

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
Issued: December 21, 2021
Application No.: 17/221,154
Filed: April 2, 2021

Title: ANALYTE SENSOR AND
APPARATUS FOR INSERTION OF THE SENSOR

PETITION FOR
INTER PARTES REVIEW OF U.S. PATENT NO. 11,202,591

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LIST OF 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 ”)
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 ”)
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No.	Description
1023	<i>intentionally left blank</i>
1024	<i>intentionally left blank</i>
1025	U.S. Publication No. 2008/0319414 (“ Yodfat-414 ”)
1026	U.S. Patent No. 7,207,974 (“ Safabash ”)
1027	U.S. Publication No. 2004/0204687 (“ Mogensen-687 ”)
1028	U.S. Publication No. 2002/0022855 (“ Bobroff-855 ”)
1029	U.S. Patent No. 9,566,384 (“ Gyrn ”)
1030	U.S. Patent No. 8,747,363 (“ Nielsen ”)
1031	U.S. Publication No. 2007/0093754 (“ Mogensen-754 ”)
1032	<i>intentionally left blank</i>
1033	<i>intentionally left blank</i>
1034	Steven W. Smith, <i>The Scientist and Engineer’s Guide to Digital Signal Processing</i> (2nd ed. 1999) (excerpted)
1035	B.A. Sheno, <i>Introduction to Digital Signal Processing and Filter Design</i> (2006) (excerpted)
1036	U.S. Publication No. 2009/0099521 (“ Gravesen ”)
1037	U.S. Publication No. 2009/0216215 (“ Thalmann ”)
1038	U.S. Publication No. 2008/0255440 (“ Eilersen ”)
1039	Scheduling Order, <i>Abbott Diabetes Care Inc. v. DexCom Inc.</i> , No. 1-23-cv-00239 (D. Del. filed Mar. 3, 2023)
1040	PCT Publication No. WO2008/115409 (“ Brenneman ”)
1041	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
1042	U.S. Publication No. 2008/0114280 (“ Stafford-280 ”)

MANDATORY NOTICES UNDER 37 C.F.R. § 42.8

1. Real Party-In-Interest

Dexcom, Inc. is the sole real party-in-interest.

2. Related Matters

The '591 patent (EX1001) has been asserted in the following litigations:

- *Abbott Diabetes Care Inc. et al. v. DexCom, Inc.*, Case No. 1:23-cv-00239 (DED), filed March 3, 2023.

3. Lead And Back-Up Counsel, And Service Information

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Petitioner consents to service via email at the above email addresses.

Pursuant to 37 C.F.R. § 42.10(b), concurrently filed with this Petition is a Power of Attorney executed by Petitioner and appointing the above counsel.

I. INTRODUCTION

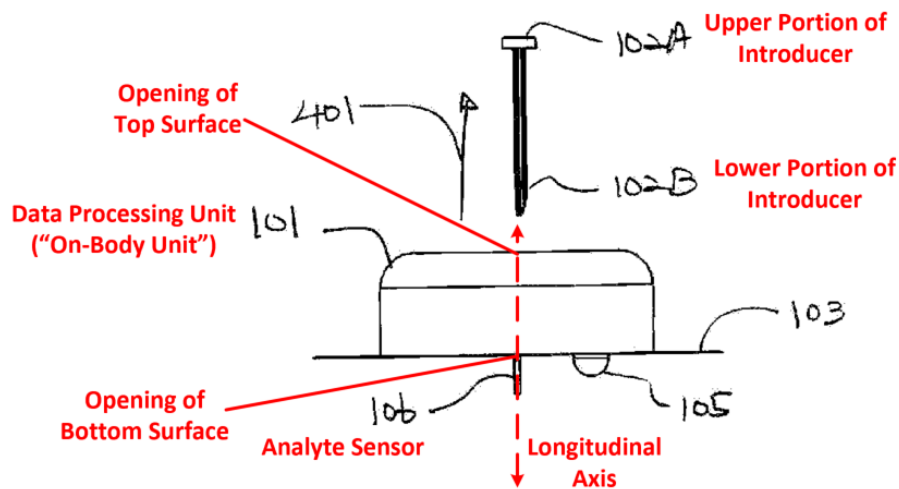
Dexcom, Inc. (“Petitioner”) respectfully requests *inter partes* review (“IPR”) of claims 1-30 of U.S. Patent No. 11,202,591 (“’591 patent”) (EX1001), allegedly owned by Abbott Diabetes Care Inc. (“Patent Owner”). As discussed below, these claims should be found unpatentable and cancelled.

The ’591 patent relates to on-body medical devices with a sensor placed partially under the skin to allow for monitoring of blood glucose levels. The challenged claims relate to an insertion assembly that includes (i) an on-body unit having electronics and a glucose sensor and (ii) an inserter with a sharp (*e.g.*, a needle) for inserting the sensor under the user’s skin and leaving the on-body unit secured to the user’s skin. *E.g.*, EX1001 (claim 1).

The supposed distinction over the prior art is the on-body unit comprising respective openings in top and bottom surfaces through which the sharp extends, and the inserter being configured to advance the on-body unit and sharp from a first position to a second position to pierce the skin of the user with the sharp and secure the on-body unit to the skin. EX1002, 977.¹

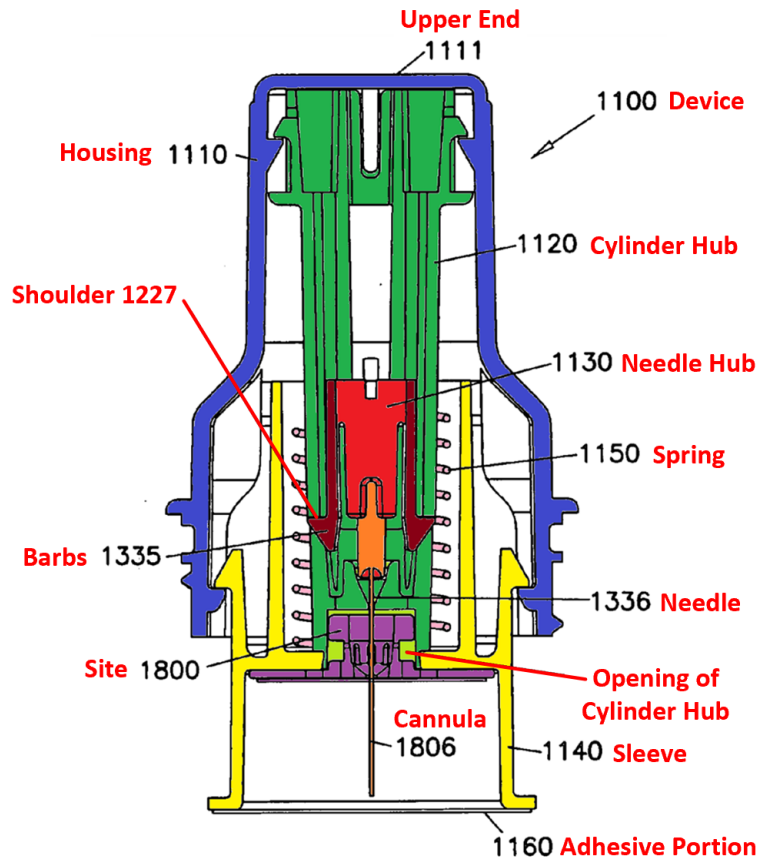
¹ Unless otherwise noted, file history cites are to the page numbers added by Petitioner.

Yet, known glucose sensing devices, such as that taught by Stafford (EX1004), included on-body electronics units with glucose sensors inserted using a sharp that extends through openings in the top and bottom surfaces, as shown in FIG. 4A below.



Stafford, FIG. 4A (annotated)

And inserters known to be useable for insertion of glucose sensors advanced an on-body unit and sharp from a first position to a second position to pierce the skin of the user with the sharp and secure the on-body unit to the skin. For example, Cote (EX1005) teaches an inserter with a needle that extends through openings in the top and bottom surfaces of an on-body unit ("site"), as shown below, and is used for inserting a portion of the device ("cannula") below the skin while leaving the on-body unit on the user's skin. EX1005, [0204]-[0213].



Cote, FIG. 80A, “delivery state” (annotated)

As explained below, a POSITA would have naturally combined the teachings of Stafford and Cote to create an insertion assembly that renders many challenged claims obvious. *Infra* Section VII. Other secondary references teach additional features that, when combined with Cote and Stafford, render obvious every other challenged claim. *Infra* Sections VIII-XI.

II. GROUND(S) FOR STANDING PER SECTION 42.104(a)

Petitioner certifies that the '591 patent is available for IPR and that Petitioner is not barred or estopped from requesting an IPR challenging the patent claims on the grounds identified in this Petition.

III. IDENTIFICATION OF CHALLENGE

A. Statement Of The Precise Relief Requested / Statutory Grounds

Petitioner requests *inter partes* review of claims 1-30 (the “Challenged Claims”) of the '591 patent, on the following statutory grounds:

	Reference(s)	35 U.S.C. §	Claims
Ground 1	Stafford (EX1004) and Cote (EX1005)	103	1-6, 9-14, 16-24, 27, 29-30
Ground 2	Stafford, Cote, and Say (EX1008)	103	4, 7-8, 15, 19-30
Ground 3	Stafford, Cote, and Brenneman (EX1040)	103	18, 21-24, 27, 29-30
Ground 4	Stafford, Cote, and Shah (EX1006)	103	9, 22-24, 27, 29-30
Ground 5	Stafford, Cote, Say, and Brenneman	103	21-30
Ground 6	Stafford, Cote, Say, and Shah	103	25-26, 28
Ground 7	Stafford, Cote, Brenneman, and Shah	103	22-24, 27, 29-30
Ground 8	Stafford, Cote, Say, Brenneman, and Shah	103	25-26, 28

For each ground, in Sections VII-XI below, the Petition presents evidence of unpatentability establishing a reasonable likelihood that the Petitioner will prevail in showing that each Challenged Claim is unpatentable.

With the filing of this Petition an electronic payment of \$52,750.00 for the requisite fees is being charged to deposit account no. 02-4550. 37 C.F.R. § 42.15 (a). Any fee adjustments may be debited/credited to that deposit account.

B. No Examiner Addressed These Unpatentability Grounds

Cote (EX1005) and Brenneman (EX1040) were neither cited nor discussed during prosecution of the '591 patent. Each provides express teachings on inserters for on-body units that were not considered by the Examiner.

While prior art references Stafford (EX1004), Shah (EX1006), and Say (EX1008), PCT publication WO2005/046780 to Cote, and US Publication No. 2010/0113897 to Brenneman were each identified on an IDS, nothing suggests the Examiner gave any of them more than a “[c]ursory consideration.” *See, e.g., Intex Rec. Corp. v. Team Worldwide Corp.*, IPR2018-00871, 2018 WL 4404107 at *5, Paper 14 at 13 (PTAB Sept. 14, 2018). Such minimal review “weighs against exercising discretion to deny under § 325(d).” *Id.*

C. Parallel Proceeding

Patent Owner asserts the '591 patent against Petitioner in district court, with trial set for March 2026. EX1039, 14. Any IPR based on this Petition would conclude well in advance of this date and thus the Board should not discretionarily deny institution in view of the district court case.

IV. THE '591 PATENT

The '591 patent, titled “Analyte Sensor And Apparatus For Insertion Of The Sensor” issued December 21, 2021, from an application filed April 2, 2021, and claims priority through a series of continuing applications to a provisional application filed February 3, 2009.

A. The '591 Patent's Specification

The '591 patent describes an inserter that inserts part of an on-body medical device (*e.g.*, a cannula or an analyte sensor) into a subject using an automatically retractable sharp. *E.g.*, EX1001, 2:13-36, 14:57-59, 16:20-28, FIGS. 8, 10, 28-31. The '591 patent describes an on-body unit that includes a data processing unit and an analyte sensor “constructed to be maintained ‘on the body’ of the subject for a period of time.” *Id.*, 9:31-41, FIGS. 1-9.

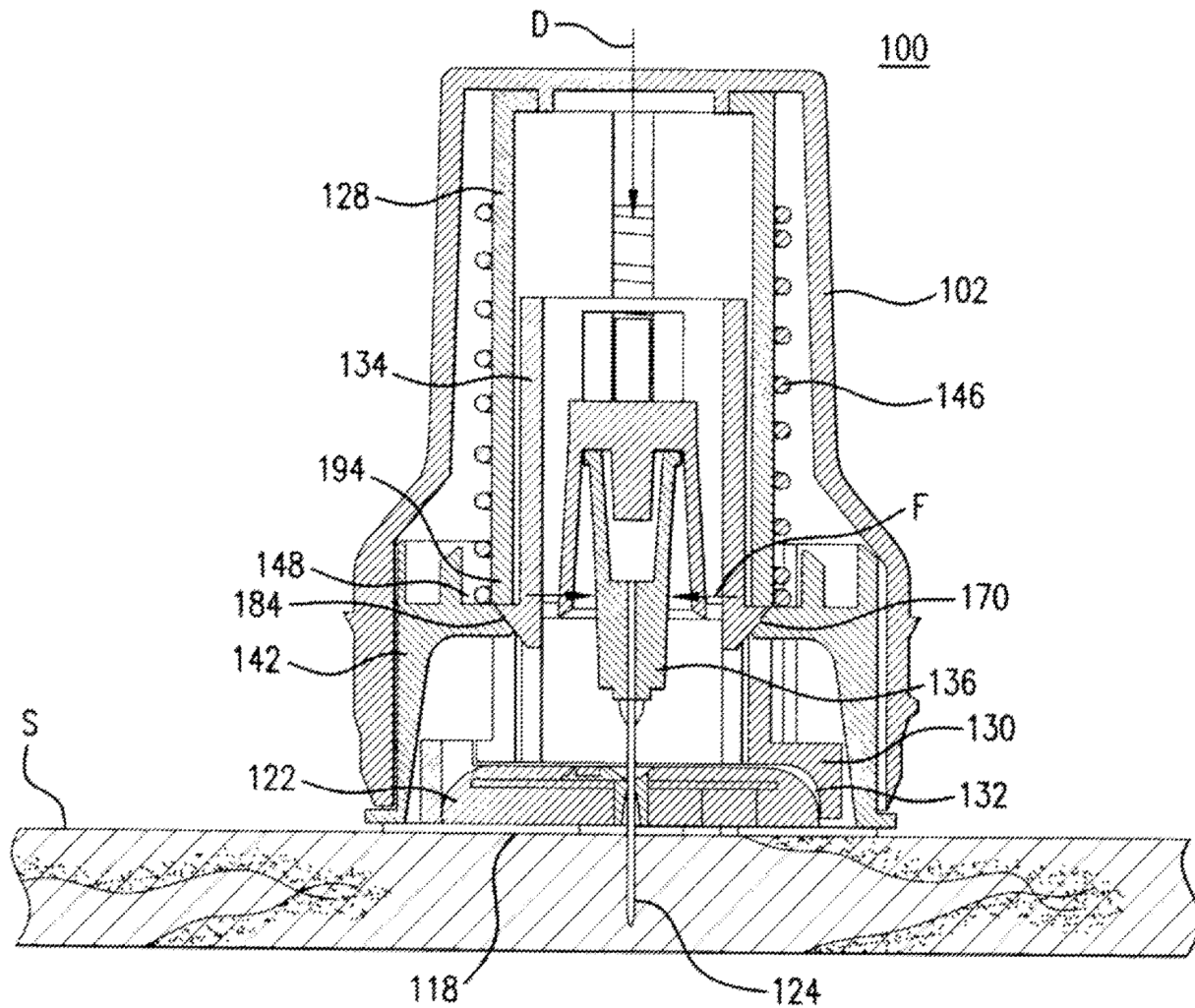


FIG. 30

'591 patent, FIG. 30

B. The Prosecution History

The application was filed April 2, 2021, along with a preliminary amendment canceling original claims 1-20 and adding claims 21-50. EX1002, 13-19, 124-125. Another preliminary amendment filed August 30, 2021, amended certain dependent claims. *Id.*, 174-184. Following an interview on November 2, 2021, the Examiner

entered minor amendments and applicant filed terminal disclaimers as to two patents and a then-co-pending application. *Id.*, 963, 876-885, 976 (indicating Examiner amendments to claim 21, which issued as claim 1). A Notice of Allowance issued November 12, 2021. *Id.*, 971-978.

C. Claims Listing

Claim 1 is exemplary and recites:

[1.1] ²	An insertion assembly, comprising:
[1.2]	(a) an on-body unit, comprising:
[1.3]	a housing comprising a top surface and a bottom surface, wherein the top surface comprises an opening of the top surface, wherein the bottom surface comprises an opening of the bottom surface, and wherein a longitudinal axis extends through the opening of the top surface and the opening of the bottom surface;
[1.4]	a glucose sensor; and
[1.5]	sensor electronics disposed within the housing and coupled with the glucose sensor; and
[1.6]	(b) an inserter, comprising:
[1.7]	a proximal end, a distal end, and an interior; and
[1.8]	a sharp,
[1.9]	wherein the on-body unit and the sharp are entirely disposed in the interior of the inserter,
[1.10]	wherein at least a portion of the glucose sensor is disposed in the sharp,
[1.11]	wherein the sharp extends through the opening of the top surface and the opening of the bottom surface along the longitudinal axis when the on-body unit is in a first position,
[1.12]	wherein the inserter is configured to advance the on-body unit and the sharp in a linear direction from the first position to a second position such that the sharp pierces skin of a user and the housing of the on-body unit is secured to the skin of the user in the second position,

² Numbering in left-hand column added by Petitioner.

[1.13]	wherein the distal end of the inserter is configured to be positioned on the skin of the user before advancement of the on-body unit and the sharp,
[1.14]	wherein the inserter is further configured to automatically retract the sharp from within the user and entirely into the interior of the inserter and leave a part of the glucose sensor in the skin of the user, and
[1.15]	wherein the distal end of the inserter is further configured to be removed from the skin of the user after automatic retraction of the sharp from within the user.

EX1001, 23:5-46 (claim 1).

The only other independent claim, claim 19, includes features from claim 1 along with limitations from certain claims that depend from claim 1:

[19.1]	An insertion assembly, comprising:
[19.2]	(a) an on-body unit, comprising:
[19.3]	a housing comprising a top surface and a bottom surface, wherein the top surface comprises an opening of the top surface, wherein the bottom surface comprises an opening of the bottom surface, and wherein a longitudinal axis extends through the opening of the top surface and the opening of the bottom surface;
[19.4]	a glucose sensor; and
[19.5]	sensor electronics disposed within the housing and coupled with the glucose sensor,
[19.6]	wherein the sensor electronics comprise a processor, a power source, an analog interface, a data storage unit, and wireless communication circuitry configured to communicate data indicative of a glucose level; and
[19.7]	(b) an inserter, comprising:
[19.8]	a proximal end, a distal end, and an interior; and
[19.9]	a sharp,
[19.10]	wherein the on-body unit and the sharp are entirely disposed in the interior of the inserter,
[19.11]	wherein at least a portion of the glucose sensor is disposed in the sharp,
[19.12]	wherein the inserter is configured to advance the on-body unit and the sharp in a linear direction from a first position to a second position such

	that the sharp pierces skin of a user and the housing of the on-body unit is secured to the skin of the user in the second position,
[19.13]	wherein a distance between the housing when the on-body unit is in the first position and the housing when the on-body unit is in the second position is greater than a maximum height of the housing,
[19.14]	wherein a height profile of the housing is less than or equal to approximately 10 millimeters,
[19.15]	wherein the sharp is configured to pierce the skin of the user at an angle substantially perpendicular to the skin of the user,
[19.16]	wherein the sharp extends through the opening of the top surface and the opening of the bottom surface along the longitudinal axis when the on-body unit is in the first position,
[19.17]	wherein the distal end of the inserter is configured to be positioned on the skin of the user before advancement of the on-body unit and the sharp,
[19.18]	wherein the inserter is further configured to automatically retract the sharp from within the user and entirely into the interior of the inserter and leave a part of the glucose sensor in the skin of the user, and
[19.19]	wherein the distal end of the inserter is further configured to be removed from the skin of the user after automatic retraction of the sharp from within the user.

Id., 24:62-25:48 (claim 19).

Each of the remaining challenged claims depends directly or indirectly either from claim 1, or claim 19, and their text is set forth in the specific Grounds in Sections VII-XI, below.

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

A. Person Of Ordinary Skill In The Art

The POSITA had a bachelor's degree in bioengineering, mechanical engineering, electrical engineering, or a related subject, and one or more years of experience researching, developing, and/or designing insertable medical devices,

including, *e.g.*, systems for implanting wearable medical devices such as cannulas, infusion sets, and analyte sensors, or equivalent experience. Less work experience may be compensated by a higher level of education, such as a master's degree, and vice versa. EX1003, ¶28.

B. State Of The Art

1. Inserters With Auto-Retracting Needles Were Known

Inserters using automatically retractable sharps to insert part of an on-body unit (*e.g.*, a cannula or glucose sensor) into a subject were well-known before 2009. For example, Cote describes a device comprising an automatically retractable needle for inserting part of a cannula into a subject. *See, e.g.*, EX1005, [0207], [0211]. Likewise, Raymond (EX1009) describes an insertion device including a needle with an “automatic retraction feature.” *See also* EX1009, [0127]; EX1014, [0108], [0110]; EX1003, ¶29.

2. Inserters Reduce Subject Pain And Anxiety

It was known that manual use of a needle to insert a device through the skin causes a patient pain and anxiety. *See, e.g.*, EX1036, [0004]-[0005] (“When performed manually, the penetration of the catheter-carrying needle into the body, however, may be considered uncomfortable for a patient, or may cause some other anxiety.”); EX1037, [0005].

It was also known that more automatic inserters reduced the amount of pain and anxiety felt by subjects, *e.g.*, by providing for faster needle puncturing and/or retraction. *See, e.g.*, EX1036, [0007] (“[O]ne advantage of the invention is to increase the comfort of a patient during the insertion [by using an inserter in which] the needle, after reaching its extended state, can be withdrawn quickly and automatically by a retraction apparatus.”); EX1037, [0005]. Indeed, by 2007, other patents had recognized that “many manufacturers” had designed inserters to reduce the amount of pain felt by subjects during transcutaneous device insertion. *Id.*; EX1036, [0007]; EX1003, ¶¶30-32.

**3. Inserter Designs Were Interchangeably Used
For Insertion Of Different Types Of Subcutaneous Devices**

It was well-known in the art that various inserters were interchangeably used for inserting analyte (*e.g.*, glucose) sensors or cannulas or other transcutaneous devices. *See, e.g.*, EX1010, [0015]–[0016], [0020]–[0023] (teaching an inserter for either a cannula or a glucose sensor), and EX1011, 4:20-5:2 (teaching an inserter used to deliver either an infusion device or a sensor device); *see also* EX1025, [0070]; EX1026, 1:33-40; EX1027, [0079]; EX1028, [0019]; EX1029, 2:23-26; EX1030, 13:12-16. In an IPR involving similar technology, the Board recently found a POSITA in March 2010 “would [be] aware of the interchangeability of sensors and

cannulas in inserter devices.” *Dexcom, Inc. v. Abbott Diabetes Care Inc.*, IPR2022-00605, Paper 29 at 32-34 (PTAB July 10, 2023).

Indeed, the ’591 patent states that its “inserter can be configured to insert various medical devices to the subject, such as for example, an analyte sensor, an infusion set, a cannula, or a lancet” (EX1001, 14:54-59), yet provides no meaningful guidance on how to configure or adapt the inserter for the various types of devices. *See also id.*, 1:21-31 (“an inserter device, for example, to insert an analyte sensor and/or an infusion set”), 2:13-20. This reflects the known interchangeability of inserter devices between infusion sets and analyte sensors and similar devices. EX1003, ¶¶33-34.

4. Low-Profile On-Body Devices Were Known

The desirability of “low profile,” “unobtrusive” on-body units was well known. *E.g.*, EX1005, [0228]; *see also* EX1004, [0045] (describing benefits of “smaller profile” on-body unit). Specifically, on-body-units were known to have a height profile of 10 mm or below. *See, e.g.*, EX1012, [0334]; EX1013, [0425]; EX1014, [0074]; EX1015, 29:63-64; EX1016, 30:33-34; EX1003, ¶35.

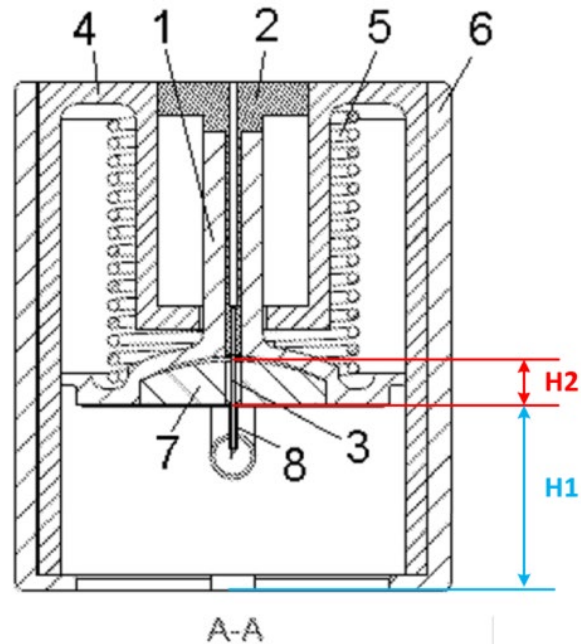
5. It Was Known To Protect Needles And Avoid Needle Sticks

Designing inserters to conceal the needle and prevent needle sticks was also well-known. *See, e.g.*, EX1009, [0127]. It was known to implement a needle/sharp extending past the distal tip of a transcutaneous device to protect the transcutaneous

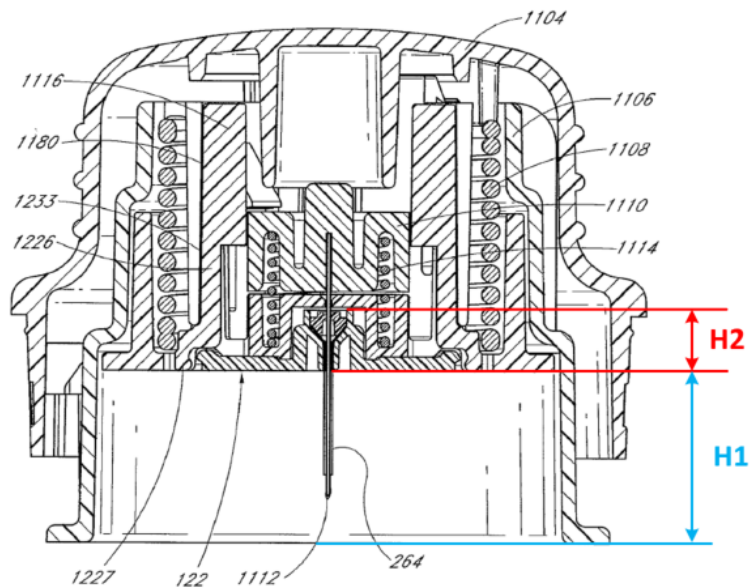
device (*see e.g.*, EX1004, FIG. 2; EX1005, FIG. 6A) and to shroud the needle within the inserter prior to and after insertion to minimize anxiety and avoid inadvertent needle-sticks. EX1005, [0005], [0235].

It was well-known that, to insert a transcutaneous device using an inserter, the needle and the on-body unit must travel a distance (“distance of travel”) at least equal to an implantable length of the transcutaneous device in order for the transcutaneous device to be fully inserted into the skin. *See, e.g.*, EX1017, [0027].

It was routine for this distance of travel (“H1”) to be greater than a height of the housing of the on-body unit (“H2”), to prevent the needle from being exposed at the distal end of the inserter for the reasons mentioned above. As shown below, Hasted (EX1011), Raymond (EX1009), Kovelman (EX1020), and Cote (EX1005) disclose on-body medical devices (*e.g.*, glucose sensors, infusion sets, etc.) with travel distances greater than the heights of their housings.



Hasted, FIG. 1 (partial, annotated)³



Raymond, FIG. 29 (partial, annotated)

³ Unless otherwise noted, all color annotations to the FIGS. throughout this Petition are added by Petitioner.

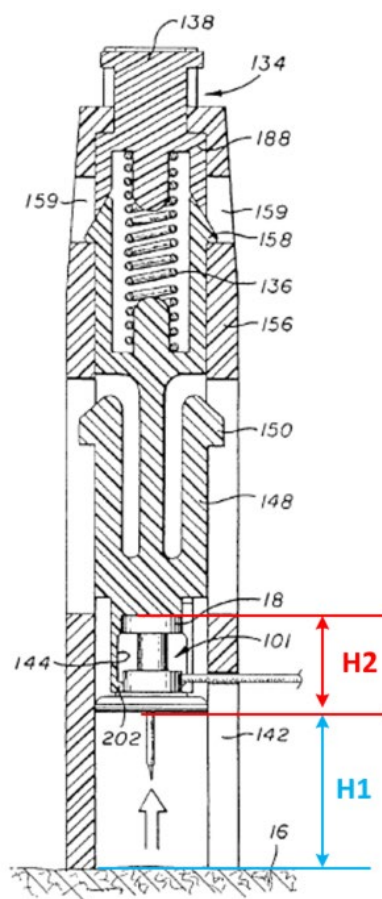
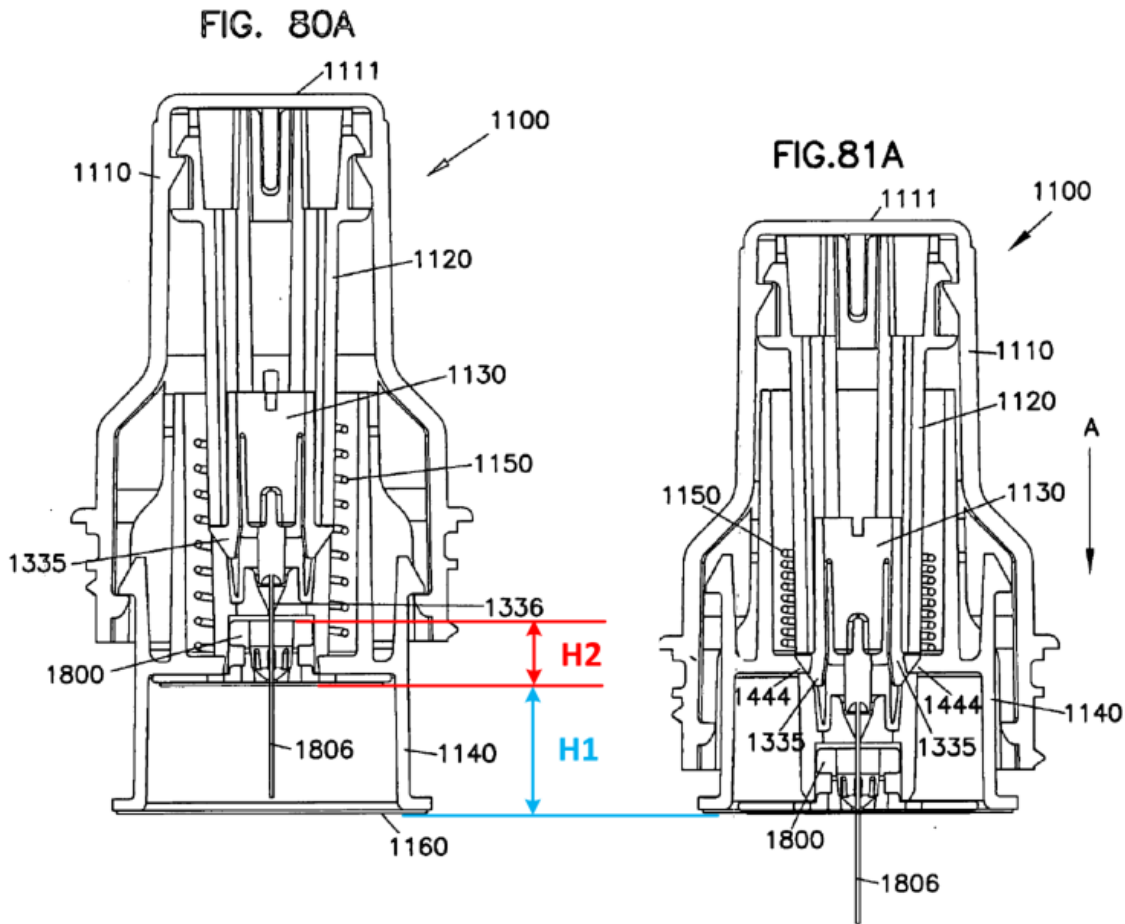


FIG. 23

Kovelman, FIG. 23 (annotated)



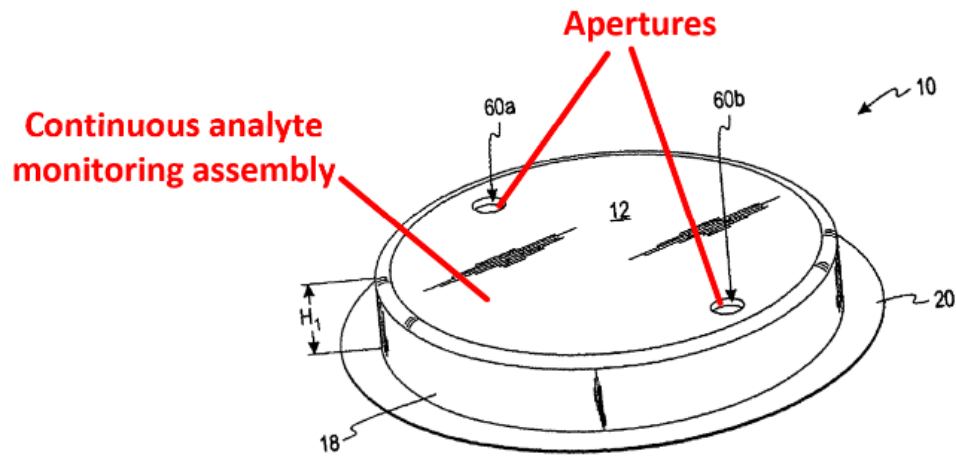
Cote, FIGS. 80A, 81A (annotated)

Accordingly, it was understood that the distance of travel should be greater than the implantable length of the transcutaneous device such that the needle is not exposed at the distal end of the inserter prior to use, thereby avoiding unwanted needle sticks prior to insertion. EX1003, ¶¶36-40.

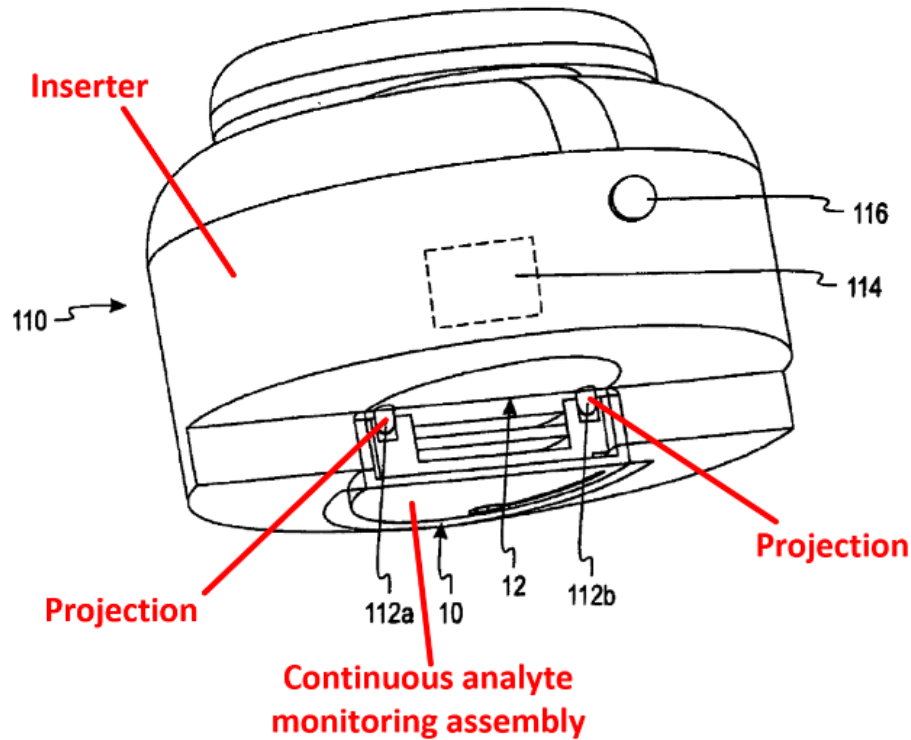
6. It Was Known To Couple The On-Body Unit To The Inserter By Using Peripheral Apertures On The Unit That Engaged With Projections On The Inserter

Using peripheral apertures on an on-body unit configured to engage corresponding features of an inserter to secure the on-body unit (and a

transcutaneous medical device coupled thereto) to the inserter was known. For example, Brenneman (EX1040), shown below, discloses peripheral apertures 60 which engage projections 112 of inserter 110 to couple the continuous analyte monitoring assembly 10 (“on-body unit”) to the inserter. EX1040, [0042], FIGS. 1, 8; *see also* EX1007, [0069] (peripheral recesses 77 engage protrusions 71); EX1003, ¶41.



Brenneman, FIG. 1 (annotated)



Brenneman, FIG. 8 (annotated)

VI. CLAIM CONSTRUCTION

For *inter partes* review, claim terms should be given the ordinary meaning that the terms would have to a person of ordinary skill in the art on the earliest effective filing date, in view of the specification and file history. 83 Fed. Reg. 51340; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (*en banc*).

Unless expressly discussed, Petitioner applies the plain and ordinary meaning of all claim terms below. Petitioner does not, however, waive any argument in any litigation that claim terms in the '591 patent are indefinite or otherwise invalid nor does Petitioner waive its right to raise or address issues of claim construction in any litigation. EX1003, ¶¶42-43.

**VII. GROUND 1: CLAIMS 1-6, 9-14, 16-24, 27, 29-30
ARE UNPATENTABLE OVER STAFFORD IN VIEW OF COTE**

A POSITA would have been motivated, with a reasonable expectation of success, to combine the teachings of Stafford and Cote in implementing an inserter device like that taught by Cote to insert and position an analyte sensor and associated on-body unit like that taught by Stafford. Stafford expressly describes the desire to avoid unwanted needle sticks (*e.g.*, EX1004, [0003], [0022]) and to provide “simple and accurate sensor deployment to the desired subcutaneous position” on a patient (*e.g.*, *id.*, [0007]).

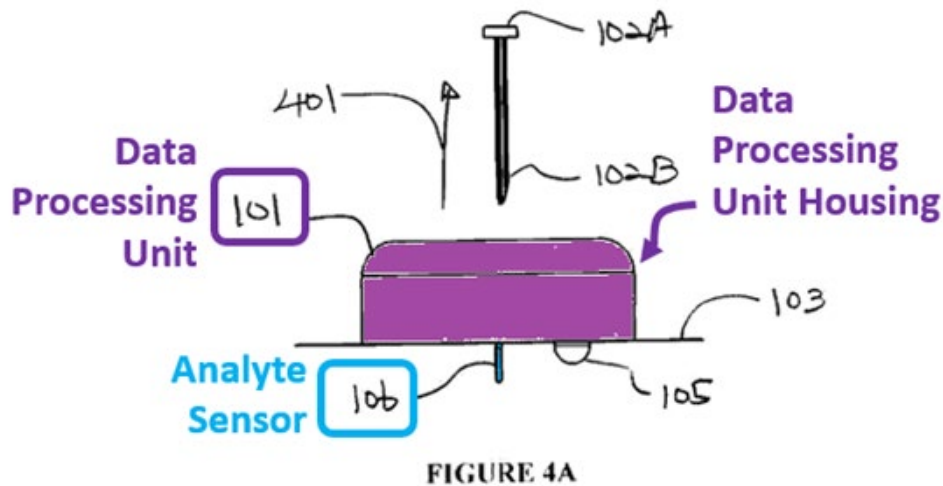
A POSITA implementing Stafford would seek out complementary teachings that further these goals and readily appreciate the benefits of Cote, which teaches an insertion device that further reduces the risk of accidental needle-sticks and provides quick, accurate insertion and positioning of the transcutaneous device and associated on-body unit while minimizing pain and anxiety of the patient. EX1005, [0005], [0235]-[0236]; EX1003, ¶44.

A. Stafford

U.S. Publication No. 2008/0097246 (“Stafford,” EX1004) published April 24, 2008, from an application filed September 10, 2006. Stafford qualifies as prior art

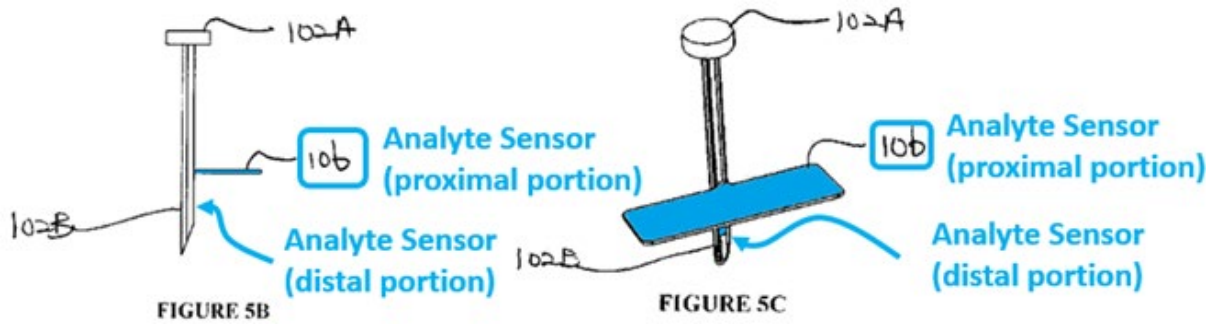
under Pre-AIA⁴ Section 102(b) if Abbott cannot show priority to the '639 provisional application and otherwise under at least Section 102(a).

Stafford describes an assembly comprising an analyte sensor and a data processing unit coupled thereto for processing analyte level measurements. *See, e.g.*, EX1004, [0036]. Stafford's data processing unit comprises a housing mounted on the skin and an analyte sensor. *See, e.g., id.*, FIG. 4A, [0027]. EX1003, ¶¶45-46.



Stafford, FIG. 4A (annotated)

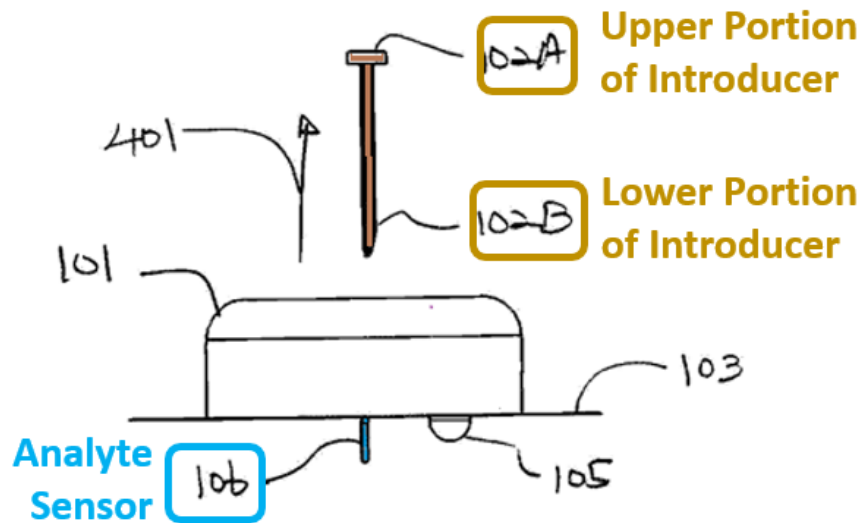
⁴ Throughout, Petitioner assumes applicability of the pre-AIA version of the Patent Statute, without conceding that Patent Owner is entitled to a pre-AIA priority date.



Stafford, FIGS. 5B, 5C (annotated)

Stafford specifies that its analyte sensor (in blue, above) may be a glucose sensor. EX1004, [0051], [0029]-[0030] (explaining that glucose is one of the analytes that may be monitored using its system).

Stafford further describes an introducer comprising a needle-like lower portion that pierces the subject's skin to insert part of the sensor coupled to the data processing unit into the subject. *Id.*, [0021], [0024], FIG. 4A. Subsequently, the introducer is withdrawn from the subject, leaving part of the sensor within the skin. *Id.*, [0024]. EX1003, ¶¶47-48.



Stafford, FIG. 4A (annotated)

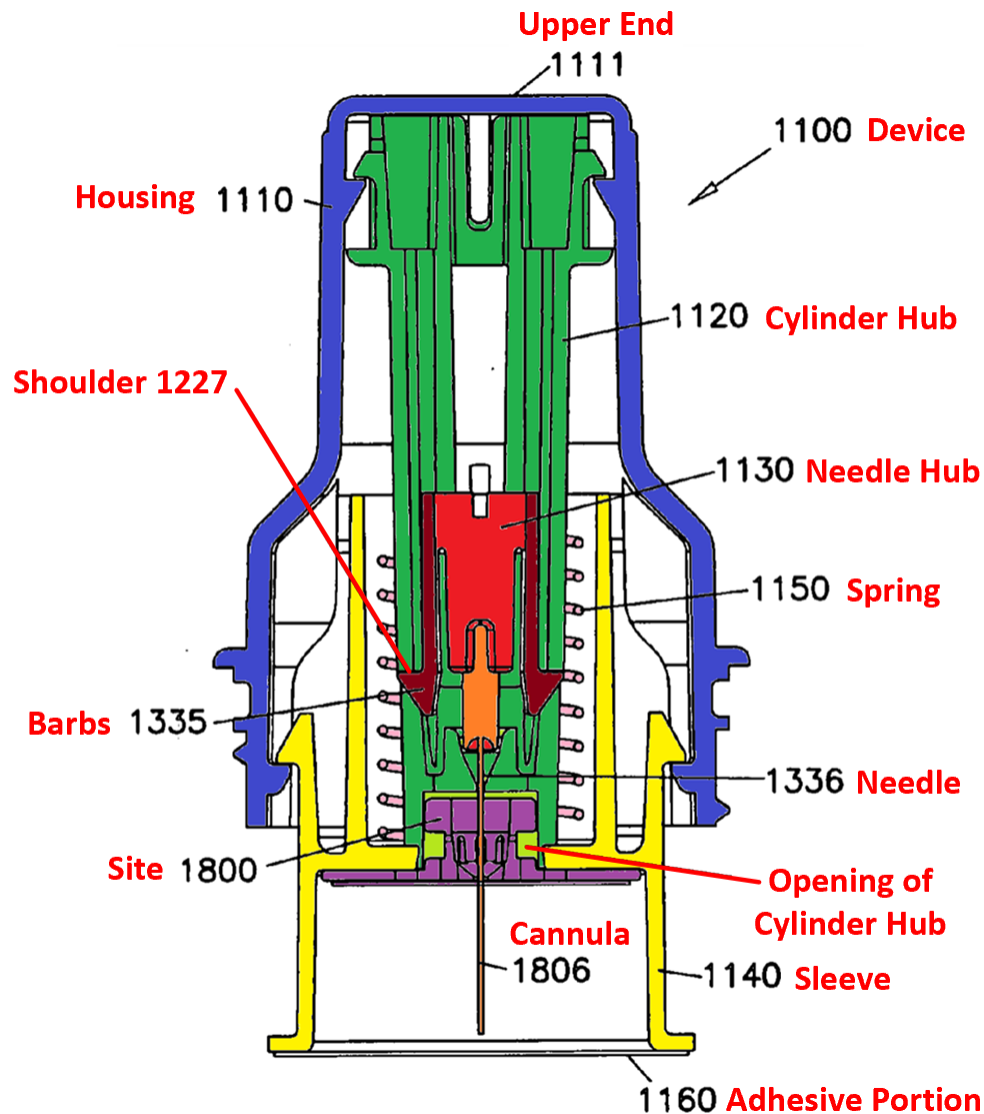
Stafford explains that withdrawing and discarding the introducer “requires a level of care” to avoid injury from an introducer’s sharp tip and that “particular precautions” should be taken to avoid contact with the sharp tip, after it has contacted the subject’s biological fluids. EX1004, [0003]; EX1003, ¶49.

B. Cote

U.S. Publication No. 2005/0101932 (“Cote,” EX1005), published May 12, 2005, from an application filed November 10, 2003. Cote qualifies as prior art under at least pre-AIA Section 102(b).

Cote teaches a device that uses an automatically retractable needle to insert a cannula of an infusion device into a patient’s skin. EX1005, [0179], [0236]. As shown below, Cote’s insertion device generally includes a housing (blue), a cylinder

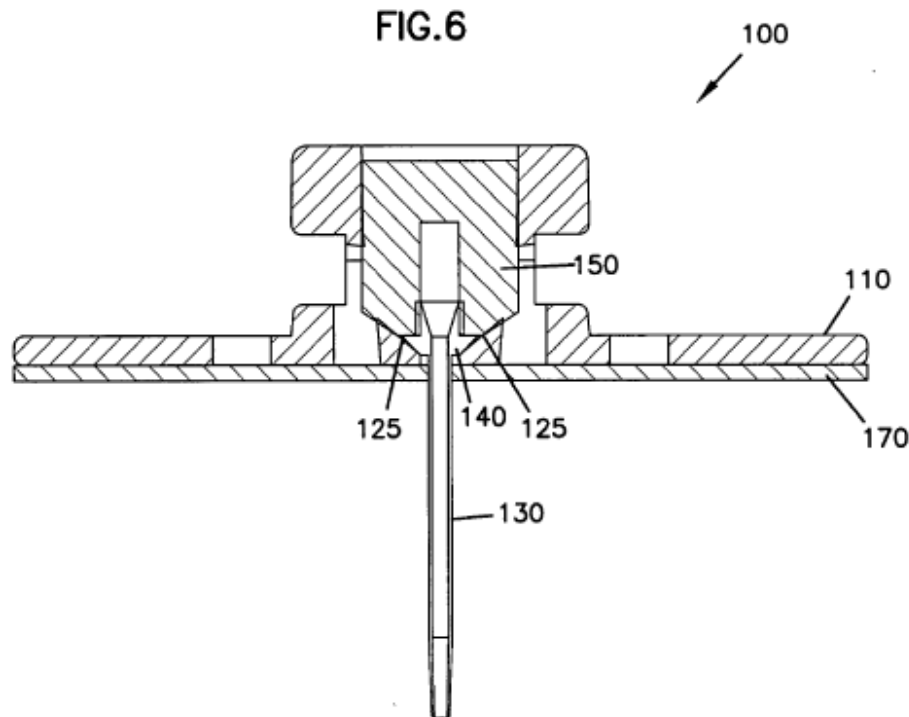
hub (green), a needle hub (red) including needle (orange), a sleeve (yellow), and a spring (pink). *Id.*, [0180], FIG. 80A;⁵ EX1003, ¶¶50-51.



Cote, FIG. 80A, “delivery state” (annotated)

⁵ For clarity purposes, only the cross-sectional surfaces of housing 1110 and sleeve 1140 are annotated in color.

Cote's cannula is part of a "site," an on-body unit that includes a base "coupled to the skin of the patient." *E.g.*, EX1005, [0134], [0195]. Cote FIG. 6A shows an exemplary on-body site with transcutaneous cannula 130, base 110, and adhesive portion 170 for affixing the site to the patient's skin:



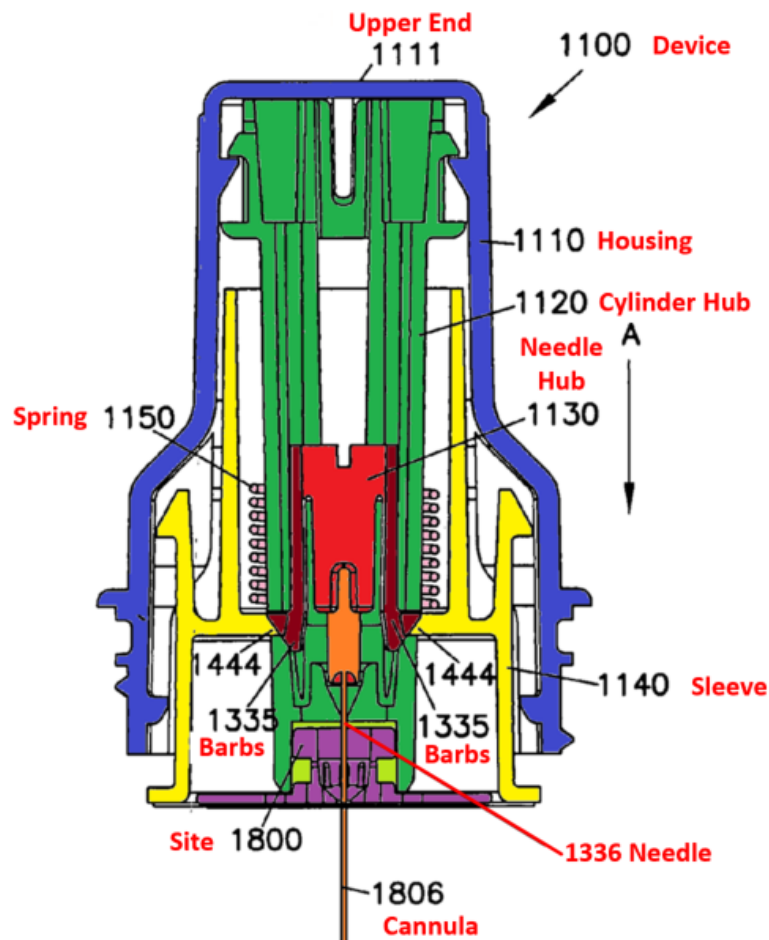
Cote, FIG. 6A, cross-section of a "site" device

In Cote's pre-insertion "delivery state," the needle extends through the site and cannula, and is disposed within and shrouded by the rest of the inserter. *Id.*, [0205]; FIG. 80A; EX1003, ¶¶52-53.

To retain the site within the inserter, an elastomeric diaphragm of the site frictionally engages the needle, as shown in FIG. 6A, above. EX1005, [0145],

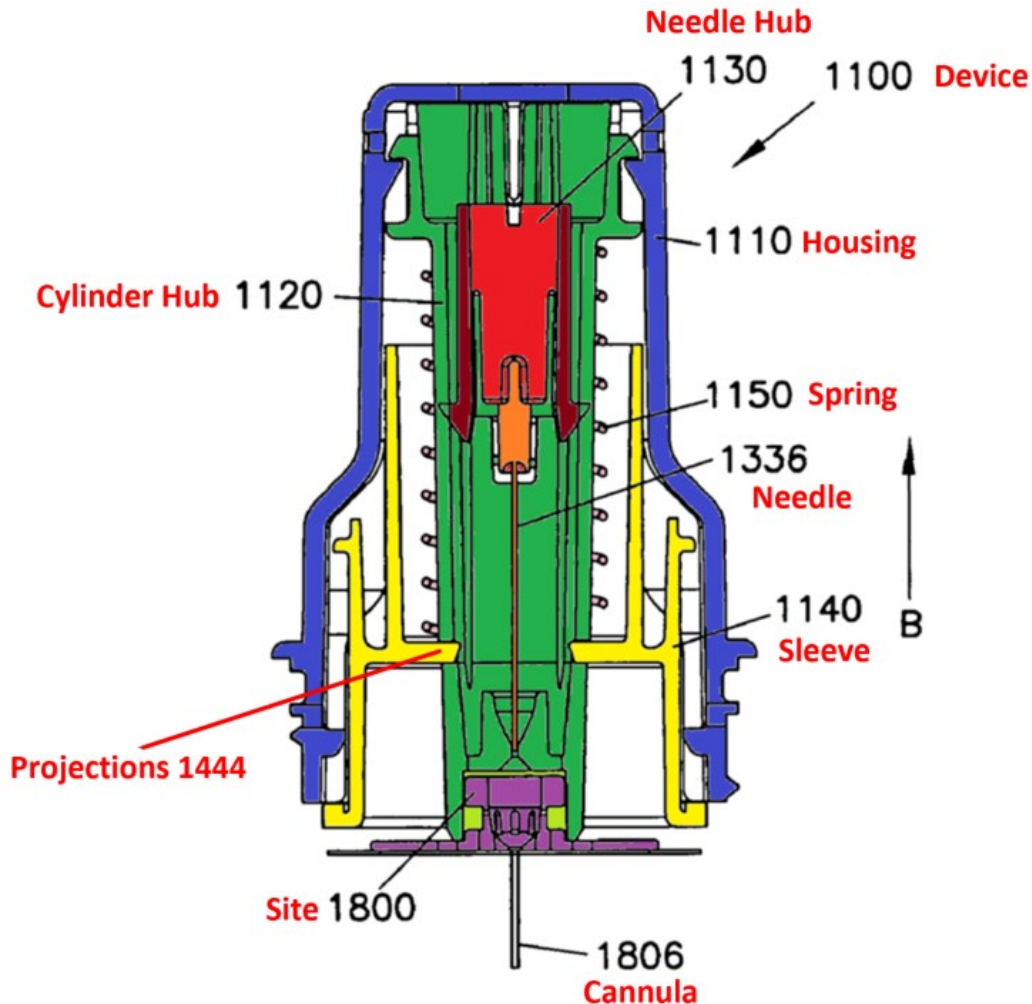
[0205]; *see also id.*, [0165] (describing diaphragm resealing itself once needle is removed). EX1003, ¶¶54-56.

To transition the device from the delivery state (FIGS. 77, 80A-80B) to a trigger state (FIGS. 78, 81A-81B) in which the cannula is “inserted into the skin of a patient,” “the patient applies pressure to the upper end 1111 of the housing 1110...” EX1005, [0012], [0203], [0207].



Cote, FIG. 81A, “trigger state” (annotated)

Specifically, several structures (housing, cylinder hub, needle hub) move together relative to the sleeve as the device is transitioned from the delivery state to the trigger state. *Id.*, [0183], [0185]; EX1003, ¶¶57-58.



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

Thereafter, the device “automatically retract[s] the needle while leaving the site placed on the skin, thereby reducing the patient’s contact with the exposed needle.” EX1005, [0236]. Finally, the inserter is removed from the patient’s skin. *Id.*, [0213]; EX1003, ¶¶59-60.

C. Combining The Teachings Of Stafford And Cote

A POSITA would have been motivated, with a reasonable expectation of success, to combine Stafford's teachings on an analyte sensor, introducer ("sharp"), and data processing unit ("on-body unit") with Cote's teachings on automatically-retracting insertion devices ("inserters"). A skilled artisan would have combined these respective teachings into an improved design (hereinafter, "Stafford+Cote"), that included benefits from each reference and adjusted the inserter and/or on-body unit as needed for them to cooperate and function as intended, as discussed below.

The resulting combination has the following elements cooperating as follows:

- A data processing unit as taught by Stafford, including:
 - a housing with openings in the top and bottom surfaces;
 - an analyte sensor, *e.g.*, a glucose sensor; and
 - electronics coupled with the analyte sensor;
- an introducer sharp, as taught by Stafford, configured to insert a portion of the sensor into a subject, the sharp extending through the data processing unit and integrated within a Cote-like inserter device; and
- a device for insertion as taught by Cote, including the inserter's needle-based insertion and automatic retraction mechanisms.

EX1003, ¶¶61-62.

Stafford+Cote includes an inserter as taught by Cote integrated with Stafford's introducer sharp and configured to advance Stafford's data processing unit and introducer from a first position to a second position such that Stafford's data processing unit is secured to the skin of the user in a second position. Stafford+Cote is further configured to retract Stafford's introducer sharp entirely into the interior of the inserter leaving a part of the sensor in the user's skin.

A POSITA would have been motivated, with a reasonable expectation of success, to combine Stafford and Cote by implementing a Cote-like inserter to deploy Stafford's on-body unit and sensor for at least the following reasons. *Id.*, ¶¶63-64.

First, Cote improves upon an aspect of insertion specifically identified by Stafford, namely, preventing accidental needle sticks when withdrawing the needle from the subject. EX1004, [0003], [0022]. Stafford lacks a way to prevent contact with the introducer's exposed lower portion after the guard is removed prior to insertion and after the introducer is withdrawn. Cote teaches an inserter that guards the needle not only prior to insertion but also "protect[s] against inadvertent contact with the needle" during insertion (EX1005, [0235]) and automatically retracts the sharp after insertion (*id.*, abstract, [0236]), thus avoiding undesired contact with "the tip of [Stafford's] inserter [that] has come into fluid contact with the patient's biological fluids." EX1004, [0003]; *see id.*, FIGS. 5B-5C. A POSITA would be

motivated to utilize Cote’s teachings to obtain benefits from shrouding the needle both prior to and after insertion. EX1005, [0235]-[0236].

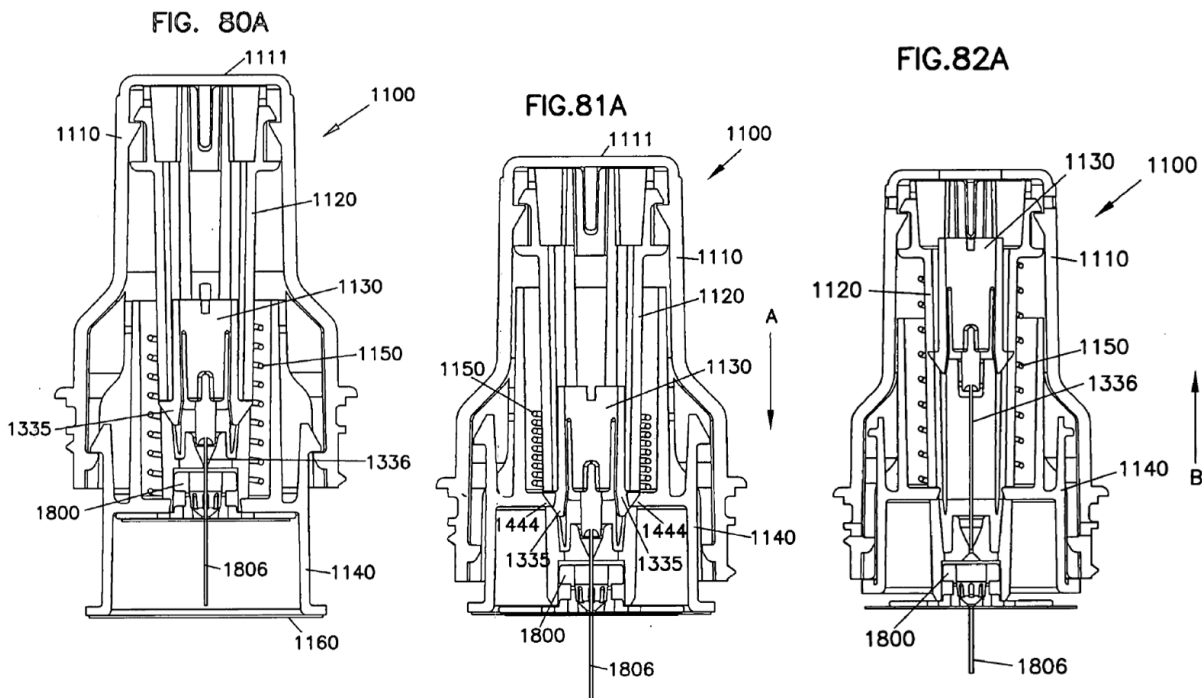
Second, and relatedly, a POSITA would have recognized the benefits of using a shrouded and automatically-retracting inserter to minimize any pain or anxiety that the patient might experience due to use of a needle-implanted device like that taught by Stafford. EX1003, ¶¶65-66; *see also Dexcom, Inc. v. Abbott Diabetes Care Inc.*, IPR2022-00605, Paper 29 at 32-34.

Third, the teachings complement one another, as Cote teaches an all-in-one insertion assembly that comes with the on-body unit pre-loaded within the inserter and that separates from the on-body unit only after insertion. This aligns with Stafford’s goal of “a single disposable assembly” that does not require “a *separate* sensor introducing device.” EX1004, [0044].⁶ A POSITA would recognize that such all-in-one systems provided benefits over other assembly-required systems that used a separate insertion device, *e.g.*, the Say insertion gun referenced in Stafford (EX1008, 2:66-3:15), which the user had to align with and affix to the on-body unit prior to insertion. Like Stafford, Cote teaches an inserter assembly that obviates the need for users to perform these additional, potentially intimidating steps.

⁶ Emphases throughout are added, unless otherwise noted.

Similarly, Cote teaches an insertion assembly that is easily graspable and operable by a single hand, and notes the advantages of such an assembly. EX1005, [0234], [0181], [0197]. This aligns with Stafford's teachings on an assembly that "may be easily operated using one hand by the user or the patient" (EX1004, [0007]), thus further motivating a POSITA to combine the two teachings as described herein.

Finally, a POSITA would have had a reasonable expectation of success in combining the teachings of Stafford and Cote as both references are directed to the deployment of transcutaneous medical devices and use of infusion devices (Stafford's sensor can be used in connection with infusion devices), the teachings in these references complement one another and combining their teachings would have yielded nothing more than predictable results. *Id.*, [0032], [0042]; EX1005, [0002]. EX1003, ¶¶67-69.



Cote, FIGS. 80A, 81A, 82A

Both Stafford's introducer and Cote's device comprise a needle (*e.g.*, lower portion of Stafford's introducer and Cote's needle, respectively) configured to actuate in a direction substantially perpendicular to the subject's skin to deploy a transcutaneous device. EX1004, FIG. 4A; EX1005, FIGS. 79A-83B. Since a POSITA would have realized that the lower portion of Stafford's introducer and Cote's needle perform the same function with similar structures, a POSITA would have easily combined the teachings to create an insertion assembly that would position Stafford's on-body unit and sensor using Cote's insertion device.

For at least these reasons, a POSITA would have naturally implemented an insertion assembly that incorporated Cote's teachings on an inserter device with

Stafford's teachings on a sensor device with a partially implantable sensor and an on-body unit with associated sensor electronics. As explained in the following sections, such an insertion assembly meets all elements of the independent claims and many dependent claims.

Like the '591 patent, Stafford and Cote are each directed to the insertion of transcutaneous medical devices for diabetes treatments. Thus, Stafford and Cote are analogous art to the claimed invention of the '591 patent. EX1003, ¶¶70-72.

1. Claims 1/19⁷

[1.1]/[19.1]⁸ An insertion assembly, comprising:

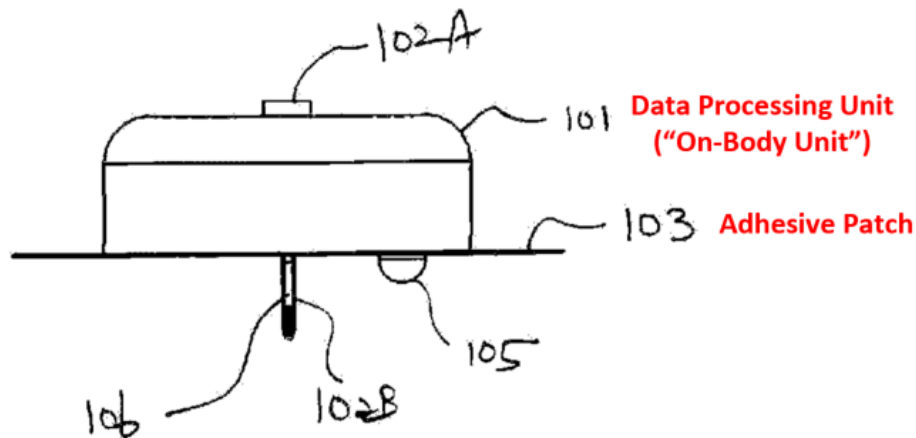
To the extent the preamble is limiting, the Stafford and Cote combination described above (hereinafter, "Stafford+Cote") includes an insertion assembly. As explained in the following paragraphs, this assembly has all the features recited in the remaining elements of claims 1 and 19. EX1003, ¶73.

⁷ The elements of claim 19 that correspond to those of claim 1 are mapped herein with claim 1, the remaining elements are mapped with claims 3, 4, 5, and 14.

⁸ Reference numbers in the format of [claim#.limitation#] are added throughout for ease of reference.

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

Stafford+Cote includes an on-body unit based on Stafford's teachings of an on-body data processing unit that adheres to "a surface of a subject such as the skin of a patient." EX1004, [0019], FIG. 2.

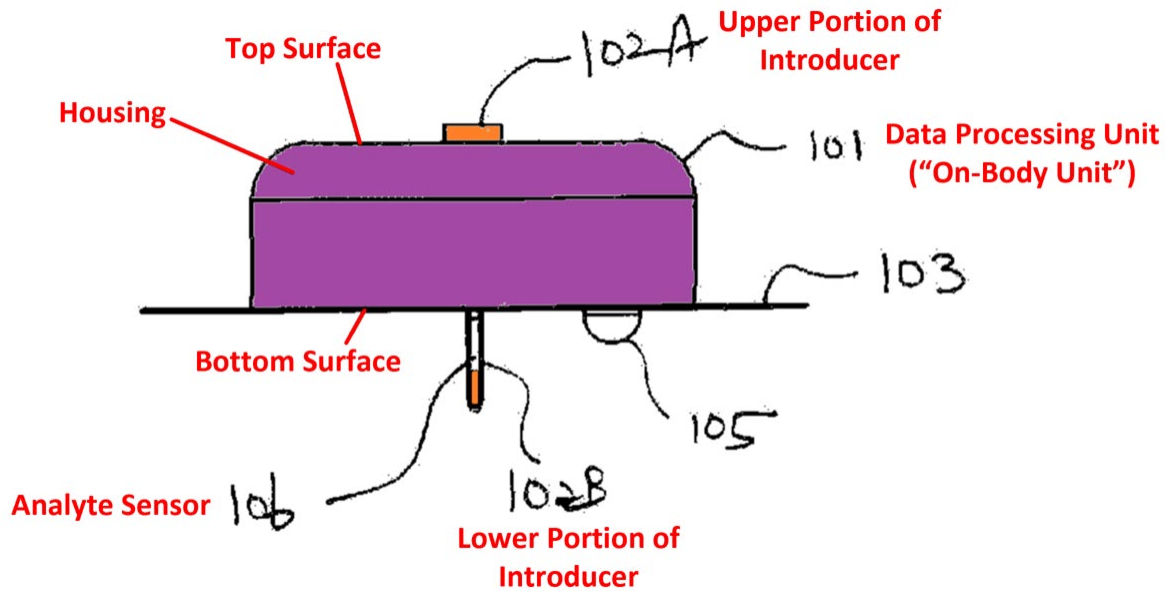


Stafford, FIG. 2 (annotated)

EX1003, ¶74.

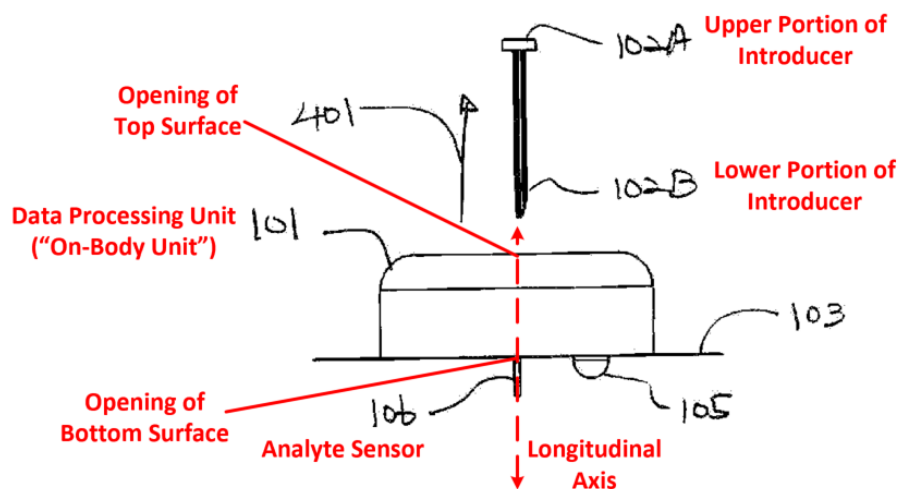
[1.3]/[19.3] a housing comprising a top surface and a bottom surface, wherein the top surface comprises an opening of the top surface, wherein the bottom surface comprises an opening of the bottom surface, and wherein a longitudinal axis extends through the opening of the top surface and the opening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

Stafford+Cote's on-body unit includes a "housing" (purple) comprising an "upper surface" (top surface) and a "bottom surface," as taught by Stafford. *E.g.*, EX1004, [0020].



Stafford, FIG. 2 (annotated)

Each of these top and bottom surfaces comprises an opening, and a longitudinal axis extends through the opening of the top surface and the opening of the bottom surface, allowing the introducer 102A/B to extend through the housing from top to bottom. EX1004, [0020], FIG. 2 (above).



Stafford, FIG. 4A (annotated)

Stafford FIG. 4A (above) shows how the introducer may be removed through this longitudinal axis in the housing, confirming that the longitudinal axis extends through the two openings. *Id.*, [0026]; EX1003, ¶¶75-77.

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

Stafford+Cote's on-body unit includes an "analyte sensor" of the type taught by Stafford. *E.g.*, EX1004, [0023], FIGS 2, 4A-4B. Stafford teaches that "[t]he analyte sensor may include a glucose sensor." *Id.*, [0051]. Thus, it was obvious to implement Stafford+Cote using an on-body unit comprising a glucose sensor as the analyte sensor. EX1003, ¶78.

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

Stafford+Cote's on-body unit includes sensor electronics disposed within the housing, as taught by Stafford. EX1004, [0006] ("a data processing unit substantially disposed within the housing"), [0040] (describing sensor electronics "components in the data processing unit 101"). Stafford teaches sensor electronics that include a "processor 704," a power source ("power supply 707"), an "analog interface 701," and wireless communication circuitry ("RF transceiver 706") configured to communicate data indicative of a glucose level. *Id.*, [0039]-[0040], [0052], FIG. 7.

These sensor electronics are coupled with the glucose sensor. *Id.*, [0028], [0039] (describing data processing unit's "analog interface 701 configured to

communicate with the sensor 106 (FIG. 2) ...”); *see also id.*, [0036], [0039]-[0043], FIG. 7; EX1003, ¶79.

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

Stafford+Cote includes a Cote-like inserter (*e.g.*, similar to Cote’s “device 1100”) configured to insert part of a transcutaneous device into a patient and place the on-body unit on the skin of the patient. EX1005, [0202] (“device 1100 can be used to insert a cannula 1806 of an infusion device, such as site 1800, into the subcutaneous layer of skin of a patient”).

FIG.54

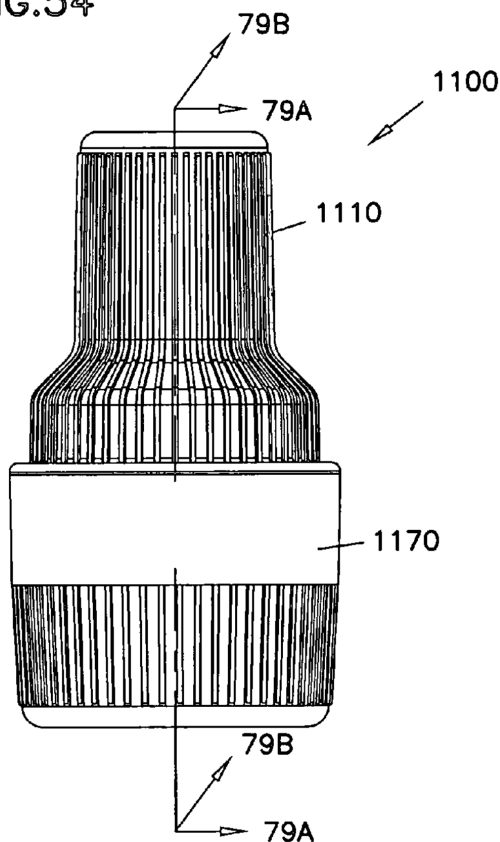
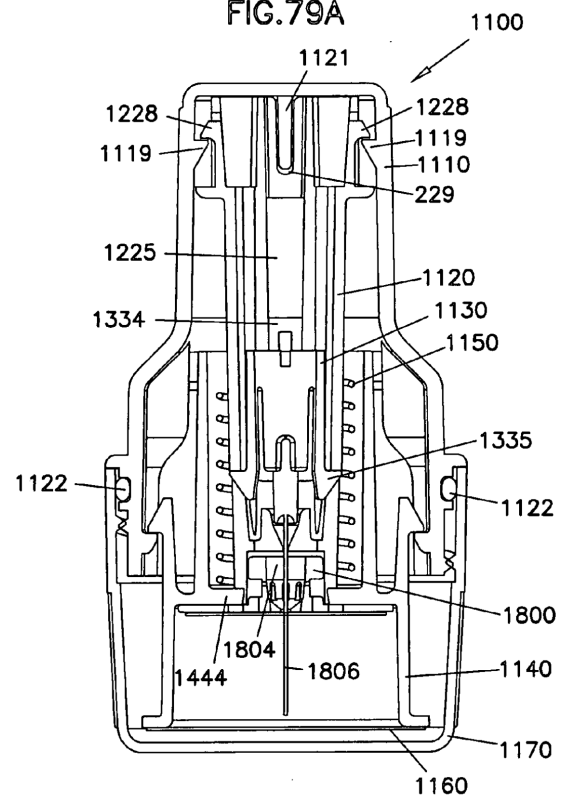


FIG.79A

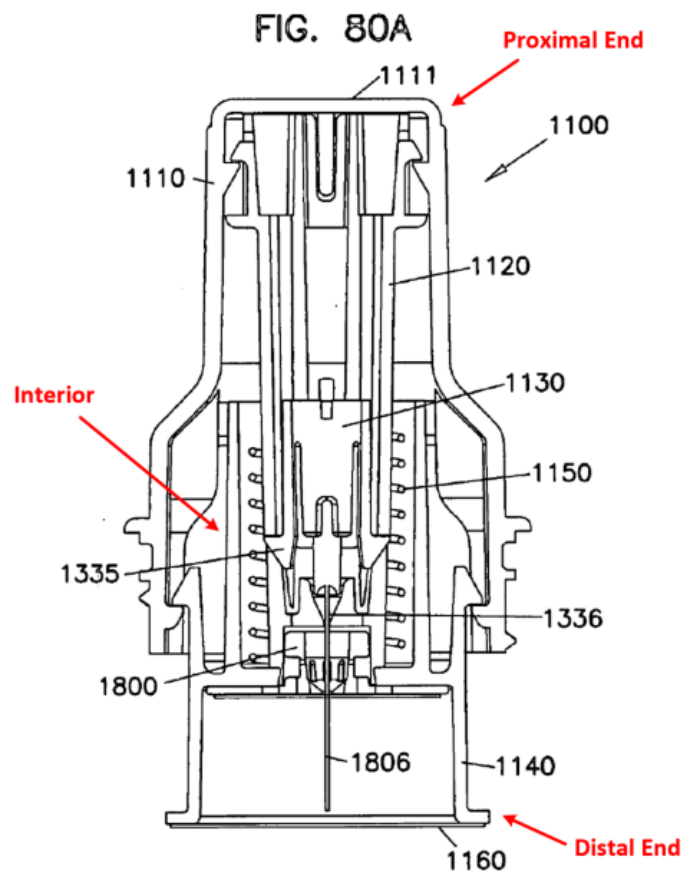


Cote, FIGS. 54 and 79A

In Stafford+Cote, an inserter like that taught by Cote deploys an on-body unit and analyte sensor as taught by Stafford. EX1003, ¶¶80-81.

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

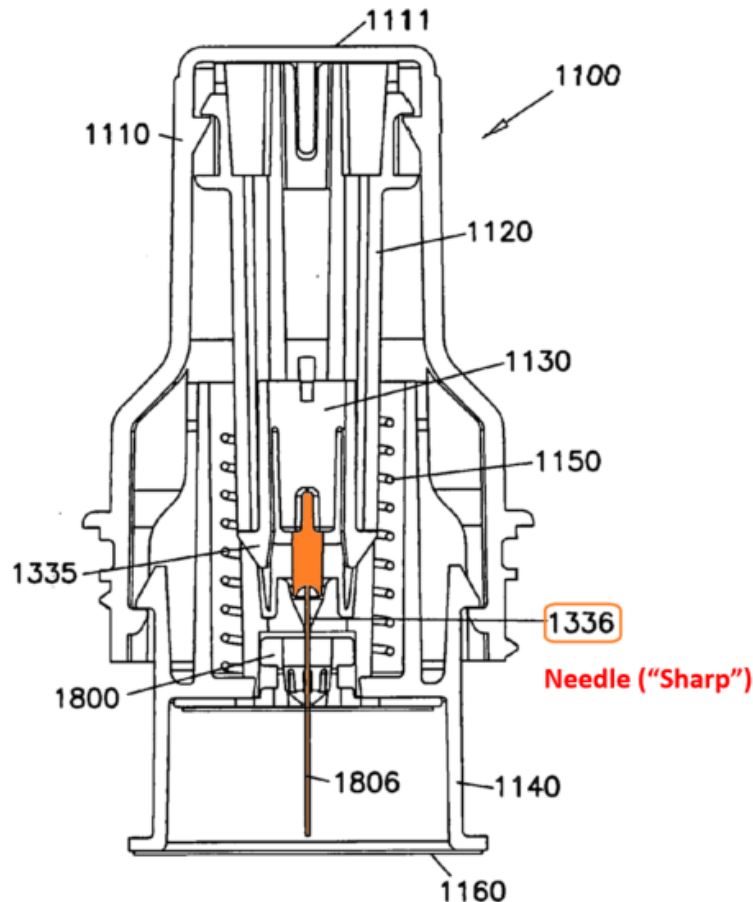
Stafford+Cote's inserter includes a proximal end, a distal end, and an interior, as taught by Cote, e.g., with respect to Cote inserter 1100. EX1005, FIG. 80A, below. EX1003, ¶82.



Cote, FIG. 80A (annotated)

[1.8]/[19.9] a sharp,

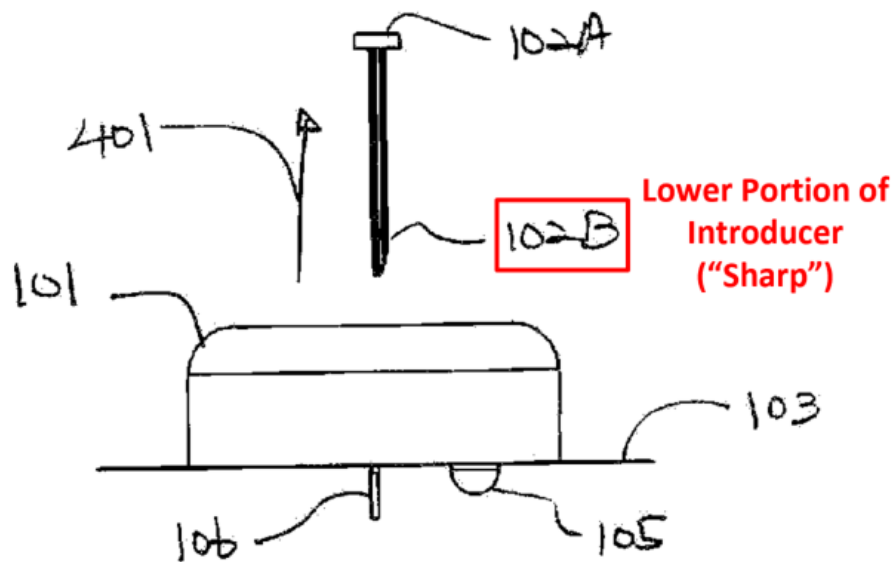
Stafford+Cote includes a sharp like that taught by Stafford, with at least a lower portion having a channel/U-shaped cross-section for surrounding and guiding the in-body portion of the sensor during insertion. *See, e.g.*, EX1004, [0021]; FIGS. 4A, 5C; *see also* EX1005, [0184] (Cote teaching “needle 1336 (hollow or solid)”), [0207], FIG. 80A.



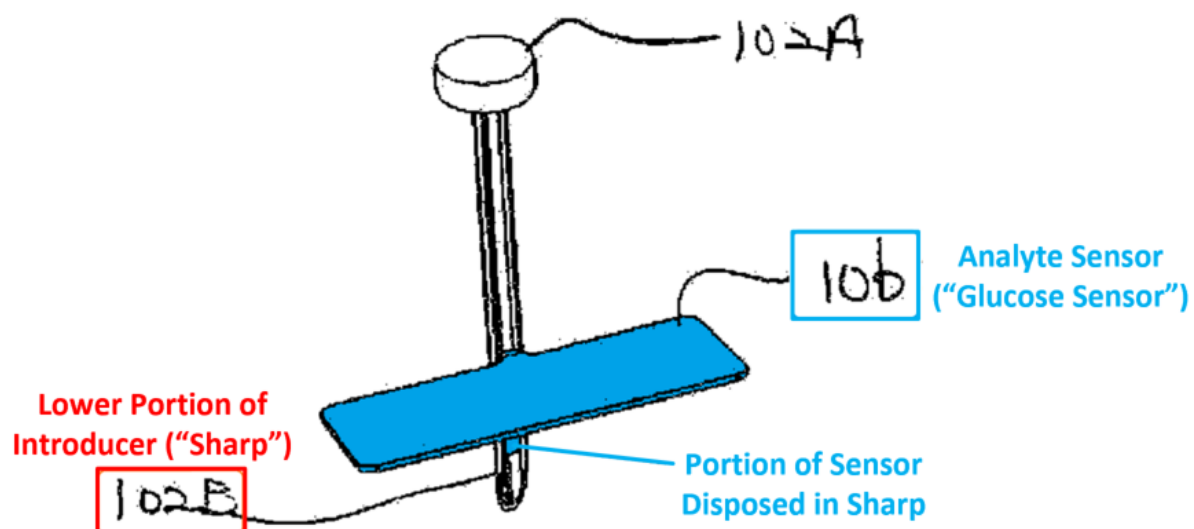
Cote, FIG. 80A (annotated)

Stafford FIGS. 4A and 5C (annotated versions below) show the sharp’s channel/U-shaped cross-section that accommodates a portion of the sensor. Thus,

during insertion, “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.” EX1004, [0028], [0002] (“introducer includes a sharp needle shaped inserter”).



Stafford, FIG. 4A (annotated)

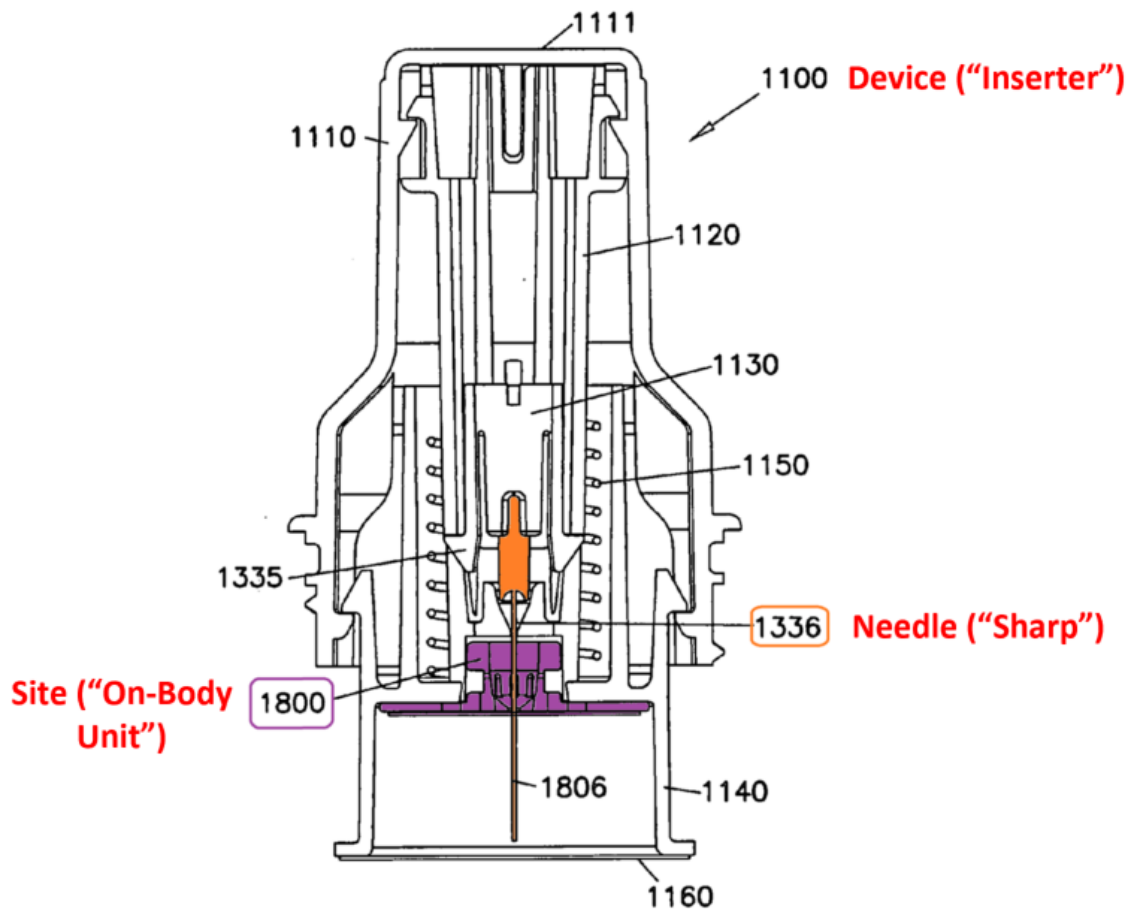


Stafford, FIG. 5C (annotated)

Cote recognizes the use of either solid or hollow needles for insertion (EX1005, [0184], [0207]; EX1004, [0021]), confirming that a POSITA would have naturally implemented the Stafford+Cote insertion assembly with a sharp having a channel/U-shaped cross-section for surrounding and guiding Stafford's sensor during insertion, as taught by Stafford. EX1003, ¶¶83-85; *see also* EX1008, FIGS. 13B-C, 27:63-66 (prior art patent incorporated into Stafford, reflecting knowledge in art of sharp insertion devices that “support the sensor ... during insertion”).

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

In Stafford+Cote's insertion assembly, the on-body unit and sharp are disposed entirely within the interior of the inserter, as taught in Cote and shown below. EX1005, [0198] (“the internal components of the device 1100 (e.g., needle 1336 and site 1800)”), [0215] (“sleeve 1140 [functions] to shroud the needle 1336 prior to insertion”), FIG. 80A (below).



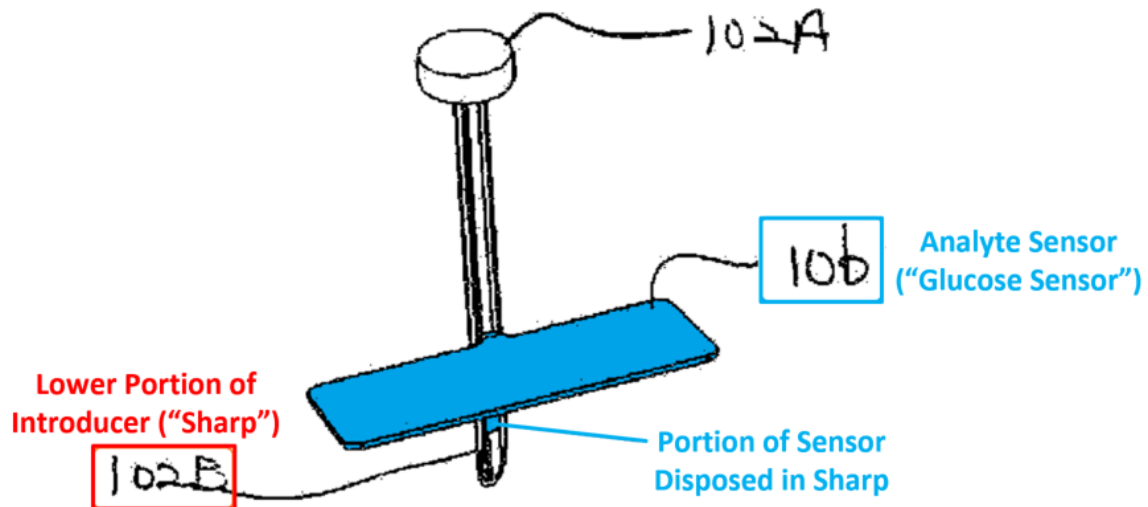
Cote, FIG. 80A (annotated)

Cote teaches the benefits of this implementation, *e.g.*, maintaining internal components of the device “in a substantially sterile state” (EX1005, [0198]) and “cover[ing] or hid[ing] the needle prior to insertion of the site ... protect[s] against inadvertent contact with the needle.”); *see also id.*, [0235].

Stafford+Cote’s on-body unit and sharp/needle are thus disposed entirely within the inserter. EX1003, ¶¶86-88.

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

In the Stafford+Cote insertion assembly, a portion of the glucose sensor is disposed in the sharp, *i.e.*, within the channel of the lower portion of the sharp, as taught by Stafford. EX1004, [0028], FIG. 5C (below); EX1003, ¶89; *see supra* Section [1.8]/[19.9].

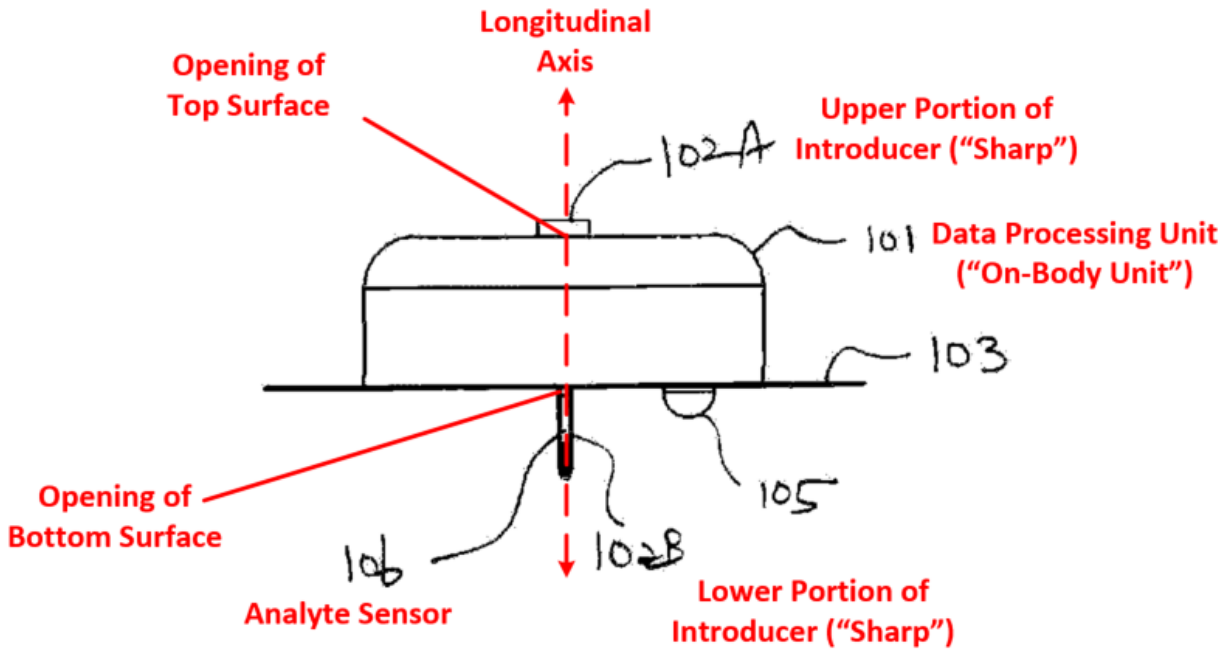


Stafford, FIG. 5C (annotated)

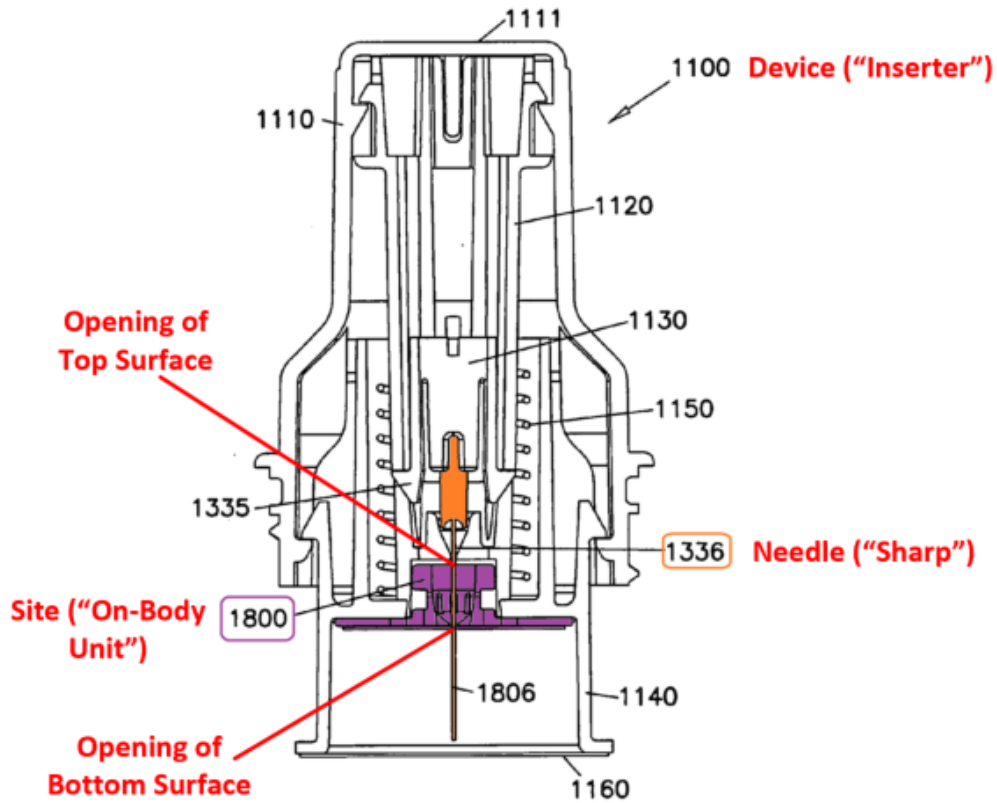
[1.11]/[19.16] wherein the sharp extends through the opening of the top surface and the opening of the bottom surface along the longitudinal axis when the on-body unit is in [a]/[the] first position,

In Stafford+Cote's insertion assembly, the sharp extends through openings in top and bottom surfaces of the housing, along the longitudinal axis, when the on-body unit is in a first position, as taught and shown by both Stafford and Cote. *E.g.*,

EX1004, [0020]; FIG. 2 (immediately below); *see supra* Section [1.3]/[19.3]; *see also* EX1005, FIG. 80A (further below), [0135], [0137], [0202].



Stafford, FIG. 2 (annotated)

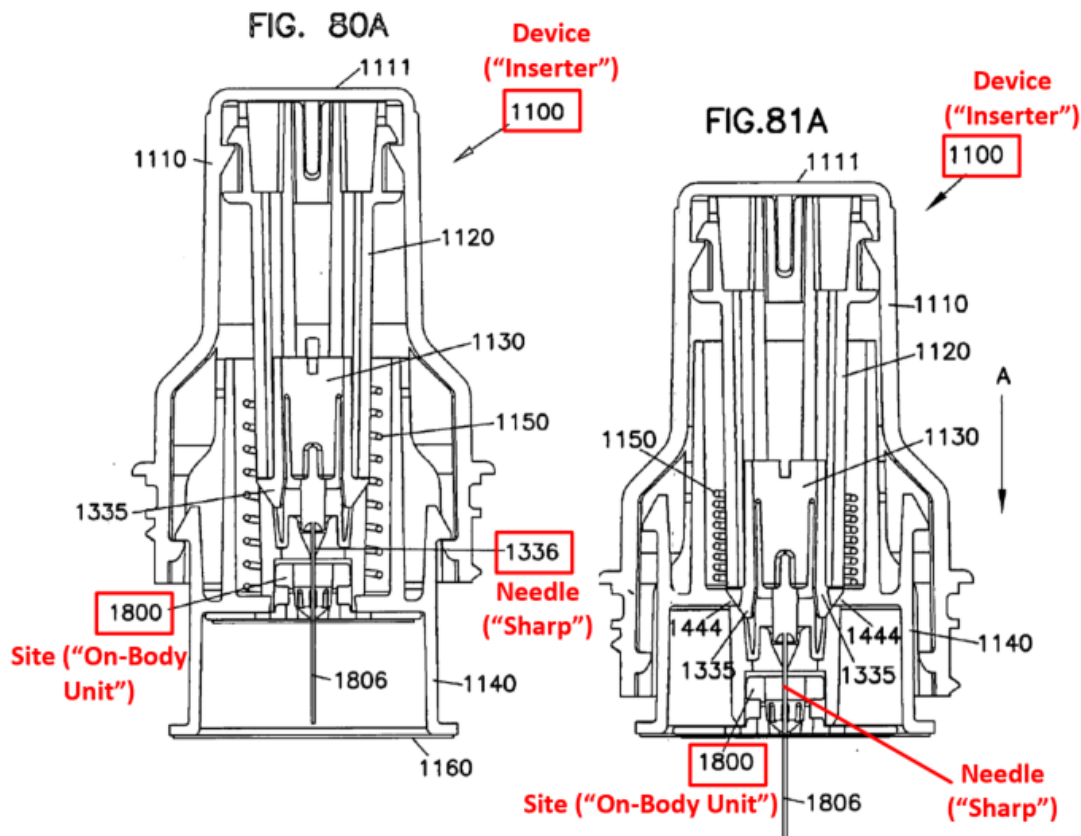


Cote, FIG. 80A (first position, annotated)

As shown and taught by Cote, in its pre-insertion “delivery state,” the on-body unit is in a first position and the sharp extends longitudinally through the openings in both top and bottom surfaces, as it would in the Cote+Stafford on-body unit. EX1005, FIG. 80A (above), [0139], [0143], [0145], [0165], [0205]; *see also* EX1004, [0027]; EX1003, ¶¶90-93.

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

Stafford+Cote's inserter is configured to advance the on-body unit and sharp from the first position ("delivery state") to a second position ("trigger state"), as taught by Cote. EX1005, [0012], [0203], FIGS. 77, 80A-80B ("delivery state"), FIGS. 78, 81A-81B ("trigger state"). *See also* Section VII.B (describing operation of Cote's device).



Cote, annotated FIGS. 80A (first position) and 81A (second position)

Cote teaches that, as the inserter goes from the delivery state to the trigger state, associated structures, including the sharp and the on-body unit, move in direction A “toward the skin 1900 of the patient.” EX1005, [0207]. The inserter is thus configured to advance the on-body unit and the sharp in a linear direction (“direction A”) from the first position (“delivery state,” *e.g.*, FIG. 80A) to the second position (“trigger state,” *e.g.*, FIG. 81A). *Id.*, [0203], [0207]; EX1003, ¶¶94-95.

In the second position, Cote’s sharp pierces the skin and the housing of the on-body unit is secured to the skin. EX1005, [0012], [0203], [0207], [0236], FIGS. 80A, 81A.

Stafford+Cote’s adhesive secures the on-body unit to the skin of the patient in the second position, as taught by both Stafford and Cote. *E.g.*, EX1004, [0019] (“adhesive patch” on the bottom of on-body unit provides “sufficient adhesive strength ... to securely attach the adhesive patch 103 and the data processing unit 101 on a surface of a subject such as the skin of a patient”), [0025], [0047]; EX1005, [0191], [0210],[0237], FIGS. 81A and 81B; *infra* Section [2.1]/[20.1].

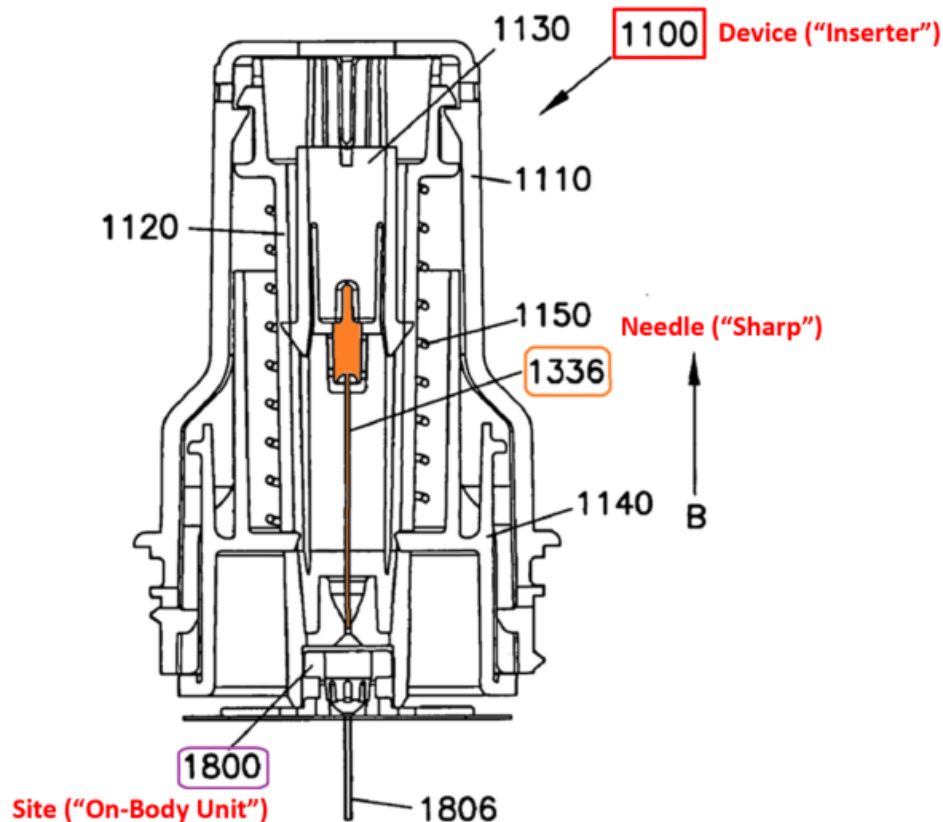
Cote further teaches that the inserter “hold[s] the site on the surface of the skin during needle retraction” and “assist[s] in adherence of the adhesive portion to the skin.” EX1005, [0237], FIG. 81A; EX1003, ¶¶96-99.

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

Stafford+Cote includes a distal end of the inserter configured to be positioned on the skin of the user before advancement of the on-body unit and the sharp, as taught by Cote. EX1005, [0206]-[0207] (explaining how the distal end of the inserter “contacts the skin 1900 of the patient” prior to moving the on-body unit and sharp towards the patient’s skin). EX1003, ¶100.

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

As Stafford+Cote’s inserter is advanced in the linear direction, the needle hub becomes uncoupled from engagement with the cylinder hub, allowing the needle hub and sharp to be automatically retracted by a spring, while the cylinder hub and site remain down in an extended position, as taught by Cote. EX1005, [0211]. After this automatic retraction of the sharp, the sharp is entirely within the interior of the inserter. *Id.*, FIG. 82A (below), [0236] (“devices disclosed herein can *automatically retract the needle while leaving the site placed on the skin*, thereby reducing the patient’s contact with the exposed needle.”).



Cote, FIG. 82A annotated

In inserting Stafford+Cote's on-body unit, then, a portion of the on-body unit's sensor is left in the user's skin when the needle retracts. By leaving a portion of the sensor within the user's skin, the Stafford+Cote insertion assembly allows the sensor to "maintain fluid contact with the patient's analyte," as taught in Stafford. EX1004, [0027]; EX1005, [0237], FIG. 81A; EX1003, ¶¶101-103.

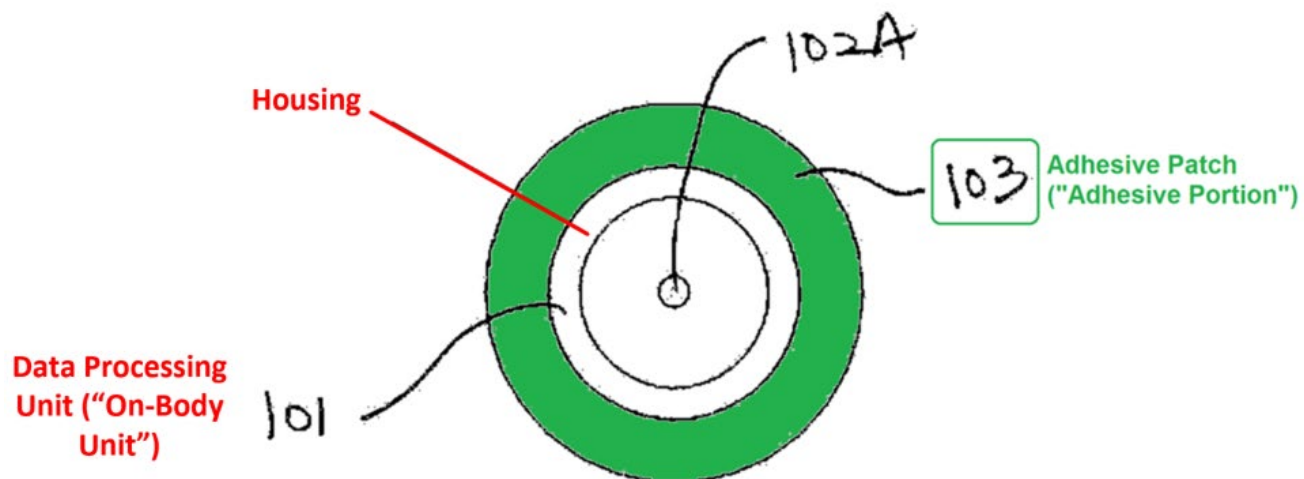
[1.15]/[19.19] wherein the distal end of the inserter is further configured to be removed from the skin of the user after automatic retraction of the sharp from within the user.

In Stafford+Cote's insertion assembly, the distal end of the inserter is configured to be removed from the skin of the user after automatic retraction of the sharp, as taught by Cote. EX1005, [0213] ("Finally, the sleeve 1140 is removed from contact with the skin 1900..."). EX1003, ¶104.

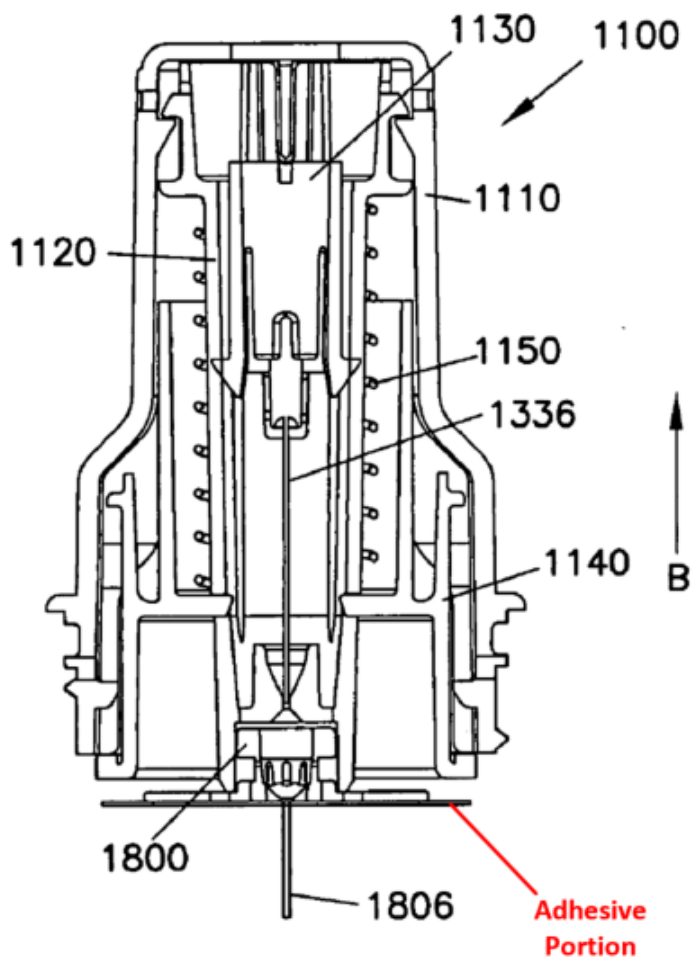
2. Claims 2/20

[2.1]/[20.1] The insertion assembly of claim [1/19], further comprising an adhesive portion configured to secure the housing to the skin of the user, wherein the adhesive portion is further configured to extend outwardly beyond the bottom surface of the housing along the skin in all directions when the housing is secured to the skin of the user.

Stafford+Cote's insertion assembly includes an adhesive portion extending outwardly beyond the bottom surface of the housing to secure the unit to the user's skin, as taught by both Stafford and Cote ("adhesive patch 103" and "adhesive portion 1160," respectively). EX1004, [0019]; EX1005, [0195].



Stafford, FIG. 3B (annotated)



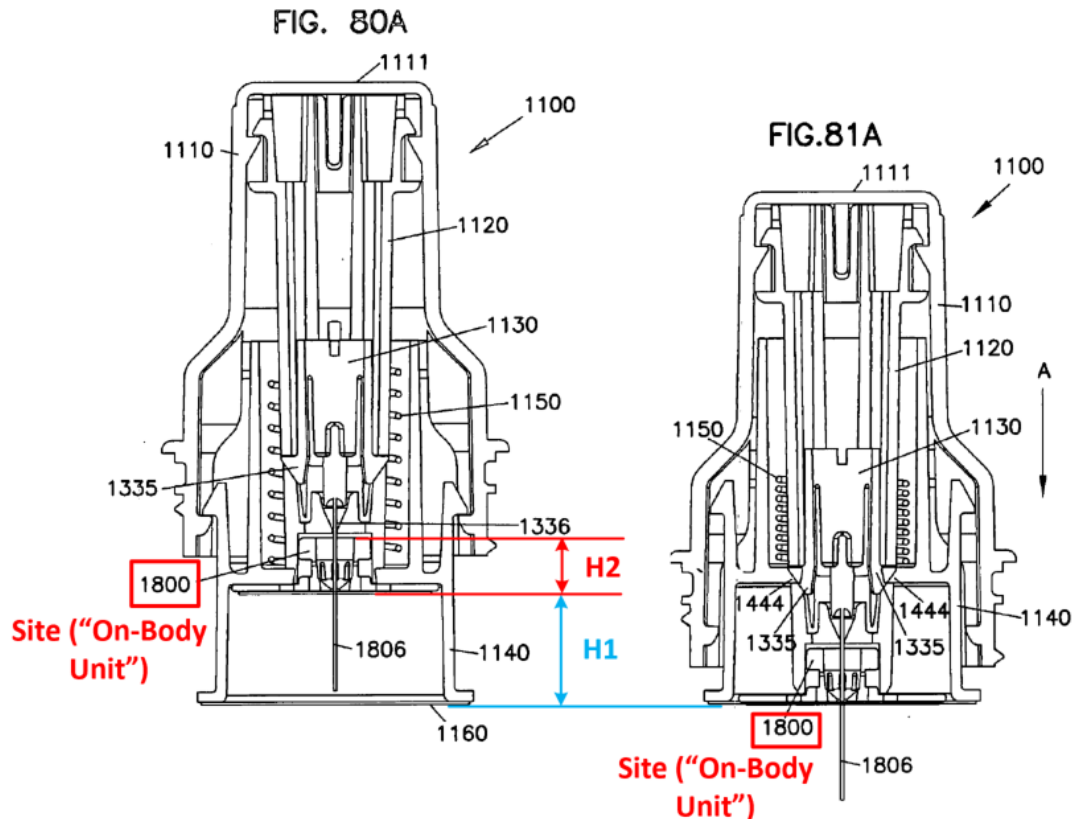
Cote, FIG. 82A (annotated)

Both Stafford's and Cote's adhesive portions extend outwardly beyond the on-body unit housing's bottom surface in all directions, at least when the housing is secured to the patient's skin. EX1004, FIG. 3B (above); EX1005, FIG. 82A (also above); EX1003, ¶¶105-108.

3. Claims 3/19

[3.1]/[19.13] [The insertion assembly of claim 2,] wherein a distance between the housing when the on-body unit is in the first position and the housing when the on-body unit is in the second position is greater than a maximum height of the housing[.]/[,]

Stafford+Cote includes an on-body unit in the first position when the inserter is in a delivery state (similar to, *e.g.*, Cote's inserter in FIGS. 77, 80A-80B) and in the second position when in a trigger state (similar to, *e.g.*, Cote's inserter in FIGS. 78, 81A-81B), as taught by Cote. EX1005, [0203].



Cote, FIG. 80A (first position), FIG. 81A (second position)⁹ (annotated)

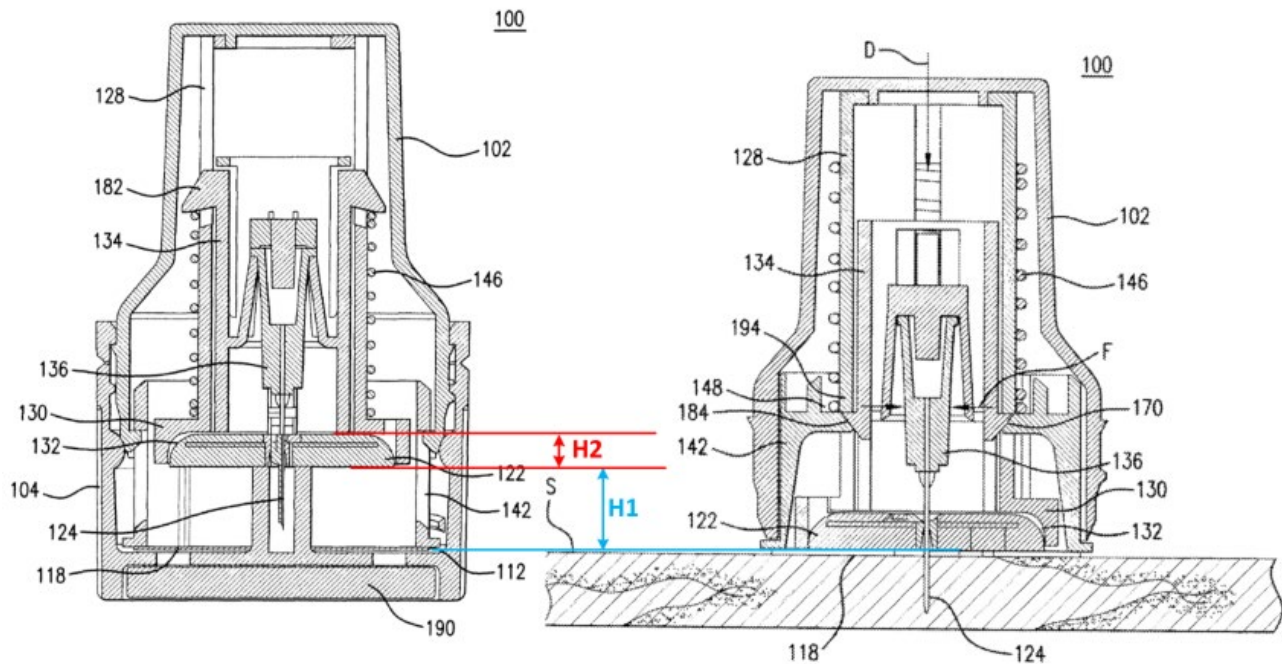
As shown above, Cote teaches that the distance (“H1,” blue arrow) between an infusion device’s site (“on-body unit”) in the first position (FIG. 80A) and the

⁹ Petitioner opted to compare FIG. 80A (delivery state) to FIG. 81A (trigger state, without “over-travel”). A POSITA would understand that while the on-body unit must travel beyond the distal end of Cote’s inserter to enable automatic retraction of the sharp (EX1005, [0209]-[0211]), Fig. 81C—which purports to show this trigger state with “over-travel” for the 1100 device—is incorrectly labeled. Rather, FIG. 81C illustrates over-travel for the 1100” device of FIGS. 85-91, which replaces

second position (FIG. 81A) is greater than a maximum height (“H2,” red arrow) of the site. *Id.*, FIGS. 80A, 81A. Since Cote’s figures clearly illustrate the relationship between travel distance and housing height, Cote discloses this limitation. *See In re Aslanian*, 590 F.2d 911, 914 (CCPA 1979) (drawings are “evaluat[ed] and appl[ied] . . . on the basis of what they reasonably disclose and suggest to one skilled in the art”) (quoting *In re Baum*, 374 F.2d 1004, 1009 (CCPA 1967)); *id.* (drawings may be used to show unpatentability of claims “even though the feature shown in the drawing was unintended or unexplained in the specification of the reference patent.”). Based on Cote’s teachings, a POSITA would have configured the travel distance of Stafford’s on-body unit (“H1”) to be greater than the height of the on-body unit’s housing (“H2”).

Cote’s disclosure of the relative dimensions is at least equivalent to what is described in the ’591 patent. *Compare*, Cote, FIGS. 80A, 81A (above) *with* EX1001, FIGS. 28, 30 (below).

sleeve 1140 with trigger 1140’. EX1005, [0215]. A POSITA would recognize that “over-travel” would further increase the distance H1 shown above.



'591 patent, FIGS. 28 and 30 (annotated)

In particular, the specification of the '591 patent does not describe a distance between the housing when the on-body unit is in the first position and when the on-body unit is in the second position, let alone that this distance is greater than the height of the housing. Rather, to the extent Patent Owner would claim it is supported in the '591 patent,¹⁰ such support appears to come exclusively from its figures, *e.g.*, FIGS. 28 and 30, above. EX1003, ¶¶109-112.

Even without Cote's express teachings, it was an obvious design choice to configure Stafford+Cote such that the on-body unit's travel distance is greater than

¹⁰ Petitioner takes no position as to whether there is § 112 support in the '591 patent for this limitation, as that is beyond the scope of this IPR.

the height of the on-body unit. As discussed *infra, e.g.*, in Section VII.C.12 addressing elements [14.1]/[19.14], a POSITA would find a low-profile on-body unit desirable, and both Stafford and Cote describe their on-body units as such. EX1005, [0228]; EX1004, [0045]. A POSITA additionally would have found it desirable for the needle to extend past a distal end of the sensor to protect the tip of the sensor during insertion. *Supra* Section V.B.5.

Further, a POSITA understood that transcutaneous devices (*e.g.*, sensors or cannulas) routinely had an *in vivo* portion that was longer than the on-body portion was tall. *See e.g.*, EX1006, FIG. 1A, [0034]; EX1018, FIG. 3; EX1038, FIGS. 6-11. A POSITA would thus have found it at least an obvious design choice in Stafford+Cote to implement the sensor with an *in vivo* length longer than the on-body unit is tall.

Additionally, 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. EX1005, [0235]. Further, such positioning allows the needle to accelerate prior to hitting the skin, which can be beneficial for patients with higher-than-average skin thickness and/or skin density. EX1042, [0004]. Thus, it would have been obvious to a POSITA to position the Stafford+Cote sharp some distance away from the distal end of the inserter, thus requiring some initial travel before the sharp

contacts the user's skin, *e.g.*, to “shroud” the needle prior to insertion, as taught in Cote. EX1005, [0215]; EX1003, ¶¶113-115.

This obvious implementation of the on-body electronics unit (with the length of the *in vivo* sensor portion greater than the height of the low-profile housing) and the inserter device (with the needle extending past the end of the sensor and the needle point withdrawn from the edge of the inserter prior to insertion) results in a travel distance H1 greater than the height of the housing H2. Such a configuration for inserter devices was well-known in the art. *See supra* Section V.B.5.

This is consistent with what is depicted in Cote's Figures 80A and 81A, namely, that the travel distance (H1) is greater than the height of the housing (H2). Indeed, “it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom.” *In re Preda*, 401 F.2d 825, 826 (CCPA 1968); *see also Cummins-Allison Corp. v. SBM Co., Ltd.*, 484 F. App'x 499, 507 (Fed. Cir. 2012) (non-precedential) (“As long as a person of skill in the art could derive the claimed dimensions from the patent's disclosure, there is no additional requirement that the specification must explicitly disclose the precise proportions or particular sizes.”).

Furthermore, if the only difference between the prior art and the claims is a recitation of relative dimensions, and the claimed dimensions do not affect the performance of the device, then the claimed device is not patentably distinct from

the prior art. *Gardner v. TEC Syst., Inc.*, 725 F.2d 1338, 1349, 220 USPQ 777 (Fed. Cir. 1984) (affirming district court’s decision invalidating claims where “the dimensional limitations did not specify a device which performed and operated any differently from the prior art”). The ’591 patent does not describe the claimed relative dimensions affecting the performance of the device in any way, but merely depicts the device in the first and second positions. EX1001, FIGS. 28, 30 (above). Claim elements that the specification does not describe in detail are presumed to be known to those of ordinary skill in the art. *In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994); *In re Fox*, 471 F.2d 1405, 1407 (CCPA 1973).

Nothing in the ’591 patent indicates that the relative dimensions are a critical aspect of the claimed invention. *See In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990) (requiring criticality of a claimed range); *First Quality Baby Prod., LLC v. Kimberly-Clark Worldwide, Inc.*, IPR2014-01021, Paper 57 at 23 (PTAB Dec. 10, 2015) (relative size limitations “do not distinguish the claim from the prior art...”). To the extent the claimed relative dimensions suggest a low-profile on-body unit and/or protection against the sharp, these features were well-known in the art and taught by Stafford and Cote. Accordingly, the claimed height dimensions are not patentably distinct from the prior art. EX1003, ¶¶116-118; *see supra* Sections V.B.4, V.B.5.

4. Claims 4/19

[4.1]/[19.6] [The insertion assembly of claim 3,] wherein the sensor electronics comprise a processor, a power source, an analog interface, a data storage unit, and wireless communication circuitry configured to communicate data indicative of a glucose level[.]/[; and]

Stafford's sensor electronics ("components in the data processing unit 101") include a processor ("processor 704"), a power source ("power supply 707"), an analog interface ("analog interface 701"), and wireless communication circuitry ("RF transceiver 706") configured to communicate data indicative of a glucose level. EX1004, [0039]-[0040], [0052], FIG. 7.

A POSITA also knew that a data storage unit would be required for the data processing unit to store incoming data, use for working data, and store output data. Stafford teaches that the data processing unit can be configured to perform data processing such as filtering or encoding and can transmit the encoded data at one-minute intervals. *Id.*, [0036]-[0037]. A POSITA would recognize this lag between when sensor data is measured and when processed/encoded data is transmitted requires that the data be stored in a data storage unit to allow for processing. *See, e.g.*, EX1034, 509 (acknowledging the role of data storage in executing processing routines (such as encoding)); *see also* EX1035, 23-25 (describing the use of stored data in an exemplary digital signal processing system).

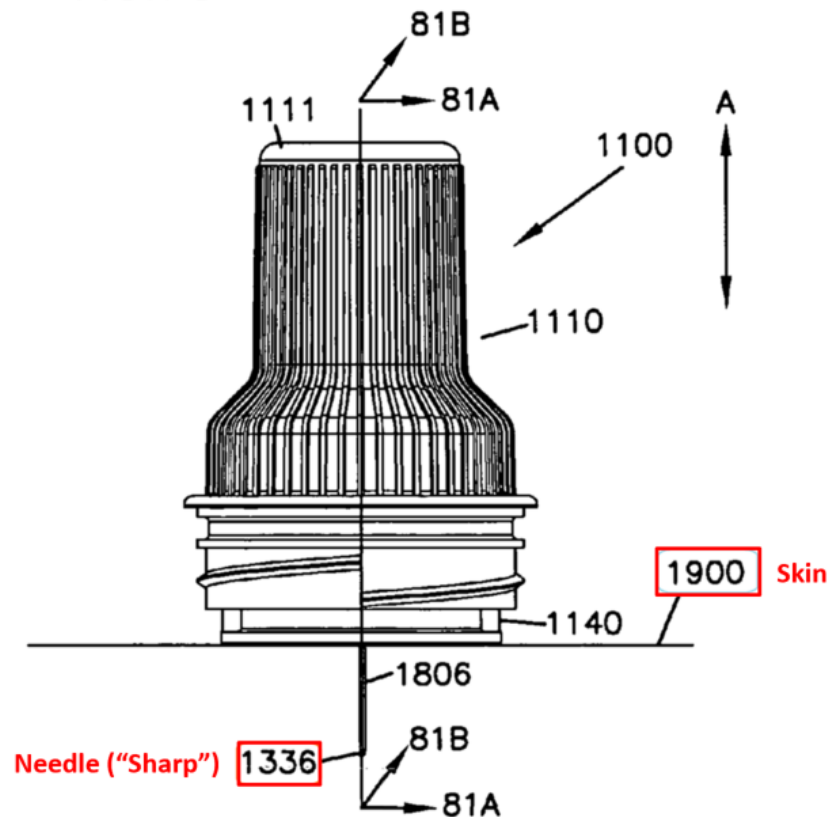
Further, Stafford teaches that additional details on the data processing unit are disclosed in Say, which teaches that the on-skin sensor control unit electronics (“sensor electronics”) optionally include a data storage unit. EX1004, [0043]; EX1008, 44:54-45:7 (“The on-skin sensor control unit 44 may include an optional data storage unit 102 [which] typically includes a readable/writeable memory storage device”), 36:40-43 (“The on-skin sensor control unit 44 also typically includes at least a portion of the electronic components that operate the sensor 42”). Thus, use of a data storage unit would have at least been an obvious design choice for a POSITA implementing the Stafford+Cote inserter. EX1003, ¶¶119-121.

5. Claims 5/19

[5.1]/[19.15] [The insertion assembly of claim 3,] wherein the sharp is configured to pierce the skin of the user at an angle substantially perpendicular to the skin of the user[.]/[.,]

Stafford+Cote’s inserter is configured to advance the Stafford sharp in the linear direction A perpendicular to the skin of the user, as taught by Cote. EX1005, FIG. 78 (below). As such, the Cote-like inserter advances the sharp such that it pierces the skin at a substantially perpendicular angle.

FIG. 78



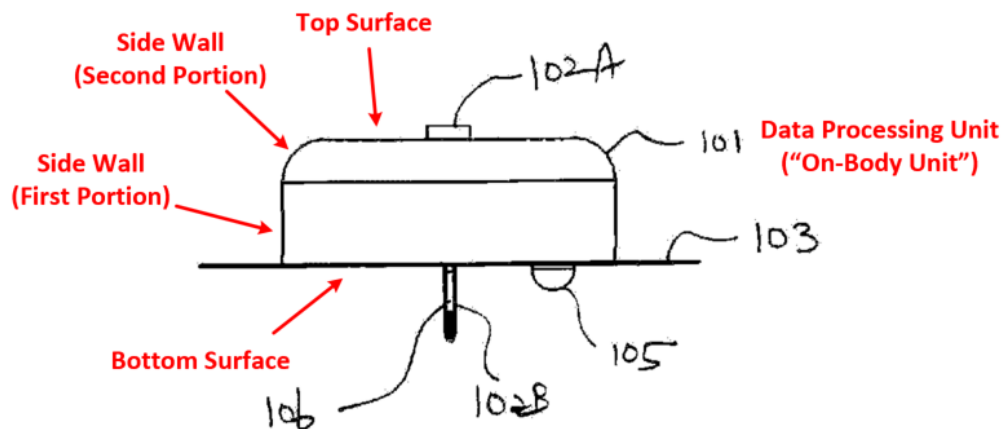
Cote, FIG. 78 (annotated)

Similarly, Stafford's sharp is introduced in a perpendicular orientation. EX1004, FIGS. 2, 4A, [0026]. Thus, in combination, it would be obvious to introduce Stafford's on-body unit using the Cote-like inserter by inserting Stafford's sharp into the skin of the patient in a perpendicular orientation. EX1003, ¶¶122-123.

6. Claims 6/27

[6.1]/[27.1] The insertion assembly of claim [3/23], wherein the on-body unit further comprises a side wall of the housing, wherein the side wall is located between the top surface and the bottom surface, wherein the side wall comprises a first portion and a second portion, and wherein the second portion of the side wall defines a non-orthogonal angle relative to both the first portion of the side wall and the top surface of the housing.

Stafford's on-body unit's housing includes a side wall located between the top and bottom surfaces. EX1004, FIG. 2. As shown below, a second portion of the side wall defines a non-orthogonal angle (*i.e.*, an angle other than a right angle) relative to both a first portion of the side wall and the top surface of the housing.



Stafford, FIG. 2 (annotated)

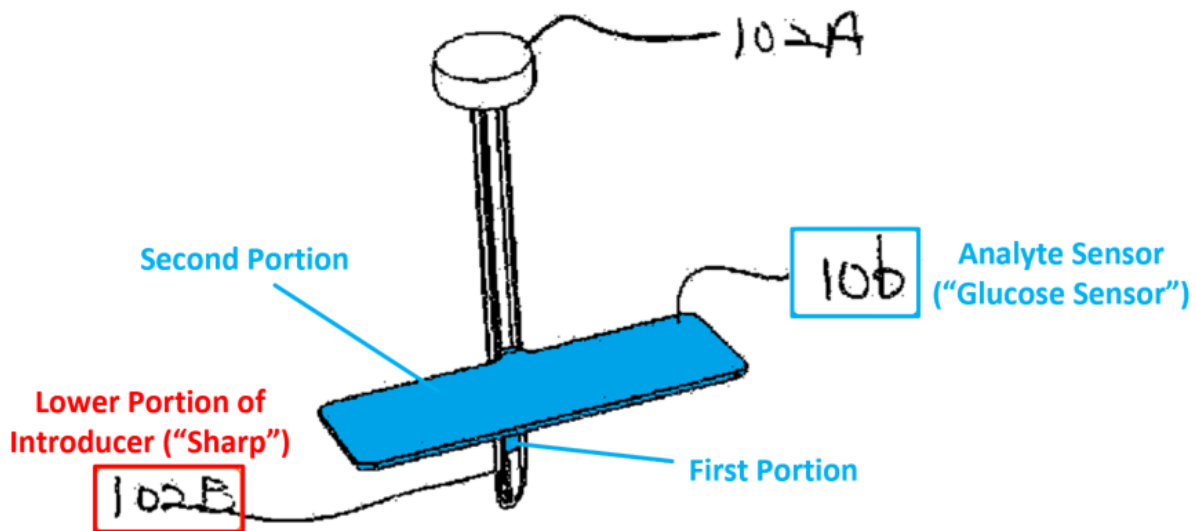
EX1003, ¶¶124-125.

7. Claims 9/22

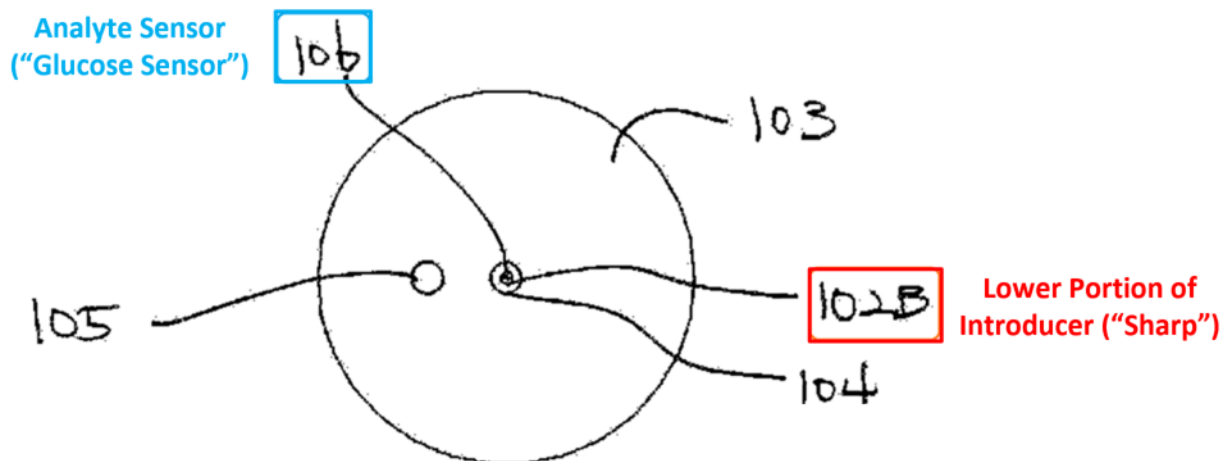
[9.1]/[22.1] The insertion assembly of claim [3/21], wherein the sensor electronics further comprise an opening of the sensor electronics along the longitudinal axis, and wherein the sharp extends through the opening of the sensor electronics when the on-body unit is in the first position.

Stafford+Cote includes sensor electronics provided by Stafford's data processing unit, which comprises sensor electronics (components of "data processing unit 101"). *See* Section [1.5]/[19.5].

Stafford's sensor has a first or lower portion that is "disposed within the lower portion 102B of the introducer" and a second or upper portion that is "disposed within the housing and in electrical communication with the data processing unit." EX1004, [0028], [0006]. To make electrical contact, a POSITA would understand that the upper portion of the sensor physically contacts the sensor electronics, and that adjacent to this area of physical contact, the sharp holds the lower portion of the sensor. *Id.*, [0028]; EX1003, ¶¶126-127.



Stafford, FIG. 5C (annotated)



Stafford, FIG. 3C (showing skin-side of on-body unit, annotated)

A POSITA would understand that while the upper portion of the sensor contacts the sensor electronics (e.g., a circuit board), the adjacent lower portion of the sensor, contained within the sharp, extends out of the on-body unit to contact the subject. It was well-known in the art at the time to include an opening in the sensor electronics to allow a sharp including a portion of an analyte sensor to pass through,

allowing the sensor to contact both the electronics and the subject. *See e.g.*, EX1006, FIG. 6.

To achieve the benefit of minimal size and avoid any wasted space, the POSITA would have implemented the on-body unit such that the housing was no larger than the electronics; in other words, the electronics would occupy the entirety of the cavity within the housing. Such a configuration was known in the art, for example as shown in Shah. *Id.* And as in Shah, the electronics would include a hole through the middle aligned with the hole in the housing, such that the Stafford's sharp passed through the on-body unit to partially surround the in-vivo portion of the sensor.

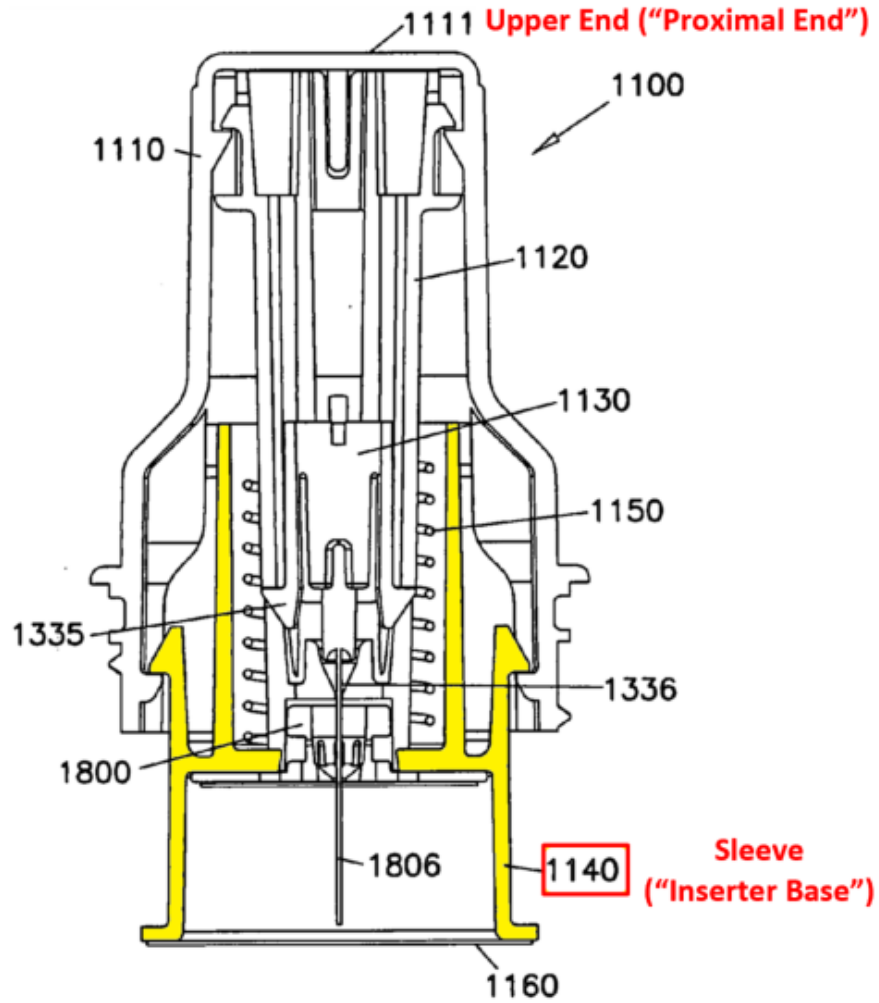
To the extent there was any other way to implement the electronics, an implementation as in Shah was at the very least the most obvious design choice as it minimized the amount of space needed for the housing by leaving no wasted space within that housing. This obvious design choice allowed the upper portion of the sensor to contact the sensor electronics while allowing the needle to pass through the on-body unit and into the subject, thus facilitating insertion.

Thus, a POSITA would have found it obvious to implement Stafford+Cote with an opening in the sensor electronics along the longitudinal axis, through which the sharp extends when the on-body unit is in the first position. EX1003, ¶¶128-131.

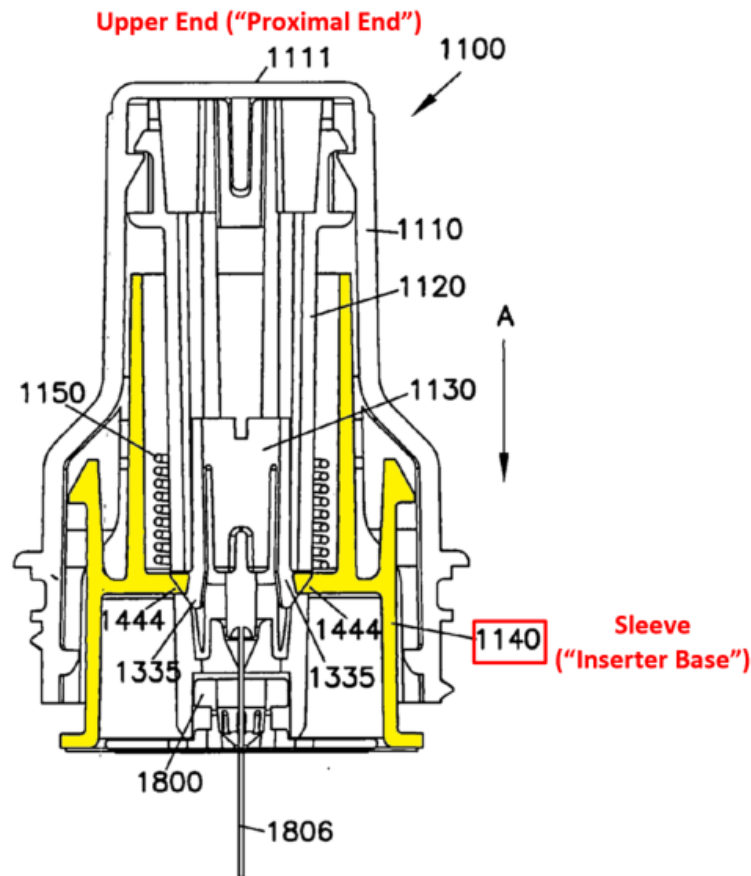
8. Claims 10/24

[10.1]/[24.1] The insertion assembly of claim [3/23], wherein the inserter further comprises an inserter base, and wherein the proximal end of the inserter is configured to move in a downward direction toward the skin of the user relative to the inserter base in response to an application of force on the proximal end of the inserter[.]/[, and]

Stafford+Cote's inserter includes an inserter base, such as taught in Cote. As illustrated below, Cote's inserter includes an inserter base ("sleeve 1140"). The proximal end of Cote's inserter ("upper end 1111") is configured to move in a downward direction ("direction A") relative to the inserter base (towards the skin of the user) in response to an application of force to the proximal end of the inserter. EX1005, [0207] ("the patient applies pressure to the upper end 1111 of the housing 1110 to move the housing 1110 and associated structures ... in a direction A with respect to the sleeve 1140 and toward the skin 1900 of the patient."); *see id.*, FIGS. 80A and 81A, below.



Cote, FIG. 80A (annotated)



Cote, FIG. 81A (annotated)

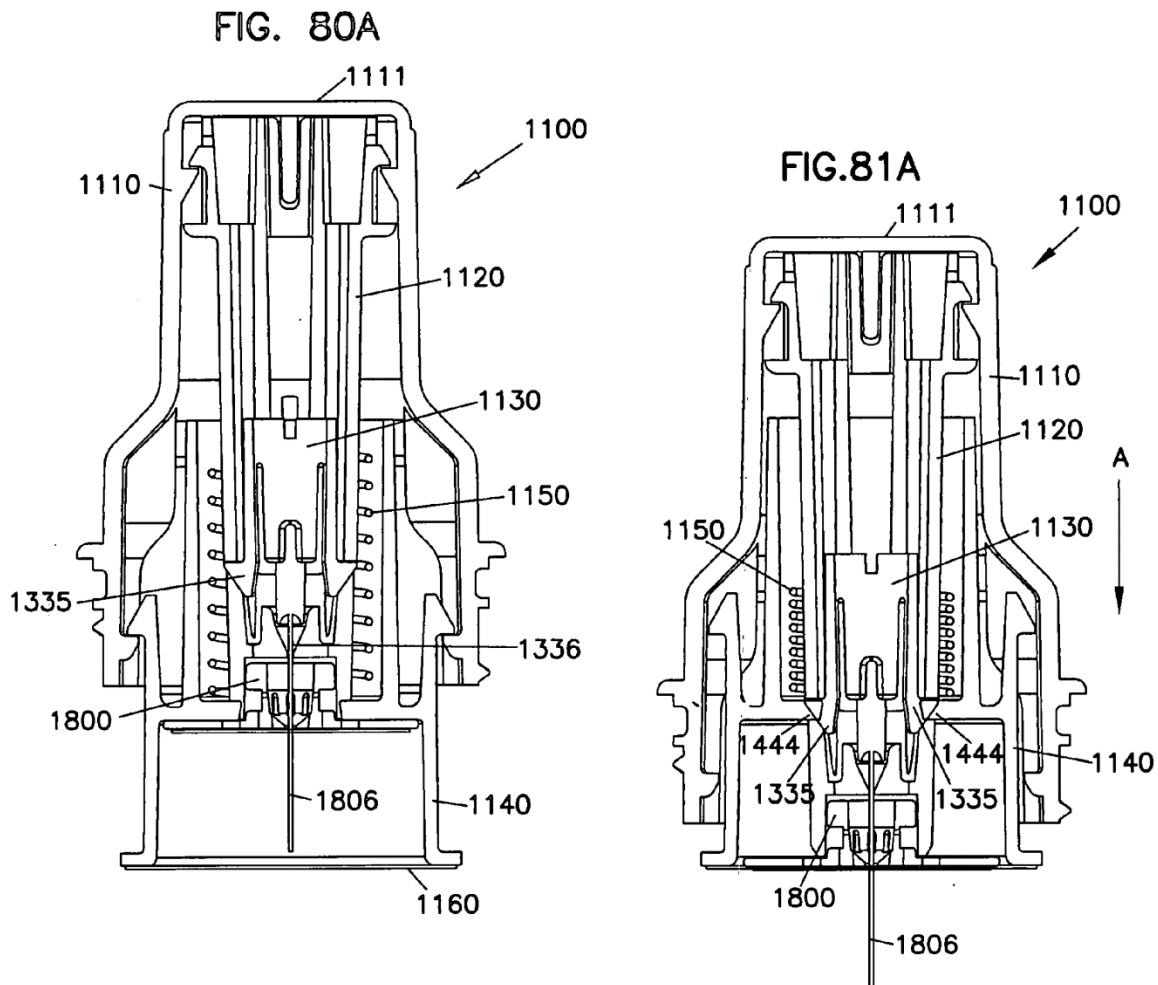
EX1003, ¶132.

9. Claims 11/24

[11.1]/[24.2] [The insertion assembly of claim 10,] wherein the inserter is configured to advance the on-body unit and the sharp from the first position to the second position after the application of force on the proximal end of the inserter.

Stafford+Cote includes an inserter that advances the on-body unit and the sharp from the first position to the second position after the application of force on

the proximal end of the inserter, as taught by Cote. EX1005, [0207], FIGS. 80A (first position)-81A (second position).



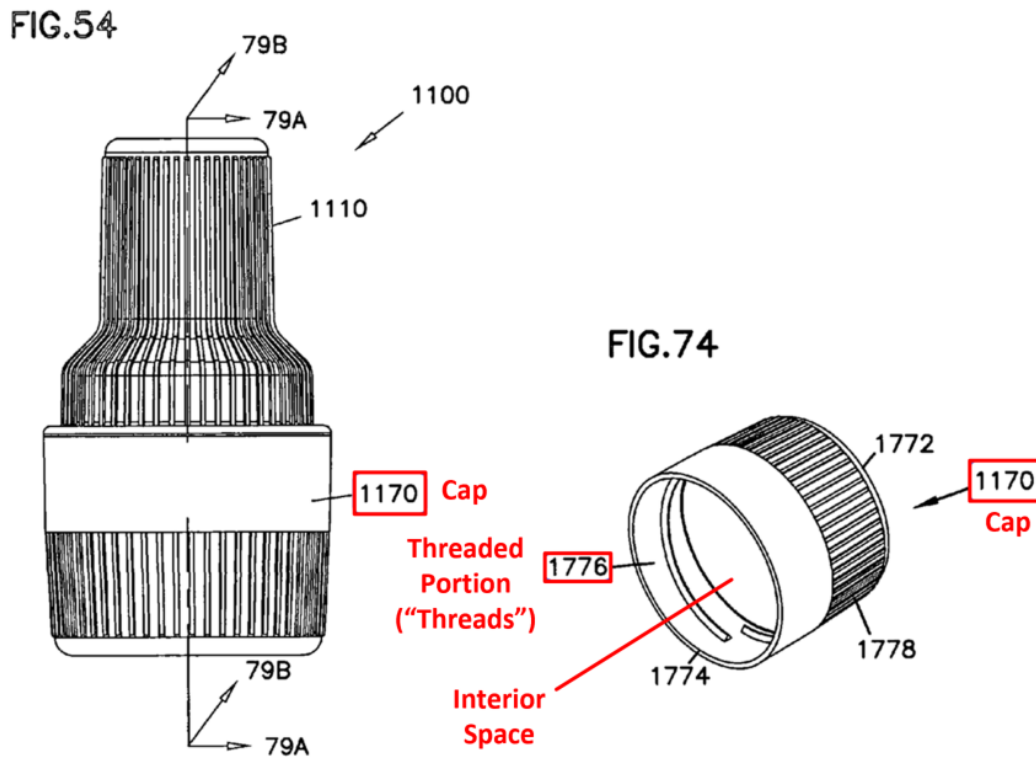
Cote, FIG. 80A (first position), FIG. 81A (second position)

EX1003, ¶133.

10. Claims 12/29

[12.1]/[29.1] The insertion assembly of claim [3/23], further comprising a cap removably attached to a distal portion of the inserter by a plurality of threads, and wherein the cap comprises an interior space comprising a sterile environment.

Stafford+Cote's inserter includes a cap removably attached to a distal portion of the inserter by a plurality of threads, similar to cap 1170 taught in Cote which includes a threaded portion 1776 for attaching to a distal portion of the inserter. EX1005, [0197], FIGS. 54, 57, 74. Cote teaches that the cap maintains the internal components in a "substantially sterile state". *Id.*, [0198]. A POSITA would thus understand that in the Stafford+Cote inserter, the cap comprises an interior space comprising a sterile environment.



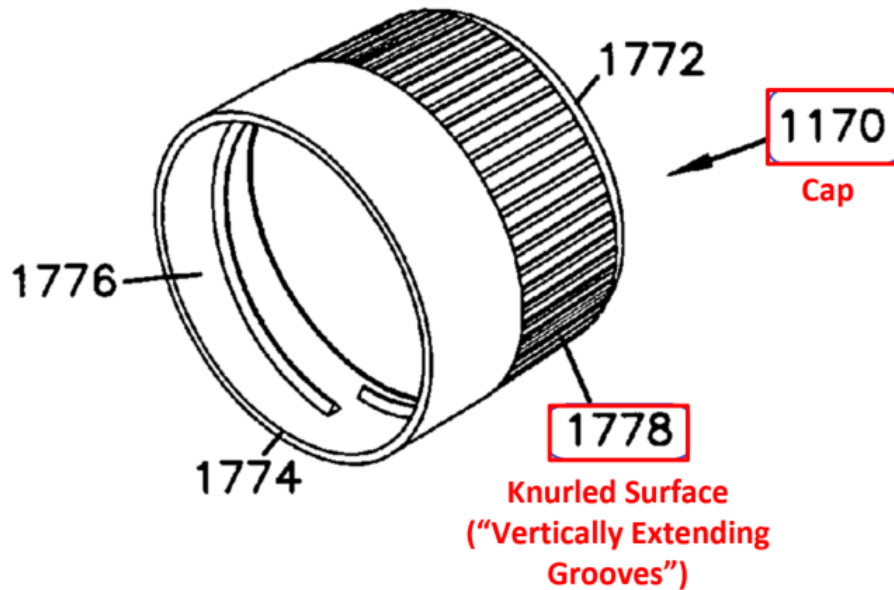
Cote, FIGS. 54, 74 (annotated)

EX1003, ¶134.

11. Claims 13/30

[13.1]/[30.1] The insertion assembly of claim [12/29], wherein the cap further comprises a plurality of vertically extending grooves spaced apart around an outer perimeter surface of the cap.

Stafford+Cote's inserter's cap includes a plurality of vertically extending grooves spaced apart around an outer perimeter surface of the cap, as taught by Cote ("knurled surface 1778"). EX1005, [0197] ("The cap 1170 preferably includes an exterior with a knurled surface 1778 to enhance the patient's grip on the cap 1170."); FIG. 74.



Cote, FIG. 74 (annotated)

EX1003, ¶135.

12. Claims 14/19

[14.1]/[19.14] [The insertion assembly of claim 3,] wherein a height profile of the housing is less than or equal to approximately 10 millimeters[.]/[.,]

A POSITA would have found it obvious to configure the Stafford+Cote on-body unit housing to have a height profile of 10 mm or less. Stafford and Cote both teach that the housing for the on-body unit has a low height profile. *See, e.g.*, EX1005, [0228]; EX1004, [0045]. Additionally, it was well-known in the art for such low height profile housings to be approximately 10 mm or less. *See* Section V.B.4.

As discussed above in Section VII.C.3, if the only difference between the prior art and the claims is a recitation of relative dimensions that do not affect the

performance of the device, then the claimed device is not patentably distinct from the prior art. The '591 patent does not describe the claimed height as affecting the performance of the device in any way, but merely states that the data processing unit has a reduced height to “provide a low-profile when sitting on the skin of the subject.” EX1001, 14:4-5.

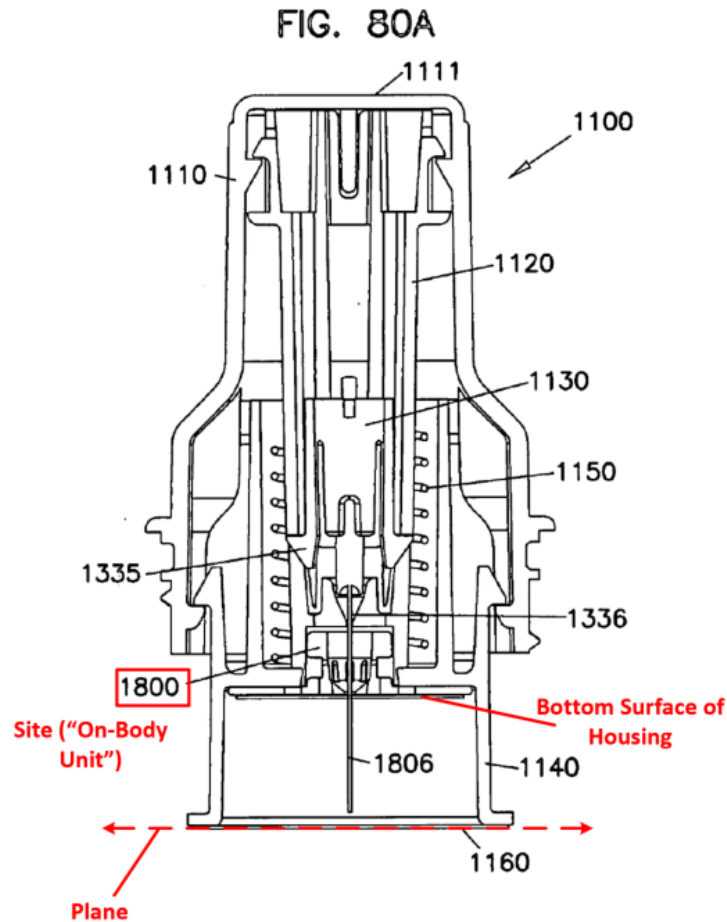
Even assuming a “low-profile” affects performance of the device, the height profile of the housing is not a critical aspect of the claimed invention, as providing a “low-profile” is well-known in the art. *See, e.g.*, EX1005, [0228]; EX1004, [0045]; Section V.B.4. *See In re Woodruff*, 919 F.2d at 1578; *First Quality Baby Prod., LLC.*, IPR2014-01021, Paper 57 at 23. Accordingly, the claimed height dimensions are not patentably distinct from the prior art. EX1003, ¶¶136-138.

13. Claims 16/23

[16.1]/[23.1] The insertion assembly of claim [3/22], wherein the distal end of the inserter defines a plane, and wherein the bottom surface of the housing is parallel to the plane when the on-body unit is in the first position.

In *Stafford+Cote*, a POSITA would position Stafford’s on-body unit within the inserter such that the bottom surface of Stafford’s housing is parallel to a plane defined by the distal end of the inserter, as taught in *Cote* (EX1005, *e.g.*, FIG. 80A) and would have a reasonable expectation of success in doing so.

Cote teaches the distal end of the inserter defining a plane and the bottom surface of the housing of the on-body unit being parallel to the plane when the on-body unit is in the first position. *Id.*



Cote, FIG. 80A (first position, annotated)

The specification of the '591 patent does not describe the bottom surface of the housing being parallel to a plane defined by the distal end of the inserter. To the

extent Patent Owner would claim it is supported in the '591 patent,¹¹ such disclosure appears to come exclusively from its figures, *e.g.*, FIGS. 28 and 30, which provides nothing more than from Cote's disclosure of this feature. EX1003, ¶¶139-141.

14. Claim 17

[17.1] The insertion assembly of claim 3, wherein the on-body unit is configured to be disposed after a single use.

Stafford teaches that the on-body unit is disposable. EX1004, [0044] (“a single disposable assembly”). Cote also teaches disposable devices. EX1005, [0238] (“The configuration and disposable nature of the devices further allow ease in discarding of the devices after use.”), [0241] (“single use devices”).

Thus, Stafford+Cote teaches an on-body unit configured to be disposed after a single use to “allow ease in discarding of the device[] after use,” as taught in Cote. EX1005, [0238]. EX1003, ¶¶142-143.

¹¹ Petitioner does not concede that the '591 patent provides § 112 support for this limitation.

15. Claims 18/21

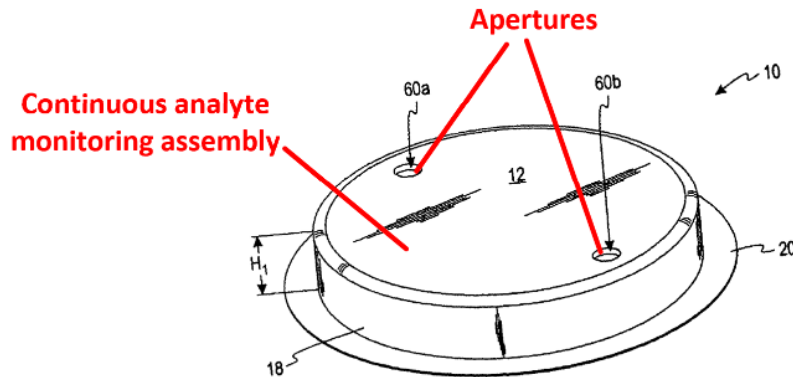
[18.1]/[21.1] The insertion assembly of claim [2/20], wherein the opening of the top surface is a first opening of the top surface, wherein the top surface further comprises a second opening of the top surface,

As described above, Stafford teaches an on-body unit with an opening in the top surface of the housing. EX1004, [0020], [0027]. In Stafford+Cote, a POSITA would understand that the sensor assembly as taught by Stafford should remain fixed relative to the insertion device to maintain the position of the on-body unit relative to the inserter and prevent unintended movement and potential damage during shipment or use. The POSITA knew how to add peripheral apertures to the outer edges of the top surface of Stafford's housing to interface with corresponding protrusions on the insertion device for the aforementioned purposes.

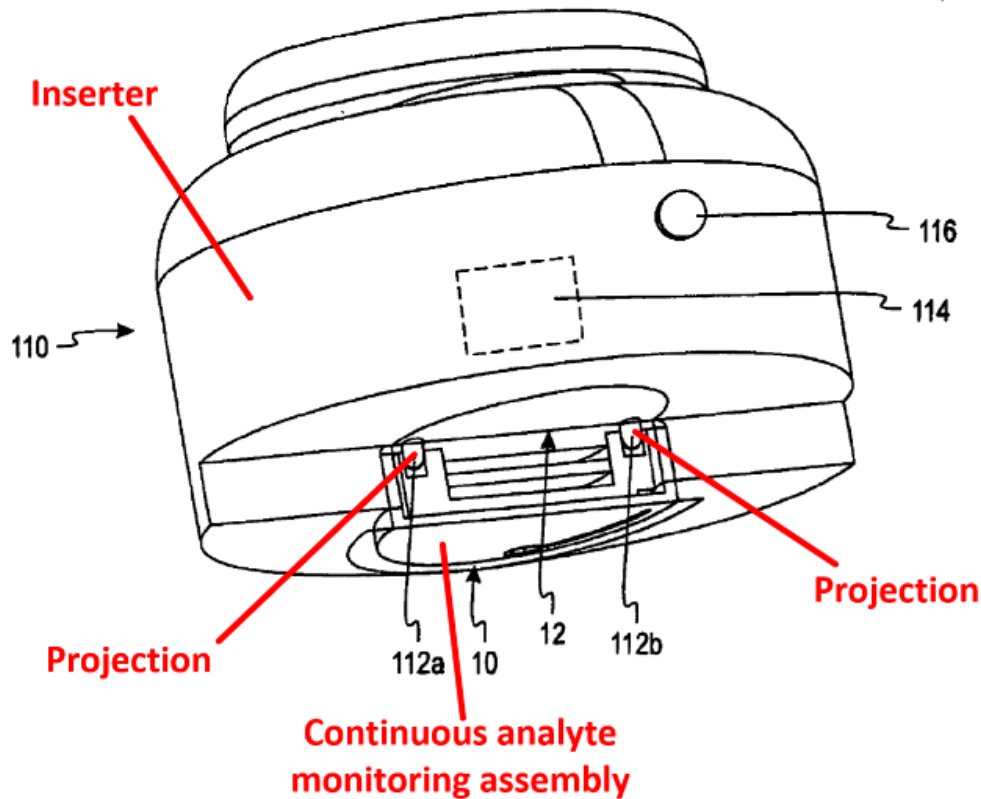
The utility and desirability of adding apertures to the outer periphery of an on-body unit is reflected in, for example, Brenneman.¹² EX1040, FIGS. 1, 8, [0042] (which teach projections/pins 112 that interface with apertures 60 in the outer periphery of the top surface of the continuous analyte monitoring assembly 10 to “form a snug fit therein to couple the continuous analyte monitoring assembly 10 and the inserter 110.”). Positioning the apertures on a periphery of the top surface

¹²For purposes of Ground 1, Petitioner relies on Brenneman and Turner as background references that reflect the state of the art and knowledge of the POSITA.

desirably secures the outer edges of the on-body unit within the inserter, e.g., the “snug fit” aids in maintaining the on-body unit within the housing prior to insertion. The POSITA would also recognize that this helps maintain alignment and reduces tipping/tilting within the inserter.



Brenneman, FIG. 1 (annotated)

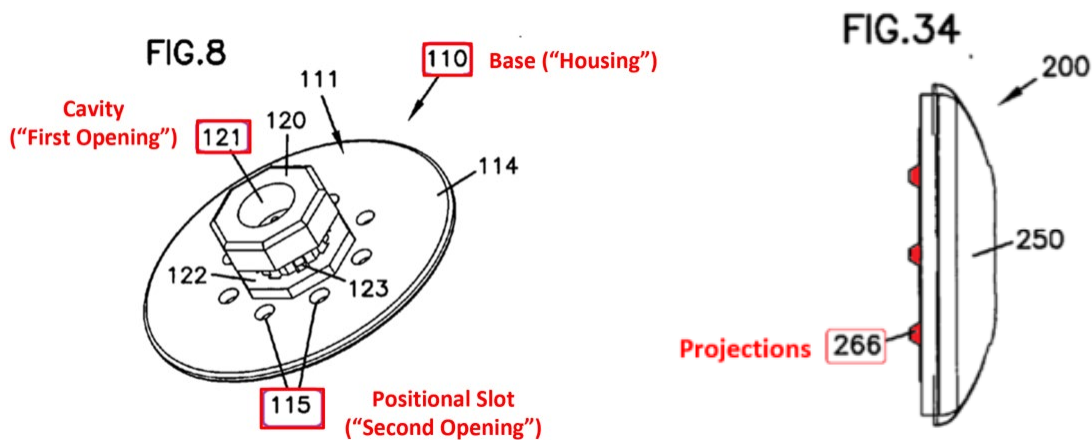


Brenneman, FIG. 8 (annotated)

The POSITA would recognize the further benefit of the peripheral apertures taught by Brenneman, as those peripheral apertures and associated pins would also assist in avoiding rotation of the on-body unit. The desire to avoid rotation is reflected in, e.g., Turner, which teaches recesses and associated protrusions to avoid rotation. EX1007, [0068]-[0069], FIG. 3, (protrusions 71 on the insertion device interface with complementary recesses 77 “to prevent rotation of the insertion device relative to body 20 [of the on-body unit].”).

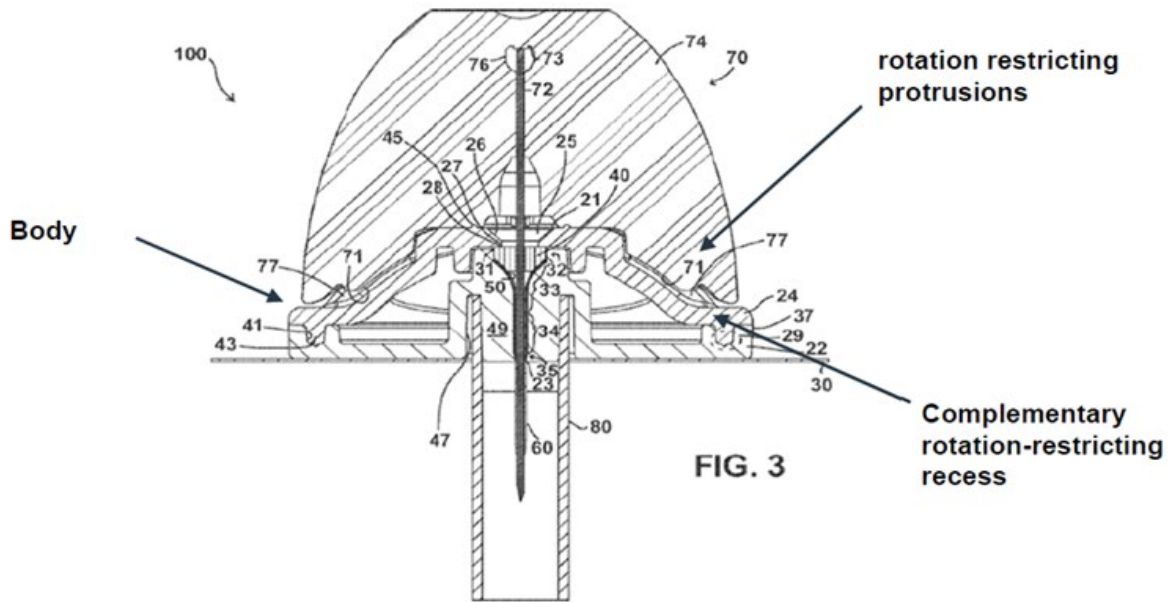
Accordingly, a POSITA would have been motivated to add peripheral apertures to the top surface of Stafford+Cote’s on-body unit to better couple the on-

body unit to the inserter in a desired position and retain it there, as taught by Brenneman and Turner. The POSITA would have reasonably expected success in adding such peripheral apertures as evidenced by the fact that both Brenneman and Turner did so, and further as confirmed by Cote itself which teaches use of similar concepts for a slightly different purpose, namely openings (“positional slots” 115 on the base 110) that interface with corresponding projections 266 to maintain alignment between the different portions of the infusion device. EX1005, [0135], [0137], [0168], FIGS. 8 and 34 (below); EX1003, ¶¶144-147.



Cote, FIGS. 8 and 34 (annotated)

To the extent Patent Owner argues that such “second opening[s] of the top surface” were not at least obvious over Stafford+Cote alone, Patent Owner effectively admitted in foreign litigation that a POSITA would have been motivated to include complementary recesses to mate with corresponding protrusions as disclosed in Turner. Patent Owner annotated Turner FIG. 3 as follows:



Turner, FIG. 3 (as annotated by Patent Owner)

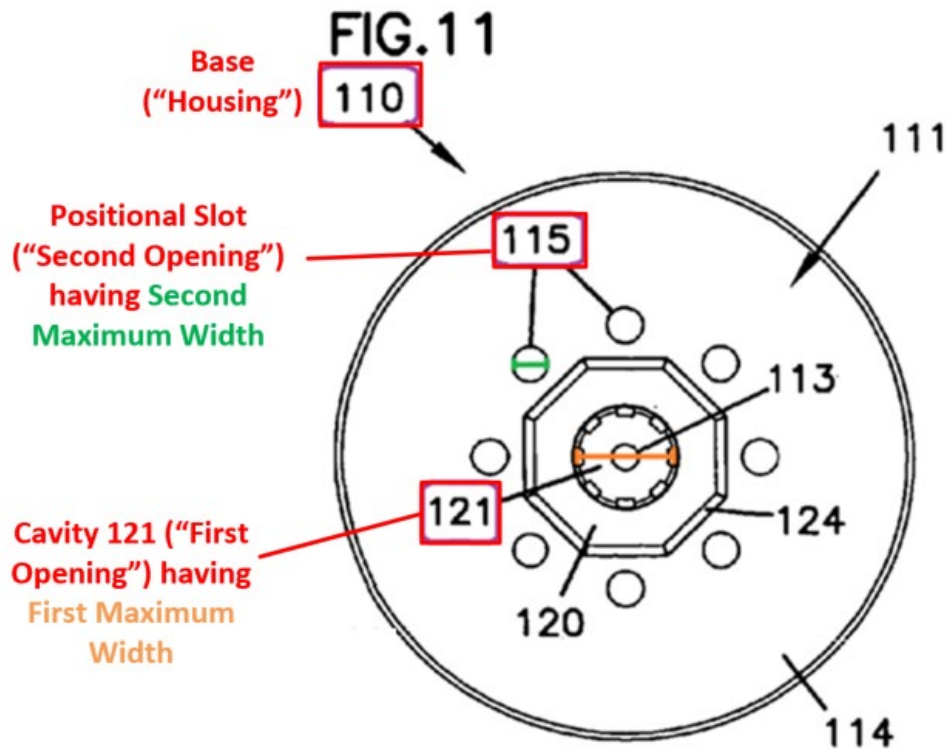
EX1041, 66. Patent Owner then contended that “the skilled person would transfer the protrusions for preventing rotation of the hub 74 disclosed in [Turner] to a CGM device.” *Id.*, 67; *see also id.*, 66 (quoting EX1007 (Turner), [0069]); *cf. Qualcomm Inc. v. Apple Inc.*, 24 F.4th 1367, 1376 (Fed. Cir. 2022) (noting that uses of “a patentee's admissions include, for example, furnishing a motivation to combine”).

Thus, a POSITA would be motivated, with a reasonable expectation of success, to add at least one peripheral aperture (“second opening”) to the top surface of the Stafford+Cote on-body unit in order to maintain the position of the on-body unit relative to the inserter. EX1003, ¶¶148-149.

[18.2]/[21.2] wherein the first opening of the top surface has a first maximum width, and wherein the second opening of the top surface has a second maximum width less than the first maximum width.

As discussed *supra*, in Section [18.1]/[21.1], in Stafford+Cote, Stafford's on-body unit includes Stafford's self-sealing aperture ("first opening") and peripheral apertures ("second openings") on the outer edges of the top surface of the housing, as taught by, e.g., Brenneman. A POSITA would have found it obvious to configure the peripheral apertures with a smaller maximum width than Stafford's 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. Further, this simple design choice is explicitly shown in Cote. EX1005, FIGS. 8, 11.

Cote teaches a first opening ("cavity 121") having a first maximum width and a second opening ("positional slots 115") having a second maximum width less than the first maximum width. *Id.*, FIG. 11, [0135], [0137].



Cote, FIG. 11 (annotated)

Furthermore, if the only difference between the prior art and the claims is a recitation of relative dimensions, and the claimed dimensions do not affect the performance of the device, then the claimed device is not patentably distinct from the prior art. *Gardner v. TEC Syst., Inc.*, 725 F.2d 1338, 1349, 220 USPQ 777 (Fed. Cir. 1984) (affirming district court's decision invalidating claims where "the dimensional limitations did not specify a device which performed and operated any differently from the prior art"). The '591 patent does not describe the claimed relative widths affecting the performance of the device in any way, but merely

depicts the housing 122 with circles of smaller size than its central opening on its top surface. EX1001, FIG. 23 (below).

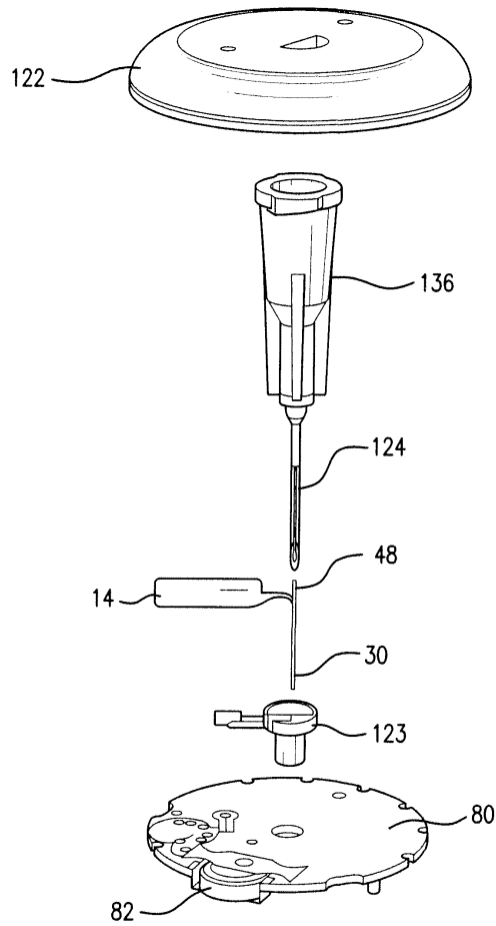


FIG.23

'591 patent, FIG. 23

EX1003, ¶¶150-152.

16. Claim 19, 20-24, 27, 29-30

Claim 19 is similar to claim 1, except that it adds limitations similar to those in claims 3-5, and 14, which are also taught or suggested by Stafford+Cote, as described in Sections VII.C.1, VII.C.3-VII.C.5, and VII.C.12, above.

Each of claims 20-24, 27, 29-30 depends from claim 19, and recites elements taught or suggested by Stafford+Cote. *See* Sections VII.C.2, VII.C.6-VII.C.11, VII.C.13, and VII.C.15.

To the extent Patent Owner argues certain claims are not obvious over Stafford+Cote, these claims are also obvious over Stafford+Cote, further in view of Say, Brenneman, and/or Shah, as set forth below. EX1003, ¶¶153-155.

VIII. GROUND 2: STAFFORD+COTE+SAY (CLAIMS 4, 7-8, 14-15, 19-30)

Dependent claims 4, 7-8, 14-15, 19, 25-26, and 28 each recite elements that, to the extent Patent Owner argues they are not obvious over Stafford+Cote alone, are further obvious over Say. Claims 20-21, 23-30 depend directly or indirectly from claim 19 and are also obvious over Stafford+Cote in view of Say. EX1003, ¶156.

A. Say

U.S. Patent No. 6,175,752 (EX1008, “Say”) issued January 16, 2001, and qualifies as prior art under at least Pre-AIA Section 102(b).

Say describes a glucose monitoring system including a sensor control unit (functionally similar to Stafford’s data processing unit) that can include a memory.

EX1008, 5:25-28, 44:54-45:7 (“The on-skin sensor control unit 44 may include an optional data storage unit 102 The data storage unit 102 typically includes a readable/writeable memory storage device”).

Say also describes that the sensor control unit’s sensor electronics can enter a “sleep mode” prior to use to conserve battery power. EX1008, 31:41-62 (“The on-skin sensor control unit 44 optionally remains in a sleep mode prior to use to conserve the battery’s power”).

Say further describes its sensor control unit as being “thin” to “enhance concealment” and specifically teaches that the on-body unit “has a height of ... preferably 0.7 cm [7 mm] or less.” EX1008, 29:38, 29:45-47.

Say further teaches that a support can be disposed within a housing of the sensor control unit to promote adequate contact between an analyte sensor and electrical contacts of the sensor electronics. *Id.*, 34:53-35:5; EX1003, ¶¶157-161.

B. Combining The Teachings Of Stafford+Cote+Say

Say (disclosing a transcutaneous medical device for diabetes treatments) is analogous art to the claimed invention of the ’591 patent and to Stafford and Cote.

Stafford expressly discloses that additional details of its data processing unit are disclosed in Say. EX1004, [0043]. Thus, a POSITA implementing Stafford+Cote would have been motivated to consult Say and incorporate its beneficial teachings on (1) memory for storing instructions or sensor data, (2) promoting adequate

contact between a sensor and associated sensor electronics, and (3) conserving battery power. A POSITA reading Say would, with a reasonable expectation of success, be motivated to add Say's memory, support, and sleep mode functionality to Stafford's data processing unit to further improve Stafford's data processing unit. EX1003, ¶¶162-163.

1. Claims 4/19, 14/19

[4.1]/[19.6] [The insertion assembly of claim 3,] wherein the sensor electronics comprise a processor, a power source, an analog interface, a data storage unit, and wireless communication circuitry configured to communicate data indicative of a glucose level[.]/[; and]

As to claims 4 and 19, to the extent not already expressly disclosed, a POSITA would have been motivated to include a data storage unit as taught by Say to Stafford+Cote to store collected sensor data and/or instructions for operating Stafford's on-body unit.

Specifically, Say describes that the on-skin sensor control unit electronics ("sensor electronics") include a data storage unit. EX1008, 44:54-45:7 ("The on-skin sensor control unit 44 may include an optional data storage unit 102 The data storage unit 102 typically includes a readable/writeable memory storage device"), 36:40-43. A POSITA would be motivated to include a data storage unit in Stafford's sensor electronics to hold data (*e.g.*, measurements from the sensor or

processed data) for analysis by the processor, as taught in Say. *Id.*, 44:54-45:7; EX1003, ¶¶181-182.

[14.1]/[19.14] [The insertion assembly of claim 3,] wherein a height profile of the housing is less than or equal to approximately 10 millimeters[.]/[.,]

As to claims 14 and 19, Say describes its on-body unit as being “thin” to “enhance concealment” and specifically teaches that the on-body unit “has a height of ... preferably 0.7 cm [7 mm] or less.” EX1008, 29:38, 29:45-47. Accordingly, in further view of Say, a POSITA would have found it obvious to configure the housing of Stafford’s on-body unit in Stafford+Cote to have a height profile of 7 mm or less. EX1003, ¶183.

2. Claims 7/25

[7.1]/[25.1] The insertion assembly of claim [3/23], wherein the sensor electronics are in a sleep mode or an idle mode when the on-body unit is in the first position.

Say teaches that on-skin sensor control units (“on-body units”) “optionally remain[] in a sleep mode prior to use to conserve the battery’s power.” EX1008, 31:45-47. A POSITA would understand that “prior to use” of the on-body unit (*i.e.*, prior to insertion of the sensor), Stafford’s on-body unit is in the first position within the inserter.

Accordingly, in Stafford+Cote+Say, Stafford’s sensor electronics are in a sleep mode while Stafford’s on-body unit is in the first position within the inserter.

It would have been obvious to a POSITA to make such a modification to “conserve the battery’s power,” as taught in Say (EX1008, 31:45-47); EX1003, ¶¶164-165.

3. Claims 8/26

[8.1]/[26.1] The insertion assembly of claim [3/23], wherein the sensor electronics are configured to be activated when the on-body unit is at or near the second position.

While the ’591 patent does not provide a specific definition of the term “activated,” the specification uses the term “activating” synonymously with “switching on”: “thereby closing the circuit to/from the battery/power source and thus *activating or switching on* the sensor electronics.” EX1001, 22:9-10. Accordingly, a POSITA would understand that the claim limitation is met if the sensor electronics are switched on when the on-body unit is at or near the second position.

In Stafford+Cote, Stafford’s on-body unit is in a “second position” when Stafford’s on-body unit is secured to the skin of a user and Stafford’s sharp pierces the user’s skin. *See* Section [1.12]/[19.12].

Stafford teaches that “the data processing unit 101 may be configured to transmit the encoded sampled data signals ... *after the completion of the initial power on procedure.*” EX1004, [0037]. A POSITA would therefore understand that Stafford’s data processing unit is powered on (*i.e.*, activated) when transmitting data

(*i.e.*, when the sensor has been inserted). Thus, Stafford's data processing unit ("sensor electronics") is activated when at the second position (on the patient's skin).

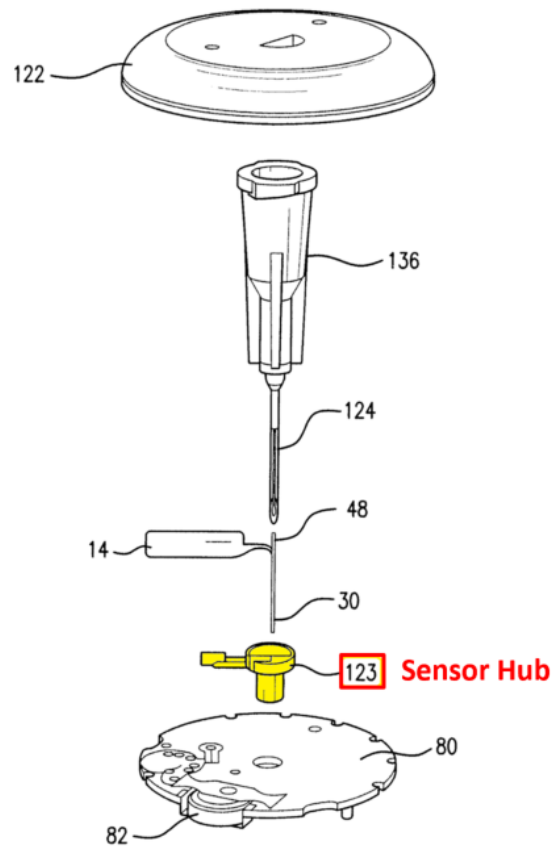
Additionally, Say teaches sensor electronics that remain in sleep mode to conserve battery power and that "[t]he on-skin sensor control unit 44 detects that it is being used and activates itself. Detection of use may be through a number of mechanisms." EX1008, 31:45-49. In view of this, a POSITA would understand that, to conserve battery life, it is advantageous to activate the sensor electronics once Stafford's on-body unit is at or near the second position, *i.e.*, on or near the patient's skin. Accordingly, a POSITA would have found it obvious in Stafford+Cote to configure Stafford's sensor electronics to be activated when at or near the second position. 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..."). EX1003, ¶¶166-169.

4. Claims 15/28

[15.1]/[28.1] The insertion assembly of claim [3/23], further comprising a sensor hub,
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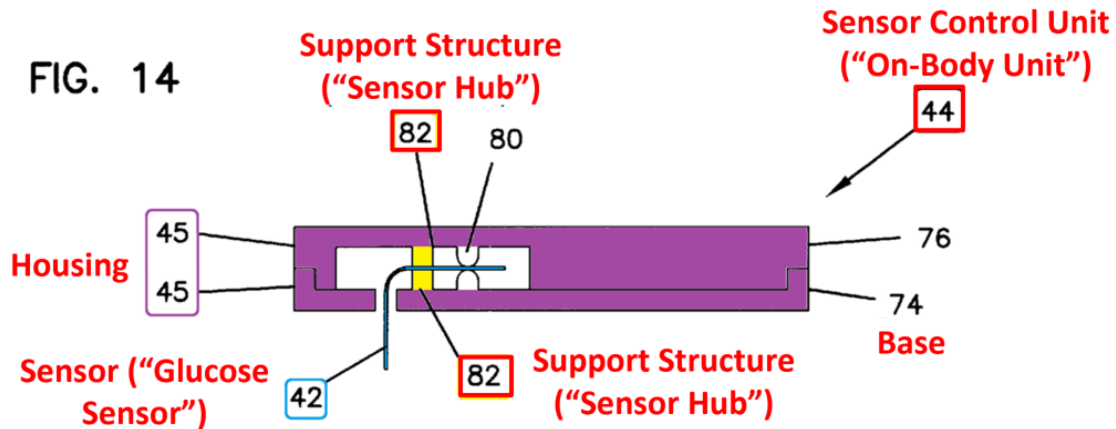
The '591 patent discloses that the sensor hub includes a structure positioned within the housing of the on-body unit supporting the portion of the sensor that is

electrically coupled to electrical contacts. *See, e.g.*, EX1001, FIG. 23 (element 123), 17:56-59, [15.3]/[28.3].

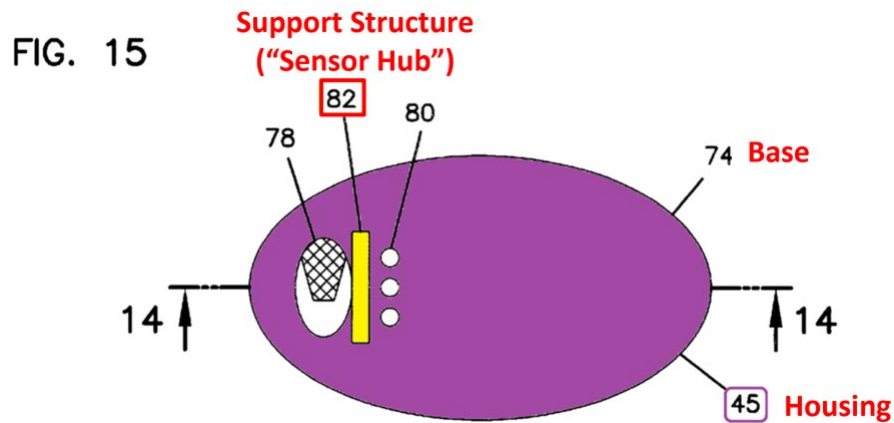


'591 patent, FIG. 23 (annotated)

Say teaches a sensor control unit (“on-body unit”) containing a support structure (“sensor hub”) to “hold, support, and/or guide the sensor 42 into the correct position.” EX1008, 34:50-52, FIGS. 14-16. The 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.” *Id.*, 34:59-61. *See also id.*, FIG. 19A. Thus, Say discloses an on-body unit comprising a “sensor hub.”



Say, FIG. 14 (annotated)

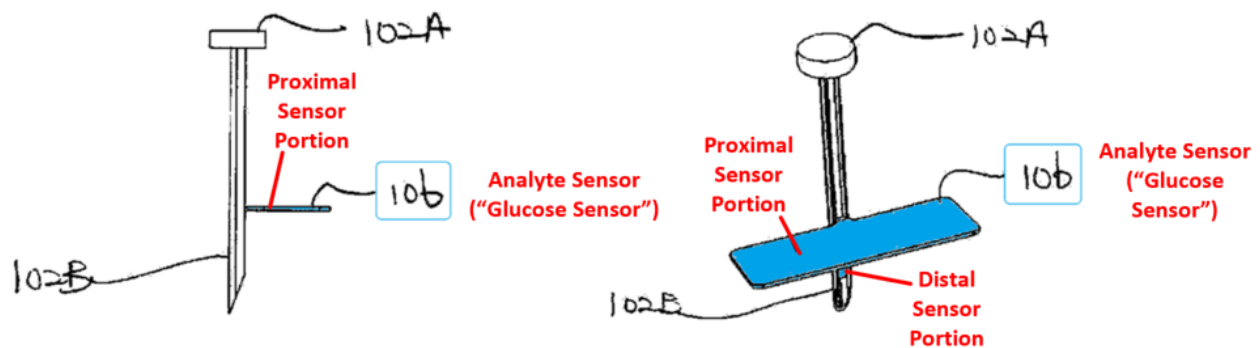


Say, FIG. 15 (annotated)

The most natural understanding of Say's support structure is that item 82 is indeed a separate structure that satisfies the claimed "sensor hub" limitation. EX1003, ¶¶170-173.

[15.2]/[28.2] wherein the glucose sensor comprises a distal sensor portion and a proximal sensor portion, wherein the distal sensor portion is configured to sense a glucose level of the user,

Stafford's sensor has a first portion ("distal sensor portion") and a second portion ("proximal sensor portion"). EX1004, [0006]. Stafford's distal sensor portion senses a patient's analyte level (*id.*, [0028]), and that analyte is glucose. EX1004, [0029], FIGS. 5B, 5C.



Stafford, FIGS. 5B, 5C (annotated)

EX1003, ¶¶174-175.

[15.3]/[28.3] wherein the proximal sensor portion is engaged with the sensor hub, and

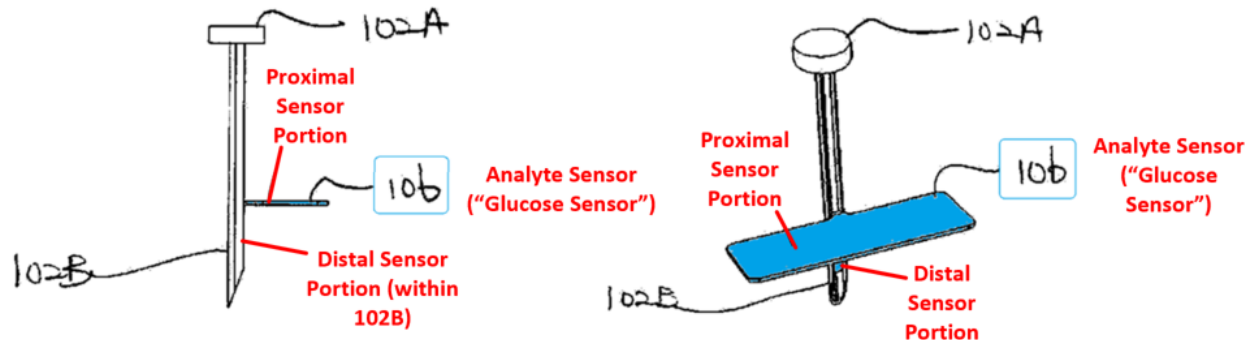
Say teaches that the proximal portion of the sensor is engaged with a support structure. EX1008, 34:50-52, 34:59-61, FIG. 14. *See* Section [15.1]. Thus, in Stafford+Cote, a POSITA would be motivated to hold or support the proximal sensor portion of Stafford's sensor with a support structure to "hold, support, and/or guide the sensor [...] into the correct position," and to help promote adequate electrical

contact between Stafford's proximal sensor portion and Stafford's sensor electronics, as taught by Say. EX1008, 34:51-62, 34:59-61 ("A support 82 may be provided under the sensor 42 to promote adequate contact between the contact pads 49 on the sensor 42 and the pins 84."); EX1004, claim 1 ("...wherein the second portion of the analyte sensor is in electrical contact with the data processing unit...").

A POSITA would have a reasonable expectation of success in making the combination because Say's sensor and Stafford's analyte sensor have similar shapes and the proximal sensor portion of each would be supported in a similar fashion. Moreover, it was well-known for on-body units to include sensor hubs to engage a proximal portion of a sensor. *See e.g.*, EX1018 (Bickoff), [0034], [0035], FIG. 4 (teaching a separate "sensor hub 46" that receives a "shank proximal end 60b" of "sensor 60").

Accordingly, a POSITA would have found it obvious to modify Stafford to have a proximal portion of Stafford's sensor engaged with a support structure ("sensor hub"), as such a configuration is explicitly taught by Say. EX1003, ¶¶176-179.

[15.4]/[28.4] wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.



Stafford, FIGS. 5B, 5C (annotated)

In Stafford+Cote, the distal sensor portion of Stafford's sensor is substantially orthogonal to the proximal sensor portion, as taught by Stafford and as shown above.

EX1004, FIGS. 5B, 5C; EX1003, ¶180.

5. Claims 20-30

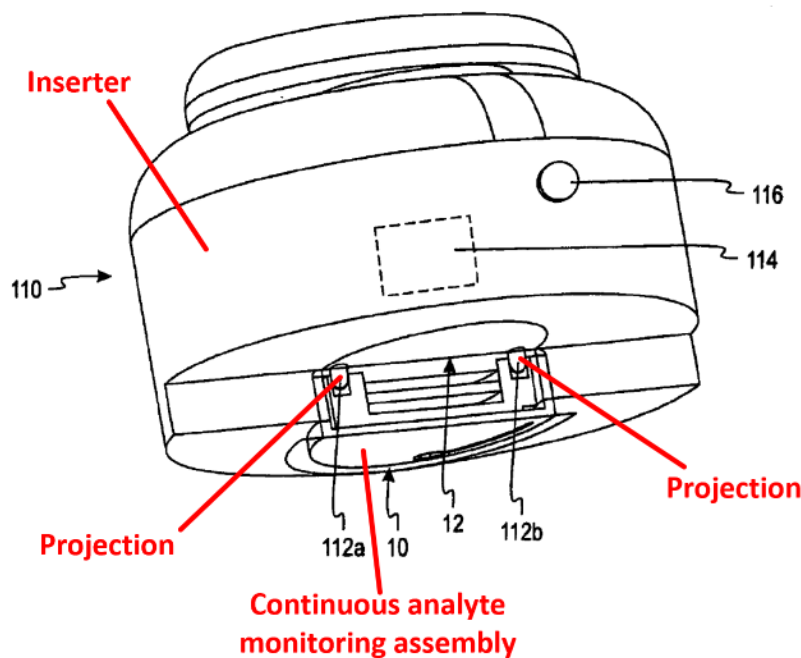
Each of claims 20-30 depends from claim 19, and recites elements that are substantially identical to those in claims already shown to be obvious over Stafford and Cote (Sections VII.C.2, VII.C.6-VII.C.11, VII.C.13, and VII.C.15-VII.C.16), and/or in further view of Say (Sections VIII.B.2-5). EX1003, ¶184.

**IX. GROUND 3:
STAFFORD+COTE+BRENNEMAN (CLAIMS 18, 21-24, 27, 29-30)**

A. Brenneman

PCT Publication No. WO2008/115409 (“Brenneman,” EX1040) published on September 25, 2008, from an application filed March 14, 2008. Brenneman qualifies as prior art under Pre-AIA Sections 102(a), and 102(e).

Brenneman describes an insertion device 110 for delivering a continuous analyte monitoring assembly 10 to the skin of a subject, glucose being one of the measured analytes. EX1040, [0023], [0041]-[0048].



Brenneman, FIG. 8 (annotated)

As shown above, Brenneman’s insertion device 110 comprises a plurality of projections 112, each of which engages a corresponding one of a plurality of

peripheral apertures 60 disposed on a top surface of the cover 12 of the continuous analyte monitoring assembly 10. EX1040, [0028], [0041]; EX1003, ¶¶185-186.

B. Combining The Teachings Of Stafford+Cote+Brenneman

Brenneman (directed to the insertion of transcutaneous analyte sensors for diabetes treatments) is analogous art to the claimed invention of the '591 patent and to Stafford, Cote, and Say.

A POSITA implementing Stafford+Cote would have been further motivated to use Brenneman's teachings on mechanisms for coupling an on-body unit to an inserter, which are complementary to Cote's teachings. For example, Cote teaches an on-body unit that is retained within the inserter using frictional engagement between a diaphragm of the on-body unit and a needle of the inserter. EX1005, [0205]. Likewise, Brenneman's peripheral apertures "form a snug fit" with the projections "to couple the continuous analyte monitoring assembly 10 and the inserter 110." EX1040, [0042], FIG. 8.

A POSITA knew it was desirable to secure the on-body unit within the inserter in Stafford+Cote in a desired position, for example, to prevent dislodging of the on-body unit during shipping and/or reduce tipping/tilting of the on-body unit within the inserter. *Supra* Section V.B.6. A POSITA understanding this need and reading Brenneman would, with a reasonable expectation of success, implement Stafford+Cote with peripheral apertures on the top surface of the on-body unit, as

taught by Brenneman, and corresponding projections on the insertion device (*e.g.*, at the distal end of the cylinder hub), as taught by Brenneman, such that the on-body unit remains in a desired position within the inserter. EX1040, [0042]; *see also* EX1007, [0069] (which teaches the use of corresponding recesses and protrusions to maintain the on-body unit and inserter in a desired position relative to one another).

Brenneman thus further reinforces that a POSITA would have found it obvious to include peripheral aperture(s) on a top surface of an on-body unit in Stafford+Cote to couple the on-body unit and inserter to one another. EX1003, ¶¶187-190.

1. Claims 18, 21-24, 27, 29-30

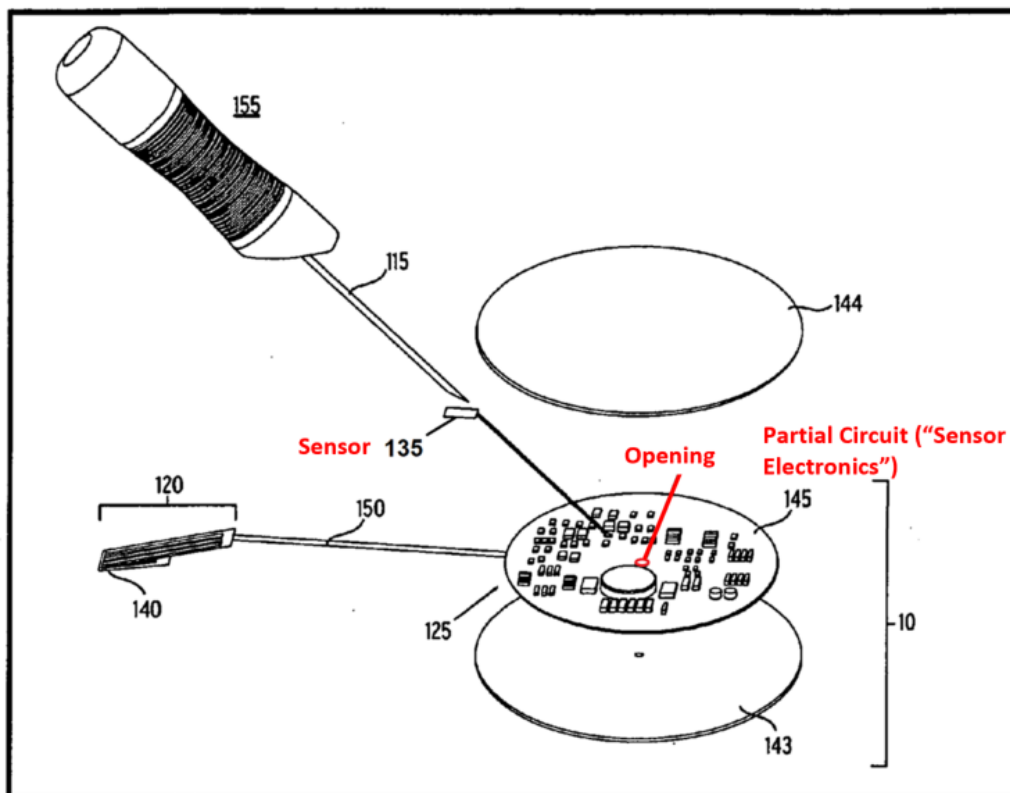
Dependent claims 18 and 21 each recite “a second opening on the top surface.” This was obvious in view of Stafford+Cote, as described above. *See* Section VII.C.15. To the extent Patent Owner argues otherwise, Brenneman—presented here in Ground 3 as part of the combination itself (and not merely as a background reference)—confirms obviousness, as it teaches peripheral apertures (*e.g.*, a “second opening”) positioned on a top surface of an on-body unit, *e.g.*, for coupling the on-body unit with an inserter. EX1040, [0042], FIGS. 1, 8.

Claims 22-24, 27, 29-30 depend directly or indirectly from Claim 21, and the Stafford+Cote combination teaches the additional limitations of these claims. *See* Sections VII.C.6-VII.C.11, and VII.C.13; EX1003, ¶¶191-192.

X. GROUND 4: STAFFORD+COTE+SHAH (CLAIMS 9, 22-24, 27, 29-30)

A. Shah

U.S. Publication No. 2007/0073129 (“Shah,” EX1006), published on March 29, 2007, from an application filed September 23, 2005. Shah qualifies as prior art under Pre-AIA Section 102(b).



Shah, FIG. 6 (annotated)

Shah teaches a transcutaneous analyte sensor coupled to a flexible partial circuit with an opening (red) through which the sensor and needle pass. EX1006, [0045], [0046], FIG. 6; EX1003, ¶¶193-194.

B. Combining The Teachings Of Stafford+Cote+Shah

Shah (disclosing a transcutaneous medical device for diabetes treatments) is analogous art to the claimed invention of the '591 patent and to Stafford and Cote.

A POSITA would have been motivated to implement Shah's teachings in Stafford+Cote, to include an opening in Stafford's sensor electronics allowing passage of the sensor and sharp therethrough.

Specifically, Stafford teaches a data processing unit comprising sensor electronics and an introducer configured to extend through a central portion of the data processing unit. EX1004, FIGS. 2-4A. Likewise, Shah teaches a flexible mounting base (functionally similar to Stafford's data processing unit) comprising a flexible partial circuit having an opening and an insertion needle configured to extend partially through the opening in the central portion of the mounting base. EX1006, [0045] FIG. 6. Given that Stafford does not explicitly show the arrangement of the sensor electronics within the on-body unit, a POSITA would have naturally turned to other sensor disclosures on specific electronics arrangements. The POSITA would have understood that one implementation of the electronics would be as in Shah, with a printed circuit board that occupies the entire

cavity within Stafford's housing. A POSITA would have implemented this PCB with a hole aligned with the hole in Stafford's housing, so that Stafford's introducer extended through both the housing and electronics, as taught by Shah. EX1003, ¶¶195-198.

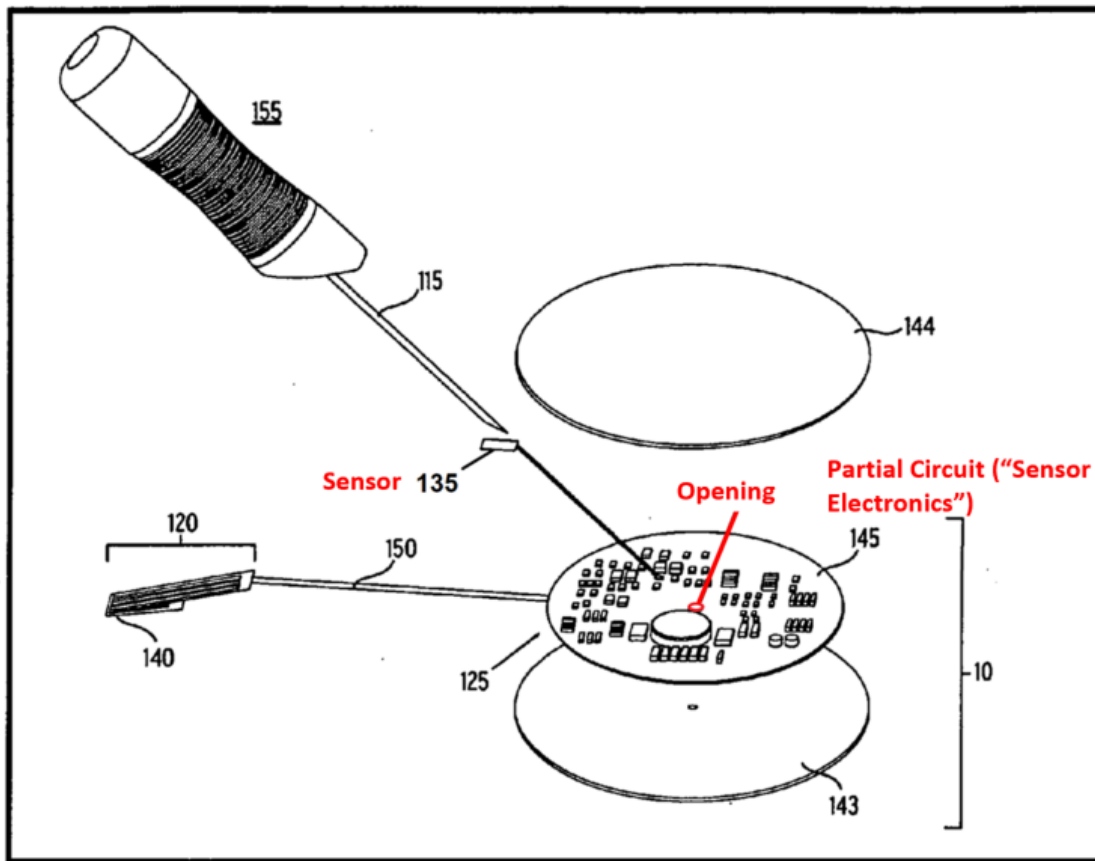
There was a reasonable expectation of success in such an arrangement, because Shah depicts it functioning for another type of on-body unit with a housing and an in-vivo portion. Further, adding an opening to the circuit board is an obvious design choice and one of a finite number of solutions for positioning the sharp such that it extends through the on-body unit.

Thus, a POSITA would be motivated to combine the teachings of Stafford, Cote, and Shah (hereinafter "Stafford+Cote+Shah") with a reasonable expectation of success. EX1003, ¶¶199-200.

1. Claims 9, 22, 23-24, 27, 29-30

Claims 9 and 22 depend from claims 3 and 21, respectively, which are obvious in view of Stafford+Cote. *See* Sections VII.C.3 and VII.C.15.

Shah teaches a partial circuit ("sensor electronics") having an opening through which an insertion needle ("sharp") extends. EX1006, [0045], FIG. 6. An opening in the sensor electronics would thus have been an obvious variation in shape in view of Shah.



Shah, FIG. 6 (annotated)

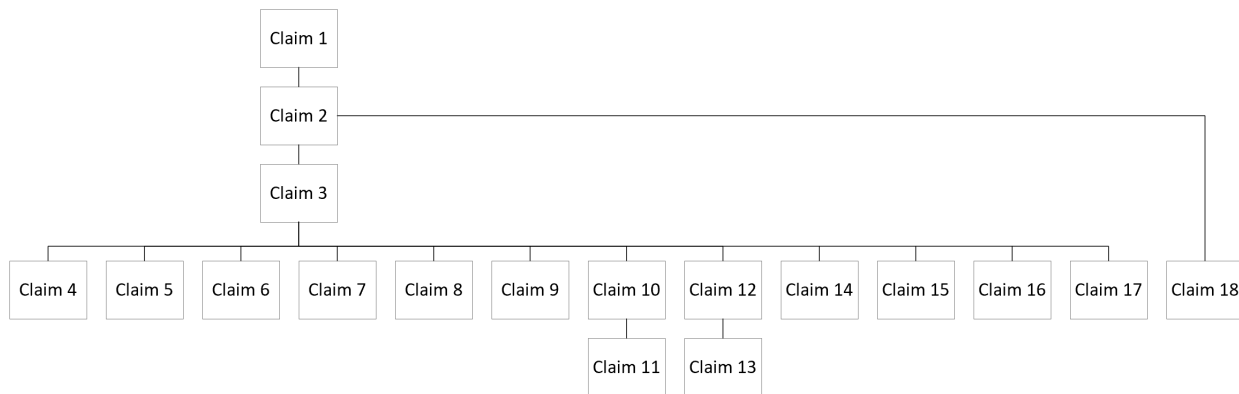
Moreover, Shah teaches that “the sensor electronics may be contained in a housing.” EX1006, [0046]. As such, Shah’s sensor electronics are expressly contemplated as being positioned within a housing, such as the housing of Stafford’s on-body unit.

A POSITA would have thus been motivated to combine Stafford+Cote with Shah’s teachings of an opening of the sensor electronics, with a reasonable expectation of success.

Claims 23-24, 27, 29-30 depend directly or indirectly from Claim 22. Stafford+Cote teaches the additional limitations of these claims. *See* Sections VII.C.6, VII.C.8-VII.C.11, and VII.C.13; EX1003, ¶¶201-204.

XI. GROUNDS 5-8 (CLAIMS 21-30)

As shown in the below claim dependency trees, the '591 patent includes various groupings of indirectly dependent claims, particularly in the group of claims depending from independent claim 19. These indirectly dependent claims require the presentation of several contingent grounds to cover different combinations of the same set of features.



'591 patent, claim tree showing dependent claims of independent claim 1



'591 patent, claim tree showing dependent claims of independent claim 19

For example, claims 21 and 22 depend indirectly from claim 19, and claims 25-26, and 28 indirectly depend from both claims 19 and 22, as shown above, requiring the addition of Grounds 5-8 covering various subsets of claims 21-30, despite no new features being added.

A. Ground 5: +Brenneman To Ground 2 (Claims 21-30)

Claim 21 depends from claim 20, which, as shown in Ground 2, is obvious over Stafford+Cote+Say. *See* Section VIII.B.5. As described in Ground 3, Brenneman further demonstrates the obviousness of the additional limitations of claim 21. *See* Section IX.B.1. A POSITA would have been motivated to further

combine Brennehan's teachings with those of Stafford+Cote+Say, with a reasonable expectation of success. *See* Section IX.B.

Claims 22-30 depend directly or indirectly from Claim 21. As shown above, Stafford+Cote and Stafford+Cote+Say satisfy these claims' added limitations. *See* Sections VII.C.6-VII.C.11, VII.C.13, and VIII.B.2-VIII.B.4; EX1003, ¶¶205-206.

B. Grounds 6-8: +Shah To Grounds 2, 3, And 5 (Claims 22-30)

As explained in Ground 4, Shah teaches use of printed circuit board electronics that, when combined with Stafford+Cote, further render claim 22 obvious. A POSITA would have been motivated with a reasonable expectation of success to incorporate Shah's teachings into Stafford+Cote, with or without the other references' teachings combined therewith. *See* Section X.B; EX1003, ¶207.

1. Ground 6: Stafford+Cote+Say+Shah (Claims 25-26, 28)

As explained above in Ground 2, Stafford, Cote, and Say render obvious *inter alia* claim 21, from which claim 22 depends, as well as claims 25-26, and 28, which depend indirectly from claim 22. *See* Sections VIII.B.1-5. As noted in Ground 4, a POSITA would have been motivated with a reasonable expectation of success to incorporate Shah's teachings into Stafford+Cote+Say, thus further rendering obvious claims 25-26 and 28. *See* Sections X.B, X.B.1; EX1003, ¶208.

2. Ground 7:
Stafford+Cote+Brenneman+Shah (Claims 22-24, 27, 29-30)

As explained above in Ground 3, Stafford, Cote, and Brenneman render obvious *inter alia* claim 21, from which claim 22 depends, as well as claims 24, 27, 29, and 30, which depend indirectly from claim 22. *See* Section IX.B.1. A POSITA would have been motivated with a reasonable expectation of success to incorporate Shah's teachings into Stafford+Cote+Brenneman, thus further rendering obvious claims 22-24, 27, 29, and 30. *See* Sections X.B, X.B.1; EX1003, ¶209.

3. Ground 8:
Stafford+Cote+Say+Brenneman+Shah (Claims 25-26, 28)

As explained above in Ground 5, Stafford, Cote, Say, and Brenneman render obvious *inter alia* claim 21, from which claim 22 depends, as well as claims 25-26, and 28, which depend indirectly from claim 22. *See* Section XI.A. A POSITA would have been motivated with a reasonable expectation of success to incorporate Shah's teachings into Stafford+Cote+Say+Brenneman, thus further rendering obvious claims 25-26 and 28. *See* Section X.B, X.B.1; EX1003, ¶210.

XII. NO OBJECTIVE INDICIA OF NON-OBVIOUSNESS

Petitioner is unaware of any objective indicia of non-obviousness as to any Challenged Claim.

XIII. CONCLUSION

Petitioner requests institution on the Grounds presented herein.

Respectfully submitted,

October 11, 2023

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**CERTIFICATE OF COMPLIANCE WITH
TYPE-VOLUME LIMITATION PURSUANT TO 37 C.F.R. § 42.24**

This brief complies with the type-volume limitation of 37 C.F.R. § 42.24
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CERTIFICATE OF SERVICE
IN COMPLIANCE WITH 37 C.F.R. § 42.6 (E)(4)

The undersigned certifies that the **Petition for *Inter Partes* Review of U.S. Patent No. 11,202,591 and Exhibits 1001 – 1021, 1025 – 1031, and 1034 – 1042** were served on October 11, 2023, via **Express Mail** on the Patent Owner at the following address of record as listed on the USPTO Patent Center:

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