

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIFESCAN, INC.,
Petitioner,

v.

FACET TECHNOLOGIES, LLC,
Patent Owner.

IPR2023-00712
Patent 8,840,635 B2

Before ULRIKE W. JENKS, JAMES A. TARTAL, and DAVID COTTA,
Administrative Patent Judges.

TARTAL, *Administrative Patent Judge.*

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

I. INTRODUCTION

LifeScan, Inc. (“Petitioner”)¹ filed a Petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of claims 1–3, 5–8, 14, and 16–18 of U.S. Patent No. 8,840,635 B2 (Ex. 1001, “the ’635 patent”). Paper 1 (“Pet.”). Facet Technologies, LLC (“Patent Owner”)² filed a Preliminary Response. Paper 9 (“Prelim. Resp.”). In its Preliminary Response, Patent Owner states that it has disclaimed claims 1–5 of the ’635 patent, which includes claims 1–3 and 5 challenged by Petitioner in this proceeding. *Id.* at 6 n.3 (citing Ex. 2012 (the “Disclaimer”); 37 C.F.R. § 42.107(e)). In light of the Disclaimer, only claims 6–8, 14, and 16–18 of the ’635 patent remain at issue in this proceeding.

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b) (2018); 37 C.F.R. § 42.4(a) (2022). An *inter partes* review may not be instituted “unless . . . the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). Moreover, a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018).

Upon consideration of the Petition, the Preliminary Response, and the evidence of record, we conclude that the information presented shows a reasonable likelihood that Petitioner will prevail in showing the unpatentability of at least one of the challenged claims at issue.

¹ Petitioner identifies Asahi Polyslider Company Ltd. as an additional real party in interest. Pet. 1.

² Patent Owner identifies Facet Holdings Corporation as an additional real party in interest. Paper 5, 1.

Accordingly, we authorize an *inter partes* review to be instituted as to claims 6–8, 14, and 16–18 of the '635 patent on the grounds raised in the Petition. Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far. This is not a final decision as to patentability of claims for which *inter partes* review is instituted. Any final decision will be based on the record, as fully developed during trial.

II. BACKGROUND

A. *The '635 Patent*

The '635 patent, titled “Lancets With Improved Coupling Features and Sterility Caps,” issued on September 23, 2014, from U.S. Patent Application No. 13/675,209, filed November 13, 2012. Ex. 1001, codes (21), (22), (45), (54). The '635 patent also refers back to Provisional Application No. 61/084,456, filed July 29, 2008. *Id.* at code (60).

The '635 patent “relates generally to the field of medical devices, and more particularly to lancets and lancing devices for blood sampling and testing.” *Id.* at 1:17–19. The '635 patent explains as follows:

[l]ancets typically comprise a sharp metal tip in the form of a needle or blade. The needle or blade is typically embedded in a plastic body that has a size and shape configured for releasable engagement with the receiver or lancet carrier of a lancing device. The sharp tip of the lancet is commonly embedded in a removable plastic cap to maintain sterility and prevent inadvertent sticks prior to use. The endcap may be replaceable onto the lancet after use to re-cover the sharp lancet tip for safety and hygienic purposes.

Id. at 1:47–52. According to the '635 patent, one aspect of “the invention relates to a protective sterility cap for a lancet, the sterility cap comprising a primary sheath for initial embedment of a sharp lancing tip of an unused

lancet therein, and a gripping handle portion extending from the primary sheath.” *Id.* at 2:21–25.

Figure 1B of the ’635 patent is reproduced below.



FIG. 1B

Figure 1B of the ’635 patent depicts an example of a lancet according to one embodiment. *Id.* at 2:50–51. Lancet 10 includes body portion 12 having thickness T and lancet tip 14 projecting from one end thereof. *Id.* at 3:32–38.

Figure 5A of the ’635 patent is reproduced below.

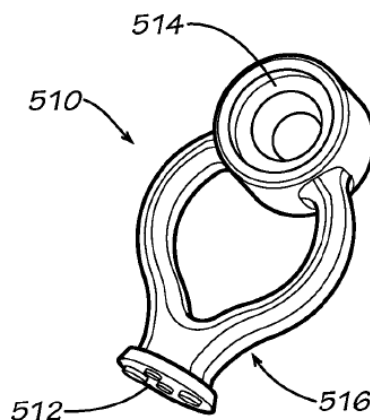


FIG. 5A

Figure 5A of the ’635 patent depicts an example of a lancet endcap according to one embodiment. *Id.* at 2:58–59. Protective sterility cap 510 includes primary sheath portion 512 for receiving and protecting the sharp tip of an unused lancet. *Id.* at 6:1–9. Secondary sheath portion 514 is for receiving and protecting the sharp tip of a used lancet. *Id.* Handle portion 516 extends between primary sheath 512 and secondary sheath 516 and assists in removal and replacement of the cap from a lancet. *Id.*

Figure 5D of the '635 patent is reproduced below.

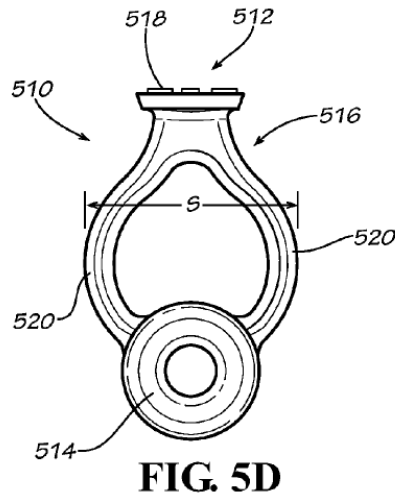


Figure 5D of the '635 patent depicts another view of protective sterility cap 510 shown in Figure 5A. *Id.* at 5:66–6:1. Handle portion 516 has a forked split configuration with first and second arms 520 transversely spaced apart from one another and an open center portion therebetween. *Id.* at 6:49–52. The '635 patent explains that the forked arrangement provides handle 516 with a greater width, which allows a user to easily twist the endcap during removal from a lancet. *Id.* at 6:52–54. According to the '635 patent, lateral span “S” of handle portion 516 is “at least about 1.5 times, and more preferably at least about 2 times the diameter or thickness of the lancet body. *Id.* at 6:56–58.

B. Illustrative Claim

Claims 6–8, 14, and 16–18 of the '635 patent are at issue in this proceeding. Claims 6–8 each depend, directly or indirectly, from disclaimed claim 1, and thus incorporate the subject matter of claim 1. *Id.* at 8:53–57. Claim 14 is independent. Ex. 1001, 9:22–10:11. Claims 16–18 each depend directly from claim 14. *Id.* at 10:15–23.

Claim 6 is illustrative of the claimed subject matter at issue and is reproduced below, along with disclaimed independent claim 1, from which claim 6 depends.

1. A protective sterility cap for a lancet, said sterility cap comprising a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein, a secondary sheath for receiving the sharp lancing tip of a used lancet, and a gripping handle portion extending between the primary sheath and the secondary sheath, with the primary sheath attached at a first end of the gripping handle portion and the secondary sheath attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet.

Id. at 8:34–42.

6. The protective sterility cap of claim 1, in combination with a lancet having a lancet body defining a lancet thickness, and a sharp lancet tip initially embedded in the primary sheath, wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.

Id. at 8:53–57.

C. Asserted Grounds of Unpatentability

In the Petition, Petitioner asserts that claims 1–3, 5–8, 14, and 16–18 of the '635 patent are unpatentable. Pet. 4. As noted above, after the Petition was filed, Patent Owner explained that it disclaimed claims 1–5 of the '635 patent. Prelim. Resp. 6 n.3 (citing Ex. 2012). Accordingly, our determination of whether to institute *inter partes* review is based on Petitioner's allegations directed to claims 6–8, 14, and 16–18. See 37 C.F.R. § 42.107(e) (stating that “[n]o *inter partes* review will be instituted based on disclaimed claims”).

Petitioner asserts the following grounds:

Claims Challenged	35 U.S.C. § ³	References/Basis
6–8, 14, 16–18	102(b)	Saikley ⁴
6–8, 14, 16–18	103(a)	Saikley, Stout ⁵
16	103(a)	Saikley, FreeStyle ⁶
6–8, 14, 16–18	102(b)	Iio ⁷
6–8, 14, 16–18	103(a)	Iio, Peckham ⁸
16	103(a)	Iio, Freestyle

Petitioner relies on the supporting Declaration of Joel Delman, dated March 20, 2023. Ex. 1002 (the “Delman Declaration”). Patent Owner relies on the Declaration of John M. Collins, dated June 25, 2023. Ex. 2001 (the “Collins Declaration”).

D. Related Proceedings

The Parties identify the ’635 patent as a subject of *Facet Technologies, LLC v. LifeScan, Inc.*, C.A. No. 22-cv-01717 (C.D. Cal.), filed on March 15, 2022 (the “Parallel Litigation”). Pet. 1; Paper 5, 1.

³ The Leahy-Smith America Invents Act (“AIA”) included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. For purposes of this Decision, we apply the pre-AIA version of § 103 here because the earliest provisional application identified in the ’635 patent was filed before the effective date of the AIA and Petitioner does not currently challenge this priority date. *See* Ex. 1001, code (60). We note that our analysis would not change under the AIA version of § 103.

⁴ US 2004/0138588 A1, published July 15, 2004 (Ex. 1005, “Saikley”).

⁵ US 2006/0241669 A1, published Oct. 26, 2006 (Ex. 1018, “Stout”).

⁶ Exhibit 1010 comprises a declaration from a Records Request Processor at the Internet Archive describing the Wayback Machine system and authenticating various webpage captures showing an Owner’s Booklet for a FreeStyle Blood Glucose Monitoring System (Ex. 1010, “FreeStyle”).

⁷ US 2005/0131441 A1, published June 16, 2005 (Ex. 1006, “Iio”).

⁸ US 5,569,286, issued Oct. 29, 1996 (Ex. 1008, “Peckham”).

Additionally, Petitioner filed a second petition challenging claims 1, 4, and 9–15 of the '635 patent in IPR2023-00713.⁹ Paper 3, 1; Paper 5, 1.

III. ANALYSIS

A. *Discretionary Denial Under 35 U.S.C. § 314(a)*

Under 35 U.S.C. § 314(a), the Director has discretion to deny institution of an *inter partes* review. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) (“[T]he agency's decision to deny a petition is a matter committed to the Patent Office’s discretion.”); *SAS Inst. v. Iancu*, 138 S. Ct. 1348, 1356 (2018) (“[Section] 314(a) invests the Director with discretion on the question *whether* to institute review.”); *Harmonic v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (“[T]he PTO is permitted, but never compelled, to institute an IPR proceeding.”).

In determining whether to exercise discretion to deny institution under 35 U.S.C. § 314(a), the Board considers the trial date in related litigation as part of an assessment of all relevant circumstances of the case, including the merits, in an effort to balance considerations such as system efficiency, fairness, and patent quality. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 5–6 (PTAB Mar. 20, 2020) (precedential) (“*Fintiv* Order”); *see also NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 at 19–20 (PTAB Sept. 12, 2018) (precedential) (denying institution relying, in part, on § 314(a) because the parallel district

⁹ Petitioner filed an Explanation of Parallel Petitions in both this proceeding and in IPR2023-00713 stating that it requests that the Board consider the Petition in this proceeding first, followed by the petition filed in IPR2023-00713. Paper 4, 1. Accordingly, we do not reach the issue of whether institution of *inter partes* review based on a second petition is warranted in this proceeding.

court proceeding was scheduled to finish before the Board reached a final decision). In particular, the Board evaluates the following factors:

1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;
3. investment in the parallel proceeding by the court and the parties;
4. overlap between issues raised in the petition and in the parallel proceeding;
5. whether the petitioner and the defendant in the parallel proceeding are the same party; and
6. other circumstances that impact the Board's exercise of discretion, including the merits.

Fintiv Order 5–6. In evaluating these factors, “the Board takes a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review.” *Id.* at 6. Additionally, the Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation issued by the Director of the United States Patent and Trademark Office (the “Memorandum”)¹⁰ provides that the Board will not discretionarily deny institution of *inter partes* review “where a petitioner presents a stipulation not to pursue in a parallel proceeding the same grounds or any grounds that could have reasonably been raised before the PTAB.” Memorandum, 3.

¹⁰ Available at: https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621_.pdf

Petitioner contends that we should not exercise our discretion under 35 U.S.C. § 314(a) to deny institution in this case. Pet. 6–7. In particular, Petitioner asserts that it provided a stipulation, which states that “if the Patent Trial and Appeal Board (PTAB) institutes an IPR based on the grounds identified below, then it will (i) not pursue the grounds identified below in the District Court Case, and (ii) not pursue any other ground that reasonably could have been raised during the IPR (should it be instituted) in the District Court Case.” *Id.* (quoting Ex. 1013, 1–2).

Patent Owner does not dispute the sufficiency of the language of Petitioner’s stipulation, but instead argues that the stipulation is ineffective because “the trial date in the district court is scheduled to be completed weeks before the expected institution decision here.” Prelim. Resp. 38; *see also id.* at 39 (arguing that the district court scheduled a four-day trial to begin on September 12, 2023, which is before the statutory deadline for an institution decision in this proceeding) (citing Ex. 2005, 4). After Patent Owner filed its Preliminary Response, the district court entered an order on August 16, 2023, vacating “all future dates” in the district court’s prior scheduling order, including the trial date previously set. Ex. 1027, 3–4.

We are not persuaded by Patent Owner’s argument, because the district court has vacated the trial date and, regardless, this Decision will be entered prior to the district court trial date originally identified by Patent Owner in its Preliminary Response. *See* Prelim. Resp. 39; Ex. 1027. Accordingly, Patent Owner’s concern that an institution decision will not be entered prior to the district court trial date is not at issue here.

Petitioner’s stipulation complies with our binding guidance, which states that the Board “will not discretionarily deny institution of an

IPR . . . in view of parallel district court litigation where a petitioner stipulates not to pursue in a parallel district court proceeding the same grounds as in the petition or any grounds that could have reasonably been raised in the petition.” Memorandum 7; Ex. 1013. Accordingly, in view of Petitioner’s stipulation, we decline to exercise our discretion under § 314(a) to deny institution of *inter partes* review.

B. Legal Standards for Anticipation and Obviousness

A claim is anticipated if a single prior art reference either expressly or inherently discloses every limitation of the claim. *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 975 (Fed. Cir. 2010). “A single prior art reference may anticipate without disclosing a feature of the claimed invention if such feature is necessarily present, or inherent, in that reference.” *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 958 (Fed. Cir. 2014) (citing *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003)).

A patent claim is unpatentable for obviousness 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. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). In *Graham v. John Deere Co.*, 383 U.S. 1 (1966), the Supreme Court set out a framework for assessing obviousness that requires consideration of four factors: (1) the “level of ordinary skill in the pertinent art,” (2) the “scope and content of the prior art,” (3) the “differences between the prior art and the claims at issue,” and (4) “secondary considerations” of nonobviousness such as “commercial success, long felt but unsolved needs, failure of others, etc.” *Id.* at 17–18; *KSR*, 550 U.S. at 407.

C. Level of Ordinary Skill in the Art

The level of skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999) (citing *Graham*, 383 U.S. at 17–18; *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)). In determining the level of ordinary skill in the art, various factors may be considered, including the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.” *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (citation omitted). Petitioner contends that a person of ordinary skill in the art “would have had a bachelor’s degree and/or master’s degree in mechanical engineering or industrial design, along with at least 4 to 6 years of experience designing consumer or medical device products to optimize human factors such as handleability or ergonomics.” Pet. 7. Patent Owner asserts that a person of ordinary skill in the art would have “completed college-level coursework, and/or obtained a bachelor’s degree, in engineering, such as mechanical engineering or biomechanical engineering, or another similar discipline, and (2) have had at least one year of experience researching, developing, and/or designing mechanical medical devices.” Prelim. Resp. 5. Patent Owner further states that its Preliminary Response “does not turn on the definition of a [person of ordinary skill in the art].” *Id.*

Although Patent Owner notes that Petitioner proposes “a higher level of skill,” at this stage of the proceeding neither Party has shown a material difference between the levels of skill each has proposed and either Party may further address the issue, if necessary, during the trial. For purposes of

this Decision, we apply Petitioner’s proposed level of skill because, on the current record, it is consistent with the level of skill at the time of the claimed invention reflected by the ’635 patent and the cited prior art references. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

D. Claim Construction

We apply 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 that 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. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). “In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17). Extrinsic evidence is “less significant than the intrinsic record in determining ‘the legally operative meaning of claim language.’” *Phillips*, 415 F.3d at 1317.

Petitioner states in the Petition that, in the Parallel Litigation, “[t]he district court issued a claim construction order determining that ‘a secondary sheath for receiving the sharp lancing tip of a used lancet’ means ‘a secondary sheath for covering the sharp lancing tip of a used lancet by embedding or enclosing the lancet tip.’” Pet. 8 (citing Ex. 1004, 13:24–14:3). Petitioner also states that it “has applied the district court’s ‘secondary sheath’ construction when analyzing the prior art discussed

herein, and Petitioner has applied the plain and ordinary meaning for all other terms.” *Id.*

In the Preliminary Response, Patent Owner states that it also applies the district court’s construction for “secondary sheath,” and “applies the plain meaning to all other claim terms.” Prelim. Resp. 6. Accordingly, we determine no claim term requires an express construction for purposes of this Decision. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘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)).

E. Overview of Cited References

In challenging the ’635 patent, Petitioner relies on Saikley, Stout, FreeStyle, Iio, and Peckham, each of which we briefly summarize in relevant part below. *See* Pet. 3–4.

1. Summary of Saikley (Ex. 1005)

Saikley “relates to skin lancing devices, analyte sensors and analysis meters for determining biological analyte levels.” Ex. 1005 ¶ 2. Saikley states that the short length of disposable lancets for use with a lancing device can make the lancets difficult to handle. *Id.* ¶ 50. To address this, Saikley discloses a lancet cap that is “made much larger than usual to aid handling.” *Id.*

Figure 6 of Saikley is reproduced below.

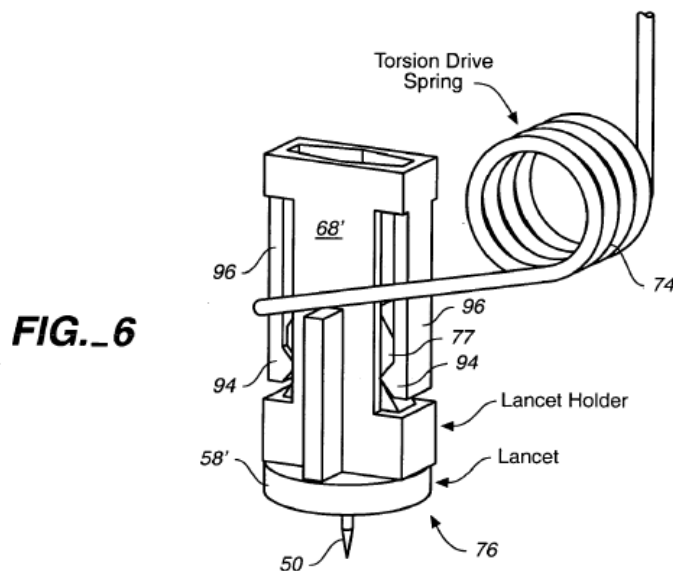


Figure 6 of Saikley is a perspective view of a torsion spring lancing mechanism. *Id.* ¶ 12. Lancet holder 68' of an integrated lancing device (not shown) engages shortened lancet 76, which includes sharp 50. *Id.* ¶¶ 41, 48, 50.

Figure 7A of Saikley is reproduced below.

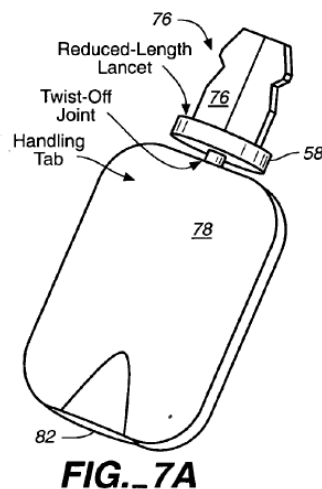


Figure 7A of Saikley is a perspective view of a lancet and cap combination according to a first embodiment. *Id.* ¶ 13. Protective cap 78 is an integrally-molded pull-off tab that is removed before use of shortened lancet 76. *Id.*

¶ 50. Cap 78 includes a pin cushion type area 82 used to cover the sharp of shortened lancet 76 for disposal. *Id.*

2. *Summary of Stout (Ex. 1018)*

Stout relates “to lancing devices for medical sampling of blood or other body fluids of a human or animal subject.” Ex. 1018 ¶ 2. Stout discloses “[a] miniature lancet ha[ving] an oversized sterility cap with a T-shaped end for ease of handling and loading into a lancing device.” *Id.*, code (57).

Figure 8a of Stout is reproduced below.

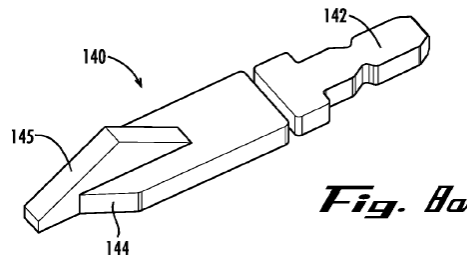


Figure 8a of Stout depicts a lancet according to an exemplary embodiment. *Id.* ¶¶ 23, 41. Lancet 140 includes lancet body 142 and endcap 144 having an inclined or curved removal surface 145. *Id.* ¶ 41. Stout explains that the sterility cap is relatively large compared to the lancet body in order “to facilitate easier handling and loading of the lancet into the lancing device, which is of particular advantage to users having reduced visual acuity and/or reduced manual dexterity.” *Id.* ¶ 35.

3. *Summary of FreeStyle (Ex. 1010)*

FreeStyle is a collection of archived webpages titled “Owner’s Booklet” for the FreeStyle Blood Glucose Monitoring System. Ex. 1010, 3.¹¹ FreeStyle explains that the “[t]he FreeStyle System is used for

¹¹ We refer to the page numbers added by Petitioner at the lower right corner of Exhibit 1010.

measuring blood glucose (also known as *blood sugar*) from samples taken from the forearm, upper arm, hand, thigh, calf, or fingers (refer to page 1 for more information).” *Id.* at 5. The FreeStyle System uses test strips, control solution, meter, lancing device, and sterile lancets. *Id.* at 7. FreeStyle discloses that each lancet has a rounded top that twists off to expose a needle after the lancet is inserted firmly into the lancing device. *Id.* at 16–17.

4. *Summary of Iio (Ex. 1006)*

Iio “relates to a lancet for blood collection and a puncture needle unit, which are used for measuring blood sugar or the like.” Ex. 1006 ¶ 1. Iio states that, “when attaching or detaching the puncture needle to/from the lancet, the needle is unprotected because it is not covered with the protection cap, and the puncture rod easily moves because it is held by only the spring, leading to puncture by mistake.” *Id.* ¶ 4. Iio discloses a puncture needle with a cap that is removed after attaching the puncture needle to a lancet, and the cap is replaced so that the puncture needle may be safely removed from the lancet and discarded. *Id.* ¶¶ 23–24.

Figure 8 of Iio is reproduced below.

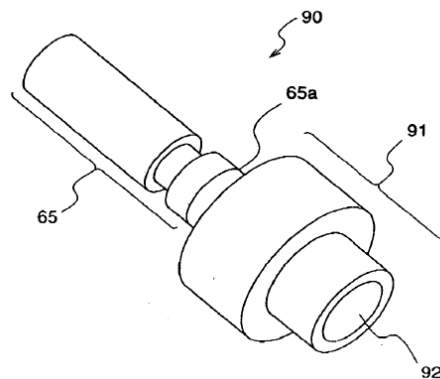


Figure 8 of Iio is a perspective view depicting a puncture needle unit for a lancet according to one embodiment. *Id.* ¶ 44. Puncture needle unit 90 includes puncture needle body 65 embedded in puncture needle cap 91.

Id. ¶ 104. Separation groove 65*a* acts as a boundary between puncture needle body 65 and cap 91, which are connected to each other by thin plastic film. *Id.* Cap 91 also includes disposal slot 92 into which puncture needle body 65 is snugly inserted for removal after a puncture is carried out.

Id. ¶¶ 104, 117.

5. *Summary of Peckham (Ex. 1008)*

Peckham “relates to a lancet assembly and, more particularly, to a lancet assembly having an injection molded housing with a metal stylet mounted therein and an injection molded removable cap or shield over the housing to protect the stylet.” Ex. 1008, 1:6–10.

Figure 2 of Peckham is reproduced below.

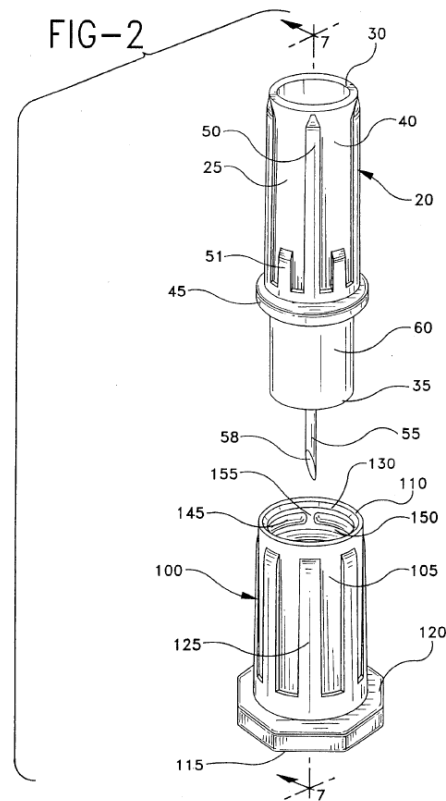


Figure 2 of Peckham depicts an unshielded lancet assembly. *Id.* at 2:37–38. Lancet assembly 20 attaches to removable cap 100 to shield a user from stylet 55. *Id.* at 2:56–59. Removable cap 100 has cylindrical housing 105

with longitudinal ribs 125, which provide a textured surface to improve handling of cap 100 as it is removed from lancet assembly 20. *Id.* at 3:11–16.

F. Alleged Anticipation by Saikley

Petitioner contends that claims 6–8, 14, and 16–18 are anticipated by Saikley. Pet. 36–44. Petitioner provides a detailed explanation of its contentions in the Petition, including a clause-by-clause analysis specifying how Saikley discloses each limitation, and those contentions are supported by the testimony of Mr. Delman. *Id.*; Ex. 1002 ¶¶ 71–114.

1. Analysis of Claim 6

Petitioner contends that Saikley anticipates the subject matter of claim 6. Pet. 36–40. Petitioner’s contentions are supported by testimony from Mr. Delman. Ex. 1002 ¶¶ 98–105. Our consideration of claim 6 includes consideration of the limitations of claim 1 from which claim 6 depends.¹² See Ex. 1001, 12:53–57. We note that Patent Owner does not dispute Petitioner’s contentions based on Saikley as to the limitations of disclaimed claim 1. See Prelim. Resp. 8–12.

*[Ipre]*¹³ *A protective sterility cap for a lancet,*

Petitioner initially contends that the preamble of claim 1 is not limiting. Pet. 9. Petitioner also contends, to the extent that the preamble is limiting, that Saikley discloses a protective sterility cap (protective cap 78)

¹² Our analysis of Petitioner’s contentions directed to claim 6 necessarily references portions of the Petition concerning limitations of disclaimed claims 1 and 2, because Petitioner’s contentions directed to claim 6 refer to sections of the Petition addressing limitations appearing in disclaimed claims 1 and 2. See, e.g., Pet. 36–37.

¹³ We refer to the bracketed claim limitation identifiers used in the Petition. See Pet. 9–26, 36–38.

for a lancet (shortened lancet 76). *Id.* at 9–10 (citing Ex. 1005 ¶¶ 13, 50, Fig. 7a; Ex. 1002 ¶¶ 52–57).

[1a] said sterility cap comprising a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein, [the “primary sheath limitation”]

Petitioner contends that Saikley’s protective cap 78 includes a primary sheath (twist-off joint) embedding an unused sharp lancing tip of shortened lancet 76. *See* Pet. 11–14 (citing Ex. 1005 ¶¶ 37, 50–52, 65, Fig. 7a; Ex. 1002 ¶¶ 58–60, 63–65). Petitioner asserts that Saikley discloses protective cap 78 of shortened lancet 76 as being an integrally-molded pull off tab, and one of ordinary skill in the art would understand that the needle tip of shortened lancet 76 is embedded in integrally-molded protective cap 78. *Id.* at 12 (citing Ex. 1005 ¶ 50; Ex. 1002 ¶¶ 59–60).

[1b] a secondary sheath for receiving the sharp lancing tip of a used lancet, and

Petitioner contends that Saikley discloses a secondary sheath for receiving the sharp lancing tip after use. *See* Pet. 14–18 (citing Ex. 1005 ¶¶ 50–52, 64; Ex. 1002 ¶¶ 66–72). Petitioner asserts that Saikley’s protective cap 78 includes solid pin cushion type area 82 to receive and cover the sharp lancing tip for disposal after shortened lancet 76 is used. *Id.* at 14–15 (citing Ex. 1005 ¶¶ 50, 52).

[1c] a gripping handle portion extending between the primary sheath and the secondary sheath,

Petitioner contends that Saikley discloses a gripping handle portion between its primary and secondary sheaths. *See* Pet. 19–26 (citing Ex. 1005 ¶¶ 4, 49–52, 87, Fig. 7a; Ex. 1002 ¶¶ 73–82). In particular, Petitioner asserts that Saikley’s protective cap 78 incorporates a “handling tab” extending between pin cushion type area 82 and the twist-off joint, and the handling

tab is made large to aid user handling. *Id.* at 20–23 (citing Ex. 1005 ¶¶ 4, 50, 87; Ex. 1002 ¶¶ 75–77).

[1d] with the primary sheath attached at a first end of the gripping handle portion and the secondary sheath attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet.

Petitioner contends that Saikley discloses the primary sheath (twist-off joint) and secondary sheath (pin cushion type area 82) attached to respective first and second ends of the gripping handle portion (protective cap 78). Pet. 26–28 (citing Ex. 1005 ¶ 50, Fig. 7a; Ex. 1002 ¶¶ 83–85). Petitioner asserts that the twist-off joint and pin cushion type area 82 are integrally molded at opposing ends of protective cap 78 and remain attached to the cap as it is removed. *Id.* at 27–28 (citing Ex. 1005 ¶ 50; Ex. 1002 ¶¶ 83–85).

[6a] The protective sterility cap of claim 1, in combination with a lancet

[6b] having a lancet body defining a lancet thickness, and

[6c] a sharp lancet tip initially embedded in the primary sheath,

Petitioner contends that Saikley discloses a protective sterility cap (protective cap 78) in combination with a lancet (shortened lancet 76). Pet. 28–30, 36 (citing Ex. 1005 ¶¶ 37, 50, 65, Fig. 7a; Ex. 1002 ¶¶ 86–88). Petitioner also asserts that Saikley’s shortened lancet 67 has elongate body 48. *Id.* at 36 (citing Ex. 1005 ¶¶ 37, 41–42, 44, Figs. 6, 8; Ex. 1002 ¶ 100).

Petitioner provides an annotated version of Figure 8 of Saikley, which is reproduced below. *Id.* at 36–37.

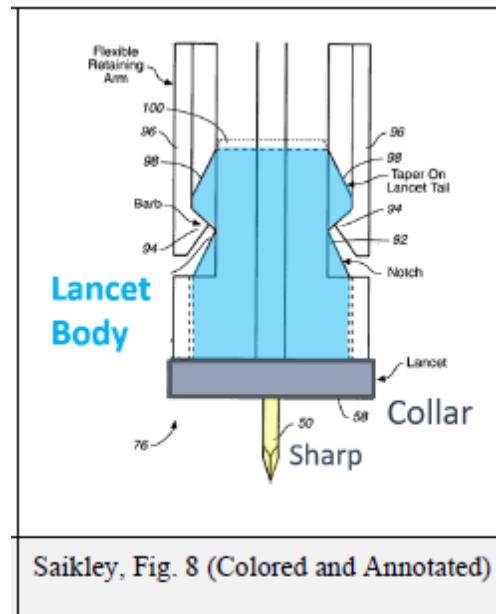


Figure 8 of Saikley, as annotated by Petitioner, depicts lancet body 48 (colored light blue) and lancet sharp 50 (colored yellow). *Id.* Petitioner further asserts that a person of ordinary skill “would have recognized from Saikley’s disclosures of an ‘integrally molded cap’ that the sharp lancing tip 50 is initially embedded in twist-off joint and the adjoining portion of pull-off tab 78.” *Id.* at 28–30, 37. Patent Owner does not dispute Petitioner’s contentions based on Saikley as to limitations [6a], [6b], and [6c]. *See* Prelim. Resp. 8–12.

[6d] wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness [the “lateral span limitation”]

Petitioner contends that the “handling tab” of Saikley’s protective cap 78 defines a lateral span at least 1.5 times the lancet thickness. Pet. 37 (citing Ex. 1005 ¶¶ 4, 50, 87; Ex. 1002 ¶¶ 75–77). Petitioner provides an

annotated version of Figure 7a of Saikley, which is reproduced below. *Id.* at 38.

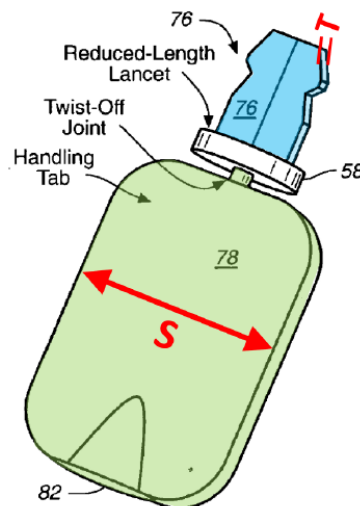


Figure 7a of Saikley, as annotated by Petitioner, depicts shortened lancet 76 with protective cap 78 and includes annotations identifying a lateral span with arrows and the letter “S” and a lancet thickness with lines and the letter “T.” *Id.* Petitioner contends that the annotated figure discloses a handling tab (colored green) with a lateral span (annotated ‘S’ with arrows) that is far more than 1.5 times the lancet thickness of the lancet body (colored light blue).” *Id.* at 37–38 (citing Ex. 1002 ¶ 102). From this, Petitioner reasons a person of ordinary skill in the art would have understood the lateral span limitation “to be expressly or, at least inherently, disclosed.” *Id.* at 39 (citing Ex. 1002 ¶ 103).

Petitioner also contends that a person of ordinary skill in the art “would have appreciated that Saikley’s lancet would have been handled by a user pinching the handling tab between a thumb and a digit on the user’s hand.” Pet. 39 (citing Ex. 1002 ¶ 104). Petitioner asserts as follows:

[a person of ordinary skill in the art] would also have appreciated that the average human thumb is 16 mm wide. Ex.1022, 157. In light of this, a [person of ordinary skill in the art] would have

understood Saikley's instruction to make its cap 78 "much larger than usual to aid handling" (Ex.1005, [0050]) as indicating that the lateral span for its cap 78 would have needed to be larger than the 16 mm width of an average human thumb to ensure that the handling goal was achieved. Because the "standard lancet" had a diameter of less than 6 mm (Ex.1017, 9:67–10:10, which is incorporated by reference in Saikley and referred to hereinafter as "incorporated-by-reference LeVaughn"), a [person of ordinary skill in the art] would have understood Saikley to teach that its lateral span was more than twice the lancet thickness.

Id.; *see also id.* at 40 (asserting that LeVaughn "teaches that a 'transverse ratio (W/t) of at least 3:2, and more preferably about 2:1, provides an easy to grip [lancing] device which resists twisting about the central axis'" (quoting Ex. 1017, 5:15–18) (alteration in original)).

Patent Owner contests Petitioner's assertion that Saikley discloses the lateral span limitation. Prelim. Resp. 8–12. First, Patent Owner argues that Petitioner's "deriving dimension S and dimension T from . . . [Saikley's] figure is improper as a matter of law" because "Saikley's specification is *completely* silent as to whether Figure 7A or any other figure is to scale or any dimension of any component in Figure 7A." *Id.* at 9–10 (citing *Hockerson-Halberstadt, Inc. v. Avia Grp. Int'l, Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000)).

Patent Owner also argues that Petitioner relies on improper assumptions in arguing that one of ordinary skill in the art would have understood Saikley to disclose a protective cap with a span larger than 16mm and a lancet with a diameter less than 6mm. Prelim. Resp. 10–11. Patent Owner asserts that "there is *zero* disclosure in Saikley as to what is any usual dimension for protective cap 78 is or how much larger protective cap 78 should be," and "Saikley provides no disclosure whatsoever about the relationship between the alleged gripping handle and

the lancet's thickness.” *Id.* at 11 (citing Ex. 2001 ¶¶ 86–89). According to Patent Owner, “Saikley offers no indication about what the thickness of a standard lancet is.” *Id.* (citing Pet. 39–40). Patent Owner also asserts that the identified ratios “in LeVaughn include lancing device 10 as part of the ratio,” and “[t]he lancing device 10 is distinct from a lancet.” *Id.* at 12 n.4 (citing Ex. 1017, 5:15–18, Fig. 1).

Patent Owner's arguments are not persuasive on the current record at this stage of the proceeding. First, Saikley addresses the size of the disclosed lancet cap, expressly stating that the “large lancet cap” is “made much larger than usual to aid handling.” Ex. 1005 ¶¶ 49–50. Moreover, we consider what the drawings in a reference “reasonably disclose and suggest to one skilled in the art.” *In re Aslanian*, 590 F.2d 911, 914 (CCPA 1979). More particularly, a patent drawing may serve as prior art “without referring to the surrounding description” if “the prior art features are clearly disclosed by the drawing.” *PlaSmart, Inc. v. Kappos*, 482 F. App'x 568, 572–73 (Fed. Cir. 2012) (citing *In re Mraz*, 455 F.2d 1069, 1072 (CCPA 1972); *In re Seid*, 161 F.2d 229, 231 (CCPA 1947); *In re Wagner*, 63 F.2d 987, 988 (CCPA 1933)). We are not persuaded on the current record that the absence of dimensional information makes “any exact dimensional information derived from the figures ... unreliable,” as Mr. Collins opines for Patent Owner. *See* Ex. 2001 ¶¶ 83–90. Claim 6 does specify a precise size, but only a relative relationship: “a lateral span of at least 1.5 times the lancet thickness.” Mr. Delman explains that both the “textual descriptions” and Figure 7A of Saikley, which illustrates “cap 78 with a lateral span much larger than 1.5 times the lancet thickness,” would have been understood by a person of ordinary skill in the art to disclose the claimed limitation. *See*

Ex. 1002 ¶ 103. Additionally, although LeVaughn’s lancing device 10 may be distinct from a lancet, as Patent Owner argues, that does not address persuasively what a person of ordinary skill in the art would have understood from LeVaughn, as incorporated by reference by Saikley, in relation to the lateral span limitation.

2. *Dependent Claims 7 and 8*

Petitioner contends that claims 7 and 8, which depend from claim 6, are anticipated by Saikley. Pet. 40–43. Claim 7 further recites “wherein the gripping handle portion defines a length at least equal to its lateral span” and claim 8 recites “wherein the gripping handle portion defines a length at least equal to the lancet thickness,” (collectively, the “length limitations”). Ex. 1001 8:58–64. Patent Owner does not dispute Petitioner’s contentions based on Saikley as to the additional limitations of claims 7 and 8. Prelim. Resp. 12–13. We have reviewed the evidence and argument presented in the Petition, including relevant portions of the Delman Declaration, and determine, on this record, that Petitioner sufficiently shows how it contends Saikley discloses every limitation of claims 7 and 8 to support institution. *See id.*; Ex. 1002 ¶¶ 106–111.

3. *Independent claim 14 and dependent claims 16–18*

Petitioner contends that independent claim 14 is anticipated by Saikley for substantially the same reasons discussed above in connection with claim 6. Pet. 78–79. Claim 14 recites the identical lateral span limitation as claim 6. Ex. 1001, 8:53–57, 9:22–10:11. Claims 17 and 18 recite the same length limitations, respectively, as claims 7 and 8. Patent Owner argues that Saikley fails to disclose the lateral span limitation of claim 14 for the same reasons discussed above with regard to claim 6.

Prelim. Resp. 8–12. For the reasons explained above in our discussion of claim 6, and based on our review and consideration of Petitioner’s arguments and evidence directed to claim 14, we determine, on this record, that Petitioner sufficiently shows how it contends Saikley discloses every limitation of claim 14, as well as claims 16–18, to support institution. *See* Pet. 78–79; Ex. 1003 ¶¶ 112–114; *see also* Prelim. Resp. 12–13 (Patent Owner does not dispute Petitioner’s additional contentions directed to claims 16–18).

4. *Finding of a Reasonable Likelihood of Prevailing*

Based on our review of the evidence and consideration of the arguments, we find, on this record, that Petitioner sufficiently shows how it contends that Saikley discloses the limitations of claim 6, including the limitations of claim 1 from which it depends, to support institution of *inter partes* review. We reach the same determination, as explained above, with respect to claims 7, 8, 14, and 16–18.

G. *Alleged Obviousness Over Saikley and Stout*

Petitioner contends that claims 6–8, 14, and 16–18 are unpatentable as obvious in light of the teachings of Saikley and Stout. Pet. 45–57. Petitioner supports its contentions with the testimony of Mr. Delman. *See* Ex. 1002 ¶¶ 115–136. Patent Owner disputes Petitioner’s contentions. *See* Prelim. Resp. 13–23

First, Petitioner contends that if Saikley does not “expressly or inherently disclose” the primary sheath limitation (which appears in both claims 1 and 14), “then it would have been obvious to a [person of ordinary skill in the art] in view of Stout (Ex.1018).” Pet. 45. Petitioner asserts that Stout’s sterility cap 44 is co-molded with lancet body portion 42 to embed

sharp lancet tip 43. *Id.* at 46 (citing Ex. 1018 ¶ 35). According to Petitioner, one of ordinary skill “would have appreciated that embedding the lancet needle into Saikley’s cap 78 would not only protect the integrity of the needle tip, but also would protect the sterility of the needle and would prevent contamination during post-manufacturing packaging, shipping, and storage.” *Id.* (citing Ex. 1002 ¶¶ 117–118). Petitioner also asserts as follows:

a [person of ordinary skill in the art] would have been motivated to embed the lancet needle within the twist-off joint and adjoining portion of the handling tab of the protective cap 78 because it was well known that this would make the needle tip 50 more resistant to the non-axial cocking or pivoting movement of the endcap when it is twisted off by the user, which could bend or break the needle tip.

Id. at 47 (citing Ex. 1002 ¶¶ 119–121).

As noted above in our discussion of anticipation of claim 6 by Saikley, Patent Owner does not dispute that Saikley teaches the primary sheath limitation. *See* Prelim. Resp. 15–16. Nor does Patent Owner dispute that Stout teaches the primary sheath limitation. *See id.* Patent Owner does argue a lack of motivation to combine the teachings of Saikely and Stout, which we address below. *See id.* at 17–18.

Second, Petitioner argues that if Saikley does not “expressly or inherently” disclose the span limitation or the length limitations, they would have been obvious because “[t]he only material difference between the [’635] patent and [Saikley] are those dimensions, which are meaningless.” Pet. 48 (quoting *Hamilton Products, Inc. v. O’Neill*, 492 F. Supp. 2d 1328 (M.D. Fla. 2007) (alteration in original)). Petitioner contends that it would have been obvious to make Saikley’s lancet cap handle larger or wider in order to yield the predictable result of making the cap easier to handle. *Id.*

at 48–49 (citing Ex. 1005 ¶ 4; Ex. 1002; *Ohio Willow Wood Co. v. Thermo-Ply, Inc.*, 2009 WL 6499349, at 4–5 (E.D. Tex. 2009)). According to Petitioner, sizing the handle as recited in the challenged claims would have been “an obvious design choice.” *Id.* at 49 (citing *Rexnord Indus., LLC v. Kappos*, 705 F.3d 1347, 1355–56 (Fed. Cir. 2013)).

Petitioner further contends that the span limitation and the length limitations “would have been obvious for a [person of ordinary skill in the art] to try when determining the optimum ‘length’ and ‘lateral span’ of the handling tab on Saikley’s protective sterility cap 78.” Pet. 50. Petitioner asserts that it was an art-recognized problem of accidental poking if sharp needle tips were not sheathed before and after use. *Id.* (citing Ex. 1002 ¶ 123). Petitioner asserts that a person of ordinary skill in the art “would routinely be required to experiment with the dimensions of the gripping handle portion (in both its lateral span and length) in seeking to optimize sterility caps for mass-market use,” and “[t]his experimentation would have encompassed the finite number of potential dimensions the gripping handle portion as compared to the thickness of the lancet.” *Id.* at 50–51 (citing Ex. 1002 ¶ 123). Further, Petitioner argues as follows:

Designing a gripping handle’s lateral span to be at least 1.5 times the lancet thickness would have been pursued by a [person of ordinary skill in the art] as a matter of routine optimization and with a reasonable expectation of success, particularly in view of Saikley’s express instruction to create a cap that “should be made much larger than usual to aid handling.” Ex. 1005, [0050].

Id. at 51.

Patent Owner argues that Petitioner failed to include a request to find any claim at issue obvious over Saikley, alone. Prelim. Resp. 19. Patent Owner appears to be referring to the table of grounds provided in the

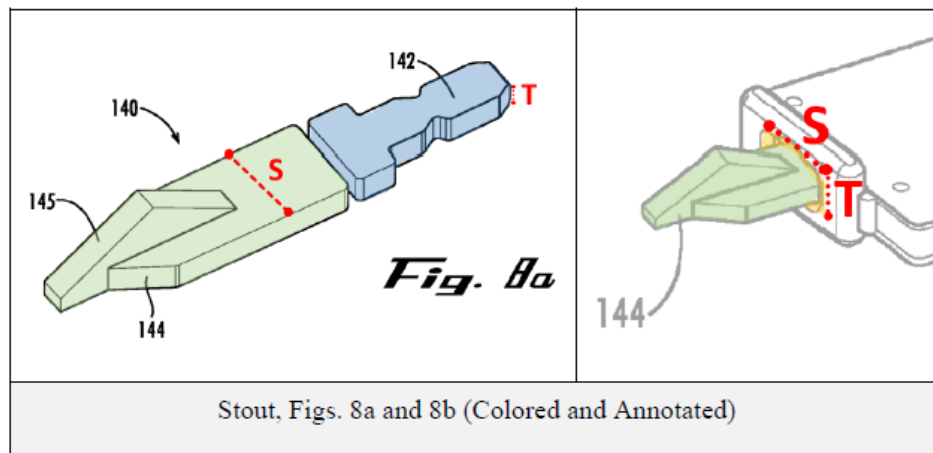
Petition, which does not independently list obviousness over Saikley, alone, as a ground. *See* Pet. 4. The Petition, however, makes abundantly clear to Patent Owner how Petitioner relies on Saikley to establish obviousness, as shown by Patent Owner’s extensive preliminary response directed specifically to the teachings of Saikley, alone, upon which Petitioner relies to show obviousness. *See* Prelim. Resp. 19–23.

In this regard, Patent Owner argues that Saikley fails to recognize “the specific relationship” claimed between the handle and the thickness of the lancet, has not shown it was an obvious design choice, and fails to show an “obvious to try/routine optimization rationale” because Petitioner did not show a “finite number of known solutions.” According to Patent Owner, Petitioner “gives no indication from the art the ratio of the span of the gripping handle portion to the lancet thickness was critical to the design of protective caps or what ratios would have been beneficial.” Prelim. Resp. 19–22 (citing, e.g., Ex. 2001 ¶¶ 109–117). We have considered each of Patent Owner’s arguments and find, in light of the recited range which encompasses any “gripping handle portion” with “a lateral span of at least 1.5 times the lancet thickness,” that Petitioner has adequately demonstrated the limitation would have been obvious over Saikley in light of the knowledge of a person of ordinary skill in the art for purposes of institution for the reasons set forth in the Petition, as summarized above.

Third, Petitioner contends that the span limitation and the length limitations (referred to by Petitioner as the “dimensional limitations”) would have been obvious over “Saikley in view of Stout.” Pet. 53. Petitioner asserts that Stout “teaches that ‘the slotted opening 32 [of the lancing device]’—which lancet must pass through—‘has a [lateral span]

considerably greater than its [lancet thickness], most preferably having a [lateral span] at *least twice* its [lancet thickness].” Pet. 53 (citing Ex. 1018 ¶¶ 32, 35; Ex. 1002 ¶ 128) (emphasis and alteration in original). The portion of the disclosure of Stout quoted by Petitioner is directed to an embodiment illustrated in Figures 1–7 of Stout. See Ex. 1005 ¶¶ 31–35. Petitioner also provides annotated versions of Figures 8a and 8c of Stout, depicting “another example embodiment.” Pet. 53; Ex. 1005 ¶ 41.

Petitioner’s annotated versions of Figures 8a and 8b of Stout are reproduced below.



Figures 8a and 8b of Stout, as annotated by Petitioner, depict lancet body 142 marked with the letter “T” to show its thickness and endcap 144 marked with the letter “S” to show its lateral span. Pet. 53. Petitioner asserts that one of ordinary skill “would have understood Stout’s Figures 8a–8c (in conjunction with the textual descriptions) to plainly depict a gripping handle portion with a much greater length than the lancet thickness and a lateral span ‘considerably greater’ and ‘at least twice,’ *i.e.*, more than 1.5 times, the lancet thickness.” *Id.* at 54 (citing Ex. 1002 ¶ 129).

Patent Owner argues that Petitioner “mismatches Stout’s disclosure of one embodiment” shown in Figures 1–7 of Stout with another embodiment

of Stout shown in Figures 8a and 8b of Stout without providing a “basis as to why the description of one embodiment in Stout is applicable to another.” Prelim. Resp. 16. Further, according to Patent Owner, “Stout does not disclose dimensional information for the Figure 8 embodiment.” *Id.* at 16–17. Patent Owner does not refute on the current record Petitioner’s contentions based on Stout’s description of the embodiment shown in Figures 1–7. Nor are we persuaded that the absence of dimensional information in the figures directed specifically to the embodiment shown in Figures 8a and 8b relied upon by Petitioner shows that those figures “cannot be relied upon to disclose any dimension” in light of the limitations at issue and how Petitioner contends Figures 8a and 8b would have been understood by a person of ordinary skill in the art.

With regard to reasoning in support of the asserted combination of teachings, Petitioner contends that, in light of Stout’s teachings, one of ordinary skill in the art “would have been motivated to combine Saikley and Stout because such a combination would be commercially desirable and it would be obvious to try.” Pet. 56. Petitioner asserts that Stout’s lancing system is backwards-compatible with the meter disclosed by Saikley, and a person of ordinary skill in the art “would have had a reasonable expectation of success in combining Saikley and Stout because both Saikley’s protective cap 78 and Stout’s sterility cap 144 perform the same function and would yield predictable results.” *Id.* (citing Ex. 1018 ¶ 46; Ex. 1005 ¶ 3). According to Petitioner, “[m]odifying Saikley’s protective cap with the features of Stout’s sterility cap, including the embedment of the needle sharp and the dimensions discussed above, would yield the predictable result of a

large lancet cap that is easy to handle.” *Id.* at 57 (citing Ex. 1002 ¶¶ 131–136).

Patent Owner argues that the testimony of Petitioner’s declarant, Mr. Delmont, is insufficient and that the asserted rationale is “mere attorney argument,” that it is not enough for the asserted art to merely fall within the same alleged field, and that the teachings of Stout relied on by Petitioner have “nothing to do with the compatibility of Stout working with another device.” *Id.* at 18. Having considered Patent Owner’s arguments, as supported by Mr. Clements (Ex. 2001 ¶¶ 93–117), we find that Petitioner’s rationale for combining the teachings of Saikley and Stout, as summarized above, is sufficient to support institution.

We have reviewed the evidence and argument presented in the Petition, including relevant portions of the Delman Declaration, and determine, on this record, that Petitioner shows, sufficiently to support institution, how it contends the asserted combination of Saikley and Stout teaches or suggests every limitation of claims 6–8, 14, and 16–18, and why one of ordinary skill in the art would have had sufficient reason to modify Saikley, alone, or to combine Saikley with the teachings of Stout, with a reasonable expectation of success. As further explicit notice to Patent Owner, we understand Petitioner to have properly presented arguments to show that (1) if Saikley is found not to expressly or inherently disclose the primary sheath limitation, that limitation would have been obvious over Saikley in combination with Stout (Pet. 45–47, 54–57); (2) if Saikley is found not to expressly or inherently disclose the span limitation or the length limitations, those limitations would have been obvious over Saikley, alone (*id.* at 47–53); and (3) if Saikley is found not to expressly or inherently

disclose the span limitation or the length limitations, those limitations would have been obvious over Saikley in combination with Stout (*id.* at 53–57). Thus, an issue for trial presented in the Petition is whether Saikley, alone and/or in combination with Stout, renders obvious claims 6–8, 14, and 16–18.

H. Alleged Obviousness Over Saikley and FreeStyle

Petitioner contends that claim 16 is unpatentable as obvious over the combination of Saikley and Freestyle. Pet. 57–59. Petitioner supports its contentions with the testimony of Mr. Delman. *See* Ex. 1002 ¶¶ 137–150.

Petitioner asserts that the language in claim 16 “for placement of branding indicia thereon” is merely an intended use recitation that is not entitled to patentable weight. Pet. 57 (citing *Marrin v. Griffin*, 599 F.3d 1290, 1294 (Fed. Cir. 2010)). Petitioner also asserts that, “[s]hould Patent Owner argue that the recitation of ‘for placement of branding indicia thereon’ is entitled to patentable weight (which it is not), this is disclosed by a combination of Saikley and FreeStyle.” *Id.* Petitioner asserts that “FreeStyle expressly teaches using a flat display surface of a cap to display branding indicia (*i.e.*, the FreeStyle logo).” *Id.* at 58. According to Petitioner, “Saikley provides ample motivation to add FreeStyle-related branding to Saikley’s protective cap.” *Id.* at 59 (citing Ex. 1002, ¶¶ 143–150).

Patent Owner does not specifically dispute Petitioner’s contentions based on FreeStyle. *See* Prelim. Resp. 23 (asserting that “Saikley does not disclose all claim limitations of claim 14 on which claim 16 depends,” and that Petitioner “does not rely on Freestyle Manual to teach any of the claim limitations Saikley does not disclose” (citing Pet. 57–59)).

We have reviewed the evidence and argument presented in the Petition, including relevant portions of the Delman Declaration, and determine, on this record, that Petitioner sufficiently shows how it contends the asserted combination of Saikley and FreeStyle teaches or suggests every limitation of claim 16, and why one of ordinary skill in the art would have had sufficient reason to combine Saikley and FreeStyle, with a reasonable expectation of success in doing so, to support institution.

I. Alleged Anticipation by Iio

Petitioner contends that claims 6–8, 14, and 16–18 are anticipated by Iio. Pet. 78–86. Petitioner supports its contentions with the testimony of Mr. Delman. *See* Ex. 1002 ¶¶ 185–200.

1. Analysis of Claim 6

Petitioner contends that Iio anticipates the subject matter of claim 6. Pet. 78–82. Petitioner’s contentions are supported by testimony from Mr. Delman. Ex. 1002 ¶¶ 185–192. Our consideration of claim 6 includes consideration of the limitations of claim 1 from which claim 6 depends. *See* Ex. 1001, 12:53–57. On the current record, Patent Owner does not dispute Petitioner’s contentions based on Iio as to the limitations of disclaimed claim 1. *See* Prelim. Resp. 27–31.

[1pre] A protective sterility cap for a lancet,
[1a] said sterility cap comprising a primary sheath for
initial embedment of a sharp lancing tip of an unused lancet
therein,
[1b] a secondary sheath for receiving the sharp lancing tip
of a used lancet, and

Petitioner contends that the preamble of claim 1 is not limiting. Pet. 59. Petitioner also contends, to the extent that the preamble is limiting, that Iio discloses a protective sterility cap (puncture needle cap 91) for a

lancet (puncture needle body 65). *Id.* at 59–60 (citing Ex. 1006 ¶¶ 13, 50, Fig. 7a; Ex. 1002 ¶¶ 153–155). Next, Petitioner contends that Iio’s puncture needle cap 91 includes a primary sheath that embeds an unused puncture needle. *See* Pet. 60–63 (citing Ex. 1006 ¶¶ 104, 106, 117, Figs. 8, 9(a)–9(c); Ex. 1002 ¶¶ 156–159). Petitioner further contends that Iio’s puncture needle cap 91 includes disposal slot 92, which represents a secondary sheath for receiving a used lancet tip. Pet. 63–66 (citing Ex. 1006 ¶¶ 104, 115, Figs. 8, 11(a)–11(c); Ex. 1002 ¶¶ 160–164).

[1c] a gripping handle portion extending between the primary sheath and the secondary sheath,

Petitioner contends that Iio’s puncture needle cap 91 includes a gripping handle extending between the primary and secondary sheaths. Pet. 66–71 (citing Ex. 1006 ¶¶ 4–7, 23, 106, Fig. 8, 9(a); Ex. 1002 ¶¶ 165–174). Petitioner provides an annotated version of Iio’s Figure 8, which is reproduced below. *Id.* at 67.

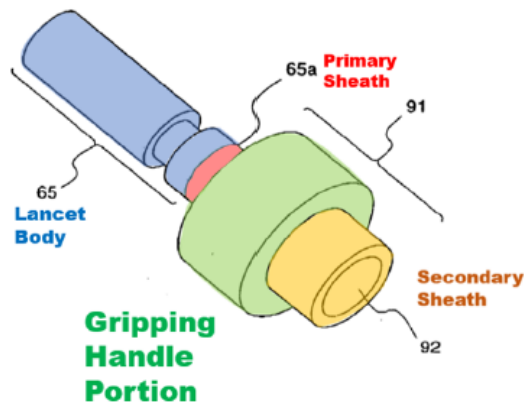


Figure 8 of Iio, as annotated by Petitioner, depicts puncture needle cap 91 with a green-highlighted section labeled “Gripping Handle Portion” between a red-highlighted section (adjacent puncture needle separation groove 65a) labeled “Primary Sheath” and a yellow-highlighted section (disposal slot 92) labeled “Secondary Sheath.” *Id.* Petitioner asserts that, “[b]y positioning a

handle directly between the primary and secondary sheaths, Iio makes it easier for the operator to grip the puncture needle unit 90 when inserting the puncture needle 65 into the lancing device before use, and when subsequently removing the puncture needle 65 after use for disposal.” *Id.* (citing Ex. 1006 ¶ 166).

[1d] with the primary sheath attached at a first end of the gripping handle portion and the secondary sheath attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet.

Petitioner contends that “the gripping handle portion of [Iio’s] puncture needle cap 91 extends between the primary sheath (*i.e.*, sheath formed adjacent the puncture groove 65a) and the secondary sheath (*i.e.*, sheath with the disposal slot 92),” and, thus, “each sheath is attached at an opposite end of the gripping handle portion of the protective needle cap 91.” Pet. 71 (citing Ex. 1006 ¶ 117, Figs. 8–9(c)); *see also id.* at 72–73 (citing Ex. 1006 ¶¶ 47, 93, 102–104, 116–117, Figs. 9(a), 11(b); Ex. 1002 ¶¶ 175–178).

[6a] The protective sterility cap of claim 1, in combination with a lancet

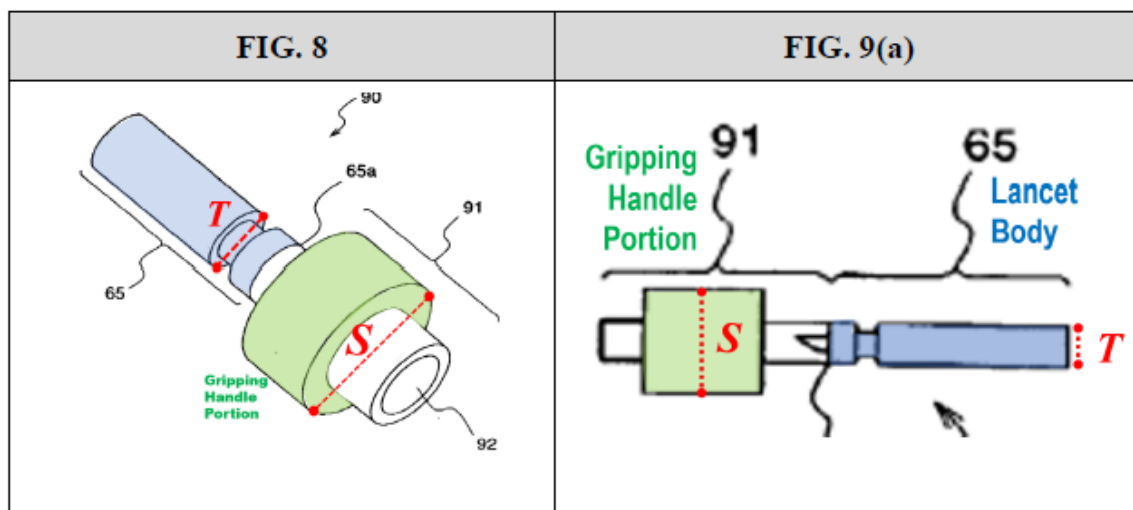
[6b] having a lancet body defining a lancet thickness, and

[6c] a sharp lancet tip initially embedded in the primary sheath

Petitioner contends that Iio discloses a protective sterility cap (puncture needle cap 91) in combination with a lancet having puncture needle body 65 with a lancet thickness and a sharp lancet tip embedded in the primary sheath. Pet. 78–79 (citing Ex. 1006, Figs. 8, 9(a); Ex. 1002 ¶ 186). Patent Owner does not dispute Petitioner’s assertion based on Iio as to limitations [6a]–[6c]. *See Prelim. Resp.* 27–31.

[6d] wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness [the “lateral span limitation”]

Petitioner contends that the gripping handle portion of Iio’s puncture needle cap 91 has a lateral span at least 1.5 times the thickness of puncture needle body 65. Pet. 79–80 (citing Ex. 1002 ¶ 187). Petitioner provides annotated versions of Iio’s Figures 8 and 9(a), which are reproduced below. *Id.* at 80.



Figures 8 and 9(a) of Iio, as annotated by Petitioner, depict puncture needle cap 91 with a green-highlighted section labeled “Gripping Handle Portion” and marked with the letter “S” to indicate the lateral span. *Id.* The figures also show puncture needle body 65 highlighted in blue and marked with the letter “T” to identify the lancet thickness. *Id.* Petitioner contends that the figures show that the lateral span S is at least 1.5 times the puncture needle body thickness T. *Id.* (citing Ex. 1002 ¶ 188).

Petitioner also points to Figures 11(b)–(c) of Iio to support its assertion that the identified lateral span S is at least 1.5 times the lancet thickness T. *Id.* at 81. Figure 11(c) is reproduced below.

Fig.11(c)

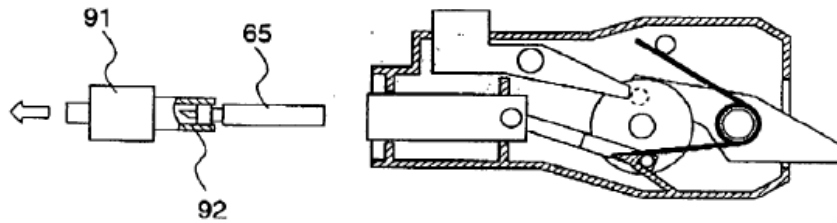


Figure 11(c) of Iio depicts puncture needle cap 91 attached to puncture needle body 65 via disposal slot 92 for removal. Ex. 1006 ¶¶ 53, 104.

Petitioner asserts as follows:

As shown, for example, in Figures 11(b) and (c), the entire thickness of the puncture needle body is able to fit into Iio's secondary sheath and, thus, this secondary sheath must have a greater lateral span than the lancet thickness. And, as also shown, for example, in the Figures 8, 9 and 11, Iio's gripping handle portion has a significantly broader lateral span than the secondary sheath. This reinforces that the dimensions depicted reflect that the lateral span of the gripping handle portion is more than 1.5 times the lancet thickness.

Pet. 81 (citing Ex. 1002 ¶¶ 188–189). Petitioner further asserts that the claimed “relative proportions are also confirmed by of the size of the user's thumb depicted in Iio's Figure 9(a) as compared to the gripping handle portion and the lancet thickness.” *Id.*

Figure 9(a) of Iio is reproduced below.

Fig.9(a)

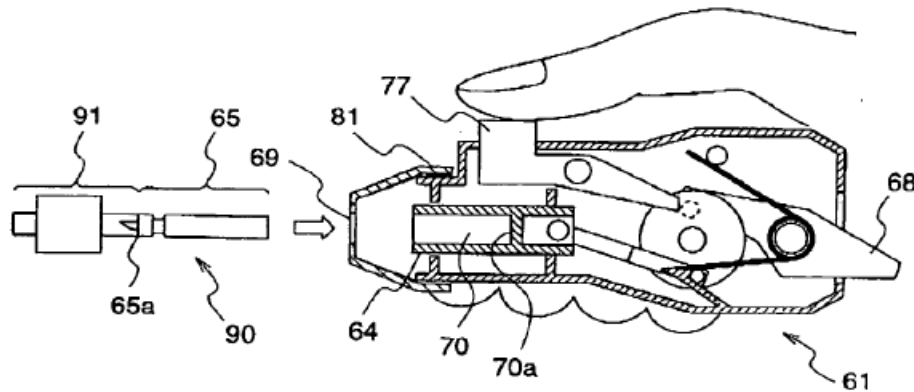


Figure 9(a) of Iio depicts, in relevant part, puncture needle 65 attached to puncture needle cap 91 for insertion into lancet 61. Ex. 1006 ¶¶ 45, 106. Petitioner asserts that, in the figure, “the user’s thumb appears to have a lateral span that is comparable to the lateral span of the gripping handle portion, whereas the lancet thickness appears to be very small in comparison to size of the user’s thumb.” Pet. 81 (citing Ex. 1002 ¶ 190). Petitioner also asserts that “Iio textually describes a specific thickness for ‘a thin plastic film having a thickness of 0.1 mm or less in the puncture needle separation groove.’” *Id.* at 82 (citing Ex. 1006 ¶ 104). According to Petitioner, a person of ordinary skill in the art “could visually discern that the lancet thickness is around 5 times thicker than the depicted needle separate groove 65a (Figure 9(a)) and also that lateral span of the gripping handle portion is 20 or more times larger than the depicted thickness of the needle separation groove 65a.” *Id.* (citing Ex. 1002 ¶ 191).

With regard to the additional limitations of claim 6, Patent Owner only disputes Petitioner’s assertions based on Iio with respect to the lateral span limitation. Prelim. Resp. 27–31. Patent Owner argues that Petitioner

improperly relies upon Iio’s figures to define precise proportions and particular sizes. *Id.* at 28 (citing *Hockerson-Halberstadt, Inc.*, 222 F.3d at 956). Patent Owner asserts that “Iio provides no dimensional information of puncture needle body 65 or the puncture needle cap 91,” and “is also completely silent as to the scale of its figures.” *Id.*

Patent Owner also argues that Iio’s components appear to change size among its figures. *Id.* at 29 (citing Ex. 1006, Figs. 1–13). Referring to Petitioner’s annotated Figures 8 and 9(a) of Iio, Patent Owner argues that “the block labeled ‘Gripping Handle Portion’ in Figure 8 (annotated) is has a diameter larger than it is long, while the diameter of same block in Figure 9 (annotated) is smaller than it is long.” *Id.* (citing Pet. 80; Ex. 2001 ¶¶ 122–124). Patent Owner similarly asserts that annotated Figures 9(a) and 11(c) show different relative sizes for components. *See id.* (asserting that “Figure 9a . . . has a disposal slot 92 that is much shorter than the block, but Figure 11b . . . shows that the two are about the same length—the disposal slot 92 also appears to double in diameter”). According to Patent Owner, the thumb shown in Figure 9(a) of Iio “provides no information that can be used to derive dimensional information of ‘a lateral span’ of ‘a gripping handle portion’ or ‘a lancet thickness’ of ‘a lancet body.’” *Id.* at 30–31.

Patent Owner further argues that “[t]here is no way to correlate the thin film to either the thickness of the lancet or the lateral span of the block.” Prelim. Resp. 31. According to Patent Owner, the “[t]he written specification of Iio does not disclose that any figure includes the thin plastic film,” and “Iio does not disclose any dimension of puncture needle unit 90 is connected to the thickness of the thin plastic film.” *Id.* (citing Ex. 2001 ¶ 129). In regard to the particular thickness of the thin film of Iio relied on

by Petitioner, on the current record, Patent Owner's arguments appear to have merit as Petitioner has not identified a persuasive basis to correlate the precise thickness of the film to other elements illustrated in Iio.

Patent Owner's other arguments are not persuasive on the current record at this stage of the proceeding. Claim 6 does not specify a precise size, but only a relative relationship: "a lateral span of at least 1.5 times the lancet thickness." As noted above, we consider what the drawings in a reference "reasonably disclose and suggest to one skilled in the art."

Aslanian, 590 F.2d at 914. We are not persuaded on the current record that the absence of dimensional information makes "any exact dimensional information derived from the figures ... unreliable," as Mr. Collins opines for Patent Owner. *See* Ex. 2001 ¶¶ 121–129. Mr. Delmont explains that in his opinion, a person of ordinary skill in the art "would have understood Iio to disclose a gripping handle portion with a lateral span and a length that is greater than 1.5 times the lancet thickness," based both on the illustrations of the device of Iio explicitly showing such a relationship as well as figures showing the relative relationship of a user's thumb to the device. Ex. 1002 ¶ 190.

2. *Dependent Claims 7 and 8*

Petitioner contends that claims 7 and 8, which depend from claim 6, are anticipated by Iio. Pet. 82–85. Patent Owner does not dispute Petitioner's contentions based on Saikley as to the additional limitations of claims 7 and 8. Prelim. Resp. 31. We have reviewed the evidence and argument presented in the Petition, including relevant portions of the Delman Declaration, and determine, on this record, that Petitioner

sufficiently shows how it contends Iio discloses every limitation of claims 7 and 8 to support institution. *See id.*; Ex. 1002 ¶¶ 193–197.

3. *Independent claim 14 and dependent claims 16–18*

Petitioner contends that independent claim 14 is anticipated by Iio for substantially the same reasons discussed above in connection with claim 6. Pet. 85. Patent Owner argues that Iio fails to disclose the lateral span limitation of claim 14 for the same reasons discussed above with regard to claim 6. Prelim. Resp. 27–31. For the reasons explained above in our analysis of claim 6, and based on our review and consideration of Petitioner’s arguments and evidence directed to claim 14, we determine, on this record, that Petitioner sufficiently shows how it contends Iio discloses every limitation of claim 14, as well as claims 16–18, to support institution. *See* Pet. 85–86; Ex. 1003 ¶¶ 198–200; *see also* Prelim. Resp. 31 (Patent Owner does not dispute Petitioner’s additional contentions directed to claims 16–18).

4. *Finding of a Reasonable Likelihood of Prevailing*

Based on our review of the evidence and consideration of the arguments, we find, on this record, that Petitioner sufficiently shows how it contends that Iio discloses the limitations of claim 6, including the limitations of claim 1 from which it depends, to support institution of *inter partes* review. We reach the same determination, as explained above, with respect to claims 7, 8, 14, and 16–18.

J. *Alleged Obviousness Over Iio and Peckham*

Petitioner contends that claims 6–8, 14, and 16–18 are unpatentable as obvious over the combination of Iio and Peckham. Pet. 86–100. Petitioner

supports its contentions with the testimony of Mr. Delman. *See* Ex. 1002 ¶¶ 201–226.

The Petition states that, “[s]hould the Board find that a PHOSITA would not have understood the cylindrical grip on Iio’s lancet cap to be a ‘gripping handle portion,’ . . . then Petitioners alternatively contend that Iio renders obvious the challenged claims in light of Peckham.” Pet. 87–88. Petitioner asserts that Peckham teaches protective sterility cap 100 with cylindrical housing 105 that includes longitudinal ribs or splines 125, which provide a textured surface to improve handling of the cap. *Id.* at 88–89 (citing Ex. 1008, 3:13–15; Ex. 1002 ¶¶ 203–204). According to Petitioner, one of ordinary skill in the art would have been motivated to add the textured ribs of Peckham to Iio’s puncture needle unit to improve handling and maneuverability. *Id.* at 89 (citing Ex. 1008, 3:13–15).

Patent Owner does not dispute Petitioner’s assertion that it would have been obvious to modify Iio’s puncture needle unit to have textured ribs. *See* Prelim. Resp. 32–36 (contesting only Petitioner’s assertion that the combination of Iio and Peckham renders obvious “the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness,” as recited in claims 6 and 14).

Next, Petitioner states that, “[s]hould Patent Owner argue that any of the relative dimensional limitations are not expressly taught by Iio, those limitations, at a minimum, would have been obvious to try.” Pet. 90. Petitioner asserts that accidental needle sticks were a “well-recognized problem [that] led to many sterility caps, including Iio’s, being developed with both primary and secondary sheaths and gripping handles therebetween to facilitate ease of handling.” *Id.* (citing Ex. 1002 ¶ 208). Petitioner

contends that one of ordinary skill in the art “would have routinely experimented with the dimensions of the gripping handle portion (including both its lateral span and length) to try to optimize the sterility caps for mass-market use,” and “would recognize that there are only a finite number of potential dimensions for the gripping handle portion as compared to the thickness of the lancet.” *Id.* at 90–91 (citing Ex. 1002 ¶ 208). Petitioner asserts:

In designing larger gripping handle portions, a [person of ordinary skill in the art] would have routinely experimented with optimizing the size of the gripping handle including its lateral span and length. This would have included trying various relative dimensions to ensure that the gripping handle portion was usable and handleable even by those with dexterity challenges, such as elderly users. Ex.1002, ¶209. In doing so, a [person of ordinary skill in the art] would have tried dimensions in which the gripping handle’s lateral span was much more than 1.5 times the lancet thickness as this would have improved a user’s ability to safely handle a lancet both before and after use. *Id.* And doing so would have been achieved with a reasonable expectation of success as the iterative process of testing various dimensions for a prototype product is a standard practice utilized in designing consumer products prior to arriving at a final product design, particularly in the medical device field where safety is critically important. *Id.*

Id. at 91. Petitioner also contends that adding Peckham’s ribs to Iio’s cap “would have led a [person of ordinary skill in the art] to increase the lateral span of the gripping handle portion even more (*i.e.*, further beyond 1.5 times the lancet thickness) because the ribs would have extended beyond an outer surface of Iio’s cap, thereby extending the cap’s lateral span.” *Id.* at 93 (citing Ex. 1002 ¶ 213).

Patent Owner opposes Petitioner’s contention that the combination of Iio and Peckham renders obvious “the gripping handle portion defines a

lateral span of at least 1.5 times the lancet thickness,” as recited in claims 6 and 14. *See* Prelim. Resp. 32–36. Patent Owner argues that “Peckham does not fill the hole in Iio: the proposed combination does not disclose the claimed dimensional ratios.” *Id.* at 32. Patent Owner asserts that Petitioner’s “obvious to try” rationale is deficient because Petitioner did not argue there were only a finite number of known solutions. *Id.* at 34 (citing *Rolls-Royce, PLC v. United Techs. Corp.*, 603 F.3d 1325, 1339 (Fed. Cir. 2010)). According to Patent Owner, there were other avenues to improve lancet maneuverability, such as “adding a cover to the areas of the cap gripped by a user (e.g., rubber, polymer, textured coating), mechanical features to the areas of the cap gripped by a user (e.g., dimples).” *Id.* at 35. Patent Owner asserts that, “[e]ven pursuing only the changing of the dimensions of the gripping handle portion, there is still a broad selection of choices for further investigation, such as the length, width, and thickness of the gripping handle portion.” *Id.* (citing Ex. 2001 ¶¶ 109–117, 132).

Patent Owner further argues that “Peckham is silent as to any dimension of the shielded lancet assembly, including ribs 125,” and, “like Iio, Peckham’s figures cannot be used for dimensional information given there is no indication they are to scale and the disclosure is silent as to dimensional information in them.” *Id.* at 36 (citing *Hockerson-Halberstadt, Inc.*, 222 F.3d at 956).

Having considered Patent Owner’s arguments, as supported by Mr. Clements (Ex. 2001 ¶¶ 130–137), we find Petitioner’s rationale for combining the teachings of Iio and Peckham, as summarized above, is sufficient to support institution. We have reviewed the evidence and argument presented in the Petition, including relevant portions of the

Delman Declaration, and determine, on this record, that Petitioner sufficiently shows how it contends the asserted combination of Iio and Peckham teaches or suggests every limitation of claims 6–8, 14, and 16–18, and why one of ordinary skill in the art would have had sufficient reason to combine Iio with the teachings of Peckham, with a reasonable expectation of success in doing so, to support institution.

K. Alleged Obviousness Over Iio and FreeStyle

Petitioner contends that claim 16 is unpatentable as obvious over the combination of Iio and Freestyle. Pet. 100–101. Petitioner supports its contentions with the testimony of Mr. Delman. *See* Ex. 1002 ¶¶ 227–229.

Petitioner asserts that the language in claim 16 “for placement of branding indicia thereon” is merely an intended use recitation that is not entitled to patentable weight. Pet. 100 (citing *Marrin*, 599 F.3d at 1294). Petitioner also asserts that, “[s]hould Patent Owner argue that the recitation of ‘for placement of branding indicia thereon’ is entitled to patentable weight (which it is not), this is disclosed by a combination of Iio and FreeStyle.” *Id.* at 101. Petitioner contends that the asserted combination would have been obvious for the same reasons provided in support of the asserted combination of Saikley and Freestyle discussed above.” *Id.*

Patent Owner does not specifically dispute Petitioner’s contentions based on FreeStyle. *See* Prelim. Resp. 37 (asserting that “Iio does not disclose all claim limitations of claim 14 on which claim 16 depends,” and that Petitioner “does not rely on Freestyle Manual to teach any of the claim limitations Iio does not disclose” (citing Pet. 100–101)).

We have reviewed the evidence and argument presented in the Petition, including relevant portions of the Delman Declaration, and

determine, on this record, that Petitioner shows sufficiently to support institution how it contends the asserted combination of Iio and FreeStyle teaches or suggests every limitation of claim 16, and why one of ordinary skill in the art would have had sufficient reason to combine Iio and FreeStyle, with a reasonable expectation of success.

IV. CONCLUSION

For the foregoing reasons, we determine that Petitioner demonstrates a reasonable likelihood of prevailing with respect to at least one of the claims challenged in the Petition. Accordingly, *inter partes* review of claims 6–8, 14, and 16–18 of the '635 patent shall proceed in this case on all of the grounds raised in the Petition. *See SAS Inst.*, 138 S. Ct. at 1359–60 (holding that a decision to institute under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (stating that the decision whether to institute *inter partes* review requires “a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition”).

Our determination in this Decision is not a final determination on either the patentability of any Challenged Claims or the construction of any claim term. The factual findings set forth in this Decision are preliminary and provided for the sole purpose of deciding whether to institute a review. Any final findings will be based on the full trial record, including any information presented by Patent Owner in a timely filed response to the Petition. *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”) (quoting 35 U.S.C. § 314(a) and comparing *id.* with § 316(e)).

IV. ORDER

Upon consideration of the record before us, it is:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 6–8, 14, and 16–18 of U.S. Patent No. 8,840,635 B2 is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of U.S. Patent No. 8,840,635 B2 shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

IPR2023-00712
Patent 8,840,635 B2

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