

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT DIABETES CARE INC.,
Petitioner,

v.

DEXCOM, INC.,
Patent Owner.

IPR2024-00860
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
2102	Disclaimer In A Patent Under 37 CFR 1.321(a) as to Claims 22-27
2103	Compare of Petition to Declaration (Overview of Prior Art)
2104	Compare of Petition to Declaration (Asserted Grounds of Unpatentability)
2105	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

Neither 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. 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-2102, 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.”); *see also Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996) (“A statutory disclaimer under 35 U.S.C. § 253 has the effect of canceling the claims from the patent and the patent is viewed as though the disclaimed claims had never existed in the patent.”).

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 a user 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.

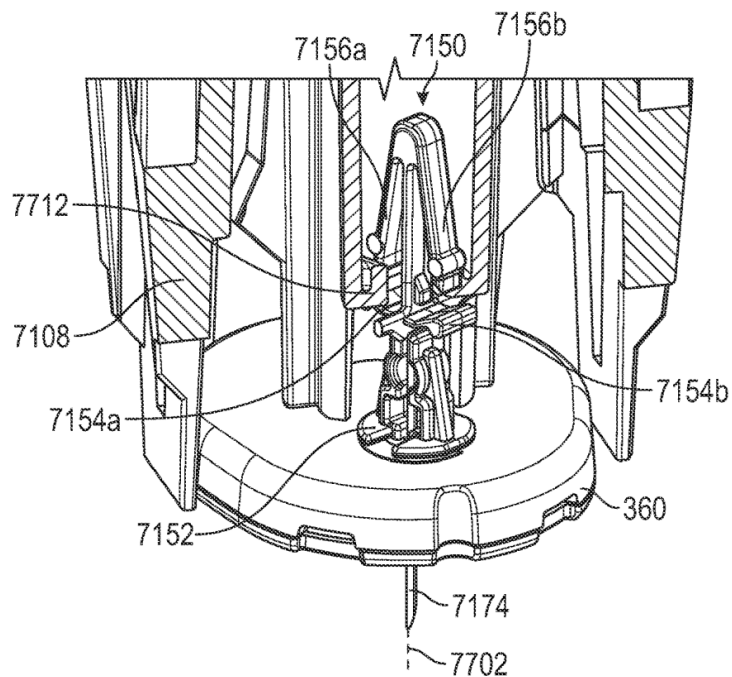


FIG. 77

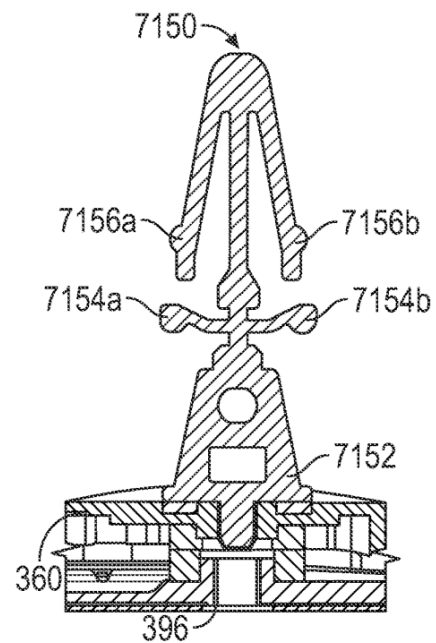


FIG. 78

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:

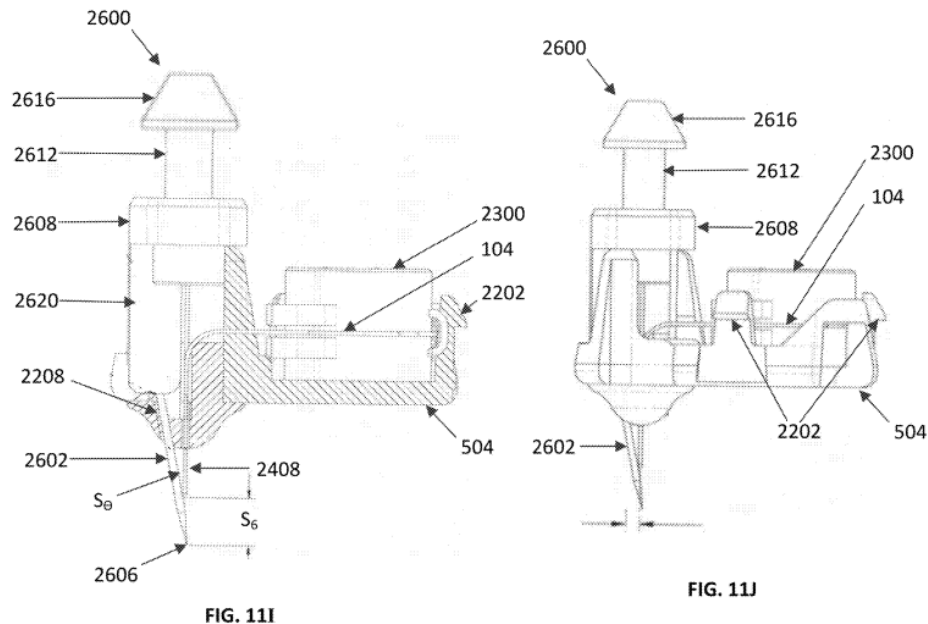
The anti-rotation feature may comprise a key having a shape complementary to at least a portion of sensor assembly aperture 396 of on-skin sensor assembly 360 and may be configured to substantially prevent needle hub 7150 from rotating about an axis 7702 parallel to insertion element 7174 with respect 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. Rao

Rao discloses an analyte sensor insertion system, including components depicted in Figures 11I and 11J, reproduced below.



Ex-1012, Figs. 11I-11J. The depicted components include a sharp module 2600 including sharp 2602, hub push cylinder 2608, hub small cylinder 2612, hub snap pawl 2616. *Id.*, [0143]-[0144]. Rao further discloses that the sharp module can include a bend fin guide 2620 “for maintaining ‘pre-bent’ sharp 2602 in position during assembly and/or use, and can prevent lateral or rotational movement of sharp 2602 relative to hub components.” *Id.*, [0143]. Rao identifies “hub components” as the hub snap pawl, hub small cylinder, and hub push cylinder. *Id.*, [0139]. The sharp module is assembled with a sensor module 504, with the sensor module including a

sensor 104 having a sensor tail 2408 and a sensor connector 2300 housing a proximal portion of the sensor. *Id.*, [0144]-[0145].

2. 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.

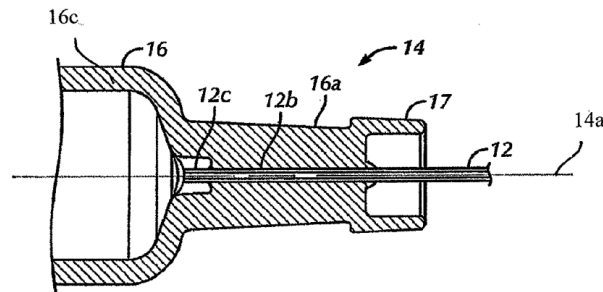


FIG. 1F

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 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 III.A and III.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 III.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. “[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 and accompanying expert declaration substantially disregard the POSITA when arguing any *express disclosure* in the relied-on

references. The Petition at pages 17 to 22 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,” “on-skin sensor assembly,” 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. 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 42 through 48 of the declaration, there is not a single mention of a POSITA and no explanation how a POSITA would have understood the references. *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). The Petition’s substantial disregard of the POSITA infects 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.”)

Second, the Petition disregards the POSITA to the extent it relies on inherent (necessary) disclosure. The Petition relies on allegedly inherent prior art disclosures at various points, including asserting that some feature “necessarily” is present in an asserted prior art reference (Petition, 47, 54, 60), which is the test for inherent disclosure. For two of those “necessarily” assertions, the Petition fails to assert (or show) that a POSITA would have recognized that the feature necessarily was present. *Id.*, 47, 60. 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 54, does the Petition make that legally required assertion, and the only extrinsic evidence it cites for that proposition is an *ipse dixit* assertion of its expert (Ex-1004, ¶¶ 100-101). 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 *Cont’l Can*).

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, 15), which Abbott's expert declaration parrots verbatim (Ex-1004, ¶ 39). 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 asserts that “In such [sensor] 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. Similarly, he states: “because bend fin guide 2620 is a vertical fin that restrains rotational movement, a

POSITA would understand that it must engage with a slot.” Ex-1004, ¶ 62. But again, he cites no objective evidence to support 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 (¶¶ 42-48) is nearly verbatim the same as the corresponding Section VII of the Petition. *See* Ex-2103.¹ Likewise the Declaration’s substantive argument Section VIII (“The Asserted Grounds of Unpatentability”, ¶¶ 49-129) is nearly verbatim the same as the corresponding Petition section. *See* Ex-2104.

¹ Submitted herewith as Exhibit 2105 is a declaration explaining how redline comparison Exhibits 2103 and 2104 were prepared.

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

Neither of the asserted prior art references 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 III.C, neither of the asserted prior art references would have been so viewed by a skilled artisan *ex ante* without hindsight. The Petition 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 asserts obviousness as the sole basis for its two grounds. Petition,

4. 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 challenged claims in Ground 1. The Petition does not even mention the words “reasonable” or “success” in Ground 1. For example, the Petition argues “a POSITA would have been motivated to utilize the needle of Figure 11A as the insertion element when inserting a sensor with a tail in order to protect the sensor tail” (Petition 51) without addressing reasonable expectation of success.

Its only brief mentions of reasonable expectation of success appear only in relation to the seven dependent claims it challenges in Ground 2. Petition, 62. Even if Ground 2’s brief mention of reasonable expectation of success vis-à-vis some dependent claim elements were sufficient for those elements (which it is not), that would not cure, for any challenged claim, the petition’s failure to address this essential element for any element of the claims not challenged in Ground 2, from which these dependent claims depend.

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 for Ground 1, 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 Corporation*, 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 in presenting an obviousness challenge is another reason to deny institution.

**C. **Grounds 1 & 2 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).² 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,”
- 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.³

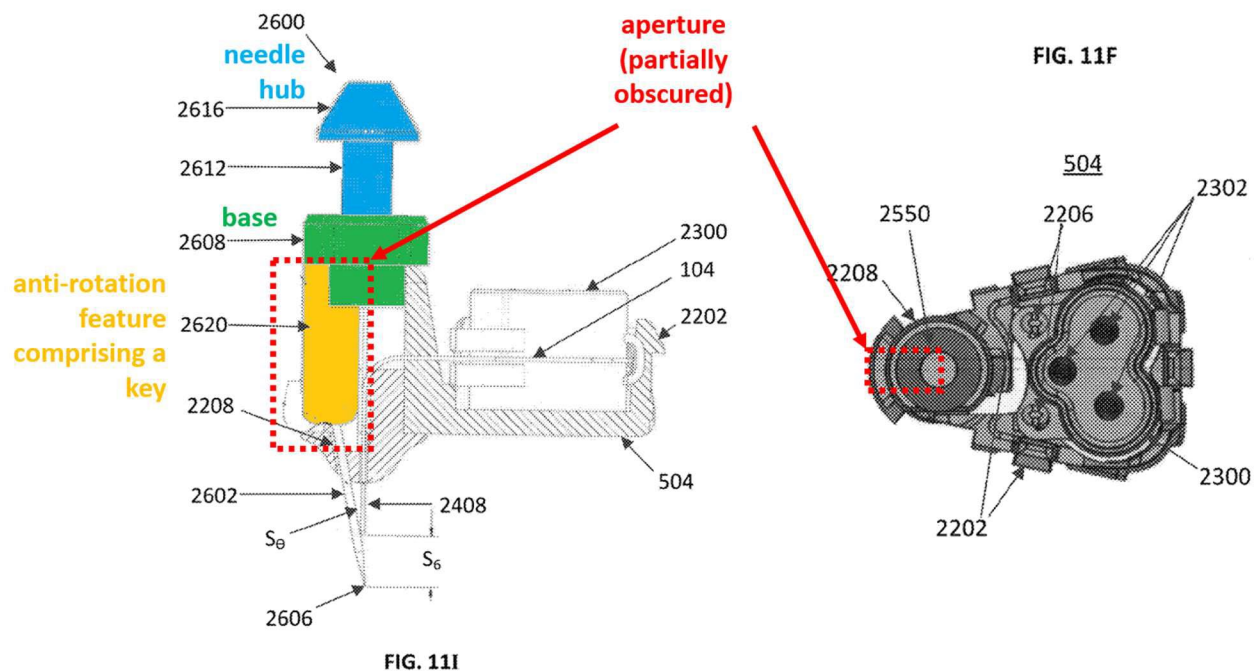
² Patent Owner herein uses the term “**anti-rotation feature/key**” to refer, respectively, to claims 1 and 28’s recitation of an “anti-rotation feature” and claim 13’s recitation of an “anti-rotation key”.

³ 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 (Rao)**

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

The Petition asserts that the claimed “needle hub” corresponds to Rao’s sharp module 2600 and that a lower portion of the sharp module corresponds to the claimed “base.” Petition, 25-26. The Petition further argues that the claimed “anti-rotation feature/key” corresponds to Rao’s bend fin guide 2620 (*id.*, 26) and that Rao’s sensor module 504 includes an aperture in which bend fin guide 2620 is inserted (*id.*, 32-33). The Petition purports to show this alleged aperture using an annotated version of Rao Figures 11I and 11F, reproduced below.



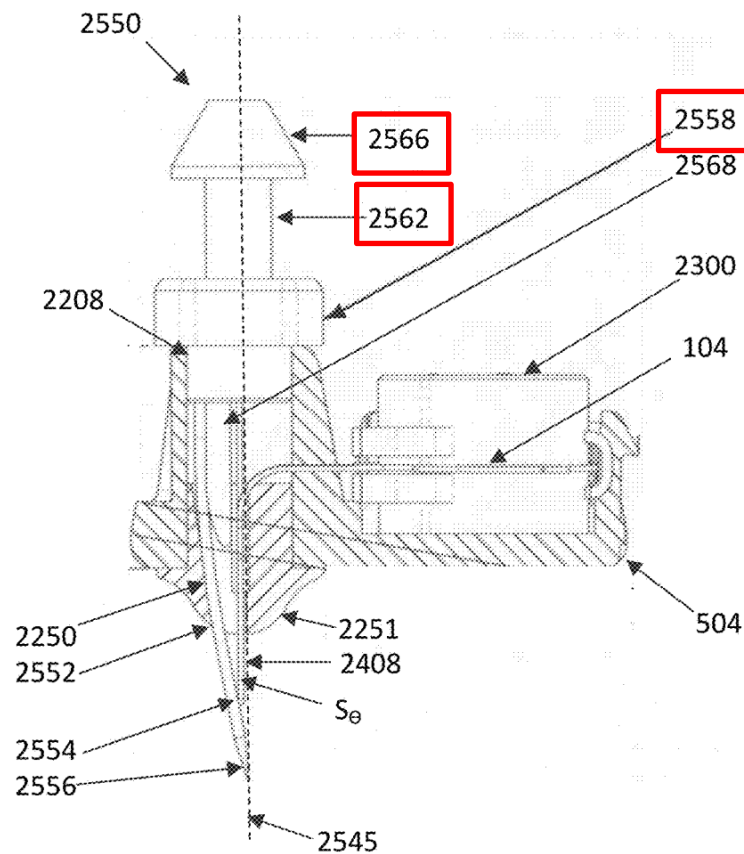
Id., 33 (annotated Ex-1012, Figs. 11I, 11F). With regard to the alleged rotation prevention of Rao, the Petition argues that bend fin guide 2620 prevents the claimed rotation “by being inserted within the aperture in the sensor control device.” Petition 34-35; *see also* Petition, 27 (“As seen in Figure 11J below, the hub 2600 cannot rotate relative to the sensor module 504, which is part of the on-skin sensor assembly as seen in Figure 12A, as the bend fin guide (i.e., the anti-rotation feature comprising a key) is prevented from rotating by the sensor module 504.”).⁴ However, for the reasons explained below, this argument fails and the Petition fails to show that Rao discloses or teaches an anti-rotation feature/key that prevents rotation as claimed.

First, the portions of Rao’s written description the Petition relies on do not support the argument that Rao’s bend fin guide 2620 prevents rotation as claimed. Specifically, the Petition focuses on Paragraph [0143] of Rao as allegedly disclosing “that bend fin guide 2620 (i.e., the anti-rotation feature comprising a key) prevents rotational movement of sharp 2602).” Petition, 27. However, merely preventing rotational movement of sharp 2602 is not sufficient to meet the claims, which require an anti-rotation feature/key to be configured to prevent a specific type of rotation,

⁴ For subsequent independent claims, the Petition cites back to its analysis concerning alleged rotation prevention for independent claim 1. *Id.*, 35-36, 42-43, 47.

namely preventing rotation of a needle hub/base within an aperture (claims 1/28) or preventing rotation of a needle hub with respect to an on-skin sensor assembly (claim 13). Paragraph [0143] of Rao does not disclose such type of rotation prevention. Instead, the paragraph explicitly states that bend fin guide prevents rotation “**of sharp 2602 relative to hub components.**” Ex-1012, [0143]. Rao also specifically defines the “hub components”: “FIG. 11E depicts a side cross-sectional side view of sharp module 2550, including sharp 2552, sharp spacer 2568 and hub components (hub snap pawl 2566, hub small cylinder 2562, and hub push cylinder 2558).” *Id.*, [0139]. These hub components (2558, 2562, 2566) are depicted in Fig. 11E, reproduced below (hub component labels annotated).

FIG. 11E



Id., Fig. 11E (annotated). In other words, the bend fin guide 2602, is not configured or intended to prevent rotation of Rao's sharp module relative to an aperture or on-skin sensor assembly, but rather prevents rotation of the sharp relative to other components of the sharp module 2550.

The Petition also cites to Paragraph [0144] of Rao, which vaguely states that “a proximal portion of sharp 2602 passes through bend fin guide 2620, which is coupled with a distal portion of sensor module 504.” Ex-1012, [0144]. The Petition

asserts that this statement regarding “coup[ling]” in combination with Rao’s alleged disclosure that Rao’s bend fin guide prevents rotational movement⁵ would lead a POSITA to understand that “the aperture in sensor module 504 ... has structures to restrain rotational movement of the ‘fin’ 2620 in either direction.” Petition, 34. The Petition, however, provides no reasoning or explanation for this bare conclusion and it does not explain how the Paragraph [0144] disclosure of components “coupled” to sensor module 504 would prevent rotational movement of such components. As an analogy, a bicycle wheel is coupled to a bicycle’s frame by way of a hub, but that doesn’t prevent the wheel from rotating relative to the bike frame. Neither Rao nor the Petition provide any indication that the coupling described in Paragraph [0144] prevents rotation of bend fin guide 2620 relative to the alleged aperture or sensor module 504. Therefore, the Petition has failed its basic burden of explaining why Rao would convey to a POSITA what Petitioner says it does. Accordingly, Rao’s written description does not support Petitioner’s argument that bend fin guide 2602 prevents rotation as claimed.

⁵ As explained above, Rao describes preventing rotational movement of the sharp only “relative to hub components,” and not relative to the sensor module as the Petition suggests.

Unable to identify in Rao's written description any explicit disclosure of an anti-rotation feature/key configured to prevent rotation as claimed, the Petition relies on speculation based on ambiguous patent drawings. Specifically, the Petition hand-waves to Rao's Figures 11J and 12A and concludes that these figures show that "hub 2600 cannot rotate relative to the sensor module 504." Petition, 27. While a prior art reference may disclose a limitation expressly or inherently, the figures of Rao do neither with regard to an anti-rotation feature configured to prevent the claimed rotation.⁶ As to express disclosure, for a drawing alone to disclose a claim limitation, the limitation must be shown clearly. *PlaSmart, Inc. v. Kappos*, 482 F. App'x 568, 572 (Fed. Cir. 2012) (non-precedential) ("[D]rawings can be used as prior art, without referring to the surrounding description, only if the prior art features are clearly disclosed by the drawing."). Here, the Petition provides no explanation for why a POSITA viewing Figures 11J and 12A would understand them to *clearly disclose* that bend fin guide 2620 is configured to prevent rotation as claimed and therefore fails to demonstrate that this limitation is expressly disclosed by Rao. To the contrary, Figure 11J shows only a side view of Rao's sharp module 2600

⁶ The Petition is unclear as to whether a POSITA would understand an anti-rotation key/feature configured to prevent the claimed rotation to be expressly or inherently disclosed and Patent Owner therefore addresses both standards herein.

disposed in sensor module 504 without clearly showing how the bend fin guide is disposed within the alleged aperture and Figure 12A provides a cross-sectional view of Rao's applicator with the components of the sharp module being small and difficult to make out. Figures 11J and 12A, as annotated and presented in the Petition, are reproduced below.

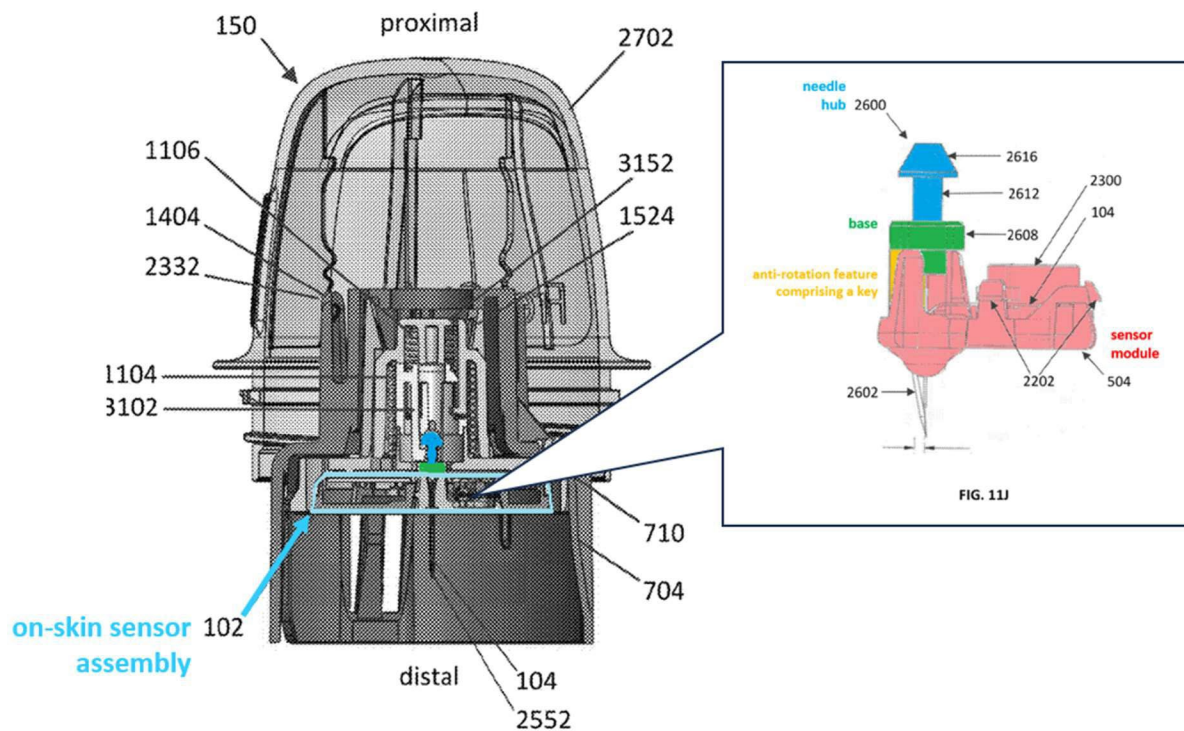


FIG. 12A

Petition, 30 (presenting annotated Ex-1012, Figs. 12A, 11J). Neither of these drawings depict bend fin guide 2620 interacting with the sensor module in such a way to clearly show to a POSITA that rotation is prevented, and, again, the Petition fails to provide any explanation for why they do so. Therefore, the relied-on

drawings of Rao do not expressly disclose an anti-rotation feature/key configured to prevent the claimed rotation.

As to any alleged inherent disclosure in the relied-on figures, “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); *see also MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999) (“Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.”). 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). Here, the Petition provides no argument or explanation that a POSITA would consider rotation prevention to be necessarily present in the structures depicted in the drawings of Rao. As explained above, the drawings of Rao are ambiguous, and a POSITA would not be able to determine that anti-rotation functionality is necessarily present simply from viewing them. The Petition also fails to consider important factors that a POSITA would need to consider in determining whether the

disclosed structures of Rao necessarily prevent rotation. One such factor is the fit and relative dimensions between structures. In order to prevent rotation, the identified components would need to fit tightly because otherwise the bend fin guide 2620 of Rao would be able to move and rotate within Rao's alleged aperture. Rao provides no disclosure of fit or relative dimensions for its components. The Petition provides no explanation for why any such properties would be understood from the relied-on figures and any inference regarding such properties from the figures alone would be improper. *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))). Another factor a POSITA would consider in determining whether Rao's drawings 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 Rao's components such as bend fin guide 2620 were bendable or flexible, this could allow the bend fin guide to rotate relative the Rao's alleged aperture or sensor module 504 even if the bend fin guide had a tight or snug fit within the aperture. Therefore, because the Petition fails to address relevant factors as to whether the depicted structures of Rao would prevent rotation, including fits, relative dimensions, and materials, the Petition has not

established that anti-rotation is a *necessary* feature of Rao, and the Petition does not meet the high bar for showing inherent disclosure. *See Fujian Sanan Group 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 property (refractive index) relevant to whether reference necessarily emits light).

Finally, 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 expressly or implicitly disclosed by Rao. 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 extrinsic evidence offered by Petitioner in support of its bare conclusions regarding Rao's alleged anti-rotation functionality is a blanket citation to Petitioner's expert declaration. Petition, 22-23 ("Rao renders obvious claim 1, as explained below and as supported by Ex-1004, ¶¶49-64."). The cited declaration paragraphs, however, cite no additional extrinsic

evidence and arguments beyond the bare conclusions presented in the Petition.⁷ In fact, as shown in a redline comparison of the Petition and the supporting declaration, the declaration parrots the Petition almost verbatim. *See* Ex-2104, 1-13. 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

⁷ The Petition makes an additional citation to ¶ 62 of the expert declaration for its conclusion that “a POSITA would understand the aperture in sensor module 504 ... has structures to restrain rotational movement of the ‘fin’ 2620 in either direction.” Petition, 34. The declaration provides a single sentence in support: “For example, because bend fin guide 2620 is a vertical fin that restrains rotational movement, a POSITA would understand that it must engage with a slot.” Ex-1004, ¶ 62; Ex-2104, 12. This, however, is itself an unsupported conclusion and does not explain why a POSITA would have such an alleged understanding and should therefore be disregarded.

“[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 arguments that Rao discloses to a POSITA, either expressly or implicitly, an anti-rotation feature configured to prevent the claimed rotation fails because they are unsupported by objective evidence to show how a POSITA would understand the disclosures of Rao.

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

While the Petition styles Ground 1 as an obviousness challenge, it fails to explain any subject matter that would be obvious to a POSITA beyond the express disclosures of Rao. The Petition for Ground 1 does not even make a conclusory argument that anti-rotation functionality would be obvious. The Petition does not explain any proposed modification to Rao that a POSITA would find obvious, does not describe any motivation for the POSITA to make such a modification, and does not explain why a POSITA would have a reasonable expectation of success in doing so. Therefore, to the extent the Petition relies on obviousness for Ground 1, such argument should be rejected.

2. Ground 2 (Rao And Lundquist)

The Petition's Ground 2 relies on the combination of the inserter of Rao 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," (Petition, 62) which the Petition relies on in challenging dependent claims 4-5, 14-15, 26-27, and 30 (*id.*, 62-67). As explained in section III.C.1, *supra*, the Petition fails to demonstrate that the challenged independent claims of the '625 patent are unpatentable in view of Rao. Because Ground 2 introduces Lundquist for subject matter only included in dependent claims, and not to fill Ground 1's failure to demonstrate Rao's disclosing or teaching of an anti-rotation feature/key configured to prevent 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 Servs., 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).

IV. CONCLUSION

Neither 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

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**CERTIFICATE OF COMPLIANCE WITH
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This brief complies with the type-volume limitation of 37 C.F.R. § 42.24
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CERTIFICATE OF SERVICE

The undersigned certifies that on August 23, 2024, a complete copy of
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