

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIFESCAN GLOBAL CORPORATION,
Petitioner,

v.

PHC HOLDINGS CORPORATION,
Patent Owner.

IPR2019-01127
Patent 8,480,878 B2

Before GRACE KARAFFA OBERMANN, JEFFREY W. ABRAHAM, and
AVELYN M. ROSS, *Administrative Patent Judges*.

ABRAHAM, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

Lifescan Global Corporation (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting *inter partes* review of claims 1–8 and 12–18 of U.S. Patent No. 8,480,878 B2 (Ex. 1001, “the ’878 patent”). PHC Holdings Corporation (“Patent Owner”) filed a Preliminary Response to the Petition (Paper 8, “Prelim. Resp.”).

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314; 37 C.F.R. § 42.4(a) (2018). The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted “unless the Director determines . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

For the reasons set forth below, upon considering the Petition, Preliminary Response, and evidence of record, we determine the information presented in the Petition fails to establish a reasonable likelihood that Petitioner would prevail with respect to at least one of the challenged claims. Accordingly, we deny the Petition, and do not institute an *inter partes* review.

A. Related Proceedings

Petitioner states that as of the filing date of the Petition, it is not aware of any related matters. Pet. 10. Patent Owner identifies several patents and patent applications as related matters. Paper 4, 2–3. Patent Owner also notes that Petitioner filed a petition seeking to institute *inter partes* review of US Patent No. 8,349,157 B2, which is a child of the ’878 patent. Prelim. Resp. 3; IPR2019-01128, Paper 1.

B. The '878 Patent

The '878 patent, titled “Biosensor, Thin Film Electrode Forming Method, Quantification Apparatus, and Quantification Method,” issued on July 9, 2013. Ex. 1001, at code (45), (54). The '878 patent is directed to “a biosensor which quantifies a substrate included in a sample liquid.”

Ex. 1001, 1:29–35. The '878 patent explains that biosensors are utilized in the medical diagnostics and food industries, and can be used to measure, *inter alia*, glucose, lactic acid, cholesterol, and amino acids in sample liquids (e.g., blood). Ex. 1001, 1:51–55.

The biosensors disclosed in the '878 patent contain insulating supports, an “electrode part” containing at least a working electrode and a counter electrode, a specimen supply path for introducing the sample liquid to the electrodes, and a reagent layer for quantifying the substrate included in the sample liquid. Ex. 1001, 4:21–28. The '878 patent discloses particular arrangements of the specimen supply path, reagent layer, and electrodes formed using a simple manufacturing method to increase the accuracy of each biosensor and to “easily form biosensors having the same performance.” Ex. 1001, 4:5–17, 4:38–46.

C. Illustrative Claim

Petitioner challenges claims 1–8 and 12–18 of the '878 patent. Claim 1 is the only independent claim challenged and is reproduced below:

1. A biosensor for quantifying a substrate in a sample liquid comprising:

an insulating support;

a working electrode formed from an electrically conductive layer that is made of a noble metal and is provided on a surface of the insulating support;

a reagent layer on the working electrode;

a spacer layer provided on and covering part of the reagent layer, where the spacer layer defines a supply path for bringing the sample liquid into contact with the reagent layer and where the supply path formed by the spacer layer is narrower than the reagent layer; and

a cover provided on the spacer layer, where the cover comprises a counter electrode formed from an electrically conductive layer that is made of a noble metal and is provided on an inner surface of the cover;

wherein a portion of the counter electrode and a portion of the working electrode are in the supply path, and

wherein part of the reagent layer is in the supply path.

Ex. 1001, 35:14–32.

D. The Asserted Unpatentability Challenges

Petitioner contends claims 1–8 and 12–18 of the '878 patent are unpatentable based on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)
1–3, 8, 12–15, 17, 18	102	Heller ¹
4–6	103	Heller, Bhullar, ² Hodges ³
7	102	Heller, Todd, ⁴ Vitos ⁵

¹ WO 98/35225, published Aug. 13, 1998 (Ex. 1002).

² US 6,662,439 B1, issued Dec. 16, 2003 (Ex. 1005).

³ US 5,942,102, issued Aug. 24, 1999 (Ex. 1013).

⁴ B.D. Todd and R.M. Lynden-Bell, *Surface and bulk properties of metals modelled with Sutton-Chen potential*, Surface Science 281 (1993), 191–206 (Ex. 1011).

⁵ L. Vitos et al., *The surface energy of metals*, Surface Science 411 (1998), 186–202 (Ex. 1012).

Claim(s) Challenged	35 U.S.C. §	Reference(s)
16	103	Heller, Ito, ⁶ Applicant Admitted Prior Art (AAPA)
1–3, 8, 12, 14, 15, 17, 18	102	Ohara ⁷
4–6	103	Ohara, Bhullar, Hodges
7	102	Ohara, Todd, Vitos
13	103	Ohara, Ikeda '417, ⁸ Bhullar
16	103	Ohara, Ito, AAPA
1–3, 8, 12–15, 17, 18	102	Liamos ⁹
4–6	103	Liamos, Bhullar, Hodges
7	102	Liamos, Todd, Vitos
16	103	Liamos, Ito, AAPA
1–8, 12–18	103	Blatt, ¹⁰ Heller, Ohara, Liamos, Bhullar, Hodges, Ikeda '417, Ito, AAPA

Petitioner also relies on a declaration from John L. Smith, Ph.D. (Ex. 1008, “the Smith Declaration”), and a declaration from Mr. Geoffrey McGarraugh (Ex. 1009, “the McGarraugh Declaration”).

⁶ US 5,384,028, issued Jan. 24, 1995 (Ex. 1010).

⁷ US 6,193,873 B1, issued Feb. 27, 2001 (Ex. 1003).

⁸ US 6,212,417 B1, issued Apr. 3, 2001 (Ex. 1006).

⁹ US 6,616,819 B1, issued Sept. 9, 2003 (Ex. 1004).

¹⁰ EP 0 287 833 A1, published Oct. 26, 1988 (Ex. 1014).

II. ANALYSIS

A. Claim Construction

In an *inter partes* review filed after November 13, 2018, we construe claim terms according to the standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–17 (Fed. Cir. 2005) (en banc). 37 C.F.R. § 42.100(b) (2018). Under *Phillips*, claim terms are afforded “their ordinary and customary meaning.” *Phillips*, 415 F.3d at 1312. “[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Id.* at 1313. “Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” *Id.*

Petitioner proposes constructions for four terms, “vertical,” “wettability index,” “air hole,” and “correcting unit.” Pet. 19–20. Patent Owner argues that the Board does not need to construe any claim terms at this time. Prelim. Resp. 5.

After reviewing the parties’ arguments and evidence, we determine that we do not need to expressly construe any terms for purposes of this Decision. See *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.”)).

B. Claims 1–3, 7, 8, 12–15, 17, 18 – Alleged Anticipation by Heller

Petitioner contends claims 1–3, 8, 12–15, 17, and 18 are unpatentable as anticipated by Heller. Pet. 22–34. Petitioner directs us to portions of Heller that purportedly disclose all the limitations of the challenged claims. Petitioner also relies on the Smith Declaration and McGarraugh Declaration to support its arguments.

1. Heller (Ex. 1002)

Heller relates to analytical sensors for determining the concentration of a biological analyte in a small volume of sample. Ex. 1002, 1:22–27.¹¹ Heller discloses sensors that include a working electrode, counter electrode, and a sample chamber. Ex. 1002, 8:28–31, Figs. 1–4. In one embodiment, a non-leachable redox mediator is immobilized on the working electrode, the sample chamber holds a sample in electrolytic contact with the working electrode, the counter electrode faces the working electrode and forms a measurement zone within the sample chamber between the two electrodes, and a sorbent material is positioned in the sample chamber and measurement zone to reduce the volume of sample needed for measurement. Ex. 1002, 1:26–2:9, 13:30–14:4. Heller also indicates that certain embodiments may include a spacer positioned between electrodes. Ex. 1002, 16:20–26. Heller depicts these various components in different embodiments of its invention in Figures 1–4.

¹¹ For this exhibit, we cite to the original pagination of WO 98/35225 (appearing at the top of each page) as opposed to Petitioner’s pagination (appearing in the bottom, right-hand corner of each page).

2. *Claim 1*

Claim 1 of the '878 patent requires a biosensor comprising, *inter alia*, a working electrode, a reagent layer on the working electrode, and “a spacer layer provided on and covering part of the reagent layer, where the spacer layer defines a supply path for bringing the sample liquid into contact with the reagent layer and where the supply path formed by the spacer layer is narrower than the reagent layer.” Ex. 1001, 35:21–25.

In support of its anticipation argument, Petitioner directs us to Figures 1 and 3 of Heller, which are reproduced below.

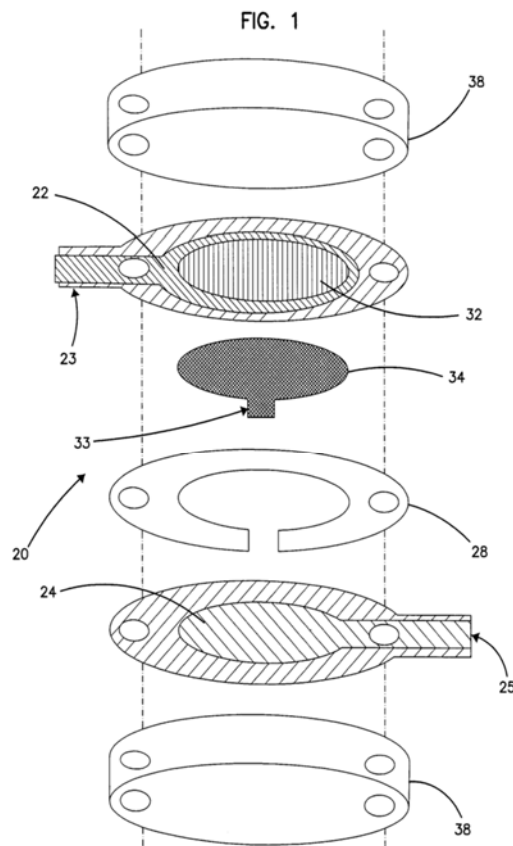


Figure 1 provides a schematic view of one embodiment of an electrochemical sensor having working electrode 22 and counter electrode 24 facing each other. Ex. 1002, 5:17–19; 13:30–32.

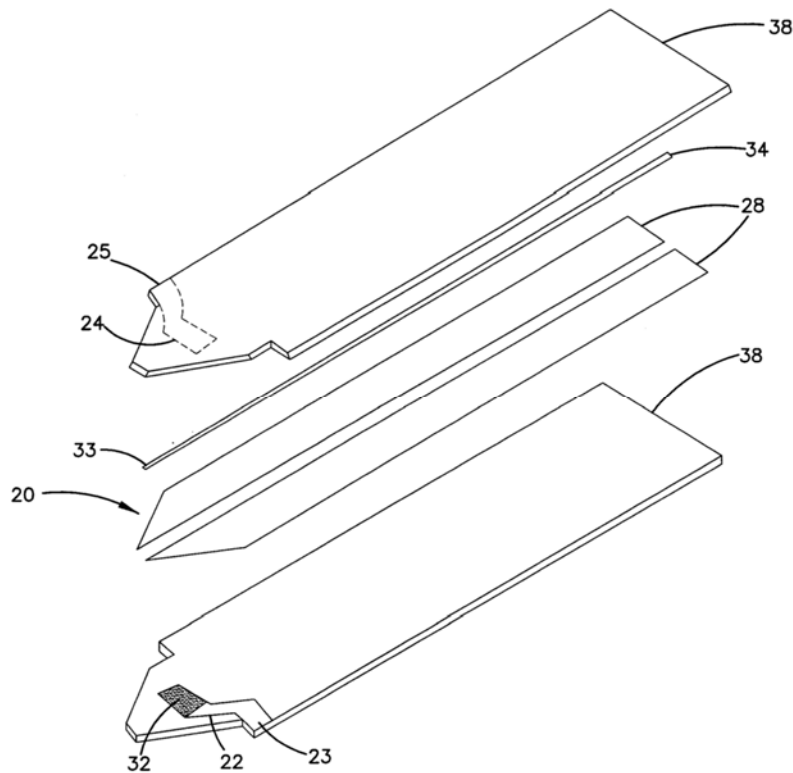


Figure 3 is a schematic view of a different embodiment of an electrochemical sensor having working electrode 22 and counter electrode 24 facing each other, and having an extended sample chamber. Ex. 1002, 5:23–26; 13:30–32.

Petitioner contends Heller discloses the spacer layer recited in claim 1 based on Heller’s discussion and illustration of sensors with working electrode 22, a reagent layer (sensing layer 32) disposed on a portion of the working layer, and spacer 28 which “often functions as a portion of the

boundary for the sample chamber 26.” Pet. 25–27 (citing Ex. 1002, 8:29–30, 9:21–22, 16:20–26). Petitioner asserts that “sample chamber 26, being defined by the spacer 28, anticipates the supply path recited in claim 1 as it allows the flow of sample liquid (e.g., blood) onto the sensor measurement zone.” Pet. 27 (citing Ex. 1002, 21:24–22:22).

Petitioner also argues Heller teaches that portions of the sensing layer “may be covered by a dielectric or other material, thereby anticipating a spacer layer on and covering part of the reagent layer as recited in claim 1.” Pet. 27. According to Petitioner, because part of the sensing layer is covered, it will not contact the sample, and, therefore, the sample supply path—defined by the covering spacer—is necessarily narrower than the reagent/sensing layer. Pet. 27.

Additionally, Petitioner argues that Figure 3 “shows that spacer 28 covers part of sensing layer 32 in the assembled sensor and that sample chamber 26 is narrower than sensing layer 32.” Pet. 27 (citing Ex. 1008 ¶ 30; Ex. 1009 ¶ 29). Petitioner also argues that Figure 1 “shows a gap in the circular spacer 28 that is narrower than the diameter of the sensing layer 32, further anticipating a narrower supply path formed by the spacer for bringing the sample liquid into contact with a reagent layer as recited in claim 1.” Pet. 28.

Patent Owner argues that Heller does not disclose a spacer layer that meets all of the requirements recited in claim 1. Prelim. Resp. 6–14. Patent Owner contends there is no text in Heller that supports Petitioner’s argument that spacer 28 covers any part of sensing layer 32. Prelim. Resp. 8. According to Patent Owner, Petitioner’s argument regarding what Figures 1 and 3, which are exploded views of sensors, allegedly show is not supported

adequately by any text in Heller or the declaration testimony of any expert witness. Prelim. Resp. 8–9. Patent Owner further argues that Petitioner’s argument relies on its declarants “imagin[ing] what the assembled sensors of Figures 1 and 3 would look like (an **unexploded** view).” Prelim. Resp. 9. In contrast, Patent Owner directs us to Figure 4, which purportedly shows an assembled sensor and the relative positions of the reagent layer 32 and sample chamber 26 defined by spacer 28. Prelim. Resp. 10–11. Patent Owner asserts that Figure 4 shows the exact opposite of what Petitioner and its experts allege Figures 1 and 3 show, namely, that spacer 28 is not provided on and does not cover any part of the reagent layer 32. Prelim. Resp. 11.

Patent Owner also disputes Petitioner’s anticipation argument based on Heller’s disclosure that the sensing layer “may be covered by a dielectric or other material.” Prelim. Resp. 12–14. Patent Owner emphasizes that the dielectric and spacer 28 are two separate components. Prelim. Resp. 12–13. Patent Owner further argues that although Heller states that the dielectric may cover a portion of the sensing layer, nothing in Heller indicates that the dielectric defines a sample supply path, as claim 1 requires. Prelim. Resp. 13.

After considering the arguments and information presented by the parties, we determine Petitioner has failed to demonstrate adequately that Heller discloses the spacer layer required in claim 1.

The spacer layer in claim 1 must cover part of the reagent layer. Ex. 1001, 35:21–22. It must also define a supply path for bringing the sample liquid into contact with the reagent layer. Ex. 1001, 35:22–24. Petitioner does not demonstrate adequately that a single component in Heller

satisfies both limitations and, thereby, represents a “spacer layer” within the meaning of claim 1.

Petitioner directs us to language in Heller supporting its assertion that spacer 28 defines a supply path for bringing sample liquid into contact with the reagent layer. Pet. 27 (citing Ex. 1002, 16:20–26 (spacer 28 “often functions as a portion of the boundary for sample chamber 26 as shown in Figures 1-4”), 21:24–22:22). Petitioner, however, fails to direct us to any portion of Heller that discusses spacer 28 covering sensing layer 32.

Instead, Petitioner argues spacer 28 in Heller covers part of sensing layer 32 based on the orientation of components depicted in Figure 3. Pet. 27–28. Petitioner cites to a paragraph in the Smith Declaration and one in the McGarraugh Declaration to support its argument. In those paragraphs, each declarant states that Figure 3 “shows that spacer 28 covers part of sensing layer 32 in the assembled sensor.” Ex. 1008 ¶ 30; Ex. 1009 ¶ 29.

Figure 3 of Heller, however, does not show an “assembled sensor.” Instead, it provides an exploded view of a sensor, and does not show spacer 28 actually covering sensing layer 32. Thus, Petitioner and its declarants do not even rely on the actual figure in Heller, but instead rely on an imaginary adaptation (an unexploded version) of the figure. Furthermore, Dr. Smith and Mr. McGarraugh offer little more than a conclusory sentence that spacer 28 covers part of sensing layer 32. See Ex. 1008 ¶ 30; Ex. 1009 ¶ 29. Neither declarant offers any evidence to support the conclusion that spacer 28 in Heller actually covers sensing layer 32. Although Dr. Smith discusses possible benefits of having a spacer that covers part of a reagent layer, he directs us to no evidence sufficient to determine that spacer 28 in Heller actually does cover the reagent layer. Ex. 1008 ¶ 30. Such

unsupported conclusions are entitled to little weight. 37 C.F.R. § 42.65(a). In sum, Petitioner does not show that Figures 1 and 3 disclose the “spacer layer” of claim 1 with anticipatory specificity.

Petitioner's reliance on Figures 1 and 3 is further undermined by its failure to address Figure 4 of Heller, which is reproduced below.

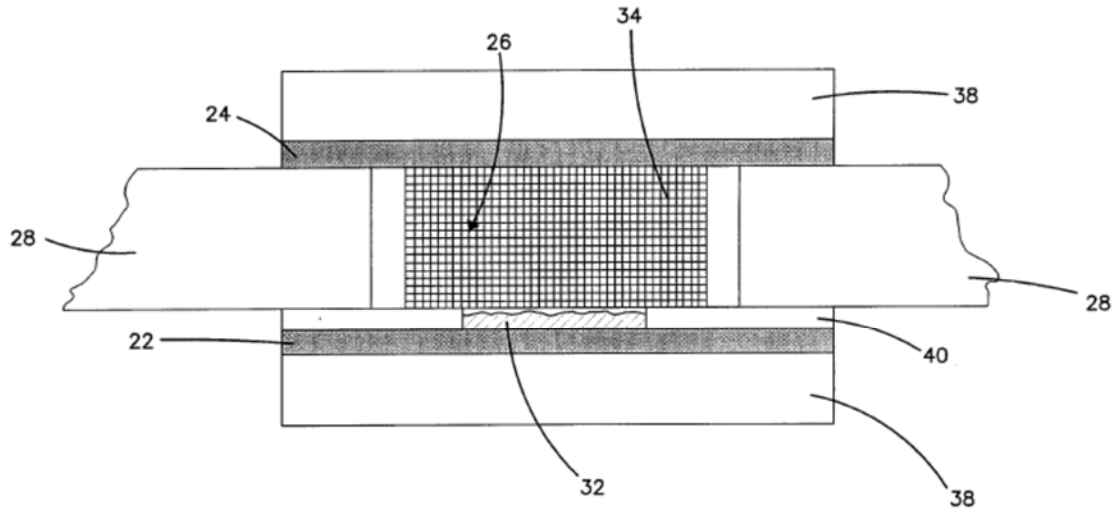


FIG. 4

Figure 4 of Heller shows the relative positions of various components of the sensor of Figures 1 and 3, including electrodes 22 and 24, sensing layer 32, spacer 28, sample chamber 26, and dielectric 40. Ex. 1002, 5:27–29, 8:28–9:3, 13:9–16. In contrast to the exploded views shown in Figures 1 and 3, Figure 4 appears to depict an unexploded, side view of a sensor. This view shows that spacer 28 does not cover any part of sensing layer 32. Thus, the only image in Heller actually providing a side view of an unexploded sensor (as opposed to the imaginary “assembled sensors” referenced in the Smith and McGarraugh Declarations) contradicts

Petitioner's arguments and the conclusions drawn by Dr. Smith and Mr. McGarraugh.

Petitioner also directs us to language in Heller that teaches portions of the sensing layer may be coated by “a dielectric or other material.” Pet. 27 (citing Ex. 1002, 10:3–8, 13:9–16). Although this language addresses a component that covers the reagent layer, Petitioner does not direct us to evidence sufficient to demonstrate that the “dielectric or other material” satisfies any other requirement of the sensing layer of claim 1, such as defining a sample supply path. In fact, when discussing the dielectric or other layer, Petitioner maintains that a different element in Heller (the covering spacer) defines the supply path. Pet. 27. As a result, the “dielectric or other material,” which Heller describes as actually covering the sensing layer, does not have all of the properties of the spacer layer required in claim 1. Furthermore, Figure 4 depicts dielectric 40 and spacer layer 28 as separate components.

In view of this, we determine that Petitioner has failed to demonstrate adequately that Heller discloses a component corresponding to the spacer layer recited in claim 1. Therefore, Petitioner has failed to demonstrate sufficiently that Heller discloses all limitations of claim 1, and, as a result, Petitioner has not shown a reasonable likelihood that it would prevail with respect to its argument that claim 1 is anticipated by Heller.

3. Dependent Claims 2, 3, 7, 8, 12–15, 17, and 18

Claims 2, 3, 7, 8, 12–15, 17, and 18 each depend from claim 1, and, therefore, include all of the limitations of claim 1. In view of our determination that Petitioner fails to establish that Heller discloses all

limitations of claim 1, we reach the same result for claims 2, 3, 7, 8, 12–15, 17, and 18.

C. Claims 4–6 and 16 – Alleged Obviousness under 35 U.S.C. § 103

Claims 4–6 and 16 depend from claim 1. Petitioner contends these claims are unpatentable as obvious in view of the combined teachings of Heller, Bhullar, and Hodges (claims 4–6) and Heller, Ito, and Applicant admitted prior art (“AAPA”) (claim 16). Pet. 34–36, 38–40. Petitioner, however, does not argue or provide evidence that Bhullar, Hodges, Ito, or the AAPA disclose the spacer layer required by the claims. Pet. 34–36, 38–40. Accordingly, none of the references that form the basis of Petitioner’s obviousness challenges cure the aforementioned deficiency regarding its challenge to independent claim 1. See Pet. 34–36, 38–40. As a result, for the reasons discussed above, we reach the same result for these claims as we do for claim 1.

D. Claims 1–3, 7, 8, 12, 14, 15, 17, 18 – Alleged Anticipation by Ohara

Petitioner contends claims 1–3, 7, 8, 12, 14, 15, 17, and 18 are unpatentable as anticipated by Ohara. Pet. 40–46, 48. Petitioner directs us to portions of Ohara that purportedly disclose all the limitations in the challenged claims. Petitioner also relies on the Smith Declaration and McGarraugh Declaration to support its arguments.

1. Ohara (Ex. 1003)

Ohara describes an electrochemical assay method for measuring analyte concentrations in biological fluids. Ex. 1003, 1:6–10. In particular, Ohara measures an analyte concentration of a biological fluid “applied to an

electrochemical diagnostic strip of the type that includes juxtaposed working and reference electrodes.” Ex. 1003, 2:36–40. According to Ohara,

The present invention provides a method and apparatus for measuring analyte concentration electrochemically, which includes defining with great accuracy the time at which a sample that is applied to the reaction zone of an electrochemical diagnostic strip bridges the gap between the electrodes. Determining the sample application time (more precisely, the sample detection time; we use the terms interchangeably) accurately permits greater accuracy and precision of the assay done on the sample.

Ex. 1003, 3:10–14.

2. Claim 1

Claim 1 requires a biosensor comprising, *inter alia*, a working electrode, a reagent layer on the working electrode, and “a spacer layer provided on and covering part of the reagent layer, where the spacer layer defines a supply path for bringing the sample liquid into contact with the reagent layer and where the supply path formed by the spacer layer is narrower than the reagent layer.” Ex. 1001, 35:21–35.

In support of its anticipation arguments, Petitioner directs us to Figure 5 of Ohara, reproduced below. Pet. 40–42.

FIG. 5

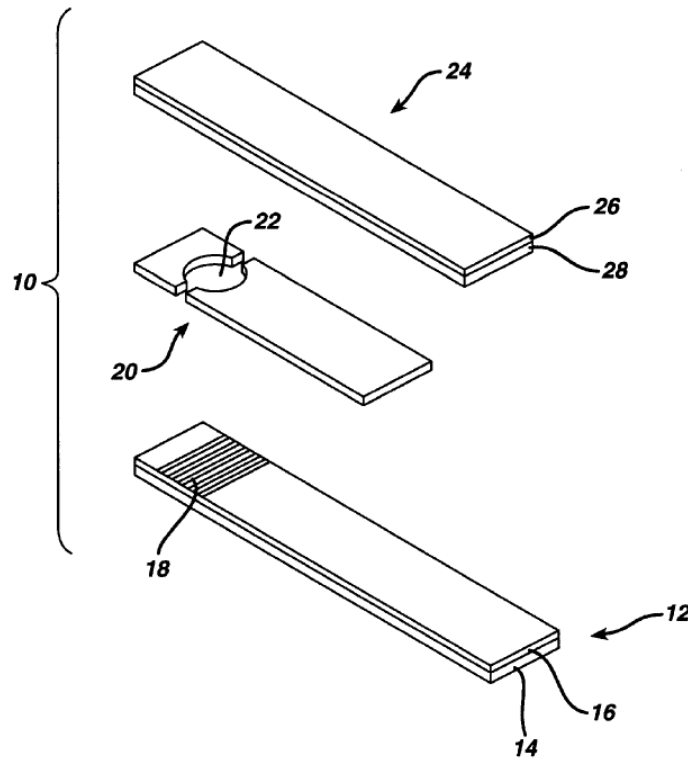


Figure 5 “depicts an electrochemical device suitable for use in the assay method” described by Ohara. Ex. 1003, 3:53–54. Ohara explains that device 10 comprises a substrate 12 including a polyester base and a palladium coating 16 which together form a working electrode. Ex. 1003, 5:25–29. Ohara states that “[a] dry reagent . . . is deposited near one end 18 of the electrode.” Ex. 1003, 5:29–30. Spacing layer 20, having a cutout 22 that delineates a sample chamber, is positioned in between top layer 24 and the working electrode. Ex. 1003, 5:31–33. Top layer 24 includes polyester layer 26 and gold coating layer 28 which together form the reference electrode. Ex. 1003, 5:33–36.

Relying on the testimony of Dr. Smith and Mr. McGarraugh, Petitioner contends that Ohara discloses the spacer layer recited in claim 1 because:

FIG. 5 [of Ohara] shows that spacing layer 20 in Ohara covers part of reagent layer at one end 18 of the electrode. Visual inspection of FIG. 5 reveals that, due to the cutout 22, the spacer layer 20 defines a supply path for bringing a sample liquid into contact with the reagent layer near the end 18 of the electrode and also that the supply path is narrower than the reagent layer.

Pet. 42 (citing Ex. 1008 ¶¶ 50–51; Ex. 1009 ¶ 47).

Patent Owner argues that, although the reagent may be placed *at one end 18* of the electrode, “there is no teaching in Ohara that the reagent layer is item 18 or that the reagent layer covers the entire end 18 of the electrode.” Prelim. Resp. 16. Patent Owner contends that the reagent layer is not actually shown in Figure 5, and Ohara provides no information about the size and shape of the reagent layer itself. Prelim. Resp. 17 (“No information is given as to the boundaries, length, width, and location of the reagent layer.”). According to Patent Owner, because Ohara provides little information about the reagent layer, “there is absolutely no support for Petitioner’s assumptions ‘that the spacing layer 20 in Ohara covers part of the reagent layer’ and that ‘the supply path is narrower than the reagent layer.’” Prelim. Resp. 17 (citing Pet. 42).

On this record, we determine that Petitioner has not demonstrated sufficiently that Ohara discloses the spacer layer recited in claim 1. In particular, Petitioner does not direct us to any teaching in Ohara demonstrating that spacer layer 20 actually covers the reagent layer in Ohara.

Petitioner's reliance on a "visual inspection" of Figure 5 for its anticipation argument is not persuasive, as Figure 5 presents an exploded view of the sensor. Petitioner does not direct us to an image of an assembled version of Ohara's sensor that would allow us to determine whether spacer layer 20 actually covers the reagent layer, as opposed to simply being arranged above it in an exploded view.

Nor does Petitioner direct us to any language in Ohara that indicates spacer layer 20 covers the reagent layer. The portion of Ohara upon which Petitioner relies for this limitation states that "[a] dry reagent, consisting of buffer, mediator, and enzyme, is deposited *near one end 18* of the electrode." Ex. 1003, 5:29–31. This language merely indicates that the reagent is deposited near one end of the electrode, and offers little insight into the particular dimensions, shape, and placement of the reagent layer, or the arrangement of the spacer layer in relation to the reagent layer.

The lack of any discussion in Ohara regarding the dimensions of the reagent layer and the relative arrangement of the spacer layer and reagent layer further undermines Petitioner's reliance on Figure 5 of Ohara. "[I]t is well established that patent 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." *Hockerson-Halberstadt, Inc., v. Avia Group Int'l Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000); *see also In re Olson*, 212 F.2d 590, 592 (CCPA 1954) ("Ordinarily drawings which accompany an application for a patent are merely illustrative of the principles embodied in the alleged invention claimed therein and do not define the precise proportions of elements" shown in those drawings).

Although Petitioner’s declarants address the spacer layer limitation, they offer little more than conclusory opinions based on a visual inspection of Figure 5. Aside from the aforementioned flaws in Figure 5, such unsupported conclusory opinions are entitled to little weight. *See* 37 C.F.R. § 47.65(a). We further note that Dr. Smith and Mr. McGarraugh inaccurately refer to “*reagent layer 18* at one end of the electrode,” which is inconsistent with Ohara’s description of that component. *See* Ex. 1008 ¶ 50 (emphasis added); Ex. 1009 ¶ 47 (emphasis added).

In view of the foregoing, we are not persuaded by Petitioner’s arguments that Ohara discloses a spacer layer that covers the reagent layer, as claim 1 requires, with anticipatory specificity. Thus, we determine Petitioner has failed to demonstrate sufficiently that Ohara discloses all limitations of claim 1 and, as a result, that Petitioner has not shown a reasonable likelihood that it would prevail with respect to its argument that claim 1 is anticipated by Ohara.

3. Dependent Claims 2, 3, 7, 8, 12, 14, 15, 17, and 18

Claims 2, 3, 7, 8, 12, 14, 15, 17, and 18 each depend from claim 1, and, therefore, include all of the limitations of claim 1. In view of our determination that Petitioner fails to establish that Ohara discloses all limitations of claim 1, we reach the same result for claims 2, 3, 7, 8, 12, 14, 15, 17, and 18.

E. Claims 4–6, 13, and 16 – Alleged Obviousness under 35 U.S.C. § 103

Claims 4–6, 13, and 16 depend from claim 1. Petitioner contends these claims are unpatentable as obvious in view of the combined teachings of Ohara, Bhullar, and Hodges (claims 4–6), Ohara, Ikeda ’417, and Bhullar

(claim 13), and Ohara, Ito, and AAPA (claim 16). Pet. 46–50. Petitioner, however, does not argue or provide evidence that Bhullar, Hodges, Ito, Ikeda '417, or the AAPA disclose the spacer layer required by the claims.

Accordingly, none of the references that form the basis of Petitioner's obviousness challenges cure the aforementioned deficiency regarding its challenge to independent claim 1. See Pet. 46–50. As a result, for the reasons discussed above, we reach the same result for these claims as we do for claim 1.

F. Claims 1–3, 7, 8, 12–15, 17, 18 – Alleged Anticipation by Liamos
Petitioner contends claims 1–3, 7, 8, 12–15, 17, and 18 are unpatentable as anticipated by Liamos. Pet. 51–67. Petitioner directs us to portions of Liamos that purportedly disclose all the limitations in the challenged claims. Petitioner also relies on the Smith Declaration and McGarraugh Declaration to support its arguments.

1. Liamos (Ex. 1004)

Liamos is directed to “[a] small volume sensor . . . for determining the concentration of an analyte, such as glucose or lactate, in a biological fluid, such as blood or serum.” Ex. 1004, Abstract. In one embodiment, the sensor in Liamos has a working electrode and a counter electrode formed on separate substrates, and a spacer layer between the substrates defining a sample chamber that provides access to the working electrode and counter electrode. Ex. 1004, 7:28–43.

2. Claim 1

Claim 1 requires a biosensor comprising, *inter alia*, a working electrode, a reagent layer on the working electrode, and “a spacer layer provided on and covering part of the reagent layer, where the spacer layer

defines a supply path for bringing the sample liquid into contact with the reagent layer and where the supply path formed by the spacer layer is narrower than the reagent layer.” Ex. 1001, 35:21–25.

In support of its anticipation arguments, Petitioner directs us to one embodiment in Liamos having a working electrode on one substrate, a counter electrode on a second substrate, and a spacer that defines a sample chamber and provides spacing between the electrodes when they are positioned opposite and facing one another. Pet. 54–57 (citing Ex. 1004 Figs. 5A–5C, 13:28–31, 19:56–59). Petitioner argues that “Liamos also contemplates and explains the advantages of an insulating material (like the spacer 433) covering a portion of the redox mediator.”¹² Pet. 56–57 (citing Ex. 1004, 8:14–23, 11:32–45). Petitioner further argues that based on these advantages and “the figures and descriptions in Liamos describing an insulating spacer formed over electrodes to define a sample chamber (i.e., supply path),” a person of ordinary skill in the art would “understand Liamos as teaching a spacer-defined supply path narrower than a reagent layer as claimed in claim 1 of the ’878 Patent.” Pet. 57 (citing Ex. 1008 ¶ 69, Ex. 1009 ¶ 63).

Patent Owner argues that there is no teaching in Liamos that the spacer covers part of the reagent layer or that the supply path defined by the spacer is narrower than the reagent layer, as claim 1 requires. Prelim.

¹² Petitioner argues that sensing chemistry materials in Liamos form the reagent layer on the working electrode as required in claim 1. Pet. 52. Liamos states that the “sensing chemistry preferably includes a redox mediator.” Ex. 1004, 8:26–29. We understand Petitioner to use “redox mediator” interchangeably with “reagent layer” when discussing Liamos. See Pet. 57 (stating “redox mediator (i.e., reagent layer)”).

Resp. 19. Patent Owner further argues that there is no teaching in Liamos that the insulating material discussed in Liamos is part of the spacer, that these two separate elements can or should be combined, or that upon such a combination, the result would be a spacer layer meeting the limitations of claim 1. Prelim. Resp. 19–21.

After considering the arguments and information presented by the parties, we determine Petitioner has failed to demonstrate adequately that Liamos discloses the spacer layer required in claim 1.

The spacer layer in claim 1 must cover part of the reagent layer. Ex. 1001, 35:21–22. It must also define a supply path for bringing the sample liquid into contact with the reagent layer. Ex. 1001, 35:22–24. Petitioner does not demonstrate adequately that a single component in Liamos satisfies both limitations.

Although Petitioner directs us to the portion of Liamos discussing a spacer that separates the electrodes and defines a sample chamber (Ex. 1004, 13:28–31), Petitioner does not direct us to any portion of Liamos that explicitly teaches, or otherwise anticipates, the spacer covers part of the reagent layer.

We are not persuaded by Petitioner’s argument that “Liamos also contemplates and explains the advantages of an insulating material (like the spacer 433) covering a portion of the redox mediator.” Pet. 56–57. To arrive at this position, Petitioner cites to one paragraph in Liamos that indicates the spacer may be made from “an inert non-conducting material” (Ex. 1004, 11:33–45), and directs us to a separate paragraph in Liamos stating that a dielectric or other insulating material may be deposited on an electrode “over, under, or surrounding the region with the redox mediator,”

and that “[t]he dielectric material can also cover a portion of the redox mediator on the electrode” (Ex. 1004, 8:13–23).

Petitioner, however, fails to provide evidence sufficient to demonstrate that the “dielectric or other insulating material deposited on an electrode” is, or at the very least can be, the spacer in Liamos. To the contrary, the spacer and “dielectric or other insulating material” appear to comprise two different components of Liamos’ sensors that perform two different functions. For example, the portion of Liamos that discusses the “dielectric or other insulating material” appears in a section titled “Working Electrode,” which describes the formation of that particular electrode. Ex. 1004, 7:45–8:23. In that context, Liamos explains that a “dielectric or other insulating material” may be deposited on the electrode and can cover a portion of the reagent layer on the electrode, in order to “prevent chemical reactions from occurring on portions of the working electrode not coated by the mediator” in certain configurations. Ex. 1004, 8:14–24 (stating that the “covered portion of the redox mediator will not contact the sample”).

The spacer in Liamos is not described in that “Working Electrode” section. To the contrary, the figure Petitioner cites in support of its anticipation arguments depicts the spacer as a component formed separate from the electrodes. *See* Ex. 1004, Figs. 5A–5C; Pet. 53. Other figures in Liamos portray the spacer in a similar fashion. *See, e.g.*, Ex. 1004, Figs. 2, 3, 6A–6C, 7A–7C, 8A–8C, 9A–9C, 10A–10C, 11A–11C, 12A–12C, 11:28–44, 12:1–5, 13:32–15:42. Liamos teaches that the spacer can be used to keep the electrodes apart and can function as a portion of the boundary for the sample chamber. Ex. 1004, 11:32–45, 13:28–31. In view of this, although both components may be made from an insulating material, we are

not persuaded that Lamos necessarily is referring to the spacer when it states that “a dielectric or other insulating material can be deposited on the electrode over, under, or surrounding the region with the redox mediator.” Ex. 1004, 8:13–23. This is especially true considering Lamos teaches that other portions of the sensor, including the working electrode itself, can be formed from non-conducting/insulating materials. *See, e.g.*, Ex. 1004, 7:46–50, 7:63–8:4. Accordingly, we are not persuaded that Lamos discloses a spacer that covers part of the reagent layer with anticipatory specificity.

To the extent that Petitioner argues that the “dielectric or other insulating material” in Lamos (as opposed to the component expressly identified as the “spacer”) corresponds to the spacer layer recited in claim 1, we agree with Patent Owner that Petitioner has failed to demonstrate sufficiently that this component defines a supply path for bringing the sample liquid into contact with the reagent layer. Prelim. Resp. 19 (explaining that “there is no teaching in Lamos that the dielectric defines a supply path”—a circumstance that “is not surprising” given that “the dielectric or other insulating material is described as ‘waxes and non-conducting organic polymers’ that ‘can be deposited on the electrode’”) (quoting Ex. 1004, 8:14–23).

Additionally, Petitioner’s arguments about what a person of ordinary skill in the art would have understood from the various teachings in Lamos are misplaced. *See* Pet. 57. “Because the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements ‘arranged as in the claim.’” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369

(Fed. Cir. 2008) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)). As discussed above, Petitioner does not demonstrate adequately that Lamos discloses a single component possessing all of the elements of claim 1 as arranged in the claim. The question of whether a person of ordinary skill in the art could have, and would have, pieced together the different teachings from Lamos to arrive at the claimed invention could be a relevant inquiry in an obviousness analysis under 35 U.S.C. § 103. Petitioner's only argument here, however, is that Lamos anticipates claim 1 under 35 U.S.C. § 102.

In view of this, we determine Petitioner has failed to demonstrate sufficiently that Lamos discloses all limitations of claim 1. As a result, Petitioner has not shown a reasonable likelihood that it would prevail with respect to its argument that claim 1 is anticipated by Lamos.

3. Dependent Claims 2, 3, 7, 8, 12–15, 17, and 18

Claims 2, 3, 7, 8, 12–15, 17, and 18 each depend from claim 1, and, therefore, include all of the limitations of claim 1. In view of our determination that Petitioner fails to establish that Lamos discloses all limitations of claim 1, we reach the same result for claims 2, 3, 7, 8, 12–15, 17, and 18.

G. Claims 4–6 and 16 – Alleged Obviousness under 35 U.S.C. § 103

Claims 4–6 and 16 depend from claim 1. Petitioner contends these claims are unpatentable as obvious in view of the combined teachings of Lamos, Bhullar, and Hodges (claims 4–6) and Lamos, Ito, and AAPA (claim 16). Pet. 65–67. Petitioner, however, does not argue or provide evidence that Bhullar, Hodges, Ito, or the AAPA disclose the spacer layer required by the claims. Pet. 65–67. Accordingly, none of the references that

form the basis of Petitioner’s obviousness challenges cure the aforementioned deficiency regarding its challenge to independent claim 1. *See* Pet. 65–67. As a result, for the reasons discussed above, we reach the same result for these claims as we do for claim 1.

H. Claims 1–8 and 12–18 – Alleged Obviousness under 35 U.S.C. § 103 over Blatt (among others)

Petitioner contends that claims 1–8 and 12–18 would have been obvious over Blatt in view of Heller, Ohara, Liamos, Bhullar, Hodges, Ikeda ’417, Ito, and AAPA. Pet. 68–69. Petitioner also relies on the declarations of Dr. Smith and Mr. McGarraugh to support its arguments.

1. Blatt (Ex. 1014)

Blatt describes a method and test strip device for rapid testing of biological samples, in particular fluids, using a “dip and read” method. Ex. 1014, 3:18–24. Blatt explains that the structural configuration of its device is “especially well suited for use in dip and read applications when there is a need to test large volumes of liquid, such as in the case when performing urine analysis.” Ex. 1014, 3:35–41. Blatt’s capillary gap structure allows for sample volume control and uniform distribution of the sample across the reactive surface such that “[a]ny excess sample will simply drain off the outer surfaces of the device.” Ex. 1014, 3:42–4:1.

2. Analysis

Petitioner argues that each element of claims 1–8 and 12–18 is anticipated or rendered obvious by Heller, Ohara, Liamos, Bhullar, Hodges, Ikeda ’417, Ito, and/or Applicant-admitted prior art” and that Blatt suggests “a spacer-defined supply path narrower than a reagent layer.” Pet. 68.

According to Petitioner, Figure 3 of Blatt reproduced below, illustrates this feature.

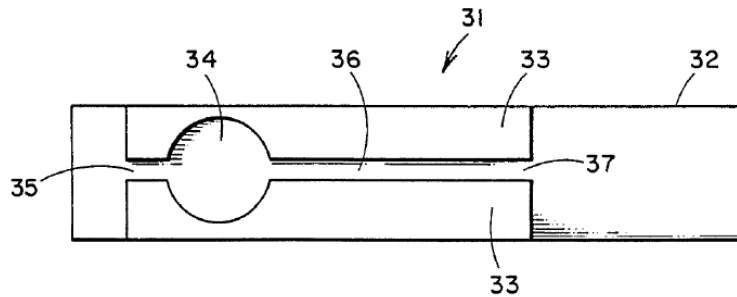


FIG. 3

Figure 3 is a top view of Blatt's capillary gap device. Ex. 1014, 4:16–18. Figure 3 depicts device 31 including handle layer 32 and spacer layer 33. Ex. 1014, 7:45–48. The sample enters through entry port 35 and into sample chamber read area 34. Ex. 1014, 7:48–53. Though the reagent layer is not shown, it “will normally extend over the entire distance of the spacer layer 33.” Ex. 1014, 7:56–58.

Petitioner asserts that because the reagent layer extends over the entire distance of the spacer layer, Blatt “disclos[es] a spacer-defined supply path that is narrower than the reagent layer.” Pet. 69. Petitioner contends that one skilled in the art would have had reason to use the spacer layout of Blatt “in order to achieve uniform distribution of a sample onto their reactive surface.” Pet. 69 (citing Ex. 1014, 3:35–46; Ex. 1008 ¶¶ 83–84; Ex. 1009 ¶¶ 77–78).

Patent Owner argues that “the Petitioner does not discuss any teachings of the seven other prior art references and ‘admitted prior art’ that Petitioner is somehow combining with [Blatt].” Prelim. Resp. 23. Patent Owner further contends that “the Petition likewise fails to specify what features of each of the eleven challenged claims are missing in Blatt that are

cured by some teachings of the seven other secondary references” and that “the Petition does not articulate reasoning with some rational underpinnings to support obviousness based on a combination of specific references.”

Prelim. Resp. 23–24.

We agree with Patent Owner that the Petition lacks requisite clarity and does not satisfy Petitioner’s burden of identifying “how the construed claim is unpatentable under the statutory ground on which petitioner challenges the claims, . . . [by] specify[ing] where each element of the claim is found in the prior art patents or printed publications relied upon.” 37 C.F.R. § 42.104(b)(4); *see also* 37 C.F.R. § 42.22(a)(2) (requiring “[a] full statement of the reasons for the relief requested, including a detailed explanation of the significance of the evidence including material facts, and the governing law, rules, and precedent.”). According to our Trial Practice Guide, “parties should avoid submitting a repository of all the information that a judge could possibly consider, and instead focus on concise, well-organized, easy-to-follow arguments supported by readily identifiable evidence of record.” 77 Fed. Reg. 48,756, 48,763 (Aug. 14, 2012).

Here, Petitioner dedicates two pages to its discussion of how the challenged claims would have been obvious over the combined teachings of eight references. Pet. 68–69. Petitioner does not detail how each of the eight references are to be combined or which teachings from each reference are relied upon to suggest each limitation of the claims.¹³ Furthermore, neither Petitioner nor Petitioner’s declarants provide a reason that the skilled

¹³ It is also unclear whether Petitioner intends for Ground 14 to be a single ground based on a combination of eight references or multiple grounds based on different references in combination with Blatt.

artisan would have initially sought the teachings of Blatt—describing a large volume, dip and read method that relies on color change to indicate concentration of an analyte—in combination with Heller, Ohara, and Lamos (among others)—each testing small volume samples implementing electrochemical methods that use changes in current between electrodes to indicate the concentration of the analyte. *Compare* Ex. 1014, 1:5–15, 3:18–24, 12:8–41 *with* Ex. 1002, 1:5–13, 3:25–4:9, Ex. 1003, 2:55–3:4, Ex. 1004, 1:6–10, 1:53–58, 2:55–3:2. Petitioner and Petitioner’s declarants also fail to address whether a person of ordinary skill in the art would have had a reasonable expectation of successfully achieving the claimed invention. *See Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1360 (Fed. Cir. 2012). Petitioner’s arguments instead amount to an invitation for us to cobble together arguments, search for pertinent facts, and inject our own reasoning. That is not our role. *See Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularly . . . the evidence that supports the grounds for the challenge to each claim”)); *see DeSilva v. DiLeonardi*, 181 F.3d 865, 866–67 (7th Cir. 1999) (“A brief must make all arguments accessible to the judges, rather than ask them to play archeologist with the record.”).

Therefore, on this record, Petitioner has failed to show a reasonable likelihood of demonstrating that claims 1–8 and 12–18 are rendered obvious in view of Blatt in combination with Heller, Ohara, Lamos, Bhullar, Hodges, Ikeda ’417, Ito, and AAPA.

III. CONCLUSION

For the foregoing reasons, Petitioner has not demonstrated a reasonable likelihood that at least one challenged claim of the '878 patent is unpatentable over the prior art of record. Accordingly, we decline to institute *inter partes* review.

IV. ORDER

It is hereby

ORDERED that the Petition is denied, and no trial is instituted.

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Patent 8,480,878 B2

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