

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, Cover. Accordingly, Pace qualifies as prior art under at least 35 U.S.C. §§102(a)(1) and (a)(2) (AIA). Pace was listed in an IDS along with hundreds of references during prosecution of the ’625 patent, but the Examiner never cited or discussed Pace in any rejection.~~ [Ex-1006 at Cover](#).

39. Pace discloses multiple CGM ~~applicators with on-body devices.~~ [applicator embodiments](#). In each embodiment, a glucose sensor mates with an electronics assembly inside the applicator ~~prior to use, forming~~ [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 ~~yellow~~ [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 ~~the~~ electronics assembly 2102 ~~with~~ and the sensor assembly 2104) have complementary shapes, which prevent the sharp hub/ gripper 2106 (*i.e.*, needle hub) from rotating ~~relative~~ with respect to the on-skin sensor assembly.

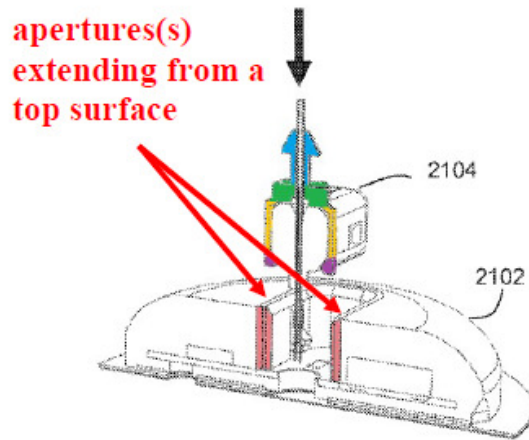


FIG. 21A

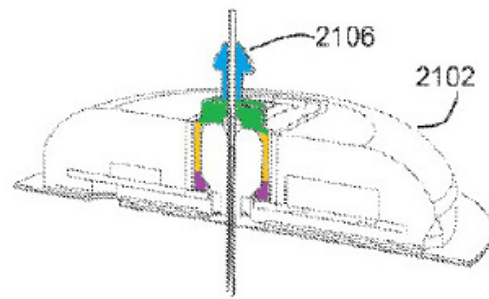


FIG. 21B

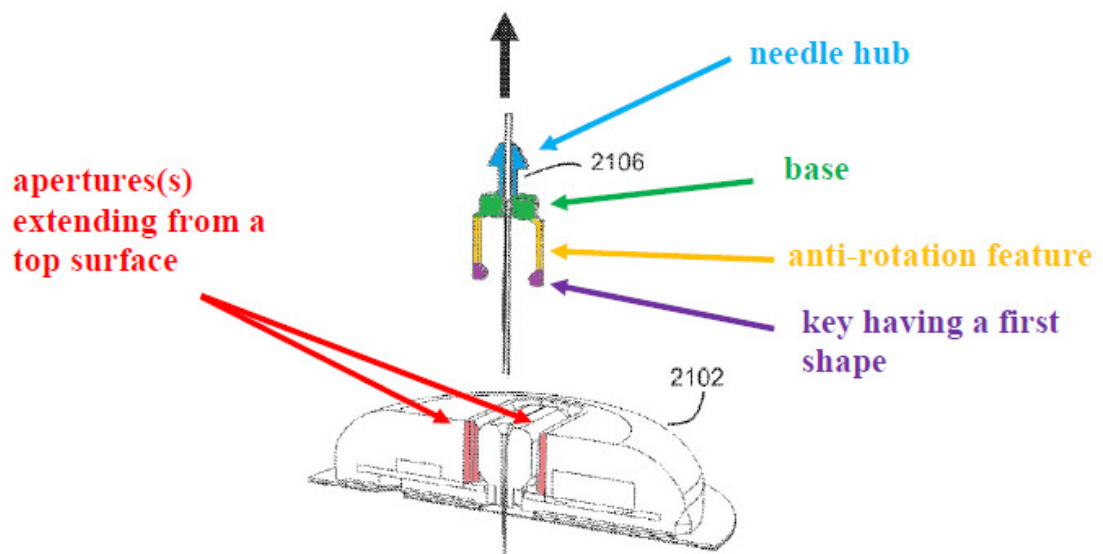


FIG. 21C

Id.

40. Pace further discloses a second embodiment (“embodiment B”) ~~in~~ related

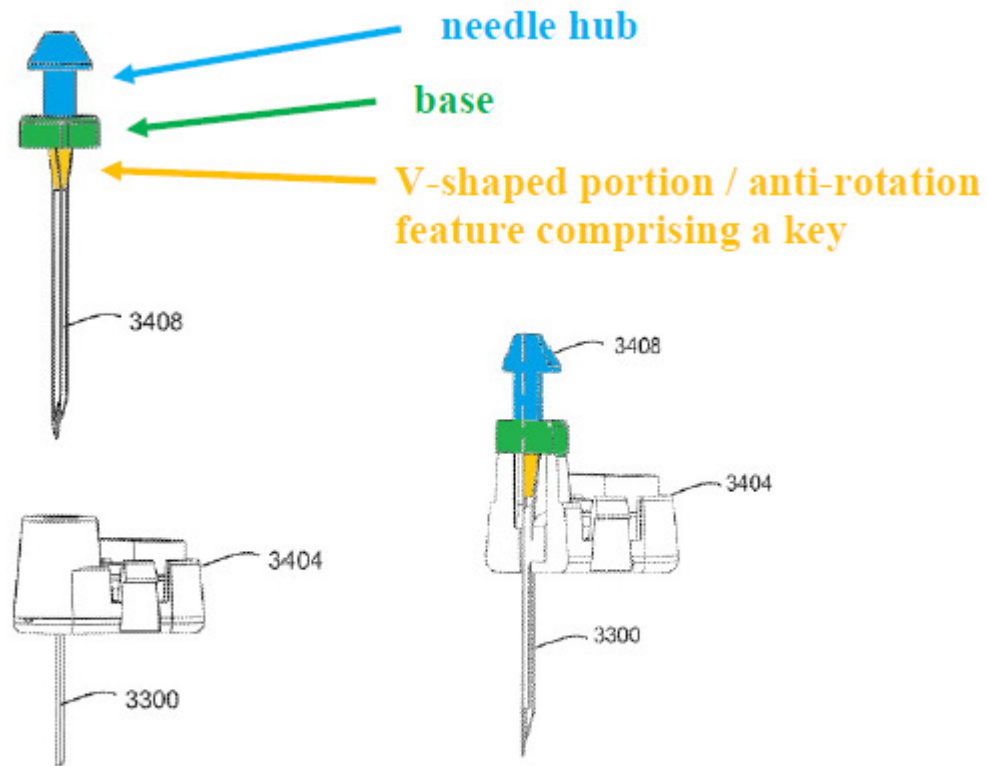


FIG. 35A

FIG. 35B

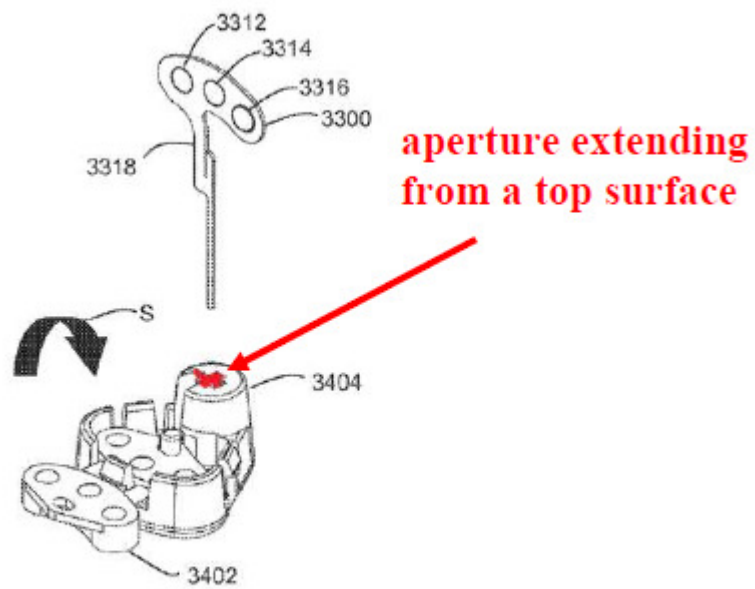


FIG. 34C

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):

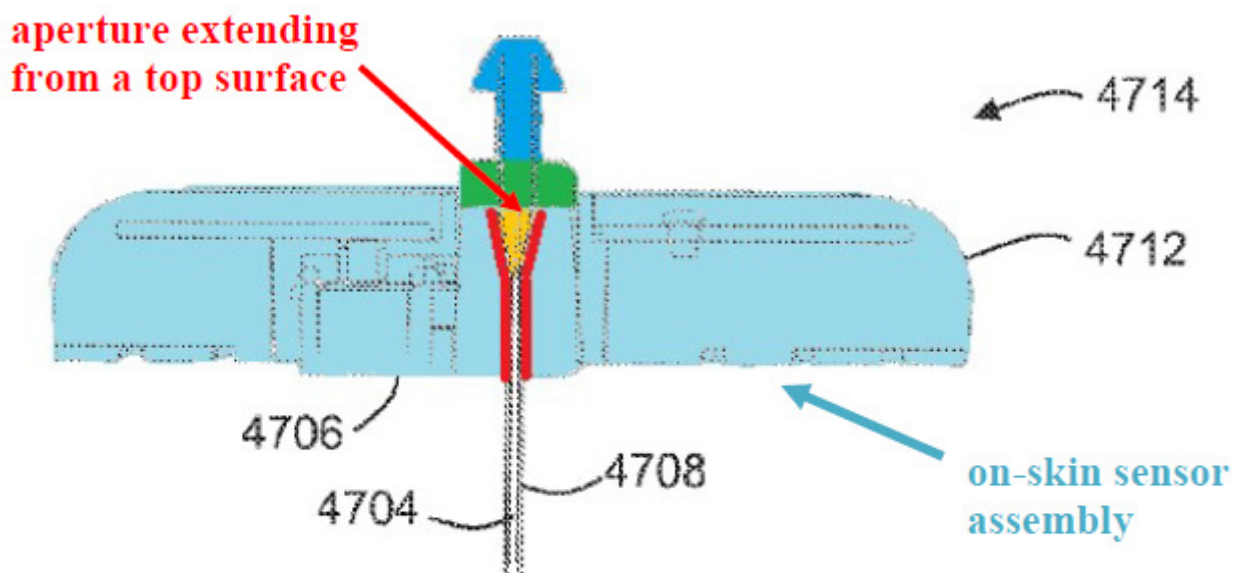


FIG. 47C

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.

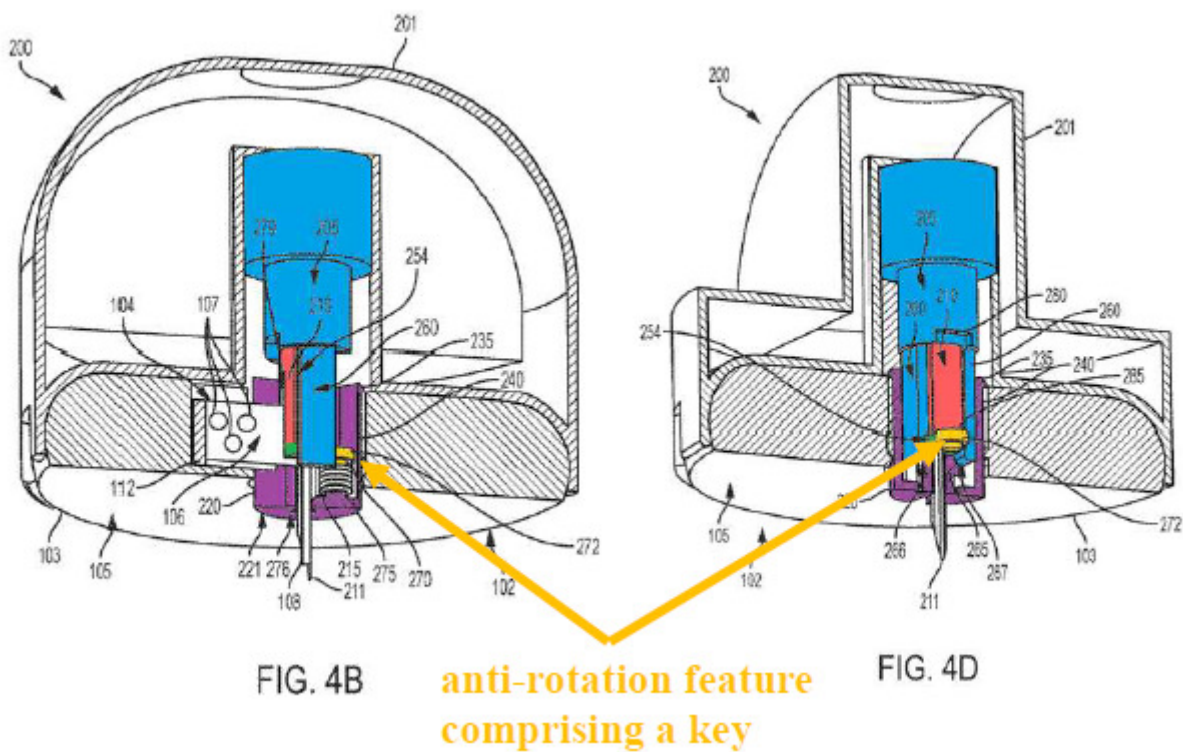
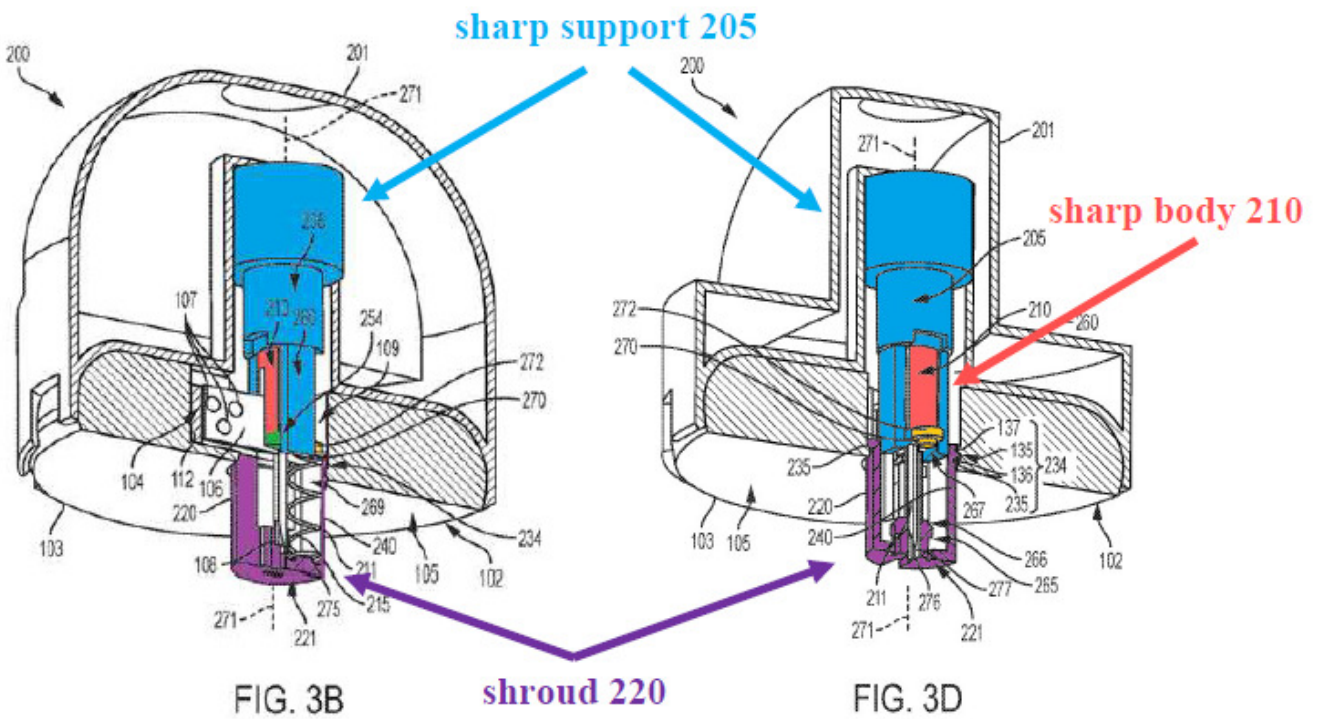
42. ~~Pace is analogous art, as~~ Pace discloses a CGM and applicator and is thus from the same field of endeavor. ~~See *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004).~~ as the '625

[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, Cover. Accordingly, Pace 2 qualifies as prior art under at least 35 U.S.C. §§102(a)(1) and (a)(2) (AIA). Pace 2 was not of record during prosecution of the ‘625 patent~~[Ex-1007 at Cover.](#)

44. Pace 2 discloses ~~a CGM~~[an](#) applicator [for a CGM](#) comprising a housing 201, ~~a~~sharp support 205, and a sharp body 210, ~~that applies~~[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:



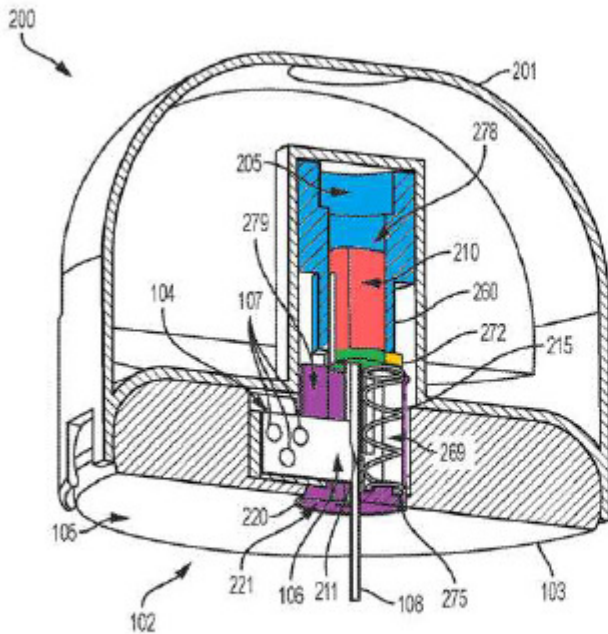


FIG. 5B

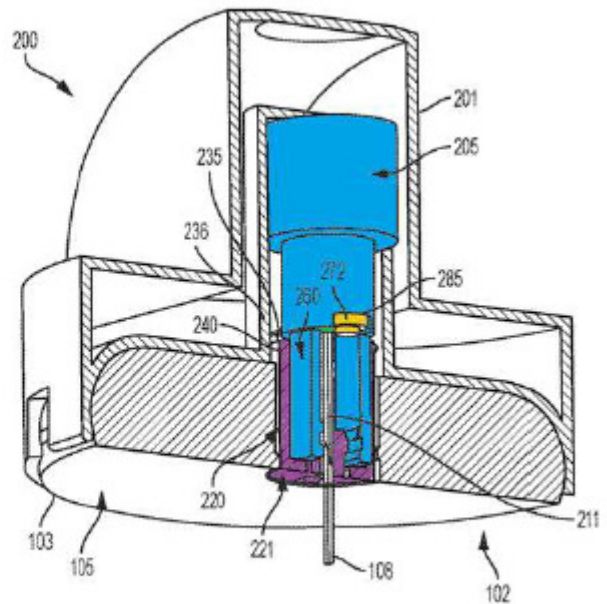


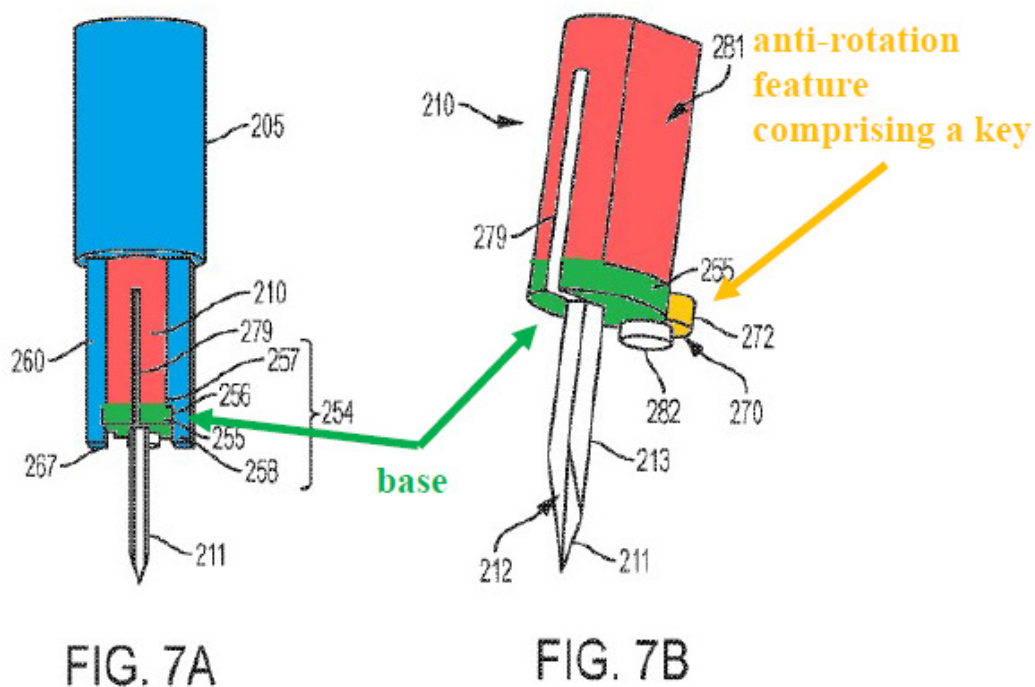
FIG. 5D

Id., [at](#) Figs. 3B-5D.

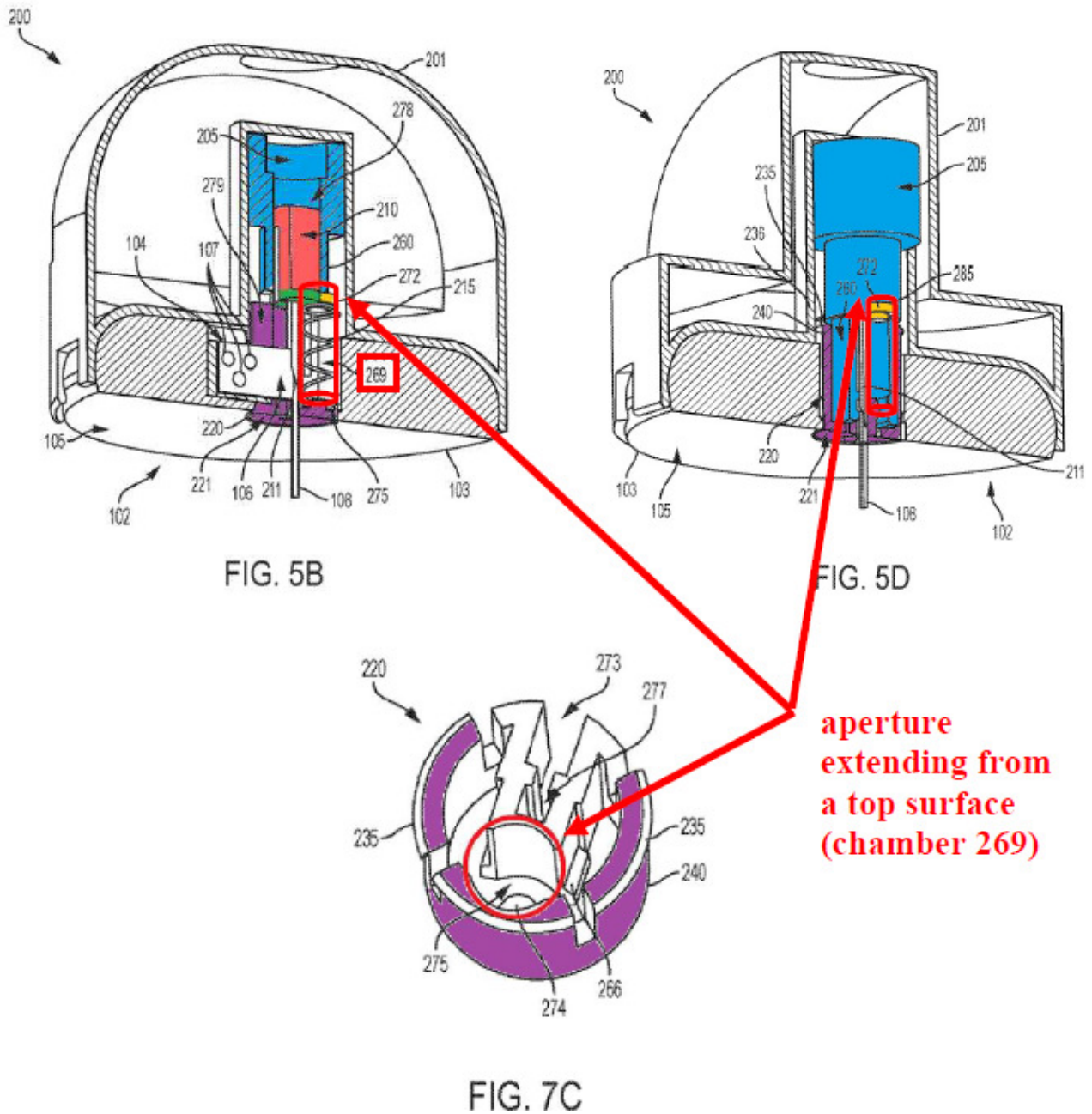
45. In Figures 3B-3D, the shroud 220 (annotated in purple) extends below the bottom surface of the housing 103 to protect the sharp 211 and a portion of the sensor 108. *Id.*, [at](#) Figs. 3B-D, [0056]-[0057]. As the applicator is pressed to the user's skin, the shroud 220 retracts into the housing 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 ~~surface 270 under~~ 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.*, ~~[0067]~~, [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 ~~form~~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. 3B, 5B, 5D, 7C, [0068], [0089].

47. Pace 2 is analogous art, as Pace 2 also discloses a CGM and applicator and is thus from the same field of endeavor. See *Bigio*, 381 F.3d at 1325 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. ~~Chae was not of record during prosecution of the ’625 patent.~~

~~1. Overview Of Chae~~

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

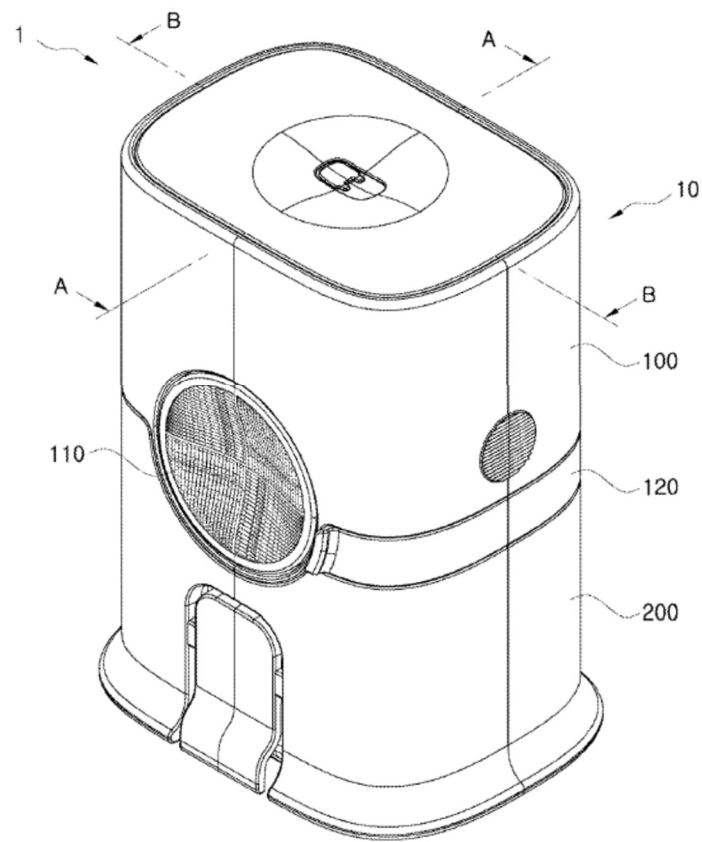
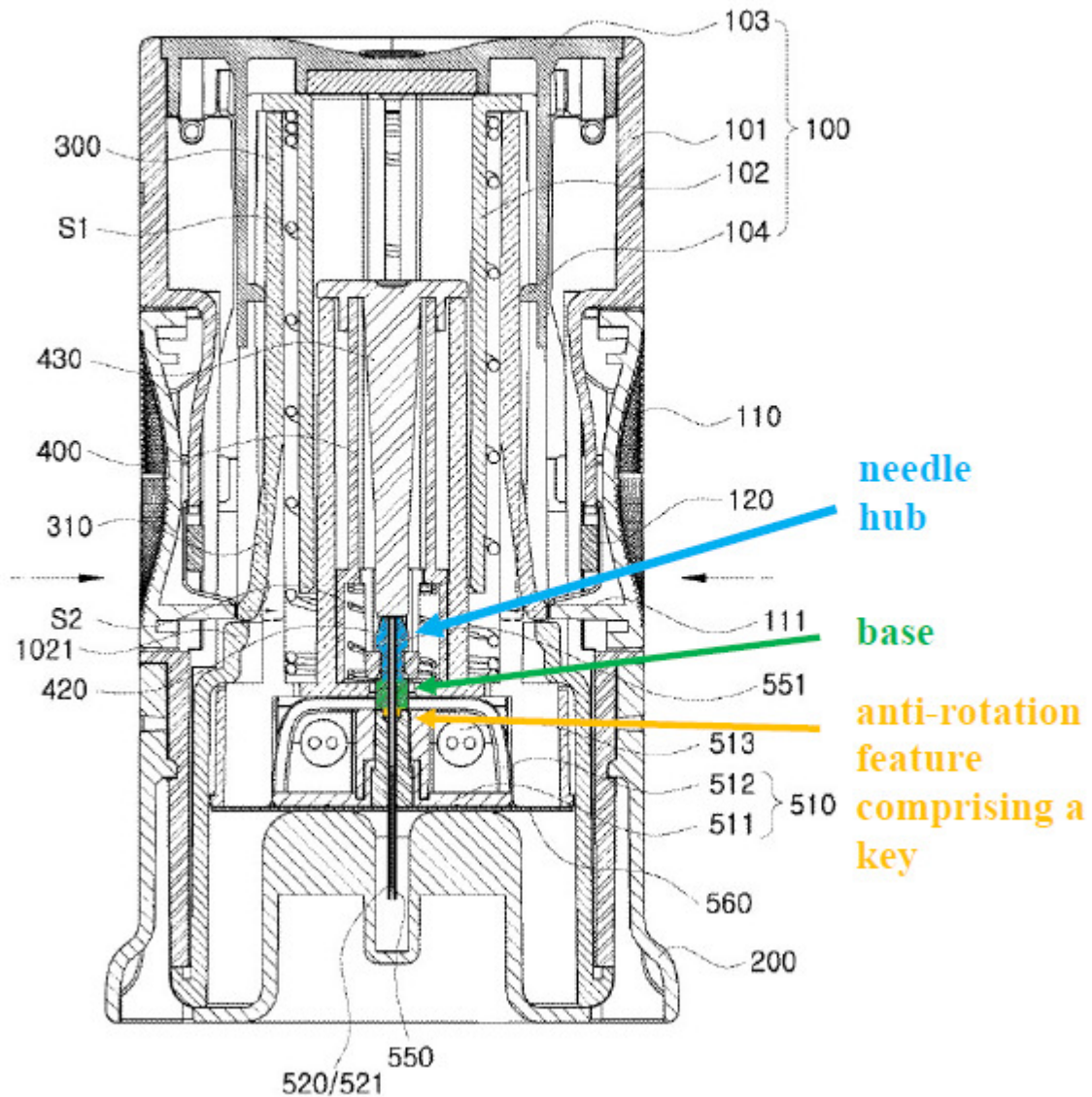


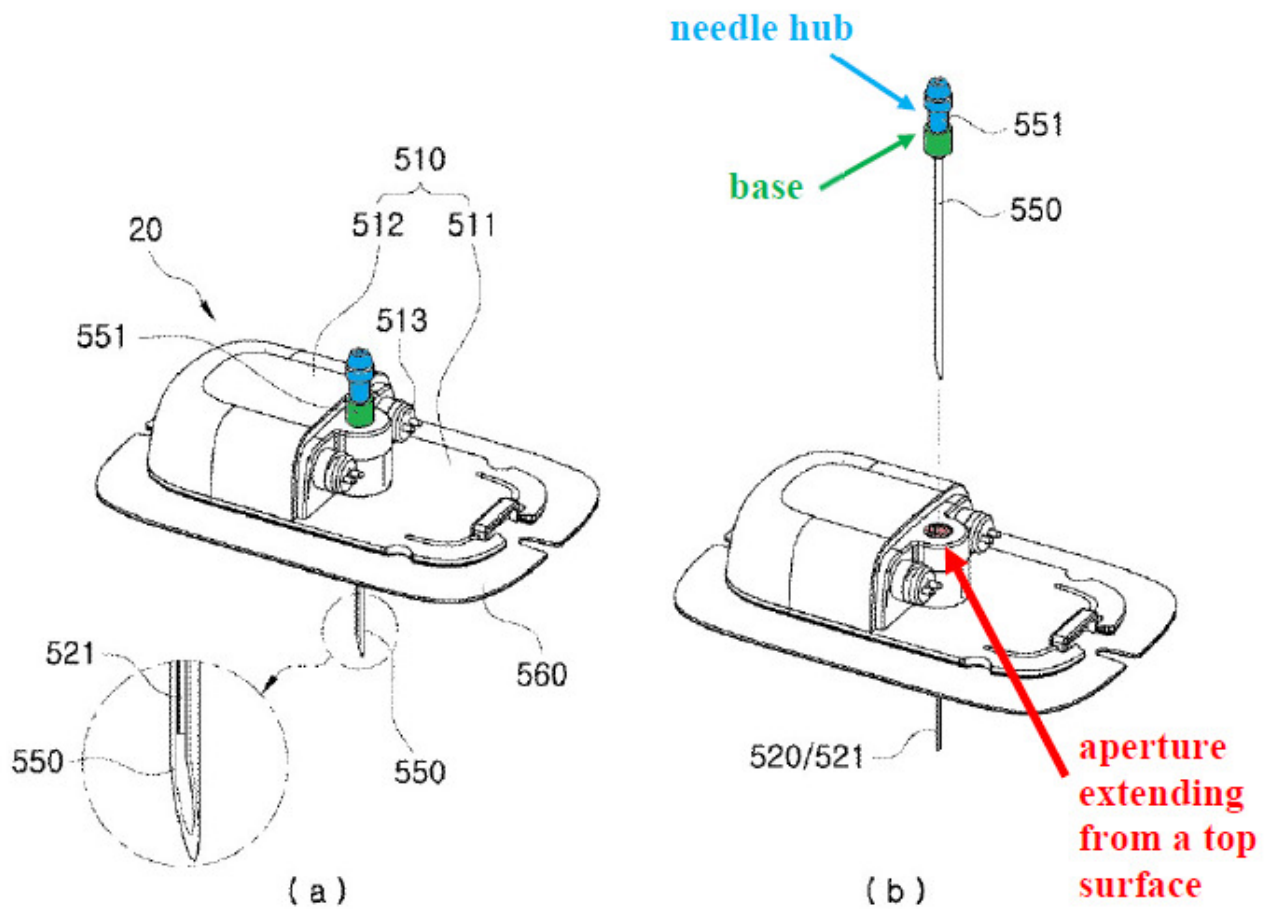
FIG. 5



Id., at Figs. 1, 54, [0053].

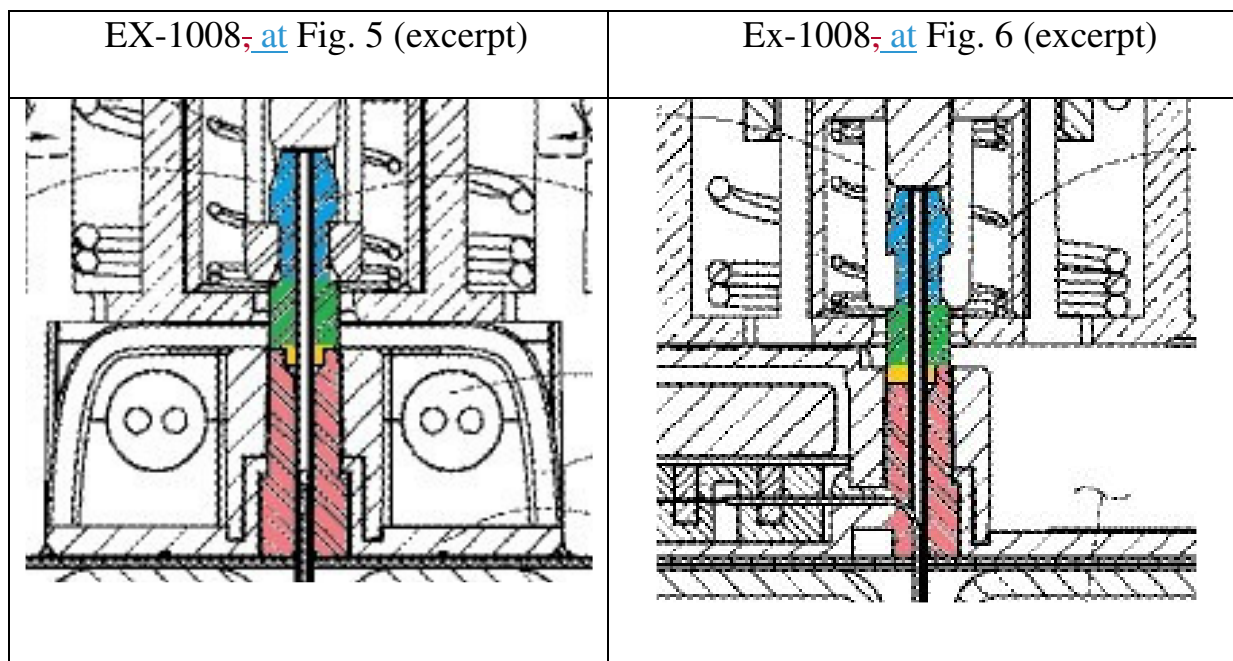
50. Figure 2 below depicts a sensor module 20 with a needle 550 configured to be inserted into the body together with the sensor probe 521, so one end portion of the sensor probe 521 is inserted into the body:

FIG. 2



Id.,

~~Fig. 2, [0085].~~ The base of the needle head 551 has a protrusion that fits into a recess in the sensor housing's aperture:



[Id.](#) [at](#) Fig. 2, [0085]. ~~Chae is analogous art, as~~ Chae discloses a CGM [and](#) applicator and is thus from the same field of endeavor. ~~See *Bigio*, 381 F.3d at 1325.~~

~~2. — Chae Is Entitled To A June 2, 2017, Effective Filing Date~~

51. ~~As noted above, Chae claims priority to two documents, including the '964 Application (Ex-1009, with certified English translation Ex-1010). Because [as](#) the '625 patent is an AIA patent, Chae "need only meet the 'ministerial requirements' of~~

~~§§119 and 120, and [the '964 Application] must 'describe[] the subject matter' relied upon," for Chae to be entitled to the '964 Application's filing date. *Penumbra, Inc. v. RapidPulse, Inc.*, IPR2021-01466, Paper 34 at 32 (P.T.A.B. March 10, 2023) (quoting 35 U.S.C. §102(d)(2) (precedential as to section II.E.3)).~~

~~First, Chae was entitled to claim the benefit of the '964 Application's June 2, 2017, filing date under 35 U.S.C. §§119 and 365, because Chae's PCT application~~

~~designated the United States and at least one other country, and was filed on June 1, 2018, i.e., within 12 months of the '964 Application's filing date.~~

~~Second, the '964 Application includes the figures and description from Chae relied upon below. For example, Figures 5 and 6, which depict the cross section of the applicator with the protrusion from the needle head, are identical in Chae and the '964 Application. Similarly, Chae's Figure 3, which depicts the aperture in the top of the sensor module having a recess corresponding to the protrusion depicted in Figures 5 and 6, also appears as Figure 3 in the '964 Application. While Chae has additional figures and description not explicitly in the '964 Application, Petitioner does not rely on them.~~

~~Accordingly, Chae qualifies as prior art under at least 35 U.S.C. §102(a)(2) (AIA).~~

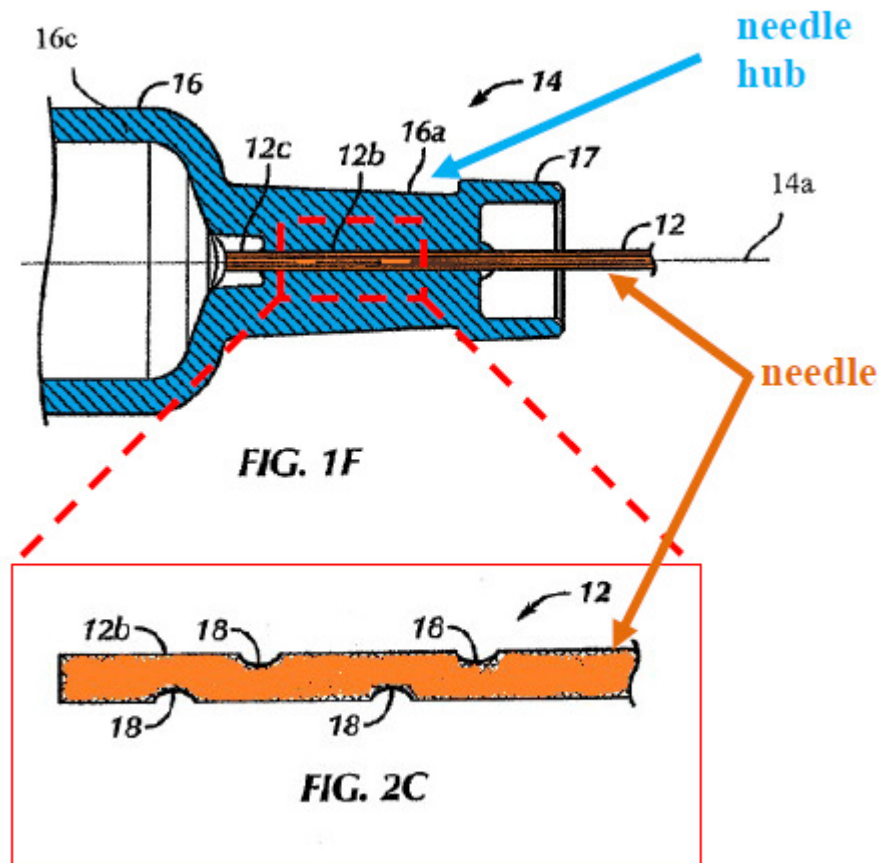
D. Lundquist (Ex-1011)

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. ~~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.~~

53. Lundquist discloses a syringe having a cannula 12 (e.g., a hollow needle) integrally formed with a barrel 16, comprising "hub" 16a, by insert molding.

Ex-1011, at Abstract, [0002]. Figure 2C (below) shows a fine-gauge hollow metallic needle 12 with ~~several~~ 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 ~~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.~~

E. Summary Chart

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