Petitioner LifeScan, Inc.’s Demonstratives

LifeScan, Inc. v. Facet Technologies, LLC

IPR2023-00712 (U.S. Patent No. 8,840,635)

LifeScan, Inc. Ex. 1061
LifeScan, Inc. v. Facet Technologies LLC
IPR2023-00712 - U.S. Patent No. 8,840,635

1. Overview of the ’635 Patent
2. Saikley
   - Anticipation
   - Obviousness
3. Iio
   - Anticipation
   - Obviousness
4. Secondary Considerations Do Not Support Nonobviousness
5. Petitioner’s Motion to Exclude Evidence
6. Petitioner’s Opposition to Patent Owner’s Motion to Exclude Evidence

1 Overview of the ’635 Patent

2 Saikley

- Anticipation
- Obviousness

3 Iio

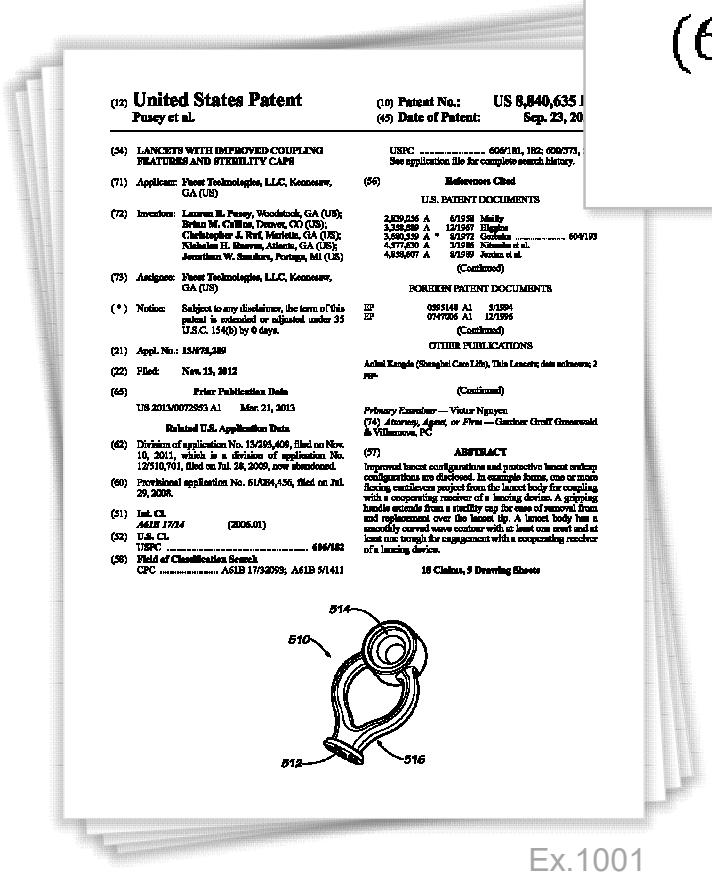
- Anticipation
- Obviousness

4 Secondary Considerations Do Not Support Nonobviousness

5 Petitioner’s Motion to Exclude Evidence

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’635 Patent Claims Priority to Provisional Application



(12) **United States Patent**
Pusey et al.

(10) Patent No.: US 8,840,635 B
(45) Date of Patent: Sep. 23, 20

(54) LANCETS WITH IMPROVED COUPLING FEATURES AND STERILITY CAPS

(71) Applicant: Pfizer Technologies, LLC, Kennesaw, GA (US)

(72) Inventors: Lauren B. Pusey, Woodstock, GA (US); Brian M. Collins, Denver, CO (US); Christopher J. Rul, Marietta, GA (US); Nicholas D. Sherron, Atlanta, GA (US); Jonathan W. Sandkvist, Portage, MI (US)

(73) Assignee: Pfizer Technologies, LLC, Kennesaw, GA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 13/678,389

(22) Filed: Nov. 15, 2012

(65) Prior Publication Data

US 2013/0072953 A1 Mar. 21, 2013

Related U.S. Application Data

(62) Division of application No. 12/205,406, filed on Nov. 10, 2011, which is a division of application No. 12/510,701, filed on Jul. 28, 2009, now abandoned.

(60) Provisional application No. 61/084,456, filed on Jul. 29, 2008.

(51) Int. Cl.
A61B 17/14 (2006.01)

(52) U.S. Cl.
USPC 606/182

(58) Field of Classification Search
CPC A61B 17/32093; A61B 5/1411
USPC 606/181, 182; 600/573
See application file for complete search history.

(56) References Cited

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(Continued)

Primary Examiner — Victor Nguyen
(74) *Attorney, Agent, or Firm* — Gardner Groff Greenwald & Villanueva, PC

(57) ABSTRACT

Improved lancet configurations and protective lancet sealing configurations are disclosed. In example forms, one or more flexing cantilevers project from the lancet body for coupling with a cooperating receiver of a lancing device. A gripping handle extends from a sterility cap for ease of removal from and replacement over the lancet tip. A lancet body has a smoothly curved wave contour with at least one crest and at least one trough for engagement with a cooperating receiver of a lancing device.

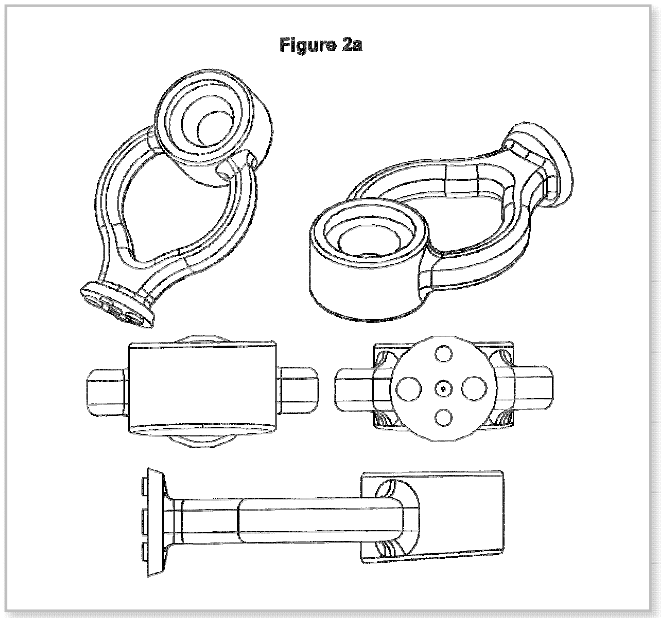
18 Claims, 9 Drawing Sheets

Ex.1001

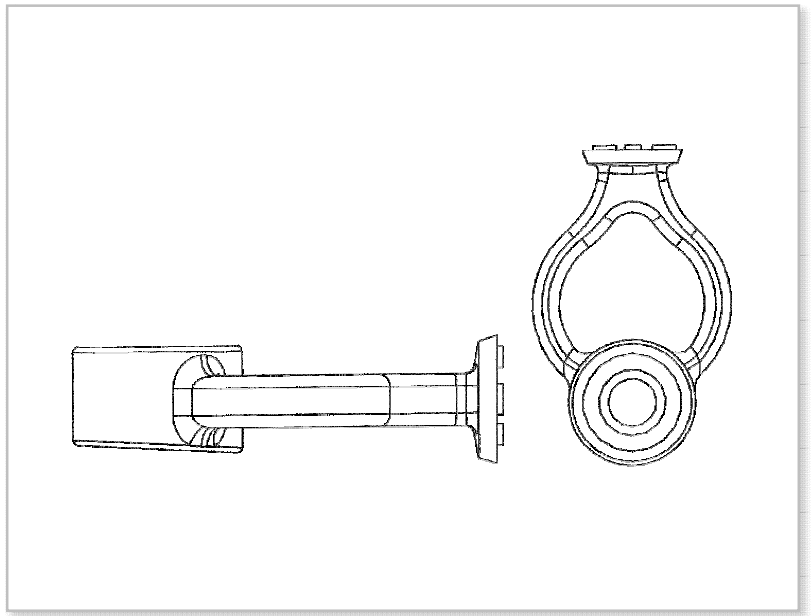
(60) Provisional application No. 61/084,456, filed on Jul. 29, 2008.

Ex.1001

NO WRITTEN DISCLOSURE OF DIMENSIONAL INFORMATION IN PROVISIONAL APPLICATION

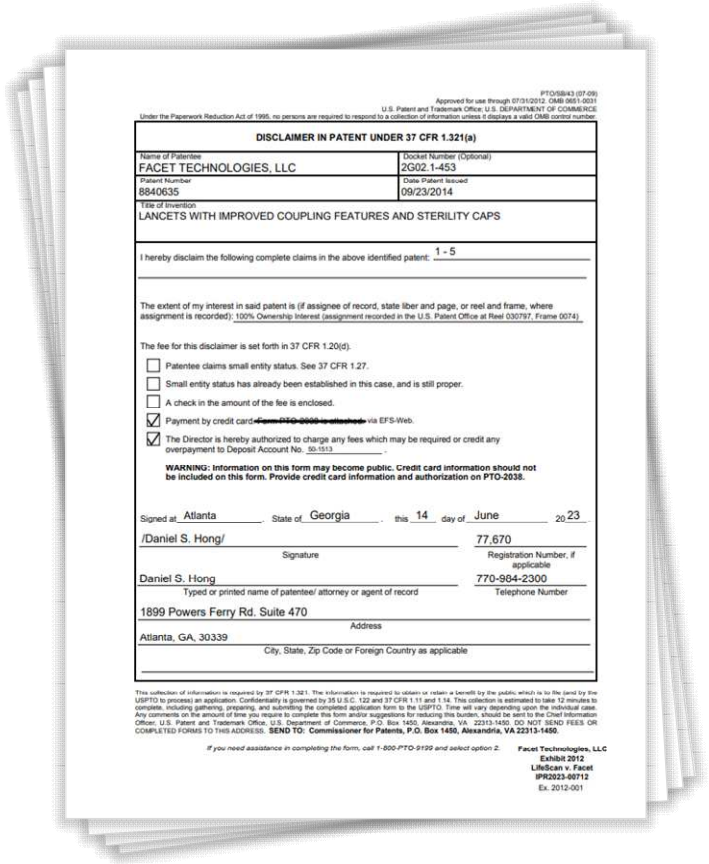


Ex.1031



Ex.1031

Patent Owner Abandoned Claims 1 through 5 After LifeScan Filed Petition



PTO/SB/43 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

DISCLAIMER IN PATENT UNDER 37 CFR 1.321(a)

Name of Patentee	Docket Number (Optional)
FACET TECHNOLOGIES, LLC	2G02.1-453
Patent Number	**Date Patent Issued**
8840635	09/23/2014

Title of Invention
LANCETS WITH IMPROVED COUPLING FEATURES AND STERILITY CAPS

I hereby disclaim the following complete claims in the above identified patent: 1 - 5

The extent of my interest in said patent is (if assignee of record, state liber and page, or reel and frame, where assignment is recorded): 100% Ownership Interest (assignment recorded in the U.S. Patent Office at Reel 030797, Frame 0074)

The fee for this disclaimer is set forth in 37 CFR 1.20(d).

- ☐ Patentee claims small entity status. See 37 CFR 1.27.
- ☐ Small entity status has already been established in this case, and is still proper.
- ☐ A check in the amount of the fee is enclosed.
- ☑ Payment by credit card ~~Form PTO-2038 is attached~~ via EFS-Web.
- ☑ The Director is hereby authorized to charge any fees which may be required or credit any overpayment to Deposit Account No. 50-1513 .

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Signed at Atlanta, State of Georgia, this 14 day of June 2023.

/Daniel S. Hong/ — Signature
77,670 — Registration Number, if applicable
Daniel S. Hong — Typed or printed name of patentee/ attorney or agent of record
770-984-2300 — Telephone Number
1899 Powers Ferry Rd. Suite 470 — Address
Atlanta, GA, 30339 — City, State, Zip Code or Foreign Country as applicable

This collection of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Facet Technologies, LLC
Exhibit 2012
LifeScan v. Facet
IPR2023-00712
Ex. 2012-001

DISCLAIMER IN PATENT UNDER 37 CFR 1.321(a)

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- ☑ The Director is hereby authorized to charge any fees which may be required or credit any overpayment to Deposit Account No. 50-1513 .

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Signed at Atlanta, State of Georgia, this 14 day of June 2023.

Ex.2012

Remaining Challenged Claims

Claim 6	The protective sterility cap of claim 1, in combination with a lancet having a lancet body defining a lancet thickness, and a sharp lancet tip initially embedded in the primary sheath, wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.
Claim 7	The protective sterility cap of claim 6, wherein the gripping handle portion defines a length at least equal to its lateral span.
Claim 8	The protective sterility cap of claim 6, wherein the gripping handle portion defines a length at least equal to the lancet thickness.
Claim 14	A protective sterility cap for a lancet, said sterility cap comprising a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein, a secondary sheath for receiving the sharp lancing tip of a used lancet, and a gripping handle portion extending between the primary sheath and the secondary sheath, with the primary sheath attached at a first end of the gripping handle portion and the secondary sheath attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet, said protective sterility cap being in combination with a lancet having a lancet body defining a lancet thickness, and a sharp lancet tip initially embedded in the primary sheath, wherein 10 the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.
Claim 16	The protective sterility cap of claim 14, further comprising at least one flat display surface for placement of branding indicia thereon.
Claim 17	The protective sterility cap of claim 14, wherein the gripping handle portion defines a length at least equal to its lateral span.
Claim 18	The protective sterility cap of claim 14, wherein the gripping handle portion defines a length at least equal to the lancet thickness.

’635 Patent: “gripping handle portion”

1. A protective sterility cap for a lancet, said sterility cap comprising a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein, a secondary sheath for receiving the sharp lancing tip of a used lancet, and a gripping handle portion extending between the primary sheath and the secondary sheath, with the primary sheath attached at a first end of the gripping handle portion and the secondary sheath attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet.

* * *

6. The protective sterility cap of claim **1**, in combination with a lancet having a lancet body defining a lancet thickness, and a sharp lancet tip initially embedded in the primary sheath, wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.

7. The protective sterility cap of claim **6**, wherein the gripping handle portion defines a length at least equal to its lateral span.

8. The protective sterility cap of claim **6**, wherein the gripping handle portion defines a length at least equal to the lancet thickness.

Ex.1001 (’635 Patent at Claims 1, 6, 7, 8)

14. A protective sterility cap for a lancet, said sterility cap comprising a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein, a secondary sheath for receiving the sharp lancing tip of a used lancet, and a gripping handle portion extending between the primary sheath and the secondary sheath, with the primary sheath attached at a first end of the gripping handle portion and the secondary sheath attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet, said protective sterility cap being in combination with a lancet having a lancet body defining a lancet thickness, and a sharp lancet tip initially embedded in the primary sheath, wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.

* * *

17. The protective sterility cap of claim **14**, wherein the gripping handle portion defines a length at least equal to its lateral span.

18. The protective sterility cap of claim **14**, wherein the gripping handle portion defines a length at least equal to the lancet thickness.

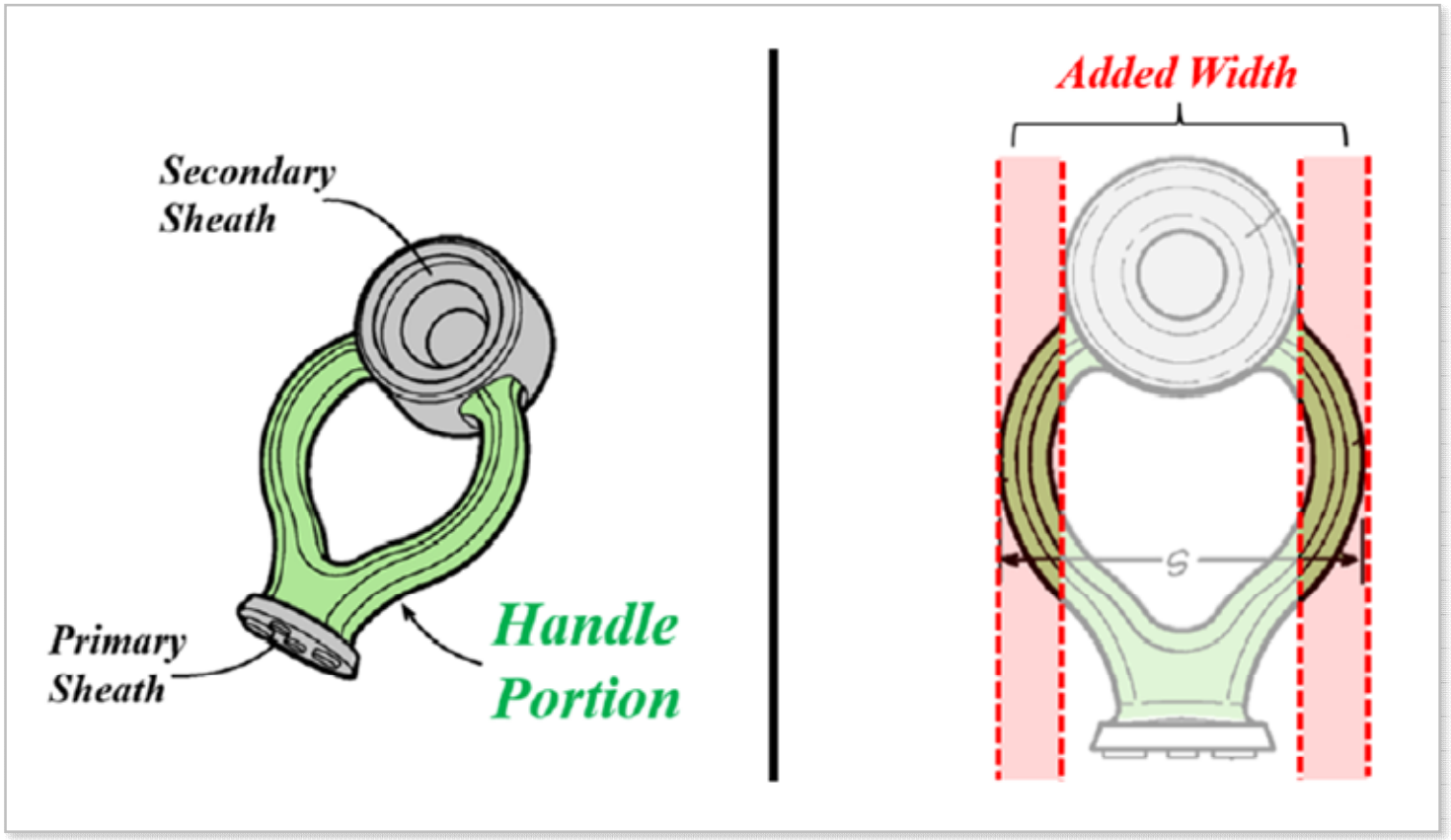
Ex.1001 (’635 Patent at Claims 14, 17, 18)

Ex. 1001; Paper 1 (Pet.) at 19-45, 47-54, 66-86, 90-93; Paper 32 (Pet. Reply) at 10-13, 17-23, 25-28

’635 Patent: “gripping handle portion”

The handle or extension arm portion **516** defines a forked or split configuration having first and second arms **520** transversely spaced apart from one another, with an open center portion therebetween. This forked arrangement provides the handle with a greater width, allowing the user to more easily twist the endcap during removal from the lancet.

Ex.1001, 6:48-55



Ex.1001, Figs. 5A, 5D

’635 Patent: Dimensional Limitations

6. The protective sterility cap of claim **1**, in combination with a lancet having a lancet body defining a lancet thickness, and a sharp lancet tip initially embedded in the primary sheath, wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.

7. The protective sterility cap of claim **6**, wherein the gripping handle portion defines a length at least equal to its lateral span.

8. The protective sterility cap of claim **6**, wherein the gripping handle portion defines a length at least equal to the lancet thickness.

* * *

17. The protective sterility cap of claim **14**, wherein the gripping handle portion defines a length at least equal to its lateral span.

18. The protective sterility cap of claim **14**, wherein the gripping handle portion defines a length at least equal to the lancet thickness.

Ex.1001 (’635 Patent at Claims 6, 7, 8, 17, 18)

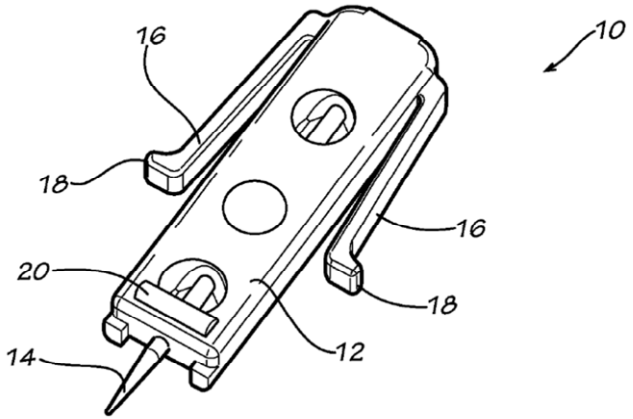


FIG. 1A

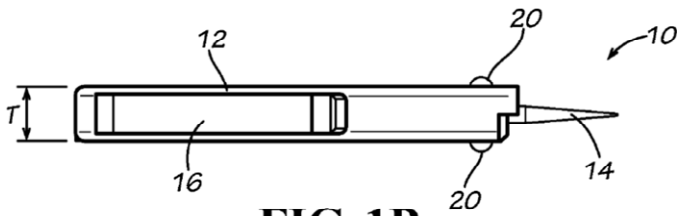


FIG. 1B

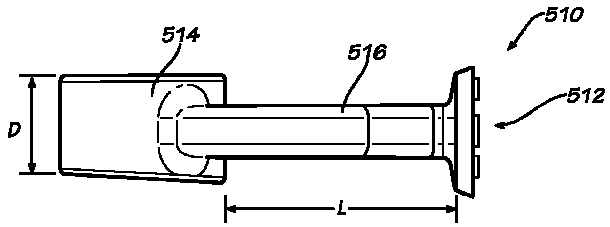


FIG. 5C

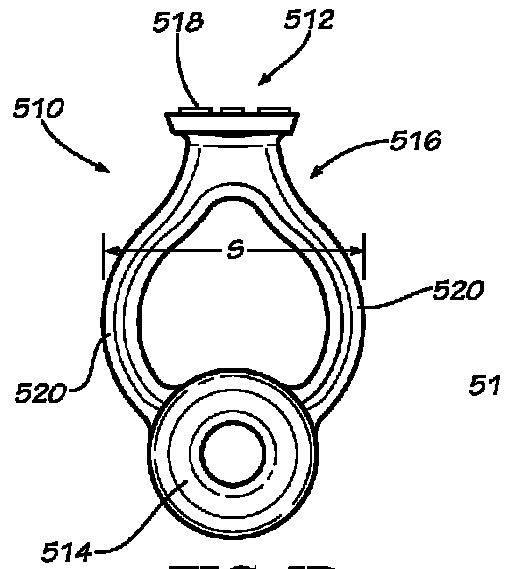


FIG. 5D

Ex.1001 (’635 Patent at Figs. 1A, 1B, 5C, 5D)

Ex. 1001; Paper 32 (Pet. Reply) at 17-25, 26-29; Paper 1 (Pet.) at 36-44, 47-54, 78-86, 90-93

LifeScan's Demonstratives, not evidence

1 Overview of the ‘635 Patent

2 **Saikley**

- Anticipation
- Obviousness

3 Iio

- Anticipation
- Obviousness

4 Secondary Considerations Do Not Support Nonobviousness

5 Petitioner’s Motion to Exclude Evidence

6 Petitioner’s Opposition to Patent Owner’s Motion to Exclude Evidence

Patent Owner ONLY Challenges Anticipation Based on the "Gripping Handle Portion" limitation

1. Patent Owner challenges whether Saikley has a discrete gripping handle portion extending between the sheaths;

2. Patent Owner challenges whether Saikley's gripping handle portion meets the dimensional limitations.

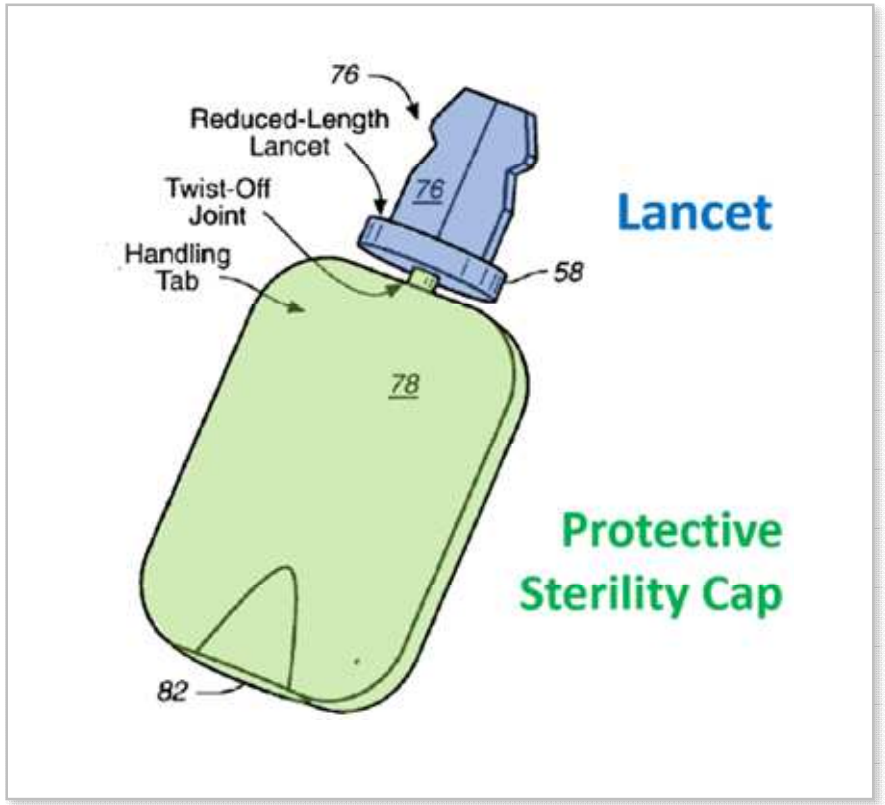
6. The protective sterility cap of claim **1**, in combination with a lancet having a lancet body defining a lancet thickness, and a sharp lancet tip initially embedded in the primary sheath, wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.

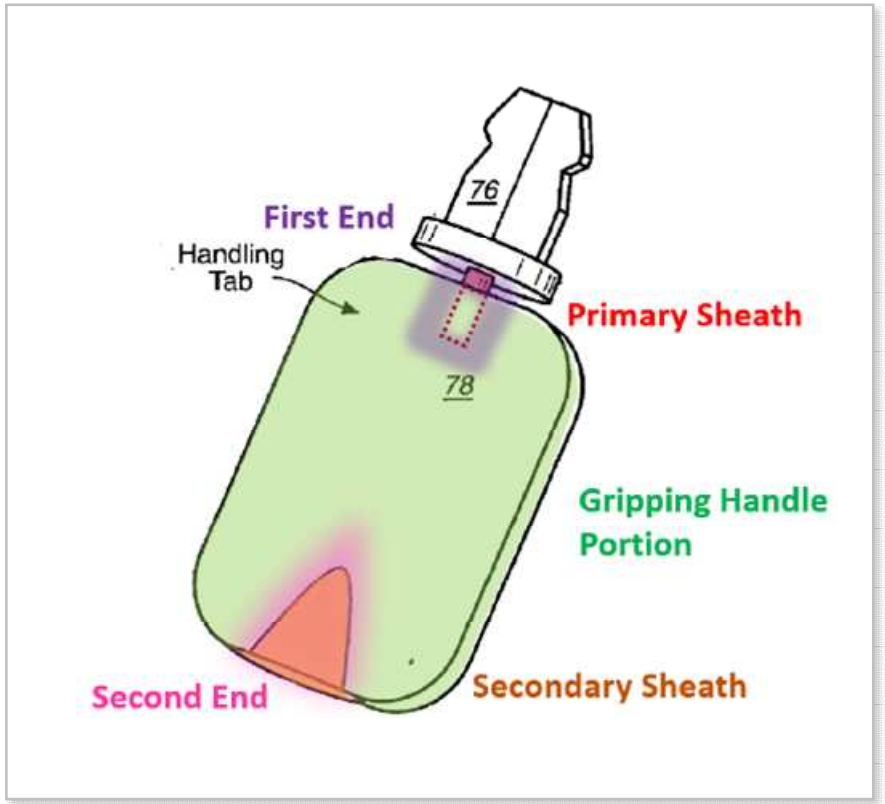
Ex.1001

14. A protective sterility cap for a lancet, said sterility cap comprising a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein, a secondary sheath for receiving the sharp lancing tip of a used lancet, and a gripping handle portion extending between the primary sheath and the secondary sheath, with the primary sheath attached at a first end of the gripping handle portion and the secondary sheath attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet, said protective sterility cap being in combination with a lancet having a lancet body defining a lancet thickness, and a sharp lancet tip initially embedded in the primary sheath, wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.

Ex.1001

Petitioner Consistently Identifies the Claimed Features in Saikley

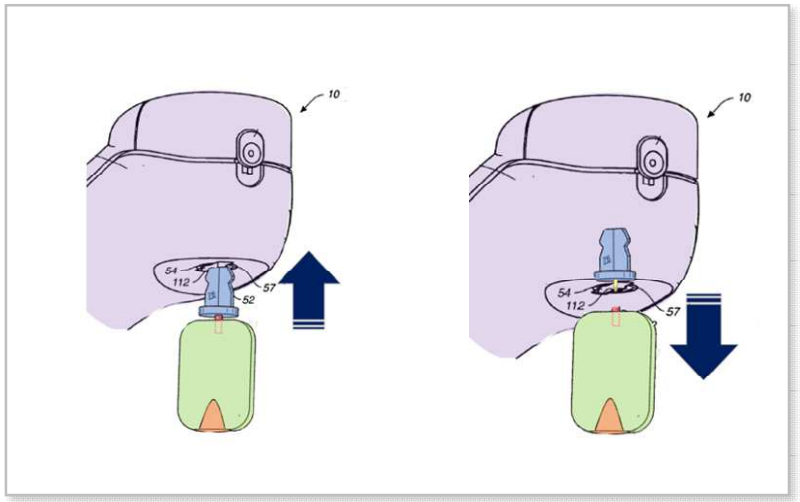


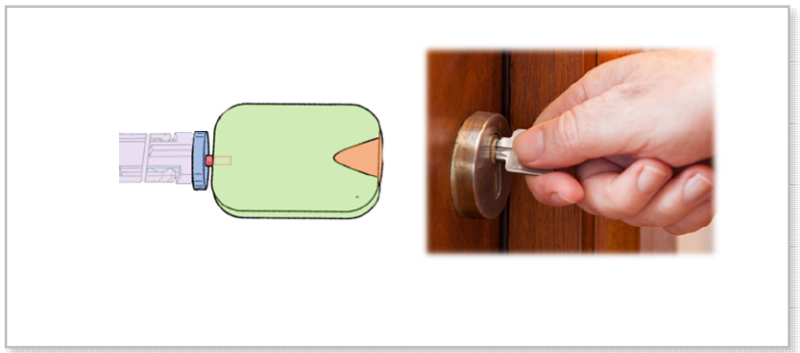


Paper 1 (Pet.) at 10, 27; Ex.1005, Fig. 7A; Paper 21 (POR) at 6-13

LifeScan's Demonstratives, not evidence

Saikley Discloses the "gripping handle portion" Limitation





Paper 1 (Pet.) at 23-24; Ex. 1005

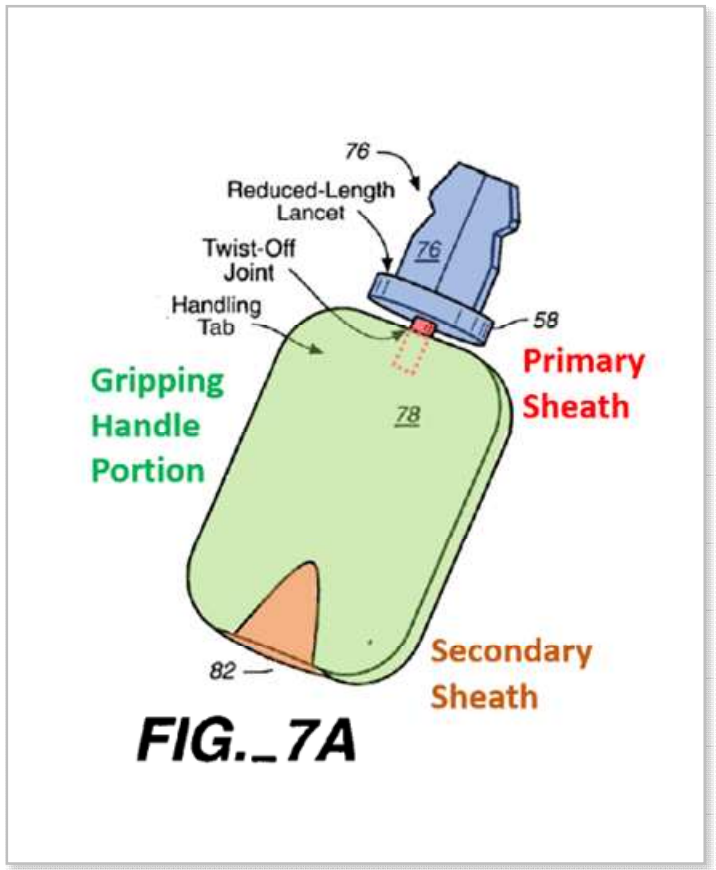


FIG._7A

Ex.1005

This short length might make the lancet difficult for the user to handle and install, so the protective cap **78** (that is removed before use) should be made much larger than usual to aid handling. Cap **78** may be an integrally molded, pull-off tab such as shown in **FIG. 7A**, or may be a hollow cap **80** with large handle molded separately or in the same cavity as lancet **76** and placed over lancet **76** after molding, such as shown in **FIG. 7B**. A hollow cup or solid "pin cushion" type area **82** can be provided at the opposite end of cap **78**, as shown in **FIG. 7A**, to cover the sharp during removal from the device and disposal.

Ex.1005 (Saikley at [0050])

Patent Owner's Narrow Interpretation of Extending Between

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.

To distinguish Saikley, Patent Owner wrongly interprets the claims to require that the gripping handle portion to extend **only** between the primary and secondary sheaths.

Paper 21 (POR) at 10; Paper 32 (Pet. Reply) at 10

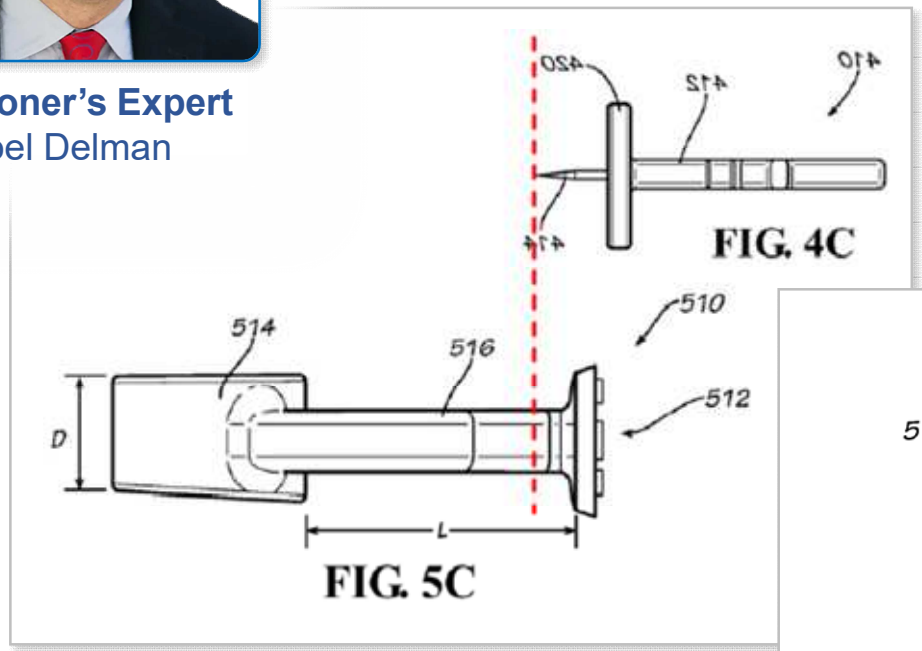
Saikley Shows a Discrete Gripping Handle Portion Extending Between the Sheaths



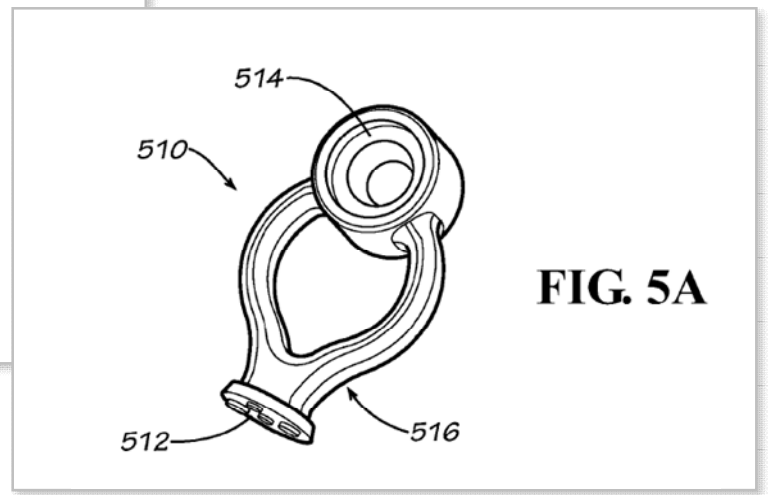
Petitioner's Expert
Joel Delman

"In this context, there is nothing about the claimed sheaths and gripping handle which prevents them from being embedded within or enclosed by each other. In many products, there are separate structural features which are embedded or enclosed, but are nonetheless distinct."

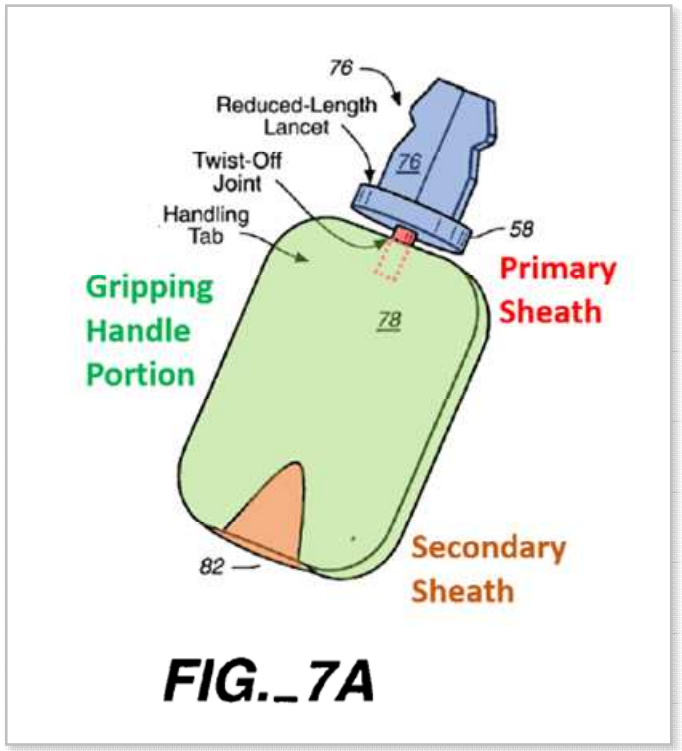
Ex.1034, ¶ 11



Paper 32 (Pet. Reply) at 21; Ex. 1001



Ex.1001

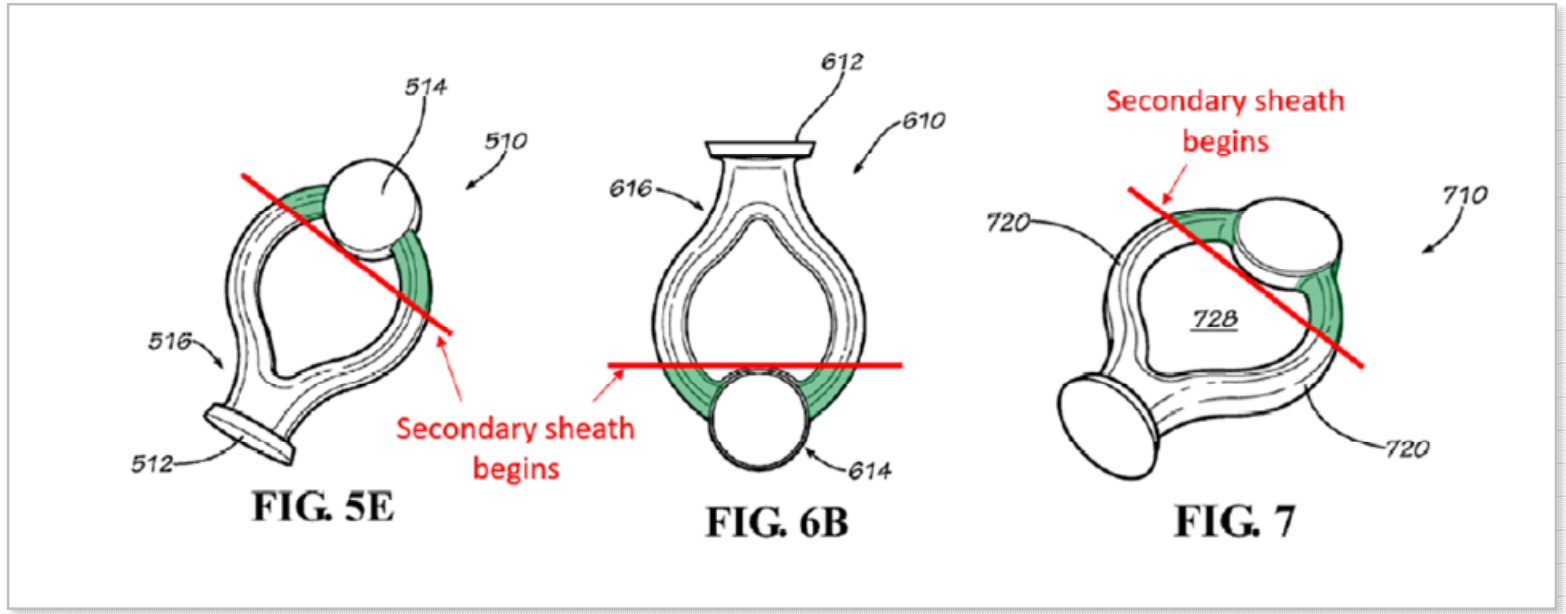


Ex.1005

Paper 32 (Pet. Reply) at 10-12

LifeScan's Demonstratives, not evidence

Patent Owner's Narrow Interpretation Excludes '635 Patent Cap Embodiments



Paper 32 (Pet. Reply) at 11



An interpretation of a claim term that excludes a preferred embodiment in the specification is "rarely, if ever, correct."

Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1996)

Paper 32 (Pet. Reply) at 10-11

"Gripping handle portion": Patent Owner Uses Broader Interpretation to Assert Infringement



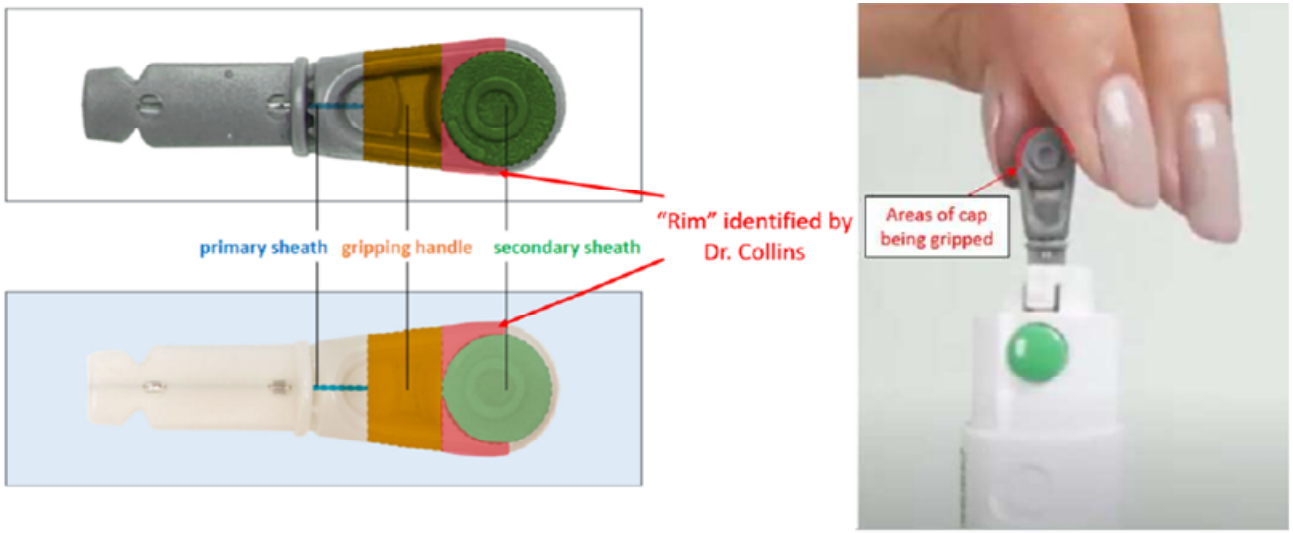
Patent Owner's Expert
Dr. John M. Collins

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

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

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

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



Paper 32 (Pet. Reply) at 11-12; Ex. 1035, 142:8-16; Paper 47 (POSR) at 15-21

Patent Owner Argues the "Gripping Handle Portion" Does Not Meet the Dimensional Limitations

According to Patent Owner, "drawings that are not to scale cannot be used by themselves to show that the art teaches or suggests dimensions, relative dimensions, or proportions."

Patent Drawings Can Disclose Dimensional Limitations

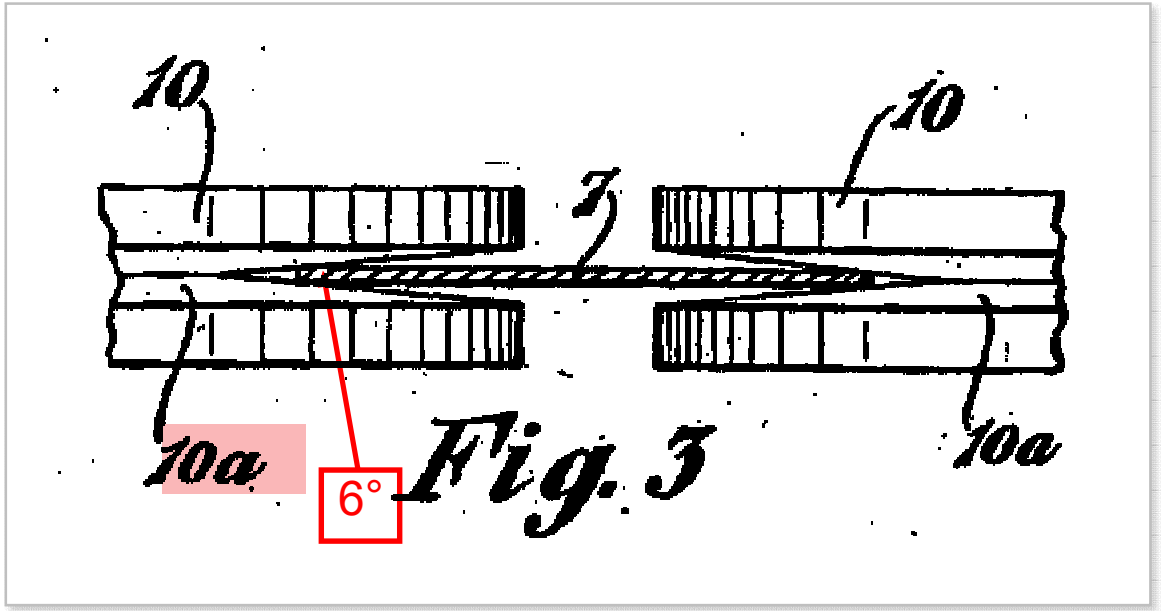


Judge Rich
United States Court of Customs and Patent Appeals

"**Description for the purposes of anticipation can be by drawings alone** as well as by words . . . Fig. 3 in the Wilson reference focuses on the edge rolls, showing them with great particularity and showing the grooves thereon to have an angularity well within the ["not exceeding 15°"] range recited in appellant's claims."

"The half-angle of the V-shaped groove 10a measures about 6° on this drawing, but the specification says nothing about the angle."

In re Mraz, 455 F.2d 1069, 1072, 1071 (CCPA 1972)



Patent Owner's Cases Are Distinguishable

Patent Owner's cases do not require disregarding what is clear in the figures

"HHI's argument [based on the figure] therefore reduces to a request for a mulligan that would erase from the prosecution history the inventor's disavowal of a particular aspect of the claim term's meaning."

Hockerson-Halberstadt, Inc. v. Avia Grp. Int'l, 222 F.3d 951, 956-57 (Fed. Cir. 1996)

Dealt with claim construction assertions at odds with relevant patents and associated prosecution histories.

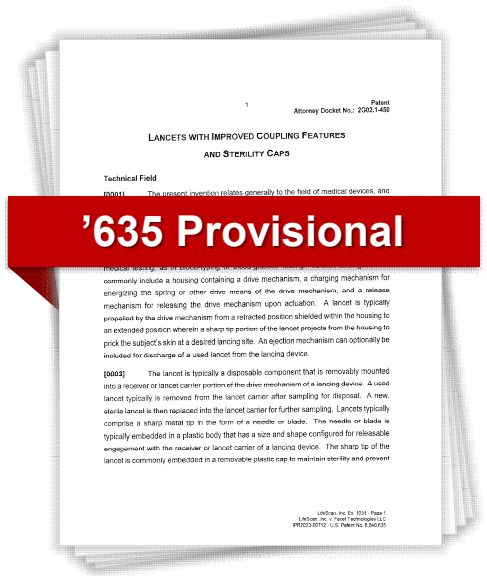
Source Vagabond Systems Limited v. Hydrapak, Inc., 753 F.3d 1291, 1300-01(Fed. Cir. 2014);
Plantronics, Inv. v. Aliph, Inc., 724 F.3d 1343, 1349-52 (Fed. Cir. 2013)

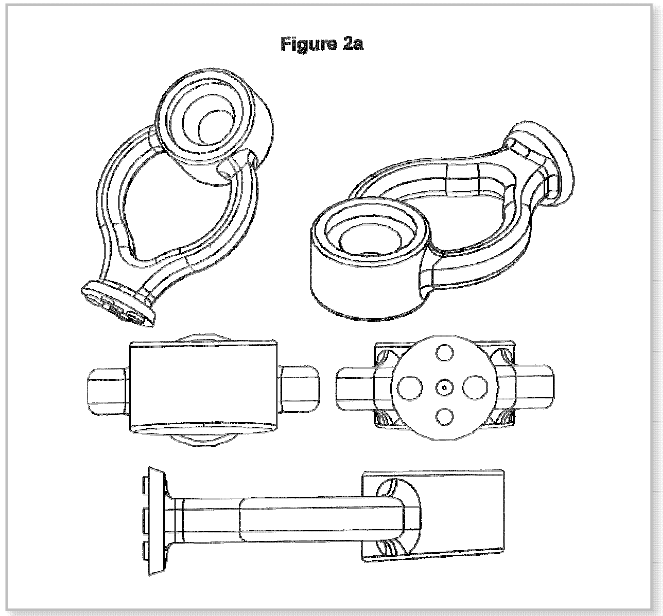
Rejected invalidity finding based on computations performed on a software model rather than on the materials contained in the patent.

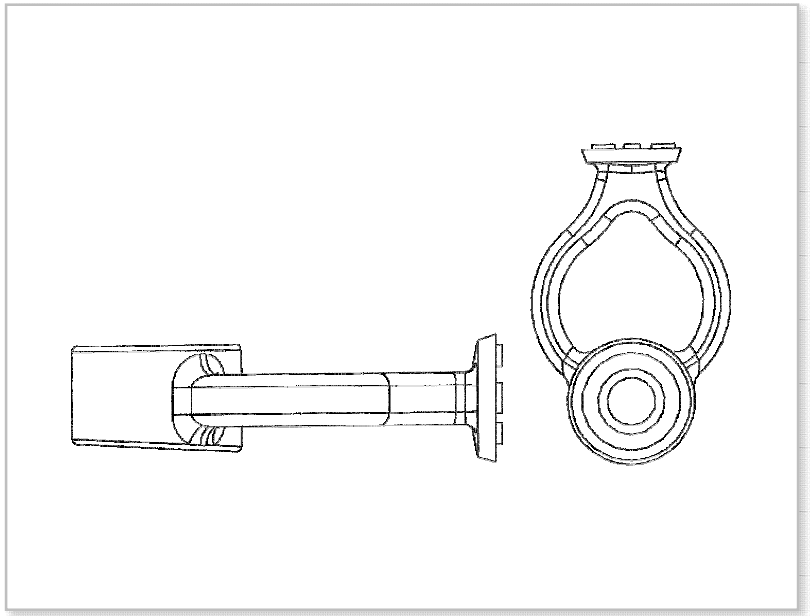
Nystrom v. TREX Co., 424 F.3d 1136, 1148 (Fed. Cir. 2005), *aff'd*, 200 F. App'x 987 (Fed. Cir. 2006)

Paper 32 (Pet. Reply) at 13-16; Paper 21 (POR) at 15-19;
Paper 47 (POSR) at 26-28

’635 Provisional Application: No Dimensional Limitations







Ex.1031

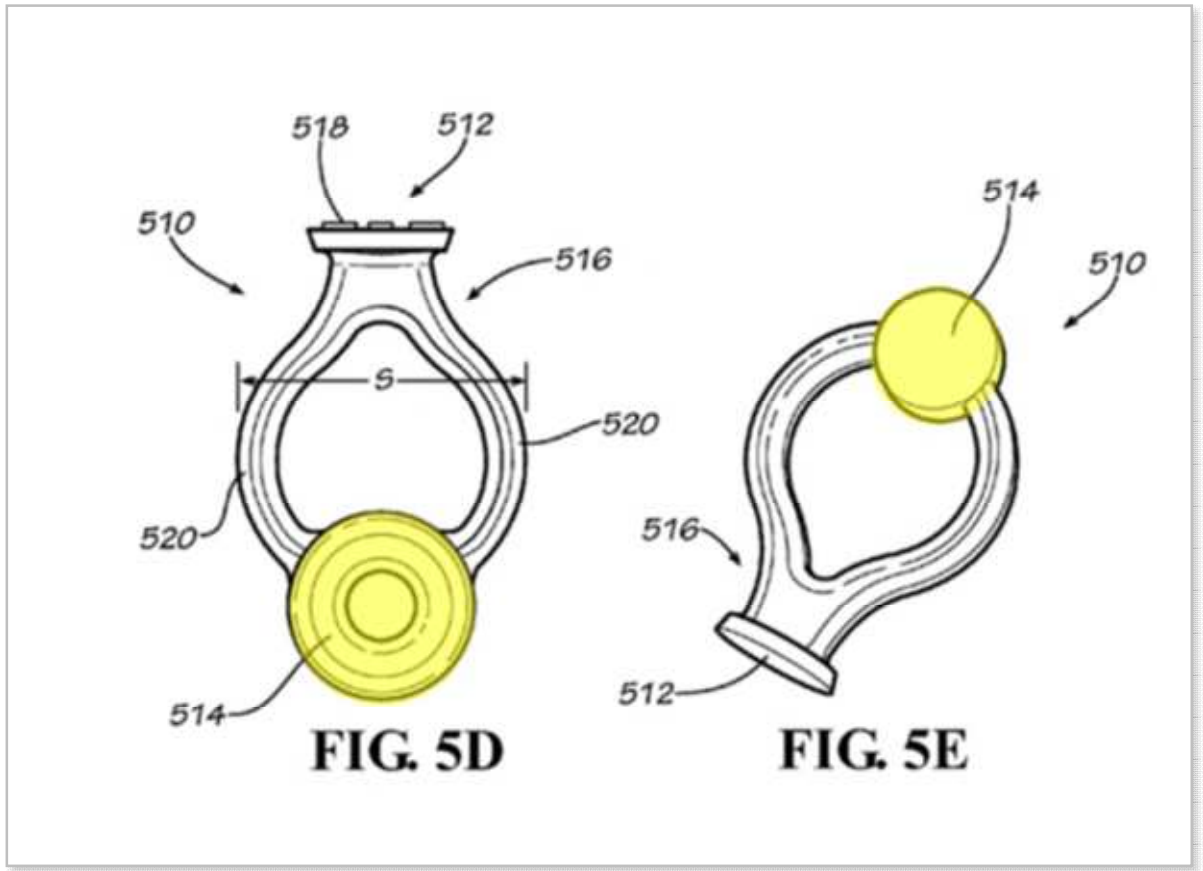


Patent Owner’s Expert
Dr. John M. Collins

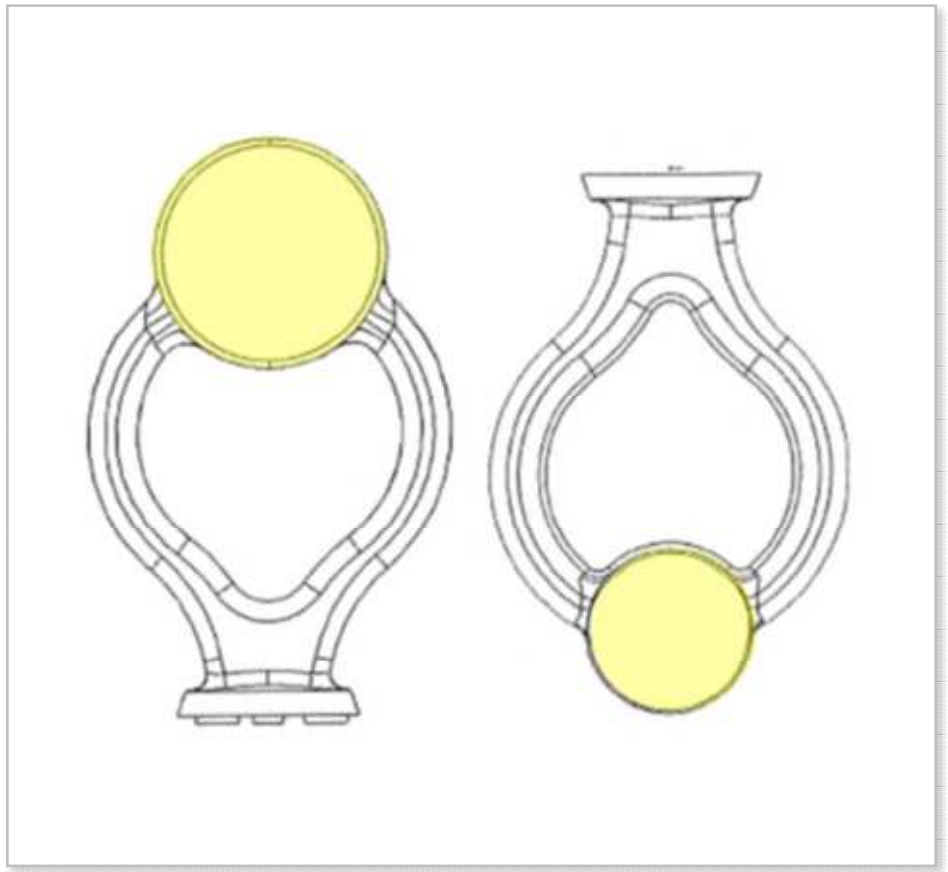
A. It’s not -- yeah, there aren’t specific dimensions called out in the provisional.

Ex.1035, 128:12-14

Patent Owner's Arguments Regarding Inconsistencies in Saikley's Figures Neglect Inconsistencies in '635 Patent Figures



Ex.1001



Ex.1031

Saikley's Figure 7A Resembles a Perspective Photograph

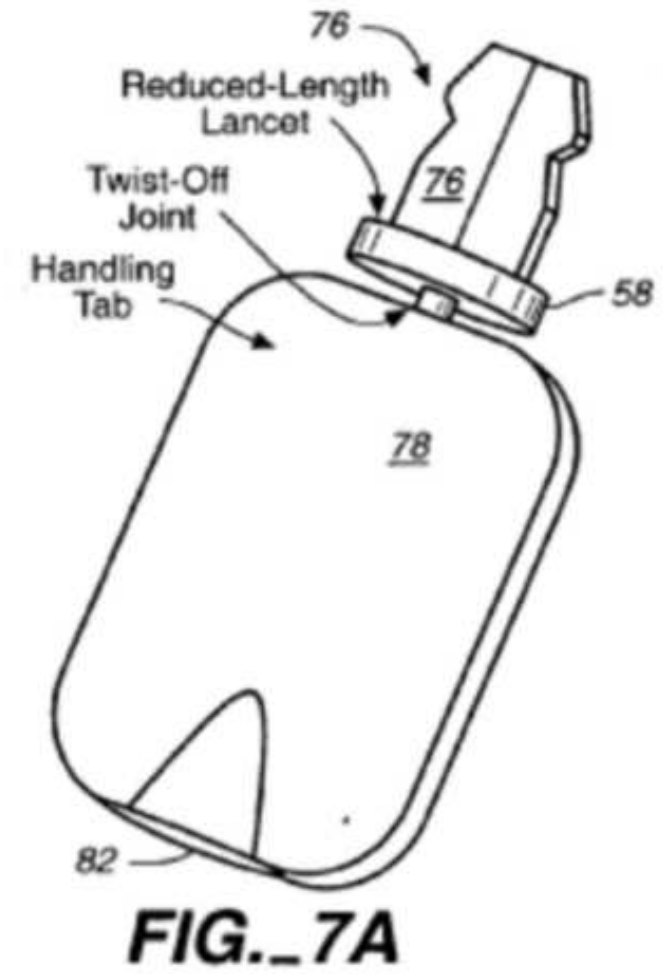


FIG._7A



Dimensional Claims Require Only Relative Dimensions

6. The protective sterility cap of claim **1**, in combination with a lancet having a lancet body defining a lancet thickness, and a sharp lancet tip initially embedded in the primary sheath, wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.

7. The protective sterility cap of claim **6**, wherein the gripping handle portion defines a length at least equal to its lateral span.

8. The protective sterility cap of claim **6**, wherein the gripping handle portion defines a length at least equal to the lancet thickness.

17. The protective sterility cap of claim **14**, wherein the gripping handle portion defines a length at least equal to its lateral span.

18. The protective sterility cap of claim **14**, wherein the gripping handle portion defines a length at least equal to the lancet thickness.

Ex.1001 ('635 Patent at Claims 6, 7, 8, 17, 18)

"Claim 6 does not specify a precise size, but only a relative relationship: 'a lateral span of at least 1.5 times the lancet thickness.' As noted above, we consider what the drawings in a reference 'reasonably disclose and suggest to one skilled in the art.' *Aslanian*, 590 F.2d at 914."

Paper 13 (Inst. Dec.) at 42

Paper 32 (Pet. Reply) at 17-19

Saikley Discloses the Dimensional Limitations

[0050] Referring to **FIGS. 7A, 7B** and **7C**, alternate embodiments of lancets and caps are shown. Another factor that affects the overall size of the lancing mechanism is the length of the lancet itself. Traditional disposable lancets, such as shown in **FIG. 3**, have an elongate body **48** and a short cap **51**. In order to reduce the profile of device head **34**, a shortened lancet **76** can be used that is just long enough to engage lancet holder **68** (shown in **FIG. 6**.) This short length might make the lancet difficult for the user to handle and install, so the protective cap **78** (that is removed before use) should be made much larger than usual to aid handling. Cap **78** may be an integrally molded, pull-off tab such as shown in **FIG. 7A**, or may be a hollow cap **80** with large handle molded separately or in the same cavity as lancet **76** and placed over lancet **76** after molding, such as shown in **FIG. 7B**. A hollow cup or solid "pin cushion" type area **82** can be provided at the opposite end of cap **78**, as shown in **FIG. 7A**, to cover the sharp during removal from the device and disposal.

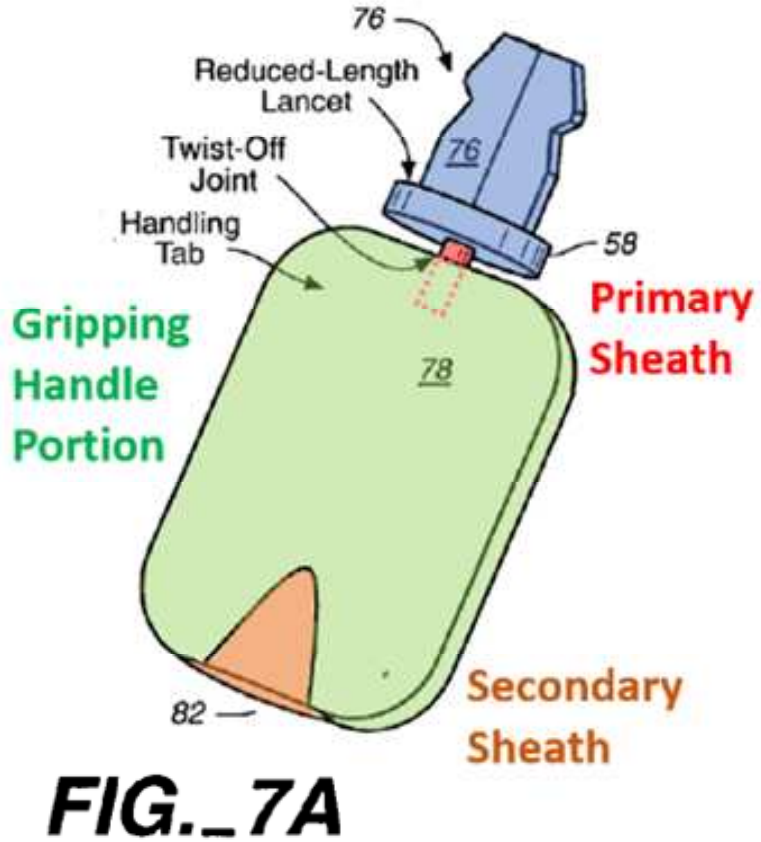


FIG._7A

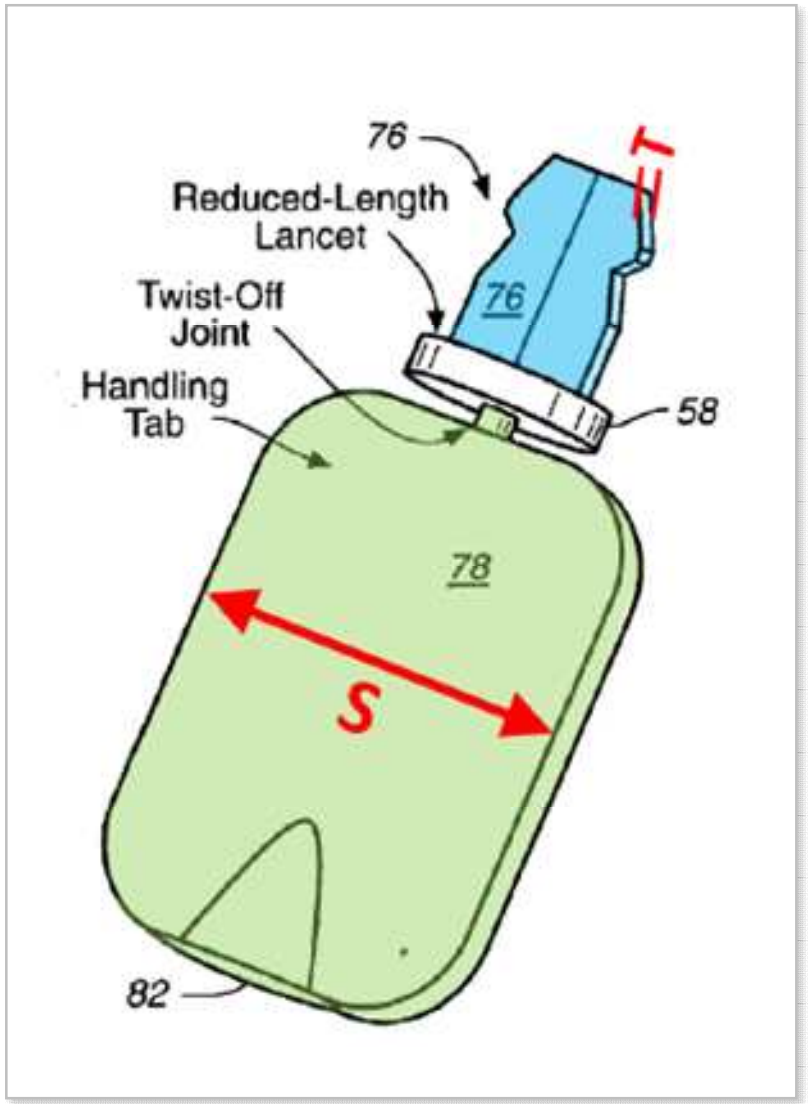
Ex.1005, ¶[0050]

Saikley Discloses A Lateral Span Far More Than 1.5 Times Thickness

6. The protective sterility cap of claim **1**, in combination with a lancet having a lancet body defining a lancet thickness, and a sharp lancet tip initially embedded in the primary sheath, wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.

14. A protective sterility cap for a lancet, said sterility cap comprising a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein, a secondary sheath for receiving the sharp lancing tip of a used lancet, and a gripping handle portion extending between the primary sheath and the secondary sheath, with the primary sheath attached at a first end of the gripping handle portion and the secondary sheath attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet, said protective sterility cap being in combination with a lancet having a lancet body defining a lancet thickness, and a sharp lancet tip initially embedded in the primary sheath, wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.

Ex.1001, Claims 6 and 14



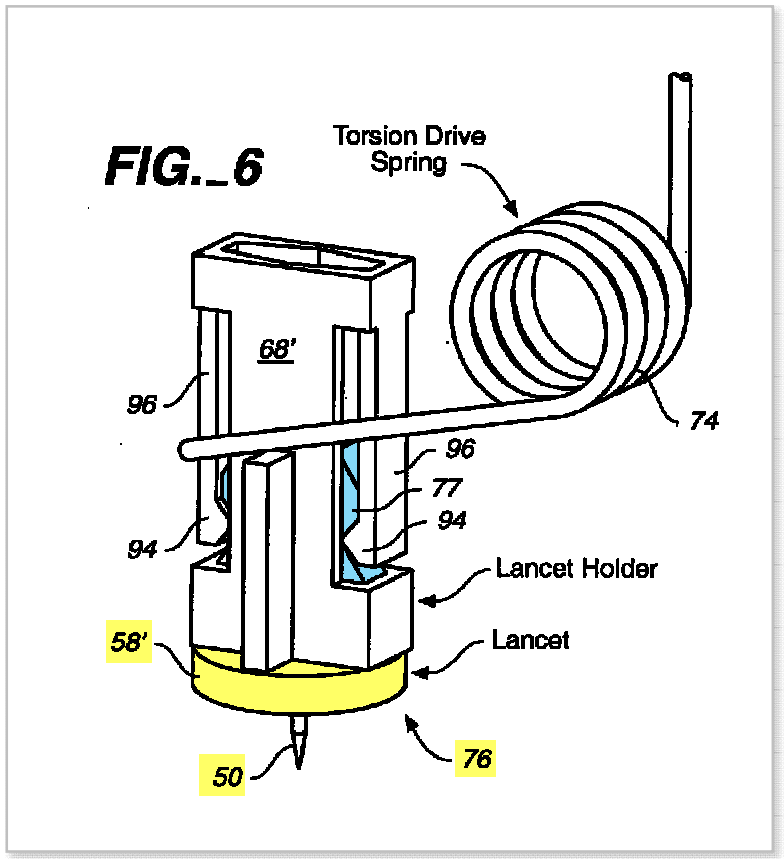
Paper 1 (Pet.) at 38

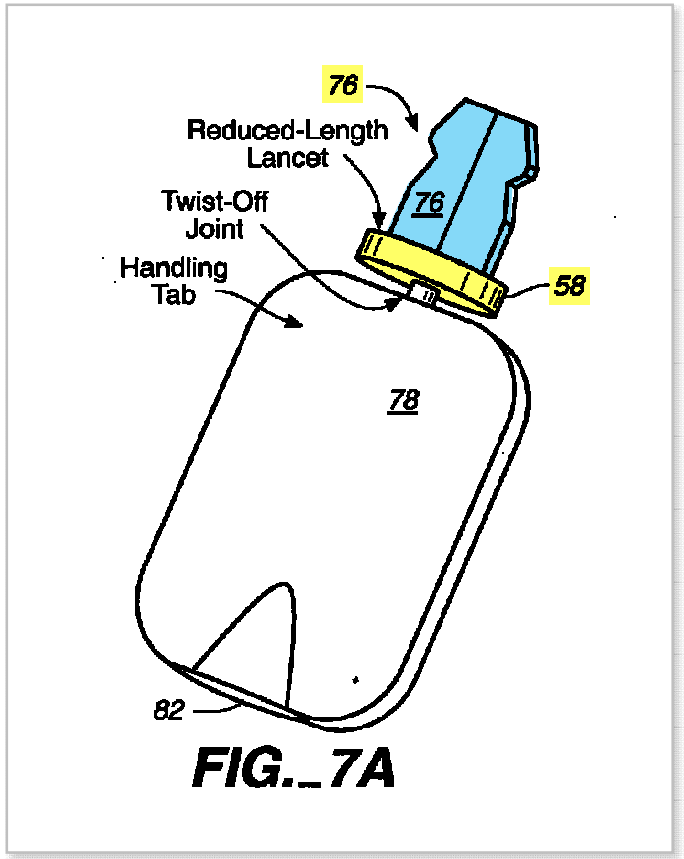
Paper 32 (Pet. Reply) at 17-22; Paper 1 (Pet.) at 36-40; 43

LifeScan's Demonstratives, not evidence

Saikley Discloses Lateral Span to Thickness Limitation

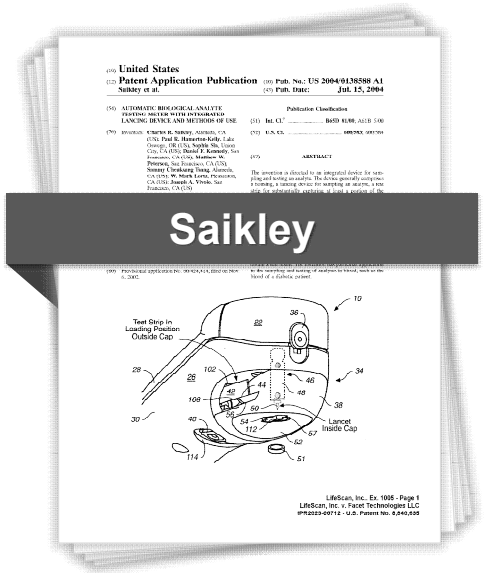
[0042] In the embodiment of integrated device **10** shown in **FIG. 4**, the guiding feature on the lancet **46** is a cylindrical collar **58** about 3 mm from the needle point, concentric with needle **50**.





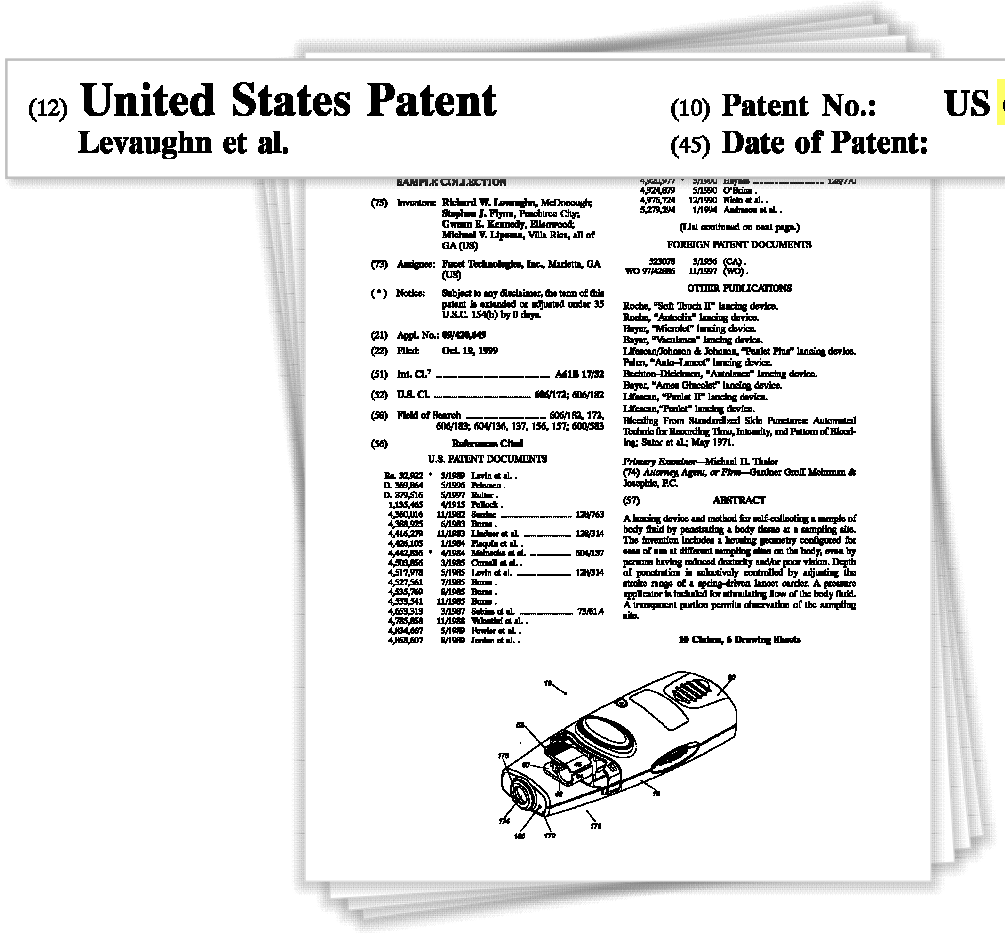
Ex. 1005, ¶[0042], Fig. 6, Fig. 7A

Saikley Discloses Lateral Span to Thickness Limitation



operation of the above FreeStyle system. U.S. Pat. No. 6,283,982 issued Sep. 4, 2001 to TheraSense, Inc. and incorporated herein by reference describes a lancing device that is used in the FreeStyle system.

Ex.1005, ¶ [0003]



Ex.1017

Levaughn, Incorporated By Reference in Saikley, Discloses Claimed Ratio

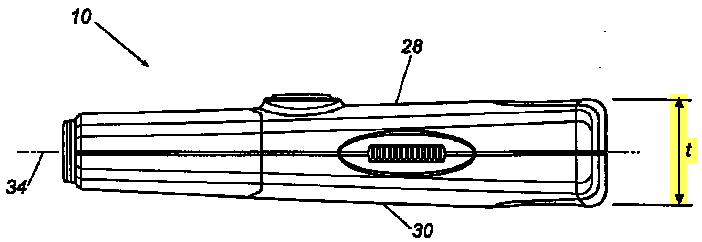


Fig. 2

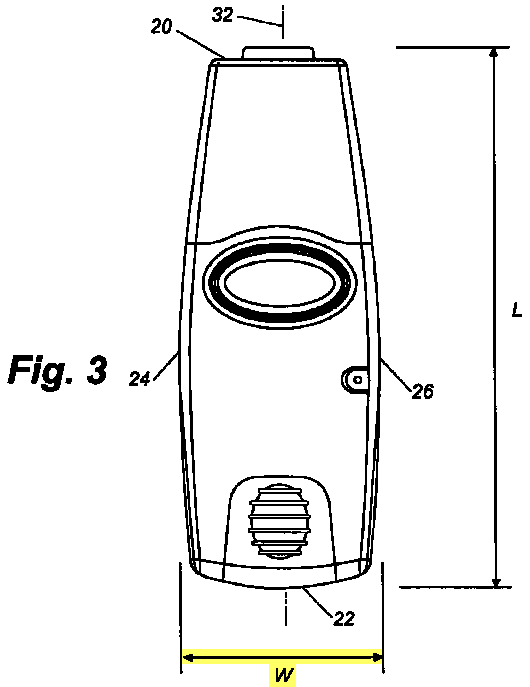


Fig. 3

end **20** and a sampling site. According to preferred form, the overall width W of the lancing device **10** is at least 1½ times, and more preferably about twice the overall thickness t. This transverse ratio (W/t) of at least 3:2, and more preferably about 2:1, provides an easy to grip device which resists twisting about the central axis. As used herein, "overall"

Ex.1017, 5:13-18

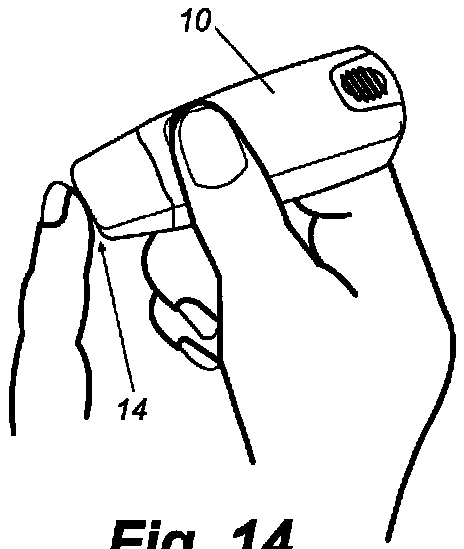
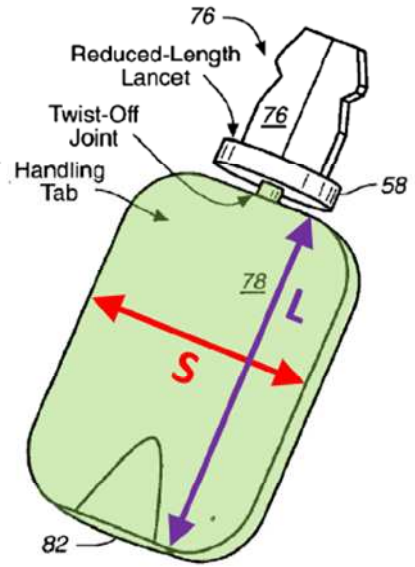


Fig. 14

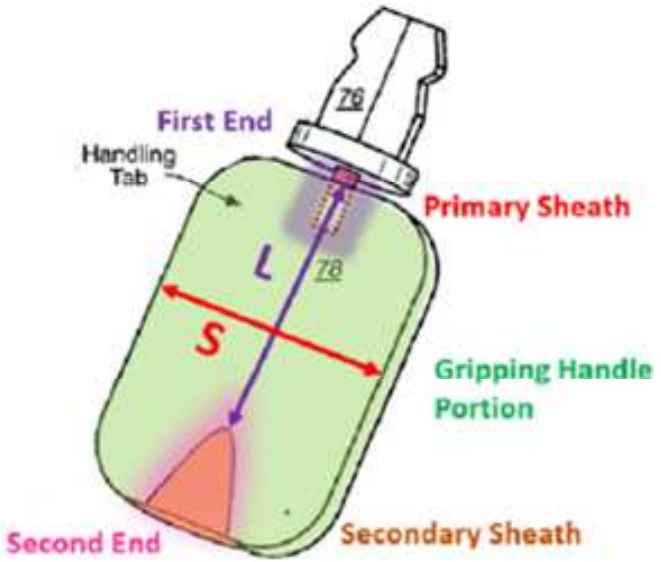
Petitioner's Length Measurement is Correct

Length Drawn in Petition



Paper 1 (Pet.) at 41

Alternative Length Drawn in Reply



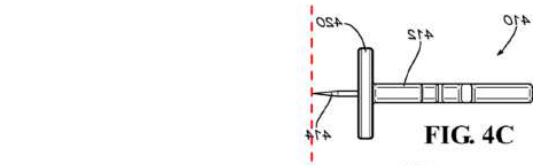


FIG. 4C

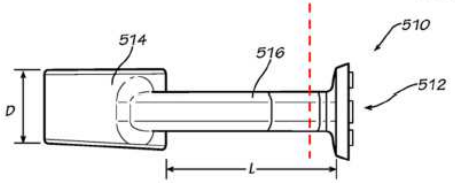
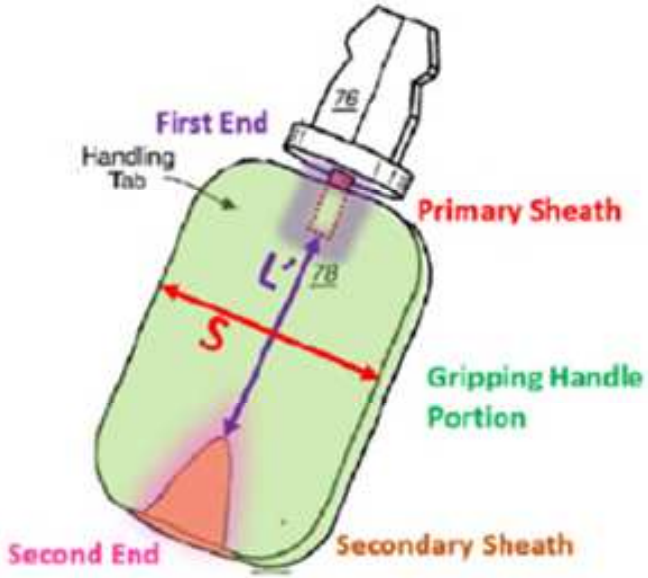


FIG. 5C

Paper 32 (Pet. Reply) at 21-22

Dr. Collins' Incorrect Length



Ex.2056, ¶104

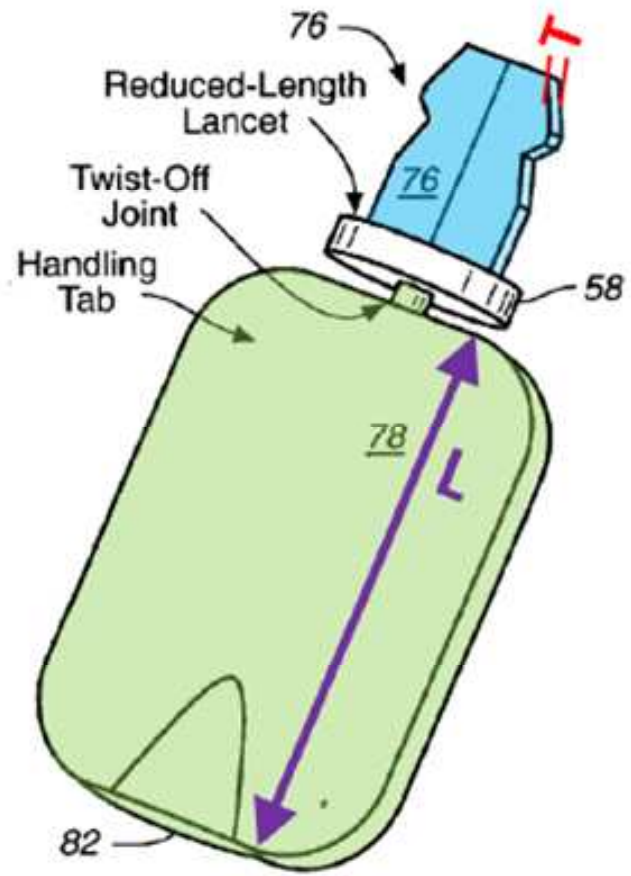
Paper 32 (Pet. Reply) at 17-22; Ex.1034, ¶¶ 32-34; Ex.1005, Fig. 7A; Ex.1001, Figs. 4C, 5C; Paper 47 (POSR) at 16-21, 24-25; Paper 21 (POR) at 19-32

Saikley Discloses Length to Thickness Limitation

8. The protective sterility cap of claim **6**, wherein the gripping handle portion defines a length at least equal to the lancet thickness.

18. The protective sterility cap of claim **14**, wherein the gripping handle portion defines a length at least equal to the lancet thickness.

Ex.1001, Claims 8 and 18



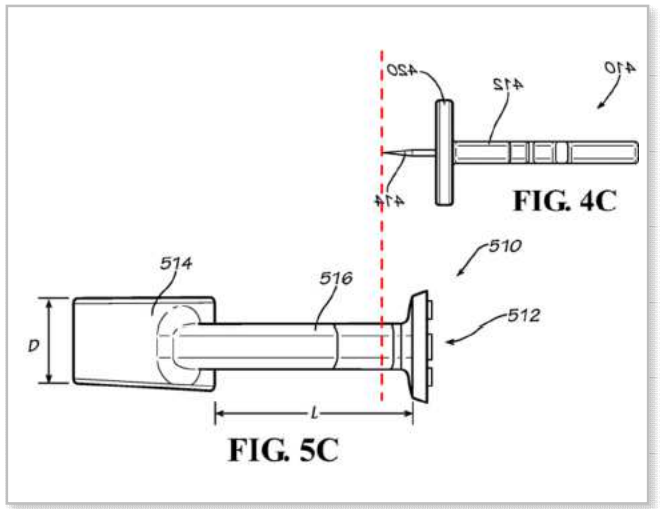
Paper 1 (Pet.) at 43

Saikley Discloses Lateral Span to Length Limitation

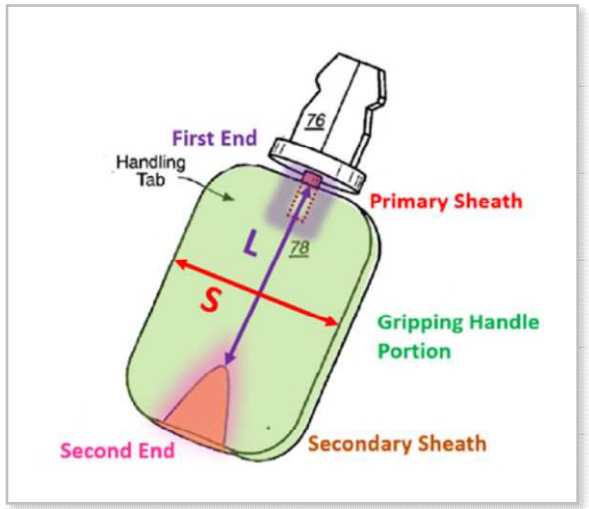
7. The protective sterility cap of claim **6**, wherein the gripping handle portion defines a length at least equal to its lateral span.

17. The protective sterility cap of claim **14**, wherein the gripping handle portion defines a length at least equal to its lateral span.

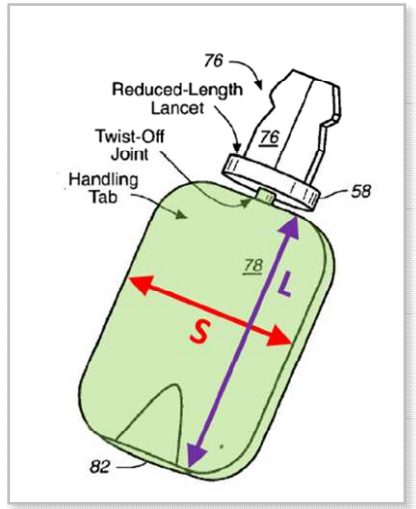
Ex.1001, Claims 7 and 17



Paper 32 (Pet. Reply) at 20-22



Paper 32 (Pet. Reply) at 20-22



Paper 1 (Pet.) at 41

Paper 32 (Pet. Reply) at 17-22; Paper 1 (Pet.) at 36-44; Paper 21 (POR) at 19-32; Paper 47 (POSR) at 16-21, 24-25

LifeScan's Demonstratives, not evidence

1 Overview of the ‘635 Patent

2 **Saikley**

- Anticipation
- Obviousness

3 Iio

- Anticipation
- Obviousness

4 Secondary Considerations Do Not Support Nonobviousness

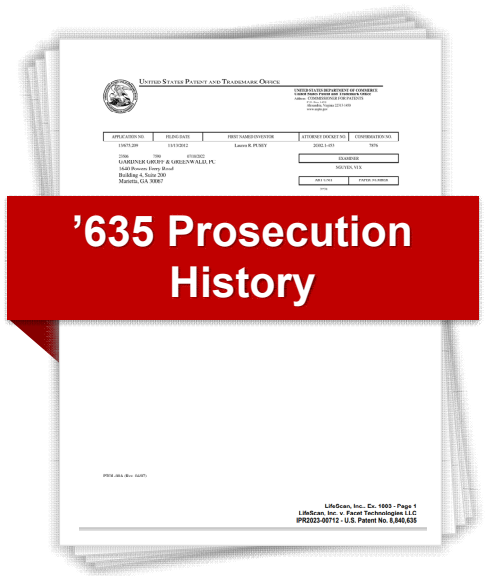
5 Petitioner’s Motion to Exclude Evidence

6 Petitioner’s Opposition to Patent Owner’s Motion to Exclude Evidence

Paper 32 (Pet. Reply) at 23-26; Paper 1 (Pet.) at 45-59

LifeScan's Demonstratives, not evidence

There is No Criticality in the Dimensional Limitations



Claims 7, 21, 24: Gorbahn discloses the invention substantially as claimed (see claim 1 above) but is silent regarding the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness. It would have been obvious to modify the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re. Aller, 220F, 2d 454, 105 USPQ 233

Ex. 1003 at 60



Patent Owner's Expert
Dr. John M. Collins

Q. But the thing I'm trying to understand is whether the number 1.5 times is magical somehow. So that's why I was asking about 1.4 times, for instance, to show that if you're at 1.4 times, you don't get the magic, but you jump to 1.5 times and all these great benefits happen. Is there anything like that described in the patent application?

A. I don't think the patent tried to explain away everything, no. It clearly described what they thought was important for the invention to work.

Q. But it didn't sort of explain that, for instance, in my example of 1.4 times of lateral span relative to lancet thickness, why that would provide the benefits that 1.5 times does.

A. The patent didn't go into those details, no. And it didn't need to. It described what they felt was important.

Ex. 1035, 102:22-103:23

Paper 32 (Pet. Reply) at 23-24; Paper 1 (Pet.) at 47-53;
Paper 21 (POR) at 32-41; Paper 47 (POSR) at 28-29

Both Experts Agree: Relative Dimensions Would Be Obvious to Try



Petitioner's Expert
Joel Delman

Q. Would a POSITA at the relevant time, which is the 2009 time frame, understand what the usual cap size is?

A. They would have had access to a broad range of lancets and lancet caps to benchmark against and to measure, take measurements from, and to test in their prototyping stage, and compare the performance of a much larger cap that they were instructed to design by this patent to the standard smaller caps which were available at the time.

Ex. 2028, 62:9-20 (objections omitted)



Patent Owner's Expert
Dr. John M. Collins

Q. Specifically for lancets though. Would it be typical [to make dimensional changes] for developing lancet products?

A. … I don't see why lancets would be different from other products, that once you've got your design, once you've got your concept and you're in the process of refining that product, you know, for optimization, for commercialization. So it could be for user interface. It could be for cost issues. It could be for appearance issues that you'd end up tweaking the design, tweaking the dimensions during the development process.

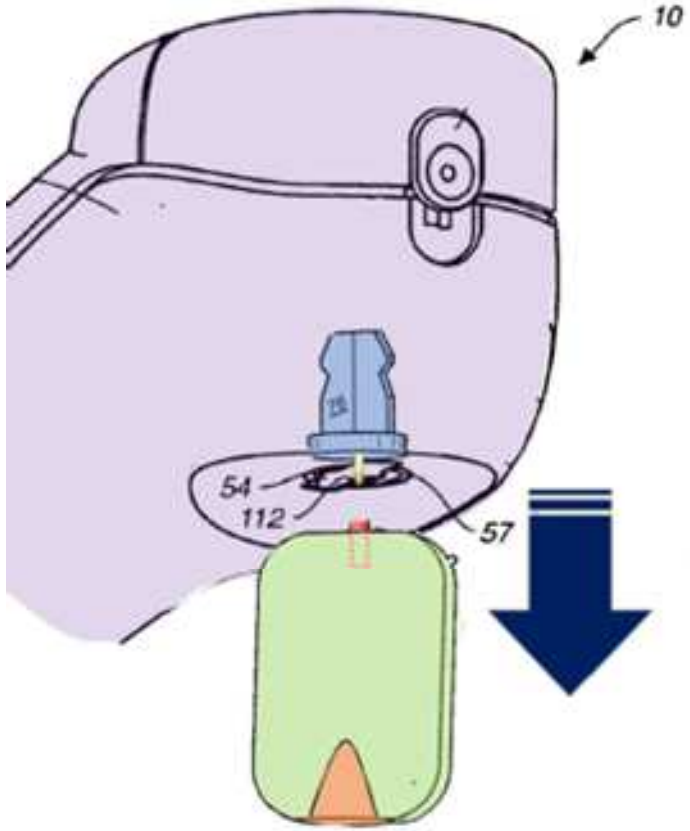
Q. And would that include making one aspect of a product larger than another aspect of the product?

A. Well, I think the only way I can answer that question is yes, because if it changed one dimension, then certainly something is made a different size than another.

Ex. 1035, 20:4-21:15 (objections omitted)

Paper 32 (Pet. Reply) at 23-24; Paper 21 (POR) at 33-41; Paper 47 (POSR) at 28-29; Ex.1034, ¶ ¶24-31; Ex.1002, ¶¶ 122-127

Saikley and Stout Render the Dimensional Limitations Obvious



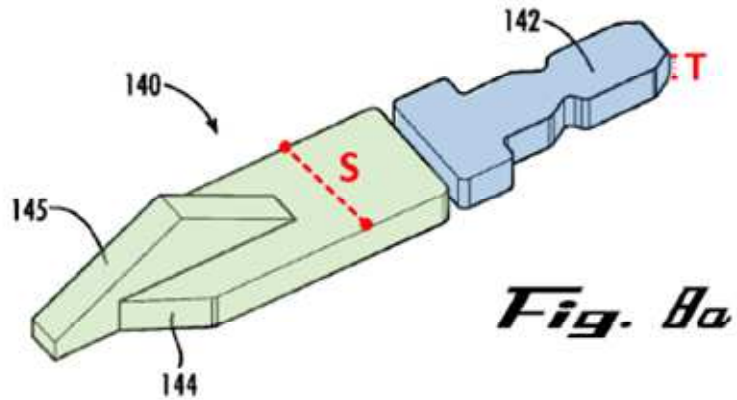
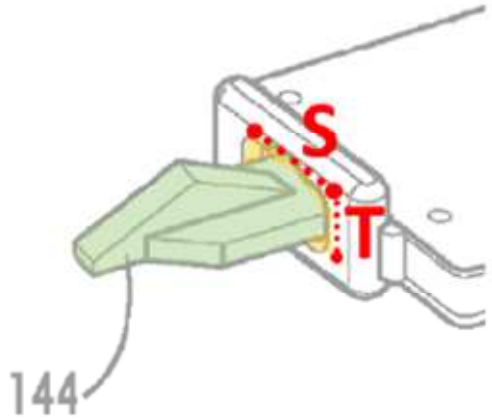


Fig. 8a



The slotted opening **32** has a length considerably greater than its width, most preferably having a length at least twice its width.

Ex. 1018, ¶ [0032]

Paper 32 (Pet. Reply) at 25-26; Paper 1 (Pet.) at 47-54;
Paper 32 (POR) at 41-47; Paper 48 (POSR) at 29-32

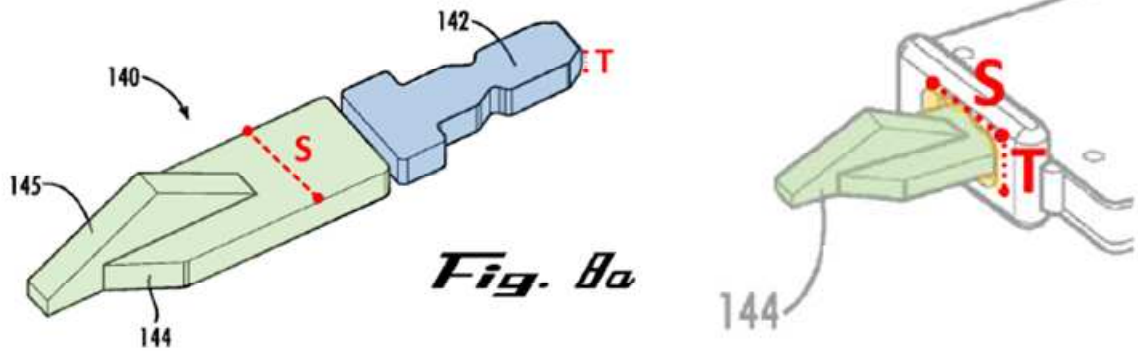
LifeScan's Demonstratives, not evidence

Stout Renders the Lateral Span to Thickness Limitation Obvious

6. The protective sterility cap of claim **1**, in combination with a lancet having a lancet body defining a lancet thickness, and a sharp lancet tip initially embedded in the primary sheath, wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.

14. A protective sterility cap for a lancet, said sterility cap comprising a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein, a secondary sheath for receiving the sharp lancing tip of a used lancet, and a gripping handle portion extending between the primary sheath and the secondary sheath, with the primary sheath attached at a first end of the gripping handle portion and the secondary sheath attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet, said protective sterility cap being in combination with a lancet having a lancet body defining a lancet thickness, and a sharp lancet tip initially embedded in the primary sheath, wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.

Ex.1001, Claims 6 and 14



The slotted opening **32** has a length considerably greater than its width, most preferably having a length at least twice its width.

Ex. 1018, ¶ [0032]

Stout Renders the Length to Thickness Limitation Obvious

8. The protective sterility cap of claim **6**, wherein the gripping handle portion defines a length at least equal to the lancet thickness.

18. The protective sterility cap of claim **14**, wherein the gripping handle portion defines a length at least equal to the lancet thickness.

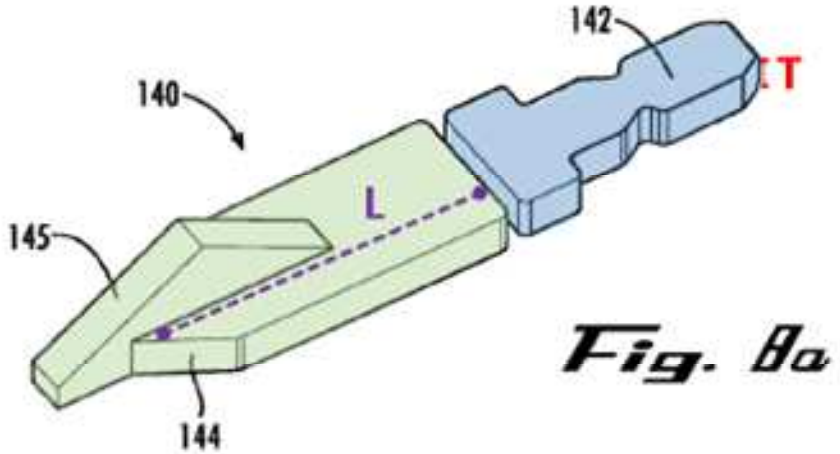


Fig. 8a

Ex.1001, Claims 8 and 18

Paper 1 (Pet.) at 47-54; Paper 32 (Pet. Reply) at 25-26; Paper 32 (POR) at 41-47; Paper 48 (POSR) at 29-32

Stout Renders the Lateral Span to Length Limitation Obvious

7. The protective sterility cap of claim **6**, wherein the gripping handle portion defines a length at least equal to its lateral span.

17. The protective sterility cap of claim **14**, wherein the gripping handle portion defines a length at least equal to its lateral span.

Ex.1001, Claims 7 and 17

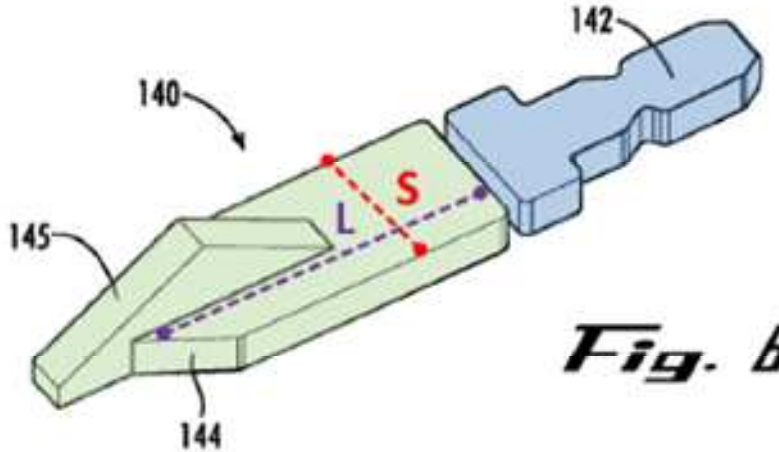
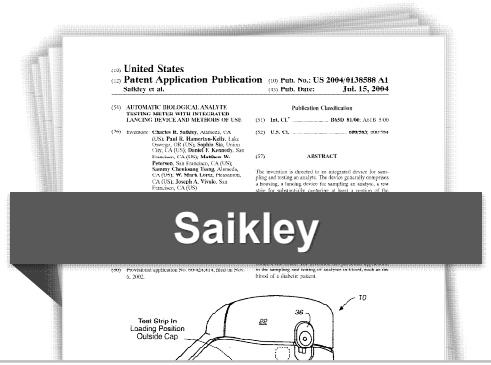


Fig. 8a

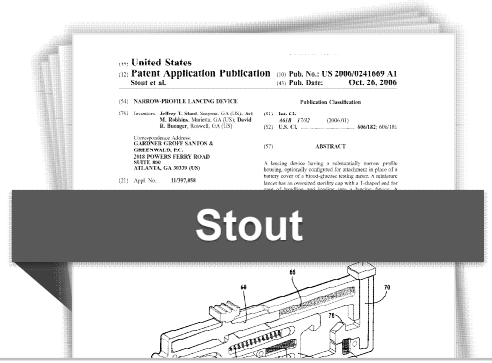
Paper 1 (Pet.) at 47-54; Paper 32 (Pet. Reply) at 25-26; Paper 32 (POR) at 41-47; Paper 48 (POSR) at 29-32

Motivation to Combine Saikley and Stout



This short length might make the lancet difficult for the user to handle and install, so the protective cap **78** (that is removed before use) should be made much larger than usual to aid handling. Cap **78** may be an integrally molded, pull-off tab such as shown in **FIG. 7A**, or may be a hollow cap **80** with large handle molded separately or in the same cavity as lancet **76** and placed over lancet **76** after molding, such as shown in **FIG. 7B**.

Ex. 1005,¶ [0050]

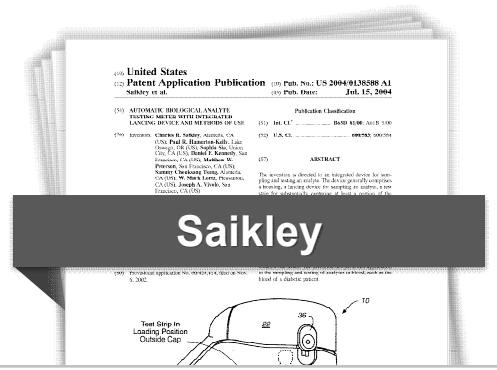


The sterility cap **44** is preferably co-molded with the lancet body portion **42**, and the two are connected at a narrow or notched neck portion for ease of separation upon removal of the sterility cap. The sterility cap **44** is preferably relatively large or oversized, as compared to the lancet body **42**, to facilitate easier handling and loading of the lancet into the lancing device, which is of particular advantage to users having reduced visual acuity and/or reduced manual dexterity.

Ex. 1018,¶ [0035]

Paper 1 (Pet.) at 54-57; Paper 32 (Pet. Reply) at 25-26;
Paper 32 (POR) at 41-47; Paper 48 (POSR) at 29-32;
Ex.1002, ¶¶ 131-136

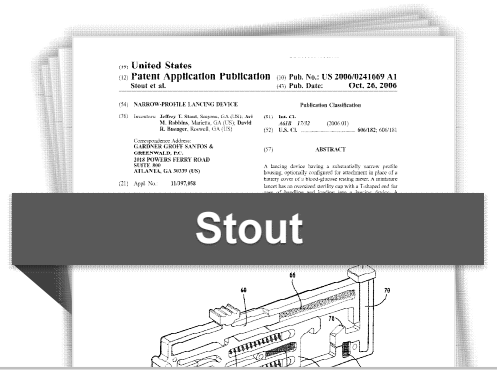
Motivation to Combine Saikley and Stout



Saikley

The recently introduced FreeStyle™ Blood Glucose Monitoring System developed by TheraSense, Inc. of Alameda, Calif., is capable of consistently, accurately and precisely measuring sample sizes of only ⅓ microliter using this preferred "alternate site testing" (AST). U.S. Pat. No. 6,299,757, issued Oct. 9, 2001 to TheraSense, Inc. and incorporated herein by reference describes the construction and operation of the above FreeStyle system. U.S. Pat. No. 6,283,982 issued Sep. 4, 2001 to TheraSense, Inc. and incorporated herein by reference describes a lancing device that is used in the FreeStyle system.

Ex. 1005,¶ [0003]



Stout

The lancing device can be provided as original equipment as a detachable or integral part of a new meter, and/or can be provided as an upgrade or retrofit component for backwards-compatible attachment to an existing meter, such as for example the Bayer Ascensia Contour™ blood glucose meter sold by Bayer Healthcare LLC of Mishawaka, Ind.; the BD Logic Meter; the Lifescan OneTouch Ultra Meter, and/or the Abbott FreeStyle Flash Meter.

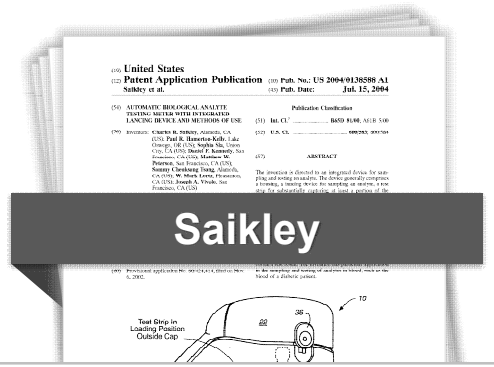
Ex. 1018,¶ [0046]

Paper 1 (Pet.) at 54-57; Paper 32 (Pet. Reply) at 25-26;
Paper 32 (POR) at 41-47; Paper 48 (POSR) at 29-32;
Ex.1002, ¶¶ 201-226

Saikley and the FreeStyle Manual Render Claim 16 Obvious

16. The protective sterility cap of claim **14**, further comprising at least one flat display surface for placement of branding indicia thereon.

Ex.1001, Claim 16



Preferably, an existing test strip, such as the FreeStyle™ brand test strip developed and marketed by TheraSense, Inc., is used with the present invention rather than a propriety format designed especially for the integrated device. Advantages to using existing test strips

Ex. 1005,¶ [0036]



Paper 1 (Pet.) at 58

Paper 32 (Pet. Reply) at 29; Paper 1 (Pet.) at 57-59; Paper 21 (POR) at 63-64; Paper 47 (POSR) at 38; Ex.1002, ¶¶ 137-150

Claim 16: Recites Only an Intended Use



Patent Owner's Expert
Dr. John M. Collins

Q. Well, the circular or flat areas that it's describing here, could you use them for something else? Is the patent mandating that these must be used for applying branding/logos?

A. That's not how I read it, no.

Q. So it's an intended use of that area of the sterility caps, but that flat area of the sterility caps isn't limited to that use; is that right?

A. Again, it's described as an option that can be implemented. It doesn't have to be.

Ex.1058, 106:13-107:2 (objections omitted)

1 Overview of the ‘635 Patent

2 Saikley

- Anticipation
- Obviousness

3 **lio**

- Anticipation
- Obviousness

4 Secondary Considerations Do Not Support Nonobviousness

5 Petitioner’s Motion to Exclude Evidence

6 Petitioner’s Opposition to Patent Owner’s Motion to Exclude Evidence

Paper 1 (Pet.) at 59-86; Paper 32 (Pet. Reply) at 26-27

LifeScan's Demonstratives, not evidence

Patent Owner Challenges Anticipation Based on "Lateral Span" and "Thickness" Limitations

1. Patent Owner challenges whether Iio's cylindrical gripping handle portion has a "lateral span" and whether Iio's cylindrical lancet body has a "thickness";

2. Patent Owner challenges whether Iio's gripping handle portion meets the dimensional limitations.

> **6**. The protective sterility cap of claim **1**, in combination with a lancet having a lancet body defining a lancet thickness, and a sharp lancet tip initially embedded in the primary sheath, wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.

> **7**. The protective sterility cap of claim **6**, wherein the gripping handle portion defines a length at least equal to its lateral span.

> **8**. The protective sterility cap of claim **6**, wherein the gripping handle portion defines a length at least equal to the lancet thickness.

Paper 21 (POR) at 47-64; Ex.1001; Paper 21 (POR) at 47-59; Paper 47 (POSR) at 32-35

Dr. Collins Agreed Iio Disclosed All Limitations Except for the Relative Dimensions

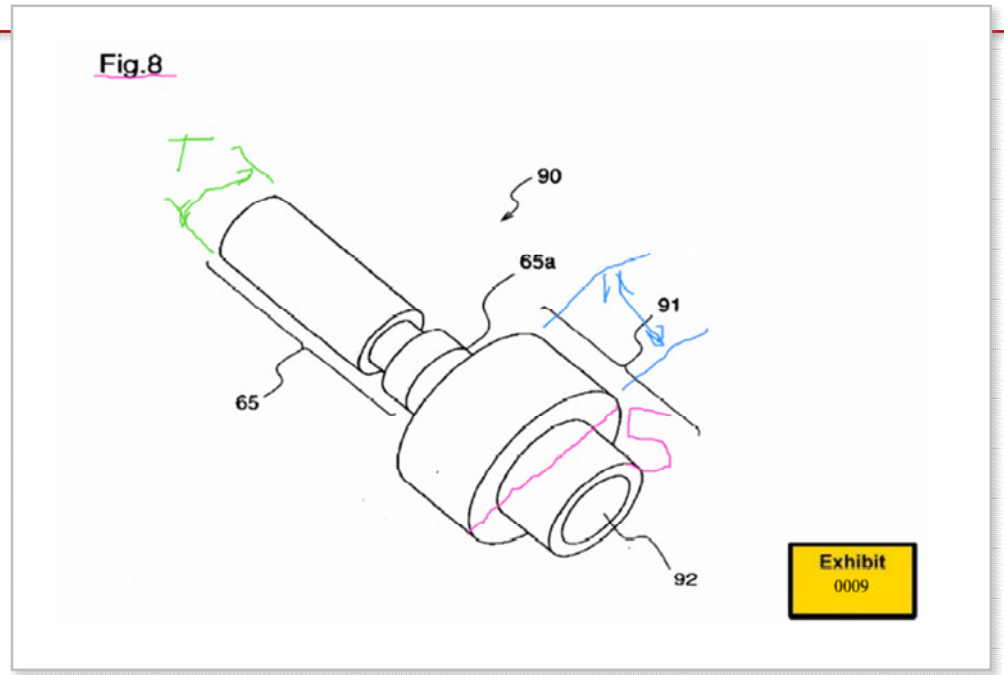


Patent Owner's Expert
Dr. John M. Collins

Q. So what you dispute as far as I understand it is whether Iio discloses dimensional aspects for its gripping handle portion relative to other portions. Is that accurate?

A. Yes, it does not have any dimensional information at all.

Ex.1035, 51:22-52:3



Ex.1059, Annotation of Iio Figure 8 by Dr. Collins

Paper 32 (Pet. Reply) at 26; Paper 21 (POR) at 47-59; Paper 47 (POSR) at 32-35

LifeScan's Demonstratives, not evidence

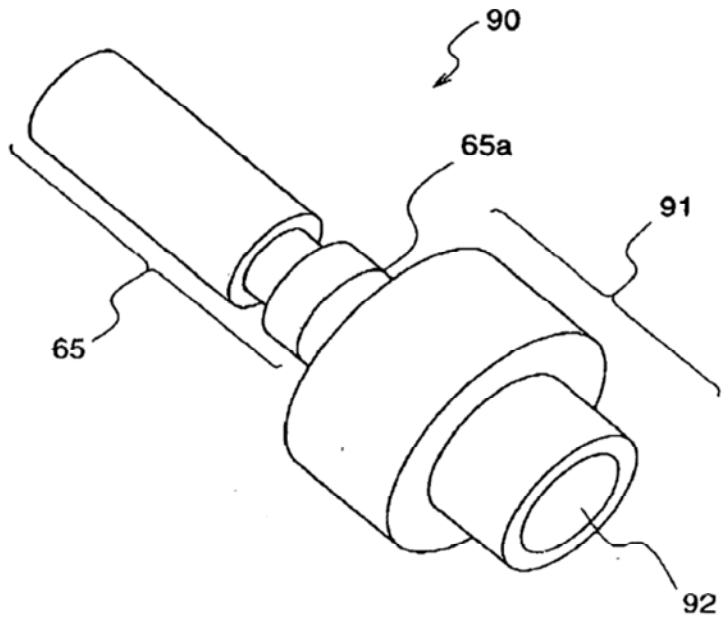
Iio Discloses a Lancet That Is Easy to Handle

[0005] The present invention is made to solve the above-mentioned problems and has for its object to provide a lancet for blood collection and a puncture needle unit, which are able to reduce pain and fear of a patient due to shock, sound, and vibration when performing puncture using a puncture needle, and prevent the puncture needle from puncturing the same portion a few times, and further, ensure excellent usability and handleability with safety.

[0124] According to the present invention, it is possible to provide a lancet and a puncture needle unit, which reduce shock, sound, and vibration during puncture, prevent plural times of puncture by a puncture needle, reduce pain and fear of a patient, and are easy to handle and highly reliable. Therefore, the lancet and the puncture needle unit are useful for performing measurement that requires blood collection.

Ex.1006, [0005], [0124]

Fig.8



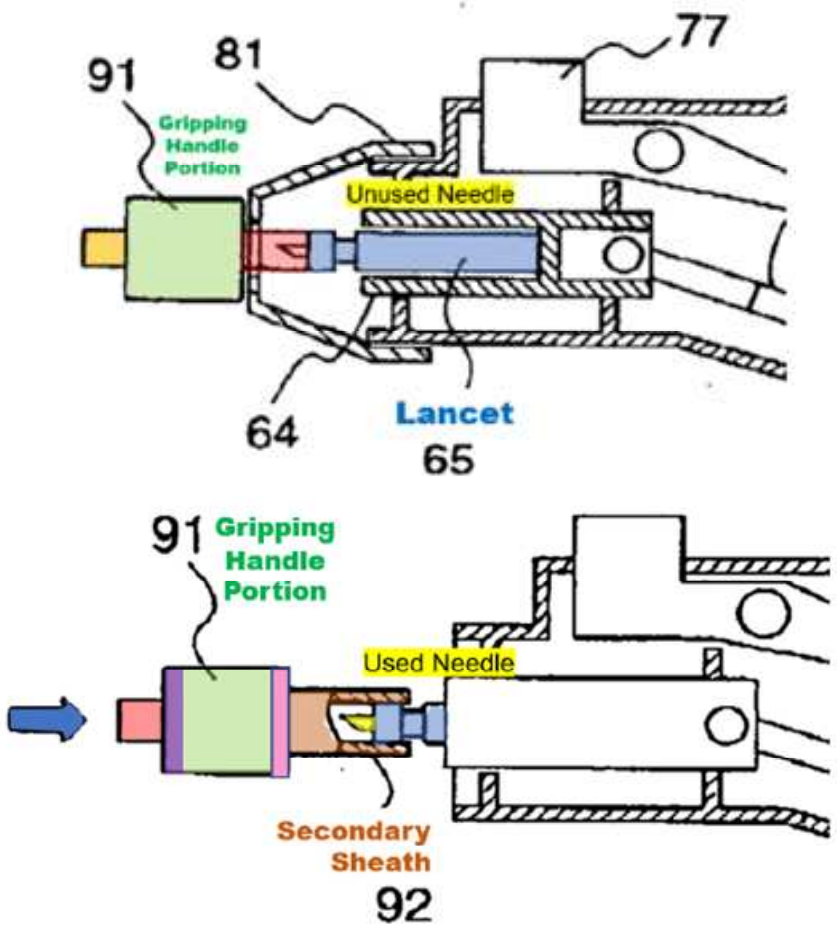
Ex.1006, Fig. 8

Paper 1 (Pet.) at 59-86; Ex.1006, [0005], [0007],[0009], [0013], [0015], [0021], [0022], [0028], [0029], [0030],[0124], Fig. 8

Iio Discloses the Dimensional Limitations

[0026] According to a twentieth aspect of the present invention, in the lancet according to the sixteenth aspect, the puncture needle cap is cylindrical in shape, and has a protection slot for protecting the puncture needle, which is formed from an end of the cylindrical shape, and a disposal slot for taking the puncture needle after performing the puncture operation from the lancet body and discarding the needle, which is formed from the other end of the cylindrical shape, and fitting of the puncture needle to the disposal slot is easier than fitting of the puncture needle to the protection slot. Therefore, it is possible to easily and safely discard a used puncture needle.

Ex.1006, [0026]



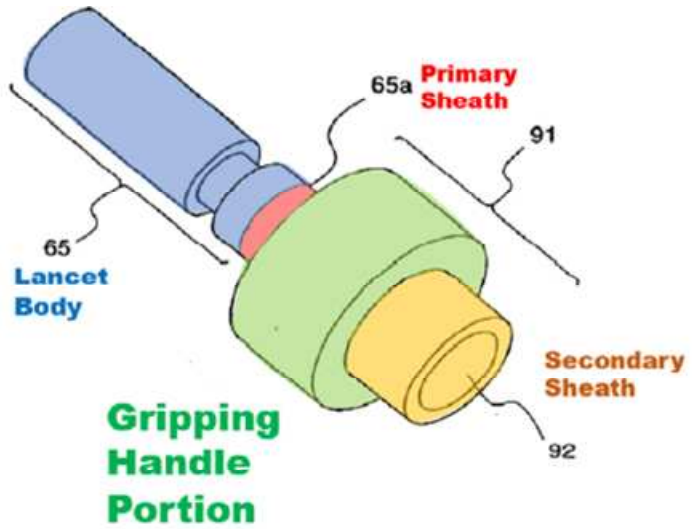
Paper 1 (Pet.) at 69, 74

Paper 1 (Pet.) at 58-86; Paper 32 (Pet. Reply) at 26-27; Ex.1034, ¶ 39; Ex.1002, ¶ ¶151-229; Ex.1006, Figs. 9(b), 11(b); Paper 21 (POR) at 48-59; Paper 47 (POSR) 32-34

Iio Discloses the Dimensional Limitations

[0104] Further, a puncture needle unit **90** according to the second embodiment is constituted as shown in **FIG. 8**. The puncture needle unit **90** is divided into a puncture needle body **65** and a puncture needle cap **91** with a puncture needle separation groove **65***a* as A boundary, and the body **65** and the cap **91** are connected to each other by a thin plastic film having a thickness of 0.1 mm or less in the puncture needle separation groove **65***a*.

Ex.1006, [0104]



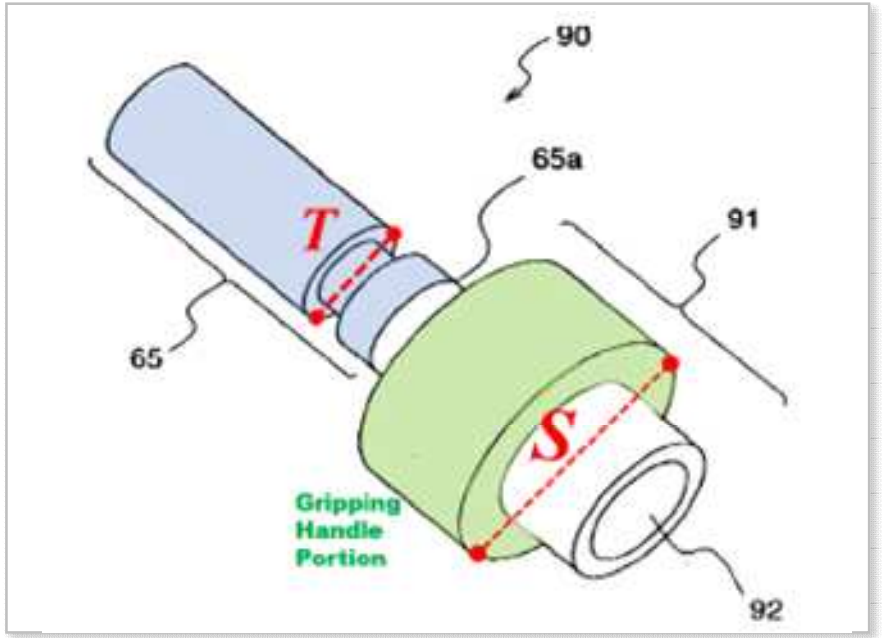
Paper 1 (Pet.), 67

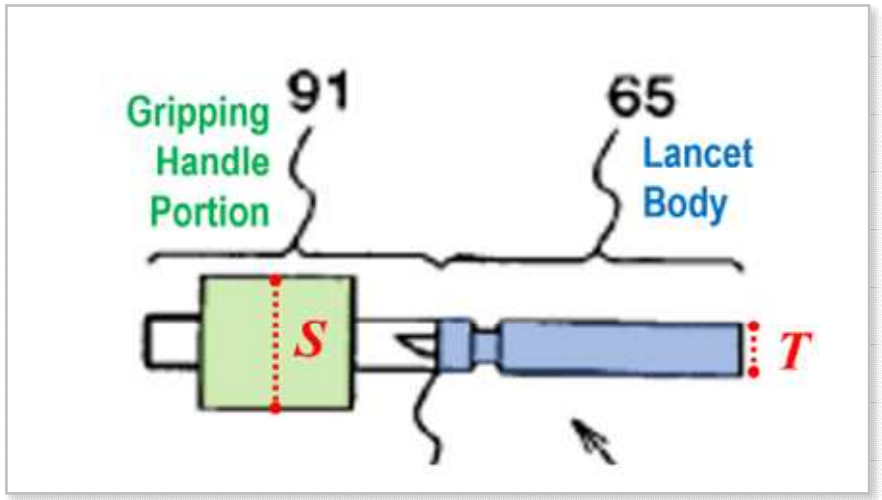
Paper 1 (Pet.) at 58-86; Paper 32 (Pet. Reply) at 26-27; Ex.1034, ¶ 39; Ex.1002, ¶ ¶151-229; Ex.1006, Fig. 8

Iio Discloses the Lateral Span to Thickness Limitation

6. The protective sterility cap of claim **1**, in combination with a lancet having a lancet body defining a lancet thickness, and a sharp lancet tip initially embedded in the primary sheath, wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.

14. A protective sterility cap for a lancet, said sterility cap comprising a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein, a secondary sheath for receiving the sharp lancing tip of a used lancet, and a gripping handle portion extending between the primary sheath and the secondary sheath, with the primary sheath attached at a first end of the gripping handle portion and the secondary sheath attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet, said protective sterility cap being in combination with a lancet having a lancet body defining a lancet thickness, and a sharp lancet tip initially embedded in the primary sheath, wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.





Ex.1001, Claims 6 and 14

Paper 1 (Pet.), 80

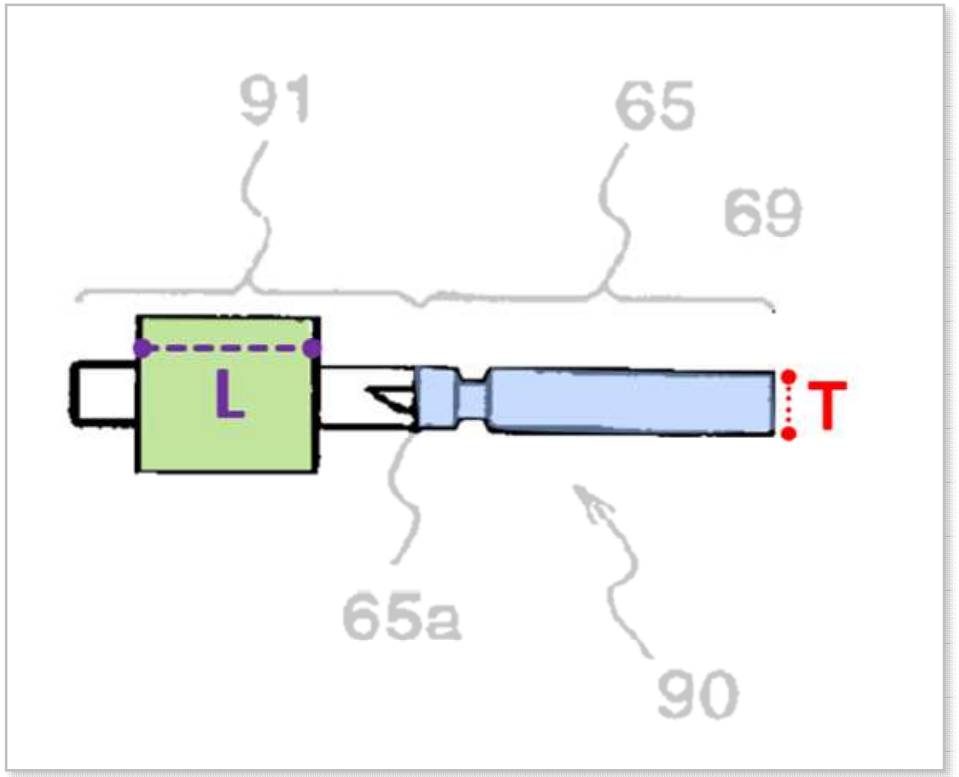
Paper 1 (Pet.) at 58-86; Paper 32 (Pet. Reply) at 26-27; Ex.1034, ¶ 39; Ex.1002, ¶ ¶151-229; Ex.1006, Figs. 8, 9(a); Paper 21 (POR) at 48-59; Paper 47 (POSR) 32-34

Iio Discloses the Length to Thickness Limitation

8. The protective sterility cap of claim **6**, wherein the gripping handle portion defines a length at least equal to the lancet thickness.

18. The protective sterility cap of claim **14**, wherein the gripping handle portion defines a length at least equal to the lancet thickness.

Ex.1001, Claims 8 and 18



Paper 1 (Pet.), 84

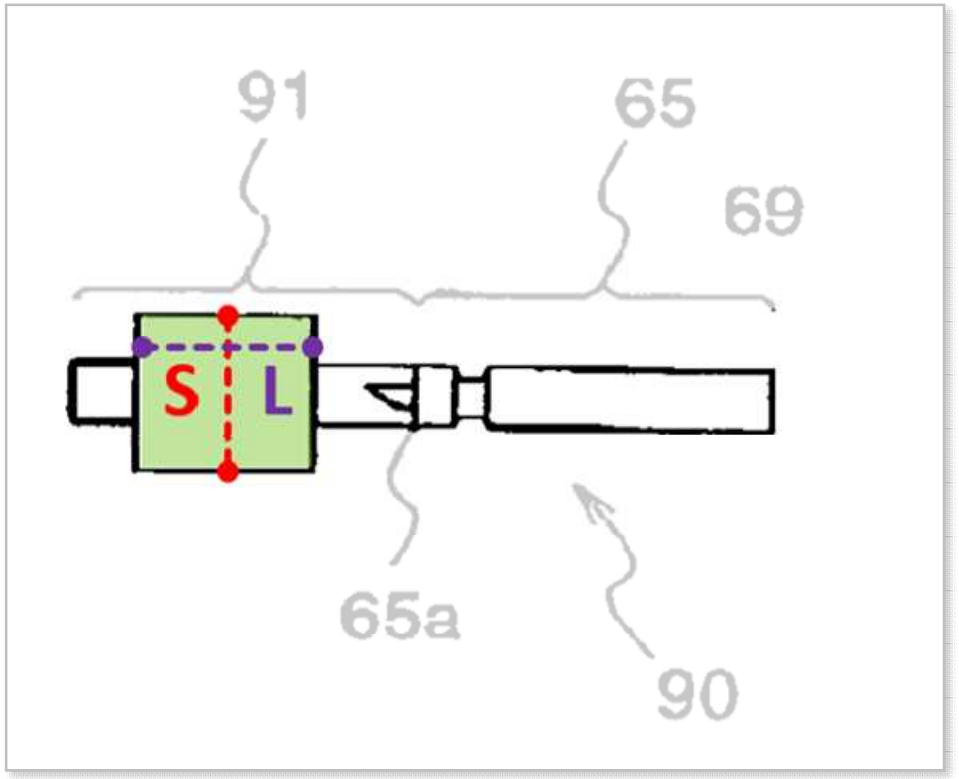
Paper 1 (Pet.) at 58-86; Paper 32 (Pet. Reply) at 26-27; Ex.1034, ¶ 39; Ex.1002, ¶ ¶151-229; Ex.1006, Fig. 9(a); Paper 21 (POR) at 48-59; Paper 47 (POSR) 32-34

Iio Discloses the Length to Lateral Span Limitation

7. The protective sterility cap of claim **6**, wherein the gripping handle portion defines a length at least equal to its lateral span.

17. The protective sterility cap of claim **14**, wherein the gripping handle portion defines a length at least equal to its lateral span.

Ex.1001, Claims 7 and 17



Paper 1 (Pet.), 83

Paper 1 (Pet.) at 58-86; Paper 32 (Pet. Reply) at 26-27; Ex.1034, ¶ 39; Ex.1002, ¶ ¶151-229; Ex.1006, Fig. 9(a); Paper 21 (POR) at 48-59; Paper 47 (POSR) 32-34

1 Overview of the ‘635 Patent

2 Saikley

- Anticipation
- Obviousness

3 Iio

- Anticipation
- Obviousness

4 Secondary Considerations Do Not Support Nonobviousness

5 Petitioner’s Motion to Exclude Evidence

6 Petitioner’s Opposition to Patent Owner’s Motion to Exclude Evidence

Paper 1 (Pet.) at 86-101; Paper 32 (Pet. Reply) at 27-29

LifeScan's Demonstratives, not evidence

Iio Renders the Dimensional Limitations Obvious



Petitioner's Expert
Joel Delman

"For lancet users, like diabetic patients with poor dexterity, a PHOSITA who would like to improve the Iio lancet for 'excellent useability and handleability' would adjust the lateral span of the lancet and take into account variations in pinch grip, hand and fingertip size, and other guidelines to understand the bounds and range of interactions lancet users would have with the product. Such adjustments would, of necessity, fall far short of the 'infinite' ratios Dr. Collins suggests."

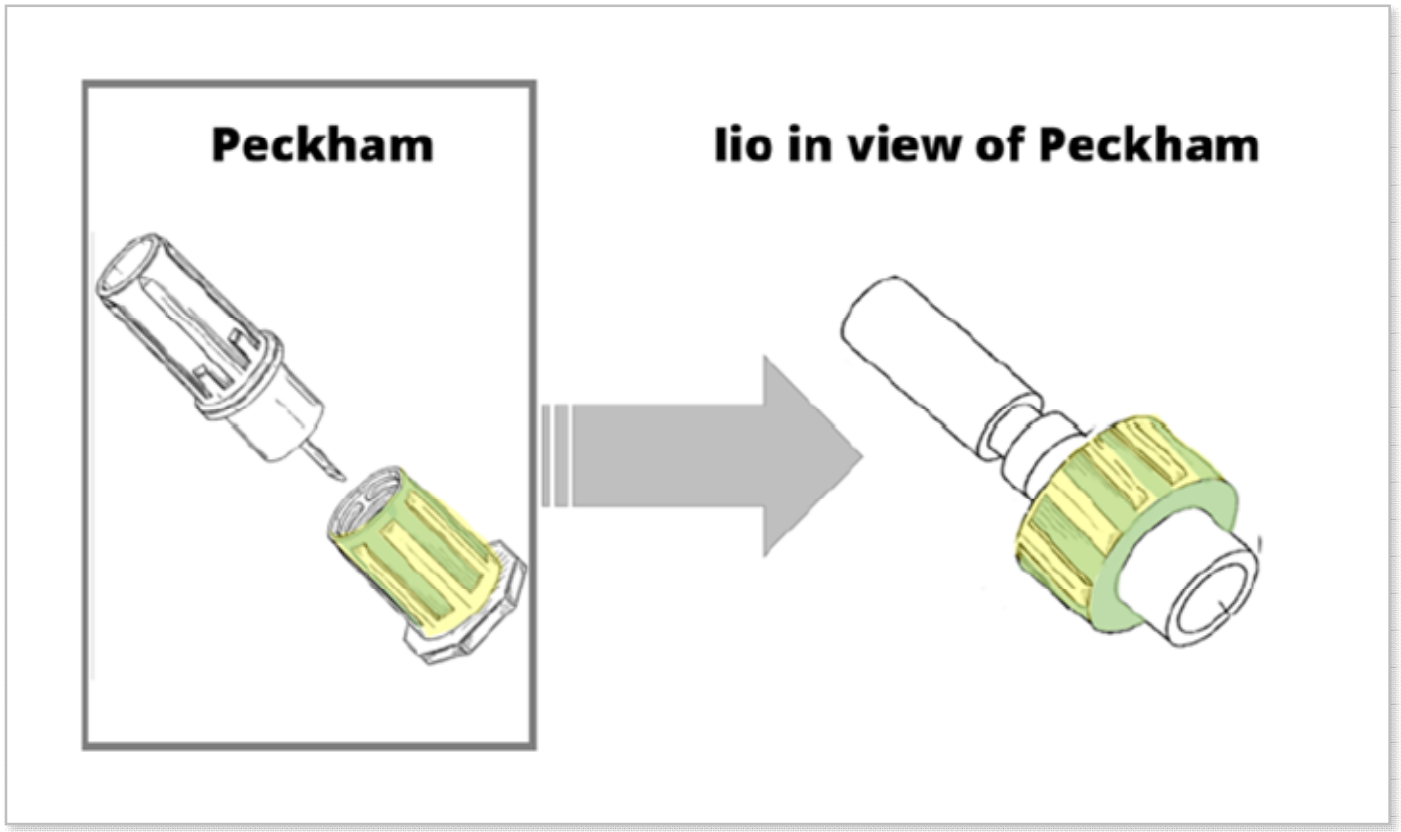
Ex.1034, ¶41

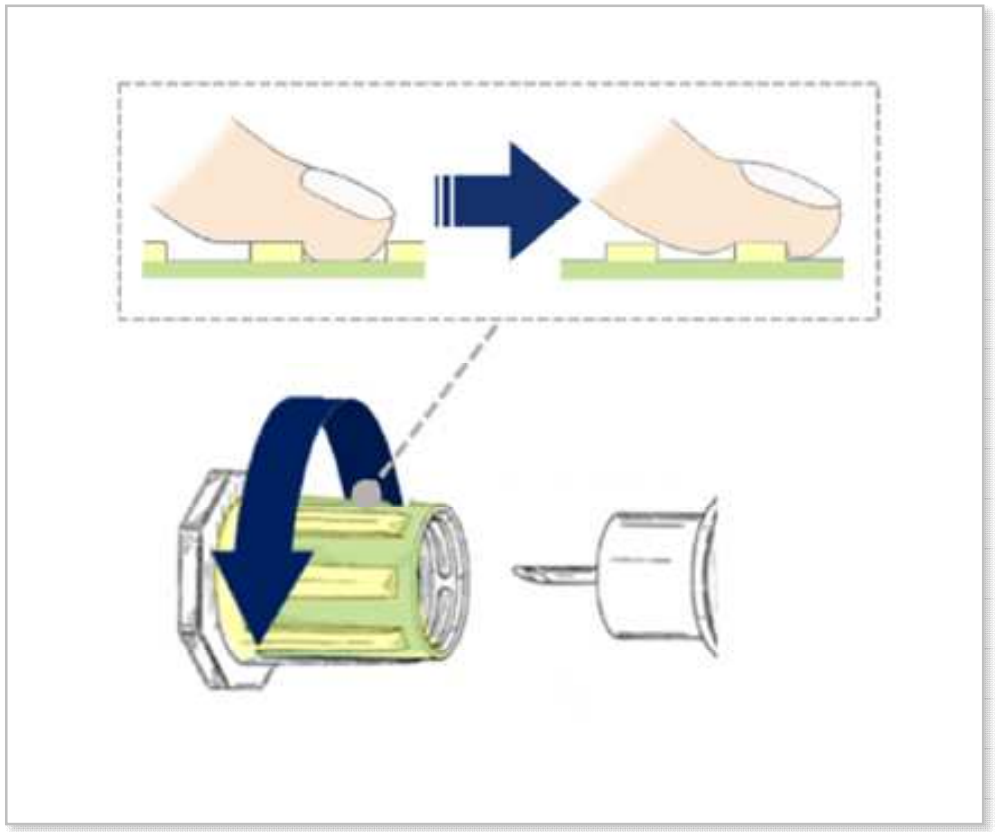
Dimension	Men				Women			
	5th %ile	50th %ile	95th %ile	SD	5th %ile	50th %ile	95th %ile	SD
1. Hand length	173	189	205	10	159	174	189	9
2. Palm length	98	107	116	6	89	97	105	5
3. Thumb length	44	51	58	4	40	47	53	4
4. Index finger length	64	72	79	5	60	67	74	4
5. Middle finger length	76	83	90	5	69	77	84	5
6. Ring finger length	65	72	80	4	59	66	73	4
7. Little finger length	48	55	63	4	43	50	57	4
8. Thumb breadth (IPJ)[a]	20	23	26	2	17	19	21	2
9. Thumb thickness (IPJ)	19	22	24	2	15	18	20	2
10. Index finger breadth (PIPJ)[b]	19	21	23	1	16	18	20	1
11. Index finger thickness (PIPJ)	17	19	21	1	14	16	18	1
12. Hand breadth (metacarpal)	78	87	95	5	69	76	83	4
13. Hand breadth (across thumb)	97	105	114	5	84	92	99	5
14. Hand breadth (minimum)[c]	71	81	91	6	63	71	79	5
15. Hand thickness (metacarpal)	27	33	38	3	24	28	33	3
16. Hand thickness (including thumb)	44	51	58	4	40	45	50	3
17. Maximum grip diameter[d]	45	52	59	4	43	48	53	3
18. Maximum spread	178	206	234	17	165	190	215	15
19. Maximum functional spread[e]	122	142	162	12	109	127	145	11
20. Minimum square access[f]	57	67	77	6	51	59	66	5

Ex.1040, Table 6.1

Paper 32 (Pet. Reply) at 27-28; Paper 1 (Pet.) at 86-101; Ex.1034, ¶ ¶ 40-41; Paper 21 (POR) at 59-61; Paper 47 (POSR) at 35-37

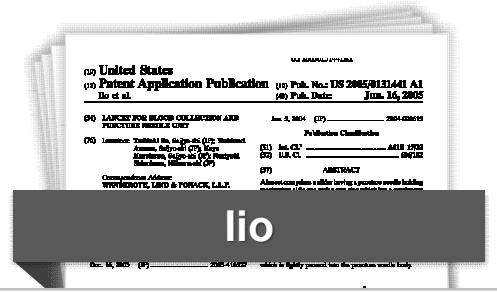
Iio and Peckham Render the Dimensional Limitations Obvious





Paper 32 (Pet. Reply) at 27-28; Paper 1 (Pet.) at 86-100; Ex. 1034, ¶¶ 42-43; Ex.1002, ¶¶ 201-226; Paper 21 (POR) at 62-63; Paper 48 (POSR) at 37-38

Motivation to Combine Iio and Peckham



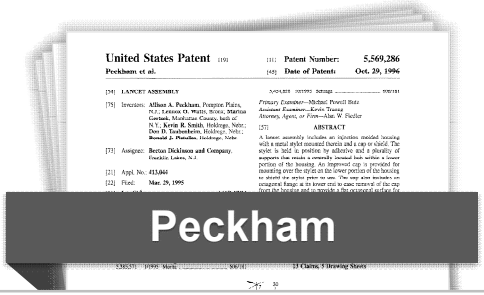
Iio

[0005] The present invention is made to solve the above-mentioned problems and has for its object to provide a lancet for blood collection and a puncture needle unit, which are able to reduce pain and fear of a patient due to shock, sound, and vibration when performing puncture using a puncture needle, and prevent the puncture needle from puncturing the same portion a few times, and further, ensure excellent usability and handleability with safety.

* * *

The shape of the puncture needle cap of the puncture needle unit **90** is not restricted to that shown in **FIG. 8**.

Ex.1006, [0005]



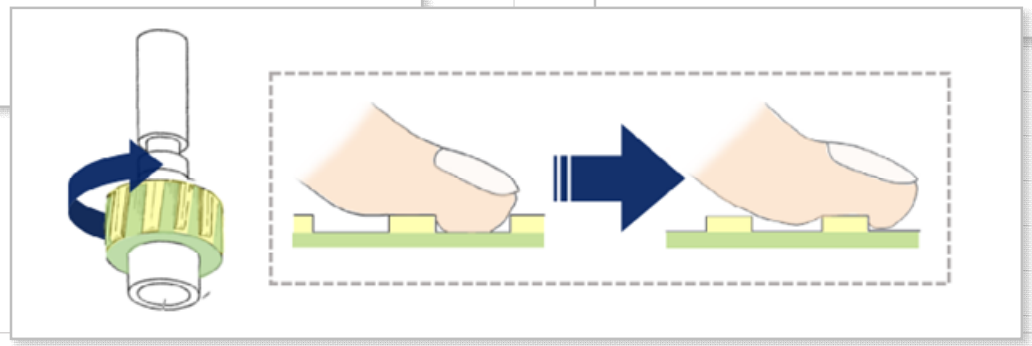
Peckham

Molded-in longitudinal splines form a surface on the exterior of the housing to make the housing easier to handle and manipulate when loading the lancet assembly into a blood sampling instrument.

* * *

25. A plurality of longitudinal ribs or splines **50** and **51** on outer wall **40** extend frown flange **45** towards proximal end **30**. Ribs **50** are longer than ribs **51** and alternate around outer wall **40** to provide a novel textured surface to improve handling, maneuverability and fit when lancet assembly **20** is mounted in a socket on the blood sampling instrument.

Ex.1008, 2:7-10; 2:64-3:2



Paper 32 (Pet. Reply) at 27-28; Paper 1 (Pet.) at 86-100; Ex.1002, ¶¶ 201-226; Paper 21 (POR) at 62-63; Paper 48 (POSR) at 37-38

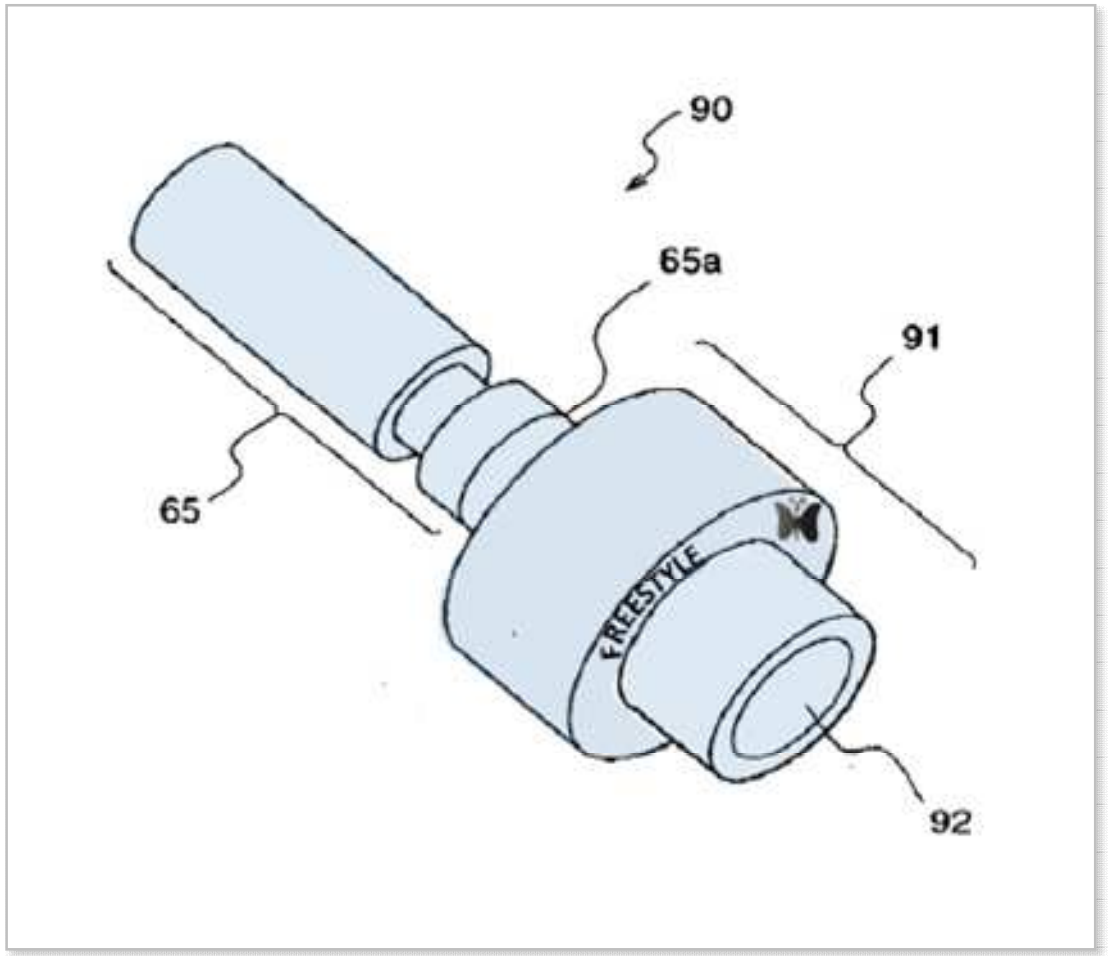
lio and the FreeStyle Manual Render Claim 16 Obvious



Petitioner's Expert
Joel Delman

"[F]or disposable medical devices, such as a lancet, it is not unheard of to use small, less prominent surfaces to provide an 'identification brand' as a type of authenticator. These identifiers offer a guarantee or assurance of product quality, i.e., that the lancet was manufactured by a particular brand, but are not intended as prominent advertisements of brand."

Ex.1034, ¶44



Paper 1 (Pet.) at 101

Paper 32 (Pet. Reply) at 29; Paper 1 (Pet.) at 100-101; Paper 21 (POR) at 63-64; Paper 47 (POSR) at 38

Secondary Considerations Do Not Support Nonobviousness

4 Secondary Considerations Do Not Support Nonobviousness

A Commercial Success

- The Delica Plus and Delica Do Not Practice the ’635 Patent
- No Presumption of Commercial Success Because No Coextensiveness
- No Evidence Sales Are a Direct Result of the ’635 Patent

B Long Felt Need

- Prior Art Addresses Long Felt Need

C Copying

- Both Experts Agree the Delica and Delica Plus Use Different Designs
- Cross-Compatibility Is Irrelevant

4 Secondary Considerations Do Not Support Nonobviousness

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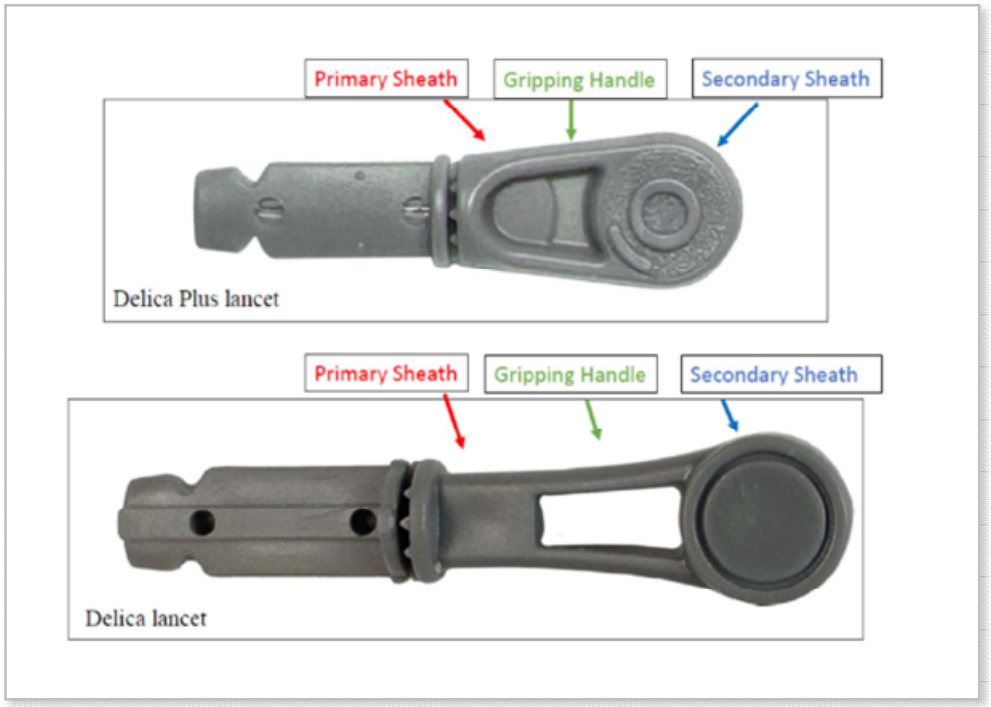
- Both Experts Agree the Delica and Delica Plus Use Different Designs
- Cross-Compatibility Is Irrelevant

Patent Owner's Expert Offers No Analysis as to How the Delica and Delica Plus Practice Patent



Patent Owner's Expert
Dr. John M. Collins

"The Delica Plus and Delica 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."



Paper 32 (Pet. Reply) at 37; Paper 21 (POR) at 69-70; Ex. 2056, ¶ 144

LifeScan's Demonstratives, not evidence

Patent Owner's Expert Conducted No Analysis of the "Gripping Handle Portion"



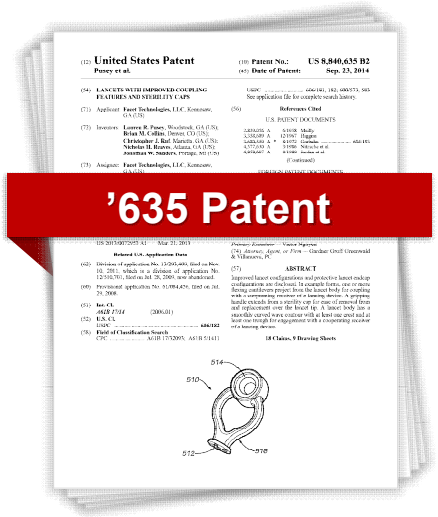
Patent Owner's Expert
Dr. John M. Collins

Q. Did you conduct an analysis to figure out which portions of that cap are gripped?

A. I did not conduct a formal analysis, no.

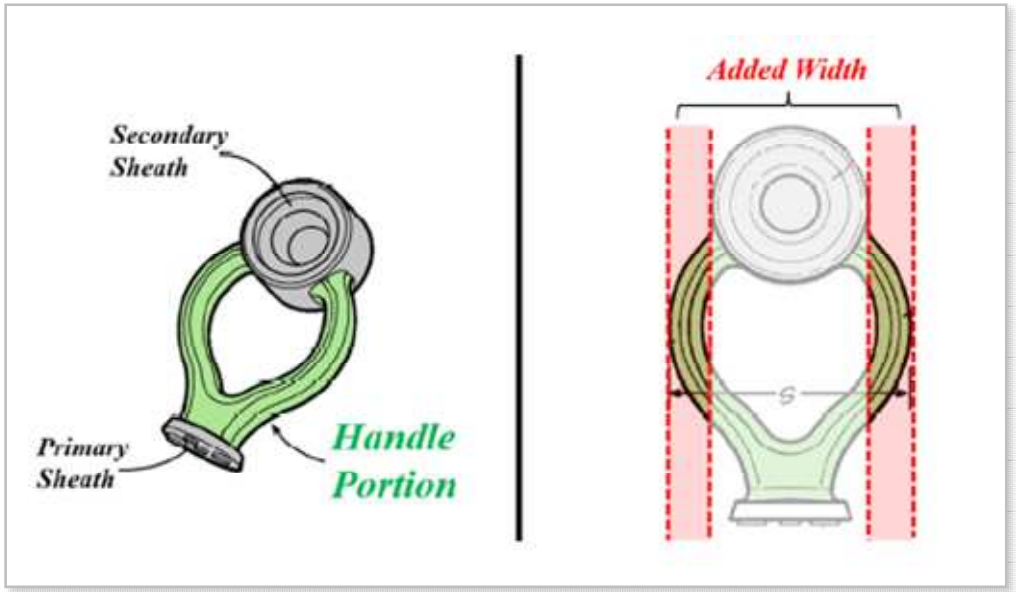
Ex.1035, 142:17-21

The ’635 Patent’s Handle Provides a Mechanical Advantage



The handle or extension arm portion **516** defines a forked or split configuration having first and second arms **520** transversely spaced apart from one another, with an open center portion therebetween. This forked arrangement provides the handle with a greater width, allowing the user to more easily twist the endcap during removal from the lancet.

Ex.1001 at 6:48-55



Ex.1001, Figs. 5A, 5D

Petitioner's Experts Thoroughly Analyzed the Design of a Handle



Petitioner's Expert
Paul Hatch

Handle

"In my experience, touchpoints and handles have two things in common: they are designed to

(i) Physically fit or accommodate the users' hand or fingers; and

(ii) Provide a physical advantage to use.

Typically, both of these physical attributes would be visually communicated to the user using visual cues."

Ex.1045 ¶ 118

Paper 32 (Pet. Reply) at 30; Paper 47 (POSR) at 7-11

The ’635 Patent’s Handle Provides a Mechanical Advantage



Petitioner’s Expert
Joel Delman

“The ’635 Patent describes two main purposes for the gripping handle where the handle may offer mechanical advantages;

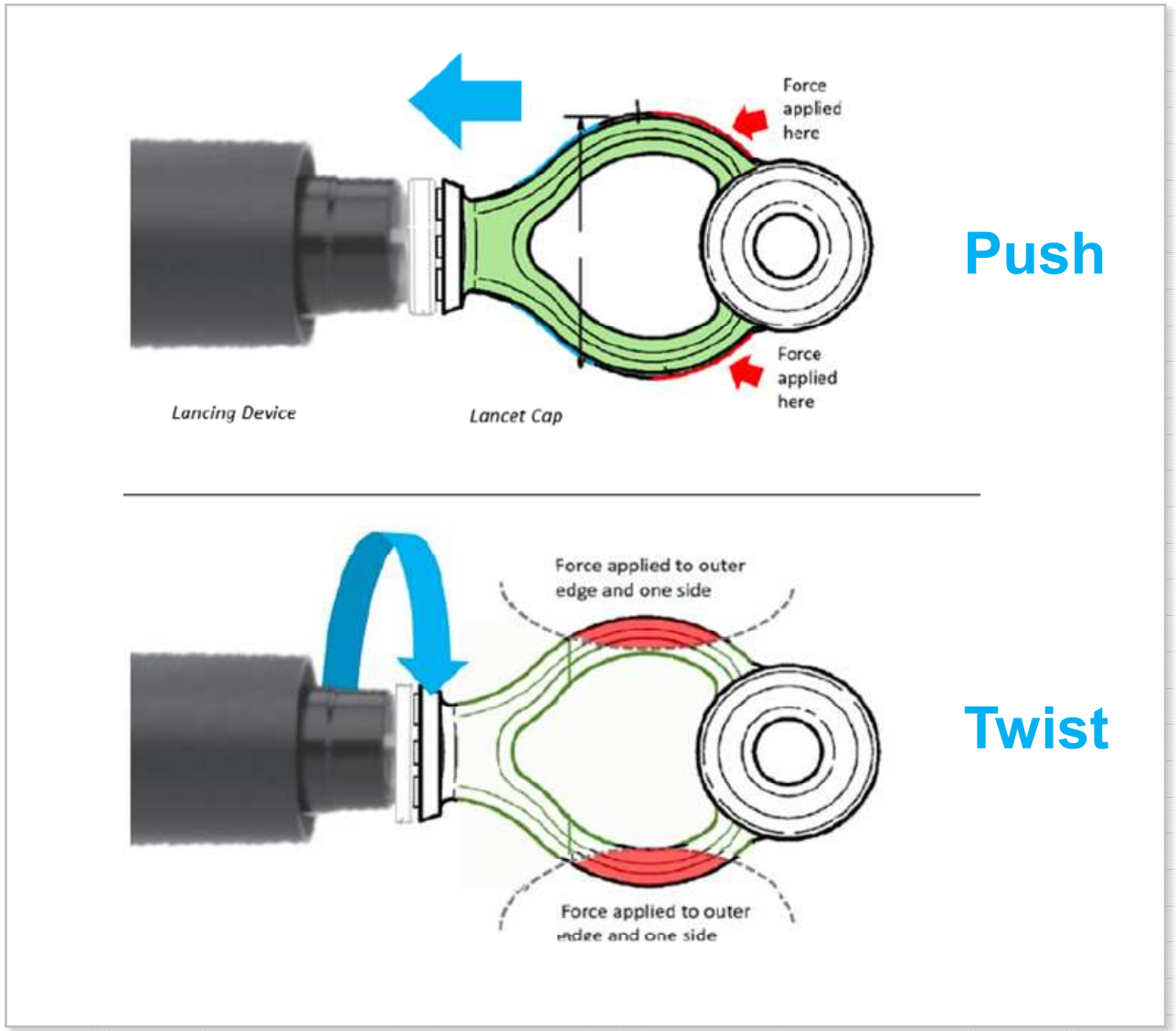
1. to grip when pushing the lancet into the device, and
2. to grip when twisting.”

Ex.1034 ¶ 53

The ’635 Patent’s Handle Provides a Mechanical Advantage

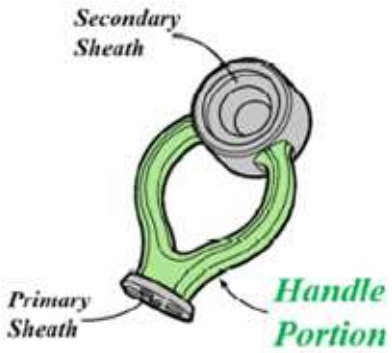


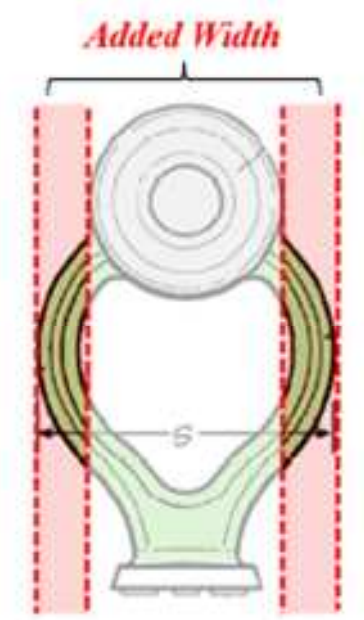
Petitioner’s Expert
Paul Hatch



Paper 32 (Pet. Reply) at 32; Ex.1044, ¶ 12;
Paper 47 (POSR) at 7-11

The Neck of the Delica and Delica Plus Lancets Are Not Handles





Delica

1. Neck structure is not especially designed to physically fit or accommodate a user's hand or fingers;
2. Neck is much narrower than secondary sheath and does not make the cap wider or easier to grab or twist.


Delica lancet

Delica Plus

1. Neck is short, narrow, and tapers inward, providing no surface to push against nor surfaces to provide easier twisting;
2. Neck lacks typical visual cues a designer would use to communicate to the user to interact with that portion.


Delica Plus lancet

Paper 32 (Pet. Reply) at 31-35; Ex.1034, ¶¶49-56; Ex.1044, ¶¶ 10-15; Ex.1045, ¶¶ 210-211; Ex.2056, ¶139; Paper 47 (POSR) at 7-11

LifeScan's Demonstratives, not evidence

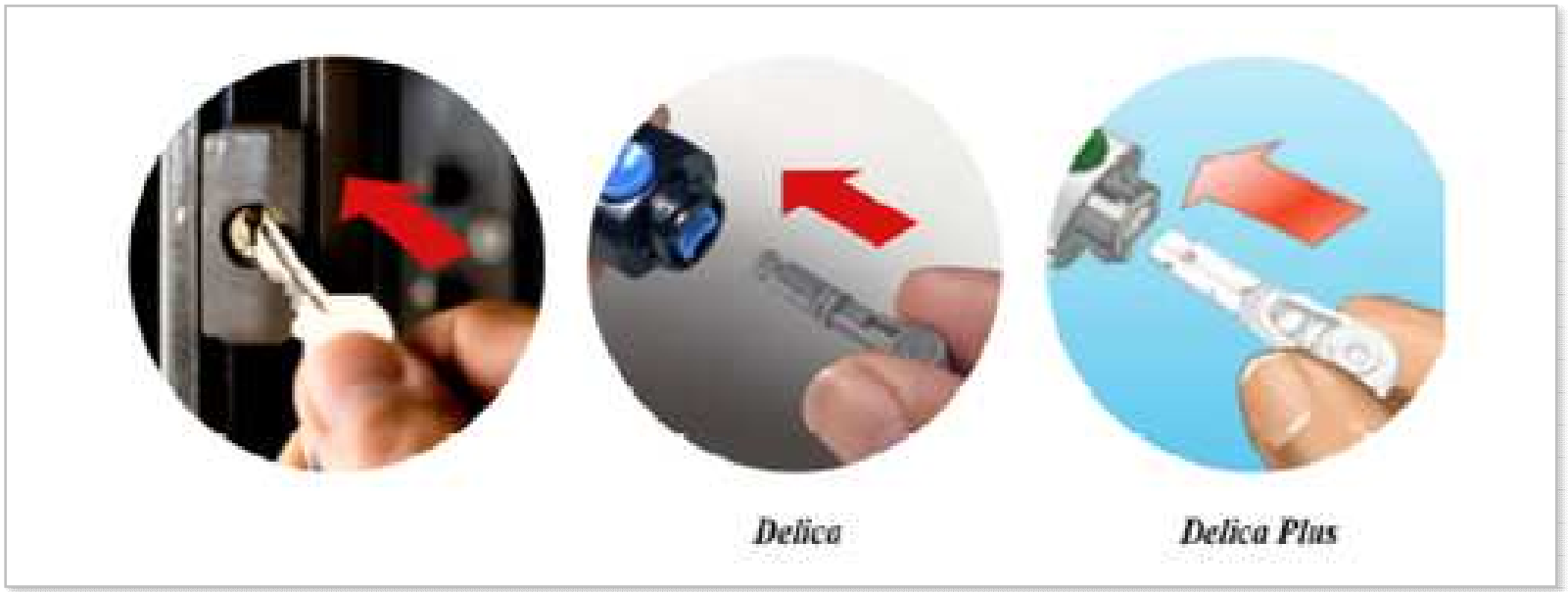
Only the Secondary Sheath Contains Structural Elements of a Handle



Petitioner's Expert
Paul Hatch

"In my opinion, only the relatively flat, round shape of the secondary sheath on the Delica and Delica Plus lancets accommodates a fingertip, providing both a surface that is easy to grasp and a visual cue for the user to employ a pinch grip when holding the Delica and Delica Plus lancets."

Ex.1044, ¶ 14



Paper 32 (Pet. Reply) at 33

Paper 32 (Pet. Reply) at 33-35; Paper 47 (POSR) at 7-11

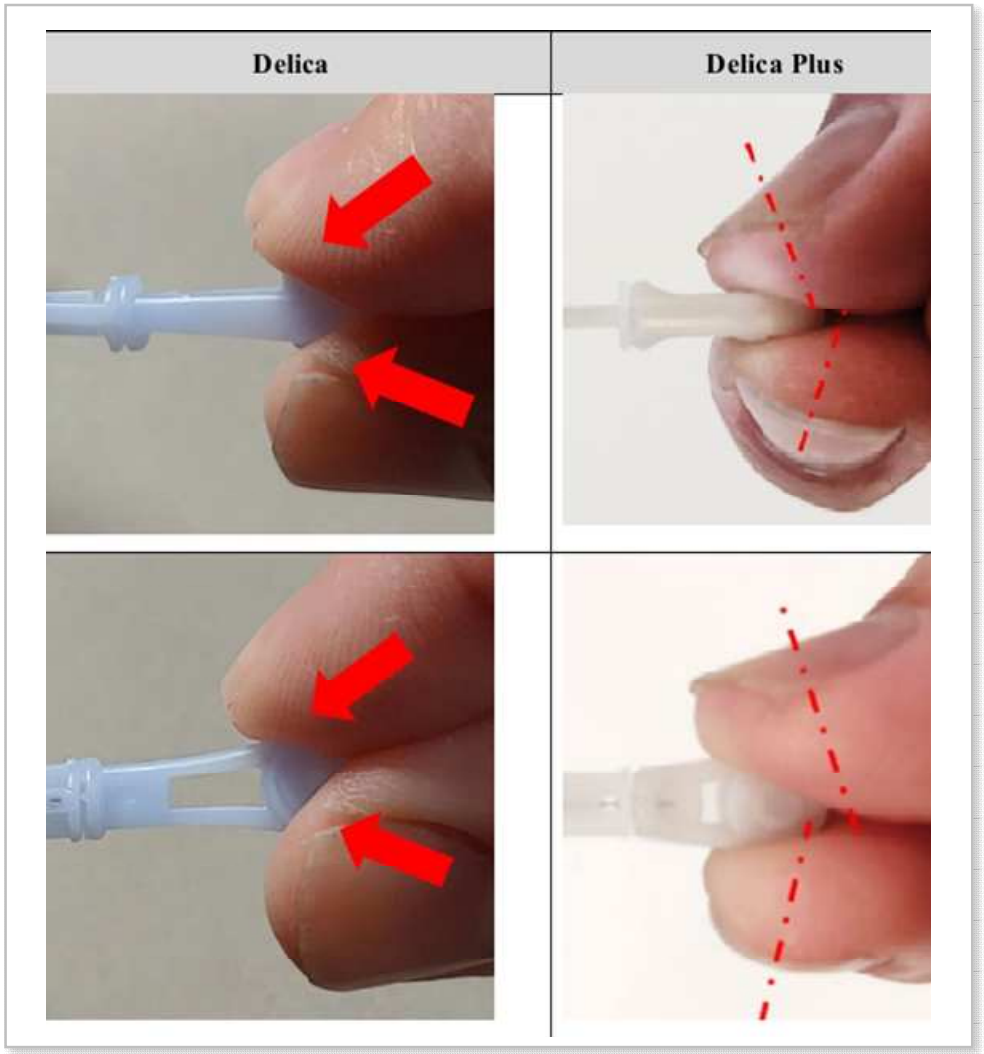
LifeScan's Demonstratives, not evidence

Only the Secondary Sheath Contains Structural Elements of a Handle



Petitioner's Expert
Paul Hatch

Push Movement



Paper 32 (Pet. Reply) at 35, 36; Ex. 1044, ¶16; Ex. 1045, ¶¶ 218-227;
Paper 47 (POSR) at 7-11

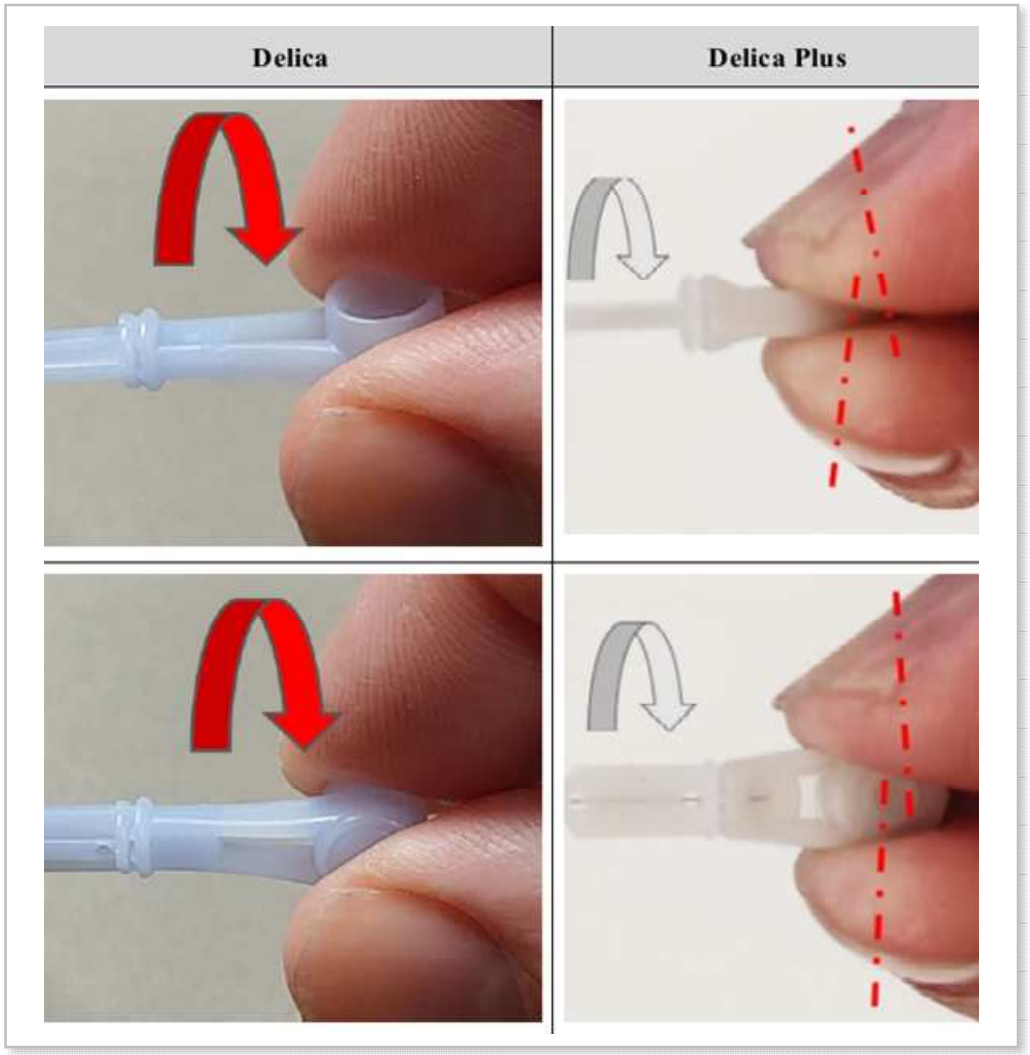
LifeScan's Demonstratives, not evidence

Only the Secondary Sheath Contains Structural Elements of a Handle



Petitioner's Expert
Paul Hatch

Twist Movement



Paper 32 (Pet. Reply) at 35-37; Ex. 1044, ¶16; Ex. 1045, ¶¶ 218-227;
Paper 47 (POSR) at 7-11

LifeScan's Demonstratives, not evidence

Patent Owner's Reliance On a Third-Party YouTube Video Supports Petitioner's Arguments





Ex. 1045, ¶ 170; Paper 47 (POSR) at 8-9;
https://www.youtube.com/watch?v=OVSrbH25oo0

4 Secondary Considerations Do Not Support Nonobviousness

A Commercial Success

- The Delica Plus and Delica Do Not Practice the ’635 Patent
- No Presumption of Commercial Success Because No Coextensiveness
- No Evidence Sales Are a Direct Result of the ’635 Patent

B Long Felt Need

- Prior Art Addresses Long Felt Need

C Copying

- Both Experts Agree the Delica and Delica Plus Use Different Designs
- Cross-Compatibility Is Irrelevant

Presumption of Nexus: Coextensiveness Required



"Although we do not require the patentee to prove perfect correspondence to meet the coextensiveness requirement, what we do require is that the **patentee demonstrate that the product is essentially the claimed invention**."

Fox Factory, Inc. v. SRAM, LLC, 944 F.3d 1366, 1374 (Fed. Cir. 2019)

PO Fails to Demonstrate Coextensiveness

> Here, Facet's Delica lancets and LifeScan's Delica Plus lancets[15] 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.

Paper 21 (POR) at 66

PATENT OWNER HAS NO EVIDENCE OF COEXTENSIVENESS

> [2] Petitioner falsely asserts that Dr. Collins did not evaluate co-extensiveness. Reply 38; *but see* Ex.2056 ¶¶136-51.

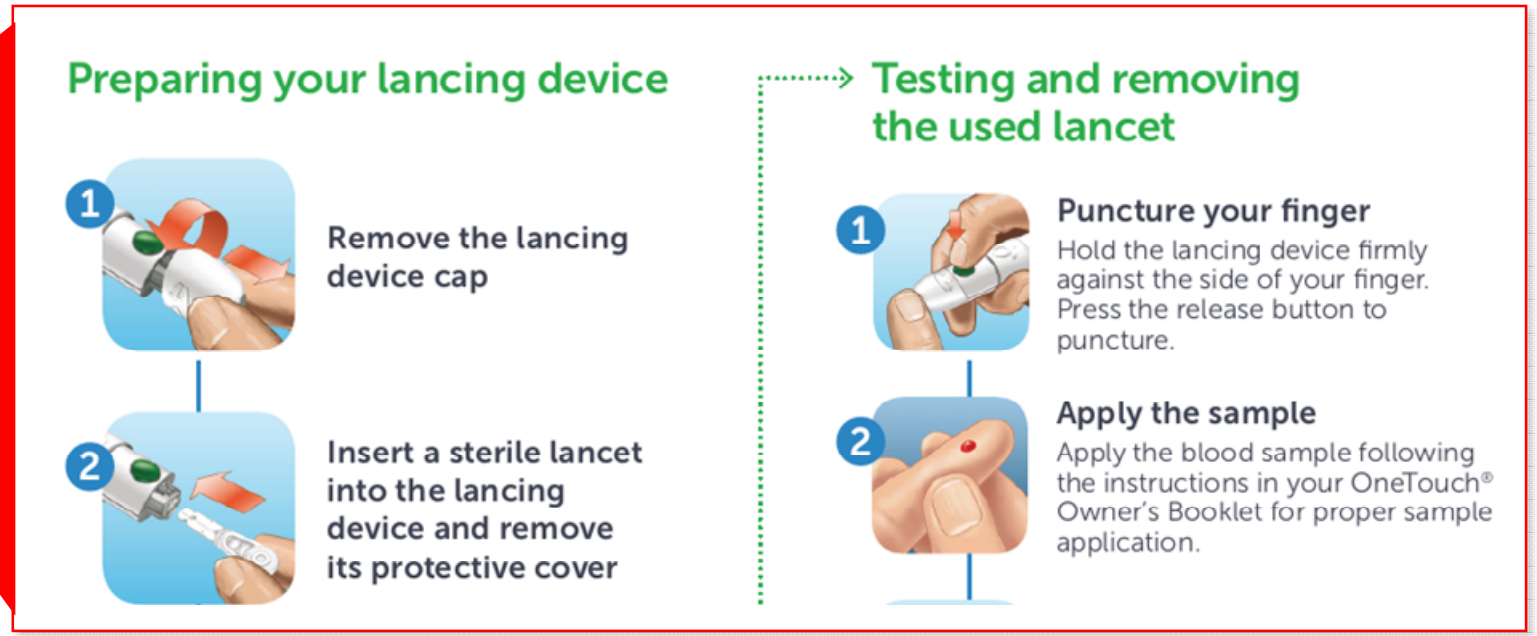
Paper 47 (POSR) at 12 n.2

Paper 32 (Pet. Reply) at 38-43

LifeScan's Demonstratives, not evidence

The Product is the Lancing System





Ex.2047-001

Numerous Unclaimed and Significant Features Defeat Coextensiveness Claims



Petitioner's Expert
Joel Delman

The Lancing Device

"If one considers the overall lancing system to be the product *(i.e.*, the Delica/Delica Plus lancet seated in the lancing device), there are a host of significant and unclaimed features that have nothing to do with the '635 Patent, including:

- The design of the lancing device;
- Its features for seating and propelling the lancet body; and
- Its puncture depth settings."

Ex.1034, ¶72

Paper 32 (Pet. Reply) at 38-39; Paper 47 (POSR) at 12-13

Numerous Unclaimed and Significant Features Defeat Coextensiveness Claims



Petitioner's Expert
Joel Delman

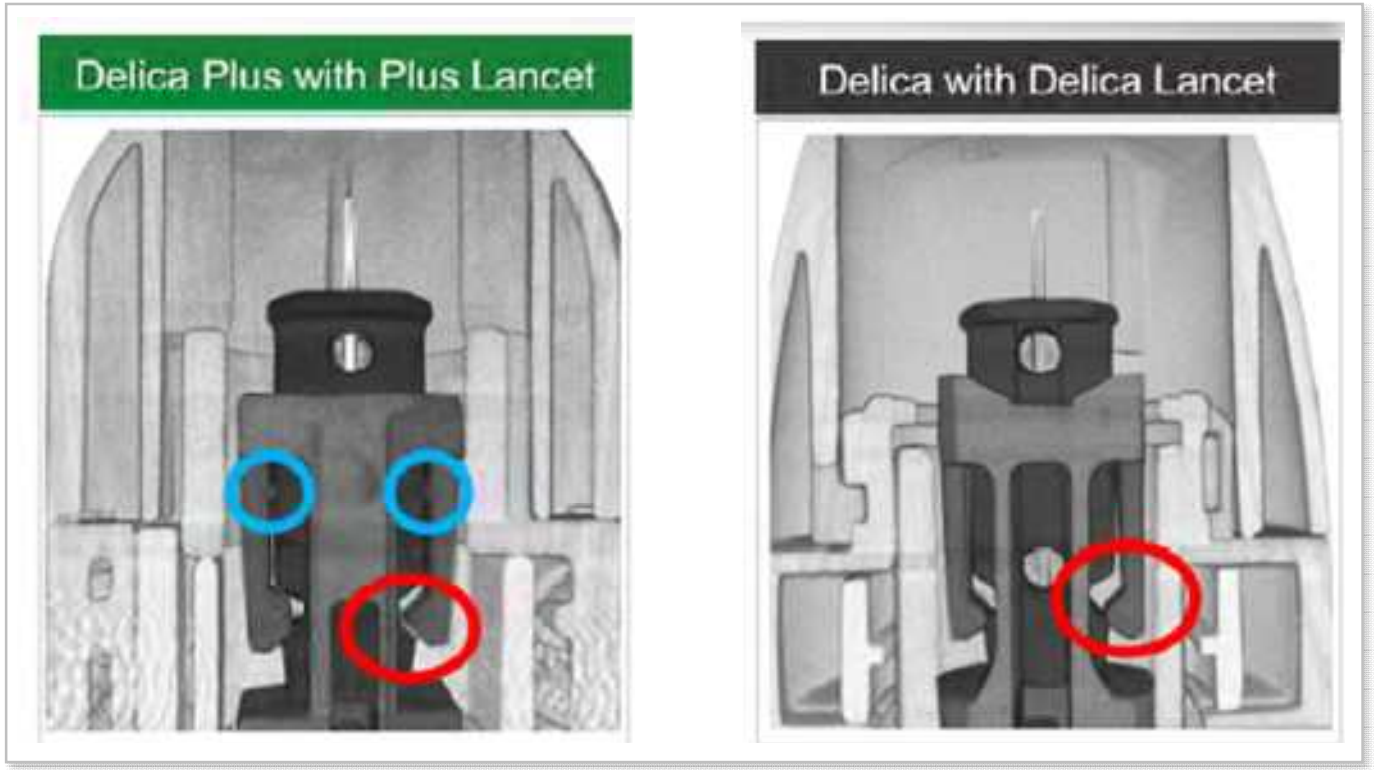
The Lancet

"And even if one considers the lancet on its own to be the product, there are also several critical features not claimed in the '635 Patent, the two most significant being:

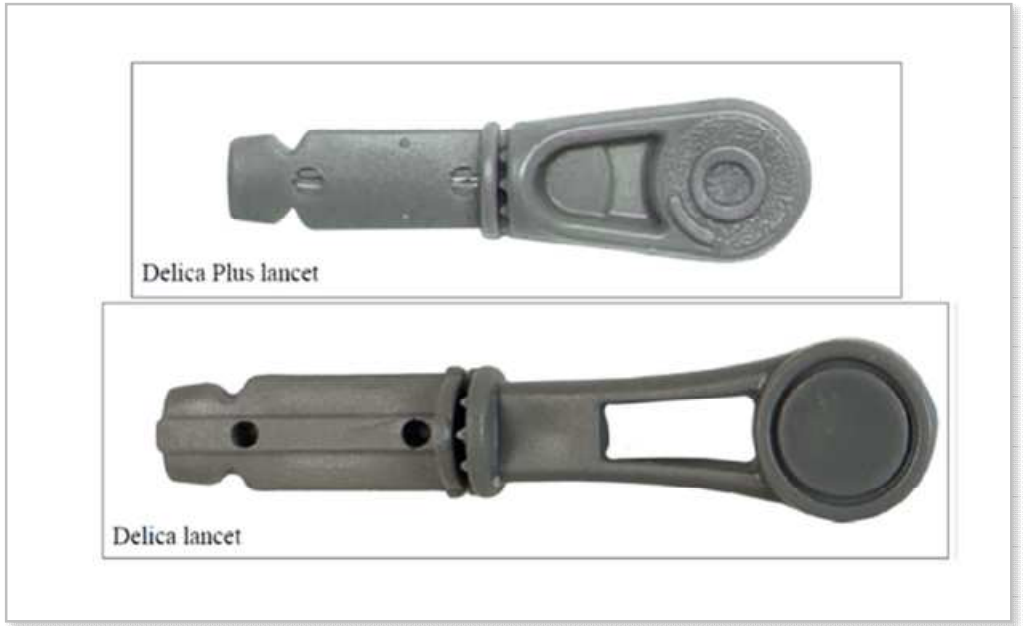
1. The structure and design of the lancet body that allows the lancet to be seated within the Delica or Delica Plus lancing device; and
2. The particularized design of the lancet needle (including its 30 or 33 gauge)."

Ex.1034, ¶72

Lancet



Ex.1045 at 124



Paper 32 (Pet. Reply) at 46

Paper 32 (Pet. Reply) at 39-40; Paper 47 (POSR) at 12-13

LifeScan's Demonstratives, not evidence

Patent Owner's Assertions of Coextensiveness Contradicted by Marking Practices

Patent Notice

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

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

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

Ex.1047

"A patent claim is not coextensive with a product that includes a 'critical' unclaimed feature that is claimed by a different patent and that materially impacts the product's functionality…"

Fox Factory, Inc. v. SRAM, LLC, 944 F.3d 1366, 1375 (Fed. Cir. 2019)

"Furthermore, for the fifteen years that the product was on the market—during which the '382 patent was valid and in force for the entire period save for the final three months—Abbott marked the product with the '382 patent, both before and after the '551 patent issued. As such, there is no presumption that the product's success was due only to the '551 patent."

Therasense, Inc. v. Becton, Dickinson & Co., 593 F.3d 1289, 1299 (Fed. Cir. 2010), *invalidity reinstated*, 649 F.3d 1276 (Fed. Cir. 2011)

4 Secondary Considerations Do Not Support Nonobviousness

A Commercial Success

- The Delica Plus and Delica Do Not Practice the '635 Patent
- No Presumption of Commercial Success Because No Coextensiveness
- No Evidence Sales Are a Direct Result of the '635 Patent

B Long Felt Need

- Prior Art Addresses Long Felt Need

C Copying

- Both Experts Agree the Delica and Delica Plus Use Different Designs
- Cross-Compatibility Is Irrelevant

Paper 32 (Pet. Reply) at 42-43

LifeScan's Demonstratives, not evidence

Secondary Considerations Must Be Direct Result of Unique Characteristics of Claimed Invention



"A finding that a presumption of nexus is inappropriate does not end the inquiry into secondary considerations. To the contrary, the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is the 'direct result of the unique characteristics of the claimed invention.'"

Fox Factory, Inc. v. SRAM, LLC, 944 F.3d 1366, 1373-74 (Fed. Cir. 2019)

No Evidence Customers Purchased Delica/Delica Plus Lancets for Protective Caps

- Facet offers no evidence that lancet purchasing decisions have anything to do with the protective cap.
- The protective cap is not even mentioned as a key feature in any of the FMT, Delica, or Delica Plus marketing material.
- The key drivers for lancet purchases are:
  - Glucometer
  - Insurance coverage
  - Availability at the customer's store
  - Doctor or Nurse Practitioner Recommendations
  - Brand Familiarity



Ex.2047-002, Ex.2048-002

Paper 32 (Pet. Reply) at 42-43; Ex.1046, ¶¶ 11-25; Ex.1052, 173:4-21, 45:16-46:14, 48:9-49:17, 60:12-62:5, 136:19-137:10, 225:20-226:24, 227:15-20, 228:14-229:10, 238:7-13

Facet Does Not Address the Significant Disparity in Sales of its FMT Lancets vs. Sales of Delica Plus Lancets

Paper 32 (Pet. Reply) at 42-43; Ex.1046, ¶¶ 26-31;
Paper 21 (POR) at 76-77; Paper 47 (POSR) at 14-15

4 Secondary Considerations Do Not Support Nonobviousness

A Commercial Success

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B Long Felt Need

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- Both Experts Agree the Delica and Delica Plus Use Different Designs
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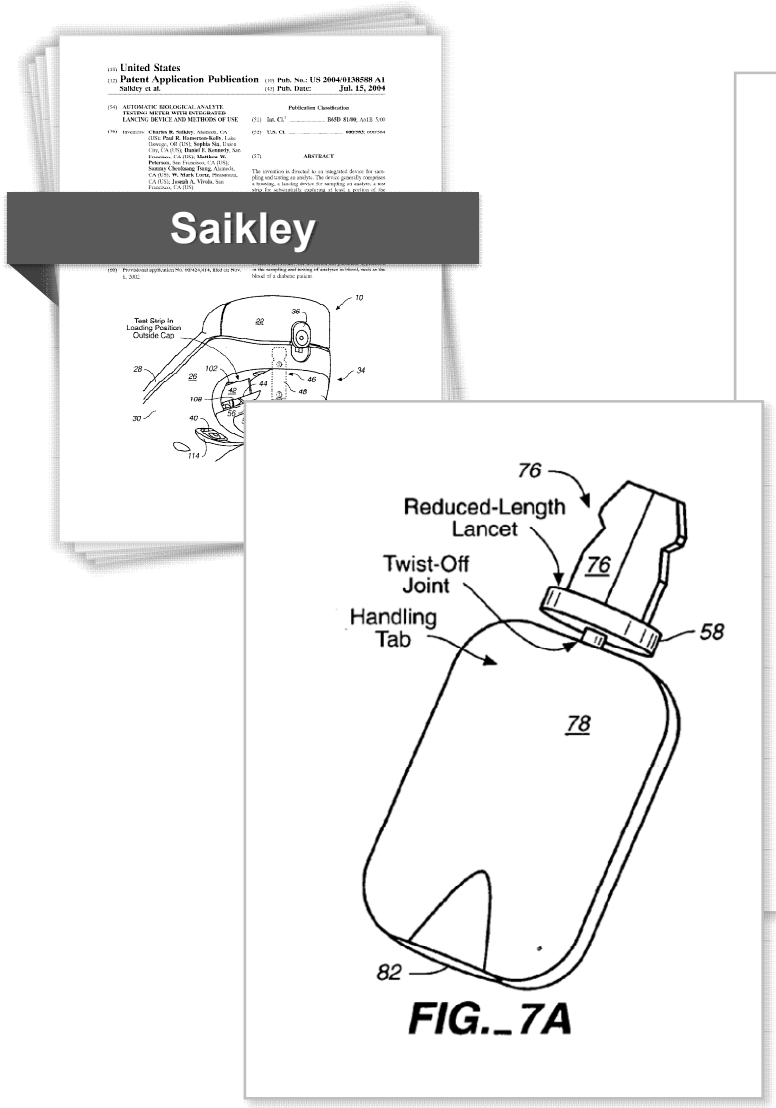
Need Is Not Long Felt if Addressed By the Prior Art



"As we have said before, '[w]here the differences between the prior art and the claimed invention are as minimal as they are here, however, it cannot be said that any long-felt need was unsolved.' That is true here, where the differences between the claimed invention and the prior art are minimal."

ZUP, LLC v. Nash Mfg., Inc., 896 F.3d 1365, 1374 (Fed. Cir. 2018)

Saikley Met PO's Alleged Long Felt Need



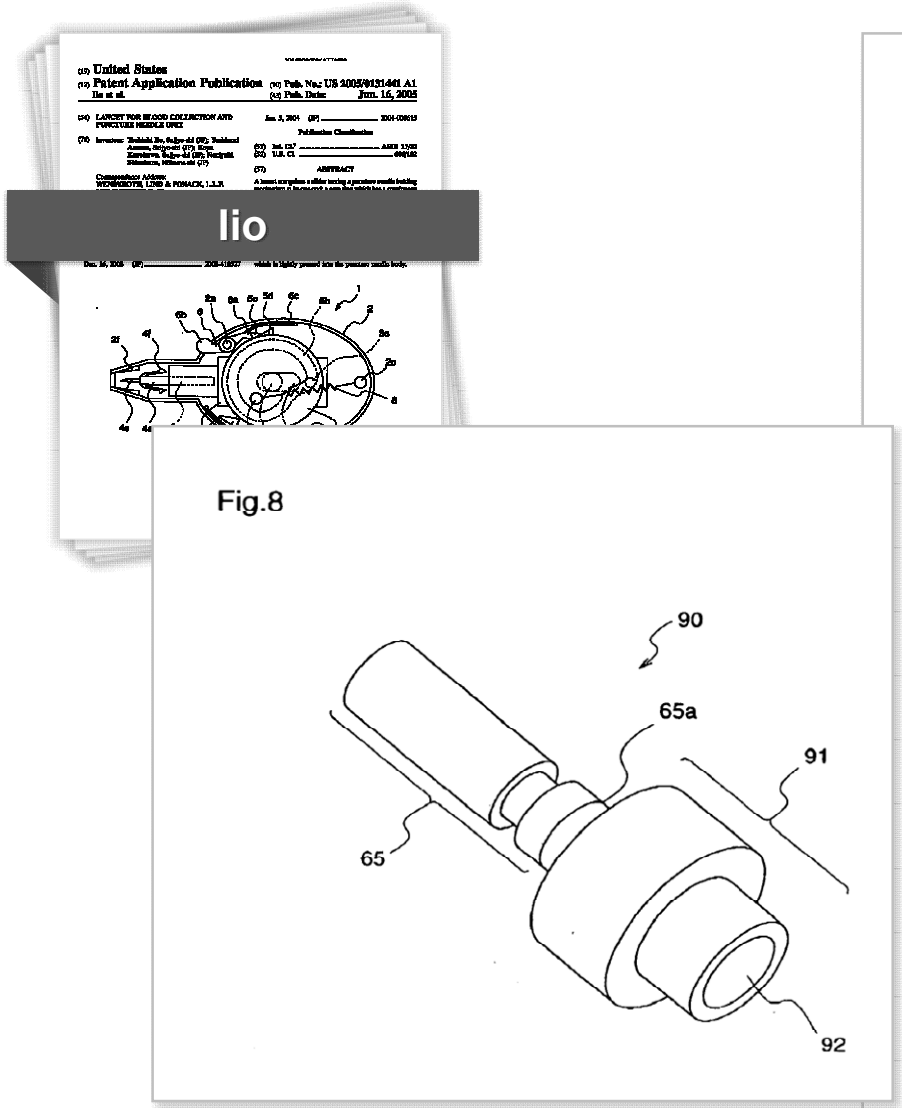
[0004] A ⅓ microliter sample is about the size of a pinhead. Elderly patients and those with reduced eyesight and dexterity can have problems seeing and capturing such a small sample.

* * *

This short length might make the lancet difficult for the user to handle and install, so the protective cap **78** (that is removed before use) should be made much larger than usual to aid handling.

Ex.1005 at [0004], [0050], Fig. 7A

Iio Met PO's Alleged Long Felt Need



for blood collection and a puncture needle unit, which are able to reduce pain and fear of a patient due to shock, sound, and vibration when performing puncture using a puncture needle, and prevent the puncture needle from puncturing the same portion a few times, and further, ensure excellent usability and handleability with safety.

* * *

[0023] According to a seventeenth aspect of the present invention, in the lancet according to the sixteenth aspect, in the puncture needle unit, the puncture needle main part is snugly fitted and attached to the lancet with the puncture needle cap being attached to the puncture needle body part; and after the puncture needle main part is attached to the lancet, the puncture needle cap is removed from the puncture needle main part. Therefore, it is possible to provide a lancet and a puncture needle unit which are able to safely set a puncture needle.

Ex. 1006 at [0005], [0023], Fig. 8

Paper 32 (Pet. Reply) at 43-44; Paper 21 (POR) at 77-78; Paper 47 (POSR) at 15

Patent Owner Mischaracterizes *Monarch Knitting*

The Federal Circuit reversed summary judgment of obviousness because there were genuine issues of material fact about whether evidence of contemporaneous development solved the long-felt need in the art.

- The two designs discussed were not prior art despite predating the alleged invention;
- The Federal Circuit remanded for further proceedings to resolve these and other factual questions.

Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH, 139 F.3d 877, 884 (Fed. Cir. 1998)

Here, Saikley and Iio are prior art and Patent Owner's expert fails to address why Saikley and Iio did not already meet Patent Owner's alleged long felt need.

Paper 47 (POSR) at 15; Paper 21 (POR) at 77-78;
Ex.2056, ¶ ¶ 152-154; Ex.1005; Ex.1006

4 Secondary Considerations Do Not Support Nonobviousness

A Commercial Success

- The Delica Plus and Delica Do Not Practice the '635 Patent
- No Presumption of Commercial Success Because No Coextensiveness
- No Evidence Sales Are a Direct Result of the '635 Patent

B Long Felt Need

- Prior Art Addresses Long Felt Need

C Copying

- Both Experts Agree the Delica and Delica Plus Use Different Designs
- Cross-Compatibility Is Irrelevant

Patent Owner Submits No Expert Testimony of Similarity Between the Delica and Delica Plus

Both Petitioner's and Patent Owner's experts agree there are significant differences between the Delica and Delica Plus.

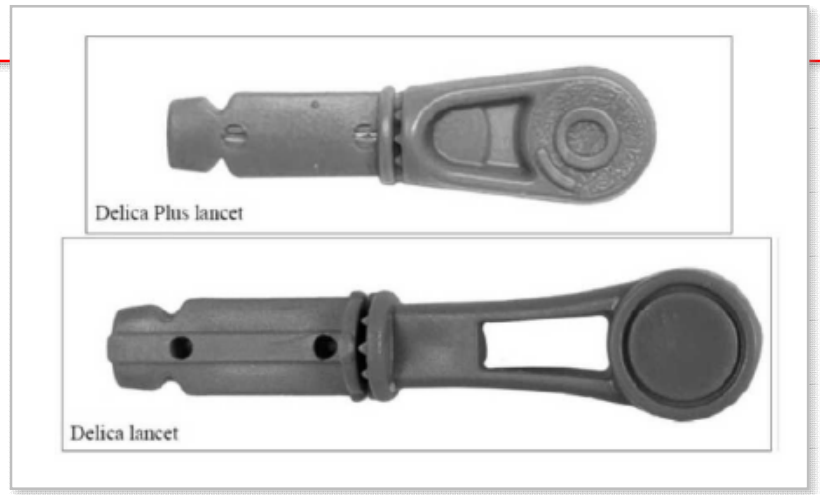
PO's Sur-Reply Did not Address Admitted Significant Differences from Expert



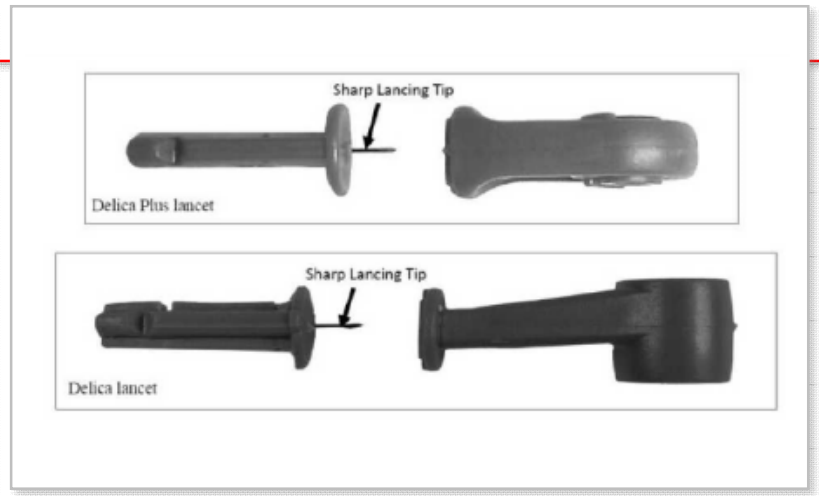
Patent Owner's Expert
Dr. John M. Collins

When asked during his deposition "are there differences that you can see between the Delica Plus lancet and the Delica lancet?" Dr. Collins described the following differences:

- "They're **different shapes**" Ex. 1058 at 22:17-18
- "…in the Delica lancet, there's an **open cavity between the arms**, between the primary sheath and the secondary sheath, and **that's closed in the Delica Plus**…" Ex. 1058 at 22:25-23:3
- "The Delica lancet has a **more pronounced flange**, where the Delica Plus lancet, that **flange blends into the arms more**. That would be something else." Ex. 1058 at 23:6-9
- "The thickness in the image below 142 of the Delica lancet is -- at the far right hand of the **secondary sheath is thicker than the secondary sheath in the Delica Plus lancet.**" Ex. 1058 at 23:24-24:2



Ex. 2056 at 70



Ex. 2056 at 72

Significant Differences Between Delica and Delica Plus Lancet Caps

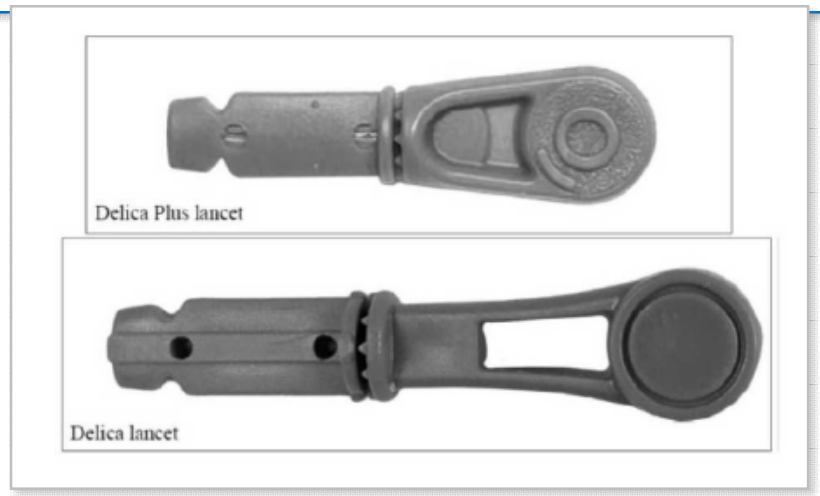


Petitioner's Expert
Joel Delman

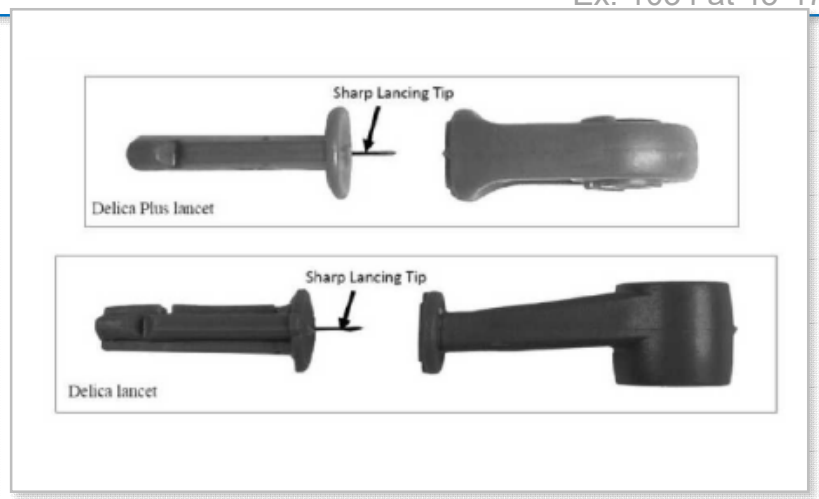
As one can see from the images in Dr. Collins' declaration, the protective caps for the Delica and Delica Plus have numerous significant differences.

- The overall designs are different;
- The sizes and shapes are different;
- The shape of the Delica neck (which is hollow) is different from the shape of the Delica Plus neck (which is filled in and shaped differently);
- The Delica Plus uses a two-sided disc shape at the end of its protective cap;
- The Delica instead uses a one-sided cup shape at the end of its protective cap.

Ex. 1034 at 45-47, ¶¶ 80-82



Ex. 2056 at 70



Ex. 2056 at 72

4 Secondary Considerations Do Not Support Nonobviousness

A Commercial Success

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- No Evidence Sales Are a Direct Result of the '635 Patent

B Long-Felt Need

- Prior Art Addresses Long-Felt Need

C Copying

- Both Experts Agree the Delica and Delica Plus Use Different Designs
- Cross-Compatibility Is Irrelevant

Cross-Compatibility With Lancing Device is Irrelevant

> Copying a feature is "legally irrelevant unless the [] feature is shown to be an embodiment of the claims."

Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1366 (Fed. Cir. 2001)

Cross-Compatibility With Lancing Device is Irrelevant

Cross-Compatibility with Lancing Device Results From Similarities in the Shape of the Lancet Body, Not the Cap



Petitioner's Expert
Joel Delman

"In my opinion, whatever similarities exist between the lancet bodies of the Delica and the Delica Plus is not evidence of copying the patented invention, because the asserted claims of the '635 Patent do not recite a lancet body having any particular structure, or otherwise claim the lancet body shape or structure being used in the Delica or Delica Plus lancets."

Ex.1034, ¶¶ 78-79

Patent Owner Grossly Mischaracterizes Mr. Lamps' Testimony

Paper 32 (Pet. Reply) at 48; Ex. 2024, 145:10-147:11, 160:17-166:19;
Paper 47 (POSR) at 6-7; Paper 21 (POR) at 72-76

LifeScan's Demonstratives, not evidence

Petitioner’s Motion to Exclude Evidence

5 Petitioner's Motion to Exclude Evidence

A Certain Paragraphs of Exhibit 2056 Are Unreliable

B Exhibits 2044, 2045, 2050, and 2051 Are Inadmissible Hearsay

C Exhibits 2024, 2044, 2045, 2050, and 2051 Are Irrelevant

D Exhibits 2040, 2044, 2045, 2050, and 2051 Are Not Authenticated

5 Petitioner's Motion to Exclude Evidence

A Certain Paragraphs of Exhibit 2056 Are Unreliable

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C Exhibits 2024, 2044, 2045, 2050, and 2051 Are Irrelevant

D Exhibits 2040, 2044, 2045, 2050, and 2051 Are Not Authenticated

Paragraphs 137 Through 151 of Exhibit 2056 Are Unreliable

Dr. Collins merely restates the claim language:

14. A protective sterility cap for a lancet, said sterility cap comprising a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein, a secondary sheath for receiving the sharp lancing tip of a used lancet, and a gripping handle portion extending between the primary sheath and the secondary sheath, with the primary sheath attached at a first end of the gripping handle portion and the secondary sheath attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet, said protective sterility cap being in combination with a lancet having a lancet body defining a lancet thickness, and a sharp lancet tip initially embedded in the primary sheath, wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.

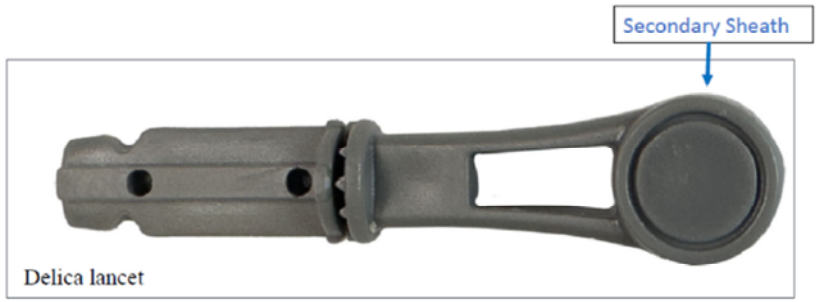
Ex.1001, Claim 14

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

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

Ex. 2056, ¶143





Paragraphs 137 Through 151 of Exhibit 2056 Are Unreliable

Dr. Collins merely restates the claim language:

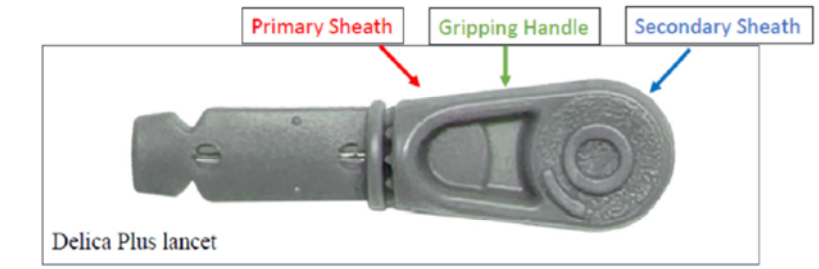
14. A protective sterility cap for a lancet, said sterility cap comprising a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein, a secondary sheath for receiving the sharp lancing tip of a used lancet, and a gripping handle portion extending between the primary sheath and the secondary sheath, with the primary sheath attached at a first end of the gripping handle portion and the secondary sheath attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet, said protective sterility cap being in combination with a lancet having a lancet body defining a lancet thickness, and a sharp lancet tip initially embedded in the primary sheath, wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.

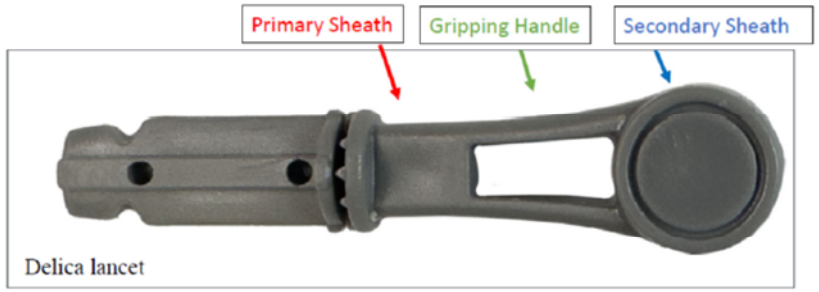
Ex.1001, Claim 14

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

144. The Delica Plus and Delica 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





Dr. Collins Conducted No Analysis of the "Gripping Handle Portion"



Patent Owner's Expert
Dr. John M. Collins

Q. Did you conduct an analysis to figure out which portions of that cap are gripped?

A. I did not conduct a formal analysis, no.

Ex.1035, 142:17-21

Paper 44 at 3; Paper 21 (POR) at 65-72; Ex.2056, ¶ ¶ 137-151

5 Petitioner's Motion to Exclude Evidence

A Certain Paragraphs of Exhibit 2056 Are Unreliable

B Exhibits 2044, 2045, 2050, and 2051 Are Inadmissible Hearsay

C Exhibits 2024, 2044, 2045, 2050, and 2051 Are Irrelevant

D Exhibits 2040, 2044, 2045, 2050, and 2051 Are Not Authenticated

Patent Owner Utilizes Exhibits 2044, 2045, 2050, and 2051 for Hearsay Purposes

- No hearsay exclusions apply
- The residual exception does not apply

5 Petitioner's Motion to Exclude Evidence

A Certain Paragraphs of Exhibit 2056 Are Unreliable

B Exhibits 2044, 2045, 2050, and 2051 Are Inadmissible Hearsay

C Exhibits 2024, 2044, 2045, 2050, and 2051 Are Irrelevant

D Exhibits 2040, 2044, 2045, 2050, and 2051 Are Not Authenticated

Patent Owner Grossly Mischaracterizes the Testimony in Exhibit 2024

Patent Owner Failed to Explain the Relevance of Exhibits 2044, 2045, 2050, 2051

Patent Owner's Cases Are Distinguishable

In *Fox Factory*, the Board determined expert's testimony that the competing product shown in the exhibits were copies of Patent Owner's product was sufficient to establish the exhibits were relevant.

Fox Factory, Inc. v. SRAM, LLC, IPR2017-01440 (Paper 62) at 81-82 (PTAB Dec. 6, 2018)

Dealt with deposition testimony that was argued to be cumulative of other testimony or had questions asked that were vague and ambiguous.

Int'l Bus. Machines Corp. v. Intell. Ventures II LLC, IPR2014-00180 (Paper 50) at 10 (PTAB Apr. 3, 2015);
Amazon.com, Inc. v. Customplay, LLC, IPR2018-01498 (Paper 37) at 49 (PTAB Mar. 11, 2020)

5 Petitioner's Motion to Exclude Evidence

A Certain Paragraphs of Exhibit 2056 Are Unreliable

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Patent Owner Presented Insufficient Evidence of the Authenticity of Exhibits 2040, 2044, 2045, 2050, and 2051

- No evidence as to the genuineness of the contents of these exhibits;
- No statement from the author of these exhibits or an individual who saw the author compose the emails in these exhibits;
- Declaration from counsel that an exhibit is a “true and correct copy” is insufficient.

Paper 44 at 7-10; Paper 55 at 4-5; Ex. 2060

Petitioner's Opposition to Patent Owner's Motion to Exclude Evidence

6 Petitioner's Opposition to Patent Owner's Motion to Exclude Evidence

A Exhibit 1052 Qualifies Under the Residual Exception

B Mr. Rosenfarb's Independent, Expert Opinions Are Admissible

6 Petitioner's Opposition to Patent Owner's Motion to Exclude Evidence

A Exhibit 1052 Qualifies Under the Residual Exception

B Mr. Rosenfarb's Independent, Expert Opinions Are Admissible

Federal Rule of Evidence 807: Residual Exception

"Under the following conditions, a hearsay statement is not excluded by the rule against hearsay even if the statement is not admissible under a hearsay exception in Rule 803 or 804:

1. the statement is supported by sufficient guarantees of trustworthiness—after considering the totality of circumstances under which it was made and evidence, if any, corroborating the statement; and

2. it is more probative on the point for which it is offered than any other evidence that the proponent can obtain through reasonable efforts."

EXHIBIT 1052 MEETS BOTH REQUIREMENTS

Exhibit 1052 Is Supported By Sufficient Guarantees of Trustworthiness

- Ms. Voyten was deposed under oath in the related district court litigation.
- Patent Owner's counsel cross examined Ms. Voyten regarding the specific factual issues on which LifeScan relies on her in this proceeding.

Exhibit 1052 Is More Probative On the Point For Which It Is Offered

- Submitting a declaration from Ms. Voyten would not have been more probative than the testimony she already provided under Patent Owner's cross-examination in the related district court litigation.

- A declaration would have contained the same testimony and facts Patent Owner already elicited from Ms. Voyten's deposition.

- Patent Owner could have requested the opportunity to retake her deposition, as it did with Petitioner's three experts.

Patent Owner's Cases Are Distinguishable

The Board noted the deposition testimony did not qualify for the residual exception because it was cumulative of other evidence Petitioner had identified and was therefore not "more probative on the point for which it is offered."

ABS Global, Inc. v. XY, LLC, IPR2018-01224 (Paper 28) at 19 (PTAB Dec. 9, 2019)

The Board excluded deposition transcripts from a trial involving Patent Owner and "non-parties to these proceedings." Thus, the testimony was never subject to cross-examination by Petitioner.

The Data Co. Techs. Inc. v. Bright Data Ltd., IPR2022-00135 (Paper 51) at 80-81 (PTAB May 31, 2023)

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Patent Owner Mischaracterizes Mr. Rosenfarb's Testimony As Hearsay

Mr. Rosenfarb Was Permitted to Rely on Exhibit 1052 Under FRE 703

Federal Rule of Evidence 703: Bases of an Expert

> "…If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted."

The Board Considers the Data, Not a Jury



"Fed. R. Evid. 703 includes the caveat that if the underlying facts are inadmissible, those facts may only be disclosed to the jury if their probative value in helping evaluate the opinion substantially outweighs their prejudicial effect. Our determination is not made by a jury, so this caveat does not apply. *See* 37 C.F.R. § 42.62(b) (portions of the Federal Rules of Evidence relating to juries do not apply)."

Nestle Healthcare Nutrition, Inc. v. Steuben Foods, Inc., IPR2015-00249 (Paper 76) at 13 (PTAB June 2, 2016)

Patent Owner Fails to Explain Why Mr. Rosenfarb's Expert Opinion is Unreasonable

- Patent Owner fails to explain why it would be unreasonable for Mr. Rosenfarb to rely on Ms. Voyten's testimony in his expert opinion.
- Patent Owner had the opportunity to depose Mr. Rosenfarb on the basis for his opinions but elected not to do so.
- Exhibit 1052 provides some of the underlying facts that form the basis of Mr. Rosenfarb's opinion and should be considered.
- Even Patent Owner's damages expert relied on similar deposition testimony of Facet witnesses and private conversations with Facet personnel as the basis for her opinions on the same subject matter in the district court case.

Paper 50 at 5-10; Ex.1046, ¶¶ 20, 22, 23