

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

**PATENT OWNER PRELIMINARY
RESPONSE PURSUANT TO 37 C.F.R. § 42.107**

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EXHIBIT LIST

LIST OF NEWLY FILED EXHIBITS

Exhibits concurrently filed with Patent Owner's Preliminary Response:

No.	Description
2002	Disclaimer In A Patent Under 37 CFR 1.321(a) as to Claims 22-27
2003	U.S. Patent No. 9,402,570 B2 (" 570 patent ")
2004	PCT Patent Pub. WO2016/183493 A1 (" Pace WO-349 ")
2005	Compare of U.S. Patent Pub. No. 2016/0331284 ("Pace 2") to WO2016/183493 A1 ("Pace WO-349")
2006	European Patent App. EP 3 632 314 A1 (" Chae EP-314 ")
2007	Compare of U.S. Patent Pub. No. 2020/0178899 ("Chae") to EP 3 632 314 A1 ("Chae EP-314")
2008	Compare of Petition to Declaration (Overview of Prior Art)
2009	Compare of Petition to Declaration (Asserted Grounds of Unpatentability)
2010	U.S. Prov. Patent App. No. 61/569,287 (" Pace Provisional ")
2011	Declaration of Julia Castellano dated August 21, 2024

LIST OF PREVIOUSLY FILED EXHIBITS

Patent Owner previously filed the following exhibits:

No.	Description
2001	Declaration of Scott E. Davis

Patent Owner Dexcom, Inc. (“Patent Owner” or “Dexcom”) submits this Preliminary Response to Abbott Diabetes Care Inc.’s (“Petitioner” or “Abbott”) Petition for *Inter Partes* Review of U.S. Patent No. 11,510,625 (“the ’625 patent”), filed May 9, 2024.

I. INTRODUCTION

None of the Petition’s asserted references mentions, much less purports to solve, the needle-rotation problem addressed by the invention claimed by the challenged ’625 patent. Given these deficiencies, the Petition resorts to hindsight. Starting from the claimed invention, it tries to persuade the Board that drawings in the references can be viewed, *post hoc*, as having the claimed features unbeknownst, apparently, to the prior art authors. The use of hindsight is confirmed by *inter alia* the Petition’s repeated reliance on inherency without any explanation or evidence showing why the allegedly inherent feature is necessarily present. And these deficiencies are not cured by the Petition’s reliance on similarly conclusory expert testimony that largely parrots the Petition. The lack of explanation or evidence confirms that, absent hindsight, a skilled artisan would not have arrived at the claimed invention. As explained further below with respect to each ground, Petitioner fails to demonstrate a reasonable likelihood that it would prevail at trial in establishing the unpatentability of any challenged claim, and the Board should deny institution of *inter partes* review.

II. BACKGROUND

A. Claims 22-27 Are No Longer At Issue

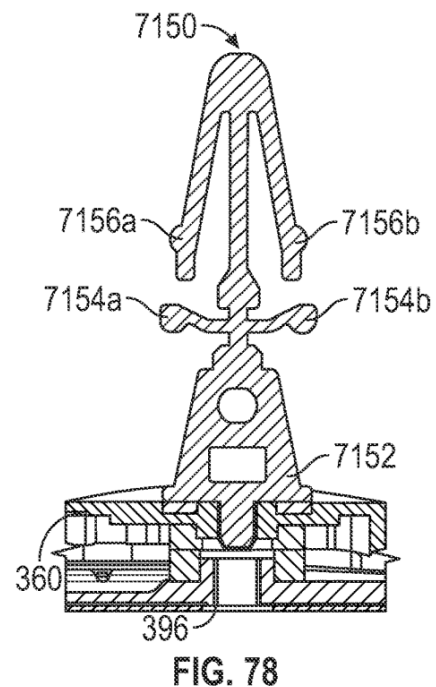
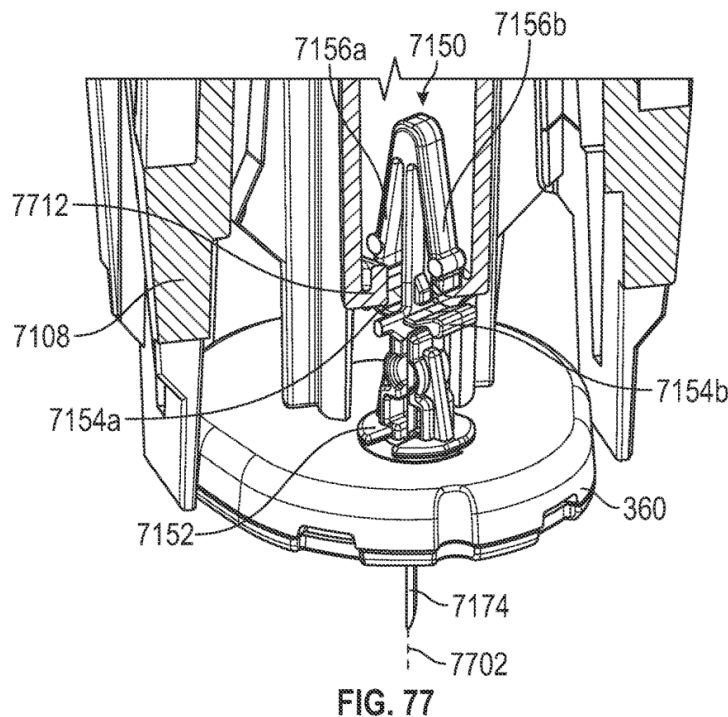
On August 21, 2024, Patent Owner filed a statutory disclaimer under 35 U.S.C. § 253(a) disclaiming claims 22-27. Ex-2002, 1. Accordingly, claims 22-27 are no longer at issue in this proceeding. *See* 37 C.F.R. § 42.107(e) (“No *inter partes* review will be instituted based on disclaimed claims.”); *Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996).

B. The '625 Patent

The '625 Patent relates to “applicators of on-skin sensor assemblies for measuring an analyte in a host, as well as their method of use and manufacture.” Ex-1001, Abstract. An on-skin sensor assembly, such as those addressed in the '625 Patent, allows users to continuously monitor levels of an analyte in their body, one example being an individual with diabetes measuring glucose levels. *Id.*, 1:47-49, 1:55-57. Such sensors provide advantages over conventional glucose-monitoring, “which typically requires uncomfortable finger pricking methods.” *Id.*, 1:47-50. On-skin sensors also allow for continuous analyte monitoring, as opposed to a normal interval of two to four daily measurements using conventional finger pricking, the latter often being unable to adequately catch an adverse hyper- or hypoglycemic condition. *Id.*, 1:50-57. The '625 Patent teaches that the “process of applying the

sensor to the person is important for such a system to be effective and user friendly.”
Id., 1:61-62.

The '625 Patent discloses such a system for safe and user-friendly application of an on skin-sensor assembly, with various embodiments for sensor assemblies and applicator mechanisms that safely and effectively apply a sensor assembly to the skin of a host, while placing a sensor element in contact with a target analyte within the host's body. One such embodiment is disclosed, *inter alia*, in Figures 77 and 78, reproduced below.



Id., Figs. 77, 78. The applicator system depicted in Figures 77 and 78 includes an applicator 7100 comprising a needle carrier assembly 7108 holding a needle hub 7150. *Id.*, 67:63-65. The needle hub 7150 connects to an insertion element 7174

(e.g., a needle) configured to insert a sensor 338 of on-skin sensor assembly 360 into the skin of a host through the sensor assembly aperture 396. *Id.*, 68:6-11. The applicator is configured to move the needle hub and connected insertion element from a proximal retracted position to a distal insertion position and then again to a proximal retracted position. *Id.*, 59:45-49, 59:62-66.

The '625 Patent discloses that the needle hub 7150 may include a pair of upper arms 7156a, 7156b and lower arms 7154a, 7154b that secure the needle hub in a desired orientation with respect to needle carrier assembly 7108. *Id.*, 68:12-22. The needle hub's base 7152 comprises an anti-rotation feature, describing that feature as follows:

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.

Id., 68:41-48.

C. **Art Cited By The Petition**

1. **Pace**

a) **Embodiment A**

The Petition relies on an embodiment the Petition styles as “embodiment A” (Petition, 16), which is depicted in Figures 21A-21C of Pace, reproduced below.

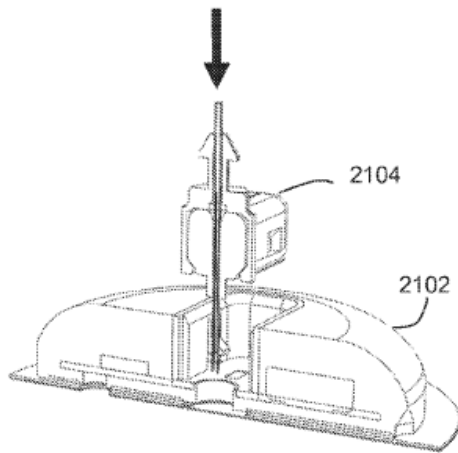


FIG. 21A

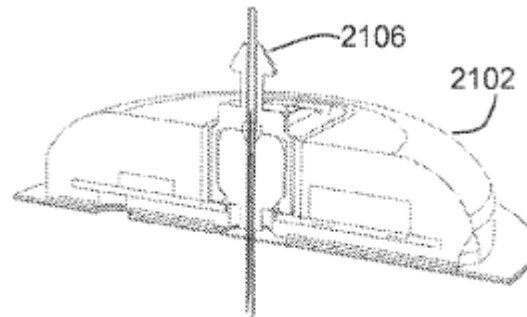


FIG. 21B

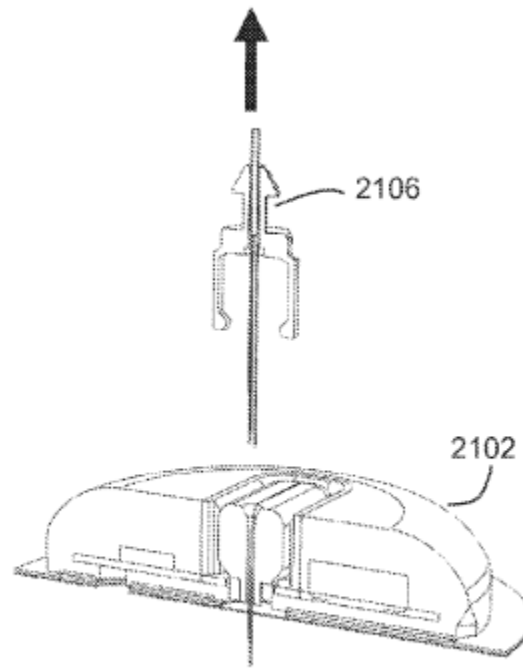
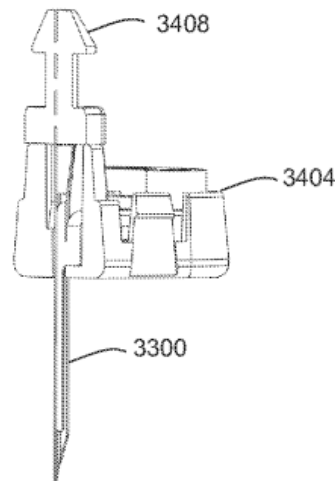
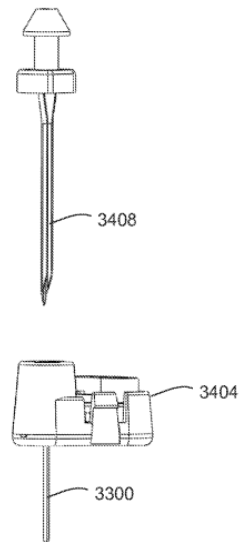
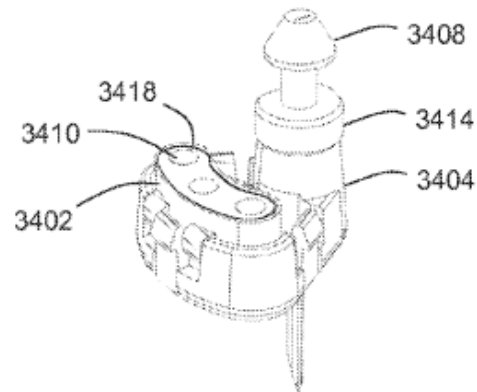
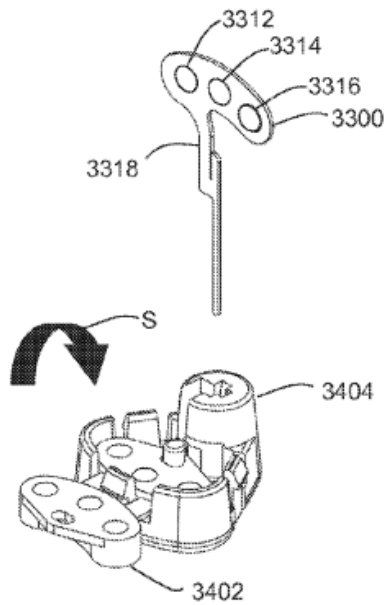


FIG. 21C

Ex-1006, Figs. 21A-21C. These figures depict a “hand-off” between sensor assembly 2104, sensor assembly gripper 2106, and electronics assembly 2102. *Id.*, [0123]. As shown in the figures, the sensor assembly first is held by the sensor assembly gripper via a snap fit and lowered into the electronics assembly. *Id.* Thereafter, the sensor assembly snaps into the electronics assembly and the sensor assembly gripper releases its grip and is retracted. *Id.* Pace provides no explicit disclosure that any components of embodiment A prevent any form of rotation of the components relative to one another.

b) Embodiment B

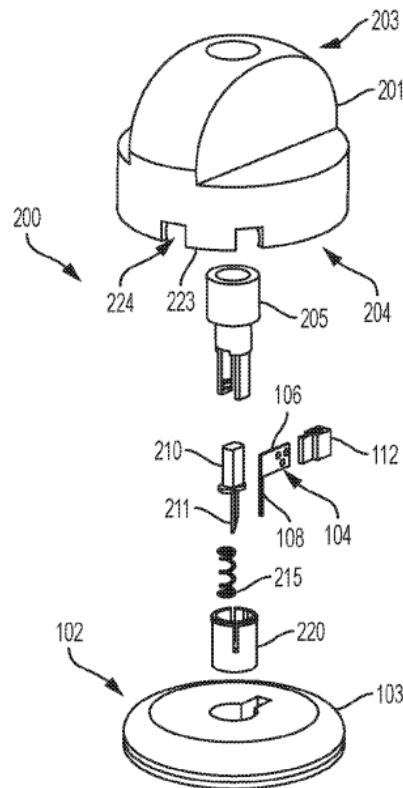
The Petition also relies on another embodiment the Petition styles as “embodiment B” (Petition, 18), which is depicted *inter alia*, in Figures 34C, 34D, 35A, and 35B, reproduced below.



Id., Figs. 34C-34D, 35A-35B. Embodiment B includes a hub 3414 connected to a sharp 3408. *Id.*, [0142]. The sharp is introduced into a connector support 3404 such that it surrounds and supports a tail portion of a sensor 3300. *Id.* Pace provides no explicit disclosure that any components of embodiment B prevent any form of rotation of the components relative to one another.

2. Pace 2

Pace 2 discloses a medical device inserter having components depicted in Figure 2B, reproduced below.



Ex-1007, Fig. 2B. These components include a housing 201, sharp support 205, sharp body 210 coupled to a sharp 211, sensor 104, biasing element 215, shroud 220, and sensor control device 102. *Id.*, [0047], [0049]. The components are configured to move the sharp body from a first stage (*id.*, [0054]) to a second insertion position wherein the sharp punctures the skin of a host and the sensor is coupled to the sensor control device (*id.*, [0070]-[0073]), whereafter the sharp body moves to a third post-insertion position while leaving the sensor in place (*id.*, [0073]). These positions are respectively shown in cross-sectional figures 3B, 4B, and 5B, reproduced below.

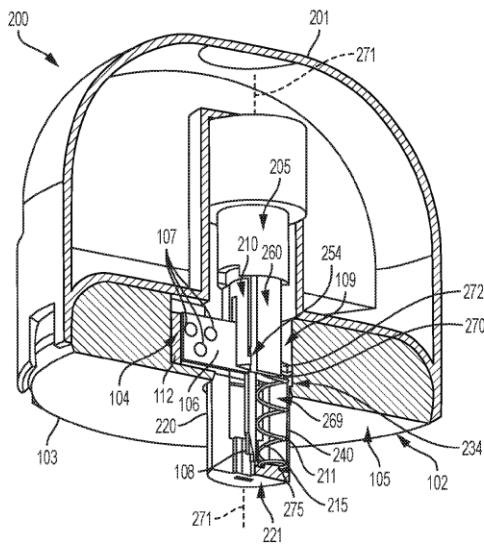


FIG. 3B

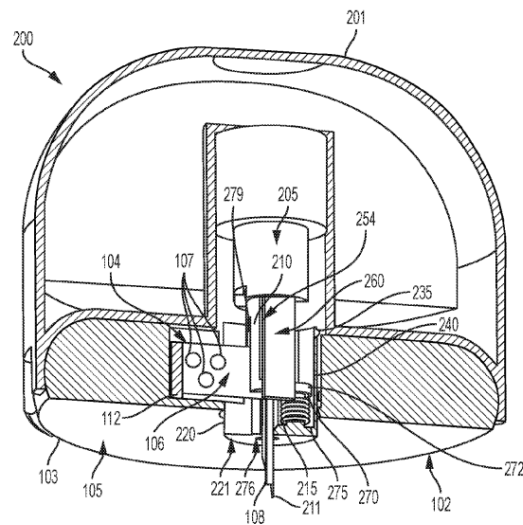


FIG. 4B

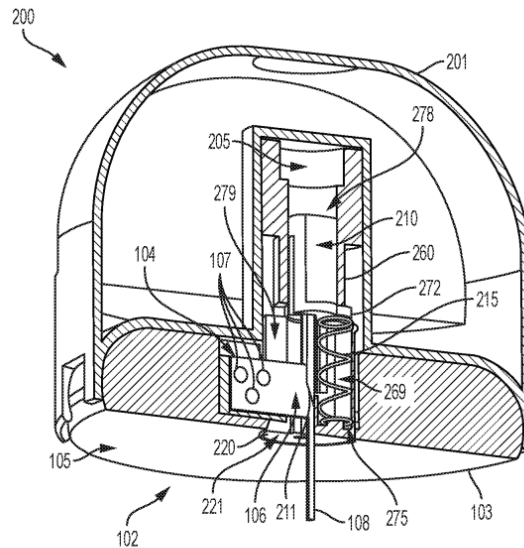


FIG. 5B

Id., Figs. 3B, 4B, 5B. As shown in Figure 3B the shroud 220 is extended away from sharp support 205. As the inserter is pressed against the skin of the host, the shroud retracts toward the sharp support, exposing the sharp 211 and sensor projection 108 to be inserted into a host, as shown in Figure 4B. Subsequently, the sharp moves upward, leaving the sensor in place and coupled to sensor control device 102, as shown in Figure 5B.

The shroud is extended and retracted relative to the sharp body by means of biasing element 215 (e.g., a spring). *Id.*, [0066]. This biasing element engages and extends between a semi-cylindrical projection 282 positioned on ledge 272 of the sharp body and a semi-cylinder projection 274 positioned on an inner surface of shroud 220. *Id.*, [0087]-[0088]. These projections for engaging the biasing element are depicted in Figures 7B and 7C, reproduced below.

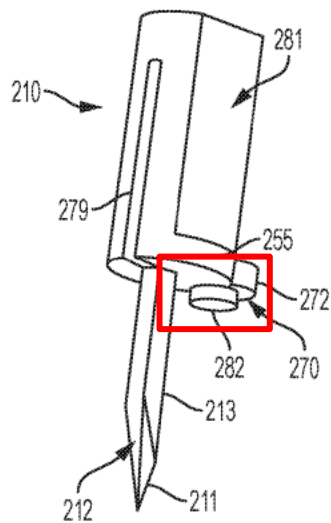


FIG. 7B

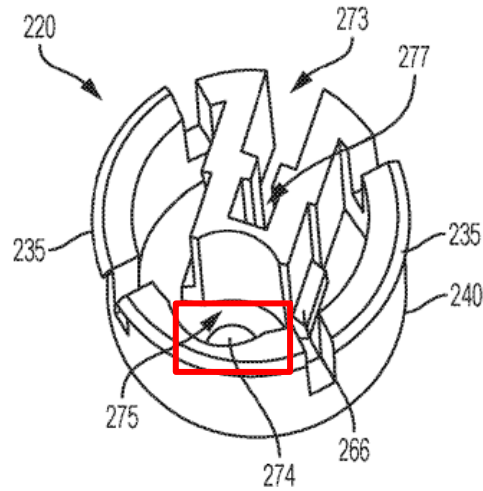
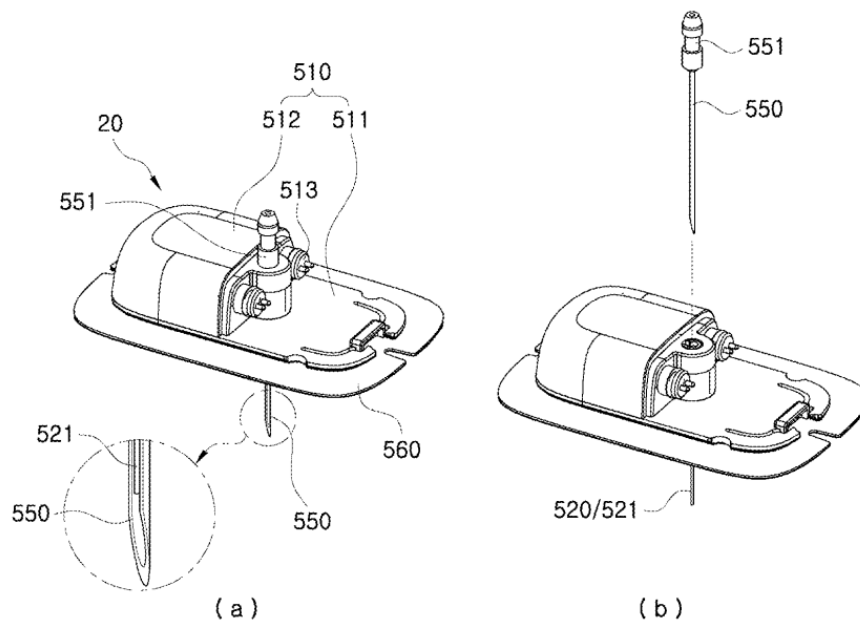


FIG. 7C

Id., Figs. 7B-7C (annotated). As the shroud extends and retracts relative to the sharp body during operation, ledge 272 is sized to slide longitudinally within a chamber 269 of shroud 220. *Id.*, [0068]; *see also id.*, Fig. 5B. Pace 2 provides no explicit disclosure that ledge 272 engages with shroud 220 or any other component in a manner that would prevent rotational movement of sharp body 210.

3. Chae

Chae discloses a sensor application assembly including components as shown in Figure 2, reproduced below.



Ex-1008, Fig. 2. These components include a needle head 551 connected to a needle 550. *Id.*, [0086]. The needle is disposed in and extends through a pod 510 of a sensor module 20 and surrounds a sensor probe 521. *Id.*, [0079], [0086]. Chae provides no explicit disclosure that rotation is prevented between needle head 551 and pod 510.

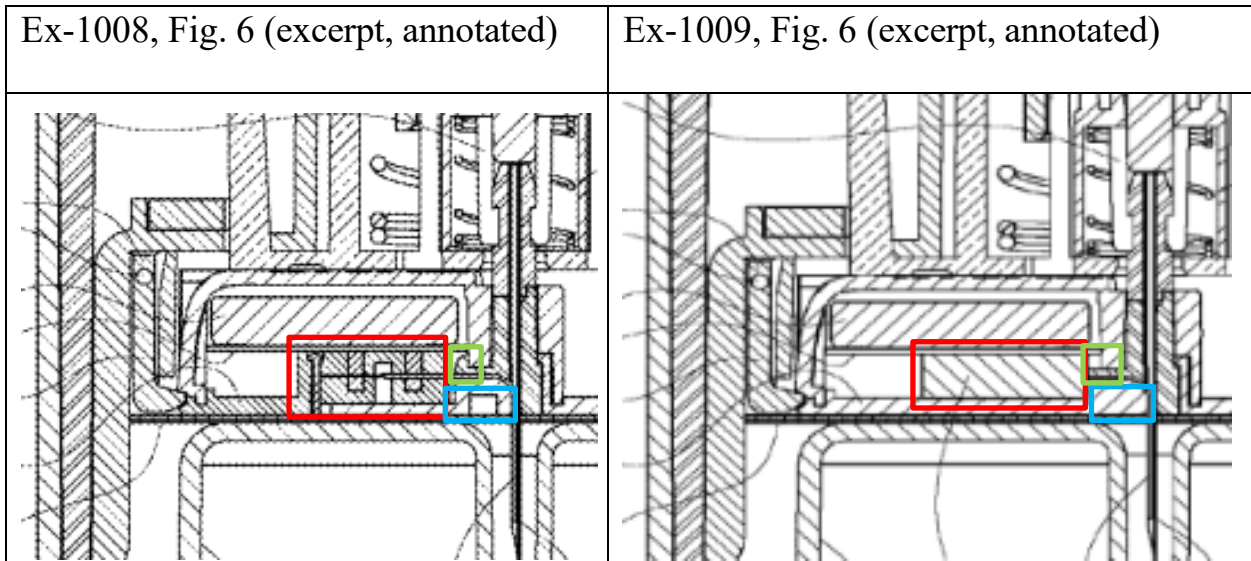
**a) Only Chae Figures 1-9, 14-16, 18-19,
And 21-24 Are Alleged By Petitioner To Be Prior Art**

Chae alleges priority to two different Korean patent applications, Nos. 10-2017-0068964 (the “’964 application”, filed June 2, 2017) and 10-2018-0063368 (filed June 1, 2018). Ex-1008, Cover at (30); *see also* Petition, 27. The ’625 Patent claims priority to U.S. Provisional Application Nos. 62/524,247, filed June 23, 2017, and 62/658,486, filed April 16, 2018. Ex-1001, p. 2. Thus, of Chae’s Korean priority applications, only the ’964 application was filed before the ’625 Patent’s June 23,

2017, priority date applied by Petitioner (Petition, 14), and therefore Chae may be considered prior art under 35 U.S.C. § 102(d) only for subject matter described in the '964 application.

The Petition relies on only the following figures of Chae: Figures 1-7, 8A-8B, 9A-9B, 14-15, 16A-16B, 18A-18B, 19A-19B, 21-24. *E.g.*, Petition, 28-31, 103-104. The Petition cites no other figures of Chae, nor alleges that such figures or associated written descriptions are prior art described in the priority '964 application. The Petition does not rely on figures 10-13 or 20, or allege that any of these figures or associated description are prior art.

Should the Board institute IPR, Patent Owner reserves the right to challenge Chae's prior art status. For example, contrary to Petitioner's assertion that Figures 6 "are identical in Chae and the '964 Application" (Petition, 32), the below comparison of those figures shows at least three differences, as indicated by the sets of boxes:



4. Lundquist

Lundquist discloses a “prefilled syringe for injecting medicament into a patient.” Ex-1011, Abstract. A cross-sectional view of such a needle is depicted in Figure 1F, reproduced below.

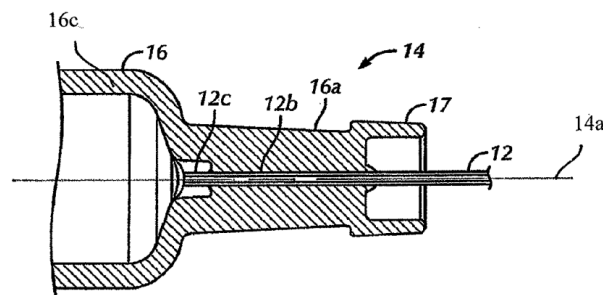


FIG. 1F

Id., Fig. 1F. The depicted syringe 14 includes a polymer barrel 16 having a distal tip 16a and a generally hollow distal end. *Id.*, [0039]. Disposed within the syringe is a cannula 12 (e.g., a needle) with the syringe’s distal tip insert molded over the cannula. *Id.*, [0039-0040].

**III. THE BOARD SHOULD DENY
INSTITUTION UNDER 35 U.S.C. § 325(d)**

The Board should decline institution under Section 325(d), which provides that the Board may elect not to institute trial if “the same or substantially the same prior art or arguments previously were presented to the Office.” In analyzing this issue, the Board applies a two-part framework: “(1) whether the same or substantially the same art previously was presented to the Office”; and, if so, (2) “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 8 (PTAB Feb. 13, 2020) (precedential). “Previously presented art includes ... art provided to the Office by an applicant, such as on an Information Disclosure Statement (IDS), in the prosecution history of the challenged patent.” *Id.*; see also *Biocon Pharma Ltd. v. Novartis Pharms. Corp.*, IPR2020-01263, Paper 12 at 9, 18 (PTAB Feb. 16, 2021) (denying institution based on art previously presented in an IDS).

In applying the two-part framework, the Board considers several nonexclusive 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 § III.C.5, first paragraph).

As explained in the following sections, discretionary denial is appropriate here because each of the three primary references relied on by the Petition – or substantially the same references – were before the Office during the patent’s prosecution and Petitioner fails to demonstrate any error by the examiner in considering those references.¹

¹ While Grounds 2 and 4 introduce Lundquist as a secondary reference, the Petition relies on Lundquist only for subject matter recited in certain dependent claims, namely Lundquist’s alleged disclosures related to insert molding. Lundquist is thus irrelevant to the Section 325(d) inquiry. *See Kayak Software Corp. v. IBM*, CBM2016-00075, Paper 16 at 10 (P.T.A.B. Dec. 15, 2016) (informative) (holding that Petitioners’ citation of a reference not considered by the Examiner disclosing

A. The Examiner Considered The Same Or Substantially The Same Art During Prosecution (*Becton, Dickinson* Factors (a), (b), And (d))

While Petitioner admits that Pace was presented to the Office during prosecution of the '625 patent, Petitioner asserts that Pace 2 and Chae were not of record. However, substantially the same references were before the Examiner.

During prosecution of the '625 patent, following an initial Notice of Allowance (Ex-1002, 526-36), the applicant filed a Request for Continued Examination (*id.*, 599-602) on September 2, 2022, followed by an Information Disclosure Statement (*id.*, 619-22, the “RCE IDS”) on September 9, 2022, identifying a total of 15 new prior art references. Less than two weeks later, on September 22, 2022, the Examiner issued a second Notice of Allowance (*id.*, 629-40) accompanied by a list of prior art references considered by the Examiner corresponding to the RCE IDS² (*id.*, 649-51). As detailed below, for each primary

only “additional subject matter of certain dependent claims[] is insufficient to persuade us that exercising our discretion under 35 U.S.C. § 325(d) is inappropriate”).

² The September 22, 2022, list of references cited by the Examiner reproduces the RCE IDS with the annotation at the bottom of each page “ALL REFERENES

reference relied on in the Petition, the RCE IDS either included that reference or included a substantially similar reference having the same disclosures relied on by Petitioner.

Pace

The published application of Pace subsequently issued as U.S. Patent No. 9,402,570 (Ex-2003), which was listed on the face of the RCE IDS. Ex-1002 at 619. Accordingly, Pace satisfies the first prong of *Advanced Bionics*.

Pace 2

The RCE IDS lists PCT Appl. No. WO2016/183493A1 (Ex-2004, “Pace WO-349”). Ex-1002 at 620. 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. Pace 2 and Pace WO-349 share the same abstract, drawings (Figures 1-9), and substantially the same written description.³ See Ex-1007, Cover, Figs. 1-9; Ex-2004, Cover, Figs. 1-9; Ex-

CONSIDERED EXCEPT WHERE LINED THROUGH.” *Id.*, 649-51. No listed references are lined through. *Id.*

³ The only difference between the written descriptions of Pace 2 and Pace WO-349 is that paragraph [0001] of Pace 2 includes U.S. priority information. Otherwise,

2005. Therefore, a substantially identical reference to Pace 2 was presented to the office during prosecution of the '625 patent, satisfying the first prong of *Advanced Bionics* as to Pace 2.

Chae

The RCE IDS lists European Patent Application No. EP3632314A1 (Ex-2006, “Chae EP-314”). Ex-1002 at 620. Chae EP-314 identifies the same inventors as Chae and was filed on the same day. Ex-1008, Cover; Ex-2006, Cover. Moreover, Chae EP-314 contains the same disclosures as Chae. Both references contain the same abstract, same drawings (Figs. 1-24), and substantially the same written description.⁴ Ex-1008, Cover, Figs. 1-24; Ex-2006, Cover, Figs. 1-24; Ex-2007. Therefore, a substantially identical reference to Chae was presented to the office during

paragraphs [0002]-[0120] are the same as Pace WO-349 paragraphs [0001]-[00119].
See Ex-2005 (redline comparison of Pace 2 and WO-349).

⁴ Aside from paragraph numbering, 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]. The remaining substantive disclosures are substantially identical. *See* Ex- 2007 (redline comparison of Chae and Chae EP-314).

prosecution of the '625 patent, satisfying the first prong of *Advanced Bionics* as to Chae.

**B. The Petition Does Not Show That The Office
Materially Erred In Evaluating The Prior
Art (*Becton, Dickinson* Factors (c), (e), And (f))**

Under *Advanced Bionics*, a Petitioner is required to “make a showing of material error” by the Office during prosecution with regard to previously presented prior art. *Advanced Bionics*, IPR2019-01469, Paper 6 at 8-9. Here, Petitioner does not even attempt to identify any material error made by the examiner during prosecution. The Petition instead merely hand-waves back to its merits arguments. Petition, 123. Prior Board decisions have rejected similar attempts to rely vaguely on the Petition’s merits arguments without particularly identifying how the Office materially erred in considering the previously presented prior art. *See Google LLC v. Valtrus Innovations Ltd.*, IPR2022-01197, Paper 18 at 20-21 (PTAB June 13, 2023) (“We find that Petitioner’s invitation to review the entirety of Ground 6, without more, does not point out sufficiently how the examiner erred pursuant to factor (e). ... [Prior] non-precedential decisions do not establish any requirement that a Board panel must independently review and assess the merits of a petition’s ground to conclude whether and how any material error occurred when a petitioner makes no attempt to explain what the alleged material error is.”) Here, Petitioner similarly invites the Board to review the entirety of its proposed grounds, alluding

to unspecified “new arguments and evidence that were unavailable to the examiner.” Petition, 123. Because the Petition does not specifically state what aspects of its presented grounds were overlooked or mis-considered, the Board should decline Petitioner’s invitation to search the Petition for such a showing. As discussed above, each of the primary references (or substantively identical references) were considered by the Office among just a handful of references (15 in total) less than two weeks before final allowance. There is nothing presented in the Petition to indicate or suggest that the Examiner failed to appreciate the teachings of those references.

Further, Petitioner’s assertion that the Petition presents “arguments and evidence that were unavailable to the examiner” fails because, as explained herein, 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. Accordingly, the examiner had before them during prosecution the very same information and evidence relied on in the Petition and, as explained in detail below, the relied-on disclosures of the primary references are ambiguous and do not support a finding that anti-rotation as claimed in the ’625 Patent was a functionality present in the prior art.

**IV. THE PETITION DOES NOT MEET ITS
BURDEN ON ANY CLAIM, FOR ANY GROUND**

The Petition rests on a series of assertions about prior art drawings. But those assertions are untethered to the perspective of a sufficiently defined POSITA, unsupported by genuine expert analysis entitled to weight, and fueled by hindsight knowledge of the patented invention. The Petition also mostly disregards the need to show a reasonable expectation of success when asserting obviousness.

As explained in Sections IV.A and IV.B, these basic shortcomings pervade each ground and prevent the Petition from establishing a reasonable likelihood that any challenged claim will be shown unpatentable under any ground. Section IV.C addresses each ground more specifically, explaining in detail why it fails to meet the requisite burden.

**A. The Petition Is Untethered To A Skilled Artisan, Unsupported By
Expert Analysis Entitled To Weight, And Fueled By Hindsight**

1. The Petition Is Untethered To A Skilled Artisan

The Petition is deficient because it disregards the POSITA where the law mandates an analysis centered on the POSITA, especially so when offering conclusions on what a reference “necessarily” discloses. “[T]he level of skill in the art is a prism or lens through which a judge or jury views the prior art and the claimed invention.” *Al-Site Corp. v. VSI Int’l, Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999). “This reference point prevents [factfinders] from using their own insight or, worse

yet, hindsight, to gauge obviousness.” *Id.* As the Petition here at best pays lip service to that essential reference point for each of its unpatentability grounds, it lacks the factual support necessary to make a legally sound unpatentability showing.

First, the Petition repeatedly disregards the POSITA when arguing inherent (necessary) disclosure. The Petition relies on allegedly inherent prior art disclosures throughout, asserting eleven times that some feature “necessarily” is present in an asserted prior art reference (Petition, 41 (three references to “necessarily”), 59, 65, 70, 80 81, 92, 98, and 120), which is the test for inherent disclosure. For ten of those “necessarily” assertions, the Petition fails to assert (or show) that a POSITA would have recognized that the feature necessarily was present. But the law demands extrinsic evidence showing such POSITA-recognition to establish inherency. *See, e.g., Cont’l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991) (vacating summary judgment of anticipation: “To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and *that it would be so recognized by persons of ordinary skill.*”) (emphasis added); *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1381 (Fed. Cir. 2002) (reversing judgment of invalidity under section 102(e): for inherency the question is “whether *one skilled in the art* would read the [reference] as inherently

disclosing the [claimed] invention, that is, whether *one skilled in the art* would read the [reference] as showing” the claimed feature) (emphasis added); *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (reversing BPAI finding of anticipation in part because no finding that reference’s element “‘necessarily’ disclosed” the claim limitation “or that *an artisan of ordinary skill would so recognize*”) (emphasis added). Only once, discussing three dependent claims on page 65, does the Petition make that legally required assertion, and the only extrinsic evidence it cites for that proposition is a single-sentence *ipse dixit* assertion of its expert (Ex-1004, ¶ 110). Consequently, the Petition lacks the factual support necessary to make a legally sound showing of inherent disclosure. *See Daihen Corp. v. Reno Tech., Inc.*, IPR2019-00248, Paper No. 13 at 3-5 (PTAB Jul. 25, 2019) (denying request for rehearing of decision denying institution of IPR in part because expert’s conclusory declaration did not show that a skilled artisan would recognize a claim limitation to be necessarily present in the asserted prior art reference, citing *Continental Can*).

Second, the Petition and accompanying expert declaration substantially disregard the POSITA also when arguing any *express disclosure*. The Petition at pages 16 to 33 purports to describe what various figures in the prior art references supposedly disclose, annotating figures in the references using the language of the ’625 Patent claims, such as “needle hub,” “aperture,” and “anti-rotation feature.” But the Petition does not once mention a POSITA in these pages, much less explain why

a POSITA would view these drawings to have said features. Its first reference to “POSITA,” after its skeletal definition of the POSITA on page 14, is on page 42, and even that late mention did not concern how a POSITA would understand a prior art disclosure. The same is true of Abbott’s expert declaration (Ex-1004). Its nearly identical overview of the prior art likewise not once mentions the POSITA. From paragraphs 38 to 101 of the declaration, there is only one paragraph mentioning a POSITA (*id.*, ¶ 65, and that asserts what supposedly would have been “obvious” to a POSITA not what a reference disclosed to a POSITA. *See In re Baxter Travenol Labs.*, 952 F.2d 388, 390 (Fed. Cir. 1991) (finding that “[t]he Board was correct in characterizing the dispositive question regarding anticipation as whether *one skilled in the art* would reasonably understand or infer from the [reference] that” an element had the feature required by the later claim) (emphasis added). This is a second fatal flaw in the Petition, infecting each unpatentability ground, causing the Petition to lack the factual support necessary to make a legally sound showing of express disclosure. *Cf. Content Square SAS v. Medallia, Inc.*, IPR2022-00316, Paper No. 13 at 37-38 (PTAB July 14, 2022) (denying institution in part because the testimony of the petitioner’s expert “does not explain sufficiently how or why a person of ordinary skill in the art would have inferred” that a prior art reference asserted as part of an obviousness unpatentability ground disclosed or taught a particular claim limitation); *Marvell Semiconductor, Inc. v. Intellectual Ventures I LLC*, IPR2014-

01562, Paper No. 11 at 12 (PTAB April 16, 2015) (denying institution in part because the expert declaration submitted by the petitioner “does not address what the [prior art reference] discloses to a person of ordinary skill in the art. Instead, the Declaration states an opinion from [the expert’s] own perspective as to what is ‘contemplated by the [reference]. We do not find this type of opinion persuasive.’”)

Third, the Petition offers only a cursory definition of the POSITA which is both unsubstantiated and also so vague as to be effectively meaningless. The Petition purports to define the POSITA’s level of skill in three sentences (Petition, 14), which Abbott’s expert declaration parrots verbatim (Ex-1004, ¶ 35). They cite no evidence to substantiate their assertions about the level of skill. The third and final sentence of their definition states: “The prior art also evidences the level of skill in the art”—without identifying that prior art or explaining how it evidences the level of skill. Having barely even paid lip service to the POSITA when asserting what the references supposedly disclosed, it is unsurprising that the Petition and expert declaration made no real effort to define a POSITA in a clear and substantiated manner. As the POSITA is the lens through which the Board must view prior art, this failure to define and substantiate the POSITA causes the Petition to lack the factual support necessary to make a legally sound showing of express or inherent disclosure in the prior art.

Viewing the art and obviousness through the lens of a POSITA is not optional. It is in the obviousness statute itself: “obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.” 35 U.S.C. § 103. But here the Petition gives a cursory, unsubstantiated, and unclear definition of a POSITA and then mostly ignores the POSITA when asserting what the prior art reference’s figures supposedly expressly disclose or necessarily disclose. These errors mean that the Petition lacks the necessary factual support for any asserted ground of unpatentability and therefore the Board should deny institution. *Cf. Fieldpiece Instruments, Inc. v. Twin Rivers Engineering, Inc.*, IPR2017-00362, Paper No. 16 at 4 (PTAB September 25, 2017) (denying rehearing of decision denying institution in part because the asserted “overviews of the references” in the petition did not “*explain* why the ordinarily skilled artisan would have understood the references to teach or suggest the negative limitation” at issue) (emphasis in original).

**2. The Petition Is Unsupported By A
Genuine Expert Analysis Entitled To Weight**

Expert testimony often is needed to provide the perspective of the POSITA. But here Abbott paid as little attention to its expert declaration as it did to the POSITA. Abbott’s expert declaration is entitled to no weight in part because (1) it constitutes *ipse dixit* and (2) it substantially is a verbatim parroting of the Petition.

First, the expert declaration for the most part is mere *ipse dixit* unaccompanied by reasoning and citation to evidence showing the perspective of a skilled artisan. For example, he states: “To the extent Pace 2 does not expressly describe the anti-rotation function of ledge 272 and the chamber 269, a POSITA would have considered it obvious that the combination would provide an anti-rotation function.” Ex-1004, ¶ 150. But he cites no experience, example, study, reference, or anything else in support of his conclusion. Similarly, he asserts that “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).” Ex-1004, ¶ 21. But he cites no experience, example, study, reference, or anything else in support of his conclusion. These and countless other assertions lack explanation, insight, or reasoning that might aid a factfinder. There is only the expert’s say-so.

The Board has denied institution in similar circumstances where the petition was supported by mere *ipse dixit* of an expert. *See, e.g., ARRIS Solutions, Inc. v. Realtime Adaptive Streaming LLC*, IPR2019-01586, Paper No. 7 at 24 (March 16, 2020) (denying institution where petitioner’s expert made various assertions about the prior art reference but “provide[d] no analysis or explanation of why the assertion must be as he says. Such *ipse dixit* is an insufficient evidentiary basis and cannot substitute for disclosure in a prior art reference itself.”)

Second, Board precedent warns that conclusory expert opinions merely parroting the petition will be given little or no weight, including on the factual question of what a prior art reference would have disclosed to a POSITA. *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15 (PTAB Aug. 24, 2022) (precedential) (“[T]he cited declaration testimony is conclusory and unsupported, adds little to the conclusory assertion for which it is offered to support, and is entitled to little weight.”). In designating *Xerox* as precedential, the Director explained:

The declaration does not provide any technical detail, explanation, or statements supporting why the expert determines that the feature in question was required or would have been obvious based on the prior art disclosure. See Ex. 1003 ¶ 54. Instead, the declaration copies, word-for-word, Petitioner’s conclusory assertions. Compare *id.*, with Pet. 28–29. The declaration sets forth Petitioner’s conclusory assertions as though they are facts, rather than setting forth facts and evidence in support of Petitioner’s assertions. Accordingly, I agree with the Board’s explanation that “the cited declaration testimony is conclusory and unsupported, adds little to the conclusory assertion for which it is offered to support, and is entitled to little weight” under 37 C.F.R. § 42.65(a).

IPR2022-00624, Paper 12 at 5 (USPTO Director February 10, 2023); *see also Unirac, Inc. v. EcoFasten Solar, LLC*, IPR2021-00532, Paper No. 7 at 22 (July 22, 2021) (rejecting obviousness ground and denying institution).

Abbott ignored this clear warning from the Director and the Board. Its expert declaration substantially is a copy and paste of the Petition. For example, the Declaration's "Overview of the Prior Art" Section VII (§§ 38-55) is nearly verbatim the same as the corresponding Section VII of the Petition. *See* Ex-2008.⁵ Likewise, the Declaration's substantive argument Section VIII ("The Asserted Grounds of Unpatentability", §§ 57-247) is nearly verbatim the same as the corresponding Petition section. *See* Ex-2009.

The expert declaration on which the Petition relies is thus entitled to no weight, further confirming the Board should deny institution.

3. The Petition Is Fueled By Hindsight

What the asserted prior art references have in common is that none of them mentions the needle-rotation problem addressed by the challenged '625 patent, or purports to solve that problem. Instead, the Petition starts with the claimed invention and tries to persuade the Board that drawings in these references can be viewed, *post hoc*, as having those same claimed features unbeknownst, apparently, to the prior art authors. As shown in Section IV.C, none of the asserted prior art references would have been so viewed by a skilled artisan *ex ante* without hindsight. The Petition

⁵ Submitted herewith as Exhibit 2011 is a declaration explaining how redline comparison Exhibits 2005 and 2007-2009 were prepared.

relies on hindsight to urge the Board to see in the prior art what is not there. *Cf. Ferno-Washington, Inc. v. Stryker Corp.*, IPR2024-00042, Paper No. 9 at 21-22 (PTAB March 19, 2024) (denying institution, observing “Petitioner has not shown that either [prior art reference] teaches or suggests the limitation at issue, and Petitioner’s proposed modification is not supported by reasoning beyond what appears to be a hindsight reconstruction of the claimed feature.”))

**B. The Petition And Expert Ignore The Mandate
To Show Reasonable Expectation Of Success**

The Petition’s first ground asserts obviousness as one of its two bases for unpatentability while its remaining four grounds assert obviousness as the sole basis. But the Petition and the (mostly parroting) expert declaration substantially disregard what any legally sound obviousness challenge must show. In particular, the Petition and expert ignore reasonable expectation of success when arguing obviousness of the independent claims in Grounds 1, 3, and 5. The Petition does not even mention the words “reasonable” or “success” in Grounds 1, 3, and 5. Its only brief mentions of reasonable expectation of success appear only in relation to the seven dependent claims it challenges in Grounds 2 and 4.

Showing reasonable expectation of success is mandatory when asserting obviousness. In addition to showing motivation to combine or modify references, a patent challenger is “required to show that a skilled artisan would have had a

‘reasonable expectation’ of success ..., even if such success was not guaranteed in all cases.” *Eli Lilly & Co. v. Teva Pharms. Int’l GmbH*, 8 F.4th 1331, 1348 (Fed. Cir. 2021) (affirming obviousness based on PTAB finding of no reasonable expectation of success, despite finding of motivation to combine); *Teva Pharms. USA, Inc. v. Corcept Therapeutics, Inc.*, 18 F.4th 1377, 1383 (Fed. Cir. 2021) (affirming no reasonable expectation of success; “[Petitioner] describes the prior art as ‘disclos[ing] the problem, ... the solution, ... and the way to find the solution’ ... [but] ignores the reasonable-expectation-of-success requirement. At best, the prior art directed a skilled artisan to try combining [references]. But without showing a reasonable expectation of success, [Petitioner] did not prove obviousness.”).

This reasonable-expectation-of-success mandate applies equally to obviousness assertions based, as here, on a single reference. *Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1338-39 (Fed. Cir. 2020) (addressing reasonable expectation of success when affirming PTAB obviousness finding over single reference lacking two elements); *In re Stepan Co.*, 868 F.3d 1342, 1346 n.1 (Fed. Cir. 2017) (vacating obviousness rejection of application claims over a single reference; “[W]hether a rejection is based on combining disclosures from multiple references, combining multiple embodiments from a single reference, or selecting from large lists of elements in a single reference, there must be a motivation to make the combination and a reasonable expectation that such a combination would be

successful, otherwise a skilled artisan would not arrive at the claimed combination.”); *Delta Electronics, Inc. v. Vicor Corp.*, IPR2024-00134, Paper No. 8 at 35, 47 (PTAB May 17, 2024) (denying IPR institution where two of the grounds asserted obviousness over a single reference, in part because there was no showing of reasonable expectation of success as to the proposed asserted modification of that reference.); *NJOY, LLC v. JUUL Labs, LLC*, IPR2024-00267, Paper No. 15, at 39 (PTAB June 12, 2024) (denying IPR institution for failure to show reasonable expectation of success; “[N]oticeably absent from Petitioner’s contentions is any persuasive discussion of an explicit or implicit reasonable expectation of success. ... [The expert’s] testimony addresses additional reasons to combine and is silent as to whether a reasonable expectation of success exists in the combination.”).

This neglect of the essential element of reasonable expectation of success, at least for each challenge to the independent claims, is another reason to deny institution.

**C. Grounds 1-5 Fail To Show That
Any Reference Discloses Or Teaches An Anti-Rotation
Feature Or Key Configured To Prevent The Claimed Rotation**

Each of the challenged claims includes similar limitations that the Petition fails to demonstrate were disclosed or taught by the prior art. Specifically, each challenged claim requires either an “anti-rotation feature” (claims 1, 28) or an “anti-

rotation key” (claim 13).⁶ Each challenged claim further recites that the claimed anti-rotation feature/key is configured to prevent a specific type of rotation:

- claim 1’s anti-rotation feature is “configured to prevent rotation of the needle hub within the aperture,”
- claim 13’s anti-rotation key is “configured to prevent rotation of the needle hub with respect to the on-skin sensor assembly,” and
- claim 28’s anti-rotation feature is “configured to prevent rotation of the base within the aperture.”

As explained in detail below, the Petition fails to establish that any cited prior art reference discloses or teaches an anti-rotation feature/key that is configured to prevent rotation as claimed.⁷

⁶ Patent Owner herein uses the term “**anti-rotation feature/key**” to refer, respectively, to claims 1 and 28’s recitation of an “anti-rotation feature” and claim 13’s recitation of an “anti-rotation key”.

⁷ Patent Owner herein uses the term “**claimed rotation**” or “**rotation as claimed**” to refer to the specific type of rotation that each respective anti-rotation feature/key of claims 1, 13, and 28 is “configured to prevent.”

1. **Ground 1 (Pace Embodiments A And B)**

a) **Pace Does Not Inherently Disclose
An Anti-Rotation Key/Feature
Configured To Prevent The Claimed Rotation**

The Petition admits that neither embodiment of Pace explicitly discloses a structure providing anti-rotation functionality, and instead relies on inherency by arguing that such functionality is necessarily present. Petition, 41 (“Although Pace does not specifically state that the hub 2106 in embodiment A or the V-shaped portion in embodiment B have ‘anti-rotation’ functionality, these arrangements necessarily prevent the sharp from rotating.”). Inherency, however, is a demanding standard. “Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.” *MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999). “Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325, 1332 (Fed. Cir. 2010). Whether a claimed limitation is necessarily present in a reference is determined from the viewpoint of the POSITA. *See Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1381 (Fed. Cir. 2002) (for inherency the question is “whether one skilled in the art would read the [reference] as inherently disclosing the [claimed] invention, that is, whether one skilled in the art would read the [reference] as

showing” the claimed feature). The Petition fails to establish that a POSITA would recognize any structure of embodiments A or B of Pace to constitute an anti-rotation key/feature configured to prevent rotation as claimed. Instead, as detailed below, the Petition relies on only hindsight-fueled speculation based on ambiguous drawings while failing to explain why a POSITA would consider any structure in Pace to prevent rotation.

(1) Embodiment A

Regarding Pace’s embodiment A, the Petition relies on Pace’s Figures 21A-21C (reproduced below), which depict Pace’s “sensor assembly gripper 2106” respectively before, during, and after a hand-off procedure to connect “sensor assembly 2104” to “electronics assembly 2102.” Petition, 37-39; Ex-1006, [0123].

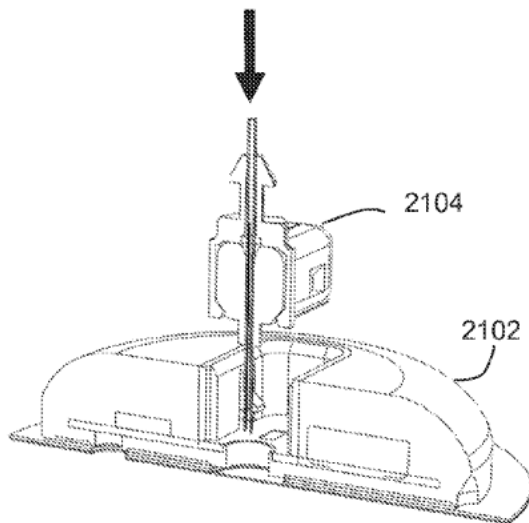


FIG. 21A

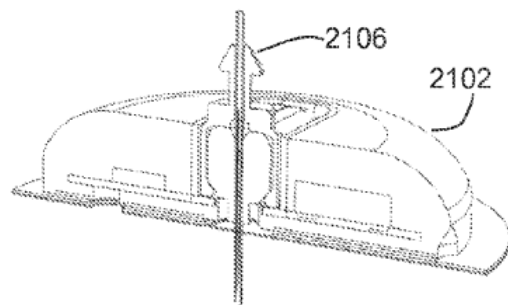


FIG. 21B

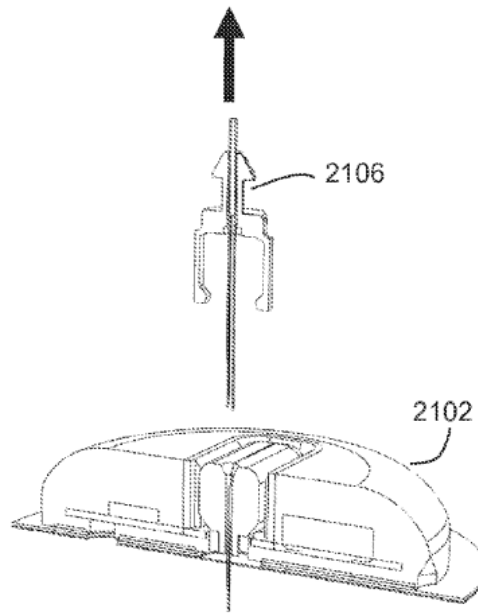


FIG. 21C

Id., Figs. 21A-21C. The Petition contends that gripper 2106 corresponds to the claimed needle hub, lower section of gripper 2106 corresponds to a needle hub base, “vertical legs and feet” extending from gripper 2106 correspond an “anti-rotation feature extending from the base,” and that “feet” at the bottom of gripper 2106 correspond to a key. Petition, 38-39, 51, 58. However, regarding the identified structures preventing rotation as claimed, the Petition just hand-waves to the structures as configured in Figures 21A-21C and concludes that rotation is necessarily prevented. Petition, 41 (“Specifically, for embodiment A, Figures 21A-21C depict vertical slots in the electronics assembly 2102, into which the hub 2106 legs are inserted, which necessarily prevent rotation of hub 2106, and thus the sharp, relative to the on-body device.”), 50 (“[T]he legs and feet of the hub 2106 in

embodiment A prevent rotation of the hub (and the needle coupled to it) relative to the on-body device 222 (i.e., the on-skin sensor assembly) when inserted within the vertical slots (i.e., the aperture) in the on-body device 222.”⁸ That is the full extent of the Petition’s analysis of Pace embodiment A’s alleged inherent disclosure of an anti-rotation feature/key configured to prevent rotation and, for at least the reasons explained below, this analysis is insufficient to meet the legal standard for inherency.

First, the Petition makes multiple unexplained assumptions from the drawings of embodiment A of Pace regarding factors that a POSITA would need to consider in determining whether the disclosed structures prevent rotation. One such factor is the fit and relative dimensions between components. In order to prevent rotation, the identified components would need to fit tightly because otherwise the gripper 2106 of Pace would be able to move and rotate within Pace’s alleged aperture. Pace provides no disclosure of fit or relative dimensions for its components and the Petition provides no explanation for why any such properties would be understood from the relied-on figures. The Petition’s conclusion that the configuration of components shown in Figures 21A-21C necessarily prevents rotation is pure

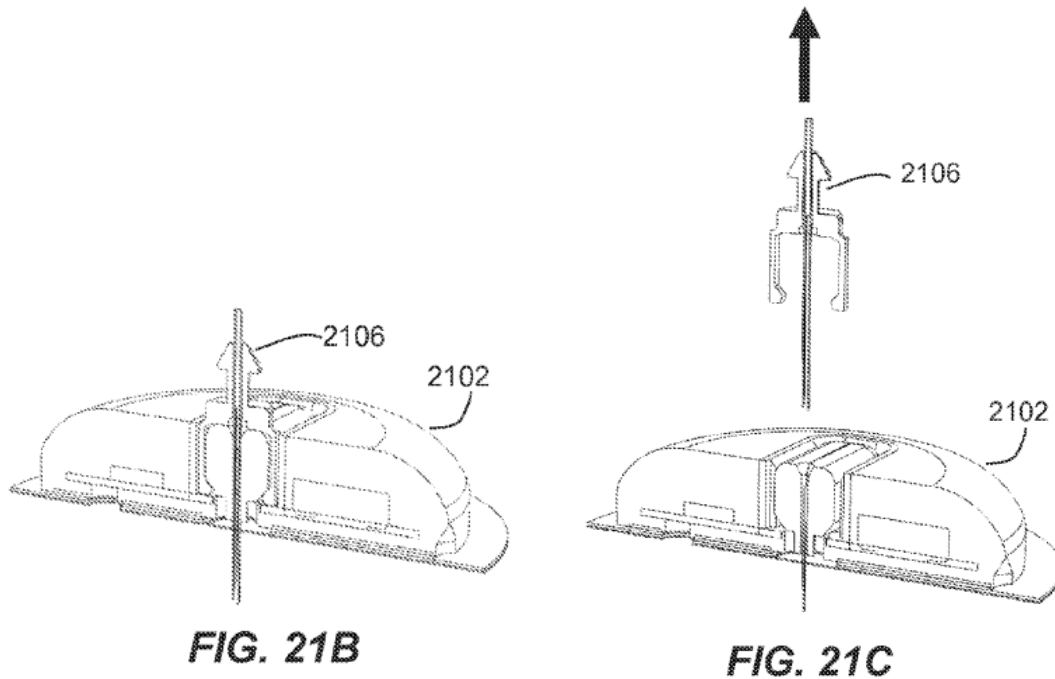
⁸ For subsequent independent claims, the Petition cites back to its analysis concerning alleged rotation prevention for independent claim 1. Petition, 51-52, 58-59.

speculation, based on improper inferences of measurements and dimensions from figures on which Pace is silent. *See Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1351 (Fed. Cir. 2013) (holding that “[p]atent drawings [] do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue” (quoting *Hockerson–Halberstadt, Inc. v. Avia Grp. Int’l, Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000))). The Board has rejected similar Petitioner arguments in the past. In *Edwards Lifesciences Corp. v. Cardiovalve Ltd.*, IPR2021-01051, Paper 36 (PTAB Dec. 6, 2022), the petitioner challenged proposed amended claims as obvious based solely on the petitioner’s interpretation of the configuration of components in a drawing from the relied-on reference as disclosing an alleged function.⁹ *Id.*, 53-57. The Board rejected the petitioner’s arguments because, “[l]acking any textual support to show [the limitation], Petitioner’s reliance upon Figures 22A and 22B as teaching this limitation is unavailing because it is largely speculative, depending upon what the length of distal element 18 *could* be.” *Id.*, 56-57 (citing *Plantronics*, 724 F.3d at

⁹ Petitioner argued that the structure depicted in the reference drawings disclosed the function of “advancing the end of the first-clip arm and the end of the second-clip arm out of the delivery tube before advancing the support portion out of the delivery tube.” *Edwards*, IPR2021-01051, Paper 36 at 54.

1351). Here, similarly, Petitioner relies on what Figures 21A-21C *could* depict, but not what those figures *necessarily* would convey to one of skill in the art.

Another factor a POSITA would consider in determining whether Pace's Figures 21A-21C necessarily show "anti-rotation" functionality, and on which the Petition is silent, is the various materials used to construct the depicted components. For example, if Pace's components such as gripper 2106 are bendable or flexible, this might allow the gripper 2106 and attached needle to rotate even if there were a tight or snug fit between the gripper's legs and the alleged aperture of electronics unit 2102, because such flexibility would allow the other components of gripper 2106 to still move relatively to the gripper legs. Pace itself suggests that the gripper 2106 is constructed to be flexible. Pace discloses that "sensor assembly gripper 2106, with a **light snap fit**, grabs and orients the sensor assembly 2104 for connection to the electronics assembly 2102. After 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." Ex-1006, [0123] (emphasis added); *see also id.*, Figs. 21B & 21C.



If gripper 2106 were constructed to be rigid this would prevent the gripper legs from deforming to release their snap fit grip on sensor assembly 2104 and would thereby prevent the intended handoff functionality of embodiment A and depicted in Figures 21B and 21C.

Further, Pace does not support the Petition assertion that embodiment A provides a “snug fit” (Petition, 47) of components. To the contrary, Pace requires enough clearance between the gripper 2106 and the alleged aperture to allow the gripper’s legs to open wide to allow the gripper’s feet to separate far enough apart to cause the gripper to release its grip on the sensor subassembly, like a pair of tongs opening wider until it releases its grip on a piece of food. Pace claims priority to and incorporates U.S. Provisional Patent Application No. 61/569,287, which confirms

that the gripper requires adequate clearance to function properly. Ex-2010, [00111] (“However, the approach [shown in Figs. 21A-21C] also requires adequate clearance to facilitate such activity.”). This refutes Petitioner’s speculation that the figures of Pace alone necessarily disclose a snug fit between components. 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.

Because the Petition fails to address relevant factors as to whether the depicted structures of embodiment A would prevent rotation, including fits, relative dimensions, and materials—and indeed, other disclosures in Pace suggest an inability to prevent rotation—the Petition has not established that anti-rotation is a *necessary* feature of embodiment A, thus failing to meet the high bar for showing inherency. *See Fujian Sanan Gr. Co., Ltd. v. Epistar Corp.*, IPR2018-00970, Paper 9 at 20-21 (PTAB Nov. 20, 2018) (rejecting argument that prior art surfaces inherently emit light because Petitioner did not consider a property (refractive index) relevant to whether the reference necessarily emits light).

Second, the Petition’s speculative conclusion that embodiment A includes anti-rotation functionality is based solely on ambiguous drawings that do not support such a conclusion. Specifically, the Petition relies on the cross-sectional perspective drawings of Figures 21A-21C. *See* Ex-1006, Figs. 21A-21C, [0034] (“FIGS. 21A-21C are perspective section views illustrating sensor assembly receipt by the sensor

mount and sharp withdrawal from the assembled complex”). These cross-sectional drawings only appear to show a portion of electronics assembly 2102. The drawings do not disclose, and the specification does not describe, how far or in what manner any of the gripper 2106, sensor assembly 2104, or electronics assembly 2102 extend beyond the plane defining the cross-section of the figures. As such, it is impossible to determine from the figures alone the relationship between portions of the components that are not depicted. For example, 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. The Petition does not address this silence in Pace and for this additional reason fails to establish that anti-rotation is a necessary feature solely from viewing the references.

Third, the above deficiencies in the Petition are compounded by Petitioner’s failure to present extrinsic evidence, including adequate expert testimony, as to why a POSITA would recognize anti-rotation to be a necessary feature of the components depicted in Figures 21A-21C. Where a “reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.” *Cont’l Can*, 948 F.2d at 1268. Here,

the only extrinsic evidence offered by Petitioner in support of its bare conclusions regarding embodiment A's alleged anti-rotation functionality is a single blanket citation to Petitioner's expert declaration. Petition, 34 ("Pace anticipates or renders obvious claim 1, as explained below and as supported by Ex-1004, ¶¶57-73."). The cited declaration paragraphs, however, cite no additional extrinsic evidence and present no new arguments beyond the bare conclusions presented in the Petition. In fact, as shown in a redline comparison of the Petition and the supporting Riviere Declaration, the declaration parrots the Petition almost verbatim. *See* Ex-2009 at 1-17. Under the Board's precedent and operative rules, such a declaration is entitled to little or no evidentiary weight. *Xerox*, IPR2022-00624, Paper 9 at 15 ("[T]he cited declaration testimony is conclusory and unsupported, adds little to the conclusory assertion for which it is offered to support, and is entitled to little weight."); 37 C.F.R. § 42.65(a). The Board has repeatedly rejected inherency arguments based on conclusory expert testimony. *See, e.g., Nokia of Am. Corp. v. Gen. Access Sols. Ltd.*, IPR2023-01415, Paper 13 at 15-17 (PTAB Mar. 22, 2024) (rejecting inherency argument where "[a]lmost all of [the cited expert] testimony repeats the conclusory assertions made in the Petition"); *Spansion Inc. v. Macronix Int'l Co.*, IPR2014-01116, Paper 12 at 9 (PTAB Dec. 22, 2014) (finding insufficient support for a finding of inherency where "Petitioner does not provide objective evidence" aside from conclusory expert declaration). Accordingly, the Petition's argument that the

disclosed structures of Pace's embodiment A necessarily prevent rotation fails because it is unsupported by objective evidence to show that a POSITA would recognize such allegedly necessary functionality.

(2) Embodiment B

Turning to Pace's embodiment B, the Petition relies on an embodiment depicted in Pace's Figures 34C-34D, 35A-35B, and 47C. Petition, 39-41. These Figures depict a "sensor 3300 captured within the seal 3402, a sharp 3408 is then introduced, with its hub 3414 contacting the connector support 3404 as shown in FIG. 34D." Ex-1006, [0142].

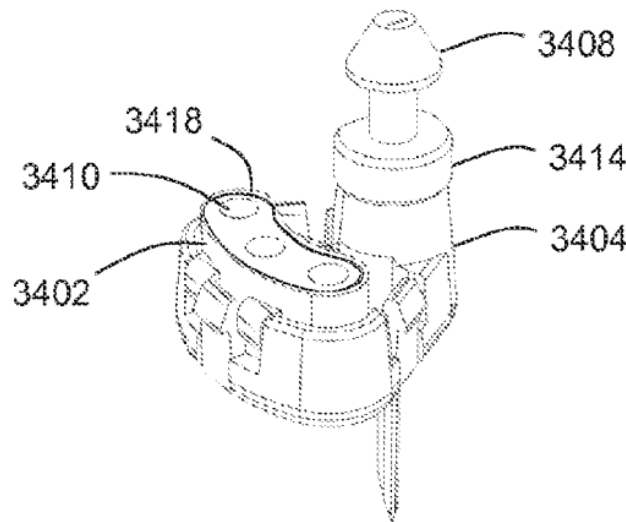


FIG. 34D

Id., Fig. 34D. The Petition contends that hub 3414 corresponds to the claimed "needle hub," a lower section of hub 3414 corresponds to the claimed "base," and

that a purportedly V-shaped portion at top of sharp 3408 corresponds to the claimed anti-rotation feature/key. Petition, 39, 51, 58. The Petition contends that the claimed aperture corresponds to a cross-shaped opening in connector support 3404. Petition, 40, 49, 50-58. With regard to embodiment B allegedly preventing rotation, as with embodiment A, the Petition simply points to the configuration of components presented in Pace's figures and concludes that they necessarily prevent rotation. Petition, 41-42 ("Similarly for embodiment B, Figures 34B and 34C depict a cross-shaped aperture . . . , into which the V-shaped portion of the sharp hub is inserted, as explained below in claims 1.8-1.10, which necessarily prevents rotation of the sharp hub relative to the on-body device."), 50 ([I]n embodiment B, the V-shaped portion extending from the base of the hub prevents rotation of the hub (and the needle coupled to it) relative to the on-body device 222 when inserted into the aperture (i.e., the aperture) in the connector support in the on-body device 222."). That is the full extent of the Petition's analysis of Pace embodiment B's alleged rotation prevention. Therefore, as explained further below, the Petition's inherency analysis as to embodiment B fails for the same reasons as explained above for embodiment A.

First, as with embodiment A, the Petition's conclusion that the structures of embodiment B necessarily prevent rotation is based on speculation regarding properties on which Pace's figures and written description are silent. For example, the Petition does not address properties such as fit between components, relative

dimensions and distances between components that would control whether there is a tight fit between the Petition's relied on V-shaped structure and connector support 3404, or the materials used to construct the components depicted in embodiment B and the flexibility or rigidity of such materials. These are all factors a POSITA would consider in determining whether the structures depicted in embodiment B *necessarily* prevent rotation of the alleged needle hub relative to a sensor assembly and, therefore, the Petition does not meet its burden for establishing inherency.

Second, the Petition's conclusion that rotation is necessarily prevented in embodiment B is based solely on vague figures that do not support such a conclusion. The Petition relies on Figure 47C as allegedly showing that connector support 3404 "is internally tapered to complement the V-shaped portion." Petition, 21. The Petition, however, never reproduces Figure 47C as presented in Pace. Instead, the Petition relies on a misleadingly annotated version of Figure 47C that includes solid lines not present in the figure. Figure 47C as it appears in Pace is presented below contrasted against the annotated version presented in the Petition.

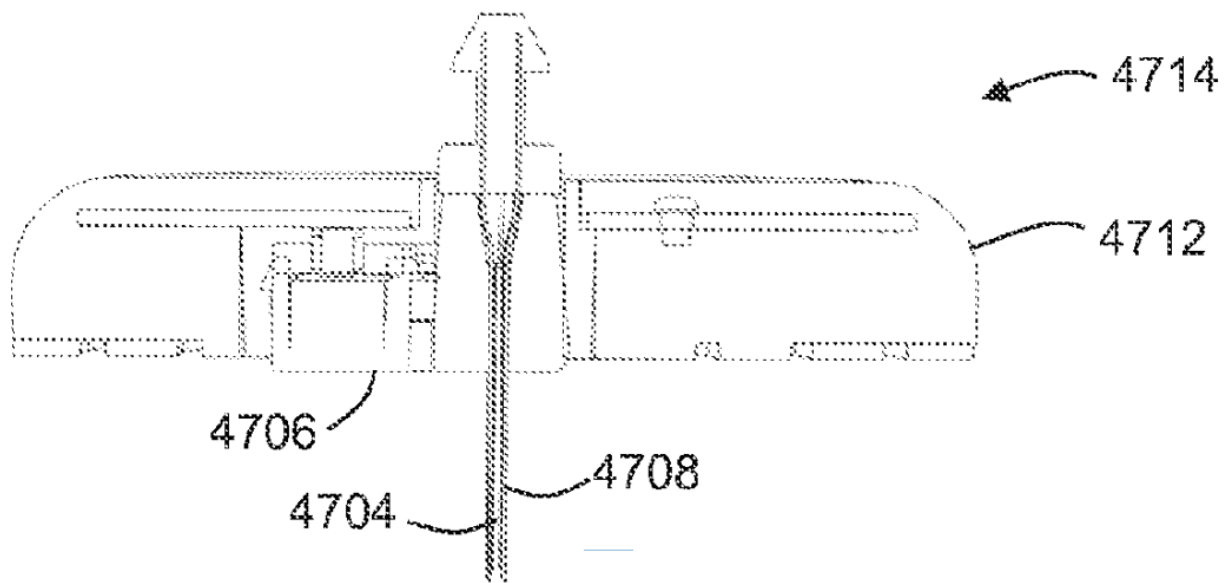
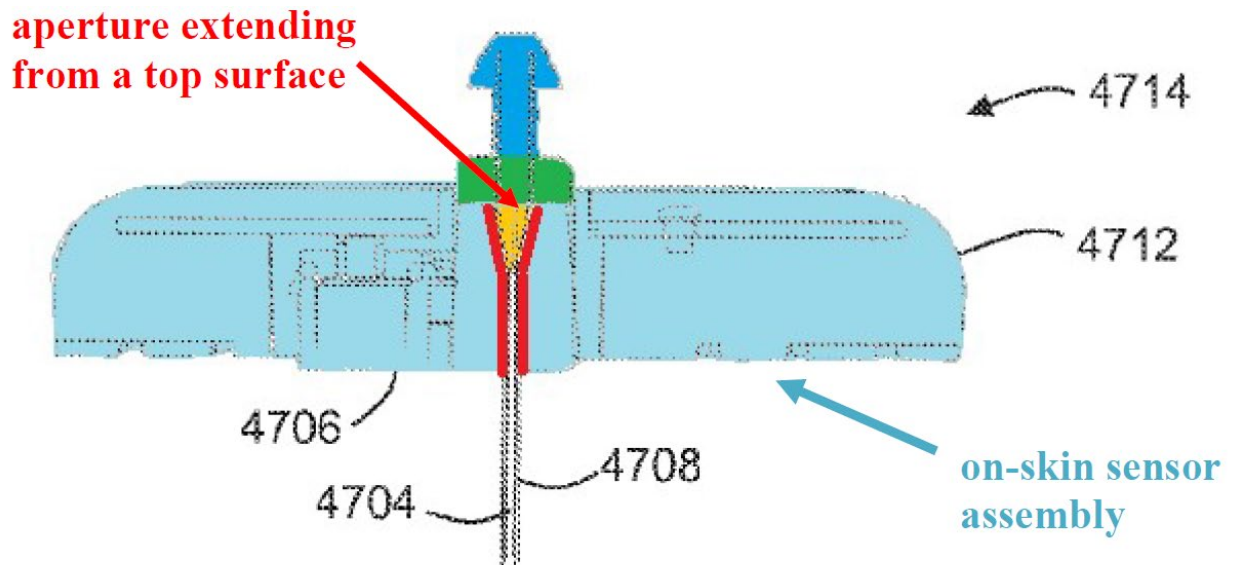


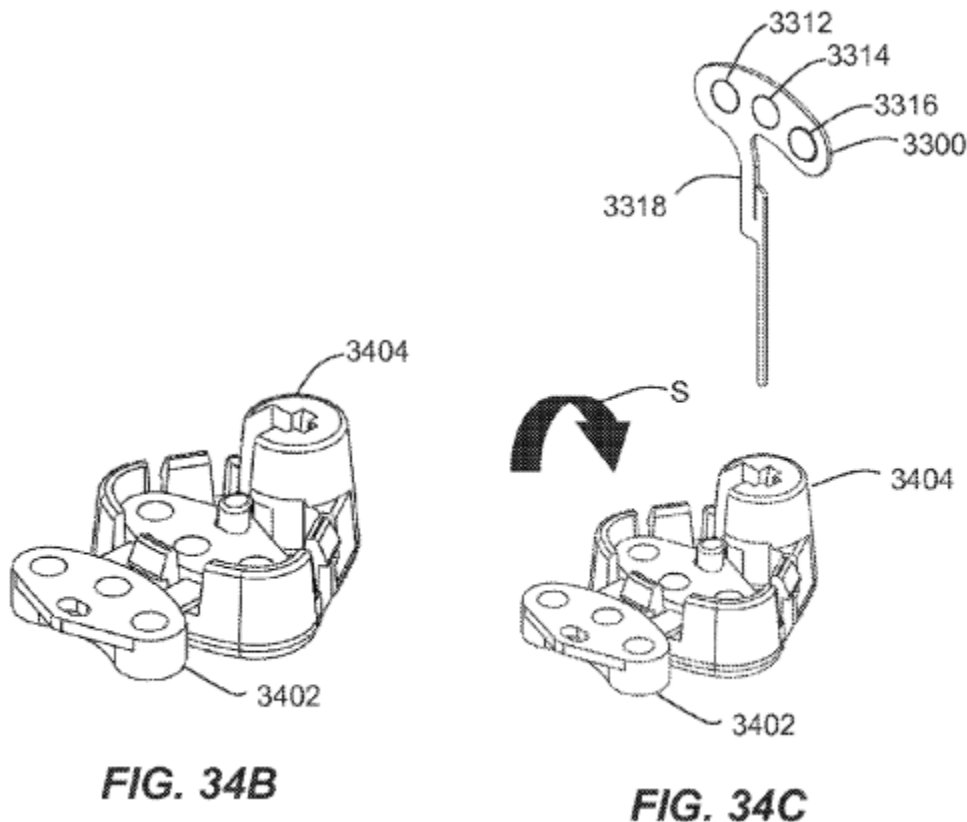
FIG. 47C

Ex-1006, Fig. 47C.



Petition, 21 (annotated version of Pace Fig. 47C). As shown in Figure 47C as actually presented in Pace, the figure is comprised of dotted lines, and the fit and

relative distances between components is ambiguous. Moreover, Figure 47C is a “cross-sectional view” (Ex-1006, [0064]) that only shows an on-body device in two dimensions. The Figure therefore does not fully depict the structures surrounding the relied-on V-shaped portion from which a POSITA could determine the relationship between the V-shaped portion and surrounding structures as an objective fact. The Petition does not explain how a POSITA viewing the ambiguous disclosures of Figure 47C would determine that it shows structures that necessarily prevent rotation. The Petition also relies on the depictions in Figures 34B and 34C of a cross-shaped opening in which the relied-on V-shaped portion is inserted. Petition, 41-42.



Ex-1006, Figs. 34B-34C. These figures are ambiguous as to how the relied-on V-shaped portion sits within the cross-shaped opening of connector support 3404 and, again, the Petition fails to explain why a POSITA viewing the figures would conclude that the depicted structures prevent rotation.

Third, as with embodiment A, the Petition does not provide adequate extrinsic evidence to establish that a POSITA would recognize anti-rotation functionality to be a necessary feature of the structures in embodiment B. The only evidence offered in support of the Petition's conclusion is the declaration of Petitioner's expert, which cites no additional evidence or argument and parrots the portions of the Petition concerning the alleged inherent disclosures of embodiment B nearly verbatim. *See* Ex-2009 at 8-9. As with embodiment A, such conclusory expert testimony is insufficient to support an inherency argument and should be rejected. Accordingly, the Petition's argument that the disclosed structures of Pace's embodiment B necessarily prevent rotation fails because it is unsupported by objective evidence to show that a POSITA would recognize such allegedly necessary functionality.

**b) Pace Does Not Render Obvious An Anti-Rotation
Key/Feature Configured To Prevent Rotation**

The Petition provides a fallback to its inherency theory, arguing in a single paragraph that “a POSITA would have considered it obvious for hub 2106 or the V-shaped portion in Figures 35A and 47C to provide an anti-rotation function.”

Petition, 42. However, as with the inherency theory, Petitioner's obviousness argument is legally deficient. As detailed below, the Petition fails to establish a *prima facie* case for obviousness, failing 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.

First, the Petition fails to identify any modification a POSITA would make to Pace to meet the language of the claim. Instead, the Petition concludes that “[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” (embodiment A) and “because the V-shaped portion in Figures 35A and 47C is directly coupled to the needle, it would have been obvious to restrain the rotation of the V-shaped portion of the needle hub relative to the on-skin sensor assembly and the sensor therein” (embodiment B). Petition, 42. But how would a POSITA restrain the rotation of hub 2106 or the V-shaped portion of the needle hub relative to the on-skin sensor assembly? The Petition does not explain. The Petition does not explain what properties of the disclosed structures of Pace a POSITA would consider relevant in attempting to prevent rotation, nor does the Petition explain what changes a POSITA would make to either embodiment A or B to prevent rotation. Petitioner's challenge is therefore legally insufficient to raise a *prima facie* case of obviousness. *See* 37 C.F.R. § 42.104(b) (requiring IPR petition to be

“precise” and “specify” challenge); *cf.* MPEP § 2142 (requiring rejection to specify “the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter”). Petitioner’s argument instead relies on textbook improper hindsight as it starts with the claimed function (preventing rotation) and argues that it would have been obvious to a POSITA to perform that function with no explanation for how a POSITA would do so. *See Man Wah Holdings, Ltd. v. Raffel Sys., LLC*, IPR2019-00616, Paper 7 at 21-23 (PTAB Aug. 21, 2019) (finding, where Petitioner failed to explain how a POSITA would implement a proposed modification, that “hindsight, not evidence, is the basis for Petitioner’s proposed assertion that the challenged claims would have been obvious”) (citing *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1367 (Fed. Cir. 2017)).

Second, the Petition provides only a single sentence to explain why a POSITA would purportedly be motivated to make the unexplained modification to Pace to prevent rotation between a needle hub and on-skin sensor assembly. Petition, 42 (“A POSITA 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.”) This explanation, however, is conclusory, speculative, and unsupported by objective evidence. The Petition cites no evidence showing that rotation of a needle relative to a sensor causing sensor damage was a problem or consideration to a POSITA. And the

Petition performs no analysis to show that a POSITA would find any such problem to be applicable to the specific configuration of components disclosed in Pace embodiments A and B. For example, Pace discloses relevant sensor components, including its sensor substrate and connector between sensor and circuit board, being constructed of flexible materials. Ex-1006, [0135] (“As can be seen in FIG. 33E, the electrodes 3304, 3306, 3308 are formed as layers on a substrate 3322. The substrate 3322 is made of a flexible, non-conductive dielectric material.”), [0140] (“As shown in FIG. 34A, a flexible one-piece seal or connector 3402 is molded in silicone or other practicable elastic material. ... The result is a generally malleable/flexible hybrid connection and sealing unit or connector 3402 incorporating a living hinge joining two (as-shown) symmetrical sections.”). The Petition gives no consideration to a POSITA’s understanding of the interconnected components of Pace and whether a POSITA would consider potential damage to electronics caused by needle rotation an issue given Pace’s use of flexible sensors and connectors.

While the Petition cites a supporting expert declaration, the declaration adds little as to a POSITA’s motivation to modify Pace. As shown in a redline comparison of the Petition and declaration, the corresponding portion of the declaration largely parrots the Petition, adding only that a “POSITA would have understood that glucose sensors for insertion into a user are small and fragile, and have delicate electrical circuitry that includes electrical leads and contacts.” Ex-1004, ¶65; Ex-2009, 9. But

as with the Petition, this statement is devoid of any objective evidence to support Dr. Riviere's conclusion that a POSITA would consider potential damage to electronics caused by needle rotation a problem to be solved,¹⁰ and, like the Petition, Dr. Riviere ignores any analysis of whether a POSITA would consider such a problem in the context of Pace's specific sensor embodiments. The Petition's conclusory motivation to combine, bolstered only by parroting and unsupported expert testimony, should be rejected. *See Qiagen Inc. v. Oxford Immunotec Ltd.*, IPR2016-01548, Paper 9 at 14 (PTAB Feb. 22, 2017) (finding insufficient arguments and evidence for motivation to combine where "the sole support for Petitioner's assertion" of purported advantages to the proposed combination was expert testimony that was "conclusory and [did] not present any supporting facts or data.")

¹⁰ Dr. Riviere's "Technology Background" section provides additional statements regarding purported damage to sensor devices caused by needle rotation, including that "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)." Ex-1004, ¶ 21. But as with Dr. Riviere's analysis for the proposed Grounds, these opinions cite no independent evidence and therefore do not "disclose the underlying facts or data on which the opinion is based." 37 C.F.R. § 42.65(a).

Third, the Petition and supporting declaration fail to address any reasonable expectation of modifying Pace to prevent rotation between a needle hub and on-skin sensor assembly. *See* Petition, 42; Ex-1004, ¶ 65. While the Petition alleges a reasonable expectation of success for Grounds 2 and 4, which are proposed combinations of prior art references, it does not do so for its single-reference obviousness theory for Ground 1. However, a reasonable expectation of success is required for a modification of a single prior art reference as well as for a combination of references. *In re Stepan Co.*, 868 F.3d 1342, 1346 n.1 (Fed. Cir. 2017) (“Whether a rejection is based on combining disclosures from multiple references, combining multiple embodiments from a single reference, or selecting from large lists of elements in a single reference, there must be a motivation to make the combination and a reasonable expectation that such a combination would be successful, otherwise a skilled artisan would not arrive at the claimed combination.”). A reasonable expectation of success is a necessary element for a *prima facie* showing of obviousness and it is Petitioner’s burden to make such showing by a preponderance of the evidence. 35 U.S.C. § 316(e); *see also Eli Lilly*, 8 F.4th at 1348 (“[I]t was, at all times, [Petitioner’s] burden to show that the claims would have been obvious, including that a skilled artisan would have had a reasonable expectation of success in achieving the claimed invention.”). Petitioner fails to address a necessary element of an obviousness inquiry, and its obviousness challenge should be denied for that

reason alone. *See NJOY*, IPR2024-00267, Paper 15 at 37-40 (denying obviousness challenge where Petition is silent as to a reasonable expectation of success).

In summary, the Petition's single-paragraph obviousness rationale fails to establish three key elements for a showing of obviousness: (1) an explanation of the proposed modification to the prior art; (2) a motivation for a POSITA to make such modification; and (3) a reasonable expectation of success by the POSITA in making such a modification. The Petition's Ground 1 obviousness challenge should therefore be denied.

2. Ground 2 (Pace And Lundquist)

The Petition's Ground 2 relies on the inserter of either of Pace's embodiments A or B in combination with Lundquist. The Petition relies on Lundquist only for allegedly disclosing subject matter relevant to certain dependent claims. Specifically, the Petition asserts that Lundquist "discloses a method of securing a hollow needle to a hub where a polymeric material used to form the hub during an insert molding step 'flows into and fills' a plurality of notches in the proximal end of the needle to provide 'enhanced friction and gripping force' between the hub and the needle," which the Petition relies on in challenging dependent claims 4-5, 14-15, 26-27, and 30. Petition, 71-76. As explained in section IV.C.1, *supra*, the Petition fails to demonstrate that the challenged independent claims of the '625 patent are unpatentable in view of Pace. Because Ground 2 introduces Lundquist for subject

matter relevant only to dependent claims, and not to fill Ground 1's failure to demonstrate Pace's disclosing or teaching of an anti-rotation feature/key configured to prevent claimed rotation, Ground 2 suffers from the same shortcomings as Ground 1 and should be denied for the same reasons as Ground 1. *See, e.g., U.S. Well Services, LLC v. Halliburton Energy Servs, Inc.*, IPR2022-01162, Paper 10 at 24-25 (PTAB Dec. 20, 2022) (rejecting ground challenging dependent claims where prior art references added to the proposed combination for the ground "d[id] not remedy the deficiency [the Board] identif[ied] with respect to" the independent claims).

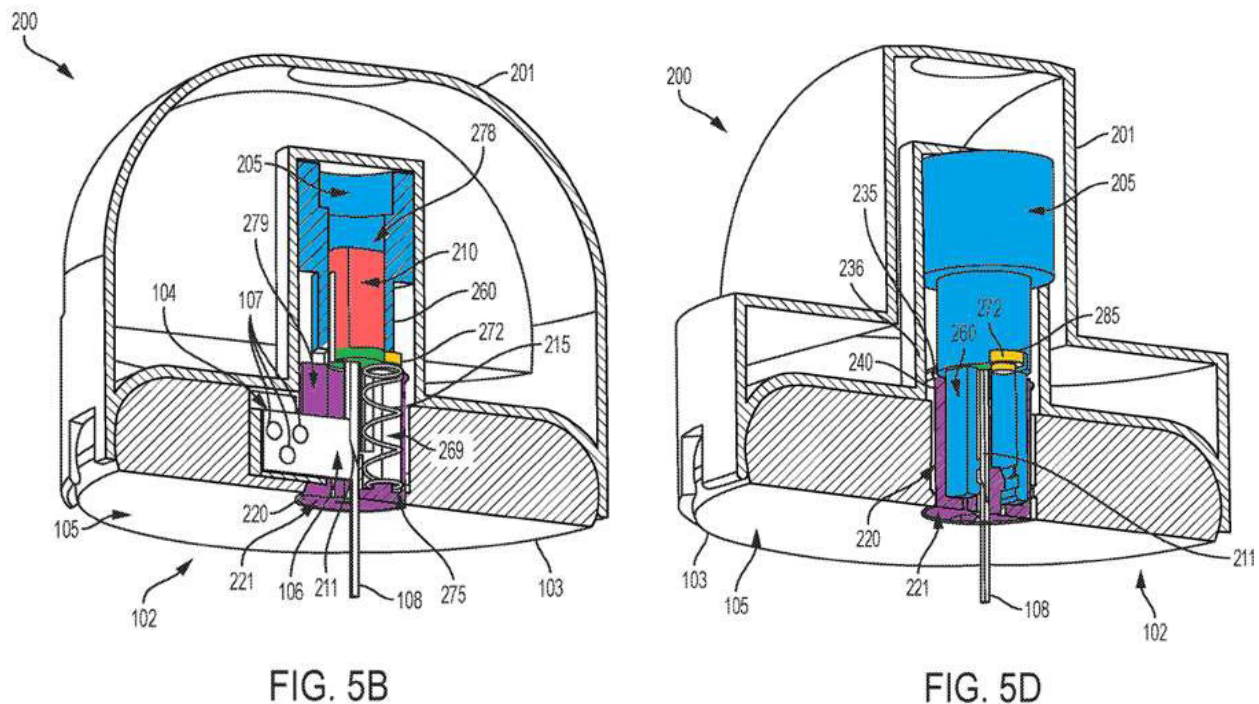
3. Ground 3 (Pace 2)

a) Pace 2 Does Not Inherently Disclose An Anti-Rotation Key/Feature Configured To Prevent Rotation

The Petition admits that Pace 2 does not explicitly disclose a structure providing anti-rotation functionality, and instead relies on inherency. Petition, 80 ("Although Pace 2 does not specifically state that ledge 272 has an 'anti-rotation' functionality, such functionality necessarily results from Pace 2's arrangement."). As with Ground 1, the Petition does not meet the high bar for establishing inherency, failing to show that a POSITA would recognize any structures of Pace 2 to necessarily perform anti-rotation functionality.

The Petition argues that the claimed "needle hub" corresponds to Pace 2's sharp support 205 with a sharp body 210. Petition, 77-78. The Petition further

contends that a lower portion of sharp body 210 corresponds to the claimed “base” and that a ledge 262 corresponds to the claimed anti-rotation feature/anti-rotation key. Petition 78, 86, 91. Finally, the Petition asserts that the claimed “aperture” corresponds to Pace 2’s chamber 269. *Id.* These components are shown in annotated Figures 5B and 5D, reproduced below as annotated in the Petition.



Ex-1007, Figs. 5B, 5D (annotations in Petition). With regard to Pace 2’s alleged anti-rotation functionality, the Petition argues that “[b]ecause the ledge 272 projects outwardly from the sharp body 210, offset from the sharp 211, the walls of the chamber 269 necessarily prevent the ledge 272, and thus the sharp body 210 and sharp support 205, from rotating relative to the shroud, and thus the remainder of the sensor control device.” Petition 80-81, *see also* Petition 85 (“[T]he ledge 272 of the

sharp body 210 (i.e., the anti-rotation feature comprising a key) prevents rotation of the needle hub (and the needle coupled to it) relative to the on-body device ... by being inserted within the chamber 269 in the on-body device (i.e., the aperture).”). As explained below, and for the same reasons as discussed for Ground 1 (*supra* IV.C.1), this argument is insufficient to meet Petitioner’s high burden of establishing inherency (i.e., that the structures identified in the prior art necessarily prevent rotation as claimed).

First, as with its Ground 1 challenge, the Petition’s conclusion that the structures disclosed by Pace 2 necessarily prevent rotation is based on speculation regarding properties on which Pace’s figures and written description are silent. The Petition relies on Pace 2’s disclosure that ledge 272 fits and slides within chamber 269. Petition 78-81. However, neither Pace 2 nor the Petition address the relative dimensions and distances between components (such as the spacing between ledge 272 and the walls of chamber 269) that would control whether there is a tight fit between ledge 272 within chamber 269. The Petition also does not address materials used to construct the components of Pace 2. For example, if the ledge 272 were constructed of a flexible or compressible material, the walls of chamber 269 would not necessarily prevent its lateral or rotational movement within the chamber. Therefore, the Petition fails to address multiple factors a POSITA would consider in determining whether the structures depicted in Pace 2 necessarily prevent rotation

of the alleged needle hub relative to a sensor assembly and, therefore, the Petition does not meet its burden for establishing inherency.

Second, the Petition's conclusion that rotation is necessarily prevented in Pace 2 is based on ambiguous figures and disclosures that do not support such a conclusion. For example, while Pace 2 states that ledge 272 "is sized to fit and slide longitudinally within chamber 269," (Ex-1007, [0068]) there is no disclosure in Pace 2 that ledge 272 fits within chamber 269 in such a way as to prevent lateral or rotational movement of ledge 272 or sharp body 210 attached to the ledge. Moreover, Pace 2's figures suggest that there is *not* a tight fit between the alleged anti-rotation feature/key (ledge 272) and the alleged aperture (chamber 269). Figure 4B, for example, is a cross-sectional drawing of the inserter of Pace 2 with shroud 220 retracted and spring biasing element 215 compressed. Ex-1007, [0071], [0078], Fig. 4B. In this position ledge 272 sits above compressed spring biasing element 215 and within the surrounding chamber. *Id.*, Fig. 4B. As shown in Fig. 4B, annotated and expanded below, there is a gap between the edge of ledge 272 (annotated in red) and the inner walls (annotated in green) of the surrounding shroud chamber.

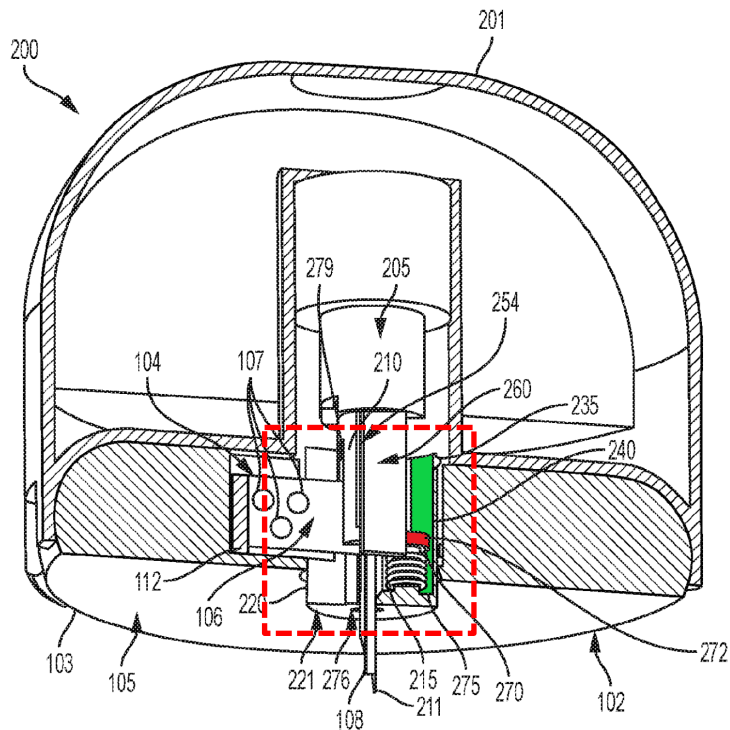
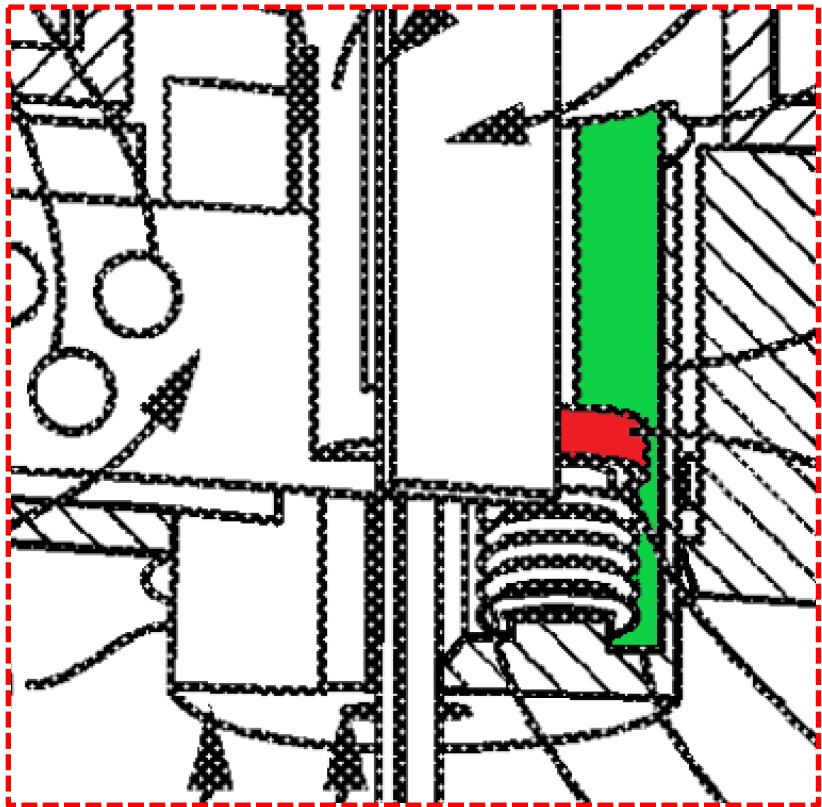


FIG. 4B



Id., Fig. 4B (annotated and excerpted). The figures of Pace 2 therefore show space between ledge 272 and the surrounding inner walls of shroud 220. The ledge 272 is connected to the shroud through spring biasing element 215, which extends between projection 282 on ledge 272 and projection 274 on shroud 220. *Id.*, [0087]-[0088]. Neither Pace 2 nor the Petition suggest that spring biasing element 215 would inhibit lateral or rotational movement of the ledge and connected sharp body, and a flexible spring would not do so. Accordingly, the figures of Pace 2 do not support the Petition's speculation that the ledge being sized to fit within the shroud's inner chamber necessarily prevents the ledge 272 and sharp body 210 from rotating relative to the shroud.

The Petition also relies on disclosures from paragraph [0089] of Pace 2 which describe the use of “elongate grooves, spaces, or channels ... in which a projection or extension can slide” to “assist in guiding advancement and/or retraction of shroud 220.” Petition, 80 (quoting Ex-1007, [0089]). Pace 2 discloses one exemplary arrangement of such grooves, spaces or channels in shroud 220 receiving projections or extensions “**on the interior of housing 201**” thereby preventing rotation of shroud 220. Ex-1007, [0089] (emphasis added). The Petition, however, argues that ledge 272 constitutes “one such extension” discussed by Pace in paragraph [0089] and that, therefore, the walls of the chamber 269 necessarily prevent the ledge 272 ... from rotating relative to the shroud.” Petition, 80-81. This misrepresents the

specification of Pace 2. Pace 2 nowhere discloses or suggests that ledge 272 is contemplated as one of the “projections or extension[s]” addressed in paragraph [0089]. To the contrary, where paragraph [0089] discusses such projections or extensions “preventing shroud 220 from rotating,” it’s the result of “a projection or extension **on the interior of housing 201**” received in a groove, space, or channel of shroud 220. Ex-1007, [0089] (emphasis added).¹¹ As shown in Pace 2’s Fig. 5D (reproduced and annotated below), which depicts the inserter in its fully retracted state (Ex-1007, [0075]), housing 201 (highlighted in yellow) is an entirely separate structure from ledge 272 (highlighted in red) and shroud 220 (highlighted in green).

¹¹ The Petition’s block quotation of paragraph [0089] omits the final sentence of the paragraph: “Alternatively, the projection or extension can be present on shroud 220 and can be received in a groove, space, or channel in housing 201 with similar effect.” Ex-1007, [0089]. This sentence further shows that Pace 2 contemplates using projections or extensions to prevent rotation between shroud 220 and housing 201, and not between ledge 272 and shroud 220.

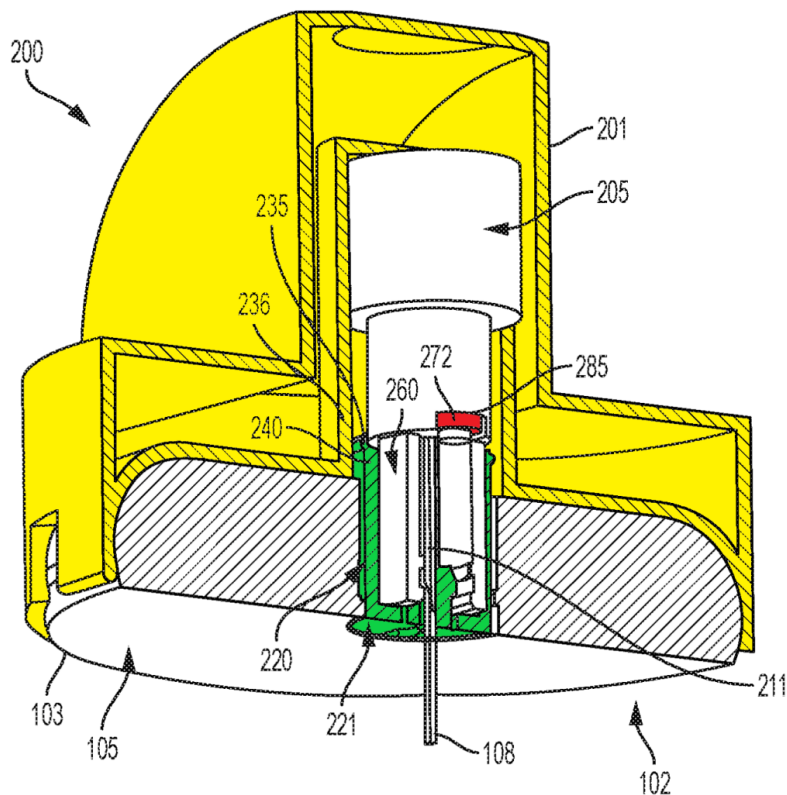


FIG. 5D

Id., Fig. 5D (annotated). Further, if ledge 272 necessarily prevents rotation of shroud 220 as the Petition argues, then there would be no reason to include projections on the interior of housing 201 as described in paragraph [0089] to perform that same function. Thus, paragraph [0089] of Pace 2 does not support that anti-rotation is a necessary functionality created by ledge 272.

Third, as with Ground 1, the Petition does not provide adequate extrinsic evidence to establish that a POSITA would recognize anti-rotation functionality to be a necessary feature of the structures in Pace 2. The only evidence offered in support of the Petition's conclusion is the declaration of Petitioner's expert, which

cites no additional evidence or argument and parrots the portions of the Petition concerning the alleged inherent disclosures of Pace 2 nearly verbatim. See Ex-2009 at 46-47. As with the Petition's arguments for Ground 1, such conclusory expert testimony is insufficient to support an inherency argument and should be rejected. Accordingly, the Petition's argument that the disclosed structures of Pace 2 necessarily prevent rotation fails because it is unsupported by objective evidence to show that a POSITA would recognize such functionality as necessarily present.

b) Pace 2 Does Not Render Obvious An Anti-Rotation Key/Feature Configured To Prevent Rotation

The Petition provides a fallback to its inherency theory by arguing “[t]o the extent Pace 2 does not expressly describe the anti-rotation function of ledge 272 and the chamber 269, a POSITA would have considered it obvious that the combination would provide an anti-rotation function.” Petition, 81. That is the full extent of the Petition's obviousness argument as to Ground 3 and is deficient on its face. The Petition does not propose how a POSITA would modify the structures of Pace 2 to provide anti-rotation functionality, does not explain why a POSITA would be motivated to make any such modification, and does not explain why a POSITA would have a reasonable expectation of success in doing so. Therefore, and for the same reasons as explained for Ground 1, the Petition fails to provide essential

elements for a showing of obviousness and the Petitions bare assertion of obviousness as to Ground 2 should be rejected.

4. Ground 4 (Pace 2 And Lundquist)

The Petition's Ground 4 relies on the combination of the inserter of Pace 2 with Lundquist. As with Ground 2, Ground 4 of the Petition adds Lundquist only for subject matter relevant to certain dependent claims, specifically Lundquist's alleged disclosures regarding insert molding. Petition, 100-102. Because Ground 4 introduces Lundquist for subject matter relevant only to dependent claims, and not to fill Ground 3's failure to demonstrate Pace 2 as disclosing or teaching an anti-rotation feature/key configured to prevent rotation, Ground 4 suffers from the same shortcomings as Ground 3 and should be denied for the same reasons as Ground 3.

5. Ground 5 (Chae)

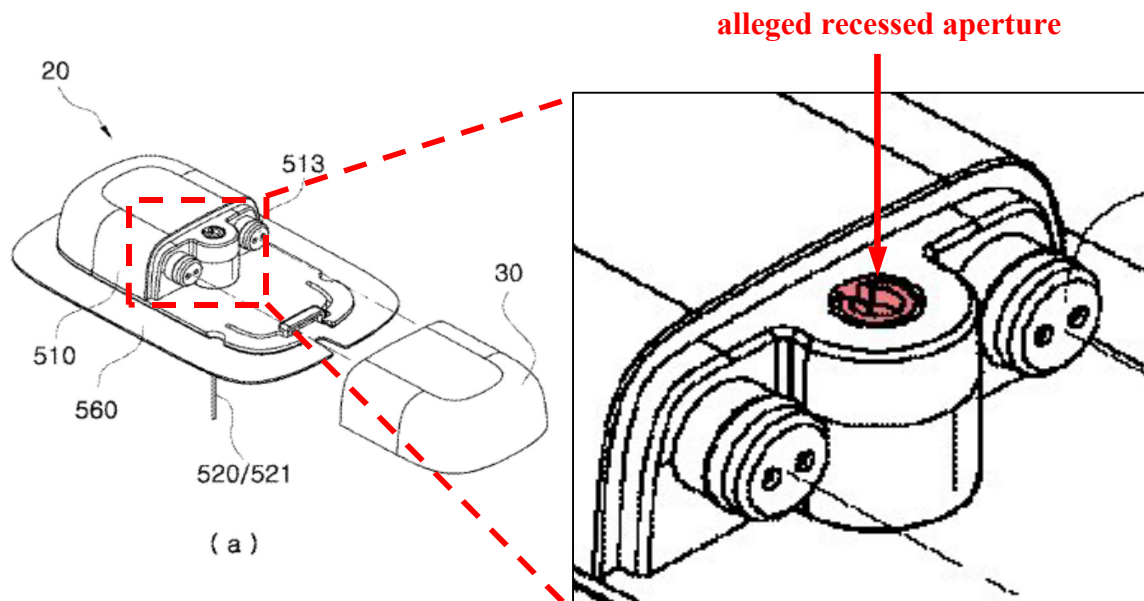
a) Chae Does Not Explicitly Or Inherently Disclose An Anti-Rotation Key/ Feature Configured To Prevent Rotation

To the extent portions of Chae are prior art, they provide no explicit disclosure that its structures prevent rotation between a needle hub/base and an aperture/sensor assembly as claimed, and the Petition identifies no such disclosure. Instead, the Petition relies on speculation and inferences from various drawings of Chae that certain depicted structures would allegedly prevent rotation. And as discussed further below, the relied-on drawings are ambiguous and do not clearly show anti-

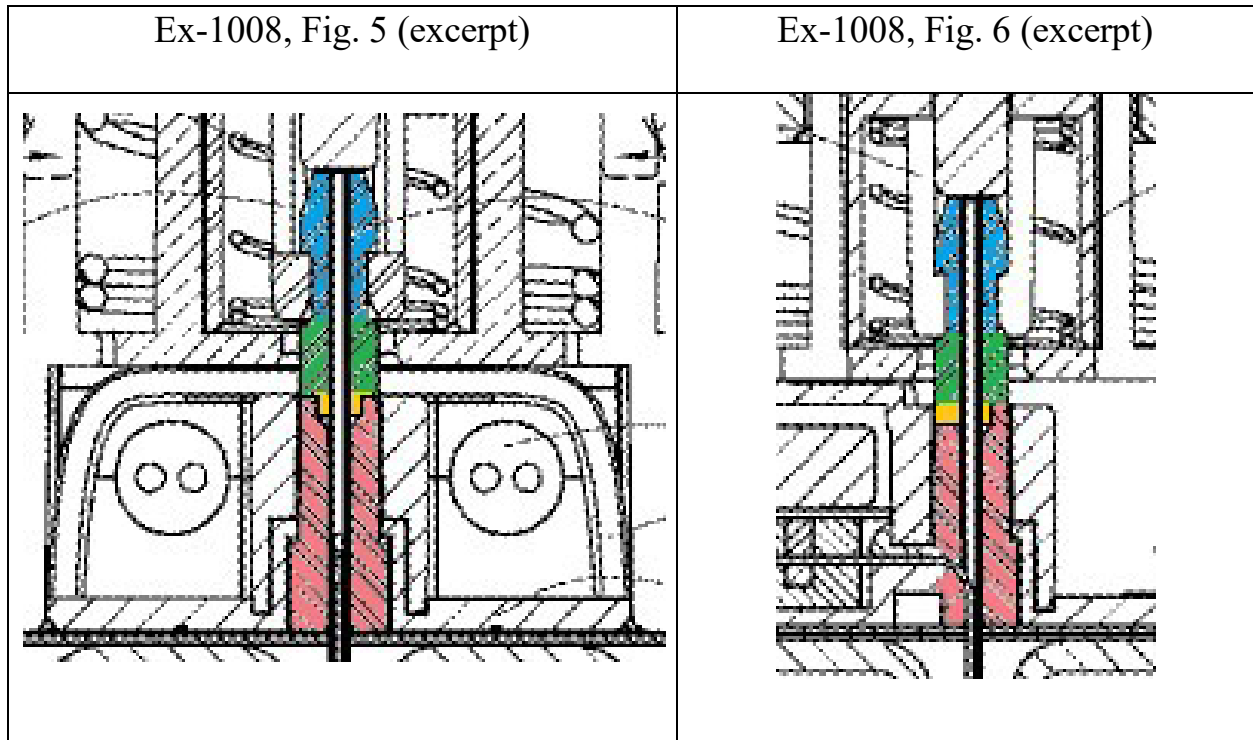
rotation functionality such that they could provide an explicit disclosure thereof. *See PlaSmart, Inc. v. Kappos*, 482 F. App'x 568, 572–73 (Fed. Cir. 2012) (“Our precedent has held that drawings can be used as prior art, without referring to the surrounding description, only if the prior art features are clearly disclosed by the drawing.”). Thus, the basis for Ground 5’s arguments that Chae discloses an anti-rotation feature/key configured to prevent rotation as claimed appears to be the same as for Grounds 1 and 3 – that anti-rotation is an inherent feature provided by the structures depicted in the drawings – and, like those prior grounds, Ground 5 should be considered as relying on inherent disclosure in the prior art.

The Petition asserts that Chae includes an alleged aperture including a recess in its sensor module 20. Petition, 111-13. The alleged recessed aperture is shown in annotated Fig. 3, below.

FIG. 3



Ex-1008, Fig. 3 (excerpt left); Ex-1009, Fig. 3 (enlarged and annotated). The Petition further asserts that the claimed needle hub corresponds to Chae's disclosed needle head 551 and that the base of the needle hub corresponds to a lower portion of needle head 551. Petition, 111-13. The Petition relies on two cross-sectional drawings, Figures 5 and 6, as allegedly showing that needle head 551 includes a protrusion to which the alleged aperture is complementary and within which the alleged protrusion is disposed. Petition 109, 113-14. The Petition excerpts and annotates these two cross-sectional drawings as shown below.

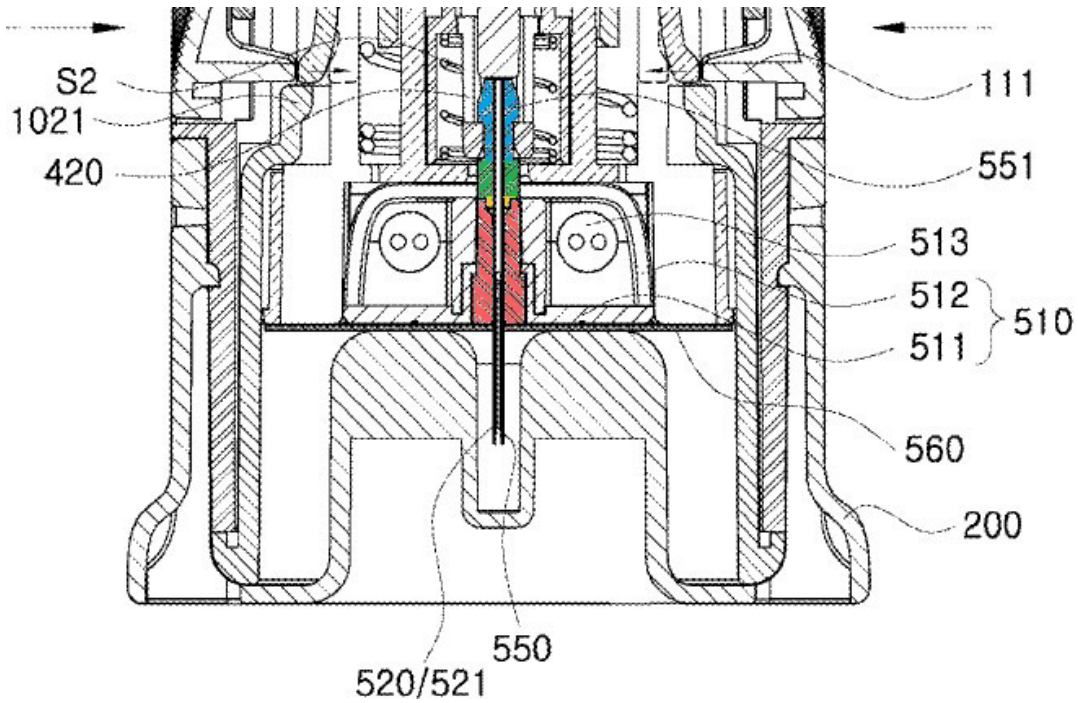


Petition, 109; *see also* Petition, 113. The Petition argues that the protrusion engages the side and back walls of the recess, thereby preventing rotation. Petition, 109, 114. As explained below, and for the same reasons as discussed for Ground 1 (*supra* IV.C.1), this argument is insufficient to meet Petitioner’s high burden of establishing inherency (i.e., that the structures identified in the prior art necessarily prevent rotation as claimed).

First, as with its Ground 1 challenge, the Petition’s conclusion that the structures disclosed by Chae necessarily prevent rotation is based on speculation regarding properties on which Chae’s figures and written description are silent. For example, neither Chae nor the Petition address the relative dimensions and distances between components (such as the spacing between the alleged protrusion of Chae’s

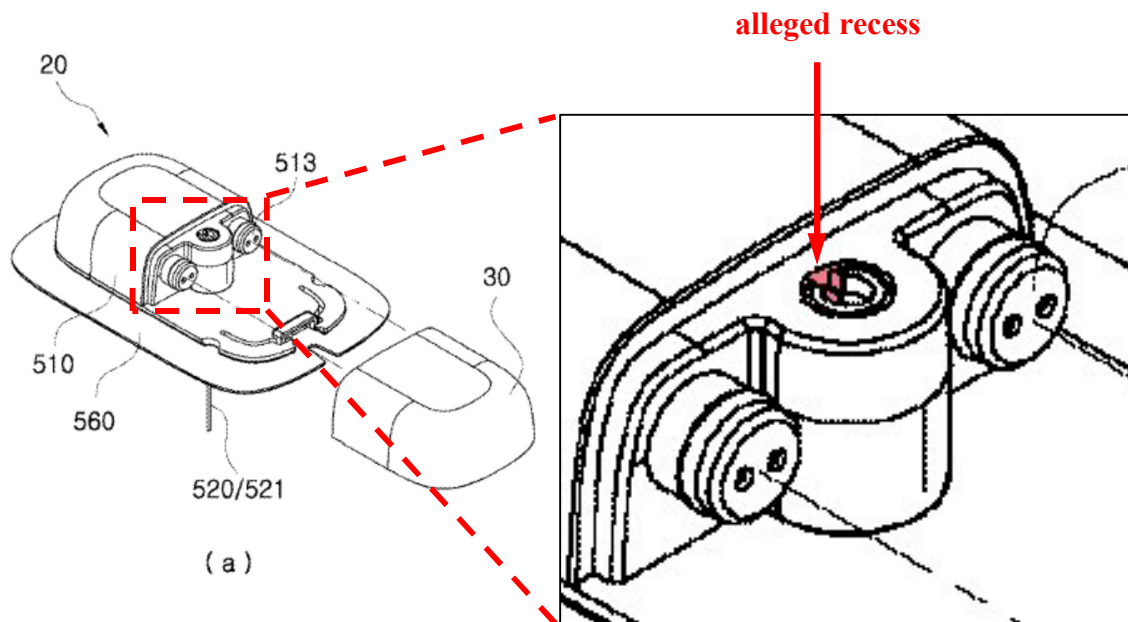
needle head 551 and the alleged aperture recess) that would control whether the recess interacts with the alleged protrusion so as to prevent rotation. The Petition also does not address materials used to construct the components of Chae. For example, if the alleged protrusion on Chae's needle head 551 were constructed of a flexible or compressible material, the walls of the alleged aperture recess would not necessarily prevent its lateral or rotational movement within the chamber due to deformation of the alleged protrusion. Therefore, the Petition fails to address multiple factors a POSITA would consider in determining whether the structures depicted in Chae necessarily prevent rotation of the alleged needle hub relative to a sensor assembly and, therefore, the Petition does not meet its burden for establishing inherency.

Second, the relied-on drawings of Chae are ambiguous and do not support the Petition's conclusion that they prevent rotation of needle head 551 relative to Chae's sensor module. Turning first to Chae's Figure 5 (excerpted below), this cross-section depicted in this drawing appears to laterally bisect the center of the alleged aperture, because it depicts sensor 520 and needle 550, which run through the alleged aperture's center.



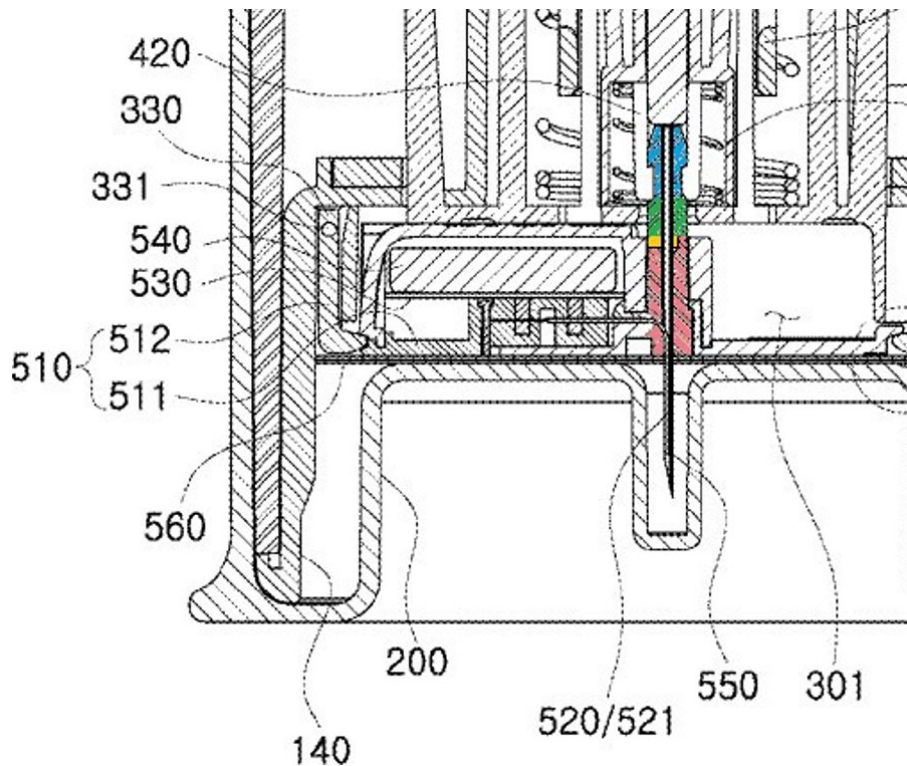
Ex-1008, Fig. 5 (annotated and excerpted). The alleged aperture recess (highlighted in red in the figure below), however, is offset from the lateral centerline of the aperture (i.e., it is offset toward pod 510) and the opening created by the recess does not extend to the lateral centerline.

FIG. 3



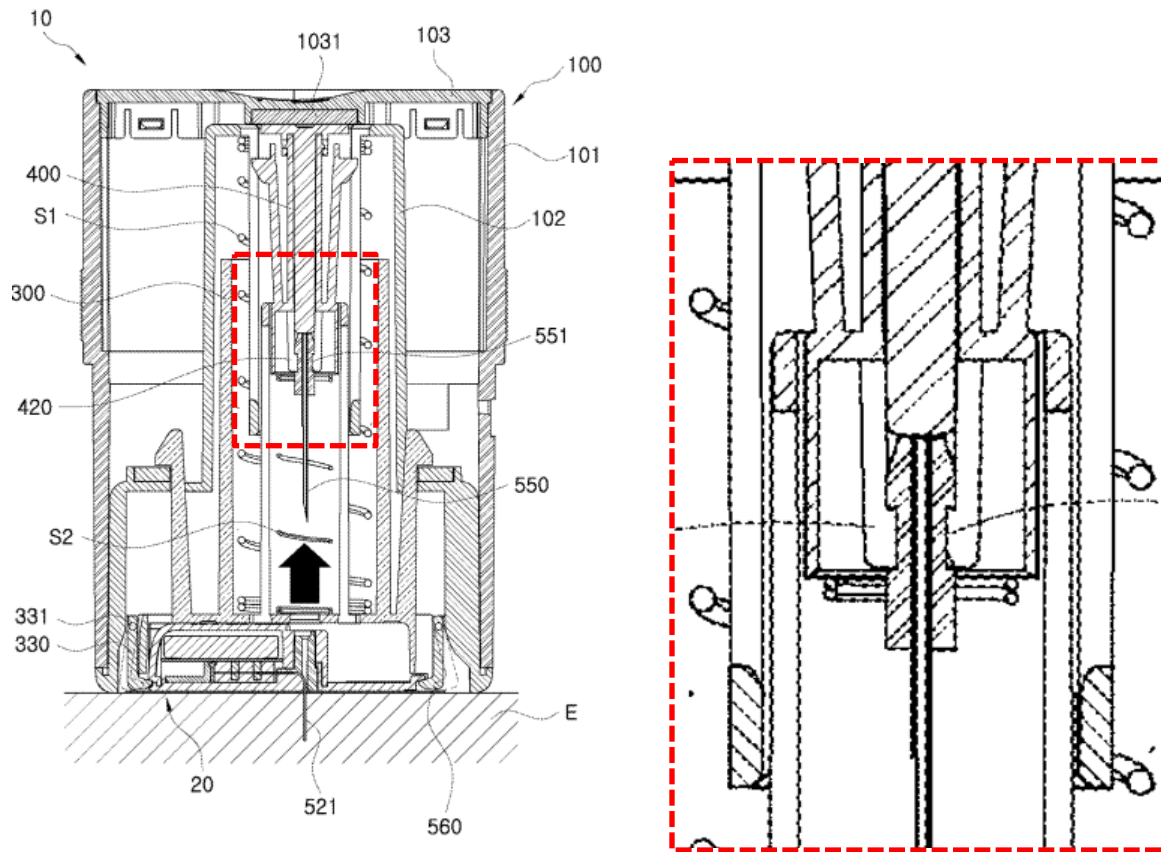
Ex-1008, Fig. 3 (excerpt left); Ex-1009 at Fig. 3 (enlarged demonstrative). Therefore, Chae's Figure 5 shows neither the alleged aperture recess nor any protrusion of needle head 551 that would fit into such recess, and the figure does not support the Petition's argument.

In addition to Figure 5, the Petition also relies on Chae's Figure 6 as allegedly disclosing its alleged protrusion because "the needle hub's base is asymmetrical" and thereby "prevents the needle head/hub from rotating about its vertical axis." Petition, 109. Figure 6 of Chae, excerpted below, is a cross-sectional drawing that appears to bisect the alleged aperture of sensor module 20 longitudinally (as opposed to Figure 5's lateral cross-section).



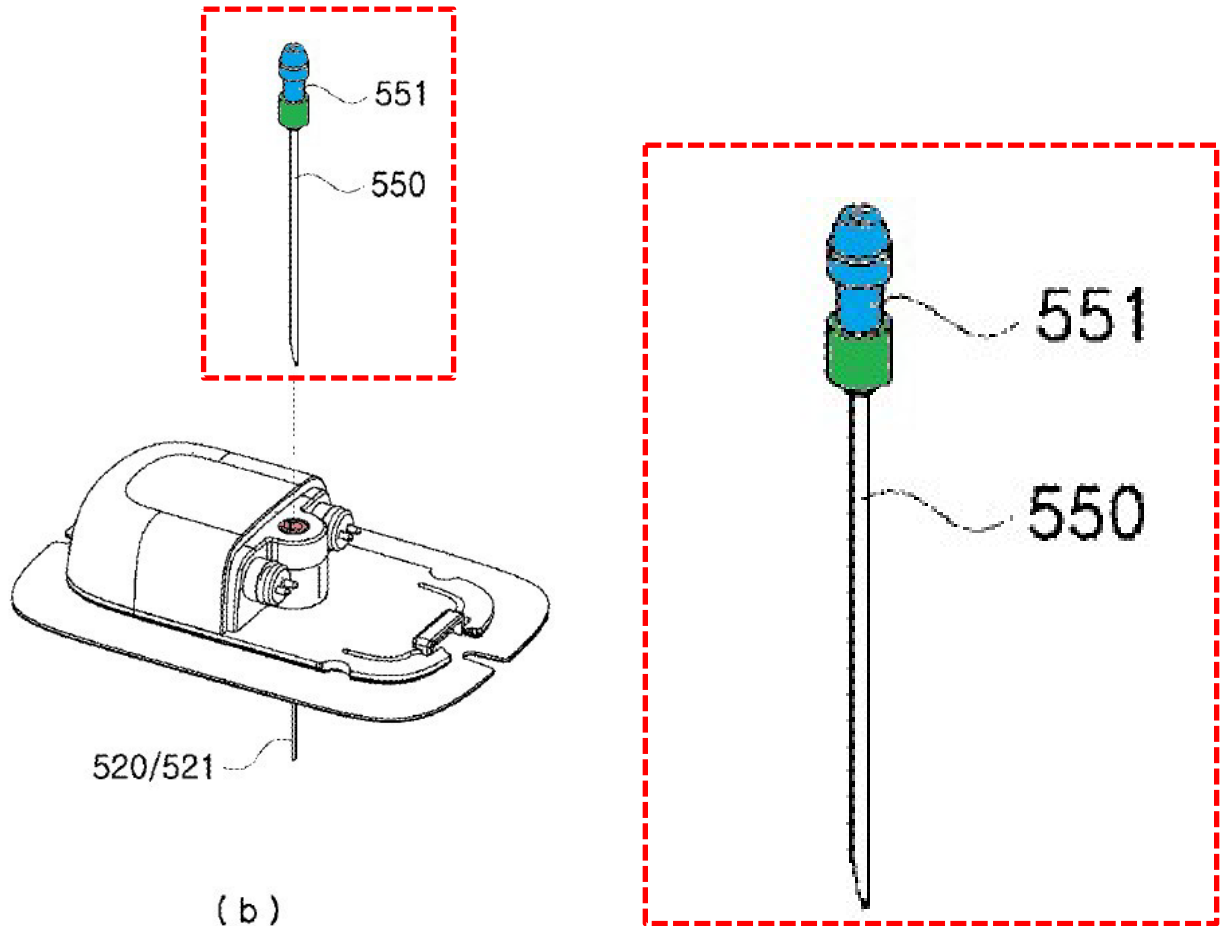
Ex-1008, Fig. 6 (annotated and excerpted). However, Figure 6 would not clearly disclose to a POSITA a protrusion at the base of needle head 551 because other disclosures of Chae contradict Figure 6. For example, Chae's Figure 23, reproduced below, shows a cross-sectional view of Chae's inserter along the same cross-section as Figure 6. This figure shows the needle head 551 to have a flat, symmetrical base.

FIG. 23



Id., Fig. 23. *See also id.*, Fig. 24 (showing same); Ex-1009, Figs. 9, 10 (showing same symmetrical needle hub configuration in priority application). Neither Petitioner nor Petitioner's expert addresses this contradiction in Chae's figures nor offers any explanation of how a POSITA would interpret Chae's contradictory figures. Accordingly, a POSITA would not rely on Chae's contradictory drawings showing the same cross-sectional view of the needle head as clearly disclosing a protrusion on that needle head, and the Petition has not shown otherwise.

Even if, *arguendo*, a POSITA were to consider Figure 6 as disclosing a protrusion at the base of needle head 551, that is not sufficient for a POSITA to also conclude that such a structure prevents rotation of the needle head. Figure 6 shows only a single two-dimensional slice of the alleged protrusion. There is simply no disclosure in Chae about the width of this alleged protrusion or how it relates to the width of the aperture's recess or fits within the recess. Notably, the only prior art drawing relied on by Petitioner showing the needle head 551 in a three-dimensional perspective (Figure 2, excerpt reproduced below) does not depict such a protrusion or give any indication as to the shape or dimensions of a protrusion or how it fits in to or relates to the alleged aperture recess.



Ex-1008, Fig. 2 (excerpted and annotated). Accordingly, the figures of Chae are silent about whether the alleged protrusion on needle head 551 fits into the aperture recess in such a way as to prevent rotational movement of the needle head and there is therefore no disclosure in Chae to support the Petition's conclusion that the depicted structures prevent such rotation.

Third, as with Ground 1, the Petition does not provide adequate extrinsic evidence to establish that a POSITA would recognize anti-rotation functionality to be a necessary feature of the structures in Chae. The only evidence offered in support of the Petition's conclusion is the declaration of Petitioner's expert, which cites no

additional evidence or argument and parrots the portions of the Petition concerning the alleged disclosures of Chae nearly verbatim. See Ex-2009 at 75-84. As with the Petition's arguments for Ground 1, such conclusory expert testimony is insufficient to support an inherency argument and should be rejected. Accordingly, the Petition's argument that the disclosed structures of Chae necessarily prevent rotation fails because it is unsupported by objective evidence to show that a POSITA would recognize such functionality as necessarily present.

**b) Chae Does Not Render Obvious An Anti-Rotation
Key/Feature Configured To Prevent Rotation**

While the Petition styles Ground 5 as an obviousness challenge, it fails to explain any subject matter that would be obvious to a POSITA beyond the express disclosures of Chae. Unlike for Grounds 1 and 3, the Petition for Ground 5 does not even make a conclusory argument that anti-rotation functionality would be obvious. Therefore, to the extent the Petition relies on obviousness for Ground 5, such argument should be rejected.

V. CONCLUSION

None of the Petition's asserted prior art references mentions the needle-rotation problem or purports to solve it. The Petition instead resorts to hindsight: starting from the claimed invention, it argues that drawings in the references can be viewed, *post hoc*, as having the claimed features unbeknownst, apparently, to the

prior art authors. It mostly ignores the POSITA's understanding and perspective and instead relies on the *ipse dixit* parroting of an expert, all contrary to well-settled law. For these and the other reasons explained, the Petition has failed to meet its initial burden as to any challenged claim, and the Board should deny institution.

Respectfully submitted,

Dated: August 23, 2024

By: /Andrew M. Mason/

Andrew M. Mason, Reg. No. 64,034
andrew.mason@klarquist.com
KLARQUIST SPARKMAN, LLP
One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, Oregon 97204
Tel: 503-595-5300
Fax: 503-595-5301

Counsel for Patent Owner

**CERTIFICATE OF COMPLIANCE WITH
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This brief complies with the type-volume limitation of 37 C.F.R. § 42.24
(a)(1)(i).

The brief contains 13,848 words, excluding the parts of the brief exempted by
37 C.F.R. § 42.24(a).

The brief has been prepared in a proportionally spaced typeface using
Microsoft Word 2013 in a 14-point Times New Roman font.

Dated: August 23, 2024

By: /Andrew M. Mason/

Andrew M. Mason, Reg. No. 64,034
andrew.mason@klarquist.com
KLARQUIST SPARKMAN, LLP
One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, Oregon 97204
Tel: 503-595-5300
Fax: 503-595-5301

Counsel for Patent Owner

CERTIFICATE OF SERVICE

The undersigned certifies that on August 23, 2024, a complete copy of
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Scott C. Weidenfeller
David A. Garr
Covington & Burling LLP
One City Center
850 Tenth Street NW
Washington, DC 20001
Email: sweidenfeller@cov.com
dgarr@cov.com
Abbott-IPR@cov.com

Peter P. Chen
Covington & Burling LLP
3000 El Camino Real
5 Palo Alto Square, 10th Floor
Palo Alto, CA 94306
Email: pchen@cov.com
Abbott-IPR@cov.com

By: /Andrew M. Mason/
Andrew M. Mason, Reg. No. 64,034
andrew.mason@klarquist.com
KLARQUIST SPARKMAN, LLP
One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, Oregon 97204
Tel: 503-595-5300
Fax: 503-595-5301

Counsel for Patent Owner