

Filed on behalf of: Facet Technologies, LLC

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIFESCAN, INC.,
Petitioner,

v.

FACET TECHNOLOGIES, LLC,
Patent Owner.

IPR2023-00712
Patent 8,840,635

**DECLARATION OF JOHN COLLINS IN SUPPORT OF
PATENT OWNER'S RESPONSES**

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I, John M. Collins, Ph.D., declare the following:

I. Introduction

1. I am over the age of eighteen and competent to make this Declaration.

2. Unless stated otherwise, all facts stated herein are within my personal knowledge and are true and correct. If called upon, I would be willing to testify as set forth in this Declaration.

3. I have been retained by Facet Technologies, LLC (“Facet”) to provide my opinion concerning the validity of U.S. Patent No. 8,840,635 (“’635 Patent”).

4. I understand Petitioner LifeScan, Inc. (“LifeScan”) filed two Petitions for Inter Partes Review of U.S. Patent No. 8,840,635: (1) IPR2023-00712 (“Petition” or “Pet.”); and (2) IPR2023-00713 (“’713 Petition” or “’713 Pet.”) (collectively, “Petitions” or “Pets.”). I further understand that on September 1, 2023, IPR2023-00712 was instituted (Pet., Paper No. 13) and the ’713 Petition was denied institution (’713 Pet., Paper No. 13).

5. I have previously provided my opinions in support of the Patent Owner’s Preliminary Responses to the Petition and the ’713 Petition. While I believe that those declarations are accurate in all respects, this new Declaration represents my considered opinion and supersedes my previous Declarations.

6. I understand LifeScan challenged claims 1-3, 5-8, 14, and 16-18 of the ’635 Patent in the Petition. I understand Facet then disclaimed claims 1-5 and

9-10. Thus, I understand only claims 6-8, 14, and 16-18 remain at issue for the Petition.

7. I submit this declaration in support of Facet's Responses to the Petition for Inter Partes Review of U.S. Patent No. 8,840,635.

8. I am being compensated for the time I spent preparing this Declaration at my customary rate of \$450 per hour. The opinions I express in this Declaration are my own. My compensation does not depend upon the outcome of this IPR, the contents of this Declaration, or any testimony I may provide in this IPR.

9. This Declaration summarizes the opinions I have formed to date. I reserve the right to modify or update my opinions, if necessary, based on my review and analysis of information or materials that I may receive after this Declaration is submitted. I further reserve the right to respond to any new or updated positions LifeScan or its expert(s) may take in this IPR.

II. Qualifications

10. I have over 40 years of product design and product development expertise covering a wide range of industries and products, including consumer, industrial, and medical products and devices. Over that time, I have had a consistent focus on medical devices and technologies. I have been responsible for all aspects of a product's development, including defining the need in the market as well as the requirements, user interface, overall look and feel (industrial design),

construction (design for manufacturing, etc.), and performance/functionality validation. In addition to doing engineering work, including technology assessment and planning, my responsibilities have included assembling and managing teams to develop new products.

11. I received a B.S. (1980) in mechanical engineering from Rensselaer Polytechnic Institute, and an M.S. (1982) and Ph.D. (1988) in mechanical engineering from Massachusetts Institute of Technology (“MIT”). At MIT, my academic work was in mechanical engineering with a concentration on biomedical applications of fluid dynamics, including heat/mass transfer. My Ph.D. and M.S. thesis projects applied these principles to pulmonary dynamics.

12. Since 2008 I have been employed at the Consortia for Improving Medicine with Innovation and Technology (“CIMIT”), an operating unit within Massachusetts General Hospital. Founded by Massachusetts General Hospital, Brigham and Women’s Hospital, Charles Stark Draper Laboratory and Massachusetts Institute of Technology, CIMIT is a consortium of thirteen of the greater Boston area’s premier clinical, research and academic institutions, including the Harvard Medical School and its teaching hospitals, along with a growing list of national and international affiliates. *See* www.CIMIT.org.

13. CIMIT’s mission is to improve patient care by facilitating collaboration among clinicians, academics, engineers, and entrepreneurs to

catalyze the discovery, development and implementation of innovative technologies and procedures/systems that improve patient care. For most of my tenure, I have been responsible for ensuring CIMIT's "Finding, Funding, Facilitating, and Following" functions are effective. In addition, I worked on supporting teams of clinicians, engineers, and entrepreneurs in start-ups or emerging from academic labs in the commercialization of healthcare technologies. I am now focused on using these experiences to develop and refine CIMIT's web-based platforms to scale the support available to innovators. These include a secure, interactive platform for teams to apply for funding called CoLab. See <https://www.cimit.net/web/cimit-colab/cimit-colab>. It also includes a novel way to plan, track, and display a project's maturity as well as provide guidance on how to execute tasks. See www.GAITS.org. In addition, I manage CIMIT's Commercialization Readiness Assessment and Accelerator for Solutions in Healthcare ("CRAASH") program which supports teams commercialize promising healthcare innovations. See: <https://www.craash.org>.

14. A recent example of the use of these platforms to support innovation is in CIMIT's work as the coordinating center for the National Institutes of Health's Rapid Acceleration of Diagnostics Technology ("RADx Tech") initiative. This \$500M-plus initiative was highly successful in speeding innovation in the development and deployment of Point of Care ("POC") testing technologies

capable of testing millions of Americans for the presence of the SARS-CoV-2 virus. A paper describing the use of these platforms is available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8112669/>.

15. Also, since 2008, I have been the Chief Technology and Innovation Officer of Reed Collins LLC. In this role, I provide consulting services on technology, intellectual property, commercialization, and business development and serve on review, steering, and advisory boards for non-profit organizations that support healthcare innovation. Examples include the Scientific Advisory Board for the Massachusetts Life Science Center, and the Strategic and Industry Partnerships Programme Oversight Group at the Oxford Academic Life Science Network. I also consult for and provide expert technical opinions in patent-related matters, including patent infringement disputes.

16. Prior to 2008, I held various positions at technology and product development companies. From 1982 to 1986, after receiving my M.S. degree at MIT, I worked at Booz, Allen & Hamilton, where I developed automotive, consumer, and industrial products. Examples include GE's under-counter coffee maker, GM's hydraulic systems for automotive anti-lock brakes, Engelhard's coating and drying system for catalytic converters, Rubbermaid's ergonomic table, and the Regina rug scrubber.

17. After completing my Ph.D. in 1988, I joined Arthur D. Little, Inc. (“ADL”). I joined ADL as a design engineer and helped form its medical products business. I progressed from being a design engineer to being responsible for the Technology and Innovation (“T&I”) Directorate at ADL, with more than 250 staff. From the resources of ADL’s T&I, I helped form TIAX LLC, a privately held technology transformation company focused on advancing and developing technologies for commercialization in several core technology areas, including medical devices and products, clean energy and material, appliances and HVAC systems, and enhanced security.

18. I have worked on a wide range of medical products over my career, including:

- Lancets;
- Minimally invasive surgical access (cutting) devices called trocars with automated safety covers as well as universal seals;
- Minimally invasive surgical devices including clip appliers, ligate & divide absorbable clip appliers (which collected, cut, and clipped tissue) and arthroscopic shaver blades;
- Intraosseous infusion needles;
- Blood and IV fluid warmers along with the associated containers;
- Chest drainage devices;

- Ambulatory infusion pumps;
- Neurological and vascular surgical navigation systems;
- Blood pressure monitors for high noise environments; and
- Scroll pumps for applications in blood handling, pulsed lavage in orthopedic surgery, irrigation/aspiration in ophthalmic microsurgery.

19. I am a named inventor on over 20 United States patents, in addition to foreign counterparts, on products and manufacturing processes. Many of these patents are directed to technologies relating to medical devices. A complete list of my patents is set forth in my curriculum vitae (Ex. 2002), which I incorporate here by reference.

20. I have over 27 years of experience consulting for and testifying as an independent technical expert witness in patent infringement and related disputes, including disputes involving mechanical, electro-mechanical, and thermo-fluid medical devices.

III. Summary of Materials Reviewed and Considered

21. All of the opinions contained in this Declaration are based on the documents I reviewed and my knowledge and professional judgment. In forming the opinions expressed in this Declaration, while drawing on my experience in the field of medical devices and similar-type consumer products, I reviewed the following documents:

Exhibit	Description
1001	U.S. Patent No. 8,840,635 to Pusey et al. (the “’635 Patent”)
1002	Declaration of Expert Joel Delman
1004	Claim Construction Order for <i>Facet Technologies, LLC v. LifeScan, Inc.</i> , Case No. 2:22-cv-1717-MCS-MAR, Dkt. 122 (C.D. Cal. Jan. 20, 2023)
1005	U.S. Patent Application Publication 2004/0138588 to Saikley (“Saikley”)
1006	U.S. Patent Application Publication to Iio 2005/0131441 (“Iio”)
1008	U.S. Patent No. 5,569,286 to Peckham et al. (“Peckham”)
1017	U.S. Patent No. 6,283,982 to LeVaughn et al. (“LeVaughn”)
1018	U.S. Patent Application Publication 2006/0241669 to Stout (“Stout”)
1022	Lengths, girths, and diameters of children’s fingers from 3 to 10 years of age, <i>Annals of Anatomy</i> (2010)
2002	<i>Curriculum Vitae</i> of John M. Collins
2009	Memorandum of Points and Authorities in Support of LifeScan, Inc.’s Motion for Summary Judgment of Invalidity, <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal. May 29, 2023), ECF No. 190-1
2026	BD Medical, <i>BD Ultra-Fine Lancets — A Difference You Can See and Feel</i> (June 2007), https://www.bd.com/resource.aspx?IDX=4437 (English & French versions)
2028	Deposition transcript of Joel Delman, <i>LifeScan, Inc. v. Facet Techs., LLC</i> , IPR2023-00712 (P.T.A.B. Dec. 5, 2023) (“Delman IPR Dep.”)

Exhibit	Description
2029	Bettina Barisch-Fritz et al., <i>Evaluation of the Rule-of-Thumb: Calculation of the Toe Allowance for Developing Feet</i> , Footwear Sci. 1 (2016), https://www.tandfonline.com/doi/full/10.1080/19424280.2016.1144654
2034	U.S. Food & Drug Administration (FDA) letter to James Bonds of Facet Technologies, LLC, dated July 15, 2022, Re: Trade/Device Name: Facet 28G Universal Lancet, Regulation Number: 21 CFR 878.4850, Regulation Name: Blood Lancets, Regulatory Class: Class II, Product Code: QRK, QRL, Dated: May 16, 2022, Received: May 17, 2022
2036	Mass. Inst. Tech. (MIT), Design And Manufacturing I, Undergraduate Course (Spring 2009), Design Handbook: Engineering Drawing and Sketching, MIT (2001-2023)
2043	<i>Anatomy of the Hand</i> , Johns Hopkins Medicine, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/anatomy-of-the-hand (last visited Dec. 14, 2023, 10:01 AM)
2053	<i>Wire-Twist™ Wire Connectors: Models WT1, WT2, WT3, WT4, WT6</i> (Product Fact Sheet), Ideal Industries, Inc.
2054	Japan Patent Office, Patent Publication (B2), No. 3621502 (“Morita”)

22. My opinions are additionally guided by my appreciation of how a person of ordinary skill in the art would have understood the claims of the ’635 patent at the time of the invention, which I have been asked to assume is July 29, 2008. I will sometimes refer to this time as the “relevant time.”

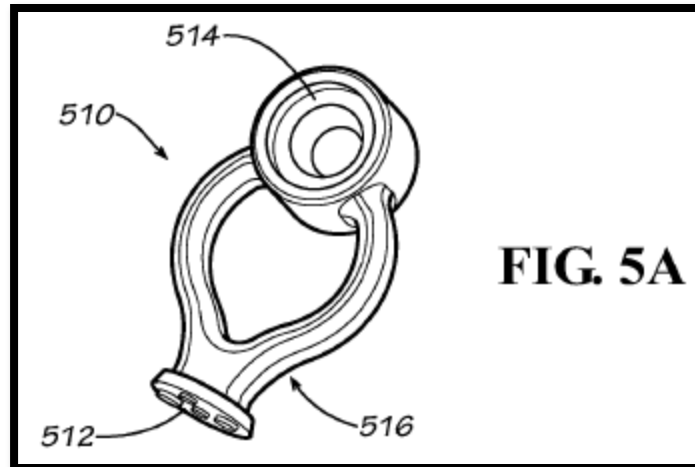
IV. Background

A. The '635 Patent (Ex. 1001)

23. The '635 Patent, titled "Lancets With Improved Coupling Features and Sterility Caps," was filed on November 13, 2012 and issued on September 23, 2014.

24. The '635 Patent relates to lancets with protective sterility caps and lancing devices. '635 Patent Abstract, 1:17-19. Lancing devices often look like a small pen, which is used to hold the lancet. Lancets and lancing devices are used to penetrate the skin of a human subject to obtain a sample of blood for medical testing, such as blood sugar (glucose) testing. '635 Patent 1:17-19, 1:23-26.

25. The '635 Patent discloses and claims improved lancet designs and protective sterility caps for covering the sharp tip of the lancet. '635 Patent, Claims 1-3, 5-8, 14, and 16-18, Abstract, 1:58-60, 1:66-2:8, 2:21-36. It provides several non-limiting examples of embodiments of the claimed lancet and the claimed protective sterility cap for the lancet. '635 Patent 2:41-46, 3:10-16. For instance, Figures 1A-1C, 2A-2C, 3A-3D, 4A-4D, 8A-8B, 9A-9B, and 10A-10B show example embodiments of the patented lancet. Figures 5A-5E, 6A-6D, and 7 show example embodiments of the patented endcap. Figure 5A is shown below:



'635 Patent Fig. 5A, 5:65-7:34.

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

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

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

29. The challenged claims include specific dimensional limitations. For example, in claims 6 and 14 recite a 1.5 ratio of the lancet gripping handle lateral span to lancet thickness. '635 Patent Claims 6 and 14. This ratio makes the device easier to handle and use. *See* '635 Patent 6:66-7:3 (The “greater width[] allow[s] the user to more easily twist the endcap during removal from the lancet” and for “easier use by persons with limited dexterity or vision.”). Similarly, in claims 7, 8, 17, and 18, the recited length of the handle portion, “allows the user to grab the lancet further from the needle during decapping and disposal, providing a larger safety margin from the needle tip, protecting the patient and other persons handling the lancet from accidental needle sticks.” '635 Patent Claims 7, 8, 17, and 18, 6:61-66.

30. The '635 Patent provides for two sheaths: a primary sheath for initial embedment, and a secondary sheath for recapping the used needle. The specification provides that “[t]he primary shroud or sheath portion 512 comprises a wide circular flange or ring at one end of the sterility cap 510, which abuts, confronts or interfaces with the front end of the lancet body in the lancet's original, unused state,” and “[t]he 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.” '635 Patent 6:18-21; 6:49:52.

B. Person of Ordinary Skill in the Art

31. I have been instructed by counsel to assume that the POSA definition provided by Joel Delman in his Declaration in Support of Petition for *Inter Partes* Review of All Claims of U.S. Patent No. 8,840,635 (Ex. 1002 ¶¶ 34, 35) is correct and to apply it herein.

V. Legal Principles

32. For the purposes of this Declaration, I have been informed about certain aspects of the law that are relevant to my analysis and opinions. My understanding of these principles is set forth below.

A. Validity Framework

33. I understand that a validity analysis is a two-step process. First, the patent claims are construed to ascertain their proper scope. Second, the construed claims are compared to the identified prior art to determine if the claims are valid over the prior art.

34. I understand that a person having ordinary skill in the art (i.e., a POSA) is a hypothetical person who is presumed to have known the relevant art at the relevant time, i.e., the time the invention was made.

35. I also understand that an expert is to analyze the prior art from the perspective of a POSA at the relevant time (i.e., the time of the invention), and not simply to provide his/her own personal conclusions.

1. Anticipation (35 U.S.C. § 102)

36. I understand that for a claim to be anticipated, a single prior art reference must disclose to a POSA every limitation of the claimed invention, either expressly or inherently, arranged as in the claim. I understand that a reference cannot anticipate if it is ambiguous as to whether it disclosed the respective claim limitations to the POSA.

37. I understand patent figures are merely illustrative of the principles embodied in the alleged invention. They are presumed to not be at scale, unless otherwise indicated in patent.

38. I understand that an element may be inherently disclosed only if it is necessarily present, not merely probably or possibly present, in the prior art. I understand that inherency may be shown through extrinsic evidence.

2. Obviousness (35 U.S.C. § 103)

39. I understand that an obviousness determination in a question of law based on the following factual inquiries: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the claimed invention and the prior art; (3) resolving the level of ordinary skill in the pertinent art; and (4) taking into consideration any objective indicia of non-obviousness. I am not a lawyer and therefore not providing an opinion herein regarding the final legal

determination of obviousness. I am instead opining on the underlying factual issues.

40. I understand that for a claim to be obvious the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a POSA.

41. While obviousness analyses are often based on more than one piece of prior art, only one is required. Also, it is not sufficient that the prior art reference(s) merely recite the various elements of a challenged patent claim. Rather, there must be an articulated rationale explaining why the POSA could have and would have made the combination of teachings (or modified them) to arrive at the claimed invention. I understand that obviousness cannot be based on the hindsight combination of components selectively culled from the prior art.

42. I understand that obviousness (and its underlying factual matters) is determined as of the date of the invention (i.e., the effective filing date or priority date of the patent). Thus, in considering the reason or motivation to combine or modify references, it is essential to avoid using hindsight. For example, the problem examined when considering obviousness is the general problem that confronted the inventor before the invention was made, not the specific problem solved by the invention. Defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness.

43. Further, an overly narrow statement of the problem can represent a form of hindsight, because often the inventive contribution lies in defining the problem in a new revelatory way. Similarly, an assertion that a person of ordinary skill could combine the references, rather than that they would have been motivated to do so, is an impermissible form of hindsight. Moreover, knowledge of a problem and motivation to solve it are entirely different from motivation to combine particular references to reach the particular claimed invention.

44. I understand that the analysis of the motivation to combine or modify should be explicit. Additionally, it must include articulated reasoning with rational underpinnings to support the conclusion of obviousness.

45. I understand that obvious to try may be used to support a motivation to combine or modify, so long as the possible approaches and selection to solve the problem must be known and finite.

46. I understand that routine optimization may be used to support a motivation to combine or modify, so long as there is an explanation with rational underpinning explaining why a POSA would have arrived at the claimed invention through routine optimization.

47. I understand that objective indicia of non-obviousness may include (1) a long felt but unsolved need that was satisfied by the claimed invention; (2) commercial success attributable to the claimed invention; (3) unexpected results

achieved by the claimed invention; (4) praise by those in the field of the claimed invention; (5) taking of licenses under the patent by others for reasons related to the alleged non-obviousness of the claimed invention; and (6) evidence that competitors in the marketplace are copying the invention instead of using the prior art. I also understand that there must be a link, or nexus, between any such objective indicia and the claimed invention, i.e., objective evidence of non-obviousness must be attributable to the claimed invention.

VI. Claim Construction

48. I have been instructed by counsel to assume the constructions proposed by Mr. Delman—which follow the district court order (Ex. 1004)—are correct and to apply them in my analysis. I have provide the following summary of those constructions below:

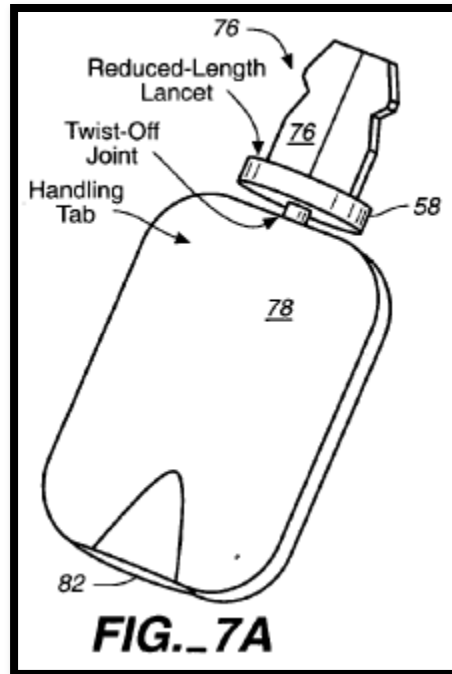
Term	Construction (Ex. 1004)
“a secondary sheath for receiving the sharp lancing tip of a used lancet”	“a secondary sheath for covering the sharp lancing tip of a used lancet by embedding or enclosing the lancet tip”
“a gripping handle portion extending between”	No construction necessary (ordinary meaning) ¹
“lancet thickness”	No construction necessary (ordinary meaning)
“lateral span”	No construction necessary (ordinary meaning)
“thickness”	No construction necessary (ordinary meaning)

VII. The Asserted References

A. Saikley (Ex. 1005)

49. U.S. Pat. App. Pub. No. 2004/0138588 (“Saikley,” Ex. 1005) is directed to a shortened lancet and cap, (Fig. 7A) (§ 50):

¹ In this table, “ordinary meaning” is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, in the context of the particular claim in which the disputed term appears, and in the context of the entire patent, including the specification. I have read the district court’s explanation of the ordinary meaning of these claim terms in Exhibit 1004, and apply those ordinary meanings herein.

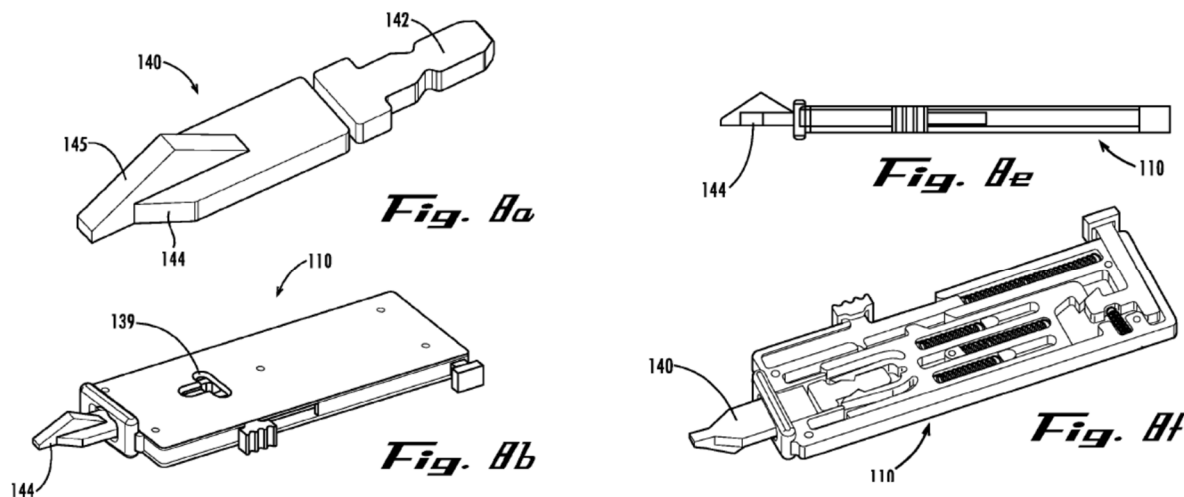


Saikley Fig. 7A.

50. The shortened lancet 76 has a main body 76, cylindrical collar 58, and protective cap 78. Saikley ¶ 50, Fig. 7A. Saikley describes protective cap 78 as “an integrally molded, pull-off tab.” Saikley ¶ 50, Fig. 7A. Fig. 7A includes the words “Twist-Off Joint” with an arrow pointing to an interface of a cylindrical portion and rounded cuboid of protective cap 78. Saikley Fig. 7A. Saikley states the protective cap 78 is removed before use and “should be made much larger than usual to aid handling.” Saikley ¶ 50, Fig. 7A. The protective cap 78 has a “hollow cup or solid ‘pin cushion’ type area 82” to “cover the sharp during removal from the device and disposal.” Saikley ¶ 50, Fig. 7A.

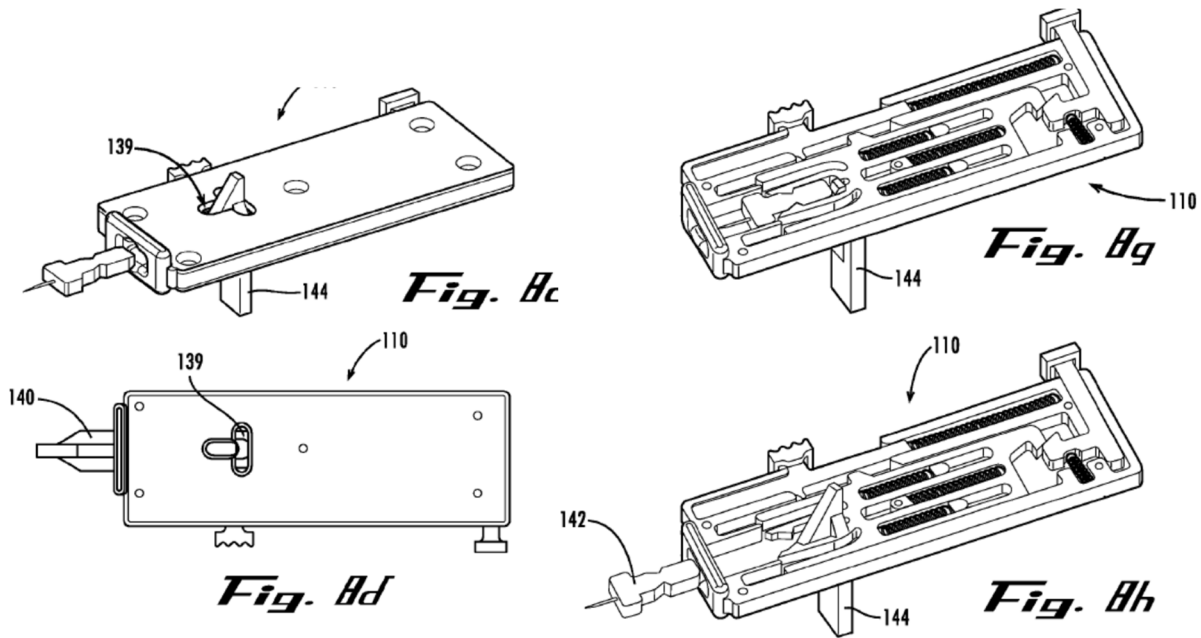
B. Stout (Ex. 1018)

51. U.S. Pat. App. Pub. No. 2006/0241669 (“Stout,” Ex. 1018) is directed to a lancing device for medical sampling of blood or other body fluids that has a thin profile, for easy and convenient stowage. Stout ¶¶ 2, 6. The lancing device 110 receives a lancet 140, which includes a lancet body 142, sharp lancing tip, and endcap 144. Stout Figs. 8a-h, ¶ 41. The lancet body and cap of Stout are depicted as having the same lateral cross section such that the lancet body and lancet cap both fit into the receiving end of the lancing device 110. Stout Figs. 8a-h.



Stout Figs. 8a-b, 8e-f.

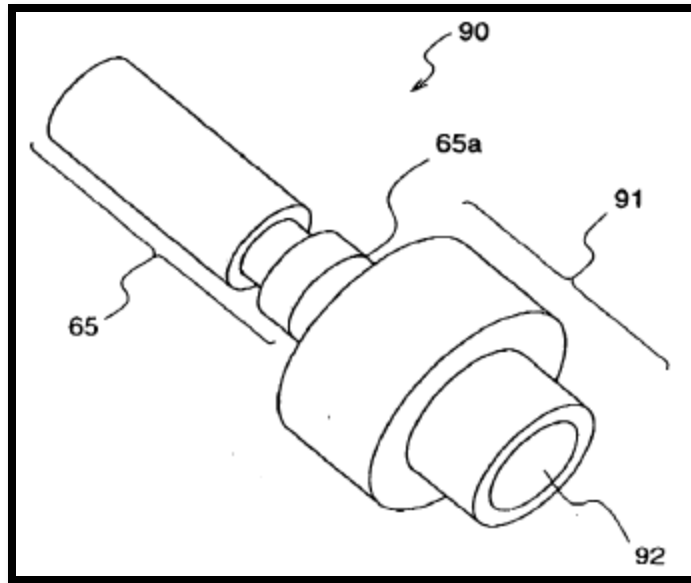
52. Stout’s cap has an “inclined or curved removal surface 145” that “acts as a wedge or cam when pushed into the lancet-removal opening 139, to release the lancet body 142,” providing leverage to open the lancet device to release the lancet after use, as shown in Figures 8c-d and 8g-h. Stout ¶ 41.



Stout Figs. 8c-d, 8g-h. Stout states that its sharp lancing tip is “securely embedded” in lancet body 42, which is molded plastic. Stout ¶ 35. The sterility cap 44 is “large or oversized” compared to lancet body 42. Stout ¶ 35.

C. Iio (Ex. 1006)

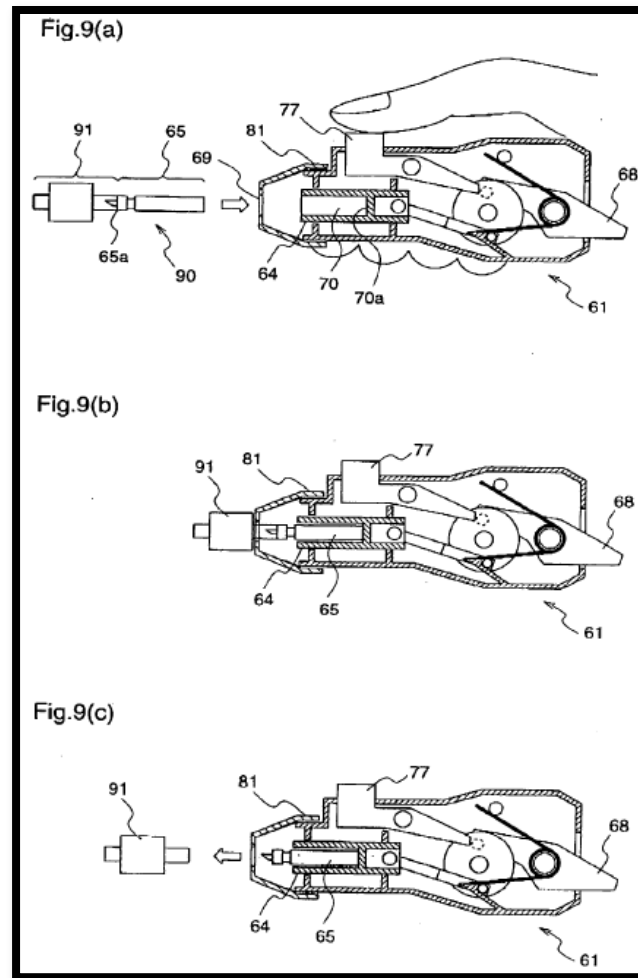
53. U.S. Pat. App. Pub. No. 2005/0131441 (“Iio,” Ex. 1006) is directed to a lancet for blood collection and a puncture needle unit. Iio ¶¶ 1, 5, Fig. 6. Iio depicts a puncture needle unit 90 that has a puncture needle body 65 and a puncture needle cap 91, with a puncture needle separation groove 65a between them. Iio ¶104, Fig. 8.



Iio Fig. 8.

54. Iio states, “The puncture needle body 65 is set in a state where it is embedded in the puncture needle cap 91, and a disposal slot 92 for pulling out the puncture needle 65 after puncture has been carried out is provided at an end of the puncture needle cap 91.” Iio ¶ 104.

55. Iio also discusses loading and discarding the puncture needle. Iio ¶¶ 106, 117, Figs. 9, 11. For loading, the puncture needle unit 90 is pushed into a puncture needle slot 69 of a lancet device 61. Iio ¶ 106, Fig. 9. Then the lancet 61 is pulled while twisting the puncture needle unit 90, which separates the puncture needle 65 and puncture needle cap 91. Iio ¶ 106, Fig. 9.

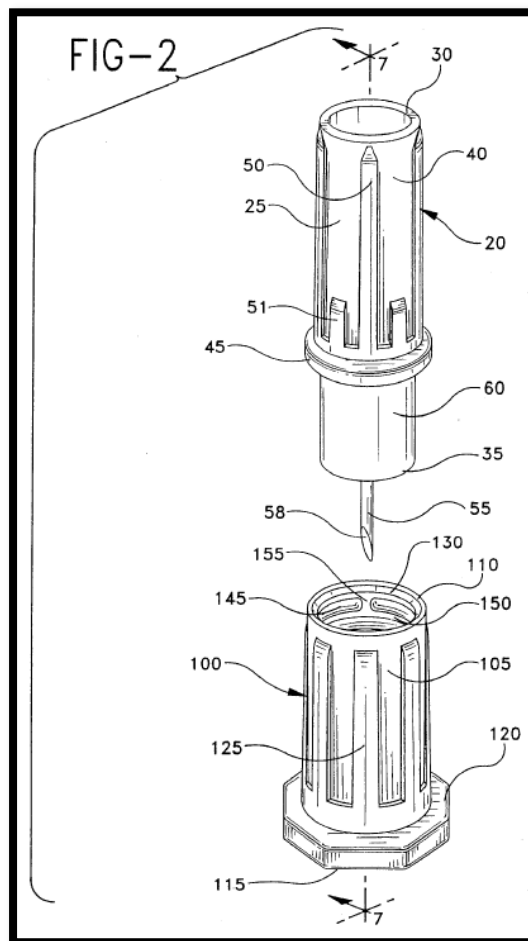


Iio Fig. 9.

56. For discarding, the disposal slot 92 of puncture needle cap 91 “is fitted” to the front end of the puncture needle 65, such that puncture needle 65 “is captured into the disposal slot 92.” Iio ¶ 117, Fig. 11. Thereafter, the puncture needle cap 91 with puncture needle 65 is pulled out of the lancet 61 and discarded. Iio ¶ 117, Fig. 11.

D. Peckham (Ex. 1008)

57. U.S. Pat. No. 5,569,286 (“Peckham,” Ex. 1008) is directed to a disposable lancet assembly for use in a blood sampling instrument. Peckham 1:65-2:4. Peckham’s lancet assembly 10 has (a) a lancet assembly 20 containing a cylindrical housing 25 and stylet 55; and (b) a removable cap or shield 100. Peckham Fig. 2, 2:52-62.



Peckham Fig. 2

58. The removable cap 100 includes a cylindrical housing 105 that has closed bottom end 115 with octagonal shaped flange 120. Peckham Fig. 2, 3:3-11.

The outside cylindrical housing 105 includes ribs 125 extending from the octagonal shaped flange 120. Peckham Fig. 2, 3:11-14.

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

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

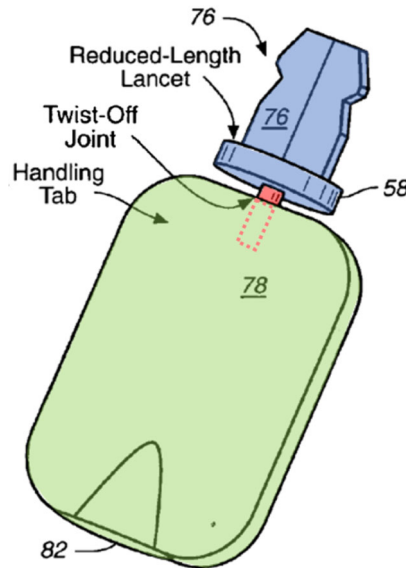
59. The challenged claims of the '635 Patent all require three distinct components: “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein,” “a secondary sheath for receiving the sharp lancing tip of a used lancet,” and “a gripping handle portion extending between the primary sheath and the secondary sheath.” '635 Patent, claims 6, 14.² The components are arranged “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.” *Id.*

60. Because these components are recited separately, and also because the claims recite that they are “attached” to each other, a POSA would understand that the claims require three distinct components, attached to each other.

61. Referring to Mr. Delman’s colored version of Saikley’s Figure 7A, Mr. Delman contends (at times) that Saikley’s “primary sheath” consists of “the

² I have been informed by counsel that claims 1-5 have been disclaimed, but claim 6 retains the elements recited in the now-disclaimed claim 1.

‘twist-off joint’ [*colored red in Fig. 7a below*] and the adjoining portion of the ‘handling tab’ [*red dashed lines*] that ‘covers the lancet sharp 50’ of the ‘shortened lancet 76’ [*blue*] prior to use.”



Ex. 1002 ¶ 55.

62. I note that Mr. Delman’s opinion is inconsistent on this point. When contending that Saikley’s tab/cap 78 extends between the primary and secondary sheaths, he states that the primary sheath is merely the twist-off joint. (Ex. 1002 ¶ 82 (“the primary sheath [i.e., twist-off joint]”)).

63. The twist-off joint cannot by itself be the claimed primary sheath even under Mr. Delman’s own reasoning. The claims recite the primary sheath is “*for initial embedment of a sharp lancing tip of an unused lancet therein.*” But as shown above and in his written testimony, Mr. Delman understands that Saikley’s sharp lancing tip is not embedded in the twist off joint, but in tab/cap 78. Specifically,

and in addition to the figure above, Mr. Delman stated that Saikley's needle/sharp is embedded in its cap 78:

A. All Claims: "Primary Sheath for Initial Embedment"

116. As I explained in Ground 1 above, Saikley anticipates this limitation by depicting and disclosing that "cap 78 may be an integrally molded, pull-off tab, such as shown in FIG. 7A" because a PHOSITA would know that "the needle tip is embedded in [a] removable protective cap integrally molded with the plastic body to form a single integral unit prior to use." *See, supra*, Section IX.A.2.

117. In my opinion, even if Saikley did not expressly or inherently disclose a needle sharp embedded in the protective cap 78, then it would have been obvious to a PHOSITA in view of Stout (Ex.1018), whose sterility cap (*colored*

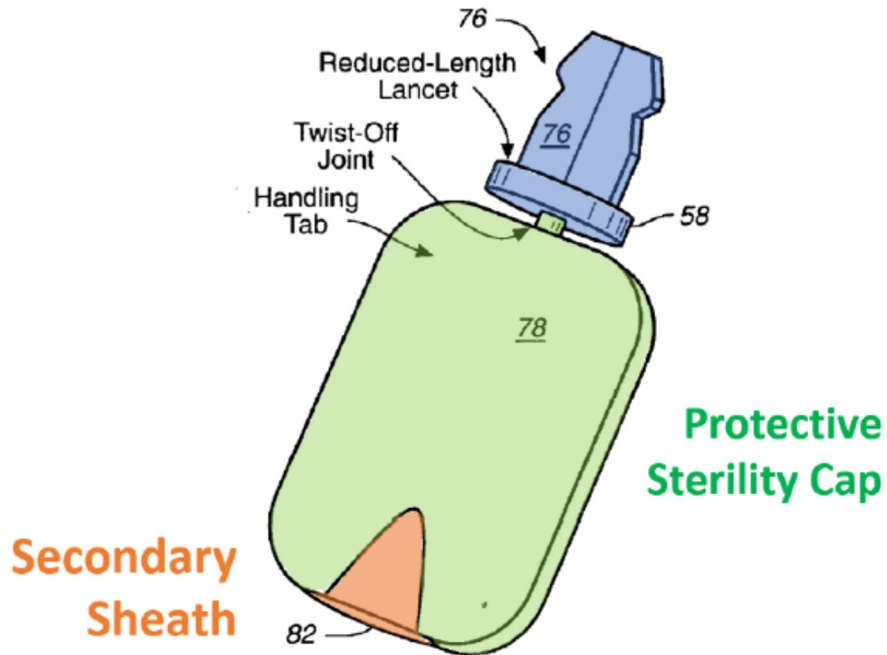
and

119. It would have also been obvious to a PHOSITA to embed the lancet needle into Saikley's cap 78 to not only protect the integrity of the needle tip, but also to protect the sterility of the needle and prevent contamination during post-manufacturing packaging, shipping, and storage. To modify Saikley's cap to

Ex. 1002 ¶¶ 116-117, 119; see also *id.* ¶118 ("I believe a PHOSITA would have appreciated that embedding the lancet needle into Saikley's cap 78 would...").

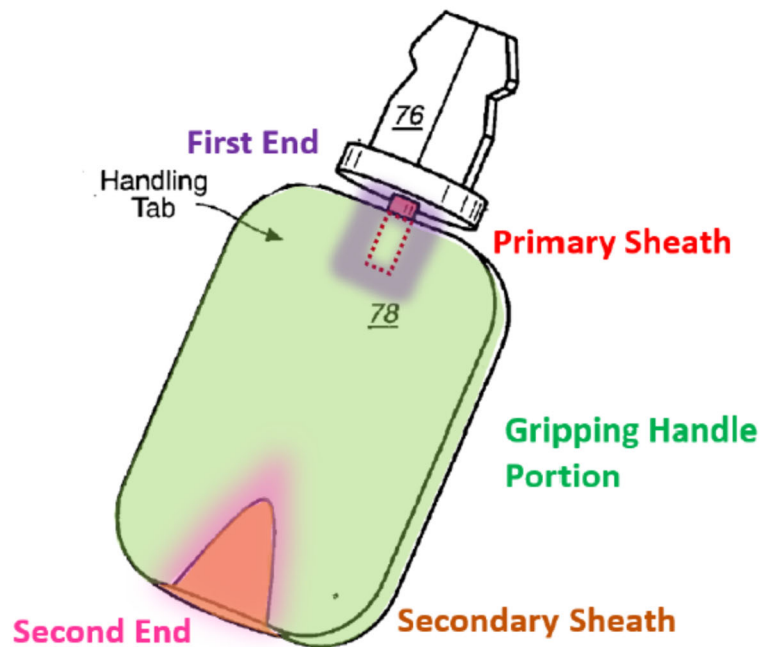
64. I agree with Mr. Delman in that Saikley's lancet needle tip is embedded in Saikley's tab/cap 78. The twist-off joint therefore cannot be the "a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein," as required by the claims, because the sharp lancing tip is embedded in the cap instead.

65. Regarding the claimed secondary sheath, Mr. Delman contends that Saikley's "secondary sheath" consists of the "hollow cup or solid 'pin cushion' type area 82 at the opposite end of cap 78, as shown in FIG. 7A [*orange below*]." Ex. 1002 ¶ 66.



Ex. 1002 ¶ 66.

66. Mr. Delman contends that the “primary sheath is attached at one end gripping handle (i.e., a first end, colored purple below) and the secondary sheath is attached at the other end of the gripping handle (i.e., a second end, colored magenta)” (Ex. 1002 ¶ 83) but what Mr. Delman identifies as the gripping handle is not “between” or “attached to” the primary and secondary sheaths as required by the claims or point to a “first end” or “second end” of the alleged gripping handle portion. Instead, the alleged gripping handle portion engulfs the sheaths entirely, surrounding the alleged secondary sheath and subsuming the same portion of the tab/cap Mr. Delman alleges is the primary sheath. As a result, the alleged primary sheath is not “attached” to the end of the gripping handle portion (but is part of it), and the gripping handle portion is not “between” the primary and secondary sheaths, as required by the claims.



Ex. 1002 ¶ 83.

67. As demonstrated by Mr. Delman's own annotated figures (including the figure above), the lancet tip of Saikley extends beyond the twist off joint and is embedded and enclosed in Saikley's tab/cap 78. Indeed, as I discussed a few paragraphs earlier, Mr. Delman stated that Saikley's sharp is embedded in the cap/tab 78. As such, under Mr. Delman's mapping, the tab/cap 78 is both the gripping handle and the primary sheath: the two are not distinct components, and the gripping handle portion is not between and attached to the two sheaths as required.

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

1. All challenged claims: Saikley does not disclose the dimensional limitations

68. Claims 6 and 14, from which all other claims depend, recites that the "gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness."

69. Saikley does not disclose this dimensional relationship. Saikley's text provides no dimensional information for shortened lancet 76 or tab/cap 78. And for the reasons I explain in the following paragraphs, a POSA would have recognized that Figure 7A could not be relied upon (and was not meant to convey)

dimensions or even relative dimensions or proportions. Accordingly, Saikley does not provide dimensional information for the claimed dimensional relationship.

70. None of Saikley's figures have a reference for scale. The written specification for Saikley lacks any information concerning whether any figure is to scale, proportion, or in any way indicative of relative dimensions.

71. Mr. Delman asserts that Saikley Figure 7A discloses the dimensional limitations because the dimensions are "visually apparent" from the figure. Ex. 1002 ¶ 124. But Figure 7A cannot be used to infer dimensions because it is not drawn to scale, and even if it was, it is not drawn in a proper isometric manner.

72. A proper isometric drawing represents a 3-D figure in such a way that lengths in some dimensions, namely those parallel to one of the three (X, Y, or Z) axes, are to scale and may be measured. A POSA would have understood that a proper isometric drawing requires that the three axes be drawn with a first axis completely vertical, vertical and two other axes one at an angle 30 degrees above the horizontal and the other at an angle 30 degrees below horizontal (or at 150 degrees from the same horizontal) on the page as shown below.

Isometric Drawing

The representation of the object in figure 2 is called an isometric drawing. This is one of a family of three-dimensional views called pictorial drawings. In an isometric drawing, the object's vertical lines are drawn vertically, and the horizontal lines in the width and depth planes are shown at 30 degrees to the horizontal. When drawn under these guidelines, the lines parallel to these three axes are at their true (scale) lengths. Lines that are not parallel to these axes will not be of their true length.

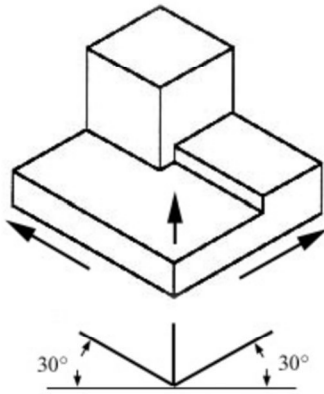


Figure 2 - An Isometric Drawing.

Any engineering drawing should show everything: a complete understanding of the object should be possible from the drawing. If the isometric drawing can show all details and all dimensions on one drawing, it is ideal. One can pack a great deal of information into an isometric drawing. However, if the object in figure 2 had a hole on the back side, it would not be visible using a single isometric drawing. In order to get a more complete view of the object, an orthographic projection may be used.

Ex. 2036. Thus, as explained in the quote from MIT Open Courseware above, “in an isometric drawing, the object’s vertical lines are drawn vertically, and the horizontal lines in the width and depth planes are shown at 30 degrees to the horizontal.” *Id.*

73. When drawn correctly, as explained above, “the lines parallel to these three axes are at their true (scale) lengths,” such that they may actually be measured and compared, despite being in three dimensions. *Id.*

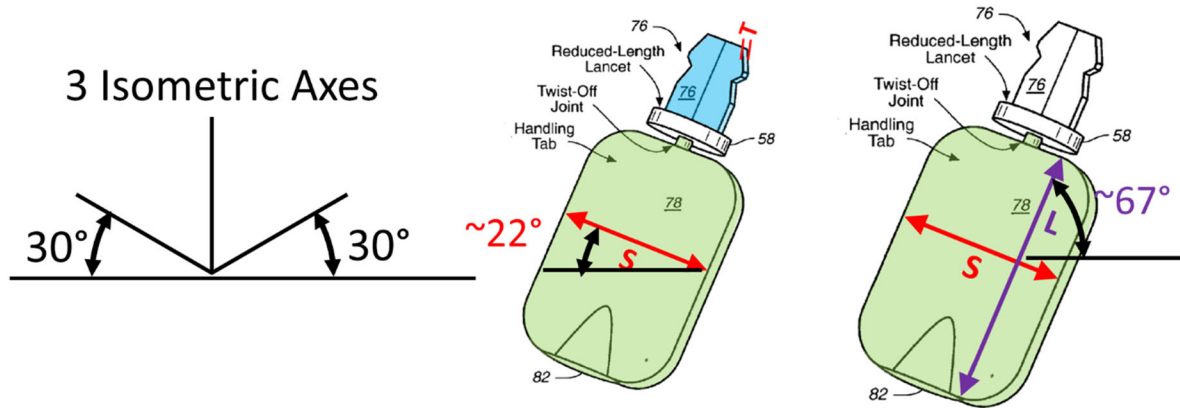
74. Importantly, “lines that are not parallel to these axes will not be of their true (scale) lengths.” *Id.* Thus, lines not parallel to one of the three axes cannot be measured. A POSA would understand that, if scale is to be conveyed, the proper

manner to do so would be with an isometric drawing with these precise axes labeled as such. A POSA would also understand that a three dimensional figure not drawn in this manner would not be measurable to scale.

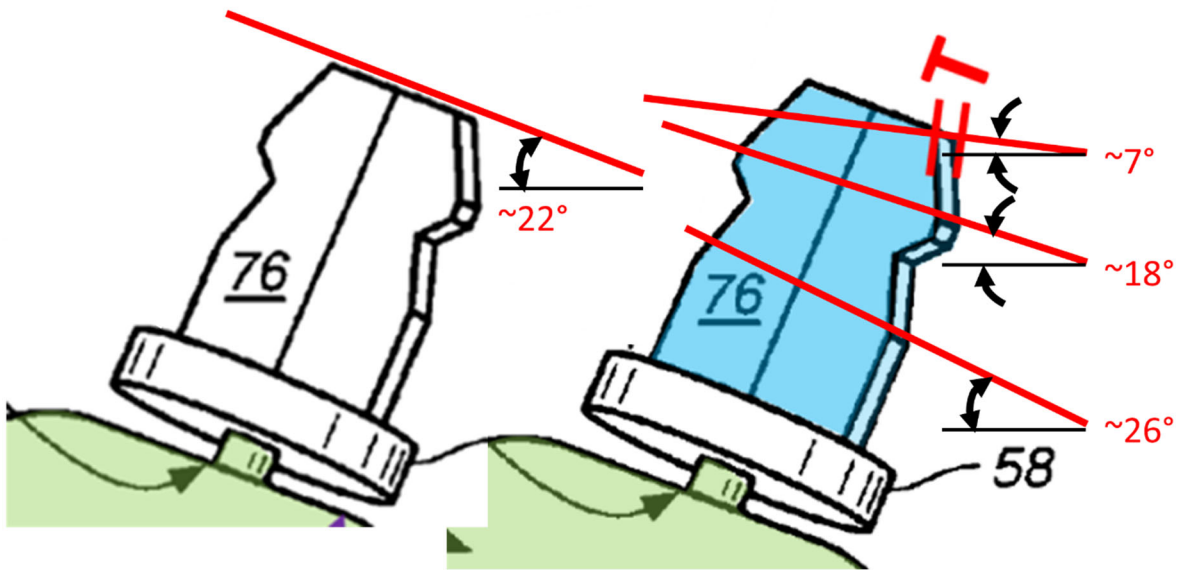
75. Saikley's Figure 7A is not marked as an isometric drawing, and I see no indication that it is. I cannot tell with any certainty what angles the lancet cap and lancet are in relative to the 2D, i.e., the relative angles between the X, Y, and Z axes as portrayed in the drawing. And as I will discuss in a few paragraphs, the drawing is inconsistent with itself in this respect.

76. Mr. Delman determined the length "L" and span "S" in his annotated drawing.³ I measured his annotated drawings, shown below with angles off of the horizontal axis added, and found that the "S" axis is approximately 22 degrees from the horizontal. The "L" axis is approximately 67 degrees from the horizontal. These are not at 30 degrees from the horizontal, or even 120 degrees from each other. Therefore, Figure 7A is not a proper isometric drawing, and lines in the S and L directions cannot be measured to determine their length (in the 3-D object) or directly compared to each other.

³ Mr. Delman's annotated Figure 7A appears to be a faithful reproduction of Saikley's Figure 7A, but with added coloring and annotations.



77. The third axis, i.e., thickness “T”, is not even at any consistent angle. Measuring the angle perpendicular to the two lines Mr. Delman used to indicate the thickness dimension shows that it is ~ 7 degrees from the horizontal. However, the lines Mr. Delman added covered the end of the lancet, which shows that the thickness dimension extends parallel to the line representing the top of the lancet body at approximately 22 degrees from horizontal. As further examples of inconsistency, two other thickness lines in Figure 7A are drawn at angles of approximately 18 and 26 degrees (see annotated figure below).

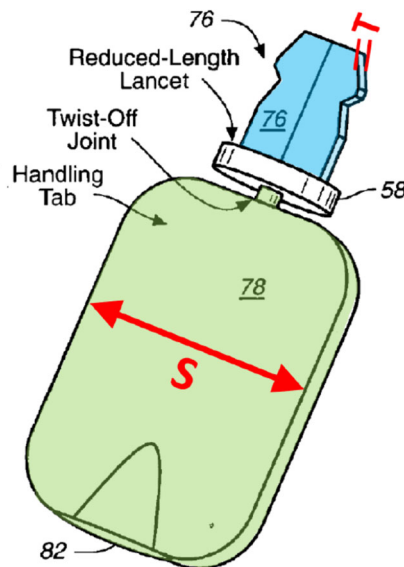


Thus, as shown above, the lancet is not drawn with any consistent thickness axis, so distances in the “T” axis direction cannot be measured in the Figure to determine their length (in the 3-D object), or directly compared to any distances parallel to the “S” or “L” axes.

78. In addition, in isometric drawings, the lines parallel to these three axes may be measured because they reflect their true (scale) lengths. But lines that are not parallel to these axes do not reflect their true (scale) length. Ex. 2036. The thickness of the lancet does not appear to be parallel to any axis, and worse, is inconsistently represented in the figure. As a result, the lancet thickness is not at a proper isometric angle. For all of these reasons, a POSA would have correctly understood that no reliable “thickness” measurements could be made in Figure 7A. Further, there is no indication in Saikley that any line lengths are to scale. Absent

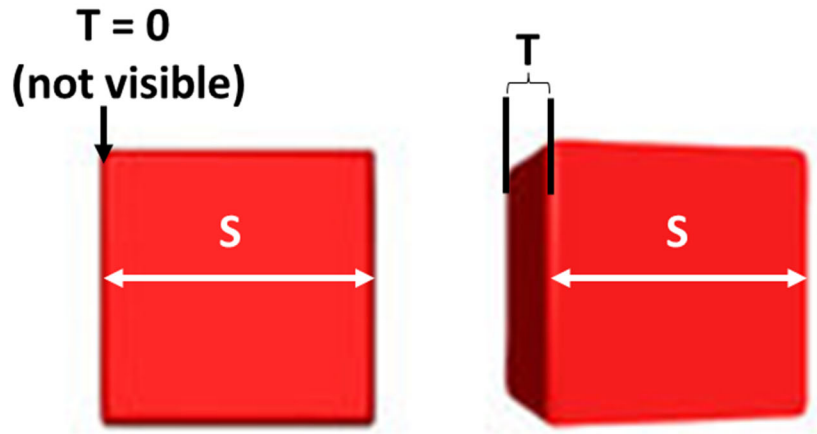
such indication, no conclusions regarding line length should be drawn even if the relative angles are known.

79. Mr. Delman states that he “believe[s] Saikley’s Figure 7A embodiment clearly depicts a handling tab (green) with a lateral span (annotated “S” with arrows) that is far more than 1.5 times the lancet thickness (yellow) of the lancet body (light blue),” (Ex. 1002 ¶ 102) referring to the figure below.



Again, as explained above, the drawing is not isometric, so no scaling is appropriate. Moreover, a POSA cannot compare S to T directly and reasonably conclude, as did Mr. Delman, that S is indeed much larger (or even 1.5 times larger) than S. The length of S and T as drawn on as a 2D image page is a function how far (at what angle) the lancet and cap are rotated about a longitudinal axis. For example, if one views a perfect cube straight-on, one will see only a square with an apparent thickness of zero, as shown below on left. If the cube is rotated slightly,

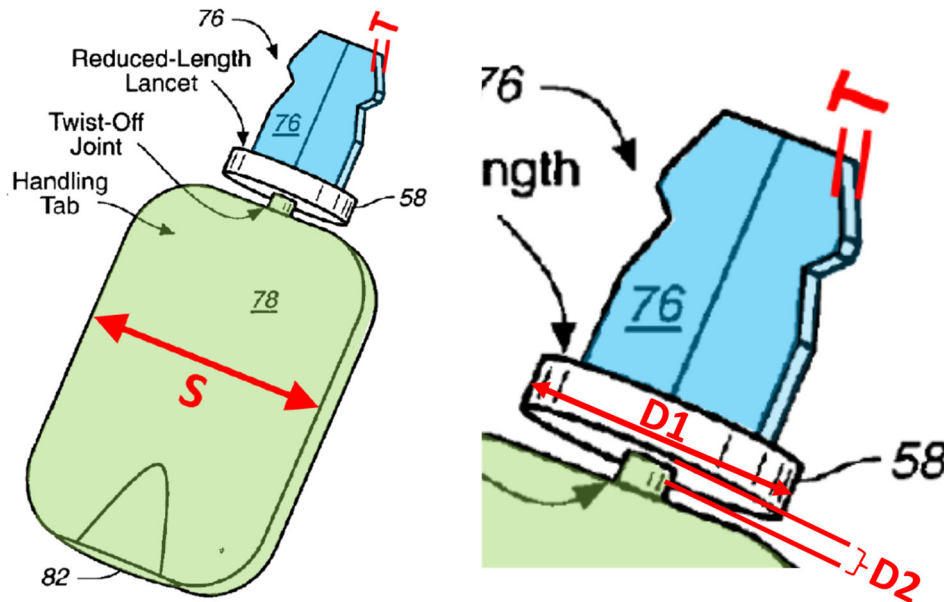
one will now also see the side of the cube, and the lateral span S would appear in a 2-D rendering as being much larger than the thickness, T , as shown below on the right:⁴



But we know S and T are actually equal to each other because the shape is a cube. They only appear to have very different lengths (in other words, they are drawn on the page as having different lengths) because the cube has been rotated some small amount.

80. This same effect is apparent in Figure 7A itself. For example, “cylindrical collar 58” (e.g., Saikley [0042]) has a circular base. Yet in Figure 7A, it is drawn on the paper as a narrow ellipse (or ellipse-like) shape: As drawn, $D1$ (in the lateral span direction) is much larger than $D2$ (in the thickness direction):

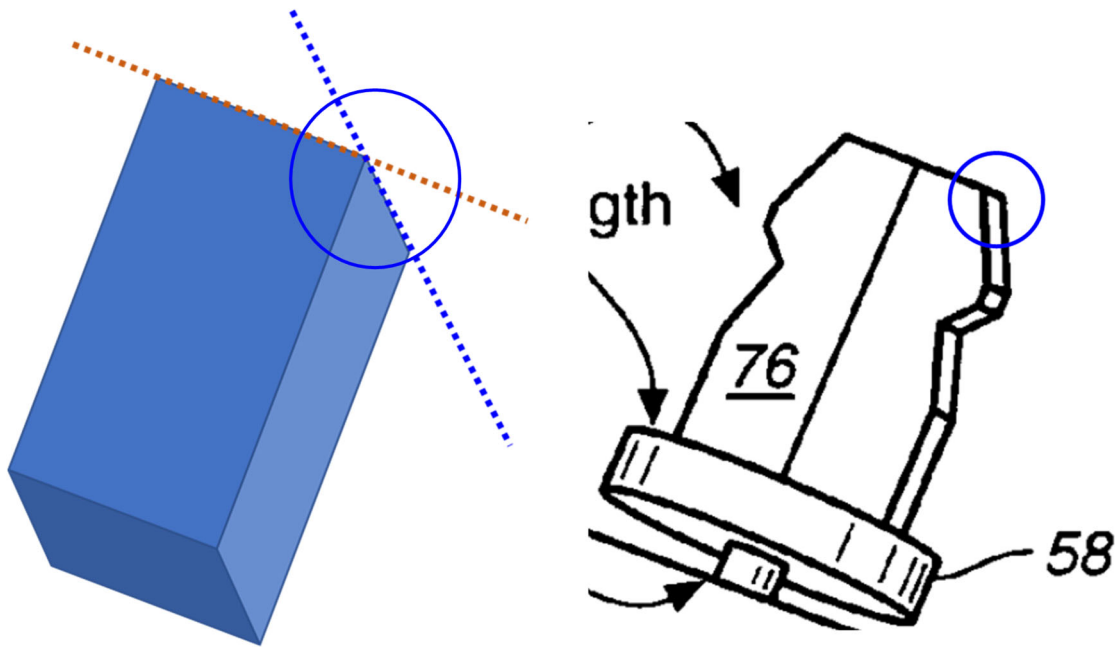
⁴ The demonstrative of the red cubes above is a perspective drawing. As discussed in paragraphs 82-84 below Saikley Figure 7A is not a perspective drawing. The demonstrative of the red cubes is to provide an example of varying S and T dimensions based on the depiction in the drawing.



But we know that $D1=D2$. It would not be reasonable to conclude that $D1$ is much larger than $D2$, or even 1.5 times $D2$. For the same reason, a POSA would not reasonably conclude that S is 1.5 times longer than T based on Figure 7A.

81. I also note yet another reason, related to my discussion above, that Figure 7A is inconsistently drawn and cannot be used to determine sizes or even relative sizes. The bottom of cylindrical collar 58 is visible in Figure 7A, as shown above, indicating that the lancet is rotated some amount about a lateral axis, putting the top of the lancet further away from the viewer than the bottom. But when an object is rotated in that manner, dimensions in the thickness direction should be similarly rotated. In other words, the blue rectangular cube below on the left is rotated about a lateral axis, revealing its bottom surface to the viewer. As a result,

the lines showing its thickness are rotated, too, so that they are not parallel with the top, front edge of the cube:



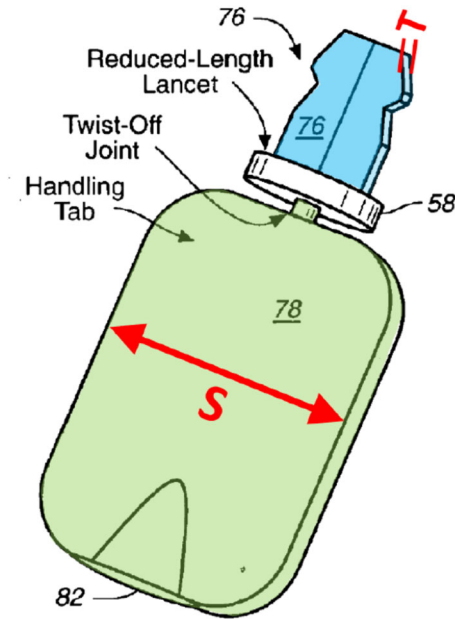
But as shown above, the thickness lines in Figure 7A's lancet body were not similarly rotated (or even consistent, and I discussed above). In addition to the other reasons I already discussed, this is another reason a POSA would have understood that Figure 7A is unreliable and cannot be used to determine dimensions, relative sizes, or proportions.

82. As I explained above, Figure 7A is not an isometric drawing. I understand from counsel that Mr. Delman testified during his deposition that Figure 7A might be drawn in perspective. Ex. 2028 at 13-14. If Figure 7A was drawn with perspective as Mr. Delman suggests, then a POSA seeking to compare

the lengths of various lines (e.g., S, T, and L) would have needed to take “foreshortening” into consideration.

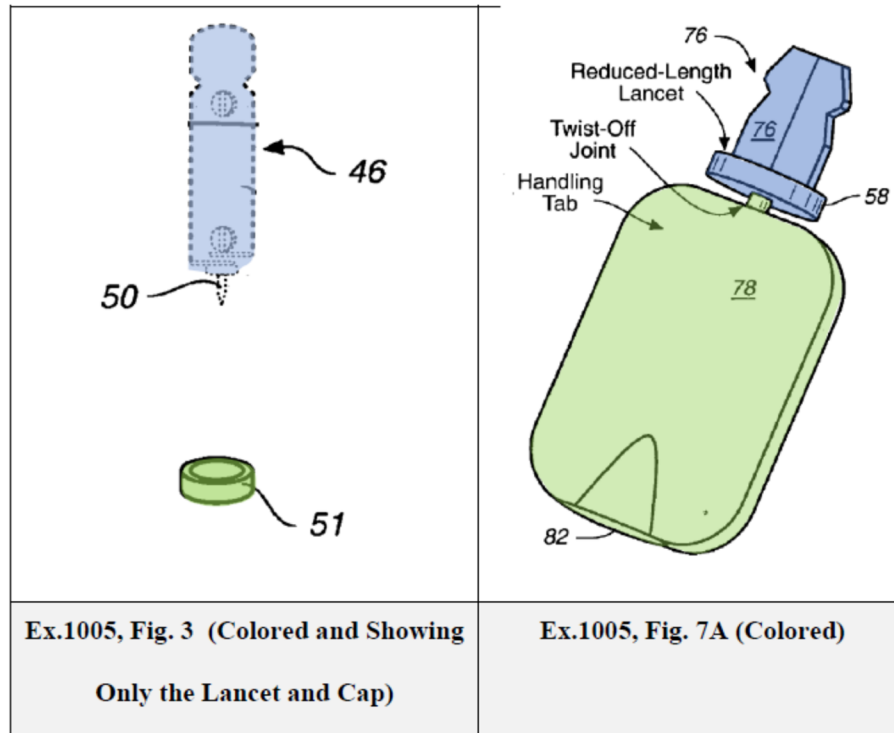
83. In a perspective drawing, foreshortening is used to convey an object’s distance. For example, if an illustrator was drawing two identical objects of the same size, but one object is farther away in the drawing, the distant object is drawn smaller on the paper and the closer object is drawn larger. Thus, perspective drawings provide the impression of depth or distance from the viewer by making dimensions appear larger or smaller depending upon the distance from the point of view. Also, different views can be from a different vantage point so the relative sizes will change without knowing how the vantage point has changed. For all of these reasons, perspective views/drawings are never used to convey dimensional information (without text labels showing the sizes).

84. In Figure 7A, the bottom of the cap and the bottom of the cylindrical lancet collar 58 are both visible. This indicates that the bottom of figure (the lancet cap) is closer to the viewer than the top of the figure (the end of the lancet body, where Mr. Delman drew “T”). Thus, assuming Figure 7A is drawn in perspective as Mr. Delman suggests, the bottom of the cap (which is closer) should be drawn relatively larger than the end of the lancet (which is farther away). But Mr. Delman did not take this foreshortening effect into account in his declaration when comparing how T and S appear in the figure.



Ex. 1002 ¶ 102.

85. Saikley discloses a “Large Lancet Cap for Handling” (Saikley ¶ 49) and cap 78 “should be made much larger than usual to aid handling” (Saikley ¶ 50). But these statements do not provide either absolute or relative dimensional information, including for “a lateral span” or “a length” of “a gripping handle portion” or “a lancet thickness” of “a lancet body.” For example, cap 78 may be larger in the thickness dimension. There is no basis to conclude, for example, that a “much larger than usual cap” has a lateral span that is 1.5 times the lancet’s thickness. For example, Mr. Delman provided the following demonstrative comparing Saikley’s “Traditional Disposable Lancet[]” to “Saikley’s Improved Lancet.”



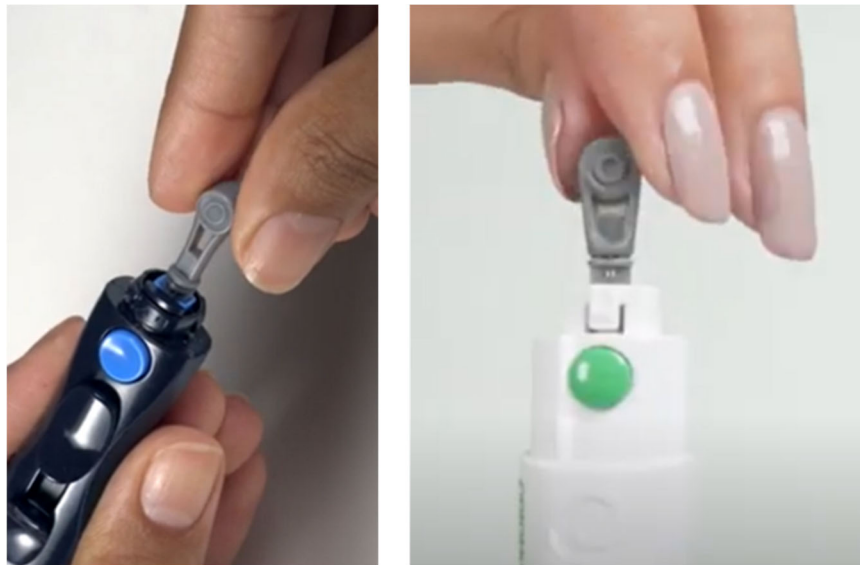
Ex. 1002 at ¶ 76 (page 56). In Saikley’s Figure 3, the cap appears quite small compared to the lancet.⁵ There is no reason to conclude that a cap “much larger” than cap 51 would have a lateral span of 1.5 times the lancet’s thickness.

86. Mr. Delman states that “a PHOSITA would have understood Saikley’s instruction to make its cap 78 “much larger than usual to aid handling” (Saikley ¶ 50) as indicating that the lateral span for its cap 78 would have needed to be larger than the 16 mm width of an average human thumb to ensure that the handling goal was achieved.” Ex. 1002 ¶ 104. But the reference Mr. Delman points to for the average width of a human thumb (Ex. 1022) is a study of children’s

⁵ In my personal experience, this was also the case for typical lancets at the time having similar configurations.

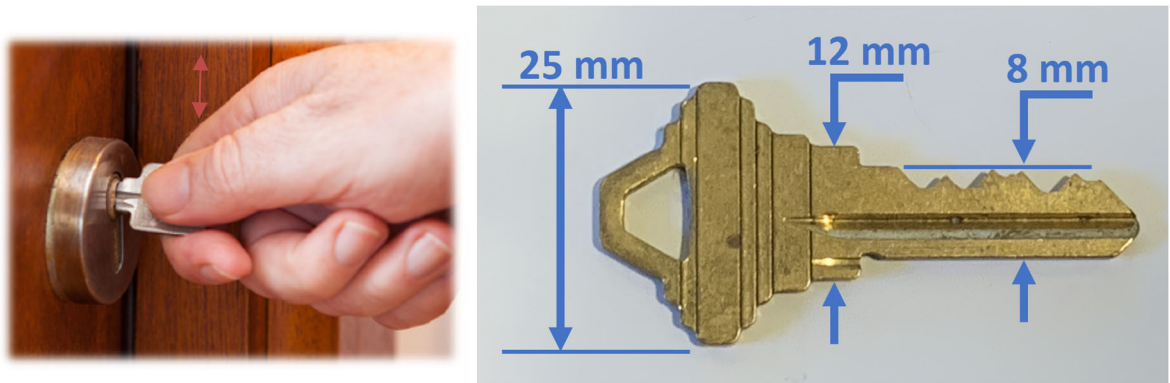
thumbs. Ex. 1022. But the average adult human thumb is about 25 mm wide. Ex. 2029 at 6.

87. I am not aware of a lancet cap that approaches a 25mm width or span (or even a 16mm-wide cap). As I will discuss with respect to “nexus” (in the Objective Evidence section below), I measured the lateral spans of the Delica and Delica Plus products, which are both much larger than the usual prior-art caps, and they were much less than 25mm. The spans of the caps are 5.7 to 6.9 mm – far from 16 mm or 25 mm. That this these caps are nowhere near the size of a human thumb (or even a finger) is illustrated in the following photographs:



88. Mr. Delman states that “Saikley’s ‘much larger’ ‘handling tab’ functions like the head of a key that is left protruding after the blade is inserted into a lock so that a user can provide torque when turning the key.” Ex. 1002 ¶ 79. A POSA would not have understood Saikley’s cap 78 to be larger than a thumb, like

some keys. I took measurements of my own key, which is similar to the key from Mr. Delman's photo below, and found the portion that goes inside the keyway slot to be 8 mm wide, while the shoulder portion of the key (pictured below as just outside the lock) to be more than 12 mm wide and the widest portion being more than 25 mm wide. In other words, the shoulder of the key visible just outside of the lock in Mr. Delman's photograph is, at 12 mm wide, is at least *double* the width of Mr. Delman's standard lancet (which Mr. Delman's states is less than 6 mm wide—see Ex. 1002 at ¶ 104). Even the thin portion of the key that enters the lock is wider than Mr. Delman's standard “less than 6mm” wide lancet.



89. It is also incorrect that removing the cap from a typical commercial lancet requires a significant torque compared to, say for example, a house key. Based on my own personal experience with both, the torque needed to twist off a lancet is far less than turning the above key in my own front door. A POSA would have had similar experiences, and would have known that the amount of torque required to remove lancet caps is very small.

90. My personal experience that cap removal requires very little torque is confirmed by two references that reported the measured torque to remove a lancet cap. First, the Facet 28G Universal Lancet “Cap Twist-off torque” is less than 4.9 Newton-centimeters (N-cm). Ex. 2034. Second, the 1996 patent JP3621502B2 states that: “When the torque required for twisting the torsion cover was measured with a torque meter, the average value for the five assemblies was 480 g-cm [4.7 N-cm].” Ex. 2054 at [0054].

91. Similar to Saikley’s twist-off joint, Stout acknowledges that caps and lancets are connected by a “narrow or notched neck portion for ease of separation.” Stout [0035]. Neither Saikley nor Stout suggest that decapping requires any significant amount of torque. And like Saikley, Stout’s cap is not wider than its lancet. And as I discuss below, Stout’s cap is larger than normal to give the user leverage to twist or otherwise force/pry open the lancet device’s “forks” to release the lancet after use.

92. Indeed, in determining the torque required to remove a cap, a POSA needs to balance making it small enough to make it easy to de-cap and minimize the chances of bending, with making it large enough that a cap would not come off inadvertently, for example during shipping or installation into the lancing device. A POSA would understand that the whole purpose of a cap is to prevent the needle tip from being exposed when not being used. A POSA would understand that the

need is not to minimize the torque required, but to balance the ease of de-capping with the concern of inadvertent opening, both during shipping and use. This balancing could be achieved in a number of ways: for example, if a POSA found Saikley's twist-off cap to be too difficult to open, the POSA could have made the twist-off joint smaller or the connecting material thinner (and thereby reducing materials/costs rather than adding to it).

93. I also note that general design principles favor reducing cap size, not making them larger, thereby reducing raw materials and manufacturing expense. A POSA would have understood at the time of the invention that smaller designs were favored from a cost and manufacturing standpoint, whereas larger designs would not only present more cost, but provide greater risk of torsion or breakage, both in transit and in use. Smaller designs also provided the advantage of being more compact and transportable. Together, these factors led to standard lancet designs at the time of the invention to be small, compact, and short.

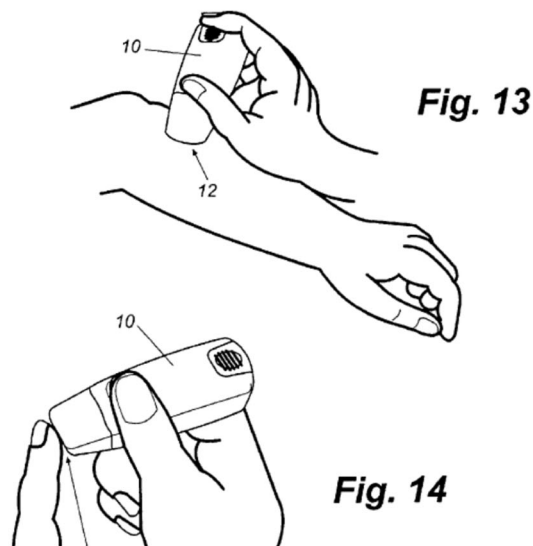
94. Moreover, the amount of materials used (and thereby cost) would have been an important consideration to a POSA here because the lancets are single-use, meaning even a small increase in size would have a more significant effect on the amount of materials and cost over multiple lancets.

95. While a POSA would have understood the various advantages and disadvantages of particular lancet size decisions, a POSA would have also

understood that, from a practical standpoint, there are limitless potential dimensions and dimensional relationships to pick from. For example, looking only at minimizing material costs, a POSA could design a small square cap, a small round cap, a short and long cap, or even a tall and skinny cap, all of varying lengths, all just focused on limiting cost. When other factors are also considered, including usability and maneuverability features, the number of design possibilities and dimensional possibilities only increase.

96. With respect to a lancing device, a POSA would have taken into account different considerations. A POSA determining the size of the lancing device would have predicated that decision primarily on the desired functionality of the lancing device, meaning that the size would need to apply the required pressure at the required angle at the sampling location on the person's body.

97. For example, Mr. Delman points to the size of LeVaughn's lancing device as having some bearing on lancet cap size. Ex. 1002 ¶ 104. That is incorrect. A POSA reading LeVaughn would have understood that its lancing device, like a real lancing device, has a width that is the same or slightly larger width than a typical thumb, at 25-35 mm wide.



Ex. 1017 Figs. 13-14, 5:43-52 (25-35 mm lancing device width); Ex. 2029 at 6 (human thumb is about 25 mm wide). Mr. Delman provides no viable reason to conclude that Saikley's cap has the same or nearly the same width (or width to length ratio) as a typical lancing device. Lancing devices are sized to be held by a much larger portion of the hand and to provide sufficient leverage to take a sample, while the cap removal requirements are de minimis compared to the forces to be applied via the device when taking a sample.

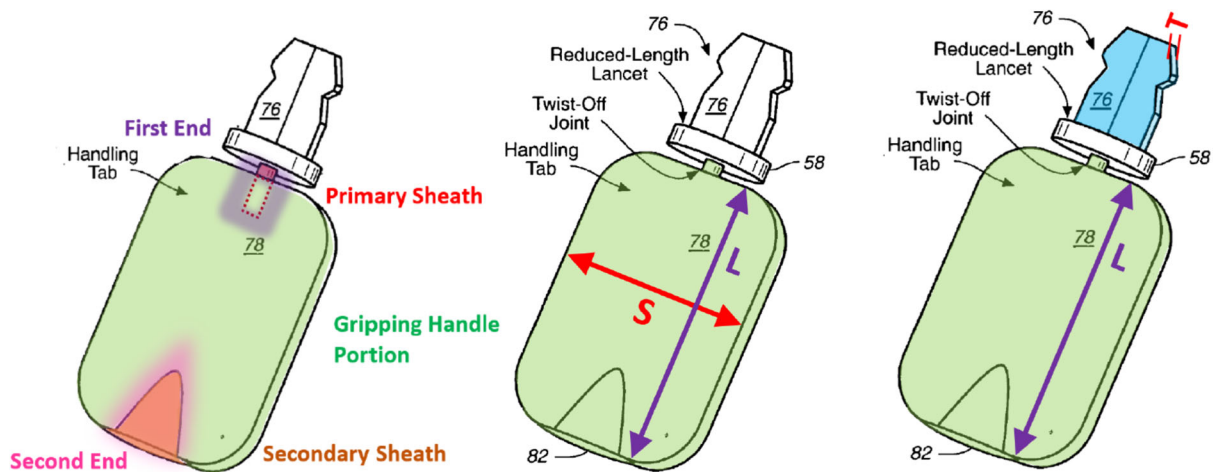
2. Claims 7, 8, 17, and 18: Saikley does not disclose the claimed dimensions

98. These claims depend from claims 6 and 14. Claims 7 and 17 further recite that "the gripping handle portion defines a length at least equal to its lateral span." Claims 8 and 18 further recite that "the gripping handle portion defines a length at least equal to the lancet thickness."

99. In addition, these claims depend from claims 6 and 14, which require the “gripping handle portion [to]extend[] between the primary sheath and the secondary sheath.”⁶

100. My discussion above applies to these claims, too, in that Saikley’s text and figures do not disclose these claimed dimensional relationships for the same reasons as above.

101. In addition, Mr. Delman failed to identify a gripping handle length that “extend[]s between the primary sheath and secondary sheath” as required by these claims, as shown below using Mr. Delman’s annotated copies of Saikley’s Figure 7A:



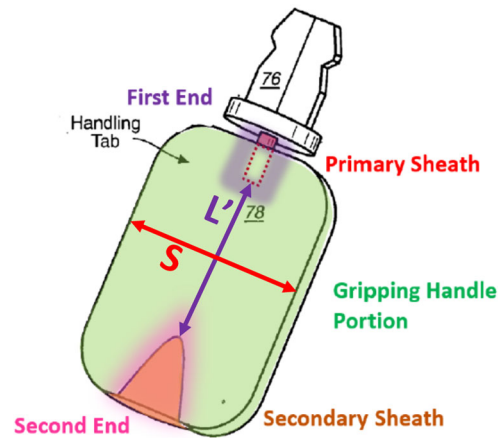
⁶ Claim 6 recites this feature via its reference to now-disclaimed claim 1.

Ex. 1002 ¶¶ 83, 107, 110. As shown above, Mr. Delman identifies a length “L” that is not between the sheaths as recited in the claims, but includes the entire length of the entire cap 78.

102. I also note that Saikley does not disclose where any alleged primary sheath would end, i.e., how far its lancet needle penetrates in to cap 78. Mr. Delman does not explain why he extended his red dotted line (outlining his alleged primary sheath) as far as he did into Saikley, rather than extending it farther or not as far as he did. I see nothing in Saikley that justifies the size of Mr. Delman’s alleged primary sheath shown above.

103. Putting aside all of the reasons I have discussed showing why one could not merely measure distances in Saikley’s figure to make any conclusions about the portrayed lancet and cap’s dimensions, relative dimensions, or proportions, and the inability to accurately identify where the primary sheath ends, Saikley still does not disclose the gripping handle portion length at least equal to its lateral span as recited in claims 7 and 17.

104. As shown below, I measured the distance L’ between Mr. Delman’s alleged sheaths, and it is *shorter* than his alleged lateral span:



For this additional reason, Saikley does not disclose or render obvious claims 7 and 17, which expressly require L' to be longer than S .

3. Saikley alone does not render obvious the claimed dimensions

105. It would not have been obvious to make Saikley's cap as large as Mr. Delman contends (e.g., the size of a thumb) for the reasons I already discussed above—namely, Saikley would not have reasonably taught or suggested such a large cap to a POSA (and although it says its cap should be “much larger” than usual, it does not say by how much and in what dimensions), a POSA would have concluded that the enormous cap proposed by Mr. Delman was unprecedented in the art, there was no need to give the user than much leverage to remove the cap, using that much extra material would drive costs upwards for no reason, and inadvertent removal of the cap (e.g., during shipping or handling) would be more likely.

106. I understand from counsel that LifeScan argues that the claimed dimensional relationships are meaningless. I disagree. The '635 patent explains

their importance, namely making the lancet easier to see and handle, allows the use of smaller lancets, and reduces inadvertent needle sticks. '635 patent 6:53-7:3. Mr. Delman agrees that the claimed dimensions have meaning and bring advantages. E.g., Ex. 1002 ¶ 103 (explaining that the claimed gripping handle lateral span 1.5 times larger than the lancet thickness would aid handling), ¶¶ 123-124.

107. Mr. Delman also contends that there are a “finite number of potential dimensional solutions [of] the gripping handle portion as compared to thickness of the lancet” available.” Ex. 1002 ¶ 123. That is simply not true. There is an *infinite* number of potential ratios between lateral span of the gripping handle and the lancet thickness, as well as the other claimed dimensional relationships. There is an infinite number of numbers and therefore ratios between two numbers.

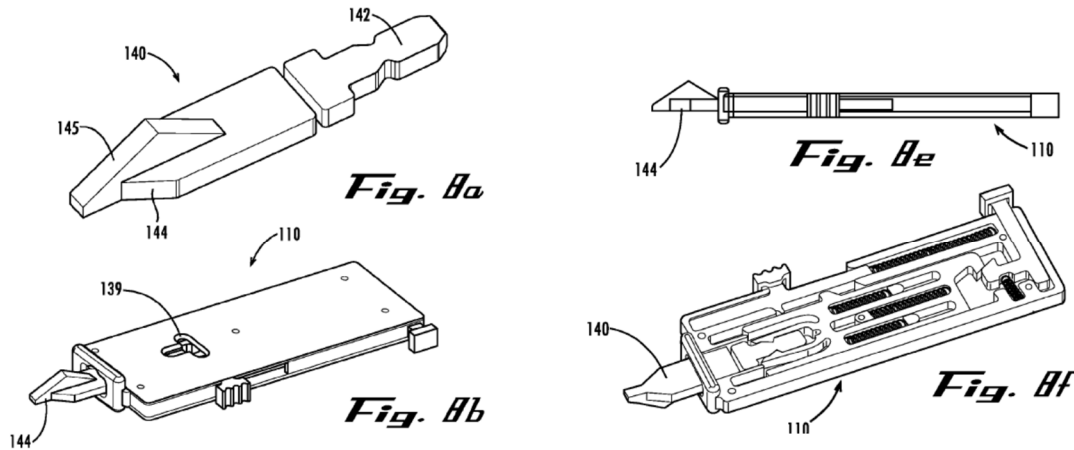
4. Saikley in view of Stout does not render obvious the claimed dimensions

108. I will first discuss motivation to combine, and then I will discuss the deficiencies in Stout’s teachings.

109. I first note that Mr. Delman did not provide a *motivation to combine* Saikley and Stout to arrive at the claimed dimensions. Mr. Delman contends that a POSA would make Saikley’s cap wider than the lancet to achieve the claimed dimensions (E.g., Ex. 1002 at ¶ 104).

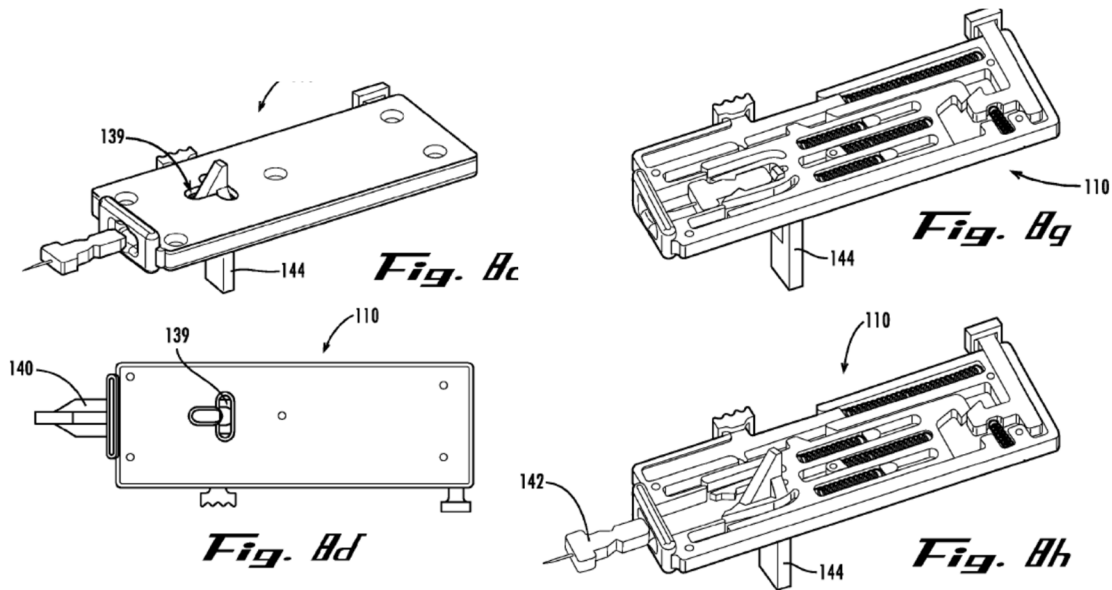
110. But Stout’s cap is *not* wider than its lancet: the cap is inserted with the lancet into the lancing device. As a result, Stout’s cap has the same cross-

section as the widest portion of the lancet, as shown in the Figures reproduced below.



Stout Figs. 8a, b, e, f. As an aside, I note that only the tip of Stout’s cap is accessible to the user when the cap and lancet are inserted. This will be important later in my discussion.

111. Further, Stout’s cap—even though it is just as wide as its lancet—provides more than sufficient leverage to remove the cap. Indeed, Stout’s cap and lancet “are connected at a narrow or notched neck portion for ease of separation.” Stout [0035]. A POSA would have understood that Stout’s cap is not larger than normal to provide sufficient torque for removing the cap. Rather, Stout’s large cap size—which is no wider than its lancet—is to give the user sufficient leverage to twist or otherwise force/pry open the lancet device’s “forks” to release the lancet after use, as shown below:



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

112. In other words, a POSA would have understood that Stout’s cap is sized and designed to release the cap from the lancing device after use. It is not, like Saikley, aimed at making a shortened lancet easier to handle or to provide sufficient leverage to remove the cap from the lancet. For these reasons, a POSA would not have used Stout’s cap to determine an appropriate cap size for Saikley.

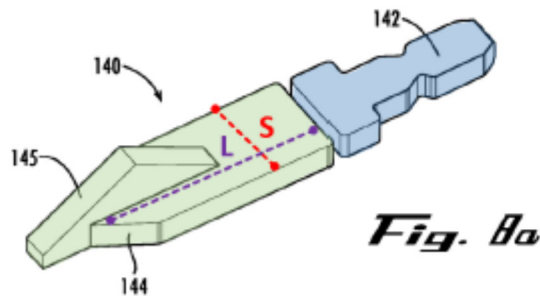
113. Further, even if the teachings were combined, **Stout does not provide the missing teachings of the dimensional limitations**. Like Saikley, Stout provides no dimensional information for the end cap 144 or lancet 140. And, again like Saikley, none of Stout’s figures have a reference for scale, nor does the written specification for Stout have indication of scale.

114. I also note that Stout does not and cannot disclose a gripping handle between and attached to the two sheaths, as required by the claims. Stout does not disclose a secondary sheath at all. And without a secondary sheath, there is no “gripping handle portion” as defined in the contested claims because the gripping handle portion must be “between” the primary and secondary sheaths. Without a “gripping handle portion” as defined in the claims, the dimensions of the gripping portion, or any other portion of the cap, cannot correlate to any dimensions of a gripping handle portion, as required.

115. In addition, Stout’s sharp lancing tip is embedded in Stout’s cap, as Mr. Delman recognizes:

118. Indeed, just like Saikely, Stout teaches that “[t]he 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,” with the “sharp lancet tip 43 ... securely embedded therein.” Ex.1018, [0035]. I believe a PHOSITA would have appreciated that embedding

Ex. 1002 ¶ 118. Mr. Delman, however, stated that the Stout’s gripping handle portion includes all of Stout’s cap:



Ex. 1002 at ¶ 129. That cannot be the case, as Stout's sharp lancing tip is embedded at least some of the distance into its cap, rendering at least that portion of the cap a primary sheath and not a gripping handle. Mr. Delman also failed to take that into consideration in his alleged measurements.

116. Further, only the leftmost tip of Stout's cap (in the figure above) can be gripped by the user when the cap is being extracted from the device because that is all that protrudes from the device, as I discussed earlier. Also as I discussed earlier, that portion of the cap is inserted into the lancing device to release the lancet after use.

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

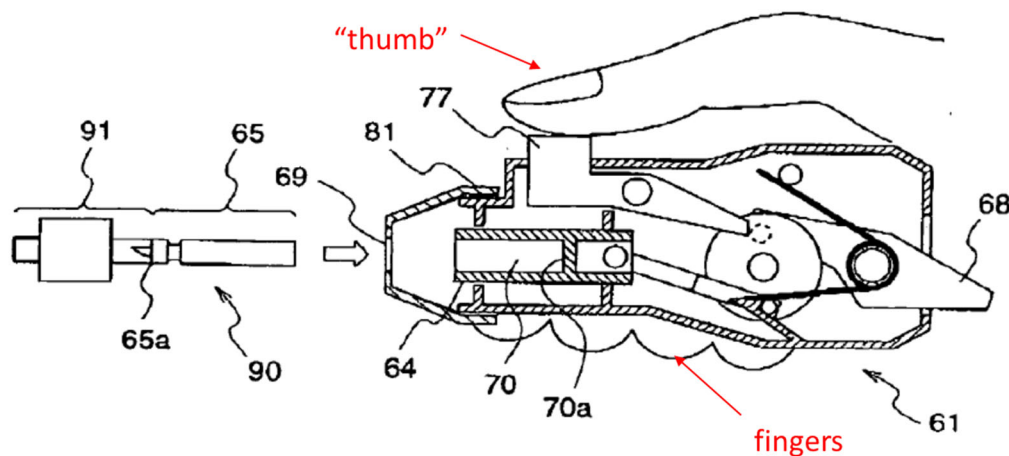
A. Iio, Alone or In Combination, Does Not Disclose or Render Obvious the Dimensional Limitations

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

117. Iio does not disclose the claimed dimensional limitations for essentially the same reasons I discussed with Saikley: Iio's figures are not to scale

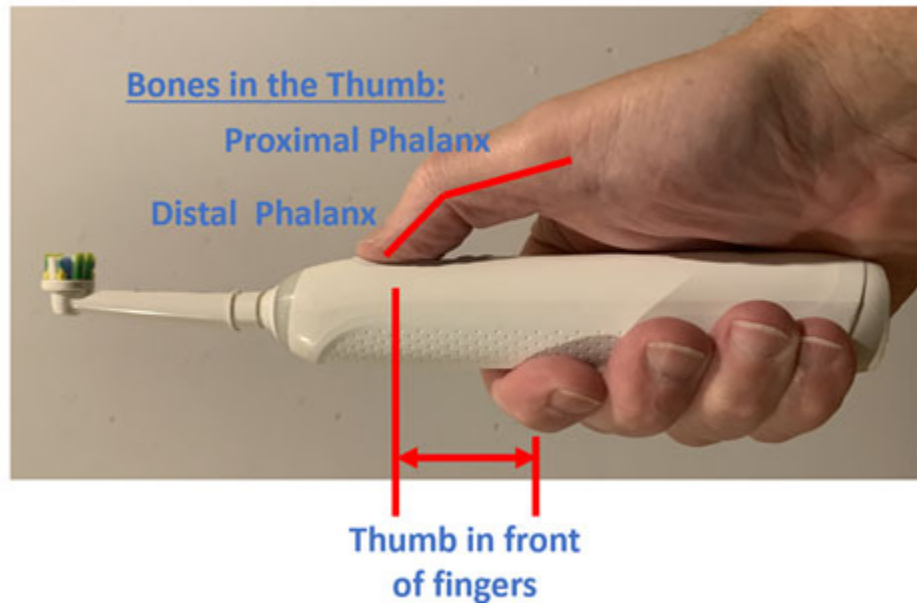
and Iio does not state otherwise. Looking at the figures in Iio, they are unreliable and inconsistent, with inconsistent proportions throughout, and cannot reasonably be relied on to determine dimensions, relative sizes, or proportions. Mr. Delman's efforts to do so are unreasonable.

118. For example, Mr. Delman relies on a representation of thumb in one of Iio's diagrams (Fig. 9a) to draw conclusions regarding the relative sizes of other objects, including the lancet cap:

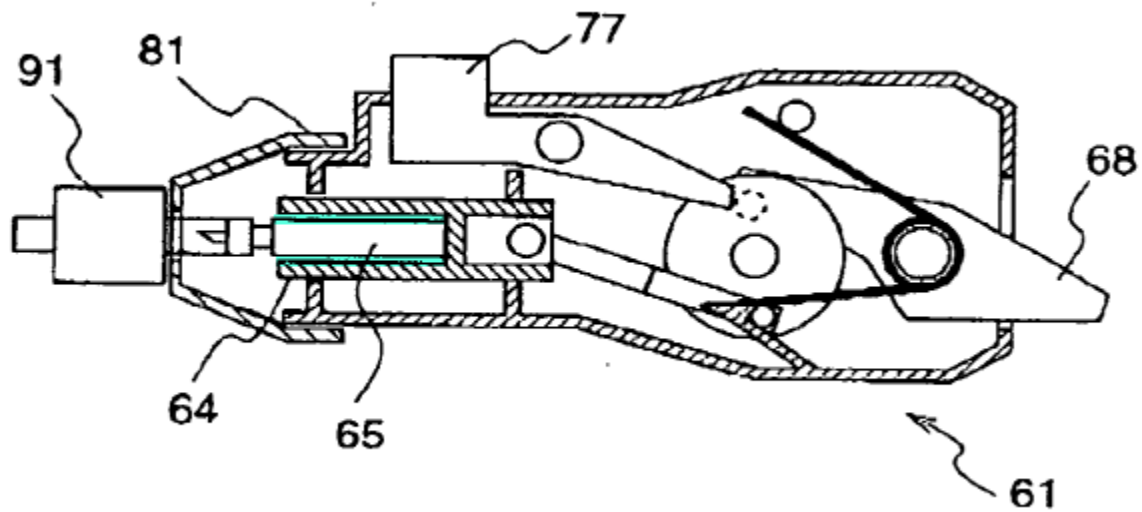


Iio at Fig. 9(a) (annotated); Ex. 1002 ¶ 190. However, the depiction of the hand in Iio Fig. 9(a) does not represent a normal human hand. A normal human thumb does not have the overly long proportions and misplaced and misaligned knuckles shown in Iio Fig. 9(a), as a POSA or even a layman looking at their own thumb would recognize. *See also* Ex. 2043 at 1. Also, the thumb and forefingers of a normal human hand cannot be placed in the illustrated positions: an extended thumb would be far forward of the fingers, not behind. An example of this is shown

below in an annotated picture showing a normal human hand holding a handheld device, i.e., an electronic toothbrush.



119. The rest of Iio Fig. 9(a) is out of proportion as well. For example, the base of the lancet does not fit snugly into the device channel as there is space (highlighted blue below) between the base of the lancet and cross-hatched portion of the device channel as seen Iio Fig. 9(b).

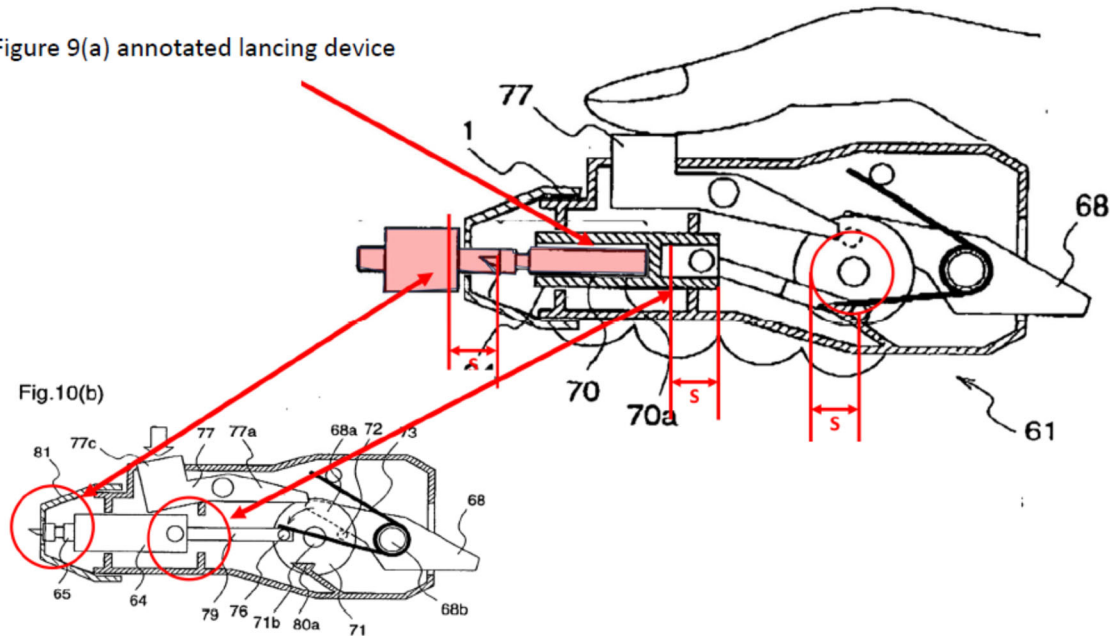


Iio at Fig. 9(b) (annotated).

120. In addition, the lancet is not drawn properly as a side view or a section view. For example, the lancet needle is shown, but there is no cross-hatching indicating that the view is a section view. Also, there is no reason to believe that the thicknesses shown in the cross-hatched section are correct.

121. As another example that Iio's figures are unreliable and inconsistent such that they cannot be relied on to determine dimensions, relative sizes, or proportions, the mechanism in Iio Fig. 9 is sized to extend the lancet farther than what is described in Iio Fig 10. In Iio Fig. 9, the lancet would extend a "S" distance, which is how far the "lug" on the wheel would rotate.

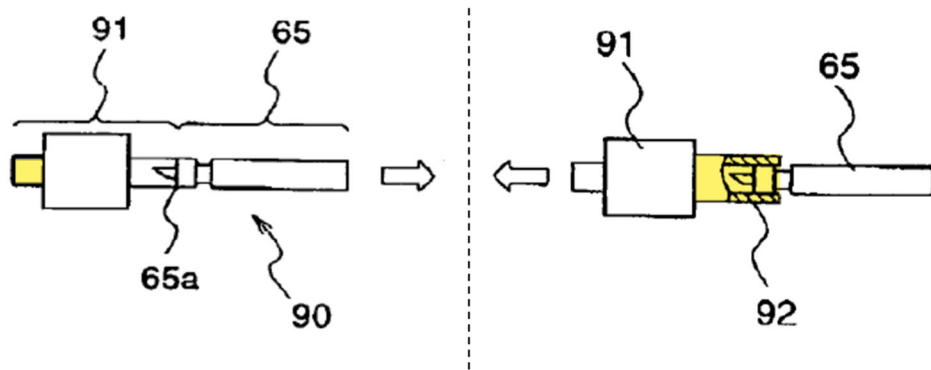
Figure 9(a) annotated lancing device



Iio at Fig. 9(b) (annotated). However, in Iio's figures shown in Figures 10(a) and 10(b), the body of the lancet, when in use, does not go past the inner surface of the housing. Only the needle tip itself extends beyond the housing of the lancing device as shown above in Figure 10(b). But, when looking at Figure 9(a) and distance the lancet would travel based on the wheel rotation, the lancet body itself would extend past the outer surface of the lancing device, as shown above. Moreover, if the lancet body traveled the distance S, the lancet carrier would also extend to far and would fall out of the guides in the lancing device.

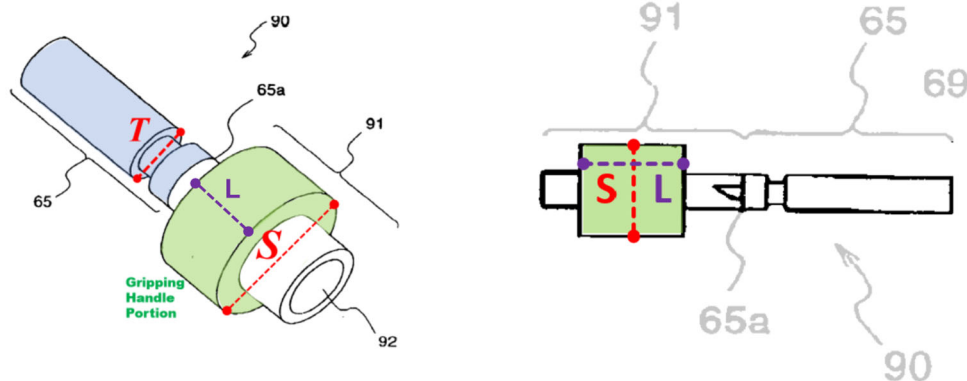
122. Further, the lancet 65 and cap 91 are represented by a line drawing and have no discernable thickness or width, as compared to a cross-sectional drawing with hatching shown elsewhere in Iio's figures.

123. Additional examples show Iio's figures are not drawn to scale, and they are unreliable and inconsistent such that they cannot be relied on to determine dimensions, relative sizes, or proportions. For example, what Mr. Delman identifies as the secondary sheath (shaded yellow below) is drawn with substantially different length and diameters in Iio Fig. 9(a) versus Iio Fig. 11(c):



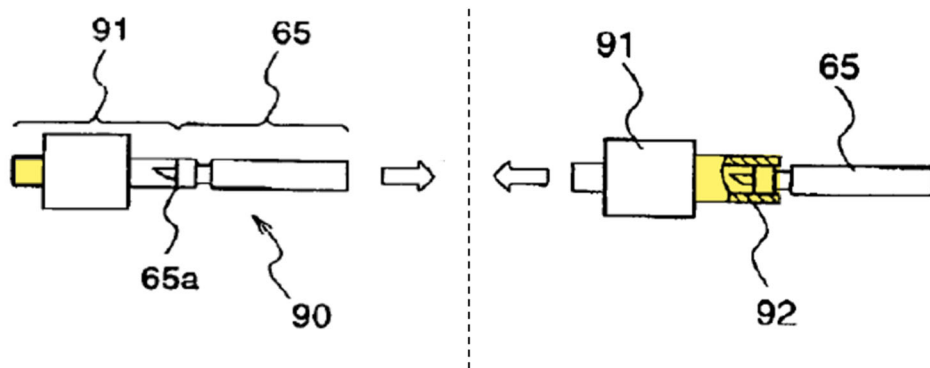
Iio Figs. 9A, 11A (excerpted and annotated). A POSA would conclude that these figures are merely illustrate how the device functions and is used, and do not convey dimensions, relative sizes, or proportions.

124. Similarly, the relative sizes of the gripping handle's diameter ("S") and length ("L") and lancet thickness ("T") are inconsistent across Iio's figures:



Iio Fig. 8 (annotated by Mr. Delman, with “L” added by me), Fig. 9a (annotated by Delman); Ex. 1002 ¶¶ 187, 193.

125. Iio also discloses that “the body 65 and the cap 91 are connected to each other by a thin plastic film having a thickness of 0.1 mm or less in the puncture needle separation groove 65a.” Iio ¶ 104. Mr. Delman contends that “[k]nowing this dimension, it is my view that a PHOSITA could visually discern that the lancet thickness is around 5 times thicker than the depicted thickness of the needles separation groove 65a.” Ex. 1002 ¶ 191. I disagree. A POSA would not reasonably draw any conclusions based on the line thickness labeled 65a in the diagram to the left below.



Iio Figs. 9A and 11A (excerpts and annotated). That thickness is the same as every other line thickness in the figure, and there is no reason to suspect they all represent the same thickness, much less 0.1 mm as Mr. Delman appears to contend. This is especially so given the fact that the alleged secondary sheath is shown having a line thickness in Figure 9A (left, above), but is much wider in Figure 11A (right,

above). Also, Mr. Delman's reasoning does not make any sense. If the film in 65a is only 0.1 mm thick, and the lancet was five times thicker than that, the lancet would be only 0.5 mm thick. Indeed, the thin film is not shown in this or any other figure.

126. For the above reasons, a POSA would look at these figures from Iio and understand dimensions, relative sizes, or proportions are not being accurately portrayed. Iio's figures are not to scale or even mechanically accurate and cannot be used as such. They merely illustrate the general idea of the purported invention.

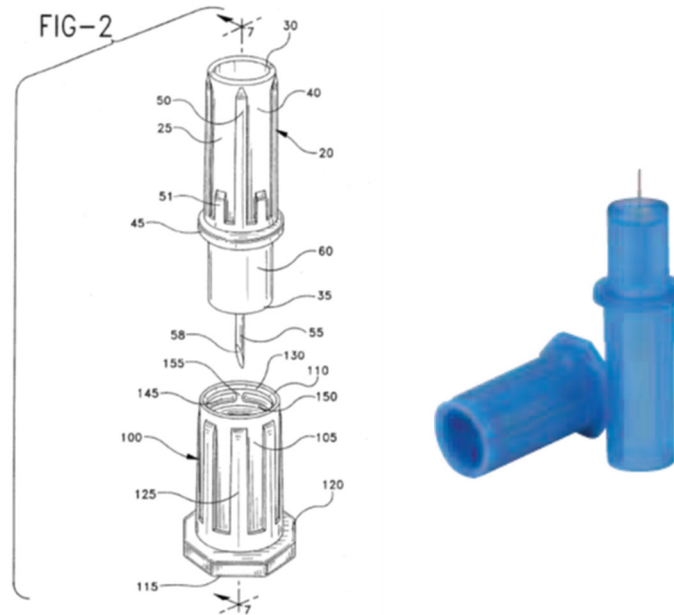
2. All Challenged Claims: Iio alone does not render obvious the claimed dimensions

127. As I discussed above, Iio does not disclose or reasonably suggest to a POSA the claimed dimensions. Iio's figures are plainly out of scale and disproportioned.

128. I also note that Mr. Delman contends "there are only a finite number of potential dimensions for the gripping handle portion as compared to the thickness of the lancet." Ex. 1002 ¶ 208. That is incorrect. As I discussed with respect to a similar assertion regarding Saikley, there are an *infinite* number of ratios between those two variables, as well as the other claimed dimensional relationships.

3. All Challenged Claims: Iio in view of Peckham does not render obvious the claimed dimensions

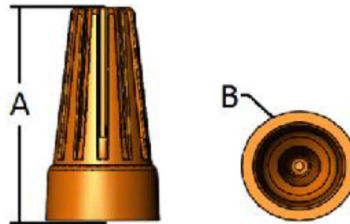
129. Peckham discloses a cylindrical lancet, as was commonly available at the relevant time. Similar cylindrical caps were about the same diameter as their associated lancets, not 1.5 times larger:



Peckham Fig. 2; Ex. 2026 at 1.

130. A POSA reading Peckham would have understood that adding ridges to Iio would give the user a better grip. An improved grip would decrease the need to provide the overly large gripping handle that Mr. Delman envisions. Ex. 1002 ¶ 219. This would save material cost because the cap as a whole could be smaller and use less material in each cap—using less material means less material costs, which helps drive profits or price competitiveness.

131. Mr. Delman provides the example of a standard wire connector. Ex. 1002 ¶ 222. Such wire connectors, as shown in Mr. Delman’s declaration, have a ridged shell for improved grip:



Ex. 2053. I have used such wire connectors, and from my personal experience, know that users apply a significant amount of torque to them despite their small diameter on the order of millimeters. This is possible because the ribbing on the cap improves grip, reducing the need for increasing the proportions of the connector cap to provide sufficient leverage.

B. Dependent Claim 16 Is Further Patentable

132. Claim 16 requires that the sterility cap “further compris[es] at least one flat display surface for placement of branding indicia thereon.”

133. This limitation is not disclosed or rendered obvious by Iio, alone or in combination with any other asserted reference.

134. Iio does not teach that any branding should be placed anywhere on the lancet, let alone on the second end. And Iio does not teach that branding should be placed on “at least one flat display surface for placement of branding indicia thereon.”

135. Mr. Delman's proposed branding (Ex. 1002 ¶ 228) shows and extremely zoomed in lancet to make Mr. Delman's proposed branding placement legible. In reality, due to the small nature of lancets, Mr. Delman's proposed branding would be nearly invisible to the naked eye, including to the target audience that are elderly or with eyesight issues. A POSA would understand that branding should be placed in a readily visible area, as contemplated by the '635 Patent ('635 Patent at 6:11-16), not in an area that could not be read or seen by the user, as Mr. Delman proposes.

X. Objective Evidence Further Demonstrates Patentability

136. I have been asked to consider certain issues related to the objective indicia of non-obviousness and provide my opinions. In particular, I have been asked to evaluate whether the Delica and Delica Plus practice claims 6 and 14 of the '635 Patent and whether there was a long-felt, but unmet need for the claimed invention.

A. The Delica and Delica Plus Lancets Practice Claims 6 and 14 of the '635 Patent

137. I have examined and measured physical samples of LifeScan's Delica Plus 30-gauge and 33-gauge lancets, which I refer to collectively as the "Delica Plus lancets". I have also examined and measured physical samples of the Facet Delica lancet. I used a Digital Caliper, M MOOCK 6 inch Digital Micrometer Vernier Caliper Measuring Tool with Large LCD Screen measuring system to take

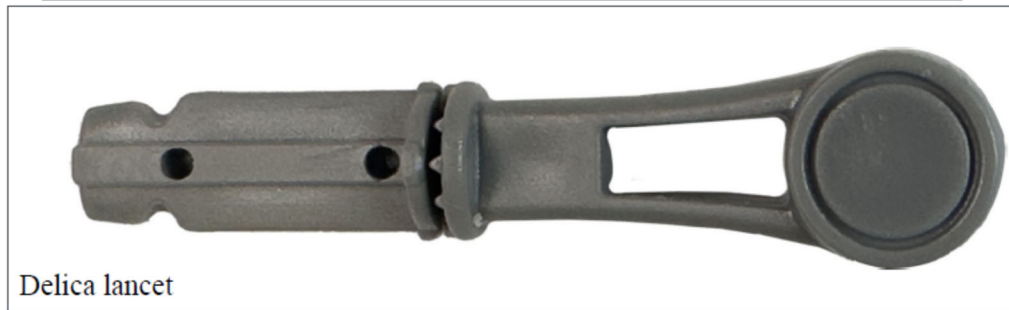
precise measurements of the Delica Plus and Delica lancets, which I include below. Based on my examination and measurements of the physical samples, in my opinion, the LifeScan Delica Plus lancets and the Facet Delica lancets practice claims 6 and 14 of the '635 Patent. I address the limitations of the claims below. I include photos of the lancets below to point out the parts that meet the claim limitations. I will use the term demonstrative to refer to the photos below because they are annotated and at different scales. That is, the photos are magnified to make it easier to see the lancets, but the amount of magnification in one photo may be different than that in another. As a result, a dimension/size of an object in one photo cannot be compared directly to that in another.

138. I used the 30-gauge lancets (gray) for the demonstratives because it is easier to see the contours in the photos. I also include a photo that shows the Delica Plus 33-gauge (which uses white plastic) because you can see the lancet needle through the plastic cap.

1. Claims 6/14 - Preamble⁷

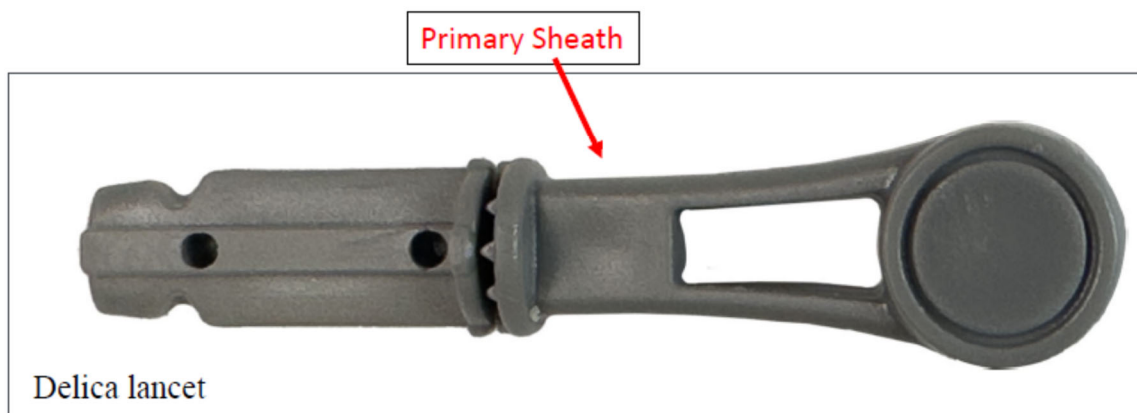
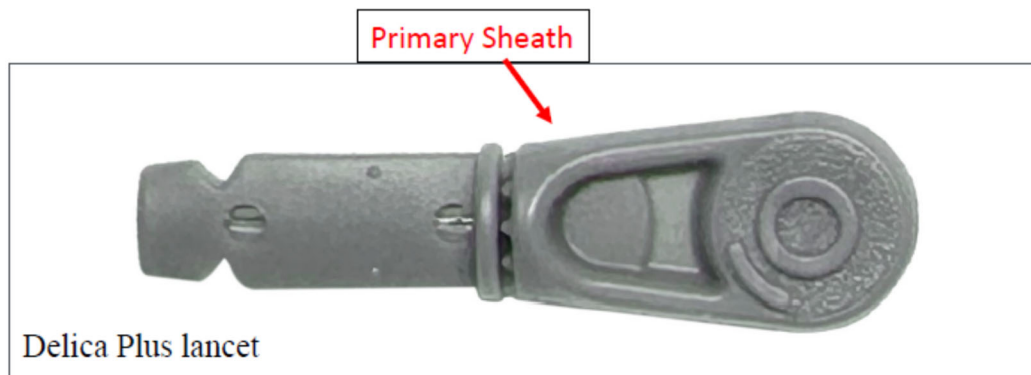
139. The Delica Plus and Delica are lancets that include a protective sterility cap. The demonstratives below show a Delica Plus product (on the top) and a Delica product (on the bottom). Each of the lancet products includes a cap.

⁷ Claim 6 depends from claim 1, so claim 6 includes the limitations recited in now-disclaimed claim 1.



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

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

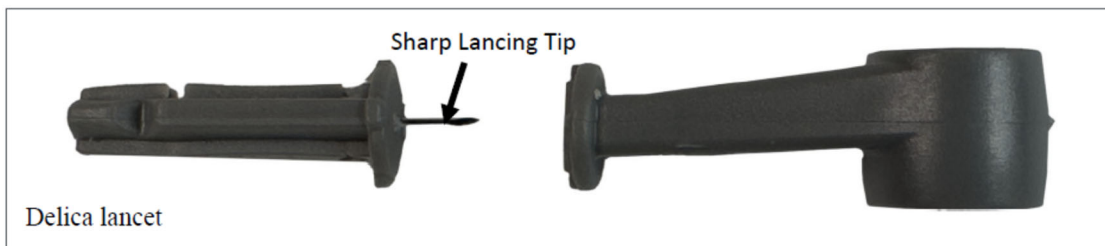
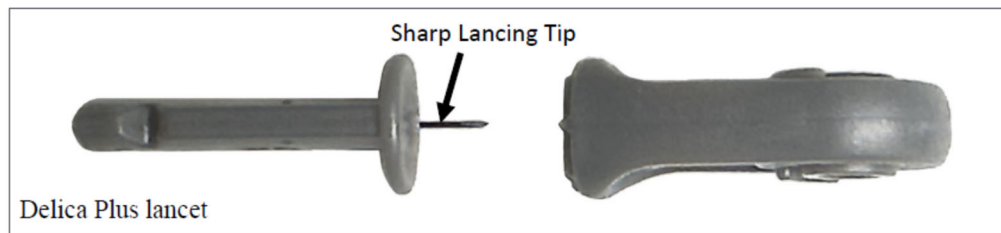


141. In the demonstrative below, a photograph of the 33-gauge Delica Plus made with white plastic, the lancet needle is visible through the white plastic, showing both the sharp lancing tip in the primary sheath.



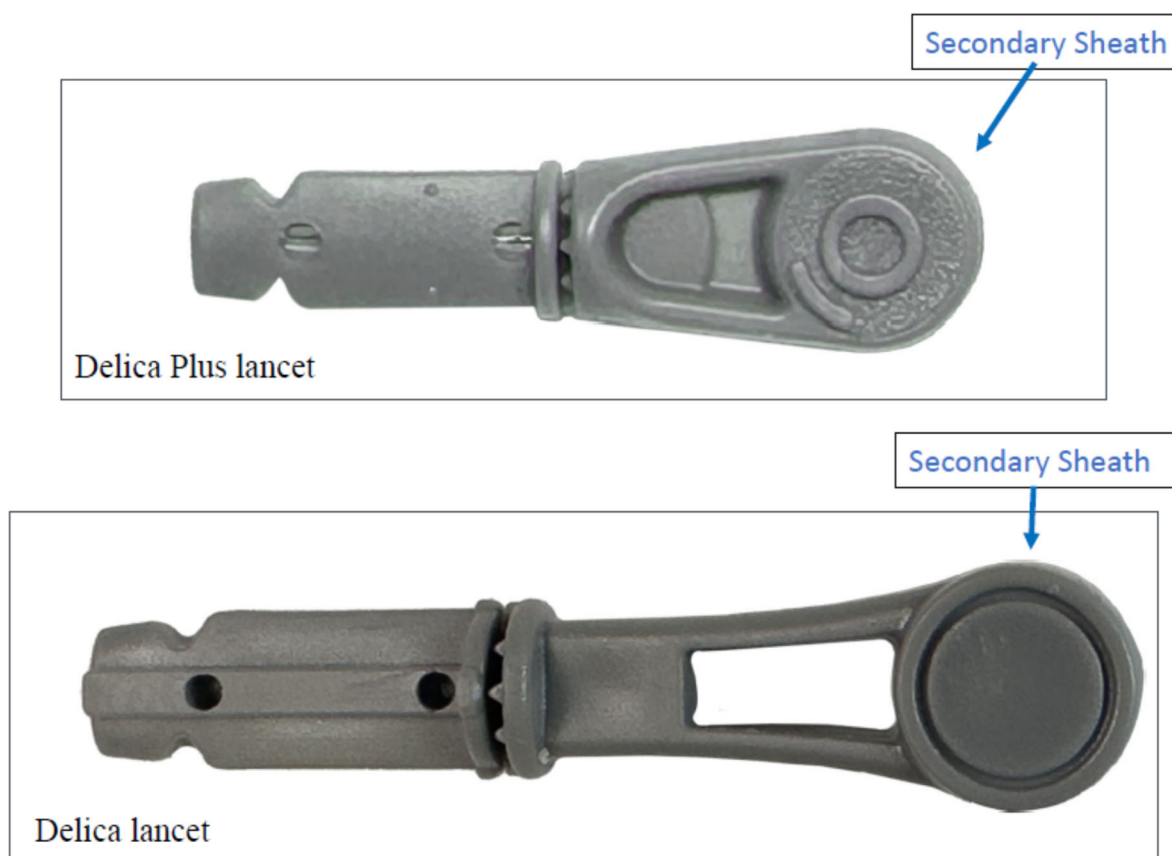
The Delica's needle primary sheath is similarly located in the primary sheath at that end of its cap.

142. I confirmed through my physical inspection of the Delica Plus and Delica lancets that both lancets include a sharp lancet tip and that the sharp lancing tip in initially embedded in the primary sheath.



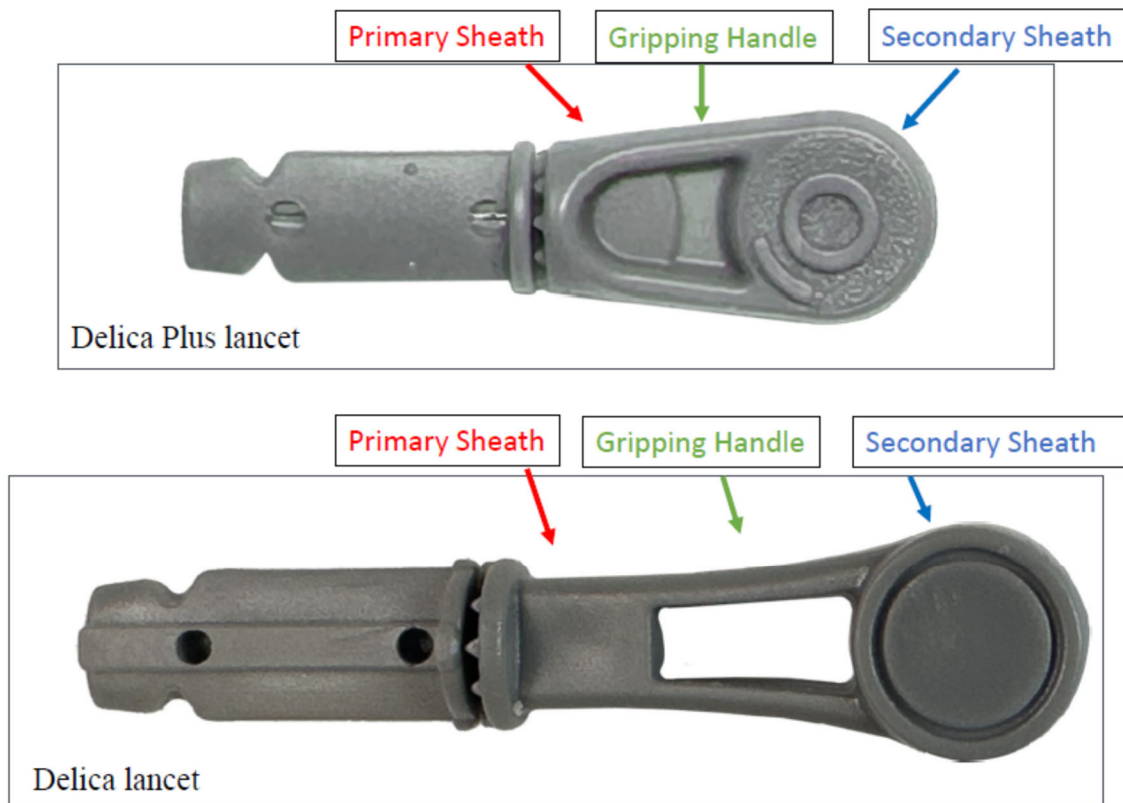
3. Limitation 1.b/14.b - secondary sheath

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



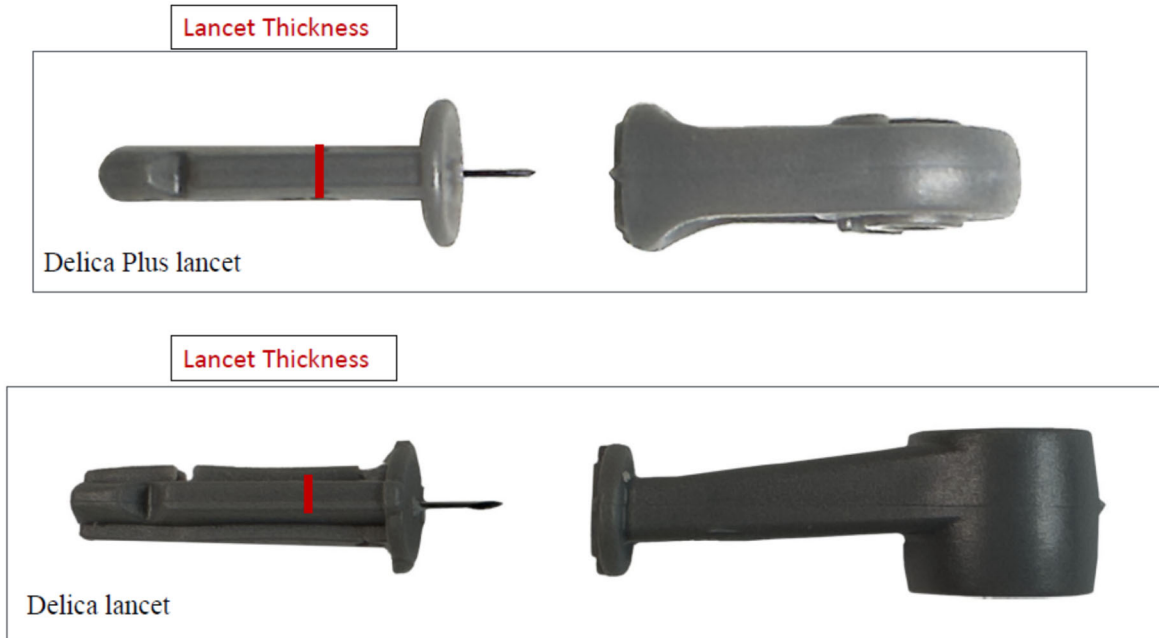
4. Limitation 1.c/14.c - gripping handle portion

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.



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

145. The Delica Plus and Delica include a lancet with a lancet body having a thickness, and a sharp lancet tip initially embedded in the primary sheath. As I explained above, the Delica Plus and Delica lancets each have a sharp lancet tip initially embedded in the primary sheath. Based on my examination the Delica Plus and Delica also have a lancet body with a thickness, as shown below in the demonstrative.



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

146. The Delica and Delica Plus lancets include a protective sterility cap wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.

147. I measured the lancet thickness at several places along the length using the flat portion of the calipers. The lancet thickness was not found to vary for the Delica Plus or Delica lancets beyond expected tolerances. In determining the lateral span of the gripping handle portion, I applied the language from the claim construction in the related district court litigation (Ex. 1004) “lateral span” can only mean the maximum side-to-side (or horizontal) distance separating the gripping handle portion.” To be conservative, I also measured the widths of the lancet

cap at a place of minimum width, which would generate the smallest possible ratio of gripping handle width to thickness.

148. Based on my measurement, the Delica and Delica Plus gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness. I measured 10 products of the Delica Plus and Delica lancets. The measurements are provided below in millimeters:

DELICA PLUS LANCETS (30-GAUGE)			
#	Span	Min. Cap Width	Lancet Thickness
1	6.87	5.50	1.77
2	6.88	5.65	1.74
3	6.91	5.70	1.75
4	6.95	5.60	1.73
5	6.80	5.62	1.73
6	6.95	5.68	1.73
7	6.91	5.55	1.76
8	6.83	5.69	1.72
9	6.88	5.56	1.74
10	6.85	5.63	1.74
Avg.	6.88	5.63	1.74
Std.	.05	0.07	0.02

149. For each of the 10 samples of the Delica Plus lancets, the gripping handle portion defined a lateral span of at least 1.5 times the lancet thickness. For example, using sample 5 (the smallest lateral span), the span is 6.80 mm and the lancet thickness is 1.73. The lateral span is 3.93 times the lancet thickness. Even using the minimum cap width, the claim limitation is met.

DELICA LANCETS (30-GAUGE)			
#	Span	Min. Cap Width	Lancet Thickness
1	5.73	4.25	2.70
2	5.72	4.26	5.69
3	5.72	4.32	2.71
4	5.72	4.25	2.69
5	5.74	4.24	2.71
6	5.73	4.26	2.71
7	5.74	4.25	2.73
8	5.73	4.28	2.69
9	5.71	4.27	2.71
10	5.71	4.28	2.72
Avg.	5.74	4.27	2.71
Std.	0.03	0.02	0.01

150. For each of the 10 samples of the Delica lancets, the gripping handle portion defined a lateral span of at least 1.5 times the lancet thickness. For example, using sample 10 (the smallest lateral span), the span is 5.71 mm and the lancet thickness is 2.72. The lateral span is 2.099 times the lancet thickness. Even using the minimum cap width, the claim limitation is met.

151. I note that the gripping handle portion is sloped at the span measurement point, so measurements slightly above or below the target location will introduce some error. Also, the minimum widths (“W”) of each of the sterility caps was also measured and were still found to have widths far in excess of 1.5 times the lancet thickness, so any small measurement errors are not significant in

the conclusion that the range expected due to the accuracy of the calipers for the Delica Plus products. The claim limitation is still met even using the narrowest portion of the sterility cap.

B. The '635 Patent Met a Long-Felt but Unmet Need

152. Prior to the invention of the '635 Patent, in my opinion, there was a long-felt need for lancing systems that provide increased safety and usability, including preventing accidental needle sticks.

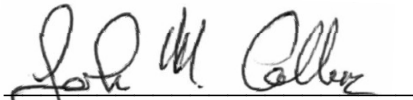
153. The patented lancet and cap are used for testing by diabetics. This patient population is typically older, and may be suffering from limited mobility or vision. In addition, diabetes can cause neuropathy, which causes damage to the nerves and results in pain and numbness in the limbs, including hands. Lancets are very small, on the order of millimeters. As a result, a person of ordinary skill in the art would have understood there was a need to create lancets that were easier to handle for this patient population, to assist with handling the lancet, removing the lancet cap, and providing a safe way to cover the used lancet needle and then dispose of the lancet.

154. The claimed invention met this need, by providing for a separate gripping handle and the specific dimensional relationships included in the claims. For example, the gripping handle combined with the claimed ratio of its lateral span to lancet thickness makes the device easier to use. The '635 Patent explains

that “[t]he “greater width[] allow[s] the user to more easily twist the endcap during removal from the lancet” and “easier use by persons with limited dexterity or vision.” ’635 Patent at 6:66-7:3.

All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true. Further, I am aware that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001. I declare under penalty of perjury that the foregoing is true and correct.

Executed on December 18, 2023 in Lexington, MA.



John M. Collins, Ph.D.