

Filed on behalf of: Facet Technologies, LLC

Entered: June 28, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIFESCAN, INC.,
Petitioner,

v.

FACET TECHNOLOGIES, LLC,
Patent Owner.

IPR2023-00713
Patent 8,840,635

**PATENT OWNER'S
PRELIMINARY RESPONSE**

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Exhibit List

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2101	Declaration of John M. Collins (“Collins Decl.”)
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2111	U.S. District Courts, National Judicial Caseload Profile (as of Dec. 31, 2023)

Exhibit	Description
2112	Daniel S. Hong Disclaimer in Patent Under 37 C.F.R. 1.321(a) regarding Claims 1-5, Facet Techs., LLC, U.S. Patent No. 8,840,635, signed June 14, 2023 (U.S. Pat. & Trademark Dkt. No. 2G02.1-453)
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2119	U.S. Patent No. 5,569,286 ("Peckham '286")
2120	Daniel S. Hong Disclaimer in Patent Under 37 C.F.R. 1.321(a) regarding Claims 9 & 10, Facet Techs., LLC, U.S. Patent No. 8,840,635, signed June 22, 2023 (U.S. Pat. & Trademark Dkt. No. 2G02.1-453)

I. Introduction

Patent Owner Facet Technologies, LLC (“Facet”) submits its Preliminary Response to the Petition for *Inter Partes* Review of U.S. Patent No. 8,840,635 (“’635 Patent”) (“Petition” or “Pet.”), filed by Petitioner LifeScan, Inc. (“LifeScan”).

Facet’s ’635 Patent describes lancets with protective sterility caps for blood sampling and testing, e.g., blood-typing or blood-glucose testing. The ’635 Patent claims a protective sterility cap with a primary and secondary sheath for the sharp lancing tip before and after use, respectively, and a gripping handle portion extending between them, with certain dimensional ratios between the gripping handle portion and the lancet body, including the ratio of the gripping handle portion lateral span to the lancet thickness.

The Petition is fatally deficient. For Ground 1 (Coe), LifeScan asserts only claim 1 is anticipated. But Facet disclaimed claim 1, so the Board cannot institute an IPR on it.

LifeScan’s obviousness grounds are no help to its deficient Petition. For the Coe-based grounds (Ground 2 – Coe and Sakata; Ground 3 – Coe, Starnes, and One Touch Book), Coe fails to disclose “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein” because the alleged cap does not fix a sharp lancing tip firmly and deeply in a surrounding solid mass or surround closely the sharp lancing tip. And none of the secondary references fill that hole. Moreover,

none of the references address the missing dimensional ratio limitation at all. And a person of ordinary skill in the art would not have adjusted the needed dimensions to the claimed dimensional ratio because there is no reason, other than hindsight, to pick the dimensions for comparison or optimization and adjust the ratio between them to obtain the claimed range.

For these and other reasons explained below, the Board should deny institution.

II. Background

A. The '635 Patent (Ex.1101)

The '635 Patent, titled "Lancets With Improved Coupling Features and Sterility Caps," was filed on November 13, 2012 and issued on September 23, 2014. It names the following individuals as inventors: Lauren Pusey, Brian Collins, Christopher Ruf, Nicholas Reaves, and Jonathan Sanders.

The '635 Patent claims priority to U.S. Provisional Application No. 61/084,456, which was filed on July 29, 2008.

The '635 Patent relates to lancets with protective sterility caps and lancing devices. '635 Patent Abstract, 1:17-19. Lancets and lancing devices are used to penetrate the skin of a human subject to obtain a sample of blood for medical testing, such as blood sugar (glucose) testing. *Id.* 1:17-19, 1:23-26; Collins Decl. (Ex.2101) ¶26.

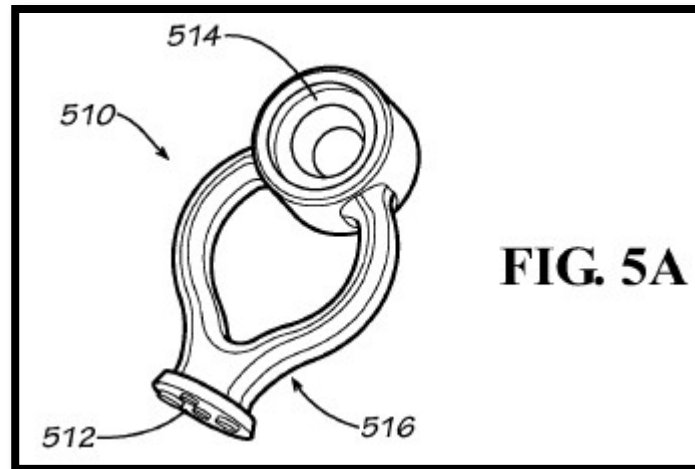
Lancets typically have a sharp metal tip like a needle or blade. '635 Patent 1:43-44. They are typically single-use, disposable components that are designed to be removably mounted in a corresponding lancing device. *Id.* 1:38-43; Collins Decl. ¶27.

To take a blood sample using a lancet, an unused lancet is inserted into the corresponding lancing device. '635 Patent 1:38-43. The lancing device propels the sharp tip of the lancet, typically via a drive mechanism in the lancing device, forward to prick the subject's skin at the lancing site and draw blood. *Id.* 1:26-35. The used lancet is removed from the lancing device and then disposed of. *Id.* 1:35-37, 1:40-43; Collins Decl. ¶28.

To protect users from inadvertent sticks and to maintain sterility, lancets typically are provided with a removable plastic cap covering the sharp tip of the lancet prior to the lancet's use. '635 Patent 1:47-50. That cap may be placed back onto the tip of the lancet after the lancet is used. *Id.* 1:50-52; Collins Decl. ¶29.

The '635 Patent discloses and claims improved lancet designs and protective sterility caps for covering the sharp tip of the lancet. '635 Patent Abstract, 1:58-60, 1:66-2:8, 2:21-36. It provides several non-limiting examples of embodiments of the claimed lancet and the claimed protective sterility cap for the lancet. *Id.* 2:41-46, 3:10-16. For instance, Figures 1A-1C, 2A-2C, 3A-3D, 4A-4D, 8A-8B, 9A-9B, and 10A-10B show example embodiments of the patented lancet. Figures 5A-5E, 6A-

6D, and 7 show example embodiments of the patented endcap. Figure 5A is shown below:



Id. Fig. 5A, 5:65-7:34; Collins Decl. ¶30.

B. Prosecution History

During almost two years of prosecution of the '635 Patent, the Examiner considered a wide variety of art from their own search and provided by the applicant. Facet responded to two sets of art rejections by first adding “a secondary sheath for receiving the sharp lancing tip of a used lancet” and moving a limitation that the gripping handle portion is “extending between the primary sheath and the secondary sheath” from an initially filed dependent claim, and then further by adding the limitation that the primary sheath is attached at a first end of the gripping handle portion and the secondary sheath is attached at a second end of the gripping handle portion. Ex.1102 48-60, 74-76, 187-89. Facet argued the art did not teach these

limitations in combination with the other claim limitations. *Id.* 51-53. The Examiner agreed and allowed the claims. *Id.* 15-21; Collins Decl. ¶¶31-34.

C. Person of Ordinary Skill in the Art

A person of ordinary skill in the art (“POSA”) at the time of the invention would (1) have completed college-level coursework, and/or obtained a bachelor’s degree, in engineering, such as mechanical engineering or biomechanical engineering, or another similar discipline, and (2) have had at least one year of experience researching, developing, and/or designing mechanical medical devices. Less work experience may be compensated by a higher level of education, such as a Master’s Degree, and vice versa. Collins Decl. ¶¶35-36.

LifeScan’s asserts that a POSA would have a higher level of skill. Pet. 6-7.

This POPR is not dependent on the definition of a POSA. All challenged claims would not be anticipated or rendered obvious on the grounds asserted by LifeScan. Collins Decl. ¶37.

D. Claim Construction

The Board construes the claims “using the same claim construction standard that would be used” in district court. 37 C.F.R. § 42.100(b). Here, the district court construed “a secondary sheath for receiving the sharp lancing tip of a used lancet” to mean “a secondary sheath for covering the sharp lancing tip of a used lancet by

embedding or enclosing the lancet tip.” Ex.1105 13-14.¹ The district court declined to construe the other disputed terms (“gripping handle portion,” “lancet thickness,” “lateral span,” and “length”). *Id.* 28-29. Facet applies those constructions in this POPR.² Facet applies the plain meaning to all other claim terms, including “attached at a[n] . . . end of the gripping handle portion,” which LifeScan and Facet agreed to do in district court. Ex.1105 7.

The art asserted in LifeScan’s Petition does not disclose the subject matter of the challenged claims under any reasonable construction, including their plain meaning.

III. Ground 1: Claim 1

LifeScan asserts claim 1 is anticipated over Coe. Pet. 8-24. Facet disclaimed claim 1, so the Board cannot institute an IPR on this disclaimed claim. 37 C.F.R. § 42.107(e); *Intuitive Surgical, Inc. v. Ethicon LLC*, IPR2018-01248, Paper 7 at 2 n.1, 9-10 (P.T.A.B. Feb. 7, 2019).³

¹ Unless otherwise stated, all emphases herein are added and internal quotation marks, citations and footnotes are omitted.

² Facet reserves the right to argue alternative constructions in other proceedings.

³ This applies to any ground challenging disclaimed claim 1.

IV. Ground 2: Coe in View of Sakata Fails to Render Obvious Claims 11-15⁴

LifeScan asserts claims 4, 9-15 are obvious over Coe in view of Sakata.⁵ Pet. 24-44. Moreover, as described below, the Petition does not establish that the Coe in view of Sakata discloses “a primary sheath for initial embedment of a sharp

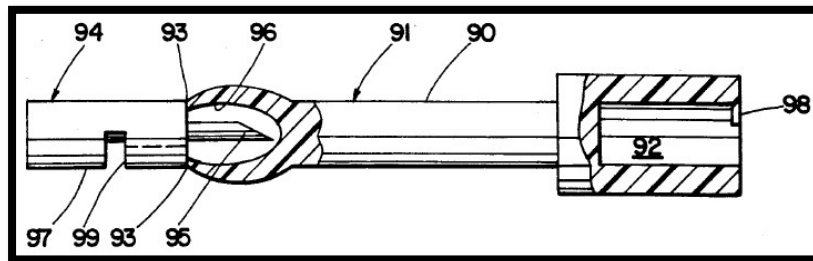
⁴ At the start of Ground 2 (Coe in View of Sakata), LifeScan argues that a POSA would combine embodiments of Coe to arrive at the protective sterility cap from Ground 1. Pet. 24-25. But this is non-sensical as Ground 1 relies only on the embodiment in Coe Figure 9. *Id.* 8 n.1. No combining is needed to arrive at the cap used by LifeScan in Ground 1. Also, LifeScan's argument is improper as it is a unique invalidity ground not identified as such in LifeScan's Petition. 37 C.F.R. § 42.22(a)(1) (requiring a statement of precise relief requested); Pet. 2-4 (not requesting institution of its Petition on Coe alone under 35 U.S.C. § 103). This is fatal. *See Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1337 (Fed. Cir. 2020) (finding the Board erred in instituting an IPR ground not advanced in the Petition).

⁵ Facet disclaimed claims 1-5 and 9-10. *See* Exs.2112, 2120. The Board cannot institute an IPR on a disclaimed claim. 37 C.F.R. § 42.107(e); *Intuitive Surgical*, IPR2018-01248, Paper 7 at 2 n.1, 9-10. So the Board cannot institute an IPR on claims 1-5 in this or any other ground.

lancing tip of an unused lancet therein” (Claims 9, 14) and “the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness” (Claims 11, 14). Also, the Petition does not establish that a POSA would be motivated to combine Coe in view of Sakata to derive the claimed invention. Thus, the Board should deny institution on this Ground.

A. Coe (Ex.1106)

Coe discloses a lancet 94 and extractor 91.⁶ Coe Fig. 9, 5:22-24. The lancet 94 includes lancet hub 97 with slot 99 and sharp tip 95. *Id.* Fig. 9, 5:22-38. The extractor 91 includes an extractor cavity 92, handle portion 90, second cavity 96, and extractor tab 98. *Id.*



Id. Fig. 9; Collins Decl. ¶72.

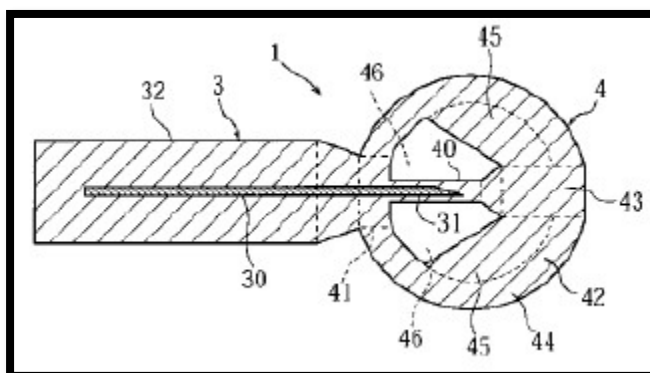
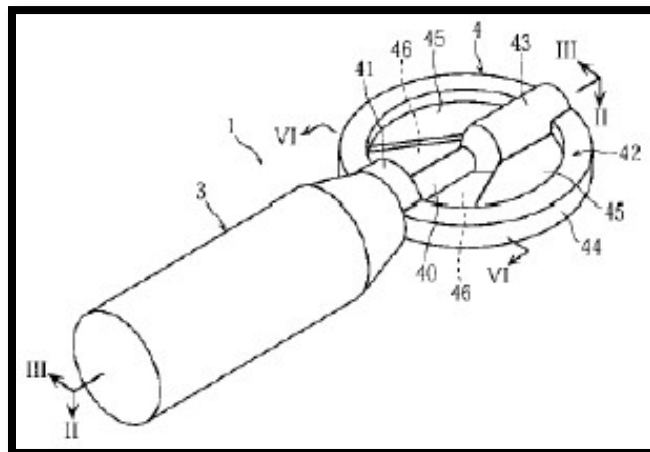
The lancet 94 and extractor 91 are connected through integral molding at breakaway points 93. Coe Fig. 9, 5:22-24, 5:28-30. The connections are broken by

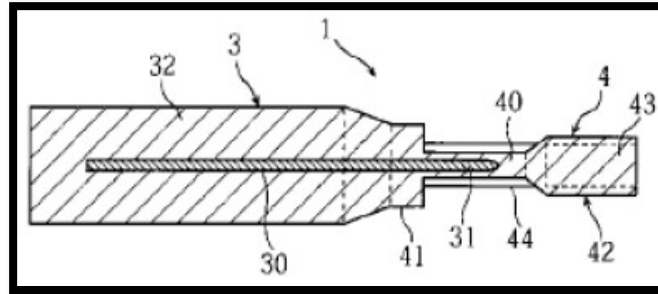
⁶ LifeScan only relies on the embodiment shown in Coe's Figure 9 in Ground 1, which forms the basis for Grounds 2 and 3. Pet. 8 n.1.

“gentl[y] twisting” while the lancet 94 is in a lancet device. *Id.* Fig. 9, 5:30-33. After the use, the lancet 94 “is inserted (point first) into the extractor cavity until the extractor tab (98) engages the slot (99) in the lancet hub thereby locking the sharp lancet tip protectively within the extractor cavity for safe handling and disposal.” *Id.* Fig. 9, 5:33-38; Collins Decl. ¶73.

B. Sakata (Ex.1107)

Sakata discloses a lancet 1. Sakata [0008], [0014]. The lancet 1 includes a lancet body 3 and cap portion 4, which separated which are separated by twisting them relative to each other. *Id.* Figs. 1-3, [0014], [0020].





Id. Figs. 1-3; Collins Decl. ¶74.

The lancet body 3 includes a holding portion 32 and puncture needle 30 with needle tip 31. Sakata [0015], Figs. 2-3. The cap portion 4 includes small diameter covering portion 40, a large diameter covering portion 41, and an operating portion 42. *Id.* [0016], Figs. 1-3. The small diameter covering portion 40 covers needle tip 31. *Id.* [0017], Figs. 1-3. The large diameter covering portion 41 covers the root portion of the puncture needle 30. *Id.* [0018], Figs. 1-3. The operating portion 42 has a cylindrical portion 43, an arch portion 44, and a pair of thin-walled portions 45. *Id.* [0019], Figs. 1-3. There is a gap 46 interposed between the arch portion 44 and the small diameter covering portion 40. *Id.* [0019], Figs. 1-2. The cap portion 4 purportedly reduces the load applied to edge of blade's surface of the puncture needle when separating the cap portion 4 and does not significantly disturb the blade surface. *Id.* [0012]; Collins Decl. ¶75.

C. The Proposed Combination Does Not Disclose All Claim Limitations

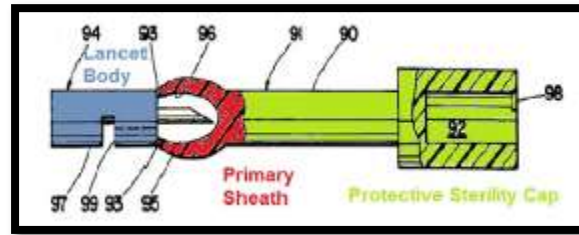
The proposed combination does not disclose all the claim limitations. For this reason alone, the Board should deny institution on this Ground.

First, the proposed combination fails to disclose “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein.” ’635 Patent cls. 9, 14. The sharp lancing tip is not embedded in Coe because there is a significant distance between the tip and what LifeScan points to as the protective sheath in Coe. LifeScan does not rely on any other reference or the proposed combination to teach this limitation in the Petition. Second, the proposed combination does not disclose “the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.” *Id.* cls. 11, 14 (corresponding to LifeScan’s “Claim No. 11[c]” and “Claim No. “14[g]”). Neither Coe nor Sakata disclose this dimensional ratio in their written description or figures. LifeScan improperly derives dimensions of their figures in contravention of direction from the Federal Circuit.

LifeScan’s Petition thus should be denied because it does not “specify where each element of the claim is found in the prior art patents or printed publications relied upon[.]” 37 C.F.R. § 42.104(b)(4).

1. The Proposed Combination Does Not Disclose “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein” (Claims 11, 14)

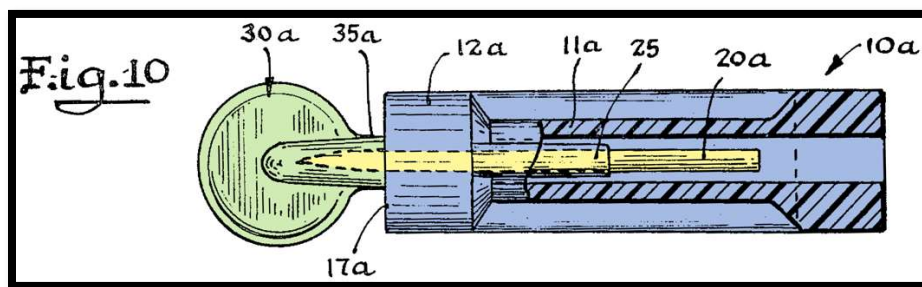
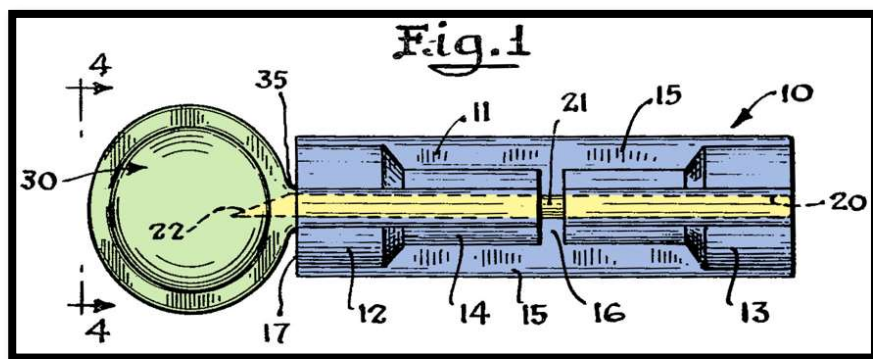
The proposed combination does not disclose this limitation. LifeScan asserts the red portion below is the “primary sheath,” which includes second cavity 96:



Pet. 11; *see also* Coe Fig. 9. The sharp lancet tip (which Coe labels as 95 in Figure 9), as plainly seen, is not “embedded” within the second cavity 96. Collins Decl. ¶142.

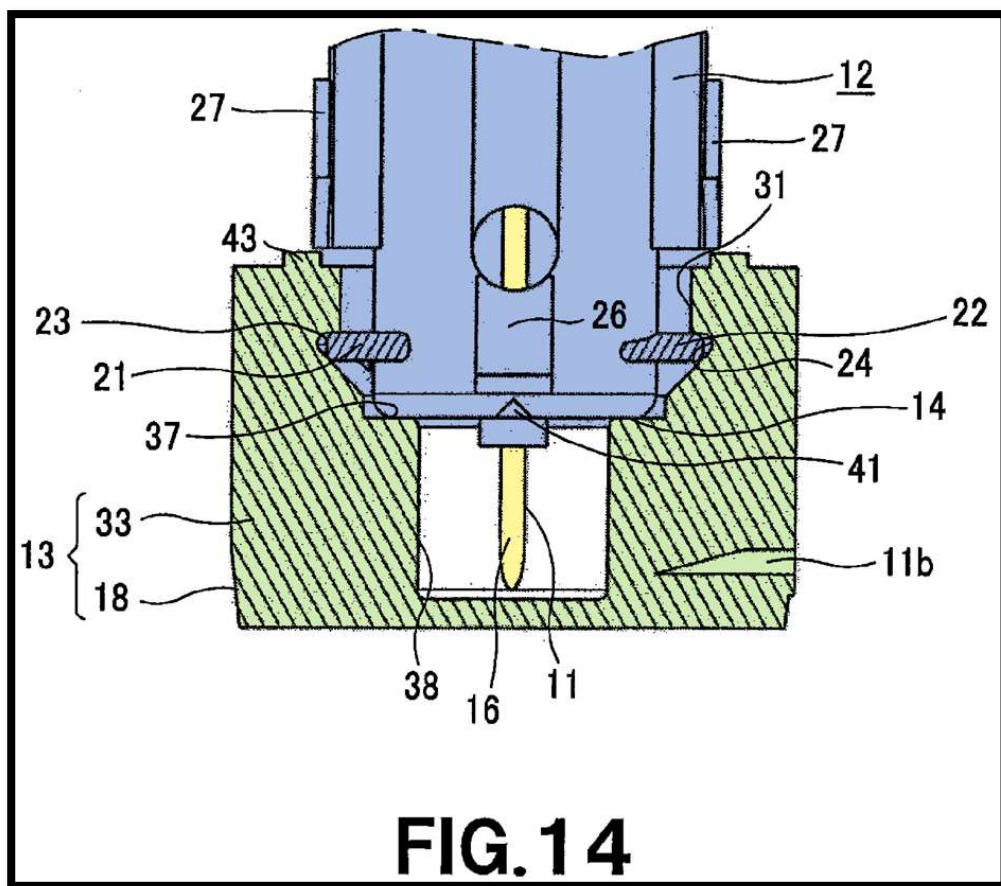
A sharp lancing tip is “embedded” when fixed firmly and deeply in a surrounding solid mass or surrounded closely. Ex.2117 (Collins English Dictionary) (embed: “to fix or become fixed firmly and deeply in a surrounding solid mass”); Ex.2115 (McGraw-Hill Dictionary) (embed: “To closely surround”); Ex.2113 (Merriam-Webster Dictionary) (embed: “to enclose closely in or as if in a matrix;” “to surround closely”). In contrast, Coe’s sharp tip 95 is not fixed firmly and deeply in a surrounding solid mass or surrounded closely. Coe Fig. 9, 5:22-38. Indeed, Coe recognizes that what LifeScan labels as the “primary sheath” does not embed a sharp lancing tip. Coe calls 96 a “second cavity.” *Id.* 5:25-28. A POSA would understand a “cavity” to mean an unfilled or hollow space. Ex.2117 (Collins English Dictionary) (cavity: “a hollow space”); Ex.2113 (Merriam-Webster Dictionary) (cavity: “an unfilled space within a mass”). There is nothing for the sharp tip to be embedded in. Collins Decl. ¶¶143-147.

Other references LifeScan relies on support Facet's reading of Coe. Starnes (Ex.1116) describes the art including U.S. Patent No. 3,358,689 to Higgins (Ex.1118). Ex.1116 [0006]-[0013]. Starnes (Ex.1116) states Higgins teaches "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." *Id.* [0008]. Below is an embodiment of Higgins where the cap 30 or 30a and body section 11 or 11a are integrally molded and the cap 30 or 30a surrounds closely the needle tip:



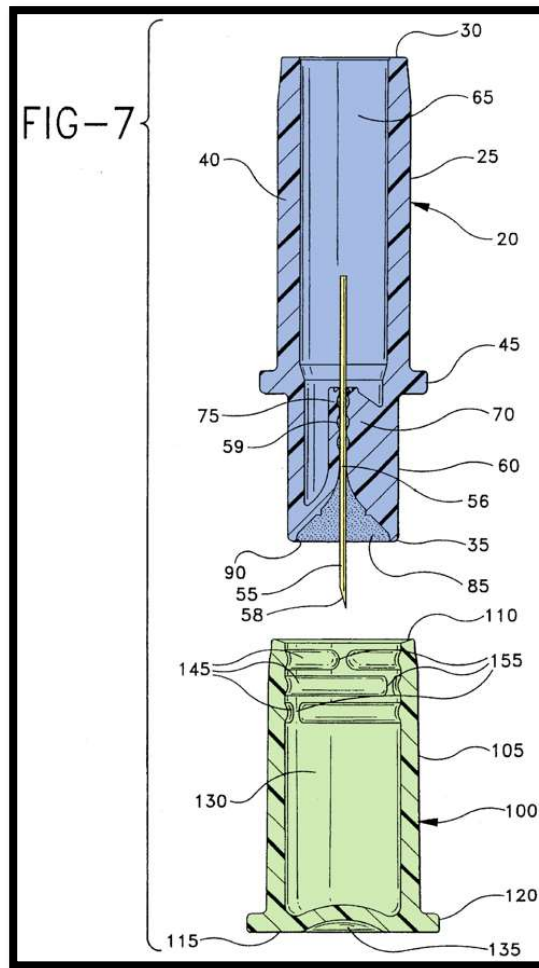
Higgins Figs. 1 (annotated), 10 (annotated), 2:21-26, 4:5-11, 4:74-5:2. The cap 30 or 30a is a solid mass that the needle is present in. There is no space or cavity in the cap 20 or 30a. Collins Decl. ¶¶148-149.

In contrast, when the art describes a cap that does not have mass that fixes firmly and deeply a sharp lancing tip or surrounds the sharp lancing tip closely, the art does not describe the cap as “embedding” the sharp lancing tip. For example, Horie (Ex.1114) describes a distal end 11a of a needle 11 attached to pricking member body 12 being inserted into a needle protective cap 13 where there is an appreciable space between the needle 11 and the protective cap 13 (as seen below) “such as to isolate the distal end 11a from outside.”



Horie Fig. 14 (annotated), [0081]. Horie does not say that the needle 11 is “embedded” by the needle protective cap 13, but rather that it is “isolate[d].” *See id.* [0081]; Collins Decl. ¶150.

As another example, Peckham (Ex.2119) describes a shielded lancet assembly 10 with (a) a lancet assembly 20 containing a cylindrical housing 25 and stylet 55; and (b) a removable cap or shield 100. Peckham Figs. 2, 7, 2:52-62. When the lancet assembly 20 is inserted into removable cap or shield 100, the stylet 55 is “shield[ed]”—not “embedded,” especially as seen in the figure below where there would be an appreciable distance between the stylet 55 and removable cap or shield 100 upon insertion.



Id. Fig. 7, 2:56-59, 3:4-8; Collins Decl. ¶151.

LifeScan relies solely on Coe to teach this limitation—not Sakata nor the proposed combination. Pet. 31.

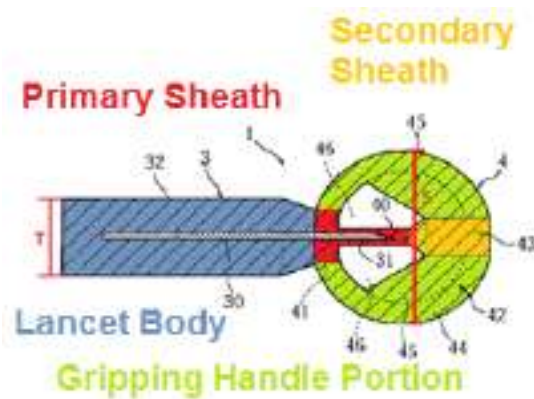
Thus, Coe in view of Sakata fails to disclose this limitation. Collins Decl. ¶141.

2. The Proposed Combination Does Not Disclose “the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness” (Claims 11, 14)

The proposed combination does not disclose this limitation. LifeScan improperly relies upon “dimensions” in Sakata’s figures contrary to direction from

the Federal Circuit. Also LifeScan makes unfounded assumptions about Sakata and about POSA's understanding of it.

First, LifeScan relies upon “dimensions” in Sakata's figures to meet this limitation. Pet. 36-37. LifeScan provides the following annotated image and purports to derive a ratio between the lateral span of the purported gripping handle to the thickness of the lancet:



Id. 37. LifeScan's attempt to derive dimension S and dimension T from the patent figure is improper as a matter of law. The Federal Circuit has repeatedly held that “patent drawings do not define the precise proportions of the elements and **may not be relied on to show particular sizes if the specification is completely silent on the issue.**” *Hockerson-Halberstadt, Inc. v. Avia Grp. Int'l, Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000); *see also White v. H.J. Heinz Co.*, 640 F. App'x 930, 934-35 (Fed. Cir. 2016); *Nystrom v. TREX Co.*, 424 F.3d 1136, 1149 (Fed. Cir. 2005) (“Under the principles set forth in our prior cases, the speculative modeling premised on unstated assumptions in prior art patent drawings cannot be the basis for challenging the

validity of claims reciting specific dimensions not disclosed directly in such prior art.”), *aff'd*, 200 F. App'x 987 (Fed. Cir. 2006) (per curiam); *In re Wright*, 569 F.2d 1124, 1127 (C.C.P.A. 1977) (“Absent any written description in the specification of quantitative values, arguments based on measurement of a drawing are of little value.”).

Here, Sakata's specification is *completely silent* as to whether any figure or any dimension of any component in the figures is to scale. Sakata provides no written disclosure that any figure is to scale. Nor does LifeScan even contend that Sakata discloses that its figures are to scale. Sakata's description includes no information about dimensions of any component in the figures except the distance between puncture needle 30 and small diameter covering portion 40 *may be* between 0.1 and 3 mm. Sakata [0010], [0017]. But this falls short of being sufficient to rely upon Sakata's figures for dimensional information, which requires the specification state the drawings are to scale in order. *Hockerson-Halberstadt*, 222 F.3d at 956. Thus, Sakata's figures cannot be relied upon to disclose any dimension—along with any dimensional ratio. This means Sakata's figures cannot be used to disclose this limitation. Collins Decl. ¶¶155-156.⁷

⁷ LifeScan's statement that gripping handles with a span at least 1.5 times their lancet's thickness were disclosed in prior art references does not help its

Second, LifeScan makes unsupported assumptions about Sakata. These assumptions are not accurate, which prevents the proposed combination from disclosing this limitation. LifeScan asserts that Sakata “discloses that covering portion 40 is between 0.1-3.0 mm.” Pet. 35-36. But as noted *supra*, that is not the case. Rather, Sakata discloses the distance between puncture needle 30 and small diameter covering portion 40 **may be** between 0.1 and 3 mm. Sakata [0010], [0017]. Regardless, this does not provide information about the lateral span of Sakata. The specification is devoid of exact dimensions of it and as noted above reliance on figures that are not to scale cannot be used to derive the information either. Next, without citing to any source, even its alleged expert, LifeScan asserts the lateral span of cap portion 4 would need “to be much larger than the 16 mm diameter of an average human thumb to ensure that the handling goal was achieved.” Pet. 36. But

cause. Pet. 36 n.8. First, the cited examples do not disclose it. For example, LifeScan improperly relies on patent figures for dimensions and dimensional ratio with no indication of their reliability for dimensions. *See Hockerson-Halberstadt*, 222 F.3d at 956. Second, LifeScan does not tie its statement to the asserted obviousness ground. “An invention is not obvious simply because all of the claimed limitations were known in the prior art at the time of the invention.” *Forest Lab’ys, LLC v. Sigmapharm Lab’ys, LLC*, 918 F.3d 928, 934 (Fed. Cir. 2019).

there are plenty of items maneuvered by hand that are less than the diameter of the average human thumb, including those where pieces are separated, such as a pen and pen cap and an eyeliner pencil and cap. Also, LifeScan assumes Sakata includes a “standard lancet” with a diameter of less than 6 mm as taught by LeVaughn (Ex.1120). But Sakata says nothing about using a “standard lancet,” much less about the dimensions of such a standard lancet. In fact, Sakata distinguishes its purported lancet with a “conventional lancet.” Sakata [0022]. Without LifeScan’s incorrect assumptions, a POSA would not “have understood Sakata to teach that its lateral span was at least 2.67 times the lancet thickness.” Pet. 36; Collins Decl. ¶¶157-158.⁸

Thus, Coe in view of Sakata fails to disclose this limitation. Collins Decl. ¶153.

⁸ LifeScan’s allusion to Sakata’s “ratio” being consistent with LeVaughn’s ratio of lancing device’s width and thickness has no bearing on the obvious determination. The ratios LifeScan points to in LeVaughn refer to lancing device 10 (Ex.1120 Fig. 1, 5:15-18), which is different and not necessarily correlated with the ratio of the lateral span of a gripping handle portion of a protective sterility cap and a lancet thickness. Collins Decl. ¶¶91-92.

D. A POSA Would Not Have Adjusted a Lateral Span of a “gripping handle portion” to be At Least 1.5 Times a “lancet thickness” (Claims 11, 14)

The claims of the '635 Patent recite a protective sterility cap “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness” '635 Patent cls. 11, 14 (corresponding to LifeScan's “Claim No. 11[c]” and “Claim No. “14[g]”). LifeScan argues it would be obvious to try the limitation. Pet. 41-43. This is unpersuasive. LifeScan put forth an argument that POSA would vary all the parameters of dimensions of various components of a lancing device and would come across this limitation. This Petition should be denied on this Ground because LifeScan fails to establish that a POSA would modify Coe in view of Sakata in this way.

For an obvious to try analysis to apply, the Federal Circuit has held “that the possible approaches and selection to solve the problem must be ‘known and finite.’” *Rolls-Royce, PLC v. United Techs. Corp.*, 603 F.3d 1325, 1339 (Fed. Cir. 2010). LifeScan has not bothered to present a finite number of identified and predictable solutions. That is fatal. *Id.*; *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1359 (Fed. Cir. 2007) (holding the invention not obvious to try because the prior art disclosed a broad selection of compounds that an ordinarily skilled artisan could have selected for further investigation). What is more, a POSA could take multiple avenues to “allow[] a user to easily handle the cap with their

fingers.” Pet. 43. That would include at least adding a cover to the areas of the cap gripped by a user (e.g., rubber, polymer, textured coating), adding mechanical grips to the areas of the cap gripped by a user (e.g., dimples), or changing certain dimensions. Even only pursuing the changing of the dimensions of the areas of the cap gripped by a user, there is still a broad selection of choices for further investigation, such as the length, width, and thickness of the areas of the cap gripped by a user and the ratio of each of those dimensions to any other dimension of the lance or lancet device. LifeScan gives no indication from the art the ratio of the span of the gripping handle portion to the lancet thickness was critical to the design of protective caps or what ratios would have been beneficial. *Id.* 50-52; Collins Decl. ¶¶159-173.

Also, the proposed combination of Coe in view of Sakata does not disclose this limitation. Section IV.C.2. Coe’s object of its purported invention of “effectively minimiz[ing] hazards to medical personnel resulting from accidental lancet punctures” has nothing to do with dimensions of extractor 91 as Coe’s object deals with covering the sharp tip of a disposable lancet via an extraction member—not the size or dimensions of the extractor 91. Coe 3:17-22, 3:33-36; Collins Decl. ¶161. LifeScan’s reliance on the declaration of its alleged expert is of no help to it. The declaration is substantially if not entirely verbatim of the Petition with no supporting evidence or technical reasoning. *Compare* Pet. 41-43, with Ex.1103 ¶¶100-101. And

thus it should be given little to no weight by the Board. *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15-16 (P.T.A.B. Aug. 24, 2022) (precedential); 37 C.F.R. § 42.65(a). This is especially true as LifeScan is relying on an expert declaration to supply a limitation missing from the prior art.

In short, LifeScan is merely throwing darts at a board filled with combinatorial prior art possibilities in the hope that the Board succumbs to hindsight. *See In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988) (improper to simply “vary all parameters” to arrive at a claimed invention where the prior art gave no indication the parameters were critical or direction as to which choices would likely be successful).

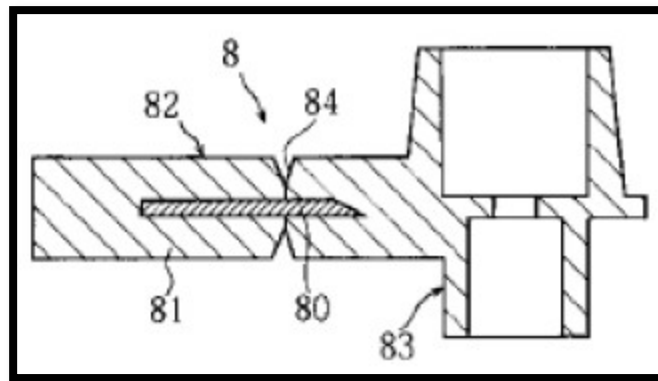
E. A POSA Would Not Have Combined Coe and Sakata

LifeScan gives multiple purported motivations to combine Coe and Sakata. None of them are persuasive. Collins Decl. ¶175. Thus, this Petition should be denied on this Ground because LifeScan fails to establish that a POSA would modify Coe in view of Sakata.

First, LifeScan asserts that POSA “would have been motivated to prevent damage to the lancet tip and pain to the user.” Pet. 26-28. LifeScan says that tips of lancets may be broken during transport and storage without a cap and Sakata solves a problem of damaging needle tips when removing a cap from the lancet. *Id.* But, Coe itself addresses this problem with the second cavity (96) protectively covering

the sharp tip (95) of the lancet (94). Coe 5:26-28. In addition, protective caps for needle tips were already known in the art to solve this problem. '635 Patent at 1:47-50 ("The sharp tip of the lancet is commonly embedded in a removable plastic cap to maintain sterility and prevent inadvertent sticks prior to use."); Collins Decl. ¶176.

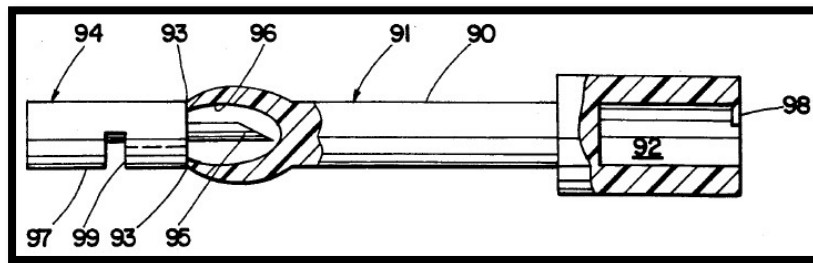
Moreover, the problem that Sakata supposedly solves is not present in Coe. Sakata describes a conventional lancet 8 with a cap portion 83 and a lancet body 82 having a puncture needle 80 and cylindrical portion 81. Sakata Figs. 6, 7, [0003].



Id. Fig. 7. The puncture needle 80 is insert-molded into lancet body 82 and cap portion 83 and thus formed in close contact with the cap portion 83. *Id.* Figs. 6, 7, [0003]. When the cap portion 83 is in close contact with puncture needle 80 and the diameter of the cavity covering it is large, the twisting of cap portion 83 puts relatively large stress acts on the blade surface of puncture needle 80 that may disrupt the blade surface. *Id.* Figs. 6, 7, [0004]. Sakata purportedly solves this issue by reducing the thickness of the cover around portions of the needle and including an

arch portion to concentrate stress away from the needle. *Id.*[0009]-[0010]; Collins Decl. ¶177.

But Sakata's solution is inapplicable to Coe's Figure 9. Unlike Sakata's conventional lancet, as described above, the sharp tip 95 is initially not embedded in the cap. Instead, the needle and tip are in a void defined as the second cavity 96. Coe Fig. 9, 5:25-28.



Id. Fig. 9. There is no contact between the sharp tip 95 and the structure that defines second cavity 96—let alone close contact. *Id.* Fig. 9, 5:25-28. This is one of the necessary conditions in Sakata for its purported problem of inducing stress and “disrupting” the needle during the twisting action of decapping and resulting in pain for the user. Sakata [0004]. And there is no indication in Coe that removing the extractor 91 from lancet hub 97 causes any damage to sharp tip 95. *See* Coe 5:22-38; Collins Decl. ¶178.

Second, LifeScan also posits a POSA would have been motivated to combine Coe and Sakata because they “are within the same field of endeavor as the ’635 Patent.” Pet. 26. But “a broad characterization of [prior art references] as both falling

within the same alleged field . . . without more, is not enough for [Petitioner] to meet its burden of presenting a sufficient rationale to support an obviousness conclusion.” *Securus Techs., Inc. v. Global Tel*Link Corp.*, 701 F. App’x 971, 977 (Fed. Cir. 2017); Collins Decl. ¶179.

Third, LifeScan asserts that POSA “would have been motivated to identify used or tampered with lancets.” Pet. 29-30.⁹ But Coe already provides a way to identify used or tampered lancets, so there is no need for POSA to look to Sakata. Coe describes extractor 91 is connected at breakaway points 93 at the outer edge of an upper bearing face of lancet hub 97. Coe Fig. 9, 5:22-38.¹⁰ Once the connection

⁹ LifeScan also makes a reasonable expectation of success argument, i.e., Coe’s and Sakata’s caps have common components that can be easily interchanged at a minimal cost through integral molding (Pet. 30), in the motivation to combine section of the Petition, which is a separate legal concept from motivation to combine and thus should not be considered when analyzing whether there is a motivation to combine. *See Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1368 (Fed. Cir. 2016) (explaining motivation to combine and reasonable expectation of success are different legal concepts).

¹⁰ For this motivation to combine, LifeScan bases its argument on an embodiment other than the one in Figure 9, which it relies upon in Ground 1 and uses in the

is broken, the extractor 91 will not be able to easily go back on top of the upper bearing surface of lancet hub 97, if at all. Coe does not disclose any way, mechanical or chemical, to reconnect the pieces. *See* Coe Fig. 9, 5:22-38. And placing the extractor 91 on top of lancet hub 97 after breaking the connection would be unstable and the extractor 92 would be prone to fall off given the interface between the pieces would be uneven with no component to bind the pieces and the center of gravity of the extractor would be relatively high above the interface. Once the lancet 97 is used, the extractor cavity is used for disposal of the used lancet 97. *Id.* 5:22-38; Collins Decl. ¶180.

Furthermore, Sakata does not teach a solution to the problem posited by LifeScan. Pet. 30. Sakata does not indicate that the “deformation” of the covering portions 40, 41 would prevent the puncture needle 30 and needle tip 31 from being reinserted in cap portion 4 such that a person could identify a used or tampered lancet. *Id.*; Collins Decl. ¶181. Also, LifeScan’s expert provides no support for its argument regarding Sakata or this motivation to combine argument as the cited paragraphs of his declaration has nothing to do with its assertion and should not be a factor in

proposed combination with Sakata, with no explanation of why the argument would be applicable to the embodiment in Figure 9. This argument should be discounted on this basis alone.

analyzing this argument. *See* Pet. 30; Ex.1103 ¶¶90-93 (asserting Coe and Sakata are analogous art, repeating what is exactly in the Petition, and discussing other points). In fact, the declaration is devoid of facts, explanations, or conclusions for this argument.

F. Dependent Claims

Because the claims upon which claims 10-13 and 15 depend are not obvious, the Board should deny the Petition on this Ground on the dependent claims for the same reasons. *See Neptune Generics, LLC v. Eli Lilly & Co.*, 921 F.3d 1372, 1378 (Fed. Cir. 2019); *Home Semiconductor Corp. v. Samsung Elecs. Co.*, 701 F. App'x 1006, 1013 (Fed. Cir. 2017); *see also Cadence Pharms., Inc. v. Exela Pharma Scis., LLC*, C.A. No. 11-cv-00733, 2013 WL 11083853, at *25 (D. Del. Nov. 14, 2013); *CA, Inc. v. Simple.com, Inc.*, 780 F. Supp. 2d 196, 260 (E.D.N.Y. 2009).

V. Ground 3: Coe in View of Starnes and One Touch Book Fails to Render Obvious Claims 11-15

LifeScan asserts claims 4 and 9-15 are obvious over Coe in view of Starnes and One Touch Book.¹¹ Pet. 44-55.¹² As described below, Coe in view of Starnes and One Touch Book does not disclose “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein” (Claims 1, 9, 14). Also, the Petition fails to establish that a POSA would be motivated to combine Coe in view of Starnes and One Touch Book to derive the claimed invention. Thus, the Board should deny institution on this Ground.

¹¹ The Board cannot institute an IPR on disclaimed claims 4 and 9-10 in this or any other ground. 37 C.F.R. § 42.107(e); *Intuitive Surgical*, IPR2018-01248, Paper 7 at 2 n.1, 9-10.

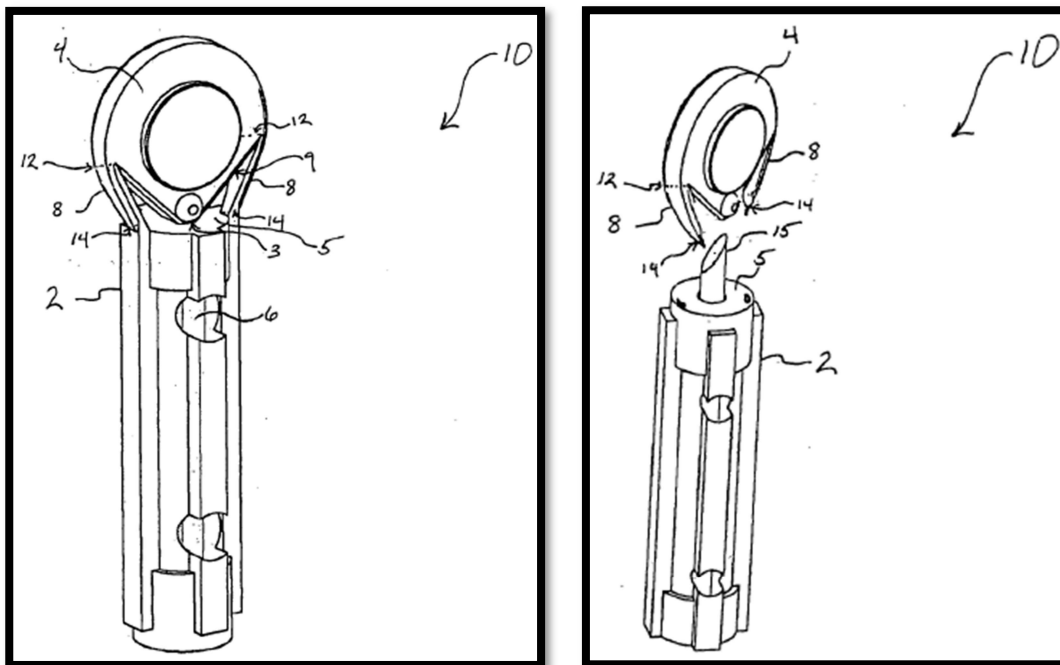
¹² In the Identification of Grounds and Claims Section, LifeScan asserts claims 4 and 9-15 are obvious over Coe in view of Starnes and One Touch Book. Pet. 4. But LifeScan only substantively addresses claims 4, 9-10, and 15 for the proposed combination. *Id.* 44-55. Thus, the Board should not institute based on claims 11-14 of this Ground solely based on LifeScan failing to provide “[a] full statement of the reasons for the relief requested.” 37 C.F.R. § 42.22(a)(2).

A. Starnes (Ex.1108)¹³

Starnes discloses a protective lancet. Starnes [0003], [0012]. In a first embodiment (*id.* Figs. 1-3),¹⁴ Starnes describes a lancet unit 10 including a cap member 4 and lancet body 2 with a pointed end section 15. Starnes [0023]-[0024].

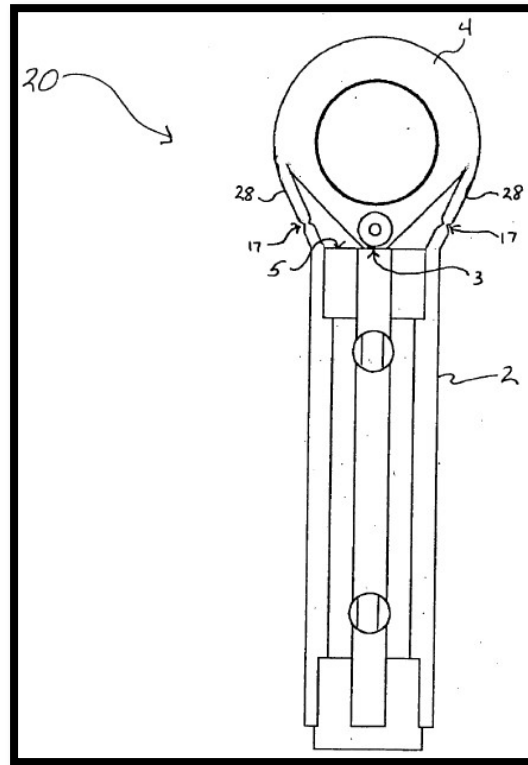
¹³ LifeScan also relies on One Touch Book (Ex.1110) in this combination, but only for claim 10. *See* Pet. 50-54. Facet will not address the additional claim limitation in claim 10 or One Touch Book in this POPR because Facet disclaimed claim 10.

¹⁴ LifeScan appears to rely on two embodiments in its Petition—the embodiment in Starnes Figures 1-3 and 4. *See, e.g.,* Pet. 48; *see also* Starnes [0015]-[0018] (stating the two separate embodiments). LifeScan apparently uses both embodiments in its combination. Pet. 48. Although improper to combine embodiments with no explanation, the proposed combination still does not render any claim of the '635 Patent obvious regardless of what embodiment of Starnes LifeScan uses—even if the embodiments are combined.



Id. Figs. 1, 2. The cap member 4 covers the pointed end section 15 and connects to lancet body 2 by frangible junction 3 and narrower tear-away ends 14 of tab members 8. *Id.* [0026]-[0027]. The tab members 8 “provide a readily perceptible user indication of the status of whether or not the cap member has been re-attached or tampered with.” *Id.* [0012]. The cap member 4 is separated from the lancet body 2 by “a twisting or pulling force.” *Id.* [0024]. Upon twisting of cap member 4, the narrower tear-away ends 14 should disengage from an upper bearing surface 5 of lancet body 2, along with frangible junction 3. *Id.* [0027]; Collins Decl. ¶¶76-77.

In a second embodiment (Starnes Fig. 4), Starnes describes a lancet unit 20 including a cap member 4 and lancet body 2. *Id.* [0035].



Id. Fig. 4. The cap member 4 connects to lancet body 2 by frangible junction 3 and tab members 28 with medial tear-away joints 17. *Id.* [0026]-[0027]. The tab members 28 “provide a readily perceptible user indication of the status of whether or not the cap member has been re-attached or tampered with.” *Id.* [0012]. The cap member 4 is separated from the lancet body 2 by “a twisting or pulling force.” *Id.* [0035]. When cap member 4 detaches from lancet body 2, the medial tear-away joints 17 should fracture such that a substantial appendage portion of tab member 28 remains attached to cap member 4 and a visually perceptible stub remains on upper bearing surface 5 of lancet body 2., which provides “a readily perceptible indicator of de-attachment.” *Id.* [0035]; Collins Decl. ¶¶78-79.

B. The Proposed Combination Does Not Disclose All Claim Limitations

The proposed combination does not disclose all the claim limitations. For this reason alone, the Board should deny institution on this Ground.

The proposed combination fails to disclose “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein.” ’635 Patent cls. 9, 14. Coe does not disclose this limitation for the reasons in Section IV.C.1. LifeScan solely relies on Coe to teach this limitation—not Starnes, One Touch Book, nor the proposed combination. Pet. 47. Thus, Coe in view of Sakata fails to disclose this limitation. Collins Decl. ¶¶182-183.

C. A POSA Would Not Have Combined Coe and Starnes

A POSA would not make the combination of Coe and Starnes as described by LifeScan. The purported added function of the tab members 8 or 28 of Starnes is unnecessary or redundant of structures that already provide the same function in Coe. And, adding the tab members 8 or 28 of Starnes would detrimentally interfere with operation of Coe.

First, LifeScan asserts a POSA would be motivated to combine Coe and Starnes as it “provides a solution to the problem of determining whether a lancet has been used.” Pet. 45. But Starnes solution of determining whether a lancet has been used is not needed in Coe. Coe describes extractor 91 as being connected at breakaway points 93 at the outer edge of an upper bearing face of lancet hub 97. Coe

Fig. 9, 5:22-38. Once the connection is broken, the extractor 91 will not be able to easily go back on top of the upper bearing surface of lancet hub 97, if at all. Coe does not disclose any way, mechanical or chemical, to reconnect the pieces. *See id.* With pieces disconnected and no way to be put back together, Coe already provides a way to determine whether a lancet has been used. Collins Decl. ¶187.

Second, Coe already discloses a structure that provides the purported added function of tab members 8 or 28 of Starnes, i.e., determining whether a lancet has been used, and thus making them redundant or unnecessary in Coe. As noted, Coe describes extractor 91 as being connected at breakaway points 93 at the outer edge of an upper bearing face of lancet hub 97. Coe Fig. 9, 5:22-38. The extractor 91 is removed from lancet hub 97 at those breakaway points. *Id.* The extractor 91 will not be able to easily go back on top of the upper bearing surface of lancet hub 97, if at all. The breakaway points 93 tell a user whether a lancet has not been used or tampered with—if they are not broken, the lancet has not been used or tampered with and if they are broken, the lancet may have been used or tampered with. The tab members 8 or 28 of Starnes are not needed to provide this information as lancet 94 of Coe already provides the same information. Adding them would not be helpful or provide any additional benefit. Collins Decl. ¶188.

Third, adding the tab members 8 or 28 of Starnes would likely detrimentally interfere with operation of Coe such that a POSA would not combine them as

proposed by LifeScan. Coe describes breakaway points 93 at the outer edge of an upper bearing face of lancet hub 97. Coe Fig. 9, 5:22-38. This means the tab members 8 or 28 of Starnes would have to be connected on the sides of lancet hub 97. When doing so, the tab members would leave a “visually perceptible stub” on lancet hub 97 upon disconnection. Starnes [0035]. The visually perceptible stub would likely interfere with, and potentially prevent, insertion of lancet hub 97 into extractor cavity 92 as it would hit the walls of extractor cavity 92, extractor tab 98, or the end face of the structure defining extractor cavity 92. Collins Decl. ¶189.

Thus, LifeScan fails to establish that a POSA would modify Coe with Starnes. *Id.* ¶184.

D. Dependent Claims

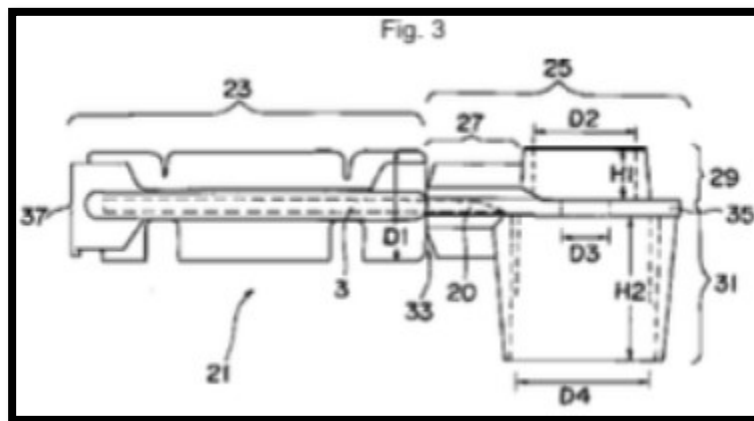
Because the claims upon which claims 10-13 and 15 depend are not obvious, the Board should deny the Petition on this Ground on the dependent claims for the same reasons. *See Neptune Generics*, 921 F.3d at 1378; *see also Cadence Pharms.*, C.A. No. 11-cv-00733, 2013 WL 11083853, at *25; *CA, Inc.*, 780 F. Supp. 2d at 260.

VI. Ground 4: Sakata in View of Morita Fails to Render Obvious Claims 11-15

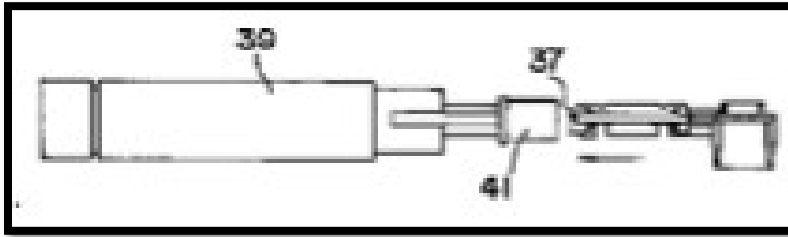
LifeScan asserts claims 1, 4, and 9-15 are obvious over Sakata in view of Morita.¹⁵ Pet. 55-77. As described below, Sakata in view of Morita does not disclose “a secondary sheath for receiving the sharp lancing tip of a used lancet” (Claims 1, 9, 14), and “the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness” (Claims 11, 14).

A. Morita (Ex.1109)

Morita discloses a blood collection lancet. Morita [0001]. A device accepts a lancet 21 having a lancet body 23, needle part 3 (including needle tip part 20), and protective platform 25. *Id.* [0029], [0033], Figs. 3, 10.

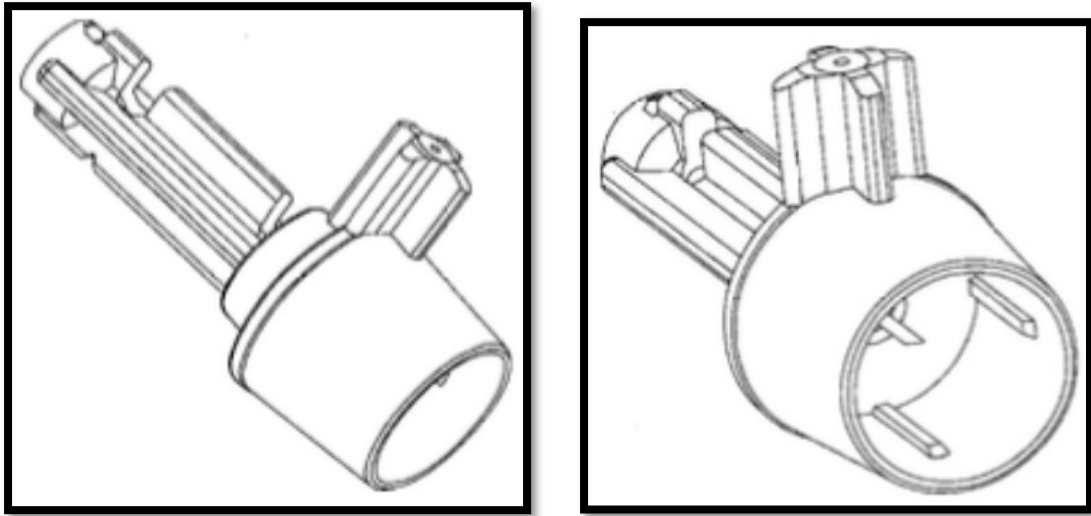


¹⁵ The Board cannot institute an IPR on disclaimed claims 1, 4, and 9-10 in this or any other ground. 37 C.F.R. § 42.107(e); *Intuitive Surgical*, IPR2018-01248, Paper 7 at 2 n.1, 9-10.



Id. Figs. 3, 5; Collins Decl. ¶81.

Morita discloses processes for loading and discarding the lancet 21. Morita [0033]-[0035], [0042], Figs. 5-13, 15-19. For loading, the lancet 21 through lancet body 23 is fixed to the device and the lancet body 23 and protective platform 25 are separated to expose needle tip part 20 from needle tip protection portion 27. *Id.* [0033], Figs. 5-7. The detached protective platform 25 is then fitted onto the end of the end cap 43 of the finger-pricking device (*see id.* Fig. 8). The end cap 43 with a protective platform 27 is fitted onto the device with the lancet body attached. *Id.* [0034]. The combination is then placed on the user and triggered. *Id.* The needle tip part 20 creates a wound for blood collection. *Id.* [0034], Fig. 9. For discarding, the lancet body 23 with the needle tip part 20 is fitted into the platform part 29. *Id.* [0035], Fig. 11. The device releases the lancet body 23. *Id.* [0035], Fig. 12. The combination of the lancet 21 and protective platform 25 are discarded. *Id.* [0035]. The height of an end cap connection part 31 is sufficient that the needle tip does not protrude out and has an opening to connect with an end cap that is too small for a finger to enter. *Id.* [0036], Figs. 3, 19.



Id. Figs. 18, 19; Collins Decl. ¶82.

B. The Proposed Combination Does Not Disclose All Claim Limitations

The proposed combination does not disclose all the claim limitations. For this reason alone, the Board should deny institution on this Ground.

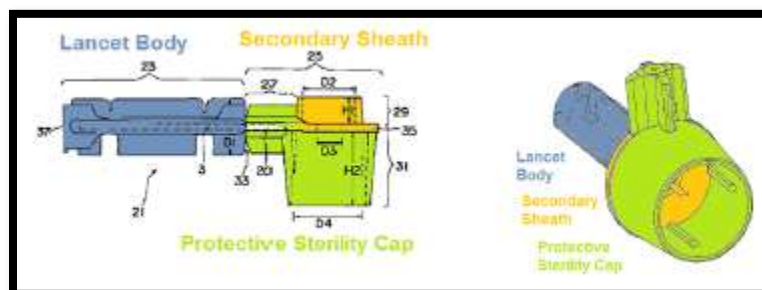
First, the proposed combination does not disclose “a secondary sheath for receiving the sharp lancing tip of a used lancet.” ’635 Patent cls. 9, 14 (corresponding to LifeScan’s “Claim No. 1[b],” “Claim No. 9[b],” and “Claim No. 14[b]”). The structures relied upon by LifeScan in *Morita* to be a secondary sheath do not embed or enclose the sharp lancing tip of a used lancet as it is exposed to the environment. Second, the proposed combination does not disclose “the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.” *Id.* cls. 11, 14 (corresponding to LifeScan’s “Claim No. 11[c]” and “Claim No. “14[g]”). LifeScan

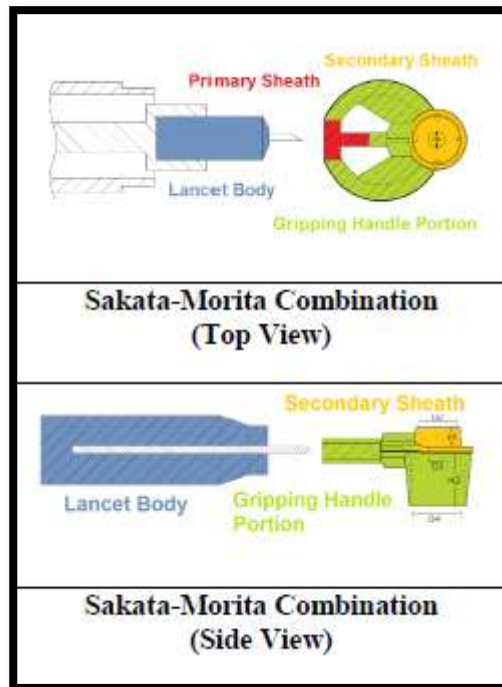
uses hindsight to twist the disclosure of Morita in view of hindsight to purportedly disclose the claim limitations. But LifeScan's combination fails to actually do so.

LifeScan's Petition thus should be denied because it fails to "specify where each element of the claim is found in the prior art patents or printed publications relied upon[.]" 37 C.F.R. § 42.104(b)(4).

1. The Proposed Combination Does Not Disclose "a secondary sheath for receiving the sharp lancing tip of a used lancet" (Claims 11, 14)

The proposed combination does not disclose this limitation. To supposedly teach this limitation, LifeScan relies on Morita's platform portion, more specifically only platform part 29 and connection part 35 highlighted in yellow:





Pet. 64; Collins Decl. ¶191.

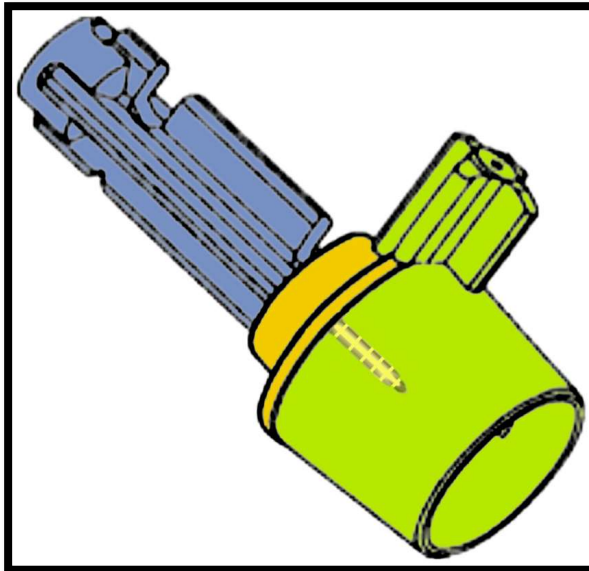
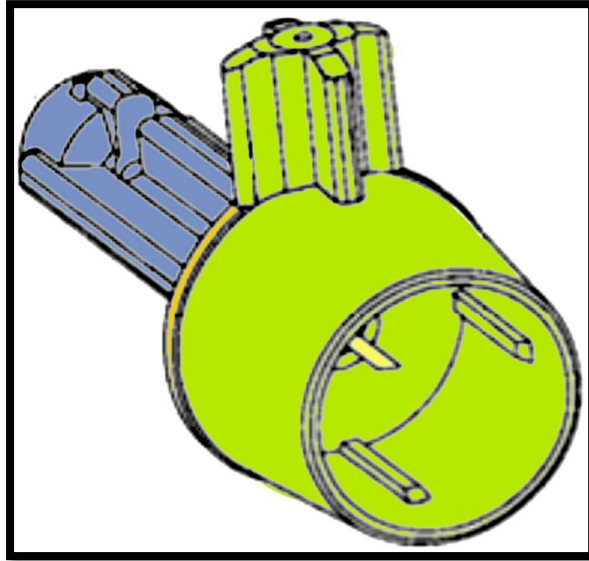
As shown above, LifeScan does not include end cap connection part 31 in the components of Morita incorporated into Sakata that replaces cylindrical portion 43 of Sakata as part of the secondary sheath.¹⁶ Pet. 63-65. However, neither platform

¹⁶ Before relying on Morita's platform portion, LifeScan argues that cylindrical portion 43 of Sakata is a secondary sheath. Pet. 62-63. LifeScan is wrong. Sakata does not disclose cylindrical portion 43 receives any portion of puncture needle 30 or has any role in disposing of a lancet or is hollow. *See, e.g.*, Sakata [0019]-[0020]. And LifeScan's expert does not opine that it does either. *See* Ex.1103 ¶¶ 124-135.

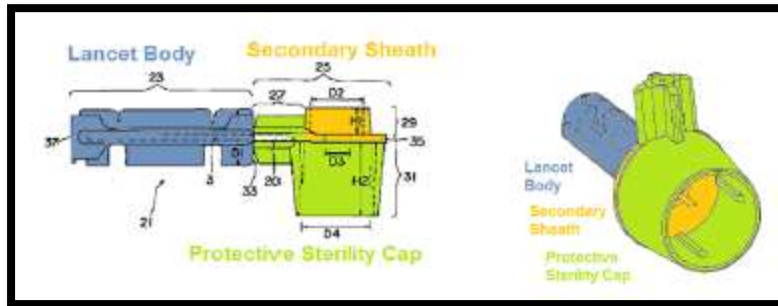
part 29 nor connection part 35, alone nor combine, “receiv[es] the sharp lancing tip of a used lancet.” Collins Decl. ¶192.

The district court construed this limitation to be “a secondary sheath for covering the sharp lancing tip a used lancet *by embedding or enclosing* the lancet tip.” Ex.1105 14. LifeScan’s Petition correctly applied this construction. Pet. 7. But Morita’s alleged secondary sheath (platform part 29 and connection part 35) alone or combined, do not “embed[,]” meaning “fixed firmly and deeply in a surrounding solid mass or surrounded closely,” the lancet tip. *See* Section IV.C.1. And the ordinary meaning of “enclosing” means “closing or surrounding on all sides.” Ex.2113 (Merriam-Webster Dictionary) (enclose: “to close in: surround”); Ex.2117 (Collins English Dictionary) (enclose: “to close; hem in; surround”). Morita fails to disclose platform part 29 and connection part 35, alone or combined, either closely surrounds the lancet tip or closes or surrounds it on all sides. Collins Decl. ¶¶193-196.

After blood collection, Morita describes fitting the end of the lancet body 23 with the protruding needle part 3 into platform part 29 where the top of needle part 3 passes through platform part 29 (through D2) and connection part 35 (through D3). Morita Figs. 11, 18, 19, [0020], [0035]. Once done, the sharp lancing tip sits in a cavity formed by platform part 29 and end cap connection part 31. *Id.* Figs. 11, 18, 19, [0020], [0029], [0035].



Id. Figs. 18, 19 (annotated). The needle part 3 sits and extends through the platform part 29 and connection part 35, which LifeScan contends is the secondary sheath. Pet. 64.



Id. A POSA would understand that such a configuration of the “secondary sheath” of Morita as defined by LifeScan as not embedding or enclosing a sharp lancing tip. Collins Decl. ¶¶197-198.

The sharp lancing tip (needle tip part 20) of needle part 3 is not fixed firmly and deeply in a surrounding solid mass or surrounded closely by the platform part 29 and connection part 35. In fact, the needle tip extends beyond the connection part 35. Even if it did not, there is no mass close to the needle part 3 at all. It sits in an open cavity beyond the purposed secondary sheath. The needle part 3 sticks through and out of connection part 35. Also, the claims require a “sharp lancing tip of a used lancet” to be received by the secondary sheath. So this claim limitation is not satisfied by the platform part 29 and connection part 35 holding or touching lancet body 25 with the shaft portion of needle part 3. The needle tip part 20 of needle part 3 is not within the lancet body 25. It is the needle tip (the end portion of the needle that is angled), which causes the “sticks” which puncture a user with potentially contaminated blood. *Id.* ¶199.

The sharp lancing tip (needle tip part 20) of needle part 3 is not closed or surrounded on all sides platform part 29 and connection part 35. The needle tip part 20 sticks out from connection part 35. Connection part 35 only emanates from the needle part 3 in a horizontal dimension. Neither it nor platform part 29 extend in a vertical direction such that either or both are even with the needle tip part 20. *Id.* ¶200.

That the end cap connection part 31 purportedly protects the needle after blood collection does not help LifeScan's position. LifeScan consistently maps platform part 31 as the "gripping handle portion" of the claims. *See, e.g.,* Pet. 64, 71. But claims 11 and 14 of the '635 Patent require *the secondary sheath* to receive the sharp lancing tip of a used lancet—not the gripping handle portion. Collins Decl. ¶201.

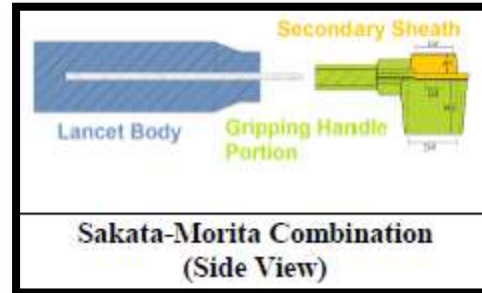
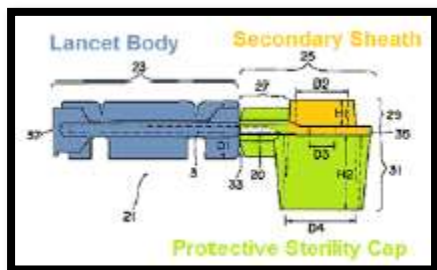
Thus, Sakata in view of Morita fails to disclose this limitation. *Id.* ¶190.

2. The Proposed Combination Does Not Disclose “the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness” (Claims 11, 14)

The proposed combination fails to disclose this limitation. First, LifeScan, after using hindsight to concoct allegedly claimed structures in Morita's cap, switches its claim mapping to maximize the “span” of the alleged gripping handle. The Board has two options, both of which leads to this combination not disclosing a claim limitation and thus denial of the Petition on this ground: (1) use LifeScan's original claim mapping to Morita, in which case LifeScan failed to show in its

Petition the span of the mapped gripping handle portion needed to calculate the dimensional ratio; or (2) use LifeScan's alternative claim mapping, in which case the Petition failed to show the Sakata-Morita combination has a secondary sheath. Second, LifeScan improperly relies upon "dimensions" in Sakata's and Morita's figures contrary to direction from the Federal Circuit.

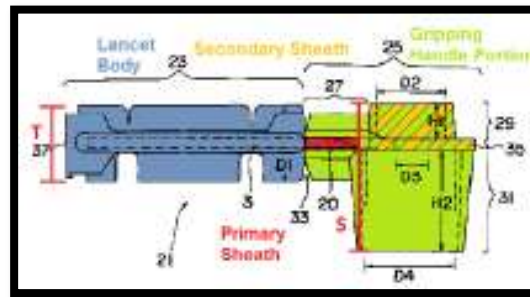
First, LifeScan takes a shifting-sands approach in mapping components of Morita. Specifically, LifeScan initially asserts that platform part 29 and connection part 35 highlighted in yellow are the secondary sheath and everything highlighted in green are the gripping handle portion in Morita and combination of Sakata and Morita.



Pet. 64. This is an already dubious mapping at least with respect to the gripping handle portion. LifeScan has not shown, or even tried to show, that the small volume between Morita's "primary sheath" (unhighlighted portion) and purported "secondary sheath" (platform part 29 and connection part 35 highlighted in yellow) is gripped or is a gripping handle. This small volume is not the place one would grip

Morita's cap given the small area's uneven topography and better locations on Morita's cap for torque in order to twist the cap. Collins Decl. ¶¶204-206.

When it addresses the dimensional ratio limitation in claims 11 and 14, LifeScan changes gears. Specifically, LifeScan dumps Morita's "secondary sheath" of platform part 29 and connection part 35 into the gripping handle portion. Pet. 71.

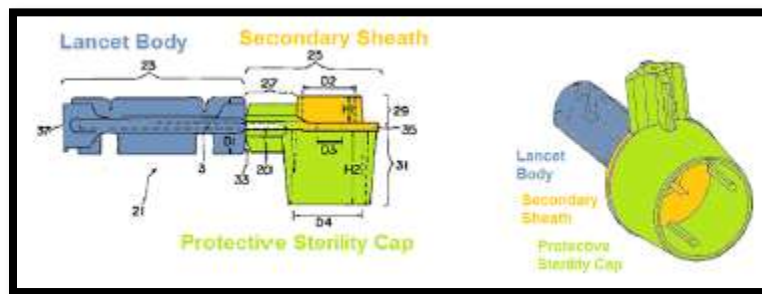


Id. 72; Collins Decl. ¶207.

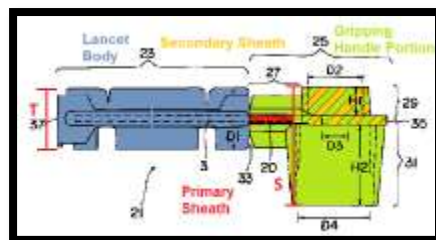
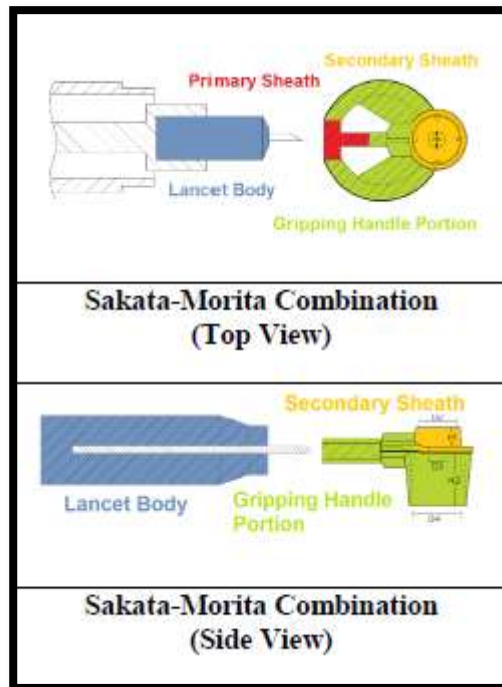
LifeScan's hindsight driven approach tries to maximize the alleged span of the gripping handle portion to help reach the claimed ratio of the span of the gripping handle portion to the lancet thickness of a lancet body. Assuming LifeScan's original mapping of Morita is correct, the "span" of the gripping handle would be H2 plus the distance of H2 to the top of the ridge needle protection part 27. But LifeScan does not calculate this span in its Petition. Even if it tried, it would not have been able to do so. Morita does not disclose the distance of H2 to the top of the ridge 27; a POSA would be left to guess what it would be. *See* Morita [0032]; Collins Decl. ¶208. Guessing as to whether a reference discloses a limitation is not sufficient for disclosing a limitation. *See Wasica Fin. GmbH v. Continental Auto. Sys., Inc.*,

853 F.3d 1272, 1284 (Fed. Cir. 2017) (“*sufficient precision and detail*” is required “to establish that the subject matter existed in the prior art”) (emphasis in original).

Assuming LifeScan's alternative mapping of Morita is correct, there is no structure in the Sakata-Morita combination that can be the secondary sheath. As shown in the figure below only platform part 29 and connection part 35 are highlighted in yellow representing the “secondary sheath.”



Pet. 64. But as shown in the below figures, everything in Morita's cap is the gripping handle portion highlighted in green except for the “primary sheath” highlighted in red.

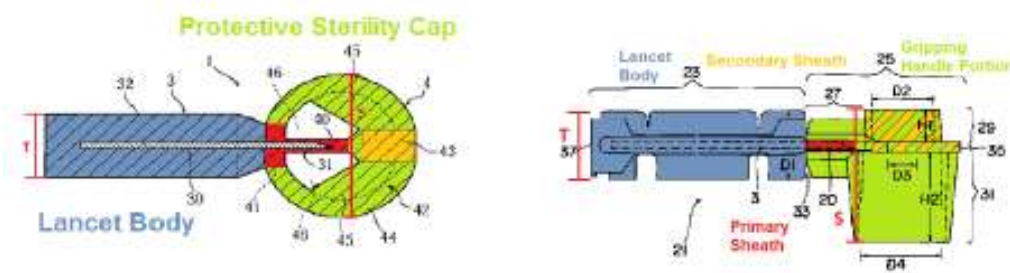


Id. 64, 71. A POSA would not understand that a “gripping handle portion” would be extending between the “primary sheath” and a “secondary sheath” as required by the claims under this claim mapping because the “gripping handle portion” cannot extend between itself. Also, claims 11 and 14 recite the gripping handle portion and secondary sheath as separate components, and therefore there is a presumption that the two components must be separate and distinct and LifeScan has pointed to nothing in the intrinsic evidence to overcome the presumption. *Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010). So it cannot

say that the platform part 29 and connection part 35 of Morita are both part of the gripping handle portion and secondary sheath. Collins Decl. ¶209.

Under either mapping, LifeScan does not show in its Petition that this combination discloses all claim limitations of claims 11 and 14.

Second, LifeScan relies upon “dimensions” in Sakata’s and Morita’s figures to meet this limitation. Pet. 72. LifeScan provides the following annotated images and purports to derive a ratio between the lateral span of the purported gripping handle to the thickness of the lancet:



Id. LifeScan’s attempt to derive dimension S and dimension T from the patent figure is improper as a matter of law. The Federal Circuit has repeatedly held that “patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.” *Hockerson-Halberstadt*, 222 F.3d at 956; *see also White*, 640 F. App’x at 934-35; *Nystrom*, 424 F.3d at 1149; *Wright*, 569 F.2d at 1127.

Here, Sakata’s figures cannot be relied upon to disclose any dimension—along with any dimensional ratio. Section IV.C.2. Similarly, Morita’s specification

is *completely silent* as to whether any figure or any dimension of any component in any figure is to scale. Morita provides no written disclosure that any figure is to scale. Nor does LifeScan even contend that Morita discloses that its figures are to scale. Although, Morita does provide certain dimensional information ([0032]), it does not disclose what dimensions are used in the figures. Collins Decl. ¶¶210-213. This means the figures of Sakata and Morita cannot be used to disclose this limitation.¹⁷

Thus, Sakata in view of Morita fails to disclose this limitation.

C. Dependent Claims

Because the claims upon which claims 10-13 and 15 depend are not obvious, the Board should deny the Petition on this Ground on the dependent claims for the same reasons. *See Neptune Generics*, 921 F.3d at 1378; *see also Cadence Pharms.*, C.A. No. 11-cv-00733, 2013 WL 11083853, at *25; *CA, Inc.*, 780 F. Supp. 2d at 260.

¹⁷ LifeScan also manipulates figures such that no dimensional or dimensional ratios can be trusted. For example, in LifeScan's annotated figure of "Sakata-Morita Combination (Side View)," the "span" of the protective sterility cap of the proposed combination (H1 + H2) appears to be about the same distance as a lancet thickness of the lancet body (blue). Pet. 64.

VII. The Board Should Deny Institution Under *Fintiv*

Fintiv was designed prevent abuse and delay that LifeScan seeks to impose on Facet. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020) (precedential); *see also* USPTO, Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (“Interim Procedure”) 4 (June 21, 2022).¹⁸ LifeScan waited until the last minute to file its Petition—364 days after being served the complaint—and through its own delays, secured the ability to showcase the very same invalidity grounds in the parallel district court case, no matter what the PTAB does here: the trial date in the district court is scheduled to be completed weeks before the expected institution decision here. LifeScan’s *Sotera*-type stipulation is thus meaningless.

The Board should therefore disregard the LifeScan’s stipulation, and exercise its discretion to deny institution because all the *Fintiv* factors cut against institution.

A. The District Court Has Not Stayed the Case Due to the Filing of this IPR (Factor No. 1)

This factor favors denying institution. The district court denied LifeScan’s motion to stay. Ex.2104. The district court found the stage of the proceedings,

¹⁸ https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621_.pdf.

simplification of issues, and potential undue prejudice all pointed to disfavoring a stay. *Id.* 3-6.

B. The District Court Trial Will Likely Occur Before Even the Expected IPR Institution Date (Factor No. 2)

This factor strongly favors denying institution. The district court trial date for a four-day trial is set for Sep. 12, 2023. Ex.2105. That is *before the expected institution date* in late September 2023. It is *about a year before* the Board's likely statutory deadline for a final written decision of September 2024—twelve months from the expected institution date. The district court has shown that it is not willing to move major case deadlines, including trial. *See* Ex.2103 (declining to extend any deadlines other than those related to claim construction). Indeed, the district court “will not entertain any stipulation, ex parte application, or motion to extend any other deadline absent extraordinary circumstances” and “is *strongly* disinclined to grant any modifications that risk delaying the start of trial.” Ex.2105 2-3 (emphasis in original). Even so, if the median time to trial date in the district court is used (22.9 months), the trial date would be about Feb. 2024—still about seven months before the Board's likely statutory deadline for a final written decision. Ex.2111 68.

C. Fact Discovery Is Completed, Expert Discovery Is Days Away from Completion, Summary Judgment Motions Are Underway, and Trial Is Only About Two and a Half Months Away in the District Court (Factor No. 3)

This factor favors denying institution. The district court, Facet, and LifeScan have each made a substantial investment in the parallel district court case. Fact discovery, including the exchange invalidity and infringement contentions, is now closed. Ex.2105 3. Expert discovery is set to close on June 30 with expert reports already exchanged. *Id.* The district court issued a claim construction order (Ex.1105), which both parties submitted briefing for. LifeScan and Facet each filed a motion for summary judgment that the district court will hear in about a month. Ex.2105 3; Exs.2107, 2108. Facet and LifeScan are in the midst of preparing pre-trial filings, which are due in Aug. 2023 for the scheduled trial starting on Sep. 12, 2023. Ex.2105 3-4. The district court itself noted that the district court case “is not in its early stages” and “[t]he Court and parties have already invested significant resources into this case.” Ex.2104 3. This investment warrants this factor weighing in favor of denying institution. *See, e.g., Apcon, Inc. v. Gigamon Inc.*, IPR2020-01583, Paper 9 at 11-12 (P.T.A.B. Mar. 16, 2021) (determining this factor weighed in favor of denial given that substantial investment had already occurred as the parties had severed contentions, completed the claim construction briefing, and completed fact and expert discovery).

D. LifeScan Asserts the Same or Substantially the Same Claims, Grounds, Arguments, and Evidence in District Court (Factor No. 4)

This factor favors denying institution. LifeScan has argued the asserted claims in the parallel district court (Claims 6, 8, 14, 18) are invalid, which includes one of challenged claims in this Petition, i.e., claim 14. *Compare* Ex.2110 ¶7, *with* Pet. 4. LifeScan uses the same or substantially the same grounds, arguments, and evidence in the district court case and this proceeding for those claims. For example, LifeScan asserts claim 14 is rendered obvious by Sakata in view of Morita (Ground 4) in both proceedings. *Compare* Ex.2110 199-204 (¶¶43-53), *with* Pet. 4.¹⁹

E. LifeScan is the Only Petitioner and Only Defendant in the District Court Case Brought by Facet (Factor No. 5)

This factor favors denying institution. There is no dispute that LifeScan is the only defendant in the district court case and the only Petitioner for this Petition and the parties are the same in both proceedings. *See Fintiv, Inc.*, IPR2020-00019, Paper 15 at 15 (May 13, 2020) (informative).

¹⁹ Note, Exhibit 2110 appears to have restarted paragraph numbering on page 179 after paragraph 400.

F. LifeScan's IPR Petition Lacks Compelling Evidence of Unpatentability and "Sotera-type" Stipulation is Illusory (Factor No. 6)

This factor favors of denying institution. As explained in Sections III-VI, LifeScan does not present a reasonable likelihood of success with respect to at least one claim, which is much less than "compelling evidence of unpatentability." Interim Procedure 9. And even if LifeScan made that showing—it did not—the Board can still deny institution. *Id.* 4.

LifeScan's tactics smack of gamesmanship. LifeScan waited until the day before the one-year bar applied to file its IPR, and by doing so rendered its stipulation useless. LifeScan has stipulated that it "will (i) not pursue the grounds identified below in the District Court Case, and (ii) not pursue any other ground that reasonably could have been raised during the IPR (should it be instituted) in the District Court Case." Ex.1111 1-2. But the trial date is set for Sep. 12, 2023, and by waiting till March 20, 2023 to file its IPR (Ex.2105; *see generally* Pet.), LifeScan ensured that the PTAB will not decide whether to institute before the trial date. So through its own delays, LifeScan set itself up to have two bites at the invalidity apple in this situation—once at the trial and once in the IPR proceeding. This defeats the purpose of the *Sotera*-type stipulation and the Director's reasoning why a *Sotera*-type stipulation should defeat a discretionary denial under 35 U.S.C. § 314(a).

VIII. Conclusion

LifeScan's Petition should be denied because the asserted prior art references, alone or in combination, fail to disclose all claim limitations. Regardless, the *Fintiv* factors favor denial given the substantial investment by Facet and LifeScan in the district court litigation, a scheduled trial before the expected institution decision, which makes the *Sotera*-type stipulation meaningless, and LifeScan's far less than compelling evidence of unpatentability. The Board should deny institution.

Respectfully submitted,

Dated: June 28, 2023

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CERTIFICATE OF COMPLIANCE WITH 37 C.F.R. § 42.24

I hereby certify that this Patent Owner's Preliminary Response complies with the word count limitation of 37 C.F.R. § 42.24(b)(1) because the Patent Owner's Preliminary Response contains 10,447 words using Microsoft Word's counting feature, plus 174 words hand-counted in the imaged text, for a total of 10,621 words, excluding the cover page, signature block, and the parts of the Patent Owner's Preliminary Response exempted by 37 C.F.R. § 42.24(b)(1).

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 28th day of June, 2023, a true and correct copy of the foregoing **Patent Owner's Preliminary Response and all Exhibits** were served by electronic mail on Petitioner's lead and backup counsel at the following email addresses:

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