

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, Cover. Accordingly, applying an effective filing date for the Challenged Claims of the ’625 patent no earlier than April 16, 2018, see supra Section IV.D, Rao qualifies as prior art to the ’625 patent under at least 35 U.S.C. § 102(a)(2) (AIA). Rao was not of record during prosecution of the ’625 patent~~ [Ex-1012 at Cover](#).

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

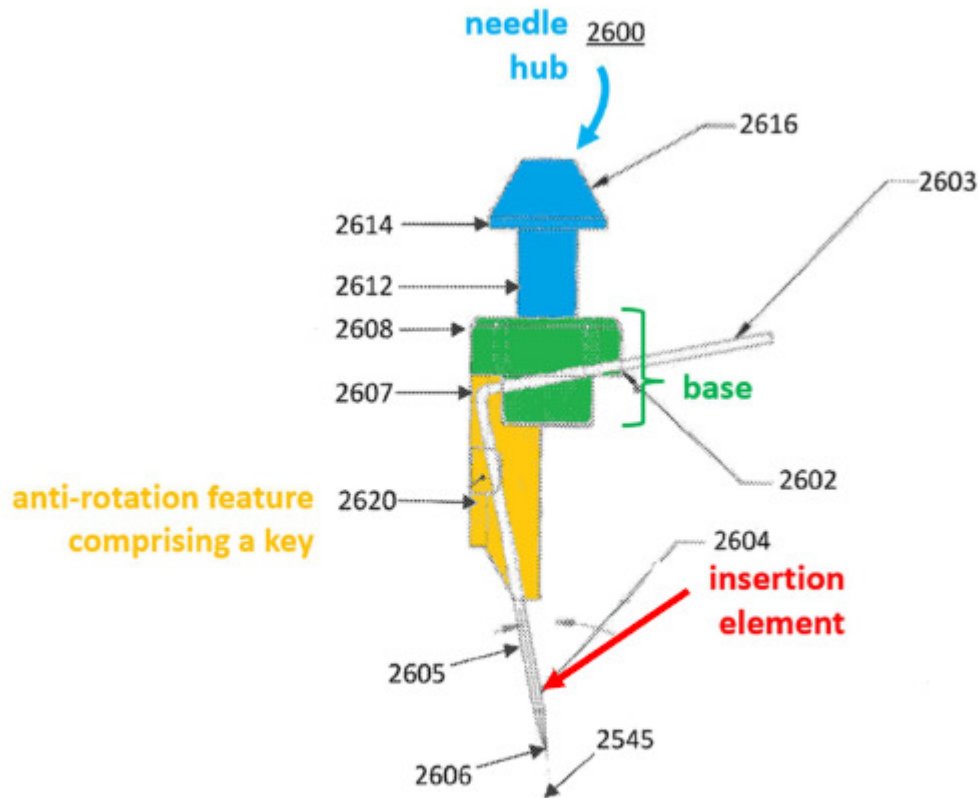


FIG. 11H

Ex-1012, at 11H. (annotated).

44. Further, ~~the~~ sharp module 2600 engages with ~~a~~ sensor module 504, as seen in Figure 11J below. The sharp module 2600 and sensor module 504 can be provided in a sterile package, separate from the applicator and electronics housing. *Id.*, 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 (~~annotated~~ call-out).

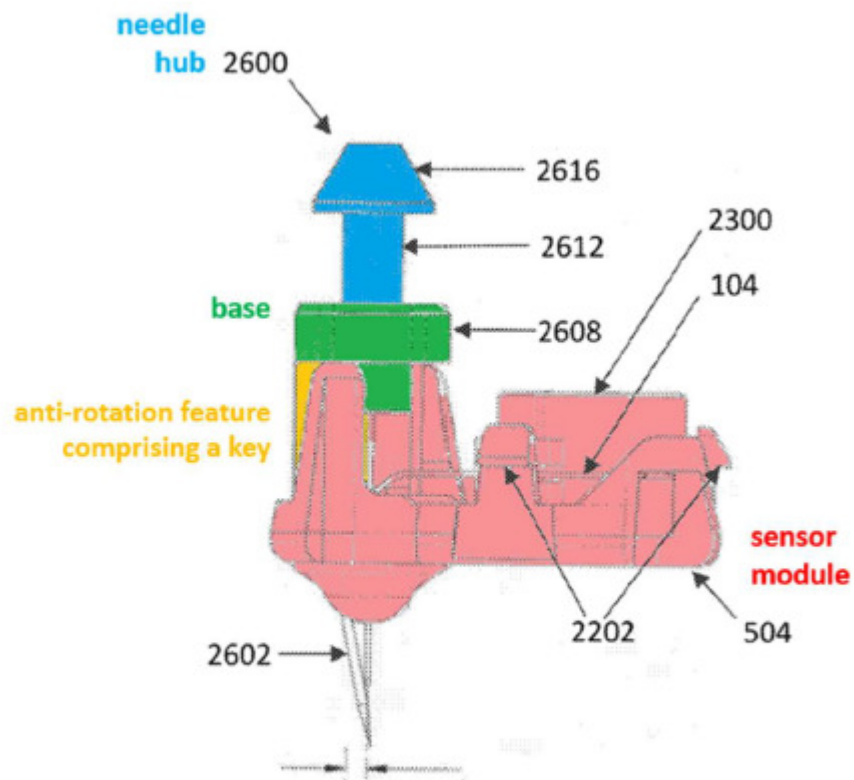
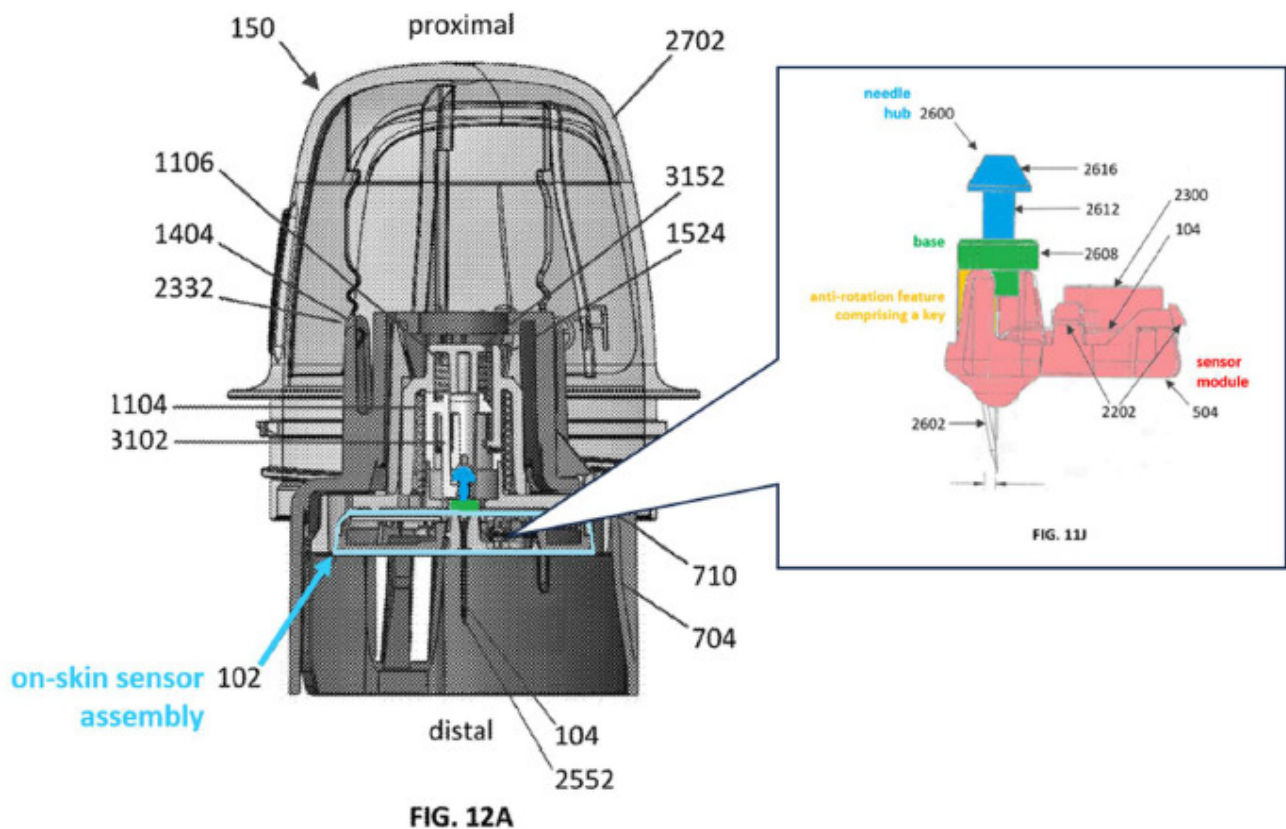


FIG. 11J



Id., at Figs. 11J, 12A and 11J; 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.

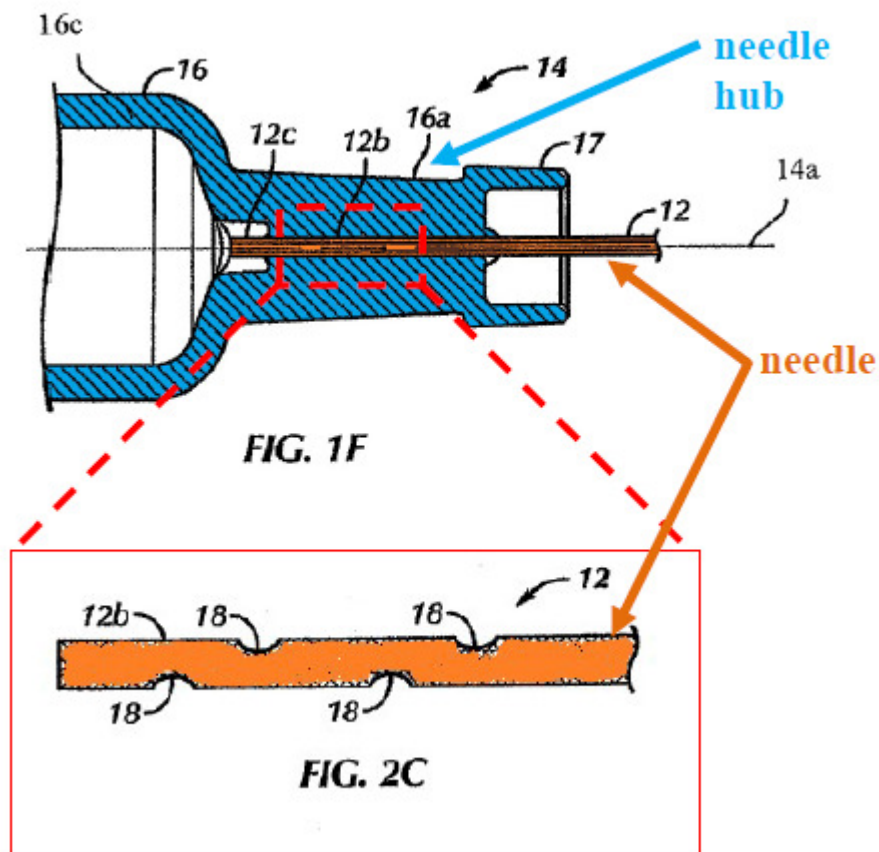
45. ~~Rao is analogous art, as~~ Rao discloses a CGM applicators and applicator and is thus from the same field of endeavor. ~~In re Bigio, 381 F.3d 1320, 1325 (Fed. Cir. 2004).~~ as the '625

[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. ~~Accordingly, Lundquist qualifies as prior art under at least 35 U.S.C. §§ 102(a)(1) and (a)(2) (AIA). Lundquist was not of record during prosecution of the ’625 patent.~~

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 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.*

48. Lundquist discloses a method of securing a needle to a needle hub in a medical device and is ~~analogous art, as Lundquist is~~ thus reasonably pertinent to ~~a~~ the problem ~~addressed by~~ with which the '625 patent inventors were involved, namely securing a needle to a needle hub in a medical device ~~to fix the needle's orientation. See Bigio, 381 F.3d at 1325.~~