

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.

IPR2023-00712
Patent 8,840,635

**PATENT OWNER'S
PRELIMINARY RESPONSE**

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Exhibit List

Exhibit	Description
2001	Declaration of John M. Collins (“Collins Decl.”)
2002	<i>Curriculum Vitae</i> of John M. Collins
2003	Order re Joint Stipulation to Modify Schedule (ECF No. 65), <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal. Sept. 21, 2022), ECF No. 68
2004	Order Regarding Motion to Stay Pending <i>Inter Partes</i> Review (ECF No. 129), <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal. May 1, 2023), ECF No. 162
2005	Order Regarding Defendant’s Motion to Amend the Scheduling Order (ECF No. 130), and Parties’ Joint Stipulation to Amend the Scheduling Order (ECF No. 166), <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal. May 4, 2023), ECF No. 171
2006	Order Regarding Motion to Strike Lifescan, Inc.’s Supplemental Invalidity Contention (ECF No. 172), <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal. June 7, 2023), ECF No. 193
2007	Plaintiff Facet Technologies, LLC’s Notice of Motion for Summary Judgment of No Inequitable Conduct and No Incorrect Inventorship, <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal. May 29, 2023), ECF No. 189
2008	Defendant LifeScan, Inc.’s Notice of Motion for Summary Judgment of Invalidity of Claims 6, 8, 14 and 18, <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal. May 29, 2023), ECF No. 190
2009	Memorandum of Points and Authorities in Support of LifeScan, Inc.’s Motion for Summary Judgment of Invalidity, <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal. May 29, 2023), ECF No. 190-1

Exhibit	Description
2010	Opening Expert Report of Joel Delman Regarding Invalidity of U.S. Patent No. 8,840,635, <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal. June 7, 2023)
2011	U.S. District Courts, National Judicial Caseload Profile (as of Dec. 31, 2023)
2012	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)

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 both the anticipatory grounds (Grounds 1 – Saikley and 4 – Iio), LifeScan's references fail to disclose at least one claim limitation in every challenged claim. LifeScan improperly relies upon figures to derive dimensions to satisfy the claimed dimensional ratio limitation, contravening Federal Circuit precedent. Saikley and Iio are silent as to the scale of the figures. Thus, LifeScan cannot derive dimensions from their figures, much less the claimed ratio.

The obviousness grounds (Grounds 2 – Saikley/Stout, 3 – Saikley/Freestyle, 5 – Iio/Peckham, and 6 – Iio/Freestyle) fare no better. Grounds 3 and 6 do not address

the missing dimensional ratio limitation at all. In Grounds 2 and 5, 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.1001)

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.2001) ¶26.

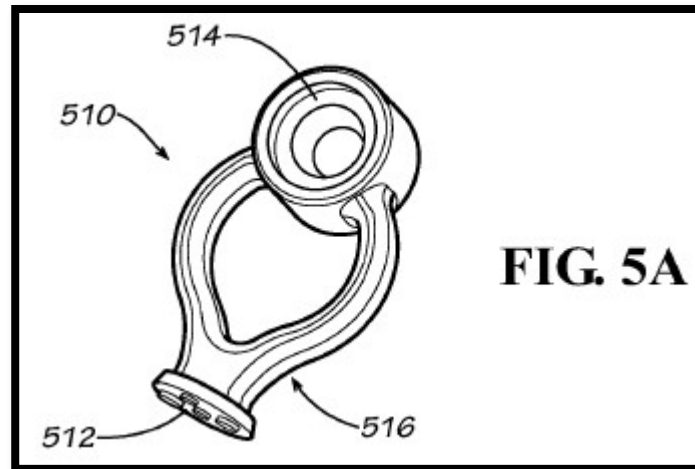
Lancets typically have a sharp metal tip like a needle or blade. '635 Patent 1:43-44. They are typically single-use, disposable components that are designed to be removably mounted in a corresponding lancing device. *Id.* 1:38-43; Collins Decl. ¶27.

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.1003 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 asserts that a POSA would have a higher level of skill. Pet. 7-8.

This POPR does not turn on the definition of a POSA. Regardless of the definition of a POSA, all challenged claims are not 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.1004 13-14. 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.¹ 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. *Id.* 7(alternations in original).²

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: Saikley Does Not Anticipate Claims 6-8, 14, and 16-18³

Anticipation requires that a “single reference ‘describe the claimed invention *with sufficient precision and detail* to establish that the subject matter existed in the

¹ Facet reserves the right to argue alternative constructions in other proceedings.

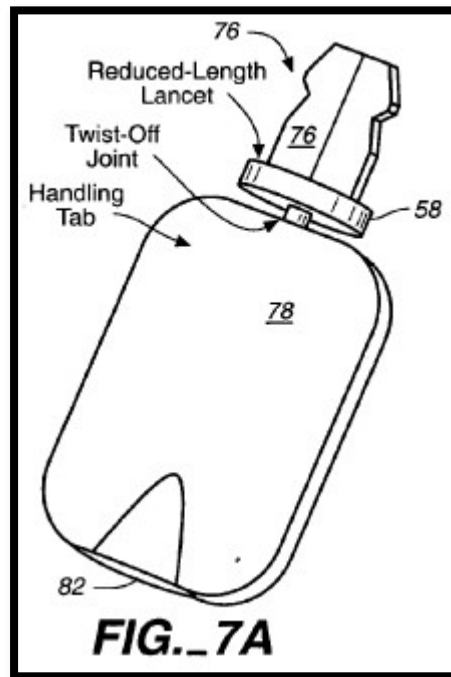
² Unless otherwise stated, all emphases herein are added and internal quotation marks, citations and footnotes are omitted.

³ Facet disclaimed claims 1-5. *See* Disclaimer in Patent Under 37 C.F.R. 1.321(a) (Ex.2012). The Board cannot institute an IPR on a 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). So the Board cannot institute an IPR on claims 1-3 or 5 in this or any other ground.

prior art.” *Wasica Fin. GmbH v. Continental Auto. Sys., Inc.*, 853 F.3d 1272, 1284 (Fed. Cir. 2017) (emphasis in original). Saikley falls well short of this high bar.

A. Saikley (Ex.1005)

Saikley describes a shortened lancet and cap, in one Figure (Fig. 7A) and one paragraph ([0050]):



Saikley Fig. 7A. The shortened lancet 76 has a main body 76, collar 58, and protective cap 78. *Id.* [0050], Fig. 7A. Saikley describes protective cap 78 as “an integrally molded, pull-off tab.” *Id.* Figure 7A includes the words “Twist-Off Joint” with an arrow pointing to an interface of a cylindrical portion and rounded cuboid of protective cap 78. *Id.* Fig. 7A. Saikley teaches the protective cap 78 is removed before use and “should be made much larger than usual to aid handling.” *Id.* [0050], Fig. 7A. The protective cap 78 has a “hollow cup or solid ‘pin cushion’ type area 82”

to “cover the sharp during removal from the device and disposal.” *Id.*; Collins Decl. ¶¶59-60.

B. Saikley Does Not Disclose All Claim Limitations

Saikley does not disclose all the claim limitations.

Saikley does not disclose “the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.” ’635 Patent cls. 6, 14 (corresponding to LifeScan’s “Claim No. 6[d]). LifeScan improperly relies upon Saikley’s figures for dimensional information, contrary to direction from the Federal Circuit, and makes incorrect assumptions to allegedly teach the dimensional ratio claim limitations.

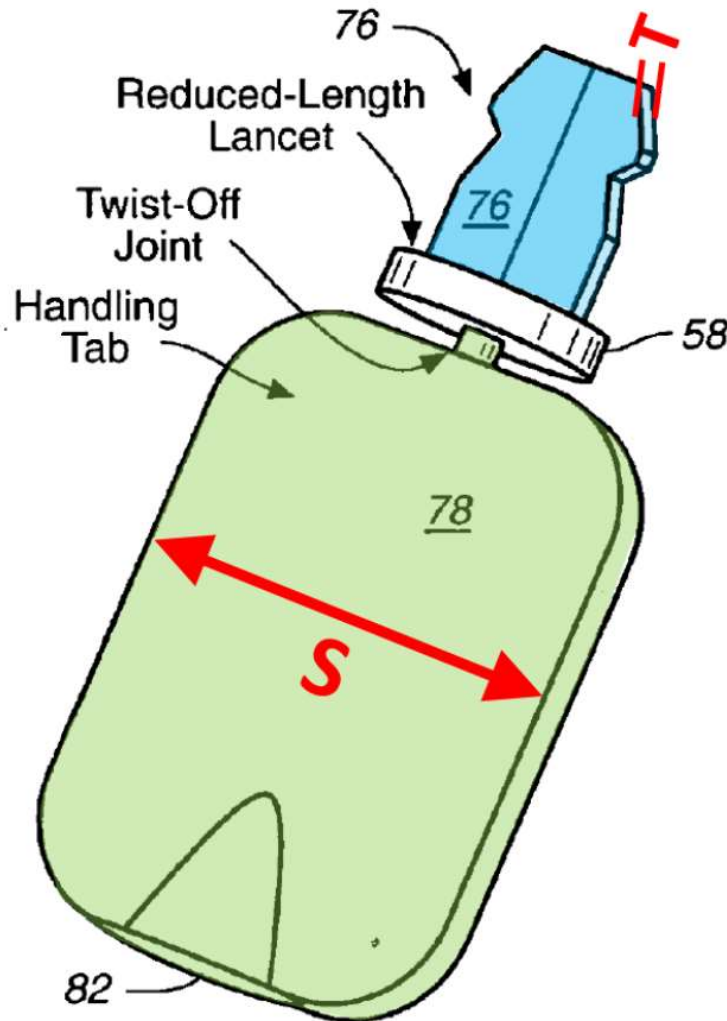
LifeScan’s Petition thus should be denied because it does not “specify where each element of the claim is found in the prior art patents or printed publications relied upon[.]” 37 C.F.R. § 42.104(b)(4).

1. Saikley Does Not Disclose “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness” (Claims 6, 14)

Saikley does not disclose this limitation. First, LifeScan improperly relies upon “dimensions” derived from Saikley’s figures contrary to direction from the Federal Circuit. Second, LifeScan makes incorrect assumptions about Saikley and about POSA’s understanding of it.

First, LifeScan relies upon “dimensions” in Saikley’s figures to meet this limitation. Pet. 37-38. 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. 38. LifeScan's deriving 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, Saikley's specification is *completely* silent as to whether Figure 7A or any other figure is to scale or any dimension of any component in Figure 7A. Saikley provides no written disclosure that any figure, including Figure 7A, is to scale. Nor does LifeScan even contend that Saikley discloses that its figures are to scale. Thus, Saikley's Figure 7A cannot be relied upon to disclose any dimension—along with any dimensional ratio. This means Saikley's Figure 7A cannot be used to disclose this limitation. Collins Decl. ¶¶84-85.

Second, without a disclosure of any dimension of any component in Saikley's Figure 7A, LifeScan piles on inference upon inference based on the general knowledge of a POSA—and entirely outside the four corners of Saikley itself. LifeScan asserts the span of the protective cap would have been larger than 16 mm—

the average width of a human thumb—and a standard lancet has a diameter of less than 6 mm, which means the ratio of the gripping handle span to lancet thickness would be at least 1.5 (16 mm/6 mm = 2.7). Pet. 39-40. Both of LifeScan's assumptions are incorrect.

As to the lateral span assumption, LifeScan bases it on Saikley stating, "This short length might make the lancet difficult for the user to handle and install, so the protective cap 78 (that is removed before use) should be made much larger than usual to aid handling." *See id.* 39; Saikley [0050]. But there is **zero** disclosure in Saikley as to what is any usual dimension for protective cap 78 is or how much larger protective cap 78 should be. In fact, Saikley's reference to the protective cap being made "much larger," is because of the Figure 7A lancet's "shortened length," not thickness. Saikley [0050]. In other words, Saikley provides no disclosure whatsoever about the relationship between the alleged gripping handle and the lancet's thickness. Collins Decl. ¶¶86-89. Nor does LifeScan even offer expert opinion to attempt to fill these holes.

As to the standard lancet assumption, Saikley offers no indication about what the thickness of a standard lancet is. Pet. 39-40. In fact, Saikley discloses the embodiment in Figure 7A as not traditional. Saikley [0050]. Specifically, Saikley discloses a "[t]raditional disposable lancets, such as shown in FIG. 3" to contrast its

description of the lancet in Figure 7A. *Id.*; Collins Decl. ¶¶90.⁴ At a minimum, Saikley's disclosures are ambiguous, at best, and thus "do not, as a matter of law, anticipate a claim." *Wasica*, 853 F.3d at 1284.

Thus, Saikley does not disclose this limitation. Collins Decl. ¶¶83.

C. Dependent Claims

Because the claims upon which claims 7, 8, and 16-18 depend are not anticipated, the Board should deny the Petition on the dependent claims for the same reasons. *See Home Semiconductor Corp. v. Samsung Elecs. Co.*, 701 F. App'x 1006, 1013 (Fed. Cir. 2017) ("Because independent claim 9 is not anticipated by Doshi, dependent claims 10-14 are also not anticipated by Doshi."); *see also CA, Inc. v. Simple.com, Inc.*, 780 F. Supp. 2d 196, 260 (E.D.N.Y. 2009) ("As a dependent claim contains at least one more limitation than the independent claim upon which it

⁴ LifeScan's appeal to consistency of LeVaughn (Ex.1017) for its argument is unavailing. The ratios LifeScan points to in LeVaughn include lancing device 10 as part of the ratio. Ex.1017 Fig. 1, 5:15-18. The lancing device 10 is distinct from a lancet. There is no basis to correlate the ratio of the lateral span of a gripping handle portion of a protective sterility cap or a lancet thickness with that of a lancing device. Collins Decl. ¶¶91-92.

depends, it cannot be invalid under § 102 of the Patent Act if the independent claim upon which it depends is not anticipated.”).

IV. Ground 2: Saikley in View of Stout Does Not Render Obvious Claims 6-8, 14, and 16-18⁵

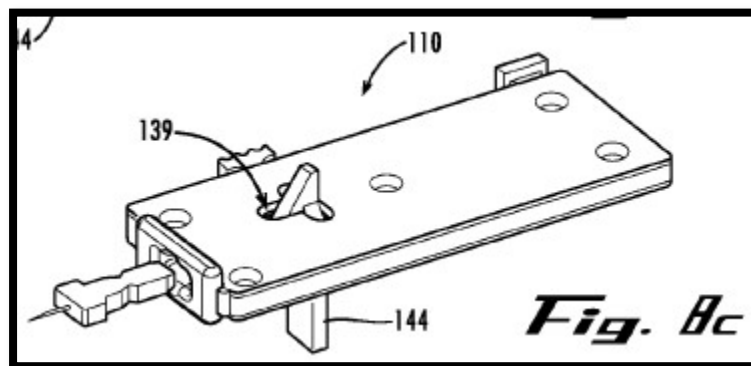
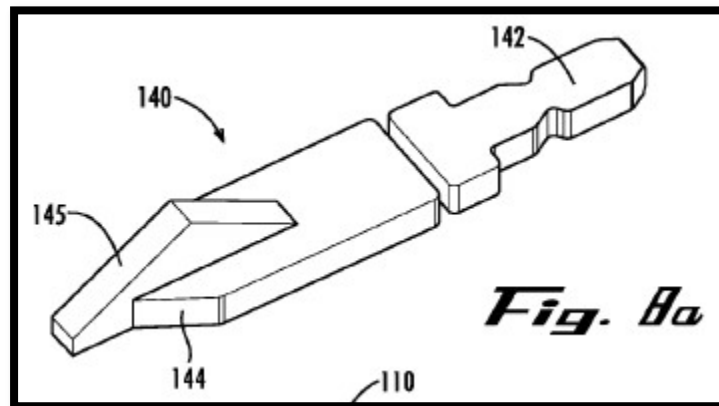
LifeScan asserts the “primary sheath for initial embedment” (Claims 6-8, 14, 16-18) and “length” and “lateral span” of the “gripping handle portion” (Claim 6-8, 14, and 17-18) limitations are obvious over Saikley in view of Stout. Pet. 45, 47. LifeScan does not establish that Saikley in view of Stout discloses those limitations or that a POSA would be motivated to combine Saikley in view of Stout to derive the claimed invention.

LifeScan makes further obviousness arguments based on an unidentified ground—single-reference obviousness over Saikley—that the Board should ignore as not being listed as a ground for institution. Regardless, the argument is baseless: LifeScan simply adjusts all parameters to eventually arrive at the claimed invention, relying on hindsight in the absence of any guidance from the art. Thus, the Board should deny institution on this Ground too.

⁵ The Board cannot institute an IPR on disclaimed claims 1-3 or 5 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.

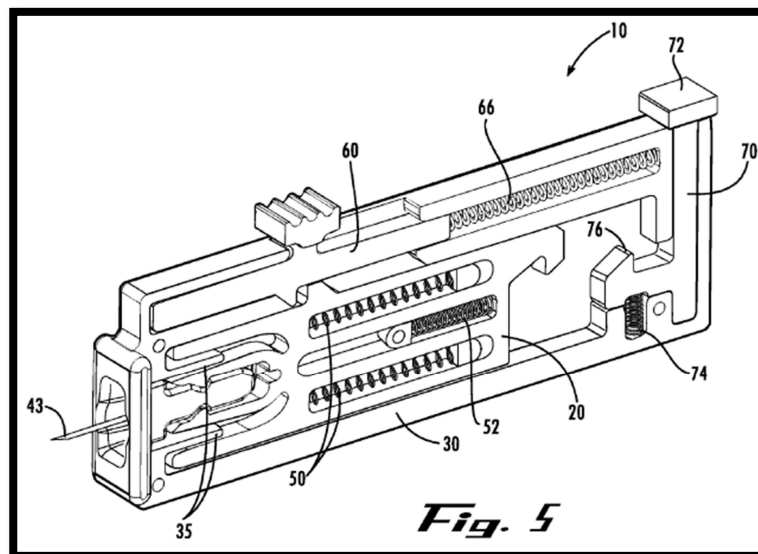
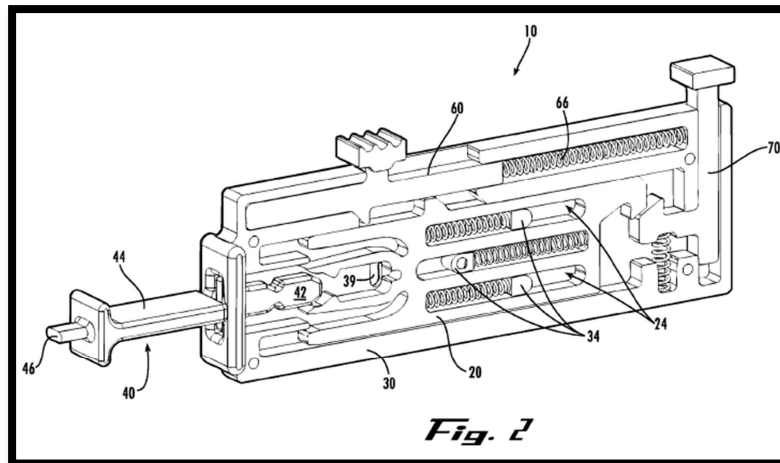
A. Stout (Ex.1018)

Stout describes a lancing device for medical sampling of blood or other body fluids that has a thin profile, for easy and convenient stowage. Stout [0002], [0006]. The lancing device 110 receives a lancet 140, which includes a lancet body 142, sharp lancing tip, and endcap 144. *Id.* Figs. 8a-h, [0041].



Id. Figs. 8a, 8c; Collins Decl. ¶61.

Stout discloses another embodiment of lancing device 10 that receives a lancet 40, which includes a lancet body 42, sharp lancing tip 43, and sterility cap 44. Stout Figs. 1-7, [0035].



Id. Figs. 2, 5. Stout states that its sharp lancing tip is “securely embedded” in lancet body 42, which is molded plastic. *Id.* [0035]. The sterility cap 44 is “large or oversized” compared to lancet body 42. *Id.*; Collins Decl. ¶¶62-63.

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 does not disclose “the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.” ’635 Patent cls. 6, 14 (corresponding to LifeScan’s “Claim No. 6[d]”).

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 “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness” (Claims 6, 14)

The proposed combination does not disclose this limitation. As seen in Section III.B.1, Saikley does not disclose this limitation. Stout likewise does not disclose this limitation. **First**, LifeScan mismatches Stout’s disclosure of one embodiment (Stout Figs. 1-7, [0032])—“The slotted opening 32 has a length considerably greater than its width, most preferably having a length at least twice its width”—with the embodiment primarily relied upon by LifeScan (*id.* Figs. 8a-h, [0041]). Pet. 53-54. Stout does not disclose dimensional information for the Figure 8 embodiment. Stout [0041]; Collins Decl. ¶96. And LifeScan provides no basis as to why the description of one embodiment in Stout is applicable to another.

Second, LifeScan improperly derives “dimensions” in Stout’s figures to meet this limitation. Pet. 53. Stout is silent as to whether Figures 8a-h or any other figure is to scale or any dimension of any component in Figures 8a-h. Thus, Stout’s Figures

8a-h cannot be relied upon to disclose any dimension—along with any dimensional ratio. *Hockerson-Halberstadt*, 222 F.3d at 956; *see also White*, 640 F. App'x at 934-35; *Nystrom*, 424 F.3d at 1149; *In re Wright*, 569 F.2d at 1127. And combining Saikley and Stout is no avail, because neither disclose this limitation. Collins Decl. ¶¶94-95, 97-98.

Thus, Saikley in view of Stout does not disclose this limitation. *Id.* ¶93.

C. A POSA Would Not Have Combined Saikley and Stout

LifeScan gives multiple purported motivations to combine Saikley and Stout. All fail. Collins Decl. ¶¶99-103.

First, LifeScan argues a POSA would have been motivated

“to embed the lancet needle within the twist-off joint and adjoining portion of the handling tab of the protective cap 78 because it was well known that this would make the needle tip 50 more resistant to the non-axial cocking or pivoting movement of the endcap when it is twisted off by the user, which could bend or break the needle tip.”

Pet. 47. But this is mere attorney argument, unsupported by even LifeScan's own expert. Although LifeScan's expert opines about making the needle tip more resistant to nonaxial cocking, he only uses that for modifying Saikley to “embed[] the lancet needle into Saikley's cap 78.” Ex.1002 ¶119. This has nothing to do with embedding the lancet needle within Saikley's twist off joint. Collins Decl. ¶101. LifeScan's “[a]ttorney argument is not evidence” of obviousness. *Icon Health &*

Fitness, Inc. v. Strava, Inc., 849 F.3d 1034, 1043 (Fed. Cir. 2017) (vacating PTAB's obviousness findings based on mere attorney argument).

Second, LifeScan argues that Saikley and Stout “are **within the same field of endeavor** and **address the same problem**.” Pet. 55 (emphases in original). 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); *see also* Collins Decl. ¶102.

Third, LifeScan argues it would be commercially desirable to have and obvious to try the combination of Saikley and Stout as Stout's components could be used with an Abbott FreeStyle Flash Meter—a “system disclosed by Saikley.” Pet. 56. But the supposed teachings LifeScan lifts from Stout—primary sheath embedding a sharp lance tip and gripping handle span to lancet thickness ratio limitations—has nothing to do with the compatibility of Stout working with another device. Collins Decl. ¶103; *Andrea Elecs. Corp. v. Apple Inc.*, No. 2021-1248, 2022 WL 1197341, at *5 (Fed. Cir. Apr. 22, 2022) (vacating obviousness finding of the Board because “motivation is needed for making the specific combination that was made by the applicant”).

D. LifeScan's Unidentified Single-Reference Obviousness Ground for the "wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness" Limitation (Claims 6, 14) Lacks Motivation

LifeScan makes a raft of improper arguments based on Saikley alone. Pet. 48-52. In particular, LifeScan argues that the dimensional ratios recited in the claims are obvious, because they are "meaningless." *Id.* 48. As a threshold matter, a Petitioner is required to provide a "statement of the precise relief requested" in its petition. 37 C.F.R. § 42.22(a)(1). Here, LifeScan's requested relief did *not* include a request to find any claim of the '635 Patent invalid under 35 U.S.C. § 103 based on Saikley alone, which dooms this argument. *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).

Regardless, LifeScan's premise that the claimed dimensional ratio is "meaningless" is blighted by hindsight.⁶

⁶ LifeScan argues that this claimed dimensional ratio is meaningless as it is only difference between the '635 Patent and Saikley. Pet. 48. LifeScan is wrong. In *Hamilton Products, Inc. v. O'Neill*, 492 F. Supp. 2d 1328 (M.D. Fla. 2007), the inventor admitted the only difference between a prior art reference and the asserted claims were the dimensions in the claim to make a seat belt universal. *Id.* at 1341-

First, LifeScan cites *no* prior art that recognized the specific relationship claimed in claims 6 and 14—between the lateral span of the gripping handle and the lancet thickness, much less the specific ratio claimed therein. LifeScan points to Saikley's disclosure that its cap should be "larger than usual to aid handling," but that provides no reason to size the handle in relation to the thickness of the lancet, as opposed to, for example, the length or width of the lancet or specific ranges of dimensions. *See In re Rijckaert*, 9 F.3d 1531, 1533 (Fed. Cir. 1993) (reversing an obviousness rejection because the prior art did not "discuss the claimed relationship of the three variables"); Collins Decl. ¶¶105-106.

Next, LifeScan asserts that the claimed dimensional ratio was an obvious design choice. Pet. 49. But merely stating, without explaining why, "an element is a design choice does not make it obvious." *Cutsforth, Inc. v. MotivePower, Inc.*, 636 F. App'x 575, 578 (Fed. Cir. 2016). What is more, the '635 Patent teaches why the ratio of at least 1.5 is important, and the prior art does not recognize this importance. '635 Patent 3:52-56, 6:52-7:3. Specifically, the '635 Patent states:

42. There is no such admission here. In fact, there are multiple differences between the '635 Patent and Saikley. *See, e.g.*, Section III.B.

The provision of the elongate handle portion 516 [of at least 1.5 times span of the lancet thickness] allows the user to grab the lancet further from the needle during decapping and disposal, providing a larger safety margin from the needle tip, protecting the patient and other persons handling the lancet from accidental needle sticks.

Id. 6:52-7:3; Collins Decl. ¶¶107-108.

Finally, LifeScan relies upon an obvious to try/routine optimization rationale. Pet. 50-52. This too fails. 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 known 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 improve the use or maneuverability of a lancet for people. That would include at least adding a cover to the areas of the cap gripped by a user (e.g., rubber, polymer, textured coating), mechanical features to the areas of the cap gripped by a user (e.g., dimples), or changing certain dimensions. Even pursuing only the changing of the dimensions of the gripping handle portion, there is still a broad selection of choices for further investigation, such as the length, width,

and thickness of the gripping handle portion and the ratio of each of those dimensions to any other dimension of the lancet device.⁷ 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. Pet. 50-52; Collins Decl. ¶¶109-117.

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

⁷ LifeScan incorrectly asserts that because Facet did not respond to an obviousness rationale from the examiner regarding this limitation, it has no patentable weight. Pet. 50 n.2. Facet did not need to respond to every single argument from the examiner and not doing so does not show Facet agreed with the examiner. *Nartron Corp. v. Borg Indak, Inc.*, 848 F. Supp. 2d 725, 741 (E.D. Mich. 2012) (“An uncontested statement made by the Patent Examiner does not alter the scope of the claims.”); *Salazar v. Procter & Gamble Co.*, 414 F.3d 1342, 1347 (Fed. Cir. 2005) (“the examiner’s unilateral remarks alone do not affect the scope of the claim, let alone show a surrender of claimed subject matter”).

the parameters were critical or direction as to which choices would likely to be successful).

E. Dependent Claims

Because the claims upon which claims 7, 8, and 16-18 depend are not obvious, the Board should deny the Petition on the dependent claims for the same reasons. *See Neptune Generics, LLC v. Eli Lilly & Co.*, 921 F.3d 1372, 1378 (Fed. Cir. 2019).

V. Ground 3: Saikley in View of Freestyle Manual Does Not Render Obvious Claim 16⁸

A. Freestyle (Ex.1010)

Freestyle discloses a blood glucose monitoring system in the form of an “Owner’s Booklet.” Freestyle 3. Freestyle includes a picture of blood glucose testing components, which a component labelled “Lancet.” *Id.* 17; Collins Decl. ¶¶64-65, 118-120.

B. Saikley in View of Freestyle Manual Does Not Disclose All Claim Limitations

Saikley does not disclose all claim limitations of claim 14 on which claim 16 depends. *See* Section III.B.

⁸ The Board cannot institute an IPR on disclaimed claim 3 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.

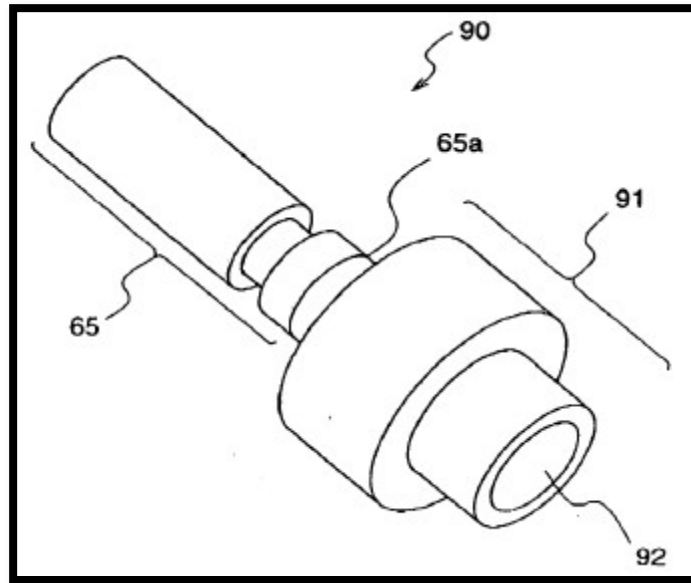
LifeScan does not rely on Freestyle Manual to teach any of the claim limitations Saikley does not disclose. Pet. 57-59. Instead, LifeScan purports to rely on Freestyle Manual to disclose “placement of branding indicia.” *Id.*

Because the primary reference does not disclose all the claim limitations of the independent claim upon which a dependent claim relies upon and the secondary reference does not cure that deficiency, the Board should deny the Petition on this Ground. *See SynQor, Inc. v. Artesyn Techs., Inc.*, 709 F.3d 1365, 1375 (Fed. Cir. 2013); *Cadence Pharms., Inc. v. Exela Pharma Scis., LLC*, C.A. No. 11-cv-00733, 2013 WL 11083853, at *25 (D. Del. Nov. 14, 2013) (“Given that claims 5, 9, 10, and 12 each depend from valid independent claim 1, and because [a secondary reference] does not cure the deficient disclosure of [a primary reference] with respect to the limitations found in claim 1 and incorporated into dependent claims 5, 9, 10, and 12, these dependent claims, too, are valid.”).

VI. Ground 4: Iio Does Not Anticipate Claims 6-8, 14, and 16-18

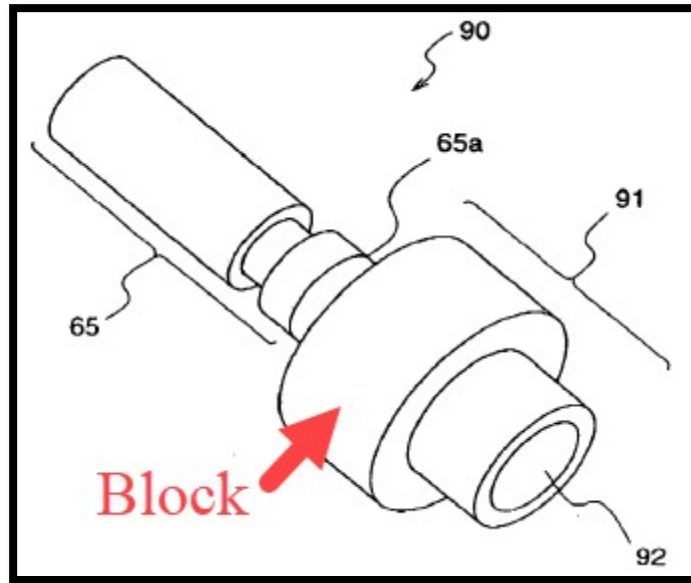
A. Iio (Ex.1006)

Iio describes a lancet for blood collection and a puncture needle unit. Iio [0001], [0005], Fig. 6. Iio discloses a puncture needle unit 90 that is divided into a puncture needle body 65 and a puncture needle cap 91 with a puncture needle separation groove 65a as boundary. *Id.* [0104], Fig. 8.



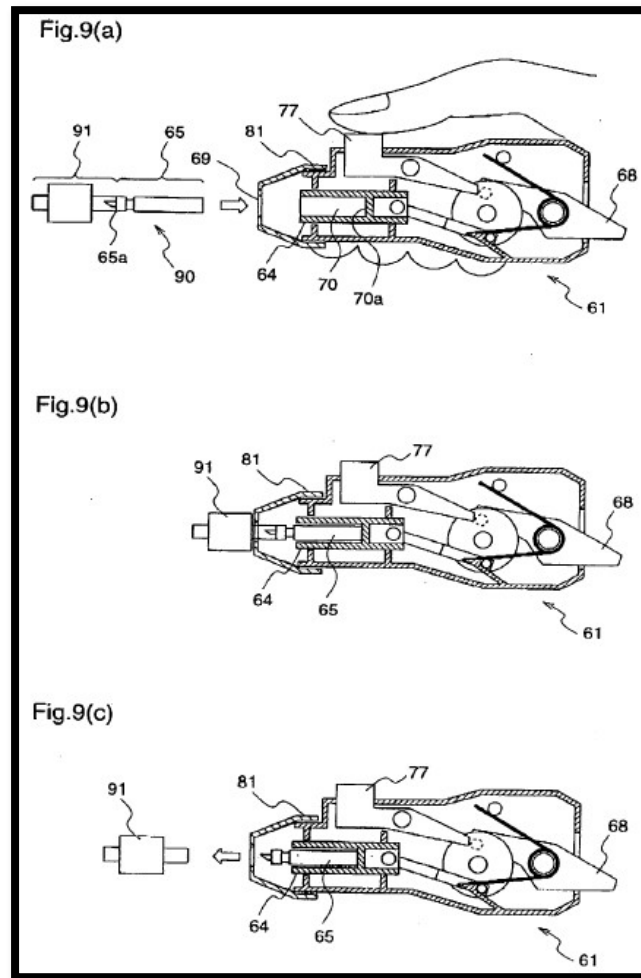
Id. Fig. 8. Iio states, “The puncture needle body 65 is set in a state where it is embedded in the puncture needle cap 91, and a disposal slot 92 for pulling out the puncture needle 65 after puncture has been carried out is provided at an end of the puncture needle cap 91.” *Id.* [0104]. The puncture needle cap 91 includes a block connected to the disposable slot 92 and portion that receives the puncture needle 65.

Id. Fig. 8.



Id. (annotated); Collins Decl. ¶¶66-67.

Iio discloses processes for loading and discarding the puncture needle. Iio [0106], [0117], Figs. 9, 11. For loading, the puncture needle unit 90 is pushed into a puncture needle slot 69 of a lancet 61. *Id.* [0106], Fig. 9. Then the lancet 61 is pulled while twisting the puncture needle unit 90, which separates the puncture needle 65 and puncture needle cap 91. *Id.*



Id. [0106], Fig. 9. For discarding, the disposal slot 92 of puncture needle cap 91 “is fitted” to the front end of the puncture needle 65, such that puncture needle 65 “is captured into the disposal slot 92. *Id.* [0117], Fig. 11. Thereafter, the puncture needle cap 91 with puncture needle 65 is pulled out of the lancet 61 and discarded. *Id.*; Collins Decl. ¶¶68-69.

B. Iio Does Not Disclose All Claim Limitations

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

Iio does not disclose “the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.” ’635 Patent cls. 6, 14 (corresponding to LifeScan’s “Claim No. 6[d]”). LifeScan improperly relies upon Iio’s figures, contravening Federal Circuit law.

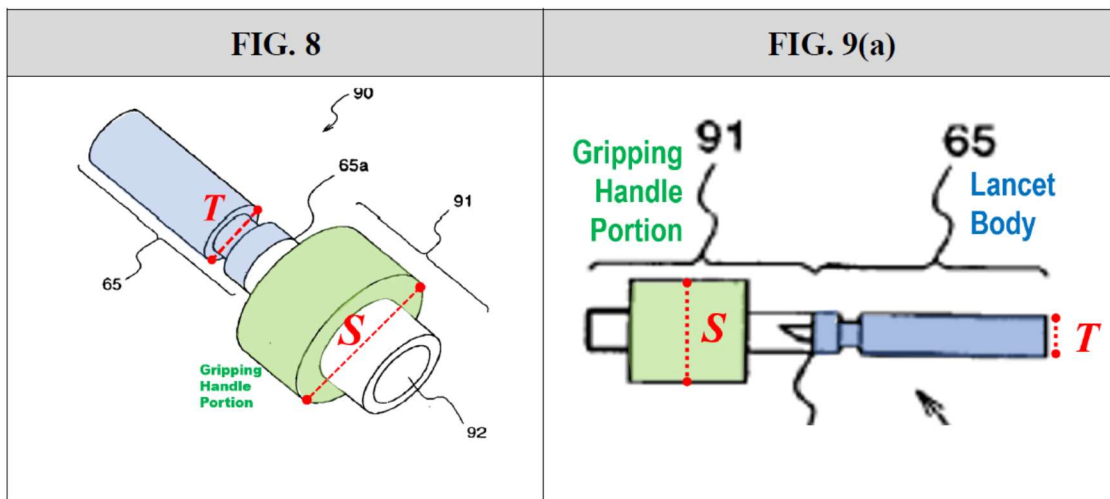
LifeScan’s Petition thus should be denied because it does not “specify where each element of the claim is found in the prior art patents or printed publications relied upon[.]” 37 C.F.R. § 42.104(b)(4).

1. Iio Does Not Disclose “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness” (Claims 6, 14)

Iio does not disclose this limitation. LifeScan argues that “[a] cursory visual comparison of the gripping handle portion’s lateral span (“S”) with the lancet’s thickness (“T”) shown in Iio’s figures confirms that the ‘gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.’” Pet. 80. This is improper: “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.*, 222 F.3d at 956; *see also White*, 640 F. App’x at 934-35; *Nystrom*, 424 F.3d at 1149; *In re Wright*, 569 F.2d at 1127.

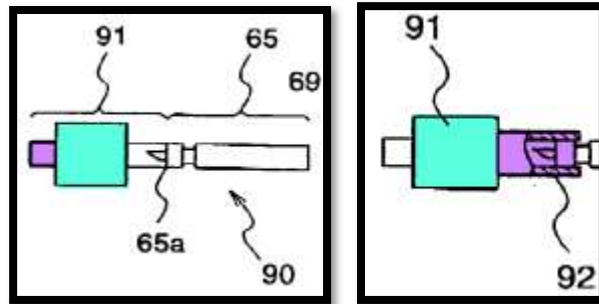
Here, Iio provides no dimensional information of puncture needle body 65 or the puncture needle cap 91. Iio is also completely silent as to the scale of its figures. None of Iio’s figures have a reference for scale. Iio Figs. 1-13. Indeed, Iio’s figures

are clearly not drawn to scale. For example, components in Iio's figures appear to change size across figures. *Id.* For example, Figure 8 and Figure 9(a) annotated by LifeScan show different relevant sizes for the same components that LifeScan marked as "S" and "T" and the block labeled "Gripping Handle Portion" in Figure 8 (annotated) is has a diameter larger than it is long, while the diameter of same block in Figure 9 (annotated) is smaller than it is long.



Pet. 80; Collins Decl. ¶¶122-124.

As another example, Figure 9 and Figure 11 annotated below show different relevant sizes for the same components, i.e., disposal slot 92 (purple) and the block (teal). Figure 9a (on the left below) has a disposal slot 92 that is much shorter than the block, but Figure 11b (on the right below) shows that the two are about the same length—the disposal slot 92 also appears to double in diameter.



Iio Figs. 9(a), 11(a) (annotated); Collins Decl. ¶125.

LifeScan unsuccessfully tries to turn to “Iio’s textual descriptions of its primary and secondary sheaths further confirm that these relative proportions in Iio’s fiuger are essential to Iio’s cap performing as described in the specification.” Pet. 80-81. Iio discloses that “fitting of the puncture needle to the disposal slot is easier than fitting of the puncture needle to the protection slot.” Iio [0026]. That disclosure provides no dimensional information of “a lateral span” of “a gripping handle portion” or “a lancet thickness” of “a lancet body.” Collins Decl. ¶126.

Figure 8, Figure 9, and Figure 11 may show that the block is broader than the disposal slot 92, but that does not mean it is “significantly broader” or that any dimensional information may be derived from them because the figures and written description provide no information about its scale, including whether things in the figures are scale to each other in the figure. *Id.* ¶127.

The thumb in Figure 9(a) provides no information that can be used to derive dimensional information of “a lateral span” of “a gripping handle portion” or “a

lancet thickness” of “a lancet body.” Figure 9(a) is a side view of “a method for loading a puncture needle on the lancet according to the second embodiment.” Iio [0045]. Figure 9(a) is like every other figure in Iio in that the figures and written description provide no information about its scale, including whether things in the figures are scaled to each other in the figure. Collins Decl. ¶128.

Lastly, LifeScan points to Iio's reference to “the body 65 and the cap 91 are connected to each other by a thin plastic film having a thickness of 0.1 mm or less in the puncture needle separation groove 65a.” Iio [0104]. But that does not help LifeScan. There is no way to correlate the thin film to either the thickness of the lancet or the lateral span of the block. This thin film is not even shown in Figures 8 and 9(a) or any other figure. The written specification of Iio does not disclose that any figure includes the thin plastic film. Iio does not disclose any dimension of puncture needle unit 90 is connected to the thickness of the thin plastic film. Collins Decl. ¶129.

Thus, Iio does not disclose this limitation. *Id.* ¶121.

C. Dependent Claims

Because the claims upon which claims 7, 8, and 16-18 depend are not anticipated, the Board should deny the Petition on the dependent claims for the same reasons. *See Home Semiconductor*, 701 F. App'x at 1013; *see also CA, Inc.*, 780 F. Supp. 2d at 260.

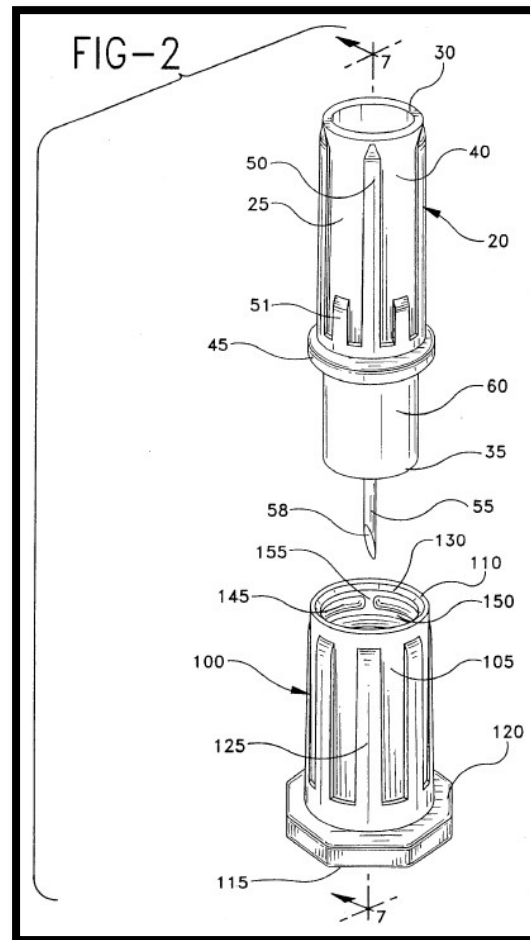
VII. Ground 5: Iio in View of Peckham Does Not Render Obvious Claims 6-8, 14, 16-18⁹

LifeScan asserts the “gripping handle portion” (Claims 6-8, 14, 16-18) and “length” and “lateral span” thereof (Claim 6-8, 14, and 17-18) limitations are obvious over Iio in view of Peckham. Pet. 90, 93. But Peckham does not fill the hole in Iio: the proposed combination does not disclose the claimed dimensional ratios. Thus, the Board should deny institution.

A. Peckham (Ex.1008)

Peckham describes a disposable lancet assembly for use in a blood sampling instrument. Peckham 1:65-2:4. Peckham discloses 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. *Id.* Fig. 2, 2:52-62.

⁹ The Board cannot institute an IPR on disclaimed claims 1-3 or 5 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. Fig. 2; Collins Decl. ¶70.

The removable cap 100 includes a cylindrical housing 105 that has closed bottom end 115 with octagonal shaped flange 120. Peckham Fig. 2, 3:3-11. The inside of cylindrical housing 105 includes three labyrinth rings to provide sterility. *Id.* Fig. 2, 3:46-50. The outside cylindrical housing 105 includes ribs 125 extending from the octagonal shaped flange 120. *Id.* Fig. 2, 3:11-14. Peckham discloses nothing about the sizes of either its cylindrical housing 105 or its lancet assembly. Collins Decl. ¶71.

B. 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 6, 14)

The challenged claims 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. 6, 14 (corresponding to LifeScan’s “Claim No. 6[d]”). But as described above, Iio discloses neither the block (what LifeScan calls the handle)’s lateral span nor the lancet thickness. And Peckham fails to remedy these holes in LifeScan’s obviousness case, because Peckham does not disclose these dimensions either, much less the relationship between the two.

Nonetheless, LifeScan makes two arguments why this limitation is obvious. LifeScan argues that, (1) it would have been obvious to try to adjust any relative dimensions limitations of Iio; and (2) it would have been obvious to add Peckham’s ribs to the portion of Iio that LifeScan calls a handle (block), which would have allegedly increased the lateral span of Iio’s block even more. Pet. 90-91, 93. Both are wrong.

First, as to the obvious to try argument, LifeScan’s obvious to try argument fails for the same reasons as ground 2. For an obvious to try analysis to apply, the “possible approaches and selection to solve the problem must be ‘known and finite.’” *Rolls-Royce*, 603 F.3d at 1339. But LifeScan has not argued that there were only a finite number of known solutions. That is fatal. *Id.*; *Takeda*, 492 F.3d at 1359

(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 improve the use or maneuverability of a lancet for people. That would include at least adding a cover to the areas of the cap gripped by a user (e.g., rubber, polymer, textured coating), mechanical features to the areas of the cap gripped by a user (e.g., dimples), or changing certain dimensions. Even pursuing only the changing of the dimensions of the gripping handle portion, there is still a broad selection of choices for further investigation, such as the length, width, and thickness of the gripping handle portion and the ratio of each of those dimensions to any other dimension of the lancet device. Collins Decl. ¶¶109-117, 132. LifeScan gives no indication from the art the ratio of the span of the gripping handle portion to the lancet thickness was recognized as critical to the design of protective caps or what ratios would have been beneficial. Pet. 50-52.

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 at 903 (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 to be successful).

Second, as to the Peckham's rib argument, that is just speculation. Peckham is silent as to any dimension of the shielded lancet assembly, including ribs 125. And like Iio, Peckham's figures cannot be used for dimensional information given there is no indication they are to scale and the disclosure is silent as to dimensional information in them. *See Hockerson-Halberstadt, Inc.*, 222 F.3d at 956. Without these dimensions, the ratio cannot be calculated. Also, Iio and Peckham do not provide a lancet thickness of a lancet body, which may vary. So the proposed combination fails. Collins Decl. ¶¶133-137.

C. Dependent Claims

Because the claims upon which claims 7, 8, and 16-18 depend are not anticipated or 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; *Home Semiconductor*, 701 F. App'x at 1013; *see also CA, Inc.*, 780 F. Supp. 2d at 260.

VIII. Ground 6: Iio in View of Freestyle Manual Does Not Render Obvious Claim 16¹⁰**A. Iio in View of Freestyle Manual Does Not Disclose All Claim Limitations**

Iio does disclose all claim limitations of claim 14 on which claim 16 depends.

See Section VI.B.

LifeScan does not rely on Freestyle Manual to teach any claim limitation Iio does not disclose. Pet. 100-101. Instead, LifeScan purports to rely on Freestyle Manual to disclose “placement of branding indicia.” *Id.*; Collins Decl. ¶¶64-65, 138-140.

Because the primary reference does not disclose all the claim limitations of the independent claim upon which a dependent claim relies upon and the secondary reference does not cure that deficiency, the Board should deny the Petition on this Ground. *See SynQor*, 709 F.3d at 1375; *Cadence Pharms.*, 2013 WL 11083853, at *25.

IX. 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,

¹⁰ The Board cannot institute an IPR on disclaimed claim 3 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.

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).¹¹ 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.2004. The district court found the stage of the proceedings, simplification of issues, and potential undue prejudice all pointed to disfavoring a stay. *Id.* 3-6.

¹¹ https://www.uspto.gov/sites/default/files/documents/interim_proc_discretionary_denials_aia_parallel_district_court_litigation_memo_20220621_.pdf.

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.2005 4. 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.2003 (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.2005 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.2011 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.2005 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.1004), 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.2005 3; Exs.2007, 2008. 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.2005 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.2004 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 are some of the challenged claims in this Petition. *Compare* Ex.2010 ¶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 claims 6, 8, 14, and 18 are anticipated by Iio (Ground 4) in both proceedings. *Compare* Ex.2010 ¶¶210-251, *with* Pet. 4. In fact, LifeScan moved for summary judgment based on anticipation of Iio (Ground 4) where the art and arguments are almost indistinguishable from their Petition. Ex.2009. The lack of complete overlap between the invalidity grounds for claims 6, 8, 14, and 18 between the IPR and the district court case is only due to the district court striking LifeScan's supplemental contention containing the art and arguments contained therein, which includes references in Grounds 1, 2, and 4. Ex.2006.

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*, IPR2020-00019, Paper 15 at 15 (May 13, 2020) (informative).

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-VIII, 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 the Board can still deny institution in such situations. *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.1013 1-2. But the trial date is set for Sep. 12, 2023, and by waiting until March 20, 2023 to file its IPR (Ex.2005 4; *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).

X. 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 8,185 words using Microsoft Word's counting feature, plus 60 words hand-counted in the imaged text, for a total of 8,245 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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