

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. IPR2024-00860

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 1011-1012 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-1006.

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. Lehocky, 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")
1011	U.S. Patent Publication No. 2014/0188053 (Lundquist)
1012	U.S. Patent Publication No. 2018/0235520 (Rao)
1015	Neil Sclater and Nicholas P. Chironis, <i>Mechanisms and Mechanical Devices Sourcebook</i> (4th ed. McGraw-Hill, 2007)
1016	M. A. Meltsner, et al., <i>Observations on rotating needle insertions using a brachytherapy robot</i> , 52 <i>Physics in Medicine and Biology</i> 6027-6037 (2007)
1017	Ryosuke Tsumura, et al., <i>Histological evaluation of tissue damage caused by rotational needle insertion</i> , Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 5120-5123 (2016)

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. Petitioner's counsel has informed me 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 hollow 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.

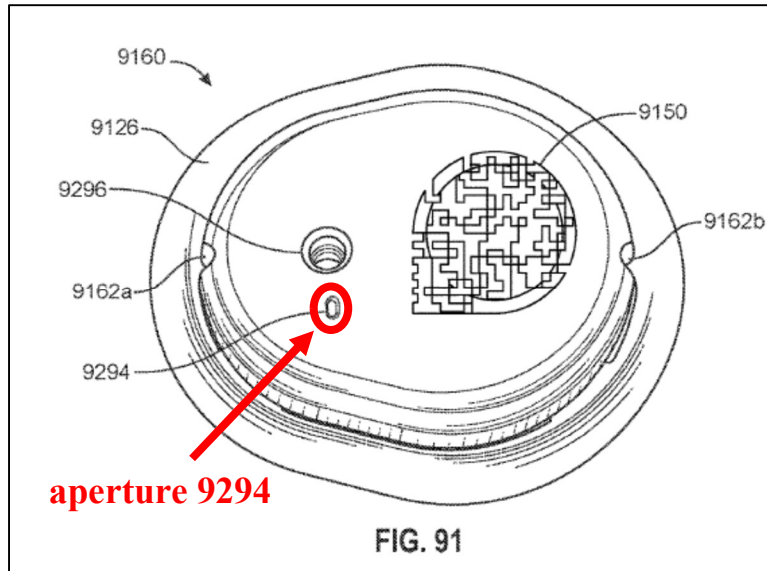
Fukushima, and H. Iwata, “Histological evaluation of tissue damage caused by rotational needle insertion,” Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society, pp. 5120-5123, 2016)).

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.

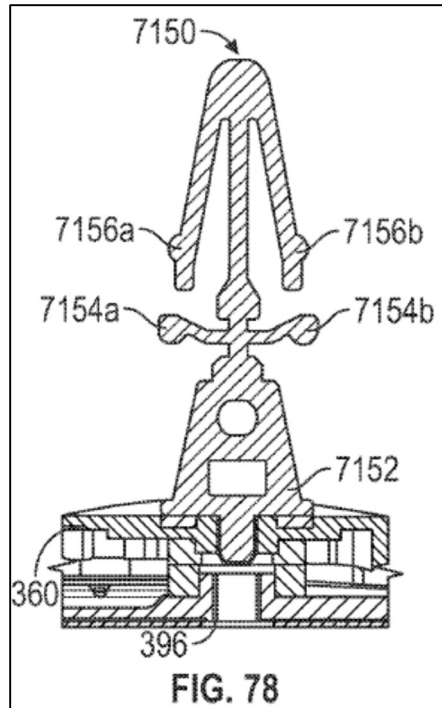
28. While the '625 patent describes multiple CGM applicator embodiments for applying an on-skin sensor assembly to the skin of a host, there is scarce disclosure, beyond mere functional description, of structures constituting an “anti-rotation feature” or “key” to prevent rotation of a needle hub within 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:



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

C. Effective Filing Date Of The ’625 Patent

33. The ’625 patent claims priority to U.S. Provisional Application No. 62/658,486, filed on April 16, 2018, and U.S. Provisional Application No. 62/524,247, filed on June 23, 2017. Ex-1001 at 1-2.

34. I have been asked to determine whether a POSITA would understand that the inventors of the ’625 patent possessed the invention(s) claimed in the ’625 patent as of the date of filing of the ’247 Provisional on June 23, 2017.

35. All independent claims of the ’625 patent require a “needle hub” comprising a “base” with an “anti-rotation feature” or “anti-rotation key,” with the anti-rotation “feature” or “key” being “at least partially disposed in [the / an] aperture” of an on-skin sensor assembly. *See* claims 1, 13, 22, and 28. However, the ’247 Provisional does not contain *any* disclosure of *any* “anti-rotation feature” or “anti-rotation key.” Indeed, there is not a single reference to any “anti-rotation

feature,” any “anti-rotation key,” or indeed any anti-rotation function at all. *See generally*, Ex-1004.

36. Furthermore, the '247 Provisional only contains Figures 1 through 70 from the '625 patent and does not include Figures 78 and 91 from the '625 patent discussed above or the corresponding description of those figures from the '625 patent specification. *Compare* Ex-1001 and Ex-1004. Nor are there any other figures in the '247 Provisional that a POSITA would understand to depict an “anti-rotation feature” or “anti-rotation key” of, or extending from, a needle hub, with the “anti-rotation feature” or “anti-rotation key” at least partially disposed in an aperture of an on-skin sensor assembly.

37. Thus, in my opinion, a POSITA would not have understood the inventors to be in possession of the claimed invention as of the June 23, 2017 filing of the '247 Provisional application.

38. For purposes of this declaration, I have been instructed to apply April 16, 2018 as the effective filing date of the claims of the '625 patent.

D. Level Of Ordinary Skill In The Art

39. 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

40. 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.

41. 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. Rao (Ex-1012)

42. U.S. Patent Publication No. 2018/0235520, titled “Systems, Devices, and Methods for Analyte Sensor Insertion,” to Rao et al. (“Rao”) was filed on January 22, 2018, and published on August 23, 2018. Ex-1012 at Cover.

43. Rao discloses multiple applicators for use in CGM systems, including an applicator comprising a “[s]harp module 2600” with a “bend fin guide 2620 for maintaining ‘pre-bent’ sharp 2602, including sharp shaft 2604 and sharp tip 2606, in position during assembly and/or use.” Ex-1012 at [0143].

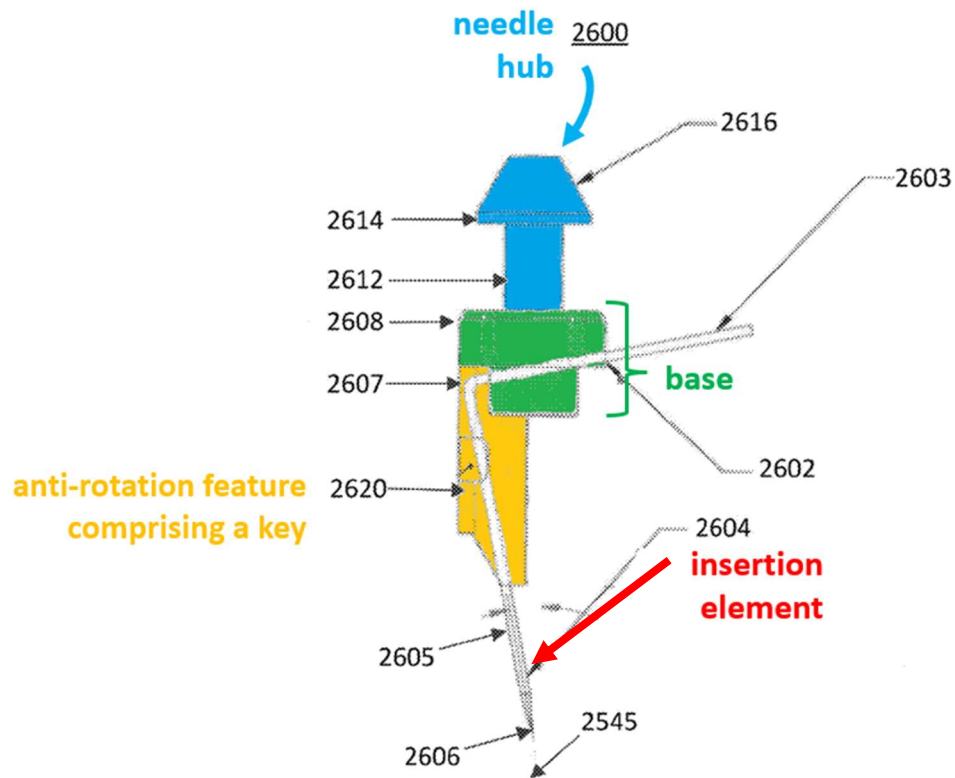


FIG. 11H

Ex-1012 at 11H (annotated).

44. Further, sharp module 2600 engages with sensor module 504, as seen in Figure 11J below. The sharp module 2600 and sensor module 504 can be provided in a sterile package, separate from the applicator and electronics housing. *Id.* at [0008]; *see also id.* at Fig. 3C, [0083]-[0084]. Prior to use of the applicator, the user couples the sharp module 2600 and sensor module 504 with the electronics inside the applicator housing, to form the complete sensor control device 102 (i.e., an on-skin sensor assembly), as shown below in Figures 12A and 11J (call-out).

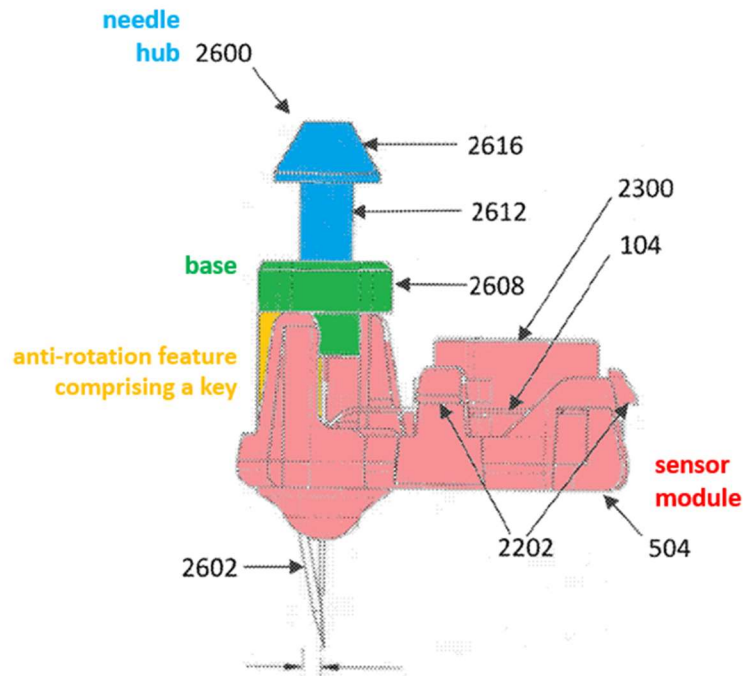


FIG. 11J

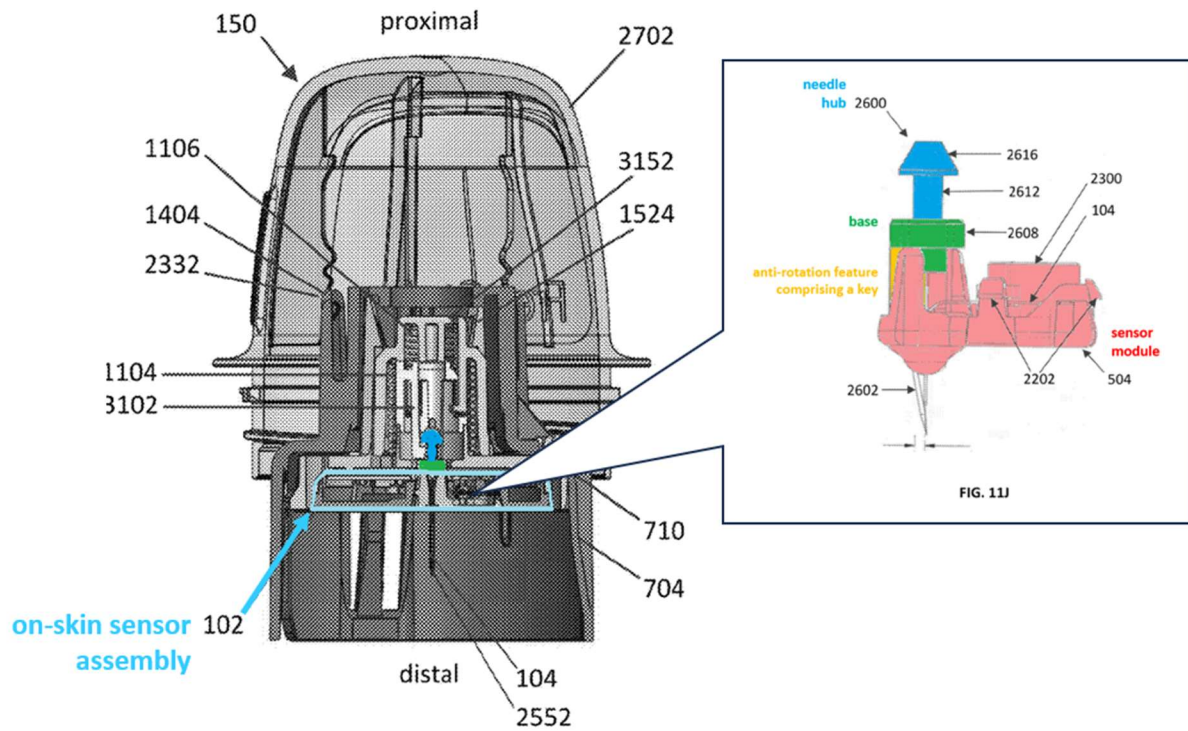


FIG. 12A

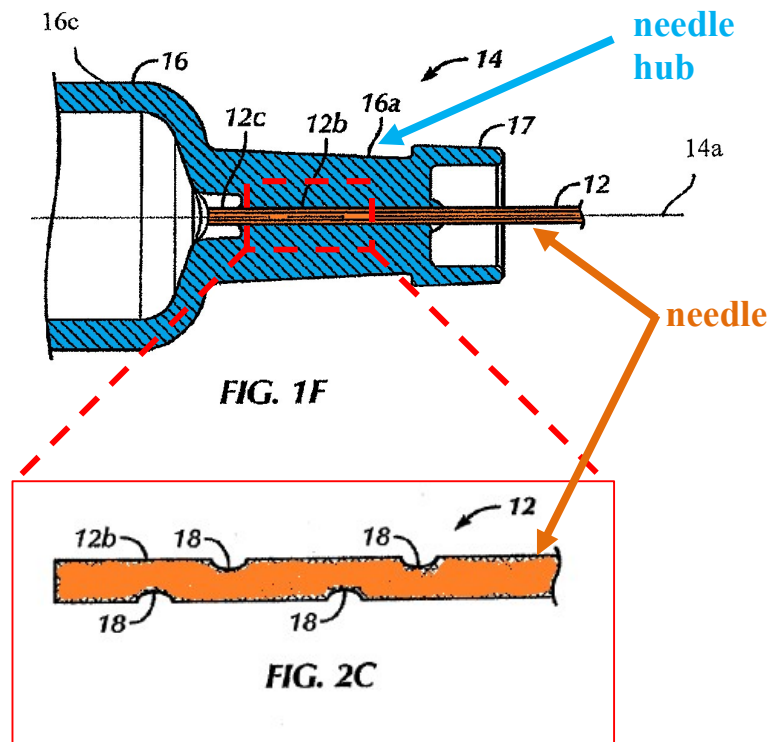
Id. at Figs. 11J, 12A; *see also id.* at Fig. 3C, [0083]-[0084]. Rao discloses that bend fin guide 2620 “can prevent lateral or rotational movement of sharp 2602 relative to hub components.” *Id.* at [0143]. As seen in Figure 11J, the hub 2600 cannot rotate relative to the sensor module 504, which is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

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

B. Lundquist (Ex-1011)

46. 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.

47. Lundquist discloses a syringe having a cannula 12 (e.g., a hollow needle) integrally formed with a barrel 16, comprising a “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]. The notches “aid in affixing or securing” the proximal end of the needle 12 to the hub 16a (as shown in Figure 1F), because the polymeric material forming the hub 16a “flows into and fills the notches 18” in the needle during the insert molding process. *Id.*

48. Lundquist discloses a method of securing a needle to a needle 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.

VIII. THE ASSERTED GROUNDS OF UNPATENTABILITY

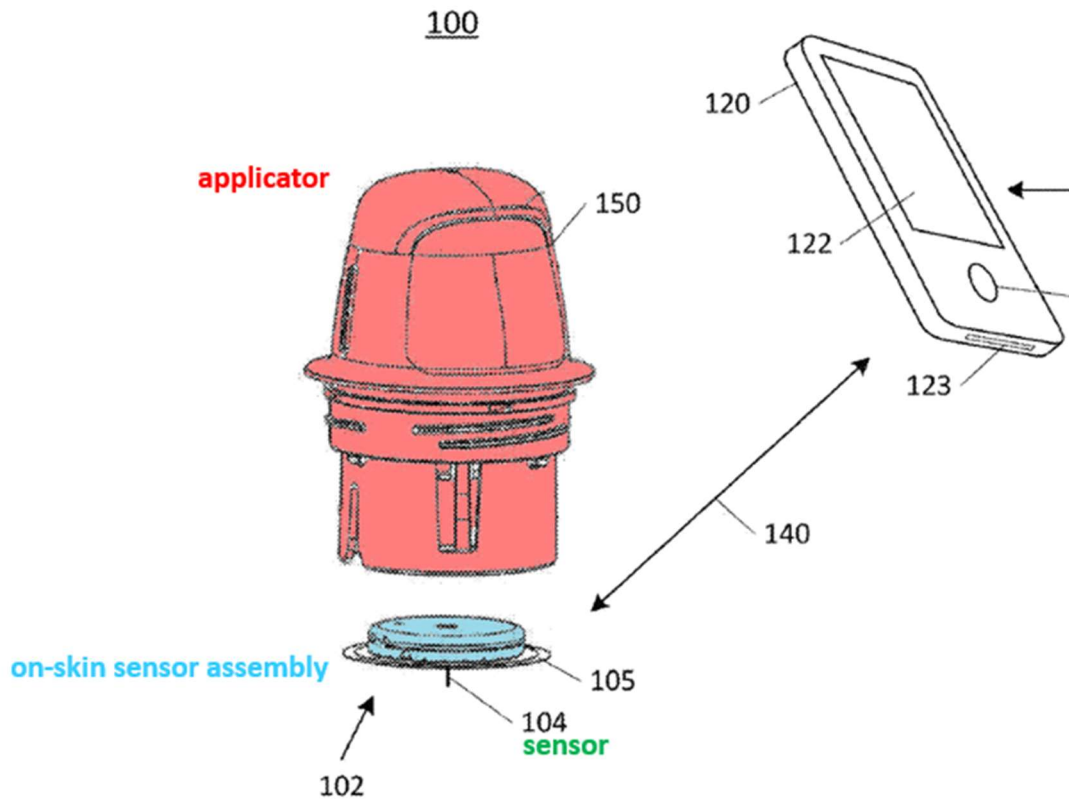
A. Ground 1: Rao Renders Obvious Claims 1-9, 13-19, And 22-30

1. Independent Claim 1

49. In my opinion, Rao 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:”*

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



Id. at Fig. 1, [0075]; *see also id.* at Figs. 3E-3F (depicting application of the sensor control device 102 to a user's skin) and Figs. 4A-4C, [0089].

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

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

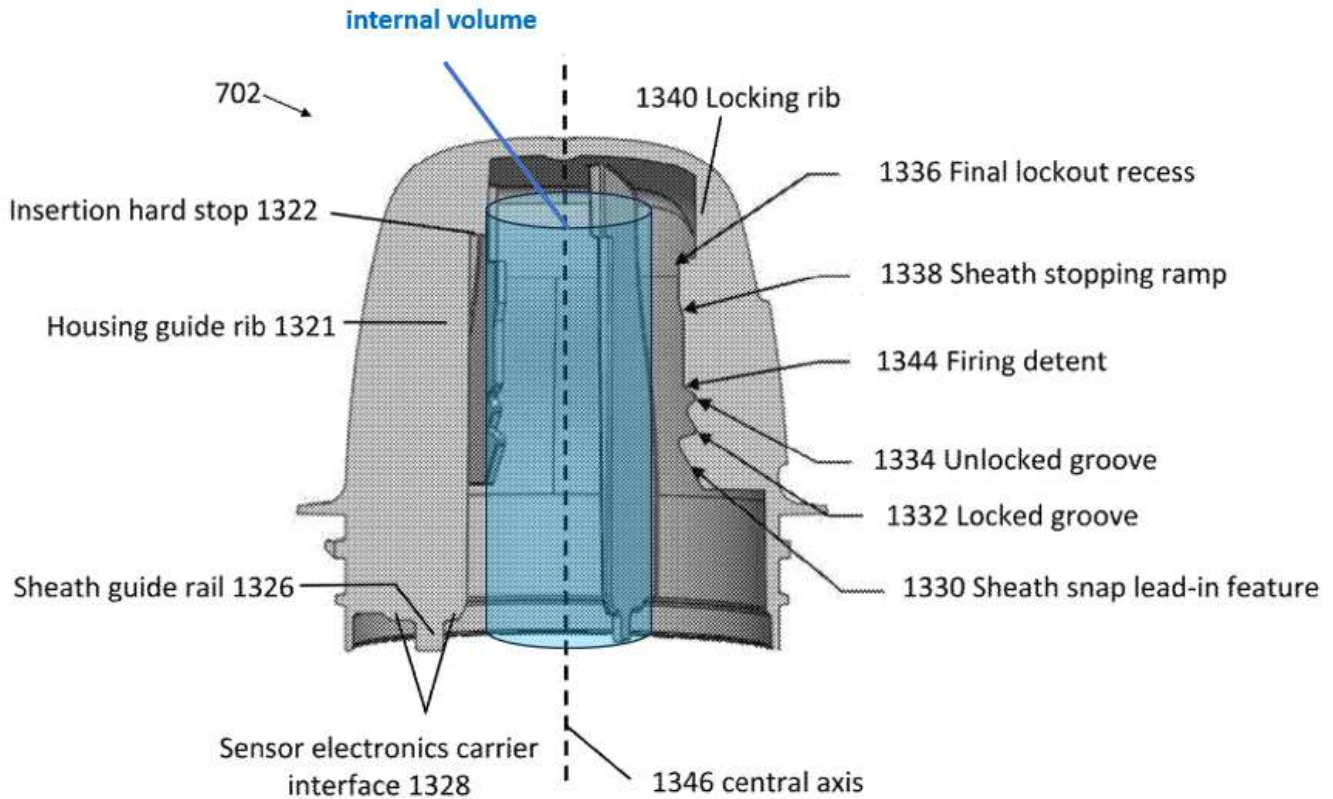


FIG. 7C

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

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

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

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

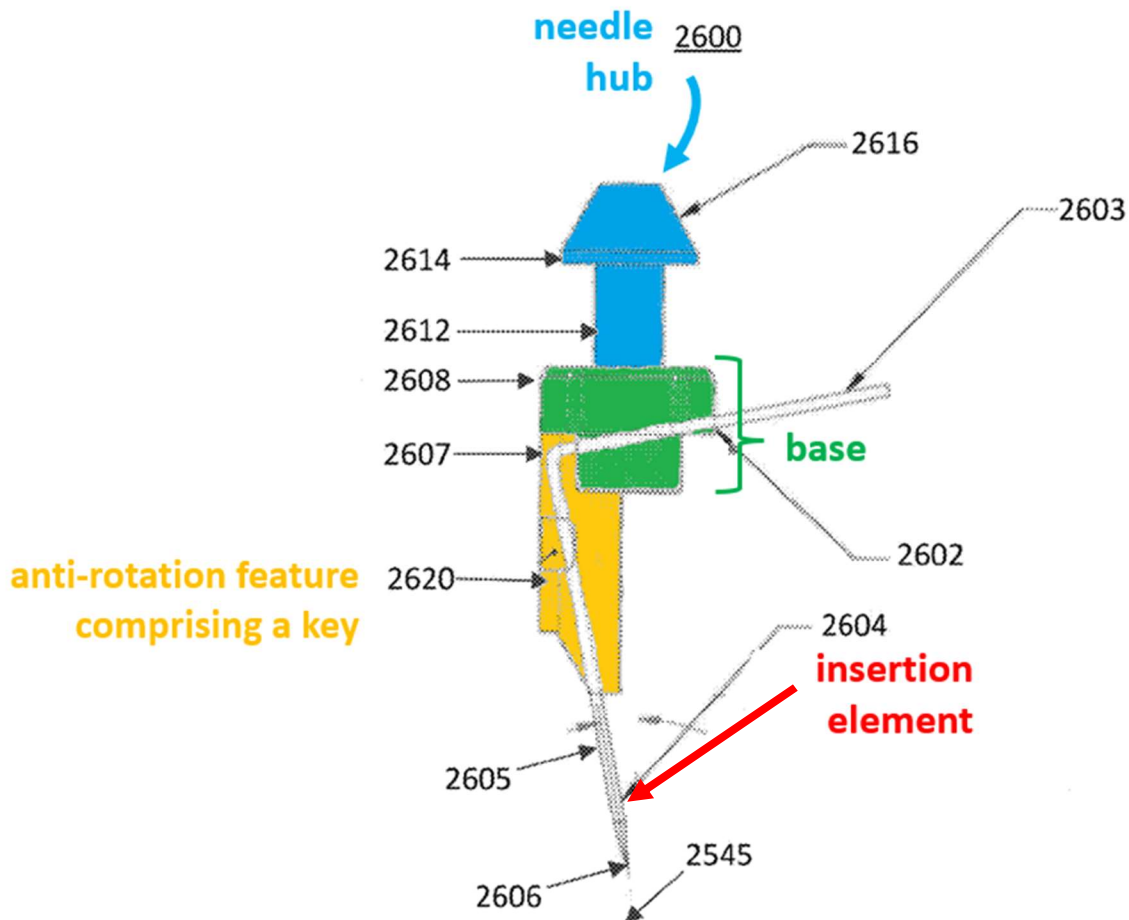


FIG. 11H

Ex-1012 at Fig. 11H (annotated), [0134], [0143]. Rao further discloses that sharp

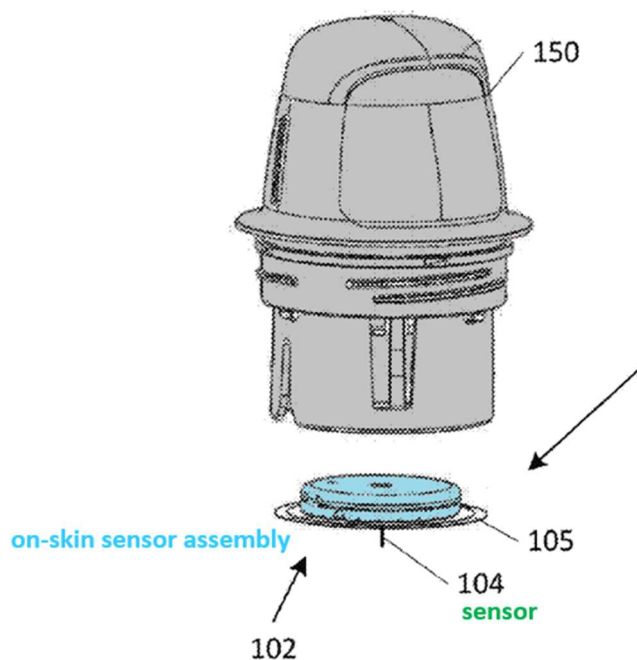
2602, with distal portion 2605 and proximal portion 2603, is configured to pierce the skin of a user/host. *Id.* at [0134], [0143], [0164].

53. In Figure 11H above, sharp module 2600 comprises upper conical pawl 2616 and a lower portion, including bend fin guide 2620. *Id.* at [0143]. The lower portion of sharp module 2600 (annotated in green) corresponds to the claimed “base” of the needle hub, and the bend fin guide 2620 (annotated in yellow) corresponds to the “anti-rotation feature extending from the base, the anti-rotation feature comprising a key, the key having a first shape.” *Id.* at Figs. 11H-11J, [0143]-[0145].

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

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

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



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

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

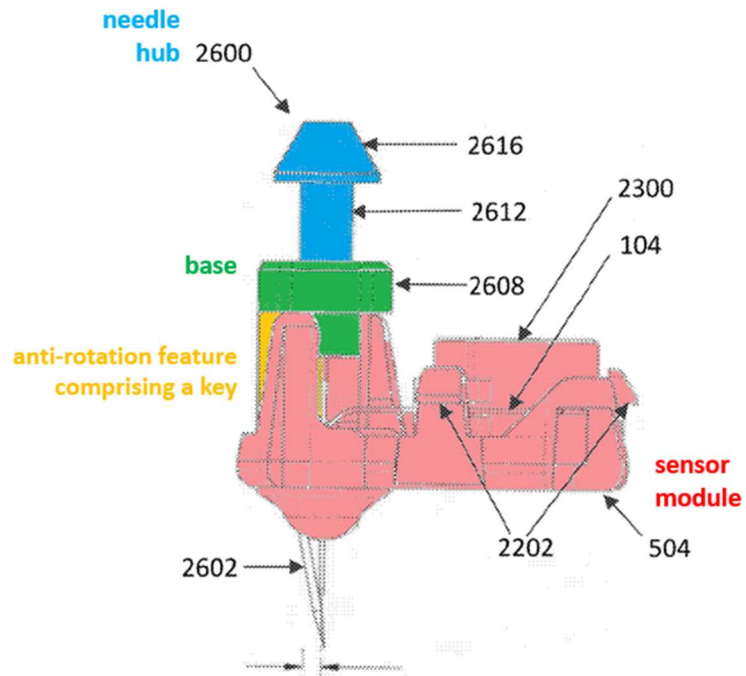


FIG. 11J

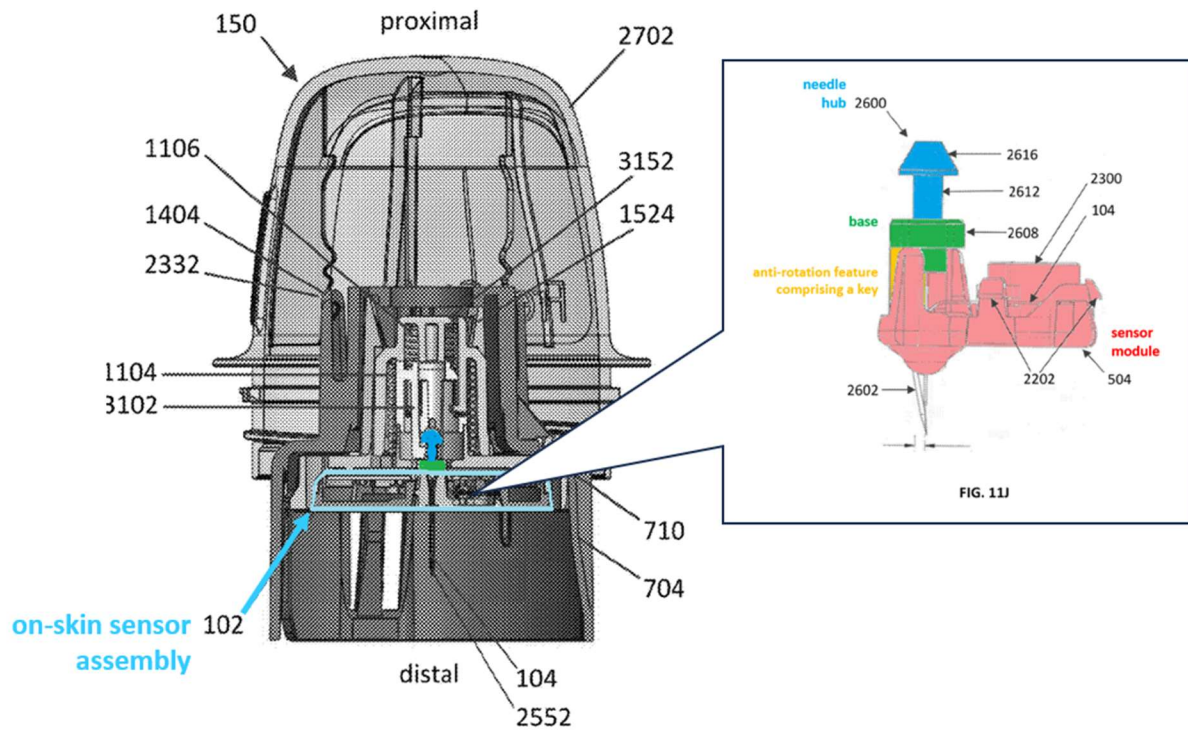


FIG. 12A

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

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

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

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

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

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

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

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

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

the on-skin sensor assembly) having a channel (i.e., the aperture) extending from a top surface of sensor control device 102, and through which the needle passes:

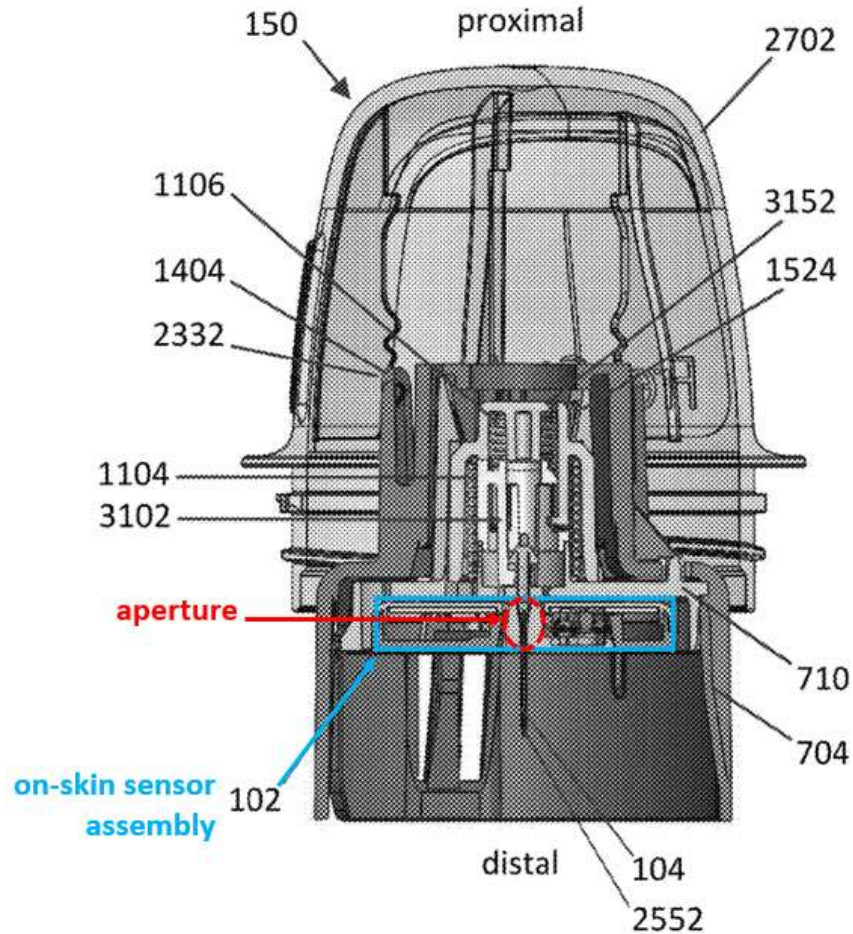
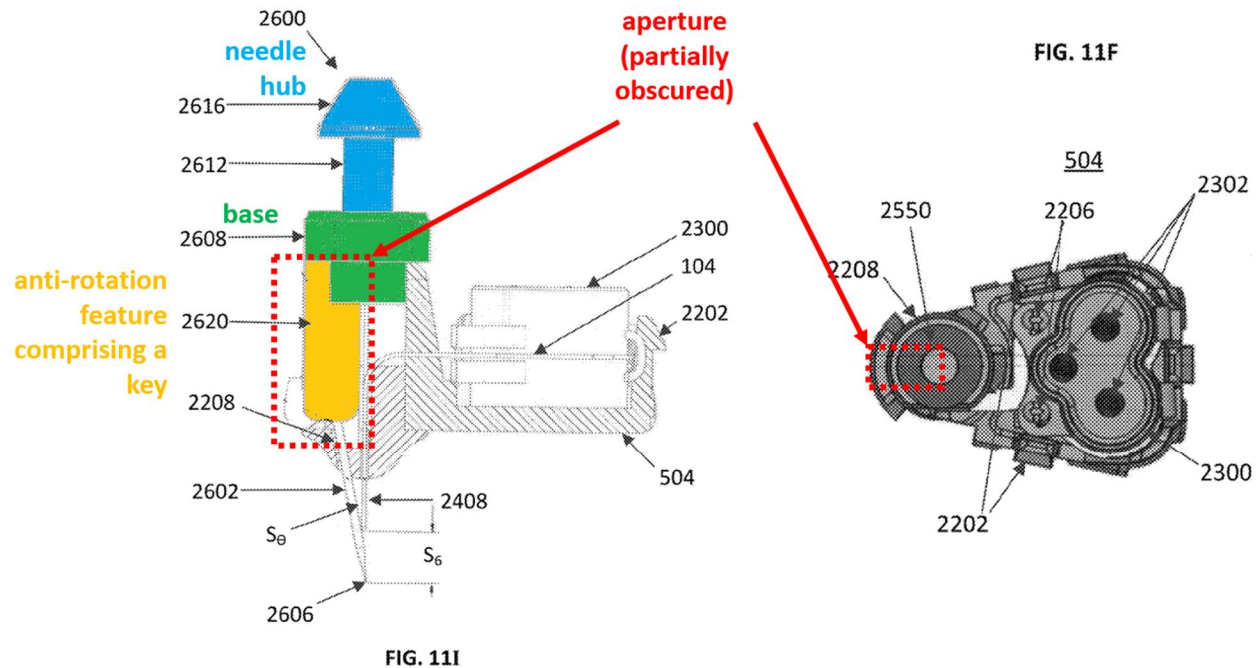


FIG. 12A

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

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

side view in Figure 11I (below left) and the top-down view in Figure 11F (below right).



Id. at Figs. 11I (annotated), 11F (annotated); *see also* Fig. 11H and [0143]-[0145].

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

61. Rao further discloses that bend fin guide 2620 is “coupled” to sensor module 504.

As can be seen in FIG. 11I, sensor module 504 includes sharp slot 2208, through which sharp 2602 can extend in an angled and distal direction. As described earlier, a proximal portion of sharp 2602 passes through bend fin guide 2620, which is coupled with a distal portion of sensor module 504.

Id. at [0144].

62. Because Rao discloses that bend fin guide 2620 is “coupled” to a portion of sensor module 504, and discloses that the bend fin guide “prevents ... rotational movement of sharp 2602,” a POSITA would understand the aperture in sensor module 504 (and thus the sensor control device 102, which the sensor module 504 is a component thereof) has structures to restrain rotational movement of the ‘fin’ 2620 in either direction. For example, because bend fin guide 2620 is a vertical fin that restrains rotational movement, a POSITA would understand that it must engage with a slot.

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

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

64. As explained above for claims 1.2-1.5, bend fin guide 2620 (i.e., the anti-rotation feature comprising a key) prevents rotation of the sharp (and the needle hub coupled to it) within the sensor module 504, which is part of sensor control device 102 (i.e., the on-skin sensor assembly). It does so by being inserted within the aperture in the sensor control device.

2. Independent Claim 13

65. In my opinion, Rao 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:”

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

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

67. See, *supra*, claim 1.1.

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

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

13.4 “wherein the needle hub comprises a base,”

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

68. 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.

69. In addition, claim 13.5 recites an “anti-rotation key,” rather than claim 1.5’s “anti-rotation feature comprising a key.” As explained in claim 1.4–1.5, Rao discloses bend fin guide 2620 extending from the base of a sharp module 2600. Ex-1012 at Figs. 11G-11J, [0143]-[0144]. The bend fin guide corresponds to the claimed “anti-rotation key.”

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

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

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

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

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

70. 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.”

71. See, *supra*, claim 1.11. While claim 1.11 recites preventing rotation of the needle hub with respect to the “aperture” rather than the “on-skin sensor

assembly” in claim 13.11, claim 13.8 makes clear that the aperture is part of the on-skin sensor assembly and thus the needle hub in Rao is prevented from rotating with respect to the on-skin sensor assembly.

3. Independent Claim 22

72. In my opinion, Rao renders obvious claim 14, 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:”

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

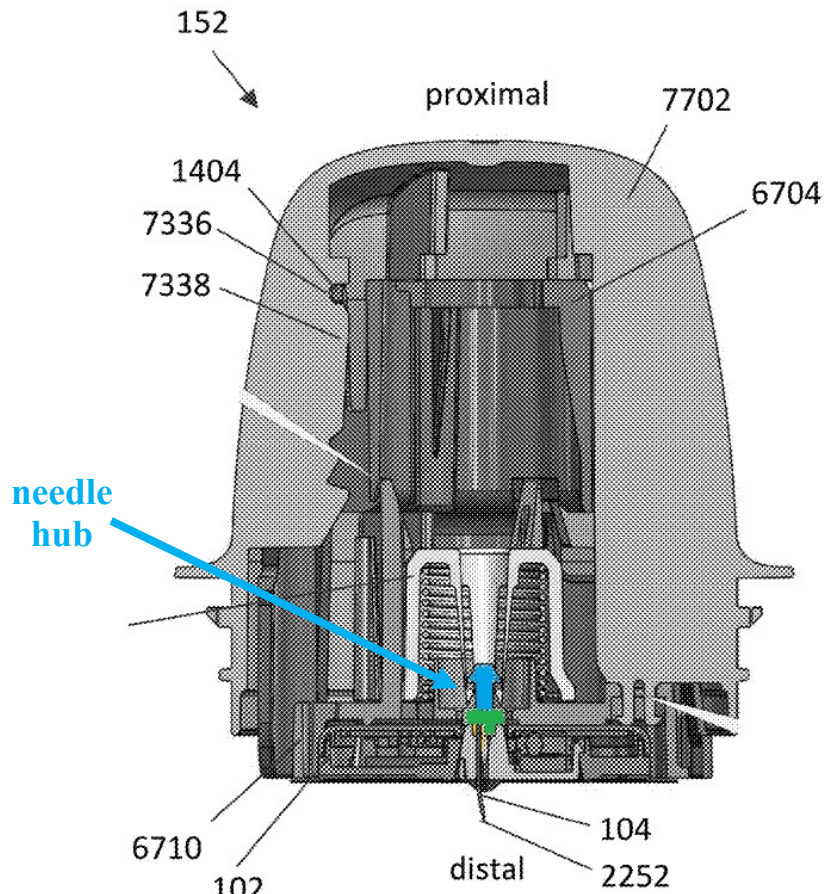


FIG. 14A

Id. at Fig.14A (excerpt, annotated), [0164]-[0165]; *see also id.* at Figs. 12A-12D, 13A-13D.

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

74. *See, supra*, claim 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,”

75. *See, supra*, claim 1.11.

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

76. 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.”

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

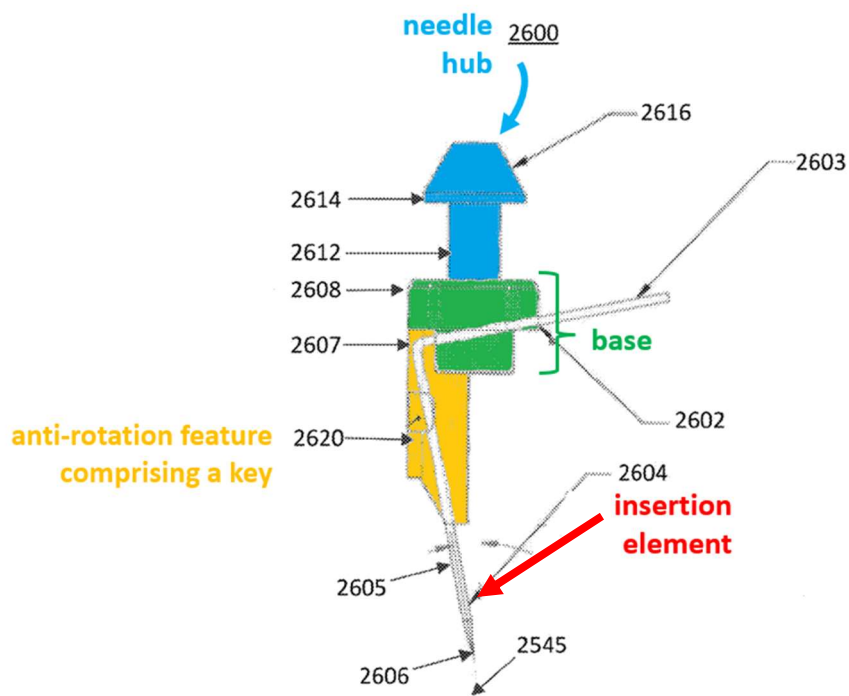


FIG. 11H

Id. at Figs. 11H (annotated), [0143]; *see also id.* at Fig. 11G, 11I-11J.

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

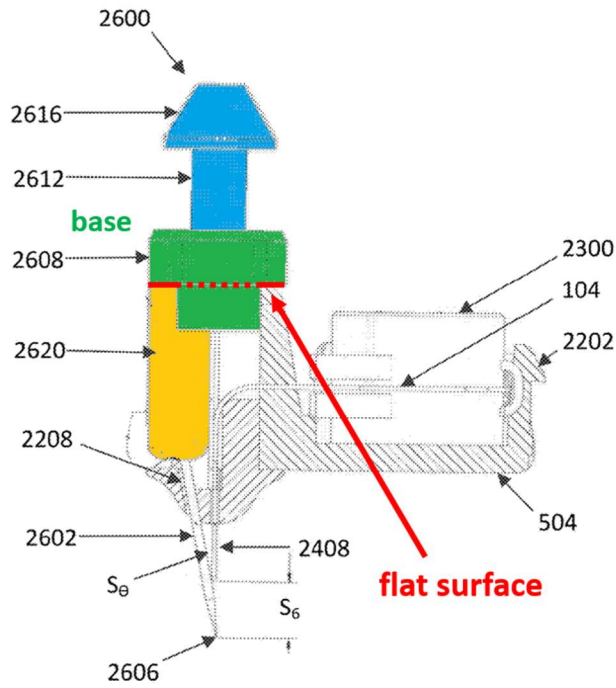


FIG. 11I

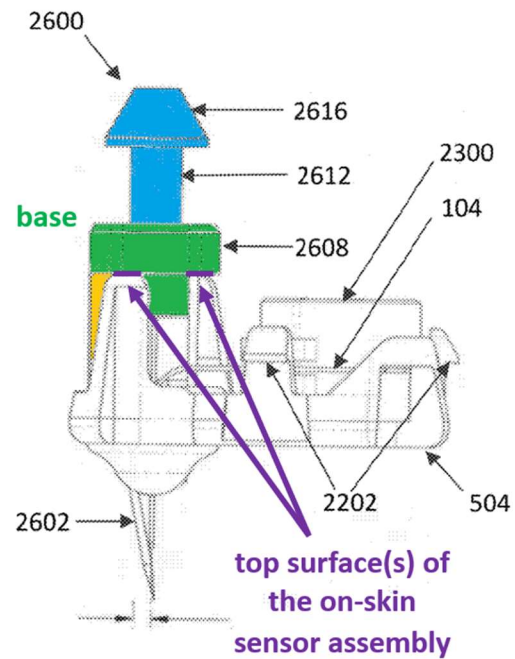


FIG. 11J

Id. at Figs. 11I-11J (annotated).

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

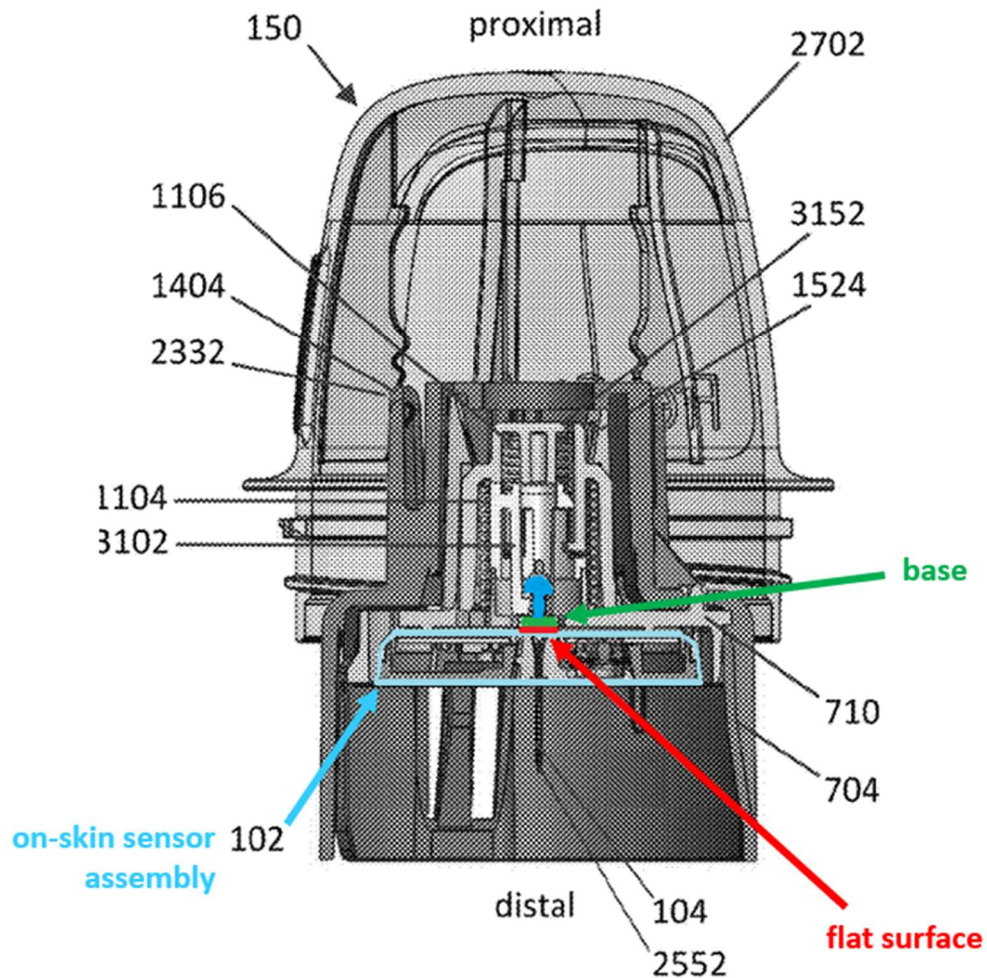


FIG. 12A

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

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

would consider an angle of 5 degrees from the longitudinal axis to be a “substantially perpendicular orientation to the top surface of the on-skin sensor assembly.”

4. Independent Claim 28

81. In my opinion, Rao 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:”

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

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

83. *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:”

84. *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;”

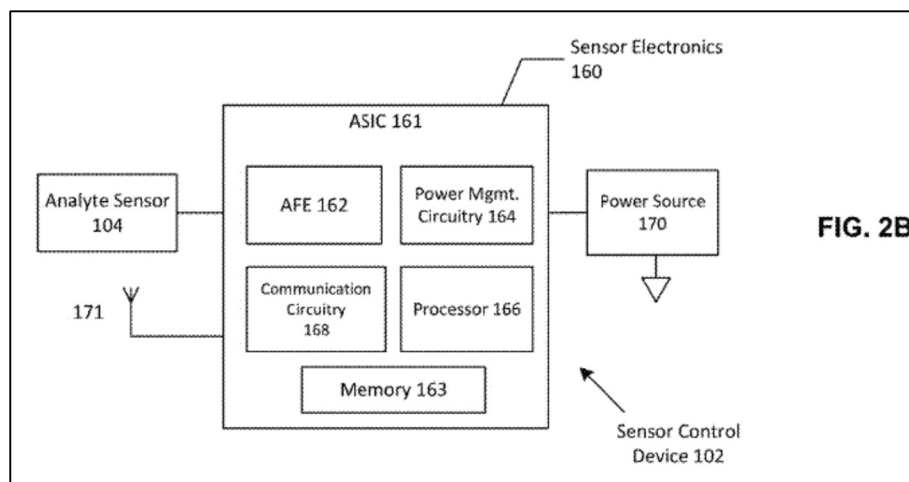
28.8 “an aperture extending from a top surface of the on-skin sensor assembly,”

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

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

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

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



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

...

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

Ex-1012 at Fig. 2B, [0077]-[0078]. Rao further discloses that the sensor electronics are operably connected to the sensor in the applicator:

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

Id. at [0008].

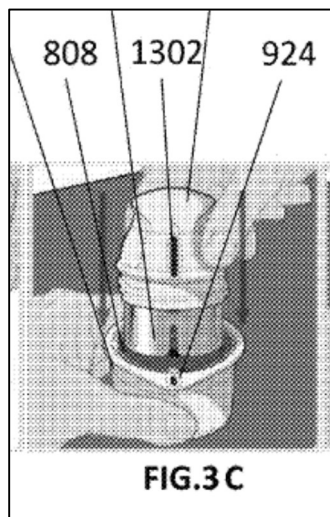
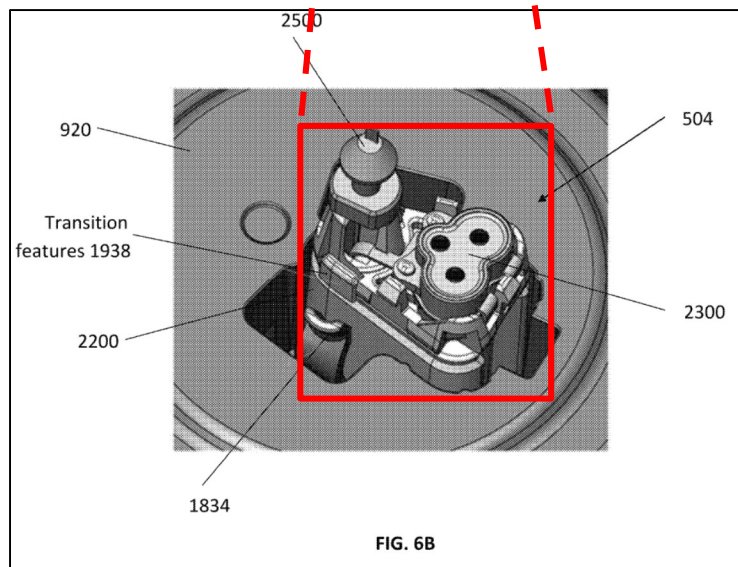
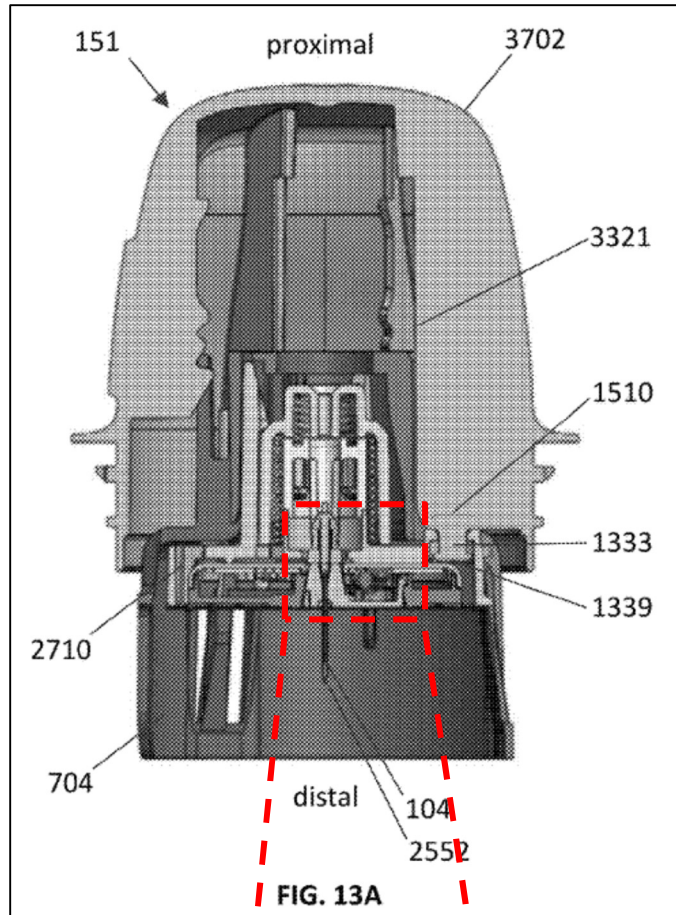


FIG. 3C is a proximal perspective view depicting an example embodiment of a user inserting an applicator device 150 into a tray 810 during an assembly. ... *A sharp and sensor (not shown) within tray 810 can be coupled with an electronics housing (not shown) within housing 702 at the end of the distal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

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



Id. at Fig. 9D, 6B (annotated to show relationship between figures).

87. Rao further discloses that the electrical connection between the sensor and the sensor electronics is made via electrical conductive contacts:

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

Id. at [0142].

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

88. *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”

89. *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.”

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

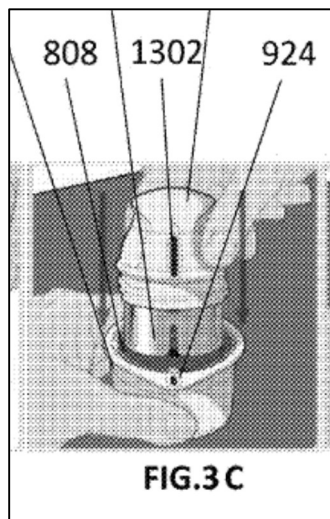


FIG. 3C is a proximal perspective view depicting an example embodiment of a user inserting an applicator device 150 into a tray 810 during an assembly. ... ***A sharp and sensor (not shown) within tray 810 can be coupled with an electronics housing (not shown) within housing 702 at the end of the distal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

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

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

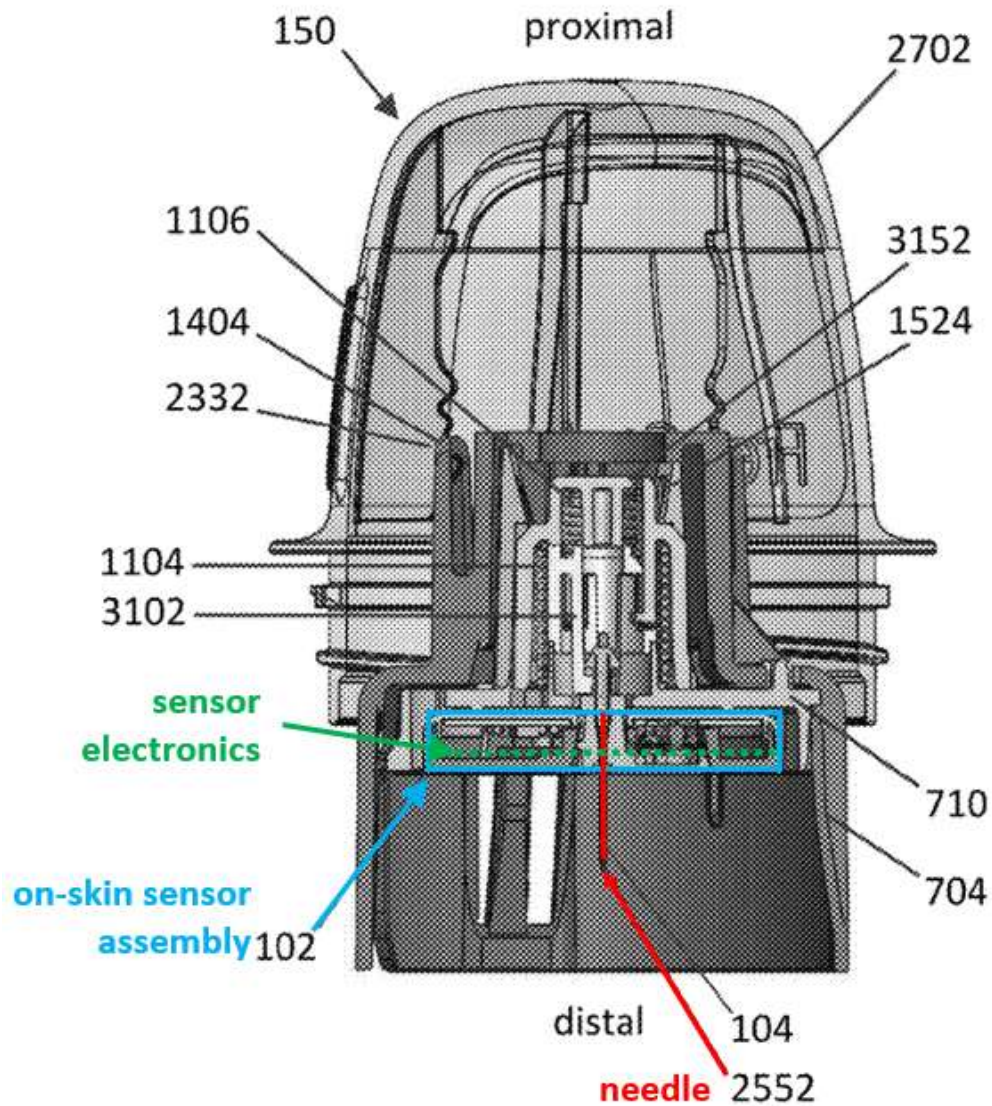


FIG. 12A

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

5. Claims 2 & 25

91. In my opinion, Rao 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].”

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

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

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

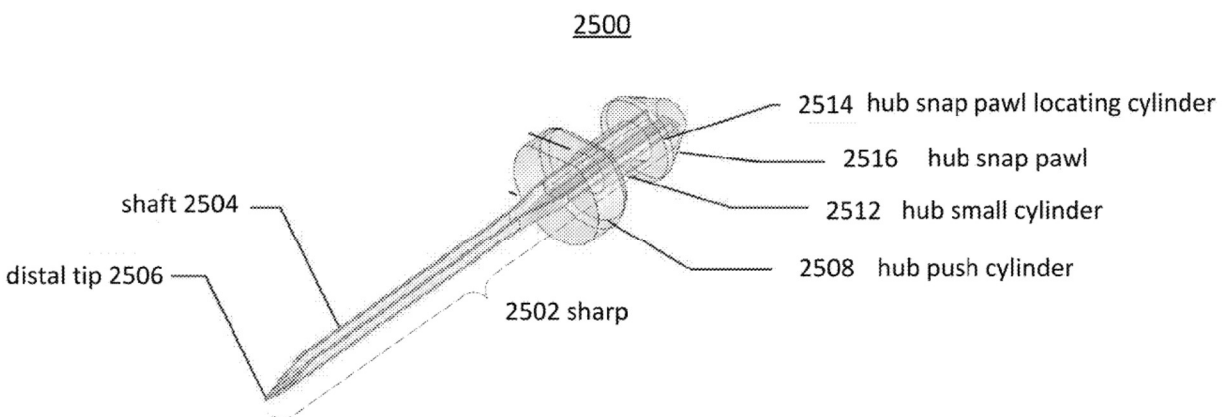


FIG. 11A

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

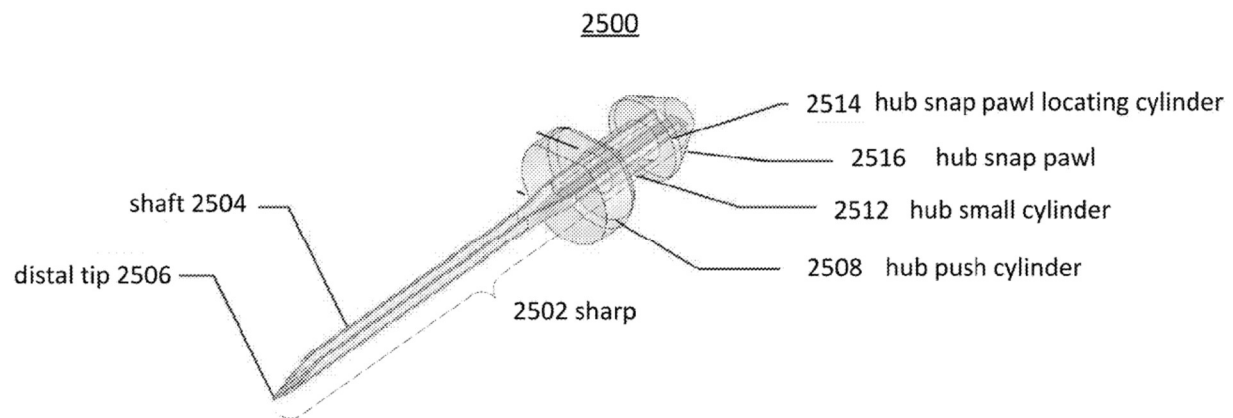
recessed shaft to hold the sensor tail). A POSITA would have been motivated to utilize the needle of Figure 11A as the insertion element when inserting a sensor with a tail in order to protect the sensor tail.

6. Claim 3

93. In my opinion, Rao 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.”

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



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

7. Claims 4, 14, 26, & 30

95. In my opinion, Rao 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, and 28.

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

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

97. Rao discloses that the sharp module may be formed by molding: Sharp 2552 can be positioned in an off-center location during a **molding process with hub components** 2558, 2562, 2566, each of which may consist of a rigid plastic material.

Ex-1012 at [0137].

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

Id. at [0143].

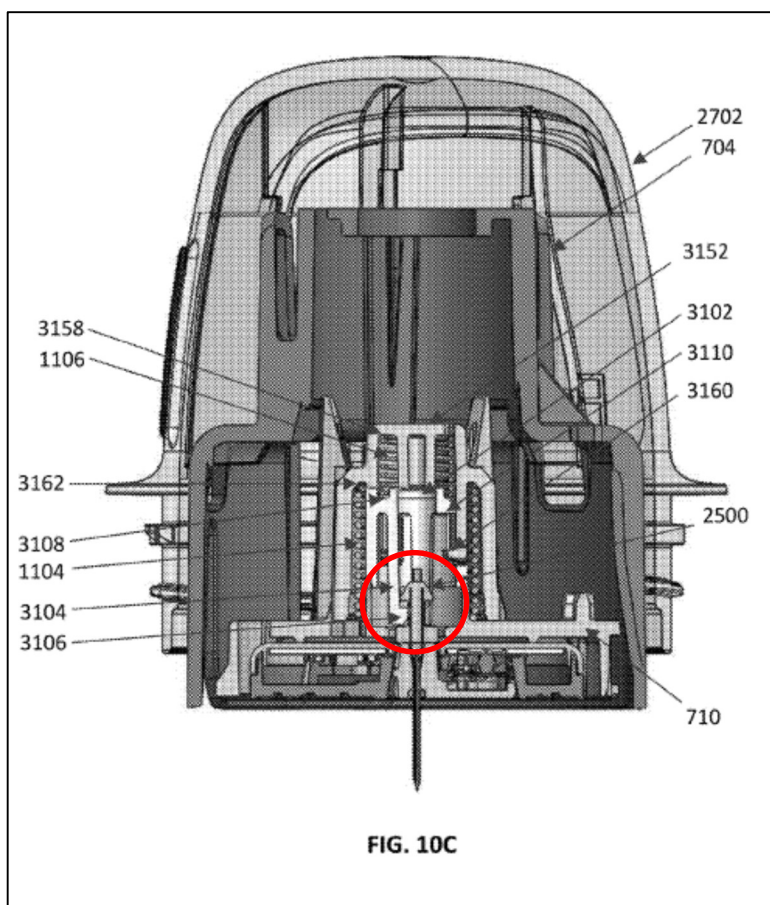
98. A POSITA would understand the above-described “molding process” to be “insert molding.”

8. Claims 5, 15, & 27

99. In my opinion, Rao 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.”

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



Ex-1012 at Fig. 10C (annotated), [0124]; *see also id.* at Figs. 12D, 13D (depicting retraction process).

101. Because the sharp module (i.e., needle hub) is able to retract the needle out of the user, a POSITA would understand that the needle necessarily has some structure to secure it to the sharp module, otherwise there would be a risk of the needle separating from the needle hub.

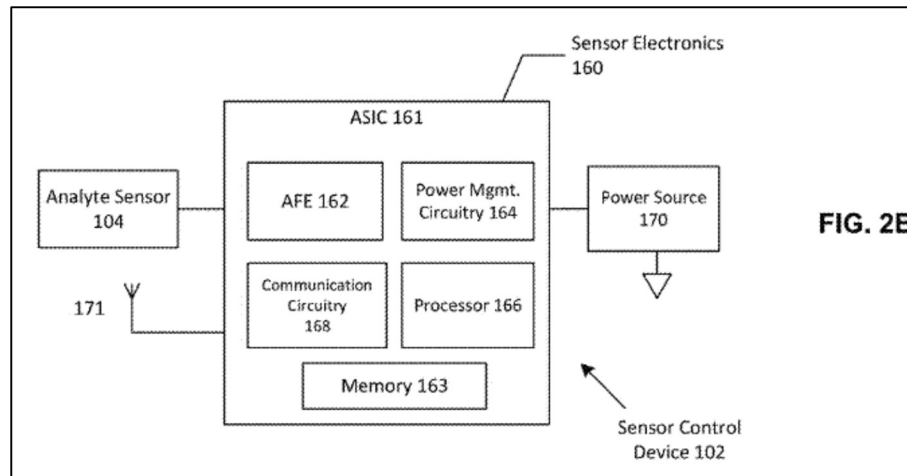
102. As explained for claims 4, 14, 26, and 30 above, Rao discloses or suggests coupling the needle to the needle hub “by insert molding.” *See* claim 4, 14, 26, and 30.

9. Claims 6 & 16

103. In my opinion, Rao 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].”

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



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

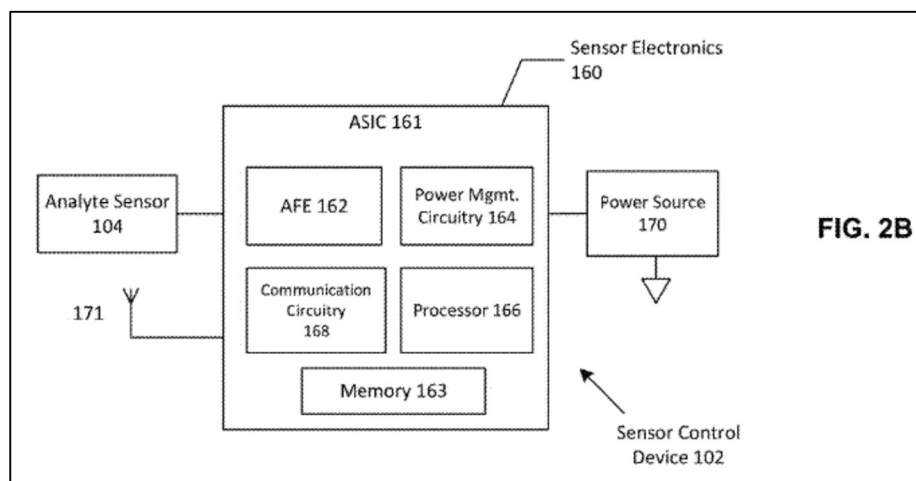
Ex-1012 at Fig. 2B, [0077]-[0078]; *see also id.* at Fig. 2C, [0079].

10. Claims 7, 17, & 29

105. In my opinion, Rao 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.”

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



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

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

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

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

11. Claims 8 & 18

107. In my opinion, Rao 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.”

108. *See, supra*, claim 28.10.

12. Claim 9

109. In my opinion, Rao 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.”

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

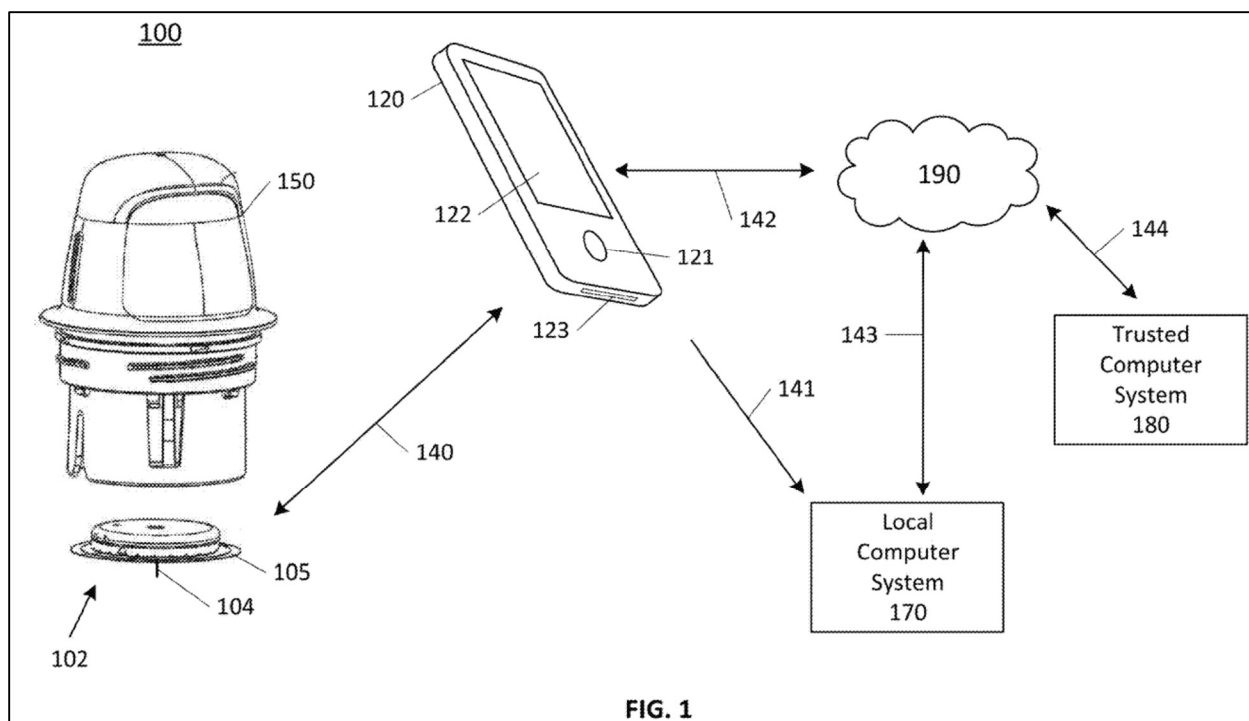


FIG. 1 is a conceptual diagram depicting an example embodiment of an analyte monitoring system 100 that includes a sensor applicator 150, a sensor control device 102, and a reader device 120. Here, sensor applicator 150 can be used to deliver sensor control device 102 to a monitoring location on a user's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

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

13. Claim 19

111. In my opinion, Rao 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.”

112. *See, supra*, claim 28.13.

14. Claim 23

113. In my opinion, Rao 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.”

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

15. Claim 24

115. In my opinion, Rao 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.”

116. *See, supra*, claim 1.9. Claim 24 recites that the anti-rotation key has a shape complementary to at least a portion of the aperture, not vice-versa. This does not impact the analysis, because, by definition, if two structures have

“complementary” shapes, it is irrelevant which structure is compared to the other; the result is the same.

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

1. A POSITA Would Have Been Motivated to Combine Rao and Lundquist and Would Have Reasonably Expected Success

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

118. A POSITA would understand the importance of ensuring that sharp 2602 is coupled to the sharp module 2600 securely enough to ensure proper insertion of the needle and sensor in the user, and to ensure that the needle is successfully

retracted out of the user when the sharp module is retracted. *See id.* at [0119] (“... ensure **full retraction** of sharp carrier 1102 through sheath 704 upon retraction of sharp carrier 1102 at the end of the deployment procedure.”).

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

120. A POSITA would have been motivated to adopt Lundquist’s method of securing the needle to the hub using notches in the needle of Rao’s CGM applicators to achieve Rao’s stated goal of ensuring “full retraction” of the sharp from the user and into the applicator. Ex-1012 at [0119].

121. A POSITA would have a reasonable expectation of success with adopting Lundquist’s manufacturing process in Rao’s CGM systems, as Rao discloses that its sharp (*i.e.*, needle or insertion element) may be “a varying, *i.e.*, changing, width along at least a portion of its length” (Ex-1012, [0146]), and “can include hollow or partially hollow insertion needles” (*id.* at [0147]). Lundquist also

discloses that its insert molding method with notches in the needle can be used with “any sized and shaped [needle].” Ex-1011 at [0041].

122. Furthermore, adding notches for the sharp of Rao to engage the polymeric material used in the sharp module would have been predictable and within the skill of a POSITA.

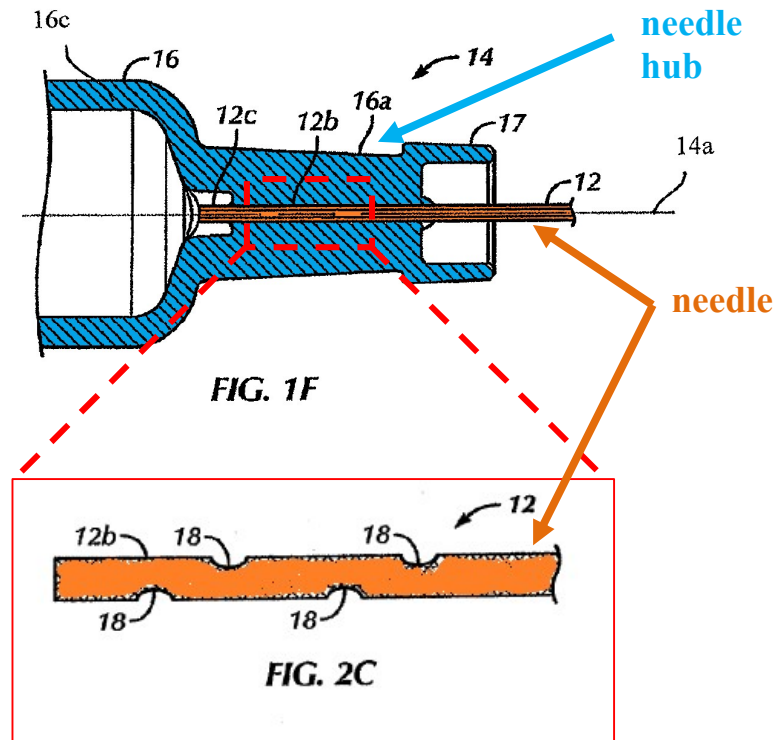
2. Claims 4, 14, 26, & 30

123. Claims 4, 14, 26, and 30 depend from claims 1, 13, 22, and 28 respectively. As explained above, in my opinion, Rao renders obvious claims 1, 13, 22, and 28. In my opinion, the combination of Rao 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.”

124. As discussed above in Ground I, Rao discloses multiple embodiments of sharp modules. In one embodiment, sharp module 2600 (*i.e.*, a needle hub) of Figures 11G-11J is coupled to sharp 2602 (*i.e.*, a needle or insertion element). Ex-1012 at Fig. 11G-J, [0134], [0143]. The sharp module 2600 comprises upper conical pawl 2616 and a lower portion, including bend fin guide 2620. *Id.* at [0143]. Rao further discloses that the sharp module 2600 may be formed by a “molding process.” *Id.*; *see also id.* at [0137]. A POSITA would understand that the “molding process” disclosed in Rao to be “insert molding.”

125. In addition, Lundquist explicitly discloses that a needle 12 is coupled to a hub 16a by insert molding:



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

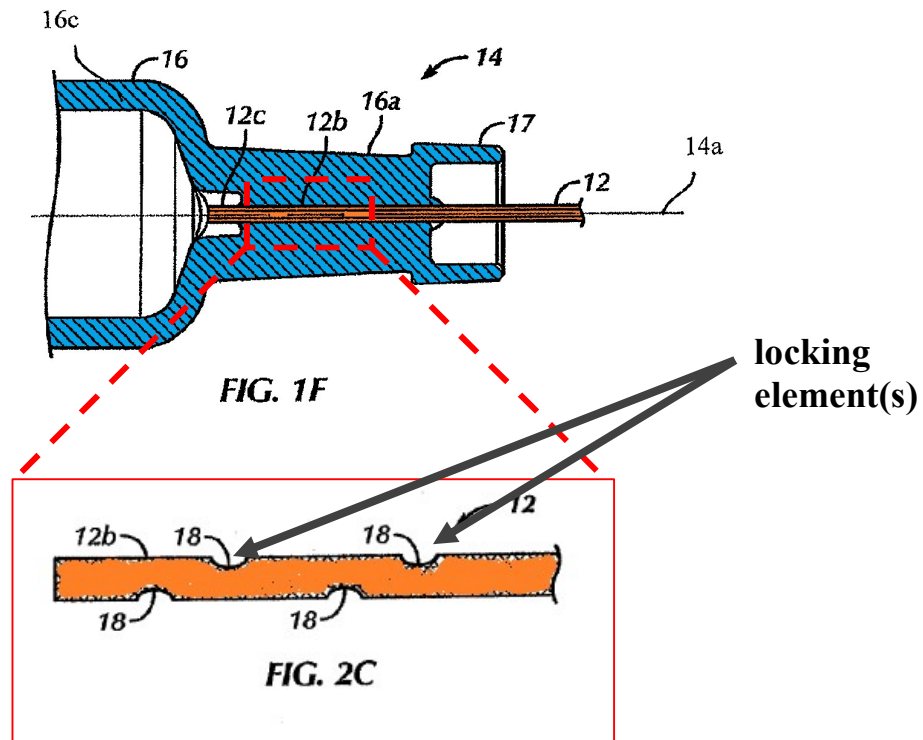
126. In the Rao-Lundquist combination, the sharp module 2600 and sharp 2602 of Rao are coupled together by insert molding the sharp module over the needle, as taught in Lundquist.

3. Claims 5, 15, & 27

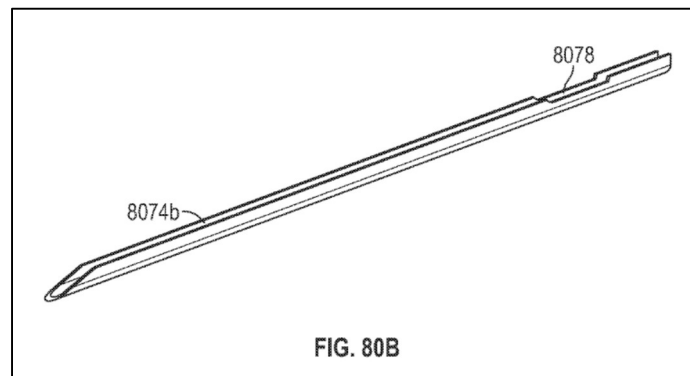
127. Claims 5, 15 and 27 depend from claims 4, 14 and 26 respectively. As explained above, in my opinion, the combination of Rao and Lundquist renders obvious claims 4, 14, and 26. In my opinion, the combination of Rao and Lundquist further renders obvious claims 5, 15, and 27, as explained below.

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

128. As explained above, Rao discloses that a sharp module 2600 is coupled to a sharp 2602, with the sharp module being formed by a “molding process,” which a POSITA would understand to be insert molding, and Lundquist further discloses coupling a needle 12 to a hub 16a by “insert molding.” *See, supra*, claims 4, 14, and 26. Lundquist further discloses that the “cannula” or “fine gauge hollow needle” 12 includes a plurality of “notches” 18 (seen in Figure 2C below), such that the polymeric material that forms the hub 16a “flows into and fills the notches” during the insert molding step.



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

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

IX. AVAILABILITY FOR CROSS-EXAMINATION

130. 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

131. 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

132. 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.