

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIFESCAN, INC.

Petitioner,

v.

FACET TECHNOLOGIES, LLC

Patent Owner.

Case No. IPR2023-00712

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

**PETITIONER'S REPLY TO
PATENT OWNER'S RESPONSE TO PETITION**

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PETITIONER’S EXHIBIT LIST (New Exhibits in *Italics*)

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Ex. 1038	U.S. Patent No. 2,326,715 to Wilson et al.
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Ex. 1041	Excerpts from Jonathan M. Cagan, et al., <i>Creating Breakthrough Products: Innovation from Product Planning to Program Approval</i> (1 st Ed. 2001) (Chapters 1, 3, 7)
Ex. 1042	Excerpts from Paul Hatch et al., <i>IMPACT: The Synergy of Design, Technology, and Business</i> (1 st Ed. 2005)
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Ex. 1048	U.S. Patent No. 8,652,159
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Ex. 1051	U.S. Design Patent No. D621,045
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Ex. 1053	Facet Technologies, LLC's Proposed Trial Schedule and Supporting Memorandum, <i>Facet Technologies, LLC v. LifeScan, Inc.</i> , Case No. 2:22-cv-1717 (C.D. Cal. Sept. 13, 2023), ECF No. 276
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Ex. 1055	Exhibit 1 to Declaration of Jeff Homrig in Support of Facet Technologies, LLC's Proposed Trial Schedule and Supporting Memorandum, <i>Facet Technologies, LLC v. LifeScan, Inc.</i> , Case No. 2:22-cv-1717 (C.D. Cal. Sept. 13, 2023), ECF No. 276-3
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Ex. 1057	Excerpts from Mary Berth Privitera, <i>Applied Human Factors in Medical Device Design</i> (1 st Ed. 2019) (Sections III and IV)
Ex. 1058	Transcript from the Deposition of John M. Collins, Ph.D., <i>LiferScan, Inc. v. Facet Technologies, LLC</i> , IPR2023-00712 (PTAB Mar. 5, 2024)
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I INTRODUCTION

Claims 6-8, 14, and 16-18 (the “Remaining Claims”) are unpatentable. The Patent Owner’s (PO) Response (POR, Paper 21) does not show otherwise.

II SAIKLEY ANTICIPATES THE REMAINING CLAIMS

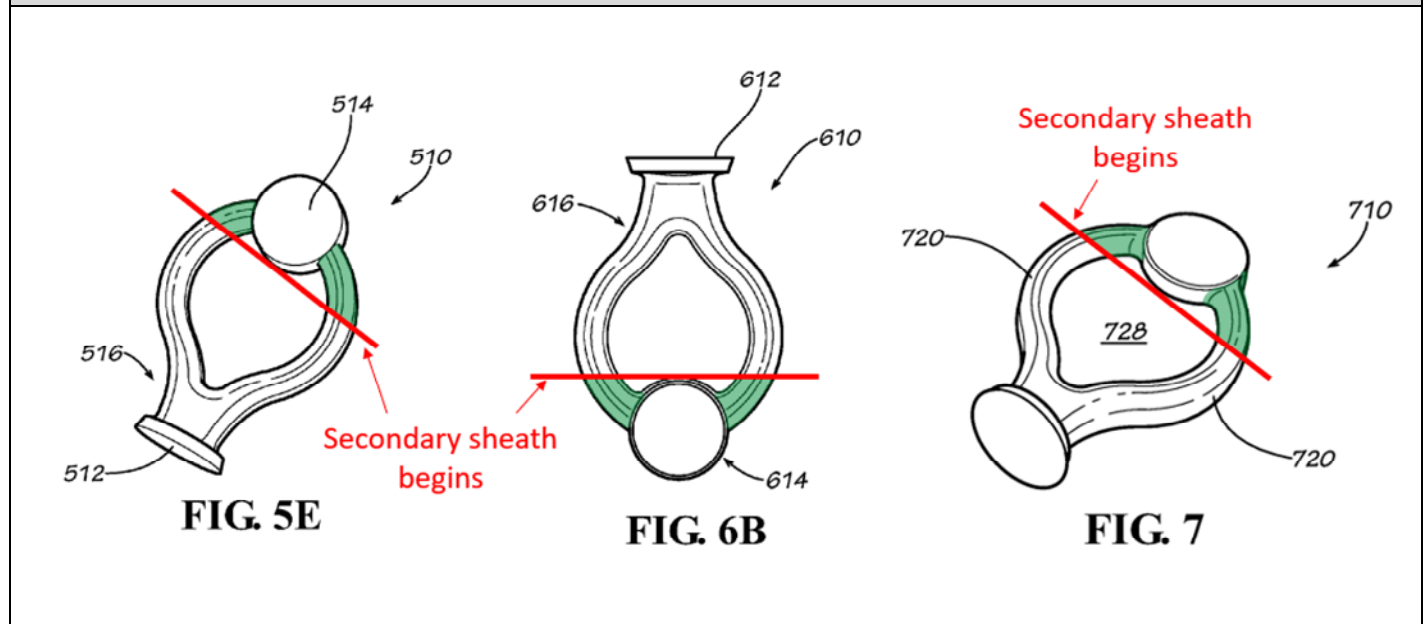
A. Saikley Discloses the Claimed Gripping Handle Portion

PO’s dismissal of Saikley’s gripping handle portion is a poorly-disguised claim-construction argument that fails because it is (1) inconsistent with the claims, (2) inconsistent with the ’635 Patent’s embodiments, and (3) inconsistent with PO’s arguments for infringement.

First, nothing in the claim language requires the gripping handle portion to *only* extend between the primary and secondary sheaths. A gripping handle portion extends between the sheaths even if portions of the handle also extend around one or both sheaths. *See* Ex.1034 ¶¶ 8-11 (PHOSITA’s understanding of “extends between”).

Second, PO’s overly narrow interpretation of gripping handle portion excludes every cap embodiment in the ’635 Patent. The arms of the gripping handle portion in Figures 5, 6, and 7 not only extend between the sheaths, but also extend around parts of the secondary sheath:

Ex.1001, Figure 5E, 6B, 7



Because PO's argument would exclude every cap embodiment, it is untenable. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

Third, despite narrowly applying the “gripping handle portion” limitation to Saikley, PO's expert applied it more broadly to assert infringement:

Dr. Collins' Testimony

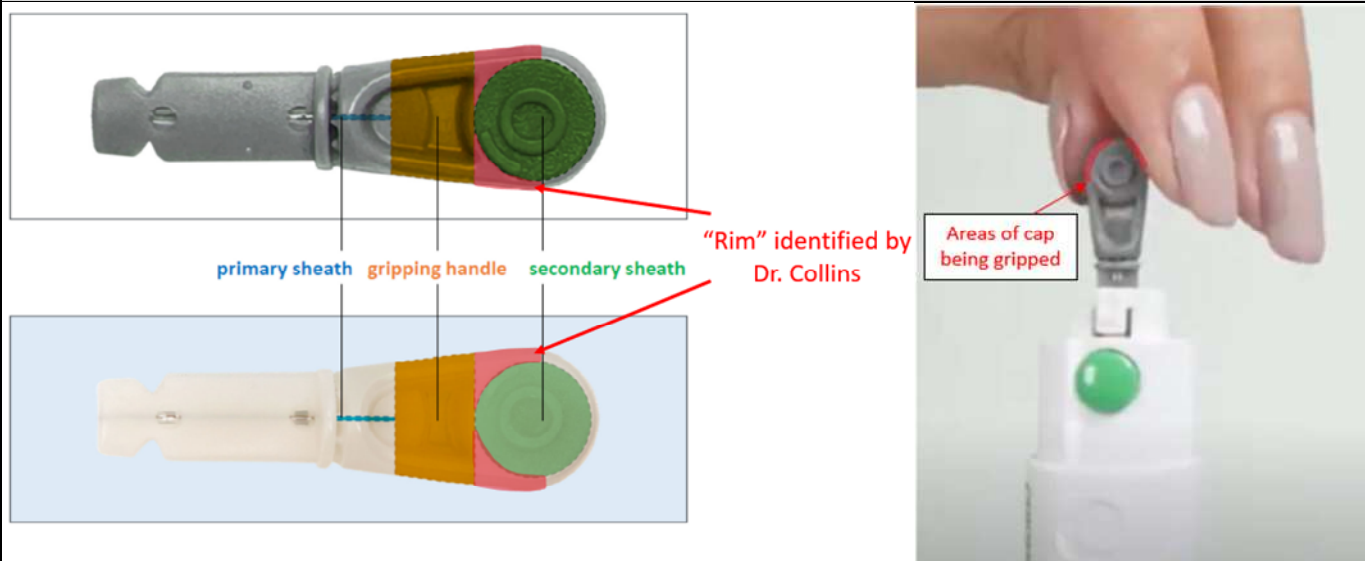
Q. The **rim** that you described for me earlier as being something that can't be part of the gripping handle.

A. I did not say it could not be part of the gripping handle.

Q. So then can it be part of the gripping handle?

A. It could be, but I don't think it is because I don't think it's gripped.

Dr. Collins' Delineation of Gripping Handle for Purposes of Infringement

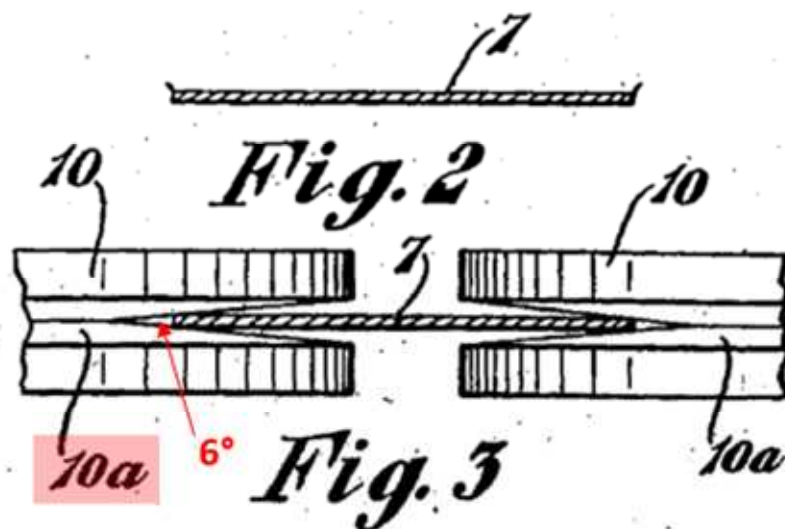


See also Ex.1035, 139:9-142:21 (no analysis as to what is excluded from the gripping handle and noting it can extend further); 142:17-143:7 (admitting that part of secondary sheath is gripped). PO cannot narrow its gripping handle portion for validity purposes and broaden that same element when assessing infringement.

B. PO's "Legal Background" Misstates the Law

PO argues that patent figures “cannot be used to determine dimensions, proportions, or relative sizes.” POR, 18. In essence, PO contends that the Board is compelled to disregard even what the figures clearly show. Not so.

As Judge Rich explained in *In re Mraz*, the court’s decisions noting that “[p]atent drawings are not working drawings ... did not mean that things patent drawings show clearly are to be *disregarded*.” 455 F.2d 1069, 1072 (CCPA 1972) (*italics original*); Inst. Dec. at 25. He observed that in the primary prior art reference the “half-angle of the V-shaped groove 10a measures about 6° on this drawing [of Fig. 3 reproduced below], but the specification says nothing about the angle.” *Id.* at 1071.



Ex. 1038 (U.S. Patent No. 2,326,715 to Wilson et al.).

The Court rejected the argument—like PO’s arguments here—that the Board erred in finding the prior art met the limitation requiring a groove “not exceeding 15°” because, according to patent owner, the Board “treated diagrammatic drawings ... as working drawings” and “scaled the drawing to find a disclosure meeting a critical maximum angular limitation in all of appellant’s claims but not otherwise disclosed” in the primary reference. *Id.* The Court confirmed that the “[d]escription for the purposes of anticipation can be by drawings alone” and held that Fig. 3 shows “the grooves thereon to have an angularity well within the range recited in appellant’s claims.” *Id.*

The other cases cited by the Board align with *In re Mraz*. Inst. Dec. at 25. The Board can and should apply this controlling line of cases to find that Petitioner’s reliance on relative proportions (along with descriptive text and a PHOSITA’s general knowledge) is permissible.

Federal Circuit jurisprudence also consistently holds it is appropriate to rely on patent figures as written-description support for limitations concerning relative proportions. *See, e.g., Koito Mfg. Co., Ltd. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1155 (Fed. Cir. 2004) (finding “the limitation ‘significantly thicker and wider’ finds adequate support in Figure 1” because it “clearly shows flow channel 6 is ‘significantly thicker and wider,’ than the adjacent mold cavity 2”); *see also In re*

Heinle, 342 F.2d 1001, 1007 (Fed. Cir. 1965) (finding sufficient disclosure in figures to support limitation “approximately one-fourth of the circumference” despite no mention of this relationship in specification); *In re Wolfensperger*, 302 F.2d 950, 958-59 (C.C.P.A. 1962).

PO’s cases (POR, 15-19) are distinguishable and do not require disregarding what is clear in figures. Contrary to PO’s misleading summary of *Hockerson*, that holding relied on the “prosecution history as clearly disclaiming a groove having a width greater than the combined width of the fins” and found this clear disavowal could not be overcome by a silent specification and a patent figure where the groove arguably appeared to be slightly wider than the fins. 222 F.3d 951, 956-57 (“HHI’s argument [based on the figure] therefore reduces to a request for a mulligan that would erase from the prosecution history the inventor’s disavowal of a particular aspect of the claim term’s meaning.”). Similarly, both *Source Vagabond* and *Plantronics* dealt with claim-construction issues that were at odds with the relevant patents and associated prosecution histories.

Here, Petitioner is not relying on Saikley (or Iio) to overcome a clear disavowal of relative proportions. Even if any of these cases were on-point, the specifications of Saikley and Iio are not “completely silent on the issue” (POR 18-20) of relative proportions (Petition, 9-44; 59-86).

Nystrom is distinguishable, too. There, the Federal Circuit rejected basing an invalidity finding on computations performed on a software model rather than on the materials contained in the patent. 424 F.3d 1136, 1149 (Fed. Cir. 2005). The issue here is different—a PHOSITA’s ability to discern relative proportions plainly visible in a figure, not the reliability of software measurements.

C. PO’s Arguments Contradict its Priority Claims

Throughout prosecution and district court litigation, PO has claimed priority to its Provisional Application (Ex. 1031, “Provisional”). Ex.1003, 22, 152, 159. But PO’s own expert admitted that “there aren’t specific dimensions called out in the provisional.” Ex.1035, 128:12-14. Lacking textual support, PO’s priority claim can only be grounded in the Provisional’s figures that are not indicated as being to scale, do not label a lateral span or a lancet thickness,¹ and do not even show a single drawing sheet with both a cap and a lancet together.² PO’s position

¹ Annotations in Figures 1B-1C and 5C-5D of the ’635 Patent are not in the Provisional.

² Both Saikley and Iio have figures depicting the lancet and its cap on one drawing sheet. Ex.1005, Fig.7; Ex.1006, Figs.8,9.

on what a figure can disclose under the caselaw cannot be reconciled with its own priority claim.

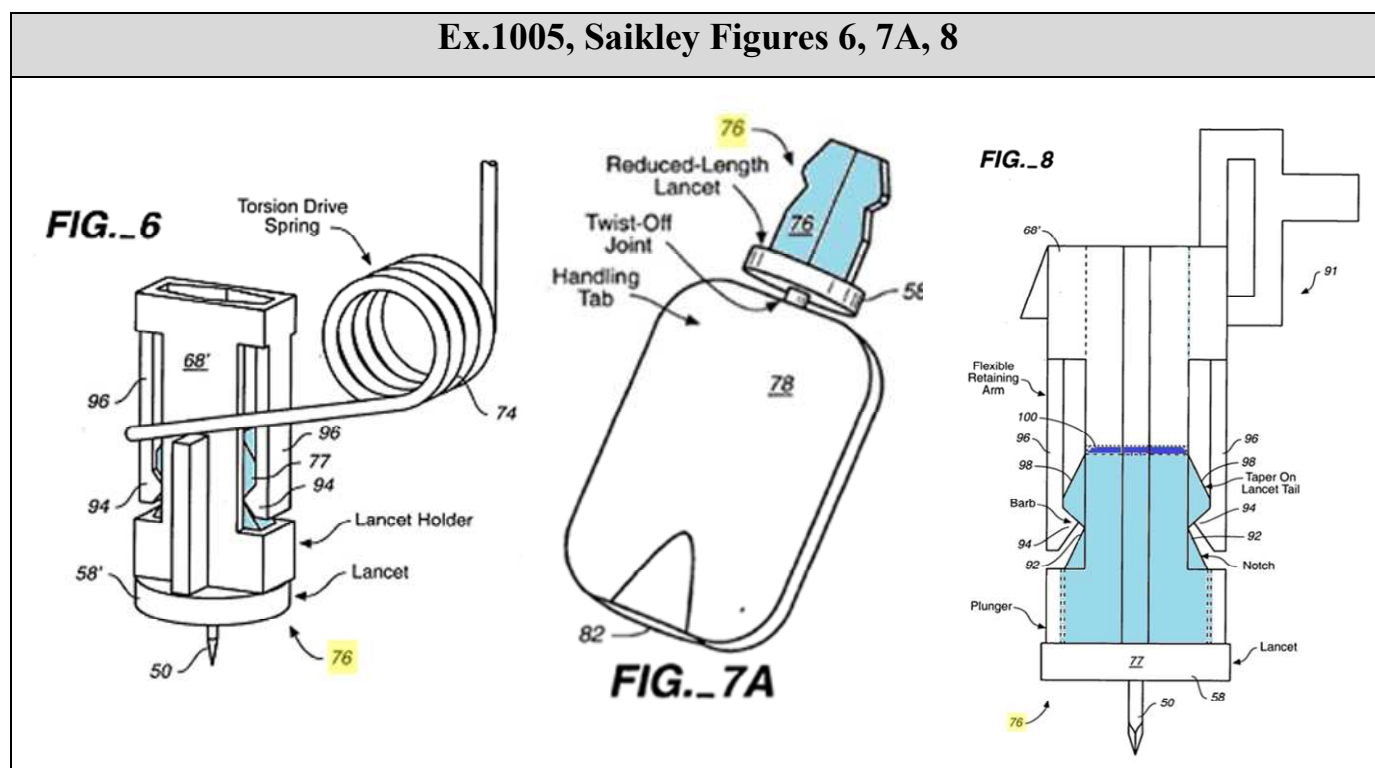
The Board should reject PO’s misreading of the caselaw, that ignores the on-point cases cited by the Board and contradicts PO’s own priority claim. The drawings of Saikley and Iio “show clearly” certain relative proportions and should not be “disregarded.”

D. Saikley Discloses the Dimensional Limitations

As the Board correctly observed, the claims do not require “a precise size, but only a relative relationship.” Inst. Dec. at 25. And even this “relative relationship” only requires *exceeding* a relative threshold. PO tries to manufacture uncertainty about Saikley’s Fig. 7A by questioning viewing angles. But Saikley’s Figures 6, 7A, and 8 provide three different views, all depicting the same *thin, flat* lancet.³

³ In response to PO’s arguments based on generic geometric structures, Petitioner’s expert compared a 3D-printed model of Saikley’s lancet and cap to Figure 7A and found that they closely line up, including having the lancet’s circular bottom appear elliptical. Ex.1034, ¶¶ 12-16.

In Figure 6, the entire lancet body is thin enough to fit inside lancet holder 68', which itself is much thinner than the diameter of the cylindrical collar 58. Petition, 36-37. Figure 7A makes plain that the handling tab has a lateral span that is wider than the diameter of collar 58 and, thus, far wider than the even-thinner lancet body. *Id.* at 37-40. From these figures, a PHOSITA would understand that the lancet body is—just as it appears—much thinner than the diameter of the lancet collar and also that the handling tab is many multiples the thickness of the lancet body. Ex.1034 ¶¶ 16-23.



Furthermore, Saikley is not silent as to the relative relationship between the dimensions of the gripping handle and its short, flat lancet. *See* Ex.1005, [0050] (due to shortened lancet, “the protective cap should be made much larger than

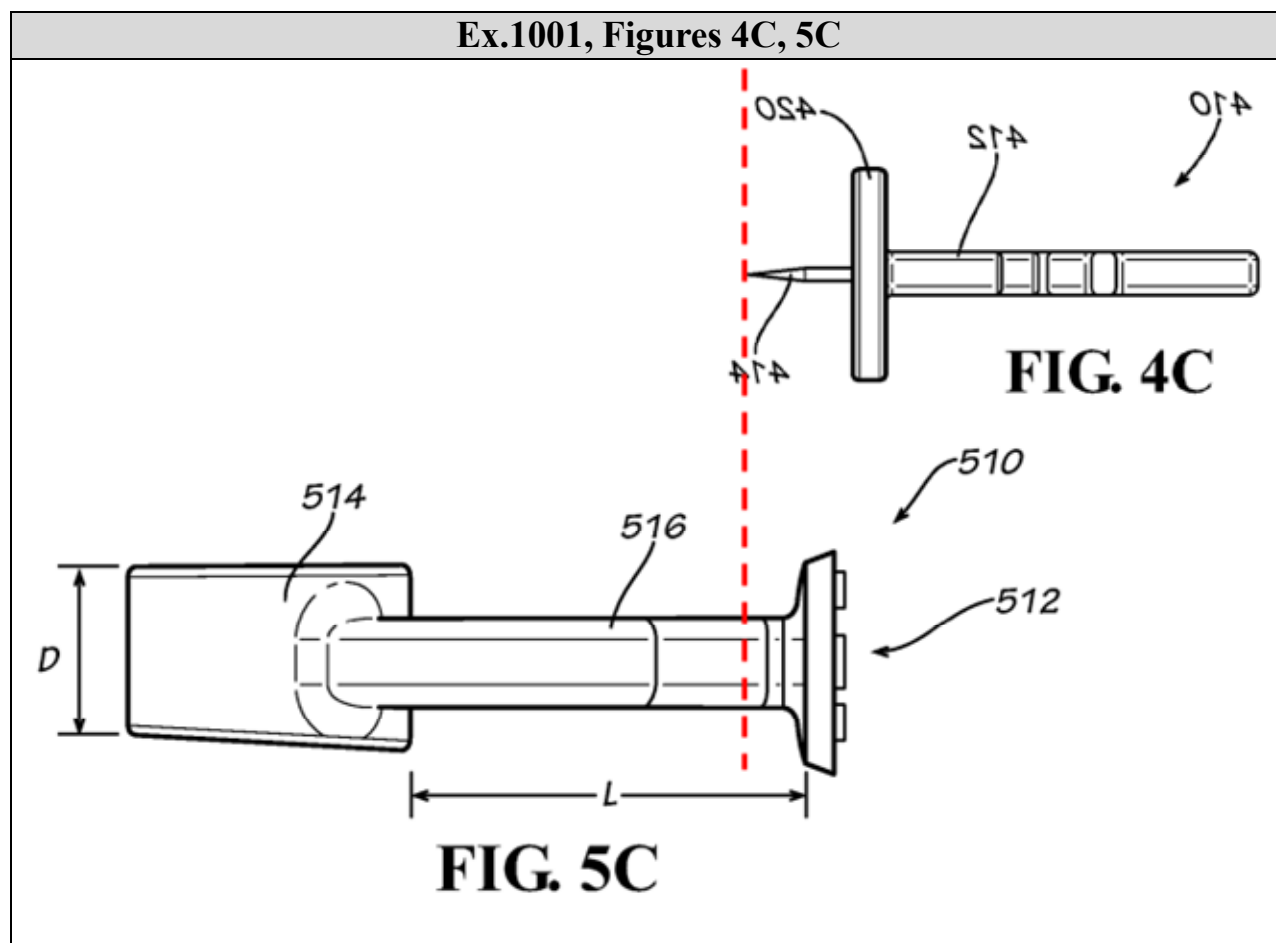
usual to aid handling”); Petition, 39. Saikley also discloses that the needle sharp 50, included in Figures 6 and 8, is about 3 mm. *Id.*, [0042]; Ex.1058, 80:21-82:17. Mr. Delman explains that the length of the sharp 50 provides a reference point that further confirms the relative proportions that Saikley so clearly shows and describes. Ex.1034 ¶¶ 22-23.

As further confirmation, Mr. Delman also pointed to aspects of the general knowledge in the art, including size of human thumbpads and torque needed to twist-off Saikley’s cap. Petition, 19-26, 38-40; *Telemac Ceullar Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1327-31 (Fed. Cir. 2001) (relying on extrinsic evidence for anticipation). While PO belittles this confirmatory evidence (POR, 25), it misses the mark. Mr. Delman’s reliance on aspects of common general knowledge (related to torque and finger pad sizes) merely confirms what a PHOSITA already knows from Saikley’s figures and descriptive text. A PHOSITA would have understood that the lancet cap should be what Saikley says it is—a wider handle to facilitate gripping and twisting, i.e., a “handling tab.” *Id.*; Ex.1034, ¶¶ 24-27. And a PHOSITA would have known that certain dimensions produced easy-to-grip devices and would have used this to confirm what Saikley plainly discloses. Ex.1017, 5:15-17 (“This transverse ratio (W/t) of at least 3:2, and more preferably about 2:1, provides an easy to grip device”); Inst. Dec., 26.

E. Saikley Anticipates Claims 7, 8, 17, and 18

Regarding the length limitations of claims 7, 8, 17, and 18, PO fails to measure the full length of Saikley’s “gripping handle portion” (POR, 31-32) by using its flawed claim construction of “extending between” addressed above.

Even under PO’s incorrect construction, Dr. Collins does not properly measure the length of Saikley’s gripping handle. Per Dr. Collins, the embedded needle sharp would not extend beyond the righthand side of the length line in Figure 5C in the patent. Ex.1058, 141:14-25. This is not correct. The sharp would have extended into the gripping handle:



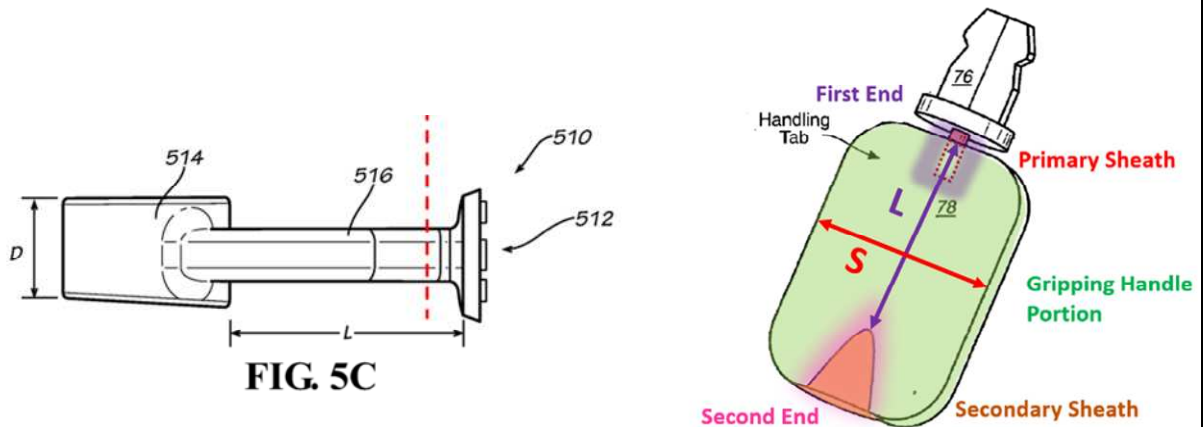
Ex.1034 ¶¶ 32-34.

The length is measured from where the sharp enters the primary sheath, not where the sharp terminates therewithin.⁴ Measured like this, the length of

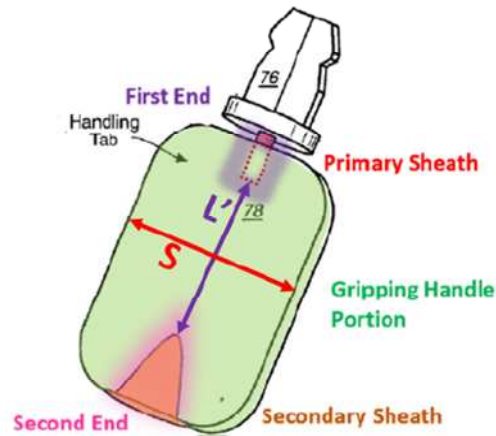
⁴ PO argues that Saikley does not disclose distinct sheathes and a gripping handle. But these are features of the claimed "protective sterility cap," not discrete and separate components. And as shown above, the primary sheath in the patent extends well into the gripping handle.

Saikley's tab remains at least equal to its lateral span (claims 7 and 17) and at least equal to the much-smaller lancet thickness (claims 8 and 18).

Ex.1001, Figure 5C and Saikley's Length



Ex. 2056, Dr. Collins' Incorrect Annotation



III SAIKLEY RENDERS THE DIMENSIONAL LIMITATIONS OBVIOUS

If not anticipated, the dimensional limitations are (i) an obvious design choice involving routine optimizations and/or (ii) obvious to try.

During prosecution, the Examiner made clear that there was no criticality to the dimensional limitations. Petition, 50. PO never disputed the Examiner's determination. PO's expert confirmed this lack of criticality. *See* Ex.1035, 101:12-103:23 (admitting patent does not explain benefit of having lateral span that is 1.5 times the lancet thickness versus 1.4 times). Petitioner's expert agrees—any handleability benefits for the cap relate to its size relative to the grasping fingertip and not relative to the lancet body. Ex.1034, ¶¶ 25-27.

Without criticality, and given Saikley's directive that the cap “should be made much larger than usual to aid handling” by diabetics with dexterity challenges, it was an obvious matter for a PHOSITA to routinely optimize Saikley's “Handling Tab” to reach the relative dimensional limitations. *See, e.g., In re Applied Materials, Inc.*, 692 F.3d 1289, 1295-98 (Fed. Cir. 2012) (claimed dimensions were obvious where there was no evidence of unexpected results or criticality).

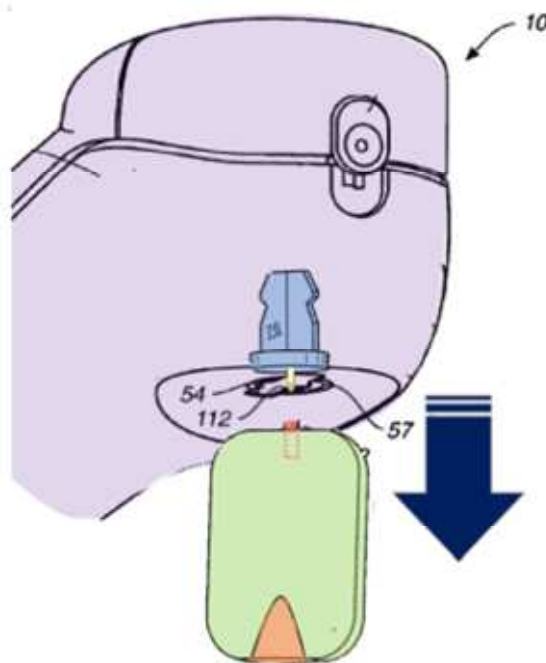
The relative dimensions were also obvious to try. A PHOSITA looking at Saikley and reading that the cap should be made larger for handling would readily

try various dimensions for Saikley’s handling tab. A PHOSITA would be aware that a wider handling tab would provide a larger gripping surface relative to the area of a fingertip, thus improving stability and control while twisting, pulling off, and handling the cap. Indeed, Mr. Delman described a PHOSITA’s process for designing the larger cap taught by Saikley. *See* Ex.2028, 62:9-20 (describing access to broad range of lancet caps to measure, testing in the prototyping stage, and comparing performance to much larger cap). Even PO’s expert testified that in the development lifecycle for lancets, making relative dimensional changes would be expected. Ex.1035, 19:11-21:15.

A PHOSITA at the time would have recognized the benefits of a larger handling tab because “the industry trend toward miniaturization was creating designs that were increasingly difficult to use.” Ex.1042, 7; Ex.1034, ¶¶28-31. PO’s claims that a PHOSITA would have chosen not to implement a handling tab with the claimed dimensions so that they could save material and reduce cost is inconsistent with design philosophies focused on ergonomics, particularly in the healthcare field. *See* POR, 35; *see also* Ex.2056 ¶¶ 93, 105; Ex.1040, 23-24; Ex.1034 ¶¶ 28-31. A PHOSITA, recognizing that Saikley may be for “elderly patients and those with reduced eyesight and dexterity,” would have obviously tried a larger cap encompassing the claimed dimensional limitations.

IV SAIKLEY-STOUT RENDERS THE DIMENSIONAL LIMITATIONS OBVIOUS

PO's arguments against Saikley-Stout (POR, 43) misunderstand the proposed combination. PO appears to believe that the proposed combination required Saikley's handling tab to fit inside Stout's lancing device. POR, 42-43. But that was not the combination presented. Instead, the Petition identified a motivation to modify Saikley in view of Stout to ensure "backwards-compatible attachment" to the system disclosed in Saikley (not Stout). Petition, 56. That existing Saikley system did not need the handling tab inserted into the lancing device (shown below):



Petition, 24. The Petition never proposed inserting Saikley's handling tab into the lancing device, it instead proposed backwards-compatibility with Saikley's system

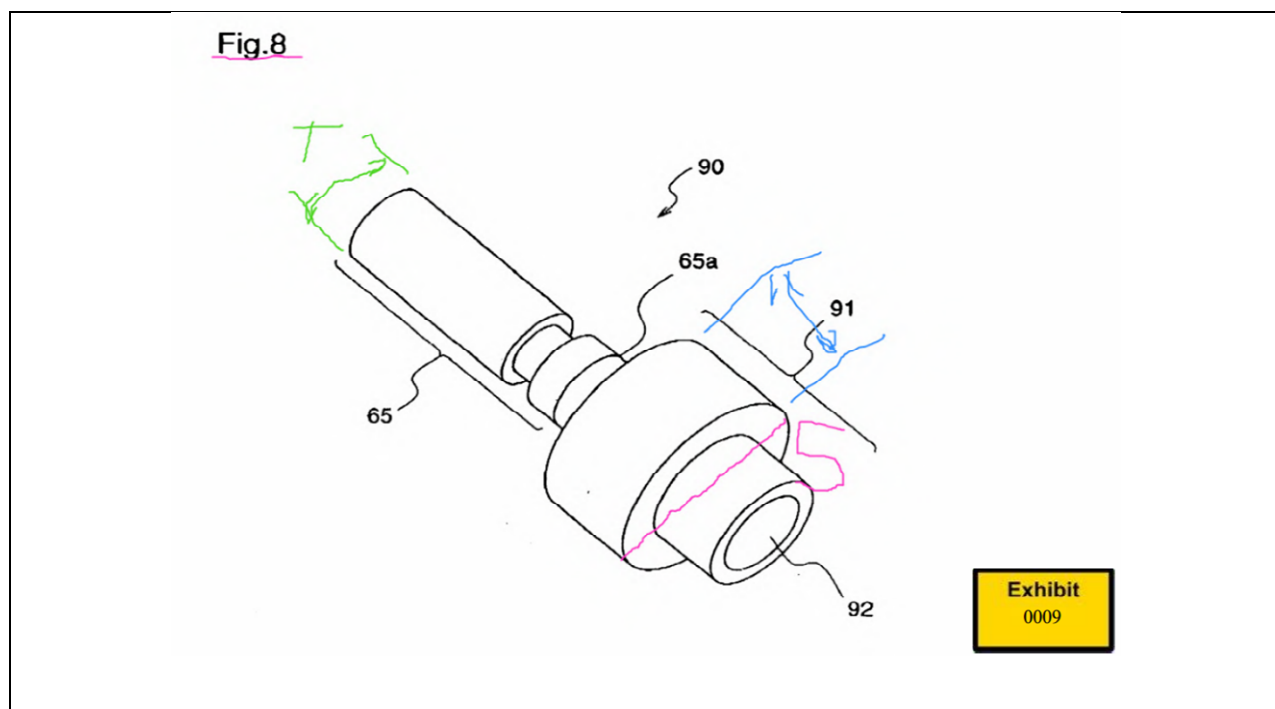
and modifying Saikley's handling tab in view of Stout's dimensions. Ex.1018, [0032] (disclosing slotted opening for lancet and cap having a lateral span twice its thickness). PO's misdirected arguments ignore this and should be rejected.

Stout provides ample motivation (Petition, 54-56) to implement its dimensional parameters in Saikley to create a sterility cap that "is preferably relatively large or oversized, as compared to the lancet body" and "facilitate[s] easier handling and loading of the lancet into the lancing device, which is of particular advantage to users having reduced visual acuity and/or reduced manual dexterity." Ex.1018, [0035]; Ex.1034, ¶¶ 35-38.

V IIO ANTICIPATES THE CHALLENGED CLAIMS (GROUND 4)

PO's argument that Iio cannot disclose a lateral span or a thickness because it is a cylinder fails because it does not comport with its expert's testimony where he agreed that Iio disclosed all limitations except for the relative dimensions. Ex.1035,49:18-52:3. He even annotated the lateral span and the thickness in the same locations as Mr. Delman:

Ex.1059, Annotation of Iio Figure 8 by PO's Expert
--



Regarding the dimensional limitations, Mr. Delman relied not only on the figures, but the patent's disclosures and technical benefits, and a PHOSITA's knowledge. *See* Petition, 78-86. Petitioner properly relied on Iio's disclosures and the PO cannot overcome them. *See, e.g., Unified Patents, LLC v. Oceana Innovations LLC*, IPR2020-01463, Paper 27 at 44-56 (PTAB Feb. 14, 2022) (holding claim limitations directed to length was disclosed by figure in prior art showing how first and second sides were longer than the third). Ex.1034, ¶ 39.

VI IIO RENDERS THE DIMENSIONAL LIMITATIONS OBVIOUS

Because the relative dimensional limitations lack criticality, routine optimization by a PHOSITA renders the claims obvious.

Additionally, the relative dimensions were obvious to try in view of Iio. Contrary to Dr. Collins' baseless assertion that there are an *infinite* number of dimensional design choices, a PHOSITA would appreciate that practical constraints left only a *finite* number of choices. Ex.1034, ¶¶ 39-41. The process to determine dimensions suitable for handling a medical device must balance numerous factors including anthropometric guidelines, user feedback, and critical hand dimensions. *Id.* For lancet users, like diabetic patients with poor dexterity, a PHOSITA seeking to improve Iio's lancet for "excellent useability and handleability" would adjust its lateral span to take into account the variation in pinch grips, hand and fingertip sizes, and other guidelines. Ex.1006 [0005]; Ex.1034 ¶¶ 39-41.

VII IIO-PECKHAM RENDERS THE DIMENSIONAL LIMITATIONS OBVIOUS

PO does not dispute the Petition's motivation to combine Iio and Peckham. Petition, 93-100. PO's arguments (POR, 62-63) focus on alleged deficiencies with Iio or Peckham alone, not in combination. For example, PO complains that the Petition made assumptions about "the diameter of Iio's alleged gripping handle" (POR, 62), which ignores that the combination relied on obvious modifications to Iio (Petition, 90-92) before adding Peckham's gripping ridges as well (Petition, 93). Adding Peckham's 28reppable ridges to Iio's modified cap would have been desirable and renders the dimensional limitations obvious. Ex.1034, ¶¶ 42-43.

VIII CLAIM 16 IS OBVIOUS

PO's expert admitted that claim 16 recites only an intended use. Ex.1058, 103:25-107:2.

Putting that dispositive point aside, PO presents no separate arguments rebutting the Saikley-FreeStyle combination. Petition, 57-59. PO's argument against Iio-Freestyle (POR, 63-64) fails because it focuses on Iio alone, not the combination, and because it imposes additional visibility requirements that are not present in claim 16. Ex.1034, ¶ 44.

IX PATENT OWNER'S ALLEGED SECONDARY CONSIDERATIONS FAIL

Facet's allegations of long-felt need, commercial success, and copying lack merit and have no nexus to the '635 patent.

A. Facet Cannot Prove Nexus Because the Delica and Delica Plus Lancets Do Not Practice the '635 Patent.

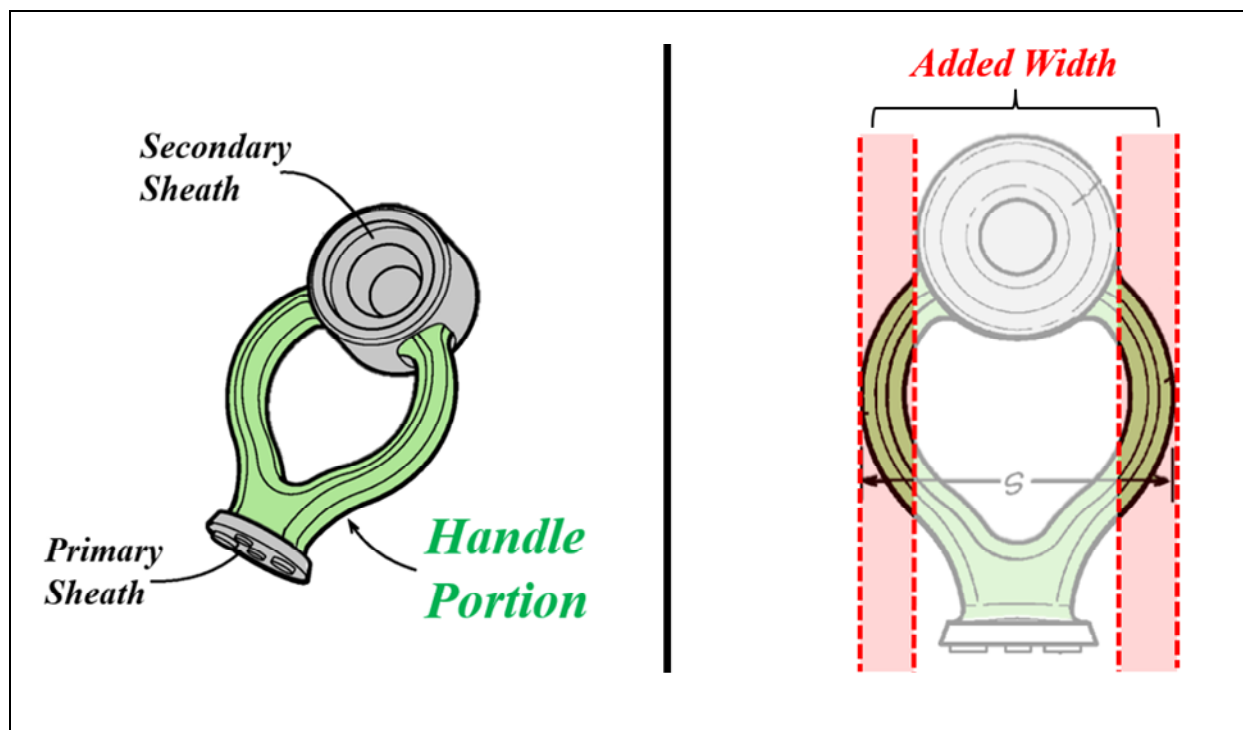
There is no nexus between the '635 patent and the One Touch Delica ("Delica") and the One Touch Delica Plus ("Delica Plus") lancets because neither of these lancets practices the challenged claims of the '635 patent.⁵

⁵ Facet attempts to show only that these lancets practice challenged claims 6 and 14.

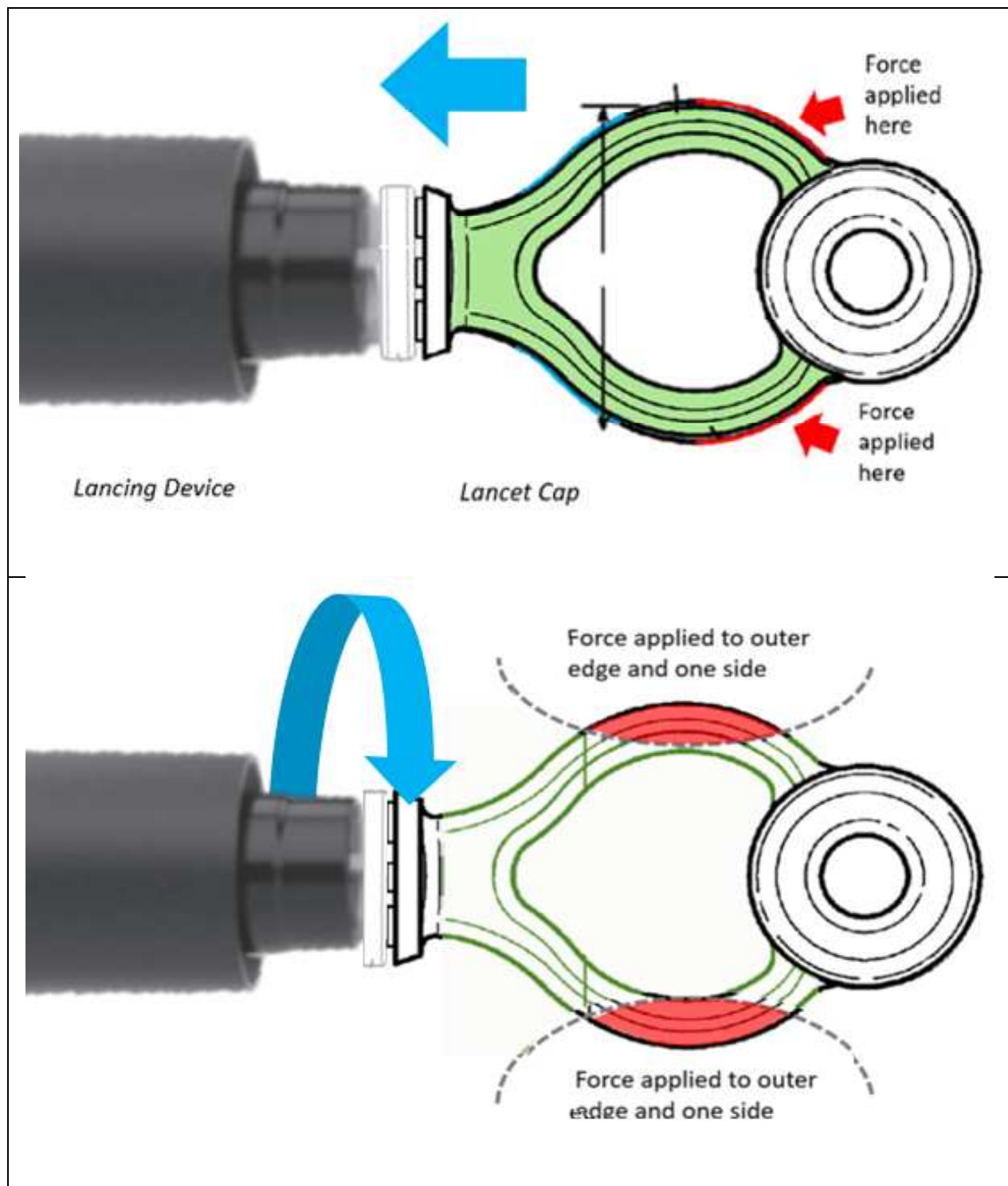
LifeScan’s design experts, Paul Hatch and Joel Delman, demonstrate why the protective cap on the Delica and Delica Plus lacks the “gripping handle portion *extending between* the primary sheath and the secondary sheath” required by the claims. These experts explain that a PHOSITA would not consider any portion of the Delica and Delica Plus protective cap that extends between their primary and secondary sheaths (known as the “neck” portion) to be a handle. Ex.1044, ¶¶7-17; Ex.1045, ¶¶ 49-136, 196-228; Ex.1034, ¶¶48-63. Neither neck portion has any structural elements or touchpoints to (i) physically fit or accommodate the users’ hand or fingers or (ii) provide a mechanical advantage to the user. Ex. 1044, ¶¶10-11; Ex.1045, ¶¶206-211; Ex.1034, ¶¶49-55.

Unlike the “extension arm” in the ’635 patent’s protective cap, the neck portions of the Delica and Delica Plus caps do not have the structure of a handle. *See* Ex.1004, 18:14 (District Court finding “a handle is a structural element.”). The ’635 patent teaches that because the “extension arm portion 516” has “arms 520 transversely spaced apart from one another,” this “arrangement provides the handle with a greater width, allowing the user to more easily twist the endcap during removal.” Ex.1001, 6:48-55; Ex.1045, ¶¶ 124-136, 222-24; Ex.1034, ¶ 58. The ’635 patent’s extension arms bulge outward to form a handle with contact surfaces that a user can grasp to push or twist. Because the extension arm portion

in the '635 patent has a “greater width” than the secondary sheath, it forms a handle that provides a mechanical advantage, increasing the amount of torque a user can apply with a given amount of effort, as depicted below. Ex.1045, ¶¶ 209-224.



A PHOSITA would understand that the outwardly-bulging arms of the '635 patent's handle visually communicate to a user where to grasp the cap, accommodate the user's fingers, and make it easier to apply force when inserting the lancet into the lancing device (upper image below) and twisting off the cap (lower image below). Ex.1044, ¶12; Ex.1034, ¶¶58-63.



In stark contrast, the neck portion of the Delica and Delica Plus protective caps do not have any structure *especially designed* to physically fit or accommodate a user's hand. Neither neck portion bulges outward to provide a “greater width” for gripping as in the '635 patent. And while a user's finger may have incidental contact with the neck portion on these caps, the neck structure is much narrower than the secondary sheath and does not make the caps wider or otherwise easier to grab or twist. Ex.1044, ¶13; Ex.1045, ¶¶207-210; Ex.1034, ¶¶51-55.

The only structure on the Delica and Delica Plus that a PHOSITA would understand to act as a handle is the secondary sheath because that is the structure that physically accommodates the user's fingers and provides mechanical advantage when handling the lancet during normal use. Ex.1045, ¶¶212-17; Ex.1034, ¶¶58-63. Only the flat, round shape of the secondary sheath accommodates a fingertip, providing a surface that is easy to grasp and a visual cue for the user to employ a “pinch grip” when holding the lancet. Ex.1044, ¶14.



Delica

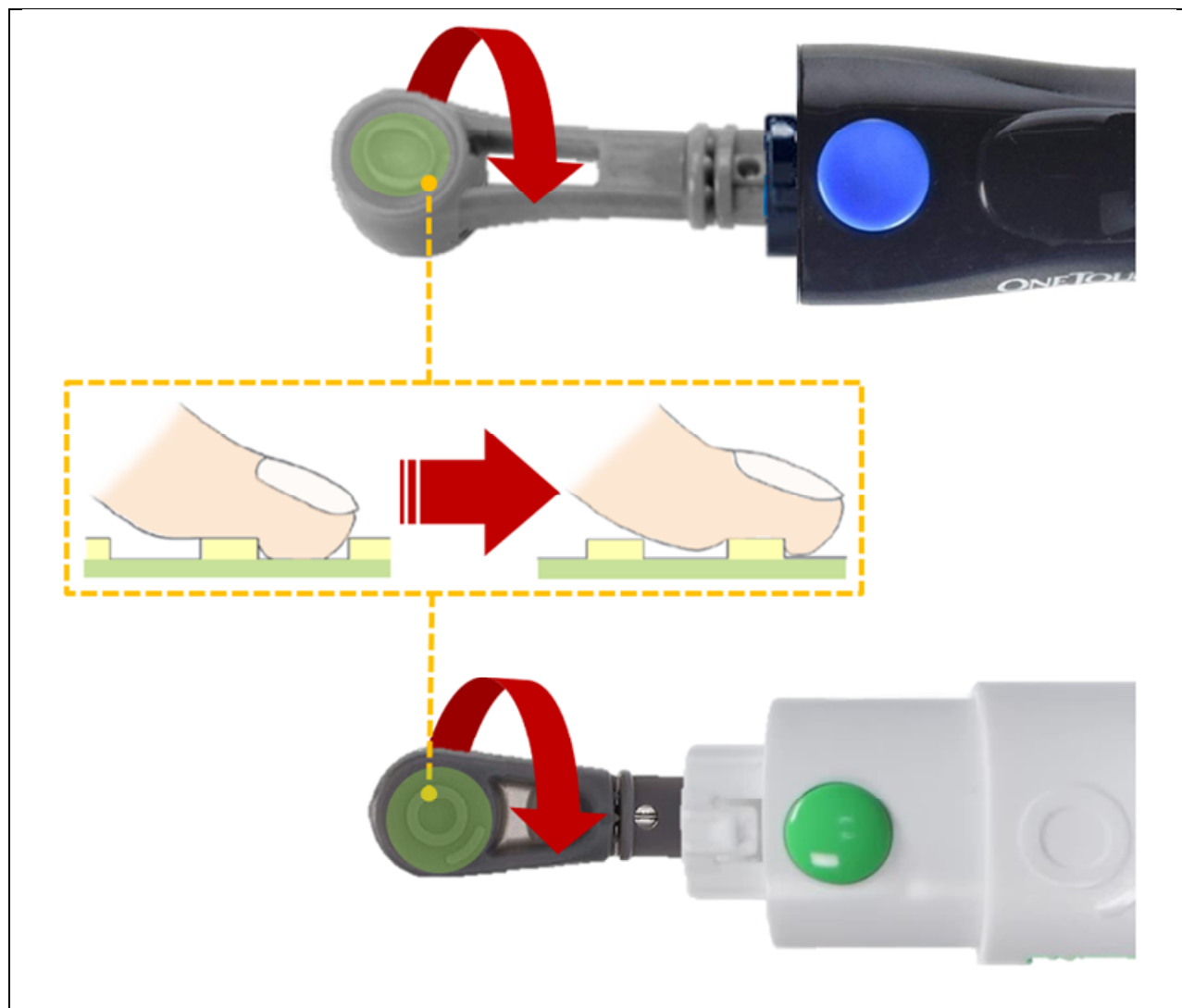


Delica Plus

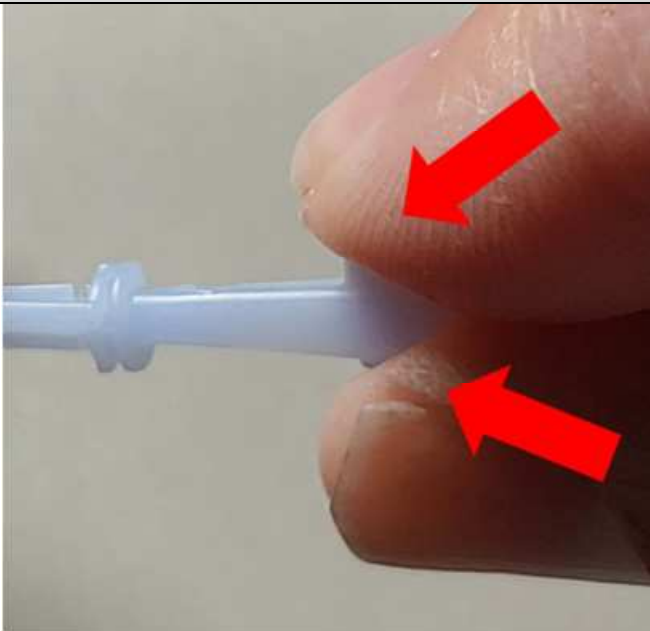
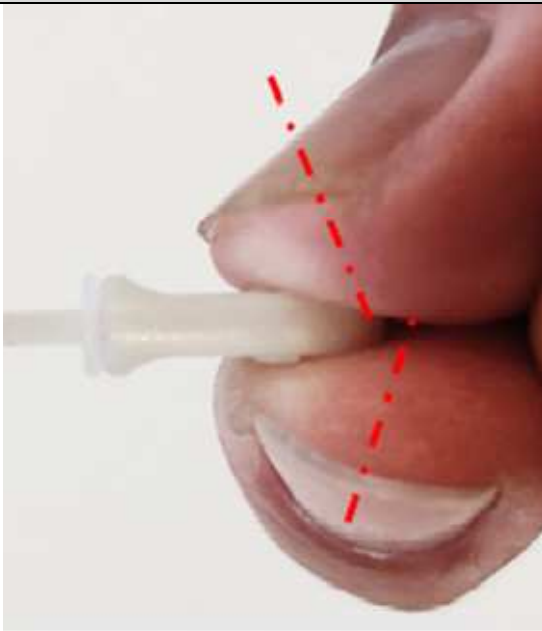
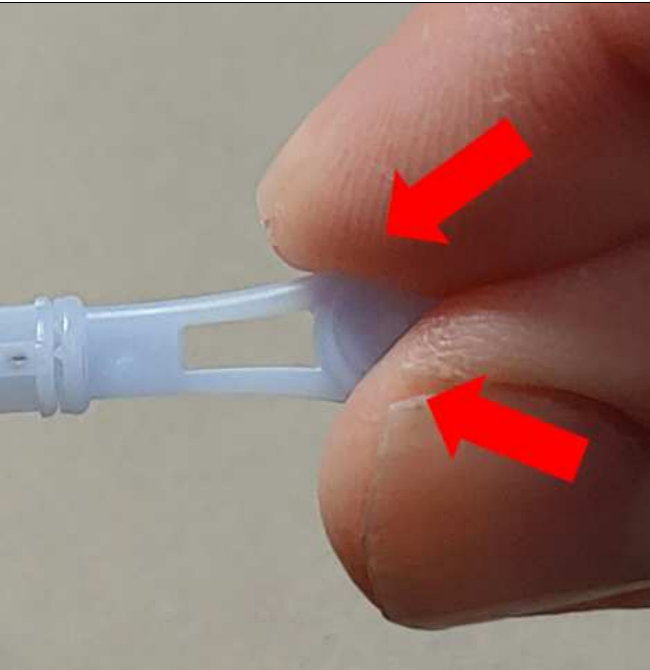
The ribs on the secondary sheath also communicate that this area is for gripping.

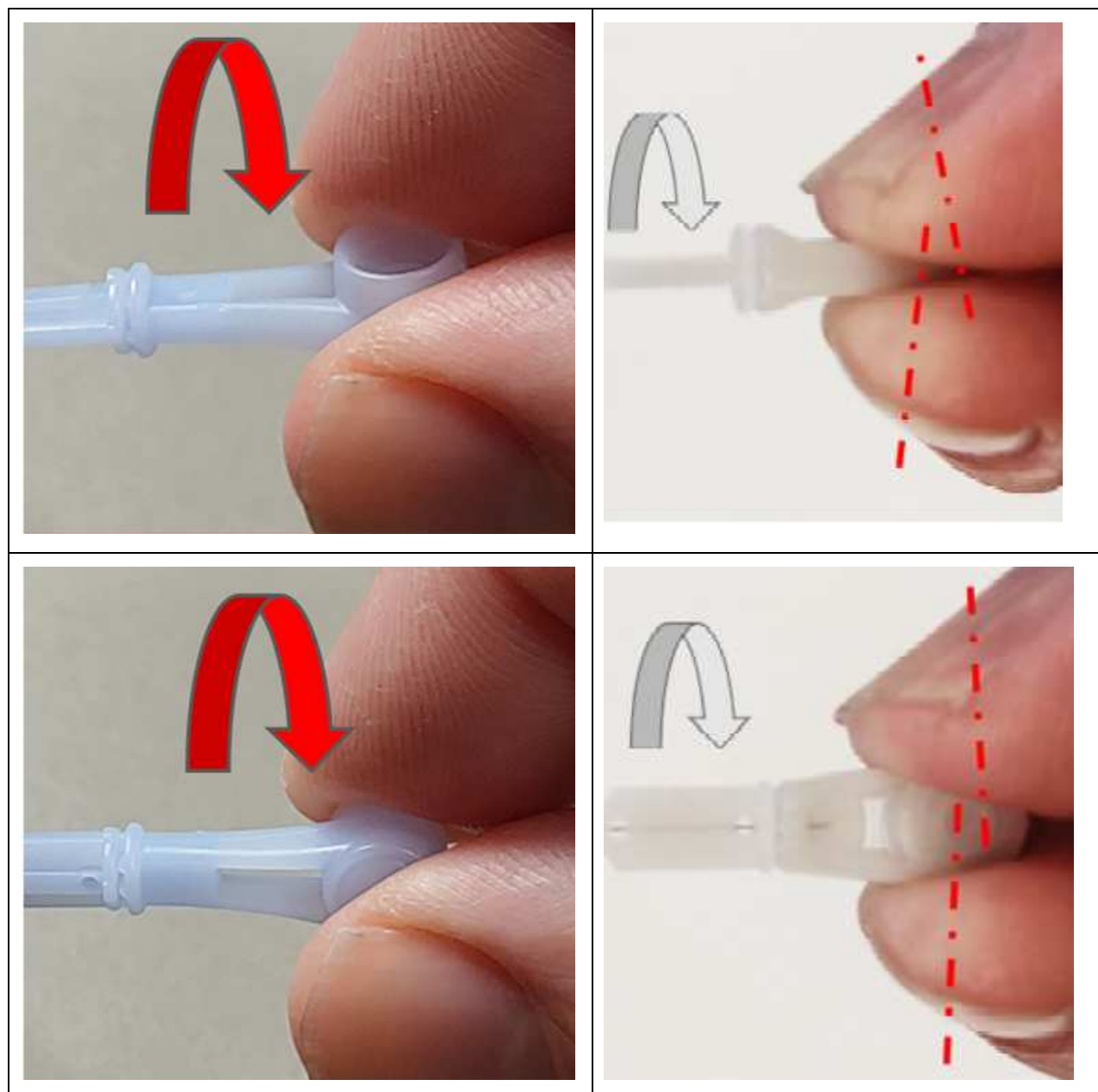
This ribbed surface design increases the friction and contact surface area with a user's finger, making it easier for the user to remove the lancet cap. Finally, when inserting the lancet into the lancing device, the secondary sheath provides the only outwardly oriented surfaces against which the user can push (as shown above).

The secondary sheath is also the widest structure on the cap and, thus, provides the most mechanical advantage for twisting during removal. Ex.1044, ¶15; Ex.1045, ¶¶212-227; Ex.1034, ¶¶56-63.



Mr. Hatch conducted a handleability assessment and confirmed that the secondary sheath in both the Delica and Delica Plus is the only structure that physically accommodates the human finger and provides advantages when handling the lancet during normal use. Ex.1044, ¶16; Ex.1045, ¶¶218-27; Ex.1034, ¶¶50-63.

Push Positions	
Delica	Delica Plus
	
	
Twist Positions	
Delica	Delica Plus



Other than an annotated photograph, Facet offers nothing to demonstrate that the neck portion of the Delica and Delica Plus protective caps is a “handle.” POR, 69-70; Ex. 2056, ¶144. These conclusory assertions that the Delica and Delica

Plus lancets have the claimed “gripping handle” fail to demonstrate nexus. *See Krippelz v. Ford Motor Co.*, 667 F.3d 1261, 1268 (Fed. Cir. 2012).

B. Facet’s Commercial Success Allegations Fail.

Even if the Board accepted Facet’s contention that the Delica and Delica Plus lancets practice the ’635 patent (they do not), Facet has still failed to show any nexus between these allegations and any commercial success of these products. In fact, Facet relies entirely on a purported presumption that—as discussed below—does not apply.

1. Nexus cannot be presumed because Facet failed to prove coextensiveness.

To prove entitlement to a presumption of nexus based on sales of the Delica and Delica Plus lancets, Facet needed to prove “that the product is essentially the claimed invention,” *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1375 (Fed. Cir. 2019), and resolve “whether unclaimed features are insignificant,” *Campbell Soup Co. v. Gamon Plus, Inc.*, 10 F.4th 1268, 1277 (Fed. Cir. 2021). But Facet performed no such analysis. Its lawyers merely asserted “the claimed invention is not a mere subcomponent of the products,” POR 66, and its expert did not even analyze coextensiveness. The Board should reject these conclusory assertions. *Volvo Penta of the Americas LLC v. Brunswick Corp.*, 81 F.4th 1202, 1211 (Fed. Cir. 2023).

The claimed “protective sterility cap” is not coextensive with the Delica and Delica Plus lancing systems because the protective caps on both lancets *are twisted off and removed* from the lancet body before performing a lancing operation. Ex.1034, ¶¶ 68-77. Numerous unclaimed and significant features of the Delica and Delica Plus lancets, and their lancing devices, defeat Facet’s claim of coextensiveness.

The Lancing Device. The combined system that performs a lancing operation is the Delica or Delica Plus lancet seated into either the Delica or Delica Plus lancing device. *E.g.*, Ex.2046-002 (LifeScan’s user instructions). This combined lancing system has numerous unclaimed and significant features, including the design of the lancing device, its features for seating and propelling the lancet body, and puncture depth settings. Ex.1034, ¶72.

The Lancet. The lancet in isolation from the lancing device also has several critical and unclaimed features, including (1) the structure and design of the lancet body that allows the lancet to be seated within the Delica or Delica Plus lancing device and (2) particular aspects of the lancet needle (including its 30 or 33 gauge). Ex.1034, ¶72. The ’635 patent is directed to a purportedly novel protective sterility cap for a lancet with the preamble of each challenged claim reciting that the claimed invention is “[a] protective sterility cap for a lancet” and the body of the

claims reciting the allegedly novel features of this cap. Although some challenged claims recite a “protective sterility cap” in combination with a generic “lancet body” and “sharp lancet tip,” they do not recite any specific characteristics of either component. *Id.*

Facet’s allegations of commercial success ignore these unclaimed features and its own marking practices, in which Facet admits that its FMT lancets (*i.e.*, the rebranded Delica lancets) may be covered by the ’635 patent *along with four additional patents*:

Patent Notice

This page is intended to serve as notice under 35 U.S.C. § 287(a). The following U.S. patents may apply to Facet products. Each product may also be covered by one or more foreign patents, and additional patent application(s) may be pending.

Product Brand	U.S. Patent(s)
FMT Lancet	8,652,159; 8,840,635; 9,095,293; D621,044; D621,045
FMT Lancing Device	8,398,664; 9,095,293; 9,095,294; D621,042; D628,695

The products and patent numbers shown above may not be all-inclusive. Other patents may protect the products listed above as well as other products and services commercialized by Facet. Granted patents and published U.S. patent applications may be viewed at the [United States Patent and Trademark Office](#) website.

Ex. 1047; Ex.1034 ¶¶ 74-77. Significantly, each additional Facet patent claims lancets with a particular body structure. Ex.1034, ¶¶74-76; Exs.1048-1051.

The Federal Circuit has repeatedly rejected claims of coextensiveness when a product is covered by multiple patents. *Fox Factory*, 944 F.3d at 1375; *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1289, 1299 (Fed. Cir. 2010), *invalidity reinstated*, 649 F.3d 1276 (Fed. Cir. 2011) (no presumption of nexus

because patentee “marked the product with [another] patent, both before and after the [asserted] patent issued.”).

2. Facet adduced no evidence that sales of the Delica and Delica Plus lancets are the direct result of the ’635 Patent.

Because nexus cannot be presumed, Facet had the burden of “showing that the evidence of secondary considerations is the direct result of the unique characteristics of the claimed invention.” *Fox Factory*, 944 F.3d at 1373-74 (internal quotations omitted). Facet offered nothing.

Facet failed to identify any evidence that customers purchased the Delica or Delica Plus lancets because of their protective caps. Ex.1046, ¶¶11-25. [REDACTED]

[REDACTED]

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C. Saikley and Iio Met Facet’s Alleged Long Felt Need

Facet’s only alleged long felt need—“for a lancet and cap that was easier for users to handle”—was clearly taught by the prior art, including Saikley and Iio.

Saikley teaches that its “**protective cap 78**” “**should be made much larger than usual to aid handling.**” Ex.1005, [0050] (emphasis added). Saikley’s protective cap addressed the needs of “[e]lderly patients and those with reduced

eyesight and dexterity [who] can have problems seeing and capturing such a small [blood] sample.” *Id.*, [0004]; Ex.1034, ¶¶ 64-66.

Iio likewise discloses a lancet with a puncture needle cap 91 that has a cylindrical grip providing “**excellent usability and handleability**” that “safely set[s] a puncture needle” at the same depth for every puncture. Ex.1006, [0023] (emphasis added); Ex.1034, ¶ 67. Because “the record evidence indicates that the claimed invention was not the first to achieve” what Facet alleges to be a long felt need, the Board should reject this alleged secondary consideration. *ZUP, LLC v. Nash Mfg., Inc.*, 896 F.3d 1365, 1374 (Fed. Cir. 2018); *Nike, Inc. v. Adidas AG*, 955 F.3d 45, 54-55 (Fed. Cir. 2020) (affirming Board’s conclusion that “any alleged, long-felt need was met by the teachings of [the prior art]”).

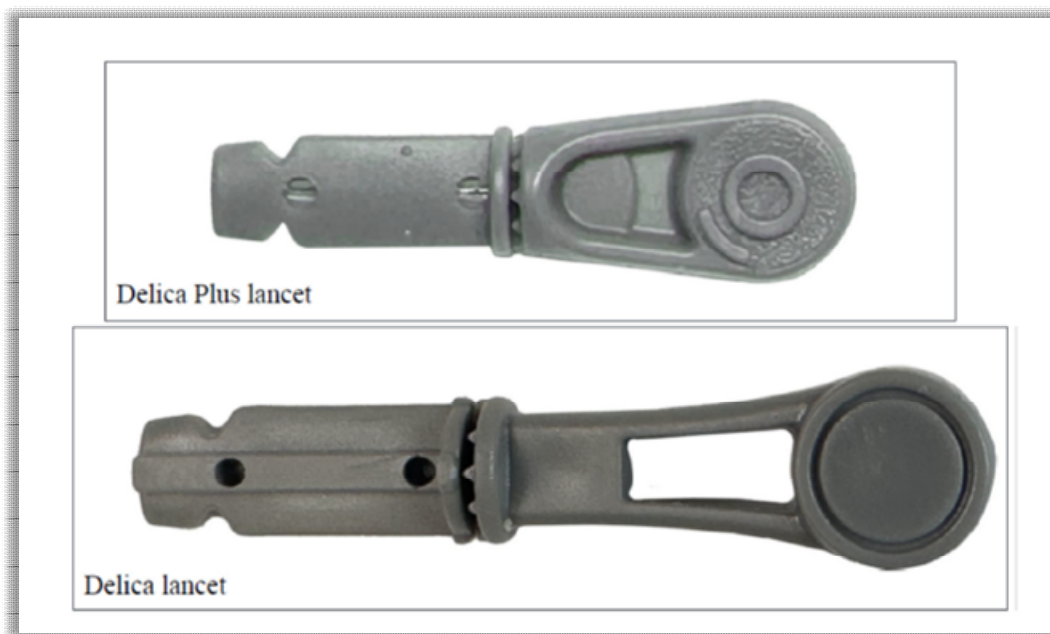
D. LifeScan Did Not Copy the Claimed Invention.

There is no evidence of copying because the Delica Plus lancet does not infringe the ‘635 patent. Even if Facet had evidence to the contrary, “more than the mere fact of copying by an accused infringer is needed to make that action significant to a determination of the obviousness issue.” *In re GPAC, Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995). The Board should reject Facet’s copying allegations.

First, Facet claims that the “Delica Plus products were designed specifically to be cross-compatible with the original Facet Delica lancing device and lancets.”

POR 75. But a lancet’s cross-compatibility with a lancing device results from similarities in the shape of the lancet body that is inserted into the lancing device—not the cap. Ex.1034, ¶¶78-79. The structural similarities of the lancet body that makes it cross-compatible with a lancing device are irrelevant here because the ’635 patent does not claim a particular lancet body structure—and certainly not the Delica or Delica Plus lancet body structure. Ex.1034, ¶79. Copying a feature “is *legally irrelevant* unless the [] feature is shown to be an embodiment of the claims.” *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1366 (Fed. Cir. 2001) (emphasis added).

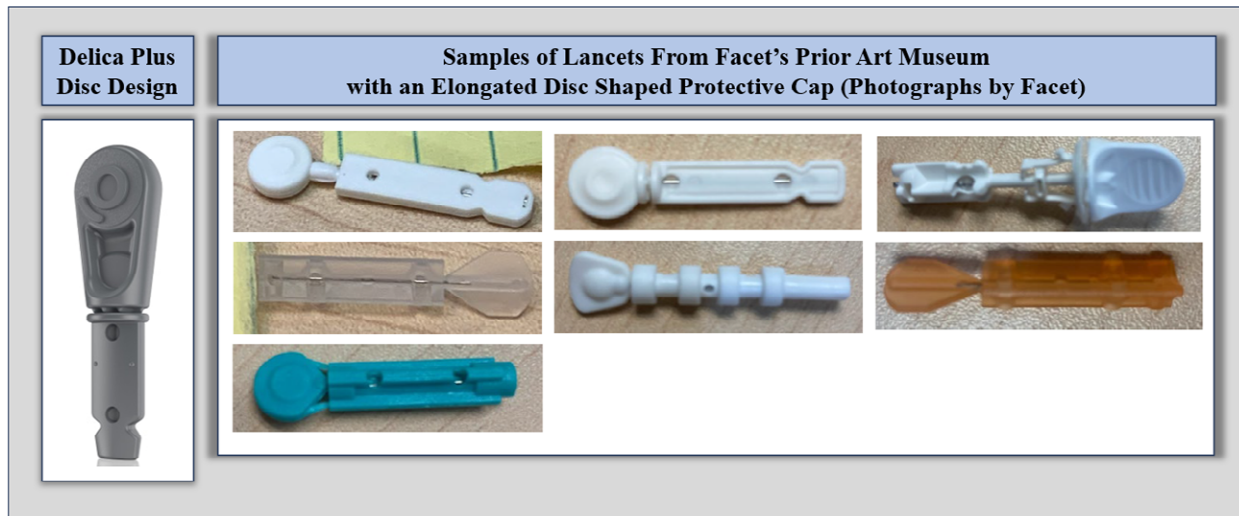
Second, no evidence or testimony supports Facet’s claim of “overwhelming” similarities between the Delica and Delica Plus. POR 73. Facet’s own brief illustrates several significant differences between their protective caps.



POR 67.

As illustrated by Facet, the overall designs, sizes, and shapes of these protective caps are different. The hollow Delica neck is different from the filled-in neck of the Delica Plus. The Delica Plus uses a two-sided disc shape. The Delica, by contrast, uses a one-sided cup shape. Ex.1034, ¶¶80-83; Ex.1058, 22:12-24:2 (Dr. Collins agreeing to similar differences).

Further, both protective caps borrow elements from the crowded field of prior art—proving that one is not a copy of the other. In fact, Facet maintained a museum of prior art lancets, many of which have elongated disc-shape protective caps like the Delica Plus:



Ex.1053 at 6; Ex.1054, ¶ 4; Ex.1055; Ex.1056 at 15-19.

Many of the lancets in Facet's prior art museum also have a cup-shaped protective cap similar to the Delica.



See id.; Ex.1053 at 1-2.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

X CONCLUSION

For the reasons set forth above and in the Petition, the Remaining Claims are unpatentable.

Dated: March 22, 2024

Respectfully submitted,

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CERTIFICATION OF COMPLIANCE WITH TYPE-VOLUME LIMITS

This Petition includes 5,546 words, as counted by Microsoft Word, and is therefore in compliance with the 5,600-word limit established by 37 C.F.R. 42.24(c)(1). Accordingly, pursuant to 37 C.F.R. 42.24(d), lead counsel for Petitioner hereby certifies that this Petition's Reply complies with the applicable type-volume limits.

Dated: March 22, 2024

Respectfully Submitted,

/Michael J. Lyons/

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

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(b), I certify that on March 22, 2024, I caused to be served a true and correct copy of Petition's Reply and the exhibits cited therein by email to Patent Owner's counsel:

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