

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

IPR2023-01409
U.S. Patent No. 11,202,591

SECOND DECLARATION OF GARY D. FLETCHER, Ph.D.

DEXCOM EXHIBIT 1045
Dexcom v. Abbott Diabetes
IPR2023-01409

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I, Gary D. Fletcher, Ph.D., do hereby declare as follows:

I. INTRODUCTION AND ENGAGEMENT

1. Information regarding my engagement is set forth in my previous declaration (EX1003; “Fletcher Decl.”) at Section I.

II. BACKGROUND AND QUALIFICATIONS

2. My background and qualifications have been set forth in my previous declaration at Section II.

III. MATERIALS CONSIDERED AND INFORMATION RELIED UPON REGARDING ’591 PATENT

3. In preparing this declaration, I have reviewed the following materials bearing Exhibit Nos. that I understand are being referenced in the IPR to which this declaration is also an exhibit, as well as any other materials referenced herein.

Exhibits Filed With Petitioner’s Reply

No.	Description
1046	Abbott FreeStyle Navigator Continuous Glucose Monitoring System User’s Guide dated May 2008
1047	Neil T. Clancy, <i>et al.</i> , <i>A New Device for Assessing Changes in Skin Viscoelasticity Using Indentation and Optical Measurement</i> , Skin Research and Technology (2010) at 1-19 (“ Clancy ”)
1048	Alvin H. Sacks, Ph.D., <i>et al.</i> , <i>Skin Blood Flow Changes and Tissue Deformations Produced by Cylindrical Indentors</i> , Journal of Rehabilitation Research and Development Vol. 22 No. 3 (July 1985) at 1-6 (“ Sacks ”)

No.	Description
1050	Cleo90 Infusion Set Training Guide (from Wayback Machine)
1051	Food and Drug Administration approval of Cleo90 Infusion Set dated October 7, 2004
1053	Photographs showing patent marking on CLEO90 device
1054	DexCom STS Continuous Glucose Monitoring System User's Guide (from Wayback Machine)
1056	Medtronic Guardian REAL-Time Features and Components, from Wayback Machine, available at https://web.archive.org/web/20071025084715/http://www.medtronicdiabetes.com/products/guardian/features.html , https://web.archive.org/web/20071013095355/http://www.medtronicdiabetes.com/products/guardian/components.html
1057	U.S. Publication No. 2004/0186365 (" Jin ")
1058	U.S. Patent No. 7,731,691 (" Cote Patent ")
1059	Amendment and Response filed January 7, 2008, from Cote File History for U.S. Patent No. 7,731,691
1062	"Answers to Frequently Asked Questions," Freestyle Navigator System, from Wayback Machine, available at https://web.archive.org/web/20080917183534/http://www.freestylenavigator.com/ab_nav/url/content/en_US/30.10.10:10/general_content/General_Content_0000004.htm (" Navigator FAQ ")
1063	U.S. Patent No. 7,585,287 (" Bresina Patent ")
1064	U.S. Publication No. 2005/0283114 (" Bresina ")
1065	Code of Federal Regulations (2007) 29 CFR § 1910.1030, Bloodborne pathogens

No.	Description
1066	FDA 510(k) Premarket Notification page for CLEO90
1067	Smiths Medical Cleo90 Infusion Set Product Literature, available at https://web.archive.org/web/20220816002119/https://www.smiths-medical.com/-/media/M/Smiths-medical_com/Files/Import-Files/Product-Literature/IN193873GB-092019_LR.pdf

Previously Filed Petitioner Exhibits

No.	Description
1001	U.S. Patent No. 11,202,591 (“ 591 patent ”)
1002	File History of U.S. Patent No. 11,202,591
1003	Declaration of Dr. Gary D. Fletcher, dated October 10, 2023 (“ Fletcher Decl. ”)
1004	U.S. Publication No. 2008/0097246 (“ Stafford ”)
1005	U.S. Publication No. 2005/0101932 (“ Cote ”)
1006	U.S. Publication No. 2007/0073129 (“ Shah ”)
1007	U.S. Publication No. 2007/0135774 (“ Turner ”)
1008	U.S. Patent No. 6,175,752 (“ Say ”)
1009	U.S. Publication No. 2009/0124979 (“ Raymond ”)
1010	U.S. Publication No. 2006/0095014 (“ Ethelfeld ”)
1011	PCT Publication No. WO2008/155377 (“ Hasted ”)
1012	U.S. Publication No. 2009/0076360 (“ Brister-360 ”)
1013	U.S. Publication No. 2006/0155180 (“ Brister-180 ”)
1014	U.S. Publication No. 2004/0133164 (“ Funderburk-164 ”)
1015	U.S. Patent No. 6,560,471 (“ Heller ”)

No.	Description
1016	U.S. Patent No. 6,579,690 (“ Bonnecaze ”)
1017	U.S. Publication No. 2003/0225373 (“ Bobroff-373 ”)
1018	U.S. Publication No. 2009/0240121 (“ Bickoff ”)
1019	PCT Publication No. WO2008/114223 (“ Pesach ”)
1020	U.S. Publication No. 2004/0002682 (“ Kovelman ”)
1021	U.S. Patent No. 7,381,184 (“ Funderburk ”)
1022	U.S. Publication No. 2008/0319414 (“ Yodfat-414 ”)
1023	U.S. Patent No. 7,207,974 (“ Safabash ”)
1024	U.S. Publication No. 2004/0204687 (“ Mogensen-687 ”)
1025	U.S. Publication No. 2002/0022855 (“ Bobroff-855 ”)
1026	U.S. Patent No. 9,566,384 (“ Gyrn ”)
1027	U.S. Patent No. 8,747,363 (“ Nielsen ”)
1028	U.S. Publication No. 2007/0093754 (“ Mogensen-754 ”)
1029	Steven W. Smith, <i>The Scientist and Engineer’s Guide to Digital Signal Processing</i> (2nd ed. 1999) (excerpted)
1030	B.A. Sheno, <i>Introduction to Digital Signal Processing and Filter Design</i> (2006) (excerpted)
1031	U.S. Publication No. 2009/0099521 (“ Gravesen ”)
1032	U.S. Publication No. 2009/0216215 (“ Thalmann ”)
1033	U.S. Publication No. 2008/0255440 (“ Eilersen ”)
1034	Scheduling Order, <i>Abbott Diabetes Care Inc. v. DexCom Inc.</i> , No. 1-23-cv-00239 (D. Del. filed Mar. 3, 2023)
1035	PCT Publication No. WO2008/115409 (“ Brenneman ”)

No.	Description
1036	Statement of Defense (Counterclaim), <i>Dexcom Inc. v. Abbott Diabetes Care Inc.</i> , Case No. 21 O 6562/23 (Munich D. Ct. I), Sept. 1, 2023
1037	U.S. Publication No. 2008/0114280 (“ Stafford-280 ”)

Previously Filed PO Exhibits (Cited Or Referred To Herein)

No.	Description
2002	Declaration of Karl Leinsing with Appendix A (curriculum vitae) and Appendix B (Claim Chart for U.S. Patent No. 11,202,591)
2010	FreeStyle Libre 3 Continuous Glucose Monitoring System User’s Manual, Rev. A (2023)
2036	Transcript of the Deposition of Dr. Gary Fletcher, dated June 26, 2024.

IV. UNDERSTANDING OF PATENT LAW

4. Information regarding my understanding of patent law is set forth in my previous declaration at Section IV.

V. LEVEL OF SKILL IN THE ART AND STATE OF THE ART

A. Person Of Ordinary Skill In The Art

5. Information regarding my understanding of a POSITA is set forth in my previous declaration at Section VI.A.

6. I understand that Patent Owner (“PO”) and Mr. Leinsing did not dispute this understanding.

B. State Of The Art

7. Information regarding my understanding of the State Of The Art is set forth in my previous declaration at Section VI.B, and also described in conjunction with specific points herein.

VI. THE OBVIOUS STAFFORD+COTE COMBINATION

8. Stafford teaches an all-in-one on-body unit (“OBU”) like the one claimed, and Cote teaches an inserter like the one claimed. A POSITA would have found it obvious to combine the complementary teachings of the two references to arrive at the claimed insertion devices that insert an analyte sensor, apply the OBU to the patient, and retract the needle after use, with a reasonable expectation of success, as I previously described. *See, e.g.*, EX1003, ¶¶61-72.

9. As an initial matter, I note that Mr. Leinsing took issue with the use of the term “on-body unit” (OBU) as allegedly over-inclusive. EX2002, ¶117. There is no dispute that the *claimed* OBU requires a certain set of features, but “an” OBU as used generally herein, and as was understood by a POSITA, can include any number of medical device units placed on the body. I am not implying that *all* OBUs teach all of the claimed limitations. As is made clear in my prior declaration, it is the teachings associated with Stafford’s OBU that are relied upon in the proposed Stafford+Cote combination. EX1003, ¶¶62-63, 74. That said, and as detailed herein, a POSITA would have understood the wide range of OBUs known in the art—both

those used with an automatic inserter and those used with a manual inserter—and taken that knowledge into account to design insertion assemblies meeting all the requirements of the '591 patent claims. Taking into account the background knowledge of a POSITA of the wide range of OBUs used with insertable medical devices is consistent with the undisputed definition of a POSITA in this proceeding, which includes “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.” EX1003, § VI.A. Accordingly, the state of the art and background knowledge of a POSITA includes knowledge of OBUs used in conjunction with insertable medical devices such as analyte sensors and infusion sets, and I have taken that into account. Indeed, I understand that analyzing whether claims would have been obvious is always from the perspective of an ordinarily skilled artisan and one must consider knowledge generally available to one of ordinary skill in the art.

**A. Cote’s Simple-To-Use Inserter Complements Stafford’s
Teachings By Addressing Problems Raised By Stafford**

10. As I previously discussed, a POSITA would have recognized the advantages of Stafford’s design, but also recognized at least two disadvantages: (1) the exposed introducer (which causes anxiety and risks needlesticks) and (2) manual retraction of the introducer (which increases pain). *See* EX1003, ¶¶29-32, 37.

11. A POSITA would have further recognized that a Cote-like inserter addressed these shortcomings by reducing anxiety and mitigating the risk of needlesticks (via shrouding using the sleeve) and reducing pain (via automatic retraction). *See* EX1003, ¶¶51, 60-61, 65-72.

12. Mr. Leinsing alleges that a POSITA would not have been motivated to combine Stafford and Cote, because the proposed combinations allegedly “ignore[] the numerous advantages provided by Stafford’s streamlined design” (EX2002, ¶136) referring to Stafford’s statements regarding “reducing the number of components,” and that “a separate sensor introducing device...is not necessary.” EX1004, [0044]-[0045]. Essentially, Mr. Leinsing argues that the alleged additional complexity and cost of a Cote-like inserter would outweigh any benefits provided by the proposed combination, rendering it non-obvious. EX2002, ¶¶137-145. As laid out in my previous declaration, use of a Cote-like inserter would have been obvious as it complements and improves upon Stafford’s teachings by addressing many of the problems explicitly identified by Stafford. EX1003, ¶¶61-72. Further, the Stafford+Cote combination delivers the OBU to the user within the inserter in a “self-contained, sterile environment,” as taught by Cote, which directly addresses Stafford’s goals by “*minimiz[ing] the need for packaging* surrounding the devices...*increasing ease in use of the devices.*” EX1005, [0238].

13. Features of Stafford on which Mr. Leinsing relies are primarily purported advantages to the *manufacturer* of the device, rather than to the *user* of the device, e.g., reducing manufacturing components and costs. As I have explained, the Stafford+Cote combination provides numerous benefits for a user, supporting a motivation for a POSITA to make such a system to satisfy user preferences despite any additional manufacturing complexity or cost. That idea is not unique to insertion assemblies for continuous glucose monitors (CGM), as it is often the case that product designs are improved and features added to meet consumer or market preferences or needs notwithstanding corresponding increases in manufacturing complexity and cost. In an obviousness inquiry, I understand that it is appropriate to take into account how market demand may drive design trends and any design need or market pressure to solve a problem.

14. Despite purported advantages of the Stafford system, Stafford itself notes certain problems with its design. For example, Stafford discloses that discarding the inserter “requires a level of care” as it “may damage other parts of the patient’s skin if not properly handled,” and further that disposal of the inserter must include “particular precautions” as it has contacted biological fluids. EX1004, [0003]. A Cote-like inserter addresses these issues by guarding the needle not only prior to insertion, but also during insertion (EX1005, [0235]) and after insertion via

automatic retraction of the needle into the inserter (EX1005, Abstract, [0236]), thus avoiding undesired contact with biological fluids.

15. Mr. Leinsing suggests that Stafford's needle guard would mitigate the issue of contact with a contaminated needle. EX2002, ¶140. However, a POSITA would have understood that a user (especially a caregiver or healthcare worker) would **not** want to re-cap Stafford's needle after the needle guard 104 is removed, as it is a delicate procedure that **adds** to the risk of accidental needle sticks. Mr. Leinsing attempts to draw a parallel between Stafford's needle guard and Cote's cap, alleging that it was "common practice" to replace a needle guard after use. EX2002, ¶140. However, Cote's cap can be more safely reapplied to the inserter, as the needle is completely withdrawn within the inserter and shrouded by the sleeve 1140. This shrouding in Cote provides additional safety against accidental needle sticks, even if its cap is not reapplied. *See e.g.*, EX1005, FIGS. 83A, 83B. Not so with Stafford's needle guard 104, which, to follow Mr. Leinsing's suggestion, would have to be reapplied to a bare, biologically contaminated needle. A POSITA would be motivated to avoid such a practice as the one Mr. Leinsing suggests, as it would be inconsistent with health policies and standards, e.g., EX1065, 29 CFR

1910.1030(d)(2)(vii) (2007), 268.¹ Hence, a POSITA knew that recapping the Stafford needle after use was not a viable option and so, unlike a Cote-like inserter, users would need immediate access to a sharps container for safe disposal of a Stafford introducer needle after use, and even so would risk additional accidental needle sticks with a contaminated needle after use that users of Cote's device would not. A POSITA would have been motivated to avoid these and other shortcomings of Stafford.

16. Mr. Leinsing further alleges that I “fail[] to explain why a ‘Cote-like inserter’ would reduce ‘pain and anxiety’ over Stafford’s existing capped design.” EX2002, 141. But Cote explicitly teaches reducing pain and anxiety based on (1) needle shrouding (not simply via the cap but also via sleeve 1140) and (2) automatic

¹ “Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B) below. Shearing or breaking of contaminated needles is prohibited.

(A) Contaminated needles and other contaminated sharps shall not be bent, recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure.

(B) Such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.”

retraction of the needle (not based on its method of **insertion**, as Mr. Leinsing alleges, EX2002, ¶144), as I discussed in my prior declaration. *See* EX1005, [0005], [0235]-[0236]; EX1003, ¶¶65-72; *see also id.*, ¶¶29, 31, 51, 60-61.

17. It was well-known in the art that “patients may react adversely to viewing the needle prior to insertion and may, for example, be reluctant to place the needle into the skin.” EX1005, [0005], *see also* EX1020, [0005]. Unlike Stafford, a Cote-like inserter shrouds the needle with the sleeve 1140 prior to use (even after removal of the cap), during use, and after use, thereby minimizing anxiety that the patient might experience at having to view the needle during the insertion process. EX1005, [0235]-[0236]. A Cote-like inserter also includes automatic retraction of the needle (something not taught by Stafford) which “limits the dwell time of the needle in the patient, increasing comfort for the patient.” *Id.*, [0236].

18. According to Mr. Leinsing, Cote’s inserter allegedly does not reduce pain or anxiety compared to Stafford, due to Cote’s use of “manual force to pierce the skin (just like Stafford).” EX2002, ¶144 (emphasis original). However, Cote’s automatic **retraction** would reduce pain, as discussed above, and Cote further stabilizes the inserter on the skin prior to manual insertion, allowing steadier perpendicular insertion (which Mr. Leinsing agrees is advantageous, EX2002, ¶171). In Stafford’s device, the introducer is not stabilized on the skin prior to

insertion, leading to potentially arbitrary insertion angles and potential lateral movement of the introducer during insertion, and thereby more pain.

19. Mr. Leinsing asserts that “[s]tabilizing 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.” EX2002, ¶171 (citing EX2043). He points to nowhere, however, where the ’591 patent itself describes such an advantage, suggesting it was already a known advantage to a POSITA. Indeed the ’591 patent’s only discussion of reducing “trauma” from insertion is describing the well-understood (and unclaimed) shape of its insertion needle. EX1001, 17:41-44. A POSITA would have therefore understood that stabilizing the inserter on the skin prior to insertion, something taught by Cote that Stafford does not provide, would have been an additional reason motivating a POSITA to implement a Cote-like inserter with a Stafford-like OBU. Mr. Leinsing contends (EX2002, ¶¶194-195) that Cote does not provide this advantage, but, as discussed, e.g., in § VII.A, *infra*, this relies on a fundamental misunderstanding of how Cote functions.

20. Mr. Leinsing refers to my deposition testimony to assert that I agreed that the proposed Stafford+Cote combination would “increase[] complexity.” EX2002, ¶137 (citing EX2036, 98:25-106:12). Not so. While the proposed combination may have more components, that ***does not necessarily make it more complex for the user***. Indeed, the use of a Cote-like inserter (which as mentioned, is

configured to be stabilized on the skin prior to insertion, includes automatic needle retraction, and is designed to automatically shroud the contaminated needle to protect against injury) is *less complex* than the use of Stafford's device, which includes none of these advantages. Further, to the extent the "increased complexity" is referring to complexity in *manufacture*, POSITAs have long understood that when balancing patient experience (including comfort, reduced pain, reduced anxiety, safety, ease of use, and the like) against manufacturing complexity (including costs, number of components and the like), improving patient experience is often given more weight as that drives customer acceptance and product marketability.

21. Mr. Leinsing alleges that the proposed combination has only the same benefits as Stafford "such as being 'easily graspable and operable by a single hand.'" (EX2002, ¶154, quoting EX1003 at ¶68) while ignoring the various other advantages detailed in my declaration (EX1003, ¶¶61-72), and reiterated above, as well as the additional stability that Cote provides (contrary to Mr. Leinsing's assertions, e.g., at EX2002, ¶¶194-205).

1. PO's "Separate Sensor Introducing Device" Point Fails

22. Mr. Leinsing alleges the proposed combination would not be obvious because Stafford teaches away from using a "*separate* sensor introducing device." EX2002, ¶¶134-135 (emphasis original). The Cote-like inserter of the proposed

combination is no more a separate introducer than Stafford's own introducer 102. In both cases the OBU and introducer are provided to the user as a unit, and the introducer is removed from the OBU and discarded after sensor insertion. Indeed, in the proposed Stafford+Cote combination, Stafford's introducer 102 is *integrated* with Cote's inserter, it is not added "on top of" the introducer as Mr. Leinsing alleges. EX2002, ¶135; EX1004, [0002] ("the introducer includes a sharp needle shaped inserter that is configured to pierce through the skin of the patient and substantially concurrently guide the sensor through the patient's skin so as to place at least a portion of the sensor in fluid contact with the target biological fluid of the patient"), [0028] ("a portion of the analyte sensor 106 is disposed within the lower portion 102B of the introducer such that, the user or patient may easily, and accurately position the analyte sensor 106 under the skin layer to establish fluid contact with the patient's analyte"), [0027] ("When the introducer is removed, in one embodiment, the entire introducer including the upper portion 102A and the lower portion 102B is withdrawn from the housing of the data processing unit 101 to completely separate from the data processing unit"). As explained in the portion of Stafford quoted by Mr. Leinsing (EX1004, [0044]), when Stafford was referring to a separate insertion device, he was referring to, e.g. Say's separate "insertion gun" (see EX2002, ¶61), which as I described in my previous declaration, the user had to align with and affix to the on-body unit prior to insertion. EX1003, ¶67. Stafford

was therefore distinguishing an entirely different system where the *user* would be required to assemble or connect the inserter with the on-body unit before use. Cote requires no such user assembly step.

23. If, as Mr. Leinsing seems to allege (EX2002, ¶¶134-135), Stafford’s goal of a “single disposable assembly” requires no separable components whatsoever, then Stafford itself does not achieve this goal. EX1004, [0024] (“the introducer may be removed to detach or decouple from the data processing unit 101 by, for example, pulling at the upper portion 102A of the introducer, thereby withdrawing the introducer from the patient and separating from the data processing unit 101...”).

2. The Interchangeability Of Cannula And Sensor Inserter Technology Was Well-Known In The Art

24. Mr. Leinsing alleges that “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.” EX2002, ¶177. This unsubstantiated statement runs contrary to the accepted state of the art knowledge regarding the interchangeability of cannula and sensor inserter technology. *See* EX1003, § VII.B.3. As I discussed in my previous declaration, the ’591 patent itself teaches this cannula/sensor interchangeability with respect to its claimed inserter device. EX1003, ¶34, citing EX1001, 14:54-59.

25. Mr. Leinsing generally alleges that I did not establish a reasonable expectation of success in combining a Cote-like inserter with a Stafford-like OBU. EX2002, ¶¶159-161. He purports to identify distinctions between inserting cannulas and allegedly “more fragile” sensors, including requiring “proper placement,” minimizing “tissue trauma,” avoiding “contaminants or moisture” entering the OBU and the like. EX2002 ¶160. However, Mr. Leinsing provides no analysis or reasoning to support his conclusory assertions or to show how the Stafford+Cote combination would not (with a reasonable expectation of success) address or avoid each of the concerns that he raised. In my opinion, a POSITA would have readily implemented the Stafford+Cote combination with a reasonable expectation of success and with no more than routine optimization (if any were even required). And this cursory analysis from Mr. Leinsing of differences in sensor insertion is also missing from the alleged teachings of the ’591 patent, which, as stated above, discusses interchangeability with respect to its claimed inserter device. EX1001, 14:54-59.

26. A POSITA would have successfully implemented the Stafford+Cote combination in a way that avoided every potential issue or problem that Mr. Leinsing identified. It also is important to note that none of the alleged “challenges” Mr. Leinsing identified in making the Stafford+Cote combination with a reasonable

expectation of success is tied to anything *required by the challenged claims* in the '591 patent. *No claim requires:*

- (a) inserting a “fragile” glucose sensor (*see, e.g.,* EX2002, ¶57), e.g., no claim requires inserting a glucose sensor with any particular success or failure rate so alleged “fragility” is of little or no relevance;
- (b) any particular “placement” of the glucose sensor (*see, e.g., id.,* ¶¶57, 160);
- (c) preventing or minimizing “tissue trauma” (*see, e.g., id.,* ¶¶57, 58, 160, 171);
- (d) “stabilizing the distal end of the inserter on the skin before and during insertion” (*see, e.g., id.,* ¶171);
- (e) any level of accuracy for glucose readings (*see, e.g., id.,* ¶¶57, 58, 160), or even that glucose levels are actually measured;
- (f) a seal or any means to prevent “contaminants or moisture” entering the OBU (*see, e.g., id.,* ¶160); or
- (g) a commercial or mass producible “insertion assembly,” much less one that would be approved by the FDA for use in humans (*see, e.g., id.,* ¶¶55, 58), undermining Mr. Leinsing’s focus on manufacturing costs and complexity.

Compare above list *with* EX1001, claims 1-30. Evaluating reasonable expectation of success in the context of what the challenged claims actually require shows that the alleged issues conceived by Mr. Leinsing are not relevant to whether a POSITA would have been able to make an “insertion assembly” meeting each requirement of the challenged claims with a reasonable expectation of success. Nevertheless, as stated above, *even if* the alleged issues raised by Mr. Leinsing were relevant, it is my opinion that the Stafford+Cote combination would have been implemented with a reasonable expectation of success, thus avoiding those alleged issues.

27. Mr. Leinsing alleges a lack of interchangeability with cannula inserter technology due to the necessity of stability of the inserter on the skin during insertion of a sensor. EX2002, ¶¶170-172. Mr. Leinsing’s analysis of this point relies on his incorrect interpretation of how the Cote inserter would function to wrongly conclude “[i]t 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.” EX2002, ¶174 (emphasis original). As discussed in detail in § VII.A, *infra*, Mr. Leinsing is wrong about how the Cote inserter functions.

28. In any event, my opinion is that the Cote-like inserter in the Stafford+Cote combination would provide sufficient stability to avoid any related issues identified by Mr. Leinsing. Further, such an implementation would solve any

issues with Stafford's stability, such as a user positioning the OBU/insertor incorrectly during insertion and/or retraction of the introducer.

B. Alternative Designs Would Also Have Been Obvious And Do Not Undermine Obviousness Of The Proposed Combination

29. As discussed in § VI.A.2, *supra*, and in my original declaration (EX1003, § VI.B.3), the interchangeability of cannula and sensor inserter technology was well-known in the art. It is my understanding that the existence of other possible combinations does not negate obviousness of the proposed combination.

30. A POSITA would have understood that Cote's disclosure of alternative designs does not teach away from the use of any one specific design. A POSITA would have further understood how to implement Cote's teachings regarding reducing pain and anxiety, one handed operation, and reducing inadvertent needle sticks to complement the goals stated by Stafford and provide an all-in-one insertion assembly that comes pre-loaded with a Stafford-like OBU. EX1005, [0005]-[0006], [0235]-[0239]; EX1004, [0044]-[0045]. That other designs may also have solved this problem is irrelevant.

**VII. THE COMBINATIONS TEACH ALL OF
THE FEATURES OF THE '591 PATENT
CLAIMS AND RENDER THE CLAIMS OBVIOUS**

**A. Stafford+Cote Teaches And Provides An Inserter Having A
Distal End “Configured To Be Removed From The Skin
Of The User After Automatic Retraction Of The Sharp...”**

31. Mr. Leinsing alleges that “the distal end of Cote’s inserter 1100 is specifically configured to be removed away from the skin before its sharp is retracted.” EX2002, ¶179 (emphasis original). Mr. Leinsing’s characterization of Cote is incorrect at least because it: (1) ignores Cote’s express teachings that the inserter is removed after needle retraction, (2) misinterprets Cote’s clear disclosure of what the figures illustrate, (3) incorrectly annotates Cote’s figures, suggesting that a user’s skin surface is a rigid plane that does not deform under the user-applied pressure of an inserter, (4) disregards the fact that a user would maintain pressure on the inserter throughout the insertion process, and (5) improperly imports a requirement into the claims that the inserter can only be removed from the skin once.

**1. Cote Expressly Teaches Removing The Inserter
From The Skin As The Final Step *After* Needle Retraction**

32. As described in my previous declaration and reiterated below, Cote expressly teaches that the inserter’s removal from the skin occurs only after automatic retraction of the sharp. EX1003, ¶104. Paragraph [0213] of Cote states:

“*[f]inally*, the sleeve 1140 is removed from contact with the skin 1900...” *after* describing needle retraction in a prior paragraph [0211]. EX1005, [0211], [0213].²

33. Mr. Leinsing alleges that Cote “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.” EX2002, ¶207 (emphasis original). Mr. Leinsing offers no evidence supporting this contention, aside from figures from Cote that have been (mis-)annotated by Mr. Leinsing to show a fictional skin surface that did not exist in the original figures and would not be positioned as Mr. Leinsing has drawn it, as discussed in more detail in § VII.A.2, *infra*. Cote nowhere describes or depicts the inserter being removed from the skin by the over-travel process, then being repositioned thereon, then being removed again as a final step, as Mr. Leinsing alleges would occur. EX2002, ¶¶204-211.

34. Claim 1 of U.S. Patent 7,731,691 (EX1058, the “Cote patent”), which issued from the application that published as Cote, underscores the point that Cote’s sleeve remains in contact with the skin of the patient not only during manual insertion, but also throughout subsequent automatic retraction of the needle, reciting:

upon full manual insertion of the cannula by the insertion
device and the insertion device reaching a trigger state,
automatically moving the needle of the insertion device

² Emphases throughout are added, unless otherwise noted.

***from the extended position to the retracted position while
leaving the sleeve in contact with the skin of the patient.***

EX1058, Claim 1, 19:15-20 (emphasis added); *see generally id.*, 18:62 – 19:20.

35. I understand that the applicant in prosecuting Cote first included the above claim language in a claim amendment filed on January 7, 2008, in response to a prior art rejection:

upon full manual insertion of the cannula by the insertion device and the insertion device reaching a trigger state, automatically ~~retracting~~ moving the needle of the insertion device from the extended position to the retracted position while leaving the ~~infusion device positioned on~~ sleeve in contact with the skin of the patient.

EX1059, 2, Applicant's January 7, 2008 Amendment and Response to Final Office Action in Application No. 10/705,719.

36. I understand that all papers relating to the file of a published patent application are open to inspection by the public at the U.S. Patent Office and that the file history, at least for patent applications filed after June 2003, also were available online via the U.S. Patent Office website. I understand that the Cote claim amendment excerpted above was part of the public file history for Cote by January 2008.

37. In short, Cote clearly teaches that the distal end of its inserter is maintained on the skin during both needle insertion and retraction, and is configured

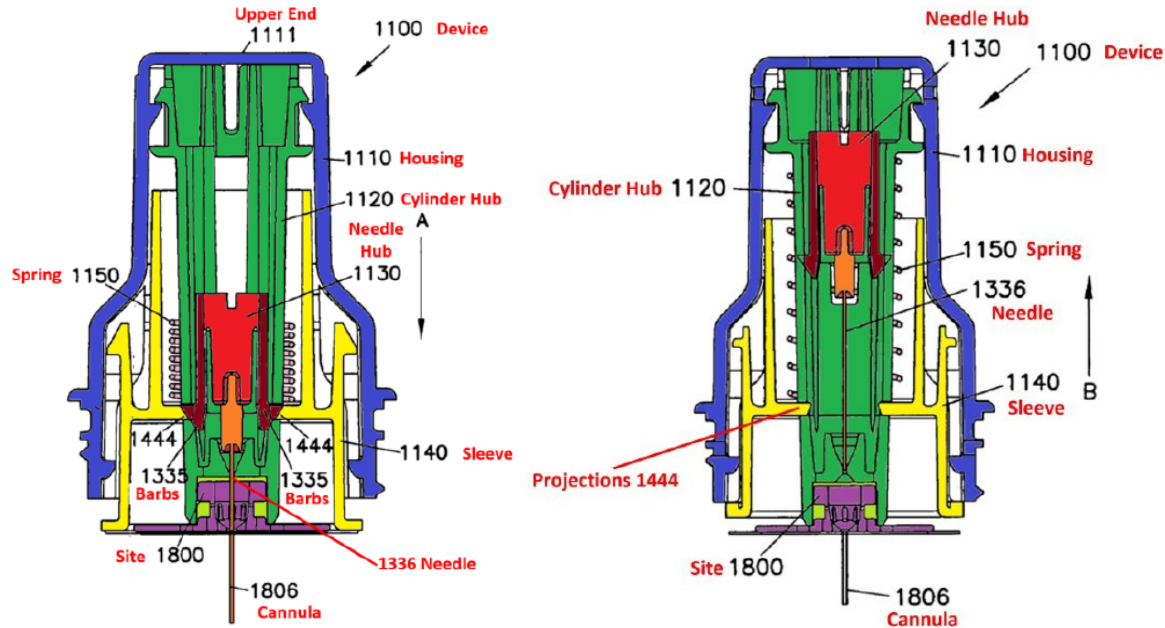
to be removed from the skin only after its sharp is retracted. Mr. Leinsing's contrary assertion is unsupported and incorrect.

2. Mr. Leinsing's Annotated Figures Contradict Cote's Clear Disclosure

38. Mr. Leinsing offers a series of annotated figures purporting to show the relative positioning of Cote's inserter to a user's skin throughout the insertion process. EX2002, ¶¶209-211. But, Mr. Leinsing's figures ignore that Cote's FIGS. 80A-83B were not intended to show the position of the skin in Cote. When Cote wanted to illustrate the position of the skin in figures, it did so, *e.g.*, in FIGS. 77 and 78, discussed further below. The skin surface is not depicted in Cote's original figures 80A-83B on which Mr. Leinsing relies, and a POSITA would understand that it would not be positioned as Mr. Leinsing has (mis-)annotated it.

39. Mr. Leinsing alleges that the "over-travel" taught by Cote results in the distal end of Cote's inserter being removed from a user's skin prior to retraction of the needle. EX2002, ¶¶194-211. He further alleges that my colored rendition of Cote's FIGS. 81A and 82A (shown below) "clearly depict the distal end of the inserter removed away from its positioning on the skin." EX2002, ¶199. On the contrary, as in Cote's original images, ***neither image includes a depiction of the skin at all***, nor does the accompanying text in my prior declaration (EX1003, ¶¶57, 59) or in Cote itself refer to removing the inserter from the skin prior to needle

retraction. Rather, the contrary is consistently described, both in my prior declaration and in Cote itself.



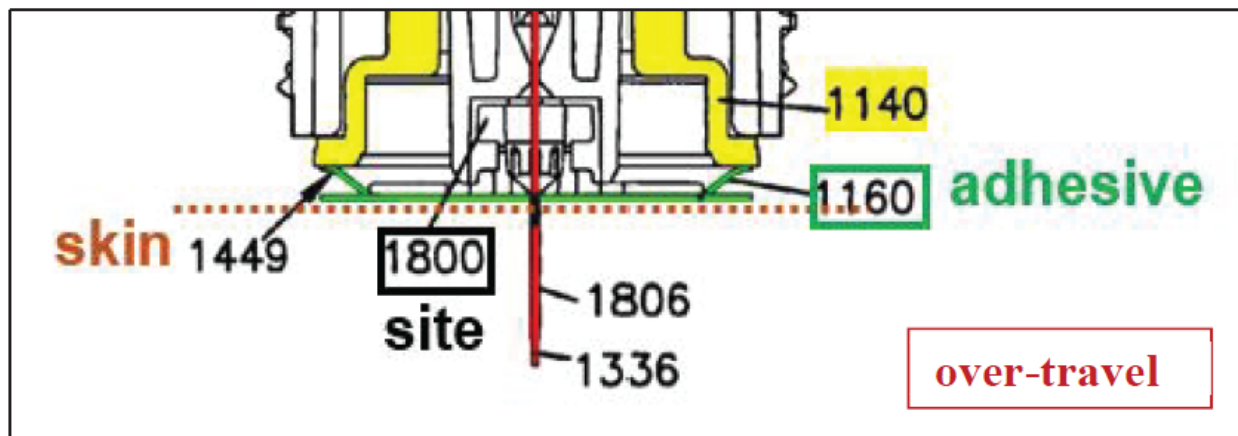
Cote, FIG. 81A, "trigger state" (annotated)

Cote, FIG. 82A, "needle hub retracted" (annotated)

Cote, FIGS. 81A, 82A (from EX1003, ¶¶57, 59)

40. Mr. Leinsing's own annotated figures directly contradict the express disclosures by Cote discussed in the prior section, *i.e.*, that the needle of the insertion device is retracted while the inserter sleeve remains in contact with the skin of the patient. To support his argument, Mr. Leinsing *added* the location of the skin surface to his annotated figures where he (wrongly) alleges it would be located, ignoring that it is not depicted in Cote's original figures on which he relies. A POSITA would understand that the annotation of the skin surface by Mr. Leinsing is incorrect, as it fails to take into account that skin is an elastic surface, and not a rigid line or plane

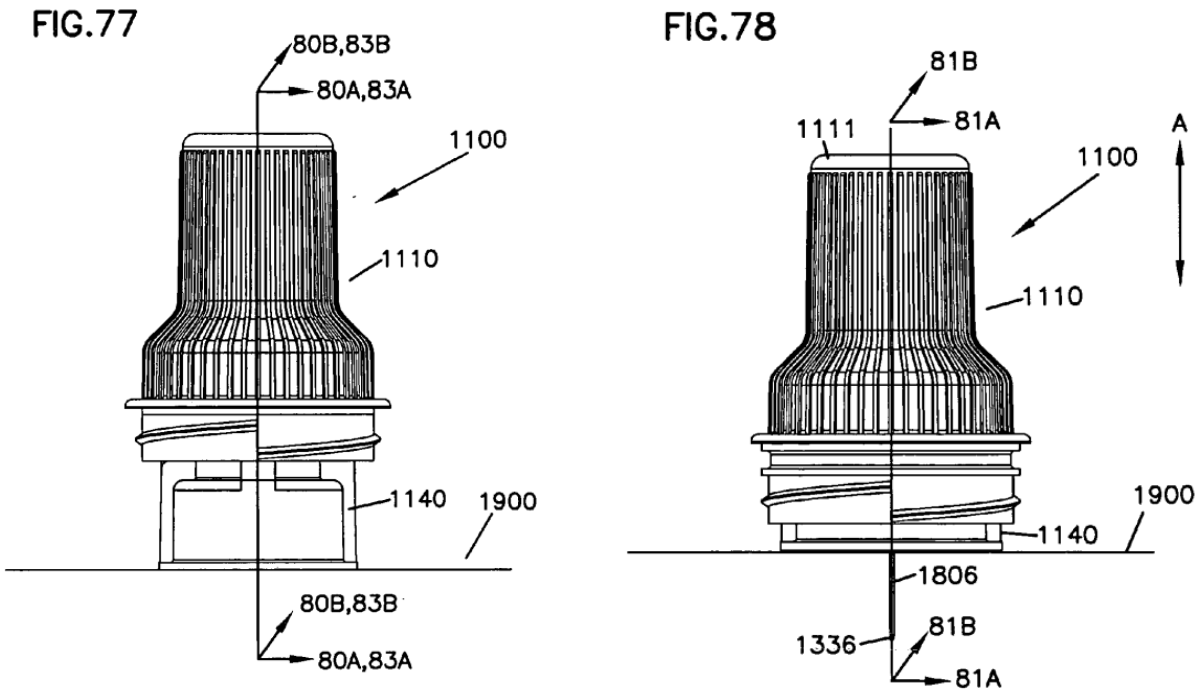
through the insertion process as Mr. Leinsing drew it. *See generally* Clancy (EX1047); Sacks (EX1048). And the over-travel in Cote is very slight, described by Cote as “between 50 to 100 thousandths of an inch, more preferably approximately 70 thousandths of an inch.” EX1005, [0210]. Such slight over-travel would not overcome the force the user continues to place down on the sleeve both during the trigger state and during needle retraction in a manner that would cause the inserter 1100 to lose contact with the skin, as Mr. Leinsing asserts. That is especially true in view of the elasticity of the skin surface that would be indented and conform to the distal end of the inserter, including sleeve 1140.



Cote, FIG. 81C (as incorrectly annotated by Mr. Leinsing, EX2002, ¶184)

41. Of Cote’s many figures, only FIGS. 77-78 (reproduced below) illustrate the skin surface 1900 of the subject, and it should be noted that both figures clearly illustrate the distal end of the inserter positioned thereon. Mr. Leinsing’s reliance on his own annotated figures as allegedly showing separation of the sleeve from the skin during over-travel is misplaced. His annotations are contrary to Cote’s express

disclosure of its trigger state. Cote's FIG. 78 clearly shows that the distal end of sleeve 1140 remains on the skin 1900 during this trigger state, just as it was in the delivery state, shown in FIG. 77:



Cote FIG. 77 and FIG. 78

42. Cote refers to its trigger state as “the state at which the needle 1336 and the cannula of the site 1800 have been fully inserted into the subcutaneous layer of skin of the patient, and the needle hub 1130 and associated needle 1336 are about to be retracted.” EX1005, [0203]. Cote makes clear that this trigger state *includes* FIG. 81C: “As shown in FIGS. 78, 81A, 81B, **and 81C** the device 1100 is in a trigger state.” *Id.* (emphasis in original removed; emphasis added). And, Cote’s description and figures make clear that during this stage of insertion, the sleeve remains in contact with the skin (*see* above).

43. In addition to showing it in FIG. 78, above (which Mr. Leinsing appears to ignore), Cote further reinforces that its sleeve maintains contact with the skin during needle retraction, as needle retraction from the patient automatically occurs *before* “the patient removes pressure...” *see id.*, [0211]-[0212], and *before* the inserter “sleeve 1140 is removed from contact with the skin,” *id.*, [0213]. Like FIG. 81C, above, FIGS. 82A-82B show the housing 1110 fully compressed against sleeve 1140 by patient pressure, holding the inserter on the skin throughout needle retraction. EX1005, [0211]-[0213]. This additionally confirms a POSITA’s understanding that patient-applied pressure keeps the inserter in contact with the skin until *after* the needle is retracted.

44. Other than incorrectly annotated figures, Mr. Leinsing provides no evidence that Cote’s sleeve is positioned anywhere other than in contact with the skin, or that it is removed from the skin at any time prior to the time (after needle retraction) that the patient removes pressure from the inserter. Rather, Cote describes allowing the needle to move to a *fully retracted* state after the needle retracts from the patient and then only after the patient removes pressure:

- in FIGS. 83A and 83B, “[o]nce the patient removes pressure from the upper end 1111 of the housing 1110, the spring 1150 causes the housing 1110 and cylinder hub 1120 to move in the direction B as shown in FIGS. 83A and 83B to a fully retracted state” (*id.*, [0212]); and

- *only thereafter*, “[f]inally, the sleeve 1140 is removed from contact with the skin 1900” (*id.*, [0213]).

45. Cote describes its preferred method in paragraphs [0206] to [0213] of the specification, mentioning the skin 1900 six times during those paragraphs: The first mention is when the sleeve is positioned on the skin in paragraph [0206], and the last is in paragraph [0213], when the sleeve is, finally, removed from the skin. *Compare* EX1005, [0206] (“the sleeve 1140 of the device 1100 is positioned so that the adhesive portion 1160 (i.e., surface 1668) contacts the skin 1900 of the patient. See FIGS. 77, 80A, and 80B”) *with id.*, [0213] (“Finally, 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.”).

46. None of Cote’s intervening mentions of the skin describe or even suggest removing the inserter sleeve from contact with the skin, or that the inserter sleeve could otherwise lose contact with the skin for any reason before the patient removes the sleeve from skin contact, let alone before the needle retracts from the patient:

- “Next, in the illustrated preferred embodiment, the patient applies pressure to the upper end 1111 of the housing 1110 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 1900* of the patient.”
Id., [0207]

- “As the needle 1336 of the needle hub 1130 and associated site 1800 are moved in the direction A, the needle 1336 and the cannula 1806 of the site 1800 are introduced into the *skin 1900* of the patient. In addition, as the needle hub 1130 is moved toward the *sleeve 1140*, the spring 1150 is further compressed.” *Id.*
- “Once the needle 1336 and cannula 1806 of the site 1800 have been fully inserted into the *skin 1900*, the device 1100 is in a trigger state, as illustrated in FIGS. 78, 81A, 81B, and 81C.” *Id.*, [0208]
- “The spring 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 up through the cylinder hub 1120 into the upper end 1111 of the housing 1110, while the site 1800 and associated cannula 1806 are held on the *skin 1900* of the patient, as shown in FIGS. 82A and 82B.” *Id.*, [0211]

47. Simply put, Cote consistently teaches that the inserter is removed from the skin surface only *after* automatic needle retraction completes. *Id.*, [0211]-[0213]. No credible evidence supports Mr. Leinsing’s theory that over-travel causes the inserter to momentarily lose contact with the skin before the inserter is “finally” removed.

48. Finally, the “over-travel” on which Mr. Leinsing relies is optional in “preferred embodiments” of Cote’s inserter 1100, *id.*, [0209]-[0210], rendering Mr.

Leinsing's argument irrelevant to other embodiments of that inserter that a POSITA would know to use when appropriate, for example, with a CGM sensor and all-in-one OBU if "over-travel" was a concern for a particular implementation. I do not understand Mr. Leinsing to have addressed or offered an opinion relating to a Cote-like inserter excluding the optional "over-travel" feature; nor did he offer an opinion that such an inserter could lose skin contact if "over-travel" were omitted from the inserter design.

**3. Mr. Leinsing's Annotated Figures Are
At Odds With The Reality Of Human Anatomy**

49. Not only are Mr. Leinsing's annotations of the skin in FIG. 81C at odds with Cote, they also fail to take into account that skin is elastic, not rigid as drawn. *See generally*, EX1047; EX1048.

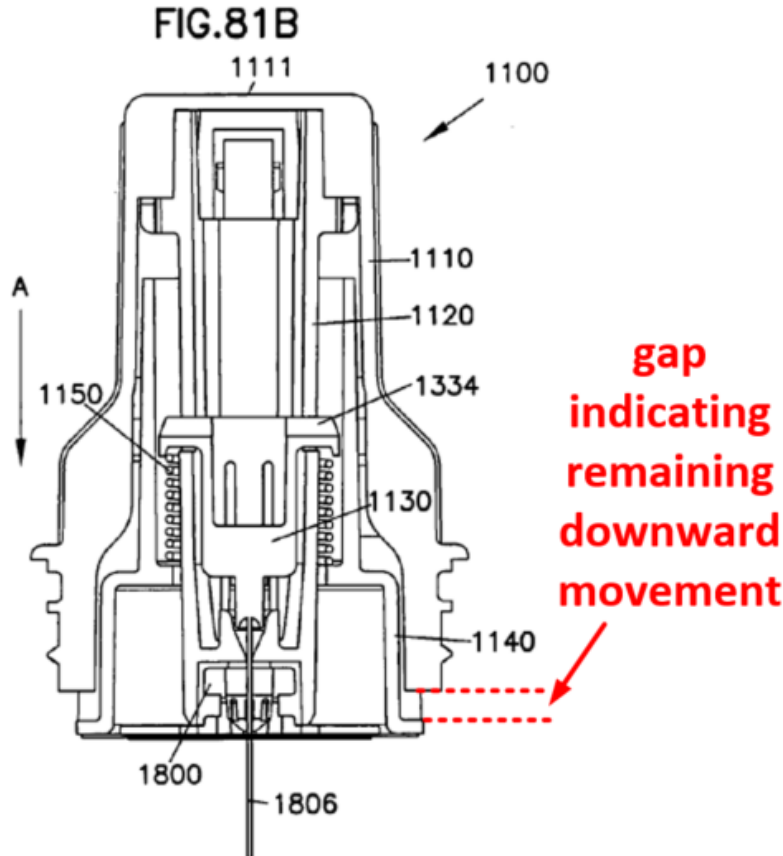
50. A POSITA understood, and common experience establishes, that when an object is pressed against a non-rigid surface, such as skin, the surface will deform around the object. EX1047, 212 ("When pressure is applied to the skin, the water directly underneath the point of contact is squeezed to the side. This results in a build-up of fluid to either side of the indenter..."); EX1048, 5 (showing skin displacements over 5 mm at 5 kPa (0.7 psi) and over 8 mm at 10 kPa (1.5 psi) applied average pressure for subjects under the age of 60 using a cylindrical indenter over the proximal femur). A POSITA understood that the "firm" pressure indicated for

inserters would indent the skin and soft tissue such that the skin would deform around the distal end of the inserter. *See, e.g.*, EX1050 (Cleo90 instructions). One need only lightly press a finger against skin on one's back (one insertion site disclosed in Cote, EX1005, [0229]) or abdomen or back-of-arm (locations where CGM sensors are often inserted)³ to see that pressing a Cote-like inserter against the skin would deform the skin around its distal end.

51. As illustrated in FIG. 81B below, which shows Cote's device in a "trigger state" with the needle fully inserted and the needle hub/needle not yet retracted (EX1005, [0203]), a POSITA would have understood that the user *continues to push on housing 1110 to close the gap between housing 1110 and sleeve 1140 on the skin*. During this trigger state, Cote describes that "housing 1110, cylinder hub 1120, and needle hub 1130 are displaced further in the direction A" (i.e., towards the skin). *Id.*, [0209]. In advancing these components, compressed spring 1150—which is positioned between needle hub 1130 and sleeve 1140, as

³ *See* EX1054, 30 ("Choose a site on a fatty area of your abdomen (belly) to put your STS Sensor. You can choose a site above or below your beltline. The best areas are usually flat, 'pinchable,' and relatively free from where rubbing can occur (i.e., pant line, seatbelts)."); EX1046, 38 ("Select a site ONLY on the back of the upper right arm, on the back of the upper left arm, or on your abdomen.").

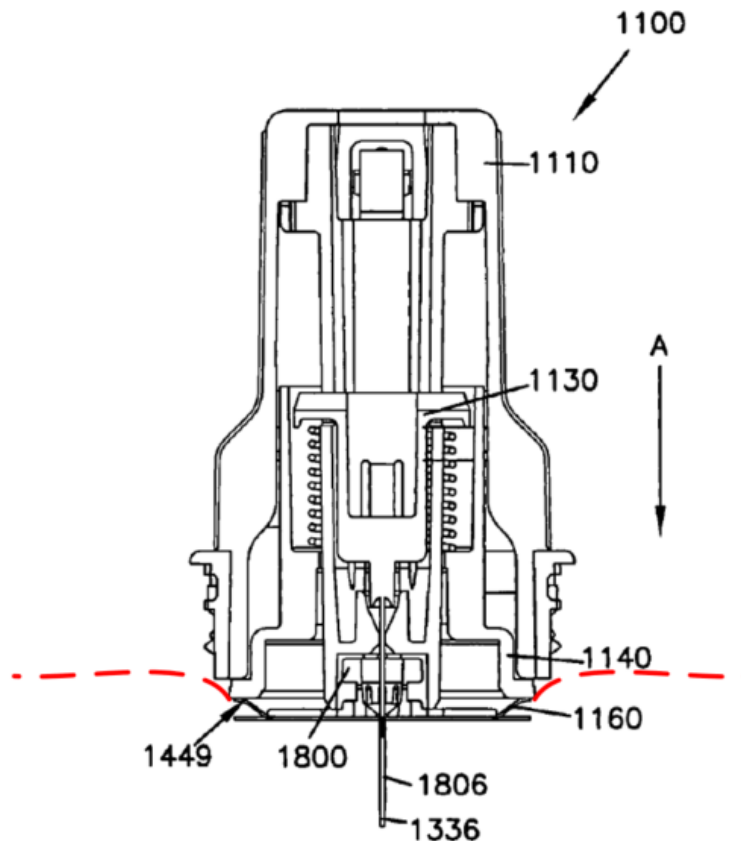
shown below—*also* provides a downward pushing force on sleeve 1140, helping to maintain contact of sleeve 1140 with the skin surface. *Id.*, [0207]:



Cote, FIG. 81B (annotated)

52. FIG. 81C shows “a cross-sectional view of the device of FIG. 81B *illustrating the adhesive portion being sheared from a surface of the sleeve*” (EX1005, [0101]), while the user is placing continued downward force on housing 1110, which reaches the end of downward travel by contacting sleeve 1140. A POSITA would understand that at this point, the user maintaining this downward force (and the force of spring 1150 on sleeve 1140, as discussed above) would function to keep the sleeve pressed against the skin, as illustrated in the exemplary

annotation below. As indicated above, Cote did not intend to illustrate the position of the skin in these figures (FIGS. 80A-83B). Therefore, the below illustration is not intended to show the precise deformation of the skin for any particular user, but rather to illustrate that a POSITA would understand that Cote's sleeve would, indeed, be in contact with the user's skin throughout the trigger state, including during over-travel:⁴

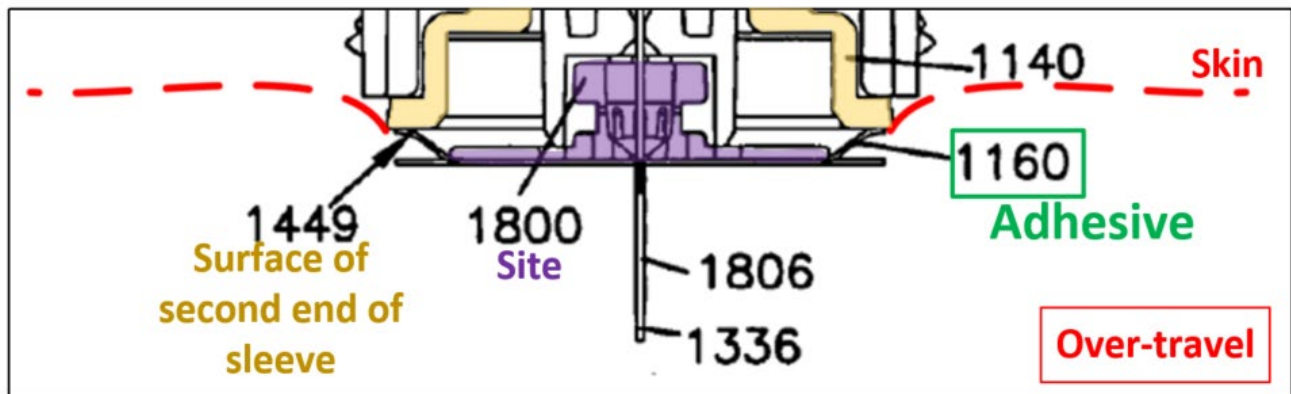


Cote, FIG. 81C (red annotation illustrates a portion of skin surface)

⁴A similar exemplary illustration is provided for FIG. 82A in ¶63, demonstrating a similar principle.

53. With this continued downward force, inserter sleeve 1140 is pushed down to maintain contact with the skin surface, as illustrated in the next paragraph and discussed in further detail in the following section.

54. As illustrated in the annotated portion of FIG. 81C, below, a POSITA would have understood that the force applied by Cote's site 1800 as it over-travels (and the manual force applied by the user to the sleeve 1140 via the housing 1110) would deform the skin around the distal end of the inserter:



**Cote, FIG. 81C (partial, annotated;
red dashed line annotation illustrates a portion of skin surface)**

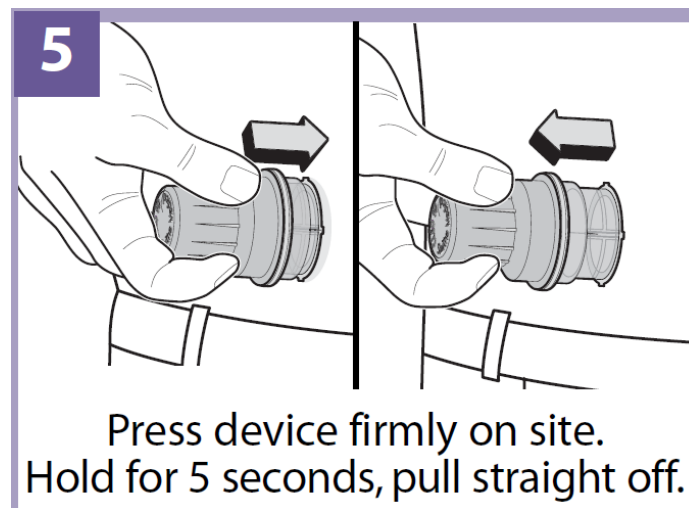
55. Cote describes that retraction of the needle from the user automatically occurs before the “the patient removes pressure...” (*see id.*, [0211]-[0212]), and before the inserter “sleeve 1140 is removed from contact with the skin” (*id.*, [0213]), supporting that pressure applied by the user keeps the inserter in contact with the user’s deformed skin until after the needle is retracted.

56. Cote also teaches that the “over-travel assures that the adhesive portion 1160 is properly sheared away from the surface 1449 of the sleeve 1140...” EX1005,

[0209]. As shown in Cote's annotated FIG. 81C above, the site 1800 shears away from the radially inner edge of the surface 1449. A POSITA would have understood that this allows the adhesive 1160 to conform to the skin surface such that an increased surface area of the adhesive can contact the skin, thereby facilitating the "coupling of the site 1800 to the adhesive portion 1160" and, later as a final step, the removal of the inserter 1100 from the skin. *Id.*, [0209]. This shearing of adhesive from the Cote inserter in no way requires or even implies that the inserter is removed or otherwise loses contact with the skin of the user before automatic retraction of the needle from the patient completes. Indeed, throughout insertion, including "over-travel," the Cote OBU is being driven into soft skin and tissue by downward force on the inserter 1100, so even as "shearing" takes place a POSITA would understand that the sleeve 1140 does not lose contact with the skin surface.

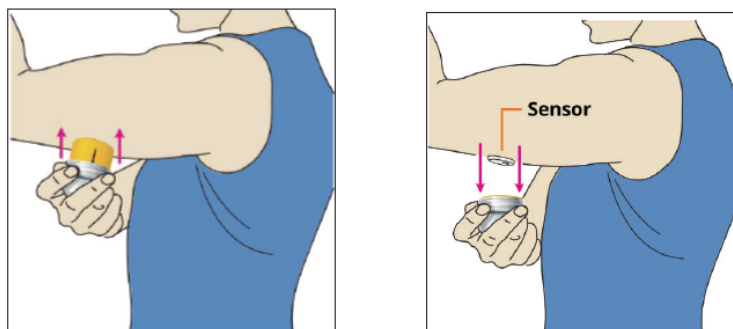
57. My understanding and description of how a POSITA would have properly interpreted Cote's "over-travel" is consistent with the user instructions for the commercial embodiment of Cote, Cleo90, instructing users to "press device firmly" and "hold for 5 seconds" before "pull[ing] straight off" (EX1050). I am familiar with the Cleo90 device and have a sample. It is marked with U.S. Patent No. 7,731,691, assigned to Smiths Medical. That patent recites on its face that it previously published as Cote (US 2005/0101932 A1). The Smiths Medical Cleo90 device appears to be a commercial embodiment of the Cote inserter. *See also*

EX1051 (showing Cleo90 FDA approval); EX1066 (showing no changes or supplements to original FDA approval); EX1053 (showing marking of approved Cleo90 product with USP7,731,691 that issued from Cote); EX1058 (USP7,731,691); EX1067 (showing the instructions were materially the same for Cleo90 in 2022 to “press device firmly” and “maintain for 5 seconds” before “pull[ing] straight off”):



Excerpt from Cleo90 instructions (EX1050) dated 2005

58. In this way, Cleo90’s insertion method appears similar to the method Mr. Leinsing describes for Abbott’s later Libre products that he asserts practice the ’591 patent. *See* EX2002, ¶¶384-389, including images from EX2010 at 39:



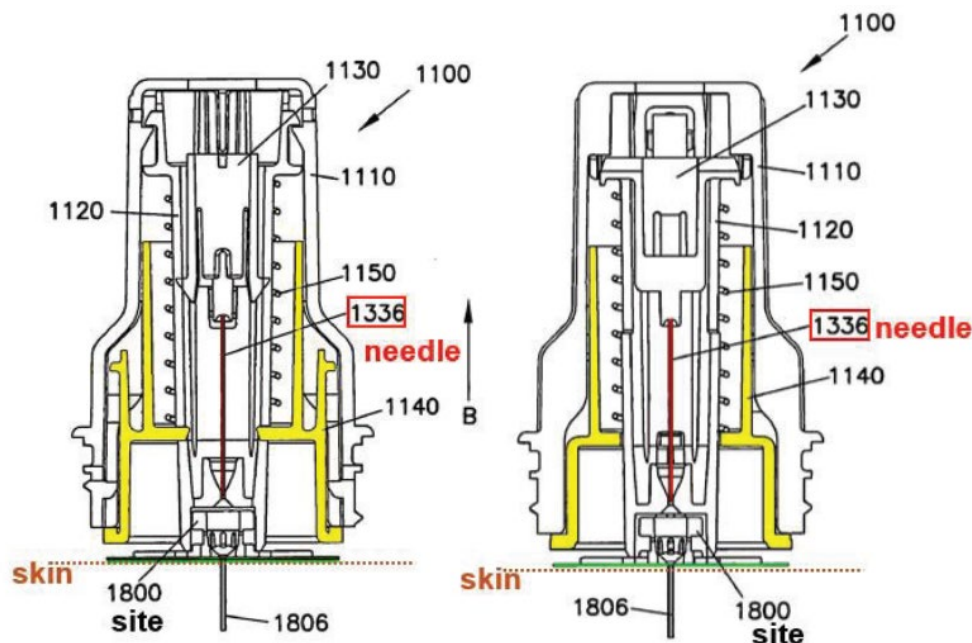
59. A POSITA would have understood that the automatic needle retraction of the Cleo90 inserter would occur in a fraction of a second and that if a user followed the instructions to “press” and “hold” the inserter for 5 seconds, the needle would have retracted before removing the inserter from the user’s skin.

60. As relevant here, a POSITA would have understood the inserter described in Cote to function as shown in the Cleo90 instructions, dated in 2005. EX1050. In particular, a POSITA would have expected that a Cote-like inserter such as the Cleo90 should be pressed firmly against the skin long enough for the adhesive to bond to the skin and that while the inserter remains held against the skin, the needle retraction process would complete (which would take a fraction of a second). Pressing the inserter device firmly against skin on the abdomen, as shown in the image in the Cleo90 instructions above, would cause the skin to deform around the distal end of the inserter, and the skin (like that on the abdomen as depicted in the instructions) would remain in contact with the distal end of the inserter until the inserter is removed—i.e., until after retraction of the needle from the skin of the user has completed. Of course, the same would be true of common insertion sites other than the abdomen, such as the back (one insertion site disclosed in Cote (EX1005, [0229]) or back-of-arm (where CGM sensors, e.g., Abbott’s Libre product, as shown above, are often inserted). *See, e.g.*, EX2010 at 39.

**4. The User's Manual Force Would Continue To Hold
The Inserter On The Skin Until After Needle Retraction**

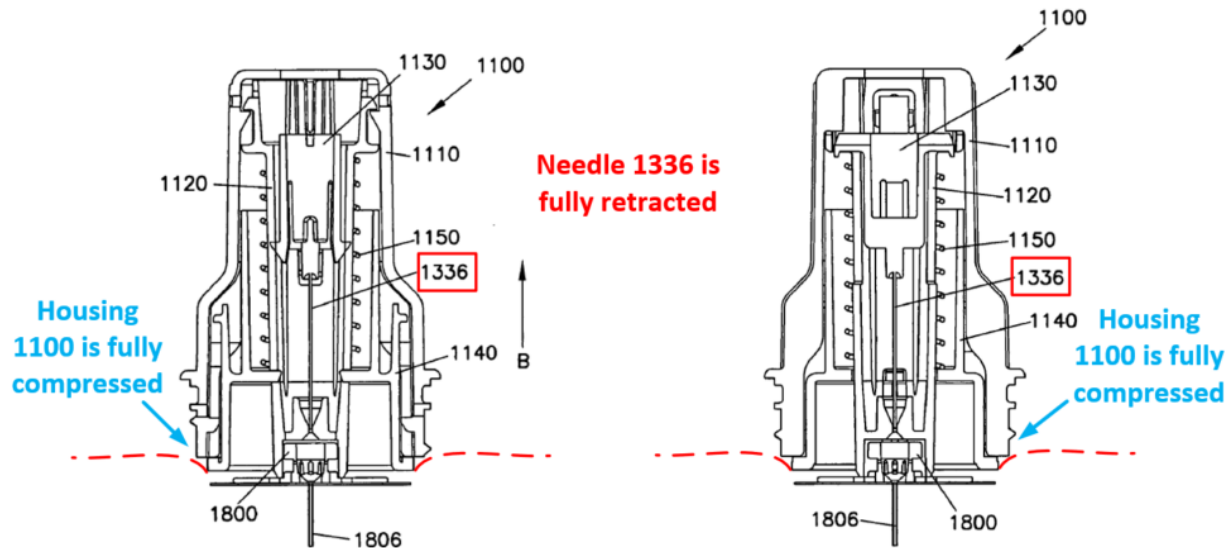
61. As mentioned in the previous section, a POSITA would have understood that manual force would be applied to the Cote inserter throughout the insertion/retraction process (and potentially longer, e.g., if desirable to enhance adhesion to the skin surface by pressing and holding the inserter against the skin) thereby maintaining the distal end of the inserter against the skin until after automatic retraction of the sharp. EX1005, [0211]-[0213]; EX1003, ¶104.

62. Mr. Leinsing alleges that FIGS. 82A and 82B show Cotes inserter “with the distal end (end of sleeve 1140) still separated from the skin.” EX2002, ¶189 (emphasis original). He provides an annotated figure allegedly showing this alleged separation:



**Cote, FIGS. 82A and 82B (as incorrectly annotated by Mr. Leinsing,
EX2002, ¶188)**

63. However, Mr. Leinsing's interpretation (and his corresponding annotations) fail(s) to take into account that the user *would still be pressing down on the housing* at this point during the insertion process (as described above, and as further evidenced by the fully compressed state of the housing 1110 in contact with the sleeve 1140. Thus, both the housing 1110 and spring 1150—"which has been compressed through the movement of the housing 1110 in the direction A" (EX1005, [0211]), and which is not yet fully uncompressed since the user is still applying pressure to the housing (*compare id.*, [0212])—would still be pressing down on sleeve 1140. Thus, as reflected in the illustration below, the distal end of the inserter would still be contacting the skin (illustrated by the red dashed line) due to the user's manual downward pressure and the downward pressure from the *distal* end of spring 1150 on the sleeve 1140, even as the *proximal* end of the spring 1150 "propels the needle hub 1130 and associated needle 1336 in the direction B up through the cylinder hub 1120 into the upper end 1111 of the housing 1110, while the site 1800 and associated cannula 1806 are held on the skin 1900 of the patient, as shown in FIGS. 82A and 82B" (*id.*, [0211]):



Cote, FIGS. 82A and 82B
(annotated, red dashed line annotation illustrates a portion of skin surface)

64. Cote's inserter uses manual power for insertion, which is provided by the user's hand pressing down on the proximal end of the device. Paragraph [0207] specifies that the user "applies pressure to the upper end 1111 of the housing 1110 to move the housing 1110 and associated structures including the cylinder hub 1120 and needle hub 1130 (including the needle 1336 and site 1800) [...] toward the skin...". EX1005, [0207]. A POSITA would have understood that Cote's 'over-travel' is also manually powered as the cylinder hub 1120 and needle hub 1130 are what move the needle 1336 and site 1800 within the housing. *Id.*, [0209], FIG. 81C. Cote does not describe an insertion spring or any alternative means of providing the force during over-travel.

65. A POSITA would have therefore further understood that the user's hand would remain on the upper end 1111 of Cote's housing in order to provide the over-travel force, and that *the user would not remove their hand until after completion of the over-travel*, (because the force applied by the hand on the inserter is what *causes* the over-travel). A POSITA also understood that the user's hand would maintain that force on the upper end of the housing 1110 until after needle retraction is complete. This is further evidenced by FIG. 82A, which shows the housing 1110 in the fully compressed position relative to the sleeve 1140 (indicating continued manual pressure by the user) *and* the needle in a fully retracted state *prior* to the user releasing pressure on housing 1110. *Id.*, [0211] ("The spring 1150...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 1900 of the patient, as shown in FIGS. 82A and 82B."). Cote in subsequent paragraph [0212] then describes that the "*patient removes pressure from the upper end 1111 of the housing 1110...as shown in FIGS. 83A and 83B...*" *Id.*, [0212]. A POSITA would understand that throughout insertion, (including "over-travel" and needle retraction from the patient), the Cote OBU is being driven into soft skin and tissue by downward force on the inserter 1100, so the inserter sleeve 1140 does not lose contact with the skin surface until after the needle has retracted from the patient.

66. Accordingly, there is no functional way that a Cote-like inserter could be removed from the user's skin during over-travel, as alleged by Mr. Leinsing, because the user is applying a downward force to the proximal end of the inserter throughout the over-travel process and retraction of the needle from the user. *Id.*, [0207]-[0213]; *see also* EX1050 (excerpt from Cleo90 instructions dated 2005, which are consistent with how a POSITA would have understood the Cote inserter's use and function).

67. Simply put, Cote teaches that the inserter is removed from the skin surface only after automatic retraction of the sharp, EX1005, [0211]-[0213], and no credible evidence supports Mr. Leinsing's theory that over-travel could cause the inserter to momentarily lose contact with the skin before the inserter is removed from the skin surface.

68. Finally, as mentioned previously, the "over-travel" on which Mr. Leinsing's contention relies is only a "preferred" configuration, not a necessary one in Cote. EX1005, [0207]-[0210]. A POSITA would have understood that there are various ways to implement Cote's inserter 1100 that do not include "over-travel," and would have implemented a Cote-like inserter without "over-travel" when appropriate for a given application. As just some possible examples, a POSITA would understand that the "over-travel" feature would be removed/excluded from a Cote-like inserter by shortening components (such as cylinder hub 1120) or

lengthening components (such as distal end of sleeve 1140 and/or distal end of housing 1110) and/or performing other design optimization that is routine in this art (e.g., optimizing the adhesive for ready detachment from the sleeve 1140 when the OBU contacts the skin), as necessary). In other words, if “over-travel” was not appropriate or desirable for a particular implementation to insert a glucose sensor, a POSITA would have understood that, and designed a Cote-like inserter without “over-travel.” That is consistent with Cote’s description that “over-travel” was only a preferred configuration, leaving to the knowledge of a POSITA the determination when/whether to include or exclude that feature from a design. Making such a determination was, indeed, within the knowledge of a POSITA. With a reasonable expectation of success, a POSITA would have made a Cote-like inserter (with or without “over-travel”) for the Stafford+Cote combination, if that was desirable for a particular OBU/sensor/needle design.

69. Mr. Leinsing states that I acknowledge that overtravel “must” occur “to enable automatic retraction of the sharp...” EX2002, ¶201 (citing EX1003, ¶110, n6) (emphasis original). While the cited footnote reflects my understanding that the “preferred embodiment” of *the particular embodiment 1100* illustrated in FIGS. 81A and 81B cited in my prior declaration uses over-travel to enable retraction, I do not agree that such a configuration is necessary in every single embodiment of Cote’s inserter. Indeed, as discussed above, a POSITA would understand that there are

various ways to design a Cote-like inserter 1100 that does not have an “over-travel” function.

**5. Mr. Leinsing’s Interpretation Of The Claims
Add Claim Limitations That Are Not Present**

70. Even if Mr. Leinsing’s interpretation of Cote’s over-travel feature causing the inserter to ‘jump’ off, or move away from its position on, the skin was correct (which it is not), a POSITA would have understood that the claims of the ’591 patent do not require that the distal end of the inserter remain on the skin *at all times* prior to needle retraction. Mr. Leinsing’s interpretation of the claim language is that the distal end 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.” EX2002, ¶167 (emphasis original). Mr. Leinsing is effectively rewriting the claims to add both a precise positional limitation (removed from “that [exact] positioning on” the skin) and an “*only* after” limitation, when the claims require neither.

71. Mr. Leinsing states that at my deposition I “acknowledged that this is exactly what the claims require.” EX2002, ¶176 (citing EX2036, 95:15-96:2). Untrue. I affirmatively responded to counsel’s question that claim 1 requires that the “distal end of the inserter is further configured to be removed from *that positioning*

on the skin.” Id. However, in so doing, I was merely referring to the positioning identified in counsel’s prior question, namely “the distal end of the inserter is configured to be positioned *on the skin.” Id.* I was not asked—nor did I offer an opinion on—whether either claim limitation requires a specific skin position, let alone that the inserter be removed from a position on the skin that is *identical* to the position where it is applied. Nor did I offer any opinion on whether the claimed removal must be performed *only* after automatic retraction, as Mr. Leinsing now asserts. And, as stated above, it is my opinion that the claims require neither.

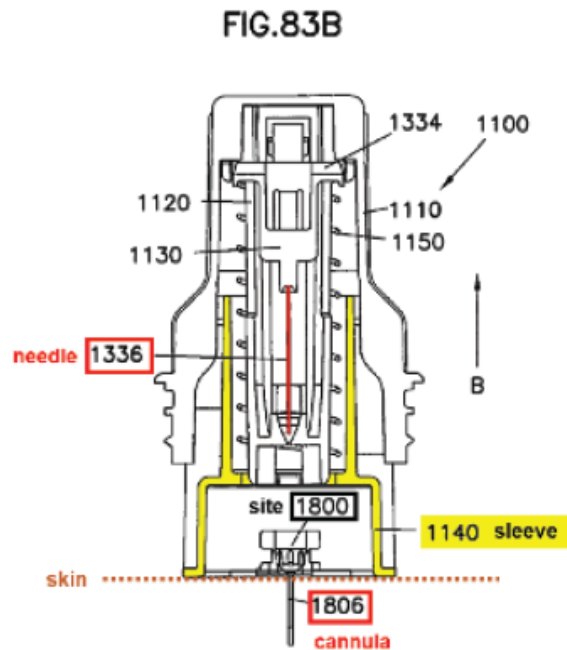
72. Rather, their plain language requires “the distal end of the inserter is configured to be positioned on the skin of the user before advancement of the on-body unit and the sharp” and then “the distal end of the inserter is further configured to be removed from the skin of the user after automatic retraction of the sharp from within the user.” The claim includes neither of the additional limitations that Mr. Leinsing now tries to inject.

73. Had the applicants wished to write a claim requiring the distal end of the inserter (e.g., the sleeve) to be *maintained* in contact with the skin throughout, e.g., automatic retraction, they could have done so, as did the Cote inventors. *See* EX1058, Claim 1, 19:15-20 (claiming “automatically moving the needle of the insertion device from the extended position to the retracted position *while leaving*

the sleeve in contact with the skin of the patient.”) The ‘591 patent claims are not so narrowly tailored.

74. Rather, the claims merely recite that the distal end of the inserter be “configured to be removed from the skin of the user after automatic retraction of the sharp...” EX1001, claims 1 and 19. Mr. Leinsing alleges that Cote’s inserter is removed from and then replaced on the user’s skin prior to sharp retraction and then is later again removed from the skin after sharp retraction completes. As described above, a POSITA would understand that is *not* how Cote functions. Nevertheless, a POSITA would understand that even *were* that how Cote operates, Cote’s inserter is nevertheless still “removed from the skin of the user after automatic retraction of the sharp,” thus satisfying the claim limitation.

75. Even Mr. Leinsing’s own annotated version of FIG. 83B illustrates the distal end of Cote’s inserter (still) on the skin and ready to be removed from the skin after the needle is fully retracted:



Cote, FIG. 83B (as annotated by Mr. Leinsing, EX2002, ¶209)

76. As shown above, Cote meets the claim requirement that the distal end of the inserter be “configured to be removed from the skin of the user after automatic retraction of the sharp...” under the correct plain and ordinary interpretation of the claims, without reading in Mr. Leinsing’s additional unrecited limitation. And, as discussed above, Cote (as properly understood) satisfies even Mr. Leinsing’s (improperly narrow) additional unrecited limitation.

B. Stafford+Cote Teaches The Claimed Height Limitations

1. Stafford+Cote Teaches The Claimed OBU Height Profile

77. Claims 14/19 require an OBU housing height “less than or equal to approximately 10 millimeters.” As discussed in my previous declaration, both Stafford and Cote note the desirability of a “smaller profile” OBU. EX1004, [0045];

EX1005, [0228]; EX1003, ¶¶136-138, and § V.B.4 (discussing the general knowledge in the art of low-profile devices).

78. Mr. Leinsing dismisses Cote's and Stafford's disclosures because they allegedly do not provide all of the claimed electronics. EX2002, ¶253. However, even putting aside the electronics that are taught or suggested by Stafford+Cote that are discussed both in my prior declaration and herein, both Cote and Stafford are still wearable units, and a POSITA would have understood that it was desirable to make any OBU as low-profile as possible to maximize patient comfort, as was well-known in the art. *See e.g.*, EX1006, [0011] ("In further embodiments, the mounting base is configured to be in a slim configuration so that it can fit closer against the patient's body when worn. The slim shape provides more comfort while being less conspicuous, for example, when worn under clothes."); *id.*, [0034] ("The slim shape provides comfort while being relatively inconspicuous, for example, when worn under clothes."), FIG. 1B; EX1003, § VI.B.4.

79. Stafford itself describes the desirability of a small OBU. EX1004, [0045]. Stafford also references Say (reflecting the state of the art as a background reference in this ground, but expressly relied on in Ground 2, 6, and 8), which teaches that the OBU has a height "preferably 0.7 cm [7 mm] or less." EX1008, 29:45-47; EX1004, [0043]. Stafford also references Jin (further reflecting the state of the art), which teaches an OBU height of 12 mm (EX1057, [0043]), which, while not

expressly meeting the claimed size requirement, would have rendered the claimed “less than or equal to approximately 10 millimeters” obvious because the difference in size is trivial where there is neither teaching away in the prior art, nor affirmative teaching in the ’591 patent of any advantages or technological advance specifically associated with the claimed 10 mm or less size. Indeed, the “less than or equal to approximately 10 millimeters” measurement is never specifically included in the specification, which instead includes a range of sizes as low as 3 mm and as high as 25 mm. EX1001, 14:5-7 (“In some embodiments, the height is *about 3 mm to about 25 mm*, e.g., may be about 4 mm, about 5 mm, *about 10 mm*, or about 15 mm.”).

80. As to the claimed height profile, Mr. Leinsing has not presented any evidence of a relevant difference between an “all-in-one” OBU and a multi-part OBU that includes, e.g., a sensor and a transmitter, *after* coupling of the transmitter to the sensor. And Mr. Leinsing fails to explain why the height of an assembled multi-part OBU, such as the OBU described in Say, would not have been relevant here. If anything, a POSITA would have understood that an “all-in-one” unit typically would be *at least as small in height, if not smaller*, than a multi-part unit because it would eliminate any need for a separate mount with added height between the skin and the electronics housing.

81. Further, Say includes embodiments wherein the OBU is a single piece (EX1008, 30:33-34), including even the “electronics components and/or other

items.” *Id.*, 30:19-22. A POSITA would have understood the height of a single piece unit as taught by Say (*id.*, 30:19-22, 30:33-34) would likely be as small or even smaller than the height of Say’s multi-part unit, which it describes as “preferably 0.7 cm [7 mm] or less.” *Id.*, 29:45-47. A POSITA would have further understood that Say’s ‘single piece’ OBU implementation is similar to the design of Stafford.

82. Moreover, a POSITA would have been motivated to make an OBU wearable no taller or larger than those already known and commercialized in the art at the time. EX1003, § VI.B.4. As discussed above, there were user comfort advantages as well as a preference to make a wearable medical device less conspicuous. For at least these reasons, a POSITA would not have even considered making a wearable OBU for a CGM system any taller or larger than what was already known and commercialized, and there were several examples of such OBU wearables having a height profile of “less than or equal to approximately 10 millimeters.” EX1008, 9:49-52, 29:5-8, 29:45-47; EX1006, [0034], FIG. 1B; EX1054, 104; EX1062, 1.

83. If anything, as with natural evolution of other electronic devices, there were design incentives and market reasons to reduce the size and height profile of an OBU to meet common sense consumer preferences for a less conspicuous and more comfortable wearable medical device. *See, e.g.*, EX1056 (“[a]n ultra-sleek, thin profile allows the MiniLink REAL-Time Transmitter to lay flat without a

bulge....Small and thin profile (approximately 1/3 of an inch thick) — easy to hide under clothing.”).

84. In other words, why would a designer have made or a user preferred an OBU larger than those known in the art? Simply put, they would not. Finally, there are no new teachings in the '591 patent that facilitated making an OBU—including an OBU as claimed containing all the electronics and connection to a glucose sensor—with a height profile less than or equal to approximately 10 mm, as providing such low-profile integrated OBU units was already known. *See, e.g.,* EX1004, [0043] (referring POSITA to Say disclosing preferred ≤ 7 mm height for an OBU with electronics); EX1006, Fig. 6, [0034] (“the entire mounting base 10 with the flexible sensor 70 is approximately 0.06 inches thick, including the adhesive layer 20, not to exceed past 0.1 inches [2.54 mm]”).

85. Given Stafford and Cote’s teachings, a POSITA would have at the very least found it obvious to implement an OBU with a height less than or equal to 10 mm. Say and other background references confirm this, and it is expressly taught in Say. In any case, a low-profile OBU “less than or equal to approximately 10 millimeters,” as the '591 patent claims, was known, conventional and preferred for a wearable medical device, as described previously and above. *See* EX1003, § VI.B.4; *see also* § VII.B.2.b, below.

86. Further, Mr. Leinsing has not provided any evidence of any alleged criticality of the claimed “less than or equal to approximately 10 mm” height range. To the contrary, as described above, the ’591 patent gives a wide range of values for the height of the OBU. EX1001, 14:5-7 (“the height is about 3 mm to about 25 mm, e.g., may be about 4 mm, about 5 mm, about 10 mm, or about 15 mm.”). Accordingly, the ’591 patent itself acknowledges that the design selection of an appropriate OBU height was within the skill and domain of a POSITA. Thus, it would have been obvious to a POSITA to implement the Stafford+Cote combination with an OBU height of 10 mm or less.

87. Finally, as to reasonable expectation of success, OBUs including all of the claimed electronics and a pre-coupled sensor were known and well within the capabilities of a POSITA to effectively implement. There is no reason that a POSITA would not have made the claimed OBU having a 10 mm or less height profile, with a reasonable expectation of success. To the extent that some prior art OBUs such as Say required coupling the sensor to the electronics after sensor insertion, there is no reason that an OBU with a height of 10 mm or less and a pre-coupled glucose sensor would not have been readily made by a POSITA. The connection to the glucose sensor need not affect the height profile of the OBU, at least because the sensor can be coupled in generally the same plane as the OBU electronics, i.e., to the side (as in Say (EX1008)), or in the center (as in Shah (EX1006) Fig. 6 and Stafford

(EX1004)) relative to the electronics. The claims have no requirement for the size of the OBU other than the height, allowing an OBU to meet the claim even if it is made larger in width or length or diameter than a prior art OBU, as needed or if desired in a particular design to accommodate a pre-coupled connection to the glucose sensor.

2. Stafford+Cote Teaches The Relative Heights Limitation

88. The proposed Stafford+Cote combination combines the teachings of *both* Cote and Stafford, but clearly relies on a Stafford-like OBU. *See* EX1003, ¶110 (“[b]ased on Cote’s teachings, a POSITA would have configured the travel distance of *Stafford’s [OBU]* (“H1”) to be greater than the height of the [OBU]’s housing (“H2”).”) EX1003, ¶110. The proposed combination does not rely solely on Cote for this limitation, as Mr. Leinsing alleges (*see* EX2002, ¶¶219-222), but rather on the combined teachings of Stafford+Cote as they would have been understood and applied by a POSITA based on the state of the art.

a) Mr. Leinsing Misstates The Relevant Heights

89. Mr. Leinsing further alleges that the limitation is clearly not satisfied by Stafford because “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).” EX2002, ¶223 (emphasis original). Mr. Leinsing misstates the claim limitation: H1 does not, as he states, measure the “length of the needle/sensor

extending below Stafford's sensor-comprising OBU." *Id.* H1 is a measure of "a distance between the housing when the [OBU] is in the first position and the housing when the [OBU] is in the second position." EX1001, 23:53-57 and 24:62-25:48 (claims 3 and 19); *see also* EX2002, ¶¶212-213:

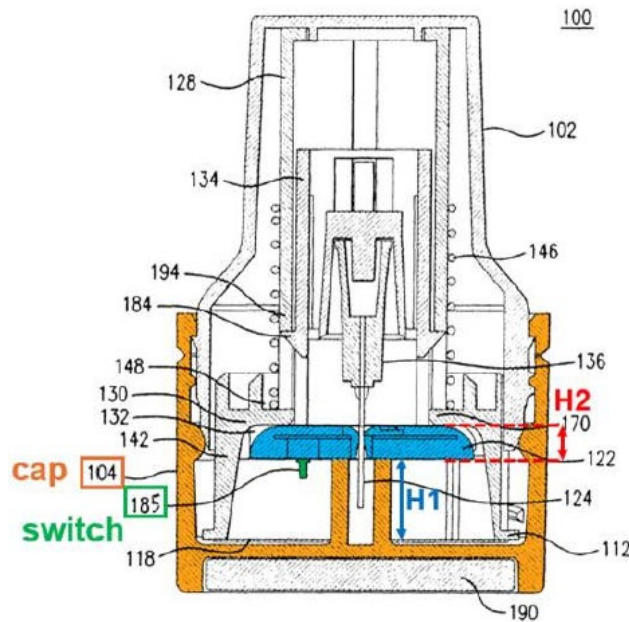


FIG. 29

'591 Patent FIG. 29 (as annotated by Mr. Leinsing, EX2002, ¶213)

POSITAs knew that H1 preferably should be greater than the length of the sharp/sensor extending below the OBU. Otherwise, the sharp/needle would not be shrouded by the inserter before use, risking premature/inadvertent needlesticks and increasing needle-anxiety.

**b) The ≤ 10 mm OBU Height
Limitation And $H1 > H2$ Relationship
Were Known And Would Have Been An Obvious
Implementation Of The Stafford+Cote Combination**

90. While the length of the sharp/sensor may have some correlation to the distance (H1) selected by a designer (*see e.g.*, EX1003, § VI.B.5) it is not the *sole factor*, as Mr. Leinsing appears to suggest. *See* EX2002, ¶¶223-224 (“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).... Thus, if Stafford’s OBU was used with Cote’s inserter...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.” (emphasis original)) Mr. Leinsing has identified no reason, as there is none, that H1 in obvious designs would not be appreciably greater than the length of the sharp/sensor extending from, e.g., Stafford’s OBU, resulting in H1 being greater than H2.

91. There was in fact good reason to design H1 to be appreciably greater than the length of the sharp extending from the OBU, including to further reduce the risk of inadvertent needle pricks by keeping the needle away from the end of the inserter before it is deployed. *See* EX1005, FIG. 80A. Numerous background references show that this was already well-known in the art of medical device

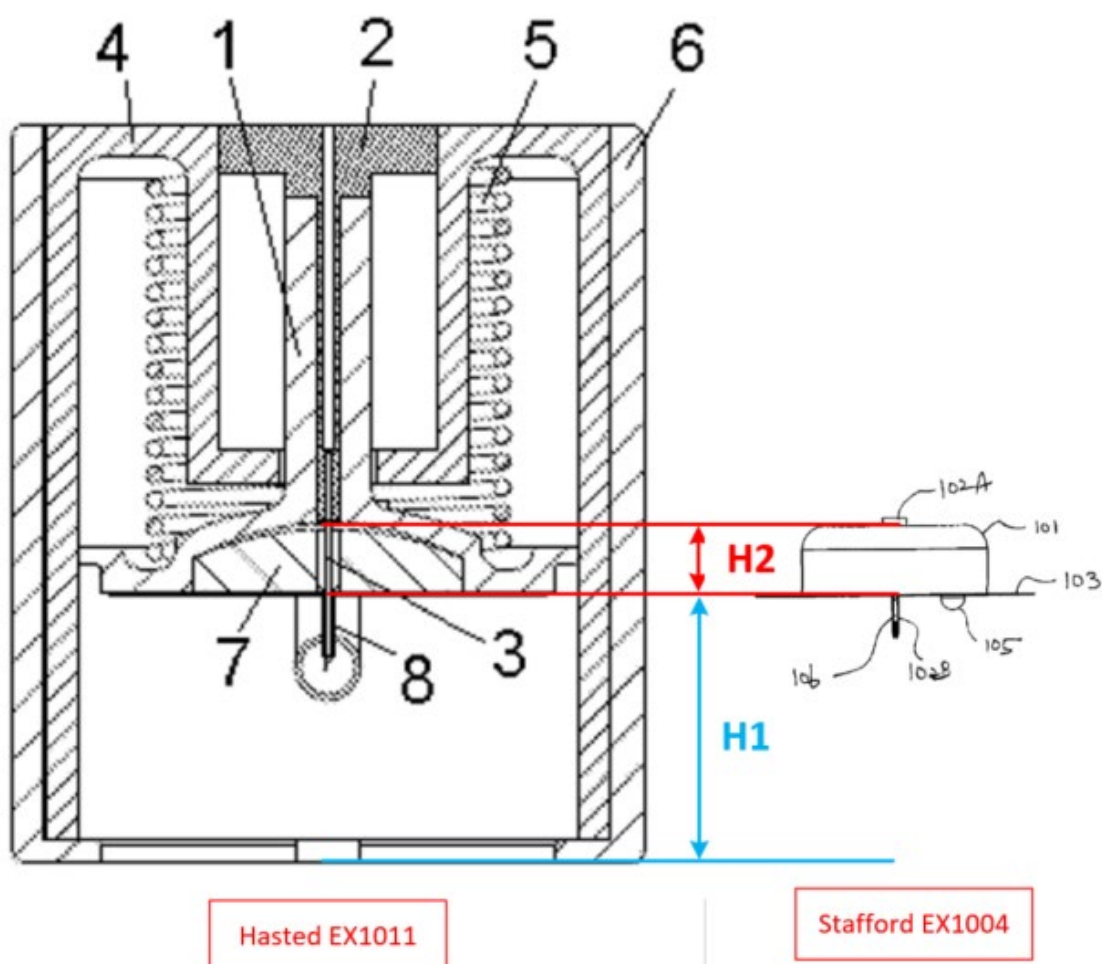
inserters. *See* EX1009, FIG. 29; EX1011, Fig. 1; EX1014, FIG. 21; EX1025, Fig. 10d; EX1042, FIG. 20A.

92. And, that the $H1 > H2$ relationship was known is further confirmed by the fact that the '591 patent applicants included figures purportedly illustrating it (e.g., in FIG. 29) without providing *any* corresponding explanation to a POSITA in their specification regarding the existence of (let alone reasons for) the claimed relationship. This further reflects applicants' implicit acknowledgement that a POSITA would have understand how to implement—and/or the significance (if any) of—this unexplained $H1 > H2$ relationship. I explained this in my first declaration. *See, e.g.*, EX1003, § VI.B.5, ¶¶109-118. And, in response to Mr. Leinsing's unsupported assertions, in the following paragraphs I provide additional explanation further confirming my original opinions on this issue.

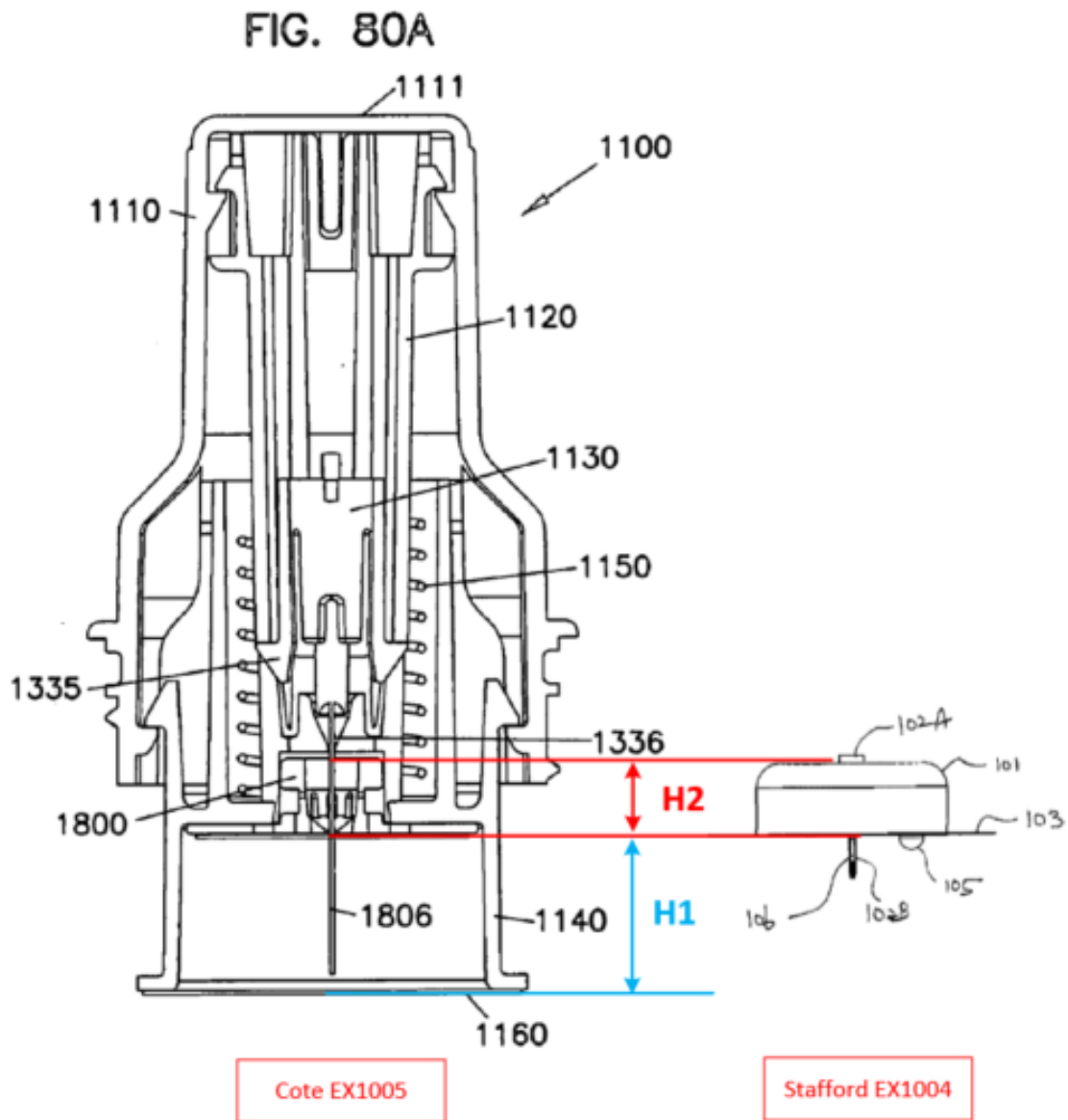
93. As an initial matter, I understand that patent figures are not drawn to scale and that the test for obviousness is not whether one reference can be bodily incorporated into another. However, for purposes of illustration, the following figures illustrate that a POSITA would have understood how to scale Stafford's OBU to fit within a variety of prior art inserters (and/or scale prior art inserters to accommodate Stafford's OBU), and in doing so, a combined device would meet the claimed $H1 > H2$ relationship.

94. As illustrated in several examples below, provided merely for the sake of illustration, and not precisely drawn to show specific measurements or scale as would be done for engineering drawings:

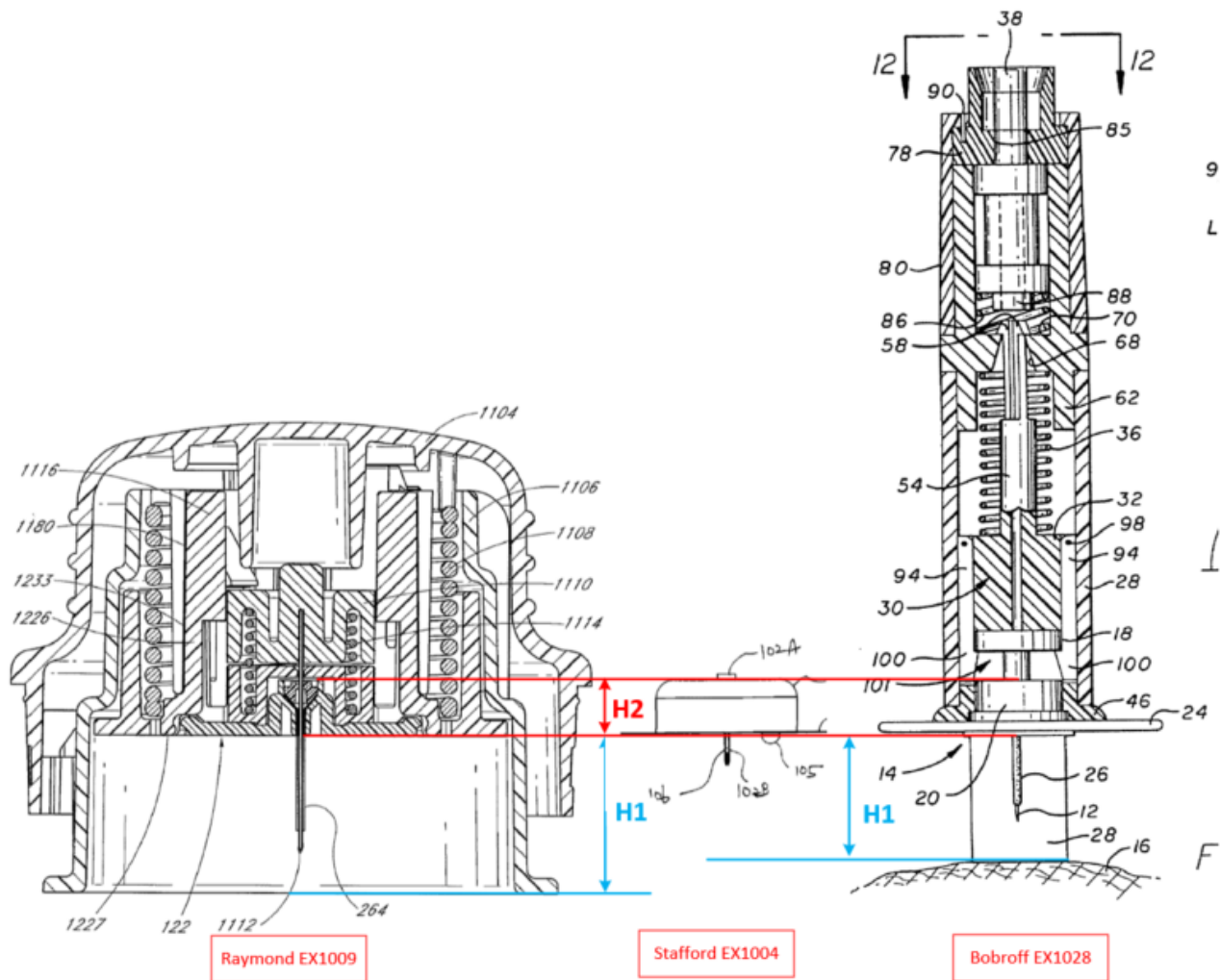
- (a) there is no direct or necessary relationship between H1 and the length of the needle/sensor extending below an OBU (other than that H1 would need to be greater than the length of the needle/sensor to avoid accidental/premature needlesticks, as further discussed below);
- (b) it was well-known to design H1 to be appreciably greater than the length of the sharp extending from the OBU (because if it was not, the sharp/needle would not be shrouded by the distal end of the inserter prior to use, causing a needlestick when the inserter is placed on the skin and prior to activating the inserter, and/or risking inadvertent needlesticks); and
- (c) “scaling” the Stafford OBU as it was drawn in Stafford’s figures to approximately “fit” prior art inserters as they were drawn in prior art patent documents shows the “combinations” would meet the claimed $H1 > H2$ requirement even without changing the length of the needle/sensor extending below Stafford’s OBU:



**Comparison of Hasted (EX1011) FIG. 1 and
Stafford (EX1004), FIG. 2 (annotated)**



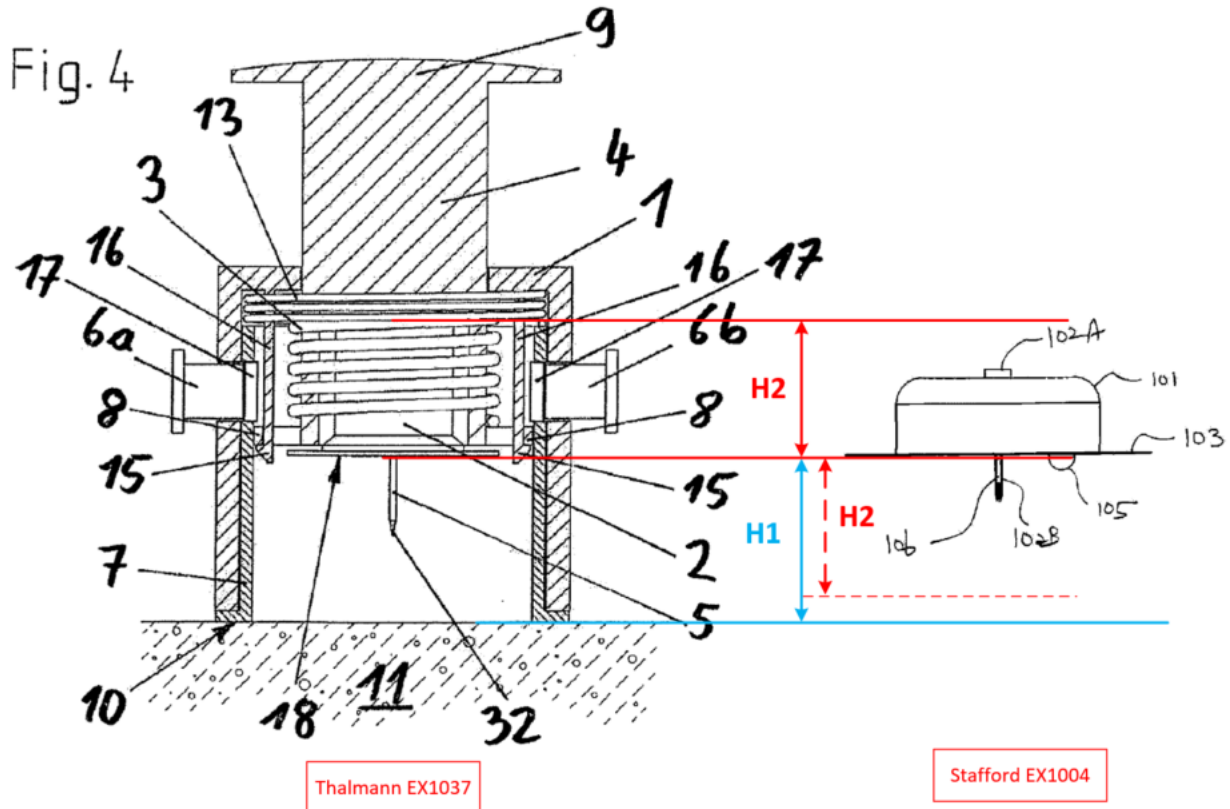
**Comparison of Cote (EX1005), FIG. 80A and
Stafford (EX1004), FIG. 2 (annotated)**



**Comparison of Raymond (EX1009) FIG. 29,
Stafford (EX1004), FIG. 2, and Bobroff (EX1028) FIG. 11 (annotated)**

95. As shown in the annotated comparison figures above, a POSITA would have understood that were one to scale Stafford's OBU to fit within, for example, Hasted's inserter (which teaches insertion of a cannula and/or a sensor, EX1011, 4/5:29-6:2), or Cote's inserter, or Raymond's inserter, or Bobroff's inserter, *the H1>H2 claim limitations would be met in each of these examples*. Even Thalmann (EX1037, also published as WO 2008/022476), which shows a relatively tall OBU,

meets the $H1 > H2$ claim limitation, as shown below. (Thalmann's $H2$ has been reproduced adjacent to $H1$ to facilitate comparison between the heights.)



**Comparison of Thalmann (EX1037) FIG. 4 and
Stafford (EX1004) FIG. 2 (annotated)**

96. Mr. Leinsing further states: “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.” EX2002, ¶233. First, to meet the claim requirements, the combination does not **require** making Stafford’s *in vivo* sensor longer than its OBU housing is tall for $H1$ to be greater than $H2$, nor did I indicate that this was required. To the contrary, as discussed and shown above, it is not required to have a sensor

longer than the housing is tall in order for H1 to be greater than H2. Indeed, there is good reason to design H1 to be appreciably greater than the length of the needle/sensor extending from the OBU, regardless of whether that needle is longer or shorter than the OBU is tall. The Stafford+Cote combination does not require “redesign[ing] Stafford so that the needle extending from the distal end of its OBU is longer than the OBU housing’s height,” as Mr. Leinsing alleges. *See* EX2002, ¶228. Rather, as illustrated above, a Stafford-like OBU would readily be scaled and integrated into a Cote-like inserter even without changing the relative length of the sharp/sensor extending below the OBU to the OBU height as drawn in Stafford Figures 1-2, and thereby meet the $H1 > H2$ limitations. A POSITA would have had a reasonable expectation of success implementing such designs.

97. Moreover, making $H1 > H2$ would not have been arbitrary, as it was well understood that:

- (a) OBU height (H2) should be minimized for patient comfort and preference (*see e.g.*, EX1006, [0034], FIG. 1B; EX1005, [0228], EX1004, [0045]; EX1056 (“[a]n ultra-sleek, thin profile allows the MiniLink REAL-Time Transmitter to lay flat without a bulge....Small and thin profile (approximately 1/3 of an inch [8.5 mm] thick) — easy to hide under clothing.”)); and

- (b) the minimum travel distance (H1) would be dictated by depth of needle/sensor/cannula insertion, which is typically not less than 5 mm to pass through the dermis and into the interstitial fluid, and was often significantly longer than 5 mm for glucose sensors (*see* EX1062 (PO's Navigator CGM system used a sensor insertion depth of 5 mm); *see also* chart below providing insertion depths for Dexcom's STS CGM system).

98. H1 would be greater than the needle/sensor length that extends below the OBU (and thus greater than the insertion depth under the skin) to allow for needle "shrouding" to prevent the needle from extending to or beyond the distal end of the inserter before it is deployed. Otherwise, the insertion needle/sharp would be exposed, subjecting users to the risk of inadvertent needle pricks and risking inadvertent contact with the user or environment that could jeopardize the sterility of the needle before it is deployed.

99. Additionally, as shown below, many dimensions and ranges of dimensions for needle/sensor length and/or insertion depth were well-known in the art, as were many low-profile OBU heights (H2) similar to those claimed:

Reference	Sensor Length ($<H1$ for 90 degree insertion angle relative to skin)	Insertion depth under skin ($<H1$)	OBU Height (H2)
Say (EX1008)	2.5 mm to 20 mm (Say, 9:49-52)	2 mm to 12 mm (Say, 29:5-8)	preferably ≤ 7 mm (Say, 29:45-47)
DexCom STS (EX1054, 17, 104)		12.5 mm	10 mm
Abbott Navigator ⁵ (EX1062, 1)		5 mm	11 mm
Shah (EX1006)	>2.5 mm (Shah, FIG. 1B)		0.06 in. (1.5 mm) to 0.1 in. (2.5 mm) (Shah, ¶0034)
Guardian REAL-Time (EX1056, 1-4)			1/3 in. (8.5 mm)

100. A POSITA would understand that many of these sensor lengths/insertion depths would result in a travel distance (H1) being greater than a corresponding OBU height (H2) when used in a Cote-like inserter that shrouded the needle/sharp. For example, at least the 8 mm to 12 mm portion of Say's disclosed ranges of insertion depths would result in $H1 > H2$ using Say's preferred 7 mm or less

⁵ Note that PO's Navigator CGM system marketed in the 2008-2009 timeframe had an OBU height slightly above 10 mm, but the claimed height profile in the '591 patent is "less than or equal to *approximately* 10 millimeters." Note also that Dexcom's STS and Medtronic's Guardian REAL-Time systems of the same era had OBU heights ≤ 10 mm, meeting the '591 patent's claimed height profile.

OBU height if an OBU of that height was integrated with the sensor to make a Stafford-like OBU and used in a Cote-like inserter. The 12.5 mm insertion depth for Dexcom's STS also would result in $H1 > H2$ based on its 10 mm OBU height if that OBU was integrated with the sensor and inserted using a Cote-like inserter. The same is true for the dimensions of the Shah OBU (Shah's FIG. 1B illustrates scale and relative dimensions of sensor length to OBU height). A POSITA would have had a reasonable expectation of success implementing such known dimensions and designs in a Cote-like inserter using a Stafford-like all-in-one OBU.

101. Adjusting the length of the sensor and/or needle, and adjusting $H1$ to accommodate that length, would have been a routine design choice for a POSITA. Moreover, the $H1 > H2$ relationship was taught by references discussed above and obvious in view of the State of the Art, which included numerous OBU units wherein the sharp/sensor/cannula was longer than a height of the OBU. EX1003, ¶¶115-116, *see also id.*, § VI.B.5. It is my understanding that Mr. Leinsing did not dispute that sensors/sharps with a length longer than a height of the OBU were well-known in the art.

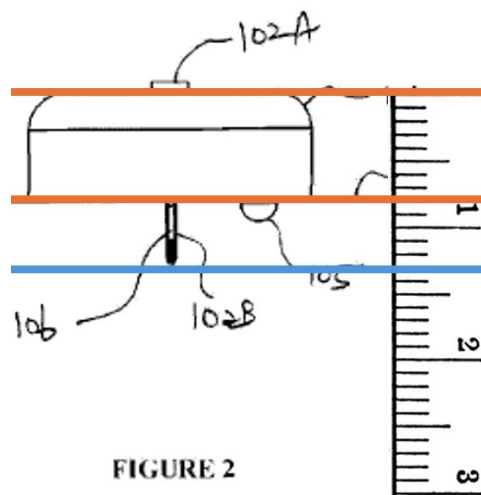
102. Indeed, the '591 patent itself describes a wide range of sensor/sharp lengths and housing heights, explaining no particular benefit to or criticality for any of them. For example, the '591 patent describes a wide range of values for the length of the needle, including anything from 5 mm to 50 mm, stating that the length could

be “selected based upon the desired depth of the insertion portion 30 of the sensor 14.” EX1001, 17:30-32. The ’591 patent has a similarly broad disclosure with regard to the range of heights suitable for the OBU housing, specifying heights from 3 mm to 25 mm for “data processing unit 12.” *Id.*, 14:1-7. Offering such ranges without further guidance serves as an implicit admission that a POSITA knew how to select whatever length needle/sensor (and travel distance (H1), of which needle length is one of many affecting factors) was needed for the desired use.⁶

⁶ Incidentally, the claimed “approximately” ≤ 10 mm height of the OBU housing relative to a 5 mm needle length / insertion depth (in the range described in the ’591 patent) includes the approximate ratio of Stafford’s OBU height to its insertion needle as it was drawn in Stafford’s figures (for which dimensions are not recited in Stafford and, just like the ’591 patent, are not drawn to scale). In other words, if one were to treat the Stafford figures as drawn to scale and assume a 5 mm needle/insertion depth (which was known in the art, and used by PO in its Navigator system in the same 2008 timeframe, (EX1062, 1)) then the height of the OBU as drawn in Stafford would meet the claimed height profile of “approximately” ≤ 10 mm in the ’591 patent (Stafford’s FIG. 2 and ruler below were both scaled to show relative dimensions of the OBU housing to needle/insertion depth in FIG. 2 as drawn

103. Likewise, Stafford and the '591 patent both refer to Say (*see* EX1004, [0043]; EX1001, 22:55-23:4), which similarly discloses a range of OBU heights and sensor lengths that could be longer or shorter relative to one another. EX1008, 9:46-57, 29:45-47. For example, Say teaches that the sensor can be injected “between 2 to 12 mm into the interstitial tissue” and that the on-skin sensor control unit (OBU) “has a height of 1.3 cm [13 mm] or less, and preferably 0.7 cm [7 mm] or less.” EX1008, 29:5-6, 29:45-47. Nothing in the '591 patent provides guidance to a POSITA when choosing the relative height of the OBU to the length of the sensor/sharp, just as prior art Say did not specify a preference. Rather, the '591 patent left it to the POSITA's understanding, which underscores that it was an obvious design choice.

in Stafford; increments between each line on the ruler correspond to one scaled millimeter):



104. The claimed height of the OBU (H2) and the unclaimed, but result-effective variable of needle length—which dictates the minimum travel distance (H1) if one is going to shroud the needle in a Cote-like inserter to avoid inadvertent needle sticks and lessen needle-anxiety—are within the ranges known to POSITAs, as reflected in numerous background prior art references, as cited in my prior declaration and herein. Therefore, $H1 > H2$ would have been obvious to a POSITA, particularly where there is neither teaching away in the references themselves nor any unexpected result asserted/explained in the challenged patent. Moreover, the preferred OBU height of about ≤ 7 mm disclosed in Say, combined with a sensor insertion depth of 8 mm to 12 mm (within the range disclosed in Say) would be understood to teach $H1 > H2$ when used with an “all-in-one” OBU in a Cote-like inserter—and to effectively require $H1 > H2$ to avoid inadvertent needlesticks from the sharp/needle extending beyond the distal end of the inserter before use.

105. To reiterate my previous declaration, “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.” EX1003, ¶115. Various factors described previously and herein support such an implementation, and while the specific positioning of the OBU is a simple matter of design choice (*see id.*, ¶¶113-118), these factors support positioning the OBU such that the distance of travel (H1) is greater than a height of the OBU (H2); indeed, they effectively require $H1 > H2$

where, as was known in the art, the OBU height is less than the needle/sensor insertion depth.

106. Further, since Cote illustrates an implementation (inserter 1100) wherein the OBU is configured and positioned such that $H1 > H2$, it would have been obvious to a POSITA to try such a configuration. EX1005, FIGS. 79A-83B. As I noted in my previous declaration, Cote also teaches the “housing-distance limitation” to the same extent that the ’591 patent does (*see* EX1003, ¶117)—that is, a POSITA reading the ’591 patent is left to infer this relationship from the figures, just as they would have with the prior art Cote reference.

107. Mr. Leinsing alleges that Cote “depicts the needle at or extending beyond and outside the distal end of the inserter,” however, Mr. Leinsing is relying on a different Cote embodiment (1100”) than the one relied upon as part of the Stafford+Cote combination (1100). EX2002, ¶234 (emphases original). The fact that Cote—or Brenneman, which Mr. Leinsing also mentions (EX2002, ¶235)—discloses embodiments that teach a needle adjacent to the distal end does not negate the above-mentioned and well-understood advantages provided by positioning the OBU within the inserter such that the needle is well within and enshrouded by the inserter to avoid inadvertent needle pricks and lessen needle-anxiety, resulting in $H1 > H2$ in many if not most cases, as further discussed previously and herein.

108. Accordingly, the combined teachings of Stafford+Cote teach (in as much detail as does the '591 patent itself) —or at the very least suggest—positioning the OBU within the inserter, such that the OBU's travel distance ($H1$) would be greater than the maximum housing height ($H1 > H2$). Additionally, the state of the art and knowledge of a POSITA, as demonstrated by the other inserters described above, shows that the idea of $H1 > H2$ was not new. Rather, $H1 > H2$ was a conventional design that would have been implemented with a reasonable expectation of success.

109. Even if the “housing-distance limitation” were not taught or suggested by Cote (which, as discussed above, it is), positioning an OBU within an inserter such that it travels a distance ($H1$) greater than a maximum height of the OBU housing ($H2$) would have been obvious to a POSITA for the additional reasons that: (1) such a configuration was well-known in the art (EX1003, § VI.B.5) and (2) it is my understanding that a mere recitation of relative dimensions does not render a device patentable unless they cause the device to operate differently from the prior art. Neither the '591 patent applicants, nor Mr. Leinsing has demonstrated such a causal relationship, as further explained herein.

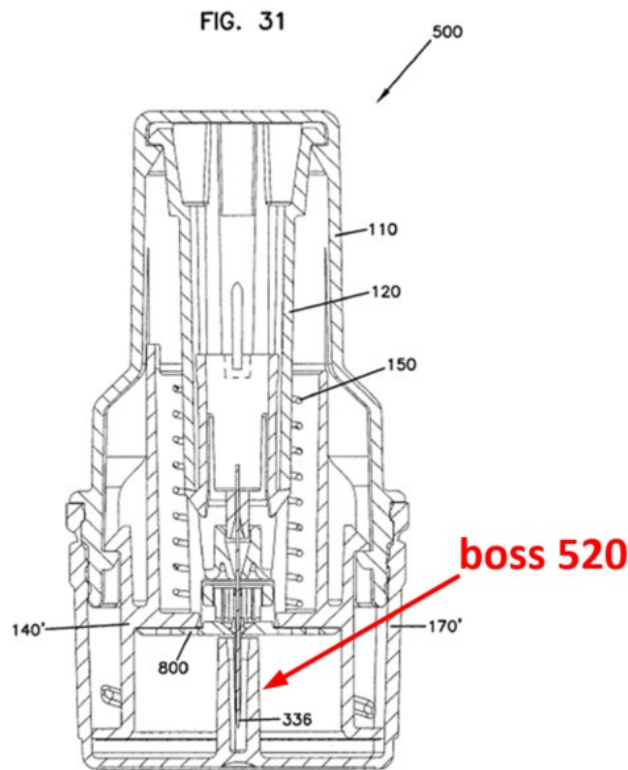
c) **PO's Alleged Benefits Are Not Tied
To The Relative Heights Limitations**

110. Mr. Leinsing lists two advantages allegedly provided by the '591 inserter's design: (1) preventing inadvertent activation of the "plunger switch 185" and (2) "allowing space for the presence of a 'boss 125' in 'cap 104'." EX2003, ¶¶214-215. However, nowhere does the '591 patent describe the claimed $H1 > H2$ relationship as providing these advantages. In fact, nowhere is the claimed $H1 > H2$ relationship described in the '591 patent at all. PO has not established that these *post hoc* alleged advantages are ***necessarily provided*** by the claimed $H1 > H2$ relationship. On the contrary, these alleged advantages are ***not necessarily provided*** by the $H1 > H2$ relationship; there is no direct correlation between them.

111. It would have been well within a POSITA's skill to implement a cap boss, even if the height of the OBU housing ($H2$) was equal to or ***greater than*** its travel distance ($H1$), i.e., $H2 \geq H1$. For example, keeping the travel distance ($H1$) the same as in the current Cote figures while increasing the height of the OBU housing ($H2$) could result in $H2 \geq H1$.⁷ However, making such a change (and therefore falling outside the claim limitation) would have no impact on whether a cap with a boss

⁷ Of course the size of the inserter and corresponding parts would be increased as needed to accommodate the larger OBU, but that would not necessarily change $H1$.

could be used. The height of the OBU housing is immaterial to the functioning of the (unclaimed) cap boss. Further, including a boss in the cap was neither a novel nor a groundbreaking advantage. Indeed, Bresina, U.S. 2005/0283114 (EX1064)—which like Cote predates the '591 patent—teaches a similar inserter to the one taught in Cote,⁸ and includes a boss in its cap. *See, e.g.*, EX1064, [0010], [0106], FIG. 31:



Bresina, FIG. 31 (annotated)

⁸ Indeed, Bresina was assigned to Smiths Medical, as was Cote. The application that published as Bresina issued as U.S. Patent No. 7,585,287 (EX1063), which, like the Cote patent, is marked on the Cleo90 device.

112. Likewise, even if Cote's OBU had a greater maximum height H_2 , a POSITA would have understood how to prevent inadvertent activation of a switch on the bottom surface of the OBU, simply by maintaining the travel distance H_1 that is already currently disclosed in Cote. Again, the height of the OBU housing is immaterial to the functioning of the activation switch.

113. Adjusting the height of the OBU housing and the OBU within the inserter to achieve the activation switch and cap boss objectives that Mr. Leinsing identified (which, again, are not described or claimed in the '591 patent) would have simply been another obvious design choice for a POSITA to consider and optimize for an inserter.

114. Further, Mr. Leinsing has not shown that an inserter having the claimed $H_1 > H_2$ "housing-distance limitation" would have necessarily performed differently than the inserter of the Stafford+Cote combination (which teaches the "housing-distance limitation" as set out in the foregoing and through application of Cote's teachings). Put another way, there is no reason that an inserter/OBU having the opposite proportions where $H_2 \geq H_1$ would have necessarily performed differently or lacked the supposed advantages Mr. Leinsing identified of accommodating a cap/boss, or placing the activation switch away from the distal opening of the inserter. Accommodating a cap/boss is not *solely* dependent on H_1 or H_2 let alone the relationship between H_1 and H_2 . Similarly, placing the activation switch away

from the distal opening of the inserter also is not dependent on H2, let alone the relationship between H1 and H2.

115. Positioning the OBU within the inserter such that $H1 > H2$ was expressly taught by Cote and would have at the very least been obvious to a POSITA to try in the Stafford+Cote combination, where it would have been a simple design choice.

C. Stafford+Cote Teaches The Claimed “Data Storage Unit”

116. In view of Stafford’s teaching that data is processed by the data processing unit (DPU) and transmitted from the OBU by the DPU in one-minute intervals (EX1004, [0036]-[0037]), a POSITA would have found it obvious to include a data storage unit to store the data to allow for processing and/or to allow for a lag/buffer between data collection and transmission. EX1003, ¶¶119-121. Further, Stafford at [0043] teaches that additional details of its DPU are disclosed in Say, which expressly teaches “an optional data storage unit 102...” (EX1008, 36:40-43, 44:54-45:7), and in Jin, which similarly teaches that “the transmitter processor 204 also includes a memory...for storing data such as...the data signals received from the sensor 101.” EX1057, [0042].

117. Moreover, it was well-known and conventional in the art for analyte sensor OBUs to optionally include a data storage unit. EX1003, ¶¶119-121, 181-182; *see also, e.g.*, EX1057, [0042]; EX1012, [0315]; EX1013, [0469] (“The processor typically provides semi-permanent storage of data...”); EX1014, [0007];

EX1015, 2:28-32; EX1021, 2:35-39 (“The sensor control unit may also include a variety of optional components, such as...a data storage unit...”); EX1016, 37:48-51 (“The on-skin sensor control unit 44 may optionally contain...a data storage unit 102...”); EX1030, 30:45-48 (“The control unit may comprise...a memory...”); EX1040, [0053] “[A] continuous analyte monitoring assembly 310 includes...memory 334...”).

118. Accordingly, it would have at the very least been an obvious choice for a POSITA to include a data storage unit in a Stafford-like OBU. EX1003, ¶¶119-121, 181-182.

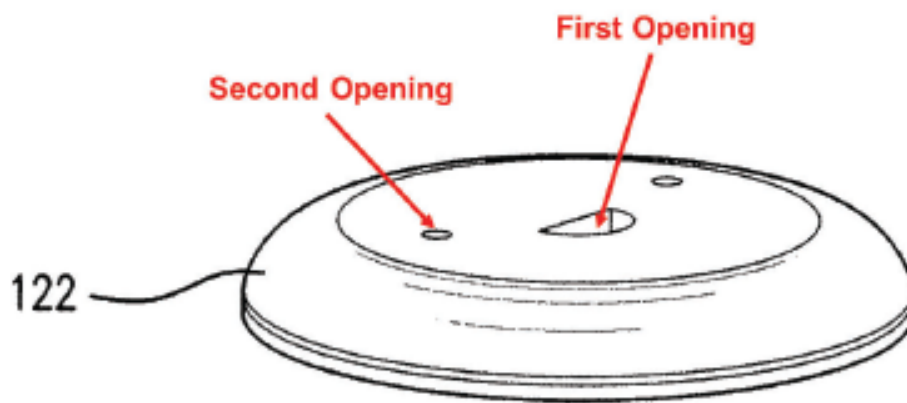
D. Stafford+Cote Renders The “Second Opening” Claims Obvious

**1. “Second Opening” Limitations
Entitled To Little Or No Weight**

119. The ’591 patent never expressly discloses providing a second opening in the top surface of the housing. Further, it associates no function or utility with the claimed “second opening.” A “second opening” is not described anywhere in the text of the ’591 patent, nor does any claim require that the second opening serve any function or purpose, nor does the specification describe any function or purpose because it does not describe a second opening at all. EX1003, ¶¶144-149. That said, it was known in the art to provide openings on the top of an OBU, e.g., to interface

with an inserter. *Id.* (citing EX1040, FIGS. 1, 8, [0042]; EX1007, [0068]-[0069], FIG. 3; EX1005, [0135],[0137], [0168], FIGS. 8, 34).

120. Mr. Leinsing's sole support for an alleged "second opening" is annotating FIG. 23 of the '591 patent to point out a small two-dimensional ("2D") circle atop the housing:



Yee '591, FIG. 23, as annotated by Mr. Leinsing (EX2002, ¶265)

121. However, nothing in the patent indicates that the 2D circle is an opening and a POSITA would not have understood that the inventors possessed and described an embodiment having a "second opening" as claimed. The patent specification never refers to a "second opening" at all, and nothing in the specification or the figures suggests whether the 2D circle (which has no reference numeral or description in the specification) is a through-hole in the housing or an ornamental feature. Nor is any purpose or function for the feature depicted as a 2D circle described.

122. Mr. Leinsing alleges that the purpose of such a second opening is to aid in manufacturing. EX2002, ¶265 (“The second opening, as well as a third, serve [as] an alignment mechanism for the OBU during manufacturing.”). Mr. Leinsing offers no evidence, analysis or reasoning to support this conclusory statement. As stated above, the ’591 patent does not mention the opening at all, and certainly does not describe it serving any such function during manufacturing.

123. Mr. Leinsing provides no evidence and the ’591 patent provides no disclosure or other indication that the claimed “second opening” or corresponding dimensional limitation performs any critical function or causes the invention to operate any differently from the prior art. *See* EX1003, ¶¶150-152. Accordingly, nothing supports that adding a second opening or selecting a first maximum width greater than a second maximum width (as claimed) is anything more than an obvious matter of design choice. *See id.*, ¶¶144-152.

124. Mr. Leinsing alleges that I “concede[] that [my] primary references (Stafford and Cote) do not teach the ‘second opening’ limitation...” EX2002, ¶266. I make no such concession, as my previous declaration cites Cote’s openings 115 as disclosing or at the least rendering obvious second openings in the top surface. EX1003, ¶¶147, 151; EX1005, [0135]-[0137], [0168], FIGS. 8, 34. Mr. Leinsing was clearly aware of this, as he goes on to attempt to rebut my arguments by alleging that Cote’s second openings “are located in the interior of Cote’s infusion device

(specifically on a lower surface of the bottom portion).” EX2002, ¶286 (emphases original). While Cote’s openings are used to couple the OBU to an infusion device, they clearly teach the concept of using an opening in a top surface to interface with a corresponding projection. EX1003, ¶147. And, the ’591 patent’s claims do not require the “second opening” to serve any function at all, let alone engage with the inserter, nor do they preclude covering the “second opening” after the OBU is deployed as in Cote where infusion set components are placed atop the OBU after insertion. *See, e.g.*, EX1005, FIGS. 21-50. Further, Cote’s openings 115 are located on a top surface (i.e., one of one or more upwardly-facing surfaces) as opposed to a downwardly-facing surface, and the ’591 patent’s claims likewise require “a” (i.e., one or more) top surface. EX1005, [0135]-[0137], [0168], FIGS. 8, 34. A POSITA would understand that in implementing a Cote-like second opening in Stafford+Cote, it would be placed on the one planar top surface of Stafford, which has only one such surface on which a “second opening” could be placed.

125. If for some reason a second opening were required or desirable for a given application, a POSITA would have found it obvious to configure a second opening with a smaller maximum width than Stafford’s central aperture (“first opening”). EX1004, [0027], FIG. 2. Such a configuration is an obvious design choice and one of a finite number of solutions for adding aperture(s) to the top surface. EX1003, ¶¶150-152. There are only three choices for the relative sizes of

the openings—they could be the same, the first could be larger than the second, or the second could be larger than the first. Each choice is an obvious variation that represents selection from a very finite list, thus lacking patentable significance, absent any described or claimed reason for the relative dimensions. Again, the '591 patent offers no such reasons.

126. While a POSITA would have understood that alignment (e.g., between the sensor and needle, the sensor and OBU, and/or the OBU and inserter) could be useful, there is no criticality disclosed in the '591 patent to the particular claimed implementation of a second opening. There are various ways alignment between components could be achieved, and there is nothing special or unique about using a second opening in the top surface. This is evidenced by, e.g., Brenneman and Turner. EX1040, FIGS. 1, 8, [0042]; EX1007, [0068]-[0069]. And if any criticality to the use of a second opening or a second opening of a particular dimension relative to a first opening exists, Mr. Leinsing has failed to describe it, and the '591 patent is silent on it, as well. Indeed, the '591 patent does not even describe its second opening at all, let alone its purpose. The '591 patent's silence implicitly acknowledges that a POSITA would have understood any advantages of or need for alignment and how to achieve it. This would include using a smaller "second opening" as claimed, which, as discussed above, was one of a small, finite number of options available to a POSITA.

**2. It Would Have Been Obvious To Include
A Second Opening To Prevent Unintended
Movement Between An OBU And Inserter Prior To Use**

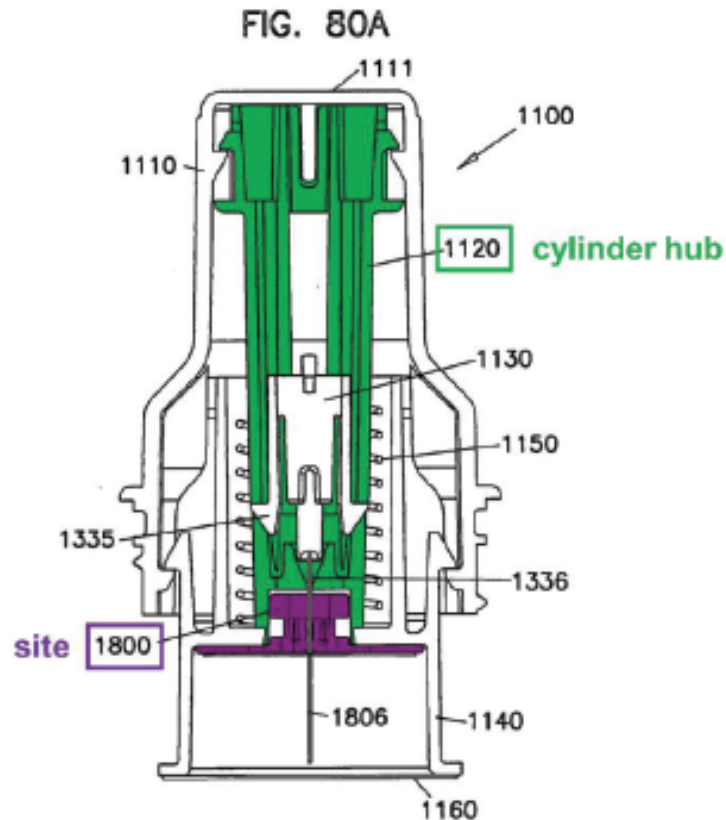
127. Mr. Leinsing alleges that it was not obvious to include a second opening in a Stafford-like OBU inserted by a Cote-like inserter because “Cote’s pre-existing design...already secures the alleged OBU to the inserter.” EX2002, ¶269 (emphasis original). However, while Cote’s friction fit between the diaphragm and needle holds its OBU within the inserter, it does not prevent rotation of the OBU within the inserter, nor does it prevent tipping of the OBU relative to the inserter. Mr. Leinsing himself states that “sensors are more fragile than infusion cannulas, and proper placement requires care and precision.” EX2002, ¶160. For this, among other reasons, a POSITA would have been motivated to ensure that a Stafford-like OBU inserted using a Cote-like inserter does not tip/tilt within such an inserter prior to use.

128. Further, a POSITA would have had a reasonable expectation of success in including a second opening in Stafford’s OBU, because it was well-known in the art to do so, as evidenced by Brenneman (EX1040, [0042]), which uses peripheral openings on the top surface for coupling the OBU and inserter, and Turner, which uses complementary protrusions and recesses to prevent rotation between the inserter and OBU. EX1007, [0069]. Indeed, as pointed out by Mr. Leinsing, Turner

also includes a friction fit between the needle and inserter (“just like Cote’s”), and yet *still includes* anti-rotation openings and protrusions. EX2002, ¶¶273-274.

129. A second opening would not have been used *solely* to ‘secure’ the OBU to the inserter (as discussed, Cote already provides a mechanism for such securing), but also to prevent undesired rotation (the very reason discussed in Turner), tipping/tilting, and also to aid in maintaining the OBU within the inserter. EX1007, [0069]; EX1003, ¶¶144-149. Further, a POSITA would have been motivated by the teachings of both Brenneman and Turner to position the second opening on the top surface of the OBU, and would have had a reasonable expectation of success in doing so.

130. Mr. Leinsing further alleges that Petitioner’s anti-rotation benefit would not have motivated a POSITA because the “cylinder hub 1120 (green [in the] annotated figure below) of Cote’s inserter pinches opposite sides of Cote’s alleged OBU (purple below), which likewise would prevent OBU rotation.”

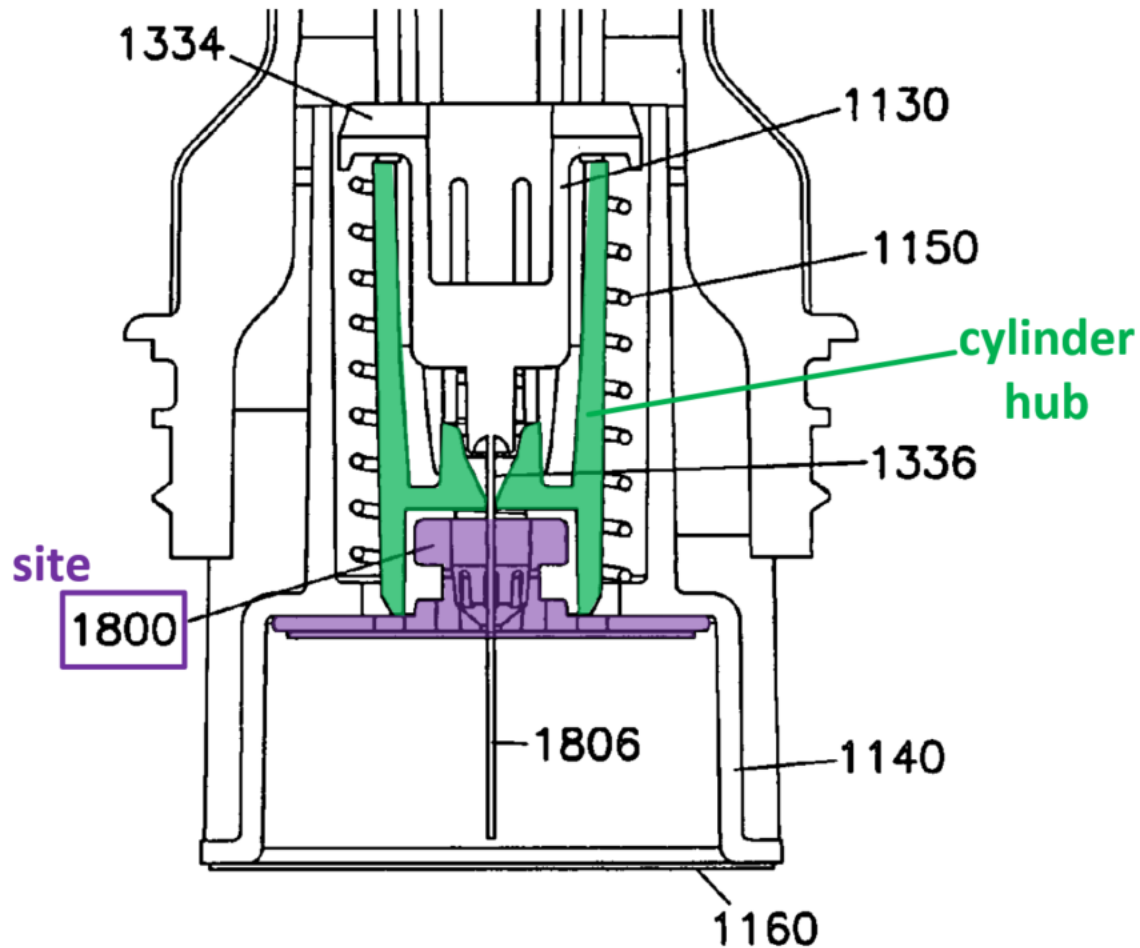


Cote, FIG. 80A (annotated)

EX2002, ¶281.

131. Mr. Leinsing relies on my previous statement that “Cote’s friction fit... ‘maintains the positioning of the site relative to the needle’” to support this interpretation. EX2002, ¶280 (citing EX1003, ¶55). However, Mr. Leinsing omits that I was referring to “frictional engagement between the *needle* and the *diaphragm*” not, as alleged, engagement between the inserter’s *cylinder hub* and *site*. EX1003, ¶55. Nowhere does Cote indicate a frictional engagement between the inserter’s cylinder hub and site/OBU. Mr. Leinsing relies on FIG. 80A to allegedly show this frictional engagement, however, Cote’s FIG. 80B (see below), which

shows a different cross-sectional view of the same device (EX1005, [0098]-[0100]) shows *clear spacing between the OBU and the sleeve 1120*. Accordingly, Cote's sleeve 1120 does not necessarily frictionally engage its OBU.



Cote, FIG. 80B (partial; annotated)

132. Further, unlike the site 1800 in Cote that includes an octagonal shape, the proposed Stafford+Cote combination implements a round, Stafford-like OBU, which would have additionally motivated a POSITA to include an anti-rotation feature like a second opening atop the OBU. The round shape of the Stafford OBU

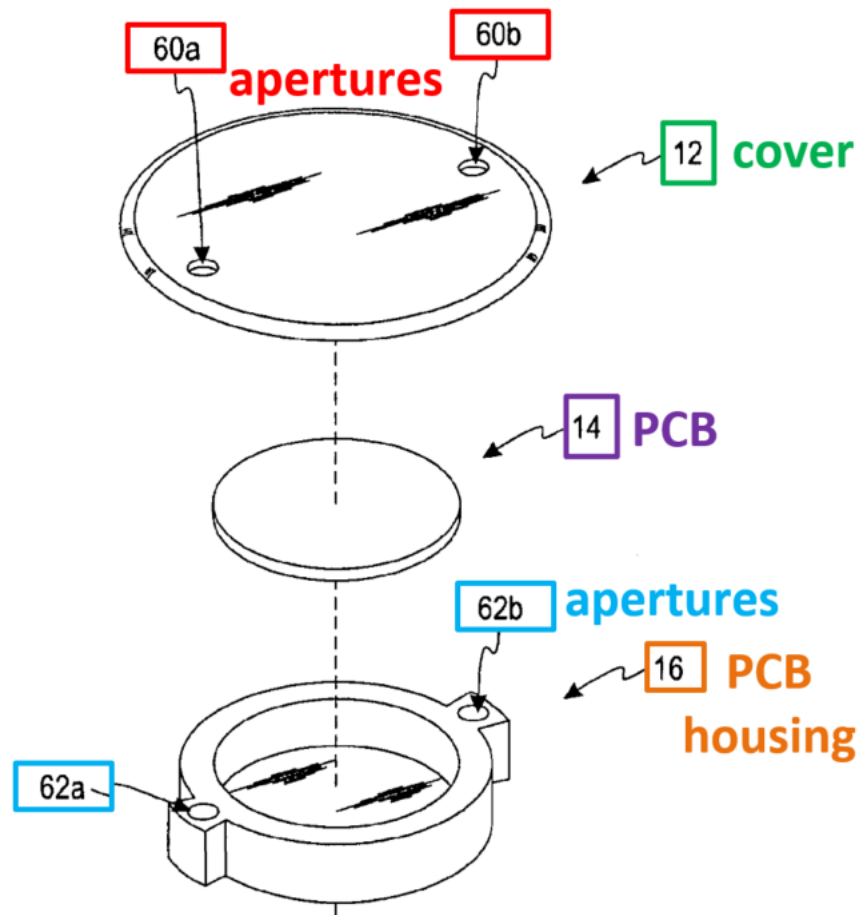
undermines Mr. Leinsing's position that the "cylinder hub 1120...of Cote's inserter pinches opposite sides of Cote's alleged OBU...which likewise would prevent OBU rotation," EX2002, ¶281, because a POSITA would understand that unlike the octagonal Cote OBU, "pinching" opposite sides of a round Stafford OBU would not effectively "prevent OBU rotation" in the Stafford+Cote combination.

133. Including an anti-rotation feature like a second opening atop the Stafford OBU would have been understood by a POSITA to allow the overall shape of the Stafford OBU to remain round, as proposed in the Stafford+Cote combination. And, a POSITA would have understood that Stafford's round OBU shape advantageously reduces the chance of Stafford's OBU snagging or catching (e.g., on a user's clothing), while in use.

134. Mr. Leinsing's argument that Brenneman does not teach preventing rotation (EX2002, ¶282) also fails. In order to function as described, Brenneman prevents *inadvertent* rotation *between portions of the OBU and the inserter* to allow the inserter and portions of the OBU to *rotate together* to affect needle insertion. EX1040, [0044]-[0046] ("The inserter 110 is typically spring-loaded such the reusable assembly 40 (including the cover 12 and the printed circuit board housing 16) are rotated...[w]hen using the cannula 24, during rotation of the continuous analyte monitoring assembly 10, the disposable housing 18 is stationary. The

remainder of the components...are rotated with respect to the disposable housing 18.”).

135. Mr. Leinsing alleges that in order to avoid moisture/contamination, a POSITA would not have been motivated to include openings such as taught by Brenneman. EX2002, ¶275. This argument is misleading and not responsive to the proposed combination. First, nowhere have I suggested that a POSITA would have been motivated to add tertiary apertures or through-holes to the OBU housing in a way that would expose electronics in the OBU housing to moisture/contamination. Second, Brenneman was aware of moisture/contamination considerations, as shown by the positioning of the apertures on the PCB housing 16, and demonstrated by its discussion that this positioning “assists in preventing or inhibiting contaminants from reaching the printed circuit board 14...” EX1040, [0029]. As clearly shown in Brenneman’s FIG. 3, the apertures 62a/62b (blue in the figure below) are positioned peripherally within the walls of the PCB housing 16 (orange) and configured such that they are away from and not in the same compartment as the PCB 14 (purple), which sits in the center of the PCB housing.



Brenneman, FIG. 3 (partial; annotated)

136. Further, a POSITA would have recognized, even in designing the “second opening” to provide the functions discussed above (about which the ’591 was silent), this second opening need not be located in a position where it could expose the housing compartment containing electronics or the sensor to moisture or contamination. In fact a POSITA would understand that this would not be a preferred design, for the same reasons Brennen recognized. Nowhere in my prior declaration do I state that the second opening would extend fully through the housing into the

compartment containing electronics, nor has PO proposed a claim construction to require that the claimed “second opening” do so.

E. Stafford+Cote+Say Teaches And Renders Obvious Claims 4, 7-8, 14-15, And 19-30

1. Stafford+Cote+Say Teaches The Claimed Height Profile

137. As discussed in § VII.B.1, *supra*, in denigrating the proposed Stafford+Cote+Say combination, Mr. Leinsing has not shown why the height of a two-part OBU such as taught by Say (which is referenced in Stafford) should be ignored here. Further, Say includes embodiments wherein the electronics are formed as part of the housing and only the *sensor* is later coupled thereto, which would not necessarily affect the height of the OBU. EX1008, 30:19-34 (“In some embodiments, the housing 45 of the on-skin sensor control unit 44 is a single piece.”). A POSITA would have understood the height of a single piece unit as taught by Say (EX1008, 30:19-22 and 30:33-34) or “all-in-one” OBU would be as small (or likely smaller) than the height of a multi-part unit.

2. Stafford+Cote+Say Teaches And Renders Obvious The Sleep/Idle Mode And Activation Claims

138. Say describes a sleep mode for conserving battery power of the electronics. EX1008, 31:45-47 (“The on-skin sensor control unit 44 optionally remains in a sleep mode prior to use to conserve the battery’s power”). Mr. Leinsing has not shown why a sleep mode for conserving battery power in a two-part OBU

such as taught by Say (and referenced in Stafford) should be ignored here. Further, Say teaches the OBU “detects that it is being used and activates itself...through a number of mechanisms” a POSITA knew, for example, using “actuation of a switch” or “change in resistance.” *Id.*, 31:47-52. Say does not provide extensive details on how to implement activation from a sleep mode because activating electronics when they were put in use was well-known and a POSITA would be able to implement a number of techniques to do so with a reasonable expectation of success. (I also understand that Say should be presumed to enable a POSITA to implement sleep/activation of electronics.) Say refers to the switch being activated when the control unit is coupled to a mounting unit—an indication that the sensor and OBU were deployed and the system should turn “on.” A POSITA knew a “change in resistance” also could be leveraged in several ways when an OBU is deployed to the skin and a sensor inserted under the skin—e.g., a change in resistance from skin contact or the sensor contacting subcutaneous fluid.

139. A POSITA would have understood that such a switch would have just as easily been placed on an “all-in-one” OBU to be activated upon contact with the user’s skin. It was known in the art to have on-body units that did not activate until they were in position on the skin. *See, e.g.*, EX1019, [0084], [0086]-[0087] (disclosing an on-skin treatment element wherein “the attachment of treatment element 1210 to the tissue is configured to activate it automatically...”). Placing

Say's activation switch on a Stafford-like OBU to be triggered when the OBU is deployed to the skin by a Cote-like inserter would have been an obvious design choice, and designed to work in the same way as the switch disclosed in Say: the electronics would activate when the sensor is inserted and electronics are ready to be used. Similarly, Say also teaches activation based on a change in resistance, which would include changed resistance of contacts on the OBU contacting the skin surface or the sensor contacting subcutaneous fluid. It would have been obvious from Say's teachings to activate an all-in-one Stafford-like OBU as in claims 8/26 of the '591 patent ("the sensor electronics are configured to be activated when the on-body unit is at or near the second position"). That is, based on Say's teachings, the sensor electronics in all-in-one Stafford-like OBU would be configured to activate when it contacted the skin (by way of a switch on the OBU or a change in resistance) or when the sensor was inserted under the skin and contacted subcutaneous fluid (causing a change in resistance). Indeed, a POSITA knew from the "sleep" mode teachings in the prior art that the electronics must be activated when put in use, and the lack of extensive details about how to do that only further establishes that it was well-known to POSITAs. Say's teachings to activate from a sleep mode were applicable to an all-in-one Stafford-like OBU and nothing about an all-in-one OBU changes the motivation or reasonable expectation of success to implement Say's teachings to activate an all-in-one Stafford-like OBU using a "switch" or "change in

resistance.” Until the OBU was deployed and sensor inserted, the battery would be conserved. Say’s express disclosure of conserving battery life would motivate a POSITA implementing Stafford+Cote+Say to include sleep/idle/ activation features to switch the OBU “on” when it is deployed. Based on the state of the art, a POSITA would have had a reasonable expectation of success in implementing such features in a Stafford-like OBU.

140. In any case, Stafford also teaches using a sleep mode for the OBU by referring a POSITA to Jin for details about the electronics. EX1004, [0043]. Jin teaches that “in one embodiment, the final step during the manufacturing process of the [OBU] transmitter 102 places the transmitter 102 in the lower power, non-operating state (i.e., post-manufacture sleep mode). In this manner, the shelf life of the transmitter 102 may be significantly improved.” EX1057, [0044].

3. Stafford+Cote+Say Teaches A Sensor Hub

141. Mr. Leinsing does not dispute that a “sensor hub” is a feature that supports the sensor and electrical contact between the sensor and electronics, and has offered no competing definition of what is meant by the term “sensor hub,” which is not defined in the ’591 patent and has no clear accepted meaning in the art. A POSITA would have understood that it would be advantageous for any OBU, including a Stafford-like OBU, to include a feature to ensure adequate contact between the sensor and electronics to ensure proper function of the device. Stafford

refers to Say, which provides one example of how to implement such adequate contact in the form of a support structure. EX1008, 34:59-61 (support structure is “provided under the sensor 42 to promote adequate contact between the contact pads 49 on the sensor 42 and the pins 84”).

142. Mr. Leinsing alleges that it would not have been obvious to include Say’s sensor hub because “Stafford’s sensor and electronics are already connected by the manufacturer.” EX2002, ¶310. Regardless of whether it is the manufacturer or the user connecting the sensor and electronics, supporting the sensor “to promote adequate contact between the...sensor 42 and the [electronics]” as taught by Say (EX1008, 34:60-61) would still have motivated a POSITA to implement a sensor hub providing those functions in a Stafford-like OBU. Say’s sensor and Stafford’s sensor have similar shapes and as such it would have been obvious to support the proximal sensor portion of each in a similar fashion with a reasonable expectation of success.

143. Moreover, a POSITA knew that a Stafford-like OBU, where a “portion of the analyte sensor [is] disposed within the housing and in electrical communication with the data processing unit,” EX1004, [0056], would require a way to hold the sensor and maintain electrical contact and it was well-known and conventional to use a feature like a sensor hub to do so. *See, e.g.*, EX1018, [0034], [0035], FIG. 4; EX1013, FIG. 4A; EX1021, FIGS. 29-32.

**F. A POSITA Would Have Had
A Reasonable Expectation Of
Success Implementing Grounds 3 And 4**

144. Mr. Leinsing alleges, referring to Stafford+Cote+Brenneman and Stafford+Cote+Shah, that I have not “explained why success would be reasonably expected from the combination.” EX2002, ¶¶338, 344. A POSITA would have had a reasonable expectation of success in implementing apertures (in either the top surface of the housing or in the DPU), because these are simple mechanical changes that a POSITA would have understood how to implement. A POSITA would have been motivated to make such a combination for the reasons discussed herein and in my previous declaration. *See* EX1003, ¶¶126-131, 144-149.

145. The ’591 patent does not describe the “second opening” or the “opening of the sensor electronics,” or describe any purpose or function for them. Brenneman and Shah are analogous art in the transcutaneous medical device field that teach the claimed openings and thus such openings are clearly relevant. Mr. Leinsing does not dispute that Brenneman and Shah are analogous art. Further, he has not provided any reasoning or evidence to suggest that implementing an “opening” would have been outside the skill set or ordinary creativity of a POSITA.

VIII. CONCLUSION

146. In my opinion, a POSITA would have viewed claims 1-30 of the '591 patent as being obvious in view of the cited references and the background knowledge of a POSITA, whether alone, or in the combinations described herein.

IX. AVAILABILITY FOR CROSS-EXAMINATION

147. In signing this declaration, I recognize that the declaration may be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross examination in the case. If cross examination is required of me, I will cooperate to the best of my ability to appear for cross examination by video or in person during the time allotted for cross examination.

X. RIGHT TO SUPPLEMENT

148. I reserve the right to supplement my opinions in the future to respond to any arguments that the Patent Owner raises and to take into account new information as it becomes available to me.

XI. SIGNATURE

149. I, Dr. Gary D. Fletcher, do hereby declare and state, 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 so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: October 25, 2024



Signature