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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION**

FACET TECHNOLOGIES, LLC,

Plaintiff,

vs.

LIFESCAN, INC.,

Defendant.

Case No. 2:22-cv-01717-MCS
(MARx)

**MEMORANDUM OF POINTS
AND AUTHORITIES IN
SUPPORT OF LIFESCAN, INC.'S
MOTION FOR SUMMARY
JUDGMENT OF INVALIDITY**

Pretrial Conference: August 28, 2023
Trial Date: September 12, 2023

Hearing Date: July 3, 2023
Time: 9:00 A.M.
Location: Courtroom 7C

Honorable Mark C. Scarsi

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1 **I. INTRODUCTION**

2 Facet Technologies, LLC (“Facet”) accuses LifeScan, Inc.’s (“LifeScan”)
3 OneTouch Delica Plus lancets of infringing claims 6, 8, 14, and 18 of U.S. Patent
4 No. 8,840,635 (the “’635 Patent”).¹ This motion seeks summary judgment of
5 invalidity of all of Facet’s asserted claims.
6
7

8 **II. FACTUAL BACKGROUND**

9 **A. The ’635 Patent**

10 The ’635 Patent is titled “Lancets with improved coupling features and sterility
11 caps.” Declaration of Gerald W. Griffin in Support of LifeScan, Inc.’s Motion for
12 Summary Judgment (“Griffin Decl.”), Ex. 1.² It was filed on July 29, 2009, claiming
13 priority to Provisional Application No. 61/084,456 filed on July, 29, 2008, and issued
14 on September 23, 2014. *Id.* The ’635 Patent contains 18 claims. *Id.* Claims 6 and
15 8 depend directly or indirectly from independent claim 1. *Id.*: claims 1, 6, 8. Claim
16 18 depends from independent claim 14. *Id.*: claims 14, 18.
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19 The ’635 Patent describes multiple lancet and protective lancet endcap
20 configurations. *Id.*, Abstract. In particular, the ’635 Patent provides for a lancet
21 having a “sterility cap” or “protective cover” with a handle or grip portion for
22 assisting in removal or replacement of the cap. *Id.*, 1:66-2:8.
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27 ¹ Facet recently withdrew its allegation that claim 1 of the ’635 Patent is infringed.
28 *See* Ex. 2. Claim 1 is thus no longer at issue in this case.

² All citations in this Motion to Exhibits (“Ex.”) are to the exhibits annexed in the
Griffin Declaration unless noted otherwise.

1 **B. This Court’s Claim Construction**

2 The Court construed the term “a secondary sheath for receiving the sharp
3 lancing tip of a used lancet” of independent claim 14 in its January 20, 2023 Order
4 Regarding Claim Construction. Court Order Regarding Claim Construction, ECF.
5 No. 122, 13:26-14:3. The Court construed the term to mean “a secondary sheath for
6 covering the sharp lancing tip of a used lancet by embedding or enclosing the lancet
7 tip.” *Id.* The Court also determined no construction was necessary for the terms
8 “gripping handle portion,” “lancet thickness,” “lateral span,” and “length.” *Id.*,
9 18:10-12, 23:11-12, 28:19-20. However, regarding “gripping handle,” the Court “did
10 not make much of the modifier ‘gripping’” and noted “all handles are ‘gripping
11 handles’.” *Id.*, 17:12-13.
12

13 **III. LEGAL PRINCIPLES**

14 **A. Summary Judgment**

15 Summary judgment should be granted when no “reasonable jury could return
16 a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242,
17 248 (1986); Fed. R. Civ. P. 56(c). An accused infringer must establish by clear and
18 convincing evidence that the claims at issue are invalid, whether it is by anticipation
19 or obviousness. *Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1370
20 (Fed. Cir. 2002). Once evidence is presented establishing a prima facie case of
21 invalidity, “the opponent of invalidity must come forward with evidence to counter
22 the prima facie challenge.” *Cable Elec. Prods., Inc. v. Genmark, Inc.*, 770 F.2d 1015,
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1 1022 (Fed. Cir. 1985), *overruled on other grounds by Midwest Indus., Inc. v. Karavan*
2 *Trailers, Inc.*, 175 F.3d 1356, 1358-60 (Fed. Cir. 1999). The mere existence of an
3
4 alleged factual dispute between the parties will not defeat an otherwise properly
5 supported summary judgment motion. *Anderson*, 477 U.S. at 247-48. There must
6 be no genuine dispute of material fact and a dispute of material fact is only genuine
7
8 “if the evidence is such that a reasonable jury could return a verdict for the
9 nonmoving party.” *Id.* at 248. General assertions of facts, denials, and conclusory
10 statements are insufficient. *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1578 (Fed. Cir.
11 1989). Mere denials or conclusory statements are also insufficient to create
12 evidentiary conflicts. *Collins, Inc. v. N. Telecom, Ltd.*, 216 F.3d 1042, 1046 (Fed.
13 Cir. 2000).
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16 **B. Level of Ordinary Skill in the Art**

17 A POSITA would have at least a bachelor’s degree and/or master’s degree in
18 mechanical engineering or industrial design, including coursework in designing
19 consumer products for mass markets, along with at least 4 to 6 years of experience
20 designing medical device products to optimize human factors such as handleability
21 or ergonomics. Ex. 3; Ex. 4, ¶34. Additional advanced education degrees could
22 substitute for some years of experience while additional industry experience could
23 substitute for educational degrees. *Id.* Facet’s expert, Dr. Collins, has previously
24 provided a similar definition for the level of ordinary skill in the art required at the
25 time of the ’635 Patent’s invention. Rebuttal Expert Declaration, ECF. No. 115-2
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¶32 (opining that a POSITA at the time of invention would (1) have completed college-level coursework and/or obtained a bachelor's degree, in mechanical engineering or other similar discipline; and (2) have at least one year of experience designing mechanical medical devices with less experience being compensated by a higher level of education and vice versa).

IV. ARGUMENT

Claims 6, 8, 14, and 18 of the '635 Patent are invalid because they are anticipated by Saikley. Saikley was filed on November 4, 2003 and published on July 15, 2004. Ex. 5. Because its publication date is more than four years prior to the filing date of the '635 Patent, Saikley is prior art to the '635 Patent pursuant to 35 U.S.C. § 102(b) (pre-AIA). Facet has not challenged whether Saikley qualifies as prior art. Saikley discloses an integrated device for puncturing the skin to collect a small blood droplet for testing. *Id.* at Abstract. As part of these methods, Saikley describes various embodiments of inventive skin-puncturing lancet and cap combinations, including a lancet cap made much larger than usual to aid handling. *Id.*, [0049-50].

Saikley discloses each of the limitations of claims 1 (to which claim 6 depends), 6, and 14. The limitations disclosed by Saikley are highlighted in color below.

Claims 1, 6, and 14

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

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.

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.

Saikley also discloses claims 8 and 18, which depend on claims 6 and 14 respectively.

The limitations disclosed by Saikley are highlighted below.

Claims 8 and 18

8. The protective sterility cap of claim 6, wherein the gripping handle portion defines a length at least equal to the lancet thickness.

18. The protective sterility cap of claim 14, wherein the gripping handle portion defines a length at least equal to the lancet thickness.

1 Should Facet assert the limitations are not disclosed by Saikley, the claims are
2 rendered obvious by Stout. Stout was filed on April 4, 2006 and published on
3 October 26, 2006. Ex. 6. Because its publication date is more than one year before
4 the '635 Patent filing date, it is undisputed Stout is prior art pursuant to 35 U.S.C. §
5 102(b) (pre-AIA). Stout discloses a miniature lancet with an oversized sterility cap
6 for ease of handling and loading into a lancing device. *Id.* at Abstract. A POSITA
7 would have been motivated to apply the teachings in Stout to Saikley to render the
8 “primary sheath for initial embedment,” the “length,” and “lateral span” limitations
9 of the asserted claims obvious. Ex. 4, ¶¶116-130 (Expert Declaration advancing
10 rationale).

14 The asserted claims are also invalid because they are anticipated by Iio. Iio
15 was filed on December 15, 2004 and published on June 16, 2005. Ex. 7. Because
16 Iio’s publication date is more than three years before the '635 Patent filing date, it is
17 undisputed Iio qualifies as prior art under 35 U.S.C. § 102(b) (pre-AIA). Iio discloses
18 a puncture needle unit with a needle integrally molded with a protrusion to be fitted
19 to a lancet. *Id.* at Abstract. Like Saikley, Iio discloses each of the limitations of
20 claims 6, 8, 14, and 18.

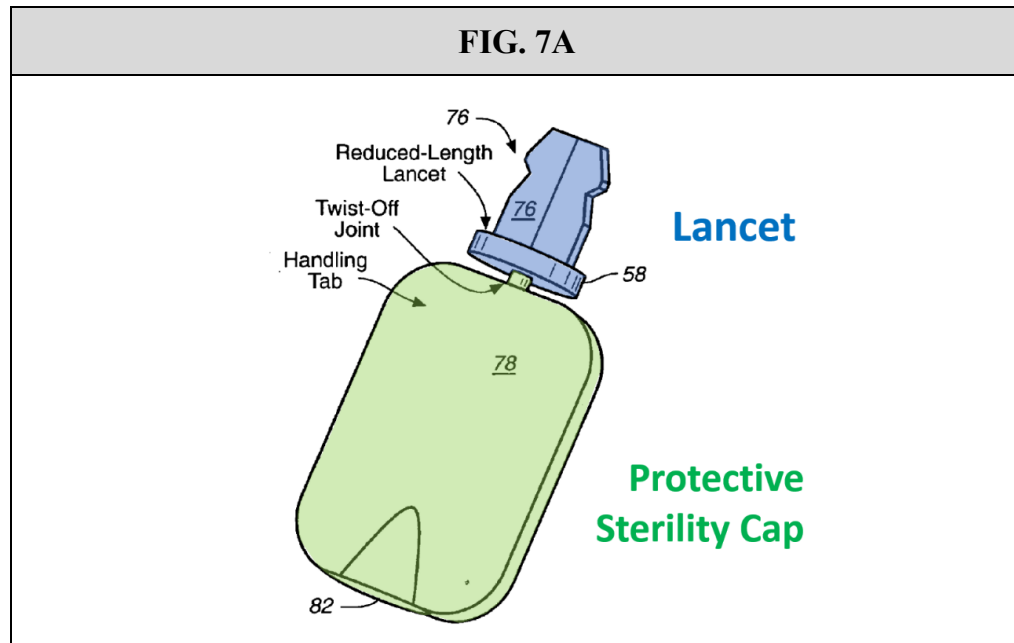
24 Iio also renders the claims obvious in view of Peckham. Peckham was filed
25 on March 29, 1995 and issued on October 29, 1996. Ex. 8. Because its issuance date
26 is more than one year before the effective filing date of the '635 Patent, it is
27 undisputed Peckham is prior art pursuant to at least 35 U.S.C. § 102(b) (pre-AIA).

1 Peckham, like the '635 Patent, discloses a lancet assembly with an improved cap. *Id.*
2 at Abstract. The lancet cap in Peckham includes a “plurality of longitudinal ribs or
3 splines” which provide a sufficient textured surface to “improve handling and
4 maneuverability” of the cap when it is being removed from the lancet assembly. *Id.*
5 at 3:11-16. A POSITA would have had ample motivation to apply the teachings in
6 Peckham to Iio in order to render the “gripping handle,” “length,” and “lateral span”
7 limitations of the asserted claims obvious. Ex. 4, ¶¶202-226 (Expert Declaration
8 advancing rationale).

11
12 **A. Claims 6 and 14 Are Anticipated By Saikley**

13 **1. [1P]“protective sterility cap”**

14 Saikley discloses the “protective sterility cap.” *See* Ex. 1, claims 6, 14.
15 Saikley discloses this limitation because it describes using “protective cap 78” with
16 a “shortened lancet 76.” Ex. 5, Fig. 7A, [0050]; Ex. 4, ¶55. Saikley further discloses
17 the “cap 78 may be an integrally molded, pull-off tab, such as shown in FIG. 7A,”
18 which maintains the sterility of “lancet sharp 50.” Ex. 5, [0050]; Ex. 4, ¶56. Thus,
19 Saikley discloses the “protective sterility cap.”
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2. [1A]“a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein”

14 Saikley discloses the “primary sheath for initial embedment of a sharp lancing

15 tip of an unused lancet therein.” Ex. 1, claims 1, 6, 14. The “protective cap 78” in

16 Saikley includes a “primary sheath”—namely, the “twist off joint” [*colored red in*

17 *Fig. 7A below*] and the adjoining portion of the “handling tab” [*red dashed lines*] that

18 “covers the lancet sharp 50” of the “shortened lancet 76” [*blue*] prior to use. Ex. 5:

19 Fig. 7A, [0037], [0050-52], [0065]; Ex. 4, ¶58. Facet also previously identified the

20 primary sheath in its Preliminary Infringement Contentions as a structure similar to

21 the twist-off joint in Saikley. See Ex. 9 at 11.

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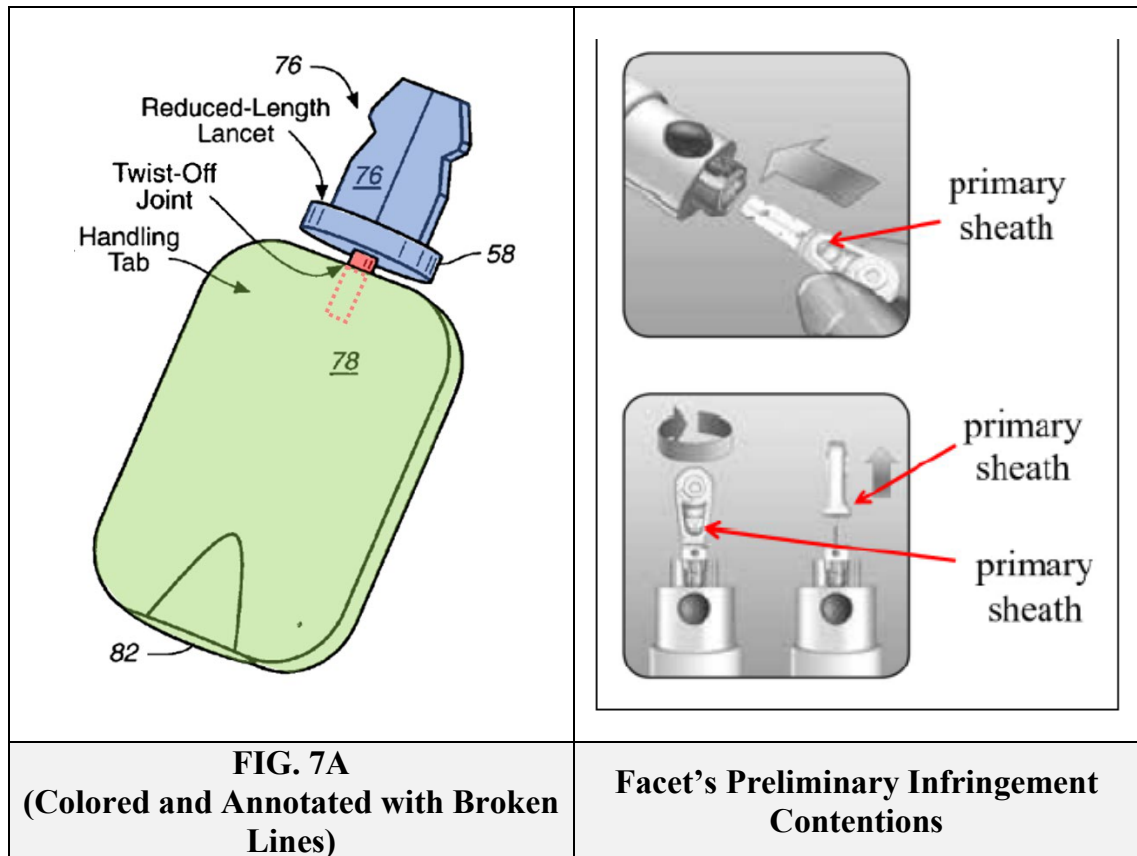
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Although, Saikley does not use the term “embedment,” an anticipatory prior art reference “need not disclose the elements in the *very same terms* used by the [’635] patent.” *Adasa Inc. v. Avery Dennison Corp.*, 55 F.4th 900, 912-13 (Fed. Cir. 2022) (“district court erred in interpreting linguistic differences as fatal to a finding of anticipation,” noting “[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*.”).

Rather than using “embedment,” Saikley describes the removable “protective cap 78” of “lancet 76” as an “integrally molded pull-off tab 78.” Ex. 5, [0050]. This description aligns with the ’635 Patent, where the “primary sheath” is described as

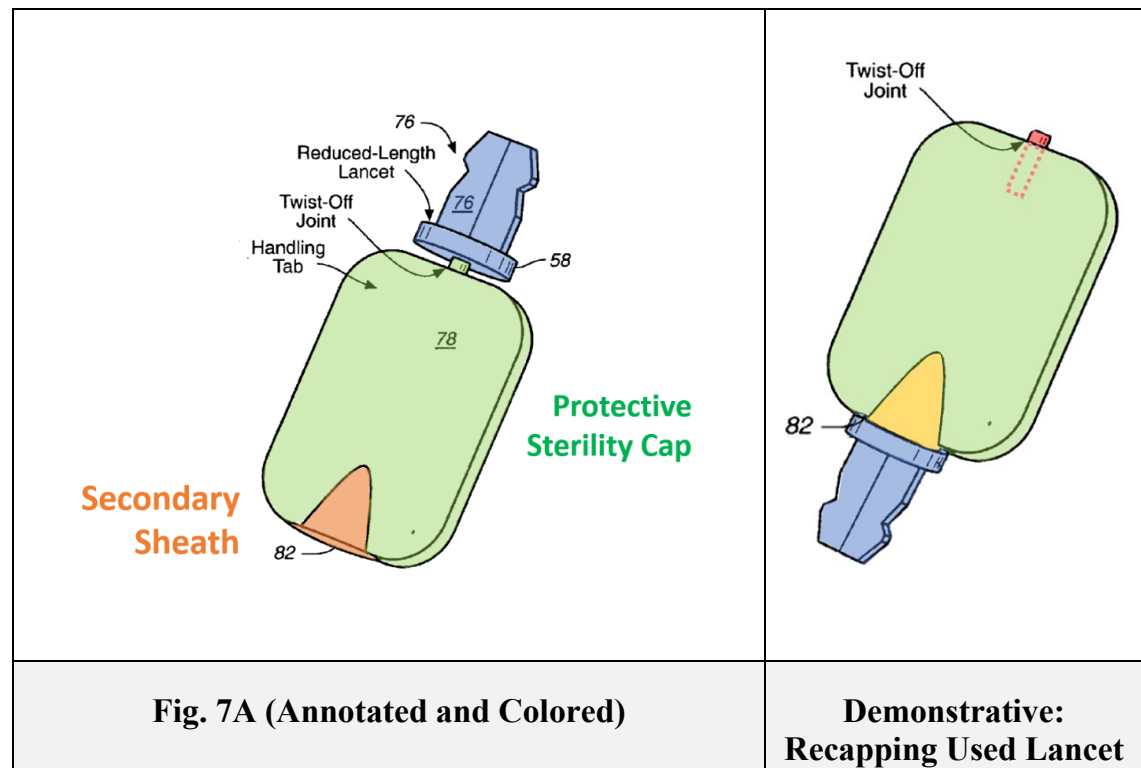
1 the “flange or ring at one **end of the sterility cap** 510, which abuts, confronts or
2 interfaces with the front end of the lancet body in the lancet’s original, unused state”
3 and “is **integrally molded** with the lancet body.” Ex. 1, 6:22-23. A POSITA would
4 have understood using “integrally molded” in these disclosures indicates the needle
5 sharp of the lancet would be **embedded** in the protective cap. See Ex. 4, ¶¶59-65.
6
7 Saikley therefore discloses the “primary sheath for initial embedment of a sharp
8 lancing tip of an unused lancet therein.”

10 **3. [1B]“secondary sheath for receiving the sharp lancing tip of a**
11 **used lancet”**

12 Saikley discloses the “secondary sheath for receiving the sharp lancing tip of
13 a used lancet.” Ex. 1, claims 6, 14. Saikley discloses “[a] **hollow cup** or solid ‘pin
14 cushion’ type area 82” “which is “provided at the opposite end of [protective] cap
15 78, as shown in FIG. 7A [*orange below*], to **cover the sharp** during **removal** from
16 the [lancing] device and **disposal.**” Ex. 5, [0050]. Saikley teaches that “solid ‘pin-
17 cushion’ type areas”—like the one at the end of protective cap 78—“can be used for
18 **receiving** [the] sharp *after use* and *prior to disposal.*” *Id.*, [0052]. A POSITA would
19 understand to push the “lancet sharp 50” into the “pin cushion type area 82” of the
20 “protective cap 78.” Ex. 4, ¶¶66-72.

24 Saikley’s disclosures also comport with the ‘635 Patent’ written description
25 and the Court’s claim construction order. The ‘635 Patent describes the secondary
26 sheath as a “**cup** having an outer rim and a **hollow** interior chamber.” Ex. 1, 6:35-
27 36. “[R]eceiving” is also used to describe both a lancet needle “enclosed” within a
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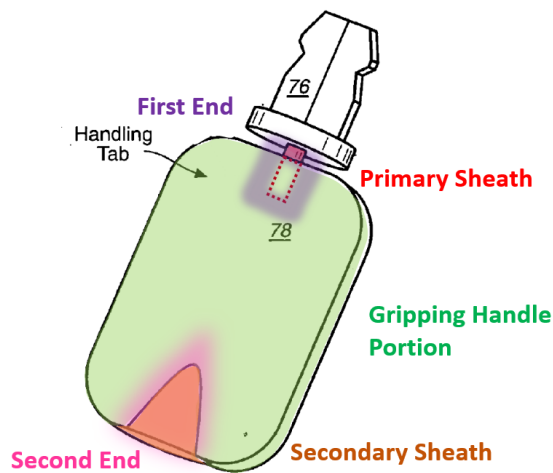
“hollow cup” and one “embedded” within a “flat panel.” *Id.*, 6:1-5, 7:6-10; *compare id.* Figs. 5A-5D with Figs. 6A-6D. Facet conceded the claims’ use of the word “receiving” conveys the secondary sheath “may come in a variety of forms.” Facet’s Responsive Claim Construction Brief, ECF. No. 115 at 9. Saikley’s disclosure also aligns with the Court’s broad construction of this term as “a secondary sheath for covering the sharp lancing tip of a **used** lancet by **embedding** or **enclosing** the lancet tip.” Court’s Claim Construction Order, ECF. No. 122, 13:25-14:3. Thus, Saikley discloses the “secondary sheath for receiving the sharp lancing tip of a used lancet.”



4. [1C]“gripping handle portion extending between the primary sheath and the secondary sheath”

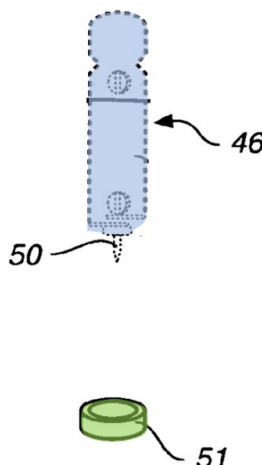
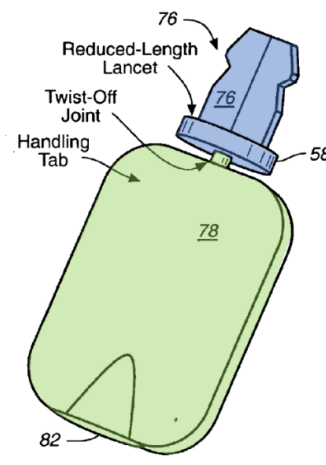
Saikley discloses a “gripping handle” which extends “between the primary sheath and the secondary sheath.” Saikley’s “protective cap 78” includes a “handling tab” (*colored green below*), which extends between the primary sheath—i.e., the “twist-off joint” (*colored red*) and the adjoining portion of the protective cap (*dashed red*)—and the secondary sheath—i.e., the “hollow cup or solid pin-cushion style area 82” (*orange*). Ex. 5, Fig. 7A; Ex. 4, ¶¶73-82.

FIG. 7A (Annotated)



Like the '635 Patent, Saikley recognizes “[t]raditional disposable lancets, such as shown in FIG. 3, have an elongated body 48 and a short cap 51,” which “may make it difficult for the user to handle and install”—especially “elderly patients and those with reduced eyesight and dexterity.” Compare Ex. 5, [0004], [0050] with Ex. 1, 7:26-33. To address this problem, Saikley incorporates a “handling tab” in its “protective cap 78” to provide “a large lancet cap for handling” (*i.e.*, gripping). Ex. 5, [0049]. Saikley teaches “the protective cap 78 (that is removed before use) should

be made **much larger** than usual to **aid handling.**” *Compare id.*, [0004], [0050] with Ex. 1, 6:66-7:3; 7:26-33; Ex. 4, ¶¶74-77. 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 and for inserting a “fresh lancet into the lancet holder 68.” *Compare* Ex. 5, ¶¶[0050], [0087] with Ex. 1, 8:17-20. Saikley improved the prior art cap that was difficult to handle (FIG. 3) by adding a “much larger” “handling tab” (FIG. 7A):

Traditional Disposable Lancets	Saikley’s Improved Lancet
 FIG. 3 (Colored and Showing Only the Lancet and Cap)	 FIG. 7A (Colored)

The wide “handling tab” forms the gripping handle of Saikley’s “protective cap 78” and provides users with a firmer grip for removing the cap, making it easier to twist it off at its “twist-off joint” so the lancet is not “damage[d]” or “pulled from the lancet holder 68” when the patient tries to uncap the “lancet 76.” *Compare* Ex. 5, [0050-52], [0087] with Ex. 1, 6:1-10; Ex. 1, 6:53-55; Ex. 4, ¶¶78-82. This is

1 consistent with the plain and ordinary meaning of “gripping handle portion,” which
2 the Court considered the “handle” portion of the claimed sterility cap because “[t]he
3 Court does not make much of the modifier ‘gripping’ and finds the term merely
4 restates the purpose of the handle.” Court’s Claim Construction Order, ECF. No.
5 122, 17:12-13. Indeed, “all handles are ‘gripping handles.’” *Id.* Facet’s expert also
6 opined a POSITA would understand the term is not directed to any specific gripping
7 handle portion, but to a “structural element on the claimed protective sterility cap that
8 extends between (i.e., occupies the space between) the primary and secondary
9 sheaths and forms a gripping handle that assists in removal of the cap from the lancet
10 before use and/or replacement of the cap after use.” Rebuttal Expert Declaration,
11 ECF. No. 115-2 ¶86. The ’635 Patent also refers to a “handle or grip”
12 interchangeably and describes a “handle” or “handle portion of the cap.” Ex. 1, 1:66-
13 2:3, 6:5-9, 7:6-12, 8:17-22.

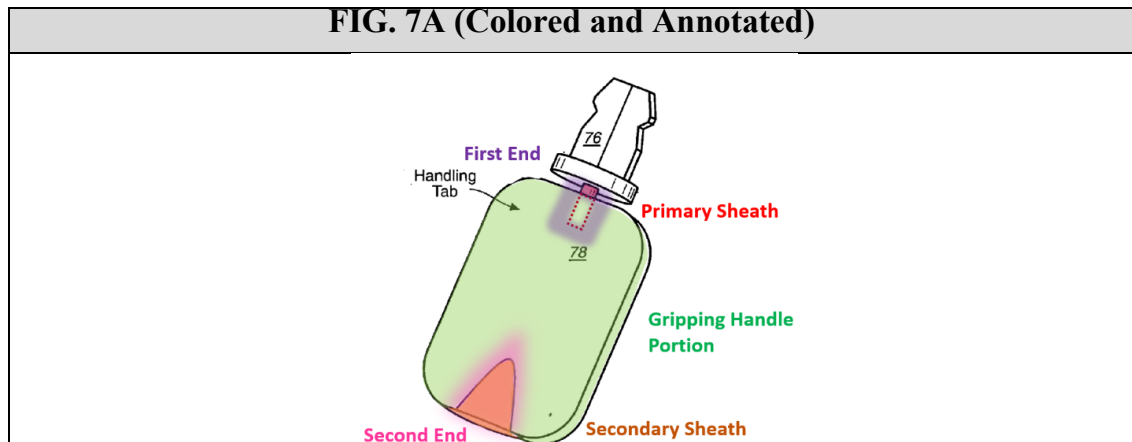
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Saikley therefore discloses “a gripping handle portion [*i.e.*, handling tab]
extending between the primary sheath [*i.e.*, twist-off joint] and the secondary sheath
[*i.e.*, hollow cup or pin-cushion type area 82].”

**5. [1D]“with the primary sheath attached at a first end of the
gripping handle portion and the secondary sheath attached at a
second end of the gripping handle portion when the protective
sterility cap is removed from the lancet”**

Saikley discloses 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 twist-off joint and adjoining portion of the handling tab (*i.e.*, the primary sheath) is attached at one end (*i.e.*, a first end, colored purple below) of the handling tab (*i.e.*, gripping handle portion) and the “hollow cup” or “pin cushion type area 82” (*i.e.*, the secondary sheath) is attached at the other end (*i.e.*, a second end, colored magenta), as illustrated in Figure 7A below. Ex. 5: Fig. 7A, [0050]. Nothing in Saikley suggests 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. *Id.*, [0050]; Ex. 4, ¶¶83-85. The “hollow cup or solid ‘pin cushion’ type area 82 at the opposite end of cap 78” must remain available “to cover the sharp *during removal* from the [lancing] device and *disposal.*” *Id.*

FIG. 7A (Colored and Annotated)



6. [6A]The protective sterility cap “in combination with a lancet”

Saikley discloses the protective sterility cap “in combination with a lancet.”

Ex. 1, claims 6, 14. Specifically, it discloses 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. 5: Fig. 7A, [0037], [0050], [0065]; Ex. 4 ¶¶86-88, 99.

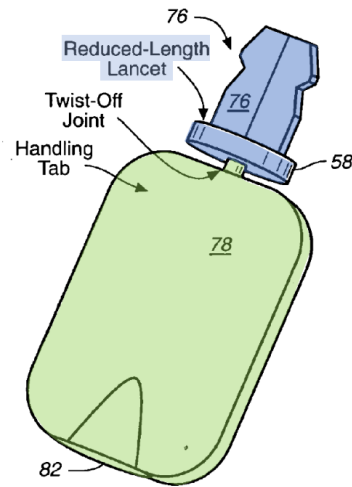


FIG. 7A

7. [6B]“having a lancet body defining a lancet thickness”

Saikley discloses the lancet “having a lancet body defining a lancet thickness.” Ex. 1, claims 6, 14. Saikley discloses the “reduced-length lancet 76” consists of (1) a “lancet body 77” (*colored light blue 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 58” (*grey*) that engages with the lancing device. Ex. 5: Fig. 6, Fig. 8, [0037], [0043-44], [0060]; Ex. 4, ¶100.

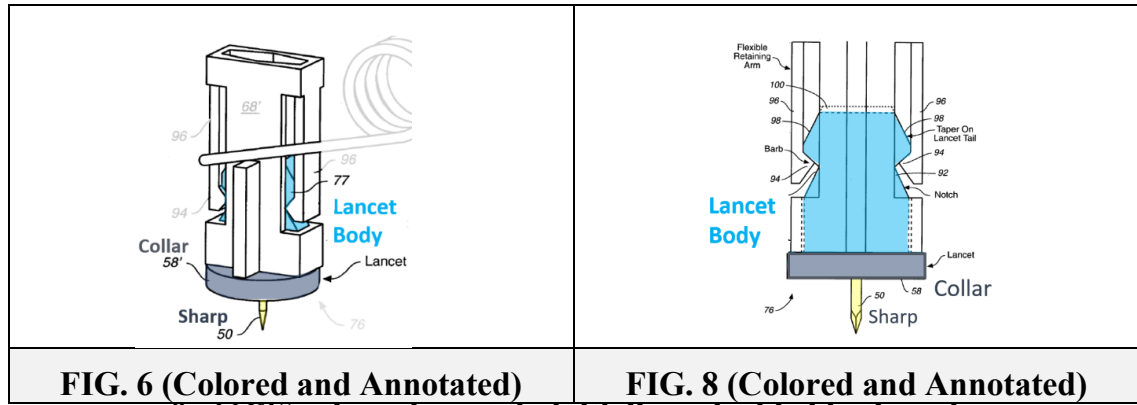


FIG. 6 (Colored and Annotated)

FIG. 8 (Colored and Annotated)

8. [6C]“a sharp lancet tip initially embedded in the primary sheath”

Saikley discloses the “sharp lancet tip initially embedded in the primary sheath.” Ex. 1, claims 6, 14. As previously discussed, a POSITA would have recognized from Saikley’s disclosures of an “integrally molded cap” that the “sharp lancing tip 50” is initially embedded in the pull-off tab 78. Ex. 4, ¶¶58-65.

9. [6D]“the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness”

Saikley discloses a lateral span (*annotated “S”*) that is more than 1.5 times the lancet thickness of the lancet body. Ex. 5, Fig. 7A.

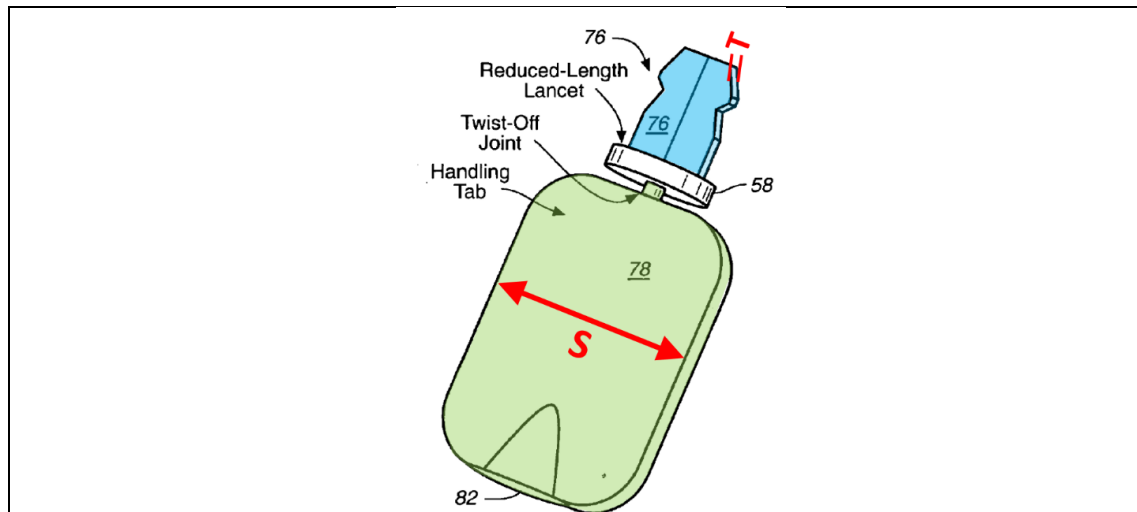


FIG. 7A (Colored and Annotated)

Saikley emphasizes the size of the handling tab relative to the lancet by describing the “large lancet cap for handling” and noting it is “**made much larger** than usual to aid handling.” *Id.*, [0049-0050]. By contrast, Saikley makes clear the lancet is smaller than the much larger handling tab where it notes the “short length [of the lancet] might make [it] difficult for the user to handle and install.” *Id.* In view of these descriptions and Figure 7A, a POSITA would have understood that Saikley expressly, or inherently, discloses this limitation. Ex. 4, ¶103.

B. Claims 8 and 18 Are Anticipated By Saikley

Saikley discloses the “gripping handle portion defines a length at least equal to the lancet thickness” for the same reasons it discloses that the gripping handle portion is at least 1.5 times the lancet thickness. The length of Saikley’s “cap 78” is depicted significantly larger than the lancet’s thickness. *See* Ex. 5, Fig. 7A; Ex. 4, ¶¶109-110, 114.

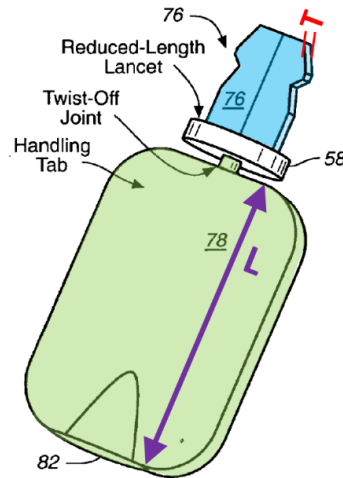


FIG. 7A (Colored and Annotated)

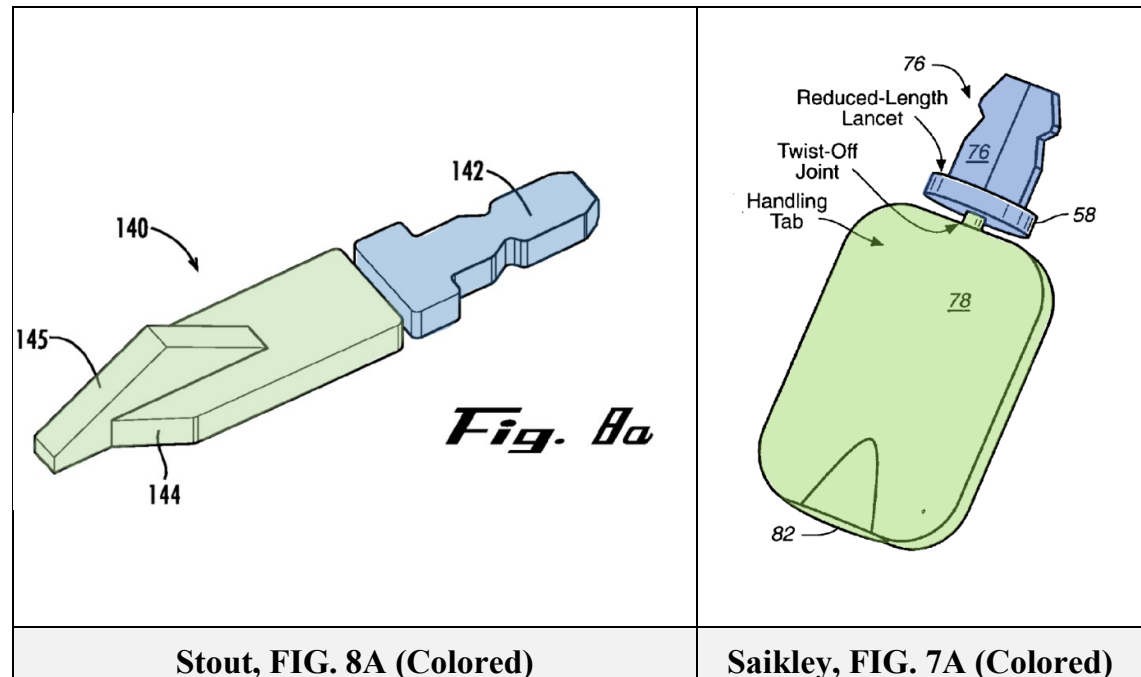
C. Alternatively, Claims 6, 8, 14, and 18 Are Obvious In Light of Saikley and Stout

1. “primary sheath for initial embedment”

LifeScan believes Saikley discloses a “primary sheath for initial embedment of a sharp lancing tip” as Saikley’s sharp is initially embedded in the “twist-off joint” and the adjoining portion of the “handling tab” that “covers the lancet sharp 50” of the “shortened lancet 76” prior to use. Even if Facet contends this limitation is not disclosed by Saikley, the claims would still be invalid because it would have been obvious to modify the cap in Saikley to include the “primary sheath for initial embedment” described in Stout.

Like Saikley, Stout depicts a sterility cap (*colored green in FIG. 8A below*), that Stout describes as “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

1 manual dexterity.” Ex. 6, [0035]. Also, like Saikley, Stout teaches “[t]he sterility
2 cap 44 is preferably **co-molded** with the lancet body portion 42” with the “sharp
3 lancet tip 43 . . . securely **embedded** therein.” *Id.* A POSITA would appreciate that
4 embedding the lancet needle into Saikley’s “protective cap 78” would not only
5 protect the integrity of the needle, but would also protect its sterility. Ex. 4, ¶¶117-
6 119.
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8



21 To modify Saikley’s cap to include an embedded needle sharp, a POSITA
22 would only need to use “traditional insert molding methods” and, thus, would have
23 had a reasonable expectation of success. *Id.*, ¶119. Additionally, a POSITA would
24 have been motivated to embed the lancet needle within Saikley’s handling tab of
25 “protective cap 78” because it was well known this would make the “needle tip 50”
26 more resistant to the non-axial cocking/pivoting movement of the endcap when
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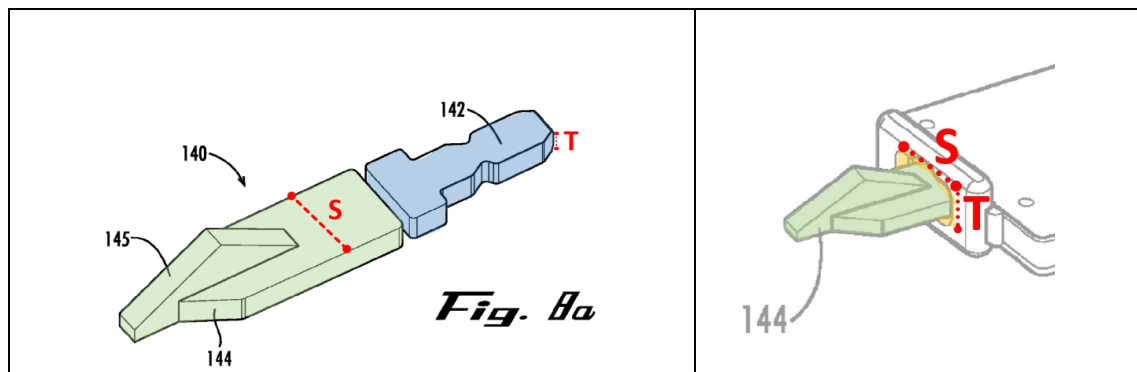
1 twisted off by the user. *Id.*

2 **2. The “length” and “lateral span” limitations**

3
4 LifeScan believes that in addition to being anticipated by Saikley, the “length”
5 and “lateral span” limitations would have been obvious because “[t]he only material
6 difference between the [’635] patent and [Saikley] are those dimensions, **which are**
7 **meaningless.**” *Hamilton Prods., Inc. v. O’Neill*, 492 F. Supp. 2d 1328, 1343 (M.D.
8 Fla. 2007) (finding obvious claims to a seatbelt with a buckle “at least less than
9 approximately 0.8 inches” and an overall width of greater than approximately 0.53”
10 where the dimensions were the only differences between the invention and prior art).
11 It would also be obvious to make Saikley’s “large lancet cap” even “**larger than**
12 **usual** to aid handling,” especially in light of Saikley’s explicit teaching that “[e]lderly
13 patients and those with reduced eyesight and dexterity can have problems seeing and
14 capturing such a small sample.” Ex. 5, [0004]. The straightforward modification of
15 “making a [lancet cap’s handle longer or wider] merely yields the predictable result
16 of [making the cap easier to handle], and is thus obvious.” *Ohio Willow Wood Co.*
17 *v. Thermo-Ply, Inc.*, No. 9-07-cv-274, 2009 WL 6499349, at *4-*5 (E.D. Tex. 2009).
18 “The fact that [a larger handle] will [make a lancet cap easier to handle] is not only
19 common sense, but was recognized in this field by those of ordinary skill,” as
20 demonstrated by the prior art lancet caps. *Id.*; Ex. 5, [0050]; Ex. 6, [0035]; Ex. 4
21 ¶¶122-127; Ex. 10 at 129 (where the Examiner noted “[i]t would have been obvious
22 to modify the gripping handle portion to define a lateral span of at least 1.5 times the
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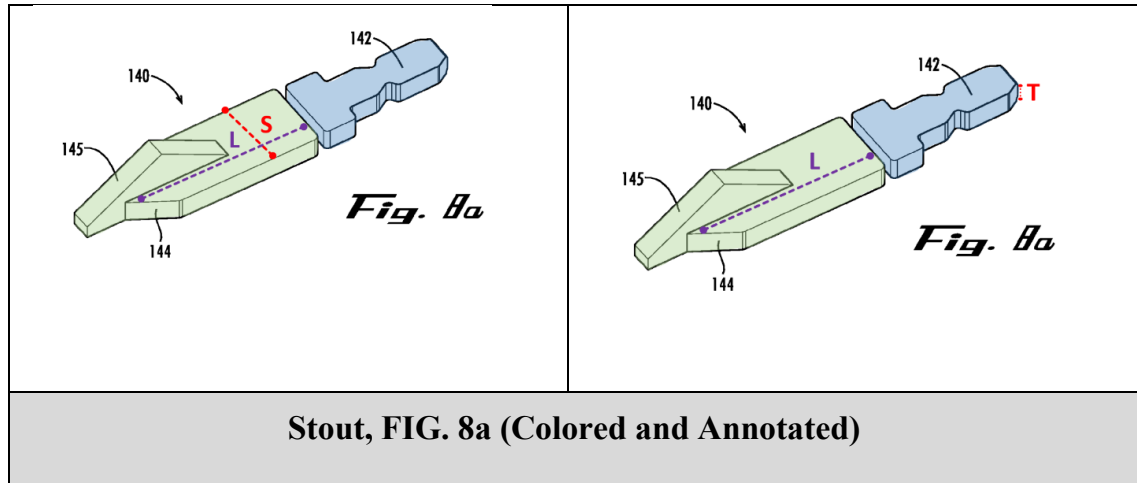
lancet thickness, since...discovering the optimum or workable ranges involves only routine skill in the art”—an argument the patentee never rebutted).

The dimensional limitations would also be obvious by Saikley in view of Stout, which teaches “the slotted opening 32 [of the lancing device]”—which the 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. 6: Fig. 8a, [0032], [0035]; Ex. 4 ¶¶128-130.



Stout, FIGS. 8a and 8b (Colored and Annotated)

A POSITA would have understood Stout’s figures and descriptions plainly depict a gripping handle with a greater length than the lancet thickness and a lateral span “considerably greater” and “at least twice” the lancet thickness. Ex. 6: Figs. 8a-c, [0032], [0035]; Ex. 4, ¶¶128-129.



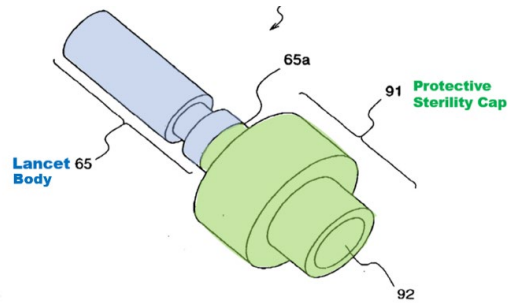
Saikley in view of Stout thus renders obvious the asserted claims of the '635 Patent.

D. Claims 6 and 14 Are Also Anticipated By Iio

1. [Claim 1P]

Iio discloses the “protective sterility cap.” Iio discloses “a protective sterility cap for a lancet”—namely, the “puncture needle cap 91” (sterility cap) for the lancet body or “puncture needle body 65” (collectively, the “puncture needle unit 90” or lancet) are “connected to each other by a thin plastic film having a thickness of 0.1 mm or less in the puncture needle separation groove 65a.” Ex. 7: Fig. 8, [0044], [0104]; Ex. 4, ¶¶153-155.

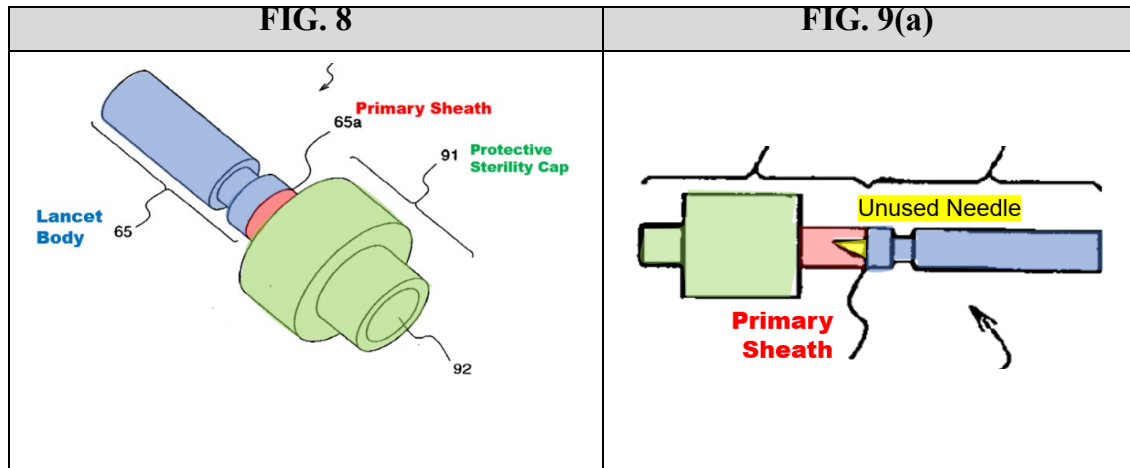
FIG. 8



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.” *Id.*, [0095].

2. [Claim 1A]

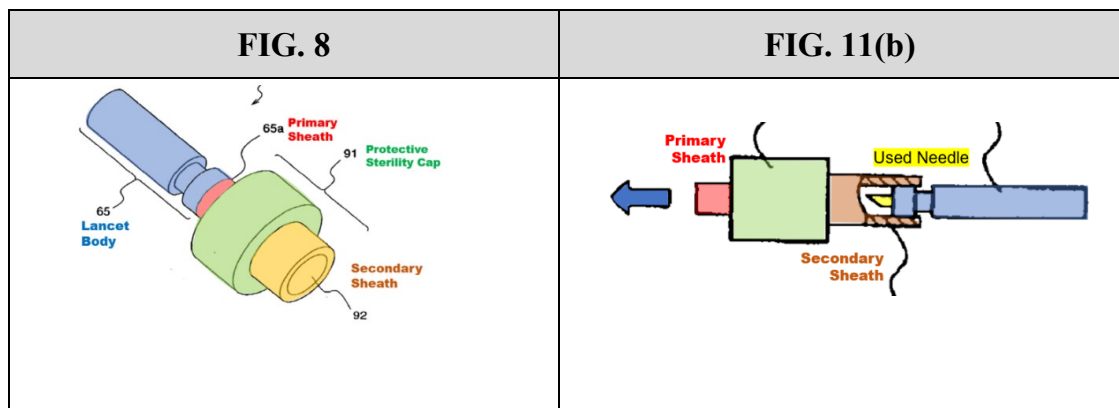
Iio discloses the “primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein.” Iio’s “puncture needle cap 91” includes a primary sheath at one “end” with a “puncture needle separation groove 65a,” where “the body 65 and the cap 91” connect to each other “by a thin plastic film having a thickness of 0.1 mm or less.” Ex. 7, [0104]. The primary sheath “cover[s] the front end of the puncture needle 65 before [it is] used.” *Id.*, [0117]. Iio further teaches that the primary sheath (*colored red in Figures 8 and 9(a) below*) ensures the “puncture needle body 65 is set in a state where it is **embedded** in the puncture needle cap 91.” *Id.*, [0104].



Iio discloses the primary sheath because it teaches “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]; Ex. 4 ¶¶156-159.

3. [Claim 1B]

Iio discloses a “secondary sheath for receiving the sharp lancing tip of a used lancet.” Iio teaches that the other “end of the puncture needle cap 91” has “a disposal slot 92 [colored yellow in Figure 8 below] for pulling out the puncture needle 65 after puncture has been carried out.” Ex. 7, [0104]; Ex. 4 ¶¶160-164.



1 After “puncture,” Iio describes the process for “discarding the puncture needle
2 65” by fitting “the shaft of the disposal slot 92 ... to the front end of the puncture
3 needle 65,” and then pressing “the front end of the puncture needle 65 ... into the
4 disposal slot 92 to snugly insert the needle 65 into the slot 92, whereby the **puncture**
5 **needle 65 is captured into the disposal slot 92** (FIG. 11(b)).” *Id.*, [0115]. Then,
6
7 “the puncture needle cap 91 having the puncture needle 65 is pulled out of the lancet
8 61, whereby discarding of the **used puncture needle 65** is completed (FIG. 11(c)),
9 and the puncture needle 65 can be discarded safely and easily without exposing the
10 front end of the puncture needle.” *Id.*; *id.*, Figs. 11(a)-(c). Facet also identified in its
11 Preliminary Infringement Contentions a similar process for discarding the lancet
12 needle using the secondary sheath. Ex. 9 at 11.
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FIGS. 11(a)-11(c)

Fig.11(a)

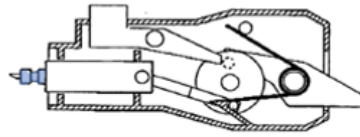


Fig.11(b)

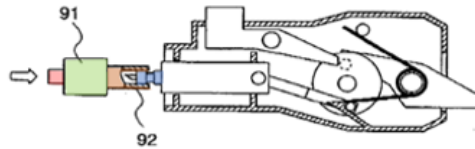
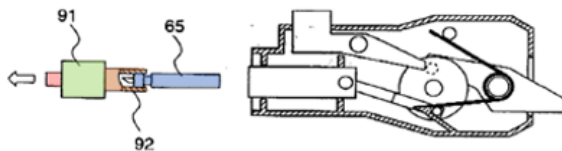
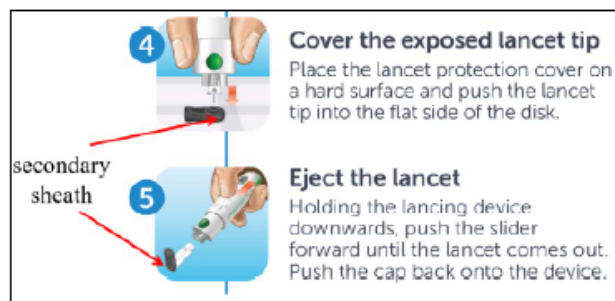


Fig.11(c)



Facet's Preliminary Infringement Contentions

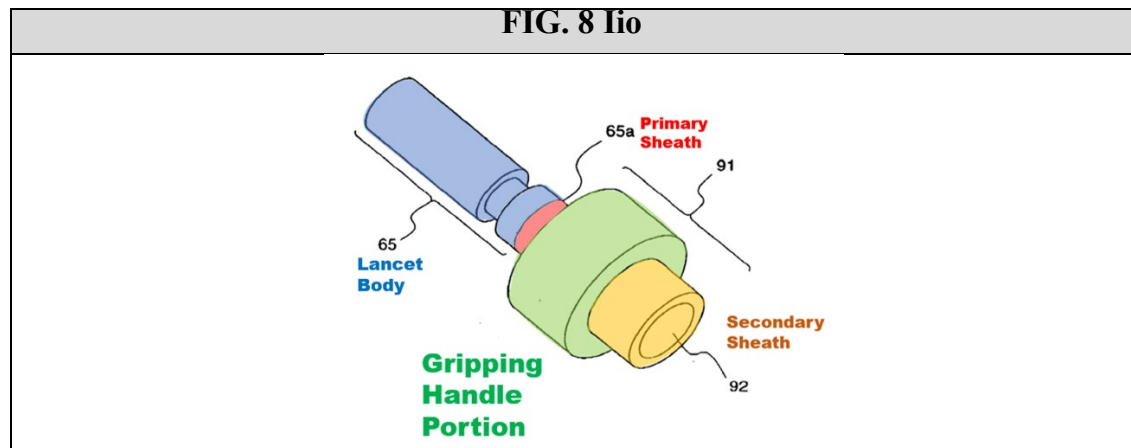


Facet has also acknowledged a broad reading of “secondary sheath” when it noted that it is “generally for covering, placing over, or otherwise receiving the sharp tip of a used lancet” and the “secondary sheath may come in a variety of forms.”

Facet's Opening Claim Construction Brief, ECF. No. 94 at 13; Facet's Responsive Claim Construction Brief, Dkt No. 115 at 9. By having the puncture needle "captured" into the disposal slot, the needle is "enclosed" within the hollow portion of the shaft. Ex. 4, ¶163. Iio discloses what the Court broadly construed as "a secondary sheath for covering the sharp lancing tip of a used lancet by embedding or *enclosing* the lancet tip." Court's Claim Construction Order, ECF. No. 122, 13:24-14:3.

4. [Claim 1C]

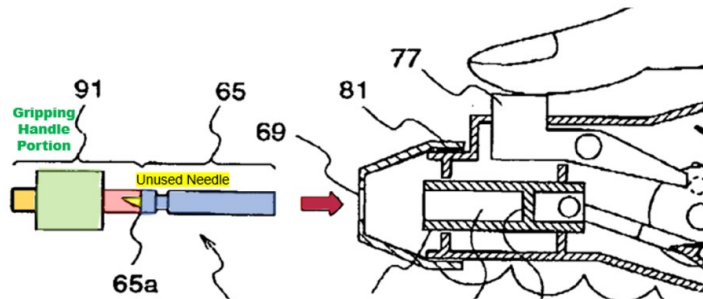
Iio discloses a "gripping handle portion extending between the primary sheath and the secondary sheath." Iio's "puncture needle cap 91" includes a handle (*colored green below*) extending between the primary sheath (*red*) and the secondary sheath (*yellow*). Ex. 7, Fig. 8; Ex. 4 ¶¶165-174.



The "puncture needle unit 90" has a handle directly between the primary and secondary sheaths to provide an easier grip when inserting the "puncture needle 65" into the lancing device. Ex. 4, ¶166. To prepare the "puncture needle 65" for use,

Iio discloses the operator must first load the puncture needle into the “lancet 61” (lancing device) by pushing “puncture needle unit 90” until “puncture needle 65” is seated within the lancing device. Ex. 7, Fig. 9(a), [0106].

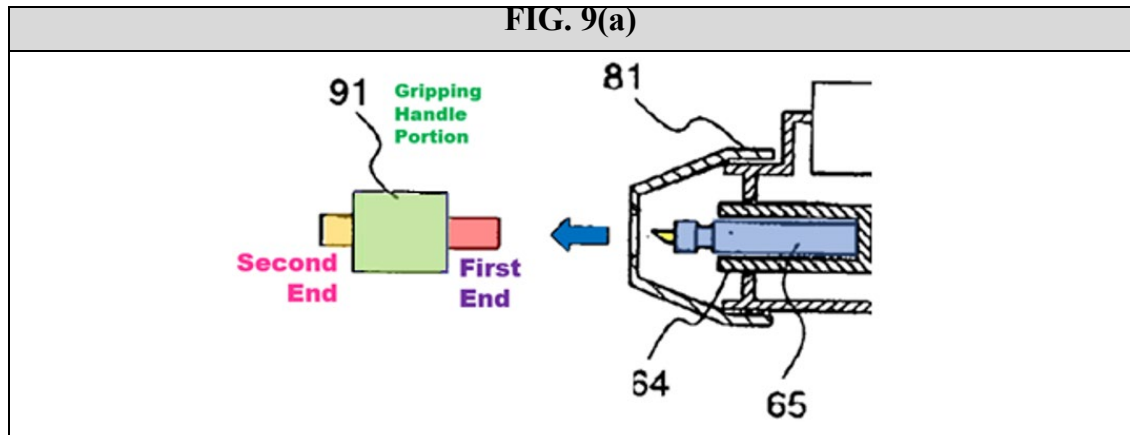
FIG. 9(a) Iio



When pushing the “puncture unit 90” into the lancing device, the operator is unable to grip the “puncture needle 65” because it must be “snugly fitted to the inner wall of the puncture needle fixing hole 70 of the slider 64.” *Id.*, Fig. 9(b), [0106]. To expose the tip of the unused needle after it has been snugly fitted in the lancing device, Iio teaches the operator must simultaneously pull the lancing device “while twisting the puncture needle unit 90” until “the puncture needle 65 [is] separated from the puncture needle cap 91.” *Id.*, Fig. 9(c), [0106]. By extending the length and lateral span of the gripping handle of the “puncture needle cap 91” and positioning it directly against the lancing device, the handle portion is designed to “ensure excellent usability and handleability with safety.” Ex. 7,[0005], [0007] (explaining “the puncture needle unit” is “safely handleable”); Ex. 4 ¶¶171-174.

5. [Claim 1D]

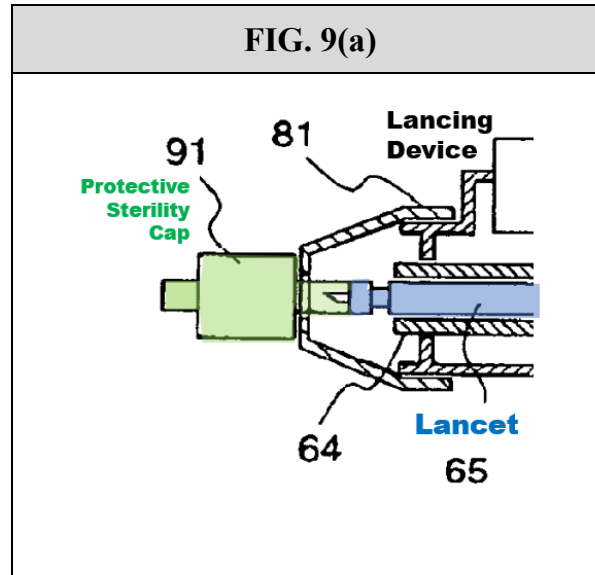
Iio discloses the “primary sheath” is attached at a “first end of the gripping handle” and the “secondary sheath” is attached at a “second end” when the cap is removed from the lancet. Because the gripping handle portion of the “puncture needle cap 91” extends between the primary sheath (*i.e.*, sheath formed adjacent the puncture groove 65a) and the secondary sheath (*i.e.*, sheath with the disposal slot 92), each is attached at an opposite end of the gripping handle portion. Ex. 7, 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”); *id.*, claims 19-20, [0025]; Ex. 4, ¶¶175-176.



Even after separating the “puncture needle cap 91” from “puncture needle 65” to expose the unused needle tip, the first and second ends of the gripping handle of the puncture needle cap 91 remain attached to the primary and secondary sheaths, respectively. Ex. 7, [0047], [0093], [0102-0104]; Ex. 4, ¶177-180.

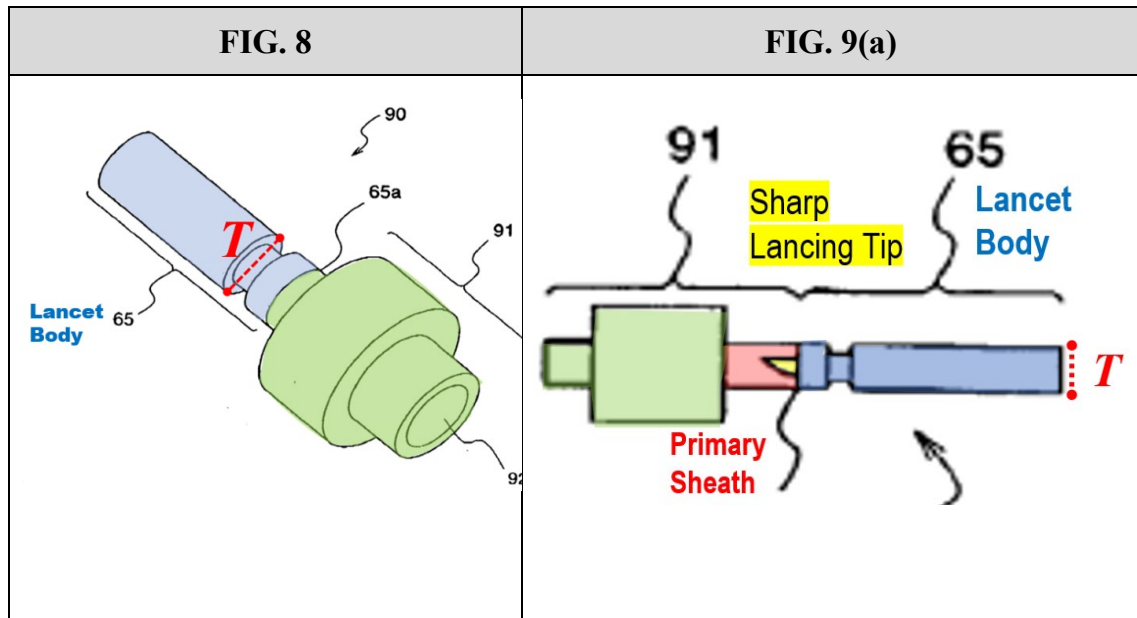
6. [Claim 6A]

Iio discloses the lancet cap “in combination with a lancet.” Iio discloses the “puncture needle unit 90,” which comprises a lancet (puncture needle 65) combined with a protective sterility cap (puncture needle cap 91), capable of puncturing skin and collecting blood. Ex. 7: Fig. 9(a), [106]; Ex. 4, ¶¶181, 186.



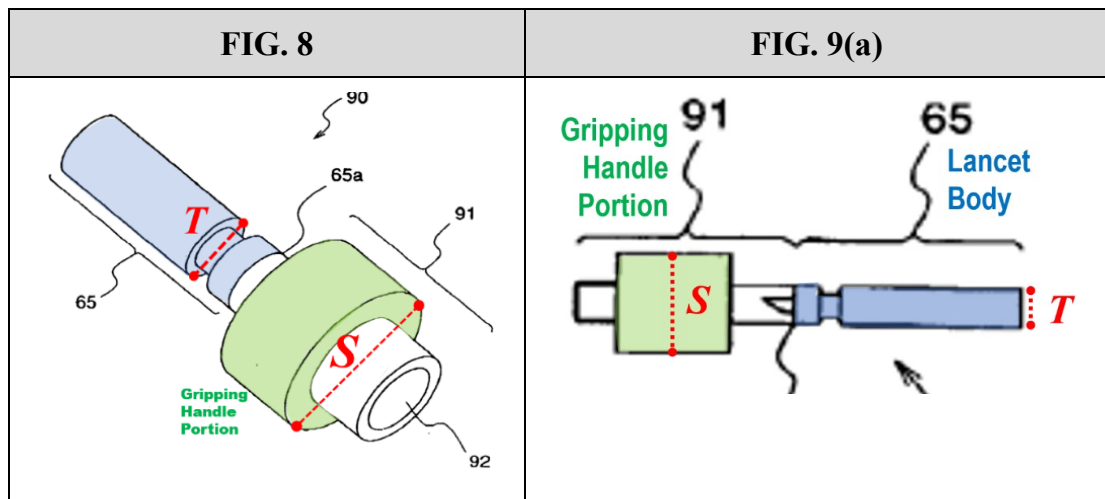
7. [Claims 6B and 6C]

Iio discloses a 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. 7, Figs. 8, 9(a); Ex. 4 ¶¶185-186.



8. [Claim 6D]

Iio discloses “the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness,” as seen in the lateral span for its gripping handle portion (annotated “S” below with lancet thickness annotated “T”) consistent with the lateral span depicted in Figure 5D of the ’635 Patent. Ex. 7, Figs. 8, 9(a); Ex. 4 ¶¶187-192.



1 Visual comparison of the gripping handle's lateral span ("S") with the
2 lancet's thickness ("T") in Iio's figures confirm the "gripping handle portion defines
3 a lateral span of at least 1.5 times the lancet thickness." Ex. 4, ¶188. The descriptions
4 of the primary and secondary sheaths also confirm the proportions in Iio's figures are
5 essential to Iio's cap performing as described. For example, Iio teaches "fitting of
6 the puncture needle to the disposal slot [the "secondary sheath"] is easier than fitting
7 of the puncture needle to the protection slot [the "primary sheath"]." Ex. 7, claim 20,
8 [0026]. In Figures 11(b) and (c), the entire thickness of the puncture needle body can
9 fit into Iio's secondary sheath, thus, the secondary sheath must have a greater lateral
10 span than the lancet thickness. *Id.*, Figs. 11(b)-(c). Figures 8, 9, and 11 in Iio also
11 show the gripping handle portion has a significantly broader lateral span than the
12 secondary sheath. *Id.*, Figs. 8, 9, 11. Furthermore, the size of the user's thumb in
13 Figure 9(a) has a lateral span comparable to the lateral span of the gripping handle
14 while the lancet thickness is very small in comparison. *Id.*, Fig. 9(a); Ex. 4, ¶190.

20 Iio also describes the measurement for "a thin plastic film having a
21 thickness of 0.1 mm or less in the puncture needle separation groove." Ex. 7, [0104].
22 With these dimensions, a POSITA could visually discern the lancet thickness is
23 around five times thicker than the "needle separation groove 65a" and the lateral span
24 of the gripping handle portion is 20 or more times larger than the "needle separation
25 groove 65a." Ex. 4, ¶¶191-192.

E. Claims 8 and 18 Are Also Anticipated By Iio

Iio discloses the “gripping handle portion defines a length at least equal to (including larger than, as shown in Iio) the lancet thickness.” Iio’s figures show the gripping handle is larger than the outer diameter of the secondary sheath. Ex. 7, Figs. 8, 9, 11. The inner diameter of the secondary sheath is also described as being large enough to receive the entire thickness of the lancet. *Id.*, claim 20, [0026]; Ex. 4 ¶¶196-197,200.

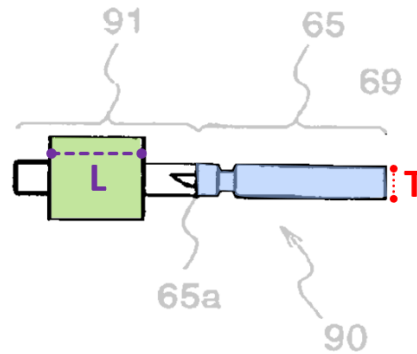


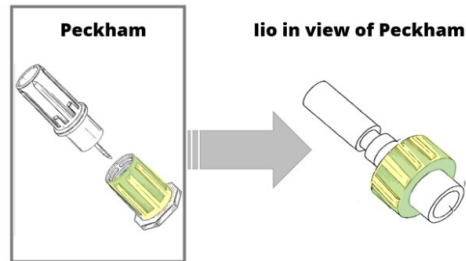
FIG. 9(a) (Colored and Annotated)

Because the entire thickness of the lancet body must fit within the inner diameter of the secondary sheath (which is smaller than the length and lateral span of the gripping handle portion), a POSITA would have understood the length of Iio’s gripping handle is at least equal to the lancet thickness. Ex. 4, ¶197.

F. Alternatively, Claims 6, 8, 14, and 18 Are Obvious In Light of Iio and Peckham

1. “gripping handle portion”

Even if Iio did not disclose a gripping handle (which it does), the asserted claims would be invalid because it would have been obvious to modify Iio to include the longitudinal ribs disclosed in Peckham to “improve handling” of the cap. Ex. 8: Fig. 2, 3:11-16.



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 iteration of FIG. 2 above*] on housing 105 that extend from octagonal shaped flange 120 toward open end 110.” *Id.* 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.” *Id.* A POSITA would have had ample motivation to apply the ribbed design from Peckham’s “protective cap 100” to the cylindrical handle on Iio’s puncture needle unit and thereby “provide a sufficient textured surface to improve handling and maneuverability of [Iio’s puncture needle unit].” *Id.* For example, like the ’635 Patent, both Iio and Peckham relate to lancets for blood collection *and* disclose solutions which assist patients with handling lancets better. *Id.*, 1:5-8; Ex. 7, [0001]; Ex. 4, ¶¶215-226 (describing multiple reasons why a POSITA would have been motivated to combine Iio and

1 Peckham); *In re Kahn*, 441 F.3d 977, 986-87 (Fed. Cir. 2006) (describing how a
2 reference is analogous prior art if it is either in the field of the applicant's endeavor
3 or is reasonably pertinent to the problem with which the inventor was concerned).
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5 **2. The "length" and "lateral span" limitations**

6 Iio discloses the "length" and "lateral span" limitations of the asserted claims.
7
8 To the extent that Facet argues it does not, the dimensional limitations would have
9 been obvious to try. Preventing inadvertent needle sticks had long been a goal of the
10 prior art, particularly when "attaching or detaching the puncture needle to/from the
11 lancet." Ex. 7, [0004]. Like the dimensions in the '635 Patent, a POSITA would
12 have routinely experimented with the dimensions of the gripping handle (including
13 its lateral span and length) and recognized there are only a finite number of potential
14 dimensions for the gripping handle as compared to the thickness of the lancet. Ex.
15 4, ¶208. In view of Iio's instruction to "ensure excellent usability and handleability
16 with safety," a POSITA would have focused on designing larger gripping handles to
17 achieve these goals. *Id.*; Ex. 7, [0005]; *ZUP, LLC v. Nash Mfg., Inc.*, 896 F.3d 1365,
18 1372 (Fed. Cir. 2018) (affirming summary judgment of obviousness where a long
19 goal of the prior art was accomplished by enhancing the same components employed
20 in the asserted patent).
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25 When designing larger gripping handles, a POSITA would have tried
26 dimensions in which the gripping handle's lateral span was more than 1.5 times the
27 lancet thickness as this would have improved a user's ability to safely handle a lancet
28

1 both before and after use, even for those with dexterity challenges. Ex. 4, ¶209. A
2 POSITA would have also tried measurements where the length of Iio’s gripping
3 handle was at least equal to the lateral span. *Id.*, ¶211. Trying to implement these
4 dimensions would have been achieved with a reasonable expectation of success as
5 the process of testing dimensions for a prototype product is a standard practice for
6 designing consumer products in the medical device field where safety is critical. *Id.*

7
8 It would have also been obvious to add extra gripping features as taught by
9 Peckham to Iio’s cap. Ex. 4 ¶213. A POSITA would have increased the lateral span
10 of the gripping handle even more (*i.e.*, beyond 1.5 times the lancet thickness) because
11 the ribs would have extended beyond the outer surface of Iio’s cap, extending the
12 cap’s lateral span. This would have furthered Peckham’s goals of “improv[ing]
13 handling and maneuverability of [the] cap” and render obvious the dimensional
14 limitations of the asserted claims. Ex. 8, 3:14-16; Ex. 4, ¶213.
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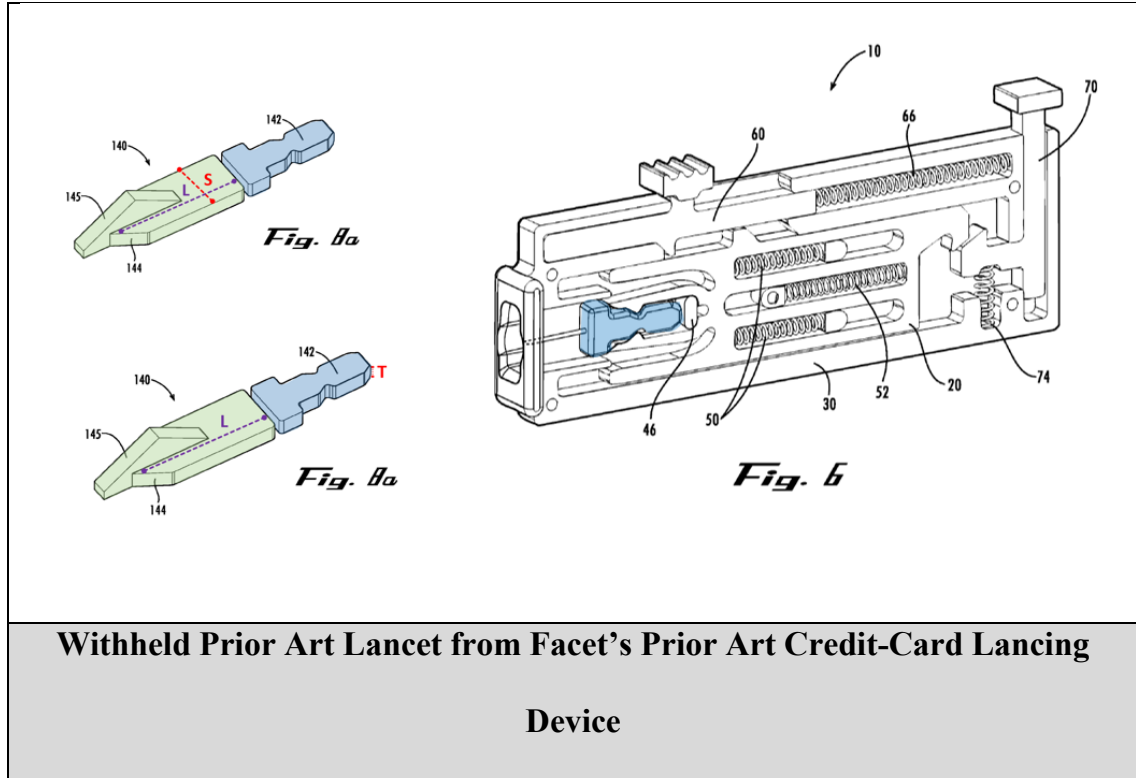
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19 **V. FACET HAS WITHHELD ITS OWN PRIOR ART LANCETS THAT**
20 **DISCLOSE THE “LATERAL SPAN” AND “LENGTH”**
21 **LIMITATIONS OF THE ’635 PATENT CLAIMS**

22 For the last nine months, LifeScan has been demanding that Facet produce
23 physical samples of its own prior art lancets—including the embodiments developed
24 from Stout (Ex. 8), and other Facet prior art patents—so that LifeScan can measure
25 and confirm that the “lateral span” of each cap’s gripping handle is “at least least 1.5
26 times the lancet thickness” (claims 6 and 14), and that the “length” of each cap’s
27 gripping handle is “at least equal to the lancet thickness” (claims 8 and 18). *See* Joint
28

1 Stipulation dated May 3, 2023 (ECF 167-2), 1-2. Rather than timely produce its own
2 lancets, Facet withheld them altogether on the grounds that LifeScan’s discovery
3 requests called for expert opinion. *Id.* Worse yet, Facet last week mooted LifeScan’s
4 Motion to Compel these prior art lancets by representing to the Court that it had
5 produced all responsive documents and things—just one day before Facet’s own
6 employee testified during his deposition that he was instructed by Facet’s attorneys
7 to only produce prior art lancets from the “museum” containing more than fifty (50)
8 prior art lancets that Facet currently maintains in its office. Ex. 11 at 146-49
9 (Goodrow Rough Transcript).

13 LifeScan has more than a good-faith belief that these lancets disclose the added
14 limitations of the challenged ‘635 patent claims; recent deposition testimony from a
15 former Facet engineer confirms it. Just three days ago (May 25), Mr. Greg
16 Lamps—the former Facet engineer who led the development of the Delica lancet and
17 oversaw the named inventors of the ‘635 patent—testified during his deposition that
18 Facet made physical samples of the credit-card sized lancing device shown in Stout,
19 and that the lancet for that credit-card shaped lancing device was interchangeable
20 with the one from the Delica lancing device that Facet would later develop. Ex. 12
21 at 454-55 (Lamps Rough Transcript). Indeed, just like the Delica lancet and lancing
22 device, Mr. Lamps testified that “the lancet had to be inserted deeper into the lancing
23 device, so there was a need for a long, thin handle on the lancet for the credit card
24 device.” *Id.* at 370-71. If and when Facet produces this lancet, LifeScan will

supplement this Motion to address this art and any other Facet prior art lancets. However, at a minimum, Mr. Lamps' testimony demonstrates that the specific "lateral span" and "length" of the handle recited by asserted claims 6, 8, 14, and 18 would have been obvious to a skilled artisan in view of Stout.



VI. CONCLUSION

LifeScan's Motion should be granted and claims 6, 8, 14, and 18 of the '635 Patent found invalid for the reasons above.

1 Dated: May 29, 2023

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CERTIFICATION OF COMPLIANCE

The undersigned, counsel of record for Defendant LifeScan, Inc., certified that this brief contains 6,896 words, which complies with the word limit of L.R. 11-6.1.

Dated: May 29, 2023

Respectfully Submitted,

/s/ Gerald W. Griffin