VIII. THE ASSERTED GROUNDS OF UNPATENTABILITY

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

1. Independent Claim 1

57. In my opinion, 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:"*

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

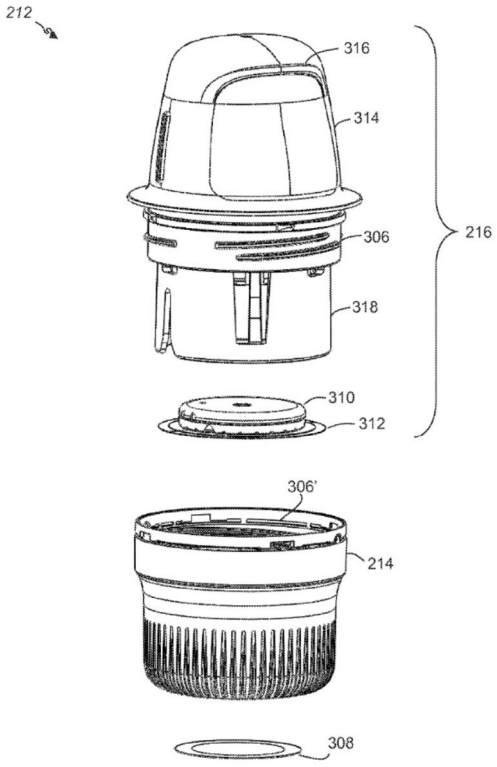


FIG. 3

Abbott Diabetes v. Dexcom
IPR2024-00859
EXHIBIT 2009

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

b. *1.1"an applicator housing having an internal volume;"*

59. Pace discloses an applicator housing having an internal volume. Ex-1006~~,~~ at 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:

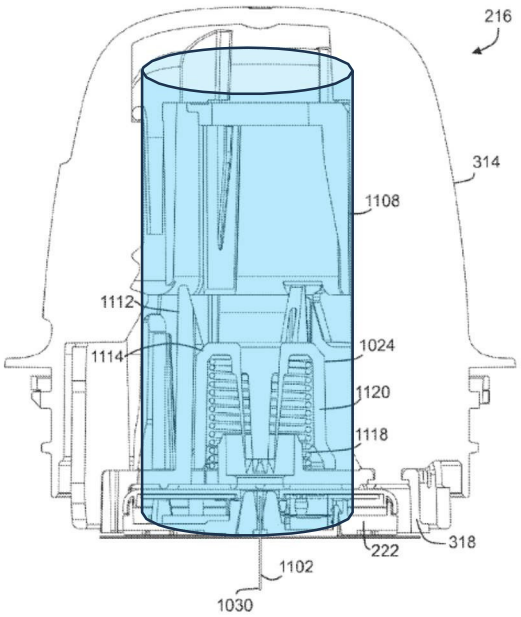


FIG. 11C

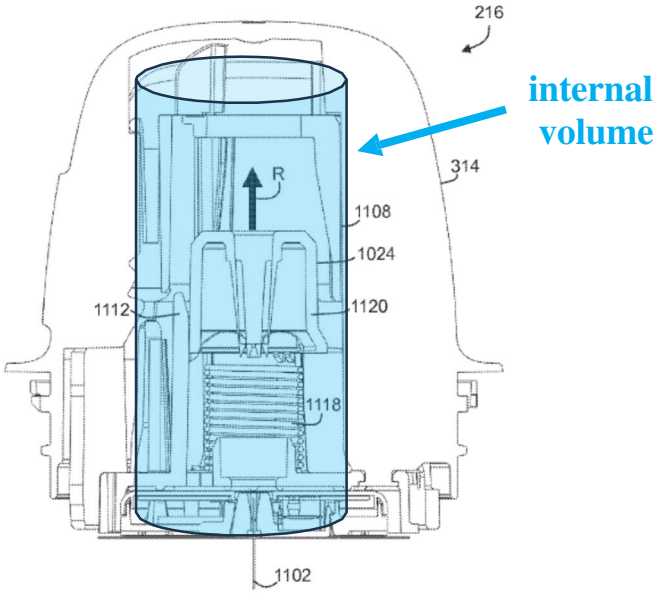


FIG. 11D

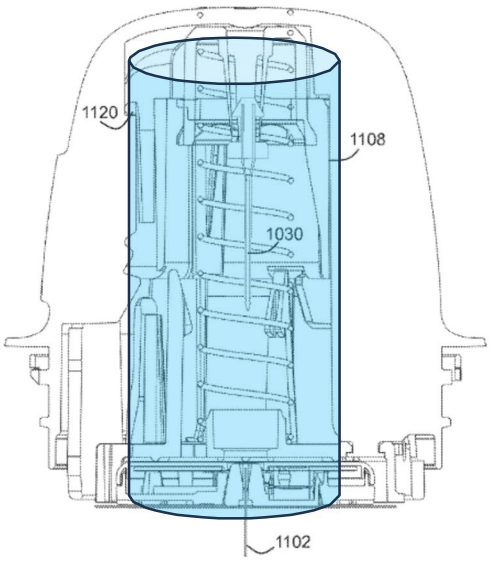


FIG. 11E

Id., at 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"

60. 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, at [0123].

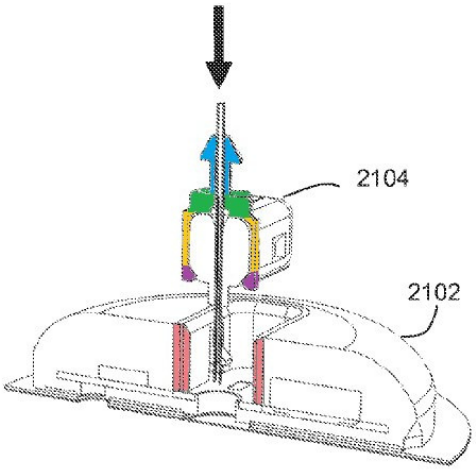


FIG. 21A

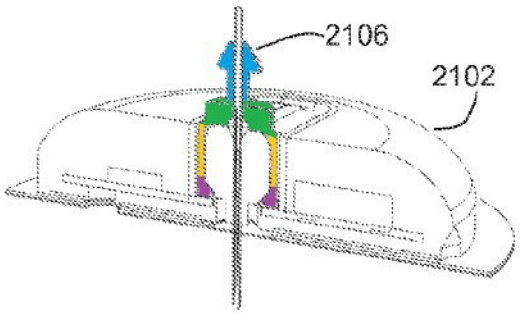


FIG. 21B

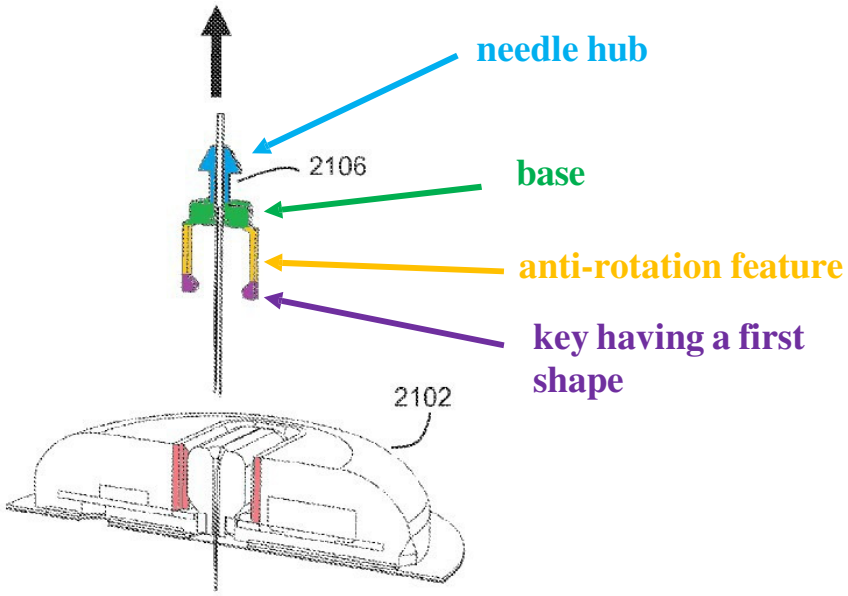


FIG. 21C

Id., at Figs. 21A-21C, [0123]. The snap features of the gripper 2106 "may be incorporated in[to] the sharp hub/boss." *Id.*, at [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.*, at 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).

61. 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.*, at 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."

62. 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."

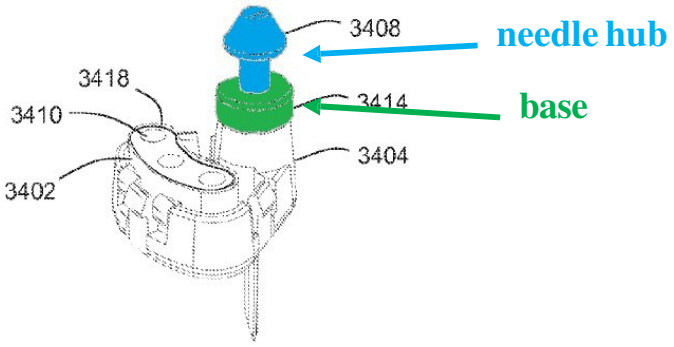


FIG. 34D

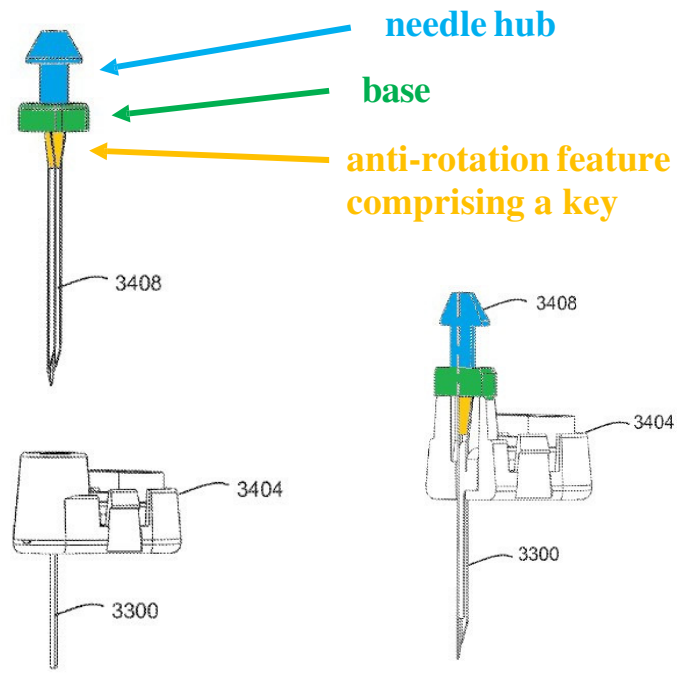


FIG. 35A FIG. 35B

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

63. 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).

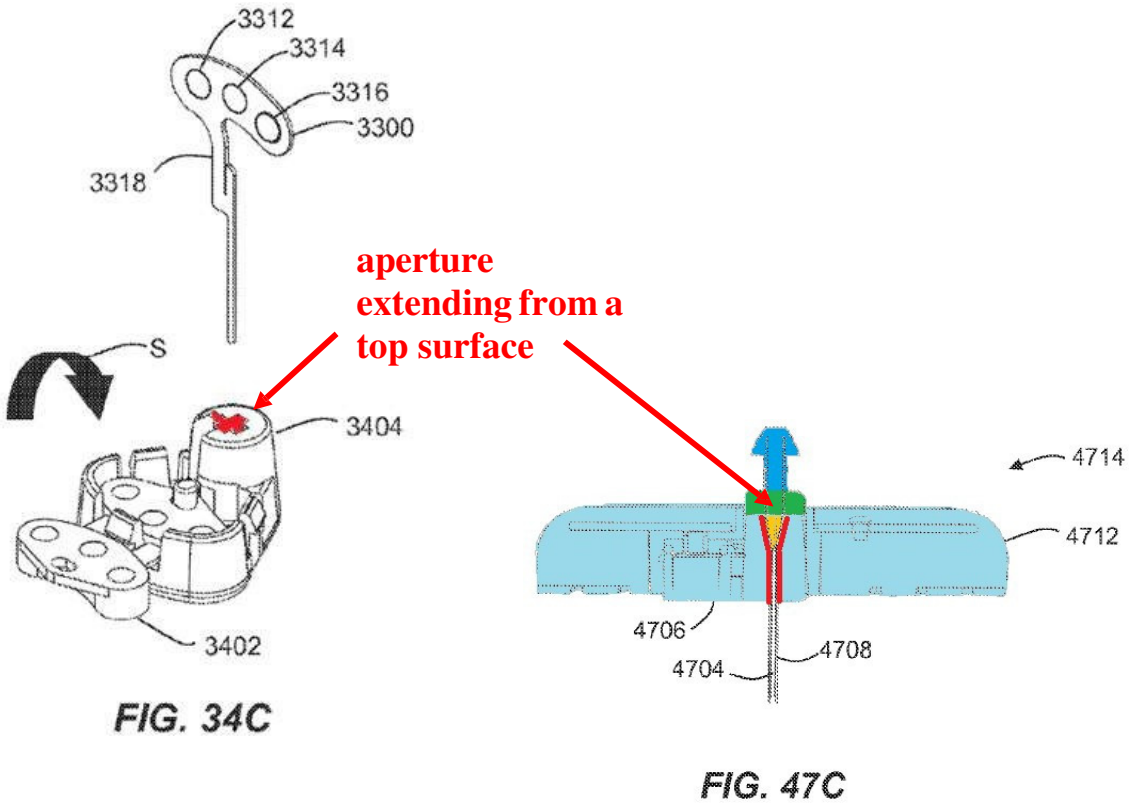


FIG. 34C

FIG. 47C

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

64. 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~~ The V-shaped portion has a rectangular cross section and 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.

65. In addition, 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~~A POSITA would have understood that glucose sensors for insertion into a user are small and fragile, and have delicate electrical circuitry that includes electrical leads and contacts. A POSITA would therefore understand 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~~the on-skin sensor assembly~~. *Id*~~ and the sensor therein. 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:"*

66. Pace discloses the claimed on-skin sensor assembly. Ex-1006~~,~~ at 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.

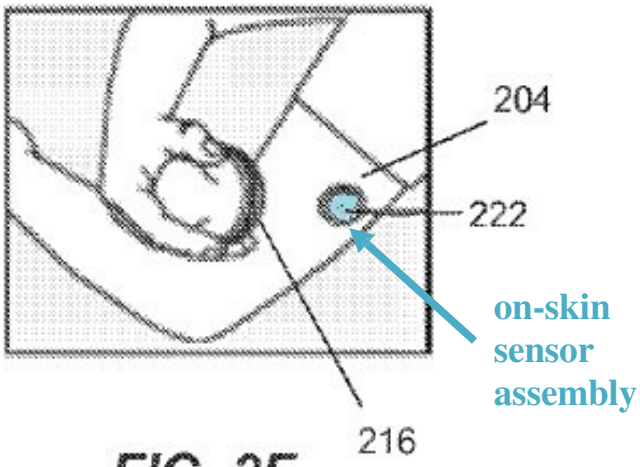


FIG. 2F

Id., at Fig. 2F, [0081], [0092], [0110], [0116]; *see also Id.*, at 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).

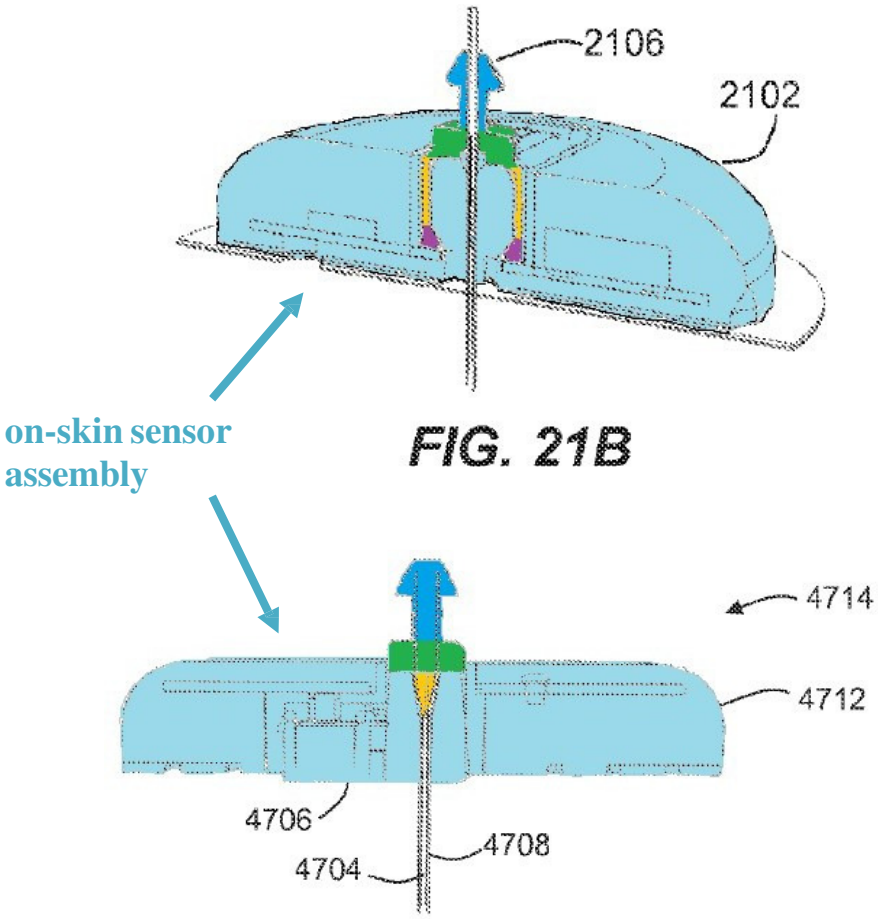


FIG. 21B

FIG. 47C

Id.~~,~~. at 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.*~~,~~. at Fig. 21C.

e. *1.7 "a sensor, the sensor configured to measure a glucose concentration of a host, and"*

67. 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, at [0007]-[0008]; *see also Id.*, at [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;"*

68. 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:

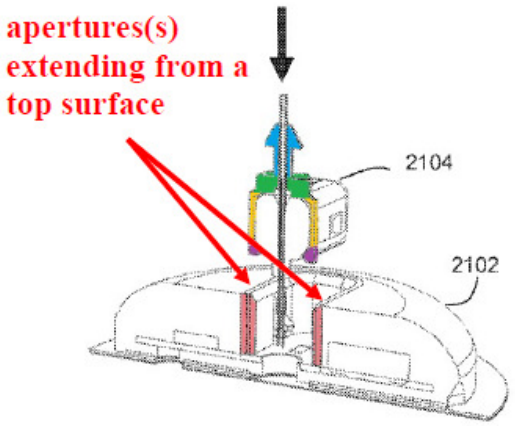


FIG. 21A

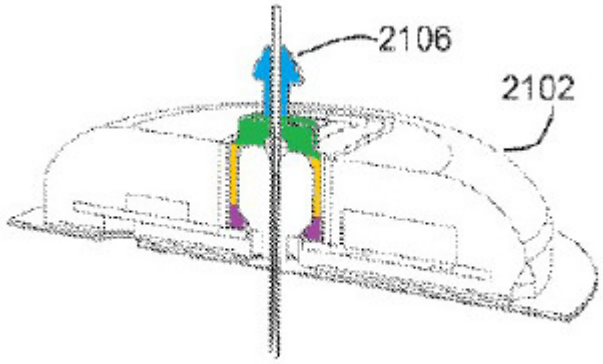


FIG. 21B

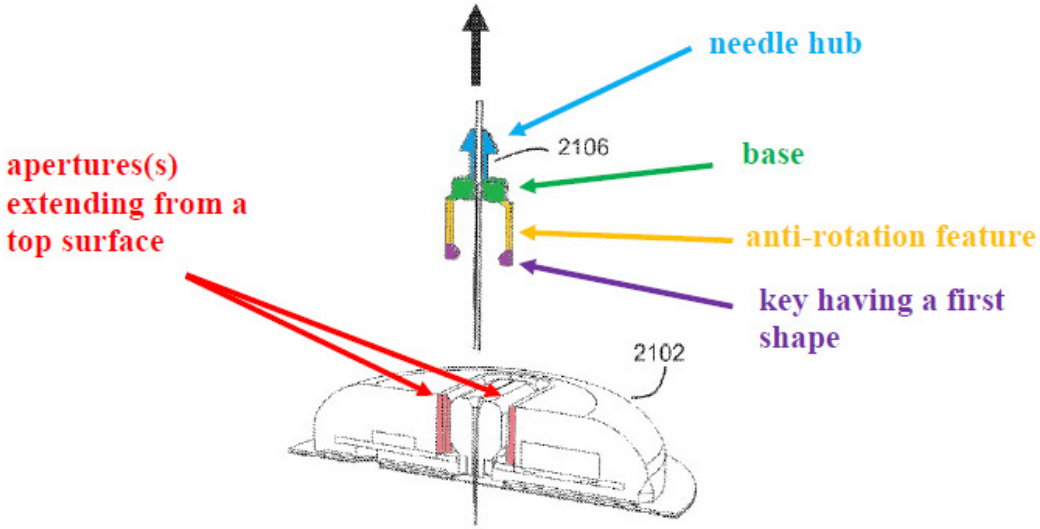


FIG. 21C

Ex-1006~~,~~ at 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~~in the '625 patent are offset from the aperture through which the needle passes:

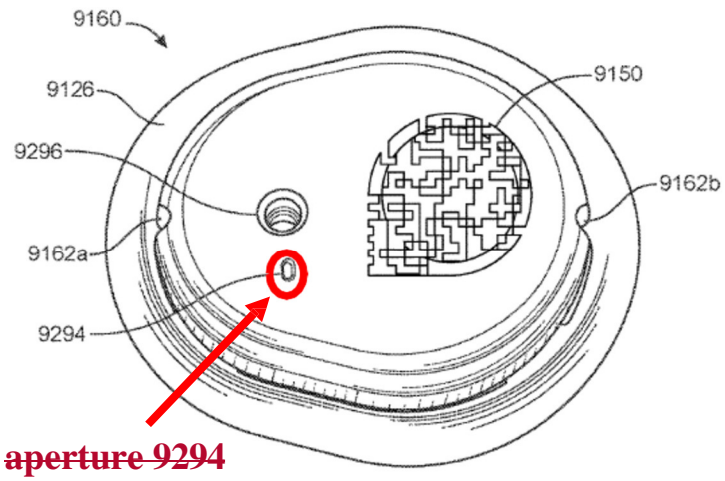


FIG. 91

Ex-1001, at Fig. 91.

69. 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.

70. 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).

71. 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:

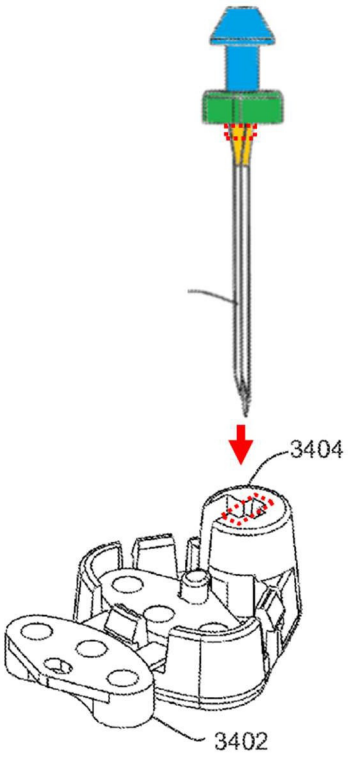


FIG. 34B

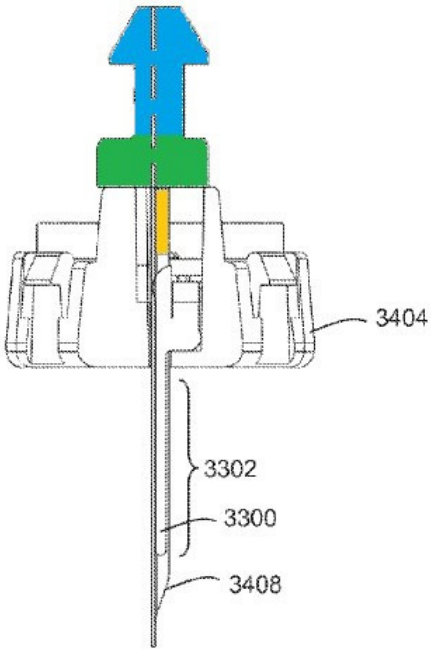


FIG. 35C

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

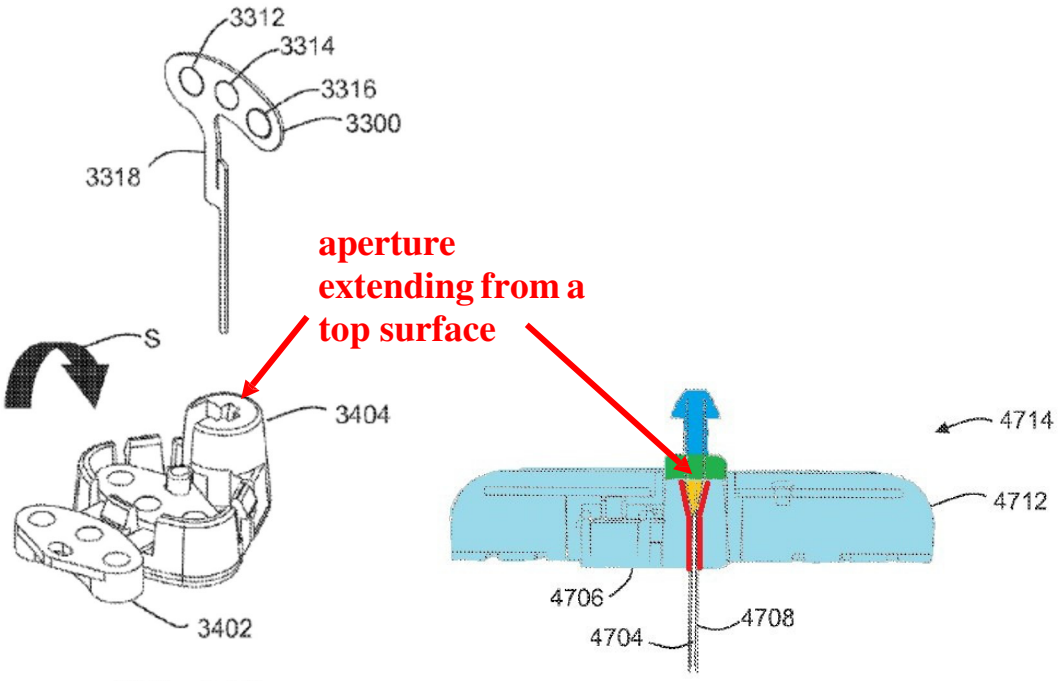


FIG. 34C

FIG. 47C

Id.~~,~~. at Figs. 34C, 47C [0140]-[0142], [0149]; *see also Id.*~~,~~. at 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."

72. 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."*

73. 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

74. In my opinion, 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:"*

75. *See*, *supra*, claim 1.P.

b. *13.1 "an applicator housing having an internal volume;"*

76. *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;"

77. *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, at 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.

78. 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, at 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"*

79. *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."*

80. *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

81. In my opinion, 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:"*

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

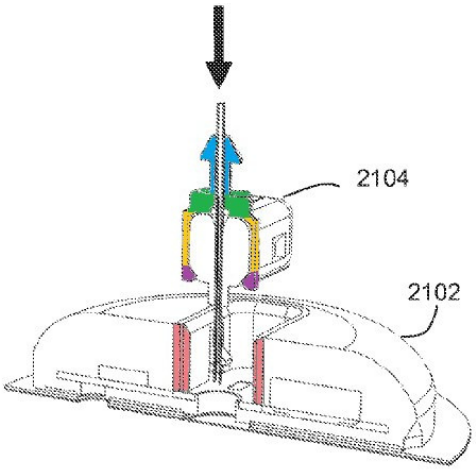


FIG. 21A

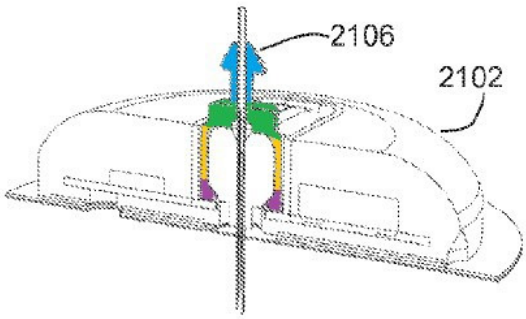


FIG. 21B

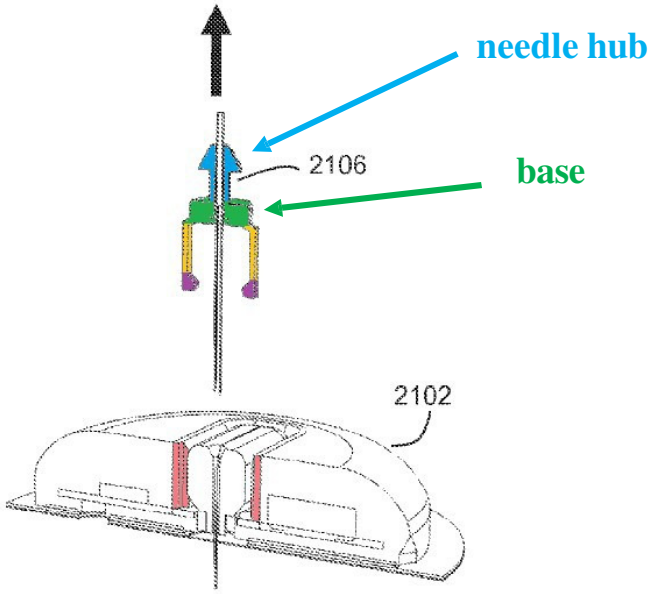


FIG. 21C

Ex-1006~~,~~ at Figs. 21A-21C; *see also Id.*~~,~~ at [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.*

83. In embodiment B, Pace discloses a hub 3414 coupled to a sharp 3408. *Id.*, at 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.*

84. In both embodiments, this connection is made inside the applicator housing, prior to application of the on-body device to the user. *Id.*, at [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 that 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,"*

85. *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,"*

86. *See*, *supra*, claim 1.11.

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

87. *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."

88. 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):

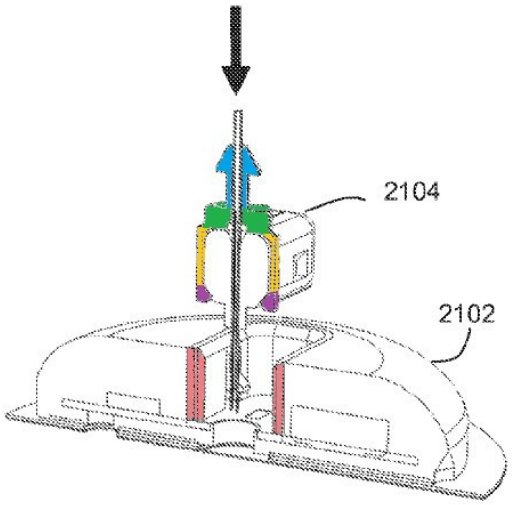


FIG. 21A

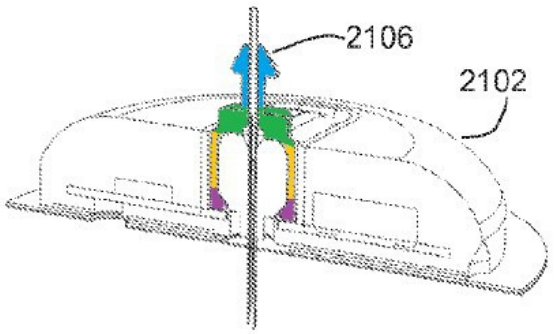


FIG. 21B

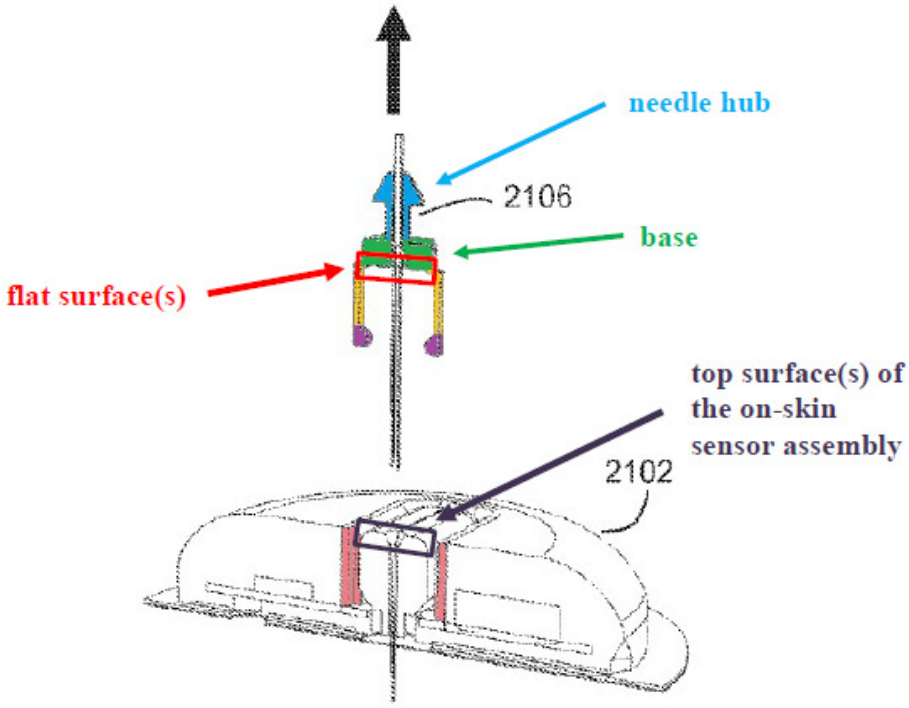


FIG. 21C

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

89. 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:

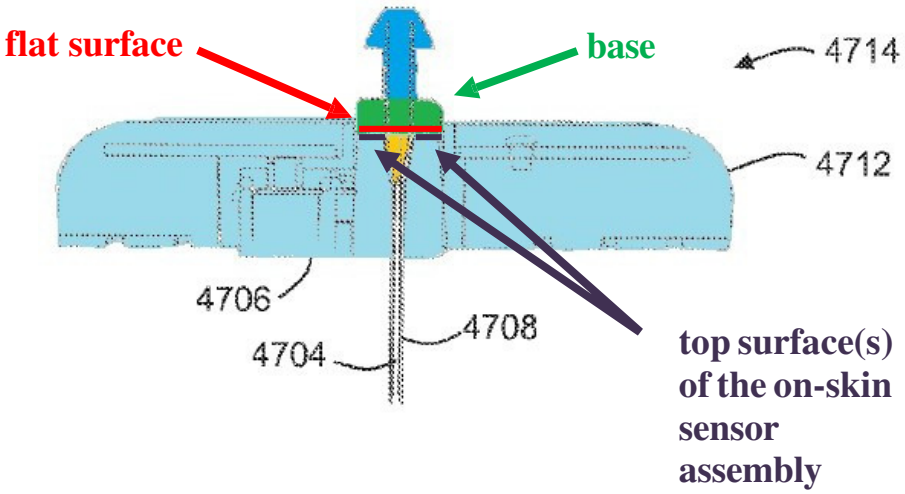


FIG. 47C

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

4. Independent Claim 28

90. In my opinion, 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:"*

91. *See*, *supra*, claim 1.P.

b. *28.1 "an applicator housing having an internal volume;"*

92. *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:"*

93. *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"

94. *See*, *supra*, claim 1.3-1.9.

e. *28.10 "sensor electronics operably connected to the sensor in the applicator housing;"*

95. Pace discloses a sensor assembly~~, including the sensor,~~ connected with the electronics assembly ~~in~~inside 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.

Id. ~~Ex. 1006,~~at [0077][1]; *see also Id.*~~,~~. at Figs. 1, 10I-M~~, 15B~~, [0116] ("[T]he applicator 1400 is inserted into container 1500 to load the electronics assembly 1504 into the 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~~the complete on-body

[1] ~~Emphasis in quotations added throughout unless otherwise noted.~~

device, meaning the sensor assembly~~, including the sensor,~~ is connected to the electronics assembly during manufacture. *Id.*~~.~~. at [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;"*

96. *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"*

97. *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."*

98. 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:

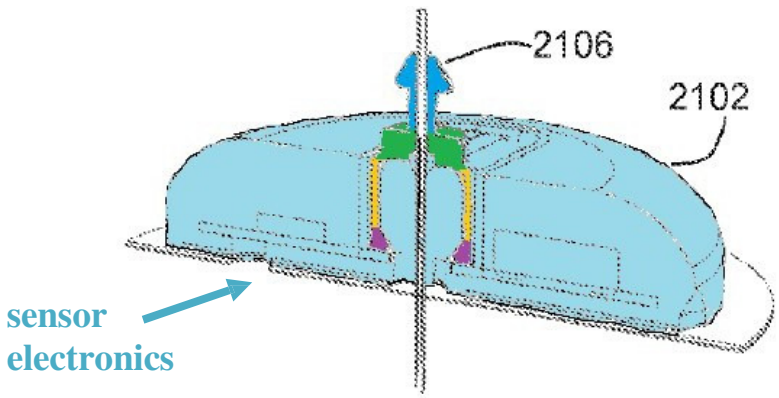


FIG. 21B

Id.~~,~~. at 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:

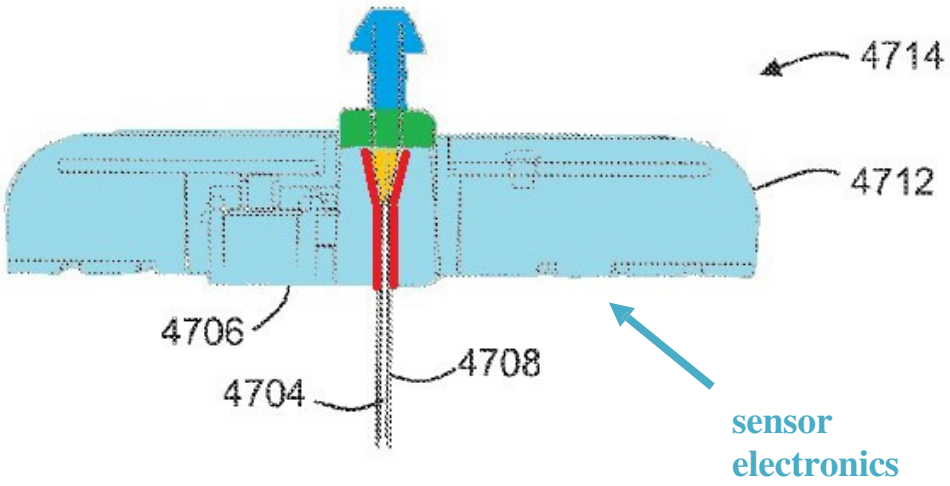


FIG. 47C

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

5. Claims 2 & 25

99. In my opinion, 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]."*

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

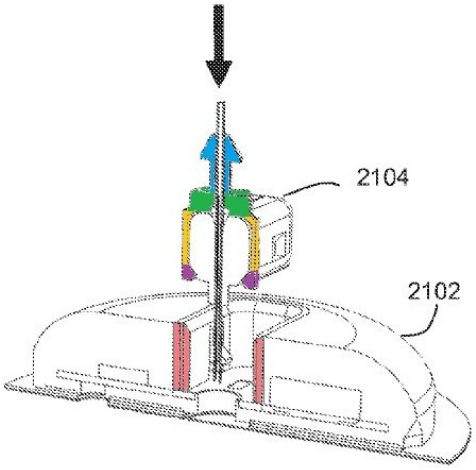


FIG. 21A

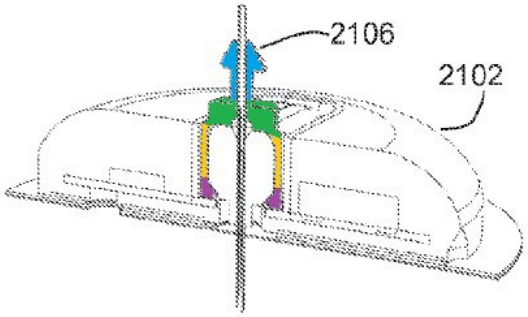
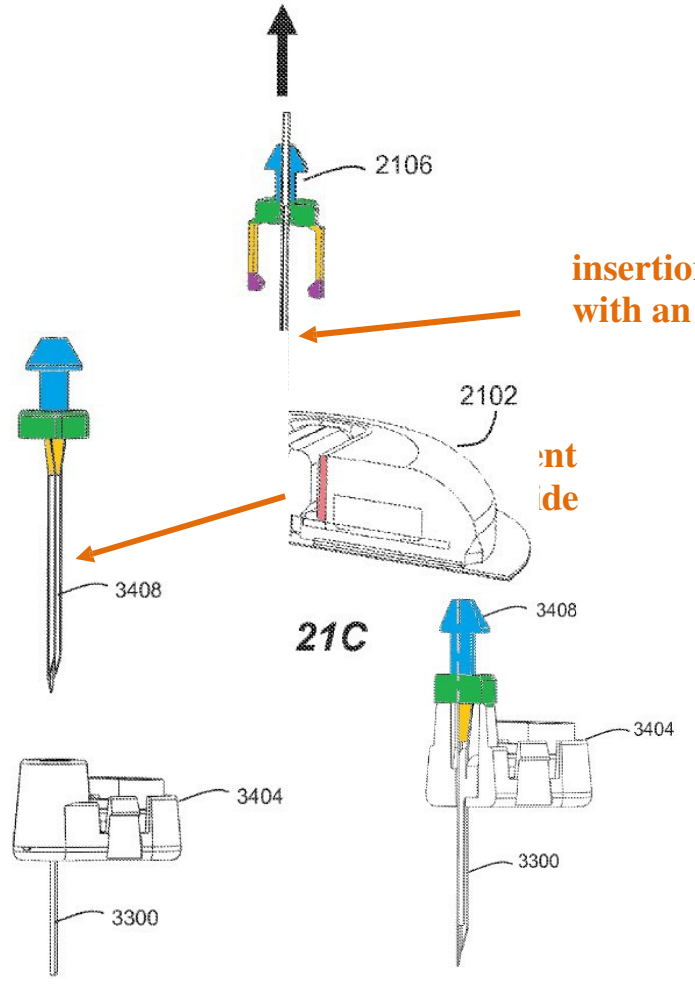


FIG. 21B



21C

FIG. 35A

FIG. 35B

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

6. Claim 3

101. In my opinion, 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."*

~~101.~~102. Pace further suggests ~~an~~the insertion sharp ~~having~~has 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*~~*See* Ex-1014, 27:63-66 (incorporated by reference in Pace, Ex-1006 at [0009]).

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

7. Claims 4, 14, 26, & 30

~~102.~~103. In my opinion, 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."*

~~103.~~104. 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~~,~~ at 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~~

~~104.~~105. Pace further discloses that components of the applicator can be made by using a variety of processes, including injection molding. *See* Ex-1006~~,~~ at [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,~~

106. A POSITA would understand that the claimed insert molding is a type of injection molding.

~~105.~~107. In addition, Pace discloses that "heat stakes" can be used to couple structures together. *See* Ex-1006~~,~~ at [0126] ("heat stakes 2412" are used to couple the sensor PCB to its housing).

~~106.~~108. 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

~~107.~~109. In my opinion, 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."*

~~108.~~110. Pace further discloses that the sharp hub is able to retract the needle out of the user. Ex-1006~~,~~ at Figs. 10F-M, [0102]-[0104] (describing how the sharp hub/boss engages the sharp retraction assembly in the applicator), *Id.*~~,~~ at 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.

~~109.~~111. 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

~~110.~~112. In my opinion, 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]."*

~~111.~~113. *See, supra*, claim 28.10.

10. Claims 7, 17, & 29

~~112.~~114. In my opinion, 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."*

~~113.~~115. 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":

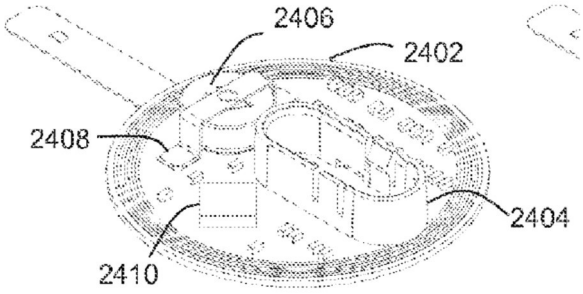


FIG. 24A

Ex-1006~~,~~ at Fig. 24A, [0126]. In addition, "the on-body device may include sensor electronics and other adaptation to communicate with a monitoring device." *Id.~~,~~* at [0010].

~~114.~~116. Pace further discloses:

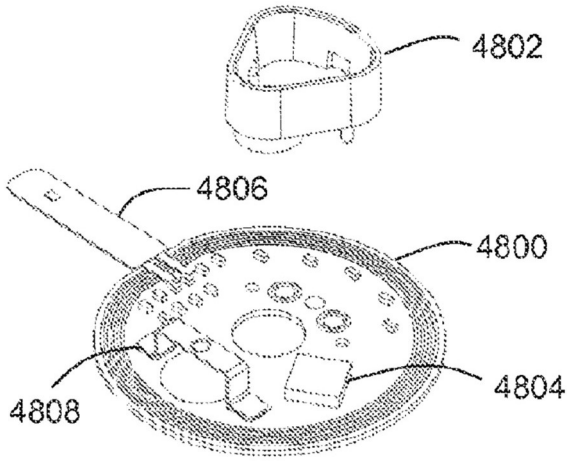


FIG. 48A

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.~~.~~. at Fig. 48A, [0150].

~~115.~~117. 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~~,~~ at [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

~~116.~~118. In my opinion, 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.~~

~~117.~~119. *See, supra*, claim 28.10.

12. Claim 9

~~118.~~120. In my opinion, 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."*

~~119.~~121. Pace further discloses an "adhesive patch 312" (light green below) configured to secure the on-body device a user's skin:

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

13. Claim 19

~~120.~~122. In my opinion, 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."*

~~121.~~123. *See*, *supra*, claim 28.13.

14. Claim 23

~~122.~~124. In my opinion, 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."*

~~123.~~125. *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

~~124.~~126. In my opinion, 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."*

~~125.~~127. *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 in Doing So.

~~126.~~128. Pace discloses a hub 2106 in embodiment A and a sharp hub 3414 with a V-shaped portion in embodiment B. Ex-Ex-1006~~,~~ at Figs. 21A-C, 34A-D, 35A-D, 47B-C, [0123], [0142]. Pace further discloses that a retraction assembly engages the sharp hub to retract the ~~needle~~sharp out of the user and away from the sensor. *Id.*~~,~~ at [0102], [0109].

~~127.~~129. A POSITA would understand the importance of ensuring that 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,~~*Id.* at [0106] ("retracting the sharp 1030 ***safely*** back into the used applicator assembly 216.").

~~128.~~130. Lundquist similarly states that it is "desirable to construct a hub … that ***effectively secures*** the cannula … and provides sufficient strength to withstand the operating conditions…." Ex-1011~~,~~ at [0006]. Lundquist then discloses a method of securing a hollow needle 12 to a hub 16a where a polymeric material used to form the hub during an insert molding step "flows into and fills" a plurality of notches 18 in the proximal end of the needle to provide "enhanced friction and gripping force" between the hub 16a and the needle. *Id.*~~,~~ at [0041], Fig. 2C. Lundquist discloses its method can be used with "any sized and shaped [needle]." *Id.*~~,~~ at [0041].

~~129.~~131. 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.

~~130.~~132. ~~Ex. 1004, ¶131.~~ A POSITA would have had a reasonable expectation of success with adopting Lundquist's manufacturing process in Pace's CGM system, as Pace discloses that its sharp/needle may be "slotted or otherwise configured" and can be coupled to the sharp hub/boss via molding (Ex-Ex-1006~~,~~ at [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.~~ at [0041]).

133. Because the sharp of Pace is partially "slotted" 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.

2. Claims 4, 14, 26, & 30

~~131.~~134. Claims 4, 14, 26, and 30 depend from claims 1, 13, 22, and 28, respectively. As explained in Ground 1, in my opinion Pace anticipates and renders obvious claims 1, 13, 22, and 28. In my opinion, 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.~~

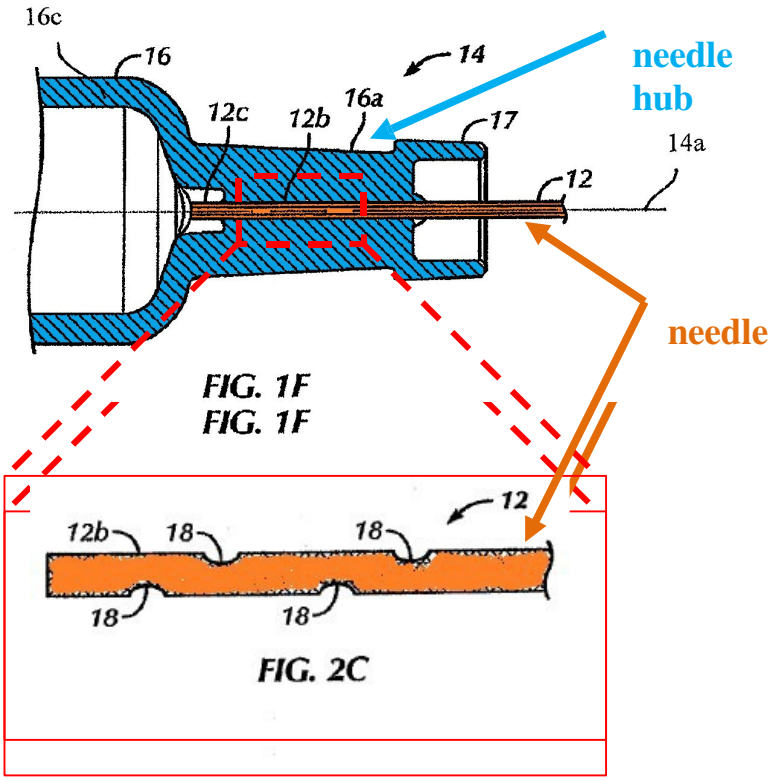
a. *"wherein the needle hub is coupled to the [insertion element / needle] by heat staking, snap-fit, friction-fit, clamshell, or insert molding."*

~~132.~~135. Pace discloses a hub 2106 in embodiment A and a sharp hub 3414 with a V-shaped portion in embodiment B. Ex-1006~~,~~ at 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.~~. at [0121].

136. A POSITA would understand that the claimed insert molding is a type of injection molding.

~~133.~~137. 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 16 a or hub 200 of the barrel 16, 16' that is ***directly insert molded over the cannula 12, 12'***.

Abbott Ex. 1004 - 26/134

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

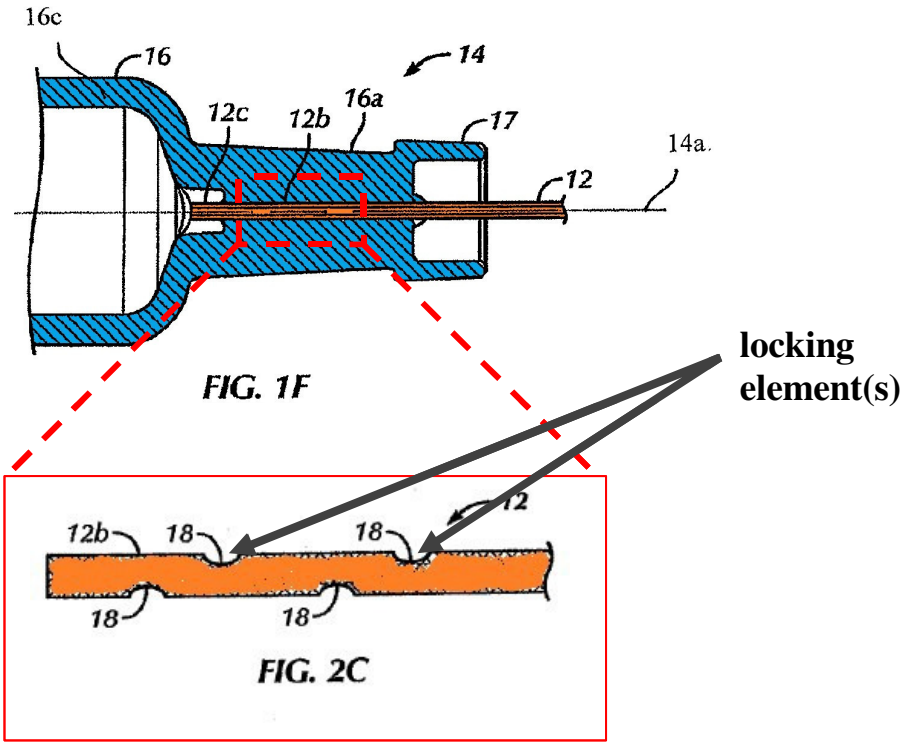
~~134.~~138. In the Pace-Lundquist combination, the hub (either 2106 in Figure 21 or 3414 in Figures 34, 35, and 47) and needle of Pace are coupled together by insert molding the sharp hub over the needle, as taught in Lundquist.

3. Claims 5, 15, & 27

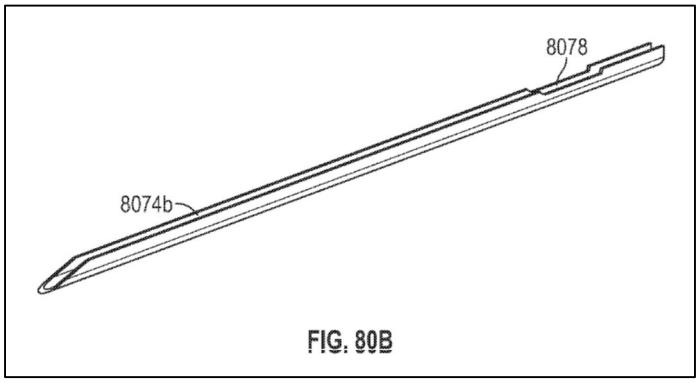
~~135.~~139. Claims 5, 15 and 27 depend from claims 4, 14, and 26, respectively. As explained above, in my opinion the combination of Pace and Lundquist renders obvious claims 4, 14, and 26. In my opinion, the combination of Pace and Lundquist further renders obvious claims 5, 15, and 27, as explained below ~~and as supported by Ex-1004, ¶¶128-141.~~

a. *"wherein the [insertion element / needle] comprises a locking element configured to couple the [insertion element / needle] to the needle hub by insert molding."*

~~136.~~140. As explained above, Pace discloses that a sharp is 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 that 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~~,~~ at Figs 1F, 2C, [0039]-[0041]. The "notches" 18 in the needle 12 correspond to the claimed "locking element," as seen by comparing ~~Figure~~Fig. 2C of Lundquist (above) with ~~Figure~~Fig. 80B of the '625 patent (below~~):~~)



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

~~137.~~141. 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 sharp 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

~~138.~~142. In my opinion, Pace 2 renders obvious claim 1, as explained below ~~and as supported by Ex. 1004, ¶¶142-155~~.

~~**a.** *1.P*~~

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

~~139.~~143. Pace 2 discloses an applicator 200 for applying a CGM to a user's skin. Ex-1007~~,~~ at [0083], Figs. 2A-2B, [0047]; *see also Id.*~~,~~ at Fig. 8, [0090]-[0094], Figs. 3E-3F.

~~**b.** *1.1*~~

b. *1.1 "an applicator housing having an internal volume;"*

~~140.~~144. Pace 2 discloses an applicator housing having an internal volume. Ex- 1007~~,~~ at 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 below) for holding sensor control device 102, which may include shroud 220 and other components:

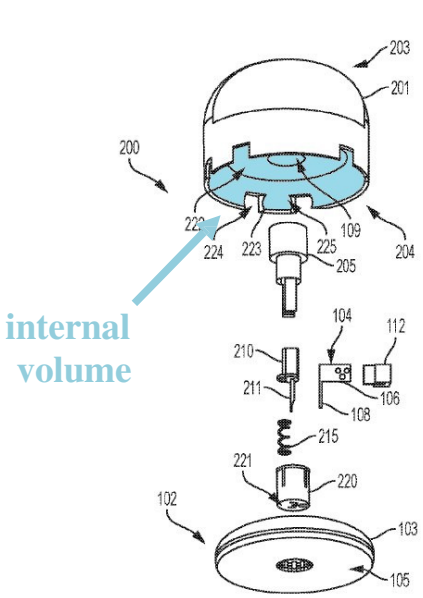


FIG. 2A

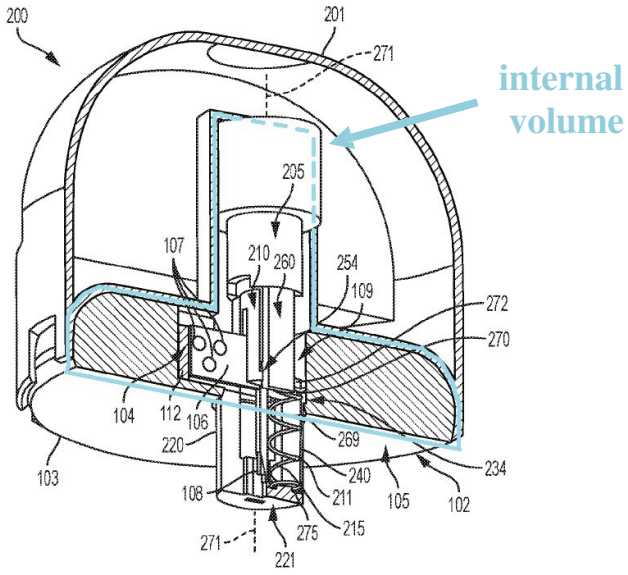


FIG. 3B

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

~~**c.** *1.2-1.5*~~

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"

~~141.~~145. 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.

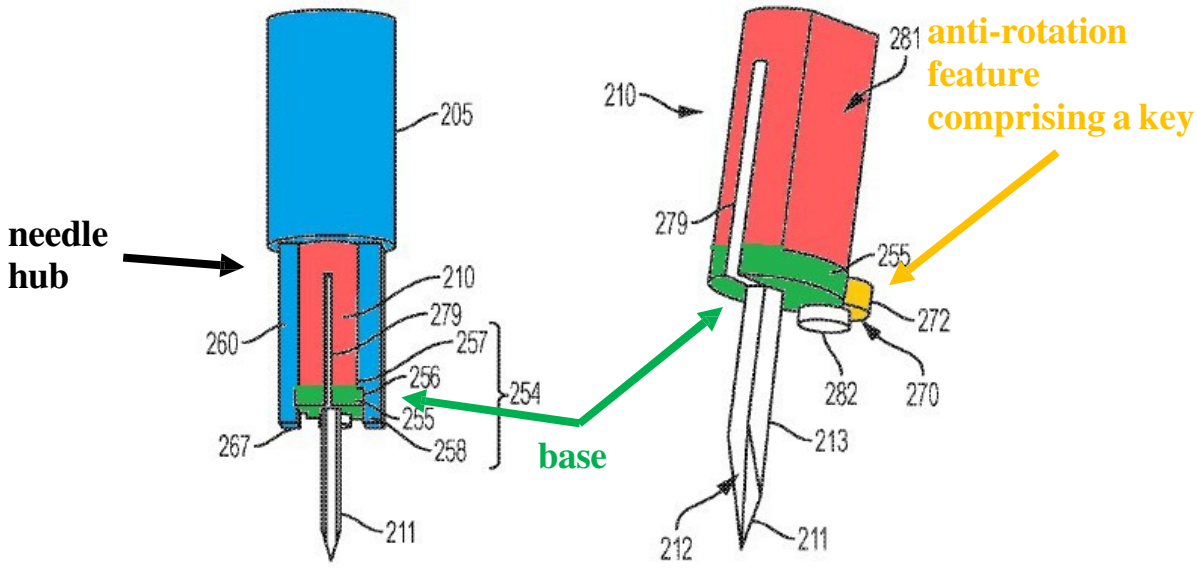


FIG. 7A FIG. 7B

Ex-1007~~,~~ at 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).

~~142.~~146. Pace 2 discloses a "ledge 272 of sharp body 210 that is offset and extends away from sharp 211." *Id.*~~,~~ at [0068]. The ledge 272 "is sized to fit and slide longitudinally within chamber 269" (*i.e.*, the aperture, highlighted below):

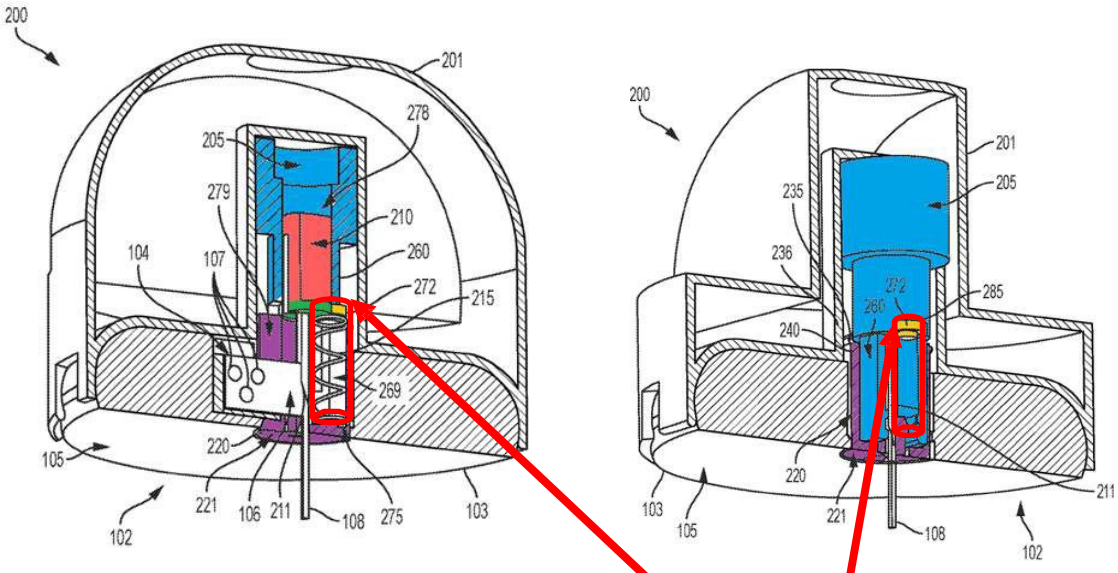
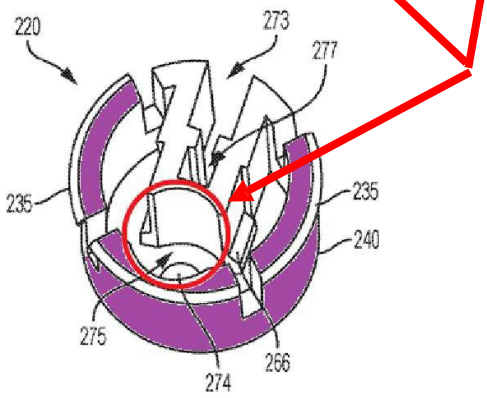


FIG. 5B

FIG. 5D



aperture extending from a top surface

FIG. 7C

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

~~143.~~147. Figures 5B and 7C show a chamber 269 within shroud 220, which protects the needle before application. During the application process, the shroud retracts vertically relative to the housing 103. *Id.*~~.~~, at [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.*~~.~~, at [0086].

~~144.~~148. 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 channe***l*** and thereby guide the motion of shroud 220, ***preventing shroud 220 from rotating or tilting during advancement and/or retraction***.

Id.~~,~~. at [0089].

~~145.~~149. Although Pace 2 does not specifically state that ledge 272 has an "anti- rotation" functionality, but 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.*~~,~~. at [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.

~~146.~~150. 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*~~

d. *1.6 "an on-skin sensor assembly comprising:"*

~~147.~~151. Pace 2 discloses an on-skin sensor assembly. Ex-1007~~,~~ at 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:"

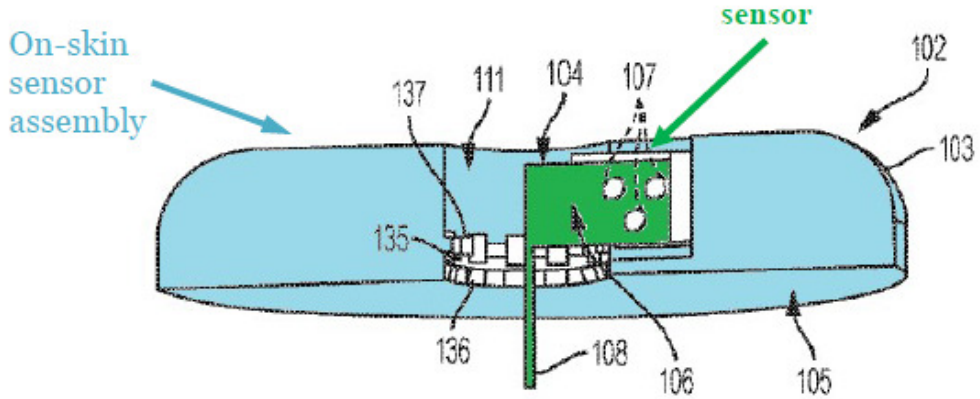


FIG. 6B

Id.~~,~~ at Fig. 6B, [0038]; *see also Id.*~~,~~ at [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:

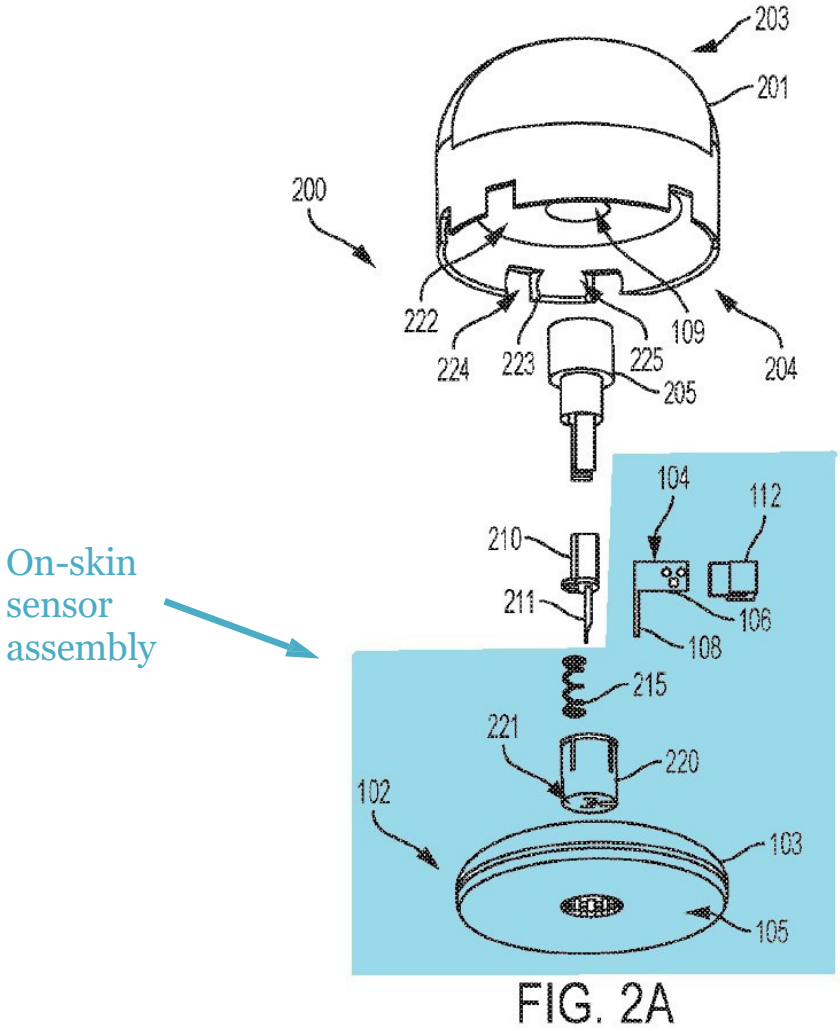


FIG. 2A

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

e. ~~*1.7*~~

e. *1.7 "a sensor, the sensor configured to measure a glucose concentration of a host, and"*

~~148.~~152. Pace 2 discloses a sensor 104 for measuring an analyte such as glucose in the sensor control device 102:

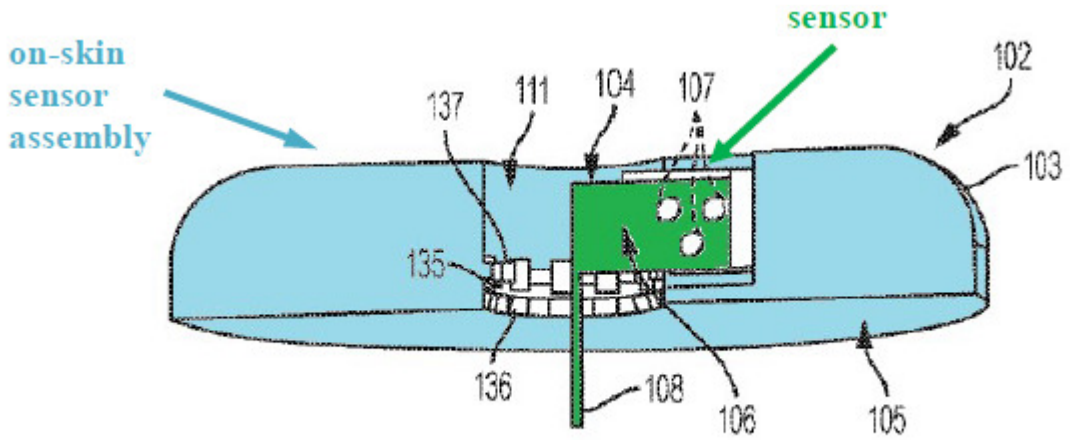


FIG. 6B

Ex-1007~~,~~ at Fig. 6B, [0083]; *see Id~~.,~~.* at [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*~~

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;"

~~149.~~153. 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~~,~~ at [0068]:

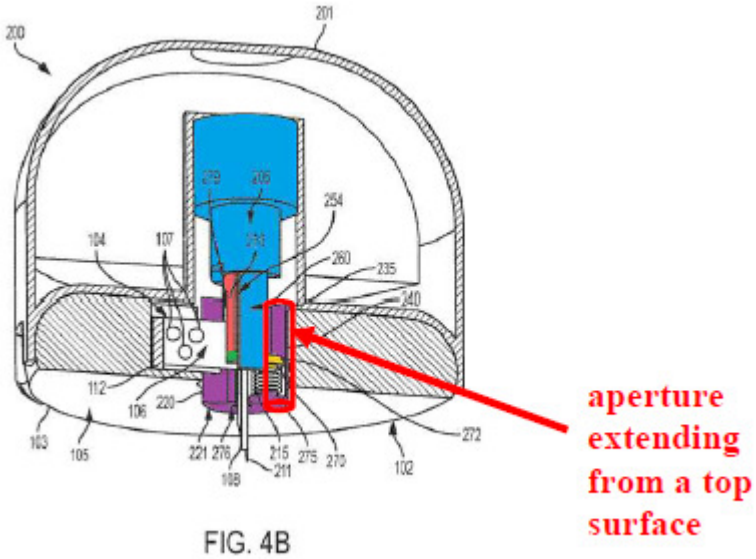
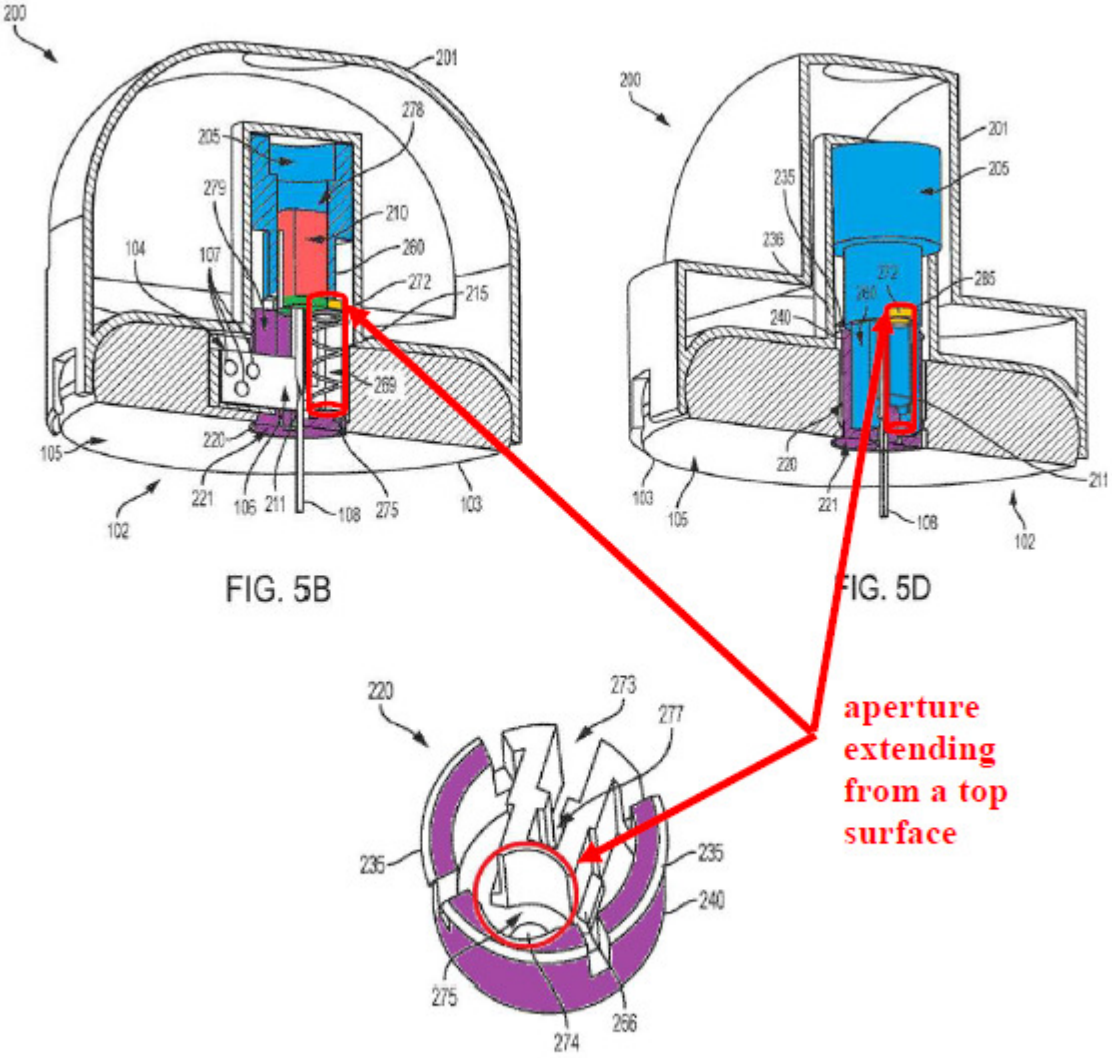

200
201
254
260
235
240
104
107
112
106
220
103
105
221
276
215
211
275
270
102
272
aperture extending from a top surface

FIG. 4B



Id., at 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).

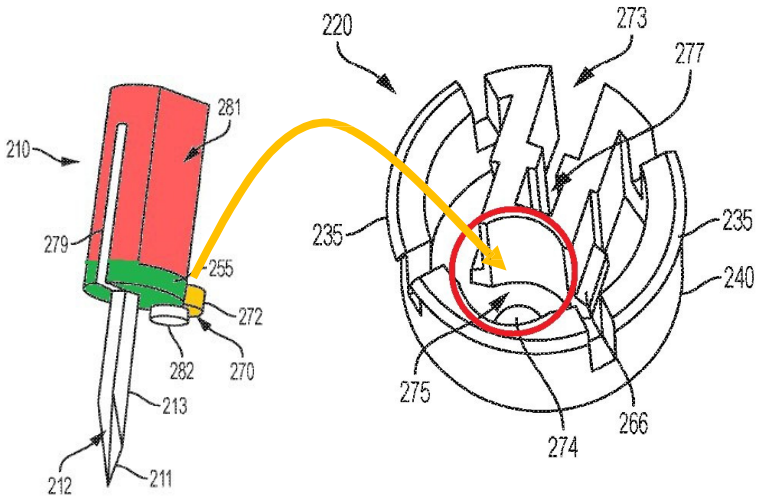


FIG. 7B FIG. 7C

Id.~~,~~. at Figs. 7B-C.

~~150.~~154. Furthermore, Figure 4B above shows that 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*~~
g. *1.11 "wherein the anti-rotation feature is configured to prevent rotation of the needle hub within the aperture."*

~~151.~~155. 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

~~152.~~156. In my opinion, Pace 2 renders obvious claim 13, as explained below ~~and as supported by Ex. 1004, ¶¶156-162~~.

~~**h.** *13.P*~~

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

~~153.~~157. *See*, *supra*, claim 1.P.

~~**i.** *13.1*~~

b. *13.1 "an applicator housing having an internal volume;"*

~~154.~~158. *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;"

~~155.~~159. *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~~,~~ at 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.

~~156.~~160. 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.

~~**j.** *13.6-13.10*~~

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"

~~157.~~161. *See*, *supra*, claims 1.6-1.10.

~~k. 13.11~~

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."*

~~158.~~162. *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 that 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

~~159.~~163. In my opinion, Pace 2 renders obvious claim 22, as explained below ~~and as supported by Ex. 1004, ¶¶163-169~~.

~~l. 22.P~~

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

~~160.~~164. 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~~,~~ at Fig. 8, [0072]-[0073], [0090]-[0094].

~~**m.** *22.1*~~

b. *22.1 "a base comprising an anti-rotation key,"*

~~161.~~165. *See*, *supra*, claims 1.3-1.5 and 13.2-13.5.

~~**n.** *22.2*~~

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

~~162.~~166. *See*, *supra*, claim 1.11.

~~**o.** *22.3*~~

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

~~163.~~167. *See*, *supra*, claim 1.2.

~~**p.** *22.4*~~

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."*

~~164.~~168. 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).

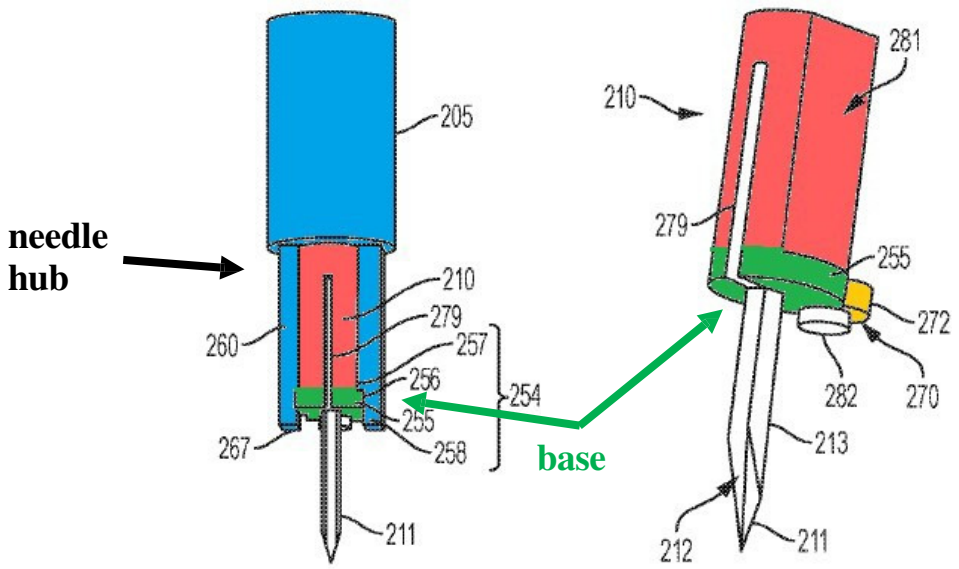


FIG. 7A FIG. 7B

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

~~165.~~169. 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.

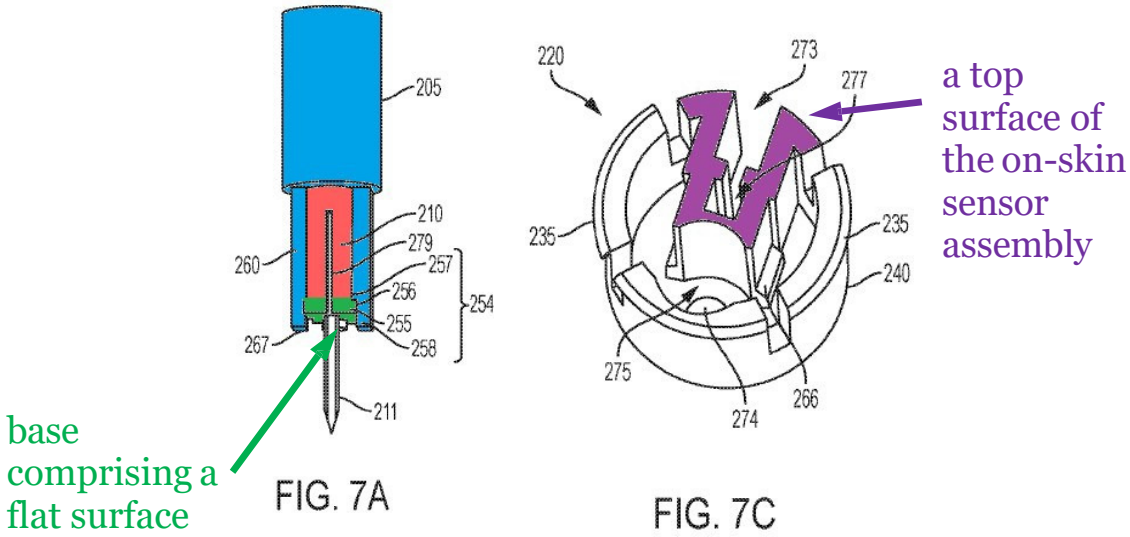


FIG. 7A FIG. 7C

Id.~~,~~ at 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):

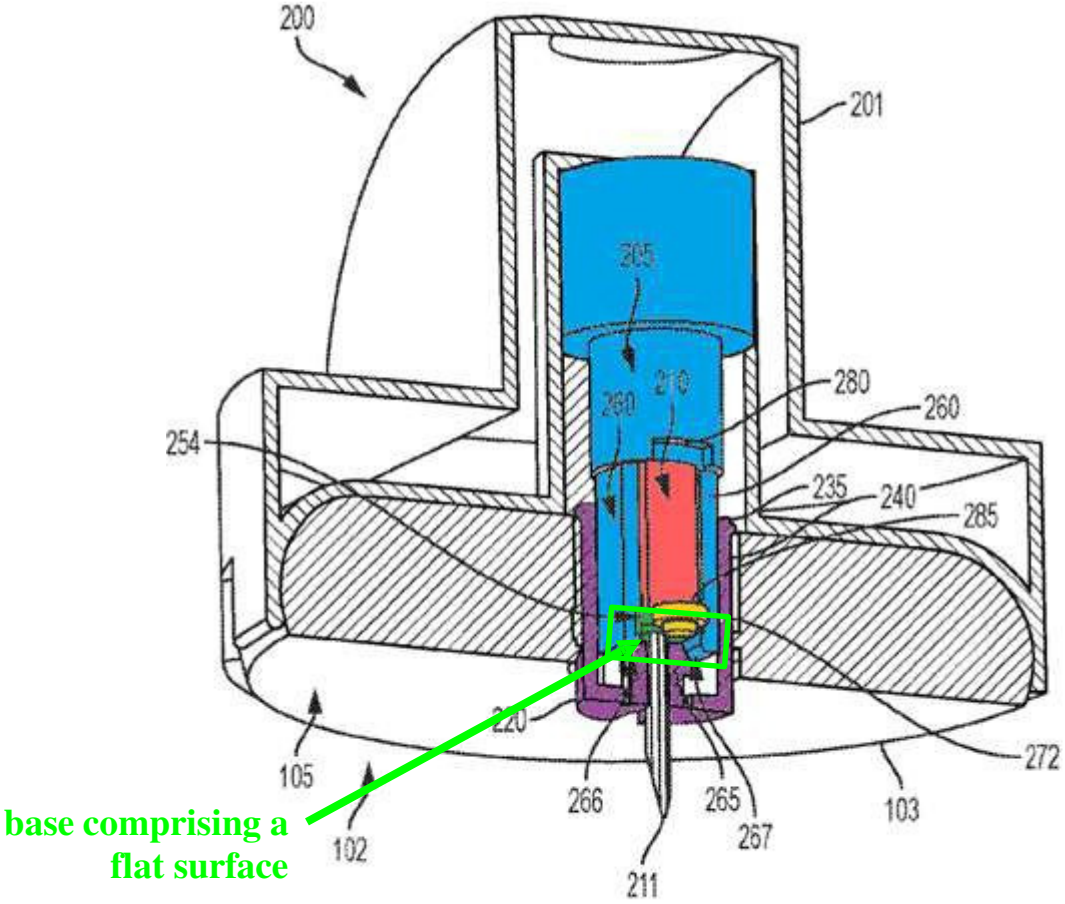


FIG. 4D

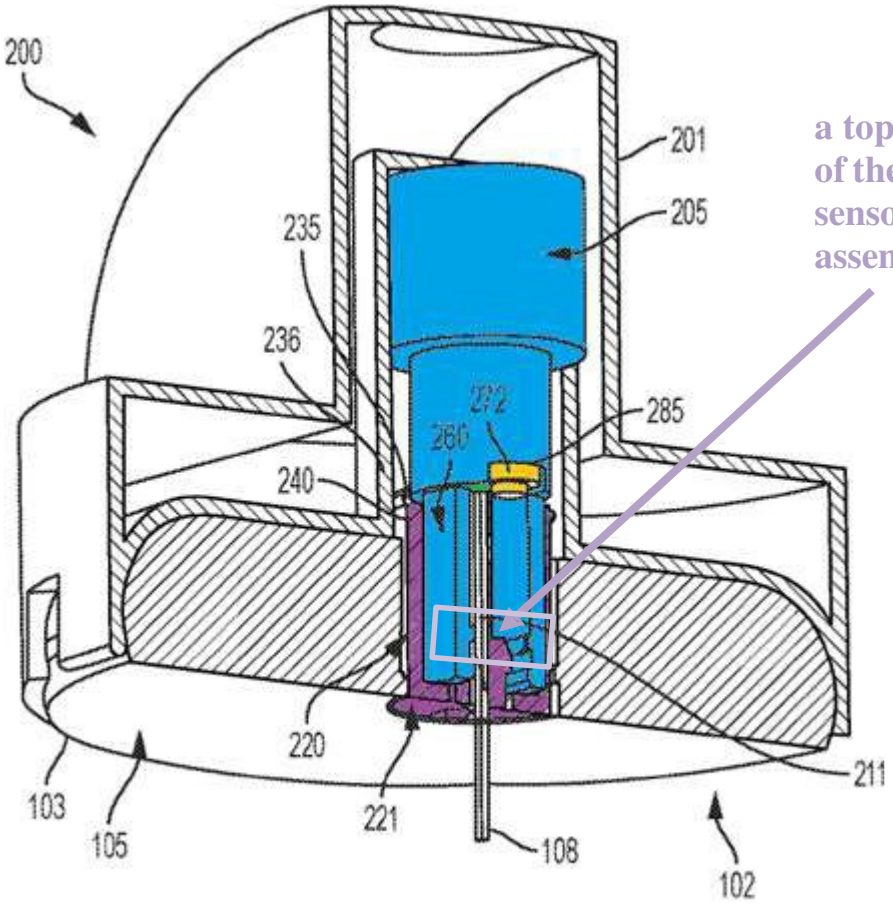


FIG. 5D

Id.~~., Figs~~. at Fig. 4D~~, 5D~~. In some embodiments of Pace 2, the shroud 220 "remains with device 102" after the sharp is removed. *Id.*~~.~~, at [0086]. Thus, the annotated surface of shroud 220 in Figure 7C above is a "top surface" of the on-skin sensor assembly. *Id.*~~.~~, at Fig. 7C; *see also Id.*~~.~~, at 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

~~166.~~170. In my opinion, Pace 2 renders obvious claim 28, as explained below ~~and as supported by Ex. 1004, ¶¶170-179~~.

~~q. 28.P~~

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

~~167.~~171. *See*, *supra*, claim 1.P.

~~r. 28.1~~

b. *28.1 "an applicator housing having an internal volume;"*

~~168.~~172. *See*, *supra*, claim 1.1.

~~s. 28.2~~

c. *28.2 "a needle hub coupled to a needle configured to pierce a skin of a host, the needle hub comprising:"*

~~169.~~173. *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~~,~~ at 27:12-18.

~~b.~~**d.** *28.3~~-28.9~~ "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"

~~170.~~174. *See*, *supra*, claims 1.3-1.9.

~~t. 28.10~~

e. *28.10 "sensor electronics operably connected to the sensor in the applicator housing;"*

~~171.~~175. 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~~,~~ at [0040], [0051], [0100].

~~172.~~176. 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:

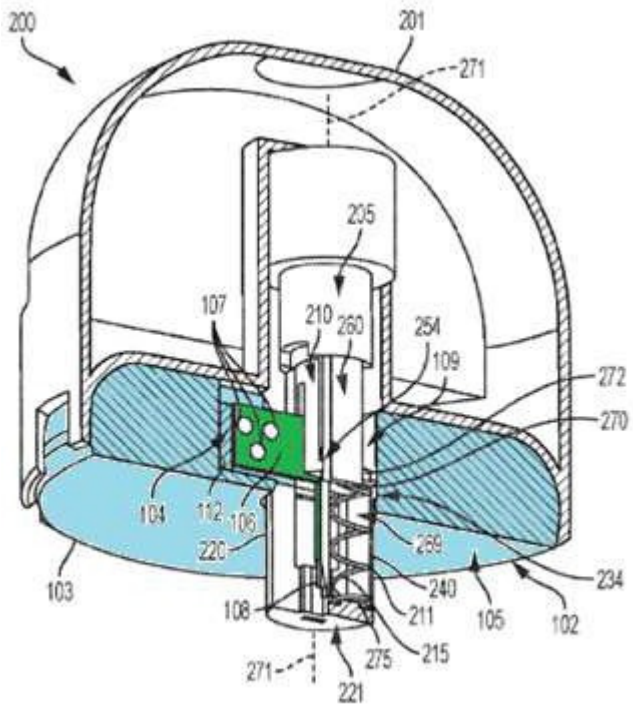


FIG. 3B

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

~~**u.** *28.11*~~

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;"*

~~173.~~177. *See*, *supra*, claim 1.10.

~~**v.** *28.12*~~

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

~~174.~~178. *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.

~~**w.** *28.13*~~

h. *28.13 "wherein the needle is configured to be inserted through at least a portion of the sensor electronics."*

~~175.~~179. 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):

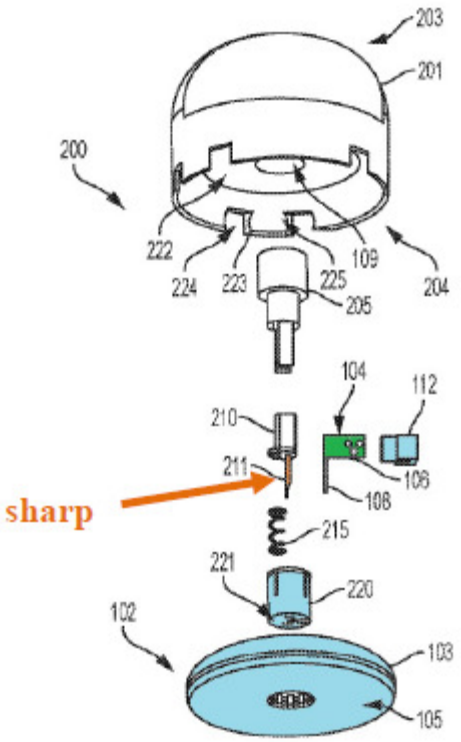


FIG. 2A

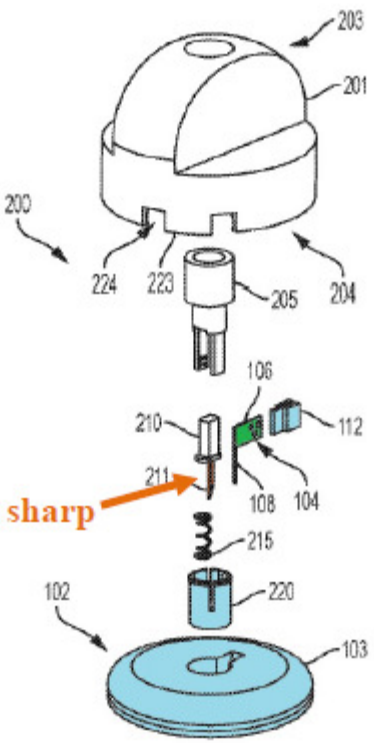


FIG. 2B

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

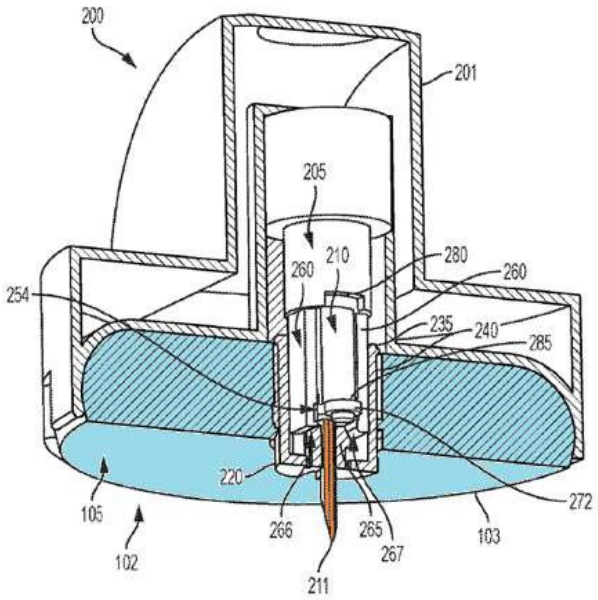


FIG. 4D

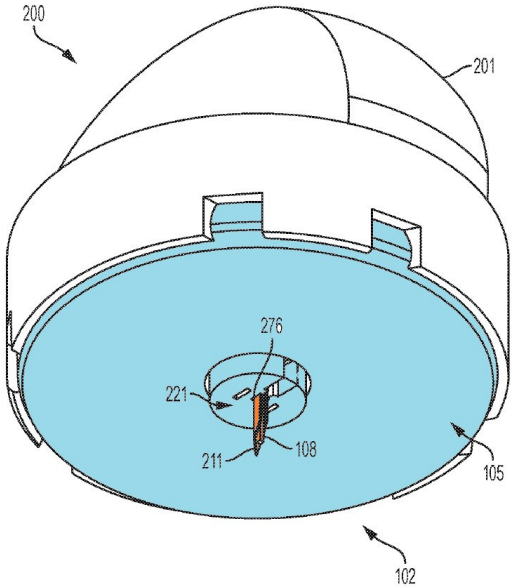


FIG. 4E

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

5. Claims 2 & 25

180. In my opinion, 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.

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

~~176.~~181. 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~~,~~ at [0087]:

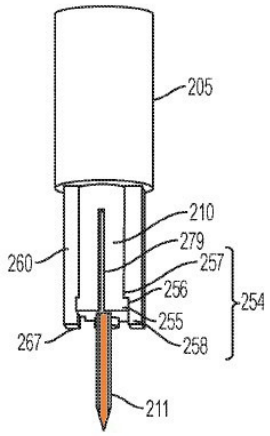


FIG. 7A

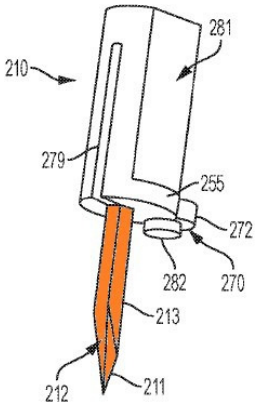


FIG. 7B

Id.~~,~~. at Fig. 7A-7B.

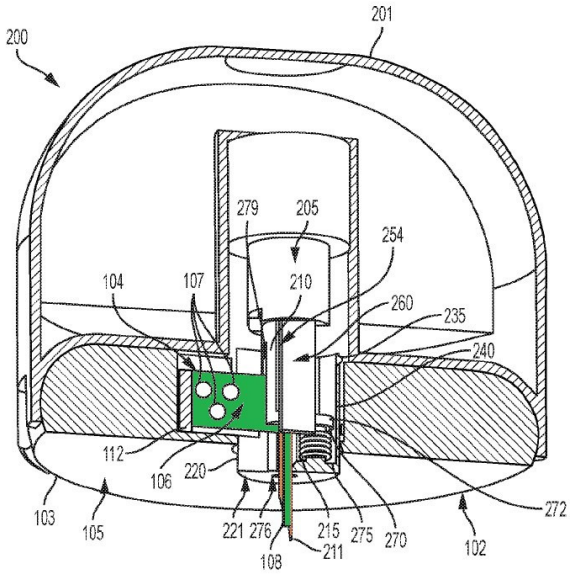


FIG. 4B

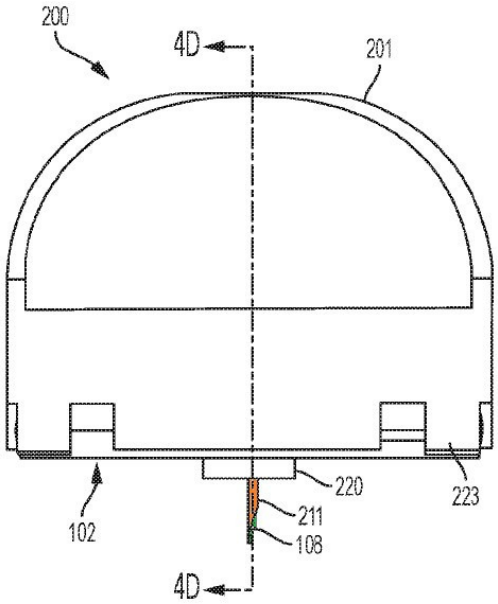


FIG. 4C

Id.~~,~~. at Figs. 4B-C.

6. Claim 3

~~177.~~182. In my opinion, 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.

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

~~178.~~183. Pace 2 further discloses the needle has a U-shaped cross-section.

See, *supra*, claim 2.

7. Claims 6 & 16

184. In my opinion, 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~~

a. *"wherein the ~~additional limitations of claims 6 and 16.~~ on-skin sensor assembly comprises [an electronics unit / sensor electronics]."*

~~179.~~185. *See, supra*, claim 28.10.

8. Claims 7, 17, & 29

~~180.~~186. In my opinion, 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.

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

~~181.~~187. Pace 2 further discloses that the sensor electronics include a power source 960, processor 956, memory 953, and communication circuitry 958:

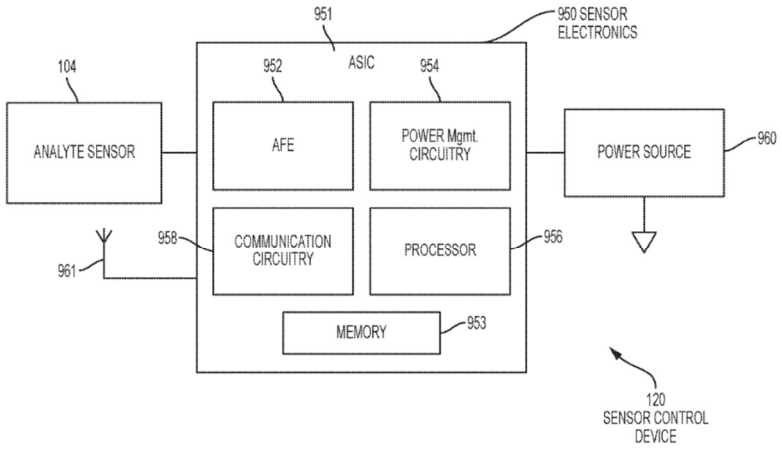


FIG. 9

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

9. Claims 8 & 18

188. In my opinion, 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~~

a. *"wherein the* ~~additional limitations of claims 8 and 18.~~ *sensor is connected to the [electronics unit / sensor electronics] in the applicator housing."*

~~182.~~189. *See, supra*, claim 28.10.

10. Claim 9

190. In my opinion, 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.

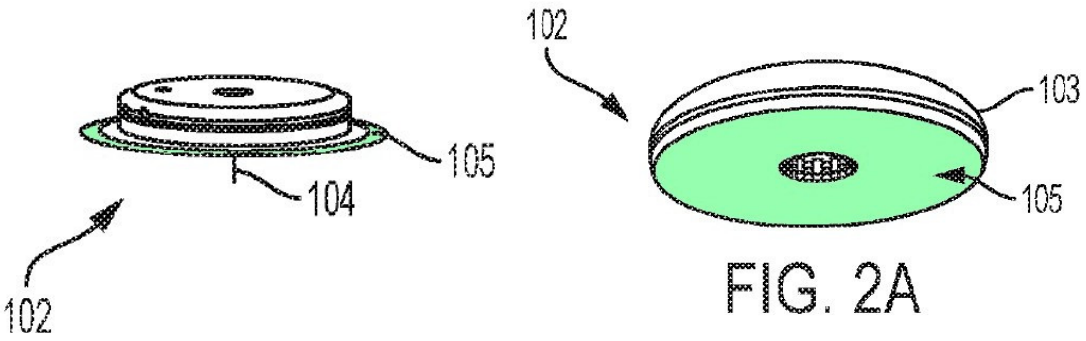


FIG. 2A

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."*

~~183.~~191. Pace 2 further discloses that 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:

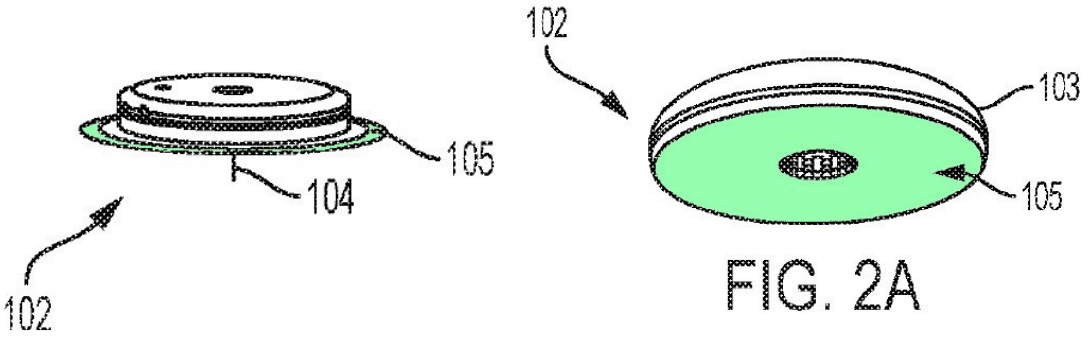


FIG. 2A

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

11. Claim 19

192. In my opinion, 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~~

a. *"wherein the* ~~additional limitation of claim 19.~~ *needle is configured to be inserted through the sensor electronics."*

~~184.~~193. *See*, *supra*, claim 28.13.

12. Claim 23

194. In my opinion, 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~~

a. *"wherein the* ~~additional limitation~~*anti-rotation key is configured to prevent rotation of* ~~claim 23.~~ *the base within the aperture."*

~~185.~~195. *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

196. In my opinion, 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.~~

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

~~186.~~197. *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

~~187.~~198. Pace 2 discloses an applicator for a CGM comprising a sharp 211 coupled to a sharp support 205 with sharp body 210. Ex-1007~~,~~ at [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.*, at Abstract, [0053], [0073].

188.199. A POSITA would understand the importance of ensuring that 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* *See* Ex-1007, at [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.)").

189.200. 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, at [0006]. Lundquist then discloses a method of securing a hollow needle 12 to a hub 16a where a polymeric material used to form the hub during an insert molding step "flows into and fills" a plurality of notches 18 in the proximal end of the needle to provide "enhanced friction and gripping force" between the hub 16a and the needle 12. *Id.*, at [0041], Fig. 2C. Lundquist discloses that its method can be used with "any sized and shaped [needle]." *Id.*, at [0041].

190.201. 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.

~~191.~~202. ~~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~~,~~ at [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~~,~~ at [0041]).

~~192.~~203. ~~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

~~193.~~204. Claims 4, 14, 26, and 30 depend from claims 1, 13, 22, and 28, respectively. As explained in Ground 3, in my opinion, Pace 2 renders obvious claims 1, 13, 22, and 28. In my opinion, the combination of Pace 2 and Lundquist further renders obvious claims 4, 14, 26, and 30, as explained below ~~and as supported~~.

a. *"wherein the needle hub is coupled to the [insertion element / needle] by* ~~Ex-1004, ¶¶198-207.~~*heat staking, snap-fit, friction-fit, clamshell, or insert molding."*

~~194.~~205. 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~~,~~ at [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~~,~~ at [0063], [0069].

~~195.~~206. 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.

~~196.~~207. 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

~~197.~~208. Claims 5, 15 and 27 depend from claims 4, 14 and 26, respectively. As explained above, in my opinion the combination of Pace 2 and Lundquist renders obvious claims 4, 14, and 26. In my opinion, 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~~.

a. *"wherein the [insertion element / needle] comprises a locking element configured to couple the [insertion element / needle] to the needle hub by insert molding."*

~~198.~~209. 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.

~~199.~~210. 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

~~200.~~211. In my opinion, Chae renders obvious claim 1, as explained below ~~and as supported by Ex. 1004, ¶¶211-222~~.

~~x. *1.P*~~

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

~~201.~~212. Chae discloses an applicator 10 for applying a CGM sensor to a user's skin. Ex-1008~~,~~ at 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

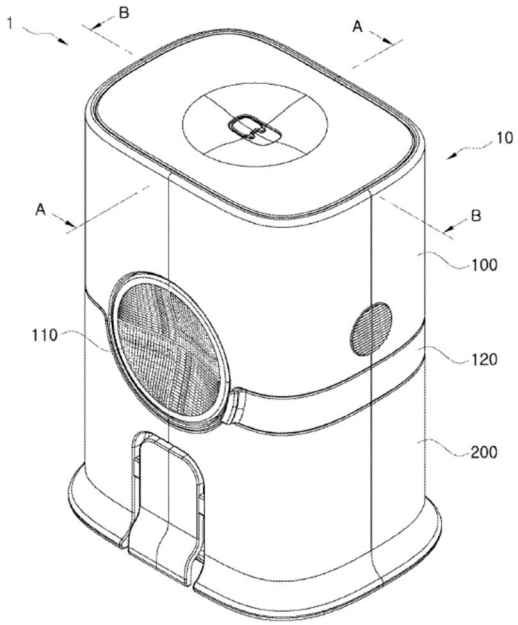
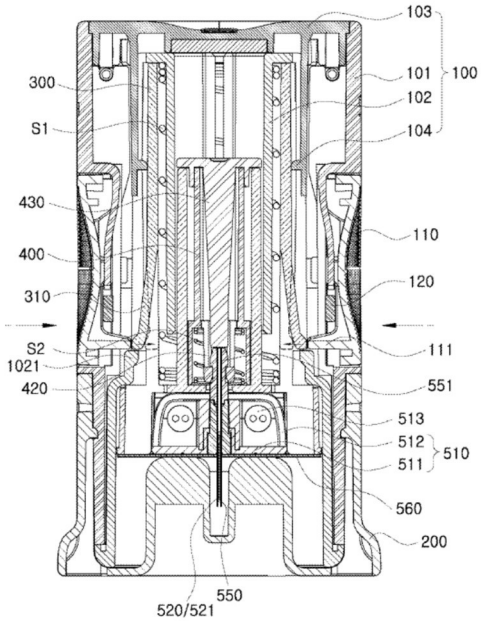


FIG. 5



Id., at Figs. 1, 4, [0053]; *see generally Id.*, at Figs. 18A-18B, 19A-19B, 21-24.

Figures 2 and 24 further show a sensor module as applied to the skin:

FIG. 2

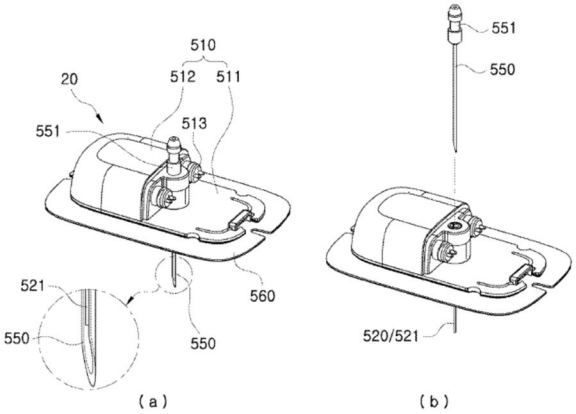
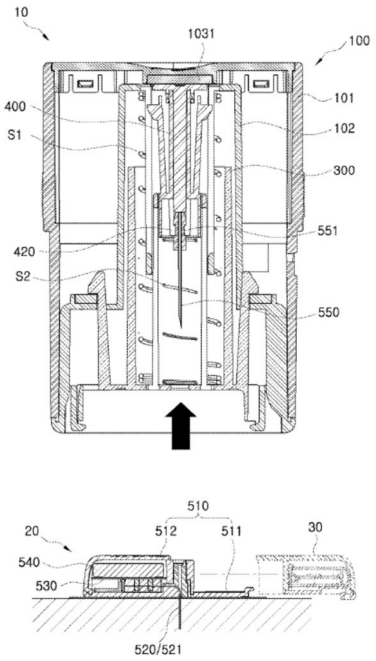


FIG. 24



Id., at Figs. 2, 24.

y. 1.1

b. *1.1 "an applicator housing having an internal volume;"*

~~202.~~213. Chae's applicator has an internal volume, Ex-1008~~,~~ at 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 cross-sections in Figures 5 and 6:

FIG. 5

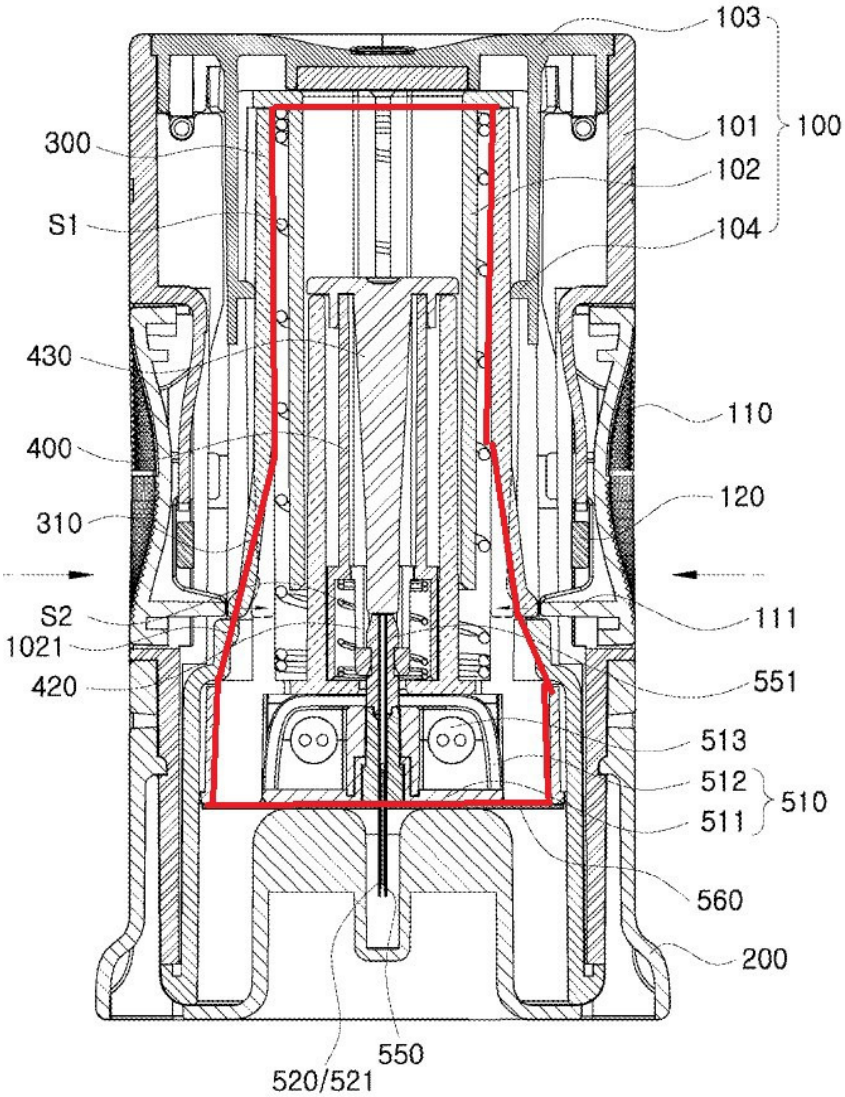
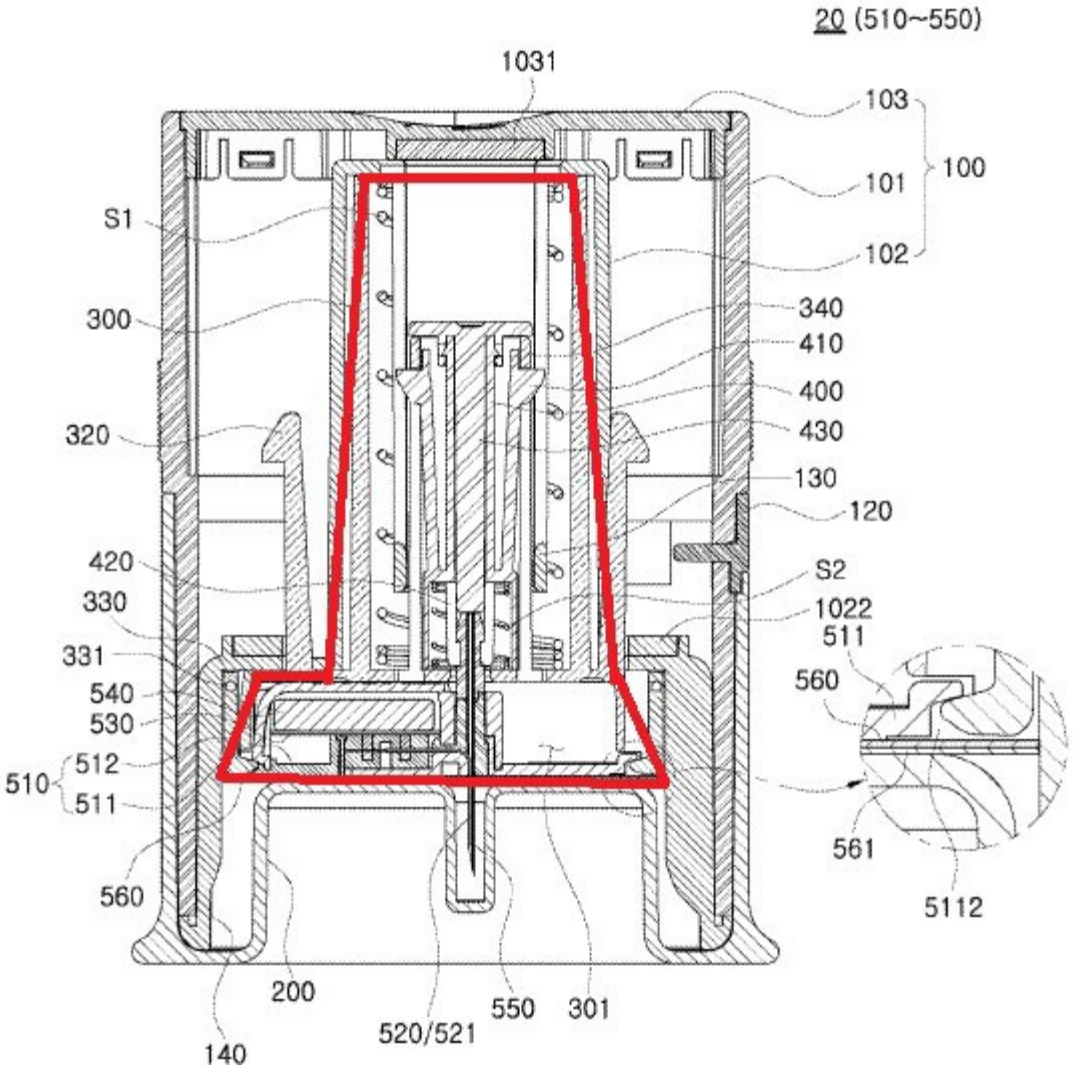


FIG. 6



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

~~z.~~ ~~*1.2-1.5*~~

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

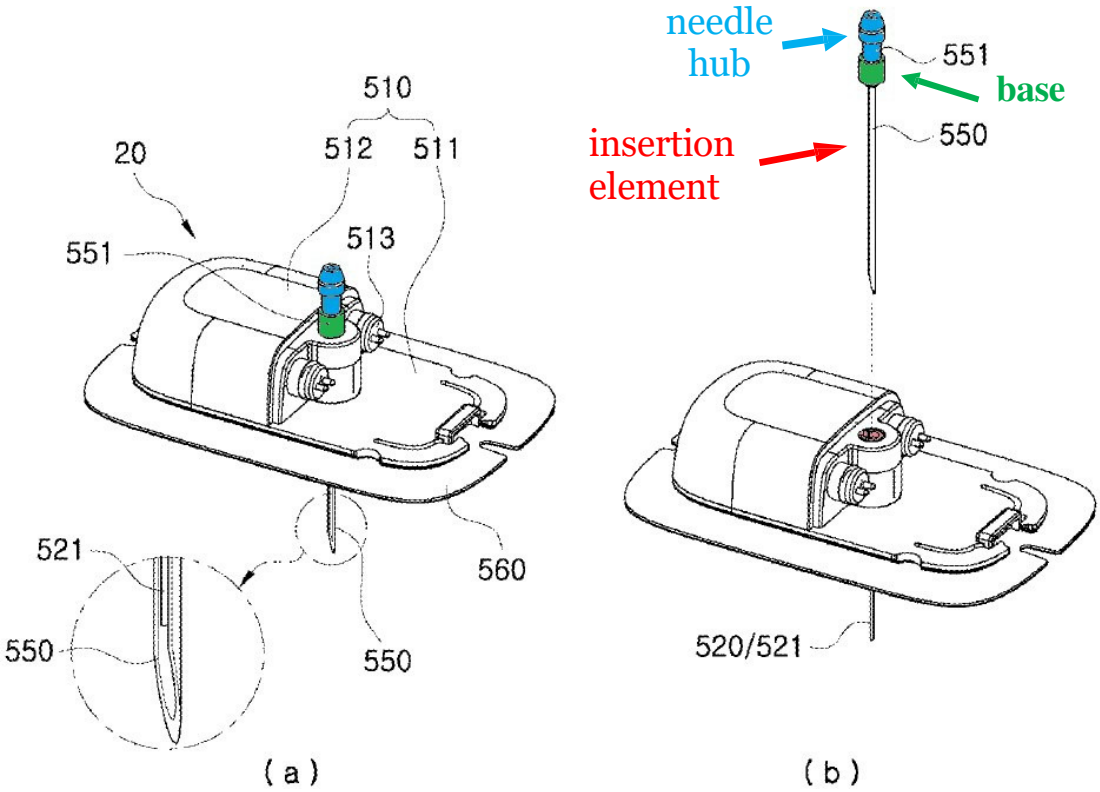
~~111~~

Abbott Ex. 1004 - 116/134

having a first shape"

~~203.~~214. 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":

FIG. 2



Ex-1008~~,~~ at Fig. 2, [0085]-[0086].

~~204.~~215. 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:

FIG. 5

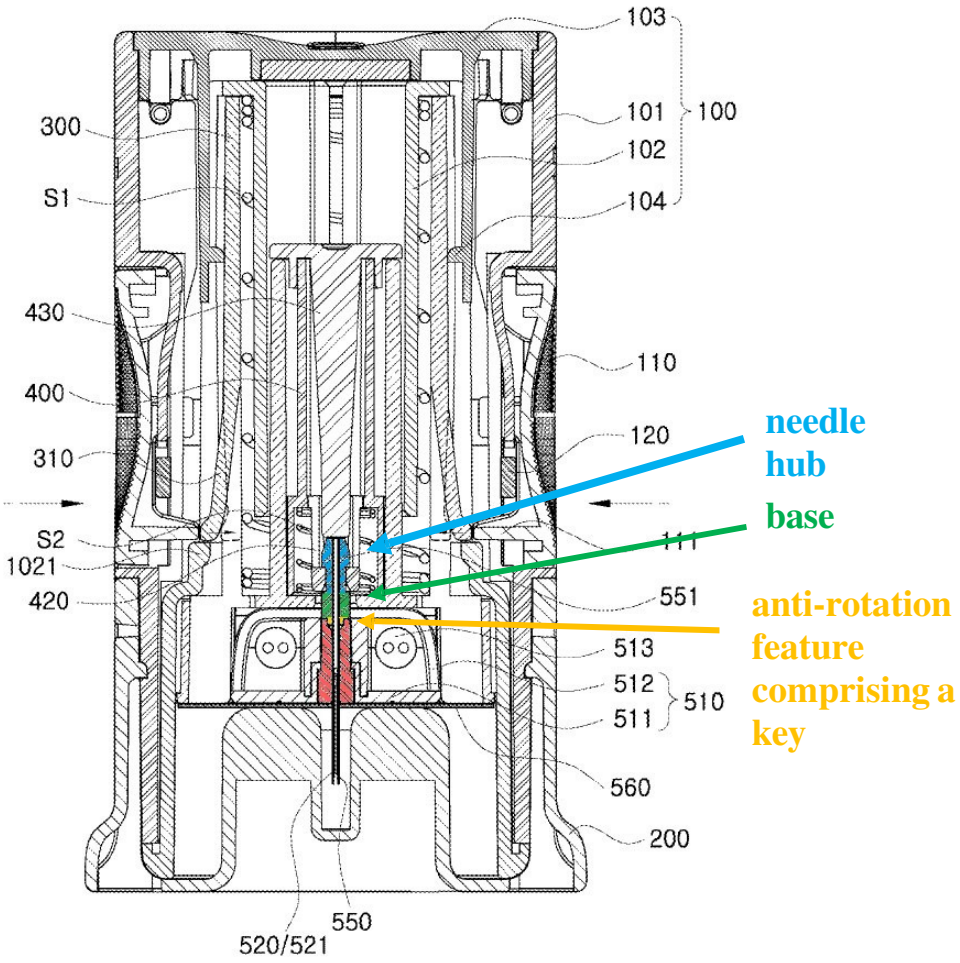
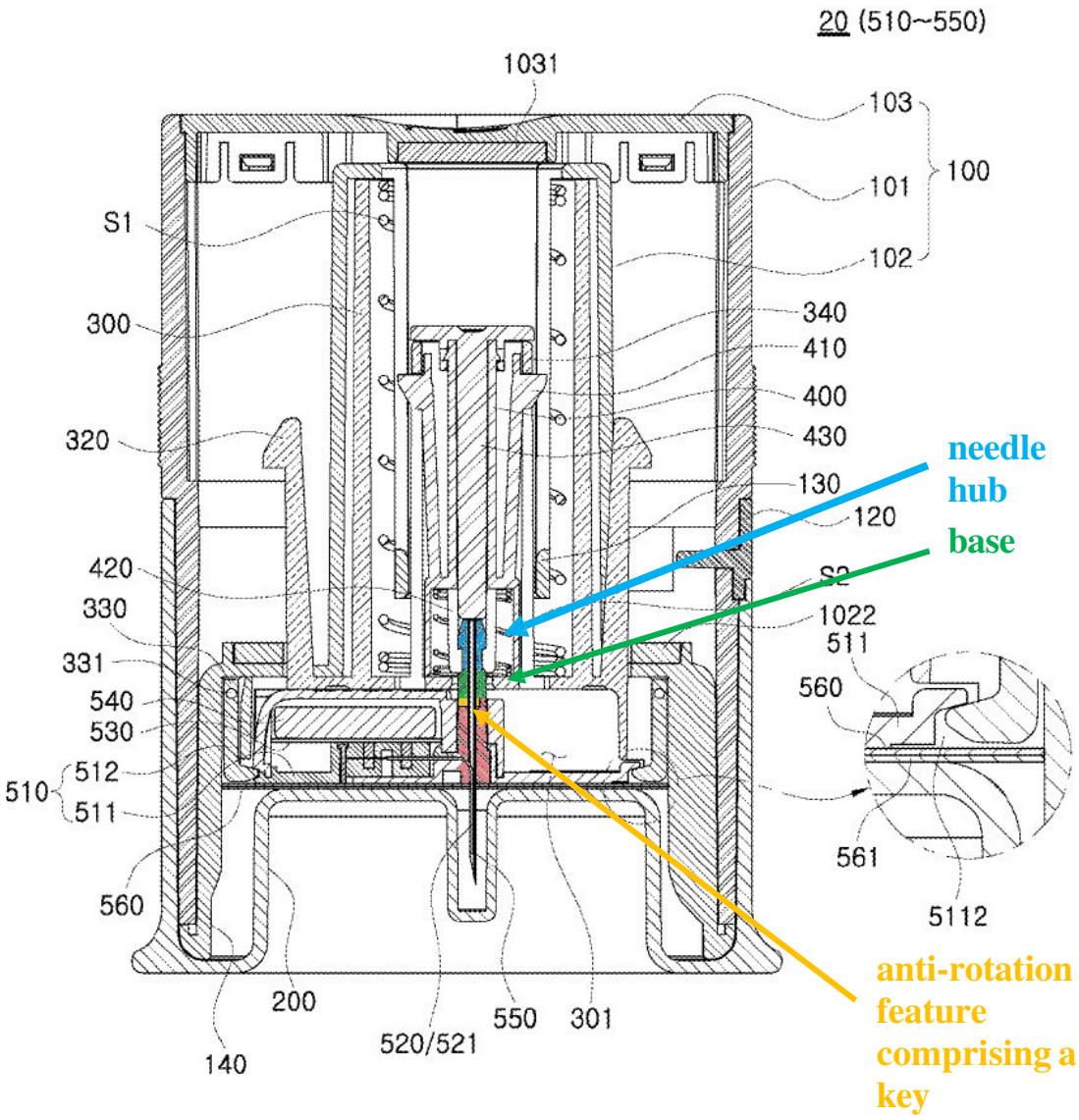
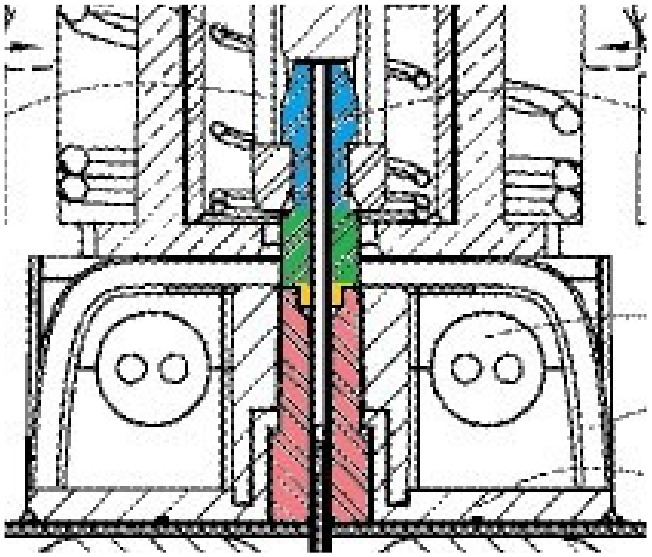
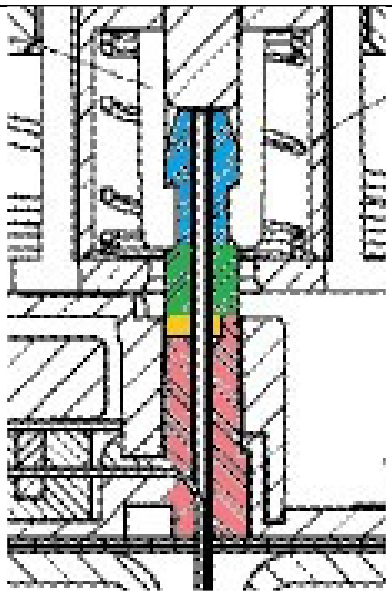


FIG. 6



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

Ex-1008~~,~~ at Fig. 5 (excerpt)	Ex-1008~~,~~ at Fig. 6 (excerpt)
	

~~205.~~216. 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."

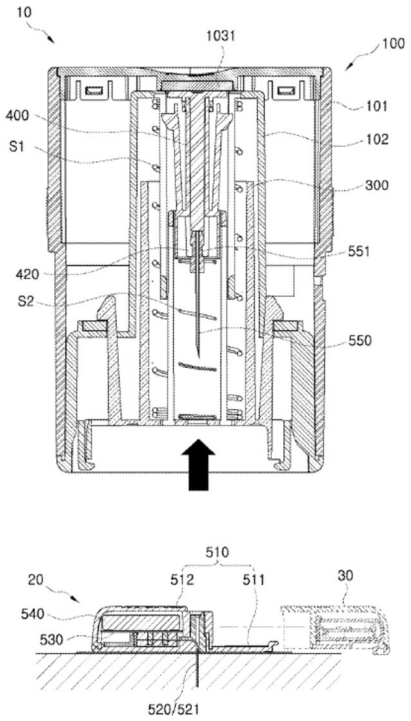
~~**aa.** *1.6*~~

d. *1.6 "an on-skin sensor assembly comprising:"*

~~206.~~217. The sensor module 20 is configured to be attached to a user's skin,

Ex- 1008~~,~~ at [0055], as shown in Figure 24:

FIG. 24



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

~~**bb.** *1.7*~~

e. *1.7 "a sensor, the sensor configured to measure a glucose concentration of a host, and"*

~~207.~~218. Chae discloses that the sensor module 20 includes a sensor 520 that is used to "measure a ***blood glucose level***." Ex-1008~~,~~ at [0079], [0081]; *see also Id.*~~,~~. at 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").

~~**cc.** *1.8-1.10*~~

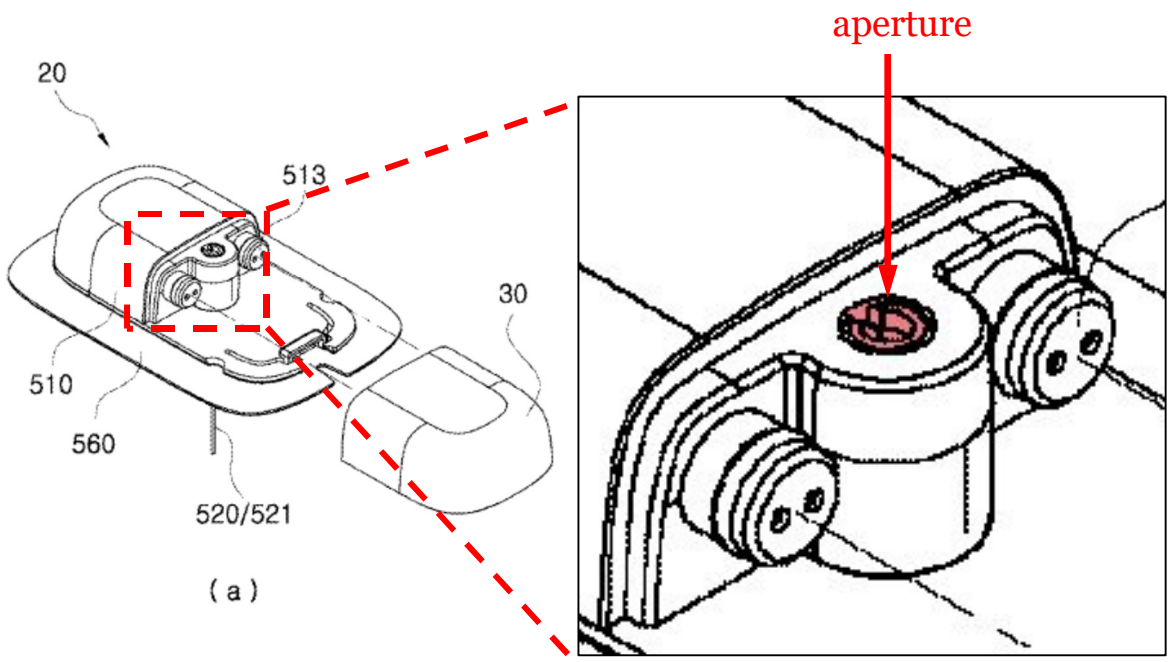
f. *1.8 "an aperture extending from a top surface of the on-skin sensor assembly,"*

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;"

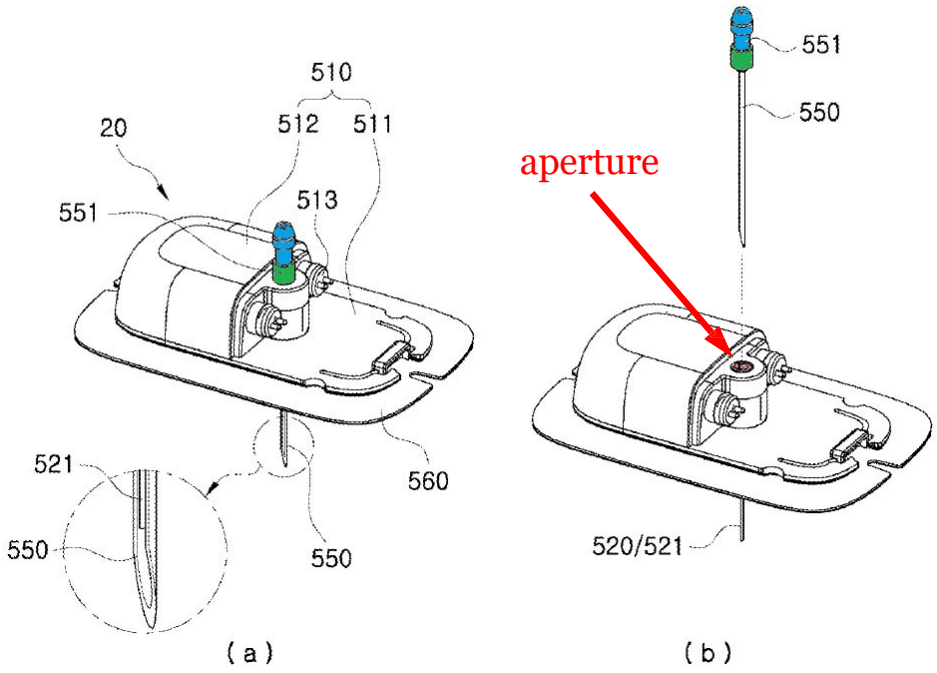
~~208.~~219. Chae's sensor module 20 contains an aperture ~~extending from a top surface~~ (annotated in red~~),~~) extending from a top surface, into which the needle 550 is ~~insert~~inserted, as seen in Figure 3:

FIG. 3



Ex-1008~~,~~ at 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:

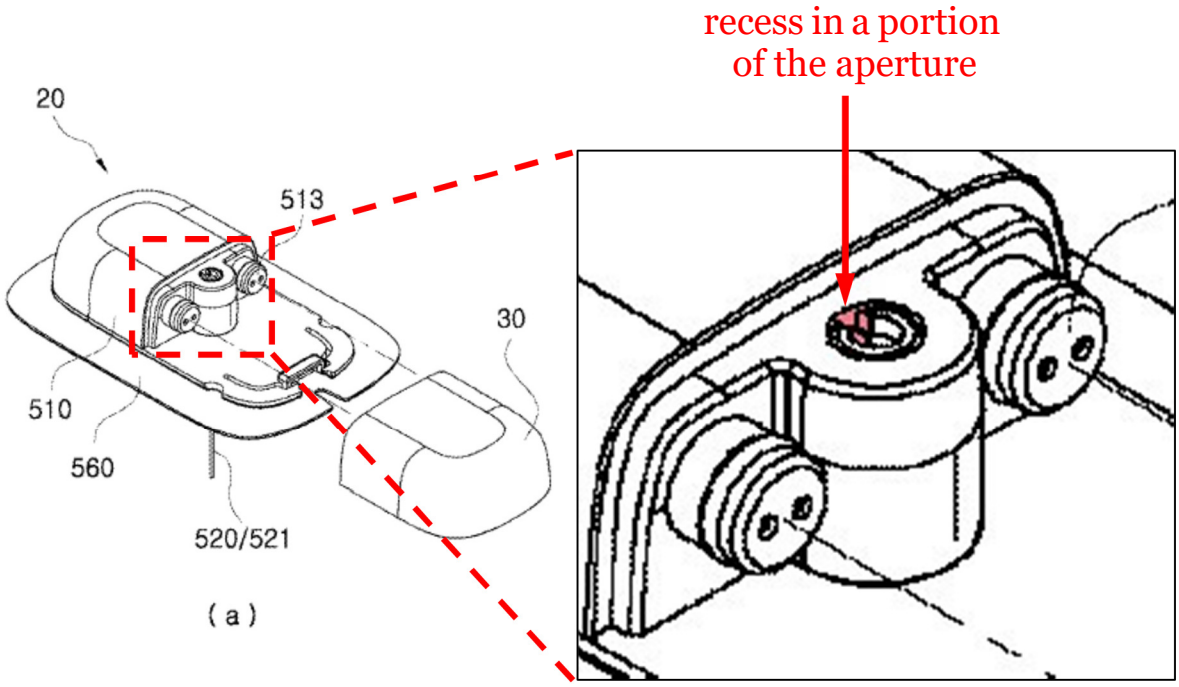
FIG. 2



Ex-1008~~,~~ at Fig. 2, [0086]-[0087].

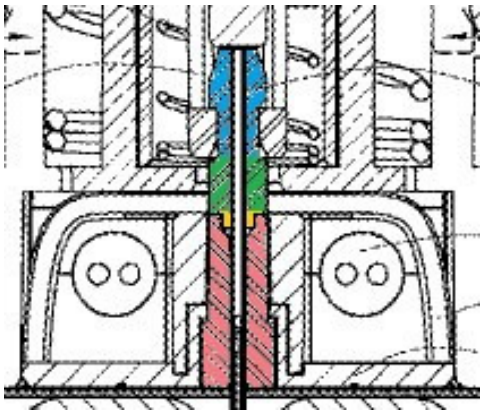
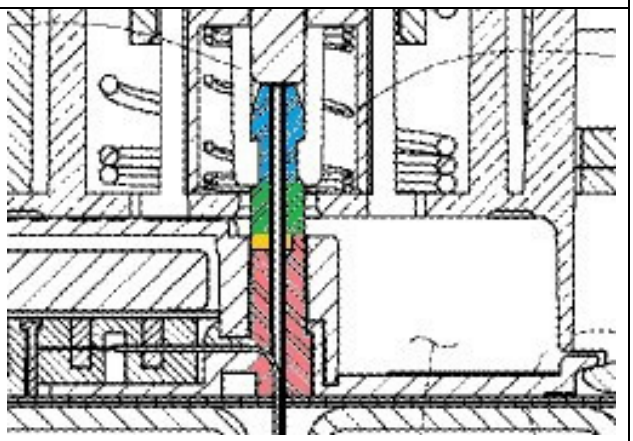
~~209.~~220. Chae further discloses that the aperture of the sensor module 20 has a recess that is shaped complementary to the protrusion on the needle head 551. For example, Figure 3 (enlarged, right below) shows a recess in one side of the aperture:

FIG. 3



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

~~210.~~221. 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):

Ex-1008~~,~~ at Fig. 5 (excerpt)	Ex-1008~~,~~ at Fig. 6 (excerpt)
	

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

dd. *1.11*

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

211.222. 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

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

ee. *13.P*

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

213.224. *See*, *supra*, claim 1.P.

ff. *13.1*

b. *13.1 "an applicator housing having an internal volume;"*

214.225. *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;"

~~215.~~226. *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~~,~~ at 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.

~~216.~~227. 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~~,~~ at Figs. 5-6. The shape of the protrusion corresponds to the claimed "anti-rotation key."

~~**gg.** *13.6-13.10*~~

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"

~~217.~~228. *See*, *supra*, claims 1.6-1.10.

~~**hh.** *13.11*~~

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."*

~~218.~~229. *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

~~219.~~230. In my opinion, Chae renders obvious claim 22, as explained below ~~and as supported by Ex. 1004, ¶¶230-236~~.

~~**ii.** *22.P*~~

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

~~220.~~231. 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~~,~~ at 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.

FIG. 22A

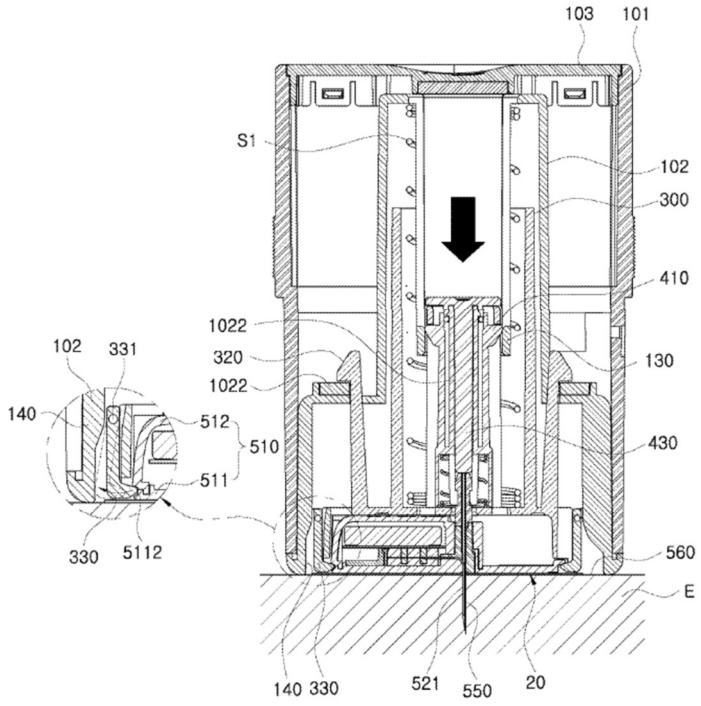
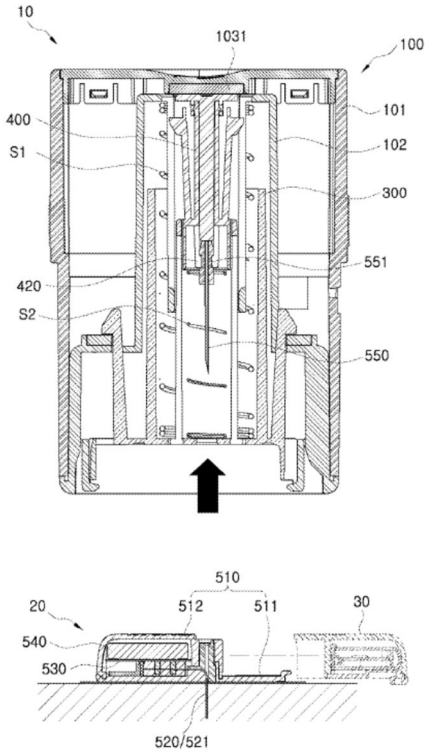


FIG. 24



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

~~**jj.** *22.1*~~

b. *22.1 "a base comprising an anti-rotation key,"*

~~221.~~232. *See*, *supra*, claims 1.3-1.5 and 13.2-13.5.

~~**kk.** *22.2*~~

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

~~222.~~233. *See*, *supra*, claim 1.11.

~~**ll.** *22.3*~~

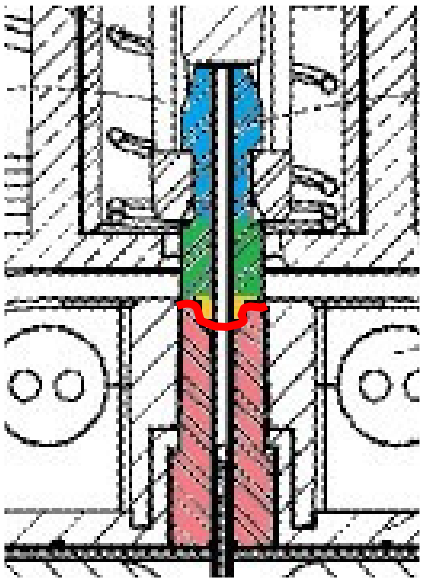
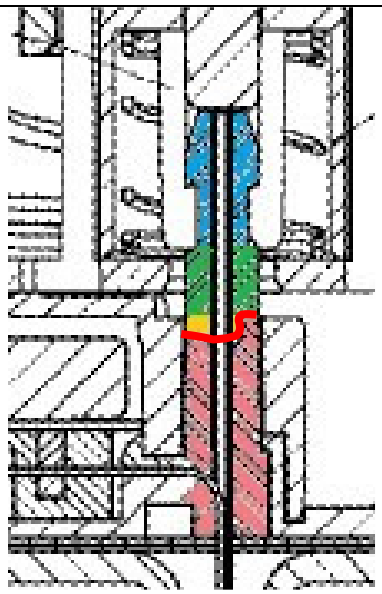
d. *22.3 "wherein the needle hub is configured to couple with an insertion element; and"*

~~223.~~234. *See*, *supra*, claim 1.2.

~~**mm.** *22.4*~~

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."*

~~224.~~235. Chae discloses that 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~~,~~ at Fig. 5 (excerpt)	Ex-1008~~,~~ at Fig. 6 (excerpt)
	

Ex-1008~~,~~ at 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 surfaceof the sensor module 20.

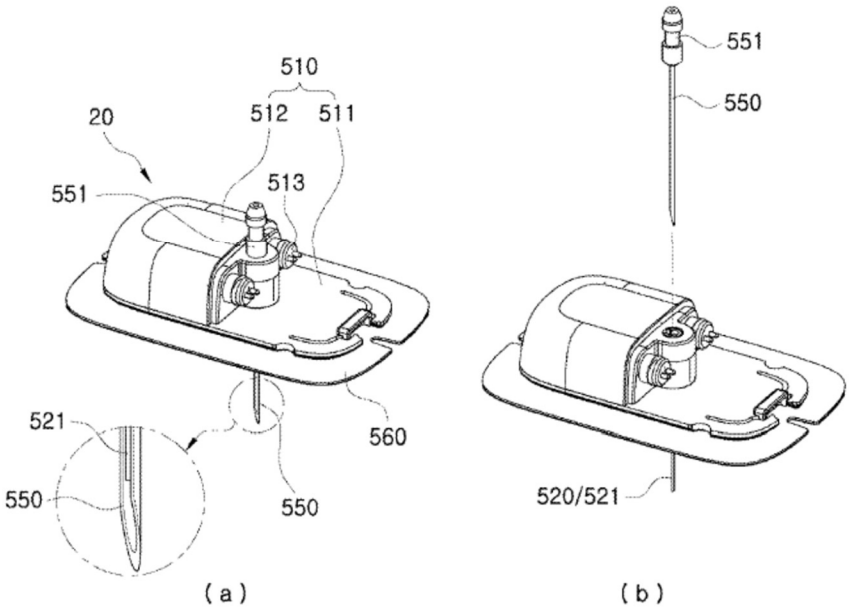
4. Claims 2 & 25

236. In my opinion, 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.

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

~~225.~~237. 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~~,~~ at Fig. 2, [0085]-[0086]; *see Id.*~~,~~ at 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

238. In my opinion, 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.

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

~~226.~~239. 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~~is 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~~,~~ at Fig. 22b (corresponds to Ex-1009, Fig. 8a), Fig. 24 (corresponds to Ex- 1009, Fig. 9).

6. Claims 6 & 16

240. In my opinion, 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.

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

~~227.~~241. Chae further discloses that the sensor module 20 "includes a pod 510, a sensor 520, a printed circuit board (PCB) 530, and a battery 540." Ex-1008~~,~~ at [0079]. A transmitter 30 can be coupled to the sensor module 20. *Id.*~~,~~ at [0055], [0058]. A POSITA would understand that a sensor module containing a pod, sensor, printed circuit board, battery, and transmitter comprises sensor electronics. ~~Ex-1004, ¶241.~~

7. Claim 9

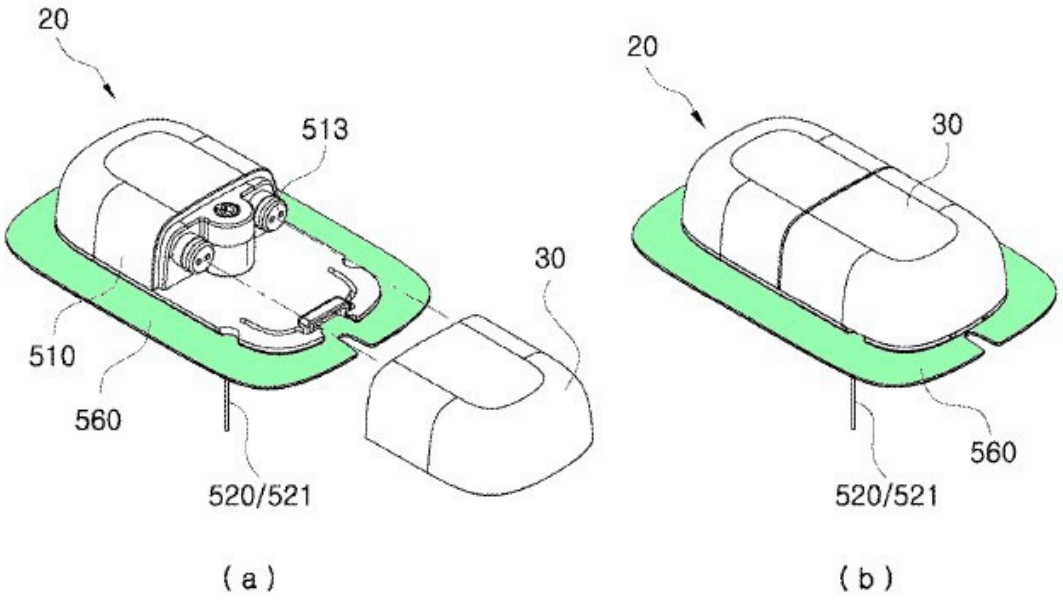
242. In my opinion, Chae renders obvious claim 9, as explained below ~~and as supported by Ex-1004, ¶¶242-243.~~.

Claim 9 depends from claim 1. *See*, *supra*, claim 1.

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."*

~~228.~~243. 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~~,~~ at [0080], [0114].

FIG. 3



Id.~~,~~. at Fig. 3.

8. Claim 23

244. In my opinion, 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.~~

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

~~229.~~245. *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

246. In my opinion, 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~~

a. *"wherein the* ~~additional limitation~~*anti-rotation key has a shape complementary to at least a portion of* ~~claim 24.~~ *the aperture."*

~~230.~~247. *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.