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Paper 45
Date: November 2, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT DIABETES CARE INC.,
Petitioner,

v.

DEXCOM, INC.,
Patent Owner.

IPR2022-00921
Patent 10,993,642 B2

Before MITCHELL G. WEATHERLY, JAMES A. TARTAL, and FREDERICK C. LANEY, *Administrative Patent Judges.*

WEATHERLY, *Administrative Patent Judge.*

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

We have authority to hear this *inter partes* review under 35 U.S.C. § 6(c). We enter this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Briefly, we determine that Abbott Diabetes Care Inc. ("Petitioner") has proven by a preponderance of the evidence that claims 1,

5, 7, 8, 66, 67, 89, and 91 (the "challenged claims") of U.S. Patent No. 10,993,642 B2 (Ex. 1001, "the '642 patent") are unpatentable. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

A. Background

Petitioner filed a corrected petition for *inter partes* review of the challenged claims. Paper 5 ("Petition" or "Pet."). DexCom, Inc. ("Patent Owner") timely filed a Preliminary Response. Paper 11 ("Prelim. Resp."). On November 3, 2022, based on the record before us at the time, we instituted an *inter partes* review of all challenged claims on all grounds alleged, as indicated in the table below. Paper 15 ("Institution Decision" or "Dec.").

Claim(s) challenged	35 U.S.C. §[1]	Reference(s)
1, 5, 7, 8, 66, 67	103	Heller,[2] Flaherty[3]
89	103	Heller, Flaherty, Shults[4]
91	103	Heller, Flaherty, Shults, Mastrototaro[5]

[1] The Leahy-Smith America Invents Act ("AIA") included revisions to 35 U.S.C. §§ 102 and 103 that became effective March 16, 2013. The application for the '642 patent was filed on November 3, 2020. Ex. 1001, code (22). That application also claims priority as a "continuation" of a large number of applications filed before March 16, 2013. *Id.* at code (62). For example, the '642 patent claims priority to a series of "continuation" applications with the earliest filed application having been filed February 22, 2006. *Id.* We apply the pre-AIA versions of those statutes.

[2] International Patent Publication No. WO 02/058537 A2 (Ex. 1005, "Heller")

[3] U.S. Patent No. 7,220,387 B2 (Ex. 1019, "Flaherty").

[4] U.S. Patent No. 6,001,067 (Ex. 1020, "Shults").

[5] U.S. Patent No. 6,424,847 B1 (Ex. 1023, "Mastrototaro").

Claim(s) challenged	35 U.S.C. §[1]	Reference(s)
1, 5, 66, 67	103	Gross,[6] Flaherty
7, 8	103	Gross, Flaherty, Mastrototaro
89, 91	103	Gross, Flaherty, Shults

After we instituted this review, Patent Owner filed a Patent Owner Response in opposition to the Petition (Paper 25, "PO Resp.") that was supported by a Declaration from Gail D. Baura, Ph.D. (Ex. 2010). Petitioner filed a Reply in support of the Petition (Paper 31, "Reply"), and Patent Owner filed a Sur-reply (Paper 37, "Sur-reply"). Patent Owner did not move to amend any claim of the '642 patent. We heard oral argument on August 4, 2023, and a transcript of the argument has been entered in the record (Paper 44 ("Tr.")).

Petitioner moved to exclude certain portions of Dr. Baura's testimony based on her alleged lack of qualifications to provide expert opinion or because her testimony allegedly lacked a basis in facts or data or "reliable principles or methods." Paper 38, 1 ("Motion" or "Mot."). Patent Owner opposed the Motion. Paper 39 ("Opposition" or "Opp."). Petitioner filed a Reply in support of the Motion. Paper 41 ("Mot. Reply").

B. Real Parties-in-Interest

Petitioner states that Abbott Diabetes Care Inc., Abbott Diabetes Care Sales Corp., and Abbott Laboratories are the real parties in interest and Abbott Diabetes Care Inc, is the Petitioner. Pet. 3. Petitioner points out that "Abbott Diabetes Care Inc. is directly owned by Abbott Laboratories," and "Abbott Diabetes Care Inc. directly owns Abbott Diabetes Care Sales Corp."

[6] U.S. Patent No. 6,275,717 B1 (Ex. 1004, "Gross").

Id. Patent Owner states that DexCom Inc., is the sole real party in interest. Paper 8, 1.

C. Related Proceedings

Patent Owner identified as related proceedings the following co-pending district court proceedings:

- *DexCom, Inc. v. Abbott Diabetes Care, Inc. et al.*, Civil Action No. 1-22-cv-00605 (D. Del.) (transferred from the U.S. District Court for the Western District of Texas, Civil Action No. 6-21-cv-00690) ("WDTX Litigation")); and
- *Abbott Diabetes Care Inc. v. DexCom, Inc.*, Civil Action No. 1-21-cv-01699 (D. Del.).

Paper 12, 4.

The parties also identify as related proceedings the petitions filed in the following Board proceedings relating to patents asserted in at least one of the district court proceedings above:

- IPR2022-00908 concerning U.S. Patent No. 10,702,193 B2;
- IPR2022-00909 concerning U.S. Patent No. 10,702,215 B2;
- IPR2022-00913 and IPR2022-00914 concerning U.S. Patent No. 11,000,213 B2;
- IPR2022-00917 and IPR2022-00918 concerning U.S. Patent No. 10,980,452 B2; and
- IPR2022-00921 and IPR2022-00922 concerning U.S. Patent No. 10,993,642 B2.

Id. at 3; Pet. 3–4.

D. The '642 Patent

The '642 patent is entitled "Analyte Sensor" and particularly "relates to systems and methods for transcutaneous measurement of glucose in a host." Ex. 1001, 1:1, 1:32–33. An exemplary embodiment illustrated in the '642 patent, Figure 1, reproduced at right depicts sensor system 10 including applicator 12, mounting unit 14, and electronics unit 16. *Id*. at 23:60–63. Mounting unit 14 includes base 24 that mounts to the host's skin and a sensor that is inserted through the host's skin. *Id*. at 23:66–24:2. Contacts 28 provide an electrical connection between the transdermal sensor and electronics unit 16, and mounting unit 14 keep the sensor in the same location under the host's skin. *Id*. at 24:2–7.

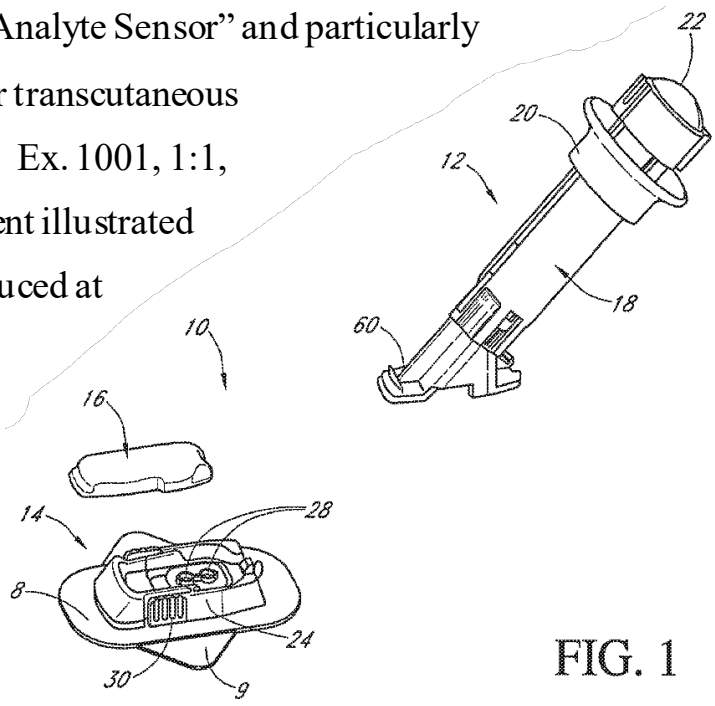

FIG. 1

Patent Owner contends that the '642 patent "discloses a number of innovations," with the claims focusing, in part, on "the ability to calibrate sensor data using 'prior sensitivity information,' 'without reliance on' or 'without a need for a reference [analyte/glucose] concentration measurement obtained after insertion'." Prelim. Resp. 4. Petitioner argues that Patent Owner previously attempted and failed to obtain claims focusing on "calibration without post-insertion reference measurements." Pet. 1–2.

E. Illustrative Claim

Three of the challenged claims, 1, 66, and 89, are independent. Independent claims 1 and 66 are directed to a "glucose monitoring system,"

and independent claim 89 is directed to a "method." Ex. 1001, 119:62–120:15 (claim 1), 126:25–49 (claim 66), 128:1–17 (claim 89).

Claim 1, which is representative, recites:

> 1.[pre] A glucose monitoring system comprising:
>
> [a] a transcutaneous glucose sensor comprising:
>
> an *in vivo* portion configured to be inserted into a body of a host; and
>
> an *ex vivo* portion configured to remain outside of the body of the host; and
>
> [b] a processor programmed to calibrate sensor data based at least in part on prior calibration information generated before insertion of the transcutaneous glucose sensor in the host,
>
> [c] wherein the sensor data is associated with a glucose concentration of the host,
>
> [d] wherein the prior calibration information comprises prior sensitivity information associated with the transcutaneous glucose sensor,
>
> [e] wherein the prior calibration information is associated with a sensor code,
>
> wherein the sensor code is located in or on a packaging holding the transcutaneous glucose sensor,
>
> [f] wherein the processor is programmed to calibrate the sensor data without a need for a reference analyte concentration measurement obtained after insertion of the *in vivo* portion of the transcutaneous glucose sensor.

Id. at 119:62–120:15 (as corrected in Certificate of Correction and with bracketed labels by Petitioner to ease discussion).

II. RULE 42.104

Patent Owner substantively reasserts the argument from its Preliminary Response that Petitioner has run afoul of the requirements of 37 C.F.R. § 42.104(b)(3) by failing to expressly interpret claim limitations relating to a "processor programmed to calibrate sensor data" under 35 U.S.C. § 112, ¶ 6. PO Resp. 1–2. The panel addressed this issue in the Institution Decision, Dec. 8–14, and again in its Decision Denying Patent Owner's Request on Rehearing of Decision Granting Institution of *Inter Partes* Review, Paper 27, 3–7. Both decisions included dissents by Judge Tartal on this issue. Dec. dissent; Paper 27, dissent.

The majority discerns no material change in the evidentiary record or arguments presented during the trial that warrants additional comment beyond what has already been expressed in the Institution Decision and Decision on Rehearing. For the same reasons expressed in those papers, the majority concludes that Petitioner has complied with all requirements set forth in 37 C.F.R. § 42.104(b).

III. ANALYSIS

A. Claim Interpretation

We interpret claims in the same manner used in a civil action under 35 U.S.C. § 282(b) "including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b). When applying that standard, we interpret the claim language as it would be understood by one of ordinary skill in the art in light of the specification. *Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1279–80 (Fed. Cir. 2017). Thus, we give claim terms their ordinary

and customary meaning as understood by an ordinarily skilled artisan. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). Only terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

We read the claims according to the principles set forth above because neither party expressly interprets any language in the independent claims. *See generally* Pet. and PO Resp. We also address below other portions of the various claims as required by our analysis.

B. The Parties' Post-Institution Arguments

In our Institution Decision, we concluded that the argument and evidence adduced by Petitioner demonstrated a reasonable likelihood that at least one of the challenged claims was unpatentable as obvious based on the challenges identified in the table in Part I.A above. Dec. 26–27. We must now determine whether Petitioner has established by a preponderance of the evidence that the specified claims are unpatentable over the cited prior art. 35 U.S.C. § 316(e) (2018). We previously instructed Patent Owner that "any arguments for patentability not raised in the [Patent Owner Response] may be deemed waived." Paper 16, 9; *see also In re Nuvasive, Inc.*, 842 F.3d 1376, 1381 (Fed. Cir. 2016) (holding that patent owner's failure to proffer argument at trial as instructed in scheduling order constitutes waiver). Additionally, the Board's Trial Practice Guide states that the Patent Owner Response "should identify all the involved claims that are believed to

be patentable and state the basis for that belief." Patent Trial and Appeal Board Consolidated Trial Practice Guide (Nov. 2019) 66.[7]

C. Legal Standards

To prevail in its challenges to the patentability of the claims, Petitioner must establish unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). "In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *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 particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1326–27 (Fed. Cir. 2008)) (discussing the burden of proof in *inter partes* review).

The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), reaffirmed the framework for determining obviousness as set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The *KSR* Court summarized the four factual inquiries set forth in *Graham* that we apply in determining whether a claim is unpatentable as obvious under 35 U.S.C. § 103(a) as follows: (1) determining the scope and content of the prior art, (2) ascertaining the differences between the prior art and the claims at issue, (3) resolving the level of ordinary skill in the pertinent art, and (4) when in

[7] *See* https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf.

evidence, considering objective evidence indicating obviousness or nonobviousness.[8] *KSR*, 550 U.S. at 406 (citing *Graham*, 383 U.S. at 17–18).

Petitioner must explain how the proposed combinations of prior art would have rendered the challenged claims unpatentable. An obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418; *accord In re Translogic Tech., Inc.*, 504 F.3d 1249, 1259 (Fed. Cir. 2007). However, Petitioner cannot satisfy its burden of proving obviousness by employing "mere conclusory statements," but "must instead articulate specific reasoning, based on evidence of record" to support an obviousness determination. *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380–81 (Fed. Cir. 2016). Petitioner also must articulate a reason why a person of ordinary skill in the art would have combined the prior art references. *NuVasive*, 842 F.3d at 1382.

At this final stage, we determine whether a preponderance of the evidence of record shows that the challenged claims would have been rendered obvious in view of the asserted prior art. We analyze the asserted grounds of unpatentability in accordance with these principles.

D. Level of Ordinary Skill

We review the grounds of unpatentability in view of the understanding of a person of ordinary skill in the art at the time of the invention. *Graham*, 383 U.S. at 17. Petitioner contends that a person of ordinary skill in the art at the time of the invention would have:

[8] Neither party relies on objective evidence in this proceeding.

> a bachelor's degree in biomedical engineering, chemical engineering, chemistry (or a related or equivalent field), and two or more years of experience researching, developing, designing and/or evaluating (or supervising the same) medical devices for measuring analyte levels, including some experience with algorithms for calibrating such devices, or equivalent experience" and that "[s]uch experience could include either formal coursework in signal processing, computer science, or electrical engineering, or could also be obtained during on-the-job experience.

Pet. 15–16.

Patent Owner does not dispute Petitioner's formulation of the level of ordinary skill. PO Resp. 8. We find that the '642 patent and the cited prior art references reflect the appropriate level of skill at the time of the claimed invention and that the level of appropriate skill reflected by those sources is consistent with the description of a person of ordinary skill in the art proposed by Petitioner. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Accordingly, for purposes of this Decision, we adopt Petitioner's asserted level of ordinary skill in the art.

E. Claims 1, 5, 7, 8, 66, and 67: Obviousness in View of Heller and Flaherty

Petitioner argues that the combined teachings of Heller and Flaherty, with context provided by the knowledge of an ordinarily skilled artisan at the time of the alleged invention, render claims 1, 5, 7, 8, 66, and 67 unpatentable as obvious. Pet. 31–53. For the reasons expressed below, we conclude that Petitioner has demonstrated by a preponderance of evidence that the combined teachings of Heller and Flaherty render claims 1, 5, 7, 8, 66, and 67 unpatentable as obvious.

1. Independent Claim 1

At the outset, we note that Patent Owner does not contest Petitioner's showing that the combined teachings of Heller and Flaherty describe every element recited in claim 1. Rather, Patent Owner argues that Petitioner's challenge to claim 1 fails because Petitioner fails to establish sufficient motivation to combine teachings of Heller and Flaherty to teach the requirements recited in element 1e. PO Resp. 14–21. For the reasons expressed below, Petitioner persuades us that the combined teachings of Heller and Flaherty render claim 1 unpatentable as obvious.

a. Preamble

The preamble for claim 1 recites: "A glucose monitoring system." Ex. 1001, 119:62. Petitioner contends, without opposition by Patent Owner, that Heller describes a system that monitors glucose. Pet. 36 (citing Ex. 1005, 8:12–16; Ex. 1002 ¶ 151). Based on our review of Petitioner's argument and the evidence supporting that argument, Petitioner persuades us that Heller describes the elements recited in the preamble.

b. Element 1a

Element 1a refers to the following portion of claim 1: "a transcutaneous glucose sensor comprising: an *in vivo* portion configured to be inserted into a body of a host; and an *ex vivo* portion configured to remain outside of the body of the host." Ex. 1001, 119:63–67 (as modified by Certificate of Correction, 5). Petitioner identifies Heller's sensor 42 "a portion of which is configured for implantation . . . into a patient" as describing the subject matter of limitation 1a. Pet. 36–37 (quoting Ex. 1005, 10:24–27 *and* citing (*id*. at 13:25–14:24, 15:9–13, 15:27–29, 34:24–29, 39:8–10, 44:25–27, 53:29–54:10, 59:1–5, 89:13–17, Figs. 2, 28B; Ex. 1002

¶ 152)). Patent Owner does not contest Petitioner's showing for element 1a. *See* PO Resp. 14–20 (arguing only that an ordinarily skilled artisan would not have been motivated to combine teachings of Heller and Flaherty as proposed by Petitioner). Based on our review of Petitioner's argument and the evidence supporting that argument, Petitioner persuades us that Heller describes the elements recited in element 1a.

c. Element 1b

Element 1b refers to the following portion of claim 1: "a processor programmed to calibrate sensor data based at least in part on prior calibration information generated before insertion of the transcutaneous glucose sensor in the host." Ex. 1001, 120:1–4. Petitioner identifies Heller's on-skin control unit "that can 'modify the signals from the sensor circuit 97 using calibration data and/or output from the temperature probe circuit 99,' including to 'determine a level of an analyte in the bloodstream based on the sensor signals obtained from interstitial fluid.'" Pet. 38 (quoting Ex. 1005, 66:3–13 and citing (*id*. at 61:19–22, 77:14–15; Ex. 1002 ¶ 153)). Patent Owner does not contest Petitioner's showing for element 1b. *See* PO Resp. 14–20 (arguing only that an ordinarily skilled artisan would not have been motivated to combine teachings of Heller and Flaherty as proposed by Petitioner). Based on our review of Petitioner's argument and the evidence supporting that argument, Petitioner persuades us that Heller describes the elements recited in element 1b.

d. Element 1c

Element 1c refers to the following portion of claim 1: "wherein the sensor data is associated with a glucose concentration of the host." Ex. 1001, 120:4–5. Petitioner contends that Heller's sensor 42 directly

measures current to determine the wearer's glucose concentration. Pet. 38 (citing Ex. 1005, 34:24–29, 62:29–32, 65:30–66:13, 68:8–11, 89:13–17; Ex. 1002 ¶ 154). Patent Owner does not contest Petitioner's showing for element 1c. *See* PO Resp. 14–20 (arguing only that an ordinarily skilled artisan would not have been motivated to combine teachings of Heller and Flaherty as proposed by Petitioner). Based on our review of Petitioner's argument and the evidence supporting that argument, Petitioner persuades us that Heller describes the elements recited in element 1c.

e. Element 1d

Element 1d refers to the following portion of claim 1: "wherein the prior calibration information comprises prior sensitivity information associated with the transcutaneous glucose sensor." Ex. 1001, 120:5–8.

Petitioner contends that Heller describes "calibration information" that includes "sensitivity information associated with the transcutaneous sensor" because Heller's system uses a "particular sensor current-analyte level profile" to provide a "known direct relationship between sensor current and analyte level." Pet. 39 (citing Ex. 1005, 66:20–26; Ex. 1002 ¶ 155) (emphasis omitted).

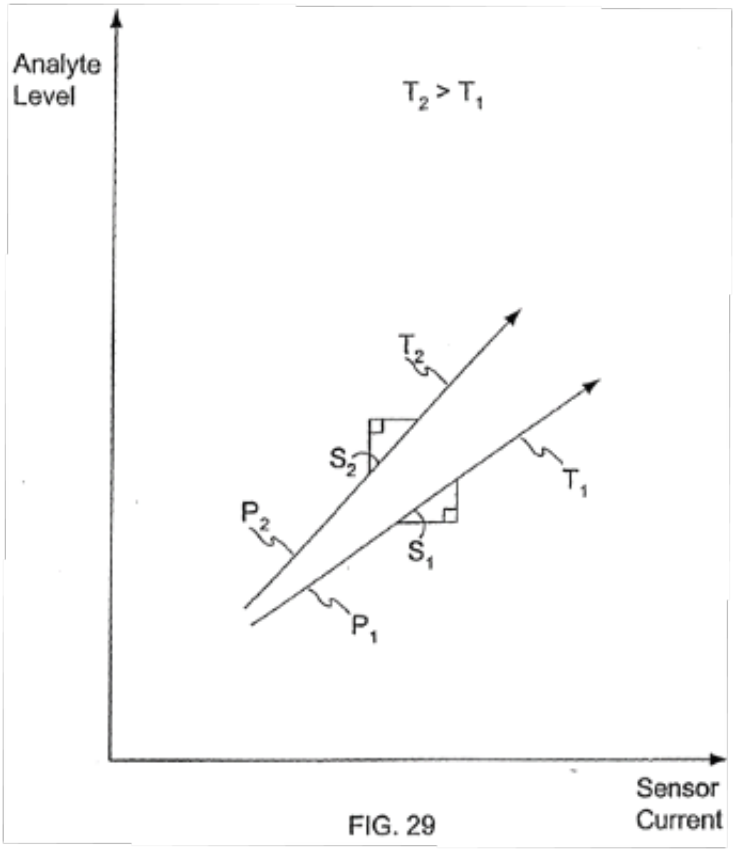

FIG. 29

Petitioner contends that the "calibration" and "sensitivity" information are "prior" information associated with Heller's sensor because Heller's system uses "factory-determined calibration measurements" like those illustrated in Heller's Fig. 29, reproduced at right. Petitioner contends Figure 29 illustrates two sensor profiles P1, P2 that reflect different slopes S1, S2, which constitute two different sensitivities between current and glucose concentration. *Id*. at 39 (citing Ex. 1005, 66:24–31, Fig. 29; Ex. 1002 ¶ 155).

Petitioner further contends that an ordinarily skilled artisan would have recognized that Heller's "factory-determined calibration measurements" included "data regarding the pre-insertion *in vitro* sensitivity of the sensor and would have recognized that information's usefulness as a predictor of post-insertion *in vivo* sensitivity, without using post-insertion reference measurements." *Id*. at 40 citing (Ex. 1002 ¶ 156 (citing Ex. 1004, 14:10–18, Fig. 5; Ex. 1024, Abstract, 12:38–13:11, 12:43–46, 13:2–11; Ex. 1025, Abstract, 94, 99, 102; Ex. 1014, 163; Ex. 1009, i297, i299, i300; Ex. 1008, 29–30, 52–53)).

Patent Owner does not contest Petitioner's showing for element 1d. *See* PO Resp. 14–20 (arguing only that an ordinarily skilled artisan would not have been motivated to combine teachings of Heller and Flaherty as proposed by Petitioner). Based on our review of Petitioner's argument and the evidence supporting that argument, Petitioner persuades us that Heller describes the elements recited in element 1d.

f. Element 1e

Element 1e refers to the following portion of claim 1: "wherein the prior calibration information is associated with a sensor code, wherein the

sensor code is located in or on a packaging holding the transcutaneous glucose sensor." Ex. 1001, 120:8–11.

Petitioner identifies the combined teachings of Heller and Flaherty as describing limitation 1e. Pet. 40–42. More specifically, Petitioner contends that Heller describes storing factory-determined calibration measurements in storage unit 100 within control unit 44. *Id.* at 40 (citing Ex. 1005, 77:13–20; Ex. 1002 ¶ 157). Petitioner contends that Flaherty describes "calibration coefficients" associated with a "calibration code" that are encoded in a look-up table stored in its sensor's memory. *Id.* (citing Ex. 1019, 5:53–58). Flaherty further describes printing the sensor code on the sensor packaging so that it "can be entered into the analyzer and used for the calculation of the analyte concentration." *Id.* (citing Ex. 1019, 5:58–62). Petitioner identifies Flaherty as describing a "sensor code . . . located in or on a packaging" of the sensor that is associated with the "prior calibration information" of limitation 1e by disclosing "a calibration code that, when entered into the device, could be used as an index in a lookup table to find the appropriate coefficients." *Id.* at 40–41 (citing Ex. 1019, 5:63–66). Flaherty further describes placing sensors in packaging to control the environment in which the sensor exists. *Id.* at 41–42 (citing Ex. 1019, 8:5–7, 8:17–25, 8:25–27, Figs. 5b, 5c).

Petitioner argues that an ordinarily skilled artisan would have found it obvious to place Heller's sensor in packaging, place Flaherty's code on that packaging, and use Flaherty's code to access "prior calibration information," such as Heller's "factory-determined calibration measurements." *Id.* at 41–42 (citing Ex. 1002 ¶¶ 158-159 *and* Pet. 31–34 (detailing motivation to combine teachings from Heller and Flaherty to arrive at the limitations of

claim 1 and reasonable expectation of success in doing so)). Based largely on testimony from Dr. Smith, Petitioner argues that an ordinarily skilled artisan would have considered incorporating Flaherty's sensor code into Heller's system to have been a combination of known prior art elements in accordance with their known methods of use to yield predictable results. Pet. 31–34 (citing Ex. 1002 ¶¶ 144–145[9]). Petitioner argues that an ordinarily skilled artisan would have made the proffered combination of Heller and Flaherty to allow

> individually calibrated sensors, without the need to customize the memory of every sensor. Instead, the manufacturer would use Flaherty's single memory image for every sensor, with a look-up table correlating the various possible calibration parameters . . . to particular calibration codes. The manufacturer would then only need to provide the user with the correct calibration code associated with the particular sensor's corresponding factory-determined calibration parameters that the user could enter upon first use.

Id. at 34 (citing Ex. 1002 ¶ 145;[10] Ex. 1004, 14:10–27).

Patent Owner does not contest Petitioner's showing that Flaherty describes printing a code on the packaging of its sensor and entering that code into Flaherty's analyzer to access calibration information for the sensor that is stored in the memory of the analyzer. *See* PO Resp. 14–20 (arguing only that an ordinarily skilled artisan would not have been motivated to combine teachings of Heller and Flaherty as proposed by Petitioner).

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[9] Based on our review of the record and the context provided in the Petition, Petitioner inadvertently cites Ex. 1002 ¶¶ 114–115 when it intended to cite ¶¶ 144–145.

[10] Based on our review of the record and the context provided in the Petition, Petitioner inadvertently cites Ex. 1002 ¶ 115 when it intended to cite ¶ 145.

However, Patent Owner argues that the portions of Heller and Flaherty cited by Petitioner do not sufficiently support combining the teachings of these references in the manner that Petitioner argues to meet the requirements of element 1e. *Id*. at 14.

Patent Owner contends that Petitioner proposes that an ordinarily skilled artisan would have been motivated to use a code printed on sensor packaging (as suggested by Flaherty) to avoid "the need to customize the memory of every sensor," and allow the combination to use a "single memory image for every sensor, with a look-up table." *Id*. at 15 (citing Pet. 32–34). Patent Owner criticizes Petitioner's showing for failing to demonstrate that Heller's "tiny implantable sensor even ***has*** a memory" or that Heller's sensor requires customizing a sensor memory. *Id*. at 15–16. Without demonstrating that the sensors in Heller have a memory, Patent Owner argues that insufficient motive exists (1) to avoid customizing that memory or (2) to realize a benefit of using a single image for that memory. *Id*. Patent Owner further criticizes Petitioner's showing because Heller's control unit 44 has "factory-determined calibration measurements" that are already "stored in a calibration data storage unit 100." *Id*. at 16. Based on this feature of Heller's control unit, Patent Owner contends that an ordinarily skilled artisan would have had no motive to modify Heller's system to: (1) "avoid" the need for customized memory in the sensor or (2) benefit from every sensor having a "single memory image." *Id*. at 16–17.

Petitioner persuasively points out that conveying calibration information via a sensor code in or on sensor packaging was well known and that it had cited numerous references along with Flaherty to support this conclusion. Reply 3 (citing Pet. 31–36; Ex. 1002 ¶ 150; Ex. 1004; Ex. 1019;

Ex. 1038; Ex. 1039; Ex. 1040; Ex. 1041; Ex. 1042; Ex. 1043). Petitioner also persuasively points out that Heller describes not only storing calibration data, but also entering such data into its sensor control unit. *Id*. at 3–4 (citing Ex. 1005, 77:14–18). Petitioner criticizes Patent Owner's argument as resting upon a "misunderstanding of the Petition's argument" when Patent Owner contends that memory is required in both Heller's sensor and control unit. *Id*. at 4 (citing PO Resp. 17, 22). Rather, Petitioner relies upon Flaherty's description of "printing a bar code on the sensor" or "on sensor packaging" that could be entered into Flaherty's control unit "to look up calibration coefficients." *Id*. at 4 (citing Pet. 32). Based on this aspect of Flaherty, Petitioner persuasively argues that an ordinarily skilled artisan "would have recognized that printing a calibration code on sensor packaging that corresponds to an entry in a look-up table stored in memory would merely require combining these features by known methods." Pet. 34.

Petitioner persuades us that Flaherty suggests entering a code printed on a sensor or its packaging into the control device for that sensor and using that code as an index to access the correct calibration data for the sensor. Pet. 40–41 (cross-referencing Pet. 38–39). Flaherty explains:

> Depending on the repeatability of the manufacturing process, calibration coefficients could be determined for a batch of sensors or, if necessary, for each individual sensor. The calibration coefficients or code corresponding to a look-up table could then be printed on the sensor packaging so that they can be entered into the analyzer and used for the calculation of the analyte concentration.

Ex. 1019, 5:55–62. Petitioner persuasively relies on this portion of Flaherty to demonstrate a motive to modify Heller by using Flaherty's printed code to access correct calibration data in the control device. Pet. 40 (citing

Ex. 1019, 5:53–58), *id*. at 32 (citing Ex. 1019, 5:58–62, 5:64–6:6 ("sensors could be provided with a calibration code that, when entered into the device, could be used as an index in a lookup table to find the appropriate coefficients. . . . The analyzer could read a bar code printed on the sensor and use that code to look up coefficients.")). Because Petitioner made its showing in the Petition as just described, we disagree with Patent Owner's argument that Petitioner "attempts to rewrite the Petition" in the Reply. Sur-reply 1–2. Based on our review of Petitioner's argument and cited evidence, we conclude that Petitioner has demonstrated by a preponderance of evidence that an ordinarily skilled artisan would have modified Heller as suggested by Flaherty to meet the requirements of element 1e.

g. Element 1f

Element 1f refers to the following portion of claim 1: "wherein the processor is programmed to calibrate the sensor data without a need for a reference analyte concentration measurement obtained after insertion of the *in vivo* portion of the transcutaneous glucose sensor." Ex. 1001, 120:11–15 (as modified by Certificate of Correction, 6).

For element 1f, Petitioner first cross-references its showing for element 1b, which we address above. Pet. 42. Petitioner also identifies Heller as describing element 1f when it discloses that its calibration data can "*simply* be factory determined calibration measurements." *Id*. (quoting Ex. 1005, 77:15–15 with emphasis). More specifically, Petitioner contends that this phrase "teaches calibration without post-insertion analyte/glucose reference measurements." *Id*. (citing Ex. 1002 ¶ 160). Petitioner also argues

that the Office had previously found that Heller's disclosure[11] taught calibrating sensor data "without reliance on any reference analyte measurement made after insertion" because the Office found that the disclosure supported a claim reciting: "process the sensor signals with the factory set calibration data without using a reference measurement during the sensor lifetime." *Id.* at 45 (citing Ex. 1044, claim 1; Ex. 1045, 9–10).

Patent Owner does not contest Petitioner's showing for element 1f. *See* PO Resp. 14–20 (arguing only that an ordinarily skilled artisan would not have been motivated to combine teachings of Heller and Flaherty as proposed by Petitioner). Based on our review of Petitioner's argument and the evidence supporting that argument, Petitioner persuades us that Heller describes the elements recited in element 1f.

h. Conclusion

For the reasons expressed above, we find that Petitioner has demonstrated by a preponderance of evidence that the combined teachings of Heller and Flaherty render claim 1 unpatentable as obvious.

2. Dependent Claims 5, 7, and 8

Claims 5 and 7 depend directly from claim 1, and claim 8 depends from claim 7. Ex. 1001, 120:26–29 (claim 5), 120:34–44 (claims 7 and 8). Petitioner identifies portions of Heller and Flaherty that describe or suggest the limitations introduced in each of these claims. Pet. 43–46. Patent Owner does not address the patentability of claims 5, 7, and 8, except to

[11] "Heller's disclosure" refers to the specification of U.S. Patent No. 9,610,034, which claims priority to the U.S. Application 09/753,746, the same application listed as the priority document for Heller. *Compare* Ex. 1044, code (63), *with* Ex. 1005, code (30) (listing U.S. Application 09/753,746 as priority application).

argue for patentability of independent claim 1, which we have addressed in Part III.E.1 above. PO Resp. 9–39 (proffering argument for only claims 1, 66, 67, and 89). Based on our review of Petitioner's argument and the evidence cited in support, we conclude that Petitioner has demonstrated by a preponderance of evidence that the combined teachings of Heller and Flaherty render claims 5, 7, and 8 unpatentable as obvious.

3. Independent Claim 66

Independent claim 66, like independent claim 1, is directed to a "glucose monitoring system" recites:

66[pre]. A glucose monitoring system comprising:

[a] a first component comprising:

[b] a transcutaneous glucose sensor having an *in vivo* portion and an *ex vivo* portion, wherein the transcutaneous glucose sensor is configured to measure a signal indicative of glucose concentration in a host; and

[c] electrical contacts operably connected to the transcutaneous glucose sensor,

[d] wherein the first component is associated with a sensor code, wherein the sensor code is associated with calibration information, and

[e] wherein the calibration information enables calibration of sensor data without requiring a reference glucose measurement during sensor use; and

[f] a second component, separate from the first component, wherein the second component comprises:

[g] sensor electronics configured to be operably connected to the transcutaneous glucose sensor through the electrical contacts of the first component when the second component is attached to the first component by the host,

> [h] wherein the sensor electronics are configured to wirelessly communicate with a receiver, and
>
> [i] wherein the second component is associated with the sensor code;
>
> [j] wherein at least one of the first component and the second component comprise packaging, and wherein the packaging is labeled with the sensor code.

Ex. 1001, 126:25–49 (as corrected in Certificate of Correction and with bracketed labels by Petitioner to ease discussion and certain line breaks to ease readability).

Petitioner argues that the combined teachings of Heller and Flaherty render claim 67 obvious and supports its argument with citations to specific portions of each reference and testimony from Dr. Smith. Pet. 47–53. Petitioner relies solely upon teachings from Heller as describing limitations recited in the preamble and elements 66a–66c and 66e–66h, and relies upon a combination of teachings from Heller and Flaherty as suggesting the limitations recited in elements 66d, 66i, and 66j. *Id*.

Patent Owner argues that Petitioner's challenge to claim 66 fails for three reasons. First, Patent Owner contends that Petitioner fails to demonstrate sufficient motivation to combine teachings for elements 66d, 66i, and 66j for the same reasons asserted in connection with element 1e in Petitioner's challenge to claim 1. PO Resp. 21 (cross-referencing arguments for claim 1). Except as addressed below, and for materially the same reasons expressed in connection with our analysis of claim 1, Petitioner persuades us by a preponderance of evidence that an ordinarily skilled artisan would have been motivated to combine teachings of Heller and Flaherty to meet the limitations recited in elements 66d, 66i, and 66j. *See* Part III.E.1.f above.

Second, Patent Owner argues that the combined teachings of Heller and Flaherty fail to teach that the "second component is associated with the sensor code" as recited in element 66i. PO Resp. 21–26. Patent Owner contends that element 66i requires that "associated with the [sensor] code" requires that the sensor code "represents information about both [first and second] components." *Id*. at 22. That is, Patent Owner contends that the sensor code must "represent information" about the sensor (first component) and the electronics unit (second component). Patent Owner further contends that element 66i is not satisfied when "the code represents information about the sensor component, and the sensor electronics component merely *accesses* and *uses* that information." *Id*. at 22–23 (citing Ex. 1001, 105:33–35 ("a code or serial number that identifies a sensor and/or electronics unit"), 106:14–17 ("the electronics units and/or mounting unit can be labeled or coded…to differentiate unique sensor systems"), 107:45–47 ("each sensor system is associated with a unique or near-unique serial number")).

Setting aside whether Patent Owner's quoted portions of the Specification support its argument that the sensor code must "represent information"[12] about the sensor and the electronics, we find that Petitioner has demonstrated that its proposed Heller-Flaherty combination is associated with both the sensor and the sensor electronics. More specifically, we find

[12] We also find Patent Owner's argument unavailing because none of the cited portions of the Specification explains precisely what it means for a code to "represent information" about the sensor or sensor electronics. Nor do we discern any portion of the Specification that defines or discusses a code that "represents information" about the item with which it is "associated."

that Flaherty's sensor code is entered into a control unit, which uses that entry to access a lookup table and retrieve calibration information. Because Flaherty's control unit is functionally able to use the code that is entered to retrieve calibration information, we find that the control unit (i.e., second component) is "associated with the sensor code" as recited in element 66i. Stated another way, only a sensor code that is "associated with" the lookup table stored in Flaherty's control unit can function as a key to the index of that lookup table.

Third, Patent Owner argues that the combined teachings of Heller and Flaherty fail to disclose "packaging the electronics device [second component]" or "packaging the sensor [first component] together in the same packaging with the electronics device [second component]." PO Resp. 26–27 (citing Ex. 2012, 169–170). Without deciding whether Patent Owner's assertions are true, we find that claim 66 does not require that the second component include packaging or that the first and second components be place in the same packaging. Rather, element 66j recites: "at least one of the first component and the second component comprise packaging, and wherein the packaging is labeled with the sensor code." Ex. 1001, 126:47–49. By its plain language, this portion of claim 66 may be met by only the first component having packaging, and the language does not require that both the first and second components have packaging or that they be packaged together. Petitioner relies on Flaherty's express disclosure of sensors including their own packaging 110. Pet. 52 (citing Ex. 1019, 8:5–27, Figs. 5b, 5c). We find that Petitioner has demonstrated by a preponderance of evidence that Flaherty describes the limitations recited in element 66j.

For all the reasons expressed above, we find that Petitioner has demonstrated by a preponderance of evidence that the combined teachings of Heller and Flaherty render claim 66 unpatentable as obvious.

4. Dependent Claim 67

Claim 67 depends from claim 66 and further recites: "wherein the first component and the second component each comprise packaging and the packaging of each of the first component and the second component are labeled with the sensor code." Ex. 1001, 126:50–54.

Based on testimony by Dr. Smith, Petitioner contends that an ordinarily skilled artisan would have recognized that when a sensor and control unit are shipped "as a unit," each of the sensor and control unit could be packaged in its own "primary packaging" and that these separately packaged units (sensor and control unit) could also be placed inside outer, "surrounding packaging. Pet. 53 (citing Ex. 1002 ¶ 179). To support his opinion, Dr. Smith cites Flaherty's disclosure of using primary packaging for its sensors 110, which are further packaged inside surrounding packaging 120. Ex. 1002 ¶ 178 (citing Ex. 1019, 8:5–7, 8:17–25, Figs. 5b, 5c). Flaherty describes the need to control the environment in which sensors are shipped as the reason for considering primary and surrounding packaging 110 and 120 for its sensors. Ex. 1019, 8:5–27, Figs. 5b, 5c. Dr. Smith further opines that an ordinarily skilled artisan would have considered it obvious to place Heller's control unit and sensors in surrounding packaging such as Flaherty's packaging 120. Ex. 1002 ¶ 178. Essentially, based on his review of packaging options for sensors described by Flaherty, Dr. Smith opines that it would have been obvious to print the sensor code on any one or all of three hypothetical types of packaging,

including: (1) a surrounding packaging containing both a sensor and a control unit, (2) a primary packaging for a sensor, and (3) a primary packaging for a control unit. *Id.* ¶¶ 178–179. We thus discern six different combinations of printing the sensor code on the packaging for the combination of the sensor and control unit. *See* Reply 9–10 (summarizing all six alternatives graphically in tabular form).

Patent Owner contends that claim 67 requires that each of the sensor (first component) and electronics (second component) have separate packaging and both packages are labeled with a sensor code. PO Resp. 27–28. Although Petitioner argues otherwise in the Reply, we find that the plain language recited in claim 67 unambiguously supports Patent Owner's reading. More specifically, claim 67 recites: "the packaging of each of the first component and the second component are labeled with the sensor code." Ex. 1001, 126:52–54.

Patent Owner argues that Petitioner's challenge to claim 67 fails because "nothing in Heller of Flaherty discloses or suggests any of the Petition's various hypotheticals." *Id.* at 28. Patent Owner considers the Petition to set forth three hypothetical arrangements of codes printed on packaging, which includes printing a code on primary packaging for a sensor and separate primary packaging for a control unit. *Id.* Patent Owner implicitly recognizes that this hypothetical meets the requirements of claim 67, but Patent Owner argues that the hypothetical "makes little sense in connection with Flaherty's teachings." *Id.* at 30.

"When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within

his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 402–03 (2007). Petitioner demonstrates that only six possibilities exist for labeling the primary and surrounding packaging for a sensor and control unit with the code needed to ensure that the sensor is calibrated to the control unit. Petitioner also persuasively demonstrates that printing sensor codes on packaging that are associated with factory-generated calibration information was well known. Pet. 35–36 (citing Ex. 1004, 12:30–44; Ex. 1019, 5:53–6:16; Ex. 1038, 785–87; Ex. 1039, 5:3–22, FIG. 6; Ex. 1040, Abstract, ¶¶ 6, 9; Ex. 1041, Abstract, 1:60–2:10, 2:21–33; Ex. 1042, Abstract, ¶¶ 6, 7, 11, 12; Ex 1043 ¶ 56; Ex. 1002, ¶¶ 147–49). For all these reasons, we find that Petitioner has demonstrated by a preponderance of evidence that the combined teachings of Heller and Flaherty render claim 67 unpatentable as obvious.

F. Claim 89: Obviousness in View of Heller, Flaherty, and Shults

Claim 89 recites a method:

89[pre]. A method comprising:

[a] manufacturing at least one transcutaneous electrochemical glucose sensor, wherein the at least one transcutaneous electrochemical glucose sensor comprises: an *in vivo* portion; and an *ex vivo* portion;

[b] determining a sensor sensitivity using *in vitro* testing; determining that the sensor sensitivity is within a predetermined sensitivity range; and

[c] assigning a code to the at least one transcutaneous electrochemical glucose sensor,

[d] wherein the code is associated with at least a prior sensitivity information associated with the at least one transcutaneous electrochemical glucose sensor, wherein the code enables

> calibration of sensor data without reliance on a reference glucose concentration measurement obtained after insertion of the at least one transcutaneous electrochemical glucose sensor in a host.

Ex. 1001, 128:1–17 (as corrected in Certificate of Correction and with bracketed labels by Petitioner and certain line breaks removed to ease discussion).

Petitioner argues that the combined teachings of Heller, Flaherty, and Shults render claim 89 obvious and supports its argument with citations to specific portions of each reference and testimony from Dr. Smith. Pet. 53–57. Petitioner relies solely upon teachings from Heller as describing limitations recited in the preamble and elements 89a and 89d, and relies upon a combination of teachings from Heller and Shults as suggesting the limitations recited in element 89b and a combination of teachings of Heller, Flaherty, and Shults as suggesting the limitations recited in element 89c. *Id*.

Patent Owner argues that Petitioner's challenge to claim 89 fails for three reasons. We address each in turn below.

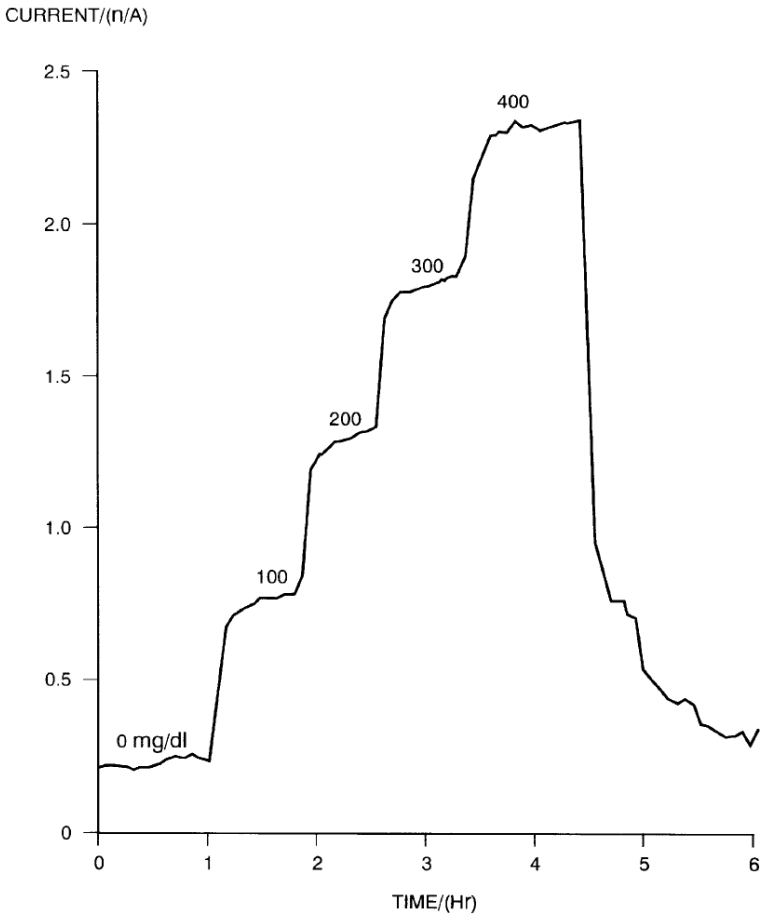
1. Motive to Combine Teachings of Heller and Flaherty

Patent Owner contends that Petitioner fails to demonstrate sufficient motivation to combine teachings of Heller and Flaherty for elements 89b and 89c for the same reasons asserted in connection with Petitioner's challenge to claim 1. PO Resp. 21 (cross-referencing arguments for claim 1). For materially the same reasons expressed in connection with our analysis of claim 1, Petitioner persuades us by a preponderance of evidence that an ordinarily skilled artisan would have been motivated to combine teachings of Heller and Flaherty to meet the limitations recited in element 89c for which Petitioner relies on that combination. *See* Part III.E.1.f above.

2. Motive to Combine Teachings of Heller, Flaherty, and Shults

Patent Owner also argues that Petitioner fails to demonstrate sufficient motive to combine Heller and Shults to meet the steps of "determining a sensor sensitivity using in vitro testing; [and] determining that the sensor sensitivity is within a predetermined sensitivity range" as recited in element 89b. PO Resp. 33–38. Patent Owner points out that Shults's sensor is an implantable subcutaneous sensor designed to work for months to years, unlike Heller's sensor, which is designed to work for days. *Id*. at 33 (citing Ex. 1020, 2:40–44, 7:24–27, 8:6–8; Ex. 2010 ¶ 109). Because the performance of Shults's sensor changes as the body reacts to its presence, verifying the stability of the sensor's sensitivity to glucose using an in vitro testing regime is crucial. *Id*. at 34 (citing Ex. 1020, 21:1–24, Fig. 4; Ex. 2010 ¶¶ 111–113). Patent Owner argues that the differences between the sensors in Heller and Shults fatally undermine Petitioner's argument than an ordinarily skilled artisan would have used in vitro sensitivity testing as taught by Shults with Heller's sensor. *Id*. at 34–37.

Petitioner responds that it identified several independent rationales for why an ordinarily skilled artisan would have been motivated to combine Shults's suggestion to determine the sensitivity of a glucose sensor using in vitro testing. Reply 11. Petitioner also argues that differences in the sensors of Shults and Heller are "irrelevant." *Id.* (citing *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985) ("A reference must be considered for everything it teaches by way of technology and is not limited to the particular invention it is describing and attempting to protect. On the issue of obviousness, the combined teachings of the prior art as a whole must be considered."). We agree. Petitioner relies on Shults's Figure 4, which is reproduced at right, to establish that it was well known to use *in vitro* testing over a period of hours to verify that the sensitivity of a glucose sensor to changes in glucose levels remains within an acceptable range. Pet. 55–57 (citing Ex. 1020, 21:4–22, Fig. 4).



Based on the cited portions of Shults, Dr. Smith testifies that an ordinarily skilled artisan would have understood Shults to describe using *in vitro* sensitivity testing to verify that sensitivity is within a predetermined range.

Ex. 1002 ¶ 189. An ordinarily skilled artisan would have been motivated to use Shults's in vitro testing method with Heller's sensors because Shults expressly suggests that such methods address a need to "continuously determine the presence and the amounts of a particular analyte, such as glucose, in biological fluids." Pet. 54 (citing Ex. 1020, 2:7–9). Petitioner notes that Heller's sensors address the same need. *Id*. (citing Ex. 1005, 1:25–2:25). Dr. Smith opines that an ordinarily skilled artisan would have considered using Shults's methods of in vitro testing would have involved merely combining prior art elements according to known methods to yield predictable results. Ex. 1002 ¶ 184 (citing Ex. 1020, 21:3–5 (noting prior art methods of in vitro testing); Ex. 1050, 882, 883).

For all these reasons, we find that Petitioner has demonstrated that an ordinarily skilled artisan would have been motivated to combine teachings of Shults and Heller to arrive at the limitations recited in element 89b.

3. Whether Shults Suggests "determining that the sensor sensitivity is within a predetermined range"

Petitioner contends that Shults suggests "determining that the sensor sensitivity is within a predetermined range" by describing a testing method that requires the measured sensitivity of a glucose sensor to remain within a range of 20% of measured values to "pass" a calibration check. Pet. 56–57 (citing Ex. 1020, 21:16–22; Ex. 1002 ¶ 189). Patent Owner argues that Petitioner's showing fails because holding the variation of a sensor to within 20% is not a "sensitivity . . . within a predetermined range." Patent Owner contends that the '642 patent describes several examples of desirable predetermined sensitivity ranges that are measured in units of pA/mg/dL rather than variations in sensitivity measured in percentage terms. PO Resp. 38–39.

Petitioner responds, and we agree, that the requirement in element 89b for "determining that the sensor sensitivity is within a predetermined sensitivity range" does not specify or limit the claim to specific methods of determining the "sensitivity range" as "***specific, absolute*** predetermined sensitivity ranges, rather than ***relative*** predetermined sensitivity ranges based on a prior test." Reply 12–13 (citing Ex. 1001, 49:29–49). We also discern no attempt in the Specification to limit claims only to the types of absolute sensitivity ranges that are mentioned and cited by Patent Owner. Shults describes using a first measurement of the sensitivity of a sensor to glucose as a benchmark against which a second measurement is compared to determine whether the difference in sensitivity is within 20% of the original. We find that a difference of less than 20% between two sensitivity measurements is a type of sensitivity range that falls within the broad recitation of "sensitivity [] within a predetermined range" as recited in element 89b.

Patent Owner argues in its Sur-reply that claim 89 requires the "sensitivity range" to be "predetermined" before the first step in the method, i.e., manufacturing a glucose sensor, is performed. Sur-reply 15. We discern no such temporal limitation in the plain language of the claim or how setting a relative sensitivity range between two measurements of a sensor fails to constitute a "predetermined sensitivity range." The recited "predetermined sensitivity range" can just as easily be "predetermined" after the sensor is manufactured as before. Thus, we find that when Shults sets a 20% difference in sensitivity between two measurements, Shults describes a "predetermined sensitivity range."

4. Conclusion

For all the reasons expressed above, we find that Petitioner has demonstrated by a preponderance of evidence that the combined teachings of Heller, Flaherty, and Shults render claim 89 unpatentable as obvious.

G. Claim 91: Obviousness in View of Heller, Flaherty, Shults, and Mastrototaro

Claim 91 depends from claim 89 and further recites: "wherein the determining that the sensor sensitivity is within a predetermined sensitivity range is performed at least in part by testing a plurality of other transcutaneous electrochemical glucose sensors." Ex. 1001, 128:22–25. Petitioner contends that the combined teachings of Heller, Flaherty, Shults, and Mastrototaro render claim 91 unpatentable as obvious. Pet. 57–59. Petitioner relies on its showing for claim 89 supplemented by Mastrototaro's teaching of testing a sample of a number of sensors made in the same manufacturing lot to determine the sensitivity of that type of glucose sensor. *Id*. (citing Ex. 1023, 18:11–15). Petitioner contends that an ordinarily skilled artisan would use Mastrototaro's sampling method in the combination to streamline the manufacturing process and reduce costs. *Id*. at 58 (citing Ex. 1002 ¶ 195).

Patent Owner does not dispute Petitioner's showing beyond arguing that the challenge fails for the reasons it proffered relating to the base claim 89 from which claim 91 depends. PO Resp. 39. Based on our review of Petitioner's reasoning, which we adopt as our own, and the evidence supporting the reasoning, we find that Petitioner has demonstrated by a preponderance of evidence that the combined teachings of Heller, Flaherty, Shults, and Mastrototaro render claim 91 unpatentable as obvious.

H. Petitioner's Obviousness Challenges Based on Gross

Because we have determined that Petitioner demonstrates the unpatentability of all challenged claims based on Heller and other prior art as set forth above, we need not reach the merits of Petitioner's challenges based on Gross. We express no opinion on the merits of these challenges in this decision.

IV. PETITIONER'S MOTION TO EXCLUDE

Petitioner seeks to exclude paragraphs 26–35, 42–219, and 220–224 of the Declaration of Dr. Baura (Exhibit 2010) under Rules 701 and 702 of the Federal Rules of Evidence ("FRE"). Mot. 1. Petitioner argues that the declaration testimony of Dr. Barua should be excluded because "Dr. Baura is not qualified to provide expert opinion in this matter and because her opinions are not based on sufficient facts or data, nor are they the product of reliable principles or methods." *Id.* FRE 701 pertains to the testimony of a lay witness, which is not at issue here. FRE 702 provides as follows:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

A. Petitioner's Challenge to the Qualifications of Dr. Baura

Petitioner argues that "Dr. Baura does not qualify as an expert to provide testimony in this proceeding because she lacks 'knowledge, skill,

experience, training, or education' in the pertinent art." *Id.* at 2 (citing FRE Rule 702; *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F. 3d 1356, 1364 (Fed. Cir. 2008) (holding that it is an abuse of discretion to allow "a witness to testify as an expert on the issues of … invalidity unless that witness is qualified as an expert in the pertinent art").

The entire premise of Petitioner's argument is that Dr. Baura does not have the "required experience" of a person of ordinary skill in the art, as defined by Petitioner. *Id.* In support of its argument, however, Petitioner first misrepresents what Petitioner, *itself*, asserts to be the applicable level of ordinary skill in the art. *Id.* at 2. In its Motion, Petitioner argues as follows:

> The level of ordinary skill which requires, among other things,
>
> > two or more years of experience researching, developing, designing and/or evaluating (or supervising the same) medical devices for measuring analyte levels, including some experience with algorithms for calibrating such devices, or equivalent experience.

Id. (quoting Pet. 15–16) (emphasis omitted). The Petition does not state that the level of ordinary skill in the art "requires, among other things" the qualifications Petitioner identifies above. Rather, as discussed above (*see* Part III.D above), the Petition states as follows:

> A [person of ordinary skill in the art] as of the claimed priority date would have had a bachelor's degree in biomedical engineering, chemical engineering, chemistry (or a related or equivalent field), and two or more years of experience researching, developing, designing and/or evaluating (or supervising the same) medical devices for measuring analyte levels, including some experience with algorithms for calibrating such devices, or equivalent experience. Such experience could include either formal coursework in signal processing, computer science, or electrical engineering, or could also be obtained during on-the-job experience. A person with less or different

> education but more relevant practical experience, or vice versa, may also meet this standard. A [person of ordinary skill in the art] may have been part of an interdisciplinary team with others having the relevant experience set forth above and/or with clinicians. The prior art also evidences the level of skill in the art.

Pet. 15–16 (citing Ex. 1002 ¶¶ 58–64). Petitioner's failure to address in its Motion the actual definition of a person of ordinary skill in the art advanced *by Petitioner* is a critical omission.

Further, Petitioner claims its Motion is proper because it purports to have "timely objected to this evidence as improper expert testimony" and identified the basis of the objections "with sufficient particularity." *Id.* at 11 (citing Paper 26). Petitioner again misrepresents what it has previously asserted. As Patent Owner notes, Petitioner's objections to Exhibit 2010 did not include any assertion that Dr. Baura was unqualified as an expert based on any purported failure to possess a level of ordinary skill in the art. *See* Opp. 1–2; Paper 26, 2.

Rather than rectify either of the first two misrepresentations in the Reply to support its Motion, Petitioner instead misrepresents for a third time what it has previously asserted, stating that "Petitioner is not contending that Dr. Baura is not qualified as an expert under FRE 702(a)." Mot. Reply 5. To the contrary, Petitioner expressly argues in the Motion that Dr. Baura is "unqualified to opine as an expert, rendering her opinion inadmissible under Rule 702(a) of the FRE." Mot. 7; *see also id.* at 1 (arguing that Dr. Baura's testimony "is inadmissible under Rules 701–702 . . . because Dr. Baura is not qualified to provide expert opinion in this matter); *id.* at 2 (section heading in Motion stating "DR. BAURA IS NOT QUALIFIED TO PROVIDE EXPERT TESTIMONY IN THIS PROCEEDING"); *id.* at 2

(stating "Dr. Baura does not qualify as an expert to provide testimony in this proceeding because she lacks 'knowledge, skill, experience, training, or education' in the pertinent art" (citing "FRE 702"); *id.* at 5 (arguing that Patent Owner "has failed to show Dr. Baura has the knowledge, skill, and experience required to opine on the pertinent art"). By asserting in its Reply to the Motion that Petitioner "is not contending that Dr. Baura is not qualified under FRE 702(a)," we presume Petitioner has abandoned its prior arguments to the contrary. *See* Mot. Reply 7.

In light of the foregoing multiple egregious misrepresentations, Petitioner's Motion is denied regarding the sufficiency of Dr. Baura's qualifications because Petitioner did not timely object to the evidence on the basis asserted in the Motion, fails to refute Patent Owner's showing that Dr. Baura is sufficiently qualified (*see* Opp. 3–7; Ex. 2010 ¶ 30), and abandons its argument in its Reply to the Motion.

B. Petitioner's Challenge to the Basis of Dr. Baura's Opinions

Petitioner argues that Dr. Baura's opinions should be excluded because they are "not based on the relevant facts, are not based on any articulated scientific principle or method, and therefore are not the product of reliable application of scientific principles or methods to the facts of this proceeding." Mot. 7. Petitioner proceeds to the merits of Dr. Baura's opinions in regard to various references, arguing that her opinions should be excluded, for example, due to her "lack of understanding" and "confusion." *Id.* at 10; *see also* Mot. Reply, 4 (arguing there were purported "inconsistencies" between Dr. Baura's declaration and deposition testimony illustrating that he declaration opinions "were not reliable").

In opposition, Patent Owner first argues, and we agree, that Petitioner failed to timely object to Dr. Laura's declaration with sufficient particularity. Opp. 1 (citing 37 C.F.R. § 42.64(b)(1)). Our Rule requires that an "objection must identify the grounds for the objection with sufficient particularity to allow correction in the form of supplemental evidence." 37 C.F.R. § 42.64(b)(1)). Petitioner's objection to Dr. Baura's testimony identifies hundreds of paragraphs from her declaration followed by an objection stating her "testimony is based on insufficient facts or data, is not the product of reliable principles and methods, and does not reliably apply the appropriate principles and methods to the fact of the case." Paper 26, 2. Petitioner's boilerplate objection is woefully insufficient to show that Petitioner objected with sufficiently particularity to allow correction in the form of supplemental information, as our Rule requires. We further agree with Patent Owner that Petitioner's arguments in the Motion are no more than a "transparent attempt to . . . circumvent the word-count limits of its merits briefing by injecting merits arguments in its evidentiary motion." Opp. 9. In short, Petitioner's arguments go to the weight to be afforded Dr. Baura's testimony, not to its admissibility, and are, therefore, an improper basis for seeking the exclusion of hundreds of paragraphs Dr. Baura's declaration. Accordingly, Petitioner's Motion is denied.

V. CONCLUSION[13]

In summary,

Claim(s)	35 U.S.C. §[14]	Reference(s)	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1, 5, 7, 8, 66, 67	103	Heller, Flaherty	1, 5, 7, 8, 66, 67	
89	103	Heller, Flaherty, Shults	89	
91	103	Heller, Flaherty, Shults, Mastrototaro	91	
1, 5, 66, 67	103	Gross, Flaherty		
7, 8	103	Gross, Flaherty, Mastrototaro		
89, 91	103	Gross, Flaherty, Shults		
Overall Outcome			1, 5, 7, 8, 66, 67, 89, 91	

[13] Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. §§ 42.8(a)(3), (b)(2).

[14] We do not reach the merits of Petitioner's challenges based on Gross for the reasons expressed in Part III.H.

VI. ORDER

For the reasons given, it is:

ORDERED, based on a preponderance of evidence, that claims 1, 5, 7, 8, 66, 67, 89, 91 of U.S. Patent 10,993,642 B2 are *unpatentable* as obvious under 35 U.S.C. § 103;

FURTHER ORDERED that Petitioner's Motion to Exclude Evidence (Paper 38) is *denied*, and

FURTHER ORDERED because this is a final written decision, the parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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