

Filed on behalf of: Facet Technologies, LLC

Entered: December 19, 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 RESPONSE

[REDACTED]

[REDACTED]

TABLE OF CONTENTS

I.	Introduction.....	1
II.	'635 Patent Overview	3
A.	Person of Ordinary Skill in the Art	4
III.	Claim Construction.....	4
IV.	Grounds 1-3: The Challenged Claims Are Patentable over Saikley, Stout, and the FreeStyle Manual.....	4
A.	Saikley Does Not Disclose a Lancet Cap With a Gripping Handle Portion <i>Between</i> the Primary and Secondary Sheaths.....	5
B.	Saikley, Alone or in Combination, Does Not Disclose or Render Obvious the Dimensional Limitations.....	15
1.	Legal Background: "Proportions of features in a drawing are not evidence of actual proportions when drawings are not to scale"	15
2.	All Challenged Claims: Saikley does not disclose the claimed dimensions.....	19
3.	Claims 7, 8, 17, and 18: Saikley does not disclose the claimed length dimension	31
4.	All Challenged Claims: Saikley, alone or in combination with Stout, does not render obvious the claimed dimensions	32
a.	The claimed dimensions would not have been obvious over Saikley alone.....	33
b.	Stout does not remedy Saikley's deficiencies	41
5.	Claims 7-8 and 17-18: Saikley, alone or with Stout, does not render obvious the claimed length dimension	46
V.	Grounds 4-6: The Challenged Claims Are Patentable over Iio, Peckham, and the FreeStyle Manual	47

A.	Iio Does Not Disclose A “Gripping Handle Portion” With A “Lateral Span” Or A “Lancet” With a “Thickness”	48
1.	The plain meaning of “lateral span” and “thickness”	48
2.	Iio does not disclose the claimed “lateral span” or “thickness”	51
B.	Iio, Alone or In Combination, Does Not Disclose or Render Obvious the Dimensional Limitations, ...	54
1.	All Challenged Claims: Iio does not disclose the claimed dimensions	54
2.	All Challenged Claims: Iio, alone or with Peckham, does not render obvious the claimed dimensions.....	59
a.	The claimed dimensions would not have been obvious over Iio alone	59
b.	Peckham does not remedy Iio’s deficiencies.....	62
C.	Claim 16: The Iio combination fails to teach or suggest the recited flat display surface.....	63
VI.	Objective Evidence Further Demonstrates Patentability.....	65
A.	A Strong Nexus Exists Between the Objective Evidence and the Claimed Invention	65
1.	Claims 6/14 - Preamble.....	66
2.	Limitation 1.a/14.a – primary sheath.....	67
3.	Limitation 1.b/14.b - secondary sheath.....	68
4.	Limitation 1.c/14.c - gripping handle portion.....	69
5.	Limitation 6.a/14.d - lancet body thickness	70
6.	Limitation 6.b/14.f - gripping handle lateral span at least 1.5 times the lancet thickness.....	72

B.	LifeScan’s Delica Plus Lancets Are Blatant Copies of Facet’s Delica Lancets	72
C.	The Invention Achieved Substantial Commercial Success.....	76
D.	The ’635 Patent Satisfied a Long-Felt but Unmet Need.....	77
VII.	Conclusion	78



TABLE OF AUTHORITIES**Page(s)****CASES**

<i>Airlite Plastics Co. v. Plastilite Corp.</i> , 526 F.2d 1078 (8th Cir. 1975)	33
<i>Apple Inc. v. Samsung Elecs. Co.</i> , 839 F.3d 1034 (Fed. Cir. 2016)	76
<i>Arendi S.A.R.L. v. Apple Inc.</i> , 832 F.3d 1355 (Fed. Cir. 2016)	39
<i>Bayer Schering Pharma AG v. Barr Laboratories, Inc.</i> , 575 F.3d 1341 (Fed. Cir. 2009)	36
<i>Cutsforth, Inc. v. MotivePower, Inc.</i> , 636 F. App'x 575 (Fed. Cir. 2016)	39
<i>Engel Indus., Inc. v. Lockformer Co.</i> , 96 F.3d 1398 (Fed. Cir. 1996)	11
<i>Gardner v. TEC Sys., Inc.</i> , 725 F.2d 1338 (Fed. Cir. 1984)	34
<i>Gaus v. Conair Corp.</i> , 363 F.3d 1284 (Fed. Cir. 2004)	10
<i>Graham v. John Deere Co. of Kan. City</i> , 383 U.S. 1 (1966)	65
<i>Hamilton Prods., Inc. v. O'Neill</i> , 492 F. Supp. 2d 1328 (M.D. Fla. 2007)	33
<i>Harmonic Inc. v. Avid Tech., Inc.</i> , 815 F.3d 1356 (Fed. Cir. 2016)	37, 47, 60, 61
<i>Hockerson-Halberstadt, Inc. v. Avia Grp. Int'l</i> , 222 F.3d 951 (Fed. Cir. 2000)	<i>passim</i>

<i>In re Aslanian</i> , 590 F.2d 911 (C.C.P.A. 1979)	19
<i>In re Magnum Oil Tools Int'l, Ltd.</i> , 829 F.3d 1364 (Fed. Cir. 2016)	46, 60, 61, 62
<i>In re Olson</i> , 212 F.2d 590 (C.C.P.A. 1954)	15, 56
<i>In re Rijckaert</i> , 9 F.3d 1531 (Fed. Cir. 1993)	36
<i>In re Stepan Co.</i> , 868 F.3d 1342 (Fed. Cir. 2017)	37, 61
<i>In re Wright</i> , 569 F.2d 1124 (C.C.P.A. 1977)	17
<i>Intelligent Bio-Systems, Inc. v. Illumina Cambridge, Ltd.</i> , 821 F.3d 1359 (Fed. Cir. 2016)	14
<i>Iron Grip Barbell Co. v. USA Sports, Inc.</i> , 392 F.3d 1317 (Fed. Cir. 2004)	72
<i>Liqwd, Inc. v. L'Oreal USA, Inc.</i> , 941 F.3d 1133 (Fed. Cir. 2019)	72, 73
<i>Marrin v. Griffin</i> , 599 F.3d 1290 (Fed. Cir. 2010)	64
<i>Medtronic, Inc. v. Teleflex Innovations S.A.R.L.</i> , 70 F.4th 1331 (Fed. Cir. 2023)	73
<i>Neutrino Dev. Corp. v. Sonosite, Inc.</i> , 423 F. Supp. 2d 673 (S.D. Tex. 2006), <i>aff'd</i> , 210 F. App'x 991 (Fed. Cir. 2006) (per curiam)	18
<i>Nystrom v. Trex Co.</i> , 424 F.3d 1136 (Fed. Cir. 2005), <i>aff'd</i> , 200 F. App'x 987 (Fed. Cir. 2006) (per curiam)	16, 17, 37
<i>Ohio Willow Wood Co. v. Thermo-Ply, Inc.</i> , No. 9:07-cv-00274, 2009 WL 6499349 (E.D. Tex. Nov. 20, 2009)	38

<i>Paragon Sols., LLC v. Timex Corp.</i> , 566 F.3d 1075 (Fed. Cir. 2009)	7
<i>Plantronics, Inc. v. Aliph, Inc.</i> , 724 F.3d 1343 (Fed. Cir. 2013)	17
<i>PlaSmart, Inc. v. Kappos</i> , 482 F. App'x 568 (Fed. Cir. 2012)	18
<i>Polaris Indus., Inc. v. Arctic Cat, Inc.</i> , 882 F.3d 1056 (Fed. Cir. 2018)	65, 66
<i>Rexnord Indus., LLC v. Kappos</i> , 705 F.3d 1347 (Fed. Cir. 2013)	40
<i>Rolls-Royce, PLC v. United Techs. Corp.</i> , 603 F.3d 1325 (Fed. Cir. 2010)	40, 60
<i>Rovalma, S.A. v. Bohler-Edelstahl GmbH & Co. KG</i> , 856 F.3d 1019 (Fed. Cir. 2017)	35
<i>Source Vagabond Sys. Ltd. v. Hydrapak, Inc.</i> , 753 F.3d 1291 (Fed. Cir. 2014)	17, 18, 19, 37
<i>Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.</i> , 492 F.3d 1350 (Fed. Cir. 2007)	40, 60
<i>TorPharm, Inc. v. Ranbaxy Pharms., Inc.</i> , 336 F.3d 1322 (Fed. Cir. 2003)	20
<i>TQ Delta LLC v. Cisco Sys., Inc.</i> , 942 F.3d 1352 (Fed. Cir. 2019)	41, 61
<i>Trintec Indus., Inc. v. Top-U.S.A. Corp.</i> , 295 F.3d 1292 (Fed. Cir. 2002)	31
<i>WBIP, LLC v. Kohler Co.</i> , 829 F.3d 1317 (Fed. Cir. 2016)	65
<i>Xerox Corp. v. Bytemark, Inc.</i> , IPR2022-00624, Paper 9 (P.T.A.B. Aug. 24, 2022).....	37, 47, 60, 61

STATUTES

35 U.S.C. § 312(a)(3).....	14
----------------------------	----

REGULATIONS

37 C.F.R.	
§ 42.22.....	14
§ 42.65(a)	23
§ 42.104.....	14



EXHIBIT LIST

Exhibit	Description
2001	Declaration of John M. Collins in support of the Patent Owner Preliminary Response ("Collins POPR 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

Exhibit	Description
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
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, <i>Facet Techs., LLC</i> , U.S. Patent No. 8,840,635, signed June 14, 2023 (U.S. Pat. & Trademark Dkt. No. 2G02.1-453)
2013-2020	RESERVED
2021	Order Regarding LifeScan's Motion for Summary Judgment [ECF No. 190], <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal. July 27, 2023), ECF No. 224
2022	U.S. Patent No.4,259,792 ("Halberstadt")
2023	LifeScan, Inc.'s Third Supplemented Objections and Responses to Facet Technologies, LLC's First Set of Interrogatories (Response to No. 3), <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal. May 26, 2023) (CONFIDENTIAL)
2024	Deposition transcript of Gregory A. Lamps, <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal. May 25, 2023) ("Lamps Dep.") (CONFIDENTIAL)
2025	Deposition transcript of Joel Delman, <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal. July 7, 2023) ("Delman Dist. Ct. Dep.")

Exhibit	Description
2026	BD Medical, <i>BD Ultra-Fine Lancets — A Difference You Can See and Feel</i> (June 2007), https://www.bd.com/resource.aspx?IDX=4437 (English & French versions)
2027	Centers for Disease Control & Prevention (CDC), <i>Diabetes: Monitoring Your Blood Sugar</i> (CDC last review Dec. 30, 2022), https://www.cdc.gov/diabetes/managing/managing-blood-sugar/bloodglucosemonitoring.html (last visited Dec. 13.2023, 5:27 AM)
2028	Deposition transcript of Joel Delman, <i>LifeScan, Inc. v. Facet Techs., LLC</i> , IPR2023-00712 (P.T.A.B. Dec. 5, 2023) (“Delman IPR Dep.”)
2029	Bettina Barisch-Fritz et al., <i>Evaluation of the Rule-of-Thumb: Calculation of the Toe Allowance for Developing Feet</i> , FOOTWEAR SCI. 1 (2016), https://www.tandfonline.com/doi/full/10.1080/19424280.2016.1144654
2030	Facet P&L [produced in <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal.), FACET_532894] (HIGHLY CONFIDENTIAL – AEO & REDACTED VERSIONS)
2031	RESERVED
2032	<i>Lateral</i> , MERRIAM-WEBSTER.COM, https://www.merriam-webster.com/dictionary/lateral (last visited Dec. 10, 2023, 2:16 PM)
2033	<i>Lateral Orientation</i> , MEDLINEPLUS MED. ENCYC., https://medlineplus.gov/ency/imagepages/9505.htm (last visited Dec. 10, 2023, 2:49 PM)
2034	U.S. Food & Drug Administration (FDA) letter to James Bonds of Facet Technologies, LLC, dated July 15, 2022, Re: Trade/Device Name: Facet 28G Universal Lancet, Regulation Number: 21 CFR 878.4850, Regulation Name: Blood Lancets, Regulatory Class: Class II, Product Code: QRK, QRL, Dated: May 16, 2022, Received: May 17, 2022

Exhibit	Description
2035	Certification & Notice of Interested Parties (Local Rule 7.1-1), <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal. May 18, 2022), ECF No. 46
2036	Mass. Inst. Tech. (MIT), Design And Manufacturing I, Undergraduate Course (Spring 2009), DESIGN HANDBOOK: ENGINEERING DRAWING AND SKETCHING, MIT (2001-2023)
2037	RESERVED
2038	<i>Cylinder</i> , OXFORD ENGLISH DICTIONARY, OED.COM, https://www.oed.com/dictionary/cylinder_n?tab=meaning_and_use&tl=true#7621109 (last visited Dec. 1, 2023, 7:38 PM)
2039	<i>Span</i> , MERRIAM-WEBSTER.COM, https://www.merriam-webster.com/dictionary/span (last visited Dec. 10, 2023, 3:49 PM)
2040	LifeScan P&L [produced in <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal.), (LSI0000245820.xlsx)] (HIGHLY CONFIDENTIAL – AEO)
2041	<i>Thickness</i> , MERRIAM-WEBSTER.COM, https://www.merriam-webster.com/dictionary/thickness (last visited Dec. 10, 2023, 2:23 PM)
2042	<i>Transverse</i> , MERRIAM-WEBSTER.COM, https://www.merriam-webster.com/dictionary/transverse (last visited Dec. 10, 2023, 2:19 PM)
2043	<i>Anatomy of the Hand</i> , Johns Hopkins Medicine, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/anatomy-of-the-hand (last visited Dec. 14, 2023, 10:01 AM)
2044	Asahi email exchanges <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal.), ASA08257–8260] (CONFIDENTIAL)

Exhibit	Description
2045	Asahi PowerPoint [produced in <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal.), ASA258968–258969] (HIGHLY CONFIDENTIAL – AEO)
2046	LifeScan IP Holdings, LLC, <i>OneTouch® Delica® Plus Lancing Device: Frequently Asked Questions (FAQ) Guide</i> (2019) [produced in <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal.), FACET_002122–2126]
2047	Lifescan IP Holdings, LLC, <i>Getting Started Guide: OneTouch® Delica® Plus Lancing Device</i> (2019) [produced in <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal.), FACET_002127–2128]
2048	LifeScan IP Holdings, LLC, <i>Lancets – 33 Gauge OneTouch® Delica® Plus Lancets OneTouch Solutions</i> (Mar. 11, 2022), https://shop.onetouch.com/onetouch-delica-plus-lancets-33g/product/OTSUS01_0014 (last visited Jan. 5, 2023, 16:47:17 GMT) [produced in <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal.), FACET_002129–2131]
2049	LifeScan IP Holdings, LLC, <i>OneTouch® Delica® Plus Lancets - 30 Gauge OneTouch Solutions</i> (Mar. 11, 2022), https://shop.onetouch.com/onetouch-delica-plus-lancets-30g/product/OTSUS01_0008 (last visited Jan. 5, 2023, 16:47:19 GMT) [produced in <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal.), FACET_002132–2134]
2050	Email exchanges between Facet and Asahi [produced in <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal.), LSI0000003603–3604] (CONFIDENTIAL)
2051	Email exchanges between Facet and Asahi [produced in <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal.), LSI0000003605–3607] (CONFIDENTIAL)
2052	LifeScan Agreement [produced in <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal.), LifeScan000001–14] (CONFIDENTIAL)

Exhibit	Description
2053	<i>Wire-Twist™ Wire Connectors: Models WT1, WT2, WT3, WT4, WT6</i> (Product Fact Sheet), Ideal Industries, Inc.
2054	Japan Patent Office, Patent Publication (B2), No. 3621502 (“Morita”)
2055	Karl Warsi, SIMPLY MATHS 101 (Michael Clark et al. eds. 2022) (excerpt)
2056	Declaration of John M. Collins in support of the Patent Owner Response (“Collins POR Decl.”)
2057	Answer to Complaint, <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal. May 11, 2022), ECF No. 42
2058	Facet Supply Agreement [produced in <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal.), FACET_00005340] (CONFIDENTIAL)

I. Introduction

According to the Centers for Disease Control and Prevention, “[r]egular blood sugar monitoring is *the most important thing* you can do to manage type 1 or type 2 diabetes.” Ex. 2027.¹ Such monitoring requires pricking a finger with a lancet, collecting a small blood sample, and testing the blood sample with a test strip. *Id.* The poor design of traditional lancets, however, made them difficult to handle and easily resulted in inadvertent needle pricks.

Patent Owner Facet Technologies (“Facet”) changed that. The invention claimed in the ’635 patent made lancets much easier to handle and reduced the risk of accidental needle pricks—increasing sales and spurring competitors, like Petitioner LifeScan, to copy Facet’s innovative lancet design. Facet initially supplied LifeScan with patented, proprietary lancets embodying the ’635 patent, which LifeScan sold as the OneTouch Delica—selling [REDACTED] in under a decade.

[REDACTED]

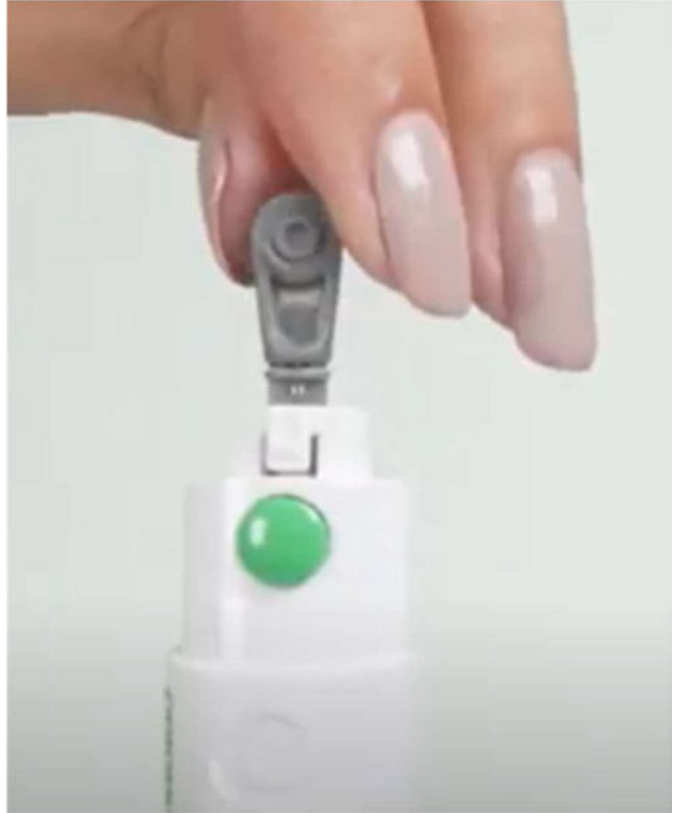
[REDACTED]

[REDACTED]

[REDACTED]

¹ Unless otherwise noted, all emphases are added and internal quotation marks and citations are omitted.

OneTouch Delica Plus lancet and lancing system (on the right, below), is a blatant copy of Facet’s Delica (on the left, below).



When its knock-off product was ready in 2019, LifeScan abruptly

[REDACTED] And because LifeScan copied Facet's proprietary lancets, they are interchangeable with the Delica products (i.e., they may be used in the same lancing devices (Exs. 2046-2049), unfairly capitalizing on LifeScan's customer base that was built with Facet's patented technology.

II. '635 Patent Overview

The inventors of the '635 patent recognized certain weaknesses in the then-existing lancets and caps—namely that they were difficult to handle, especially for diabetics with mobility issues—and invented a solution. The challenged claims reflect that solution via specific dimensional limitations. For example, the claimed ratio of the lancet gripping handle lateral span to lancet thickness (claims 6, 14) makes the device easier to handle. '635 Patent (Ex. 1001), 6:51-54, 6:66-7:3 (The “greater width[] allow[s] the user to more easily twist the endcap during removal from the lancet” and “easier use by persons with limited dexterity or vision.”). As another example, the length of the handle portion (claims 7, 8, 17, 18), “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.* 6:61-66; Ex. 2056 (Collins POR Decl.), ¶¶ 23-30.

Facet's patented lancets and caps were a huge commercial success.

[REDACTED] Ex. 2030 (FACET_532894); *infra* Section VI.C (objective evidence of commercial success).

[REDACTED]

[REDACTED] *See*

Ex. 2024 (deposition testimony of [REDACTED] 159:23-161:9, 164:13-165:19; *see also infra* Section VI.B (objective evidence of copying)).

A. Person of Ordinary Skill in the Art

For the purposes of this IPR only, Facet does not dispute LifeScan's definition of a person of ordinary skill in the art (POSA). Pet. 7-8. Facet reserves the right to argue alternative POSA definitions in other proceedings.

III. Claim Construction

For the purposes of this IPR only, Facet does not dispute LifeScan's proposed constructions and reliance on plain meaning as set forth in the district court's claim construction order. Pet. 8. Facet reserves the right to argue alternative constructions in other proceedings.

IV. Grounds 1-3: The Challenged Claims Are Patentable over Saikley, Stout, and the FreeStyle Manual

LifeScan failed to meet its burden for Grounds 1-3 for multiple reasons.

First, the challenged claims require, *inter alia*, three distinct components, namely a primary sheath, secondary sheath, and a gripping handle portion between and attached to the two sheaths. LifeScan does not, and cannot, consistently identify

² [REDACTED] is a witness for LifeScan in the co-pending litigation. [REDACTED]

[REDACTED] *See* Ex. 2035 (notice of interested parties).

three components in Saikley that correspond to these three components. In short, LifeScan identifies Saikley's protective cap 78 (also called a "handling tab" in the figure), as the gripping handle portion, but that component is not between and attached to the alleged sheaths as required by the claims. To hide that fact, LifeScan changes its mapping of the claims to Saikley's components as needed to meet certain claim elements.

Second, LifeScan acknowledges that the art fails to expressly disclose the dimensions required by the claims. LifeScan argues instead that a POSA would have known that Saikley possesses the claimed dimensions, or that the dimensions would have been obvious. LifeScan's arguments fail for multiple reasons, as explained in the following sections.

A. Saikley Does Not Disclose a Lancet Cap With a Gripping Handle Portion *Between* the Primary and Secondary Sheaths

The challenged claims recite a protective sterility cap with three distinct components arranged and "attached" to each other as follows:

- "*a primary sheath* for initial embedment of a sharp lancing tip of an unused lancet therein,"
- "*a secondary sheath* for receiving the sharp lancing tip of a used lancet,"

- “*a gripping handle portion* extending between the primary sheath and the secondary sheath,”
- “with the *primary sheath attached* at a first end of the gripping handle portion and the *secondary sheath attached* at a second end of the gripping handle portion.”

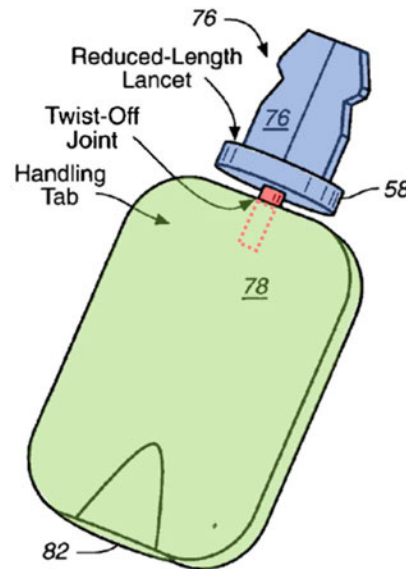
E.g., '635 Patent, cls. 6 (via disclaimed claim 1), 14; Ex. 2056 ¶¶ 59-60.

Grounds 1-3 fail because LifeScan failed to show that Saikley teaches these three components arranged and attached as in the claims and does not argue that they would have been obvious. Specifically, LifeScan identifies Saikley's “protective cap 78” (also called “handling tab” in Figure 7A)³ as corresponding to the claimed gripping handle. Pet. 19. Saikley's protective cap/handling tab does not, however, “extend[] *between* the primary sheath and the secondary sheath,” as recited in the claims. Ex. 2056 ¶ 67. To obfuscate that fact, LifeScan inconsistently maps these three claim features to Saikley in an attempt to create the illusion that Saikley's cap/tab 78 is between and attached to the two alleged sheaths.

To explain, LifeScan first contends that Saikley's “primary sheath” consists of “the ‘twist-off joint’ [*colored red in Fig. 7a below*] and the adjoining portion of

³ LifeScan inconsistently refers to Saikley's “handling tab” and “protective cap 78,” as will be discussed shortly.

the 'handling tab' [*red dashed lines*] that 'covers the lancet sharp 50' of the 'shortened lancet 76' [*blue*] prior to use."



Pet. 11 & Fig. 7A (annotations in Petition); *see also id.* 13 (“the twist-off joint and adjoining portion of the protective sterility cap 78”), 19, 20, 26.

But apparently realizing that this mapping fails to meet the claims—the lancet tip is embedded in Saikley’s tab/cap 78, not the twist-off joint⁴—LifeScan changes

⁴ The claims recite a “primary sheath *for initial embedment of a sharp lancing tip* of an unused lancet therein,” and LifeScan does not contend that “sheath” should be construed differently with respect to the claimed primary and secondary sheaths. *See* Pet. 8 (a sheath ““*cover[s] the sharp lancing tip* of a [] lancet by *embedding or enclosing the lancet tip*””); *Paragon Sols., LLC v. Timex Corp.*, 566 F.3d 1075, 1087

its position later in the Petition. LifeScan argues that Saikley's primary sheath is cap 78 by itself, now without the twist-off joint—alleging that Saikley discloses a primary sheath because its “needle tip is embedded in [a] removable protective cap” and that it would have been obvious to “embed[] the lancet needle into Saikley's cap 78.” Pet. 45-47 (emphasis in Petition); Ex. 2056 ¶¶ 61-64.

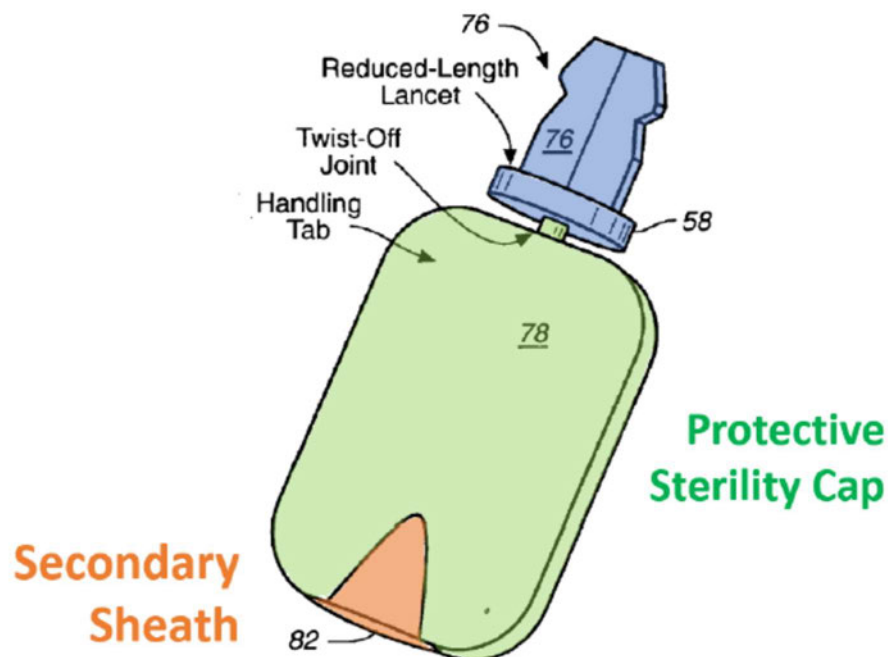
Before going further, note that LifeScan sometimes interchanges the terms “handling tab” and “cap 78,” especially when discussing the primary sheath. Compare e.g., Pet. 11 (“adjoining portion of the ‘*handling tab*’”), with *id.* 13 (“adjoining portion of the *protective sterility cap 78*”). Other times, LifeScan contends that Saikley's cap 78 merely “includes” a handling tab, as opposed to being the same thing. E.g., *id.* 19 (“protective cap 78 includes a ‘handling tab’”), 47 (primary sheath includes the “adjoining portion of the handling tab of the protective cap 78”). For clarity and brevity, this brief has been and will continue to refer to “tab/cap 78” or similar as the alleged gripping handle portion.

And elsewhere depending upon the claim feature at hand, LifeScan contends the alleged primary sheath is (i) the twist-off joint and a portion of the tab/cap, (ii) just the twist-off joint (without the tab/cap), and (iii) the cap 78 by itself. *Id.* 11, 13,

(Fed. Cir. 2009) (discussing the presumption that “the same terms appearing in different portions of the claims should be given the same meaning”).

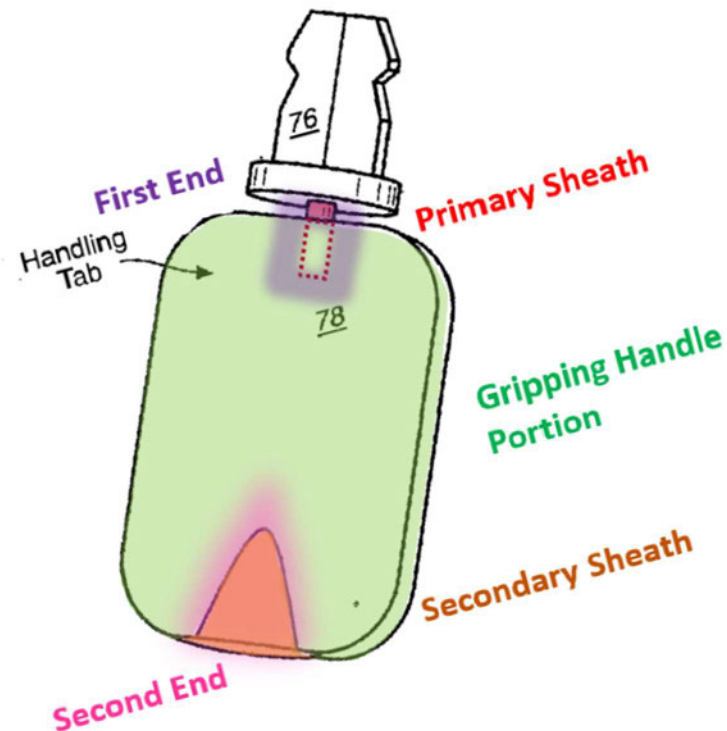
26, 45-47. As will be discussed below, these are not the only internal contradictions in LifeScan's mapping to Saikley, but it should be understood that LifeScan's Petition is fatally inconsistent on these points.

Moving on, LifeScan further contends that the claimed secondary sheath corresponds to Saikley's "hollow cup or solid 'pin cushion' type area 82 at the opposite end of cap 78, as shown in FIG. 7A [*orange below*]."



Pet. 14-15 & Fig. 7A (annotations and emphasis in Petition); Ex. 2056 ¶ 65. LifeScan also contends that tab/cap 78 corresponds to the claimed gripping handle, but fails to show that it is "between" and "attached to" the primary and secondary sheaths as required by the claims. That is, LifeScan contends that the primary sheath corresponds to "the adjoining portion of the 'handling tab' [*red dashed lines*]" (Pet.

11, 13 (referring to cap 78 instead of the tab (original emphasis)), as shown above and below in another of LifeScan's annotations of Saikley's Figure 7A:



Id. 27-28. But Saikley's tab/cap 78 is not between and attached to the alleged sheaths, and the sheaths are not attached at its first or second "end" as required by the claims. Instead, tab/cap 78 surrounds the alleged sheaths and itself forms a portion or all of the primary sheath rather than being attached to it. Ex. 2056 ¶ 66.

Where, as here, the claim lists physical elements separately, "the clear implication of the claim language" is that those elements are "distinct component[s]" of the patented invention. *Gaus v. Conair Corp.*, 363 F.3d 1284, 1288 (Fed. Cir.

2004). For example, where a claim provides for two distinct elements, a “second portion” and a “return portion,” these two elements “logically cannot be one and the same.” *Engel Indus., Inc. v. Lockformer Co.*, 96 F.3d 1398, 1404-05 (Fed. Cir. 1996). Further, the conclusion that the gripping handle and two sheaths are all distinct components is compelled by the claims’ requirement that they are “attached” to each other, as just discussed. Ex. 2056 ¶ 60.

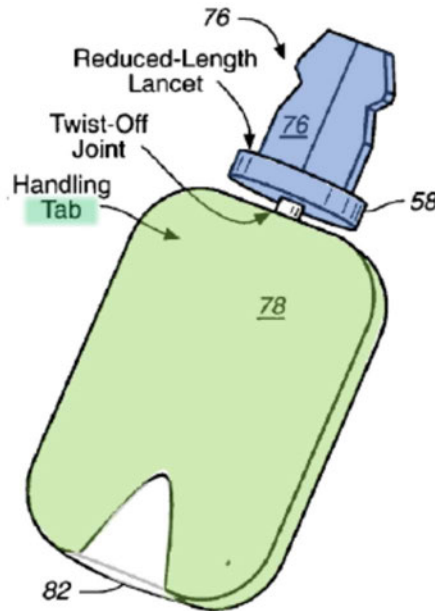
But LifeScan fails to point to distinct components for each. When addressing the “between” and “attached” limitations, LifeScan hides this fatal fact by changing its position regarding the primary sheath. Saikley’s primary sheath is now limited to the twist-off joint by itself, and no longer includes the “adjoining portion of the handling tab” (Pet. 11, 28, 47) or “cap 78” (*id.* 13, 19; *see also id.* 37 (“pull-off tab 78”)):

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

Id. 26 (original alterations). Importantly, this claim mapping is plainly incorrect, as the needle tip is embedded in the primary sheath (as LifeScan admits, *see, e.g., id.* 27-28), not the twist-off joint. Ex. 2056 ¶ 67; *see also* Pet. 8 (construing sheath).

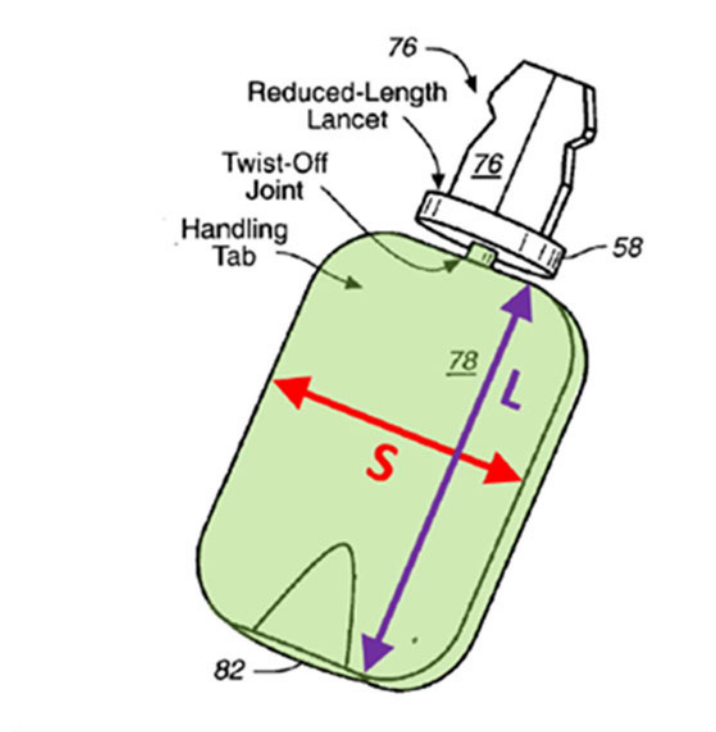
LifeScan also sometimes alleges that the entire cap 78—by itself and without the twist-off joint—is the primary sheath. Pet. 45-47. But LifeScan also argues with respect to dependent claim 5 that all of “protective cap 78,” without any primary

sheath, is the alleged gripping handle, as show in its annotated drawing reproduced below:



Pet. 34-35.

Other LifeScan arguments also hinge on Saikley's handling tab/cap 78 being decidedly ***not*** between the two sheaths. For claim 7, LifeScan includes the lengths of both sheaths in its alleged length of the gripping handle (tab/cap 78), as shown below in another LifeScan-annotated Figure 7A:



See Pet. 41 (original annotations); see also *id.* 43 (similar figure for claim 8).

LifeScan also argues that “the length of [Saikley’s] cap 78 is significantly larger than the cap’s lateral span,” again equating cap 78 with the gripping handle to meet the length limitation. *Id.* 40-41. Note that LifeScan now identifies the entirety of “cap 78” as the gripping handle portion—it is no longer some undefined and amorphous “handling tab” that might, or might not, be coextensive with cap 78.

And later, LifeScan unequivocally contends that the primary sheath is just cap 78 itself, without the twist-off joint:

A. All Claims: “Primary Sheath for Initial Embedment”

As shown in Ground 1 above, Saikley anticipates this limitation by depicting and disclosing that “cap 78 may be an **integrally molded**, pull-off tab, such as shown in FIG. 7A” because a PHOSITA would

know that “the needle tip is **embedded** in [a] removable protective cap integrally molded with the plastic body to form a single integral unit prior to use.”

Id. 45 (heading and emphases in Petition); *see also id.* (“needle sharp embedded in the protective cap 78”), 46 (“embedding the lancet needle into Saikley’s cap 78”), 47 (meeting the primary sheath limitation by “modify[ing] Saikley’s cap to include an embedded needle sharp”). This mapping at least tracks the claims, unlike others, in that the lancet tip is embedded and enclosed in Saikley’s tab/cap 78 rather than the twist-off joint, but it precludes meeting the “between” limitation. Ex. 2056 ¶ 64.

LifeScan cannot have it all these different ways, changing its claim mapping as needed to meet the different claim elements. LifeScan’s failure to identify its position with particularity, by itself, compels a finding that LifeScan failed to meet its burden. *See* 35 U.S.C. § 312(a)(3); 37 C.F.R. §§ 42.104, 42.22; *Intelligent Bio-Systems, Inc. v. Illumina Cambridge, Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016).

The Petition also fails on the merits. LifeScan did not even allege, much less demonstrate, that any one of its different mappings meets all of the claim elements of all of the challenged claims. Instead, LifeScan varied its position as needed to meet the claim limitation at hand—thus failing to meet its burden to demonstrate unpatentability.

* * *



In sum, LifeScan failed to demonstrate that Saikley teaches the claimed gripping handle between and attached to the two sheaths as recited in the claims. LifeScan does not contend that either Stout or Freestyle remedy this defect in Saikley. Accordingly, LifeScan's Grounds 1-3 fail.

B. Saikley, Alone or in Combination, Does Not Disclose or Render Obvious the Dimensional Limitations

Saikley, alone or with Stout, does not teach or render obvious the recited dimensional limitations, namely, that the gripping handle have:

- “a lateral span of at least 1.5 times the lancet thickness” (claims 6-8 and 14-18),
- “a length at least equal to its lateral span” (claims 7 and 17), and
- “a length at least equal to the lancet thickness” (claims 8 and 18).

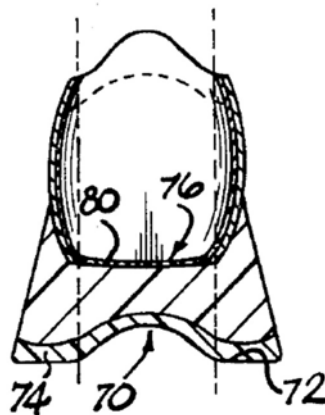
These points will be discussed in the following subsections after a review of the law.

1. Legal Background: “Proportions of features in a drawing are not evidence of actual proportions when drawings are not to scale”

The above heading is a quote of MPEP 2125's title that accurately sums up the law. Patent figures are not ordinarily drawn to scale, but are instead “merely illustrative of the principles embodied in the alleged invention.” *In re Olson*, 212 F.2d 590, 592 (C.C.P.A. 1954). Unless they are drawn to scale, patent figures do not reasonably disclose or suggest dimensions, proportions, or relative sizes.



In *Hockerson-Halberstadt, Inc. v. Avia Group International*, for example, the Federal Circuit rejected HHI's argument that patent figures clearly "depict[ed] a groove that is wider than the fins[]" on the sole of a shoe. 222 F.3d 951, 956 (Fed. Cir. 2000). The patent-at-issue's figures show a groove 70 that clearly appears to be much wider than fins 72 and 74:



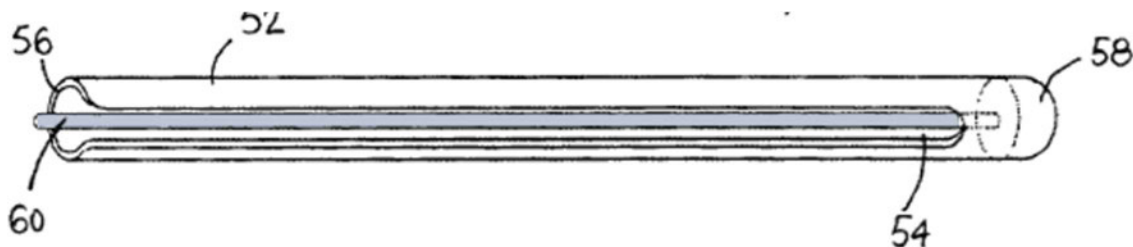
Ex. 2022 Fig. 10. But as the Court explained, "HHI's argument ... hinges on an inference drawn from certain figures about the quantitative relationship between the respective widths of the groove and fins," and the "patent [wa]s devoid of any indication that the proportions of the groove and fins are drawn to scale." *Hockerson*, 222 F.3d at 956. "[F]igures in a patent are not drawn to scale unless otherwise indicated," and, absent any such indication, they cannot be relied upon even to show relative sizes. *Id.*

And in *Nystrom v. Trex Co.*, the Federal Circuit reversed a district court ruling that a patent figure disclosed a claimed height-width ratio of "about 1:40" when it was measured as 1:39. 424 F.3d 1136, 1148 (Fed. Cir. 2005), *aff'd*, 200 F. App'x

987 (Fed. Cir. 2006) (per curiam). “The district court erred” because “arguments based on drawings not explicitly made to scale in issued patents are unavailing.” *Id.* at 1148-49.

And in *Plantronics, Inc. v. Aliph, Inc.*, the Federal Circuit relied on *Hockerson* to reject argument that certain objects were “elongated,” i.e., longer than they are wide. 724 F.3d 1343, 1351 (Fed. Cir. 2013) (also quoting *In re Wright*, 569 F.2d 1124, 1127 (C.C.P.A. 1977) (“[a]bsent any written description in the specification of quantitative values, arguments based on measurement of a drawing are of little value”).

Likewise, the Federal Circuit also rejected an attempt to rely on “relative sizes shown in the [patent] figures” to show that “slot 54” is wider than “rod 60.” *Source Vagabond Sys. Ltd. v. Hydrapak, Inc.*, 753 F.3d 1291, 1300 (Fed. Cir. 2014). In this case, the patent figures show a slot 54 that appears to be significantly wider than rod 60 (shaded):



Id. at 1294-95 (reproducing the relevant patent figures).

Nonetheless, the Federal Circuit confirmed that it would be improper to draw any conclusions regarding the relative sizes of these components. “[P]atent drawings

do not define the precise proportions of the elements depicted and may not be relied on to show particular sizes if the specification is completely silent on the issue.” *Id.* at 1300 (quoting *Hockerson*, 222 F.3d at 956); *see also Neutrino Dev. Corp. v. Sonosite, Inc.*, 423 F. Supp. 2d 673, 678 (S.D. Tex. 2006) (“[T]he Court does not believe that the Federal Circuit in *Hockerson-Halberstadt* intended for ‘precise proportions’ to carry a meaning distinct from ‘relative size.’”), *aff’d*, 210 F. App’x 991 (Fed. Cir. 2006) (per curiam).

The Board cited the Federal Circuit’s non-precedential *PlaSmart* decision in finding that patent drawings that are not to scale can somehow convey dimensions, proportions, or relative sizes despite clear Federal Circuit precedent to the contrary. Institution Decision at 25. But *PlaSmart* did not, and cannot, overturn decades of binding Federal Circuit jurisprudence consistently holding that patent drawings cannot be used to determine dimensions, proportions, or relative sizes—not even relative sizes that appear to be clearly met in the figures—unless the figures are drawn to scale. In fact, relative sizes were not even at issue in *PlaSmart*. The *PlaSmart* court merely found that the Board “properly referred to the rest of the disclosure” after concluding that the figure “did not clearly disclose a safety wheel attached to an arm” in the particular manner—not size—required. *PlaSmart, Inc. v. Kappos*, 482 F. App’x 568, 573 (Fed. Cir. 2012).

Likewise, *Aslanian* (cited in Institution Decision at 25 and 42) does not eviscerate an entire body of Federal Circuit case law with the true statement that, in an obviousness analysis (but not anticipation), disclosures should be evaluated for “what they reasonably disclose and suggest” to a POSA. *In re Aslanian*, 590 F.2d 911, 914 (C.C.P.A. 1979). Like *PlaSmart*, *Aslanian* has nothing to do with dimensions, proportions, and relative sizes, and is therefore not in tension with the Federal Circuit's longstanding jurisprudence.

In sum, drawings that are not to scale cannot be used by themselves to show that the art teaches or suggests dimensions, relative dimensions, or proportions. For example, *Hockerson's* groove looked much wider than its fins, and *Source Vagabond's* slot looked much wider than its rod. Nonetheless, those drawings did not convey—reasonably or otherwise—relative size or proportion information to the POSA because there was no indication that the drawings were to scale.

2. All Challenged Claims: Saikley does not disclose the claimed dimensions

Saikley fails to expressly disclose any dimensions, much less the claimed ratios of the alleged gripping handle span to its length, the gripping handle span to the lancet body thickness, or the gripping handle length to the lancet body thickness. LifeScan presents no argument or evidence to the contrary.

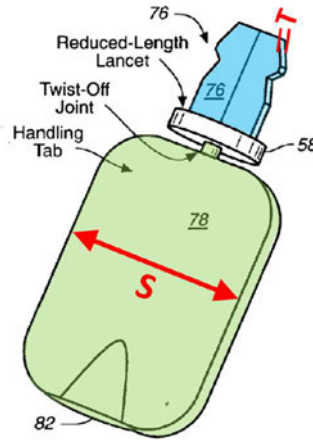
LifeScan instead legally errs by relying on its own measurements and annotations of Saikley's Figure 7A, despite the fact that Saikley is completely silent



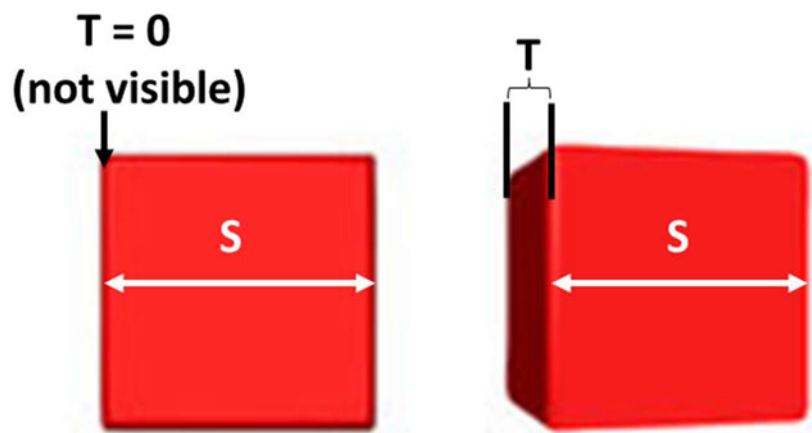
as to whether its figures are to scale, proportional, or in any way indicative of dimensions. Ex. 2056 ¶¶ 68-71; *see supra* Section IV.B.1 (Legal Background).⁵ Indeed, the district court in the related litigation denied LifeScan's motion for summary judgement as contrary to Federal Circuit law for this very reason. Ex. 2021. As explained in the above Legal Background section, "proportions of features in a drawing are not evidence of actual proportions when the drawings are not to scale." MPEP 2125 (title).

Further, LifeScan's measurements of Saikley's Figure 7A are demonstrably unreliable. Ex. 2056 ¶¶ 68-85. For example, LifeScan contends that Figure 7A "clearly depicts a handling tab (*green*) with a lateral span (annotated "S" with arrows) that is far more than 1.5 times the lancet thickness (*yellow*) of the lancet body (*light blue*)," pointing to its annotated version of Figure 7A, reproduced below:

⁵ LifeScan also contends that Facet acquiesced to the patentability of the claimed ratios because Facet did not argue them during prosecution. Pet. 50 n.2. That is not the law. *TorPharm, Inc. v. Ranbaxy Pharms., Inc.*, 336 F.3d 1322, 1330 (Fed. Cir. 2003).

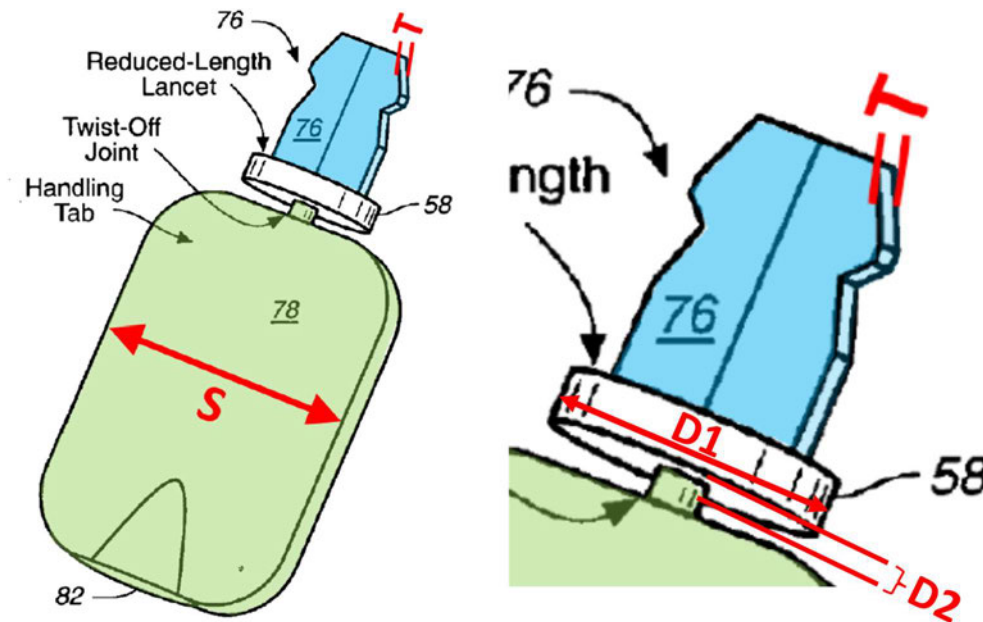


Pet. 37-38 (annotating Saikley Figure 7A, and citing Exhibit 1002 ¶ 102, where Mr. Delman merely professes his belief that the above statement is true without further explanation). LifeScan's (and Mr. Delman's identical) conclusory assertions are contrary to law (*see infra* Legal Background section), and incorrect as a factual matter. Ex. 2056 ¶¶ 71-79. A POSA would have understood that the size of T as drawn in the figure is a function of how far the lancet is rotated about a longitudinal axis. For example, if a cube is rotated a small amount, its lateral span "S" appears much larger than its thickness "T," even though they are in fact equal size:



Id. ¶ 79. A POSA could not reasonably conclude the figure on the right above “clearly depicts” an object with a lateral span S “that is far more than 1.5 times” the object’s thickness, T . *Id.*

Similarly, the base of cylindrical collar 58 appears as a narrow ellipse or ellipse-like shape in Figure 7A, with $D1$ drawn much larger than $D2$:



Pet. 41 & Fig. 7A (annotations in Petition); Ex. 2056 ¶ 80 (excerpting and further annotating LifeScan’s figure). Again, a POSA could not reasonably conclude that Figure 7A “clearly depicts” cylindrical collar with an elliptical base having a major axis $D1$ “that is far more than 1.5 times” the minor axis $D2$. Ex. 2056 ¶ 80. Indeed, the parties agree that $D1 = D2$, i.e., cylindrical collar 58’s base is a circle. *Id.*; Ex. 2028 (Delman IPR Dep.), 17-23 (Mr. Delman admitting during cross that cylindrical collar’s base is circular).

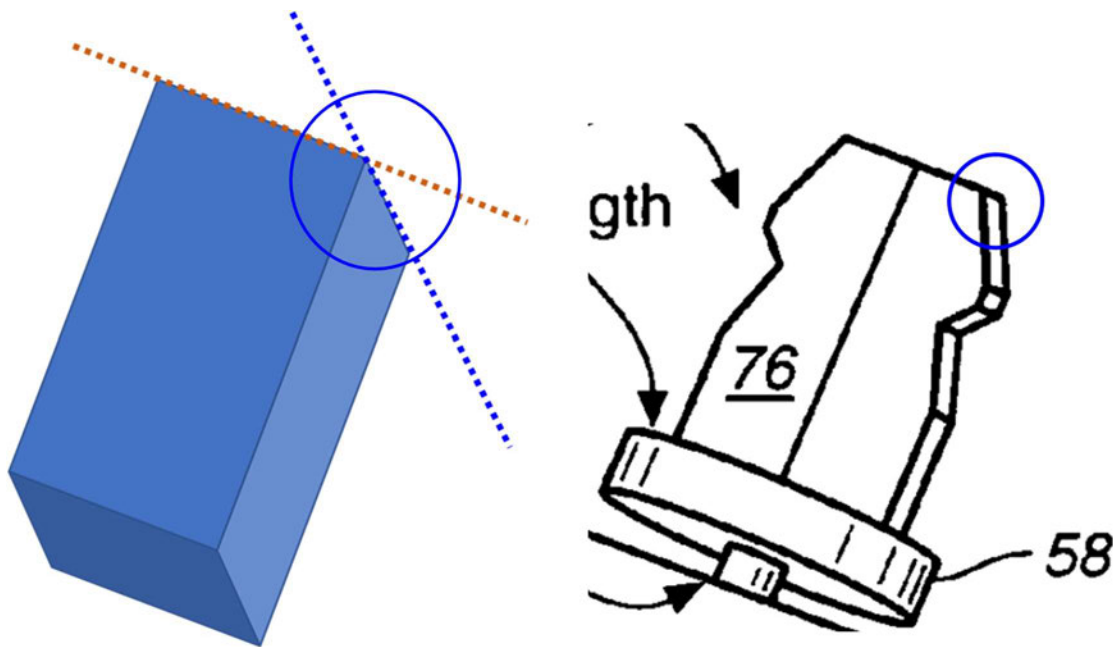
Likewise, a POSA could not reasonably conclude that Figure 7A clearly depicts a lateral span S that is at least 1.5 times as long as thickness T . Even if Figure 7A was to scale (it is not), LifeScan and Mr. Delman would have needed to determine and account for the relative angles (in all three dimensions) between the portrayed lancet and the paper. But Mr. Delman failed to take any such angles into account, and his testimony is therefore unreliable as a factual matter. Ex. 2056 ¶¶ 71-79. And even if he did take these relative angles into account, his opinion is due no weight because he failed to include those “underlying facts or data on which [his] opinion is based,” as well as his analysis. 37 C.F.R. § 42.65(a).

In addition, LifeScan (and Mr. Delman) failed to account for foreshortening, which is why distant objects are drawn smaller than closer objects of the same size. Ex. 2028 at 10-11. Mr. Delman testified that, at least to him, Figure 7A seems like it may be drawn in perspective (as opposed to an isometric drawing, that has no foreshortening). *Id.* 10-14. And here, the viewer can see the bottom of the cap and the lancet's cylindrical collar 58, indicating that the lancet is further away from the viewer than the cap—thus, “ T ” should appear smaller on the paper than it actually is for this additional reason. Ex. 2056 ¶¶ 82-84. Yet LifeScan and Mr. Delman failed to take foreshortening into account, either.

Even worse, Figure 7A is internally inconsistent—demonstrating that it is wholly unreliable. The lancet's cylindrical collar 58 is rotated some amount about a



lateral axis, revealing the collar's circular bottom surface. But the lancet body itself is not, as evidenced by the fact that its thickness lines are not also rotated in the same direction—with the top thickness line on the lancet remaining perfectly parallel with the top, front edge of the lancet body. To explain, the blue rectangular 3-D object to the left below has been similarly rotated about a lateral axis to reveal its bottom surface. Its thickness lines are thus rotated from parallel to its width as illustrated by the dotted blue line. In contrast, the thickness lines in the lancet body (including where LifeScan measured “T”), are not rotated as they would be if the lancet body was rotated with its collar, as shown below on the right:



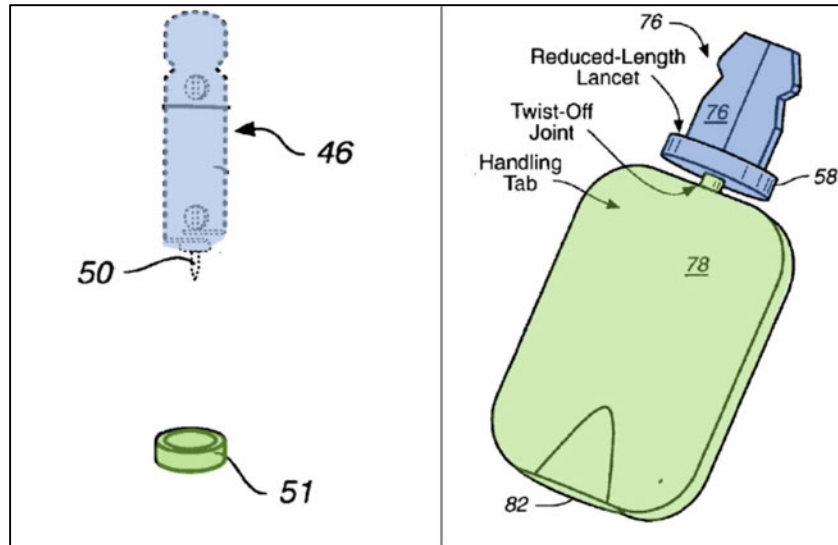
Ex. 2056 ¶ 81. Indeed, Figure 7A is so poorly drawn that Mr. Delman could not even determine the actual shape of item 82 on the bottom of the cap. Ex. 2028 at 24. Thus, Figure 7A therefore *cannot* be used to determine 3-D measurements for the

additional reason that the lancet body, collar, and cap are not rotated any consistent, particular amount. This true as a factual matter, and as a matter of law.

LifeScan's arguments looking outside of the figures fail, and further call into question the credibility of LifeScan's industrial design expert⁶ on matters involving lancets. In particular, LifeScan and Mr. Delman argue that the dimensional limitations are met because Saikley states that "protective cap 78 ... should be made *much larger than usual* to aid handling." Saikley (Ex. 1005), [0050]; Pet. 38-39.

The foundational question, then, is much larger than *what*—how large was the "usual" cap? Lacking an answer in the Petition, LifeScan's argument fails. And when pressed, Mr. Delman admitted that he did not know, but offered to measure prior-art caps if provided. Ex. 2028 at 58-63. Indeed, Mr. Delman could not even state the size of the Delica and Delica Plus lancet caps at issue in the parties' disputes. *Id.* 57-58. Mr. Delman's unfamiliarity with the very basics of this case—typical cap sizes—demonstrates that his opinion is unreliable and unsupported. And notably, he provides the following example in his declaration that shows, according to Mr. Delman, a "traditional lancet" on the left and Saikley's "improved lancet" on the right:

⁶ Mr. Delman admits he is not an engineer, but holds an industrial design degree, and has never designed a lancet cap himself. Ex. 2028 at 7-8.



Ex. 1002 ¶ 76 (annotating Saikley Figures 3 and 7A). LifeScan provides no reason to conclude that a cap “much larger” than the very small one on the left would meet the claims. Ex. 2056 ¶ 85.

LifeScan and Mr. Delman further damage their credibility by contending that a POSA would have understood that Saikley’s cap is wider than an average human thumb.⁷ Pet. 39. But lancets and caps are tiny, and Mr. Delman admits that he has

⁷ LifeScan and Mr. Delman carelessly allege that an average thumb is 16 mm wide based on Exhibit 1022’s measurements of the thumbs of *three- and four-year-old children*. Pet. 39; Ex. 1002 ¶ 104; Ex. 1022 at 158 (table, with thumb diameter increasing to 19 mm for ten-year-olds). An adult human thumb is approximately 25 mm wide. Ex. 2056 ¶ 86; Ex. 2029 at 6. Notably, LifeScan later asserts that

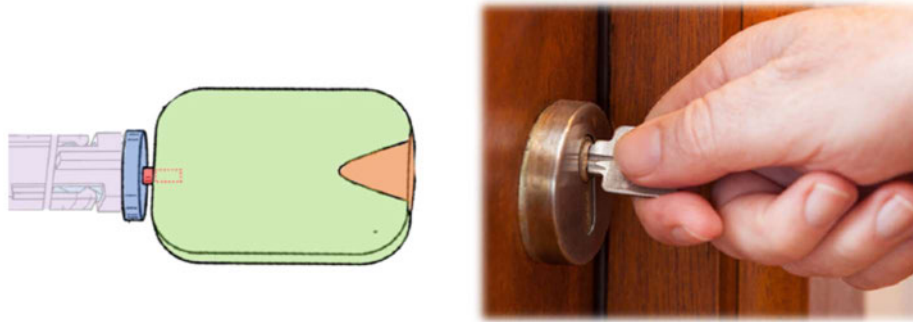
never seen such a gargantuan cap on an actual lancet. Ex. 2028 at 63-64.⁸ For example, Facet's products and LifeScan's infringing copies are nowhere near the width of a human thumb:



Ex. 2056 ¶ 87 (also showing that the spans of these caps are 5.7 to 6.9 mm, which is far less than 25 mm or even 16 mm). LifeScan and Mr. Delman point to no *evidence*, other than their own ill-informed say-so, that a POSA would have understood that Saikley's cap 78 is larger than a thumb, like a key used to open a door lock:

human *fingertips* are 16-20 mm wide—bigger than their alleged average *thumb*. Pet. 52.

⁸ The only possible exception is a prototype Mr. Delman constructed based solely on Saikley's figures for the purposes of this litigation, and therefore would be unreliable, too, even if it had been included in this proceeding. Ex. 2028 at 63-64.



Pet. 24-25 (“Demonstratives”); Ex. 1002 ¶¶ 79-80.

A POSA, who is by definition familiar with typical lancet cap sizes, would have disagreed with Mr. Delman, who admitted he is not. Pet. 7-8; Ex. 2028 at 58-63. To start, LifeScan’s two “demonstratives” (reproduced above), are not to scale. As LifeScan admits, a POSA would have known that a typical lancet was under 6 mm across. Pet. 39. That is *smaller* than the 8 mm wide portion of a key like the one pictured above that goes *inside* of a lock—the shoulder portion visible just outside the lock is typically well over 12 mm wide—far wider than the lancet body in LifeScan’s figure on the left. Ex. 2056 ¶ 88 (measuring his own house key).

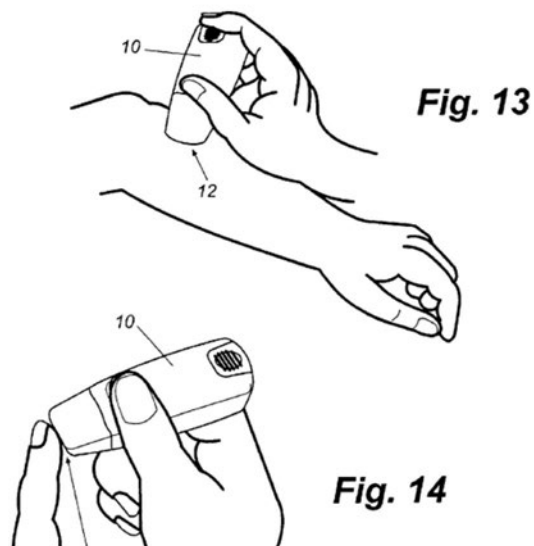
And despite Mr. Delman’s speculation to the contrary, removing the cap from a typical commercial lancet requires a relatively minute amount of torque or force compared to a house key. *Id.* ¶¶ 89-90 (explaining that removing twist-off lance caps require only a few newton-centimeters of torque). LifeScan’s reference, Stout, includes the well-known fact that caps and lancets “are connected at a narrow or notched neck portion for ease of separation” (Stout (Ex. 1018), [0035]), just as

shown by Saikley's twist-off joint. Ex. 2056 ¶ 91. Notably, Stout's cap is no wider than its presumably 6 mm-wide lancet (and certainly nowhere near the typical thumb width of 25 mm), yet plenty of force is available to remove the cap *and even to release a used lancet from the device*. See Stout [0041] & Figs. 8c-d, 8g-h.

Rather than providing insufficient leverage because the cap is too small, a significant concern in the lancet industry was *inadvertent* cap removal, such as during transit or when handling. Ex. 2056 ¶ 92. Saikley is no different—it never hints that significant torque is needed to remove its cap, as LifeScan speculates. *E.g.*, Saikley [0050]; Ex. 2056 ¶ 91. And even if Saikley's cap were difficult to remove, a POSA would have made the twist-off joint smaller, rather than adding material (and thus cost) to the cap as LifeScan suggests. Ex. 2056 ¶¶ 92-95.⁹

LifeScan also points to the size of the lancing device (not the lancet) in Levaughn as support for its gargantuan-cap theory. Pet. 40. Levaughn, however, illustrates the absurdity of LifeScan's position that a lancet cap would be larger than a human thumb. Levaughn's lancing device has, like a real lancing device, the same width as, or slightly larger than, a thumb at 25-35 mm wide—far larger than a lancet or even a large cap like the Delica's.

⁹ LifeScan frames its argument as a POSA's understanding, but it approaches or even crosses the line into obviousness, which is further addressed later.



Levaughn (Ex. 1017), Figs. 13-14, 5:43-52 (stating a 25-35 mm lancing device width); Ex. 2029 at 6 (human thumb is about 25 mm wide); Ex. 2056 ¶ 97; *see also* Ex. 1010 at 15 (showing a lancet cap much smaller than the thumb). A POSA would have understood that a lancing device's size allows the user to apply sufficient pressure at the correct angle against a sampling site—and is not needed to provide sufficient leverage for removing a lancet cap as LifeScan suggests. Levaughn 1:50-2:8, 5:6-18; Ex. 2056 ¶ 96. LifeScan provides no valid reason to assume Saikley would subvert its stated goal of providing a “compact” system by using a gargantuan cap roughly as wide as the lancing device itself. Saikley [0050], [0064], [0101].

Finally, LifeScan repeatedly states that Saikley “inherently” discloses the claimed dimensions. *E.g.*, Pet. 39-40. LifeScan's inchoate inherency argument fails because LifeScan failed to allege (or proffer any evidence that could show) the claimed dimensions are “*necessarily* present, not merely probably or possibly

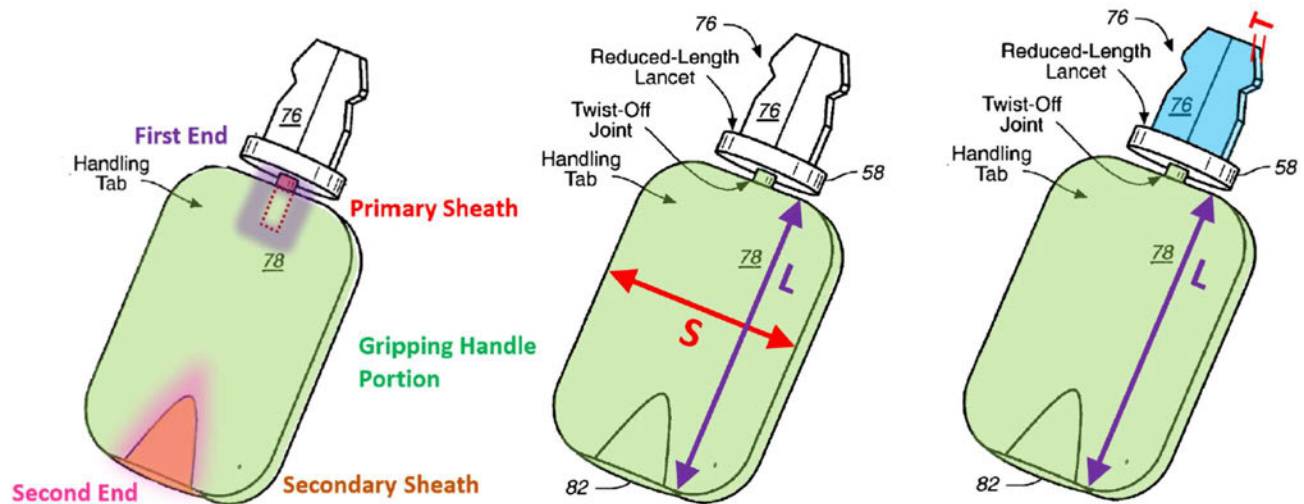
present, in [Saikley].” *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002). To the contrary, the evidence shows that the claimed dimensions are not present.

In sum, LifeScan failed to show that Saikley discloses any of the claimed dimensions in the challenged claims.

3. Claims 7, 8, 17, and 18: Saikley does not disclose the claimed length dimension

LifeScan makes similar arguments with respect to claims 7 and 8 (and thus 17 and 18), and they fail for the same reasons already discussed. Ex. 2056 ¶¶ 98-100.

LifeScan's arguments also fail for the additional reason that LifeScan's proposed “length” dimension is not the length of a gripping handle “between the primary sheath and secondary sheath,” as required by the claims:



Pet. 27, 41, 43 & Fig. 71 (annotations in Petition); Ex. 2056 ¶¶ 98-101. LifeScan's failure stems from its inconsistent claim mapping, as discussed above. LifeScan

cannot have it both ways, including the sheaths in the alleged gripping handle length when needed (as here) and other times not including them (e.g., when attempting to show the gripping handle “extending between” and “attached” to the ends of sheaths).

Further, Saikley does not show how far the needle penetrates into cap 78. LifeScan's red dotted line is nothing but speculation, as would be any measurement based on its placement. Even so, the distance between the two sheaths (assuming they are as LifeScan drew them in the far left figure above), appears less than Saikley's width. Ex. 2056 ¶¶ 102-104.

* * *

In sum, LifeScan failed to show that a POSA would have understood Saikley as disclosing the claimed dimensions in all of the challenged claims. LifeScan's flawed arguments regarding a POSA's knowledge notwithstanding, Figure 7A cannot be used to determine even relative dimensions, and provides a textbook example of why the Federal Circuit consistently forbids relying on patent drawings to determine dimensions or proportions of components.

4. All Challenged Claims: Saikley, alone or in combination with Stout, does not render obvious the claimed dimensions

LifeScan's obviousness arguments fall into two categories: (i) the claimed dimensions would have been obvious over Saikley alone (Pet. 47-53), and (ii) it



would have been obvious to use Stout's dimensions in Saikley (*id.* 53-57). LifeScan failed to meet its burden on both accounts, as explained in the following subsections.

a. The claimed dimensions would not have been obvious over Saikley alone

LifeScan's unsupported and hindsight-driven arguments regarding obviousness all fail.

To begin, LifeScan argues that the claimed dimensions are “meaningless” and therefore obvious. Pet. 48 (emphasis in original). Not so. LifeScan does not dispute that the claimed dimensions increase usability. Indeed, LifeScan argues throughout—even in the very next paragraph on the very same page—that the dimensions increase usability. *Id.* LifeScan also resorts to mischaracterizing *Hamilton* to support its dubious “meaningless” argument. The district court in *Hamilton* found that the claimed dimensions were indefinite: the combination of “less than approximately” and “greater than approximately” dimensions of a seatbelt buckle could not be construed and had no meaning. *Hamilton Prods., Inc. v. O'Neill*, 492 F. Supp. 2d 1328, 1340-41 (M.D. Fla. 2007) (“Indeed, if those dimensions read on any buckle that could be termed ‘universal,’ then they have actually no meaning.”). That is not the case here, and LifeScan does not allege otherwise.

LifeScan also contends—citing a non-binding 8th Circuit case—that claimed proportions and sizes are not patentable distinctions. Pet. 49 (citing *Airlite Plastics Co. v. Plastilite Corp.*, 526 F.2d 1078, 1082 (8th Cir. 1975)). But binding Federal



Circuit law differs—differences in size are patentable when the size provides a functional improvement, as here. *Gardner v. TEC Sys., Inc.*, 725 F.2d 1338, 1345-46 (Fed. Cir. 1984); *see also* MPEP 2144.04.

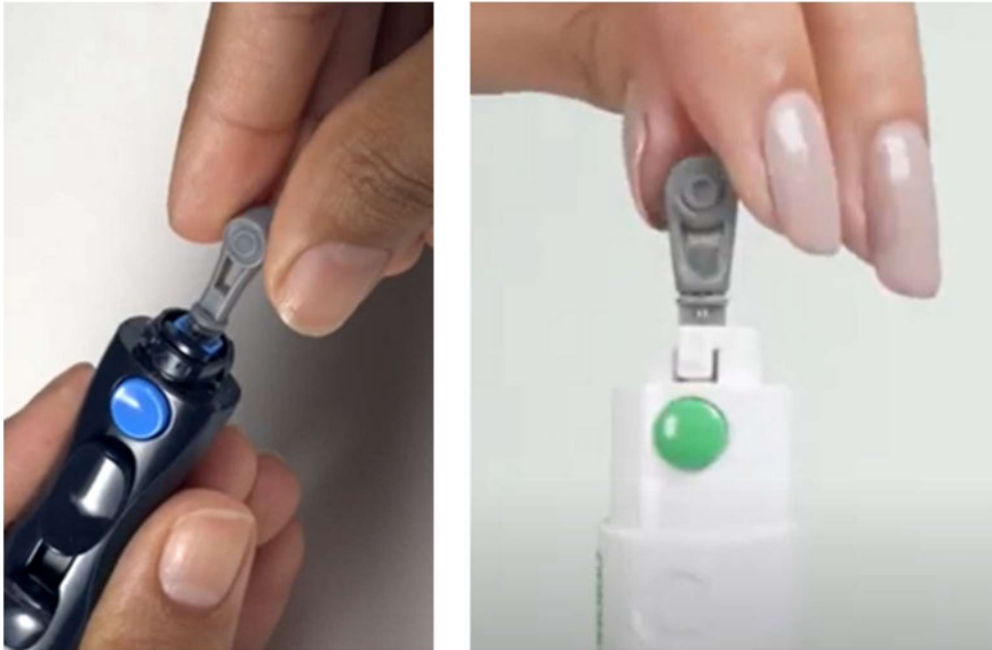
LifeScan also argues that the claimed dimensions were a matter of routine optimization because Saikley instructs the POSA to make its cap “larger than usual to aid handling.” Pet. 48-51. This argument fails, too, for multiple reasons. *First*, and as discussed with respect to anticipation, LifeScan and Mr. Delman do not know the usual cap size—they cannot answer the questions, “larger than what and in what way?”

Second, LifeScan argues again that it would have been obvious to make a gargantuan cap, this time larger than a human finger (16-20 mm wide) rather than a thumb. *See supra* Section IV.B.2 (debunking LifeScan’s argument that Saikley’s cap is larger than a human thumb); Pet. 52. That argument fails for similar reasons—there is no evidence that a POSA would have found it obvious to make such a gargantuan cap. LifeScan and Mr. Delman provide no examples of such large caps because there are none—such a large cap would be fraught with problems. The larger the lancet cap, the more raw material (and thus expense) required for manufacturing. Ex. 2056 ¶ 105. Indeed, LifeScan’s expert, Mr. Delman even acknowledged that cost was a significant factor in design, given that “[t]here is little leeway on such products for extra material costs.... The amount of plastic used in molding is thus among the

considerations when determining the overall form factor for the lancing device.” Ex. 1002 ¶ 23; Ex. 2056 ¶ 94 (explaining that material costs are particularly acute in lancets because, unlike lancet devices, they are used only one time). And a POSA would not have made such a gargantuan gap to aid removal from the lancet. As discussed with respect to anticipation, a POSA would have simply made the cap easy to remove, as was the practice at the time.

Moreover, there is no evidence that a POSA would been motivated to make Saikley's cap any larger than it already is. “[I]t does not necessarily follow from prior-art disclosures of the general desirability of high [usability] that a person of ordinary skill would have been motivated to increase [usability] beyond levels previously achieved.” *Rovalma, S.A. v. Bohler-Edelstahl GmbH & Co. KG*, 856 F.3d 1019, 1026 (Fed. Cir. 2017). In fact, the evidence points the other way. As discussed with respect to anticipation, only a minute amount of torque is required to remove a cap. Further, a larger and longer cap costs more to produce and presents a greater risk of torsion or breakage both in transit and on removal. For these reasons, the standard design at the time was small, compact, and short. Ex. 2056 ¶ 93. Indeed, Facet's lancet caps and LifeScan's infringing copies are nowhere near LifeScan's proposed size, despite being much larger than the usual prior-art caps:





Ex. 2056 ¶¶ 87, 148-149 (also showing that the spans of these caps are 5.7 to 6.9 mm, much less than the fingertips' 16-20 mm width).

In addition, Saikley merely directs the user to make the cap larger, but does not say in which dimensions or how much.¹⁰ Such “vague prior art does not guide an inventor toward a particular solution[,]” namely the claimed dimensional relationships. *Bayer Schering Pharma AG v. Barr Laboratories, Inc.*, 575 F.3d 1341, 1347 (Fed. Cir. 2009); *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”) (footnote omitted). LifeScan presents no

¹⁰ And as discussed with respect to anticipation, LifeScan's expert cannot even answer the question, larger than *what*?

evidence that a POSA would have selected the particular dimensional relationships recited in the claims. And just as a POSA could not rely on the relative dimensions in *Hockerson*, *Nystrom*, and *Source Vagabond* that appeared to clearly meet the claims, LifeScan cannot do so here as a matter of law. *See supra* Section IV.B.1 (Legal Background).

Further, LifeScan's bare assertions of "routine optimization" are not enough. *In re Stepan Co.*, 868 F.3d 1342, 1346 (Fed. Cir. 2017). LifeScan must also "[explain] why it would have been routine optimization to arrive at the claimed invention[.]" in particular, and "provide some rational underpinning explaining why a [POSA] would have arrived at the claimed invention through routine optimization." *Id.* LifeScan failed on both counts. It cites no evidence (other than the '635 patent itself) showing that the claimed dimensional relationships provides any benefit. Mr. Delman's conclusory and hindsight-driven testimony is due no weight because it merely repeats LifeScan's conclusory attorney argument. *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) ("[Petitioner's] expert testimony in support of this theory is equally unavailing, adding nothing beyond the conclusory statements in [the] petition."); *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15-16 (P.T.A.B. Aug. 24, 2022) (precedential). Further, LifeScan contradicts itself—arguing out of one side of its mouth that the claimed dimensions

are “meaningless” (Pet. 48 (emphasis in original), while arguing out of the other that a POSA would have arrived at them based on routine optimization.

LifeScan's cited *Ohio Willow Wood* district court case also lays bare fatal flaws in LifeScan's arguments. Specifically, the issue in that case was whether it would have been obvious to make a prior-art gel cushion for a prosthetic thicker, and it was undisputed that “the degree of cushioning depends merely on the thickness of the gel.” *Ohio Willow Wood Co. v. Thermo-Ply, Inc.*, No. 9:07-cv-00274, 2009 WL 6499349, at *4 (E.D. Tex. Nov. 20, 2009). The court therefore concluded that “[m]aking a soft substance thicker merely yields the predictable result of providing more cushioning, and is thus obvious.” *Id.* In contrast, the claims here do not simply recite making the lancet cap larger than the prior art. They recite specific relationships between the dimensions of distinct components, e.g., a gripping handle with a lateral span at least 1.5x the lancet thickness (claim 6) and with a length at least equal to its span (claim 7). That is not merely larger, and that is not what Saikley directs. Indeed, there is no evidence in the record showing any appreciation in the art for the claimed dimensional relationships except the patent-at-issue. Without that evidence, LifeScan's obviousness arguments are based solely on hindsight.

LifeScan also contends that these claimed dimensional relationships would have been simply a matter of “common sense.” Pet. 49. But as the Federal Circuit has cautioned, “our cases repeatedly warn that references to ‘common sense’ ...



cannot be used as a wholesale substitute for reasoned analysis and evidentiary support, *especially when dealing with a limitation missing from the prior art references specified[,]*” as here. *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1362 (Fed. Cir. 2016); Pet. 49.

LifeScan cites Saikley and Stout (and undefined “other prior art,” but gives no examples), but as discussed herein, these reference do not disclose the recited relationships having the advantages first disclosed in the '635 patent. For example, the '635 patent teaches the importance of the 1.5x ratio between gripping handle span and lancet thickness, and also the relationship between handle length and span. '635 Patent 6:52-7:3; Ex. 2056 ¶ 106. But none of LifeScan's prior art recognizes such relationships.

LifeScan also asserts that the dimensional limitations were obvious design choices. Pet. 49. But “[m]erely stating that a particular [claim] element is a design choice does not make it obvious. The Board must offer a reason for why a [POSA] would have made *the specific design choice.*” *Cutsforth, Inc. v. MotivePower, Inc.*, 636 F. App'x 575, 578 (Fed. Cir. 2016). And here, LifeScan fails on that point—it never alleges, much less demonstrates, that the dimensional relationships recited in any of the challenged claims would have been obvious design choices. Instead, LifeScan alleges that it would have been an obvious design choice to make the cap “longer or wider,” without picking one or both, or stating by how much. Pet. 48-49.



LifeScan's *Rexnord* case shows what is missing here. In that case, it was an obvious design choice to make the spaces between conveyor belt modules less than 10 mm where the art taught making the space small enough to avoid pinching fingers—a POSA knew that particular size would keep fingers out. *Rexnord Indus., LLC v. Kappos*, 705 F.3d 1347, 1355-56 (Fed. Cir. 2013). But here, there is no teaching regarding the relationship between different dimensions as recited in the claims. The art merely says to make the cap larger than usual, without saying how large and in what dimensions.

Finally, LifeScan asserts that dimensional limitations would have been “obvious for a [POSA] to try.” Pet. 50. These arguments fail, too, because LifeScan failed to show why a POSA would have tried the particular dimensional relationships recited in the claims. The Federal Circuit has explained that “the possible approaches and selection to solve the problem must be ‘known and finite’” for an obvious-to-try argument to succeed. *Rolls-Royce, PLC v. United Techs. Corp.*, 603 F.3d 1325, 1339 (Fed. Cir. 2010); *see also Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1359 (Fed. Cir. 2007) (not obvious to try because the prior art disclosed

a broad selection of possibilities). But here, LifeScan failed to present a finite number of known solutions.¹¹ That, too, is fatal to its case.

Accordingly, LifeScan failed to meet its burden to show obviousness over Saikley alone.

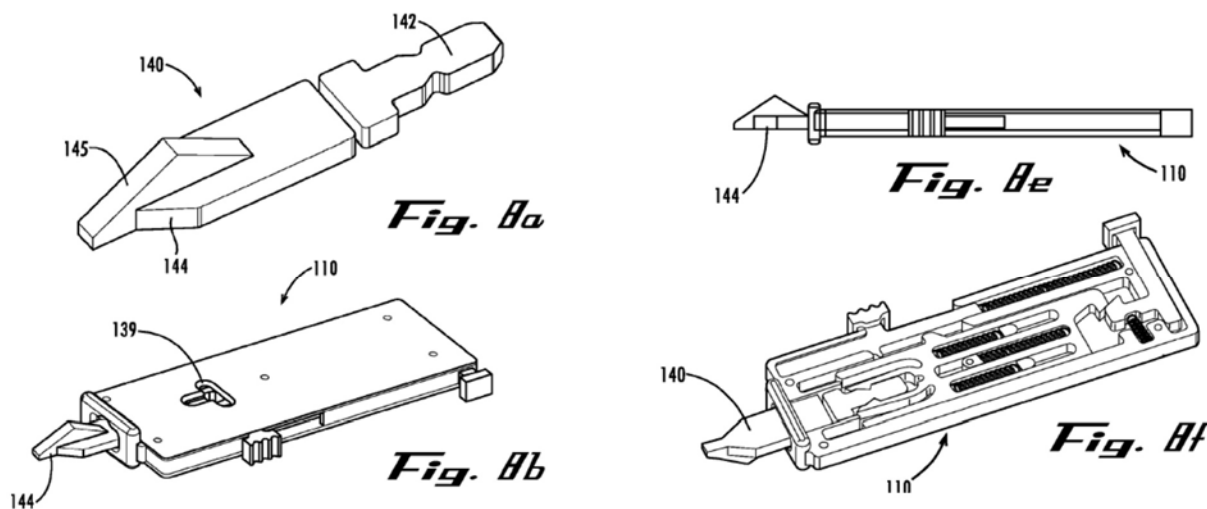
b. Stout does not remedy Saikley's deficiencies

Recognizing that Saikley alone was not enough, LifeScan also brought in Stout. But LifeScan's proposed combination with Stout also fails because (1) a POSA would not have combined Stout and Saikley to arrive at the claimed invention, and (2) Saikley does not disclose the claimed dimensions.

Motivation to Combine: LifeScan alleges that Saikley and Stout are “from the same field of endeavor” and that both might be used to improve the Abbott (or Therasense) FreeStyle meter. Pet. 55-56. Assuming those allegations are true, that merely establishes that the references are analogous art. The next step is to show a motivation to combine, i.e., to demonstrate that a POSA could have and would have “combined elements from specific references in the way that the claim does.” *TQ Delta LLC v. Cisco Sys., Inc.*, 942 F.3d 1352, 1360 (Fed. Cir. 2019) (emphasis omitted).

¹¹ LifeScan alleges that is a “finite number” of potential dimensions and relationships (Pet. 50-51), but that is plainly false. Ex. 2056 ¶ 107.

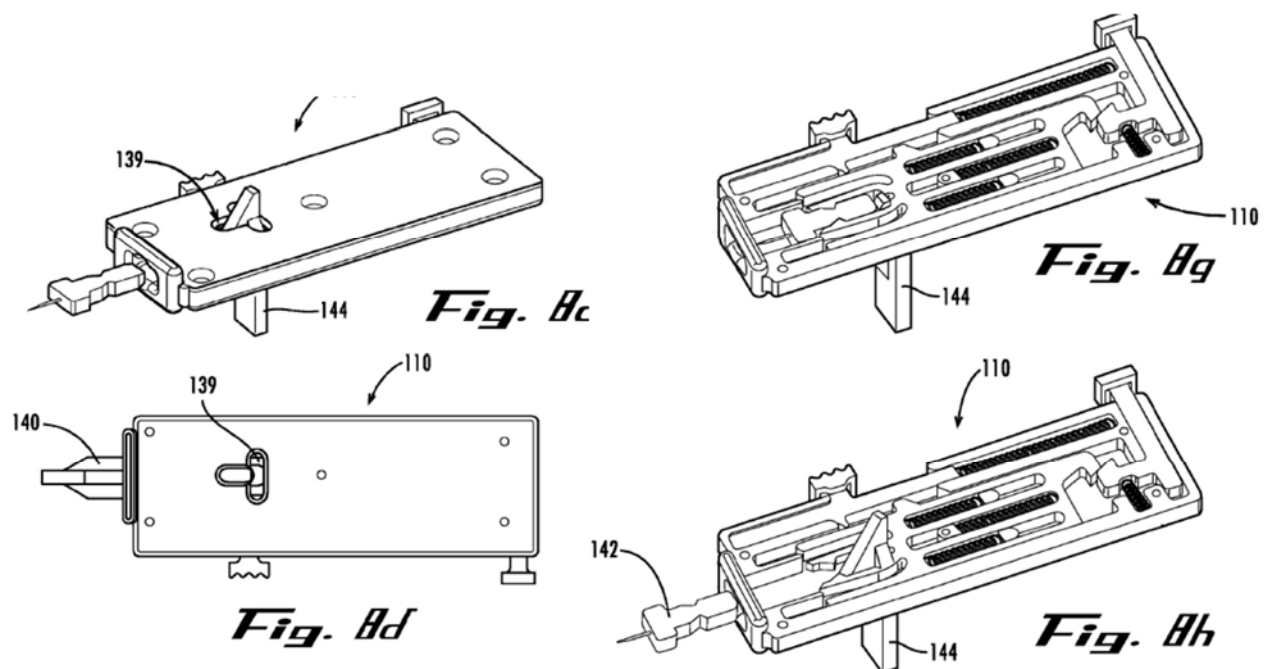
But even assuming *arguendo* that a POSA would have modified “Saikley’s cap to include an embedded needle sharp” (Pet. 45-47), LifeScan failed to show that a POSA would have further modified Saikley’s cap to have Stout’s dimensions. In particular, LifeScan completely ignores that, unlike Saikley, the cross section of Stout’s cap is no wider than the widest portion of the lancet so that the cap may be inserted with the lancet body into the device through the device’s slotted opening:



Stout Figs. 8a-b, 8e-f; Ex. 2056 ¶¶ 108-110. But LifeScan also argues that Saikley’s cap is wider than the lancet—indeed, even wider than a human finger or thumb. LifeScan never addresses the internal conflict of its arguments: how could a POSA have made a cap so much wider than the lancet while also making narrower?

In addition, Stout eviscerates LifeScan’s position regarding Saikley’s actual or obvious size. Stout’s narrower cap still provides plenty of torque for removing it from the lancet—no additional leverage is needed as LifeScan supposes because, as

was common in the art, the cap and lancet “are connected at a narrow or notched neck portion *for ease of separation.*” Stout [0035]; *see also* Anticipation discussion above (demonstrating that caps required only a minute amount of torque to remove). In fact, Stout’s cap is designed to give the user plenty of leverage to twist or otherwise force/pry open the lancet device’s “forks” to release the lancet after use, as shown below:



Stout Figs. 8c-d, 8g-h, [0041] (“[I]nclined or curved removal surface 145 ... acts as a wedge or cam when pushed into the lancet-removal opening 139, to release the lancet body 142.”); Ex. 2056 ¶¶ 111-112.

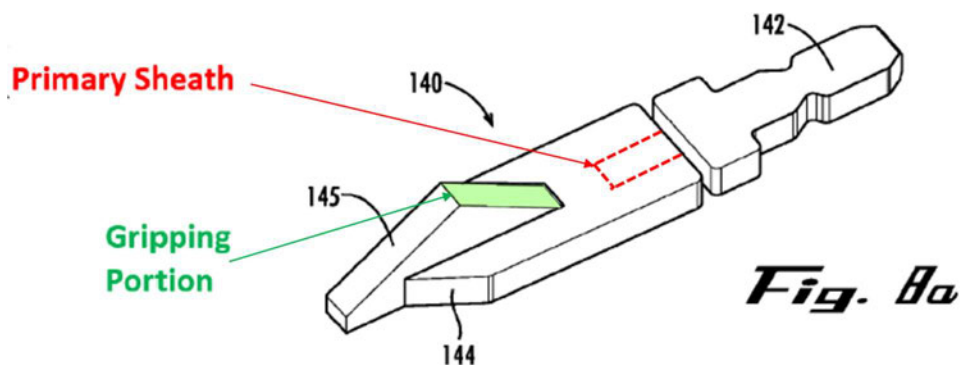
In sum, Stout’s cap is designed differently and for different purposes than Saikley’s. LifeScan failed to explain why a POSA would have used Stout’s cap as a

sizing guide to achieve the claimed dimensions—while making Saikley's cap both wider and narrower at the same time. Ex. 2056 ¶¶ 109-112.

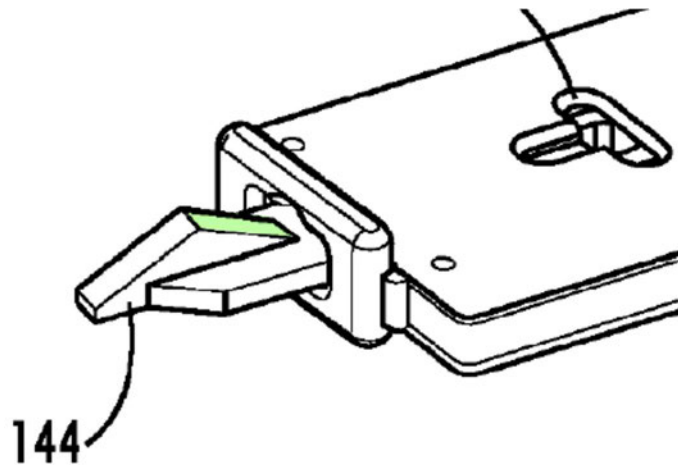
Stout's Dimensions: Stout fails to disclose the claimed dimensions and therefore any combination does not cure the deficiencies in Saikley Ex. 2056 ¶ 113.

First and as matter of law, Stout's figures cannot be used to determine dimensions because they are not to scale. *See supra* Section IV.B.1 (Legal Background).

Second, Stout lacks a gripping handle between and attached to two sheaths, as recited in the claim. Stout instead has a primary sheath at one end, and a portion for gripping at the other, and no secondary sheath:

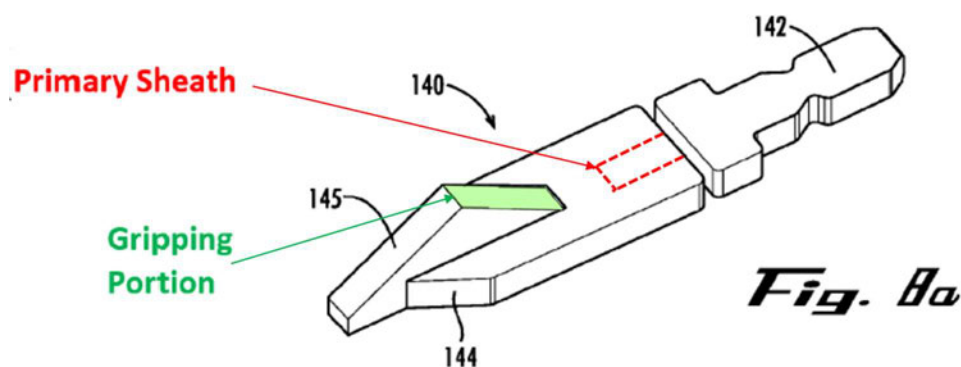


Stout Fig. 8a (annotated); Ex. 2056 ¶¶ 113-114. LifeScan's expert admitted during cross that a POSA grips the green-shaded portion labeled "gripping portion" above when removing the cap because that is what is exposed when the cap and lancet are inserted into the lancing device:

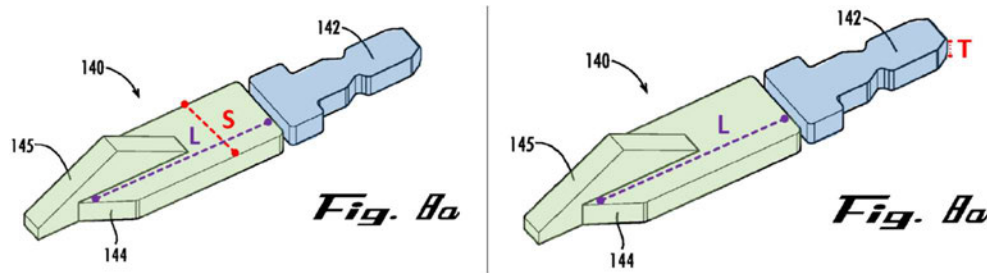


Stout Fig 8b (annotated and excerpted); Ex. 2028 at 51-55. As a result, if Stout has a “gripping handle portion” at all, it is much narrower than the cap itself. There is no reason to conclude it is 1.5 times the lancet thickness. Ex. 2056 ¶¶ 113-116.

Notably, the portion of Stout's cap that LifeScan identified as the gripping handle in the Petition is *not accessible for gripping* when removing the cap, as shown above. Further, the lancet needle is embedded in much of the portion that LifeScan identifies in its Petition as the gripping handle—rendering it the primary sheath under the Petition's construction:



Stout Fig. 8a (annotated); Ex. 2056 ¶¶ 115-116. Thus, LifeScan has not identified a gripping handle that is not already serving as the primary sheath. And any possible gripping handle has a length that is much shorter than LifeScan indicates in its annotated figure, reproduced below:



Pet. 54. Regardless, and as shown above, LifeScan's alleged gripping handle and its length does not extend between the primary and secondary sheaths, as required by the claims.

In sum, LifeScan failed to show that Stout discloses the claimed dimensions, either.

5. Claims 7-8 and 17-18: Saikley, alone or with Stout, does not render obvious the claimed length dimension

LifeScan's arguments for these claims fail for the same reasons explained above.

Further, LifeScan's conclusory attorney arguments that the claimed dimensions in these claims are a "natural option" or "natural choice" are insufficient as a matter of law to support a conclusion of obviousness. Pet. 52-53; *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016) ("To satisfy its burden of

proving obviousness, a petitioner cannot employ mere conclusory statements.”). This is especially so because Mr. Delman’s conclusory testimony merely repeats LifeScan’s attorney argument. *Harmonic Inc.*, 815 F.3d at 1363 (“[Petitioner’s] expert testimony in support of this theory is equally unavailing, adding nothing beyond the conclusory statements in [the] petition.”); *Xerox*, IPR2022-00624, Paper 9 at 15-16.

* * *

Accordingly, all of LifeScan’s obviousness arguments in Grounds 1-3 fail.

V. Grounds 4-6: The Challenged Claims Are Patentable over Iio, Peckham, and the FreeStyle Manual

LifeScan failed to meet its burden for Grounds 4-6 for multiple reasons.

First, the challenged claims require, *inter alia*, a gripping handle portion with a “lateral span” and a lancet with a “thickness.” Iio’s alleged gripping handle and lancet are cylindrical, and as such, do not have a *lateral* span or a thickness.

Second, LifeScan acknowledges that the art fails to expressly disclose the dimensions required by the claims. LifeScan argues instead that a POSA would have known that Iio possesses the claimed dimensions based on its drawings that are plainly not to scale, or that they would have been obvious to try or a matter of routine optimization. LifeScan’s arguments fail for multiple reasons, as explained in the following sections.

A. Iio Does Not Disclose A “Gripping Handle Portion” With A “Lateral Span” Or A “Lancet” With a “Thickness”

1. The plain meaning of “lateral span” and “thickness”

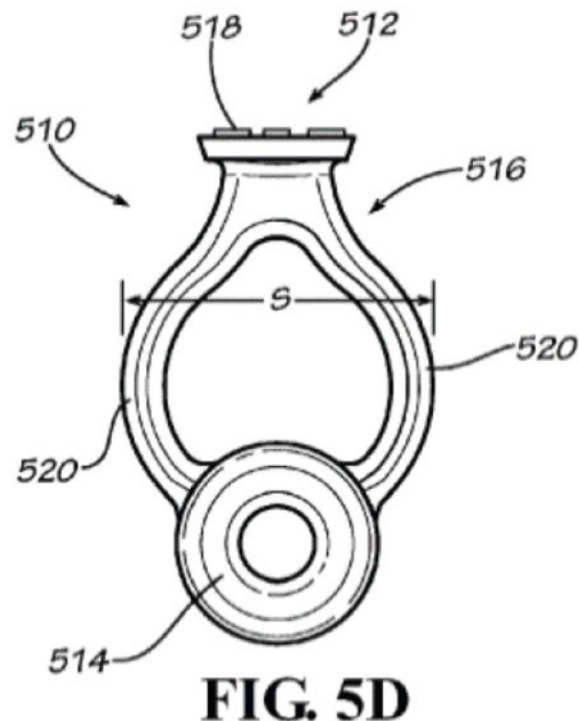
LifeScan contends that the plain meaning of these terms control, referencing the District Court's claim construction order. Pet. 8 (citing Ex. 1004). The Court explained the plain meaning of lateral span:

Lateral means “side-to-side.” Span clearly refers to a maximum distance. Accordingly, “lateral span” can only mean the maximum side-to-side (or horizontal) distance separating the gripping handle portion. A [POSA] would understand that this is the meaning of “lateral span.”

Reference to FIG. 5D would immediately confirm that understanding.

Ex. 1004 at 25 (citing the dictionary definitions of “lateral” and “span,” attached as Exhibits 2032-2033 and 2039. The Court also recognized that Figure 5D of the '635 patent shows a well-defined “side-to-side (horizontal) distance, i.e., a lateral span”

S:

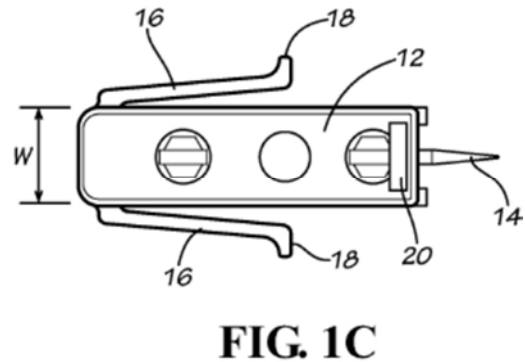
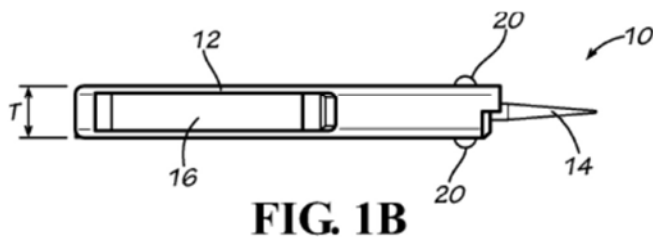


Ex. 1004 at 24 (reproducing Figure 5D).

The court got it right. The term “lateral” modifies “span,” and requires a side-to-side (or horizontal) measurement. *See also* Ex. 2033 (differentiating “lateral” from “anterior” and “posterior” in the medical field); ’635 Patent 3:45-47 (“shoulder or barb 18 extending laterally outward” in Figures 1A-1C), 5:15-16 (“lateral sides of the lancet body”).¹²

¹² Notably, the term “lateral” is narrower than “transverse.” Lateral is side-to-side/horizontal, while transverse is in any direction perpendicular to the long axis of a body. Ex. 2042 (definition of transverse); ’635 Patent 4:30-34 (“A flange or ring

Similarly, the Court found that the plain meaning of thickness is “the smallest of three dimensions, length, width, and thickness,” i.e., the vertical distance through a transverse cross section, as the district court explained and as illustrated in the '635 patent:



'635 Patent Figs. 1B-C; Ex. 1004; *id.* 21-22; Ex. 2041 (definition of thickness). That is how the term is used in the specification, too. *E.g.*, '635 Patent 3:52-56 (“The lancet body has a thickness T and a width W, with the width W preferably being at least about 1.5 times, and more preferably at least about twice the thickness T.”).

Thus, and as the Court explained, “lateral span,” “thickness,” and “length” are three different terms with different meanings. A lateral span is from side-to-side (or horizontal), while thickness is the shorter, vertical distance through a transverse

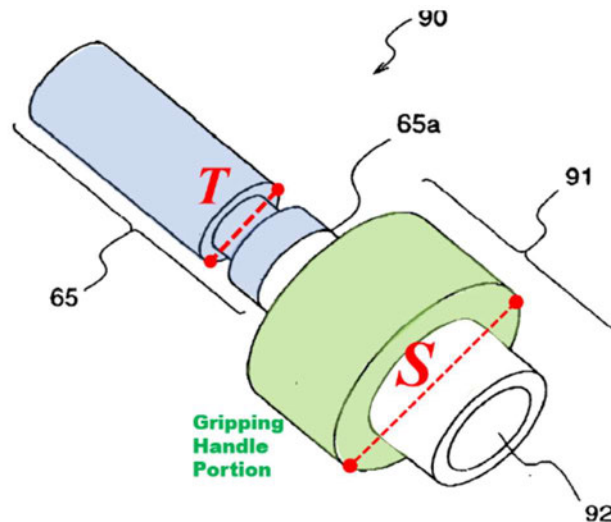
220 is optionally provided extending transvers[e]ly outward around at least a portion of the periphery of the front end of the lancet body 212.”).

cross section, and the length is the distance along the longitudinal axis. *See* Ex. 1004 at 21-22, 27-28.

These points should be undisputed, as both parties agree for the purposes of this IPR that the District Court got it right.

2. Iio does not disclose the claimed “lateral span” or “thickness”

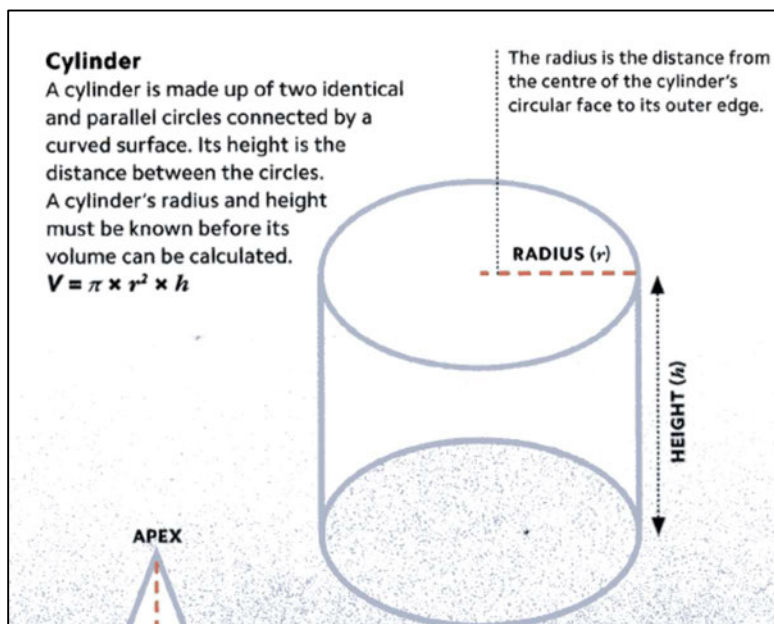
LifeScan argues that the cylinder it colored green (see below), corresponds to the claimed gripping handle, and that this cylinder has a lateral span labeled “S”:



Pet. 66-67, 78-79 (annotating Iio Figure 8). LifeScan also asserts that Iio's cylindrical lancet has a thickness “T.” LifeScan's arguments fail because “S” is not a *lateral* span and “T” is not a thickness. Lateral span and thickness have different meanings according to the District Court and the specification. Yet as shown above, LifeScan collapses them into the same thing—both are measuring the same dimension in the same direction.

Starting with the first term, the claims expressly require a “lateral span,” not the broader terms “transverse span” or “diameter,” which is what LifeScan identified instead of a lateral span. And because LifeScan agrees that the district court’s plain meaning controls (as discussed in the immediately preceding subsection), it is undisputed that “lateral span can *only* mean the maximum side-to-side (or horizontal) distance separating the gripping handle portion.” Ex. 1004 at 25 (also stating that “lateral means side-to-side”) (footnote omitted)).

But LifeScan’s green cylindrical portion of cap 9 does not have a side-to-side (or horizontal) distance, i.e., a lateral span, because it has a circular cross section—which precludes having a “side-to-side (or horizontal)” span. That is, a cylinder has two circular surfaces separated by a height and connected by a single curved surface:



Ex. 2055 at 107 (textbook excerpt). The distance across a circular base (such as span S drawn by LifeScan) or any circular cross section of a circular cylinder is a “diameter” or a “transverse span,” not a “lateral span” (i.e., “side-to-side (or horizontal) distance”).

Similarly, the claims require a lancet “thickness.” But the plain meaning of “thickness” is “the smallest of three dimensions, length, width, and thickness,” as discussed above. Iio’s cylindrical lancet does not have width or a thickness, but has a diameter or transverse span instead.

To be sure, the inventors knew how to claim the diameter or a transverse span of a circular cylinder, but they chose not to do so. For example, the specification discusses a lancet body with a “diameter *or* thickness” and a handle with a “lateral *or* transverse span S.” ’635 Patent 6:52-61; *see also id.* 3:52-56, 7:45-49 (discussing lancet bodies with a “thickness” and a “width,” as opposed to a diameter), 3:45-48 (“shoulder or barb 18 extending laterally”), 4:30-32 (flange or ring extending “transversely outward,” as opposed to laterally).

These words have different meanings—as discussed above, lateral means side-to-side, transverse means any direction perpendicular to the long axis of a body, and thickness is the shorter, vertical distance through a transverse cross-section—and the inventors used them correctly. For the gripping handle and lancet body in these claims, the inventors chose to require a “lateral span” and “thickness,”



respectively, rather than a “diameter” or a “transverse span.” But LifeScan’s arguments collapses all of them into the same thing, contrary to the intrinsic evidence and the Court’s opinion that LifeScan’s Petition relies upon.

As a result, the claims do not read on Iio’s cylindrical cap or lancet even under LifeScan’s proposed plain meanings, and Grounds 4-6 fail.

B. Iio, Alone or In Combination, Does Not Disclose or Render Obvious the Dimensional Limitations,

Iio, alone or with Peckham, does not teach or render obvious the recited dimensional limitations.¹³

1. All Challenged Claims: Iio does not disclose the claimed dimensions

LifeScan’s efforts to rely on Iio’s drawings to determine dimensions or even relative dimensions are legal error. In fact, the district denied LifeScan’s motion for summary judgment for this reason. Ex. 2021 at 2, 8. The Board should likewise reject LifeScan’s legally erroneous arguments.

As explained in the Saikley grounds’ Legal Background section, drawings that are not to scale cannot be used by themselves to determine dimensions, relative sizes, or proportions. The MPEP correctly sums up Federal Circuit caselaw in MPEP 2125,

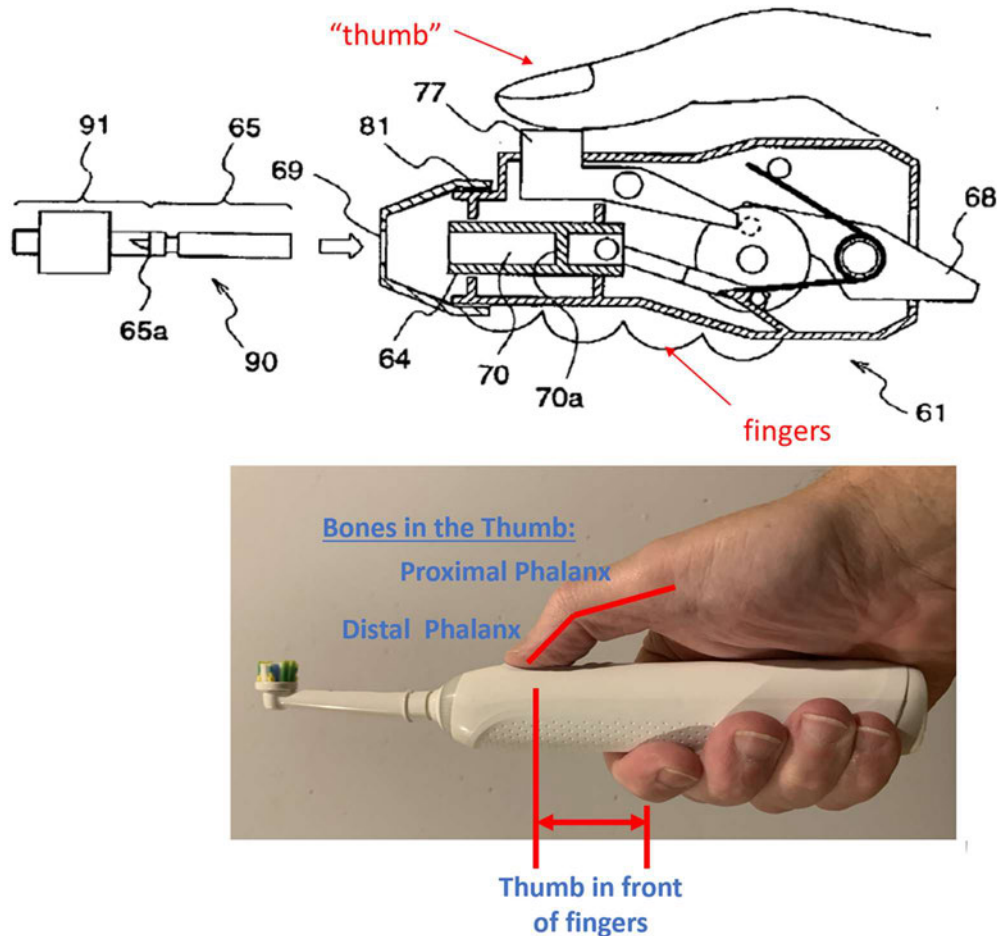
¹³ These limitations are listed in the corresponding section for the Saikley grounds.

and does so succinctly in its title: “proportions of features in a drawing are not evidence of actual proportions when the drawings are not to scale.”

And here, Iio's figures are not to scale. Iio does not state otherwise. Further, its figures are plainly not to scale and have grossly incorrect proportions. Ex. 2056 ¶¶ 117-118. Indeed, Mr. Delman admitted as much in the parallel district court proceeding, stating: “a POSITA would not be looking to these diagrams necessarily to understand those proportions as being accurately portrayed.” Ex. 2025 (Delman Dist. Ct. Dep.), 88-89. Accordingly, any reliance on the sizes, relative sizes, and proportions in Iio's figures is contrary to law and unreasonable as a factual matter.

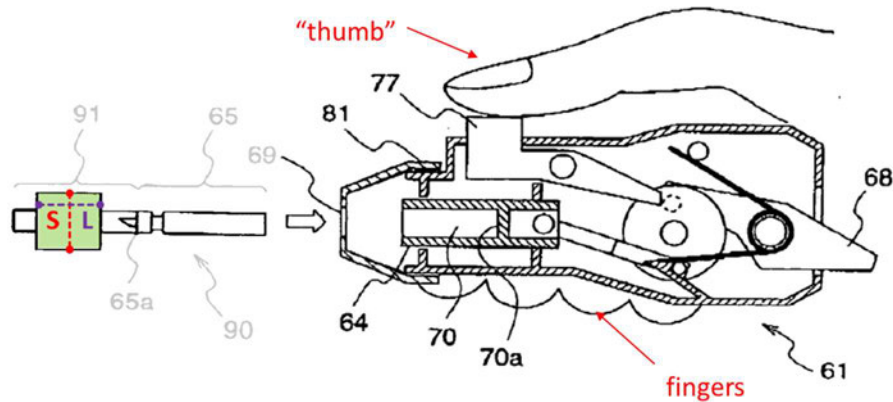
For example, Mr. Delman (and LifeScan) rely on a cartoon thumb in Iio's figures to draw conclusions regarding the relative sizes of other objects, including the lancet cap. But even a layman would recognize that a normal human thumb does not have the elongated proportions and misplaced knuckles shown in the figure, and that, absent gross deformity or severe injury, the thumb and forefingers of a human hand could not be placed in the illustrated positions:





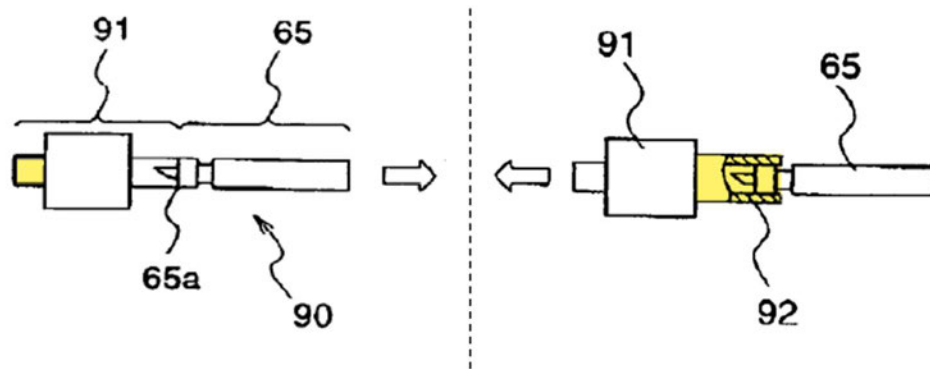
lio Fig. 9(a) (annotated); Ex. 2056 ¶¶ 117-118 (comparing his own hand shown in the photo above). The rest of the figure is also out of proportion: the internal mechanisms are as cartoon-like as the thumb and fingers, as are the cross-hatched thicknesses of the lancing device and its component, while the notional lancet and cap is represented by a line drawing with no discernible thickness. Ex. 2056 ¶¶ 119-122. In short, this drawing is a typical patent figure: it is not to scale or even mechanically accurate and cannot be used as such. It is instead “merely illustrative of the principles embodied in [lio’s] alleged invention.” *Olson*, 212 F.2d at 592; Ex. 2056 ¶¶ 117-122, 126.

Further, it is legal error and unreasonable to compare dimensions on this figure's notional diagram lancet and cap, as did LifeScan:

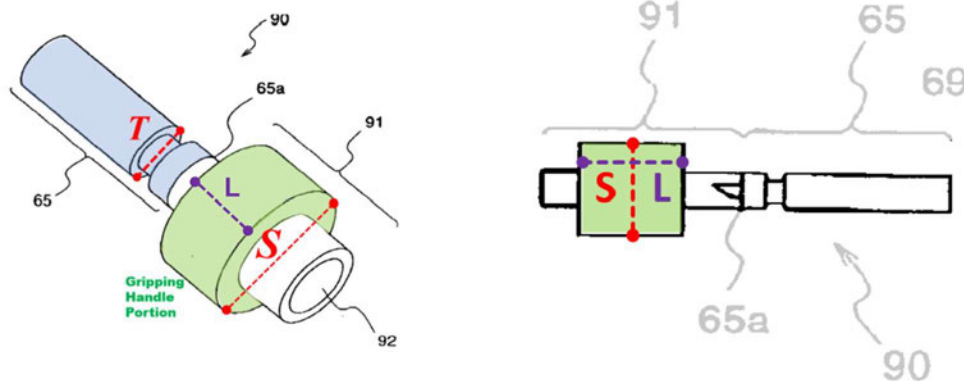


lio Fig. 9A (with annotations added by LifeScan (*see* Pet. 83) and Facet); *see also supra* Section IV.B.1 (Legal Background) (in Saikley ground). Nothing indicates that the cap is drawn to scale or proportional. To the contrary, the oversized needle and too-small alleged secondary sheath show that this figure is decidedly not to scale and out of proportion. It does not reasonably convey reliable size, proportion or even relative size information. Ex. 2056 ¶¶ 118-122. This is true as a matter of fact, and as a matter of law (as explained in the above Legal Background section).

Even worse, the above notional diagram does not comport with other figures—confirming beyond any doubt that these figures were never meant to convey sizes, relative sizes, or proportion, and that LifeScan's measured dimensions are patently unreliable. For example, the alleged secondary sheath (shaded yellow below), is drawn with substantially different length and diameters in Figure 9(a) versus Figure 11(c):



lio Figs. 9A, 11A (annotated and excerpted). That is because these figures are merely illustrative of how the cap is meant to be used, and do not convey dimensions or relative sizes. Ex. 2056 ¶¶ 123, 126. Similarly, the relative sizes of the alleged gripping handle's diameter ("S") and length ("L") are inconsistent across figures:



lio Fig. 8 (annotated by LifeScan, with "L" added by Facet), Fig. 9a (annotated by LifeScan); Ex. 2056 ¶¶ 124, 126. Thus, as a matter of fact *and* law, a POSA could not reasonably ascertain any relative sizes or proportions from these figures (including spans, thicknesses and lengths) even if making more than LifeScan's "cursory visual comparison" (Pet. 80).

LifeScan also argues that a POSA could somehow determine the lancet thickness and lateral span based on the “thin plastic film having a thickness of 0.1 mm or less.” *Id.* 82. That argument fails for all of the above reasons, and also because the film is not depicted at all in the figures—as Mr. Delman admitted in district court. Ex. 2025 at 97-99; Ex. 2056 ¶¶ 125-126.

In sum, Iio discloses none of the claimed dimensional relationships recited in *any* challenged claims.

2. All Challenged Claims: Iio, alone or with Peckham, does not render obvious the claimed dimensions

LifeScan's obviousness arguments fall into two categories: (i) the claimed dimensions would have been obvious over Iio alone (Pet. 90-93), and (ii) it would have been obvious to increase the size of Iio's alleged gripping handle by adding ridges as taught by Peckham (*id.* 93). LifeScan failed to meet its burden on both accounts, as explained in the following subsections.

a. The claimed dimensions would not have been obvious over Iio alone

LifeScan argues that the claimed dimensional relationships would have been obvious to try and a matter of routine optimization. Both conclusory, hindsight-driven arguments fail.

Starting with obvious to try, LifeScan merely alleges that the claimed dimensions would be obvious to try, and Mr. Delman simply repeats LifeScan's



conclusory arguments. That is not enough to establish obviousness. *Magnum Oil*, 829 F.3d at 1380 (“To satisfy its burden of proving obviousness, a petitioner cannot employ mere conclusory statements.”); *Harmonic Inc.*, 815 F.3d at 1363 (“[Petitioner’s] expert testimony in support of this theory is equally unavailing, adding nothing beyond the conclusory statements in [the] petition.”); *Xerox*, IPR2022-00624, Paper 9 at 15-16.

Further, LifeScan failed to show why a POSA would have tried the particular dimensional relationships recited in the claims other than hindsight—there would be no reason to try the claimed dimensions. The Federal Circuit has explained that “the possible approaches and selection to solve the problem must be ‘known and finite’” for an obvious to try argument to succeed. *Rolls-Royce*, 603 F.3d at 1339; *see also Takeda Chem.*, 492 F.3d at 1359 (not obvious to try because the prior art disclosed a broad selection of possibilities). But here, LifeScan failed to present a finite number of known solutions.¹⁴ That, too, is fatal to its case.

Likewise, LifeScan’s bare assertions of “routine optimization” are not enough to establish obvious. Further, LifeScan must “[explain] why it would have been routine optimization to arrive at the claimed invention[,]” in particular, and “provide

¹⁴ LifeScan alleges that is a “finite number” of potential dimensions and relationships (Pet. 90-91), but that is plainly false. Ex. 2056 ¶¶ 127-128.

some rational underpinning explaining why a [POSA] would have arrived at the claimed invention through routine optimization.” *Stepan Co.*, 868 F.3d at 1346.

LifeScan failed on both counts. It cites no evidence (other than the '635 patent itself), showing that the claimed dimensional relationships provides any benefit, other than Mr. Delman's conclusory testimony, which is due no weight because it merely repeats LifeScan's conclusory attorney argument.

Similarly, LifeScan's conclusory attorney arguments that the dimensions in claims 7/17 and 8/18 are a “natural option” or “natural choice” are insufficient as a matter of law to support a conclusion of obviousness. Pet. 92; *Magnum Oil*, 829 at 1380. Further, LifeScan asserts that the claimed dimensions were “commonplace,” but provides no evidence that is true. Pet. 92. Such conclusory allegations are insufficient. In sum, LifeScan points to no evidence supporting its conclusory obviousness arguments, other than Mr. Delman's equally conclusory verbatim recitation of those same arguments. That is not sufficient. *Harmonic Inc.*, 815 F.3d at 1363; *TQ Delta*, 942 F.3d at 1361 (“[C]rediting such testimony risks allowing the challenger to use the challenged patent as a roadmap to reconstruct the claimed invention using disparate elements from the prior art—i.e., the impermissible ex post reasoning and hindsight bias that *KSR* warned against.”) (emphasis omitted); *Xerox*, IPR2022-00624, Paper 9 at 15-16.

Accordingly, LifeScan failed to meet its burden to show obviousness over Iio alone.

b. Peckham does not remedy Iio's deficiencies

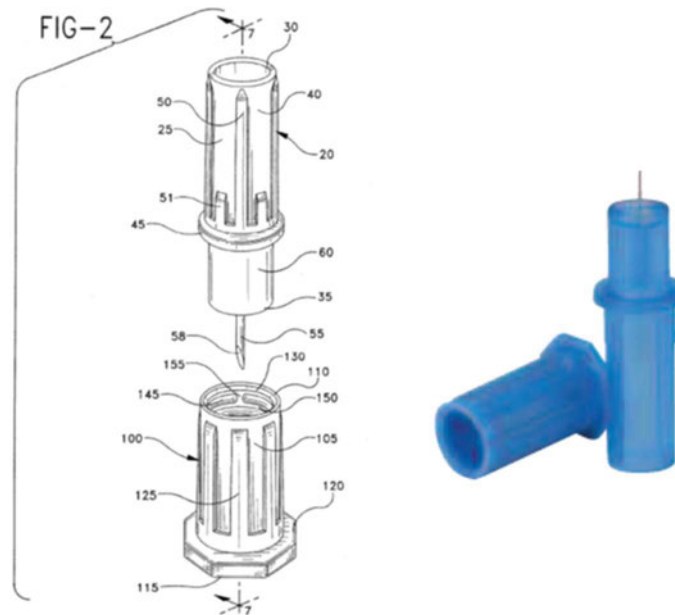
Recognizing that Iio alone is not enough, LifeScan also added Peckham. But it is undisputed that Peckham does not disclose the claimed dimensional relationships.

LifeScan argues instead that adding Peckham's ridges to the alleged gripping handle "would ... increase the lateral span ... even more" (Pet. 93), but that argument assumes that the diameter of Iio's alleged gripping handle is just under the threshold needed to meet the claims, and that Peckham's ridges would be large enough to make up the difference.

LifeScan provides no evidence or argument establishing these points. For his part, Mr. Delman relies solely on his conclusory "belie[f] [that] these relative-dimensional limitations would have been satisfied by the combination of Iio and Peckham." Ex. 1002 ¶ 213. Such conclusory statements are not enough to support a finding of obviousness. *Magnum Oil*, 829 at 1380.

Further, Peckham, like commonly available tubular lancets and caps of similar construction, demonstrates that similar cylindrical caps were about the same diameter as their associated lancets, not 1.5 times larger:





Peckham (Ex. 1008), Fig. 2; Ex. 2026. As illustrated above, a POSA reading Peckham would have understood that adding ridges to Iio would give the user a better grip, alleviating any need to provide the overly large gripping handle that LifeScan envisions—thus saving material costs. Ex. 2056 ¶¶ 129-131.

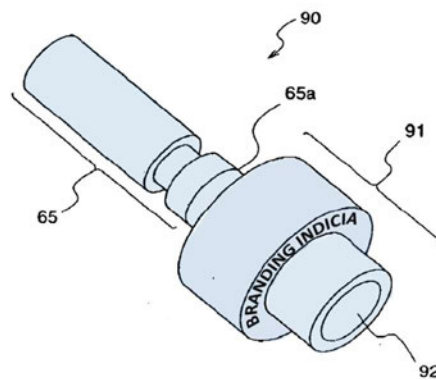
C. Claim 16: The Iio combination fails to teach or suggest the recited flat display surface

Claim 16 requires the claimed cap to have “at least one flat display surface for placement of branding indicia thereon.”

Contrary to LifeScan’s arguments, this feature has patentable weight. It is a structural limitation—the surface must be a “flat display surface” suitable for the “placement of branding indicia thereon.” The specification confirms this reading. ’635 Patent 6:11-16 (“readily visible circular or flat areas that can be used for applying branding/logos”). LifeScan’s argument that this feature lacks patentable

weight fails for that reason, and also because its argument applies only to the preamble, not the body, of a claim. *Marrin v. Griffin*, 599 F.3d 1290, 1294 (Fed. Cir. 2010) (“[p]reamble language that merely states the purpose or intended use of an invention is generally not treated as limiting the scope of the claim”).

LifeScan further argues that, despite the lack of any express disclosure, “the second end of the gripping handle portion” meets this claim feature, as illustrated below in LifeScan’s modified version of Iio’s Figure 8:



Pet. 77. But LifeScan fails to show that the alleged “flat display surface” is indeed suitable for placement of branding. LifeScan provides no evidence, other than conclusory testimony, that this tiny surface is a “*display* surface” suitable for “placement of branding” as recited. Indeed, lancets and their caps are typically very small, and this small, narrow surface is not a display surface for the placement of branding—especially for the target audience that often has weak eyesight. Ex. 2056 ¶¶ 132-135.

VI. Objective Evidence Further Demonstrates Patentability

Objective evidence of a patented invention's non-obviousness "may often be the most probative and cogent evidence in the record" and "must be considered in every case." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328-37 (Fed. Cir. 2016) (original emphasis); see also, e.g., *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1071-72 (Fed. Cir. 2018). Such evidence serves "to 'guard against slipping into use of hindsight' ... and to resist the temptation to read into the prior art the teachings of the invention." *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 36 (1966).

Here, the objective indicia support a finding of non-obviousness: [REDACTED]

[REDACTED]—the patented lancets satisfied a long-felt need, and were commercially successful.

A. A Strong Nexus Exists Between the Objective Evidence and the Claimed Invention

Objective evidence is afforded substantial weight when there is a nexus between the evidence and the patented invention. *WBIP*, 829 F.3d at 1329. There is a "presumption of nexus" when "the asserted objective evidence is tied to a specific product and that product is the invention disclosed and claimed in the patent," and the claims are not merely a "component" of the product. *Polaris Indus.*, 882 F.3d at 1071, 1074 (quoting *WBIP*, 829 F.3d at 1329).

Here, Facet's Delica lancets and LifeScan's Delica Plus lancets¹⁵ are "the invention disclosed and claimed in the patent." *Polaris Indus.*, 882 F.3d at 1071. These products both practice the claims, and the claimed invention is not a mere subcomponent of the products. Ex. 2056 ¶¶ 137-151 (showing that both products practice claims 6 and 14). As indicated below, the lancets are coextensive with claims 6 and 14 of the '635 patent.

1. Claims 6/14 - Preamble¹⁶

The Delica and Delica Plus are lancets that include a protective sterility cap.

¹⁵ Facet uses the term "Delica lancets" to refer to the covered products Facet produced for LifeScan from 2010-2019. The "Delica Plus lancets" refer to the infringing lancet LifeScan introduced in 2019 after copying Facet's design.

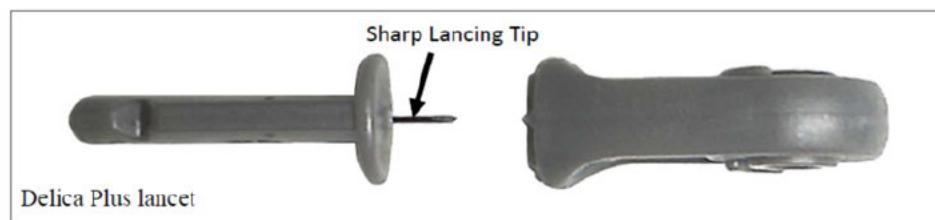
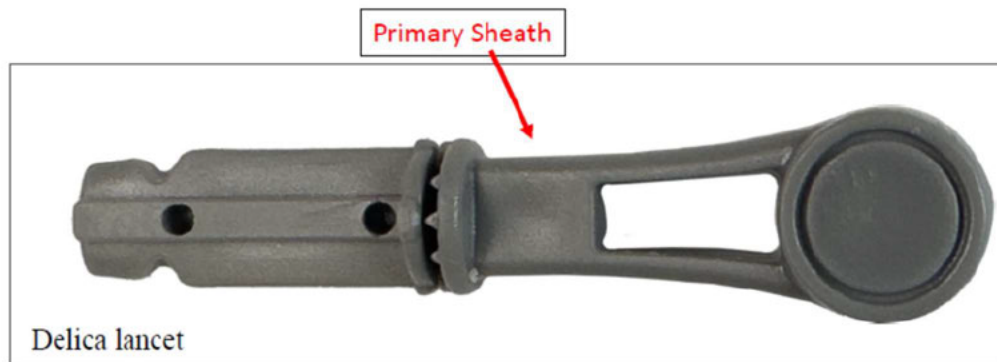
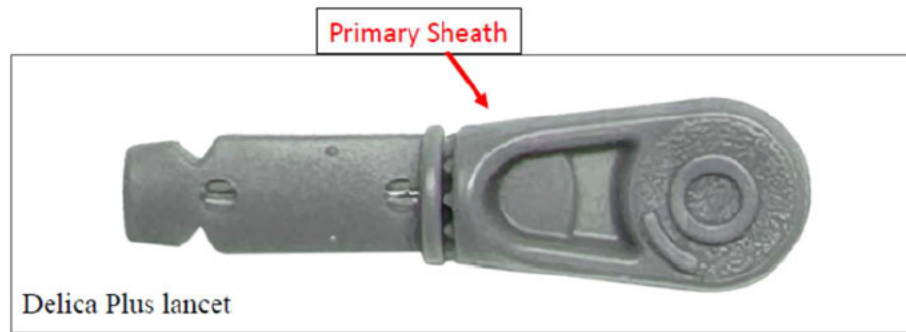
¹⁶ Claim 6 depends from claim 1, so claim 6 includes the limitations recited in now-disclaimed claim 1.



Ex. 2056 ¶ 139 (also noting that his photos used throughout are not the same scale).

2. Limitation 1.a/14.a – primary sheath

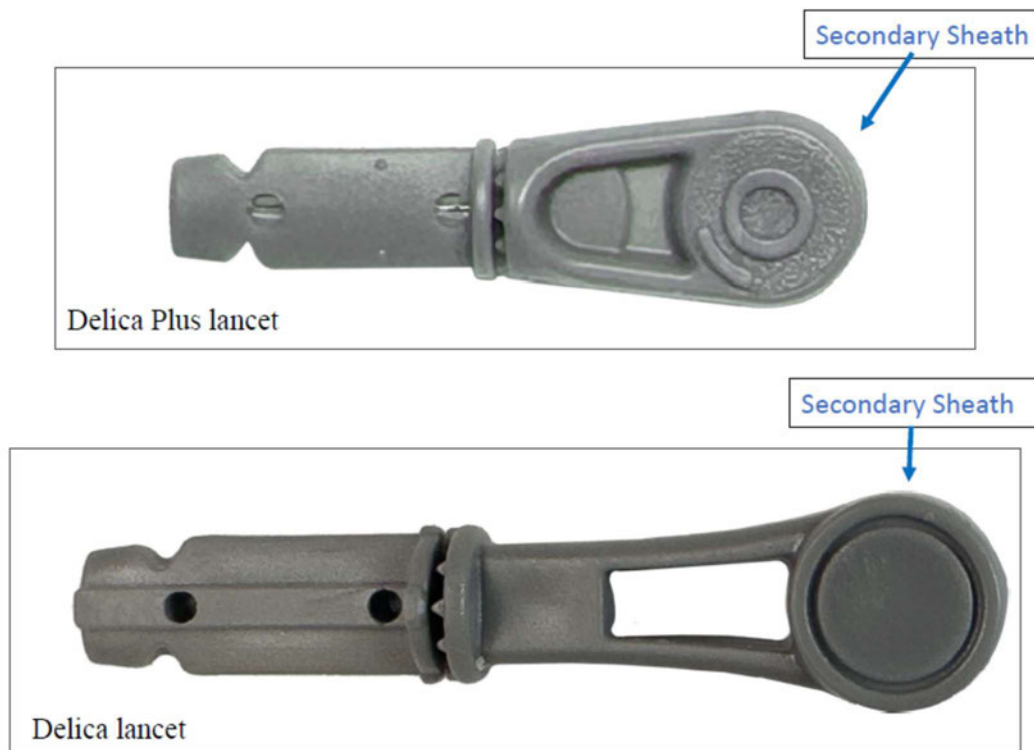
The Delica and Delica Plus include a primary sheath for initial embedment of sharp lancing tip of an unused lancet therein.



Ex. 2056 ¶¶ 140-142.

3. Limitation 1.b/14.b - secondary sheath

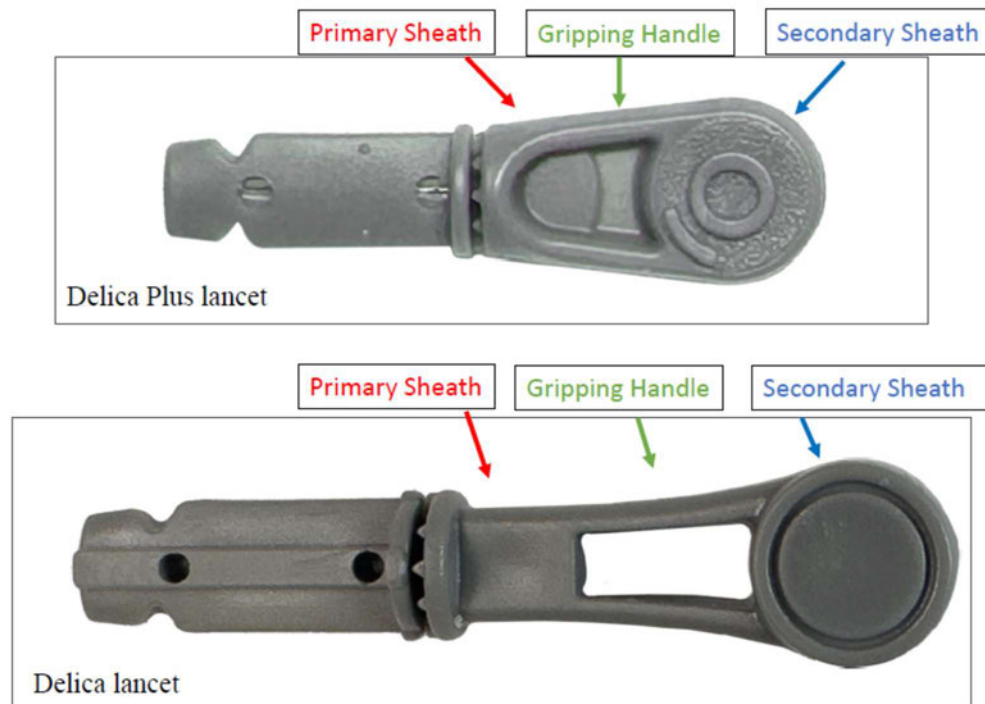
The Delica and Delica Plus include a secondary sheath for receiving the sharp lancing tip of a used lancet.



Ex. 2056 ¶ 143.

4. Limitation 1.c/14.c - gripping handle portion

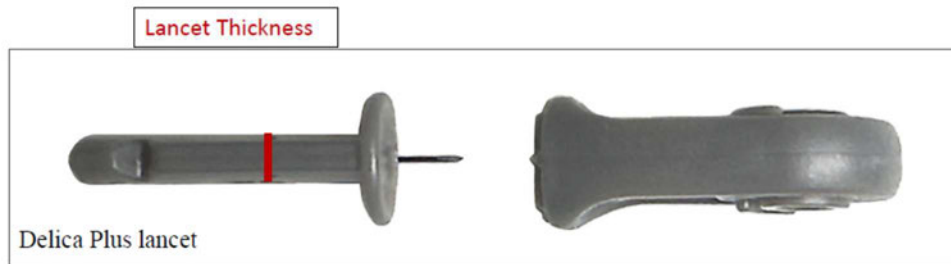
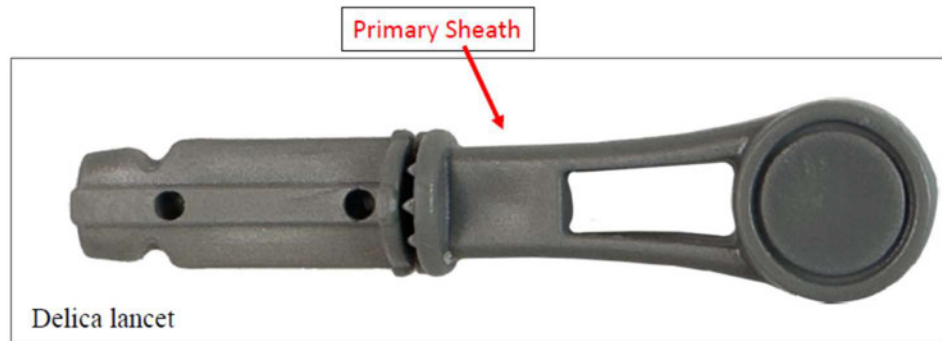
The Delica and Delica Plus include a gripping handle portion extending between the primary sheath and the secondary sheath, with the primary sheath attached at a first end of the gripping handle portion and the secondary sheath attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet.



Ex. 2056 ¶ 144.

5. Limitation 6.a/14.d - lancet body thickness

The Delica and Delica Plus include a lancet with a lancet body having a thickness, and a sharp lancet tip initially embedded in the primary sheath. Ex. 2056 ¶ 145.



Ex. 2056 ¶ 145.

6. Limitation 6.b/14.f - gripping handle lateral span at least 1.5 times the lancet thickness

The Delica and Delica Plus lancets include a protective sterility cap wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness, as measured by Dr. Collins, including the exemplars provided in the table below:

	Lancet thickness	Gripping Handle Lateral Span
Delica	2.73 mm	5.74 mm
Delica Plus	1.77 mm	6.87 mm

Ex. 2056 ¶¶ 146-151.

B. LifeScan's Delica Plus Lancets Are Blatant Copies of Facet's Delica Lancets

“It is well established that copying by a competitor” is objective evidence of nonobviousness. *Liqwd, Inc. v. L'Oreal USA, Inc.*, 941 F.3d 1133, 1137 (Fed. Cir. 2019). Here, there is unmistakable copying of the lancet and protective sterility cap claimed in the '635 patent. “[C]opying requires the replication of a specific product.” *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004). Here, that specific product is the patented Delica lancet, and after Facet supplied it to LifeScan for years, [REDACTED].

Specifically, [REDACTED].

Ex. 2030. After that, [REDACTED]

[REDACTED]

with full knowledge of the '635 patent. "The fact that a competitor copied the patentee's invention, rather than one within the public domain, is probative of nonobviousness because it suggests the competitor saw value in the invention that he could not achieve without copying." *Medtronic, Inc. v. Teleflex Innovations S.A.R.L.*, 70 F.4th 1331, 1339 (Fed. Cir. 2023).

"[A]ccess to an issued patent coupled with circumstantial evidence regarding changes to a competitor's design is sufficient to support copying." *Liqwd*, 941 F.3d at 1138 (emphasis omitted). As Facet's partner for ten years (Exs. 2030, 2057, 2058), LifeScan long knew of and had access to the '635 patent. In fact, LifeScan admitted to possessing knowledge of the '635 patent since at least December 5, 2016, prior to the release of the Delica Plus. Ex. 2023 (LifeScan's Third Supplemented Response to Interrogatory No. 3 at 7-8 (May 26, 2023)).

There is [REDACTED]. *First*, the similarities between Facet's Delica and LifeScan's copies, tellingly called "Delica Plus," are overwhelming, as shown below:



Ex. 2056 ¶ 87 (showing Facet’s Delica lancets on the left and LifeScan’s Delica Plus on the right).

[REDACTED] [REDACTED] See, e.g., Ex. 2058 ([REDACTED] [REDACTED] [REDACTED]),
FACET_00005410 ([REDACTED]
[REDACTED]); Ex. 2051 ([REDACTED]

¹⁷ See Ex. 2035 (LifeScan’s Notice of Interested Parties naming Asahi as LifeScan’s indemnitor).

[REDACTED]). [REDACTED]
[REDACTED]
[REDACTED] Ex. 2050 (LSI0000003603); Ex. 2051
(LSI0000003605). And, as discussed below, [REDACTED]
[REDACTED]
[REDACTED]. Exs. 2050, 2051.
[REDACTED]
[REDACTED]
[REDACTED] Ex. 2024 ([REDACTED] Dep.), 159:23-161:9, 164:13-165:19. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] Ex. 2044 (ASA08257) (email chain [REDACTED]
[REDACTED]
[REDACTED]); *see also* Ex. 2045 (ASA258968-969)
([REDACTED]
[REDACTED]
[REDACTED]).

Thus, [REDACTED]

[REDACTED]. Ex. 2052
(LSI0000004307, 4314) (LifeScan Agreement). And LifeScan's marketing

materials, through the present day, similarly tout the cross-compatibility of the Delica Plus lancets to the Delica lancets, [REDACTED]. Exs. 2046-2049 (FACET_002122, 2127, 2129, 2132). This cross-compatibility was [REDACTED].

In sum, there can be no reasonable dispute that LifeScan arrived at its Delica Plus design by [REDACTED]. LifeScan's blatant copying of Facet's patented product is strong evidence of non-obviousness.

C. The Invention Achieved Substantial Commercial Success

Facet's Delica lancets and LifeScan's Delica Plus achieved remarkable commercial success, which provides additional evidence of non-obviousness. *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1056 (Fed. Cir. 2016).

Facet's Delica lancet went to market in 2010. [REDACTED]

[REDACTED]

Ex. 2030 (FACET_532894). At that point, [REDACTED]

[REDACTED]

Prior to LifeScan's duplicity, [REDACTED]

[REDACTED] In its first year of launch, Facet sold [REDACTED] lancets to [REDACTED]

LifeScan. *Id.*¹⁸ By 2018, that number had skyrocketed to [REDACTED] in a single year. *Id.* Similarly, Facet's revenues [REDACTED] [REDACTED] over the course of five years, growing from [REDACTED] [REDACTED] to over [REDACTED] [REDACTED]. *Id.*

LifeScan has benefited from Facet's claimed invention. Delica entered the market with its copied Delica Plus product in 2019, and b [REDACTED] [REDACTED] Delica Plus lancets, [REDACTED]. Ex. 2040 (LSI00000245820). In 2019, in LifeScan's first year selling the infringing copy, it enjoyed over [REDACTED] in revenue. *Id.* By 2020, LifeScan's revenues for the infringing lancets [REDACTED], exceeding [REDACTED]. *Id.* LifeScan continued to generate over [REDACTED] [REDACTED]. *Id.*

Thus, the products' commercial success provides compelling evidence that the '635 patent was nonobvious.

D. The '635 Patent Satisfied a Long-Felt but Unmet Need

The claimed lancets are directed to blood testing for individuals with diabetes. These lancet users frequently suffer from limited mobility or vision, and may suffer from neuropathy attributable to diabetes. As such, prior to the claimed invention of

¹⁸ Exhibit 2030 describes units sold by carton. There are 100 lancets per carton.

the '635 patent, there existed a long-felt need for a lancet and cap that was easier for these users to handle. Ex. 2056 ¶¶ 152-154.

The claimed invention met this need, including specific dimensional limitations reflecting their solution. For example, the gripping handle combined with the claimed ratio of its lateral span to lancet thickness makes the device easier to use. '635 Patent 6:51-54, 6:66-7:3 (The “greater width[] allow[s] the user to more easily twist the endcap during removal from the lancet” and “easier use by persons with limited dexterity or vision.”).

VII. Conclusion

For the above reasons, the Board should find that LifeScan failed to demonstrate unpatentability of any of the challenged claims.

Respectfully submitted,

Dated: December 19, 2023

By: / Jonathan M. Strang /

Jonathan M. Strang (Reg. No. 61,724)
jonathan.strang@lw.com
Latham & Watkins LLP
555 Eleventh Street, NW, Ste. 1000
Washington, D.C. 20004-1304
Telephone: 202.637.2200
Fax: 202.637.2201

*Counsel for Patent Owner
Facet Technologies, LLC*



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

I hereby certify that this Patent Owner's Response complies with the word count limitation of 37 C.F.R. § 42.24(b)(2) because the Patent Owner's Response contains 13,616 words using Microsoft Word's counting feature, excluding the cover page, signature block, and the parts of the Patent Owner's Response exempted by 37 C.F.R. § 42.24(b)(2).

By: / Jonathan M. Strang /

Jonathan M. Strang (Reg. No. 61,724)
jonathan.strang@lw.com
Latham & Watkins LLP
555 Eleventh Street, NW, Ste. 1000
Washington, D.C. 20004-1304
Telephone: 202.637.2200
Fax: 202.637.2201

*Counsel for Patent Owner
Facet Technologies, LLC*



CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 19th day of December, 2023, a true and correct copy of the foregoing **Patent Owner's Response and all Exhibits** were served by electronic mail on Petitioner's lead and backup counsel at the following email addresses:

Michael J. Lyons (Reg. No. 37,386)
Alexander B. Stein (Reg. No. 71,397)
Gerald W. Griffin (*pro hac vice* pending)
MORGAN, LEWIS & BOCKIUS LLP
1400 Page Mill Road
Palo Alto, CA, 94304
Tel.: 650.843.4000
Fax: 650.843.4001
Email: LifeScanFacetIPRs@morganlewis.com

By: / Jonathan M. Strang /

Jonathan M. Strang (Reg. No. 61,724)
jonathan.strang@lw.com
Latham & Watkins LLP
555 Eleventh Street, NW, Ste. 1000
Washington, DC 20004-1304
Telephone: 202.637.2200
Fax: 202.637.2201

*Counsel for Patent Owner
Facet Technologies, LLC*

