

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

IPR2023-01396
U.S. Patent No.: 11,266,335
Issued: March 8, 2022
Application No.: 17/019,110
Filed: September 11, 2020

Title: MEDICAL DEVICE INSERTERS AND PROCESSES OF
INSERTING AND USING MEDICAL DEVICES

PETITION FOR
INTER PARTES REVIEW OF U.S. PATENT NO. 11,266,335

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LIST OF EXHIBITS

No.	Description
1001	U.S. Patent No. 11,266,335 (“ 335 Patent ”)
1002	File History of U.S. Patent No. 11,266,335 (“ 335 FH ”)
1003	Declaration of Gary D. Fletcher, Ph.D., dated October 6, 2023 (“ Fletcher Decl. ”)
1004	U.S. Provisional Application No. 61/411,262, filed November 8, 2010
1005	U.S. Patent Application No. 13/071,461, filed March 24, 2011
1006	U.S. Provisional Application No. 61/317,243, filed March 24, 2010
1007	U.S. Provisional Application No. 61/345,562, filed May 17, 2010
1008	U.S. Provisional Application No. 61/361,374, filed July 2, 2010
1009	U.S. Publication No. 2008/0097246 (“ Stafford ”)
1010	U.S. Publication No. 2009/0124979 (“ Raymond ”)
1011	U.S. Publication No. 2007/0135774 (“ Turner ”)
1012	U.S. Patent No. 6,175,752 (“ Say ”)
1013	U.S. Publication No. 2009/0240121 (“ Bickoff ”)
1014	U.S. Publication No. 2007/0073129 (“ Shah ”)
1015	U.S. Publication No. 2006/0095014 (“ Ethelfeld ”)
1017	PCT Publication No. WO 2008/155377 (“ Hasted ”)
1018	U.S. Publication No. 2004/0002682 (“ Kovelman ”)
1023	U.S. Publication No. 2008/0294024 (“ Cosentino ”)
1028	U.S. Patent No. 7,381,184 (“ Funderburk ”)
1030	U.S. Publication No. 2007/0093754 (“ Mogensen ”)

No.	Description
1035	Sybil P. Parker (ed.), <i>McGraw-Hill Dictionary of Mechanical and Design Engineering</i> , 1984 (excerpted)
1037	U.S. Publication No. 2009/0099521 (“ Gravesen ”)
1039	U.S. Publication No. 2008/0319414 (“ Yodfat ”)
1040	U.S. Patent No. 7,207,974 (“ Safabash ”)
1041	U.S. Publication No. 2004/0204687 (“ Mogensen ”)
1042	U.S. Publication No. 2002/0022855 (“ Bobroff ”)
1043	U.S. Patent No. 9,566,384 (“ Gyrn ”)
1044	U.S. Patent No. 8,747,363 (“ Nielsen ”)
1056	U.S. Publication No. 2009/0216215 (“ Thalmann ”)
1057	U.S. Publication No. 2005/0131346 (“ Douglas ”)
1059	U.S. Publication No. 2008/0146904 (“ Hunn ”)
1060	V. Poitout, et al., <i>A glucose monitoring system for on line estimation in man of blood glucose concentration using a miniaturized glucose sensor implanted in the subcutaneous tissue and a wearable control unit</i> , <i>Diabetologia</i> , Vol. 36, Issue 7, 1993
1061	Steven W. Smith, <i>The Scientist and Engineer’s Guide to Digital Signal Processing</i> , 2 nd ed., 1999 (excerpted)
1062	B. A. Shenoi, <i>Introduction to Digital Signal Processing and Filter Design</i> , 2006 (excerpted)
1063	Marc D. Breton, et al., <i>Optimum Subcutaneous Glucose Sampling and Fourier Analysis of Continuous Glucose Monitors</i> , <i>Journal of Diabetes Science and Technology</i> , Vol. 2, Issue 3, May 3, 2008
1064	Antonios E. Panteleon, et al., <i>The Role of the Independent Variable to Glucose Sensor Calibration</i> , <i>Diabetes Technology & Therapeutics</i> , Vol. 5, Number 3, 2003

No.	Description
1065	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
1066	Scheduling Order, <i>Abbott Diabetes Care Inc. v. DexCom Inc.</i> , No. 1-23-cv-00239 (D. Del. filed Mar. 3, 2023)

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 '335 patent (EX1001) has been asserted in the following litigation:

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

A parallel IPR petition is contemporaneously being filed on October 6, 2023, in IPR2023-01397.

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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 1-4, 8-9, and 11-27 (“challenged claims”) of U.S. Patent No. 11,266,335 (“’335 patent”) (EX1001), allegedly assigned to Abbott Diabetes Care Inc. (“Patent Owner”).

The challenged claims are directed to a glucose monitoring assembly with (1) an inserter that includes a sharp, and (2) an on body electronics unit that includes a glucose sensor and an on body electronics unit housing (purple)¹ with plural recesses (red) configured to engage the inserter. EX1001, 48:53-49:26 (claims 1-4), 49:47-55 (claims 8-9); 49:58-51:6 (claims 11-27). The glucose sensor is inserted using the sharp. *Id.* In many dependent claims, the inserter also includes gripping arms (green). *Id.*, 49:12-26 (claims 2-4), 49:47-55 (claims 8-9).

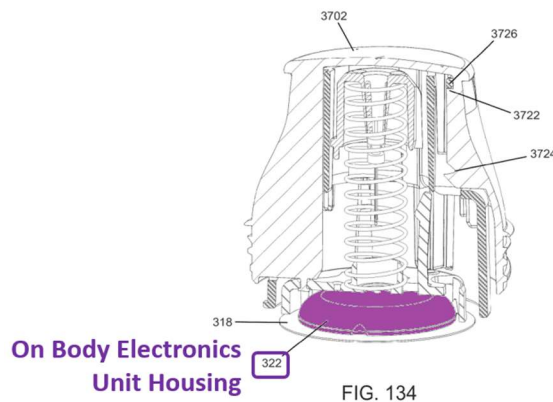


FIG. 134

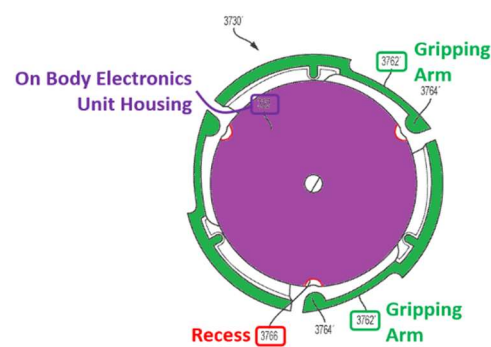


FIG. 135

’335 Patent, FIGS. 134-135 (annotated)

¹ Colors in parentheticals refer to highlighting added to corresponding figures.

However, the prior art included inserters with gripping arms for engaging corresponding recesses on medical devices. *Infra* Section VI.B.3. For example, as shown below, Raymond (EX1010) discloses (1) an insertion device that includes base-retaining arms (green) and a needle, and (2) an infusion device that includes a cannula and recesses (red) configured to engage the insertion device's base-retaining arms. EX1010, FIGS. 29-30, [0123]. The cannula is inserted using the needle. *Id.*

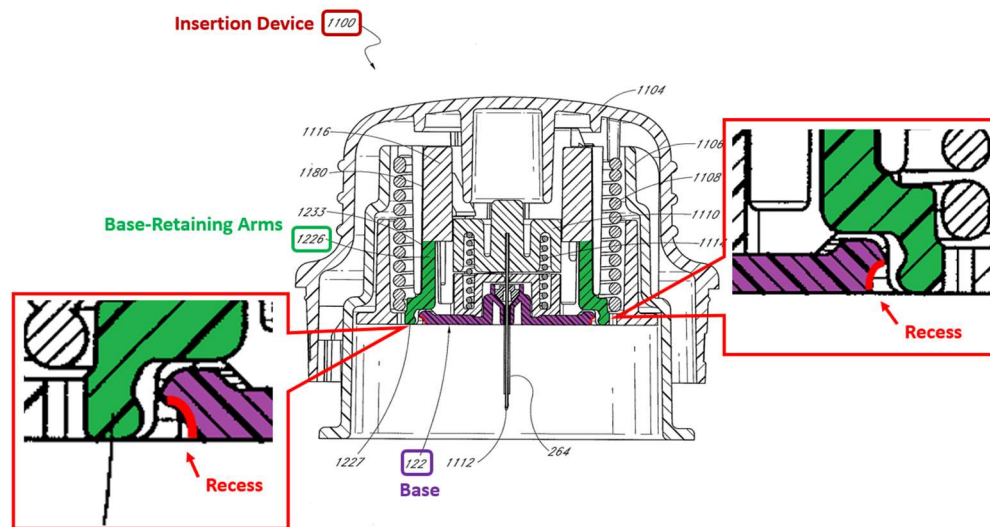


FIG. 29

Raymond, FIG. 29 (annotated)

Furthermore, known glucose sensing devices, such as the integrated assembly disclosed by Stafford (EX1009), included on body electronics units with glucose sensors inserted using a sharp. As explained below, skilled artisans would have naturally combined the teachings of Stafford and Raymond to create a glucose monitoring assembly that renders many challenged claims obvious. *Infra* Section VIII. Other secondary references—*e.g.*, Turner (EX1011), Say (EX1012), Bickoff

(EX1013), and Shah (EX1014)—teach additional features that skilled artisans would have naturally incorporated into such an assembly, thus rendering obvious each challenged claim. *Infra* Sections VIII-XI.

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

Petitioner certifies that the '335 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 1-4, 8-9, and 11-27 of the '335 patent, on the following statutory grounds:

	Reference(s)	35 U.S.C. §	Claims
Ground 1	Stafford (EX1009) and Raymond (EX1010)	103	1-4, 8-9, 11-15, and 17-27
Ground 2	Stafford, Raymond, and Turner (EX1011)	103	1-4, 8-9, 11-15, and 17-27
Ground 3	Stafford, Raymond, and Say (EX1012)	103	16
Ground 4	Stafford, Raymond, Turner, and Say	103	16
Ground 5	Stafford, Raymond, and Bickoff (EX1013)	103	16

Ground 6	Stafford, Raymond, Turner, and Bickoff	103	16
Ground 7	Stafford, Raymond, and Shah (EX1014)	103	17-18
Ground 8	Stafford, Raymond, Turner, and Shah	103	17-18

For each ground, in Sections VIII-XI below, this petition presents evidence of unpatentability and establishes a reasonable likelihood that the Petitioner will prevail in establishing that each challenged claim is unpatentable.

With the filing of this petition an electronic payment of \$44,875 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 the deposit account.

**IV. THE BOARD SHOULD NOT USE ITS
DISCRETION TO DENY INSTITUTION OF THIS PETITION**

A. No Examiner Addressed These Unpatentability Grounds

While four of the references relied on herein (Raymond, Stafford, Say, and Shah) were identified by Applicant on an IDS during prosecution of the '335 patent, there is no indication that the Examiner considered the pertinent teachings, and in particular, the combinations relied on herein. Applicant cited over 1,000 prior art references during prosecution. EX1002, 6-40, 293, 1055-59. None of the references relied on herein were mentioned by the Examiner in an Office action and “there is no evidence that the Examiner considered the particular disclosures” or teachings relied on in this petition. *Microsoft Corp. v. Parallel Networks Licensing, LLC*,

IPR2015-00486, Paper 10 at 15, 2015 WL 4760578, at *8 (PTAB July 15, 2015); *see also e.g., Intex Recr. Corp. v. Team Worldwide Corp.*, IPR2018-00871, Paper 14 at 13 (PTAB Sept. 14, 2018); *HTC Corp. v. Motiva Patents, LLC*, IPR2019-01666, Paper 9 at 6-10 (PTAB Apr. 3, 2020).

Turner, disclosing a transcutaneous device with plural recesses configured to engage an inserter's corresponding plural protrusions, was not cited during prosecution of the '335 patent.

Because the key teachings in the prior art were not previously considered by the Office, this petition should not be denied under Section 325(d).

B. Parallel Proceeding

Patent Owner asserts the '335 patent against Petitioner in district court, with trial set for March 2026. EX1066, 14. Any IPR based on this petition would conclude well in advance of that date and thus the Board should not discretionarily deny institution in view of the district court case.

V. THE '335 PATENT

The '335 patent issued March 8, 2022, from an application filed September 11, 2020, and claims priority through a series of applications to a non-provisional application filed March 24, 2011, and provisional applications filed November 8,

2010; July 2, 2010; May 17, 2010; and March 24, 2010.² EX1004, EX1006, EX1007, EX1008.

The challenged claims relate to (1) an inserter that includes a sharp configured to insert a portion of a glucose sensor into a subject, and (2) an on body electronics unit that includes a housing comprising a plurality of recesses on its periphery, on body electronics, and the glucose sensor. EX1001, 48:53-49:11; EX1003, ¶22. The inserter is configured to first advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position, then retract the sharp from the distal position to a retracted position entirely within the inserter. EX1001, 48:53-49:11; EX1003, ¶22.

Representative embodiments pertinent to the challenged claims appear to be inserters 3700 and 3700', illustrated in FIGS. 109-140. EX1001, 41:12-45:56, 45:57-46:23; EX1003, ¶23.

A. The Prosecution History

The '335 patent's September 11, 2020, application was followed by a series of preliminary amendments, after which the Examiner rejected all pending claims as

² Petitioner applies pre-AIA Sections 102-103 as discussed in Section V.B but does not concede that any priority application supports the claims.

anticipated by U.S. Publication No. 2010/0198034 (“Thomas-034”) and/or obvious over Thomas-034 and other references. EX1002, 333-45.³

In response, Applicant amended all previously presented claims. *Id.*, 412-24. The Examiner then rejected each of the amended claims as obvious over Thomas-034 in view of U.S. Publication No. 2008/024961 and other references. *Id.*, 428-42. In response, Applicant filed a Request for Continued Examination, claim amendments, and a declaration pursuant to 37 C.F.R. § 1.131 (“the 131 Declaration”) arguing that Thomas-034 does not qualify as prior art. *Id.*, 471-1050. The 131 Declaration alleges that the application’s subject matter was conceived before August 5, 2010 (*id.*, 491-495), and that Applicant reduced to practice the alleged invention no later than November 8, 2010, as purportedly evidenced by the filing of the November 8, 2010, provisional application. *Id.*, 498-499. The Examiner then allowed the claims. *Id.*, 2068-75.

B. Effective Filing Date

In the 131 Declaration, Patent Owner relied on a constructive reduction to practice date of November 8, 2010 (the filing date of the last provisional) and did not allege Section 112 support in any of the earlier provisional applications. *E.g.*, EX1002, 499. While Petitioner disputes that the challenged claims are entitled to a

³ Prosecution history cites are to Petitioner’s exhibit page numbers.

November 8, 2010 date,⁴ each prior art reference relied on herein qualifies as prior art under Section 102(b) because each was published more than one year before that date. Even if *arguendo* the earliest March 2010 provisional did provide Section 112 support (it does not, nor do the May and June 2010 applications), each prior art reference relied on herein qualifies as prior art under at least Section 102(a).

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

A. Person Of Ordinary Skill In The Art (“POSITA”)

A POSITA would have had a bachelor’s degree in bioengineering, mechanical engineering, electrical engineering, or a related subject, and one or more years of experience researching, developing, and/or designing insertable medical devices, including, *e.g.*, systems for implanting wearable medical devices such as cannulas, infusion sets, and analyte sensors, or equivalent experience.⁵ Less work experience would have been compensated by a higher level of education, such as a master’s degree, and vice versa. EX1003, ¶24.

⁴ This is further explained in the petition in Case No. IPR2023-01397.

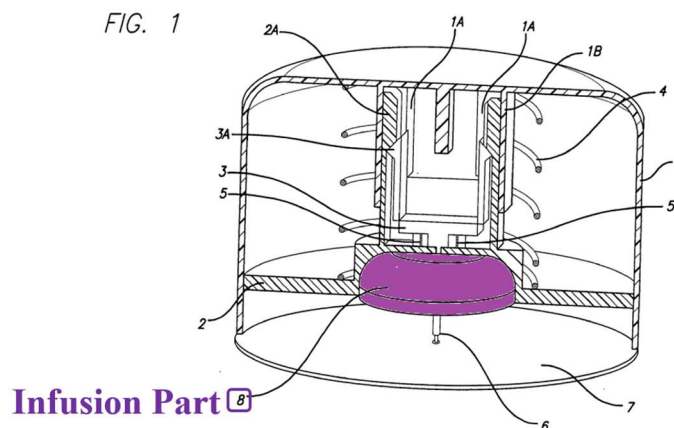
⁵ Regardless of whether the date of alleged invention is March 2010, March 2011 (the date of the first non-provisional), or somewhere in between, the pertinent level of skill in the art would not differ.

B. State Of The Art

The features claimed in the '335 patent—namely, inserters configured to secure an on body unit therein, retractable sharps to insert transcutaneous medical devices (*e.g.*, a glucose sensor, a cannula) into subjects, and wearable on body units—were known before 2010. EX1003, ¶25 (citing EX1010, EX1018, EX1040, EX1042, EX1057).

1. Inserters For Transcutaneous Medical Devices Were Known

Inserters for inserting transcutaneous medical devices (*e.g.*, cannulas and glucose sensors) into subjects were known in the prior art. *See, e.g.*, EX1003, ¶26; EX1010, [0109]; EX1015, [0020]-[0023]; EX1017, 1:25-3:9; EX1018, [0015]-[0016]; EX1030, FIGS. 1-5, [0008]. For example, as shown below, in an application published in 2007, Mogensen (EX1030) describes an inserter for inserting a transcutaneous cannula of an infusion part (purple). EX1030, FIG. 1, [0005], [0008].



Mogensen, FIG. 1 (annotated)

It was known that inserter-based insertion methods caused subjects to experience comparatively less pain and anxiety than the manual insertion of needles, *e.g.*, by providing for faster needle puncturing and/or retraction. *See, e.g.*, EX1003, ¶27; EX1037, [0004], [0007], [0008], [0011]; EX1056, [0004]-[0005]. Indeed, by 2007 “many manufacturers” used inserters to reduce the amount of pain subjects felt during the insertion of transcutaneous medical devices. EX1003, ¶27; EX1056, [0005].

It was also known to pre-load or pre-assemble transcutaneous medical devices and inserters, thereby eliminating the need for users to load the devices into inserters before use. EX1003, ¶28; *see, e.g.*, EX1010, [0100], [0109].

2. The Interchangeability Of Infusion Device Inserters And Glucose Sensor Inserters Was Known

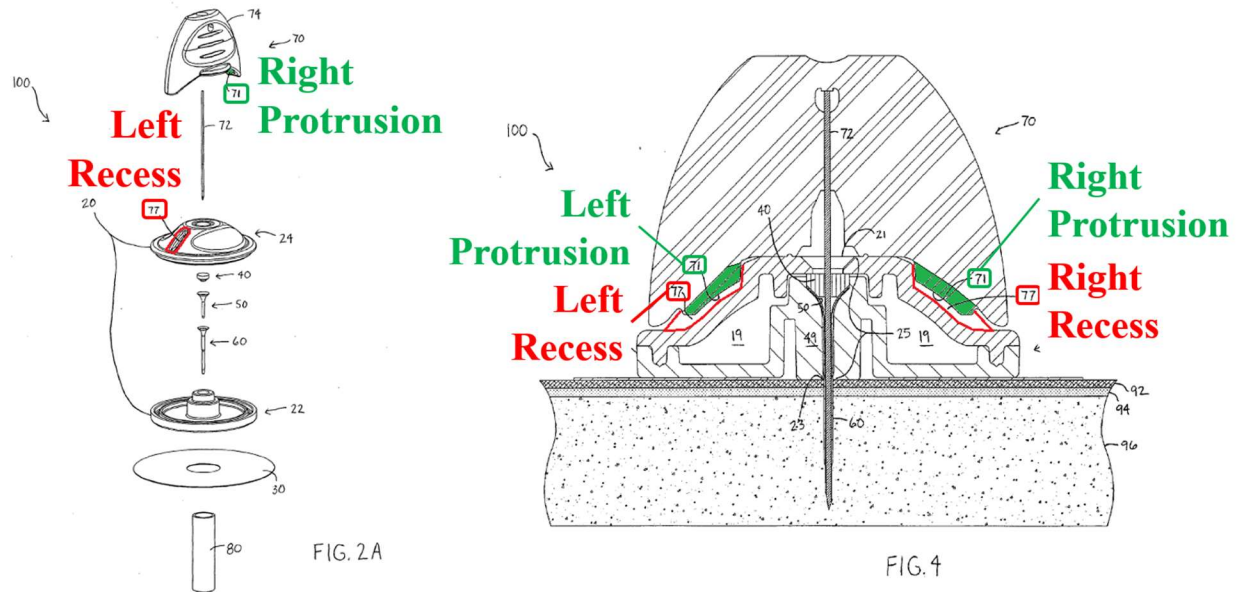
Inserters were known to be interchangeably configurable to insert glucose sensors and cannulas. EX1003, ¶29; *see also Dexcom, Inc., v. Abbott Diabetes Care Inc.*, IPR2022-00605, paper 29 at 32-34 (PTAB July 10, 2023) (finding a POSITA “would have been aware of the interchangeability of sensors and cannulas in inserter devices” for an invention date of March 24, 2010, in IPR on patent that alleges priority to the same Provisional Application No. 61/317,243 to which the ’335 patent alleges priority). It was known to configure a cannula-insertion inserter to insert a glucose sensor, *e.g.*, by substituting the cannula insertion needle with a sensor

insertion needle, as needed, along with other changes that were within a POSITA's skill. EX1003, ¶29; *see, e.g., id.*; EX1039, Abstract; EX1040, 1-33:40; EX1041, [0079]; EX1042, [0019]; EX1043, 2:23-26; EX1044, 13:12-16.

**3. Using Plural Recesses
For Securing Transcutaneous
Medical Devices To An Inserter Was Known**

When designing inserter devices for transcutaneous medical devices, it was known to implement an on-body unit with plural recesses configured to engage corresponding features (*e.g.*, protrusions or arms) on the inserter, to secure the on body unit of the transcutaneous medical device in a particular position relative to the inserter. EX1003, ¶30; EX1011, [0069]; EX1018, [0011] (“[T]he safety lock mechanism comprises ... preferably a pair of safety lock arms Each safety lock arm includes a cam lobe for engaging an appropriately shaped recess on the insertion set”); EX1040, 2:45-57 (same); EX1042, [0010] (same); EX1057, [0015] (“[T]he safety lock mechanism comprises at least one safety lock arm(s) Each safety lock arm may optionally include a cam lobe for engaging an appropriately shaped recess on the insertion set”). For example, as shown below, Turner (EX1011) discloses using plural rotation-restricting recesses (red) formed on the left and right sides of an on body infusion device to engage corresponding rotation-restricting protrusions (green) of an insertion device, thereby ensuring that the on body infusion device

remains in a particular position relative to the insertion device. EX1003, ¶30; EX1011, [0069].



Turner, FIGS. 2A and 4 (annotated)

VII. CLAIM CONSTRUCTION

Claim terms should be given the ordinary meaning that the terms would have to a POSITA at the time of the invention, 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 otherwise expressly discussed, Petitioner applies the plain and ordinary meaning of all claim terms below. Petitioner does not, however, waive any argument elsewhere that claim terms in the '335 patent are indefinite or otherwise

invalid, nor does Petitioner waive its right to raise additional issues of claim construction.

**VIII. GROUNDS 1 & 2: CLAIMS 1-4, 8-9, 11-15, AND
17-27 ARE OBVIOUS OVER STAFFORD AND RAYMOND
(GROUND 1), AND FURTHER IN VIEW OF TURNER (GROUND 2)**

As explained below, claims 1-4, 8-9, and 11-15, and 17-27 are obvious over Stafford and Raymond (Ground 1), and further in view of Turner (Ground 2). EX1003, ¶31.

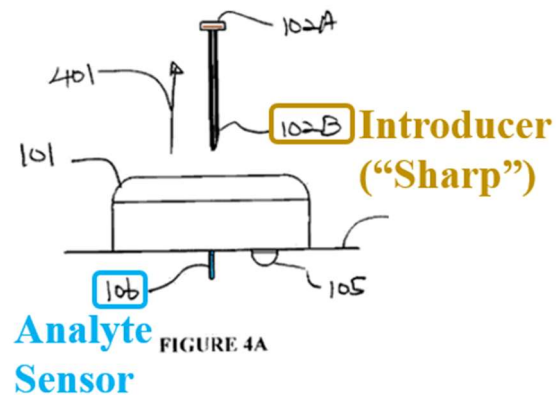
A. Stafford

U.S. Publication No. 2008/0097246 (“Stafford,” EX1009) was published April 24, 2008, from an application filed September 10, 2006. Stafford qualifies as prior art under Pre-AIA Section 102(b).⁶

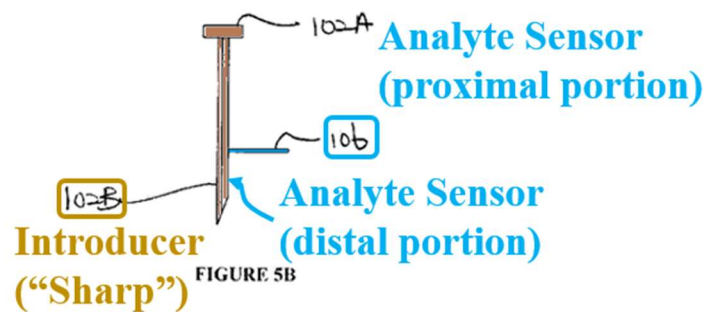
Stafford describes an integrated assembly that includes a transcutaneous analyte sensor and a data processing unit coupled thereto for processing analyte level measurements therefrom. *See, e.g.*, EX1009, [0006]. The data processing unit is disposed within a housing. EX1003, ¶33; *see, e.g.*, EX1009, FIG. 4A, [0006], [0020], [0027], [0053].

⁶ Without conceding that the claims find support in any of the parent applications, for purposes of the petition Petitioner assumes application of the pre-AIA Statute.

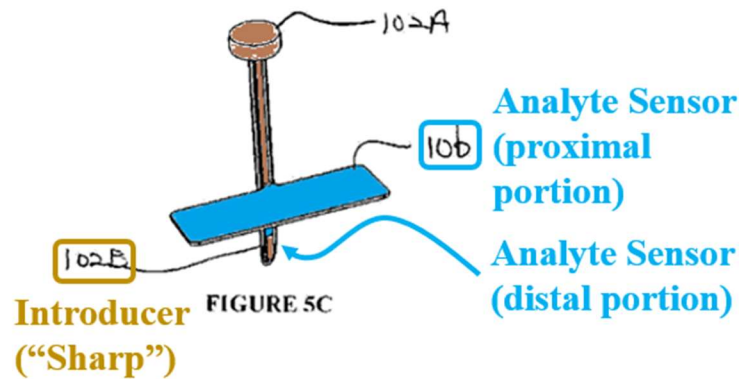
Stafford describes a glucose sensor (referred to herein as “Stafford’s sensor”). EX1009, [0051]. As shown below, Stafford’s sensor (blue) includes a distal portion perpendicular to the subject’s skin and a proximal portion parallel to the subject’s skin. EX1003, ¶34; EX1009, FIGS. 4A, 5B-5C.



Stafford, FIG. 4A (annotated)



Stafford, 5B (annotated)



Stafford, FIG. 5C (annotated)

The lower portion of Stafford's introducer has a sharp tip that pierces the subject's skin to deliver the sensor thereunder. EX1003, ¶35; EX1009, FIGS. 4A, 5B-5C, [0021], [0024].

Stafford's data processing unit includes electronics, *e.g.*, a processor, a power supply, and an RF transceiver for wirelessly transmitting sensor data. EX1003, ¶36; EX1009, FIG. 7, [0040], [0052].

Stafford's data processing unit is initially powered off and can be powered on. EX1003, ¶37; EX1009, [0037] (discussing a "power on procedure").

Stafford explains that withdrawing the introducer "requires a level of care" to avoid injury from the introducer's sharp tip and that "particular precautions" should be taken to avoid contact with the tip (*e.g.*, the distal lower portion), after contact with the subject's biological fluids. EX1003, ¶38; EX1009, [0003], [0022]. Although Stafford proposes a guard segment for preventing pre-insertion needlesticks, Stafford provides no solution for preventing post-insertion

needlesticks. EX1009, [0022]. As such, Stafford recognizes a need—but does not itself articulate a solution—for preventing needlesticks after the introducer’s lower portion has been withdrawn from the subject. EX1003, ¶38.

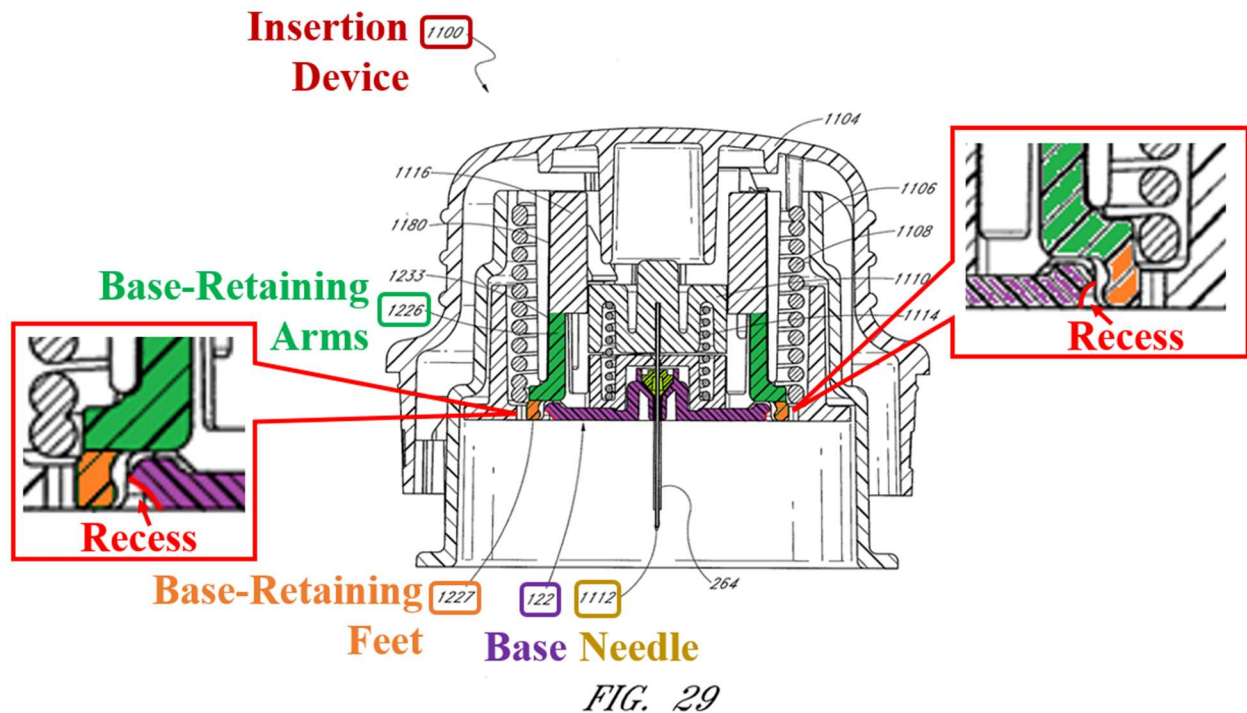
B. Raymond

U.S. Publication No. 2009/0124979 (“Raymond,” EX1010), was published May 14, 2009, from an application filed September 10, 2008. Raymond qualifies as prior art under Pre-AIA Sections 102(a) and 102(e). As discussed at Section V.B, Raymond also qualifies as prior art under Pre-AIA Section 102(b) because Raymond was published more than one year before the March 24, 2011 non-provisional application first disclosed a “plurality of recesses.”

Raymond describes an insertion device that inserts a transcutaneous infusion device “quickly, safely, and conveniently.” EX1010, [0008], [0109]. The infusion device, including a base housing at least a portion of an infusion set therein. EX1003, ¶40; EX1010, FIGS. 29-30. The infusion device delivers insulin. *Id.*, [0005].

The insertion device includes an actuator, a sleeve, a needle, a shuttle, and a protective cap. EX1010, [0109]. The shuttle includes plural base-retaining arms extending therefrom, each of which includes a base-retaining foot at a tip portion thereof for securing the infusion device within the insertion device. EX1003, ¶41; EX1010, [0123].

As shown below, Raymond's infusion device is in a proximal position within the insertion device before insertion, such that Raymond's infusion device and needle (brown) are disposed entirely within the insertion device. EX1003, ¶42; EX1010, FIG. 29. In this proximal position, Raymond's left and right base-retaining feet (orange) detachably engage recesses (red) on the periphery of the infusion device's base (purple). EX1003, ¶42; EX1010, [0123]. Each base-retaining foot is located at a tip portion of a corresponding base-retaining arm (green). EX1003, ¶42; EX1010, FIG. 29.



Raymond, FIG. 29 (annotated)

As shown below, when the insertion device advances the infusion device to a distal position during insertion, the insertion device's outwardly-biased base-

¶43; EX1010, [0127].

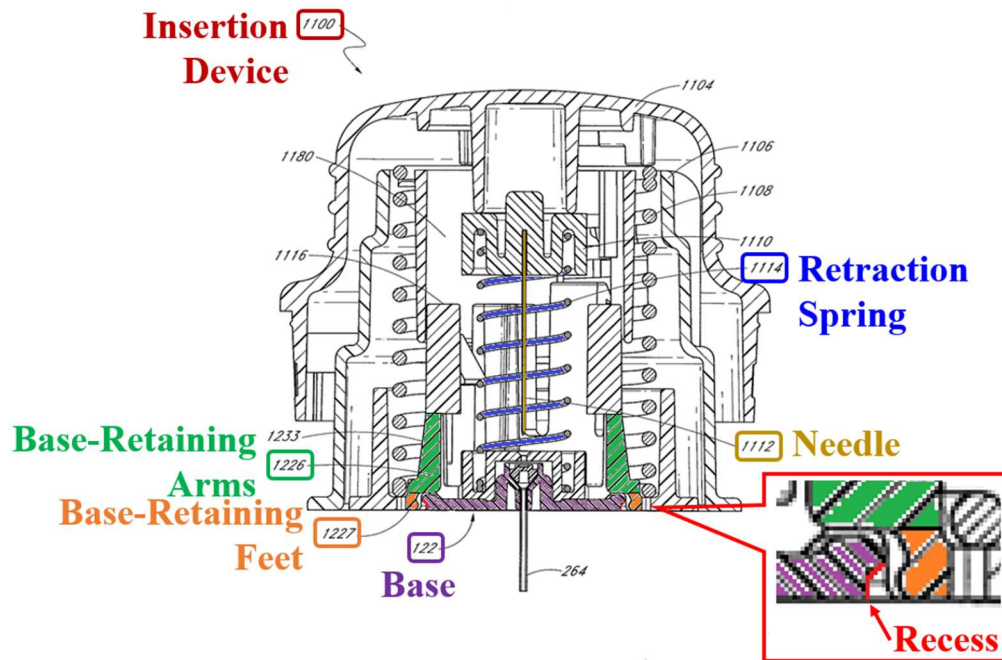


FIG. 30

Raymond, FIG. 30 (annotated)

[0104], [0109].

C. Turner

U.S. Publication No. 2007/0135774 (“Turner,” EX1011) was published June 14, 2007, from an application filed November 3, 2006. Turner qualifies as prior art under Pre-AIA Section 102(b).

Turner describes an insertion device for delivering a fluid delivery device for the treatment of diabetes. EX1003, ¶46; EX1011, [0008], [0064].

As shown in the annotated figure of Section VI.B.3, Turner discloses an insertion device that includes a plurality of rotation-restricting protrusions. EX1011, [0069]. Each protrusion is configured to engage a corresponding one of a plurality of rotation-restricting recesses disposed on the periphery of the fluid delivery device’s body. *Id.* The protrusions and recesses are configured to secure the fluid delivery device in a particular position relative to the insertion device. EX1003, ¶47; EX1011, [0069]; *see supra* Section VI.B.3.

D. The Stafford+Raymond Combination

The combination of Stafford and Raymond (“Stafford+Raymond”) applied herein combines Stafford’s teachings related to a glucose sensor, introducer (“sharp”), integrated assembly (“on-body electronics unit”), and housing (“on body electronics unit housing”) and Raymond’s teachings related to an insertion device (“inserter”) with base-retaining arms (“gripping arms”). EX1003, ¶48. Stafford+Raymond combines these respective teachings into an improved design

featuring the benefits from each reference, with minor adjustments as needed for them to cooperate and function together for the intended function of insertion, as discussed below. *Id.* Stafford+Raymond also includes plural recesses on the on-body electronics unit housing's periphery to detachably engage the inserter's gripping arms, as taught by Raymond. *Id.* The resulting combination includes the following elements cooperating as follows:

- an insertion device as taught by Raymond, adjusted to accommodate and engage a housing as taught by Stafford, and to use a needle/introducer to insert a portion of a glucose sensor like that taught in Stafford beneath the skin of a subject; and
- an integrated assembly as taught by Stafford, including:
 - the housing adjusted to include spaced-apart recesses disposed on a periphery of the housing, with the recesses detachably engageable with the insertion device as taught by Raymond;
 - a glucose sensor; and
 - electronics coupled to the glucose sensor, wherein the electronics include a memory, processor, power supply, and RF transceiver for wirelessly communicating glucose level data;

- wherein the insertion device is configured to advance the integrated assembly and needle/introducer from a proximal position entirely within the insertion device to a distal position, and
- wherein the insertion device is further configured to retract the needle/introducer from the distal position to a retracted position entirely within the insertion device.

Like the '335 patent, Stafford and Raymond are each directed to the insertion of transcutaneous medical devices for diabetes treatments. EX1003, ¶49. Thus, Stafford and Raymond are analogous art to the claimed invention of the '335 patent. *Id.*

1. A POSITA Would Have Been Motivated To Combine Stafford And Raymond

A POSITA would have been motivated to combine Stafford and Raymond for at least the following reasons. EX1003, ¶50.

Raymond improves upon an aspect of insertion identified by Stafford, namely, to prevent accidental needlesticks when withdrawing the needle from a subject. EX1003, ¶51; EX1009, [0003], [0022]; EX1010, [0008], [0127]; *see also id.*, [0104], [0109]. Stafford describes a glucose sensor introducer with a “sharp tip” and a desire to prevent both pre-insertion and post-insertion needlesticks, but only proposes a guard segment for preventing pre-insertion needlesticks. EX1009, [0002], [0003],

[0021], [0022], [0049]. Raymond describes a needle-based insertion device designed to “minimize the possibility of accidental needle sticks” and “provid[e] safe operation and disposal” by ensuring that the needle is only exposed during insertion. EX1003, ¶51; EX1010, [0008], [0127]; *see also id.*, [0104], [0109]. A POSITA implementing Stafford would have not only recognized that Stafford’s and Raymond’s teachings to prevent needlesticks are complementary but would have further understood that, as compared to Stafford’s solution that only prevents pre-insertion needlesticks, Raymond’s improved solution prevents against both pre-insertion and post-insertion needlesticks. EX1003, ¶51. Thus, a POSITA would have been motivated to implement Raymond’s teachings to cure the deficiencies of Stafford’s introducer. *Id.*

Raymond also improves upon the insertion process as taught by Stafford by reducing pain and anxiety caused by exposed insertion needles. EX1003, ¶52. A POSITA would have understood that Stafford’s manual insertion needle’s exposed sharp tip causes a patient pain and anxiety. *Id.*; *see supra* Section VI.B.1. A POSITA would have understood that using an insertion device as taught by Raymond lessens the subject’s pain and anxiety by maintaining the introducer’s sharp tip within an enclosed structure before and after insertion. EX1003, ¶52; *see, e.g.*, EX1010, [0127]; EX1037, [0004], [0007], [0008], [0011], *supra* Section VI.B.1.

A POSITA would have recognized the complementary nature of Stafford and Raymond. EX1003, ¶53. For example, each reference teaches the benefits of an easily graspable inserter assembly. *Id.*; EX1009, [0007]; EX1010, [0008]. Additionally, as discussed later at [1.5], a POSITA would have recognized that the arms as taught by Raymond work with the housing's recesses to keep the on body electronics unit (and its sensor) as taught by Stafford aligned with the inserter as taught by Raymond during insertion. Thus, a POSITA would have understood that Stafford's and Raymond's teachings are complementary. EX1003, ¶53.

Raymond, with its pre-assembled inserter/device configuration, also comports with Stafford's teaching that "a *separate* sensor introducing device such as a *separate* insertion gun ... is not necessary." EX1003, ¶54; EX1009, [0044].⁷ Unlike systems that rely on a separate insertion gun, *e.g.*, Say (EX1012, 36:18-39), Raymond's pre-assembled insertion device and on body unit obviates the need for the user to manually align and apply a separate insertion gun. EX1003, ¶54; EX1009, [0028]; EX1010, [0100], [0109]; *see supra* Section VI.B.1.

Thus, a POSITA would have been motivated to combine the teachings of Stafford and Raymond. EX1003, ¶55.

⁷ Emphasis added unless otherwise indicated.

**2. A POSITA Would Have
Had A Reasonable Expectation Of
Success In Combining Raymond And Stafford**

A POSITA would have had a reasonable expectation of success in combining Stafford and Raymond for the following reasons. *Id.*, ¶56.

Given the known interchangeability of insertion devices for cannulas and sensors, a POSITA would have easily adapted the inserter as taught by Raymond for use with the housing as taught by Stafford, *e.g.*, by using a needle-like introducer that accommodated the sensor therein, as taught by Stafford. *Id.*, ¶57; *see supra* Section VI.B.2. Indeed, the '335 patent itself states that its “inserter can be configured to insert various medical devices into the subject, such as for example, an analyte sensor, an infusion set, or a cannula” (EX1001, 22:27-29), yet provides no meaningful guidance on how to configure or adapt the inserter for the various types of devices. This confirms the known interchangeability of inserter devices between infusion sets and analyte sensors and similar devices. EX1003, ¶57. Similarly, a POSITA would have easily implemented the on body electronics unit with recesses that engaged with the gripping arms, as taught by Raymond. *Id.*; *see supra* Section VI.B.3. These adaptations required only basic skill and knowledge, possessed by a POSITA. EX1003, ¶57.

Thus, a POSITA would have had a reasonable expectation of success in combining the teachings of Stafford and Raymond. EX1003, ¶58.

E. The Stafford+Raymond+Turner Combination

The Petition relies on Turner with respect to the “plural recesses” recited in Element 1.5. For Ground 1, Turner serves as background art reflecting the knowledge and skill of a POSITA, confirming the obviousness of the recited recesses. Ground 2 relies expressly on Turner as a secondary reference for its teachings on use of recesses and protrusions to avoid rotational movement. Turner (directed to the insertion of transcutaneous medical devices for diabetes treatments) is analogous art to the claimed invention of the ’335 patent and, furthermore, is analogous art to Stafford and Raymond. EX1003, ¶59; *see supra* Section VIII.C.

To the extent Patent Owner argues that “plural recesses” were not at least obvious over Stafford+Raymond alone, Turner confirms the obviousness of adding plural recesses to the periphery of the housing to beneficially prevent relative rotational movement between the housing and the inserter. EX1003, ¶60; EX1011, [0069]. Turner provides express teachings on the use of “rotation-restricting recesses” that “prevent rotation of the insertion device relative to [the on-body unit],” thus confirming a benefit of this type of feature. EX1011, [0069]. Given the motivation to avoid relative movement between the housing and the inserter, and Turner’s express teachings of plural recesses (further discussed at [1.5]), a POSITA would have naturally implemented the Stafford+Raymond housing with plural recesses that engage corresponding portions of the inserter. EX1003, ¶60; *see supra*

Sections VI.B.3, VIII.C; *infra* Section VIII.F. As Raymond already teaches an inserter with base-retaining feet (similar to Turner's protrusions) at the tip portion of each base-retaining arm, a POSITA would have simply ensured that the on-body electronics unit housing included spaced-apart recesses (in line with Turner's teachings) that were engageable with the engagement bosses (similar to Raymond's base-retaining feet) on the tip portions of the inserter's gripping arms (similar to Raymond's base-retaining arms). EX1003, ¶60; *see supra* Sections VI.B.3, VIII.B-C, VIII.D.1. As with Stafford+Raymond alone, the POSITA would have had a reasonable expectation of success in implementing such simple mechanical features as at least two recesses. EX1003, ¶60.

F. Claim 1

[1.1]⁸ A glucose monitoring assembly, the assembly comprising:

Stafford discloses a glucose sensor. EX1003, ¶61; *see, e.g.*, EX1009, [0051].

As previously discussed, a POSITA would have been motivated to combine the teachings of Stafford and Raymond (and Turner), for example, by configuring an inserter as taught by Raymond to advance an on body electronics unit as taught

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

by Stafford and insert the glucose sensor as taught by Stafford. EX1003, ¶62; *see supra* Sections VIII.D.1, VIII.E.

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “a glucose monitoring assembly.” EX1003, ¶63; *see also* Sections VIII.D, VIII.E.

[1.2] (1) an inserter comprising:

As discussed at [1.1], Stafford+Raymond (and Stafford+Raymond+Turner) includes “an inserter.” EX1003, ¶64; *see also* Sections VIII.D, VIII.E.

[1.3] a sharp configured to insert a portion of a glucose sensor into a subject; and

Stafford discloses an introducer (“sharp,” brown) including a lower portion for inserting Stafford’s sensor. EX1003, ¶65; EX1009, FIG. 5C, [0028].

Raymond’s insertion device (“inserter”) includes a needle (“sharp”) for inserting a cannula. EX1003, ¶66; EX1010, FIGS. 29-30, [0109].

A POSITA would have employed a sharp like that disclosed in Stafford for compatibility with the sensor as taught by Stafford and would have had a reasonable expectation of success of doing so. EX1003, ¶67; *see supra* Sections VI.B.2, VIII.D.1-2.

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “a sharp configured to insert a portion of a glucose sensor into a subject.” EX1003, ¶68; *see also* Sections VIII.D, VIII.E.

[1.4] (2) an on body electronics unit, comprising:

As discussed at [1.5], Stafford+Raymond (and Stafford+Raymond+Turner) includes an “on body electronics unit.” EX1003, ¶69; *see also* Sections VIII.D, VIII.E.

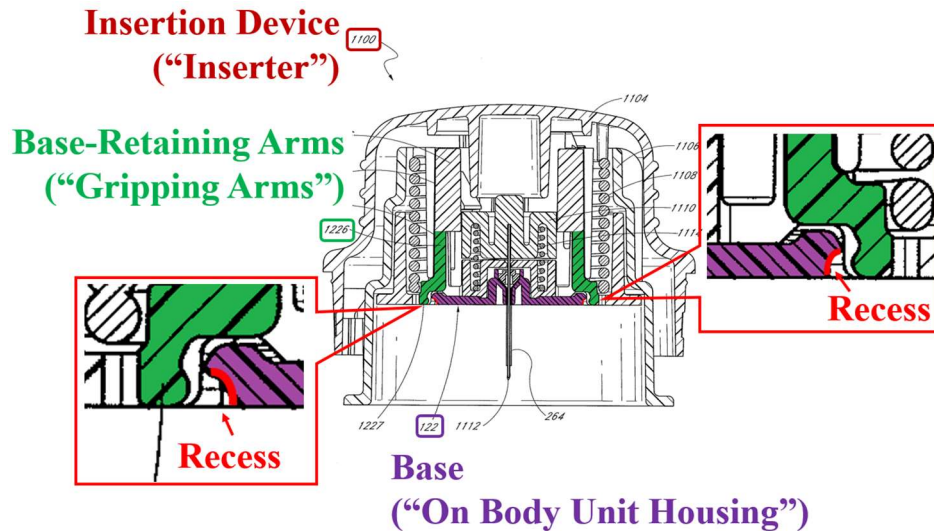
[1.5] an on body electronics unit housing comprising a plurality of recesses disposed on a periphery of the on body electronics unit housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is detachably engaged with the inserter;

Stafford+Raymond includes an assembly (“on body electronics unit”) that includes a housing (“on body electronics unit housing”) configured to be adhered to a subject’s body, as taught by Stafford. EX1003, ¶70; EX1009, [0019].

Stafford teaches that its on body electronics unit includes electronics (“on body electronics”) located within a housing. EX1003, ¶71; EX1009, FIG. 7, [0040], [0052].

As shown below, Raymond teaches an insertion device with “base-retaining arms” that “engage” the on-body unit. EX1003, ¶72; EX1010, [0123]. More specifically, Raymond teaches arms with inward protrusions, called “base-retaining feet,” that “engage the base” of the on-body unit “and secure it” to the insertion device. EX1003, ¶72; EX1010, [0123]. Raymond’s FIG. 29 shows how each of these feet/protrusions on the arms (green) detachably engages recesses (red) disposed on

opposite sides of the base (“on body unit housing,” purple). EX1003, ¶72; EX1010, FIGS. 29-30, [0126] (describing disengagement of the base-retaining feet), [0127]-[0128].



Raymond, FIG. 29 (annotated)

While the text of Raymond does not describe these recesses in narrative, based on the figures of Raymond a POSITA would have at least found it obvious to implement an on-body unit with recesses to engage the feet/protrusions of the retaining arms. EX1003, ¶73; *see, e.g.*, EX1010, FIGS. 29-30; *see, e.g.*, *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’” and 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.”) (citation omitted).

A POSITA knew that feet/protrusions like those taught by Raymond (EX1010, [0123]) were regularly designed to engage corresponding recesses or notches on associated components, in order to retain the components in relative position to one another. EX1003, ¶74; *see, e.g.*, EX1018, [0011] (describing inserter with a plurality of safety lock arms, wherein each safety lock arm includes “a cam lobe for engaging an appropriately shaped recess on the insertion set”); EX1040, 2:45-57 (same); EX1042, [0010] (same); EX1057, [0015] (same). Indeed, Raymond itself elsewhere employs a similar concept, describing a bounded recess on one component that engages a foot/protrusion on another component “to prevent unintentional rotation.” EX1010, [0074]; *see also id.*, [0095] (describing recess that “receives a portion” of a corresponding component so that it “can be held securely”). As one purpose of the feet is to “secure” the on-body unit to the insertion device prior to insertion, a POSITA thus would have been motivated with a reasonable expectation of success to provide recesses on the on body electronics unit housing in order to securely engage the on body electronics unit to the inserter. EX1003, ¶74; EX1010, [0123].

To the extent Patent Owner cites to Raymond FIG. 18 and argues that it discloses a single annular recess around the periphery of the on-body unit, that cannot change the FIGS. 29-30 depiction of plural recesses. Moreover, even if Raymond taught only a single annular recess, it would have been an obvious design

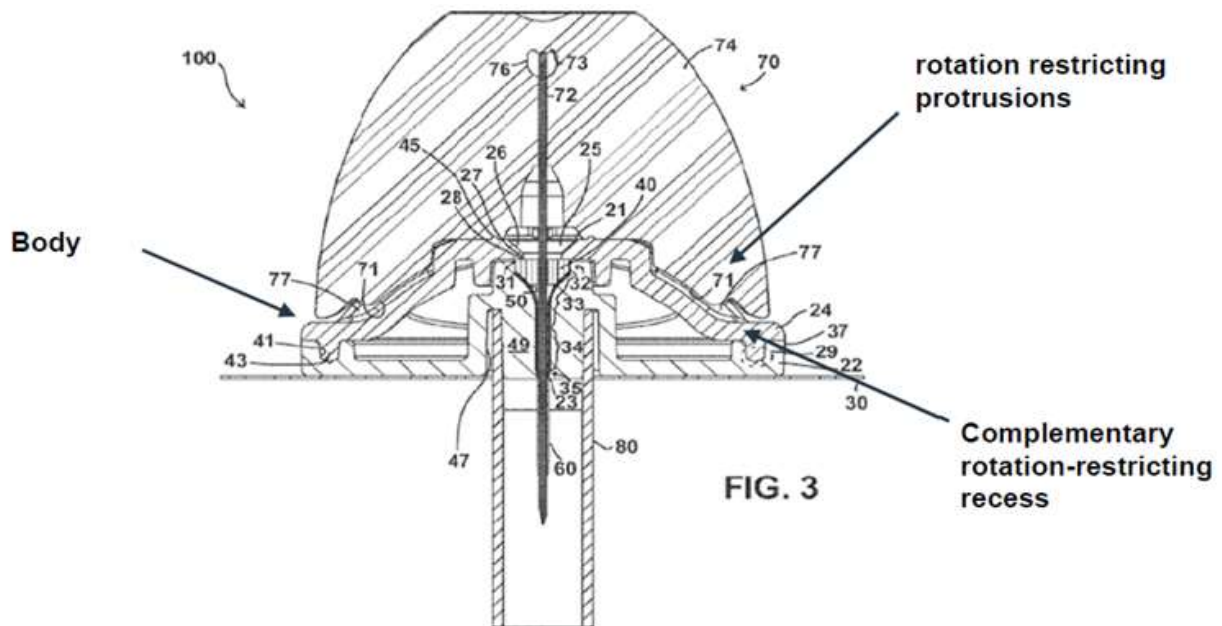
choice to implement two spaced-apart plural recesses on the housing—one to engage the protrusions on each of the two arms taught by Raymond. EX1003, ¶75; *see also* EX1010, FIGS. 18, 25-27 (illustrating two arms); *see, e.g., id.*, FIGS. 29-30 (illustrating two recesses for engaging the two arms). A POSITA would have recognized that there were only two possibilities for a system having arms with protrusions that engage some type of recess: either the two arms engage different points of a single annular recess *or* each arm engages its own independent recess. EX1003, ¶75. As explained in the preceding paragraphs, a recess for each arm provided a more secure fit between the inserter and on-body unit, and FIGS. 29-30 show a recess for each arm, thus making it the better choice. *Id.*; *Perfect Web Tech., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1331-32 (Fed. Cir. 2009) (obvious to try one of three predicable solutions).

Thus, a POSITA would have implemented Stafford+Raymond with an on-body unit housing containing electronics, as taught by Stafford, and having recesses to engage each of the feet on the two base-retaining arms, as taught by Raymond. EX1003, ¶76.

Turner, which reflects the knowledge and skill of a POSITA, further confirms the obviousness of implementing spaced-apart plural recesses on the housing taught by Stafford to engage the inserter taught by Raymond. *Id.*, ¶77. For example, as discussed at Section VIII.C, Turner teaches the utility and desirability of a plurality

of rotation-restricting recesses configured to engage a corresponding one of a plurality of rotation-restricting protrusions. EX1011, [0069]. Thus, as expressly reflected by Turner, a POSITA would have been motivated to implement similar plural rotation-restricting recesses on the periphery of the housing as taught by Stafford to prevent rotation between the housing as taught by Stafford and the inserter as taught by Raymond. EX1003, ¶77.

Moreover, Patent Owner effectively admitted that a POSITA would have been motivated to include complementary recesses to mate with corresponding protrusions as disclosed in Turner. Patent Owner annotated Turner's FIG. 3 as shown below. EX1065, 66.



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

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 EX1011, [0069]); *cf. Qualcomm Inc. v. Apple Inc.*, 24 F.4th 1367, 1376 (Fed. Cir. 2022) (noting the uses of “a patentee’s admissions [i]nclude, for example, furnishing a motivation to combine”). Thus, since Patent Owner contends that a POSITA would have been motivated to implement Turner’s rotation-restricting teachings on a CGM device, this confirms that a POSITA would have been motivated to implement rotation-restricting features on the periphery of the housing taught by Stafford.

Given the known interchangeability of sensor/cannula inserters, and the relative simplicity of adding recesses to any devices, the POSITA would have had a reasonable expectation of success in implementing Stafford+Raymond with two recesses on the on body electronics unit, one to engage or mate with each of the bosses/protrusions on the arms. EX1003, ¶78; *Allied Erecting and Dismantling Co., Inc. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) (“The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference.”) (citations omitted). For example, a POSITA would have “fit pieces of the invention together,” if needed, by adjusting the housing as taught by Stafford to include features (e.g., plural recesses) for engaging the corresponding plural arms of the inserter as taught by Raymond.

EX1003, ¶81; *see also id.* ¶¶78-80 (discussing other exemplary adjustments); *see, e.g., Ethicon LLC v. Intuitive Surgical, Inc.*, 2022 WL 1613188, at *4 (Fed. Cir. 2022) (affirming the Board’s finding of a reasonable expectation of success in combining references even though the “combination would require some modifications to fit pieces of the invention together,” because a POSITA would have “know[n] how to account for ‘routine considerations’ such as ‘location [and] positioning’” of mechanical components) (internal citation omitted); *see supra* Sections VIII.D.1-2.

Since any adjustments to the housing and the inserter constitute routine design choices, there is neither evidence of any unexpected result associated with the plural recesses nor evidence that a POSITA would not have had a reasonable likelihood of success in using plural recesses to engage the corresponding plural gripping arms of the inserter. EX1003, ¶82; *supra* Section VIII.D.2.

Thus, Stafford+Raymond includes “an on body electronics unit housing comprising a plurality of recesses disposed on a periphery of the on body electronics unit housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is detachably engaged with the inserter.” EX1003, ¶83; *see also* Section VIII.D.

GROUND 2

Alternatively, claims 1-4, 8-9, 11-15, and 17-27 are obvious over Stafford and Raymond, further in view of Turner (EX1011). EX1003, ¶84.

As shown in the annotated figure of Section VI.B.3, Turner discloses plural rotation-restricting recesses disposed on an infusion device's housing, wherein the plural recesses include a first recess in a spaced relation to a second recess, and wherein the plural recesses are detachably engaged with corresponding rotation-restricting protrusions disposed on an insertion device ("insertor"). EX1003, ¶85; EX1011, [0069]; *see supra* Section VI.B.3.

As previously discussed, Turner's teachings further confirm that a POSITA would have been motivated, with a reasonable expectation of success, to implement Stafford+Raymond with a housing having plural recesses spaced apart from one another so as to be engageable with the inserter, and specifically the corresponding engagement bosses on the tip portions of the gripping arms as taught by Raymond. EX1003, ¶86; *see supra* Section VIII.E.

Thus, Stafford+Raymond+Turner includes "an on body electronics unit housing comprising a plurality of recesses disposed on a periphery of the on body electronics unit housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is detachably engaged with the inserter." EX1003, ¶87; *see also* Section VIII.E.

[1.6] the glucose sensor; and

As discussed at [1.1], Stafford+Raymond (and Stafford+Raymond+Turner) includes “a glucose sensor.” EX1003, ¶88; *see also* Sections VIII.D, VIII.E.

[1.7] on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level,

Stafford’s electronics include a processor, a power supply, and an RF transceiver (“wireless communication circuitry”) for wirelessly communicating glucose level data. EX1003, ¶89; EX1009, FIG. 7, [0040], [0052]. Stafford’s electronics are coupled with Stafford’s sensor. EX1003, ¶89, EX1009, [0028], [0039].

Because Stafford discloses a processor and wireless communication circuitry, a POSITA would have found it at least obvious to implement Stafford’s on body electronics with a memory in order to store the data processed by the processor and transmitted by the wireless communication circuitry. EX1003, ¶¶90-92 (discussing EX1012, EX1014, EXS1059-1064).

Stafford+Raymond (and Stafford+Raymond+Turner) includes the processor, memory, power supply, and wireless communication circuitry as taught by Stafford disposed within the housing as taught by Stafford. EX1003, ¶93. The electronics as

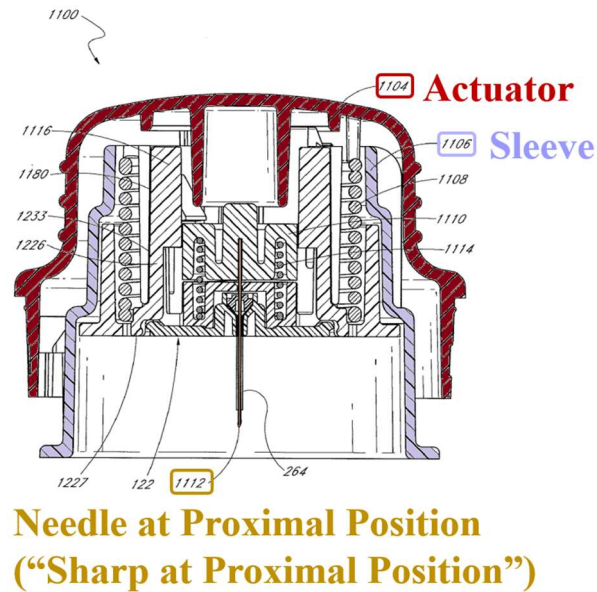
taught by Stafford are coupled with the sensor as taught by Stafford. *Id.*; *see also* Sections VIII.D, VIII.E.

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level.” EX1003, ¶94; *see also* Sections VIII.D, VIII.E.

[1.8] wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position, and

A lower portion of Stafford’s introducer (“sharp”) inserts Stafford’s sensor. EX1003, ¶95; EX1009, [0024].

As shown below, Raymond’s needle (“sharp,” brown) is entirely within an actuator (red) and a sleeve (purple) of Raymond’s insertion device (“inserter”) when Raymond’s sharp is in a proximal position to protect the user from needlesticks. EX1003, ¶96; EX1010, FIG. 29, [0127].



Raymond, FIG. 29 (annotated)

As discussed at [1.3], Stafford+Raymond (and Stafford+Raymond+Turner) uses the inserter as taught by Raymond in combination with the sharp like that disclosed in Stafford to advance the on body electronics unit as taught by Stafford and insert the sensor as taught by Stafford. EX1003, ¶97. Since both Stafford and Raymond teach that sharps should be covered to prevent needlesticks, a POSITA would have configured the sharp to be disposed entirely within the inserter (*e.g.*, within the actuator and sleeve of the inserter as taught by Raymond) in the proximal position. *Id.*, ¶97; EX1009, [0003], [0022]; EX1010, [0127]; *see also id.*, [0104], [0109]. Since the sensor is a part of the on body electronics unit, a POSITA would have configured the inserter to advance the on body electronics unit and the sharp in unison from a position entirely within the inserter to a distal (insertion) position in

which the distal surface of the on body electronics unit is aligned with the distal end of the inserter and contacts the subject's skin. EX1003, ¶97.

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the inserter ... configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position.” EX1003, ¶98; *see also* Sections VIII.D, VIII.E.

[1.9] wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.

The lower portion of Stafford's introducer is a sharp. EX1003, ¶99; EX1009, [0021].

As shown below, Raymond's insertion device (“inserter”) retracts Raymond's needle (“sharp,” brown) from a distal position to a retracted position entirely within the actuator (red) and the sleeve (purple) of Raymond's inserter. EX1003, ¶100; EX1010, FIG. 30, [0127].

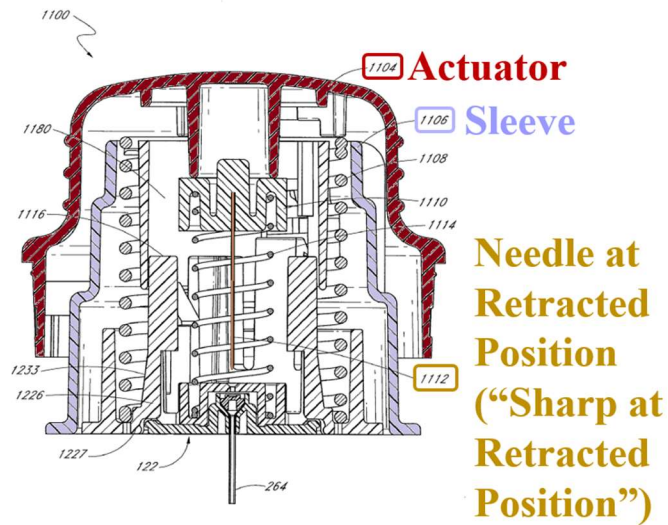


FIG. 30

Raymond, FIG. 30 (annotated)

Stafford+Raymond (and Stafford+Raymond+Turner) includes the inserter as taught by Raymond and a sharp like that disclosed in Stafford. EX1003, ¶101. Based on Stafford’s and Raymond’s teachings, the sharp is retracted entirely within the inserter to cover the sharp. *Id.*; see EX1009, [0003], [0022]; EX1010, [0127]; see also *id.*, [0104], [0109].

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the inserter ... configured to retract the sharp from the distal position to a retracted position entirely within the inserter.” EX1003, ¶102; see also Sections VIII.D, VIII.E.

G. Claim 2

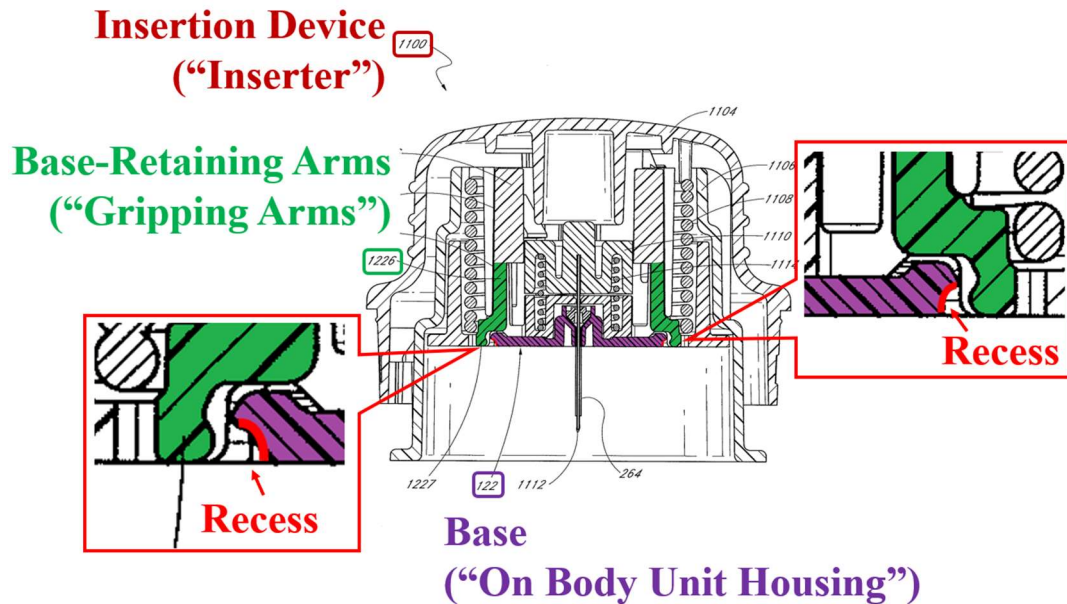
2. The glucose monitoring assembly of claim 1, wherein the inserter further comprises a plurality of gripping arms.

As discussed at [1.5] and [3.1], Stafford+Raymond (and Stafford+Raymond+Turner) includes “the inserter ... [comprising] a plurality of gripping arms.” EX1003, ¶104; *supra* Section VIII.F; *infra* Section VIII.H.

H. Claim 3

[3.1] The glucose monitoring assembly of claim 2, wherein each gripping arm of the plurality of gripping arms is configured to be engaged with a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

As discussed at [1.5], Raymond discloses two gripping arms, each engaging a corresponding recess of the on body unit housing, or at least renders these recesses obvious. EX1003, ¶106; EX1010, FIG. 29, [0123]; *supra* Section VIII.F. As shown below, Raymond illustrates how, with the unit in its position proximal to the user, a left base-retaining arm (“gripping arm,” green) engages a left recess (red) and a right gripping arm (green) engages a right recess (red). EX1003, ¶106.



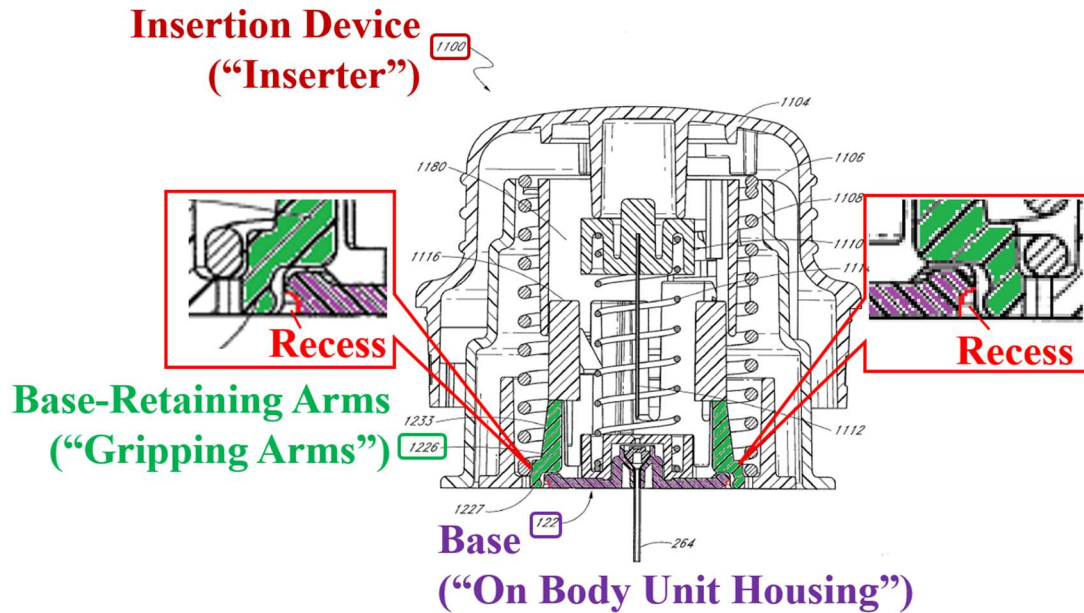
Raymond, FIG. 29 (annotated)

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes plural recesses and plural gripping arms, wherein each gripping arm engages a corresponding recess of the housing when the on body electronics unit is in a proximal position within the inserter. EX1003, ¶107; *supra* Section VIII.F.

[3.2] wherein the each gripping arm of the plurality of gripping arms is further configured to be disengaged from the corresponding recess of the plurality of recesses when the on body electronics unit is in the distal position.

As shown below, each of Raymond's base-retaining arms ("gripping arms," green) clears a cam surface and spreads radially outwardly to be disengaged with Raymond's base's ("on body unit housing," purple) recesses by the time the base reaches the distal position. EX1003, ¶108; EX1010, FIGS. 29-30, [0126]. Thus, each of Raymond's gripping arms are disengaged with a corresponding recess (red) of

Raymond's housing when Raymond's on body unit is in the distal position. EX1003, ¶108.



Raymond, FIG. 30 (annotated)

As discussed at [1.5] and [3.1], Stafford+Raymond (and Stafford+Raymond+Turner) includes plural recesses formed on the periphery of the on body electronics unit housing as taught by Stafford, wherein each of the gripping arms as taught by Raymond (specifically, the base-retaining foot at the tip portion of each one of the arms as taught by Raymond) engage a corresponding recess. EX1003, ¶109; *supra* Section VIII.F. A POSITA would have also understood that each of the gripping arms disengages a corresponding recess on the housing when the housing is in the distal position. EX1003, ¶109.

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the plurality of gripping arms ... [each] configured to be disengaged from the corresponding recess of the plurality of recesses when the on body electronics unit is in the distal position.” *Id.*, ¶110.

I. Claim 4

4. The glucose monitoring assembly of claim 2, wherein each gripping arm of the plurality of gripping arms is biased in a radially outward direction.

As discussed at [3.2], Raymond discloses that each base-retaining arm (“gripping arm”) spreads radially outwards when unconstrained by the sleeve. EX1010, FIGS. 29-30, [0126]; *supra* Section VIII.H. Stafford+Raymond (and Stafford+Raymond+Turner) includes the inserter and gripping arms as taught by Raymond. EX1003, ¶112.

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the plurality of gripping arms ... [each] biased in a radially outward direction.” *Id.*, ¶113.

J. Claim 8

8. The glucose monitoring assembly of claim 2, wherein each gripping arm of the plurality of gripping arms comprises an engagement boss configured to engage with a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.

The ’335 patent does not define “engagement boss” other than to explain that it is the portion of a gripping arm that is “configured to engage with corresponding

recesses 3766 provided on the side walls of the on body housing 322.” EX1001, 44:9-12, 45:61-64; EX1003, ¶115. Thus, consistent with the term’s plain and ordinary meaning, the Petition understands “engagement boss” to encompass a protrusion. EX1003, ¶115; EX1035, 44 (defining a “boss” as a “[p]rotuberance”).

Raymond discloses a foot (“engagement boss”) on a tip of each base-retaining arm (“gripping arm”). EX1010, FIGS. 29-30, [0123]. As discussed at [1.5], a POSITA would have understood Raymond to at least suggest that each boss engages a corresponding one of the plural recesses when Raymond’s on body unit is in a proximal position. EX1003, ¶116; *supra* Section VIII.F. Thus, it was at least obvious to implement Stafford+Raymond (and Stafford+Raymond+Turner) with plural recesses on an on body electronics unit housing to engage bosses on the tip portions of corresponding ones of gripping arms. EX1003, ¶117; *supra* Section VIII.F.

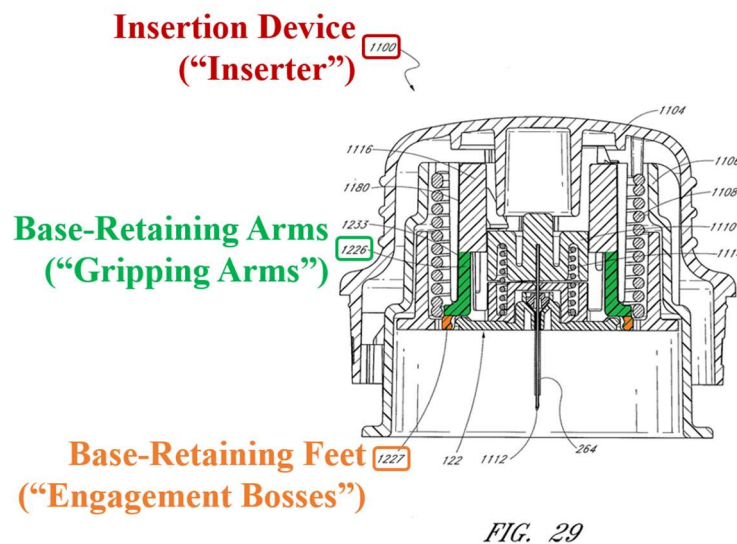
Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the plurality of gripping arms [each comprising] an engagement boss configured to engage with a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.” EX1003, ¶118.

K. Claim 9

9. The glucose monitoring assembly of claim 8, wherein the engagement boss is disposed on a tip portion of the gripping arm.

Claim 9 is the only place “tip portion” is recited in reference to the gripping arms. EX1003, ¶120. Although the ’335 patent recites “first-angled tip portion” (EX1001, 26:8, 27:4) and “steep-angled tip portion” (*id.*, 26:9, 27:5), these refer to the tip of the sharp. EX1003, ¶120. Thus, since the term “tip portion” is only used with respect to the gripping arms in claim 9, a POSITA would have understood this term to refer to the “end portion of the gripping arm.” *Id.*

As shown below, Raymond discloses a foot (“engagement boss,” orange) on an end portion or tip portion of each base-retaining arm (“gripping arm,” green). EX1010, FIGS. 26-27, 29-30; see *id.*, [0123]. As discussed at claim 8, Stafford+Raymond (and Stafford+Raymond+Turner) includes the engagement bosses and gripping arms as taught by Raymond. EX1003, ¶121; *supra* Section VIII.J.



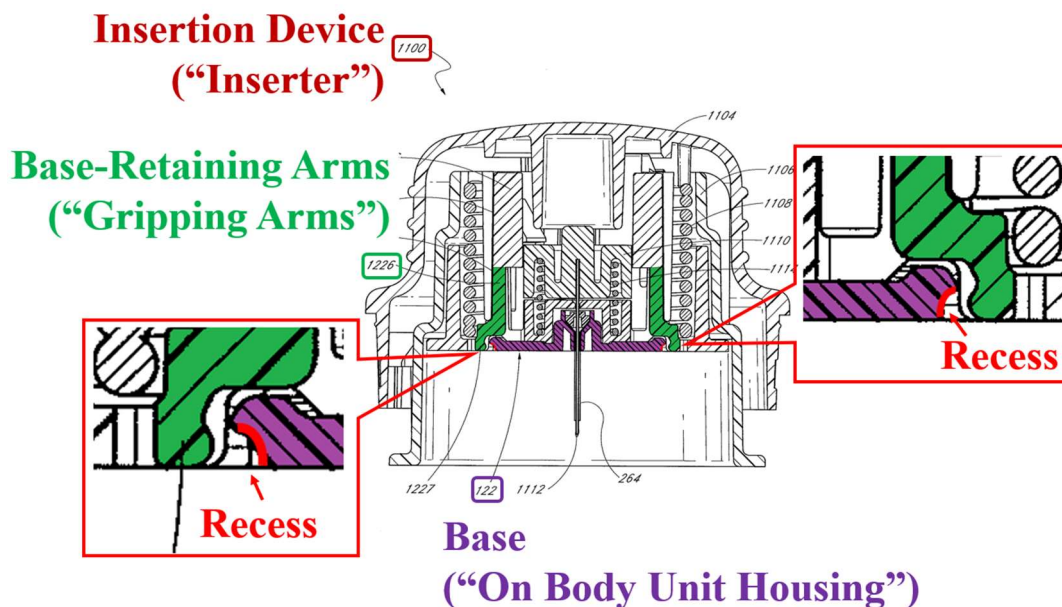
Raymond, FIG. 29 (annotated)

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes an “engagement boss ... disposed on a tip portion of the gripping arm.” EX1003, ¶122.

L. Claim 11

11. The glucose monitoring assembly of claim 1, wherein each recess of the plurality of recesses comprises a concave portion.

As shown below, Raymond illustrates concave left and right recesses (red). As discussed at [1.5], a POSITA would have found it at least obvious to form such recesses on the housing as taught by Stafford. EX1003, ¶124; *supra* Section VIII.F.



Raymond, FIG. 30 (annotated)

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the plurality of recesses [each comprising] a concave portion.” EX1003, ¶125.

M. Claim 12

12. The glucose monitoring assembly of claim 1, wherein each recess of the plurality of recesses is disposed on a side wall of the on body electronics unit housing.

Stafford discloses a housing (“on body electronics unit housing”). EX1003, ¶127; *supra* Section VIII.A.

As illustrated in the figures at [1.5], Raymond discloses recesses disposed on the sidewall of a base (“on body unit housing”). EX1003, ¶128; EX1010, FIGS. 29-30; *supra* Section VIII.F.

As discussed at [1.5], a POSITA would have found it obvious to form plural recesses on the on body electronics unit housing as taught by Stafford. EX1003, ¶129; *supra* Section VIII.F. A POSITA would have been motivated by Raymond’s disclosure to form the recesses on the sidewalls of the housing. EX1003, ¶129; *see supra* Section VIII.B. Stafford+Raymond (and Stafford+Raymond+Turner) includes the housing as taught by Stafford and the plural recesses on the sidewall thereof as taught by Raymond. EX1003, ¶129.

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the plurality of recesses ... [each] disposed on a side wall of the on body electronics unit housing.” *Id.*, ¶130.

N. Claim 13

13. The glucose monitoring assembly of claim 1, wherein the inserter further comprises a driver disposed in the inserter, wherein the driver is configured to apply a force that retracts the sharp after the sharp reaches the distal position.

As discussed at [1.3], Stafford discloses a lower portion (“sharp”) of an introducer for inserting Stafford’s sensor. EX1003, ¶132; *supra* Section VIII.F.

Raymond’s retraction spring (“driver”) retracts a needle (“sharp”) after the needle reaches the distal position. EX1003, ¶133; EX1010, FIG. 30, [0127].

Stafford+Raymond (and Stafford+Raymond+Turner) includes the driver as taught by Raymond, which applies a force to retract a sharp like that disclosed in Stafford after the sharp reaches the distal position. EX1003, ¶134.

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “a driver disposed in the inserter, wherein the driver is configured to apply a force that retracts the sharp after the sharp reaches the distal position.” *Id.*, ¶135.

O. Claim 14

14. The glucose monitoring assembly of claim 1, further comprising a cap removably attached to a distal portion of the inserter.

Raymond’s cap is removably attached to the distal portion of Raymond’s insertion device (“inserter”). EX1010, FIG. 18, [0101], [0109]. Stafford+Raymond (and Stafford+Raymond+Turner) includes the inserter and cap as taught by Raymond. EX1003, ¶137.

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “a cap removably attached to a distal portion of the inserter.” *Id.*, ¶138.

P. Claim 15

[15.1] The glucose monitoring assembly of claim 1, wherein the inserter further comprises an inserter housing and a sheath, and wherein the inserter housing is configured to move in a downward direction towards a skin surface relative to the sheath in response to an application of force on the inserter housing, and

Raymond’s actuator (“housing”) moves downward relative to a sleeve (“sheath”) placed on the subject’s skin. EX1010, FIGS. 29-30, [0124], [0125]. Stafford+Raymond (and Stafford+Raymond+Turner) includes the inserter, housing, and sheath as taught by Raymond. EX1003, ¶140.

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “an inserter housing and a sheath ... wherein the inserter housing is configured to move in a downward direction towards a skin surface relative to the sheath in response to an application of force on the inserter housing.” *Id.*, ¶141.

[15.2] wherein the sheath is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing.

Raymond’s sleeve (“sheath”) is pressed against the subject’s skin both before and after force is applied to the actuator (“housing”). EX1010, FIGS. 29-30 (illustrating “sleeve 1106” placed against the subject’s skin before and after actuation), [0124]. As discussed at [15.1], Stafford+Raymond (and

Stafford+Raymond+Turner) includes the sheath and housing as taught by Raymond. EX1003, ¶142.

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the sheath ... configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing.” *Id.*, ¶143.

Q. Claim 17

17. The glucose monitoring assembly of claim 1, wherein the on body electronics comprises an aperture, and wherein the sharp extends through the aperture of the on body electronics.

As shown below, Stafford’s integrated assembly (“on body electronics unit”) includes a lower portion of an introducer (“sharp”) extending through a housing (“on body electronics unit housing”). *See, e.g.*, EX1009, FIG. 2. As discussed at [1.4], Stafford includes on body electronics disposed within the housing. EX1003, ¶145; *supra* Section VIII.F.

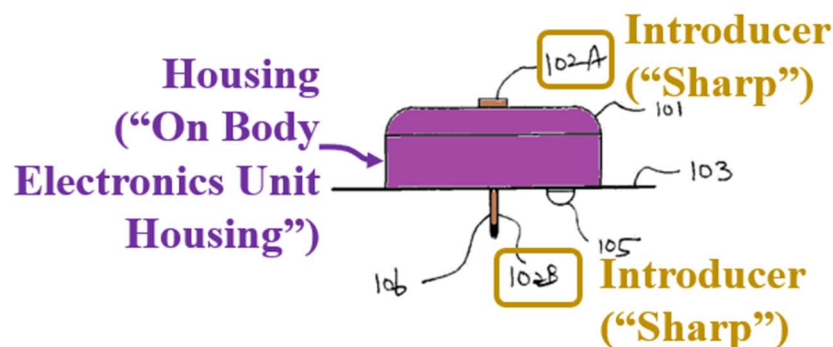


FIGURE 2

Stafford, FIG. 2 (annotated)

A POSITA would have found it at least obvious to form the first aperture in the electronics taught by Stafford. EX1003, ¶146.

For example, Stafford discloses that the housing (and, consequently, the electronics disposed within the housing) desirably has a “small profile.” EX1009, [0045]; *see supra* Section VIII.F. A POSITA implementing a “small profile” on body electronics unit would have made the electronics as large as possible relative to the housing to minimize empty space within the housing. EX1003, ¶147. Since relatively large electronics would have naturally occupied a center portion of the housing, and Stafford illustrates the sharp extending through the center portion, a POSITA would have formed the first aperture in the electronics for the sharp to extend therethrough. *Id.*

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “an aperture, and wherein the sharp extends through the aperture of the on body electronics.” *Id.*, ¶148.

R. Claim 18

18. The glucose monitoring assembly of claim 17, wherein the aperture of the on body electronics is a first aperture, wherein the on body electronics unit housing further comprises a top surface and a bottom surface, wherein the top surface comprises a second aperture, wherein the bottom surface comprises a third aperture, and wherein the sharp extends through the first aperture, the second aperture, and the third aperture when the on body electronics unit is in the proximal position.

As discussed at claim 17, Stafford teaches a first aperture in Stafford's electronics. EX1003, ¶150; *supra* Section VIII.Q. Stafford's sharp extends through the first aperture before insertion. EX1003, ¶150; *supra* Section VIII.Q.

Stafford's introducer ("sharp") extends through top and bottom surfaces of a housing ("on body electronics unit housing"). *See* EX1009, FIG. 2. Since Stafford's sharp is unable to extend through these surfaces without apertures therein, a POSITA would have understood that Stafford at least suggests second and third apertures in the top and bottom surfaces of the housing. EX1003, ¶151.

A POSITA would have found it at least obvious to form the first aperture in the on body electronics as taught by Stafford and the second and third apertures in the top and bottom surfaces of the housing as taught by Stafford. *Id.*, ¶152. A sharp like that disclosed in Stafford extends through the first, second, and third apertures before insertion. *Id.* As discussed at [1.8], the housing is in the proximal position within the inserter as taught by Raymond before insertion. *Id.*; *supra* Section VIII.F.

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes "the [first] aperture of the on body electronics ... the on body electronics unit housing further [comprising] a top surface and a bottom surface, wherein the top surface comprises a second aperture, wherein the bottom surface comprises a third aperture, and wherein the sharp extends through the first aperture, the second aperture, and

the third aperture when the on body electronics unit is in the proximal position.”

EX1003, ¶153.

S. Claim 19

19. The glucose monitoring assembly of claim 1, wherein the inserter further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit and the sharp.

Stafford discloses an integrated assembly (“on body electronics unit”) and an introducer (“sharp”). EX1003, ¶155; *supra* Section VIII.A.

Raymond’s insertion device (“inserter”) includes a distal end (*e.g.*, a distal end of sleeve 1106) placed on the subject’s skin before advancement of Raymond’s infusion device (“on body unit”) and needle (“sharp”). EX1003, ¶156; EX1010, [0124].

Stafford+Raymond (and Stafford+Raymond+Turner) includes the on body electronics unit as taught by Stafford, a sharp like that disclosed in Stafford, and the distal end of the inserter as taught by Raymond. EX1003, ¶157.

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “a distal end [of an inserter] configured to be placed on a skin surface of the subject before advancement of the on body electronics unit and the sharp.” *Id.*, ¶158.

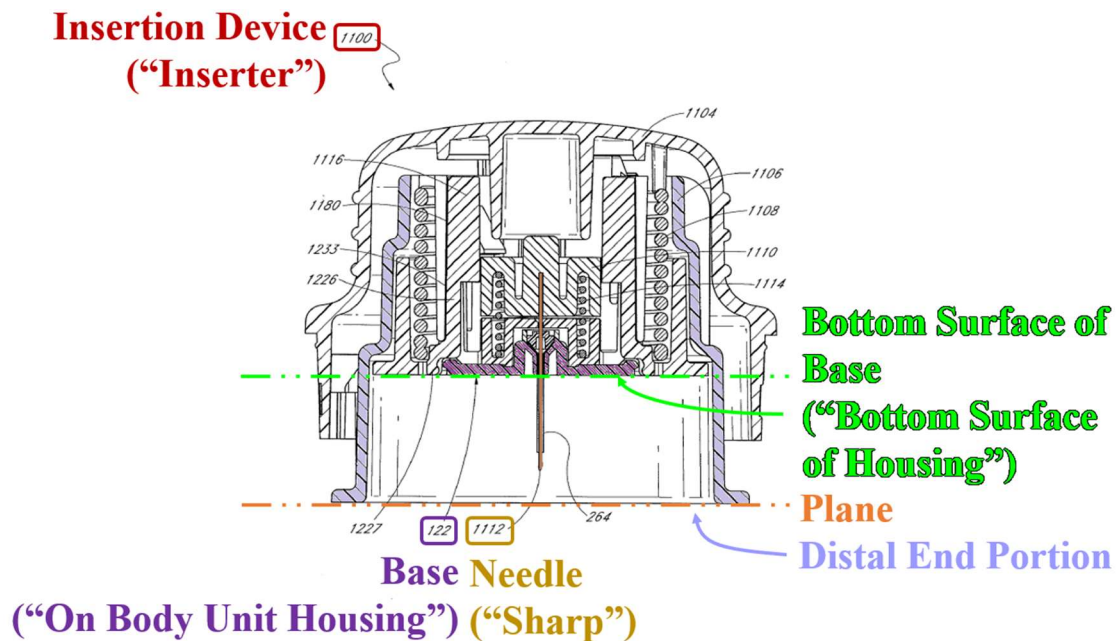
T. Claim 20

20. The glucose monitoring assembly of claim 19, wherein the distal end of the inserter defines a plane, and wherein a bottom surface of the on body electronics

unit housing is parallel to the plane when the on body electronics unit and the sharp are in the proximal position.

As discussed at claim 18, Stafford's housing ("on body electronics unit housing") includes a bottom surface. EX1003, ¶160; *supra* Section VIII.R. As discussed at [1.3], Stafford discloses a sharp. EX1003, ¶160; *supra* Section VIII.F.

As shown below, Raymond's insertion device ("inserter") includes a distal end defining a plane (orange). EX1003, ¶161. Furthermore, Raymond's base ("on body unit housing," purple) includes a bottom surface parallel (as shown by the green line) to the plane when the housing and a needle ("sharp," brown) are in a proximal position. *Id.*



Raymond, FIG. 29 (annotated)

Stafford+Raymond (and Stafford+Raymond+Turner) includes the distal end of the inserter as taught by Raymond, a sharp like that disclosed in Stafford, and the on body electronics unit housing as taught by Stafford. *Id.*, ¶162. The distal end of the inserter defines a plane parallel to the bottom of the housing when the sharp and housing are in the proximal position. *Id.*

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the distal end of the inserter [defining] a plane, and wherein a bottom surface of the on body electronics unit housing is parallel to the plane when the on body electronics unit and the sharp are in the proximal position.” *Id.*, ¶163.

U. Claim 21

21. The glucose monitoring assembly of claim 1, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit is in the proximal position.

The '335 patent discloses a “no power state” and “inactive mode” as examples of the claimed “low power state.” EX1001, 11:45-49; EX1003, ¶165.

Stafford discloses an integrated assembly (“on body electronics unit”) that includes a data processing unit that is powered off before use. EX1009, [0037] (discussing an “initial power on procedure”). Since Stafford’s “powered off” state is a “no power state” as well as an “inactive mode,” Stafford also discloses a “low power state.” EX1003, ¶166.

Even without Stafford's express disclosure, a POSITA would have found it obvious to place on body electronics in a low power state before use to conserve battery power. *Id.*, ¶167 (discussing EX1012, EX1023).

As discussed at [1.8], Stafford+Raymond (and Stafford+Raymond+Turner) includes the on body electronics unit as taught by Stafford retained in the proximal position within the inserter as taught by Raymond. *Id.*, ¶168; *supra* Section VIII.F.

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “at least a portion of the on body electronics ... in a low power state when the on body electronics unit is in the proximal position.” EX1003, ¶169.

V. Claim 22

22. The glucose monitoring assembly of claim 1, further comprising an adhesive portion configured to secure the on body electronics unit housing to a skin surface of the subject.

Stafford discloses an adhesive patch (“adhesive portion”). EX1003, ¶172; EX1009, [0019]. Stafford+Raymond (and Stafford+Raymond+Turner) includes the adhesive portion as taught by Stafford. EX1003, ¶171.

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “an adhesive portion configured to secure the on body electronics unit housing to a skin surface of the subject.” *Id.*, ¶172.

W. Claim 23

23. The glucose monitoring assembly of claim 1, wherein at least a portion of the on body electronics is in a no power state when the on body electronics unit is in the proximal position.

The “no power state” of claim 23 would have been obvious for the reasons discussed at claim 21. EX1003, ¶174; *see supra* Section VIII.U.

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “at least a portion of the on body electronics ... in a no power state when the on body electronics unit is in the proximal position.” EX1003, ¶175.

X. Claim 24

24. The glucose monitoring assembly of claim 1, wherein at least a portion of the on body electronics is in an inactive mode when the on body electronics unit is in the proximal position.

The “inactive mode” of claim 24 would have been obvious for the reasons discussed at claim 21. EX1003, ¶177; *see supra* Section VIII.U.

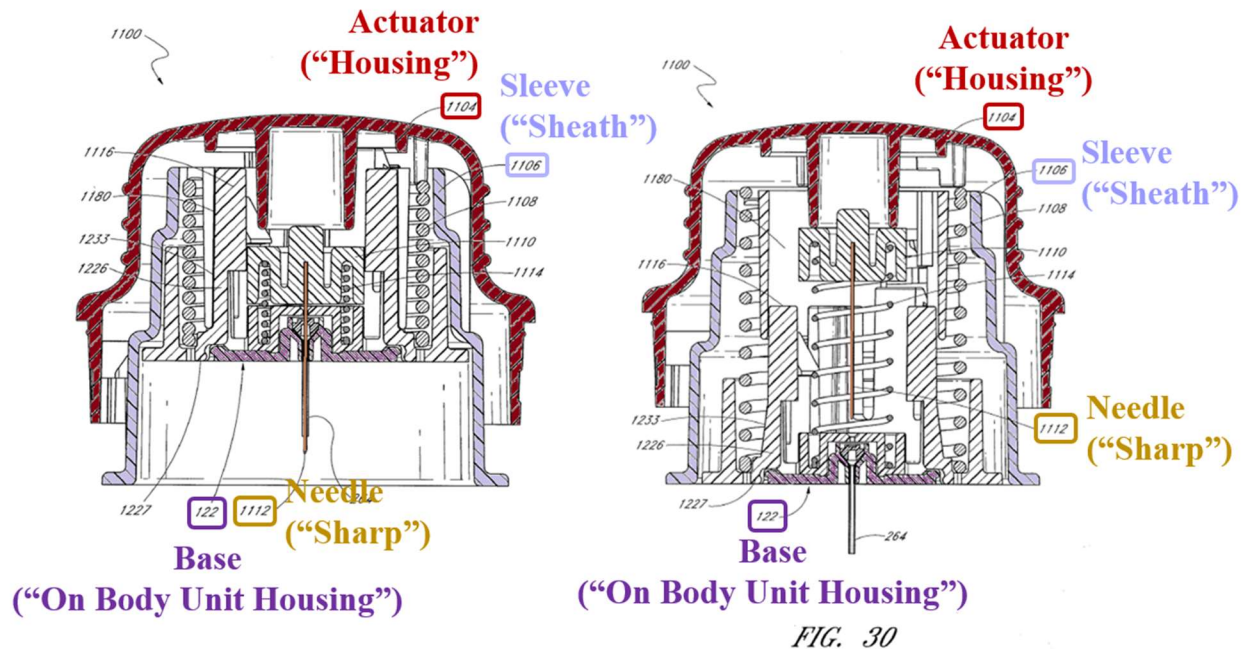
Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “at least a portion of the on body electronics ... in an inactive mode when the on body electronics unit is in the proximal position.” EX1003, ¶178.

Y. Claim 25

25. The glucose monitoring assembly of claim 1, wherein the on body electronics unit and the sharp are configured to advance in a linear direction when advancing from the proximal position within the inserter to the distal position.

Stafford discloses an integrated assembly (“on body electronics unit”) and an introducer (“sharp”). EX1003, ¶180; EX1009, [0006], [0021].

As shown below, Raymond discloses an infusion set (“on body unit,” purple) and a needle (“sharp,” brown), both of which linearly advance from a proximal position (FIG. 29) within an actuator (red) and sleeve (light purple) of Raymond’s insertion device (“inserter,”) to a distal position (FIG. 30). EX1003, ¶181; EX1010, FIGS. 29-30.



Raymond, FIGS. 29-30 (annotated)

In Stafford+Raymond (and Stafford+Raymond+Turner), the inserter as taught by Raymond linearly advances the on body electronics unit as taught by Stafford and

a sharp like that disclosed in Stafford between proximal and distal positions. EX1003, ¶182.

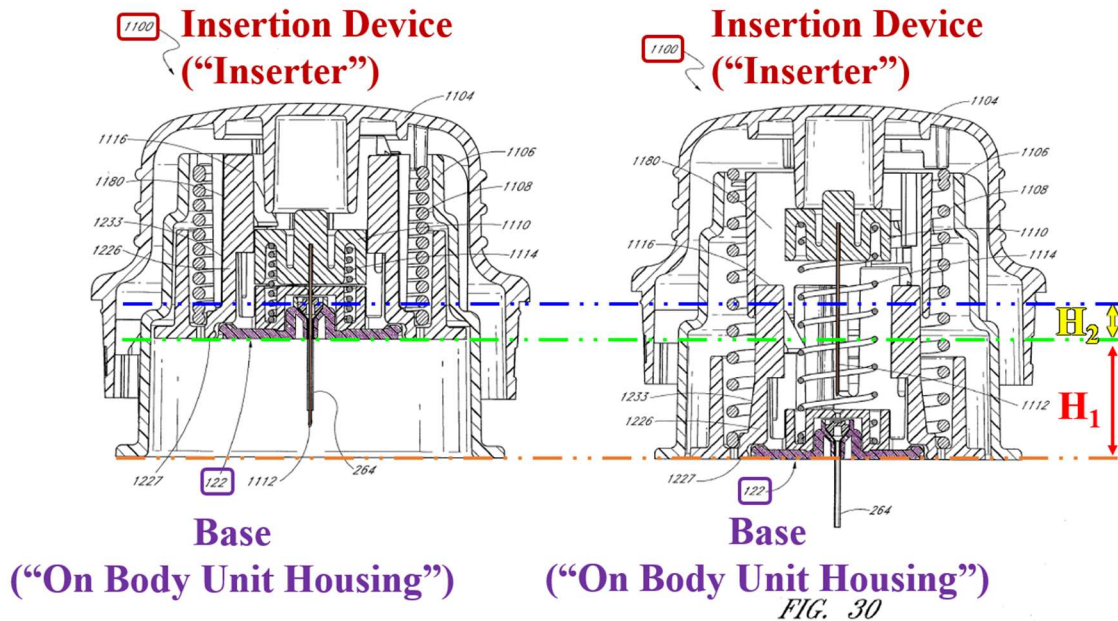
Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the on body electronics unit and the sharp ... configured to advance in a linear direction when advancing from the proximal position within the inserter to the distal position.” *Id.*, ¶183.

Z. Claim 26

26. The glucose monitoring assembly of claim 1, wherein a distance between the on body electronics unit housing when the on body electronics unit is in the proximal position and the on body electronics unit housing when the on body electronics unit is in the distal position is greater than a maximum height of the on body electronics unit housing.

As shown below, Raymond discloses that a distance (“H₁,” red, between the green and orange lines) between an infusion device’s base (“on body unit housing,” purple) in a proximal position (FIG. 29) and the base in a distal position (FIG. 30) is greater than a maximum height (“H₂,” yellow, between the blue and green lines) of the base. EX1003, ¶185; EX1010, FIGS. 29-30. Since Raymond’s drawings clearly illustrate the relationship between travel distance and housing height, Raymond discloses this limitation. EX1003, ¶185; *see In re Aslanian*, 590 F.2d at 914 (quoting *In re Baum*, 374 F.2d at 1009). Based on Raymond’s teachings, a POSITA would have configured the travel distance of the on body electronics unit as taught by

Stafford to be greater than the height of the on body electronics unit housing as taught by Stafford. EX1003, ¶185.



Raymond, FIGS. 29-30 (annotated)

Raymond's disclosure of these relative dimensions is at least equivalent to what is described in the '335 patent. EX1003, ¶186; *compare*, EX1001, FIGS. 123-125 *with* EX1010, FIGS. 29-30. In particular, the '335 patent's specification neither describes a distance between the housing when the on body electronics unit is in a proximal position and when the on body electronics unit is in a distal position nor that this distance of travel is greater than the housing's height. EX1003, ¶186.

Even without Raymond's express teachings, it was an obvious design choice to configure Stafford+Raymond (and Stafford+Raymond+Turner) such that the on body electronics unit's travel distance is greater than the housing's height. EX1003,

¶187. A POSITA would have formed the housing to have a small profile to reduce packaging and cost as taught by Stafford. EX1009, [0045]. It was also known to implement glucose sensors that were longer than the housing's height. EX1003, ¶187; *see, e.g.*, EX1014, FIG. 1A, [0034]; EX1028, 8:53-55, 16:3-5, 17:11-12. A POSITA would have understood that a longer sensor would also ensure contact with sub-dermal fluids and provide better glucose readings. EX1003, ¶187. Thus, it was a natural design choice to implement a sensor with a subcutaneous portion at least as long as the housing's height. *Id.*

Furthermore, a POSITA would have been motivated to configure the *in vivo* portion of the sharp to have a length greater than the length of the glucose sensor's *in vivo* portion to ensure sufficient protection of the sensor during insertion. *Id.*, ¶188. Additionally, as taught by Raymond, a POSITA would have configured the travel distance of the *in vivo* portion of the sharp and the housing fixedly coupled thereto to be greater than the length of the corresponding portion of the sharp to ensure that the sharp is protected before insertion to prevent against needlesticks. *Id.*, ¶188; EX1010, [0127]; *see also id.*, [0104], [0109].

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) would result in a travel distance H_1 greater than the height of the housing H_2 . EX1003, ¶189.

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) at least renders obvious “a distance between the on body electronics unit housing when the on body electronics unit is in the proximal position and the on body electronics unit housing when the on body electronics unit is in the distal position [that] is greater than a maximum height of the on body electronics unit housing.” *Id.*, ¶190.

AA. Claim 27

27. The glucose monitoring assembly of claim 1, wherein the sharp is further configured to pierce a skin surface of the subject at an angle substantially perpendicular to the skin surface of the subject.

As discussed at claim 25, Raymond’s needle (“sharp”) advances in a linear direction perpendicular to the subject’s skin. EX1010, FIGS. 29-30; *see supra* Section VIII.Y. Stafford+Raymond (and Stafford+Raymond+Turner) includes the inserter as taught by Raymond and a sharp like that disclosed in Stafford that advances in the same linear direction to pierce the subject’s skin. EX1003, ¶192.

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the sharp ... further configured to pierce a skin surface of the subject at an angle substantially perpendicular to the skin surface of the subject.” EX1003, ¶193.

**IX. GROUND 3 & 4: CLAIM 16 IS OBVIOUS
OVER STAFFORD, RAYMOND, AND SAY (GROUND 3),
AND FURTHER IN VIEW OF TURNER (GROUND 4)**

As explained below, claim 16 is obvious over Stafford+Raymond and further in view of Say (and Turner). EX1003, ¶195.

A. Say

U.S. Patent No. 6,175,752 (EX1012, “Say”), entitled “Analyte Monitoring Device and Methods of Use,” was issued January 16, 2001. Say qualifies as prior art under Pre-AIA Section 102(b).

Say discloses that a support can be disposed within a housing of a sensor control unit to promote adequate contact between an analyte sensor and the electrical contacts of corresponding sensor electronics. EX1003, ¶197; EX1012, 34:53-35:5.

**B. The Stafford+Raymond+Say
(And Stafford+Raymond+Turner+Say) Combination**

The combinations of Stafford, Raymond, and Say (“Stafford+Raymond+Say”) and Stafford, Raymond, Turner, and Say (“Stafford+Raymond+Turner+Say”) applied herein further combine teachings from Stafford+Raymond and Stafford+Raymond+Turner with teachings from Say related to the combination an on body electronics unit with Say’s support. EX1003, ¶198. In addition to the aforementioned elements of Stafford+Raymond, Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) further include the following elements cooperating as follows:

- an integrated assembly as taught by Stafford comprising a support as taught by Say.

Say (disclosing a transcutaneous medical device for diabetes treatments) is analogous art to the claimed invention of the '335 patent and is further analogous art to Stafford, Raymond, and Turner. *Id.*, ¶199.

1. A POSITA Would Have Been Motivated To Combine Stafford, Raymond, And Say (And Turner)

A POSITA would have understood that it is desirable to promote adequate contact between a sensor and its associated electronics. *Id.*, ¶200. A POSITA understanding such goals and reading Say would have been motivated to add a support as taught by Say to electronics as taught by Stafford to ensure adequate electrical contact between the sensor and electronics. *Id.*

Thus, a POSITA would have been motivated to combine teachings from Stafford+Raymond with teachings from Say (and Turner). *Id.*, ¶201.

2. A POSITA Would Have Had A Reasonable Expectation Of Success In Combining Raymond, Stafford And Say (And Turner)

A POSITA would have had a reasonable expectation of success of adding the support as taught by Say to the electronics as taught by Stafford because Say's sensor and Stafford's sensor have similar shapes and are supported in a similar fashion. *Id.*, ¶202; compare, e.g., EX1009, FIGS. 5B-5C with EX1012, FIG. 14.

A POSITA would have only required mere ordinary skill to combine teachings from Stafford+Raymond with teachings from Say (and Turner). EX1003, ¶203.

Thus, a POSITA would have had a reasonable expectation of success in combining the teachings of Stafford, Raymond, and Say (and Turner). *Id.*, ¶204.

C. Claim 16

[16.1] The glucose monitoring assembly of claim 1, wherein the on body electronics unit further comprises a sensor hub,

The '335 patent provides several examples of a sensor hub, all of which encompass a structure positioned within the housing of the on body unit that supports the portion of the sensor electrically coupled to electrical contacts. *See, e.g.*, EX1001, FIGS. 17, 17A, 148; *id.*, 27:25-49, 46:58-47:4, 47:18-49; EX1003, ¶205.

Say discloses an on-skin sensor control unit (an “on body electronics unit” functionally similar to Stafford’s data processing unit) comprising a support (“sensor hub”) disposed under an analyte sensor (“glucose sensor”). EX1003, ¶206; EX1012, FIG. 14, 34:53-35:5. Say’s sensor hub is disposed within a housing (“on body electronics unit housing”). Thus, Say discloses an on body electronics unit comprising a “sensor hub.” EX1003, ¶206.

The most natural understanding of Say’s support structure is a separate structure that satisfies the claimed “sensor hub” limitation. EX1003, ¶207.

Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) includes the sensor as taught by Stafford and the support as taught by Say supporting a proximal portion of the sensor (*e.g.*, the proximal portion of the sensor coupled to the electronics at the analog interface). EX1003, ¶208. A POSITA would have been motivated to add the support with a reasonable expectation of success. *Id.*; *supra* Sections IX.B.1-2.

Thus, Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) includes “the on body electronics unit further [comprising] a sensor hub.” EX1003, ¶209.

[16.2] wherein the glucose sensor comprises a distal sensor portion and a proximal sensor portion,

As shown in the annotated figures of Section VIII.A, Stafford’s sensor has proximal and distal sensor portions. EX1003, ¶210; EX1009, FIGS. 5B-5C; *see supra* Section VIII.A. As discussed in Grounds 1-2, Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) includes the sensor as taught by Stafford. EX1003, ¶210; *see supra* Section VIII.F.

Thus, Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) includes “the glucose sensor [comprising] a distal sensor portion and a proximal sensor portion.” EX1003, ¶211.

[16.3] wherein the distal sensor portion is configured to sense the glucose level of the subject,

Stafford's glucose sensor includes a distal sensor portion configured to sense the subject's glucose levels. EX1009, [0028], [0051]. As discussed in Grounds 1-2, Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) includes the sensor as taught by Stafford. EX1003, ¶212; *see supra* Section VIII.F.

Thus, Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) includes "the distal sensor portion ... configured to sense the glucose level of the subject." EX1003, ¶213.

[16.4] wherein the proximal sensor portion is engaged with the sensor hub, and

As discussed at [16.1], Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) teaches this element. *Id.*, ¶214.

[16.5] wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

As shown in the annotated figures of Section VIII.A, the distal portion of Stafford's sensor is orthogonal to Stafford's sensor's proximal portion. EX1009, FIG. 5B. As discussed in Grounds 1-2, Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) includes the sensor as taught by Stafford. EX1003, ¶215; *see supra* Section VIII.F.

Thus, Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) includes “the distal sensor portion ... substantially orthogonal to the proximal sensor portion.” EX1003, ¶216.

X. GROUND 5 & 6: CLAIM 16 IS OBVIOUS OVER STAFFORD, RAYMOND, AND BICKOFF (GROUND 5), AND FURTHER IN VIEW OF TURNER (GROUND 6)

As explained below, if claim 16 is deemed non-obvious over Stafford+Raymond (and Turner), this claim is obvious over Stafford+Raymond and further in view of Bickoff (and Turner). EX1003, ¶218.

A. Bickoff

U.S. Publication No. 2009/0240121 (“Bickoff,” EX1013), entitled “INTRAVASCULAR SENSOR AND INSERTION SET COMBINATION,” was published September 24, 2009, from an application filed March 21, 2008. Bickoff qualifies as prior art under Pre-AIA Sections 102(a), 102(b) (for the reasons discussed above), and 102(e).

Bickoff discloses a hub that receives a proximal portion of a sensor. EX1013, [0034], [0035]. The hub helps retain the sensor to maintain good electrical contact between the sensor and sensor electronics. EX1003, ¶220; EX1013, [0035], [0038].

B. The Stafford+Raymond+Bickoff (And Stafford+Raymond+Turner+Bickoff) Combination

The combinations of Stafford, Raymond, and Bickoff (“Stafford+Raymond+Bickoff”) and Stafford, Raymond, Turner, and Bickoff

(“Stafford+Raymond+Turner+Bickoff”) applied herein further combine teachings from Stafford+Raymond and Stafford+Raymond+Turner with teachings from Bickoff related to the combination an on body electronics unit (*e.g.*, Stafford’s integrated assembly) with Bickoff’s hub. EX1003, ¶221. In addition to the aforementioned elements of Stafford+Raymond, Stafford+Raymond+Bickoff and Stafford+Raymond+Turner+Bickoff further include the following elements cooperating as follows:

- an integrated assembly as taught by Stafford comprising a hub as taught by Bickoff.

Bickoff (disclosing a transcutaneous medical device for diabetes treatments) is analogous art to the ’335 patent and, furthermore, is analogous art to Stafford, Raymond, and Turner. EX1003, ¶222.

1. A POSITA Would Have Been Motivated To Combine Stafford, Raymond, And Bickoff (And Turner)

A POSITA would have understood the importance of maintaining electrical contact between a sensor and electronics coupled thereto. EX1003, ¶223. A POSITA understanding such a problem and reading Bickoff would have been motivated to use a hub as taught by Bickoff to ensure good electrical contact between the sensor and electronics as taught by Stafford. *Id.*

Thus, a POSITA would have been motivated to combine teachings from Stafford+Raymond with teachings from Bickoff (and Turner). *Id.*, ¶224.

2. A POSITA Would Have Had A Reasonable Expectation Of Success In Combining Raymond, Stafford And Bickoff (And Turner)

Stafford+Raymond+Bickoff (and Stafford+Raymond+Turner+Bickoff) is a simple combination of known elements that achieves the predictable result of maintaining a sensor's position relative to sensor electronics and which a POSITA would have only required mere ordinary skill to implement. EX1003, ¶225.

Thus, a POSITA would have had a reasonable expectation of success in combining the teachings of Stafford, Raymond, and Bickoff (and Turner). EX1003, ¶226.

C. Claim 16

Petitioner will not repeat the language of claim 16 previously recited in Grounds 3-4. *See supra* Section IX.C. As discussed in Grounds 3-4, Stafford discloses [16.2]-[16.3] and [16.5]. *See supra* Section IX.C. Thus, Stafford+Raymond+Bickoff (and Stafford+Raymond+Turner+Bickoff) teaches these limitations. EX1003, ¶¶232-33, 235-36.

[16.1]

Stafford discloses a glucose sensor in electrical contact with on body electronics (*e.g.*, at an analog interface). EX1003, ¶228; EX1009, [0039].

Bickoff discloses a hub (“sensor hub”) configured to receive a proximal portion of a sensor (“glucose sensor”) therein. EX1003, ¶228; EX1013, [0034], [0035].

Stafford+Raymond+Bickoff (and Stafford+Raymond+Turner+Bickoff) includes the on body electronics and glucose sensor as taught by Stafford and the sensor hub as taught by Bickoff disposed therebetween. EX1003, ¶229.

A POSITA would have been motivated to augment Stafford+Raymond (and Stafford+Raymond+Turner) to include the sensor hub as taught by Bickoff with reasonable expectation of success. EX1003, ¶230; *supra* Sections X.B.1-2.

Thus, Stafford+Raymond+Bickoff (and Stafford+Raymond+Turner+Bickoff) includes “the on body electronics unit further [comprising] a sensor hub.” EX1003, ¶231.

[16.4]

As discussed at [16.1], Stafford+Raymond+Bickoff (and Stafford+Raymond+Turner+Bickoff) teaches this element. EX1003, ¶234.

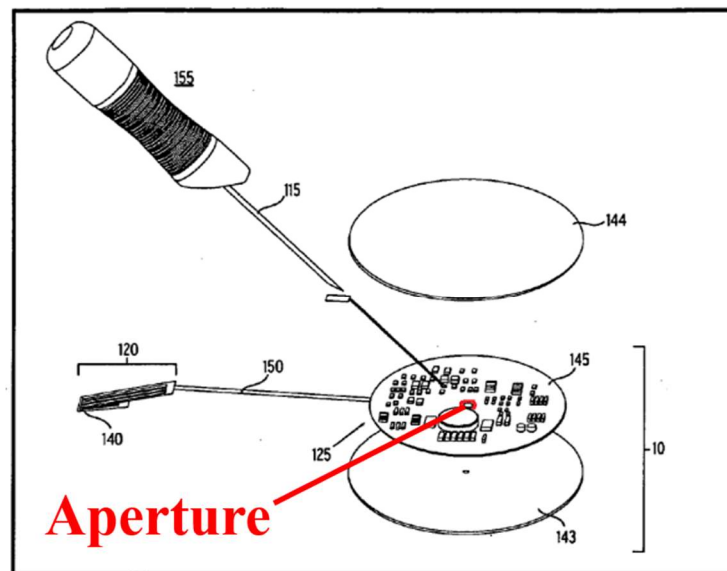
**XI. GROUNDS 7 & 8: CLAIMS 17-18 ARE
OBVIOUS OVER STAFFORD, RAYMOND, AND SHAH
(GROUND 7), AND FURTHER IN VIEW OF TURNER (GROUND 8)**

As explained below, if claims 17-18 are deemed non-obvious over Stafford+Raymond (and Turner), claims 17-18 are obvious over Stafford+Raymond and further in view of Shah (and Turner). EX1003, ¶238.

A. Shah

U.S. Publication No. 2007/0073129 (“Shah,” EX1014) was published March 29, 2007. Shah qualifies as prior art under Pre-AIA Section 102(b)).

Shah discloses a transcutaneous analyte sensor coupled to a flexible partial circuit with an aperture through which a sensor and insertion needle pass. EX1003, ¶240; EX1014, Abstract, FIG. 6, [0045].



Shah, FIG. 6 (annotated)

**B. The Stafford+Raymond+Shah
(And Stafford+Raymond+Turner+Shah) Combination**

The combinations of Stafford, Raymond, and Shah (“Stafford+Raymond+Shah”) and Stafford, Raymond, Turner, and Shah (“Stafford+Raymond+Turner+Shah”) applied herein further combine teachings from Stafford+Raymond and Stafford+Raymond+Turner with teachings from Shah

related to the combination of on body electronics and an aperture extending therethrough. EX1003, ¶241. In addition to the aforementioned elements of Stafford+Raymond, Stafford+Raymond+Shah and Stafford+Raymond+Turner+Shah further include the following elements cooperating as follows:

- on body electronics as taught by Stafford comprising an aperture as taught by Shah, wherein a sharp like that disclosed in Stafford extends through the aperture of the on body electronics.

Shah (disclosing a transcutaneous medical device for diabetes treatments) is analogous art to the claimed invention of the '335 patent and is further analogous to Stafford, Raymond, and Turner. EX1003, ¶242.

1. A POSITA Would Have Been Motivated To Combine Stafford, Raymond, And Shah (And Turner)

A POSITA would have been motivated to implement Shah's teachings in Stafford+Raymond (and Stafford+Raymond+Turner) to form a first aperture as taught by Shah in the on body electronics as taught by Stafford. EX1003, ¶243. Stafford discloses a data processing unit comprising electronics and an introducer extending through a central portion of the data processing unit. *See supra* Sections VIII.Q-R. Likewise, Shah teaches a flexible mounting base (functionally similar to Stafford's data processing unit) comprising a flexible partial circuit having an

aperture and a needle extending partially through a central portion of the base. EX1014, Abstract, FIG. 6, [0045]. Although Stafford does not explicitly show electronics within the data processing unit, a POSITA would have been motivated to form the aperture in the on body electronics as taught by Stafford to maximize the electronics space and minimize empty space within the housing as taught by Stafford and create the smallest-profile on body unit (as taught by Stafford) and, consequently, would have needed an aperture for the sharp like that of Stafford to extend through. EX1003, ¶243.

Thus, particularly in view of Shah, it would have been obvious to implement the electronics as taught by Stafford in a circular shape with an aperture in a central portion thereof, wherein the sharp extends through the aperture. EX1003, ¶244.

Thus, a POSITA would have been motivated to combine teachings from Stafford+Raymond with teachings from Shah (and Turner). *Id.*, ¶245.

2. A POSITA Would Have Had A Reasonable Expectation Of Success In Combining Raymond, Stafford And Shah (And Turner)

A POSITA would have only required mere ordinary skill to combine teachings from Stafford+Raymond with teachings from Shah (and Turner). EX1003, ¶246. For example, a POSITA would have formed the aperture as taught by Shah—a simple hole—in the on body electronics as taught by Stafford with a reasonable expectation of success. *Id.*

Thus, a POSITA would have had a reasonable expectation of success in combining teachings from Stafford+Raymond with teachings from Shah (and Turner). *Id.*, ¶247.

C. Claim 17

Petitioner will not repeat the language of claim 17 previously recited in Grounds 1-2. *See supra* Section VIII.Q.

Shah discloses a flexible mounting base comprising a flexible partial circuit having an aperture and an insertion needle configured to extend partially through the aperture. EX1003, ¶248; EX1014, Abstract, FIG. 6, [0045].

A POSITA would have at least found it obvious to form the aperture as taught by Shah in the on body electronics as taught by Stafford with a reasonable expectation of success. EX1003, ¶249; *see supra* Sections XI.B.1-2.

Thus, Stafford+Raymond+Shah (and Stafford+Raymond+Turner+Shah) includes “the on body electronics [comprising] an aperture, and ... the sharp [extending] through the aperture of the on body electronics.” EX1003, ¶250.

D. Claim 18

Petitioner will not repeat the language of claim 18 previously recited in Grounds 1-2. *See supra* Section VIII.R.

As discussed at claim 17, a POSITA would have found it obvious to form the aperture as taught by Shah (a “first aperture”) in the on body electronics as taught by Stafford. EX1003, ¶252; *see supra* Section XI.C.

As discussed in Grounds 1-2, a POSITA would have understood that Stafford teaches second and third apertures in the top and bottom surfaces of Stafford’s housing. EX1003, ¶253; *see supra* Section VIII.R.

Stafford+Raymond+Shah (and Stafford+Raymond+Turner+Shah) includes the first aperture as taught by Shah in the on body electronics and the second and third apertures in the top and bottom surfaces of the housing as taught by Stafford. EX1003, ¶254. A sharp like that disclosed in Stafford extends through the first, second, and third apertures before insertion. *Id.*; *see supra* Section VIII.R. As discussed at [1.8], the housing is in the proximal position within the inserter as taught by Raymond before insertion. EX1003, ¶254; *see supra* Sections VIII.F, VIII.R.

Thus, Stafford+Raymond+Shah (and Stafford+Raymond+Turner+Shah) includes “the aperture of the on body electronics [defining] a first aperture, ... [and] the on body electronics unit housing further [comprising] a top surface and a bottom surface, wherein the top surface comprises a second aperture, wherein the bottom surface comprises a third aperture, and ... the sharp extends through the first aperture, the second aperture, and the third aperture when the on body electronics unit is in the proximal position.” EX1003, ¶255.

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 for claims 1-4, 8-9, and 11-27, on the grounds specified in this petition.

Respectfully submitted,

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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(a)(1)(i).

The brief contains 13,717 words, excluding the parts of the brief exempted by 37 C.F.R. § 42.24(a).

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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. 11,266,335 and Exhibits 1001-1015, 1017-1018, 1023, 1028, 1030, 1035, 1037, 1039-1044, 1056-1057, 1059-1066** were served on October 6, 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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