

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

IPR2023-01397
U.S. Patent No.: 11,266,335
Issued: March 8, 2022
Application No.: 17/019,110
Filed: September 11, 2020

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

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

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LIST OF EXHIBITS

No.	Description
1101	U.S. Patent No. 11,266,335 (“ 335 Patent ”)
1102	File History of U.S. Patent No. 11,266,335 (“ 335 FH ”)
1103	Declaration of Gary D. Fletcher, Ph.D., dated October 6, (“ Fletcher Decl. ”)
1104	U.S. Provisional Application No. 61/411,262, filed November 8, 2010
1105	U.S. Patent Application No. 13/071,461, filed March 24, 2011
1106	U.S. Provisional Application No. 61/317,243, filed March 24, 2010
1107	U.S. Provisional Application No. 61/345,562, filed May 17, 2010
1108	U.S. Provisional Application No. 61/361,374, filed July 2, 2010
1109	PCT Publication No. WO 2010/091005 (“ Thomas ”)
1110	U.S. Publication No. 2009/0124979 (“ Raymond ”)
1111	U.S. Publication No. 2007/0135774 (“ Turner ”)
1112	U.S. Patent No. 6,175,752 (“ Say ”)
1114	U.S. Publication No. 2007/0073129 (“ Shah ”)
1118	U.S. Publication No. 2004/0002682 (“ Kovelman ”)
1128	U.S. Patent No. 7,381,184 (“ Funderburk ”)
1135	Sybil P. Parker (ed.), <i>McGraw-Hill Dictionary of Mechanical and Design Engineering</i> , 1984 (excerpted)
1139	U.S. Publication No. 2008/0319414 (“ Yodfat ”)
1140	U.S. Patent No. 7,207,974 (“ Safabash ”)
1141	U.S. Publication No. 2004/0204687 (“ Mogensen ”)

No.	Description
1142	U.S. Publication No. 2002/0022855 (“ Bobroff ”)
1143	U.S. Patent No. 9,566,384 (“ Gyrn ”)
1144	U.S. Patent No. 8,747,363 (“ Nielsen ”)
1157	U.S. Publication No. 2005/0131346 (“ Douglas ”)
1165	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
1166	Scheduling Order, <i>Abbott Diabetes Care Inc. v. DexCom Inc.</i> , No. 1-23-cv-00239 (D. Del. filed Mar. 3, 2023)

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

1. Real Party-In-Interest

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

2. Related Matters

The '335 patent (EX1101) has been asserted in the following litigations:

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

A parallel IPR petition is contemporaneously being filed on October 6, 2023, in IPR2023-01396.

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

I. INTRODUCTION

DexCom, Inc. (“Petitioner”) respectfully requests *inter partes* review (“IPR”) of claims 1-4, 8-9, and 11-27 (“challenged claims”) of U.S. Patent No. 11,266,335 (“’335 patent”) (EX1101), allegedly assigned to Abbott Diabetes Care Inc. (“Patent Owner”).

The challenged claims are directed to a glucose monitoring assembly with (1) an inserter that includes a sharp, and (2) an on body electronics unit that includes a glucose sensor and an on body electronics unit housing (purple)¹ with plural recesses (red) configured to engage the inserter. EX1101, 48:53-49:26 (claims 1-4), 49:47-55 (claims 8-9); 49:58-51:6 (claims 11-27). The glucose sensor is inserted using the sharp. *Id.* In many dependent claims, the inserter also includes gripping arms (green). *Id.*, 49:12-26 (claims 2-4), 49:47-55 (claims 8-9).

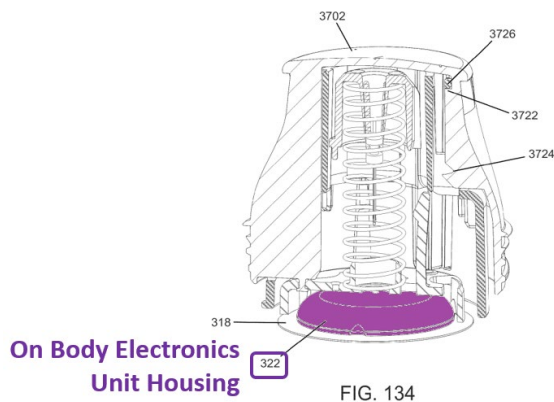


FIG. 134

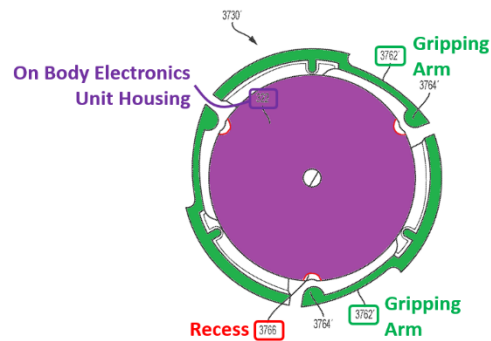
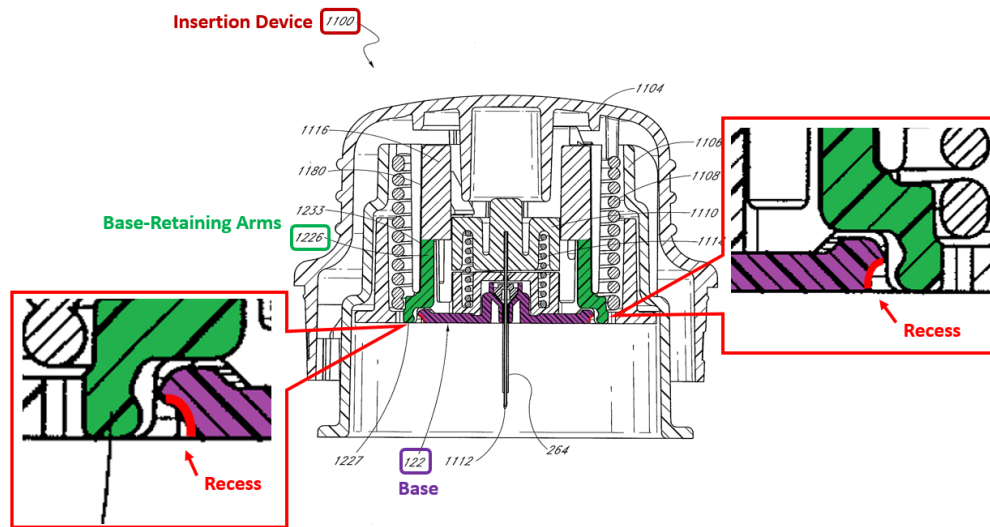


FIG. 135

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

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

However, the prior art included inserters with gripping arms for engaging corresponding recesses on medical devices. *Infra* Section VI.B.2. For example, as shown below, Raymond (EX1110) 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. EX1110, FIGS. 29-30, [0123]. The cannula is inserted using the needle. *Id.*



Raymond, FIG. 29 (annotated)

Furthermore, known glucose sensing devices, such as the on body unit disclosed by Thomas (EX1109), included on body electronics and glucose sensors inserted using a sharp. As explained below, skilled artisans would have naturally combined the teachings of Thomas and Raymond to create a glucose monitoring assembly that renders the challenged claims obvious. *Infra* Section VIII. Turner (EX1111), a secondary reference, teaches additional features that skilled artisans

would have naturally incorporated into such an assembly, thus rendering obvious each challenged claim. *Id.*

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 the challenged claims of the '335 patent, on the following statutory grounds:

	Reference(s)	35 U.S.C. §	Claims
Ground 1	Thomas (EX1109) and Raymond (EX1110)	103	1-4, 8-9, and 11-27
Ground 2	Thomas, Raymond, and Turner (EX1111)	103	1-4, 8-9, and 11-27

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

With the filing of this petition an electronic payment of \$44,875 for the requisite fees is being charged to deposit account no. 02-4550. 37 C.F.R. § 42.15(a). Any fee adjustments may be debited/credited to the deposit account.

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

A. No Examiner Addressed These Unpatentability Grounds

This petition relies on three prior art references: Thomas (EX1109), Raymond (EX1110), and Turner (EX1111).

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.

Thomas also was not cited, though a related publication was—U.S. Patent Publication No. 2010/0198034 (“Thomas-034”).² Specifically, the Examiner found the claims to be obvious over Thomas-034 and other secondary references. EX1102, 425-42.³ Applicant subsequently argued that Thomas-034 does not qualify as prior art and submitted a declaration in support pursuant to § 1.131 (“the 131 Declaration”). *Id.*, 471-1050. The Thomas reference cited herein was published only

² Thomas and Thomas-034 each names the same inventors and each claims priority to Provisional Application No. 61/149,639.

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

one week after Thomas-034 but contains a more robust disclosure, including additional details on the inserter device and on body unit not expressly disclosed in Thomas-034. *See, e.g.*, EX1109, FIGS. 10-31 (illustrating additional features of the inserter device and on body unit not shown in Thomas-034).

While Raymond was identified by Applicant 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. EX1102, 6-40, 293, 1055-59. None of the references relied on herein was mentioned by the Examiner in an Office action and “there is no evidence that the Examiner considered the particular disclosures” and combinations relied on in this petition. *Microsoft Corp. v. Parallel Networks Licensing, LLC*, IPR2015-00486, Paper 10 at 15, 2015 WL 4760578, at *8 (PTAB July 15, 2015); *see also e.g., Intex Recr. Corp. v. Team Worldwide Corp.*, IPR2018-00871, Paper 14 at 13 (PTAB Sept. 14, 2018); *HTC Corp. v. Motiva Patents, LLC*, IPR2019-01666, Paper 9 at 6-10 (PTAB Apr. 3, 2020).

The Board should not deny institution under Section 325(d) for at least the following reasons.

First, the Examiner erred in accepting the 131 Declaration because Applicant did not show reasonably continuous diligence during the correct critical period as detailed below. *Infra*, Section V.B. Thus, since the 131 Declaration is insufficient to

antedate Thomas-034, and likewise the Thomas reference relied on herein that was also published during the correct critical period, the Board should consider the Thomas reference.

Second, as explained above, the Thomas reference relied on herein contains a more robust disclosure than Thomas-034, in that Thomas includes additional details on the inserter device and on body unit not expressly disclosed in Thomas-034. *See, e.g.*, EX1109, FIGS. 10-31.

Third, there is no indication that the other prior art references relied on herein—Raymond and Turner—were ever substantively considered by the Examiner. Turner was never cited at all, while Raymond was only listed in among 1,000+ references in Applicant’s lengthy IDS. EX1102, 6-40, 293, 1055-59. The Examiner never cited or discussed Raymond on the record. *See* EX1102.

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

B. Parallel Proceeding

Patent Owner asserts the ’335 patent against Petitioner in district court, with trial set for March 2026. EX1166, 14. Any IPR based on this petition would conclude well in advance of that date and thus the Board should not discretionarily deny institution in view of the district court case.

V. THE '335 PATENT

The '335 patent issued March 8, 2022, from an application filed September 11, 2020, and claims priority through a series of applications to a non-provisional application filed March 24, 2011, and provisional applications filed November 8, 2010; July 2, 2010; May 17, 2010; and March 24, 2010.⁴ EX1104, EX1106, EX1107, EX1108.

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. EX1101, 48:53-49:11; EX1103, ¶22. The inserter is configured to first advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position, then retract the sharp from the distal position to a retracted position entirely within the inserter. EX1101, 48:53-49:11; EX1103, ¶22.

Representative embodiments pertinent to the challenged claims appear to be inserters 3700 and 3700', illustrated in FIGS. 109-140. EX1101, 41:12-45:56, 45:57-46:23; EX1103, ¶23.

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.

A. The Prosecution History

The '335 patent's September 11, 2020, application was followed by a preliminary amendment cancelling all original claims (claims 1-25) and adding new claims 26-48, with the sole independent claim (claim 26) reciting the key feature of the “plurality of recesses” on the on body electronics unit housing. EX1102, 234-37. Following further preliminary amendments, the Examiner rejected independent claim 26 as anticipated by U.S. Patent Publication No. 2010/0198034 (“Thomas-034”) (*id.*, 333-35) and rejected all other claims as anticipated by Thomas-034 and/or as obvious over Thomas-034 in view of other references. *Id.*, 335-45.

In response, Applicant amended independent claim 26 to recite that the plurality of recesses are disposed “on a periphery of the on body electronics unit housing” (*id.*, 419) and argued that these peripheral recesses distinguish Thomas-034 (*id.*, 414-16).

The Examiner then rejected all pending claims as obvious over Thomas-034 in view of U.S. Patent Publication No. 2008/024961 (“Brister”) and other secondary references. *Id.*, 428-42. Specifically, the Examiner cited to Thomas-034 for all claim elements except those directed to the gripping arms and recesses. *Id.*, 429-35. For the recesses, the Examiner cited to Brister. *Id.*, 429-32. For the gripping arm claim elements, the Examiner cited to several additional references: U.S. Patent No. 7,381,184 to Funderburk et al. (EX0128, “Funderburk”), U.S. Patent Application

Publication No. 2010/0137695 to Yodfat et al. (“Yodfat”), and U.S. Patent Application Publication No. 2008/0058830 to Cole et al. (“Cole”). *Id.*, 435-40.

In response, Applicant filed a Request for Continued Examination, claim amendments, and the 131 Declaration in support of an argument that Thomas-034 does not qualify as prior art due to alleged prior invention of the pending claims. *Id.*, 471-1050. The 131 Declaration alleges that the subject matter of the invention was conceived at least before August 5, 2010 (*id.*, 491-95), and that Applicant reduced to practice the alleged invention no later than November 8, 2010, as purportedly evidenced by the filing of the November 8, 2010, provisional application. *Id.*, 498-99.

The Examiner then allowed the claims. *Id.*, 2068-75.

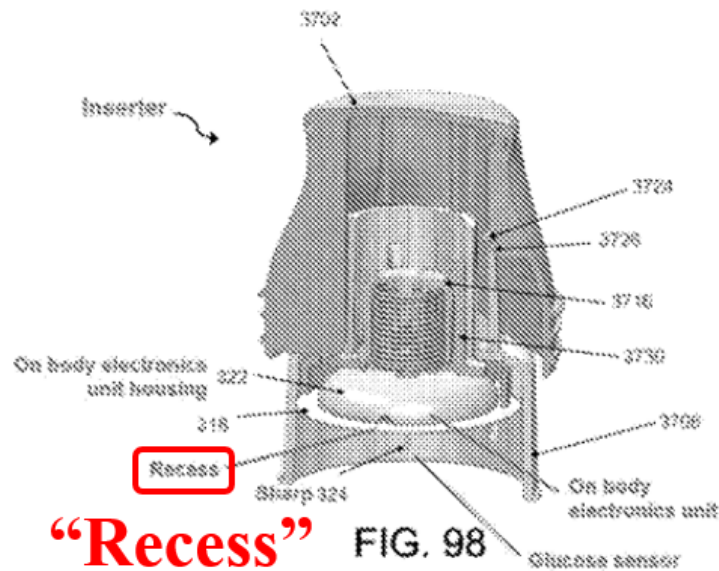
B. The Examiner Erred In Accepting The 131 Declaration

As noted above, the Examiner allowed the '335 patent to issue after Applicant filed the 131 Declaration. The Examiner erred in finding that the 131 Declaration was sufficient to antedate Thomas-034 for at least two reasons. First, the Examiner erred in accepting Applicant's argument that the claims were constructively reduced to practice on November 8, 2010, through the filing of the '262 provisional application. EX1102, 489-785. Second, the Examiner erred in accepting Applicant's argument that the submitted evidence shows that the named inventors exercised reasonably continuous diligence in reducing the claimed invention to practice.

Applicant alleged that the inventors conceived of the claimed invention by July 2010—before Thomas-034’s August 5, 2010 102(a) publication date. However, Petitioner disputes that Applicant constructively reduced the alleged invention to practice through the filing of the ’262 provisional application.

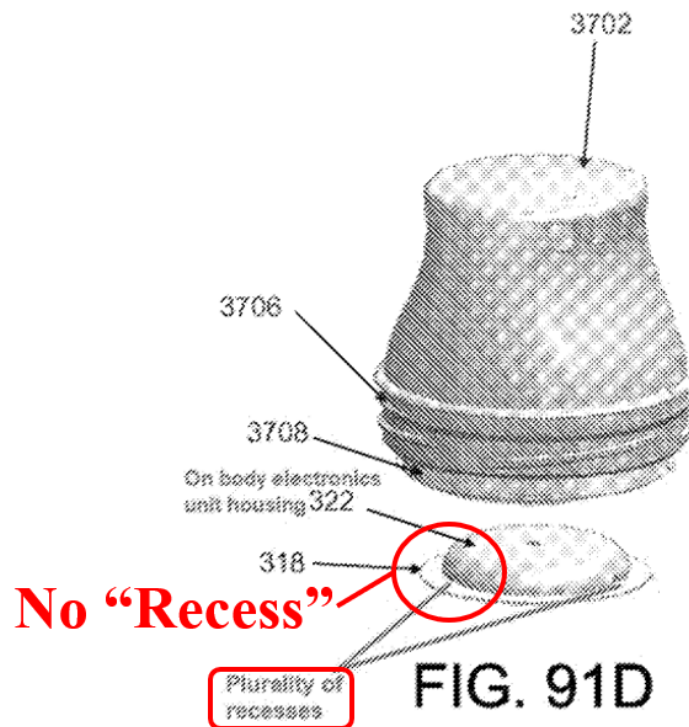
As discussed below, the ’262 provisional application does not adequately support a plurality of recesses on the periphery of the on body unit, as recited by independent claim 1. EX1104, 233-238 (FIGS. 91A–103). Indeed, this feature of the claims was not expressly disclosed until the non-provisional application (U.S. 13/071,461) was filed March 11, 2011.

During prosecution, Applicant cited the ’262 provisional application’s Figure 98 in the 131 Declaration and Figure 91A in Appendix B of the 131 Declaration as supposed support for the “plural recesses.” EX1102, 498-99; *id.*, 1017. However, at best, Figure 98 illustrates only a single recess that is not labelled in the drawings or described in the specification of the ’262 provisional application. EX1103, ¶26; EX1104, 233; *see id.* Indeed, as shown below, Applicant’s annotation (circled in red) in the 131 Declaration labels the recess as a single “recess,” not “plural recesses.” EX1102, 499.



**'262 Provisional Application, FIG. 98 As Annotated By Applicant
In The 131 Declaration
(further annotated by Petitioner)**

Furthermore, as shown below, although Applicant's lead line annotations in Appendix B purport to call out a "plurality of recesses" in FIG. 91D, the left-most lead line does not point to any discernible feature, much less another "recess," disposed on the periphery of the housing and detachably engaged with the inserter. EX1102, 1017; EX1103, ¶26.

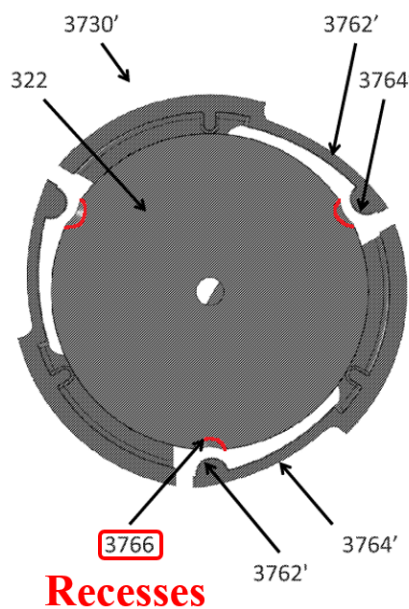


**'262 Provisional Application, FIG. 91D As Annotated
By Applicant In Exhibit B Of The 131 Declaration
(further annotated by Petitioner)**

Thus, since neither FIG. 91A nor FIG. 98 of the '262 provisional application illustrates more than one recess, and furthermore since Applicant provided no other support for “plural recesses” in the '262 provisional application, Applicant failed to demonstrate to the Office that the '262 provisional application adequately supports this limitation.

Further, the '262 provisional does not show or describe how this recess detachably engages with the inserter, as recited in independent claim 1. EX1103, ¶26; see EX1104. This detachable arrangement was not disclosed until March 11,

2011, in the non-provisional application. Specifically, as shown below, the non-provisional illustrates and describes—for the first time—how the on body unit detachably engages with the inserter via the engagement bosses 3764' of the carrier's gripping arms 3762' (part of the inserter device 3700') fitting into and engaging the recesses 3766 (red) of the on body unit 322. EX1103, ¶26; EX1105, FIG. 135, [0258], [0266]-[0267]. Thus, the critical period runs until March 11, 2011, not November 8, 2010, and Patent Owner must show reasonably continuous diligence during this additional period from November 8, 2010, to March 11, 2011.



'335 Patent, FIG. 135 (annotated)

Applicant does not show reasonably continuous diligence to March 11, 2011 in the 131 Declaration. The party attempting to antedate a prior art reference must

show that they not only were first to conceive of a patentable invention, but that they also exercised reasonably continuous diligence in reducing the patentable invention to practice during the critical period, which is the period from just prior to the competing reference's effective date to the invention's reduction to practice. *Perfect Surgical Techniques, Inc. v. Olympus Am., Inc.*, 841 F.3d 1004, 1007, 1009, 1015 (Fed. Cir. 2016); *ATI Techs. ULC v. Iancu*, 920 F.3d 1362, 1369 (Fed. Cir. 2019) (quoting *Perfect Surgical*, 841 F.3d at 1009); see also *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577 (Fed. Cir. 1996). An inventor's testimony, standing alone, is insufficient to prove conception and diligence, as some form of corroboration is required. *Mahurkar*, 79 F.3d at 1577; *Price v. Symsek*, 988 F.2d 1187, 1194 (Fed. Cir. 1993). A rule of reason applies to determine whether the inventor's testimony has been corroborated. *Price*, 988 F.2d at 1194-95. A party alleging diligence must provide corroboration with evidence that is specific both as to facts and dates. *Gould v. Schawlow*, 363 F.2d 908, 920 (CCPA 1966); *Kendall v. Searles*, 173 F.2d 986, 993 (CCPA 1949); see also *Coleman v. Dines*, 754 F.2d 353, 360 (Fed. Cir. 1985) ("The rule of reason ... does not dispense with the requirement for some evidence of independent corroboration.").

Even a short period of unexplained inactivity is sufficient to defeat a claim of diligence. *Morway v. Bondi*, 203 F.2d 742, 749 (CCPA 1953); *Ireland v. Smith*, 97 F.2d 95, 99-100 (CCPA 1938). In *In re Mulder*, 716 F.2d 1542, 1542-46 (Fed. Cir.

1983), for example, the Federal Circuit affirmed a determination of lack of reasonable diligence, where the evidence of record was lacking for a two-day critical period. Likewise, in *Rieser v. Williams*, 255 F.2d 419, 424 (CCPA 1958), there was no showing of diligence where no activity was shown during the first thirteen days of the critical period. Since the critical period at issue runs until March 11, 2011, and Applicant only provided redacted versions of progress reports until November 2010, Applicant failed to show reasonable diligence over a four-month period between November 2010 and March 2011, which is significantly longer gap of unexplained activity than *In re Mulder's* two days and *Rieser v. Williams's* thirteen days. EX1102, 495-498, 529-562. Thus, since Applicant failed to provide progress reports or any other evidence dating from the months of December 2010, January 2011, February 2011, and March 2011, Applicant did not submit sufficient evidence during prosecution to show that reasonably continuous diligence was exercised during at least the portion of the critical period spanning November 2010 and March 2011.

Even if, *arguendo*, the entire critical period runs only until November 8, 2010, the redacted reports (*id.*, 528-62) submitted with the 131 Declaration do not evidence that the inventors exercised reasonably continuous diligence during even this shorter critical period.

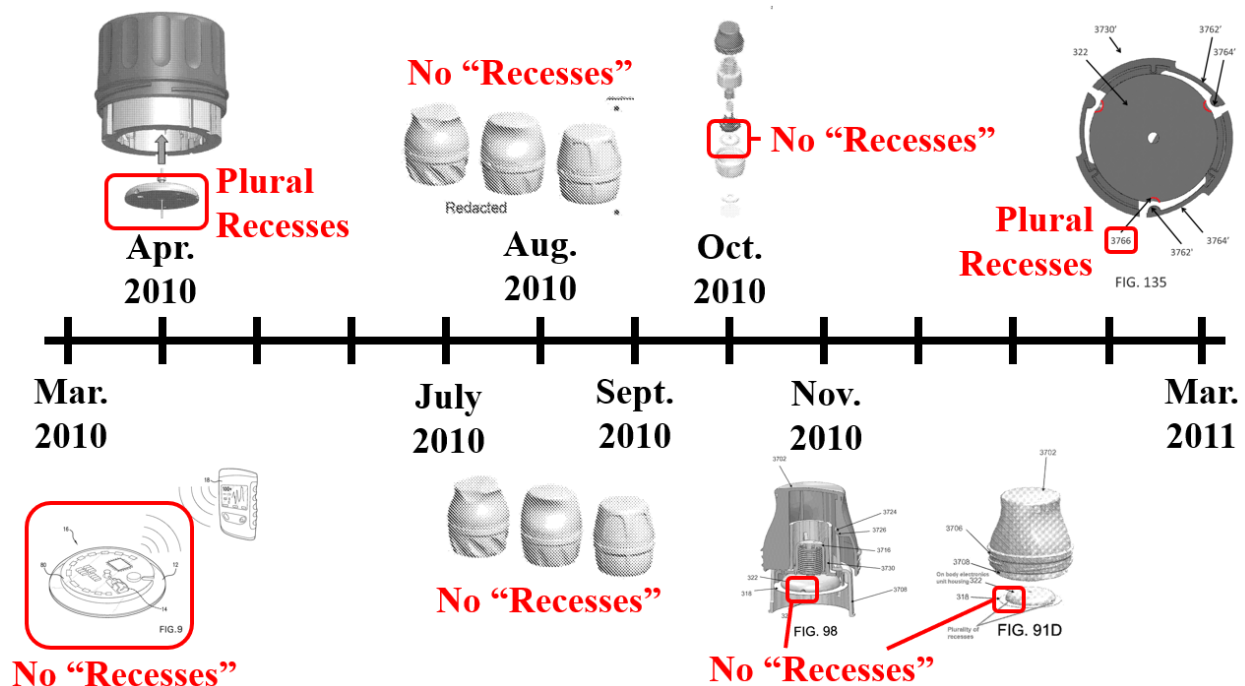
The July 2010 progress report, for example, is heavily redacted. *Id.*, 528-33. There is no indication that the “plurality of recesses” feature was worked on in July

2010. *Id.* Although the July 2010 progress report suggests that some unidentified work was performed on some aspects of the inserter and on body unit, it fails to show any specific facts or dates regarding what work was actually performed. *Id.* The August 2010 progress report (*id.*, 534-40) does not fare much better. At best it shows some work was performed related to sealing, thread geometry, and lock-out features. *Id.* As with the July report, there is no indication that any effort was given to the “plurality of recesses” feature. *Id.* The September 2010 progress report (*id.*, 541-47) notes that work was performed regarding “insertion guidance and puck/sharp stability” without any indication whether it related to the “plurality of recesses” feature. *Id.*, 542. The progress report lacks any facts regarding what was done to improve guidance and stability. Nor are any specific dates included. Although the October and November 2010 progress reports (*id.*, 549-62) provide additional information regarding other aspects of the project, there are no details suggesting that actual work on the “plurality of recesses” feature was performed.

Thus, regardless of whether the critical period runs until November 2010 or March 2011, none of the progress reports expressly shows that the “plurality of recesses” feature was ever worked on during the four-month period between July 2010 and November 2010. As discussed above, this “plurality of recesses” feature is recited in sole independent claim 1 and it is the only feature that Applicant used to try and distinguish the challenged claims over the cited Thomas-034 reference.

Id., 414-416. Thus, Applicant failed to show reasonable diligence of reducing the invention to practice for not just two days like in *In re Mulder* or thirteen days like in *Rieser v. Williams*, but for at least four months.

Indeed, as shown in the below timeline, there is no evidence in either the provisional applications or the 131 Declaration that Applicant worked on the invention at least during the portions of the critical period between April 2010 and July 2010, July 2010 and November 2010, and November 2010 and March 2011. See EX1102, EXS1104-1008.



Timeline Of Applicant's Disclosure of "Plural Recesses"

As such, the Examiner erred by not finding the 131 Declaration deficient for failing to show reasonable diligence during the critical period—from at least just before August 5, 2010, through November 8, 2010 (the date the last provisional application was filed) to March 24, 2011 (the date the first non-provisional was filed).

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

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

A POSITA would have had a bachelor’s degree in bioengineering, mechanical engineering, electrical engineering, or a related subject, and one or more years of experience researching, developing, and/or designing insertable medical devices, including, *e.g.*, systems for implanting wearable medical devices such as cannulas, infusion sets, and/or analyte sensors, or equivalent experience.⁵ Less work experience would have been compensated by a higher level of education, such as a master’s degree, and vice versa. EX1103, ¶27.

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

B. State Of The Art

The concepts claimed in the '335 patent—namely, inserters configured to secure on body units therein, with retractable sharps to insert transcutaneous medical devices (*e.g.*, a glucose sensor, a cannula) into a subject, and wearable on body units—were known before 2010. EX1103, ¶28 (discussing EX1110, EX1118, EX1140, EX1142, EX1157).

1. 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. EX1103, ¶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. EX1103, ¶29; *see, e.g., id.*; EX1109, 21:9-11, 23:31-32; EX1139, Abstract; EX1140, 1-33:40; EX1141, [0079]; EX1142, [0019]; EX1143, 2:23-26; EX1144, 13:12-16.

**2. Using Plural Recesses
For Securing A 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. EX1103, ¶30; EX1111, [0069]; EX1118, [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”); EX1140, 2:45-57 (same); EX1142, [0010] (same); EX1157, [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 (EX1111) 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. EX1103, ¶30; EX1111, [0069].

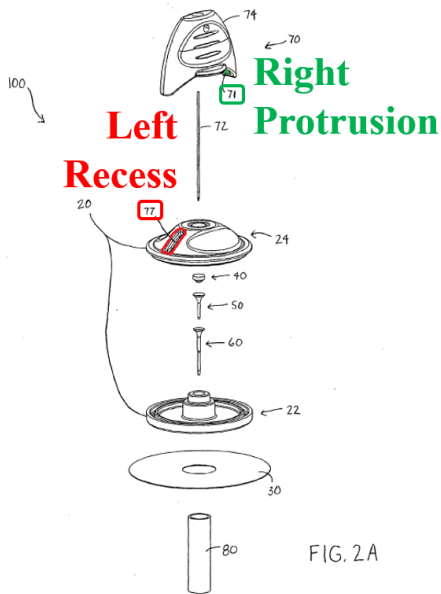


FIG. 2A

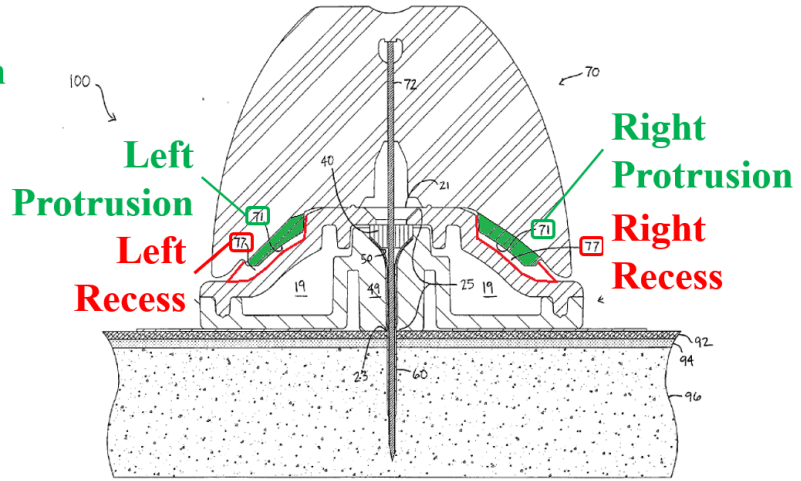


FIG. 4

Turner, FIGS. 2A and 4 (annotated)

VII. CLAIM CONSTRUCTION

For *inter partes* review, claim terms should be given the ordinary meaning that the terms would have to a person of ordinary skill in the art on at the time of 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 in any litigation 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 in any litigation.

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

As explained below, claims 1-4, 8-9, and 11-27 are obvious over Thomas and Raymond (Ground 1) and further in view of Turner (Ground 2). EX1103, ¶31.

A. Thomas

International Publication No. WO 2010/091005 (“Thomas”), titled “Analyte Sensor And Apparatus For Insertion Of The Sensor,” was published August 12, 2010. Thomas qualifies as prior art under Pre-AIA Section 102(a) because, as previously discussed in Section V.B, the ’335 patent is not entitled to an invention date earlier than Thomas’s publication date (August 12, 2010) because Patent Owner has not established that the inventors of the ’335 patent exercised reasonably continuous diligence in reducing their invention to practice during the critical period.

Thomas—also filed by Patent Owner—discloses a glucose monitoring assembly having the same overall structure and function as the ’335 patent’s claimed assembly. EX1103, ¶33; *compare, e.g.*, EX1109 (Thomas), FIGS. 7-31 *with* EX1101 (’335 patent), FIGS. 2-3, 9-13, 16-17A, 109-134, 137-140. The Patent Office itself confirmed this similarity when the Examiner found that Thomas-034—which contains less disclosure on the inserter and on body unit than Thomas—discloses all the claim elements, although it does not expressly disclose elements relating to the claimed gripping arms and recesses. EX1102, 429-40.

Thomas's inserter advances an on body unit and a sharp in response to a downward force applied on the inserter's housing (*see* challenged claim 15). EX1109, 24:3-5, 27:17-33, claim 92, FIGS. 28-30. After Thomas's sharp and sensor are inserted under the skin, a retraction spring within Thomas's inserter automatically retracts the sharp (*see* challenged claim 13) from an aperture in the on body unit (*see* challenged claim 17), leaving the on body unit adhered to the skin via an adhesive pad (*see* challenged claim 22) and the sensor subcutaneously implanted. EX1103, ¶34; EX1109, 28:1-13, FIG. 31.

Like the '335 patent's claimed on body electronics unit, Thomas's on body unit includes a sensor housing, a glucose sensor (EX1109, 2:20, 4:5-6, 4:27-28, 5:19-20, 16:11-14, 19:11-13, claims 39, 47, 54, 64, 72, 89), and a data processing unit with electronics (a processor, a data storage unit (*i.e.*, memory), a power supply, and an RF communication circuit for wirelessly communicating glucose level data). EX1103, ¶35; EX1109, 19:31-21:4.

As shown below, a distal insertion portion of Thomas's sensor is disposed in Thomas's sharp before insertion. EX1109, FIGS. 23-24, 26:21-22. Thomas's sensor also includes a proximal contact portion that extends perpendicular to the insertion portion to contact Thomas's electronics. *Id.*

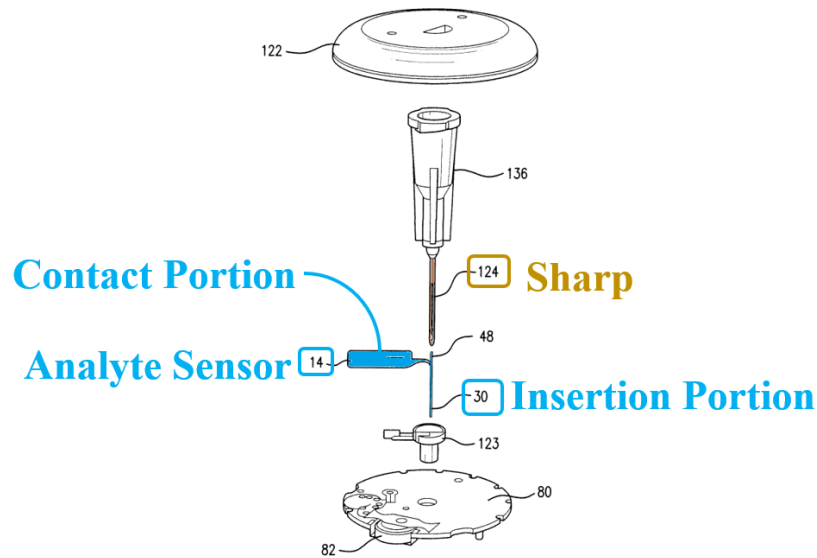


FIG. 23

Thomas, FIG. 23 (annotated)

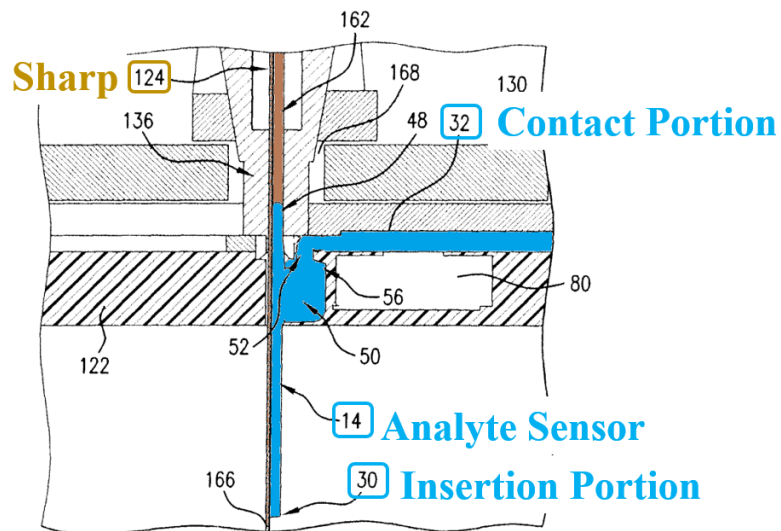


FIG. 24

Thomas, FIG. 24 (annotated)

Thomas discloses releasably coupling the on body unit with the inserter but does not expressly disclose doing so using gripping arms and recesses (*see* challenged claims 2-4, 8-9, and 11-12). *See* EX1109, 26:12-20, 27:21-28:13, FIGS.

10, 28-31. Although Thomas does not expressly disclose how the on body unit is retained within the inserter, Thomas suggests that a friction fit may be provided between the on body unit and the sharp. EX1103, ¶37; EX1109, 26:19-20.

B. Raymond

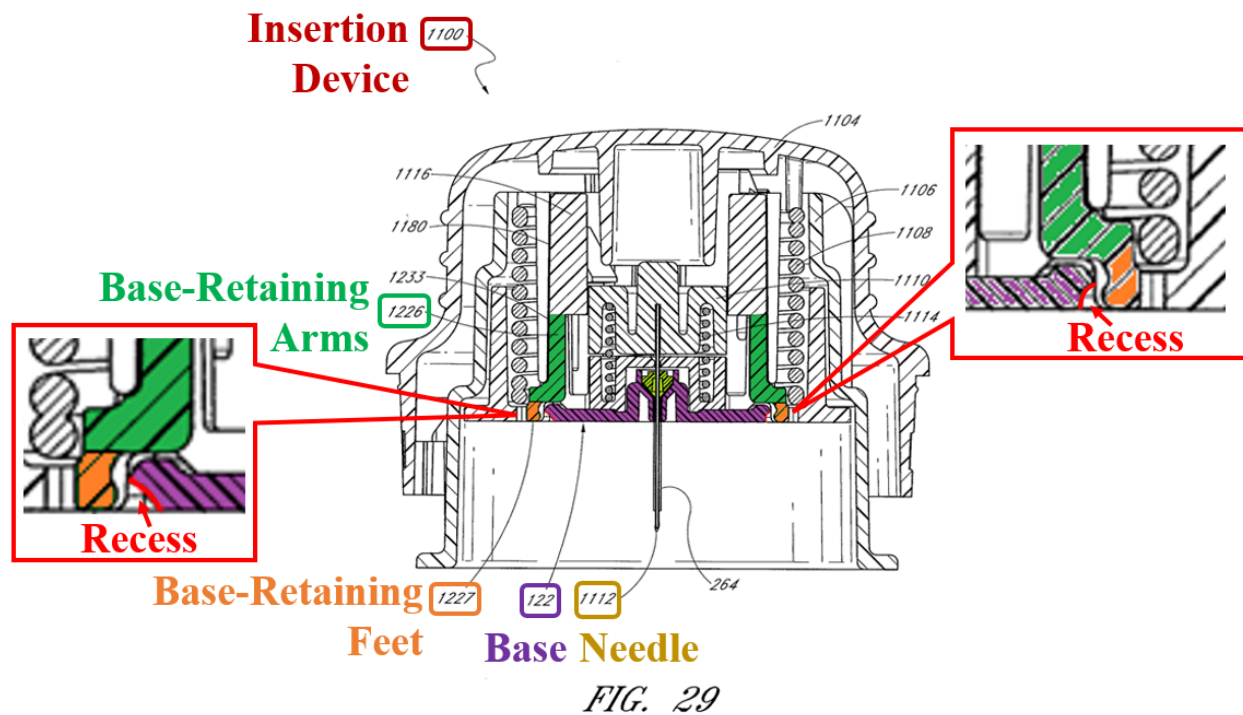
U.S. U.S. Publication No. 2009/0124979 (“Raymond,” EX1110), was published May 14, 2009, from an application filed September 10, 2008. As discussed at Section V.B, Raymond also qualifies as prior art under Pre-AIA Section 102(b) because Raymond was published more than one year before the March 24, 2011 non-provisional application first disclosed a “plurality of recesses.”

Raymond describes an insertion device that inserts a transcutaneous infusion device “quickly, safely, and conveniently.” EX1110, [0008], [0109]. The infusion device includes a base housing at least a portion of an infusion set therein. EX1103, ¶39; EX1110, 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. EX1110, [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. EX1103, ¶40; EX1110, [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. EX1103, ¶41; EX1110, FIG. 29. In this proximal position, Raymond's left and right base-retaining arms (green) with associated base-retaining feet (orange) detachably engage recesses (red) on the periphery of the infusion device's base (purple). EX1103, ¶41; EX1110, [0123]. Each base-retaining foot is located at a tip portion of a corresponding base-retaining arm (green). EX1103, ¶41; EX1110, FIG. 29.



Raymond, FIG. 29 (annotated)

As shown below, when the insertion device advances the infusion device to a distal position during insertion, the insertion device's outwardly-biased base-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. EX1110,

[0126]. Furthermore, a retraction spring (blue) retracts the needle (brown) from the distal position to a retracted position entirely within the insertion device. EX1103, ¶42; EX1110, [0127].

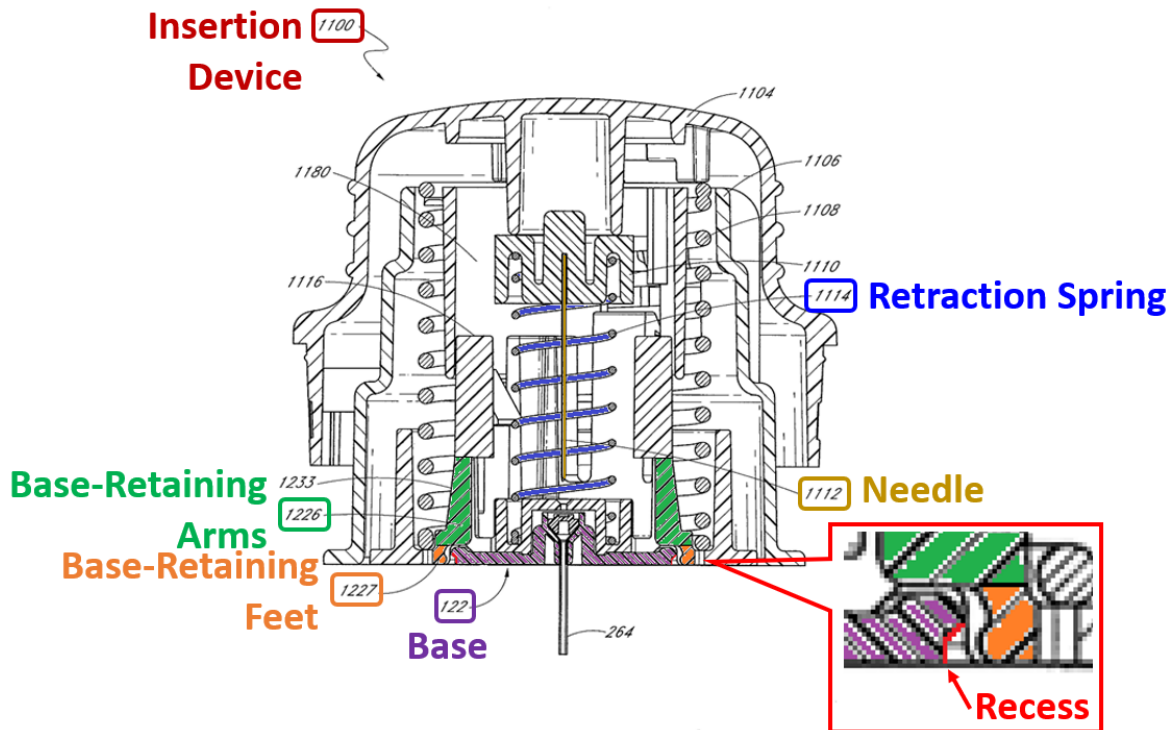


FIG. 30

Raymond, FIG. 30 (annotated)

C. Turner

U.S. Publication No. 2007/0135774 (“Turner,” EX1111) was published June 14, 2007, from an application filed November 3, 2006. Turner qualifies as prior art under Pre-AIA Section 102(b).

Turner describes an insertion device for delivering a fluid delivery device for the treatment of diabetes. EX1103, ¶44; EX1111, [0008], [0064].

As shown in the annotated figure of Section VI.B.2, Turner discloses an insertion device that includes a plurality of rotation-restricting protrusions. EX1111, [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. EX1103, ¶45; EX1111, [0069]; *see supra* Section VI.B.2.

D. The Thomas+Raymond Combination

The combination of Thomas and Raymond (“Thomas+Raymond”) applied herein combines teachings from Thomas and Raymond, namely Thomas’s teachings related to a glucose sensor, sharp, on body unit (“on-body electronics unit”), and sensor housing (“on body electronics unit housing”) and Raymond’s teachings related to an insertion device (“inserter”) with base-retaining arms (“gripping arms”). EX1103, ¶46. Thomas+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.* Thomas+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 Thomas, and to use a needle/sharp to insert a portion of a glucose sensor like that taught in Thomas beneath the skin of a subject; and
- an on body unit as taught by Thomas, including:
 - a sensor housing adjusted to include spaced-apart recesses disposed on a periphery of the housing, with the recesses detachably engaged with the inserter;
 - a glucose sensor; and
 - electronics coupled with the glucose sensor, wherein the electronics includes a memory, processor, power supply, and RF transceiver for wirelessly communicating glucose level data;
- wherein the inserter is configured to advance the on body unit and sharp from a proximal position entirely within the inserter to a distal position, and
- wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.

Like the '335 patent, Thomas and Raymond are each directed to the insertion of transcutaneous medical devices for diabetes treatments. EX1103, ¶47; EX1101, Abstract; EX1109, 4:29-30; EX1110, [0009]; *see supra* Sections VIII.A-B. Thus,

Thomas and Raymond are analogous art to the claimed invention of the '335 patent. EX1103, ¶47.

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

A POSITA would have been motivated to combine Thomas and Raymond for the following reasons. EX1103, ¶48.

A POSITA would have recognized the complementary nature of Thomas and Raymond. EX1103, ¶49. For example, each reference teaches the benefits of an inserter that protects against needlesticks. EX1109, 28:8-10; EX1110, [0127]; *see also id.*, [0104], [0109]. 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 Thomas aligned with the inserter as taught by Raymond during insertion. EX1103, ¶49. Thus, a POSITA would have understood that Thomas's and Raymond's teachings are complementary. *Id.*

Thus, a POSITA would have been motivated to combine the teachings of Thomas and Raymond. *Id.*, ¶50.

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

A POSITA would have had a reasonable expectation of success in combining Thomas and Raymond for the following reasons. EX1103, ¶51.

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 Thomas, *e.g.*, by using a needle-like sharp that accommodated the sensor therein, as taught by Thomas. EX1103, ¶52. 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” (EX1101, 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. EX1103, ¶52. Similarly, a POSITA would have easily implemented the on body unit with recesses that engagingly mated with the gripping arms, as taught by Raymond. *Id.*; *see supra* Section VI.B.2. These adaptations required only basic skill and knowledge, possessed by a POSITA. EX1103, ¶52.

Thus, a POSITA would have had a reasonable expectation of success in combining the teachings of Thomas and Raymond. *Id.*, ¶53.

E. The Thomas+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 Thomas and Raymond. EX1103, ¶54; *see supra* Section VIII.C; *see supra* Section VIII.D (characterizing the '335 patent, Thomas, and Raymond as analogous art).

To the extent Patent Owner argues that “plural recesses” were not at least obvious over Thomas+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. EX1103, ¶55; EX1111, [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. EX1111, [0069]. Given the motivation to avoid relative movement between the housing and the inserter (further discussed at [1.5]), and Turner’s express teachings of plural recesses, a POSITA would have implemented the Thomas+Raymond housing with plural recesses that engage corresponding portions of the inserter. EX1103, ¶55; *see supra* Sections VI.B.2, VII.C. 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). EX1103, ¶55; *see supra* Sections VI.B.2, VII.B-C, VII.D.1. As with Thomas+Raymond alone, the POSITA would have had a reasonable expectation of success in implementing such simple mechanical features as at least two recesses. EX1103, ¶56.

F. Claim 1

[1.1]⁶ A glucose monitoring assembly, the assembly comprising:

Thomas discloses a glucose monitoring system (“glucose monitoring assembly”) including an on body unit (“on body electronics unit”) and a glucose sensor. EX1103, ¶57; *see, e.g.*, EX1109, 13:24-25, 12:22-24, 19:31-20:1, 21:7-10, 23:23-24, 24:3-5, FIGS. 10-31; *see also supra* Section VIII.A.

As previously discussed, a POSITA would have been motivated to combine the teachings of Thomas and Raymond (and Turner), for example, by configuring an insertion device (“inserter”) as taught by Raymond to advance an on body

⁶ Reference numbers in the format of [claim#.element#] are added throughout for ease of reference.

electronics unit as taught by Thomas and insert the glucose sensor as taught by Thomas. EX1103, ¶58; *see supra* Section VIII.D.1.

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “a glucose monitoring assembly.” EX1103, ¶59; *see also* Sections VIII.D, VIII.E.

[1.2] (1) an inserter comprising:

As discussed at [1.1], Thomas+Raymond (and Thomas+Raymond+Turner) includes “an inserter.” *Id.*, ¶60; *see also* Sections VIII.D, VIII.E.

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

Thomas discloses a sharp for inserting Thomas’s sensor into a subject. EX1103, ¶61; *see, e.g.*, EX1109, 17:21-23, 26:21-22, 27:29-31.

Raymond’s insertion device (“inserter”) includes a needle (“sharp”) for inserting a cannula. EX1103, ¶62; EX1110, FIGS. 29-30, [0109].

A POSITA would have employed a sharp like that disclosed in Thomas for compatibility with the sensor as taught by Thomas and would have had a reasonable expectation of success of doing so. EX1103, ¶63; *see supra* Sections VI.B.1, VII.D.1-2.

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “a sharp configured to insert a portion of a glucose sensor into a subject.” EX1103, ¶64; *see also* Sections VIII.D, VIII.E.

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

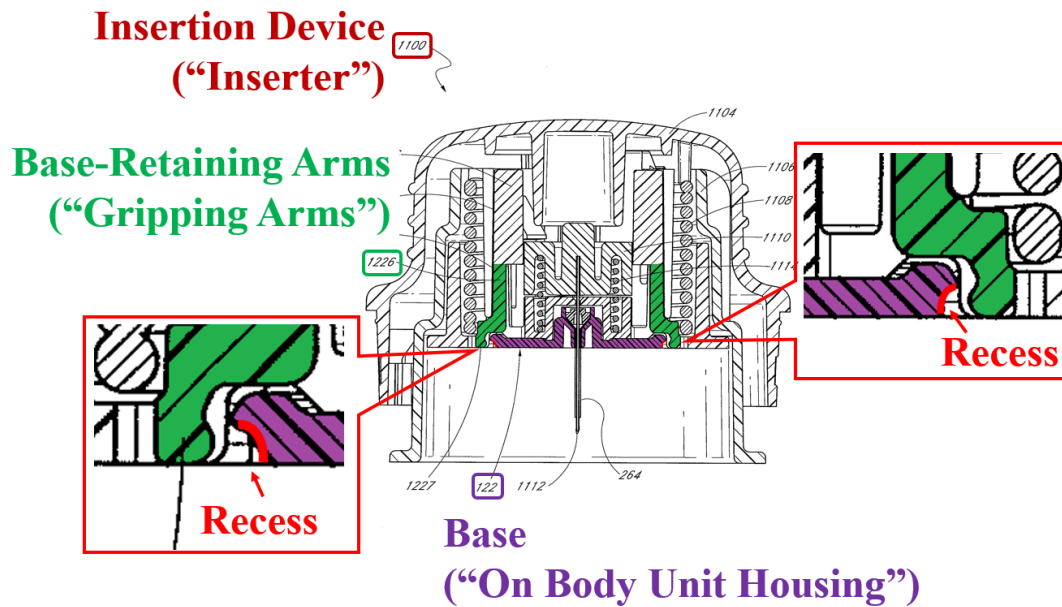
As discussed below at [1.5], Thomas+Raymond (and Thomas+Raymond+Turner) includes an “on body electronics unit.” *Id.*, ¶65; *see also* Sections VIII.D, VIII.E.

[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;

Thomas’s on body unit (“on body electronics unit”) includes electronics (“on body electronics”) housed within a sensor housing (“on body electronics unit housing”). EX1109, 13:24-25, 20:5-7. Thomas’s housing is disposed within a carriage of Thomas’s inserter before use. EX1109, 26:12-20. However, Thomas neither expressly discloses how the on body electronics unit is secured within the carriage nor how any other portion of the inserter engages Thomas’s housing to secure it therewithin. *See* EX1103, ¶66; *see supra* Section VIII.A.

As shown below, Raymond teaches an insertion device with “base-retaining arms” that “engage” the on-body unit. EX1103, ¶67; EX1110, [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. EX1110, [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). EX1103, ¶67; EX1110, 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. EX1103, ¶68; *see, e.g.*, EX1110, FIGS. 29-30; *see, e.g.*, *In re Aslanian*, 590 F.2d 911, 914 (CCPA 1979) (“drawings are ‘evaluat[ed] and appl[ied] ... on the basis of what they reasonably disclose and suggest’” and drawings may be used to show unpatentability of claims “even though the feature shown in the

drawing was unintended or unexplained in the specification of the reference patent.”)
(citation omitted).

A POSITA knew that feet/protrusions like those taught by Raymond (EX1110, [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. EX1103, ¶69; *see, e.g.*, EX1118, [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”); EX1140, 2:45-57 (same); EX1142, [0010] (same); EX1157, [0015] (same). Indeed, Raymond itself elsewhere employs a similar concept, describing a bounded recess on one component that engages a foot on another component “to prevent unintentional rotation.” EX1110, [0074]; *see also id.*, [0095] (describing a 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. EX1103, ¶69; EX1110, [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. EX1103, ¶70; *see also* EX1110, 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 two 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. EX1103, ¶70. As explained in the preceding paragraphs, a recess for each arm provided more secure engagement between the inserter and on-body unit, and FIGS. 29-30 show a recess for each arm, thus making it the better choice. *Id.*; *Perfect Web Tech., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1331-32 (Fed. Cir. 2009) (obvious to try one of three predicable solutions).

Thus, a POSITA would have implemented Stafford+Raymond with an on-body unit housing containing electronics, as taught by Stafford, and having recesses to engage each of the feet on the two base-retaining arms, as taught by Raymond. EX1103, ¶71.

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 Thomas to engage the inserter taught by Raymond. *Id.*, ¶72. For example, as discussed at Section VII.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. EX1111, [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 Thomas to prevent rotation between the housing as taught by Thomas and the inserter as taught by Raymond. EX1103, ¶72.

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. EX1165, 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 EX1111, [0069]); *cf. Qualcomm Inc. v. Apple Inc.*, 24 F.4th 1367, 1376 (Fed. Cir. 2022) (noting the uses of “a patentee’s admissions include, 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 Thomas.

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 Thomas+Raymond with two recesses on the on body unit, one to engage or mate with each of the bosses/protrusions on the arms. EX1103, ¶73; *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 Thomas to include features (e.g., plural recesses) for engaging the corresponding plural arms of the inserter as taught by Raymond. EX1103, ¶77; *see also id.* ¶¶74-76 (discussing other exemplary adjustments); *see, e.g., Ethicon LLC v. Intuitive Surgical, Inc.*, 2022 WL 1613188, at *4 (Fed. Cir. 2022) (affirming the Board’s finding of a reasonable expectation of success in combining references even though the “combination would require some modifications to fit pieces of the invention together,” because a POSITA would have “know[n] how to account for ‘routine considerations’ such as ‘location [and] positioning’” of mechanical components) (internal citation omitted); *see supra* Sections VI.B.1-2, VIII.D. 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. EX1103, ¶78; *supra* Section VIII.D.2.

Thus, Thomas+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.” EX1103, ¶79. *See also* Section VIII.D.

GROUND 2

Alternatively, claims 1-4, 8-9, 11-15, and 17-27 are obvious over Thomas (EX1109) in view of Raymond (EX1110) and further in view of Turner (EX1111). *Id.*, ¶80.

As shown in the annotated figure of Section VI.B.2, Turner discloses plural 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 protrusions disposed on an insertion device ("insertor"). EX1103, ¶81; EX1111, [0069]; *see supra* Section VI.B.2.

As previously discussed, Turner's teachings further confirm that a POSITA would have been motivated, with a reasonable expectation of success, to implement Thomas+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. EX1103, ¶82; *see supra* Section VIII.E.

Thus, Thomas+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." EX1103, ¶83; *see also* Section VIII.E.

[1.6] the glucose sensor; and

As discussed at [1.1], Thomas+Raymond (and Thomas+Raymond+Turner) includes “a glucose sensor.” *Id.*, ¶84; *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,

Thomas’s electronics (“on body electronics”) include a processor, a power supply, and a memory. EX1103, ¶85; EX1109, 4:26-27, 19:32-20:19. Thomas’s electronics further comprise communication components (“wireless communication circuitry”) configured to wirelessly communicate data indicative of a glucose level. EX1103, ¶85; EX1109, 4:13-15. Thomas’s electronics are coupled with Thomas’s sensor. EX1103, ¶85, *see, e.g.*, EX1109, 20:7-8, 17:1-18.

Thomas+Raymond (and Thomas+Raymond+Turner) includes the processor, memory, power supply, and wireless communication circuitry as taught by Thomas disposed within the housing as taught by Thomas. EX1103, ¶86. The electronics as taught by Thomas are coupled with the sensor as taught by Thomas. *Id.*

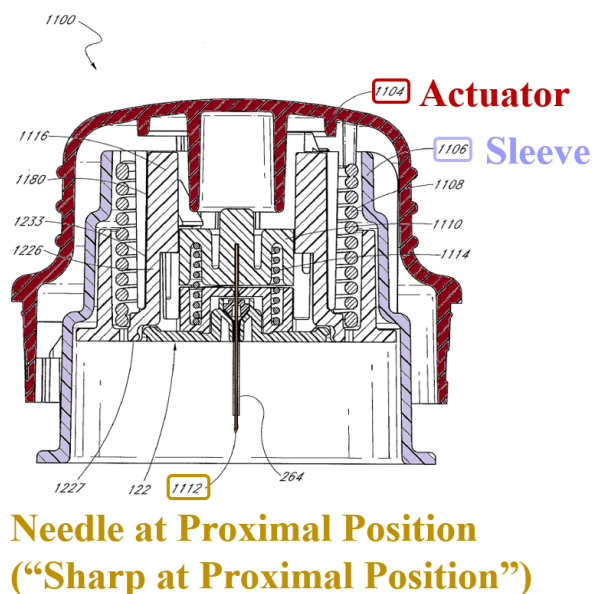
Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body

electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level.” *Id.*, ¶87; *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

Thomas’s on body unit (“on body electronics unit”) includes a sensor coupled to electronics housed in a sensor housing (“on body electronics unit housing”). EX1103, ¶88; EX1109, 19:31-20:29.

As shown below, Raymond’s needle (“sharp,” brown) is disposed entirely within an actuator 1104 (red) and a sleeve 1106 (purple) of Raymond’s insertion device (“inserter”) when Raymond’s sharp is in a proximal position to protect the user from needlesticks. EX1103, ¶89; EX1110, [0127].



Raymond, FIG. 29 (annotated)

As discussed at [1.3], Thomas+Raymond (and Thomas+Raymond+Turner) uses the inserter as taught by Raymond in combination with the sharp like that disclosed in Thomas to advance the on body electronics unit as taught by Thomas and insert the sensor as taught by Thomas. EX1103, ¶90. Since both Thomas 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.*; EX1109, 28:8-10; EX1110, [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. EX1103, ¶90.

Thus, Thomas+Raymond (and Thomas+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.” *Id.*, ¶91; *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.

Thomas discloses a sharp for inserting a glucose sensor. *See, e.g.*, EX1109, 2:13-15. Thomas further discloses an inserter configured to retract the sharp therewithin after use to prevent needlesticks. EX1103, ¶92; EX1109, 28:8-10.

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. EX1103, ¶93; EX1110, FIG. 30, [0127].

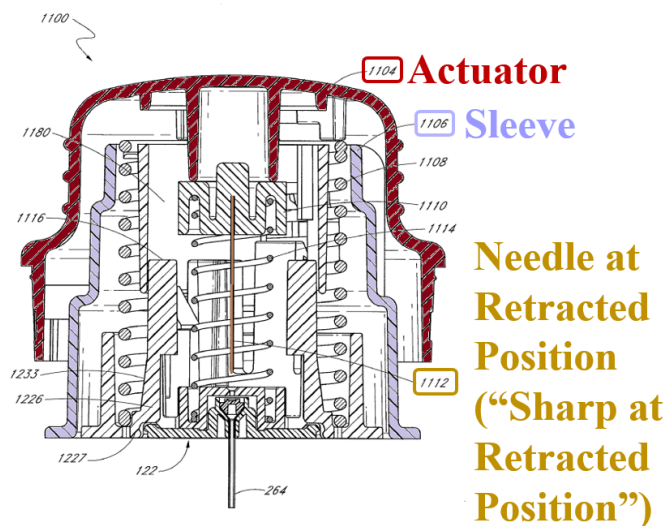


FIG. 30

Raymond, FIG. 30 (annotated)

Thomas+Raymond (and Thomas+Raymond+Turner) includes the inserter as taught by Raymond and a sharp like that disclosed in Thomas. EX1103, ¶94. Based on Thomas's and Raymond's express teachings, the sharp is retracted entirely within

the inserter to cover the sharp. *Id.*; EX1109, 28:3-13; EX1110, [0127]; *see also id.*, [0104], [0109].

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “the inserter ... configured to retract the sharp from the distal position to a retracted position entirely within the inserter.” EX1103, ¶95; *see also* Sections VIII.D, VIII.E.

G. Claim 2

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

As discussed at [1.5] and [3.1], Thomas+Raymond (and Thomas+Raymond+Turner) includes “the inserter ... [comprising] a plurality of gripping arms.” EX1103, ¶97; *supra* Section VIII.F; *infra* Section VIII.H.

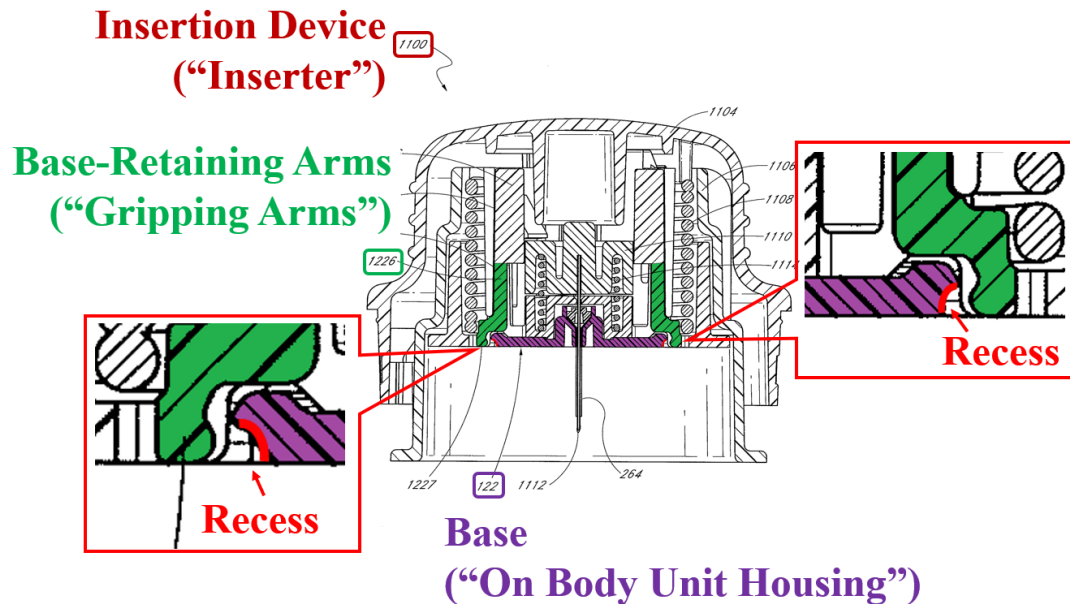
H. Claim 3

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

As shown below, Raymond illustrates a left base-retaining arm (“gripping arm”) correspondingly engaging a left recess and a right gripping arm correspondingly engaging a right recess. EX1110, FIG. 29; *see supra* Section VIII.A. Thus, as discussed at [1.5], a POSITA would have understood that Raymond

at least suggests plural arms engaging corresponding ones of plural recesses.

EX1103, ¶99; *supra* Section VIII.F.



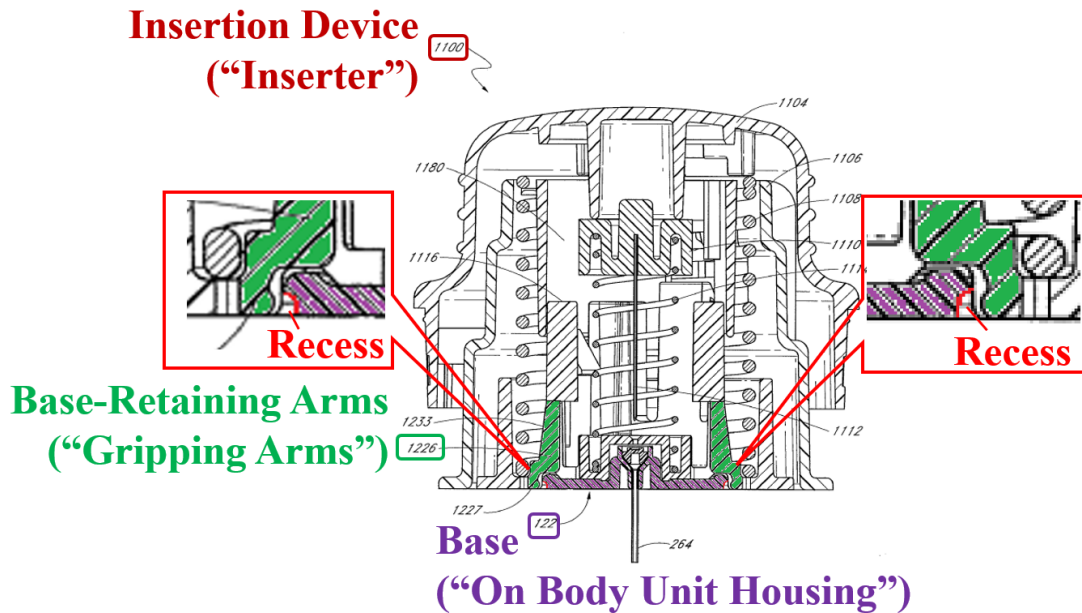
Raymond, FIG. 29 (annotated)

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “the plurality of gripping arms ... [each] configured to be engaged with a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.” EX1103, ¶100.

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

As shown below, each of Raymond’s base-retaining arms (“gripping arms,” green) clears a cam surface and spreads radially outwardly to be disengaged with Raymond’s base’s (“on body unit housing,” purple) recesses by the time the base

reaches the distal position. EX1103, ¶101; EX1110, FIGS. 29-30, [0126]. Thus, each of Raymond's gripping arms are disengaged with a corresponding recess (red) of Raymond's housing when Raymond's on body unit is in the distal position. EX1103, ¶101; EX1110, FIGS. 29-30, [0126].



Raymond, FIG. 30 (annotated)

As discussed at [1.5] and [3.1], Thomas+Raymond (and Thomas+Raymond+Turner) includes the on body electronics unit housing as taught by Thomas and plural recesses formed on the periphery thereof, wherein each of the gripping arms as taught by Raymond (specifically, the base-retaining foot at the tip portion of each one of the arms as taught by Raymond) engage a corresponding recess. EX1103, ¶102; *supra* Section VIII.F. A POSITA would have also understood

that each of the gripping arms disengages a corresponding recess on the housing when the housing is in the distal position. EX1103, ¶102.

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “the plurality of gripping arms ... [each] configured to be disengaged from the corresponding recess of the plurality of recesses when the on body electronics unit is in the distal position.” *Id.*, ¶103.

I. Claim 4

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

As discussed at [3.2], Raymond discloses that each base-retaining arm (“gripping arm”) spreads radially outwards when unconstrained by the sleeve. EX1110, FIGS. 29-30, [0126]; *supra* Section VIII.H. Thomas+Raymond includes the inserter and gripping arms as taught by Raymond. EX1103, ¶105.

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “the plurality of gripping arms ... [each] biased in a radially outward direction.” *Id.*, ¶106.

J. Claim 8

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

The '335 patent does not define “engagement boss” other than to explain that it is the portion of a gripping arm that is “configured to engage with corresponding recesses 3766 provided on the side walls of the on body housing 322.” EX1101, 44:9-12, 45:61-64. Thus, in view of the term’s plain and ordinary meaning read in light of the specification, an “engagement boss” is understood to encompass a “protrusion.” EX1103, ¶108; EX1135, 44 (defining a “boss” as a “[p]rotuberance”).

Raymond discloses a foot (“engagement boss”) on a tip portion of each base-retaining arm (“gripping arm”). EX1110, FIGS. 29-30, [0123]. A POSITA would have understood Raymond to at least suggest that each boss engages a corresponding one of the plural recesses when Raymond’s on body unit is in a proximal position. EX1103, ¶109; EX1110, FIGS. 29-30, [0123]; *supra* Section VIII.F. Thus, it was at least obvious to implement Thomas+Raymond (and Thomas+Raymond+Turner) with plural recesses on an on body electronics unit housing to engage bosses on the tip portions of corresponding ones of gripping arms. EX1103, ¶109; *supra* Section VIII.F

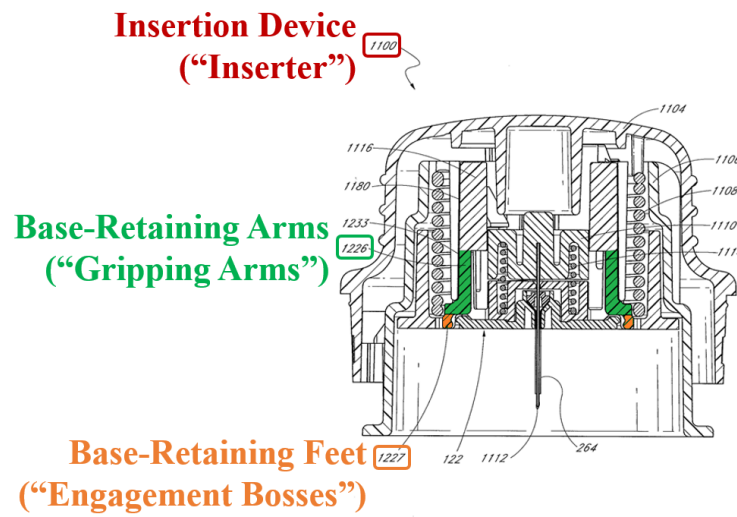
Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “the plurality of gripping arms [each comprising] an engagement boss configured to engage with a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.” EX1103, ¶110.

K. Claim 9

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

Claim 9 is the only place “tip portion” is recited in reference to the gripping arms. EX1103, ¶112. Although the ’335 patent recites “first-angled tip portion” (EX1101, 26:8, 27:4) and “steep-angled tip portion” (*id.*, 26:9, 27:5), these refer to the tip of the sharp. EX1103, ¶112. Thus, since the term “tip portion” is only used with respect to the gripping arms in claim 9, a POSITA would have understood this term to refer to the “end portion of the gripping arm.” *Id.*, ¶112.

As shown below, Raymond discloses a foot (“engagement boss,” orange) on an end portion or tip portion of each base-retaining arm (“gripping arm,” green). EX1110, FIGS. 26-27, 29-30; *see id.*, [0123]. As discussed at claim 8, Thomas+Raymond includes the engagement bosses and gripping arms as taught by Raymond. EX1103, ¶113; *supra* Section VIII.J.



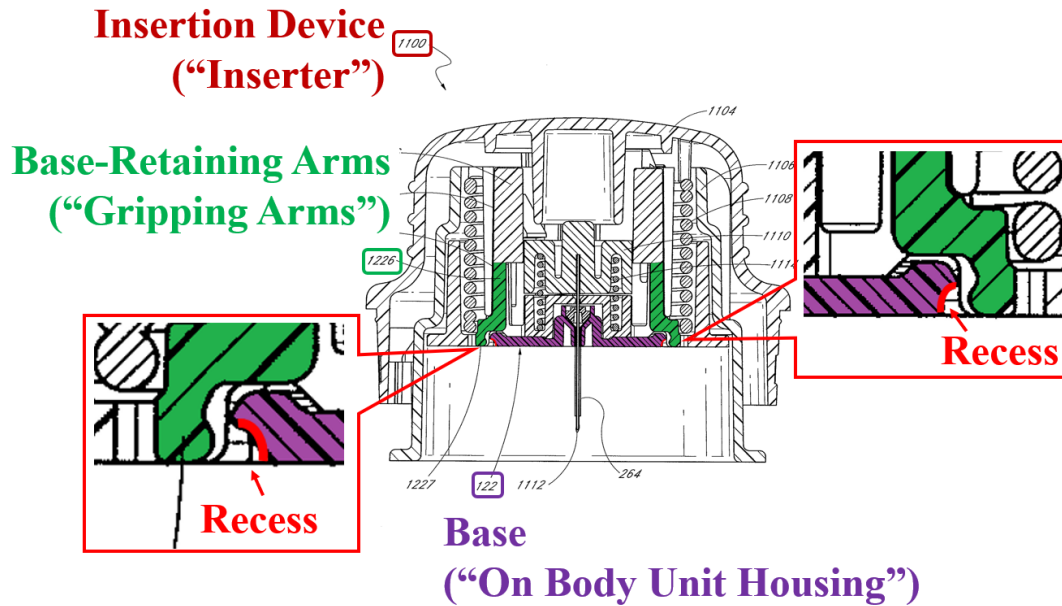
Raymond, FIG. 29 (annotated)

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes an “engagement boss ... disposed on a tip portion of the gripping arm.” EX1103, ¶114.

L. Claim 11

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

As shown below, Raymond illustrates concave left and right recesses (red). EX1110, FIGS. 29-30. As discussed at [1.5], a POSITA would have found it at least obvious to form such recesses on the housing as taught by Thomas. EX1103, ¶116; *supra* Section VIII.F.



Raymond, FIG. 30 (annotated)

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “the plurality of recesses [each comprising] a concave portion.” EX1103, ¶117.

M. Claim 12

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

Thomas discloses a sensor housing (“on body electronics unit housing”). EX1103, ¶119; EX1109, 20:5-7.

As discussed in the figures at [1.5], Raymond discloses recesses disposed on the sidewalls of a base (“on body unit housing”). EX1103, ¶120; EX1110, FIGS. 29-30; *supra* Section VIII.F.

As discussed at [1.5], a POSITA would have found it obvious to form plural recesses on the on body electronics unit housing, wherein the housing is taught by Thomas. EX1103, ¶121; *supra* Section VIII.F. A POSITA would have been motivated by Raymond's disclosure to form the recesses on the sidewalls of the housing. EX1103, ¶121; *see supra* Section VIII.B. Thomas+Raymond (and Thomas+Raymond+Turner) includes the housing as taught by Thomas and the plural recesses on the sidewall thereof as taught by Raymond. EX1103, ¶121.

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “the plurality of recesses ... [each] disposed on a side wall of the on body electronics unit housing.” *Id.*, ¶122.

N. Claim 13

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

As discussed at [1.3], Thomas discloses a sharp for inserting Thomas's sensor into a subject. EX1103, ¶124; *supra* Section VIII.F.

Raymond's retraction spring (“driver”) retracts a needle (“sharp”) after the needle reaches the distal position. EX1103, ¶125; EX1110, FIG. 30, [0127].

Thomas+Raymond (and Thomas+Raymond+Turner) includes the driver as taught by Raymond, which applies a force to retract a sharp like that disclosed in Thomas after the sharp reaches the distal position. EX1103, ¶126.

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “a driver disposed in the inserter, wherein the driver is configured to apply a force that retracts the sharp after the sharp reaches the distal position.” *Id.*, ¶127.

O. Claim 14

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

Raymond discloses a cap removably attached to the distal portion of Raymond’s insertion device (“inserter”). EX1103, ¶129; EX1110, FIG. 18, [0101], [0109]. Thomas+Raymond (and Thomas+Raymond+Turner) includes the inserter and cap as taught by Raymond. EX1103, ¶129.

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “a cap removably attached to a distal portion of the inserter.” *Id.*, ¶130.

P. Claim 15

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

Raymond’s actuator (“housing”) moves downward relative to a sleeve (“sheath”) placed on the subject’s skin. EX1110, FIGS. 29-30, [0124]-[0125]. Thomas+Raymond (and Thomas+Raymond+Turner) includes the inserter, housing, and sheath as taught by Raymond. EX1103, ¶132.

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “an inserter housing and a sheath, ... wherein the inserter housing is configured to move in a downward direction towards a skin surface relative to the sheath in response to an application of force on the inserter housing.” *Id.*, ¶133.

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

Raymond discloses that its sleeve (“sheath”) is pressed against the subject’s skin both before and after force is applied to the actuator (“housing”). EX1110, FIGS. 29-30 (illustrating “sleeve 1106” placed against the subject’s skin before and after actuation), [0124]. As discussed at [15.1], Thomas+Raymond (and Thomas+Raymond+Turner) includes the sheath and housing as taught by Raymond. EX1103, ¶134.

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “the sheath ... configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing.” *Id.*, ¶135.

Q. Claim 16

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

The ’335 patent provides several examples of a sensor hub, all of which encompass a structure positioned within the housing of the on body unit that supports

the portion of the sensor electrically coupled to electrical contacts. *See, e.g.*, EX1101, FIGS. 17, 17A, 148; *id.*, 27:25-49, 46:58-47:4, 47:18-49; EX1103, ¶137.

Thomas's on body unit includes a sensor hub. EX1103, ¶138; EX1109, FIG. 23, 25:25-27 ("As further illustrated in FIGURE 23, electronics 80 (e.g., a printed circuit board containing ASIC electronics) and sensor hub 123 are positioned within sensor housing 122."). Thomas+Raymond (and Thomas+Raymond+Turner) includes the on body electronics unit and sensor hub as taught by Thomas. EX1103, ¶138.

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes "the on body electronics unit ... [comprising] a sensor hub." *Id.*, ¶139.

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

Thomas discloses a sensor "having a proximal section and a distal section." *Id.*, ¶140; EX1109, 5:19-20, 6:3-4.

As discussed at [1.6], Thomas+Raymond (and Thomas+Raymond+Turner) includes the sensor as taught by Thomas. *Supra* Section VIII.F. The sensor as taught by Thomas has distal and proximal sections ("sensor portions"). EX1103, ¶41; EX1109, 5:19-20, 6:3-4; *see supra* Section VIII.A.

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “the glucose sensor [comprising] a distal sensor portion and a proximal sensor portion.” EX1103, ¶142.

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

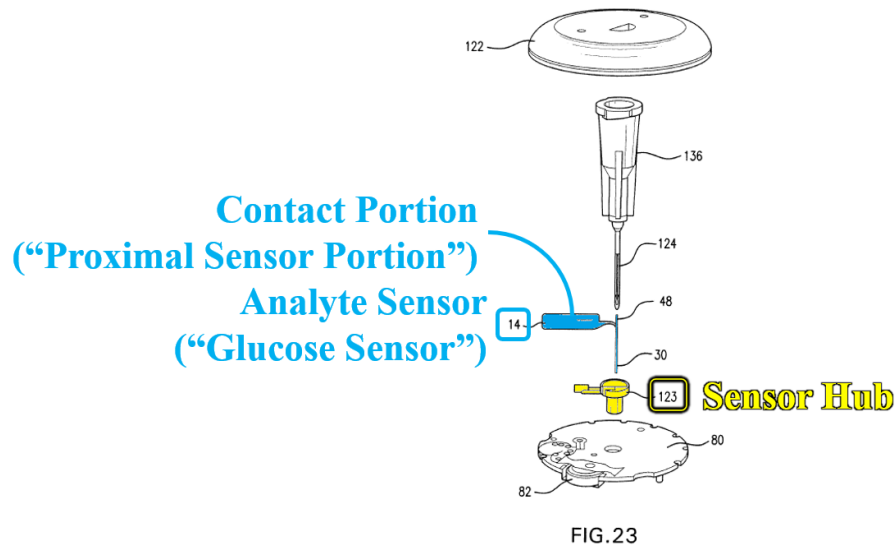
Thomas discloses a sensor whose distal portion (“distal sensor portion”) is configured to sense the glucose level of the subject. EX1103, ¶143; EX1109, 18:27-19:13.

As discussed at [1.6] and [16.2], Thomas+Raymond (and Thomas+Raymond+Turner) includes the sensor as taught by Thomas. *Supra* Section VIII.F. The sensor as taught by Thomas has the distal portion configured to sense the subject’s glucose levels. EX1103, ¶144; EX1109, 18:27-19:13; *see supra* Section VIII.A.

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “the distal sensor portion ... configured to sense the glucose level of the subject.” EX1103, ¶145.

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

As shown in the below exploded view, Thomas’s sensor (blue) includes a contact portion (“proximal sensor portion”) configured to engage the sensor hub (yellow). *Id.*, ¶146; EX1109, FIG. 23.



Thomas, FIG. 23 (annotated)

As discussed at [1.6] and [16.2], Thomas+Raymond (and Thomas+Raymond+Turner) includes the sensor as taught by Thomas. EX1103, ¶147; *supra* Section VIII.F. Furthermore, as discussed at [16.1], Thomas+Raymond (and Thomas+Raymond+Turner) includes the sensor hub as taught by Thomas. EX1103, ¶147.

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “the proximal sensor portion ... engaged with the sensor hub.” *Id.*, ¶148.

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

Thomas discloses a sensor having a distal section (“distal sensor portion”) perpendicular to a proximal section (“proximal sensor portion”). *Id.*, ¶149; EX1109, FIG. 4, 6:25-29.

As discussed at [1.6] and [16.2]-[16.3], Thomas+Raymond (and Thomas+Raymond+Turner) includes the sensor as taught by Thomas, wherein the sensor has orthogonal proximal and distal sensor portions. EX1103, ¶150; EX1109, FIG. 4, 6:25-29; *supra* Sections VIII.A, VIII.F.

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “the distal sensor portion ... substantially orthogonal to the proximal sensor portion.” EX1103, ¶151.

R. Claim 17

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

As shown in the below exploded view, Thomas’s on body unit (“on body electronics unit”) includes electronics (“on body electronics,” pink) and a sharp (“brown”) passing through an aperture (red) thereof. EX1103, ¶153; EX1109, FIG. 23.

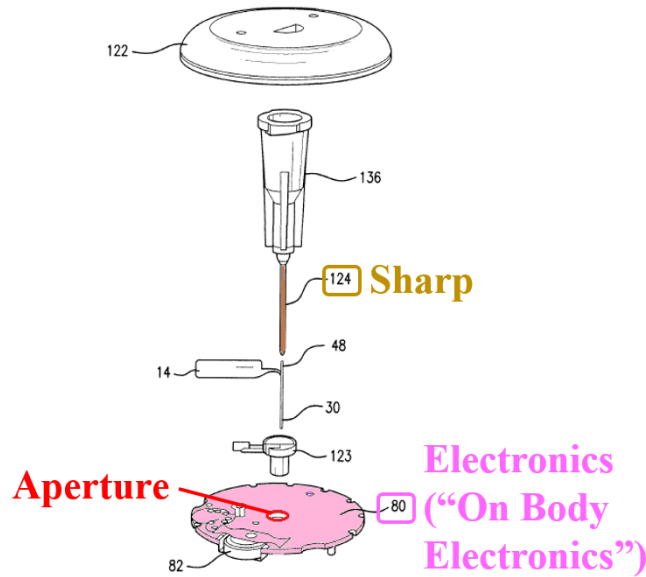


FIG.23

Thomas, FIG. 23 (annotated)

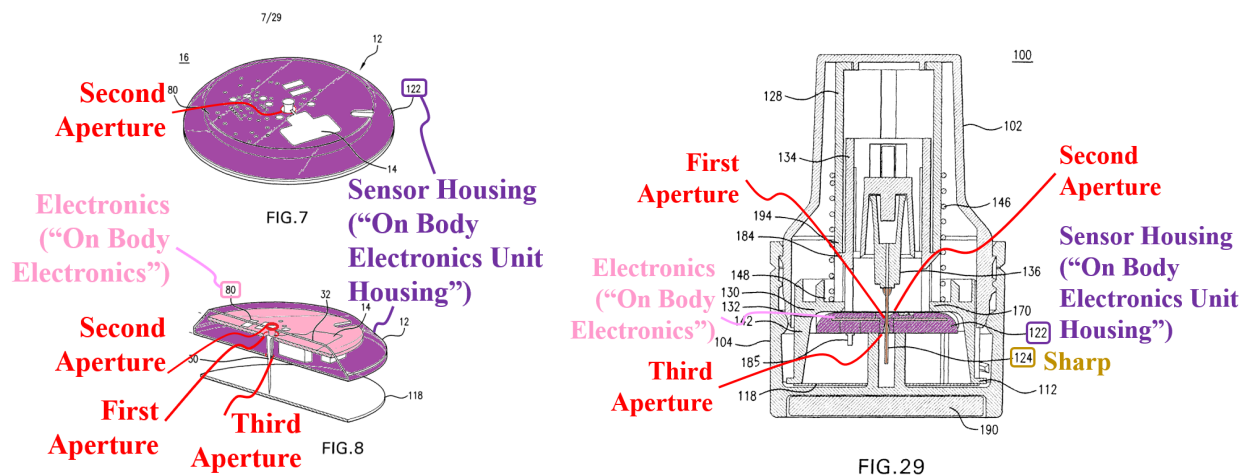
Thomas+Raymond (and Thomas+Raymond+Turner) includes the on body electronics, the aperture in the on body electronics, and the sharp like that disclosed in Thomas. EX1103, ¶154.

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “an aperture, and wherein the sharp extends through the aperture of the on body electronics.” *Id.*, ¶155.

S. Claim 18

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

As shown below and as discussed at claim 17, Thomas's on body unit includes a first aperture (red) in the electronics ("on body electronics," pink). EX1109, FIGS. 8, 23, *supra* Section VIII.R. Thomas describes a second aperture (red) in a top surface of Thomas's housing ("on body electronics housing," purple), and a third aperture (red) in a bottom surface of Thomas's housing. *See, e.g.*, EX1109, FIGS. 7-8, 22-23, 29. Thomas's sharp (brown) extends through the first aperture, second aperture, and third aperture when Thomas's housing is in the proximal position. *Id.*; EX1103, ¶157.



Thomas, FIGS. 7-8, 29 (annotated)

Thomas+Raymond (and Thomas+Raymond+Turner) includes the on body unit ("on body electronics unit") with the first, second, and third apertures as taught by Thomas. EX1103, ¶158. Furthermore, in Thomas+Raymond (and Thomas+Raymond+Turner), based on Thomas's teachings, the on body electronics

unit is retained in the proximal position within the inserter as taught by Raymond such that the sharp like that disclosed in Thomas extends through the first, second, and third apertures. *Id.*

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “the [first] aperture of the on body electronics ... the on body electronics unit housing further [comprising] a top surface and a bottom surface, wherein the top surface comprises a second aperture, wherein the bottom surface comprises a third aperture, and wherein the sharp extends through the first aperture, the second aperture, and the third aperture when the on body electronics unit is in the proximal position.” *Id.*, ¶159.

T. Claim 19

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

Thomas discloses an assembly including an on body unit (“on body electronics unit”) and a sharp. *Id.*, ¶161; *see supra* Section VIII.A.

Raymond discloses an insertion device (“inserter”) including a distal end (*e.g.*, a distal end of sleeve 1106) placed on the subject’s skin before advancement of Raymond’s infusion device (“on body unit”) and needle (“sharp”). EX1103, ¶162; EX1110, FIG. 29, [0124].

Thomas+Raymond (and Thomas+Raymond+Turner) includes the on body electronics unit and sharp as taught by Thomas and the distal end of the inserter as taught by Raymond, wherein the inserter is configured to advance the on body electronics unit and sharp. EX1103, ¶163.

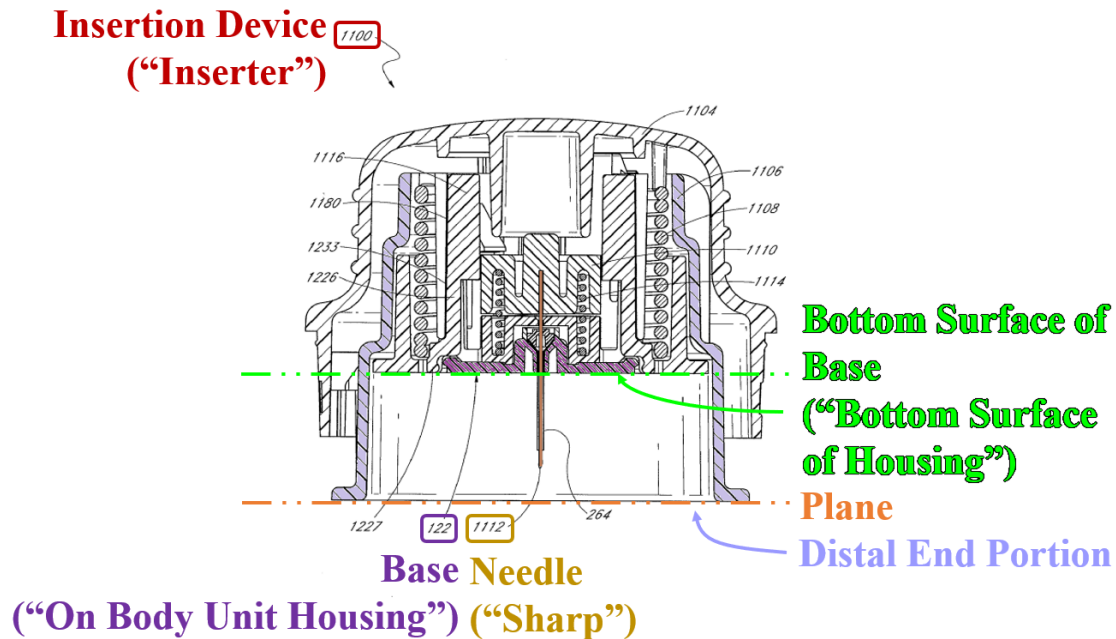
Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “a distal end [of an inserter] configured to be placed on a skin surface of the subject before advancement of the on body electronics unit and the sharp.” *Id.*, ¶164.

U. Claim 20

20. The glucose monitoring assembly of claim 19, wherein the distal end of the inserter defines a plane, and wherein a bottom surface of the on body electronics unit housing is parallel to the plane when the on body electronics unit and the sharp are in the proximal position.

As discussed at claim 18, Thomas discloses a sensor housing (“on body electronics unit housing”) with a bottom surface. EX1103, ¶166; *supra* Section VIII.S. As discussed at [1.3], Thomas discloses a sharp. EX1103, ¶166; *supra* Section VIII.F.

As shown below, Raymond’s insertion device (“inserter”) includes a distal end defining a plane (orange). Furthermore, Raymond’s base (“on body unit housing,” purple) includes a bottom surface parallel (as shown by the green line) to the plane when the housing and a needle (“sharp,” brown) are in a proximal position. EX1103, ¶167.



Raymond, FIG. 29 (annotated)

Thomas+Raymond (and Thomas+Raymond+Turner) includes the distal end of the inserter as taught by Raymond, a sharp like that disclosed in Thomas, and the on body electronics unit housing as taught by Thomas. *Id.*, ¶168. The distal end of the inserter defines a plane parallel to the bottom of the housing when the sharp and housing are in the proximal position. *Id.*

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “the distal end of the inserter [defining] a plane, and wherein a bottom surface of the on body electronics unit housing is parallel to the plane when the on body electronics unit and the sharp are in the proximal position.” *Id.*, ¶169.

V. Claim 21

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

The '335 patent discloses a “no power state” and “inactive mode” as examples of the claimed “low power state.” EX1101, 11:45-49; EX1103, ¶171.

Thomas discloses “maintaining a power source of the analyte monitoring assembly in an inactive state when the analyte monitoring assembly is positioned at or near one of the first position or the second position.” EX1109, claim 73. Furthermore, Thomas discloses that the sensor electronics assembly (“on body electronics”) may be in a “sleep” or “idle” mode before activation. EX1109, 28:14-16. Finally, Thomas discloses that the on body electronics are “switch[ed] on” by closing a circuit between the on body electronics and a power supply when the insertion device (“inserter”) is actuated. *Id.*, FIGS. 32-43, 4:3-6, 20:14-16, 28:22-25, 28:26-29:9, 29:10-30:7, 30:18-32:32 . Thus, since Thomas discloses that the on body electronics are “inactive,” “idle,” and/or “switched off” prior to delivery, Thomas also discloses the “low power” state. EX1103, ¶172.

As discussed at [1.8], the on body electronics unit as taught by Thomas is retained in the proximal position within the inserter as taught by Raymond in Thomas+Raymond (and Thomas+Raymond+Turner). EX1103, ¶173; *supra* Section VIII.F.

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “at least a portion of the on body electronics ... in a low power state when the on body electronics unit is in the proximal position.” EX1103, ¶174.

W. Claim 22

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

Thomas discloses, “[t]he sensor assembly of claim 40, further comprising an adhesive layer disposed on the skin of the subject, and wherein the member is moved from the first position to the second position when the mount contacts the adhesive layer.” EX1103, ¶176; EX1109, claim 44; *see also* 3:33-4:2, 27:31-33, 28:29-31 claims 71, 94, 95.

Thomas+Raymond (and Thomas+Raymond+Turner) includes the adhesive layer (“adhesive portion”) as taught by Thomas. EX1103, ¶177.

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “an adhesive portion configured to secure the on body electronics unit housing to a skin surface of the subject.” *Id.*, 178.

X. Claim 23

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

The “no power state” of claim 23 would have been obvious for the reasons discussed at claim 21. EX1103, ¶180; *see supra* Section VIII.V.

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “at least a portion of the on body electronics ... in a no power state when the on body electronics unit is in the proximal position.” EX1103, ¶181.

Y. Claim 24

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

The “inactive mode” of claim 24 would have been obvious for the reasons discussed at claim 21. EX1103, ¶183; *see supra* Section VIII.V.

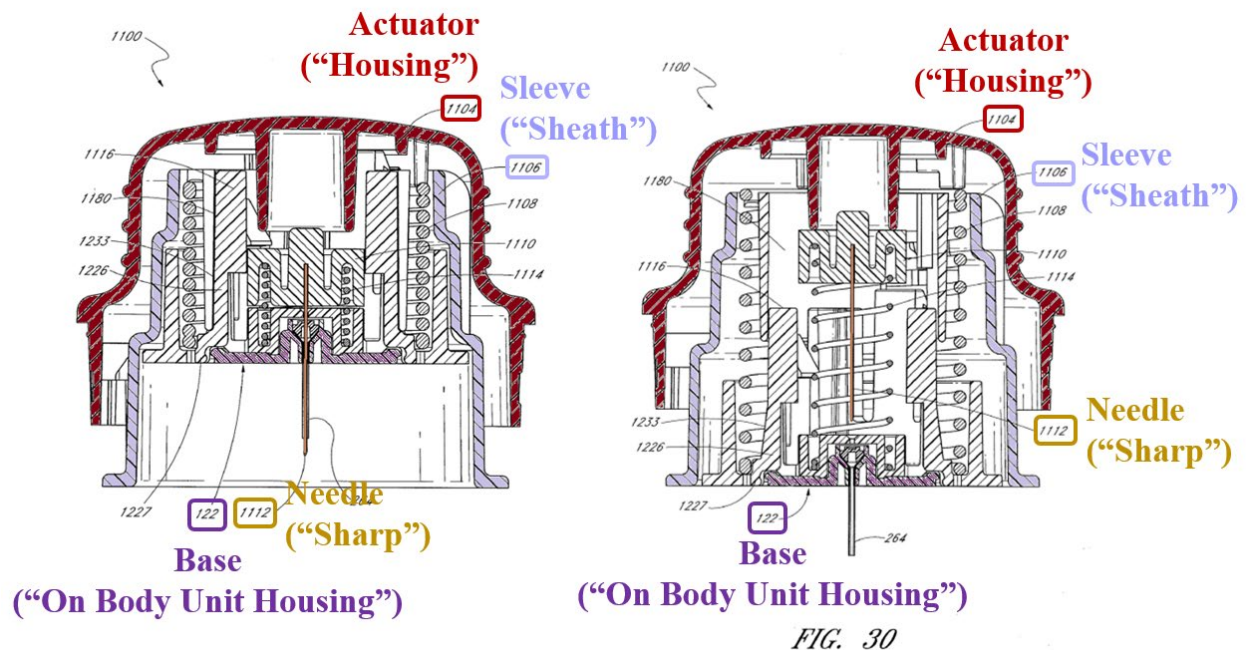
Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “at least a portion of the on body electronics ... in an inactive mode when the on body electronics unit is in the proximal position.” EX1103, ¶184.

Z. Claim 25

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

Thomas discloses an assembly including an on body unit (“on body electronics unit”) and a sharp. EX1103, ¶186; *see supra* Section VIII.A.

As shown below, Raymond discloses an infusion set (“on body unit”) and a needle (“sharp,” brown), both of which linearly advance from a proximal position (FIG. 29) within an actuator (red) and sleeve (light purple) of Raymond’s insertion device (“inserter”) to a distal position (FIG. 30). EX1103, ¶187; EX1110, FIGS. 29-30.



Raymond, FIGS. 29-30 (annotated)

In Thomas+Raymond (and Thomas+Raymond+Turner), the inserter as taught by Raymond linearly advances the on body electronics unit as taught by Thomas and a sharp like that disclosed in Thomas between proximal and distal positions. EX1103, ¶188.

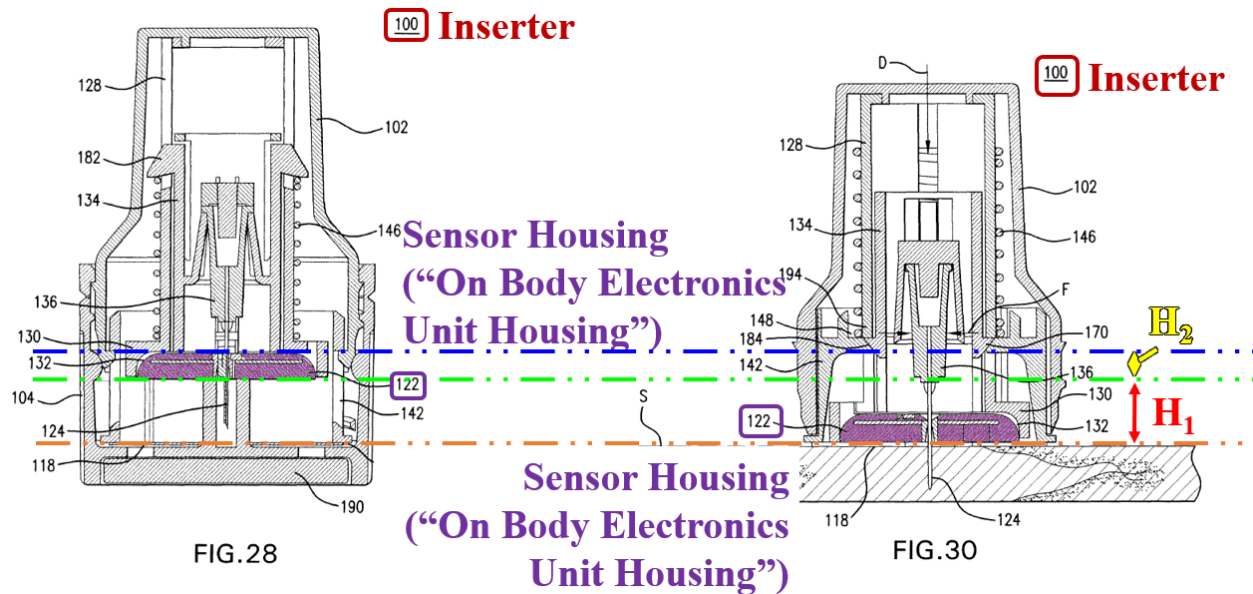
Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “the on body electronics unit and the sharp ... configured to advance in a linear direction when advancing from the proximal position within the inserter to the distal position.”

Id., ¶189

AA. Claim 26

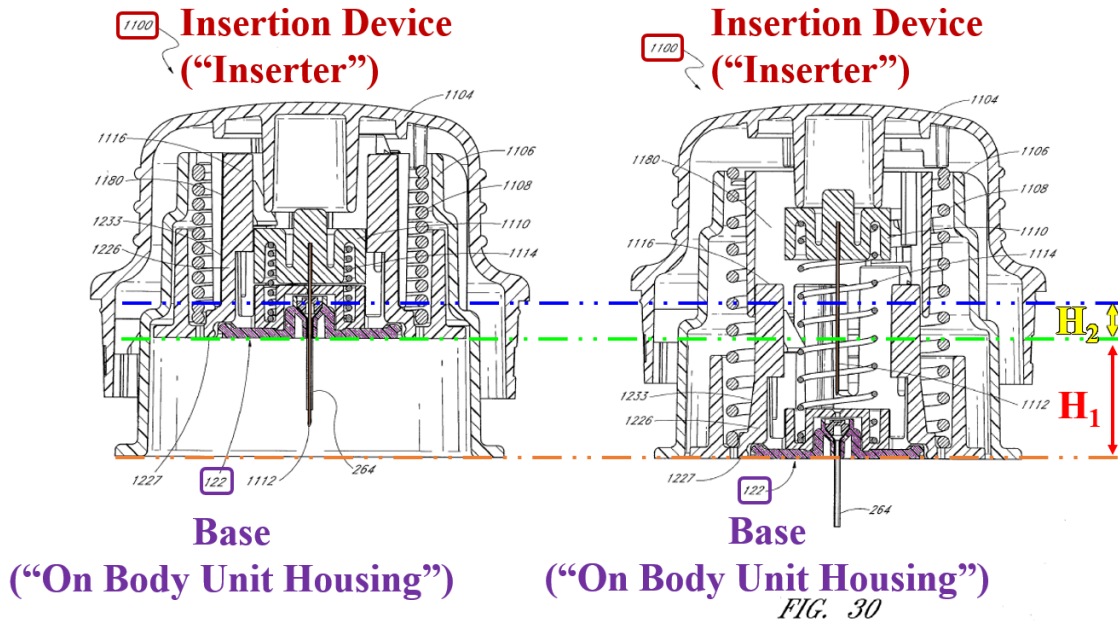
26. The glucose monitoring assembly of claim 1, wherein a distance between the on body electronics unit housing when the on body electronics unit is in the proximal position and the on body electronics unit housing when the on body electronics unit is in the distal position is greater than a maximum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

As shown below, Thomas discloses that a distance (“H₁,” red, between the green and orange lines) between a sensor housing (“on body electronics unit housing,” purple) in a proximal position (FIG. 28) and the housing in a distal position (FIG. 30) is greater than a maximum height (“H₂,” yellow, between the blue and green lines) of the housing. EX1109, FIGS. 28, 30. Since Thomas’s drawings clearly illustrate the relationship between travel distance and housing height, Thomas discloses this limitation. EX1103, ¶191; *see In re Aslanian*, 590 F.2d at 914 (quoting *In re Baum*, 374 F.2d at 1009).



Thomas, FIGS. 28, 30 (annotated)

As shown below, Raymond also discloses this limitation because Raymond's drawings clearly illustrate the relationship between travel distance and housing height. EX1103, ¶192; EX1110, FIGS. 29-30; see *In re Aslanian*, 590 F.2d at 914 (quoting *In re Baum*, 374 F.2d at 1009).



Raymond, FIGS. 29-30 (annotated)

Based on both Thomas's and Raymond's teachings, a POSITA would have configured the travel distance of the on body electronics unit as taught by Thomas to be greater than the height of the on body electronics unit housing as taught by Thomas. EX1103, ¶193.

Thomas's and Raymond's disclosure of these relative dimensions is at least equivalent to what is described in the '335 patent. *Id.*, ¶194; compare, EX1101, FIGS. 123-125 with EX1109, FIGS. 28, 30; EX1110, FIGS. 29-30. In particular, the '335 patent's specification neither describes a distance between the housing when the on body electronics unit is in a proximal position and when the on body electronics unit is in a distal position nor that this distance of travel is greater than the housing's height. EX1103, ¶194.

Raymond teaches that the inserter is designed protect the sharp “both before and after insertion ... to prevent accidental needle sticks.” EX1110, [0127]. Based on these teachings, a POSITA would have recognized that a greater distance H_1 relative to height H_2 provides protection against needlesticks before insertion and ensures automatic retraction of the sharp into the inserter. EX1103, ¶195.

Even without Raymond’s express teachings, it was an obvious design choice to configure Thomas+Raymond (and Thomas+Raymond+Turner) such that the on body electronics unit’s travel distance is greater than the housing’s height. EX1103, ¶196. It was known to implement glucose sensors that were longer than the housing’s height. *Id.*; *see, e.g.*, EX1114, FIG. 1A, [0034]; EX1128, 8:53-55, 16:3-5, 17:10-12. A POSITA would have understood that a longer sensor would also ensure contact with sub-dermal fluids and provide better glucose readings. EX1103, ¶196. Thus, it was a natural design choice to implement a sensor with a subcutaneous portion at least as long as the housing’s height. *Id.*

Furthermore, a POSITA would have been motivated to configure the *in vivo* portion of the sharp to have a length greater than the length of the glucose sensor’s *in vivo* portion to ensure sufficient protection of the sensor during insertion. *Id.*, ¶197. Additionally, as taught by both Thomas and Raymond, a POSITA would have configured the travel distance of the *in vivo* portion of the sharp and the housing fixedly coupled thereto to be greater than the length of the corresponding portion of

the sharp to ensure that the sharp is protected before insertion to prevent against needlesticks. *Id.*; EX1109, 24:18-20; EX1110, [0127]; *see also id.*, [0104], [0109].

This obvious implementation of the on-body electronics unit (with the length of the *in vivo* sensor portion greater than the height of the low-profile housing) and the inserter device (with the needle extending past the end of the sensor and the needle point withdrawn from the edge of the inserter prior to insertion) would result in a travel distance H_1 greater than the height of the housing H_2 . EX1103, ¶198.

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) at least renders obvious “a distance between the on body electronics unit housing when the on body electronics unit is in the proximal position and the on body electronics unit housing when the on body electronics unit is in the distal position [that] is greater than a maximum height of the on body electronics unit housing.” *Id.*, ¶199.

BB. Claim 27

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

As discussed at claim 25, Raymond’s needle (“sharp”) advances in a linear direction perpendicular to the subject’s skin surface. EX1110, FIGS. 29-30; *supra* Section VIII.Z. Thomas+Raymond (and Thomas+Raymond+Turner) includes the inserter as taught by Raymond and a sharp like that disclosed in Thomas that advances in the same linear direction to pierce the subject’s skin. EX1103, ¶201.

Thus, Thomas+Raymond (and Thomas+Raymond+Turner) includes “the sharp ... further configured to pierce a skin surface of the subject at an angle substantially perpendicular to the skin surface of the subject.” *Id.*, ¶202.

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

Respectfully submitted,

Dated: October 6, 2023

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

This brief complies with the type-volume limitation of 37 C.F.R. § 42.24(a)(1)(i).

The brief contains 13,161 words, excluding the parts of the brief exempted by 37 C.F.R. § 42.24(a).

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CERTIFICATE OF SERVICE
IN COMPLIANCE WITH 37 C.F.R. § 42.6(e)(4)

The undersigned certifies that the **Petition for *Inter Partes* Review of U.S. Patent No. 11,266,335 and Exhibits 1101-1112, 1114, 1118, 1128, 1135, 1139-1144, 1157, 1165-1166** were served on October 6 2023, via **Express Mail** on the Patent Owner at the following address of record as listed on the USPTO Patent Center:

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