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571-272-7822

Paper 10
Date: April 15, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

IPR2023-01409
Patent 11,202,591 B2

Before JOHN G. NEW, RYAN H. FLAX, and CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

HARDMAN, *Administrative Patent Judge*.

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

I. INTRODUCTION

Petitioner DexCom, Inc. requests *inter partes* review of claims 1–30 of U.S. Patent No. 11,202,591 B2 ("the '591 patent," Ex. 1001). Paper 2 ("Pet."). Patent Owner Abbott Diabetes Care Inc. filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

We have authority under 35 U.S.C. § 314(a), which provides that 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." After considering the parties' briefing and the cited evidence of record, we institute an *inter partes* review.

The following preliminary findings of fact and conclusions of law are made solely for determining whether to institute review. Any final decision will be based on the full trial record.

A. Real Parties in Interest

Petitioner and Patent Owner each identify only themselves as the real party in interest. Pet. ix; Paper 5 (Patent Owner's Mandatory Notices), 1; Paper 7 (Patent Owner's Updated Mandatory Notices), 1.

B. Related Matters

The parties identify as related the following matter involving the '591 patent: *Abbott Diabetes Care Inc. et al. v. DexCom, Inc.*, No. 1:23-cv-00239 (D. Del.), filed March 3, 2023. Pet. ix; Paper 5, 1; Paper 7, 1.

C. The '591 Patent (Ex. 1001)

The '591 patent, titled "Analyte Sensor and Apparatus for Insertion of the Sensor," issued on December 21, 2021, from U.S. Application 17/221,154, filed on April 2, 2021. Ex. 1001, codes (21), (22), (45), (54). It claims priority as a continuation to several utility patent applications, the

earliest of which was filed on February 1, 2010, and to a provisional patent application filed on February 3, 2009. *Id.* at codes (63), (60). The '591 patent relates to an inserter device to insert an analyte sensor and/or an infusion set in an animal, such as a human. *Id.* at 1:29–31.

The Specification describes embodiments of an on-body unit that contains an analyte sensor in a sensor housing. The analyte sensor may be used to monitor levels of analytes such as glucose. Ex. 1001, 11:39–51. The on-body unit communicates with a monitor unit to provide data from the analyte sensor. *Id.* at 8:64–9:10, 14:8–17.

One embodiment of an on-body unit is depicted in Figure 8 of the '591 patent, reproduced below.

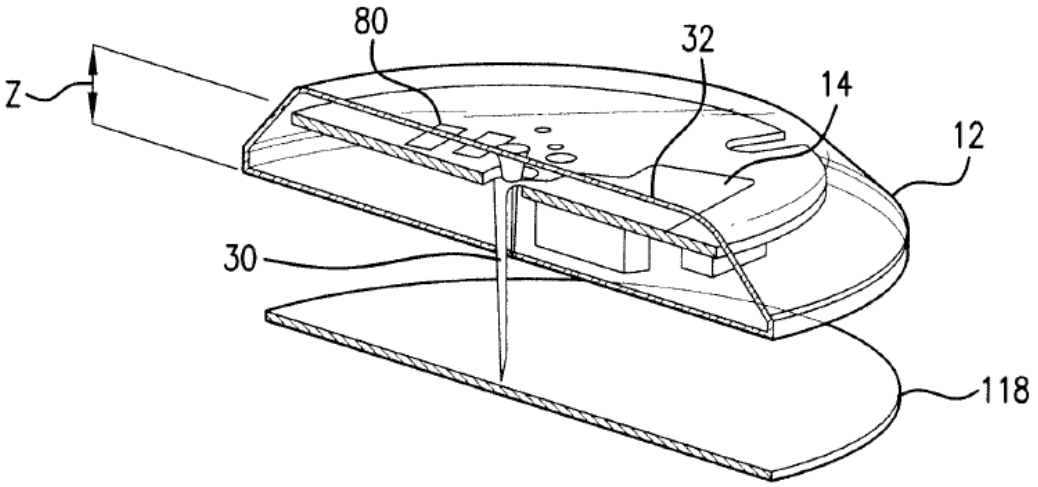

FIG.8

Figure 8 is a perspective view in partial cross-section of an on-body unit. Ex. 1001, 6:16–18. The on-body unit includes data processing unit 12, electronics 80, sensor 14, contact portion 32, and insertion portion 30. *Id.* at 13:67–14:36. Insertion portion 30 is sized and configured to be inserted into the skin of a subject using a sharp. *Id.* at 12:31–34, 14:33–36. Data

processing unit 12 may have a reduced height Z (e.g., about 3 mm to 25 mm) to provide a low profile when sitting on the skin of the subject. *Id.* at 14:1–7.

The Specification describes sensor assemblies that include an analyte sensor, glucose sensor, and/or an infusion device, and a device to position at least a portion of the medical device beneath a skin surface of a user (an "inserter" or "insertion assembly"). *Id.* at 2:1–7, 2:13–20. One embodiment of an inserter is depicted in Figure 30 of the '591 patent, reproduced below.

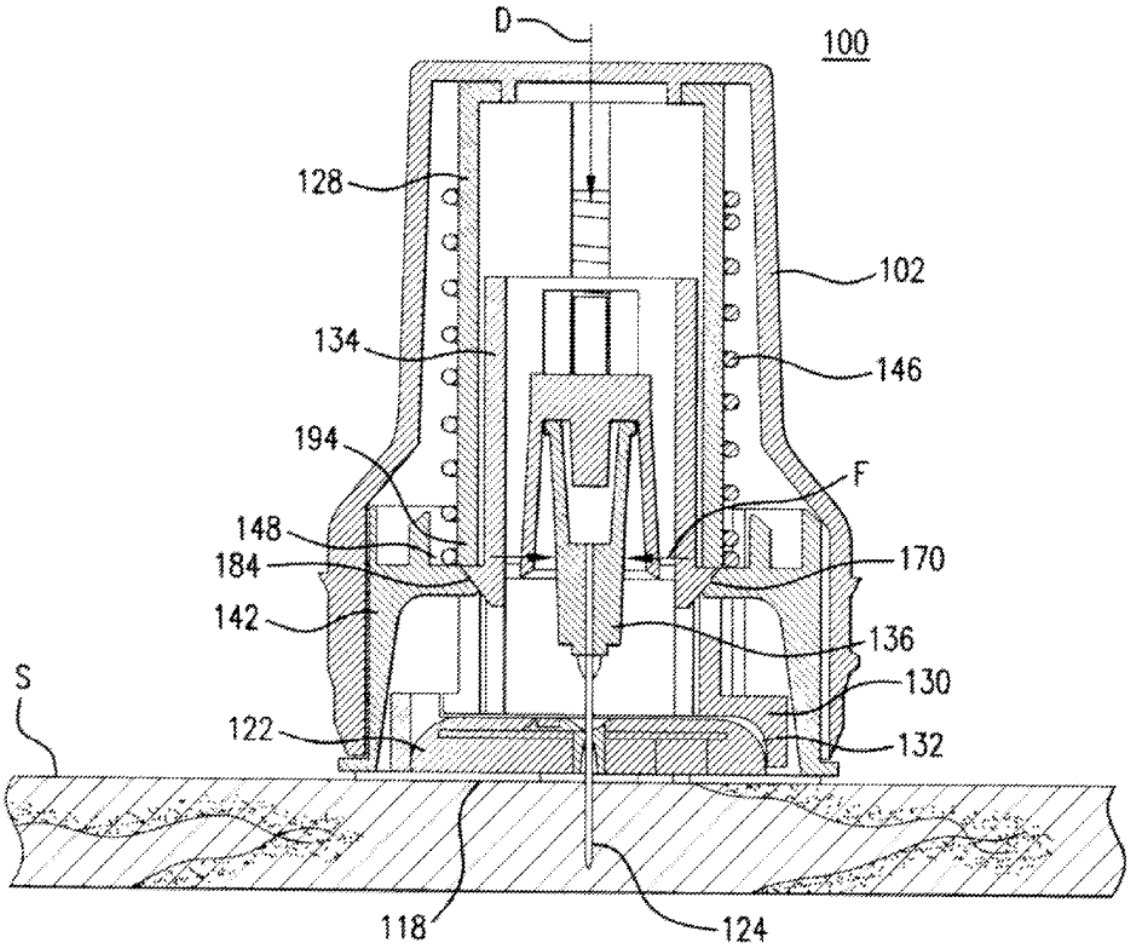

FIG.30

Figure 30 is a sectional view of an inserter. Ex. 1001, 6:56–57. Inserter 100 includes handle 102, base 142, sharp 124, sensor housing 122, and adhesive

pad 118. *Id.* at 19:6–25. Handle 102 contains additional components, including carriage 130, inner rail 128, distal edge of the inner rail 194, shuttle 134, needle hub 136, fingers of the shuttle 184, flanges 170, spring 146, and spring floor 148. *Id.* Sharp 124 extends longitudinally from needle hub 136 within inserter 100 and is supported by shuttle 134. *Id.*

Inserter 100 is used to insert a sensor insertion portion of the sensor housing into a subcutaneous layer of a subject's skin S so it is in contact with the subject's interstitial fluid. Ex. 1001, 19:6–25. Before the inserter is used, shuttle 134 is coupled to inner rail 128 by inter-engagement of fingers 184 of shuttle 134 and distal edge 194 of inner rail 128, such that shuttle 134 and inner rail 128 move together as a unit. *Id.*

The inserter is used by depressing handle 102 downwards against the bias of spring 146. *Id.* When handle 102 is depressed, inner rail 128 moves downward with carriage 130 and sensor housing 122 and guides sharp 124 distally. *Id.* Sharp 124 carries the sensor insertion portion of the sensor housing 122 into a subcutaneous layer of a subject's skin S. *Id.*

When carriage 130 reaches its distal position, the distal surface of sensor housing 122 engages the upper surface of adhesive pad 118 and adheres to the subject's skin S. *Id.* Flanges 170 on base 142 engage fingers 184 of shuttle 134 and cause them to pivot or bend inwards to disengage from the distal edge of inner rail 194. *Id.* Disengagement of shuttle 134 from inner rail 128 allows spring 146 to expand and move shuttle 134 back to its proximal position to automatically withdraw sharp 124 from sensor housing 122 and the subject's skin S. *Id.* at 19:26–40.

D. The Challenged Claims

Petitioner challenges claims 1–30 of the '591 patent. Claims 1 and 19 are independent. Claim 1, reproduced below with bracketed numbering added,[1] is illustrative:

1. [1.1] An insertion assembly, comprising:

[1.2] (a) an on-body unit, comprising:

[1.3] a housing comprising a top surface and a bottom surface, wherein the top surface comprises an opening of the top surface, wherein the bottom surface comprises an opening of the bottom surface, and wherein a longitudinal axis extends through the opening of the top surface and the opening of the bottom surface;

[1.4] a glucose sensor; and

[1.5] sensor electronics disposed within the housing and coupled with the glucose sensor; and

[1.6] (b) an inserter, comprising:

[1.7] a proximal end, a distal end, and an interior; and

[1.8] a sharp,

[1.9] wherein the on-body unit and the sharp are entirely disposed in the interior of the inserter,

[1.10] wherein at least a portion of the glucose sensor is disposed in the sharp,

[1.11] wherein the sharp extends through the opening of the top surface and the opening of the bottom surface along the longitudinal axis when the on-body unit is in a first position,

[1.12] wherein the inserter is configured to advance the on-body unit and the sharp in a linear direction from the first position to a second position such that the sharp pierces

[1] For ease of reference, we use the same bracketed numbering Petitioner uses in the Petition. *See* Pet. 8–9.

skin of a user and the housing of the on-body unit is secured to the skin of the user in the second position,

[1.13] wherein the distal end of the inserter is configured to be positioned on the skin of the user before advancement of the on-body unit and the sharp,

[1.14] wherein the inserter is further configured to automatically retract the sharp from within the user and entirely into the interior of the inserter and leave a part of the glucose sensor in the skin of the user, and

[1.15] wherein the distal end of the inserter is further configured to be removed from the skin of the user after automatic retraction of the sharp from within the user.

Ex. 1001, 23:6–46.

Challenged claims 2–18 depend directly or indirectly from independent claim 1 and recite additional features of the insertion assembly. *Id.* at 23:47–24:61.

Challenged independent claim 19 is similar to claim 1, but incorporates clam limitations from dependent claims 3–5 and 14. *Id.* at 24:62–25:48; *see also* Pet. 33 n.7. For example, claim 19 additionally requires an on-body unit "wherein the sensor electronics comprise a processor, a power source, an analog interface, a data storage unit, and wireless communication circuitry configured to communicate data indicative of a glucose level." Ex. 1001, 25:6–10. Claim 19 also recites an inserter "wherein a distance between the housing when the on-body unit is in the first position and the housing when the on-body unit is in the second position is greater than a maximum height of the housing," "wherein a height profile of the housing is less than or equal to approximately 10 millimeters," and "wherein the sharp is configured to pierce the skin of the

user at an angle substantially perpendicular to the skin of the user." *Id.* at 25:24–32.

Challenged claims 20–30 depend directly or indirectly from independent claim 19 and recite additional features of the insertion assembly. *Id.* at 25:49–26:55.

E. Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–30 are unpatentable on the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §[2]	Reference(s)/Basis
1	1–6, 9–14, 16–24, 27, 29, 30	103	Stafford,[3] Cote[4]
2	4, 7, 8, 15, 19–30	103	Stafford, Cote, Say[5]
3	18, 21–24, 27, 29, 30	103	Stafford, Cote, Brenneman[6]

[2] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended several provisions of 35 U.S.C., including § 103. The '591 patent claims priority through a series of applications, the earliest of which is Provisional Application No. 61/149,639, filed on February 3, 2009. Ex. 1001, codes (21), (22), (60), (63). Petitioner appears to assume a priority date of February 3, 2009. *See, e.g.*, Pet. 6, 11. Patent Owner does not address priority. *See generally* Prelim. Resp. For purposes of this decision, we apply a priority date of February 3, 2009, and thus the pre-AIA version of § 103; however, our decision would be no different under the AIA version of the statute.

[3] Stafford, US 2008/0097246 A1, published April 24, 2008 ("Stafford," Ex. 1004).

[4] Cote et al., US 2005/0101932 A1, published May 12, 2005 ("Cote," Ex. 1005).

[5] Say et al., US 6,175,752 B1, issued January 16, 2001 ("Say," Ex. 1008).

[6] Brenneman et al., WO 2008/115409 A1, published September 25, 2008 ("Brenneman," Ex. 1040).

Ground	Claim(s) Challenged	35 U.S.C. §[2]	Reference(s)/Basis
4	9, 22–24, 27, 29, 30	103	Stafford, Cote, Shah[7]
5	21–30	103	Stafford, Cote, Say, Brenneman
6	25, 26, 28	103	Stafford, Cote, Say, Shah
7	22–24, 27, 29, 30	103	Stafford, Cote, Brenneman, Shah
8	25, 26, 28	103	Stafford, Cote, Say, Brenneman, Shah

Pet. 4. Petitioner supports its contentions with the Declaration of Gary D. Fletcher (Ex. 1003), among other evidence.

II. DISCRETIONARY DENIAL UNDER § 325(d)

The parties dispute whether the Board should exercise its discretion to deny the Petition under 35 U.S.C. § 325(d). *See generally* Prelim. Resp.; Pet. 5. Section 325(d) provides that the Director[8] may "reject the petition" if "the same or substantially the same prior art or arguments previously were presented to the Office." 35 U.S.C. § 325(d). The Board analyzes this issue under a two-part "*Advanced Bionics*" framework:

> (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of [the] first part of the framework is satisfied, whether the petitioner has demonstrated that the

[7] Shah et al., US 2007/0073129 A1, published March 29, 2007 ("Shah," Ex. 1006).

[8] The Board institutes trial on behalf of the Director. 37 C.F.R. § 42.4(a).

> Office erred in a manner material to the patentability of challenged claims.

Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential).

In evaluating whether to deny institution under 325(d), the Board may consider several non-exclusive factors, including:

> (a) the similarities and material differences between the asserted art and the prior art involved during examination;
>
> (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
>
> (c) the extent to which the asserted art was evaluated during examination;
>
> (d) the extent of the overlap between the arguments made during examination and the manner in which a petitioner relies on the prior art or a patent owner distinguishes the prior art;
>
> (e) whether a petitioner has pointed out sufficiently how the Office erred in evaluating the asserted prior art; and
>
> (f) the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments.

Becton, Dickinson & Co. v. B. Braun Melsungen AG, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first para.).

Factors (a), (b), and (d) relate to the first part of the *Advanced Bionics* framework, i.e., whether the art or arguments in the Petition are the same or substantially the same as those previously presented to the Office. *See Advanced Bionics*, IPR2019-01469, Paper 6 at 10.

Factors (c), (e), and (f) relate to the second part of the *Advanced Bionics* framework, i.e., "whether the petitioner has demonstrated a material error by the Office" in the Office's prior consideration of that art or arguments. *Id.*

A. Part One of the Advanced Bionics Framework (whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office)

Petitioner's unpatentability challenges rely on five different prior art references. *See* Pet. 4. There is no dispute that Stafford, Shah, and Say were before the Office during prosecution of the '591 patent. *See* Pet. 5; Prelim. Resp. 3–4. There is also no dispute that a counterpart of Cote was before the Office during prosecution of the '591 patent. *See* Pet. 5; Prelim. Resp. 5–22. Patent Owner persuasively shows that this counterpart of Cote is materially identical to the version of Cote on which Petitioner relies. *See* Prelim. Resp. 5–22. Finally, Patent Owner demonstrates that Brenneman was before the Office during prosecution of the '591 patent. *See* Prelim. Resp. 4–5 (citing Ex. 1004 (pros. history), 52).

Each of Stafford, Shah, Say, and Brenneman, and the materially-identical counterpart of Cote, was listed on an Information Disclosure Statement ("IDS") filed during prosecution. *See* Prelim. Resp. 3–5, 20–21 (citing, e.g., Ex. 1002 (prosecution history) at 929, 937 (Say), 946 (Stafford, Shah), 958 (Brenneman and Cote counterpart (WO 2005/046,780 A1)). The Examiner certified that "all references" on the relevant IDSs were "considered except where lined through." *See id.* There is no line through Stafford, Shah, Say, Brenneman, or the Cote counterpart. *See id.*

Based on the above, we determine that part one of the *Advanced Bionics* framework is satisfied. *See Advanced Bionics*, IPR2019-01469, Paper 6 at 7–8 (indicating that "previously presented art" includes "art made of record by the Examiner"). Accordingly, we turn to part two of that framework. *See id.* at 8.

B. Part Two of the Advanced Bionics Framework (whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims)

Patent Owner contends that the Petition fails to address, let alone establish, that the Office erred in a manner material to the patentability of the challenged claims. *See* Prelim. Resp. 22. We disagree.

As noted above, part two of the *Advanced Bionics* framework implicates *Becton, Dickinson* factors (c), (e), and (f). *See Advanced Bionics*, IPR2019-01469, Paper 6 at 10.

As to factor (c) (the extent to which the asserted art was evaluated during examination), the parties dispute whether the Examiner's consideration of Petitioner's references was "[c]ursory" or "the opposite." *See id.* at 5 (alleging "[c]ursory consideration" and "minimal review" of the references); Prelim. Resp. 24 (arguing that "the record suggests the opposite," given that the Examiner had "more than ample time . . . to review the references"). Although the Examiner considered each of Petitioner's references to some extent (as demonstrated by the Examiner's certifications on the IDSs), the Examiner did not reject the claims based on any of Petitioner's references (or any other prior art reference), and did not otherwise mention Petitioner's references. *See* Pet. 5, 7–8 (summarizing the prosecution history); *see generally* Ex. 1002 (prosecution history). Accordingly, based on the current record, we are unable to ascertain the extent to which the Examiner evaluated the asserted art during examination.

As to factor (e) (whether a petitioner has pointed out sufficiently how the Office erred in evaluating the asserted prior art) and factor (f) (the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments), *Advanced Bionics* makes clear

that if "the record of the Office's previous consideration of the art is not well developed or silent, then a petitioner may show the Office erred by overlooking something persuasive." *Advanced Bionics*, IPR2019-01469, Paper 6 at 10.

Although Petitioner did not specifically state that the Examiner erred in not rejecting the claims over the prior art asserted here, under the second part of the *Advanced Bionics* framework, based on our analysis of the current record as a whole, we find that Petitioner has "ma[d]e a showing of material error," in fact, the Petition is premised on it. *Advanced Bionics*, IPR2019-01469, Paper 6 at 8–9. In particular, Petitioner shows that the Office erred by overlooking something persuasive, namely, the teachings of at least Stafford and Cote, as highlighted in Petitioner's unpatentability grounds. *See* Pet. 5 (arguing that each of Cote and Brenneman "provides express teachings on inserters for on-body units that were not considered by the Examiner"), 20–84 (Ground 1).

In the Reasons for Allowance, the Examiner stated that "[w]hile Brister (US 2006/0016700) teaches the bulk of the claimed limitations, it fails to teach a housing . . . and an inserter with a sharp" that extends through the housing as claimed. Ex. 1002, 977. Petitioner, however, sufficiently demonstrates for purposes of institution that Stafford and Cote disclose these limitations. *See* Pet. 33–84 (explaining why Stafford and Cote teach or suggest the limitations of the challenged claims); *see also infra* Section III.E (determining that, on the current record, Petitioner establishes a reasonable likelihood that the claims challenged in Ground 1 are unpatentable as obvious over Stafford and Cote). Based on the circumstances elucidated by the current record, we find that Petitioner adequately shows that the

Examiner "misapprehend[ed] or overlook[ed] specific teachings" of at least Stafford and Cote that "impact patentability of the challenged claims." *Advanced Bionics*, IPR2019-01469, Paper 6 at 8 n.9. That is, Petitioner shows that the Examiner materially erred by not applying at least Stafford and Cote in the manner Petitioner argues and as supported by Dr. Fletcher.

Patent Owner argues that the Board should not "infer material error from Petitioner's Grounds," because a petitioner "must affirmatively explain how the Examiner erred such that the Petition should be instituted." Prelim. Resp. 29, 27. The Petition does not cite the precedential *Advanced Bionics* case. Given Petitioner's acknowledgment that certain of its asserted prior art references were previously submitted to the Office, we reiterate that an express analysis under the *Advanced Bionics* framework should have been contemplated and could have been more expressly addressed in the Petition. *See* Paper 9, 4.

Nevertheless, other Board panels have instituted an *inter partes* review after inferring material error based on the strength of the petitioner's grounds. *See, e.g.*, *STMicroelecs., Inc. v. Trustees of Purdue Univ.*, IPR2022-00309, Paper 14 at 12–13 (PTAB July 6, 2022) (finding that petitioner demonstrated examiner erred by not appreciating that reference on IDS disclosed features recited in the challenged claims, as demonstrated by petitioner's unpatentability grounds); *Apple Inc. v. Telefonaktiebolaget LM Ericsson*, IPR2022-00457, Paper 7 at 8 (PTAB Sept. 21, 2022) (same); *Sci. Design Co. v. Shell Oil Co.*, IPR2021-01537, Paper 7 at 24–25 (PTAB Mar. 18, 2022) (same). Furthermore, *Advanced Bionics* specifically provides that we consider "whether the petitioner has *demonstrated* that the Office erred in a manner material to the patentability of challenged claims,"

not whether Petitioner has expressly stated that the Office erred in a manner material to patentability. *Advanced Bionics*, IPR2019-01469, Paper 6 at 8 (emphasis added). Consistent with these cases, here we find that Petitioner sufficiently shows material error by pointing to specific teachings of the relevant prior art that the Examiner (apparently) incorrectly found was missing in the art applied during prosecution.

C. Conclusion

For the above reasons, we decline to exercise our discretion to deny *inter partes* review under § 325(d).

III. ANALYSIS OF PETITIONER'S ASSERTED GROUNDS OF UNPATENTABILITY

Petitioner, supported by Dr. Fletcher, asserts eight grounds of unpatentability based on obviousness over various combinations of Stafford, Cote, Say, Brenneman, and Shah. *See* Pet. 4, 20–105; Ex. 1003 (Fletcher Decl.) ¶¶ 44–210. At this stage, Patent Owner does not present any arguments contesting the merits of Petitioner's obviousness challenges, and it was not required to do so. *See generally* Prelim. Resp.

As we will discuss below, we have considered the arguments and evidence of record and find that Petitioner has demonstrated a reasonable likelihood of prevailing in showing that at least one of the challenged claims would have been obvious over the cited prior art. Accordingly, we institute *inter partes* review of all challenged claims on all grounds in the Petition. *See SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348, 1358 (2018); 37 C.F.R. § 42.108(a) ("When instituting *inter partes* review, the Board will authorize the review to proceed on all of the challenged claims and on all grounds of unpatentability asserted for each claim.").

A. Principles of Law

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")). Petitioner ultimately bears the burden of persuasion to prove unpatentability of each challenged claim by a preponderance of the evidence. 35 U.S.C. § 316(e). This burden never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

The Board may authorize an *inter partes* review if we determine that the information presented in the Petition and Patent Owner's Preliminary Response shows a reasonable likelihood that Petitioner will prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314(a).

Under pre-AIA 35 U.S.C. § 103(a), a claim is unpatentable as obvious if the differences between the claimed subject matter 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. 35 U.S.C. § 103(a) (2006); *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved based on 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;[9] and

[9] *See infra* Section III.B.

(4) any objective indicia of obviousness or nonobviousness.[10] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). An obviousness determination requires finding a reason to combine accompanied by a reasonable expectation of achieving what is claimed in the challenged patent. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016). "[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *KSR*, 550 U.S. at 419–20.

B. Level of Ordinary Skill in the Art

We consider the grounds of unpatentability in view of the understanding of a person of ordinary skill in the art at the time the invention was made.[11] *See Graham*, 383 U.S. at 17–18. Petitioner contends that a person of ordinary skill in the art would have had:

> a bachelor's degree in bioengineering, mechanical engineering, electrical engineering, or a related subject, and one or more years of experience researching, developing, and/or designing insertable medical devices, including, e.g., systems for implanting wearable medical devices such as cannulas, infusion sets, and analyte sensors, or equivalent experience. Less work experience may be compensated by a higher level of education, such as a master's degree, and vice versa.

Pet. 10–11 (citing Ex. 1003 (Fletcher Decl.) ¶ 28). Patent Owner does not presently dispute Petitioner's proposal or offer an alternative definition. *See generally* Prelim. Resp.

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[10] The record does not presently include any objective indicia of obviousness or nonobviousness. *See generally* Pet.; Prelim. Resp.

[11] For purposes of this Decision, we apply a priority date of February 3, 2009. *See supra* 8 n.2.

Because Petitioner's proposed level of ordinary skill in the art appears to be consistent with the cited prior art and is undisputed on this record, we adopt it for purposes of this Decision. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (indicating that the prior art itself may reflect an appropriate skill level).

C. Claim Construction

In AIA proceedings we interpret a 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). Under this standard, we construe 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." *Id.*

Neither party proposes that any claim term requires an express construction. *See* Pet. 19; *see generally* Prelim. Resp. We find it unnecessary to construe any claim term to decide whether Petitioner satisfies the "reasonable likelihood" standard for instituting trial. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (noting that "we need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

Any final written decision entered in this case may include express claim constructions, or may include discussion of claim scope that differs from that provided in our analysis below. Any final claim constructions will be based on the full trial record.

D. Overview of Asserted Prior Art

1. Stafford (Ex. 1004)

Stafford, US 2008/0097246 A1, which published on April 24, 2008, is titled "Method and System for Providing an Integrated Analyte Sensor Insertion Device and Data Processing Unit." Ex. 1004, codes (43), (54). There is presently no dispute that Stafford is prior art. *See generally* Prelim. Resp.

Stafford relates to a "[m]ethod and apparatus for providing an integrated analyte sensor and data processing unit assembly." Ex. 1004, code (57). We reproduce below Stafford's Figure 2.

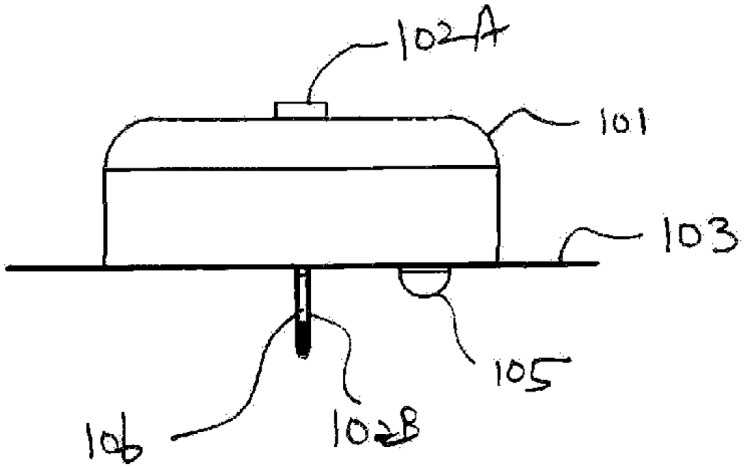

FIGURE 2

Figure 2 depicts a side view of an integrated analyte sensor delivery and data processing unit. Ex. 1004 ¶ 10. The unit may be used to monitor glucose or other analytes via a sensor in fluid contact with a subject's interstitial fluid. *Id.* ¶¶ 29–30, 46.

The unit includes an introducer with a sharp tip at one end, upper portion 102A and lower portion 102B of the introducer, temperature module

105, analyte sensor 106, data processing unit 101, and adhesive patch 103. *Id.* ¶¶ 20, 21, 23–25, 49. At least a portion of analyte sensor 106 is disposed within lower portion 102B of the introducer. *Id.* ¶ 23.

The unit is applied to a subject's skin by placing the unit on the skin and applying force to cause lower portion 102B of the introducer to pierce the subject's skin and allow analyte sensor 106 to be in fluid contact with the subject's analyte. Ex. 1004 ¶ 24. Once the unit is applied to the skin, the introducer can be removed by pulling on upper portion 102A of the introducer. *Id.* Analyte sensor 106 remains in position in fluid contact with the subject's interstitial fluid. *Id.*

2. Cote (Ex. 1005)

Cote, US 2005/0101932 A1, published on May 12, 2005, and is titled "Subcutaneous Infusion Device and Device for Insertion of a Cannula of an Infusion Device and Method." Ex. 1005, codes (43), (54). There is presently no dispute that Cote is prior art. *See generally* Prelim. Resp.

Cote "relates to an infusion device for delivery of a substance to a patient" and "a device for assisting in the introduction of a cannula of an infusion device into the skin of a patient." Ex. 1005 ¶ 1. We reproduce below Cote's Figure 80A.

FIG. 80A

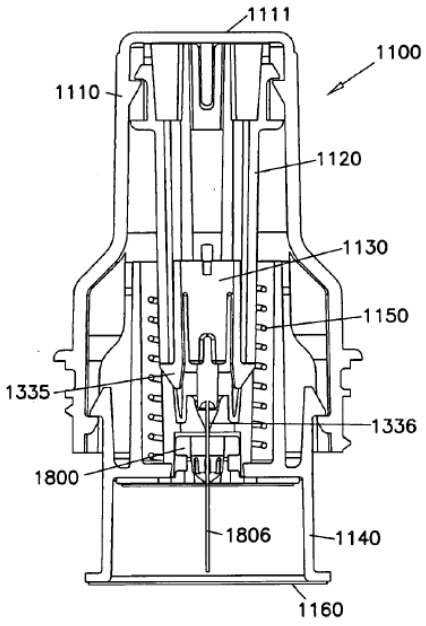

Figure 80A is a cross-sectional view of device 1110, which is used to introduce a cannula of an infusion device into a patient. Ex. 1005 ¶¶ 70, 93, 97. Device 1100 includes sleeve 1140 and housing 1110. *Id.* ¶¶ 203–08. Housing 1110 includes upper end 1111, and contains cylinder hub 1120 with barbs 1335, needle hub 1130 with needle 1336, and spring 1150. *Id.* Sleeve 1140 surrounds cannula 1806 and includes site 1800 and adhesive portion 1160. *Id.* Site 1800 is positioned on needle 1336 so that needle 1336 extends through cannula 1806. *Id.* ¶ 205.

The device is used to deliver cannula 1806 to a patient by positioning adhesive portion 1160 of sleeve 1140 so it is in contact with the skin of the patient. Ex. 1005 ¶¶ 203, 206–207. Pressure is applied to upper end 1111 of housing 1110 to compress spring 1150 and move housing 1110, cylinder hub 1120, and needle hub 1130 towards the patient's skin. *Id.* When sufficient pressure is applied to upper end 1111 of housing 1110, needle 1336 and cannula 1806 of site 1800 are introduced into the patient's skin (the "trigger state"). *Id.* Once cannula 1806 is in place, the patient removes pressure

from upper end 1111 of housing 1110. *Id.* ¶ 212. Spring 1150 expands, needle 1336 is retracted into upper end 1111 of housing 1110, and sleeve 1140 is removed from contact with the patient's skin while site 1800 and cannula 1806 remain on the patient's skin. *Id.* ¶ 211. In some embodiments, the needle is automatically retracted when the device reaches the trigger state to reduce the patient's contact with the exposed needle and the dwell time of the needle in the patient, to increase the patient's comfort. *Id.* ¶ 236.

3. Say (Ex. 1008)

Say, US 6,175,752 B1, is titled "Analyte Monitoring Device and Methods of Use" and issued on January 16, 2001. Ex. 1008, codes (45), (54). There is currently no dispute that Say is prior art. *See generally* Prelim. Resp.

Say is "directed to devices and methods for the in vivo monitoring of an analyte, such as glucose or lactate." Ex. 1008, 1:5–10. Say describes a sensor control unit that is attached to a patient's skin and transmits analyte concentration data from a subcutaneous sensor to another device. *See id.* at 2:13–31, 3:25–37, 29:29–32, 29:55–58, 31:63–32:5.

We reproduce below Say's Figure 14.

FIG. 14

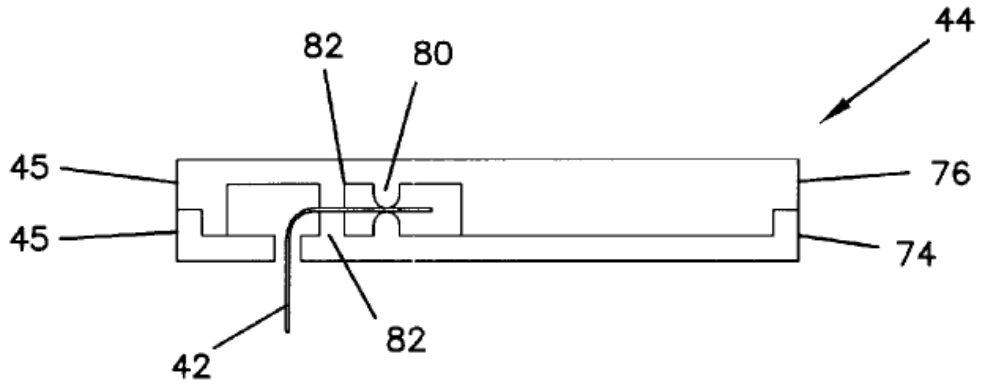

Figure 14 depicts a cross-sectional view of an on-skin sensor control unit. *Id.* at 4:26–27. On-skin sensor control unit 44 in Figure 14 includes cover 76, base 74, support structure 82, housing 45, sensor 42, and conductive contacts 80. *Id.* at 29:27–30:48, 34:43–52. On-skin sensor control unit 44 may also include electronic components, a battery, or a speaker for an audible alarm (not shown). *Id.* at 30:10–13. Sensor 42 is implanted in the patient and on-skin sensor control unit 44 is placed over sensor 42 with conductive contacts 80 in contact with sensor 42. *Id.* at 31:59–62.

We reproduce below Say's Figure 15.

FIG. 15

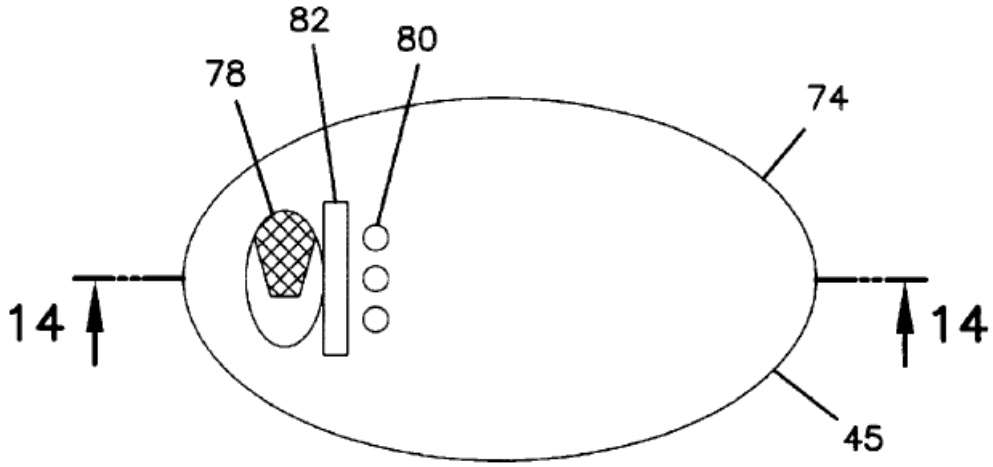

Figure 15 depicts a top view of a base of the on-skin sensor control unit shown in Figure 14. Ex. 1008, 4:28–29. The on-skin sensor control unit in Figure 15 includes base 74, support structure 82, housing 45, a sensor (not shown), conductive contacts 80, and port 78. *Id.* at 29:27–30:48, 34:43–52. Conductive contacts 80 are on the exterior of housing 45, and the sensor reaches conductive contacts 80 through port 78. *Id.* at 30:34–38.

4. Brenneman (Ex. 1040)

Brenneman (WO 2008/115409 A1) is titled "Continuous Analyte Monitoring Assembly and Method of Forming the Same," and published on September 25, 2008. Ex. 1040, codes (45), (54). There is currently no dispute that Brenneman is prior art. *See generally* Prelim. Resp.

Brenneman "relates to a continuous analyte monitoring assembly that includes an implantable sensor that is adapted to be placed in the body to assist in determining the analyte level (e.g., a concentration) of a fluid (e.g., blood)." Ex. 1040 ¶ 1. We reproduce below Brenneman's Figure 1.

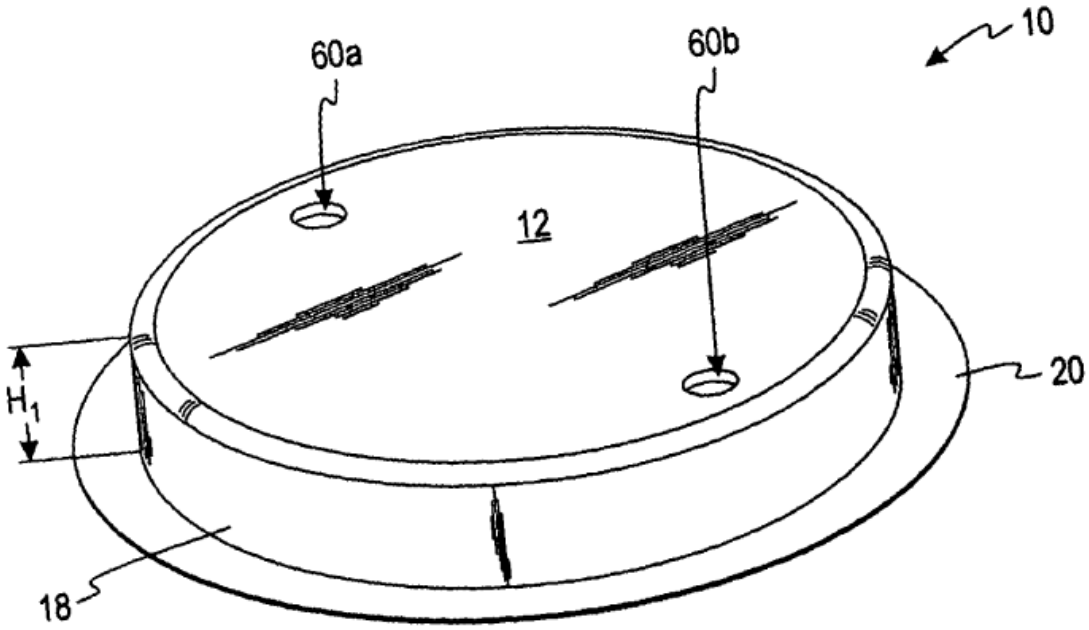

Fig. 1

Figure 1 depicts a top perspective view of a continuous analyte monitoring assembly. Ex. 1040 ¶ 8. Assembly 10 generally has a height H_1 of less than about 0.5 inches and includes cover 12, disposable housing 18, adhesive

liner 20, and apertures 60a, 60b. *Id.* ¶¶ 24, 28, 39. Adhesive liner 20 helps attach assembly 10 to the skin, and apertures 60a, 60b assist in coupling or connecting with an inserter. *Id.* ¶¶ 28, 33. Assembly 10 also includes electronics mounted on a printed circuit board, printed circuit board housing, an implantable sensor, a cannula, a connector, and a battery (not shown). *Id.* ¶¶ 24–25. The cannula helps locate the sensor in the skin and the connector mechanically and electrically connects the implantable sensor and the electronics. *Id.* ¶ 26.

We reproduce below Brenneman's Figure 8.

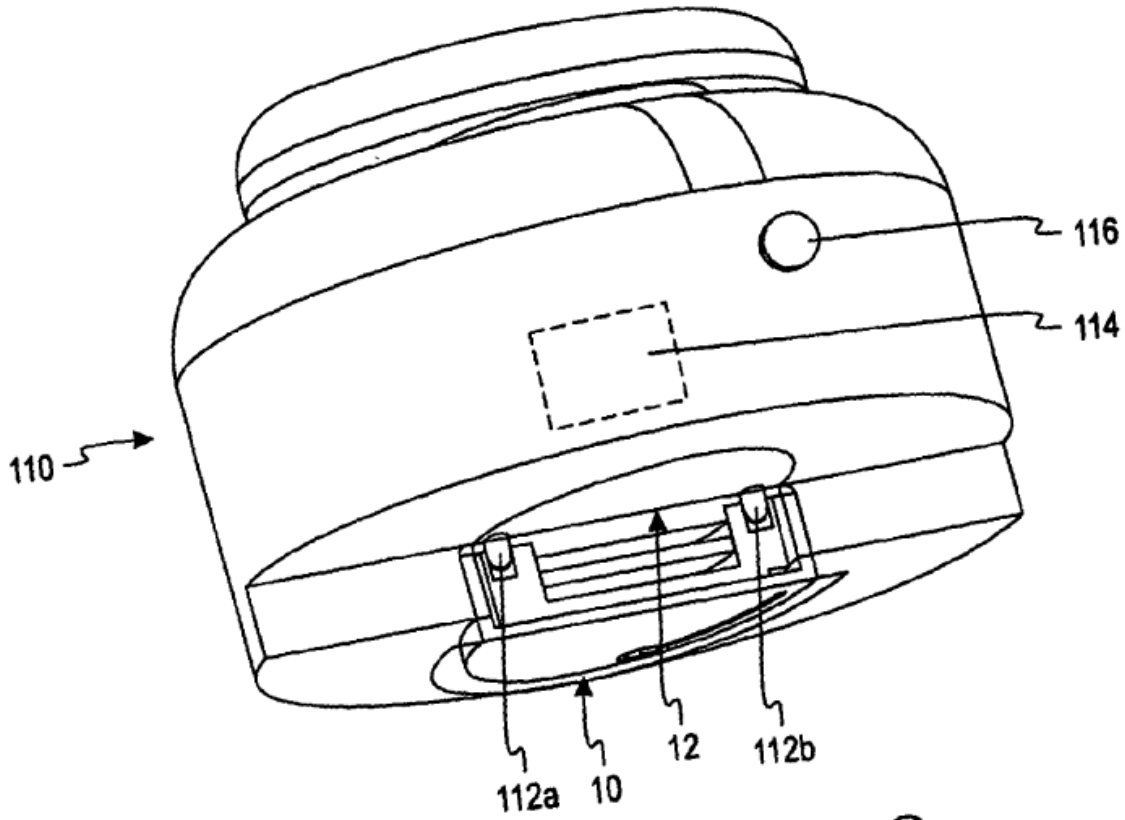

Fig. 8

Figure 8 depicts a partial cutaway bottom perspective view of an inserter with the loaded continuous analyte monitoring assembly of Figure 1.

Ex. 1040 ¶ 18. Inserter 110 receives continuous analyte monitoring assembly 10 and includes safety button 116, plunger 114, and pins 112a, 112b. *Id.* ¶¶ 42, 44. Pins 112a, 112b extend downwards and correspond with the apertures formed in cover 12 of continuous analyte monitoring assembly 10 to help couple it to inserter 110. *Id.* ¶ 42.

The inserter is typically spring-loaded to drive the sensor into the skin. Ex. 1040 ¶ 44. To drive the sensor into the skin, the user places inserter 110 coupled to continuous analyte monitoring assembly 10 on the body, activates safety button 116, and depresses plunger 114. *Id.* ¶¶ 41, 48. Once the sensor is in place, the user removes inserter 110 from continuous analyte monitoring assembly 10. *Id.* ¶ 48.

5. Shah (Ex. 1006)

Shah, US 2007/0073129 A1, is titled "Flexible Sensor Apparatus," and published on March 29, 2007. Ex. 1006, codes (45), (54). There is currently no dispute that Shah is prior art. *See generally* Prelim. Resp.

Shah "relates to a flexible mounting base for a sensor adapted for convenient and comfortable transcutaneous positioning of the sensor electrodes to obtain analyte readings, for example, blood glucose (BG) readings." Ex. 1006 ¶ 2. We reproduce below Shah's Figure 6.

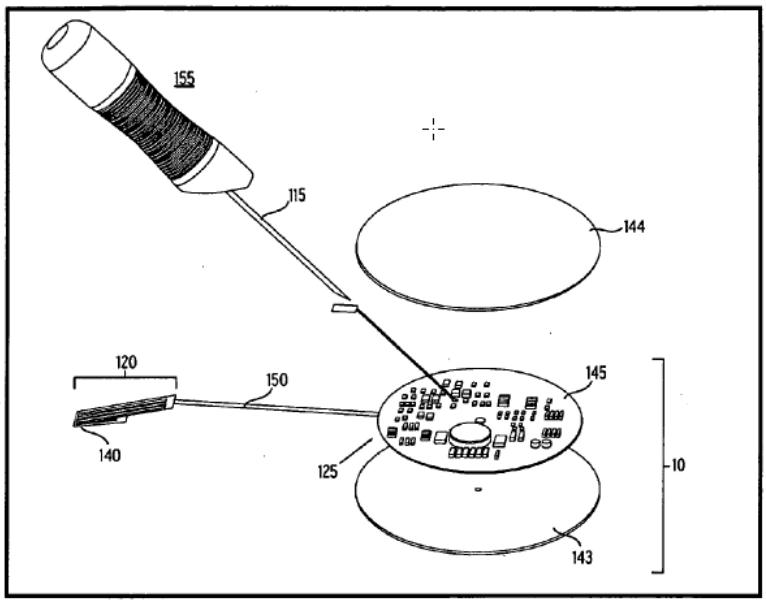

Figure 6 depicts an exploded view of a flexible sensor with flexible electronics. Ex. 1006 ¶ 31. The flexible sensor with flexible electronics includes top layer 144 and flexible mounting base 10, which comprises flexible partial circuit 145 and adhesive layer 143. *Id.* ¶¶ 35, 45–46. Flexible partial circuit 145 is connected to distal segment 125 of the sensor, which is connected to connector interface 120 with conductive contacts 140 via extension lead 150. *Id.*

Shah also teaches subcutaneous insertion set 155 for placing the sensor at a selected site within a patient's body. Ex. 1006 ¶¶ 35, 45–46. Insertion set 155 includes insertion needle 115, which is adapted to extend through flexible mounting base 10 for seated mounting onto the patient's skin. *Id.* The sensor is placed within the patient's body by pressing flexible mounting base 10 onto the patient's skin to cause insertion needle 115 to pierce the skin. *Id.* ¶ 46. Once the sensor is placed, insertion needle 115 is withdrawn from flexible mounting base 10, leaving the sensor within the patient. *Id.*

E. Ground 1 – Alleged Obviousness Over Stafford and Cote

Petitioner asserts that claims 1–6, 9–14, 16–24, 27, 29, and 30 are unpatentable as obvious over Stafford and Cote. Pet. 20–84; Ex. 1003 (Fletcher Decl.) ¶¶ 44–155. We begin by reviewing Petitioner's arguments for independent claim 1.

For claim limitation [1.1] ("[a]n insertion assembly comprising:"), Petitioner asserts that to the extent the preamble is limiting, its proposed combination of Stafford and Cote ("Stafford+Cote") includes an insertion assembly.[12] Pet. 33; *see also* Ex. 1003 (Fletcher Decl.) ¶ 80 (addressing Cote's inserter).

For part 1(a) of claim 1, which recites an on-body unit comprising a housing, a glucose sensor, and sensor electronics, Petitioner cites Stafford's teaching of an on-body data processing unit, which comprises a housing through which a sharp extends, a glucose sensor, and sensor electronics disposed within the housing and coupled to the glucose sensor, where the electronics include a processor, power source, interface, and wireless communication circuitry configured to communicate data indicative of a glucose level. *See* Pet. 34–37; Ex. 1004 (Stafford) ¶¶ 6, 19–20, 23, 26, 28, 36, 39–43, 51–52, Figs. 2, 4A, 4B, 7; Ex. 1003 (Fletcher Decl.) ¶¶ 74–79.

For part 1(b) of claim 1, which recites an inserter, Petitioner cites Cote's inserter 1110 (depicted in Cote's Figure 54), which is used to insert a

[12] "[W]hether to treat a preamble as a limitation is determined on the facts of each case in light of the overall form of the claim and the invention as described in the specification and illuminated in the prosecution history." *Cochlear Bone Anchored Sols. AB v. Oticon Med. AB*, 958 F.3d 1348, 1354 (Fed. Cir. 2020). We need not decide whether the preamble here is limiting, because Petitioner sufficiently demonstrates for purposes of institution that the cited prior art discloses the preamble.

cannula of an infusion device into a user's skin. *See* Pet. 37–38; Ex. 1005 (Cote) ¶ 202, Figure 54; Ex. 1003 (Fletcher Decl.) ¶¶ 80–81. Petitioner explains that, in its proposed combination of "Stafford+Cote, an inserter like that taught by Cote deploys an on-body unit and analyte sensor as taught by Stafford." Pet. 38; Ex. 1003 (Fletcher Decl.) ¶ 81; *see also* Pet. 12–13 ("It was well-known in the art that various inserters were interchangeably used for inserting analyte (e.g., glucose) sensors or cannulas or other transcutaneous devices.").

Petitioner argues that Cote's inserter includes each feature recited in claim 1, e.g., it has an interior that holds an on-body unit and a sharp (e.g., Stafford's on-body unit and sharp), and is configured to, among other things, (a) advance the on-body unit and sharp such that the sharp pierces the user's skin and the on-body unit is secured to the user, and (b) automatically retract the sharp from within the user and into the interior of the inserter, while leaving a part of the glucose sensor in the user's skin. *See, e.g.*, Pet. 38–50; Ex. 1005 (Cote) ¶¶ 12, 135, 137, 139, 143, 145, 165, 184, 191, 198, 202–03, 205–07, 210–11, 213, 215, 235–37, Figs. 77, 78, 80A, 80B, 81A, 81B; Ex. 1004 (Stafford) ¶¶ 2, 19–21, 25, 27–28, 47, Figs. 2, 4A, 5C; Ex. 1003 (Fletcher Decl.) ¶¶ 82–104.

Petitioner, supported by Dr. Fletcher, asserts that a person of ordinary skill in the art would have been motivated, with a reasonable expectation of success, to combine Stafford's on-body unit (comprising an analyte sensor, sharp, and data processing unit), with Cote's automatically-retracting insertion device, to arrive at an insertion assembly as claimed. Pet. 28–33; Ex. 1003 (Fletcher Decl.) ¶¶ 61–72. According to Petitioner, an ordinarily skilled artisan would have made this combination to, e.g., (a) improve safety

(i.e., Cote's inserter guards the needle during insertion and retraction, whereas Stafford lacks a way to prevent contact with the needle after retraction); and (b) minimize pain and anxiety (i.e., unlike Stafford's device, Cote's inserter shrouds and automatically retracts the needle). *See* Pet. 29–33; *see also id.* at 11–12 (discussing that automatic inserters were known to reduce user's pain and anxiety).

After considering the arguments and cited evidence of record, we find that for purposes of institution, Petitioner has demonstrated a reasonable likelihood that Stafford and Cote would have rendered claim 1 obvious. We have reviewed the arguments and evidence of record for claims 2–6, 9–14, 16–24, 27, 29, and 30 in Ground 1, and similarly find that for purposes of institution, Petitioner has demonstrated a reasonable likelihood that Stafford and Cote would have rendered these claims obvious. *See* Pet. 20–84; Ex. 1003 (Fletcher Decl.) ¶¶ 44–155.

On this basis, we institute *inter partes* review of all challenged claims on all grounds in the Petition. *See SAS Institute Inc.*, 138 S. Ct. at 1358; 37 C.F.R. § 42.108(a).

F. Petitioner's Additional Grounds of Alleged Obviousness

Petitioner presents the following additional grounds of alleged obviousness: (a) claims 4, 7, 8, 15, and 19–30 over Stafford, Cote, and Say (Ground 2); (b) claims 18, 21–24, 27, 29, and 30 over Stafford, Cote, and Brenneman (Ground 3); (c) claims 9, 22–24, 27, 29, and 30 over Stafford, Cote, and Shah (Ground 4); (d) claims 21–30 over Stafford, Cote, Say, and Brenneman (Ground 5); (e) claims 25, 26, and 28 over Stafford, Cote, Say, and Shah (Ground 6); claims 22–24, 27, 29, and 30 over Stafford, Cote, Brenneman, and Shah (Ground 7); and claims 25, 26, and 28 over Stafford,

Cote, Say, Brenneman, and Shah (Ground 8). *See* Pet. 4, 84–105; Ex. 1003 (Fletcher Decl.) ¶¶ 156–210. In general, Petitioner relies on Stafford+Cote as discussed above for Ground 1, and cites the additional references to reach the additional limitations of the claims challenged in Grounds 2–8. *See* Pet. 84–105.

As noted above, at this stage, Patent Owner does not present any arguments regarding the merits of Petitioner's obviousness challenges. *See generally* Prelim. Resp.

Because we determine that Ground 1, as discussed above, warrants institution, we do not address these additional grounds at this stage, but they are included in the instituted review. *See* 37 C.F.R. § 42.108(a).

IV. CONCLUSION

For the foregoing reasons, we determine that the information presented establishes a reasonable likelihood that Petitioner would prevail in showing that at least one of the challenged claims of the '591 patent is unpatentable, and we decline to discretionarily deny *inter partes* review.

At this preliminary stage, we have not made a final determination regarding the patentability of any challenged claim or any underlying factual or legal issue. *See TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (noting that "there is a significant difference between a petitioner's burden to establish a 'reasonable likelihood of success' at institution, and actually proving invalidity by a preponderance of the evidence at trial"). Any final decision in this proceeding will be based on the full trial record.

The Board will deem forfeited any issue not raised by Patent Owner in a timely response to the Petition, or as permitted in another manner during

trial, even if asserted in the Preliminary Response or discussed in this Decision.

Nothing in this Decision authorizes Petitioner, in a manner not otherwise permitted by the Board's rules, to supplement the information pertaining to any ground advanced in the Petition.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted based on all grounds asserted in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this Decision.

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