

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIFESCAN, INC.

Petitioner,

v.

FACET TECHNOLOGIES, LLC

Patent Owner.

Case No. IPR2023-00713

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

**PETITION FOR *INTER PARTES* REVIEW OF
CLAIMS 1, 4, and 9-15 OF U.S. PATENT NO. 8,840,635**

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PETITIONER’S EXHIBIT LIST

<u>Exhibit</u>	<u>Description</u>
Ex. 1101	U.S. Patent No. 8,840,635 to Pusey et al. (the “’635 Patent”)
Ex. 1102	File History of the ‘635 Patent
Ex. 1103	Declaration of Expert Joel Delman
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Ex. 1105	District Court Order on Claim Construction
Ex. 1106	U.S. Patent No. 5,207,699 to Coe (“Coe”)
Ex. 1107	JP Patent App. No. 2005168634 to Sakata (“Sakata”)
Ex. 1108	U.S. Patent App. Pub. No. 2007/0162064 (“Starnes”)
Ex. 1109	Japanese Patent No. JPH05285127 (“Morita”)
Ex. 1110	Wayback Declaration + One Touch Booklet: One Touch Basic Complete Diabetes Monitoring System Owner’s Booklet, Rev. 02/2004, LifeScan Inc., Milpitas, California (1999)
Ex. 1111	Stipulation Not to Pursue in a Parallel Proceeding the Same Grounds or Any Grounds that could have Reasonably been Raised
Ex. 1112	U.S. Patent No. 5,385,571 (“Morita II”)
Ex. 1113	U.S. Patent No. 8,920,454 (“Hyoue”)
Ex. 1114	U.S. Patent App. No. 2007/0293883 (“Horie”)
Ex. 1115	International Pub. No. WO2007089930 (“Lathrop”)
Ex. 1116	U.S. Patent App. No. 2005/0131440 (“Starnes ‘440”)
Ex. 1117	U.S. Patent App. No. 2003/0144608 (“Kojima”)
Ex. 1118	U.S. Patent No. 3,358,689 (“Higgins”)
Ex. 1119	U.S. Patent Application Publication No. 2006/0174592 (“Chan”)
Ex. 1120	U.S. Patent No. 6,283,982 (“LeVaughn”)
Ex. 1121	Dandekar et al., <i>3-D Finite-Element Models of Human and Monkey Fingertips to Investigate the Mechanics of Tactile Sense</i> , Journal of Biomedical Engineering (Oct. 2003, Vol. 125)
Ex. 1122	Hohendorff et al., <i>Lengths, Girths, and Diameters of Children’s Fingers from 3 to 10 Years of Age</i> , Annals of Anatomy 192 (2010)
Ex. 1123	Abbott Freestyle Freedom Manual
Ex. 1124	Goyal et al., <i>Diabetic Hand: A Neglected Complication of Diabetes Mellitus</i> (June 9, 2018)
Ex. 1125	D.C. Anderson et al., <i>Preventing Needlestick Injuries</i> (March 30, 1991)

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, 4, and 9-15 (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 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* forthcoming) 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.

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:

Coe (Ex. 1106): U.S. Patent No. 5,207,699 to Coe (“Coe”) issued on **May 4, 1993**. Because Coe’s issue date is more than **15 years before** the Effective Filing Date, Coe qualifies as prior art under pre-AIA § 102(b).

Sakata (Ex. 1107): JP Patent App. No. 2005-168634A to Sakata (“Sakata”) published on **June 30, 2005**. Because Sakata’s publication date is more than **3 years before** the Effective Filing Date, Sakata qualifies as prior art under pre-AIA § 102(b).

Starnes (Ex. 1108): U.S. Patent Application Publication 2007/0162064 to Starnes (“Starnes ‘064”) published on **July 12, 2007**. Because Starnes ‘064’s publication date is more than **1 year before** the Effective Filing Date, Iio qualifies as prior art under pre-AIA § 102(b).

Morita (Ex. 1109): Japanese Application Publication No. 19930285127 to Morita (“Morita”) published on **November 2, 1993**. Because Morita’s publication

date is more than **19 years before** the Effective Filing Date, Morita qualifies as prior art under pre-AIA § 102(b).

One Touch Basic Complete Diabetes Monitoring System Owner's Booklet (Ex. 1110): One Touch Basic Owner's Booklet (AW *05061302A*) was published on **February 5, 2004**. Because the booklet was published more than **4 years before** the Effective Filing Date, the booklet 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	Coe	§ 102	1
2	Coe and Sakata	§ 103	4 and 9-15
3	Coe, Starnes, and One Touch Booklet	§ 103	4, 9-15
4	Sakata and Morita	§ 103	1, 4, 9-15

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. Allowance was secured during prosecution based on an argument that a 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. 1102, pg. 52. Disclosures of secondary sheaths and gripping handle portions with primary and secondary sheaths at ends thereof are plainly found in the primary reference asserted herein. *See infra* Section VIII and XI. 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 also 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. 1111.

Put simply, 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, or other similar discipline, including coursework in designing consumer products for mass markets, along with at least 4-6 years of experience designing consumer products to optimize human wellbeing and overall system performance (at least some of which would be for medical-device products), including 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.

In addition, a PHOSITA would have 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,” (B) removing the plastic cap from the plastic body to expose the needle tip and then “mount[ing] into a receiver or lancet carrier portion of the drive mechanism of a lancing device,” (C) removing “a used lancet” from “the lancet carrier [of the lancing device] after sampling for disposal,” and (D) “[t]he endcap may be replaceable onto the lancet after use to recover the sharp lancet tip for safety and hygienic purposes.” Ex. 1101, 1:38-57.

VII CLAIM CONSTRUCTION

The district court has 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. 1105, pg. 28. For other terms (including “gripping handle portion”; “lancet thickness”; “lateral span”; and “length”), the district court determined that no construction was needed, *i.e.*, plain and ordinary meaning controls. *Id.* at pgs. 28-29.

Petitioner has applied the district court's one construction of secondary sheath 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: COE ANTICIPATES CLAIM 1¹

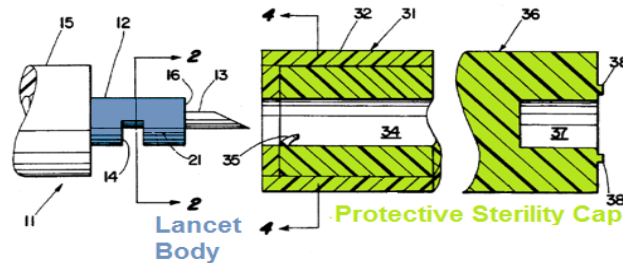
A. Claim 1[pre] - “A protective sterility cap for a lancet”

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.

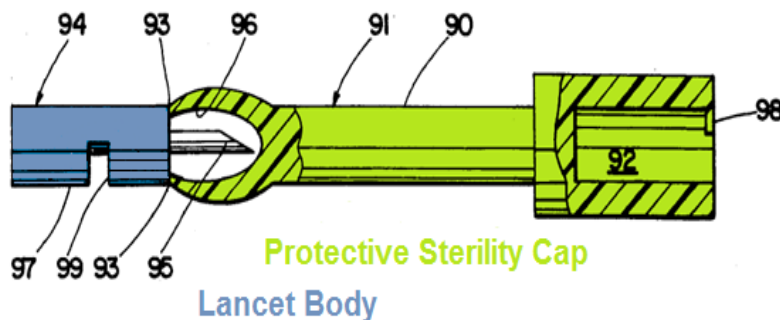
Should the Board find it limiting, Coe discloses a “protective cap (31) [that] has a releasing cavity (37) for receiving and protectively enclosing the sharp tip (13) of the blood lancet (11) prior to [use]. Breakaway contact points (38) on the surface of the protective cap (31) adjacent to the releasing cavity (37) enable the protective cap (31) to be removed from the blood lancet (11) with a simple twist” Ex. 1106, 4:48-54. Coe further discloses that the protective cap has a “non-

¹ While Ground 1 relies on the embodiment shown in Figure 9, “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.”); Coe discloses three embodiments depicted in Figures 1-4, Figures 5-6, and Figures 7-8, respectively. Ex. 1106, 3:47-68-4:1-2. Figure 9 depicts the first embodiment integrally molded to a lancet before use. Ex. 1106, 4:3-5.

releasing cavity (34) [that] receives and protectively envelops the sharp tip (13) of the lancet (11) after [use].” Ex. 1106, 4:29-33, Figures 1 and 3 annotated below.



In Figure 9, Coe depicts the protective cap (extractor 91) with both cavities “integrally molded to a lancet.” Ex. 1106, 4:3-5. Coe explains that the “handle portion [(90)] of the extractor is attached to the hub of the lancet (97) by breakaway points (93)” and that “[t]he sterile lancet tip [(95)] is then bared for use by breaking away the [cap] at the breakaway points by gentle twisting. After use, the lancet is inserted (point first) into the [non-releasing cavity] ... for safe handling and disposal.” Ex. 1106, 5:28-38; Ex.1103 ¶54; Figure 9 annotated below.

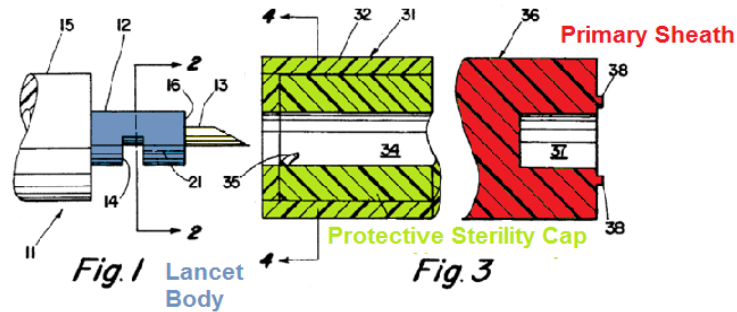


The “protective cap” (green above) is a protective sterility cap that is “integrally molded” to a lancet (blue above) to protect the “sterile lancet tip” (white) before use. The cap is separated from the lancet at breakaway points by twisting the cap’s handle portion. After use, the cap’s non-releasing cavity is fitted over the lancet tip for safe disposal. Thus, Coe discloses a “protective sterility cap for a lancet.” Ex. 1103, ¶¶55-56.

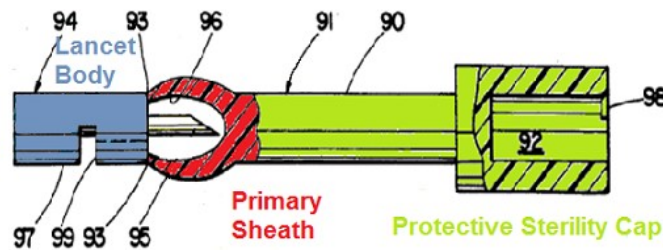
B. Claim 1[a] - “said sterility cap comprising a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein”

Coe discloses a “protective cap (31) [with a] **releasing cavity (37) for receiving and protectively enclosing the sharp tip (13) of the blood lancet (11) prior to pricking the skin.** Breakaway contact points (38) on the surface of the protective cap (31) adjacent to the releasing cavity (37) enable the protective cap (31) to be removed from the blood lancet (11) with a simple twist” Ex. 1106, 4:48-54. Coe explains that the “releasing cavity (37) in the end of the protective cap thereby serves as a releasable housing for the lancet tip (13) until the lancet (11) is ready to be used to prick the skin.” Ex. 1106, 4:56-59.

Coe claims “a protective cap [with] **a first cavity** for receiving and **protectively enveloping the sharp tip of said blood lancet prior to use** of said blood lancet.” Ex. 1106, 6:13-16, Figures 1 and 3 annotated below.



Coe depicts the protective cap “**integrally molded to a lancet.**” Ex. 1106, 4:3-5. Coe explains that the protective cap has a “[releasing] cavity (96) protectively covering the sharp tip (95) of the lancet (94). Ex. 1106, 5:27-28. Coe further explains that “[t]he sterile lancet tip is then bared for use by breaking away the [cap (91)] at the breakaway points [(93)] by **gentle twisting**” of the handle (90). Ex. 1106, 5:31-33, Figure 9 annotated below; Ex.1103 ¶57.



The “releasing cavity” (red above) of the protective cap is a primary sheath that is “**integrally molded**” to the lancet (blue) to protect the “sterile lancet tip” before use. The releasing cavity or primary sheath (red) “protectively enclos[es],” “hous[es],” “envelop[s]” and “cover[s]” the “sterile lancet tip” before use. The “sterile lancet tip” is released for use by separating the cap from the lancet by

“**gentle twisting**” at “breakaway points” on the surface of the releasing cavity or primary sheath adjacent to the lancet. Ex.1103 ¶57.

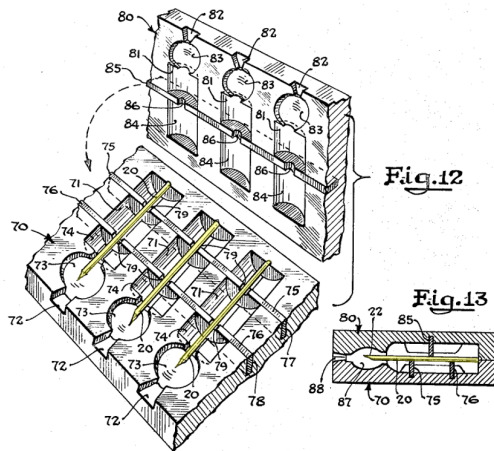
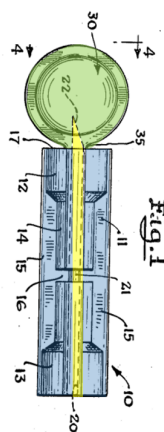
While Coe does not use the term “embedment,” an anticipatory prior art reference “need not disclose the elements in the *very same terms* used by the [‘635] patent.” *Adasa Inc. v. Avery Dennison Corporation*, 2022 WL 17725736, at *6-*9 (Fed. Cir. 2022) (“district court erred in interpreting these linguistic 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 at 1334 (“[An anticipatory prior art] reference need not satisfy an *ipsissimis verbis test*.”).

Indeed, Coe describes the protective cap as “**integrally molded** to a lancet,” and a PHOSITA would understand this to mean 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. 1103, Section IX(A)(2). A PHOSITA would understand that the “integrally molded” cap described by Coe was likewise molded to the needle tip and joins the needle in “a state where it is **embedded** in the puncture needle cap.” *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). Put

differently, a PHOSITA would understand that sharp needle tip 95 of the lancet 94 is embedded in twist-off breakaway points 93 and adjoining portion of the protective sterility cap 91 because Coe describes the cap as “**integrally molded**” to the lancet and teaches that the cap may be “gently twisted” (not pulled) off of the lancet body to avoid bending or damaging the lancet. Ex. 1103, ¶¶58-60, 76; Ex. 1106, 1:32-25.

“An example of such a [conventional] lancet is found in U.S. Patent no. 3,358,689, issued to Higgins, wherein a lancet needle is encased in an elongated plastic body with the needle tip **embedded** in a removable protective cap **integrally molded** with the plastic body to form a single integral unit prior to use.” Ex. 1116, ¶0008; Ex.1103 ¶¶58-60, 76.

What “Integrally-Molded” Means to a PHOSITA

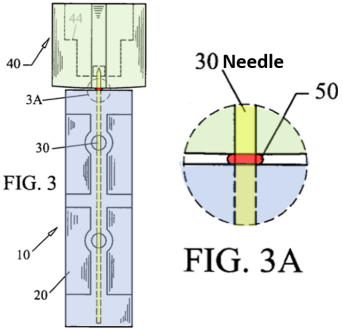
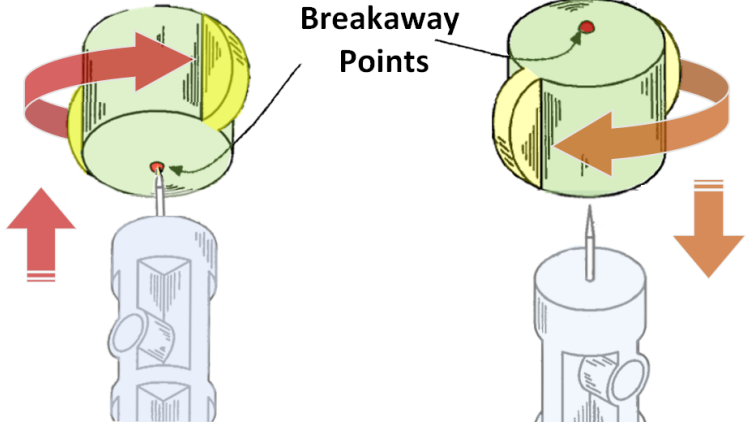


Ex. 1118, pgs. 1-2, Figures 1, 12-13

The '635 Patent also itself 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. 1101, 1:47-50, 6:18-24. So too for Higgins (Ex.1118), Starnes'440 (Ex.1116), and other prior art patents and published applications cited on the face of the '635 Patent—all of which use the term “**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.1116, ¶0008; Ex.1103, ¶¶59-60.

FIG. 9 also discloses the sharp tip 95 of Coe's lancet 91 embedded in the protective cap because a PHOSITA would recognize that the “breakaway points” are “frangible junction[s]” (*colored red below*) by which “the cap [] is integrally molded and joined to the lancet body” such that the “tip [of the lancet] is **embedded** within cap [] and frangible junction [s]” and can be separated from the lancet body by “gentle twisting.” Ex.1103, ¶¶62 (“piercing tip [of the lancet] is

embedded within cap”, which “receives the distal end of piercing tip 32 in the pre-use, ‘as manufactured’ configuration.”) (quoting Ex.1116, ¶0028). Ex.1103, ¶¶61-62.

“Breakaway Points” as understood by a PHOSITA	
 FIG. 3 and FIG. 3A diagrams showing a lancet assembly. FIG. 3 is a side view of a lancet body (10) with a needle (30) and a cap (40). FIG. 3A is a cross-sectional view of the needle (30) and cap (40) showing a breakaway point (50).	 Diagram illustrating breakaway points on a lancet cap. The cap is shown in two states: one with a red arrow indicating a breakaway point and another with an orange arrow indicating a breakaway point. The cap is labeled "Breakaway Points".
Starnes '440, Figs.3-3A(Colored)	Ex. 1103, ¶62 (Demonstrative for Starnes '440)

This is consistent with the '635 Patent, which teaches that not only that “the sterility cap 510 is **integrally molded** with the lancet body,” but also that the “spacer ribs or breakaway connections 518”—*i.e.*, breakaway points—“extend[] from the primary shroud or sheath portion 512 to the front end of the lancet body, such that intact spacer ribs or breakaway connections 518 indicate an **unused lancet**, whereas broken spacer ribs or breakaway connections 518 indicate the

lancet may have been used and therefore may not be sterile.” Ex. 1101, 6:18-26. Because the breakaway points in Figure 9 are not broken, a PHOSITA would understand that the the needle has not yet been used for sampling or testing, and therefore, remains sterile. Ex.1103, ¶61.

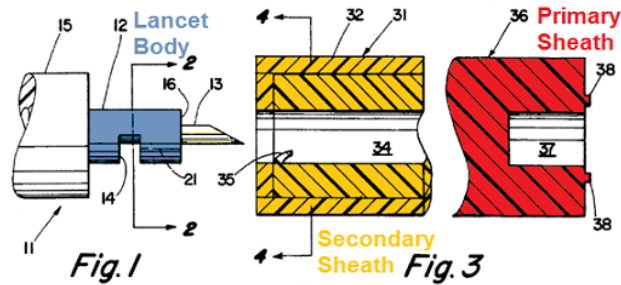
Coe’s Figure 9 also illustrates that the needle sharp 95 is embedded within extractor 91 and adjoining portion of the handle portion 90. Coe teaches that the extractor 91 may include “an extractor cavity (92)...[with] the extractor tab (98) engag[ing] the slot (99) in the lancet hub thereby locking the sharp lancet tip protectively within the extractor cavity for safe handling and disposal.” Ex.1106, 5:33-38. By differentiating the “cavity (96)...attached to the hub of the lancet (97) by breakaway points (93)” from the “extractor cavity (92)” of Figure 9, thereby showing how Coe’s cap/extractor is integrally molded with lancet 97. Ex.1103, ¶62.

Thus, Coe discloses “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein.” Ex. 1103, Section IX(A)(2).

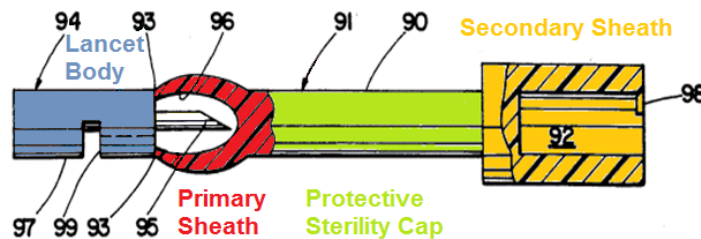
C. Claim 1[b] - “a secondary sheath for receiving the sharp lancing tip of a used lancet”

Coe discloses a protective cap with a “**non-releasing cavity (34) [which] receives and protectively envelopes the sharp tip (13) of the lancet (11) after the sharp tip (13) has been used** to puncture the skin and is contaminated with

blood.” Ex. 1106, 4:29-33. Coe claims “a protective cap [with] **a second cavity for receiving and protectively enveloping the sharp tip of said blood lancet after said blood lancet has been used to puncture the skin.**” Ex. 1106, 6:13, 6:20-23, Figures 1 and 3 annotated below.



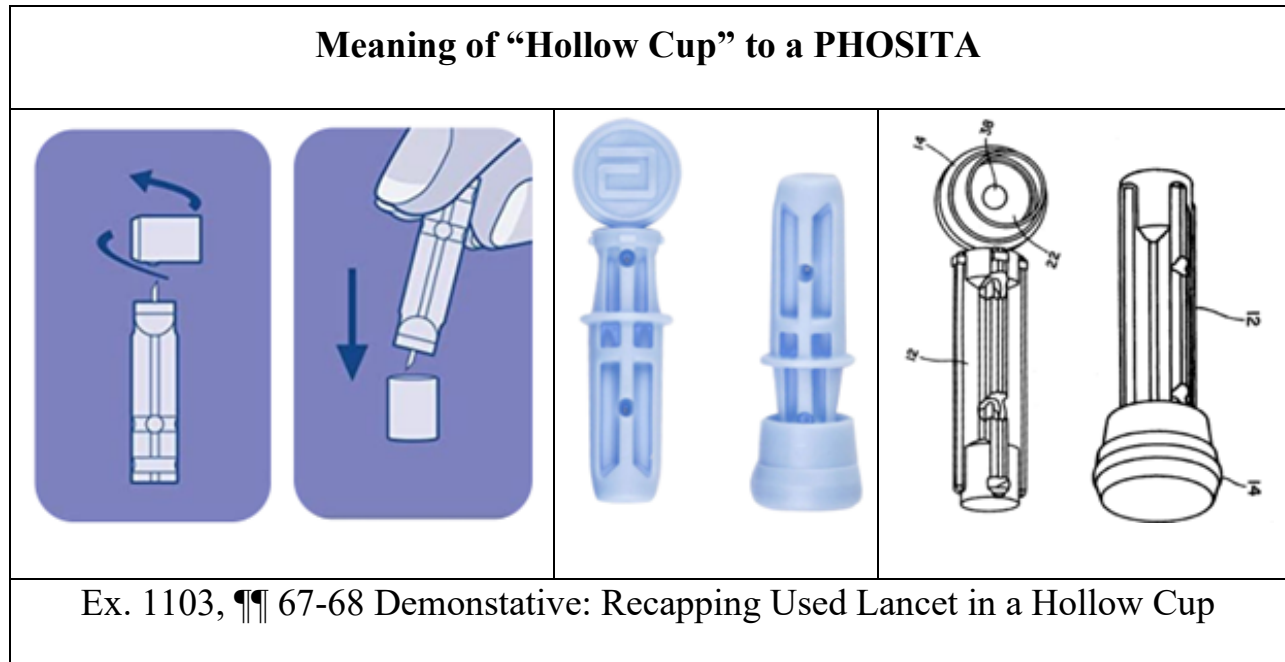
Coe depicts the protective cap “integrally molded to a lancet.” Ex. 1106, 4:3-5. Coe teaches that “[a]fter use, the lancet is inserted (point first) into the [non-releasing] cavity until the extractor tab (98) engages the slot (99) in the lancet hub thereby locking the sharp lancet tip protectively within the [non-releasing] cavity for safe handling and disposal.” Ex. 1106, 5:33-38, Figure 9 annotated below; Ex.1103, ¶65.



The non-releasing cavity of the protective cap (orange above) is a secondary sheath “which receives ... the sharp tip of the lancet after the sharp tip has been

used.” The sharp tip (white) of the lancet (blue) is inserted into the non-releasing cavity or secondary sheath (orange) to dispose of the lancet safely after use.

To prevent inadvertent needle sticks after use but prior to disposal, many conventional caps also include a hollow cup so the user can safely dispose the lancet after it has been used. The needle sharp remains encased within the hollow cup while the user finishes testing the blood sample and even after the lancet has been discarded. Ex. 1112-1115 and 1117. The hollow cup 92 is designed for receiving a used lancet because the sharp lancing tip is enclosed in the hollow cup. Ex.1103, ¶¶67-68. 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 lancing tip.” Ex. 1105, 13:24-14:3. Ex.1103, ¶¶66-69.

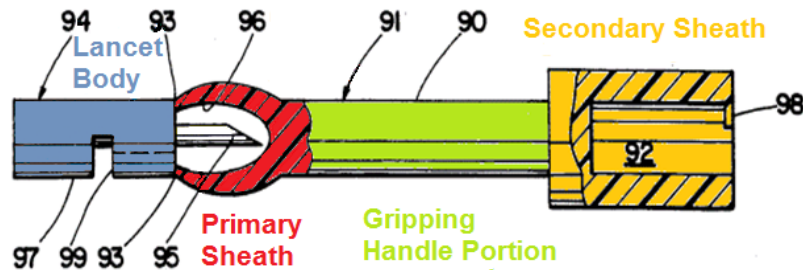


Thus, Coe discloses “a secondary sheath for receiving the sharp lancing tip of a used lancet.” Ex. 1103, Section IX(A)(3).

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

Coe discloses that the protective cap has a “**handle portion (90) and [a non-releasing] cavity (92). On the end of the handle opposite the [non-releasing] cavity, there is a [releasing] cavity (96) protectively covering the sharp tip (95) of the lancet (94).**” Ex. 1106, 5:24-28. Coe depicts the “handle portion” (green below) extending between the cavities. The handle portion (green) is longer than the cavities creating a large surface area for a user to grip the protective cap when following Coe’s teachings. Ex. 1106, Figure 9 annotated below. Ex.1103, ¶72.

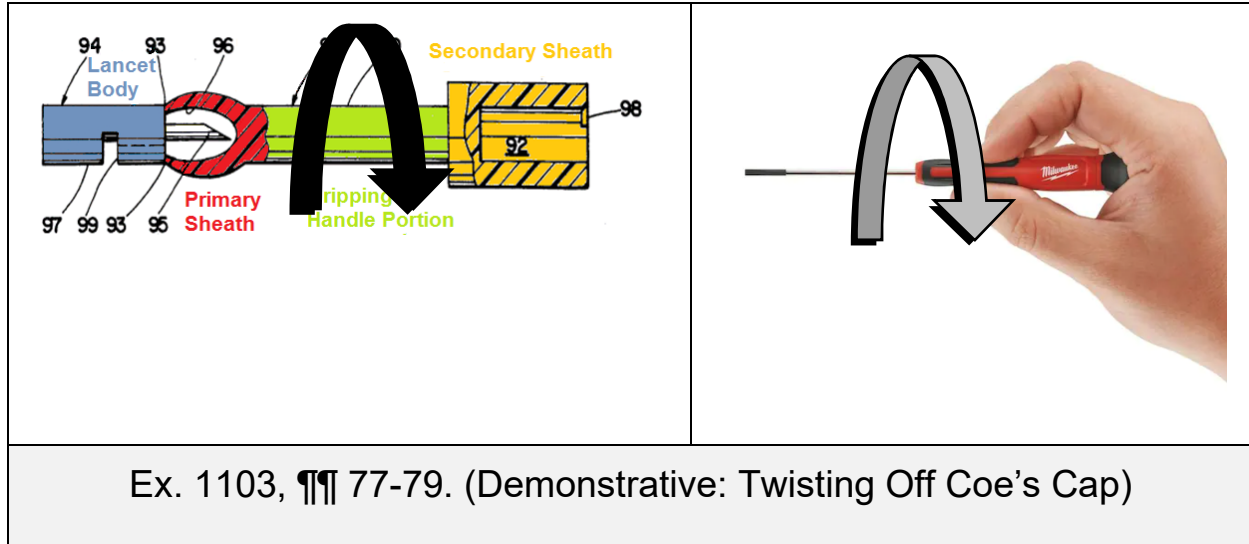
As many individuals afflicted with diabetes possess dexterity and mobility issues, the handle portion provides users with a handle for twisting (i.e., gripping) away the cap at breakaway points 93 to bare the sharp tip of the lancet 95. Ex.1106, 5:24-27; Ex. 1103, ¶73.



Coe teaches that “the lancet is **inserted** into an automatic lancet device. The sterile lancet tip [(95)] is then bared for use by **breaking away the handle portion** [(90)] at the breakaway points [(93)] by gentle **twisting**. After use, the lancet is **inserted** (point first) into the [non-releasing cavity (92)] ... for safe **handling** and disposal.” Ex. 1106, 5:30-38. This is consistent with the plain and ordinary meaning of the claim term “gripping handle portion,” which the district court considered simply 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.1105, 17:12-13. Per the Court, “all handles are ‘gripping handles.’” *Id.* The '635 patent likewise refers to a “handle or grip”

interchangeably and describes a “handle” or “handle portion of the cap.” Ex.1101, 1:66-2:3, 6:5-9, 7:6-12, 8:17-22; Ex.1103, ¶74-75.

By having the handle portion 90 on the extractor 91 between the primary sheath and secondary sheath, Coe’s protective cap provides the user with an elongated surface area, near the center of the extractor, so as to encourage and facilitate for a user to gently twist off the extractor/cap from breakaway points 93. Ex. 1103, ¶76



The elongated handling tab (green above) enables the user to apply torque when twisting the protective cap from the lancet. The surface of the handle portion allows the user to firmly grasp the protective cap with the thumb and index finger and exert pressure while twisting. Coe’s handle portion functions much like a conventional handle of a screwdriver, wherein a user is able to controllably twist

the screwdriver near its handle's center of gravity. Just like a screwdriver, Coe's handle portion provides a surface to provide a firm grip while turning. Ex. 1103, ¶77.

Coe's handle portion 90 provides leverage for applying rotational force to effectively twist the cap, making it easier to remove the protective cap 90 from the lancet 94. A PHOSITA would appreciate that the increased leverage provided by the handling tab better accommodates diabetic patients with limited dexterity by spreading the applied force efficiently across a longer contact area. Ex. 1103, ¶78.

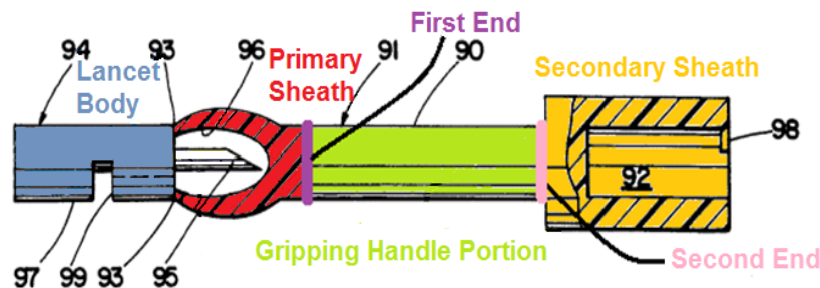
Coe's handle portion also allows the user to grip the lancet further away from the needle sharp, which helps “minimize the risk of accidental puncture wounds both during and after removal of the lancet from an automatic lancet device.” Ex. 1103 ¶¶ 77-79; Ex.1106, 3:11-14.

By extending the “handle portion” between the two cavities or sheaths, Coe assists the user with gripping the protective cap to insert the lancet (blue) into a lancet device, twist and break away the cap from the lancet at the breakaway points (93) on the surface of the releasing cavity or primary sheath (red), insert the used lancet into the non-releasing cavity or secondary sheath (orange), and handle and dispose of the used lancet safely after use. Indeed, Coe designed the handle portion (green) to ensure “safe handling and disposal” of the lancet before and after use.

Ex. 1106, 5:37-38. Thus, Coe discloses “a gripping handle portion extending between the primary sheath and the secondary sheath.” Ex. 1103, Section IX(A)(4).

E. 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”

Coe discloses a protective cap that is “integrally molded to a lancet (94).” Ex. 1106, 5:23-24. Coe explains that “[t]he handle portion of the [cap] is attached to the hub of the lancet (97) by breakaway points (93). In practice, the lancet is inserted into an automatic lancet device. The sterile lancet tip is then bared for use by **breaking away the handle portion at the breakaway points** by gentle twisting.” Ex. 1106, 5:28-33, Figure 9 annotated below; Ex. 1103, ¶¶81-83.



The protective cap is removed from the lancet (blue) at “breakaway points” (93) on the surface of the releasing cavity or primary sheath (red). After the cap is removed, the releasing cavity or primary sheath is still attached to the first end (purple above) and the non-releasing cavity or secondary sheath (orange) is still

attached to the second end (pink above) of the gripping handle portion (green). Thus, Coe discloses a gripping handle portion “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.” Ex. 1103, Section IX(A)(5).

IX GROUND #2: COE RENDERS CLAIMS 1, 4 AND 9-15 OBVIOUS IN VIEW OF SAKATA

Ample motivation existed for a PHOSITA to modify and/or combine various embodiments to arrive at the protective sterility cap from Ground 1. Ex. 1103, ¶¶83-86. First, while certain figures and descriptions in Coe refer to different embodiments, these embodiments are disclosed in adjacent figures, and Coe itself indicates the interchangeable nature of the various embodiments. Ex. 1106, 5:39-43; 6:1-6; Figures 1-9. Ex.1103 ¶¶86-87.

Second, the alternative embodiments are analogous to the first embodiment. Ex. 1106, 5:16-21 (“In addition, this embodiment, like the first two, can be integrally molded to the lancet with suitable breakaway points so that it can be used both as a protective lancet tip cover before use and a protective disposable tip cap after use.”). Although the components of the protective cap might differ across alternate embodiments, the embodiments use the same components to perform the same functions, ie. a primary sheath that protects the sterile needle tip before use, a

secondary sheath that receives the tip after use, and gripping handle portion that extends between the sheaths for “safe handling and disposal.” Ex. 1106, 5:24-38; Ex.1103 ¶¶86-87.

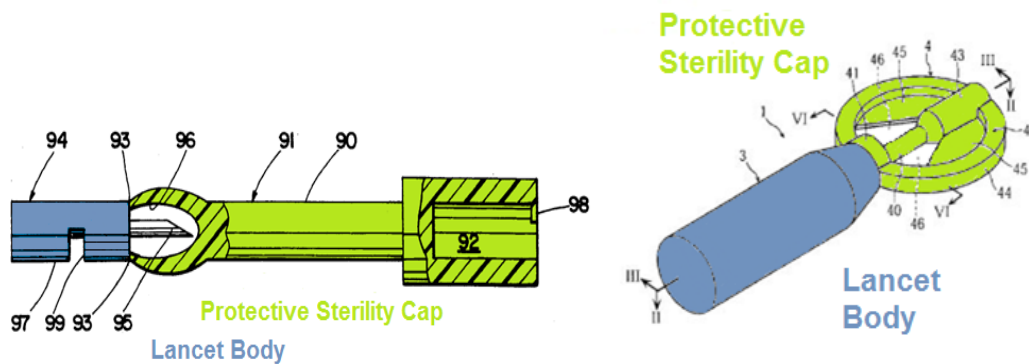
The interchangeable components of the protective sterility cap of Coe would motivate a PHOSITA to modify those components in an existing embodiment and/or combine components from multiple embodiments to create an entirely new embodiment not otherwise disclosed in Coe. Ex. 1103, ¶¶83-87.

Third, it would have also been obvious to a PHOSITA to embed the lancet needle into Coe’s cap/extractor to not only protect the integrity of the needle tip, but also to protect the sterility of the needle and prevent contamination during post manufacturing packaging, shipping, and storage. To do so, a PHOSITA would not need to use anything other than traditional insert molding methods, for high-volume, low-cost manufacturing. Thus, modifying Coe’s cap to include an embedded needle sharp would have been achieved with a reasonable expectation of success by using these common manufacturing techniques. Ex.1103, ¶86.

A. Motivation to Combine Coe and Sakata

A PHOSITA would have been motivated to modify Coe’s protective cap with Sakata’s operating and covering portions for the following reasons. Ex. 1103 ¶89.

First, a PHOSITA would have appreciated that Coe and Sakata are within the same field of endeavor as the '635 Patent, which is “lancets and lancing devices for blood sampling and testing.” Ex. 1101, 1:17-19; Ex. 1106, 1:11-14; Ex. 1107, ¶0001. Coe and Sakata also solve problems identified by the '635 Patent with gripping handle portions that “assist[] in removal of the cap for use of the lancet and/or for replacement of the cap onto a used lancet for disposal.” Ex. 1101, 1:66-2:8; Ex. 1106, 3:9-23; Ex. 1107, ¶0002; Coe’s Figure 9 and Sakata’s Figure 1 annotated below; Ex. 1103 ¶¶89-91.



Second, a PHOSITA would have been motivated to prevent damage to the lancet tip and pain to the user. Coe discloses that a lancet’s fine “tip easily breaks off during transport and storage. To make and protect a fine tip, the tip is surrounded by a plastic protective cap which is extruded in one piece with retaining attachment points and is twisted off before use of the lancet.” Ex. 1106, 1:32-35. A PHOSITA would have understood that the force applied to the large

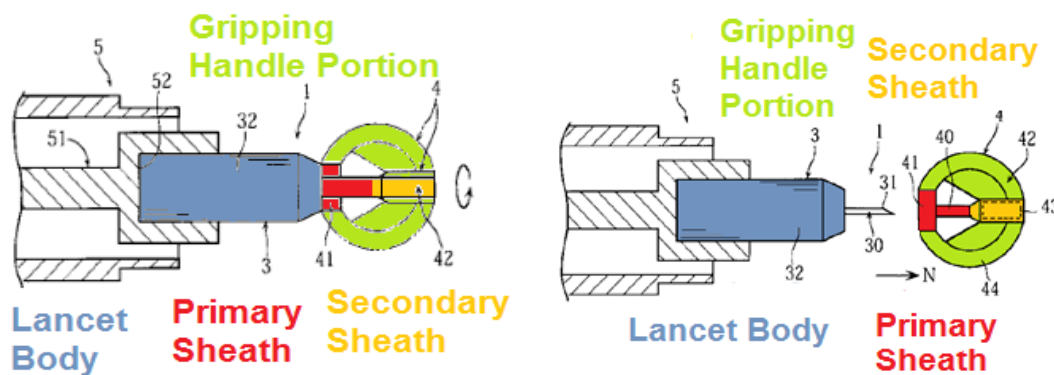
diameter of Coe's releasing cavity or primary sheath when twisting off the protective cap from the lancet can damage the fine tip of the lancet. Ex. 1103, ¶¶92-93. A PHOSITA would have further understood that a damaged lancet tip can cause additional pain to the user when puncturing the user's skin. Damage caused to the fine tip of a lancet when separating the cap from the lancet body and the increased pain caused from using a damaged tip were well-known and common problems in the industry. Ex. 1103, ¶91.²

Sakata teaches the benefits of preventing damage to a lancet's needle tip when the cap is removed from the lancet. Referring to prior art figures, Sakata states that "when the cap portion 83 is in close contact with the puncture needle 80 and the diameter of the portion of the cap portion 80 covering the puncture needle 80 is large, a relatively large stress acts on the blade surface of the puncture needle 80 when the cap portion 83 is twisted. As a result, the edge of the blade surface in the puncture needle 80 is disrupted, causing greater puncture pain when the puncture needle 80 is pierced into the skin." Ex. 1107, ¶0004, Ex. 1103, ¶92.

Sakata solves this problem with the operating and covering portions of its protective cap. Ex. 1107, ¶[0008]; Ex. 1103, ¶89-95. Sakata explains that "the force applied to the operating portion [42] is concentrated on the additional

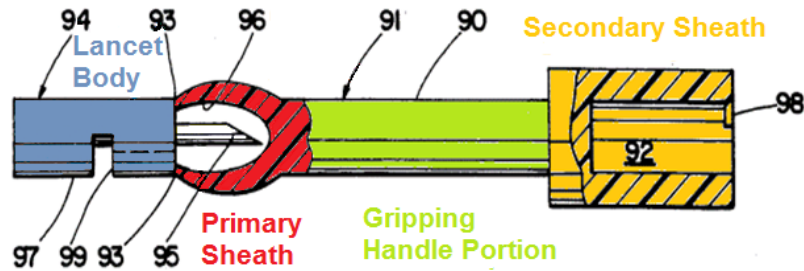
² See Ex. 1113 (Hyoe), 1:51-68-2:1-17; Ex. 1115 (Lathrop), ¶[0006]; Ex. 1103, ¶91.

covering portion [41], thus reducing the stress applied to the puncture needle. As a result, the load applied to the edge of the blade surface on the puncture needle when separating the cap portion is reduced, and the edge of the blade surface is not significantly disturbed. Therefore, ... it is possible to reduce the puncture pain to the user.” Ex. 1107, ¶[0012], Figures 5(a) and 5(b) annotated below; Ex. 1103, ¶89-93.

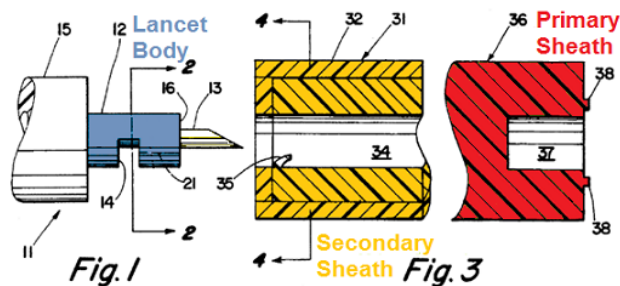


Third, a PHOSITA would have been motivated to dispose of a used lancet safely. Ex. 1106, 4:29-33, 6:20-23. Coe states that there is “a significant need for [a protective sterility cap] for lancets which will ... minimize the risk of accidental puncture wounds both during and after removal of the lancet from an automatic lancet device.” Ex. 1106, 3:9-15. Coe solves this problem with a gripping handle portion and non-releasing cavity or secondary sheath. Ex. 1106, 4:27-48. Coe explains “the lancet is inserted into an automatic lancet device. The sterile lancet tip [(95)] is then bared for use by breaking away the handle portion [(90)] at the

breakaway points [(93)] by gentle twisting. After use, the lancet is inserted (point first) into the [non-releasing cavity (92)] ... for safe handling and disposal.” Ex. 1106, 5:30-38. Ex. 1103, ¶94.



Fourth, a PHOSITA would have been motivated to identify used or tampered with lancets. Coe discloses a protective cap that can be reattached to Coe’s releasing cavity or primary sheath (red) by reinserting the lancet (blue) into releasing cavity or primary sheath instead of the non-releasing cavity or secondary sheath (orange). Ex. 1106, 6:20-23, Figures 1 and 3 annotated below. Ex. 1103, ¶94.



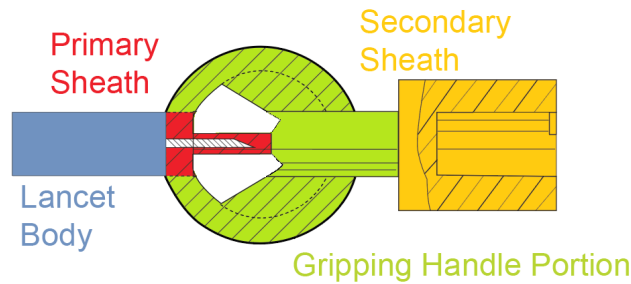
A PHOSITA would have understood that reattachment of a lancet to the releasing cavity would prevent the user from identifying whether the lancet had

been used or tampered with.³ *Id.* Sakata solves this issue with its operating and covering portions. Ex. 1107, ¶00012. Sakata explains that “when the cap portion is separated, the force applied to the operating [portion 42] is absorbed by the deformation of the covering [portion 41]” Ex. 1107, ¶00012. The deformation of the covering portion prevents a used or tampered with lancet from being reinserted into the covering portion. Ex. 1103, ¶90. A PHOSITA would have understood that using Sakata’s operating and covering portions to remove Sakata’s protective cap from the lancet was desirable to alert the user that the lancet had been used or tampered with. *Id.* at ¶¶90-93

Finally, Coe’s and Sakata’s protective caps have common components (i.e., primary sheaths, secondary sheaths, and gripping handle portions) that are easily interchangeable at a minimal cost through integral molding. Ex. 1103, ¶¶35, 61, 94. Indeed, Coe encourages changing the secondary sheaths of its protective cap. Ex. 1106, 5:16-21. Thus, a PHOSITA would have had a reasonable expectation of success in modifying Coe’s protective cap to include Sakata’s operating and covering portions. Ex. 1103, ¶¶93-95.

³ Identification of used or tampered with lancets was a well-known and common problem in the industry. Ex. 1108 (Starnes), ¶¶[0008-0011].

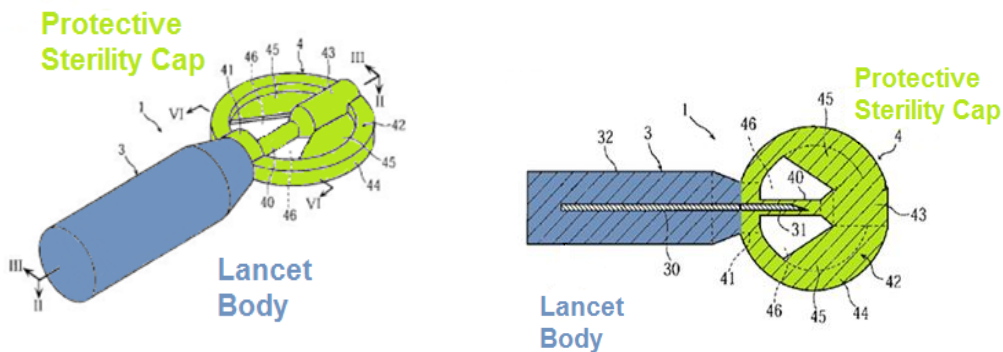
For the reasons above, it would have been obvious to a PHOSITA to add Sakata's operating and covering portions to Coe's protective cap. An illustrative example of the Coe-Sakata combination is shown below.



B. Claim 4 Is Obvious—“wherein the gripping handle portion comprises an open loop”

Claim 4 depends from Claim 1. Coe discloses the limitations of Claim 1. *Supra* §VIII. The Coe-Sakata combination renders Claim 4's additional limitation obvious. Ex. 1103, ¶88.

Sakata discloses an operating portion with “a gap 46 [that] is interposed between the arch portion 44 and the small diameter covering portion 40.” Ex. 1107, ¶[0019], Figures 1 and 2 annotated below.



As explained above, the operating portion 42 is the gripping handle portion of Sakata's protective cap. *Supra* §IX.A. Thus, the Coe-Sakata combination renders obvious a "gripping handle portion compris[ing] at least one open loop." Ex. 1103, §X.C.⁴

C. Claim 9 Is Obvious

- 1. 9[p] – “A protective sterility cap for a lancet, said sterility cap comprising”**
- 2. 9[a] – “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein”**
- 3. 9[b] - “a secondary sheath for receiving the sharp lancing tip of a used lancet”**
- 4. 9[c] - “a gripping handle portion extending between the primary sheath and the secondary sheath”**
- 5. 9[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”**

Limitations 9[p]-9[d] are identical to limitations 1[p]-1[d]. Coe discloses limitations 1[p]-1[d]. *Supra* §VIII.

⁴ Gripping handles with open loops were disclosed in publications during the prior art period. *See, e.g.*, Ex. 1115 (Lathrop), Figures 1A-1C; Ex. 1108 (Starnes), Figures 1-3.

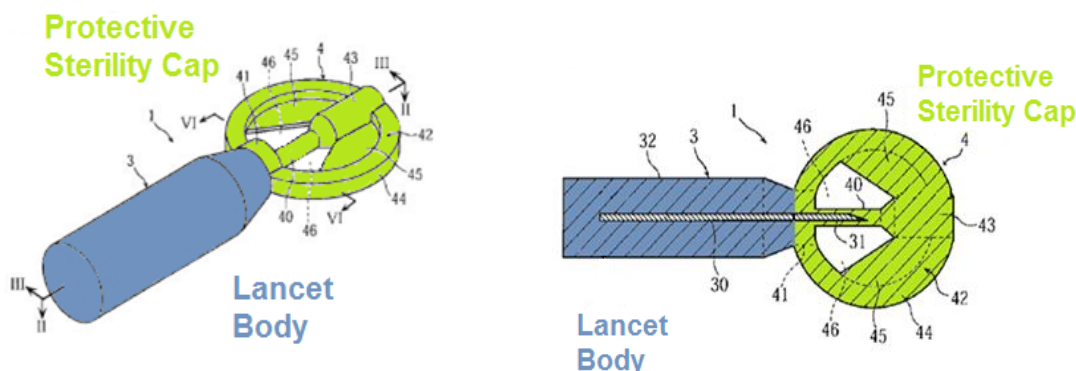
6. 9[e] - “wherein the gripping handle portion comprises at least one open loop”

This limitation is identical to the limitation of Claim 4. The Coe-Sakata combination renders Claim 4 obvious. *Supra* §IX.B.

D. Claim 10 Is Obvious—“further compromising at least one flat display surface for placement of branding indicia thereon”

Claim 10 depends from Claim 9. The Coe-Sakata combination renders claim 9 obvious. *Supra* §IX.C. Claim 10’s additional limitation is taught by the Coe-Sakata combination. Claim 10’s recitation of “for placement of branding indicia thereon” recites an intended use and does not structurally limit the protective sterility cap of Claim 9 and is therefore not limiting. Ex. 1103, §X.C.⁵ Regardless, Sakata discloses an “operating portion 42 [that] has ... a pair of thin-walled portions 45.” Ex. 1107, ¶19. The thin-walled portions are flat surfaces on which branding could be placed. Ex. 1107, Figures 1 and 2 annotated below; Ex. 1103, ¶98.

⁵ See *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990) (“[A]pparatus claims cover what a device is, not what a device does.”).



Thus, the Coe-Sakata combination renders obvious a gripping handle portion with “at least one flat display surface for placement of branding indicia thereon.”

Ex. 1103, §X.D.⁶

E. Claim 11 Is Obvious—“wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness”

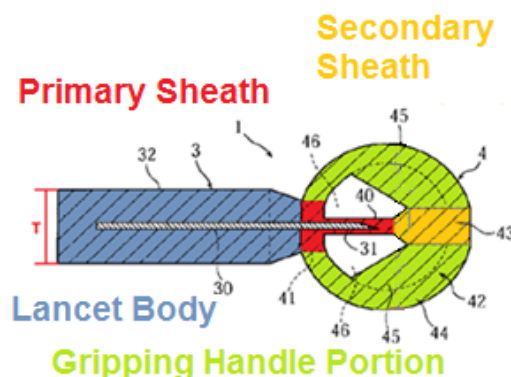
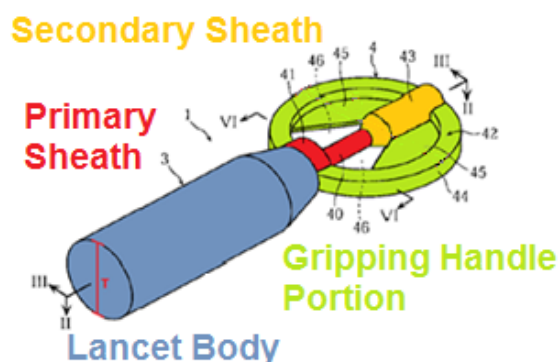
Claim 11 depends from Claim 9. The Coe-Sakata combination renders Claim 9 obvious. *Supra* §IX.C. The combination renders Claim 11’s additional limitations obvious.

1. 11[a] - “in combination with a lancet having a lancet body defining lancet thickness”

Sakata depicts a protective cap with a lancet body defining lancet thickness.

Ex. 1107, Figures 1 and 2 annotated below; Ex. 1103, ¶¶100-104.

⁶ Moreover, it would have been obvious to a PHOSITA to place branding on the flat surfaces of Sakata’s thin-walled portions. Indeed, branding on flat surfaces were disclosed in multiple publications during the prior art period. Ex. 1119 (Chan), 7:63-64; Ex.1110, pg. 28; Ex. 1103, ¶¶94-97.



Thus, the Coe-Sakata combination renders obvious a protective sterility cap “in combination with a lancet having a lancet body defining lancet thickness.” Ex. 1103, ¶¶98-104.⁷

2. 11[b] - “and a sharp lancet tip initially embedded in the primary sheath”

Limitation 11[b] is analogous to limitation 1[a]. Coe discloses limitation 1[a]. *Supra* §VIII.B

3. 11[c] - “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness”

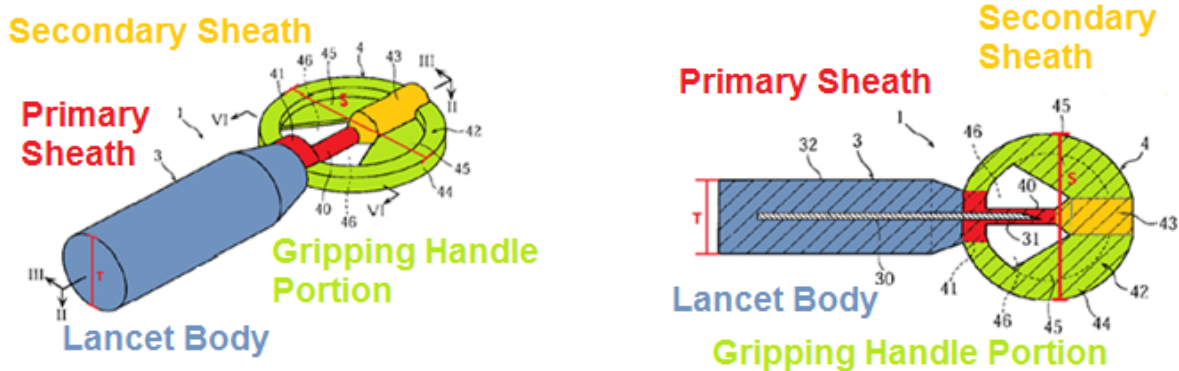
Sakata depicts an operation portion or gripping handle portion in relation to lancet’s thickness. Although Sakata does not disclose the precise dimensions of the

⁷ Lancet bodies defining lancet thickness were disclosed in publications during the prior art period. *See, e.g.*, Ex. 1112 (Morita II), Figures 1, 3-4, 7 and 11; Ex. 1113 (Hyoue), Figures 1-3; Ex. 1114 (Horie), Figures 4-7; Ex. 1116 (Starnes II), Figures 1-7; Ex. 1117 (Kojima), Figures 1(a)-2(d), 6(1)-6(b), and 8(a)-8(b); Ex. 1103, ¶¶98-102.

gripping handle portion, it discloses that covering portion 40 is between 0.1-3.0 mm. Ex. 1107, ¶0017. Additionally, Sakata's lancet would have been handled using a thumb and a digit on the user's hand and the average human thumb has a diameter of 16 mm in size (Ex.1122, §4.1), which means that the lateral span for its cap 4 would have needed to be much larger than the 16 mm diameter of an average human thumb to ensure that the handling goal was achieved. And, because the "standard lancet" had a diameter of less than 6 mm (Ex.1120, 9:67-10:10; "LeVaughn"), a PHOSITA would have understood Sakata to teach that its lateral span was at least 2.67 times the lancet thickness, so the 1.5 times recitation was expressly taught or, at a minimum, inherently disclosed. This is consistent with 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. 1120, 5:15-18; Ex. 1103, ¶¶100-104

It is clear from these dimensions and Sakata's figures that the gripping handle's span "S" is at least 1.5 times the lancet's thickness "T". Ex. 1107, Figures 1 and 2 annotated below.⁸

⁸ Gripping handles with span at least 1.5 times their lancet's thickness were similarly disclosed in publications during the prior art period. *See, e.g.*, Ex. 1115 (Lathrop), Figures 1A-1B; Ex. 1117 ("Kojima"), Figures 1A-2B and 6A-6B; Ex. 1103, ¶¶98-102.



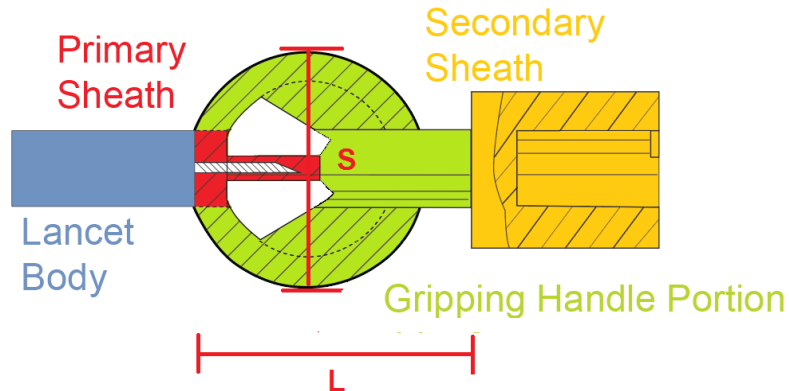
Thus, the Coe-Sakata combination renders obvious a “gripping handle portion defin[ing] a lateral span of at least 1.5 times the lancet thickness.” Ex. 1103, ¶¶ 98-102.⁹

F. Claim 12 Is Obvious—“wherein the gripping handle portion defines a length at least equal to its lateral span”

Claim 12 depends from Claim 11, which depends from Claim 9. The Coe-Sakata combination renders Claims 9 and 11 obvious. Both Coe and Sakata disclose protective caps with gripping handles. *Supra* §§VIII.A and IX.A. As was explained above, a PHOSITA would have understood the Coe-Sakata combination (in conjunction with the dimensions referenced above) to plainly depict a gripping handle portion that is much larger than 1.5 times the lancet thickness. The Coe-

⁹ Moreover, the Patent Owner was assigned a patent during the prior art period that teaches the same span to thickness ratio with respect to the gripping portion of a lancing device. The patent states, “[a]ccording to preferred form, the overall width W of the lancing device 10 is at least 1½ times, and more preferably about twice the overall thickness t.” Ex. 1120 (Levaughn), 5:13-15.

Sakata combination therefore depicts a gripping handle portion with a length at least equal to its lateral span.¹⁰ Ex. 1103, ¶¶100-104.



Thus, the Coe-Sakata combination discloses a “gripping handle portion defin[ing] a length at least equal to its lateral span.” Ex. 1103, ¶¶98-102.¹¹

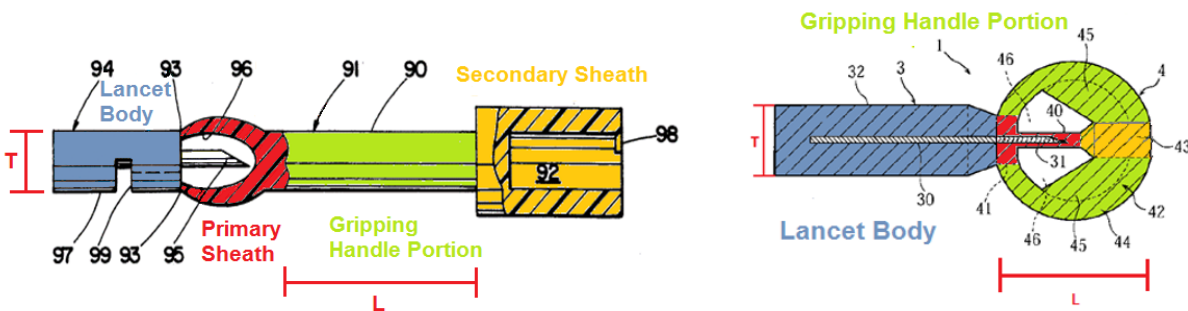
G. Claim 13 Is Obvious—“wherein the gripping handle portion defines a length at least equal to the lancet thickness”

Claim 13 depends from Claim 11, which depends from Claim 9. The Coe-Sakata combination renders Claims 9 and 11 obvious. *Supra* §§ IX.C and IX.E. Because the Coe-Sakata combination discloses both that the gripping handle portion is at least 1.5 times the lancet thickness, and that the gripping handle

¹⁰ Gripping handles with length at least equal to lateral span were disclosed in publications during the prior art period. *See, e.g.*, Ex. 1120 (Lathrop), Figures 1A-1B; Ex. 1117 (Kojima), Figures 1A-2B and 6A-6B; Ex. 1103, ¶¶98-102.

¹¹ Moreover, Levaughn teaches the same length to span ratio with respect to the gripping portion of a lancing device. Levaughn states that a length to span ratio of “4:1, and more preferably no more than 3:1, provides the lancing device 10 with improved stability in use, which is of particular benefit in enabling users with impaired dexterity” Ex. 1120, 5:9-13; Ex. 1103, ¶¶98-102.

portion's length is at least equal to the lateral span, it logically follows that the length of the Coe-Sakata combination gripping handle portion must also be at least equal to the lancet thickness. Both Coe and Sakata illustrate their protective caps with gripping handles having a length at least equal to their lancet's thickness. Ex. 1106, Figure 9 annotated below; Ex. 1107, Figure 2 annotated below.¹²



Thus, the Coe-Sakata combination renders obvious a “gripping handle portion defin[ing] a length at least equal to the lancet thickness.” Ex. 1103, ¶¶98-104.¹³

¹² Gripping handles with length at least equal to their thickness were disclosed in publications during the prior art period. *See, e.g.*, Ex. 1115 (Lathrop), Figures 1A-1B, Ex. 1117 (Kojima) Figures 1A-2B and 6A-6B; Ex. 1103, ¶¶98-102.

¹³ Moreover, Levaughn teaches the same length to thickness ratio with respect to the gripping portion of a lancing device. Levaughn discloses a lancing device having an overall length being no more than about four times the overall width, and an overall width being at least about one and one-half times the overall thickness. Levaughn therefore teaches a length at least equal to thickness. Ex. 1120, 5:9-13.

H. Claim 14 Is Obvious

1. **14[p] – “A protective sterility cap for a lancet, said sterility cap comprising”**
2. **14[a] – “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein”**
3. **14[b] - “a secondary sheath for receiving the sharp lancing tip of a used lancet”**
4. **14[c] - “a gripping handle portion extending between the primary sheath and the secondary sheath”**
5. **14[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”**

Limitations 14[p]-[d] are identical to limitations 1[p]-[d]. Coe discloses limitations 1[p]-[d]. *Supra* §VIII.

6. **14[e] - “said protective sterility cap being in combination with a lancet having a lancet body defining a lancet thickness”**
7. **14[f] - “and a sharp lancet tip initially embedded in the primary sheath”**
8. **14[g] - “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.”**

Limitations 14[e]-[g] are identical to limitations 11[a]-[c]. The Coe-Sakata combination renders limitation 11[a]-[c] obvious. *Supra* §IX.E.

**I. Claims 11-14: The “Length” and “Lateral Span”
of the Gripping Handle Portion**

As was explained above (*supra* Sections IX.E-G, incorporated here), the Coe-Sakata combination teaches the relative-dimensional aspects of these claims. Because the Coe-Sakata combination is being modified in this Ground only by combining embodiments of Coe and Sakata, and based on a PHOSITA’s general knowledge of primary and secondary sheaths, the modified Coe-Sakata combination in this Ground would have retained the features from the Coe-Sakata combination that disclose these relative-dimensional aspects, including the gripping handle’s lateral span being at least 1.5 times the lancet thickness (claims 11 and 14) and the gripping handle’s length being at least equal to the lateral span (claim 12) and the lancet thickness (claim 13). Ex. 1103, ¶¶100-104.

To the extent that Patent Owner argues that any of the relative-dimensional aspects are not expressly or inherently taught by Coe-Sakata, those relative-dimensional aspects all would have been obvious to try, as is explained below. As a threshold matter, as explained by Petitioner’s expert, there was an art-recognized problem of lancets being held by people with limited dexterity or other challenges (including the elderly and other individuals that might 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. 1103,

¶99. 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.* Determining how to dimension the gripping handle portion (in both its lateral span and length) was also an aspect that a PHOSITA would have routinely experimented with in seeking to optimize the sterility caps for mass-market use, including having only a finite number of potential solutions for dimensioning the gripping handle portion as compared to thickness of the lancet. Ex. 1103, ¶99. With this factual backdrop in mind, a discussion of the obviousness of each of the relative dimensional aspect is provided below. Ex. 1103, ¶¶100-104.

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 (e.g., Morita) were larger than the lancet thickness. Coe-Sakata is one example of this, because as is visually apparent from the depiction of the handle in the Coe-Sakata combination, a PHOSITA would have known that this cap should "effectively minimize hazards to medical personnel resulting from accidental lancet punctures" Ex.1106, 3:33-36. 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 Coe's and Sakata's express

instructions to create a cap that “minimize[s] risk to housekeeping personnel.”

Both express statements in Coe-Sakata and the knowledge of those skilled in the art which would have motivated a PHOSITA to try various larger dimensions for the gripping handle portion of Coe-Sakata. Ex.1103, ¶99. And, given the instruction to create minimally hazardous lancet, a PHOSITA would have utilized dimensions for the cap 91 in Coe or 4 in Sakata that allowed a user to easily handle the cap with their fingers, including creating a large enough cap to at least be held between the average human thumb tip of 16-20 mm or the average human fingerpad size of 10-14 mm. Ex. 1121, §4.1, Figures 2-3; Ex. 1122, abstract; Ex. 1103, ¶¶100-104.

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 Coe-Sakata, in particular to ensure proper handleability for users with limited dexterity, such as the elderly. Ex.1103, ¶101. Having the length of that handling tab at least equal its lateral span would have been a natural option that would have been achieved with 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 dimensional aspect that a

PHOSITA would have naturally chosen in exploring various sizing options for the gripping handle portion. Ex.1103, ¶103.

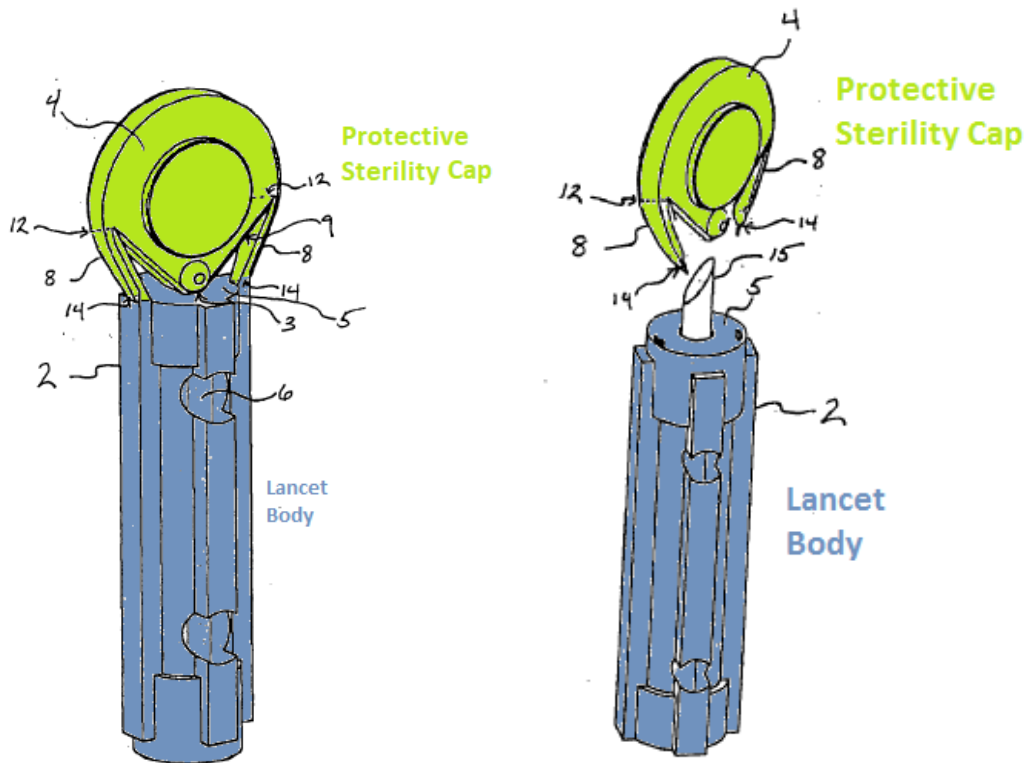
J. Claim 15 Is Obvious—“wherein the gripping handle portion comprises at least one open loop.”

Claim 15 depends from Claim 14. The Coe-Sakata combination renders Claim 14 obvious. *Supra* §IX.H. Claim 15’s additional limitation “wherein the gripping handle portion comprises at least one open loop” is identical to the limitation of Claim 4 and is obvious for the same reasons. *Supra* §IX.B.

X GROUND #3: COE RENDERS CLAIMS 4, 9-10, AND 15 OBVIOUS IN VIEW OF STARNES AND ONE TOUCH BOOKLET

A. Motivation to Combine Coe, Starnes, and One Touch Booklet

A PHOSITA would have been motivated to combine Coe and Starnes. Starnes teaches a “lancet casing further include[ing] a cap integrally molded about the pointed end of the lancet needle and joined to the lancet body by a narrow frangible junction on the upper bearing surface of the lancet body.” Ex. 1108, abstract, Figures 1 and 2, annotated below. Ex. 1103, ¶¶105-106 and 110-111.



Starnes also provides a solution to the problem of determining whether a lancet has been used. First, “the relative width of tab base 12 ensures that responsive to a twisting removal action, tab member 8 will remain attached at its upper end to cap member 4 while the lower tear-away joint 14 will disengage from upper bearing surface 5 of lancet body 2 substantially simultaneously with fracturing of frangible junction 3.” Ex. 1108, ¶¶0027. Second, “such detachment is typically effectuated by a hand twisting motion in which the suitably disk shaped cap member 4 is grasped between a user’s thumb and index finger while the lancet body 2 is grasped by the fingers of the user’s other hand...gap 19 extends

therebetween to tab members 8. Gaps 19 facilitate unobstructed viewing of the upper bearing Surface 5 both when cap member 4 is originally attached or re-attached to lancet unit 10. Specifically, the gaps 19 between each of tapered side edges 9 and the medial strip portions of tab members 8 affords an unobstructed and open view at virtually any perspective viewing angle of the points on upper bearing surface 5 at which tear-away ends 14 are or were moldedly affixed to reveal the present condition of the tear-away ends 14 as either attached to or disengaged from upper bearing surface 5.” Ex. 1108, ¶¶0031-0032; Ex. 1103, ¶¶107-109 and 111-112.

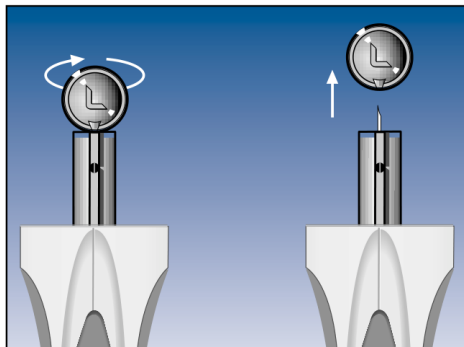
Additionally, a PHOSITA would have been motivated to modify the Coe-Starnes combination with One Touch Booklet to place branding on a flat surface of a protective sterility cap. Branding serves purposes related to commercial interests, cap handling, and to alert consumers about lancet equipment specifications. Ex. 1103, ¶¶116-122.

In addition, a PHOSITA would have been motivated to add the One Touch branding to the Coe cap because doing so would improve a patient’s grip on the lancet. Industrial designers often incorporate embossed logos or symbols on the surface of an object to provide increased friction for users when handling small objects. As seen in the example above, having the embossed logo on the protective

cap would provide areas where patients can grip the cap with higher friction.

Ex.1103, ¶121.

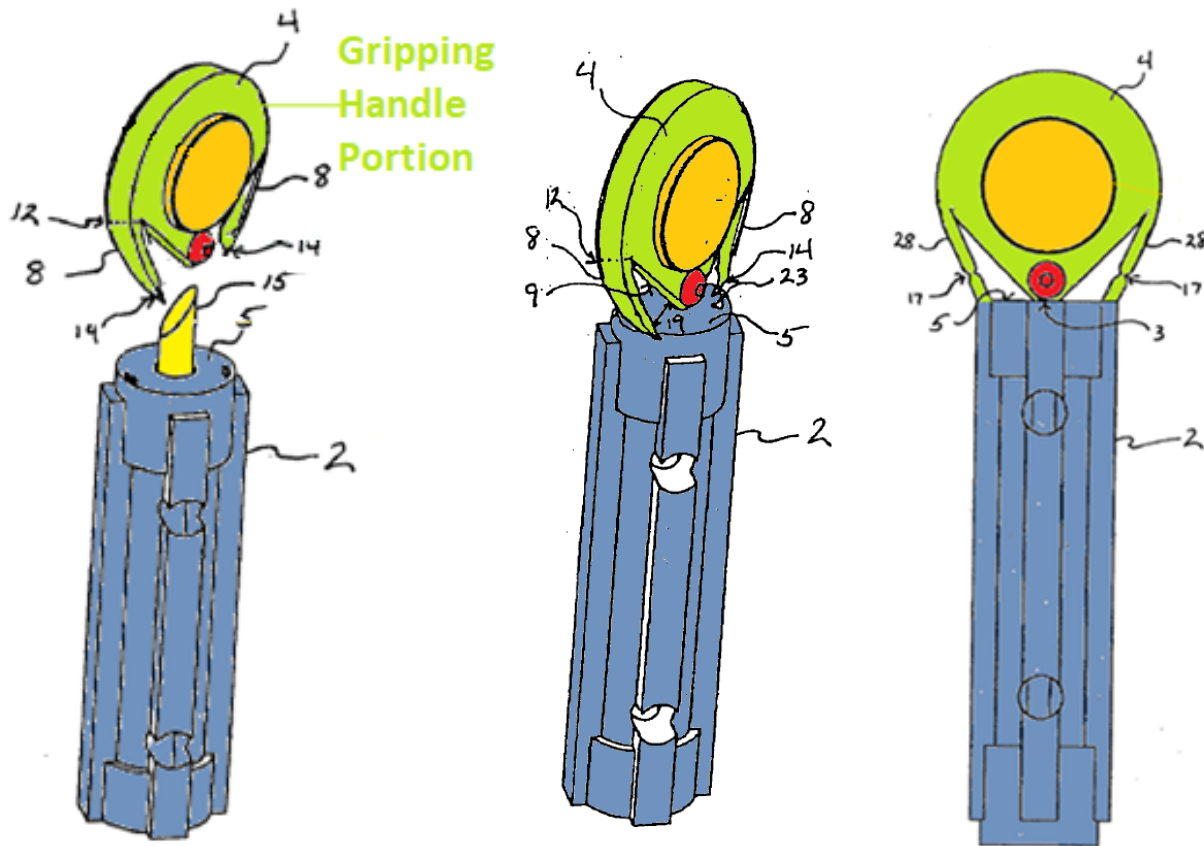
While the lancet is in the Penlet®
Plus Sampler, twist off the protective
disk. Make two full turns to ensure
that the lancet separates from the
protective disk.



**B. Claim 4 is Obvious—“wherein the gripping handle portion
comprises at least one open loop.”**

Claim 4 depends on claim 1. Coe discloses the limitations of claim 1. Starnes teaches a gripping handle portion comprising at least one open loop, as Starnes’s cap includes structures for which a user uses their fingers to twist off the cap from attachment points on the lancet body, wherein “such detachment is typically effectuated by a hand twisting motion in which the suitably disk shaped cap member 4 is grasped between a user's thumb and index finger while the lancet body 2 is grasped by the fingers of the user's other hand. In the depicted embodiment, this detachment technique is effective for the flat-faced, disk like cap

member 4 by providing a well-suited lever for applying sufficient force to simultaneously detach the pair of tab members 8 from upper bearing surface 5 of the lancet body.” Ex.1108, ¶0031. Starnes’s gripping handle portion can thus serve to modify Coe’s gripping handle in order to solve problems and reach objectives a PHOSITA may encounter. Ex.1103, ¶108-112; Figures 2-4, annotated below.



Starnes’s further teaches a gripping handle portion having “tab members 8,” “tapered side edges 9,” “tear away ends 14” and “tear away joints 17,” and “gaps 19”, which each define at least one loop. Ex.1108, ¶¶0027,0032. When the Starnes

cap is twisted, the “molden joint between the tear-away end 14 and the upper bearing surface 5” breaks, thereby “provid[ing] a “post re-attachment visual indicator that cap member 4 has previously been detached from lancet body 2.” Ex.1108, ¶0031. This meets the objective of “provid[ing] a readily perceptible user indication of the status of whether or not the cap member has been re-attached or tampered with.” *Id.*, abstract. Gaps 19 assist in achieving the objective by providing an “unobstructed viewing of the upper bearing surface 5 both when cap member 4 is originally attached or re-attached to lancet unit 10” as well as “virtually any perspective viewing angle of the points on upper bearing Surface 5 at which tear-away ends 14 are or were moldedly affixed to reveal the present condition of the tear-away ends 14 as either attached to or disengaged from upper bearing surface 5.” Ex.1108 at ¶0032; Ex.1103, ¶108-112.

The gaps and tab members of Starnes also preserve structural integrity of the lancet during removal of the cap. The “tab members 8 disengage from lancet body 2 at or near the lower tear-away ends 14 such that a minimum amount of plastic molding residue remains which will not appreciably affect the shape or contour of lancet body 2 thus preventing any potential interference by such residue with upper bearing surface 5 or with the fitting of the uncapped lancet into a lancing device.” Ex.1108 at ¶0032; Ex.1103, ¶109.

As Starnes teaches a gripping handle portion having an open loop, along with motivations to modify Coe in view of Starnes, the Coe-Starnes combination renders claim 4 obvious. Ex. 1103, ¶113

C. Claim 9 is Obvious

1. 9[p] – “A protective sterility cap for a lancet, said sterility cap comprising”
2. 9[a] – “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein”
3. 9[b] - “a secondary sheath for receiving the sharp lancing tip of a used lancet”
4. 9[c] - “a gripping handle portion extending between the primary sheath and the secondary sheath”
5. 9[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”

Limitations 9[p]-[d] are identical to limitations 1[p]-[d]. The Coe-Starnes combination renders limitations 1[p]-[d] obvious. *Supra* §X.A. The Coe-Starnes combination also renders claim 4 obvious (pertaining to the open loop limitation).

D. Claim 10 is Obvious—“at least one flat display surface for placement of branding indicia thereon”

Claim 10 depends from Claim 9. The Coe-Starnes combination render claim 9 obvious. *Supra* §X.C. “[F]or placement of branding indicia thereon” merely recites an intended use and, therefore, is not entitled to patentable weight. See,

e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997); MPEP 2111.02.

Should Patent Owner argue that the recitation of “for placement of branding indicia thereon” is entitled to patentable weight (which it should not be), this is disclosed by a combination of Coe-Starnes and One Touch Booklet. The combination of these two references is straightforward as One Touch expressly teaches using a flat display surface of a cap to display branding indicia (the LifeScan logo). This combination would be obvious given this express teaching in Coe-Starnes (e.g., Starnes also provides a flat surface). With this express guidance, a PHOSITA seeking to build the Coe-Starnes device would have naturally looked to One Touch devices and would have seen that sterility caps for the One Touch devices including branding indicia on a flat surface of the cap. Ex. 1103, ¶¶116-122.

First, both Coe-Starnes and One Touch qualify as analogous art to the claimed invention because they are both in the same field of endeavor as the '635 Patent. *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). The '635 Patent identifies the technical field of the claimed invention as relating “generally to the field of medical devices” and particularly to “lancets and lancing devices for blood sampling and testing.” Ex.1101, 1:17-19. Like the '635 Patent, Coe-Starnes

relates to skin lancing devices while One Touch provides for the “One Touch Basic Complete Diabetes Monitoring System” which is “intended for in vitro diagnostic use for quantitative determination of glucose in whole blood as an aid in monitoring effectiveness of diabetes management in the home and in clinical settings. Ex.1110, pg. 3; Ex. 1103, ¶¶116-122.

In addition, Coe-Starnes and One Touch are reasonably pertinent to the particular problem identified in the '635 Patent. *In re Bigio*, 381 F.3d at 1325. The claimed invention provides for various lancet designs which “allow a unique or proprietary matching lancet and lancet receiver or carrier” where only lancets “of a specified design will fit.” Ex.1101, 5:53-57. The '635 Patent further describes how the claimed invention can assure users “of the type and/or source of the lancet being used, including its quality, sterility, size, format [and] other characteristics.” *Id.*, 5:58-60. The '635 Patent also notes that “[i]mprecise alignment of the lancet in the lancet carrier may result in increased pain sensation by the subject.” Ex.1101, 5:28-29; Ex. 1103, ¶¶116-122.

Second, the Coe-Starnes combination would differ substantially from traditional lancets, so a PHOSITA would be motivated to further improve upon branding the Coe-Starnes combination to communicate to patients the specifications of the combination. A PHOSITA would be motivated to combine

Coe-Starnes with One Touch branding because it would improve the safety of the device for patients. By adding the One Touch-related branding to the Coe-Starnes protective cap, patients are better informed regarding the requirements of the Coe-Starnes integrated device. If a patient were to try to insert a foreign lancet into a Coe-Starnes-related integrated device, the patient would be at an increased risk of experiencing pain when lancing due to imprecise alignment of the lancet with the device. Ex.1103, ¶118. If a patient were to harm themselves by using a non-compliant lancet with the Coe-Starnes integrated device, a patient may choose to forgo testing their blood glucose for fear that they would have another painful lancing experience. *Id.* It would have been well-known to a PHOSITA that patients who need to use lancets and lancing devices tend to be hesitant or fear manually sticking themselves when using such devices. Having an obvious indicator, like the One Touch branding, on the protective cap of the lancet would mitigate the harm to the patient and inform them of the specific use requirements for Coe-Starnes-related devices. Ex. 1103, ¶120.

A PHOSITA would be further motivated to add the One Touch branding to the Coe-Starnes lancet because such a combination would be commercially desirable (e.g., trademark rights and advertising). *Id.*

In addition, a PHOSITA would have been motivated to add One Touch branding to the Coe-Starnes lancet because doing so would improve a patient's grip on the lancet. In industrial design, having an embossed or debossed logo or symbol on the surface of an object provides increased friction for users to handle small objects. Ex.1103, ¶121.

Finally, a PHOSITA would have had a reasonable expectation of success in combining Coe Starnes and One Touch because such a modification would have merely involved adding an “indicia” from the One Touch manual to the Coe-Starnes protective cap and would involve little or no experimentation, let alone undue experimentation. *Id.* at ¶122.

Overall, One Touch Booklet teaches a “Penlet® Plus Cap” that caps a lancet and is made to be twisted to bare a sharp lancet tip. Ex.1110, pg. 27. The cap is characterized as a “protective disk” plainly depicted with at least one flat display surface. *Id.* at pgs. 27 and 32. The flat display surface bears a branded “L” associated with the One Touch Basic Complete Diabetes Monitoring System. *Id.* at ¶123.

Therefore, the One Touch Booklet expressly teaches placing branding on a flat surface of a protective sterility cap. Ex. 1103, ¶¶114-123.

E. Claim 15 is Obvious—"wherein the gripping handle portion comprises at least one open loop"

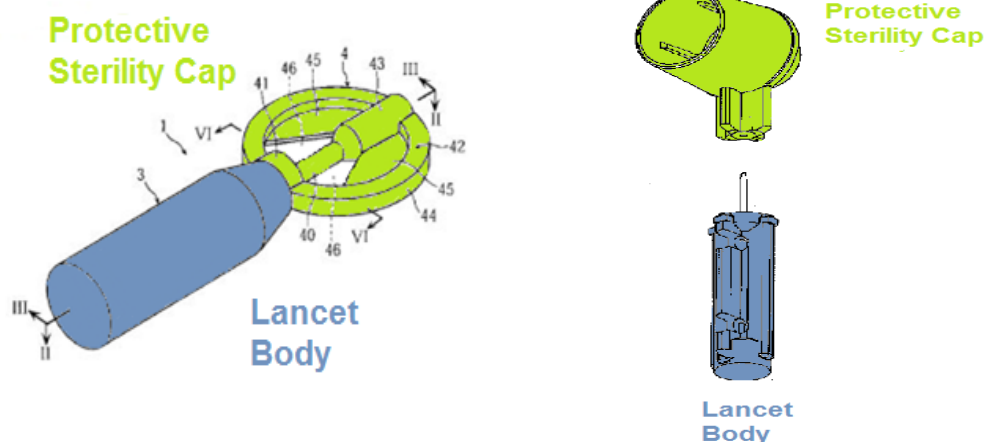
Claim 15 depends from Claim 14. The Coe-Starnes combination renders 14 obvious. Claim 15's additional limitation "wherein the gripping handle portion comprises at least one open loop" is identical to the limitation of Claim 4 and is obvious for the same reason. *Supra* §X.B.; Ex. 1103, ¶¶109-110.

XI GROUND #4: SAKATA RENDERS CLAIMS 1, 4, AND 9-15 OBVIOUS IN VIEW OF MORITA

A. Motivation to Combine Sakata and Morita

A PHOSITA would have been motivated to modify Sakata's protective cap with Morita's platform portion for the following reasons.

First, a PHOSITA would have appreciated that Sakata and Morita are within the same field of endeavor as the '635 Patent, which is "lancets and lancing devices for blood sampling and testing." Ex. 1101, 1:17-19; Ex. 1107, ¶0001; Ex. 1109, ¶0001. Sakata and Morita also solve problems similar to those identified by '635 Patent with protective caps that "assist[] in removal of the cap for use of the lancet and/or for replacement of the cap onto a used lancet for disposal." Ex. 1101, 1:66-2:8; Ex. 1107, ¶[0008], Figure 1 annotated below; Ex. 1109, ¶0033, Figure 17 annotated below; Ex. 1103, ¶¶89-95; 124-128.

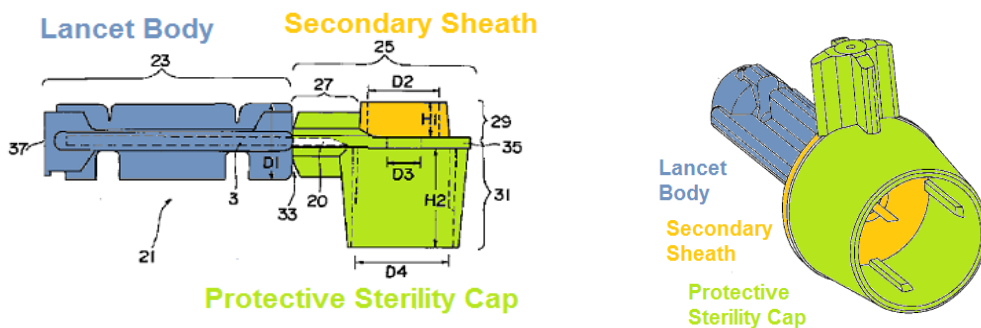


Second, a PHOSITA would have been motivated to dispose of used lancets safely. Indeed, Sakata states “that lancets are usually configured as disposable for hygiene reasons.” A PHOSITA would have understood that the exposed needle tip of a used lancet is contaminated with the blood of the user and could transfer infectious disease such as HIV and Hepatitis B to those handling the used lancet after use.¹⁴ Ex.1103, ¶¶89-95; 124-128.

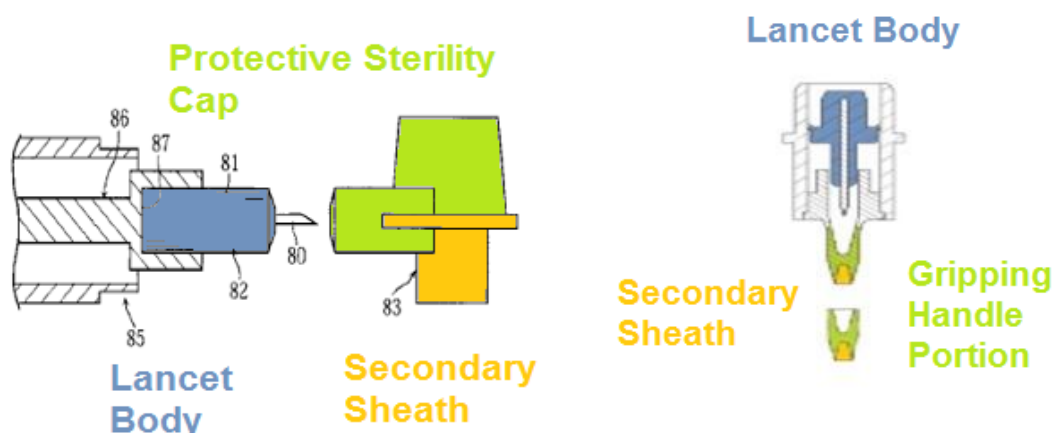
Morita teaches the health benefits of disposing of used lancets safely. Morita states, “the needle tip of the lancet has the blood of the person whose blood was drawn attached to it, ... so problems such as viral infection may occur....” Ex. 1109, ¶¶0011. Morita solves this problem with the platform portion of its protective cap. Ex. 1103, ¶¶127-129. Morita explains that after use, the end of the lancet body with the needle tip portion can be fitted into the platform portion. Ex. 1109,

¹⁴ CDC and FDA guidelines for isolation of body fluids.

[Claim1]. Morita further explains that “disposal of the lancet body with the lancet inserted into the platform portion does not pose the health and safety problem of infection as described earlier.” Ex. 1109, [0020]. A PHOSITA would have understood that disposal of a used lancet in Morita’s platform portion would prevent potential transfer of infectious disease. Ex. 1103, ¶126; Ex. 1109, Figures 3 and 19 annotated below.



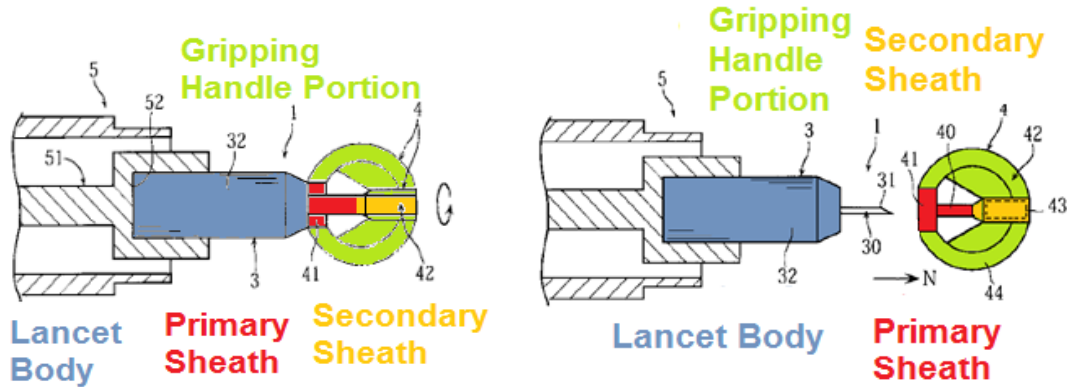
Third, it would have been obvious to use Morita’s platform portion with Sakata’s protective cap to dispose of used lancets because Sakata references and includes figures of Morita’s platform portion and a hollow end portion for disposing of used lancets. *See* Ex. 1109, Figures 8 and 9 annotated below; Ex.1103, ¶¶89-95; 124-128.



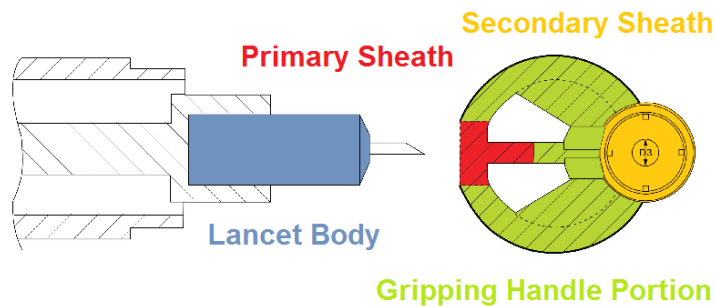
A PHOSITA would have understood that hollow platforms and end portions for disposal of used lancets were common features of protective caps of lancets during the prior art period. Ex. 1103, ¶¶69-70. Thus, a PHOSITA would have modified Sakata's protective cap to use either option with a reasonable expectation of success.

Fourth, a PHOSITA would have been motivated to retain Sakata's operating portion to separate the protective cap from the lancet. Sakata states that it is desirable to "maintain the sterile condition of the puncture needle while suppressing damage to the puncture needle during use." Ex. 1107, ¶[0007]. Sakata solves this problem by using the operating portion of its protective cap to separate the cap from the lancet. Ex. 1107, ¶[0008]. Sakata explains that "the force applied to the operating portion is concentrated on the ... covering portion, thus reducing

the stress applied to the puncture needle.” Ex. 1107, ¶[0012], Figures 5(a) and 5(b) annotated below. Ex.1103, ¶¶89-95.



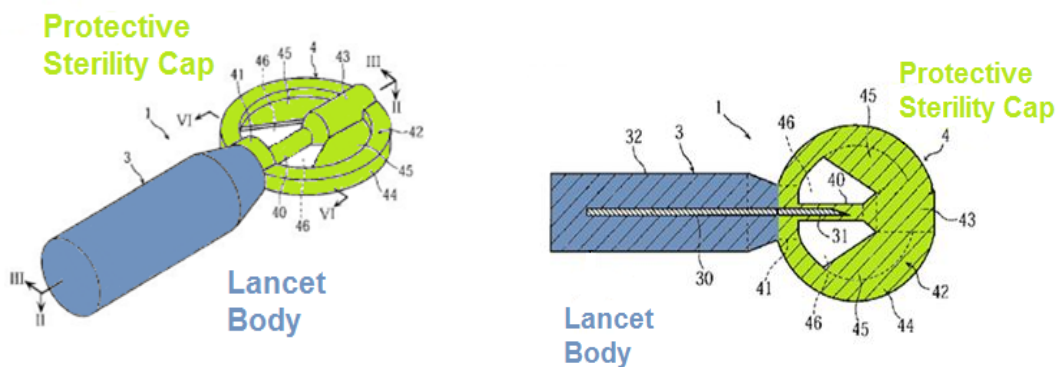
Thus, it would have been obvious to a PHOSITA during the prior art period to add Morita’s platform portion to Sakata’s protective cap to safely dispose of a used lancet, while maintaining Sakata’s operating portion to ensure that the lancet’s needle tip is not damaged when the cap is separated from the lancet. An illustrative example of this combination is shown below.



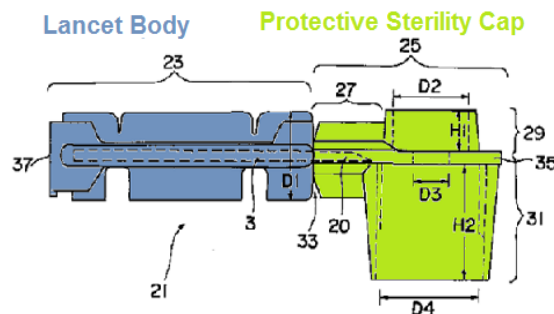
B. Claim 1 is Obvious

1. 1[p] – “A protective sterility cap for a lancet, said sterility cap comprising”

As explained above, the preamble is not limiting. Regardless, Sakata discloses a “lancet consisting of a puncture needle, a holding portion for holding the puncture needle with a needle tip protruding therefrom, and a cap portion covering the above needle tip ...” (green below). Ex. 1107, ¶[0008], Figures 1 and 2 annotated below.



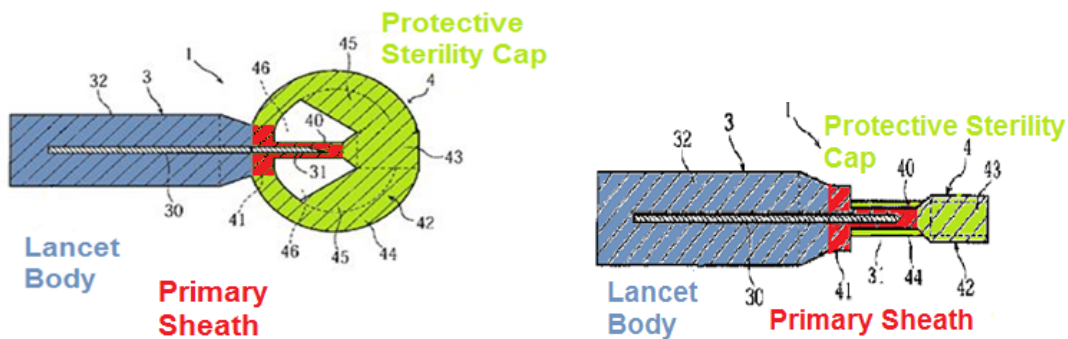
Morita similarly discloses a “lancet [that] consists of a lancet body 23 having a protruding needle 20 and a protection platform 25 adjacent thereto.” Ex. 1107, ¶[0029], Figure 3 annotated below.



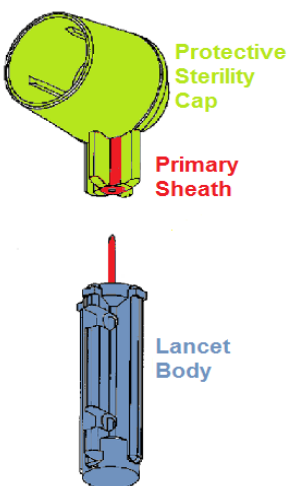
Thus, the Sakata-Morita combination renders obvious “a protective sterility cap for a lancet,” even if limiting. Ex. 1103, §XII.

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

Sakata discloses a “cap portion [with] a covering portion that adheres to the above needle tip and covers the above needle tip portion” (red below). Ex. 1107, ¶[0008]. Sakata explains that “the puncture needle can be **embedded** in the cap part by insert-molding” Ex. 1107, ¶[0013]. Sakata further explains that “[t]he puncture needle 30 is insert-molded into the lancet body 3 and cap portion 4 when the lancet body 3 and cap portion 4 are integrally molded.” Ex. 1107, ¶[0015], Figures 2 and 3 annotated below.



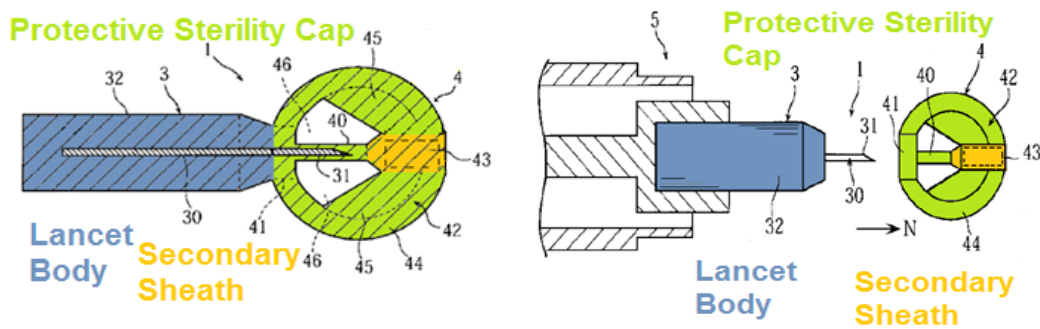
Morita similarly discloses “[t]he needle tip protection portion is designed to ... protect the needle tip protruding from the lancet body by inserting and shielding the needle tip into this portion” (red below). Ex. 1109, ¶[0016], Figures 3 and 17 annotated below; Ex. 1103, ¶¶89-95.



Thus, the Sakata-Morita combination renders obvious “a primary sheath for initial
embedment of a sharp lancing tip of an unused lancet therein.” Ex. 1103, §XII.

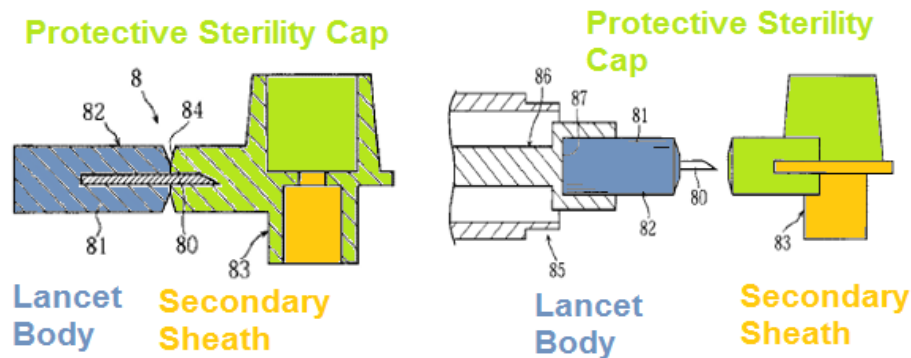
3. **1[b] - “a secondary sheath for receiving the sharp lancing tip of a used lancet”**

Sakata states that “[l]ancets are configured as disposables for hygiene reasons. Lancets are configured as disposables in the form shown in Fig. 6 and 7” Ex. 1107, ¶[0002]. Sakata depicts a hollow “cylindrical portion” (orange below) at the end of its protective cap for disposing of a used lancet. Ex. 1107, ¶[0019], Figures 2 and 5(b) annotated below.

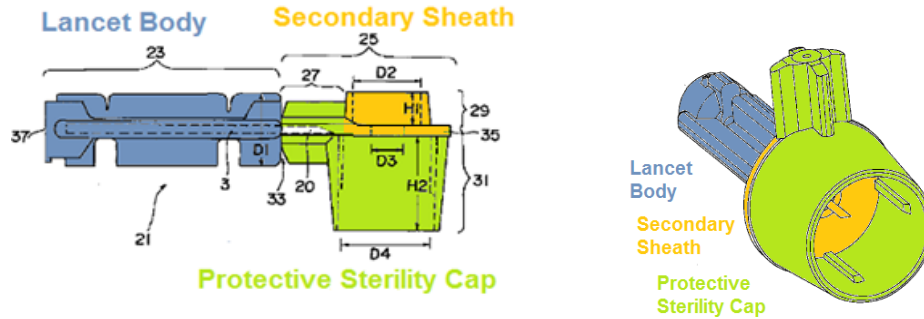


To the extent the illustration of the hollow cylindrical portion (orange) does not inherently disclose a protective cap configured for disposal of a used lancet, a PHOSITA would have understood that the hollow cylindrical portion is a secondary sheath that can receive a used lancet for its safe disposal. Ex. 1103, §XII.

Sakata also depicts the platform portion of Morita's protective cap (orange below) for disposal of a used lancet. Ex. 1107, Figures 7 and 8 annotated below.



Indeed, Morita discloses a secondary sheath for receiving a used lancet as a platform portion against which the needle tip is to be inserted. Ex. 1109, Claim 1. Morita explains that after use, the end of the lancet body with the needle tip portion can be fitted into the platform portion. Ex. 1109, ¶[0013]. Morita further explains that “disposal of the lancet body with the lancet inserted into the platform portion does not pose the health and safety problem of infection” Ex. 1109, ¶[0020], Figures 3 and 19 annotated below; Ex.1103, ¶¶89-95; 124-128.



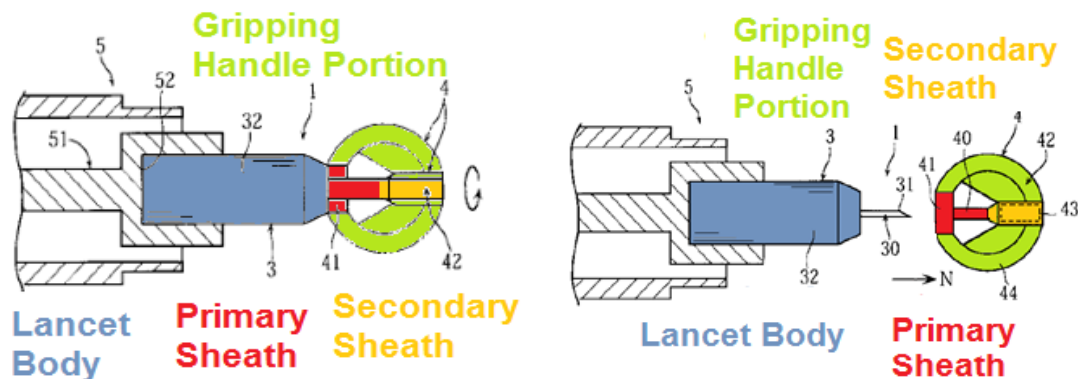
By replacing the hollow cylindrical portion of Sakata's cap with the platform portion of Morita's cap, the Sakata-Morita combination (annotated on the right below) would have a secondary sheath with a hollow platform, just like the '635 Patent (annotated on the left below). Ex.1103, §XII.

'635 Patent, Figures 1(C) and 5(D)	Sakata-Morita Combination (Top View)
'635 Patent, Figures 1(B) and 5(C)	Sakata-Morita Combination (Side View)

Thus, the Sakata-Morita combination renders obvious a “secondary sheath for receiving the sharp lancing tip of a used lancet.” Ex. 1103, §XII.¹⁵

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

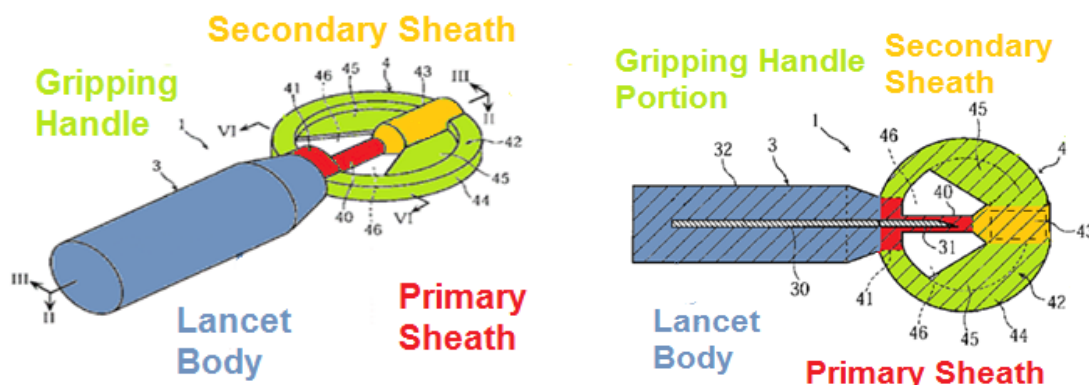
Sakata discloses an “operating portion 42 [that] has a cylindrical portion 43, an arch portion 44, and a pair of thin-walled portions 45” (green below). Ex. 1107, ¶[0019]. Sakata explains that “the cap portion 4 is twisted off the lancet body 3 by rotating the cap portion 4 using the operating portion 42, so that only the lancet body 3 is attached to the lancet holder 51.” Ex. 1107, ¶[0020], Figures 5(a) and 5(b) annotated below.



Sakata further explains that “[w]hen the cap portion 4 is rotated, the rotational force applied to the operating portion 42 is concentrated on the

¹⁵ Sakata could also be combined with other secondary sheaths with hollow platforms or ends of a protective cap, which were well known and disclosed in publications during the prior art period and which would also render obvious limitation 1[b].

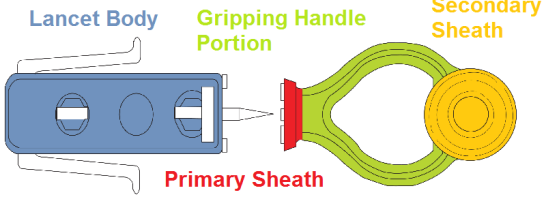
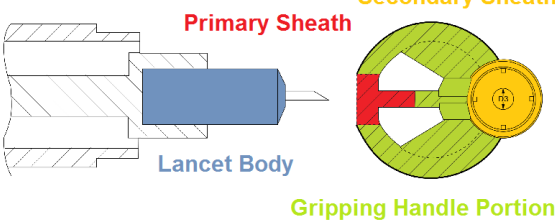
cylindrical portion 43 and the large diameter covering portion 41 because the arch portion 44 connects the cylindrical portion 43 and the large diameter covering portion 41.” Ex. 1107, ¶[0020], Figures 1 and 2 annotated below.



The operating portion (green) is a gripping handle that extends between the covering portion (red) and the cylindrical portion (orange) of Sakata’s protective cap. As explained above, Sakata’s covering portion is a primary sheath for initial embedment of a sharp lancing tip of an unused lancet, and its “cylindrical portion” is a secondary sheath for receiving the sharp lancing tip of a used lancet. *Supra* §§IX.A-B. Thus, Sakata discloses a gripping handle that extends between a primary sheath and a secondary sheath. Ex. 1103, §X.C.

While Sakata’s illustrations disclose a secondary sheath in the form of a hollow cylindrical portion at the end of its cap, by replacing the cylindrical portion with Morita’s platform portion, the Sakata-Morita combination (annotated on the right below) would have a gripping handle extending between a primary sheath

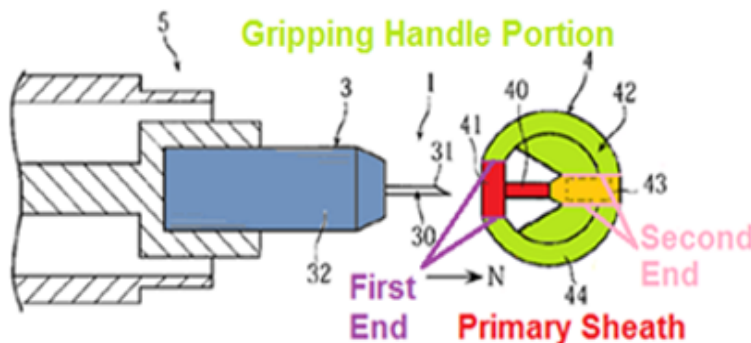
and a secondary sheath with a hollow platform just like the '635 Patent (annotated on the left below). *Supra* § XI.

	
'635 Patent, Figures 1(C) and 5(D)	Sakata-Morita Combination

Thus, the Sakata-Morita combination renders obvious “a gripping handle portion extending between the primary sheath and the secondary sheath.” Ex. 1103, §XII.

5. 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”

Sakata depicts the arch portion 44 and the thin-walled portions 45 of the operating portion 42 split into two arms. Sakata further depicts the large diameter covering portion 41 and the cylindrical portion 43 are connected at the opposite ends of each arm. Ex. 1107, Figure 5(b) (annotated below).

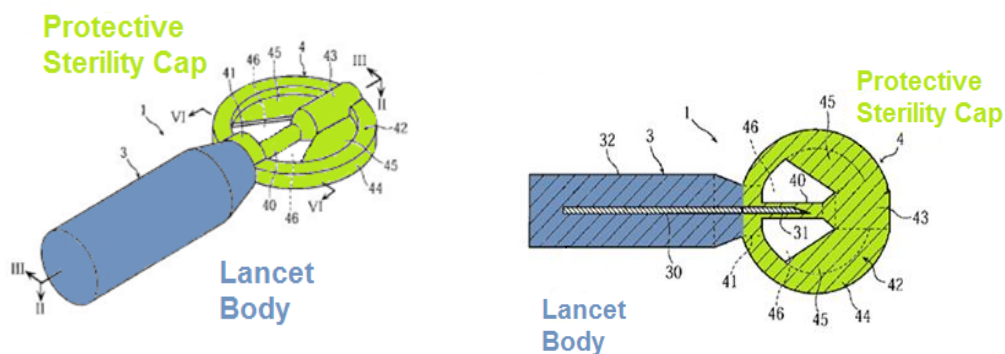


As explained above, Sakata's covering portion (red) is a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein, its cylindrical portion (orange) is a secondary sheath for receiving the sharp lancing tip of a used lancet, and its operating portion (green) is a gripping handle portion extending between the primary sheath and the secondary sheath. *Supra* §§IX.A-B. Thus, Sakata renders obvious a primary sheath attached at a first end of the gripping handle portion and a secondary sheath attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet. Ex. 1103, ¶¶89-90.¹⁶

C. Claim 4 is Obvious—“wherein the gripping handle portion comprises at least one open loop.”

Claim 4 depends from Claim 1. The Sakata-Morita combination renders Claim 1 obvious. *Supra* §XI.B. Sakata discloses an operating portion with “a gap 46 [that] is interposed between the arch portion 44 and the small diameter covering portion 40.” Ex. 1107, ¶[0019], Figures 1 and 2 annotated below.

¹⁶ As discussed above, gripping handles on protective sterility caps, were well known and disclosed in publications during the prior art period.



As explained above, the operating portion 42 is the gripping handle portion of Sakata's protective cap. Supra §IX.A. Thus, the Coe-Sakata combination renders obvious a “gripping handle portion compris[ing] at least one open loop.” Ex. 1103, §X.C.

D. Claim 9 is Obvious

1. **9[p] – “A protective sterility cap for a lancet, said sterility cap comprising”**
2. **9[a] – “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein”**
3. **9[b] - “a secondary sheath for receiving the sharp lancing tip of a used lancet”**
4. **9[c] - “a gripping handle portion extending between the primary sheath and the secondary sheath”**
5. **9[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”**

Limitations 9[p]-[d] are identical to limitations 1[p]-[d]. The Sakata-Morita combination renders limitations 1[p]-[d] obvious. *Supra* §XI.B.; Ex. 1103, §XII.

6. **9[e] - “wherein the gripping handle portion comprises at least one open loop”**

This limitation is identical to the limitation of Claim 4. The Sakata-Morita combination renders Claim 4 obvious. *Supra* §XI.C.; Ex. 1103, §XII.

E. Claim 10 is Obvious—“at least one flat display surface for placement of branding indicia thereon”

Claim 10 depends from Claim 9. The Sakata-Morita combination renders claim 9 obvious. *Supra* §XI.D. The limitations of claim 10 are identical to the limitations of claim 4. Therefore, Sakata discloses a gripping handle portion with

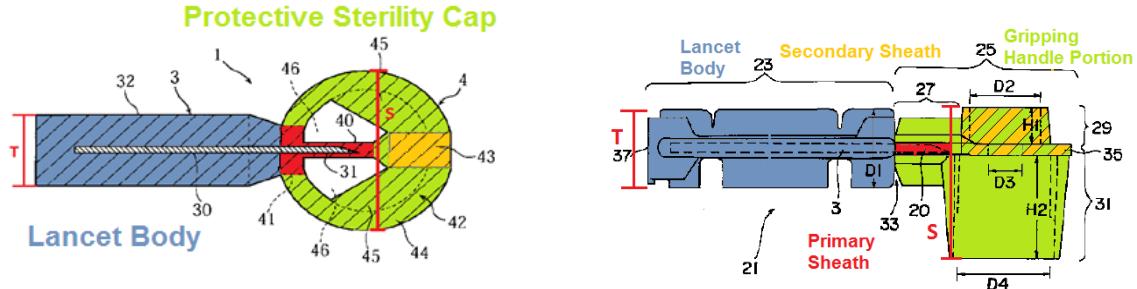
“at least one flat display surface for placement of branding indicia thereon.” *See supra*, §XIV.B.1; Ex. 1103, §XII.

F. Claim 11 is Obvious

Claim 11 depends from Claim 9. The Sakata-Morita combination renders Claim 9 obvious. *Supra* §XI.D. The combination also renders Claim 11's additional limitations obvious.

1. 11[a] - “in combination with a lancet having a lancet body defining lancet thickness”

Both Sakata and Morita depict protective caps with lancet bodies defining lancet thickness. Ex. 1107, Figure 2 and Ex. 1109, Figure 3 annotated below.



Morita further discloses the exact dimensions of the thickness of its lancet body in millimeters (mm): “width of the largest portion 4-7 mm, preferably 6.5 mm” Ex. 1109, ¶0032; Ex.1103, ¶¶130-135.

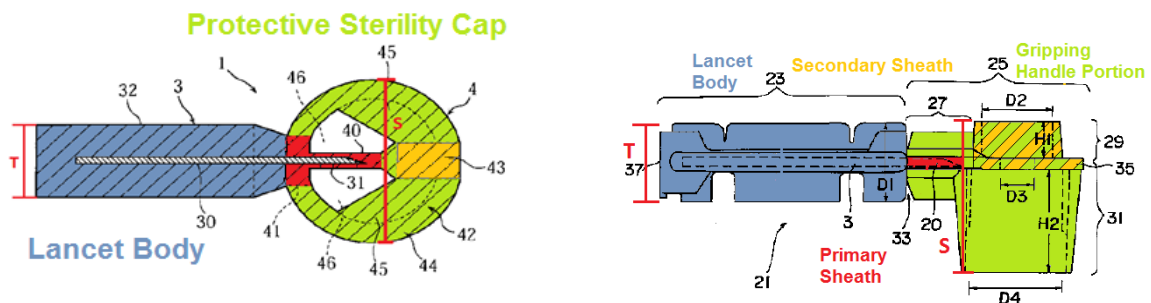
Thus, the Sakata-Morita combination renders obvious a “lancet having a lancet body defining lancet thickness.”

2. 11[b] - “and a sharp lancet tip initially embedded in the primary sheath”

This limitation is analogous to limitation 1[a]. The Sakata-Morita combination renders limitation 1[a] obvious. *Supra* §XIV.B.2; Ex. 1103, §XI.B.

3. 11[c] - “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness”

Both Sakata and Morita disclose protective caps with gripping handles. Both Sakata and Morita depict gripping handles that have spans of at least 1.5 times their lancets' thickness. *See* Ex. 1107, Figure 2 annotated below; Ex. 1109, Figure 3 annotated below.¹⁷ Ex.1103, ¶¶130-135.



Morita further discloses the exact dimensions of the span of its gripping handle, which is defined as the sum of variables H1 and H2. *Id.*

The thickness of the lancet is 4-7 mm, preferably 6.5mm. A value at least 1.5 times the lancet thickness must be *at least 6-10.5mm*. The sum of the H1 and H2, “Height H1 of the platform portion: 2-3.5 mm, preferably 2.6 mm. Height H2

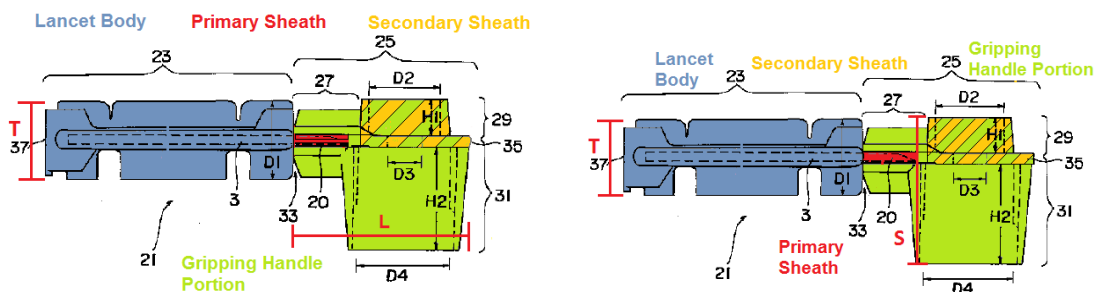
of the end cap connection portion: 6-15 mm, preferably 9 mm,” makes the total span of the gripping handle *8-18.5 mm, preferably 11.6 mm*. Ex. 1109 ¶0032. By providing the precise dimensions of the span of the gripping handle and thickness of the lancet, and with the preferred value of span (11.6 mm) being more than 1.5 times larger than the preferred lancet thickness (6.5; $6.5 \times 1.5 = 9.75$), Morita teaches a gripping handle with a span of at least 1.5 times the thickness of the lancet. Ex. 1103, §XII.E.

Thus, the Sakata-Morita combination renders obvious a “gripping handle portion defin[ing] a lateral span of at least 1.5 times the lancet thickness.” *Id.*

G. Claim 12 is Obvious—“wherein the gripping handle portion defines a length at least equal to its lateral span.”

Claim 12 depends from dependent claim 11, which depends from Claim 9. The Sakata-Morita combination renders claims 9 and 11 obvious. *Supra* §XI.D. and F. The combination also renders Claim 12’s additional limitation obvious. Ex.1103, ¶¶130-135.

Both Sakata and Morita disclose protective caps with gripping handles. *Supra* §§ XIV.B.4-5. Morita depicts a protective cap with a gripping handle having a length at least equal to its lateral span. Ex. 1109, Figure 3 annotated below.



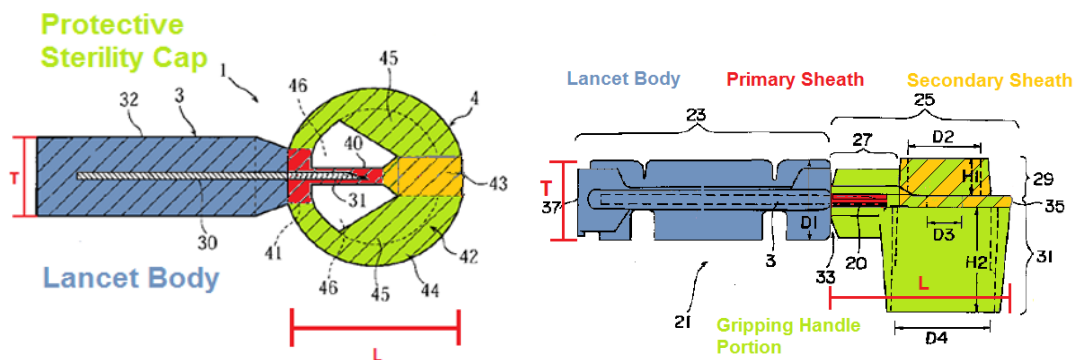
Morita further discloses the exact dimensions of the length of the gripping handle, which is the sum of the length of numeral 27 and D4: “needle tip protection portion 27: ... length 5.5-8 mm, preferably 6.2 mm [and] ... [i]nternal diameter D4 of the end cap connection: 8.5-11.5 mm, preferably 9.2 mm,” which makes the total length of the gripping handles 14-19.5 mm, preferably 15.4 mm, which exceeds the boundaries of 8-18.5 mm, preferably 11.6 mm. Ex. 1109, ¶0032. By providing the precise dimensions of the length and span of the gripping handle, Morita teaches a gripping handle with a length at least equal to its span. Ex. 1103, ¶133.

Thus, the Sakata-Morita combination renders obvious a “gripping handle portion defin[ing] a length at least equal to its lateral span.” Ex. 1103, ¶¶130-135.¹⁸

¹⁸ Moreover, it would have been obvious to a PHOSITA to use a gripping handle with a length at least equal to its span. See Ex.1103, ¶103.

H. Claim 13 is Obvious—“wherein the gripping handle portion defines a length at least equal to the lancet thickness.”

Claim 13 depends from Claim 11, which depends from Claim 9. The Sakata-Morita combination renders Claims 9 and 11 obvious. Both Sakata and Morita depict protective caps with gripping handles having a length at least equal to the lancet thickness. Ex. 1107, Figure 2 annotated below; Ex. 1109, Figure 3 annotated below. Morita further discloses the exact dimensions of the length of the gripping handle and the thickness of the lancet. *Supra* §§XI.F. By providing the precise dimensions of length and thickness, Morita teaches a gripping handle with a length at least equal to the thickness of the lancet. Also, as length by definition is larger than width/span, and as length is at least 6-10.5mm, the length of Morita's gripping handle portion is larger than Morita's lancet thickness. Thus, the Sakata-Morita combination renders Claim 13 obvious. Ex. 1103, ¶135.



I. Claim 14 is Obvious

1. **14[p] – “A protective sterility cap for a lancet, said sterility cap comprising”**
2. **14[a] – “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein”**
3. **14[b] - “a secondary sheath for receiving the sharp lancing tip of a used lancet”**
4. **14[c] - “a gripping handle portion extending between the primary sheath and the secondary sheath”**
5. **14[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”**

Limitations 14[p]-[d] are identical to limitations 1[p]-[d]. The Sakata-Morita combination renders limitations 1[p]-[d] obvious. *Supra* §XI.B.; Ex. 1103, §XII.

6. **14[e] - “said protective sterility cap being in combination with a lancet having a lancet body defining a lancet thickness”**
7. **14[f] - “and a sharp lancet tip initially embedded in the primary sheath”**
8. **14[g] - “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.”**

Limitations 14[e]-[g] are identical to limitations of claim 11. The Sakata-Morita combination renders limitations of claim 11 obvious. *Supra* §XI.F.

J. Claim 15 is Obvious—“wherein the gripping handle portion comprises at least one open loop.”

Claim 15 depends from Claim 14. The Sakata-Morita combination renders Claim 14 obvious. *Supra* §XI.I. Claim 15’s additional limitation “wherein the gripping handle portion comprises at least one open loop” is identical to the limitation of Claim 4 and is obvious for the same reasons.

**XII NO SECONDARY CONSIDERATION
SUPPORT NON-OBVIOUSNESS**

There is no indication that the Examiner relied on any secondary considerations when allowing the claims to issue. Therefore, 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) (instituting IPR despite petition’s failure to address secondary considerations where evidence of secondary considerations was submitted to the PTO but not relied on by the examiner); *Lowe’s, Cos., Inc. v. Nichia Corp.*, IPR2017-02011, Paper 13 at 18 (PTAB Mar. 12, 2018).

XIII CONCLUSION

The Challenged Claims of the '635 Patent are rendered obvious for the reasons set forth above. There is a reasonable likelihood that Petitioner will prevail

as to each of these claims. Accordingly, trial should be instituted to cancel the Challenged Claims.

Dated: March 20, 2023

Respectfully submitted,
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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.
4	The protective sterility cap of claim 1, wherein the gripping handle portion comprises at least one open loop.
9[p]	A protective sterility cap for a lancet, said sterility cap comprising
9[a]	A primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein
9[b]	A secondary sheath for receiving the sharp lancing tip of a used lancet
9[c]	A gripping handle portion extending between the primary sheath and the secondary sheath
9[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
9[e]	Wherein the gripping handle portion comprises at least one open loop
10	The protective sterility cap of claim 9, further comprising at least one flat display surface for placement of branding indicia thereon.
11[a]	In combination with a lancet having a lancet body defining lancet thickness

11[b]	and a sharp lancet tip initially embedded in the primary sheath
11[c]	wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness
12	The protective sterility cap of claim 11, wherein the gripping handle portion defines a length at least equal to its lateral span.
13	The protective sterility cap of claim 11, 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.
15	The protective sterility cap of claim 14, wherein the gripping handle portion comprises at least one open loop.

CERTIFICATION OF COMPLIANCE WITH TYPE-VOLUME LIMITS

This Petition includes 13,710 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 Express Mail 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.

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Dated: March 20, 2023

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