monitoring-system-wins-the-imsta-award-2017.html>

Declaration of Karl R. Leinsing, MSME, PE

7, 2018, recognizing Abbott's "FreeStyle Libre Flash Glucose Monitoring System" as a winner of a 2018 BIG Innovation Award (printed from <https://www.bintelligence.com/posts/55-chosen-as-winners-in-annual-big-innovation-awards>). Exhibit 2028 is an Abbott press release dated January 12, 2021, and entitled "BinaxNOW, Freestyle Libre 2 Win BIG Innovation Honors," explaining that the FreeStyle Libre 2 won a 2021 Big Innovation Award (printed from <https://www.abbott.com/corpnewsroom/strategy-and-strength/binaxnow-freestyle-libre-win-big-innovation-honors.html>).

425. Libre received the 2018 Chicago Innovation Award. Exhibit 2029 is pages from the Chicago Innovation website, describing the 2018 award for "Abbott's FreeStyle Libre Flash Glucose Monitoring System" (printed from <https://chicagoinnovation.com/winners/abbott-laboratories/>). The website recognizes Libre's small size is, noting that "Libre is about the size of two stacked quarters...." (Ex. 2029 at 1.)

426. Exhibit 2030 is an article published on the website of The Scientist magazine, recognizing its "2019 Top 10 Innovations." The article was downloaded and printed from <https://www.the-scientist.com/features/2019-top-10-innovations-66738>. Exhibit 2030 recognizes Abbott's FreeStyle Libre 2 as one of the top innovations, noting that it is an "'elegant' solution" that is the "size of two stacked quarters." (EX2030 at 4.)

427. Libre also received the 2020 German Innovation Award. Exhibit 2031 is a printout of pages from the German Innovation Award website, recognizing the FreeStyle Libre 2 as the recipient of the 2020 German Innovation Award Gold Winner (available at <https://www.german-innovation-award.de/en/winners/preis/gewinner/freestyle-libre-2-zucker-messen-ohne-stechen-per-sensor-und-app/>). Exhibit 2031 describes that the Libre “provides a simple, safe, painless and discreet alternative to blood glucose self-monitoring.” (Ex. 2031 at 1.) It also states that “[w]ith FreeStyle Libre 2, a small sensor that is easy to apply and can be worn unobtrusively under clothing provides an essentially more convenient and pain-free measurement method that continuously measures and thus increases safety....A great innovation that significantly increases the quality of life for those affected.” (*Id.*)

428. Exhibit 2032 is a printout of pages from the Good Design Award website recognizing FreeStyle Libre as a recipient of the 2017 Good Design Award (printed from <https://www.g-mark.org/gallery/winners/9dda01a3-803d-11ed-af7e-0242ac130002>) (Exhibit 2032 is the English version of that webpage). Exhibit 2032 describes how Libre allows patients “to easily measure glucose levels anytime, anywhere, even over their clothes.....” and that Libre “covers ease of understanding, ease of use, and ease of storage required for home medical devices.” (Ex. 2032 at 3, 5.)

429. Libre was awarded Consumer Technology Association's 2022 CES Innovation Award for "Best of Innovation" in "Health and Wellness." Libre was recognized for having the "world's smallest, thinnest glucose sensor" and "delivering breakthrough technology that is accessible and affordable." (Ex. 2035 at 1.) Exhibit 2035 is a print out of pages from the Consumer Technology Association website regarding the 2022 CES Innovation Award (printed from <https://www.ces.tech/innovation-awards/honorees/2022/best-of/f/freestyle-libre-3-system.aspx>).

430. As discussed above, Abbott repeatedly touts the features of the claimed inventions of the 591 Patent in promoting the Libre products. This can be seen in Abbott press releases when its new products are released. (*See, e.g.*, Exhibits 2020, 2037, 2038.)

431. Further, as I mentioned above, I understand that the Libre products are commercially successful and are the most widely used CGM worldwide. (*See* Ex. 2019 at 1.) It has been reported that the Libre products have had \$4.3 billion and \$5.3 billion in sales in 2022 and 2023, respectively. (*See* Ex. 2034 at 72; Ex. 2019 at 1.) In my opinion, this success further demonstrates the nonobviousness of the claimed inventions.

**XIX. SIGNATURE**

432. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under the Section 1001 of Title 18 of the United States Code.

Executed on 19 of July, 2024.

 Digitally signed by Karl R.  
Leinsing  
Date: 2024.07.19 17:23:20  
-04'00'

---

Karl R. Leinsing, MSME, PE

# APPENDIX A



**Karl R. Leinsing, MSME, PE**  
77 Spur Rd. Dover, NH 03820-9110  
(603) 203-0365 cell / (603) 749-0079 fax  
[kleinsing@comcast.net](mailto:kleinsing@comcast.net)

## Professional Summary

Medical device experience since 1992 and mechanical engineering experience since 1988. Areas of expertise include full life cycle medical device product development and consulting from conception through design, manufacturing, testing, qualification, validation, verification, qualification, packaging, labeling, clinical trials, FDA & EU regulatory approval, marketing, and sales training. Granted 40 patents, 7 awards, device published on cover of Life Magazine (May 2000), recognized as one of 100 notable people in the medical device industry by the Medical Device & Diagnostic Industry (MD&DI) in June 2008, recognized by Better Business Bureau and NH Magazine in 2013, and served as chairman of the Medical Device & Manufacturing Conference in 2014, and served on many boards.

## Employment History

From: 2006      **ATech Designs, Inc.**

To: Present

Position: *President*

- Medical device product development and consulting since 1998 (formerly Innovative Engineering, Inc. in North Carolina)
- Developed cardiovascular, mitral valve repair (for 3 companies), surgical, intravenous, endoluminal, and percutaneous devices including market analysis.
- Consulting on bedside blood glucose level analyzer / cartridge, glucose sensors, peritoneal dialysis pumps, safety syringes, disinfecting caps, auto-injectors, pen injectors, urinary catheters, insulin pumps, subcutaneous ports & catheters, bed rails, e-cigarettes/pharmaceutical inhalers, bone anchors, bone plates/screws, staplers, device support arms, & walkers/rollators.
- Developed medical textiles, CPAP device for HDM, catheter dressing for H2L, trachea alarm for Innovations Unlimited, urinary incontinence device for a urologist, and stapler/suturing for SubQ It
- Invented and developed Programmable Electrode Array Knitter (6,158,250) to manufacture RF mesh for endometrial ablation device
- Litigation consulting and expert witness (patent & liability cases) in United States, Canada, EPO, USPTO, ITC, and Australia
- Visit [www.atechdesigns.com](http://www.atechdesigns.com) for more information

From: 2005      **Mitralign, Inc.**

To: 2006

Position: *Director of Biomedical Engineering*

- Developed implants required for percutaneous mitral valve repair
- Invented & developed new tissue anchors within 2 months of hire
- Completed locker implant used to plicate the anchors & lock sutures



**Karl R. Leinsing, MSME, PE**  
77 Spur Rd. Dover, NH 03820-9110  
(603) 203-0365 cell / (603) 749-0079 fax  
[kleinsing@comcast.net](mailto:kleinsing@comcast.net)

From: 2002 **ONUX Medical, Inc.**

To: 2005

Position: *Manager of Design Engineering*

- Invented, developed, and tested a needlescopic Nitinol fixation device for abdominal aortic aneurysm (AAA) repair in 10 months (patent pending)
- Performed animal studies and trained surgeons on use of device
- Designed a disposable laparoscopic Q-ring fixation device below cost targets and performed market comparison study.
- Design history files were ISO compliant and most organized in the company

From: 1992

To: 2002

**IVAC/imed/Eli Lilly/ALARIS/Cardinal Health/CareFusion/BD**

Position: *Sr. Principal Design Engineer (Director Level Engineer)*

- Worked on development of medical drug infusion products including, but not limited to, disposable sets and components, syringe pump, pump systems, valves, and pump segments, insulin injection system for Eli Lilly, vial adapters, dialysis set components, catheters, and needle-free valves.
- Extensive knowledge of polymer selection, high volume production, IV therapy, chemical resistance, fracture mechanics, measurement equipment, design-of-experiments (DOE) & EtO/Gamma/E-beam sterilization, and packaging.
- Performed market analysis including focus studies.
- Researched and selected injection, compression, injection-compression, transfer, flashless, liquid injection molding (LIM), gum injection, vertical, and rotary molding methods by working closely with molding suppliers
- Designed plastic parts, ultrasonic welding fixtures and processes, decoupled molding processes, high speed leak and flow testing systems, UV adhesive and solvent joints, and automation
- Promoted five times - Product Eng. II to Sr. Principal Design Eng.
- Managed projects throughout product life cycle
- Sole inventor of the \$300 million SmartSite® Needle-Free Valve that leads the sales of IV pumps and disposables (project identified as the most successful project in the history of the company)
- Granted many patents for the SmartSite® Needle-Free Valve
- Winner of 5 design awards - 1998 Medical Design Excellence Award (MDEA), 1999 NC Governors New Product Award, 2000 NSPE New Product Award, 2001 Prototype Design Award, and 2003 MDEA Gold Winner



**Karl R. Leinsing, MSME, PE**  
77 Spur Rd. Dover, NH 03820-9110  
(603) 203-0365 cell / (603) 749-0079 fax  
[kleinsing@comcast.net](mailto:kleinsing@comcast.net)

From: 1990      **Draper Corporation**  
To: 1992  
Position: *Mechanical Design Engineer*

- Designed textile loom & knitting machines
- Used knowledge of tribology, cams, gears, bearings, servo motors, electromagnetics, pneumatics, PLC's, PC oscilloscopes, and sensors
- Deflection and stress analysis using own finite element programs
- Electromagnetic analysis using MSC/XL-EMAS

From: 1988      **Harris Graphics Corporation**  
To: 1990  
Position: *Design Engineer* - Web offset printing press design

From: 1987      **Materials Lab, Inc.**  
To: 1988  
Position: *Analyst* - Analyzed and designed plasma arc cutters

From: 1986      **Walker Power, Inc.**  
To: 1987  
Position: *Mechanical Designer* - Designed textile wrap-spin machine

From: 1979      **KRL Electronics, Inc. (Bantry Components) / Solarmetrics, Inc.**  
To: 1986  
Position: *Technician* - Designed automated resistor equipment, inventory management, assembled and tested solar controls and air-wrap systems.

## **Publications**

- 1995 - Thesis: Strength of Medical Thermoplastic Female Luers Exposed to Chemicals
- 2001 - Chemical Compatibility and the SmartSite® Needle-Free Valve
- 2013 - How a Medical Device Expert Witness Can Assist in a Case
- 2015 - A-Z Guide to Expert Witnessing ISBN: 9781892904454 (CV – pp.576 - 580)

## **Lectures**

- 1998 - Lectured MD&M Seminar on “The Science of Successful Product Design”
- 2014 - Chairman of the Medical Device & Manufacturing Conference
- 2014 to 2016 – Webinar Speaker on Medical Device Product Development Process



**Karl R. Leinsing, MSME, PE**  
77 Spur Rd. Dover, NH 03820-9110  
(603) 203-0365 cell / (603) 749-0079 fax  
[kleinsing@comcast.net](mailto:kleinsing@comcast.net)

**Granted US Patents** (Foreign filings of same are not included)

| <b><u>Patent No.</u></b> | <b><u>Issue Date</u></b> | <b><u>Title</u></b>                                                                            |
|--------------------------|--------------------------|------------------------------------------------------------------------------------------------|
| 11,826,049               | 11/28/2023               | Devices For Deploying Tissue Fasteners                                                         |
| 11,517,437               | 12/06/2022               | Cardiac Treatment System                                                                       |
| 11,406,500               | 08/09/2022               | Cardiac Treatment System and Method                                                            |
| 11,141,552               | 10/12/2021               | Systems For Providing Low-Noise Positive Airway Pressure                                       |
| 10,881,834               | 01/05/2021               | Safety Catheter System and Method                                                              |
| 10,695,046               | 06/30/2020               | Tissue Anchor and Anchoring System                                                             |
| 10,420,644               | 09/24/2019               | Cardiac Treatment System and Method                                                            |
| 10,405,981               | 09/10/2019               | Cardiac Treatment System                                                                       |
| 10,064,723               | 09/04/2018               | Cardiac Treatment System and Method                                                            |
| RE46,927                 | 07/03/2018               | Heart Band W/Fillable Chambers to Modify Heart Valve                                           |
| 9,844,437                | 12/19/2017               | Cardiac Treatment System and Method                                                            |
| 9,814,454                | 11/14/2017               | Tissue Anchor and Anchoring System                                                             |
| 9,750,907                | 09/05/2017               | Portable CPAP and Method For Reducing Noise Therefrom                                          |
| 9,707,378                | 07/18/2017               | Safety Catheter System and Method                                                              |
| 9,421,102                | 08/23/2016               | Cardiac Treatment System and Method                                                            |
| 9,375,543                | 06/28/2016               | Systems For Providing Low-Noise Positive Airway Pressure                                       |
| 9,370,425                | 06/21/2016               | Cardiac Treatment System and Method                                                            |
| 8,951,286                | 02/10/2015               | Tissue Anchor and Anchoring System                                                             |
| 8,951,285                | 02/10/2015               | Tissue Anchor, Anchoring System & Methods of Using                                             |
| D717,954                 | 11/18/2014               | Heart Treatment Device                                                                         |
| 8,740,850                | 06/03/2014               | Safety Catheter System & Method                                                                |
| 8,177,768                | 05/15/2012               | Vial Adapter With Needle-Free Valve For Use With Vials                                         |
| 8,092,363                | 01/10/2012               | Heart Band W/Fillable Chambers to Modify Heart Valve                                           |
| 8,029,472                | 10/04/2011               | Safety Catheter System and Method                                                              |
| 7,497,848                | 03/03/2009               | Needleless Medical Connector W/Expandable Valve                                                |
| 7,306,199                | 12/11/2007               | Needle Free Medical Connector With Expanded Valve Mechanism and Method of Fluid Flow Control   |
| 7,244,249                | 07/17/2007               | Needle-Free Medical Connector With Expandable Valve Mechanism and Method of Fluid Flow Control |
| 7,184,825                | 02/27/2007               | Needless Medical Connector Having Antimicrobial Agent                                          |
| 7,125,396                | 10/24/2006               | Safety Catheter System and Method                                                              |
| 7,104,520                | 09/12/2006               | Needle Free Medical Connector With Expanded Valve Mechanism and Method of Fluid Flow Control   |
| 6,971,630                | 12/06/2005               | Needle Free Medical Connector With Expanded Valve Mechanism and Method Of Fluid Flow Control   |
| 6,875,205                | 04/05/2005               | Vial Adapter with Needle-Free Valve for use with Vials                                         |
| 6,802,490                | 10/12/2004               | Needle Free Medical Connector With Expanded Valve Mechanism and Method of Fluid Flow Control   |
| 6,706,022                | 03/16/2004               | Needleless Connector Expandable Valve Mechanism                                                |
| D468,016                 | 12/31/2002               | Medical Fluid Connector                                                                        |
| 6,158,250                | 12/12/2000               | Flat-Bed Knitting Machine and Method of Knitting                                               |
| 6,142,446                | 11/07/2000               | Medical Adapter Needleless Valve & Sharpened Cannula                                           |
| 5,839,715                | 11/24/1998               | Medical Adapter Needleless Valve & Sharpened Cannula                                           |
| 5,676,346                | 10/14/1997               | Needleless Connector Valve                                                                     |
| 5,549,577                | 08/27/1996               | Needleless Connector                                                                           |



**Karl R. Leinsing, MSME, PE**  
77 Spur Rd. Dover, NH 03820-9110  
(603) 203-0365 cell / (603) 749-0079 fax  
[kleinsing@comcast.net](mailto:kleinsing@comcast.net)

## **Published Patent Applications** (others pending)

| <b><u>Pub. No.</u></b> | <b><u>Pub. Date</u></b> | <b><u>Title</u></b>                                                                                         |
|------------------------|-------------------------|-------------------------------------------------------------------------------------------------------------|
| US 2002/0133124        | Sep. 19, 2002           | Needleless Medical Connector Having Antimicrobial Agent                                                     |
| US 2003/0098430        | May 29, 2003            | Needle free Medical Connector with Expanded Valve Mechanism and Method of Fluid Flow Control                |
| US 2003/0153895        | Aug. 14, 2003           | Vial Adapter Having a Needle-Free Valve for use with Vial Closures of Different Sizes                       |
| US 2003/0199835        | Oct. 23, 2003           | Needleless Medical Connector w/Expandable Valve Mech.                                                       |
| US 2003/0209681        | Nov. 13, 2003           | Needle-Free Medical Connector with Expandable Valve Mechanism and Method of Fluid Flow Control              |
| US 2004/0073237        | Apr. 15, 2004           | Surgical Fastener and Delivery System                                                                       |
| US 2004/0127854        | Jul. 1, 2004            | Safety Catheter System and Method                                                                           |
| US 2005/0006614        | Jan. 13, 2005           | Needle Free Medical Connector with Expanded Valve Mechanism and Method of Fluid Flow Control                |
| US 2005/0148994        | Jul. 7, 2005            | Vial Adapter Having a Needle-Free Valve for use with Vial Closures of Different Sizes                       |
| US 2007/0007478        | Jan. 11, 2007           | Needle Free Medical Connector with Expanded Valve Mechanism and Method of Fluid Flow Control                |
| US 2007/0010857        | Jan. 11, 2007           | Tissue Anchor, Anchoring System & Methods of Using                                                          |
| US 2007/0100284        | May 3, 2007             | Safety Catheter System and Method                                                                           |
| US 2007/0276437        | Nov. 29, 2007           | Lockers for Surgical Tensioning Members and Methods of Using the Same to Secure Surgical Tensioning Members |
| US 2009/0062596        | Mar. 5, 2009            | Heart Band w/Fillable Chambers to Modify Heart Valve Function                                               |
| US 2009/0076547        | Mar. 19, 2009           | Tissue Anchor and Anchoring System                                                                          |
| US 2011/0230810        | Sep. 22, 2011           | Implantable Anti-Adhesion Three Layer Patch                                                                 |
| US 2011/0319827        | Dec. 29, 2011           | Safety Catheter System and Method                                                                           |
| US 2012/0059457        | Mar. 8, 2012            | Minimally Invasive Surgical Instrument for Delivery of Cardiac Devices                                      |
| US 2014/0107405        | Apr. 17, 2014           | Cardiac Treatment System and Method                                                                         |
| US 2014/0107406        | Apr. 17, 2014           | Cardiac Treatment System and Method                                                                         |
| US 2014/0107775        | Apr. 17, 2014           | Cardiac Treatment System                                                                                    |
| US 2014/0288500        | Sep. 25, 2014           | Safety Catheter System and Method                                                                           |
| US 2014/0299130        | Oct. 9, 2014            | Portable Positive Airway Pressure Apparatus and Method for Attenuating the Noise Emitted Therefrom          |
| US 2014/0299132        | Oct. 9, 2014            | Systems and Methods for Providing Positive Airway Pressure in a Tube-Like Structure                         |
| US 2014/0299406        | Oct. 9, 2014            | Systems and Methods for Providing Low-Noise Positive Airway Pressure                                        |
| US 2015/0173740        | Jun. 25, 2015           | Tissue Anchor and Anchoring System                                                                          |
| US 2016/0015919        | Jan. 21, 2016           | Systems and Methods for Providing Low-Noise Positive Airway Pressure                                        |
| US 2016/0045693        | Feb. 18, 2016           | Portable Positive Pressure Apparatus and Method for the Attenuating the Noise Emitted Therefrom             |
| US 2016/0262890        | Sep. 15, 2016           | Cardiac Treatment System and Method                                                                         |
| US 2016/0331880        | Nov. 17, 2016           | Cardiac Treatment System                                                                                    |
| US 2016/0346085        | Dec. 1, 2016            | Cardiac Treatment System and Method                                                                         |
| US 2017/0368315        | Dec. 28, 2017           | Safety Catheter System and Method                                                                           |
| US 2018/0028171        | Feb. 1, 2018            | Tissue Anchor and Anchoring System                                                                          |



**Karl R. Leinsing, MSME, PE**  
77 Spur Rd. Dover, NH 03820-9110  
(603) 203-0365 cell / (603) 749-0079 fax  
[kleinsing@comcast.net](mailto:kleinsing@comcast.net)

|                 |               |                                                                                           |
|-----------------|---------------|-------------------------------------------------------------------------------------------|
| US 2018/0368980 | Dec. 27, 2018 | Cardiac Treatment System and Method                                                       |
| US 2019/0247623 | Aug. 15, 2019 | Integrated Sealing and Securing Device for Vascular Catheters and Methods for Use of Same |
| US 2019/0343636 | Nov. 14, 2019 | Cardiac Treatment System                                                                  |
| US 2019/0358038 | Nov. 28, 2019 | Cardiac Treatment System and Method                                                       |
| US 2020/0330088 | Oct. 22, 2020 | Tissue Anchor and Anchoring System                                                        |
| US 2022/0378579 | Dec. 1, 2022  | Cardiac Treatment System and Method                                                       |
| US 2023/0285020 | Sep. 14, 2023 | Devices For Deploying Tissue Fasteners                                                    |

## Education & Licensing

| <u>Year</u> | <u>College/University</u>           | <u>Degree</u>                    |
|-------------|-------------------------------------|----------------------------------|
| 1988        | University of New Hampshire         | B.S. in Mechanical Engineering   |
| 1992        | NH: 11437                           | Professional Engineering License |
| 1995        | North Carolina A&T State University | M.S. in Mechanical Engineering   |

## Litigation Experience - (Testimony by report, deposition, declaration, or trial - last 4 years)

Arthrex vs. Parcus and Anika - Case No. 2:22-CV-0019-JLB-NPM – Middle District of Florida – Patent Litigation regarding bone syndesmosis (Defense) – Patent and prior art review, testing, analysis, and report. (October 2023 to March 2024)

NJoy vs. Juul – Case No. 337-TA-1372 – Washington, DC – ITC Patent Litigation regarding vaporizer devices (Defense) – Patent and prior art review, claim construction declaration, depositions, invalidity reports, and trial testimony. (September 2023 to June 2024)

Novo Nordisk vs. Teva (Saxenda) – Case No. 21-cv-01782-CFC – District of Delaware – Patent litigation regarding pen injector (Defense) – Patent and prior art review, analysis of accused device, reports, deposition. (January 2022 – September 2023)

Novo Nordisk vs. Dr. Reddy's Lab (Ozempic (Semaglutide)) & [Rio, Sun, Zydus, Alvogen, and Mylan] – MDL No. 22-MD-3038 (CFC) and Case No. 22-cv-294 & 1040 (CFC) – District of Delaware – Patent litigation regarding pen injector (Defense) – Patent and prior art review, analysis of accused device, claim construction declaration. (December 2021 – March 2024)

Microvention vs. Balt – Case No. 8:20-cv-02400-JLS-KES – Central District of California Western Division – Trade secret case regarding catheters and embolization coils (Defense) – Review alleged trade secrets, analysis, report. (June 2022 – December 2023)

Mizuho Orthopedic vs. Allen Medical – Case No. 1:21-cv-10979-NMG – District of Massachusetts – Patent litigation regarding surgical bed (Defense) – Patent and prior art analysis, IPR declaration. (February 2022 – October 2022)



**Karl R. Leinsing, MSME, PE**  
77 Spur Rd. Dover, NH 03820-9110  
(603) 203-0365 cell / (603) 749-0079 fax  
[kleinsing@comcast.net](mailto:kleinsing@comcast.net)

DNA Genotek vs. Spectrum Solutions - Case No. 21-cv-0516-DMS-LL – Southern District of California - Sample Collection (Defense) – Patent & prior art review, IPR declaration, report, and depositions. (October 2021 – February 2024)

OsteoMed vs. Stryker & Stryker vs. OsteoMed – Case No. 1:20-cv-6821 – Northern District of Illinois Eastern Division – Patent litigation regarding bone plates (Defense & Plaintiff) – Patent and prior art analysis, IPR declaration, deposition. Contact: Scott McBride of McAndrews, Held, & Malloy (312) 775-8131. (May 2021 – Present)

DexCom vs. Abbott and Abbott vs. DexCom – Case No: 6:21-cv-690 in Western District of TX and C.A. No. 21-977 in District of Delaware – Patent litigation regarding glucose sensors (Defense & Plaintiff respectively) – Patent analysis, IPR declaration, attend EPO hearing (parallel Europe case), reports, depositions, and jury trial. (April 2021 – Present)

Altria & US Smokeless Tobacco Co. vs RJR and Modoral Brands – Case No: 1:20-cv-00472-NCT-JLW – Middle District of NC – Patent litigation regarding vaping devices (Defense) – Invalidity analysis, reports, IPR declaration, depositions, trial. (June 2020 – September 2022)

Novo Nordisk vs Sandoz – Case No: 20-747 (CFC) – District of Delaware – Patent litigation regarding pen injector (Defense) – Analysis, report, and deposition. (June 2020 – March 2022)

Earth Animal Ventures, Inc. vs. Sage Fulfillment, LLC. – Case No: 3:20-CV-00444-VAB – District of Connecticut – Metered dispensing syringe w/CBD (Defense) – Testing, report, and deposition. (May 2021 to April 2023)

Anthony Canning vs Medtronic – Case No: CV2019-053458 – The Superior Court of the State of Arizona – Circular Surgical Stapler (Plaintiff) – Report. (November 2020 – April 2022)

Provost vs. Neuro-Rehab Associates, Inc., Elliott Hospital, and Medline Industries, Inc. – Case No: 217-2019-CV-601 – New Hampshire Superior Court – Medline Rollator Liability Case (Plaintiff) – Failure analysis, report, deposition. (July 2020 – November 2021)

Boehringer Ingelheim vs. Lupin Altantis Holdings – Case No: 18-12663 (BRM) (TJB) – District Court of New Jersey – Patent litigation regarding powder inhaler (Plaintiff) – Report and deposition. (January 2020 – October 2021)

Boston Scientific vs. Micro-Tech – Case No: 18-1869-CFC-CJB – District of Delaware – Patent litigation regarding endometrial ablation device (Plaintiff) – Review of patents & products, fracture analysis, reports, deposition. (January 2020 – January 2022)

Novartis vs. Regeneron – ITC No: 337-TA-1207 – Washington, DC – Patent litigation regarding pre-filled syringe (Plaintiff) – Patent review, declarations, Markman hearing. (August 2019 – Present)



**Karl R. Leinsing, MSME, PE**  
77 Spur Rd. Dover, NH 03820-9110  
(603) 203-0365 cell / (603) 749-0079 fax  
[kleinsing@comcast.net](mailto:kleinsing@comcast.net)

Baxter vs. BD – Case No: 1:17-cv-07576 USDC North IL Eastern Division – Patent litigation on Fluid Reconstitution Device (Plaintiff) – Review patents, declaration, report, & deposition. Contact: Denis Sullivan of Barclay Damon, LLP in Syracuse, NY (315) 425-2828. (July 2019 – December 2023)

Edwards vs. Lindel, MD - Case No: 17 CVS 1936 – Superior Court Division of Surry County, NC – Liability case on endometrial ablation device (Plaintiff) – Review of documents, medical records, deposition. (March 2017 – December 2023)

Hologic vs. Minerva & Minerva vs. Hologic – Case Nos: 15-1031-SLR / 18-217-JFB-SRF / 20-925-JFB-SRF – District of DE & CA - Patent litigation on endometrial ablation (Plaintiff & Defense) – Patents, reports, declaration, depositions, and jury trial. (April 2017 – April 2023)

Dr. Augé vs. Stryker & Howmedica – Case No: 1:14-CV-1089-KG-SMV – District of New Mexico (Santa Fe Division) – Contract case on bone anchors, guides, drills, & inserters (Defense) – Review products, patents, report, deposition, jury trial. (January 2017 – May 2022)

Covidien vs. Ethicon & Ethicon vs. Covidien – Case No: 1:11-cv-00871 & Case No: 1:16-cv-00253-SJD – Southern District of Ohio Western Div. & Case No: 1:16-cv-12556-LTS – District of MA – Patent litigation on RF & ultrasonic vessel sealing and cutting (Defense & Plaintiff) – Reports, depositions, & trial. (Dec. 2016 – March 2021)

Boston Scientific vs. Cook – Case No: 15-980-LPS-CJB – District of Delaware – Patent litigation case regarding surgical clip (Plaintiff) – Review patents, reports, depositions, and jury trial. (August 2016 – June 2023)

Medline vs. CR Bard – Case No. 1:14-CV-3618 / 1:16-cv-3529 / 1:17-cv-7216 – Northern District of Illinois Eastern Div. – Catheter packaging and trays (Defense) – Claim construction declarations, depositions, testified at two Markman hearings. (January 2016 – Present)



**Karl R. Leinsing, MSME, PE**  
77 Spur Rd. Dover, NH 03820-9110  
(603) 203-0365 cell / (603) 749-0079 fax  
[kleinsing@comcast.net](mailto:kleinsing@comcast.net)

### **Declarations in Support or Response of IPR Petitions in Last 4 Years**

| <b>Decl. Date</b> | <b>Petition #</b>                                    | <b>Patent(s)</b>                                     | <b>Parties / Type Device</b>                                                                                                      |
|-------------------|------------------------------------------------------|------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| 10/22/2020        | 2020-01317<br>2020-01318                             | 9,220,631                                            | <u>Novartis</u> vs. Regeneron / Pre-Filled Syringe                                                                                |
| 3/12/2021         | 2021-00650<br>2021-00652                             | 10,143,242<br>10,264,824                             | Altria Client Services, LLC and US Smokeless Tobacco Company, LLC vs. <u>R.J. Reynolds Vapor Company and Modoral Brands, Inc.</u> |
| 3/31/2021         | 2021-00744<br>2021-00745<br>2021-00746<br>2021-00747 | 10,299,517<br>10,485,269<br>10,492,541<br>10,588,357 | Altria Client Services, LLC and US Smokeless Tobacco Company, LLC vs. <u>R.J. Reynolds Vapor Company and Modoral Brands, Inc.</u> |
| 07/28/2021        | 2021-00816                                           | 9,220,631                                            | <u>Novartis</u> vs. Regeneron / Pre-Filled Syringe                                                                                |
| 04/23/2022        | 2022-00917<br>2022-00918                             | 10,980,452                                           | Dexcom vs. <u>Abbott</u> / Glucose Sensor                                                                                         |
| 04/22/2022        | 2022-00919<br>2022-00920                             | 10,888,481                                           | Mizuho vs. <u>Allen Medical &amp; Hill-Rom</u> / Surgical Table                                                                   |
| 11/16/2022        | 2022-01347                                           | 11,002,646                                           | Genotek vs. <u>Spectrum</u> / Sample Collection                                                                                   |
| 11/18/2022        | 2022-00487<br>2022-00488                             | 9,078,713<br>10,993,751                              | <u>Stryker</u> vs OsteoMed / Bone Plates                                                                                          |

Note: Underlined party hired me to perform analysis and write declaration.

### **Affiliations**

ASME – American Society of Mechanical Engineers since 1988  
National Society of Professional Engineers since 2000  
ASM International – American Society of Metals International since 2020  
UNH Mechanical Engineering Senior Project Sponsor & Leader - 2022  
MDG – Medical Development Group since 2006  
Inventors Workshop – Board of Directors since 2006  
Eureka Medical – Medical Device Advisory Board since 2006  
Big Brothers Big Sisters (BBBS) – Big Volunteer & Contributor – Since 2008  
BBB – Better Business Bureau of New Hampshire since 2010  
MassMedic – Massachusetts Medical Device Industry Council since 2011  
Medical Device & Manufacturing (MD&M) Conferences – Chairman 2014  
H2L Medical Technologies, LLC – Catheter Systems – Co-Founder – 2015 to 2018  
Neighborhood Community Garbage Cleanup Committee Chairman – Since 2015  
UNH STEM (Tech Camp) – Mentor and Contributor – Science, Technology, Engineering, & Mathematics – Since 2016  
All Electronic Toll (AET) - NH State Chairman – 2017  
NH Bio-Made Industry and State Partnerships Board (ISPB) – Board of Directors - 2018

### **Curriculum Vitae of Karl R. Leinsing, MSME, PE**

# **APPENDIX B**

## **APPENDIX B**

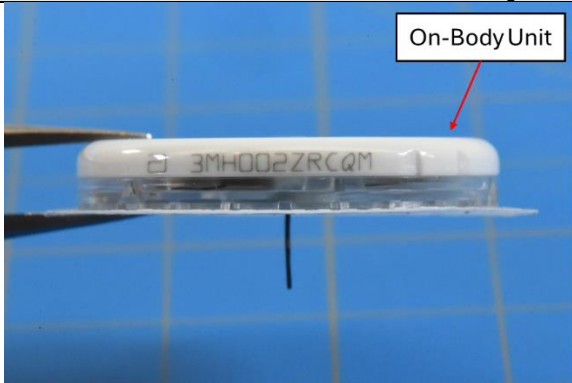
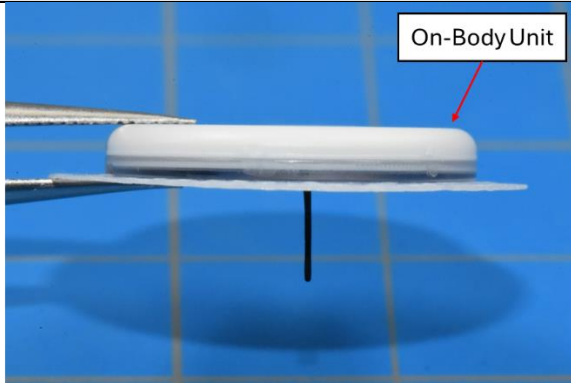
### **Claim Chart for U.S. Patent No. 11,202,591**

In support of the opinions and analysis in my Declaration, the following claim chart shows how each element of Claims 1, 3, 4, 14, and 19 of the 591 Patent is practiced by the FreeStyle Libre 14-Day, FreeStyle Libre 2, and FreeStyle Libre 3 (the “FreeStyle Libre Products”).<sup>1</sup> I personally inspected and evaluated the FreeStyle Libre Products and took numerous photos to illustrate my conclusions. The materials referenced are examples and are not exhaustive. Similarly, the annotations of images below are illustrative. As I mentioned in my Declaration, for purposes of the claims of the 591 Patent identified below, there are no material differences between the components or operation of the FreeStyle Libre 14-Day and FreeStyle Libre 2 products, and the FreeStyle Libre 3 product. As such, the claim chart below generally uses the FreeStyle Libre 2 and FreeStyle Libre 3 as representative devices.

---

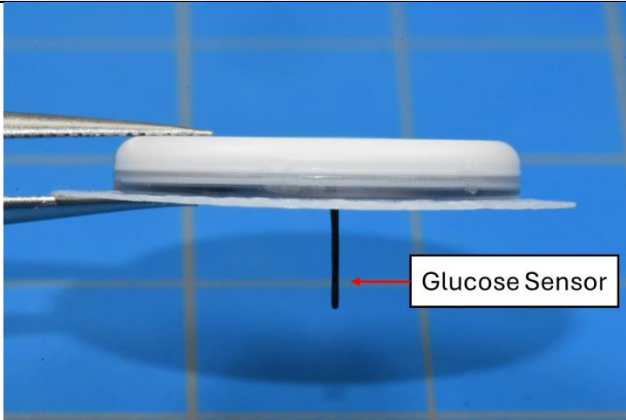
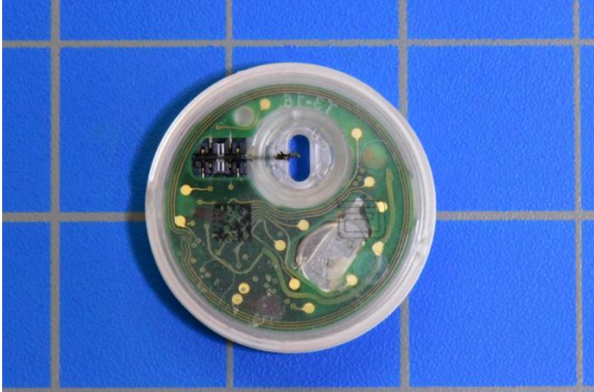
<sup>1</sup> As I explained in my Declaration, for convenience and due to the non-confidential nature of these proceedings, I have focused my analysis on how the Libre products practice Independent Claims 1 and 19, as well as Dependent Claims 3, 4, and 14 (which include limitations from Independent Claim 19).

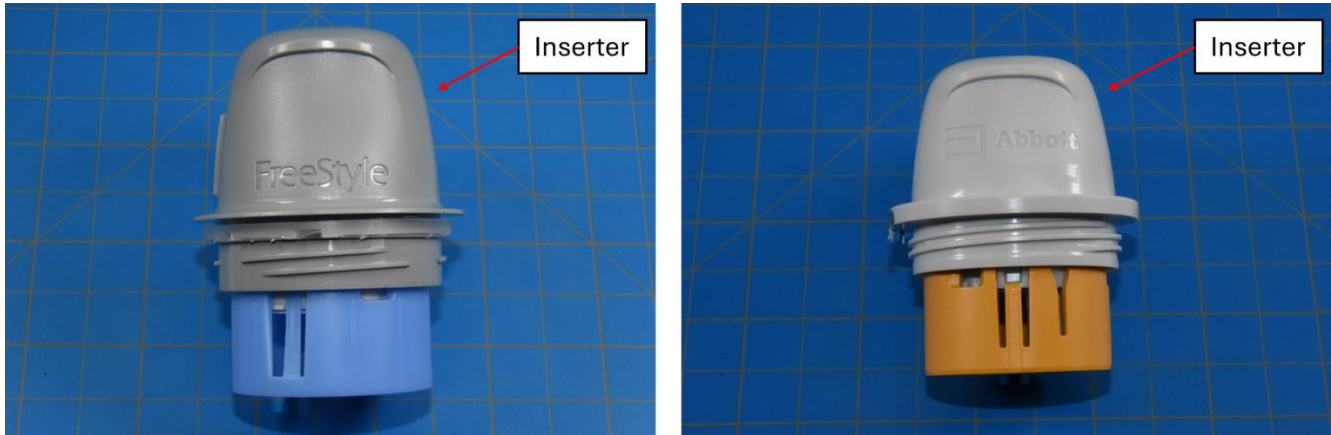
| Claim                                                  | FreeStyle Libre Products                                                                                                                                                                                                                                                                                                                                                                |
|--------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Claim 1                                                |                                                                                                                                                                                                                                                                                                                                                                                         |
| <p><b>[1.1] An insertion assembly, comprising:</b></p> | <p>The FreeStyle Libre 14-Day, FreeStyle Libre 2, and FreeStyle Libre 3 include an insertion assembly, as shown in the sample photographs below.</p> <div data-bbox="636 410 1241 813" data-label="Image"> </div> <div data-bbox="1283 410 1887 813" data-label="Image"> </div> <p>(FreeStyle Libre 2 Applicator, DSC_6080 (left); FreeStyle Libre 3 Applicator, DSC_6057 (right)).</p> |
| <p><b>[1.2] (a) an on-body unit, comprising:</b></p>   | <p>The insertion assemblies of the FreeStyle Libre 14-Day, FreeStyle Libre 2, and FreeStyle Libre 3 include an on-body unit, as shown in the sample photographs below.</p>                                                                                                                                                                                                              |

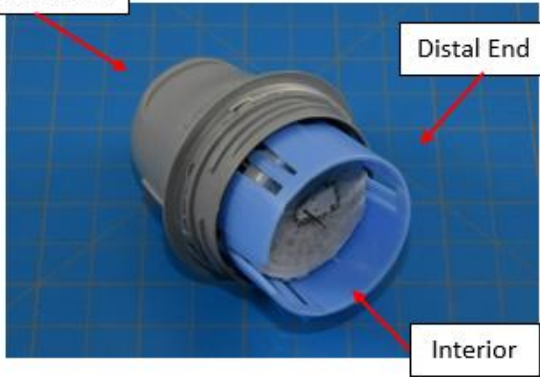
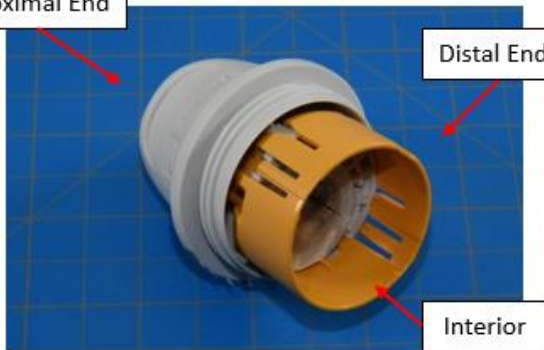
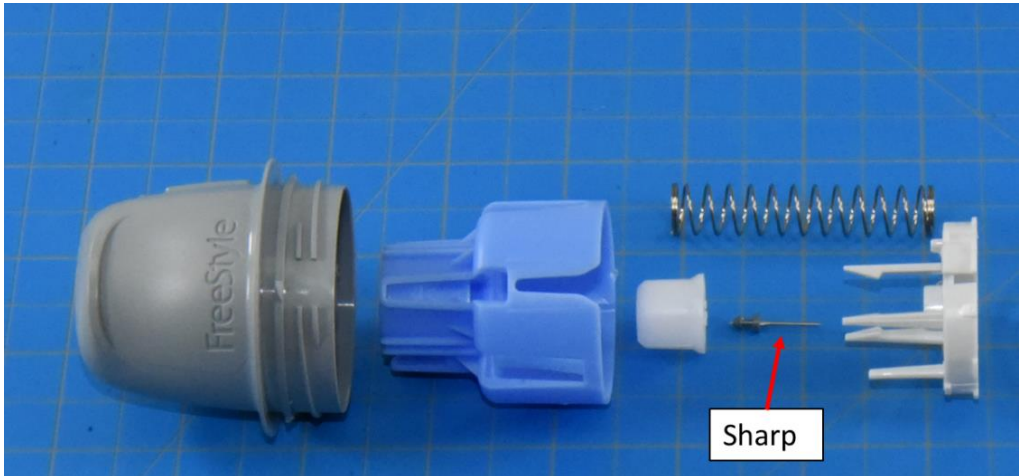
| Claim                                                                                                                                                                                                                                                                                                                                    | FreeStyle Libre Products                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                          | <div data-bbox="667 245 1234 625">  </div> <div data-bbox="1287 245 1854 625">  </div> <p data-bbox="596 673 1929 755">(FreeStyle Libre 2 On-Body Unit Profile View, DSC_6452 (annotated) (left); FreeStyle Libre 3 On-Body Unit Profile View, DSC_6585 (annotated) (right)).</p>                                                  |
| <p data-bbox="201 768 554 1399"><b>[1.3] a housing comprising a top surface and a bottom surface, wherein the top surface comprises an opening of the top surface, wherein the bottom surface comprises an opening of the bottom surface, and wherein a longitudinal axis extends through the opening of the top surface and the</b></p> | <p data-bbox="596 760 1932 1008">The on-body units of the FreeStyle Libre 14-Day, FreeStyle Libre 2, and FreeStyle Libre 3 include a housing comprising a top surface and a bottom surface, wherein the top surface comprises an opening of the top surface, wherein the bottom surface comprises an opening of the bottom surface, and wherein a longitudinal axis extends through the opening of the top surface and the opening of the bottom surface, as shown in the sample photographs below.</p> |

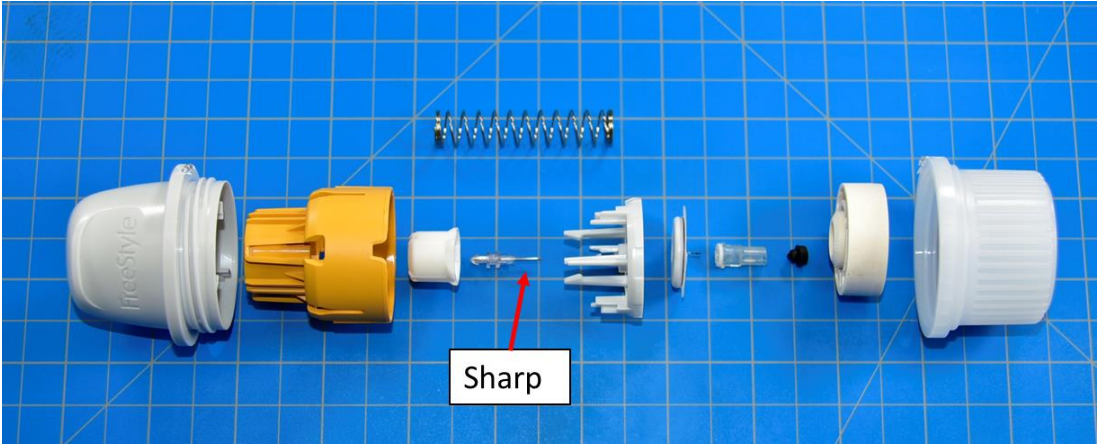
| Claim                                        | FreeStyle Libre Products                                                                                                                                                                                                                                                                                                                                                                                                       |
|----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>opening of the bottom surface;</b></p> | <div data-bbox="886 245 1635 688" data-label="Image"> </div> <p>(FreeStyle Libre 2 On-Body Unit Profile View, DSC_6452 (annotated)).</p> <div data-bbox="680 773 1247 1151" data-label="Image"> </div> <div data-bbox="1276 773 1843 1151" data-label="Image"> </div> <p>(FreeStyle Libre 2 On-Body Unit Top View, DSC_6435 (annotated) (left); FreeStyle Libre 2 On-Body Unit Bottom View, DSC_6438 (annotated) (right)).</p> |

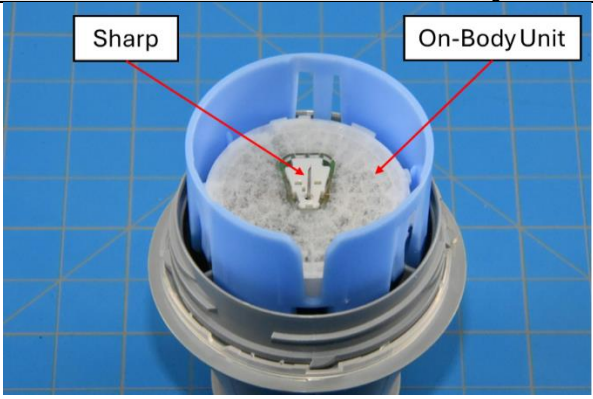
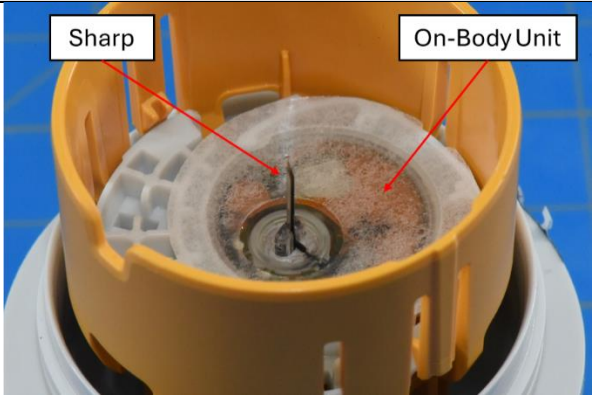
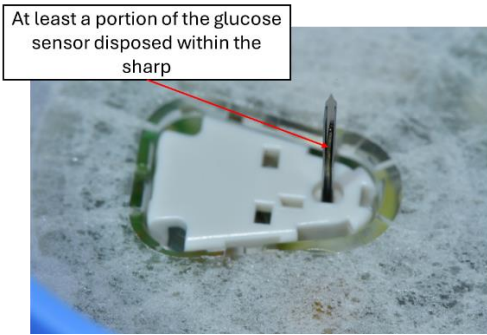
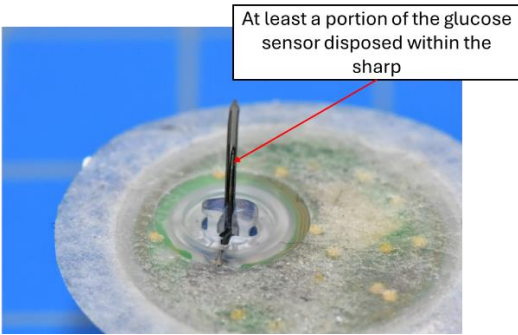
| Claim                                         | FreeStyle Libre Products                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                               | <div data-bbox="856 248 1665 743" data-label="Image"> <p>A photograph showing the profile of a white, cylindrical FreeStyle Libre 3 on-body unit. A red dashed line indicates the longitudinal axis. A bracket on the right side of the unit is labeled 'Housing'.</p> </div> <p data-bbox="596 743 1675 784">(FreeStyle Libre 3 On-Body Unit Profile View, DSC_6585 (annotated)).</p> <div data-bbox="699 824 1245 1190" data-label="Image"> <p>A photograph showing the top view of a white, circular FreeStyle Libre 3 on-body unit. A red arrow points to the center, labeled 'Opening'. Another red arrow points to the top edge, labeled 'Top Surface'.</p> </div> <div data-bbox="1276 824 1829 1190" data-label="Image"> <p>A photograph showing the bottom view of a white, circular FreeStyle Libre 2 on-body unit. A red arrow points to the center, labeled 'Opening'. Another red arrow points to the bottom edge, labeled 'Bottom Surface'.</p> </div> <p data-bbox="596 1198 1860 1279">(FreeStyle Libre 3 On-Body Unit Top View, DSC_6570 (annotated) (left); FreeStyle Libre 2 On-Body Unit Bottom View, DSC_6577 (annotated) (right)).</p> |
| <p><b>[1.4] a glucose sensor;<br/>and</b></p> | <p>The on-body units of the FreeStyle Libre 14-Day, FreeStyle Libre 2, and FreeStyle Libre 3 include a glucose sensor, as shown in the sample photographs below.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

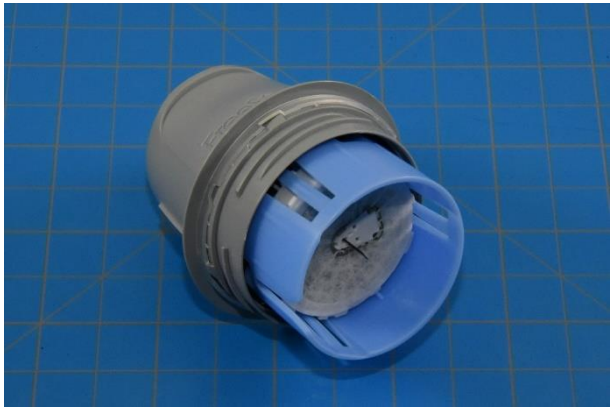
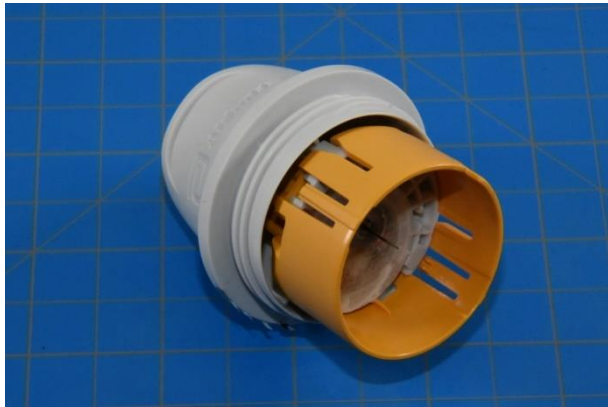
| Claim                                                                                                                                    | FreeStyle Libre Products                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                          | <div data-bbox="611 245 1232 662">  </div> <div data-bbox="1291 245 1913 662">  </div> <p data-bbox="596 711 1934 792">(FreeStyle Libre 2 On-Body Unit Profile View, DSC_6452 (annotated) (left); FreeStyle Libre 3 On-Body Unit Profile View, DSC_6585 (annotated) (right)).</p>                                                                                    |
| <p data-bbox="201 808 573 1011"><b>[1.5] sensor electronics disposed within the housing and coupled with the glucose sensor; and</b></p> | <p data-bbox="596 800 1934 922">The sensor electronics of the FreeStyle Libre 14-Day, FreeStyle Libre 2 and FreeStyle Libre 3 are disposed within the housing and coupled with the glucose sensor, as illustrated below, and in the figures from claim element [1.4].</p> <div data-bbox="655 963 1245 1352">  </div> <div data-bbox="1281 963 1871 1352">  </div> |

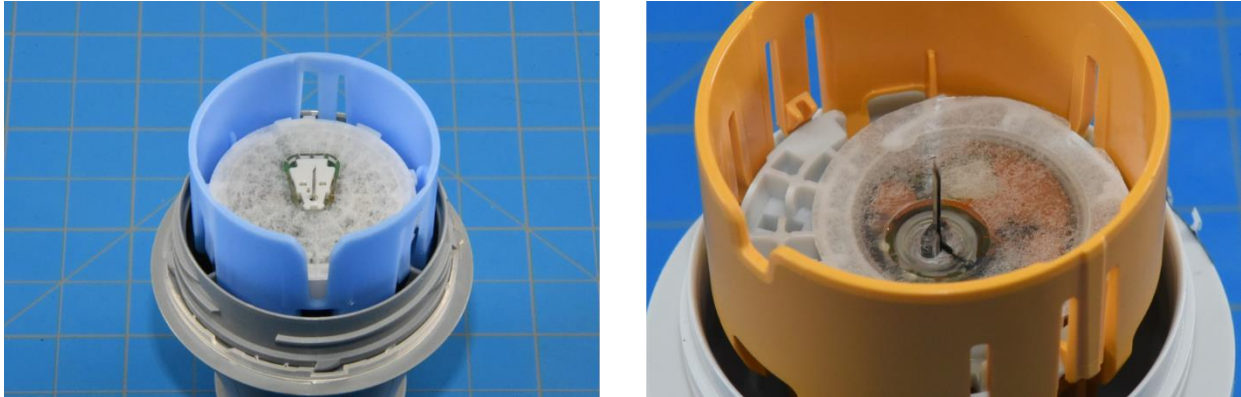
| Claim                                                                  | FreeStyle Libre Products                                                                                                                                                                                                                                                                                                                                                                                                            |
|------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                        | (FreeStyle Libre 2 On-Body Unit Bottom View, DSC_4679 (left); FreeStyle Libre 3 On-Body Unit Bottom View, DSC_4861 (right); <i>see also</i> , FreeStyle Libre 14-Day On-Body Unit Internal View, DSC_5743).                                                                                                                                                                                                                         |
| <p><b>[1.6] (b) an inserter, comprising:</b></p>                       | <p>The insertion assemblies of the FreeStyle Libre 14-Day, FreeStyle Libre 2, and FreeStyle Libre 3 include an inserter, as shown in the sample photographs below.</p> <div data-bbox="600 545 1923 977">  </div> <p>(FreeStyle Libre 2 Applicator, DSC_5927 (annotated) (left); FreeStyle Libre 3 Applicator, DSC_6052 (annotated) (right)).</p> |
| <p><b>[1.7] a proximal end, a distal end, and an interior; and</b></p> | <p>The inserters of the FreeStyle Libre 14-Day, FreeStyle Libre, and FreeStyle Libre 3 include a proximal end, a distal end, and an interior, as shown in the sample photographs below.</p>                                                                                                                                                                                                                                         |

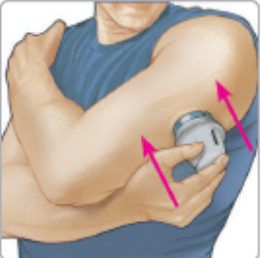
| Claim          | FreeStyle Libre Products                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                | <div data-bbox="625 256 1234 669">  <p>Proximal End</p> <p>Distal End</p> <p>Interior</p> </div> <div data-bbox="1285 279 1906 652">  <p>Proximal End</p> <p>Distal End</p> <p>Interior</p> </div> <p>(FreeStyle Libre 2 Applicator, DSC_6080 (annotated) (left); FreeStyle Libre 3 Applicator, DSC_6057 (annotated) (right)).</p> |
| [1.8] a sharp, | <p>The inserters of the FreeStyle Libre 14-Day, FreeStyle Libre 2, and FreeStyle Libre 3 include a sharp, as shown in the sample photographs below.</p> <div data-bbox="756 933 1768 1406">  <p>Sharp</p> </div>                                                                                                                                                                                                     |

| Claim                                                                                                                                          | FreeStyle Libre Products                                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                | <p data-bbox="594 297 1860 337">(FreeStyle Libre 2 Applicator Components Exploded View, DSC_7207 (annotated)).</p>  <p data-bbox="594 865 1860 906">(FreeStyle Libre 3 Applicator Components Exploded View, DSC_1137 (annotated)).</p> |
| <p data-bbox="201 959 573 1166"><b>[1.9] wherein the on-body unit and the sharp are entirely disposed in the interior of the inserter,</b></p> | <p data-bbox="594 951 1932 1073">The on-body units and sharps of the FreeStyle Libre 14-Day, FreeStyle Libre 2, and FreeStyle Libre 3 are entirely disposed in the interior of the inserter, as shown in the sample photographs and documents below.</p>                                                                 |

| Claim                                                                                           | FreeStyle Libre Products                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                 | <div data-bbox="682 245 1270 641">  <p>Sharp</p> <p>On-Body Unit</p> </div> <div data-bbox="1312 245 1900 641">  <p>Sharp</p> <p>On-Body Unit</p> </div> <p>(FreeStyle Libre 2 Applicator, DSC_6077 (annotated) (left); FreeStyle Libre 3 Applicator, DSC_6061 (annotated) (right)).</p>                                                                                                                                                                                                                                                                                                                 |
| <p><b>[1.10] wherein at least a portion of the glucose sensor is disposed in the sharp,</b></p> | <p>At least a portion of the glucose sensors of the FreeStyle Libre 14-Day, FreeStyle Libre 2, and FreeStyle Libre 3 are disposed in the sharp, as shown in the sample photographs below.</p> <div data-bbox="745 852 1228 1185">  <p>At least a portion of the glucose sensor disposed within the sharp</p> </div> <div data-bbox="1260 852 1774 1185">  <p>At least a portion of the glucose sensor disposed within the sharp</p> </div> <p>(FreeStyle Libre 2 On-Body Unit Bottom View, DSC_5308 (annotated) (left); FreeStyle Libre 3 On-Body Unit Bottom View, DSC_4842 (annotated) (right)).</p> |
| <p><b>[1.11] wherein the sharp extends through the opening of the top</b></p>                   | <p>The sharps of the FreeStyle Libre 14-Day, FreeStyle Libre 2, and FreeStyle Libre 3 extend through the opening of the top surface and the opening of the bottom surface along the longitudinal axis when the on-body unit is in its first position.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

| Claim                                                                                                                          | FreeStyle Libre Products                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|--------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>surface and the opening of the bottom surface along the longitudinal axis when the on-body unit is in a first position,</p> | <div data-bbox="606 289 1232 706">  <p>A top-down view of the FreeStyle Libre 2 sensor. It features a white circular base with a clear, slightly flared bottom section. A thin, silver-colored needle is visible protruding from the center of the base. The device is set against a blue background with a white grid pattern.</p> </div> <div data-bbox="1289 289 1915 706">  <p>A top-down view of the FreeStyle Libre 3 sensor. It has a similar design to the Libre 2, with a white base and a clear bottom section. The needle is more prominent and appears to have a small, clear protective cap or seal at its base. The background is the same blue grid.</p> </div> <p>(FreeStyle Libre 2, DSC_4835 (left); FreeStyle Libre 3, DSC_4853 (right)).</p> <div data-bbox="636 943 1241 1347">  <p>An internal view of the FreeStyle Libre 2 sensor, showing the underside of the white base. A blue plastic component is visible, which appears to be a cover or a part of the internal mechanism. The needle is visible through a central opening. The background is the blue grid.</p> </div> <div data-bbox="1283 943 1887 1347">  <p>An internal view of the FreeStyle Libre 3 sensor, showing the underside of the white base. A yellow plastic component is visible, which appears to be a cover or a part of the internal mechanism. The needle is visible through a central opening. The background is the blue grid.</p> </div> |

| Claim                                                                                                                                                                                                                                                                                                      | FreeStyle Libre Products                                                                                                                                                                                                                                                                                                                                                                                                       |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                            | <p data-bbox="594 253 1764 334">(FreeStyle Libre 2 Applicator, DSC_6080 (left); FreeStyle Libre 3 Applicator, DSC_6057 (right)).</p> <div data-bbox="646 370 1879 764">  </div> <p data-bbox="594 805 1932 886">(FreeStyle Libre 2 Applicator, DSC_6077 (annotated) (left); FreeStyle Libre 3 Applicator, DSC_6061 (annotated) (right)).</p> |
| <p data-bbox="201 898 573 1398"><b>[1.12] wherein the inserter is configured to advance the on-body unit and the sharp in a linear direction from the first position to a second position such that the sharp pierces skin of a user and the housing of the on-body unit is secured to the skin of</b></p> | <p data-bbox="594 898 1932 1097">The inserters of the FreeStyle Libre 14-Day, FreeStyle Libre 2, and FreeStyle Libre 3 are configured to advance the on-body unit and the sharp in a linear direction from the first position to a second position such that the sharp pierces skin of a user and the housing of the on-body unit is secured to the skin of the user in the second position, as illustrated below.</p>         |

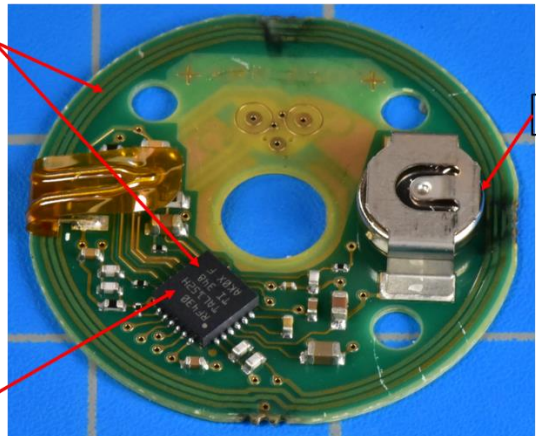
| Claim                                                                                                                                                             | FreeStyle Libre Products                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>the user in the second position,</p>                                                                                                                           | <div data-bbox="604 253 1921 573"> <div> <p><b>STEP 7</b></p>  <p><u>Place sensor applicator over site and push down firmly to apply sensor.</u></p> <p><b>CAUTION:</b> Do not push down on sensor applicator until placed over prepared site to prevent unintended results or injury.</p> </div> <div> <p><b>STEP 8</b></p>  <p>Gently pull back applicator to remove, leaving sensor on body.</p> </div> </div> <p>(Ex. 2007, Your FreeStyle Libre 14 day System, In-Service Guide at 7; <i>see also</i>, Ex. 2008, Get Started, Your Guide To The FreeStyle Libre 2 System at 7; Ex. 2009, Getting Started with the FreeStyle Libre 3 System at 5; Ex. 2010, FreeStyle Libre 3 Continuous Glucose Monitoring System User's Manual at 39.)</p> |
| <p>[1.13] wherein the distal end of the inserter is configured to be positioned on the skin of the user before advancement of the on-body unit and the sharp,</p> | <p>The distal ends of the inserters of the FreeStyle Libre 14-Day, FreeStyle Libre 2, and FreeStyle Libre 3 are configured to be positioned on the skin of the user before advancement of the on-body unit and the sharp, as illustrated below.</p> <div data-bbox="905 971 1619 1282"> <p><b>STEP 7</b></p>  <p><u>Place sensor applicator over site and push down firmly to apply sensor.</u></p> <p><b>CAUTION:</b> Do not push down on sensor applicator until placed over prepared site to prevent unintended results or injury.</p> </div> <p>(Ex. 2007, Your FreeStyle Libre 14 day System, In-Service Guide at 7; <i>see also</i>, Ex. 2008, Get Started, Your Guide To The FreeStyle Libre 2 System at 7; Ex. 2009, Getting Started</p>                                                                                 |

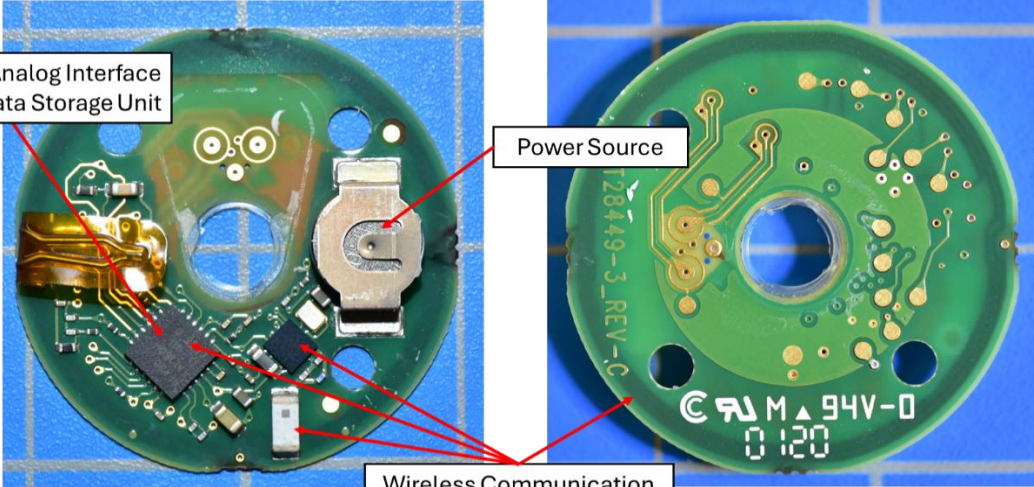
| Claim                                                                                                                                                                                                                                      | FreeStyle Libre Products                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>[1.14] wherein the inserter is further configured to automatically retract the sharp from within the user and entirely into the interior of the inserter and leave a part of the glucose sensor in the skin of the user, and</b></p> | <p>with the FreeStyle Libre 3 System at 5; Ex. 2010, FreeStyle Libre 3 Continuous Glucose Monitoring System User's Manual at 39.)</p> <p>The inserters of the FreeStyle Libre 14-Day, FreeStyle Libre 2, and FreeStyle Libre 3 are further configured to automatically retract the sharp from within the user and entirely into the interior of the inserter and leave a part of the glucose sensor in the skin of the user, as illustrated below. As explained in my Declaration, once the sharp/sensor reaches the insertion depth in the skin, a spring within the inserter is released, expanding, and thereby automatically retracting the sharp into the interior of the inserter.</p> <div data-bbox="604 634 1923 954"> <div data-bbox="604 634 869 954"> <p><b>STEP 7</b></p>  </div> <div data-bbox="869 691 1323 922"> <p><u>Place sensor applicator over site and push down firmly to apply sensor.</u></p> <p><b>CAUTION:</b> Do not push down on sensor applicator until placed over prepared site to prevent unintended results or injury.</p> </div> <div data-bbox="1360 634 1923 954"> <p><b>STEP 8</b></p>  <p>Gently pull back applicator to remove, leaving sensor on body.</p> </div> </div> <p>(Ex. 2007, Your FreeStyle Libre 14 day System, In-Service Guide at 7; <i>see also</i>, Ex. 2008, Get Started, Your Guide To The FreeStyle Libre 2 System at 7; Ex. 2009, Getting Started with the FreeStyle Libre 3 System at 5; Ex. 2010, FreeStyle Libre 3 Continuous Glucose Monitoring System User's Manual at 39.)</p> |
| <p><b>[1.15] wherein the distal end of the inserter is further configured to be removed from the skin</b></p>                                                                                                                              | <p>The distal ends of the inserters of the FreeStyle Libre 14-Day, FreeStyle Libre 2, and FreeStyle Libre 3 are further configured to be removed from the skin of the user after automatic retraction of the sharp from within the user, as illustrated below.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

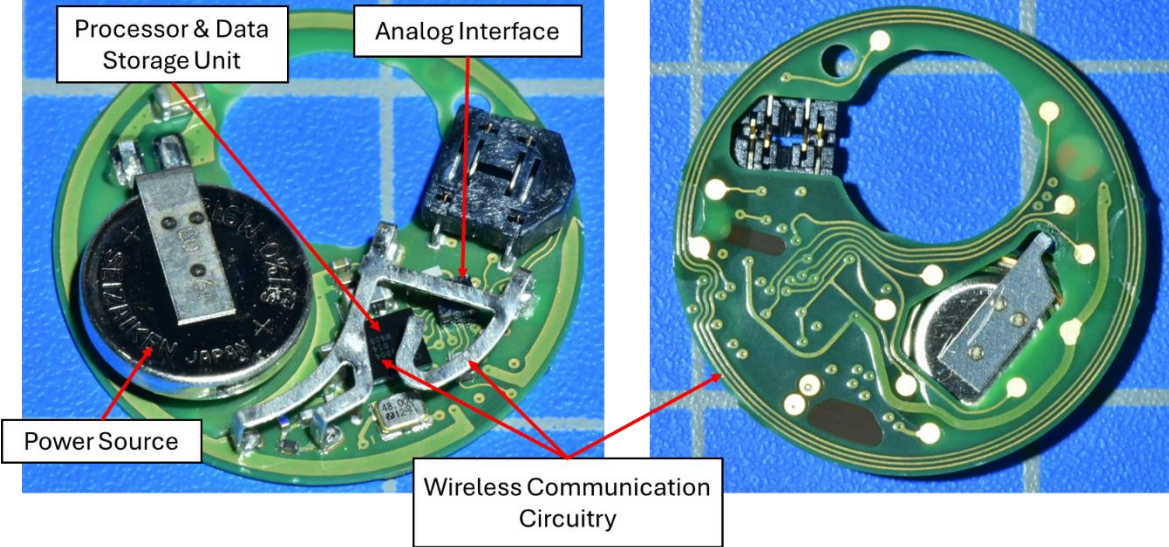
| Claim                                                                                                                                                                                                                                                       | FreeStyle Libre Products                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>of the user after automatic retraction of the sharp from within the user.</b></p>                                                                                                                                                                     | <p><b>STEP 8</b></p>  <p>Gently pull back applicator to remove, leaving sensor on body.</p> <p>(Ex. 2007, Your FreeStyle Libre 14 Day System, In-Service Guide at 7; <i>see also</i>, Ex. 2008, Get Started, Your Guide To The FreeStyle Libre 2 System at 7; Ex. 2009, Getting Started with the FreeStyle Libre 3 System at 5; Ex. 2010, FreeStyle Libre 3 Continuous Glucose Monitoring System User's Manual at 39.)</p> |
| <b>Claim 3</b>                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <p><b>[3] The insertion assembly of claim 2, wherein a distance between the housing when the on-body unit is in the first position and the housing when the on-body unit is in the second position is greater than a maximum height of the housing.</b></p> | <p>See claim element [19.13].</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Claim 4</b>                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

| Claim                                                                                                                                                                                                                                                           | FreeStyle Libre Products          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| <b>[4] The insertion assembly of claim 3, wherein the sensor electronics comprise a processor, a power source, an analog interface, a data storage unit, and wireless communication circuitry configured to communicate data indicative of a glucose level.</b> | <i>See claim element [19.6].</i>  |
| <b>Claim 14</b>                                                                                                                                                                                                                                                 |                                   |
| <b>[14] The insertion assembly of claim 3, wherein a height profile of the housing is less than or equal to approximately 10 millimeters.</b>                                                                                                                   | <i>See claim element [19.14].</i> |
| <b>Claim 19</b>                                                                                                                                                                                                                                                 |                                   |
| <b>[19.1] An insertion assembly, comprising:</b>                                                                                                                                                                                                                | <i>See claim element [1.1].</i>   |

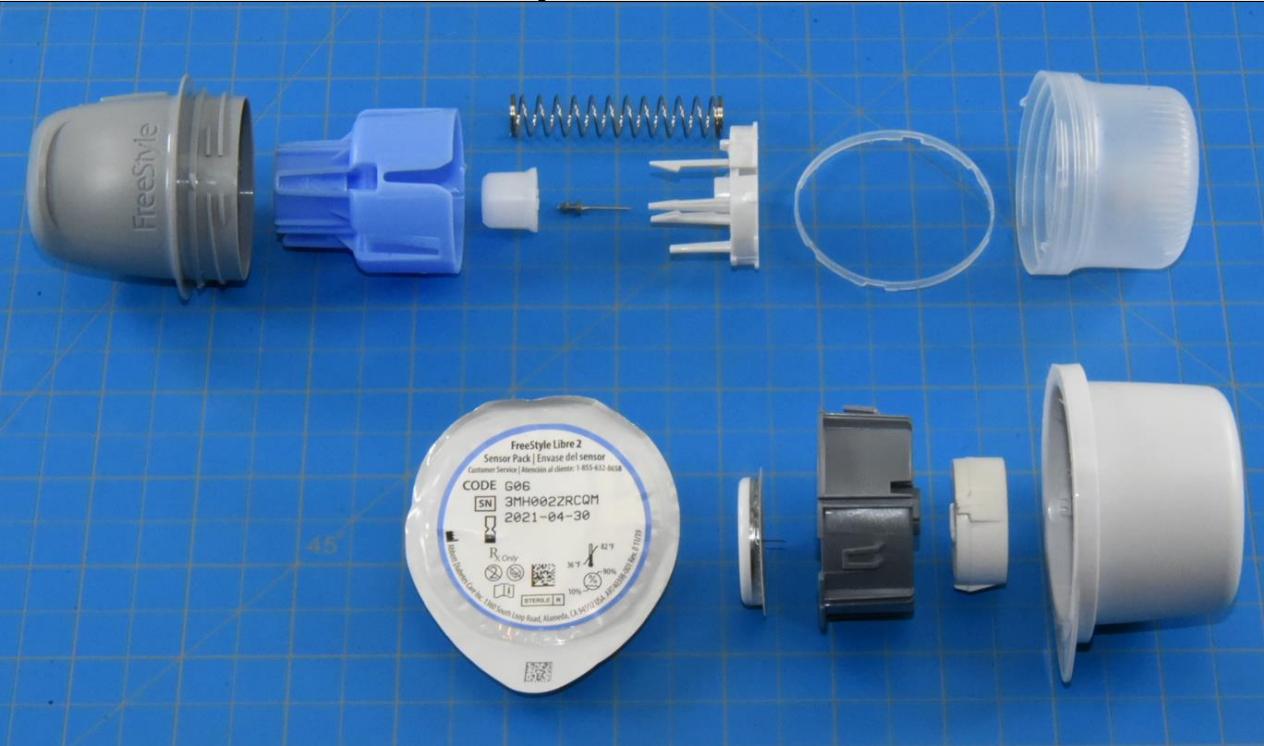
| Claim                                                                                                                                                                                                                                                                                                                                | FreeStyle Libre Products        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| <b>[19.2] (a) an on-body unit, comprising:</b>                                                                                                                                                                                                                                                                                       | <i>See claim element [1.2].</i> |
| <b>[19.3] a housing comprising a top surface and a bottom surface, wherein the top surface comprises an opening of the top surface, wherein the bottom surface comprises an opening of the bottom surface, and wherein a longitudinal axis extends through the opening of the top surface and the opening of the bottom surface;</b> | <i>See claim element [1.3].</i> |
| <b>[19.4] a glucose sensor; and</b>                                                                                                                                                                                                                                                                                                  | <i>See claim element [1.4].</i> |
| <b>[19.5] sensor electronics disposed within the housing and</b>                                                                                                                                                                                                                                                                     | <i>See claim element [1.5].</i> |

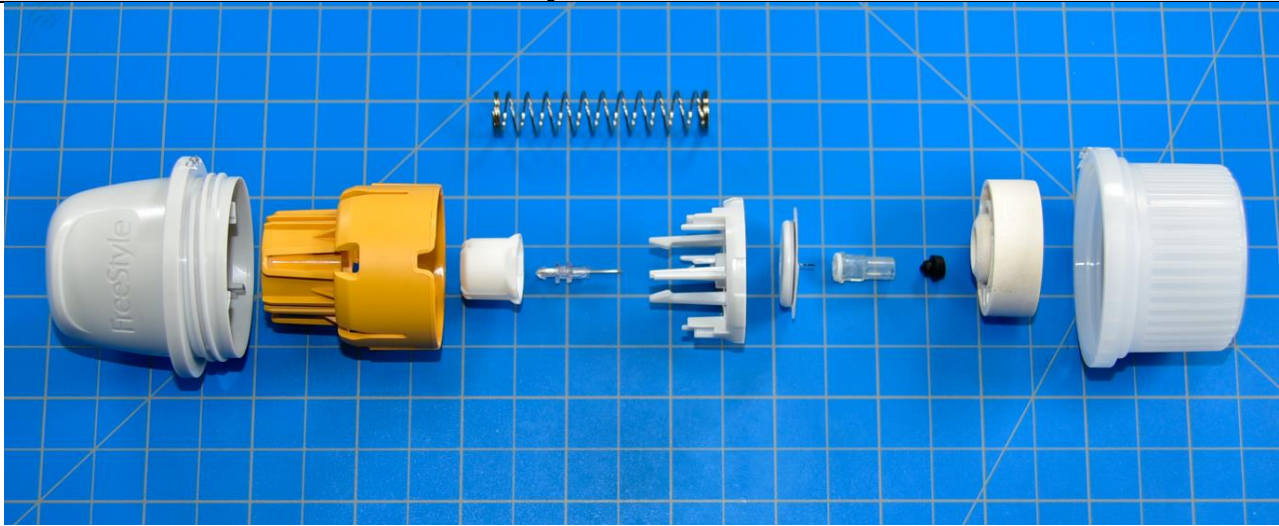
| Claim                                                                                                                                                                                                                                      | FreeStyle Libre Products                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| coupled with the glucose sensor,                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <p><b>[19.6] wherein the sensor electronics comprise a processor, a power source, an analog interface, a data storage unit, and wireless communication circuitry configured to communicate data indicative of a glucose level; and</b></p> | <p>The sensor electronics of the FreeStyle Libre 14-Day, FreeStyle Libre 2, and FreeStyle Libre 3 comprise a processor, a power source, an analog interface, a data storage unit, and wireless communication circuitry configured to communicate data indicative of a glucose level, as shown in the photographs below.</p> <div data-bbox="730 565 1789 998">  </div> <p>(FreeStyle Libre 14-Day PCB, DSC_5745 (annotated)).</p> |

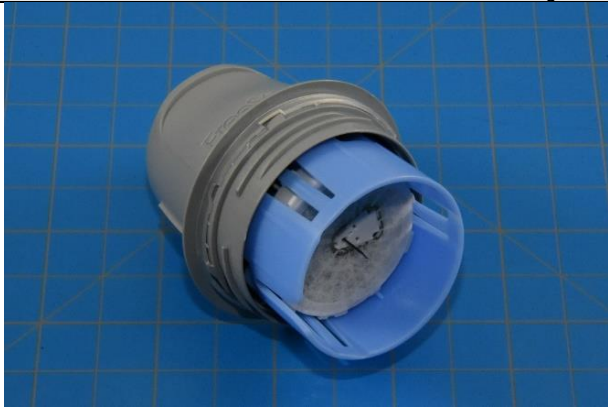
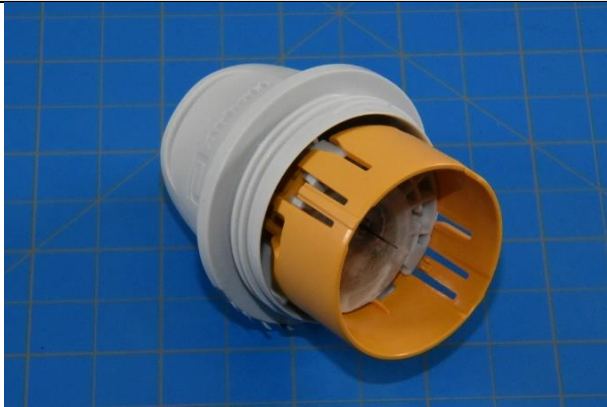
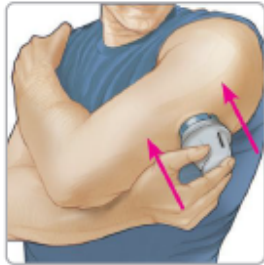
| Claim | FreeStyle Libre Products                                                                                                                                                                                                                                                    |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|       | <div data-bbox="667 248 1852 781">  </div> <p data-bbox="594 836 1906 917">(FreeStyle Libre 2 PCB (Front), DSC_4715 (annotated); FreeStyle Libre 2 PCB (Back), DSC_4725 (annotated)).</p> |

| Claim                                                              | FreeStyle Libre Products                                                                                                                                                                             |
|--------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                    |  <p>(FreeStyle Libre 3 PCB (Front), DSC_4902 (annotated); FreeStyle Libre 3 PCB (Back), DSC_4916 (annotated)).</p> |
| <b>[19.7] (b) an inserter, comprising:</b>                         | See claim element [1.6].                                                                                                                                                                             |
| <b>[19.8] a proximal end, a distal end, and an interior; and</b>   | See claim element [1.7].                                                                                                                                                                             |
| <b>[19.9] a sharp;</b>                                             | See claim element [1.8].                                                                                                                                                                             |
| <b>[19.10] wherein the on-body unit and the sharp are entirely</b> | See claim element [1.9].                                                                                                                                                                             |

| Claim                                                                                                                                                                                                                                                                                                  | FreeStyle Libre Products                                                                                                                                                                                                                                                                        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>disposed in the interior of the inserter,</b>                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                 |
| <b>[19.11] wherein at least a portion of the glucose sensor is disposed in the sharp,</b>                                                                                                                                                                                                              | <i>See claim element [1.10].</i>                                                                                                                                                                                                                                                                |
| <b>[19.12] wherein the inserter is configured to advance the on-body unit and the sharp in a linear direction from a first position to a second position such that the sharp pierces skin of a user and the housing of the on-body unit is secured to the skin of the user in the second position,</b> | <i>See claim element [1.12].</i>                                                                                                                                                                                                                                                                |
| <b>[19.13] wherein a distance between the housing when the on-body unit is in the first position and the</b>                                                                                                                                                                                           | In the FreeStyle Libre 14-Day, FreeStyle Libre 2, and FreeStyle Libre 3, the distance between the housing when the on-body unit is in the first position and the housing when the on-body unit is in the second position is greater than a maximum height of the housing, as illustrated below. |

| Claim                                                                                                           | FreeStyle Libre Products                                                                                                                                     |
|-----------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>housing when the on-body unit is in the second position is greater than a maximum height of the housing,</p> |  <p>(FreeStyle Libre 2 Applicator Components Exploded View, DSC_7207).</p> |

| Claim                                                                                                                                             | FreeStyle Libre Products                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                   |  <p data-bbox="596 771 1682 813">(FreeStyle Libre 3 Applicator Components Exploded View, DSC_1137).</p> <p data-bbox="596 852 1182 894">(See also claim element [1.11], [1.12].)</p>                                                                                                                                                                                                                                                                                                  |
| <p data-bbox="201 906 558 1157"><b>[19.14] wherein a height profile of the housing is less than or equal to approximately 10 millimeters,</b></p> | <p data-bbox="596 906 1932 1157">The housings of the FreeStyle Libre 14-Day, FreeStyle Libre 2, and FreeStyle Libre 3 include a height profile that is less than or equal to approximately 10 millimeters. The height profile of the housing in the FreeStyle Libre 14-Day and FreeStyle Libre 2 is ~5 mm. The height profile of the housing in the FreeStyle Libre 3 is ~2.9 mm. My measurements are confirmed in Exhibit 2033, which is an Abbott Website entitled “<i>How big are the FreeStyle Libre Sensors? How deeply is it inserted?</i>”. (Ex. 2033 at 1.)</p> |
| <p data-bbox="201 1190 558 1393"><b>[19.15] wherein the sharp is configured to pierce the skin of the user at an angle substantially</b></p>      | <p data-bbox="596 1190 1932 1312">The sharps of the FreeStyle Libre 14-Day, FreeStyle Libre 2, and FreeStyle Libre 3 are configured to pierce the skin of the user at an angle substantially perpendicular to the skin of the user, as illustrated below.</p>                                                                                                                                                                                                                                                                                                           |

| Claim                                                   | FreeStyle Libre Products                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>perpendicular to the skin of the user,</b></p>    | <div data-bbox="627 245 1230 649">  </div> <div data-bbox="1293 245 1896 649">  </div> <p>(FreeStyle Libre 2 Applicator, DSC_6080 (left); FreeStyle Libre 3 Applicator, DSC_6057 (right)).</p> <div data-bbox="968 781 1098 816"> <p><b>STEP 7</b></p> </div> <div data-bbox="905 834 1167 1097">  </div> <div data-bbox="1178 834 1619 927"> <p><u>Place sensor applicator over site and push down firmly to apply sensor.</u></p> </div> <div data-bbox="1178 938 1608 1068"> <p><b>CAUTION:</b> Do not push down on sensor applicator until placed over prepared site to prevent unintended results or injury.</p> </div> <p>(Ex. 2007, Your FreeStyle Libre 14 day System, In-Service Guide at 7; <i>see also</i>, Ex. 2008, Get Started, Your Guide To The FreeStyle Libre 2 System at 7; Ex. 2009, Getting Started with the FreeStyle Libre 3 System at 5; Ex. 2010, FreeStyle Libre 3 Continuous Glucose Monitoring System User's Manual at 39.)</p> |
| <p><b>[19.16] wherein the sharp extends through</b></p> | <p>See claim element [1.11].</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

| Claim                                                                                                                                                                                                   | FreeStyle Libre Products               |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| <p><b>the opening of the top surface and the opening of the bottom surface along the longitudinal axis when the on-body unit is in the first position,</b></p>                                          |                                        |
| <p><b>[19.17] wherein the distal end of the inserter is configured to be positioned on the skin of the user before advancement of the on-body unit and the sharp,</b></p>                               | <p><i>See claim element [1.13]</i></p> |
| <p><b>[19.18] wherein the inserter is further configured to automatically retract the sharp from within the user and entirely into the interior of the inserter and leave a part of the glucose</b></p> | <p><i>See claim element [1.14]</i></p> |

| Claim                                                                                                                                                                             | FreeStyle Libre Products        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| <b>sensor in the skin of the user, and</b>                                                                                                                                        |                                 |
| <b>[19.19] wherein the distal end of the inserter is further configured to be removed from the skin of the user after automatic retraction of the sharp from within the user.</b> | <i>See claim element [1.15]</i> |