

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Abbott Diabetes Care Inc.
Petitioner,

v.

DexCom, Inc.,
Patent Owner.

Case No. IPR2024-00859
Patent No. 11,510,625

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO.
11,510,625
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *et seq.***

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LIST OF EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 11,510,625 (the “’625 patent”)
1002	File History for U.S. Patent No. 11,510,625
1003	Blank
1004	Declaration of Cameron Riviere, Ph.D.
1005	Curriculum Vitae of Cameron Riviere, Ph.D.
1006	U.S. Patent Publication No. 2013/0150691 (Pace)
1007	U.S. Patent Publication No. 2016/0331284 (Pace 2)
1008	U.S. Patent Publication No. 2020/0178899 (Chae)
1009	Korean Patent Application No. 10-2017-0068964
1010	Certified English Translation of Korean Patent Application No. 10-2017-0068964
1011	U.S. Patent Publication No. 2014/0188053 (Lundquist)
1012	Blank
1013	Blank
1014	U.S. Pat. No. 6,175,752 (Say)
1015	Neil Sclater and Nicholas P. Chironis, <i>Mechanisms and Mechanical Devices Sourcebook</i> (4th ed. McGraw-Hill, 2007)
1016	M. A. Meltsner, et al., <i>Observations on rotating needle insertions using a brachytherapy robot</i> , 52 <i>Physics in Medicine and Biology</i> 6027-6037 (2007)
1017	Ryosuke Tsumura, et al., <i>Histological evaluation of tissue damage caused by rotational needle insertion</i> , Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 5120-5123 (2016)
1018	<i>Abbott Diabetes Care Inc. et al. v. DexCom, Inc.</i> , No. 1:23-cv-00239, Dkt. 54 (D. Del. Sept. 19, 2023)

I. INTRODUCTION

Since the advent of the first transdermal implantable glucose sensors in 1999, makers of continuous glucose monitoring (CGM) systems have had to address numerous engineering challenges relating to these wearable medical devices. One of those challenges is to limit unwanted rotation of the needle used to partially implant the glucose sensor in the patient.

The claims of U.S. Patent No. 11,510,625 (the “’625 patent”) purport to address this challenge. For example, independent claim 1 recites, in pertinent part, an “anti-rotation feature ... configured to prevent rotation of [a] needle hub within [an] aperture [of an on-skin sensor assembly].” As set forth in detail below, however, the claimed “anti-rotation feature,” along with all of the other claimed limitations of the ’625 patent, were disclosed long ago in the prior art, including several of Petitioner’s patent publications.

Accordingly, Abbott Diabetes Care Inc. (“Petitioner”) petitions for *inter partes* review seeking cancellation of claims 1-9, 13-19, and 22-30 (“Challenged Claims”) of the ’625 patent.

II. STANDING, MANDATORY NOTICES, AND FEE AUTHORIZATION

A. Grounds for Standing

Pursuant to 37 C.F.R. §42.104 (a), Petitioner certifies that the ’625 patent is available for *inter partes* review and that Petitioner is not barred or estopped from

requesting *inter partes* review based on the grounds identified in this petition.

B. Real Party In Interest

Petitioner certifies that the real parties-in-interest of this Petition are Abbott Diabetes Care Inc., Abbott Diabetes Care Sales Corp., and Abbott Laboratories. Abbott Diabetes Care Inc. is the Petitioner. Abbott Diabetes Care Inc. is directly owned by Abbott Laboratories. Abbott Diabetes Care Inc. directly owns Abbott Diabetes Care Sales Corp.

C. Related Matters

The '625 patent is asserted against Abbott Diabetes Care Inc. and Abbott Diabetes Care Sales Corp. as a counterclaim for infringement in *Abbott Diabetes Care Inc. et al. v. DexCom, Inc.*, No. 1:23-cv-00239 (D. Del). DexCom, Inc. ("Patent Owner" or "DexCom") asserted the '625 patent in its Answer, Affirmative Defenses, and Counterclaims, electronically served on Petitioner Abbott Diabetes Care Inc. on May 12, 2023, and hand-served on Abbott Diabetes Care Sales Corp. on May 15, 2023. Petitioner asserts that the '625 patent is not infringed.

D. Lead And Back-Up Counsel

Petitioner designates the following counsel:

Lead Counsel	Back-Up Counsel
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Pursuant to 37 C.F.R. §42.10 (b), Petitioner has filed a power of attorney with the above designation of counsel.

E. Service Information

Please address correspondence to counsel at the address above. Petitioner consents to electronic service to: Abbott-IPR@cov.com and the email addresses listed above. Service information is provided in the designation of counsel above.

F. Fee Authorization

This Petition is accompanied by the fees set forth in 37 C.F.R. §42.15(a). Please charge or credit Deposit Account No. 60-3160 with any shortage or overpayment of fees associated with this Petition and any other fees incurred by Petitioner.

III. SUMMARY OF CHALLENGE

Petitioner challenges claims 1-9, 13-19, 22-30 of the '625 patent and requests these claims be found unpatentable in view of the following references:

- (1) U.S. Patent App. Pub. No. US 2013/0150691 (“Pace”) (Ex-1006);
- (2) U.S. Patent App. Pub. No. US 2016/0331284 (“Pace 2”) (Ex-1007);
- (3) U.S. Patent App. Pub. No. US 2020/0178899 (“Chae”) (Ex-1008); and
- (4) U.S. Patent App. Pub. No. US 2014/0188053 (“Lundquist”) (Ex-1011)

Petitioner asserts the following grounds of unpatentability under 35 U.S.C. §§102 and 103 (AIA):

Ground	Reference(s)	Statutory Basis	Challenged Claims
1	Pace	§§102, 103	1-9, 13-19, 22-30
2	Pace & Lundquist	§103	4-5, 14-15, 26-27, 30
3	Pace 2	§103	1-3, 6-9, 13, 16-19, 22-25, 28-29
4	Pace 2 & Lundquist	§103	4-5, 14-15, 26-27, 30
5	Chae	§103	1-3, 6, 9, 13, 16, 22-24

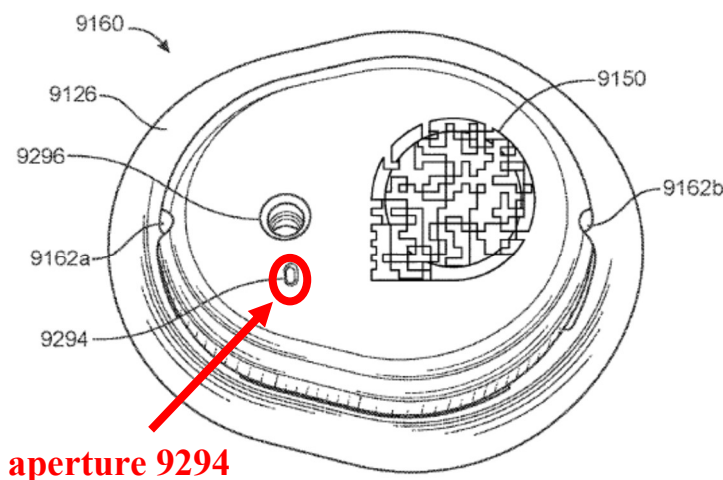
This Petition is accompanied by the declaration of Cameron Riviere, Ph.D., an expert in orienting needles in medical devices. Ex-1004.

IV. THE '625 PATENT

A. Overview Of The '625 Patent

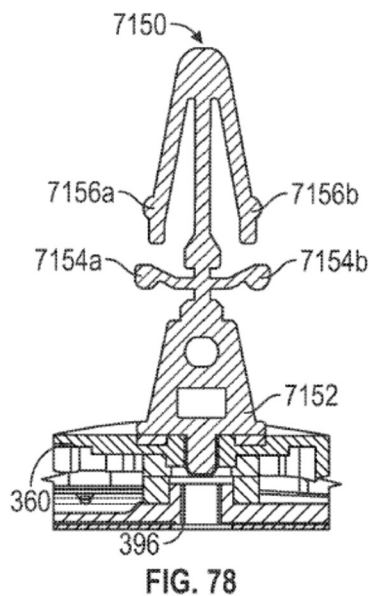
The '625 patent relates to “systems and methods for measuring an analyte in a host,” including a “transcutaneous analyte measurement system.” Ex-1001, 2:10-14. The '625 patent acknowledges that such systems were in the prior art. *Id.*, 19:55-20:8.

While the '625 patent describes multiple CGM applicator embodiments for applying an on-skin sensor assembly, there is scarce disclosure, beyond mere functional description, of structures constituting an “anti-rotation feature” or “key” to prevent rotation of a needle hub within an aperture of an on-skin sensor assembly. For example, for Figure 91, the specification describes an aperture 9294 in the on-skin sensor assembly that is “configured to” engage with an anti-rotation feature “such as base 7152 of needle hub 7150”:



Id., Fig. 91 (annotated¹); 25:40-46.

The specification calls “base 7152 of needle hub 7150” in Figure 78 “an anti-rotational feature,” *id.*, 25:45-46, but does not identify any particular structures that would prevent rotation. Completely lacking is any explanation of how the base 7152 would interact with the aperture 9294 of Figure 91:



Id., Fig. 78; *see also id.*, 68:41-56. The '625 patent therefore offers little guidance as to what constitutes the claimed “anti-rotation feature” or “anti-rotation key.”

B. Prosecution History

The '625 patent was filed with one claim as U.S. Application No. 17/592,170 on February 3, 2022, in a chain of continuation applications first filed on June 22, 2018, claiming priority to two provisional applications. Ex-1001, 1-2. On March 2,

¹ Color annotations in Figures added throughout unless otherwise noted.

2022, DexCom filed three IDSs listing over 500 references. Ex-1002, 289-373. On April 13, 2022, the Examiner issued an Office Action rejecting the sole claim as anticipated by U.S. Patent No. 6,248,067, as well as for double-patenting over nine co-pending DexCom applications. *Id.*, 379-385.

On May 13, 2022, DexCom filed an amendment cancelling original claim 1 and adding 22 new claims. *Id.*, 481-488. Six days later, DexCom filed a “supplemental” amendment adding 9 more new claims. *Id.*, 512-521. Less than one month later, on June 2, 2022, the Examiner allowed all pending claims. *Id.*, 522-536.

C. Claim Listing

1. Claim 1

1.P	An applicator for applying an on-skin sensor assembly to a skin of a host, the applicator comprising:
1.1	an applicator housing having an internal volume;
1.2	a needle hub coupled to an insertion element configured to pierce a skin of a host, the needle hub comprising:
1.3	a base, and
1.4	an anti-rotation feature extending from the base,
1.5	the anti-rotation feature comprising a key, the key having a first shape;
1.6	and an on-skin sensor assembly comprising:
1.7	a sensor, the sensor configured to measure a glucose concentration of a host, and
1.8	an aperture extending from a top surface of the on-skin sensor assembly,
1.9	the aperture having a second shape, the second shape complementary to the first shape of the key; and
1.10	wherein the key of the anti-rotation feature is configured to be at least partially disposed in the aperture of the on-skin sensor assembly;
1.11	wherein the anti-rotation feature is configured to prevent rotation of the needle hub within the aperture.

2. Claim 2

2	The applicator of claim 1, wherein the insertion element comprises an open side configured to receive the sensor.
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3. Claim 3

3	The applicator of claim 2, wherein the insertion element has a C-shaped, U-shaped, or V-shaped cross section.
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4. Claim 4

4	The applicator of claim 1, wherein the needle hub is coupled to the insertion element by heat staking, snap-fit, friction-fit, clamshell, or insert molding.
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5. Claim 5

5	The applicator of claim 4, wherein the insertion element comprises a locking element configured to couple the insertion element to the needle hub by insert molding.
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6. Claim 6

6	The applicator of claim 1, wherein the on-skin sensor assembly comprises an electronics unit.
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7. Claim 7

7	The applicator of claim 6, wherein the electronics unit includes a power source, signal processing components, data storage components, and a communication module.
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8. Claim 8

8	The applicator of claim 7, wherein the sensor is connected to the electronics unit in the applicator housing.
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9. Claim 9

9	The applicator of claim 1, wherein the on-skin sensor assembly includes an adhesive patch configured to secure the on-skin sensor assembly to the skin of the host.
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10. Claim 13

13.P	An applicator for applying an on-skin sensor assembly to a skin of a host, the applicator comprising:
13.1	an applicator housing having an internal volume;
13.2	a needle hub coupled to a needle,
13.3	wherein the needle comprises a portion configured to extend through the skin of the host,
13.4	wherein the needle hub comprises a base,
13.5	wherein the base comprises an anti-rotation key, wherein the anti-rotation key has a first shape;
13.6	and an on-skin sensor assembly comprising:
13.7	a sensor configured to measure a glucose concentration of a host;
13.8	and an aperture extending from a top surface of the on-skin sensor assembly,
13.9	wherein the aperture has a second shape, wherein the second shape is complementary to the first shape of the anti-rotation key;
13.10	and wherein the anti-rotation key is configured to be at least partially disposed in the aperture of the on-skin assembly;
13.11	and wherein the anti-rotation key is configured to prevent rotation of the needle hub with respect to the on-skin sensor assembly.

11. Claim 14

14	The applicator of claim 13, wherein the needle hub is coupled to the needle by heat staking, snap-fit, friction-fit, clamshell or insert molding.
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12. Claim 15

15	The applicator of claim 14, wherein the needle comprises a locking element configured to couple the needle to the needle hub by insert molding.
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13. Claim 16

16	The applicator of claim 13, wherein the on-skin sensor assembly comprises sensor electronics.
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14. Claim 17

17	The applicator of claim 16, wherein the sensor electronics includes a power source, signal processing components, data storage components, and a communication module.
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15. Claim 18

18	The applicator of claim 17, wherein the sensor is connected to the sensor electronics in the applicator housing.
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16. Claim 19

19	The applicator of claim 16, wherein the needle is configured to be inserted through the sensor electronics.
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17. Claim 22

22.P	A needle hub for applying an on-skin sensor assembly to a skin of a host, the needle hub comprising:
22.1	a base comprising an anti-rotation key,
22.2	the anti-rotation key configured to be at least partially disposed in an aperture of an on-skin sensor assembly,
22.3	wherein the needle hub is configured to couple with an insertion element; and
22.4	wherein the base comprises a flat surface configured to mate with a top surface of the on-skin sensor assembly, thereby maintaining the insertion element in a substantially perpendicular orientation to the top surface of the on-skin sensor assembly.

18. Claim 23

23	The needle hub of claim 22, wherein the anti-rotation key is configured to prevent rotation of the base within the aperture.
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19. Claim 24

24	The needle hub of claim 22, wherein the anti-rotation key has a shape complementary to at least a portion of the aperture.
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20. Claim 25

25	The needle hub of claim 22, wherein the insertion element comprises an open side configured to receive a sensor of the on-skin sensor assembly.
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21. Claim 26

26	The needle hub of claim 22, wherein the needle hub is coupled to the insertion element by heat staking, snap-fit, friction-fit, clamshell, or insert molding.
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22. Claim 27

27	The needle hub of claim 26, wherein the insertion element comprises a locking element configured to couple the insertion element to the needle hub by insert molding.
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23. Claim 28

28.P	An applicator for applying an on-skin sensor assembly to a skin of a host, the applicator comprising:
28.1	an applicator housing having an internal volume;
28.2	a needle hub coupled to a needle configured to pierce a skin of a host, the needle hub comprising:
28.3	a base, and

28.4	an anti-rotation feature extending from the base,
28.5	the anti-rotation feature comprising a key, the key having a first shape; and
28.6	an on-skin sensor assembly comprising:
28.7	a sensor, the sensor configured to measure a glucose concentration of a host;
28.8	an aperture extending from a top surface of the on-skin sensor assembly,
28.9	the aperture having a second shape, the second shape complementary to the first shape of the key, and
28.10	sensor electronics operably connected to the sensor in the applicator housing;
28.11	wherein the key of the anti-rotation feature is configured to be at least partially disposed in the aperture of the on-skin sensor assembly;
28.12	wherein the anti-rotation feature is configured to prevent rotation of the base within the aperture; and
28.13	wherein the needle is configured to be inserted through at least a portion of the sensor electronics.

24. Claim 29

29	The applicator of claim 28, wherein the sensor electronics includes a power source, signal processing components, data storage components, and a communication module.
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25. Claim 30

30	The applicator of claim 28, wherein the needle hub is coupled to the needle by heat staking, snap-fit, friction-fit, clamshell, or insert molding.
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D. Effective Filing Date Of The '625 Patent

The '625 patent claims priority to U.S. Provisional Application Nos. 62/658,486, filed on April 16, 2018, and 62/524,247, filed on June 23, 2017. Ex-1001, 1-2. For this Petition only, and without conceding that the '625 patent is entitled to the benefit of the earliest claimed priority date, Petitioner applies June 23, 2017, as the '625 patent's effective filing date.²

V. LEVEL OF ORDINARY SKILL IN THE ART

A POSITA as of the claimed priority date would have had a Bachelor's degree in mechanical or biomedical engineering (or a related or equivalent field) and two or more years of experience researching, developing, designing and/or evaluating medical devices utilizing needles or sharps, or equivalent experience. A person with less or different education but more relevant practical experience, or vice versa, may also meet this standard. The prior art also evidences the level of skill in the art. Ex-1004, ¶35.

VI. CLAIM CONSTRUCTION

In IPR proceedings, claims are construed in accordance with their "ordinary and customary meaning" in light of the specification. 37 C.F.R. §42.100(b); *see Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005). For purposes of

² In concurrently-filed IPR2024-00860, Petitioner asserts that the claims of the '625 patent are not entitled to the filing date of Application No. 62/524,247.

this petition, other than as discussed below, Petitioner does not believe that any specialized constructions are necessary. Petitioner reserves the right to dispute in a different forum whether the Challenged Claims meet the requirements under 35 U.S.C. §§101 or 112.

A. “[B]y heat staking, snap-fit, friction-fit, clamshell[,] or insert molding” (claims 4, 14, 26, 30) And “[B]y insert molding” (Claims 5, 15, 27)

Claims 4, 14, 26, and 30 each recite that “the needle hub is coupled to the [insertion element/needle] by heat staking, snap-fit, friction-fit, clamshell[,] or insert molding.” In addition, claims 5, 15, and 27 each further require a “locking element” configured to couple the needle to the needle hub “by insert molding.” The recited alternatives merely describe different methods by which the insertion element/needle or “locking element” thereof is physically coupled to the needle hub, not any significant structural differences. Accordingly, the phrases “by heat staking, snap-fit, friction-fit, clamshell[,] or insert molding” and “by insert molding” should be construed as product-by-process limitations.

“If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985). Notably, the ’625 patent does not suggest that the claimed molding methods are novel or non-obvious. Indeed, these alternatives are only mentioned in passing (Ex-

1001, 69:17-32), presuming a POSITA was familiar with these well-known methods. Furthermore, there is no indication that the different methods of coupling the needle to the needle hub recited in the claim would result in *any* structural differences.

VII. OVERVIEW OF THE PRIOR ART

A. Pace (Ex-1006)

U.S. Patent Publication No. 2013/0150691, titled “Analyte Sensor Devices, Connections and Methods,” to Pace et al. (“Pace”) was filed on December 11, 2012, and published on June 13, 2013. Ex-1006, Cover. Accordingly, Pace qualifies as prior art under at least 35 U.S.C. §§102(a)(1) and (a)(2) (AIA). Pace was listed in an IDS along with hundreds of references during prosecution of the ’625 patent, but the Examiner never cited or discussed Pace in any rejection.

Pace discloses multiple CGM applicators with on-body devices. In each embodiment, a glucose sensor mates with an electronics assembly inside the applicator prior to use, forming a complete on-body device (*i.e.*, the claimed “on-skin sensor assembly”). A first embodiment (“embodiment A”) is depicted in Figures 21A-C (below). In this embodiment, “a sensor assembly gripper 2106, with a light snap fit, grabs and orients the sensor assembly 2104 for connection to the electronics assembly 2102” as part of the “mating” process to form the on-body device. Ex-1006, [0123]. The sensor assembly gripper features may be “incorporated” in a “sharp hub.” *Id.* As shown in Figures 21A-21C, the base

(annotated in green) of the sharp hub/gripper 2106 (annotated in blue) has an anti-rotation feature (annotated in yellow) with a key (annotated in purple). *Id.*, Figs. 21A-21C, [0123]. The anti-rotation feature and its corresponding receiving aperture(s) (annotated in red) in the on-skin sensor assembly (formed by mating the electronics assembly 2102 with the sensor assembly 2104) have complementary shapes, which prevent the sharp hub/gripper 2106 (*i.e.*, needle hub) from rotating relative to the on-skin sensor assembly.

apertures(s)
extending from a
top surface

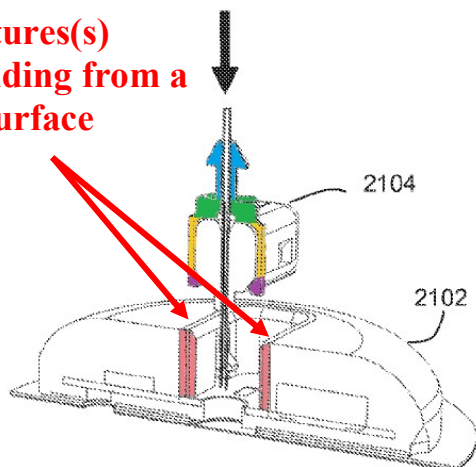


FIG. 21A

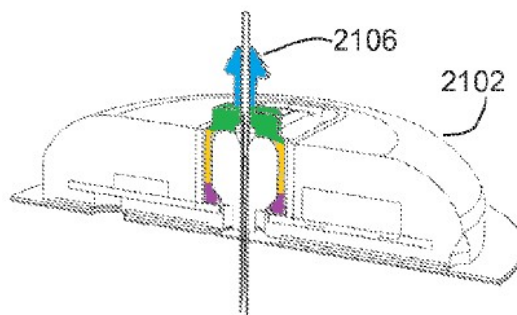


FIG. 21B

apertures(s)
extending from a
top surface

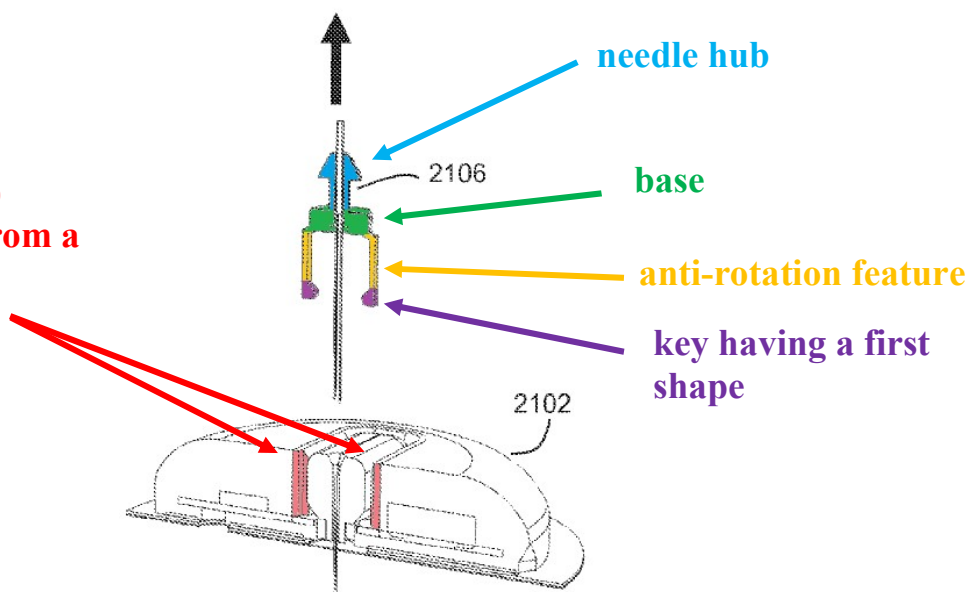


FIG. 21C

Id.

Pace further discloses a second embodiment (“embodiment B”) in Figures 34D, 35A-B, and 47C (below). This embodiment has a connector support 3404, containing a sensor and electrical contacts, which mates with an electronics

assembly in the applicator to form the on-body device. Ex-1006, Figs. 34A-D, 35A-C, [0140]-[0142]. In Figures 34D and 35A-B, a sharp hub 3414 (*i.e.*, a needle hub) with a V-shaped portion extending from its base is installed in the connector support 3404. *Id.* The V-shaped portion (annotated in gold below) extends from the sharp hub (*i.e.*, an “anti-rotation feature comprising a key”), has a rectangular cross section, and fits inside a cross-shaped aperture in the connector support 3404 (*i.e.*, an aperture), preventing rotation of the sharp hub relative to the on-skin sensor assembly.

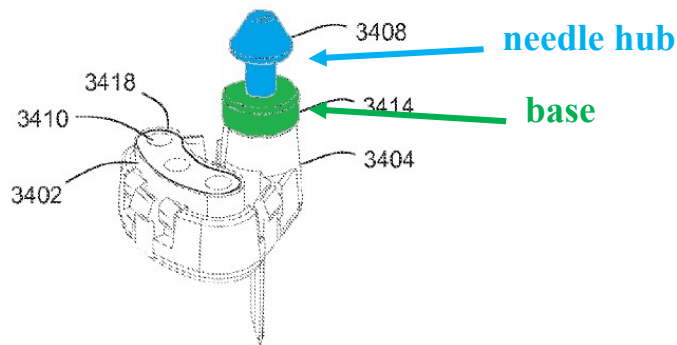
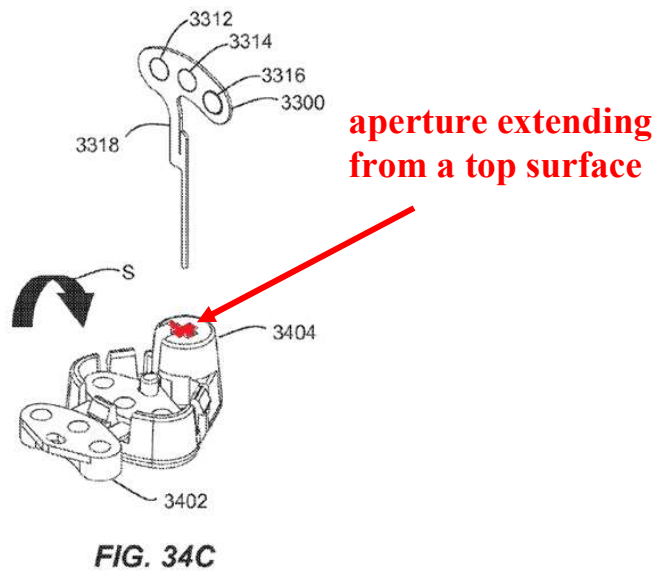
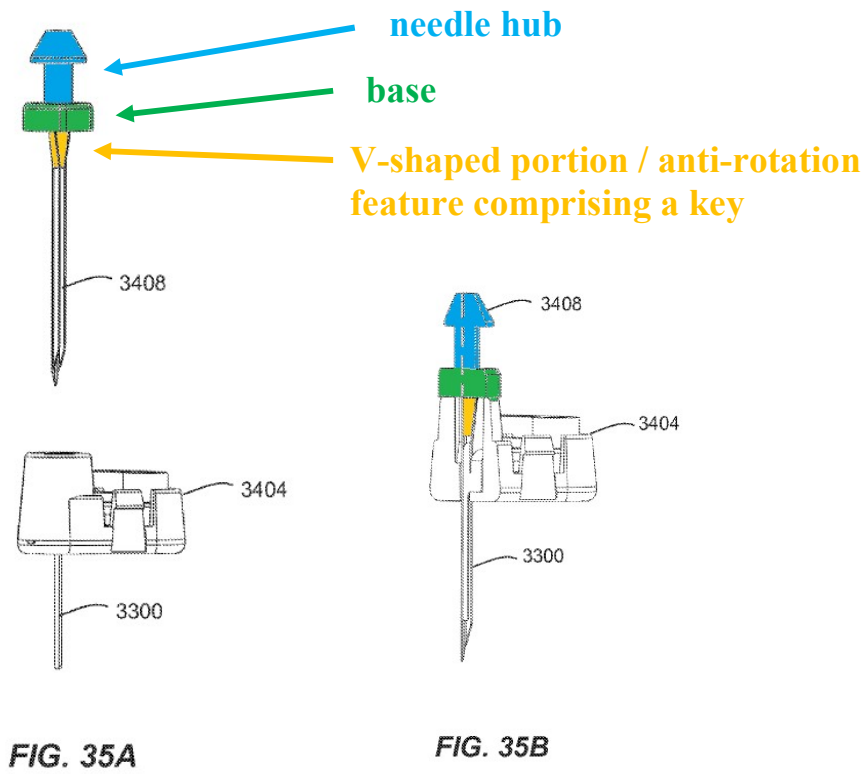


FIG. 34D



Id.

The sharp hub and connector support are shown mated with the electronics

unit in Figure 47C, forming the complete on-body device (*i.e.*, the on-skin sensor assembly):

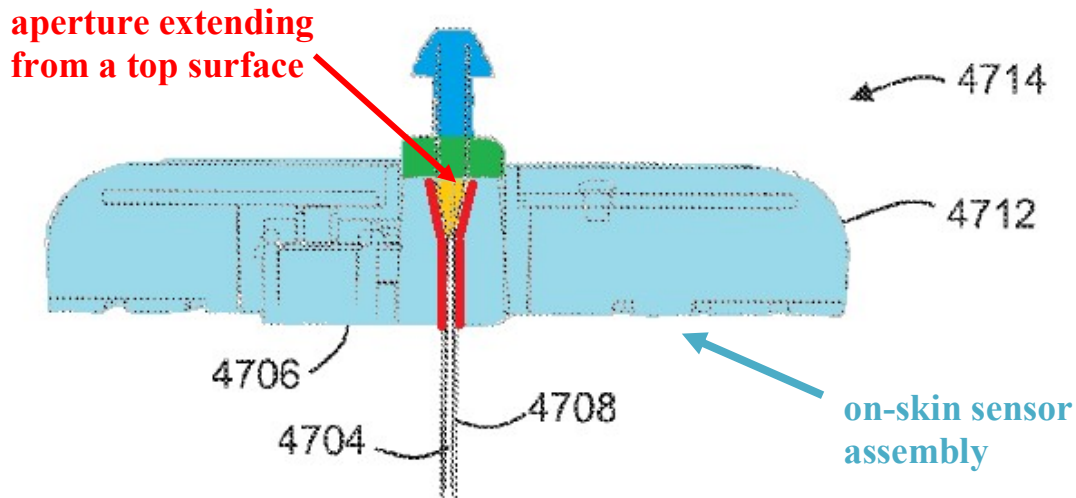


FIG. 47C

Id., Fig. 47C; *see also id.*, Figs. 47A-B, [0149] (noting that connector support 4706 is similar to the connector support in Figures 34A-D without seal 3402). The V-shaped portion slots into the cross-shaped aperture in connector support 3404 in Figure 34C, which is internally tapered to complement the V-shaped portion, as seen in Figures 35B and 47C.

Pace is analogous art, as Pace discloses a CGM applicator and is thus from the same field of endeavor. *See In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004).

B. Pace 2 (Ex-1007)

U.S. Patent Publication No. 2016/0331284, titled “Compact Medical Device Inserters and Related Systems and Methods,” to Pace (“Pace 2”) was filed on May

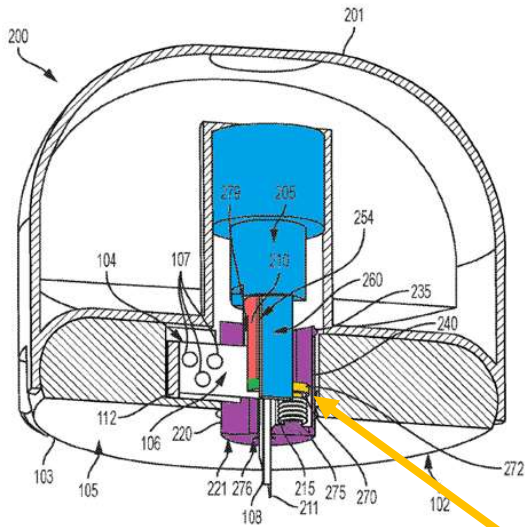


FIG. 4B

anti-rotation feature
comprising a key

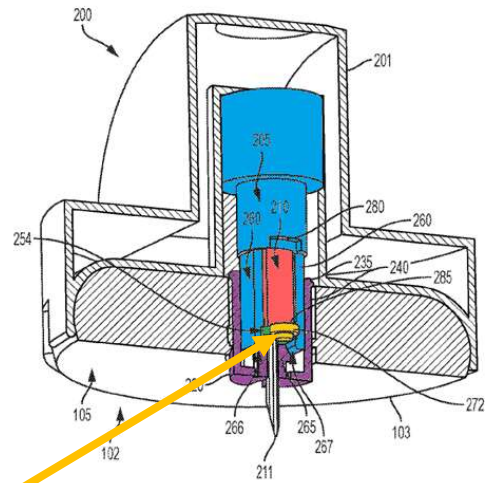


FIG. 4D

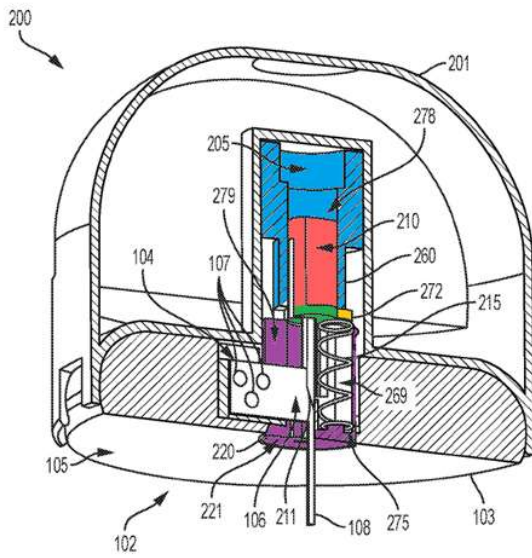


FIG. 5B

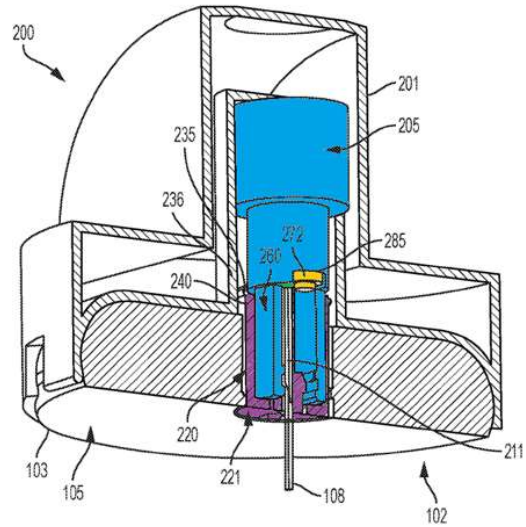


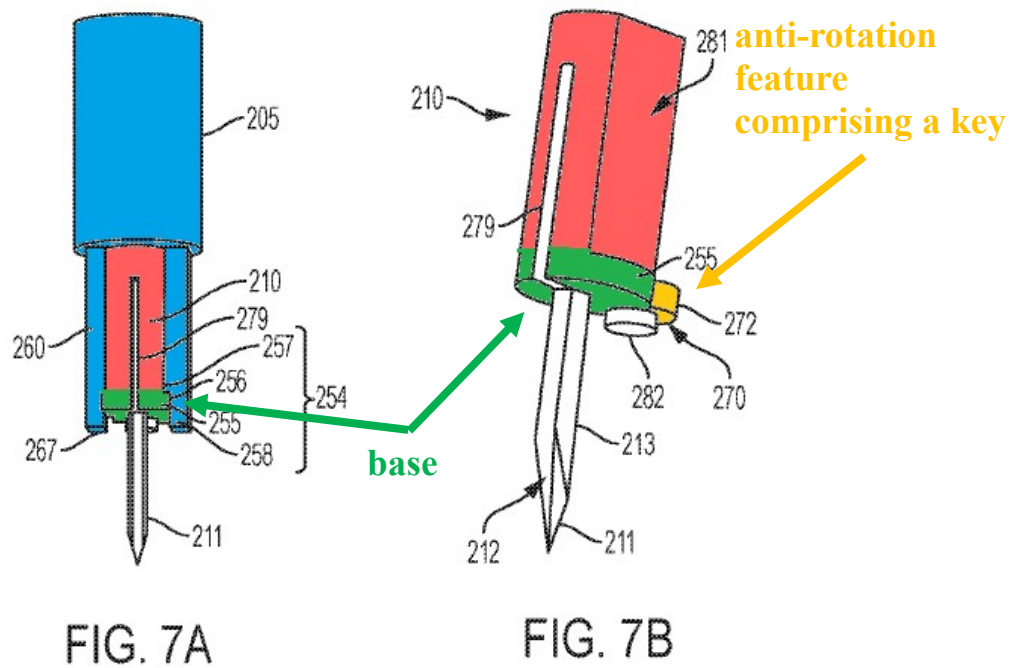
FIG. 5D

Id., Figs. 3B-5D.

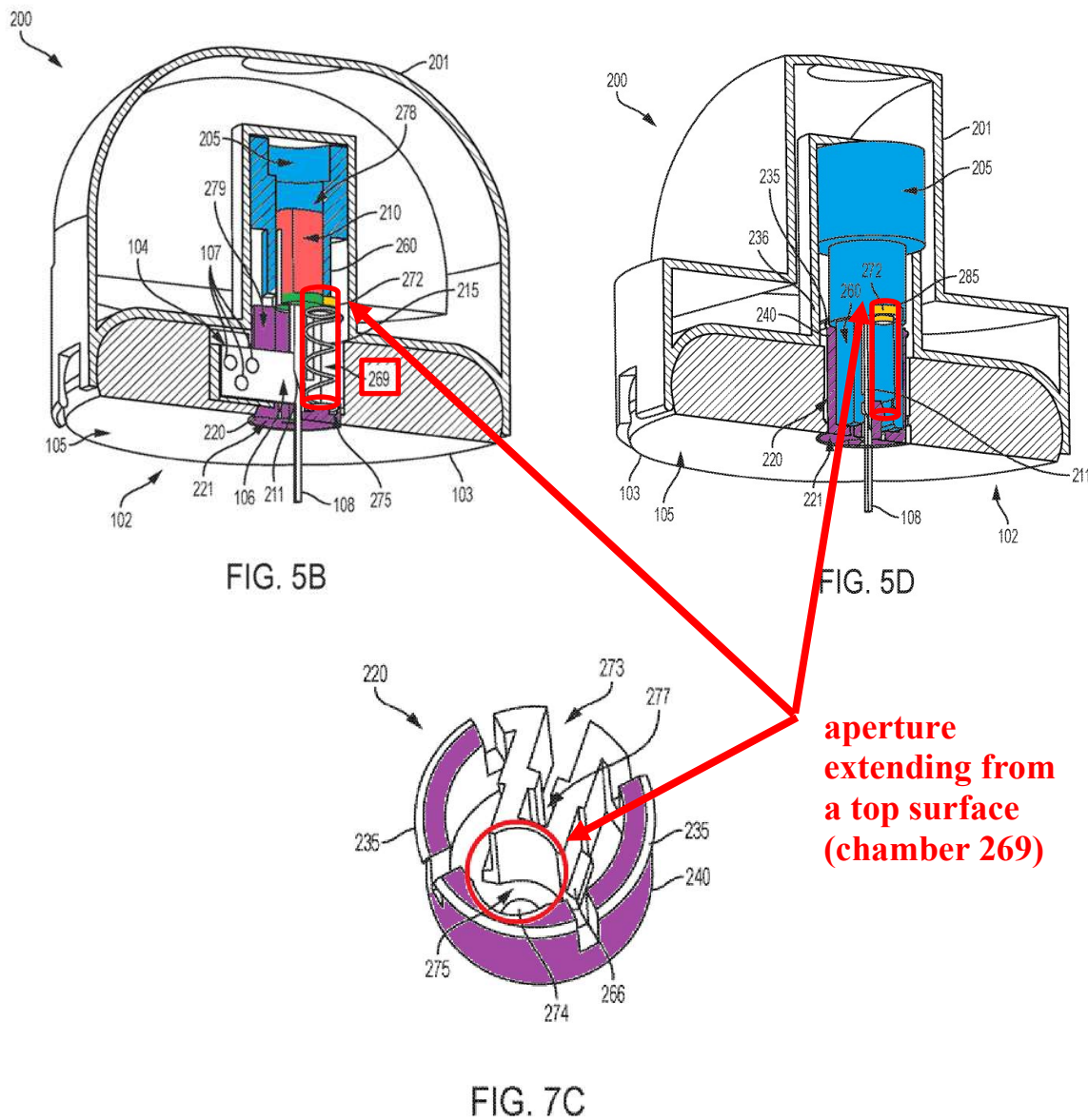
In Figures 3B-3D, the shroud 220 (annotated in purple) extends below the bottom surface of the housing 103 to protect the sharp 211 and a portion of the sensor 108. *Id.*, Figs. 3B-D, [0056]-[0057]. As the applicator is pressed to the user's skin,

the shroud 220 retracts into the housing 103, exposing the sharp 211 and a portion of the sensor 108, as seen in Figures 4B-4D. *Id.*, Figs. 4B-D, [0070]-[0071]. The continued application causes a biasing element (spring) 215 to push on surface 270 under ledge 272 (annotated in gold above), causing the sharp body 210 (annotated in red above) and the sharp 211 to retract into the sharp support 205, leaving a portion of the sensor inserted in the user's skin, as seen in Figures 5B-5D. *Id.*, [0067], [0072]-[0073]. After application, the shroud 220 can remain with the on-skin sensor control device 102, with its bottom surface flush with the bottom of the housing 103. *Id.*, [0086]. The shroud 220 and the sensor control device 102 collectively form the claimed on-skin sensor assembly.

The sharp support 205 and sharp body 210 (collectively, a needle hub, with base in green) and the ledge 272 (*i.e.*, anti-rotation feature comprising a key, in gold) are isolated in Figures 7A-7B:



Id., Figs. 7A-7B, [0087]. The ledge 272 of sharp body 210 is offset and extends away from the sharp 211, fitting and sliding within the complementary-shaped cylindrical chamber 269 (aperture extending from the top of shroud 220, highlighted in red below), preventing rotation of the sharp body and sharp within the shroud 220 and the rest of the on-skin sensor assembly.



Id., Figs. 3B, 5B, 5D, 7C, [0068], [0089].

Pace 2 is analogous art, as Pace 2 discloses a CGM applicator and is thus from the same field of endeavor. *See Bigio*, 381 F.3d at 1325.

C. Chae (Ex-1008)

U.S. Patent Publication No. 2020/0178899, titled “Sensor applicator assembly for continuous glucose monitoring system,” to Chae et al. (“Chae”) was filed as a

PCT application designating the United States on June 1, 2018, and published on June 11, 2020. Ex-1008, Cover. Chae claims priority to two Korean priority documents, Korean Patent Application No. 10-2017-0068964 filed June 2, 2017, (“’964 Application”) and Korean Patent Application No. 10-2018-0063368 filed June 1, 2018. Chae was not of record during prosecution of the ’625 patent.

1. Overview Of Chae

Chae discloses a CGM applicator assembly with a sensor module 20 and an applicator 10 fitted together so the user does not need to connect them. Ex-1008, Abstract, [0054]. Figure 1 below illustrates such a sensor applicator assembly, and Figure 5 is a cross-sectional view taken along line A-A in Figure 1.

FIG. 1

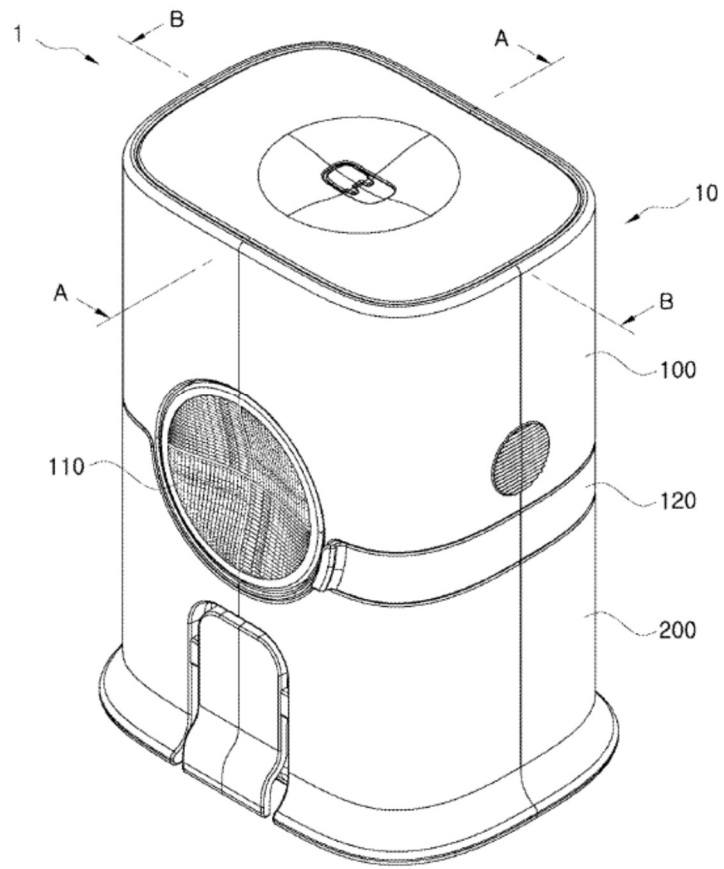
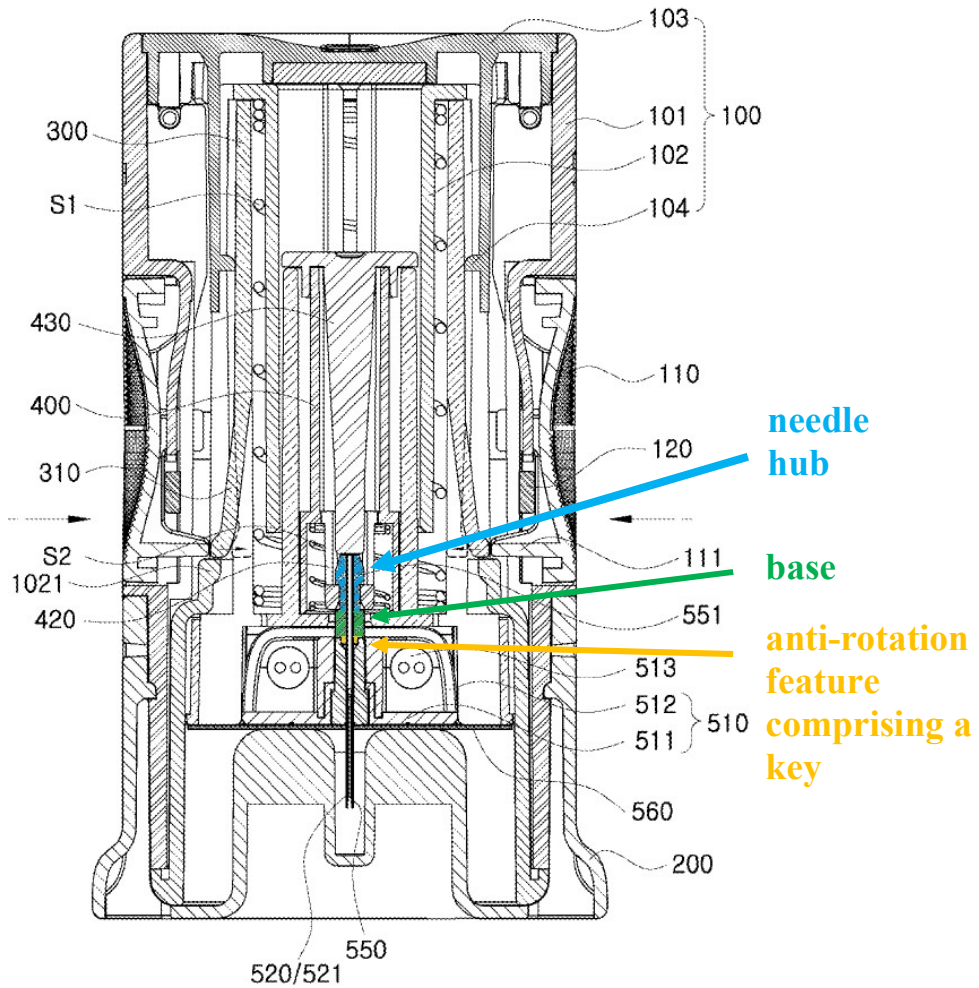


FIG. 5

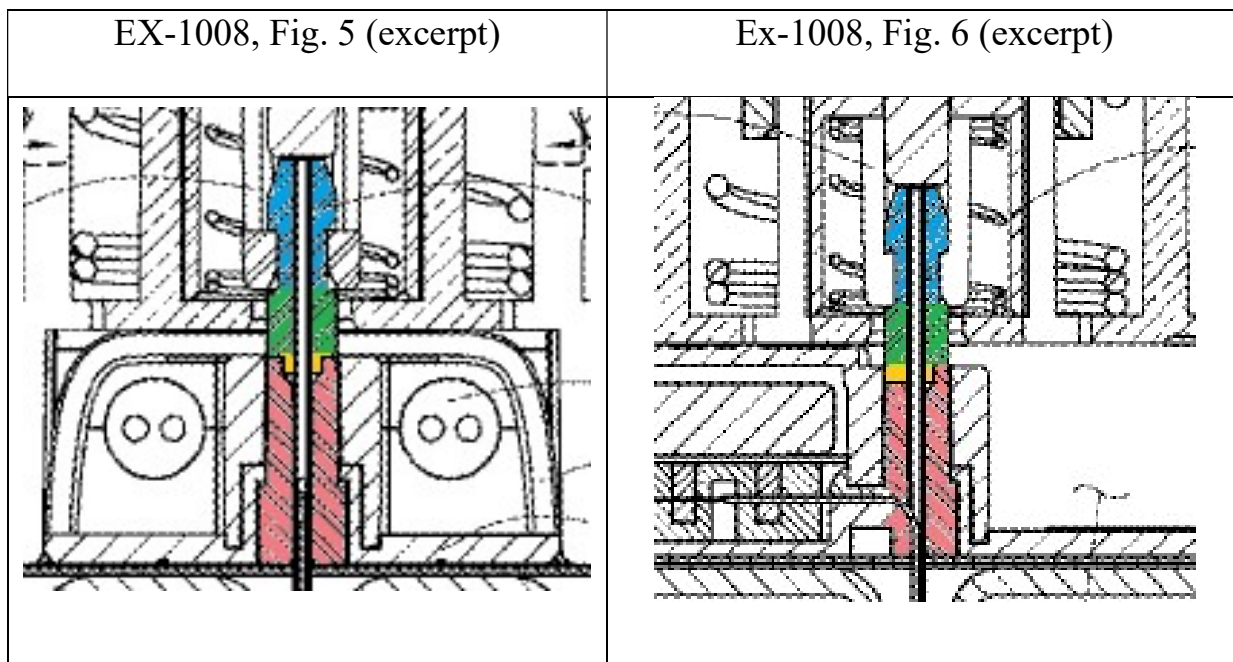


Id., Figs. 1, 5, [0053].

Figure 2 below depicts a sensor module 20 with a needle 550 configured to be inserted into the body with the sensor probe 521, so one end of the sensor probe 521 is inserted into the body:

[illegible]

- 30 -



Chae is analogous art, as Chae discloses a CGM applicator and is thus from the same field of endeavor. *See Bigio*, 381 F.3d at 1325.

2. Chae Is Entitled To A June 2, 2017, Effective Filing Date

As noted above, Chae claims priority to two documents, including the '964 Application (Ex-1009, with certified English translation Ex-1010). Because the '625 patent is an AIA patent, Chae “need only meet the ‘ministerial requirements’ of §§119 and 120, and [the '964 Application] must ‘describe[] the subject matter’ relied upon,” for Chae to be entitled to the '964 Application’s filing date. *Penumbra, Inc. v. RapidPulse, Inc.*, IPR2021-01466, Paper 34 at 32 (P.T.A.B. March 10, 2023) (quoting 35 U.S.C. §102(d)(2) (precedential as to section II.E.3)).

First, Chae was entitled to claim the benefit of the '964 Application’s June 2, 2017, filing date under 35 U.S.C. §§119 and 365, because Chae’s PCT application

designated the United States and at least one other country, and was filed on June 1, 2018, *i.e.*, within 12 months of the '964 Application's filing date.

Second, the '964 Application includes the figures and description from Chae relied upon below. For example, Figures 5 and 6, which depict the cross section of the applicator with the protrusion from the needle head, are identical in Chae and the '964 Application. Similarly, Chae's Figure 3, which depicts the aperture in the top of the sensor module having a recess corresponding to the protrusion depicted in Figures 5 and 6, also appears as Figure 3 in the '964 Application. While Chae has additional figures and description not explicitly in the '964 Application, Petitioner does not rely on them.

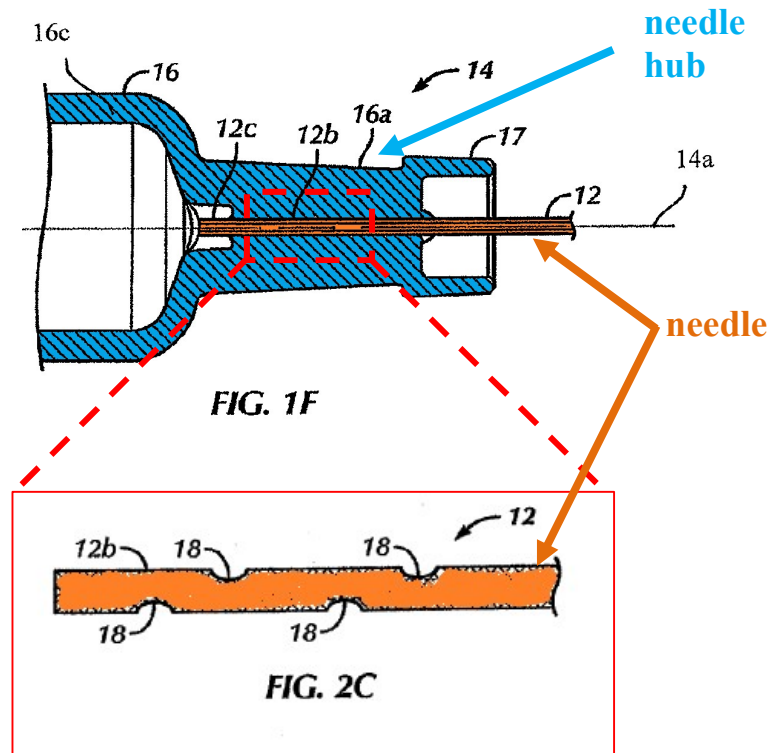
Accordingly, Chae qualifies as prior art under at least 35 U.S.C. §102(a)(2) (AIA).

D. Lundquist (Ex-1011)

U.S. Patent Publication No. 2014/0188053, titled "Syringe With Co-Molded Hub And Cannula," to Lundquist ("Lundquist") was filed on March 7, 2014, as a division of U.S. Application No. 13/237,429, and published on July 3, 2014. Ex-1011, Cover. Accordingly, Lundquist qualifies as prior art under at least 35 U.S.C. §§102(a)(1) and (a)(2) (AIA). Lundquist was not of record during prosecution of the '625 patent.

Lundquist discloses a syringe having a cannula 12 (e.g., a hollow needle)

integrally formed with a barrel 16, comprising “hub” 16a, by insert molding. Ex-1011, Abstract, [0002]. Figure 2C (below) shows a fine-gauge hollow metallic needle 12 with several notches 18 formed on its proximal end.



Id., Figs 1F, 2C, [0039]-[0041]. The notches “aid in affixing or securing” the proximal end of the needle 12 to the hub 16a (as shown in Figure 1F above), because the polymeric material forming the hub 16a “flows into and fills the notches 18” in the needle during the insert molding process. *Id.*

Lundquist is analogous art, as Lundquist is reasonably pertinent to a problem addressed by the ’625 patent inventors, namely securing a needle to a needle hub in a medical device to fix the needle’s orientation. *See Bigio*, 381 F.3d at 1325.

VIII. THE ASSERTED GROUNDS OF UNPATENTABILITY

A. Ground 1: Pace Anticipates Or Renders Obvious The Challenged Claims

1. Independent Claim 1

Pace anticipates or renders obvious claim 1, as explained below and as supported by Ex-1004, ¶¶57-73. As explained in Section VII.A above, Pace discloses multiple embodiments of CGM applicators, including embodiments “A” and “B,” as defined above. Each of embodiments “A” and “B” independently anticipates or renders obvious the subject claims.

- a. 1.P “An applicator for applying an on-skin sensor assembly to a skin of a host, the applicator comprising:”

Pace discloses multiple embodiments of an applicator assembly for applying a CGM to the skin of a host.

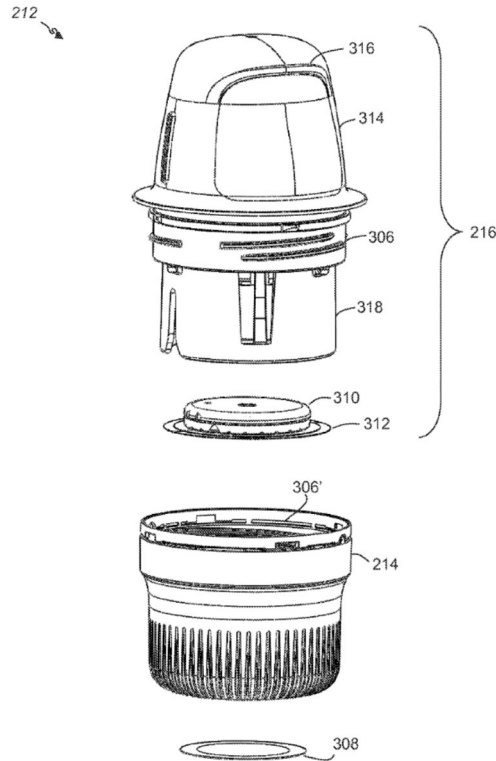


FIG. 3

Ex-1006, [0083], Fig. 3; *see also id.*, Figs. 11F, 15F.

b. 1.1 “an applicator housing having an internal volume;”

Pace discloses an applicator housing having an internal volume. Ex-1006, Fig. 3, Figs. 10E-10M, Figs. 11A-11E, [0092]. For example, Figures 11C-E show the applicator assembly 216 has an internal volume into which the sharp carrier 1120 is retracted (by way of coil return spring 1118) after insertion of the sensor:

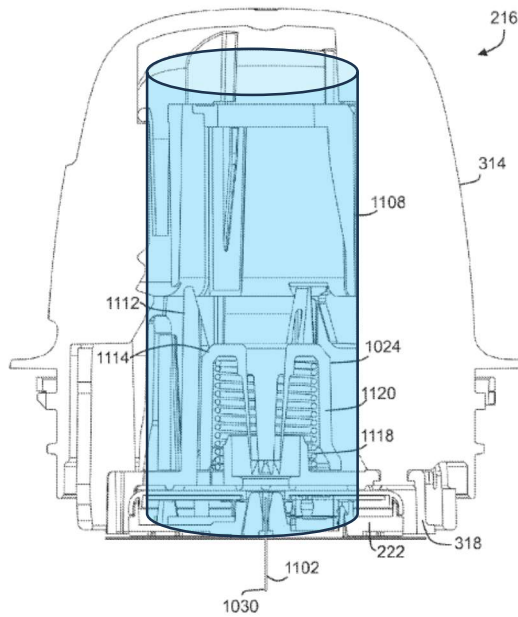


FIG. 11C

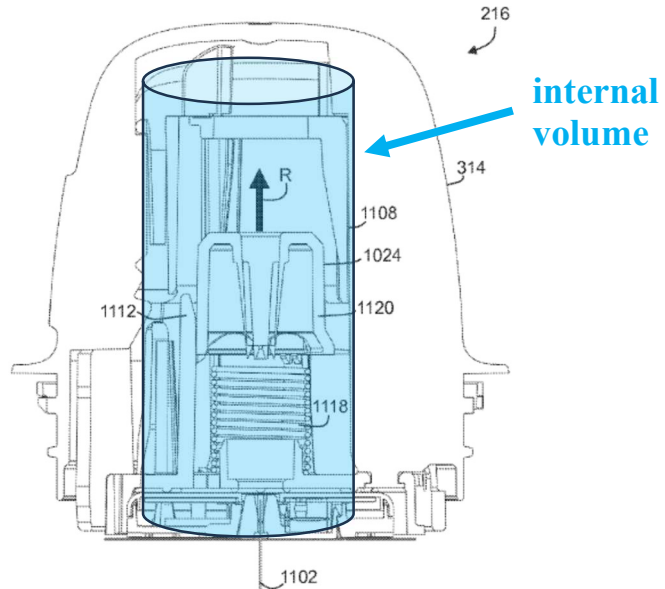


FIG. 11D

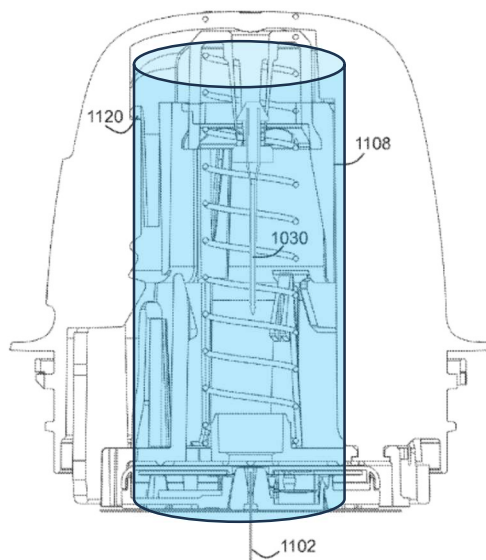


FIG. 11E

Id., Figs. 11C-11E, [0109]-[0111].

c. 1.2 “a needle hub coupled to an insertion element configured to pierce a skin of a host, the needle hub comprising:”

1.3 “a base, and”

1.4 “an anti-rotation feature extending from the base,”

1.5 “the anti-rotation feature comprising a key, the key having a first shape”

In embodiment A, Pace discloses a “sensor assembly gripper 2106” that grabs and orients a sensor assembly 2104 for connection to an electronics assembly 2102. The gripper 2106 is coupled to a needle to retract the needle after insertion of the sensor in the user’s skin, as Figures 21A-21C show. Ex-1006, [0123].

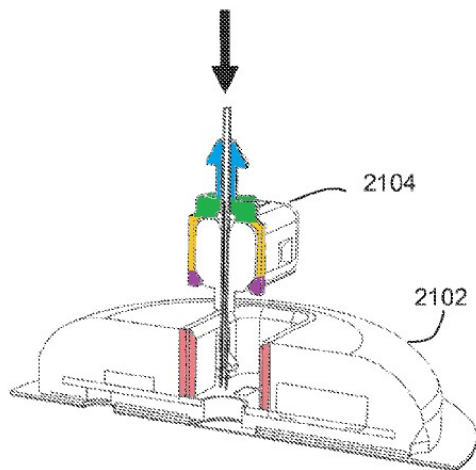


FIG. 21A

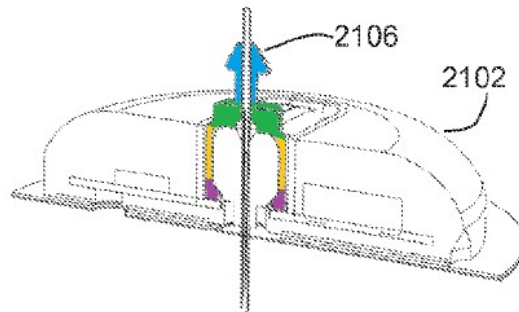


FIG. 21B

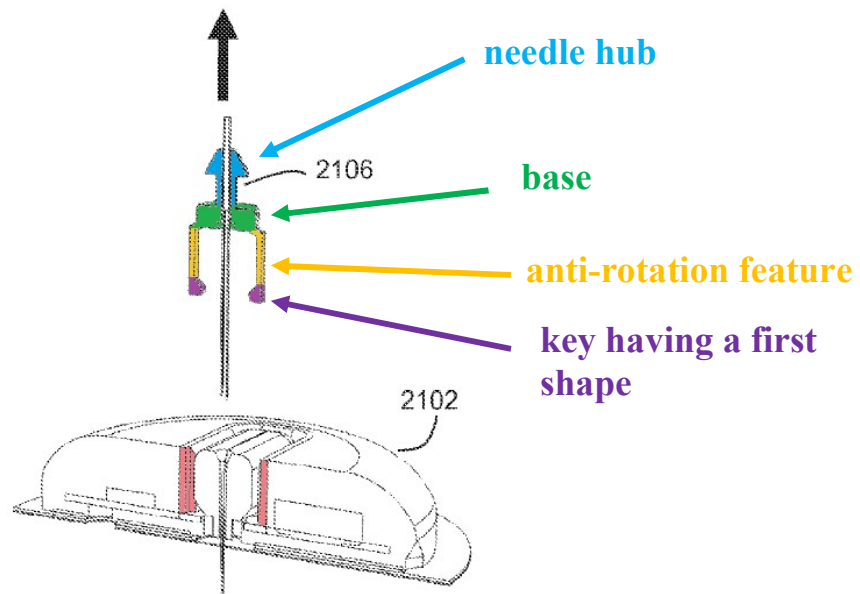


FIG. 21C

Id., Figs. 21A-21C, [0123]. The snap features of the gripper 2106 “may be incorporated in[to] the sharp hub/boss.” *Id.*, [0123]. In such an embodiment the gripper/sharp hub/boss, hereafter referred to as “hub 2106,” corresponds to the claimed “needle hub coupled to an insertion element.” *See also id.*, Figs. 10F-M, [0102]-[0104] (describing how the sharp hub engages the sharp retraction assembly in the applicator); Figs. 11C-11E, [0109] (describing how the sharp retraction assembly—coupled to the sharp hub—pulls the sharp out of the host after insertion).

As Figures 21A-21C above show, the hub 2106 comprises an upper section and a lower section with a flat segment resting on top of the sensor assembly and two vertical legs with feet. *Id.*, Figs. 21A-21C. As explained in annotated Figure 21C above, the lower section of the hub 2106 (annotated in green) corresponds to

the claimed “base,” with the vertical legs and feet (annotated in gold and purple) corresponding to the “anti-rotation feature extending from the base” and the feet (annotated in purple) corresponding to the claimed “anti-rotation feature comprising a key, the key having a first shape.”

For embodiment B, Pace discloses a sharp hub 3414 in which a V-shaped portion extends from the base of the sharp hub. As explained in annotated Figures 34D, 35A, and 35B below, the sharp hub 3414 corresponds to the claimed “needle hub” (annotated in blue) and the lower section of the sharp hub (annotated in green) corresponds to the claimed “base,” with the V-shaped portion extending from the base (annotated in gold) corresponding to the “anti-rotation feature extending from the base” and the “anti-rotation feature comprising a key, the key having a first shape.”

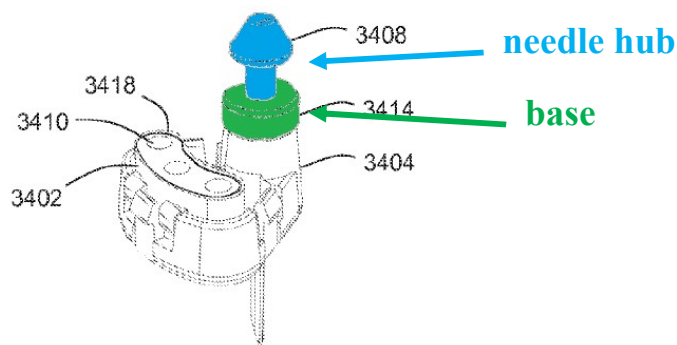
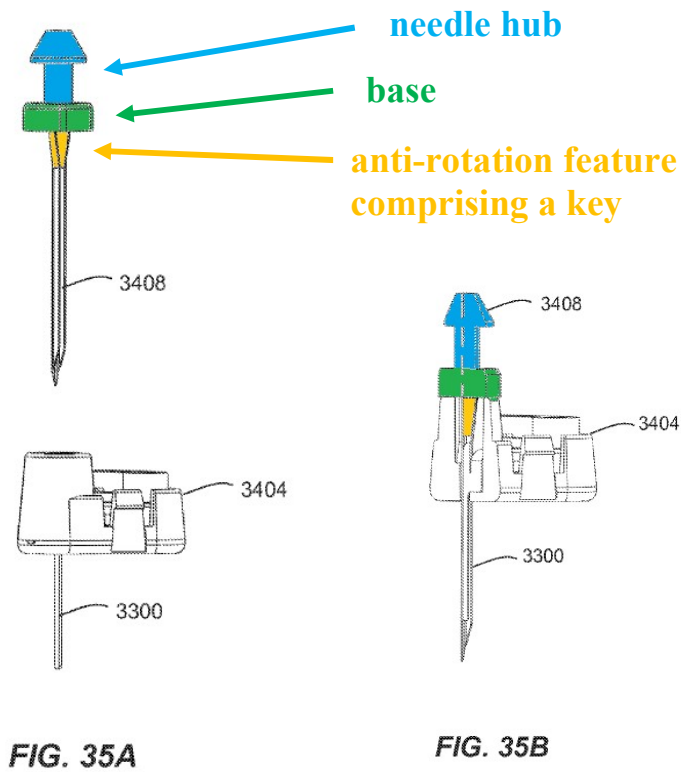


FIG. 34D



Ex-1006, Figs. 34D, 35A-35B, [0142]; *see also id.*, Figs. 47B-47C (showing the sharp hub and sensor assembly installed in the electronics assembly 4712), [0149].

As further disclosed in Figures 34C and 47C, the sharp hub, including the V-shaped portion, is inserted into a cross-shaped aperture in the connector support 3404 (which is labelled connector support 4706 after coupling with the electronics assembly in Figure 47C).

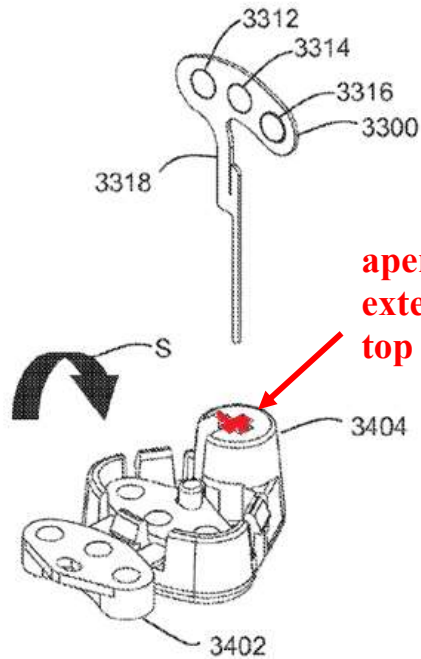


FIG. 34C

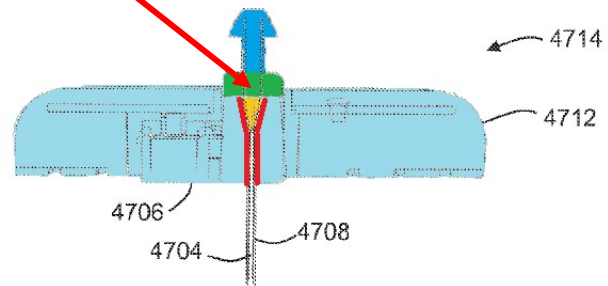


FIG. 47C

Id., Figs. 34C, 47C [0140]-[0142], [0149]; *see also id.*, Fig. 34B.

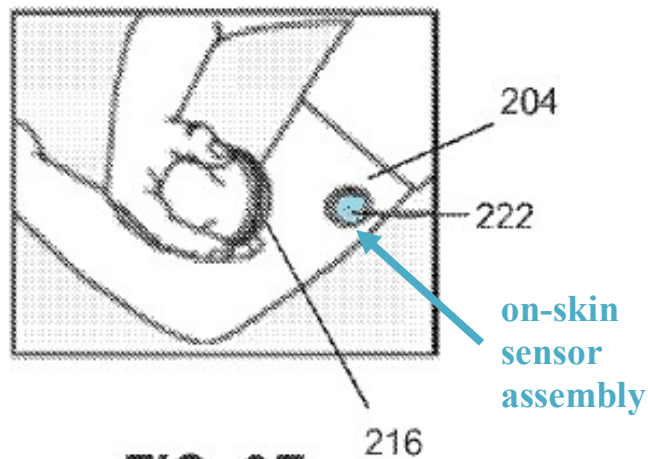
Although Pace does not specifically state that the hub 2106 in embodiment A or the V-shaped portion in embodiment B have “anti-rotation” functionality, these arrangements necessarily prevent the sharp from rotating. Specifically, for embodiment A, Figures 21A-21C depict vertical slots in the electronics assembly 2102, into which the hub 2106 legs are inserted, which necessarily prevent rotation of hub 2106, and thus the sharp, relative to the on-body device. Similarly for embodiment B, Figures 34B and 34C depict a cross-shaped aperture (annotated in red above), into which the V-shaped portion of the sharp hub is inserted, as explained below in claims 1.8-1.10, which necessarily prevents rotation of the sharp hub

relative to the on-body device.

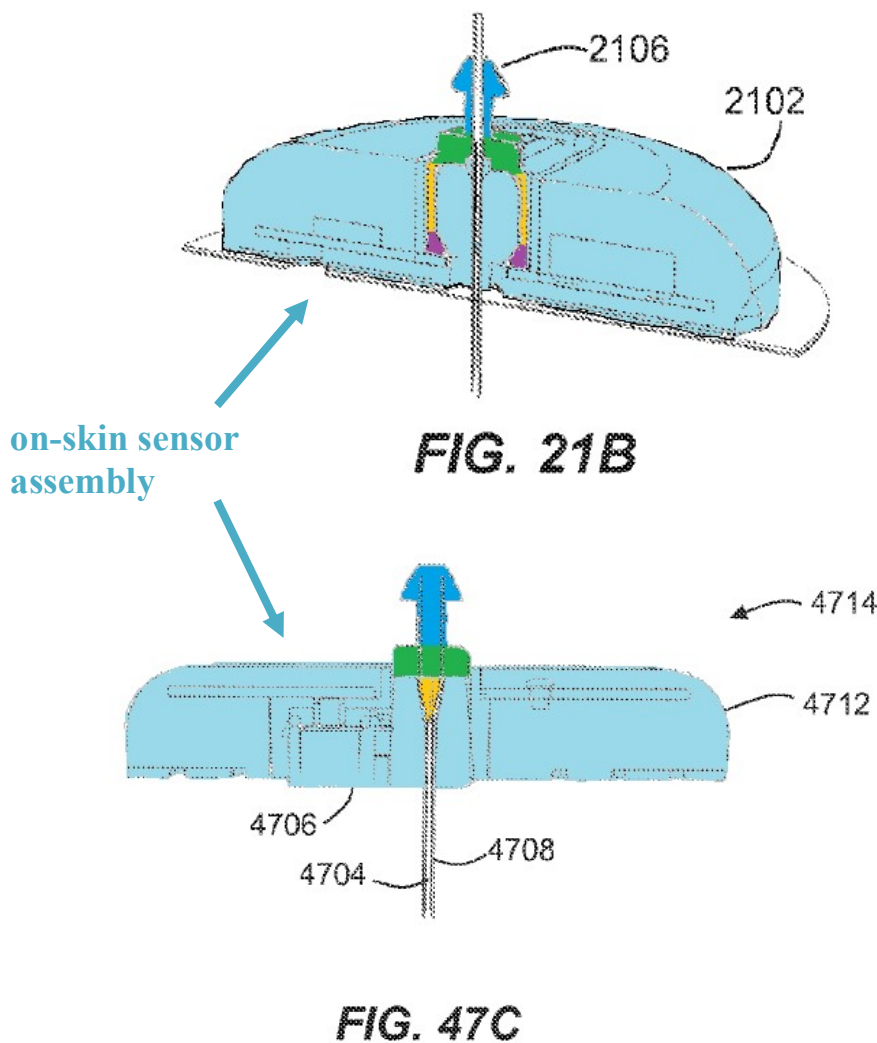
To the extent Patent Owner argues (incorrectly) that Pace does not disclose that either embodiment prevents rotation, a POSITA would have considered it obvious for hub 2106 or the V-shaped portion in Figures 35A and 47C to provide an anti-rotation function. Ex-1004, ¶65. A POSITA would have understood that any rotation of the needle relative to the sensor could damage the sensor, rendering it inoperable or causing it to inaccurately sense glucose, and therefore such rotation would need to be prevented. *Id.* Because hub 2106 is directly coupled to the needle, it therefore would have been obvious to restrain the rotation of hub 2106 relative to an aperture of an on-skin sensor assembly. *Id.* Similarly, because the V-shaped portion in Figures 35A and 47C is directly coupled to the needle, it would have been obvious to restrain the rotation of the V-shaped portion of the needle hub relative to the on-skin sensor assembly and the sensor therein. *Id.*; *see infra* claims 1.8-1.11.

d. 1.6 “an on-skin sensor assembly comprising:”

Pace discloses the claimed on-skin sensor assembly. Ex-1006, Figs. 2F, 3, 11F, 15F, 21B-21C, 25A-25B. For example, Figure 2F shows an “on-body device 222” containing a “sensor assembly” and “electronics assembly” that are mated in the applicator and then adhered to the user.



Id., Fig. 2F, [0081], [0092], [0110], [0116]; *see also id.*, Figs. 15F, 11F. For both embodiments A and B, the sensor assembly is firmly snapped into the electronics assembly inside the applicator (either inserting the sensor assembly into the top of the electronics assembly or into the underside of the electronics assembly), forming the complete on-body device 222 inside the applicator (*i.e.*, the claimed on-skin sensor assembly, annotated in light blue below).



Id., Figs. 21B, 47C, [0119]-[0123], [0149]. Once the on-body device 222 is applied to the user's skin, the applicator retracts the sharp hub (with the sharp), leaving the on-body device 222 attached to the user's skin, with the in-vivo portion of the sensor inserted in the body. *See e.g., id.*, Fig. 21C.

- e. 1.7 “a sensor, the sensor configured to measure a glucose concentration of a host, and”

Pace discloses the sensor assembly (part of the on-body device 222, *i.e.*, the

“on-skin sensor assembly”) includes an analyte sensor such as a “glucose sensor.”

Ex-1006, [0007]-[0008]; *see also id.*, [0133] (the sensor contacts the interstitial fluid to “measure the analyte concentration”).

f. 1.8 “an aperture extending from a top surface of the on-skin sensor assembly,”

1.9 “the aperture having a second shape, the second shape complementary to the first shape of the key; and”

1.10 “wherein the key of the anti-rotation feature is configured to be at least partially disposed in the aperture of the on-skin sensor assembly;”

In embodiment A, Pace discloses vertical slots (annotated in red below) extending from a top surface of the on-skin sensor assembly, into which the legs of the hub 2106 are inserted:

apertures(s)
extending from a
top surface

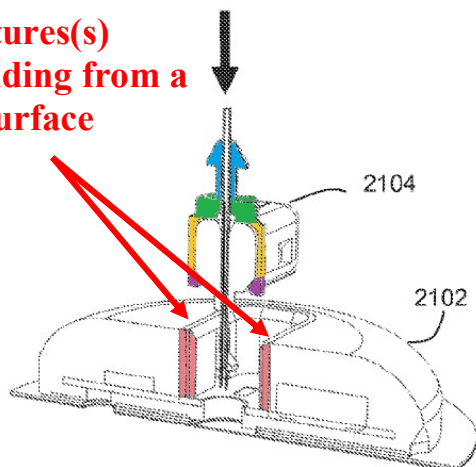


FIG. 21A

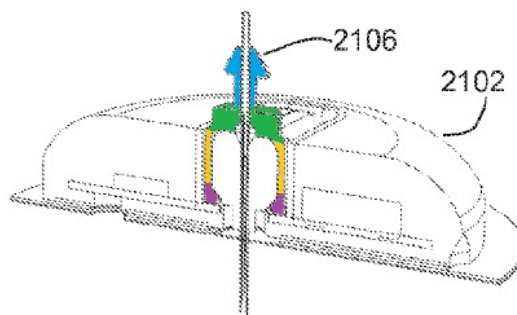


FIG. 21B

apertures(s)
extending from a
top surface

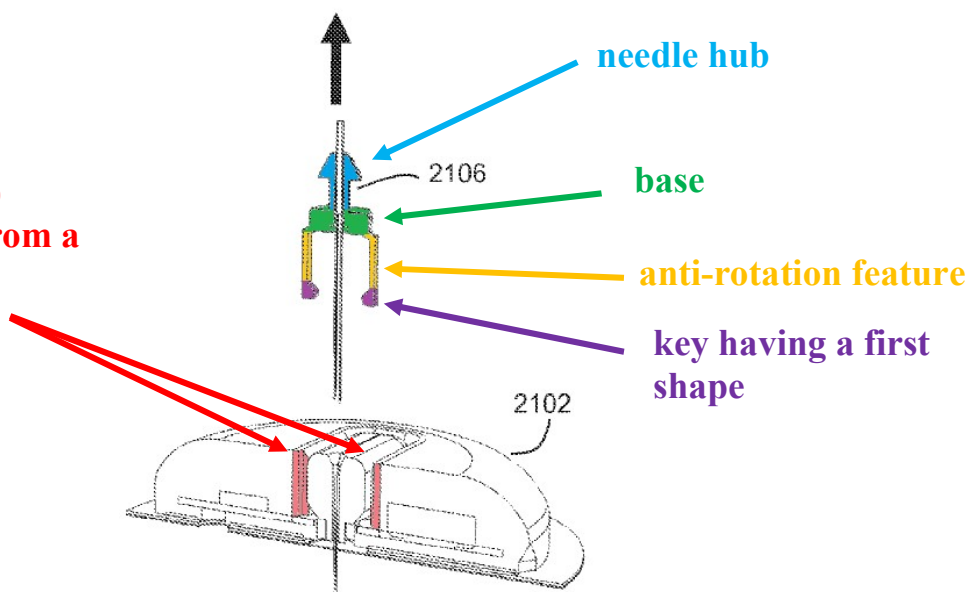
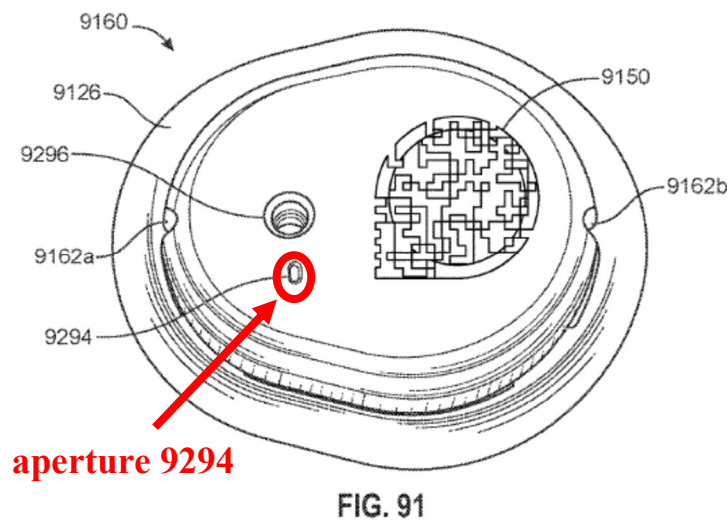


FIG. 21C

Ex-1006, Figs. 21A-21C, [0123]. These vertical slots correspond to the claimed “aperture extending from a top surface of the on-skin sensor assembly.” Notably, the vertical slots in electronics assembly 2102 are similar to the aperture 9294 of Figure 91 in the '625 patent as both the slots in Pace and the aperture 9294 are offset from

the aperture through which the needle passes:



Ex-1001, Fig. 91.

Furthermore, Figures 21A-21C of Pace (above) show that the shape of each vertical slot in electronics assembly 2102 complements the shape of a corresponding gripper leg and foot (*i.e.*, the “anti-rotation feature” and “key having a first shape” as explained above), to form a snug fit therewith. Thus, the vertical slots have a second shape complementary to the first shape of the key.

In addition, Figure 21B shows the legs and feet of hub 2106 (*i.e.*, the “anti-rotation feature” and “key”) are at least partially disposed in the vertical slots (*i.e.*, the aperture).

In embodiment B, Pace discloses a cross-shaped aperture (annotated in red below) that extends from a top surface of the on-skin sensor assembly, which the V-shaped portion (*i.e.*, the claimed key having a first shape) is inserted into:

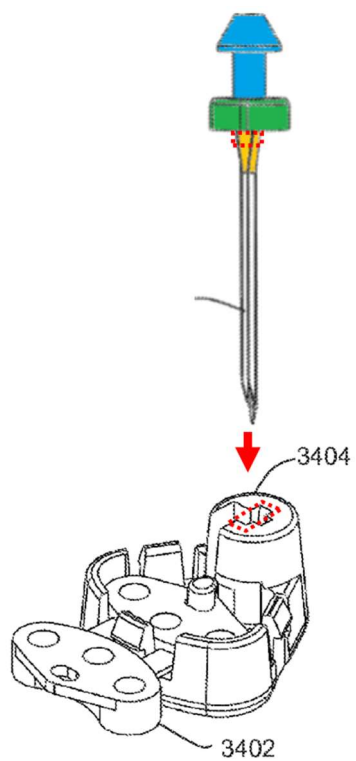


FIG. 34B

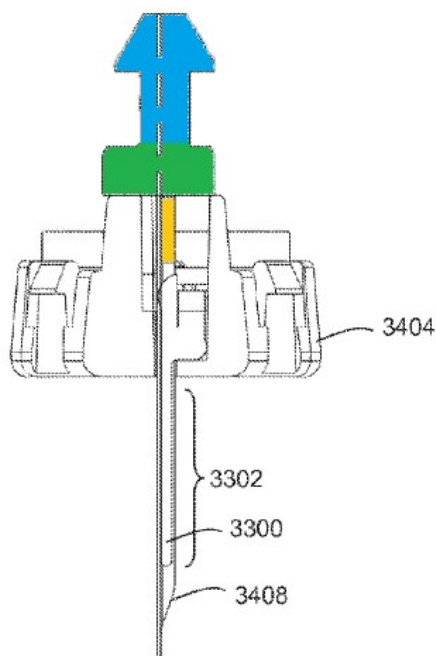


FIG. 35C

Id., Figs. 35A (excerpt, mirrored), 34B, 35C.

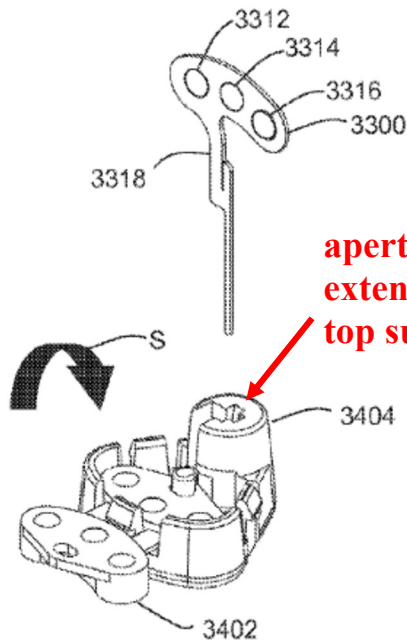


FIG. 34C

**aperture
extending from a
top surface**

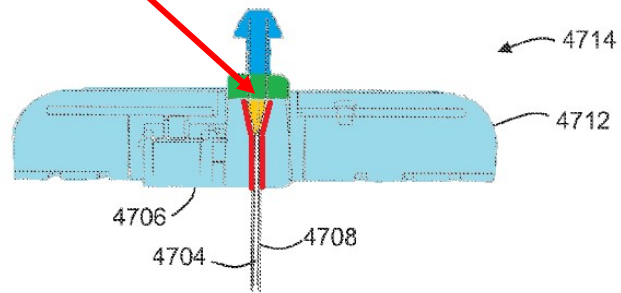


FIG. 47C

Id., Figs. 34C, 47C [0140]-[0142], [0149]; *see also id.*, Fig. 34B. The aperture in the top portion of connector 3404 (and thus the top of the completed on-skin sensor assembly as seen in Figure 47C) corresponds to the claimed “aperture extending from a top surface of the on-skin sensor assembly.”

The V-shaped portion extending from the sharp hub (*i.e.*, the anti-rotation feature comprising a key) slots into the cross-shaped aperture in connector support 3404 in Figure 34C. The shape of the V-shaped portion is complementary to the shape of the aperture in two ways. First, the aperture is vertically tapered to complement the tapered length of the V-shaped portion as seen in Figure 47C. Second, as described earlier, the V-shaped portion has a rectangular cross section

that slots into and complements the cross-shaped aperture in connector support 3404. Thus, the aperture has a second shape, complementary to the first shape of the key. Figure 47C also shows the V-shaped portion extending from the sharp hub is at least partially disposed in the aperture.

- g.** 1.11 “wherein the anti-rotation feature is configured to prevent rotation of the needle hub within the aperture.”

As explained above for claims 1.2-1.5, the legs and feet of the hub 2106 in embodiment A prevent rotation of the hub (and the needle coupled to it) relative to the on-body device 222 (*i.e.*, the on-skin sensor assembly) when inserted within the vertical slots (*i.e.*, the aperture) in the on-body device 222. Similarly, in embodiment B, the V-shaped portion extending from the base of the hub prevents rotation of the hub (and the needle coupled to it) relative to the on-body device 222 when inserted into the aperture (*i.e.*, the aperture) in the connector support in the on-body device 222.

2. Independent Claim 13

Pace anticipates or renders obvious claim 13, as explained below and as supported by Ex-1004, ¶¶74-80.

- a.** 13.P “An applicator for applying an on-skin sensor assembly to a skin of a host, the applicator comprising:”

See, supra, claim 1.P.

- b.** 13.1 “an applicator housing having an internal volume;”

See, supra, claim 1.1.

c. 13.2 “a needle hub coupled to a needle,”

13.4 “wherein the needle comprises a portion configured to extend through the skin of the host,”

13.5 “wherein the base comprises an anti-rotation key, wherein the anti-rotation key has a first shape;”

See, supra, claims 1.2-1.5. Claim 13.2 recites a needle hub coupled to a “needle” rather than the “insertion element” in claim 1.2, but in the ’625 patent, the “insertion element” can comprise a “needle.” *See, e.g.*, Ex-1001, 27:12-18. Furthermore, the base that “*comprises* an anti-rotation key” recited in claim 13.5 corresponds to the base of claim 1.4 having “an anti-rotation feature *extending from*” it.

In addition, claim 13.5 recites an “anti-rotation key,” rather than claim 1.5’s “anti-rotation feature comprising a key.” As explained for claim 1.4–1.5, in embodiment A, Pace discloses a sharp hub 2106 with legs having inwardly-extending feet that correspond to the claimed “anti-rotation key.” Ex-1006, Figs. 21A-21C. Similarly, in embodiment B, Pace discloses a sharp hub with a V-shaped portion that corresponds to the claimed “anti-rotation key.”

d. 13.6 “and an on-skin sensor assembly comprising:”

13.7 “a sensor configured to measure a glucose concentration of a host;”

13.8 “and an aperture extending from a top surface of the on-skin sensor assembly,”

13.9 “wherein the aperture has a second shape, wherein the second shape is complementary to the first shape of the anti-rotation key; and”

13.10 “wherein the anti-rotation key is configured to be at least partially disposed in the aperture of the on-skin assembly; and”

See, supra, claim 1.6-1.10.

- e. 13.11 “wherein the anti-rotation key is configured to prevent rotation of the needle hub with respect to the on-skin sensor assembly.”

See, supra, claim 1.11. While claim 1.11 recites preventing rotation of the needle hub relative to the “aperture” rather than the “on-skin sensor assembly” in claim 13.11, claim 13.8 makes clear the aperture is part of the on-skin sensor assembly. Thus, the needle hub in Pace is prevented from rotating relative to the on-skin sensor assembly.

3. Independent Claim 22

Pace anticipates or renders obvious claim 22, as explained below and as supported by Ex-1004, ¶¶81-89.

- a. 22.P “A needle hub for applying an on-skin sensor assembly to a skin of a host, the needle hub comprising:”

In embodiment A, Pace discloses a hub 2106 coupled to a needle (*i.e.*, a needle hub). *See, supra*, claim 1.2.

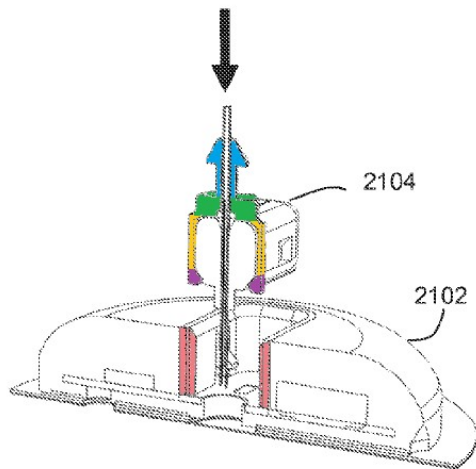


FIG. 21A

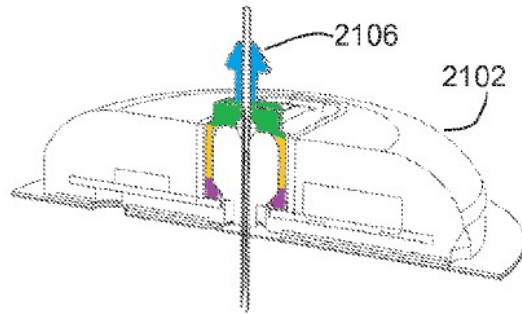


FIG. 21B

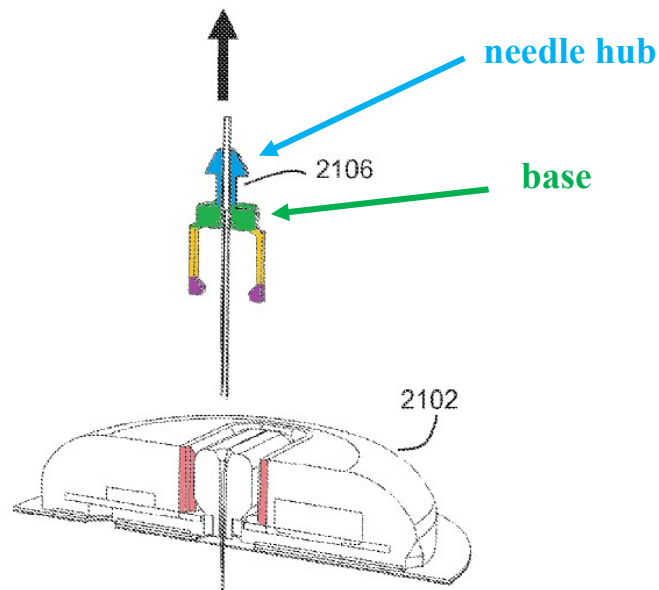


FIG. 21C

Ex-1006, Figs. 21A-21C; *see also id.*, [0123] (snap features of gripper 2106 “may be incorporated in[to] the sharp hub/boss”). The hub 2106 grabs and orients the sensor assembly 2104 for connection to the electronics assembly 2102 to form the fully assembled on-body device. *Id.*

In embodiment B, Pace discloses a hub 3414 coupled to a sharp 3408. *Id.*, Figs. 34D, 35A, 35B, 35C, 47A-47C, [0142], [0149]. The hub 3414 is inserted into connector support 3404, which in turn is coupled with the electronics assembly 4712 to form the fully-assembled on-body device (*i.e.*, the on-skin sensor assembly) depicted in Figure 47C. *Id.*

In both embodiments, this connection is made inside the applicator housing, prior to application of the on-body device to the user. *Id.*, [0116]-[0119], Figs. 15A-15F, 16A-B, 17A-B, 18. The applicator is then used to apply the on-body device onto a user's skin. *Id.* Thus, Pace discloses the sharp hub (*i.e.*, a needle hub) is used to “[apply] an on-skin assembly to a skin of a host.”

b. 22.1 “a base comprising an anti-rotation key,”

See, supra, claims 1.2-1.5 and 13.2-13.5.

c. 22.2 “the anti-rotation key configured to be at least partially disposed in an aperture of an on-skin sensor assembly,”

See, supra, claim 1.11.

d. 22.3 “wherein the needle hub is configured to couple with an insertion element; and”

See, supra, claim 1.2-1.5.

e. 22.4 “wherein the base comprises a flat surface configured to mate with a top surface of the on-skin sensor assembly, thereby maintaining the insertion

element in a substantially perpendicular orientation to the top surface of the on-skin sensor assembly.”

In embodiment A, Pace discloses a sharp hub 2106 (*i.e.*, a needle hub) with an upper portion and a lower portion (*i.e.*, a base). *See, supra*, claims 1.2-1.5. Figures 21A-21C show that a horizontal, flat surface of the lower portion of hub 2106 (annotated in red in Figure 21C) mates with the top surface of the sensor assembly 2104 (annotated in black in Figure 21C) and maintains the sharp (*i.e.*, the insertion element) in a substantially perpendicular orientation relative to the top surface of the on-body device (the combination of sensor assembly 2104 and electronics assembly 2106, *i.e.*, the on-skin sensor assembly):

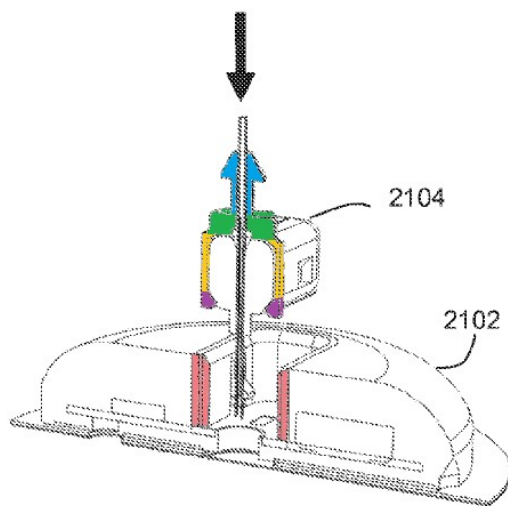


FIG. 21A

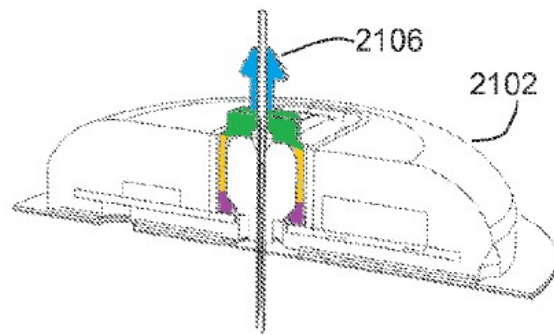


FIG. 21B

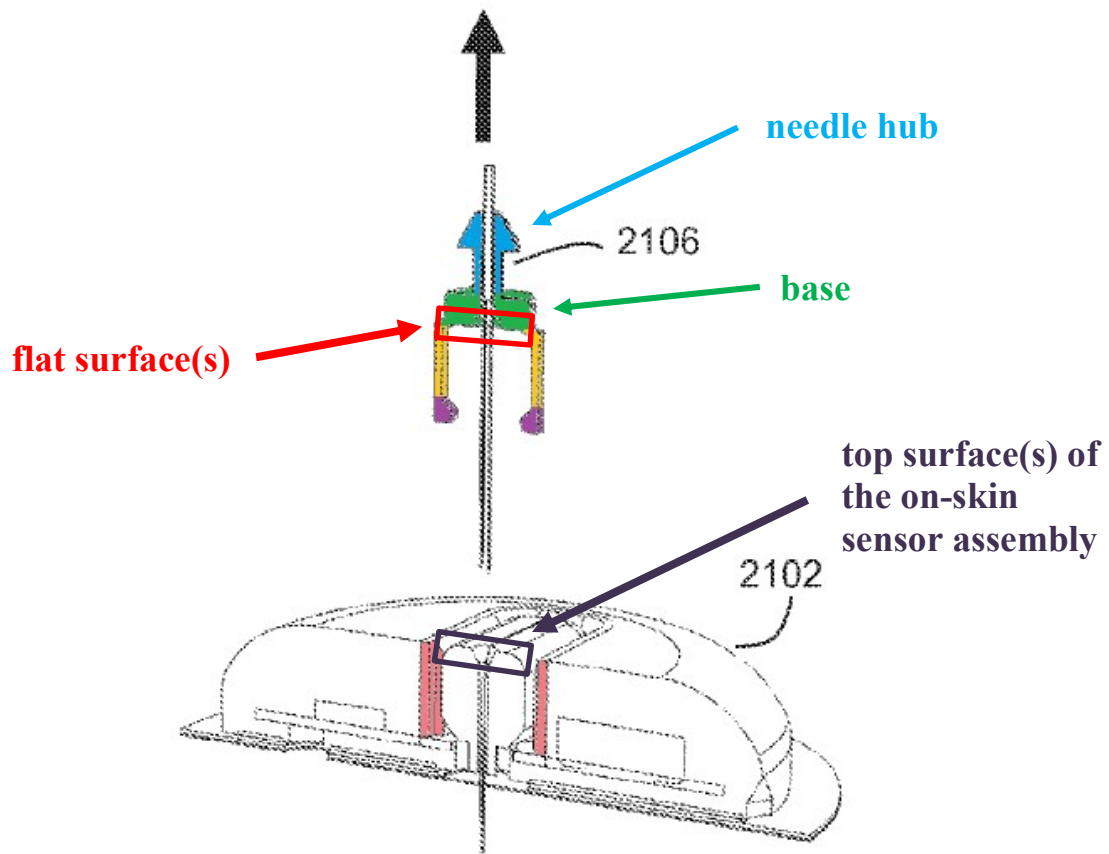


FIG. 21C

Ex-1006, Figs. 21A-21C, [0123].

Similarly, in embodiment B, Pace discloses a hub 3414 with a lower base portion, including a flat surface that mates with a top surface of the on-skin sensor assembly and maintains the sharp (*i.e.*, the insertion element) in a substantially perpendicular orientation relative to the top surface of the on-skin sensor assembly:

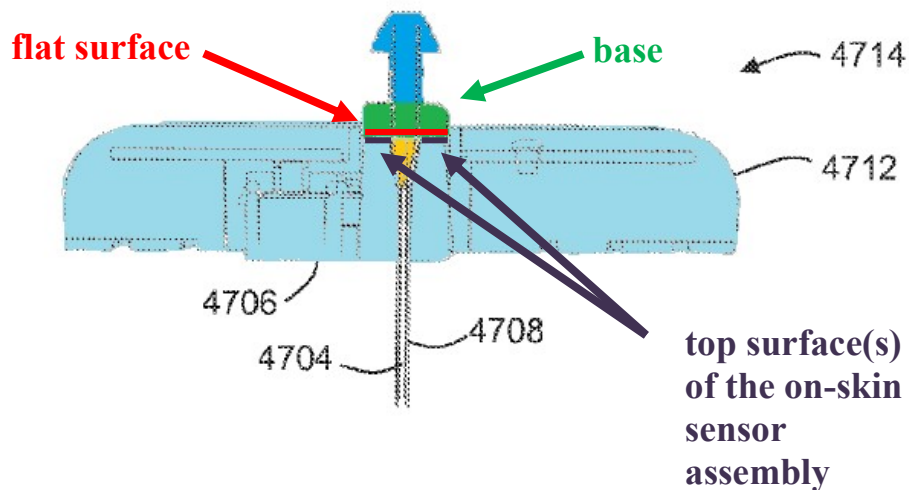


FIG. 47C

Id., Fig. 47C, [0149].

4. Independent Claim 28

Pace anticipates or renders obvious claim 28, as explained below and as supported by Ex-1004, ¶¶90-98.

- a. 28.P “An applicator for applying an on-skin sensor assembly to a skin of a host, the applicator comprising:”

See, supra, claim 1.P.

- b. 28.1 “an applicator housing having an internal volume;”

See, supra, claim 1.1.

- c. 28.2 “a needle hub coupled to a needle configured to pierce a skin of a host, the needle hub comprising:”

See, supra, claims 1.2 and 13.2.

d. 28.3 “a base, and”

28.4 “an anti-rotation feature extending from the base,”

28.5 “the anti-rotation feature comprising a key, the key having a first shape; and”

28.6 “an on-skin sensor assembly comprising:”

28.7 “a sensor, the sensor configured to measure a glucose concentration of a host;”

28.8 “an aperture extending from a top surface of the on-skin sensor assembly,”

28.9 “the aperture having a second shape, the second shape complementary to the first shape of the key, and”

See, supra, claim 1.3-1.9.

e. 28.10 “sensor electronics operably connected to the sensor in the applicator housing;”

Pace discloses a sensor assembly, including the sensor, connected with the electronics assembly in the applicator, forming a complete on-body device:

[T]he applicator is inserted into the container to ***merge or connect the sensor assembly and the electronics assembly*** together to form an on-body device and an insertion needle or sharp.

Ex-1006, [0077]³; *see also id.*, Figs. 1, 10I-M, 15B, [0116] (“[T]he applicator 1400 is inserted into container 1500 to load the electronics assembly 1504 into the

³ Emphasis in quotations added throughout unless otherwise noted.

applicator 1400 and *mate the sensor assembly (not shown) with the electronics assembly 1504....*”), [0119] (similar), [0123] (similar). Furthermore, in some embodiments, the applicator is pre-loaded with a completed on-body device, meaning the sensor assembly, including the sensor, is connected to the electronics assembly during manufacture. *Id.*, [0119].

- f. 28.11 “wherein the key of the anti-rotation feature is configured to be at least partially disposed in the aperture of the on-skin sensor assembly;”

See, supra, claim 1.10.

- g. 28.12 “wherein the anti-rotation feature is configured to prevent rotation of the base within the aperture; and”

See, supra, claim 1.11. The anti-rotation feature of claim 28.12 is configured to prevent rotation within the aperture of the *base*, as opposed to the *needle hub* in claim 1.11. As the claim language makes clear, the needle hub comprises a base, so preventing rotation of the needle hub within the aperture necessarily prevents rotation of the base within the aperture.

- h. 28.13 “wherein the needle is configured to be inserted through at least a portion of the sensor electronics.”

In embodiment A, Pace discloses a hub 2106 coupled to a needle, which is configured to be inserted through the sensor assembly 2104 and the electronics assembly 2102:

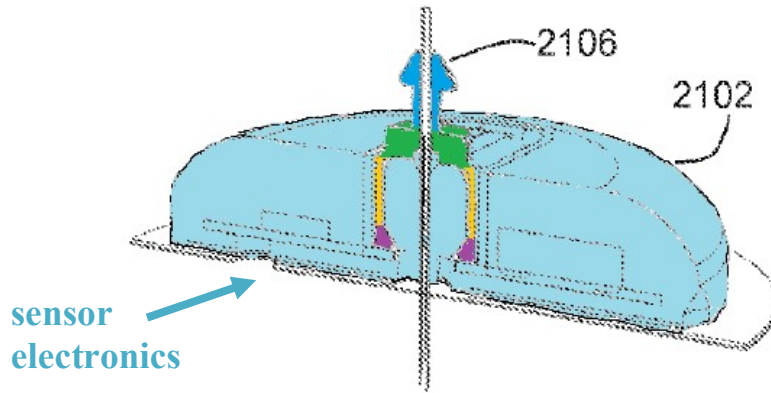


FIG. 21B

Id., Figs. 21B, [0123]; *see also id.*, Figs. 24A, 29D, and 40 (depicting sensor electronics). Similarly, in embodiment B the sharp is configured to be inserted through the electronics assembly 4712:

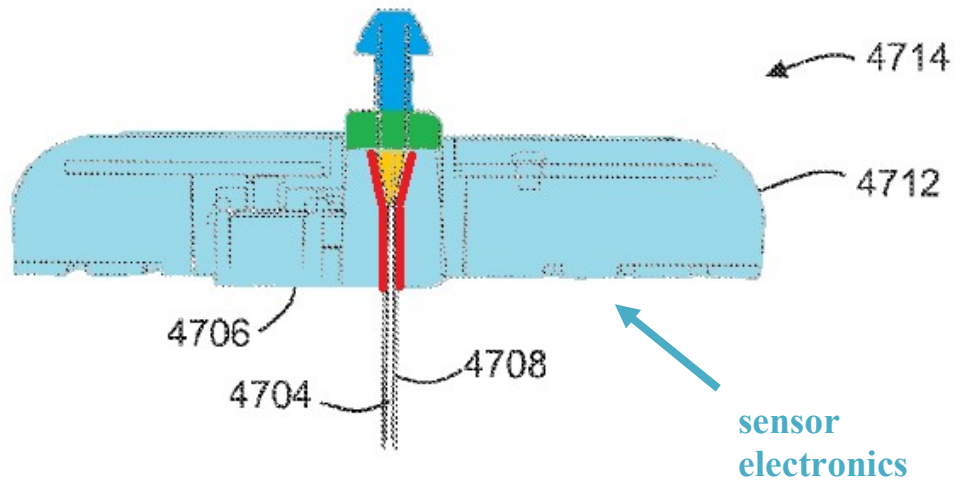


FIG. 47C

Id., Fig. 47C, [0149].

5. Claims 2 & 25

Pace anticipates or renders obvious claims 2 and 25, as explained below and as supported by Ex-1004, ¶¶99-100. Claims 2 and 25 depend from claims 1 and 22, respectively. *See, supra*, claims 1, 22.

- a. “wherein the insertion element comprises an open side configured to receive [the / a] sensor [of the on-skin sensor assembly].”

Pace further discloses an insertion sharp with a “longitudinal opening” to receive a portion of the sensor, *id.*, [0009], as shown in Figures 21A-C and 35A-B:

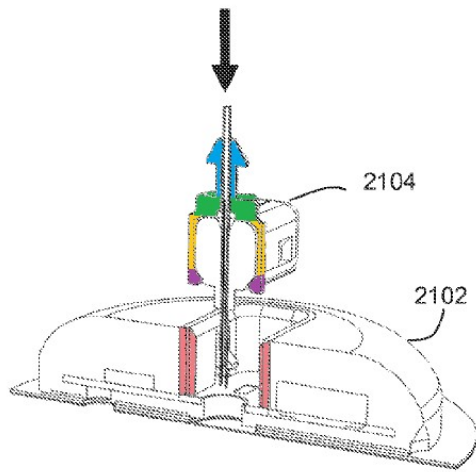


FIG. 21A

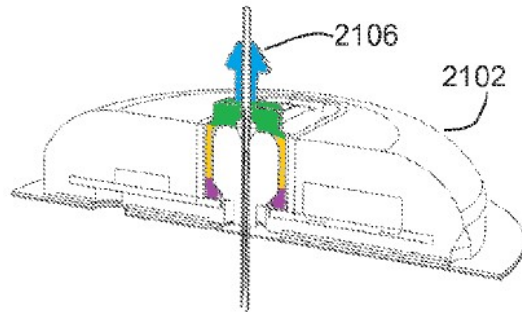
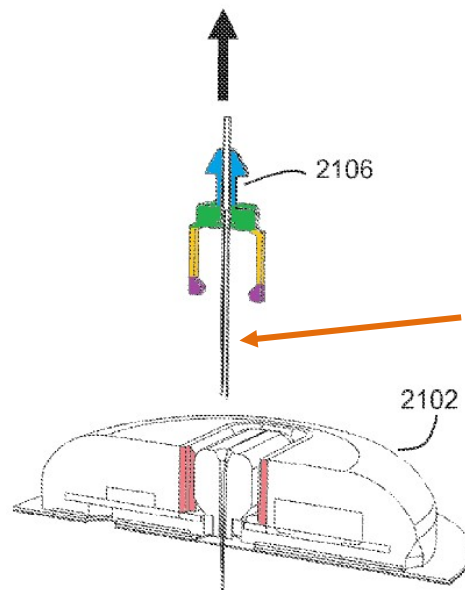
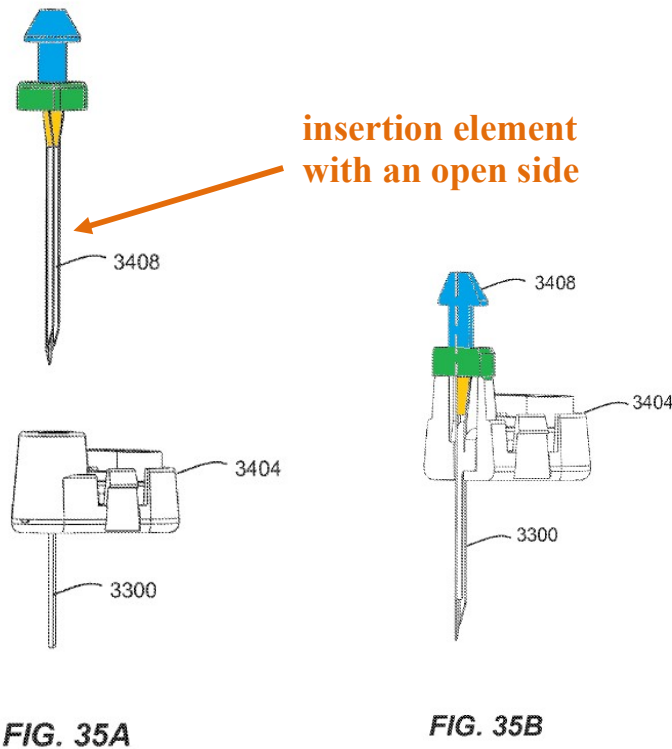


FIG. 21B



**insertion element
with an open side**

FIG. 21C



Id., Figs. 21A-21C, 35A-35B; *see also id.*, Fig. 35C-35D, 47B-C.

6. Claim 3

Pace renders obvious claim 3, as explained below and as supported by Ex-1004, ¶¶101-102. Claim 3 depends from claim 2. *See, supra*, claim 2.

- a. “wherein the insertion element has a C-shaped, U-shaped, or V-shaped cross section.”

Pace further suggests an insertion sharp having a C-, U-, or V-shaped cross section, as it has a longitudinal opening to receive a portion of the sensor. A POSITA would understand that C-, U-, and V-shaped cross sections are among the limited number of options for a needle with a longitudinal opening/channel to support a flag-shaped sensor (as shown in Figure 22). Ex-1004, ¶102; *see also* Ex-1014, 27:63-66

(incorporated by reference, Ex-1006, [0009]).

7. Claims 4, 14, 26, & 30

Pace anticipates or renders obvious claims 4, 14, 26, and 30, as explained below and as supported by Ex-1004, ¶¶103-108. Claims 4, 14, 26, and 30 depend from claims 1, 13, 22, and 28, respectively. *See, supra*, claims 1, 13, 22, 28.

- a. “wherein the needle hub is coupled to the [insertion element / needle] by heat staking, snap-fit, friction-fit, clamshell, or insert molding.”

Pace discloses hub 2106 and sharp hub 3414 (*i.e.*, a needle hub) in embodiments A and B, respectively, *see, supra*, claim 1.2, to which an insertion sharp (*i.e.*, an insertion element or needle) is coupled. Ex-1006, Figs. 21C, 35A.

As discussed above in Section 0, this limitation should be construed as a product-by-process limitation. Accordingly, the “by heat staking, snap-fit, friction-fit, clamshell, or insert molding” language of the claim should not be afforded patentable weight.

Even if the “by heat staking, snap-fit, friction-fit, clamshell, or insert molding” language is given patentable weight, Pace discloses that components of the applicator can be made by using a variety of processes, including injection molding. *See* Ex-1006, [0121] (“Any number of the parts may be injected molded, thermoformed or otherwise produced.”). A POSITA would understand that the claimed insert molding is a type of injection molding. Ex-1004, ¶107. In addition,

Pace discloses that “heat stakes” can be used to couple structures together. *See* Ex-1006, [0126] (“heat stakes 2412” are used to couple the sensor PCB to its housing). A POSITA would understand that heat staking could similarly be used to couple the needle to the needle hub. Ex-1004, ¶108.

8. Claims 5, 15, & 27

Pace anticipates or renders obvious claims 5, 15, and 27, as explained below and as supported by Ex-1004, ¶¶109-112. Claims 5, 15, and 27 depend from claims 4, 14, and 26, respectively. *See, supra*, claims 4, 14, 26.

- a. “wherein the [insertion element / needle] comprises a locking element configured to couple the [insertion element / needle] to the needle hub by insert molding.”

Pace further discloses that the sharp hub is able to retract the needle out of the user. Ex-1006, Figs. 10F-M, [0102]-[0104] (describing how the sharp hub/boss engages the sharp retraction assembly in the applicator), *Id.*, Figs. 11C-11E, [0109] (describing how the sharp retraction assembly—coupled to the sharp hub/boss—pulls the sharp out of the host after insertion). A POSITA would understand that the needle necessarily has some structure to secure it to the needle hub, otherwise the needle could separate from the needle hub. Ex-1004, ¶110. Thus Pace discloses or suggests a needle comprising a locking element configured to couple the needle to the needle hub.

As discussed above for claims 4, 14, 26, and 30, the “by insert molding” portion of this claim element should not be afforded patentable weight. Even if it is afforded patentable weight, Pace discloses or suggests coupling the needle to the needle hub by insert molding. *See, supra*, claims 4, 14, 26, and 30.

9. Claims 6 & 16

Pace anticipates or renders obvious claims 6 and 16, as explained below and as supported by Ex-1004, ¶¶112-113. Claims 6 and 16 depend from claims 1 and 13, respectively. *See, supra*, claims 1, 13.

- a. “wherein the on-skin sensor assembly comprises [an electronics unit / sensor electronics].”

See, supra, claim 28.10.

10. Claims 7, 17, & 29

Pace anticipates or renders obvious claims 7, 17, and 29, as explained below and as supported by Ex-1004, ¶¶114-117. Claims 7, 17, and 29 depend from claims 6, 16, and 28, respectively. *See, supra*, claims 6, 16, 28.

- a. “wherein the [electronics unit / sensor electronics] includes a power source, signal processing components, data storage components, and a communication module.”

Pace further discloses that the electronics assembly “includes a **battery 2406** with mount 2408, **an application specific integrated circuit (ASIC) 2410**, or other appropriate **processing unit**, and various other circuitry”:

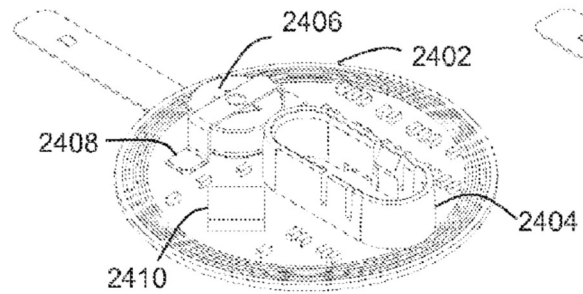


FIG. 24A

Ex-1006, Fig. 24A, [0126]. In addition, “the on-body device may include sensor electronics and other adaptation to communicate with a monitoring device.” *Id.*, [0010]. Pace further discloses:

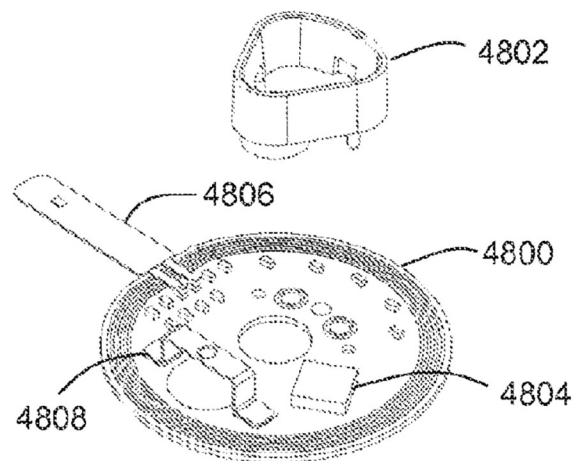


FIG. 48A

A socket 4802 or mount is fit through vias in a printed circuit board 4800 along with other associated components ***including a processor 4804 (e.g., an ASIC including a communications facility), thermistor/thermocouple 4806, a battery mount 4808, etc.***

Id., Fig. 48A, [0150].

The battery in Pace corresponds to the claimed power source, while the processor/ASIC with communications facility corresponds to the claimed signal processing components, data storage components, and communications module. Although Pace does not specifically state that the processor/ASIC contains data storage components, a POSITA would understand that it has internal storage to store inputs and outputs of computations and analyte measurements prior to transmission by the communications facility. Ex-1004, ¶117. Indeed, the purpose of Pace’s CGM device is to measure a host’s analyte concentration over time, store that data, and communicate it to another device. *E.g.*, Ex-1006, [0004] (“Another technique for monitoring glucose levels uses an in vivo analyte monitoring system, which ***measures and stores*** sensor data representative of glucose levels automatically over time.”). The ’625 patent claims do not recite the storage capacity or location of the data storage components, and the specification only repeats the “data storage components” claim language without further detail or elaboration. *See generally* Ex-1001.

11. Claims 8 & 18

Pace anticipates or renders obvious claims 8 and 18, as explained below and as supported by Ex-1004, ¶¶118-119. Claims 8 and 18 depend from claims 7 and 17, respectively. *See, supra*, claims 7, 17.

- a. “wherein the sensor is connected to the [electronics unit / sensor electronics] in the applicator housing.”

See, supra, claim 28.10.

12. Claim 9

Pace anticipates or renders obvious claim 9, as explained below and as supported by Ex-1004, ¶¶120-121. Claim 9 depends from claim 1. *See, supra*, claim 1.

- a. “wherein the on-skin sensor assembly includes an adhesive patch configured to secure the on-skin sensor assembly to the skin of the host.”

Pace further discloses an “adhesive patch 312” (light green below) configured to secure the on-body device a user’s skin:



Ex-1006, Fig. 3 (excerpt, annotated), [0083]; *see also id.*, [0085], [0127].

13. Claim 19

Pace anticipates or renders obvious claim 19, as explained below and as supported by Ex-1004, ¶¶122-123. Claim 19 depends from claim 16. *See, supra*, claim 16.

- a. “wherein the needle is configured to be inserted through the sensor electronics.”

See, supra, claim 28.13.

14. Claim 23

Pace anticipates or renders obvious claim 23, as explained below and as supported by Ex-1004, ¶¶124-125. Claim 23 depends from claim 22. *See, supra*, claim 22.

- a. “wherein the anti-rotation key is configured to prevent rotation of the base within the aperture.”

See, supra, claim 1.11. The anti-rotation key of claim 23 is configured to prevent rotation within the aperture of the *base*, as opposed to the *needle hub* in claim 1.11. As the claim language makes clear, the needle hub comprises a base, so preventing rotation of the needle hub within the aperture necessarily prevents rotation of the base within the aperture.

15. Claim 24

Pace anticipates or renders obvious claim 24, as explained below and as supported by Ex-1004, ¶¶126-127. Claim 24 depends from claim 22. *See, supra*, claim 22.

- a. “wherein the anti-rotation key has a shape complementary to at least a portion of the aperture.”

See, supra, claim 1.9. Claim 24 recites that the anti-rotation key has a shape complementary to at least a portion of the aperture, not vice-versa. This does not

impact the analysis, because, by definition, if two structures have “complementary” shapes, it is irrelevant which structure is compared to the other, the result is the same.

B. Ground 2: The Combination Of Pace And Lundquist Renders Obvious Claims 4-5, 14-15, 26-27, And 30

1. A POSITA Would Have Been Motivated To Combine Pace And Lundquist And Would Have Reasonably Expected Success

Pace discloses a hub 2106 in embodiment A and a sharp hub 3414 with a V-shaped portion in embodiment B. Ex-1006, Figs. 21A-C, 34A-D, 35A-D, 47B-C, [0123], [0142]. Pace further discloses that a retraction assembly engages the hub to retract the needle out of the user and away from the sensor. *Id.*, [0102], [0109]. A POSITA would understand the importance of ensuring the needle is coupled to the hub securely enough to ensure proper insertion of the needle and sensor in the user, and to ensure that the needle is successfully retracted out of the user when the hub is retracted. Ex-1004, ¶129; *see also*, Ex-1006, [0106] (“retracting the sharp 1030 *safely* back into the used applicator assembly 216.”).

Lundquist similarly states it is “desirable to construct a hub ... that *effectively secures* the cannula ... and provides sufficient strength to withstand the operating conditions....” Ex-1011, [0006]. Lundquist then discloses a method of securing a hollow needle to a hub where a polymeric material used to form the hub during an insert molding step “flows into and fills” a plurality of notches in the proximal end of the needle to provide “enhanced friction and gripping force” between the hub and

the needle . *Id.*, [0041], Fig. 2C. Lundquist discloses its method can be used with “any sized and shaped [needle].” *Id.*, [0041].

A POSITA would have been motivated to adopt Lundquist’s method of securing the needle to the hub using notches in the needle of Pace’s CGM applicator to achieve Pace’s stated goal of “safely” retracting the needle from the user and into the applicator. Ex-1004, ¶131. A POSITA would have a reasonable expectation of success with adopting Lundquist’s manufacturing process in Pace’s CGM system, as Pace discloses its needle may be “slotted or otherwise configured” (Ex-1006, [0109]), and Lundquist’s insert molding method with notches in the needle can be used with “any sized and shaped [needle]” (Ex-1011, [0041]). Ex-1004, ¶132. Furthermore, adding additional slots or notches to Pace’s needle to engage the polymeric material used in the hub would have been predictable and within the skill of a POSITA. *Id.*, ¶133.

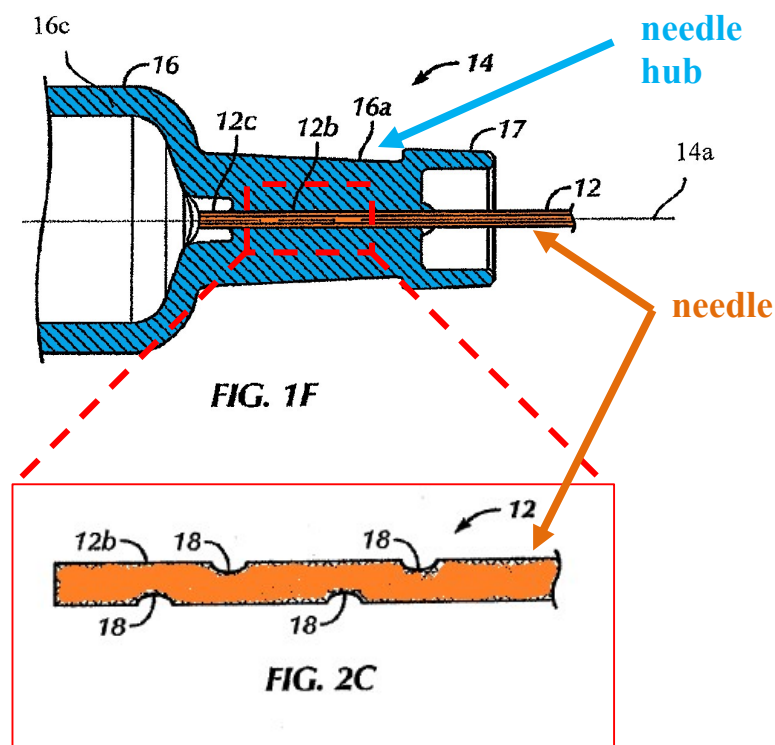
2. Claims 4, 14, 26, & 30

Claims 4, 14, 26, and 30 depend from claims 1, 13, 22, and 28, respectively. As explained in Ground 1, Pace anticipates and renders obvious claims 1, 13, 22, and 28. The combination of Pace and Lundquist further renders obvious claims 4, 14, 26, and 30, as explained below and as supported by Ex-1004, ¶¶128-138.

Pace discloses a hub 2106 in embodiment A and a sharp hub 3414 with a V-shaped portion in embodiment B. Ex-1006, Figs. 21A-C, 34A-D, 35A-D, 47B-C,

[0123], [0142]. An insertion sharp (*i.e.*, an insertion element or needle) is coupled to the hub. *Id.* Pace discloses that the applicator's components can be made using various processes, including injection molding. *Id.*, [0121]. A POSITA would understand that the "injection molding" disclosed by Pace includes the claimed "insert molding." Ex-1004, ¶136.

Although Pace does not specifically state that the needle hub may be coupled to the needle/insertion element by "insert molding," Lundquist explicitly discloses this:



Referring to FIGS. 1A-2C and 14, the staked needle or syringe 14, 14' is constructed of a polymeric barrel 16, 16' that is ***directly insert molded over the cannula 12, 12'***. ... The cannula 12, 12' is to be

attached to the *distal tip 16a* or hub 200 of the barrel 16, 16' that is *directly insert molded over the cannula 12, 12'*.

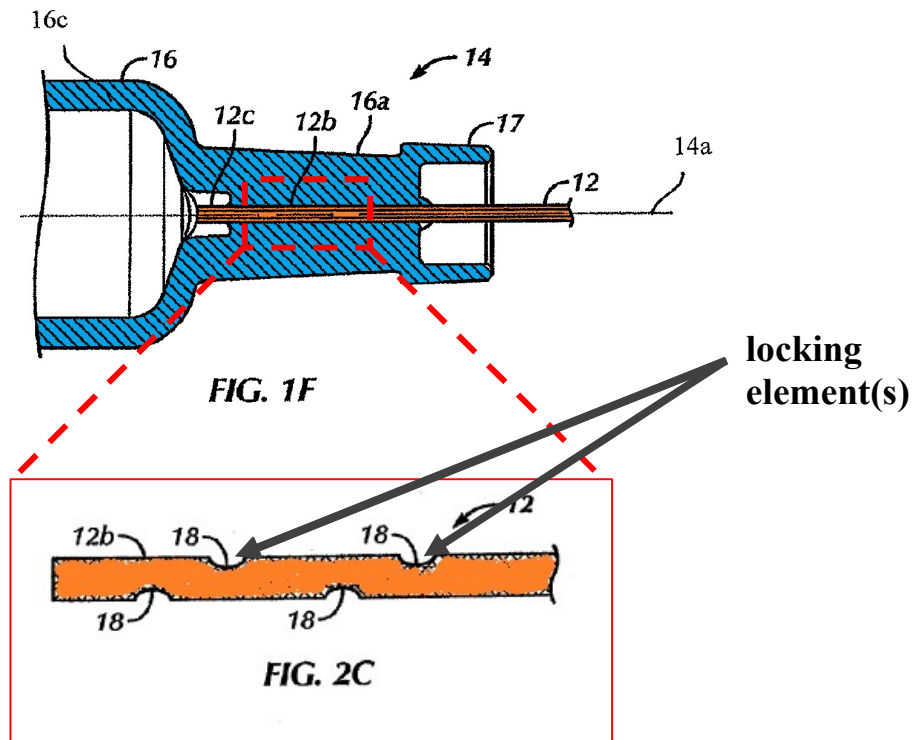
Ex-1011, Figs. 1F, 2C, [0039]; *see also id.*, [0040] (“the cannula 12, 12' is preferably a fine gauge hollow metallic needle”).

In the Pace-Lundquist combination, the hub (either 2106 in Figure 21 or 3414 in Figures 34, 35, and 47) and needle of Pace are coupled together by insert molding the hub over the needle, as taught in Lundquist.

3. Claims 5, 15, & 27

Claims 5, 15 and 27 depend from claims 4, 14, and 26, respectively. As explained above, the combination of Pace and Lundquist renders obvious claims 4, 14, and 26. The combination of Pace and Lundquist further renders obvious claims 5, 15, and 27, as explained below and as supported by Ex-1004, ¶¶128-141.

As explained above, Pace discloses a sharp coupled to a hub, with the hub being formed by “injection molding,” and Lundquist further discloses coupling a needle 12 to a hub 16a by “insert molding” the hub over the needle. *See, supra*, claims 4, 14, and 26. Lundquist further discloses the “cannula” or “fine gauge hollow needle” 12 includes a plurality of “notches” 18 (seen in Figure 2C below), such that the polymeric material that forms the hub 16a “flows into and fills the notches” during the insert molding step.



Ex-1011, Figs 1F, 2C, [0039]-[0041]. The “notches” 18 in the needle 12 correspond to the claimed “locking element,” as seen by comparing Figure 2C of Lundquist (above) with Figure 80B of the '625 patent (below):

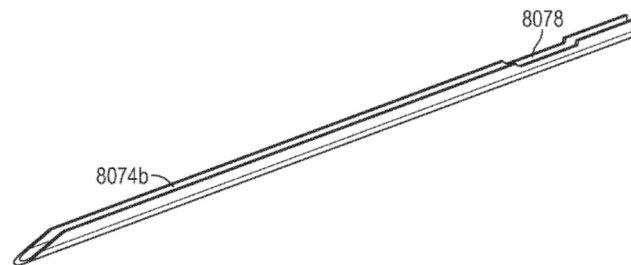


FIG. 80B

Ex-1001, Fig. 80B; *see also id.*, 69:13-16 (needle 8047b comprises a “locking feature comprising a groove 8078”).

In the Pace-Lundquist combination, the hub (either 2106 in Figure 21 or 3414

in Figures 34, 35, and 37) and needle of Pace are coupled together by adding notches to the needle and insert molding the hub over the needle, as taught in Lundquist.

C. Ground 3: Pace 2 Renders Obvious Claims 1-3, 6-9, 13, 16-19, 22-25, And 28-29

1. Independent Claim 1

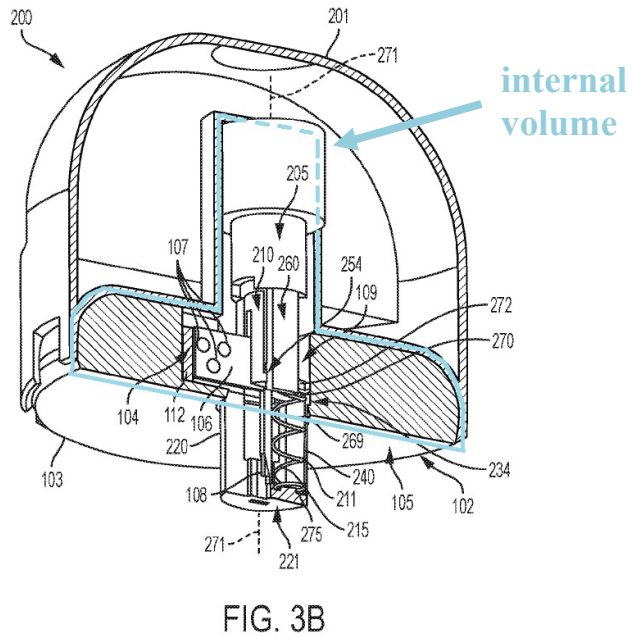
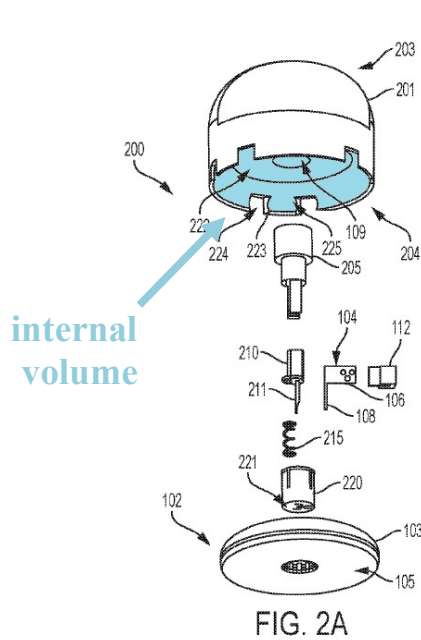
Pace 2 renders obvious claim 1, as explained below and as supported by Ex-1004, ¶¶142-155.

a. 1.P

Pace 2 discloses an applicator 200 for applying a CGM to a user's skin. Ex-1007, [0083], Figs. 2A-2B, [0047]; *see also id.*, Fig. 8, [0090]-[0094], Figs. 3E-3F.

b. 1.1

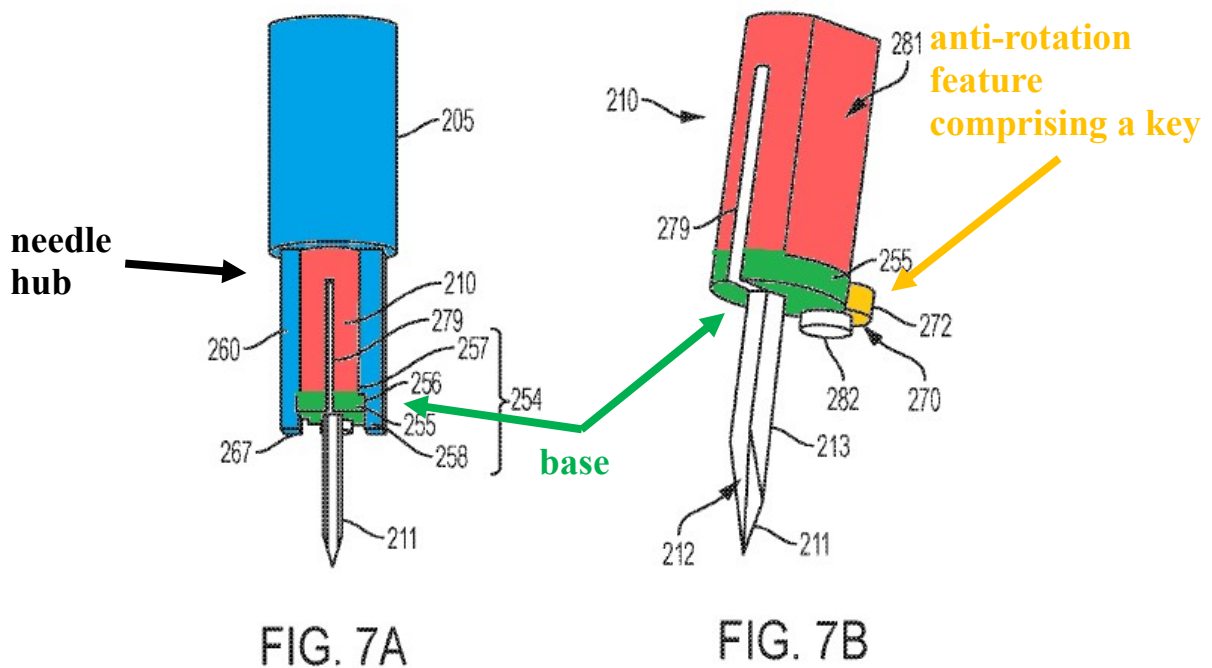
Pace 2 discloses an applicator housing having an internal volume. Ex-1007, Figs. 2A, 3B, 3D, 4B, 4D, 5B, 5D, 6A. For example, as seen in Figures 2A and 3B, inserter 200 (*i.e.*, an applicator) comprises a housing 201 which has an internal volume (annotated in light blue) for holding sensor control device 102, which may include shroud 220 and other components:



Id., Fig. 2A, [0047]-[0051]; Fig. 3B, [0052]; [0086] (“shroud 220 remains with device 102”).

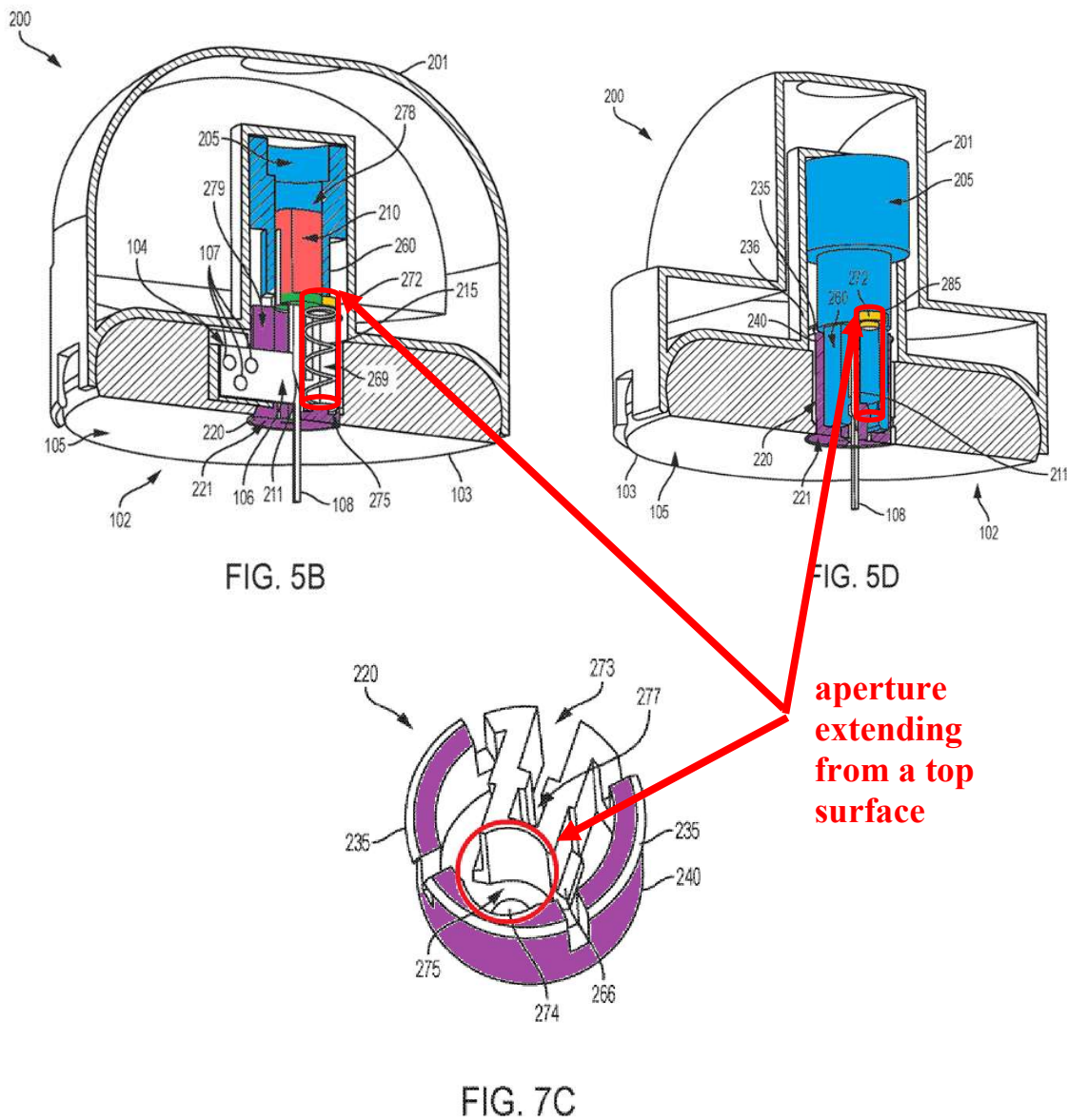
c. 1.2-1.5

Pace 2 discloses a sharp support 205 with a sharp body 210 (*i.e.*, a needle hub) coupled to a sharp 211 (*i.e.*, an insertion element) configured to pierce the user’s skin.



Ex-1007, Figs. 7A, 7B, [0006], [0047], [0087]. As annotated Figures 7A and 7B show, the lower portion of the sharp support 205 with sharp body 210 corresponds to the claimed “base” (annotated in green above), with the ledge 272 corresponding to the “anti-rotation feature extending from the base, the anti-rotation feature comprising a key, the key having a first shape” (annotated in gold above).

Pace 2 discloses a “ledge 272 of sharp body 210 that is offset and extends away from sharp 211.” *Id.*, [0068]. The ledge 272 “is sized to fit and slide longitudinally within chamber 269” (*i.e.*, the aperture, highlighted below):



Id., Figs. 5B, 5D, 7C, [0068]; *see also id.*, Figs. 3B, 3D, 4B, 4D.

Figures 5B and 7C show a chamber 269 within shroud 220, which protects the needle before application. During application, the shroud retracts vertically relative to the housing 103. *Id.*, [0077]-[0081]. After application, the shroud 220 can remain part of the on-skin sensor control assembly, with its bottom surface flush with the bottom of the housing 103. *Id.*, [0086].

Furthermore, Pace 2 discloses that projections or extensions can prevent rotation of different components during insertion:

Although not shown, to assist in guiding advancement and/or retraction of shroud 220, one or more elongate grooves, spaces, or ***channels can be implemented in which a projection or extension can slide***. For example, the elongate groove, space, or channel can be present in shroud 220 with the longitudinal axis of that groove, space, or channel generally aligned with the direction of sliding motion, such that a projection or extension on the interior of housing 201 can be received into the groove, space, or channel and thereby guide the motion of shroud 220, ***preventing shroud 220 from rotating or tilting during advancement and/or retraction***.

Id., [0089].

Although Pace 2 does not specifically state that ledge 272 has an “anti-rotation” functionality, such functionality necessarily results from Pace 2’s arrangement. As shown above, Pace 2 makes clear that various “extensions” in the applicator can slide within channels in the shroud 220 (as part of the sensor control device) and prevent rotation within the sensor control device (*i.e.*, the on-skin sensor assembly). Ledge 272 is one such extension that extends from sharp body 210 and “fit[s]” within the cylindrical chamber 269, which has an open side that allows the ledge 272 to slide vertically within the chamber. *Id.*, [0068]. Because the ledge 272 projects outwardly from the sharp body 210, offset from the sharp 211, the walls of the

chamber 269 necessarily prevent the ledge 272, and thus the sharp body 210 and sharp support 205, from rotating relative to the shroud, and thus the remainder of the sensor control device.

To the extent Pace 2 does not expressly describe the anti-rotation function of ledge 272 and the chamber 269, a POSITA would have considered it obvious that the combination would provide an anti-rotation function. Ex-1004, ¶150. Thus, Pace 2 discloses or suggests claims 1.2-1.5.

d. 1.6

Pace 2 discloses an on-skin sensor assembly. Ex-1007, Figs. 1, 2A-2B, 6B-6D, 8, 9. For example, Pace 2 discloses a “sensor control device 102 containing an in-vivo [analyte] sensor 104:”

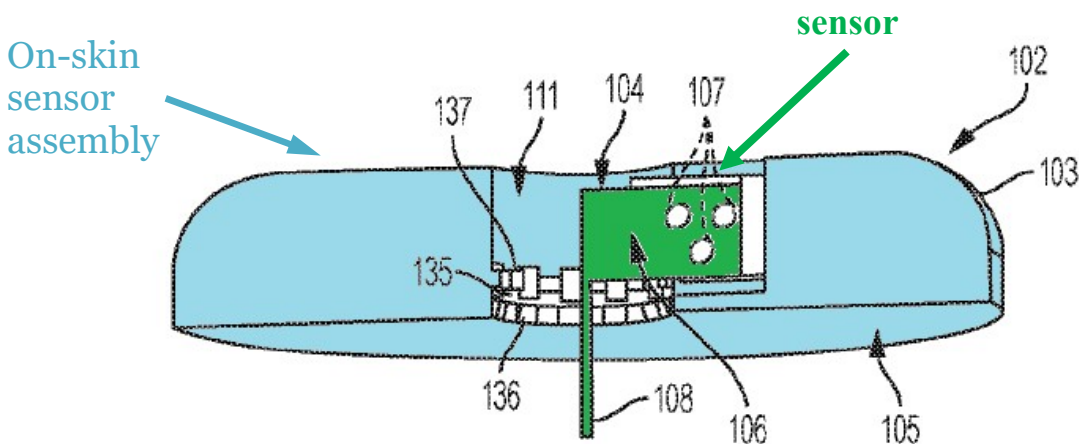
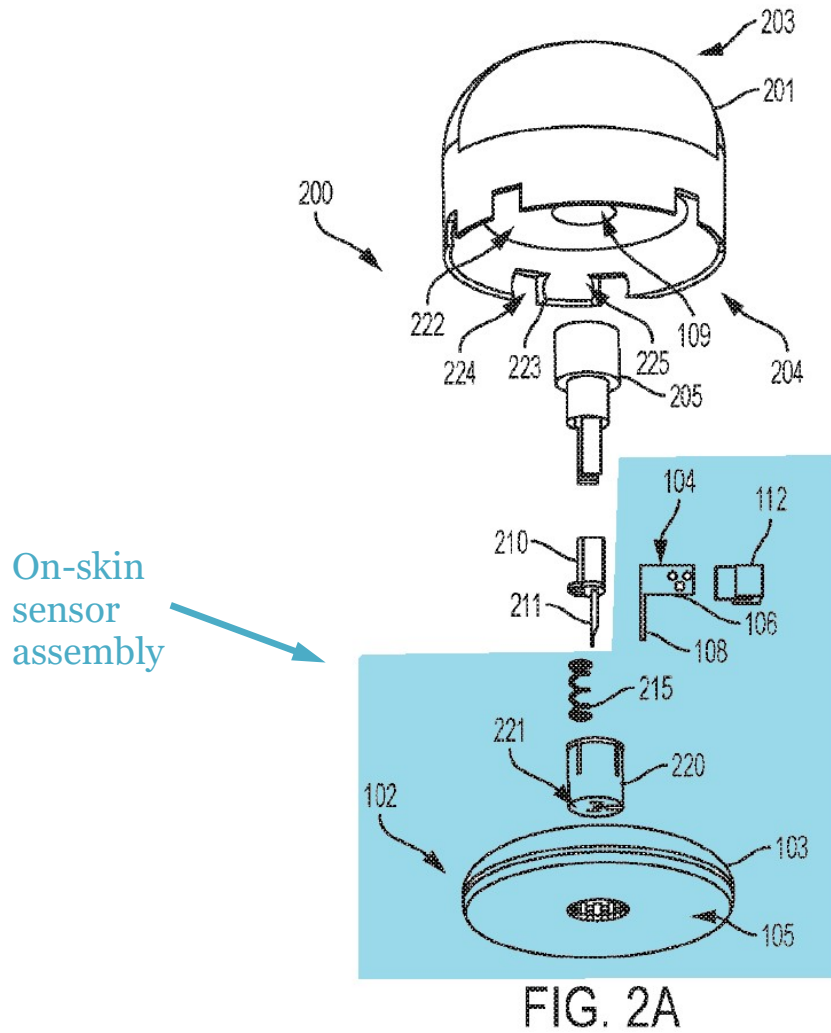


FIG. 6B

Id., Fig. 6B, [0038]; *see also Id.*, [0040] (“Sensor 104 can be part of the **sensor control device 102 that resides on the body of the recipient.**”). Figure 2A shows an exploded view of the sensor control device 102:



Id., Fig. 2A. Pace 2 further discloses the process for applying the sensor control device 102 to the user's skin. *Id.*, Fig. 8, [0090]-[0094].

e. 1.7

Pace 2 discloses a sensor 104 for measuring an analyte such as glucose in the sensor control device 102:

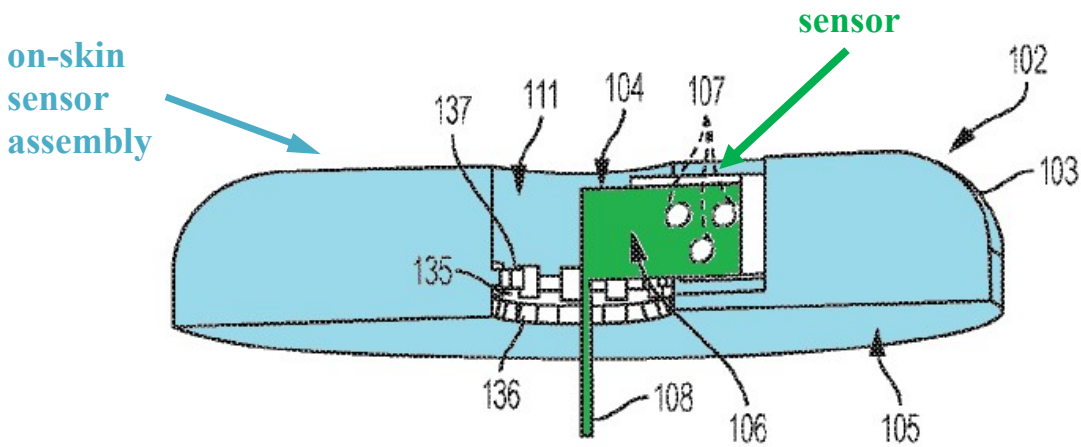


FIG. 6B

Ex-1007, Fig. 6B, [0083]; *see id.*, [0011] (describing “an *analyte monitoring system for real time analyte (e.g., glucose) measurement*, data acquisition and/or processing.”), [0038], [0037], claim 19.

f. 1.8-1.10

Pace 2 discloses a chamber 269 extending from a top surface of the shroud 220 (part of the on-skin sensor assembly) that the ledge 272 of the sharp body 210 is “sized to fit” and “slide[s] longitudinally within,” Ex-1007, [0068]:

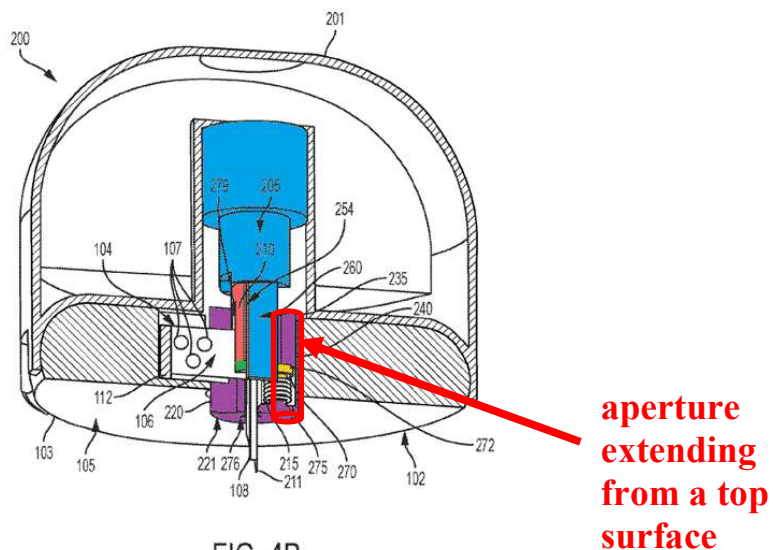
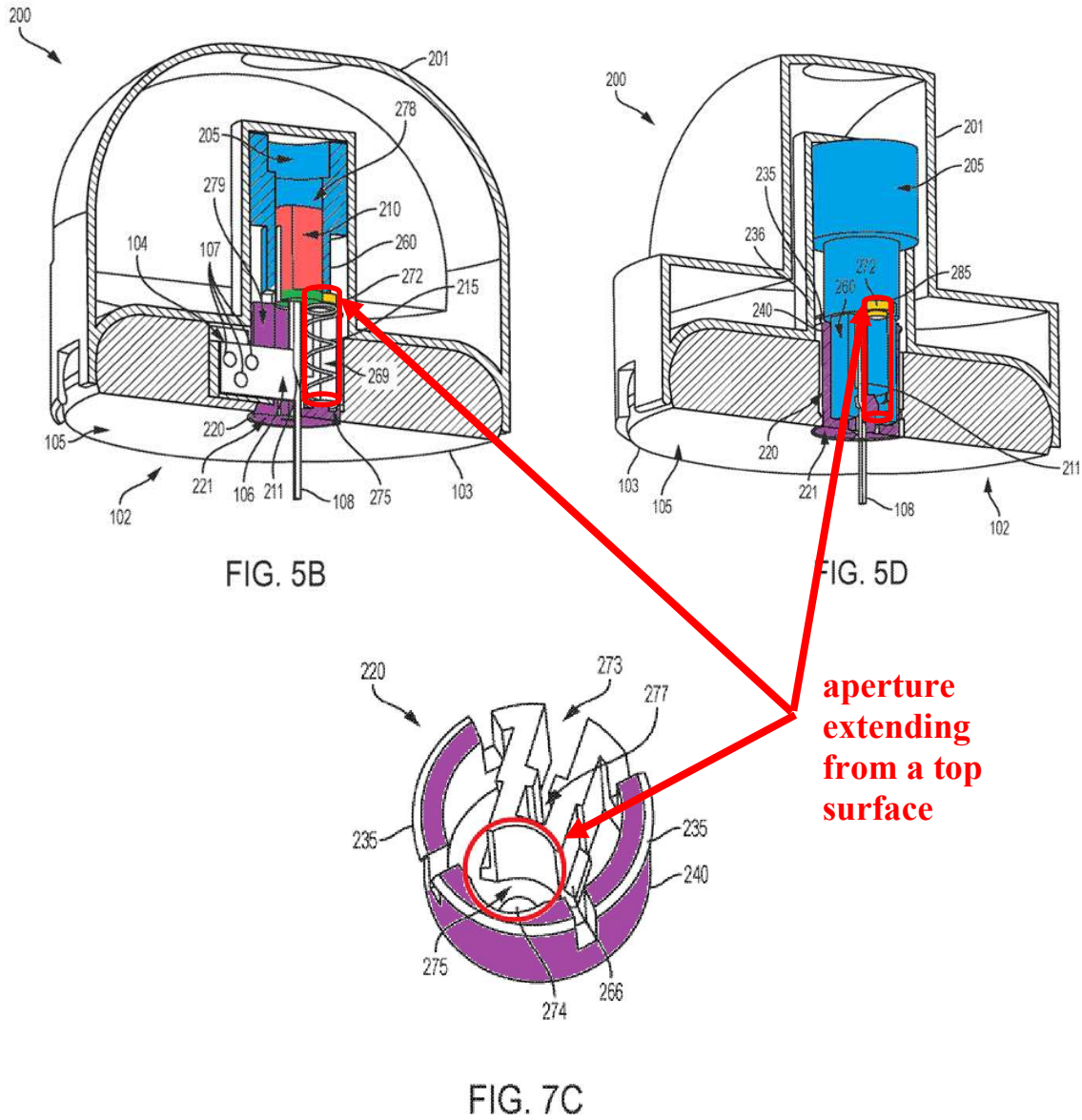
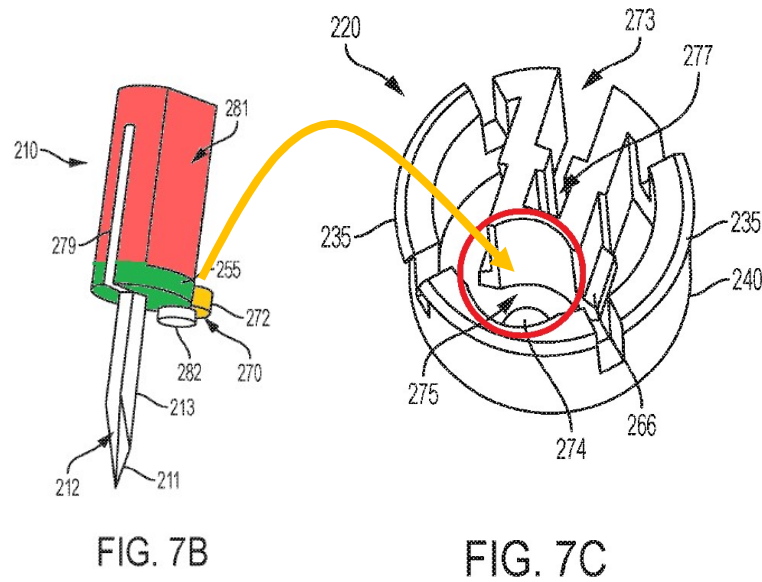


FIG. 4B



Id., Figs. 4B, 5B, 5D, 7C. As seen above, the chamber 269 (*i.e.*, the aperture) is shaped to the fit ledge/extension 272 (*i.e.*, it is complementary to the first shape of the key).



Id., Figs. 7B-C.

Furthermore, Figure 4B above shows the ledge 272 (*i.e.*, the anti-rotation feature comprising a key) is configured to be at least partially disposed in the aperture of sensor control device 102.

g. 1.11

As explained above for claims 1.2-1.5, the ledge 272 of the sharp body 210 (*i.e.*, the anti-rotation feature comprising a key) prevents rotation of the needle hub (and the needle coupled to it) relative to the on-body device. It does so by being inserted within the chamber 269 in the on-body device (*i.e.*, the aperture).

2. Independent Claim 13

Pace 2 renders obvious claim 13, as explained below and as supported by Ex-1004, ¶¶156-162.

a. 13.P

See, supra, claim 1.P.

b. 13.1

See, supra, claim 1.1.

c. 13.2-13.5

See, supra, claims 1.2-1.5. Claim 13.2 recites a needle hub coupled to a “needle” rather than the “insertion element” in claim 1.2, but in the ’625 patent, the “insertion element” can comprise a “needle.” Ex-1001, 27:12-18. Furthermore, the base that “*comprises* an anti-rotation key” recited in claim 13.5 corresponds to the base of claim 1.4 having “an anti-rotation feature *extending from*” it.

In addition, claim 13.5 recites an “anti-rotation key,” rather than claim 1.5’s “anti-rotation feature comprising a key.” As explained for claim 1.4–1.5, Pace 2 discloses a ledge 272 (*i.e.*, the anti-rotation key) extending from the sharp body 210 that is shaped to fit inside of and slide within cylindrical chamber 269.

d. 13.6-13.10

See, supra, claims 1.6-1.10.

e. 13.11

See, supra, claim 1.11. While claim 1.11 recites preventing rotation of the needle hub relative to the “aperture” rather than the “on-skin sensor assembly” in claim 13.11, claim 13.8 makes clear the aperture is part of the on-skin sensor assembly and thus the needle hub in Pace 2 is prevented from rotating relative to the

on-skin sensor assembly.

3. Independent Claim 22

Pace 2 renders obvious claim 22, as explained below and as supported by Ex-1004, ¶¶163-169.

a. 22.P

Pace 2 discloses a “needle hub coupled to an insertion element.” *See, supra*, claim 1.2. Pace 2 further discloses how the sharp support 205 and sharp body 210 are used to apply the sensor control device 102 to the user’s skin. Ex-1007, Fig. 8, [0072]-[0073], [0090]-[0094].

b. 22.1

See, supra, claims 1.3-1.5 and 13.2-13.5.

c. 22.2

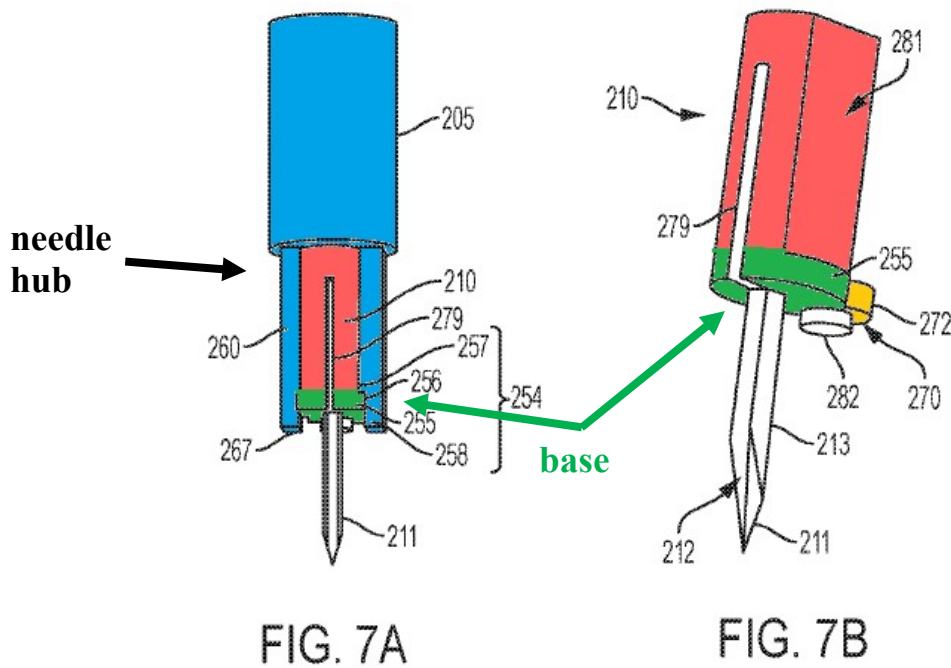
See, supra, claim 1.11.

d. 22.3

See, supra, claim 1.2.

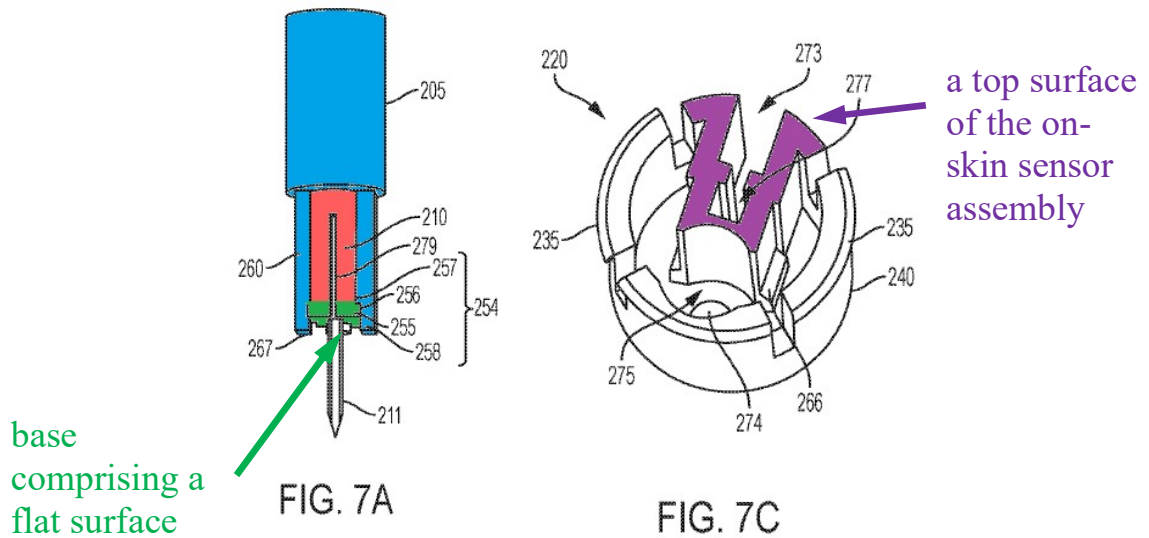
e. 22.4

Pace 2 discloses a sharp support 205 with sharp body 210 (*i.e.*, a needle hub,) with a lower portion comprising a base (annotated in green below). *See, supra*, claim 1.3. The sharp support 205 and sharp body 210 are coupled to a sharp 211 (*i.e.*, an insertion element).



Ex-1007, Figs. 7A, 7B, [0006], [0047], [0087].

Pace 2 further discloses a flat surface at the bottom of sharp body 210 rests on a top surface of shroud 220 inside the sensor control device 102.



Id., Fig. 7A, 7C. As depicted in Figures 4D and 5D below, a flat surface of the base

of sharp body 210 (annotated in bright green) is configured to mate with a top surface of the shroud (annotated in light purple):

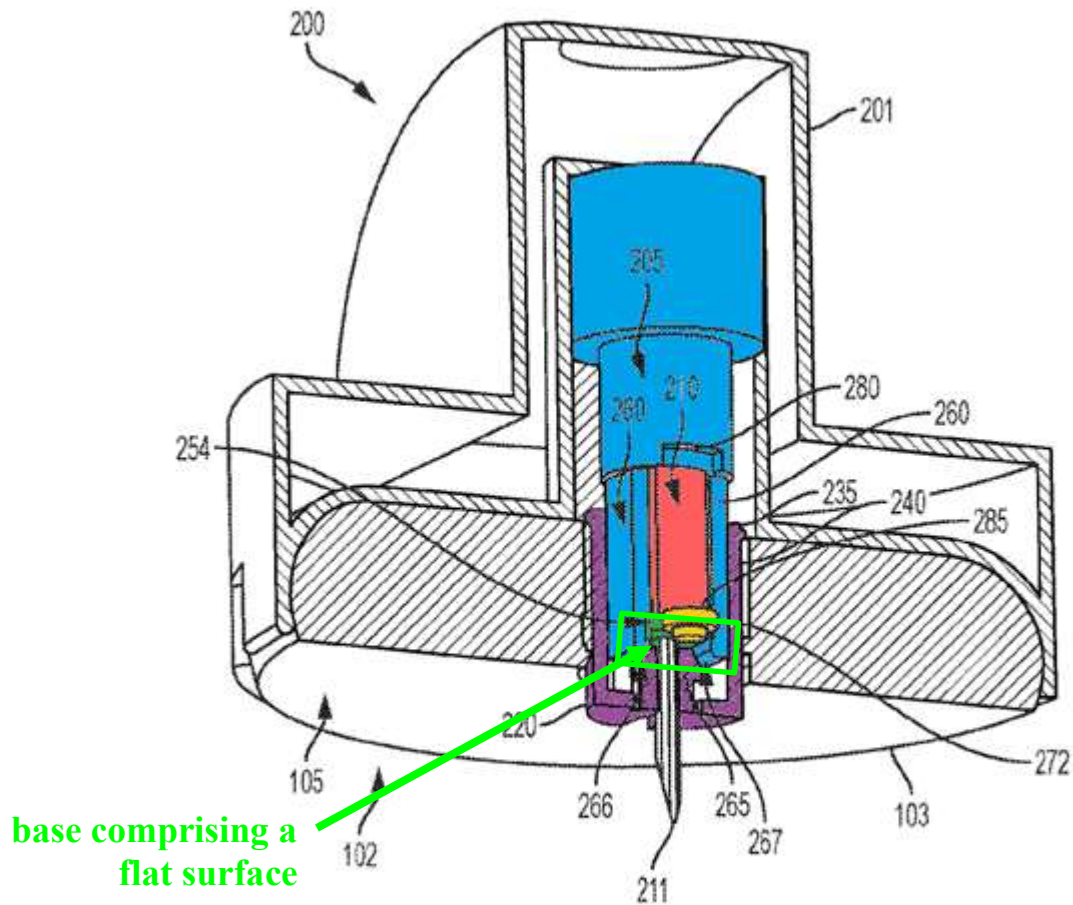


FIG. 4D

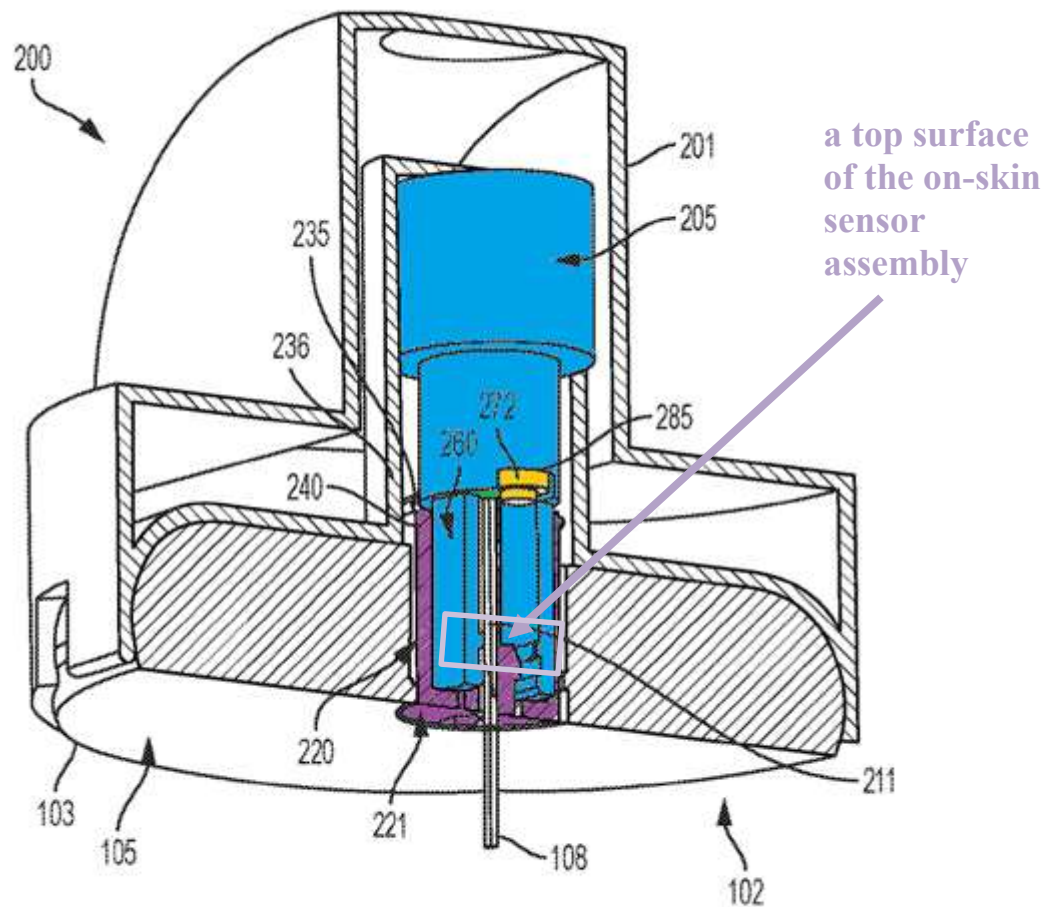


FIG. 5D

Id., Figs. 4D, 5D. In some embodiments of *Pace 2*, the shroud 220 “remains with device 102” after the sharp is removed. *Id.*, [0086]. Thus, the annotated surface of shroud 220 in Figure 7C above is a “top surface” of the on-skin sensor assembly. *Id.*, Fig. 7C; *see also id.*, Figs. 3B, 3D, 5D. As shown in Figure 4D above, sharp 211 is maintained in a substantially perpendicular orientation relative to the sensor control device and the top surface of the shroud 220.

4. Independent Claim 28

Pace 2 renders obvious claim 28, as explained below and as supported by Ex-1004, ¶¶170-179.

a. 28.P

See, supra, claim 1.P.

b. 28.1

See, supra, claim 1.1.

c. 28.2

See, supra, claim 1.2. Claim 28.2 recites the needle hub is coupled to a “needle” rather than the “insertion element” in claim 1.2., but in the ’625 patent, the “insertion element” can comprise a “needle.” Ex-1001, 27:12-18.

d. 28.3-28.9

See, supra, claims 1.3-1.9.

e. 28.10

Pace 2 discloses the sensor control device 102 contains a housing 103 with sensor electronics, and the sensor 104 is in electrical contact with the sensor electronics. Ex-1007, [0040], [0051], [0100].

Furthermore, Figure 3B shows the sensor 104 (annotated in green) electrically coupled to the sensor control unit 102 (annotated in light blue) via contacts 107, while in the applicator housing:

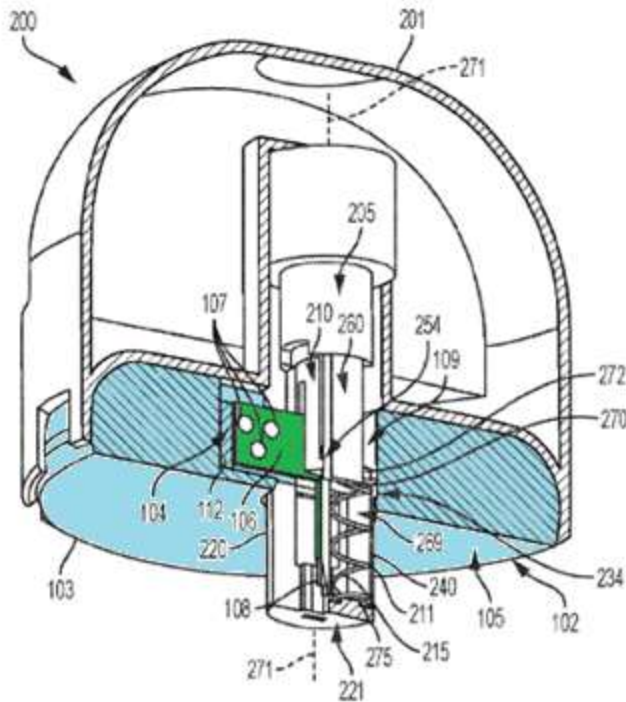


FIG. 3B

Id., Fig. 3B; *see also id.*, Fig. 6C.

f. 28.11

See, supra, claim 1.10.

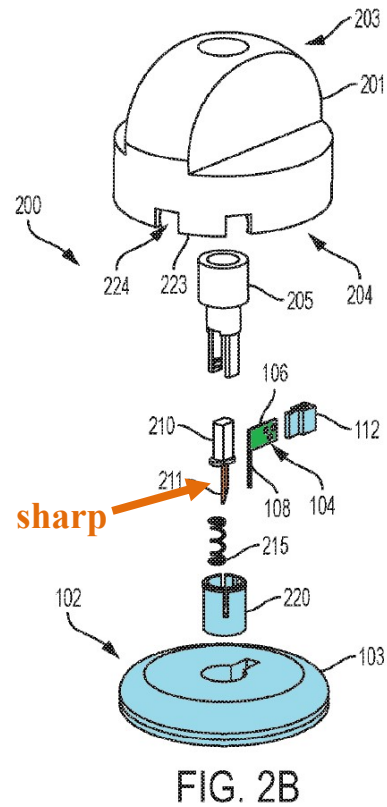
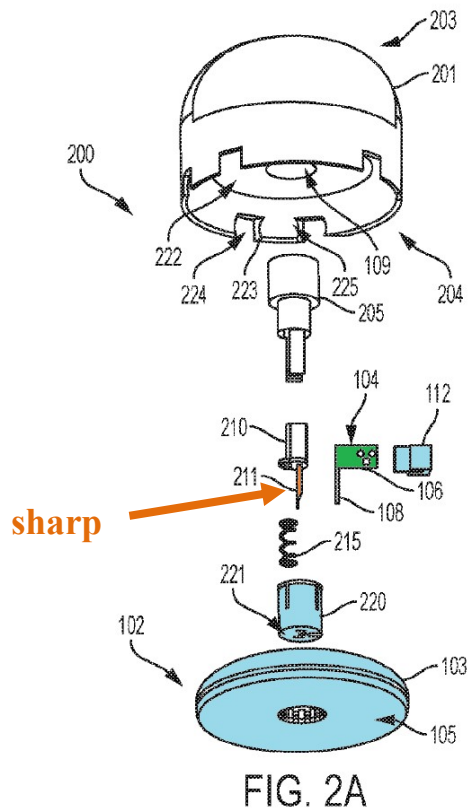
g. 28.12

See, supra, claim 1.11. The anti-rotation feature of claim 28.12 is configured to prevent rotation within the aperture of the *base*, as opposed to the *needle hub* in claim 1.11. As the claim language makes clear, the needle hub comprises a base, so preventing rotation of the needle hub within the aperture necessarily prevents rotation of the base within the aperture.

h. 28.13

Pace 2 discloses that the sharp 211 (annotated in orange below) is inserted

through at least a portion of the sensor electronics in housing 103 (annotated in light blue below):



Ex-1007, Figs. 2A-2B.

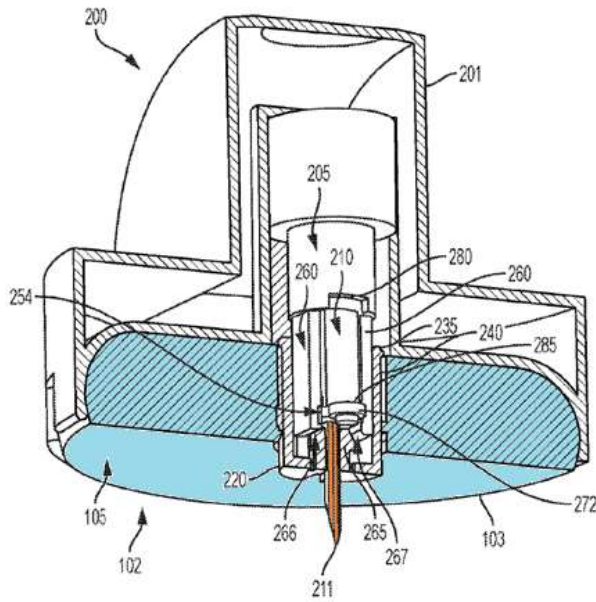


FIG. 4D

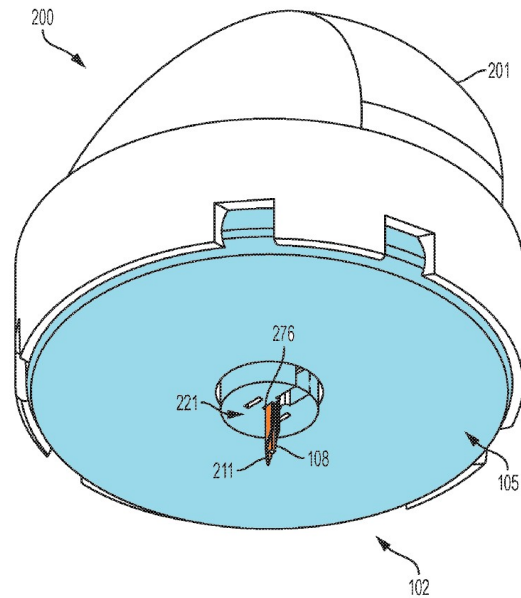


FIG. 4E

Id., Figs. 4D-4E; *see also id.*, Fig. 4A-4C.

5. Claims 2 & 25

Pace 2 renders obvious claims 2 and 25, as explained below and as supported by Ex-1004, ¶¶180-181. Claims 2 and 25 depend from claims 1 and 22, respectively. *See, supra*, claims 1, 22. Pace 2 further discloses that “sharp 211 has a U-shaped configuration where opposing sidewalls 213 form a channel 212 therebetween ... such that sharp 211 can partially surround and protect” the sensor during insertion, Ex-1007, [0087]:

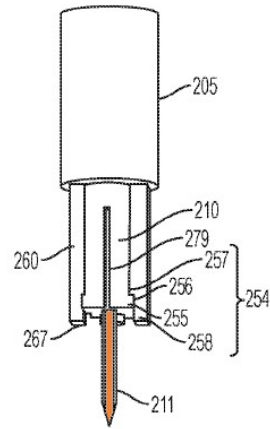


FIG. 7A

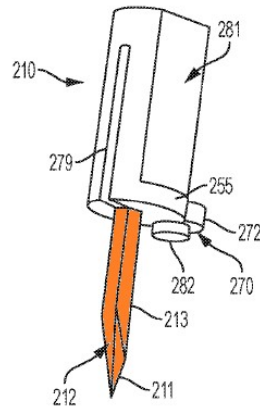


FIG. 7B

Id., Fig. 7A-7B.

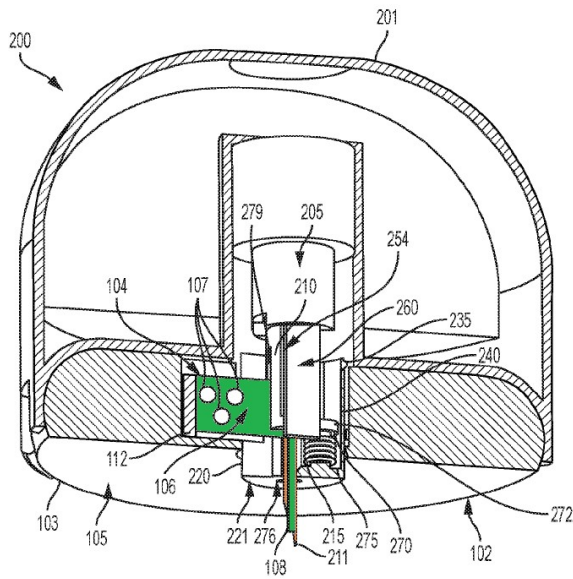


FIG. 4B

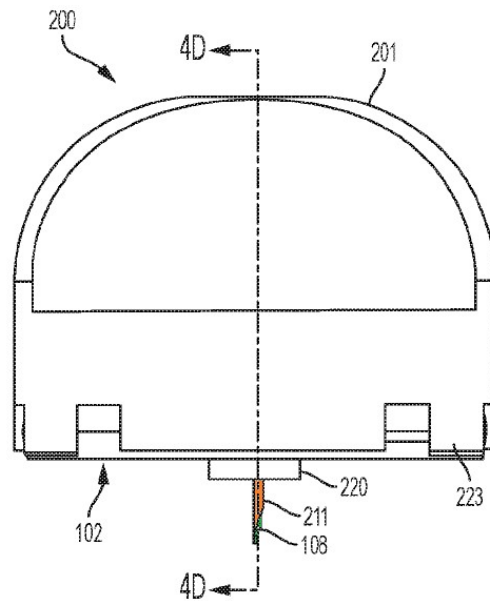


FIG. 4C

Id., Figs. 4B-C.

6. Claim 3

Pace 2 renders obvious claim 3, as explained below and as supported by Ex-

1004, ¶¶182-183. Claim 3 depends from claim 2. *See, supra*, claim 2. Pace 2 further discloses the needle has a U-shaped cross section. *See, supra*, claim 2.

7. Claims 6 & 16

Pace 2 renders obvious claims 6 and 16, as explained below and as supported by Ex-1004, ¶¶184-185. Claims 6 and 16 depend from claims 1 and 13, respectively. *See, supra*, claims 1, 13. Pace 2 further discloses the additional limitations of claims 6 and 16. *See, supra*, claim 28.10.

8. Claims 7, 17, & 29

Pace 2 renders obvious claims 7, 17, and 29, as explained below and as supported by Ex-1004, ¶¶186-187. Claims 7, 17, and 29 depend from claims 6, 16, and 28, respectively. *See, supra*, claims 6, 16, 28. Pace 2 further discloses the sensor electronics include a power source 960, processor 956, memory 953, and communication circuitry 958:

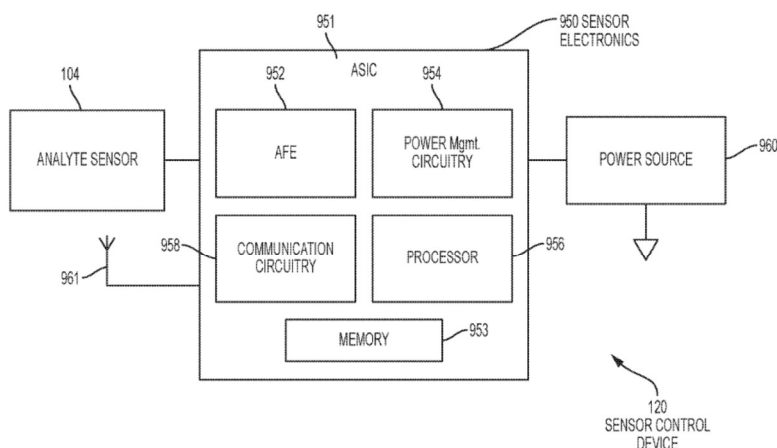


FIG. 9

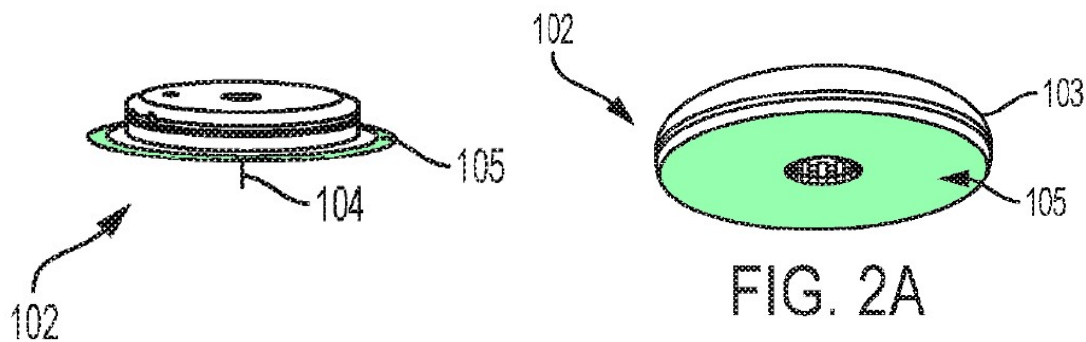
Ex-1007, Fig. 9, [0108]-[0109].

9. Claims 8 & 18

Pace 2 renders obvious claims 8 and 18, as explained below and as supported by Ex-1004, ¶¶188-189. Claims 8 and 18 depend from claims 7 and 17, respectively. *See, supra*, claims 7, 17. Pace 2 further discloses the additional limitations of claims 8 and 18. *See, supra*, claim 28.10.

10. Claim 9

Pace 2 renders obvious claim 9, as explained below and as supported by Ex-1004, ¶¶190-191. Claim 9 depends from claim 1. *See, supra*, claim 1. Pace 2 further discloses the sensor control device 102 has an “adhesive patch 105” (light green below) configured to secure the sensor control device to a user’s skin:



Ex-1007, Figs. 1 (excerpt), 2A (excerpt), [0100].

11. Claim 19

Pace 2 renders obvious claim 19, as explained below and as supported by Ex-1004, ¶¶192-193. Claim 19 depends from claim 16. *See, supra*, claim 16. Pace 2 further discloses the additional limitation of claim 19. *See, supra*, claim 28.13.

12. Claim 23

Pace 2 renders obvious claim 23, as explained below and as supported by Ex-1004, ¶¶194-195. Claim 23 depends from claim 22. *See, supra*, claim 22. Pace 2 further discloses the additional limitation of claim 23. *See, supra*, claim 1.11. The anti-rotation key of claim 23 is configured to prevent rotation within the aperture of the *base*, as opposed to the *needle hub* in claim 1.11. As the claim language makes clear, the needle hub comprises a base, so preventing rotation of the needle hub within the aperture necessarily prevents rotation of the base within the aperture.

13. Claim 24

Pace 2 renders obvious claim 24, as explained below and as supported by Ex-1004, ¶¶196-197. Claim 24 depends from claim 22. *See, supra*, claim 22. Pace 2 further discloses the additional limitation of claim 24. *See, supra*, claim 1.9. Claim 24 recites that the anti-rotation key has a shape complementary to at least a portion of the aperture, not vice-versa. This does not impact the analysis, because, by definition, if two structures have “complementary” shapes, it is irrelevant which structure is compared to the other, the result is the same.

D. Ground 4: The Combination Of Pace 2 And Lundquist Renders Obvious Claims 4-5, 14-15, 26-27, and 30

1. A POSITA Would Have Been Motivated To Combine Pace 2 And Lundquist And Would Have Reasonably Expected Success

Pace 2 discloses an applicator for a CGM comprising a sharp 211 coupled to a sharp support 205 with sharp body 210. Ex-1007, [0047]. Pace 2 further discloses that the sharp is automatically retracted from the user's skin with the aid of a biasing element acting against sharp body 210. *Id.*, Abstract, [0053], [0073]. A POSITA would understand the importance of ensuring the sharp is coupled to the sharp body 210 securely enough to ensure proper insertion of the sharp and sensor, and to ensure the sharp is successfully retracted from the user when the sharp body 210 is retracted. Ex-1004, ¶199; *see also* Ex-1007, [0054] (“Sharp 211 is movable with respect to projection 108 and can be withdrawn from the user's body while leaving sensor projection 108 implanted therein.”), [0073] (“This movement withdraws sharp 211 from the user's body without moving sensor 104, such that projection 108 remains fully extended (FIGS. 5A-E) in a position where the terminus of projection 108 would be at the desired depth within the user's body (e.g., within a dermal layer, subcutaneous layer, etc.)”).

Lundquist similarly states it is “desirable to construct a hub ... that *effectively secures* the cannula ... and provides sufficient strength to withstand the operating conditions....” Ex-1011, [0006]. Lundquist then discloses a method of securing a

hollow needle to a hub where a polymeric material used to form the hub during an insert molding step “flows into and fills” a plurality of notches in the proximal end of the needle to provide “enhanced friction and gripping force” between the hub and the needle . *Id.*, [0041], Fig. 2C. Lundquist discloses its method can be used with “any sized and shaped [needle].” *Id.*, [0041].

A POSITA would have been motivated to adopt Lundquist’s method of securing the needle to the hub using notches in the needle in Pace 2’s CGM applicator in order to achieve Pace 2’s objective of retracting the needle out of the user and back into the applicator without disturbing the sensor inserted in the skin of the user. Ex-1004, ¶201. A POSITA would have a reasonable expectation of success with adopting Lundquist’s manufacturing process in Pace 2’s CGM system as Pace 2 discloses that elements of the inserter are coupled via molding (Ex-1007, [0063], [0069]), and Lundquist discloses that its method of coupling a needle to a hub via insert molding with notches in the needle can be used with “any sized and shaped [needle]” (Ex-1011, [0041]). Ex-1004, ¶202. Because the sharp of Pace 2 has an open channel on one side to receive the sensor, adding additional slots or notches for the sharp to engage the polymeric material used in the hub would have been predictable and within the skill of a POSITA. *Id.*, ¶203.

2. Claims 4, 14, 26, & 30

Claims 4, 14, 26, and 30 depend from claims 1, 13, 22, and 28, respectively. As explained in Ground 3 Pace 2 renders obvious claims 1, 13, 22, and 28. The combination of Pace 2 and Lundquist further renders obvious claims 4, 14, 26, and 30, as explained below and as supported by Ex-1004, ¶¶198-207.

Pace 2 discloses that a sharp support 205 with sharp body 210 (*i.e.*, a needle hub) is coupled to a sharp 211 (*i.e.*, an insertion element). Ex-1007, [0047]. Pace 2 further discloses that the sharp support 205 can be “molded” or formed as a “snap or clip” or “an interference fit” with the inserter housing. Ex-1007, [0063], [0069].

Although Pace 2 does not specifically state that the needle hub may be coupled to the needle/insertion element by “insert molding,” Lundquist explicitly discloses this. *See* Ground 2, claim 4.

In the Pace 2-Lundquist combination, the sharp body 210 and sharp 211 of Pace 2 are coupled together by insert molding the sharp body 210 over the sharp, as taught in Lundquist.

3. Claims 5, 15, & 27

Claims 5, 15 and 27 depend from claims 4, 14 and 26, respectively. As explained above the combination of Pace 2 and Lundquist renders obvious claims 4, 14, and 26. The combination of Pace 2 and Lundquist further renders obvious claims 5, 15, and 27, as explained below and as supported by Ex-1004, ¶¶198-210.

As explained above, Pace 2 discloses that a sharp is coupled to a sharp support 205 with sharp body 210, with the sharp support and body being formed by “molding,” and Lundquist further discloses coupling a needle to a hub by “insert molding” the hub over the needle. *See, supra*, claims 4, 14, and 26. Lundquist further discloses a needle comprising a locking element configured to couple the needle to the needle hub by insert molding. *See* Ground 2, claim 5.

In the Pace 2-Lundquist combination, the sharp body 210 and sharp 211 of Pace 2 are coupled together by adding notches to the sharp 211 and insert molding the sharp body 210 over the sharp 211, as taught in Lundquist.

E. Ground 5: Chae Renders Obvious Claims 1-3, 6, 9, 13, 16, And 22-24

1. Independent Claim 1

Chae renders obvious claim 1, as explained below and as supported by Ex-1004, ¶¶211-222.

a. I.P

Chae discloses an applicator 10 for applying a CGM sensor to a user’s skin. Ex-1008, Abstract, Figs. 1-6. Figure 1 discloses the CGM applicator assembly, and Figure 5 shows a cross-sectional view taken along line A-A in Figure 1:

FIG. 1

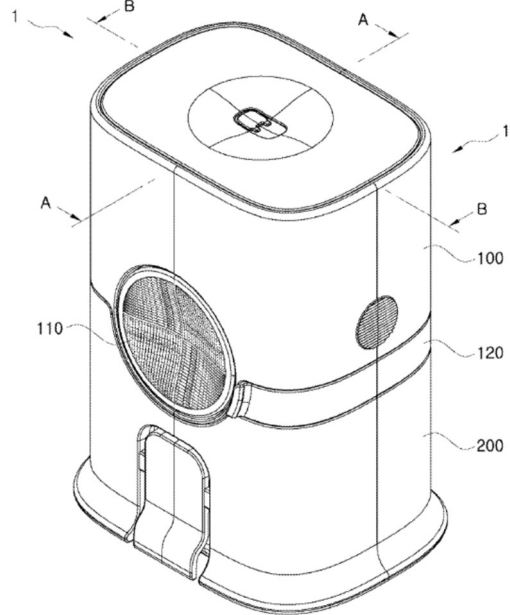
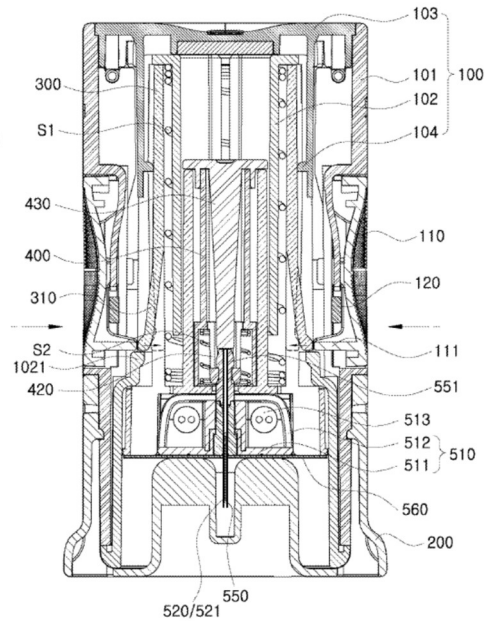


FIG. 5



Id., Figs. 1, 4, [0053]; *see generally id.*, Figs. 18A-18B, 19A-19B, 21-24. Figures 2 and 24 further show a sensor module as applied to the skin:

FIG. 2

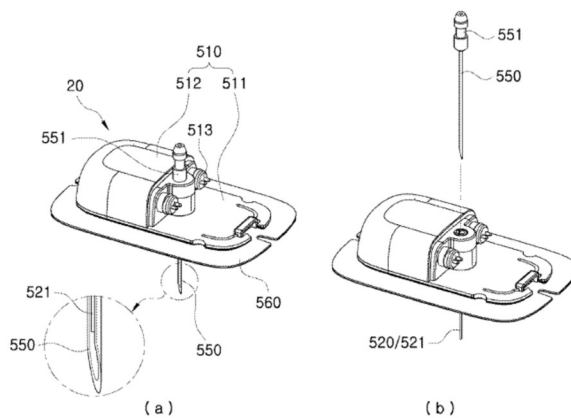
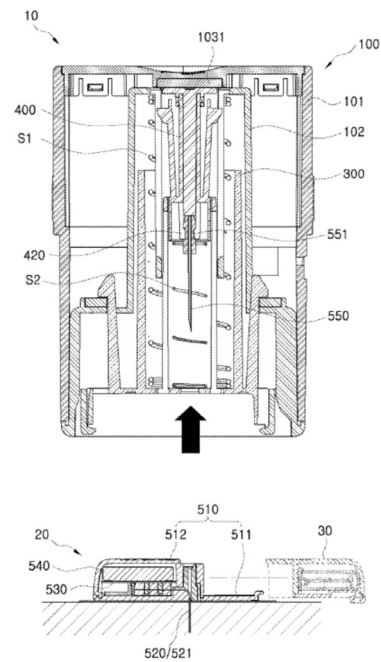


FIG. 24



Id., Figs. 2, 24.

b. 1.1

Chae's applicator has an internal volume, Ex-1008, Figs. 4-7, 8A-8B, 9A-9B, 14-15, 16A-16B, 18A-18B, 19A-B, 21, 22A-22B, 23-24, as depicted in the annotated Figures 5 and 6:

FIG. 5

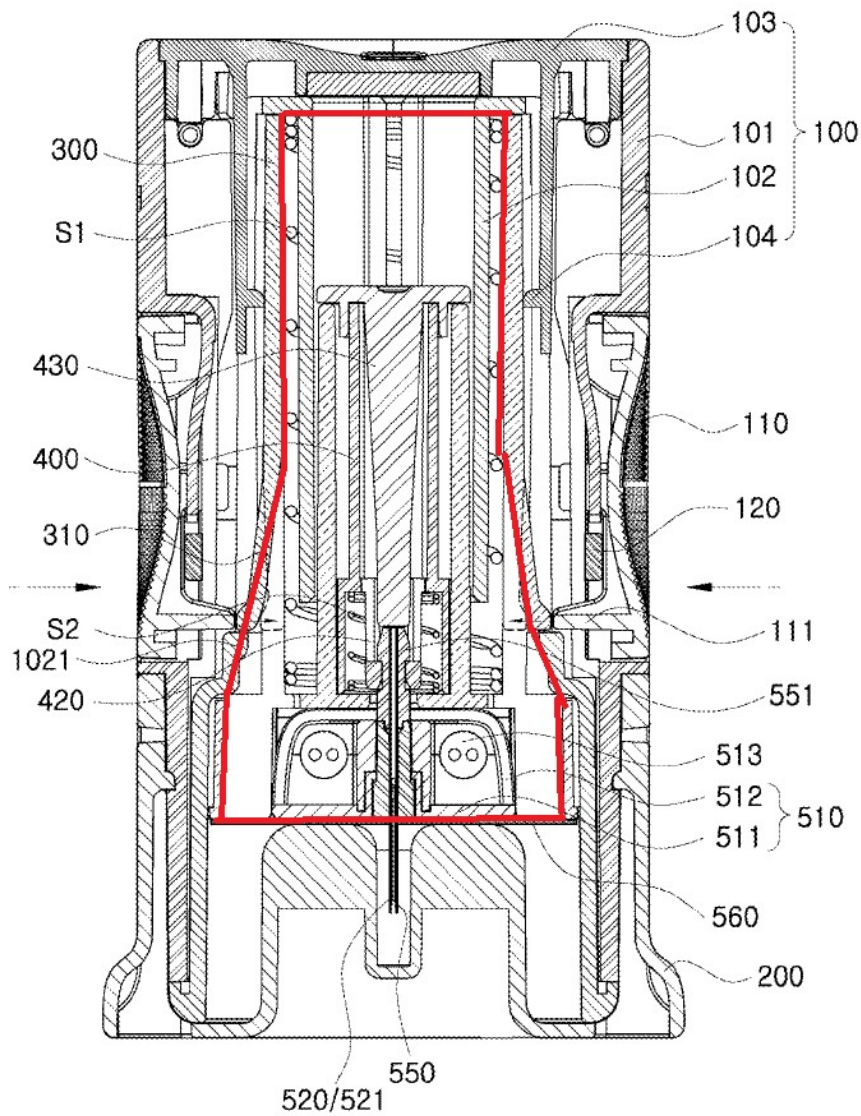
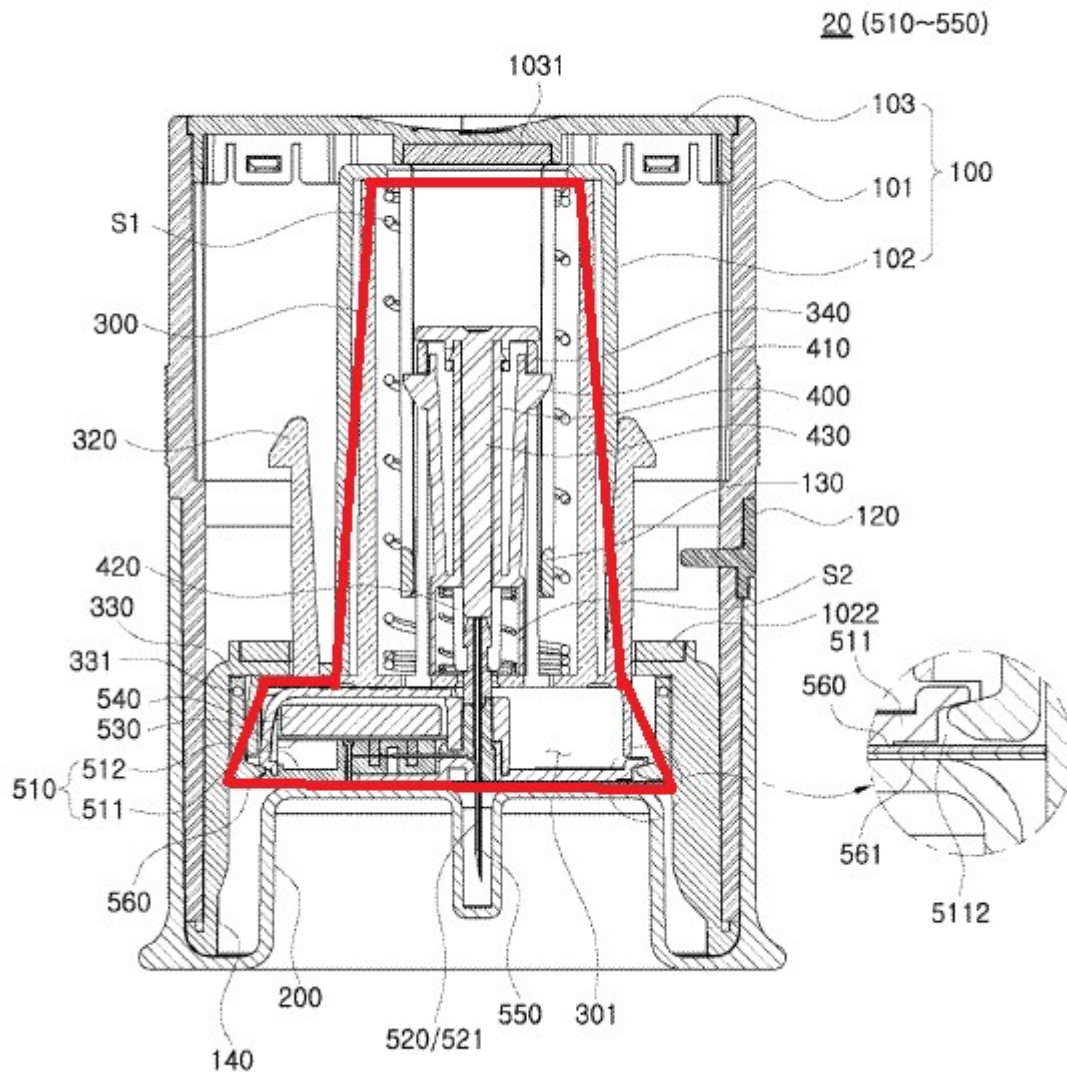


FIG. 6



Id., Figs. 5-6; *see also id.*, Fig. 23-24, [0135]-[0136].

c. 1.2-1.5

Chae discloses a needle head 551 (*i.e.*, a needle hub) coupled to a needle 550 (*i.e.*, an insertion element), which is “configured to be inserted into the body together with the sensor probe 521”:

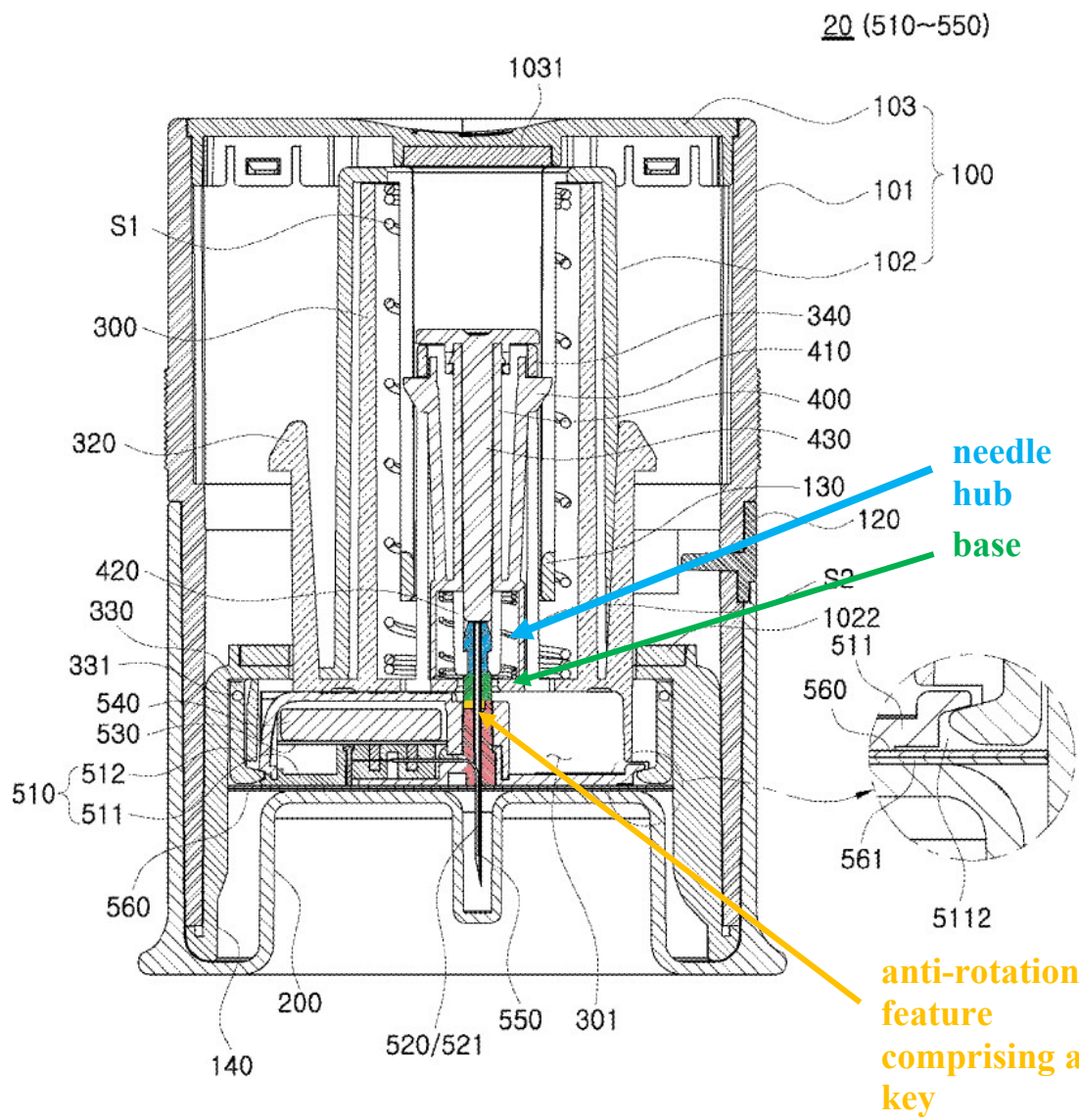
Figure 1 consists of two perspective views of a needle assembly 20.
 (a) The needle assembly 20 is shown in a first state. It includes a needle hub 510 with a base 511 and a needle element 512. The needle element 512 is partially inserted into the needle hub 510. A needle element 550 is shown in a circular inset, highlighting its sharp tip. The needle assembly 20 is mounted on a base 560.
 (b) The needle assembly 20 is shown in a second state. The needle element 550 is fully inserted into the needle hub 510. The needle element 550 is shown in a circular inset, highlighting its sharp tip. The needle assembly 20 is mounted on a base 520/521.

The needle head 551 has lower portion (*i.e.*, a base, annotated in green below) with a protrusion at the bottom (*i.e.*, an anti-rotation feature comprising a key, annotated in gold below) that orients the needle in the sensor housing and prevents rotation of the needle:

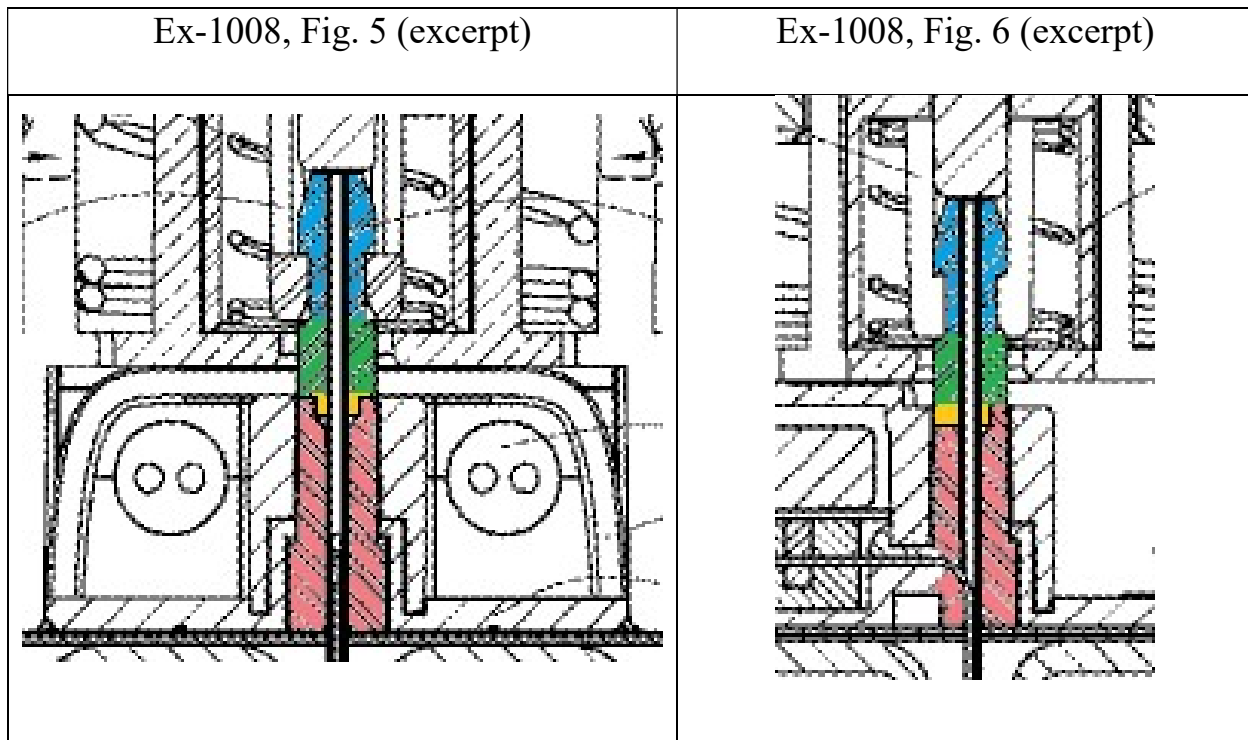
base

anti-rotation
feature
comprising a
key

FIG. 6



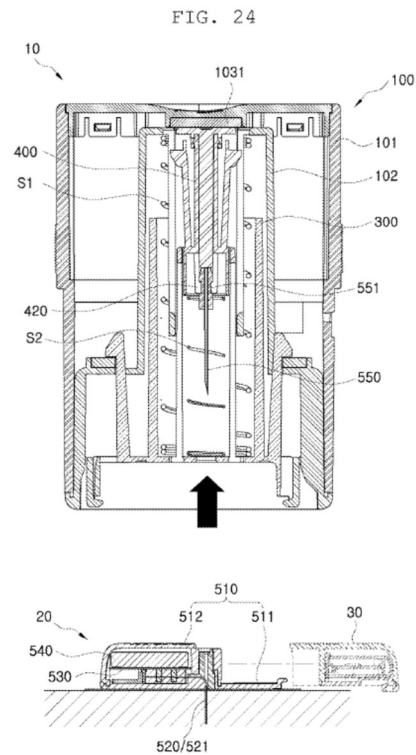
Ex. 1009, Figs. 5-6. The needle head 551 is seen in more detail in the excerpts below:



As disclosed in Figure 6 (right), the bottom of the needle hub's base is asymmetrical and comprises a protrusion that engages with a complementary shape of an aperture in the sensor module 20. As seen by comparing Figures 5 (left) and 6 (right), the protrusion engages the two side walls (Figure 5) and the back wall (Figure 6) of a recess, which prevents the needle head/hub from rotating about its vertical axis. The lower portion of the needle head 551 corresponds to the claimed "base," and the protrusion from the lower portion of the needle head corresponds to the claimed "anti-rotation feature extending from the base" and the "anti-rotation feature comprising a key, the key having a first shape."

d. 1.6

The sensor module 20 is configured to be attached to a user's skin, Ex-1008, [0055], as shown in Figure 24:



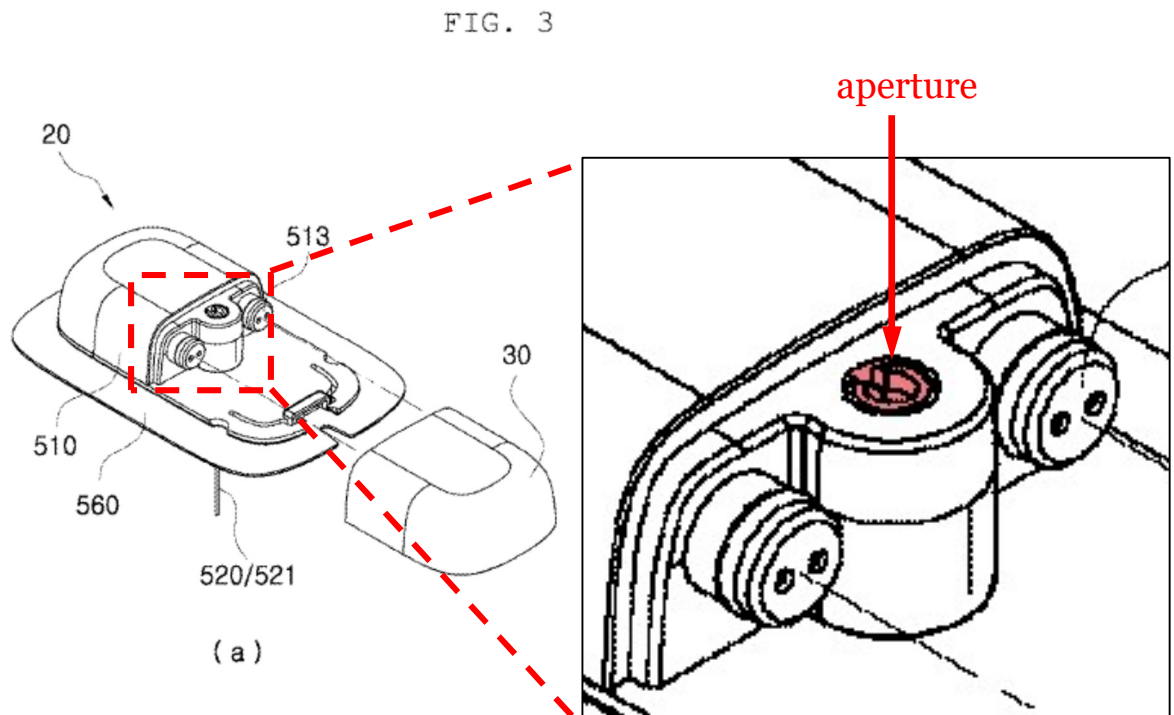
Id., Fig. 24 (corresponding to Ex-1009, Fig. 10), [0136].

e. *1.7*

Chae discloses the sensor module 20 includes a sensor 520 that is used to “measure a ***blood glucose level***.” Ex-1008, [0079], [0081]; *see also id.*, at [0082] (“Here, current change information of the sensor probe 521 occurring depending on the ***glucose concentration*** of blood is electrically transferred to the PCB 530”).

f. 1.8-1.10

Chae's sensor module 20 contains an aperture extending from a top surface (annotated in red), into which the needle 550 is insert, as seen in Figure 3:

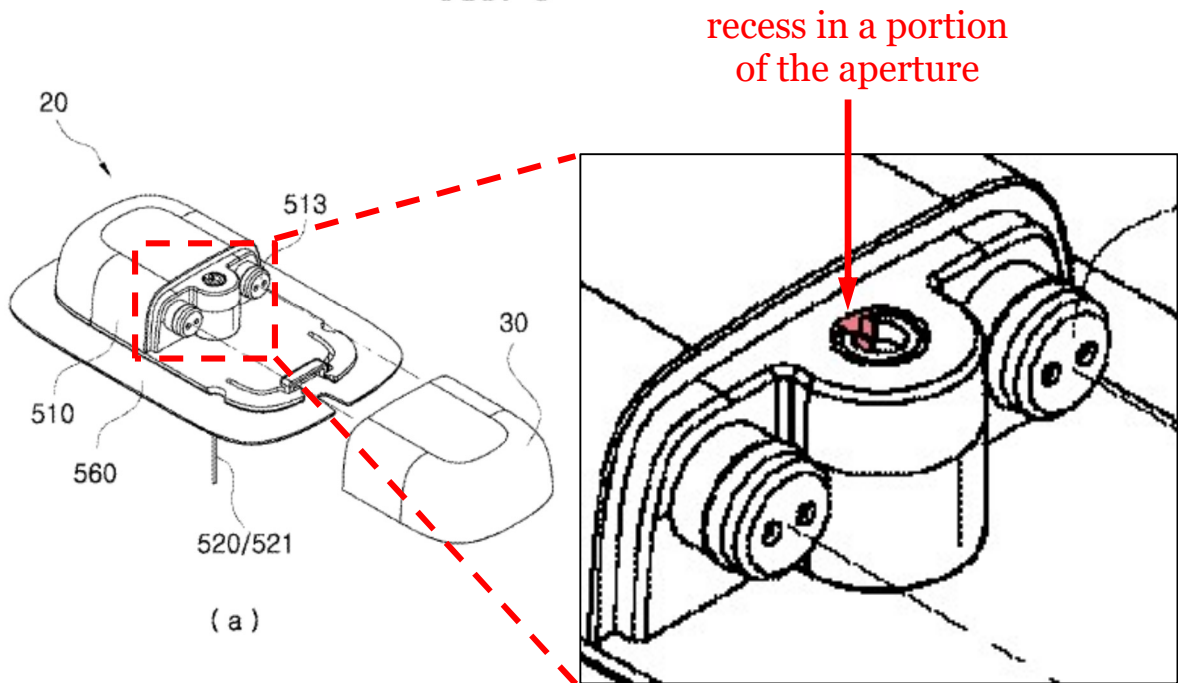


Ex-1008, Fig. 3 (excerpt left); Ex-1009 at Fig. 3 (enlarged demonstrative). Figure 2 depicts the relationship of the needle 550 with this aperture, showing the needle installed in the aperture on the left, and withdrawn on the right:

Figure 1 consists of two perspective views of a device 20. (a) Top perspective view: The device 20 is shown from above. It includes a motor 510 mounted on a bracket 511. The bracket 511 is connected to a base 560. A pin 550 is attached to the motor 510. A label 551 points to the motor 510. A label 512 points to the bracket 511. A label 513 points to the pin 550. A label 560 points to the base. A circular inset shows a magnified view of the pin 550, with a label 521 pointing to its tip and a label 550 pointing to its shaft. (b) Side perspective view: The device 20 is shown from the side. A red arrow points to an aperture 520/521 in the bracket 511. A label 551 points to the motor 510. A label 550 points to the pin 550. A label 520/521 points to the aperture.

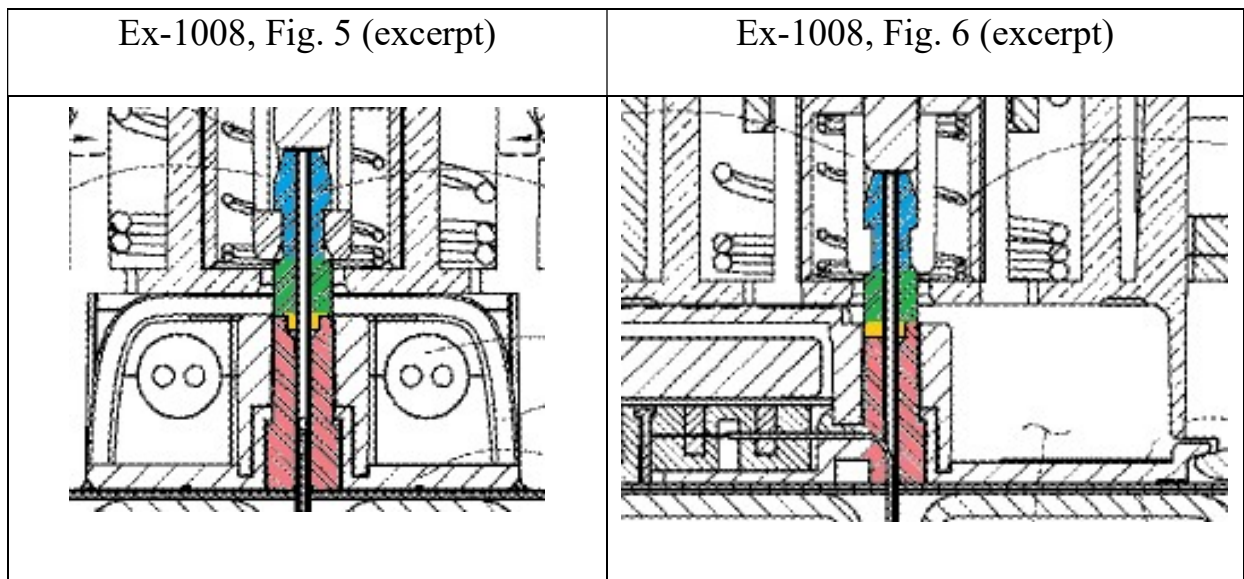
Chae further discloses the aperture of the sensor module 20 has a recess that is shaped complementary to the protrusion on the needle head 551. For example, Figure 3 (enlarged, right below) shows a recess in one side of the aperture:

FIG. 3



Ex-1008, Fig. 3 (excerpt left); Ex-1009 at Fig. 3 (enlarged demonstrative).

Figures 5 and 6 (below) show this recess in the aperture (aperture shaded in red) is complementary to the protrusion from the base of the needle head/hub 551 (shaded in gold):



Id., Figs. 5 (excerpt, annotated), 6 (excerpt, annotated). Furthermore, as seen above, the protrusion is at least partially disposed in the aperture.

g. 1.11

As explained above for claims 1.2-1.5, the protrusion from the base of the needle head 551 (*i.e.*, the anti-rotation feature comprising a key) prevents rotation of the needle 550 (and the needle head/hub coupled to it) relative to the sensor module 20 (*i.e.*, the on-skin sensor assembly). It does so by being inserted within the aperture in the sensor module 20.

2. Independent Claim 13

Chae renders obvious claim 13, as explained below and as supported by Ex-1004, ¶¶223-229.

a. 13.P

See, supra, claim 1.P.

b. 13.1

See, supra, claim 1.1.

c. 13.2-13.5

See, supra, claim 1.2-1.5. Claim 13.2 recites a needle hub coupled to a “needle” rather than the “insertion element” in claim 1.2, but in the ’625 patent, the “insertion element” can comprise a “needle.” Ex-1001, 27:12-18. Furthermore, the base that “*comprises* an anti-rotation key” recited in claim 13.5 corresponds to the base of claim 1.4 having “an anti-rotation feature *extending from*” it.

In addition, claim 13.5 recites an “anti-rotation key,” rather than claim 1.5’s “anti-rotation feature comprising a key.” As explained for claim 1.4–1.5, Chae discloses a protrusion extending from the base of a needle head. Ex-1008, Figs. 5-6. The shape of the protrusion corresponds to the claimed “anti-rotation key.”

d. 13.6-13.10

See, supra, claims 1.6-1.10.

e. 13.11

See, supra, claim 1.11. While claim 1.11 recites preventing rotation of the needle hub relative to the “aperture” rather than the “on-skin sensor assembly,” claim 13.8 makes clear that the aperture is part of the on-skin sensor assembly. Thus, the needle hub in Chae is prevented from rotating relative to the on-skin sensor assembly.

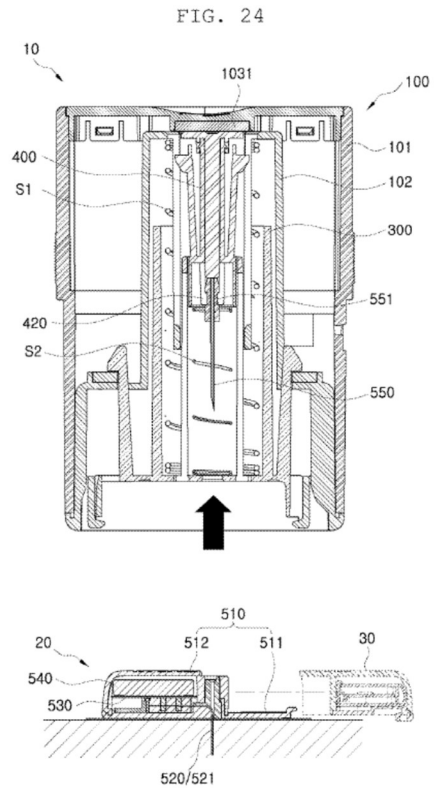
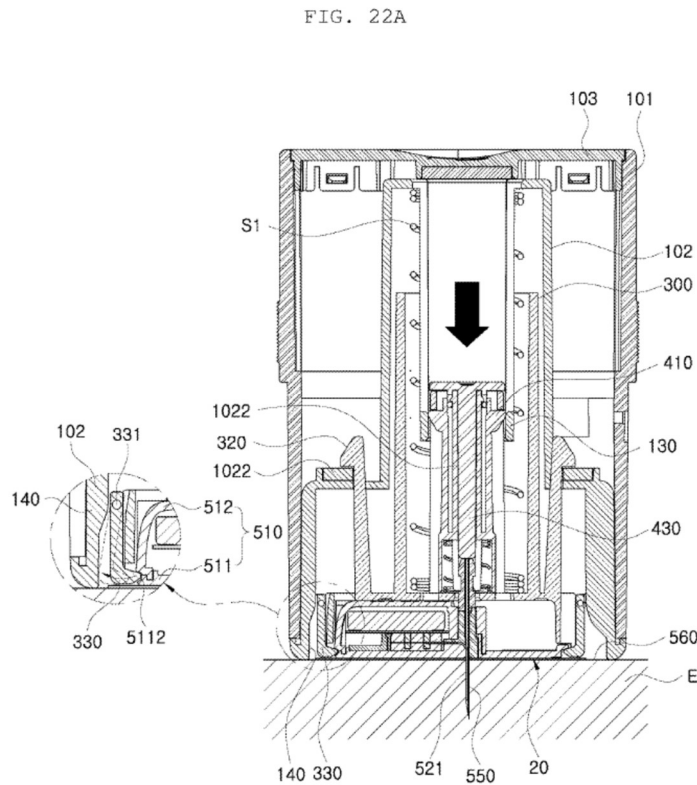
3. Independent Claim 22

Chae renders obvious claim 22, as explained below and as supported by Ex-1004, ¶¶230-236.

a. 22.P

Chae discloses a needle head 551 corresponding to a “needle hub coupled to an insertion element.” *See, supra*, claim 1.2. In addition, Chae discloses that the needle head 551 is installed in the sensor module 20 inside of the applicator 10. Ex-1008, Abstract, [0086]-[0087]. The needle head 551 is used to apply the sensor module 20 to a user’s skin and then withdraw the needle from the user and sensor

module.



Id., Fig. 22A, 24, [0133], [0136]. Thus, Chae discloses the needle head/hub 551 is used to “[apply] an on-skin assembly to a skin of a host.”

b. 22.1

See, supra, claims 1.3-1.5 and 13.2-13.5.

c. 22.2

See, supra, claim 1.11.

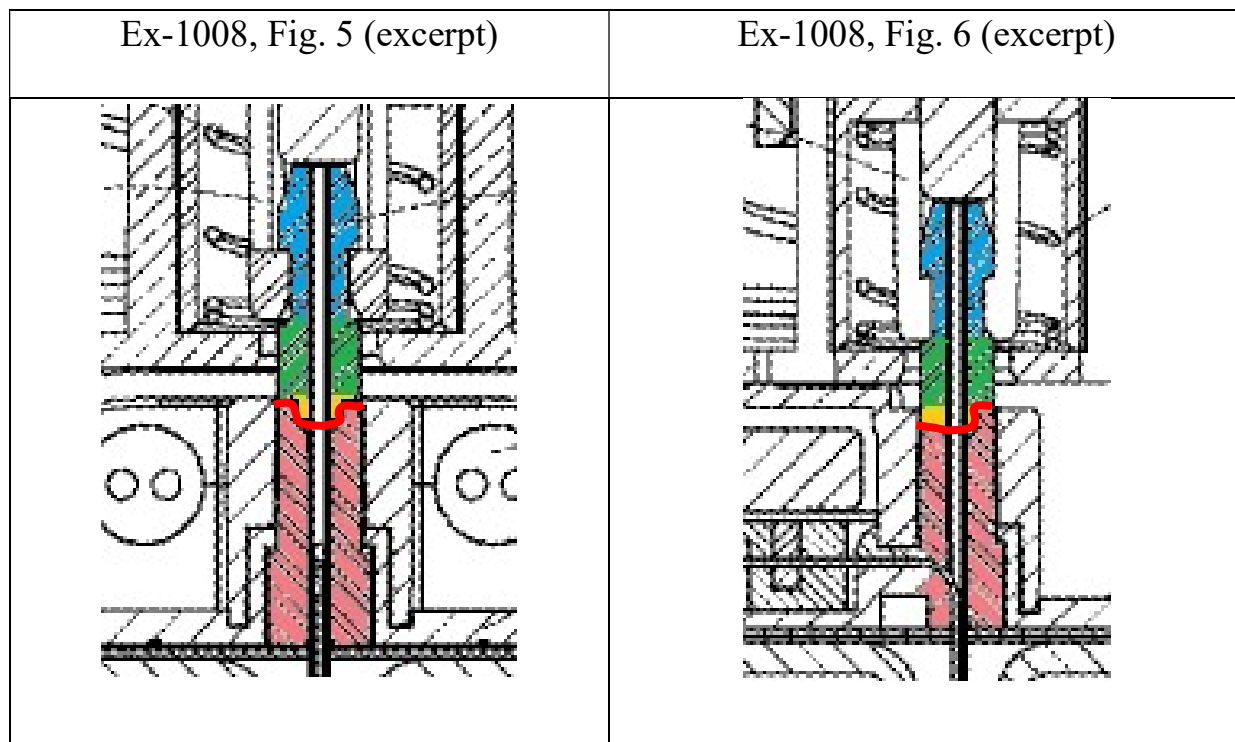
d. 22.3

See, supra, claim 1.2.

e. 22.4

Chae discloses the lower surface of the needle head 551 mates with a top

surface of the sensor module 20, shown in excerpts of Figs. 5 and 6 below as the annotated red-line interface between the needle hub and the sensor module 20.



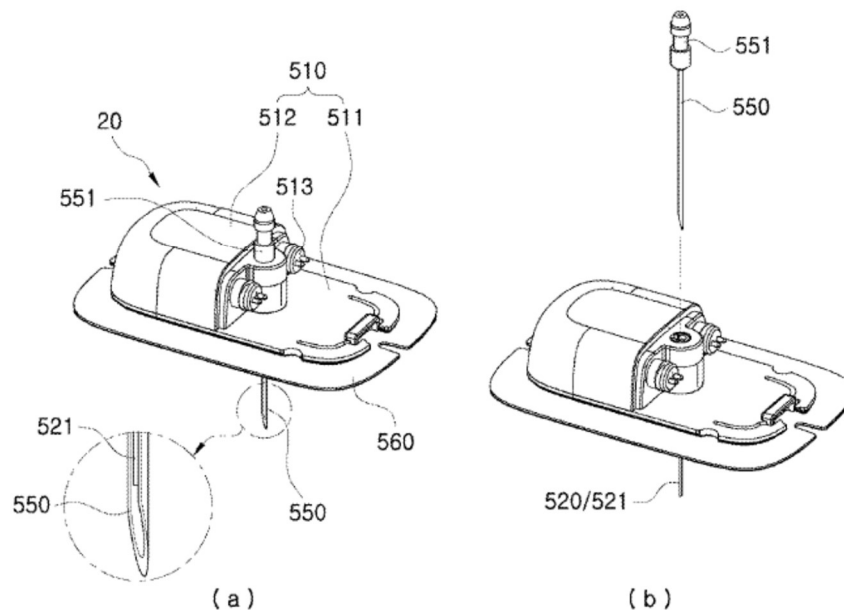
Ex-1008, Figs. 5 (excerpt, annotated), 6 (excerpt, annotated). Figures 5 and 6 disclose that the lower surface of the needle head 551 maintains the needle (*i.e.*, the insertion element) in a substantially perpendicular orientation relative to the top surface of the sensor module 20, because the sharp is held at a 90-degree angle to the bottom surface of the needle head, and thus a 90-degree angle to the top surface of the sensor module 20.

4. Claims 2 & 25

Chae renders obvious claims 2 and 25, as explained below and as supported by Ex-1004, ¶¶236-237. Claims 2 and 25 depend from claims 1 and 22, respectively.

See, supra, claims 1, 22. Chae further discloses, as shown in Figure 2, “[t]he needle 550 has the shape of a hollow pipe surrounding sensor probe 521”:

FIG. 2



Ex-1008, Fig. 2, [0085]-[0086]; *see id.*, Fig. 22b (corresponds to Ex-1009, Fig. 8a) and Fig. 24 (corresponds to Ex-1009, Fig. 9) (depicting a flag shaped sensor probe 521 in the needle 550 prior to insertion and left behind in the skin after insertion). As shown in Figure 2(a) above, the needle 550 has an open side configured to receive the sensor probe 521.

5. Claim 3

Chae renders obvious claim 3, as explained below and as supported by Ex-1004, ¶¶238-239. Claim 3 depends from claim 2. *See, supra*, claim 2. Chae further suggests the needle 550 has a U-shaped cross section, as it has the “shape of a hollow

pipe surrounding the sensor probe.” *See, supra*, claim 2. A POSITA would understand Chae to suggest the needle 550 has a C-, U-, or V-shaped cross section, because the hollow pipe shape of the needle 550 must support a flag-shaped sensor, and there are only a limited number of options for the cross section of a hollow needle with a longitudinal opening/channel to support such a sensor. Ex-1004, ¶239; *see* Ex-1008, Fig. 22b (Ex-1009, Fig. 8a), Fig. 24 (Ex-1009, Fig. 9).

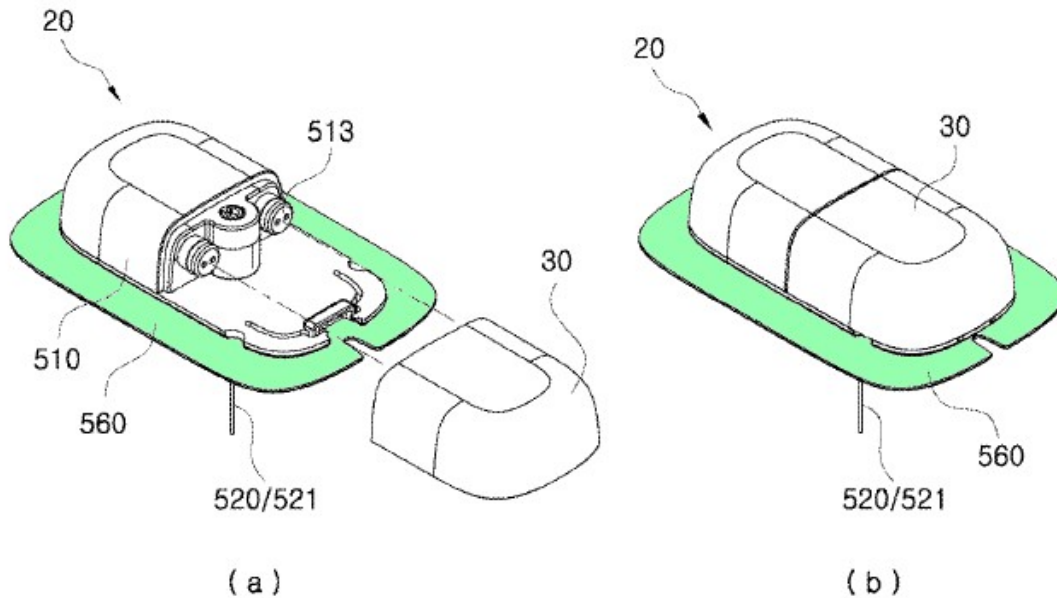
6. Claims 6 & 16

Chae renders obvious claims 6 and 16, as explained below and as supported by Ex-1004, ¶¶240-241. Claims 6 and 16 depend from claims 1 and 13, respectively. *See, supra*, claims 1, 13. Chae further discloses the sensor module 20 “includes a pod 510, a sensor 520, a printed circuit board (PCB) 530, and a battery 540.” Ex-1008, [0079]. A transmitter 30 can be coupled to the sensor module 20. *Id.*, [0055], [0058]. A POSITA would understand a sensor module containing a pod, sensor, printed circuit board, battery, and transmitter comprises sensor electronics. Ex-1004, ¶241.

7. Claim 9

Chae renders obvious claim 9, as explained below and as supported by Ex-1004, ¶¶242-243. Claim 9 depends from claim 1. *See, supra*, claim 1. Chae further discloses the sensor module 20 has a layer of “adhesive tape” 560 (light green below) for attaching the sensor module 20 to the skin. Ex-1008, [0080], [0114].

FIG. 3



Id., Fig. 3.

8. Claim 23

Chae renders obvious claim 23, as explained below and as supported by Ex-1004, ¶¶244-245. Claim 23 depends from claim 22. *See, supra*, claim 22. Chae further discloses the additional limitation of claim 23. *See, supra*, claim 1.11. The anti-rotation key of claim 23 is configured to prevent rotation within the aperture of the *base*, as opposed to the *needle hub* in claim 1.11. As the claim language makes clear, the needle hub comprises a base, so preventing rotation of the needle hub within the aperture necessarily prevents rotation of the base within the aperture.

9. Claim 24

Chae renders obvious claim 24, as explained below and as supported by Ex-1004, ¶¶246-247. Claim 24 depends from claim 22. *See, supra*, claim 22. Chae further discloses the additional limitation of claim 24. *See, supra*, claim 1.9. Claim 24 recites that the anti-rotation key has a shape complementary to at least a portion of the aperture, not vice-versa. This does not impact the analysis, because, by definition, if two structures have “complementary” shapes, it is irrelevant which structure is compared to the other, the result is the same.

IX. THE BOARD SHOULD NOT USE ITS DISCRETION TO DENY INSTITUTION

A. 314(a)

No other petitions have been filed against the '625 patent and thus the *General Plastic* factors do not weigh against institution. Under *Apple Inc. v. Fintiv, Inc.*, IPR2020-0019, Paper 11 (P.T.A.B. Mar. 20, 2020) (precedential), the district court litigation is still in an early stage, and trial on issues including the validity of the '625 patent is scheduled to occur in July 2026, many months after the Board's likely 2025 due date for a final written decision if trial is instituted. *See* Ex-1018 (Scheduling Order). The other *Fintiv* factors would not justify denying institution. The district court's claim construction process is just underway as of the filing of this Petition. By the time of institution, fact discovery may still be ongoing, but expert discovery and pre-trial motions will not have begun.

Discretionary denial is further inappropriate because this Petition presents compelling evidence of unpatentability. The references cited herein disclose or suggest all of the elements of the Challenged Claims. Thus, the *Fintiv* factors should not be applied to this proceeding.

B. 325(d)

The Board should likewise not deny institution under §325(d) because neither prong of the two-part *Advanced Bionics* framework is satisfied. *See Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019- 01469, Paper No. 6 at 8 (P.T.A.B. Feb. 13, 2020) (precedential). Under that framework, when evaluating discretionary denial arguments under §325(d), the Board looks to “(1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.” *Id.*

In applying this test, the PTAB considers the “*Becton, Dickinson*” factors, *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (P.T.A.B. Dec. 15, 2017) (precedential as to §III.C.5, first paragraph). Among these are factor (c), “the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection,” *Id.*, 17-18; *see also*

Edwards Life Sciences Corp. v. Colibri Heartvalve, LLC, IPR2020-01649, Paper No. 8 at 20-21 (P.T.A.B. Mar. 26, 2021) (declining to exercise discretionary denial where prior art references were not substantively considered during prosecution).

Here, the first part of the *Advanced Bionics* test is not satisfied. Pace 2, Chae, and Lundquist were not of record during prosecution of the '625 patent. Furthermore, although Pace was listed among over 500 references in an IDS, it was not cited or discussed in any rejection. *Cf. NPRM*, 89 Fed. Reg. 28705 (April 19, 2024) (“An initialed Information Disclosure Statement, without more, does not satisfy [the discretionary denial] standard.”).

Even if the Board considers the second *Advanced Bionics* prong, the merits of this Petition reflect the examiner’s errors in a manner material to the patentability of the Challenged Claims. The Examiner did not rely on Pace in any rejection of any claim. Furthermore, under *Becton, Dickinson* factor (f), Petitioner has presented new arguments and evidence that were unavailable to the examiner, who overlooked or did not appreciate the materiality of the references described herein as relating to the Challenged Claims. In particular, as Petitioner explained above, Pace discloses structures that prevent rotation of the needle within an aperture of an on-skin sensor assembly. The Board has routinely instituted *inter partes* review in similar circumstances. *See, e.g., STMicroelectronics, Inc. v. Trustees of Purdue University*, IPR2022-00309, Paper 14 at 12–13 (P.T.A.B. July 6, 2022) (finding that petitioner

demonstrated examiner erred by not appreciating that reference on IDS disclosed features recited in the challenged claims, as demonstrated by petitioner's unpatentability grounds).

X. CONCLUSION

Petitioner respectfully requests institution of *inter partes* review and cancellation of the Challenged Claims of the '625 patent.

Date: May 9, 2024

Respectfully submitted,

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CERTIFICATION UNDER 37 C.F.R. § 42.24(D)

I certify that the foregoing complies with the type-volume limitation of 37 C.F.R. § 42.24 and contains 13,986 words based on the word count indicated by the word-processing system used to prepare the paper, and excluding those portions exempted by § 42.24(a).

Date: May 9, 2024

/Scott C. Weidenfeller/

Scott C. Weidenfeller

Registration No. 54,531

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6 and 42.105, I hereby certify that on May 9, 2024, I caused a true and correct copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 11,510,625, supporting exhibits, and Power of Attorney to be served via Priority Mail Express on the Patent Owner at the following correspondence address of record as listed on the USPTO Patent Center:

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