

Filed on behalf of: Facet Technologies, LLC

Entered: December 11, 2024

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

PATENT OWNER'S NOTICE OF APPEAL

Notice is hereby given, pursuant to 37 C.F.R. § 90.2(a), that Patent Owner Facet Technologies, LLC (“Patent Owner”) appeals to the United States Court of Appeals for the Federal Circuit from the Final Written Decision entered by the Patent Trial and Appeal Board (the “Board”) on August 27, 2024 (public version issued on December 10, 2024 as Paper 80) (the “Final Written Decision,” a copy of which is attached hereto as Exhibit A) and the Order Denying Patent Owner’s Request for Director Review of the Final Written Decision entered by the U.S. Patent and Trademark Office (“USPTO”) on November 22, 2024 (Paper 78) (the “Order on Director Review,” a copy of which is attached hereto as Exhibit B).

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), Patent Owner further indicates that the issues on appeal may include, without limitation:

- Whether the Board erred in determining that Petitioner has shown by a preponderance of the evidence that any of the challenged claims (claims 6–8, 14, and 16–18) of U.S. Patent No. 8,840,635 are unpatentable as anticipated under 35 U.S.C. § 102, along with all reasons, findings, opinions, and orders leading thereto or underlying that decision; and
- Whether the USPTO erred in denying Patent Owner’s request for Director review of the Final Written Decision.

Pursuant to 35 U.S.C. § 142 and 37 C.F.R. § 90.2(a), this Notice is being filed with the Director of the USPTO, and a copy of this Notice is being concurrently filed

with the Board. In addition, a copy of the Notice of Appeal, along with the required docketing fee, is being filed with the Clerk of Court for the United States Court of Appeals for the Federal Circuit.

Respectfully submitted,

Dated: December 11, 2024

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CERTIFICATE OF SERVICE

I hereby certify that, pursuant to 37 C.F.R. § 90.2(a)(1), on this 11th day of December, 2024, I electronically filed the foregoing **PATENT OWNER'S NOTICE OF APPEAL** with the Patent Trial and Appeal Board via P-TACTS, in accordance with 37 C.F.R. § 42.6(b)(1).

I also hereby certify that a true and correct paper copy of the foregoing **PATENT OWNER'S NOTICE OF APPEAL** is being filed with the Director of the United States Patent and Trademark Office by electronic mail to efileSO@uspto.gov.

I also hereby certify that, pursuant to Federal Circuit Rule 52(a)(2), on the 11th day of December, 2024, a true and correct copy of the foregoing **PATENT OWNER'S NOTICE OF APPEAL** and the filing fee, were filed with the Clerk's Office of the U.S. Court of Appeals for the Federal Circuit via CM/ECF.

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 11th day of December, 2024, a true and correct copy of the foregoing **PATENT OWNER'S NOTICE OF APPEAL** was served by electronic mail on Petitioner's lead and backup counsel at the following email addresses:

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EXHIBIT A

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, JASON W. MELVIN, and DAVID COTTA,
Administrative Patent Judges.

JENKS, *Administrative Patent Judge.*

JUDGMENT

Final Written Decision

Determining All Challenged Claims Unpatentable

Dismissing Petitioner's Motion to Exclude

Dismissing Patent Owner's Motion to Exclude

5 U.S.C. § 318(a); 37 C.F.R. § 42.5

I. INTRODUCTION

In this *inter partes* review, LifeScan, Inc. (“Petitioner”) challenges claims 6–8, 14, and 16–18¹ of U.S. Patent No. 8,840,635 B2 (Ex. 1001, “the ’635 patent”) assigned to Facet Technologies, LLC (“Patent Owner”). Paper 1 (“Pet.”).

On March 20, 2023, Petitioner filed a Petition seeking *inter partes* review claims 6–8, 14, and the ’635 patent. On June 28, 2023, Patent Owner filed a Preliminary Response. Paper 9 (“Prelim. Resp.”). Pursuant to 35 U.S.C. § 314, we instituted *inter partes* review of challenged claims 6–8, 14, and 16–18 of the ’635 patent on September 1, 2023. Paper 13 (“Decision” or “Dec.”).

After institution of trial,² Patent Owner filed a Response (Paper 21, “PO Resp.”), to which Petitioner filed a Reply (Paper 32, “Reply”), and Patent Owner, in turn, filed a Sur-Reply (Paper 47, “Sur-Reply”).

Petitioner filed a Motion to Exclude Exhibits 2024, 2040, 2044, 2045, 2050, 2051, and at least paragraphs 137 through 151 of Exhibit 2056 that are cited in Patent Owner’s Response. Paper 44. Patent Owner filed an Opposition to the Motion to Exclude. Paper 48. Petitioner filed a Reply in Support of its Motion to Exclude. Paper 55.

¹ 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. Paper 9, 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.

² The parties have submitted various Motions to Seal. We will address these motions in a separate paper.

Patent Owner filed a Motion to Exclude Exhibits 1046 (Appendix F and certain portions of Ex. 1046 that reference Appendix F) and 1052 filed in Petitioner's Reply. Paper 42. Petitioner filed an Opposition to the Motion to Exclude. Paper 50. Patent Owner filed a Reply in Support of its Motion to Exclude. Paper 53.

Oral argument was held on May 23, 2024. A transcript of the oral argument is included in the record. Paper 71 ("Hearing Trans.").

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision, issued pursuant to 35 U.S.C. § 318(a), addresses issues and arguments raised during the trial in this *inter partes* review. For the reasons discussed below, we determine that Petitioner has shown by a preponderance of the evidence that claims 6–8, 14, and 16–18 of the '635 patent are unpatentable (*see* 35 U.S.C. § 316(e) (2018) ("In an *inter partes* review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.")).

We dismiss Petitioner's motion to exclude evidence as moot.

We dismiss Patent Owner's motion to exclude evidence as moot.

A. Real Parties in Interest

Petitioner identifies LifeScan, Inc. and Asahi Polyslider Company Ltd. as the real parties in interest. Pet. 1. Patent Owner identifies Facet Technologies, LLC and Facet Holdings Corporation as the real parties in interest. Paper 5, 1.

B. Related Matters

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. Additionally, Petitioner filed a second petition challenging claims 1, 4, and 9–15 of the '635 patent in IPR2023-00713. Paper 3, 1; Paper 5, 1.

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 claims priority 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.

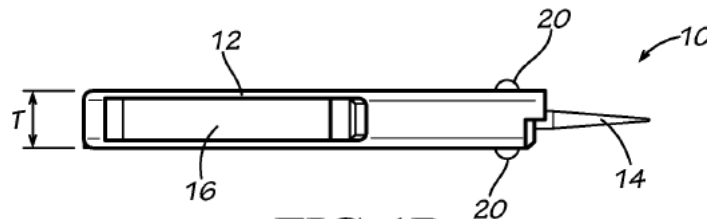


FIG. 1B

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 thickness³ T and lancet tip 14 projecting from one end thereof. *Id.* at 3:32–38.

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

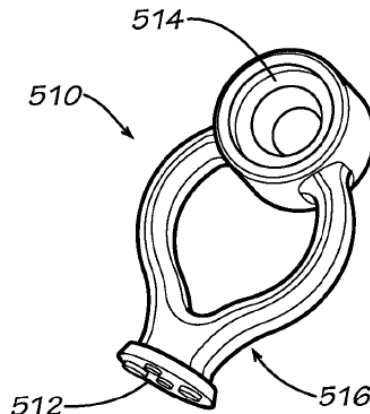


FIG. 5A

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

³ Thickness: the smallest of three dimensions, length, width, thickness.
Ex. 2041.

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:

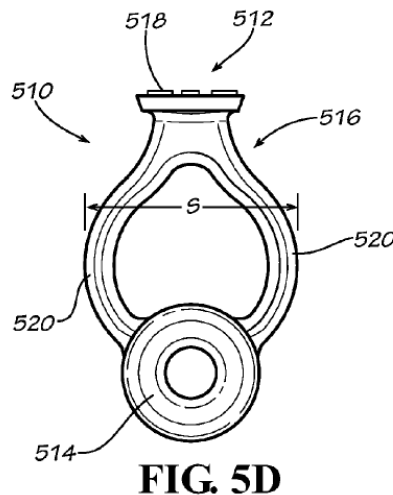


Figure 5D of the '635 patent depicts another view of protective sterility cap 510 shown in Figure 5A. *Id.* at 5:66–6:1. Handle portion 516 has a forked split configuration with first and second arms 520 transversely spaced apart from one another and an open center portion therebetween. *Id.* at 6:49–52. 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 6–8, 14, and 16–18 of the '635 patent are unpatentable. Pet. 4.

Petitioner asserts the following grounds:

Claims Challenged	35 U.S.C. §⁴	References/Basis
6–8, 14, 16–18	102(b)	Saikley ⁵
6–8, 14, 16–18	103(a)	Saikley, Stout ⁶
16	103(a)	Saikley, FreeStyle ⁷
6–8, 14, 16–18	102(b)	Iio ⁸
6–8, 14, 16–18	103(a)	Iio, Peckham ⁹
16	103(a)	Iio, Freestyle

Petitioner relies on the supporting Declarations of Joel Delman, Exhibit 1002 dated March 20, 2023, and Exhibit 1034 dated March 22, 2024. Patent Owner relies on the Declaration of Dr. John M. Collins, Exhibit 2056 dated December 18, 2023.

⁴ 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 because the application that resulted in the '635 patent was filed before the effective date of the AIA. We note that our analysis would not change under the AIA version of § 103.

⁵ US 2004/0138588 A1, published July 15, 2004 (Ex. 1005, “Saikley”).

⁶ US 2006/0241669 A1, published Oct. 26, 2006 (Ex. 1018, “Stout”).

⁷ Owner’s Booklet for FreeStyle Blood Glucose Monitoring System (Ex. 1010, “FreeStyle”). Exhibit 1010 includes a declaration from a Records Request Processor at the Internet Archive describing the Wayback Machine system and authenticating various webpage captures showing FreeStyle.

⁸ US 2005/0131441 A1, published June 16, 2005 (Ex. 1006, “Iio”).

⁹ US 5,569,286, issued Oct. 29, 1996 (Ex. 1008, “Peckham”).

III. ANALYSIS

A. *Legal Standard for Anticipation*

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)).

B. *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

does not dispute Petitioner’s definition of the person of ordinary skill in the art. PO Resp. 4.

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).

C. 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.

Patent Owner does not dispute Petitioner's proposed constructions and reliance on plain meaning as set forth in the district court's claim construction order. PO Resp. (citing Pet. 8).

Accordingly, we determine no claim term requires an express construction. *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)).

D. Overview of Cited Reference

In challenging the '635 patent, Petitioner relies on Saikley which we briefly summarize in relevant part below. *See* Pet. 3–4.

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.

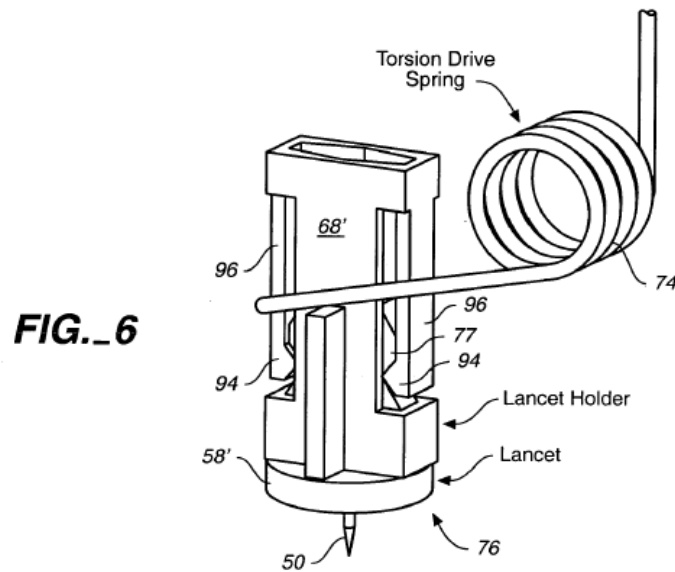


Figure 6 of Saikley is a perspective view of a torsion spring lancing mechanism. *Id.* ¶ 12. Lancet holder 68' of an integrated lancing device (not shown) engages shortened lancet 76, which includes sharp 50. *Id.* ¶¶ 41, 48, 50.

Figure 7A of Saikley is reproduced below.

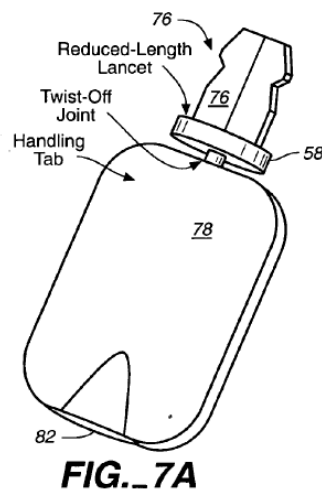


Figure 7A of Saikley is a perspective view of a lancet and cap combination according to a first embodiment. *Id.* ¶ 13. Protective cap 78 is an integrally

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.*

E. 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; Ex. 1034 ¶¶ 8–38.

1. Analysis of Claim 6

Petitioner contends that Saikley anticipates the invention of claim 6. Pet. 36–40. Petitioner’s contentions are supported by testimony from Mr. Delman. Ex. 1002 ¶¶ 98–105; Ex. 1034 ¶¶ 8–38. Our consideration of claim 6 includes consideration of the limitations of claim 1 from which claim 6 depends.¹⁰ *See* Ex. 1001, 12:53–57. Patent Owner opposes. *See* PO Resp. 6–15.

i. [1pre]¹¹ A protective sterility cap for a lancet,

Petitioner contends that the preamble of claim 1 is not limiting. Pet. 9. Petitioner also contends, to the extent that the preamble is limiting, that

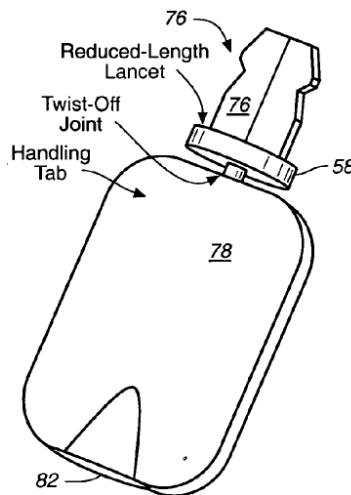
¹⁰ Our analysis of Petitioner’s contentions directed to claim 6 necessarily references portions of the Petition concerning limitations of disclaimed claims 1 and 2, because Petitioner’s contentions directed to claim 6 refer to sections of the Petition addressing limitations appearing in disclaimed claims 1 and 2. *See, e.g.,* Pet. 36–37.

¹¹ We refer to the bracketed claim limitation identifiers used in the Petition. *See* Pet. 9–26, 36–38.

Saikley discloses a protective sterility cap (protective cap 78) for a lancet (shortened lancet 76). *Id.* at 9–10 (citing Ex. 1005 ¶¶ 13, 50, Fig. 7a; Ex. 1002 ¶¶ 52–57).

Patent Owner does not dispute that Saikley discloses a tab/cap 78¹² for covering a needle. PO Resp. 6

Saikley’s Figure 7A is reproduced below:



Saikley’s Figure 7A shows lancet 76 that can engage lancet holder and the integrally molded protective cap 78 (that is removed before use). Ex. 1005 ¶ 50. Saikley discloses that “[a] hollow cup or solid ‘pin cushion’ type area 82 can be provided at the opposite end of cap 78. . . to cover the sharp during removal from the device and disposal.” *Id.*

In light of the evidence, we determine Petitioner has carried its burden to demonstrate that Saikley discloses a protective cap. Because Saikley discloses the subject matter recited in the preamble, we need not determine whether the preamble is limiting.

¹² Patent Owner refers to “tab/cap 78” as the alleged gripping handle. PO Resp. 8.

- ii. *[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 made up of the twist-off joint and an adjoining portion of the handling tab embedding an unused sharp lancing tip of a 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 twist-off joint and the adjoining portion of the integrally-molded protective cap 78. *Id.* at 12 (citing Ex. 1005 ¶ 50; Ex. 1002 ¶¶ 59–60).

Patent Owner contends that Petitioner has not shown that Saikley teaches a gripping portion between the primary and secondary sheath. PO Resp. 5–6 (citing Ex. 2056 ¶¶ 59–60), 10.

A sheath is a structure that covers a blade.¹³ Here, the ’635 patent describes a sheath as covering a sharp lancing tip. Ex. 1001, 2:22–25 (“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.”).

Saikley describes that cap 78 may be an integrally molded, pull-off tab such as shown in Figure 7A, reproduced above (§ III.E.1.i). Ex. 1005,

¹³ Sheath: “a case or covering for the blade of a sword, dagger, or the like.” Ex. 3005 (definition #1 from dictionary.com).

¶ 50. The reduced length lancet 76 is shown with the pull-off joint between the lancet 76 and cap 78. As the lancet and cap are integrally molded this suggests that the sharp is embedded in at least the pull-off joint and an adjoining portion of the cap 78. *See* Ex. 1002 ¶ 60 (a person of ordinary skill in the art would “understand that sharp 50 of the shortened lancet 76 is embedded in the twist-off joint and adjoining portion of the protective sterility cap 78”); Ex. 1034 ¶ 8; Ex. 1009 ¶ 8 (“a lancet needle is encased in an elongated plastic body with the needle tip embedded in a removable protective cap integrally molded with the plastic body to form a single integral unit prior to use.”). Because Saikley’s pull-off joint and the cap cover the sharp lancing tip before use, these structures read on the primary sheath element as claimed. Ex. 1002 ¶ 62 (citing Ex. 1009 ¶ 9 (“integral protective caps in order to prevent exposure and/or contamination of the lancet needle during post-manufacturing handling, shipping, and storage.”)).

In light of the evidence, we determine Petitioner has persuasively demonstrated that Saikley discloses a primary sheath containing the sharp lancing tip.

iii. [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).

Patent Owner contends that Petitioner has not shown that Saikley contains a gripping portion that is between the primary and secondary sheath. PO Resp. 6 (citing Ex. 2056 ¶¶ 59–60), 10. In this regard, Patent Owner challenges Petitioner’s identification of the primary and secondary sheaths in relation to the asserted gripping portion. *Id.* at 9–10.

Area 82 in Saikley’s Figure 7A, reproduced above (§ III.E.1.i), serves as a pin cushion. Specifically, Saikley explains that “pin cushion” area 82 located at the opposite end of cap 78 is used to cover the lancing tip sharp during removal from the device and disposal. Ex. 1005 ¶ 50.

As discussed above (§ III.E.1.ii), a sheath is a structure that covers a blade. By poking the lancet into the pin cushion, the sharp lancing tip is covered. Ex. 1005 ¶ 52 (“Lancet cap 84 is also provided with pin-cushion type areas 82' and 82", either of which can be used for receiving sharp 64 after use and prior to disposal.”); Ex. 1002 ¶¶ 67–70. Therefore, the pin cushion area 82 reasonably serves as a sheath for the sharp lancing tip.

In light of the evidence, we determine Petitioner has persuasively demonstrated that Saikley discloses a secondary sheath for receiving a sharp lancing tip.

iv. [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). Petitioner explains that “[a] gripping handle portion extends between the sheaths even if portions of the [gripping] handle [portion] also extend around one or both sheaths.” Reply 10 (citing Ex. 1034 ¶¶ 8–11); *see* Ex. 1034 ¶¶ 8–11 (discussing the PHOSITA’s understanding of ‘extends between’)). Petitioner’s expert explains:

Saikley’s gripping handle portion clearly extends between the sheaths, even if there are also portions which extend to the sides of the primary and secondary sheaths. This is because at least some of the gripping handle portion lies between the sheaths. As an illustration of the ordinary meaning of “between,” consider an example of a photo that is taken where I am standing in the middle of my two sons. If I am standing in the middle of my two sons with my arms around each of them on either side, anyone viewing the photo would consider that I am standing *between* my boys even though my arms are surrounding each of them. That is the ordinary meaning of between, which is consistent with a PHOSITA’s understanding of that term in the context of the patent claim.

Ex. 1034 ¶ 10.

Patent Owner contends “that tab/cap 78 corresponds to the claimed gripping handle, but fails to show that it is ‘between’ and ‘attached to’ the primary and secondary sheaths as required by the claims.” PO Resp. 9. Patent Owner does not dispute that Saikley discloses a tab/cap 78¹⁴ that covers the lancing tip, the dispute instead is directed to the structure of the tab. PO Resp. 6 (arguing that “Saikley’s protective cap/handling tab does not . . . ‘extend[] *between* the primary sheath and the secondary sheath,’ as recited in the claims”) (citing Ex. 2056 ¶ 67), 9 (“tab/cap 78 corresponds to the claimed gripping handle, but [Petitioner] fails to show that it is ‘between’

¹⁴ Patent Owner refers to “tab/cap 78” as the alleged gripping handle. PO Resp. 8.

and ‘attached to’ the primary and secondary sheaths as required by the claims.”).

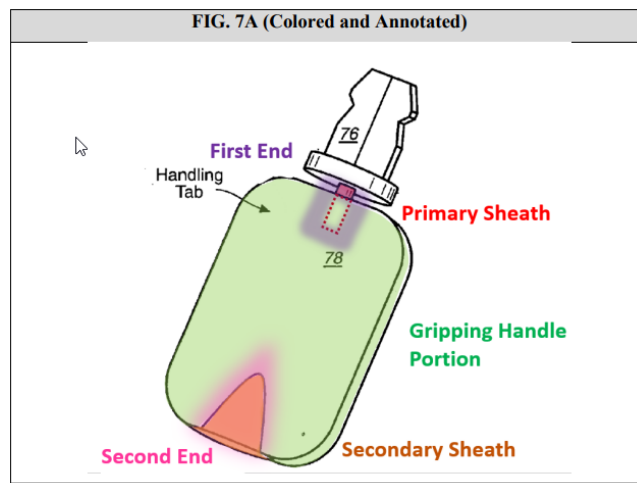
According to the ’635 patent, the lancet and sterility cap may be integrally molded.

The primary shroud or sheath portion 512 comprises a wide circular flange or ring at one end of the sterility cap 510, which abuts, confronts or interfaces with the front end of the lancet body in the lancet’s original, unused state. In example forms of the invention, the sterility cap 510 is integrally molded with the lancet body.

Ex. 1001, 6:18–23. In other words, the ’635 patent suggests that separately identified parts may be integrally molded into a single unit.

Saikley similarly discloses that cap 78 may be an integrally molded lancet with a pull-off tab and the protective cap 78. Ex. 1005 ¶ 50. Saikley further explains that the “short length [of the lancet] might make the lancet difficult for the user to handle and install, so the protective cap 78 (that is removed before use) should be made much larger than usual to aid handling.” *Id.* In Saikley the “pin cushion” area 82 (secondary sheath) and the pull-off tab and area surrounding the lancet sharp 50 (primary sheath) are integrated into the cap 78. *Id.* In other words, Saikley’s protective cap 78 contains a first and second sheath that are integrally molded with the gripping handle into a single unit.

Saikley's Figure 7A, as annotated by Petitioner, is reproduced below.



The annotated figure shows the first end in purple, the second end in magenta, the gripping handle in green, the primary sheath in red, and the secondary sheath in orange. Pet. 26–27. The lancet is not highlighted in this figure. According to Petitioner, “[b]oth sheaths are integrally molded to the protective cap so that they remain attached to the handling tab even after the user removes the puncture cap 78 from the lancet needle to collect a blood sample.” Pet. 27–28 (citing Ex. 1002 ¶ 84).

We agree with Petitioner’s assessment that the area (Figure 7A shown above in green) that lies in the middle of cap 78 extending from the end of the embedded sharp (shown as the dotted line in the figure above) and surrounding area to the hollow cup or solid “pin cushion” type area 82 and surrounding area meets the gripping handle portion limitation as claimed. *See* Pet. 25–26; Reply 10–11; Ex. 1034 ¶ 10 (“Saikley’s gripping handle portion clearly extends between the sheaths, even if there are also portions which extend to the sides of the primary and secondary sheaths. This is because at least some of the gripping handle portion lies between the sheaths.”). This is consistent with how the gripping portion is described in

the Specification. Ex. 1001, Figs. 5–7 (showing the arms of the gripping handle portion extending around parts of the secondary sheath); *see* Reply 10–11 (arguing that Patent Owner’s arguments would exclude every cap embodiment of the ’635 patent).

In light of Saikley’s disclosure of an integrally molded pull-off tab (Ex. 1005 ¶ 50; Figure 7A) and the ’635 patent’s express disclosure that distinct parts may be integrally molded (Ex. 1001, 6:21–23), we determine that Petitioner has persuasively demonstrated that Saikley discloses a gripping handle portion.

- v. *[Id] 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.*

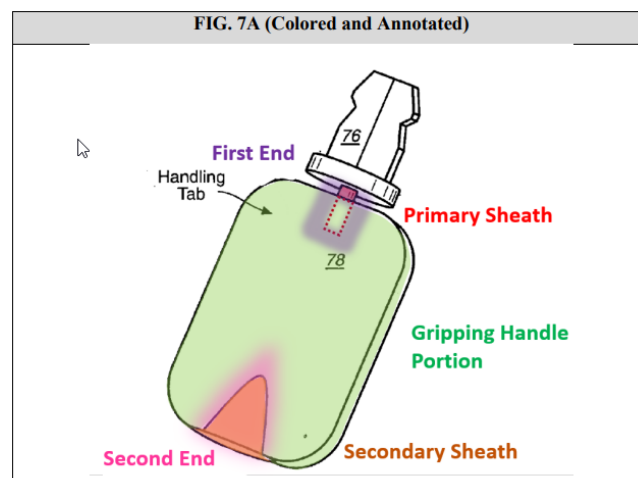
Petitioner contends that Saikley discloses the primary sheath (twist-off joint and an adjoining portion of the handling tab) and secondary sheath (pin cushion type area 82) attached to respective first and second ends of the gripping handle portion (protective cap 78). Pet. 27. Petitioner asserts that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

Patent Owner argues that “the sheaths are not attached at its first or second ‘end’ as required by the claims” because “tab/cap 78 surrounds the alleged sheaths and itself forms a portion or all of the primary sheath rather than being attached to it.” PO Resp. 10 (citing Ex. 2056 ¶ 66). Patent Owner further argues that Petitioner failed to show that Saikley met the “attached. .

.” limitation because Petitioner “fail[ed] to point to distinct components” for the sheaths and the gripping portions. We disagree.

There is no indication in the claims or the ’635 patent specification that would preclude the Saikley’s device from meeting the “attached” limitation. Nothing in the claims or the ’635 specification requires that the primary and secondary sheaths must be made of different materials than the gripping handle portion in order for the sheaths to be considered “attached” to the gripping handle portion. Nor is there any requirement that they be separate structures that must be connected or fastened to the gripping portion of the handle to meet the “attached” limitation. To the contrary, all of embodiments of the ’635 patent describe an integrally molded lancet and sterility cap that is formed as a single unit. *See* Ex. 1001, 6:18–23.

Like the ’635 patent, Saikley discloses an integrally molded lancet and protective cap. Ex. 1005 ¶ 50. Saikley’s Figure 7A, as annotated by Petitioner, is reproduced below.



The annotated figure shows the first end in purple, and the second end in magenta, the gripping handle in green, the primary sheath in red, and the secondary sheath in orange. Pet. 26–27. Petitioner identifies the primary

sheath (twist-off joint and adjoining area), the secondary sheath (pin cushion type area 82), and the gripping handle portion having first and second ends. Pet. 27–28 (citing Ex. 1005 ¶ 50; Ex. 1002 ¶¶ 83–85); *see also id.* at 8 (“[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.’” (citing Ex. 1004, 13:24–14:3”).

Saikley’s Figure 7A, reproduced above, shows the primary and secondary sheaths are located at opposing ends of the handling tab. Pet. 27. As Petitioner explains, “[b]oth sheaths are integrally molded to the protective cap so that they remain attached to the handling tab even after the user removes the puncture cap 78 from the lancet needle to collect a blood sample.” Pet. 27–28 (citing Ex. 1002 ¶ 84). Consistent with the disclosure of the ’632 patent, we find that the primary and secondary sheaths are attached to the first and second ends of the gripping handle portion notwithstanding that they are integrally formed.

We agree with Petitioner that something that is integrally molded as a single unit can have different sections that meet the structural limitations as recited in the claim. Based on Saikley’s disclosure of handling tab 78 with pin cushion type area 82 on one side and with the lancet 76 integrally molded on the other side of the handling tab 78 (Ex. 1005 ¶ 50; Figure 7A), we agree with Petitioner that Saikley discloses a primary sheath and secondary sheath located at opposite ends of the gripping handle portion.

- vi. *[6a] The protective sterility cap of claim 1, in combination with a lancet*
- vii. *[6b] having a lancet body defining a lancet thickness, and*
- viii. *[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) as required by element [6a]. Pet. 28–30, 36 (citing Ex. 1005 ¶¶ 37, 50, 65, Fig. 7A; Ex. 1002 ¶¶ 86–88). We agree. Petitioner also asserts that Saikley’s shortened lancet 76 has elongate body 48. *Id.* at 36 (citing Ex. 1005 ¶¶ 37, 41–42, 44, Figs. 6, 8; Ex. 1002 ¶ 100).

Patent Owner does not separately argue elements 6a–6c. *See* PO Resp. 5–47.

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

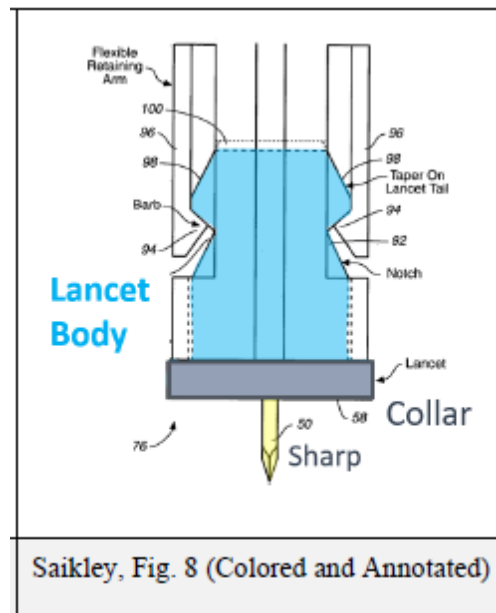


Figure 8 of Saikley, as annotated by Petitioner, depicts lancet body 48 (colored light blue) and lancet sharp 50 (colored yellow). *Id.* We find that Saikley’s lancet body—as a three-dimensional object—defines a thickness as required by claim element [6b]. Petitioner asserts that a person of ordinary 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.” Pet. 28–30, 37. In light of the evidence, we determine Petitioner has persuasively demonstrated that Saikley meets the requirements of claim element [6c].

ix. [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.

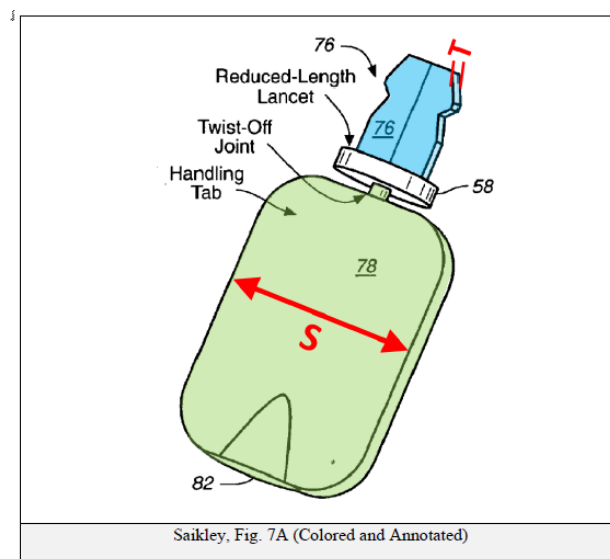


Figure 7A of Saikley, as annotated by Petitioner, depicts shortened lancet 76 with protective cap 78 and includes annotations identifying a lateral span with arrows and the letter “S” and a lancet thickness with lines and the letter “T.” Pet. 38 (citing Ex. 1002 ¶ 102). From this, Petitioner reasons that 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, which “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 meets the dimension limitation. PO Resp. 19. Patent Owner argues that Petitioner

“legally errs by relying on its own measurements and annotations of Saikley’s Figure 7A” because “Saikley is completely silent whether its figures are to scale, proportional, or in any way indicative of dimensions.” *Id.* at 19–20 (citing Ex. 2056 ¶¶ 68–71).

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 16 mm and a lancet with a diameter less than 6 mm. PO Resp. 21–24. Patent Owner asserts that “Saikley fails to expressly disclose any dimensions, much less the claimed ratios of the alleged gripping handle span to its length, the gripping handle span to the lancet body thickness, or the gripping handle length to the lancet body thickness.” *Id.* at 19.

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 contends that patent figures do not reasonably disclose or suggest dimensions, proportions, or relative sizes. PO Resp. 19 (citing *Hockerson-Halberstadt, Inc. v. Avia Group International*, 222 F.3d 951, 956 (Fed.Cir. 2000); *Source Vagabond Sys. Ltd. v. Hydrapak, Inc.*, 753 F.3d 1291, 1300 (Fed. Cir. 2014)). Patent Owner contends that one of ordinary skill in the art would have understood that in a perspective drawing of, for example, a cube, the thickness would depend on how far the figure is rotated. PO Resp. 21 (“[T]he size of T as drawn in the figure is a function of how far the lancet is rotated about a longitudinal axis.”); Ex. 2056 ¶ 79.

We understand that patent figures are not ordinarily drawn to scale, but are instead “merely illustrative of the principles embodied in the alleged invention.” *In re Olson*, 212 F.2d 590, 592 (C.C.P.A. 1954). The recent Director’s review decision in *Mahle* supports the position that figures can be relied on for what they clearly show. *Mahle Behr Charleston Inc. v. Catalano*, IPR2023-00861, Paper 15 at 7–9 (Vidal Apr. 5, 2024) (finding that the Board improperly discounted Figure 1 of a prior art reference because it did not disclose precise proportions, and remanding for consideration, taking expert testimony into account, of whether “Figure 1 of [the reference] is ‘clear on its face’ or would have reasonably suggested the placement of [the reference’s] sacrificial anode ‘within 10 inches’ of the hot air inlet”).

For a drawing alone to disclose a claim limitation, the limitation must be shown clearly. *See In re Wagner*, 63 F.2d 987, 987–88 (CCPA 1933) (“[T]he Board did not err in holding that the drawings are sufficient to afford a proper basis for the rejection” where “the shading in the drawing clearly indicates” the claimed feature.); *PlaSmart, Inc. v. Kappos*, 482 F. App’x 568, 572 (Fed. Cir. 2012) (“[D]rawings can be used as prior art, without referring to the surrounding description, only if the prior art features are clearly disclosed by the drawing.”); *see also In re Mraz*, 455 F.2d 1069, 1072 (CCPA 1972) (“[A]s we said . . . , ‘Patent drawings are not working drawings.’ However, we did not mean that things patent drawings show clearly are to be disregarded.” (citation omitted) (emphasis omitted)).

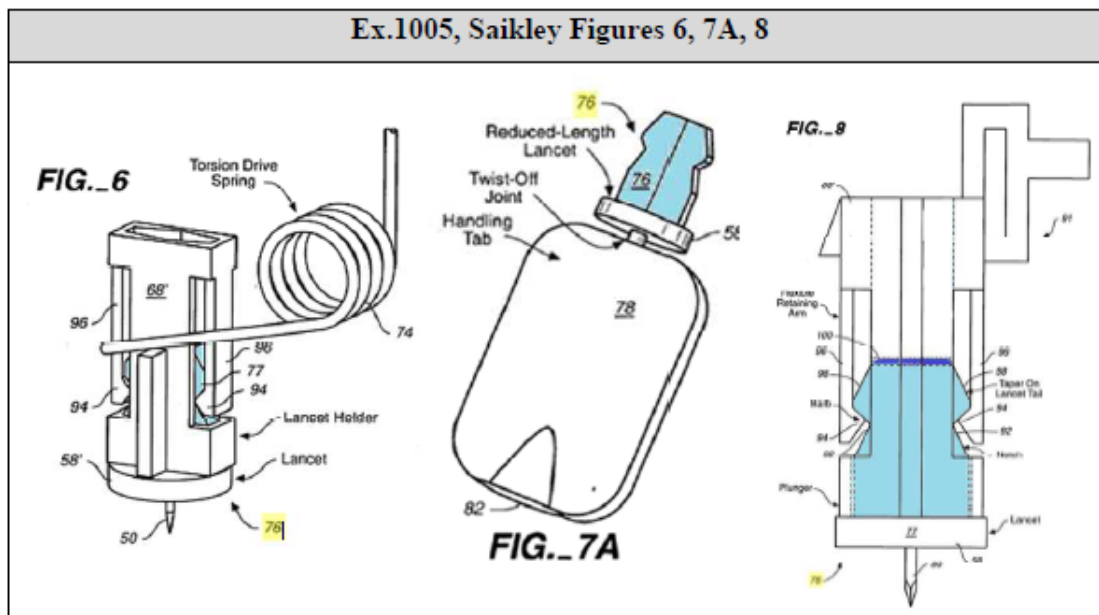
Analogously, for purposes of written description, where “a person of skill in the art could derive the claimed dimensions from the patent’s disclosure, there is no additional requirement that the specification must

explicitly disclose the precise proportions or particular sizes.” *Cummins-Allison Corp. v. SBM Co.*, 484 F. App’x 499, 507 (Fed. Cir. 2012).

We agree with Petitioner that the combination of Saikley’s specification and its drawings clearly indicate that the lateral span of the gripping handle of its device is at least 1.5 times the thickness of its lancet because: a) Saikley describes and depicts its lancet as flat, meaning it is wider than it is thick, b) Saikley depicts the diameter of its collar as substantially wider than the thickness of the lancet. c) Saikley depicts the lateral span of its gripping handle as wider than its collar.

a. Flat Lancet

With respect to the dimensions of the lancet, Saikley’s Figures 6, 7A, and 8 provide three different views, reproduced below, all depicting the same thin, flat lancet body.



Figures 6, 7A, and 8 as annotated by Petitioner are shown above. Each figure has the lancet body highlighted in blue. Reply 18. The “needle point” of the lancet is “about 3 mm” from “cylindrical collar 58.” Ex. 1005 ¶ 42;

Ex. 1034 ¶ 22; Ex. 1056, 81:7–9. Figure 6 shows that the entire lancet body is thin enough to fit inside lancet holder 68', which itself is much thinner than the diameter of the cylindrical collar 58 of the lancet. Reply 18; Pet. 37.

Saikley describes that the lancet body has a flat shape. Ex. 1005 ¶¶ 54 (“The flat shape of lancet body 66 allows for such alignment and prevents misalignment.”), 58 (“The body of lancet 89 should be flat or keyed to allow the lancet holding mechanism to keep sharp 50 oriented properly with the lancing axis.”); 60 (“Lancet body 77 is generally flat and has a notch 92 on each edge for receiving barbs 94 on the plunger’s flexible retaining arms 96.”). By describing the lancet as having a flat shape, Saikley teaches that the lancet body is wider than its thickness.¹⁵

b. Wide Lancet

That the lancet body is wider than its thickness is further supported visually in Saikley’s Figure 6, which shows the lancet seated in the lancet holder. *See* Ex. 1005, Figure 6 (shown above). The lancet holder in one direction reaches the outer diameter of the lancet collar 58'. *See* Ex. 1005, Figure 6 (shown above); Reply 18; Pet. 36–37. In the perpendicular direction, however, the lancet holder also accommodates a block for receiving the torsion drive spring all within the boundaries of the lancet collar 58'. *See* Ex. 1005, Figure 6 (shown above); Reply 18; Pet. 37–40. This establishes that the lancet body is not the same length in both directions; it is wider than it is thick (meaning the cross section of the lancet is not a square but a rectangle). *See* Reply 18 (arguing that “the lancet body is—just as it

¹⁵ Flat: “having a generally level shape or appearance; not deep or thick: *a flat plate*.” Ex. 3005 (definition #7 from dictionary.com).

appears—much thinner than the diameter of the lancet collar and also that the handling tab is many multiples the thickness of the lancet body.”). It also establishes that the collar is wider than the lancet is thick.

c. Lateral Span

That the lateral span of the cap 78 is more than 1.5 times the lancet thickness is further supported visually in Saikley’s Figure 7A (shown below) that shows that the lancet combined with the cap 78.

We credit the testimony of Mr. Delman 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. Figure 7A as annotated by Petitioner is reproduced below:

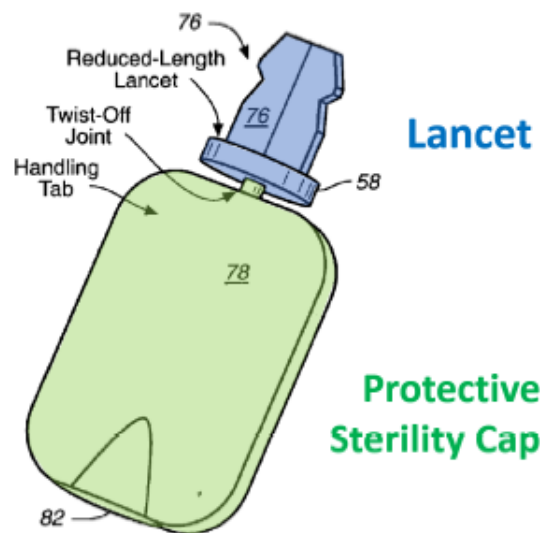


Figure 7A is a perspective view of a lancet and cap combination, showing the lancet in blue and the sterility cap in green. Pet. 10. Figure 7A of Saikley clearly shows that the lateral span of the gripping handle 78 is wider than collar 58. This is consistent with Saikley’s teaching that the cap 78 should be

made “much larger than usual to aid handling.” Ex. 1005 ¶ 50. Given that the lancet in Saikley’s Figure 7A is described as flat, the diameter of its collar in Saikley’s Figure 7A is substantially wider than the thickness of the lancet, and the lateral span of the gripping handle in Saikley’s Figure 7A is as wider than its collar, we find that Saikley’s disclosure clearly establishes that the lateral span of its gripping handle is 1.5x the thickness of its lancet. *See id.* ¶¶ 54, 58, 60; Ex. 2041. As explained above, this is also supported in the figures. We, therefore, agree with Petitioner’s expert that one of ordinary skill in the art would understand that Figure 7A of Saikley discloses a cap that falls within the claimed limitation. *See* Ex. 1002 ¶ 103.

Because the thickness of the lancet is less than the width of the lancet, we determine that Petitioner has persuasively demonstrated that Saikley’s Figure 7A discloses a sterility cap having a relative relationship between the thickness of the lancet and the span of the handle: “a lateral span of at least 1.5 times the lancet thickness.”

x. Summary

Having considered the arguments and evidence based on the full record, we determine that Petitioner has met its burden to prove by a preponderance of the evidence that claim 6 is unpatentable as anticipated.

2. Independent Claim 14

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; Ex. 1002 ¶ 112. Patent Owner does not argue any aspects of claim 14 distinct from claim 6. *See* PO Resp. 4–31. Having considered the arguments and evidence based on the full record, we determine that Petitioner has met its burden to prove by a preponderance of

the evidence that claim 14 is unpatentable as anticipated for the same reasons discussed above for claim 6.

3. *Dependent Claims 7, 8, 17, and 18*

Petitioner contends that claims 7 and 8, which depend from claim 6, and claims 17 and 18, which depend from claim 14, are anticipated by Saikley. Pet. 40–43; Reply 20–22. Claims 7 and 17 further recite “wherein the gripping handle portion defines a length at least equal to its lateral span” and claims 8 and 18 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, 10:18–23.

Patent Owner argues that Petitioner’s “proposed ‘length’ dimension is not the length of a gripping handle ‘between the primary sheath and secondary sheath,’ as required by the claims. Petitioner’s proposed length dimension is reflected in Petitioner’s annotations to Saikley’s Figure 7A. Saikley’s Figure 7A as annotated by Petitioner is shown below:



PO Resp. 31 (citing Pet. 27, 41, 43 & Fig. 7[A]) (annotations in Petition). The figure shows Saikley’s Figure 7A reproduced three times each with different annotations the gripping handle portion is highlighted in green an all three versions. In one of the annotated Figure 7A, Petitioner identifies

the length as extending the full length of the gripping handle portion. Petitioner's proposed length does not exclude the distance the sheaths extend into the handle gripping portion. Patent Owner also contends that Petitioner is not consistent with the claim mapping. PO Resp. 32 (arguing that Petitioner "cannot have it both ways including the sheaths in the alleged gripping handle length when needed (as here) and other times not including them (e.g., when attempting to show the gripping handle 'extending between' and 'attached' to the ends of sheaths)." Ex. 2056 ¶ 104.

For the reasons discussed above, with respect to claim element 1d, we find that the limitation of the handle extending between the primary and secondary sheath does not mean that the handle cannot also extend around the sheaths. *See* above § III.E.1v. We, therefore, agree with Petitioner that the length of the gripping handle portion should be measured from where the sharp enters the sheath, not where it terminates within the sheath. Reply 20–21. So measured, Figure 7A plainly discloses that the length of the gripping handle portion is at least equal to its lateral span and at least equal to the much-smaller thickness of the lancet. *Id*; *see also*, Pet. 40–43, Ex. 1002 ¶¶ 106–111; Ex. 1034 ¶¶ 32–34.

Having considered the arguments and evidence based on the full record, we determine that Petitioner has met its burden to prove by a preponderance of the evidence that claims 7, 8, 17, and 18 are unpatentable as anticipated.

4. Dependent Claim 16

Petitioner contends that claim 16, which depends from claim 14, is anticipated by Saikley. Pet. 44, 30–34; Reply 20–22. Claim 16 further recites

“comprising at least one flat display surface for placement of branding indicia thereon.” Ex. 1001, 10:15–17.

With reference to Saikley’s Figure 7A, Petitioner contends that “the handling tab includes broad, flat surfaces.” Pet. 31; Ex. 1005, Figure 7A. Petitioner contends that “[t]he remainder of the limitation — ‘for placement of branding indicia thereon’ — recites intended use and does not structurally limit the protective sterility cap recited in the claim’s body.” Pet. 31 (citing *Marrin v. Griffin*, 599 F.3d 1290, 1294 (Fed. Cir. 2010)).

Patent Owner does not address the limitations of claim 16 in the context of Saikley. *See generally* PO Resp; Sur-Reply.

We agree with Petitioner that the limitation “for placement of branding indicia thereon” is an intended use recitation and does not provide any structural limitation. Pet. 31 Our reviewing court has held that a statement of intended use in an apparatus claim cannot distinguish over a prior art apparatus that discloses all the recited structural limitations and is capable of performing the recited function. *See In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). We also note that “[a]n intended use or purpose usually will not limit the scope of the claim because such statements usually do no more than define a context in which the invention operates.” *See Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1345 (Fed. Cir. 2003). Although “[s]uch statements often . . . appear in the claim’s preamble,” a statement of intended use or purpose can appear elsewhere in a claim. *In re Stencel*, 828 F.2d 751, 754 (Fed. Cir. 1987).

In addition, we agree with Petitioner that Saikley’s flat surface on the handle would reasonably accommodate branding indicia thereon. Based on

the full record, we determine that Petitioner has met its burden to prove by a preponderance of the evidence that claim 16 is unpatentable as anticipated.

Having considered the arguments and evidence based on the full record, we determine that Petitioner has persuasively demonstrated that claim 16 are unpatentable as anticipated.

F. Remaining Grounds

As identified above (see *supra* § II.C), Petitioner presents several alternative grounds challenging claims 6–8, 14, and 16–18. Because of our determination that Petitioner establishes by a preponderance of the evidence that claims 6–8, 14, and 16–18 are anticipated by Saikley, we do not reach these alternate challenges to claims 6–8, 14, 16–18. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding that a petitioner “is entitled to a final written decision addressing all of the claims it has challenged”); *see also Boston Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App’x 984, 990 (Fed. Cir. 2020) (nonprecedential) (stating that the “Board need not address issues that are not necessary to the resolution of the proceeding,” such as “alternative arguments with respect to claims [the Board] found unpatentable on other grounds”).

G. Motions to Exclude

Because our Final Written Decision does not rely on Exhibits 2024, 2040, 2044, 2045, 2050, 2051, or paragraphs 137 through 151 of Exhibit 2056, Petitioner’s motion to exclude those exhibits is moot.

Because our Final Written Decision does not rely on Exhibits 1046 (Appendix F and certain portions of Ex. 1046 that reference Appendix F) and 1052, Patent Owner's motion to exclude those exhibits is moot.

H. Conclusion

For the reasons given, based on the arguments and evidence of record, Petitioner has met its burden to prove by a preponderance of the evidence that claims 6–8, 14, and 16–18 of the '635 patent are unpatentable under 35 U.S.C. § 102 as anticipated by Saikley.

The table below summarizes our conclusions:

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
6–8, 14, 16–18	102	Saikley	6–8, 14, 16–18	
6–8, 14, 16–18	103	Saikley, Stout ¹⁶		
16	103	Saikley, FreeStyle ¹⁷		
6–8, 14, 16–18	102	Ito ¹⁸		
6–8, 14, 16–18	103	Iio, Peckham ¹⁹		
16	103	Iio, FreeStyle ²⁰		
Overall Outcome			6–8, 14, 16–18	

¹⁶ As explained above, we do not reach this alternative ground.

¹⁷ As explained above, we do not reach this alternative ground.

¹⁸ As explained above, we do not reach this alternative ground.

¹⁹ As explained above, we do not reach this alternative ground.

²⁰ As explained above, we do not reach this alternative ground.

IV. ORDER

Accordingly, it is:

ORDERED that claims 6–8, 14, and 16–18 of the '635 patent are determined to be unpatentable;

FURTHER ORDERED that Petitioner's and Patent Owner's Motions to Exclude are dismissed as moot; and

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

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EXHIBIT B

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE OFFICE OF THE DEPUTY UNDER SECRETARY OF
COMMERCE FOR INTELLECTUAL PROPERTY AND DEPUTY
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK
OFFICE

LIFESCAN, INC.,
Petitioner,

v.

FACET TECHNOLOGIES, LLC,
Patent Owner.

IPR2023-00712
Patent 8,840,635 B2

Before DERRICK BRENT,¹ *Deputy Under Secretary of Commerce for
Intellectual Property and Deputy Director of the United States Patent and
Trademark Office.*

ORDER

¹ Katherine K. Vidal, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, delegated her authority in this case to Derrick Brent, Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office, under 37 C.F.R. § 42.75(f).

The Office received a request for Director Review of the Final Written Decision in the above-captioned case. *See* Paper 77; Ex. 3100. The request was referred to me.

Upon consideration of the request, it is:

ORDERED that the request for Director Review is denied.

IPR2023-00712
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