

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT DIABETES CARE INC.,
Petitioner,

v.

DEXCOM, INC.,
Patent Owner.

IPR2024-00859
Patent 11,510,625 B2

Before JAMES A. TARTAL, JON M. JURGOVAN, and
FREDERICK C. LANEY, *Administrative Patent Judges*.

TARTAL, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314; 37 C.F.R. § 42.4

I. INTRODUCTION

Abbott Diabetes Care Inc. (“Petitioner”)¹ filed a Petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of claims 1–9, 13–19, and 22–30 of U.S. Patent No. 11,510,625 B2 (Ex. 1001, “the ’625 patent”). Paper 1 (“Pet.”). DexCom, Inc. (“Patent Owner”)² filed a Preliminary Response. Paper 10 (“Prelim. Resp.”). Patent Owner also filed a statutory disclaimer under 35 U.S.C. § 253(a), dated August 21, 2024, disclaiming claims 22–27 of the ’625 patent. Ex. 2002. Accordingly, at this stage of the proceeding, only claims 1–9, 13–19, and 28–30 of the ’625 patent (the “Challenged Claims”) remain at issue. *See* 37 C.F.R. § 42.107(e) (providing that “[n]o *inter partes* review will be instituted based on disclaimed claims”).

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b) (2018); 37 C.F.R. § 42.4(a) (2023). An *inter partes* review may not be instituted “unless . . . the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). Upon consideration of the Petition, the Preliminary Response, and the evidence of record, we conclude that the information demonstrates a reasonable likelihood that Petitioner would prevail in showing the unpatentability of at least one of the Challenged Claims. Accordingly, we institute an *inter partes* review.

¹ Petitioner further identifies Abbott Diabetes Care Sales Corp. and Abbott Laboratories as real-parties-in-interest. Pet. 2.

² Patent Owner identifies no additional real parties-in-interest. Paper 5, 1.

II. BACKGROUND

A. The '625 Patent

The '625 patent relates to “systems and methods for measuring an analyte in a host, and for applying a transcutaneous analyte measurement system to a host.” Ex. 1001, 2:11–13. The '625 patent discloses that a transcutaneous analyte measurement system, such as an on-skin sensor assembly, may be used to continuously monitor glucose levels in a patient. *Id.* at 1:55–57. “The sensor system may have a wireless transmitter which transmits measurement data to a receiver which can process and display information based on the measurements.” *Id.* at 1:57–60. According to the '625 patent, the application process for the transcutaneous analyte measurement system “should result in the sensor assembly being attached to the person in a state where it is capable of sensing glucose level information, communicating the sensed data to the transmitter, and transmitting the glucose level information to the receiver.” *Id.* at 1:62–67.

Figure 72 of the '625 patent, reproduced below, illustrates an exploded perspective view of an applicator for an on-skin sensor assembly of an analyte sensor system. Ex. 1001, 17:32–36.

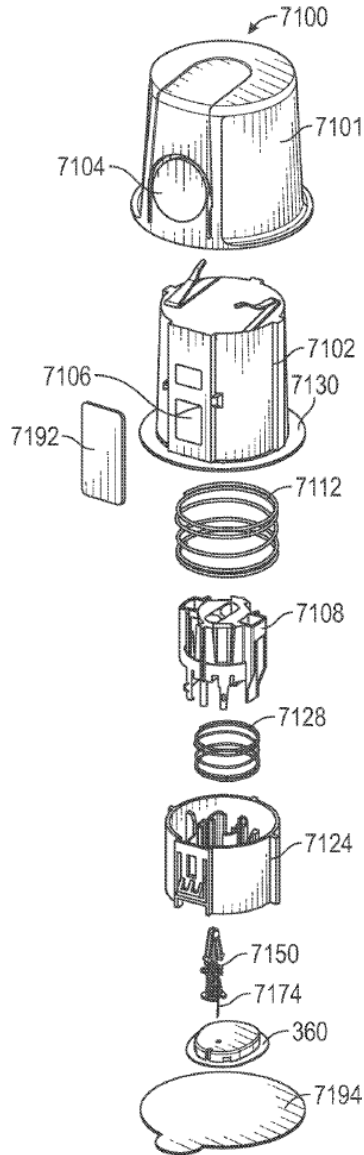


FIG. 72

As illustrated in Figure 72, applicator 7100 includes outer applicator housing 7101, inner housing 7102, needle carrier assembly 7108, holder 7124, an insertion assembly, and a retraction assembly. Ex. 1001, 58:52–59:66. The outer applicator housing 7101 comprises activation element 7104 and “may be configured to translate in a distal direction by a force applied by a host to applicator 7100, specifically to inner housing 7102, thereby aligning activation element 7104 in a position that allows applicator 7100 to fire.” *Id.* at 58:55–59.

Inner housing 7102 is configured to house at least one or more mechanisms to apply on-skin sensor assembly 360 to the skin of a host. Ex. 1001, 58:62–65. Inner housing 7102 may include distal surface 7130 that defines a bottom surface 7100 of the applicator and may have aperture 7106 that is covered with first barrier layer 7192 which is pierced or deformed by at least a portion of activation element 7104 upon activation of applicator 7100. *Id.* at 58:65–67, 59:7–14. Inner housing 7102 may also include second barrier layer 7194 disposed over the bottom opening which may be removed by the host prior to use of applicator 7100. *Id.* at 60:27–28, 31–33. “In embodiments comprising one or both of first and second barrier layers 7192, 7194, such layers may provide a sterile environment between applicator 7100 and the outside environment and/or may allow ingress and egress of gas such as during sterilization.” *Id.* at 60:33–37.

Needle carrier assembly 7108 includes “needle hub 7150 configured to couple an insertion element 7174 to needle carrier assembly 7108.” Ex. 1001, 59:18–21. Insertion element 7174 inserts the sensor of on-skin sensor assembly 360 into the host’s skin and may comprise any suitable type of needle or structure. *Id.* at 59:23–30. Holder 7124 is releasably coupled to needle carrier assembly 7108 and configured to guide needle carrier assembly 7108 and on-skin sensor assembly 360 “at least during translation from a proximal position to a distal insertion position.” *Id.* at 59:35–40. On-skin sensor assembly 360 “may be stripped or released from holder 7124 and/or needle carrier assembly 7108” once the on-skin sensor assembly is disposed on the host’s skin. *Id.* at 59:40–44.

The insertion assembly may include first spring 7112 with “a first end in contact with or coupled to inner applicator housing 7102 and a second end in contact with or coupled to holder 7124.” Ex. 1001, 59:49–54. First

spring 7112 is configured to translate holder 7124, needle carrier assembly 7108, needle hub 7150, insertion element 7174, and on-skin sensor assembly 360 in the distal direction to the distal insertion position upon activation of the insertion assembly. *Id.* at 59:54–58. The retraction assembly may include second spring 7128 with “a first end contacting or coupled to holder 7124 and a second end in contact with or coupled to at least one spring retention element . . . , at least until retraction.” *Id.* at 60:2–8. Second spring 7128 is configured to translate needle carrier assembly 7108, needle hub 7150, and insertion element 7174 from the distal insertion position to the proximal retracted position in response to on-skin sensor assembly 360 contacting the host’s skin “and/or reaching a limit of travel with a force exceeding a predetermined threshold sufficient to cause first end of second spring 7128 to overcome the at least one spring retention element.” *Id.* at 60:8–17.

Figure 77 of the '625 patent, reproduced below, illustrates a perspective partial cutaway view of the needle carrier assembly, hub, and on-skin sensor assembly of the applicator shown in Figure 72.

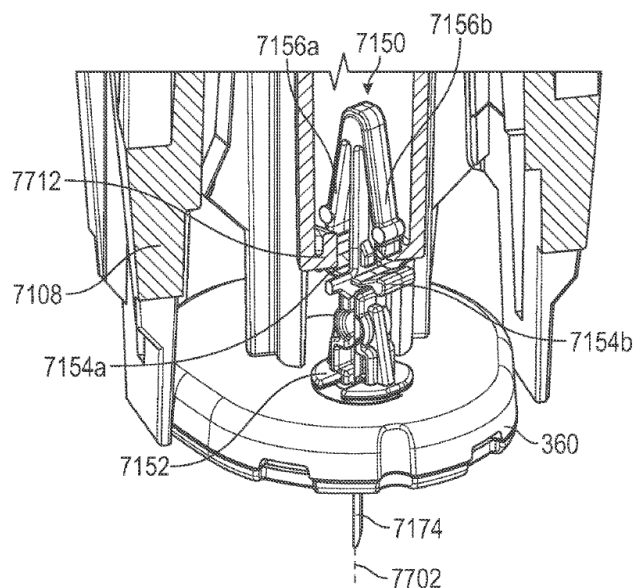


FIG. 77

Figure 77 includes needle carrier assembly 7108, needle hub 7150, and on-skin sensor assembly 360. Ex. 1001, 67:63–66. Needle hub 7150 includes “a plurality of upper arms 7156a, 7156b, a plurality of lower arms 7154a, 7154b, and a base 7152” and is configured to “couple insertion element 7174 to needle carrier assembly 7108 and to substantially maintain a desired orientation of insertion element 7174 during insertion of the sensor of on-skin sensor assembly 360 into the skin of the host.” *Id.* at 68:7–14. Upper arms 7156a, 7156b and lower arms 7154a, 7154b “may be flexible such that, when needle hub 7150 is coupled to needle carrier assembly 7108, upper arms 7156a, 7156b and lower arms 7154a, 7154b secure needle hub 7150 in a desired orientation with respect to needle carrier assembly 7108” by flexing radially inward when disposed through carrier aperture 7712 in needle carrier assembly 7108, and expanding after clearing the surface of carrier aperture 7712. *Id.* at 68:16–33.

Base 7152 of needle hub 7150 includes an anti-rotation feature which may comprise a key having a shape complementary to at least a portion of a sensor assembly aperture 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, 68:41–48. Base 7152 may further comprise “a substantially flat surface configured to mate with a top surface of on-skin sensor assembly 360 and maintain insertion element 7174 in a substantially perpendicular orientation to the top surface of on-skin sensor assembly 360.” *Id.* at 68:57–64.

B. Illustrative Claim

Of the Challenged Claims, claims 1, 13, and 28 are independent. Claims 2–9 depend from claim 1, claims 14–19 depend from claim 13, and claims 29 and 30 depend from claim 28. Claim 1 is illustrative of the claimed subject matter and is reproduced below, with bracketed labels annotated by Petitioner:

1. [1.P] An applicator for applying an on-skin sensor assembly to a skin of a host, the applicator comprising:
 - [1.1] an applicator housing having an internal volume;
 - [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; and
 - [1.6] an on-skin sensor assembly comprising:
 - [1.7] a sensor, the sensor configured to measure a glucose concentration of a host, and
 - [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; and
 - [1.11] wherein the anti-rotation feature is configured to prevent rotation of the needle hub within the aperture.

Ex. 1001, 98:32–52; Pet. 8.

C. Asserted Grounds of Unpatentability

Petitioner asserts that the Challenged Claims are unpatentable based on the following grounds:

Claims Challenged	35 U.S.C. §³	Reference(s)/Basis
1–9, 13–19, 28–30	102, 103	Pace ⁴
4, 5, 14, 15, 30	103	Pace, Lundquist ⁵
1–3, 6–9, 13, 16–19, 28, 29	103	Pace 2 ⁶
4, 5, 14, 15, 30	103	Pace 2, Lundquist
1–3, 6, 9, 13, 16	103	Chae ⁷

Pet. 4. Petitioner’s contentions are supported by the Declaration of Cameron Riviere, Ph.D., dated May 8, 2024. Ex. 1004.

D. Related Proceedings

Petitioner and Patent Owner identify *Abbott Diabetes Care Inc. et al. v. DexCom, Inc.*, No. 1:23-cv-00239 (D. Del) as a related proceeding. Pet. 2; Paper 3, 1; Paper 5, 1. Patent Owner also states that U.S. Application No. 17/960,550 and U.S. Application No. 17/960,425 “claim priority to U.S. Patent Application No. 17/592,170, from which U.S. Patent No. 11,510,625 issued.” Paper 5, 1.

³ The Leahy-Smith America Invents Act (“AIA”) included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. We apply the AIA version of § 103 here, because the ’625 patent does not reflect a priority date earlier than the effective date of the AIA. *See* Ex. 1001, codes (22), (60), (63), (65).

⁴ U.S. Patent App. Pub. No. US 2013/0150691 A1, published Jun. 13, 2013 (Ex. 1006, “Pace”).

⁵ U.S. Patent App. Pub. No. US 2014/0188053 A1, published Jul. 3, 2014 (Ex. 1011, “Lundquist”).

⁶ U.S. Patent App. Pub. No. US 2016/0331284 A1, published Nov. 17, 2016 (Ex. 1007, “Pace 2”).

⁷ U.S. Patent App. Pub. No. US 2020/0178899 A1, published Jun. 11, 2020 (Ex. 1008, “Chae”).

Petitioner also filed a second petition challenging the same claims of the '625 patent challenged in this proceeding on additional grounds in *Abbott Diabetes, Inc. v. DexCom, Inc.*, IPR2024-00860 (PTAB). In its Explanation of Parallel Petitions Challenging U.S. Patent No. 11,510,625, Petitioner requests that we consider the merits of its Petition in this proceeding first, before turning to whether the second petition filed in IPR2024-00860 is warranted. Paper 3, 4. Accordingly, we address the issue of parallel petitions in IPR2024-00860 and need not further address the issue in this proceeding.

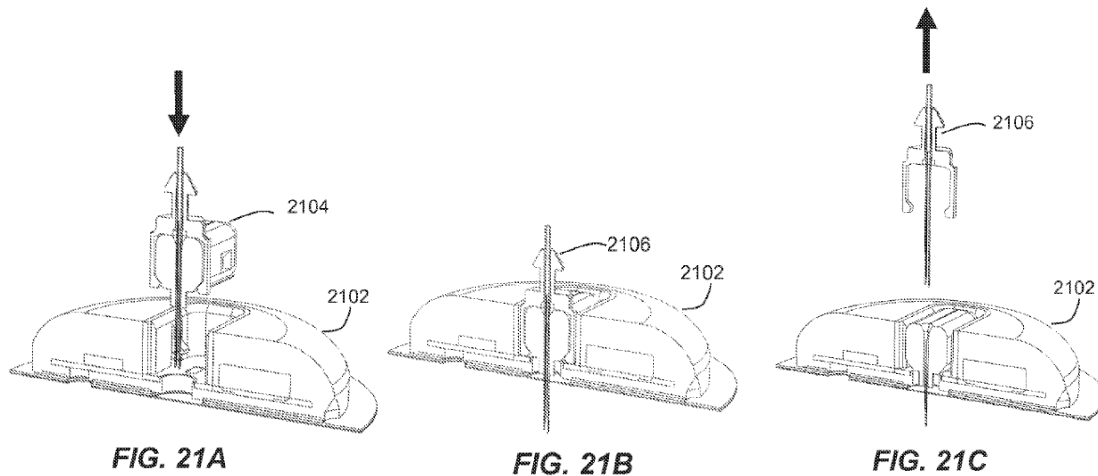
III. ANALYSIS

A. Summary of Asserted Prior Art References

1. Summary of Pace

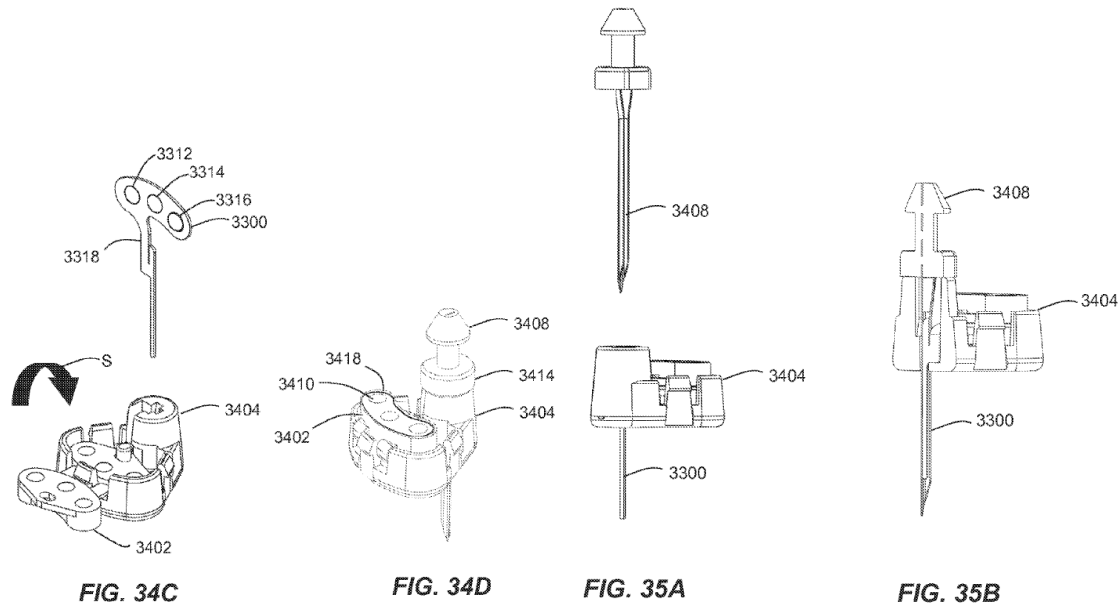
Pace, titled “Analyte Sensor Devices, Connections, and Methods,” describes “[d]evices associated with on-body analyte sensor units” including “packaging and/or loading systems, applicators and elements of the on-body sensor units themselves,” and “approaches to connecting electrochemical analyte sensors to and/or within associated on-body analyte sensor units.” Ex. 1006, codes (54), (57). Pace explains that “[i]n some embodiments, systems and methods are provided for assembling and applying the on-body device including assembling the sensor assembly to the electronics assembly and inserting a portion of the sensor under the skin of a user.” Ex. 1006 ¶ 11. In Pace, “sensor assembly includes a sensor that has a distal portion for operative contact with a fluid of the user” and the on-body device “includes an electronics assembly including a housing defining a distal surface adapted for attachment to the skin of the user and a circuit coupleable to the sensor for detecting electrical signals from the sensor.” *Id.*

“Embodiment A” of Pace is depicted in Figures 21A–C, reproduced below.



Figures 21A–C of Pace depict “perspective section views illustrating sensor assembly receipt by the sensor mount and sharp withdrawal from the assembled complex.” Ex. 1006 ¶ 34. Figures 21A–C include electronics assembly 2102, sensor assembly 2104, and sensor assembly gripper 2106. *Id.* ¶ 123. The sensor assembly gripper 2106 has a “light snap fit” and “grabs and orients the sensor assembly 2104 for connection to the electronics assembly 2102.” *Id.* According to Pace, “[a]fter the sensor assembly 2104 is firmly snapped into the electronics assembly 2102, the sensor assembly gripper 2106 is retracted with an amount of force that overcomes its grip” and the assembly of the on-body device is complete. *Id.*

“Embodiment B” of Pace is depicted in Figures 34C, 34D, 35A, and 35B, reproduced below.



Figures 34C and 34D “are perspective views illustrating combination electrical connector and sensor isolator” arrangements. Ex. 1006 ¶ 49.

Figures 35A and 35B “are side assembly and section views, respectively, of the system shown in FIGS. 34A–34D.” *Id.* ¶ 50.

Figures 34C and 34D depict “an alternative connector arrangement for connecting a circuit board to a sensor” and include sensor 3300 with bendable portion 3318 and sensor contacts 3312, 3314, 3316; connector 3402; and connector support 3404 that is a rigid or semi-rigid housing. Ex. 1006 ¶ 140. Connector 3402 is flexible and includes electrical contacts 3410 and “raised lip 3418 disposed at the top surface edge . . . that encircles the electrical contacts 3410.” *Id.* ¶ 141. Raised lip 3418 is used “to ensure that a seal is formed around the electrical contacts 3410 of the connector 3402 and the electrical contacts of the PCB before any electrical connectivity between the sensor and the electronics assembly is established” and “provides a failsafe against a short by ensuring the order of assembly

includes creating a seal and then creating electrical connectivity as the sensor assembly is mated with the electronics assembly.” *Id.* Raised lip 3418 “can be integrally formed in the elastomeric material that forms the connector 3402” such that it is “compressible when the sensor assembly is inserted into the electronics assembly,” or “can be embodied as gasket or o-ring on the top surface of the connector 3402.” *Id.*

In Figure 34C, sensor 3300 is inserted into connector support 3404 and bent at a 90-degree angle at its bendable portion 3318 so the sensor contacts 3312, 3314, 3316 align with connector 3402. Ex. 1006 ¶ 140. “[S]ensor 3300 is then captured with the upper part of the connector 3402 by folding over the connector 3402 as indicated by arrow S.” *Id.* Once sensor 3300 is captured within seal 3402, as shown in Figure 34D, sharp 3408 is introduced with its hub 3414 contacting connector support 3404. *Id.* ¶ 142.

Figures 35A and 35B include sensor 3300, connector support 3404, and sharp 3408. Ex. 1006 ¶ 142. “FIG. 35A illustrates the orientation of the sharp 3408 prior to the insertion of the sharp 3408 into the connector support 3404.” *Id.* Once sharp 3408 is “inserted in the connector support 3404, the sharp 3408 surrounds and supports the tail portion [] of the sensor 3300,” as shown in Figure 35B. *Id.*

2. *Summary of Lundquist*

Lundquist is titled “Syringe with Co-molded Hub and Cannula” and “relates to a hub for a syringe that is co-molded with a cannula and a method for forming or co-molding the cannula to the syringe barrel.” Ex. 1011, code (54), ¶ 2. Lundquist explains that it would be desirable to design, construct, and employ a mechanism that holds a cannula, “particularly a small diameter cannula, during the insert molding process to attach the

cannula directly to a polymeric syringe barrel without the use of an adhesive or the need to crimp the cannula and without damaging the cannula” and “to construct a hub at the distal end of the barrel that effectively secures the cannula to the barrel and provides sufficient strength to withstand the operating conditions of the syringe, while utilizing a cost-effective and efficient manufacturing process.” *Id.* ¶ 6.

Figure 1F of Lundquist, reproduced below, illustrates “a greatly enlarged cross-sectional view” of the needle end of a staked needle formed through the use of Lundquist’s collet mechanism. Ex. 1011 ¶¶ 10, 15.

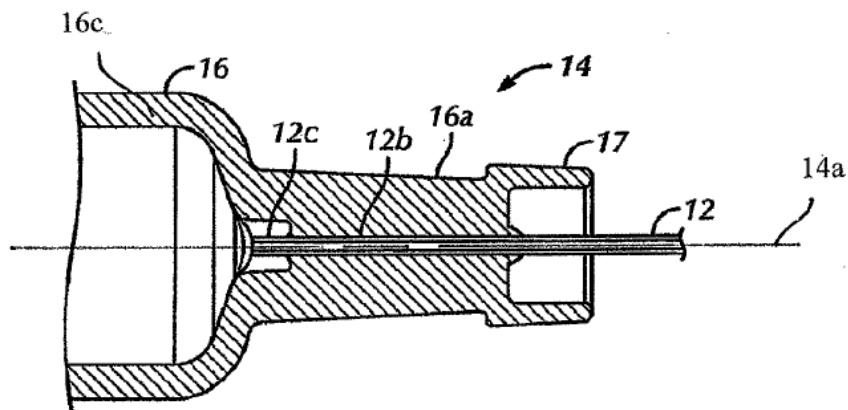


FIG. 1F

Figure 1F includes cannula 12, staked needle or syringe 14 with longitudinal axis 14a, polymeric barrel 16, and distal end 17. *Id.* ¶¶ 38–39. The cannula includes proximal end 12b with portion 12c that extends into the hollow of barrel 16, and barrel 16 includes distal tip 16a and distal end 16c. *Id.* ¶¶ 39, 41, 46, 52. According to Lundquist, distal tip 16a of barrel 16 “extends over and is preferably co-molded with a proximal end 12b of the cannula 12.” *Id.* ¶ 39. Distal end 17 is “generally hollow, so as to form a sleeve around the cannula 12” and to “reduce[] the amount of polymeric material in contact with the cannula 12” and “the cooling time required for the insert molding process.” *Id.*

Proximal end 12b of cannula 12 contains plurality of notches 18 as shown in Figure 2C, reproduced below. *Id.* ¶ 41.

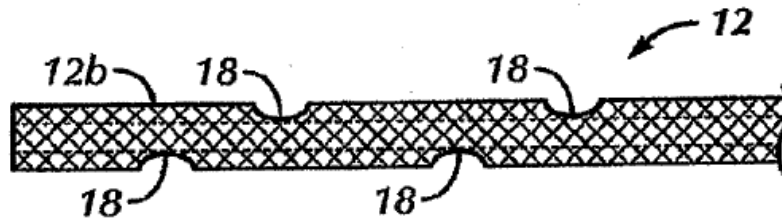


FIG. 2C

The notches depicted in Figure 2C “preferably extend radially inwardly and are axially spaced apart from each other.” Ex. 1011 ¶ 41. Lundquist explains that “[t]he notches 18 are preferably machined into the proximal end 12b of the cannula 12” and “generally replace the function of crimping the cannula 12” by aiding in affixing or securing proximal end 12b of cannula 12 to tip 16a of barrel 16 “because the polymeric material forming the distal end 17 [] flows into and fills in the notches 18 during the molding process . . . to provide enhanced friction and gripping force between the proximal end 12b and the distal end 17.” *Id.*

3. *Summary of Pace 2*

Pace 2 is titled “Compact Medical Device Inserters and Related Systems and Methods” and “relates to compact medical device inserters for inserting a medical device through the skin of a subject, as well as to systems incorporating or utilizing such inserters and methods for making and using the inserters and incorporating systems.” Ex. 1007, code (54), ¶ 2.

Figure 3B, reproduced below, is a cross-sectional perspective view of an example of Pace 2's inserter and sensor control device.

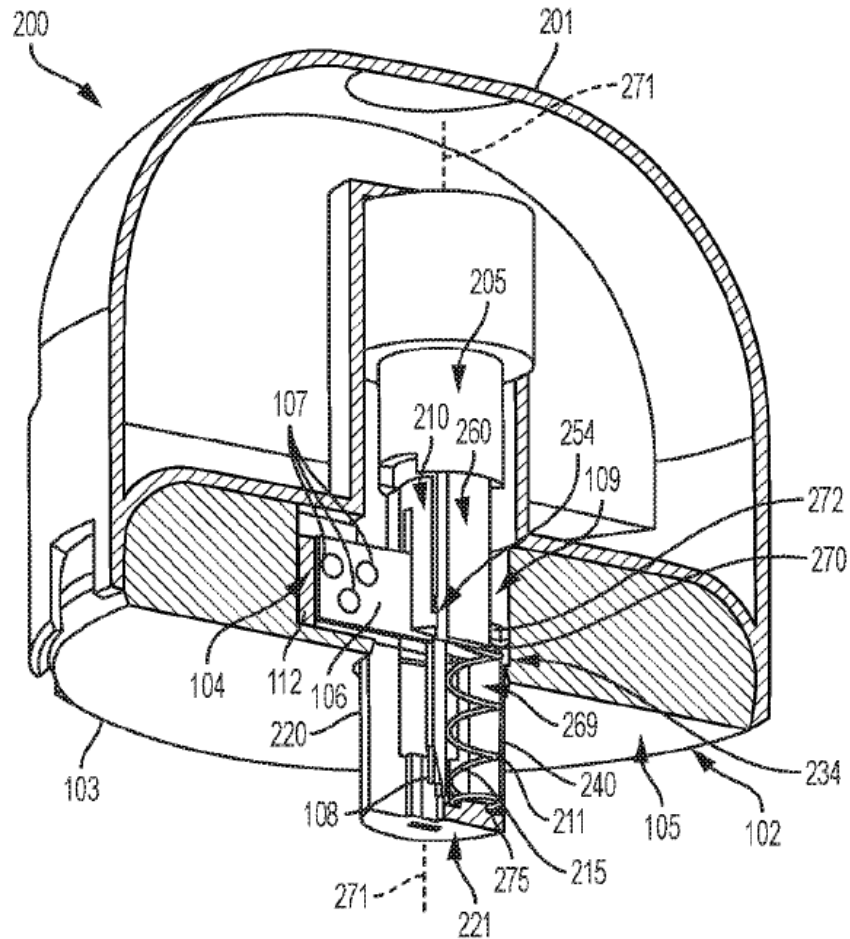


FIG. 3B

Figure 3B includes inserter or insertion device 200 with sensor control device 102. Ex. 1007 ¶ 44. Inserter 200 includes housing 201, sharp support 205, sharp body 210, sharp 211, biasing element 215, shroud 220, anterior surface 221, lock mechanism 234, elastic support 240, elastic arm 260, open chamber 269, central axis 271, and opposing surfaces 270, 275. *Id.* ¶¶ 52–54, 57–58, 62–64, 66–67. Sensor control device 102 includes sensor control device housing 103, sensor 104, adhesive layer 105, sensor projection 108, and opening 109. *Id.* ¶¶ 52–54, 61.

Inserter 200 is adapted for inserting at least a portion of sensor 104 of sensor control device 102 into a recipient's body to contact a bodily fluid, and for placing sensor control device 102 onto the recipient's body.

Ex. 1007 ¶ 44. To apply sensor control device 102 and insert sensor 104 into the user's body, anterior surface 221 of shroud 220 is placed against the skin of the user at the desired implantation site while shroud 220 is fully or mostly extended from sensor control device 102. *Id.* ¶ 52. Housing 201 is advanced relative to shroud 220 to advance at least a portion of sensor projection 108 and sharp 211 through the skin and into the body of the recipient. *Id.* The sharp creates a puncture in the recipient's skin and guides sensor projection 108 into the recipient's body. *Id.* ¶ 54. When housing 201 is fully advanced against the recipient's body, adhesive layer 105 of sensor control device 102 contacts and engages with the recipient's skin. *Id.* ¶ 53. When shroud 220 is fully or mostly retracted, sharp 211 and sensor projection 108 are advanced to the desired depth in the recipient's body, then sharp body 210 and sharp 211 are released by internal components of inserter 200 and automatically retracted by biasing element 215. *Id.* Inserter 200 can be removed from the recipient's body and the sensor control device can be released from inserter 200 once sharp body 210 and sharp 211 are retracted. *Id.*

Figures 7B and C, reproduced below, are views of an example of Pace 2's sharp body and shroud.

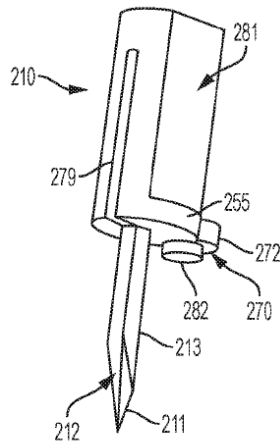


FIG. 7B

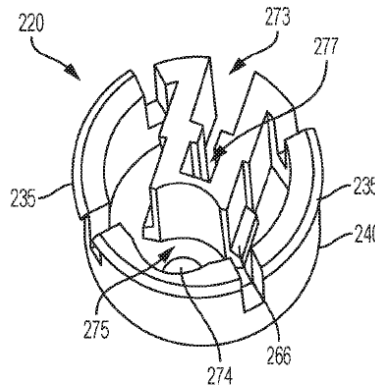


FIG. 7C

Figure 7B is perspective view of an example of Pace 2's sharp body 210 and includes sharp 211, channel 212, opposing sidewalls 213, detent 255, opposing surface 270, and semi-cylindrical projection 282 on extension or ledge 272, and posterior mount 281 with elongate gap 279. Ex. 1007 ¶¶ 67–68, 87. Sharp 211 has a U-shaped configuration that forms channel 212 between opposing sidewalls 213. *Id.* ¶ 87. A sensor projection can reside within channel 212 such that sharp 211 can partially surround and protect it during the insertion process. *Id.* Detent 255 is a rounded ledge that projects from posterior mount 281 that is fastened to sharp 211. *Id.*

Figure 7C is top view of an example of Pace 2's shroud 220 and includes detents 235, elastic arms 240, release surface 266, elongate gap or opening 273, semi-cylindrical projection 274, opposing surface 275, and interior lumen 277. Ex. 1007 ¶¶ 55, 57–58, 67, 88. Detents 235 are coupled with elastic arms 240 and extend radially outwardly from shroud 220 and releasably engage with recesses in the sensor control device to hold shroud 220 in its position relative to the sensor control device. *Id.* ¶¶ 57–58.

Sharp 211 and sensor projection 108 pass through interior lumen 277 of shroud 220. *Id.* ¶ 55.

4. *Summary of Chae*

Chae is titled “Sensor Applicator Assembly for Continuous Glucose Monitoring System” and “relates to a sensor applicator assembly for a continuous glucose monitoring system,” or more particularly, “a sensor applicator assembly for a continuous glucose monitoring system, in which the sensor applicator assembly is fabricated, with a sensor module being preinstalled in an applicator, so that a user can attach the sensor module to the skin by simply operating the applicator.” Ex. 1008, code (54), ¶ 1. Petitioner contends Chae is entitled to an effective filing date of June 2, 2017, i.e., the filing date of Korean Patent Application No. 10-2017-0068964 (“the ’964 application”) (Exs. 1009, 1010), “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 [a]pplication’s filing date.” Pet. 31–32. According to Petitioner, the ’964 application includes the figures and description from Chae upon which Petitioner relies, “[f]or 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 [a]pplication” and “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.” *Id.* at 32. Petitioner states that “[w]hile Chae has additional figures and description not explicitly in the ’964 [a]pplication, Petitioner does not rely on them.” *Id.*

Patent Owner does not dispute the prior art status of Chae at this stage of the proceeding. *See* Prelim. Resp. 13 (stating that if *inter partes* review is instituted, “Patent Owner reserves the right to challenge Chae’s prior art

status.”). Patent Owner also states that “Chae may be considered prior art under 35 U.S.C. § 102(d) only for subject matter described in the ’964 application.” *Id.*; *see also id.* at 12 (explaining that Chae “alleges priority to two different Korean patent applications,” and that, of the two, “only the ’964 application was filed before the ’625 [p]atent’s June 23, 2017, priority date applied by Petitioner”). Patent Owner also asserts that Figure 6 in Chae is not identical to Figure 6 in the ’964 application. *Id.* at 13–14. For purposes of this Decision, Petitioner has sufficiently shown, and Patent Owner does not dispute, that Chae may be considered prior art under 35 U.S.C. § 102(d) for subject matter described in the ’964 application.

Figure 1 of Chae, reproduced below, depicts a sensor applicator assembly for a continuous glucose monitoring system:

FIG. 1

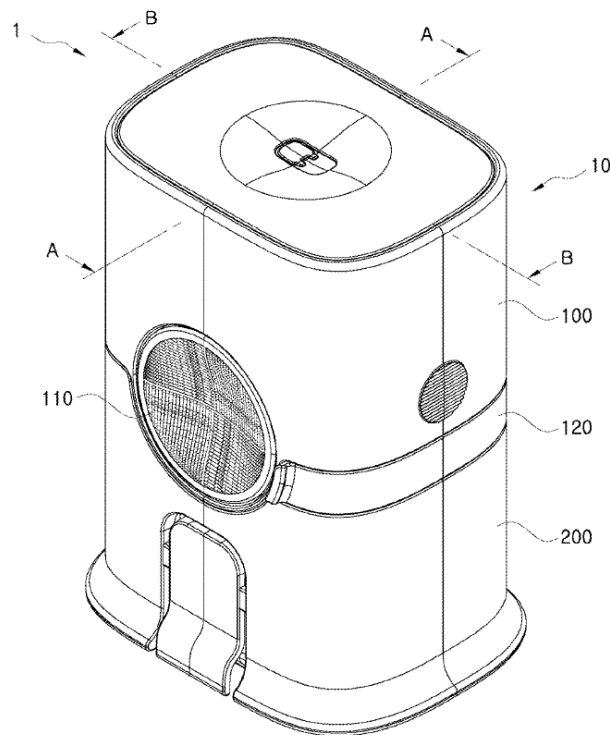


Figure 1 “is a perspective view schematically illustrating an assembled configuration of a sensor applicator assembly for a continuous glucose

monitoring system.” Ex. 1008 ¶ 32. Sensor applicator assembly 1 shown in Figure 1 includes a sensor module that is fitted to applicator 10 with main container 100, safety locking device 120, and protective cap 200. *Id.* ¶¶ 54, 64, 93, 95. Chae explains that “[t]he applicator 10 is configured such that the sensor module [] is fixedly coupled to an inner portion thereof, and operates to eject the sensor module [] in response to a user’s manipulation.” *Id.* ¶ 56. “When the applicator 10 is operated by the user’s manipulation, the sensor module [] is moved in an ejecting direction to be attached to the portion of the human body.” *Id.* ¶ 57.

Figure 2 of Chae, reproduced below, is a perspective view schematically illustrating a configuration of a sensor module.

FIG. 2

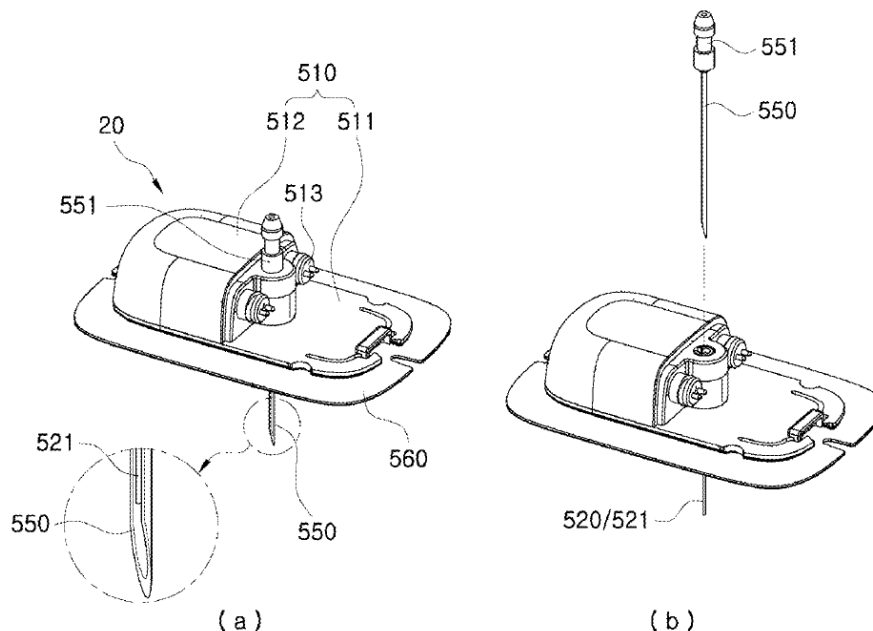
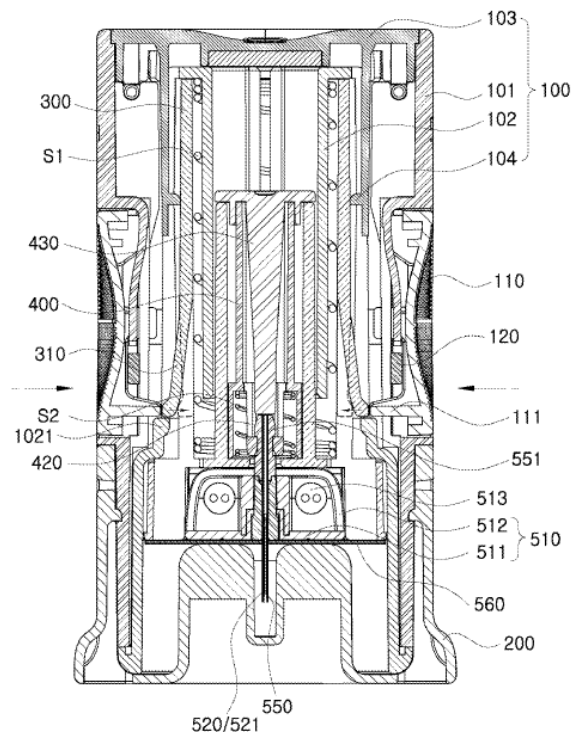


Figure 2 depicts Chae’s sensor module 20 with pod 510. Ex. 1008 ¶ 79. Pod 510 includes flat, plate-shaped pod base 511, case-shaped pod body 512, and connector terminal 513 which connects to a transmitter. *Id.* ¶ 80. Adhesive tape 560 is attached to the back of pod base 511 to attach

sensor module 20 to the human body. *Id.* Pod body 512 contains sensor 520 with “a sensor probe 521 having one end portion protruding downward from the bottom end surface of the pod base 511” that is able to be inserted into the body to extract blood. *Id.* ¶¶ 80–81. Needle 550 “is detachably coupled to the pod 510” and “facilitate[s] the insertion of the sensor probe 521 into the body.” *Id.* ¶ 85. “The needle 550 is configured to be inserted into the body together with the sensor probe 521 while surrounding one end portion of the sensor probe 521 in response to the pod 510 being ejected, so that one end portion of the sensor probe 521 is reliably inserted into the body.” *Id.* “The needle 550 has the shape of a hollow pipe surrounding the sensor probe 521, and a needle head 551 is provided on the top end portion of the needle 550.” *Id.* ¶¶ 85–86.

Figure 5, reproduced below, depicts a cross-sectional view of Chae’s sensor applicator assembly.

FIG. 5



The sensor applicator assembly shown in Chae's Figure 5 includes main container 100, press button 110, protective cap 200, plunger body 300 with elastic hooks 310 that are elastically deformable, needle withdrawing body 400, elastic plunger spring S1, needle withdrawing elastic spring S2, and pod 510. Ex. 1008 ¶¶ 78, 80, 93–94, 97, 123, 127.

Main container 100 shown in Figure 5 consists of external container 101 and internal container 102. Ex. 1008 ¶ 94. External container 101 may be pipe-shaped and may have separate container cover 103 with anti-return hooks 104 coupled to the top end portion. *Id.* “The internal container 102 is coupled to the interior of the external container 101 to guide the plunger body 300 along a linear movement path” when it moves from its first position to its second position in response to a press button 110 being manipulated. *Id.* ¶¶ 93–94. “When the plunger body 300 is in the first position, the elastic hooks 310 may be engaged with the internal container 102 to be fixed in position” via fixing stepped portions 1021. *Id.* ¶ 97. When press button 110 is manipulated inwardly, internal pressing protrusions 111 press elastic hooks 310 of plunger body 300 to disengage elastic hooks 310 from internal container 102 and move plunger body 300 linearly to the second position by the elastic force of elastic plunger spring S1. *Id.* ¶ 98. A “safety locking device 120 may be coupled to the external container 101 to prevent the press button 110 from being press-manipulated” in error. *Id.* ¶¶ 95–96.

B. Discretionary Denial of the Petition Under Section 325(d)

We have discretion to deny review when “the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d). In evaluating the exercise of discretion to deny institution under Section 325(d), we use the following two-part

framework: (1) determining whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of the first part of the framework is satisfied, determining whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims. *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 7–8 (PTAB Feb. 13, 2020) (precedential).

In applying the two-part framework, we may consider several non-exclusive factors, including:

- (a) the similarities and material differences between the asserted art and the prior art involved during examination;
- (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
- (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
- (d) the extent of the overlap between the arguments made during examination and the manner in which petitioner relies on the prior art or patent owner distinguishes the prior art;
- (e) whether petitioner has pointed out sufficiently how the examiner erred in its evaluation of the asserted prior art; and
- (f) the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments.

Becton, Dickinson & Co. v. B. Braun Melsungen AG, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to Section III.C.5, first paragraph) (“*Becton, Dickinson*”). *Becton, Dickinson* factors (a), (b), and (d) relate to whether the art or arguments presented in the Petition are the same or substantially the same as those previously presented to the Office. *Advanced Bionics*, Paper 6 at 10. Factors (c), (e), and (f) “relate to whether the petitioner has demonstrated a material error by the Office” in its

prior consideration of that art or arguments. *Id.* Only if the same or substantially the same art or arguments were previously presented to the Office do we consider whether a petitioner has demonstrated a material error by the Office. *Id.* “At bottom, this framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.” *Id.* at 9.

1. Consideration of Whether the Same or Substantially the Same Art Was Presented to the Office

Under the *Advanced Bionics* framework, we first consider whether Petitioner asserts the same or substantially the same art or arguments that previously were presented to the Office. *Advanced Bionics*, Paper 6 at 8. Petitioner relies upon Pace, Pace 2, and Chae as primary references, along with Lundquist for limitations in certain dependent claims. Pet. 4.

There is no dispute that Pace was previously presented to the Office on an Information Disclosure Statement (“IDS”) during prosecution of the ’625 patent. Pet. 123; Prelim Resp. 18 (explaining that Pace issued as U.S. Patent No. 9,402,570 (Ex. 2003), which was listed on an IDS). Petitioner alleges that “Pace 2, Chae, and Lundquist were not of record during the prosecution of the ’625 patent,” but neglects to address whether substantially similar references were presented to the Office. Pet. 123.

Patent Owner establishes that Pace 2 is substantially similar to World Intellectual Property Organization App. Pub. No. WO 2016/183493A1 (“Pace WO-349,” Ex. 2004), which was presented to the Office on an IDS during prosecution of the ’625 patent. Prelim. Resp. 18 (citing, e.g., Ex. 1002, 620; Ex. 1007, Figs. 1–9; Ex. 2004, Figs. 1–9; Ex. 2005). Specifically, Patent Owner shows that “Pace WO-349 was filed on the same day as the Pace 2 reference, identifies the same inventor, and contains

substantially the same disclosures as Pace 2, including all those relied on by Petitioner,” and that “Pace 2 and Pace WO-349 share the same abstract, drawings (Figures 1-9), and substantially the same written description.” *Id.*

Patent Owner also establishes that Chae is substantially similar to European Patent Application No. EP 3,632,314 A1 (“Chae EP-314,” Ex. 2006), which was presented to the Office on an IDS during prosecution of the ’625 patent. Prelim. Resp. 19–20 (citing, e.g., Ex. 1002, 620; Ex. 1008, Figs 1–24; Ex. 2006, Figs. 1–24). Specifically, Patent Owner shows that Chae and Chae EP-314 were filed on the same day, have the same inventors, and contain substantially the same disclosures because they share the same abstract and drawings (Figures 1–24), and have substantially the same written description such that “the main difference between Chae and Chae EP-314 is the description of the ‘Technical Solution’ of the respective claimed embodiments described in Paragraphs [0020]-[0026].” *Id.* at 19, n.4 (citing Ex. 1008, 1, Figs. 1–24; Ex. 2006, 1, Figs. 1–24; Ex. 2007).

Patent Owner does not address Lundquist in its analysis of the first prong of the *Advanced Bionics* framework because Patent Owner contends Lundquist is irrelevant to the Section 325(d) inquiry as “the Petition relies on Lundquist only for subject matter recited in certain dependent claims, namely Lundquist’s alleged disclosures related to insert molding.” Prelim. Resp. 16, n.1 (citing *Kayak Software Corp. v. IBM*, CBM2016-00075, Paper 16 at 10 (PTAB. Dec. 15, 2016) (informative)).

We find that Petitioner’s assertion that “the first part of the *Advanced Bionics* test is not satisfied,” because “Pace 2, Chae, and Lundquist were not of record during prosecution of the ’625 patent” suggests a lack of candor by Petitioner in failing to acknowledge the substantially similar references by the

same inventors in the prosecution history. Patent Owner has shown that in relying on Pace, Pace 2, and Chae as primary references, Petitioner is asserting the same or substantially the same art previously presented to the Office, as explained above. Accordingly, we next consider the second prong of the *Advanced Bionics* framework.

2. Consideration of Whether Petitioner Has Shown the Office Erred in a Manner Material to Patentability

Petitioner contends the merits of its Petition “reflect the examiner’s errors in a manner material to the patentability” of the claims challenged. Pet. 123. According to Petitioner, the “Examiner did not rely on Pace in any rejection of any claim” and, here, “Petitioner has presented new arguments and evidence that were unavailable to the [E]xaminer, who overlooked or did not appreciate the materiality of the references” Petitioner relies upon. *Id.* More specifically, Petitioner argues it has shown in the Petition that “Pace discloses structures that prevent rotation of the needle within an aperture of an on-skin sensor assembly.” *Id.*

Patent Owner argues that “Petitioner does not even attempt to identify any material error made by the examiner during prosecution.” Prelim. Resp. 20. According to Patent Owner, Petitioner merely “invites the Board to review the entirety of its proposed grounds, alluding to unspecified ‘new arguments and evidence that were unavailable to the examiner’” and “does not specifically state what aspects of its presented grounds were overlooked or mis-considered.” *Id.* at 20–21 (citing Pet. 123). Patent Owner contends “the only independent evidence relied on by the Petition is an expert declaration that almost entirely parrots the merits arguments of the Petition and, therefore, should be given little to no weight,” such that “the examiner had before them during prosecution the very same information and evidence

relied on in the Petition.” *Id.* at 21. Regarding the merits of Petitioner’s challenges, Patent Owner contends “the relied-on disclosures of the primary references are ambiguous and do not support a finding that anti-rotation as claimed in the ’625 [p]atent was a functionality present in the prior art.” *Id.*

We do not find Patent Owner’s arguments persuasive because Petitioner shows that it relies on Pace, Pace 2, and Chae as disclosing or teaching an anti-rotation feature or key configured to prevent the claimed rotation and Petitioner asserts unpatentability based on anticipation or obviousness over Pace, obviousness over Pace 2, and obviousness over Chae, each of which was not discussed by the Examiner. *See id.* at 37–42, 77–81, 105–09. Petitioner also expressly identifies in the Petition the alleged material error by the Examiner as corresponding to the Examiner’s failure to appreciate that “Pace discloses structures that prevent rotation of the needle within an aperture of an on-skin sensor assembly.” Pet. 123. For the foregoing reasons, we decline to exercise discretion to deny institution based on Section 325(d).

C. Legal Standards for Anticipation and Obviousness

A patent claim is anticipated if a single prior art reference either expressly or inherently discloses every limitation of the claim. *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 975 (Fed. Cir. 2010). “A single prior art reference may anticipate without disclosing a feature of the claimed invention if such feature is necessarily present, or inherent, in that reference.” *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 958 (Fed. Cir. 2014) (citing *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003)).

A patent claim is unpatentable for obviousness if the differences between the claimed subject matter and the prior art are such that the subject

matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). In *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1 (1966), the Supreme Court set out a framework for assessing obviousness that requires consideration of four factors: (1) the “level of ordinary skill in the pertinent art”; (2) the “scope and content of the prior art”; (3) the “differences between the prior art and the claims at issue”; and (4) “secondary considerations” of nonobviousness such as “commercial success, long felt but unsolved needs, failure of others, etc.” *Id.* at 17–18; *KSR*, 550 U.S. at 407.

“Whether an ordinarily skilled artisan would have been motivated to modify the teachings of a reference is a question of fact.” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1327 (Fed. Cir. 2016) (citations omitted). “[W]here a party argues a skilled artisan would have been motivated to combine references, it must show the artisan ‘would have had a reasonable expectation of success from doing so.’” *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1360–61 (Fed. Cir. 2017) (quoting *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1068–69 (Fed. Cir. 2012)).

D. Level of Ordinary Skill in the Art

In determining the level of ordinary skill in the art, various factors may be considered, including the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.” *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (citation omitted).

Petitioner contends a person of ordinary skill in the art at the time of the invention “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.”

Pet. 14. Petitioner also contends “[a] person with less or different education but more relevant practical experience, or vice versa, may also meet this standard.” *Id.* (citing Ex. 1004 ¶ 35).

Patent Owner contends Petitioner’s definition of a person of ordinary skill in the art is “cursory,” “unsubstantiated,” and “so vague as to be effectively meaningless.” Prelim. Resp. 26. According to Patent Owner, the Petition cites no evidence to substantiate the level of skill in the art, and Dr. Riviere’s declaration parrots the language in the Petition. *Id.* Although Patent Owner disputes the sufficiency of Petitioner’s definition of a person of ordinary skill in the art, Patent Owner does not propose a level of ordinary skill in the art of its own. *See generally* Prelim. Resp. Moreover, Patent Owner fails to present evidence that shows the level of ordinary skill in the art is different from Petitioner’s proposal, or that Petitioner’s proposal is in any way inconsistent with the level of skill reflected in the ’625 patent and the asserted references.⁸

We find that the ’625 patent and the cited prior art references reflect the appropriate level of skill at the time of the claimed invention, and that

⁸ We note Patent Owner has applied a definition of the level of ordinary skill when it has sought *inter partes* review of a patent owned by Petitioner that does not appear to be any more detailed or any less “cursory” than the level proposed by Petitioner here. *See Dexcom, Inc. v. Abbott Diabetes Care Inc.*, IPR2022-00637, Paper 1, 15 (Feb. 28, 2022).

the level of appropriate skill reflected in these references and in the '625 patent is consistent with the definition of a person of ordinary skill in the art proposed by Petitioner. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Accordingly, for purposes of this Decision, a find a person of ordinary skill in the art at the time of the invention would have had a Bachelor's degree in mechanical or biomedical engineering (or a related or equivalent field) and two years of experience researching, developing, designing and/or evaluating medical devices utilizing needles or sharps, or equivalent experience.

E. Claim Construction

In this proceeding, we construe claims using the same claim construction standard that would be used to construe the claims in a civil action under 35 U.S.C. § 282(b). *See* 37 C.F.R. § 42.100(b). The claim construction standard includes construing claims in accordance with the ordinary and customary meaning of such claims as understood by one of ordinary skill in the art at the time of the invention. *See id.*; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–14 (Fed. Cir. 2005) (en banc). In construing claims in accordance with their ordinary and customary meaning, we take into account the specification and prosecution history. *Phillips*, 415 F.3d at 1315–17.

Petitioner proposes that the claim limitations reciting “by heat staking, snap-fit, friction-fit, clamshell[,] or insert molding” in claims 4, 14, and 30 and “by insert molding” in claims 5 and 15 are product-by-process limitations because “[t]he recited alternatives merely describe different methods by which the insertion element/needle or ‘locking element’ thereof is physically coupled to the needle hub, not any significant structural differences.” Pet. 15.

Patent Owner proposes no express construction of any claim term and does not dispute Petitioner’s proposed construction at this time. *See generally* Prelim. Resp.

Only terms that are in controversy need to be construed, and these need be construed only to the extent necessary to resolve the controversy. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) (“The Board is required to construe ‘only those terms . . . that are in controversy, and only to the extent necessary to resolve the controversy.’”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). In the absence of any dispute over the construction of any claim term, we find no express construction necessary for purposes of this Decision.

F. Alleged Deficiencies Affecting All of Petitioner’s Grounds

Patent Owner contends Petitioner failed to establish a reasonable likelihood that any challenged claim will be found unpatentable under any ground because the Petition (1) is untethered to a skilled artisan; (2) is unsupported by expert analysis entitled to weight; (3) is fueled by hindsight; and (4) does not show a reasonable expectation of success. Prelim. Resp. 22–33. We consider each of these arguments below and find them insufficient to support denial of the Petition. Rather, the issues raised by Patent Owner are best addressed in our consideration of the merits of each particular ground of unpatentability asserted by Petitioner, given the standard we apply for purposes of institution is whether Petitioner has shown a reasonable likelihood that it would prevail in showing the unpatentability of at least one Challenged Claim. *See* 35 U.S.C. § 314(a).

*1. Patent Owner's Argument that the Petition is
Untethered to a Skilled Artisan*

First, Patent Owner argues that Petitioner asserts in the Petition “eleven times that some feature ‘necessarily’ is present in an asserted prior art reference,” but only once asserts a person of ordinary skill in the art “would have recognized that the feature necessarily was present.” Prelim. Resp. 23. For example, in regard to alleged anticipation by Pace, Patent Owner contrasts Petitioner’s assertion that certain figures in Pace show elements that “necessarily prevent rotation” to Petitioner’s assertion that a “[person having ordinary skill in the art] would understand” that a particular element “necessarily has some structure to secure it.” *Id.* at 23–24; Pet. 41, 65. Patent Owner then takes issue with Petitioner’s and Dr. Riviere’s purported failure to “mention” a person having ordinary skill in the art when describing, for example, various figures in the prior art. Prelim. Resp. 24–26. Patent Owner also argues Petitioner’s definition of a person of ordinary skill in the art is “cursory” and purportedly “causes the Petition to lack the factual support necessary to make a legally sound showing of express or inherent disclosure in the prior art.” *Id.* at 26–27.

As explained above, we find the level of ordinary skill relied upon by Petitioner sufficient for purposes of this Decision. *See supra* Section II.D. Further, Patent Owner directs us to no requirement that the words “person of ordinary skill in the art” appear with some particular frequency in a petition. Nor do we find it necessary that a petitioner expressly repeat in a petition that every description of the challenged patent or asserted art reflects the knowledge of a person of ordinary skill in the art. Patent Owner may dispute at trial, with supporting evidence, Petitioner’s assertion that a particular feature is necessarily shown in a figure, or whether the opinions of

Petitioner's declarant are based on something other than the knowledge of a person of ordinary skill in the art. We are not, however, persuaded on the allegations advanced by Patent Owner here that the Petition should be summarily denied merely because of the alleged general manner in which Petitioner's contentions are phrased.

2. Patent Owner's Argument that the Petition is Unsupported by Expert Analysis Entitled to Weight

Patent Owner argues that the Petition should be denied because Dr. Riviere's Declaration is purportedly "unaccompanied by reasoning and citation to evidence showing the perspective of a skilled artisan" and "it substantially is a verbatim parroting of the Petition." Prelim. Resp. 27–28. The relevant issue is not how similar an expert declaration is to a petition, but whether the declarant's expert testimony is supported by evidence. A cursory review of Dr. Riviere's declaration shows that it is not devoid of any support for the opinions expressed. Patent Owner may dispute at trial a particular opinion expressed, whether it is supported, or whether it reflects the knowledge of a person of ordinary skill on the merits. Patent Owner has made no showing that the Petition should be summarily denied based on the generally alleged insufficiency of Dr. Riviere's opinions.

3. Patent Owner's Argument that the Petition is Fueled by Hindsight

Patent Owner argues that because none of the asserted prior art "mentions the needle-rotation problem addressed by the challenged '625 patent, or purports to solve that problem," Petitioner's reliance on what is shown "in drawings in these references" would not "have been viewed by a skilled artisan *ex ante* without hindsight." Prelim. Resp. 30–31. Patent Owner directs us to no disclosure in the '625 patent of either a "needle rotation problem," or that such a problem was resolved for the first time by

the invention of the '625 patent. *See, e.g.*, Ex. 1001, 11:10–11 (stating that “[i]n some embodiments, the anti-rotation feature is configured to prevent rotation of the base with the aperture”). We are not persuaded on the current record that improper “hindsight” dictates how Petitioner shows a person of ordinary skill in the art would have viewed what is depicted in figures relied upon by Petitioner.

4. Patent Owner’s Argument that the Petition Does Not Show a Reasonable Expectation of Success

Patent Owner argues that “[s]howing reasonable expectation of success is mandatory when asserting obviousness,” but that as to three of the asserted grounds, “[t]he Petition does not even mention the words ‘reasonable’ or ‘success.’” Prelim. Resp. 31–33. Patent Owner may dispute at trial the merits of Petitioner’s particular allegations considering obviousness, but we are not persuaded that the Petition, which includes grounds based on anticipation, should be summarily denied based on how many times the words ‘reasonable’ or ‘success’ are expressly mentioned.

G. Alleged Anticipation by Pace

Petitioner contends that embodiment “A” of Pace, depicted in Figures 21A–C of Pace, and embodiment “B” of Pace, depicted in Figures 34D, 35A–B, and 47C of Pace, each anticipate the Challenged Claims. Pet. 16–21, 34–71. According to Petitioner, in embodiment A, Pace discloses that “‘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 on-body device,” and that the “sensor assembly gripper features may be ‘incorporated’ in a ‘sharp hub.’” Pet. 16 (citing Ex. 1006 ¶ 123). Petitioner also contends that the base of sharp hub/gripper 2106 has an anti-rotation feature with a key,

and that the “anti-rotation feature and its corresponding receiving aperture(s) in the on-skin sensor assembly (formed by mating the electronics assembly 2102 with the sensor assembly 2104) have complementary shapes, which prevent the sharp hub/gripper 2106 (*i.e.*, needle hub) from rotating relative to the on-skin sensor assembly.” *Id.* at 16–18.

In regard to embodiment B, Petitioner contends “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,” such that the V-shaped portion “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.” *Id.* at 19 (citing Ex. 1006 ¶¶ 140–42, Figs. 34A–D, 35A–C).

Patent Owner primarily disputes that Pace discloses an anti-rotation feature or key configured to prevent the claimed rotation.⁹ *See* Prelim. Resp. 33–56. We focus our discussion below on these disputed limitations in regard to embodiment A for purposes of this Decision.

1. Claim 1

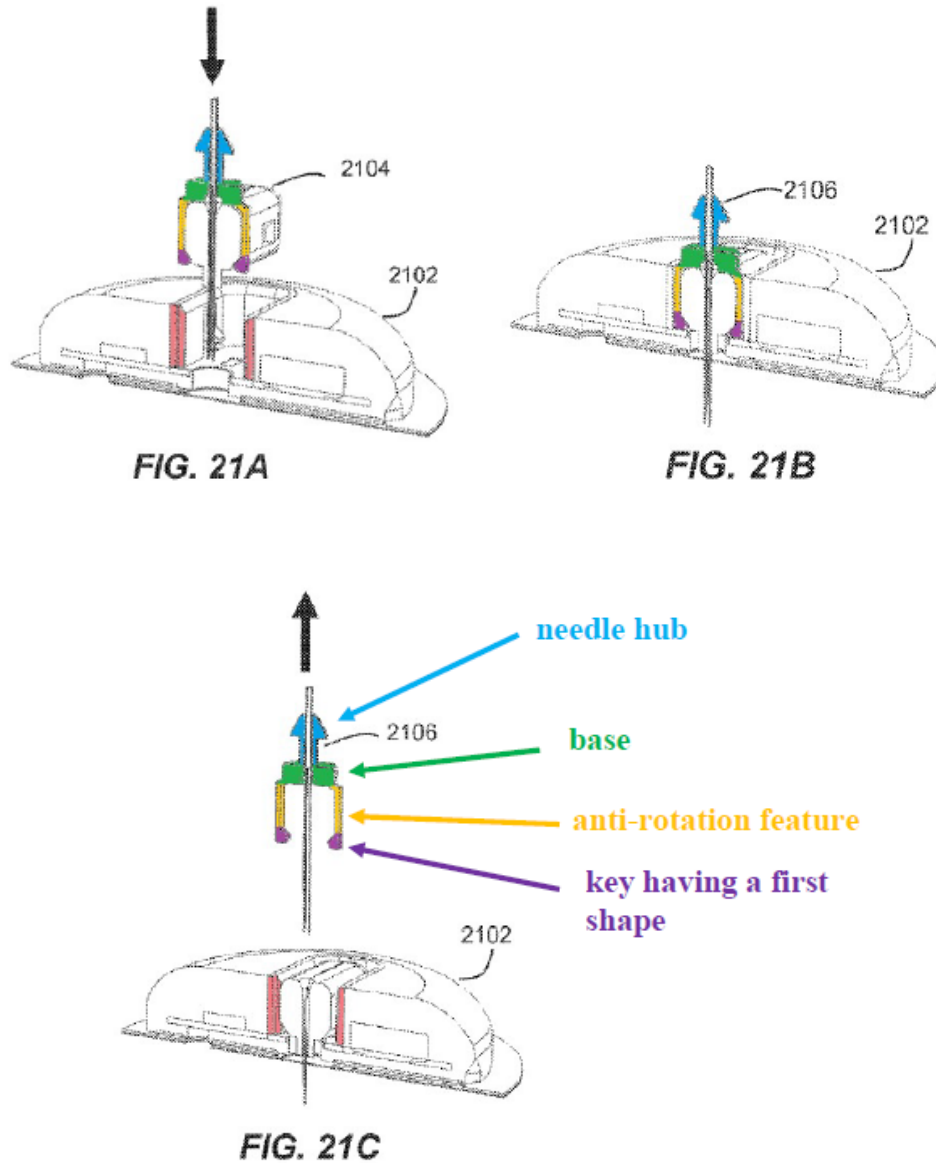
Claim 1 requires, in relevant part, the following:

- [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;
- and . . .

⁹ Patent Owner explains that claims 1 and 28 recite an “anti-rotation feature” and claim 13 recites an “anti-rotation key.” Prelim. Resp. 33–34. Patent Owner also identifies three types of “claimed rotation” as “rotation of the needle hub within the aperture” in claim 1, “rotation of the needle hub with respect to the on-skin sensor assembly” in claim 13, and “rotation of the base within the aperture” in claim 28. *Id.*

[1.11] wherein the anti-rotation feature is configured to prevent rotation of the needle hub within the aperture.

Petitioner provides the following annotated versions of Figures 21A, 21B, and 21C of Pace:



Pet. 37–38. According to Petitioner, sensor assembly gripper 2106 may be incorporated into the sharp hub/boss, which Petitioner refers to collectively as “hub 2106” and asserts corresponds to the claimed “needle hub coupled to an insertion element.” Pet. 38 (citing Ex. 1006 ¶¶ 102–104, 123). Petitioner

further asserts that the lower section of hub 2106 (annotated in green above) corresponds to the claimed “base,” the vertical legs and feet (annotated in gold and purple above) correspond to the “anti-rotation feature extending from the base,” and that the feet (annotated in purple above) correspond to the claimed “anti-rotation feature comprising a key, the key having a first shape.” Pet. 38–39. Petitioner argues that the legs of hub 2106 are inserted into vertical slots (annotated in red above) that extend “from a top surface of the on-skin sensor assembly.” Pet. 45.

Petitioner concedes that “Pace does not specifically state that the hub 2106” has “‘anti-rotation’ functionality,” and argues that the arrangement “necessarily” prevents “the sharp from rotating” because “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.” *Id.* at 41; *see also* Ex. 1004 ¶¶ 60, 61, 64 (same). Petitioner states 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’ . . .), to form a snug fit therewith,” such that “the vertical slots have a second shape complementary to the first shape of the key.”¹⁰ *Id.* at 47. Lastly, according to Petitioner, “the legs and feet of the

¹⁰ Petitioner’s assertions in the Petition are largely devoid of any specific citation to supporting evidence, other than to figures of Pace, including this statement. Essentially identical language to the Petition, however, also appears in the Declaration of Dr. Riviere. *See, e.g.*, Ex. 1004 ¶¶ 69 (stating that “the shape of each vertical slot in electronics assembly 2102 complements the shape of a corresponding gripper leg and foot . . . to form a snug fit therewith”). Petitioner also broadly cites to Dr. Riviere’s declaration as providing support for its explanation in a single introductory sentence. Pet. 34 (citing Ex. 1004 ¶¶ 57–73). For purposes of this Decision,

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.” *Id.* at 50.

Based on the preceding arguments, we find Petitioner has sufficiently shown for purposes of institution how it contends embodiment A of Pace discloses each of the disputed limitations of claim 1, as supported by Dr. Riviere. Below we discuss Patent Owner’s arguments in opposition, which we find insufficient on the current record to refute the reasonable likelihood of prevailing established by Petitioner. *See* Prelim. Resp. 35–45.

In particular, Patent Owner argues that Petitioner “fails to establish” that a person of ordinary skill in the art “would recognize any structure of embodiments A or B of Pace to constitute an anti-rotation key/feature configured to prevent rotation as claimed,” and instead relies on “hindsight-fueled speculation based on ambiguous drawings.” *Id.* 36. Specifically, as to embodiment A of Pace, Patent Owner argues that Petitioner’s analysis of the “alleged inherent disclosure of an anti-rotation feature/key configured to prevent rotation . . . is insufficient to meet the legal standard for inherency.” *Id.* at 37–38. According to Patent Owner, Petitioner’s arguments are based on “multiple unexplained assumptions from the drawings of embodiment A regarding factors that a [person of ordinary skill in the art] would need to consider in determining whether the disclosed structures prevent rotation,” including “the fit and relative dimensions between components” and “the various materials used to construct the depicted components.” *Id.* at 37–40.

we have considered Dr. Riviere’s supporting declaration, however, whether a particular argument advanced in the Petition without specific citation is sufficiently supported by evidence remains an issue for trial.

Patent Owner argues that Pace’s gripper 2106 “would require both flexibility and clearance in order to provide the disclosed ability to open and release sensor assembly 2104 from its grip, which it alleges suggests “an inability to prevent rotation.” *Id.* at 41–42. On the current record, the unsupported attorney arguments advanced by Patent Owner do not persuade us that Petitioner’s reliance on what is shown in Pace is insufficient to support a reasonable likelihood of prevailing. Claim 1 requires an anti-rotation feature “configured to prevent rotation of the needle hub within the aperture.” On the current record, Petitioner has shown, with support from Dr. Riviere, that the structure relied on in embodiment A of Pace is depicted in a manner in the Figures of Pace that would necessarily prevent rotation of the needle hub within the aperture, and Patent Owner’s unsupported assertions based on dimensions and materials do not persuade us otherwise.

Patent Owner also argues that the figures of embodiment A of Pace are “ambiguous drawings” because the illustrations are in a “cross-sectional perspective” that “only appear to show a portion of electronics assembly 2102,” and that it is “impossible to determine from the figures alone the relationship between portions of the components that are not depicted.” Prelim. Resp. 42–43. Petitioner, however, does not rely on the figures “alone.” *See, e.g.*, Pet. 16–17, 34–35, 38 (citing Ex. 1004 ¶¶ 57–73; Ex. 1006 ¶¶ 83, 92, 102–104, 109, 123. Moreover, Patent Owner directs us to no evidence that what is shown in the cross-sectional perspective of embodiment A of Pace is insufficient to disclose to a person of ordinary skill a feature “configured to prevent rotation of the needle hub within the aperture.” We find no support on the current record for Patent Owner’s assertion that “Pace does not disclose whether the visible surface of the gripper legs adjacent to the cross-section plane are enclosed or whether they

are next to open space, thereby allowing movement and rotation of gripper 2106.” Prelim. Resp. 43. Even if there was any plausible explanation for why the gripper legs would be “next to open space” because they are illustrated in a cross section perspective, there is no evidence that such open space would enable rotation of gripper 2106.

Lastly, Patent Owner argues that Petitioner failed to present “extrinsic evidence, including adequate expert testimony.” *Id.* at 43–45. Patent Owner’s reliance on the need for extrinsic evidence because Pace is “silent about the asserted inherent characteristic” is not persuasive on the current record, because Patent Owner has not shown that Pace is “silent” where the feature at issue is expressly illustrated in Pace. In this instance we don’t find Dr. Riviere’s testimony “conclusory and unsupported” because it reflects and is supported by what Petitioner contends is expressly disclosed in Pace.

2. Claims 2–9, 13–19, and 28–30

Petitioner contends Pace discloses each of the limitations of claims 2–9, 13–19, and 28–30. Pet. 50–71. Petitioner’s contentions are supported by Dr. Riviere. Ex. 1004 ¶¶ 102–119. Aside from Patent Owner’s arguments regarding an anti-rotation key/feature discussed above, at this stage of the proceeding, Patent Owner does not dispute Petitioner’s contentions showing how Pace discloses or teaches each limitation of claims 2–9, 13–19, and 28–30. *See generally* Prelim. Resp.

3. Determination of a Reasonable Likelihood of Prevailing

Petitioner has established a reasonable likelihood that it would prevail in showing that embodiment A of Pace anticipates claim 1 of the ’625 patent. Having found that Petitioner makes the necessary showing based on embodiment A of Pace, we need not resolve the issues raised by

Patent Owner in regard to Petitioner's contentions based on embodiment B of Pace.

H. Alleged Obviousness over Pace

Petitioner contends that Pace renders obvious the subject matter of the Challenged Claims. Pet. 34–71. For example, in regard to claim 1 Petitioner asserts that a person of ordinary skill “would have considered it obvious for hub 2106” in embodiment A of Pace “to provide an anti-rotation function.” Pet. 42 (citing Ex. 1004 ¶ 65). According to Petitioner, a person of ordinary skill “would have understood 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,” and “[b]ecause hub 2106 is directly coupled to the needle, it therefore would have been obvious to restrain the rotation of hub 2106 relative to an aperture of an on-skin sensor assembly.” *Id.* Patent Owner argues that Petitioner fails “to adequately argue a proposed modification to the prior art, motivation to modify the prior art, or a reasonable expectation of success in doing so.” Prelim. Resp. 51. Patent Owner's arguments appear to have merit. For example, Petitioner does not expressly propose any modification to Pace, but merely suggests that “it would have been obvious to restrain the rotation of hub 2106” in some unspecified manner, and without even alleging an a reasonable expectation of success in doing so.

I. Additional Grounds

Petitioner additionally contends that claims 4, 5, 14, 15, and 30 would have been obvious over Pace and Lundquist (Pet. 71–76); claims 1–3, 6–9, 13, 16–19, 28, and 29 would have been obvious over Pace 2 (*id.* at 76–97); claims 4, 5, 14, 15, and 30 would have been obvious over Pace 2 and

Lundquist (*id.* at 99–102); and claims 1–3, 6, 9, 13, and 16 would have been obvious over Chae (*id.* at 102–21). Patent Owner does not raise any additional arguments in regard to the combination of Pace and Lundquist beyond the issues it raised in regard to alleged unpatentability over Pace, alone. *See* Prelim. Resp. 56–57. Patent Owner disputes that Pace 2 teaches structures that “necessarily prevent rotation,” but its attorney arguments concerning what a person of ordinary skill in the art “would consider” are unsupported by expert testimony. *See id.* at 59. To the extent Pace 2 does not expressly disclose structure that meets the anti-rotation limitations of the Challenged Claims, we find Patent Owner’s argument that Petitioner’s conclusory assertion that a person of ordinary skill in the art “would have considered it obvious that the combination would provide an anti-rotation function” has merit. *See id.* at 65 (quoting Pet. 81). Patent Owner also disputes that Chae teaches structures that prevent rotation, but those arguments concerning, for example, what a person of ordinary skill in the art “would consider in determining whether the structures depicted in Chae necessarily prevent rotation of the alleged needle hub relative to a sensor assembly” are unsupported. *See id.* at 70. In sum, because we have determined above that, at this stage of the proceeding and on the present record, the information presented in the Petition and Preliminary Response shows that there is a reasonable likelihood that Petitioner will prevail with respect to at least claim 1 based on alleged anticipation by embodiment A of Pace, we need not further address, in this Decision, Petitioner’s additional challenges. *See* 35 U.S.C. § 314(a).

IV. CONCLUSION

For the foregoing reasons, we determine that Petitioner demonstrates a reasonable likelihood of prevailing with respect to at least one of the

Challenged Claims in the Petition. Accordingly, *inter partes* review of the '625 patent shall proceed in this case on all of the grounds raised in the Petition. *See SAS Inst., Inc. v. Iancu*, 584 U.S. 357, 370–71 (2018) (holding that a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (stating that the decision whether to institute *inter partes* review requires “a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition”).

Our determination in this Decision is not a final determination on either the patentability of any challenged claims or the construction of any claim term. The factual findings set forth in this Decision are preliminary and provided for the sole purpose of deciding whether to institute a review. Any final findings will be based on the full trial record, including any information presented by Patent Owner in a timely-filed response to the Petition. *See Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (noting that “there is a significant difference between a petitioner’s burden to establish a ‘reasonable likelihood of success’ at institution, and actually proving invalidity by a preponderance of the evidence at trial”) (quoting 35 U.S.C. § 314(a) and comparing *id.* with § 316(e)).

V. ORDER

Upon consideration of the record before us, it is:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–9, 13–19, and 28–30 of U.S. Patent No. 11,510,625 B2 is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of U.S. Patent No. 11,510,625 B2 shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

IPR2024-00859
Patent 11,510,625 B2

FOR PETITIONER:

Peter Chen
David Garr
Scott Weidenfeller
COVINGTON & BURLING LLP
pchen@cov.com
dgarr@cov.com
sweidenfeller@cov.com

For PATENT OWNER:

Andrew M. Mason
John D. Vandenberg
Scott E. Davis
Alexa M. Johnston
Cameron Clawson
KLARQUIST SPARKMAN, LLP
andrew.mason@klarquist.com
john.vandenberg@klarquist.com
scott.davis@klarquist.com
alexa.johnston@klarquist.com
cameron.clawson@klarquist.com