

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

IPR2024-00520
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 EXHIBITS¹

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	<i>Intentionally left blank</i>
1004	U.S. Provisional Application No. 61/411,262, filed Nov. 8, 2010
1005	U.S. Patent Application No. 13/071,461, filed Mar. 24, 2011
1006	U.S. Provisional Application No. 61/317,243, filed Mar. 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	<i>Intentionally left blank</i>
1014	U.S. Publication No. 2007/0073129 (“ Shah ”)

¹ Petitioner filed a previous petition for inter partes review of the ’335 patent in IPR2023-01396, challenging claims 1-4, 8-9, and 11-27 on similar grounds to those presented here. That petition included exhibits numbered from 1001-1066, a subset of which are resubmitted here and maintain the same numbering. Exhibits *newly filed* with this petition are numbered 1267-1268, to ensure both unique exhibit numbering and to make clear that they are newly cited in this petition.

No.	Description
1015	U.S. Publication No. 2006/0095014 (“ Ethelfeld ”)
1016	<i>Intentionally left blank</i>
1017	PCT Publication No. WO 2008/155377 (“ Hasted ”)
1018	U.S. Publication No. 2004/0002682 (“ Kovelman ”)
1019-29	<i>Intentionally left blank</i>
1030	U.S. Publication No. 2007/0093754 (“ Mogensen ”)
1031-36	<i>Intentionally left blank</i>
1037	U.S. Publication No. 2009/0099521 (“ Gravesen ”)
1038	<i>Intentionally left blank</i>
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 687 ”)
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 ”)
1045-55	<i>Intentionally left blank</i>
1056	U.S. Publication No. 2009/0216215 (“ Thalmann ”)
1057	U.S. Publication No. 2005/0131346 (“ Douglas ”)
1058	<i>Intentionally left blank</i>
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> , Diabetologia, Vol. 36, Issue 7, 1993

No.	Description
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> , Journal of Diabetes Science and Technology, 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> , Diabetes Technology & Therapeutics, Vol. 5, Nov. 3, 2003
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. Mar. 3, 2023)
1267	“ABBOTT’S INITIAL CLAIM CHARTS” served Dec. 20, 2023 in <i>Abbott Diabetes Care Inc. v. DexCom Inc.</i> , No. 1-23-cv-00239 (D. Del.) ²
1268	Third Declaration of Gary D. Fletcher, Ph.D., dated January 31, 2024 (“Third Fletcher Decl.”)

² While EX1267 is marked as “HIGHLY CONFIDENTIAL–OUTSIDE ATTORNEYS’ EYES ONLY,” footnote 1 states that Abbott made this designation “[o]nly out of an abundance of caution *based on the citation of documents produced by DexCom and marked as such.*” *Id.* at 1 n.1 (emphasis added). As EX1267 is a cover pleading that includes no citations to confidential documents, Petitioner DexCom does not file this exhibit under seal.

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.

Two separate IPR petitions were contemporaneously filed by Petitioner on October 6, 2023, in IPR2023-01396 and IPR2023-1397, each challenging claims 1–4, 8–9, 11–15, and 17–27 of the '335 patent.

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

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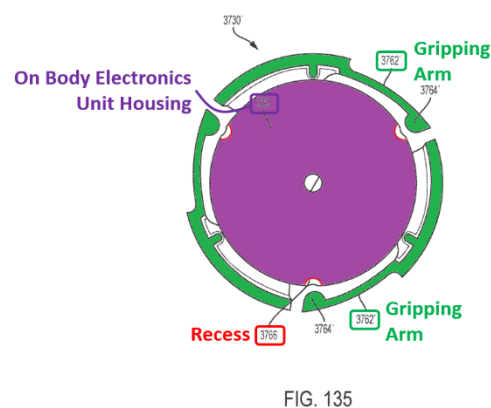
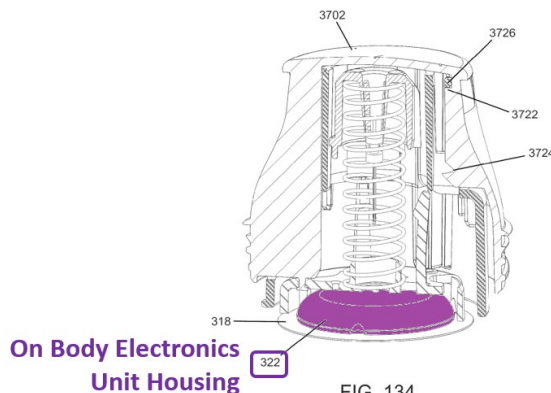
Petitioner consents to service via email at the above email addresses.

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

I. INTRODUCTION

DexCom, Inc. (“Petitioner”) respectfully requests *inter partes* review (“IPR”) of claims 5-7 (“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)³ 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.*, 49:12-13 (claim 2), 49:27-46 (claims 5-7).



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

³ 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.*

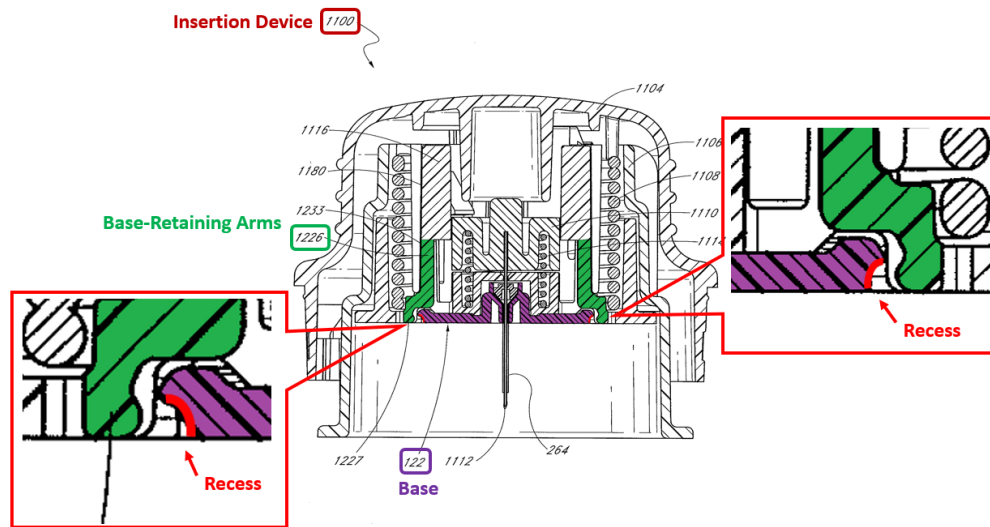


FIG. 29

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. Turner (EX1011) teaches additional features that skilled artisans would have

naturally incorporated into such an assembly, thus rendering obvious each challenged claim. *Infra* Section VIII.

II. GROUNDS 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 5-7 of the '335 patent, on the following statutory grounds:

	Reference(s)	35 U.S.C. §	Claims
Ground 1	Stafford (EX1009) and Raymond (EX1010)	103	5-7
Ground 2	Stafford, Raymond, and Turner (EX1011)	103	5-7

For each ground, in Section VIII 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 \$41,500 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 two of the references relied on herein (Raymond and Stafford) 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 (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.

Even if the Examiner *had* evaluated the references relied on herein, the Examiner materially erred in allowing claims 5-7 because he or she failed to

appreciate the disclosures and teachings in those references discussed in the Grounds below, which show that the challenged claims are unpatentable and should have never been allowed. Because these 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 District Court Proceedings

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.

C. Related PTAB Proceedings

1. 35 U.S.C. § 325(d)

This is not a case where the same or substantially the same prior art or arguments previously were presented to the Office, since the present Petition challenges only newly-asserted claims that were not challenged in any previously filed petition.

35 USC § 325(d) gives the Board discretion to deny institution of an IPR petition where “the same or substantially the same prior art or arguments previously were presented to the Office.” Here, discretionary denial pursuant to this section is not warranted. As noted above and in the concurrently-filed “Petitioner’s Explanation Of Material Differences Between The Petition In IPR2024-00520 And

Previously Filed Petitions In IPR2023-01396 And IPR2023-01397,” on October 6, 2023, Petitioner filed two petitions for *inter partes review* of claims 1-4, 8-9, and 11-27 of U.S. Patent No. 11,266,335 (the ’335 patent). *Petition 1 (IPR2023-01396)* relied on references that are prior art regardless of the ’335 patent’s asserted priority date, and *Petition 2 (IPR2023-01397)* relied on an additional reference that qualifies as prior art unless Patent Owner shows earlier conception and diligent reduction to practice.

On December 20, 2023, over two months after Petitions 1 and 2 were filed, Patent Owner first asserted ’335 patent claims 5-7 in related district court litigation. EX1267 at 2. Petitioner then promptly evaluated Patent Owner’s newly asserted claims in order to challenge these claims (and only these claims) in a separate petition—which is the present Petition.

Moreover, should all three Petitions be instituted, Petitioner would endeavor to work with Patent Owner on a proposed alignment of schedules and consolidation of the proceedings so that the Board can efficiently resolve prior art unpatentability of all asserted claims. For example, Petitioner would work with Patent Owner to reach mutual agreement on minimum amounts of briefing and deposition time needed to resolve the three proceedings.

Accordingly, instituting the present petition and consolidating it with Petition 1, on a coordinated trial schedule to Petition 2 would minimize or eliminate the

duplicative efforts contemplated by §325(d), while allowing the Office to efficiently resolve the patentability of claims 5-7.

2. TPG: “Parallel Proceedings Challenging The Same Patent”

The November 2019 Consolidated Trial Practice Guide (“TPG”) includes a section entitled, “Parallel Petitions Challenging the Same Patent.” TPG, 59-61. Contemporaneous with this petition, Petitioner files a 5-page brief explaining why ranking this petition relative to the previously filed petitions in IPR2023-01396 and IPR2023-01397 would be inappropriate, as it challenges only newly asserted claims that were not challenged in those petitions—as noted therein, if the Board requires such a ranking, Petitioner ranks this petition third—and explaining why institution is warranted for all three petitions.

3. 35 U.S.C. § 314(a)

In *General Plastic Indus. Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 16 (PTAB Sept. 6, 2017) (Precedential), the Board identified seven factors that may be weighed to determine whether to deny institution under § 314(a) (“General Plastic factors”). These factors weigh heavily against discretionary denial.

First Factor: Petitioner has not “previously filed a petition directed to the same claims.” IPRs 1 and 2 were directed to claims 1–4, 8–9, 11–15, and 17–27. The Challenged Claims in this petition are newly asserted claims 5-7. As such this factor

heavily weighs against discretionary denial. In fact, in a similar case covering different claims from those previously challenged in a prior petition, the Board has said it does not consider such a later-filed petition a “follow-on petition” at all, as that term is used in *General Plastic. See Volkswagen Grp. of Am., Inc., v. Carucel Invs., L.P.*, IPR2019-01573, Paper 7 at 7 (PTAB Jan. 22, 2020) (second petition covering different claims is not a “follow-on petition”). While this petition addresses claims 1 and 2, it only does so as necessary to challenge claims 5 and 7, which depend from those claims. And the Board has previously found that this factor does not weigh in favor of exercising its discretion to deny institution of review where (as here) the challenged claims in a subsequently filed petition depend from a previously challenged claim and “Petitioner had to address claim 1 in this petition, as our rules prevent Petitioner from simply incorporating arguments by reference from its earlier petition.” *Ericsson Inc. v. Intellectual Ventures I LLC*, IPR2018-01318, Paper 6 at 46 (PTAB Jan. 15, 2019).

Second and Fourth Factors: although Petitioner “knew of the prior art asserted” in this petition when Petitioner filed Petition 1, Petition 1 did not apply that art to the new claims challenged in this petition because Petitioner reasonably did not anticipate those claims being asserted. Upon learning on December 20, 2023, that claims 5–7 were being asserted, Petitioner acted promptly and within six weeks

prepared and filed Petition 3. Thus, factors 2 and 4 weigh against discretionary denial or are at least neutral.

Third Factor: Petitioner filed Petition 3 before institution decisions were reached on Petitions 1 and 2, so it is not informed by any Board determinations. Although Petitioner has “already received the [POPR] to [Petitions 1 and 2],” Petitioner’s arguments are unchanged as to the overlapping claim elements found in claims 1 and 2, from which the currently challenged claims 5–7 depend. As to those overlapping elements, Petitioner makes the same obviousness arguments in Petition 3 as it made in Petition 1, *without substantive modification*. Thus, Petitioner is not using the POPR or institution decision to modify arguments that were previously unsuccessful, nor shifting its prior art arguments for the purposes of this petition. Moreover, the need for this petition only arose after the Patent Owner asserted new claims *after* Petitioner filed Petitions 1 and 2, six weeks before the present Petition was filed (which period included a number of intervening holidays). The intervening time to prepare this petition, its supporting declaration, and statements addressing the differences between petitions is not unreasonable. This factor weighs against discretionary denial.

Fifth Factor: Petition 3 does not challenge “the same claims” as the earlier petitions. Moreover, after learning that claims 5–7 were asserted in the litigation, Petitioner moved promptly in preparing and filing Petition 3.

Sixth Factor: Institution of this petition will not inefficiently impact “the finite resources of the Board.” The vast majority of claim limitations mapped in this petition are common to the prior petitions, and as to those limitations Petitioner presents identical prior art and arguments as presented in Petition 1. This overlap occurs because the newly asserted claims (5–7) depend directly or indirectly from claims 1 and 2, challenged in the prior petitions. While claims 1 and 2 are not challenged again here, they are mapped as required to demonstrate the obviousness of the claims that depend from them. With this petition, Petitioner merely adds mapping for the additional limitations of the newly asserted claims, relying on the same art cited in Grounds 1 and 2 of Petition 1, as well as a subset of the “state of the art” references also cited in Petition 1. And, as stated above, Petitioner proposes consolidating Petition 1 (if instituted) with the present Petition, and coordinating the trial schedule with the concurrently filed Petition 2, ensuring efficiency in managing the Board’s finite resources. This factor weighs against discretionary denial.

Seventh Factor: For the same reasons given above, institution of this petition should not affect “the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review.” In the event Petition 1 and this petition are both instituted, Petitioner proposes consolidation, on a schedule that would allow the Board to issue a final written decision on all challenged claims within one year of the expected

institution date for Petition 1 (IPR2023-01396). Should the Board decide not to consolidate the two proceedings, the Board would have even more time to issue a final written decision on later-challenged claims 5-7. This factor, too, weighs against discretionary denial.

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 (EX1005), and provisional applications filed November 8, 2010; July 2, 2010; May 17, 2010; and March 24, 2010.⁴ 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; EX1268, ¶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

⁴ Petitioner applies pre-AIA Sections 102-103 as discussed in Section V.B, but does not concede that any priority application supports the claims.

sharp from the distal position to a retracted position entirely within the inserter. EX1001, 48:53-49:11; EX1268, ¶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; EX1268, ¶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 anticipated by U.S. Publication No. 2010/0198034 ("Thomas-034") and/or obvious over Thomas-034 and other references. EX1002, 333-45.⁵

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.*, 491-95), and that Applicant reduced to practice the

⁵ Prosecution history cites are to Petitioner's exhibit page numbers.

alleged invention no later than November 8, 2010, as purportedly evidenced by the filing of the November 8, 2010, provisional application. *Id.*, 498-99. 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 November 8, 2010 date,⁶ 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,

⁶ This is further explained in the petition in Case No. IPR2023-01397.

including, *e.g.*, systems for implanting wearable medical devices such as cannulas, infusion sets, and analyte sensors, or equivalent experience.⁷ Less work experience would have been compensated by a higher level of education, such as a master's degree, and vice versa. EX1268, ¶24.

B. State Of The Art

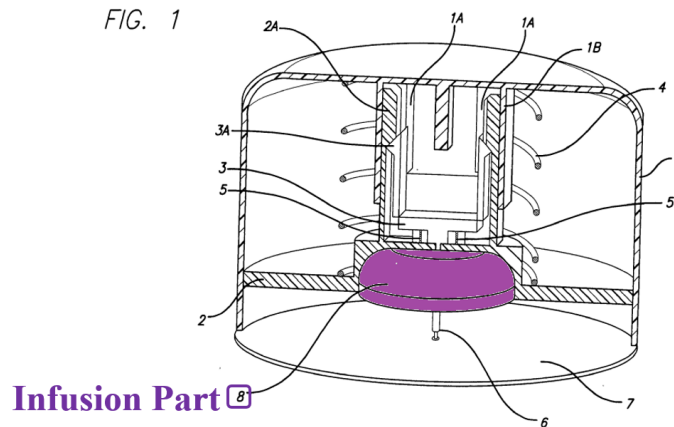
The features claimed in the '335 patent—namely, inserters configured to secure an on body unit therein, retractable sharps to insert transcutaneous medical devices (*e.g.*, a glucose sensor, a cannula) into subjects, and wearable on body units—were known before 2010. EX1268, ¶25 (citing EX1010, EX1018, 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.*, EX1268, ¶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

⁷ 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.

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.*, EX1268, ¶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. EX1268, ¶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. EX1268, ¶28; *see, e.g.*, EX1010, [0100], [0109].

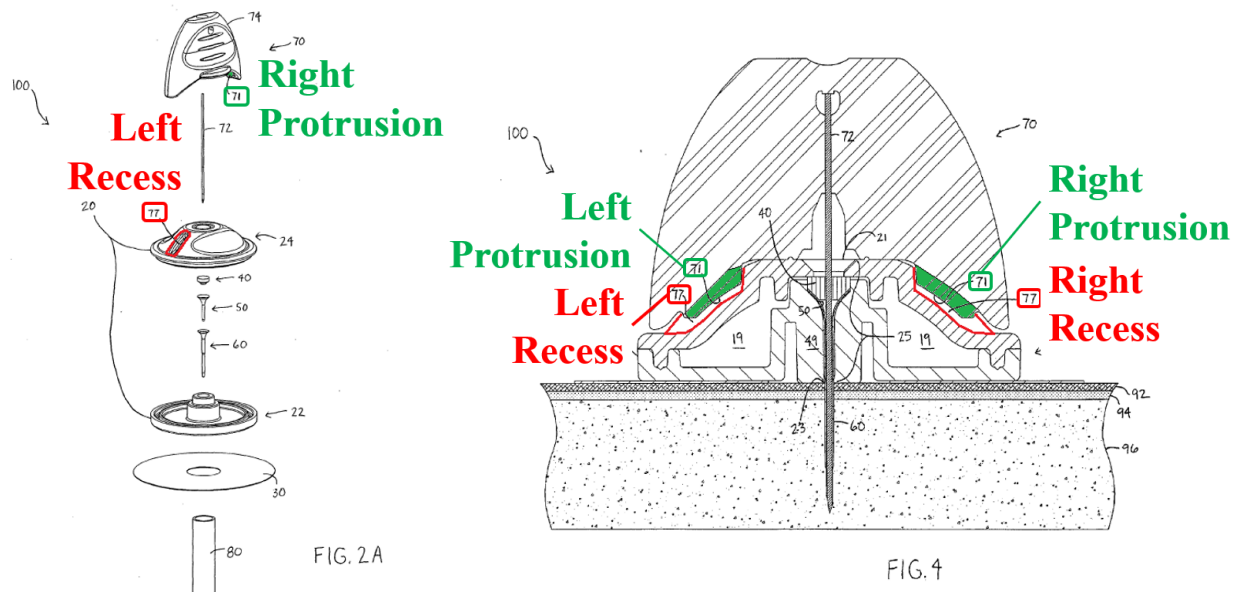
**2. The Interchangeability Of Infusion Device
Inserters And Glucose Sensor Inserters Was Known**

Inserters were known to be interchangeably configurable to insert glucose sensors and cannulas. EX1268, ¶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. EX1268, ¶29; *see, e.g.*, 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. EX1268, ¶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. EX1268, ¶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 5-7 ARE OBVIOUS OVER STAFFORD AND RAYMOND (GROUND 1), AND FURTHER IN VIEW OF TURNER (GROUND 2)

As explained below, claims 5-7 are obvious over Stafford and Raymond (Ground 1), and further in view of Turner (Ground 2). EX1268, ¶31. Claims 1 and 2, from which claims 5-7 directly or indirectly depend, are also obvious over Stafford and Raymond, alone or further in view of Turner, as previously set forth in IPR2023-01396, and both claims are mapped to Stafford and Raymond alone and in further view of Turner herein, in a similar manner, demonstrate that their dependent claims 5-7 are likewise obvious.

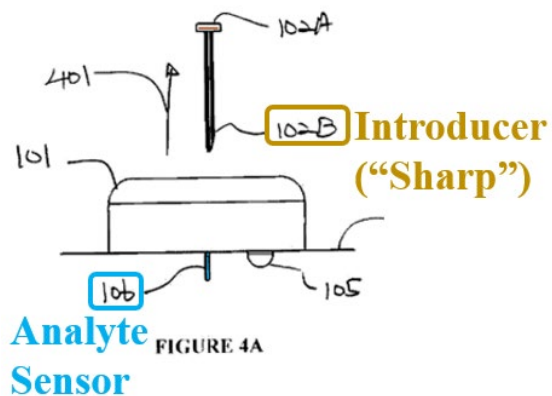
A. Stafford

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).⁸ EX1268, ¶32.

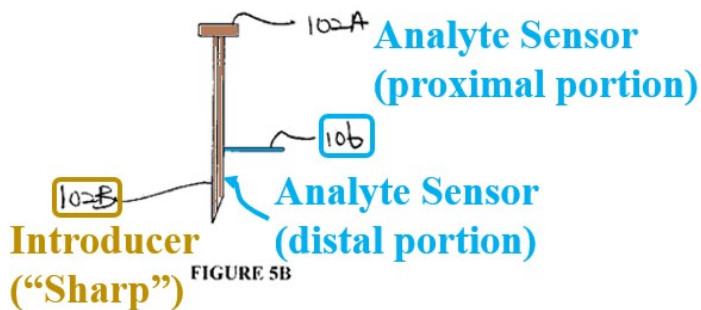
Stafford describes an integrated assembly that includes a transcutaneous analyte sensor and a data processing unit coupled thereto for processing analyte level measurements therefrom. *See, e.g.*, EX1009, [0006]. The data processing unit is disposed within a housing. EX1268, ¶33; *see, e.g.*, EX1009, FIG. 4A, [0006], [0020], [0027], [0053].

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. EX1268, ¶34; EX1009, FIGS. 4A, 5B-5C.

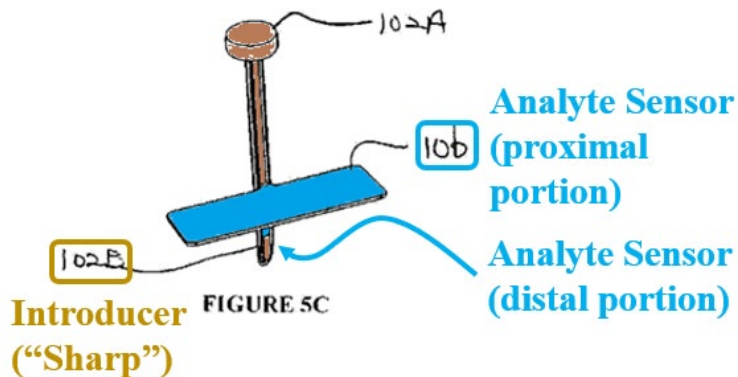
⁸ Without conceding that the claims find support in any of the parent applications, for purposes of the petition Petitioner assumes application of the pre-AIA Statute.



Stafford, 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. EX1268, ¶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. EX1268, ¶36; EX1009, FIG. 7, [0040], [0052].

Stafford's data processing unit is initially powered off and can be powered on. EX1268, ¶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. EX1268, ¶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. EX1268, ¶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

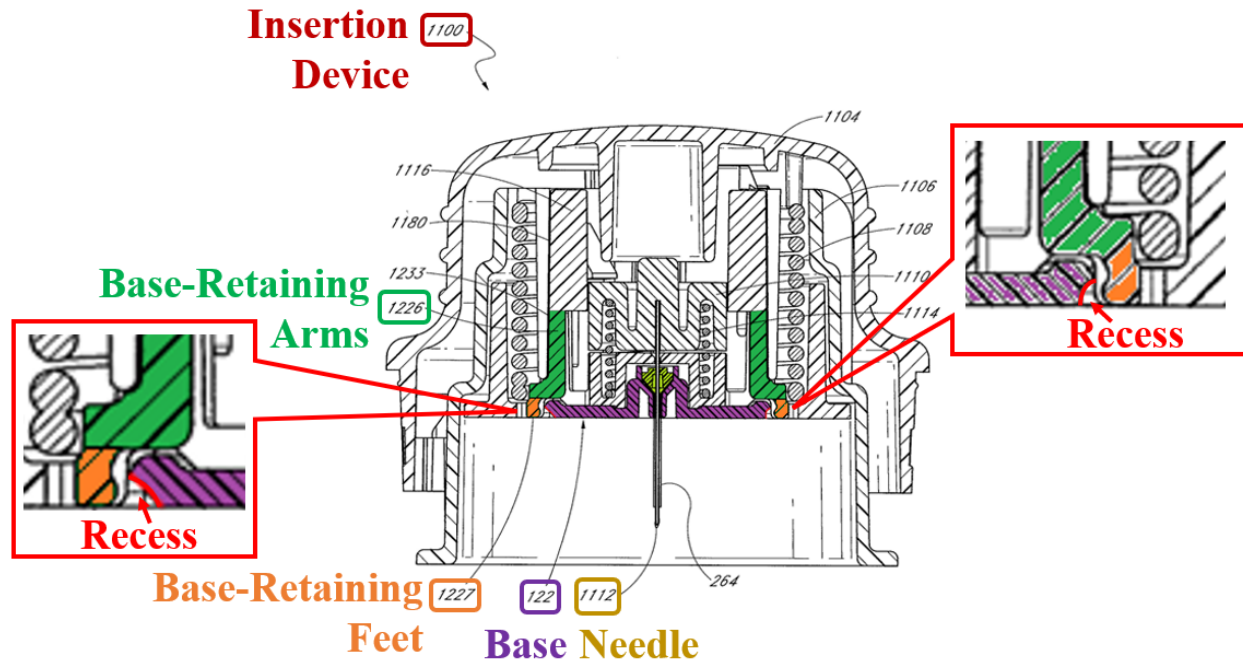
prior art under Pre-AIA Sections 102(a) and 102(e). EX1268, ¶39. As discussed at Section V.B, Raymond also qualifies as prior art under Pre-AIA Section 102(b) because Raymond was published more than one year before the March 24, 2011 non-provisional application first disclosed a “plurality of recesses.”

Raymond describes an insertion device that inserts a transcutaneous infusion device “quickly, safely, and conveniently.” EX1010, [0008], [0109]. The infusion device includes a base housing at least a portion of an infusion set therein. EX1268, ¶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. EX1268, ¶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. EX1268, ¶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). EX1268, ¶42; EX1010, [0123]. Each base-retaining foot is

located at a tip portion of a corresponding base-retaining arm (green). EX1268, ¶42; EX1010, FIG. 29.

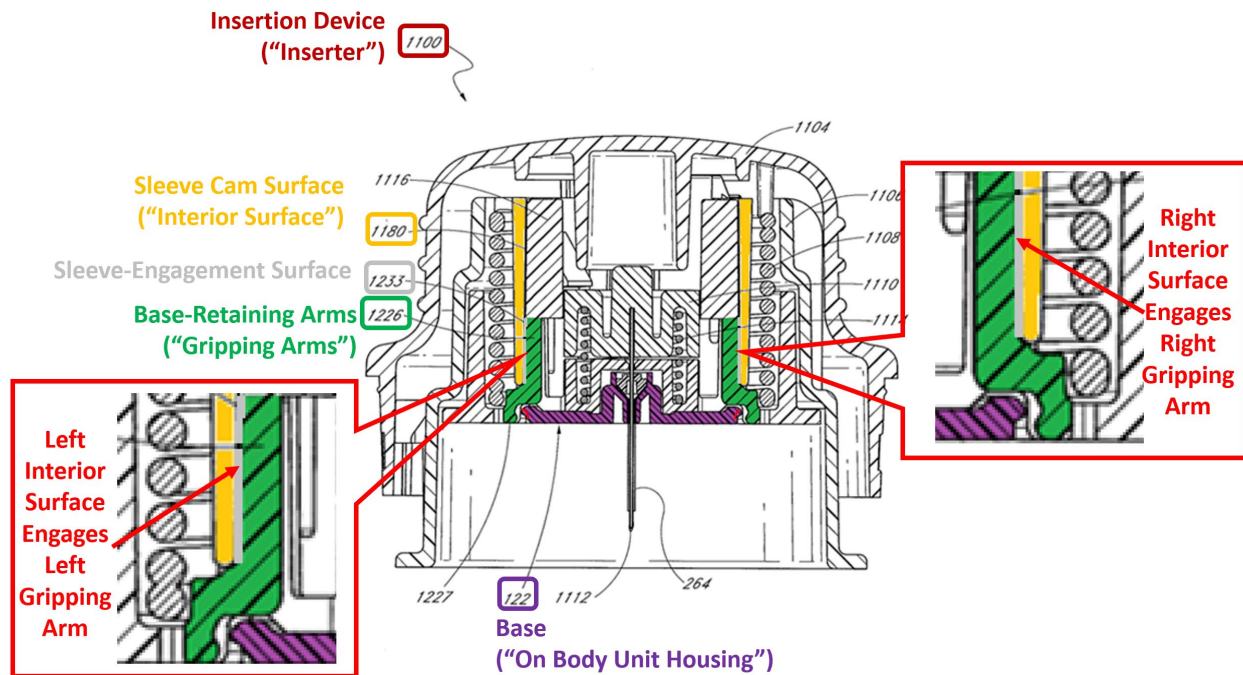


Raymond, FIG. 29 (annotated)

As can be seen in the further annotated drawing below,⁹ and as further described in Raymond, these left and right base-retaining arms are held against corresponding recesses of the base by left and right interior surfaces (yellow) on the sleeve. Raymond collectively refers to multiple such surfaces on the interior of the sleeve as a “cam surface.” Each of these interior surfaces on the sleeve engages

⁹ The additional discussion of Raymond beginning here and continuing through page 30 is added to the discussion previously submitted with Petition 1 solely to address the additional limitations of newly asserted claims 5-7.

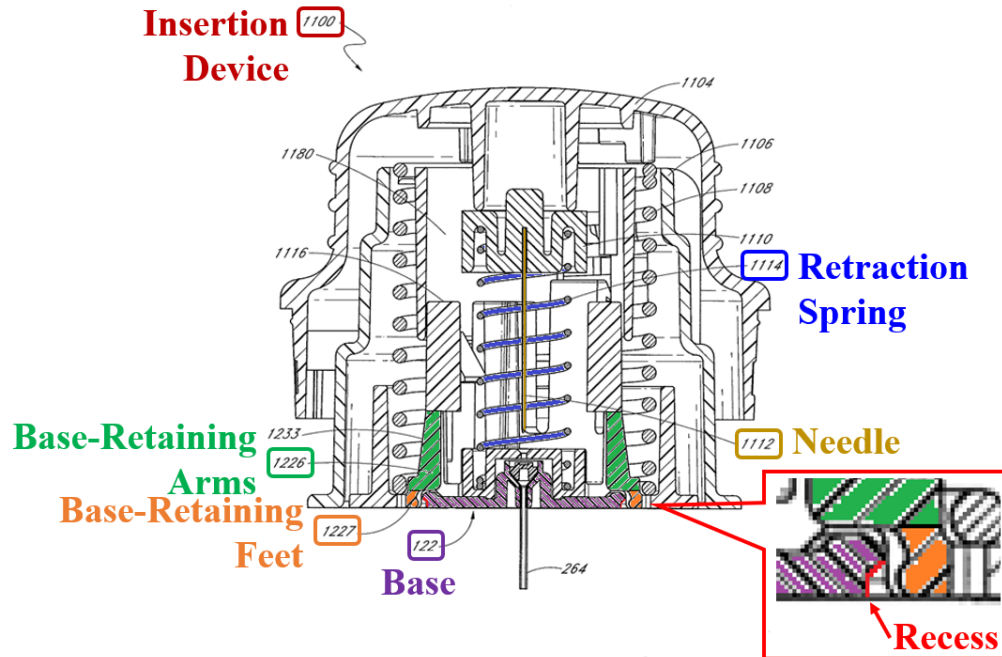
a corresponding sleeve engagement surface (grey) on one of the base-retaining arms to prevent unintentional disengagement of the base when the base is in the proximal position. EX1010, FIG. 29, [0123] (“The base-retaining arms 1226 can include sleeve-engagement surfaces 1233 positioned for engagement by the cam surface 1180 of the sleeve 1106 to urge the base-retaining feet 1227 toward the base 122 to impede unintentional disengagement of the infusion device 102 from the shuttle 1116.” EX1268, ¶43.



Raymond, FIG. 29 (annotated)

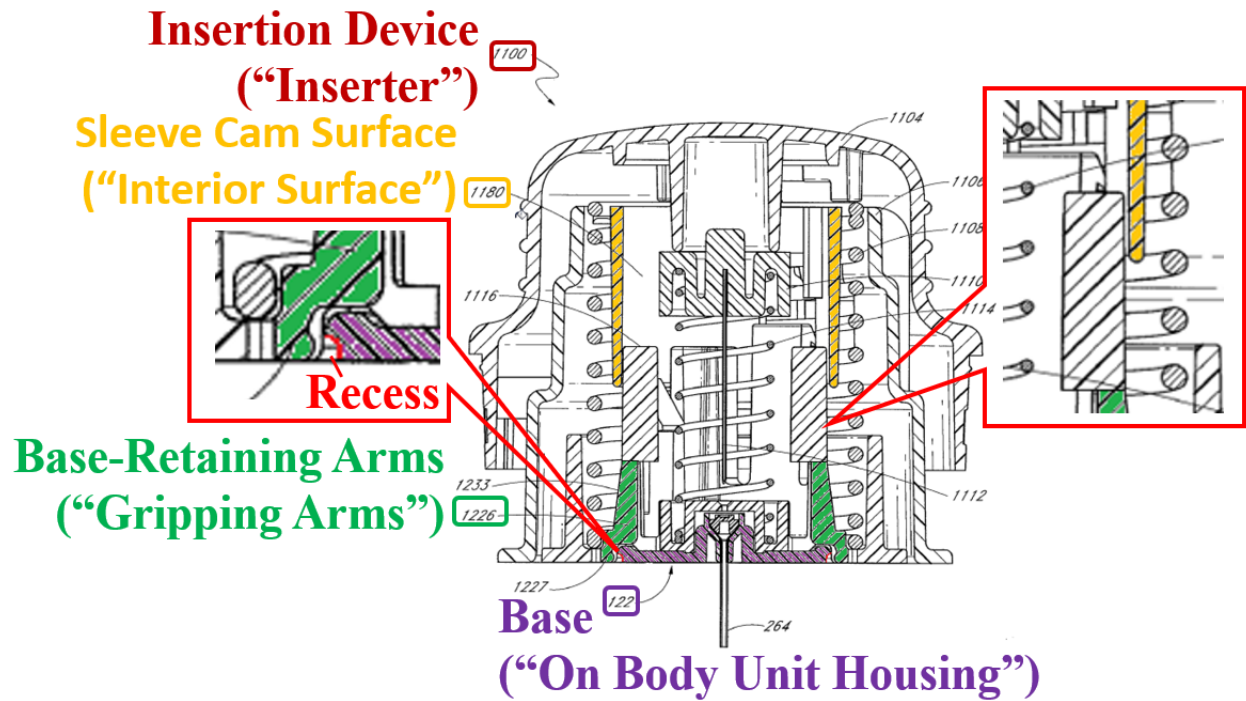
As shown below, when the insertion device advances the infusion device to a distal position during insertion, the insertion device's outwardly-biased base-retaining feet disengage the infusion device's base such that the feet disengage the

base's recesses by the time the infusion device reaches the distal position. EX1010, [0126]; EX1268, ¶44.



Raymond, FIG. 30 (annotated)

As can also be seen in the further annotated figure below, in this distal position, each of the base-retaining arms is also no longer in contact with its respective cam surface with which it was previously biased inward when in the proximal position. EX1010, FIG. 30, [0126] (“The base-retaining arms 1226 can spread outwardly when the sleeve-engagement surfaces 1233 of the shuttle 1116 clear the cam surface 1180 of the sleeve 1106 ...”); EX1268, ¶45.



Raymond, FIG. 30 (annotated)

Raymond describes several advantages of using its insertion device over prior insertion devices, such as positioning the needle within the insertion device before insertion and retracting the needle within the insertion device after insertion to prevent accidental needlesticks. EX1268, ¶46; EX1010, [0008], [0127]; *see also id.*, [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). EX1268, ¶47.

Turner describes an insertion device for delivering a fluid delivery device for the treatment of diabetes. EX1268, ¶48; 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. EX1268, ¶49; 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 (“insertor”) with base-retaining arms (“gripping arms”). EX1268, ¶50.

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. EX1268, ¶51. 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. EX1268, ¶52.

Raymond improves upon an aspect of insertion identified by Stafford, namely, to prevent accidental needlesticks when withdrawing the needle from a subject. EX1268, ¶53; 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. EX1268, ¶53; 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. EX1268, ¶53. 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. EX1268, ¶54. 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. EX1268, ¶54; *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. EX1268, ¶55. 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. EX1268, ¶55.

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." EX1268, ¶56; EX1009, [0044].¹⁰ 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. EX1268, ¶56; 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. EX1268, ¶57.

**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.*, ¶58.

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

¹⁰ Emphasis added unless otherwise indicated.

that accommodated the sensor therein, as taught by Stafford. *Id.*, ¶59; *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. EX1268, ¶59. 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. EX1268, ¶59.

Thus, a POSITA would have had a reasonable expectation of success in combining the teachings of Stafford and Raymond. EX1268, ¶60.

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. EX1268, ¶61; *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. EX1268, ¶62; 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. EX1268, ¶62; *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). EX1268, ¶62; *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. EX1268, ¶62.

F. Claim 1

[1.1]¹¹ A glucose monitoring assembly, the assembly comprising:

Stafford discloses a glucose sensor. EX1268, ¶63; *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 by Stafford and insert the glucose sensor as taught by Stafford. EX1268, ¶64; *see supra* Sections VIII.D.1, VIII.E.

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “a glucose monitoring assembly.” EX1268, ¶65; *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.” EX1268, ¶66; *see also* Sections VIII.D, VIII.E.

¹¹ Reference numbers in the format of [claim#.element#] are added throughout for ease of reference.

[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. EX1268, ¶67; EX1009, FIG. 5C, [0028].

Raymond’s insertion device (“inserter”) includes a needle (“sharp”) for inserting a cannula. EX1268, ¶68; 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. EX1268, ¶69; *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.” EX1268, ¶70; *see also* Sections VIII.D, VIII.E.

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

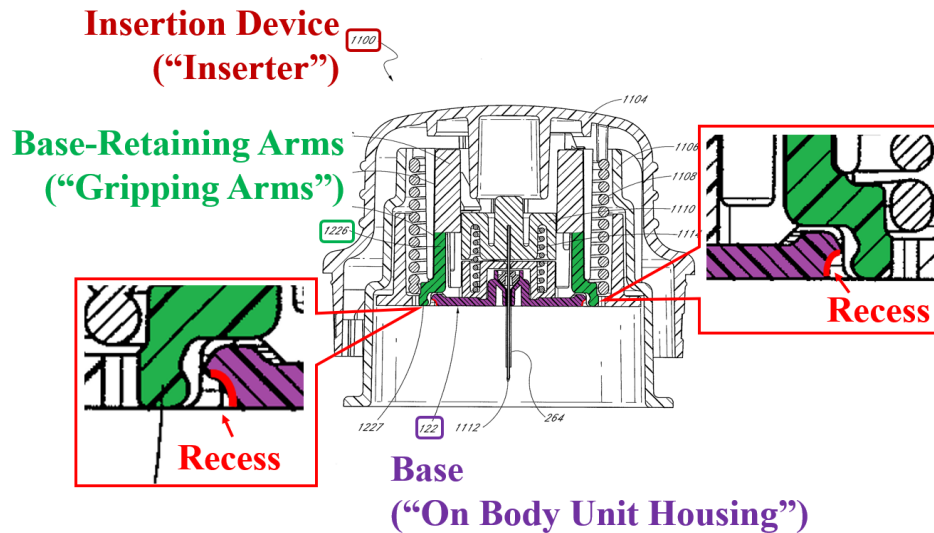
As discussed at [1.5], Stafford+Raymond (and Stafford+Raymond+Turner) includes an “on body electronics unit.” EX1268, ¶71; *see also* Sections VIII.D, VIII.E.

[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. EX1268, ¶72; EX1009, [0019].

Stafford teaches that its on body electronics unit includes electronics (“on body electronics”) located within a housing. EX1268, ¶73; EX1009, FIG. 7, [0040], [0052].

As shown below, Raymond teaches an insertion device with “base-retaining arms” that “engage” the on-body unit. EX1268, ¶74; 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. EX1268, ¶74; 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). EX1268, ¶74; 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. EX1268, ¶75; *see, e.g.*, EX1010, FIGS. 29-30; *see, e.g.*, *In re Aslanian*, 590 F.2d 911, 914 (C.C.P.A. 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. EX1268, ¶76; *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 “receive[s] 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. EX1268, ¶76; 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. EX1268, ¶77; *see also* EX1010, FIGS. 18, 25-27 (illustrating two arms); *see, e.g., id.*, FIGS. 29-30

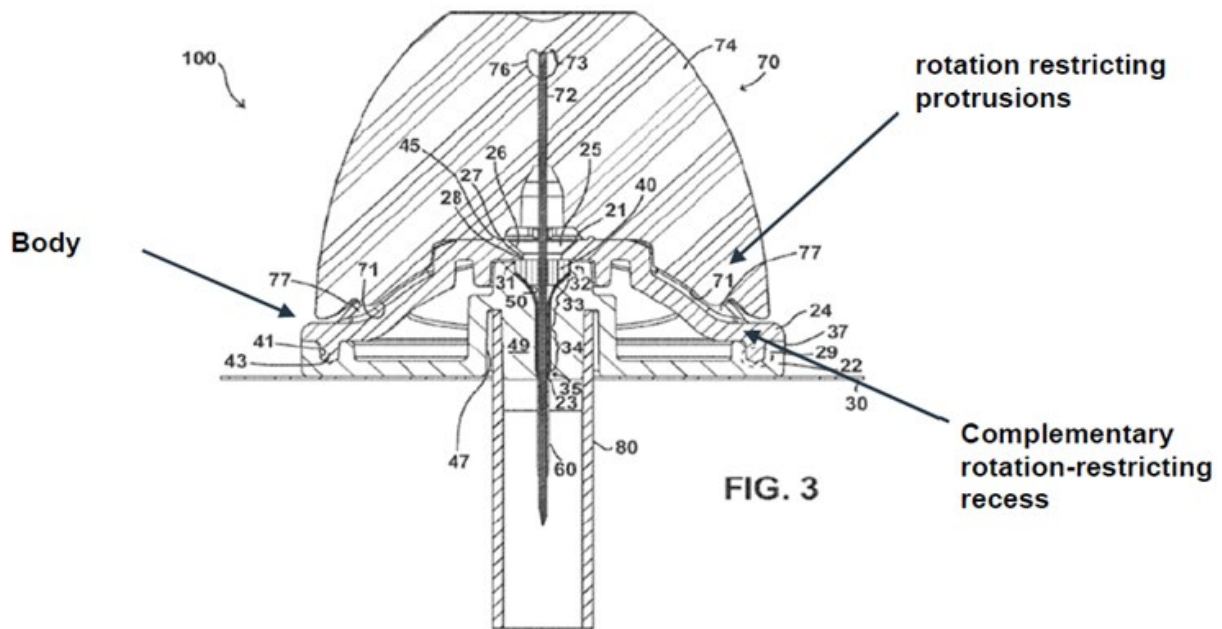
(illustrating two recesses for engaging the two arms). A POSITA would have recognized that there were only two possibilities for a system having arms with protrusions that engage some type of recess: either the two arms engage different points of a single annular recess *or* each arm engages its own independent recess. EX1268, ¶77. 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 Techs., 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. EX1268, ¶78.

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.*, ¶79. 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. EX1268, ¶79.

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. EX1268, ¶80; *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. EX1268, ¶83; *see also id.*, ¶¶80-82 (discussing other exemplary adjustments); *see, e.g., Ethicon LLC v. Intuitive Surgical, Inc.*, No. 2021-1995, 2021-1997, 2022 WL 1613188, at *4 (Fed. Cir. May 23, 2022) (unpublished) (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. EX1268, ¶84; *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.” EX1268, ¶85; *see also* Section VIII.D.

GROUND 2

Alternatively, claims 5-7 (which depend from indirectly claim 1) are obvious over Stafford and Raymond, further in view of Turner (EX1011). EX1268, ¶86.

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 (“inserter”). EX1268, ¶87; 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. EX1268, ¶88; *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.” EX1268, ¶89; *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.” EX1268, ¶90; *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. EX1268, ¶91; EX1009, FIG. 7, [0040], [0052]. Stafford's electronics are coupled with Stafford's sensor. EX1268, ¶91, 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. EX1268, ¶¶92-94 (discussing EX1012, EX1014, EXS1059-64).

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. EX1268, ¶95. The electronics as taught by Stafford are coupled with the sensor as taught by Stafford. *Id.*; see also Sections VIII.D, VIII.E, *supra*.

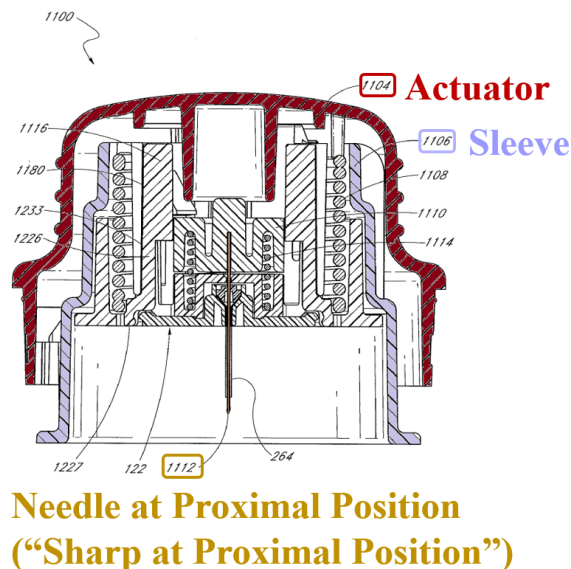
Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes "on body electronics coupled with the glucose sensor, wherein the on body electronics

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.” EX1268, ¶96; *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. EX1268, ¶97; 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. EX1268, ¶98; EX1010, FIG. 29, [0127].



Raymond, FIG. 29 (annotated)

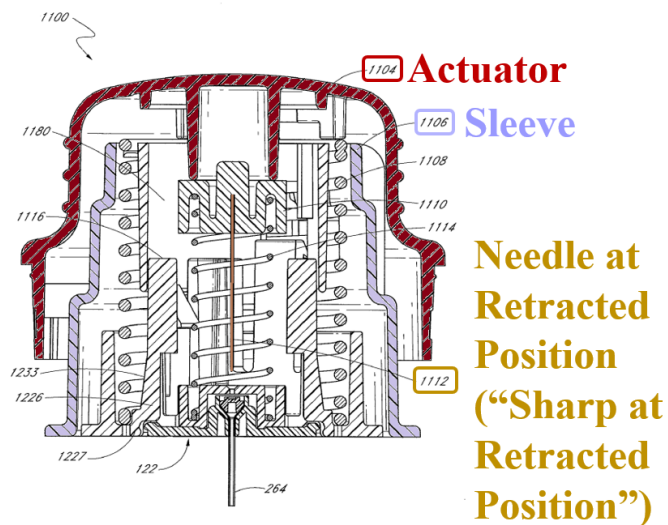
As discussed at [1.3], Stafford+Raymond (and Stafford+Raymond+Turner) uses the inserter as taught by Raymond in combination with the sharp like that disclosed in Stafford to advance the on body electronics unit as taught by Stafford and insert the sensor as taught by Stafford. EX1268, ¶99. Since both 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.*; 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. EX1268, ¶99.

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.” EX1268, ¶100; *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. EX1268, ¶101; 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. EX1268, ¶102; EX1010, FIG. 30, [0127].



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. EX1268, ¶103. Based on Stafford's and Raymond's teachings, the sharp is retracted entirely within the

inserters to cover the sharp. *Id.*; *see* EX1009, [0003], [0022]; EX1010, [0127]; *see also id.*, [0104], [0109].

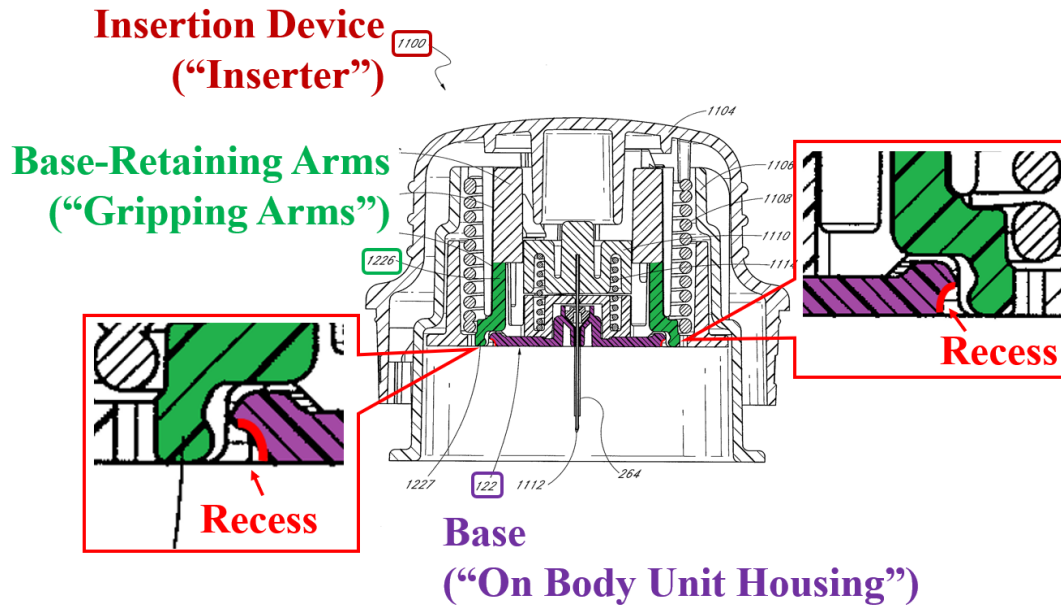
Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the inserter ... configured to retract the sharp from the distal position to a retracted position entirely within the inserter.” EX1268, ¶104; *see also* Sections VIII.D, VIII.E.

Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 1’s limitations, claim 1 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner). EX1268, ¶105.

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], Raymond discloses two gripping arms. EX1010, FIG. 29, [0123] (“In some embodiments, the shuttle 1116 can comprise one or more base-retaining arms 1226, such as those illustrated in FIGS. 25-28, to engage the infusion device 102.”); *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).



Raymond, FIG. 29 (annotated)

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the inserter ... [comprising] a plurality of gripping arms.” EX1268, ¶106; *supra* Section VIII.F.

Thus, since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 2’s limitations, claim 2 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner). EX1268, ¶107.

H. Claim 5¹²

5. The glucose monitoring assembly of claim 2, wherein the inserter further comprises a plurality of interior surfaces, wherein each interior surface of the plurality of interior surfaces is configured to hold a corresponding gripping arm of the plurality of gripping arms against 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.

Raymond describes a sleeve 1106 that has a plurality of interior surfaces, which various surfaces Raymond describes as providing a variety of functions, including, without limitation:

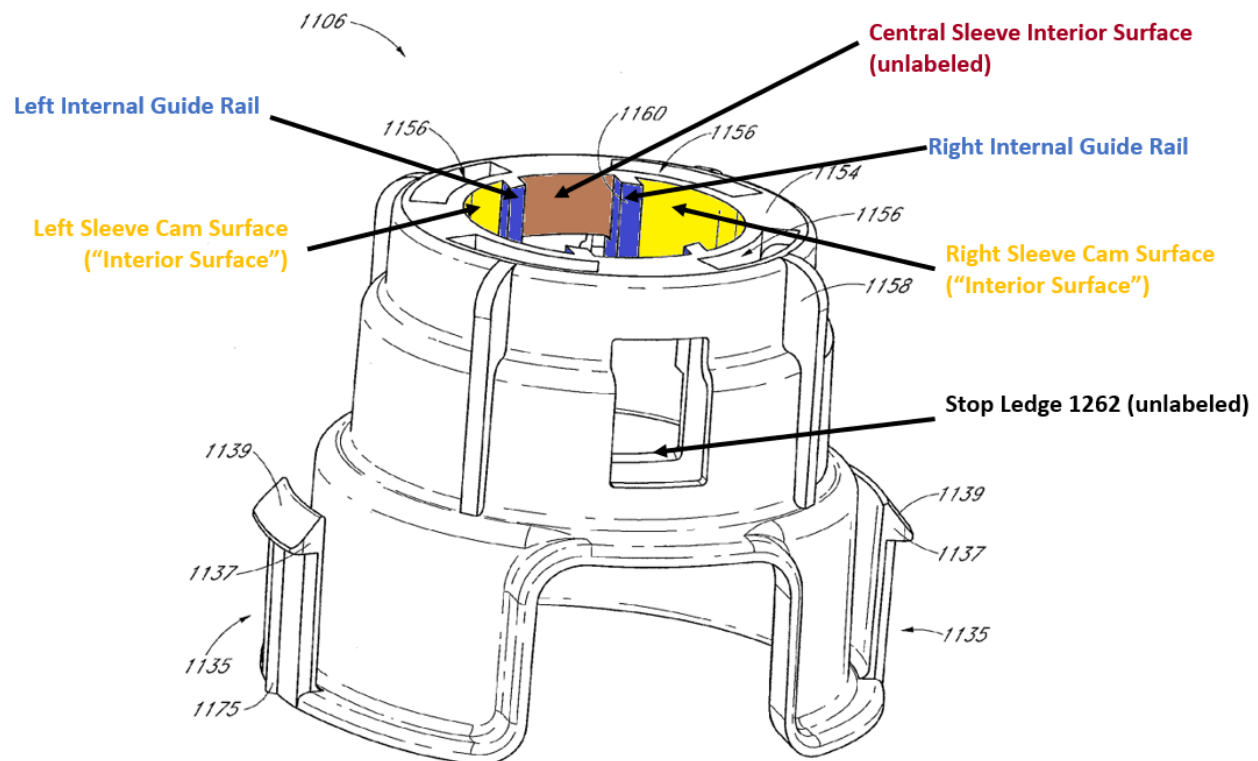
- serving as internal guide rails 1160 to orient the sleeve relative to the shuttle (EX1010, [0125]); and
- supporting and/or interacting with various other components, *e.g.*:
 - interacting with sleeve-engaging feet 1198 of the shuttle 1116 to allow the shuttle (guided by the internal guide rails, as described above) to advance within the sleeve 1106 until the shuttle hits a stop ledge 1262 on the sleeve (*id.*);

¹² While the discussion of Claims 1 and 2 above is repeated from Petition 1 without substantive modification, the further discussion below is added to address the newly asserted claims 5-7 challenged in this petition.

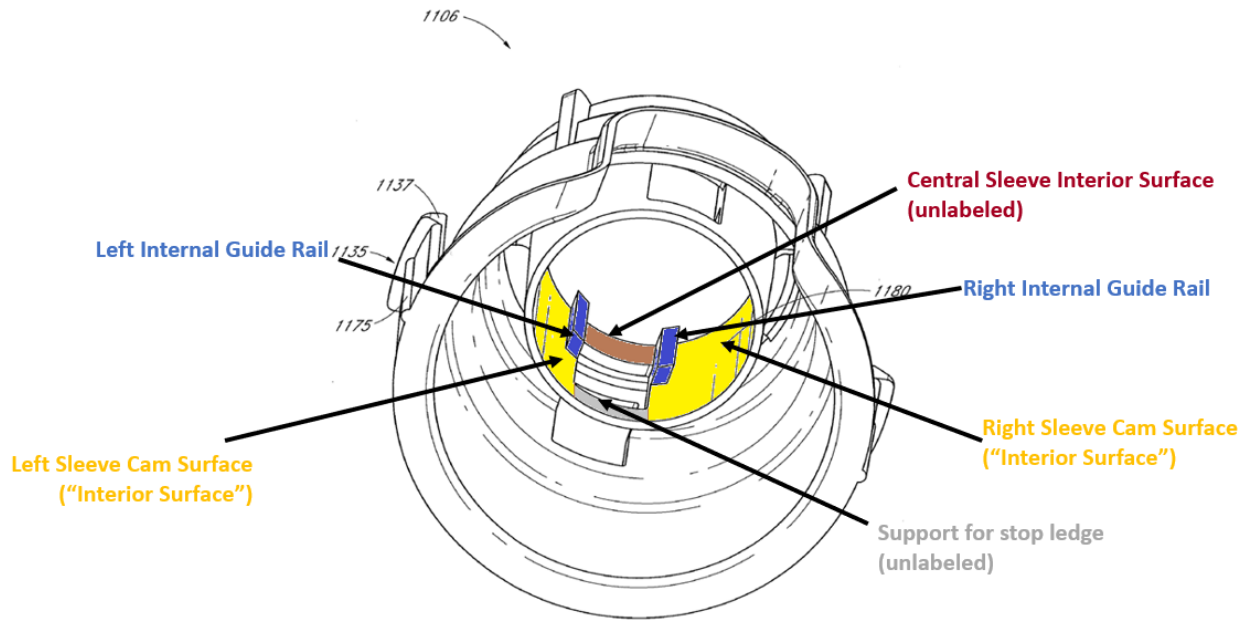
- supporting the stop ledge described above (as shown in annotated FIG. 23, below);
- constraining needle-hub-engaging arms 1210 (*id.*, [0127]); and
- finally, and directly relevant to the claimed interior surfaces:
 - *constraining sleeve engagement surfaces 1233 of base retaining arms 1226 to ensure the base is retained until it reaches the distal position. Id.*, [0126].

EX1268, ¶108.

As shown in FIGS. 22 and 23, annotated below, these various surfaces are formed around the interior of Raymond's sleeve:



Raymond, FIG. 22 (annotated)



Raymond, FIG. 23 (annotated)

EX1268, ¶109.

Internal guide rails

Among these surfaces, Raymond describes providing four internal guide rails (shown in blue in annotated FIGS. 22 and 23, above). As can be seen in these figures, each such internal guide rail has its own plurality of interior surfaces, including an inwardly-facing interior surface that is flanked by circumferentially-facing interior surfaces of the sleeve. Raymond describes these internal guide rails as cooperating with slots in the shuttle to preserve the orientation between the shuttle and the sleeve as the shuttle advances. EX1010, [0125] (“The orientation of the shuttle 1116 within the sleeve 1106 can be preserved as the shuttle 1116 advances by cooperation of internal guide rails 1160 in cooperation with slots 1218 of the shuttle 1116.”)

EX1268, ¶110. A POSITA would further understand that these interior surfaces are separately discernible from the interior surfaces engaging the base-retaining arms—which are further described below—as they do not engage the base-retaining arms. *Id.*, ¶111.

Central sleeve interior surface

As shown in FIGS. 22 and 23, annotated above, and as further described in Raymond, between these internal guide rails is another interior surface (shown in brown, above, unlabeled in Raymond, and referred to herein as a “central sleeve interior surface.” EX1268, ¶112. In view of Raymond’s disclosure, a POSITA would understand that this additional unlabeled interior surface of sleeve 1106, central sleeve interior surface interacts with sleeve-engaging feet 1198 of the shuttle 1116 to allow the shuttle (guided by the internal guide rails, as described above) to advance within the sleeve until the shuttle hits a stop ledge 1262 on the sleeve:

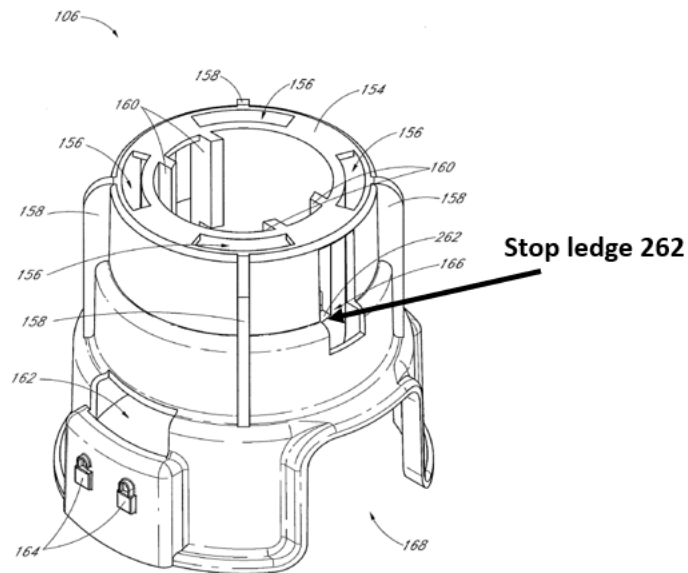
The actuator 1104 can be advanced toward the skin, with the external guide rails 1158 of the sleeve 1106 guiding the actuator 1104 as it is advanced. The actuator 1104 can compress the insertion spring 1108 until *an engagement surface 1146 of the displacement member 1144 of the actuator 1104 presses against cam surfaces 1200 of the sleeve-engaging feet 1198 of the shuttle 1116 to force the sleeve-engaging feet 1198 off of an upper surface 1154 of*

the sleeve 1106 to allow the shuttle 1116 to advance within the sleeve 1106. The orientation of the shuttle 1116 within the sleeve 1106 can be preserved as the shuttle 1116 advances by cooperation of internal guide rails 1160 in cooperation with slots 1218 of the shuttle 1116. Advancement of the shuttle 1116 within sleeve 1106 can be limited by the engagement of the sleeve-engaging feet 1198 against one or more stop ledges 1262 of the sleeve 1106 (see FIG. 30).

EX1010, [0125]; EX1268, ¶113. A POSITA would further understand that this interior surface is separately discernible from the surfaces engaging the base-retaining arms—which are further described below—as it does not engage the base-retaining arms. *Id.*, ¶114.

Stop ledge and its supporting surface

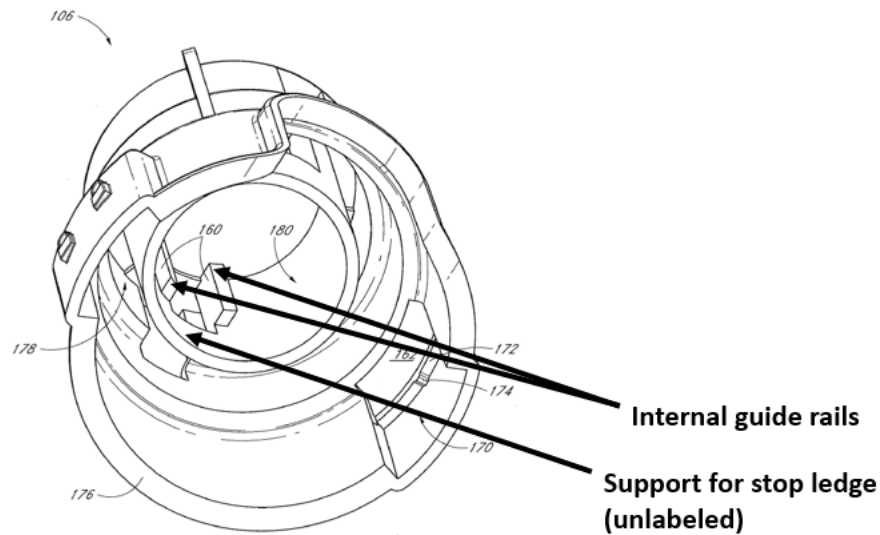
While stop ledge 1262 is not expressly labeled in the insertion device 1100 embodiment's supporting FIGS. 18-30, a corresponding piece is shown in insertion device 100. Raymond describes that the 1100 embodiment is “similar in many respects to the insertion device 100. Therefore, similar components of the insertion device 1100 are referenced by the same reference numeral as the corresponding component in the insertion device 100 incremented by one thousand.” EX1010, [0109]; EX1268, ¶115.



Raymond, FIG. 6 (annotated)

The corresponding stop ledge 262 in insertion device 100 is shown, *e.g.*, in FIGS. 6 (shown above) and 17, and described in Raymond: “Advancement of the shuttle 116 within sleeve 106 can be limited by the engagement of the sleeve-engaging feet 198 against the stop ledge 262 of the sleeve 106 (see FIG. 17).” EX1010, [0103]; EX1268, ¶116.

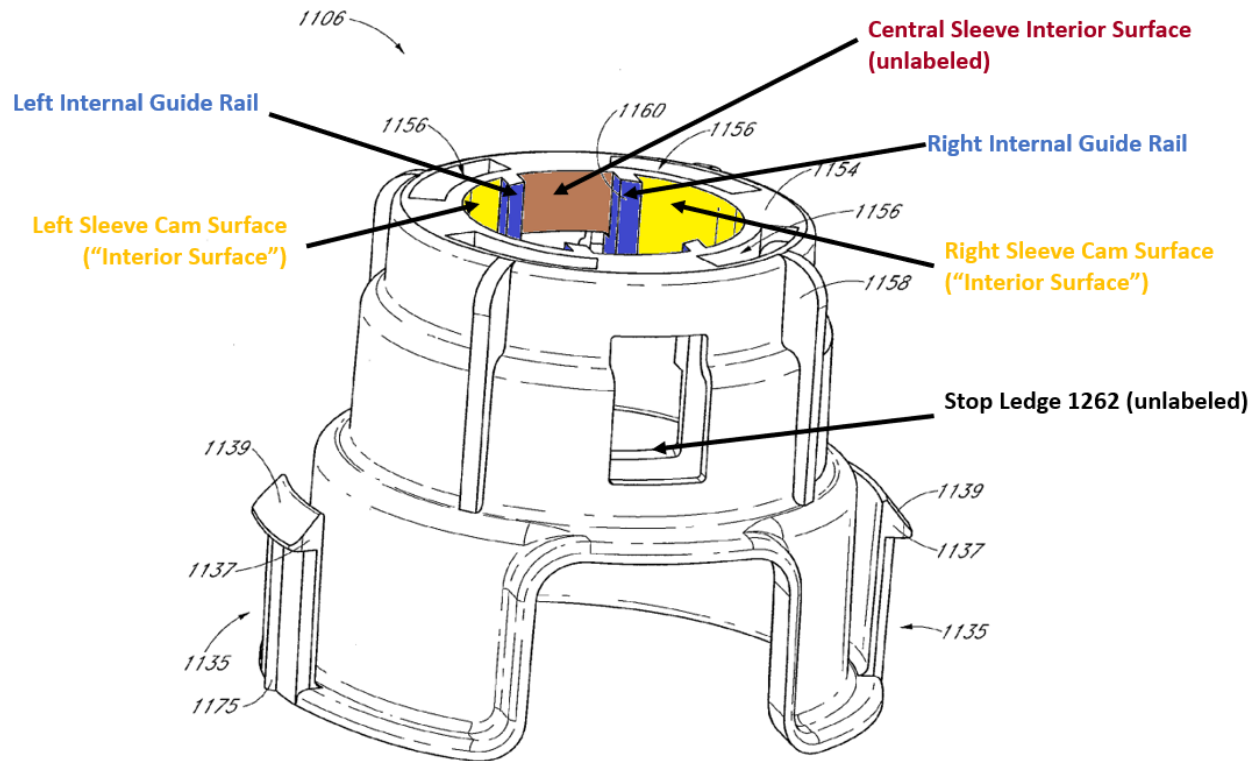
As further illustrated in FIG. 7, below, Raymond’s stop ledge is supported by the (unlabeled) interior sleeve surface and positioned below the recess that spans between internal guide rails 160 (which a POSITA would understand in view of Raymonds’s disclosure are similar to guide rails 1160):



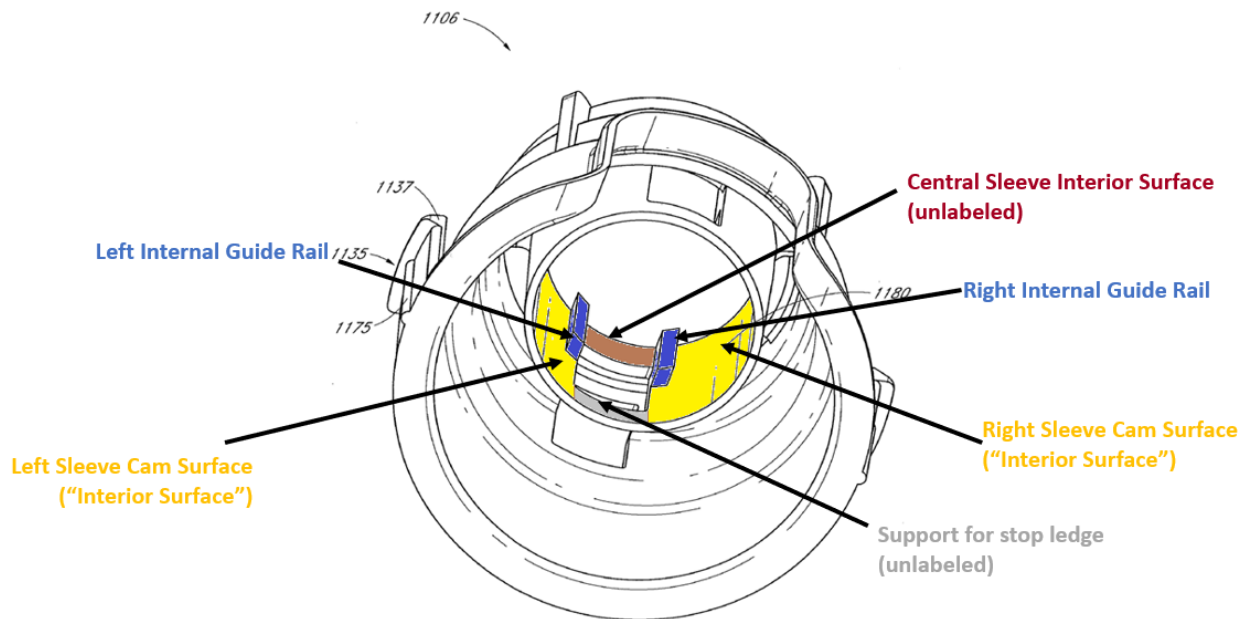
Raymond, FIG. 7 (annotated)

EX1268, ¶117.

In view of Raymond's disclosure of the similarity between these embodiments, and similarly numbered parts therein, A POSITA would understand that stop ledge 1262 and its supporting surface on the sleeve would be similarly positioned in embodiment 1100, as illustrated in the annotated FIGS. 22 and 23, respectively, which are shown again below for ease of comparison:



Raymond, FIG. 22 (annotated)



Raymond, FIG. 23 (annotated)

EX1268, ¶118. A POSITA would further understand that this stop ledge supporting surface on the interior of the sleeve is separately discernible from the surfaces engaging the base-retaining arms—which are further described below—as it does not engage the base-retaining arms. *Id.*, ¶119.

Needle-hub engaging arms' supporting interior surfaces

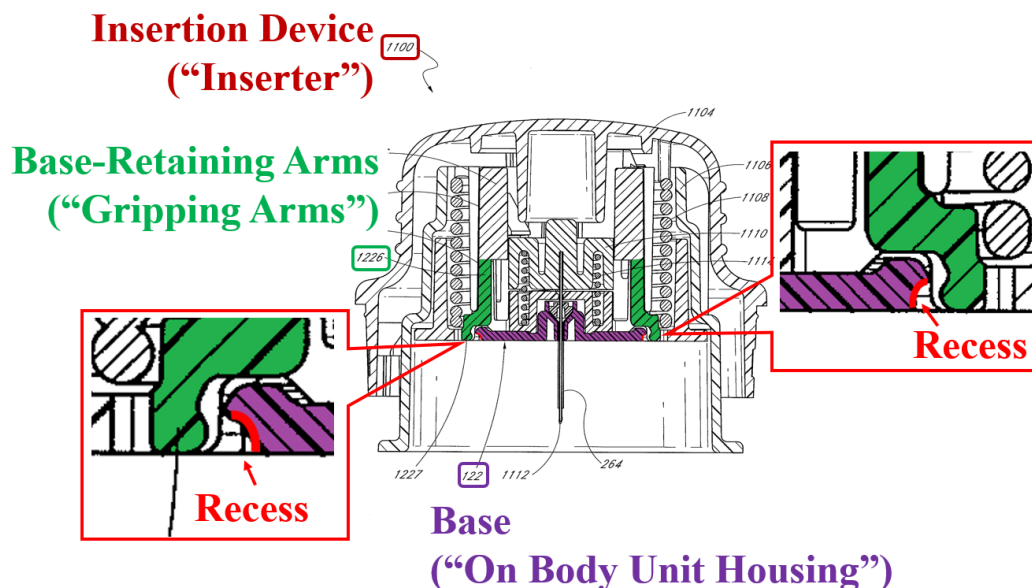
Raymond generally refers to additional interior surfaces that engage with needle-hub-engaging arms on the shuttle until it is time for the needle hub to separate from the shuttle. EX1010, [0127] (“As the shuttle 1116 approaches or arrives at the end of its range of travel within the sleeve 1106, the needle-hub-engaging arms 1210 can clear the cam surface 1180 of the sleeve 1106 to allow the needle-hub-engaging arms 1210 to move away from the needle hub 1110.”). A POSITA would understand that these interior surfaces, too, are separately discernible from the interior surfaces engaging the base-retaining arms—which are further described below—as they also do not engage the base-retaining arms. EX1268, ¶120.

Left and right interior surfaces of sleeve engage base-retaining arms

As discussed at Sections VIII.D-E, Stafford+Raymond (and Stafford+Raymond+Turner) uses the inserter as taught by Raymond to advance the on body electronics unit as taught by Stafford. *See supra* Sections VIII.D-E. Specifically, as discussed at [1.5], Stafford+Raymond (and

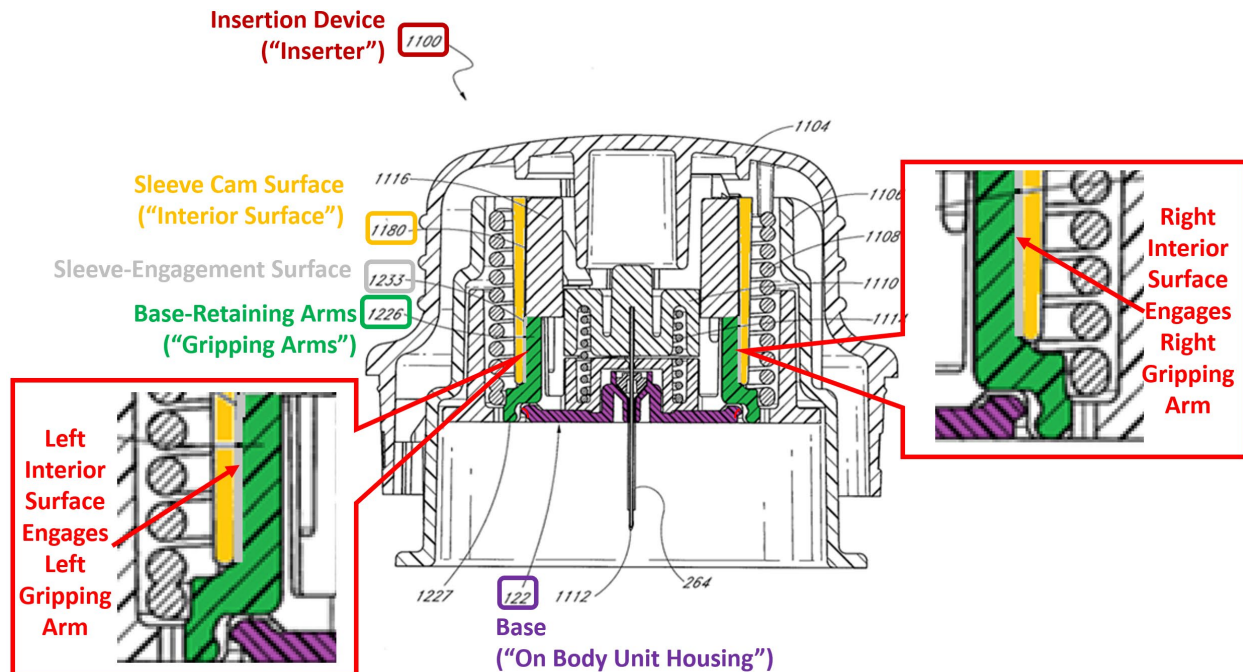
Stafford+Raymond+Turner) includes “the inserter ... [comprising] a plurality of gripping arms.” *See supra* Section VIII.F., EX1268, ¶121.

Raymond describes that each of these gripping arms (referred to in Raymond as “base-retaining arms”) engages a corresponding recess of Raymond’s base (“on body unit housing”), or at least renders these recesses obvious. EX1010, FIG. 29, [0123] (“In some embodiments, the shuttle 1116 can comprise one or more base-retaining arms 1226, such as those illustrated in FIGS. 25-28, to engage the infusion device 102.”); *supra* Section VIII.F. As shown below, Raymond illustrates how, with the on body unit housing in its proximal position, a left base-retaining arm (“left gripping arm,” green) engages a left recess (red) and a right base-retaining arm (“right gripping arm,” green) engages a right recess (red). EX1268, ¶122.



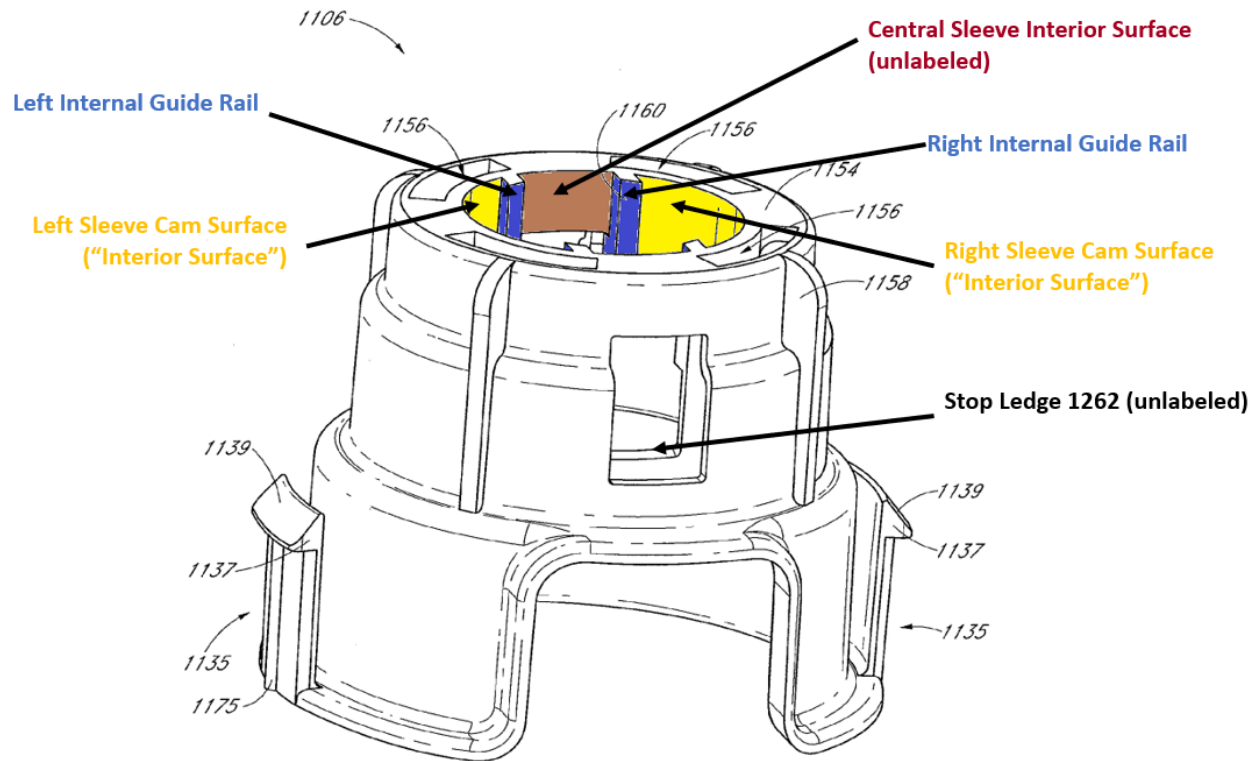
Raymond, FIG. 29 (annotated)

As can be seen in the further annotated drawing below, and as further described in Raymond, each of these gripping arms of the plurality of gripping arms is held against a corresponding recess of the on body unit housing by a corresponding one of a plurality of interior surfaces on the sleeve (*i.e.*, the “left and right interior surfaces” described above and highlighted in yellow in FIG. 29 below) that engages a corresponding sleeve engagement surface on each of the gripping arms (highlighted below in grey) to prevent unintentional disengagement of the on body unit housing when the on body unit housing is in the proximal position. EX1010, FIG. 29, [0123] (“The base-retaining arms 1226 can include sleeve-engagement surfaces 1233 positioned for engagement by the cam surface 1180 of the sleeve 1106 to urge the base-retaining feet 1227 toward the base 122 to impede unintentional disengagement of the infusion device 102 from the shuttle 1116.”). EX1268, ¶123.



Raymond, FIG. 29 (annotated)

In view of FIGS. 29-30 showing separate left and right interior surfaces (“a plurality of interior surfaces”) each engaging a corresponding surface of the left and right gripping arms, and the fact that the interior of the sleeve has multiple such surfaces, as shown, *e.g.*, in annotated FIGS. 22-23, above, a POSITA would have found Raymond as reasonably disclosing, or at least suggesting providing a plurality of interior surfaces each engaging and holding the gripping arms against their corresponding recesses. EX1268, ¶124. *See In re Aslanian*, 590 F.2d 911, 914 (CCPA 1979) (“drawings are ‘evaluat[ed] and appl[ied] ... on the basis of what they reasonably disclose and suggest’” 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).



Raymond, FIG. 22 (annotated)

Furthermore, as also illustrated in FIG. 22 above, and as further described in Raymond, these left and right interior surfaces of the sleeve are positioned opposite one another on the left and right sides (as shown in the figure) of Raymond's first set of two internal guide rails on the sleeve, and are positioned between these first two internal guide rails and the second set of two internal guide rails positioned on the opposite side of the sleeve (which are closest to the viewer in the figure). Raymond describes that at these left and right interior surfaces corresponding to the left and right gripping arms, the sleeve-engagement surfaces 1233 of the shuttle 1116 engage with the left and right interior surfaces until the shuttle advances

sufficiently in the distal direction to allow Raymond's on body electronics unit housing to be released. EX1268, ¶125.

After the sleeve-engagement surface of each of Raymond's gripping arms clears its respective interior surface, the gripping arms are allowed to spread outward to release Raymond's on body unit housing:

As the shuttle 1116 advances through the sleeve 1106, the sleeve-engagement surfaces 1233 of the shuttle 1116 can advance downwardly relative to the cam surface 1180 of the sleeve 1106. The base-retaining arms 1226 can spread outwardly when the sleeve-engagement surfaces 1233 of the shuttle 1116 clear the cam surface 1180 of the sleeve 1106.

EX1010, [0126], EX1268, ¶126.

In view of the foregoing, and considering the totality of Raymond's disclosure, when Raymond refers to a cam surface 1180 within the sleeve in the various contexts described above, a POSITA would understand that Raymond is referring to a plurality of *different* internal surfaces of the sleeve serving a plurality of *different* functions. EX1268, ¶127.

Relevant to the claims here, a POSITA would understand the interior surface that engages the sleeve-engagement surface of the left gripping arm to be a different surface than the interior surface of the sleeve that engages the sleeve-engagement

surface of the right gripping arm. Thus, Raymond describes a plurality of interior surfaces on the sleeve, two of which engage left and right sleeve engagement surfaces of the left and right gripping arms. EX1268, ¶128.

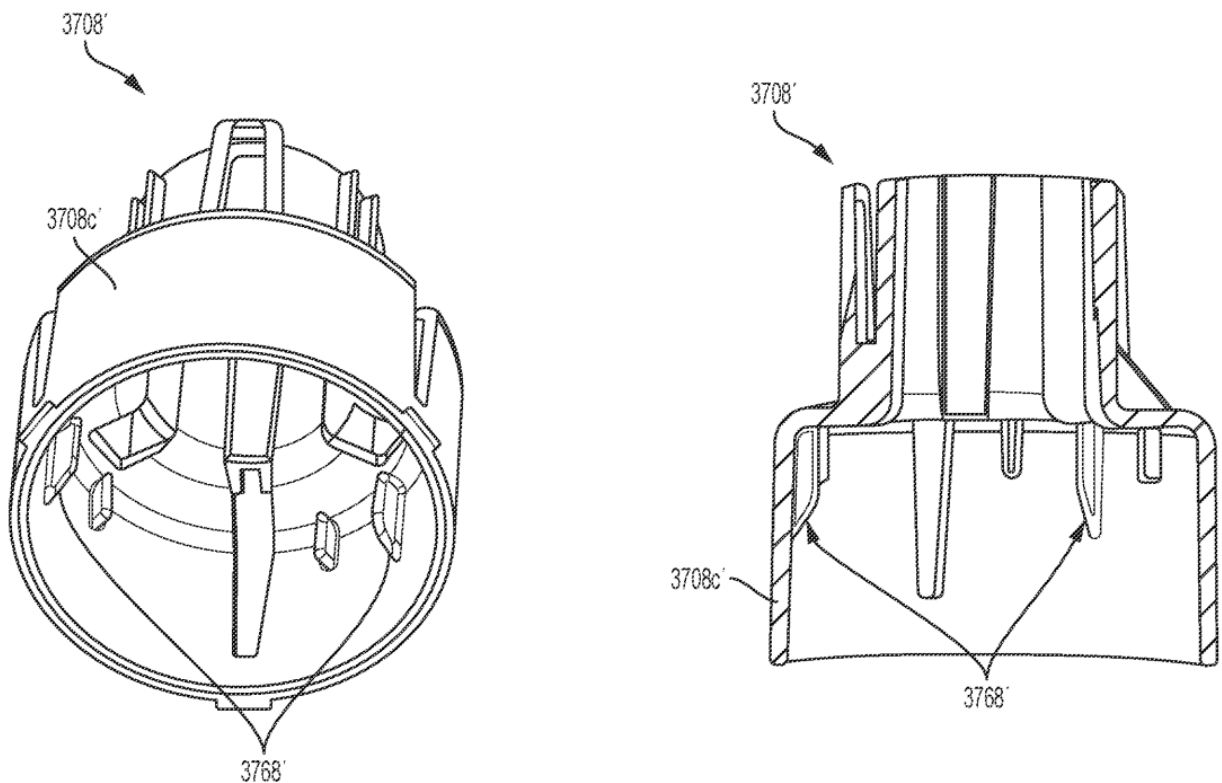
Thus, Stafford+Raymond includes an inserter that includes a plurality of interior surfaces as taught by Raymond, in which two of the plurality of interior surfaces engage left and right sleeve engagement surfaces of the left and right gripping arms when the on body electronics unit as taught by Stafford is in the proximal position. EX1268, ¶129.

Stafford+Raymond (and Stafford+Raymond+Turner) includes “a plurality of interior surfaces, wherein each interior surface of the plurality of interior surfaces is configured to hold a corresponding gripping arm of the plurality of gripping arms against 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.” *See also supra* Section VIII.F., EX1268, ¶130. Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 5’s limitations, claim 5 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner). EX1268, ¶131.

To the extent that Patent Owner argues that Raymond does not *expressly* recite a *plurality* of interior surfaces, each engaging a corresponding gripping arm, and/or does not otherwise teach or suggest this claim limitation, nothing in the claims

requires that “interior surfaces” be surfaces on physically separate or distinct parts.
EX1268, ¶132.

Indeed, the '335 patent itself appears to show ramp member surfaces 3768' that hold “gripping arms” as regions on the sheath 3708', which a POSITA would understand to be a single molded part. *See* '335 patent, FIGS. 137-138 (below).



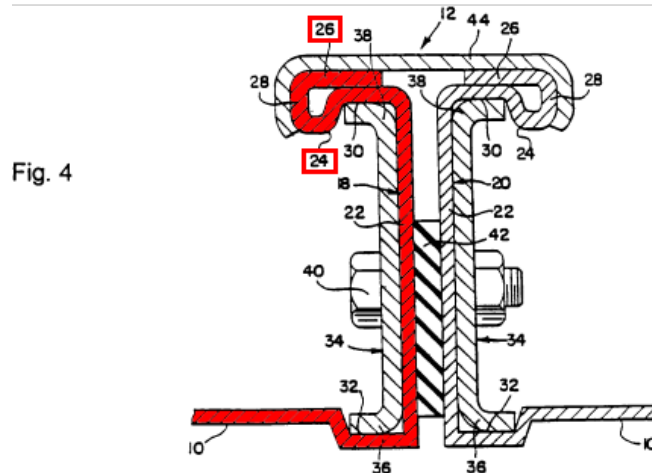
'335 patent, FIGS. 137, 138 (showing ramp member 3768')

EX1268, ¶133.

And, inserter 3700'—of which sheath 3708' and ramp arms 3768' are a part—is “substantially identical to the inserter 3700 discussed hereinabove with the differences noted herein.” '335 patent, 45:57-59. The '335 patent expressly

describes its sheath 3708 in inserter 3700 as “generally formed as a unitary tubular member” that is “formed as a single-piece and generally cylindrical member.” EX1001, 42:38-39, 47; *see generally id.*, 42:38 – 43:28. Nowhere does the ’335 patent describe (let alone require) that these ramp member surfaces 3708’ be formed as separate parts from the sheath or from each other. For at least these reasons, a POSITA would understand that the claimed “interior surfaces” can be discernible separate surfaces of the same molded part. EX1268, ¶133.

Indeed, precedent is consistent that even separate claim limitations can be mapped to a single physical part. *See Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1333 n.3 (Fed. Cir. 2006) (“the use of two terms in a claim requires that they connote different *meanings*, not that they necessarily refer to two different *structures*”) (emphases in original). In *Engel Indus., Inc. v. Lockformer Co.*, 96 F.3d 1398 (Fed. Cir. 1996), the patent owner “assert[ed] that the second portion 24 (*see* [U.S. Patent No. 4,466,641] Fig. 4) includes the return portion 26.” *Id.* at 1404–05. The Federal Circuit disagreed and held that they logically cannot be one and the same.” *Id.* But this merely required identifying a “second portion 24” and a distinct “return portion 26,” not that they be found in physically separate parts:

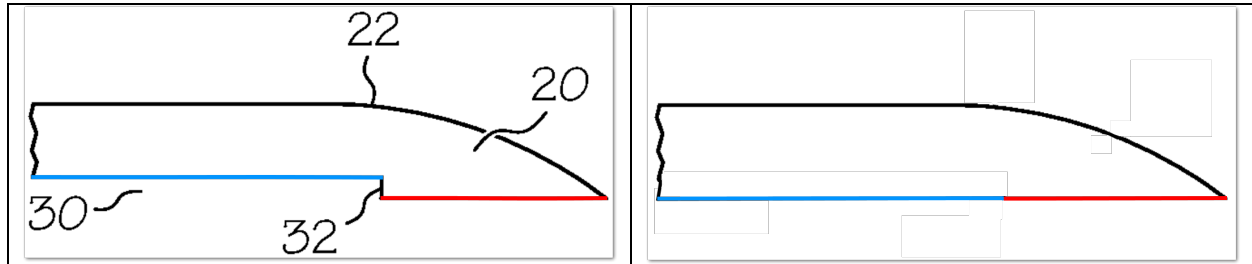


U.S. Patent No. 4,466,641, FIG. 4 (annotated) (cited in *Engel Indus.*)

Elements 24 and 26 (in red boxes above) that the Federal Circuit held “logically cannot be one and the same” and must be “separate and distinct” could still be separate regions of a single piece of metal.

Similarly, in *Lowe v. ShieldMark, Inc.*, No. 2021-2164, 2022 WL 636100 (Fed. Cir. Mar. 4, 2022) (unpublished), a patent claim required in separate elements (1) “a body that has ... a lower surface” and (2) “each of [] first and second lateral edge portions having ... a lower surface.” *Id.* at *2. (emphasis omitted.) Nowhere did the patent at issue describe an example having a single, contiguous, flat lower surface without a “structure” to retain adhesive. However, as the claim was drafted, nothing precluded each “lower surface” recited in separate claim elements from being different regions of a “single, flat lower surface” as in the accused product. *Id.* at *3 n.1, *7. Annotated in red and blue below are the “surfaces” as depicted in the

patent at issue in *Lowe* on the left and as would be within the scope of the claim as construed by the Federal Circuit on the right:

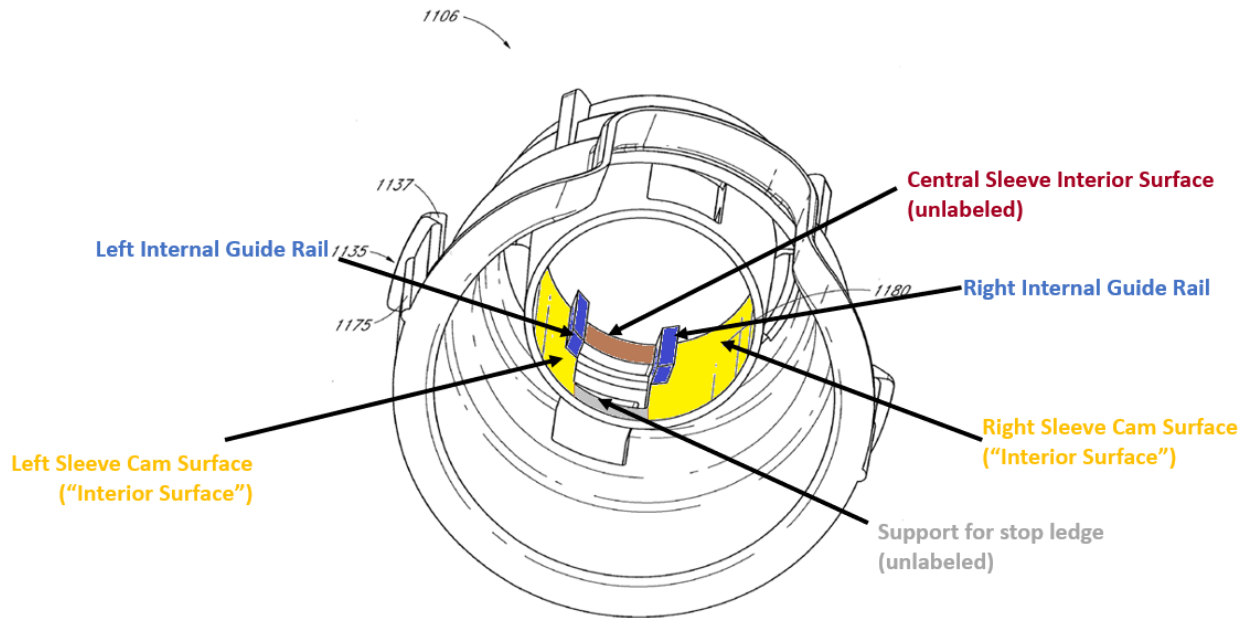


U.S. Patent No. 10,214,664, FIG. 2 (annotated) (cited in *Lowe*)

Additionally, consistent with the expert testimony provided herewith, a longstanding principle of obviousness is that merely separating one part into two, or merging two separate parts into one, having the same function is generally not a patentable distinction. *See In re Larson*, 340 F.2d 965, 968 (C.C.P.A. 1965) (“the use of a one piece construction instead of the structure disclosed in [the prior art where several parts are rigidly secured together as a single unit] would be merely a matter of obvious engineering choice”).

And, Raymond’s disclosure clearly teaches or suggests providing a *plurality* of interior surfaces. EX1268, ¶134. A POSITA would understand the left and right interior surfaces shown in at least annotated FIGS. 22, 23, 29, and 30, above, described in Raymond as a cam surface that engages each of the left and right gripping arms at their respective left and right sleeve engagement surfaces to be a *plurality* of corresponding (likewise, left and right) interior surfaces. EX1268, ¶135.

In fact, as shown in FIG. 23, annotated below, these left and right interior surfaces are discernible from one another, and are separated by an intervening opening and a number of other structural elements further described at pages 50-58, above.



Raymond, FIG. 23 (annotated)

EX1268, ¶136, referencing *id.*, ¶¶108-120.

To the extent that Patent Owner argues that the claims' recitation of a plurality of interior surfaces does not read on discernible separate surfaces of the same molded part, this would be an unduly narrow and improper interpretation, particularly in view of the '335 patent's own disclosure. *See* discussion at pages 64-66, above, citing '335 patent, FIGS. 137-138 (showing ramp member 3768'), 45:57-59, 42:38–43:28; EX1268, ¶133. Had the Patent Owner wished to describe and claim, e.g., “disconnected” surfaces, it could have done so, but did not. EX1268, ¶137.

Additionally, physically disconnecting the left interior surface of the sleeve that engages the sleeve-engagement surface of the left gripping arm from the right interior surface of the sleeve that engages the sleeve-engagement surface of the right gripping arm would have been an obvious variation on Raymond's design, to the extent the present surfaces are not viewed as being sufficiently "disconnected" by virtue of their numerous intervening surfaces and structures. EX1268, ¶138.

A POSITA would understand that providing left and right interior surfaces that are further "*disconnected*" than those already set forth in Raymond could be implemented, *e.g.*, by extending the internal guide rails 1160 that already separate the left and right interior surfaces on the upper portion of the sleeve (shown in FIGS. 22 and 23, above), and/or by providing some other linear feature extending the entire length of the sleeve between left and right sides (*e.g.*, additional internal guide rails), so that the left and right internal surfaces engaging the left and right gripping arms are *entirely* disconnected from one another. EX1268, ¶139.

Such modifications would have been particularly obvious, not only because providing such "disconnected" surfaces is a matter of simple design choice, but also in view of the intervening structures that Raymond *already* discloses as physically separating these left and right interior surfaces on the sleeve. These existing structures between the left and right interior surfaces already extend along most (if

not all) of the height of the sleeve along which these left and right interior surfaces that contact the gripping arms extend. EX1268, ¶140.

Further extending these intervening structures between the left and surfaces on the sleeve to create a *complete* separation between the left and right interior surfaces that engage the left and right gripping arms (to the extent it is determined that such a complete separation is both required and not already taught or suggested by Raymond) would merely require simple and routine implementation details that would have been well within the skill of a POSITA. EX1268, ¶141.

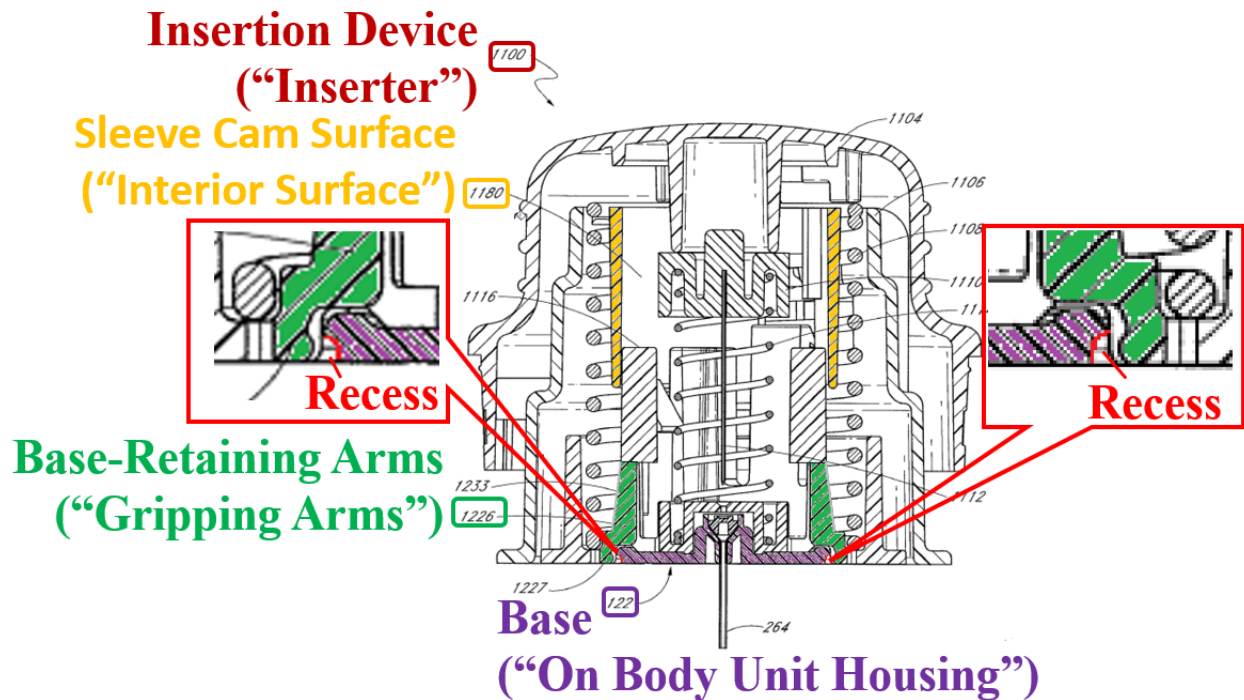
And a POSITA would have been further motivated to modify Raymond's sleeve to create such further internal separation—*e.g.*, by adding internal guide rails on the left and right sides of the engagement surfaces of the sleeve that surround each gripping arm of the shuttle—by Raymond's own disclosure of providing similar internal guide rails on the sleeve's interior on the left and right sides of the sleeve's surfaces that engage with the sleeve-engaging feet of the shuttle, *e.g.*, to further help orient the sleeve and shuttle's relative movement. EX1268, ¶142.

Thus, whether (improperly) narrowly construed by Patent Owner or read consistently with its plain and ordinary meaning, as described above, claim 5 is obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner). EX1268, ¶143.

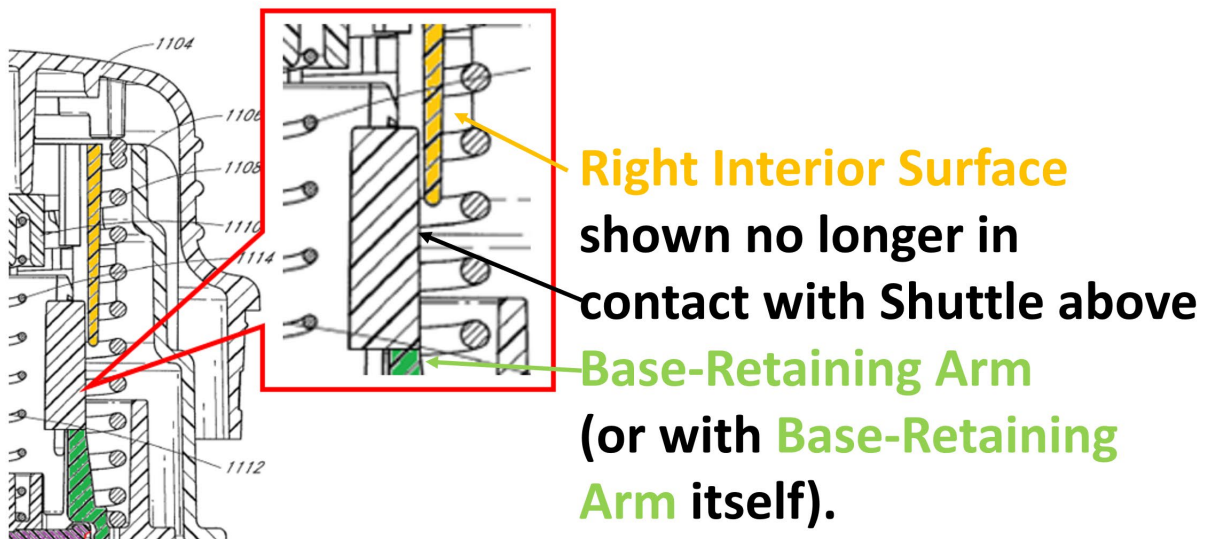
I. Claim 6

6. The glucose monitoring assembly of claim 5, wherein the inserter is further configured such that the each interior surface of the plurality of interior surfaces is not in contact with the corresponding gripping arm of the plurality of gripping arms when the on body electronics unit is in the distal position.

As shown in FIG. 30 below (and as further highlighted in the portion of FIG. 30 further annotated below), and as further described in Raymond, each of Raymond's base-retaining arms ("gripping arms," green) clears its respective interior surface (yellow) such that the sleeve engagement surface of these gripping arms no longer engages the interior surface, and the gripping arms spread radially outwardly to be disengaged with the recesses on Raymond's base's ("on body unit housing," purple) by the time the on body unit housing reaches the distal position. EX1010, FIGS. 29-30, [0126] ("The base-retaining arms 1226 can spread outwardly when the sleeve-engagement surfaces 1233 of the shuttle 1116 clear the cam surface 1180 of the sleeve 1106. The base-retaining feet 1227 can move away from the base 122 as the base-retaining arms 1126 spread outwardly such that the base 122 can be released from the shuttle 1116."). EX1268, ¶144.



Raymond, FIG. 30 (annotated)



Raymond, FIG. 30 (selected portion, annotated)

As discussed at Sections VIII.D-E, Stafford+Raymond (and Stafford+Raymond+Turner) uses the inserter as taught by Raymond to advance the on body electronics unit as taught by Stafford. *See supra* Sections VIII.D-E. Since

Raymond discloses that each gripping arm clears its respective interior surface by the time the on body unit housing reaches the distal position, a POSITA would have incorporated Raymond's teachings into Stafford+Raymond (and Stafford+Raymond+Turner) such that each one of the plurality of interior surfaces as taught by Raymond is not in contact with the corresponding one of the plurality of gripping arms as taught by Raymond when the on body electronics unit as taught by Stafford is in the distal position. EX1268, ¶145.

Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes "the inserter ... further configured such that the each interior surface of the plurality of interior surfaces is not in contact with the corresponding gripping arm of the plurality of gripping arms when the on body electronics unit is in the distal position." *Id.*, ¶146.

Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 6's limitations, claim 6 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner). *Id.*, ¶147.

J. Claim 7

7. The glucose monitoring assembly of claim 6, wherein the corresponding gripping arm of the plurality of gripping arms is configured to deflect in a radially outward direction when the each interior surface of the plurality of interior surfaces is not in contact with the corresponding gripping arm of the plurality of gripping arms.

As discussed in section VIII.I, Raymond discloses that each base-retaining arm (“gripping arm”) spreads radially outwards when unconstrained by the sleeve (*i.e.*, when each gripping arm’s sleeve engagement surface is no longer in contact with the corresponding interior surface of the sleeve) so that the base can be released from the shuttle. EX1010, FIGS. 29-30, [0126] (“The base-retaining arms 1226 can spread outwardly when the sleeve-engagement surfaces 1233 of the shuttle 1116 clear the cam surface 1180 of the sleeve 1106. The base-retaining feet 1227 can move away from the base 122 as the base-retaining arms 1126 spread outwardly such that the base 122 can be released from the shuttle 1116.”); *supra* Section VIII.H; EX1268, ¶148.

Stafford+Raymond (and Stafford+Raymond+Turner) includes the inserter and gripping arms as taught by Raymond. EX1268, ¶148. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “wherein the corresponding gripping arm of the plurality of gripping arms is configured to deflect in a radially outward direction when the each interior surface of the plurality of interior surfaces is not in

contact with the corresponding gripping arm of the plurality of gripping arms.” *Id.*, ¶149.

Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 7’s limitations, claim 7 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner). *Id.*, ¶150.

IX. NO OBJECTIVE INDICIA OF NON-OBVIOUSNESS

Petitioner is unaware of any objective indicia of non-obviousness as to any challenged claim.

X. CONCLUSION

Petitioner requests institution for claims 5-7, on the grounds specified in this petition.

Respectfully submitted,

January 31, 2024

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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 12,974 words, excluding the parts of the brief exempted by
37 C.F.R. § 42.24(a).

The brief has been prepared in a proportionally spaced typeface using
Microsoft Word 2013 in a 14-point Times New Roman font.

January 31, 2024

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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 1001-1002, 1004-1012, 1014-1015, 1017-1018, 1030, 1037, 1039-1044, 1056-1057, 1059-1066 and 1267-1268** were served on January 31, 2024, via **Express Mail** on the Patent Owner at the following address of record as listed on the USPTO Patent Center:

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A courtesy copy of the Petition only was also emailed to Patent Owner's counsel of record in IPR2023-01396 and IPR2023-01397, at the following email addresses:

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