

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

Case No. IPR2023-01397

U.S. Patent No. 11,266,335

PATENT OWNER'S PRELIMINARY RESPONSE

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2101	U.S. Pub. No. 2010/0198034
2102	U.S. Pub. No. 2010/0324392
2103	EPO Summons and Preliminary Opinion for Opposition Re EP 3 766 408 B1 (20195922.8) (Sept. 21, 2023)
2104	European Patent No. 3 928 688 B1

I. INTRODUCTION

Patent Owner Abbott Diabetes Care Inc. submits this Preliminary Response to the Petition filed by DexCom, Inc. (“Petitioner”) requesting *inter partes* review of claims 1-4, 8-9, and 11-27 (the “Challenged Claims”) of U.S. Patent No. 11,266,335 (“335 Patent”).

The Board should deny institution for at least two reasons. First, the Board should deny institution under 35 U.S.C. § 325(d) because Petitioner has failed to show that the Examiner erred in determining the priority of the Challenged Claims. Second, the Board should deny institution under § 314(a) because Petitioner’s Grounds are not reasonably likely to succeed.

This is a textbook case for § 325(d) discretionary denial. Petitioner’s Grounds present the *same* argument that the Examiner previously considered and decided in Patent Owner’s favor. Both Grounds 1 and 2 rely on PCT Publication WO 2010/091005 (“Thomas-005”), a Patent Owner publication, as the primary reference. During prosecution, the Examiner considered Patent Owner’s related publication, U.S. Patent Publication No. 2010/0198034 (“Thomas-034”), which was published one week *earlier* than Thomas-005. Importantly, the Examiner also considered a declaration under 37 CFR § 1.131 (“the 131 Declaration”) and determined that Thomas-034 is not prior art to the Challenged Claims. If Thomas-034 is not prior art, then neither is Thomas-005.

Nonetheless, Petitioner asks the Board to institute trial on its Thomas-005-based Grounds because the Examiner allegedly erred in “accepting” the 131 Declaration. *See* Pet. at 9. Notably, Petitioner does not challenge the Examiner’s determination of conception. Instead, it claims the Examiner erred in determining reduction to practice and diligence. But it is Petitioner, not the Examiner, who has erred. In attacking the Examiner’s reduction-tstao-practice determination, Petitioner ignores most of the evidence cited in the 131 Declaration that confirms the Examiner’s determination. That is fatal to Petitioner’s “Examiner error” argument. Petitioner cannot reasonably contend the Examiner erred while failing to address all the evidence set forth in the 131 Declaration supporting the Examiner’s determination; and the little evidence that Petitioner does address actually further confirms that determination.

Petitioner also improperly bases its argument on a degraded copy of just one figure from a provisional application that was included in the 131 Declaration to prove reduction to practice. While even that degraded copy supports the Examiner’s reduction-to-practice determination—especially when considered in conjunction with the other cited evidence that Petitioner ignores—the original (better quality) figure from the provisional application is even more compelling. Petitioner, however, ignores the original figure and confines its arguments to the copy

reproduced in the 131 Declaration. Accordingly, Petitioner has not met its burden to show that the Examiner erred in determining reduction to practice.

Petitioner's attack on diligence fares no better. It relies on the wrong legal standard, improperly demanding proof of work on a specific ***claim limitation*** instead of the ***claimed invention*** and evidence of diligence far beyond what is required under the law.

Petitioner's flawed arguments fail to show that the Examiner committed any error, much less a material one, in determining that Thomas-034 (and, thus, Thomas-005) is not prior art. Even when Petitioner does address a subset of the evidence set forth in the 131 Declaration, Petitioner merely quibbles with the Examiner's interpretation of that evidence. That is not sufficient to show material error. *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 9 (P.T.A.B. Feb. 13, 2020) (precedential) ("If reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability."). The Board should, therefore, deny institution under § 325(d).

The Board also should deny institution under § 314(a). First, putting aside the Examiner's previous determination of priority, the evidence in the 131 Declaration shows that Thomas-005, like Thomas-034, is not prior art. Because both Grounds require Thomas-005 to be prior art, Petitioner is not likely to succeed on either

Ground. Second, even if Thomas-005 were considered prior art, Petitioner's Grounds still fail for reasons independent of the priority determination; for example, because Petitioner's cited art fails to disclose all limitations of the Challenged Claims as shown below.

II. BACKGROUND

A. Summary of the 335 Patent

The 335 Patent is titled "Medical Device Inserters and Processes of Inserting and Using Medical Devices." Ex. 1101 at 1. It issued on March 8, 2022 from an application filed September 11, 2020 and claims priority to a non-provisional application filed March 24, 2011, and to provisional applications filed November 8, 2010, July 2, 2010, May 17, 2010, and March 24, 2010. *Id.*; *see also* Exs. 1102, 1104, and 1106-08.

The 335 Patent notes in its Background section that "[t]he detection and/or monitoring of glucose levels or other analytes ... in certain individuals is vitally important to their health" and, for diabetes, "clinical data demonstrates a strong correlation between the frequency of glucose monitoring and glycemic control." Ex. 1101 at 2:27-29, 2:37-39. It further states there is a need for analyte monitoring devices, systems, and methods that are "cost effective, convenient, and with reduced pain, provide discreet monitoring to encourage frequent analyte monitoring to improve glycemic control." *Id.* at 2:52-58. The 335 Patent provides such a device.

Claim 1, the only independent claim, is directed to a “glucose monitoring assembly” comprising “an inserter” and “an on body electronics unit,” each with certain additional components and features:

(1) an inserter comprising a sharp configured to insert a portion of a glucose sensor into a subject; and

(2) an on body electronics unit, comprising:

an on body electronics unit housing comprising a plurality of recesses disposed on a periphery of the on body electronics unit housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is detachably engaged with the inserter;

the glucose sensor; and

on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level,

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position, and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.

Ex. 1101 at claim 1.

Pertinent to this Preliminary Response, the on body electronics unit of the glucose monitoring assembly of claim 1 comprises “an on body electronics unit housing comprising a plurality of recesses disposed on a periphery of the on body electronics unit housing[.]” *Id.* The recesses are “detachably engaged” with the inserter. *Id.*

B. Prosecution of the 335 Patent, Including the 131 Declaration

During prosecution, the Examiner cited Thomas-034 against the then-pending claims. Ex. 1102 at 334-44, 429-40. Thomas-034 was published on August 5, 2010. Ex. 2101 at 1. Patent Owner successfully swore behind Thomas-034 via the 131 Declaration.

Petitioner purports to provide a summary of the prosecution of the application leading to the 335 patent. *See* Pet. at 8-9. However, Petitioner omits details of the substantial evidence that Patent Owner submitted as part of the 131 Declaration.

The 131 Declaration itself is twelve pages and signed by all four named inventors. It details work done by the inventors (along with others) during the 2010 calendar year on a new “glucose monitoring assembly (‘GMA’) comprising: (1) an inserter and (2) an on body electronics unit that included a glucose sensor and on body electronics.” Ex. 1102 at 490, ¶5; *cf.* Ex. 1101 at claim 1 (335 Patent, claim 1 reciting a “glucose monitoring assembly”).

Attached to the declaration are eight supporting exhibits, comprising nearly five hundred pages. They include: (1) an internal PowerPoint presentation dated April 27, 2010 relating to a sample embodiment, (2) five monthly progress reports detailing diligent work from July through November of 2010, and (3) two provisional applications (to which the 335 Patent claims priority).

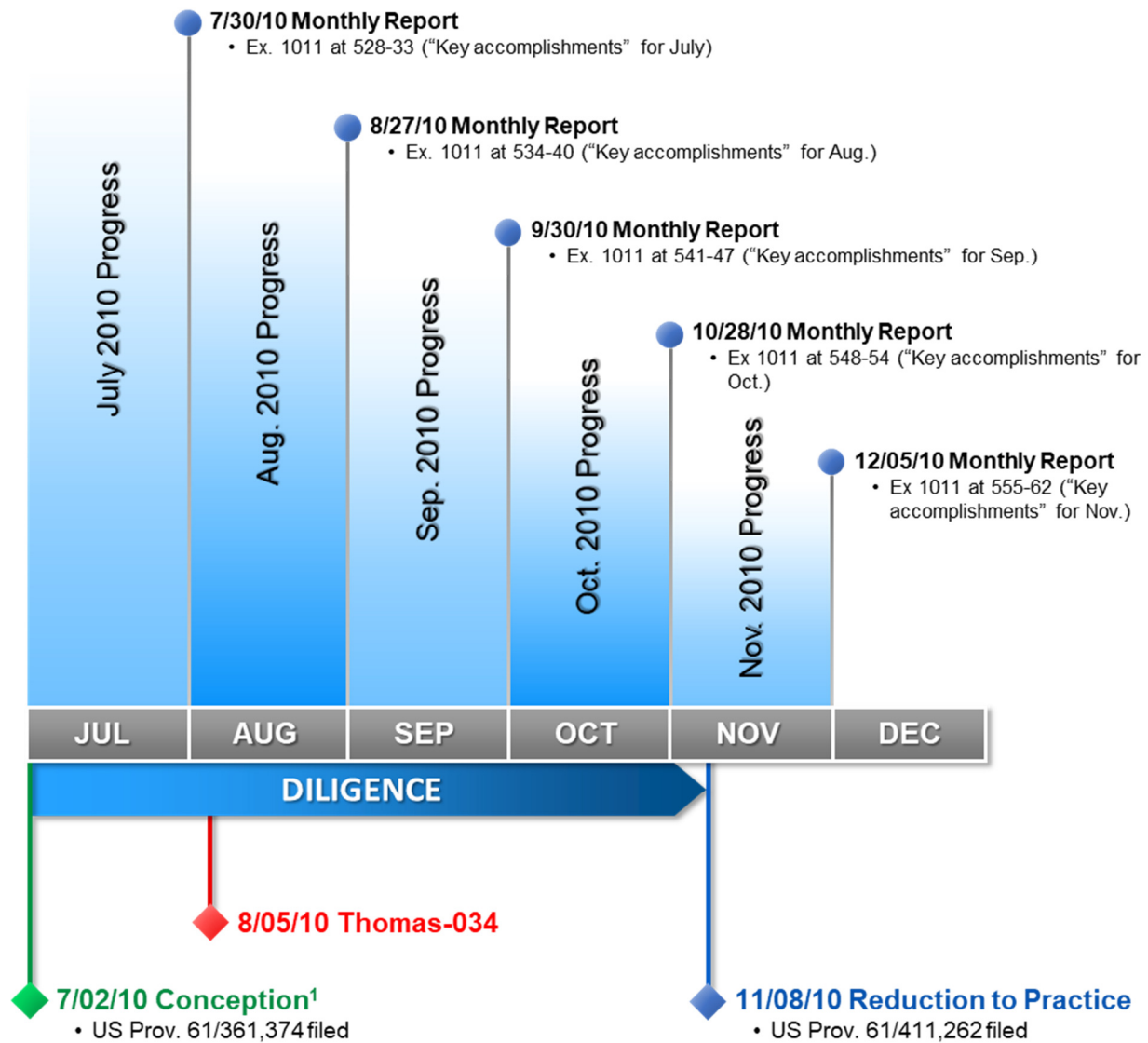
The declaration also includes two Appendices spanning over seventy pages. Appendix A (conception claim chart) summarizes support from the April 27, 2010 PowerPoint presentation and one of the provisional applications (61/361,374, filed July 2, 2010 (“the 374 Provisional”)) to show that the “subject matter of the pending claims was conceived in the United States before August 5, 2010 [*i.e.*, the publication date of Thomas-034].” Ex. 1102 at 495, 973-1013 (claim chart mapping pending claims to the disclosure of the PowerPoint and 374 Provisional). Appendix B (reduction to practice chart) summarizes support from a later provisional application (61/411,262, filed November 8, 2010 (“the 262 Provisional”)) to show that the “subject matter of the pending claims was reduced to practice in the United States by no later than November 8, 2010 [*i.e.*, the date of the 262 Provisional].” *Id.* at 499, 1014-1050 (claim chart mapping pending claims to the disclosure of the 262 Provisional).

The 131 Declaration also provides testimony from the inventors on their conception and diligent reduction to practice. On conception, the inventors cite

figures and text from the PowerPoint presentation and the 374 Provisional to show they conceived the claimed subject matter before Thomas-034's publication date. *See, e.g.*, Ex. 1102 at 491-95. Petitioner does not contest conception in its Petition.

Regarding diligence, the inventors provide testimony that steps through the monthly progress reports summarizing diligent and continuous work on the claimed inventions. *Id.* at 495-98. For example, the reports list monthly "Key accomplishments" on various aspects of the claimed inventions, including the inserter, on body unit, on body unit electronics, and the combination of these components, which is sometimes referred to as the "PDU." *Id.* The inventors further testify that they reduced the claimed inventions to practice no later than November 8, 2010, as evidenced by the 262 Provisional. *Id.* at 498-99. They also refer to the detailed claim chart of Appendix B for further evidence confirming their reduction to practice. *Id.*

The timeline below summarizes the evidence the inventors provided via the 131 Declaration to swear behind Thomas-034:



¹ Conception was no later than July 2, 2010. Patent Owner reserves the right to argue an earlier conception date in this or other proceedings involving the 335 Patent. Patent Owner also reserves the right to argue a reduction to practice date earlier than November 8, 2010.

After considering the 131 Declaration and substantial related evidence, the Examiner allowed the claims, finding that the 131 Declaration showed conception, diligence, and reduction to practice such that Thomas-034 was not prior art:

The declaration filed on 11/19/2021 under 37 CFR 1.131(a) is sufficient to overcome [Thomas-034].

The subject matter of provisional application 61/361374 (Exhibit 1) dated 7/02/2010 as well as the PowerPoint in Exhibit 2 adequately show conception of the invention prior to the 8/05/2010 date of Thomas et al, particularly, the limitation in Claim 26 regarding the plurality of recesses including a first and second recess on a periphery of the on body electronics unit housing and detachably engaged with the inserter.

Exhibits 3-7 show adequate diligence to constructive reduction to practice with monthly progress reports between before 8/05/2010 to 11/8/2010, the date of provisional application 61/411262 (Exhibit 8), which provides support for the invention as claimed.

Ex. 1102 at 2073-74 (Examiner's Response). The Primary Examiner concurred with these findings. *Id.* at 2075.

III. PETITIONER HAS FAILED TO SHOW THE EXAMINER ERRED IN DETERMINING PRIORITY OR THAT ITS GROUNDS ARE REASONABLY LIKELY TO SUCCEED

The Board should deny institution on both Grounds under § 325(d) because the first prong of *Advanced Bionics* is indisputably met, but Petitioner failed to meet its burden on the second prong to show the Examiner committed an error material to the patentability of the Challenged Claims. Institution should also be denied under § 314(a) in light of the substantial evidence that proves Thomas-005 is not prior art.

A. Legal Standard

The Board may exercise discretion to deny a petition that raises “the same or substantially the same prior art or arguments previously ... presented to the Office.” 35 U.S.C. § 325(d). The Board applies a two-part framework to determine whether it should exercise its discretion, which examines:

- (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and
- (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

Advanced Bionics, IPR2019-01469, Paper 6 at 8.

If a condition of the first part of the framework is satisfied and the petitioner fails to meet its burden under the second part to show the Examiner committed

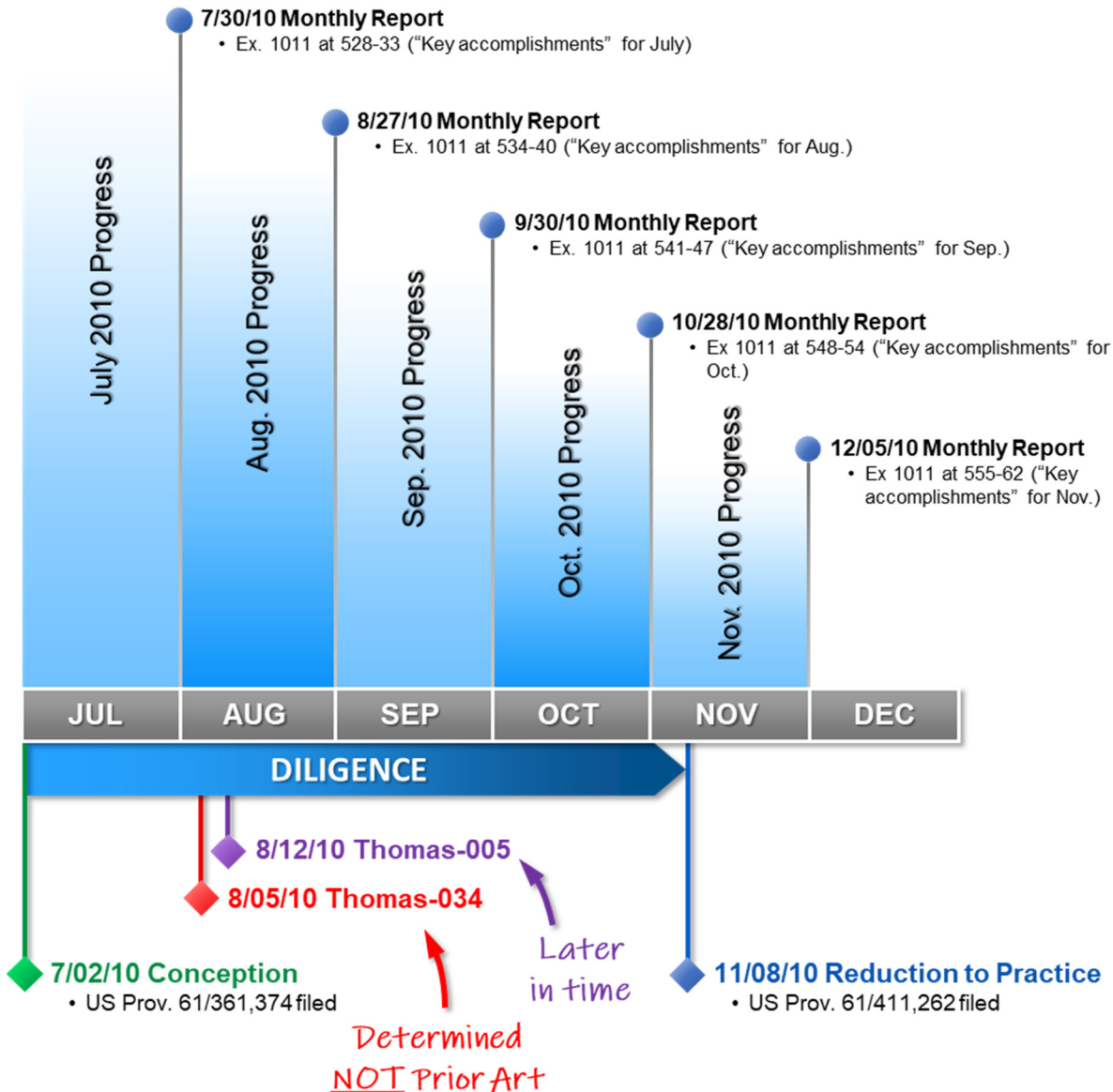
material error, the Board generally will exercise discretion and deny institution. *Id.* at 8-9. Even “[i]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.” *Id.* at 9. This two-part framework “reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.” *Id.*

In addition to discretionary denial under § 325(d), the Board must deny institution under 35 U.S.C. § 314(a) if Petitioner fails to “show[] that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a).

B. Petitioner Raises The Same Priority Argument Previously Considered By The Examiner

During prosecution, Patent Owner presented evidence and argument, and the Examiner determined, that the inventions claimed in the 335 Patent were entitled to a priority date at least earlier than Thomas-034’s August 5, 2010 publication date. The Examiner found the inventors had shown that they conceived the claimed inventions before August 5, 2010, constructively reduced to practice upon filing of the 262 Provisional, and exercised reasonably continuous diligence from just before August 5, 2010 through the filing of the 262 Provisional. As a result, the Examiner determined that Thomas-034 is not prior art to the Challenged Claims.

Petitioner admits that its primary art reference, Thomas-005, “was published ... one week *after* Thomas-034[.]” Pet. at 4-5²; *see also* Ex. 1109 (Thomas-005 publication with an August 12, 2010 publication date). That is, Thomas-005 is *later in time* than Thomas-034, which the Examiner already determined is not prior art:



² All emphasis herein is added unless indicated otherwise.

Because the Examiner already determined that Thomas-034 is not prior art based on prior conception, reduction to practice, and reasonably continuous diligence beginning before Thomas-034's publication date (which is a week before Thomas-005's publication date), Thomas-005 is likewise not prior art. Thus, from a priority perspective, Petitioner's Grounds present the Board with the *same* argument previously considered by the Examiner and decided in Patent Owner's favor.

Petitioner says its Grounds rely upon different art than the Examiner considered. Pet. at 6. But this argument is irrelevant because it ignores the threshold question: is the primary reference on which Petitioner's Grounds rely (Thomas-005) prior art? It is not. Indeed, given Thomas-005's publication date, Thomas-005 is less "prior" than Thomas-034 (which is not prior art). Their disclosures are irrelevant to the priority question.³

In sum, Petitioner's Grounds resurrect the "same arguments previously ... presented to the Office." *Advanced Bionics*, IPR2019-01469, Paper 6 at 8. Therefore,

³ Irrelevant as it may be, Patent Owner disagrees with Petitioner's claim that Thomas-005 "contains a more robust disclosure than Thomas-034." See Pet. at 5. Indeed, Thomas-034 incorporates by reference a concurrently-filed application that has the same disclosure as Thomas-005. Compare Ex. 1109 (Thomas-005), with Ex. 2102 (US 2010/0324392) (incorporated into Thomas-034).

to avoid discretionary denial of its Petition, Petitioner must show that the Examiner “erred in a manner material to the patentability of the challenged claims.” *Id.* Here, Petitioner must show the Examiner materially erred in deciding priority. As detailed below, Petitioner falls far short of making such a showing.

C. Petitioner Has Failed To Show The Examiner Materially Erred In Determining Priority

Petitioner argues the Examiner committed two errors in finding the 131 Declaration sufficient to antedate Thomas-034: (1) the Examiner allegedly erred in determining the then-pending claims were constructively reduced to practice by the filing of the 262 Provisional and (2) the Examiner allegedly erred in determining that the inventors were diligent. Pet. at 9. But Petitioner has failed to show the Examiner materially erred in making these determinations such that Thomas-005 would be considered prior art.

1. The Examiner did not materially err in determining that the inventors reduced to practice when they filed the 262 Provisional

In awarding priority to the inventors, the Examiner determined that the 262 Provisional constituted constructive reduction to practice and “provides support for the invention as claimed.” Ex. 1102 at 2074. Petitioner bears the burden of showing the Examiner materially erred in making this determination. *Advanced Bionics*, IPR2019-01469, Paper 6 at 8-9.

As an initial matter, and as explained further below, Petitioner clearly did not meet its burden at least because Petitioner and its expert failed to address most of the supporting evidence cited in the 131 Declaration. That alone is fatal to Petitioner's "Examiner error" allegation.

Even for the evidence that Petitioner and its expert did address, they provide only unsupported conclusions. Petitioner concedes that the 262 Provisional supports every element of the Challenged Claims except two. Specifically, Petitioner alleges that the 262 Provisional "does not adequately support a plurality of recesses on the periphery of the on body unit, as recited by independent claim 1" (*see* Pet. at 10) and does not disclose how the recesses "detachably engage[] with the inserter, as recited in independent claim 1" (*id.* at 12). But the only evidence Petitioner offers to support these allegations is a single, conclusory paragraph from its expert. *See id.* at 10-12 (citing ¶26 of Ex. 1103 (Fletcher Declaration) multiple times). The expert's one-paragraph opinion, however, merely parrots Petitioner's allegations of error without any analysis or application of his purported expertise. *See* Ex. 1103 at ¶26. The Board should give such testimony little weight as explained in *Xerox v. Bytemark*:

I determine that the Board was correct in giving little weight to Petitioner's expert because the expert declaration merely offered conclusory assertions without underlying factual support and repeated, verbatim, Petitioner's conclusory arguments. . . . 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. . . . Instead, ***the declaration copies, word-for-word, Petitioner’s conclusory assertions.*** . . . 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).

Xerox Corp., et al. v. Bytemark, Inc., IPR2022-00624, Paper 12 at 5 (P.T.A.B. Feb. 10, 2023) (Director review affirming and designating as precedential Board’s decision denying institution) (internal citations omitted); *cf. TQ Delta, LLC v. Cisco Sys.*, 942 F.3d 1352, 1362 (Fed. Cir. 2019) (reversing PTAB’s unpatentability determination as not supported by substantial evidence where *ipse dixit* declaration from petitioner’s expert “fail[ed] to provide any meaningful explanation for why one of ordinary skill in the art would be motivated to combine these references at the time of this invention.”) (quoting *InTouch Techs, Inc. v. VGo Commc’ns, Inc.*, 751 F.3d 1327 (Fed. Cir. 2014)). Beyond his unsupported opinion, Petitioner’s expert offers no evidence that the 262 Provisional does not disclose a plurality of recesses disposed on the periphery of the on body unit housing or describe how they detachably engage the inserter.

Simply put, Petitioner fails to show that the Examiner erred in determining reduction to practice. Each alleged error is addressed in further detail below.

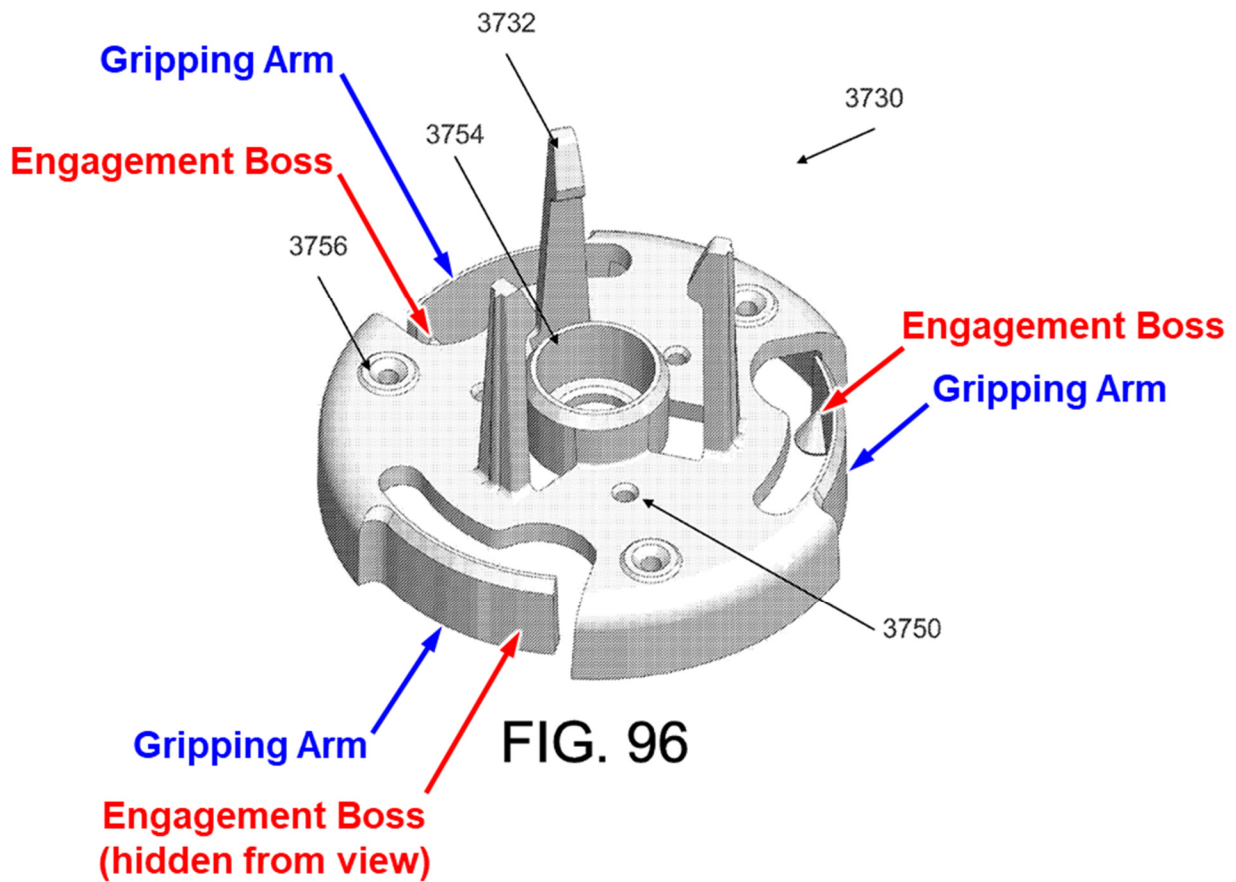
a. The Examiner did not materially err in determining that the 262 Provisional supports a plurality of recesses on the periphery of the on body unit housing

The 131 Declaration includes a “reduction to practice” claim chart (Appendix B) identifying extensive support in the 262 Provisional for each claim limitation. For the “plurality of recesses,” the chart includes four figures from the 262 Provisional and provides annotations and explanatory text. *See* Ex. 1102 at 1017-1018 (claim chart mapping then-pending claim 26 (now claim 1) to Figures 91D, 96, 97B, and 97C of the 262 Provisional); Ex. 1104 at Figures 91D, 96, 97B, and 97C). As noted in the chart, these figures confirm not only that the on body unit housing has a plurality of recesses, but also that the recesses are detachably engaged with the inserter as recited in claim 1 (*e.g.*, by depicting multiple recesses, by depicting three gripping arms with engagement bosses that detachably engage with corresponding recesses, etc.). *Id.* In addition to the claim chart, the body of the 131 Declaration also includes Figure 98 of the 262 Provisional in connection with reduction to practice. Ex. 1102 at 499. As the context of the cited figures makes clear, the recesses and their corresponding gripping arms/bosses are disposed at 120° intervals about the circular on body unit housing.

In contesting the Examiner’s determination that the inventors’ evidence disclosed the “plurality of recesses,” Petitioner and its expert address *only two of these five figures* (and only one of the four figures included in the supporting claim chart). Specifically, Petitioner addresses only Figures 98 and 91D.⁴

With respect to Figure 98, Petitioner says that it shows only a single recess. However, Petitioner ignores that, as is discernable from the additional figures included in the 131 Declaration, the two other recesses are hidden from view in Figure 98 because they are located 120° to either side of the viewable recess. *See, e.g.*, Ex. 1102 at 1017-18. For example, as the 131 Declaration explains, Figures 96, 97B, and 97C from the 262 Provisional—which neither Petitioner nor its expert address at all—“show[] parts of [the] inserter, e.g., plurality of gripping arms with engagement bosses, with which the plurality of recesses is detachably engaged.” *Id.* at 1018. Figure 96 from the 262 Provisional shows the gripping arms and engagement bosses:

⁴ Petitioner mistakenly refers to Figure 91A on occasion. *See, e.g.*, Pet. at 10, 12 (mistakenly referring to Figure 91A); *but see id.* at 11 (correctly referring to Figure 91D).



Ex. 1104 at 231 (Figure 96 from 262 Provisional attached as Exhibit 8 to the 131 Declaration, annotations provided herein); *see also* Ex. 1102 at 1018 (131 Declaration annotating Figure 96 from 262 Provisional). And Figures 97B and 97C from the 262 Provisional together show how an engagement boss on the visible gripping arm engages the visible recess on the on body unit:

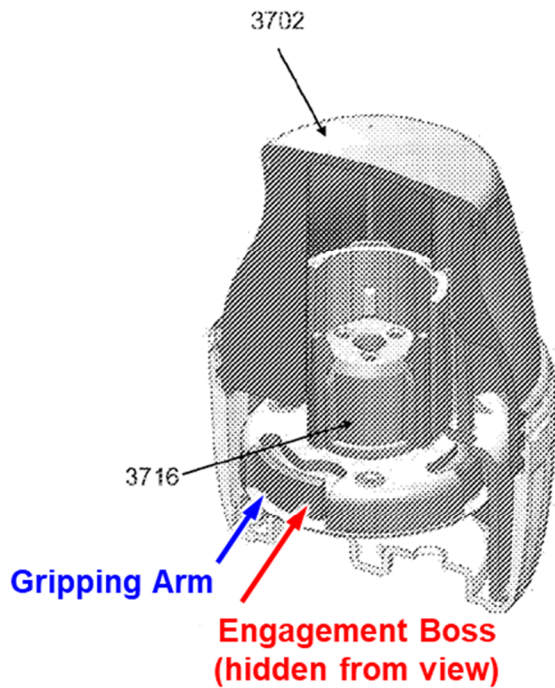


FIG. 97B

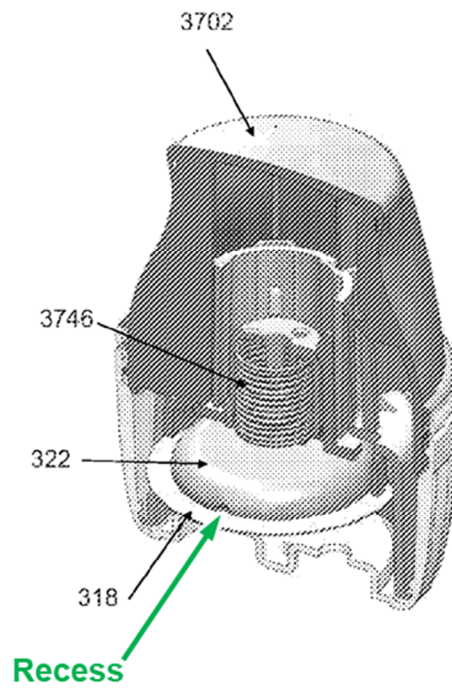


FIG. 97C

Ex. 1104 at 232 (Figures 97B and 97C from 262 Provisional attached as Exhibit 8 to the 131 Declaration, annotations provided herein); *see also* Ex. 1102 at 1018 (131 Declaration including Figures 97B and 97C from the 262 Provisional). While Petitioner admits that Figure 98 discloses a recess (*see* Pet. at 11), Petitioner ignores that same feature in Figure 97C, ignores that Figure 97B illustrates engagement with the recess, and ignores that Figure 96 discloses three gripping arms and engagement bosses spaced 120° apart.

Turning to Figure 91D, Petitioner and its expert focus only on a degraded, low quality copy of the figure to make their argument. *See* Pet. at 12 (depicting a copy of Figure 91D annotated first by the inventors and then further by Petitioner).

Petitioner's copy of Figure 91D is not the original version of that figure from the 262 Provisional. Rather, Petitioner's copy is at least a third (if not more) generation copy of the original. Nonetheless, the original Figure 91D, as well as the annotated copy from the 131 Declaration, clearly show two (*i.e.*, a plurality) recesses spaced 120° apart on the periphery of the on body unit housing (the third recess is hidden from view in this figure):

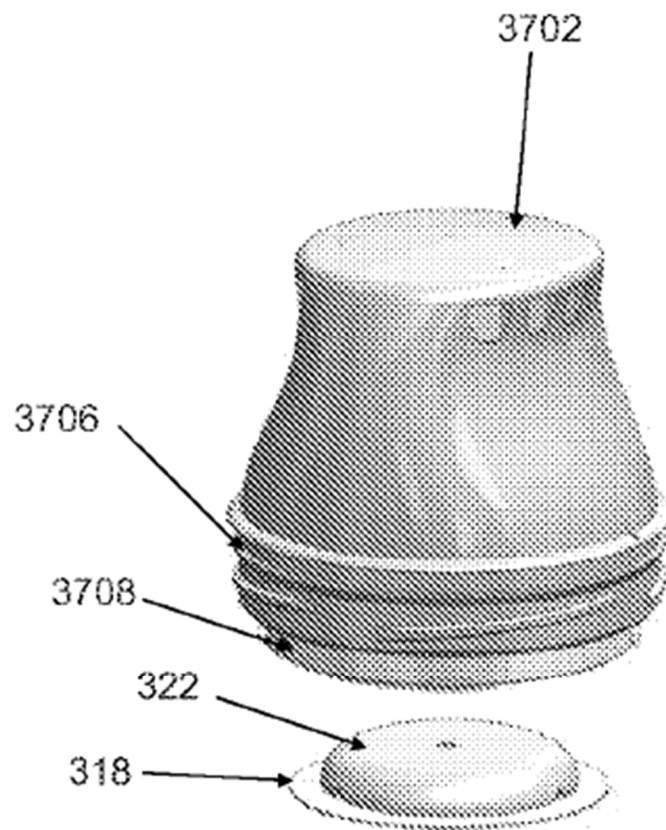
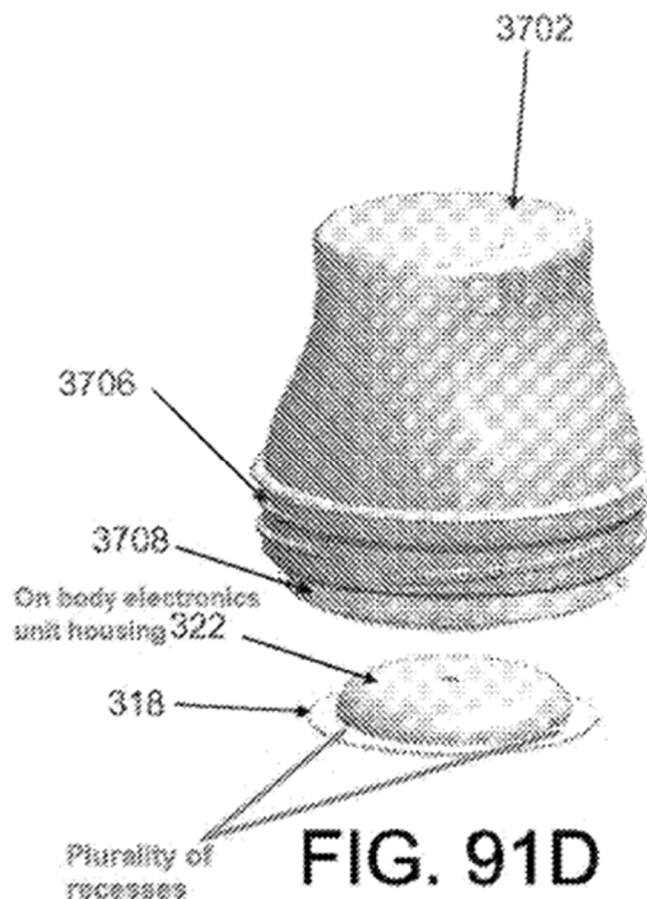


FIG. 91D

Ex. 1104 at 226 (Figure 91D from 262 Provisional attached as Exhibit 8 to the 131 Declaration).



Ex. 1102 at 1017 (Figure 91D from 262 Provisional as annotated in Appendix B to the 131 Declaration). Indeed, the Examiner, who regularly analyzes patent figures for what they disclose, concluded that a plurality of recesses are disclosed. *See Graco Children's Prods., Inc. v. Kolcraft Enters., Inc.*, IPR2016-00810, Paper 8 at 14 (P.T.A.B. Sept. 28, 2016) (denying institution under § 325(d) where the petitioner challenged a Rule 131 declaration by arguing photo exhibits submitted with the

declaration did not discernably show the claimed invention but the petitioner relied on copies, not what the Examiner considered, to make its case).

Petitioner complains that a plurality of recesses is not “expressly disclosed” or “labelled in the drawings or described in the text” of the 262 Provisional. Pet. at 10. But drawings alone can provide written description support for, or reduction to practice evidence of, a claim. *See Revolution Eyewear, Inc. v. Aspect Eyewear, Inc.*, 563 F.3d 1358, 1366 (Fed. Cir. 2009); *Petisi v. Renhard*, 363 F.2d 903, 907 (CCPA 1966) (reduction to practice evidence need not “positively identify” claimed embodiment but instead is evaluated by what it teaches to those of skill in the art). That the recesses, gripping arms, or bosses are not expressly identified via numbering in the figures of the 262 Provisional is irrelevant. They are disclosed for purposes of reduction to practice. *Id.*

Notably, after limiting their analysis to briefly discussing only Figures 98 and 91D, Petitioner and its expert contend the inventors “provided [the Examiner] no other support for ‘plural recesses’ in the ’262 provisional application[.]” Pet. at 12. ***That is factually wrong.*** As explained above, the inventors also identified Figures 96, 97B, and 97C in the 131 Declaration as depicting three gripping arms/bosses “with which the plurality of recesses [are] detachably engaged.” Ex. 1102 at 1018. The most reasonable conclusion—indeed, the correct conclusion—to be drawn is that the figures from the 262 Provisional, reproduced in the 131 Declaration, depict

an on body unit housing with a *plurality* of recesses that detachably engage with the three gripping arms/bosses.

The Examiner was satisfied with the inventors' evidence showing they reduced to practice the claimed invention via the 262 Provisional. *See* Ex. 1102 at 2073-74. The Examiner was able to discern the plurality of recesses and how they engaged with the inserter from the evidence and information provided in the 131 Declaration. Petitioner and its expert say they are unable to do so. Pet. at 11 ("the left-most lead line [in annotated Figure 91D] does not point to any discernable feature. . . ."); Ex. 1103 at ¶26 (same). However, Petitioner and its expert improperly confined their analysis to merely annotated, low-quality copies of Figures 91D and 98 provided in the reduction-to-practice claim chart *and ignored the original figures and additional cited evidence from the 262 Provisional*. Petitioner's conclusion that the Examiner allegedly erred is therefore baseless because Petitioner failed to analyze all of the evidence the Examiner considered.

Finally, even for the small subset of the cited evidence that Petitioner and its expert did address (albeit using degraded images), at best Petitioner and its expert merely quibble with the Examiner's interpretation of those figures. But merely disagreeing with an Examiner's interpretation of evidence does not mean the Examiner materially erred and does not warrant institution. *Advanced Bionics*, IPR2019-01469, Paper 6 at 9 ("If reasonable minds can disagree regarding the

purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.”); *see also Graco*, IPR2016-00810, Paper 8 at 14; *Hulu, LLC v. Intertainer, Inc.*, IPR2014-01456, Paper 8 at 8 (P.T.A.B. Mar. 6, 2015) (denying institution under § 325(d) where petitioner challenged rule 131 declarations filed during prosecution and Examiner’s reliance on declarations was reasonable); *SMR Auto. Sys. USA Inc. v. Magna Mirrors of Am. Inc.*, IPR2018-00931, Paper 7 at 14 (P.T.A.B. Sept. 14, 2018) (denying institution under § 325(d) where petitioner challenged rule 131 declaration filed during prosecution and failed to present “further sufficient evidence” challenging the Examiner’s priority determination).

In sum, the evidence submitted during prosecution with the 131 Declaration and previously considered by the Examiner shows “a plurality of recesses disposed on a periphery of the on body electronics unit housing.” Ex. 1001 at 48:59-61. Petitioner has not shown that the Examiner materially erred in reaching this conclusion.

b. The Examiner did not materially err in determining that the 262 Provisional discloses how the recesses detachably engage with the inserter

For purposes of constructive reduction of practice, Petitioner contests only one other claim limitation. Petitioner alleges that the 262 Provisional does not disclose how the recesses detachably engage with the inserter. Pet. at 12. But

Petitioner’s entire “analysis” in support of this allegation is the following conclusory sentence:

Further, the ’262 provisional does not show how this recess detachably engages with the inserter, as recited in independent claim 1. EX1103, ¶26; *see* EX1104.

Id.

As can be seen, beyond a generic citation to the 262 Provisional (Ex. 1104), Petitioner’s only support is paragraph 26 of its expert’s declaration (Ex. 1103). But paragraph 26 of the expert declaration, like the Petition, is only a single conclusory sentence. Worse, it *merely parrots the text of the sentence in the Petition that cites Petitioner’s expert*. Here is a side-by-side comparison of what Petitioner says in its Petition and what Petitioner’s expert says in his declaration (to which the Petition cites as support):

PETITION	CITED EXPERT PARAGRAPH
“Further, the ’262 provisional does not show how this recess detachably engages with the inserter, as recited in independent claim 1. EX1103, ¶26; <i>see</i> EX1104.”	“Finally, the ’262 provisional does not show or describe how this recess detachably engages with the inserter, as recited in independent claim 1. <i>See</i> EX1104.”

Pet. at 12; Ex. 1103 ¶26. Such conclusory assertions cannot show material error.

Furthermore, Petitioner and its expert ignore—and thus fail to address—the evidence cited in the 131 Declaration showing disclosure of this limitation. The same evidence discussed above for the “plurality of recesses” was also cited for this limitation (*i.e.*, “wherein the plurality of recesses is detachably engaged with the inserter”). These limitations were addressed together in the reduction-to-practice claim chart (Appendix B) provided with the 131 Declaration. *See* Ex. 1102 at 1017-18. As discussed and shown above, the cited evidence from the 262 Provisional in that chart shows how the inserter detachably engages with the recesses (*e.g.*, via the three gripping arms/bosses). *Id.* Petitioner and its expert cannot overcome evidence by simply ignoring it and resting on one, conclusory sentence.

In sum, Petitioner has failed to show the Examiner materially erred in determining the 262 Provisional evidenced reduction to practice.

2. The Examiner did not materially err in determining the monthly progress reports showed diligence

After reviewing the 131 Declaration and extensive supporting evidence, the Examiner determined that the submitted monthly progress reports (Exhibits 3-7 to the Declaration) showed the inventors were diligent during the critical period:

Exhibits 3-7 show adequate diligence to constructive reduction to practice with monthly progress reports between before 8/05/2010 to 11/8/2010, the date of provisional application 61/411262 (Exhibit 8)[.]

Ex. 1102 at 2073-74.

As an initial matter, Petitioner's expert does not contest the Examiner's diligence determination or the supporting diligence evidence at all. Nowhere in Petitioner's expert's declaration does he even mention diligence.

As for Petitioner, it first contends that reduction to practice occurred with the filing of the non-provisional application on March 24, 2011. *See* Pet. at 13-14 (incorrectly citing March 11, 2011 as the filing date of the non-provisional application). According to Petitioner, "the critical period runs until March [24], 2011, not November 8, 2010." *Id.* at 13. Petitioner is wrong for the reasons explained above. As the Examiner correctly determined, reduction to practice occurred with the filing of the 262 Provisional on November 8, 2010. Thus, the Examiner considered the proper critical period.

As for the (proper) critical period ending November 8, 2010, Petitioner challenges the Examiner's diligence determination via two arguments: (1) the submitted progress reports do not show work on the "'plurality of recesses' feature" and (2) the reports do not show "specific facts or dates" when work was performed. (Pet. at 15-16.) Petitioner's arguments, however, do not demonstrate material error because they are legally irrelevant and factually flawed.

Petitioner cites no legal authority for the novel proposition that diligence evidence must show reasonably continuous work on *a specific claim limitation*, such as the "plurality of recesses" limitation of claim 1. That is because (as confirmed by

Petitioner’s cited cases) the law instead requires evidence that the inventor “reasonably continued activity to reduce *the invention* to practice. . . .” *See, e.g., ATI Techs. ULC v. Iancu*, 920 F.3d 1362, 1369 (Fed. Cir. 2019) (cited by Petitioner); *see also Monsanto Co. v. Mycogen Plant Sci., Inc.*, 261 F.3d 1356, 1369-70 (Fed. Cir. 2001) (upholding finding of diligence when challenging party did “not offer any reason to doubt that this evidence [of monthly recording in lab notebooks] shows activity, relevant to the reducing the claimed invention to practice.”); *Marhurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577-78 (Fed. Cir. 1996) (reference not prior art where patent owner “exercised reasonable diligence in later reducing that invention to practice”) (cited by Petitioner).

Here, the claimed invention is a “glucose monitoring assembly” comprising, generally speaking, an inserter (with a sharp) and an on body electronics unit comprising an on body electronics unit housing, a glucose sensor, and electronics. *See* Ex. 1101 at claim 1. Although the “plurality of recesses” limitation may have been cited during prosecution to distinguish prior art, it is the claims, not any one limitation, that define the inventions. *See* 35 U.S.C. § 112(b) (“The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.”); *Thorner v. Sony Comput. Entm’t Am. LLC*, 669 F.3d 1362, 1367 (Fed.

Cir. 2012) (“It is the claims that define the metes and bounds of the patentee’s invention.”) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005)).

In this case, the 131 Declaration, including the monthly progress reports, unequivocally shows reasonably continuous work on a “glucose monitoring assembly” from just before August 5, 2010, through at least the filing of the 262 Provisional on November 8, 2010—the constructive reduction to practice. The inventors testify that the “subject matter of the pending claims relates to a major product development project ... during the 2010 calendar year for a new glucose monitoring assembly (‘GMA’) comprising: (1) an inserter and (2) an on body electronics unit that included a glucose sensor and on body electronics.” Ex. 1102 at 490 (referring to this work as the “GMA Project”). They then step through the five monthly progress reports describing some of the work performed by them (and others) on the GMA Project.

Each report opens with a listing of “Key accomplishments” for the month. Ex. 1102 at 529, 535, 542, 549 and 556. The accomplishments list work done on various GMA Project components such as the “Inserter,” “On Body [Unit,]” and “On/body Electronics,” as well as the collective “PDU” assembly. *See id.* at 528-62.⁵ For

⁵ Petitioner admits that the described accomplishments include work on claimed components such as the inserter, on body unit, and sharp. *See, e.g.*, Pet. at 16.

example, the reports describe accomplishments for the inserter, on body unit, sharp, and electronics, including, among other things, (1) ordering models and creating mockups, (2) prototyping manufacturing tools, (3) conducting FEA analyses, (4) completing insertion studies, (5) making design and manufacturing improvements, (6) modifying ASIC specifications for the on body unit electronics, (7) conducting inserter pain and bleeding studies, and (8) designing PCB layouts. *See* Ex. 1102 at 528-62.

As for Petitioner’s argument that the Examiner erred because the reports do not show “specific facts or dates” when work was actually performed, Petitioner overstates the law and understates the facts.

“A ‘variety of activities’ may corroborate an inventor’s testimony of reasonable diligence and such corroborating evidence is considered ‘as a whole’ under a rule of reason.” *Perfect Surgical Techniques, Inc. v. Olympus Am., Inc.*, 841 F.3d 1004, 1007-08 (Fed. Cir. 2016). “[D]iligence need not be perfectly continuous—only reasonably continuous.” *Arctic Cat Inc. v. GEP Power Prods., Inc.*, 919 F.3d 1320, 1331 (Fed. Cir. 2019). Summary evidence is acceptable, and a daily accounting of work activity is not required. *Monsanto*, 261 F.3d. at 1369-70 (upholding diligence determination where “with regard to each of the gaps [of two weeks to a month], the notebook entries suggest that the work on [the claimed invention] was ongoing without interruption, despite the lack of daily entries. The

suggestion arises from the description in the notebook entries of ongoing experiments through the period. . . .”); *Perfect Surgical*, 841 F.3d at 1009 (“That an inventor overseeing a study did not record its progress on a daily, weekly, or even monthly basis does not mean the inventor necessarily abandoned his invention or unreasonably delayed it.”); *Draeger v. Bradley*, 156 F.2d 64, 67 (CCPA 1946) (affirming diligence determination based on “weekly and monthly reports.”).

As for the facts, each progress report is dated and summarizes monthly “Key accomplishments” (*i.e.*, completed work) on the GMA Project throughout the critical period. The nature of the accomplishments—such as prototyping tools, creating mockups, conducting FEA analysis, conducting studies, and designing PCB layouts—conveys reasonably continuous work throughout each month. The inventors confirmed this by testifying the reports “summarize the continuous work for each month on various aspects of the GMA Project.” Ex. 1102 at 495; *id.* at 498 (“these monthly GMA Project progress reports, at Exhibit 3-7, reflect continuous and diligent work from just before August 5, 2010 to at least November 8, 2010”). Petitioner cannot credibly argue these extensive accomplishments took mere days, leaving long stretches of inactivity each month.

Given the scope of the claimed inventions and the details outlined in the monthly progress reports along with the inventors’ sworn testimony, the Examiner

did not err in concluding the reports “show adequate diligence[.]” Ex. 1102 at 2073-74.

Accordingly, Petitioner raises the “same arguments previously ... presented to the Office” by challenging the Examiner’s priority determination, thus meeting the first *Advanced Bionics* factor. *Advanced Bionics*, IPR2019-01469, Paper 6 at 8. Petitioner, however, failed to meet its burden to show that the Examiner “erred in a manner material to the patentability of the challenged claims.” *Id.* Consequently, the Board should refuse to institute trial under § 325(d).

D. Petitioner Has Failed To Show Its Grounds Are Reasonably Likely To Succeed Under § 314(a) Because Thomas-005 Is Not Prior Art

The 131 Declaration submitted during prosecution of the 335 Patent is substantial. It sets forth testimony from all four inventors, provides detailed claim charts mapping conception and reduction to practice evidence to the then-pending (now issued) claims, and provides substantial evidence of conception, reduction to practice, and diligence. Petitioner does not contest conception. Instead, Petitioner disagrees with the Examiner’s conclusions about the evidence and argues it cannot discern a claimed limitation (“a plurality of recesses”) from a degraded copy of a figure from the inventors’ reduction to practice document and that the inventors’

diligence evidence is insufficient. But the law and facts belie Petitioner’s arguments.
See supra.

As shown above, when all of the evidence is considered, which Petitioner and its expert did not do, it compels only one conclusion—the Challenged Claims antedate Thomas-034 and Thomas-005. And because both Grounds in the Petition rely on Thomas-005, Petitioner cannot show a reasonable likelihood of prevailing on any Challenged Claim. Thus, if the Board is not inclined to deny institution under § 325(d), it should find that Petitioner’s Grounds are not reasonably likely to succeed and deny institution under § 314(a).

IV. PETITIONER HAS ALSO FAILED TO SHOW ITS GROUNDS ARE REASONABLY LIKELY TO SUCCEED FOR OTHER REASONS

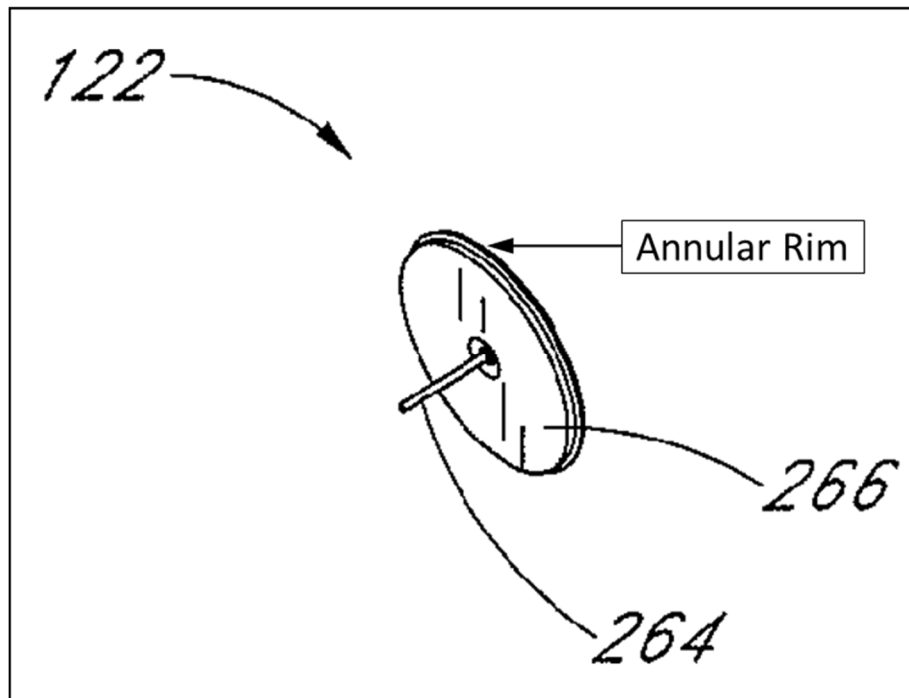
Besides the failed priority challenge, the Petition fails substantively for many other reasons. However, for purposes of this Preliminary Response, Patent Owner will not step through all of them. That is because the Petition fails for at least one additional fundamental reason. Even assuming Petitioner’s proposed combinations would be made—and to be clear, they would not be—they fail to meet all of the limitations of the 335 Patent’s sole independent claim. *See, e.g., Broadcom Ltd. v. Invensas Corp.*, IPR2017-00831, Paper 8 at 2 (P.T.A.B. July 25, 2017) (denying institution “because the Petition does not account properly for all the limitations of independent claims 1 and 9”). In particular, Petitioner’s cited art does not disclose “a plurality of recesses disposed on a periphery of the on body electronics unit

housing, ... wherein the plurality of recesses is detachably engaged with the inserter,” which, hereinafter, is referred to as the “plurality of peripheral OBU⁶ housing recesses” limitation. Consequently, Petitioner is not likely to succeed in proving that any Challenged Claim is unpatentable.

The Petition asserts two Grounds, both of which rely on Thomas-005 as the primary reference. Pet. at 3. Petitioner correctly acknowledges that Thomas-005’s on body unit lacks the claimed “plurality of peripheral OBU housing recesses” limitation. *See, e.g., id.* at 22, 24-25, 29-31. Petitioner instead relies on Raymond (Ex. 1110) and Turner (Ex. 1111)—two fluid delivery devices, not glucose sensor inserters—for this missing limitation. *See id.* at 35-42. Petitioner also cites “background” references purportedly showing the knowledge of a person of skill in the art. *See, e.g., id.* at 20-21, 37. But none of these references fills in the missing “plurality of peripheral OBU housing recesses” limitation. Indeed, Petitioner resorts to inaccurate and/or misleading characterizations of this cited art to try to create the impression that the missing limitation was known.

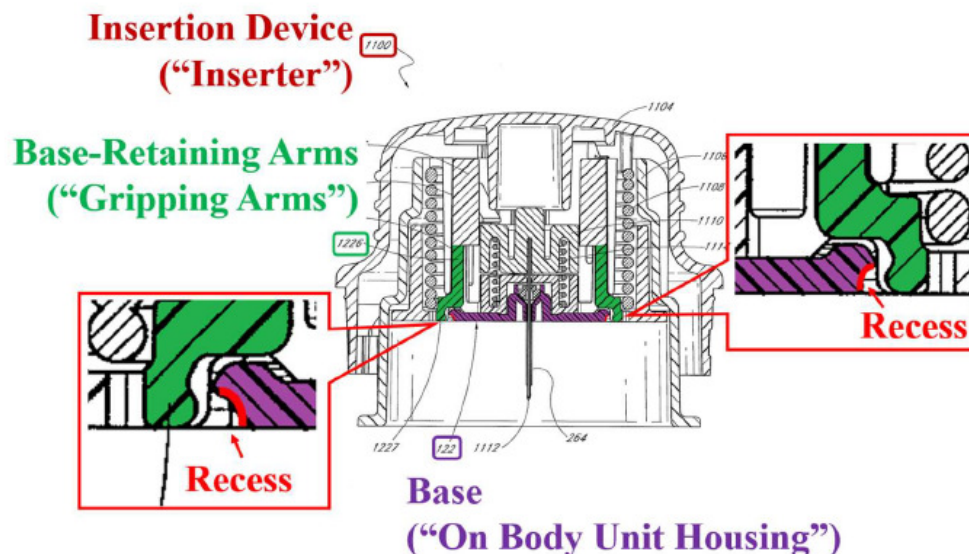
⁶ For simplicity, hereinafter, Patent Owner will refer to on body units as “OBUs.” The OBU of the Challenged Claims specifically includes a “housing” as well as “electronics coupled with [a] glucose sensor.” Ex. 1101 at claim 1.

Petitioner first relies on Raymond for the “plurality of peripheral OBU housing recesses” limitation. Indeed, Petitioner repeatedly represents that Raymond discloses a plurality of OBU housing recesses. *See, e.g., id.* at 26-27, 29, 35-36. **But it does not.** Raymond is directed to an assembly for inserting a cannula of an infusion device that serves as a conduit for delivering medication to the user. Raymond says nothing about glucose sensors, sensor electronics (on body or otherwise), or the like. Setting aside those differences, Raymond’s infusion device base 122, or alleged OBU, does not have any recesses. Instead, the base 122 has only a single annular rim. This annular rim is shown, for example, in Figure 18 of Raymond:



Ex. 1110 at Fig. 18 (excerpt, annotations added). Knowing that Raymond’s lack of OBU housing recesses is fatal to its proposed combinations, Petitioner creates the

erroneous impression that Raymond discloses a plurality of OBU recesses by using cross-sectional views from Raymond and labeling multiple alleged recesses. Here is one sample annotated image that Petitioner uses in its Petition:



Raymond, FIG. 29 (annotated)

See, e.g., Pet. at 36, 49. However, what Petitioner labels as multiple recesses *truly are not recesses at all*—it is simply a cross-section of Raymond’s OBU annular rim. See also Ex. 1110 at ¶123 (in some embodiments “the base-retaining feet 1227 extend beneath a bottom edge of the base 122”). It is surprising that Petitioner continues to advance this mischaracterization of Raymond given that the Opposition Division of the European Patent Office (“EPO”) rejected Petitioner’s same inaccurate argument in an opposition involving a patent related to the 335 Patent:

D10 [Raymond] does not appear to disclose any on-body electronics. Contrary to Opponent 1's position, however, *it also seems not to disclose recesses on an on-body unit housing*.

Opponent 1 [*i.e.*, Petitioner] refers to fig. 26 and 29 as showing recesses; however, feet 1227 of arms 1226 *do not appear to engage base 122 at a plurality of recesses*. Paragraph [0123] merely discloses that the feet clamp, grasp or otherwise engage the base, and *the base is not shown to have recesses* (see also fig. 18). Rather, it appears that the feet grasp *a rim on the base*.

For the above reasons, claim 1 as granted appears to involve an inventive step.

Ex. 2103 at ¶¶21.2, 21.5.

Tacitly acknowledging that Raymond lacks OBU housing recesses, Petitioner then alternatively asserts that it would be obvious to add OBU housing recesses to the Thomas-005 + Raymond combination (even though neither reference discloses them). Pet at 36-37. Petitioner alleges a skilled person would do so “to securely engage the [OBU] to the inserter.” *Id.* at 37; *see also, e.g., id.* at 20-21. However, as an initial matter, Petitioner's assertion makes no sense because the change proposed by Petitioner is unnecessary. As Petitioner and its expert admit, Raymond's pre-existing design already secures the OBU within its inserter. Pet. at 25; Ex. 1103 ¶40 (same). There is no suggestion that Raymond's securing is inadequate or deficient

in any way (nor does Petitioner so allege). There is simply no need to make Raymond's complex assembly even more complex. *See, e.g., In re Schweickert*, 676 F. App'x 988, 995 (Fed. Cir. 2017) (reversing Board's obviousness determination where proposed modification of prior art is "unnecessary" because prior art "already" performs function of proposed additional feature and "would do little more than add unwanted cost and complexity to the system").

Even ignoring that fundamental flaw in Petitioner's arguments, Petitioner's Grounds still fail. To prop up its assertion that it would be obvious to add a plurality of peripheral OBU housing recesses to Thomas-005 + Raymond, Petitioner alleges that it was commonly "known" to use such recesses to secure an OBU to an inserter. *See, e.g., Pet. at 20-21, 37.* As purported proof, Petitioner cites five sample references allegedly disclosing this feature. *See, e.g., id. at 20* (citing Exs. 1118, 1140, 1142, 1157, 1111), 37. But yet again, Petitioner's assertion is both misleading and wrong. First, for four of the five references, Petitioner cites the substantively identical relevant disclosure:⁷

⁷ At least three of the four references are from the same assignee and share common applications in their priority chain. *See Exs. 1118, 1140, 1142.*

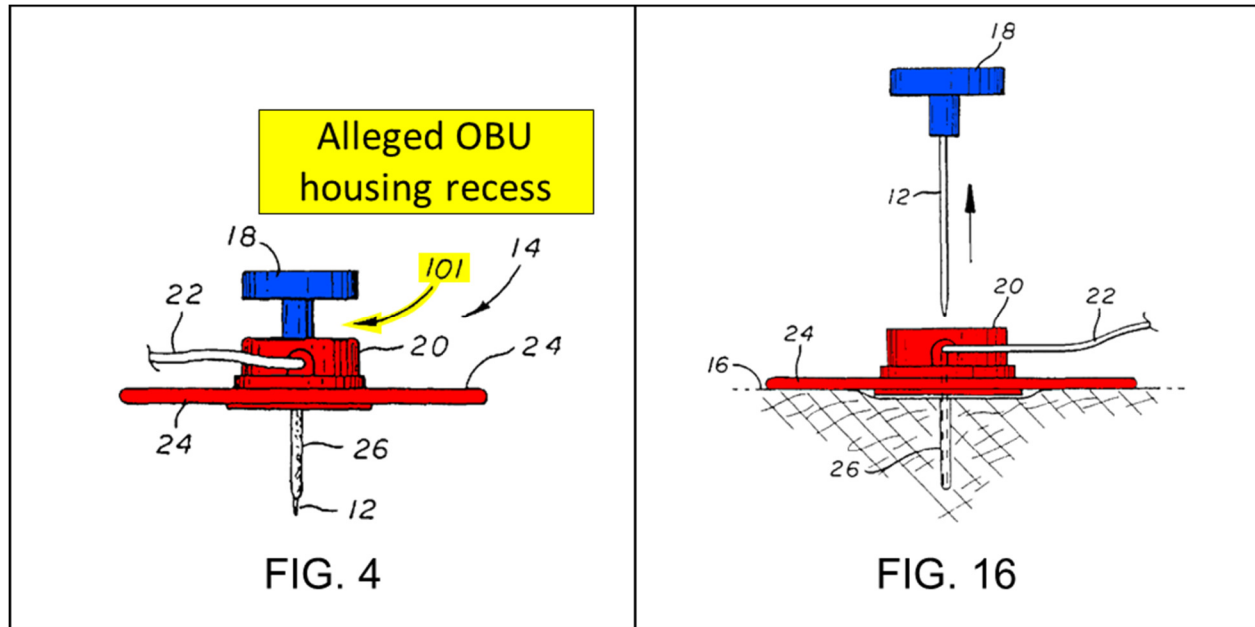
Ex. 1118 at [0011] Ex. 1140 at 2:45-57 Ex. 1142 at [0010]	Ex. 1157 at [0015]
“The plunger head includes a safety lock mechanism to retain the insertion set against projection from the injector barrel. In one preferred form, the safety lock mechanism comprises at least one and preferably a pair of safety lock arms for engaging and retaining the insertion set when the plunger is retracted from a fully advanced position. Each safety lock arm includes a cam lobe for engaging an appropriately shaped recess on the insertion set to prevent release thereof from the plunger head, unless and until the plunger head is returned to the fully advanced position. In such fully advanced position, the shape of the cam lobe permits quick and easy separation of the injector from the insertion set with a minimal separation force.”	“The plunger head ~~includes~~ <u>may optionally include</u> a safety lock mechanism to retain the insertion set against projection from the ~~injector~~ <u>inserter</u> barrel. ~~In one preferred form~~ <u>According to an embodiment</u>, the safety lock mechanism comprises at least one ~~and preferably a pair of~~ safety lock ~~arms~~ <u>arm(s)</u> for engaging and retaining the insertion set when the plunger is retracted from a fully advanced position. Each safety lock arm ~~includes~~ <u>may optionally include</u> a cam lobe for engaging an appropriately shaped recess on the insertion set to prevent release thereof from the plunger head, unless and until the plunger head is returned to the fully advanced position. In such fully advanced position, the shape of the cam lobe ~~permits~~ <u>may permit</u> quick and easy separation of the ~~injector~~ <u>inserter</u> from the insertion set with a minimal separation force.”

Id. (citing Exs. 1118, 1140, 1142, 1157). In other words, as shown in the above table, the disclosure from these four references is truly just one disclosure. Even worse, contrary to the impression created by Petitioner’s excerpted quotes from these four references, ***they do not disclose OBU housing recesses at all*** (let alone a plurality of them on the periphery of the OBU housing as required by the Challenged Claims). For example, Petitioner quotes one of the references as follows:

[T]he safety lock mechanism comprises ... preferably a pair of safety lock arms Each safety lock arm includes a cam lobe for engaging an appropriately shaped recess of the ***insertion set***.

Pet. at 20 (quoting [0011] of Ex. 1118; brackets and ellipses in original); *see also*, e.g., *id.* at 20 (equivalent quote from Ex. 1157), 37 (quoting Ex. 1118). From this quote, the reader is incorrectly led to believe that the recited “insertion set” is the OBU. Not so. In those four references, the “insertion set” referred to is actually a combination of a (a) needle hub coupled to a needle and (b) an OBU housing (where the needle hub and needle do not remain on the body). *See*, e.g., Ex. 1118 at [0119] (referring to “the hub 18 and housing 20 of the insertion set”); *compare id.* at [0011]-[0012], *with* [0119]. Critically, the “recess” cited by Petitioner in these references is ***not an OBU housing recess*** (nor is it a ***plurality*** of recesses). Indeed, it is not a recess ***in any component***. Rather, the singular feature in the needle hub-OBU housing assembly that is referred to as a “recess” (101 below) truly is a space

between two components (i.e., the needle hub 18 (blue below) and the housing 20 (red below)):



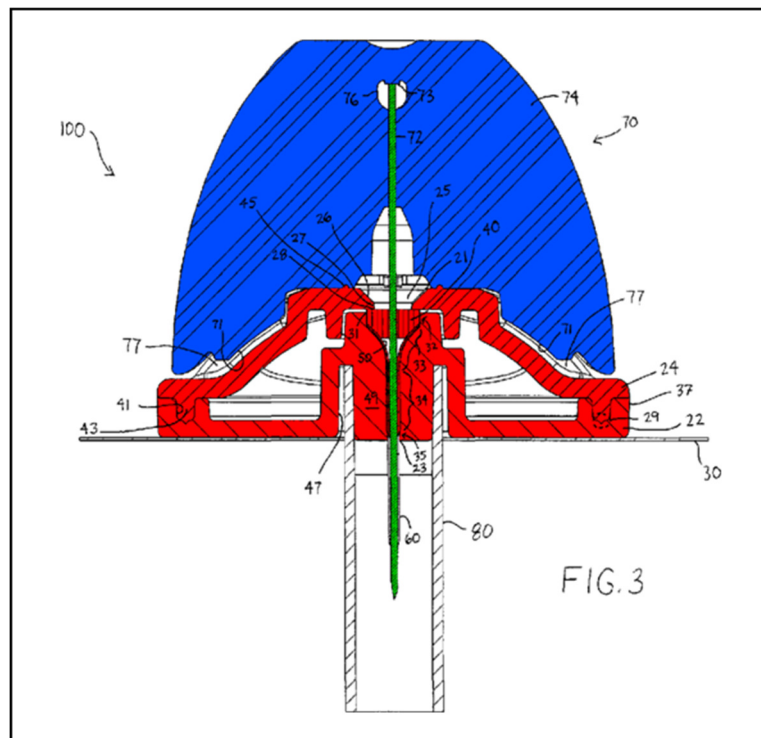
Ex. 1118 at Figs. 4 (excerpt, annotations added), 16; *see also id.* at [0119] (describing how “safety lock arms 94” fit into “a recess 101 defined between the hub 18 and housing 20 of the insertion set”). In short, these four “background” references do not address the missing “plurality of peripheral OBU housing recesses” limitation. To the contrary, they do not show any OBU housing recesses at all (let alone a plurality). Again, the Opposition Division of the EPO has already rejected Petitioner’s same factually inaccurate argument:

D1 [same as Petitioner’s Ex. 1118] does not appear to disclose a plurality of recesses on an on-body unit housing, comprising a first recess in a spaced relationship to a second recess.

Opponent 1 [*i.e.*, Petitioner] refers to element 101 in fig. 7 of D1 as recesses. What is referred to as recess 101 in D1 is, however, merely a single spacing between hub 18 and housing 20, compare fig. 4.

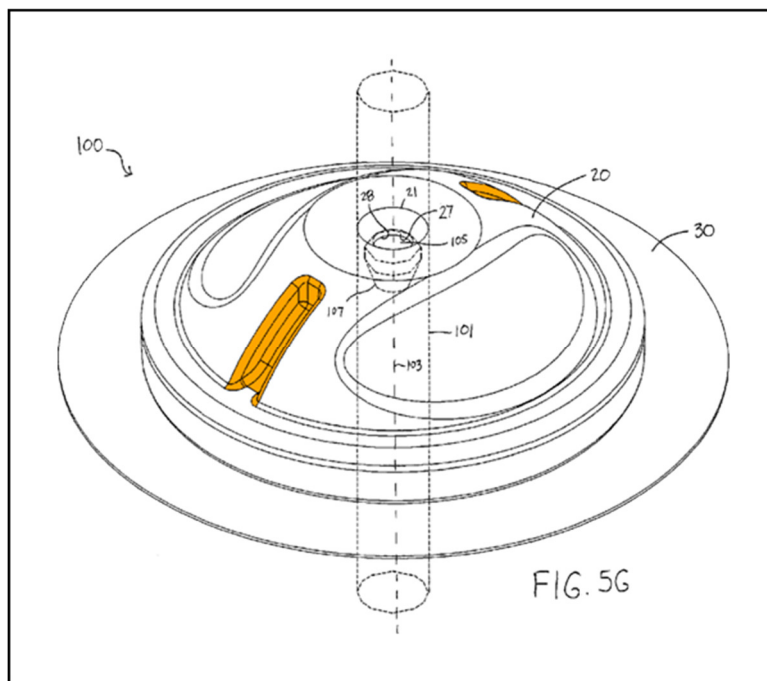
Ex. 2103 at ¶21.1.

Still needing to fill the “plurality of peripheral OBU housing recesses” gap in its argument, Petitioner looks for any reference that discloses OBU housing recesses regardless of their location or purpose. That last reference is Turner. *See* Ex. 1111. Turner is directed to a fluid delivery device comprising (a) a needle hub 74 (called “insertion device hub 74”) (blue below) coupled to a needle 72 (green below) and (b) a body 20 (the alleged OBU) (red below) with a cannula for delivering fluid to a patient:



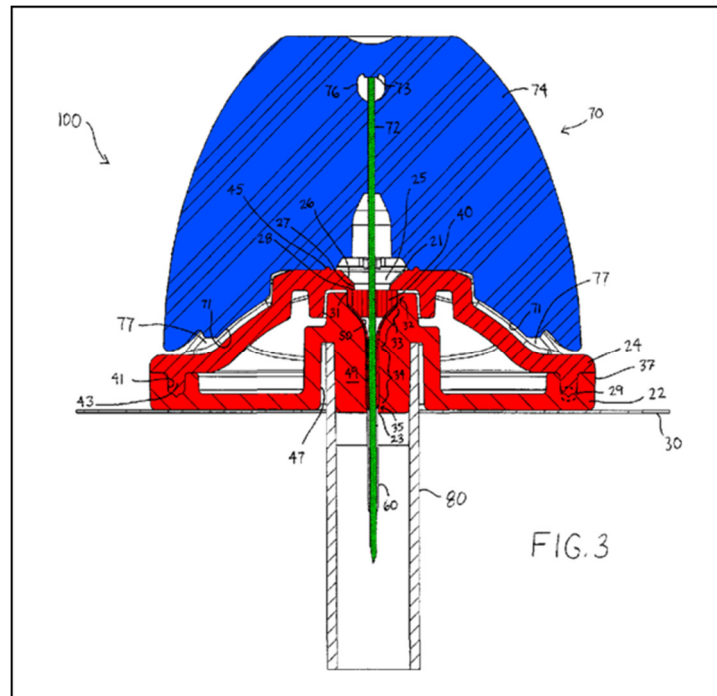
Id. at Fig. 3, ¶¶[0067-68]. Turner says nothing about glucose sensors, sensor electronics (on body or otherwise), or the like. Setting aside those differences, for Ground 1, Petitioner purports to cite Turner as a background reference (*i.e.*, it is the fifth of the five allegedly “known” references mentioned above). Pet. at 20-21, 38-39. In Ground 2, Petitioner expressly cites Turner. *See id.* at 43. Either way, the end result is the same—Turner does not fill the gap.

As an initial matter, the cited Turner recesses (orange below) are vertically-extending recesses on the upper surface of Turner’s OBU (closer to the center), not on the housing periphery (as the Challenged Claims require):

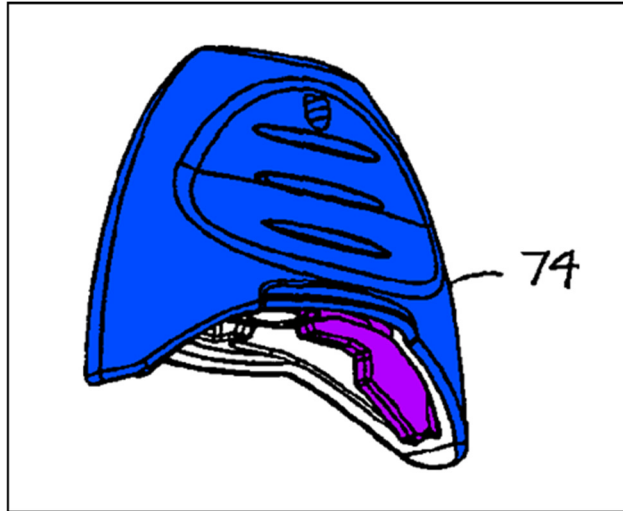


Ex. 1111 at Fig. 5G. This recess location and orientation is not happenstance—it is a necessity of Turner’s design. For example, Turner’s recesses are designed to

interact with vertically-extending protrusions from Turner's needle hub 74. Because the periphery of Turner's OBU (red below) extends beyond the width of Turner's hub 74 (blue below), Turner's recesses could not be on the OBU periphery (if so, they would not be able to interact with hub 74 as required):



Id. at Fig. 3. Further, the protrusions of Turner's hub 74 extend vertically “in a downstream or downward direction” from an interior part of the hub as shown by the example colored in purple in Figure 2B below, thus further necessitating that Turner's recesses be on the OBU upper surface away from the periphery:



Id. at [0069], Fig. 2B (excerpt).

Next, Petitioner argues that a skilled person would add Turner’s recesses to Thomas-005 + Raymond to “secure” the OBU to the inserter. *See, e.g.*, Pet. at 20-21 (citing Turner to allegedly show that “plural recesses for securing transcutaneous medical devices to an inserter was known”) (capitalization removed), 28 (“[Turner’s] protrusions and recesses are configured to secure the fluid delivery device in a particular position relative to the insertion device.”). But as noted above, such an addition is unnecessary—Raymond’s pre-existing inserter already secures the OBU (as Petitioner admits). More critically, the cited Turner “recesses” are not for securing an OBU within an inserter via detachable engagement. Indeed, they are

not for securing the OBU to anything at all.⁸ Rather, the cited Turner recesses serve an entirely different purpose, *i.e.*, to prevent rotation between Turner’s ***needle hub*** and ***OBU***. *See, e.g.*, Ex. 1111 at [0069].

Knowing these facts are fatal to its Turner-based combinations, Petitioner alternatively argues that a skilled person would use Turner’s cited recesses to prevent rotation between the ***OBU*** and ***inserters*** of Thomas-005 + Raymond. Pet. at 39; *see also id.* at 32. But this argument fails to address the claimed inventions (*e.g.*, which are directed to ***securing*** the OBU within the inserter). *See, e.g.*, Pet. at 19 (“The concepts claimed in the ’335 patent—namely, inserters configured to ***secure*** on body units therein...”); Ex. 1103 at ¶28 (same). The argument also ignores the cited Turner teaching. Turner teaches preventing rotation between ***the needle hub and an OBU***, not an OBU and an inserter (wherein the inserter advances the OBU from a

⁸ Turner does teach securing its OBU to the needle hub, but does so via a friction fit between the needle and the septum 40 of the OBU, not via Turner’s recesses. Ex. 1111 at [0099] (“[I]n the depicted embodiment, the friction force between insertion device 70 [*i.e.*, the needle hub and needle] ... and septum 40 is greater than the friction force between body 20 and the needle guard 80” such that removing the needle guard will not separate the body from the needle hub/needle).

proximal position within the inserter to a distal position). This is just one of many reasons why Petitioner’s last-ditch Turner-based “anti-rotation” argument fails.

In short, Petitioner simply ignores the specific location and purpose of Turner’s recesses. Instead, Petitioner places them in a self-serving location and orientation of its choosing—and for a different purpose than taught by Turner—to try to meet the Challenged Claims. That is improper hindsight and unsupportable. Notably, once again, the EPO’s Opposition Division rejected Petitioner’s same attempts to misapply Turner’s inapposite teachings:

Opponent 2 [Petitioner’s related German entity] argues that D21 [Turner] discloses in fig. 2A and paragraph [0069] protrusions (71) on the insertion device (70) [*i.e.*, the needle hub coupled to the needle] that extend to engage recesses (77) in the cap element (24) of body (20). According to [Turner] however, ***the protrusions and recesses serve to prevent rotation of the insertion device (70) [needle hub with needle] relative to the body (20)***. In contrast, the gripping arms and recesses according to granted claim 1 serve to hold the on-body housing (322) in place and to maintain the proper height location of the on-body housing (322), see paragraph [0258] of the original application and granted claim 1: “ ... gripping arms configured to be engaged with a corresponding recess ... when the on body electronics unit is in the proximal position”). ***It thus appears that the skilled person would not consult [Turner] when seeking means for holding the on-body unit housing of D14 in place.***

Ex. 2103 at ¶21.3 (underlining in original).

Finally, Petitioner alleges that Patent Owner made “admissions” about Turner in a German proceeding involving an unrelated patent. Pet. at 39-41. Tellingly, Petitioner provides no context or details about these alleged admissions. That is no accident. That is because, when the proper context and details are provided, it is clear that Patent Owner’s purported “admissions” in fact reinforce Patent Owner’s positions herein and further refute Petitioner’s Grounds.

In the German proceeding, Petitioner is asserting European Patent No. 3 928 688 B1 (“EP 688”) against Patent Owner. Ex. 2104. Claim 1 of EP 688 recites “a needle hub and an on-skin sensor assembly” wherein the needle hub comprises “a base ... comprising an anti-rotation feature ... [and] configured to be at least partially disposed in an aperture ... of the on-skin sensor assembly ... wherein the anti-rotation feature is configured to prevent rotation of the base [of the needle hub] ... within the aperture [of the on-skin sensor assembly].” Ex. 2104 at 62-63. In other words, *claim 1 of EP 688 is generally directed to preventing rotation between the needle hub and OBU (i.e., “on-skin sensor assembly”) similar to Turner*. In that proceeding, Patent Owner argued that claim 1 of EP 688 was not inventive because, *inter alia*, Turner teaches preventing rotation between a needle hub and an OBU—the same as Patent Owner argues here:

D4 [Turner] discloses a needle hub (insertion device hub 74) comprising rotation restriction protrusions 71, which engages complementary rotation-restricting recesses 73 on the body 20 [*i.e.*, the

OBU], *preventing rotation of the needle hub relative to the [OBU]*, ...

As a result, the anti-rotation feature disclosed in [claim 1 of EP 688] does not involve an inventive step as the skilled person would transfer the protrusions for preventing rotation of the hub 74 disclosed in [Turner] to a CGM device.

Ex. 1165 at 65-67. Thus, Patent Owner’s alleged “admissions” in Germany actually reinforce and are consistent with Patent Owner’s Turner-related positions here.

In closing, none of Petitioner’s cited art discloses the “plurality of peripheral OBU housing recesses” limitation. Consequently, Petitioner has failed to show “that there is a reasonable likelihood that [it] would prevail with respect to [any Challenged Claim] in the petition.” 35 U.S.C. § 314(a).

V. CONCLUSION

For the foregoing reasons, the Board should deny institution.

Date: January 18, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that the Patent Owner's Preliminary Response to Petition for *Inter Partes* Review Pursuant to 37 C.F.R. § 42.107 in connection with *Inter Partes* Review Case IPR2023-01397 was served on this 18th day of January 2024 by electronic mail to the following:

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CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), the undersigned attorney for the Patent Owner declares that this Patent Owner Preliminary Response has a total of 9,817 words, according to Microsoft Word® word count tool, excluding the parts of the Response exempted by 37 C.F.R. § 42.24(a)(1).

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