

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. IPR2024-00860
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	U.S. Provisional Patent App. No. 62/524,247 (the “’247 Provisional”)
1004	Declaration of Cameron Riviere, Ph.D.
1005	Curriculum Vitae of Cameron Riviere, Ph.D.
1006	Blank
1007	Blank
1008	Blank
1009	Blank
1010	Blank
1011	U.S. Patent Publication No. 2014/0188053 (Lundquist)
1012	U.S. Patent Publication No. 2018/0235520 (Rao)
1013	Blank
1014	Blank
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 that these claims be found unpatentable in view of the following references:

(1) U.S. Patent App. Pub. No. 2018/0235520 (“Rao”) (Ex-1012)

(2) U.S. Patent App. Pub. No. 2014/0188053 (“Lundquist”) (Ex-1011)

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

Ground	Reference(s)	Statutory Basis	Challenged Claims
1	Rao	§103	1-9, 13-19, 22-30
2	Rao & Lundquist	§103	4-5, 14-15, 26-27, 30

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

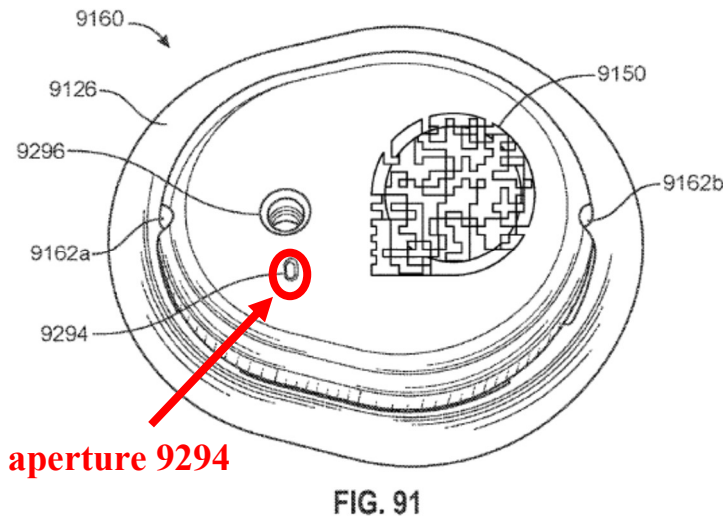
IV. THE '625 PATENT

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:

¹ Color annotations in Figures added throughout unless otherwise noted.

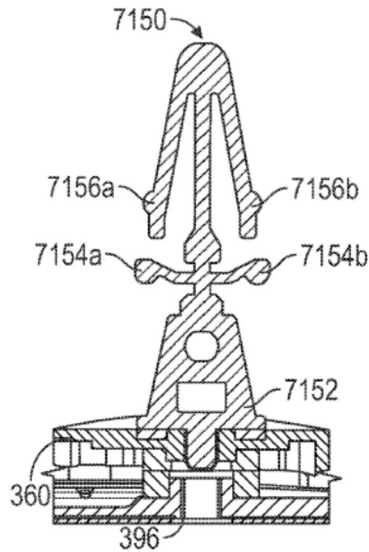


FIG. 78

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 (“the '170 Application”) 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, 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 applications filed by DexCom. *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 (the "247 provisional"), filed on June 23, 2017. Ex-1001, 1-2. As discussed below, the '625 patent is not entitled to the filing date of the '247 Provisional, and thus the Challenged Claims of the '625 patent are not entitled to an effective filing date any *earlier than* April 16, 2018.²

1. The '625 Patent Is Not Entitled To The Filing Date Of The '247 Provisional

For the Challenged Claims of the '625 patent to be entitled to the '247 Provisional's June 23, 2017 filing date, the '247 provisional must provide written description support under 35 U.S.C. § 112(a) for the Challenged Claims. In other words, "the disclosure of the earlier ['247 Provisional]...must reasonably convey to one of skill in the art that the inventor possessed the later-claimed subject matter [in the '625 patent] at the time the [earlier] application was filed." *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158 (Fed. Cir. 1998).

The '247 provisional does not disclose, either expressly or inherently, the full scope of the invention now claimed in the '625 patent, because, among other reasons,

² For purposes of this Petition, Petitioner does not take a position as to whether the '625 patent is entitled to the priority date of U.S. Provisional Application No. 62/658,486.

the '247 provisional does not contain *any* disclosure of *any* “anti-rotation feature” or “anti-rotation key.” All independent claims of the '625 patent require a “needle hub” comprising a “base” with an “anti-rotation feature” or “anti-rotation key,” with the anti-rotation “feature” or “key” being “at least partially disposed in [the / an] aperture” of an on-skin sensor assembly. *See, supra* Section IV.C (claims 1, 13, 22, and 18). However, the '247 provisional ***does not contain a single reference*** to any “anti-rotation feature,” any “anti-rotation key,” or indeed any anti-rotation function at all. Ex-1003.

Furthermore, the '247 provisional only contains Figures 1 through 70 from the '625 patent and does not include Figures 78 and 91 from the '625 patent discussed above in Section IV.A, as well as the corresponding description of those figures from the '625 patent specification. *Compare* Ex-1001 and Ex-1003.³ A

³ Petitioner does not concede that Figures 78 and 91, and the accompanying description provides adequate written description support for the full scope of the claims of the '625 patent under 35 U.S.C. § 112(a) and reserves the right to challenge this in other forums. At minimum however, the '247 Provisional cannot provide adequate written description support for the '625 patent claims without these Figures (and accompanying description), or indeed any description of anti-rotation features or functions at all.

POSITA would not understand any of the figures disclosed in the '247 provisional to disclose an “anti-rotation feature” or “anti-rotation key” of, or extending from, a needle hub, with the “anti-rotation feature” or “anti-rotation key” at least partially disposed in an aperture of an on-skin sensor assembly. Ex-1004, ¶¶33-37.

Accordingly, the Challenged Claims of the '625 patent are not entitled to the June 23, 2017 filing date of the '247 provisional. For purposes of this Petition only, Petitioner applies April 16, 2018 as the effective filing date of the Challenged Claims.

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, ¶39.

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 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. Rao (Ex-1012)

U.S. Patent Publication No. 2018/0235520, titled “Systems, Devices, and Methods for Analyte Sensor Insertion,” to Rao et al. (“Rao”) was filed on January 22, 2018, and published on August 23, 2018. Ex-1012, Cover. Accordingly, applying an effective filing date for the Challenged Claims of the ’625 patent no earlier than April 16, 2018, *see supra* Section IV.D, Rao qualifies as prior art to the ’625 patent under at least 35 U.S.C. § 102(a)(2) (AIA). Rao was not of record during prosecution of the ’625 patent.

Rao discloses multiple applicators for use in CGM systems, including an applicator comprising a “[s]harp module 2600” (*i.e.*, a needle hub) with a base and a “bend fin guide 2620 [*i.e.*, an anti-rotation feature] for maintaining ‘pre-bent’ sharp 2602, ... including sharp shaft 2604 and sharp tip 2606, ... in position during assembly and/or use.” Ex-1012, [0143].

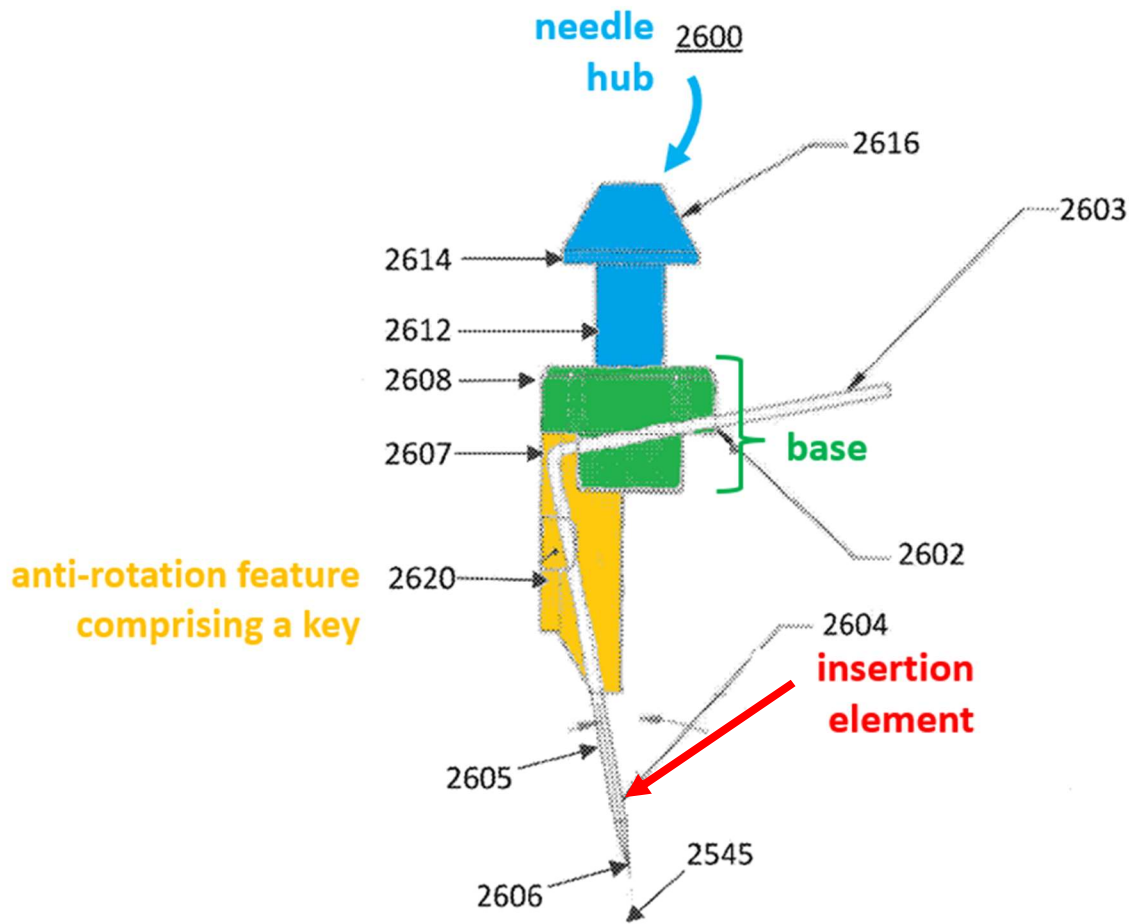


FIG. 11H

Ex-1012, 11H.

Further, the sharp module 2600 engages with a sensor module 504, as seen in Figure 11J below. The sharp module 2600 and sensor module 504 can be provided in a sterile package, separate from the applicator and electronics housing. *Id.*, [0008]; *see also id.* Fig. 3C, [0083]-[0084]. Prior to use of the applicator, the user couples the sharp module 2600 and sensor module 504 with the electronics inside the

applicator housing, to form the complete sensor control device 102 (*i.e.*, an on-skin sensor assembly), as shown below in Figures 12A and 11J (annotated call-out).

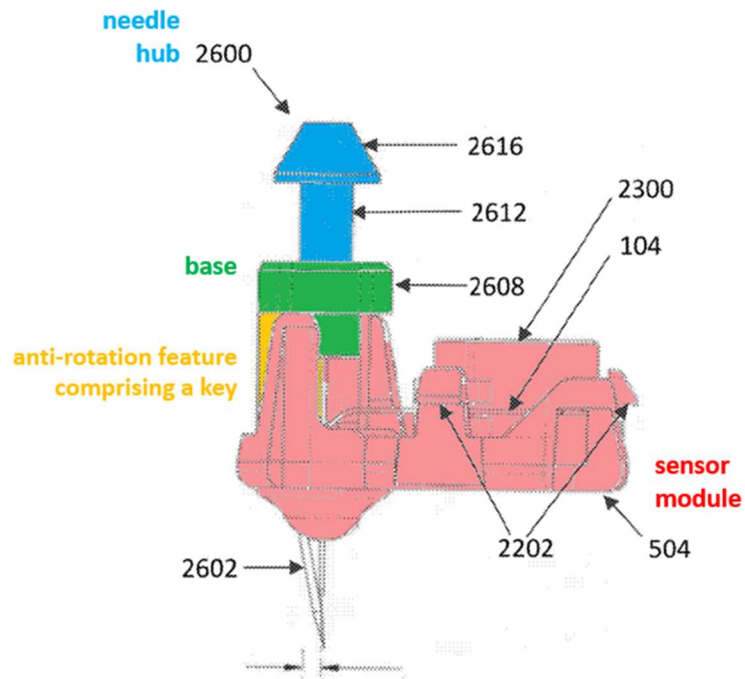
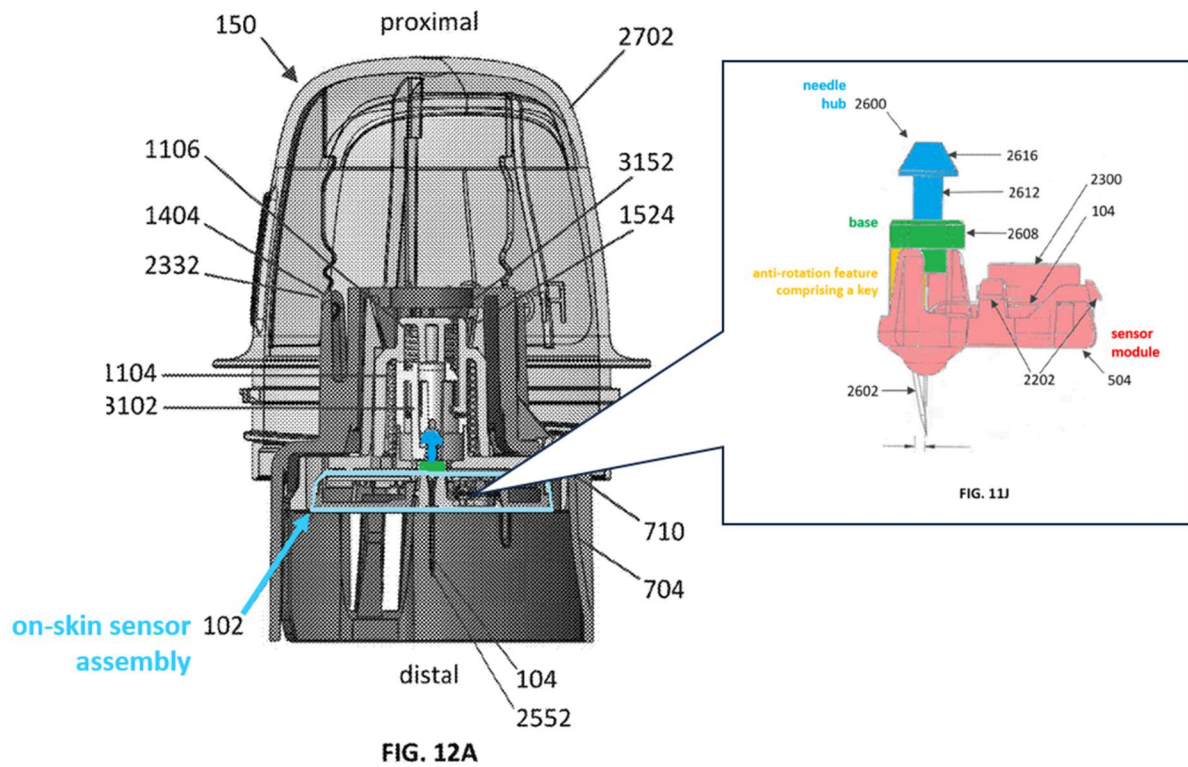


FIG. 11J



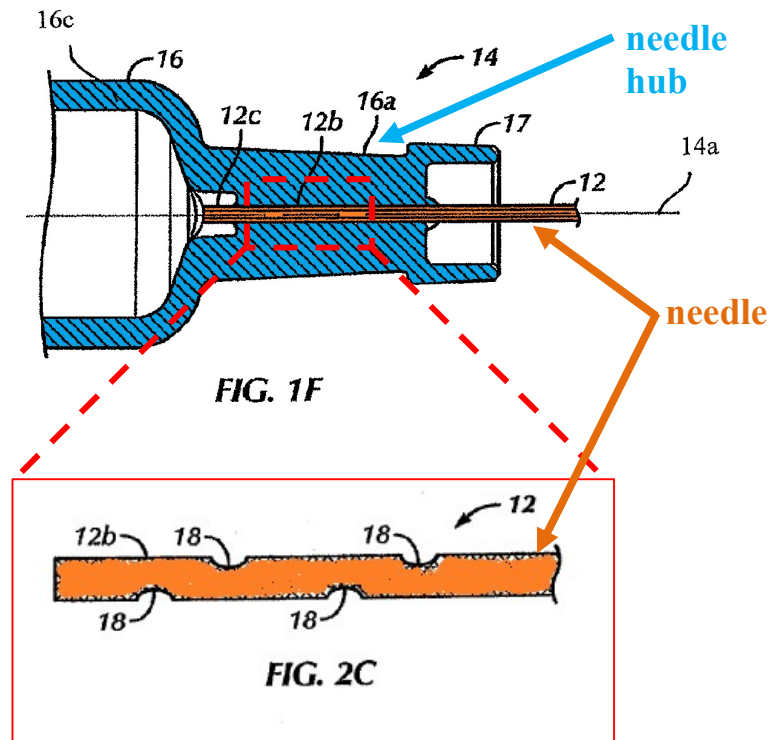
Id., Figs. 12A and 11J; *see also id.*, Fig. 3C, [0083]-[0084]. Rao discloses that bend fin guide 2620 “can prevent lateral or rotational movement of sharp 2602 relative to hub components.” *Id.*, [0143]. As seen in Figure 11J, the hub 2600 cannot rotate relative to the sensor module 504, which is part of the on-skin sensor assembly as seen in Figure 12A, as the bend fin guide (*i.e.*, the anti-rotation feature comprising a key) is prevented from rotating by the sensor module 504. Accordingly the needle 2602 and hub 2600 are prevented from rotating with respect to the on-skin sensor assembly.

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

B. 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 a number of 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: Rao Renders Obvious The Challenged Claims

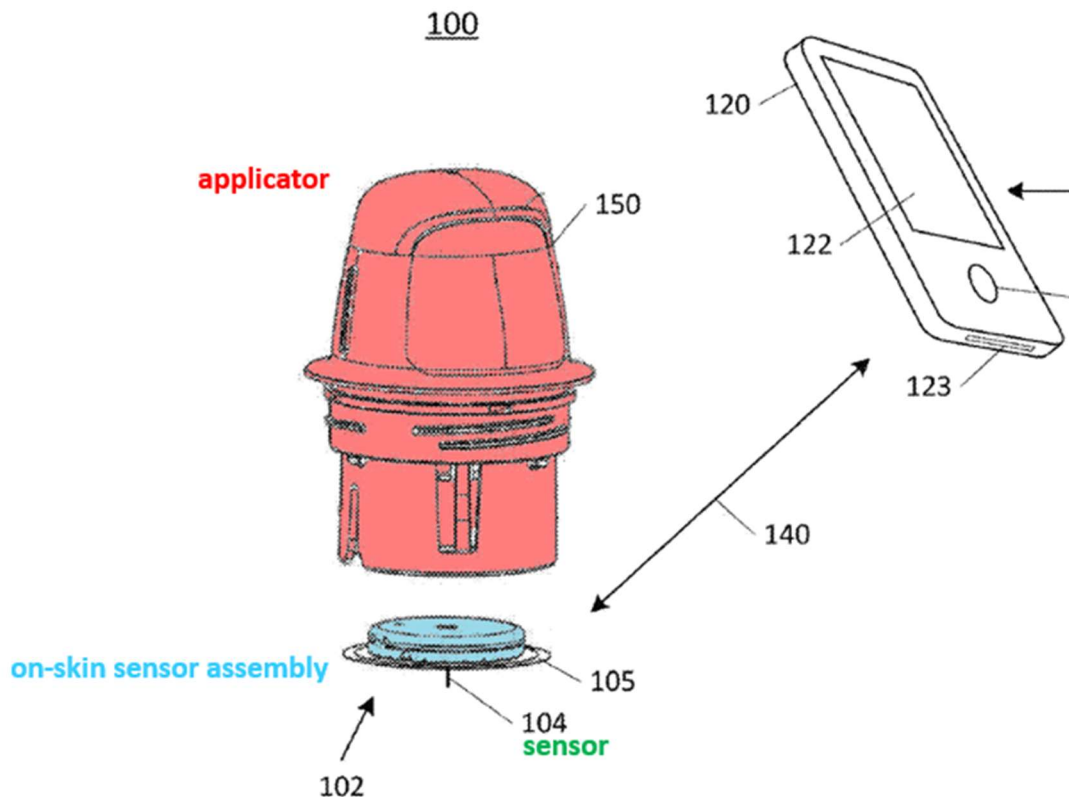
1. Independent Claim 1

Rao renders obvious claim 1, as explained below and as supported by Ex-

1004, ¶¶49-64.

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

Rao discloses multiple applicators, each of which can be used to apply an on-skin sensor assembly of a CGM system to the skin of a host. Ex-1012, Figs. 1, 4A-4C, 10C, 12A-12D, 13A-13D, 14A-14C, 15A-15B, 16A-16C, 17. For example, as seen in Figure 1 (below), Rao discloses applicator 150, which is used to apply sensor control device 102 (i.e., an on-skin sensor assembly), with an adhesive patch 105, to a user's skin.



Id., Fig. 1, [0075]; *see also id.*, Figs. 3E-3F (depicting application of the sensor

control device 102 to a user's skin), Figs. 4A-4C, [0089].

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

Each of the applicators in Rao disclose an applicator housing having an internal volume. Ex-1012, Figs. 4C, 7C, 10C, 13A-13D, 14A-14C, 15A-15B, 16A-16C, 17. For example, Rao describes “applicator housing 702 that can include an internal cavity,” as depicted in Figure 7C below:

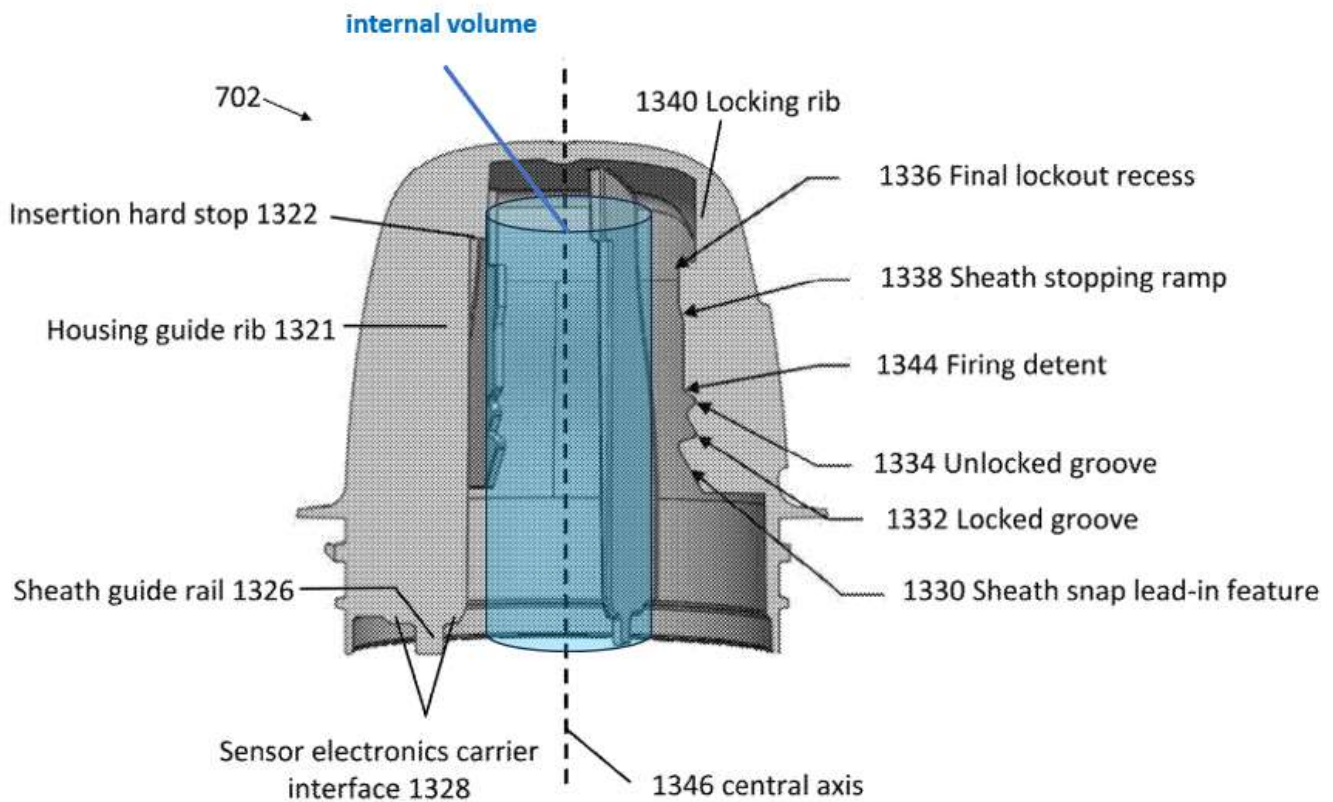


FIG. 7C

Id., Fig. 7C, [0093]-[0095]; *see also id.*, Fig. 14A (excerpt), [0164]-[0165], Figs. 12A-12D, 13A-13D, 14B-14C (similar).

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”

Rao discloses multiple embodiments of sharp modules. In one embodiment, sharp module 2600 (i.e., a needle hub) of Figures 11G-11J, is coupled to sharp 2602, including sharp shaft 2604 and sharp tip 2606 (i.e., an insertion element):

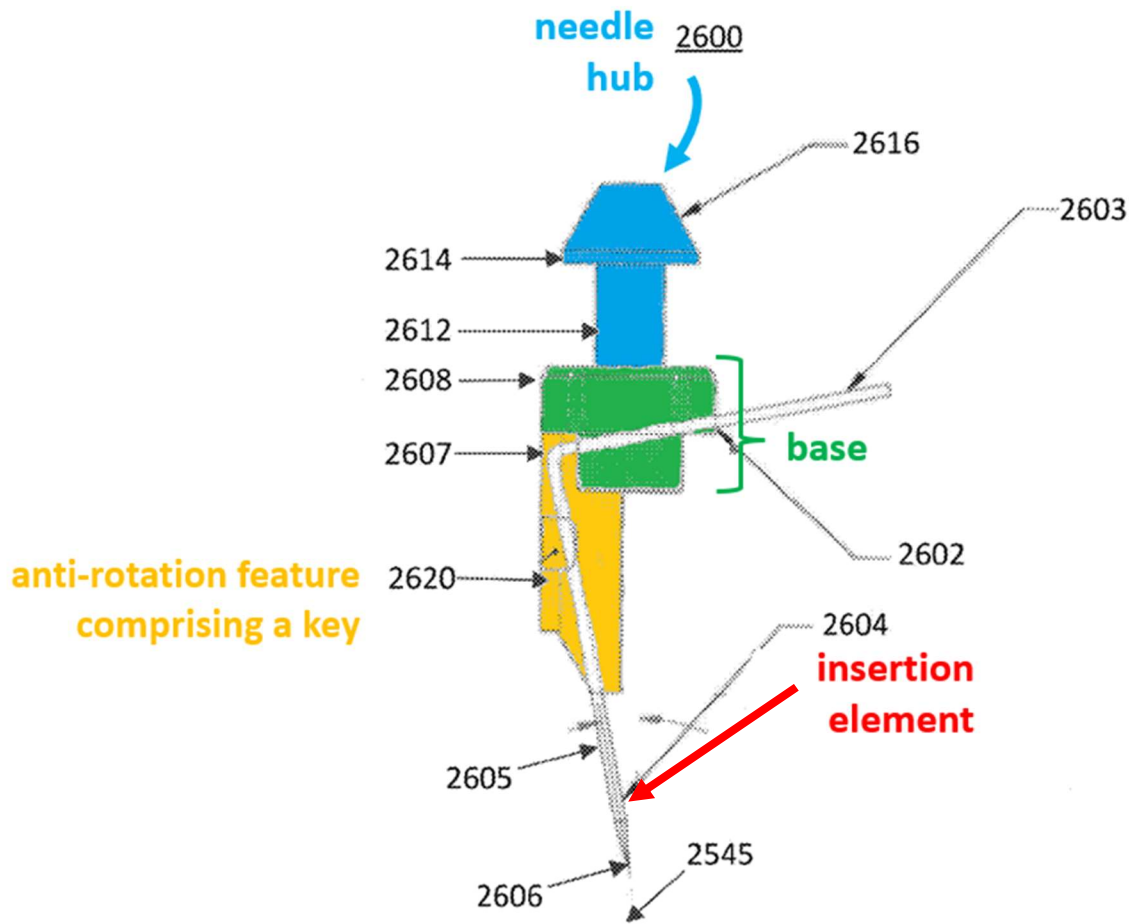


FIG. 11H

Ex-1012, Fig. 11H, [0134], [0143]. Rao further discloses that sharp 2602, with distal portion 2605 and proximal portion 2603, is configured to pierce the skin of a user/host. *Id.*, [0134], [0143], [0164].

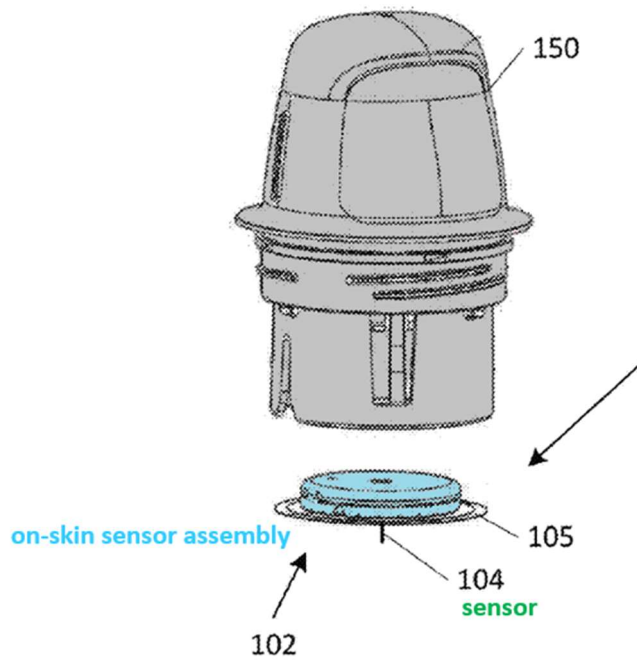
In Figure 11H above, sharp module 2600 comprises upper conical pawl 2616 and a lower portion, including bend fin guide 2620. *Id.*, [0143]. The lower portion of sharp module 2600 (annotated in green) corresponds to the claimed “base” of the

needle hub, and the bend fin guide 2620 (annotated in yellow) corresponds to the claimed “anti-rotation feature extending from the base, the anti-rotation feature comprising a key, the key having a first shape.” *Id.*, Figs. 11H-11J, [0143]-[0145].

Rao further discloses that bend fin guide 2620 (i.e., the anti-rotation feature comprising a key) prevents rotational movement of sharp 2602.

Sharp module 2600 can also include a bend fin guide 2620 for maintaining “pre-bent” sharp 2602 in position during assembly and/or use, and can ***prevent lateral or rotational movement of sharp 2602*** relative to hub components.

Id., [0143]. As seen in Figure 11J below, the hub 2600 cannot rotate relative to the sensor module 504, which is part of the on-skin sensor assembly as seen in Figure 12A, as the bend fin guide (i.e., the anti-rotation feature comprising a key) is prevented from rotating by the sensor module 504.



Id., Fig. 1 (excerpt), [0075]; *see also id.*, Figs. 3E-3F (depicting application of the sensor control device 102 to a user's skin), Figs. 13A-13D (depicting use of applicator to apply sensor control device 102 to a user's skin).

Rao further discloses that sensor module 504 (annotated in red below) and sharp module 2600 (i.e., the needle hub) are mated with the electronics of sensor control device 102 inside the applicator housing to form the on-skin sensor assembly (annotated in light blue in Figure 12A):

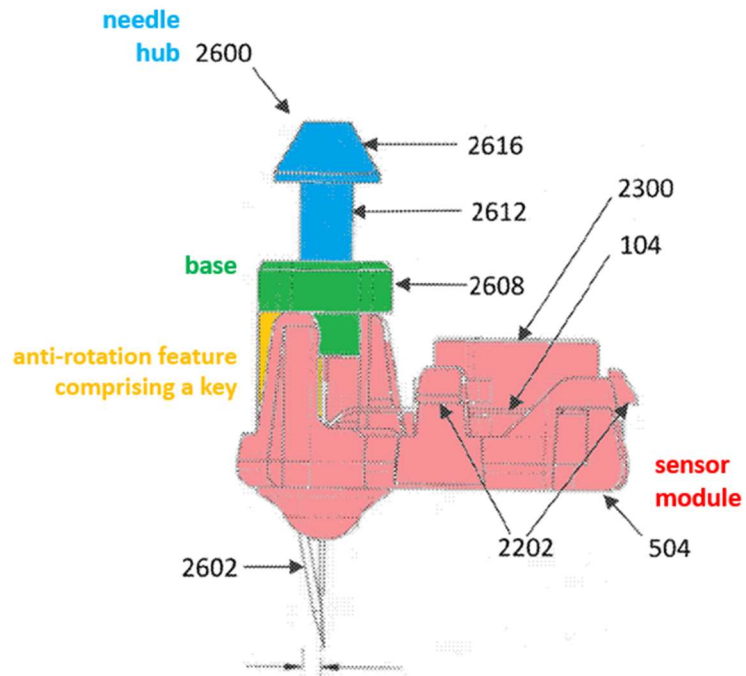


FIG. 11J

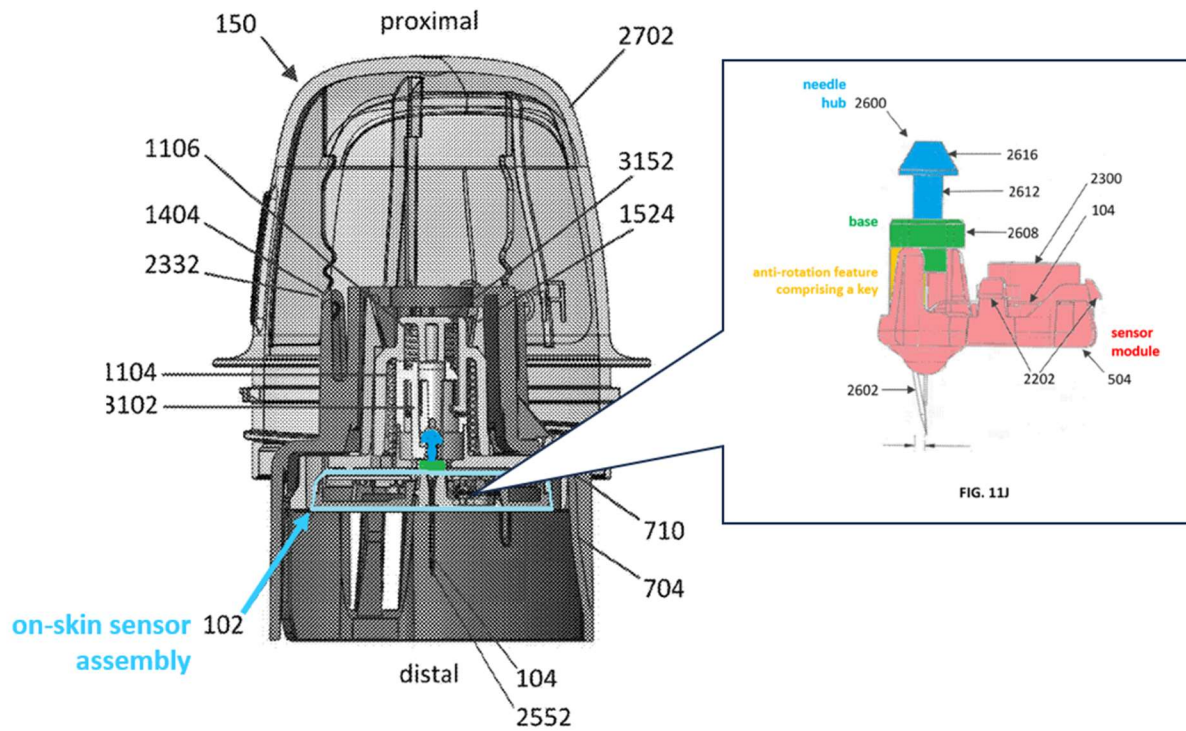


FIG. 12A

Id., Figs. 12A, 11J (excerpt).

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

Rao further discloses that the sensor control device 102 comprises an “analyte sensor 104.” Ex-1012, Figs. 2B-2C, [0077] (“sensor control device 102 having *analyte sensor 104*”), [0078] (“*in vivo analyte sensor 104*”). Rao further discloses that the ‘analyte’ level being measured can be glucose:

The detection and/or monitoring of *analyte levels, such as glucose*, ketones, lactate, oxygen, hemoglobin A1C, or the like, can be vitally important to the health of an individual having diabetes.

Id., [0003]; *see also id.*, [0071] (referring to “‘Continuous **Glucose** Monitoring’ systems”), [0078] (processor 166 in sensor control device 102 receives measurement data from *in vivo analyte sensor 104* and outputs “*end-result glucose discrete and trend values*, etc.”).

- 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;”

Rao discloses an aperture extending from a top surface of an on-skin sensor assembly. Figure 12A, for example, depicts sensor control device 102 (i.e., the on-skin sensor assembly) having a channel (i.e., the aperture) extending from a top

surface of sensor control device 102, and through which the needle passes:

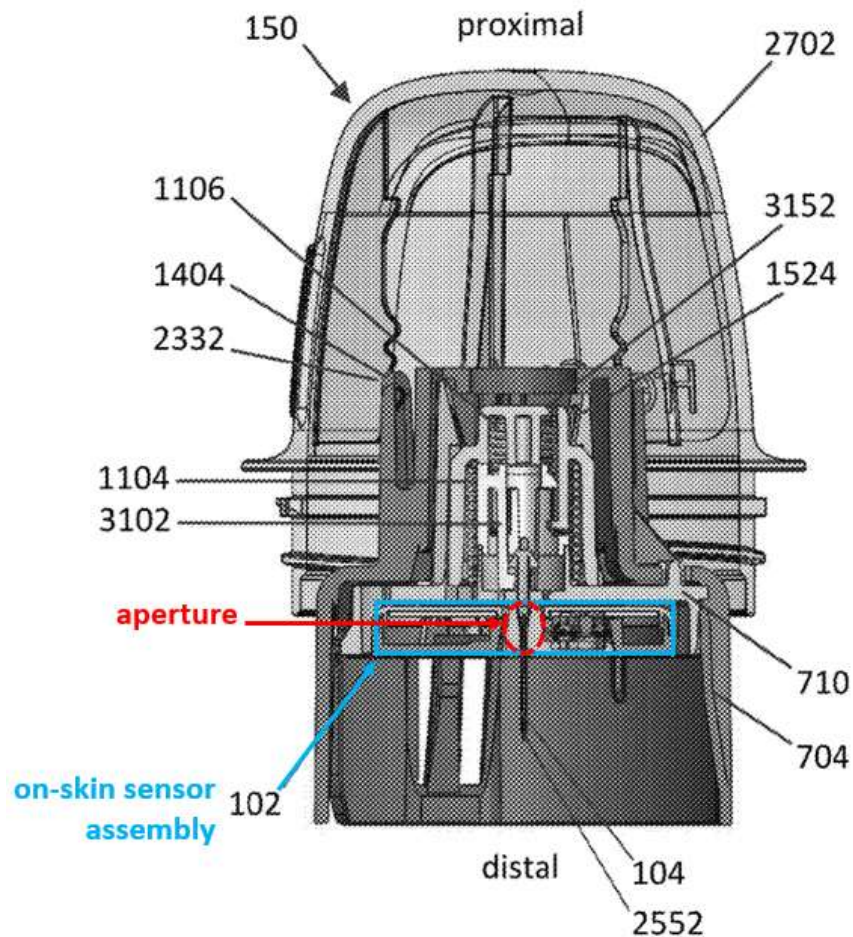
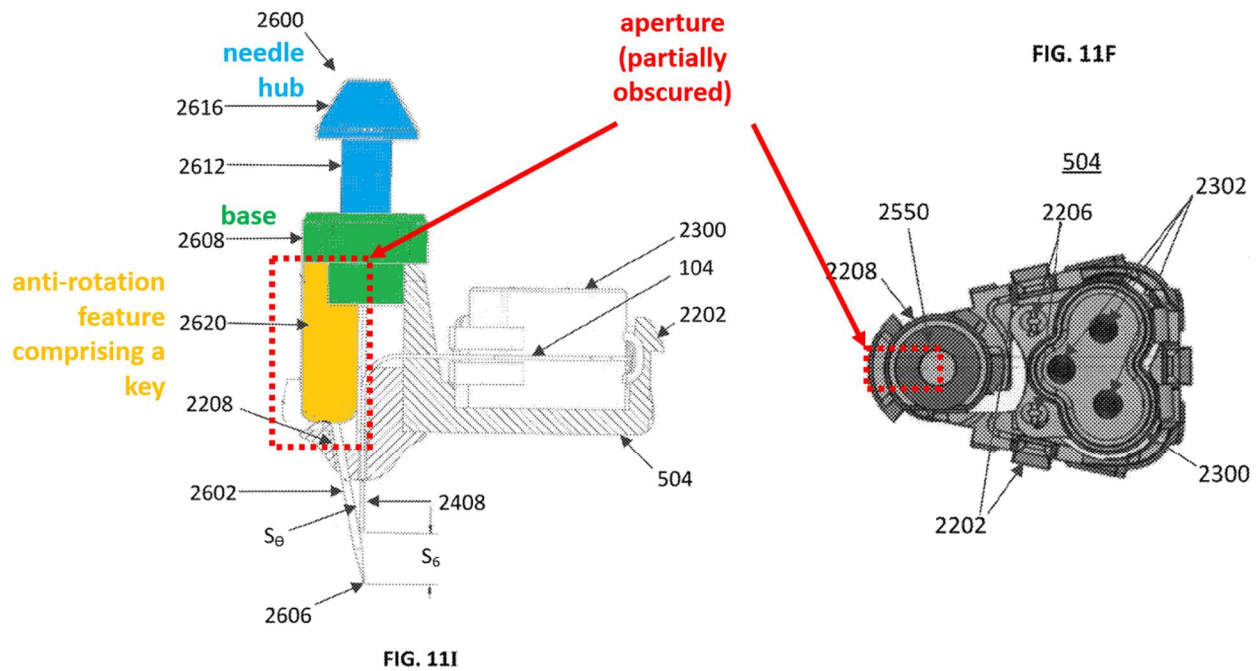


FIG. 12A

Ex-1012, Fig. 14A; *see also id.* Figs. 12A-12D, 13A-13D, 14A.

More specifically, this aperture extends from a top surface of sensor module 504, which when mated with sensor control device 102 in the applicator housing becomes part of sensor control device 102 (*i.e.*, the claimed on-skin sensor assembly). Although partially obscured, the aperture (annotated in red dashes) and its relative position with respect to sensor module 504 can be ascertained from the side view in Figure 11I (below left) and the top-down view in Figure 11F (below

right).



Id., Figs. 11I, 11F; *see also id.*, Fig. 11H, [0143]-[0145].

As discussed above, bend fin guide 2620 (annotated above in Figure 11I in yellow) corresponds to the “anti-rotation feature extending from the base, the anti-rotation feature comprising a key, the key having a first shape.” As depicted in Figures 11I, bend fin guide 2620 is inserted into (i.e., at least partially disposed in) the aperture, engages with the inside of the aperture, and prevents “rotational movement of the sharp 2602.” *See, supra*, claims 1.2-1.5. Rao further discloses that bend fin guide 2620 is “coupled” to sensor module 504.

As can be seen in FIG. 11I, sensor module 504 includes sharp slot 2208, through which sharp 2602 can extend in an angled and distal direction. As described earlier, a proximal portion of sharp 2602 passes through

bend fin guide 2620, which is coupled with a distal portion of sensor module 504.

Id., [0144]. Because Rao discloses that bend fin guide 2620 is “coupled” to a portion of sensor module 504, and discloses that the bend fin guide “prevents ... rotational movement of sharp 2602,” a POSITA would understand the aperture in sensor module 504 (and thus the sensor control device 102, which the sensor module 504 is a component thereof) has structures to restrain rotational movement of the ‘fin’ 2620 in either direction. Ex-1004, ¶62.

The aperture in Rao through which bend fin guide 2620 and sharp 2602 are inserted corresponds to the claimed “aperture extending from a top surface of the on-skin sensor assembly.” Because the bend fin guide 2620 is inserted into (i.e., at least partially disposed in) the aperture and because the bend fin guide prevents rotational movement of the sharp, the aperture has a second shape that is complementary to the shape of the bend fin guide 2620 (i.e., the first shape of the key).

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, bend fin guide 2620 (i.e., the anti-rotation feature comprising a key) prevents rotation of the sharp (and the needle hub coupled to it) within the sensor module 504, which is part of sensor control device 102 (i.e., the on-skin sensor assembly). It does so by being inserted within the

aperture in the sensor control device.

2. Independent Claim 13

Rao renders obvious claim 13, as explained below and as supported by Ex-1004, ¶¶65-71.

- 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,”

13.3 “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;”

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 in claim 1.4–1.5, Rao

discloses bend fin guide 2620 extending from the base of a sharp module 2600. Ex-1012, Figs. 11G-11J, [0143]-[0144]. The bend fin guide 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*, claims 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 with respect to the “aperture” rather than the “on-skin sensor assembly” in claim 13.11, claim 13.8 makes clear that the aperture is part of the on-skin sensor assembly and thus the needle hub in Rao is prevented from rotating with respect to the on-skin sensor assembly.

3. Independent Claim 22

Rao renders obvious claim 14, as explained below and as supported by Ex-

1004, ¶¶72-80.

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

Rao discloses a sharp module 2600 that corresponds to a “needle hub coupled to an insertion element.” *See, supra*, claim 1.2. Rao further discloses that the sharp module can be used with the applicators depicted in Figures 12, 13, and 14. For example, Figure 14A shows the applicator 152 applying sensor control device 102 to a user by engaging the needle hub.

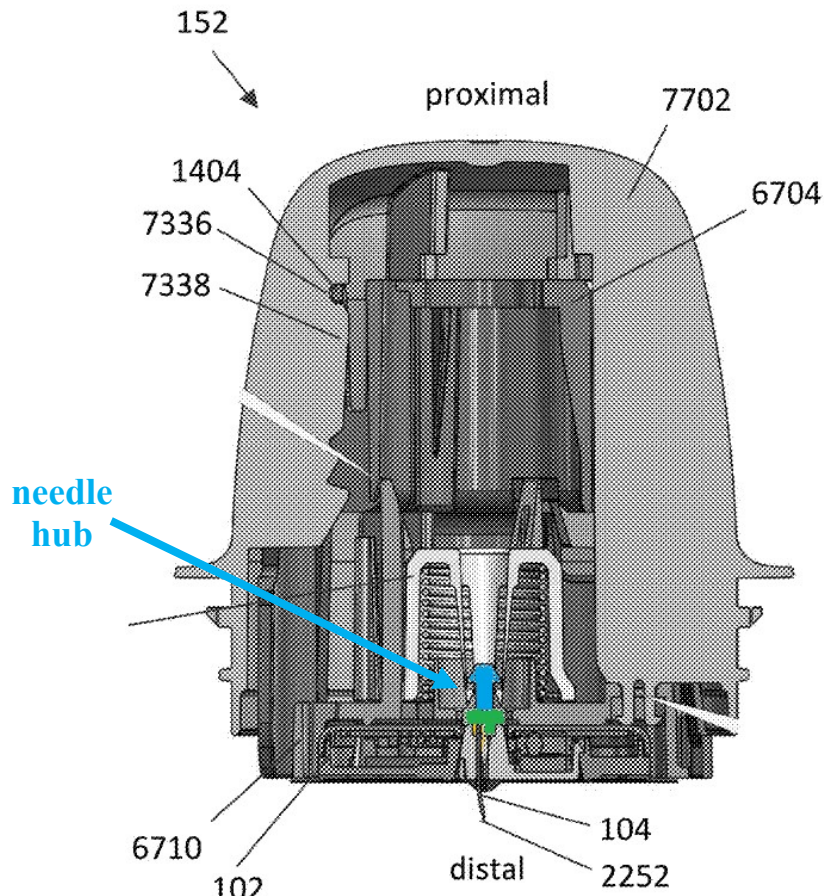


FIG. 14A

Id., Fig.14A (excerpt), [0164]-[0165]; *see also id.*, Figs. 12A-12D, 13A-13D. Thus, the Rao discloses a needle hub 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 1.3-1.5 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.

- 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.”

Rao discloses a sharp module 2600 comprising an upper conical “pawl” and bend fin guide 2620 extending from the hub push cylinder, which “prevent[s] lateral or rotational movement of the sharp 2602.” Ex-1012, [0143]. As explained in annotated Figure 11H below, the lower part of the sharp module 2600, including at least hub push cylinder 2608, corresponds to the claimed base (annotated in green).

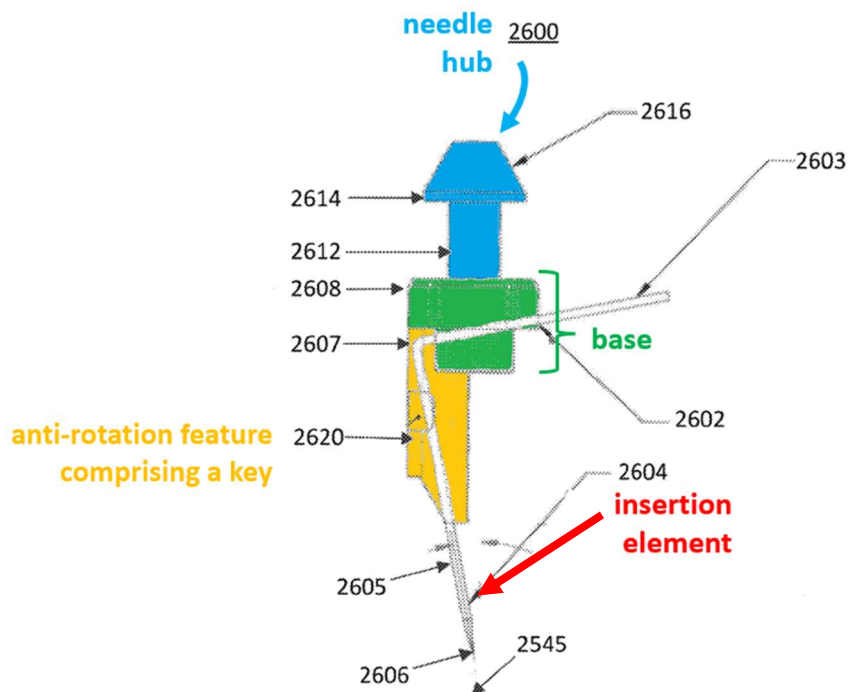


FIG. 11H

Id., Fig. 11H, [0143]; *see also id.*, Fig. 11G, 11I-11J. As depicted in two different views of Figures 11I-11J, the lower part of the sharp module 2600, including at least hub push cylinder 2608, includes a flat surface (annotated by the red-dotted line) that mates with a top surface of sensor module 504 (annotated in purple), which is a component of sensor control device 102 (i.e., the on-skin sensor assembly):

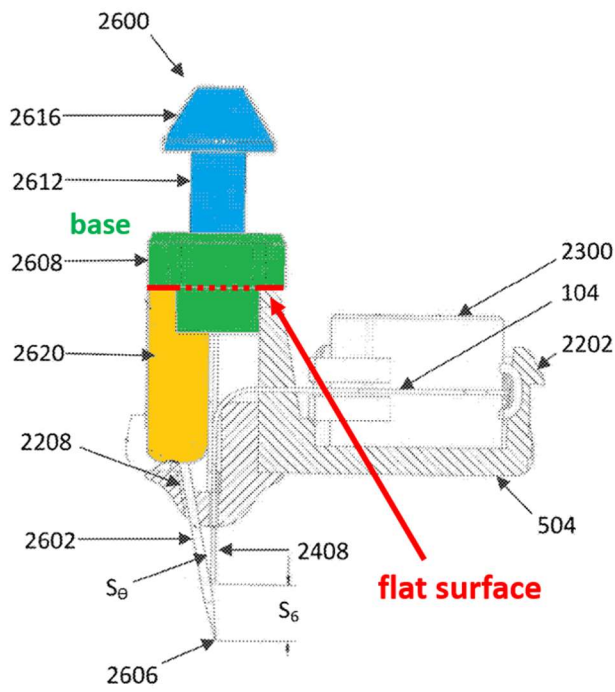


FIG. 11I

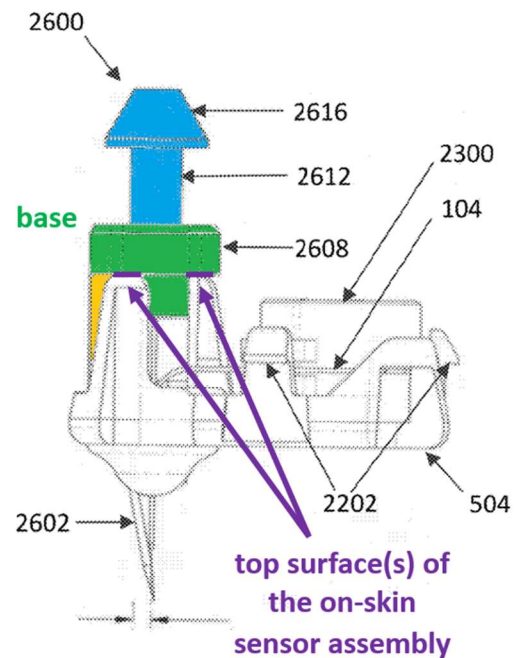
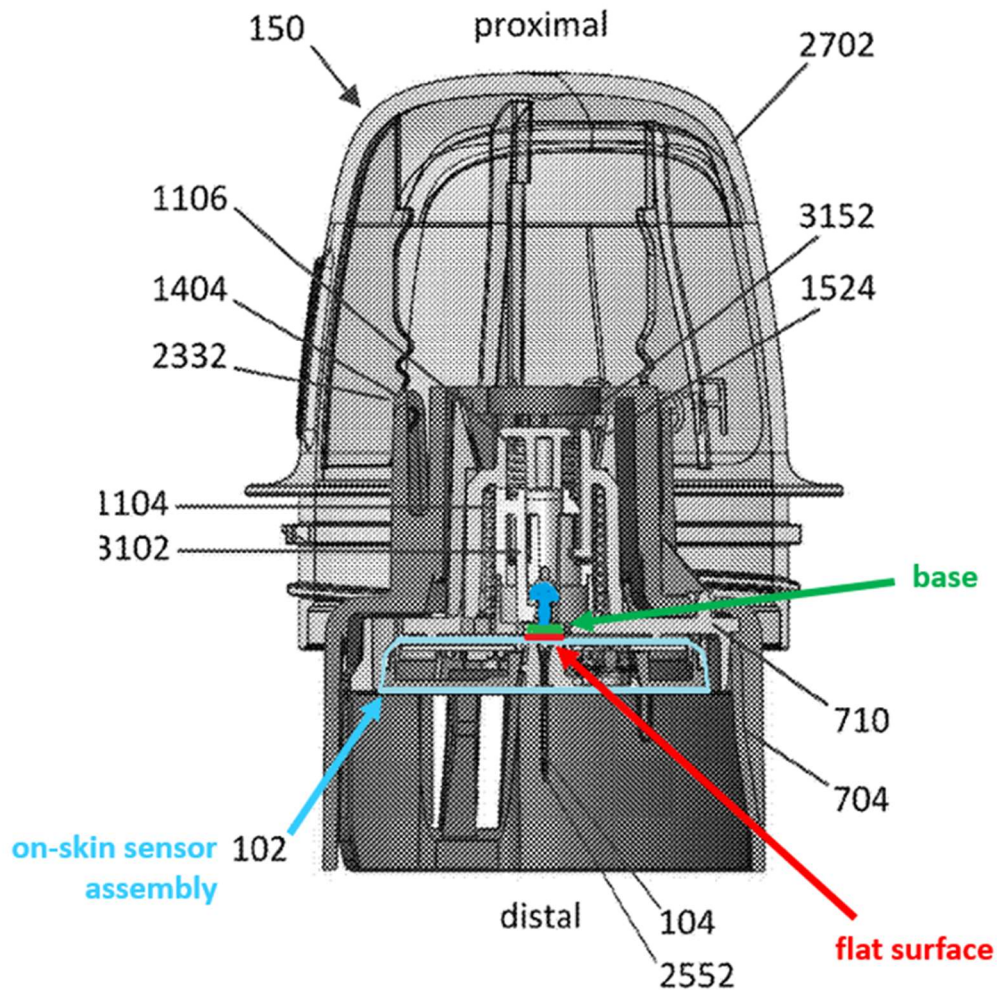


FIG. 11J

Id., Figs. 11I-11J.

Furthermore, Figure 12A depicts a sensor control device 102 (i.e., the on-skin sensor assembly, annotated in light blue) disposed within an applicator housing. A flat surface (annotated in red) of the base of sharp module 2600 (annotated in green) is mated with a top surface of sensor module 504, a component of sensor control

device 102:



Ex-1012, Fig. 12A, [0158]; *see also id.*, [0184] (stating any of the sharps, sharp modules, and sensor modules in Figures 11A-J can be used in the applicator embodiments in Figures 12A-12D, 13A-D).

While Rao discloses that in the Figures 11G-11J embodiment, the sharp 2602 can form an “acute angle” to the longitudinal axis, Rao further discloses that this acute angle can be as small as 5 degrees. *Id.*, [0144]. A POSITA would consider an

angle of 5 degrees from the longitudinal axis to be “substantially perpendicular orientation to the top surface of the on-skin sensor assembly.” Ex-1004, ¶80.

4. Independent Claim 28

Rao renders obvious claim 28, as explained below and as supported by Ex-1004, ¶¶81-90.

- 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, 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 “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-

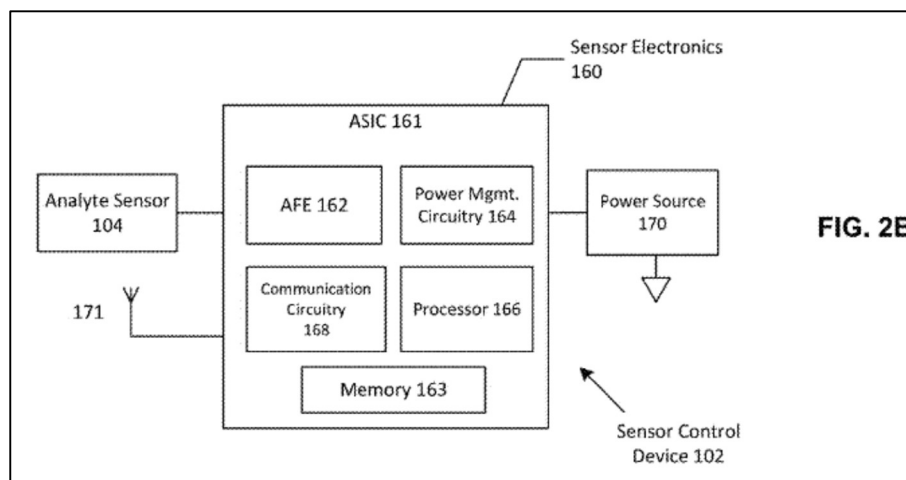
skin sensor assembly,”

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;”

Rao discloses that the sensor control device 102 comprises sensor electronics:



FIGS. 2B and 2C are block diagrams depicting example embodiments of sensor control device 102 **having analyte sensor 104 and sensor electronics 160** (including analyte monitoring circuitry) that can have the majority of the processing capability for rendering end-result data suitable for display to the user.

...

AFE 162 interfaces with in vivo analyte sensor 104 and receives measurement data therefrom and outputs the data to processor 166 in digital form, which in turn processes the data to arrive at the end-result glucose discrete and trend values, etc.

Ex-1012, Fig. 2B, [0077]-[0078]. Rao further discloses that the sensor electronics are operably connected to the sensor in the applicator housing prior to application of the sensor control device to the user:

An applicator can be provided to the user in a sterile package with an electronics housing of the sensor control device contained therein. A structure separate from the applicator, such as a container, can also be provided to the user as a sterile package with a sensor module and a sharp module contained therein. The user can couple the sensor module to the electronics housing, and can couple the sharp to the applicator with an assembly process that involves the insertion of the applicator into the container in a specified manner.

Id., [0008].

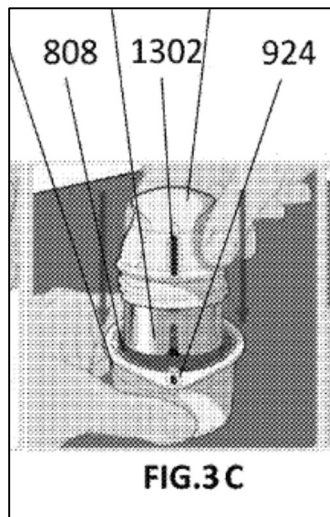


FIG. 3C is a proximal perspective view depicting an example embodiment of a user inserting an applicator device 150 into a tray 810 during an assembly. ... *A sharp and sensor (not shown) within tray*

810 can be coupled with an electronics housing (not shown) within housing 702 at the end of the distal advancement of housing 702.

Id., Fig. 3C, [0083]-[0084]. Rao further discloses in Figure 13A, sensor module 504 (including sensor 104) is installed into sensor control device 102 while disposed within the applicator housing (prior to application to the user):

sensor electronics is made via electrical conductive contacts:

FIG. 11F is a top-down cross-sectional view of sensor module 504. Sensor module 504 can include one or more sensor module snaps 2202 for coupling with a housing (not shown) of sensor control device 102. Sensor module 504 can also include sensor connector 2300, which can have *sensor contacts 2302* for coupling with a proximal portion of sensor 104. Sensor connector 2300 can be made of silicone rubber that encapsulates compliant carbon impregnated polymer modules that serve as *electrical conductive contacts 2302 between sensor 104 and electrical circuitry contacts for the electronics within sensor control device 102.*

Id., [0142].

- 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.”

Rao discloses that the sharp is inserted through at least a portion of the sensor electronics. For example, as shown in Figure 3C, Rao discloses that the sharp and sensor module is in a tray which the applicator is placed over and inserted onto, in order to couple the sharp and sensor with the electronics housing in the applicator.

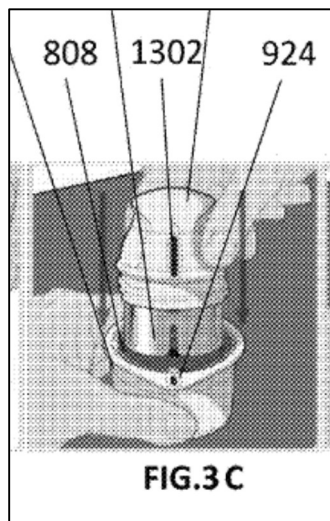
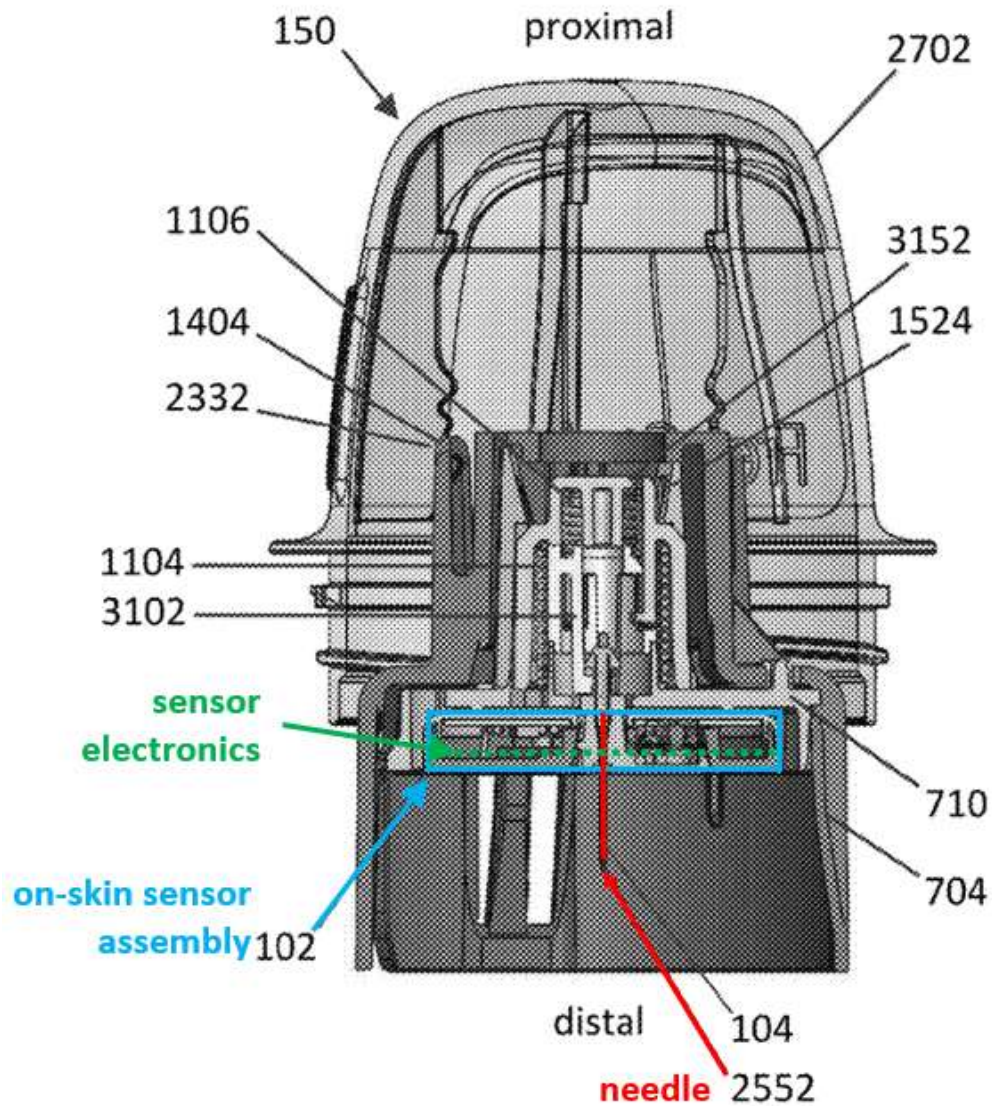


FIG. 3C is a proximal perspective view depicting an example embodiment of a user inserting an applicator device 150 into a tray 810 during an assembly. ... ***A sharp and sensor (not shown) within tray 810 can be coupled with an electronics housing (not shown) within housing 702 at the end of the distal advancement of housing 702.***

Ex-1012, Fig. 3C, [0083]-[0084]. In other words, as sensor module 504 and sharp module 2600 are installed into sensor control device 102 during a user assembly step, the sharp 2552 (i.e., the needle) is inserted through at least a portion of the sensor electronics disposed within sensor control device 102. This is depicted, e.g., in

Figure 12A, where sharp 2552 and sensor module have been installed in sensor control device 102 (i.e., the on-skin sensor assembly), and sharp 2552 (annotated in red) has been inserted through at least a portion of the sensor electronics (annotated by green-dotted line):



Id., Figs. 12A, 13A-13D, [0158]-[0161].

5. Claims 2 & 25

Rao renders obvious claims 2 and 25, as explained below and as supported by Ex-1004, ¶¶91-92. 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].”

Rao discloses that the insertion sharp may have a hollow or partially hollow shaft to receive a portion of the sensor.

Additionally, in some example embodiments, the sharps described herein can include hollow or partially hollow insertion needles, having an internal space or lumen.

Ex-1012, [0147]. In addition, Rao expressly discloses a needle with an open side in Figure 11A:

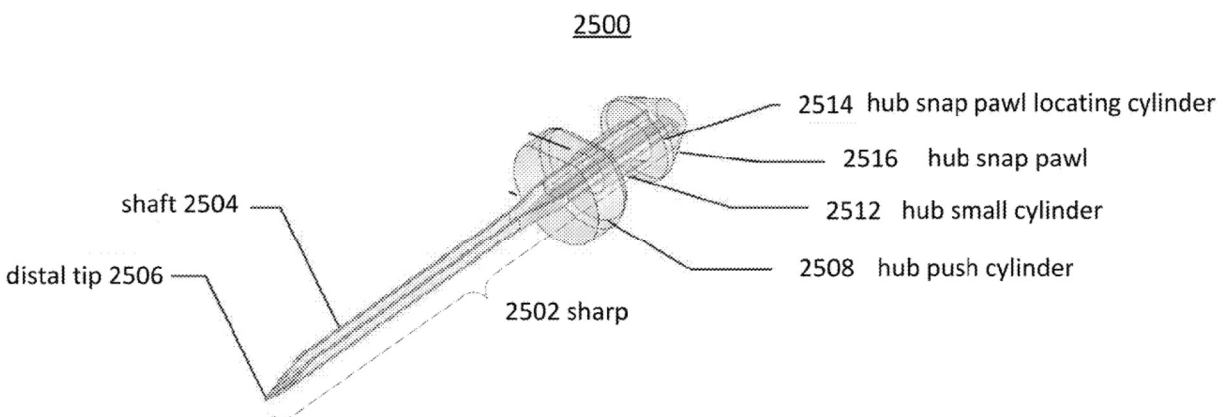


FIG. 11A

Id., Fig. 11A; *see also id.*, 11H [0134] (discussing a sharp with a hollow or recessed

shaft to hold the sensor tail). A POSITA would have been motivated to utilize the needle of Figure 11A as the insertion element when inserting a sensor with a tail in order to protect the sensor tail. Ex-1004, ¶92.

6. Claim 3

Rao renders obvious claim 3, as explained below and as supported by Ex-1004, ¶¶93-94. 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.”

Rao discloses a needle with an open side having a U-shaped cross section in Figure 11A:

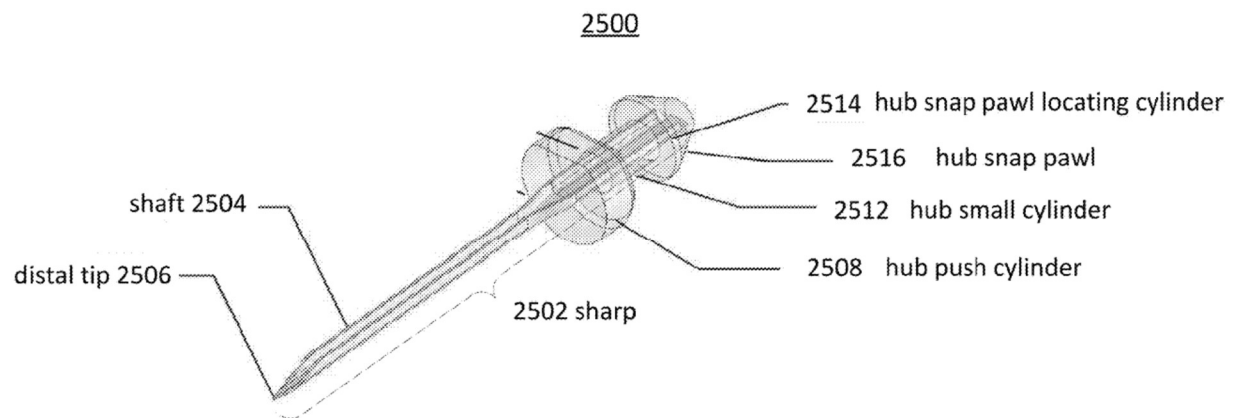


FIG. 11A

Ex-1012, Fig. 11A, [0134]. Further, a POSITA would have been motivated to utilize the needle of Figure 11A as the insertion element when inserting a sensor with a tail in order to protect the sensor tail. Ex-1004, ¶94.

7. Claims 4, 14, 26, & 30

Rao renders obvious claims 4, 14, 26, and 30, as explained below and as supported by Ex-1004, ¶¶95-98. 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.”

Rao discloses a sharp module 2600 that corresponds to a “needle hub coupled to an insertion element.” *See, supra*, claim 1.2.

As discussed above in Section 0, this limitation should be construed as a product-by-process limitation, as the '625 patent's specification does not disclose any structural or functional difference provided by the recited processes over the prior art. Accordingly, the “by heat staking, snap-fit, friction-fit, clamshell, or insert molding” language of the claim should not be afforded patentable weight. Thus, Rao discloses “wherein the needle hub is coupled to the [insertion element / needle].”

Even if the “by heat staking, snap-fit, friction-fit, clamshell, or insert molding” language is given patentable weight, Rao discloses that the sharp module may be formed by insert molding:

Sharp 2552 can be positioned in an off-center location during a ***molding process with hub components*** 2558, 2562, 2566, each of which may consist of a rigid plastic material.

Ex-1012, [0137].

Sharp module 2600 can also include a bend fin guide 2620 for maintaining “pre-bent” sharp 2602 in position during assembly and/or use, and can prevent lateral or rotational movement of sharp 2602 relative to hub components. Proximal portion 2603 of sharp 2602 can be “trimmed” from the hub after *molding process* is completed, and prior to assembly of sharp module 2600 with sensor module 504.

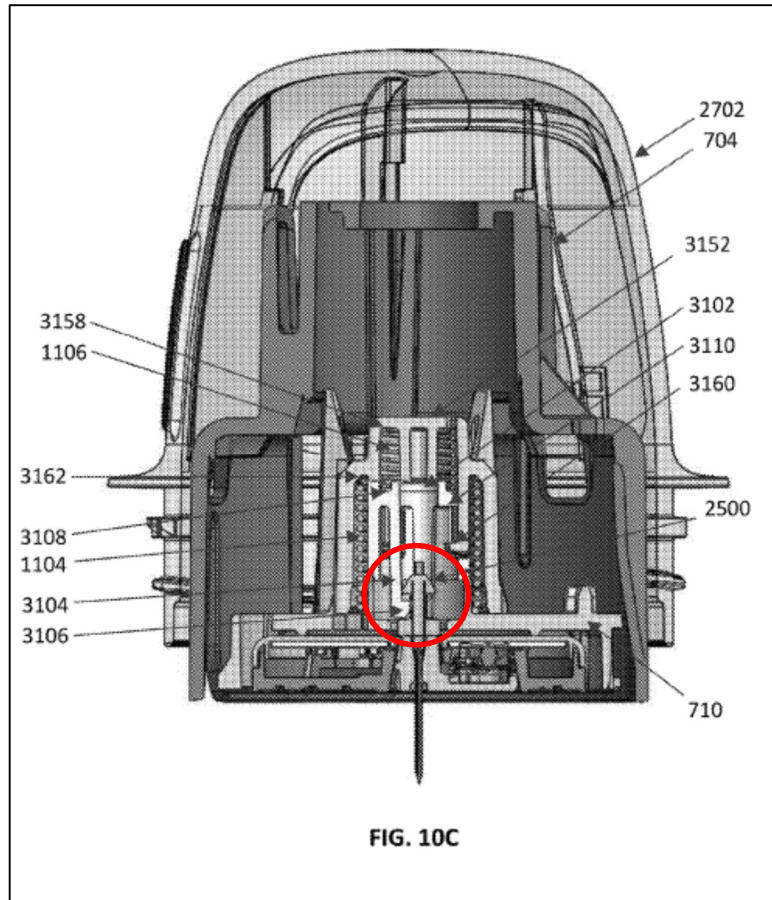
Id., [0143]. A POSITA would understand that the above-described “molding process” to be “insert molding.” Ex-1004, ¶¶97-98. Accordingly, Rao discloses or suggests a needle hub “coupled to the [insertion element / needle] by heat staking, snap-fit, friction-fit, clamshell, or insert molding.”

8. Claims 5, 15, & 27

Rao renders obvious claims 5, 15, and 27, as explained below and as supported by Ex-1004, ¶¶99-102. 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.”

Rao discloses that a sharp is coupled to the sharp module. Ex-1012, Fig. 11G-11J, [0143]-[0144]; *see also id.*, Figs. 11A-F. Rao further discloses that the applicator retracts the sharp from the user and into the applicator housing via sharp carrier 3102, which engages with the sharp module just below the conical “hub snap pawl” (as annotated below):



Ex-1012, Fig. 10C, [0124]; *see also, id.*, Figs. 12D, 13D (depicting retraction process). Because the sharp module (i.e., needle hub) is able to retract the needle out of the user, a POSITA would understand the needle necessarily has some structure to secure it to the sharp module, otherwise there would be a risk of the needle separating from the needle hub. Ex-1004, ¶¶100-101. Thus Rao discloses or suggests a needle / insertion element comprising a locking element configured to couple the needle / insertion element 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

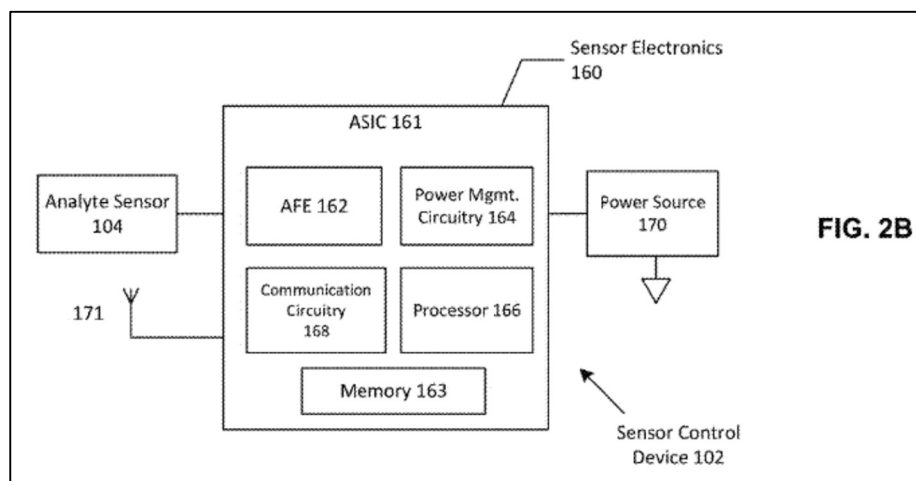
afforded patentable weight, Rao discloses or suggests coupling the needle to the needle hub “by insert molding.” *See, supra*, claims 4, 14, 26, and 30.

9. Claims 6 & 16

Rao renders obvious claims 6 and 16, as explained below and as supported by Ex-1004, ¶¶103-104. 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].”

Rao discloses that the sensor control device 102 (i.e., the on-skin sensor assembly) comprises sensor electronics:



FIGS. 2B and 2C are block diagrams depicting example embodiments of sensor control device 102 having analyte sensor 104 and ***sensor electronics 160*** (including analyte monitoring circuitry) that can have the majority of the processing capability for rendering end-result data suitable for display to the user. ...

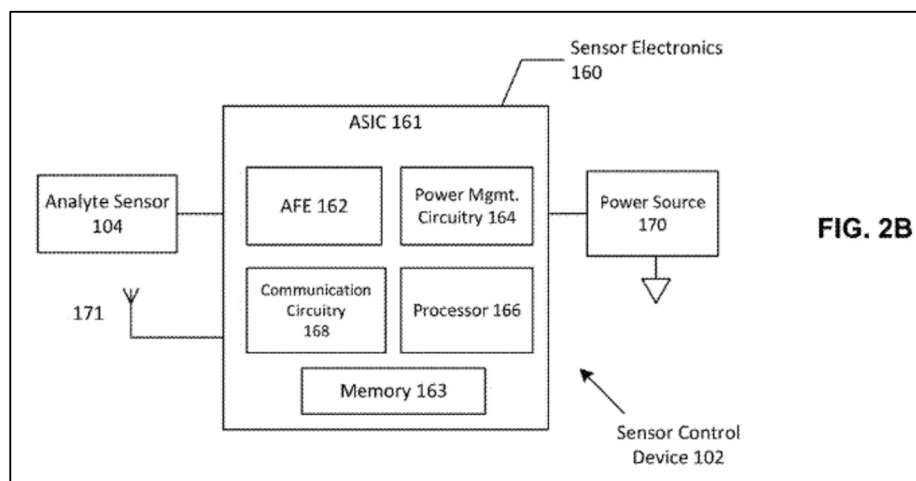
Ex-1012, Fig. 2B, [0077]-[0078]; *see also id.*, Fig. 2C, [0079].

10. Claims 7, 17, & 29

Rao renders obvious claims 7, 17, and 29, as explained below and as supported by Ex-1004, ¶¶105-106. 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.”

Rao discloses that the sensor electronics of the sensor control device 102 includes a power source and an ASIC comprising a processor (signal processing components), a memory (data storage components), and communications circuitry:



FIGS. 2B and 2C are block diagrams depicting example embodiments of sensor control device 102 having analyte sensor 104 and sensor electronics 160 (including analyte monitoring circuitry) that can have the majority of the processing capability for rendering end-result data suitable for display to the user. In FIG. 2B, a single semiconductor chip 161 is depicted that can be a custom application specific integrated

circuit (ASIC). Shown within ASIC 161 are certain high-level functional units, including an analog front end (AFE) 162, power management (or control) circuitry 164, ***processor 166***, and ***communication circuitry 168*** (which can be implemented as a transmitter, receiver, transceiver, passive circuit, or otherwise according to the communication protocol). In this embodiment, both AFE 162 and processor 166 are used as analyte monitoring circuitry, but in other embodiments either circuit can perform the analyte monitoring function. Processor 166 can include one or more processors, microprocessors, controllers, and/or microcontrollers, each of which can be a discrete chip or distributed amongst (and a portion of) a number of different chips.

A ***memory 163*** is also included within ASIC 161 and can be shared by the various functional units present within ASIC 161, or can be distributed amongst two or more of them. Memory 163 can also be a separate chip. Memory 163 can be volatile and/or non-volatile memory. In this embodiment, ASIC 161 is coupled with ***power source 170***, which can be a coin cell battery, or the like. AFE 162 interfaces with in vivo analyte sensor 104 and receives measurement data therefrom and outputs the data to processor 166 in digital form, which in turn processes the data to arrive at the end-result glucose discrete and trend values, etc. This data can then be provided to communication circuitry 168 for sending, by way of antenna 171, to reader device 120 (not shown), for example, where minimal further processing is needed by the resident software application to display the data.

Ex-1012, Fig. 2B, [0077]-[0078]; *see also id.*, Fig. 2C, [0079].

11. Claims 8 & 18

Rao renders obvious claims 8 and 18, as explained below and as supported by Ex-1004, ¶¶107-108. 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

Rao renders obvious claim 9, as explained below and as supported by Ex-1004, ¶¶109-110. 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.”

Rao discloses sensor control device 102 is applied to a user’s skin with an adhesive patch 105.

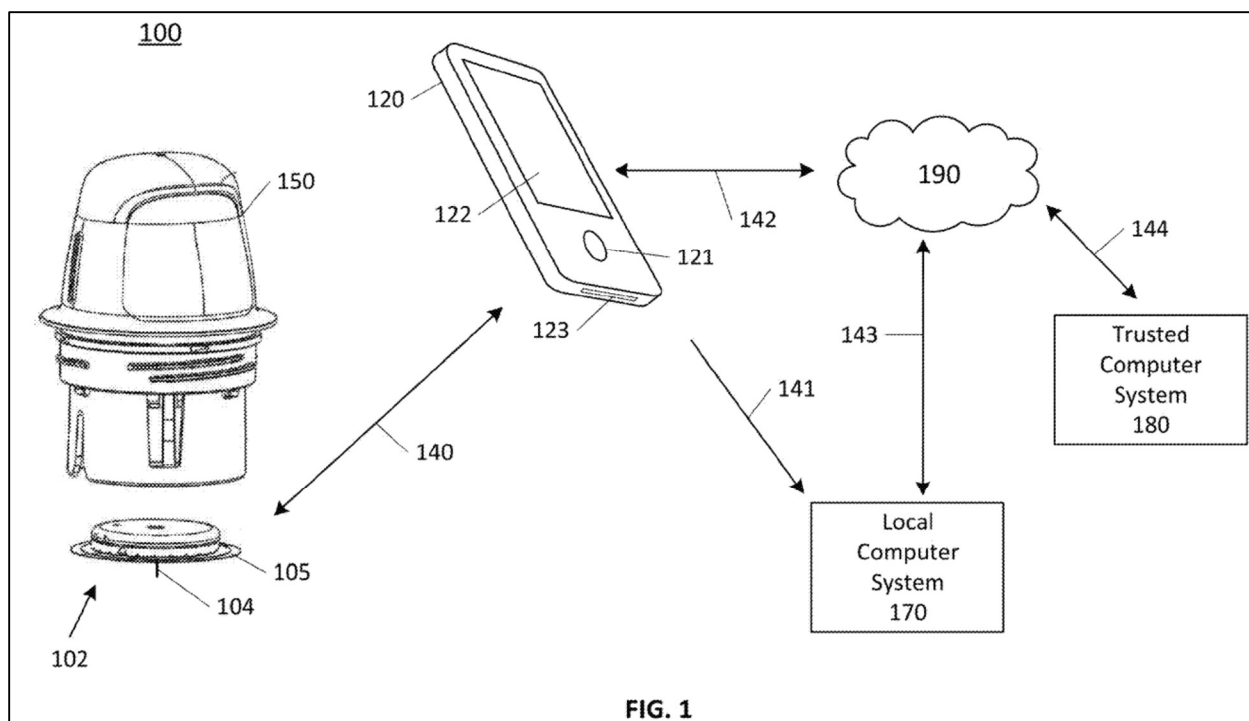


FIG. 1 is a conceptual diagram depicting an example embodiment of an analyte monitoring system 100 that includes a sensor applicator 150, a sensor control device 102, and a reader device 120. Here, sensor applicator 150 can be used to deliver sensor control device 102 to a monitoring location on a user's skin where a sensor 104 is maintained in position for a period of time by *an adhesive patch 105*.

Ex-1012, Fig. 1, [0075]; *see also id.*, [0166] (“An adhesive layer (not shown) on the bottom surface of sensor control device 102 keeps sensor control device 102 against the subject’s skin”).

13. Claim 19

Rao renders obvious claim 19, as explained below and as supported by Ex-1004, ¶¶111-112. 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 renders obvious claim 23, as explained below and as supported by Ex-1004, ¶¶113-114. 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 of the *base* within the aperture, 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

Rao renders obvious claim 24, as explained below and as supported by Ex-1004, ¶¶115-116. 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 Rao And Lundquist Renders Obvious Claims 4-5, 14-15, 26-27, And 30

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

Rao discloses multiple embodiments of sharp modules. In one embodiment, sharp module 2600 (*i.e.*, a needle hub) of Figures 11G-11J is coupled to sharp 2602 (*i.e.*, a needle or insertion element). Ex-1012, Fig. 11G-J, [0134], [0143]. The sharp module 2600 comprises upper conical pawl 2616 and a lower portion, including bend fin guide 2620 that prevents “rotational movement of sharp 2602” during use (*i.e.*, an anti-rotation feature comprising a key). *Id.*, [0143]. Rao further discloses that a sharp carrier engages 1102 with the sharp module to “automatically retract” the sharp module and the sharp it is coupled to, and discloses structures in the different applicator embodiments that ensure “full retraction” of the sharp module. *Id.*, [0086], [0119]; *see generally id.* Figs. 10A-10F, [0119]-[0133] (describing different structures involved with the retraction of the sharp module). A POSITA would understand the importance of ensuring the sharp 2602 is coupled to the sharp module 2600 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 sharp module is retracted. Ex-1004, ¶¶117-118; *see also*, Ex-1012, [0119] (“... ensure **full retraction** of sharp carrier 1102 through sheath 704 upon retraction of sharp carrier 1102 at the end of the deployment procedure.”).

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 Rao’s CGM applicators to achieve Rao’s stated goal of ensuring “full retraction” of the sharp from the user and into the applicator. Ex-1004, ¶120; Ex-1012, [0119]. A POSITA would have a reasonable expectation of success with adopting Lundquist’s manufacturing process in Rao’s CGM systems, as Rao discloses its sharp (*i.e.*, needle or insertion element) may be “a varying, *i.e.*, changing, width along at least a portion of its length” (Ex-1012, [0146]), and “can include hollow or partially hollow insertion needles” (*id.*, [0147]). Lundquist also discloses that its insert molding method with notches in the needle can be used with “any sized and shaped [needle]” (Ex-1011, [0041]). Ex-1004, ¶121. Furthermore, adding notches for the sharp of Rao to engage the polymeric material used in the sharp module would have been predictable and within

the skill of a POSITA. *Id.*, ¶122.

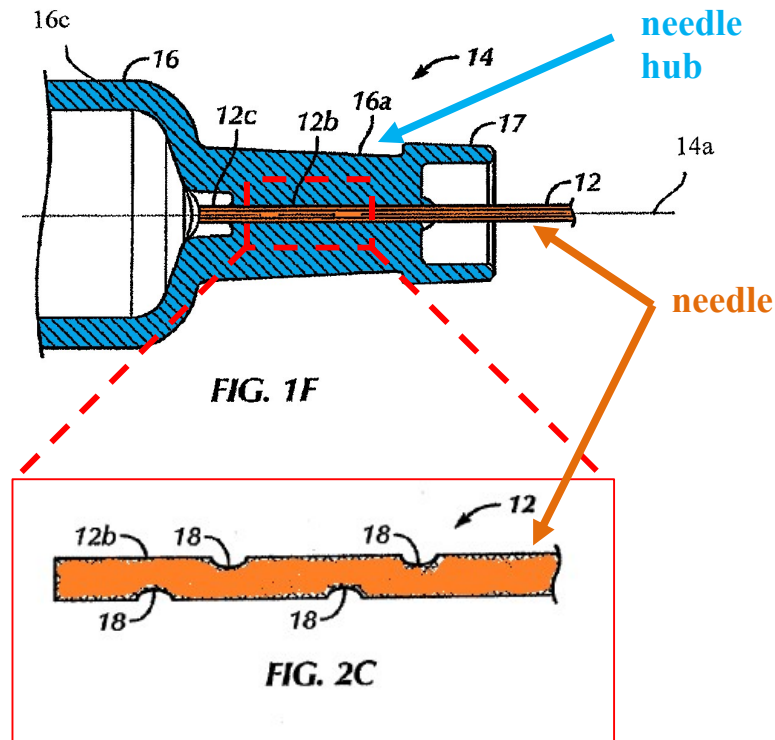
2. Claims 4, 14, 26, & 30

Claims 4, 14, 26, and 30 depend from claims 1, 13, 22, and 28 respectively. As explained in Ground 1, Rao renders obvious claims 1, 13, 22, and 28. The combination of Rao and Lundquist further renders obvious claims 4, 14, 26, and 30, as explained below and as supported by Ex-1004, ¶¶117-126.

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

As discussed above in Ground I, Rao discloses multiple embodiments of sharp modules. In one embodiment, sharp module 2600 (*i.e.*, a needle hub) of Figures 11G-11J is coupled to sharp 2602 (*i.e.*, a needle or insertion element). Ex-1011, Fig. 11G-J, [0134], [0143]. The sharp module 2600 comprises upper conical pawl 2616 and a lower portion, including bend fin guide 2620. *Id.*, [0143]. Rao further discloses that the sharp module 2600 may be formed by a “molding process.” *Id.*; *see also id.*, [0137]. A POSITA would understand that the “molding process” disclosed in Rao to be “insert molding.” Ex-1004, ¶124.

In addition, Lundquist explicitly discloses a needle is coupled to a hub by insert molding:



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 Rao-Lundquist combination, the sharp module 2600 and sharp 2602 of Rao are coupled together by insert molding the sharp module over the needle, as taught in Lundquist.

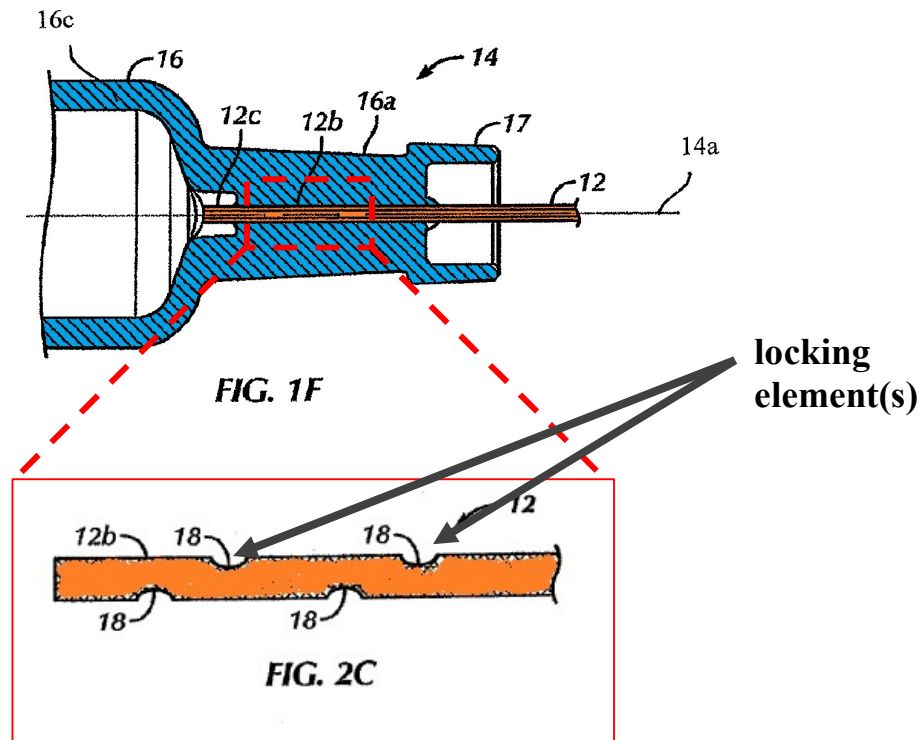
3. Claims 5, 15, & 27

Claims 5, 15 and 27 depend from claims 4, 14 and 26 respectively. As

explained above, the combination of Rao and Lundquist renders obvious claims 4, 14, and 26. The combination of Rao and Lundquist further renders obvious claims 5, 15, and 27, as explained below and as supported by Ex-1004, ¶¶117-129.

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

As explained above, Rao discloses that a sharp module 2600 is coupled to a sharp 2602, with the sharp module being formed by a “molding process,” which a POSITA would understand to be insert molding, and Lundquist further discloses coupling a needle 12 to a hub 16a by insert molding. *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):

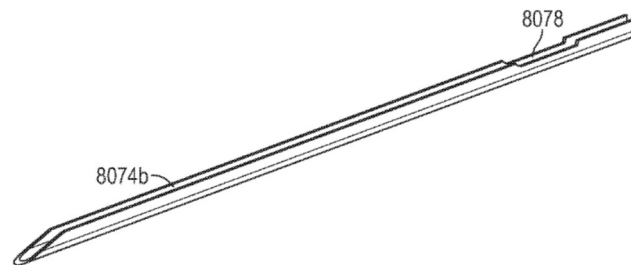


FIG. 80B

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

In the Rao-Lundquist combination, the sharp module 2600 and sharp 2602 of

Rao are coupled together by adding notches to the needle and insert molding the sharp hub over the needle, as taught in Lundquist.

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.*

Here, the first part of the *Advanced Bionics* test is not satisfied as Rao and Lundquist were not of record during prosecution of the '625 patent. 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.

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,

By: /Scott C. Weidenfeller/

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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 8,924 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/
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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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