

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

In re *Inter Partes* Review of:

U.S. Patent No. 11,510,625

Case No. IPR2024-00859

DECLARATION OF DR. CAMERON RIVIERE, PH.D.

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I. INTRODUCTION

1. I, Cameron Riviere, Ph.D., declare as follows.

2. I have been retained as a technical consultant on behalf of Abbott Diabetes Care Inc. (“Abbott” or “Petitioner”), who I understand is the petitioner in the present proceeding. I have been asked to consider whether the references listed as Exhibits 1006-1012 below disclose or render obvious the limitations recited in claims 1-9, 13-19, and 22-30 of U.S. Patent No. 11,510,625 (Ex-1001, “’625 patent”). I have also been asked to consider the state of the art and the prior art available before the time of the alleged invention of the ’625 patent. My opinions are provided in this declaration.

3. To the best of my knowledge, I have no financial interest in Petitioner. I have been informed that a company known as DexCom, Inc. (“DexCom” or “Patent Owner”) purports to own the ’625 patent. To the best of my knowledge, I have no financial interest in DexCom and, to the best of my recollection, I have had no contact with DexCom or the named inventors of the ’625 patent, John Michael Gray, Jennifer Blackwell, Paul V. Neale, Justen Deering England, Andrew Joncich, Cameron Brock, Peter C. Simpson, Thomas Metzmaker, Neel Narayan Shah, Mark Douglas Kempkey, Patrick John Castagna, Warren Terry, Jason Halac, Christian Michael Andre George, Daniel E. Apacible, John Charles Barry, Maria Noel Brown Wells, Kenneth Pirondini, Andrew Michael Reinhardt, Jason C. Wong, Remy E.

Gagnon, David DeRenzy, Randall Scott Koplin, Alan Baldwin, Young Woo Lee, David A. Keller, Louise Emma van den Heuvel, Carol Wood Sutherland. To the best of my knowledge, I similarly have no financial interest in the '625 patent. To the extent any mutual funds or other investments that I own have a financial interest in the Petitioner, the Patent Owner, or the '625 patent, I am not aware of, nor do I have control over, any financial interest that would affect or bias my judgment.

4. I am being compensated at my standard consulting rate for my time. My compensation is in no way contingent on the results of these or any other proceedings relating to the '625 patent.

II. BACKGROUND AND QUALIFICATIONS

5. A summary of my professional background and qualifications is provided below. An additional account of my work experience and qualifications is included in my curriculum vitae, which is attached as Ex-1005.

6. I hold a B.S. in aerospace engineering and a B.S. in ocean engineering, both from Virginia Polytechnic Institute and State University. I hold a Ph.D. in mechanical engineering from The Johns Hopkins University. My studies toward all of these degrees (the two bachelor's degree programs were largely mechanical in nature) involved substantial coursework dealing with analysis and design of mechanisms as well as solid mechanics.

7. Since 1995 I have been employed by Carnegie Mellon University, where I presently hold the position of Research Professor in the Robotics Institute, with additional appointments in the Department of Mechanical Engineering and the Department of Biomedical Engineering. I have over 28 years' experience in research and development dealing with mechanisms and devices for medical applications. I have published over 150 papers. I was a recipient of the Best Paper of the Year Award from the *IEEE/ASME Transactions on Mechatronics* in 2016, the Best Paper Award at the IEEE International Conference on Multisensor Fusion and Integration in 2015, the Best Application Paper Award at the IEEE/Robotics Society of Japan International Conference on Intelligent Robots and Systems in 2014, and the Best Paper Award at the 28th World Congress on Endourology and Shockwave Lithotripsy in 2010.

8. I am a Senior Member of the Institute of Electrical and Electronics Engineers (IEEE). I serve as an Associate Editor on the Conference Editorial Boards of the IEEE Robotics and Automation Society and the IEEE Engineering in Medicine and Biology Society, and as a member of the Programme Committee of the Hamlyn Symposium on Medical Robotics. I have been a reviewer for various pertinent journals and conferences, including *ASME Journal of Medical Devices*, *ASME Journal of Mechanical Design*, *IEEE Transactions on Robotics*, *International Journal of Robotics Research*, *IEEE/ASME Transactions on Mechatronics*, *IEEE*

Transactions on Instrumentation and Measurement, IEEE International Conference on Robotics and Automation, IEEE/RSJ International Conference on Intelligent Robots and Systems, and the Dynamic Systems and Control Conference.

9. I was a charter member of the National Institutes of Health (NIH) Study Section on Bioengineering, Technology, and Surgical Sciences from 2019 to 2023. I have served on proposal review panels for the U.S. National Science Foundation, National Aeronautics and Space Administration, Department of Veterans Affairs, and NIH, as well as for the National Science Foundation of Switzerland, the Natural Sciences and Engineering Research Council of Canada, the Agency for Science, Technology and Research and the National Medical Research Council of Singapore, and the Qatar National Research Foundation. I was a member of the Task Group on Robotic-Assisted Interventions of the American Association of Physicists in Medicine in 2013 and 2014.

10. My research projects have included work dealing with needle-based interventions and control of needle rotation. One example of these is “Safe Flexible Intracerebral Navigation with Steerable Needles” (NIH grant no. R21EB012209), which dealt with methods for active control of needle rotation. Publications stemming from this work included G. Wu, X. Li, C. A. Lehecky, and C. N. Riviere, “Automatic Steering of Manually Inserted Needles,” *Proceedings of the IEEE International Conference on Systems, Man, and Cybernetics*, pp. 1488-1493, 2013,

and C. A. Lehocky, W. Fellows-Mayle, J. A. Engh, and C. N. Riviere, “Tip Design for Safety of Steerable Needles for Robot-Controlled Brain Insertion,” *Robotic Surgery: Research and Reviews*, 4:107-114, 2017.

11. Other research projects of mine dealing with needle-based interventions include “Robotic Crawler for Epicardial Interventions” (NIH grant no. R01HL078839), and “An Active Handheld Micromanipulator” (NIH grant no. R01EB000526), which involved needle-based treatments in the heart and the retina, respectively, and resulted in publications such as T. Ota, N. A. Patronik, D. Schwartzman, C. N. Riviere, and M. A. Zenati, “Minimally Invasive Epicardial Injections Using a Novel Semiautonomous Robotic Device,” *Circulation*, 118:S115-S120, 2008. I have also published research into percutaneous needle-based kidney access in the following paper: N. A. Wood, K. Shahrour, M. C. Ost, and C. N. Riviere, “Needle Steering System Using Duty-Cycled Rotation for Percutaneous Kidney Access,” *Proceedings of the 32nd Annual International Conference of the IEEE Engineering in Medicine and Biology Society*, pp. 5432-5435, 2010.

12. I am not an attorney and offer no legal opinions, but in the course of my work, I have had experience studying and analyzing patent claims from the perspective of a person skilled in the art.

III. MATERIALS REVIEWED

13. In preparing this declaration, I reviewed the '625 patent, including the claims of the patent in view of the specification, and I have reviewed the prosecution history of the '625 patent and numerous prior art and technical references from the time of the alleged invention. More specifically, I have reviewed each of the following:

Exhibit	Description
1001	U.S. Patent No. 11,510,625 (the "'625 patent")
1002	File History for U.S. Patent No. 11,510,625
1003	U.S. Provisional Patent App. No. 62/524,247 (the "'247 Provisional")
1006	U.S. Patent Publication No. 2013/0150691 (Pace)
1007	U.S. Patent Publication No. 2016/0331284 (Pace 2)
1008	U.S. Patent Publication No. 2020/0178899 (Chae)
1009	Korean Patent Application No. 10-2017-0068964
1010	Certified English Translation of Korean Patent Application No. 10-2017-0068964
1011	U.S. Patent Publication No. 2014/0188053 (Lundquist)
1014	U.S. Pat. No. 6,175,752 (Say)
1015	N. Sclater and N. P. Chironis, <i>Mechanisms and Mechanical Devices Sourcebook</i> , Fourth Edition, New York: McGraw-Hill, 2007
1016	M. A. Meltsner, et al., <i>Observations on rotating needle insertions using a brachytherapy robot</i> , 52 Physics in Medicine and Biology 6027-6037 (2007)
1017	Ryosuke Tsumura, et al., <i>Histological evaluation of tissue damage caused by rotational needle insertion</i> , Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 5120-5123 (2016)

IV. RELEVANT LEGAL STANDARDS

14. For the purposes of this declaration, I have been informed about certain aspects of the law that are relevant to forming my opinions. I have applied the following understanding of the law:

15. I have been informed that a patent claim may be “anticipated” if each element of that claim is present either explicitly or inherently in a single prior art reference, and that the elements should be arranged in the reference as in the claim. Petitioner’s counsel has informed me that for a claimed limitation to be inherently present, the prior art need not expressly disclose the limitation, so long as the claimed limitation necessarily flows from a disclosure in the prior art.

16. I have been informed that a patent claim can be considered to have been obvious to a person of ordinary skill in the art (“POSITA”) at the time the application was filed. This means that, even if all of the requirements of a claim are not found in a single prior art reference, the claim is not patentable if the differences between the subject matter in the prior art and the subject matter in the claim would have been obvious to a person of ordinary skill in the art at the time the application was filed.

17. I have been informed that a determination of whether a claim would have been obvious should be based upon several factors, including, among others:

- the level of ordinary skill in the art at the time the application was filed;
- the scope and content of the prior art; and

- what differences, if any, existed between the claimed invention and the prior art.

18. I have been informed that a single reference can render a patent claim obvious if any differences between that reference and the claims would have been obvious to a person of ordinary skill in the art. Alternatively, the teachings of two or more references may be combined in the same way as disclosed in the claims, if such a combination would have been obvious to one having ordinary skill in the art. In determining whether a combination based on either a single reference or multiple references would have been obvious, it is appropriate to consider, among other factors:

- whether the teachings of the prior art references disclose known concepts combined in familiar ways, and when combined, would yield predictable results;
- whether a person of ordinary skill in the art could implement a predictable variation, and would see the benefit of doing so;
- whether the claimed elements represent one of a limited number of known design choices, and would have a reasonable expectation of success by those skilled in the art;
- whether a person of ordinary skill would have recognized a reason to combine known elements in the manner described in the claim;

- whether there is some teaching or suggestion in the prior art to make the modification or combination of elements claimed in the patent; and
- whether the innovation applies a known technique that had been used to improve a similar device or method in a similar way.

19. I have been informed that one of ordinary skill in the art has ordinary creativity and is not an automaton. Petitioner's counsel has informed me that in considering obviousness, it is important not to determine obviousness using the benefit of hindsight derived from the patent being considered.

20. I have been informed that secondary considerations of non-obviousness can include a long-felt but unmet need for the claimed invention, failure of others, copying, unexpected results, commercial success, skepticism, or industry praise. I understand that it is generally the patent owner's burden to present evidence of secondary considerations if the patent owner contends that any apply. I am not aware of any evidence of secondary considerations of non-obviousness that would apply to the claims at issue. If any such alleged evidence is later identified, I reserve the right to respond at an appropriate time.

V. TECHNOLOGY BACKGROUND

21. A variety of medical sensor devices may utilize or involve a needle for insertion of a portion of the sensor into the user. Some example devices include: lactate sensors, blood-gas sensors, and glucose sensors. In such sensor devices, a

portion of the sensor may extend through a hollow or partially-hollowed needle and be affixed to a structure through which the needle shaft passes, such as sensor electronics. In such devices, any rotation of the needle will have the effect of “rolling up” some part of the electronics and therefore is likely to damage the electronics due to flexion (bending of the electronics) or tension (pulling the electronics apart). Therefore, it is important to prevent the needle from rotating with respect to the sensor electronics during and after insertion.

22. In general, if it is important for a needle not to rotate with respect to a surrounding structure, one way this can be prevented is by friction, such as by a tight rubber fitting surrounding the needle, or by a set screw tightened against the needle shaft. Such methods are prone to slippage, however. For this reason, it is common to use methods based on the needle and its surrounding fitting not being completely round. For example, it is common for a set screw to be tightened against a shaft that is modified with a detent or flat section.

23. However, in general, the friction-based methods described above are not suited to cases in which the needle must be allowed to slide axially with regard to the surrounding structure, such as is the case with continuous glucose monitors (CGMs), in which it is necessary to remove the needle after implantation while keeping the sensor and electronics in place. The needle must be able to slide axially with respect to the electronics, but not to rotate with respect to them.

24. The common approach in such a case is to include a key that slides in a keyway. Ex-1015 (N. Sclater and N. P. Chironis, *Mechanisms and Mechanical Devices Sourcebook*, Fourth Edition, New York: McGraw-Hill, 2007) at p. 306. The key may be attached either to the surrounding fitting or to the shaft (in which case it is often called a spline). In either case, the keyway, or groove into which the key fits, is then of course incorporated into the other object. It is common for a key to have an approximately square cross-section, but this is not necessary. Many different shapes will accomplish the purpose; all that is needed is for the overall cross-section of the shaft not to be completely round, and for the surrounding structure to have a matching shape such that the two objects interlock, allowing sliding movement between the two but preventing either from rotating with respect to the other.

25. Another common solution for such a case is a longitudinal pin in either the central object or the surrounding object, with a corresponding socket or recess in the other object. Ex-1015 at p. 301. This likewise prevents relative rotation between the two objects, but enables sliding motion, as the pin is free to move in or out of the socket.

26. In addition to the damage to a device that may result from unintentional rotation, there is also a risk of damage to the tissue of the patient. This can include “coring” or cutting of fragments which can result from rotation of a bevel-tipped needle being rotated while not being inserted (or while being inserted slowly) (Ex-

1016 (M. A. Meltsner, N. J. Ferrier, and B. R. Thomadsen, “Observations on rotating needle insertions using a brachytherapy robot,” *Physics in Medicine and Biology*, 52:6027-6037, 2007)), as well as “winding,” which is tissue damage due to the tissue twisting along with the shaft of the needle (Ex-1017 (R. Tsumura, Y. Takishita, Y. Fukushima, and H. Iwata, “Histological evaluation of tissue damage caused by rotational needle insertion,” *Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society*, pp. 5120-5123, 2016)).

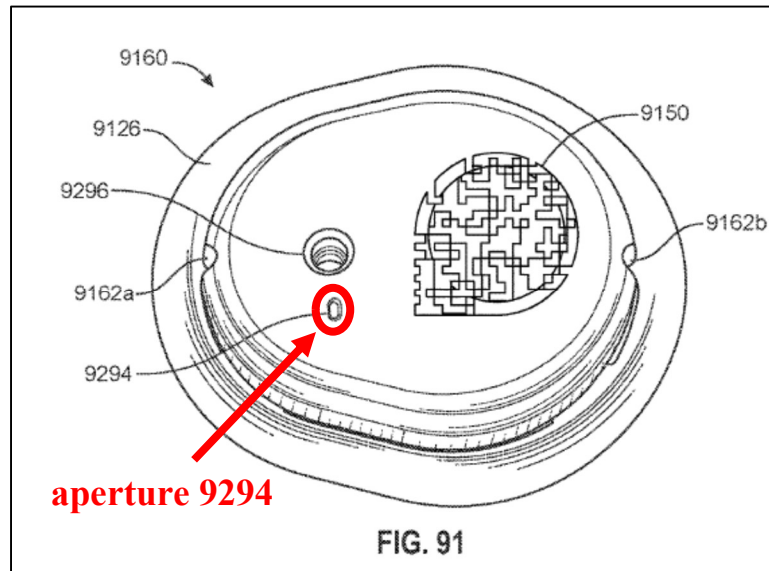
VI. OVERVIEW OF THE '625 PATENT

A. Summary

27. The '625 patent purports to relate to “systems and methods for measuring an analyte in a host,” including a “transcutaneous analyte measurement system.” Ex-1001 at 2:10-14. The '625 patent acknowledges such transcutaneous analyte sensor systems for glucose measurement were in the prior art, stating “[i]n some embodiments, sensor system 100 includes a continuous glucose sensor and comprises a transcutaneous sensor (e.g., as described in U.S. Pat. No. 6,565,509, as described in U.S. Pat. No. 6,579,690, and/or as described in U.S. Pat. No. 6,484,046).” *Id.* at 19:55-20:8.

28. While the '625 patent describes multiple CGM applicator embodiments for applying an on-skin sensor assembly to the skin of a host, there is scarce disclosure, beyond mere functional description, of structures constituting an “anti-

rotation feature” or “key” to prevent rotation of a needle hub within an aperture of an on-skin sensor assembly. For example, for Figure 91, the specification describes an aperture 9294 in the on-skin sensor assembly that is “configured to” engage with an anti-rotation feature “such as base 7152 of needle hub 7150”:

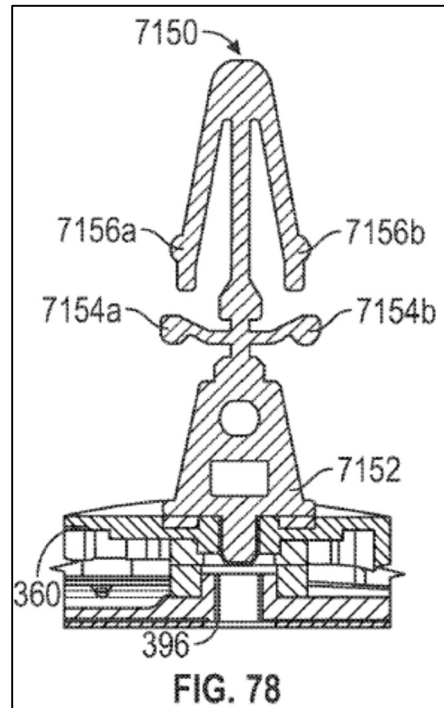


In some embodiments, on-skin sensor assembly 9160 may further include an aperture 9294. Aperture 9294 may extend from a top surface of on-skin sensor assembly 9150 a certain depth through on-skin sensor assembly 9160. In some embodiments, ***aperture 9294 is configured to engage with an anti-rotational feature such as base 7152 of needle hub 7150*** described in FIG. 78.

Ex-1001 at Fig. 91 (color annotations added throughout unless otherwise noted); 25:40-46 (emphasis added throughout unless otherwise noted).

29. The '625 patent calls “base 7152 of needle hub 7150” in Figure 78 “an anti-rotational feature,” *id.*, 25:45-46, but does not identify any particular structures

or point to specific reference numbers in the Figure that would prevent rotation. Completely lacking is any explanation of how the base 7152 would interact with the aperture 9294 of Figure 91:



Base 7152 comprises an anti-rotation feature. The anti-rotation feature may comprise a key having a shape complementary to at least a portion of sensor assembly ***aperture 396*** of on-skin sensor assembly 360 and may be configured to substantially prevent needle hub 7150 from rotating about an axis 7702 parallel to insertion element 7174 with respect to on-skin sensor assembly 360, e.g., to prevent rotation of base 7152 within sensor assembly aperture 396.

Ex-1001 at 68:41-56.

30. The '625 patent specification therefore offers little guidance as to what constitutes the “anti-rotation feature” or “anti-rotation key.”

B. Prosecution History

31. The '625 patent was filed with one claim as U.S. Application No. 17/592,170 on February 3, 2022, from a chain of continuation applications first filed on June 22, 2018. Ex-1001 at 1-2. On April 13, 2022, the Examiner issued an Office Action rejecting the sole claim as anticipated by U.S. Patent No. 6,248,067 ("Causey"), as well as for double-patenting. Ex-1002 at 379-385.

32. On May 13, 2022, DexCom filed an amendment cancelling original claim 1 and adding 22 new claims. *Id.* at 481-488. Six days later, DexCom filed a "supplemental" amendment adding 9 more new claims. *Id.* at 512-521.

33. On June 2, 2022, the Examiner allowed all pending claims. *Id.* at 522-536.

C. Effective Filing Date Of The '625 Patent

34. For the purposes of this declaration, I have been instructed to assume the effective filing date of the '625 patent is June 23, 2017.

D. Level Of Ordinary Skill In The Art

35. A POSITA as of the effective filing date would have had a bachelor's degree in mechanical or biomedical engineering (or a related or equivalent field) and two or more years of experience researching, developing, designing and/or evaluating medical devices utilizing needles or sharps, or equivalent experience. A person with less or different education but more relevant practical experience, or

vice versa, may also meet this standard. The prior art also evidences the level of skill in the art.

E. Claim Construction

36. I understand that in this proceeding, the claims should be construed in accordance with their ordinary and customary meaning in light of the specification, as understood by one of ordinary skill in the art.

37. For purposes of my opinions, I have been asked to assume that each claim term should be given its plain and ordinary meaning in light of the specification, and I have therefore applied those plain and ordinary meanings in my analysis.

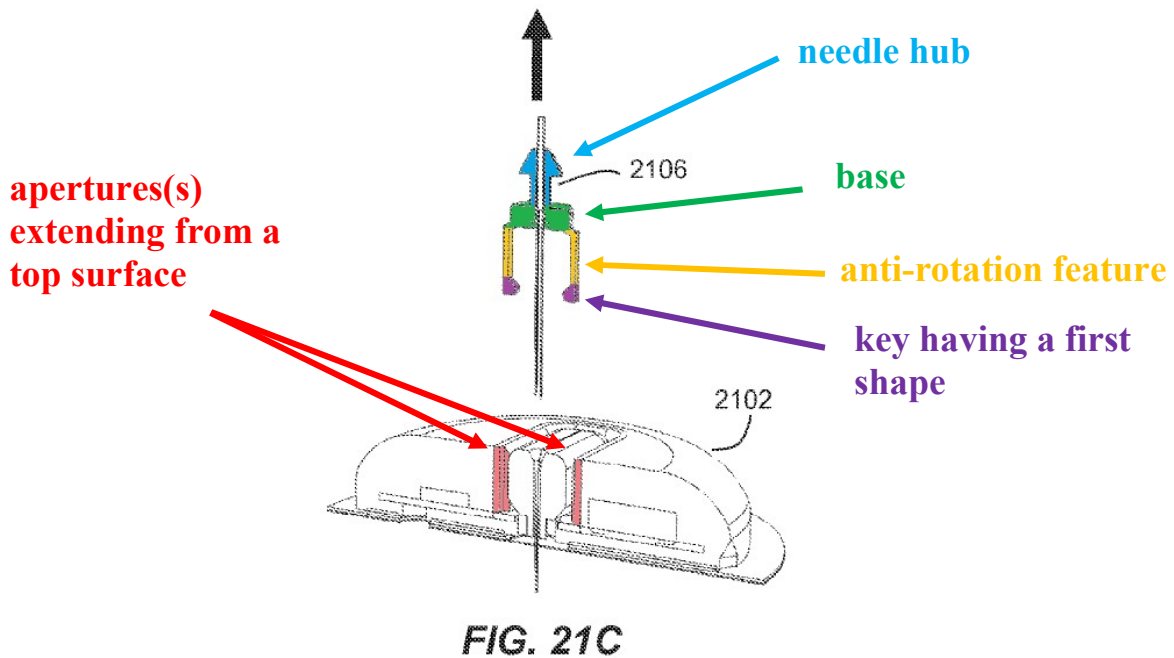
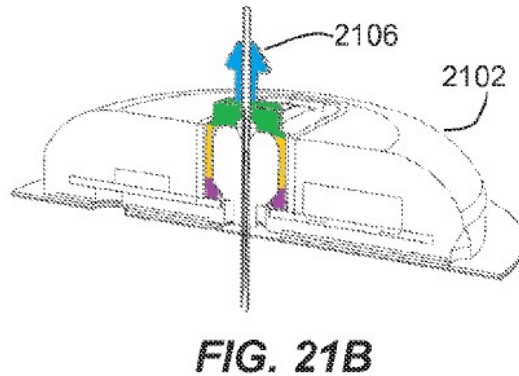
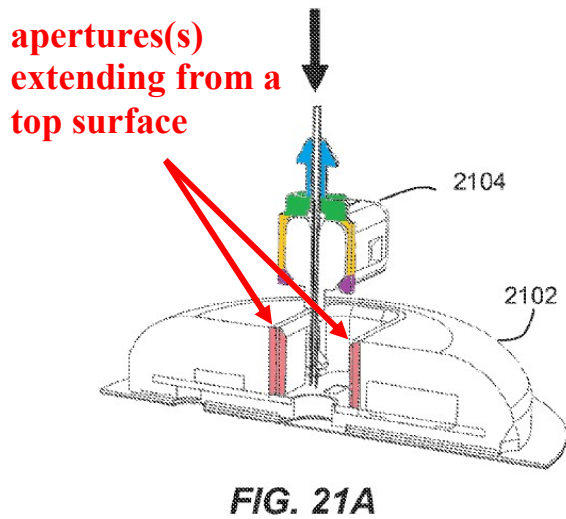
VII. OVERVIEW OF THE PRIOR ART

A. Pace (Ex-1006)

38. U.S. Patent Publication No. 2013/0150691, titled “Analyte Sensor Devices, Connections and Methods,” to Pace *et al.* (“Pace”) was filed on December 11, 2012, and published on June 13, 2013. Ex-1006 at Cover.

39. Pace discloses multiple CGM applicator embodiments. In each embodiment, a glucose sensor mates with an electronics assembly inside the applicator to form a complete on-body device (*i.e.*, the claimed “on-skin sensor assembly”). A first embodiment (“embodiment A”) is depicted in Figures 21A-C (below). In this embodiment, “a sensor assembly gripper 2106, with a light snap fit, grabs and orients the sensor assembly 2104 for connection to the electronics

assembly 2102” as part of the “mating” process to form the complete on-body device inside the applicator prior to use. Ex-1006 at [0123]. Further, the sensor assembly gripper features may be “incorporated” in a “sharp hub.” *Id.* As shown in Figures 21A-21C below, the base (annotated in green) of the sharp hub/gripper 2106 (annotated in blue) has an anti-rotation feature (annotated in gold) with a key (annotated in purple). *Id.* at Figs. 21A-21C, [0123]. The anti-rotation feature and its corresponding receiving aperture(s) (annotated in red) in the on-skin sensor assembly (formed by mating electronics assembly 2102 and the sensor assembly 2104) have complementary shapes, which prevent the sharp hub/ gripper 2106 (*i.e.*, needle hub) from rotating with respect to the on-skin sensor assembly.



Id. at Figs. 21A-21C (annotated), [0123].

40. Pace further discloses a second embodiment (“embodiment B”) related to Figures 34D, 35A-B and 47C (below). This embodiment discloses a connector support 3404, containing a sensor and electrical contacts, which is mated with an

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

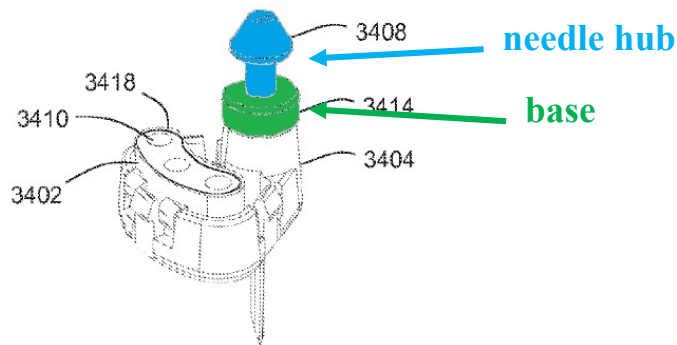


FIG. 34D

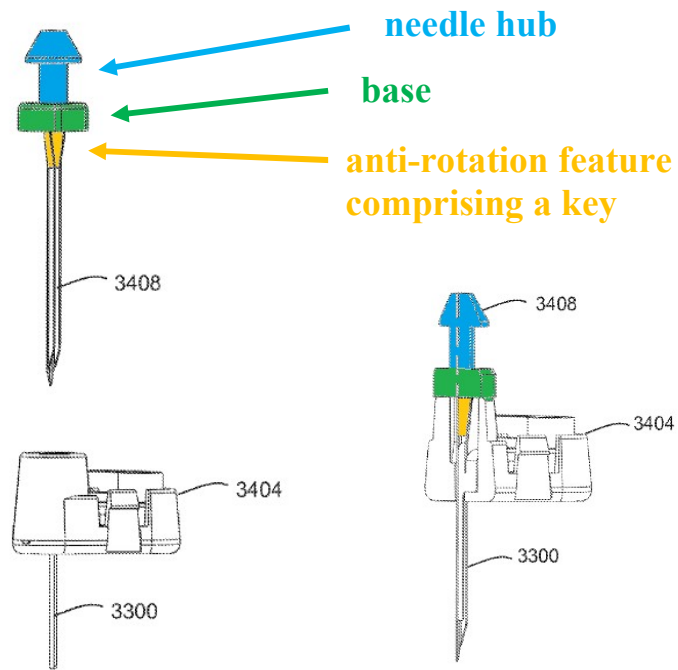


FIG. 35A

FIG. 35B

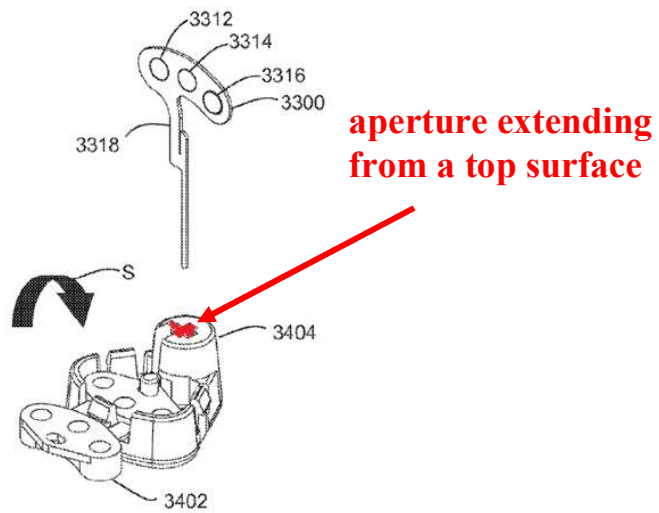


FIG. 34C

Id.

41. The sharp hub and connector support are shown mated with the electronics unit in Figure 47C, forming the complete on-body device (*i.e.*, the on-skin sensor assembly):

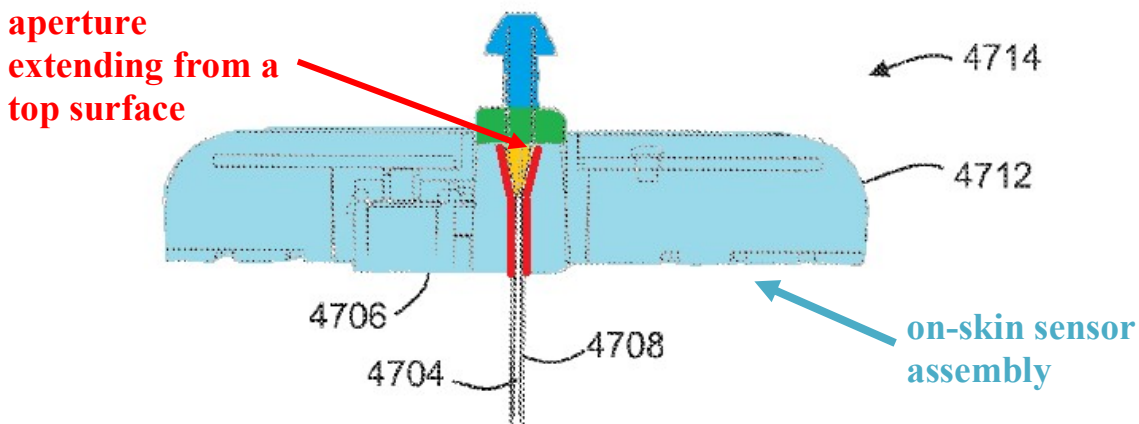


FIG. 47C

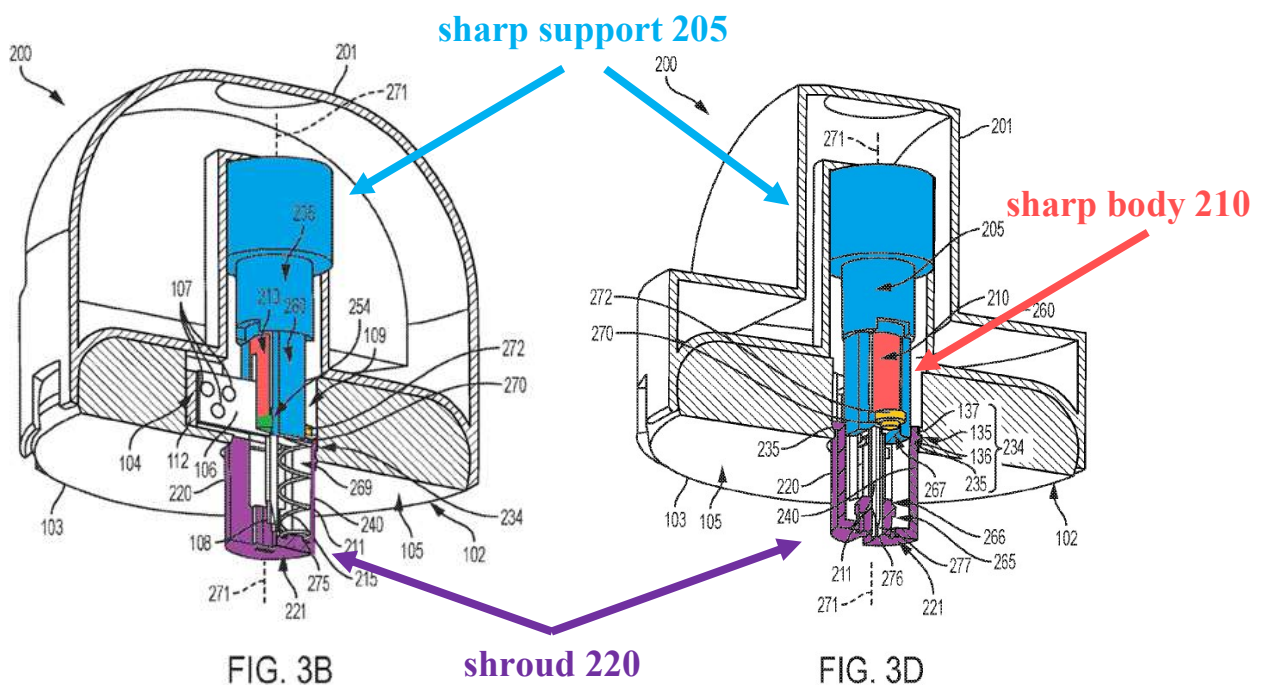
Id. at Fig. 47C; *see also id.* at Figs. 47A-B, [0149] (noting that connector support 4706 is similar to the connector support in Figures 34A-D without seal 3402). The V-shaped portion slots into one arm of the cross-shaped aperture in connector support 3404 in Figure 34C, which is internally tapered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

42. Pace discloses a CGM and applicator and is thus from the same field of endeavor as the '625 patent.

B. Pace 2 (Ex-1007)

43. U.S. Patent Publication No. 2016/0331284, titled “Compact Medical Device Inserters and Related Systems and Methods,” to Pace (“Pace 2”) was filed on May 13, 2016, and published on November 17, 2016. Ex-1007 at Cover.

44. Pace 2 discloses an applicator for a CGM comprising a housing 201, sharp support 205, and a sharp body 210, to apply a sensor control device 102 with a sensor to a user’s skin. Ex-1007 at Abstract. The sensor control device 102 includes a shroud 220 that retracts during application. Figures 3B-5D below depict the applicator at different stages of application of the sensor control device with sensor to the user, with each pair of figures depicting the same stage of application, from different perspectives:



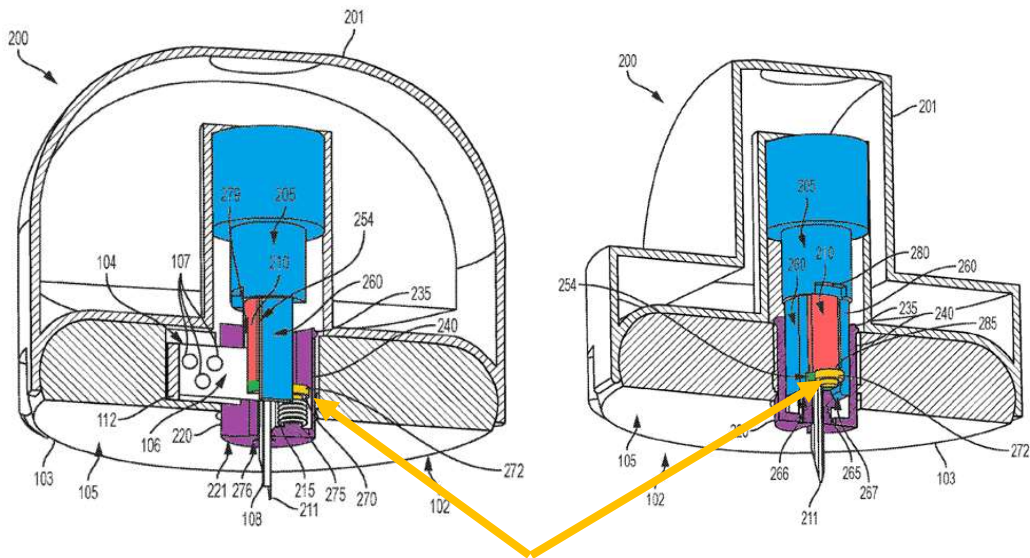


FIG. 4B

anti-rotation feature
comprising a key

FIG. 4D

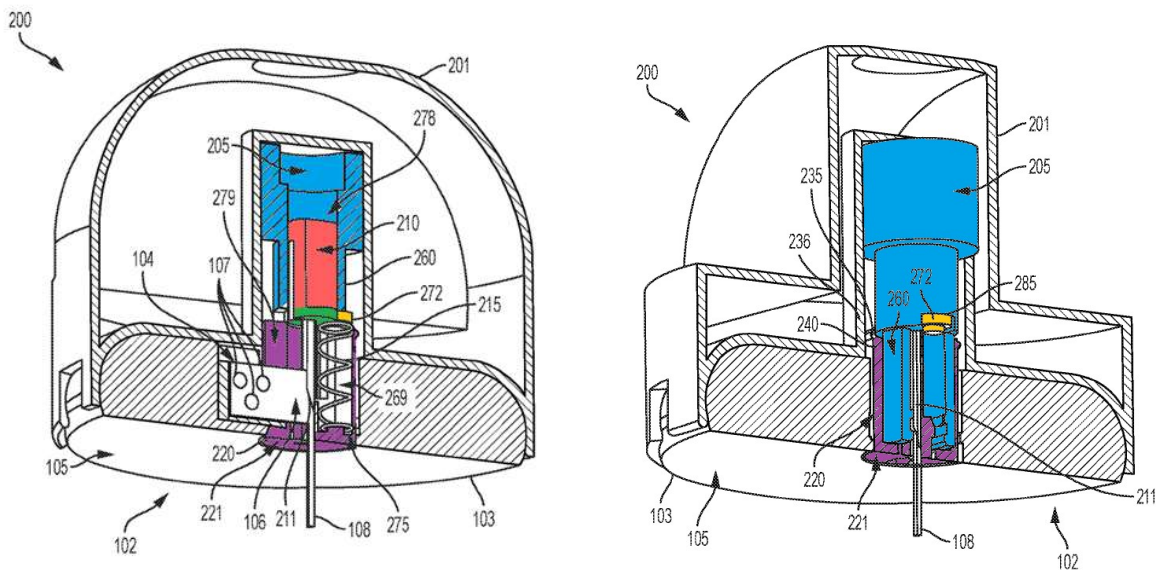


FIG. 5B

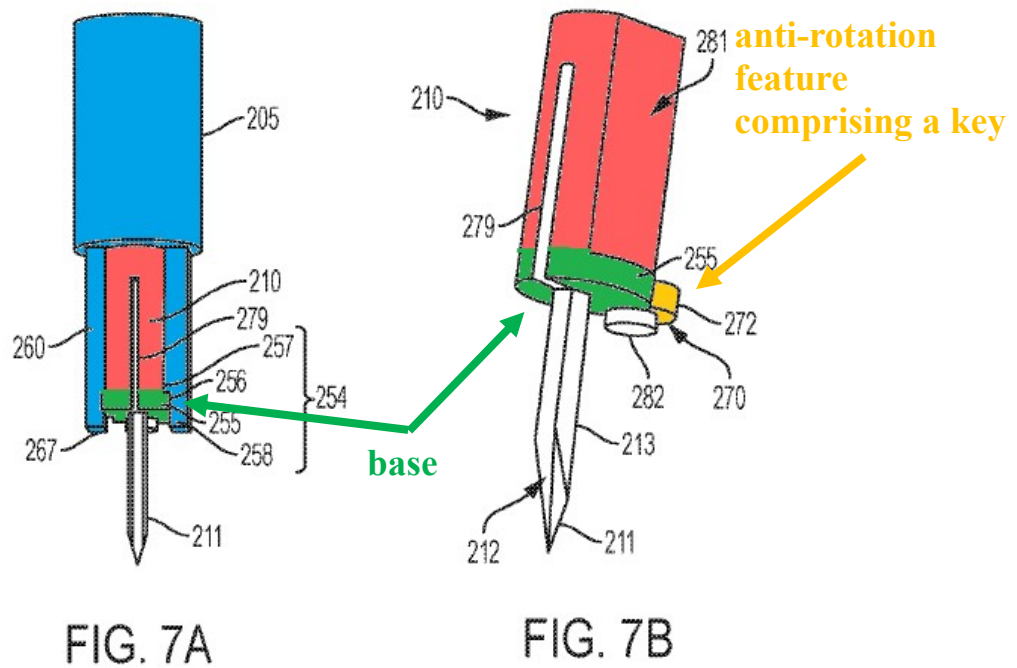
FIG. 5D

Id. at Figs. 3B-5D.

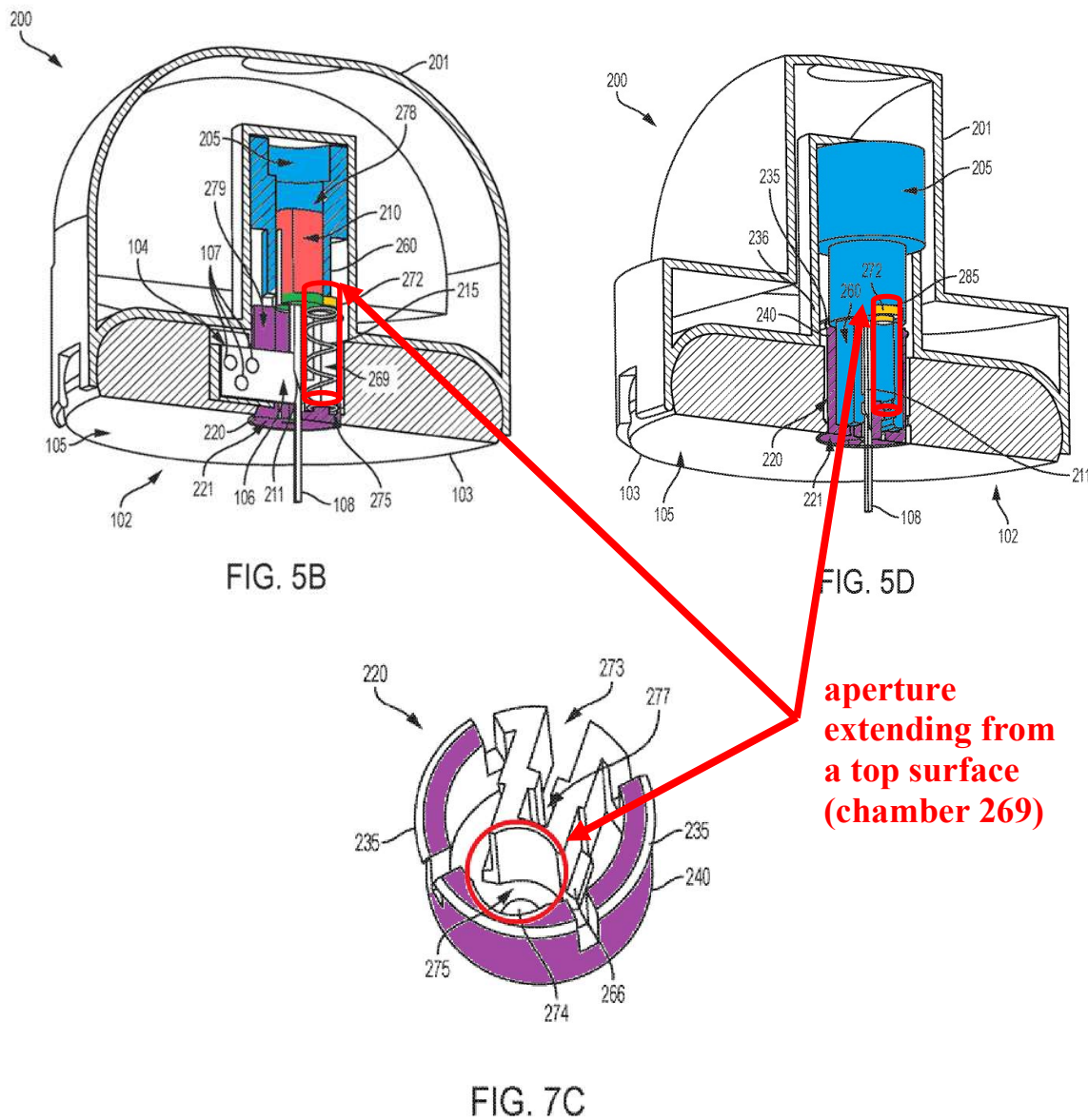
45. In Figures 3B-3D, the shroud 220 (annotated in purple) extends below the bottom surface of the housing 103 to protect the sharp 211 and a portion of the sensor 108. *Id.* at Figs. 3B-D, [0056]-[0057]. As the applicator is pressed to the

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

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



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



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

47. Pace 2 also discloses a CGM and applicator and is thus from the same field of endeavor as the '625 Patent.

C. Chae (Ex-1008)

48. U.S. Patent Publication No. 2020/0178899, titled "Sensor applicator assembly for continuous glucose monitoring system," to Chae et al. ("Chae") was

filed as a PCT application designating the United States on June 1, 2018, and published on June 11, 2020. Ex-1008 at Cover. Chae claims priority to two Korean priority documents, Korean Patent Application No. 10-2017-0068964 filed June 2, 2017 (“the ’964 Korean Application”) and Korean Patent Application No. 10-2018-0063368 filed June 1, 2018.

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

FIG. 1

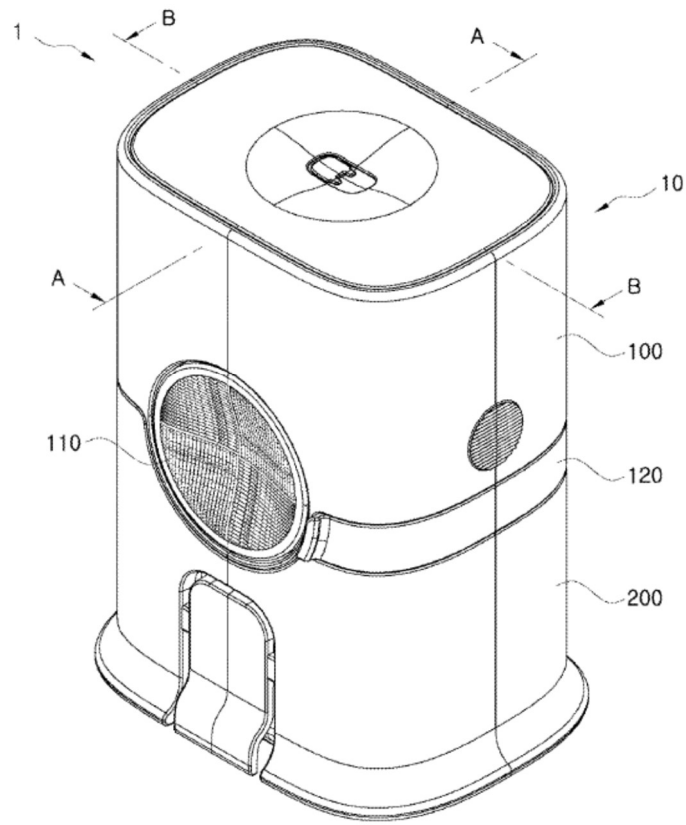
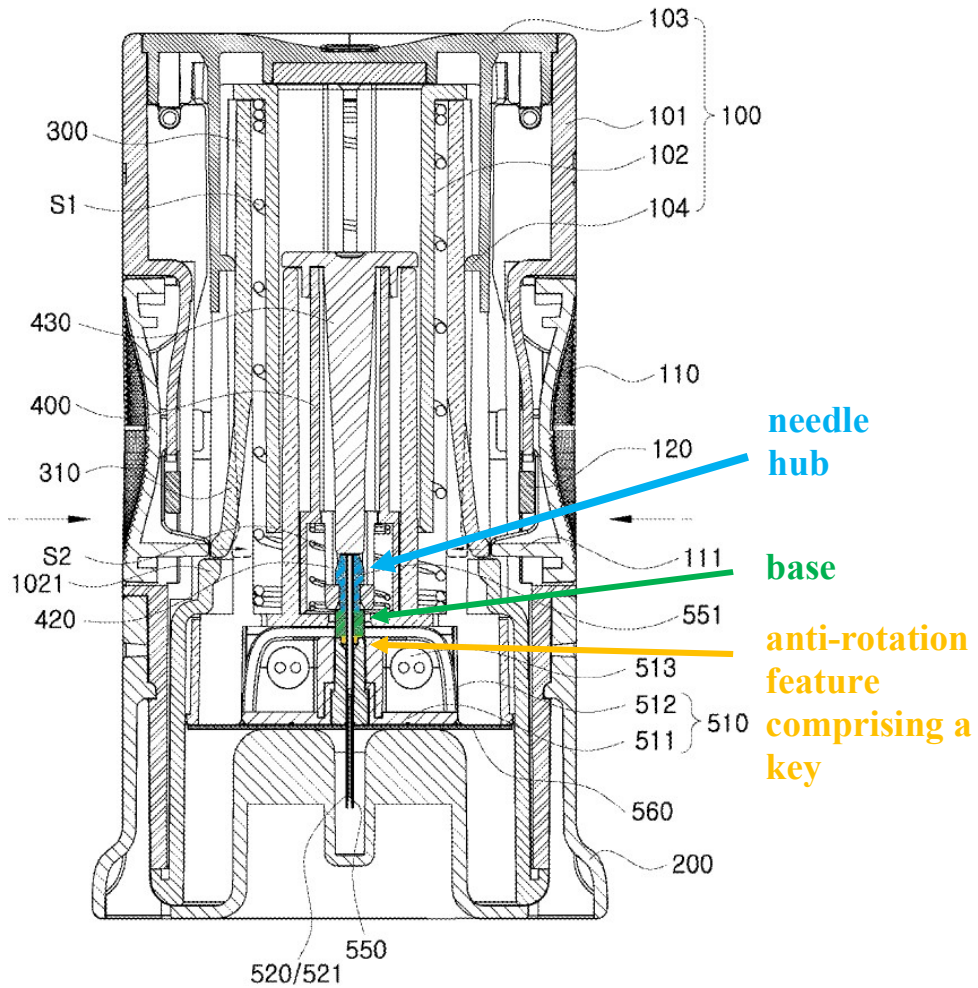


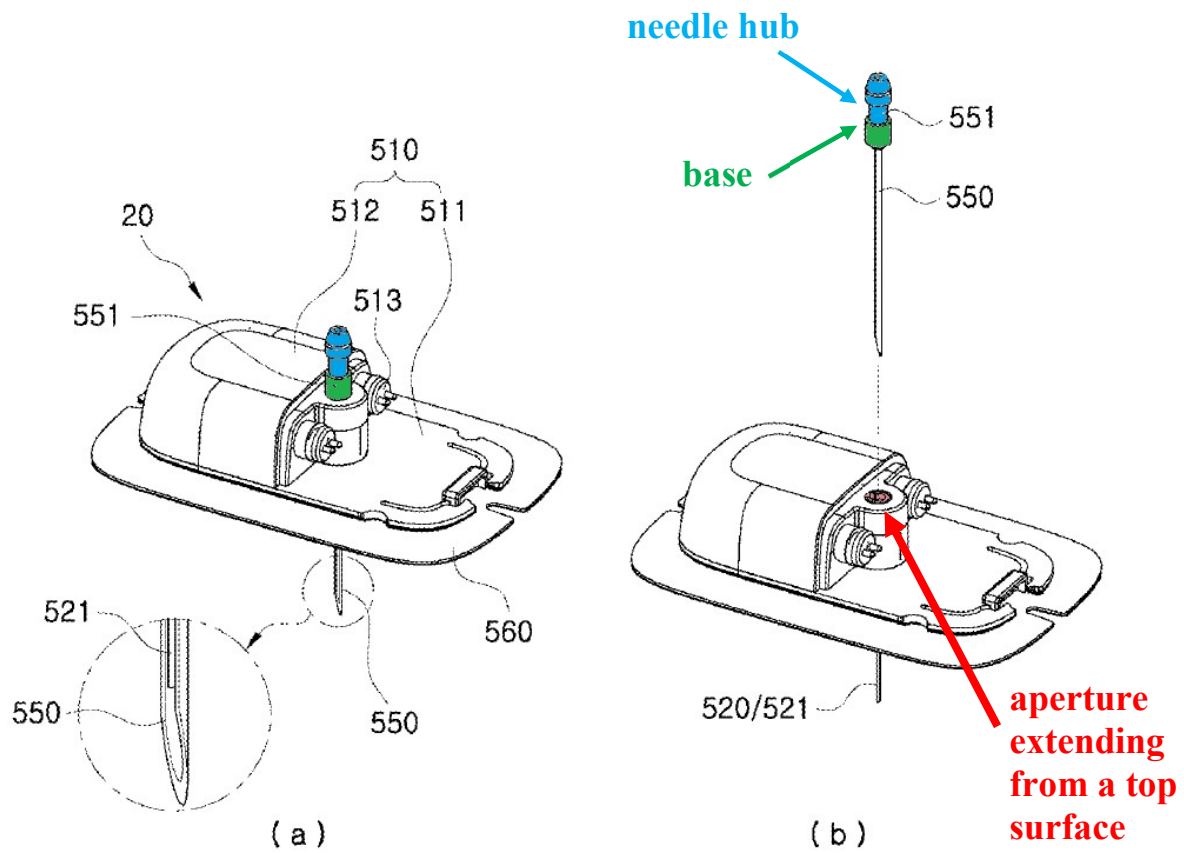
FIG. 5



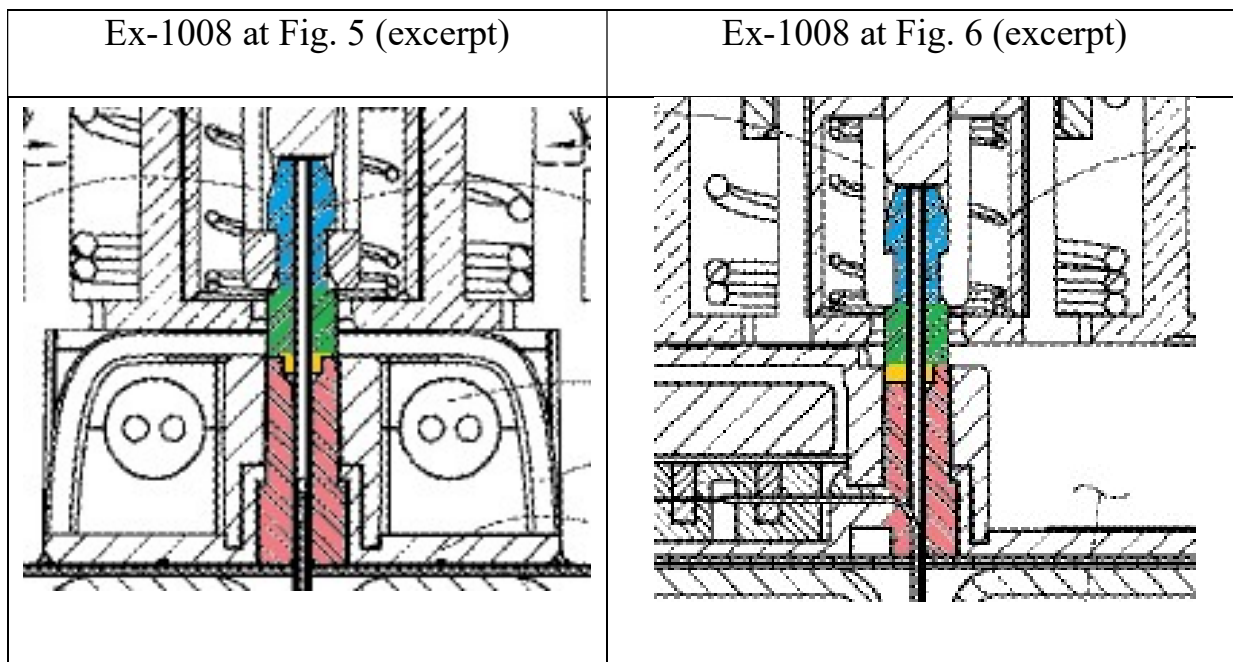
Id. at Figs. 1, 4, [0053].

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

FIG. 2



Id. at Fig. 2, [0085]. Figures 5 and 6 show that the base of the needle head 551 has a protrusion that fits into a recess in the aperture of the sensor housing:

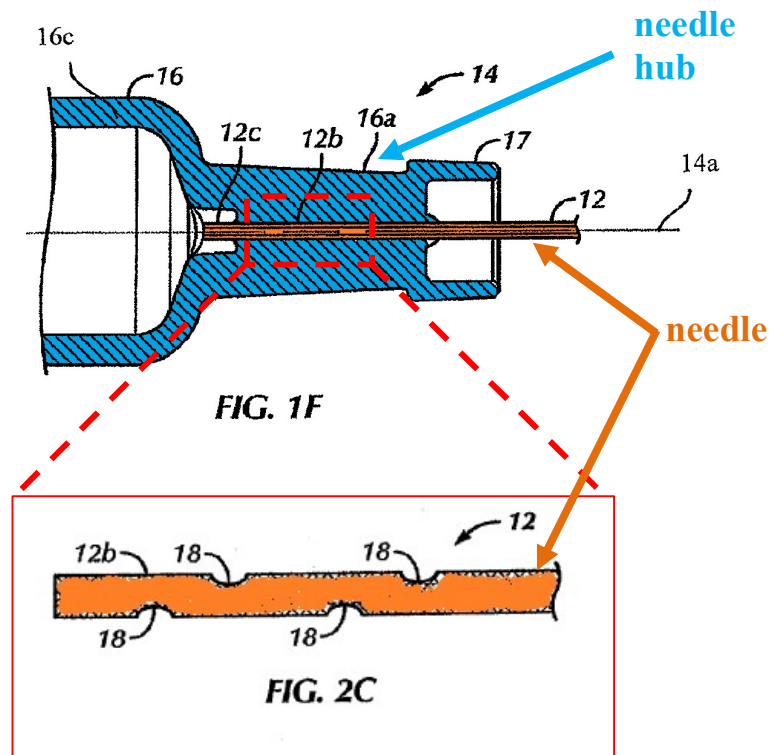


51. Chae discloses a CGM and applicator and is thus from the same field of endeavor as the '625 patent.

D. Lundquist (Ex-1011)

52. U.S. Patent Publication No. 2014/0188053, titled “Syringe With Co-Molded Hub And Cannula,” to Lundquist (“Lundquist”) was filed on March 7, 2014 as a division of U.S. Application No. 13/237,429, and published on July 3, 2014. Ex-1011 at Cover.

53. Lundquist discloses a syringe having a cannula 12 (e.g., a hollow needle) integrally formed with barrel 16, comprising “hub” 16a, by insert molding. Ex-1011 at Abstract, [0002]. Figure 2C (below) shows a fine gauge hollow metallic needle 12 with a number of notches 18 formed on its proximal end.



Id. at Figs 1F, 2C, [0039]-[0041].

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

55. Lundquist discloses a method of securing a needle to a hub in a medical device and is thus reasonably pertinent to the problem with which the '625 patent inventors were involved, namely securing a needle to a needle hub in a medical device.

E. Summary Chart

56. Attached hereto as Appendix A is a chart summarizing the embodiments in the prior art discussed above.

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.

- 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.

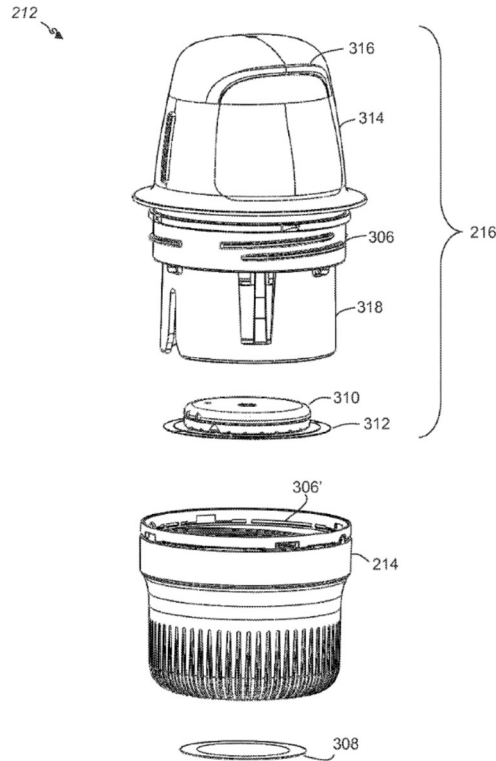


FIG. 3

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:

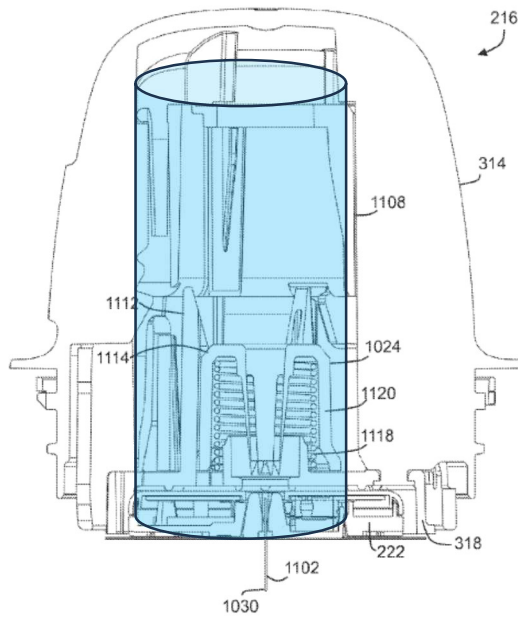


FIG. 11C

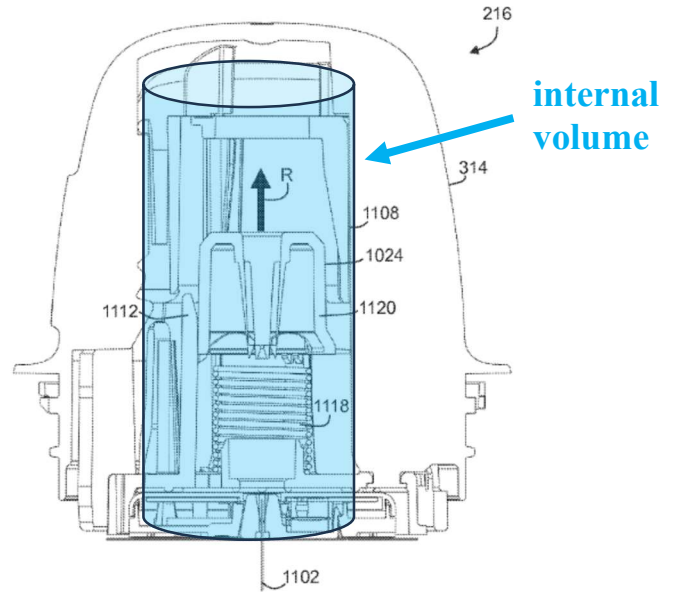


FIG. 11D

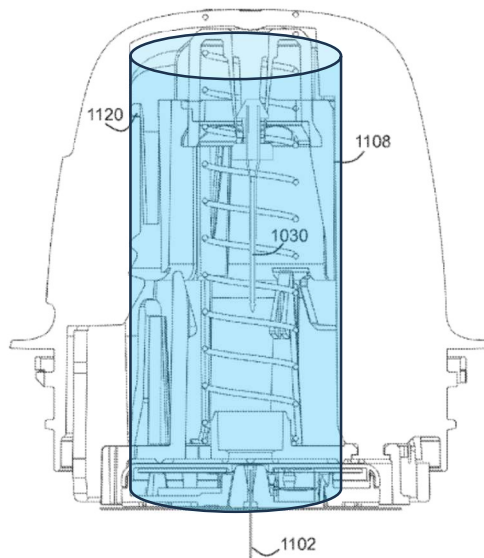


FIG. 11E

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].

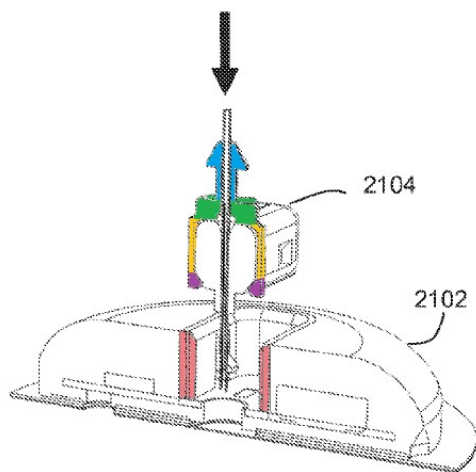


FIG. 21A

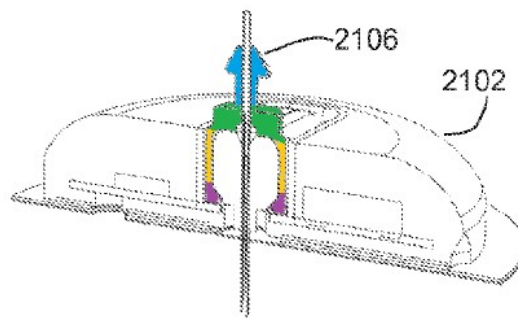


FIG. 21B

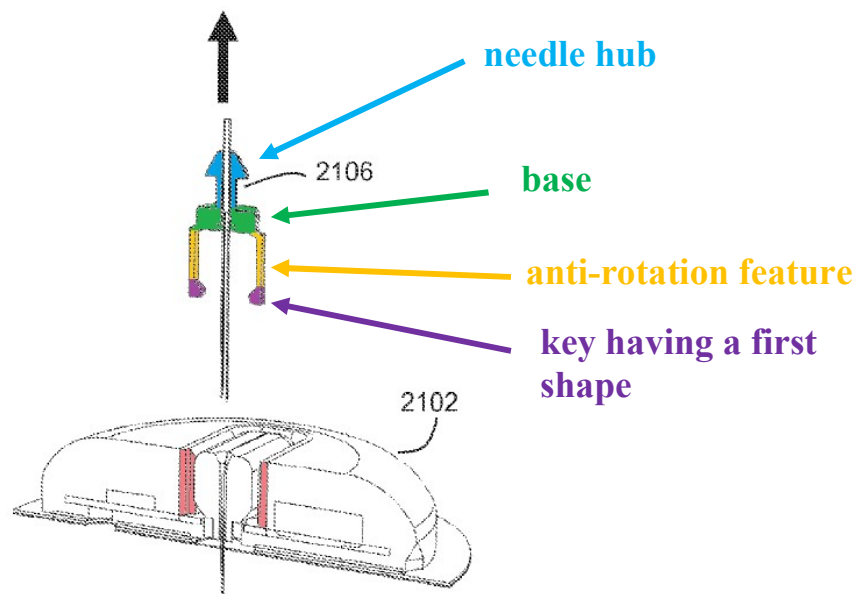


FIG. 21C

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.”

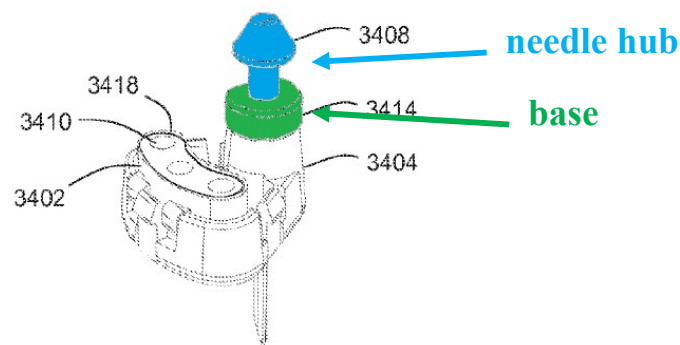
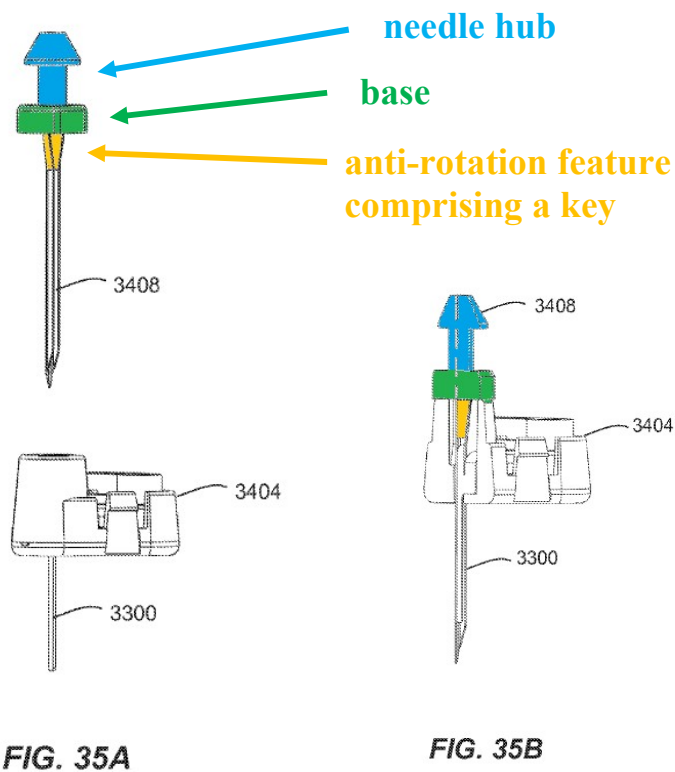
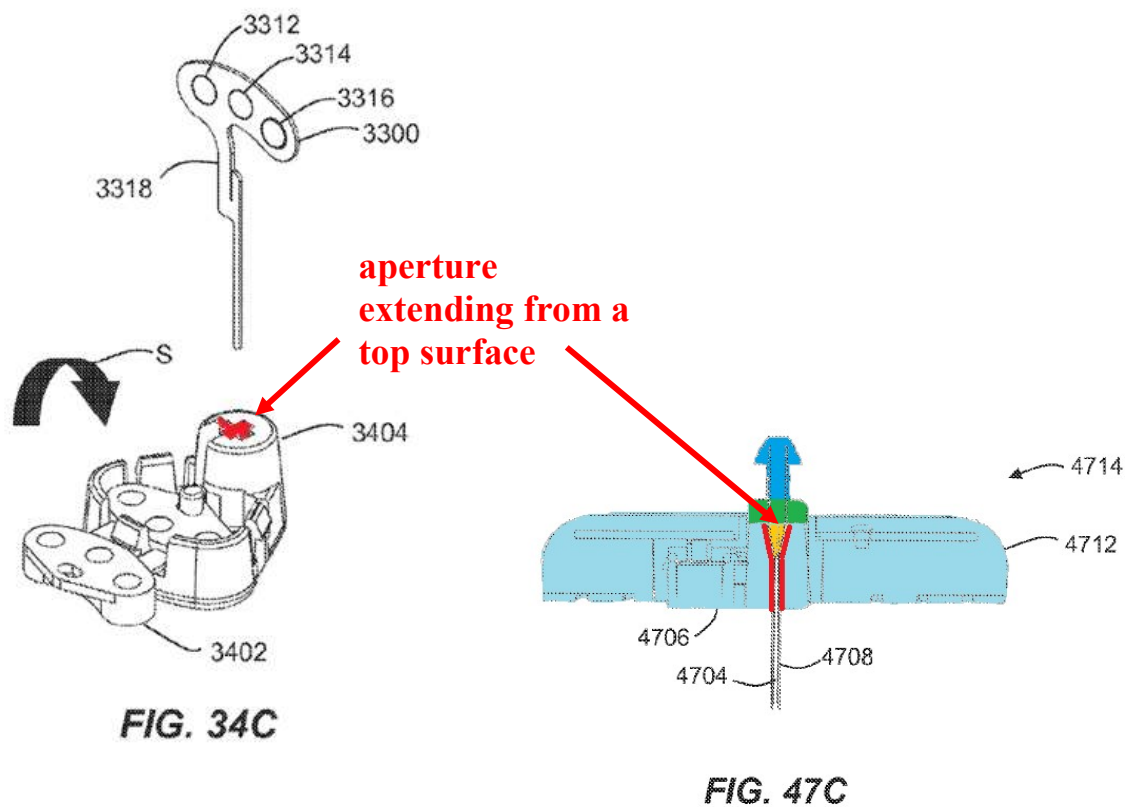


FIG. 34D



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).



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, which necessarily prevents rotation of the sharp hub relative to the on-

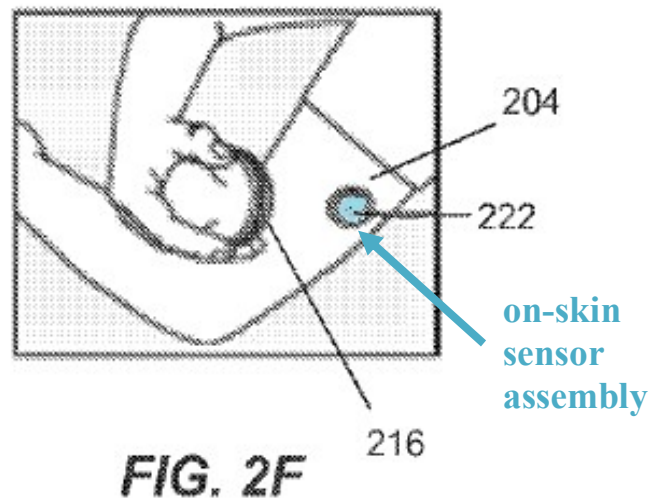
body device. The V-shaped portion has a rectangular cross section and slots into the cross-shaped aperture in connector support 3404 in Figure 34C, which is internally tapered to complement the V-shaped portion as seen in Figures 35B and 47C.

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. 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. Because hub 2106 is directly coupled to the needle, it therefore would have been obvious to restrain the rotation of hub 2106 relative to the on-skin sensor assembly 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. *See infra* claims 1.8-1.11.

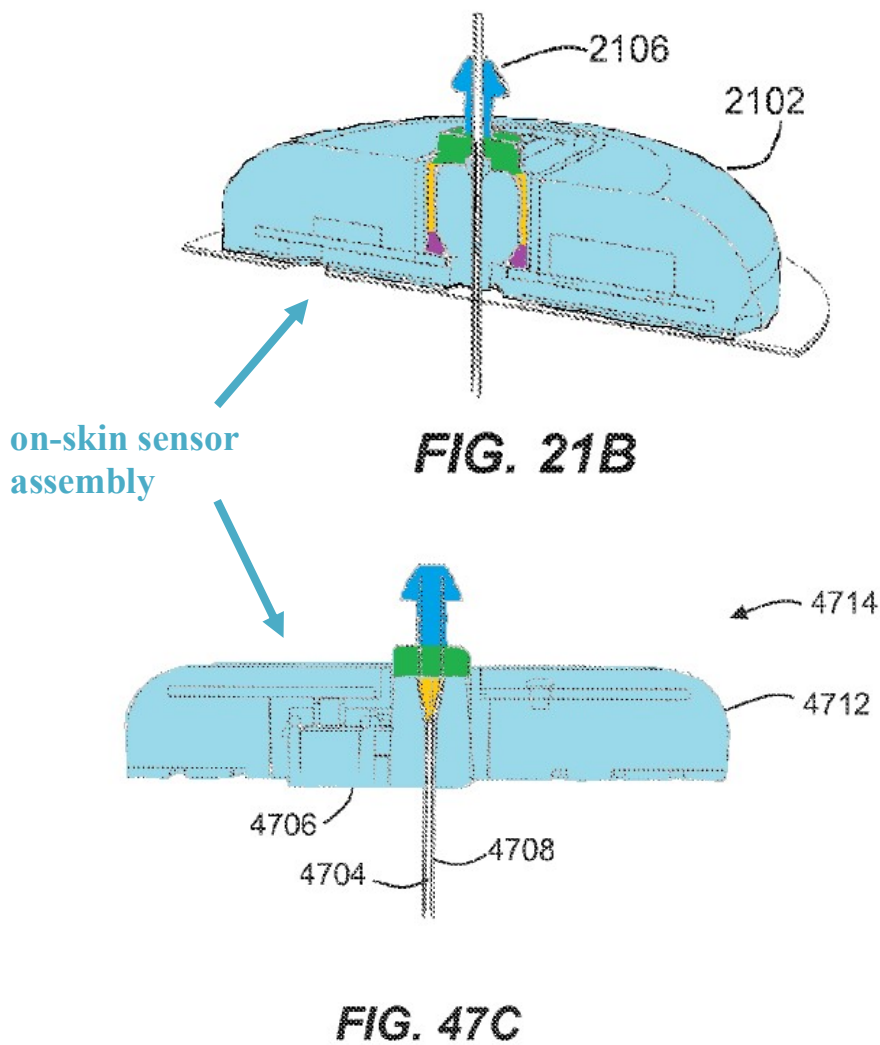
d. 1.6 “an on-skin sensor assembly comprising:”

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.



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).



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”

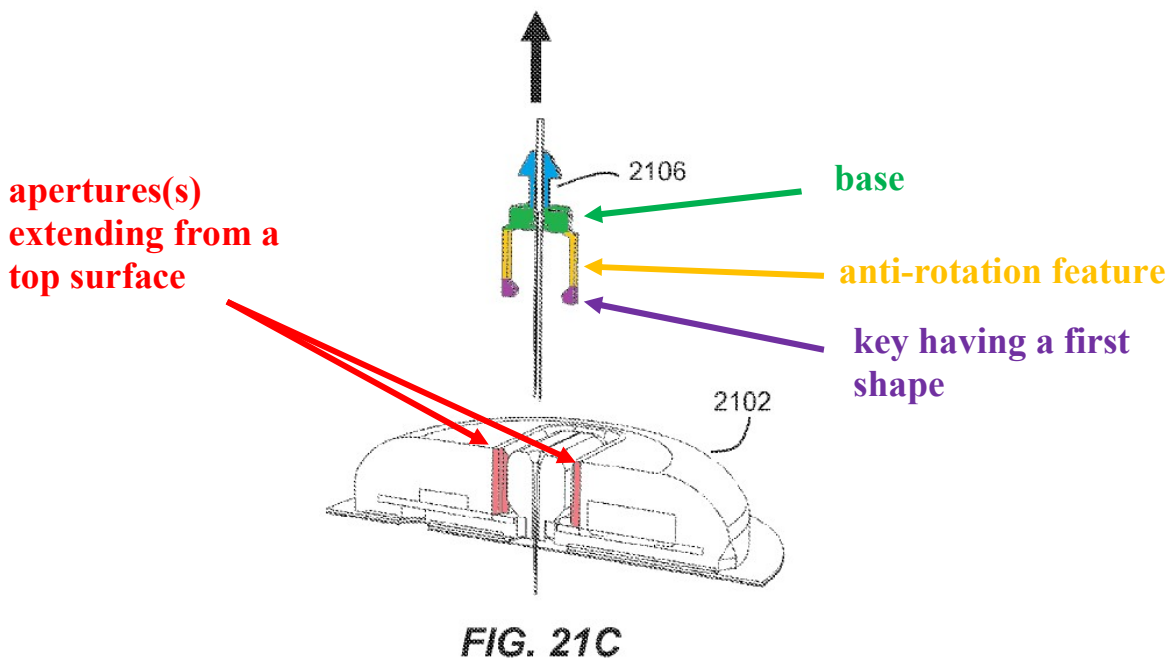
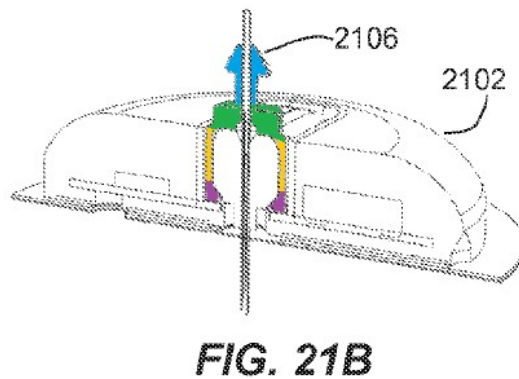
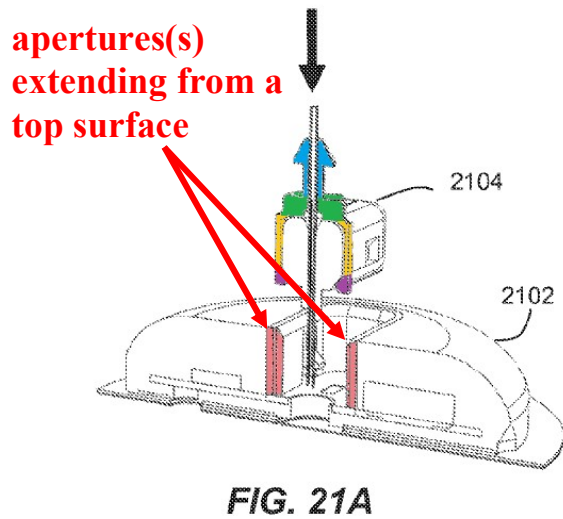
67. Pace discloses the sensor assembly (part of the on-body device 222, *i.e.*, the “on-skin sensor assembly”) includes an analyte sensor such as a “glucose sensor.” Ex-1006 at [0007]-[0008]; *see also Id.* at [0133] (the sensor contacts the interstitial fluid to “measure the analyte concentration”).

- 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”

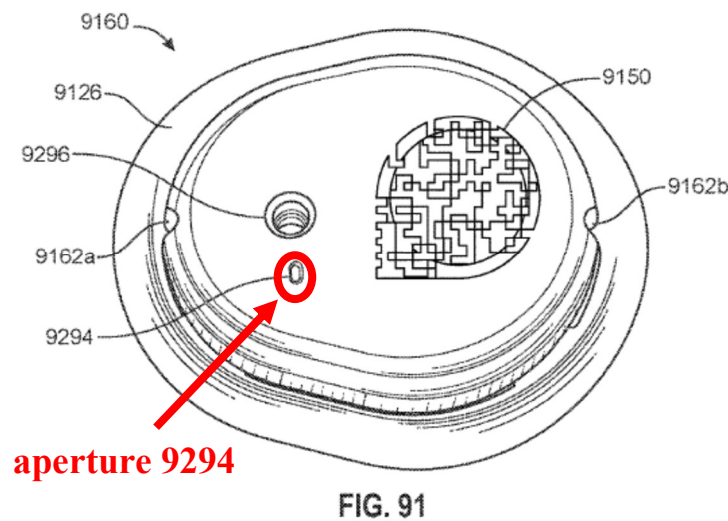
1.10 “wherein the key of the anti-rotation feature is configured to be at least partially disposed in the aperture of the on-skin sensor assembly;”

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:



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 in the '625 patent

are offset from the aperture through which the needle passes:



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:

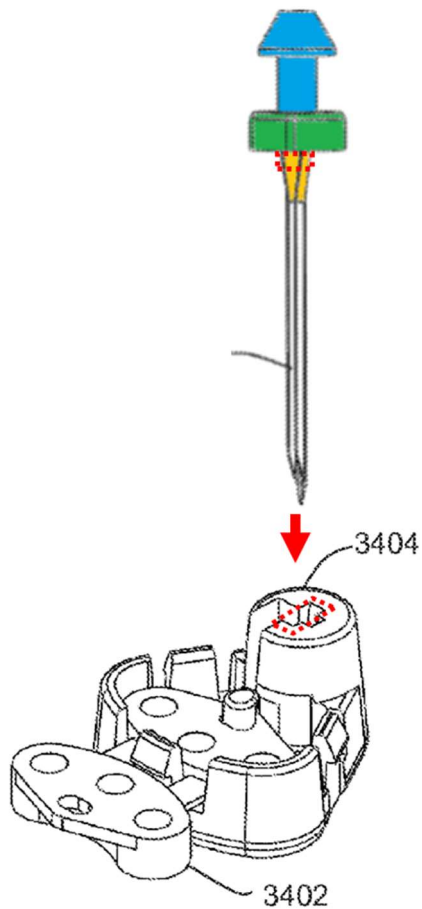


FIG. 34B

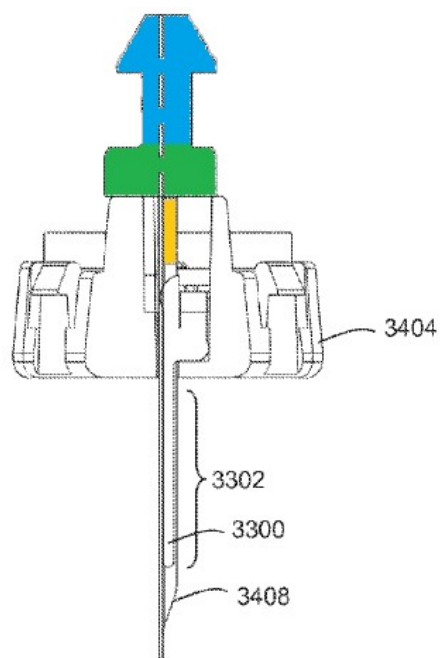


FIG. 35C

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

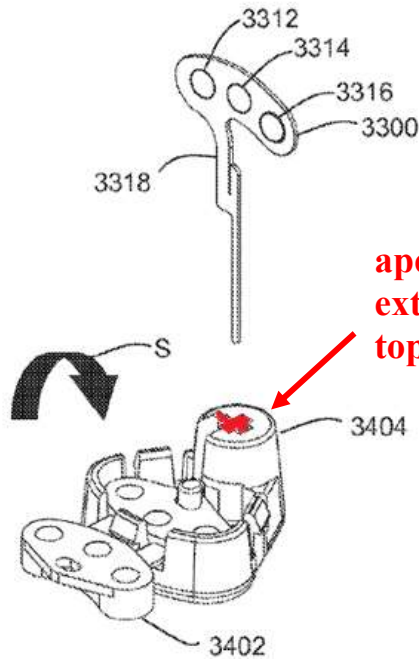


FIG. 34C

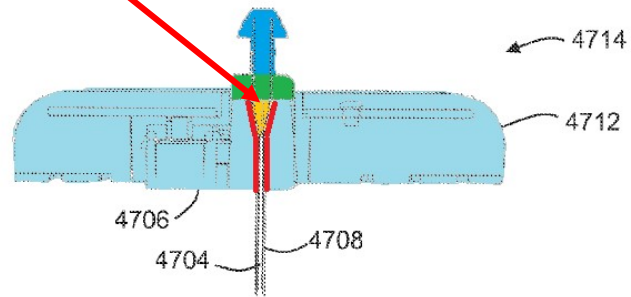


FIG. 47C

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.

- 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.

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.

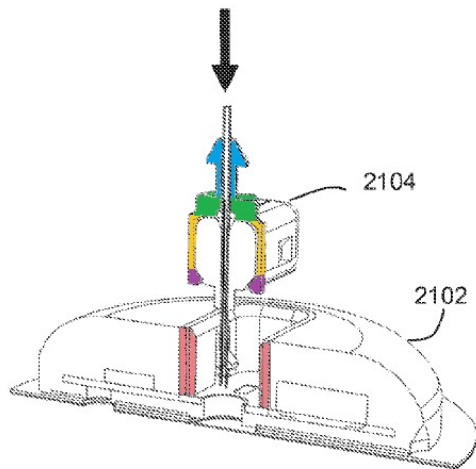


FIG. 21A

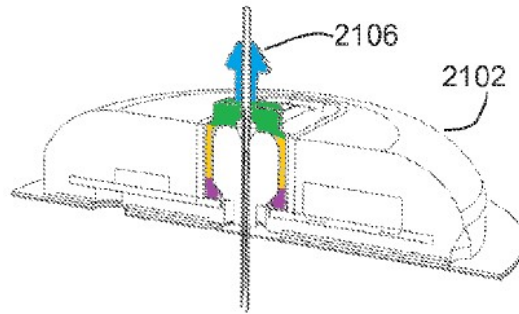


FIG. 21B

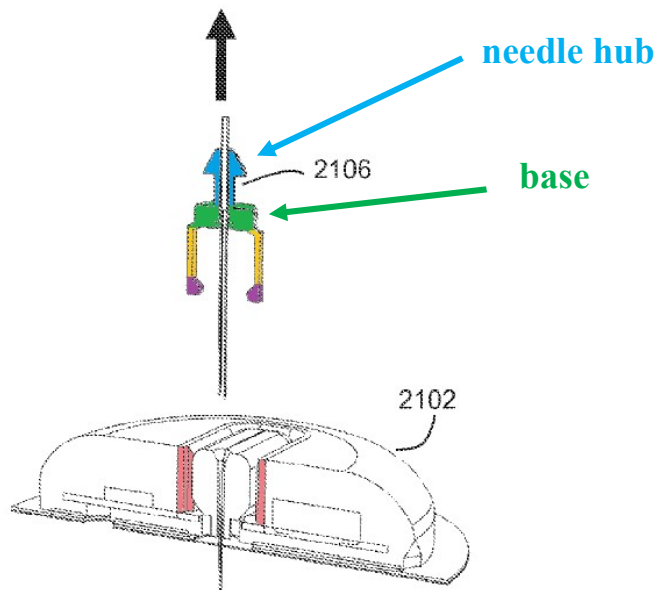


FIG. 21C

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):

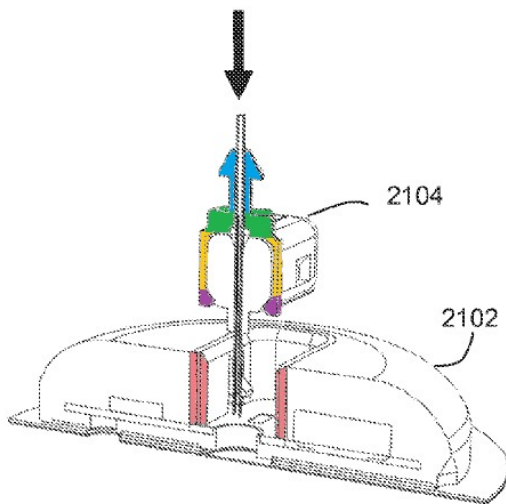


FIG. 21A

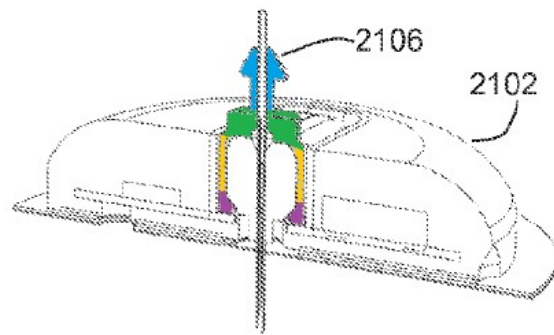


FIG. 21B

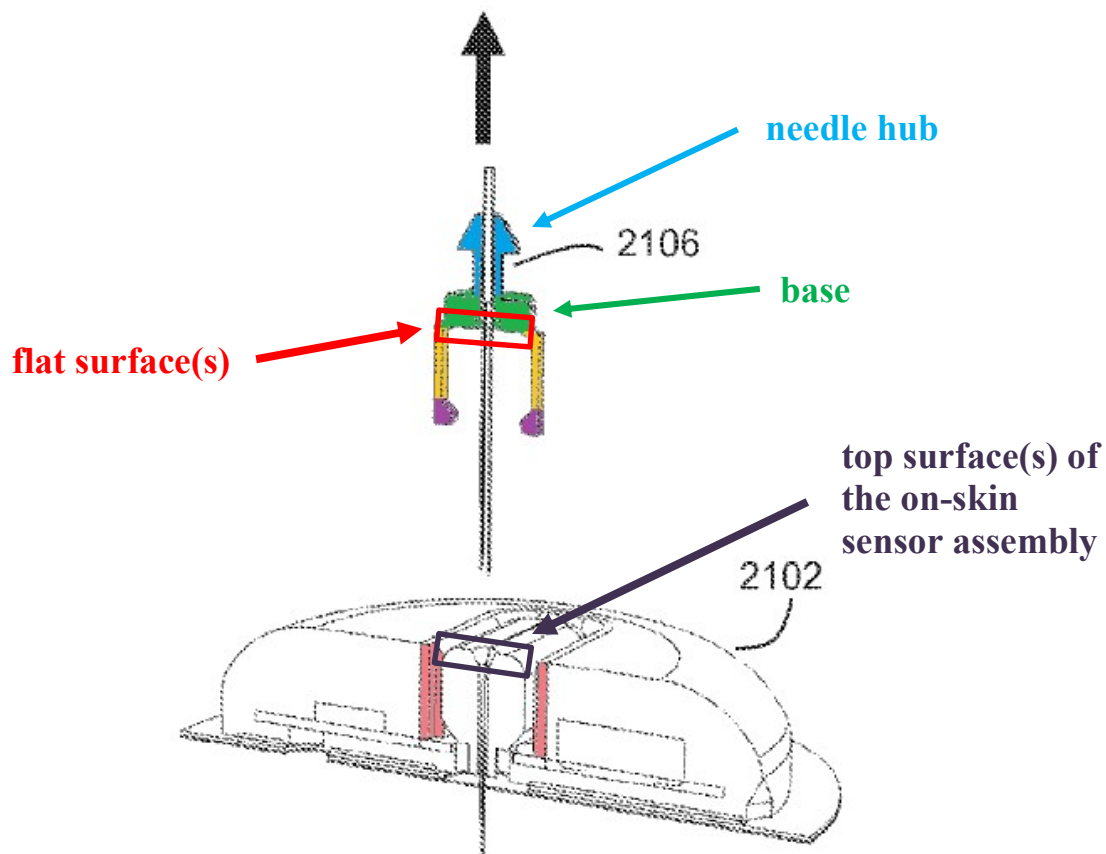


FIG. 21C

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:

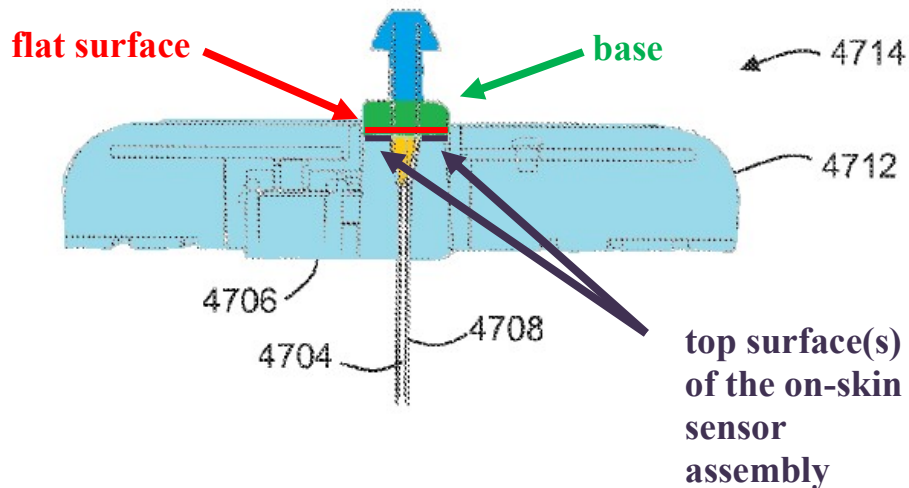


FIG. 47C

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

4. Independent Claim 28

90. In my opinion, Pace anticipates or renders obvious claim 28, as explained below.

- 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 connected with the electronics assembly 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. at [0077]; *see also Id.* at Figs. 1, 10I-M, [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 the complete on-body device, meaning the sensor assembly 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:

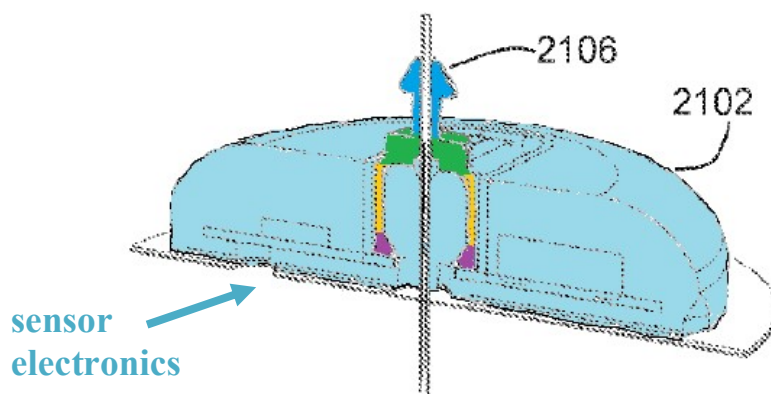


FIG. 21B

Id. at Figs. 21B, [0123]. Similarly, in embodiment B the sharp is configured to be inserted through the electronics assembly 4712:

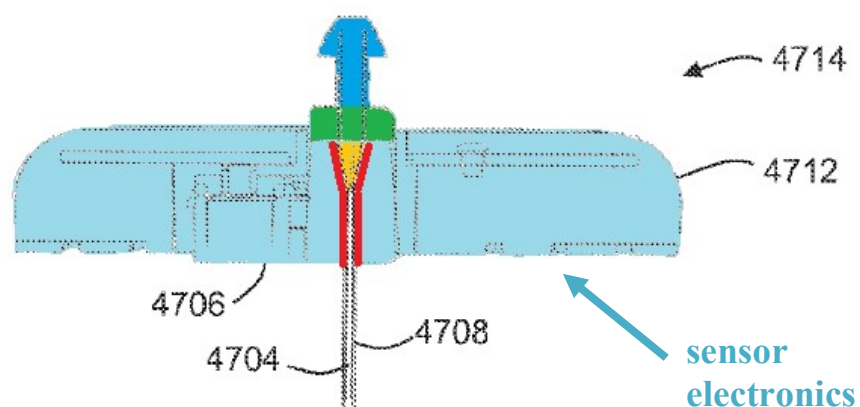


FIG. 47C

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. 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:

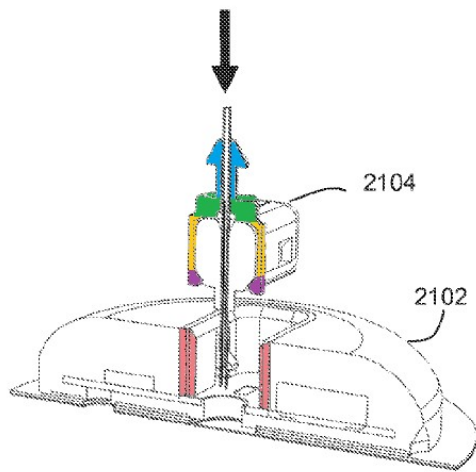


FIG. 21A

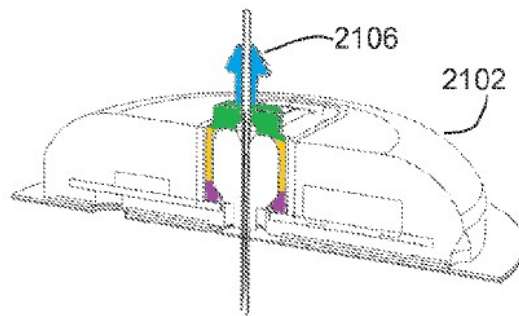


FIG. 21B

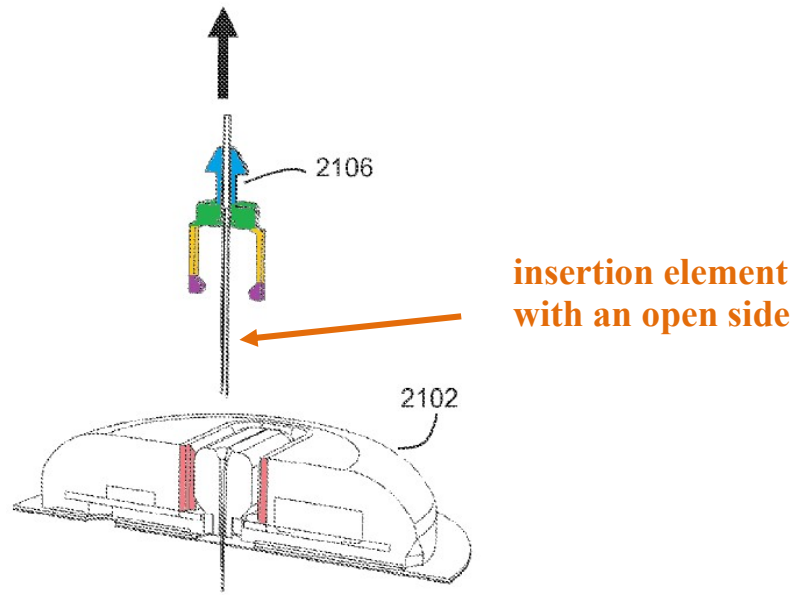


FIG. 21C

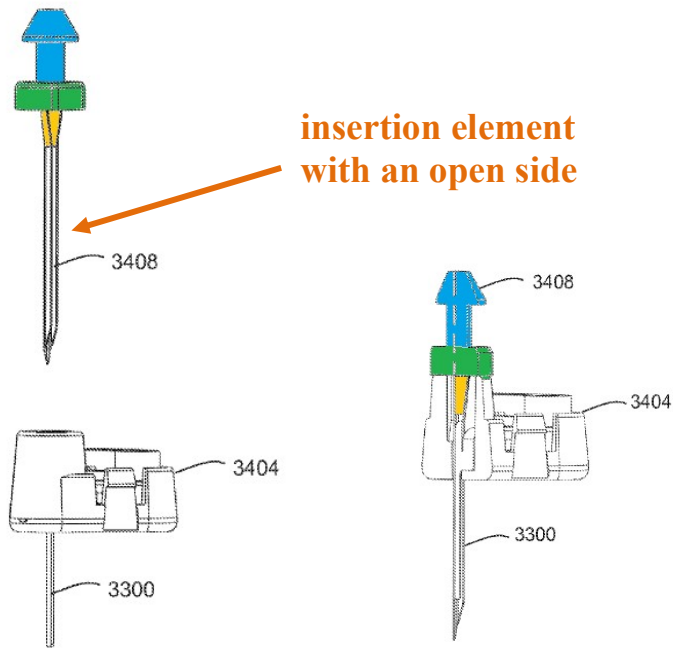


FIG. 35A

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.

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.”

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

7. Claims 4, 14, 26, & 30

103. In my opinion, Pace anticipates or renders obvious claims 4, 14, 26, and 30, as explained below. 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.”

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.

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.”).

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

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).

108. A POSITA would understand that heat staking could similarly be used to couple the needle to the needle hub.

8. Claims 5, 15, & 27

109. In my opinion, Pace anticipates or renders obvious claims 5, 15, and 27, as explained below. 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.”

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. Thus Pace discloses or suggests a needle comprising a locking element configured to couple the needle to the needle hub.

111. As discussed above for claims 4, 14, 26, and 30, Pace discloses coupling the needle to the needle hub by insert molding. *See, supra*, claims 4, 14, 26, and 30.

9. Claims 6 & 16

112. In my opinion, Pace anticipates or renders obvious claims 6 and 16, as explained below. 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].”

113. *See, supra*, claim 28.10.

10. Claims 7, 17, & 29

114. In my opinion, Pace anticipates or renders obvious claims 7, 17, and 29, as explained below. 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.”

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”:

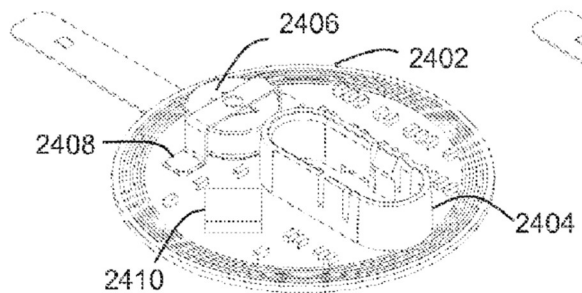


FIG. 24A

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].

116. Pace further discloses:

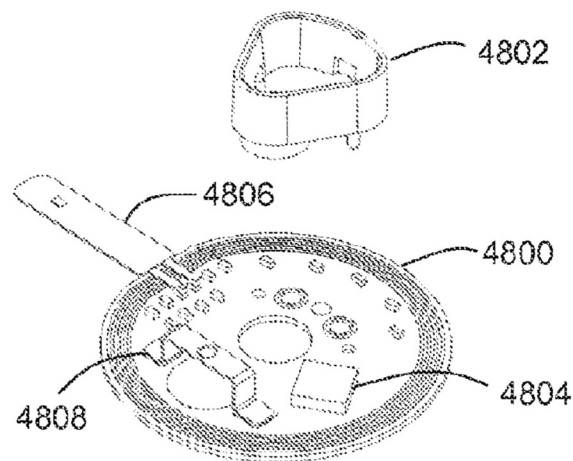


FIG. 48A

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].

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. 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.”).

11. Claims 8 & 18

118. In my opinion, Pace anticipates or renders obvious claims 8 and 18, as explained below. 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.”

119. *See, supra*, claim 28.10.

12. Claim 9

120. In my opinion, Pace anticipates or renders obvious claim 9, as explained below. 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.”

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

122. In my opinion, Pace anticipates or renders obvious claim 19, as explained below. Claim 19 depends from claim 16. *See, supra*, claim 16.

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

123. *See, supra*, claim 28.13.

14. Claim 23

124. In my opinion, Pace anticipates or renders obvious claim 23, as explained below. 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.”

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

126. In my opinion, Pace anticipates or renders obvious claim 24, as explained below. 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.”

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.

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 sharp out of the user and away from the sensor. *Id.* at [0102], [0109].

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. *Id.* at [0106] (“retracting the sharp 1030 *safely* back into the used applicator assembly 216.”).

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].

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.

132. 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 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

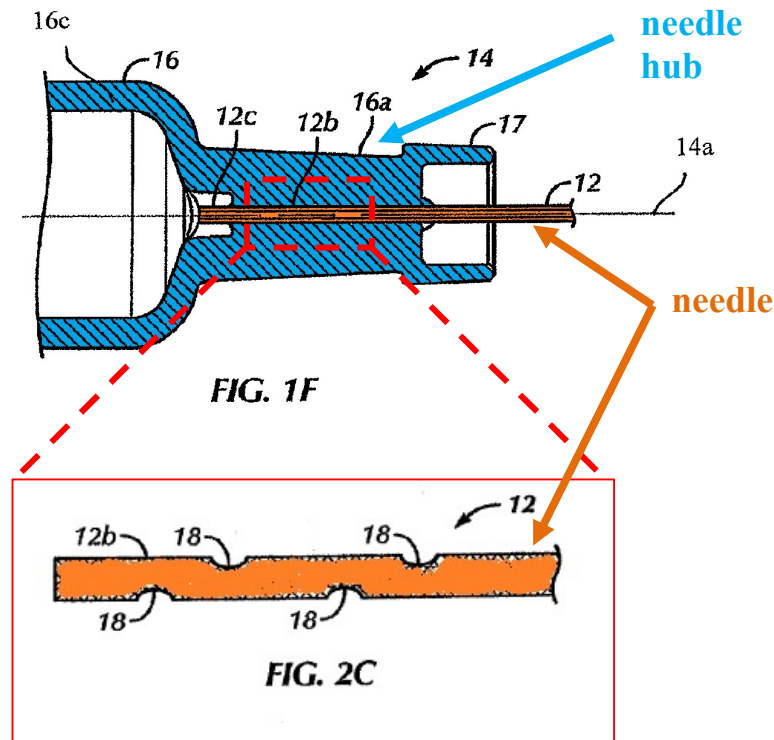
134. Claims 4, 14, 26, and 30 depend from claims 1, 13, 22, and 28, respectively. As explained in Ground 1, in my opinion Pace anticipates and renders obvious claims 1, 13, 22, and 28. In my opinion, the combination of Pace and Lundquist further renders obvious claims 4, 14, 26, and 30, as explained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

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

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.* at [0121].

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

137. Although Pace does not specifically state 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'***.

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

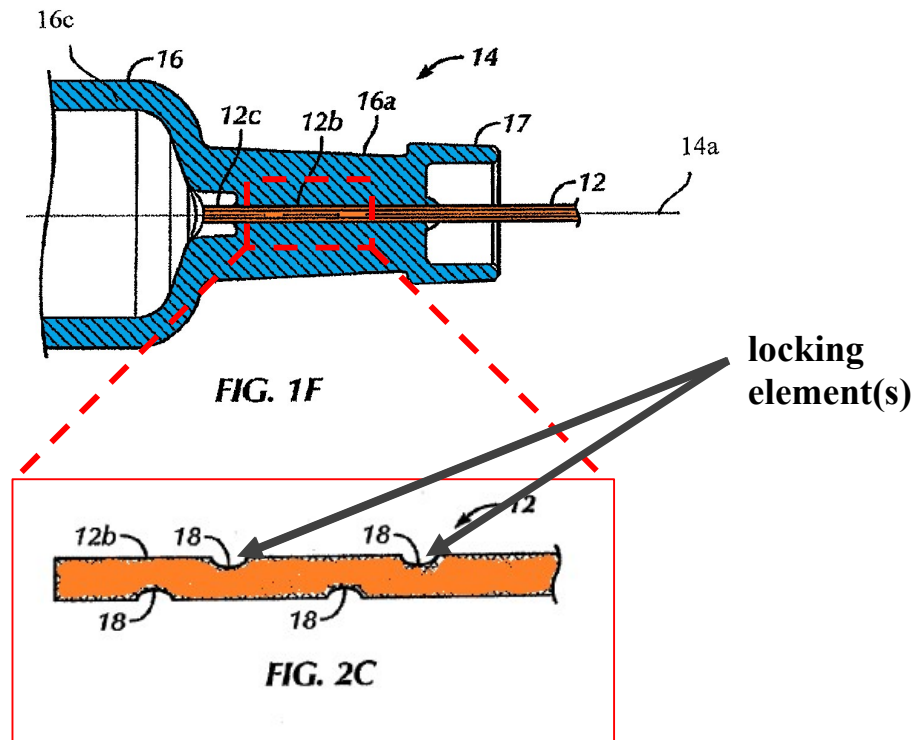
138. In the Pace-Lundquist combination, the hub (either 2106 in Figure 21 or 3414 in Figures 34, 35, and 47) and needle of Pace are coupled together by insert molding the sharp hub over the needle, as taught in Lundquist.

3. Claims 5, 15, & 27

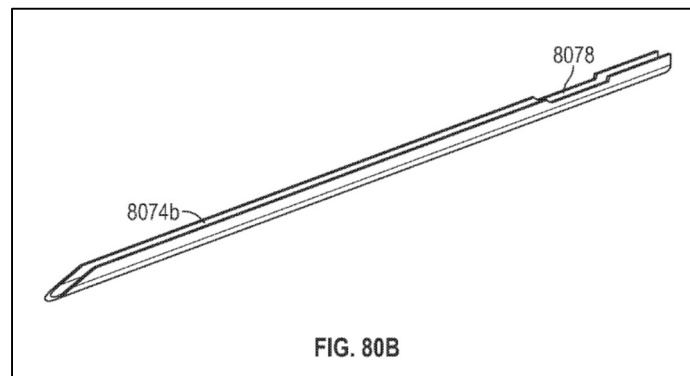
139. Claims 5, 15 and 27 depend from claims 4, 14, and 26, respectively. As explained above, in my opinion the combination of Pace and Lundquist renders obvious claims 4, 14, and 26. In my opinion, the combination of Pace and Lundquist further renders obvious claims 5, 15, and 27, as explained below

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

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 “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 Fig. 2C of Lundquist (above) with 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.”).

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

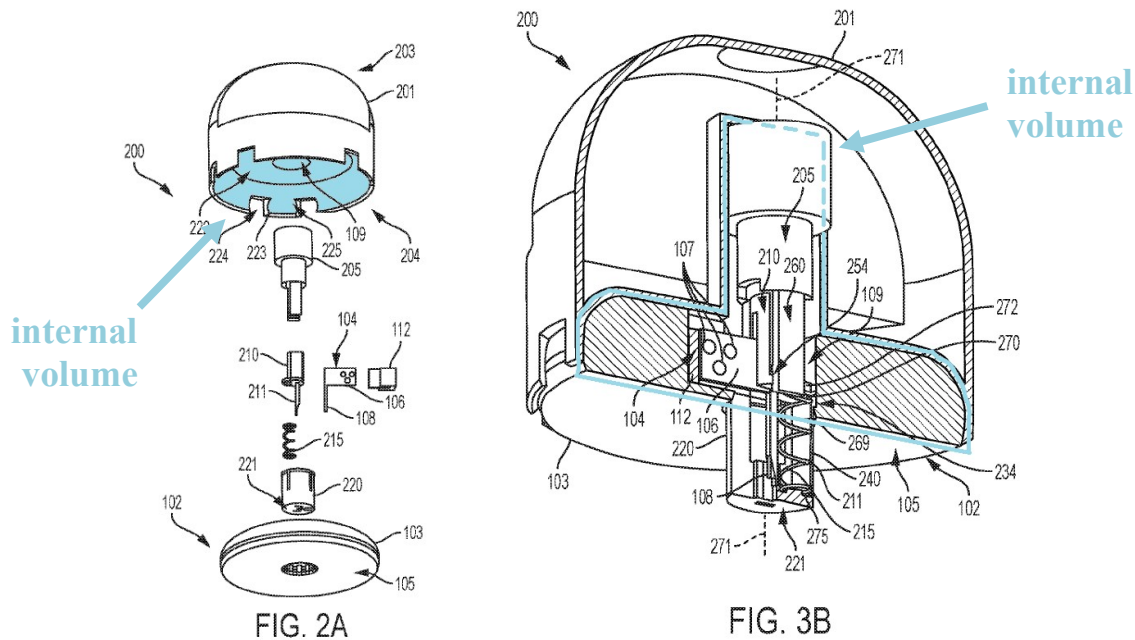
142. In my opinion, Pace 2 renders obvious claim 1, as explained below.

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

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 “an applicator housing having an internal volume;”

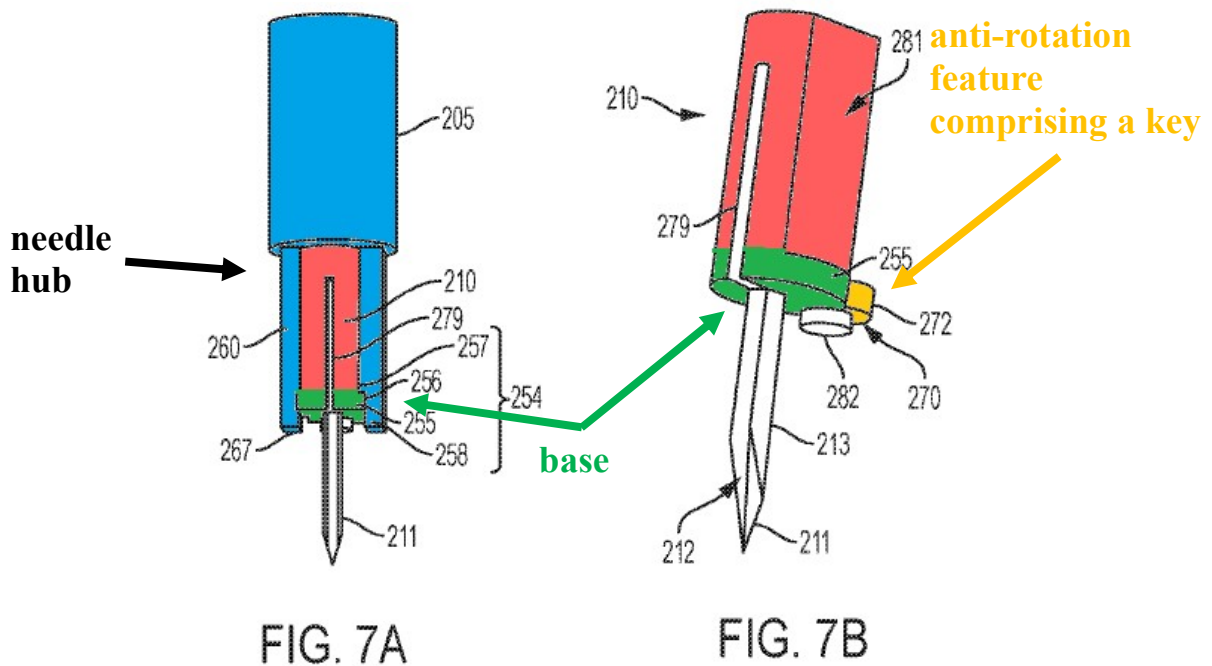
144. Pace 2 discloses an applicator housing having an internal volume. Ex-1007 at Figs. 2A, 3B, 3D, 4B, 4D, 5B, 5D, 6A. For example, as seen in Figures 2A and 3B, inserter 200 (*i.e.*, an applicator) comprises a housing 201 which has an internal volume (annotated in light blue below) for holding sensor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



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

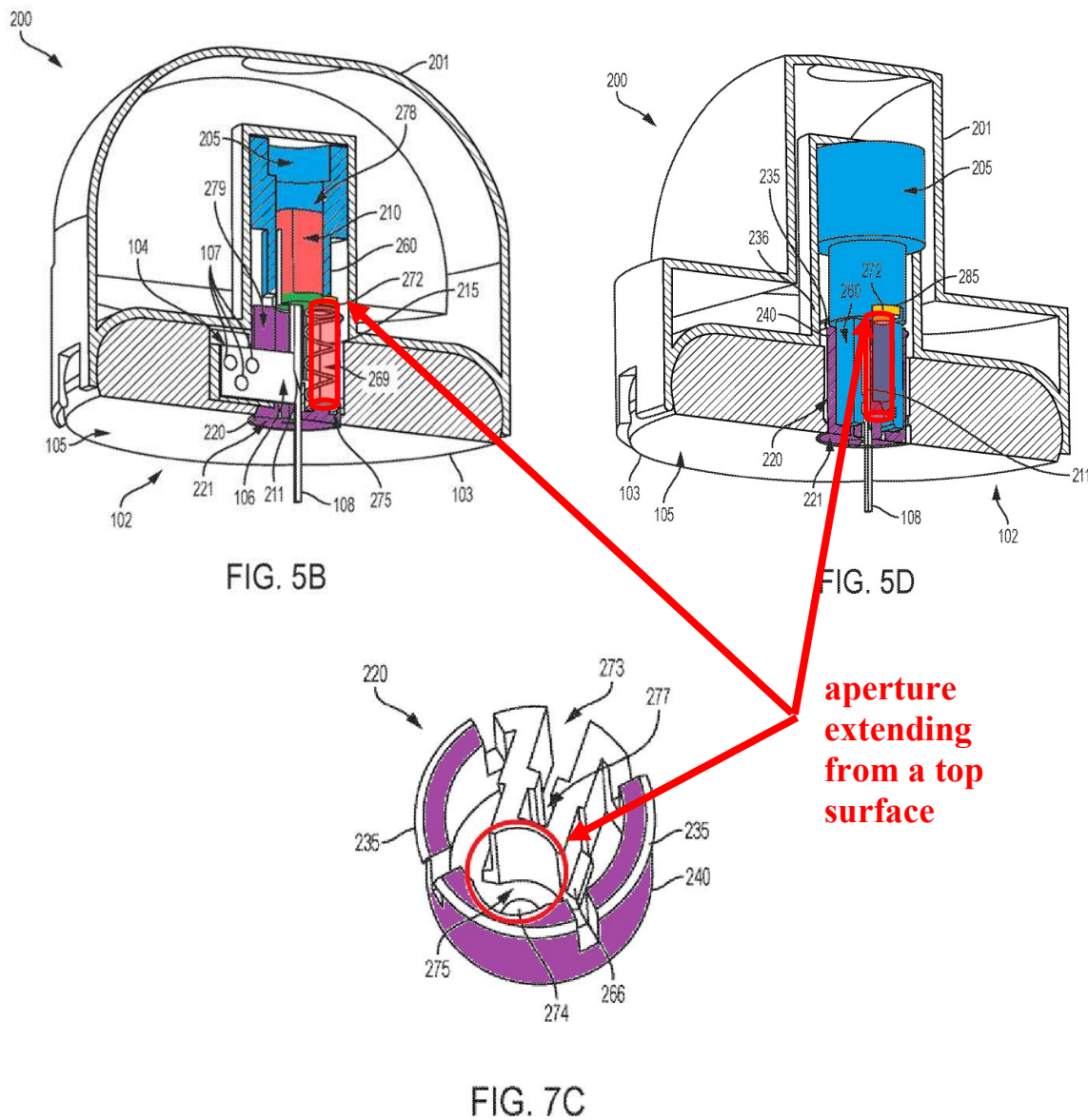
- c. 1.2 “a needle hub coupled to an insertion element configured to pierce a skin of a host, the needle hub comprising:”
- 1.3 “a base, and”
- 1.4 “an anti-rotation feature extending from the base,”
- 1.5 “the anti-rotation feature comprising a key, the key having a first shape”

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.



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).

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):



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

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 assembly, with its bottom surface flush with the bottom of the housing 103. *Id.* at [0086].

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 channel and thereby guide the motion of shroud 220, ***preventing shroud 220 from rotating or tilting during advancement and/or retraction***.

Id. at [0089].

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.

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.

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

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:”

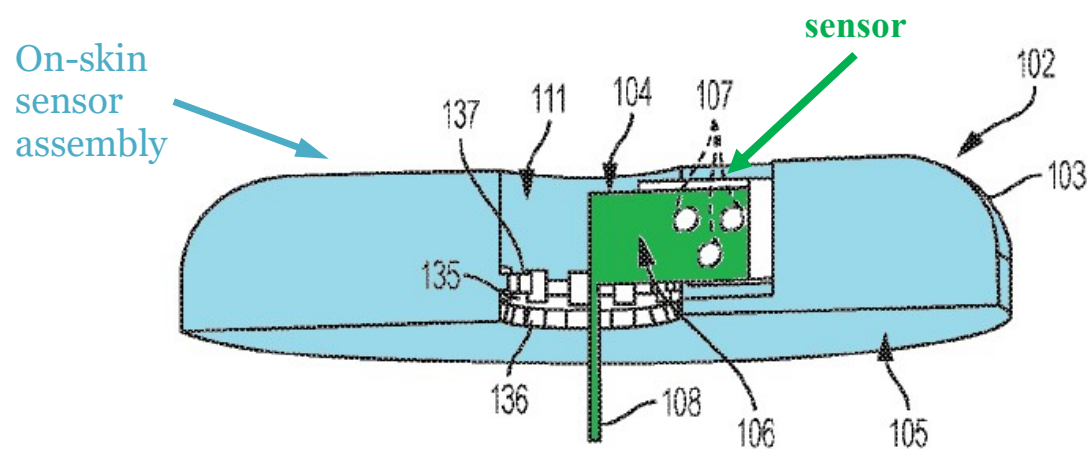


FIG. 6B

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:

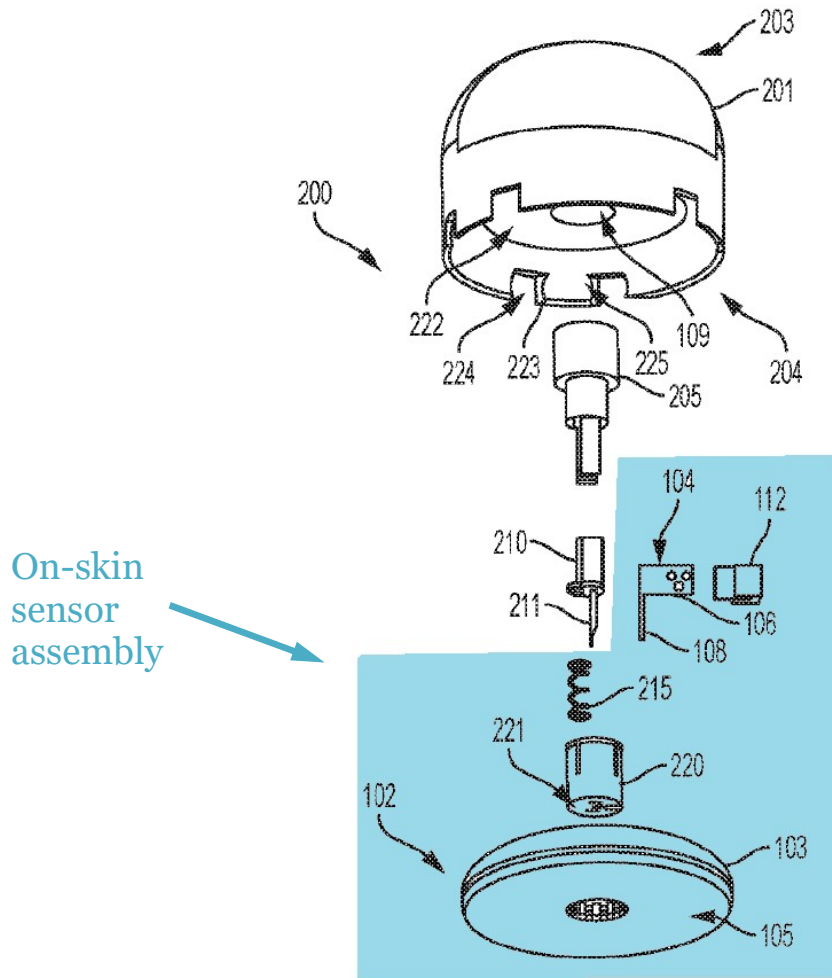


FIG. 2A

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 "a sensor, the sensor configured to measure a glucose concentration of a host, and"

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

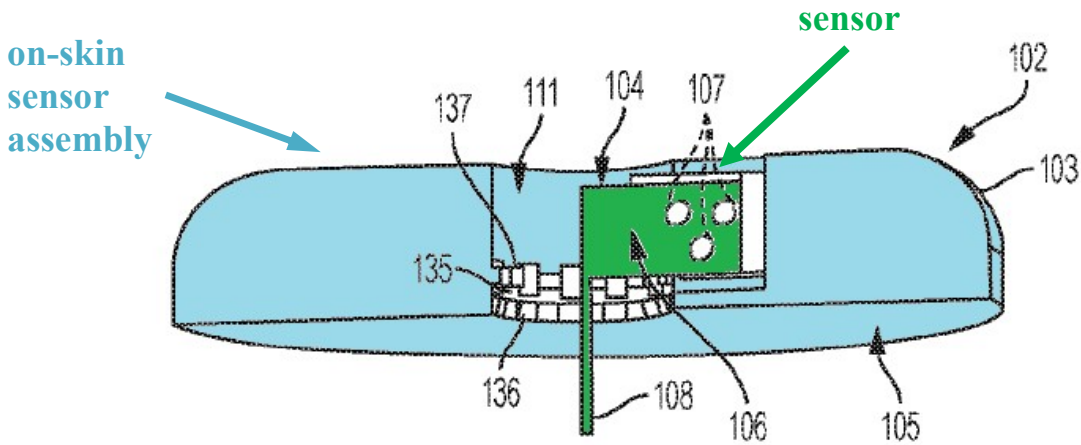


FIG. 6B

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 “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;”

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]:

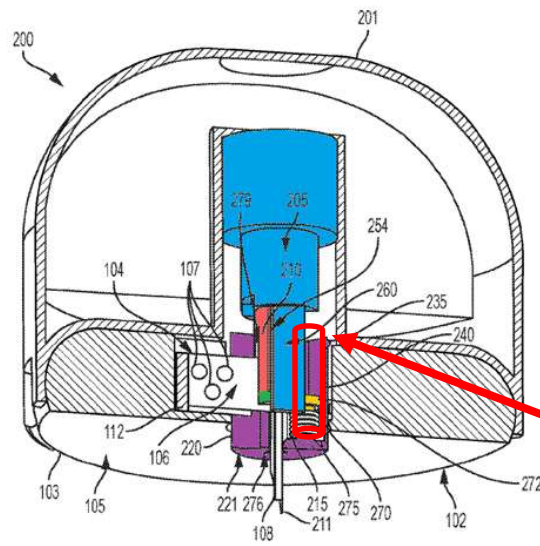
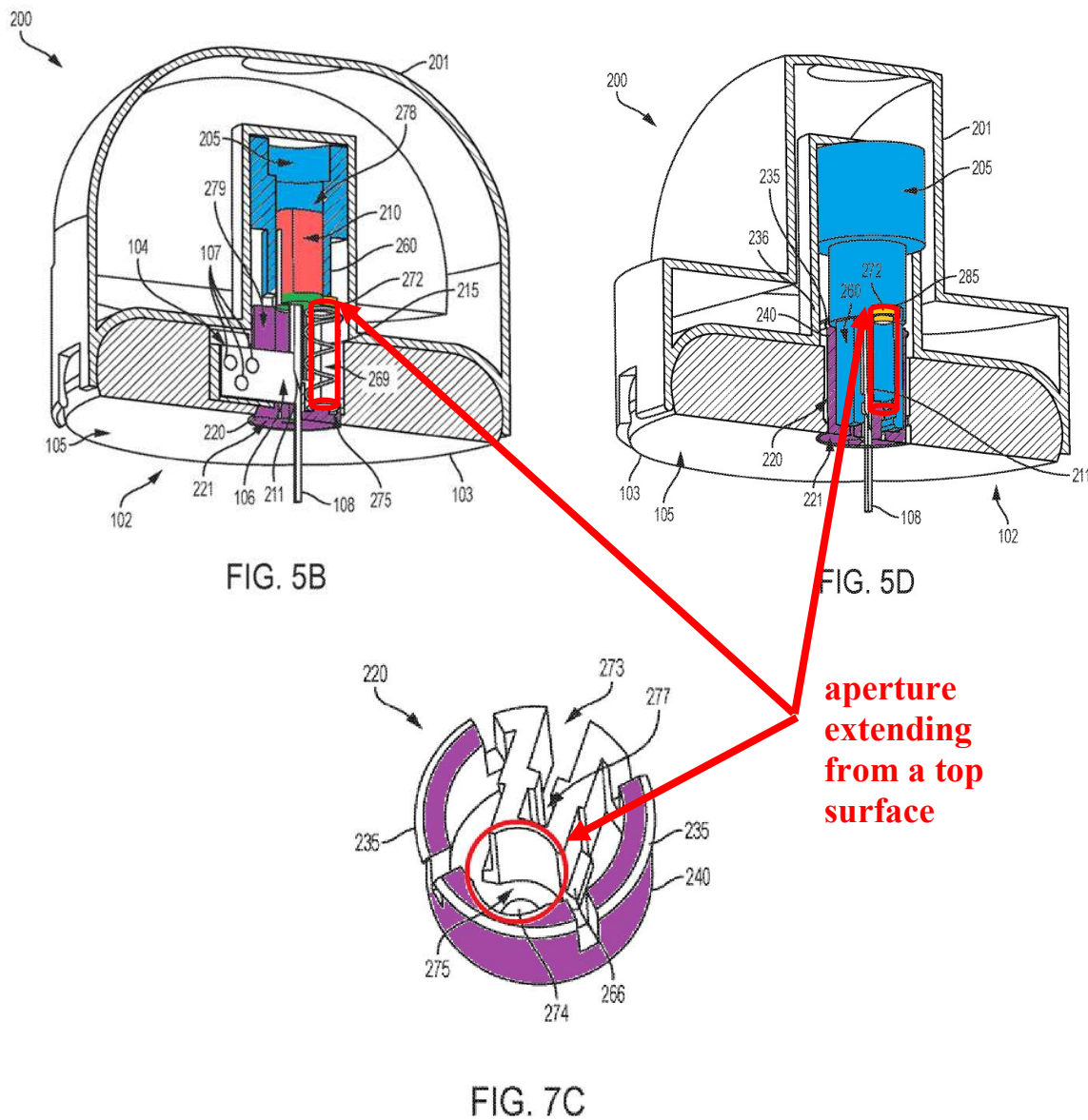
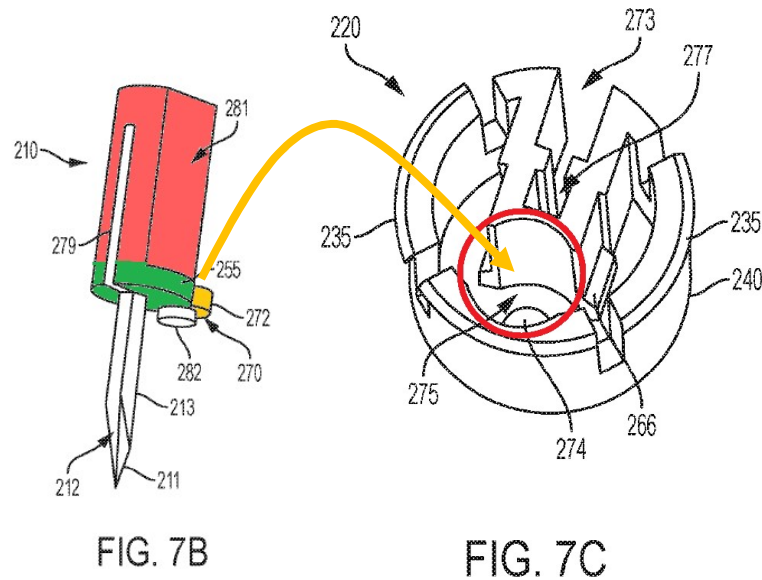


FIG. 4B

aperture
extending
from a top
surface



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).



Id. at Figs. 7B-C.

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

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

156. In my opinion, Pace 2 renders obvious claim 13, as explained below.

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

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

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

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;”

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.

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.

- 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”

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

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

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

163. In my opinion, Pace 2 renders obvious claim 22, as explained below.

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

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].

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

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

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

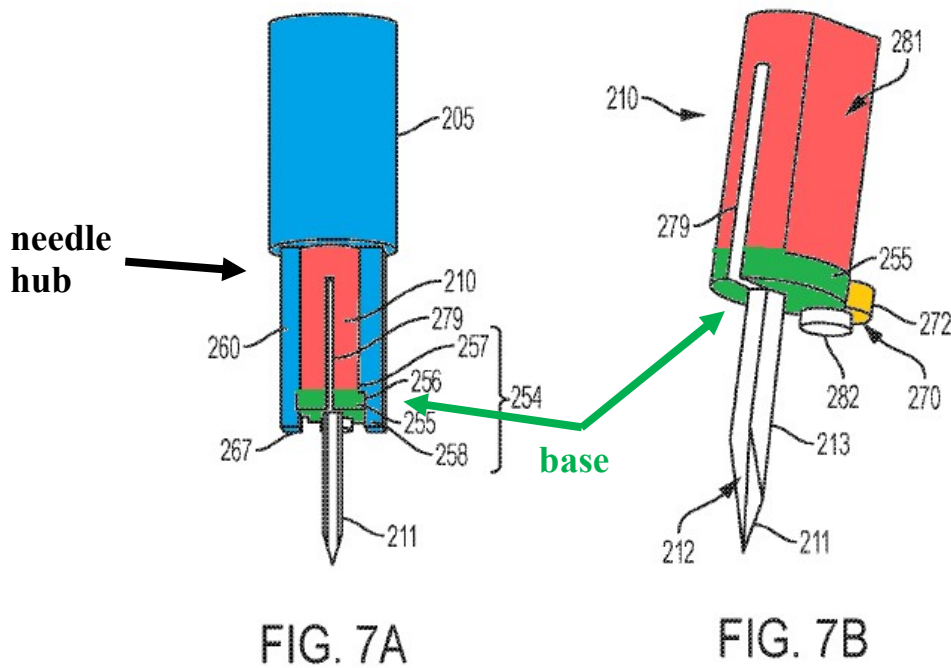
166. *See, supra*, claim 1.11.

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

167. *See, supra*, claim 1.2.

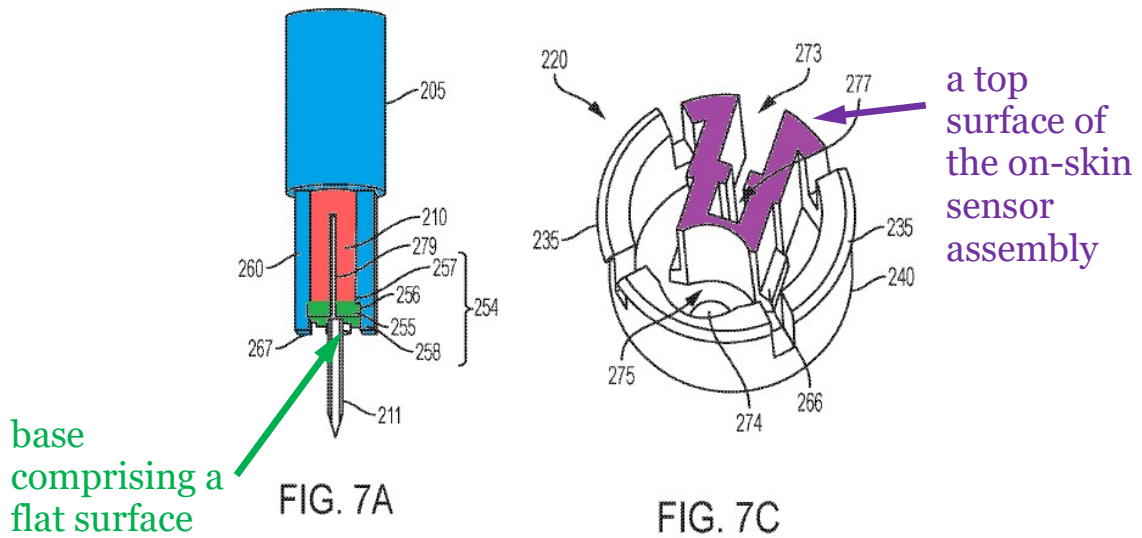
e. 22.4 “wherein the base comprises a flat surface configured to mate with a top surface of the on-skin sensor assembly, thereby maintaining the insertion element in a substantially perpendicular orientation to the top surface of the on-skin sensor assembly.”

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



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

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.



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):

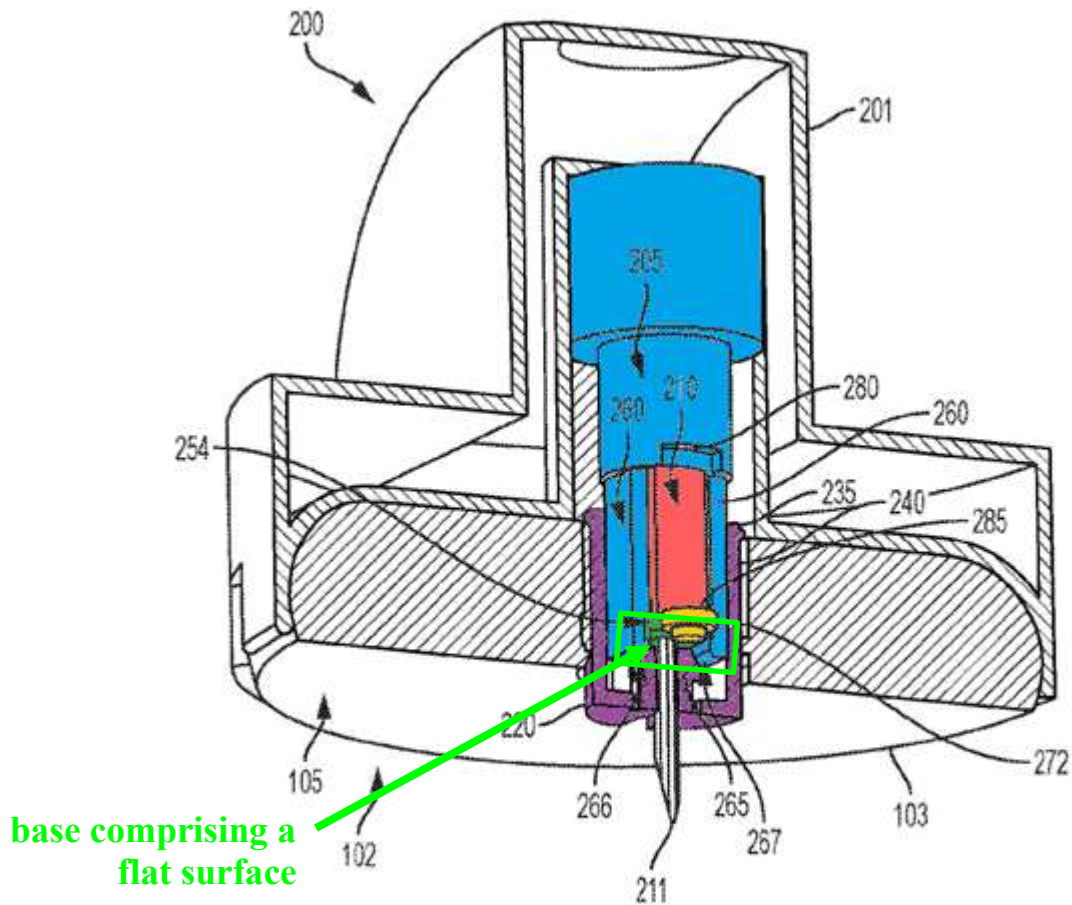


FIG. 4D

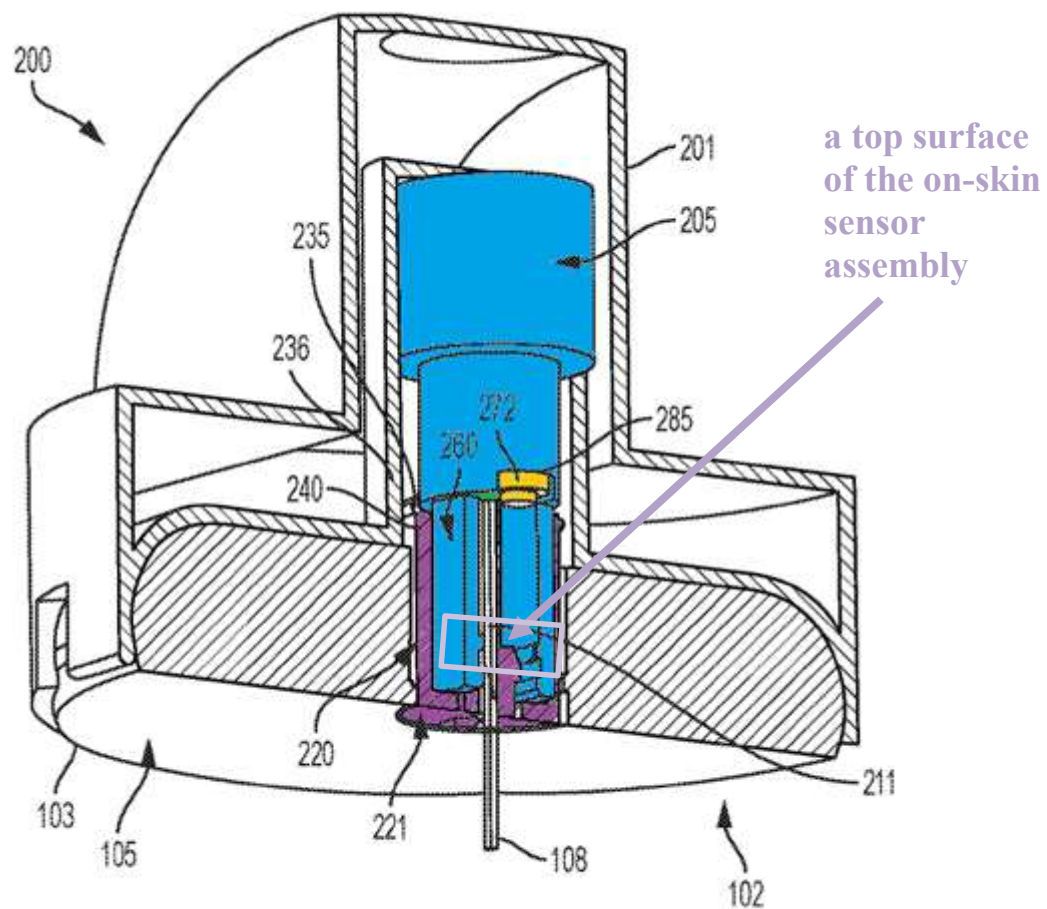


FIG. 5D

Id. at Fig. 4D. 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

170. In my opinion, Pace 2 renders obvious claim 28, as explained below.

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

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

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

172. 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:”

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.

- 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”

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

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

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].

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:

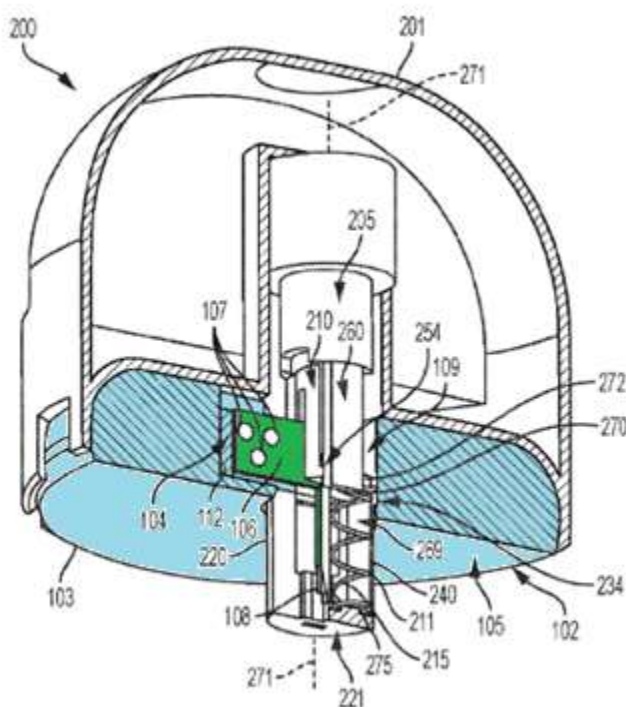


FIG. 3B

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

- 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;”

177. *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”

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.

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

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):

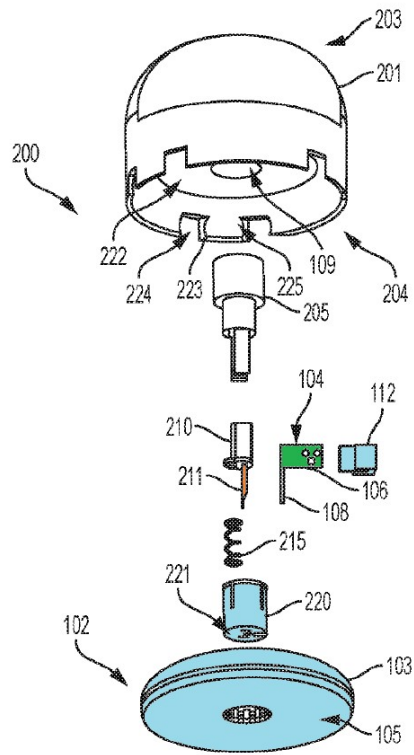


FIG. 2A

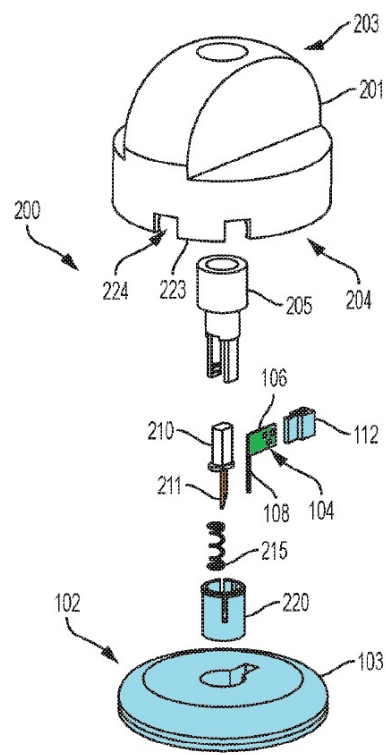


FIG. 2B

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

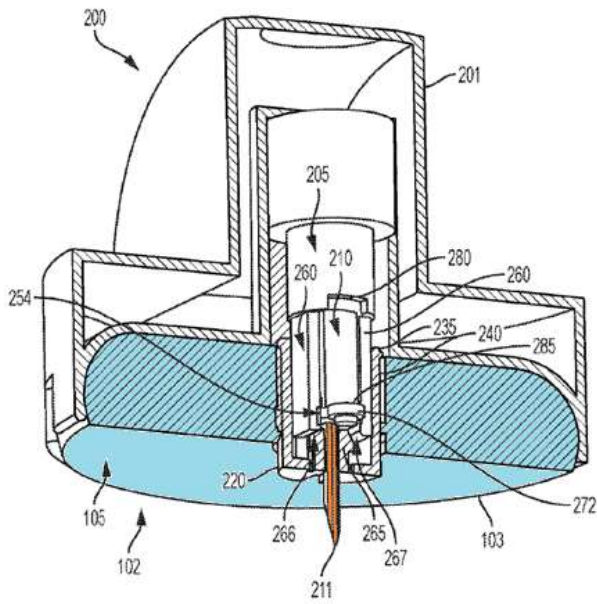


FIG. 4D

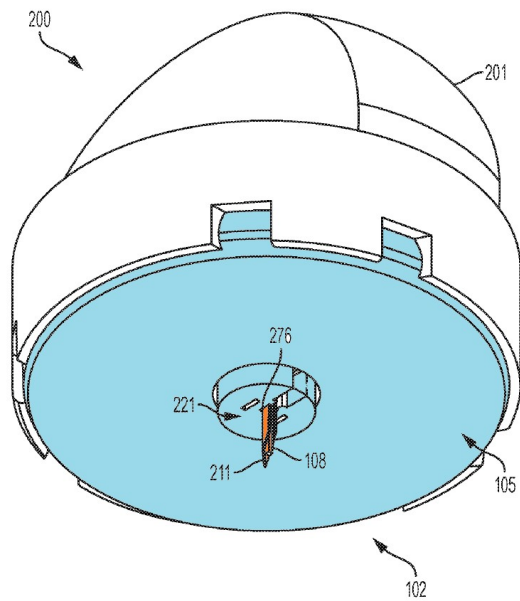


FIG. 4E

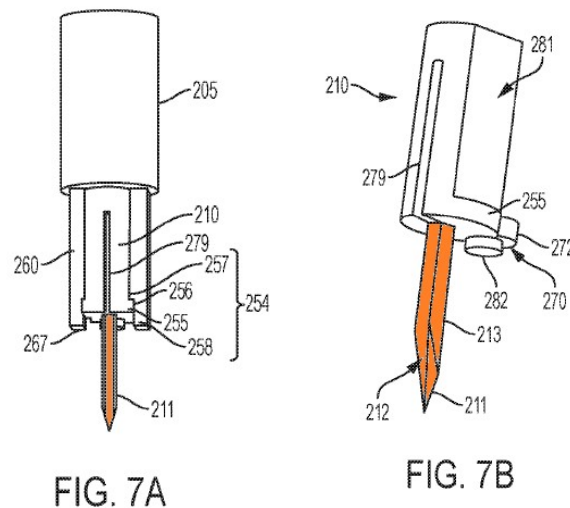
Id. at Figs. 4D-4E; *see also Id.* at Fig. 4A-4C.

5. Claims 2 & 25

180. In my opinion, Pace 2 renders obvious claims 2 and 25, as explained below. 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].”

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]:



Id. at Fig. 7A-7B.

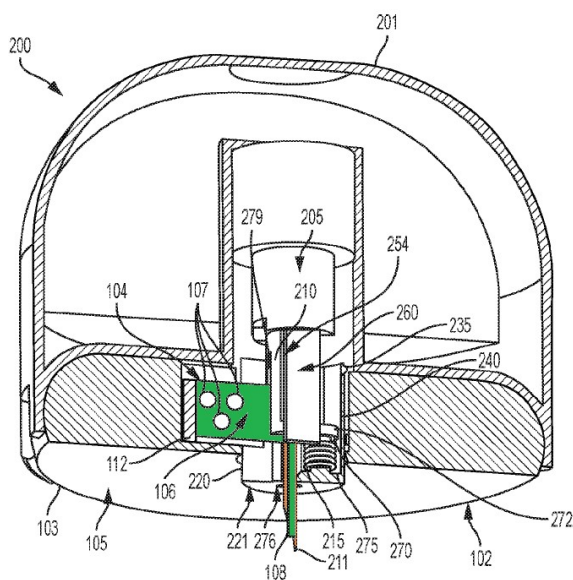


FIG. 4B

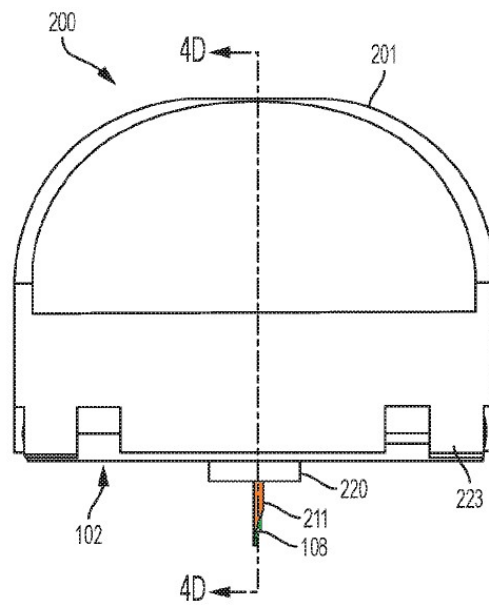


FIG. 4C

Id. at Figs. 4B-C.

6. Claim 3

182. In my opinion, Pace 2 renders obvious claim 3, as explained below.

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.”

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. 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].”

185. *See, supra*, claim 28.10.

8. Claims 7, 17, & 29

186. In my opinion, Pace 2 renders obvious claims 7, 17, and 29, as explained below. 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.”

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

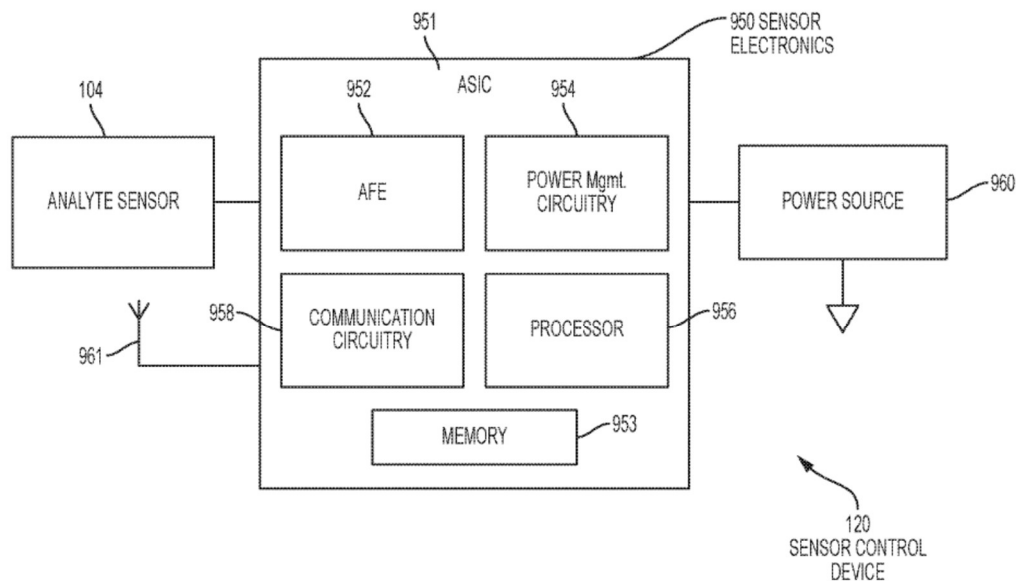


FIG. 9

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. 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.”

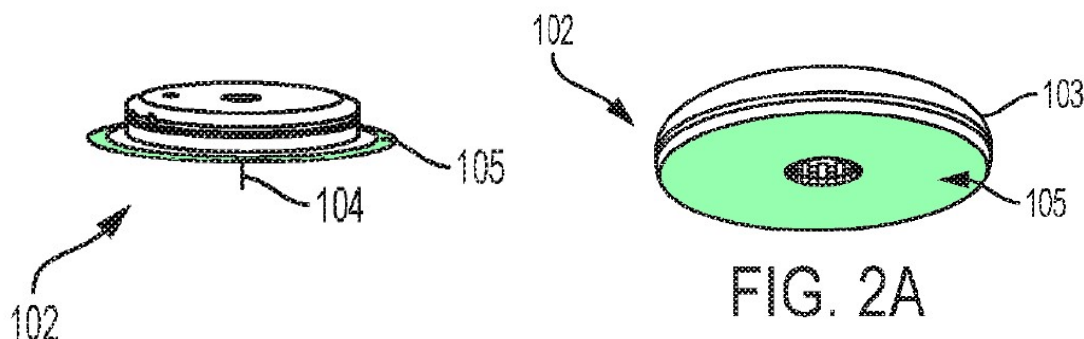
189. *See, supra*, claim 28.10.

10. Claim 9

190. In my opinion, Pace 2 renders obvious claim 9, as explained below. 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.”

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:



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.

Claim 19 depends from claim 16. *See, supra*, claim 16.

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

193. *See, supra*, claim 28.13.

12. Claim 23

194. In my opinion, Pace 2 renders obvious claim 23, as explained below.

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.”

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. 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.”

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

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].

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. *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.)”).

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].

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.

202. 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]).

203. 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.

2. Claims 4, 14, 26, & 30

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.

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

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].

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.

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

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.

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

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.

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.

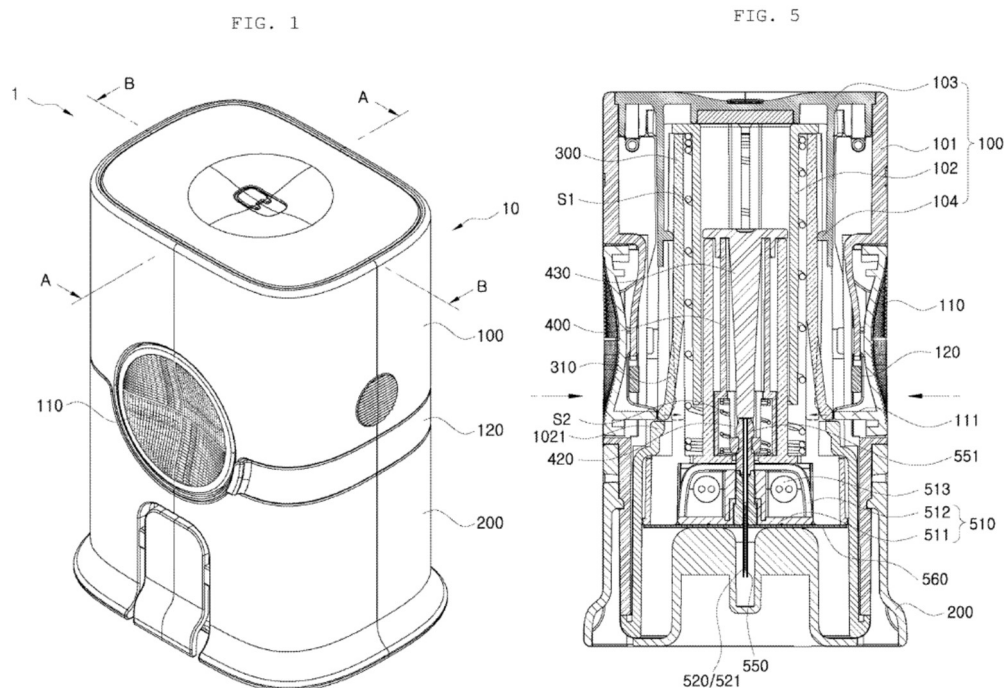
E. Ground 5: Chae Renders Obvious Claims 1-3, 6, 9, 13, 16, And 22-24

1. Independent Claim 1

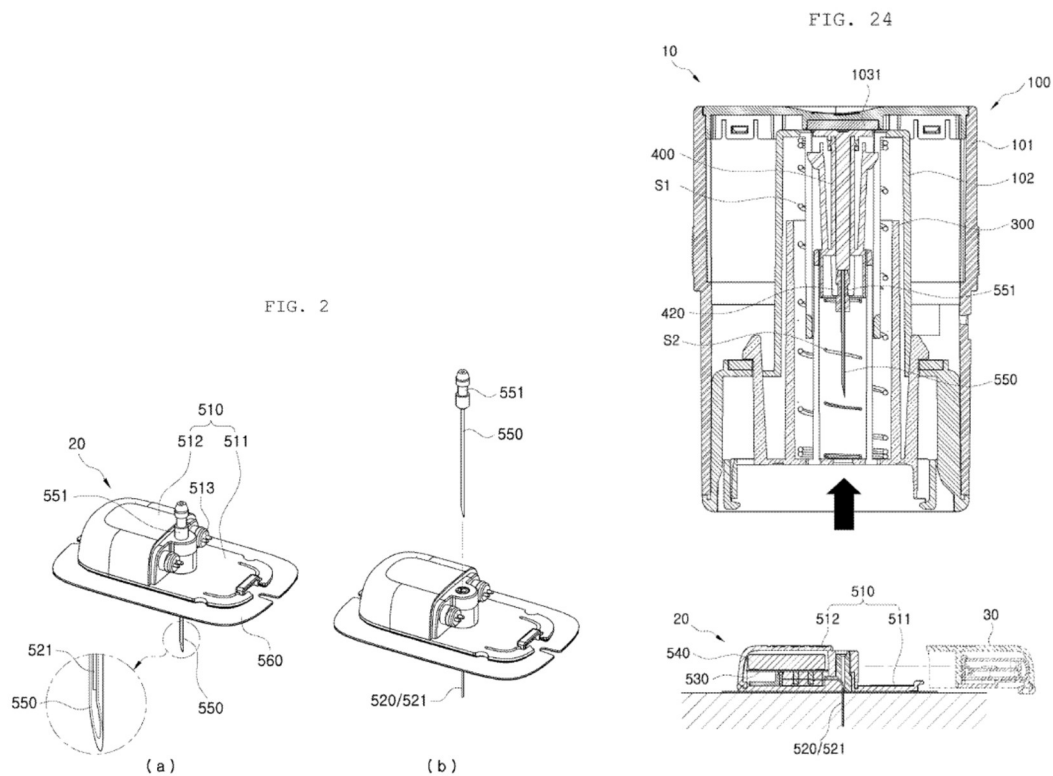
211. In my opinion, Chae renders obvious claim 1, as explained below.

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

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:



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:



Id. at Figs. 2, 24.

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

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

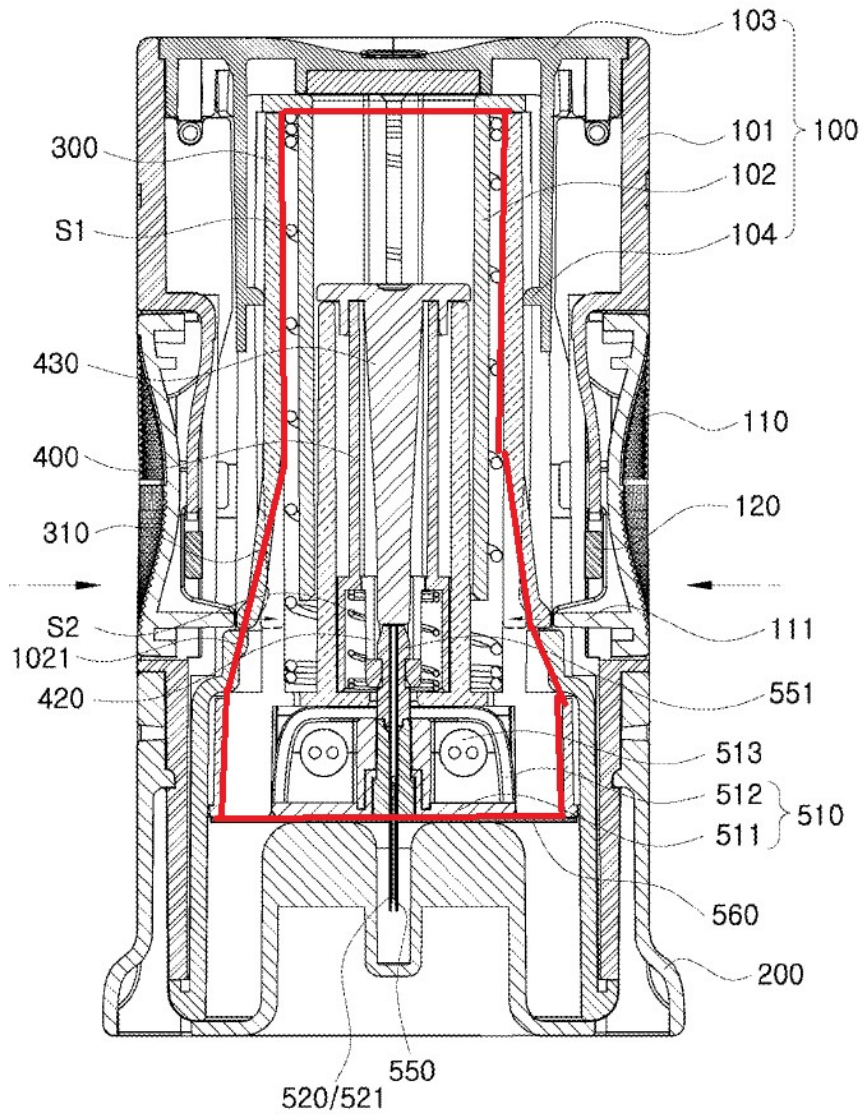
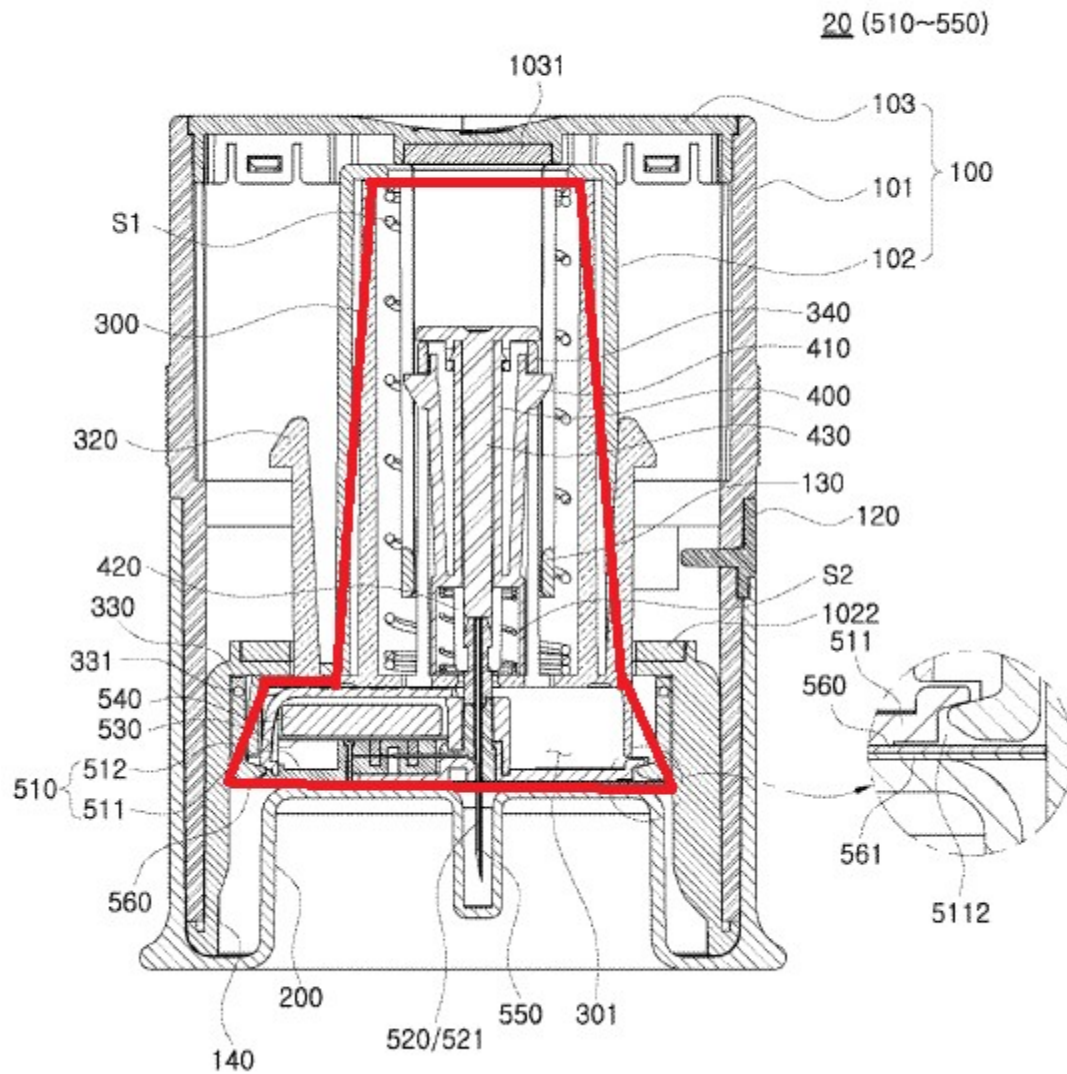


FIG. 6



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

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

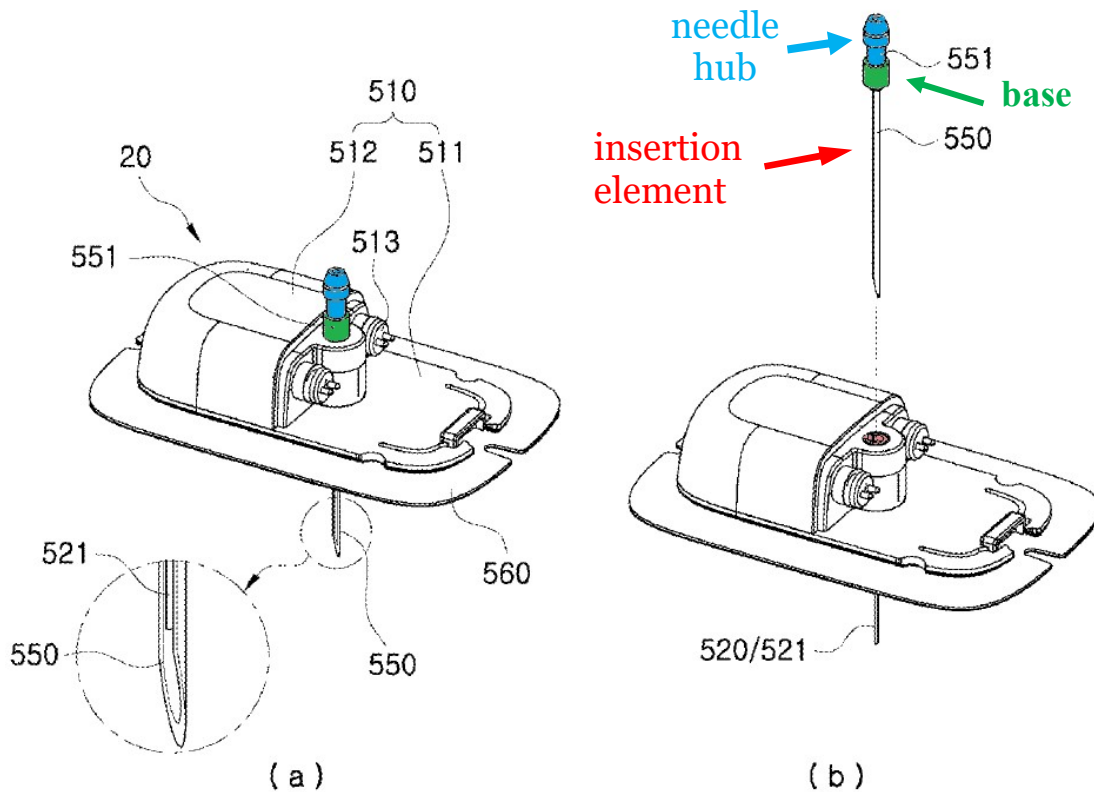
1.3 “a base, and”

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”

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].

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

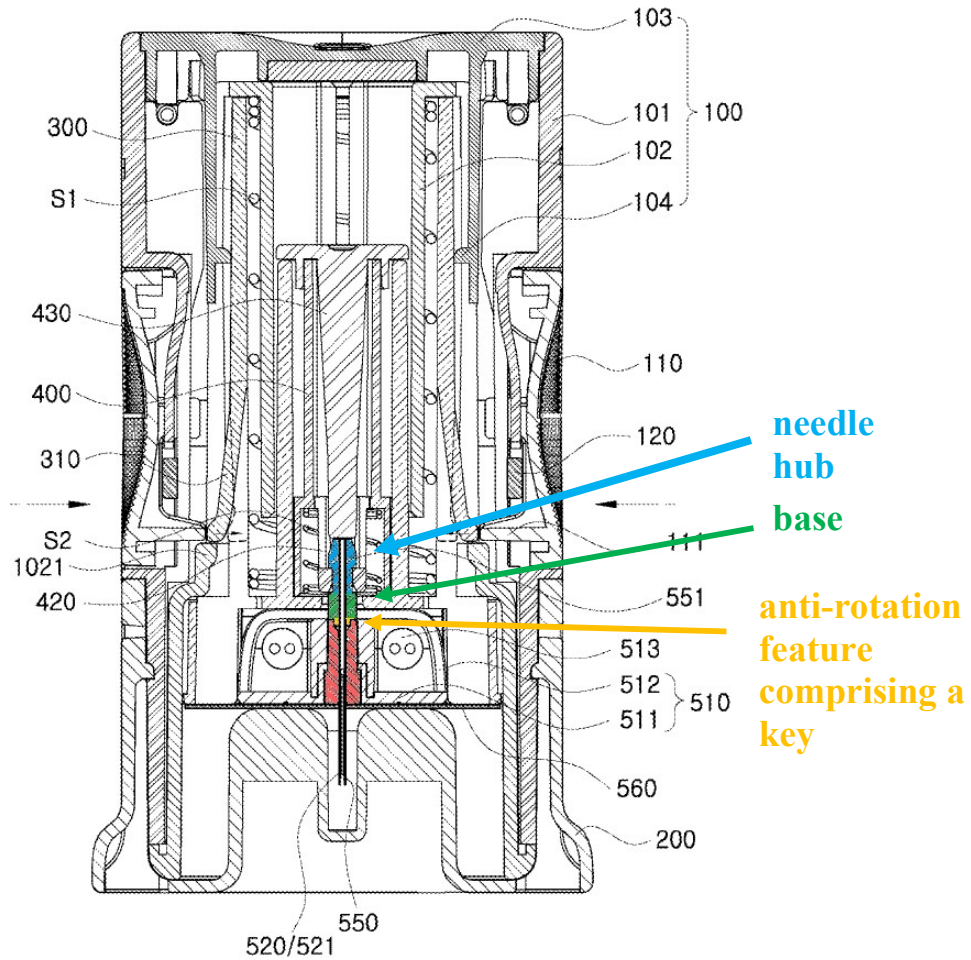
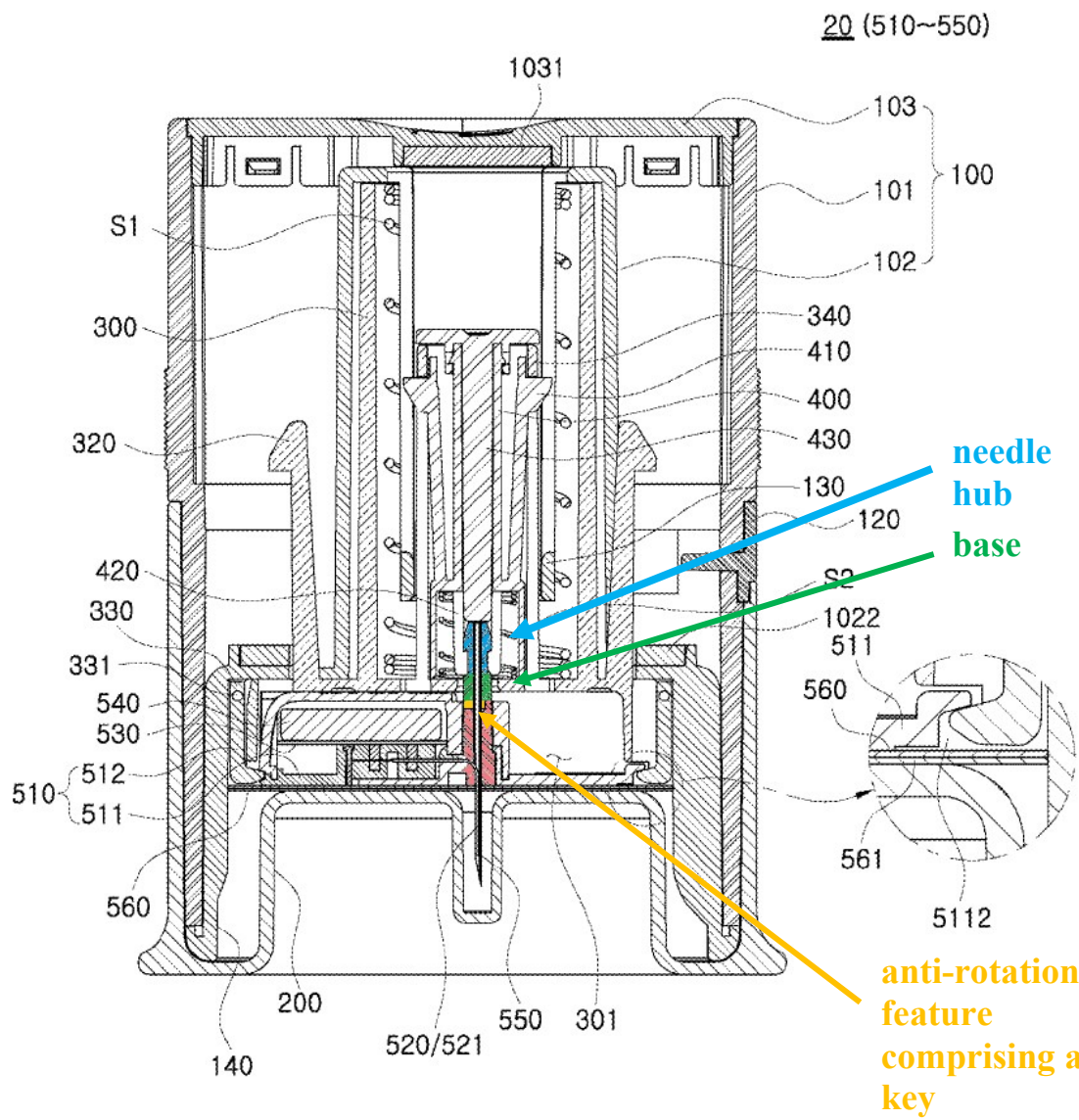
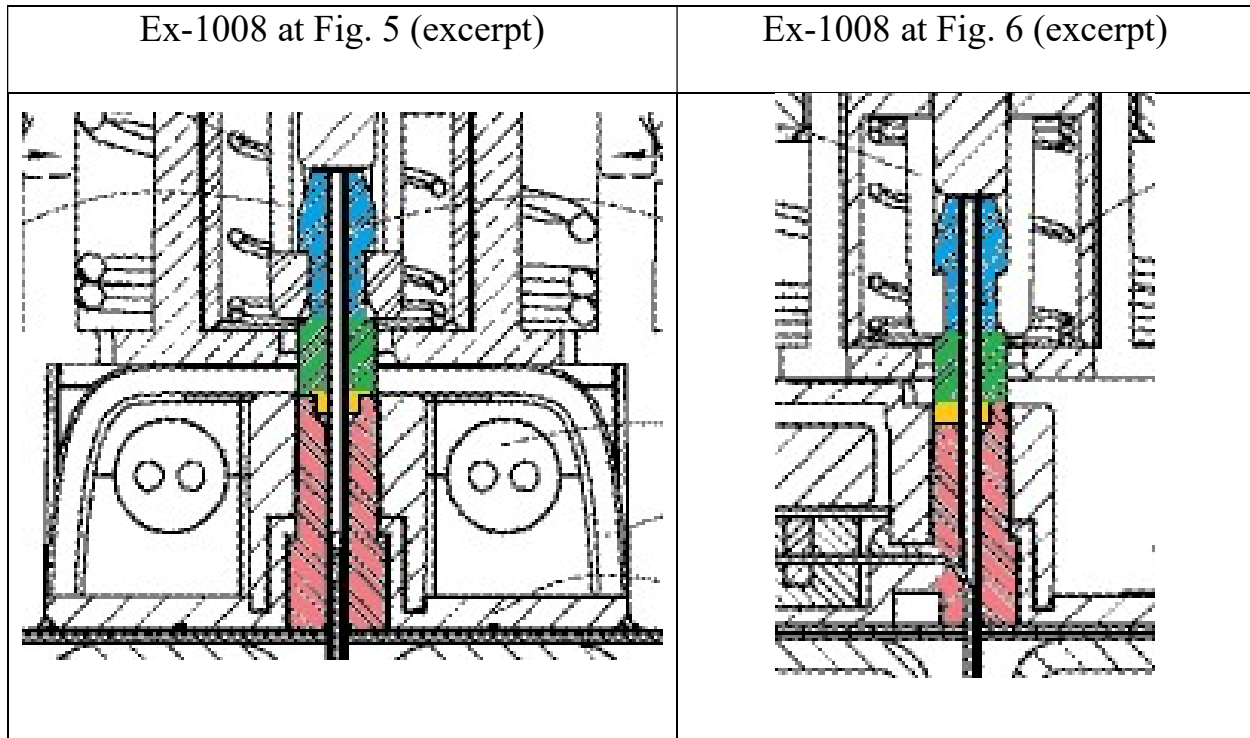


FIG. 6



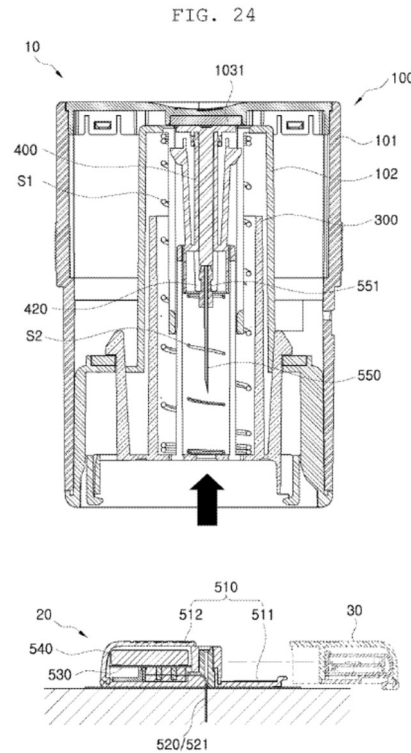
Ex. 1009, Figs. 5-6. The needle head 551 is seen in more detail in the excerpts below:



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."

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

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



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

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

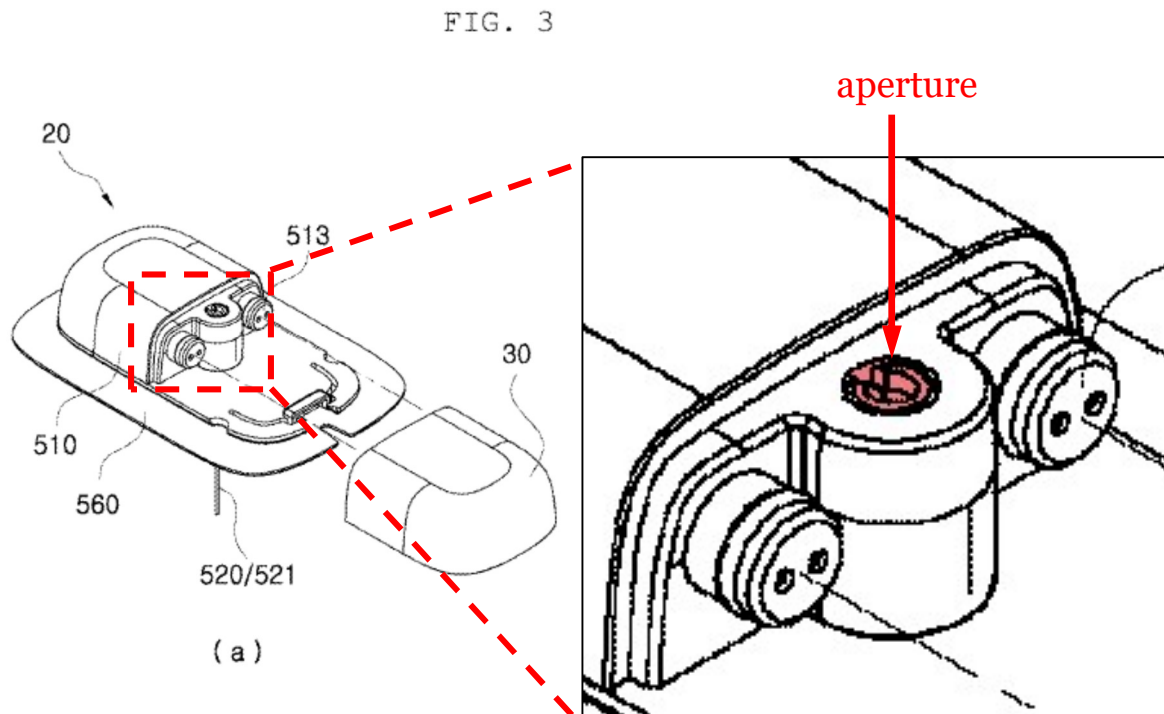
218. Chae discloses that the sensor module 20 includes a sensor 520 that is used to “measure a **blood glucose level.**” Ex-1008 at [0079], [0081]; *see also Id.* at [0082] (“Here, current change information of the sensor probe 521 occurring depending on the **glucose concentration** of blood is electrically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

f. 1.8 “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”

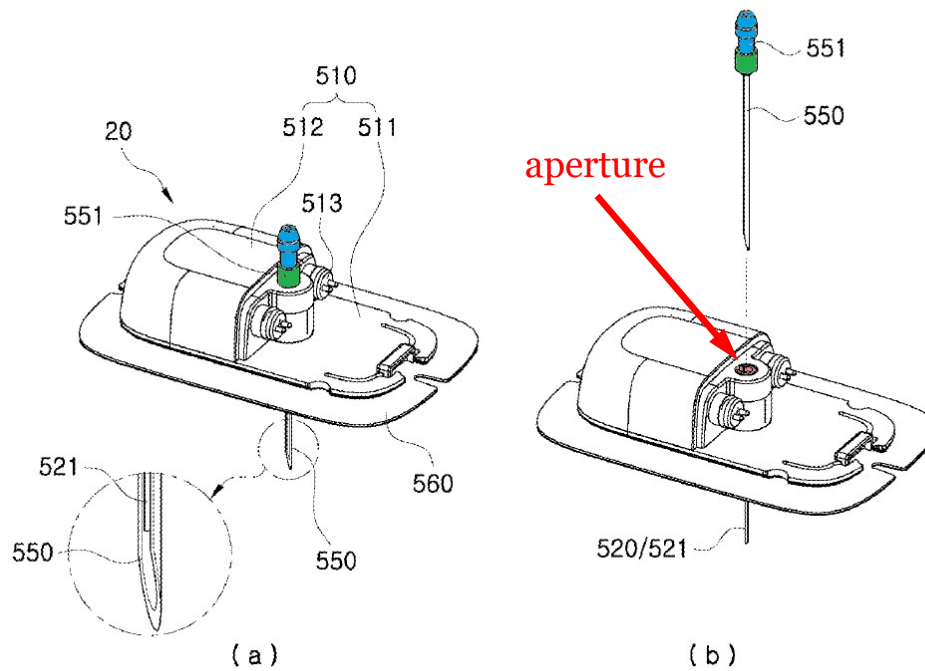
1.10 “wherein the key of the anti-rotation feature is configured to be at least partially disposed in the aperture of the on-skin sensor assembly;”

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

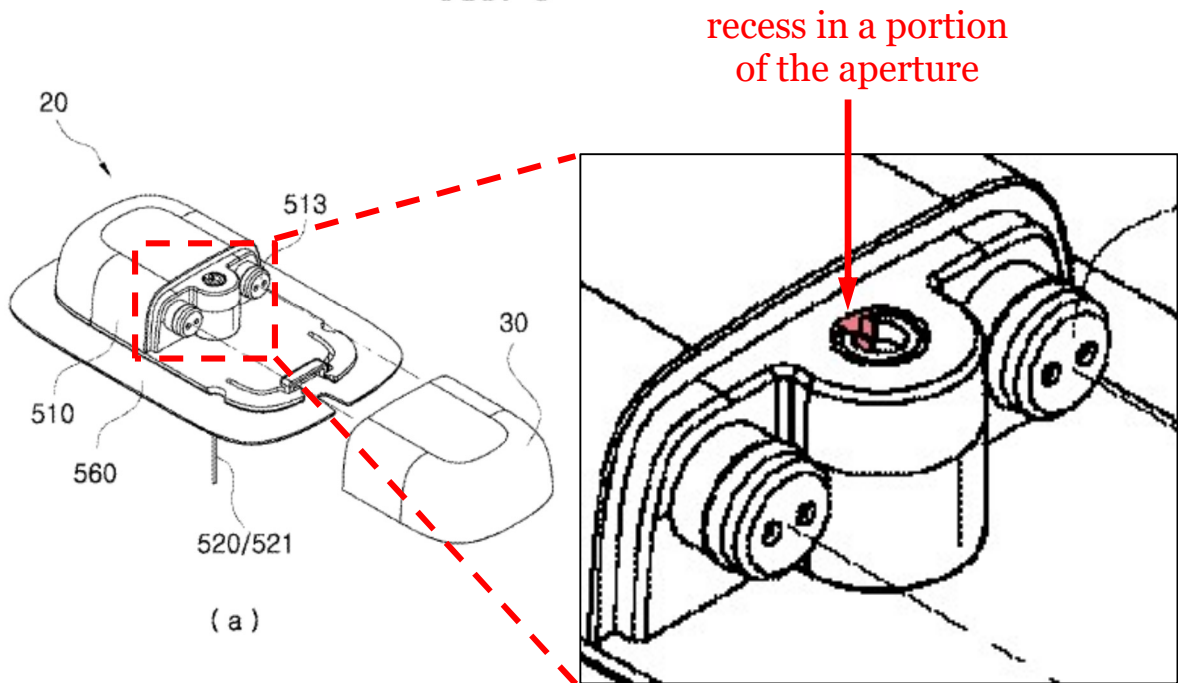
FIG. 2



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

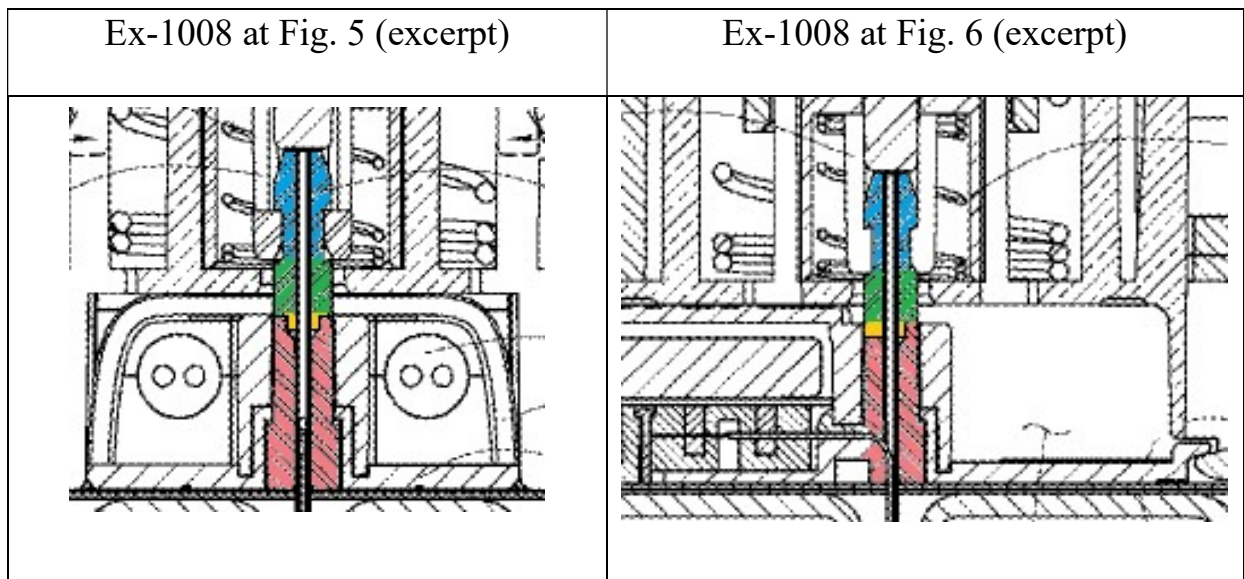
220. Chae further discloses that the aperture of the sensor module 20 has a recess that is shaped complementary to the protrusion on the needle head 551. For example, Figure 3 (enlarged, right below) shows a recess in one side of the aperture:

FIG. 3



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

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):



Id. at Figs. 5 (excerpt, annotated), 6 (excerpt, annotated). Furthermore, as seen above, the protrusion 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.”

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

223. In my opinion, Chae renders obvious claim 13, as explained below.

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

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

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

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;”

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.

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.”

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”

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

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

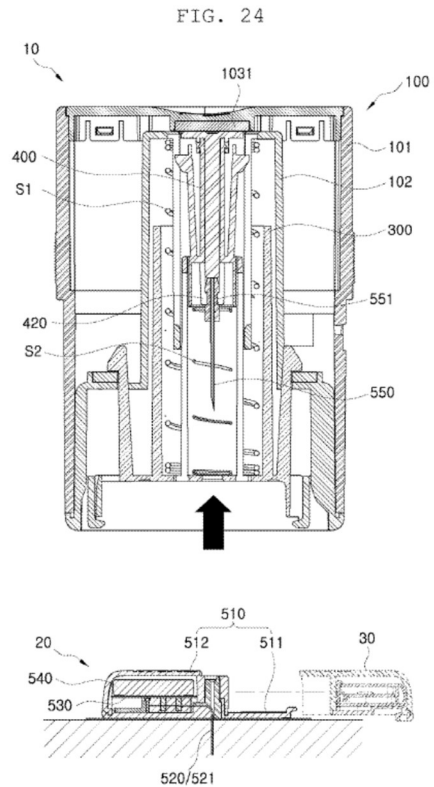
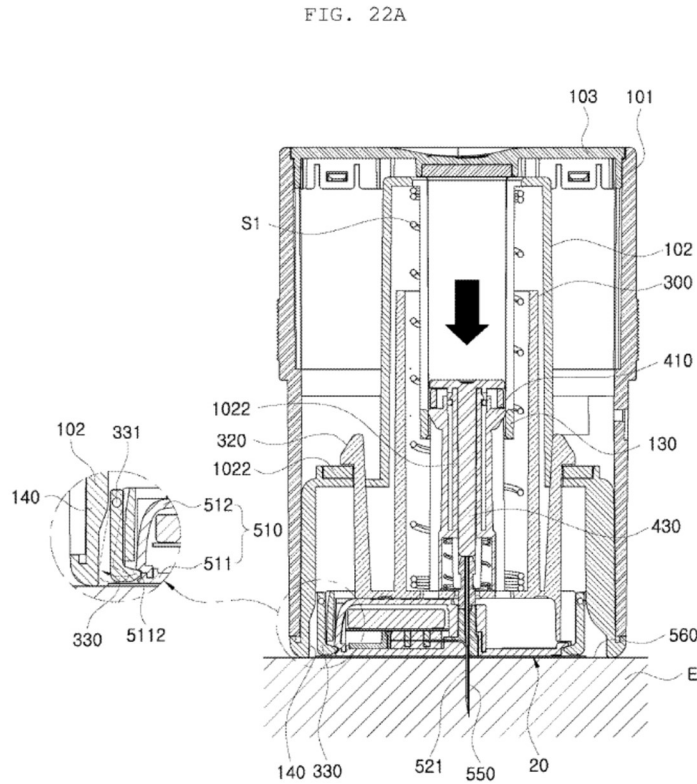
229. *See, supra*, claim 1.11. While claim 1.11 recites preventing rotation of the needle hub relative to the “aperture” rather than the “on-skin sensor assembly,” claim 13.8 makes clear that the aperture is part of the on-skin sensor assembly. Thus, the needle hub in Chae is prevented from rotating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

3. Independent Claim 22

230. In my opinion, Chae renders obvious claim 22, as explained below.

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

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.



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.”

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

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

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

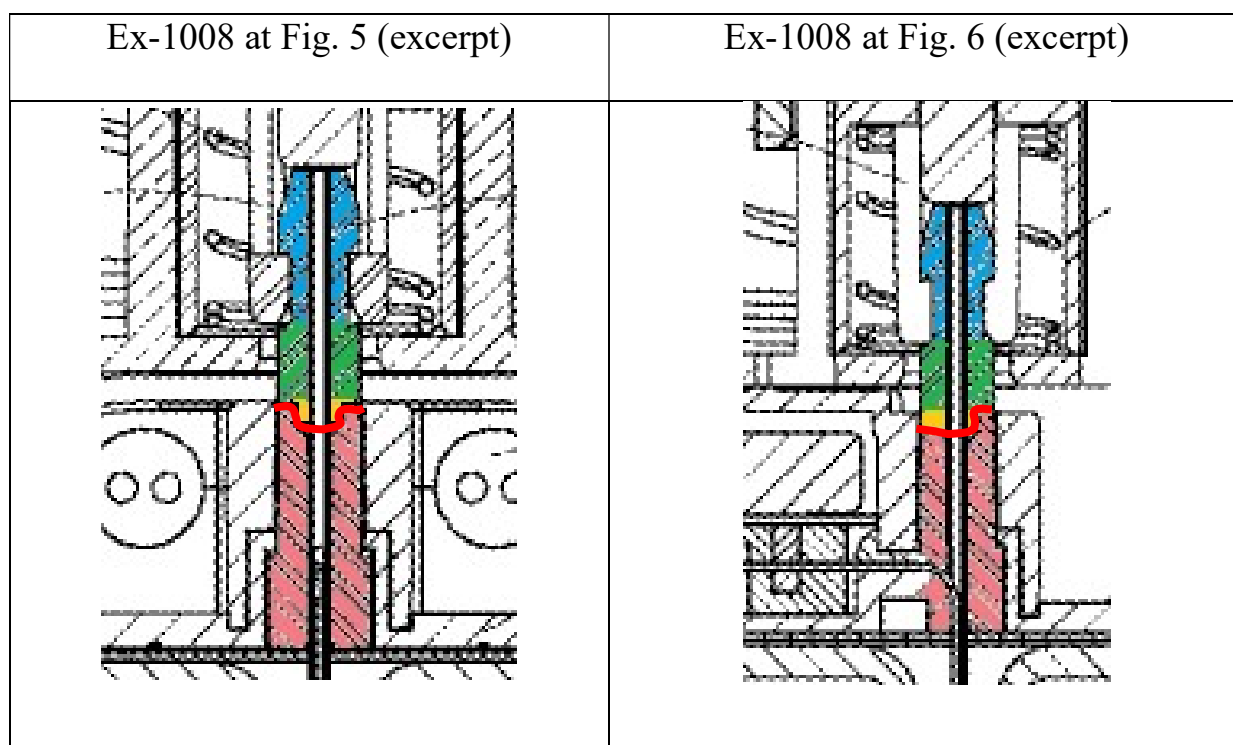
233. *See, supra*, claim 1.11.

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

234. *See, supra*, claim 1.2.

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

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

of the sensor module 20.

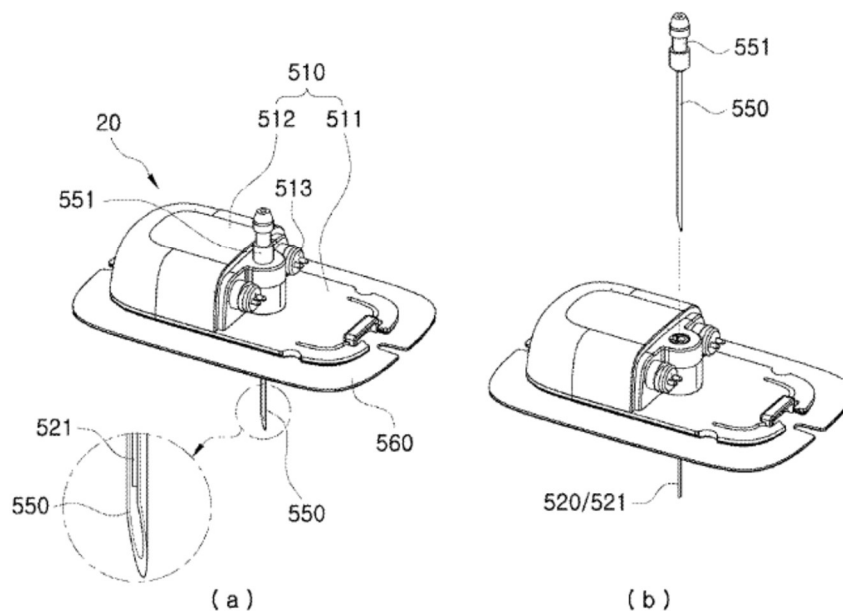
4. Claims 2 & 25

236. In my opinion, Chae renders obvious claims 2 and 25, as explained below. 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].”

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. 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.”

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 needle 550 must support a flag-shaped sensor, and there 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. *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. 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].”

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.

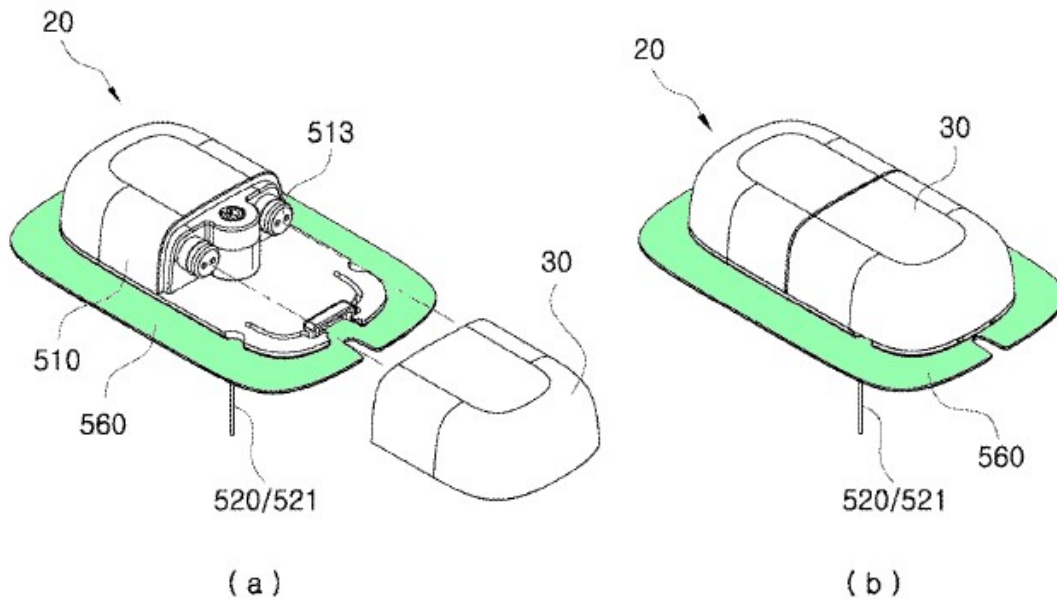
7. Claim 9

242. In my opinion, Chae renders obvious claim 9, as explained below. 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.”

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.

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.”

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.

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.”

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.

IX. AVAILABILITY FOR CROSS-EXAMINATION

248. In signing this declaration, I recognize that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during a time as mutually agreed between the parties.

X. RIGHT TO SUPPLEMENT

249. I reserve the right to supplement my opinions in the future to respond to any arguments that the Patent Owner raises. This declaration represents only those opinions that I have formed to date. I reserve the right to revise, supplement, and/or amend my opinions stated herein based on new information that becomes available to me and on my continuing analysis of the materials already provided.

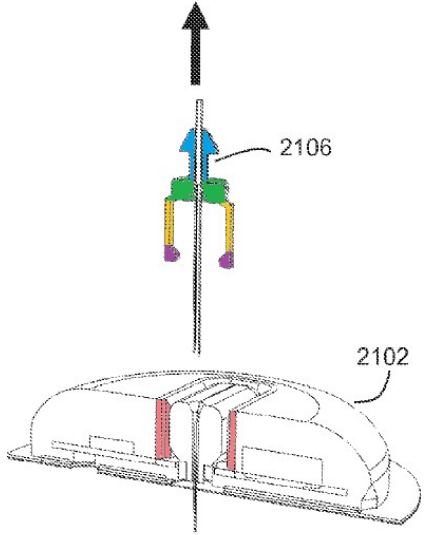
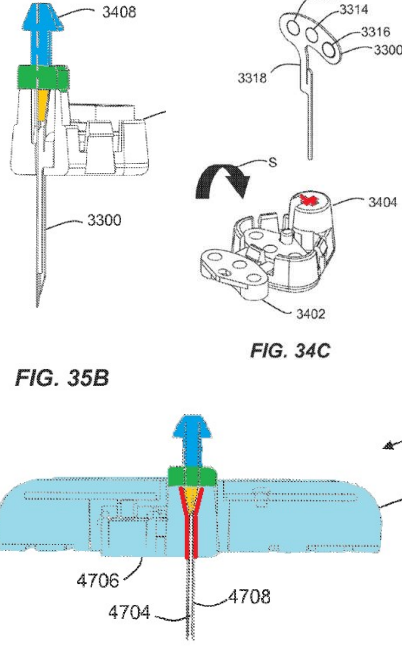
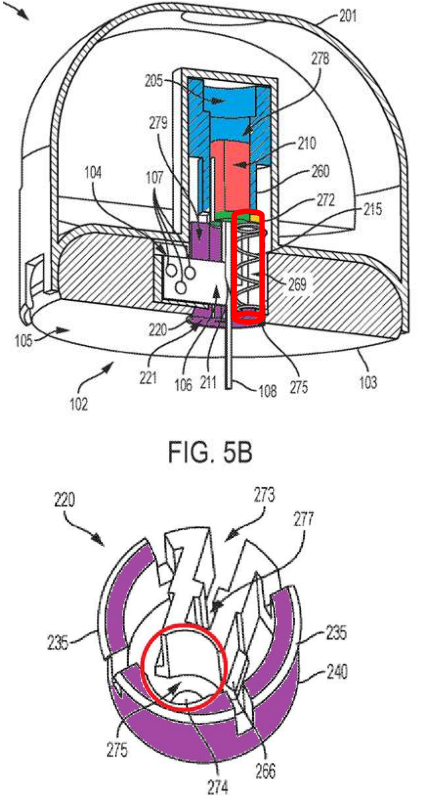
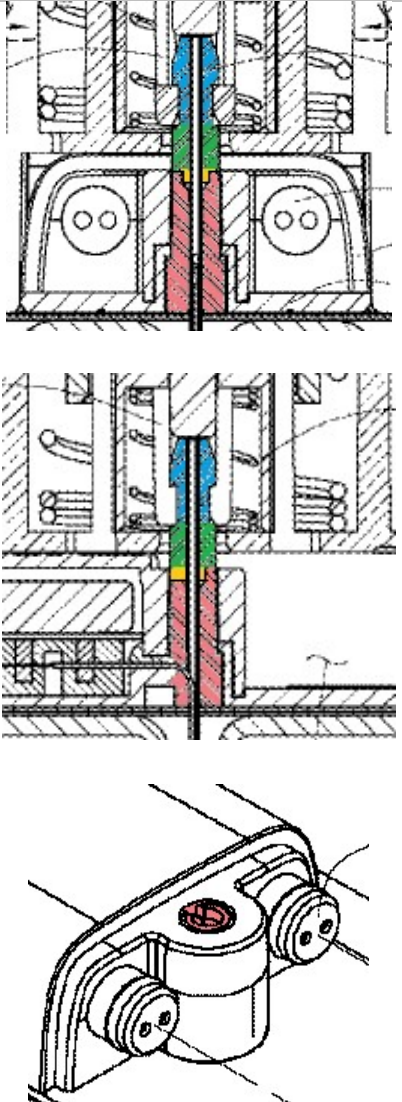
XI. CONCLUSION

250. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

May 8, 2024
Date


Cameron Riviere, Ph.D.

Appendix A – Summary of Prior Art Embodiments

Pace – Embodiment A	Pace – Embodiment B	Pace 2	Chae
 FIG. 21C	 FIG. 35B FIG. 47C	 FIG. 5B FIG. 7C	

Legend:

needle hub

base

anti-rotation feature/key

aperture