

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIFESCAN, INC.

Petitioner,

v.

FACET TECHNOLOGIES, LLC

Patent Owner.

Case No. IPR2023-00712

U.S. Patent No. 8,840,635

**PETITION FOR *INTER PARTES* REVIEW OF
ALL CLAIMS OF U.S. PATENT NO. 8,840,635**

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PETITIONER’S EXHIBIT LIST

<u>Exhibit</u>	<u>Description</u>
Ex. 1001	U.S. Patent No. 8,840,635 to Pusey et al. (the “’635 Patent”)
Ex. 1002	Declaration of Expert Joel Delman
Ex. 1003	File History of the ’635 Patent
Ex. 1004	Claim Construction Order for <i>Facet Technologies, LLC v. LifeScan, Inc.</i> , Case No. 2:22-cv-1717-MCS-MAR, Dkt. 122 (C.D. Cal. Jan. 20, 2023)
Ex. 1005	U.S. Patent Application Publication 2004/0138588 to Saikley (“Saikley”)
Ex. 1006	U.S. Patent Application Publication to Iio 2005/0131441 (“Iio”)
Ex. 1007	U.S. Patent No. 5,318,584 to Lange (“Lange”)
Ex. 1008	U.S. Patent No. 5,569,286 to Peckham et al. (“Peckham”)
Ex. 1009	U.S. Patent Application Publication 2005/0131440 (“Starnes”)
Ex. 1010	Wayback Declaration and Reference: FreeStyle Owner’s Booklet, TheraSense, Inc. (2004)
Ex. 1011	<i>Reserved</i>
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Ex. 1015	Therasense Trademark Registration and File History
Ex. 1016	U.S. Provisional Application No. 60/424,414 to Saikley (“Provisional to Saikley”)
Ex. 1017	U.S. Patent No. 6,283,982 to LeVaughn et al. (“LeVaughn”)
Ex. 1018	U.S. Patent Application Publication 2006/0241669 to Stout (“Stout”)
Ex. 1019	International Pub. No. WO 2007-089930A2 (“Lathrop”)
Ex. 1020	Wayback Declaration and Reference: One Touch

	Lancing Device User’s Instructions, Rev. 10/2006, LifeScan Inc., Milpitas California (2006)
Ex. 1021	U.S. Patent No. 4,994,068 to Hufnagle (“Hufnagle”)
Ex. 1022	Lengths, girths, and diameters of children’s fingers from 3 to 10 years of age, Annals of Anatomy (2010)
Ex. 1023	3-D Finite-Element Models of Human and Monkey Fingertips to Investigate the Mechanics of Tactile Sense, Journal of Biomechanical Engineering (2003)
Ex. 1024	CV of Joel Delman

I INTRODUCTION

Pursuant to 35 U.S.C. § 311 and 37 C.F.R. § 42.100, LifeScan, Inc. (“Petitioner”) requests *Inter Partes* Review (“IPR”) of claims 1-3, 5-8, 14, 16-18 (the “Challenged Claims”) of U.S. Patent No. 8,840,635 (the “’635 Patent”) assigned on its face to Facet Technologies, LLC (“Patent Owner”).

II MANDATORY NOTICES

A. Real Parties-in-Interest (37 C.F.R. § 42.8(b)(1))

The real parties-in-interest are Petitioner LifeScan, Inc. and Asahi Polyslider Company Ltd.

B. Related Matters (37 C.F.R. § 42.8(b)(2))

The ’635 Patent is presently the subject of a patent infringement lawsuit brought by Patent Owner against Petitioner captioned *Facet Technologies, LLC v. LifeScan, Inc.*, Case No. 2:22-cv-1717-MCS-MAR (C.D. Cal.) (the “Related Litigation”).

C. Counsel (37 C.F.R. § 42.8(b)(3)) and

D. Service Information (37 C.F.R. § 42.8(b)(3)-(4))

Petitioner designates Michael J. Lyons (Reg. No. 37,386) as lead counsel for this matter, and Alexander B. Stein (Reg. No. 71,397) and Gerald W. Griffin (*pro hac vice* pending) as back-up counsel for this matter.

Postal mailings and hand-deliveries for lead and back-up counsel should be addressed to: Morgan, Lewis & Bockius LLP, 1400 Page Mill Road, Palo Alto, CA, 94304 (Telephone: 650.843.4000; Fax: 650.843.4001).

Pursuant to 37 C.F.R. §42.8(b)(4), Petitioner consents to e-mail service at: LifeScanFacetIPRs@morganlewis.com.

Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney is filed concurrently herewith.

III CERTIFICATION AND FEES

Petitioner certifies that the '635 Patent is available for IPR and that Petitioner is not barred/estopped from requesting this IPR.

The required fees are submitted herewith in accordance with 37 C.F.R. §§ 42.103(a) and 42.15(a). Any additional fees for this IPR may be charged to Deposit Account No. 50,0310 (Order No. 010753-8001).

IV IDENTIFICATION OF CLAIMS AND GROUNDS

The '635 Patent issued from U.S. Patent Application No. 13/675,209 (the "'209 Application"), which was filed in the U.S. Patent Office ("Office") on November 13, 2012. The '209 Application claims priority to Provisional Application No. 61/084,456, filed on July 29, 2008. For purposes of this proceeding only, Petitioner treats July 29, 2008 as the priority date and effective

filing date (“Effective Filing Date,” which, because it is the earliest filing date, is treated as “the date of application for patent in the United States” per pre-AIA- 35 U.S.C. § 102(b)). Because this date is before March 16, 2013, the pre-AIA statute applies.

Petitioner relies on the following prior art references, none of which were considered by the Patent Office during prosecution of the ’635 Patent:

Saikley (Ex.1005): U.S. Patent Application Publication 2004/0138588 to Saikley (“Saikley”) published on **July 15, 2004**. Because Saikley’s publication date is **more than 4 years before** the Effective Filing Date, Saikley qualifies as prior art under pre-AIA § **102(b)**.

FreeStyle (Ex.1010): The FreeStyle Blood Glucose Monitoring System Owner’s Booklet (“FreeStyle”) is a printed publication published by TheraSense, Inc. *See* Ex.1010, 3 (“© 2004 TheraSense, Inc. Printed in U.S.A.”); *see also LG Elec., Inc. v. Advanced Micro Devices, Inc.*, IPR2015-00329, Paper 13 at 12 (PTAB July 10, 2015) (copyright date is *prima facie* evidence of publication). The Internet Archive’s Wayback Machine service also archived and preserved a copy of the booklet as it existed on October 23, 2007. *See* Ex.1010, 2. This evidence confirms that FreeStyle was disseminated before the Effective Filing Date. FreeStyle therefore qualifies as prior art under pre-AIA § **102(a)**.

Iio (Ex.1006): U.S. Patent Application Publication 2005/0131441 to Iio (“Iio”) published on **June 16, 2005**. Because Iio’s publication date is more than **3 years before** the Effective Filing Date, Iio qualifies as prior art under pre-AIA § **102(b)**.

Peckham (Ex.1008): U.S. Patent No. 5,569,286 to Peckham et al. (“Peckham”) filed on **March 29, 1995** and issued on **October 29, 1996**. Because Peckham’s issue date is **more than 11 years before** the Effective Filing Date, Peckham qualifies as prior art under pre-AIA § **102(b)**.

Stout (Ex.1018): U.S. Patent Application Publication 2006/0241669 to Stout (“Stout”) published on **October 26, 2006**. Because Stout’s publication date is more than **1 year before** the Effective Filing Date, Stout qualifies as prior art under pre-AIA § **102(b)**.

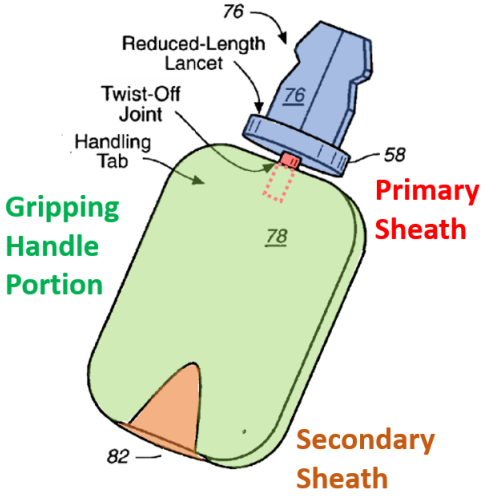
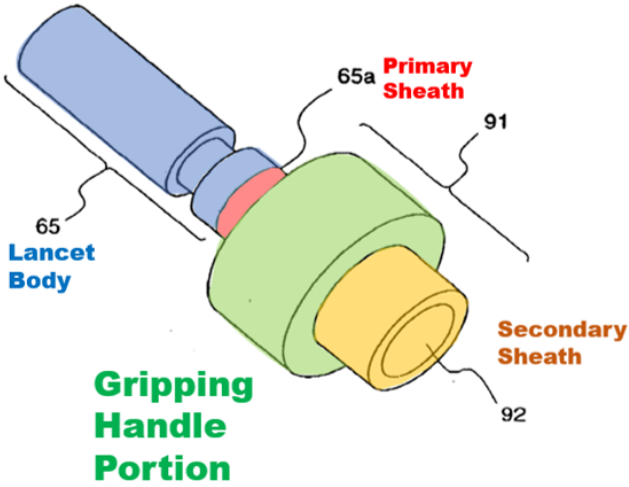
Petitioner requests that the Board find each of the Challenged Claims unpatentable based on the following Grounds:

Ground	Prior Art	Statutory Basis	Claims
1	Saikley	§ 102	1-3, 5-8, 14, and 16-18
2	Saikley and Stout	§ 103	1-3, 5-8, 14, and 16-18
3	Saikley and FreeStyle	§ 103	3 and 16
4	Iio	§ 102	1-3, 5-8, 14, and 16-18
5	Iio and Peckham	§ 103	1-3, 5-8, 14, and 16-18
6	Iio and FreeStyle	§ 103	3 and 16

V DISCRETIONARY DENIAL WOULD BE INAPPROPRIATE

The references cited herein were not considered during prosecution of the application that led to the '635 Patent, so a discretionary denial under 325(d) for rehashing arguments already made during prosecution would be inappropriate.

Additionally, to the extent that Patent Owner attempts to argue that the new references raised herein are cumulative to something cited during prosecution, such an argument fails. Applicants secured allowance during prosecution based on an argument that a cited reference failed to disclose “a secondary sheath” and that, even if the reference had a secondary sheath, then “there is no intermediate ‘handle portion’ to which each [of the primary and secondary sheath] are attached when the cap is removed.” Ex.1003, 52. Each of the two primary references asserted herein—Saikley (Ex.1005) and Ilo (Ex.1006)—discloses a protective sterility cap for a lancet comprising a primary sheath, secondary sheath, and a gripping handle portion extending therebetween. *See infra* Sections VIII.A., XI.A.,

 Diagram of a medical device (Ex.1005, FIG.7a) showing a reduced-length lancet (76) attached to a primary sheath (58) via a twist-off joint. The device includes a gripping handle portion (78) and a secondary sheath (82). A handling tab is also indicated.	 Diagram of a medical device (Ex.1006, FIG.8) showing a lancet body (65) attached to a primary sheath (65a) via a twist-off joint. The device includes a gripping handle portion (91) and a secondary sheath (92).
Ex.1005, FIG.7a (Annotated)	Ex.1006, FIG.8 (Annotated)

Thus, at a minimum, the prior art relied on in this petition plainly teaches the features that the Patent Owner said were missing from the prior art before the Examiner.

Furthermore, as to 314(a), a discretionary denial under that provision would be inappropriate. Pursuant to the Director’s guidance that “the **PTAB will not discretionarily deny institution** in view of parallel district court litigation **where petition presents a stipulation** not to pursue in a parallel proceeding the same grounds or any grounds that could have reasonably been raised” (Memorandum on “Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with

Parallel District Court Litigation” issued on June 21, 2022), Petitioner has provided such a stipulation (Ex.1013).

The Board’s resources will be well used in considering the new references identified and any potential duplication of invalidity arguments in parallel proceedings is eliminated by the stipulation filed herewith.

VI LEVEL OF ORDINARY SKILL

A person of ordinary skill in the art (“PHOSITA”) 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. Additional advanced educational degrees could substitute for some years of experience, and, likewise, additional industry experience could substitute for educational degrees as well. Ex.1002, ¶¶32-34.

A PHOSITA would have also been familiar with the principles that the ’650 patent admits as being part of the general knowledge of the art, including, but not limited to: (A) lancets comprising (i) “a plastic body” molded around “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,” and (ii) a

“plastic cap” integrally-molded to the plastic body such that “the sharp tip of the lancet is commonly embedded in a removable plastic cap to maintain sterility and prevent inadvertent sticks prior to use;” and (B) “[t]he endcap may be replaceable onto the lancet after use to re-cover the sharp lancet tip for safety and hygienic purposes.” Ex.1001, 1:38-57; Ex.1002, ¶¶ 35-36.

VII CLAIM CONSTRUCTION

The 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.” Ex.1004, 13:24-14:3. For other terms (including “gripping handle portion,” “lancet thickness,” “lateral span,” and “length”), the district court determined no construction was needed, *i.e.*, plain and ordinary meaning controls. *Id.*, 28:22-29:5.

Petitioner 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. For purposes of resolving the unpatentability issues raised in this Petition, Petitioner does not believe that any other terms need to be construed.

VIII GROUND #1: SAIKLEY ANTICIPATES CLAIMS 1-3, 5-8, 14, AND 16-18¹

A. Claim 1 Is Anticipated

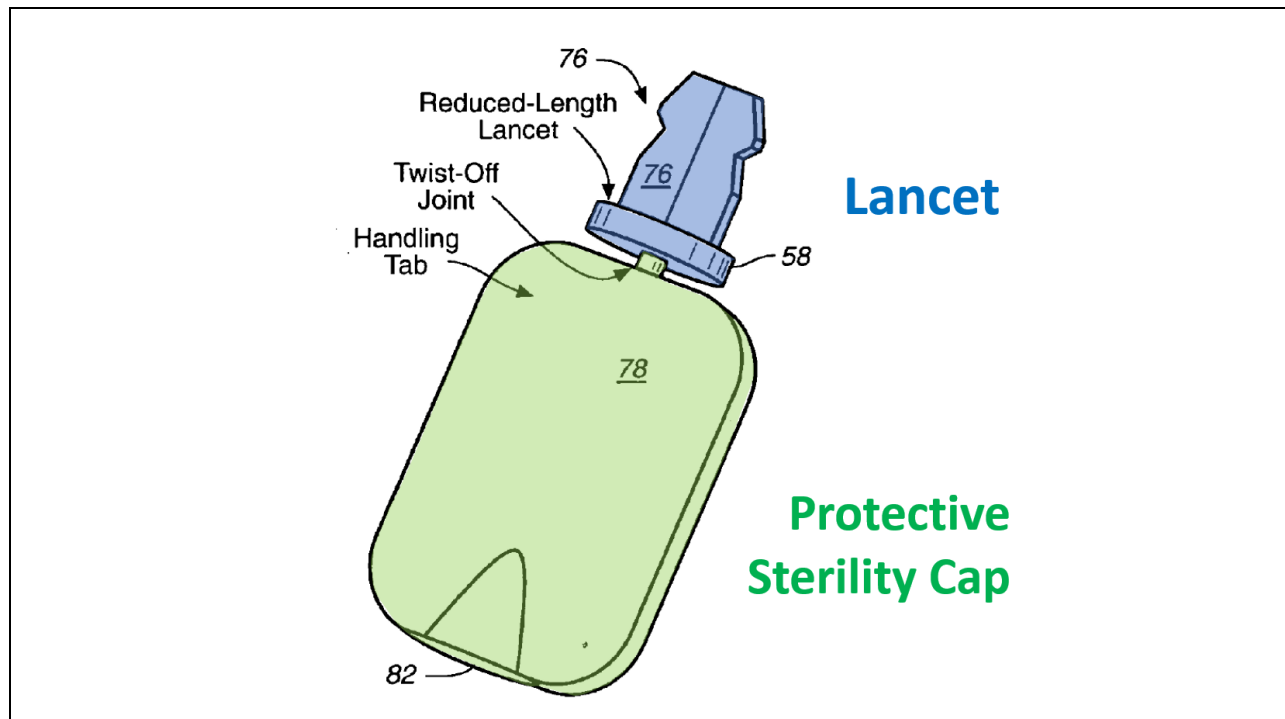
1. 1[pre] - “A protective sterility cap for a lancet”

The preamble is not limiting for two reasons. *First*, the body of independent Claim 1 is structurally complete and does not refer back to the preamble. *Second*, the preamble’s recitation of “for a lancet” recites an intended use and does not structurally limit the protective sterility cap recited in the claim’s body.

Should the Board find it limiting, Saikley discloses “a protective sterility cap for a lancet”—namely, the “protective cap 78” for the “shortened lancet 76,” as shown in annotated Figure 7a below (the “Fig. 7a Embodiment”).

FIG. 7a of Saikley

¹ While Ground 1 relies on the embodiment shown in Fig. 7a, “a reference can anticipate a claim even if it d[oes] not expressly spell out all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would ‘at once envisage’ the claimed arrangement or combination.” *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381-83 (Fed. Cir. 2015); *Hayward Indus. v. Pentair*, 2020 WL 3124259, at *2 (Fed. Cir. 2020) (“prior art references should be considered for all that they teach, rather than being limited to a particular embodiment or the claimed invention of the prior art.”).

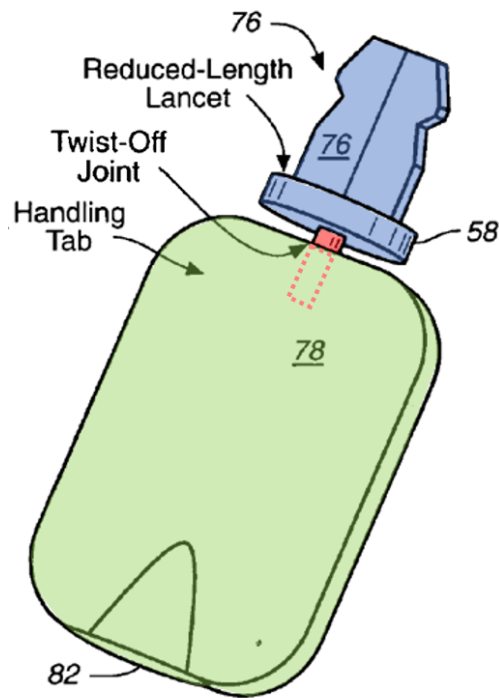


Ex.1005, [0013] (“Figure 7a is a perspective view of a first embodiment of an inventive lancet and cap combination”). To maintain the sterility of the sharp lancing tip projecting from the lancet body, *i.e.*, “lancet sharp 50,” before it is used to puncture the patient’s skin, Saikley teaches that the “cap 78 may be an integrally molded, pull-off tab, such as shown in FIG. 7A.” *Id.*, [0050].

Saikley thus discloses “a protective sterility cap [*i.e.*, protective cap 78] for a lancet [*i.e.*, shortened lancet 76].” Ex.1002, ¶¶52-57.

2. Claim 1[a]—“a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein”

Saikley’s protective cap 78 includes a primary sheath—namely, the “twist off joint” [*colored red in Fig. 7a below*] and the adjoining portion of the “handling tab” [*red dashed lines*] that “covers the lancet sharp 50” of the “shortened lancet 76” [*blue*] prior to use. Ex.1005, ¶¶[0037], [0050-52], [0065]; Ex.1002, ¶58..



Ex.1005, FIG. 7a (Colored and Annotated with Broken Lines)

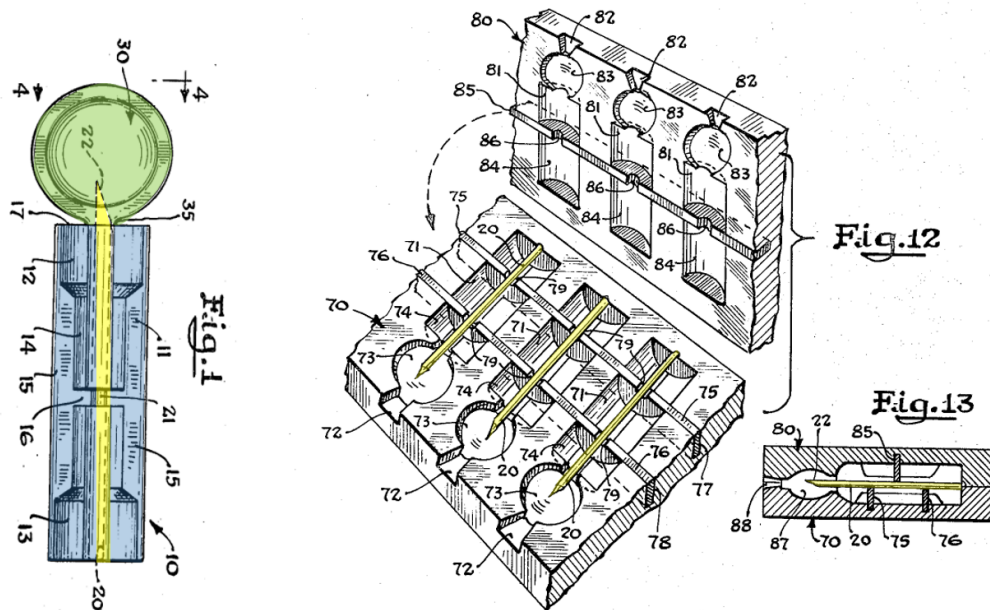
While Saikley does not use the term “embedment,” an anticipatory prior art reference “need not disclose the elements in the *very same terms* used by the

[’635] patent.” *Adasa Inc. v. Avery Dennison Corporation*, 55 F.4th 900, 912-13 (Fed. Cir. 2022) (“district court erred in interpreting these linguistic differences as fatal to a finding of anticipation,” noting that “[t]he invention is not the language of the [claim] but the subject matter thereby defined.”); *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009) (“[An anticipatory prior art] reference need not satisfy an *ipsissimis verbis test*.”).

First, Saikley depicts the removable protective cap 78 of lancet 76 as an “**integrally molded** pull-off tab 78,” and a PHOSITA would understand these disclosures to indicate that the “the needle tip [from the lancet body] is **embedded** in [handling tab portion of the] removable protective cap” because “it [is] integrally molded with the plastic body to form a single integral unit prior to use.” Ex.1005, [0050]; Ex.1002, ¶¶59-60 (citing Ex.1009, [0008]). A PHOSITA would understand the “integrally molded pull-off tab” described by Saikley was likewise molded around the the needle tip in a “state where it is **embedded** in the puncture needle cap,” as shown in the exemplary reference below. *Id.*; *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1327-31 (Fed. Cir. 2001) (relying on extrinsic evidence to find that the words “Call Detail Record” in prior art reference disclosed claim element). A PHOSITA 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 because Saikley describes the cap as an “**integrally molded**, pull-off tab” and teaches that it must be “**twisted**” (not pulled) off the lancet body to avoid bending or damaging the lancet. Ex.1002, ¶60 (citing Ex.1019, [00027]).

“Integrally-Molded” Cap as Undstood by a PHOSITA



Ex.1014 (“Higgins”), Figs.1, 12-13 (Colored)

Second, the '635 Patent admits that the “sharp tip of [a conventional] lancet is commonly **embedded** in a removable plastic cap to maintain sterility and

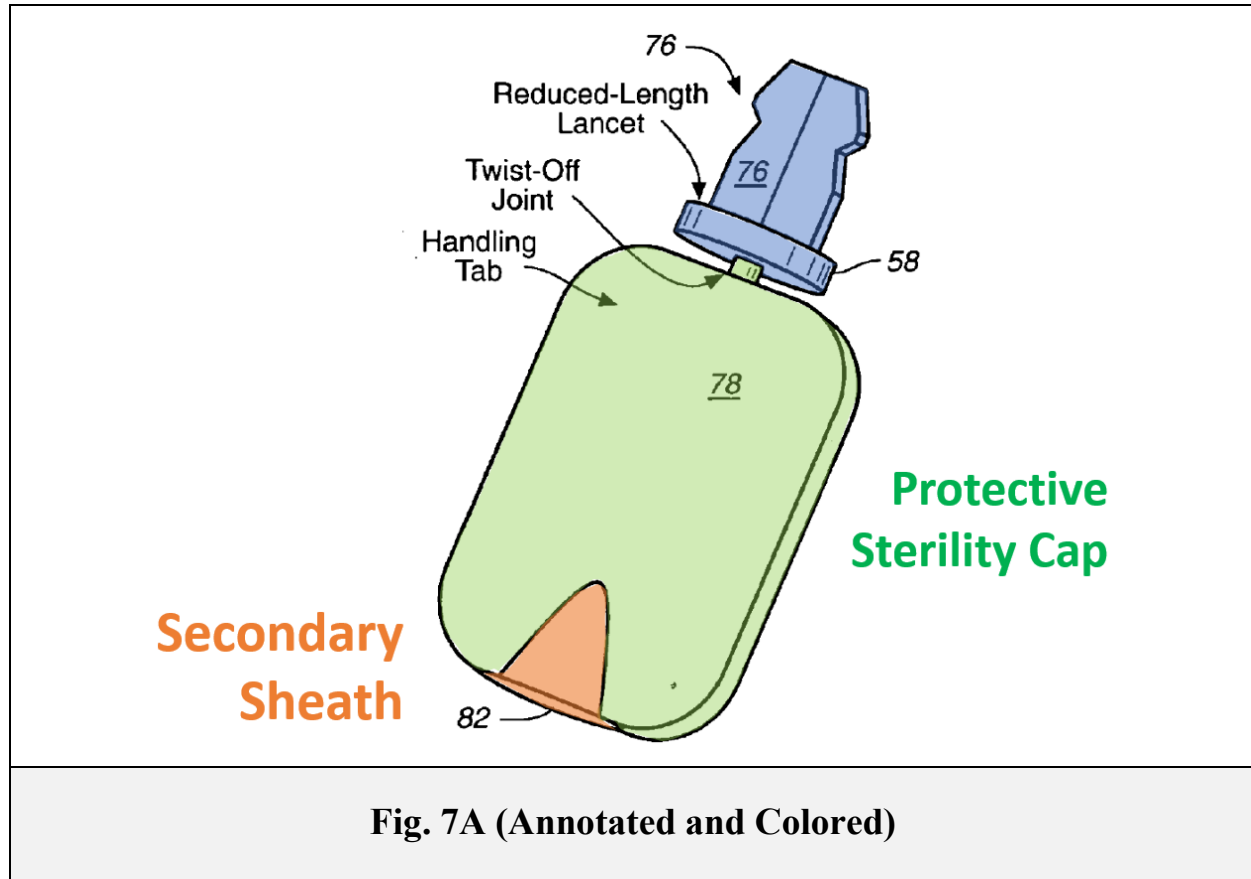
prevent inadvertent sticks prior to use,” and even describes the “primary sheath” as the “flange or ring at one **end of the sterility cap 510**, which abuts, confronts or interfaces with the front end of the lancet body in the lancet’s original, unused State” and “is **integrally molded** with the lancet body.” Ex.1001, 1:47-50, 6:18-24. So too for Higgins (Ex.1014), Starnes (Ex.1009), and other prior art cited on the face of the ’635 Patent—all of which use “integrally-molded” to describe a protective cap injection-molded to and formed around the lancet body and exposed needle tip, such that “the needle tip [is] embedded in a removable protective cap integrally molded with the plastic body to form a single integral unit prior to use.” Ex.1009, [0008]; Ex. 1002, ¶ 62

Saikley therefore discloses that the “sterility cap [*i.e.*, protective cap 78] compris[es] a primary sheath [*i.e.*, twist-off joint and] for initial embedment of a sharp lancing tip of an unused lancet therein [*i.e.*, needle point 50 of lancet 76]” Ex.1002, ¶¶63-65.

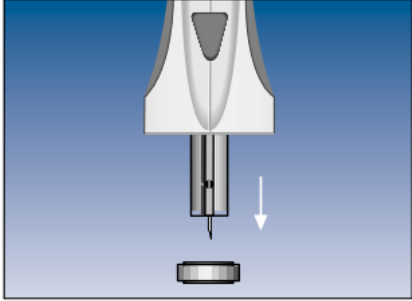
3. Claim 1[b] – “a secondary sheath for receiving the sharp lancing tip of a used lancet”

To safely handle the lancet after collecting a blood sample, Saikley’s protective cap 78 also includes “[a] hollow cup or solid ‘pin cushion’ type area 82

at the opposite end of cap 78, as shown in FIG. 7A [*orange below*], to cover the sharp during *removal* from the [lancing] device and *disposal*.” Ex.1005, ¶[0050].

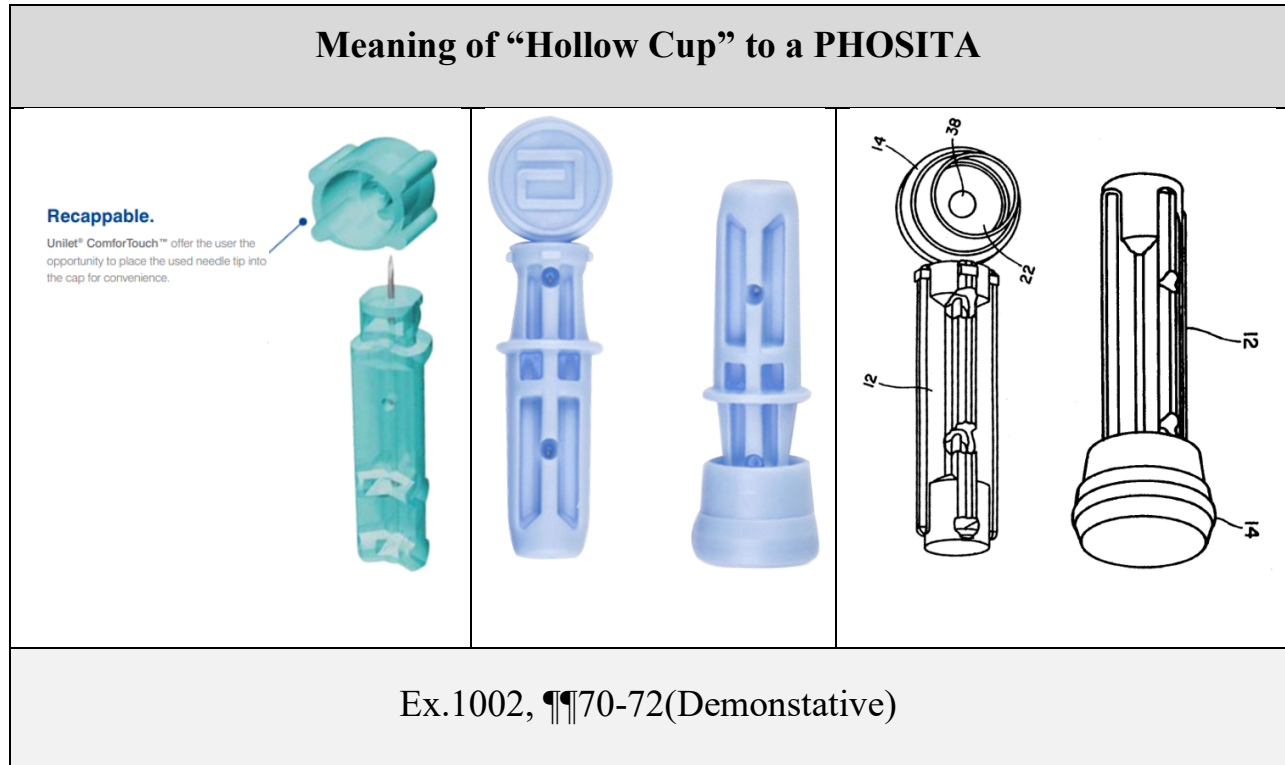


Saikley teaches that “solid ‘pin-cushion’ type areas”—like the one at the end of protective cap 78—“can be used for receiving [the] sharp *after use* and *prior to disposal*.” Ex.1005, [0052]. A PHOSITA would understand to push lancet sharp 50 into the “pin-cushion type area 82” of the protective cap 78, like pushing a needle into a pin cushion. Ex.1005, [0050-0052], [0064]; Ex.1002, ¶¶66-69.

Meaning of “Solid Pin-Cushion Style Area” to a PHOSITA	
	<i>Optional:</i> To replace the protective disk on the lancet, place the disk on a hard surface and push the exposed tip into the protective disk. 
Ex.1002, ¶¶66-69 (Demonstrative)	

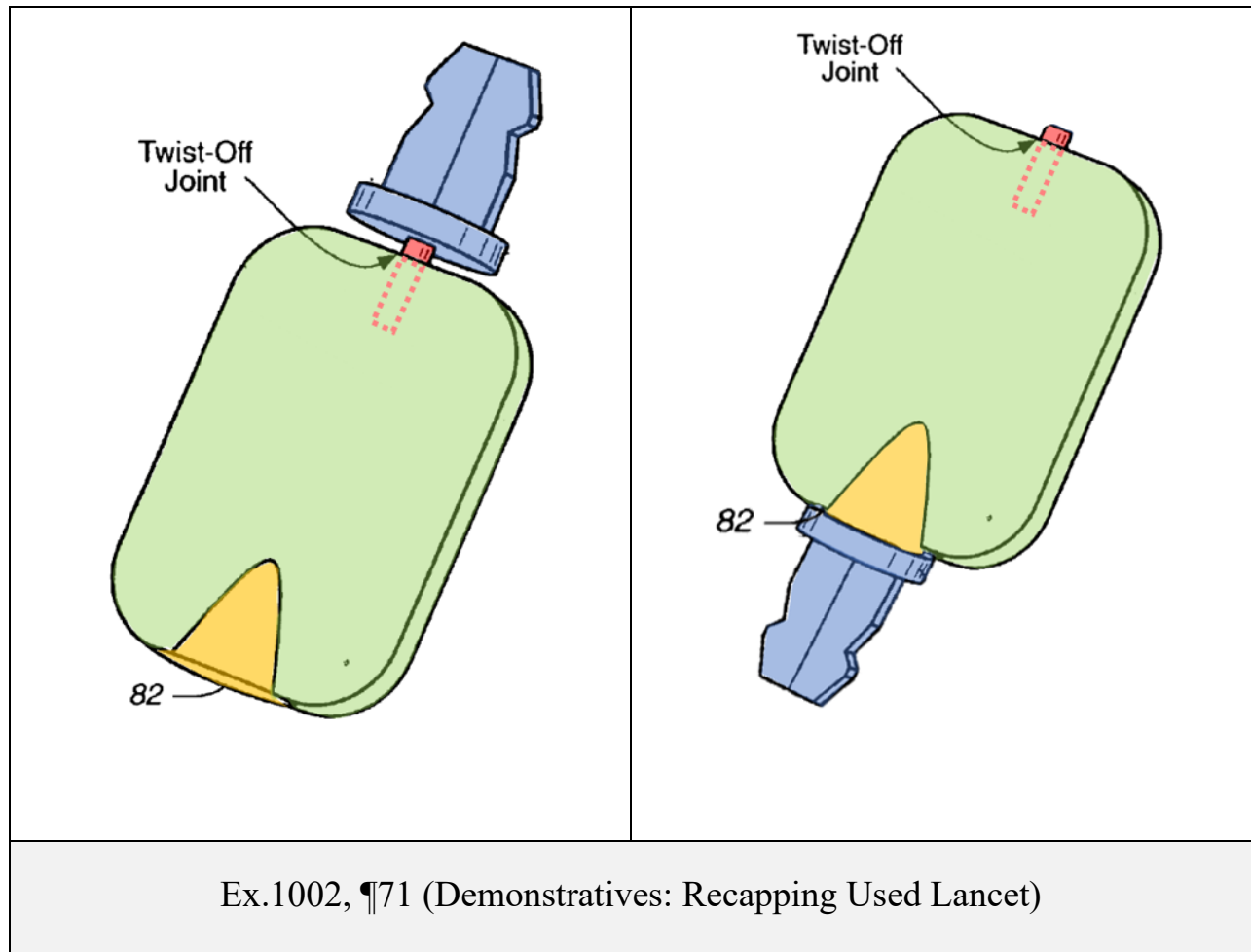
To prevent inadvertent needle sticks, the used lancet may also be encased within the hollow cup while the user finishes testing the blood sample and even after the lancet has been discarded. Ex. 1002, ¶70. For this reason, a PHOSITA would have understood that the “hollow cup” of Saikley’s protective cup 78 can also “be used for **receiving** [the] sharp *after use* and *prior to disposal*.” *Wilson v. Martin*, 2019 WL 5304173, at *7 (Fed. Cir. 2019) (“The purpose of extrinsic evidence in an anticipation analysis ‘is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill gaps in

the reference.”); *Monsanto Tech. LLC v. E.I. DuPont de Nemours & Co.*, 878 F.3d 1336, 1345 (Fed. Cir. 2018) (same).



The hollow cup and solid pin-cushion type area 82 are designed for “receiving” a used lancet because the sharp lancing tip is enclosed in the former and embedded in the latter. Ex.1002, ¶71. This is consistent with the meaning of the claim term “a secondary sheath for receiving,” which the district court broadly construed to mean “a secondary sheath for covering the sharp lancing tip of a used lancet by *embedding* or *enclosing* the lancet tip.” Ex.1004, 13:24-14:3. Like Saikley, the ‘635 Patent uses “receiving” to describe both a lancet needle

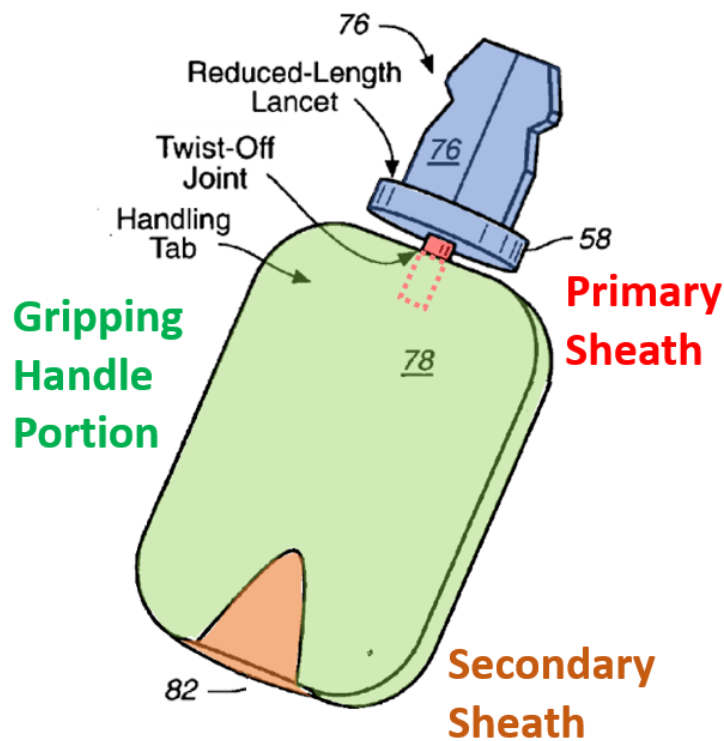
“enclosed” within a “hollow cup” and one that is “embedded” within a “flat panel.” Ex.1001, 6:1-5, 7:6-10; *compare* Ex.1001, Figs. 5A-5D with Figs. 6A-6D.



For these reasons, Saikley discloses “a secondary sheath (*i.e.*, hollow cup or pin-cushion type area 82) for receiving the sharp lancing tip of a used lancet [*i.e.*, for receiving the sharp 50 of the shortened lancet 76 after it has been used to collect a blood sample]. Ex.1002, ¶¶66-72.

4. Claim 1[c] - “and a gripping handle portion extending between the primary sheath and the secondary sheath”

Saikley’s protective cap 78 includes a “handling tab” (*colored green below*) extending between the primary sheath—i.e., the “twist-off joint” (*colored red below*) and adjoining portion of the protective cap (*dashed red below*)—and the secondary sheath—i.e. the “hollow cup or solid pin-cushion style area 82” (*orange*).



Ex.1005, FIG. 7A (Colored and Annotated)

Recognizing that many diabetics have trouble “seeing and collecting” a blood sample or “juggling all of the different pieces during a test,” Saikley incorporates a “**handling** tab” in the protective cap 78 to provide “a large lancet cap for **handling**” (*i.e.*, gripping). Ex.1005, [0049]. This is consistent with the plain and ordinary meaning of “gripping handle portion,” which the district court considered the “handle” portion of the claimed sterility cap because “[t]he Court does not make much of the modifier ‘gripping’ and finds the term merely restates the purpose of the handle.” Ex.1004, 17:12-13. Per the Court, “all handles are ‘gripping handles.’” *Id.* The ’635 Patent refers to a “handle or grip” interchangeably and describes a “handle” or “handle portion of the cap.” Ex.1001, 1:66-2:3, 6:5-9, 7:6-12, 8:17-22; Ex.1002, ¶¶73-74.

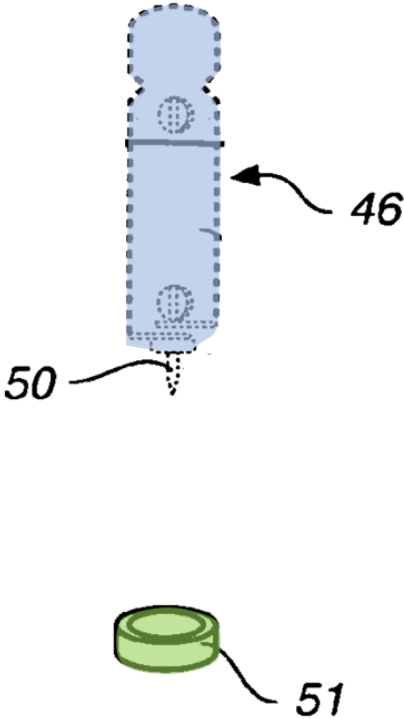
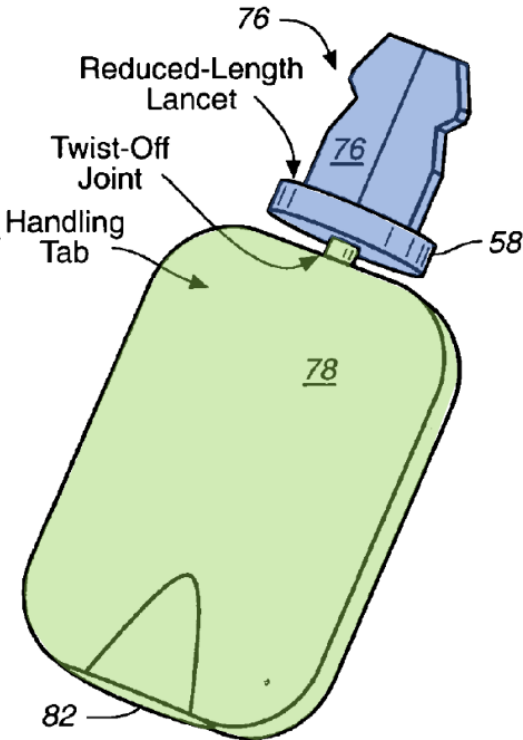
Like the ’635 Patent, Saikley recognizes that “[t]raditional disposable lancets, such as shown in **FIG. 3**, have an elongated body 48 [*blue below*] and a short cap 51 [*green*],” which “may make it difficult for the user to handle and install”—especially “elderly patients and those with reduced eyesight and dexterity.” *Compare* Ex.1005, ¶¶ [0004], [0050] *with* Ex.1001, 7:26-33. This is because users need to grip the lancet by the cap when inserting it into the lancing

device, and also need to remove the cap from the lancet prior to use and then re-insert it back into the cap after use. *Id.*

To address this problem, Saikley teaches that “the protective cap 78 (that is removed before use) should be made **much larger** than usual to **aid handling**.” *Compare* Ex.1005, ¶¶ [0004], [0050] *with* Ex.1001, 6:66-7:3 (“[T]he expanded dimensions of the endcap allow for easier use by persons with limited dexterity and vision”); 7:26-33 (“[T]he larger surface area provided by the protective/sterility cap, as compared to previously known designs, makes it easier to locate, especially for users with reduced visual acuity; and renders it easier to pick up off of a flat surface or out of a container, which is particularly advantageous for users with reduced manual dexterity.”); Ex.1002, ¶¶75-76.

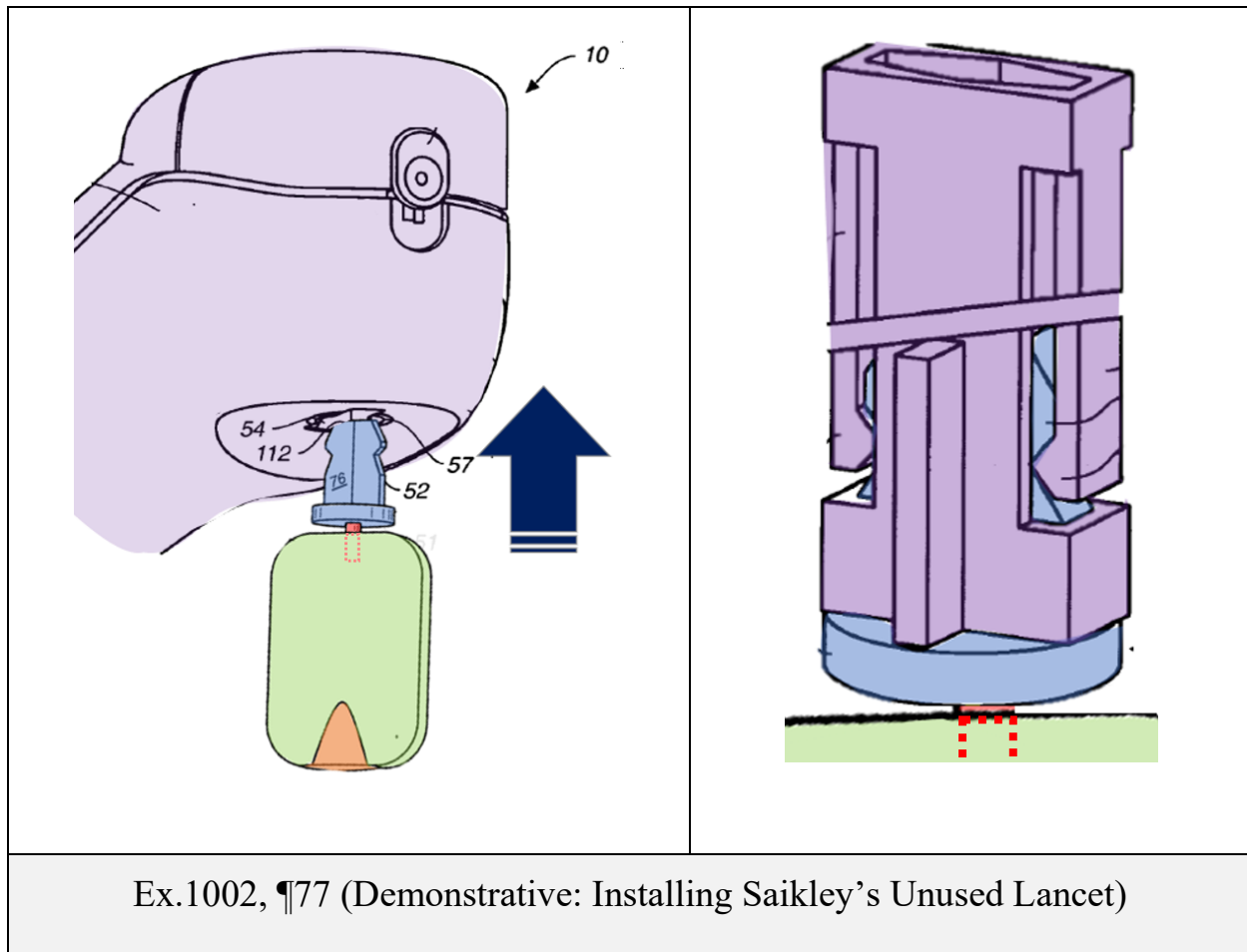
Saikley improved the prior art cap that was difficult to handle (see Fig. 3 below) by adding a large handling tab (see Fig. 7a below):

Traditional Disposable Lancets	Saikley’s Improved Lancet
---------------------------------------	----------------------------------

	
Ex.1005, Fig. 3 (Colored and Showing Only the Lancet and Cap)	Ex.1005, Fig. 7A (Colored)

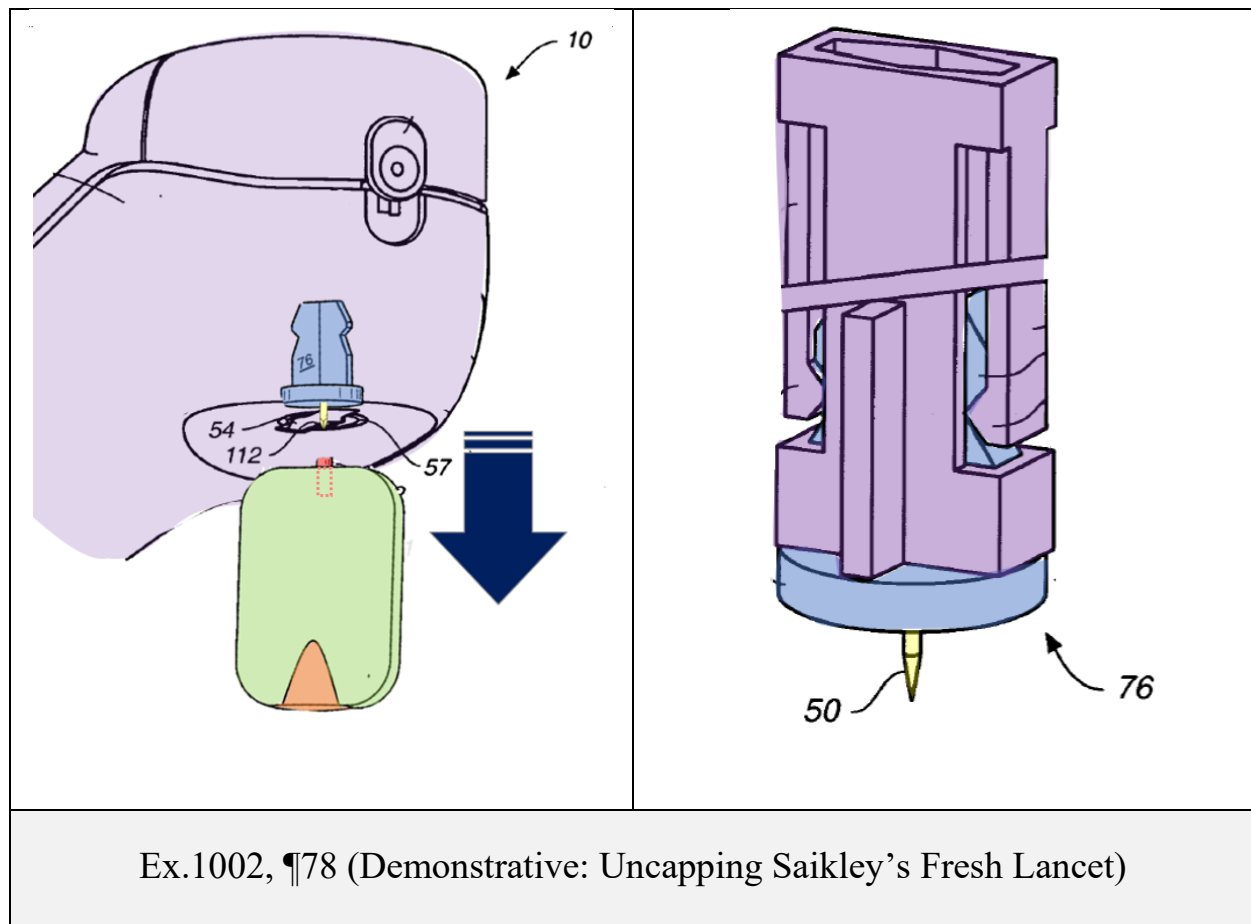
By extending the “much larger” “handling tab” between the primary sheath and secondary sheath, Saikley’s protective cap 78 provides the user with “a large protective cap for handling” the lancet prior to collecting a blood sample—or more specifically, when inserting a “fresh lancet into the lancet holder 68” of the lancing device 10. Ex. 1005, ¶¶ [0050], [0087] *with* Ex. 1001, 8:17-20 (“The user installs

the lancet into a corresponding lancing device by gripping the lancet system by the handle portion of the cap and inserting the back end of the lancet into the receiver of the lancing device.”); Ex.1002, ¶77. This installation is shown below:

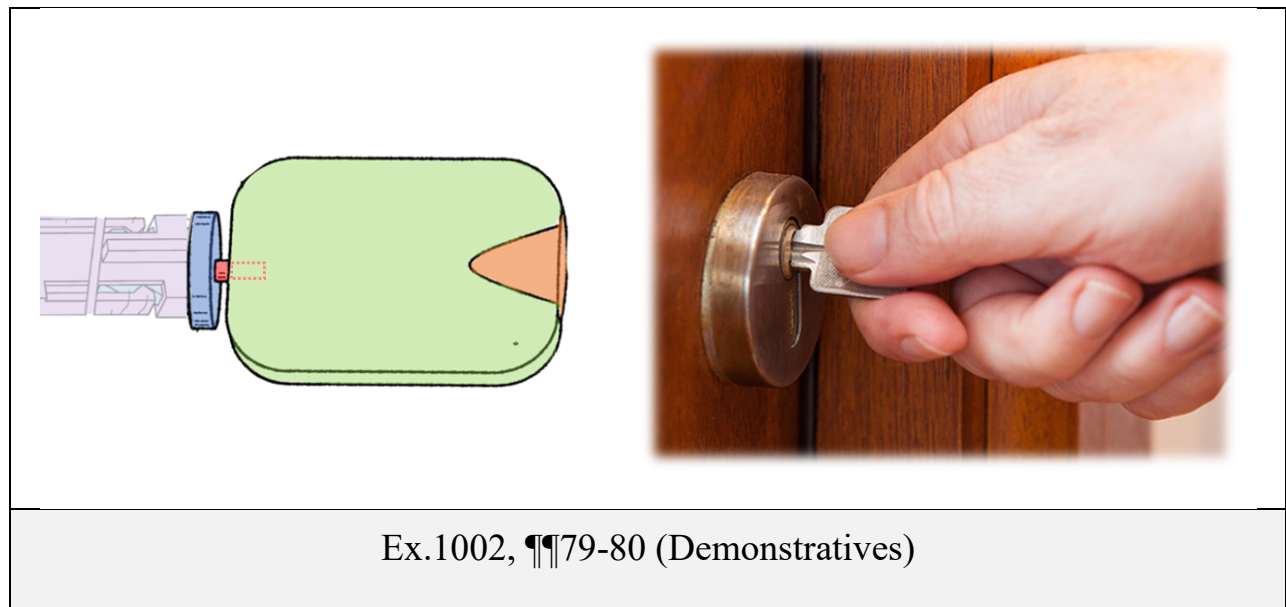


The wide “tab” forming the gripping handle portion of Saikley’s protective cap 78 provides the user with a firmer grip for removing the cap, making it easier to twist it off at its “twist-off joint” so that the lancet is not “damage[d]” or “pulled from

lancet holder 68” when the patient tries to uncap lancet 76. *Compare* Ex.1005, [0050-52], [0087] *with* Ex.1001, 6:1-10 (disclosing a “handle” for “assisting in removal of the cap from the lancet, and/or for replacement of the cap onto a used lancet for disposal.”); Ex. 1001, 53-55 (disclosing a “handle with a greater width” for “allowing the user to more easily twist the endcap during removal from the lancet.”); Ex.1002, ¶78.



The elongated handling tab (*green above*) remains protruding from the lancing device (*purple*) so the user can apply torque when twisting protective cap 78 from lancet 76 (*blue*). The flat surfaces of the handling tab allow the user to firmly grasp protective cap 78 with the thumb and index finger and exert pressure while twisting. Saikley's "much larger" "handling tab" functions like the head of a key left protruding after the blade is inserted into a lock, which provides torque when turning the key. Ex.1002, ¶79. Like a key, Saikley's handling tab provides a large flat surface for a firm grip while turning.



The "much larger" handling tab of Saikley's protective cap 78 provides leverage for applying rotational force to effectively twist the cap, making it easier to remove

protective cap 78 from lancet 76. Ex.1002, ¶80. A PHOSITA would appreciate the increased leverage provided by the handling tab accommodates patients with limited dexterity by spreading the applied force across a wider contact area. *Id.*

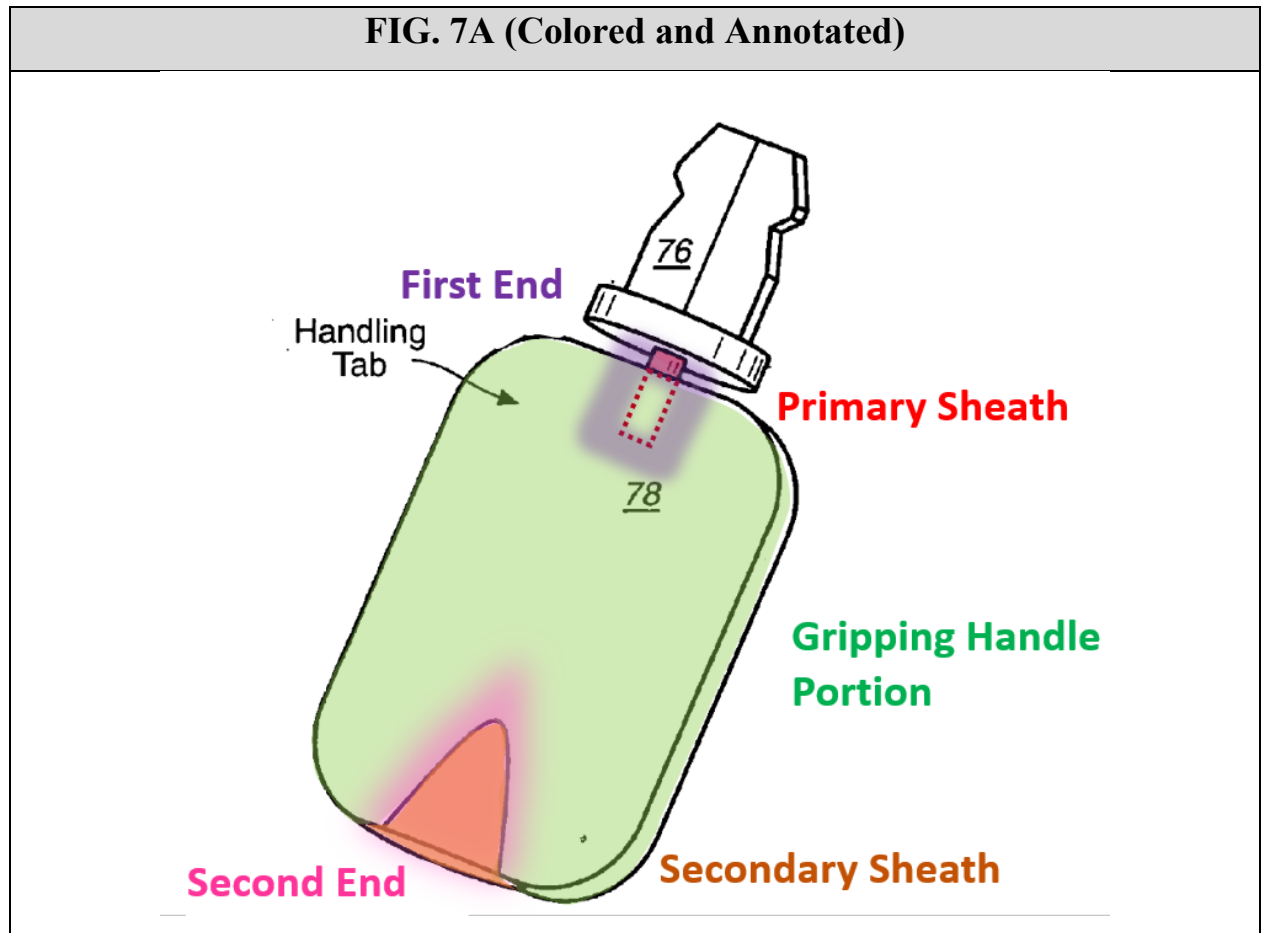
The “much larger” handling tab of Saikley’s protective cap 78 also allows the users to grip the lancet further away from the needle sharp, which helps “eliminate the likelihood of the user accidentally sticking himself on the lancet sharp 50 while uncapping the lancet” or while “cover[ing] the sharp during removal from the device.” *Compare* Ex.1005, ¶¶[0050-52],[0064] *with* Ex. 1001, 6:61-66.

Saikley therefore discloses “a gripping handle portion [i.e., handling tab] extending between the primary sheath [i.e., twist-off joint] and the secondary sheath” [i.e., hollow cup or pin-cushion type area 82].” Ex.1002, ¶¶73-82.

5. Claim 1[d] - “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”

Saikley shows the primary and secondary sheaths attached to opposing ends of the handling tab (*i.e.*, gripping handle portion) of the protective cap 78. Ex. 1005, FIG. 7A. Specifically, the primary sheath is attached at one end of the

gripping handle (*i.e.*, a first end, colored purple below) and the secondary sheath is attached at the other end of the gripping handle (*i.e.*, a second end, colored magenta), as illustrated in Figure 7A below.



The primary and secondary sheaths are attached at opposing ends of the handling tab “when the protective sterility cap is removed from the lancet” and at all other times. Both sheaths are integrally molded to the protective cap so that they remain

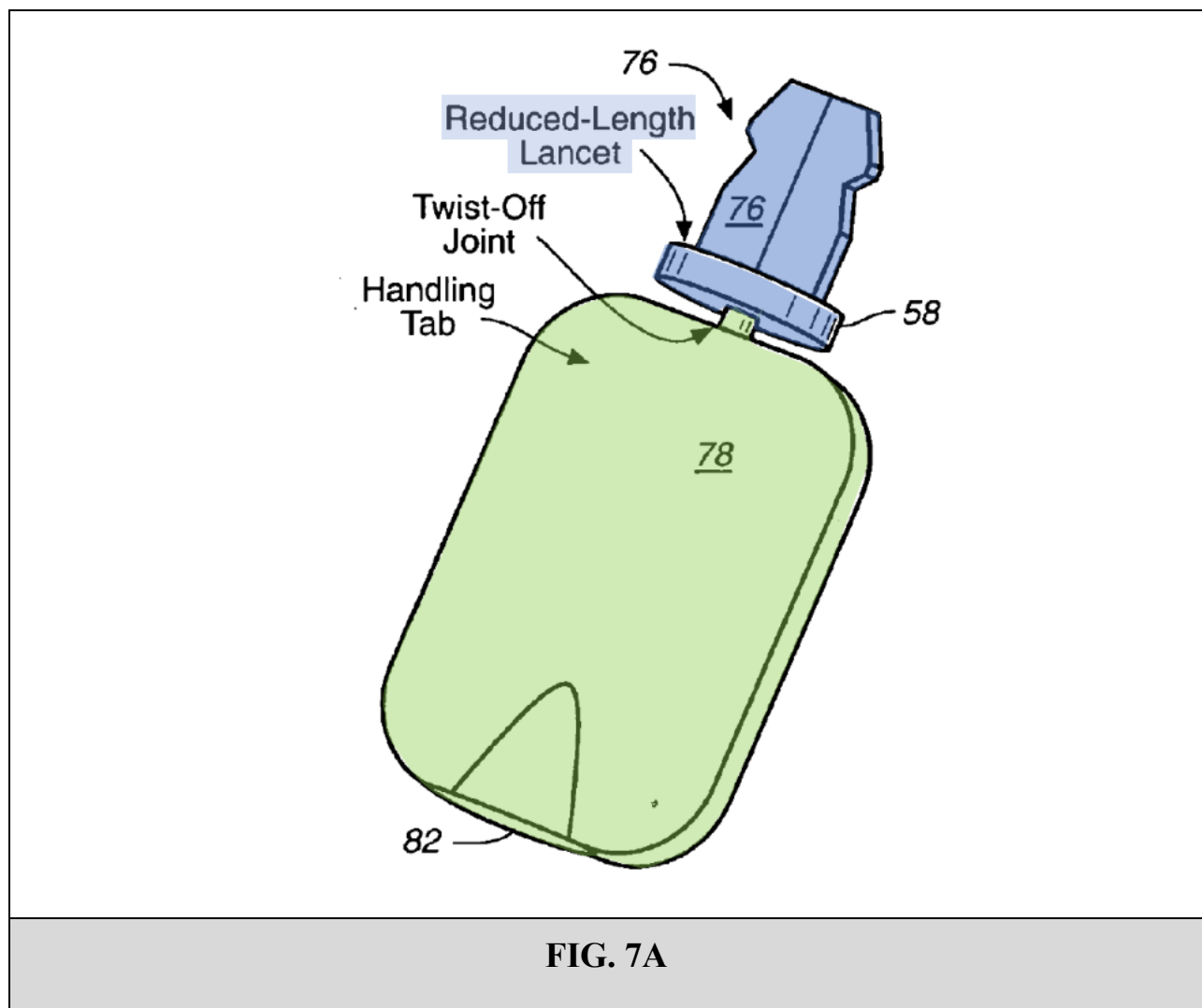
attached to the handling tab even after the user removes the puncture cap 78 from the lancet needle to collect a blood sample. Ex. 1002, ¶84. Nothing in Saikley teaches or suggests somehow changing the integral structure of the protective cap, let alone detaching one of its sheaths “when the protective sterility cap is removed from the lancet” prior to use. Indeed, the “hollow cup or solid ‘pin cushion’ type area 82 at the opposite end of cap 78” needs to remain available “to cover the sharp *during removal* from the [lancing] device and *disposal*.” Ex.1005, [0050].

Thus, Saikley discloses a “primary sheath [i.e., twist-off joint and adjoining portion of the handling tab] attached at a first end of the gripping handle portion and the secondary sheath [i.e., hollow cup or solid pin-cushion type area 82] attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet [i.e., when the protective cap 78 has been separated from the reduced-size lancet 76.]” Ex.1002, ¶¶83-85.

B. Claim 2 Is Anticipated

Claim 2 depends from claim 1, which Saikley discloses for the reasons discussed above. Section VIII.A incorporated herein. Claim 2 adds: “[t]he protective sterility cap of claim 1, in combination with a lancet.”

Saikley anticipates claim 2 by disclosing that the protective sterility cap 78 [colored green in Fig. 7A below] covers the needle sharp 50 of the “shortened lancet 76” [blue] both before it is used to collect a blood sample, and “during removal from the [lancing] device and disposal [colored blue below].” Ex.1005, [0050].



Ex.1005, [0037], [0065].

Thus, Saikley discloses “[t]he protective sterility cap of claim 1 [*i.e.*, protective cap 78], in combination with a lancet [*i.e.*, reduced-length lancet 76].”

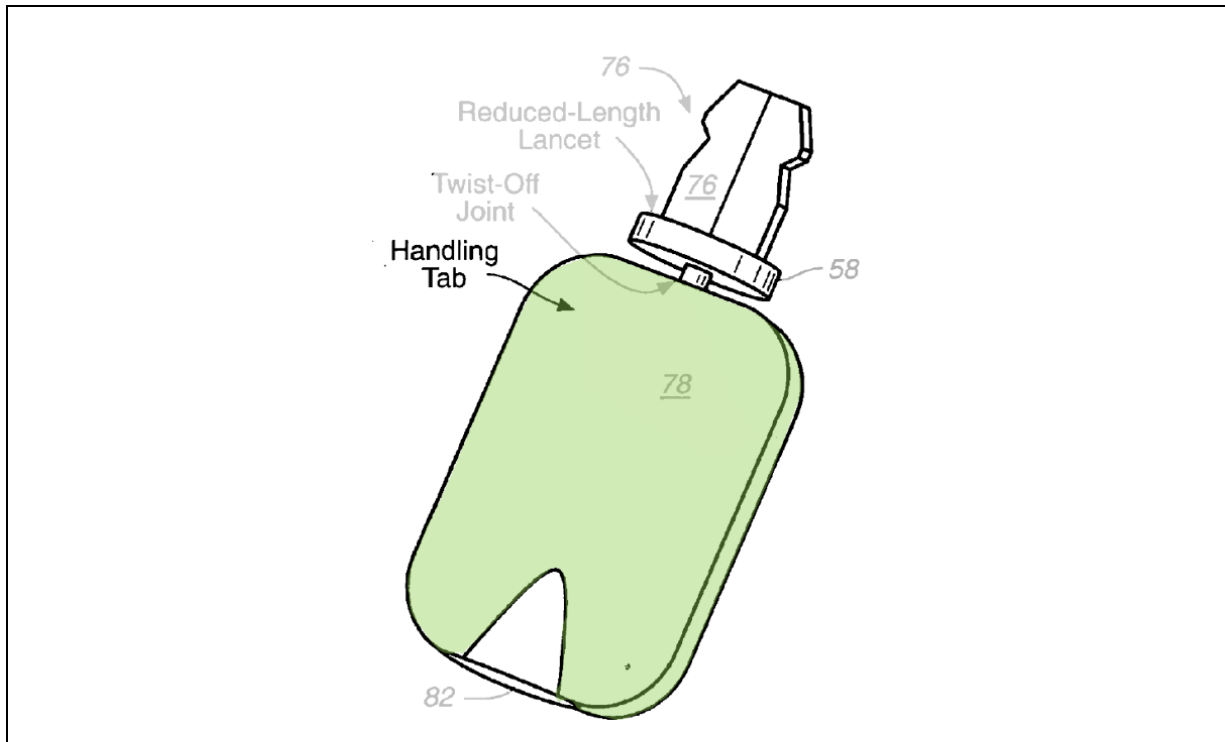
Ex.1002, ¶¶ 86-88.

C. Claim 3 Is Anticipated

Claim 3 depends from claim 1, which Saikley discloses for the reasons discussed above. Section VIII.A incorporated herein. Claim 3 adds that the claimed sterility cap further comprises: “at least one flat display surface for placement of branding indicia thereon.”

Saikley anticipates the added limitation of claims 3 by disclosing that the protective cap 78 of the Fig. 7A Embodiment comprises “at least one flat display surface”—namely, the flat display surfaces of the “handling tab.” Ex.1002, ¶¶89-90.

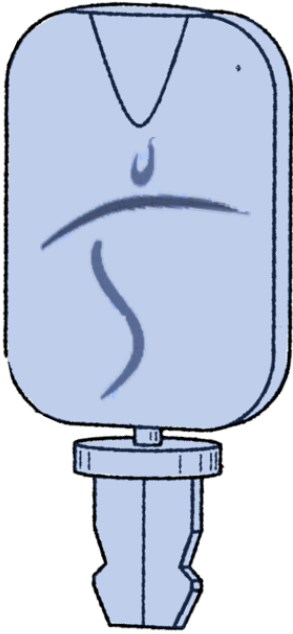
FIG. 7A (colored)



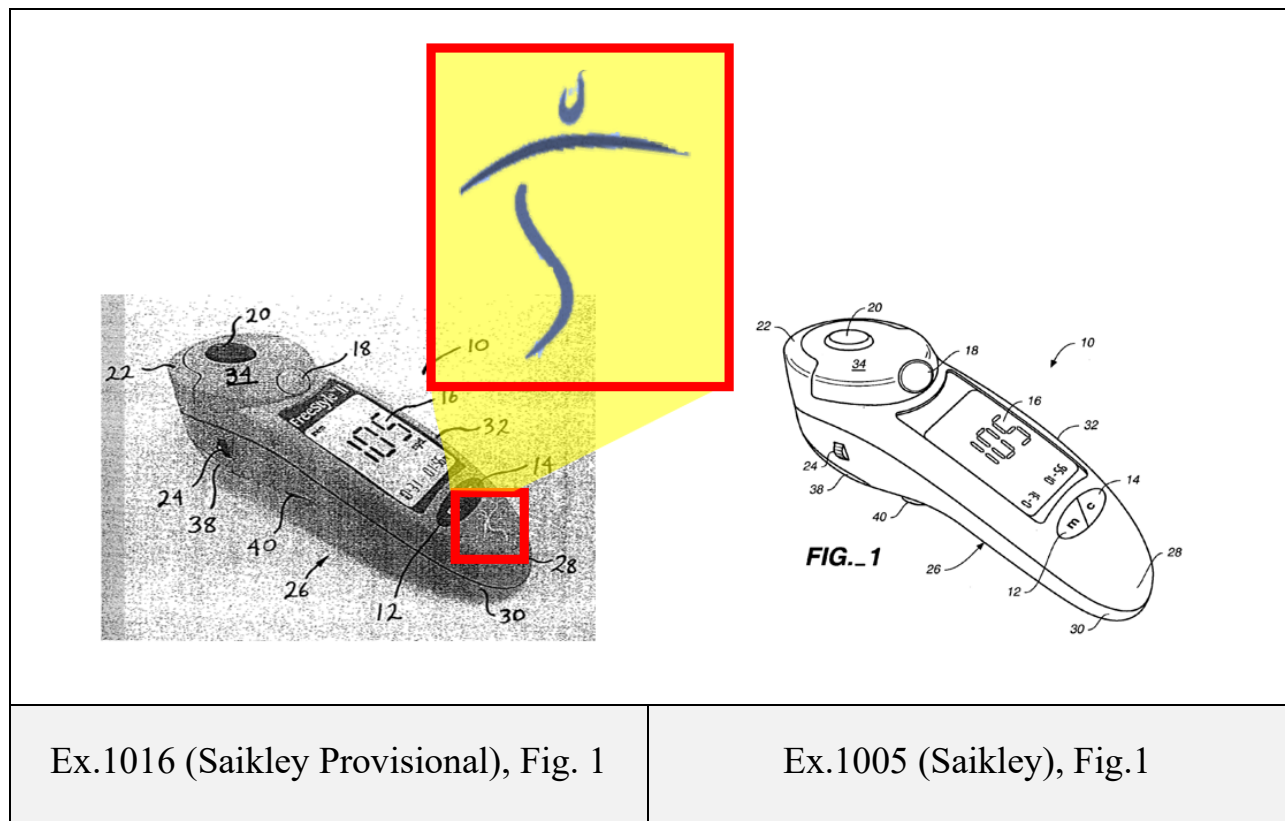
As shown above, the handling tab includes broad, flat surfaces. The remainder of the limitation—“for placement of branding indicia thereon”—recites intended use and does not structurally limit the protective sterility cap recited in the claim’s body. *Marrin v. Griffin*, 599 F.3d 1290, 1294 (Fed. Cir. 2010) (where claim recited “a scratch-off label for permitting a user to write thereon without the use of a marking implement,” in preamble language only added an intended use).

While not a limitation, a PHOSITA would understand that branding indicia could be placed on the flat surface of the handling tab. Saikley provides multiple examples of branding indicia that are suitable for display on the handling

tab of the Fig. 7a embodiment, including the “FreeStyle™” (Reg. No. 2455840; Ex.1015) trademark and the butterfly logo from the “FreeStyle™ brand test strip” that Saikley teaches “is used with the present invention.” Ex.1005, [0036]. As shown below, the flat surface of the handling tab could display the branding indicia associated with “[t]he recently introduced FreeStyle TM Blood Glucose Monitoring System developed by TheraSense, Inc” and described in the patents that Saikley incorporates by reference. Ex.1005 ¶¶[0003], [0036].

	
Ex.1015 (Registered Trademark Specimen)	Ex.1002, ¶93 (Demonstrative).

This is the same branding indicia appearing on the integrated lancing device 10 shown in Fig. 1 of “U.S. Provisional Application No. 60/424,414, entitled ‘Automatic Biological Analyte Testing Meter with Integrated Lancing Device and Methods of Use,’ filed on Nov. 6, 2002, which is incorporated herein in its entirety by [Saikley].” Ex.1005, ¶[0003]; 37 CFR § 1.57.

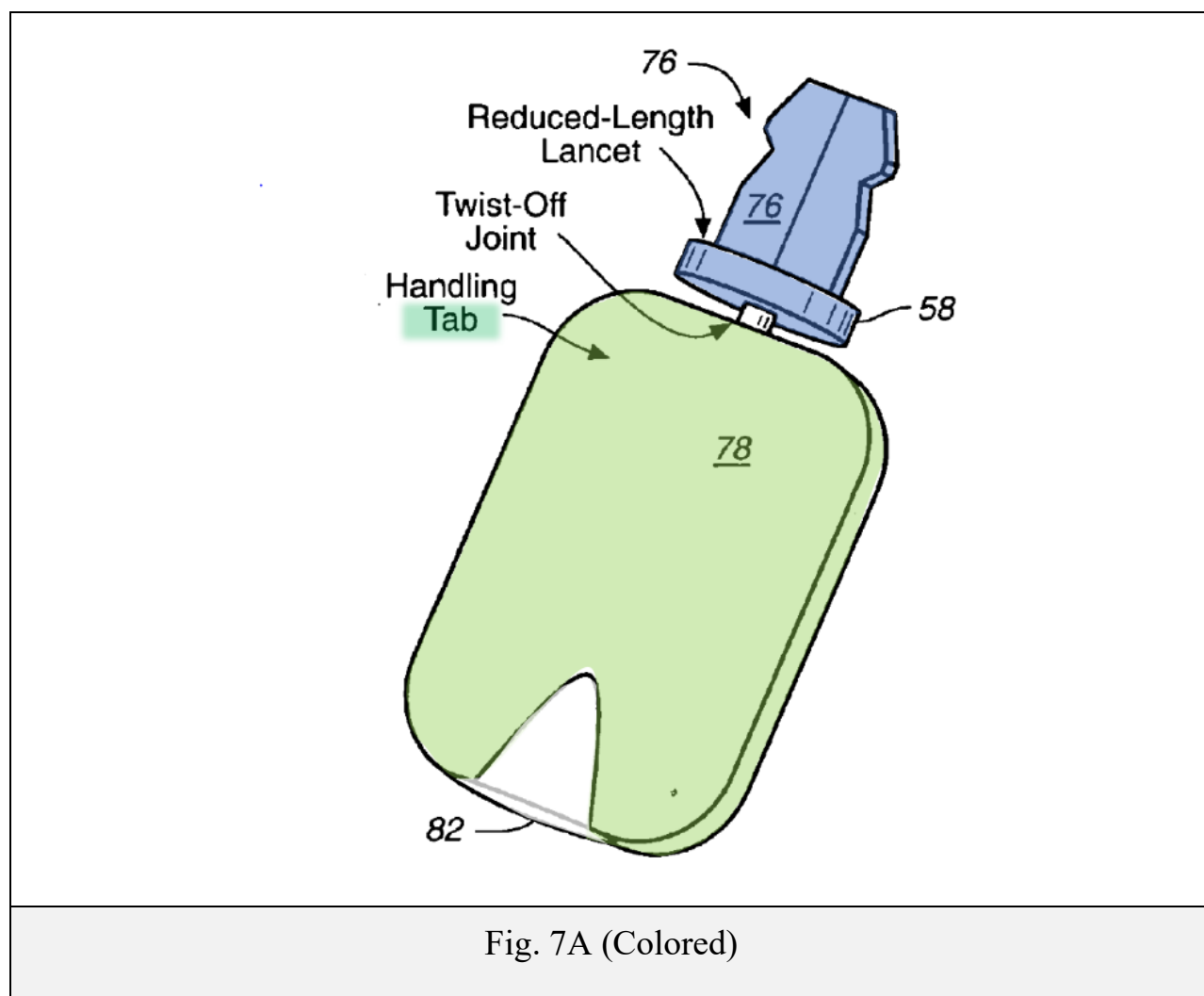


Thus, Saikley discloses that the protective sterility cap further comprises “at least one flat display surface [*i.e.*, flat display surfaces on handling tab] for placement of

branding indicia thereon [*i.e.*, branding indicia such as shown on the lancing device or test strips. Ex.1002, ¶¶89-95.

D. Claim 5 Is Anticipated

Claim 5 depends from claim 1, which Saikley anticipates for the reasons discussed above. Section VIII.A incorporated herein. Claim 5 adds “wherein the gripping handle portion comprises a solid body without an open loop.” Saikley anticipates claim 5 by disclosing that the protective cap 78 is an “integrally-molded pull-off **tab**,” which is depicted as having a solid body without any openings, let alone an open loop. Ex.1002, ¶96.



Thus, Saikley further discloses that “the gripping handle portion [i.e., handling tab] comprises a solid body without an open loop [i.e., solid body of tab without an open loop].” Ex.1002, ¶¶96-97.

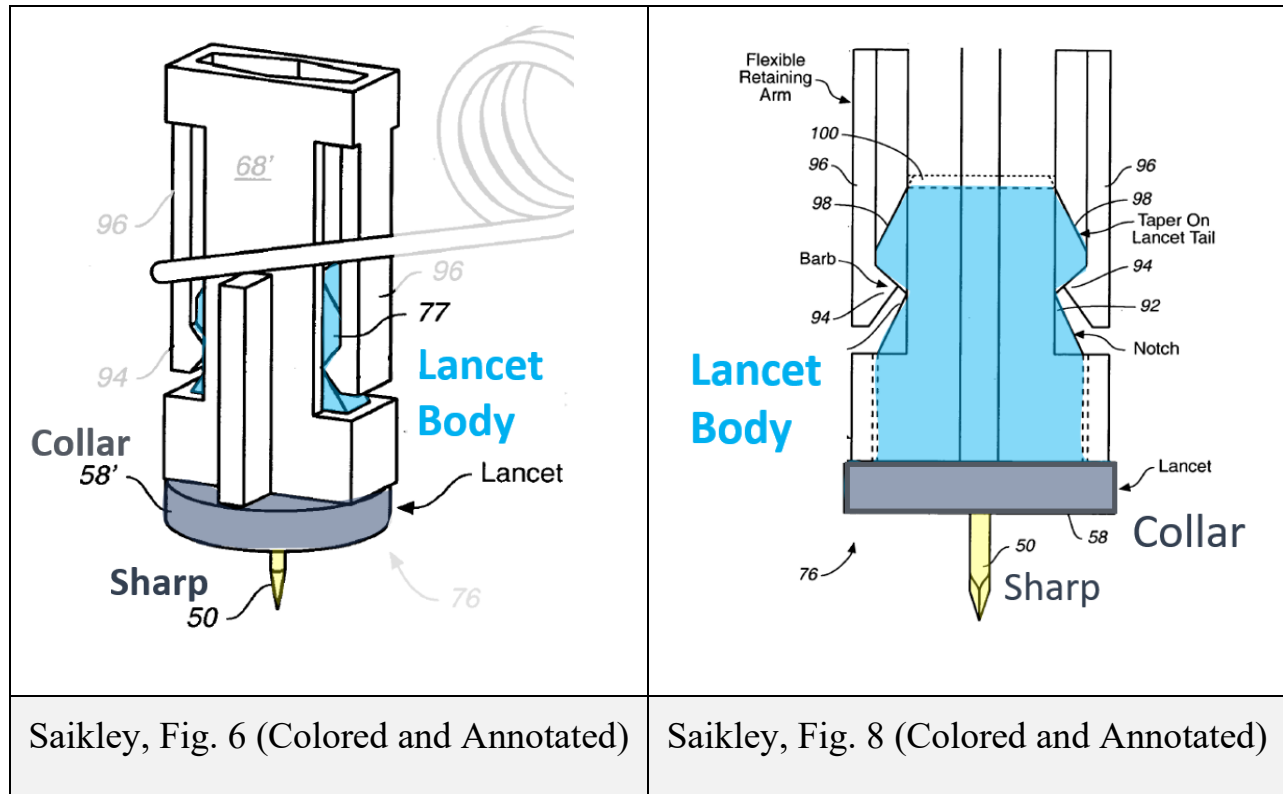
E. Claim 6 Is Anticipated

Claim 6 depends from claim 1, which Saikley anticipates for the reasons discussed above. Section VIII.A incorporated herein. Claim 6 adds: “[a] in combination with a lancet [b] having a lancet body defining a lancet thickness, [c] and a sharp lancet tip initially embedded in the primary sheath, [d] wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.”

For element 6[a], Saikley discloses the protective sterility cap of claim 1 [i.e., protective cap 78 shown in Fig. 7A] in combination with a lancet [i.e., shortened lancet 76’], for the same reasons described for claim 2. Section VIII.B, incorporated herein.

For element 6[b], Saikley teaches that the “reduced-length lancet 76” (consists of (1) a “lancet body” (colored light blue in below) forming a “plastic housing” that is “generally flat and has a notch 92 on each edge,” (2) a “sharp 50 [yellow] molded within the plastic housing,” and (3) a “lancet guiding collar” (grey) that engages with the lancing device to control the position and direction of the lancet within a lancing device Ex.1005, ¶¶[0041-42]; *id.*, [0037] (“disposable lancet 46 [has] a plastic main body 48” and “a sharp 50”); *id.*, ¶[0044] (describing

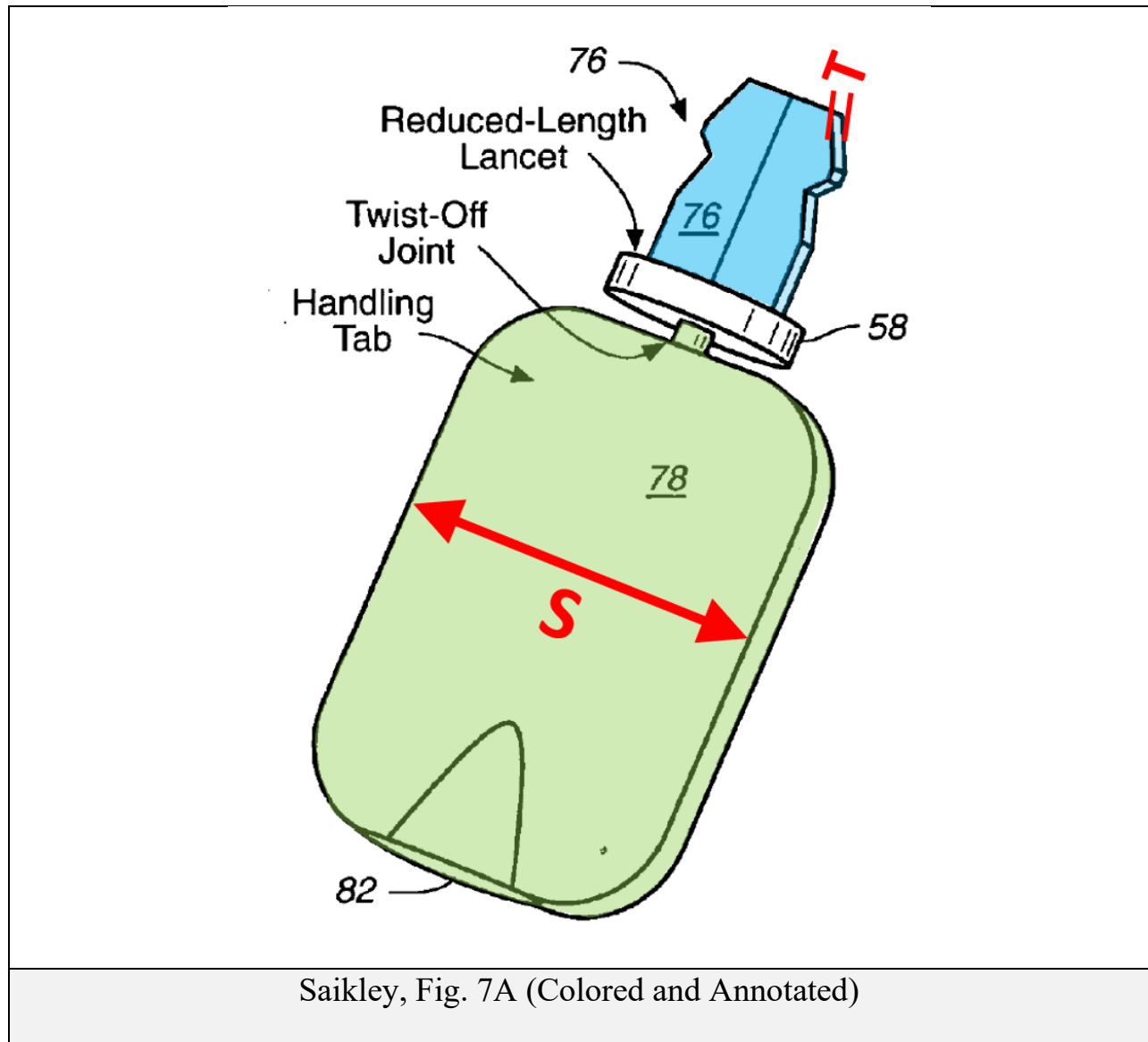
the “insert molding processes” as when “metal sharps 50 and 64 are molded within plastic housings 48 and 66, respectively.”). Ex.1002, ¶100.



For element 6[c], a PHOSITA 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, for the same reasons described for claim 2. Section VIII.B, incorporated herein.

As to the relative-dimensions recited (6[d]), Saikley’s Figure 7A embodiment clearly depicts a handling tab (*green*) with a lateral span (annotated

“S” with arrows) that is far more than 1.5 times the lancet thickness (*yellow*) of the lancet body (*light blue*). Ex.1002, ¶102.



Saikley emphasizes the size of the handling tab relative to the lancet by describing cap 78 as a “large lancet cap for handling” (Ex.1005, [0049]) and noting

that it is “made much larger than usual to aid handling.” *Id.*, [0050]. Saikley also makes clear that the lancet is smaller than the easily handled tab of cap 78, observing that the “short length [lancet] might make the lancet difficult for the user to handle and install.” *Id.* In view of these textual descriptions and the depiction in Figure 7A showing a cap 78 with a lateral span much larger than 1.5 times the lancet thickness (annotated below), a PHOSITA would have understood element 6[d] to be expressly or, at least inherently, disclosed. Ex.1002, ¶103.

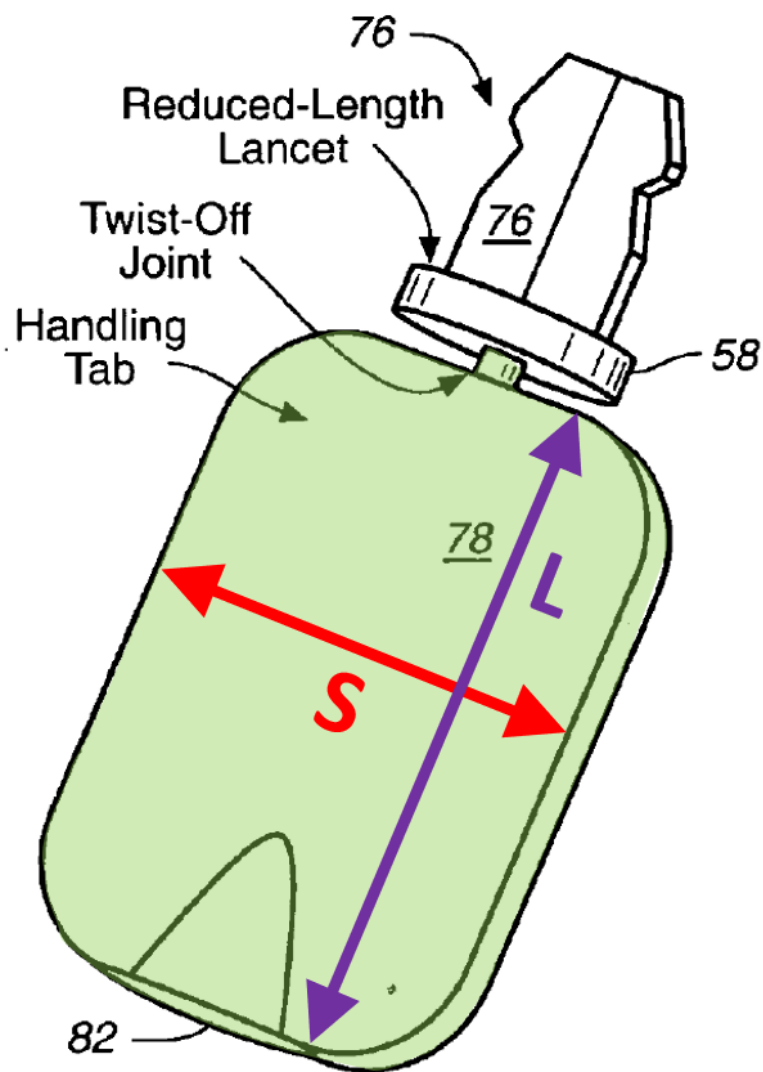
Additionally, a PHOSITA would have appreciated that Saikley’s lancet would have been handled by a user pinching the handling tab between a thumb and a digit on the user’s hand. Ex.1002, ¶104. A PHOSITA would also have appreciated that the average human thumb is 16 mm wide. Ex.1022, 157. In light of this, a PHOSITA 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 PHOSITA would have understood Saikley to teach that its lateral span was more than twice the lancet thickness.

Thus, Saikley expressly taught or, at a minimum, inherently disclosed the limitation of a gripping portion with a lateral span at least 1.5 times the lancet thickness. Ex.1002, ¶104. This is consistent with incorporated-by-reference 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.” Ex.1017, 5:15-18.

F. Claim 7 is Anticipated

Claim 7 depends from claim 6, which Saikley anticipates for the reasons discussed above. Section VIII.E incorporated herein. Claim 7 adds “wherein the gripping handle portion defines a length at least equal to its lateral span.”

As was explained above, a PHOSITA would have understood Saikley’s Figure 7A (in conjunction with the textual descriptions concerning larger lancet caps for handling) to plainly depict a gripping handle portion (cap 78) that is much larger than 1.5 times the lancet thickness. Because Saikley’s Figure 7A also shows that the length of its cap 78 is significantly larger than the cap’s lateral span, this additional limitation of claim 7 is also disclosed. Ex.1002, ¶¶106-107.



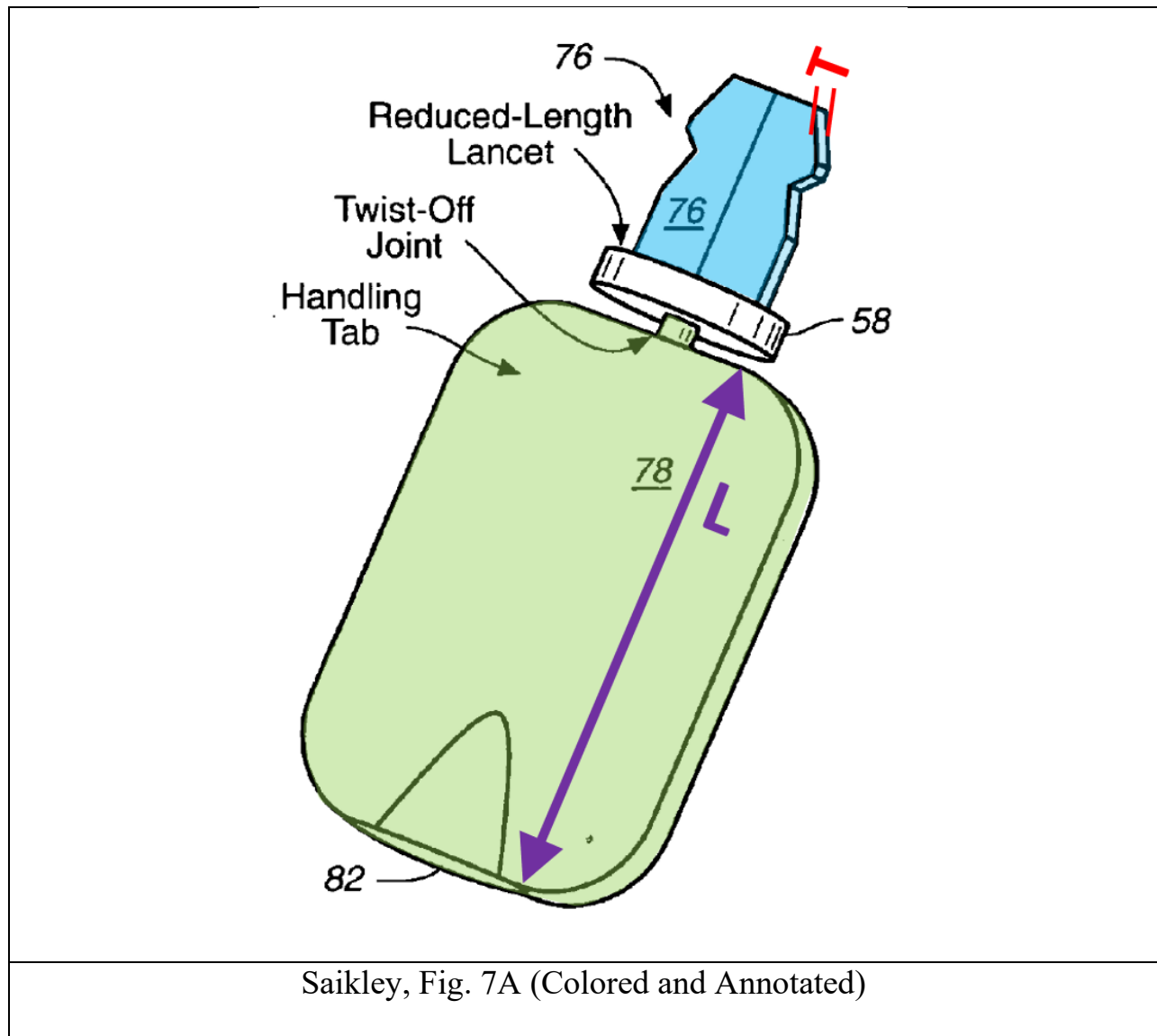
Saikley, Fig. 7A (Colored and Annotated)

Therefore, claim 7 is anticipated. Ex.1002, ¶¶106-108.

G. Claim 8 is Anticipated

Claim 8 depends from claim 6, which Saikley anticipates for the reasons discussed above. Section VIII.E incorporated herein. Claim 8 adds “wherein the gripping handle portion defines a length at least equal to the lancet thickness.”

Because Saikley discloses both that the gripping handle portion (cap 78) is at least 1.5 times the lancet thickness (*supra* Section VIII.E, incorporated here) and that the gripping handle portion’s length is at least equal to the lateral span (*supra* Section VIII.F, incorporated here), the length of Saikley’s gripping handle portion must also necessarily be at least equal to (including larger than, as Saikley teaches) the lancet thickness. Ex.1002, ¶¶109-110.



Therefore, claim 8 is anticipated. *Id.*

H. Claim 14 is Anticipated

Claim 14 includes limitations analogous in scope to limitations 1[pre]-1[d], and those are disclosed by Saikley for reasons provided above and incorporated here (*supra* Section VIII.A.1-5). Claim 14 also includes limitations analogous in

scope to those found in claim 6, and those are disclosed by Saikley for reasons provided above and incorporated here (*supra* Section VIII.E). Ex.1002, ¶112.

I. Claim 16 is Anticipated

Claim 16 depends from claim 14, which is anticipated by Saikley for reasons provided above and incorporated here (*supra* Section VIII.H). The additional limitations of claim 16 correspond in scope to those found in claim 3, and those additional limitations are disclosed for the same reasons (*supra* Section VIII.C). Ex.1002, ¶113.

J. Claims 17 and 18 Are Anticipated

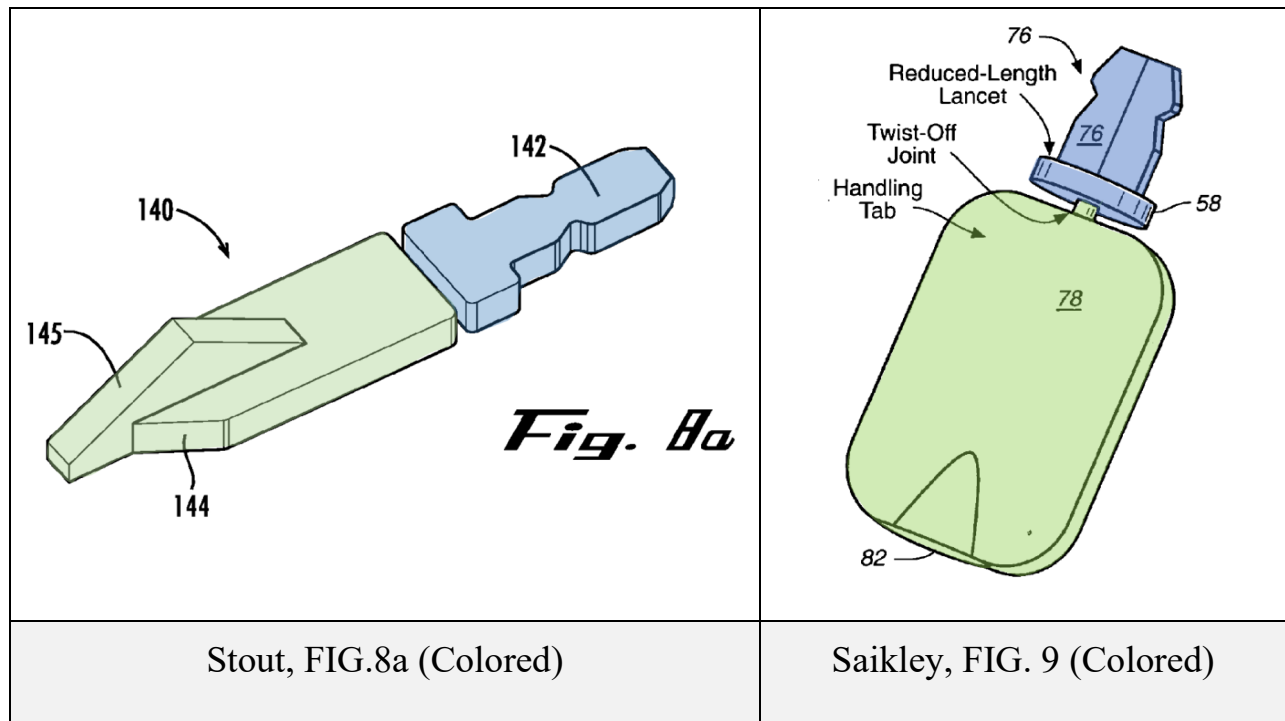
Claims 17 and 18 depend from claim 14, which is anticipated by Saikley for reasons provided above and incorporated here (*supra* Section VIII.H). The additional limitations of claim 17 correspond in scope to those found in claim 7, and those additional limitations are disclosed for the same reasons (*supra* Section VIII.F). The additional limitations of claim 18 correspond in scope to those found in claim 8, and those additional limitations are disclosed for the same reasons (*supra* Section VIII.G). Ex.1002, ¶114.

IX GROUND #2: SAIKLEY IN VIEW OF STOUT RENDERS OBVIOUS CLAIMS 1-3, 5-8, 14, AND 16-18

A. All Claims: “Primary Sheath for Initial Embedment”

As shown in Ground 1 above, Saikley anticipates this limitation by depicting and disclosing that “cap 78 may be an **integrally molded**, pull-off tab, such as shown in FIG. 7A” because a PHOSITA would know that “the needle tip is **embedded** in [a] removable protective cap integrally molded with the plastic body to form a single integral unit prior to use.” *See, supra*, Section VIII.A.2 (citing Ex. 1002, ¶¶59-65). *Adasa*, 55 F.4th at 910 (“[An anticipatory prior art] reference need not disclose the elements in the *very same terms* used by the patent.”); *Telemac Cellular Corp.*, 247 F.3d at 1327-31 (relying on extrinsic evidence to find that the words “Call Detail Record” in prior art reference disclosed claim element).

Should the Board disagree or otherwise find that Saikley does not expressly or inherently disclose a needle sharp embedded in the protective cap 78, then it would have been obvious to a PHOSITA in view of Stout (Ex.1018), whose sterility cap (*colored green in Fig. 8a below*) is likewise “relatively large or **oversized**, as compared to the lancet body 42, 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.” Ex.1018, [0035]; Ex. 1002, ¶117.



Indeed, just like Saikley, Stout teaches that “[t]he sterility cap 44 is preferably **co-molded** with the lancet body portion 42, and the two are connected at a narrow or notched neck portion for ease of separation upon removal of the sterility cap,” with the “sharp lancet tip 43 ... securely **embedded** therein.” Ex.1018, [0035]. A PHOSITA 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. Ex.1002, ¶¶117-118.

To modify Saikley’s cap to include an embedded needle sharp, a PHOSITA would only need to use “traditional insert molding methods, for high-volume, low-cost manufacturing,” (Ex.1002, ¶119) and, thus, would have had a reasonable expectation of success. Indeed, “most other lancets [that were] currently in use” at that time “encased the needle in a 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.” *Id.* Additionally, a PHOSITA 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. Ex.1002, ¶119; *see also id.*, ¶¶120-121.

B. Claims 6-8, 14, and 17-18: The “Length” and “Lateral Span” of the Gripping Handle Portion

As was explained above (*supra* Sections VIII.E-G, VIII.H, VIII.J, incorporated here), Saikley anticipates the “length” and “lateral span” limitations. This is particularly true given that Saikley’s “larger than usual” protective cap provides the same functionality purportedly achieved by the dimensions recited by

the '635 Patent claims—namely, “to aid handling.” *Compare* Ex.1005, ¶¶[0049-0050] *with* Ex.1001, 6:66-7:3.

Should Patent Owner argue that these limitations are not expressly or inherently disclosed by Saikley, they would have been obvious because “[t]he only material difference between the ['635] patent and [Saikley] are those dimensions, **which are meaningless.**” *Hamilton Products, Inc. v. O'Neill*, 492 F. Supp. 2d 1328 (M.D. Fla. 2007) (finding obvious claims to an animal seat belt with a buckle “at least less than approximately 0.8 inches” and an “overall width of greater than approximately 0.53” where the precise dimensions were the only differences between claimed invention and prior art—“Looking to all the appropriate factors, the Court finds that the '621 patent is invalid because the differences between the '621 patent and the prior art—particularly the Snyder patent—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.”).

It would be obvious to make Saikley’s “large lancet cap for handling” even “larger than usual to aid handling,” especially in light of Saikley’s teaching that “[e]lderly patients and those with reduced eyesight and dexterity can have problems seeing and capturing such a small sample.” Ex.1005, [0004]. The

straightforward modification of “making a [lancet cap’s handle longer or wider] merely yields the predictable result of [making the cap easier to handle], and is thus obvious.” *Ohio Willow Wood Co. v. Thermo-Ply, Inc.*, 2009 WL 6499349, at *4–*5 (E.D. Tex. 2009). “The fact that [a larger handle] will [make a lancet cap easier to handle] is not only common sense, but was recognized in this field by those of ordinary skill” (*id.*), as demonstrated by Saikley, Stout, and other prior art lancet caps. Ex.1005, [0050]; Ex.1018, [0035].

At the very least, Saikley shows that the claimed aspect ratios for the gripping handle were “an obvious design choice.” *Rexnord Indus., LLC v. Kappos*, 705 F.3d 1347, 1355-56 (Fed. Cir. 2013) (“we conclude that the Board erred in holding that it would not have been obvious to limit the space to the 10 mm maximum” where “[Petitioner] pointed out that the conveyor belts of the prior art show every element of the claims except the specific measure in millimeters of the maximum space between modules. ... A space that is small enough to avoid pinching of fingers is taught in the prior art, with the 10 mm dimension a design choice that takes account of the size of fingers and other small objects.”); *Airlite Plastics Co. v. Plastilite Corp.*, 526 F.2d 1078, 1082 (8th Cir. 1975) (claims obvious where difference over prior art limited to “form, proportions, or size”).

Additionally, the claimed dimensions would have been obvious for a PHOSITA to try when determining the optimum “length” and “lateral span” of the handling tab on Saikley’s protective sterility cap 78.² As a threshold matter, there was an art-recognized problem of lancets being held by people with limited dexterity or other challenges (including the elderly and others who have difficulties grasping and manipulating lancets) that might accidentally poke themselves with needles if sharp needle tips were not properly sheathed both before and after use. Ex.1002, ¶123. This recognized problem led to many sterility caps being developed with both primary and secondary sheaths and gripping handles therebetween to facilitate ease of handling. *Id.* In light of this, a PHOSITA 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. This experimentation would have encompassed the finite

² During prosecution, the Examiner also argued that “[i]t would have been obvious to modify the gripping handle portion to define a lateral span of at least 1.5 times the lancet thickness, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.” Ex.1003, 60. Patent Owner never rebutted this argument or provided any reason as to why the relative dimensional aspects has any patentable significance. These relative dimensions do not have patentable significance.

number of potential dimensions the gripping handle portion as compared to the thickness of the lancet. *Id.*

As to the gripping handle's lateral span being at least 1.5 times the lancet thickness (recited in claims 6 and 14), it was already known that gripping handles on many sterility caps were larger than the lancet thickness. Ex.1002, ¶124. Saikley is one example of this, because as is visually apparent from the depiction of the handling tab/ protective cap 78 in Saikley's Figure 7A, which Saikley describes as a "larger lancet cap for handling," a PHOSITA would have known that this cap "should be made much larger than usual to aid handling." Ex.1005, [0050]. Designing a gripping handle's lateral span to be at least 1.5 times the lancet thickness would have been pursued by a PHOSITA 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]. Both express statements in Saikley and the knowledge of those skilled in the art would have motivated a PHOSITA to try various larger dimensions for the gripping handle portion of Saikley. Ex.1002, ¶124. And, given the instruction to create a large enough gripping handle portion "to aid handling," a PHOSITA would have utilized dimensions for the cap 78 in

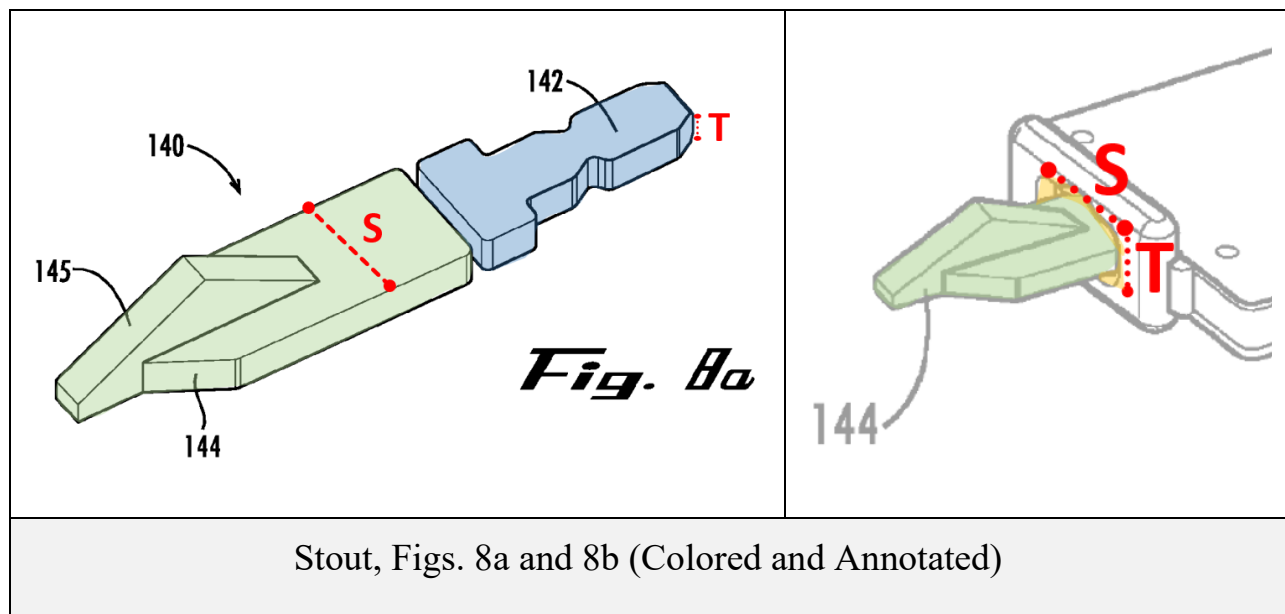
Saikley that allowed a user to easily handle the cap 78 with their fingers, including creating a large enough cap 78 to at least be held between the average human finger pad size of 16-20 mm. *Id.* (citing Ex.1023, 685).

Saikley incorporates by reference U.S. Patent No. 6,283,982, which indicates that an opening for receiving a lancet should be “*less* than about 6 mm in diameter, so that a standard lancet will not pass therethrough,” which means that “standard” lancets were 6 mm in diameter. Ex.1017, 10:3-6. Thus, in designing Saikley’s cap 78 to be held by the average human finger pad, a PHOSITA would have routinely designed a cap 78 that was as large or larger than an average finger pad and, thus, would have been at least 1.5 times the thickness (diameter) of a standard lancet. Ex.1002, ¶125.

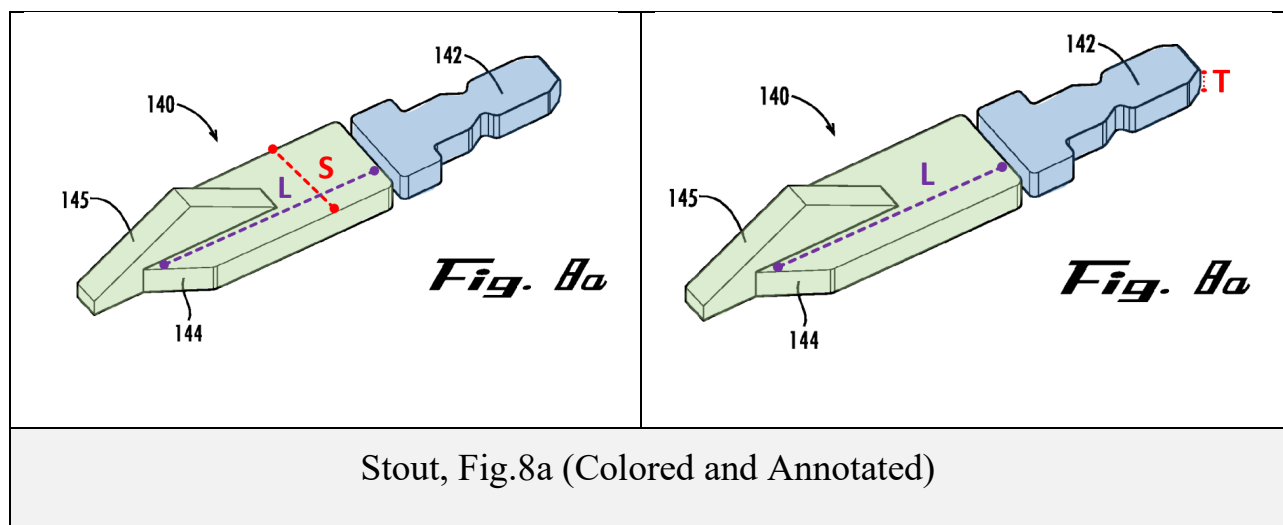
As to the gripping handle’s length being at least equal to the lateral span (recited in claims 7 and 17), a PHOSITA would have tried various dimensions for the length and lateral span of the handling tab in Saikley, in particular to ensure ease of handleability for users with limited dexterity, such as the elderly. Ex.1002, ¶126. Designing a handling tab with a length at least equal to its lateral span would have been a natural option that would have had a reasonable expectation of success. *Id.*

As to the gripping handle's length being at least equal to the lancet thickness (recited in claims 8 and 18), this again would have been a natural choice for a PHOSITA who would have appreciated that users had difficulty handling lancets and that a gripping handle should be made at least equal to, but preferably much larger than, the lancet thickness. Ex.1002, ¶127.

To the extent that these dimensional limitations were not obvious to try, they would be rendered obvious by Saikley in view of Stout, which 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].” Ex.1018, [0032]; *see also id.*, [0035]. Ex.1002, ¶128.



As PHOSITA 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. Ex.1002, ¶129.



Thus, Saikley in view of Stout renders obvious claims 6-8, 14, and 17-18.
Ex.1002, ¶¶122-130.

C. Ample Motivation Existed to Combine Saikley with Stout

A PHOSITA would have been motivated to combine Saikley and Stout for the following reasons. Ex.1002, ¶¶131-136.

As a threshold matter, a PHOSITA would have appreciated that Saikley and Stout are within **the same field of endeavor** and **address the same problem**. *See In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). At a minimum, Saikley and Stout are reasonably pertinent to a problem identified in the '635 Patent. The '635 Patent identifies the claimed invention as one which relates to “lancets and lancing devices for blood sampling and testing.” Ex.1001, 1:17-19. Both Saikley and Stout relate to lancing devices. Ex.1005, [0002]; Ex.1018, [0006]. The '635 Patent also describes how “[i]mprecise alignment of the lancet in the lancet carrier may result in increased pain sensation by the subject.” Ex.1001, 5:28-29. Saikley discloses a lancet where the “flat shape of lancet body 66 allows for such alignment and prevents misalignment.” Ex.1005, [0054]. Similarly, Stout also discloses a lancet “along at least a portion of its length having a flattened profile with a first dimension substantially larger than a second dimension” and where the “lancet body and the lancet carrier are coplanarly aligned when the lancet is installed” to provide stability to both the lancet and carrier during the lancing stroke. Ex.1018, [0009], [00040]. Thus, Saikley and Stout disclose inventions in the same field of endeavor as the '635 Patent while also addressing one of the problems identified by the '635 Patent. Ex.1002, ¶¶132-133.

A PHOSITA would have been motivated to combine Saikley and Stout because such a combination would be commercially desirable and it would be obvious to try. Indeed, Stout specifically teaches that its lancing system “can be provided as an upgrade or retrofit component for *backwards-compatible attachment to an existing meter*, such as for example ... the Abbott FreeStyle Flash Meter”—the same system disclosed by Saikley. Ex.1018, [00046]; Ex.1005, [0003]. Utilizing the Stout system with the compatible meter disclosed in Saikley would provide users with a known method to yield predictable results— allowing users to access the benefits disclosed in Stout of a “lancing device that can be attached to a blood glucose meter for convenience and to avoid loss.” Ex.1018, [0005]. A PHOSITA would also be assured that this combination would be successful because mounting the Stout lancing device to a removable portion of an existing meter “does not negatively impact the meter’s operation.” Ex.1018, [0046]; Ex.1002, ¶134

Finally, a PHOSITA 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. Saikley’s protective cap 78 may be “integrally molded” to “a shortened lancet” and

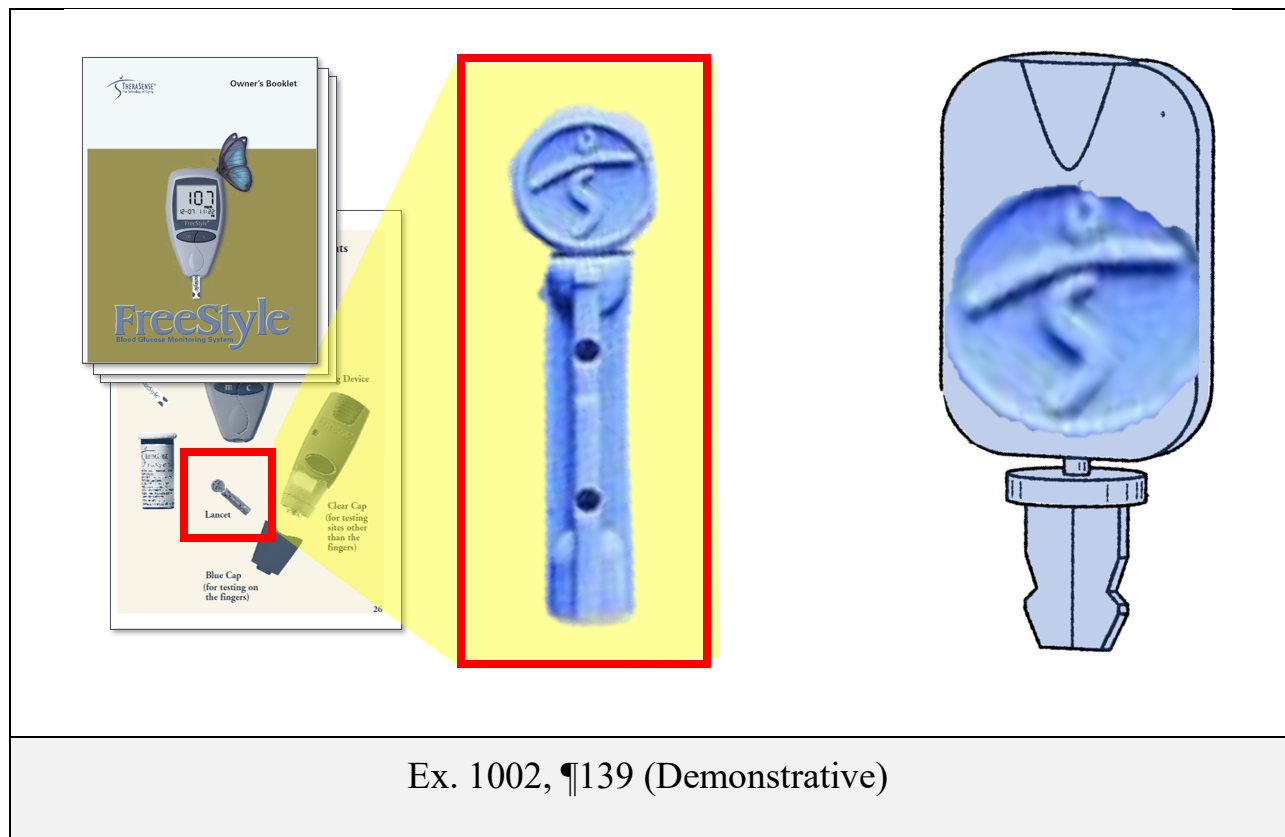
must be “made much larger than usual to aid handling.” Ex.1005, [0050]. Like Saikley, Stout’s cap 144 is co-molded with a “small and lightweight lancet body” and is preferably “large or oversized” to “facilitate easier handling and loading of the lancet into the lancet device.” Ex.1018, [0035]. Modifying 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. Ex.1002, ¶¶131-136.

**X GROUND #3: SAIKLEY IN VIEW OF THE FREESTYLE MANUAL
RENDERS OBVIOUS CLAIMS 3 AND 16**

As was explained earlier, Saikley anticipates claims 3 and 16 by disclosing the flat surface of the handling tab on the lancet’s protective cap 78 (shown below) because the remainder of the limitation—*i.e.*, “for placement of branding indicia thereon”—merely recites an intended use and, therefore, is not entitled to patentable weight. *Marrin*, 599 F.3d at 1294 (where claim recited “a scratch-off label for permitting a user to write thereon without the use of a marking implement,” in preamble language only added an intended use)

Should 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. The combination of these

two references is straightforward as FreeStyle expressly teaches using a flat display surface of a cap to display branding indicia (*i.e.*, the FreeStyle logo) as shown below. This combination would be obvious given the express teaching in Saikley of a cap with large flat surface, in conjunction with Saikley's instruction to use "an existing test strip, such as the **FreeStyle™ brand** test strip ... **with the present invention...**" Ex.1005, [0036].



Like Saikley, FreeStyle discloses the steps for testing blood glucose with the FreeStyle Blood Glucose Monitoring System, including the steps for inserting a

lancet into a lancing device. Ex.1010, 121-22. Therefore, Saikley and FreeStyle are analogous art to the '635 Patent. And Saikley provides ample motivation to add FreeStyle-related branding to Saikley's protective cap. Ex.1002, ¶¶143-150 (motivations to combine).

XI GROUND #4: IIO ANTICIPATES CLAIMS 1-3, 5-8, 14, AND 16-18³

A. Claim 1 Is Anticipated

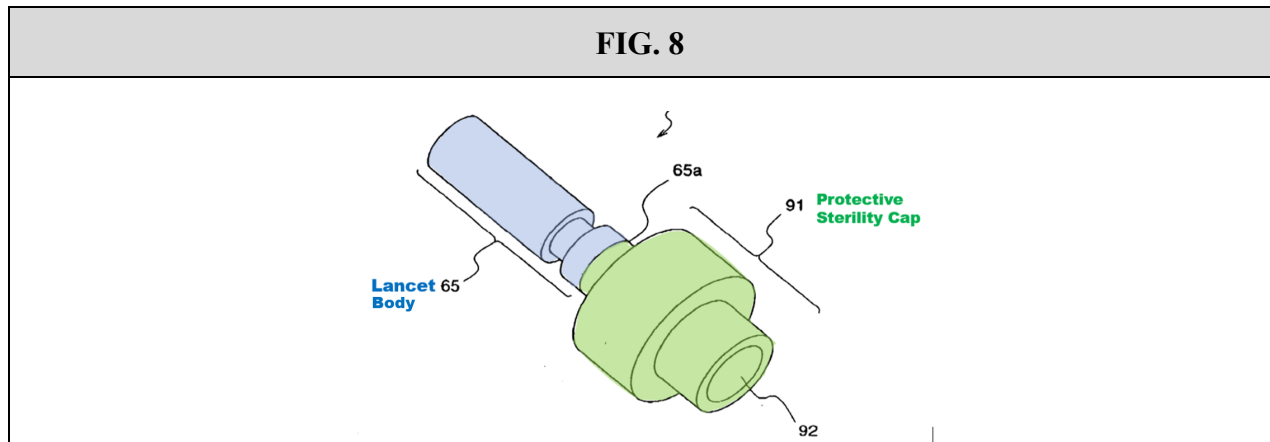
1. 1[pre]

The preamble is not limiting for two reasons. *First*, the body of independent Claim 1 is structurally complete and does not refer back to the preamble. *Second*, the preamble's recitation of "for a lancet" recites an intended use and does not structurally limit the protective sterility cap recited in the claim's body.

Should the Board find the preamble to be limiting, the second embodiment of Iio's lancet and sterility unit discloses "a protective sterility cap for a lancet"—namely, the "puncture needle cap 91" (sterility cap) for the lancet body 65 (collectively, the "puncture needle unit 90" or lancet), which as shown in annotated Figure 8 below, are "connected to each other by a thin plastic film having a

³ Iio discloses two embodiments depicted in Figures 1-5(b) and Figures 6-12, respectively. Ex.1006, ¶¶[31-55], Figures 1-12. Ground 1 relies exclusively on the second embodiment to anticipate the challenged claims.

thickness of 0.1 mm or less in the puncture needle separation groove 65a.”
Ex.1006, [0104].



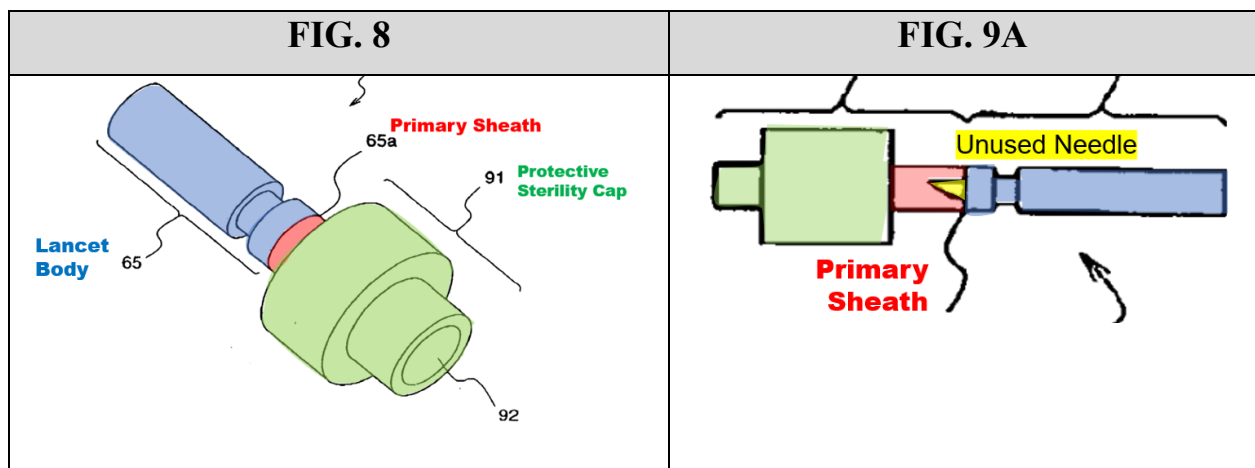
Id., Fig.8, [0044].

Iio teaches that “the lancet and the puncture needle are used to collect a small amount of blood for such as measurement of blood sugar.” Ex.1006, [0095]. Iio thus discloses “a protective sterility cap [*i.e.*, puncture needle cap 91] for a lancet [*i.e.*, puncture needle body 65 of the puncture needle unit 90].” Ex.1002, ¶¶153-155.

2. Claim 1[a]

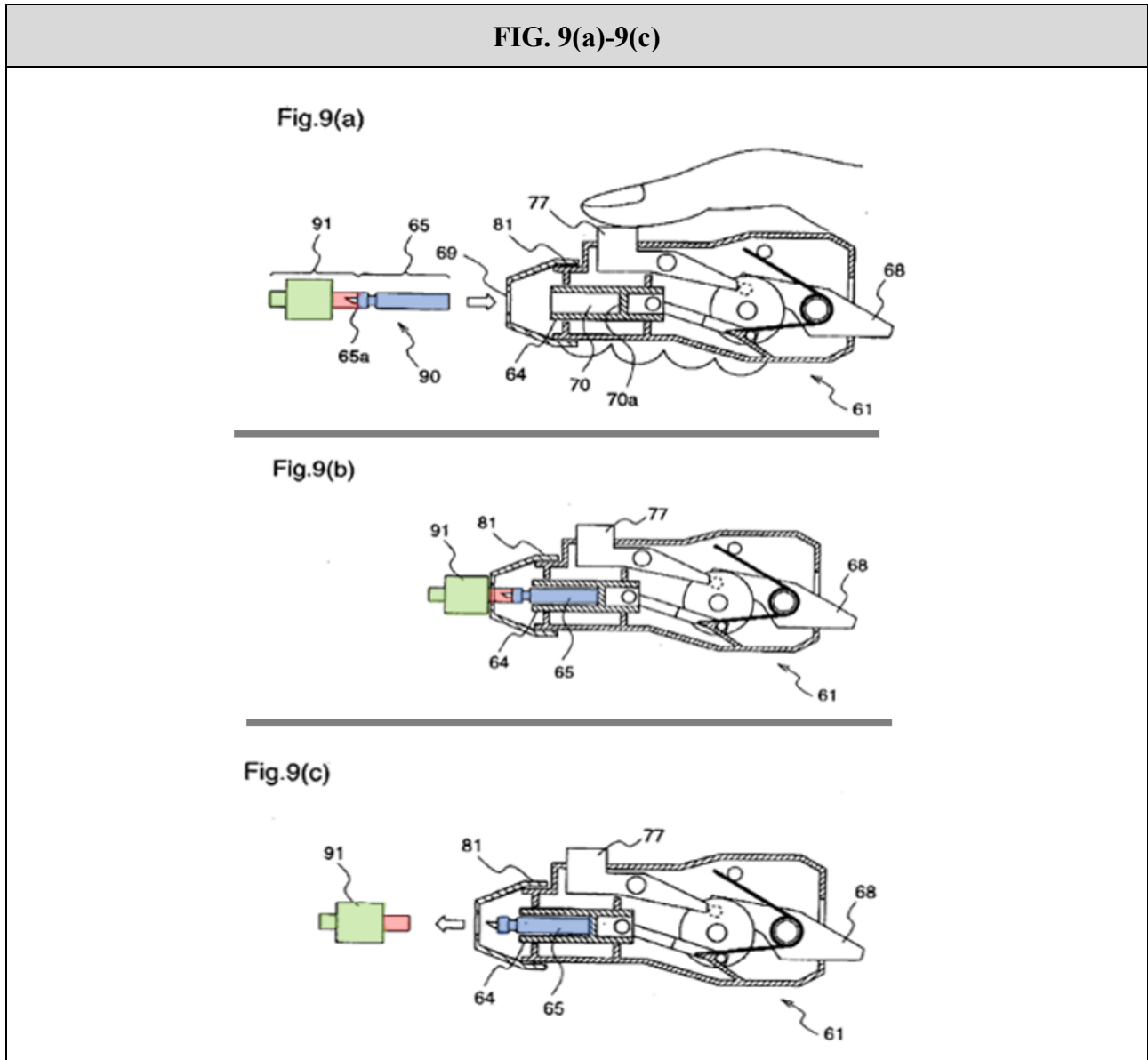
Iio’s puncture needle cap 91 includes a primary sheath at one “end” with a “puncture needle separation groove 65a,” a groove where “the body 65 and the cap 91” connect to each other “by a thin plastic film having a thickness of 0.1 mm or

less.” Ex.1006, [0104]. This primary sheath “cover[s] the front end of the puncture needle 65 before [it is] used.” Ex.1006, [0117]. Iio further teaches that the primary sheath (colored red in Figures 8 and 9(a), below) ensures that “the puncture needle body 65 is set in a state where it is embedded in the puncture needle cap 91.” *Id.*, [0104].



Before the puncture needle 65 is used to puncture a user’s skin, Iio teaches that the puncture needle unit 90 must be pushed into the lancing device 61 until “the puncture needle 65 is snugly fitted to the puncture needle fixing hole 70.” Ex.1006, [0106]. Once positioned in the lancing device 61, “the puncture needle 65 can be separated from the puncture needle cap 91” when “the lancet 61 is pulled while twisting the puncture needle unit 90.” Ex.1006, [0106] (“When the operator further applies a force against the pulling force, the puncture needle 65 can be

separated from the puncture needle cap 91 (FIG. 9(c)).”). This three-step procedure is shown in Figures 9(a)-(c), below.



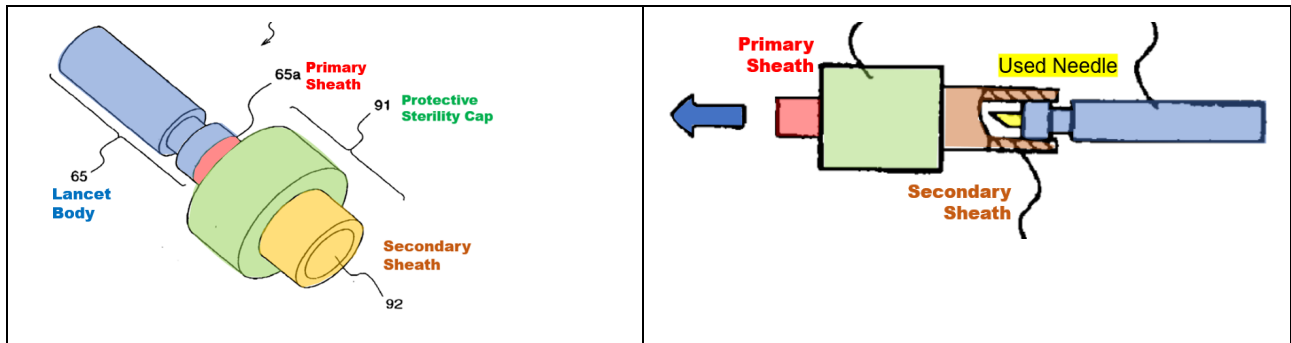
As shown in these figures and described in the specification, Iio teaches that “the puncture needle body 65 is set in a state where it is **embedded** in the puncture needle cap 91” that “cover[s] the front end of the puncture needle 65 **before** [it is] used.” *Id.*, [0104], [0117].

Iio therefore discloses that the “sterility cap (*i.e.*, puncture needle cap 91) compris[es] a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein.” Ex.1002, ¶¶156-159.

3. Claim 1[b]

The other “end of the puncture needle cap 91” has “a disposal slot 92 [colored orange in Figure 8 below] for pulling out the puncture needle 65 after puncture has been carried out.” Ex.1006, [0104] (explaining that while the “the shape of the puncture needle cap of the puncture needle unit 90 is not restricted to that shown in FIG. 8 ... [a]t this time, the puncture needle can be easily discarded by making the slot at the discarding side have a larger aperture.”).

FIG. 8	FIG. 11(b)
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“[A]fter the puncture operation has been completed [and] the front end of the puncture needle 65 is exposed (FIG. 11(a)),” Iio teaches “discarding the puncture needle 65” by fitting “the shaft of the disposal slot 92 ... to the front end of the puncture needle 65,” and then pressing “the front end of the puncture needle 65 ... into the disposal slot 92 to snugly insert the needle 65 into the slot 92, whereby the **puncture needle 65 is captured into the disposal slot 92** (FIG. 11(b)).” Ex.1006, [0115]. Then, “the puncture needle cap 91 having the puncture needle 65 is pulled out of the lancet 61, whereby discarding of the **used puncture needle 65** is completed (FIG. 11(c)), and the puncture needle 65 can be discarded safely and easily without exposing the front end of the puncture needle.” *Id.* Figures 11(a)-(c) illustrate how the hollow cavity of the disposal slot 92 receives the sharp lancing tip of a used lancet.

FIGS. 11(a)-11(c)

Fig.11(a)

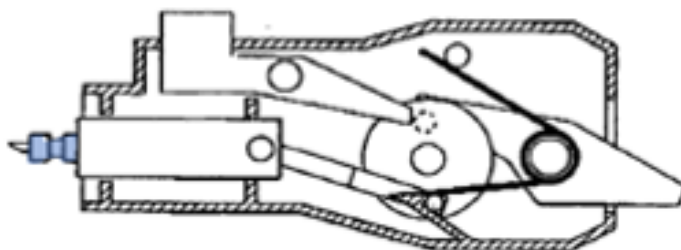


Fig.11(b)

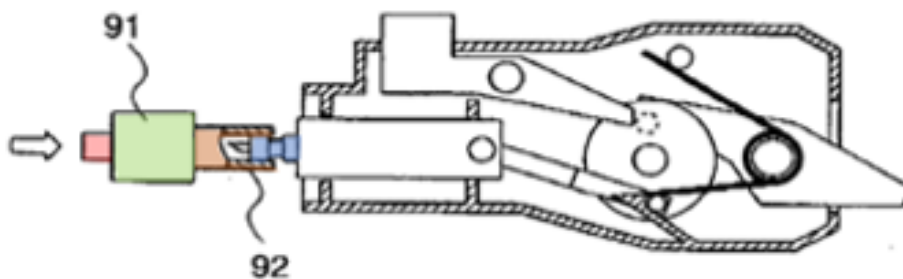
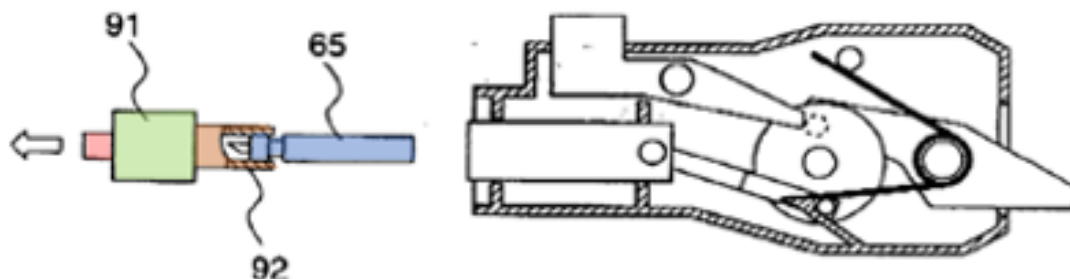


Fig.11(c)



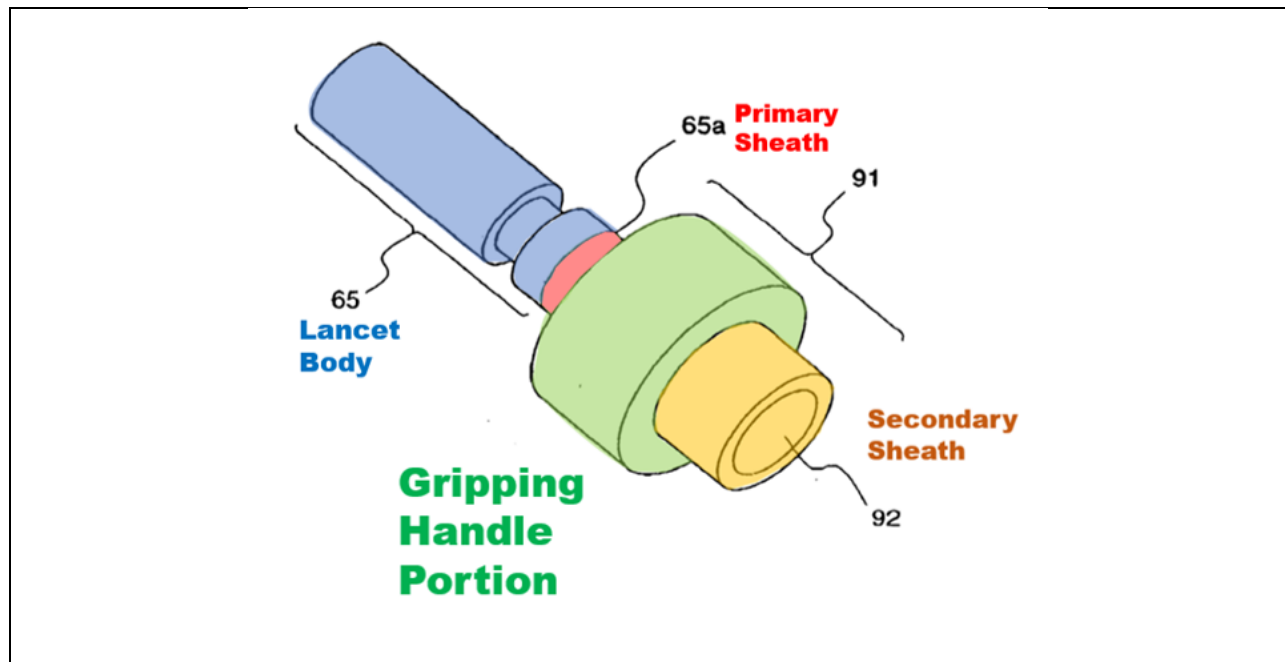
The hollow shaft is designed to receive a used lancet because the sharp lancing tip is ultimately “enclosed” within the hollow portion of the shaft. Ex.1002, ¶163. This meets the claim term “a secondary sheath for receiving,” which the district court broadly construed as “a secondary sheath for covering the sharp lancing tip of a used lancet by embedding or *enclosing* the lancet tip.” Ex.1004, 13:24-14:3. Indeed, just like Iio, the ‘635 Patent uses the term “receiving” to describe a lancet needle that is “enclosed” within a “hollow” cavity of a protective sterility cap. Ex.1001, 6:1-5, 7:6-10; *compare* Ex.1001, Figs. 5A-5D *with* Figs. 6A-6D.

Thus, Iio discloses a “a secondary sheath (*i.e.*, disposal slot 92) for receiving the sharp lancing tip of a used lancet.” Ex.1002, ¶¶160-164.

4. Claim 1[c]

Iio’s puncture needle cap 91 further includes a handle (*colored green in Figure 8, below*) extending between the primary sheath (*red*) and the secondary sheath (*orange*).

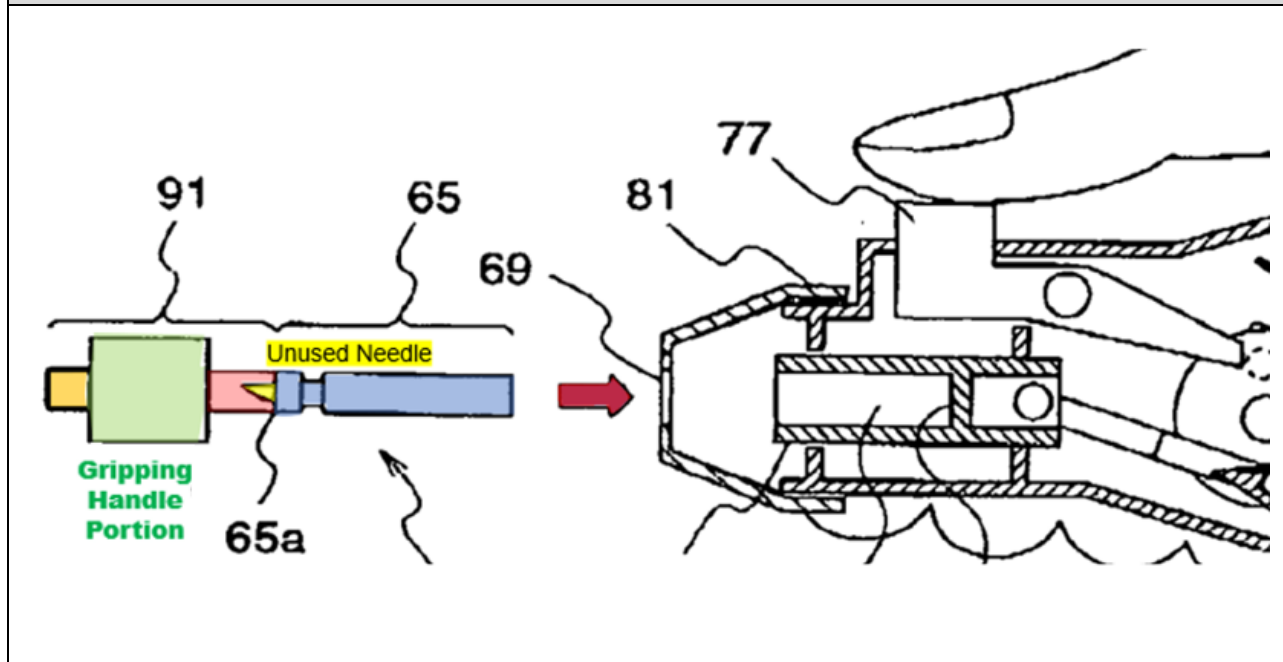
FIG. 8



By 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. Ex.1002, ¶166.

To prepare the puncture needle 65 for use, Iio discloses that the operator must first load the puncture needle into the lancet 61 (lancing device) by pushing the puncture needle unit 90—in the direction of the arrow colored dark blue in Figure 9(a), below—until the puncture needle 65 (light blue) is fully seated within the lancing device 61, as shown in Figure 9(b) further below. Ex.1006, [0106].

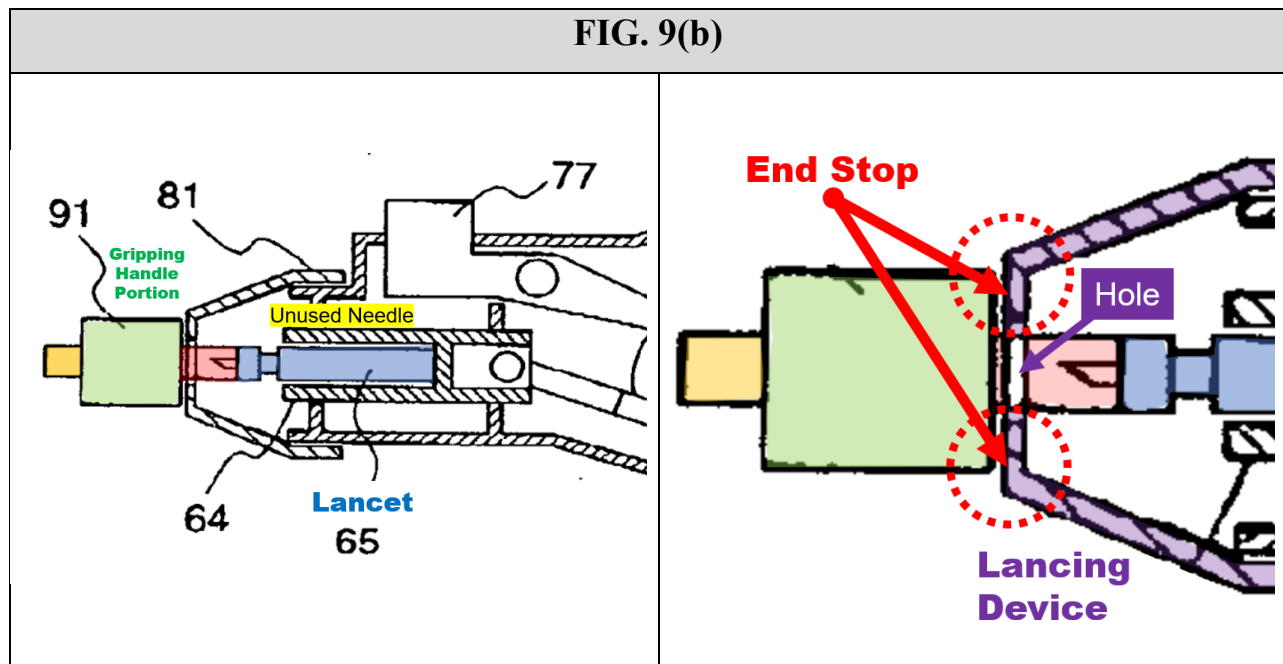
FIG. 9(a)



The operator cannot grip the puncture needle 65 when pushing the puncture needle unit 90 into the lancing device because the puncture needle 65 must be “snugly fitted to the inner wall of the puncture needle fixing hole 70 of the slider 64.” *Id.*

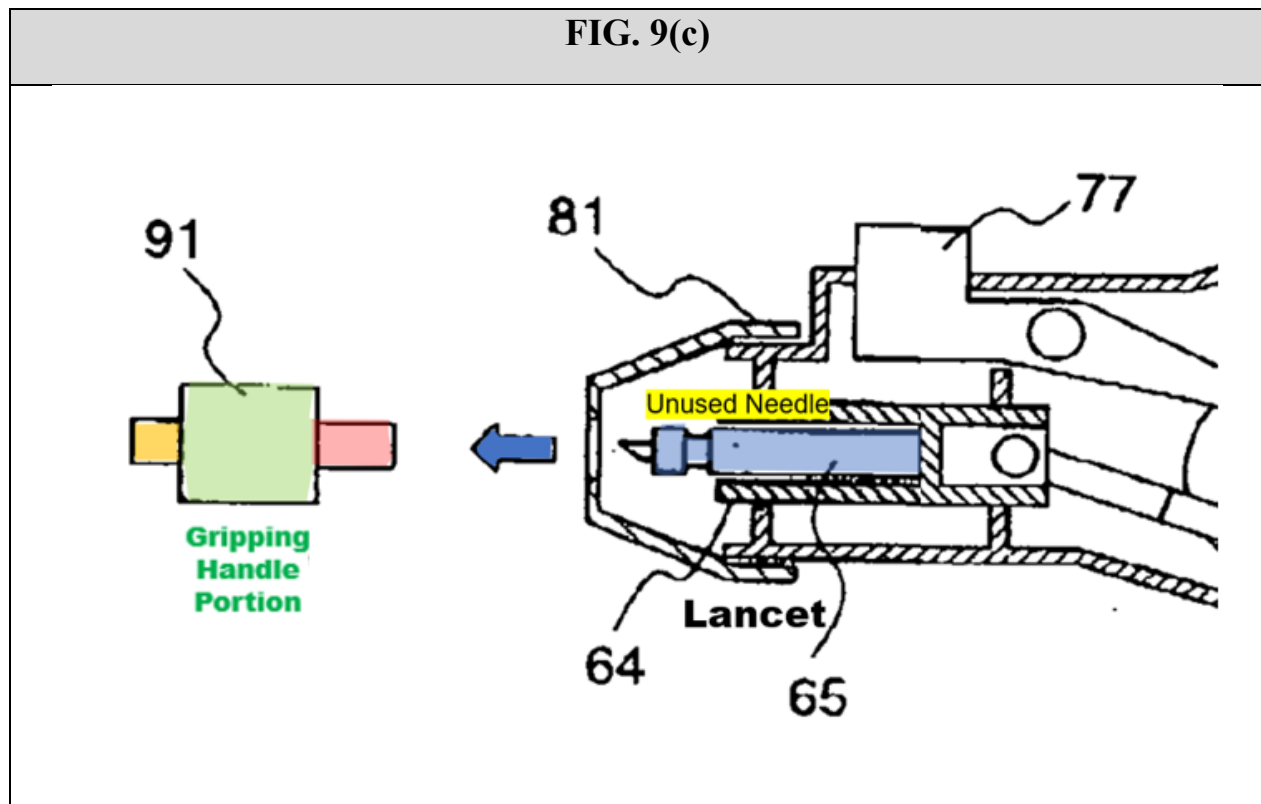
By making the diameter of the gripping portion considerably larger than that of the primary sheath (red), the secondary sheath (orange), and the puncture needle 65 (blue), the cylindrical grip of Iio's puncture needle cap 91 provides the surface area needed for "excellent usability and **handleability**." Ex.1006, [0005].

The larger diameter of the grip also acts as an end stop that “safely set[s] a puncture needle” at the same depth for every puncture, as shown in Figure 9(b) below. *Id.* at [0005], [0023]; Ex.1002, ¶¶168-170.



To expose the sharp tip of the unused needle after it has been snugly fitted within the lancing device, Iio teaches that the operator must simultaneously pull the lancing device 61 with one hand “while twisting the puncture needle unit 90” with the other hand until “the puncture needle 65 [is] separated from the puncture needle cap 91.” Ex.1006, [0106]. As shown below in Figure 9(c), the large diameter of the handle portion of the puncture needle cap 91 provides the gripping

surface needed to twist off the puncture cap 91 from the puncture needle 65 with one hand—while the other hand grips the lancing device. *Id.*, [0004-0006], [0023]; Ex.1002, ¶171.



By extending the length and lateral span of the gripping handle portion of the puncture needle cap 91 and positioning it directly against the lancing device, Iio designed the handle portion to be gripped by the operator when twisting off the puncture needle cap 91 to “ensure excellent usability and handleability with safety.” Ex.1006, [0005], [0007] (explaining that “the puncture needle unit” is

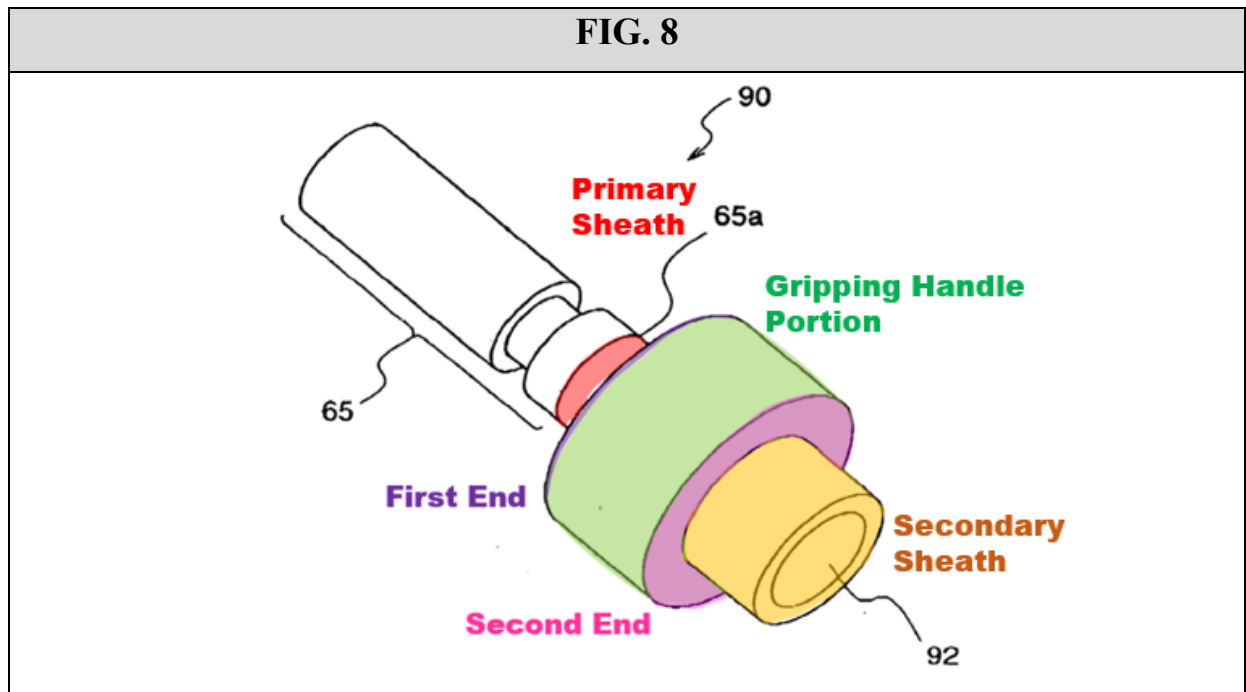
“highly operable and safely **handleable**.”). For this reason, a POSITA would understand that the cylindrical grip of Iio’s puncture needle cap 91, by design, is easy to grip and handle. Ex.1002, ¶173.

Iio therefore discloses “a gripping handle portion extending between the primary sheath and the secondary sheath.” Ex.1002, ¶¶165-174.

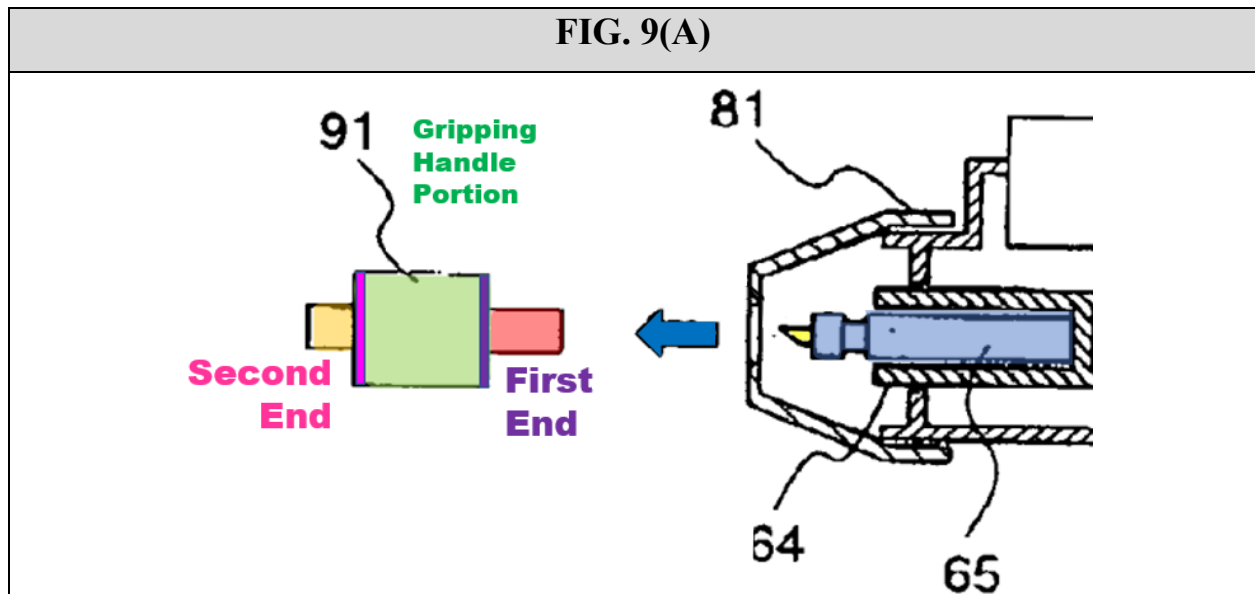
5. Claim 1[d]

Because the gripping handle portion of the 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), each sheath is attached at an opposite end of the gripping handle portion of the protective needle cap 91. Ex.1006, Figs. 8-9(c), [0117] (confirming the “the shaft of the disposal slot 92” is “provided at **an end of the puncture needle cap 91**, the **other end** of which has covered the front end of the puncture needle 65 before [the puncture needle was] used”); *see also id.* claims 19-20, [0025] (“The puncture needle cap is cylindrical in shape, and has protection slots for protecting the puncture needle after performing the puncture operation from the lancet body, which **slots are formed from both of an end and the other end of the cylindrical shape**. Therefore, it is possible to safely discard a used puncture needle.”).

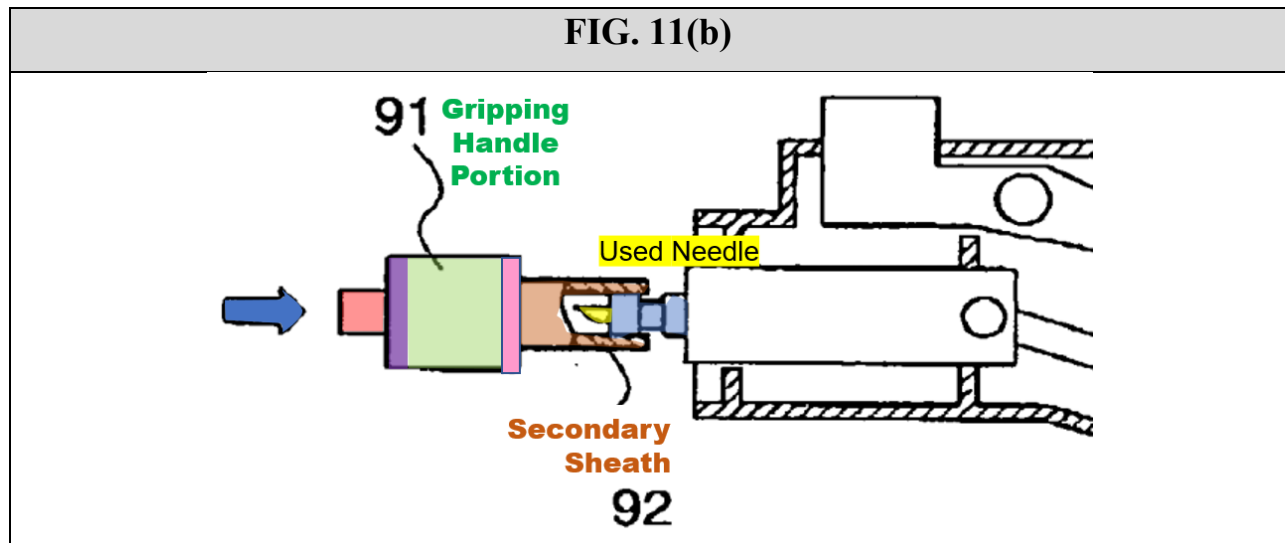
In particular, Iio discloses that the primary sheath is attached to one end of the gripping handle (*i.e.*, a first end, colored purple below) and the secondary sheath is attached to the other end of the gripping handle (*i.e.*, a second end, colored magenta), as illustrated in Figure 8 below. Ex.1002, ¶¶175-176.



Even after the operator separates the puncture needle cap 91 from the puncture needle 65 to expose the unused needle tip, the first and second ends of the gripping handle portion of the puncture needle cap 91 remain attached to the primary and secondary sheaths, respectively. *Id.*, [0047], [0093], [0102-0104]; Ex.1002, ¶177.



The same is true for “discarding the puncture needle 65 after the puncture operation has been completed.” Ex.1006, [0116]. To recap the used lancet, Iio teaches “pressing” the second end of the gripping handle portion towards “the front end of the puncture needle 65” fitted within the lancing device 61 until “the puncture needle 65 is captured into the disposal slot 92 (FIG. 11(b)).” *Id.*, [0117]; Ex.1002, ¶178.



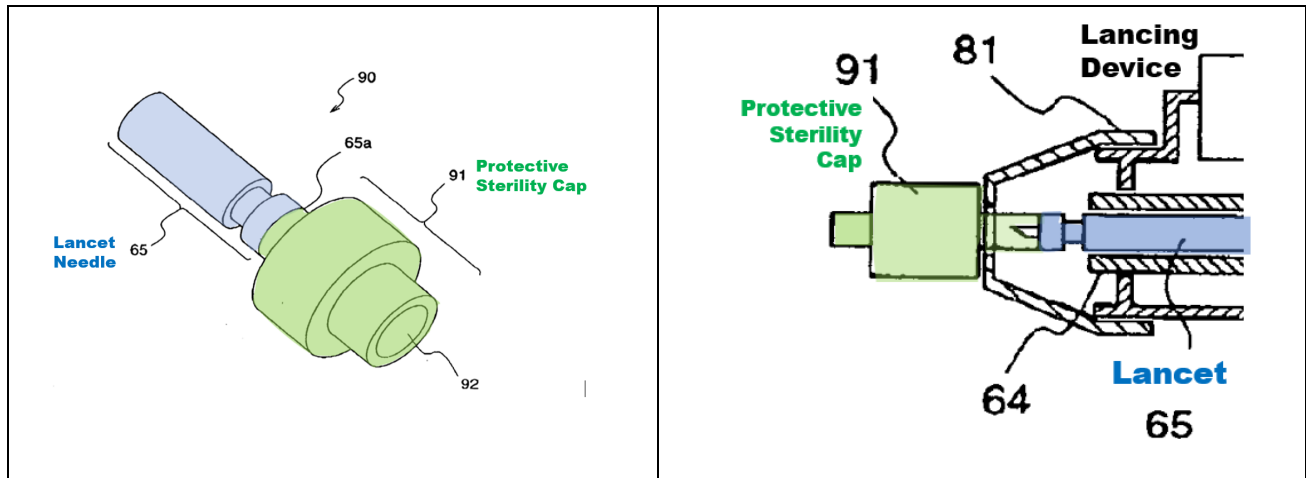
Thus, Iio discloses this limitation.

B. Claim 2 is Anticipated

Iio discloses the protective sterility cap of claim 1 for the reasons discussed in Section XI.A, incorporated here. Those same disclosures likewise anticipate the limitations added by claim 2, including the “puncture needle unit 90” disclosed by Iio, which comprises a lancet (puncture needle 65) combined with a protective sterility cap (puncture needle cap 91), capable of being used with a lancing device for puncturing skin and collecting blood. Ex.1002, ¶181.

FIG. 8

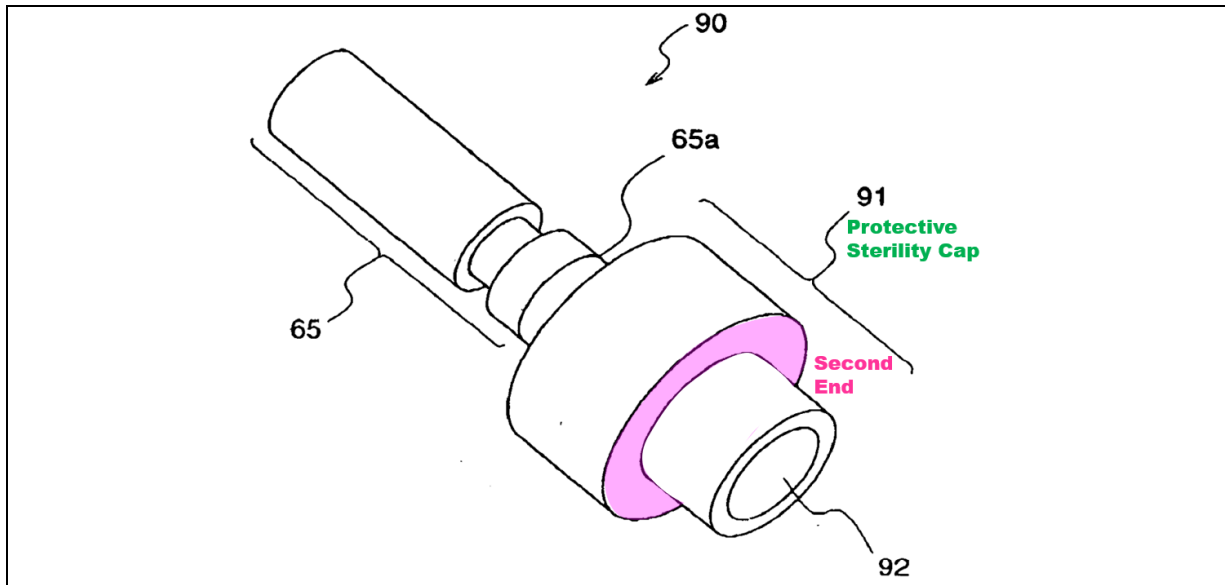
FIG. 9A



C. Claim 3 is Anticipated

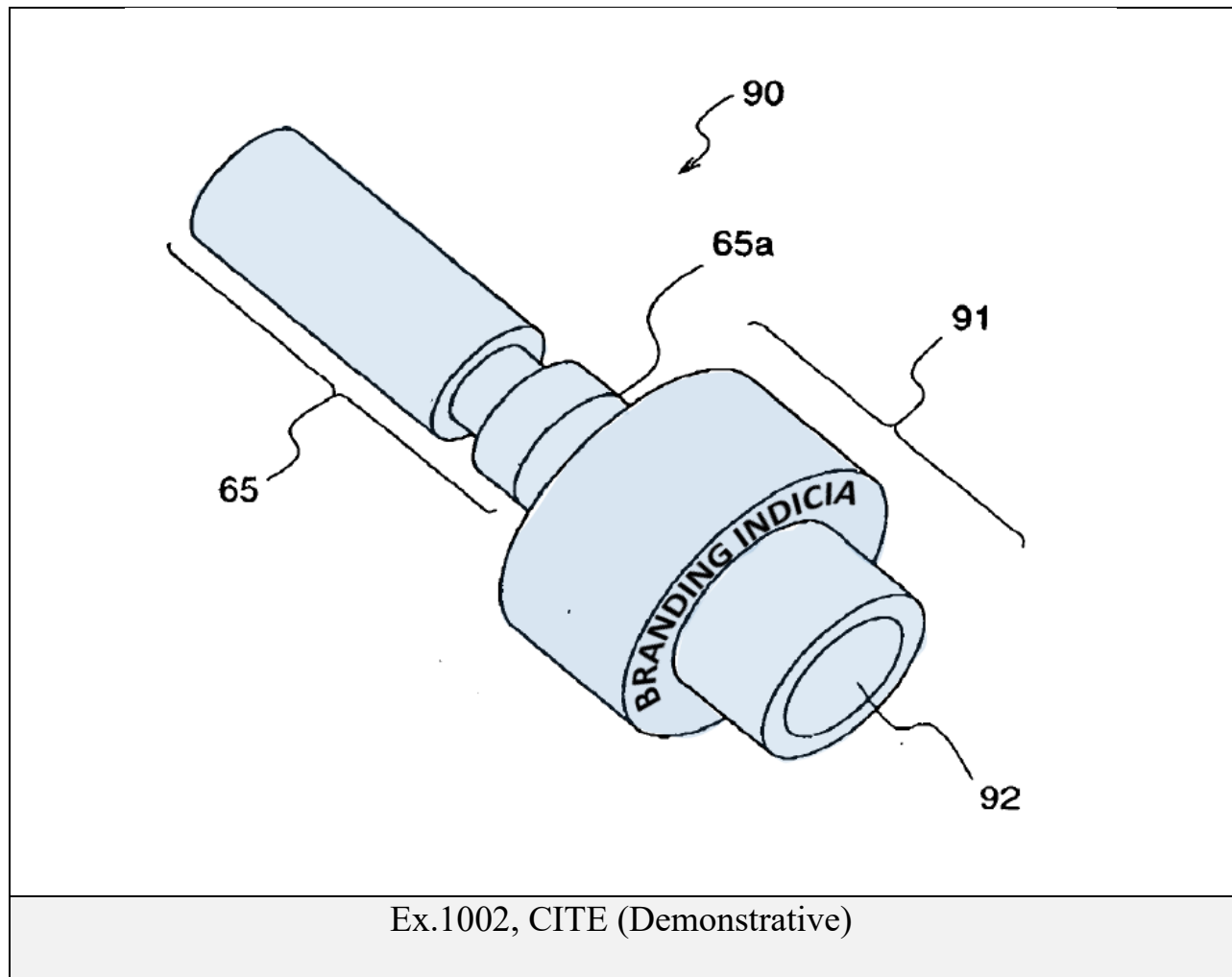
Iio discloses the protective sterility cap of claim 1 for the reasons discussed in Section XI.A, incorporated here. Iio discloses the added limitations of claim 3 by teaching that the protective sterility cap further comprises “at least one flat display surface”—namely, the second end of the gripping handle portion of the puncture needle cap 91, colored and annotated magenta below.

FIG. 8



The 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. *Marrin*, 599 F.3d at 1294.

Even if limiting, Iio discloses a flat surface and this surface could be used for many things, including placing branding indicia, such as the lancet manufacturer’s logo. *See supra* Section VIII.C (Ground 1, Claim 3).

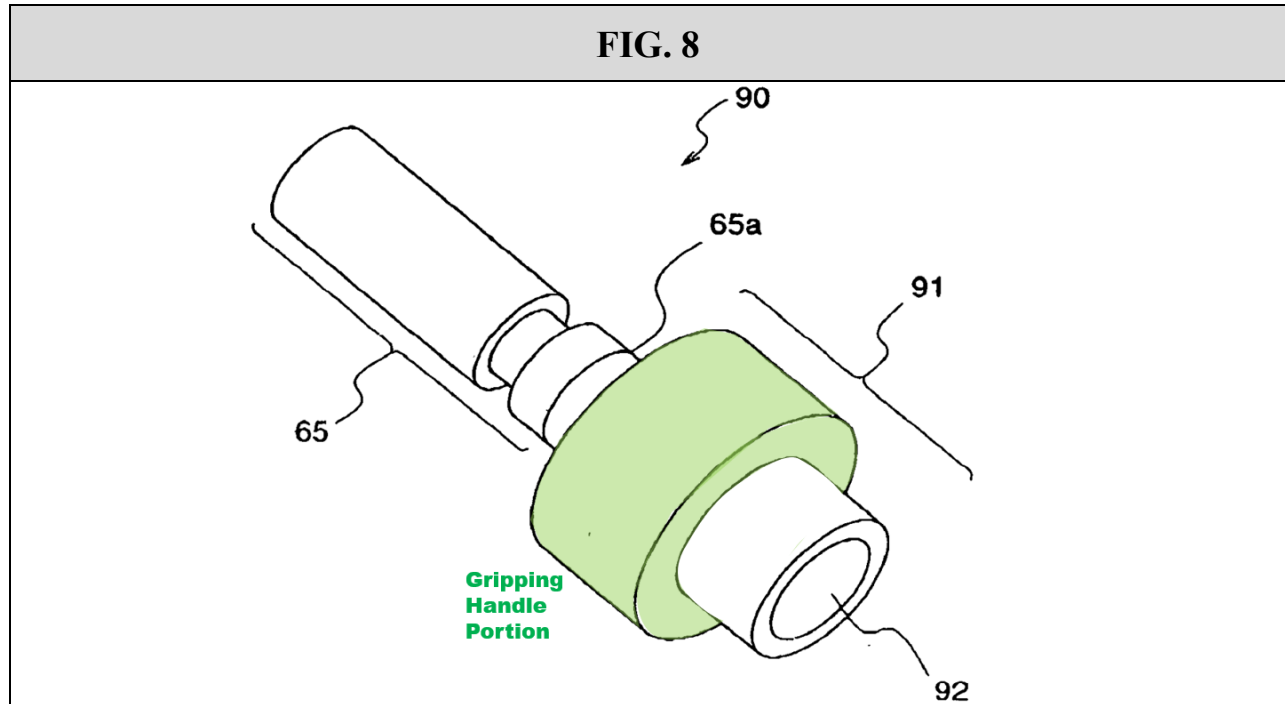


Thus, claim 3 is anticipated. Ex.1002, ¶¶182-183.

D. Claim 5 is Anticipated

Iio discloses the protective sterility cap of claim 1 for the reasons discussed in Section XI.A, incorporated here. Claim 5 depends from claim 1 and adds “wherein the gripping handle portion comprises a solid body without an open loop.” Iio anticipates the added limitations of claim 5 by disclosing a solid

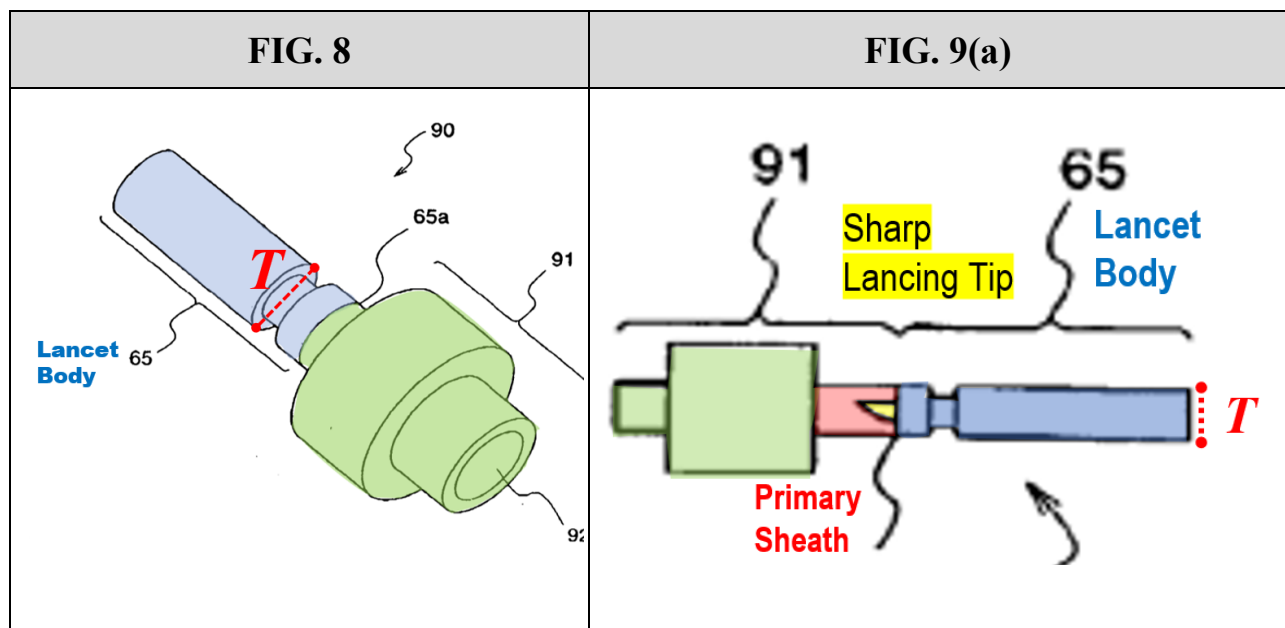
cylindrical gripping handle portion that does not include an open loop as shown, for example, in Figure 8. Ex.1002, ¶184.



E. Claim 6 Is Anticipated

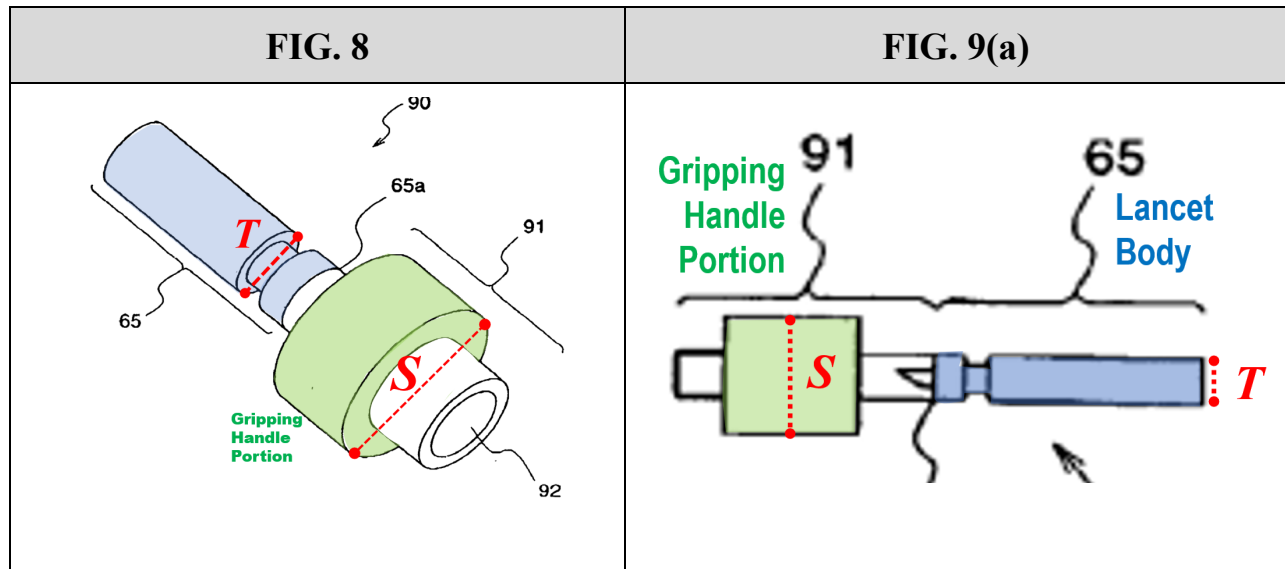
Iio discloses the protective sterility cap of claim 1 for the reasons discussed in Section XI.A, incorporated here. Claim 6 adds: “[a] in combination with a lancet [b] having a lancet body defining a lancet thickness, [c] and a sharp lancet tip initially embedded in the primary sheath, [d] wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.” Each of these elements is disclosed by Iio.

As to elements 6[a]-6[c], in Figure 9(a), Iio discloses its sterility cap “in combination with a lancet [65, blue and yellow below] having a lancet body defining a lancet thickness [“T” below], and a sharp lancet tip [yellow below] initially embedded in the primary sheath.” Ex.1002, ¶186.



As to 6[d]’s limitation of “the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness,” Iio discloses a lateral span for its

gripping handle portion, which is annotated as “S” in the figure below.⁴ Ex.1002, ¶187.



A cursory visual comparison of the gripping handle portion’s lateral span (“S”) with the lancet’s thickness (“T”) shown in Iio’s figures confirms that the “gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.” Ex.1002, ¶188. Iio’s textual descriptions of its primary and secondary sheaths further confirm that these relative proportions in Iio’s figures are essential to Iio’s cap performing as described in the specification. *Id.* For example, Iio

⁴ Lateral span being measured as depicted above for Iio is consistent with how the ’635 Patent depicts lateral span in its Figure 5D.

teaches that “fitting of the puncture needle to the disposal slot [Iio’s secondary sheath] is easier than fitting of the puncture needle to the protection slot [Iio’s primary sheath].” Ex.1006, claim 20, [0026]. 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. Ex.1002, ¶188-189.

These 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. For example, 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. Ex.1002, ¶190 (noting that this “further supports my opinion that a PHOSITA 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 on comparing

of the size of the user's thumb to each of the lancet thickness, lateral span, and length of Iio's gripping handle portion").

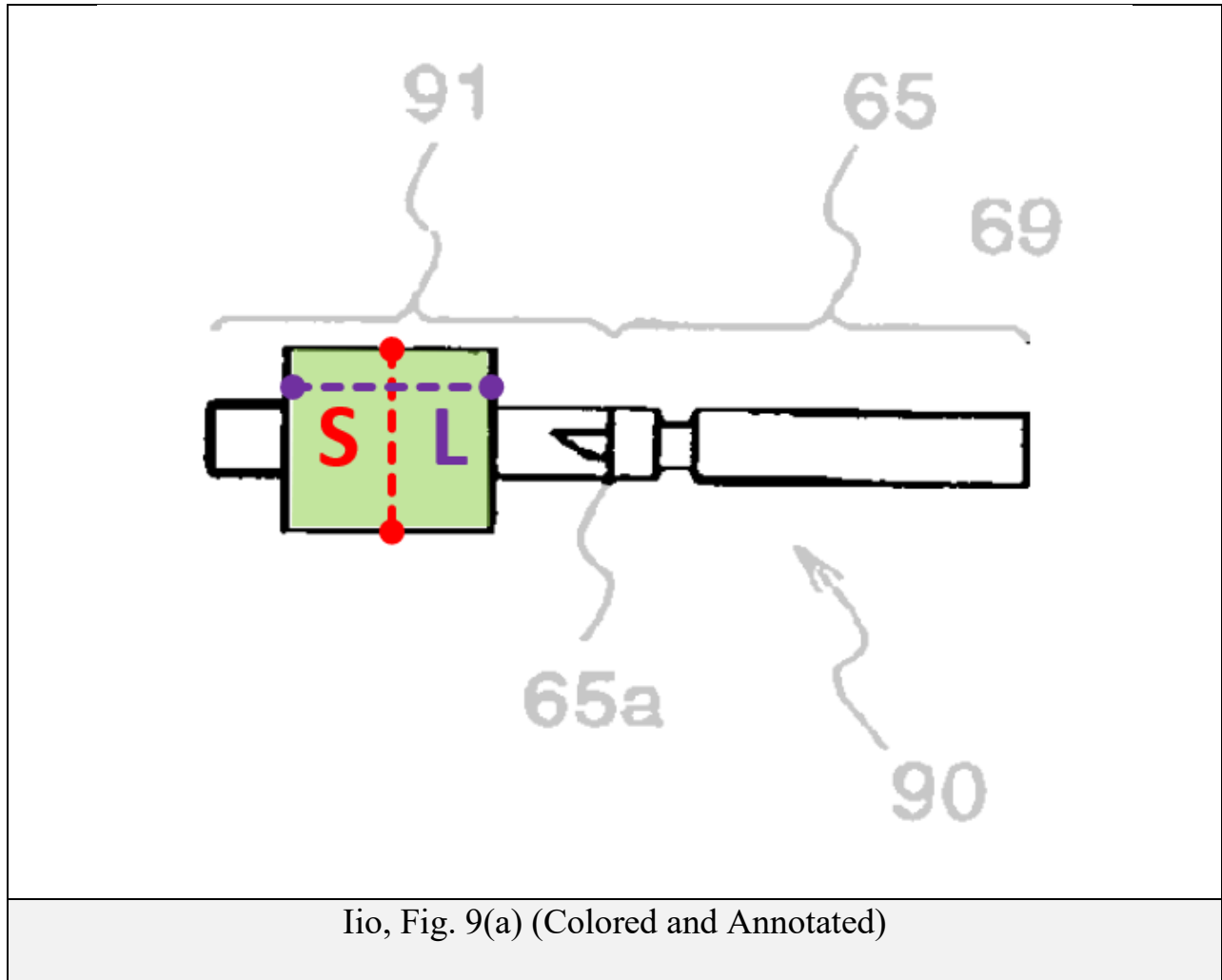
Beyond this, Iio textually describes a specific thickness for "a thin plastic film having a thickness of 0.1 mm or less in the puncture needle separation groove." Ex.1006, [0104]. Knowing this dimension, a PHOSITA could visually discern that the lancet thickness is around 5 times thicker than the depicted 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. Ex.1002, ¶191. Considering these disclosures, in conjunction with all the other reasons offered above, a PHOSITA would have understood that Iio's gripping handle portion has a lateral span of at least 1.5 times the lancet thickness.

For at least these reasons, claim 6 is anticipated. Ex.1002, ¶¶185-192.

F. Claim 7 is Anticipated

Iio discloses the protective sterility cap of claim 6 for the reasons discussed in Section XI.E, incorporated here. Those same disclosures likewise disclose the limitations of claim 7 by showing that "the gripping handle portion

defines a length at least equal to its lateral span,” annotated below as “L” and “S,” respectively. Ex.1002, ¶193.

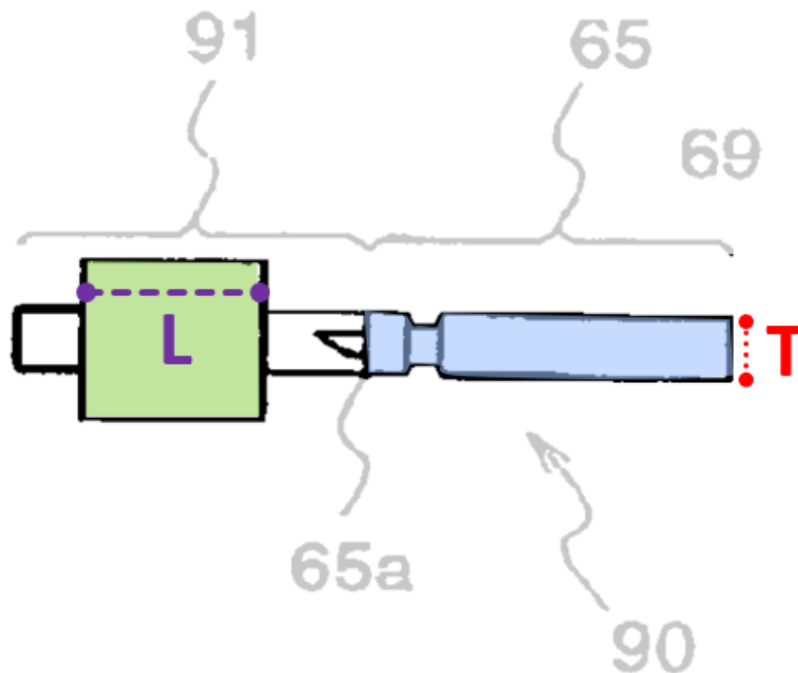


These depictions are also consistent with Iio’s repeated descriptions of a “highly operable and safely handleable” puncture needle unit that may be “handled more safely.” (*see, e.g.*, Ex.1006, [0029], [0030]). A longer gripping handle portion, with a length at least equal to its lateral span, helps to achieve these goals

and ensure that users are able to safely handle the puncture needle unit. Ex.1002, ¶¶193-195. Claim 7 is anticipated.

G. Claim 8 Is Anticipated

Iio discloses the protective sterility cap of claims 6 and 14 for the reasons discussed in Sections XI.E, XI.C, incorporated here. Those same disclosures likewise disclose the added limitations of claim 8, by showing that “the gripping handle portion defines a length at least equal to (including larger than, as shown in Iio) the lancet thickness,” annotated below as “L” and “T,” respectively.



Iio, Fig. 9(a) (Colored and Annotated)

Iio's visual depictions also show that Iio's gripping handle portion is larger than the outer diameter of the secondary sheath in Iio and the inner diameter of the secondary sheath is large enough to receive the entire thickness of the lancet body. Thus, because the length of Iio's gripping handle portion is at least equal to its lateral span (as was discussed above) and because the entire thickness of the lance body fits within the inner diameter of the secondary sheath (which is smaller than both the length and lateral span of the gripping handle portion in Iio), a PHOSITA would understand that the length of Iio's gripping handle portion is at least equal to the lancet thickness. Ex.1002, ¶¶196-197. Claim 8 is therefore anticipated.

H. Claim 14 is Anticipated

Claim 14 includes limitations analogous in scope to limitations 1[pre]-1[d], and those are disclosed by Iio for reasons provided above and incorporated here (*supra* Section XI.A.1-5). Claim 14 also includes limitations analogous in scope to those found in claim 6, and those are disclosed by Iio for reasons provided above and incorporated here (*supra* Section XI.E). Ex.1002, ¶198.

I. Claim 16 is Anticipated

Claim 16 depends from claim 14, which is anticipated by Iio for reasons provided above and incorporated here (*supra* Section XI.H). The additional

limitations of claim 16 correspond in scope to those found in claim 3, and those additional limitations are disclosed for the same reasons (*supra* Section XI.C).

Ex.1002, ¶199.

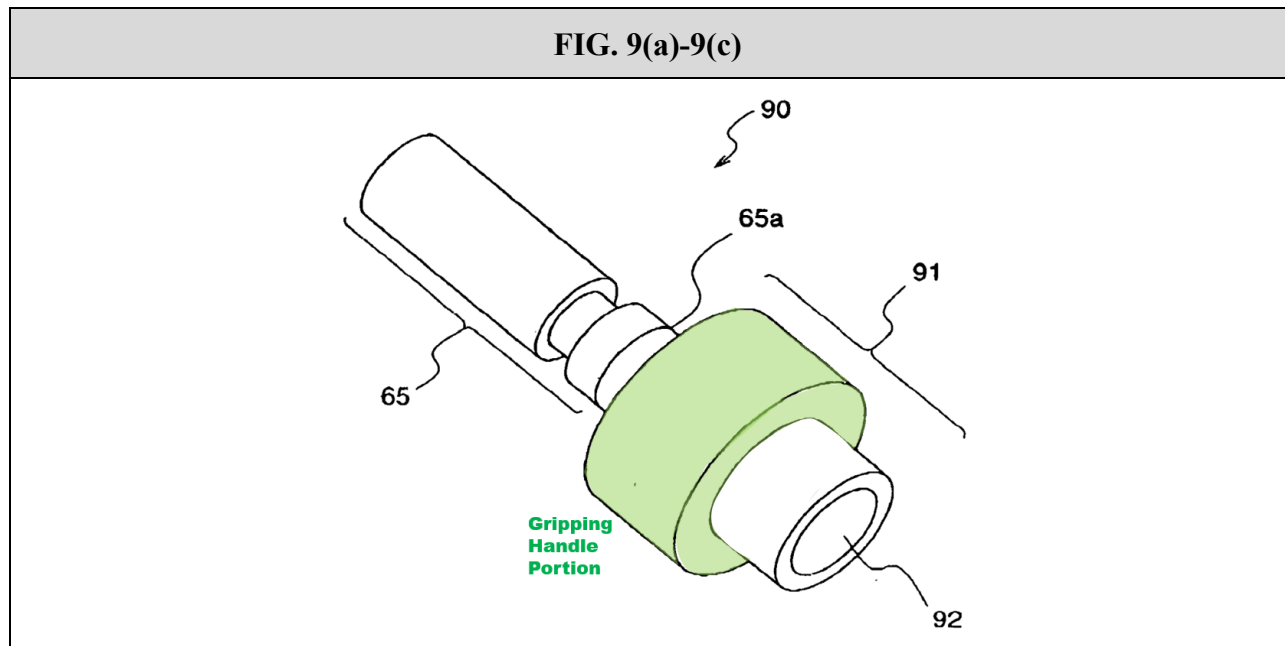
J. Claims 17 and 18 are Anticipated

Claims 17 and 18 depend from claim 14, which is anticipated by Saikley for reasons provided above and incorporated here (*supra* Section XI.H). The additional limitations of claim 17 correspond in scope to those found in claim 7, and those additional limitations are disclosed for the same reasons (*supra* Section XI.F). The additional limitations of claim 18 correspond in scope to those found in claim 8, and those additional limitations are disclosed for the same reasons (*supra* Section XI.G). Ex.1002, ¶200.

XII GROUND #5: IIO IN VIEW OF PECKHAM RENDERS OBVIOUS CLAIMS 1-3, 5-8, 14, 16-18

A. All Claims: “Gripping Handle Portion”

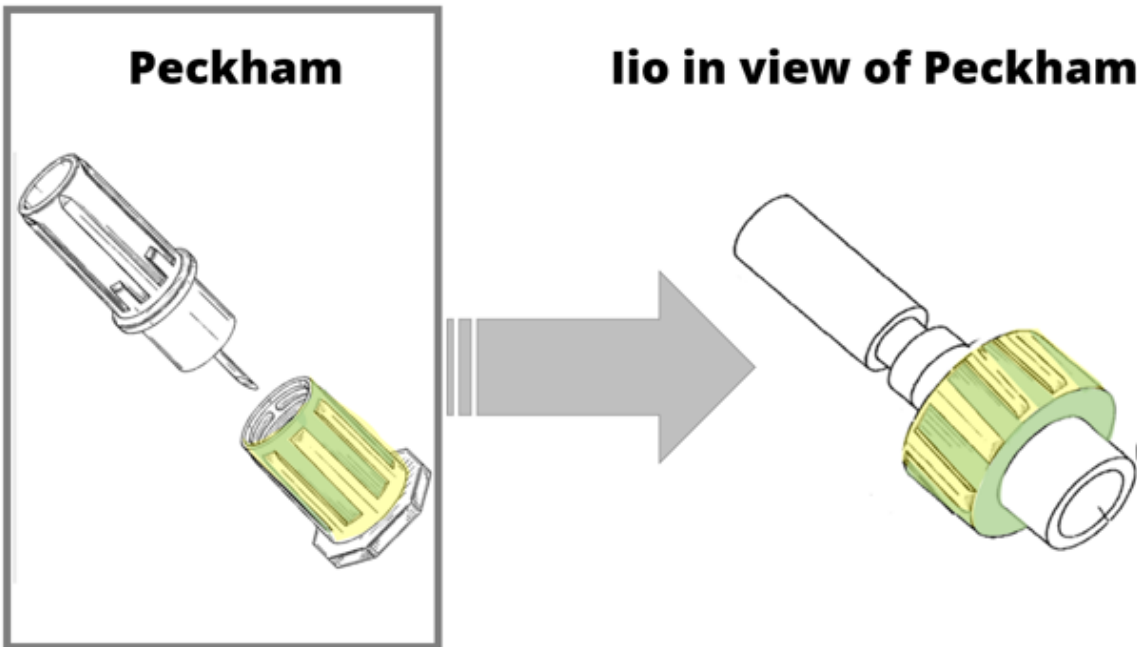
As shown above in Section XI.A.4, incorporated here, Iio’s puncture needle unit 91 includes a cylindrical grip (green below), which a PHOSITA would have recognized provides the user with “excellent usability and handleability.” Ex.1006, [0005].



A PHOSITA would appreciate that this cylindrical handle has end stops that “safely set[] a puncture needle” at the same depth before every puncture. Ex.1002, 202; Ex.1006, [0005]. A PHOSITA would understand that this cylindrical handle has the size and proportions to make it easier to grasp and “*twist[]* the puncture needle unit 90” until “the puncture needle 65 [is] separated from the puncture needle cap 91,” and to “pull[] out the lancet” and “discard it safely and easily without exposing the front end of the puncture needle.” Ex.1006, ¶¶ [0005], [0023], [106].

Should the Board find that a PHOSITA would not have understood the cylindrical grip on Iio’s lancet cap to be a “gripping handle portion,” as recited in

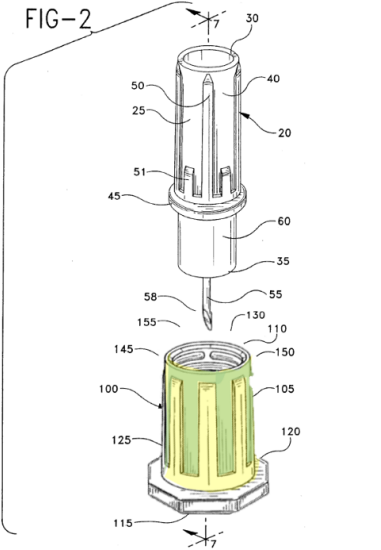
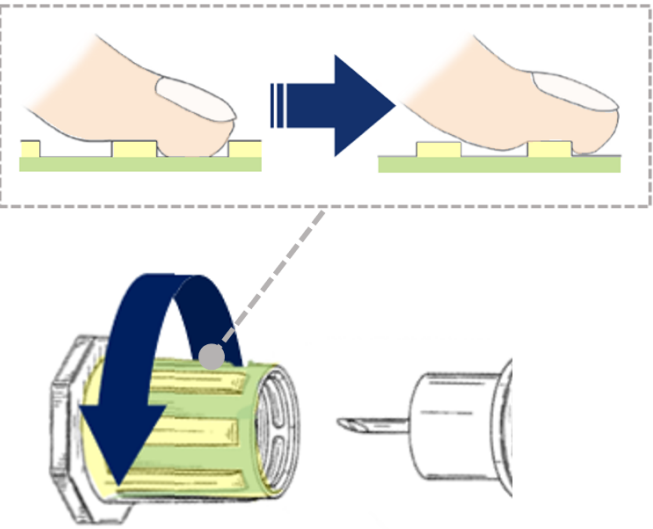
the challenged '635 Patent claims, then Petitioners alternatively contend that Iio renders obvious the challenged claims in light of Peckham.



Specifically, Peckham discloses a protective sterility cap 100 with a “cylindrical housing 105” that “includes a plurality of longitudinal ribs or splines 125 [*colored yellow in Fig. 2 below*] on housing 105 that extend from octagonal shaped flange 120 toward open end 110.” CITE. Peckham expressly teaches that the “[r]ibs 125 provide a sufficient **textured surface to improve handling** and

maneuverability of cap 100, when it is being removed from lancet assembly 20.”

Ex.1008, 3:13-15; Ex.1002, ¶¶203-204.

	
Peckham Fig. 2	Ex. 1002, ¶204 (Demonstrative)

Ample motivation existed for a PHOSITA to apply the ribbed design from Peckham’s protective cap 100 to the cylindrical handle on Ilo’s puncture needle unit (in the manner graphically demonstrated below), and thereby “provide a sufficient textured surface to improve handling and maneuverability of [Ilo’s puncture needle unit],” particularly “when it is being removed from lancet assembly 20.” Ex.1008, 3:13-15.

Thus, Iio in view of Peckham renders obvious the challenged claims. Ex. 1002, ¶¶202-206.

B. Claims 6-8, 14, and 17-18: The “Length and “Lateral Span” of the Gripping Handle Portion

As was explained above (*supra* Sections XI.E-H, XI.J, incorporated here), Iio anticipates the relative dimensional aspects of these claims.

Should 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, as is explained below. Inadvertent needle sticks were a well-recognized problem in the art, particularly when “attaching or detaching the puncture needle to/from the lancet Ex.1006, [0004].

This well-recognized problem 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. Ex.1002, ¶208. A PHOSITA 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. A PHOSITA 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.* And when provided with Iio’s instruction to “ensure excellent usability and handleability with safety” (Ex.1006, [0005]), a PHOSITA would have focused on designing larger gripping handle portions to achieve these handleability, usability, and safety goals. *Id.*

In designing larger gripping handle portions, a PHOSITA 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 PHOSITA 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.* The relative-dimensional limitation in claims 6 and 14 are, therefore, obvious.

Given the motivation and reasonable expectation of success discussed above to arrive at a lateral span of at least 1.5 times the lancet thickness for the modified Iio device, it similarly would have been obvious to have the gripping handle's length at least equal to its lateral span (recited in claims 7 and 17). The gripping handle portion in Iio is already cylindrically-shaped and designing such a cylindrical shape to have equal lateral span and length dimensions is commonplace. Ex.1002, ¶210. A PHOSITA would be motivated to try these relative dimensions to help achieve the handleability, usability, and safety goals articulated in Iio. Because the gripping handle portion would have needed to be easily held by a user's thumb and one of their digits, a PHOSITA would recognize that this would be more easily done with a longer handle than with a shorter handle that might slip out of the user's grip. Having the length of that cylindrically-shaped gripping handle portion at least equal to its lateral span would have been a natural option that a PHOSITA would have attempted with a reasonable expectation of success. *Id.*

Since there was a motivation and a reasonable expectation of success in having the lateral span of Iio's gripping handle portion be at least 1.5 times the lancet thickness and also in having the length of Iio's gripping handle portion be at

least equal to the lateral span, then it also would have been a natural and obvious choice to modify Iio's device so that the gripping handle's length would be at least equal to the lancet thickness (as recited in claims 8 and 18), Ex.1002, ¶211. For the above reasons, claims 6-8, 14, and 17-18 are obvious. *Id.*, ¶¶207-212.

Beyond the rationales articulated above, it also would have been obvious to add extra gripping features as taught by Peckham to Iio's sterility cap. This would have led a PHOSITA 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. In particular, this would have furthered Peckham's goals of providing "good grip" for the user, and thus these relative-dimensional limitations would have been satisfied by the combination of Iio and Peckham. Ex.1002, ¶213. Thus, once Peckham's gripping features were incorporated into Iio's device, this combination would have included all limitations of claims 6-8, 14, and 17-18. *Id.*

C. Ample Motivation Existed to Combine Iio with Peckham

A PHOSITA would have been motivated to combine Iio and Peckham for the following reasons. Ex.1002, ¶¶214-226. A PHOSITA would have appreciated that Iio and Peckham are within **the same field of endeavor** and **address the same**

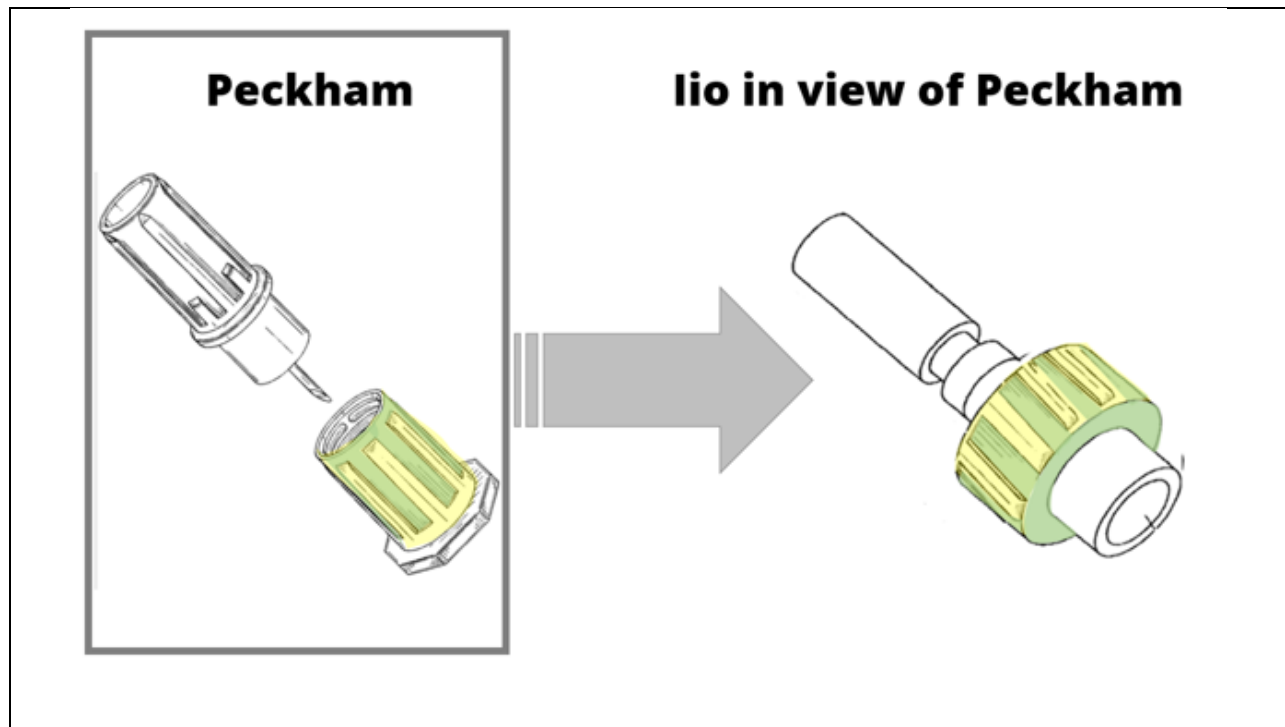
problem. *See In re Bigio*, 381 F.3d at 1325. The Technical Field of the '635 Patent is directed to “lancets and lancing devices for blood sampling and testing.” Ex.1001, 1:18-19. Both Iio and Peckham relate to lancets for blood collection. Ex.1006, [0001]; Ex.1008, 1:5-8.

At minimum, Iio and Peckham relate to a problem identified in the '635 Patent. The '635 Patent provides for a “sterility cap or cover” for a lancet “with a **handle or grip portion for assisting**” in removal or replacement of the cap. Ex.1001, 1:66-2:2. Both Iio and Peckham disclose solutions which assist patients with handling lancets. The object of Iio is to provide for a lancet with “**excellent usability and handleability** with safety,” while Peckham provides a “novel textured surface to **improve handling, maneuverability** and fit” when the lancet is mounted in a lancing device. Ex.1006, [0005]; Ex.1008, 2:67-3:2. Iio specifically teaches a lancet where its relative size, proportions, and shape make it easier to “twist[] the puncture needle unit 90” until the “puncture needle 65 [is] separated from the puncture needle cap 91.” Ex.1006, [106]. Similarly, Peckham teaches a lancet with “ribs” on the outer wall of the lancet which “provide a sufficient textured surface to improve handling and maneuverability of cap 100 [] when it is being removed from lancet assembly 20.” Ex.1008, 3:13-15. Thus, Iio

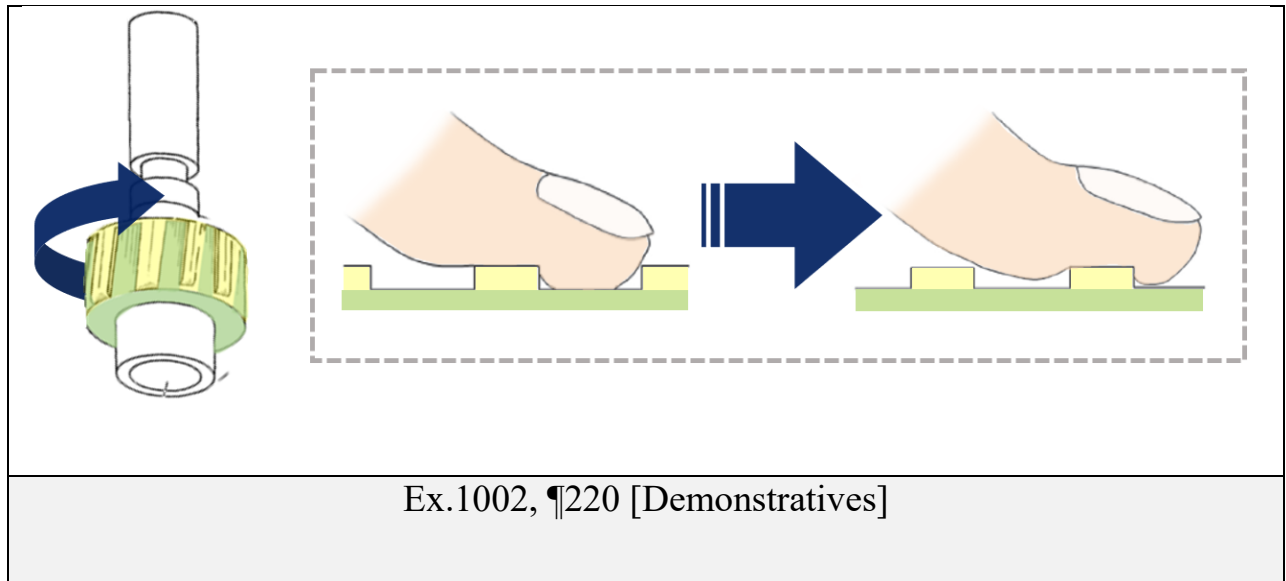
and Peckham disclose inventions in the same field of endeavor as the '635 Patent that also address one of the problems identified by the '635 Patent.

Iio also provides ample motivation for a PHOSITA to specifically modify the protective cap of the puncture needle unit 90. Ex. 1002, ¶217. Iio expressly states that “[t]he shape of the puncture needle cap of the puncture needle unit 90 is not restricted to [the second embodiment] shown in FIG. 8.” Ex.1006, [0102]. Iio further teaches that the “detailed description and specific embodiments described are provided only for illustration” and acknowledges that “various additions and modifications” to those embodiments “*will be apparent* to those of skill in the art from the detailed description.” Ex. 1006, [0006]; Ex.1002, ¶218. It would have been apparent to a PHOSITA that Peckham’s ribs are an addition or modification that could be made to improve the handling and maneuverability of Iio’s cap. Ex. 1002, ¶218.

Second, ample motivation existed for a PHOSITA to incorporate the longitudinal ribs (*highlighted yellow below*) from the cylindrical grips or handle portion of Peckham’s lancet cap into the cylindrical grips or handle portion of Iio’s lancet cap, as illustrated below. *See also* Ex.1002, ¶¶219-226.



While Iio does not disclose the use of a textured surface to improve “useability and handleability” of a lancet, a PHOSITA would have recognized that the Iio’s cap could be improved by the addition of such a gripping texture. In industrial design, ribbed patterns are routinely used to increase finger friction and thereby improve grip. Ex.1002, ¶220. When a user’s finger moves over the ribbed surface, friction increases as the rib height or width increases. *Id.*



A PHOSITA would have recognized that these common industrial design techniques had been applied to an analogous pull-top lancet in Peckham. Peckham teaches how having “molded-in longitudinal splines” on the “exterior of the [lancet] housing [makes] the housing easier to handle and manipulate.” Ex.1008, 2:7-10. Peckham also explains that the “longitudinal ribs or splines” can be “alternate[d] around” the outer wall of the lancet “to provide a novel textured surface to improve handling, maneuverability and fit.” *Id.*, 2:64-3:2. In view of these well-known industrial design concepts and Peckham’s specific teaching how to apply them to a lancet, it would have been obvious to a PHOSITA to improve the grip of Iio’s cylindrical handle by adding a ribbed surface texture. Ex.1002, ¶221.

A PHOSITA would have combined Iio's cylindrical handle with Peckham's surface texture ribs to achieve predictable results. Ridges were a well-known and conventional structure for improving the grip on handles. *Id.*, ¶222. A wide variety of products, such as toothpaste caps and the twist-on wire-nut seen below, implemented ridges as a surface texture to make the product easy to grip. *Id.*

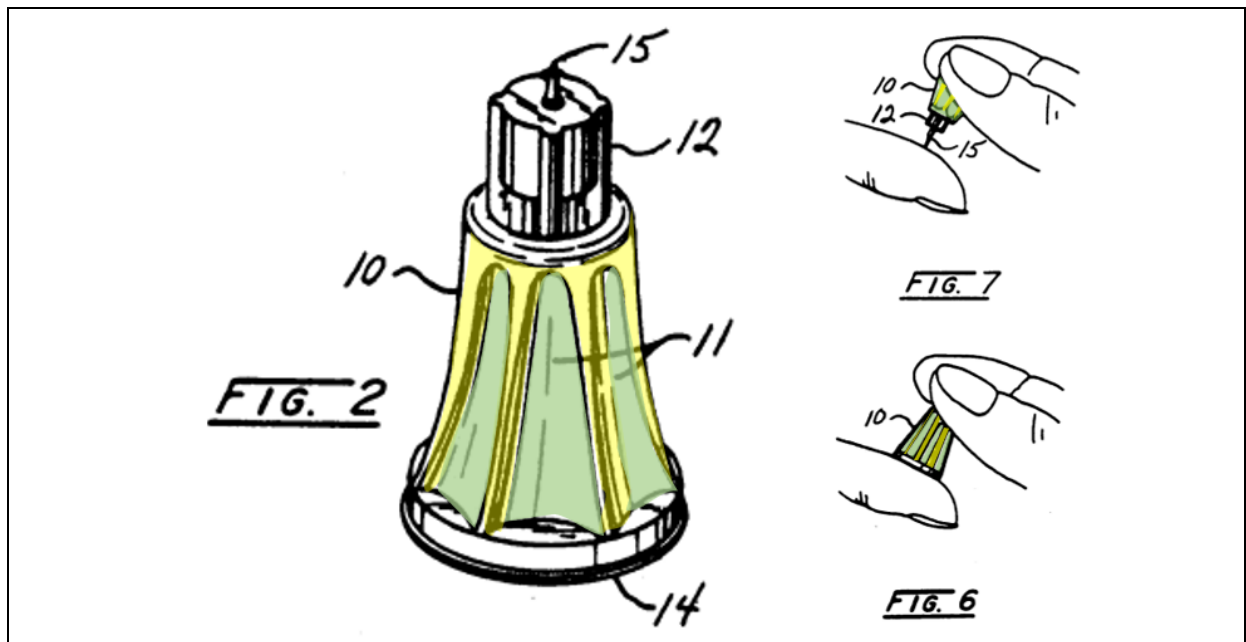


A PHOSITA would have been further motivated to combine Iio and Peckham because such a combination would be commercially desirable. When

designing a product, cost is a critical consideration. Ex.1002, ¶224. For disposable items like lancets, it is preferable to keep material costs to a minimum.

Id. Ribs are an inexpensive and economical solution for adding surface texture and improving grip for small, disposable items. *Id.*

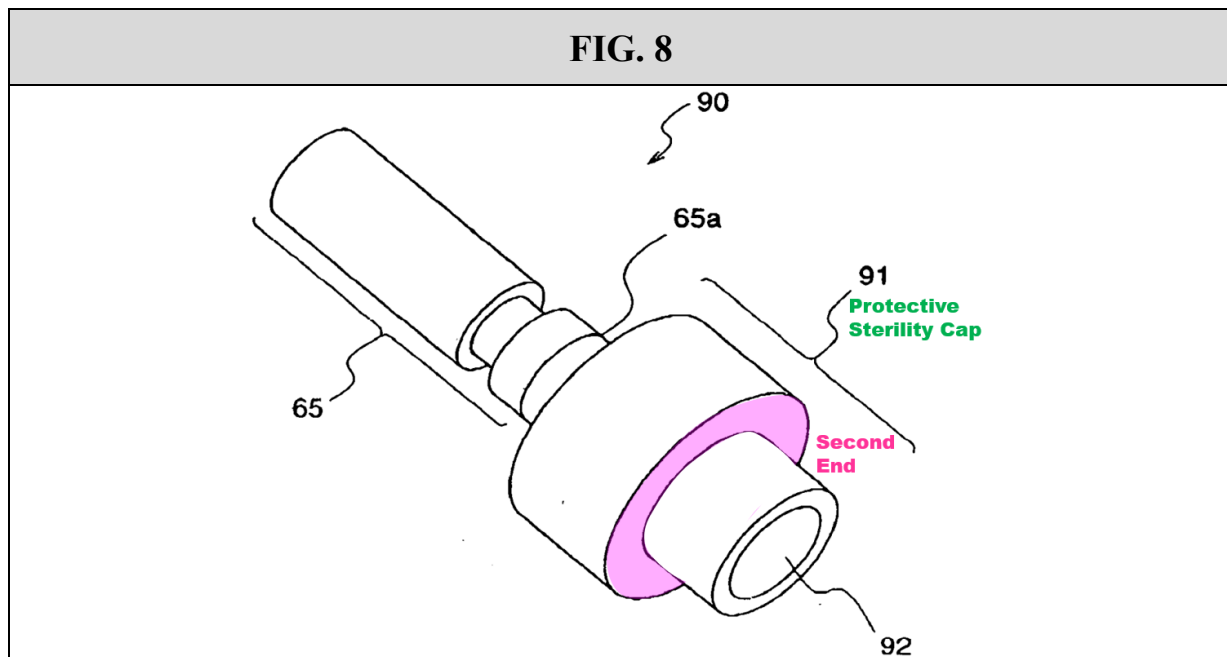
Finally, a PHOSITA would have had a reasonable expectation of success in combining the teachings of Iio and Peckham. The solution of such a combination was well-known at the time. Ex.1002, ¶225. Conventional lancets and lancing devices implemented ridges on surfaces meant to be gripped by users. Ex.1024, 2:47-49 (disclosing a lancet protective cap with a plurality of “depressed *finger engaging* portions 11—11” which “provid[e] a *good grip for the user*”).



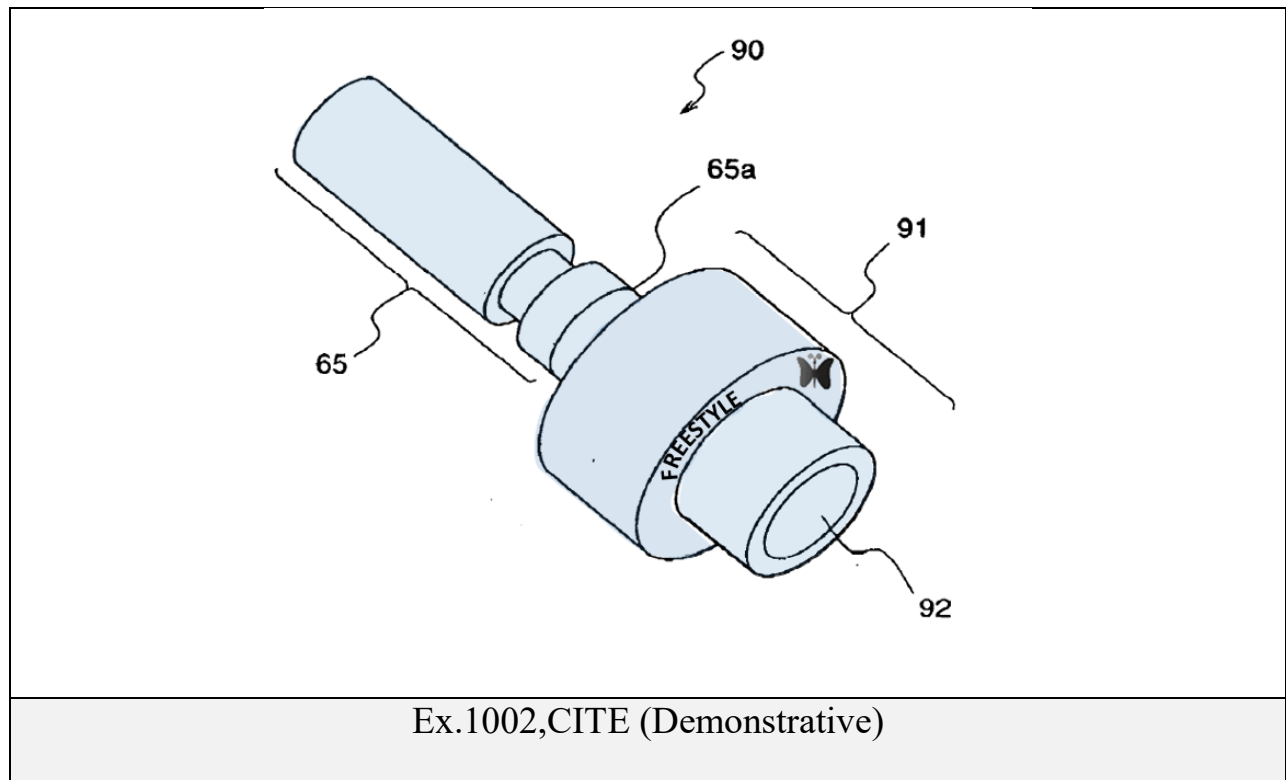
As such, it would have been straightforward for a PHOSITA to improve the grip of Iio's cylindrical handle with Peckham's ribbed surface texture and know that such a combination would be feasible. Ex.1002, ¶225-226.

**XIII GROUND #6: IIO IN VIEW OF THE FREESTYLE MANUAL
RENDERS OBVIOUS CLAIMS 3 AND 16**

As was explained earlier, Iio anticipates claims 3 and 16 by disclosing the flat surface of the cylindrical gripping handle (*colored magenta in Figure 8 below*) because the remainder of the limitation—*i.e.*, “for placement of branding indicia thereon”—merely recites an intended use and, therefore, is not entitled to patentable weight. *Marrin*, 599 F.3d at 1294.



Should 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. This combination would be obvious for the same reasons set forth in Section X (Ground 3).



Claims 3 and 6 are therefore obvious. Ex.1002, ¶¶227-229.

XIV NO SECONDARY CONSIDERATION SUPPORT NON-OBVIOUSNESS

There is no indication that the Examiner relied on any secondary considerations when allowing the claims to issue. This petition is not required to

address any purported secondary considerations and the Board should, as it has done before, institute trial to address any new evidence Patent Owner might offer. *See, e.g., Zurn Industries, LLC v. Sioux Chief MFG. Co., Inc.*, IPR2018-00975, Paper 9 at 39 (PTAB Nov. 8, 2018).

XV CONCLUSION

For the foregoing reasons, trial should be instituted to cancel the Challenged Claims.

Dated: March 20, 2023

Respectfully submitted,

/ Michael J. Lyons /
MORGAN LEWIS & BOCKIUS LLP
Michael J. Lyons
Alexander B. Stein

CARTER LEDYARD & MILBURN LLP
Gerald W. Griffin
pro hac vice pending

Attorneys for LifeScan, Inc.

U.S. PATENT NO. 8,840,635 – Listing of Challenged Claims

Claim No.	Claim Limitations
1[preamble]	A protective sterility cap for a lancet, said sterility cap comprising
1[a]	a primary sheath for initial embodiment of a sharp lancing tip of an unused lancet therein,
1[b]	a secondary sheath for receiving the sharp lancing tip of a used lancet,
1[c]	and a gripping handle portion extending between the primary sheath and the secondary sheath,
1[d]	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.
2	The protective sterility cap of claim 1, in combination with a lancet.
3	The protective sterility cap of claim 1, further comprising at least one flat display surface for placement of branding indicia thereon.
5	The protective sterility cap of claim 1, wherein the gripping handle portion comprises a solid body without an open loop.
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.
7	The protective sterility cap of claim 6, wherein the gripping handle portion defines a length at least equal to its lateral span.
8	The protective sterility cap of claim 6, wherein the gripping handle portion defines a length at least equal to the lancet thickness.
14	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, said protective sterility cap being 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.
16	The protective sterility cap of claim 14, further comprising at least one flat display surface for placement of branding indicia thereon.
17	The protective sterility cap of claim 14, wherein the gripping handle portion defines a length at least equal to its lateral span.
18	The protective sterility cap of claim 14, wherein the gripping handle portion defines a length at least equal to the lancet thickness.

CERTIFICATION OF COMPLIANCE WITH TYPE-VOLUME LIMITS

This Petition includes 13,996 words, as counted by Microsoft Word, and is therefore in compliance with the 14,000-word limit established by 37 C.F.R. 42.24(a)(1)(i). Accordingly, pursuant to 37 C.F.R. 42.24(d), lead counsel for Petitioner hereby certifies that this Petition complies with the applicable type-volume limits.

Dated: March 20, 2023

Respectfully Submitted,

/ Michael J. Lyons /

Michael J. Lyons, Reg. No. 37,386

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(b), I certify that I caused to be served a true and correct copy of the foregoing: Power of Attorney, Petition for *Inter Partes* Review of U.S. Patent No. 8,840,635 and the exhibits cited therein by Federal Express on this day, March 20, 2023, on Patent Owner's correspondence address of record for the subject patent as follows:

GARDNER GROFF & GREENWALD, PC
1640 Powers Ferry Road
Building 4, Suite 200
Marietta, GA 30067

A courtesy copy of this Petition and supporting exhibits was also served via email on March 20, 2023 on Patent Owner's counsel of record in the district court litigation involving this patent.

jeff.homrig@lw.com	madeleine.ball@lw.com
adamond@diamondmccarthy.com	rachel.cohen@lw.com
bw@witkowlaw.com	ryan.banks@lw.com
damion.robinson@diamondmccarthy.com	saishruti.mutneja@lw.com
jessica.lam@lw.com	susan.tull@lw.com
julian.cokic@diamondmccarthy.com	

Petition for IPR of U.S. Patent No. 8,840,635
Case No. IPR2023-00712

Dated: March 20, 2023

Respectfully Submitted,

/ Michael J. Lyons /

Michael J. Lyons, Reg. No. 37,386