

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT DIABETES CARE INC.,
Petitioner,

v.

DEXCOM, INC.,
Patent Owner.

IPR2022-00917
Patent 10,980,452 B2

Before SCOTT A. DANIELS, JAMES A. TARTAL, and
FREDERICK C. LANEY, *Administrative Patent Judges*.

LANEY, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. *Background and Summary*

Abbott Diabetes Care Inc., (“Abbott” or “Petitioner”), filed a Petition requesting *inter partes* review (“IPR”) of claims 1, 2, 4, 7, 10–12, 14, 18–20, 22, 23, 26–28, 62–64, and 66–68 of U.S. Patent No. 10,980,452 B2 (Ex. 1001, “the ’452 patent”). Paper 3 (“Pet.”). Dexcom, Inc., (“Dexcom” or “Patent Owner”) filed a Preliminary Response to the Petition. Paper 12 (“Prelim. Resp.”). With our authorization, Petitioner also filed a Preliminary Reply and Patent Owner filed a Preliminary Sur-reply. Paper 13 (“Prelim. Reply”); Paper 14 (“Prelim. Sur-reply”).

We have jurisdiction under 35 U.S.C. § 314. Under § 314, an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a) (2018). The Board determines whether to institute a trial on behalf of the Director. 37 C.F.R. § 42.4(a). A decision to institute is “a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition.” *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018).

For the reasons set forth below, we determine that Petitioner has not demonstrated that there is a reasonable likelihood that at least one of the challenged claims is unpatentable. Accordingly, we do not institute an *inter partes* review of the challenged claims in the Petition.

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. 6. 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.” *Id.* Patent Owner states that Dexcom Inc., is the sole real party in interest. Paper 5, 1.

C. Related Matters

The parties indicate that the ’452 patent and related U.S. Patent Nos. 10,702,193, 10,702,215, 11,000,213, and 10,993,642, are at issue in at least one of *Abbott Diabetes Care Inc. v. Dexcom, Inc.*, Case No. 1:21-cv-01699, and *DexCom, Inc. v. Abbott Diabetes Care Inc. et al.*, Case No. 1:22-cv-00605, in the U.S. District Court for the District of Delaware.¹ Pet. 6; Paper 5, 2.

The parties indicate also that Petitioner has filed other *inter partes* review proceedings including the above noted patents as follows: IPR2022-00908 (10,702,193); IPR2022-00909 (10,702,215); IPR2022-00913 and IPR2022-00914 (11,000,213); IPR2022-00918 (the ’452 patent); and IPR2022-00921 and IPR2022-00922 (10,993,642). Pet. 6–7; Paper 5, 2.

D. The ’452 Patent (Ex. 1001)

The ’452 patent, titled “Analyte Sensor,” relates to “measuring an analyte in a host,” for example, “transcutaneous measurement of glucose” in a patient. Ex. 1001, codes (54), (57). An illustrative example of the ’452 patent’s analyte sensor system is shown in Figure 3 reproduced below.

¹ *DexCom, Inc. v. Abbott Diabetes Care Inc. et al.*, Case No. 1:22-cv-00605, in Delaware was transferred from the United States District Court for the Western District of Texas (Case No. 6:21-cv-00690)). Paper 5, 2.

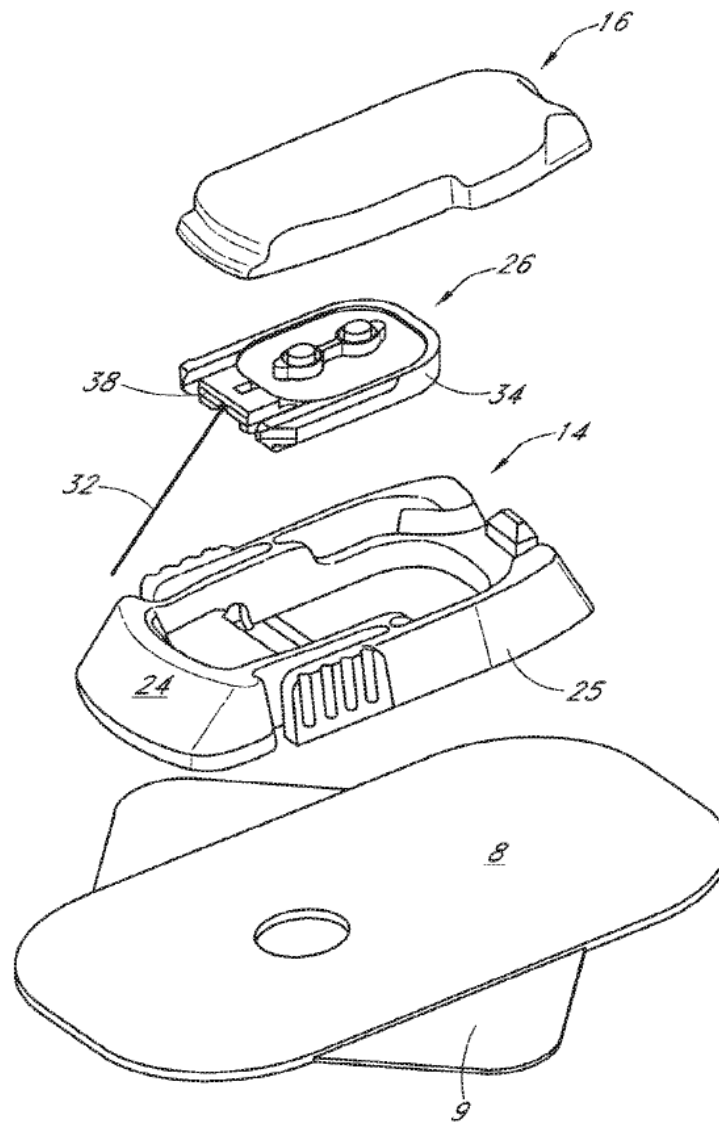


FIG. 3

Figure 3 is an exploded view of the analyte sensor system including an electronics unit 16, a contact assembly 26 with sensor 32, a mounting unit 14, and an adhesive pad 8. *Id.* at 25:23–52.

The claims in this case are more specifically directed to the contact assembly, which is illustrated in Figure 4A reproduced below.

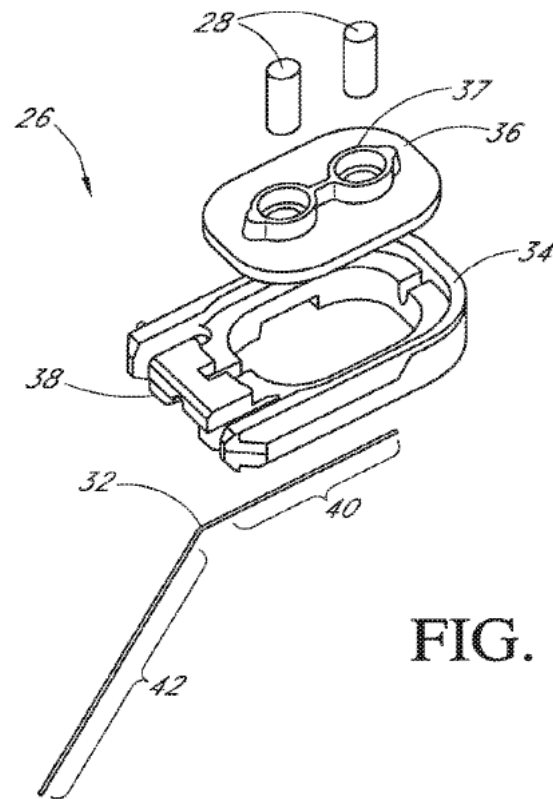


FIG. 4A

Figure 4A is an exploded perspective view of the contact subassembly 26 and includes a watertight sealing member 36 that fits within a contact holder 34. *Id.* at 26:51–55. Sealing member 36 provides a watertight seal configured to surround the electrical connection at the electrode terminals (contacts 28) within the mounting unit to protect the electrodes from damage due to moisture, humidity, dirt, and other environmental factors. *Id.* at 26:56–61. The sealing member 36 can be formed in many different configurations and materials to provide compression and improve the seal formed around the contacts 28 and sensor 32 when the contacts 28 are mated to the sensor electronics. *Id.* at 26:61–27:14. Contacts 28 fit within the seal 36 and provide for electrical connection between sensor 35 and the electronics unit 16. *Id.* at 29:27–29. “[T]he contacts 28 are formed from a conductive elastomeric material, such as a carbon black elastomer, through

which the sensor 32 extends” when assembled. *Id.* at 29:36–38. Sealing member 36 is formed to enhance the interference fit surrounding contacts 28 when the electronics unit 16 is mated to the mounting unit 14 by pressing against the electronics unit 16 to form a tight seal. *Id.* at 29:17–24.

E. Illustrative Claim

Petitioner challenges claims 1, 2, 4, 7, 10–12, 14, 18–20, 22, 23, 26–28, 62–64, and 66–68 of the ’452 patent. Pet. 8. Claims 1, 19, and 62 are the only independent claims. Ex. 1001, 119:63–120:19, 121:13–34, 125:1–24. Claims 2, 4, 7, 10–12, 14, and 18 depend from claim 1. *Id.* at 120:20–121:12. Claims 20, 22, 23, and 26–28 depend from claim 19. *Id.* at 121:35–62. Claims 63, 64, and 66–68 depend from claim 62. *Id.* at 125:25–45.

Independent claim 1 is illustrative and is reproduced below with emphasis added to highlight the limitations that are at the center of our analysis.

1. A system for measuring an analyte concentration in a host, the system comprising:
 - a transcutaneous analyte sensor;
 - sensor electronics configured to operatively connect to the transcutaneous analyte sensor; and
 - an electrical contact comprising a first material, wherein the first material is associated with a first durometer hardness, wherein the electrical contact is configured to operably connect the transcutaneous analyte sensor to the sensor electronics;
 - a sealing member comprising a second material, wherein the second material is associated with a second durometer hardness, *wherein the sealing member at least partially surrounds the electrical contact and at least a portion of the transcutaneous analyte sensor when the transcutaneous analyte sensor is operably connected to the sensor electronics,*

wherein the sealing member substantially seals at least a portion of the electrical contact from moisture;

a contact holder over which the sealing member and the transcutaneous analyte sensor are at least partially located; and

wherein the first durometer hardness is higher than the second durometer hardness.

Ex. 1001, 119:63–120:19 (emphasis added).

F. Prior Art and Asserted Grounds

Petitioner asserts that one or more of the challenged claims would have been obvious on the following ten grounds (Pet. 9–10):

Ground	Claim(s) Challenged	35 U.S.C. § ²	Reference(s)/Basis
1	1, 7, 10, 62, 63, 67	103(a)	Cheney ³ /Lord ⁴
2	1, 2, 4, 7, 10, 63, 64, 66	103(a)	Cheney/Lord, Z-Carbon ⁵
3	1, 7, 10, 14, 19, 23, 26, 68	103(a)	Cheney/Lord, Shah ⁶
4	1, 2, 4, 7, 10, 14, 20, 22	103(a)	Cheney/Lord, Z-Carbon, Shah
5	10–12, 26–28, 62, 64, 66–68	103(a)	Grounds 1–4,

² The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”), amended 35 U.S.C. § 103. Because the challenged claims of the ’452 patent have an effective filing date before the effective date of the applicable AIA amendment, we refer to the pre-AIA version of 35 U.S.C. § 103.

³ US 5,568,806, iss. Oct. 29, 1996 (Ex. 1005, “Cheney”).

⁴ US 5,482,473, iss. Jan. 9, 1996 (Ex. 1006, “Lord”).

⁵ FUJIPOLY, “New High Performance Silver ZEBRA[®] Connector,” Fujipoly Data Sheet Number FPDS 01-34, Version 5, Jan. 9, 2007 (Ex. 1011, “Z-Carbon”).

⁶ US 2007/0073129 A1, pub. Mar. 29, 2007 (Ex. 1019, “Shah”).

Ground	Claim(s) Challenged	35 U.S.C. § ²	Reference(s)/Basis
			Funderburk ⁷
6	18	103(a)	Grounds 1–4, Gross ⁸
7	1, 7, 10, 14, 19, 23, 26, 68	103(a)	Cheney/Lord, Taniguchi ⁹
8	1, 2, 4, 7, 10, 14, 20, 22	103(a)	Cheney/Lord, Z-Carbon, Taniguchi
9	10–12, 26–28, 68	103(a)	Grounds 7–8, Funderburk
10	18	103(a)	Grounds 7–8, Gross

Petitioner supports its challenge with the Declaration of Karl R. Leinsing (Ex. 1003).

II. ANALYSIS

Petitioner contends that we should institute an *inter partes* review of the '452 patent because several claims would have been obvious in view of Cheney/Lord (Ground 1) or in view of various combinations of Cheney/Lord with Z-Carbon (Grounds 2, 4–6, 8–10), Shah (Grounds 3–6), Funderbunk (Grounds 5, 9), Gross (Grounds 6, 10), and/or Tanigushi (Grounds 7–10). Pet. 9–10. Patent Owner contends that discretionary denial of *inter partes* review under 35 U.S.C. § 325(d) is appropriate because the challenges to the '452 patent are based on matters previously presented to the Office. *See* Prelim. Resp. 64–81. And even if discretionary denial is not appropriate, Patent Owner asserts that we should deny *inter partes* review because Petitioner's grounds of unpatentability are deficient. *See id.* at 16–64.

After considering the contentions and evidence submitted by both parties, for the reasons explained below, Patent Owner's discretionary

⁷ US 2004/0133164 A1, pub. July 8, 2004 (Ex. 1016, "Funderburk").

⁸ US 6,275,717 B1, iss. Aug. 14, 2001 (Ex. 1024, "Gross").

⁹ US 4,639,062, iss. Jan. 27, 1987 (Ex. 1007, "Taniguchi").

arguments are moot because we determine that the Petition fails to demonstrate sufficiently that there is a reasonable likelihood Petitioner would prevail in proving at least one of the challenged claims is unpatentable. Specifically, Petitioner has not demonstrated sufficiently that the cited prior art discloses “a contact holder over which the sealing member . . . [is] at least partially located,” as independent claims 1, 19, and 62 recite (Ex. 1001, 120:15:17, 121:32–34, 125:14–15), or a sealing member that “at least partially surrounds . . . at least a portion of the transcutaneous analyte sensor when the transcutaneous analyte sensor is operably connected to the sensor electronics,” as independent claims 1 and 19 recite (*id.* at 120:8–12, 121:21–26). Because Petitioner’s failure to establish that the prior art discloses those claim limitations is dispositive of the Petition, we focus our discussion below accordingly.

A. Principles of Law

Petitioner has the burden of proof. *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (“In an IPR, the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.”).

Section 103(a) forbids issuance of a patent when “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art;

(3) the level of ordinary skill in the art; and (4) when available, evidence such as commercial success, long felt but unsolved needs, and failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *see KSR*, 550 U.S. at 407 (“While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls.”). The Court in *Graham* explained that these factual inquiries promote “uniformity and definiteness,” for “[w]hat is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context.” *Graham*, 383 U.S. at 18.

The Supreme Court made clear that we apply “an expansive and flexible approach” to the question of obviousness. *KSR*, 550 U.S. at 415. Whether a patent claiming the combination of prior art elements would have been obvious is determined by whether the improvement is more than the predictable use of prior art elements according to their established functions. *Id.* at 417. To support this conclusion, however, it is not enough to show merely that the prior art includes separate references covering each separate limitation in a challenged claim. *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011). Rather, obviousness additionally requires that a person of ordinary skill at the time of the invention “would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention.” *Id.*; *see also Orexo AB v. Actavis Elizabeth LLC*, 903 F.3d 1265, 1273 (Fed. Cir. 2018) (“The question is not whether the various references separately taught components of the ’330 Patent formulation, but whether the prior art suggested the selection and combination achieved by the ’330 inventors.”).

In determining whether there would have been a motivation to combine prior art references to arrive at the claimed invention, it is insufficient to simply conclude the combination would have been obvious without identifying any reason *why* a person of skill in the art would have made the combination. *Metalcraft of Mayville, Inc. v. Toro Co.*, 848 F.3d 1358, 1366 (Fed. Cir. 2017). As factfinders, we also must be aware “of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.” *KSR*, 550 U.S. at 421.

Applying these general principles, we consider the evidence and arguments of the parties.

B. Level of Ordinary Skill in the Art

The level of skill in the art is “a prism or lens” through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). “This reference point prevents . . . factfinders from using their own insight or, worse yet, hindsight, to gauge obviousness.” *Id.*

Factors pertinent to a determination of the level of ordinary skill in the art include: (1) educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of workers active in the field. *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696–697 (Fed. Cir. 1983) (citing *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1381–82 (Fed. Cir. 1983)). Not all such factors may be present in every case, and one or more of these or other factors may predominate in a particular case. *Id.* Moreover, these factors are not exhaustive but are merely a guide to

determining the level of ordinary skill in the art. *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007). In determining a level of ordinary skill, we also may look to the prior art, which may reflect an appropriate skill level. *Okajima*, 261 F.3d at 1355.

Petitioner asserts, with the support of its expert, that a person of ordinary skill in the art at the relevant time would have had a “bachelor’s degree in biomedical engineering, mechanical engineering, chemical engineering, or materials science and engineering (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, *e.g.*, analyte sensors, or equivalent experience.” Pet. 12 (citing Ex. 1003 ¶¶ 17–21). Patent Owner does not dispute or address this characterization of the skill level of an artisan in the relevant field. *See generally* Prelim. Resp.

On this record, Petitioner’s proposed level of ordinary skill in the art is not disputed and is consistent with our review and understanding of the technology and descriptions in the ’452 patent and the asserted prior art references. *Okajima*, 261 F.3d at 1355. For purposes of this Decision, we rely on Petitioner’s proposed level of ordinary skill in the art.

C. Claim Construction

We construe each claim “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b).” 37 C.F.R. § 42.100(b) (2019). Under this standard, claim terms are generally given their ordinary and customary meaning as would have been understood by a person of ordinary skill in the art at the time of the invention and in the context of the entire patent disclosure. *Phillips v. AWH*

Corp., 415 F.3d 1303, 1312–14 (Fed. Cir. 2005) (en banc) (“We have frequently stated that the words of a claim ‘are generally given their ordinary and customary meaning.’”).

Petitioner contends that, for its Petition, all claim terms “should be given their plain and ordinary meaning.” Pet. 30. Presumably because the plain meaning applicable to all of the claim terms in the ’452 patent is readily apparent, Petitioner does not provide any particular construction for any of the claim terms. *See generally id.* Patent Owner likewise offers no particular construction for any of the claim terms. *See generally* Prelim. Resp. Patent Owner does argue, however, that the claimed inventions (specifically, independent claims 1, 19, and 62) are distinguishable from the various structural configurations Petitioner relies upon in the prior art when the plain meaning of “over” and “at least partially surrounds” are applied appropriately. *See* Prelim. Resp. 39–46. Thus, rather than disputing the meaning Petitioner proposes for the claim terms, Patent Owner disputes whether Petitioner properly applied the plain meaning of all the claim terms in the unpatentability contentions that the Petition presents.

Claims are construed only to the extent necessary to resolve a dispute. *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999). Here, both parties rely on the plain and ordinary meaning for all of the terms used in the claims challenged in the Petition and neither party suggests a particular meaning beyond what is clearly conveyed by the claim terms in the context of the ’452 patent. Therefore, we need not construe expressly any of the claim terms.

D. The Challenged Claims In View of Asserted Grounds 1–10

The unpatentability contentions for all of the challenged claims in Grounds 1–10 of the Petition, directly or indirectly, depend on Petitioner showing that Cheney/Lord disclose “a contact holder over which the sealing member and the transcutaneous analyte sensor are at least partially located” recited by each independent claim 1, 19, and 62. Pet. 42–44, 51, 53, 65, 68, 69, 76, 78, 85, 88, 89; *see generally id.* at 33–92. Additionally, the unpatentability contentions for claims 1, 2, 4, 7, 10–12, 14, 18–20, 22, 23, 26–28, and 68 spread across Grounds 1–10 of the Petition, directly or indirectly, depend on Petitioner showing Cheney/Lord alone or in various combinations with Shah or Taniguchi disclose a sealing member that “at least partially surrounds the electrical contact and at least a portion of the transcutaneous analyte sensor when the transcutaneous analyte sensor is operably connected to the sensor electronics” recited by each independent claim 1 and 19. Pet. 39–41, 53, 59–64, 65, 69, 81–89, 89; *see generally id.* at 33–92. Because we determine that these two limitations are dispositive of Grounds 1–10 in the Petition, we address each in turn below. But before we do, we first provide an overview of the Cheney, Lord, Shah, and Taniguchi references.

1. Cheney (Ex. 1005)

Cheney, titled “Transcutaneous Sensor Insertion Set,” is directed an improved insertion set for transcutaneous placement of a sensor, for example a glucose sensor, at a selected site within the body of a patient. Ex. 1005, codes [54], [57]. An illustrative example of Cheney’s transcutaneous sensor insertions set is shown in Figure 1 reproduced below.

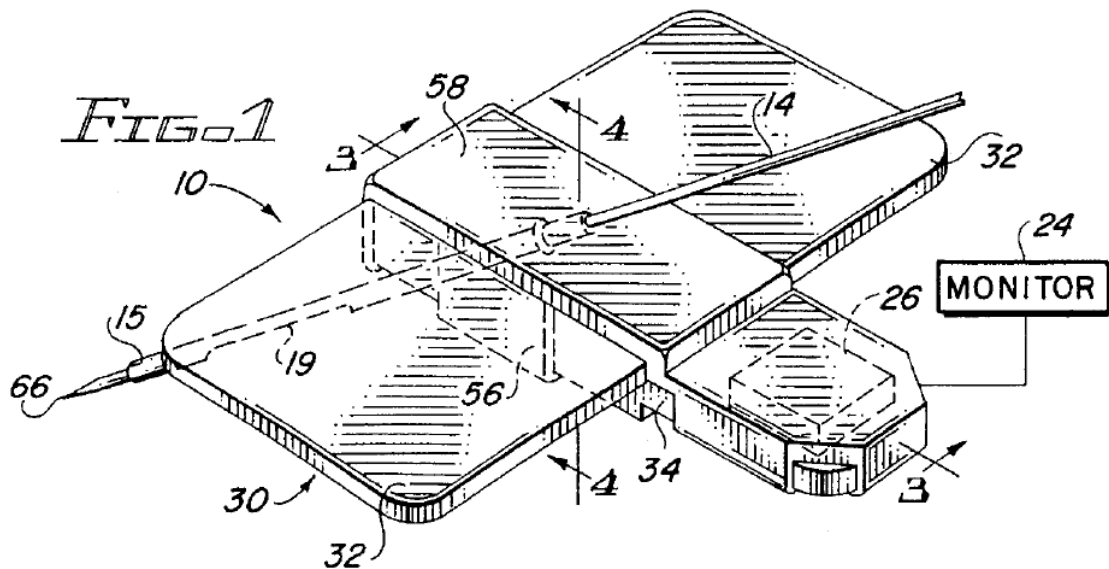


Figure 1 shows an upper side a transcutaneous sensor insertion set. *Id.* at 2:54–56. The insertion set comprises an insertion needle that extends through a mounting base adapted for mounting onto the patient’s skin. *Id.* at code [57]. A flexible thin film sensor includes a proximal segment carried by the mounting base and adapted for electrical connection to a suitable monitor and a distal segment protruding from the mounting base with sensor electrodes thereon for transcutaneous placement. *Id.* The distal segment of the sensor and a distal segment of the insertion needle are positioned within a flexible cannula extending from the mounting base to pierce the skin and place the sensor below a patient’s skin. *Id.* The insertion needle may then be withdrawn from the cannula and the mounting base, while leaving the sensor distal segment at the selected insertion position and exposing the sensor electrodes to the patient’s blood. *Id.*

2. Lord (Ex. 1006)

Lord, titled “Flex Circuit Connector,” is directed to a connector that provides electrical connection to a flex circuit in a hermetically sealed

manner. Ex. 1006, codes [54], [57]. An illustrative example of Lord's flex circuit connector is shown in Figure 1 reproduced below.

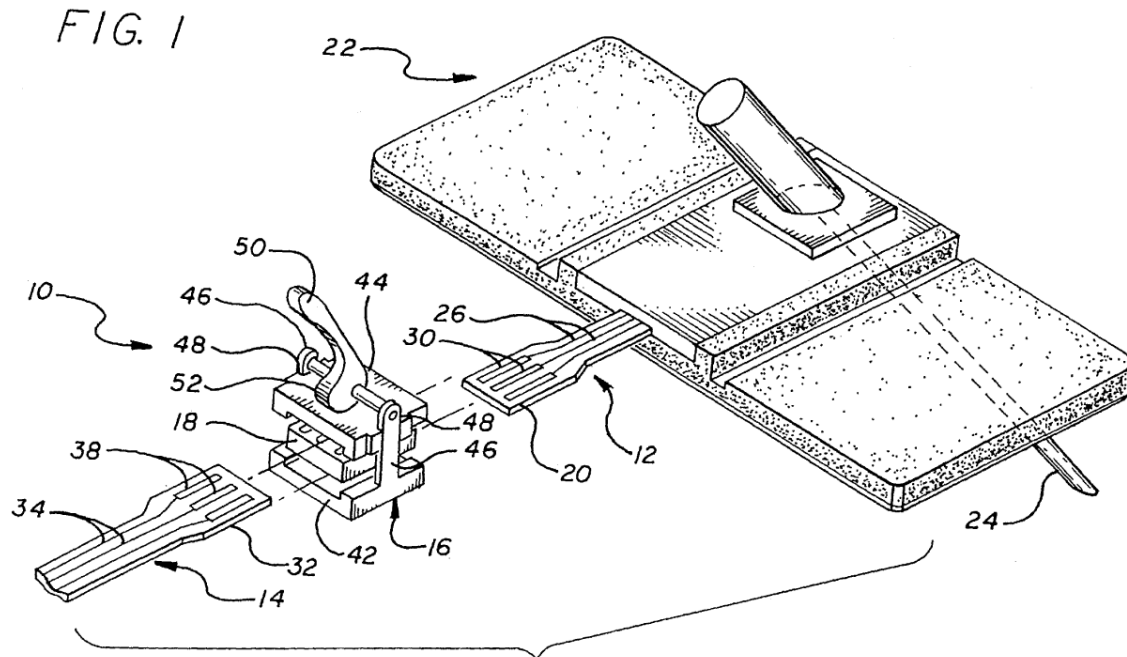


Figure 1 “is an exploded perspective view illustrating a flex circuit connector.” *Id.* at 2:47–48. The flex circuits 12, 14 comprise thin film conductors encased between layers of insulative material with conductive contact pads 30, 38 exposed through one of the insulative layers. *Id.* at code [57]. The flex circuits 12, 14 are arranged face-to-face and compressed by a clamp fixture 16 against a compressible terminal block 18. *Id.* The terminal block made of resilient insulative elastomer is embedded with conductive strips to electrically connect to the aligned pairs of the contact pads 30, 38 on the two flex circuits. *Id.*

3. *Shah (Ex. 1019)*

Shah, titled “Flexible Sensor Apparatus,” is directed to a “flexible mounting base to hold a sensor at an infusion site, the sensor being a removable in vivo sensor for monitoring analyte concentration level in a patient, such as blood glucose (BG) level.” Ex. 1019, codes [54], [57]. An

illustrative example of Shah's flexible sensor apparatus is shown in Figure 2 reproduced below.

Fig. 2

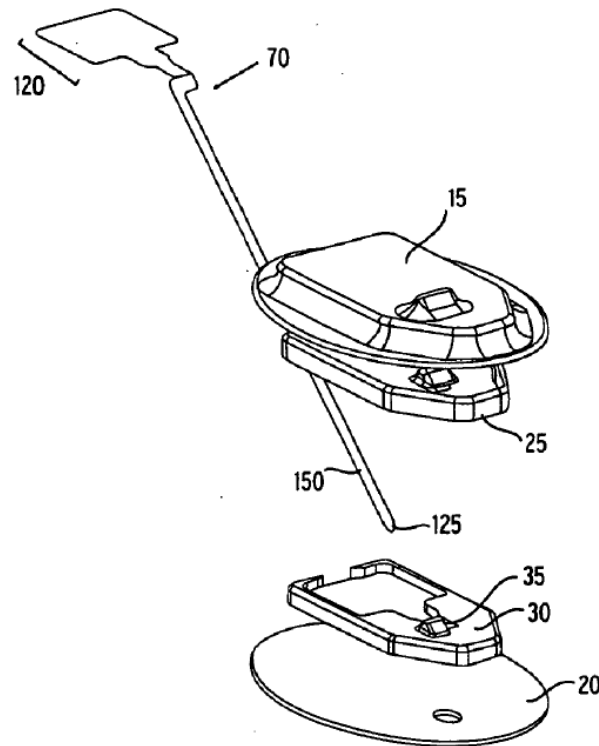


Figure 2 “is an exploded view of a flexible mounting base with a sensor.” *Id.* ¶ 23. The mounting base includes an outer flexible layer 15, a sealing layer 25, a semi-rigid housing 30, and an adhesive layer 20. *Id.* ¶ 35. The housing 30 is semi-rigid to help stabilize the base around the areas that the needle enters and exits. *Id.* A sensor 70 extends from the mounting base 10 and includes a proximal segment 120 and a distal segment 125. *Id.* “The proximal segment 120 is generally adapted for conductive connection with appropriate electronic monitoring equipment, while the distal segment 125 includes the electrodes positioned subcutaneously in direct contact with the extracellular fluid of a patient.” *Id.* Also included is a sealing layer 25 that

expands to re-fill any punctures in the layer caused by a needle being inserted and removed. *Id.* ¶ 39. When the needle is removed, the sealing layer will collapse back and re-fill the puncture, creating a seal. *Id.* “The sealing layer 25 provides a more sanitary infusion site by keeping the infusion site insulated” and “does not need to be fully extended to form an entire layer of the mounting base,” but can “be located so that it is only covering the needle insertion area.” *Id.*

4. *Taniguchi (Ex. 1007)*

Taniguchi, titled “Circuit Board Connection,” is directed to connecting an LCD glass circuit board and a printed wiring board by using rubber connectors, “each having an open part for receiving circuit boards, an edge of a first circuit board requiring connection inserted into the open part of the rubber connector, followed by pressing a second rubber connector against the circuit board to complete connection of the two circuit boards.” Ex. 1019, codes [54], [57], 1:47–49.

5. *“a contact holder over which the sealing member and the transcutaneous analyte sensor are at least partially located” (Independent Claims 1, 19, 62)*

Claims 1 and 19 recite “a contact holder over which the sealing member and the transcutaneous analyte sensor are at least partially located” and claim 62 recites “an elastomeric sealing member at least partially located over the contact holder.” Ex. 1001, 120:15:17, 121:32–34, 125:14–15. Petitioner relies on the same evidence presented in the context of claim 1 to allege the prior art discloses these limitations. Pet. 42–44, 51, 53, 65, 68, 69, 76, 78, 85, 88, 89. In particular, Petitioner contends that “Cheney/Lord teaches a contact holder (central housing member 34 having square aperture 40 and locator pin 36) over which an elastomeric sealing

member (connector block 26 seated in aperture 40 (blue trace below)) and a transcutaneous analyte sensor (port 38 on sensor proximal segment 20 mating with locator pin 36 (red trace below)) are at least partially located,” referring to an annotated version of Figure 2 from Cheney reproduced below. Pet. 42–43 (citing Ex. 1005, Figs. 1–3, 4:6–32).

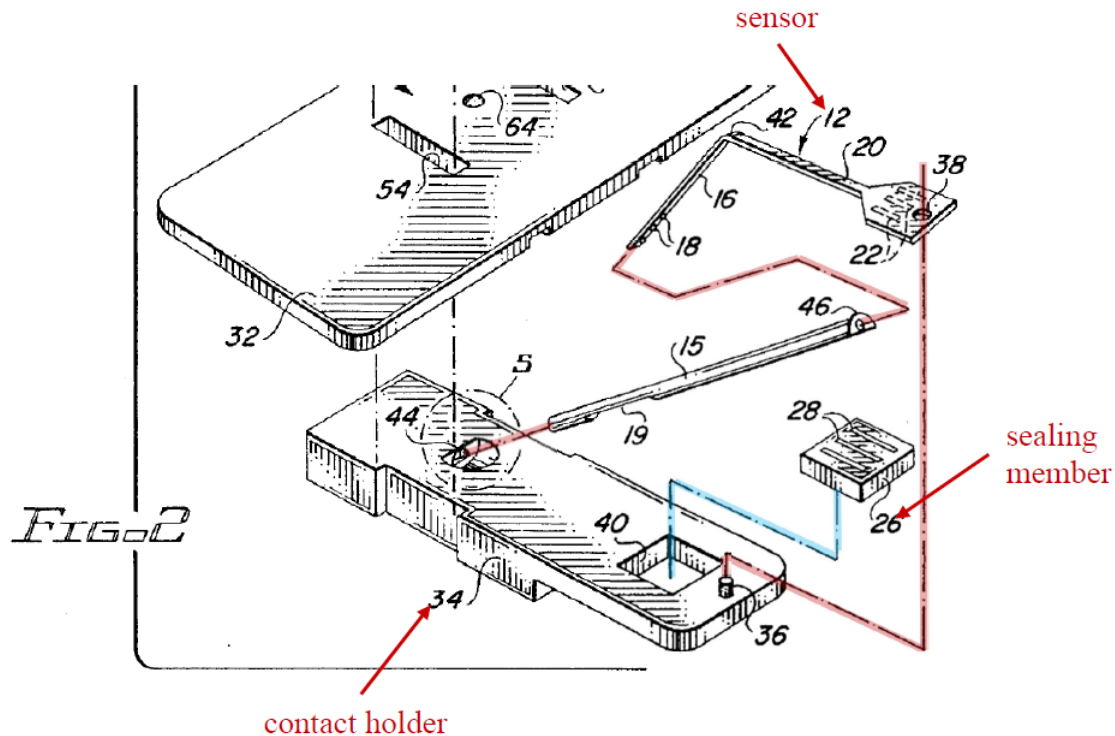


Figure 2 is “an exploded perspective view showing the transcutaneous sensor insertion set” disclosed by Cheney. Ex. 1005, 2:57–58.

Petitioner contends that “[w]hen viewed from the orientation depicted in Figures 2–3, Cheney’s connector block 26 is ‘over’ the contact holder.” Pet. 43. Figure 3 in Cheney is reproduced below.

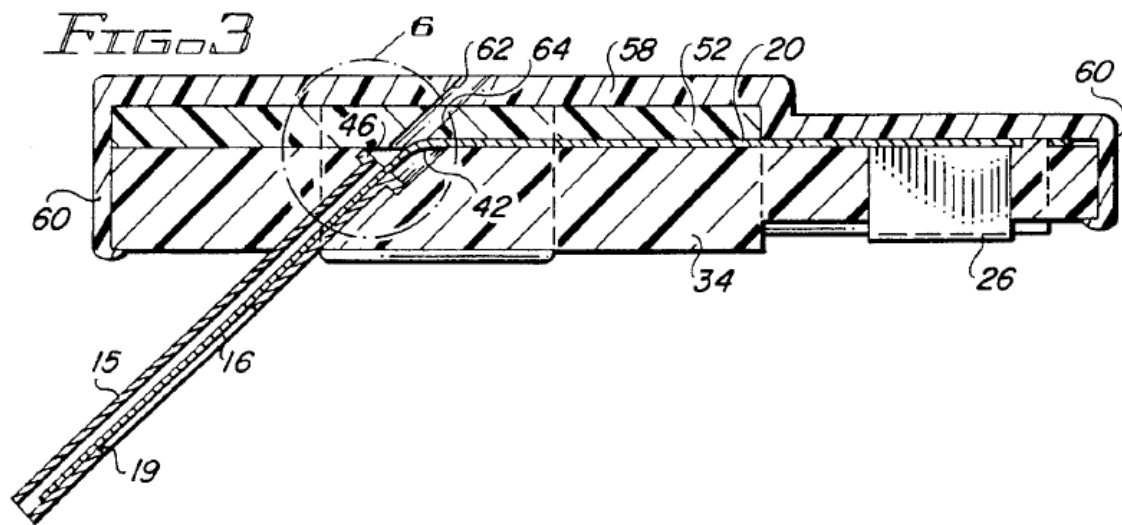


Figure 3 is an enlarged cross-sectional view along the center-line of an assembled transcutaneous sensor insertion set shown in Figure 2 of Cheney. Ex. 1005, 2:59–60. Alleging “Cheney teaches that its connector block 26 operates ‘as described in [Lord]’” and “Lord . . . teaches that ‘compression of the terminal block, preferably in excess of fifteen percent compression,’ is required ‘to provide a high quality electrical connection’ that is ‘hermetically sealed,’” Petitioner suggests Figures 2 and 3 in Cheney must show a sealing member (connector block 26) that is over the contact holder (housing member 34) when assembled because the compression described in Lord “is only possible if the connector/terminal block extends at least slightly over aperture 40 in housing member 34.” Pet. 43–44 (citing Ex. 1005, 3:61–4:6, Fig. 2; Ex. 1006, 2:31–34, 4:31–42).

Petitioner contends, alternatively, “Cheney’s sealing member and sensor will be ‘over’ the contact holder when in use, *e.g.*, when the device is on a user’s body standing upright.” Pet. 44 (citing Ex. 1005, 4:7–8).

Patent Owner argues that Petitioner’s evidence is deficient for several reasons. First, rather than showing a sealing member over a contact holder,

Patent Owner asserts Figures 2 and 3 in Cheney show the alleged sealing member (connector block 26) is “positioned within” an aperture 40 of the alleged contact holder (housing member 34). Prelim. Resp. 31–32. Patent Owner notes that, in Figure 3 of Cheney, “aperture 40 extends through housing member 34 and the bottom of Cheney’s connector block 26 extends below the bottom of housing member 34.” *Id.* at 32. Patent Owner asserts that “Cheney’s connector block 26 is not covering, on top of, or ‘over’ a surface of the housing member 34 under any plausible contextual meaning of ‘over.’” *Id.* at 32. Patent Owner argues that, in the context of the ’452 patent and its description of a sealing member that is positioned “on top of, i.e., over” a top-surface portion of a contact holder, a skilled artisan would have understood Figures 2 and 3 in Cheney does not show a connector block 26 that is “over” housing member 34 because no portion of housing member 34 is below connector block 26. *Id.* at 32–34 (citing Ex. 1001, 30:27–28, 30:39–49, Figs. 3, 4A, 4D).

Patent Owner argues next that Petitioner’s reliance on Lord is misplaced. As an initial matter, Patent Owner notes that Cheney does not teach that its connector block *operates as described in Lord*, as Petitioner alleges. Prelim. Resp. 37–38. Instead, Cheney states that “connector block 26 having conductive strip elements 28 (FIG. 2) as described in [Lord],” which Patent Owner asserts can only be “reasonabl[y] read” to describe Cheney’s connector block 26 as having conductive strips that are like the ones described in Lord. *Id.* at 38 (citing Ex. 1005, 4:3–6).

Patent Owner asserts that the compression occurring during the “operation” of Lord’s connector block is irrelevant to understanding what is shown in Cheney’s Figures 2 and 3 because Petitioner concedes that Cheney

does not use a clamp fixture 16 like the one used by the assembly shown in Lord. Prelim. Resp. 38 (citing Pet. 47).¹⁰ Moreover, Patent Owner notes that Petitioner does not propose modifying Cheney to include a clamp fixture. *Id.* Patent Owner asserts that the Petition provides no evidence that Cheney’s connector block 26 is compressed in a manner similar to the compression caused by the clamp fixture 16 in Lord. *Id.* at 36–37. And referring to Figure 3 in Cheney, Patent Owner asserts that Cheney shows no portion of connector block 26 extending even slightly over housing member 34, but instead shows connector block as being completely contained within housing member 34. *Id.*

Lastly, addressing Petitioner’s alternative contention that relies on looking at Cheney’s disclosed assembly when it is “on a user’s body standing upright,” Patent Owner argues, within the context of the ’452 patent, that a skilled artisan would recognize that the appropriate orientation for considering whether one part is “over” another part is when the device is positioned upright and horizontally. Prelim. Resp. 39. Patent Owner supports this position by pointing to the fact that the ’452 patent consistently refers to the sensor system in the same upright, horizontal orientation when describing the spatial relationship of parts, such as being *upper* or *lower* portions. *Id.* (citing Ex. 1001, 31:41–44, Figs. 2, 3, 4A, 4H. Patent Owner asserts Cheney similarly relies on the disclosed device being in the upright, horizontal position when describing the spatial relationship of parts, for

¹⁰ Patent Owner cites to page 46 of the Petition, but we view this as a typographical error because Petitioner states, “the Cheney system does not use Lord’s cam-lever mechanism to effect compression on its similar elastomeric block 26,” at page 47 of the Petition.

example when Cheney identifies “an *upper* side of a transcutaneous sensor insertion set,” “a cover plate *overlying* a portion of [the] wing member,” “a wing member *overlying* [the] central housing member,” and an “*underlying* housing member” to the cover plate. *Id.* at 41 (citing Ex. 1005, 2:54–56, 4:48–60, 7:29–32, Figs. 2, 3) (emphasis added). Patent Owner argues that Petitioner’s suggestion any spatial orientation may be used “tortures” the plain meaning of “over” and “is not supported by the ’452 patent nor the cited art.” *Id.* at 39.

We agree with Patent Owner that Petitioner has not shown sufficiently that Cheney/Lord discloses a sealing member that is at least partially located over the contact holder. Cheney’s Figure 2 and 3 show connector block 26, which Petitioner alleges is a sealing member, as being supported solely by its sides within aperture 40 of housing member 34, which Petitioner alleges is a contact holder, and no portion of the connector block 26 is above or over any portion of housing member 34. Petitioner has not demonstrated sufficiently that the plan and ordinary meaning of the term “over” in the context of the ’452 patent would have been understood to encompass such a configuration.

Petitioner’s reliance on Lord is unpersuasive. Contrary to Petitioner’s contention, compressing connector block 26 within aperture 40 of housing member 34 to expose the block’s conductive strip elements 28 and form a connection with the contact pads 22, as Lord suggests, evidences that connector block 26 is pressed down further confining it *within* aperture 40 because Figure 3 of Cheney depicts and describes conductive strip elements 28 as being held flush against the upper surface of housing member 34 by the overlying cover plate 58 to “engage and retain the sensor proximal

segment 20 tightly against the connector block 26.” Ex. 1005, 4:54–60, Fig. 3.

Finally, although Petitioner states that Cheney’s sealing member will be “over” the contact holder when the device is on a user’s body standing upright, Petitioner does not propose a construction for “over” that would encompass such an orientation. To the extent Petitioner intended “over” to be broadly construed to encompass any spatial orientation of the device, Petitioner had an obligation under 37 C.F.R § 42.104(b)(3) to identify the construction expressly with supporting evidence from the intrinsic record of the ’452 patent. As Patent Owner argues, the context of the ’452 patent informs a skilled artisan that the plain and ordinary meaning of “over” is viewed from the perspective of a device positioned upright and horizontal. Ex. 1001, 31:41–44, Figs. 2, 3, 4A, 4H; *see also* Ex. 1005, 2:54–56, 4:48–60, 7:29–32, Figs. 2, 3. Therefore, we are not persuaded that it is appropriate to consider whether the alleged sealing member is at least partially over the alleged contact holder in the device Cheney discloses by viewing the spatial relationship of those parts when the device is on a user’s body standing upright.

Therefore, for the above reasons, we find Petitioner has not demonstrated a reasonable likelihood of proving that Cheney/Lord discloses “a contact holder over which the sealing member and the transcutaneous analyte sensor are at least partially located,” independent claims 1 and 19 recite, or “an elastomeric sealing member at least partially located over the contact holder,” as independent claim 62 recites.

6. *“wherein the sealing member at least partially surrounds the electrical contact and at least a portion of the transcutaneous analyte sensor when the transcutaneous analyte sensor is operably connected to the sensor electronics” (Independent Claims 1 and 19)*

Petitioner contends that Cheney/Lord discloses a seal member that “at least partially surrounds the electrical contact and at least a portion of the transcutaneous analyte sensor when the transcutaneous analyte sensor is operably connected to the sensor electronics,” as recited in independent claims 1 and 19. Pet. 39–41, 65. And Petitioner contends, alternatively, that Cheney/Lord in view of either Shah or Taniguchi shows that limitation would have been obvious to a skilled artisan at the time of the invention. *Id.* at 59–65, 81–86. As we explain below, however, we do not find these contentions supported sufficiently in the Petition to demonstrate that Petitioner is reasonably likely to prove the prior art either discloses or renders obvious a seal member that at least partially surrounds at least a portion of the transcutaneous analyte sensor when the sensor is operably connected to the sensor electronics.

First, Petitioner contends that Figure 2 in Cheney and Figure 3 in Lord both illustrate a sealing member that at least partially surrounds an electrical contact and a portion of a transcutaneous analyte sensor. Pet. 39–41. Cheney Figure 2 is reproduced below with Petitioner’s annotations.

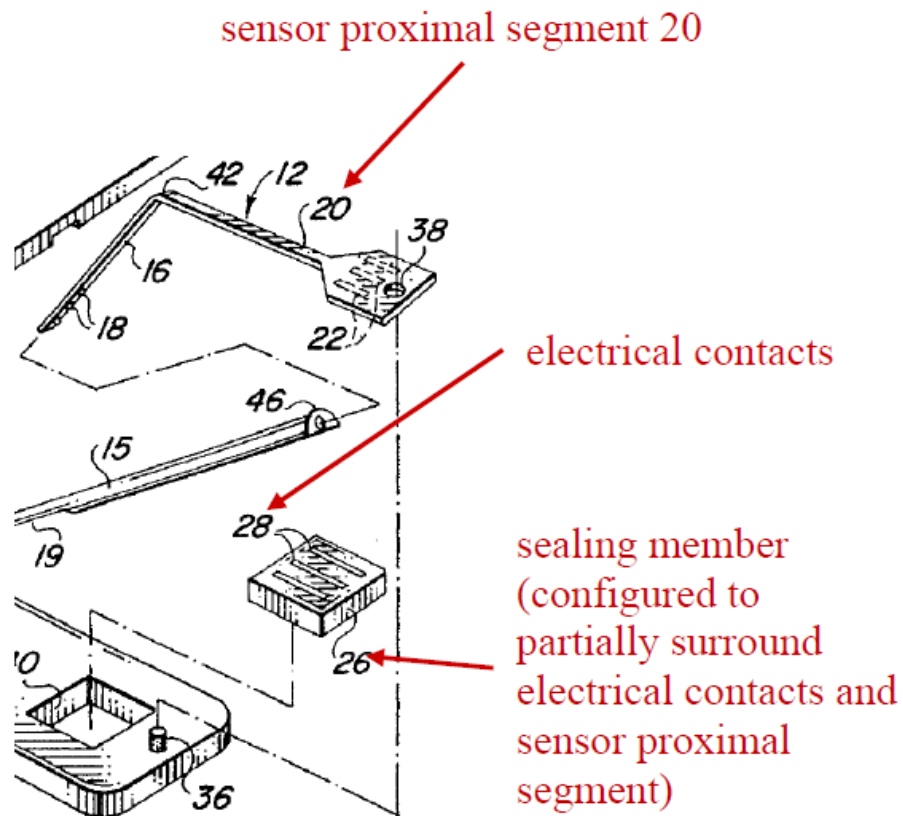


Figure 2 is “an exploded perspective view showing the transcutaneous sensor insertion set” with labeling added to identify the alleged sealing member (insulative portion of connector block 26) that Petitioner contends at least partially surrounds an electrical contact (conductive strip elements 28) and at least a portion of a transcutaneous analyte sensor (ex vivo proximal segment 20 of sensor 12). *Id.* at 40 (citing Ex. 1005, 3:60–4:6, 4:54–60, Figs. 1–3; Ex. 1003 ¶¶ 193–196); *see also* Ex. 1005, 2:57–58. Lord Figure 3 is reproduced below, also with Petitioner’s annotations.

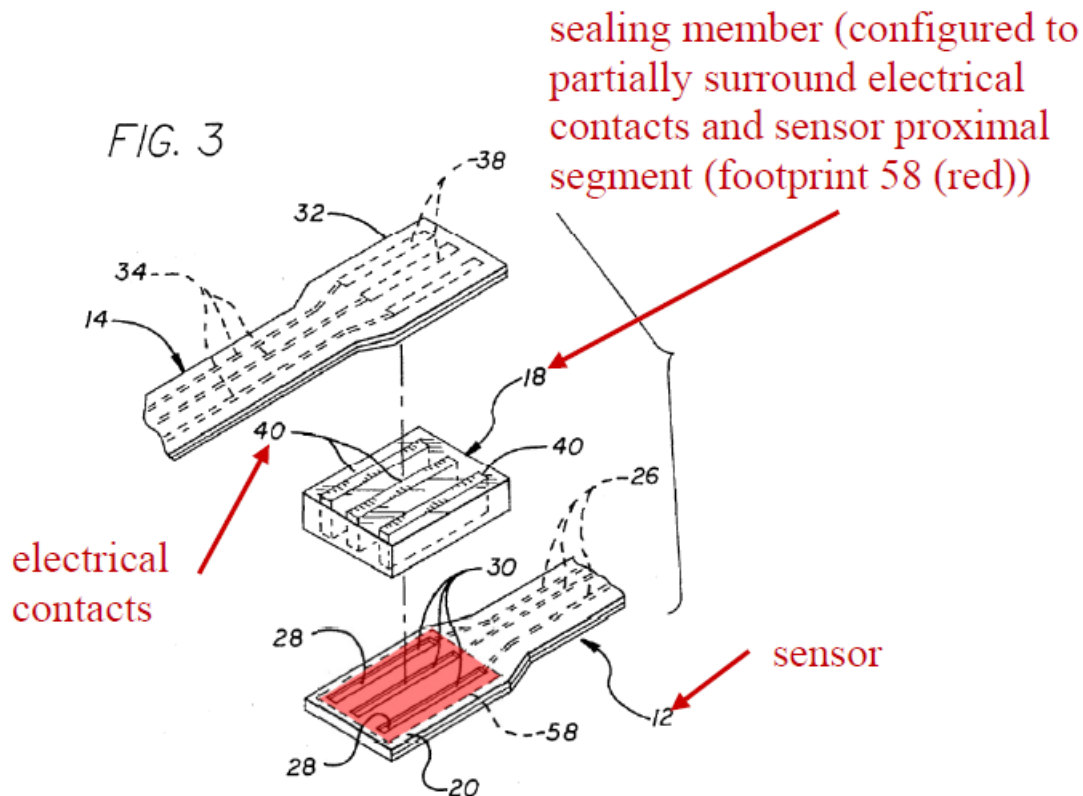


Figure 3 “is an exploded perspective view illustrating the proximal ends of a pair of flex circuits assembled in face-to-face relation with a terminal block interposed therebetween” (Ex. 1006, 2:55–58), which has labels added to identify a sealing member (insulative portion of terminal block 18) that Petitioner contends “at least partially surrounds an electrical contact (conductive strips 40) and at least a portion of a transcutaneous analyte sensor (proximal end 20 of sensor flex circuit 12 (footprint 58 [shaded red])).” Pet. 40–41 (citing Ex. 1006, code [57], 3:51–4:3, 1:58–2:10, 2:54–58, 4:36–39, Figs. 1–3; Ex. 1003 ¶¶ 193–196). Petitioner contends that a skilled artisan

would have understood that Cheney/Lord’s sealing member (connector block 26, terminal block 18) at least partially surround at least a portion of the transcutaneous sensor, because “the size and shape of the terminal block [sealing member] is

sufficient to engage the flex circuits along a footprint 58 [on sensor proximal end 20].”

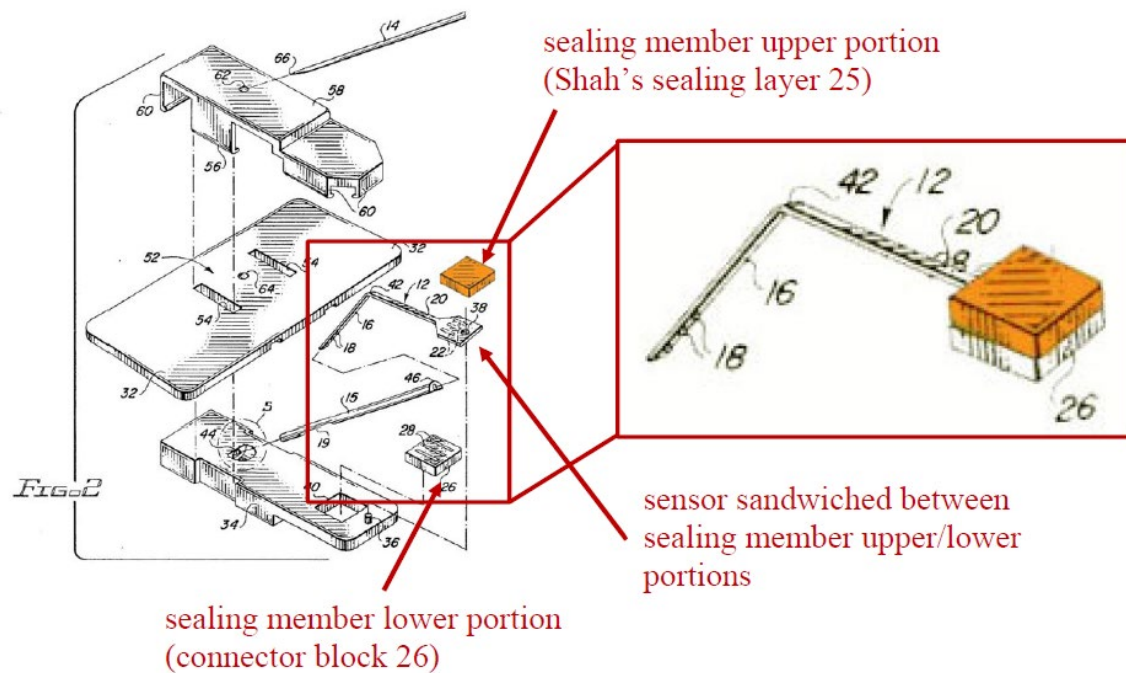
Id. at 41 (citing Ex. 1006, 4:36–40, 3:67–4:3, 2:5–10; Ex. 1003 ¶¶193–196).

Patent Owner argues that the respective Cheney/Lord Figures 2 and 3 fail to show the alleged seal member is partially surrounding the transcutaneous analyte sensor because the seal member is merely “adjacent” to the sensor. Prelim. Resp. 43. Patent Owner asserts Figure 2 in Cheney “at most suggests that connector block 26 would be adjacent to, but not surrounding, sensor proximal segment 20 when Cheney’s device is assembled.” *Id.* Regarding Figure 3 in Lord, Patent Owner asserts “a footprint on a flat surface (e.g., flex circuit 12) does not partially surround that flat surface;” “[a]t most, Lord’s discussion of ‘footprint 58’ suggests that the terminal block 18 is adjacent to the surface of the flex circuit 12 that has the openings 28 for the contact pads 30.” *Id.* at 44.

We agree with Patent Owner that the respective Cheney/Lord Figures 2 and 3 only show the alleged sealing member at a single flat side of the sensor’s proximal segment 20. To the extent Petitioner intended “at least partially surrounds” to be broadly construed to encompass two flat surfaces positioned adjacently to one another, Petitioner had an obligation under 37 C.F.R § 42.104(b)(3) to identify the construction expressly with supporting evidence from the intrinsic record of the ’452 patent. Furthermore, beyond the conclusory statements of Mr. Leinsing, Petitioner fails to provide any evidence supporting the notion that a skilled artisan, in view of the ’452 patent, would understand the plain meaning of “at least partially surrounds” to encompass such a configuration. The ’452 patent, moreover, does not clearly support such a broad interpretation because it depicts and describes sensor 32 as *passing through the internal area of sealing member 36* so that

the sealing member is located entirely around at least a portion of the sensor. *See* Ex. 1001, 29:36–50, Figs. 10B, 11B. Therefore, we find Petitioner has not demonstrated sufficiently a reasonable likelihood of proving that Cheney/Lord discloses a seal member that “at least partially surrounds the electrical contact and at least a portion of the transcutaneous analyte sensor when the transcutaneous analyte sensor is operably connected to the sensor electronics,” as recited in independent claims 1 and 19.

Second, Petitioner contends alternatively that having a seal member that “at least partially surrounds” both the electrical contact and the transcutaneous analyte sensor when the sensor is operably connected to the sensor electronics would have been an obvious modification of the Cheney/Lord configuration in view of Shah. Pet. 59–64. Petitioner states that “Shah teaches an additional sealing member portion (sealing layer 25) contacting the sensor proximal segment on the side opposite that contacted by the Cheney/Lord connector/terminal block.” *Id.* at 59 (citing Ex. 1019 ¶¶ 25, 39, Figs. 2, 3b; Ex. 1003 ¶¶ 247–258); *see also id.* at 60–63. Petitioner contends that a skilled artisan “would have been motivated to apply Shah’s teachings to the Cheney/Lord system, and specifically, to add an upper sealing layer as taught by Shah over the proximal segment 20 of Cheney/Lord’s thin film sensor and connector block 26,” and provides another annotated version of Cheney’s Figure 2, reproduced below, to illustrate this proposed modification. *Id.* at 63.

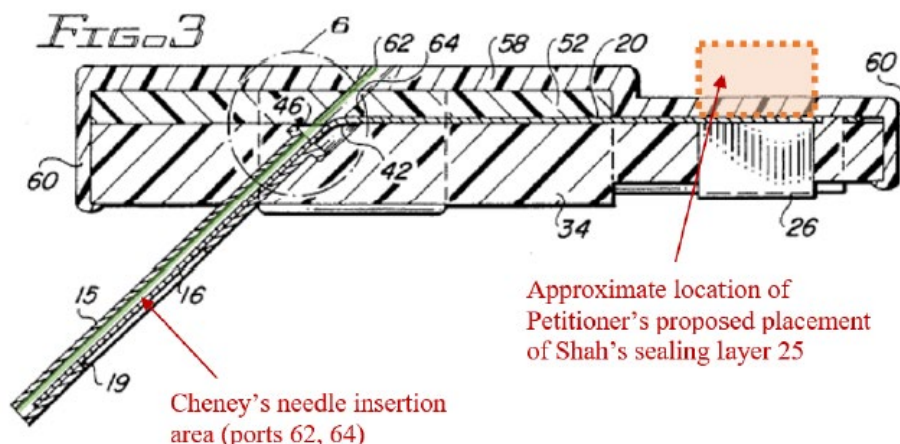


Cheney's Figure 2 is modified to add a sealing member (shaded orange) above sensor proximal segment 20 and labels that identify (1) the added sealing member as a "sealing member upper portion," (2) the connector block 26 as a "sealing member lower portion," and (3) the sensor 20 as being "sandwiched between sealing member upper/lower portions." *Id.*

Petitioner contends that a skilled artisan would have been motivated "to use Shah's upper sealing layer above the sensor and connector block in Cheney/Lord to further tighten/enhance the seal around the sensor and provide additional protection of the sensor/connector against moisture." Pet. 64. Petitioner contends that the proposed modification is nothing more than an arrangement of old elements according to known methods to yield predictable results and reflects the use of a known technique to improve a similar device in the same way to provided the predictable result of

“an enhanced seal surrounding the contact and sensor and/or sandwiching the sensor.” *Id.* (citing Ex. 1006, code [57], 1:5–11, 1:51–54; Ex. 1003 ¶¶ 247–58).

Patent Owner argues that Petitioner’s proposed combination of Cheney/Lord with Shah is “unjustified,” “untethered from the teachings of the references,” and “relies on misstatements regarding the references’ teachings.” Prelim. Resp. 46. Patent Owner contends that “Petitioner’s placement of Shah’s sealing layer 25 is untethered from the teachings of Shah” because it would actually “defeat the purpose of Shah’s sealing layer,” which is “to seal the location where the needle penetrates” mounting base 10 “to reach the infusion site” to provide “a more sanitary infusion site by keeping the infusion site insulated.” *Id.* at 51–52 (citing Ex. 1019 ¶ 39, Figs. 2, 3B). Patent Owner notes Petitioner’s proposed modification of Cheney/Lord would position the seal member of Shah at a location relatively remote and wholly separate from the location where the needle penetrates the housing member to reach an infusion site and, as a result, would prevent the seal member from performing its intended sealing function, as illustrated by the Patent Owner annotated versions of Cheney’s Figure 3 and Lord’s Figure 1 reproduced below. *Id.* at 52–53.



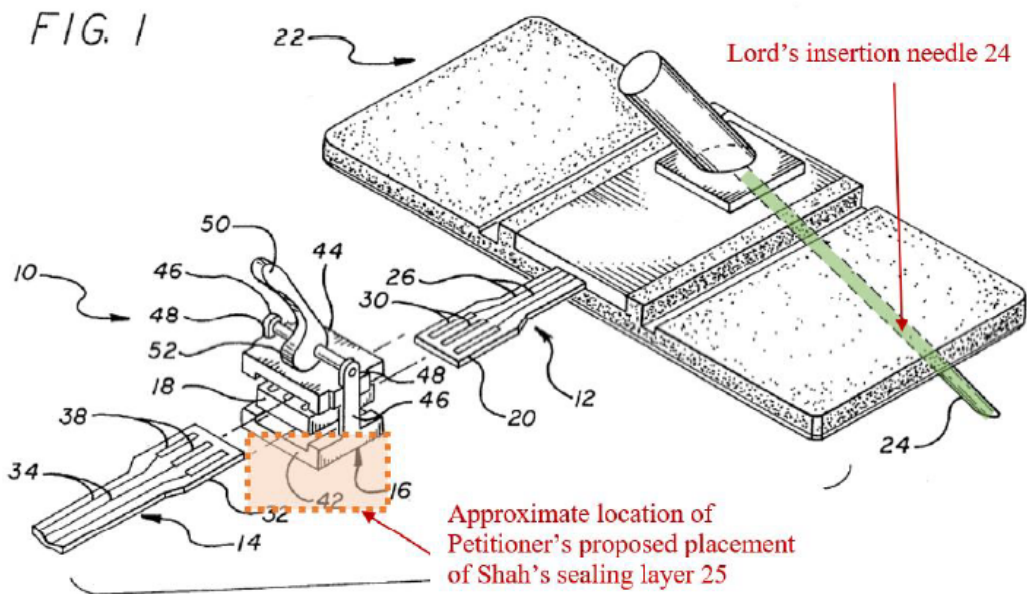


Figure 3 shows a cross-section of Cheney's transcutaneous sensor insertion set with the needle insertion area labeled and shaded in green and the approximate location of Petitioner's proposed placement of Shah's sealing layer 25 labeled and shaded in red. *Id.* at 53 (citing Ex. 1005, 4:61–67, Fig. 3). Figure 1 from Lord illustrates a transcutaneous sensor insertion set with the needle insertion area labeled and shaded in green and the approximate location of Petitioner's proposed placement of Shah's sealing layer 25 labeled and shaded in red. *Id.* (citing Ex. 1006, Fig. 1).

Patent Owner argues that the proposed modification of Cheney/Lord in view Shah is unjustified because there is no basis to conclude adding Shah's sealing layer would *further* enhance the seal around the sensor and provide *further* protection of the sensor against moisture, as Petitioner contends. Prelim. Resp. 54. Patent Owner notes that Cheney/Lord already teaches that the connector block/sensor connection creates a "hermetic seal," which indicates the sensor is already sealed and protected against moisture. *Id.* at 55 (citing Ex. 1006, 3:67–4:3, Fig. 3).

We find merit in Patent Owner's arguments. When considering the disclosures of Cheney, Lord, and Shah in their entirety, as we must, we are not persuaded Petitioner has identified sufficiently a rational underpinning that supports the reasoning for why a skilled artisan would have modified Cheney/Lord in the manner claimed. Petitioner proposes modifying Cheney/Lord by adding a *sealing* layer, such as the one Shah discloses, to the opposite side of the sensor proximal segment 20 that is connected to connector block 26 to further enhance the seal around the sensor and provide the sensor additional protection against moisture. At first glance this may seem like a valid reason, but further inspection of Cheney, Lord, and Shah demonstrates that those references provide no evidentiary support for the alleged reason.

Cheney/Lord describe the sensor proximal segment 20 as being a flexible thin film sensor including elongated thin film conductors *embedded or encased* between upper and lower layers of insulative material, which has openings for *exposing* the conductive contact pads 22 that electrically interconnect with the corresponding connective strips 40 in connector block 26, which sealingly engages with sensor proximal segment 20 to hermetically seal the contact pads against moisture ingress. Ex. 1006, 2:11–23, 3:16–24, 3:34–40, 3:51–4:3; Ex. 1005, 1:33–42, 3:45–57. We find nothing in Cheney/Lord that even suggests a skilled artisan would have had a need for improving the sealing characteristics of the insulative material on the side of the sensor proximal segment 20 that is opposite of the side connected to connector block 26. On the contrary, Cheney/Lord teaches that a *hermetic seal* can be created by connecting connector block 26 to only the side of the sensor proximal segment 20 with exposed conductive contact

pads 22; Cheney/Lord teaches that the other side is already fully *embedded or encased* within an insulative material.

Shah is no more availing as evidence supporting Petitioner's reasoning. Rather than suggesting a need to further enhance the seal covering the sensor proximal segment 20 on the side opposite of the side with exposed conductive contact pads 22, Shah teaches that its sealing layer 25 is intended "to seal the location where the needle penetrates" mounting base 10 to reach the infusion site" to provide "a more sanitary infusion site by keeping the infusion site insulated." Ex. 1019 ¶ 39, Figs. 2, 3B. As Patent Owner correctly argues, Petitioner's proposed modification would completely thwart the ability of sealing layer 25 to perform that intended function because the sensor proximal segment 20 is located a significant distance away from the needle penetration area, thus, preventing sealing layer 25 from offering any insulating protection to the infusion site. And contrary to suggesting the addition of a sealing layer to the unexposed side of the sensor proximal segment 20, Shah suggests there is no importance to having a sealing layer over the sensor's unexposed side by stating that sealing layer 25 "may be located so that it is *only* covering the needle insertion area." Ex. 1019 ¶ 39 (emphasis added).

Mr. Leinsing also offers little, if any, support to Petitioner's reasoning. In fact, the declaration of Mr. Leinsing is largely duplicative of the contentions Petitioner argues in the Petition. *Compare* Pet. 60–64 with Ex. 1003 ¶¶ 247–258. Most notably, Mr. Leinsing does not even suggest (let alone provide a reasoned basis to show) a skilled artisan would have appreciated the need to further tighten/enhance the seal above the sensor and connector block in Cheney/Lord and provide additional protection of the

sensor/connector against moisture; instead, Mr. Leinsing simply states “it would have been obvious to use Shah’s upper sealing layer above the sensor and connector block in Cheney/Lord. This would further tighten/enhance the seal around the sensor and provide additional protection of the sensor/connector against moisture.” Ex. 1003 ¶ 255. As a result, we give little persuasive weight to the testimony of Mr. Leinsing.

Therefore, we find Petitioner has not demonstrated sufficiently a reasonable likelihood of proving that Cheney/Lord in view of Shah discloses a seal member that “at least partially surrounds the electrical contact and at least a portion of the transcutaneous analyte sensor when the transcutaneous analyte sensor is operably connected to the sensor electronics,” as recited in independent claims 1 and 19.

Finally, as another alternative, Petitioner contends that Cheney/Lord in view of Taniguchi shows the obviousness of having a seal member that “at least partially surrounds” both the electrical contact and the transcutaneous analyte sensor when the sensor is operably connected to the sensor electronics. Pet. 81–85. “Taniguchi teaches using an insulative elbow attached to a zebra connector block,” as illustrated in Figure 6 reproduced below. *Id.* at 81–82.

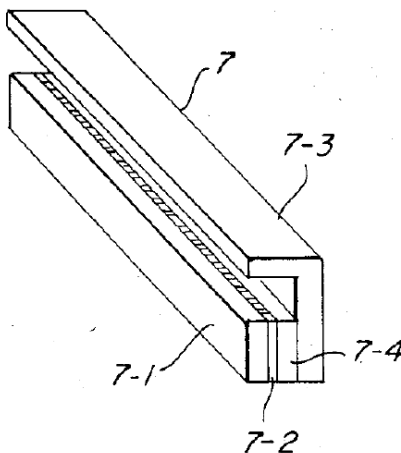
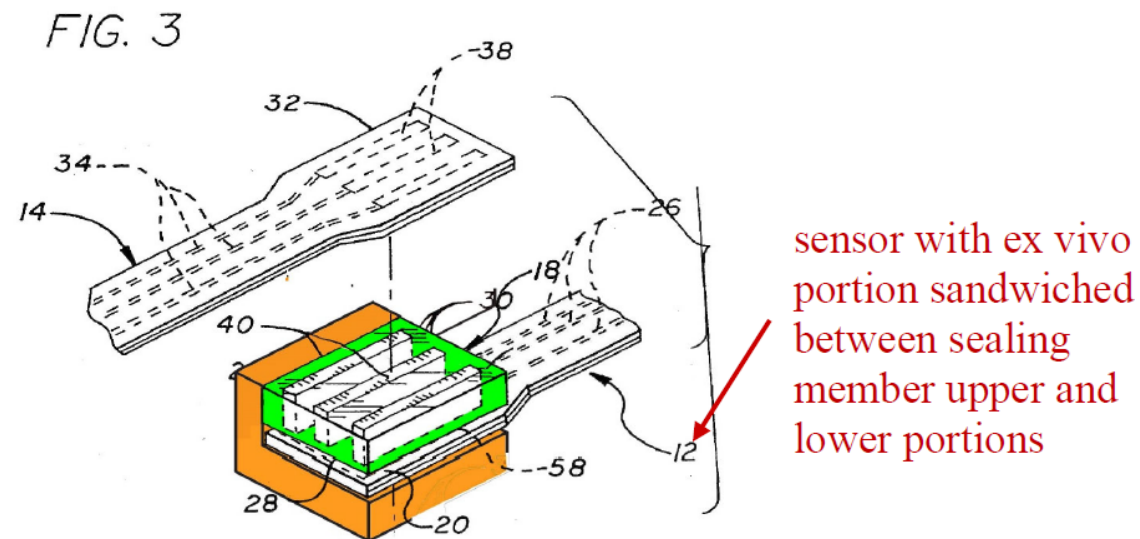
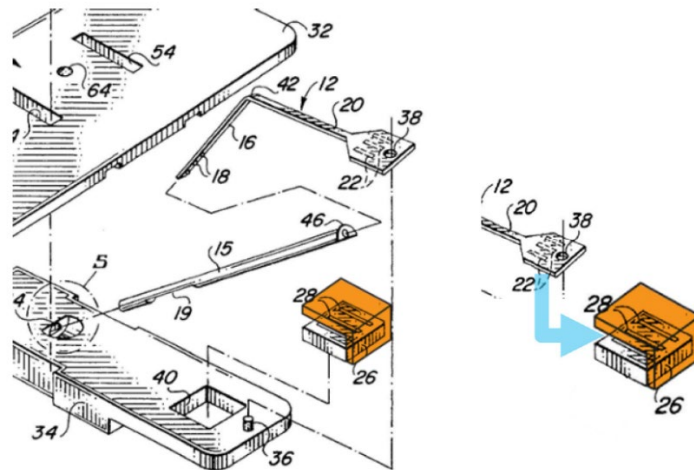


Figure 6 “is a perspective view of a rubber connector 7 in the segment side” and “is composed of part 7-2 that alternately contains the conductive and insulated layers,” as well as, “parts 7-1, 7-3, and 7-4 that respectively comprise *only the insulated rubber*.” Ex. 1007, 2:28–33 (emphasis added). Petitioner contends that “[i]t would have been obvious to adopt such an insulative elbow in the zebra connector block of Cheney/Lord.” *Id.* at 81–82.

To illustrate what this modification would look like, Petitioner provides an annotated Figure 3 from Lord and an annotated Figure 2 from Cheney, which are both reproduced below. Pet. 82–84.





Lord's Figure 3 illustrates the proximal ends of a pair of flex circuits assembled in face-to-face relation with a terminal block (shaded in green) interposed therebetween, which has been modified to include an insulated elbow (shaded in green). In Cheney's Figure 2, which shows a transcutaneous sensor insertion set that has been modified to include an insulated elbow (shaded in orange) to terminal block 26.

Petitioner contends that

[i]t would have been obvious to a skilled artisan to combine the additional sealing member portion from Taniguchi's zebra connector (elbow portion 7-3) with the zebra terminal block connector from Cheney/Lord to further tighten and supplement the seal around the sensor, and to provide additional shock and vibration protection as taught by Taniguchi

Pet. 84. Petitioner states that "insulating elbow portion 7-3 from Taniguchi facilitates an electrical connection with 'extremely high performance reliability against shock and vibration,'" which a skilled artisan would have recognized "facilitate[s] holding the sensor against the connector block in the Cheney/Lord system(s), protecting the connection against shock and vibration and enhancing the seal over the sensor." *Id.* (citing Ex. 1007, 1:17–19; Ex. 1003 ¶¶ 320–327).

Petitioner contends that the proposed modification is nothing more than an arrangement of old elements according to known methods to yield predictable results and reflects the use of a known technique to a known device ready for improvement to yield predictable result of “provid[ing] a stronger electrical/mechanical connection and/or improved seal.” *Id.* at 85 (citing Ex. 1007, 1:14–15). Petitioner contends that “[t]his would further the goal of Cheney/Lord, which teaches the benefit of maintaining a ‘high quality electrical connection’ to minimize electrical leakage between two circuits so that the patient ‘may engage in substantially normal daily activities.’” *Id.* (citing Ex. 1006, 3:34–50; Ex. 1003 ¶¶ 320–327).

Patent Owner argues that Petitioner has failed to establish Taniguchi is analogous art to the invention of the ’452 patent. Prelim. Resp. 60–62. But we need not reach this issue because, even presuming that Taniguchi is analogous art, we find Petitioner has failed to identify sufficiently a rational underpinning that supports the reasoning for why, in view of Taniguchi, a skilled artisan would have modified Cheney/Lord in the manner claimed.

Cheney/Lord describe the sensor proximal segment 20 as being a flexible thin film sensor including elongated thin film conductors *embedded or encased* between upper and lower layers of insulative material. Ex. 1006, 2:11–23, 3:16–24, 3:34–40, 3:51–4:3; Ex. 1005, 1:33–42, 3:45–57. As such, Cheney/Lord already discloses that the flexible thin film sensor has a layer of insulative material surrounding the sensor. Taniguchi teaches that insulating elbow portion 7-3 is comprised only of insulated rubber, thus, Petitioner’s proposed modification merely adds *more* insulative material to the sensor. But Petitioner does not explain adequately why a skilled artisan would have had a reason to use the alleged *sealing member* (i.e., connector

block 26) to provide the additional insulative material beyond the amount of insulative material that Cheney/Lord already disclose as being part of the flexible thin sensor construction. Furthermore, Cheney/Lord makes clear that the conductive contact pads 22 forms a hermetic seal when connected to the connector block 26, thus, it is also unclear why a skilled artisan would have had a reason to include additional sealing material to backside of the conductive contact pads 22 that is *embedded or encased* in insulative material. Ex. 1006, 2:11–23, 3:16–24, 3:34–40, 3:51–4:3; Ex. 1005, 1:33–42, 3:45–57.

Petitioner alleges a skilled artisan would have recognized that the proposed modification would *enhance* the seal over the sensor and provide *further* protection against shock and vibration, but we find insufficient evidence is presented to support these contentions. The supporting evidence that Petitioner cites from Taniguchi regarding the alleged benefits has little persuasive value because the applications of Taniguchi and Cheney/Lord are very different. As it relates to the insulating elbow portion 7-3, the application in Cheney/Lord is to a “flexible thin sensor” and the application in Taniguchi is to a structure made of glass (i.e., LCD). *See* Ex. 1005, 3:45–50; Ex. 1006, 3:25–29; Ex. 1007, 1:65–68. Petitioner provides no evidentiary basis to find a skilled artisan would have recognized the benefits realized within the context of Taniguchi’s application would translate to similar benefits within the context of Cheney/Lord. This is particularly true, here, when the apparatus being modified already includes the same material being added (i.e., an insulating elastomer) and the desired characteristic (i.e., a seal). Petitioner has not explained sufficiently why the addition of the insulating elbow portion 7-3 disclosed in Taniguchi would further enhance

and improve upon the insulating sealing layer already present on the flexible thin sensor that Cheney/Lord discloses in the context of a transcutaneous sensor insertion set.

Again, Mr. Leinsing offers little, if any, support to Petitioner’s reasoning. In fact, the declaration of Mr. Leinsing is largely duplicative of the contentions Petitioner argues in the Petition. *Compare* Pet. 81–85, with Ex. 1003 ¶¶ 320–327. As a result, we give little persuasive weight to the testimony of Mr. Leinsing.

Therefore, we find Petitioner has not demonstrated sufficiently a reasonable likelihood of proving that Cheney/Lord in view of Taniguchi discloses a seal member that “at least partially surrounds the electrical contact and at least a portion of the transcutaneous analyte sensor when the transcutaneous analyte sensor is operably connected to the sensor electronics,” as recited in independent claims 1 and 19.

7. *Challenged Claims 1, 2, 4, 7, 10–12, 14, 18–20, 22, 23, 26–28, 62–64, and 66–68*

Each of Petitioner’s various contentions regarding the unpatentability of claims 1, 2, 4, 7, 10–12, 14, 18–20, 22, 23, 26–28, 62–64, and 66–68 in Grounds 1–10 depend on Cheney/Lord disclosing the recited sealing member being at least partially located over a contact holder, as recited in independent claims 1, 19, and 62. *See* Pet. 42–44, 51, 53, 65, 68, 69, 76, 78, 85, 88, 89. Additionally, the unpatentability contentions for claims 1, 2, 4, 7, 10–12, 14, 18–20, 22, 23, 26–28, and 68 spread across Grounds 1–10 of the Petition, directly or indirectly, depend on Petitioner showing Cheney/Lord alone or in various combinations with Shah or Taniguchi disclose a sealing member that “at least partially surrounds the electrical

contact and at least a portion of the transcutaneous analyte sensor when the transcutaneous analyte sensor is operably connected to the sensor electronics,” as recited by independent claims 1 and 19. *See id.* at 39–41, 53, 59–65, 69, 81–89. Petitioner has failed to demonstrate sufficiently for the reasons explained above that Cheney/Lord, with and without Shah or Taniguchi, discloses or suggests either of those recited limitations. As a result, the Petition has not demonstrated sufficiently that Petitioner has a reasonable likelihood of success in showing independent claims 1, 19, and 62 would have been obvious in view of the various combination of prior art references identified in Grounds 1–10. Petitioner’s unpatentability contentions for dependent claims 2, 4, 7, 10–12, 14, 18, 20, 22, 23, 26–28, 63, 64, and 66–68 necessarily fail for the same reasons. Therefore, we are not persuaded there is at least one of the challenged claims in Grounds 1–10 that Petitioner is reasonably likely to be able to successfully show is unpatentable.

III. CONCLUSION

Our review of the Petition under 35 U.S.C. § 314 is not to determine whether an individual asserted fact is indisputable or whether a preponderance of the evidence supports Petitioner. Our review is to determine whether the totality of the information presented in the Petition and Preliminary Response shows that there is a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the Petition.

For the above reasons, we determine Petitioner has not established a reasonable likelihood that the unpatentability challenges in the Petition would prevail with respect to at least one challenged claim of the ’452

patent. Therefore, we deny *inter partes* review of the '452 patent on all challenged claims and all grounds asserted in the Petition. *See* 35 U.S.C. § 314(a).

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of the '452 patent is denied.

IPR2022-00917
Patent 10,980,452 B2

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