UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIFESCAN, INC.
Petitioner,

v.

FACET TECHNOLOGIES, LLC
Patent Owner.

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

DECLARATION OF JOEL DELMAN IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF ALL CLAIMS OF U.S. PATENT NO. 8,840,635

Exhibit 1002
Filed with Petition for IPR of
All Claims of U.S. Patent No. 8,840,635

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PETITIONER'S EXHIBIT LIST

Exhibit	Description
Ex. 1001	U.S. Patent No. 8,840,635 to Pusey et al. (the "'635 Patent")
Ex. 1002	Declaration of Expert Joel Delman
Ex. 1003	File History of the '635 Patent
Ex. 1004	Claim Construction Order for *Facet Technologies, LLC v. LifeScan, Inc.*, Case No. 2:22-cv-1717-MCS-MAR, Dkt. 122 (C.D. Cal. Jan. 20, 2023)
Ex. 1005	U.S. Patent Application Publication 2004/0138588 to Saikley ("Saikley")
Ex. 1006	U.S. Patent Application Publication to Iio 2005/0131441 ("Iio")
Ex. 1007	U.S. Patent No. 5,318,584 to Lange ("Lange")
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Ex. 1010	Wayback Declaration and Reference: FreeStyle Owner's Booklet, TheraSense, Inc. (2004)
Ex. 1011	*Reserved*
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Ex. 1017	U.S. Patent No. 6,283,982 to LeVaughn et al. ("LeVaughn")

Ex. 1018	U.S. Patent Application Publication 2006/0241669 to Stout ("Stout")
Ex. 1019	International Pub. No. WO 2007-089930A2 ("Lathrop")
Ex. 1020	Wayback Declaration and Reference: One Touch Lancing Device User's Instructions, Rev. 10/2006, LifeScan Inc., Milpitas California (2006)
Ex. 1021	U.S. Patent No. 4,994,068 to Hufnagle ("Hufnagle")
Ex. 1022	Lengths, girths, and diameters of children's fingers from 3 to 10 years of age, Annals of Anatomy (2010)
Ex. 1023	3-D Finite-Element Models of Human and Monkey Fingertips to Investigate the Mechanics of Tactile Sense, Journal of Biomechanical Engineering (2003)
Ex. 1024	CV of Joel Delman

I, Joel Delman, hereby declare as follows:

I ENGAGEMENT

1. I have been retained by LifeScan, Inc. ("Petitioner") in connection with the above-captioned petition for *Inter Partes Review* ("IPR") of U.S. Patent No. 8,840,635 to Pusey et al. (the "'635 Patent" or "Ex. 1001"). I understand the '635 Patent is currently assigned to Facet Technologies, LLC ("Patent Owner").

2. I have been asked by Petitioner to offer opinions regarding the '635 Patent, including whether the claims (which I may refer to subsequently as the "Challenged Claims") are valid in view of certain prior art. This declaration sets forth the opinions I have reached to date regarding these matters.

3. I am being compensated by Petitioner at my standard hourly consulting rate of $350 for my time spent on this matter. My compensation is not contingent on the outcome of the IPR or on the substance of my opinions.

4. I have no financial interest in Petitioner or Patent Owner.

II QUALIFICATIONS

A. Education and Career History

5. I hold a Master of Industrial Design from the Pratt Institute in New York. I worked with the design consultancy Product Development Technologies

LLC (PDT) beginning in 1999 and served as PDT's Los Angeles Creative Director beginning in 2007. Following PDT's acquisition in December 2017, my design practice has been through my consultancy Informed Innovation Inc.

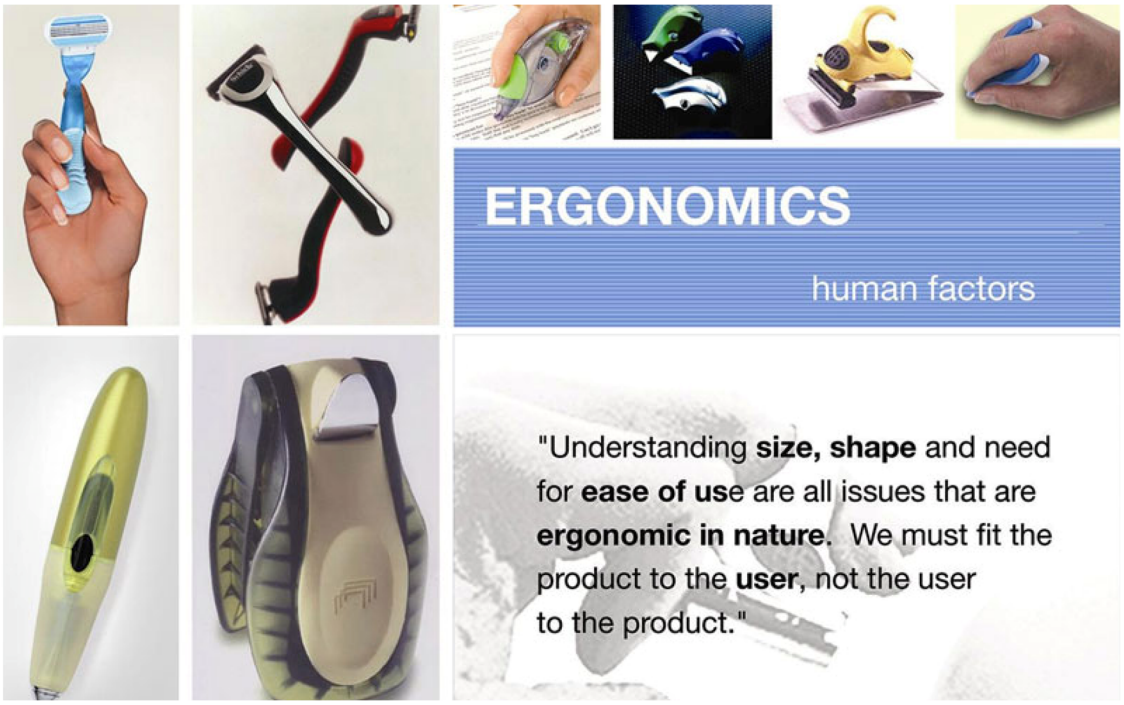
6. I currently serve as Chair of the Industrial Designer's Society of America's (IDSA) Design Protection Committee, and as an Associate Professor at ArtCenter College of Design in Pasadena, California.

B. Industrial Design Work

7. For the last 28 years, I have been a practicing industrial designer, design strategist, and inventor. My work encompasses a broad range of activities related to product design and development, including strategic user research (to guide clients toward optimal design solutions), aesthetic and functional innovation, and high-level program management. I have been engaged to assist clients with a wide variety of design challenges involving handheld ergonomics, including numerous programs focused on the development of medical devices. My clients for such designs have included Baxter, Novartis, Olympus Medical, Covidien, Roche, Carefusion, Cardinal Health, Cynvenio Bio, Medtronic, and Stryker, among others, for whom I have designed everything from home use diagnostic devices to tools relied upon by surgeons for lifesaving procedures.

8. When designing handheld consumer items, understanding the **size**, **shape**, and need for **ease of use**, are all human factors considerations that are taken into account throughout the design process. Industrial designers must fit the product to the user, not the user to the product. Below are examples of consumer products designed to fit the end-user.

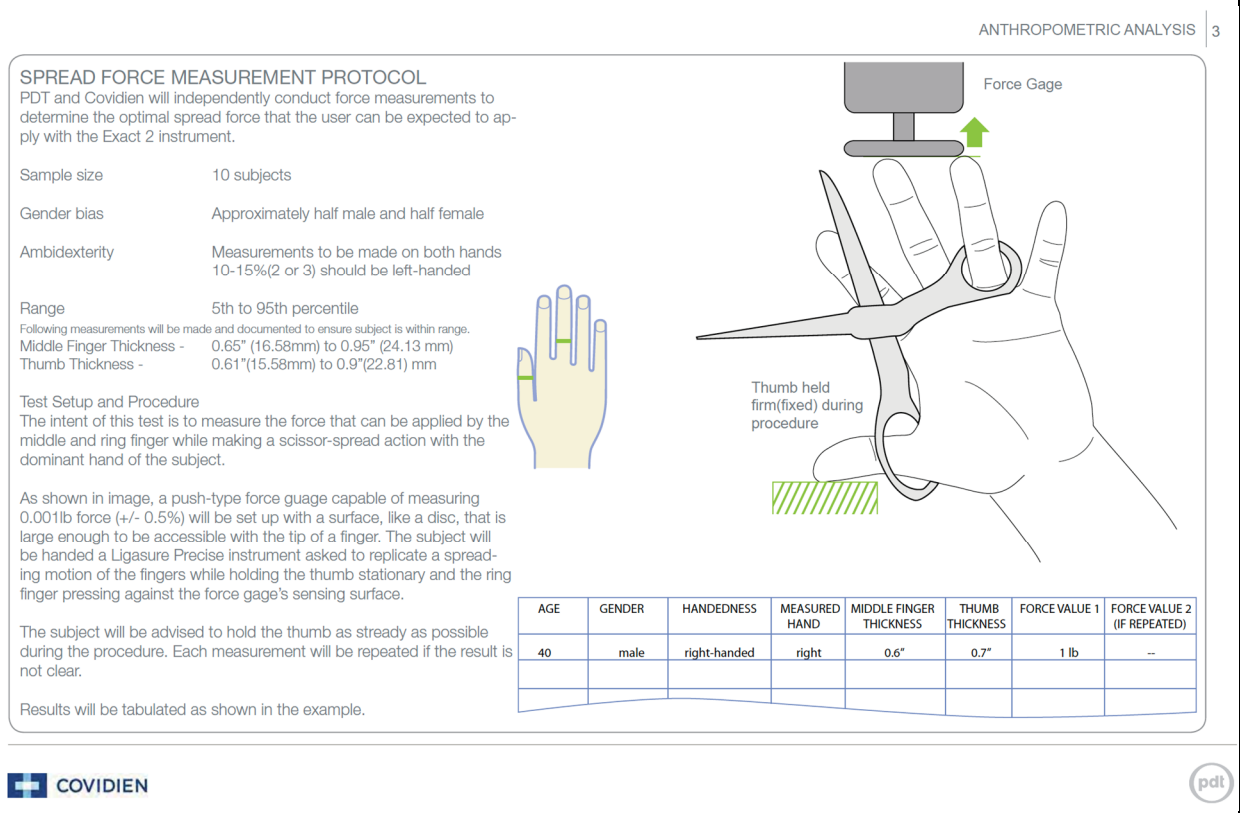
Demonstrative: Designing to Fit the Product to the User



9. Ergonomic studies are critical in the design of certain products to ensure that they fit the product to the user. These studies serve to help designers gain an understanding of the particular use case and ergonomic challenges to be

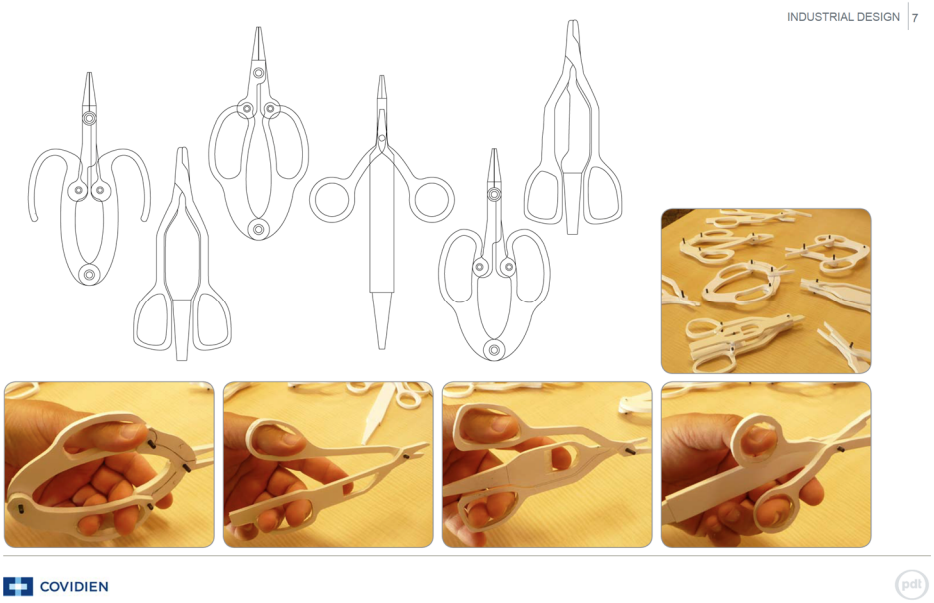
solved. Below is an example of research summarized for an ergonomic study of a surgical device.

Demonstrative: An Ergonomic Study for a Surgical Device



10. Ergonomic studies also allow designers to validate design solutions prior to production. This can be seen below in the design of various surgical device concepts for Covidien.

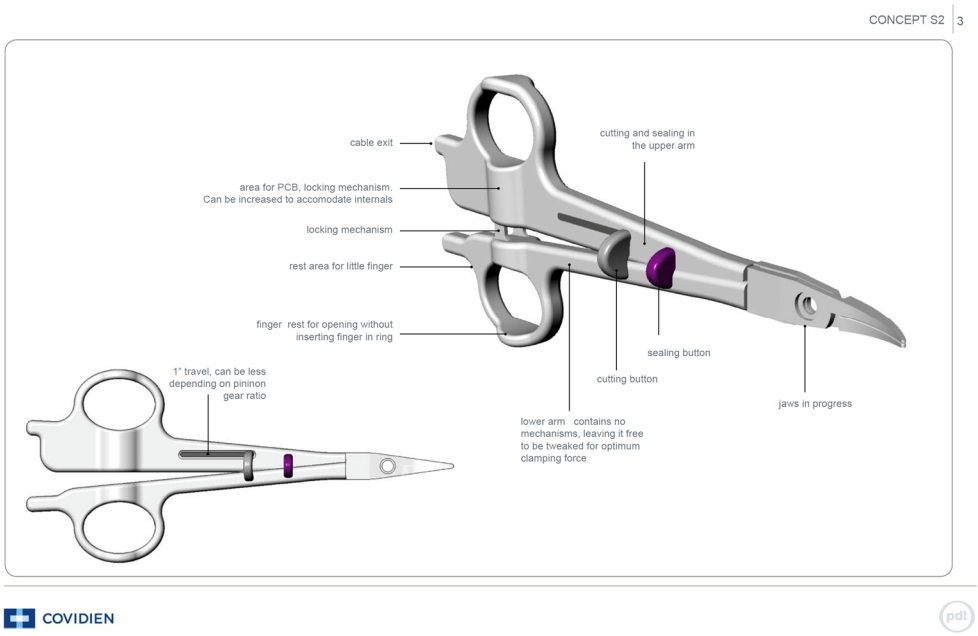
Demonstrative: Design Concept for Covidien



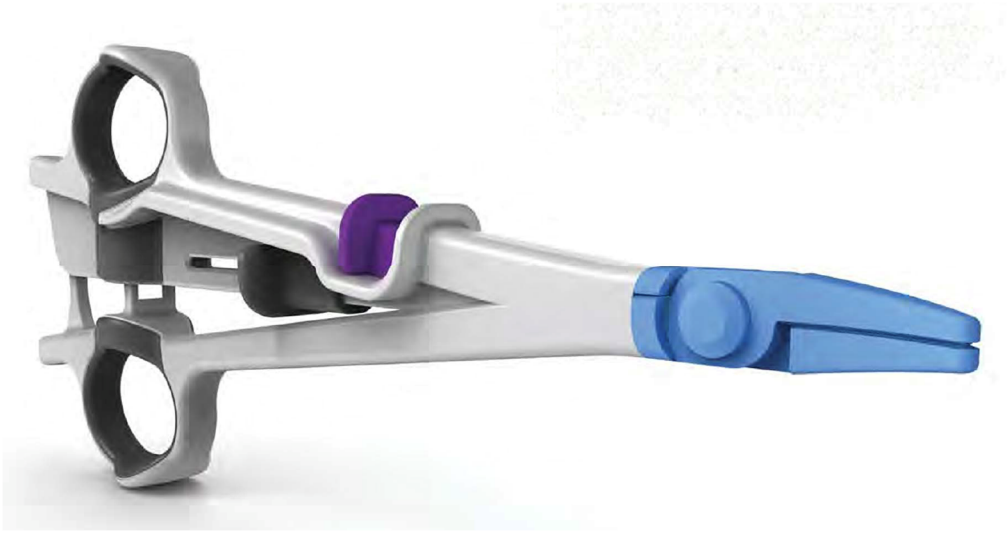
Demonstrative: Design Concept for Covidien



Demonstrative: Design Concept for Covidien

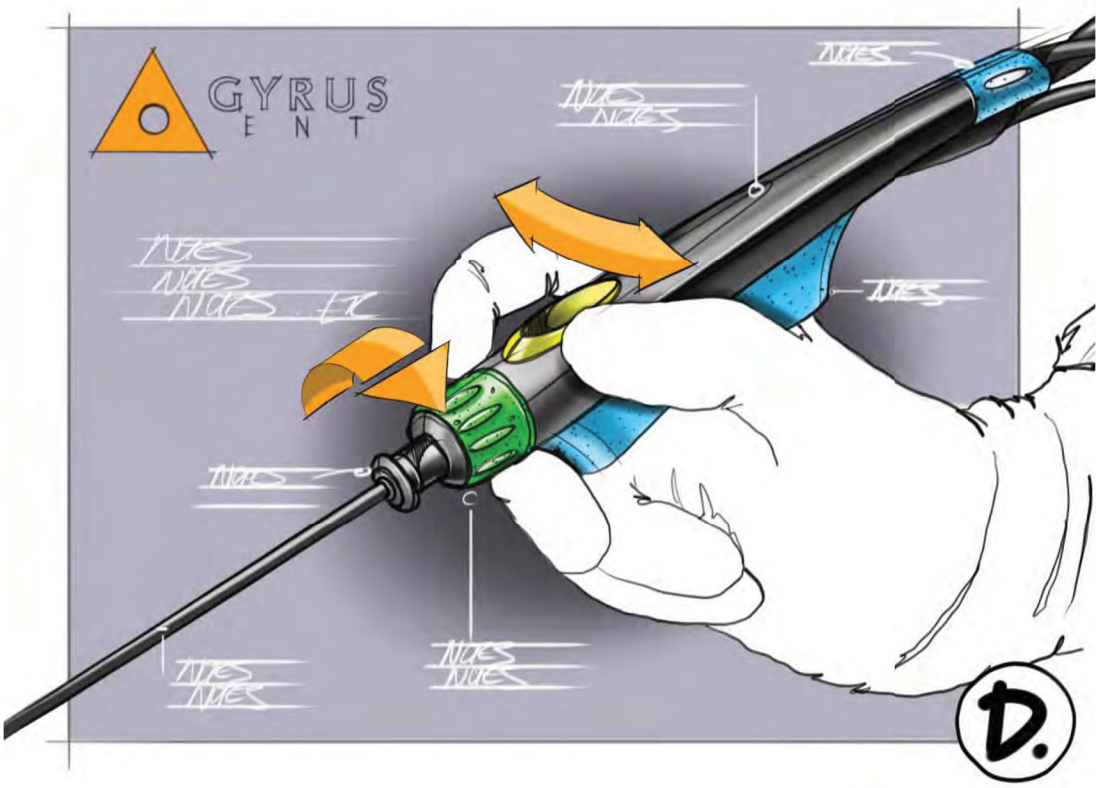


Demonstrative: Design Concept for Covidien



11. A design that I have implemented for a handheld surgical tool is shown in the preliminary sketch below for a surgical tool featuring a rotating dial for fingertip adjustment by the surgeon. The dial is located just before an abrupt "step," which helps the user's fingers locate and ensure contact with this region without conscious effort.

Demonstrative: Sketch of Surgical Tool With Rotating Dial



12. Ergonomic research studies, like the one described above for surgical tools, have also been helpful for designing products whose user base consists of users with an impaired range of motion. In the case of the Harris mobile radios seen below, our research confirmed that users often wear gloves to operate these communications devices in harsh environments. Broad cylindrical knobs were thus designed to be especially useful for these Harris mobile radio users. As shown with the sub-dials in the radio below, we specifically designed this to be the gripping region of the radio by creating a broad region which stands apart in an abrupt "step" from the remainder of the otherwise narrow form. Having the grip offset from adjacent features provides a "stopping point" for the user's fingers to understand where that grip begins and ends. In addition to the design of the sub-dials, a series of raised ribs on the back of the mobile radio housing was designed to provide extra grip for hands which are often wet or covered with perspiration.

Demonstrative: Harris Mobile Radio Knobs	**Demonstrative: Harris Mobile Radio Back With Raised Ribs**
	

13. Along with designing products for users with an impaired range of motion due to working in harsh environments, I have also designed products for users with weak grips. Children, for example, have small hands that present many of the same ergonomic challenges faced by elderly or arthritic patients. Children

have weaker grips and their ability to grasp is restricted by a lack of strength compounded by the limited size of their fingers. Below are examples of paint pens designed with these physical restrictions for children in mind. I designed the caps of these pens with an increasing cone-shaped diameter for children to use as leverage when removing the cap. The broad, flat end of the cap was also designed to show the child how to sit the pen vertically on a tabletop, which augments their strength when closing the brush, while instructing them on proper storage orientation to keep the paint flowing.

Demonstrative: Paint Pens With Cone-Shaped Caps



14. Other handheld school supplies I designed include those for Fiskars seen below. The concave and convex surface changes and textured dimples along the surface of each product provide cues to consumers about where to hold them and how they are to be used. Such form development and surface changes create natural gripping handles for effective and safe operation, while simultaneously discouraging users from holding or using the device in improper ways.

Demonstrative: Fiskars School Supplies



15. When designing school supplies, other considerations that I would take into account include where the "comfort zone" should be for the user. As seen in the examples of the Papermate mechanical pencils below, there is a larger-scale, streamlined grip area intended for writing. The significantly increased diameter of the pencil barrel and the highly visible texture contrast provide both visual and tactile cues for users to know exactly where the "comfort zone" of these pencils resides.

Demonstrative: Papermate Mechanical Pencils



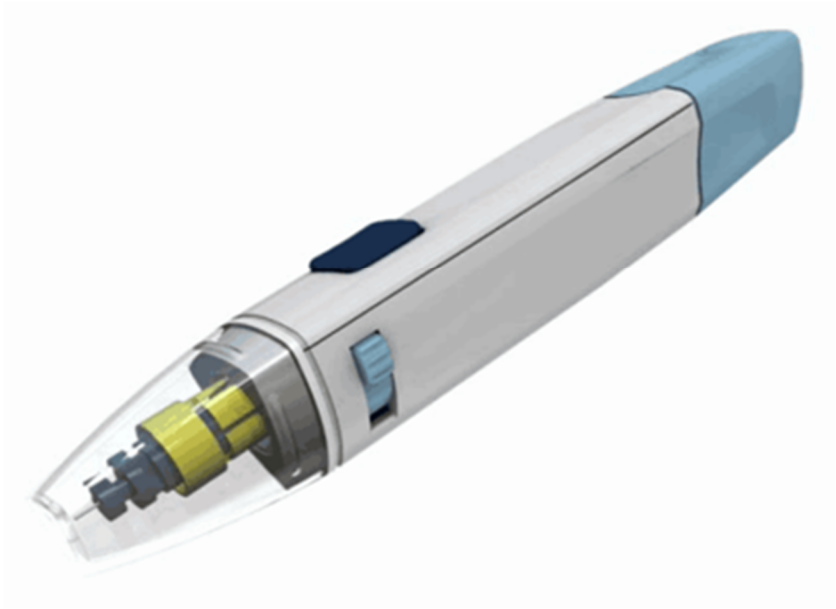
Demonstrative: Papermate Mechanical Pencils



C. Experience Designing Lancing Devices

16. Among my design work for common handheld consumer products is a magnetically-driven diabetes lancing device for which I was engaged to assist in the conception, research, prototyping, and final design of between the years 2004 to 2006. This magnetically-driven lancing device utilized magnetic attraction to eliminate vibration and oscillation from the lancet's motion, which significantly reduced pain in patients and the apprehension-inducing sound typically found in lancing devices. The final design of this device can be seen in the demonstrative below.

Demonstrative: Magnetically-Driven Diabetes Lancing Device



17. The magnetically-driven diabetes lancing device utilized a 360° magnetic field to linearly propel the tip of the lancet from a high potential energy position to a skin-puncturing position to, in final retraction, a shielded, steady-state position. The magnetic field's driving force minimized both lateral and longitudinal oscillation of the lancet tip, leading to a more precise and accurate skin puncture and, consequently, a reduction in the number of pain receptors activated. The magnetic-driven device's rapidly rising momentum at the moment of puncture also quickened penetration time. Reversal of the force also occurred

with similar acceleration and resulted in a reduction in retraction time, which led to an overall effect of shortening the duration of pain receptor stimulation in patients. The device also emitted a muted "swooshing" sound when triggered, which was far less psychologically jarring than the noise generated by typical spring-loaded lancing mechanisms. This also contributed to greatly reducing a patient's perceived pain and the fear traditionally associated with pressing the "launch" button on these devices. How the magnetically-driven diabetes lancing device is used can be seen below.

Demonstrative: Using the Magnetically-Driven Diabetes Lancing Device



Demonstrative: Using the Magnetically-Driven Diabetes Lancing Device



18. As part of the design process for this diabetes lancing device, it was critical that myself and the team of designers and engineers understand the use of the lancing device. A lancing device should be comfortable to hold, easy to use, reliable at all times, and intuitive. We studied how users used lancing devices and how such use fit into the process of blood monitoring for diabetic patients. We also studied how lancing devices were used with peripheral devices, such as the

lancets themselves and blood glucose monitoring systems, like the Abbott FreeStyle Freedom. Ex.1020, 141.

Demonstrative: Understanding Lancing Devices



Demonstrative: Understanding how Lancing Devices Are Used With Peripheral Devices Like the Blood Glucose Monitoring System



19. In order to understand the use of the lancing device, we familiarized ourselves with the characteristics, habits, and needs of the intended users of such devices. To do so, we benchmarked the performance of various lancing devices on the market as appropriate comparisons for the device we were to design. Some of the popular lancing devices used as comparisons included the OneTouch Ultra lancing device which uses the OneTouch Ultra lancet, the Becton Dickinson Adjustable Tip Lancing Device, and the Roche Accu-Chek lancing device which uses the Softclix lancet.

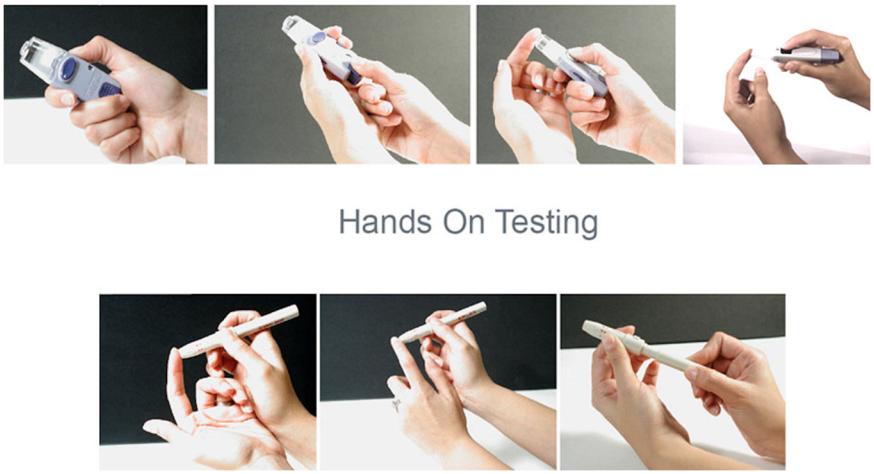
Demonstrative: Popular Lancing Devices Were Used as Comparisons



20. In addition, we met with a range of users of these devices, from children to elderly patients, and observed them taking blood samples. Patients were observed performing the entire process, from loading to disposal of the lancet, as seen below. This was critical to our ethnographic methodology, which sought to understand how people truly use these products, to uncover potential

opportunities for improvement, and to address these users' unmet and unarticulated needs. This was particularly important, as research has shown that diabetes patients often suffer from restricted ability to grasp and twist small lancing devices. We then followed up with these patients regarding our observations and they were given journals to log their lancing experience over the course of one or two weeks. The research participants were then asked for feedback on various design solutions we conceived, such as the preliminary concepts, refinement, and the proposed final design. For example, after developing preliminary prototypes, we would present these to the research participants and ask for their feedback again. We asked the research participants to provide us their feedback regarding comfort in holding the device, intuitiveness of how it would be used, general perception of aesthetics, and various ergonomic considerations.

Demonstrative: Hands on Testing of Lancing Devices

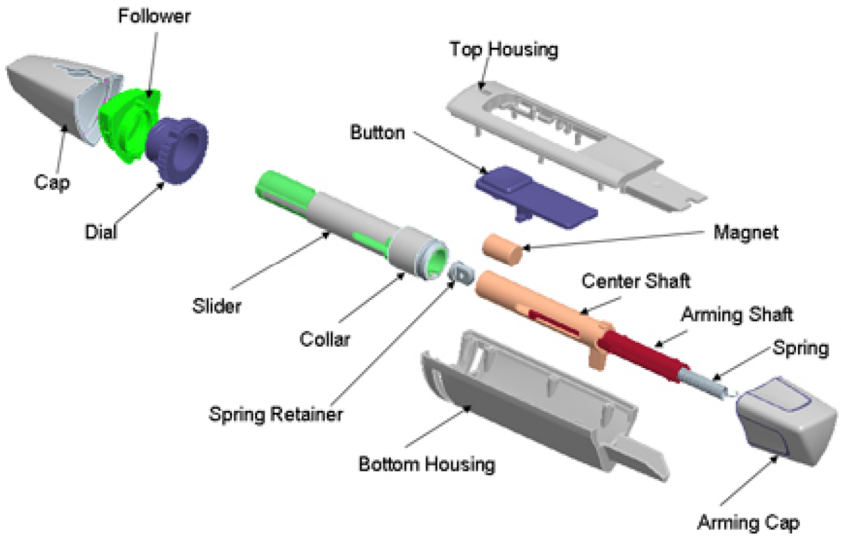


21. In addition to hands-on testing with patients of lancing devices, we engaged in validation testing of the newly developed magnetic lancing mechanism using a high-speed camera to show how the oscillation and vibration was significantly reduced in comparison to other devices. This testing also showed how our solution provided maximum momentum at the time of skin contact, as compared to other devices which slowed as the lancet approached and made contact with the patient's fingertip. Having maximum momentum at the time of skin contact reduced the duration of pain receptor stimulation in patients and allowed them to adjust the depth setting of the device to a more shallow (and thus less painful) setting. The slower penetration speed of other devices prolonged pain

receptor stimulation and often required a deeper depth setting to obtain the blood sample.

22. The final three-sided handle of the lancing device was informed by at least five factors: (1) form factor of the internal mechanism; (2) benchmarking against popular lancing devices; (3) application of appropriate ergonomic principles; (4) aesthetic considerations; and (5) manufacturing and cost considerations. Below is the final breakdown of the design of the device with the internal mechanisms taken into consideration. The cap of the device was designed as an aesthetically pleasing way to continue the form of the device handle. The three-sided design scored highly with research participants for comfort, aesthetics, and the side benefit that it would not roll away on the tabletop as some of the benchmark comparison devices were prone to do.

Demonstrative: Final Three-Sided Design with Internal Mechanisms

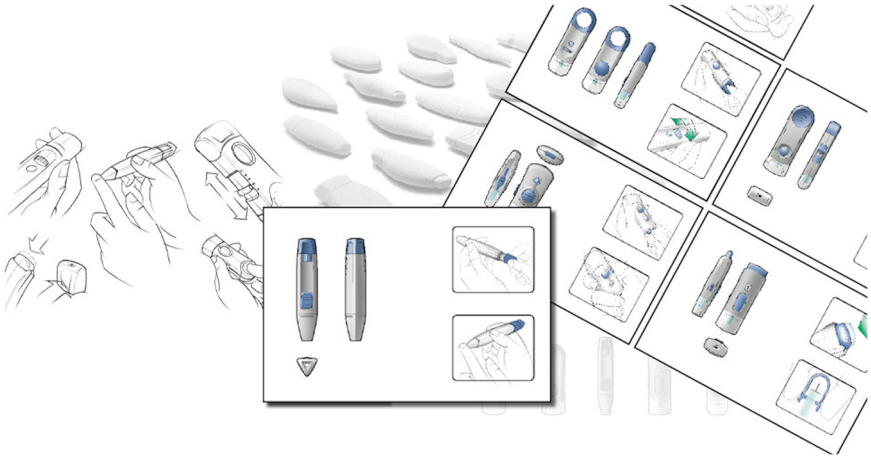


23. There were at least five factors which drove the design choices regarding the dimensions of the magnetic lancing device: (1) benchmarking against popular lancing devices; (2) the size of the lancets to be used; (3) the size and layout of the internal components; (4) human factors data; and (4) cost considerations. Addressing the first factor, to facilitate consumer adoption, it is often preferable in industrial design to provide an innovative design with functional benefits that does not force a jarring change to consumers based on what they are used to. Regarding the second factor, the standard lancet blades are the heart of the lancing device. What holds the lancet, what drives it, what sets the "launch button" and the depth, all flow from the dimensions of the disposable

lancets. The third factor, size and layout of the internal components, is a significant driver of the overall form factor, given that certain minimum clearances are required between these components and the device housing. The fourth factor, human factors data, is often integrated with the previously mentioned factors. Hand and finger size ranges are taken into consideration to ensure the design and its particular features comport with proven ergonomic practices for the intended users. Finally, cost considerations are always a critical component of a product's size when it is a commodity item like a lancing device. There is little leeway on such products for extra material costs, for example, that cannot be recouped through sales driven by the perceived value those costs impose. The amount of plastic used in molding is thus among the considerations when determining the overall form factor for the lancing device.

24. The magnetically-driven diabetes lancing device was entered into a number of industrial design and medical device design competitions, including a competition sponsored by "Medical Device Design and Engineering" magazine. Alternative preliminary concepts for lancing devices which were presented as part of this project can be seen below.

Demonstrative: Examples of Alternative Lancing Device Designs



Demonstrative: Examples of Alternative Lancing Device Designs



25. My design work has received awards and recognition from the Industrial Designers Society of America, the Chicago Athenaeum, the Consumer

Electronics Association, the Toy Industry Association, ID Magazine, and the Wall Street Journal.

26. In addition to contributing to the design of dozens of handheld products like the magnetically-driven diabetes lancing device, I am a named inventor on 10 United States utility patents, 15 United States design patents, and 19 United States patent applications. A listing of these patents is a part of my *curriculum vitae* ("CV"), which is provided as Ex.1024.

27. I have participated as a design expert witness in over 20 court cases relating to patents and trade dress.

28. Additional information regarding my background, qualifications, publications, and presentations is included as part of my CV, which is provided as Ex.1024.

29. It is for at least these reasons that I am well qualified to opine on the matters covered in this report and to testify as one skilled in the art with respect to designing lancets and lancing devices.

III MATERIALS REVIEWED

30. In forming my opinions, I have reviewed the '635 Patent, its prosecution history/file wrapper, and considered each of the documents listed in the Exhibit List above and the other references cited in my declaration.

31. In reaching my opinions, I have relied upon my experience in the field and also considered the viewpoint of a person of ordinary skill in the art at the time of the earliest claimed priority date of the '635 Patent, *i.e.*, July 2008. As explained below, I am familiar with the level of skill of a person of ordinary skill in the art regarding the relevant technology at issue as of that time.

IV DESCRIPTION OF THE RELEVANT TIMEFRAME, THE RELEVANT FIELD, AND A PERSON OF ORDINARY SKILL IN THE ART

32. All of the opinions that I provide herein are provided through the lens of a person having ordinary skill at the relevant time. I understand that the '635 Patent claims priority to Provisional Application No. 61/084,456, filed on July 29, 2008. For the purposes of my analysis, and in the absence of any information to the contrary, I have used the July 29, 2008 date as the relevant date for my analysis of the prior art.

33. I considered several factors to determine the skill level of a person of ordinary skill in the art of the ’635 Patent in July 2008, including the types of problems encountered in the art, solutions to those problems, the pace of innovation in the field, the sophistication of the technology, and the education level of active workers in the field.

34. Based on my knowledge, expertise, and the prior art cited in the ’635 Patent, it is my opinion that a person of ordinary skill in the field of the ’635 Patent would have had at least a bachelor’s degree and/or master’s degree in mechanical engineering or industrial design, including coursework in designing consumer products for mass markets, along with at least 4 to 6 years of experience designing consumer or medical device products to optimize human factors such as handleability or ergonomics. Additional advanced educational degrees could substitute for some years of experience, and, likewise, additional industry experience could substitute for educational degrees as well.

35. In addition, a PHOSITA would have been familiar with the principles that the ’635 patent admits as being part of the general knowledge of the art, including, but not limited to, (A) lancets comprising (i) “a plastic body” molded around “a sharp metal tip in the form of a needle or blade, the needle or blade is typically embedded in a plastic body that has a size and shape configured for

releasable engagement with the receiver or lancet carrier of a lancing device," and (ii) a "plastic cap" integrally-molded to the plastic body such that "the sharp tip of the lancet is commonly embedded in a removable plastic cap to maintain sterility and prevent inadvertent sticks prior to use," (B) removing the plastic cap from the plastic body to expose the needle tip and then "mount[ing] into a receiver or lancet carrier portion of the drive mechanism of a lancing device," (C) removing "a used lancet" from "the lancet carrier [of the lancing device] after sampling for disposal," and (D) "[t]he endcap may be replaceable onto the lancet after use to re-cover the sharp lancet tip for safety and hygienic purposes." Ex.1001, 1:38-57.

36. Unless noted otherwise, when I state that something would be known or understood by one skilled in the art, or a skilled artisan, or a person having ordinary skill in the art ("PHOSITA"), I am referring to a person with this level of education and experience at the time of the alleged invention, which I am assuming to be in or around July 2008, based on the date of the provisional application to which the '635 Patent claims priority.

V MY UNDERSTANDING OF CERTAIN LEGAL STANDARDS

37. In formulating my opinions, I have been instructed to apply certain legal standards. I received my Juris Doctorate from Harvard Law School in 1991

and practiced corporate and securities law for a few years. However, I have not practiced or been barred as an attorney for the last 27 years. I do not expect to offer any testimony regarding what the law is. Instead, the following section summarizes the law as I have been instructed to apply it in formulating and rendering my opinions found later in this declaration. I understand that, in an *inter partes* review proceeding, patent claims may be deemed unpatentable if it is shown that they were anticipated or rendered obvious in view of the prior art. I understand that prior art in an *inter partes* review is limited to patents or printed publications that predate the priority date of the patent at issue.

A. Anticipation

38. I have been instructed as to the definition of "anticipation" in the context of the patent laws. I understand that for a claim to be invalid as anticipated, all of the features of that claim must be present in a single previous device/system or method that was known of, used, or described in a single previous printed publication or patent. To anticipate the invention, the prior art does not have to use the same words as the claim, but all of the features of the claim must have been disclosed, either stated expressly or impliedly to a person having

ordinary skill in the art in the technology of the invention, so that looking at that one reference, that person could make and use the claimed invention.

B. Obviousness

39. I have been instructed as to the definition of "obviousness" in the context of the patent laws. It is my understanding that even though an invention may not have been identically disclosed or described before it was made by an inventor, in order to be patentable, the invention must also not have been obvious to a PHOSITA before the date of the alleged invention (which in these proceedings I am assuming to be July 29, 2008).

40. I understand that obviousness is a question of law based on underlying factual issues including the level of ordinary skill in the art at the time of the patent's alleged invention, the scope and content of the prior art, and any differences between the prior art and the claimed invention.

41. I understand that the scope and content of prior art for deciding whether the invention was obvious includes at least prior art in the same field as the claimed invention. The prior art can also come from different fields that a PHOSITA would have considered when trying to solve the problem that is addressed by the invention.

42. I understand that the existence of each and every element of the claimed invention in the prior art does not necessarily prove obviousness. Most, if not all, inventions rely on building blocks of prior art. But, in considering whether a claimed invention is obvious, I understand that one may find obviousness if, at the time of the patent's alleged invention, there was a reason that would have prompted a PHOSITA to combine the known elements in a way the claimed invention does, taking into account such factors as (1) whether the claimed invention was merely the predictable result of using prior art elements according to their known function(s); (2) whether the claimed invention provides an obvious solution to a known problem in the relevant field; (3) whether the prior art teaches or suggests the desirability of combining elements claimed in the invention; (4) whether the prior art teaches away from combining elements in the claimed invention; (5) whether it would have been obvious to try the combinations of elements, such as when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions; and (6) whether the change resulted more from design incentives or other market forces.

43. To find that the prior art renders the invention obvious, I understand that one must find that the combinations of the prior art could have been completed by a PHOSITA with a reasonable expectation of success. I also understand that it

is impermissible to find obviousness based on hindsight reasoning, *i.e.*, starting backwards from the patent's claims to stitch together the prior art.

VI SUMMARY OF MY OPINIONS

44. Having reviewed the '635 Patent and the prior art cited above, I have formed the following opinions:

- Saikley discloses all limitations of claims 1-3, 5-8, 14, and 16-18, and these claims are anticipated by Saikley;
- The combination of Saikley and Stout discloses all limitations of claims 1-3, 5-8, 14, and 16-18, and these claims are rendered obvious by the combination;
- The combination of Saikley and the FreeStyle Manual discloses all limitations of claims 3 and 16, and these claims are rendered obvious by the combination;
- Iio discloses all limitations of claims 1-3, 5-8, 14, and 16-18, and these claims are anticipated by Iio;
- The combination of Iio and Peckham discloses all limitations of claims 1-3, 5-8, 14, and 16-18, and these claims are rendered obvious by the combination; and

- The combination of Iio and FreeStyle discloses all limitations of claims 3 and 16, and these claims are rendered obvious by the combination.

The reasons for my opinions are discussed in further detail below.

VII CLAIM CONSTRUCTION

45. I have been advised that the term "a secondary sheath for receiving the sharp lancing tip of a used lancet" in independent claims 1 and 14 has been construed by Judge Mark C. Scarsi in the Central District of California in the patent infringement lawsuit of which the '635 Patent is presently the subject of. The Court construed the term to mean "a secondary sheath for covering the sharp lancing tip of a used lancet by embedding or enclosing the lancet tip." Ex. 1004, 13:26-14:3. I have applied the Court's construction of secondary sheath in my analysis of the prior art below.

46. I have been advised that for all other claim terms, including "gripping handle portion," "lancet thickness," "lateral span," and "length," the Court determined that no construction was necessary. Ex.1004, 28:21-29:4. For all other claim terms, I was instructed that they are to be given their ordinary and customary meaning as understood by a PHOSITA in view of the specification,

figures, and file history. I have followed these principles and have given all other terms their plain and ordinary meaning in my analysis throughout this declaration.

VIII THE PROSECUTION HISTORY OF THE '635 PATENT

47. U.S. Patent Application No. 13/675,209 ("'209 application"), which resulted in the '635 Patent, was filed in the U.S. Patent Office on November 13, 2012. Ex. 1003, 196-97. The application was filed with 18 claims, however, after the Examiner required restriction of the application to a single invention, the Applicant elected with traverse to continue prosecution of claims 1 through 9. *Id.*, 118-25.

48. The Examiner initially rejected claims 1, 2, and 4-9 as being anticipated under 35 U.S.C. § 102(b) by Hufnagle (U.S. Patent No. 4,994,068). *Id.*, 95. Claims 1-5 were additionally rejected under 35 U.S.C. § 102(b) as being anticipated by Morita (U.S. Patent No. 5,755,733). *Id.*, 94-97. The Applicant then amended claim 1, canceled claim 3, and added 10 claims, all of which did not introduce new matter. *Id.*, 73-79.

49. In a final Office Action, the Examiner rejected claims 1-2, and 4 under 35 U.S.C. § 102(b) as being anticipated by Gorbahn (U.S. Patent No. 3,680,559). *Id.*, 57-72. Claims 7-9, 21, 24-28, were also rejected under 35 U.S.C.

§ 103(a) as being unpatentable over Gorbahn. *Id.* It is my understanding that regarding the claims involving the "gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness," the Examiner reasoned that discovering optimum or workable ranges involved only routine skill in the art. *Id.*, 60. In response, the Applicant amended claims 1, 19, and 24. *Id.*, 47-54. However, it is also my understanding that in response to the Examiner's final office action, the Applicant did not address the Examiner's reasoning behind rejecting the "gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness" limitation for obviousness. *Id.*

50. A Notice of Allowance issued on June 3, 2014. *Id.*, 14-21. The Examiner's reasons for allowance only noted, "[t]he amendment and remarks . . . filed therein has overcome the rejection of independent claims 1, 19, 24 under 35 U.S.C. 102(b) by Gorbahn." *Id.*, 20.

51. Although U.S. Patent No. 5,569,286 ("Peckham," Ex. 1008) was cited by the Applicant in an information disclosure statement (Ex. 1003, 133-41), it is my understanding the Examiner did not rely on Peckham for any claim rejections and did not consider the combination of Iio and Peckham that is discussed in this declaration.

IX GROUND #1: SAIKLEY DISCLOSES ALL LIMITATIONS OF CLAIMS 1-3, 5-8, 14, AND 16-18

52. For the reasons I set forth below, in my opinion Saikley discloses all of the limitations of claims 1-3, 5-8, 14, and 16-18 of the '635 Patent.

A. Discussion of Claim 1

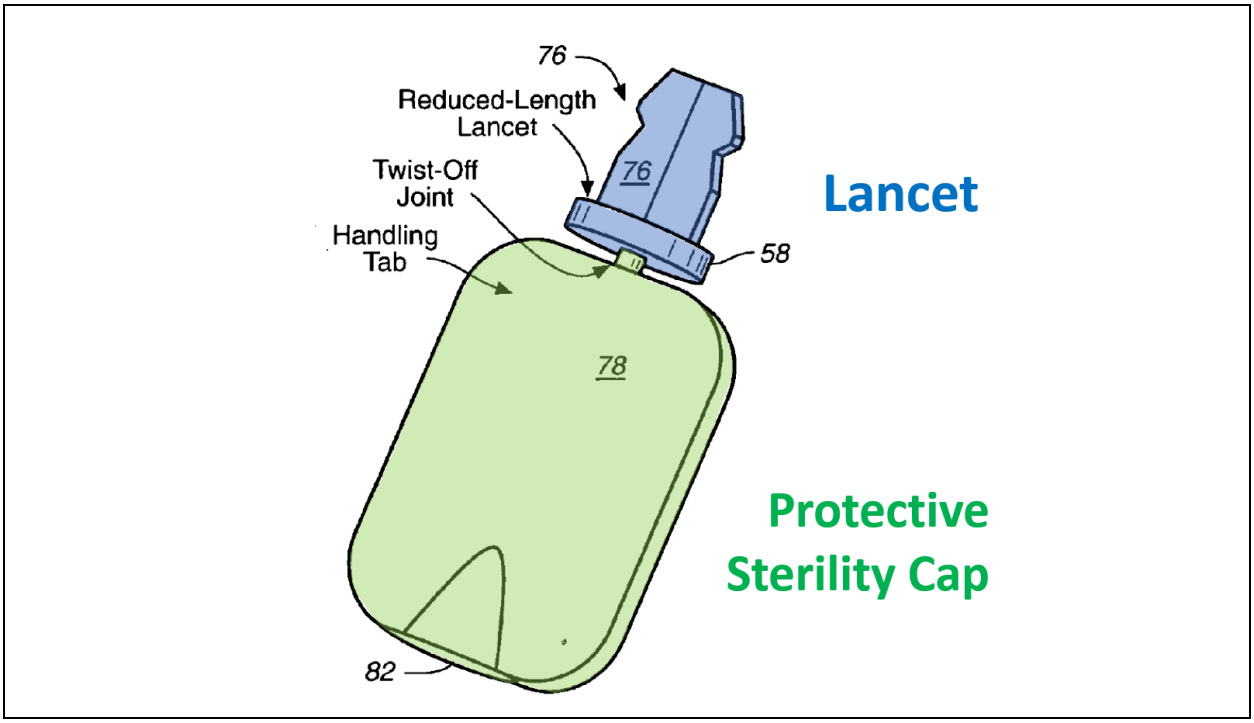
53. I discuss each limitation of claim 1 in turn below, in conjunction with the relevant disclosures of each claim limitation by Saikley.

1. Saikley discloses claim 1[p] – "A protective sterility cap for a lancet"

54. I have been informed that claim preambles are generally not limiting. In any case, even if the preamble were limiting here, I believe that Saikley discloses this preamble because Saikley discloses "a protective sterility cap for a lancet."

55. Specifically, Saikley discloses a "protective cap 78" for the "shortened lancet 76" seen in the annotations to Figure 7a (the "Figure 7a embodiment") below. Ex.1005, [0013] ("Figure 7a is a perspective view of a first embodiment of an inventive lancet and cap combination").

FIG. 7a of Saikley

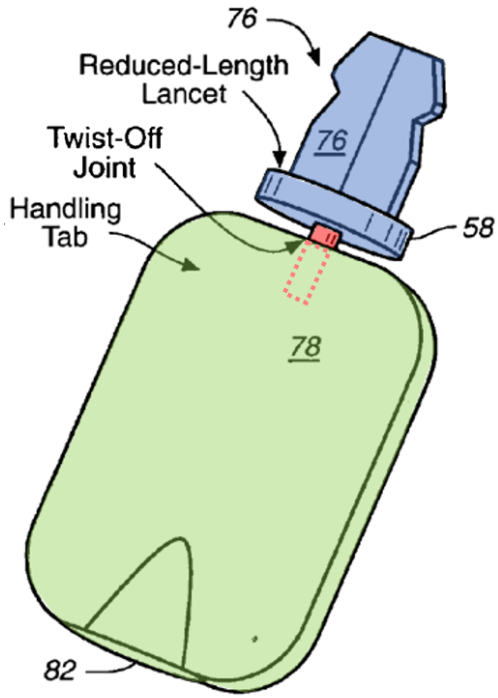


56. One observation to be made here is that Saikley states that the "cap 78 may be an integrally molded, pull-off tab, such as shown in FIG.7A." *Id.*, [0050]. The sterility of "lancet sharp 50," or the sharp lancing tip which projects from the lancet body, is maintained through Saikley's "cap 78".

57. It is therefore my opinion that Saikley discloses "a protective sterility cap [*i.e.*, protective cap 78] for a lancet [*i.e.*, shortened lancet 76]."

2. Saikley discloses claim 1[a] – "a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein"

58. Looking at an annotated version of Figure 7a below, Saikley discloses a primary sheath, or the "twist off joint" [*colored red in Fig. 7a below*] below with the adjoining portion of the "integrally-molded pull-off tab" [*yellow with dashed lines*] that "covers the lancet sharp 50" of the "shortened lancet 76" [*blue*] prior to use. Ex.1005, ¶¶[0037], [0050-52], [0065].



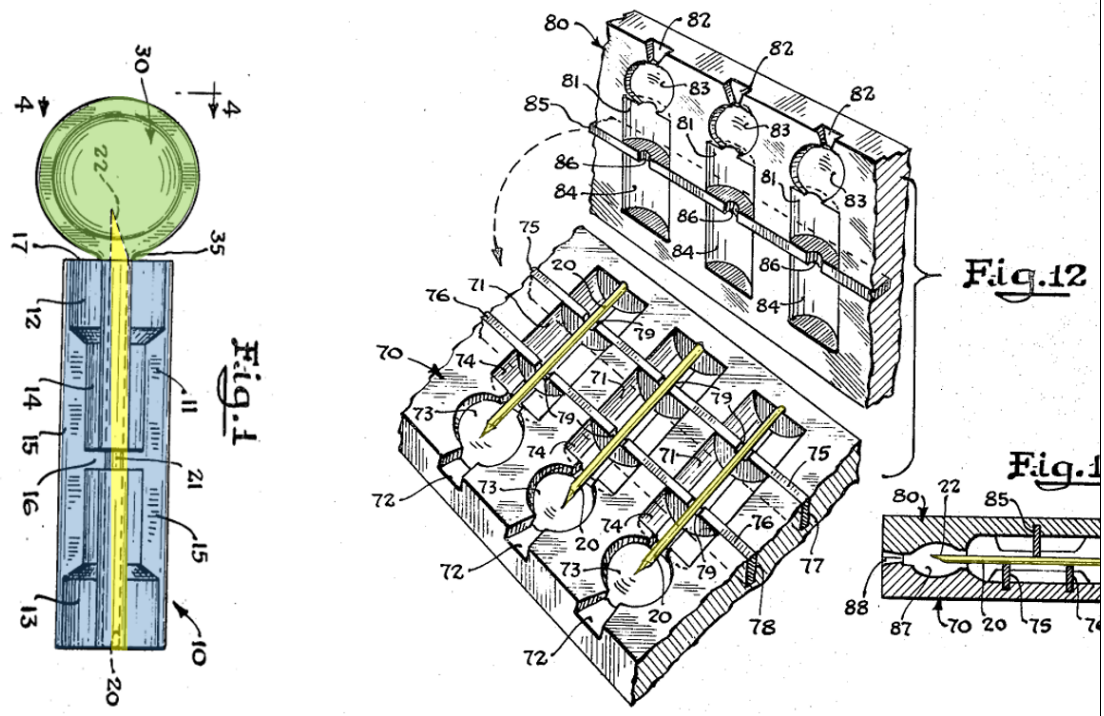
Ex.1005, FIG. 7a (Colored and Annotated with Broken Lines)

59. Saikley does not use the term "embedment" as required by the claim. However, in my opinion, Saikley otherwise discloses this claim limitation for a number of reasons.

60. *First*, Saikley describes and depicts the removable cap 78 of lancet 76 as an "**integrally molded** pull-off tab 78," and a PHOSITA would understand to indicate that the "needle tip [from the lancet body] is **embedded** in [handling tab portion of the] removable protective cap" because "it [is] integrally molded with the plastic body to form a single integral unit prior to use." (Ex.1005, [0050]; Ex.1009, [0008]). As shown in the exemplary reference below, I understand that the "integrally molded pull-off tab" described in Saikley was likewise molded to the needle tip and joins the needle in a "state where it is **embedded** in the puncture needle cap." A PHOSITA would understand that sharp 50 of the shortened lancet 76 is embedded in the twist-off joint and adjoining portion of the protective sterility cap 78 because Saikley describes the cap as an "**integrally molded**, pull-off tab" and teaches that the cap must be "**twisted**" (not pulled) off of the lancet body to avoid potentially bending or damaging the lancet. It would have been known to a PHOSITA, based on what was present in the art at the time, that an integrally molded cap must be twisted. For example, in International Application

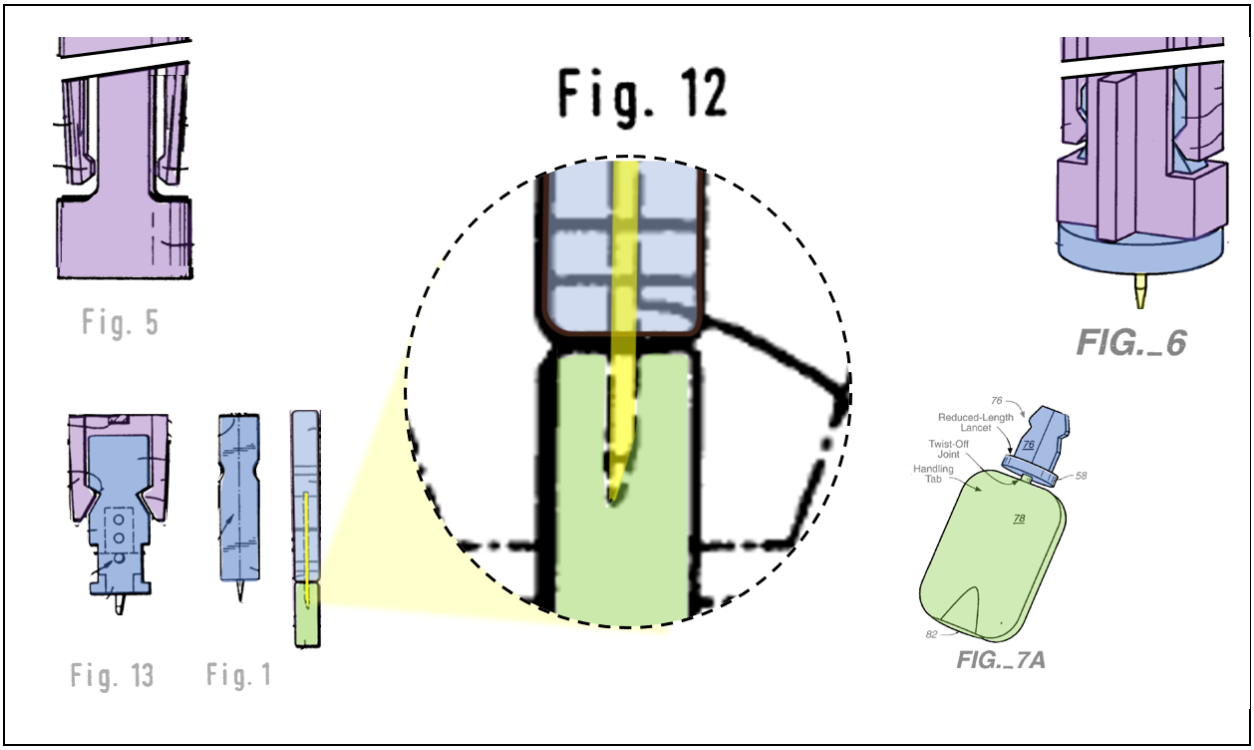
Publication WO 2007/089930 to Lathrop et al., twisting the endcap would sever the connection between the cap and integrally molded body portion to "allow easier endcap removal by reducing the amount of pulling force required to remove the endcap" and axially pulling the endcap away afterward would resist movements that "could bend or break the tip element." Ex.1019, [00027] ("Lathrop").

"Integrally-Molded" Cap as Undstood by a PHOSITA



Ex.1014 ("Higgins"), Figs.1, 12-13 (Colored)

61. Furthermore, LeVaughn (Ex.1017), which I understand to be incorporated by reference in its entirety in Saikley (Ex.1005, [0003]), discloses the "particular forms of body fluid sampling devices" from U.S. Patent No. 5,317,574 to Lange ("Lange") (Ex.1007), including lancets having the same flat and notched lancet body as Saikley's lancet 76 with "a tip protection device 177a removable by rotation" and "**injected**—as is also common practice with other lancets—**together with the plastic body** 177 on to needle 176 and removed before the lancet is used"—*i.e.*, an initial embedment of an unused needle. Ex.1007, Fig. 5, 11-13 ("Lange").

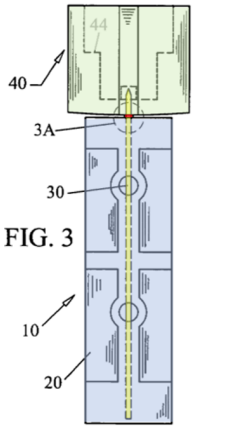
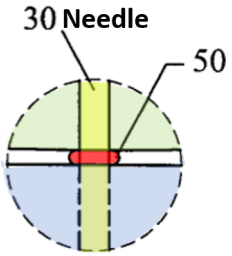
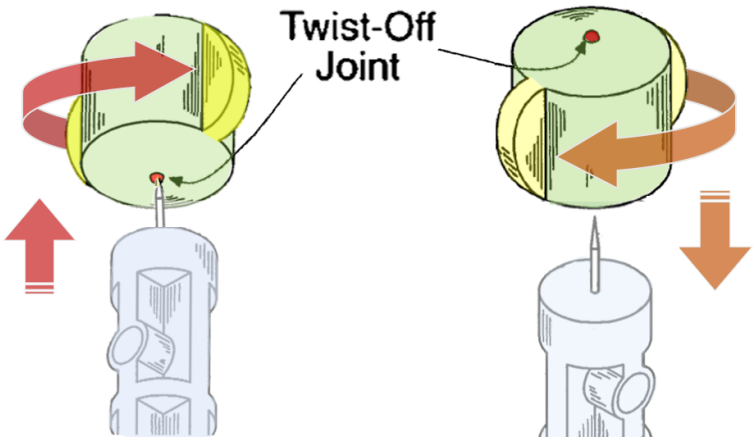


Demonstrative: Needle Embedded in "Integrally Molded Pull-Off Tab"

62. *Second*, the '635 Patent itself admits that the "sharp tip of [a conventional] lancet is commonly **embedded** in a removable plastic cap to maintain sterility and prevent inadvertent sticks prior to use," and even describes the "primary sheath" as the "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 "is **integrally molded** with the lancet body." Ex.1001, 1:47-50, 6:18-24. I observe this is also the case in Higgins (Ex.1014), Starnes (Ex.1009), and other prior art patents and published applications cited on the face of the '635 Patent. All of these references I note to use the term "integrally-molded" to describe a protective cap injection-molded to and formed around the lancet body and exposed needle tip, such 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." Ex.1009, [0008].

63. *Third*, in my opinion, Figure 7a also discloses the sharp 50 of Saikley's lancet 76 embedded in the protective cap because a PHOSITA would recognize that the "twist-off **joint**" is a "frangible junction" (*colored red below*) by which "the cap [] is integrally molded and joined to lancet body" such that the

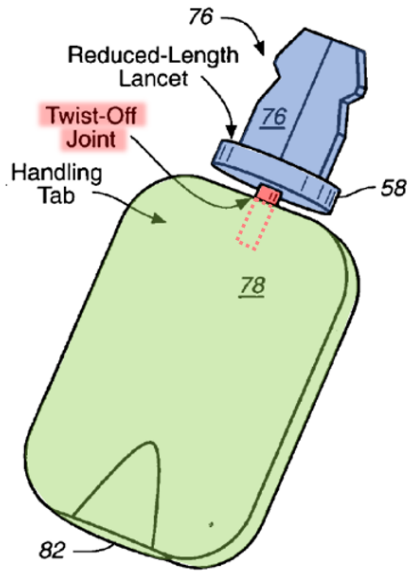
"piercing tip [of the lancet] is **embedded** within cap [] and frangible junction []." As taught in Starnes, the protective cap "receives the distal end of piercing tip 32 in the pre-use, 'as manufactured' configuration." Ex.1009, [0028].

"Twist-Off Joint" as understood by a PHOSITA	
 FIG. 3  FIG. 3A	
Starnes, Figs.3-3A (Colored)	**Demonstrative**

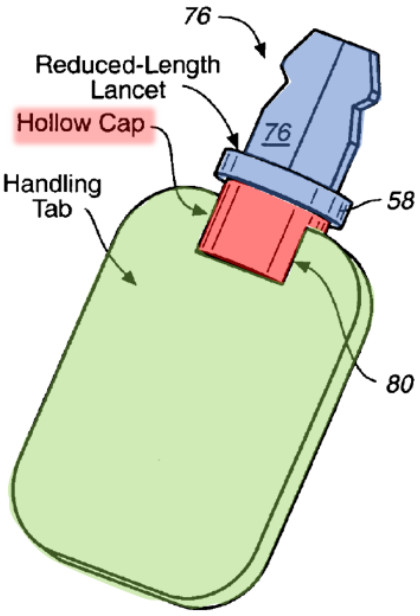
This is consistent with the '635 Patent, which teaches not only that "the sterility cap 510 is **integrally molded** with the lancet body," but also that the "spacer ribs or breakaway connections 518"—*i.e.*, twist-off joints—"extend[] from the primary shroud or sheath portion 512 to the front end of the lancet body, such that intact spacer ribs or breakaway connections 518 indicate an **unused lancet**, whereas broken spacer ribs or breakaway connections 518 indicate the lancet may have been used and therefore may not be sterile." Ex.1001, 6:18-26. I understand that because the twist-off joint in Figure 7a is not broken, the needle has not yet been used for sampling or testing, and therefore, remains sterile.

64. *Fourth*, I am further informed by the alternative embodiments disclosed by Saikley that the needle sharp 50 is embedded within the Twist-Off Joint and adjoining portion of the Handling Tab in the Figure 7a embodiment. Unlike the "integrally molded" protective cap 78 of the Figure 7a embodiment, Saikely teaches that the protective cap 78 of the alternative embodiment shown in Fig. 7b "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." Ex.1005, [0050]. By differentiating the "integrally-molded, pull-off tab 78" of the Fig. 7a Embodiment from a "***hollow*** cap 78," I understand that the lancet sharp 50 within

lancet 76 is embedded within the "integrally molded, pull-off tab 78." *Id.*, [0050-52], Figs. 7A-7B.



Saikley FIG. 7A



Saikley FIG. 7B

65. In my opinion, Saikley therefore discloses that the "sterility cap [*i.e.*, protective cap 78] compris[es] a primary sheath [*i.e.*, twist-off joint and] for initial embedment of a sharp lancing tip of an unused lancet therein [*i.e.*, needle point 50 of lancet 76]."

3. Saikley discloses claim 1[b] – "a secondary sheath for receiving the sharp lancing tip of a used lancet"

66. I observe that Saikley's protective cap 78 also includes "[a] hollow cup or solid 'pin cushion' type area 82 at the opposite end of cap 78, as shown in FIG. 7A [*orange below*], to cover the sharp during ***removal*** from the [lancing] device and ***disposal***" and safely handle the lancet after it has been used to collect a blood sample. Ex.1005, [0050].

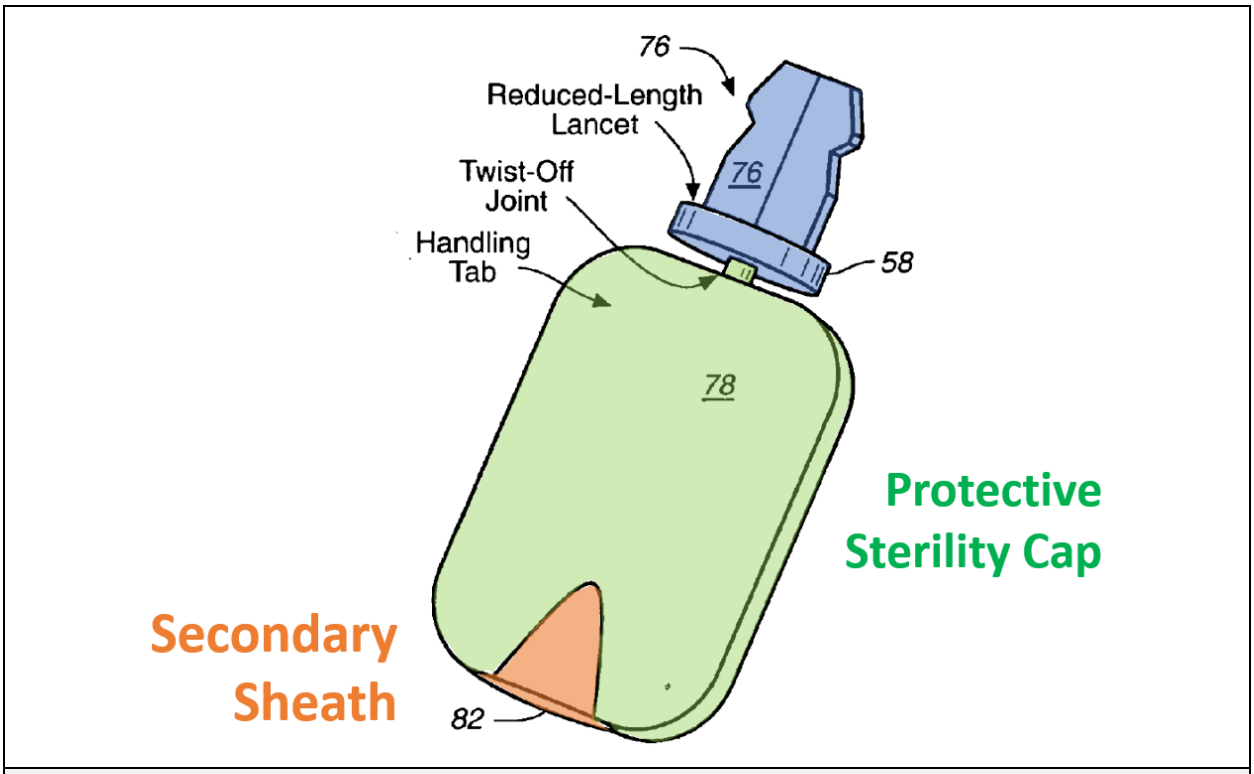


Fig. 7A (Annotated and Colored)

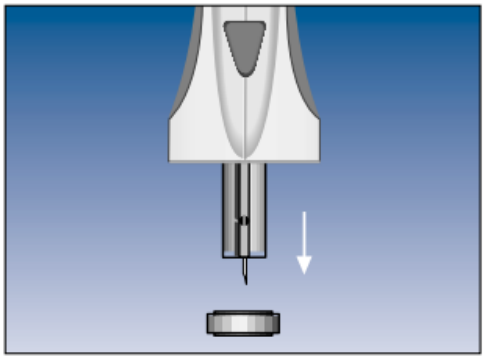
67. Saikley teaches that "solid 'pin-cushion' type areas"—like the one at the end of protective cap 78—"can be used for receiving [the] sharp after use and prior to disposal." Ex.1005, [0052]. I understand this to refer to pushing the lancet sharp 50 into the "pin-cushion type area 82" of the protective cap 78, much like pushing a needle into a pin cushion. Ex.1005, [0050-0052], [0064].



(Demonstratives)

68. Accidental needlesticks have been an art-recognized problem. Thus, having a secondary sheath has been a well-known feature of disposable lancets by the critical date. Such secondary sheaths often resembled a "pincushion" or a "hollow cup." Ex.1020 (Wayback: LifeScan One Touch); Ex. 1010 (Wayback: FreeStyle) (FreeStyle Product Manual disclosing lancet with a secondary sheath including Petitioner's own prior art lancets (excerpt from product manual

reproduced below) and other well-known lancets typically include either a solid pincushion for embedding the used lancet or a hollow cup or cavity for encasing the used lancet.) In my opinion, it is for this reason, a PHOSITA would have understood that the "hollow cup" of Saikley's protective cap 78 can also "be used for **receiving** [the] sharp ***after use*** and ***prior to disposal.***"

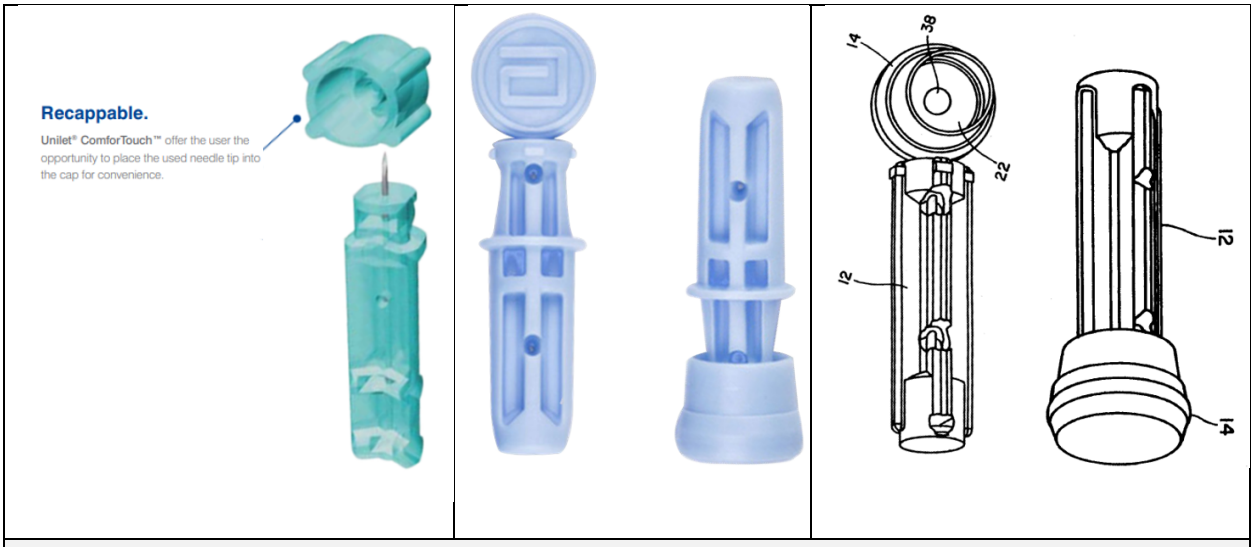
Meaning of "Solid Pin-Cushion Style Area" to a PHOSITA	
	*Optional:* To replace the protective disk on the lancet, place the disk on a hard surface and push the exposed tip into the protective disk. 
(Petitioner's Prior Art Manual for One Touch Lancet)	

69. By positioning the secondary sheath on the opposite end of the handling tab away from the primary sheath and by using a "hollow cup or solid pin-cushion type area 82" for the secondary sheath that is visually and tactilely

distinct from the primary sheath, Saikely's protective cap 78 allows users to more easily distinguish one end from the other after removing the cap and to more readily identify the sheath intended to receive the used lancet needle for disposal after use. This reduces the likelihood of an accidental needle stick caused by the patient attempting to re-insert the used lancet into the narrow twist-off joint rather than into the much wider hollow cup or solid pin-cushion type area 82.

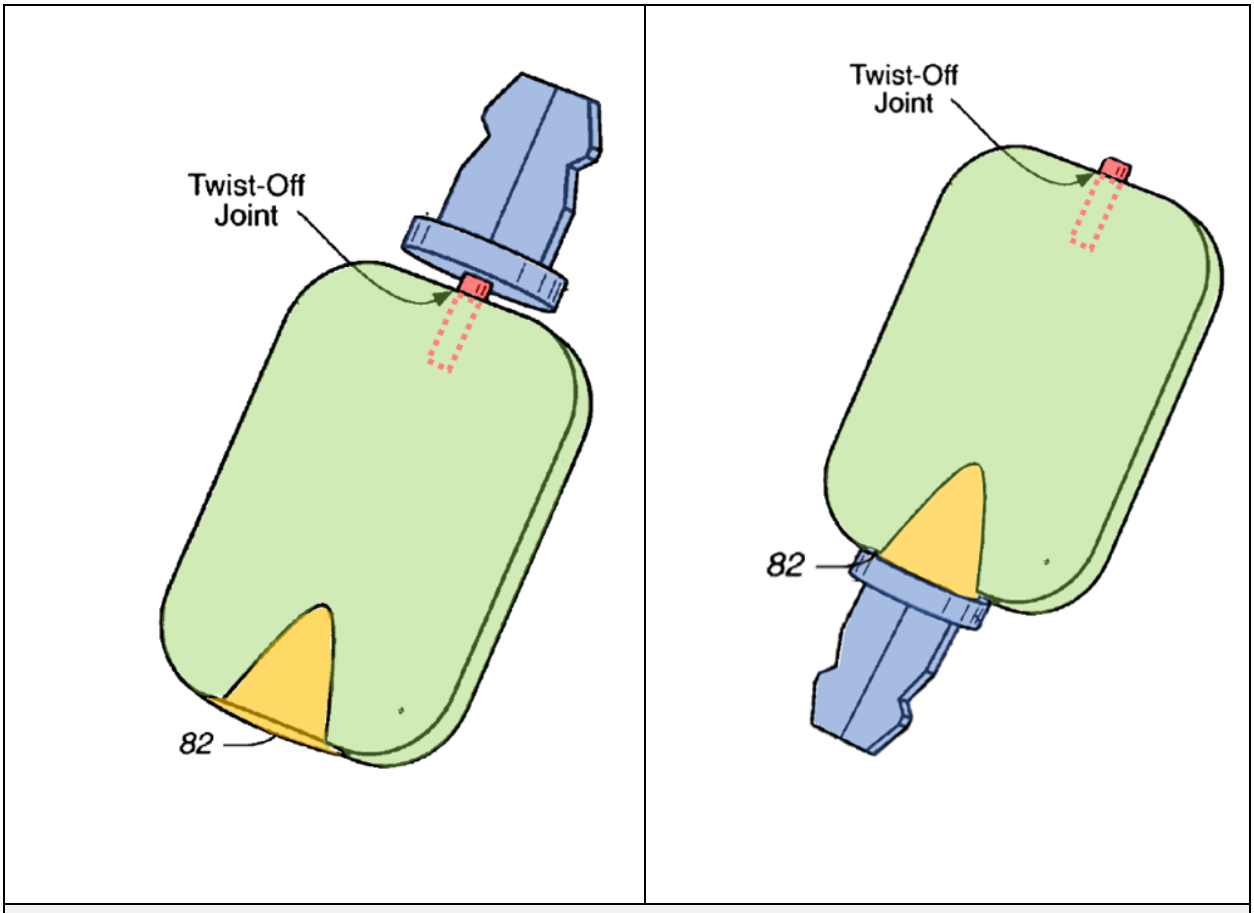
70. To prevent inadvertent needle sticks after use but prior to disposal, many conventional caps also include a hollow cup so the user can safely dispose of the lancet after it has been used. The needle sharp remains encased within the hollow cup while the user finishes testing the blood sample and even after the lancet has been discarded.

Meaning of "Hollow Cup" to a PHOSITA



(Demonstative: Recapping Used Lancet in a Hollow Cup)

71. The hollow cup and solid pin-cushion type area 82 are each designed for "receiving" a used lancet because the sharp lancing tip is enclosed in the former and embedded in the latter. This is consistent with the meaning of the claim term "a secondary sheath for receiving," which I understand the district court broadly construed to mean "a secondary sheath for covering the sharp lancing tip of a used lancet by ***embedding*** or ***enclosing*** the lancet tip." Ex.1004, 13:24-14:3. Like Saikely, the '635 Patent uses the term "receiving" to describe both a lancet needle "enclosed" within a "hollow cup" and one that is "embedded" within a "flat panel." Ex.1001, 6:1-5, 7:6-10; *compare* Ex.1001, Figs. 5A-5D *with* Figs. 6A-6D.

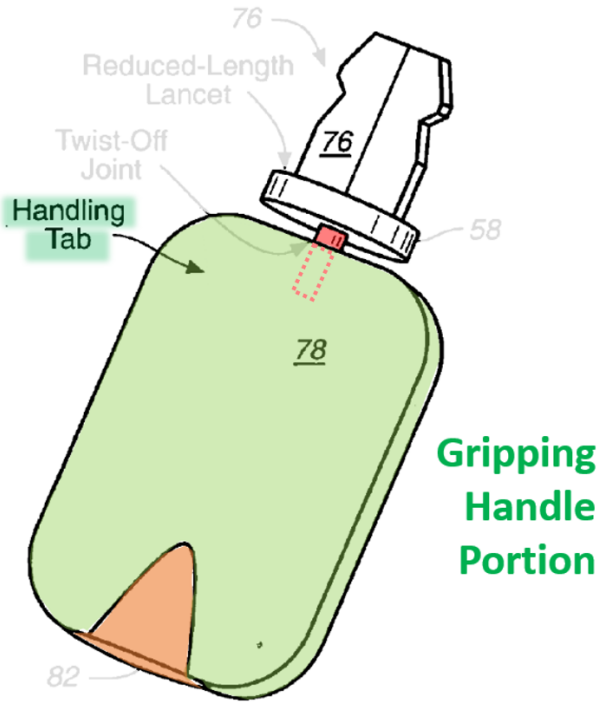


(Demonstratives: Recapping Used Lancet)

72. In my opinion, it is for at least these reasons, Saikley discloses "a secondary sheath (*i.e.*, hollow cup or pin-cushion type area 82) for receiving the sharp lancing tip of a used lancet [*i.e.*, for receiving the sharp 50 of the shortened lancet 76 after it has been used to collect a blood sample].

4. Saikley discloses claim 1[c] - "and a gripping handle portion extending between the primary sheath and the secondary sheath"

73. Saikley's protective cap 78 further includes a "handling tab" (*colored green below*) extending between the primary sheath—*i.e.*, the "twist-off joint" (*colored red below*) and adjoining portion of the protective cap (*dashed red*)—and the secondary sheath—*i.e.*, the "hollow cup or solid pin-cushion style area 82" (*orange*).



Ex.1005, FIG. 7A (Colored and Annotated)

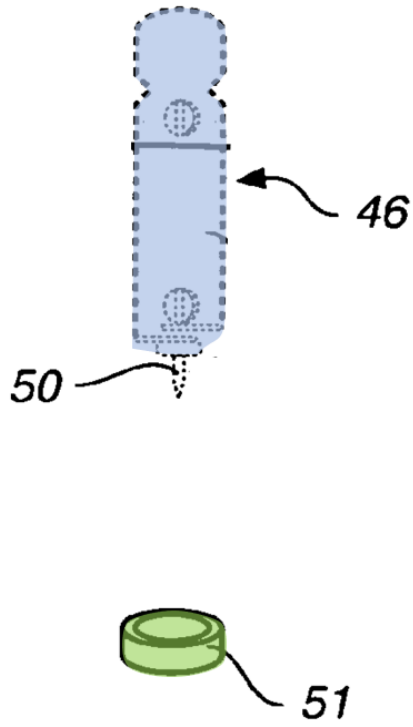
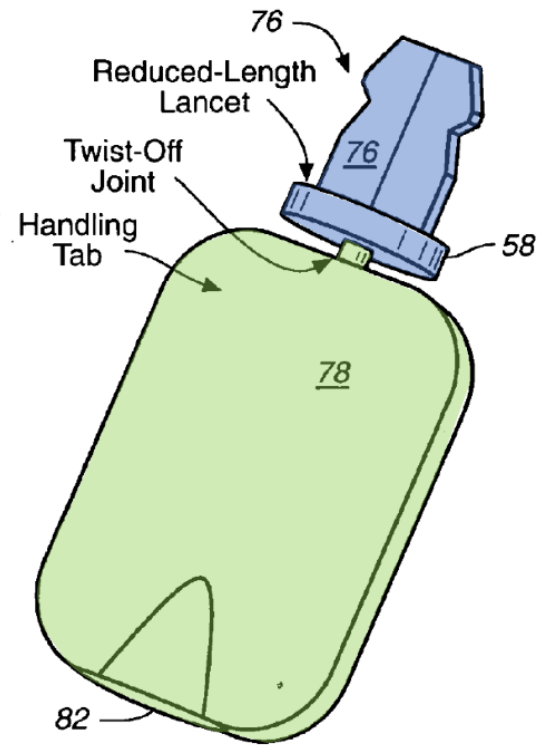
74. Many diabetics have trouble seeing and collecting a blood sample or even just juggling all of the different pieces during a test. Saikley incorporates a "**handling** tab" in the protective cap 78 to provide users with "a large lancet cap for **handling**" (*i.e.*, gripping). Ex.1005, [0049]. In my opinion, this is consistent with the plain and ordinary meaning of the claim term "gripping handle portion," which the district court considered simply the "handle" portion of the claimed sterility cap because "[t]he Court does not make much of the modifier 'gripping' and finds the term merely restates the purpose of the handle." Ex.1004, 17:12-13. Per the Court, "all handles are 'gripping handles.'" *Id.* The '635 patent likewise refers to a "handle or grip" interchangeably and describes a "handle" or "handle portion of the cap." Ex.1001, 1:66-2:3, 6:5-9, 7:6-12, 8:17-22.

75. Like the '635 patent, Saikley recognizes the problem that "[t]raditional disposable lancets, such as shown in **FIG. 3**, have an elongated body 48 [*blue below*] and a short cap 51 [*green*]," which "may make it difficult for the user to handle and install"— especially "elderly patients and those with reduced eyesight and dexterity." *Compare* Ex.1005, ¶¶ [0004], [0050] *with* Ex.1001, 7:26-33. This is because users need to grip the lancet by the cap when inserting it into

the lancing device, and also need to remove the cap from the lancet prior to use and then re-insert it back into the cap after use.

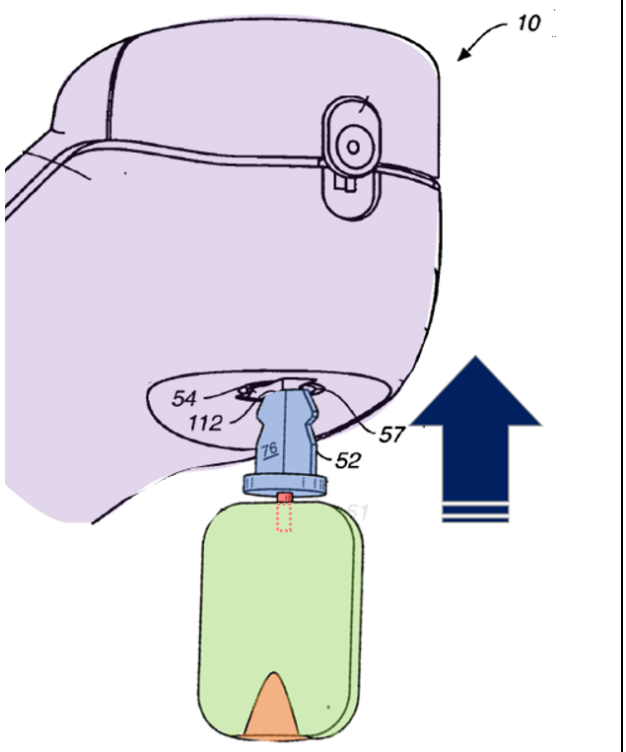
76. And just like the '635 patent, to address this problem, Saikley teaches that "the protective cap 78 (that is removed before use) should be made **much larger** than usual to **aid handling**." *Compare* Ex.1005, ¶¶ [0004], [0050] *with* Ex.1001, 6:66-7:3 ("[T]he expanded dimensions of the endcap allow for easier use by persons with limited dexterity and vision"); 7:26-33 ("[T]he larger surface area provided by the protective/sterility cap, as compared to previously known designs, makes it easier to locate, especially for users with reduced visual acuity; and renders it easier to pick up off of a flat surface or out of a container, which is particularly advantageous for users with reduced manual dexterity.").

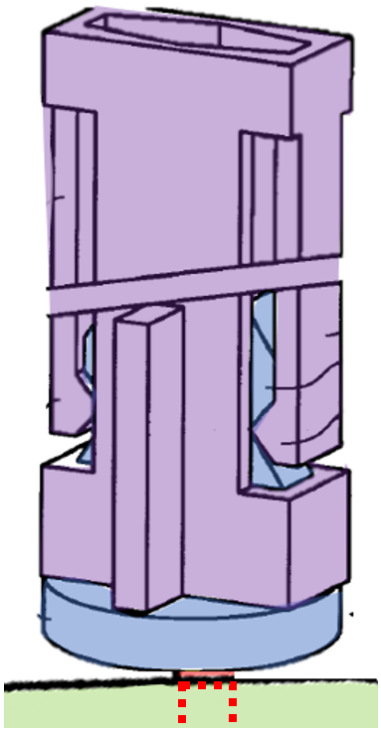
Traditional Disposable Lancets	**Saikley's Improved Lancet**

	
Ex.1005, Fig. 3 (Colored and Showing Only the Lancet and Cap)	**Ex.1005, Fig. 7A (Colored)**

77. By extending the "much larger" "handling tab" between the primary sheath and secondary sheath, Saikley's protective cap 78 provides the user with "a large protective cap for handling" the lancet prior to collecting a blood sample—or more specifically, when inserting a "fresh lancet into the lancet holder 68" of the lancing device 10. *Compare* Ex. 1005, ¶¶ [0050], [0087] *with* Ex. 1001, 8:17-20 ("The user installs the lancet into a corresponding lancing device by gripping the

lancet system by the handle portion of the cap and inserting the back end of the lancet into the receiver of the lancing device."). This installation is shown below:

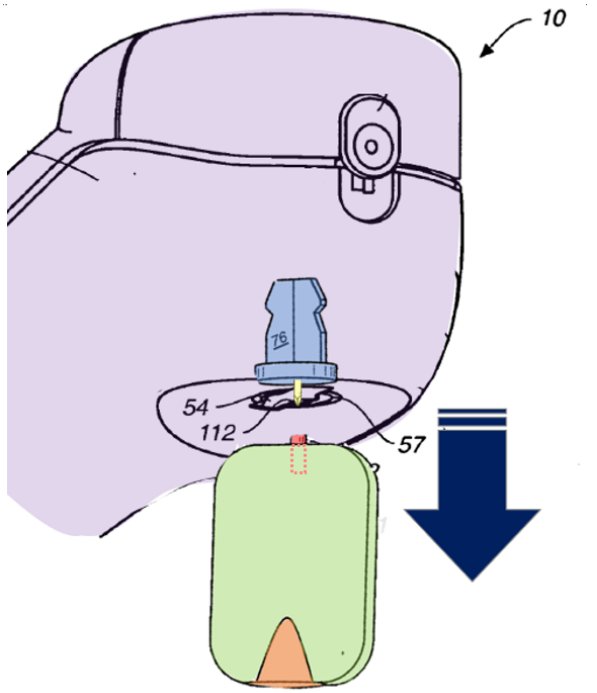


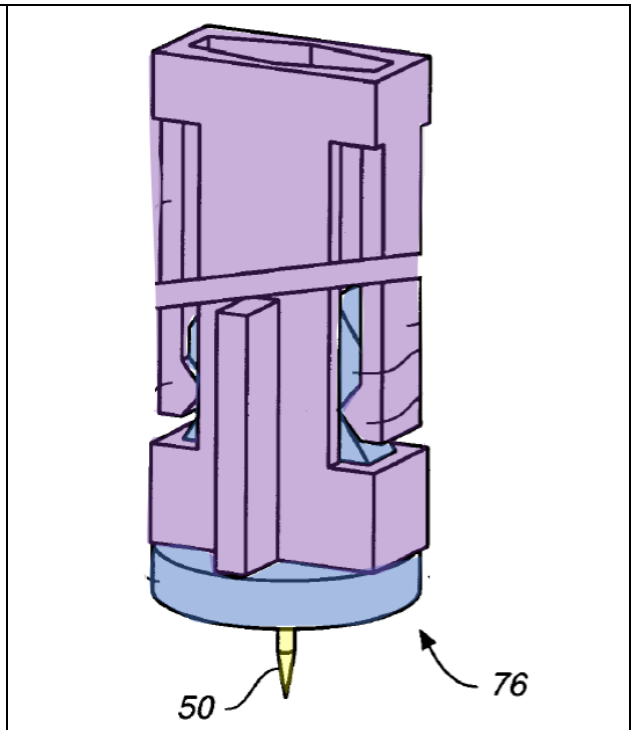


(Demonstrative: Installing Saikley's Unused Lancet)

78. The wide "tab" forming the gripping or handle portion of Saikley's protective cap 78 also provides the user with a firmer grip for removing the protective cap, making it easier to twist the cap off at its "twist-off joint" so that the lancet is not "damage[d]" or "pulled from lancet holder 68" when the patient tries to uncap the lancet 76. *Compare* Ex.1005, [0050-52], [0087] *with* Ex.1001,

6:1-10 (disclosing a "handle" for "assisting in removal of the cap from the lancet, and/or for replacement of the cap onto a used lancet for disposal."); Ex. 1001, 53-55 (disclosing a "handle with a greater width" for "allowing the user to more easily twist the endcap during removal from the lancet.")

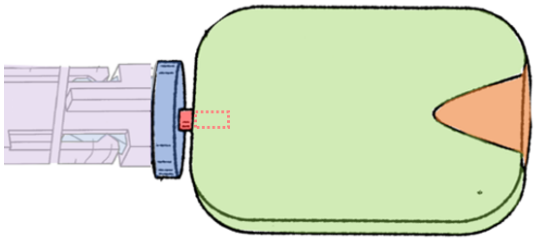




(Demonstrative: Uncapping Saikley's Fresh Lancet)

79. The elongated handling tab (*green above*) remains protruding out from the lancing device (*purple*) so that the user can apply torque when twisting the protective cap 78 from the lancet 76 (*blue*). The flat surfaces of the handling

tab allow the user to firmly grasp the protective cap 78 with the thumb and index finger and exert pressure while twisting. 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. Just like a key, Saikley's handling tab provides a large flat surface to provide a firm grip while turning.





(Demonstratives)

80. The "much larger" handling tab of Saikley's protective cap 78 provides leverage for applying rotational force to effectively twist the cap, making it easier to remove the protective cap 78 from the lancet 76. I believe a PHOSITA would appreciate that the increased leverage provided by the handling tab better

accommodates diabetic patients with limited dexterity by spreading the applied force efficiently across a wider contact area.

81. The "much larger" handling tab of Saikley's protective cap 78 also allows the users to grip the lancet further away from the needle sharp, which helps "eliminate the likelihood of the user accidentally sticking himself on the lancet sharp 50 while uncapping the lancet" or while "cover[ing] the sharp during removal from the device." Ex.1005, ¶¶[0050-52], [0064]; *Compare* Ex.1005, ¶¶[0050-52],[0064] *with* Ex. 1001, 6:61-66 ("The provision of the elongate handle portion 516 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.").

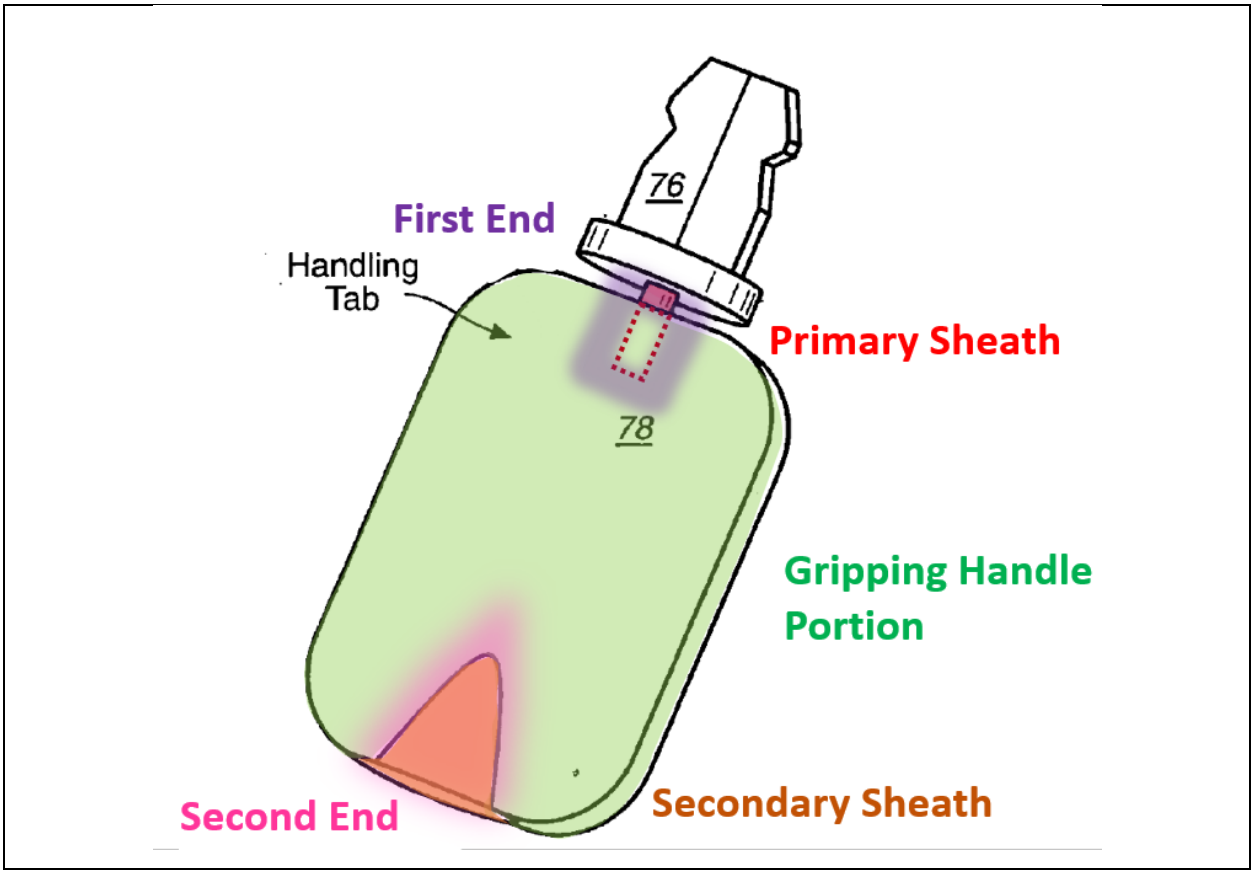
82. In my opinion, Saikley therefore discloses "a gripping handle portion [i.e., handling tab] extending between the primary sheath [i.e., twist-off joint] and the secondary sheath" [*i.e.*, hollow cup or pin-cushion type area 82]."

5. Saikley discloses claim 1[d] - "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"

83. Saikely's Figure 7a embodiment shows the primary and secondary sheaths attached to opposing ends of the handling tab (i.e., gripping handle portion) of the protective cap 78. Ex. 1005, FIG. 7A. Specifically, Saikley discloses that the primary sheath is attached at one end of the 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), as illustrated in Figure 7A below.

FIG. 7A (Annotated)



84. The primary and secondary sheaths are attached at opposing ends of the handling tab "when the protective sterility cap is removed from the lancet" and at all other times. Both sheaths are integrally molded to the protective cap so that they remain attached to the handling tab even after the user removes the puncture cap 78 from the lancet needle to collect a blood sample. Nothing in Saikley teaches or suggests somehow changing the integral structure of the protective cap, let alone detaching one of its sheaths "when the protective sterility cap is removed from the lancet" prior to use. Indeed, the "hollow cup or solid 'pin cushion' type

area 82 at the opposite end of cap 78" needs to remain available "to cover the sharp ***during removal*** from the [lancing] device and ***disposal***." Ex.1005, [0050].

85. In my opinion, Saikley therefore discloses a "primary sheath [i.e., twist-off joint and adjoining portion of the handling tab] attached at a first end of the gripping handle portion [i.e., the end of the handling tab adjacent to the reduced-size lancet in FIG. 7A] and the secondary sheath [i.e., hollow cup or solid pin-cushion type area 82] attached at a second end of the gripping handle portion [i.e., the end of the handling tab furthest from the reduced-size lancet in FIG. 7A] when the protective sterility cap is removed from the lancet [i.e., when the protective cap 78 has been separated from the reduced-size lancet 76.]"

B. <u>Discussion of Claim 2</u>

86. Claim 2 depends from independent claim 1. Saikley anticipates claim 1 for the reasons that I discussed above in Section IX.A, incorporated herein. Claim 2 adds: "[t]he protective sterility cap of claim 1, in combination with a lancet." The additional limitations of claim 2 are also disclosed by Saikley.

87. Saikely discloses that the protective sterility cap 78 [*colored green in Fig. 7A below*] covers the needle sharp 50 of the "shortened lancet 76" [*blue*] both before it is used to collect a blood sample, and "during removal from the [lancing]

device and disposal [colored blue below]." Ex.1005, [0050]; [0037] ("disposable lancet 46 having a plastic main body 48, a sharp 50 and removable cap 51 for covering sharp 50 when not in installed in device 10."); [0065] ("Cap 38 covers the lancet sharp 50 at all times and is removed only to replace the lancet 46.").

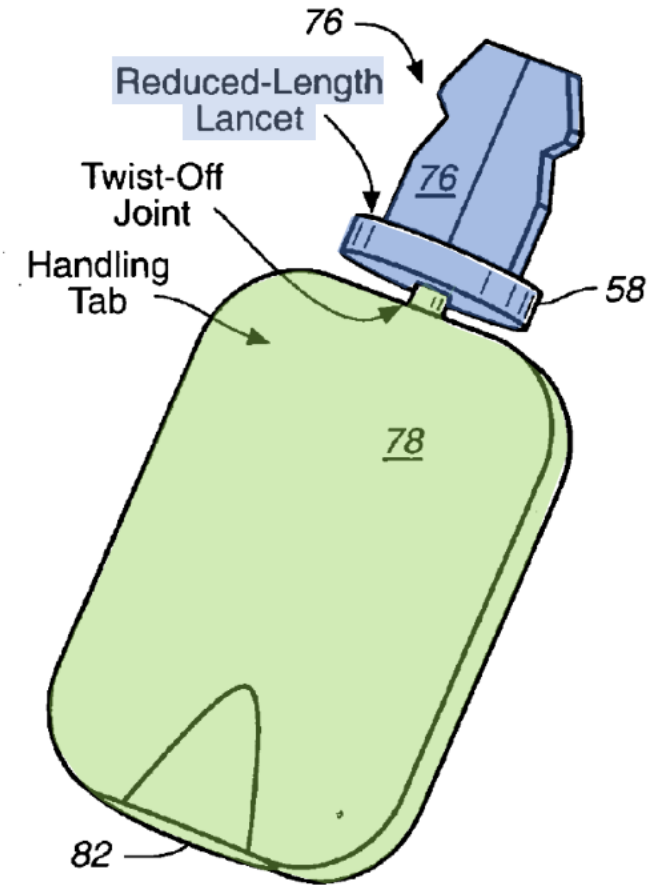


FIG. 7A

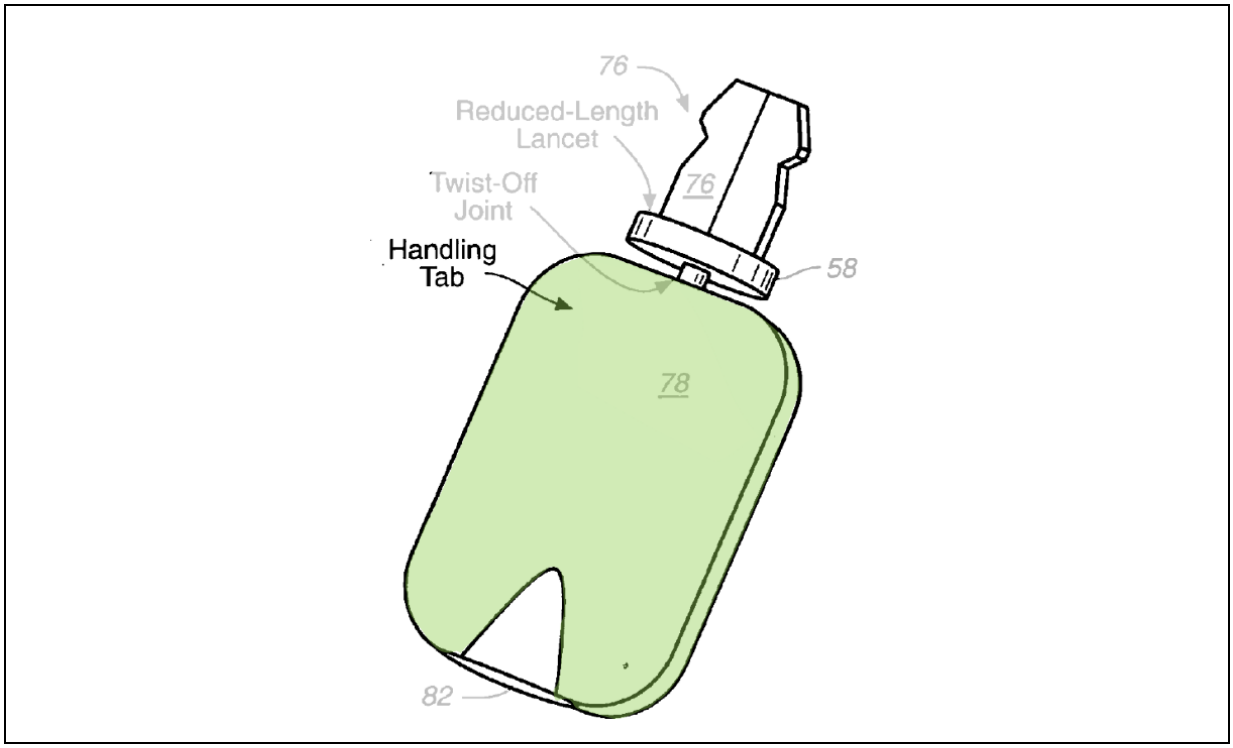
88. In my opinion, Saikley discloses "[t]he protective sterility cap of claim 1 [i.e., protective cap 78], in combination with a lancet [i.e., reduced-length lancet 76]."

C. Discussion of Claim 3

89. Claim 3 depends from claim 1, which I opined Saikley discloses for the reasons discussed above in Section IX.A, incorporated herein. Claim 3 adds that the claimed sterility cap further comprises: "at least one flat display surface for placement of branding indicia thereon."

90. In my opinion, Saikley anticipates the added limitation of claims 3 by disclosing that the protective cap 78 of the Figure 7a Embodiment comprises "at least one flat display surface"—namely, the flat display surfaces of the "handling tab."

FIG. 7A (colored)

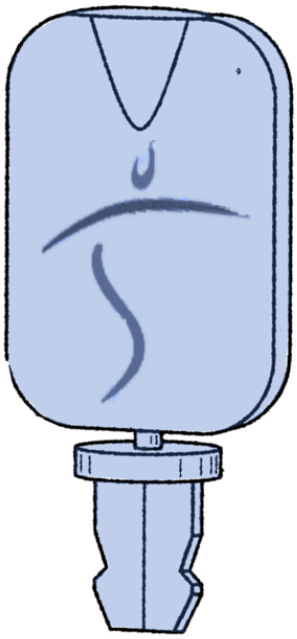


91. As shown above, the handling tab includes broad, flat surfaces. The remainder of the limitation—"for placement of branding indicia thereon"—recites the intended use of the invention and to my understanding, does not structurally limit the protective sterility cap disclosed.

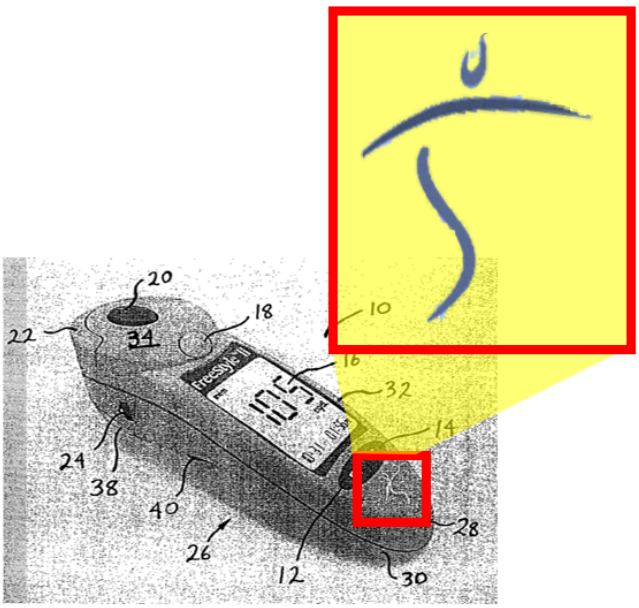
92. Saikley observes that "elderly patients and those with reduced eyesight and dexterity can have problems seeing and capturing [a] small sample," find it "difficult to remember all the steps and their proper order," and those "testing outdoors have a tough time juggling all of the different pieces during a test." Ex.1005, [0004]. To my knowledge, a PHOSITA would recognize that the

flat surfaces of Saikley's protective cap "aid handling" and would help keep the cap from rolling while the user switches between devices and proceeds to different steps.

93. Although not a limitation of the claim, Saikley discloses a flat surface on the handling tab of protective cap 38 that a PHOSITA would understand could be used for placement of branding indicia. I observe that Saikley provides multiple examples of branding indicia that are suitable for display on the handling tab of the Figure 7a embodiment, including the "FreeStyle™" (Reg. No. 2455840; Ex.1015) trademark and the butterfly logo from the "FreeStyle™ brand test strip" that Saikley teaches "is used with the present invention." Ex.1005, [0036]. As shown below, the flat surface of the handling tab is capable of displaying the branding indicia associated with "[t]he recently introduced FreeStyle TM Blood Glucose Monitoring System developed by TheraSense, Inc" and described in the patents that, to my understanding, Saikley incorporates by reference. Ex.1005 ¶¶[0003], [0036].

	
Ex.1015 (Registered Trademark Specimen)	**(Demonstrative)**

94. This is the same branding indicia appearing on the integrated lancing device 10 shown in Fig. 1 of "U.S. Provisional Application No. 60/424,414, entitled 'Automatic Biological Analyte Testing Meter with Integrated Lancing Device and Methods of Use,' filed on Nov. 6, 2002, which I understand is incorporated herein in its entirety by [Saikley]." Ex.1005, ¶[0003]; 37 CFR § 1.57.



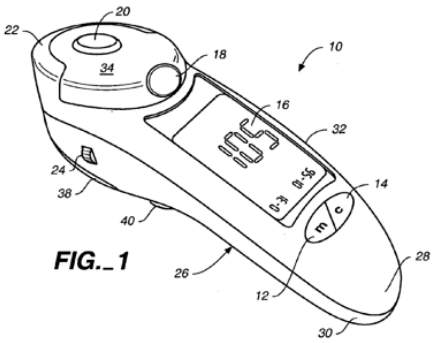


FIG._1

Ex.1016 (Saikley Provisional), Fig. 1	Ex.1005 (Saikley), Fig.1

95. In my opinion, Saikely discloses that the protective sterility cap further comprises "at least one flat display surface [*i.e.*, flat display surfaces on handling tab] for placement of branding indicia thereon [*i.e.*, branding indicia such as shown on the lancing device or test strips].

D. Discussion of Claim 5

96. Claim 5 depends from claim 1, which I believe Saikley anticipates for the reasons I discussed above in Section IX.A, incorporated herein. Claim 5 adds "wherein the gripping handle portion comprises a solid body without an open loop." In my opinion, Saikely anticipates claim 5 by disclosing that the protective

cap 78 is an "integrally-molded pull-off **tab**," which is depicted as having a solid body without any openings, let alone an open loop.

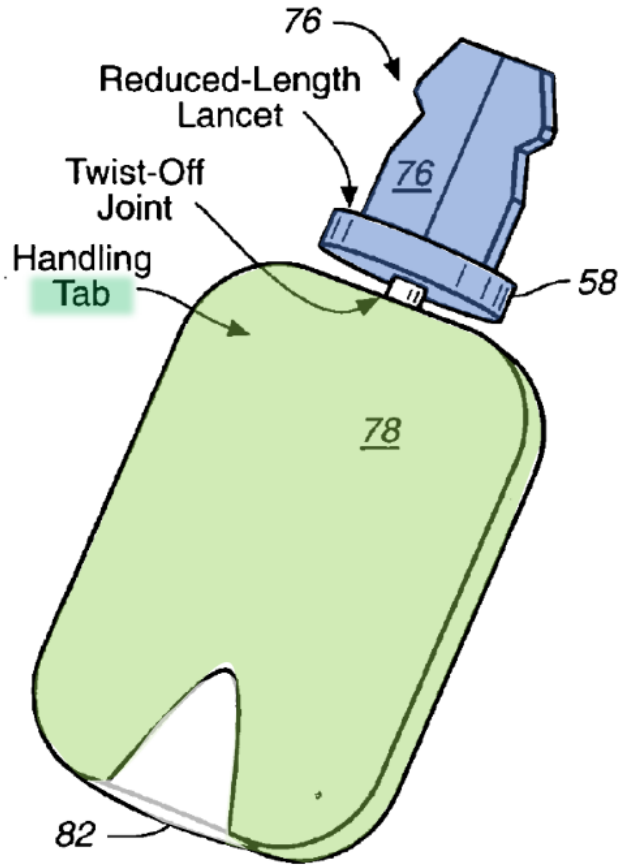


Fig. 7A (Colored)

97. In my opinion, Saikley further discloses that "the gripping handle portion [i.e., handling tab] comprises a solid body without an open loop [i.e., solid body of tab without an open loop]."

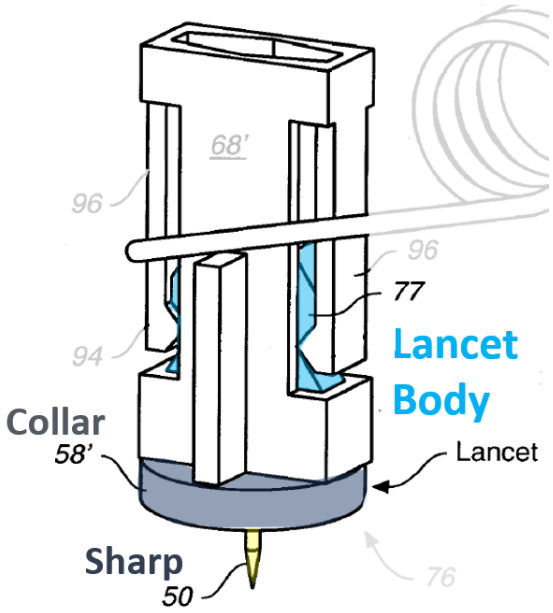
E. Discussion of Claim 6

98. Claim 6 depends from claim 1, which I believe Saikley anticipates for the reasons discussed above in Section IX.A, incorporated herein. Claim 6 adds: "[a] in combination with a lancet [b] having a lancet body defining a lancet thickness, [c] and a sharp lancet tip initially embedded in the primary sheath, [d] wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness."

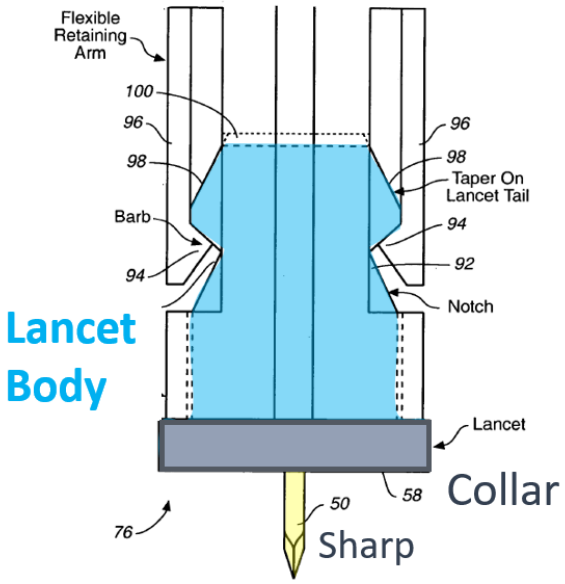
99. For element 6[a], in my opinion, Saikley discloses the protective sterility cap of claim 1 [i.e., protective cap 78 shown in Fig. 7A] in combination with a lancet [i.e., shortened lancet 76"], for the same reasons I explained for claim 2 in Section IX.B, incorporated herein.

100. For element 6[b], Saikley teaches that the "reduced-length lancet 76" (colored blue in Fig. 7A below) consists of (1) a "lancet body" forming a "plastic housing" that is "generally flat and has a notch 92 on each edge," (2) a "sharp 50 molded within the plastic housing," and (3) a "lancet guiding collar" that engages with the lancing device to control the position and direction of the lancet within a lancing device Ex.1005, ¶¶[0041-42]; *id.,* ¶[0037] ("disposable lancet 46 [has] a plastic main body 48" and "a sharp 50"); *id.,* ¶[0044] (describing the "insert

molding processes" as when "metal sharps 50 and 64 are molded within plastic housings 48 and 66, respectively.").



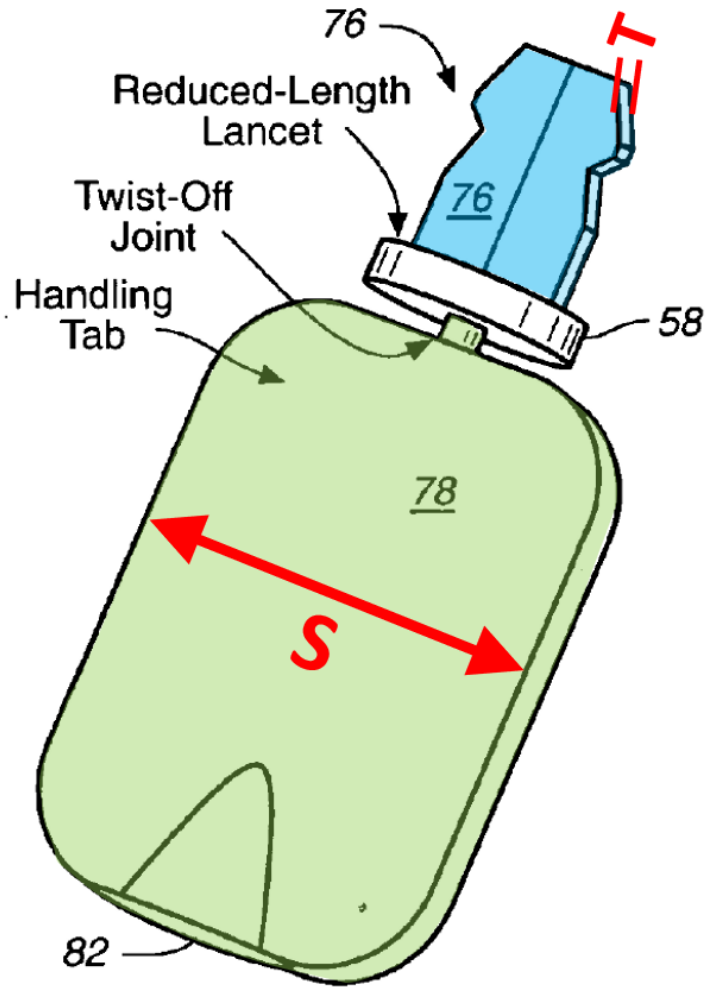
Saikley, Fig. 6 (Colored and Annotated)



Saikley, Fig. 8 (Colored and Annotated)

101. For element 6[c], a PHOSITA would have recognized from Saikley's disclosures of an "integrally molded cap" that the sharp lancing tip 50 is initially embedded in twist-off joint and the adjoining portion of pull-off tab 78, for the same reasons I provided for claim 2 in Section IX.B, incorporated herein.

102. As to the relative-dimensions recited (6[d]), I believe 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*).



Saikley, Fig. 7A (Colored and Annotated)

103. I understand Saikley emphasizes the size of the handling tab relative to the lancet by describing cap 78 as a "large lancet cap for handling (Ex.1005, [0049]) and noting that it is "made much larger than usual to aid handling." Saikley also makes clear that the lancet is smaller than the easily handled tab of cap 78, as I observe that the "short length [lancet] might make the lancet difficult for the user to handle and install." *Id.*, [0050]. In view of these textual descriptions and the depiction in Figure 7A showing a cap 78 with a lateral span much larger than 1.5 times the lancet thickness (annotated below), a PHOSITA would have understood element 6[d] to be expressly or, at least inherently, disclosed.

104. Additionally, Saikley's lancet would have been handled by a user pinching the handling tab between a thumb and a digit on the user's hand. A PHOSITA would have also appreciated that the average human thumb has a diameter of 16 mm in size. Ex.1022, 157. In light of this, a PHOSITA would have understood Saikley's instruction to make its cap 78 "much larger than usual to aid handling" (Ex.1005, [0050]) 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. Because the "standard lancet" had a

diameter of less than 6 mm (Ex.1017, 9:67-10:10, which I understand to be incorporated by reference in Saikley and referred to hereinafter as "incorporated-by-reference LeVaughn"), a PHOSITA would have understood Saikley to teach that its lateral span was more than twice the lancet thickness. I believe Saikley expressly taught or, at a minimum inherently disclosed, the limitation of a gripping portion with a lateral span at least 1.5 times the lancet thickness. This is consistent with what I understand of incorporated-by-reference LeVaughn, which teaches that a "transverse ratio (W/t) of at least 3:2, and more preferably about 2:1, provides an easy to grip [lancing] device which resists twisting about the central axis." Ex.1017, 5:15-18.

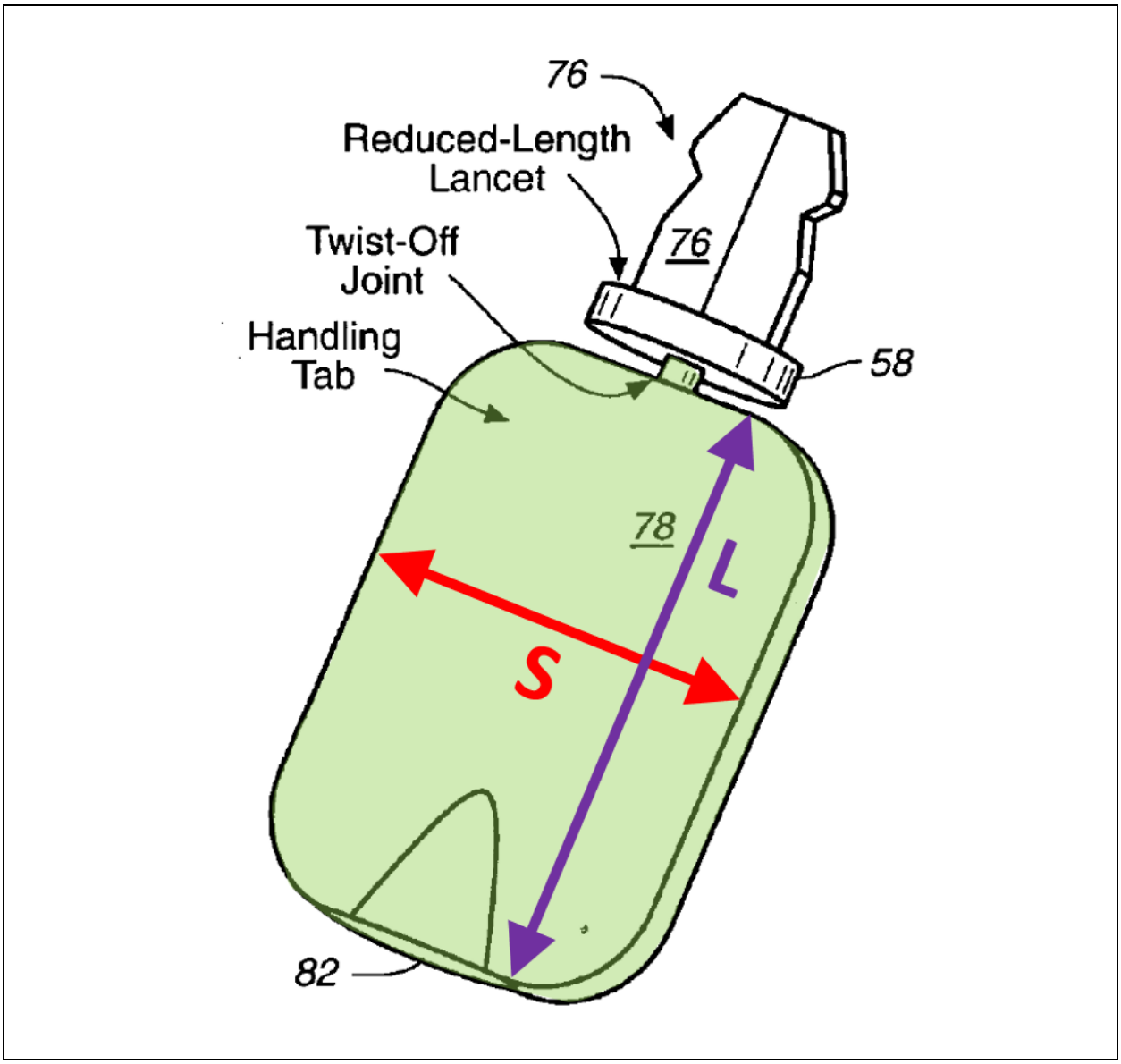
105. In my opinion, claim 6 is therefore anticipated.

F. Discussion of Claim 7

106. Claim 7 depends from claim 6, which Saikely anticipates for the reasons I provided above in Section IX.E, incorporated herein. Claim 7 adds "wherein the gripping handle portion defines a length at least equal to its lateral span."

107. As I explained above, a PHOSITA would have understood Saikley's Figure 7A (in conjunction with the textual descriptions concerning larger lancet

caps for handling) to plainly depict a gripping handle portion (cap 78) that is much larger than 1.5 times the lancet thickness. Because Saikley's Figure 7A also shows that the length of its cap 78 is significantly larger than the cap's lateral span, this additional limitation of claim 7 is also disclosed.



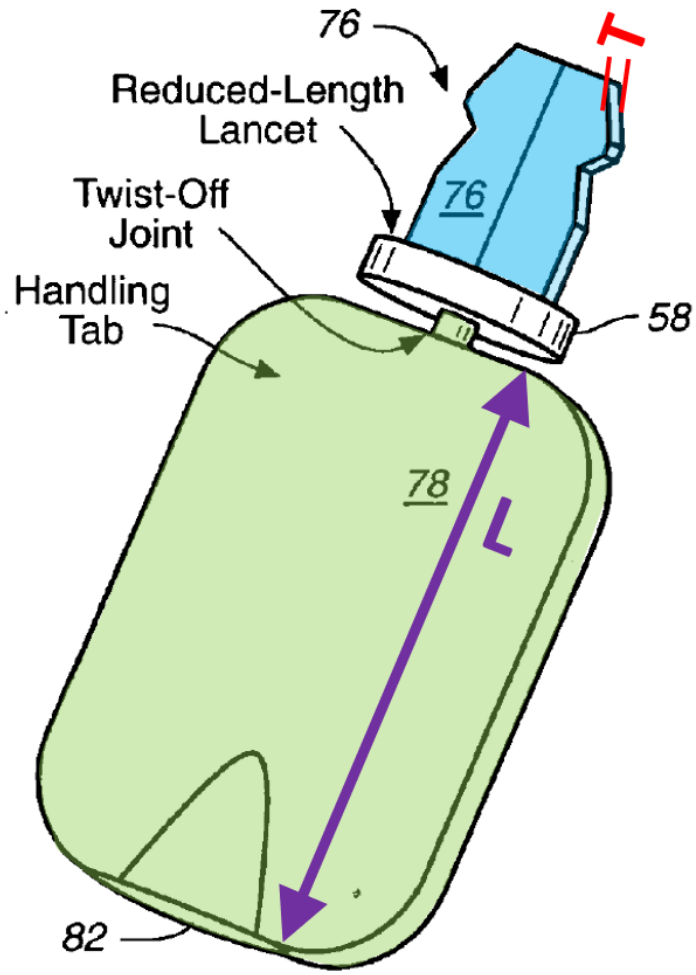
Saikley, Fig. 7A (Colored and Annotated)

108. In my opinion, claim 7 is therefore anticipated.

G. Discussion of Claim 8

109. Claim 8 depends from claim 6, which Saikely anticipates for the reasons I discussed above in Section IX.E, incorporated herein. Claim 8 adds "wherein the gripping handle portion defines a length at least equal to the lancet thickness."

110. Because Saikley discloses both that the gripping handle portion (cap 78) is at least 1.5 times the lancet thickness (*supra* Section IX.E, incorporated here) and that the gripping handle portion's length is at least equal to the lateral span (*supra* Section IX.F, incorporated here), the length of Saikley's gripping handle portion must also necessarily be at least equal to (including larger than, as Saikley teaches) the lancet thickness.



Saikley, Fig. 7A (Colored and Annotated)

111. In my opinion, claim 8 is therefore anticipated.

H. Discussion of Claim 14

112. Claim 14 includes limitations analogous in scope to limitations 1[pre]-1[d], and those are disclosed by Saikley for reasons I provided above and incorporated here (*supra* Section IX.A.1-5). Claim 14 also includes limitations

analogous in scope to those found in claim 6, and those are disclosed by Saikley for reasons I provided above and incorporated here (*supra* Section IX.E).

I. Discussion of Claim 16

113. Claim 16 depends from claim 14, which is anticipated by Saikley for reasons provided above and incorporated here (*supra* Section IX.H). The additional limitations of claim 16 correspond in scope to those found in claim 3, and, in my opinion, those additional limitations are disclosed for the same reasons (*supra* Section IX.C).

J. Discussion of Claims 17 and 18

114. Claims 17 and 18 depend from claim 14, which is anticipated by Saikley for reasons I provided above and incorporated here (*supra* Section IX.H). The additional limitations of claim 17 correspond in scope to those found in claim 7, and those additional limitations I believe are disclosed for the same reasons (*supra* Section IX.F). The additional limitations of claim 18 correspond in scope to those found in claim 8, and those additional limitations I believe are disclosed for the same reasons (*supra* Section IX.G).

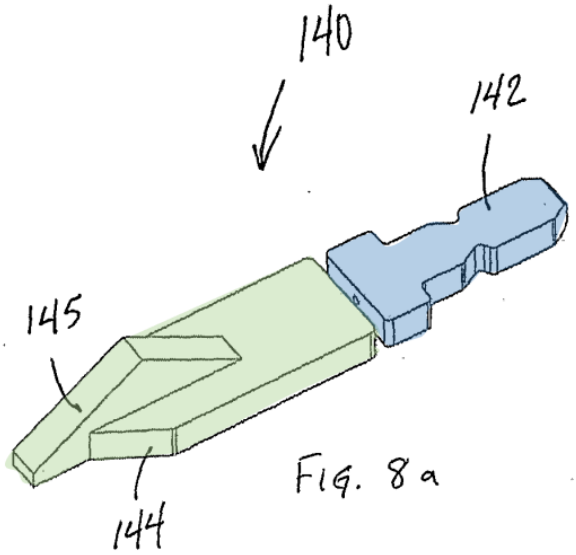
X GROUND #2: SAIKLEY RENDERS OBVIOUS CLAIMS 1-3, 5-8, 14, AND 16-18

115. For the reasons I set forth below, in my opinion, Saikley discloses all of the limitations of claims 1-3, 5-8, 14, and 16-18 of the '635 Patent and renders them obvious.

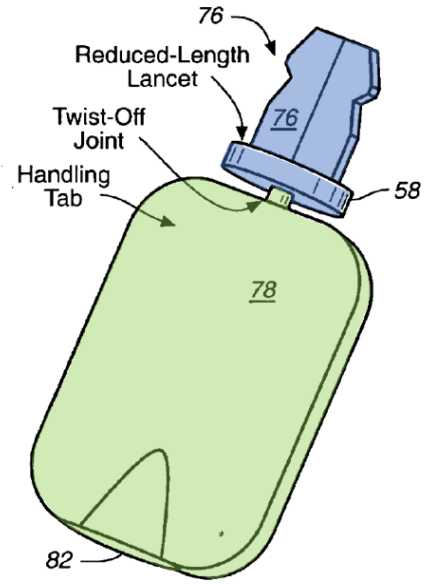
A. All Claims: "Primary Sheath for Initial Embedment"

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 green in FIG. 8A below*) is likewise "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].



Stout, Fig. 8a



Saikley, Fig. 9

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 the lancet needle into Saikley's cap 78 would not only protect the integrity of the needle tip, but also would protect the sterility of the needle and would prevent contamination during post-manufacturing packaging, shipping, and storage.

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 include an embedded needle sharp, a PHOSITA would only need to use traditional insert molding methods, for high-volume, low-cost manufacturing. Thus, modifying Saikley's cap to include an embedded needle sharp would have been achieved with a reasonable expectation of success by using these common manufacturing techniques. At that time, "most other lancets [that were] currently in use" would have "encased the needle in a plastic body with the needle tip embedded in a removable protective cap integrally molded with the plastic body to form a single integral unit prior to use." Ex.1009, [0008]. Additionally, a PHOSITA would have been motivated to embed the lancet needle within the twist-off joint and adjoining portion of the handling tab of the protective cap 78 makes the needle tip 50 more resistant to the "non-axial cocking or pivoting movement of the endcap when it is twisted off by the user, which could bend or break the needle tip." Ex.1019, [00027].

B. All Claims: "Secondary Sheath for Receiving."

120. In my opinion, not only does Saikley expressly disclose a secondary sheath 82, Saikley also teaches alternative designs for a secondary sheath that more closely resemble the secondary sheath of the embodiments in the '635 patent. Thus, to the extent Patent Owner argues that Saikley's express teaching of secondary sheath 82 fails to teach the claimed secondary sheath, it would have been obvious to modify Saikley to have (i) a different type of secondary sheath (in addition to sheath 82) or (ii) to remove sheath 82 and to instead use a different type of secondary sheath.

121. A PHOSITA would have been motivated to combine the features of Saikely's Figs. 7A and 7C embodiments, because Saikley describes advantages associated with the different type of secondary sheath (82'' in Figure 7C). Saikely emphasizes that adding an additional sheath 82'' "offers **the advantage** of **allowing the user to extend cap 84 up into device cap 38 to cover sharp 64** while lancet 62 is still in place in integrated device 10." Ex.1005, [0052]. Saikely also adds that "used lancet 62 and cap 84 can be ejected from device 10 together as a unit so that **the user need not handle small lancet 62 separately while trying to align it with cap 84**." *Id.* In view of these advantages, a PHOSITA would have

been motivated to incorporate sheath 82'' into the Figure 7A embodiment of Saikley or, at a minimum, would have been motivated to try this design for a secondary sheath to realize these advantages. A PHOSITA would have also been using a known technique (design of a perpendicularly-extending secondary sheath) to improve similar devices (Saikley's different embodiments of lancet caps) in the same way (adding an additional secondary sheath to a lancet cap).

C. Claims 6-8, 14, and 17-18: The "Length" and "Lateral Span" of the Gripping Handle Portion

122. As I explained above (*supra* Sections IX.E-G, IX.H, IX.J, incorporated here), Saikley anticipates the "length" and "lateral span" limitations. Because Saikley is being modified in this Ground only by combining embodiments of Saikley and based on a PHOSITA's general knowledge of primary and secondary sheaths, the modified Saikley in this Ground would have retained the features from Saikley that disclose these relative-dimensional aspects, including the gripping handle's lateral span being at least 1.5 times the lancet thickness (claims 6 and 14) and the gripping handle's length being at least equal to the lateral span (claims 7 and 17) and the lancet thickness (claims 8 and 18).

123. All of the relative-dimensional limitations taught in Saikley would have been obvious for a PHOSITA to try. There was an art-recognized problem of

lancets being held by people with limited dexterity or other challenges (including the elderly and others who have difficulties grasping and manipulating lancets) that might accidentally poke themselves with needles if sharp needle tips were not properly sheathed both before and after use. This recognized problem led to many sterility caps being developed with both primary and secondary sheaths and gripping handles located between them to facilitate ease of handling. In light of this, a PHOSITA would routinely be required to experiment with the dimensions of the gripping handle portion (in both its lateral span and length) in seeking to optimize sterility caps for mass-market use. This experimentation would have encompassed the finite number of potential dimensional solutions the gripping handle portion as compared to thickness of the lancet. With this context in mind, a discussion of the obviousness of each of the relative dimensional aspects below.

124. As to the gripping handle's lateral span being at least 1.5 times the lancet thickness (recited in claims 6 and 14), it was already known that gripping handles on many sterility caps were larger than the lancet thickness. Saikley is one example of this, because as is visually apparent from the depiction of the handling tab/ protective cap 78 in Saikley's Figure 7A, which Saikley describes as a "larger lancet cap for handling," a PHOSITA would have known that this cap "should be

made much larger than usual to aid handling." Ex.1005, [0050]. Designing a gripping handle's lateral span to be at least 1.5 times the lancet thickness would have been pursued by a PHOSITA as a matter of routine optimization and with a reasonable expectation of success, particularly in view of Saikley's express instruction to create a cap that "should be made much larger than usual to aid handling." Ex.1005, [0050]. Both express statements in Saikley and the knowledge of those skilled in the art would have motivated a PHOSITA to try various larger dimensions for the gripping handle portion of Saikley. And, given the instruction to create a large enough gripping handle portion "to aid handling," a PHOSITA would have utilized dimensions for the cap 78 in Saikley that allowed a user to easily handle the cap 78 with their fingers, including creating a large enough cap 78 to at least be held between the average human fingerpad size of 16-20 mm. Ex.1023, 685.

125. To my knowledge, Saikley incorporates by reference U.S. Patent No. 6,283,982, which indicates that an opening for receiving a lancet should be "less than about 6 mm in diameter, so that a standard lancet will not pass therethrough," which means that "standard" lancets were less than 6 mm in diameter. Ex.1017, 10:3-6. Thus, in designing Saikley's cap 78 to be held by the average human

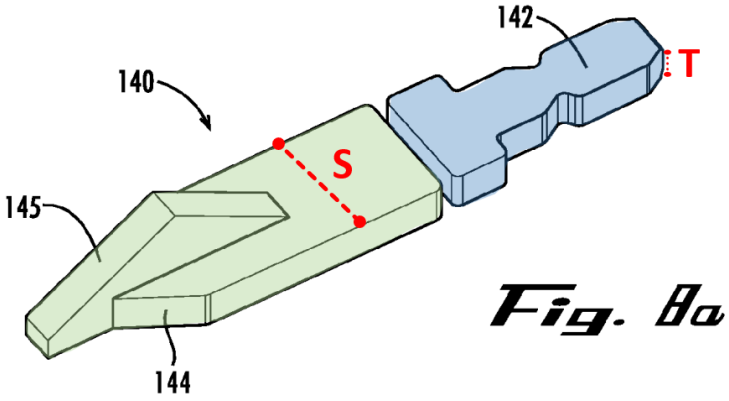
fingerpad, a PHOSITA would have routinely designed a cap 78 that would have been at least 1.5 times the thickness (diameter) of a standard lancet.

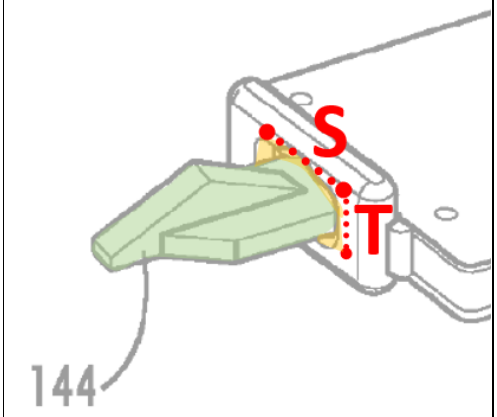
126. As to the gripping handle's length being at least equal to the lateral span (recited in claims 7 and 17), a PHOSITA would have tried various dimensions for the length and lateral span of the handling tab in Saikley, to ensure proper handleability for users with limited dexterity, such as the elderly. Designing a handling tab with a length at least equal its lateral span would have been a natural option that would have been achieved with a reasonable expectation of success.

127. As to the gripping handle's length being at least equal to the lancet thickness (recited in claims 8 and 18), this again would have been a natural choice for a PHOSITA who would have appreciated that users had difficulty handling lancets and that a gripping handle should be made at least equal to, but preferably much larger than, the lancet thickness.

128. In my opinion, the claimed limitations would also be rendered obvious by Saikley in view of Stout, which teaches that "the slotted opening 32 [of the lancing device]"—which lancet must pass through—"has a [lateral span] ***considerably greater*** than its [lancet thickness], most preferably having a [lateral

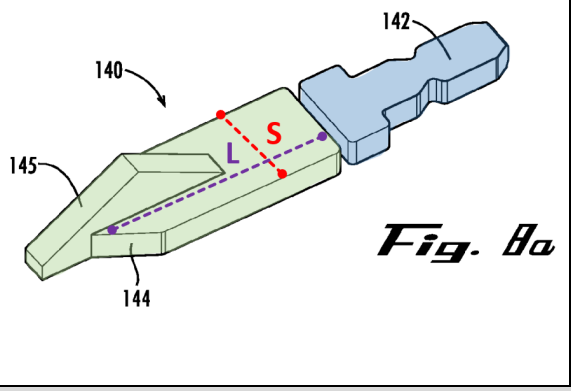
span] at ***least twice*** its [lancet thickness]." Ex.1018, [0032]; *see also id.*,[0035] ("The lancet body 42 preferably has a flattened profile along at least a proximal portion of its length, having a first dimension [lateral span] ***substantially larger*** than a second dimension [thickness], and configured to pass freely through the slotted opening 32 in the housing 30 when aligned therewith").

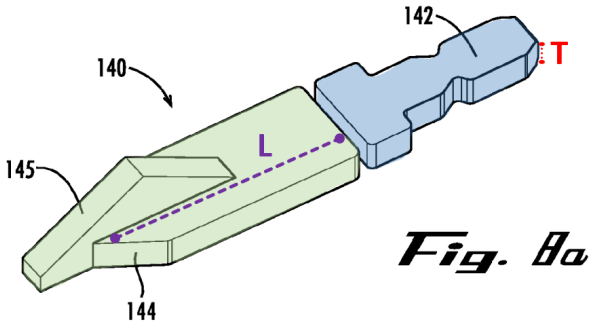




Stout, Figs. 8a and 8b (Colored and Annotated)

129. I believe a PHOSITA would have understood Stout's Figures 8a-8c (in conjunction with the textual descriptions) to plainly depict a gripping handle portion (cap 78) with a considerably greater length and lateral span than 1.5 times the lancet thickness.





Stout, Fig. 8a (Colored and Annotated)

130. In my opinion, Saikley in view of Stout renders obvious claims 6-8, 14, and 17-18.

D. Ample Motivation Existed to Combine Saikley with Stout

131. I believe a PHOSITA would have been motivated to combine Saikley and Stout for at least the following reasons.

132. *First*, a PHOSITA would have appreciated that Saikley and Stout are within **the same field of endeavor** and **address the same problem**.

133. *Second*, Saikely and Stout are reasonably pertinent to a problem identified in the '635 Patent. I understand the '635 Patent identifies the claimed invention as one which relates to "lancets and lancing devices for blood sampling and testing." Ex.1001, 1:17-19. Both Saikley and Stout relate to lancing devices.

Ex.1005, [0002]; Ex.1018, [0006]. The '635 Patent also describes how "[i]mprecise alignment of the lancet in the lancet carrier may result in increased pain sensation by the subject." Ex.1001, 5:28-29. Saikley discloses a lancet where the "flat shape of lancet body 66 allows for such alignment and prevents misalignment." Ex.1005, [0054]. Similarly, Stout also discloses a lancet "along at least a portion of its length having a flattened profile with a first dimension substantially larger than a second dimension" and where the "lancet body and the lancet carrier are coplanarly aligned when the lancet is installed" to provide stability to both the lancet and carrier during the lancing stroke. Ex.1018, [0009], [00040]. In my opinion, Saikley and Stout therefore disclose inventions in the same field of endeavor as the '635 Patent while also addressing one of the problems identified by the '635 Patent.

134. In addition, I believe a PHOSITA would have been motivated to combine Saikley and Stout because such a combination would be commercially desirable and it would be obvious to try. Indeed, Stout specifically teaches that its lancing system "can be provided as an upgrade or retrofit component for ***backwards-compatible attachment to an existing meter***, such as for example … the Abbott FreeStyle Flash Meter"—the same system disclosed by Saikley.

Ex.1018, [00046]; Ex.1005, [0003]. Utilizing the Stout system with the compatible meter disclosed in Saikley would provide users with a known method to yield predictable results—allowing users to access the benefits disclosed in Stout of a "lancing device that can be attached to a blood glucose meter for convenience and to avoid loss." Ex.1018, [0005]. A PHOSITA would also be assured that this combination would be successful because mounting the Stout lancing device to a removable portion of an existing meter "does not negatively impact the meter's operation." Ex.1018, [0046].

135. *Finally,* the Saikley and Stout combination would be one that I believe a PHOSITA would have a reasonable expectation of success in because both Saikley's protective cap 78 and Stout's sterility cap 44 perform the same function and would yield predictable results. Saikley's protective cap 78 may be "integrally molded" to "a shortened lancet" and thus must be "made much larger than usual to aid handling." Ex.1005, [0050]. Like Saikley, Stout's cap 44 is co-molded with a "small and lightweight lancet body" and is preferably "large or oversized" to "facilitate easier handling and loading of the lancet into the lancet device." Ex.1018, [0035]. In my opinion, modifying Saikley's protective cap with

the features of Stout's sterility cap would yield the predictable result of providing a large lancet cap to make a lancet easier to handle.

136. As such, I believe it would have been straightforward for a PHOSITA to improve of Saikley's protective cap 78 with Stout's sterility cap 44 and know that such a combination would be feasible.

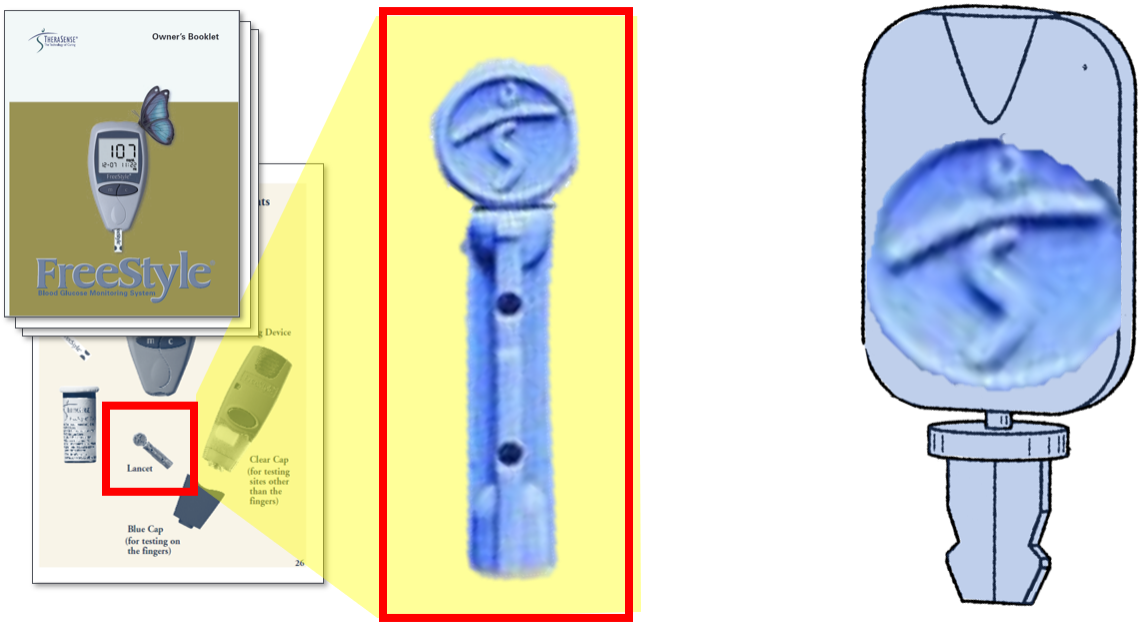
XI GROUND #3: SAIKLEY IN VIEW OF THE FREESTYLE MANUAL RENDERS OBVIOUS CLAIMS 3 AND 16

137. For the reasons I set forth below, in my opinion, claims 3 and 16 of the '635 Patent are disclosed by the combination of Saikley and the FreeStyle manual.

138. As I explained previously, Saikley anticipates claims 3 and 16 by disclosing the flat surface of the handling tab on the lancet's protective cap 78 (shown below) because it is my understanding the remainder of the limitation—i.e., "for placement of branding indicia thereon"—merely recites an intended use.

139. In my opinion, the recitation of "for placement of branding indicia thereon" is disclosed by a combination of Saikley and FreeStyle. The combination of these two references is straightforward as FreeStyle expressly teaches using a flat display surface of a cap to display branding indicia (*i.e.*, the FreeStyle logo) as

shown below. This combination would be obvious given the express teaching in Saikley of a cap with large flat surface, in conjunction with Saikley's instruction to use "an existing test strip, such as the **FreeStyle™ brand** test strip … **with the present invention**…" Ex. 1005, [0036]. With this express guidance, a PHOSITA seeking to build the Saikley device would have naturally looked to FreeStyle devices (as Saikley instructs a PHOSITA to do) and would have seen that sterility caps for the FreeStyle devices include branding indicia on a flat surface of the cap.



(Demonstrative)

140. As an initial matter, both Saikley and FreeStyle are analogous art to the '635 Patent because they are both within the same field of endeavor. It is my

understanding that the technical field of the claimed invention in the '635 Patent relates "generally to the field of medical devices" and particularly to "lancets and lancing devices for blood sampling and testing." Ex.1001, 1:17-19. Like the '635 Patent, Saikley relates to skin lancing devices while FreeStyle provides for the "FreeStyle Blood Glucose Monitoring System" which is used for "measuring blood glucose . . . from samples" taken from different areas of the body. Ex.1005, [0002]; Ex.1010, 111.

141. In addition, Saikley and FreeStyle are reasonably pertinent to the particular problem identified in the '635 Patent. The '635 Patent provides for various lancet designs which "allow a unique or proprietary matching lancet and lancet receiver or carrier" where only lancets "of a specified design will fit." Ex.1001, 5:53-57. The '635 Patent further describes how the claimed invention can assure users "of the type and/or source of the lancet being used, including its quality, sterility, size, format [and] other characteristics." *Id.*, 5:58-60. The '635 Patent also notes that "[i]mprecise alignment of the lancet in the lancet carrier may result in increased pain sensation by the subject." Ex.1001, 5:28-29.

142. Saikley addresses the same problems identified in the '635 Patent by disclosing a non-standard lancet body that is "shortened," "flattened," and

"notched" on both sides in order to fit into a distinctive lancet carrier of a lancing device. Ex.1005, ¶¶ [0050], [0054], [0060]. Saikley additionally discloses that the "flat shape of lancet body 66 allows for such alignment and prevents misalignment." Ex.1005, [0054]. Like Saikley, FreeStyle discloses the steps for testing blood glucose with the FreeStyle Blood Glucose Monitoring System, including the steps for inserting a lancet into a lancing device. Ex.1010, 121-22. For these reasons, I believe Saikley and FreeStyle are analogous art to the '635 Patent.

143. A PHOSITA would have ample motivation to add FreeStyle-related branding to Saikley's protective cap. Saikley discloses a non-standard lancet body that is only compatible with Saikley's integrated device. The Saikley lancet is "shortened" as compared to "[t]raditional disposable lancets, such as shown in FIG. 3, [which] have an elongate body 48 and a short cap 51." Ex.1005, [0050]. The Saikley lancet also has a body which "is generally flat and has a notch 92 on each edge for receiving barbs 94 on the [integrated device lancing subsystem] plunger's flexible retaining arms 96." *Id.*, [0060]. The body of the Saikley lancet is "flat or keyed to allow the lancet holding mechanism to keep sharp 50 oriented properly with the lancing axis." *Id.*, [0058]. A PHOSITA would recognize that

the dimensions and shape of the Saikley lancet are uniquely oriented to be fit in the Saikley integrated device. Indeed, while traditional lancets like the one seen in FIG. 3 are universally made to fit a wide variety of lancing devices, a PHOSITA would recognize the dimensions disclosed for the lancet in Saikley is specific to the Saikley integrated device.

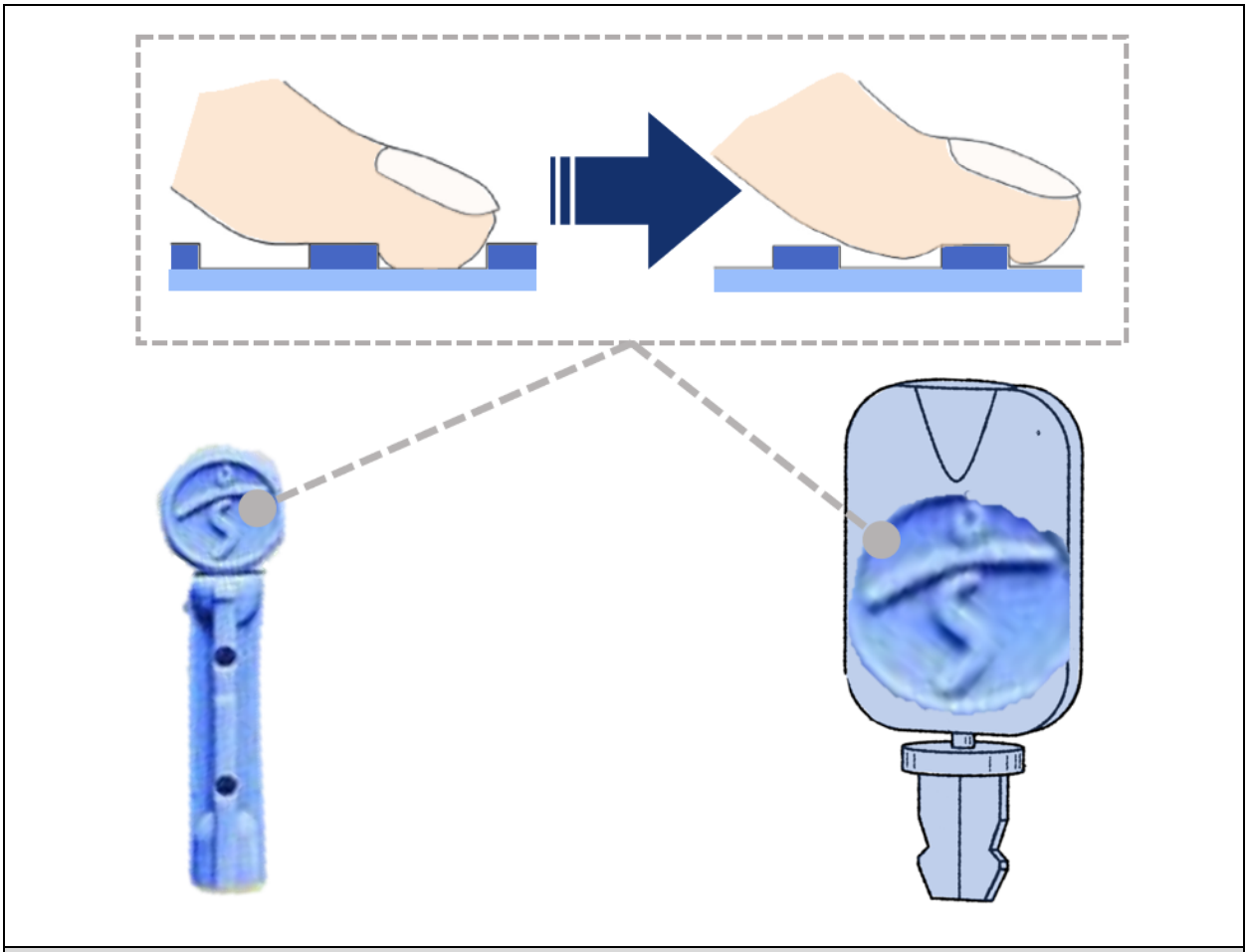
144. As the Saikley lancets are unique to the Saikley integrated device and differ substantially from traditional lancets, a PHOSITA would be motivated to further improve upon Saikley's teachings for the benefit of the patients who use the device. As Saikley explains, "[t]o assist patients who may be used to [handling] lancets differently," the lancet cap is "formed in the shape of an arrow, reminding patients to pull cap 84 off of lancet 62 rather than twisting." Ex.1005, [0051]. Saikley teaches placing "indicia," like the arrow shape of the protective cap, in order to remind patients of the proper operation of the lancet. *Id.* In view of Saikley's teachings, it would have been obvious for a PHOSITA to improve Saikley's device by placing other indicia, such as the Abbott branding associated with the FreeStyle Blood Glucose Monitoring System, to the protective cap of the lancet as a signal to patients that the lancet operated differently.

145. A PHOSITA would be motivated to combine Saikley's device with the FreeStyle branding because it would improve the safety of the device for patients. By adding the FreeStyle-related branding to the Saikley protective cap, patients are better informed regarding the requirements of the Saikley integrated device. If a patient were to try to insert a non-Saikley lancet into the Saikley integrated device, the patient would be at an increased risk of experiencing pain when lancing due to imprecise alignment of the lancet with the device. In addition, if a traditional lancet is used, because it is elongated it would have more of the lancet protruding from the integrated device when loaded. With the lancet protruding, when the user attempts to remove the cap, the user may also harm themselves and bend the needle because torque is being applied at an angle. If a patient were to harm themselves by using a non-compliant lancet with the Saikley integrated device, a patient may choose to forgo testing their blood glucose for fear that they would have another painful lancing experience. It would have been well-known to a PHOSITA that patients who need to use lancets and lancing devices tend to be hesitant or fear manually sticking themselves when using such devices. Having an obvious indicator, like the FreeStyle branding, on the protective cap of the lancet would mitigate the harm to the patient and inform them of the specific use requirements for the Saikley integrated device.

146. A PHOSITA would be further motivated to add the FreeStyle branding to the Saikley lancet because such a combination would be commercially desirable. Because the Saikley lancets are specific to the Saikley integrated device, a user risks damaging the device when attempting to use it with traditional lancets. When forcing a traditional lancet into the Saikley integrated device, either the prongs on the lancing carrier will snap when the lancet is fired or some other aspect of the lancing carrier will be damaged. If a different, non-traditional lancet was used, the lancing device may become inoperable as only a lancet with an even shorter body than the Saikley lancet would be able to fit in the lancing device. By using a shorter, non-traditional lancet, a patient would further risk damaging the device as the lancet could slide further back into the device and it would be difficult to remove. In my opinion, to prevent patients inadvertently damaging their lancing devices, it would be commercially desirable for a PHOSITA to integrate the FreeStyle branding with Saikley's lancet.

147. In addition, a PHOSITA would have been motivated to add the FreeStyle branding to the Saikley lancet because doing so would improve a patient's grip on the lancet. Industrial designers often incorporate embossed logos or symbols on the surface of an object to provide increased friction for users when

handling small objects. As seen in the example below, having the embossed logo on the protective cap of the Saikley lancet would provide areas where patients can grip the lancet with higher friction.

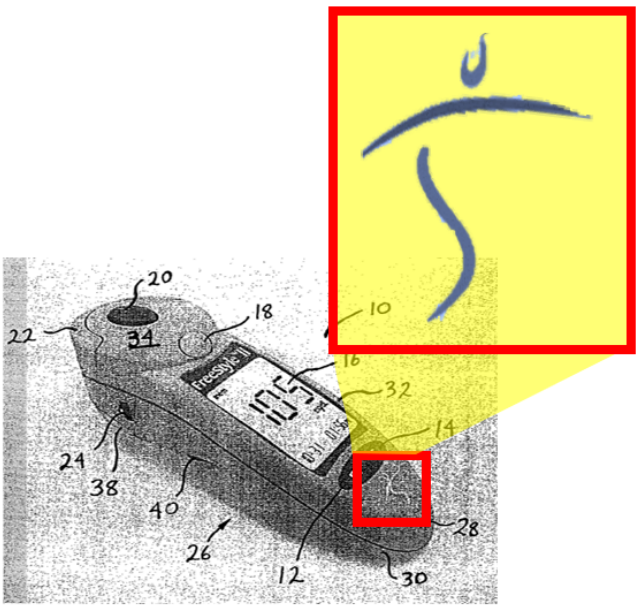


(Demonstrative)

148. In my opinion, a PHOSITA would be motivated to make this combination and improve the grip of the Saikley lancet because its "shortened,"

"flattened," and "notched" shape makes it different from traditional lancets. Ex.1005, ¶¶ [0050], [0054], [0060].

149. Lastly, a PHOSITA would have had a reasonable expectation of success in combining Saikley and FreeStyle branding because it would have entailed only a simple modification. Such a modification would have merely involved adding an "indicia" from the FreeStyle manual to Saikley's protective cap with little or no experimentation. Saikley discloses that "an existing test strip, such as the FreeStyle brand test strip developed and marketed by TheraSense, Inc., is used with the present invention." Ex.1005, [0036]. Recognizing that Saikley identified a brand for the test strips, a PHOSITA would have been aware of the branding that appeared on the integrated lancing device disclosed by Saikley, and that is visible in the photo of the integrated product shown in U.S. Provisional Application to Saikley, Ex.1005:



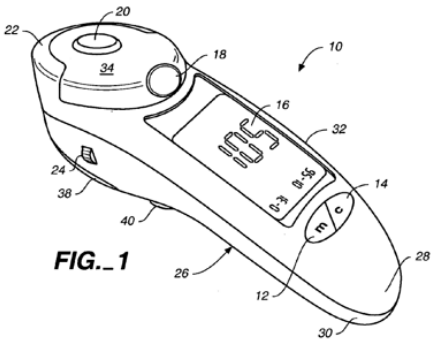


FIG._1

Ex.1016 (Saikley Provisional), Fig. 1	Ex.1005 (Saikley), Fig.1

150. Thus, in my opinion, a PHOSITA would have had a reasonable expectation of success in combining the Saikley protective cap with FreeStyle branding as such a combination would merely require replicating components that already existed in the art.

XII GROUND #4: IIO ANTICIPATES CLAIMS 1-3, 5-8, 14, AND 16-18[1]

151. For the reasons I set forth below, in my opinion, Iio discloses all of the limitations of claims 1-3, 5-8, 14, and 16-18 of the '635 Patent.

A. Discussion of Claim 1

152. I discuss each limitation of claim 1 in turn below, in conjunction with the relevant disclosures of each claim limitation by Iio.

1. Iio discloses claim 1[p] – "A protective sterility cap for a lancet"

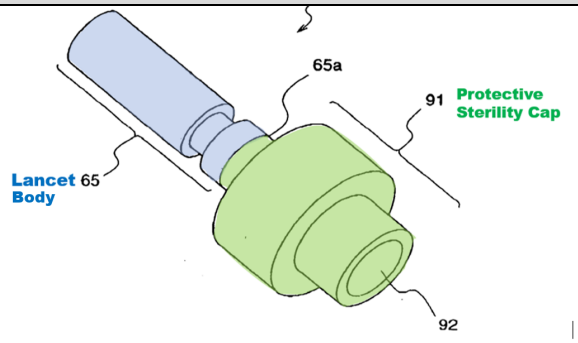
153. It is my understanding that the preamble is not limiting. However, if it were, the second embodiment[2] of Iio's lancet and sterility unit discloses "a protective sterility cap for a lancet"—namely, the "puncture needle cap 91" (sterility cap) for the lancet body 65 (collectively, the "puncture needle unit 90" or

[1] Iio discloses two embodiments depicted in Figures 1-5(b) and Figures 6-12, respectively. Ex.1006, ¶¶[31-55], Figures 1-12. My analysis of Ground 1 relies exclusively on the second embodiment to discuss why I believe the challenged claims are anticipated.

[2] As I explained in Section XII.A above, Iio discloses two embodiments for the lancet and sterility cap unit—the first one is depicted in Figures 1 through 5(b) and the second in Figures 6 through 12. Ex.1006, [0031-0055]. My analysis of Ground 1 relies on the second embodiment of the lancet and sterility unit to anticipate the challenged claims.

lancet), which as shown in annotated Figure 8 below, 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." Ex.1006, [0104], Fig. 8, [0044] ("FIG. 8 is a perspective view illustrating a puncture needle unit to be used for the lancet according to the second embodiment.").

FIG. 8

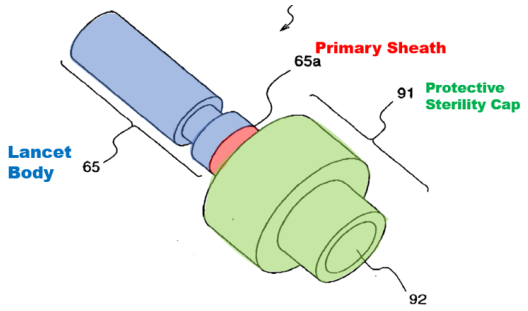
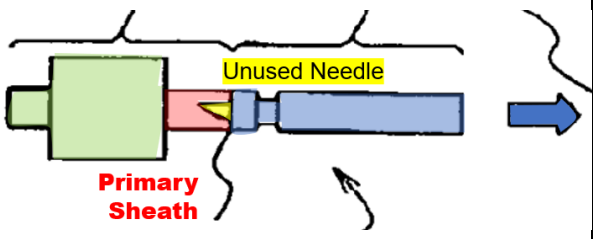


154. Iio teaches in its first embodiment that "the lancet and the puncture needle are used to collect a small amount of blood for such as measurement of blood sugar." Ex.1006, [0095]. To ensure that the lancet needle remains sterile before puncture, I understand Iio explains that "the puncture needle body 65 is set in a state where it is embedded in the puncture needle cap 91," and to maintain sterility after puncture, Iio teaches that "a disposal slot 92 for pulling out the puncture needle 65 after puncture has been carried out is provided at an end of the puncture needle cap 91." *Id*, [0104].

155. In my opinion, Iio thus discloses a protective sterility cap (*i.e.*, puncture needle cap 91) for a lancet (*i.e.*, puncture needle body 65 of the puncture needle unit 90)."

2. Iio discloses claim 1[a] – " a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein"

156. Iio's puncture needle cap 91 includes a primary sheath at one"end" with a "puncture needle separation groove 65a," a groove where "the body 65 and the cap 91" connect to each other "by a thin plastic film having a thickness of 0.1 mm or less." Ex.1006, [0104]. This primary sheath "cover[s] the front end of the puncture needle 65 before [it is] used." Ex.1006, [0117]. Iio further teaches that the primary sheath (colored red in Figures 8 and 9(a), below) ensures that "the puncture needle body 65 is set in a state where it is embedded in the puncture needle cap 91." *Id.*, [0104].

FIG. 8	FIG. 9A
	

157. Before the puncture needle 65 is used to puncture a user's skin, Iio teaches that the puncture needle unit 90 must be pushed into the lancing device 61 until "the puncture needle 65 is snugly fitted to the puncture needle fixing hole 70." Ex.1006, [0106]. Once positioned in the lancing device 61, "the puncture needle 65 can be separated from the puncture needle cap 91" when "the lancet 61 is pulled while twisting the puncture needle unit 90." Ex.1006, [0106] ("When the operator further applies a force against the pulling force, the puncture needle 65 can be separated from the puncture needle cap 91 (FIG. 9(c))."). This three-step procedure is shown in Figures 9(a)-(c), below.

FIG. 9(a)-9(c)

Fig.9(a)

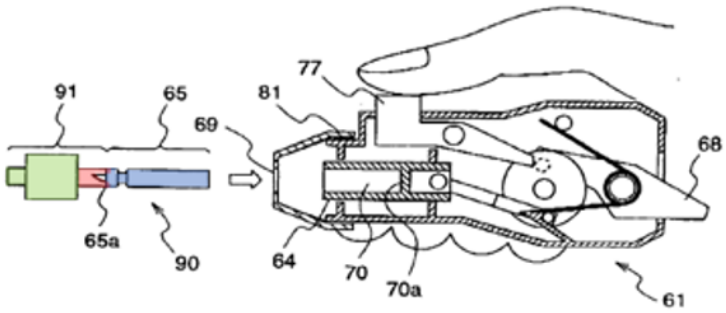


Fig.9(b)

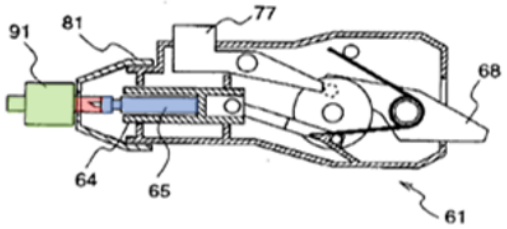
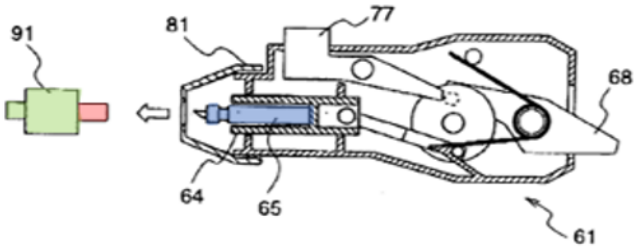


Fig.9(c)

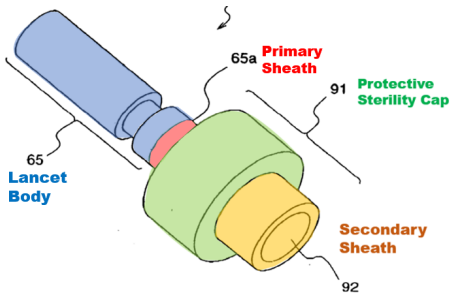
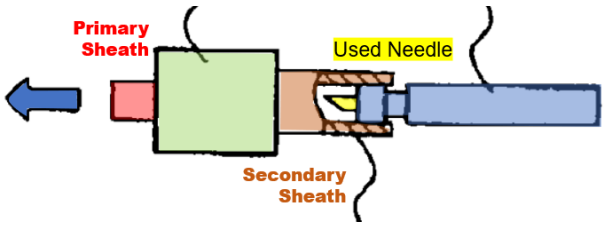


158. Based on these figures and my understanding of the descriptions in the specification, Iio teaches that "the puncture needle body 65 is set in a state where it is **embedded** in the puncture needle cap 91" that "cover[s] the front end of the puncture needle 65 **before** [it is] used." *Id*., ¶¶[0104],[0117].

159. In my opinion, Iio therefore discloses that the "sterility cap (*i.e.*, puncture needle cap 91) compris[es] a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein."

3. Iio discloses claim 1[b] - "a secondary sheath for receiving the sharp lancing tip of a used lancet"

160. The other "end of the puncture needle cap 91" has "a disposal slot 92 [colored orange in Figure 8 below] for pulling out the puncture needle 65 after puncture has been carried out." Ex.1006, [0104] (explaining that while the "the shape of the puncture needle cap of the puncture needle unit 90 is not restricted to that shown in FIG. 8 … [a]t this time, the puncture needle can be easily discarded by making the slot at the discarding side have a larger aperture.").

FIG. 8	FIG. 11(b)
	

161. "[A]fter the puncture operation has been completed [and] the front end of the puncture needle 65 is exposed (FIG. 11(a))," Iio teaches "discarding the puncture needle 65" by fitting "the shaft of the disposal slot 92 … to the front end of the puncture needle 65," and then pressing "the front end of the puncture needle 65 … into the disposal slot 92 to snugly insert the needle 65 into the slot 92, whereby the **puncture needle 65 is captured into the disposal slot 92** (FIG. 11(b))." Ex.1006, [0117]. Then, "the puncture needle cap 91 having the puncture needle 65 is pulled out of the lancet 61, whereby discarding of the **used puncture needle 65** is completed (FIG. 11(c)), and the puncture needle 65 can be discarded safely and easily without exposing the front end of the puncture needle." *Id*. Figures 11(a)-(c), reproduced and colored below, illustrate how the hollow cavity of the disposal slot 92 receives the sharp lancing tip of a used lancet.

FIGS. 11(a)-11(c)

Fig.11(a)

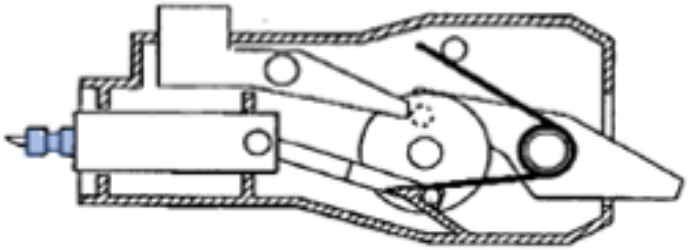


Fig.11(b)

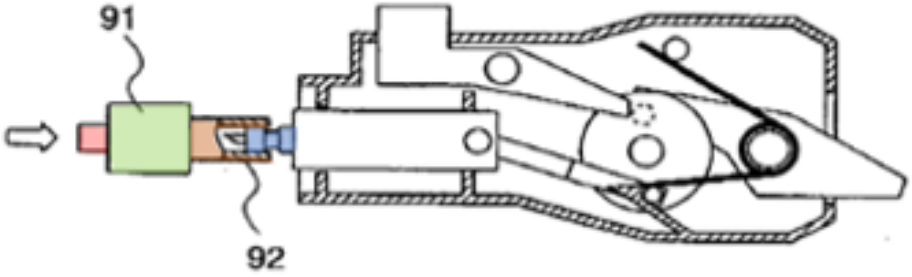
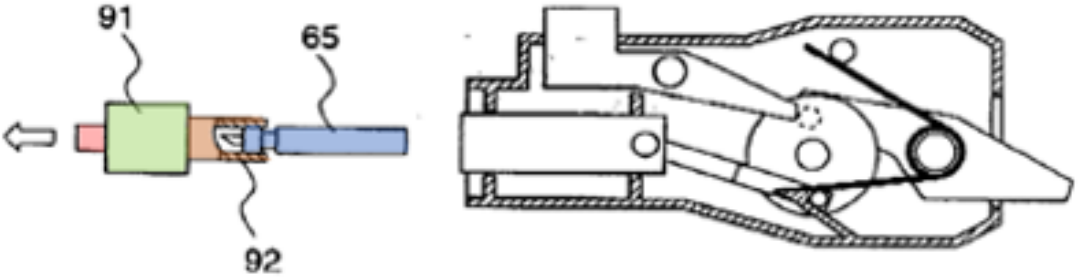
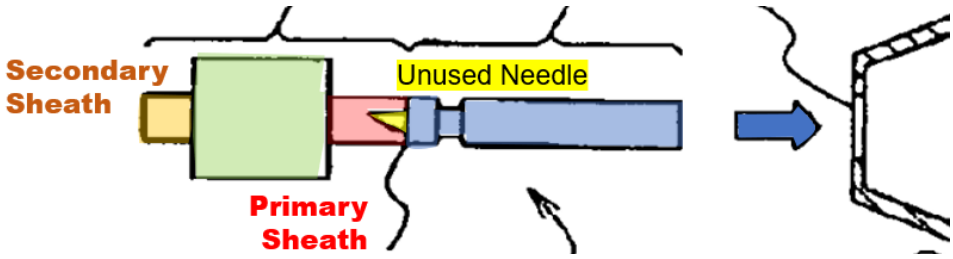
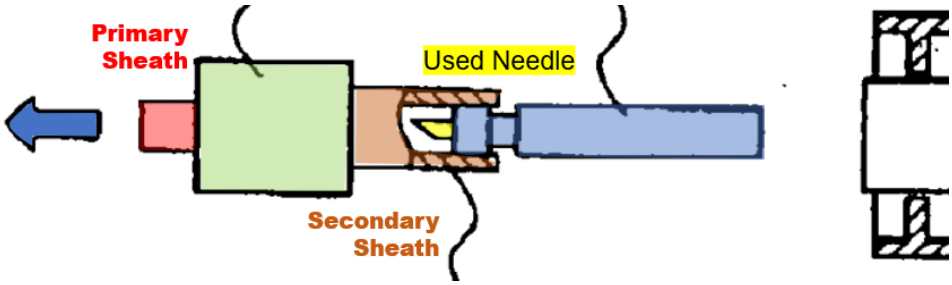


Fig.11(c)



162. Thus, as explained below, before puncturing the skin, the sharp lancing tip of the unused lancet is "embedded" in the primary sheath (colored red in Fig. 9(a) below), and then after puncturing the skin, Iio discloses that the sharp lancing tip of the used lancet is "inserted" into the hollow "shaft" of the disposal slot 92 (colored orange in Fig. 11(b), below).

FIG. 9(a)	
FIG. 11(b)	

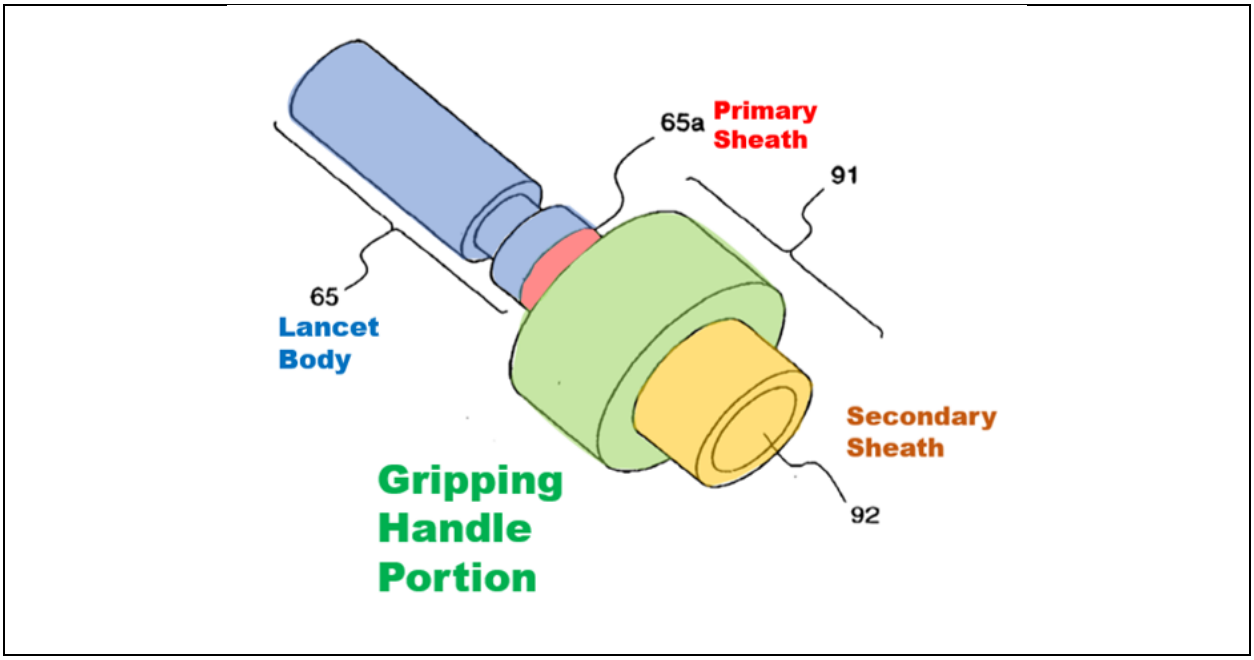
163. The hollow shaft is designed to receive a used lancet because the sharp lancing tip is ultimately "enclosed" within the hollow portion of the shaft. This meets the claim term "a secondary sheath for receiving," which the district court broadly construed as "a secondary sheath for covering the sharp lancing tip of a used lancet by embedding or enclosing the lancet tip." Ex.1004, 13:24-14:3. Indeed, just like Iio, the '635 Patent uses the term "receiving" to describe a lancet needle that is "enclosed" within a "hollow" cavity of a protective sterility cap. Ex.1001, 6:1-5, 7:6-10; *compare* Ex.1001, Figs. 5A-5D *with* Figs. 6A-6D.

164. It is for at least these reasons I conclude Iio discloses a "secondary sheath (*i.e.*, disposal slot 92) for receiving the sharp lancing tip of a used lancet."

4. Iio discloses claim 1[c] - "and a gripping handle portion extending between the primary sheath and the secondary sheath"

165. Iio's puncture needle cap 91 further includes a handle (colored green in Figure 8, below) extending between the primary sheath (red, below) and the secondary sheath (orange, below).

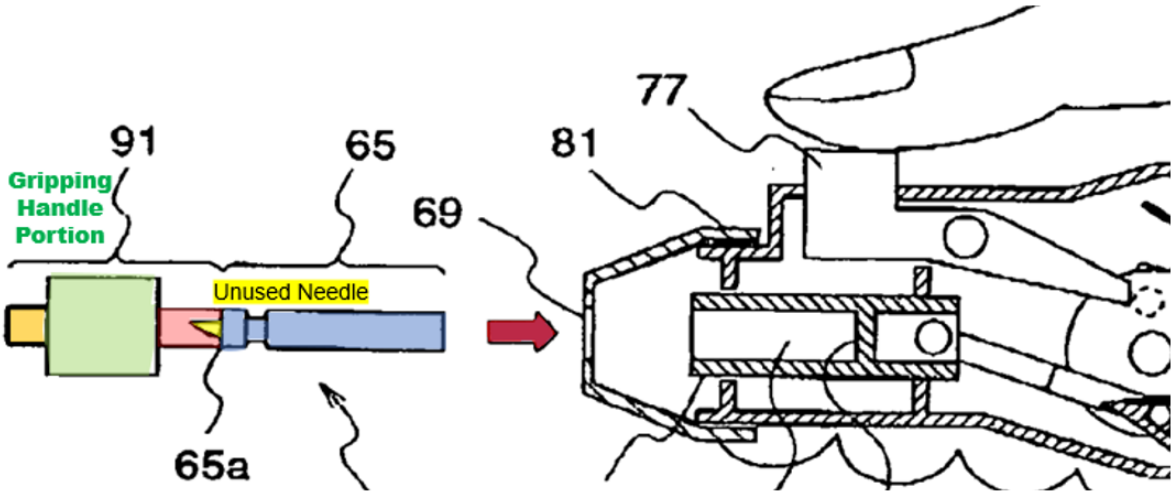
FIG. 8



166. By positioning a handle directly between the primary and secondary sheaths, Iio makes it easier for the operator to grip the puncture needle unit 90 when inserting the puncture needle 65 into the lancing device before use, and when subsequently removing the puncture needle 65 after use for disposal.

167. To prepare the puncture needle 65 for use, Iio discloses that the operator must first load the puncture needle into the lancet 61 (lancing device) by pushing the puncture needle unit 90—in the direction of the arrow colored dark blue in Figure 9(a), below—until the puncture needle 65 (light blue) is fully seated within the lancing device 61, as shown in Figure 9(b) further below. Ex.1006, [0106].

FIG. 9(a)

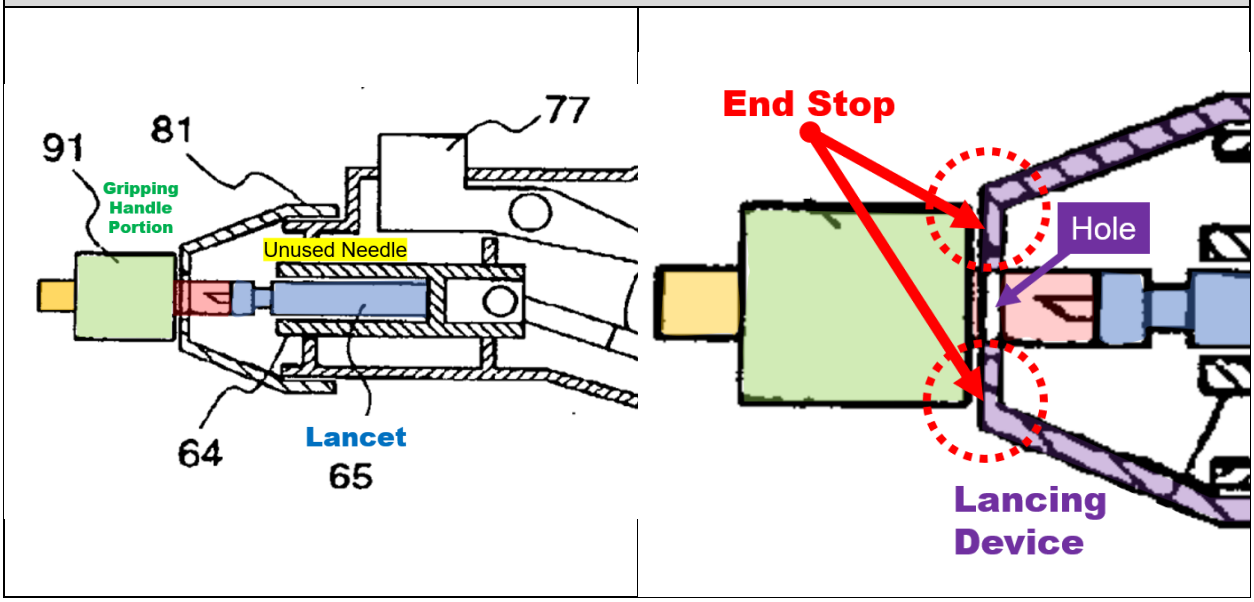


168. As illustrated above, the operator cannot grip the puncture needle 65 when pushing the puncture needle unit 90 into the lancing device because the puncture needle 65 must be "snugly fitted to the inner wall of the puncture needle fixing hole 70 of the slider 64." *Id*.

169. By making the diameter of the gripping portion considerably larger than that of the primary sheath (red), the secondary sheath (orange), and the puncture needle 65 (blue), the cylindrical grip of Iio's puncture needle cap 91 provides the surface area needed for "excellent usability and **handleability**." Ex.1006, [0005].

170. In addition, the larger diameter of the grip also acts as an end stop that "**safely set[s]** a puncture needle" at the same depth for every puncture, as shown in Figure 9(b) below. *Id.*, [0005], [0023].

FIG. 9(b)

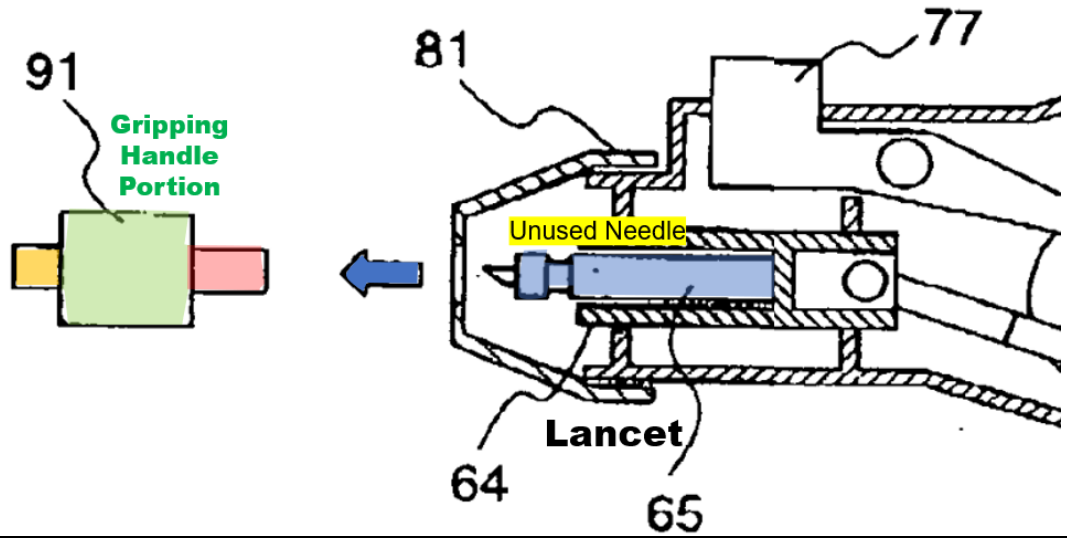


171. To expose the sharp tip of the unused needle after it has been snuggly fitted within the lancing device, Iio teaches that the operator must simultaneously pull the lancing device 61 with one hand "while twisting the puncture needle unit 90" with the other hand until "the puncture needle 65 [is] separated from the puncture needle cap 91." Ex.1006, [0106].

172. As can be seen below in Figure 9(c), the large diameter of the handle portion of the puncture needle cap 91 provides the gripping surface needed to twist

off the puncture cap 91 from the puncture needle 65 with one hand—while the other hand grips the lancing device. *Id*., [0004-0006], [0023].

FIG. 9(c)



173. By extending the length and lateral span of the gripping handle portion of the puncture needle cap 91 and positioning it directly against the lancing device, Iio designed the handle portion to be gripped by the operator when twisting off the puncture needle cap 91 to "ensure excellent usability and **handleability** with safety." Ex.1006, [0005], [0007] (explaining that "the puncture needle unit" is "highly operable and safely **handleable**."). It is for this reason I believe a PHOSITA would understand that the cylindrical grip of IIo's puncture needle cap 91, by design, is easy to grip and handle.

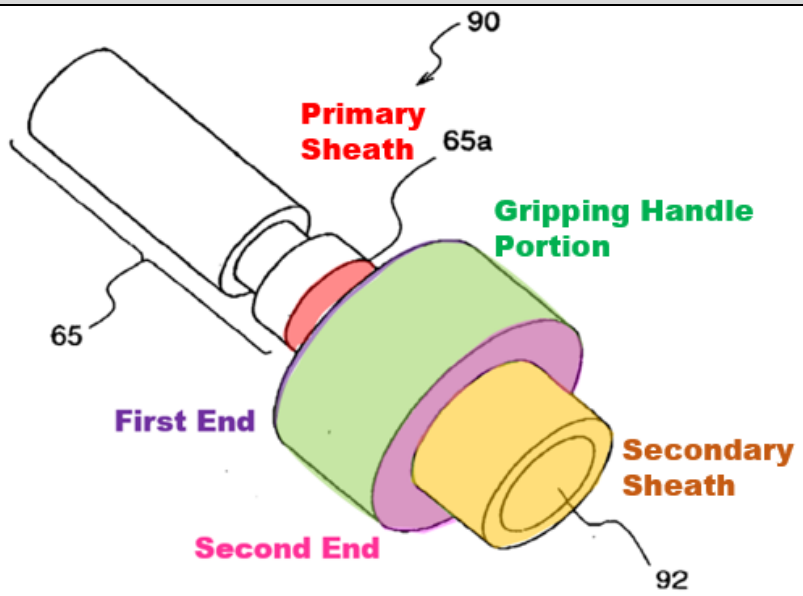
174. In my opinion, Iio therefore discloses "a gripping handle portion extending between the primary sheath and the secondary sheath."

5. Iio discloses claim 1[d] - "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"

175. As illustrated in Figure 8 below, I believe Iio discloses that the primary sheath is attached to one end of the gripping handle (i.e., a first end, colored purple below) and the secondary sheath is attached to the other end of the gripping handle (i.e., a second end, colored magenta). Because the gripping handle portion of the puncture needle cap 91 extends between the primary sheath (i.e., sheath formed adjacent the puncture groove 65a) and the secondary sheath (i.e., sheath with the disposal slot 92), each sheath is attached at an opposite end of the gripping handle portion of the protective needle cap 91. Ex.1006, Figs. 8-9(c), [0117] (confirming the "the shaft of the disposal slot 92" is "provided at **an end of the puncture needle cap 91**, the **other end** of which has covered the front end of the puncture needle 65 before [the puncture needle was] used"); *see also id.* claims 19-20, [0025] ("The puncture needle cap is cylindrical in shape, and has protection slots for protecting the puncture needle after performing the puncture operation

from the lancet body, which **slots are formed from both of <u>an end and the other end</u> of the cylindrical shape**. Therefore, it is possible to safely discard a used puncture needle.").

FIG. 8

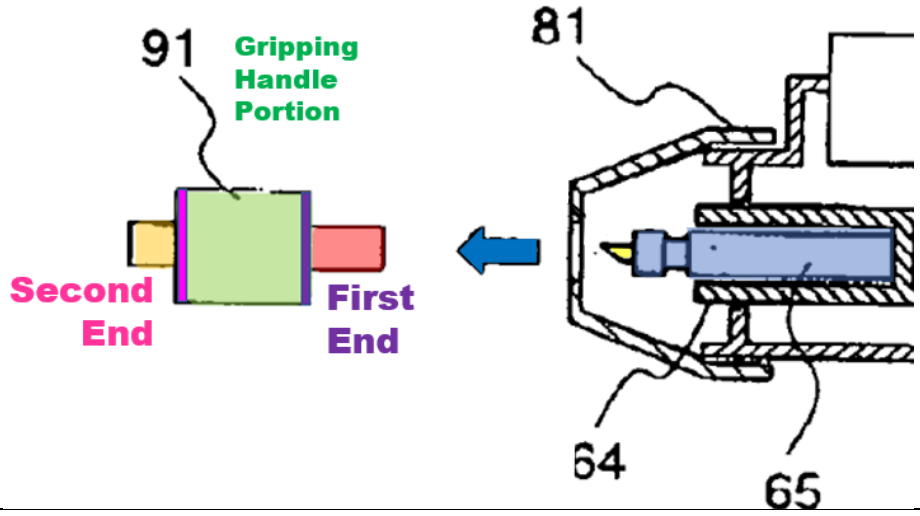


176. From my observations, even after the operator separates the puncture needle cap 91 from the puncture needle 65 to expose the unused needle tip for use in puncturing the skin, as shown in annotated Figure 9(a) below, the first and second ends of the gripping handle portion of the puncture needle cap 91 remain attached to the primary and secondary sheaths, respectively. Ex.1006,¶¶ [0047], [0093], [0102-0104] ("When the operator further applies a force against the pulling

force, the puncture needle 65 can be separated from the puncture needle cap 91 (FIG. 9(c)).").

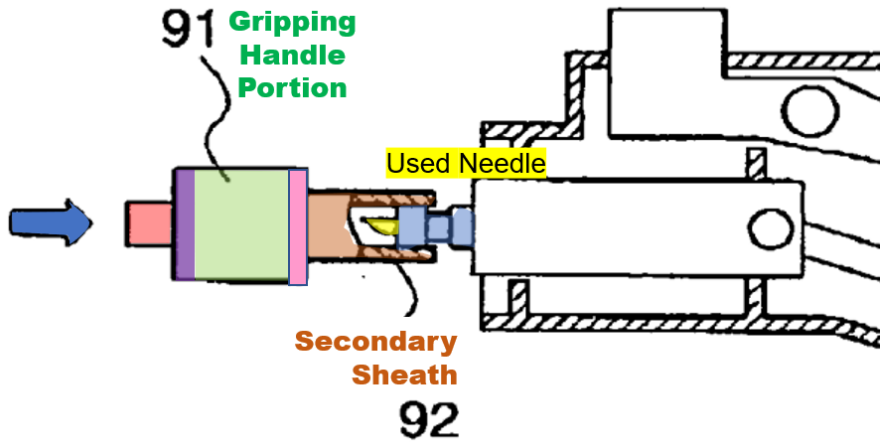
177. Because the puncture needle cap 91 is an integral structure, the location of these attachments remains the same before and after the puncture needle cap 91 is removed from the lancet. Nothing in Iio teaches or suggests reconfiguring the puncture needle cap 91 after removal, let alone removing either the primary or secondary sheaths. Quite the opposite. Figures 9(a) to 9(c) make clear that the sheaths remain attached to each end of the gripping handle portion even after "pulling" and "twisting the puncture needle unit 90" away from the lancing device 61 so that it "can be separated from the puncture needle cap 91." Ex.1006, [0104].

FIG. 9(A)



178. The same is true for "discarding the puncture needle 65 after the puncture operation has been completed." Ex.1006 at [0116]. Neither sheath is detached from the respective ends of the gripping handle when recapping the used puncture needle 65. To my understanding, Iio teaches instead that "pressing" the second end of the gripping handle portion towards "the front end of the puncture needle 65" fitted within the lancing device 61 until "the puncture needle 65 is captured into the disposal slot 92 (FIG. 11(b))." *Id*., [0117].

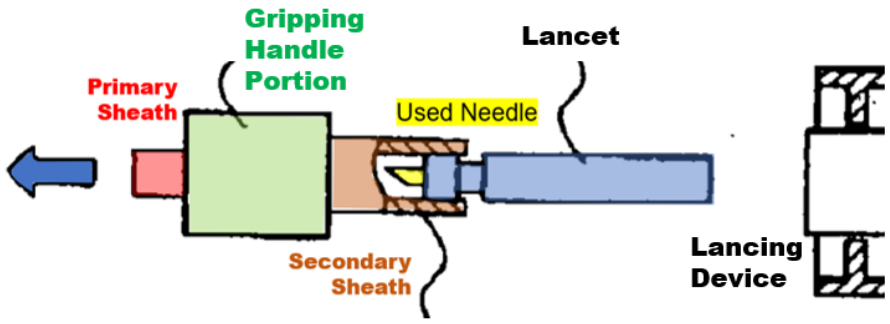
FIG. 11(b)



179. Nor does the gripping handle's configuration change after recapping the used puncture needle 65; Figure 11(c), annotated and colored below, confirms that both sheathes remain attached to the respective ends of the gripping handle even after the puncture needle 65 is "**pulled out** of the lancet 61" so that it may be

"discarded safely and easily without exposing the front end of the puncture needle." *Id*.

FIG. 11(c)

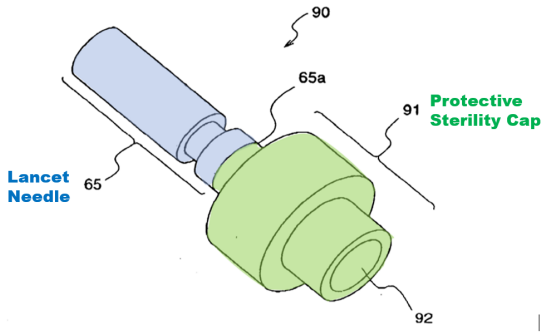
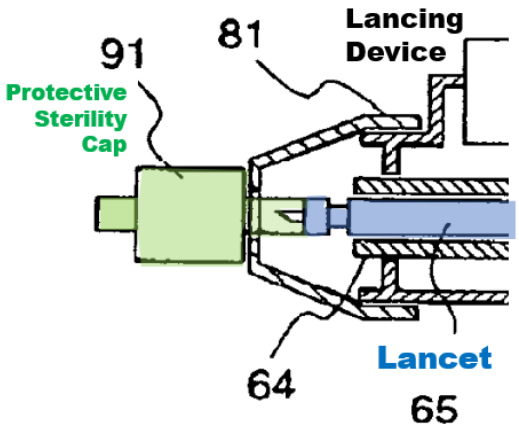


180. In my opinion, Iio therefore discloses that "the primary sheath [is] attached at a first end of the gripping handle portion and the secondary sheath [is] attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet."

B. Discussion of Claim 2

181. Iio discloses the protective sterility cap of claim 1 for the reasons I outlined in Section XII.A, incorporated here. Claim 2 depends from claim 1 and adds the claimed protective sterility cap "in combination with a lancet." In my opinion, those same disclosures likewise anticipate the limitations added by claim 2, including the "puncture needle unit 90" disclosed by Iio, which comprises a lancet (puncture needle 65) combined with a protective sterility cap (puncture

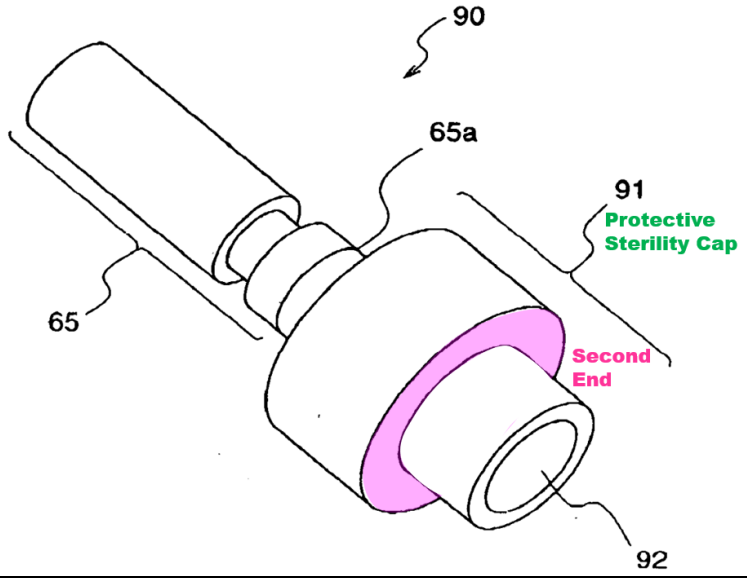
needle cap 91), capable of being used with a lancing device for puncturing skin and collecting blood.

FIG. 8	FIG. 9A
	

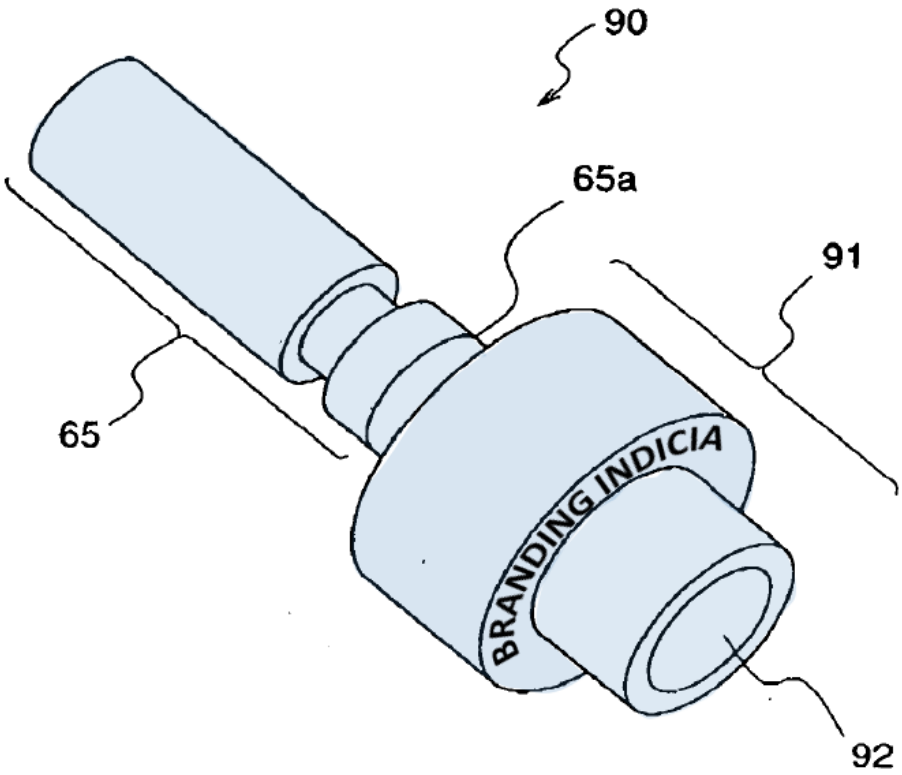
C. Discussion of Claim 3

182. Iio discloses the protective sterility cap of claim 1 for the reasons I provided in Section XII.A, incorporated here. Claim 3 depends from claim 1. Claim 3 adds that the claimed sterility cap further comprises: "at least one flat display surface for placement of branding indicia thereon." I believe that Iio discloses the added limitations of claim 3 by teaching that the protective sterility cap further comprises "at least one flat display surface"—namely, the second end of the gripping handle portion of the puncture needle cap 91, colored and annotated magenta below.

FIG. 8



183. The remainder of the limitation—"for placement of branding indicia thereon"—to my understanding recites intended use and does not structurally limit the protective sterility cap recited in the claim's body. Even if limiting, I believe Iio discloses a flat surface and this surface could be used for many things, including placing branding indicia, such as the lancet manufacturer's logo. *See supra* Section IX.C (Ground 1, Claim 3). In my opinion, claim 3 is therefore anticipated.



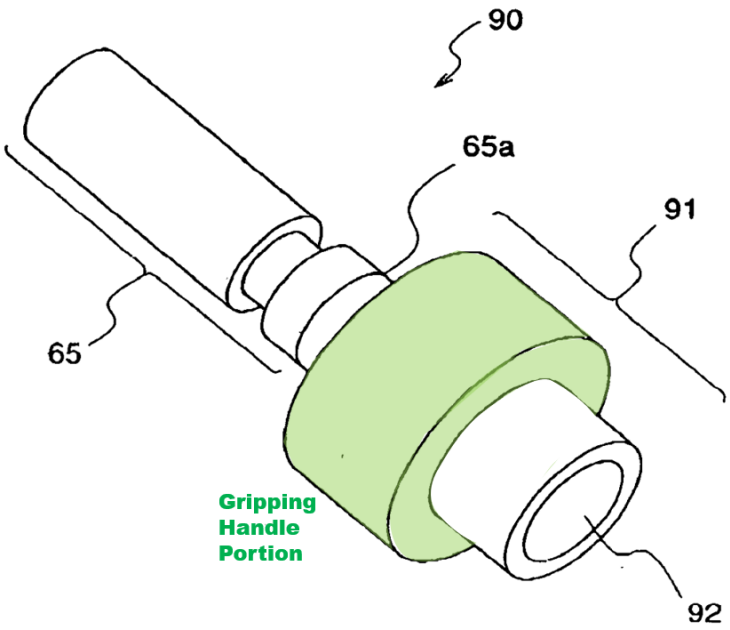
(Demonstrative)

D. Discussion of Claim 5

184. Iio discloses the protective sterility cap of claim 1 for the reasons I provided in Section XII.A, incorporated here. Claim 5 depends from claim 1 and adds "wherein the gripping handle portion comprises a solid body without an open loop." In my opinion, Iio anticipates the added limitations of claim 5 by disclosing

a solid cylindrical gripping handle portion that does not include an open loop as shown, for example, in Figure 8.

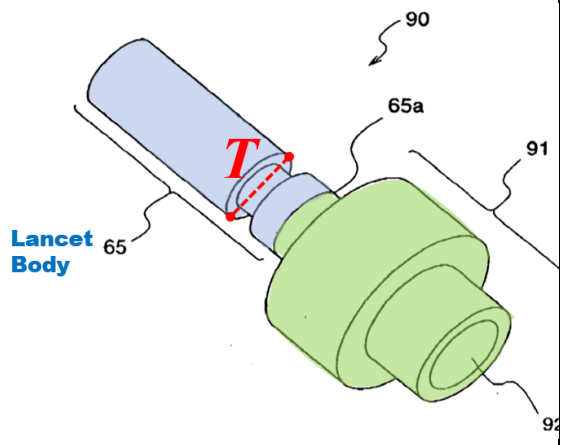
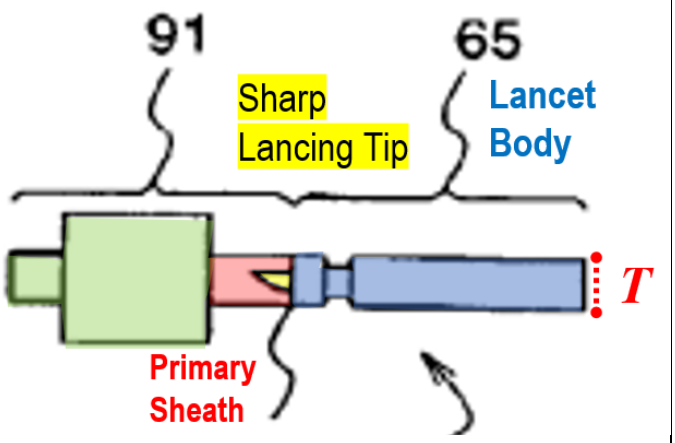
FIG. 8



E. Discussion of Claim 6

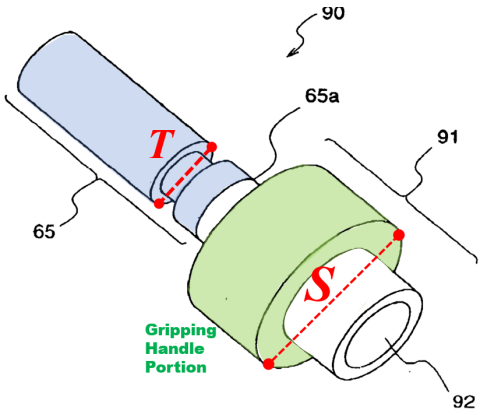
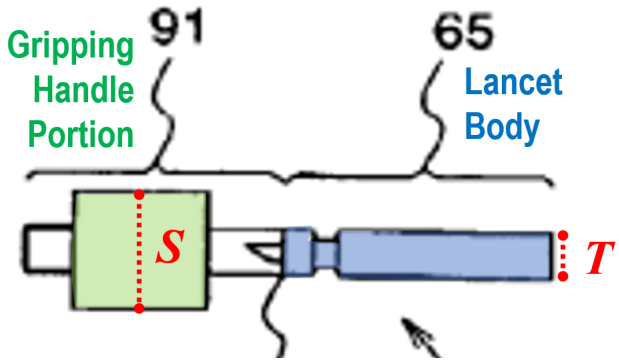
185. Iio discloses the protective sterility cap of claim 1 for the reasons I discussed in Section XII.A, incorporated here. Claim 6 adds: "[a] in combination with a lancet [b] having a lancet body defining a lancet thickness, [c] and a sharp lancet tip initially embedded in the primary sheath, [d] wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness." In my opinion, each of these elements is disclosed by Iio.

186. As to elements 6[a]-6[c], in Figure 9(a), I believe Iio discloses its sterility cap "in combination with a lancet [65, blue and yellow below] having a lancet body defining a lancet thickness ["T" below], and a sharp lancet tip [yellow below] initially embedded in the primary sheath."

FIG. 8	FIG. 9(a)
	

187. As to 6[d]'s limitation of "the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness," I believe Iio discloses a

lateral span for its gripping handle portion, which is annotated as "S" in the figure below.[3]

FIG. 8	FIG. 9(a)
	

188. A cursory visual comparison of the gripping handle portion's lateral span ("S") with the lancet's thickness ("T") shown in Iio's figures confirms to my knowledge that the "gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness." Iio's textual descriptions of its primary and secondary sheaths further confirm that these relative proportions in Iio's figures are essential

[3] Lateral span being measured as depicted above for Iio is consistent with how the '635 Patent depicts lateral span in its Figure 5D.

to Iio's cap performing as described in the specification. *Id.* For example, Iio teaches that "fitting of the puncture needle to the disposal slot [Iio's secondary sheath] is easier than fitting of the puncture needle to the protection slot [Iio's primary sheath]." Ex.1006, claim 20 and [0026]. To my understanding of what is shown in Figures 11(b) and (c), for example, the entire thickness of the puncture needle body is able to fit into Iio's secondary sheath and, thus, this secondary sheath must have a greater lateral span than the lancet thickness. And, as also shown, for example, in the Figures 8, 9 and 11, Iio's gripping handle portion has a significantly broader lateral span than the secondary sheath. This reinforces that the dimensions depicted reflect that the lateral span of the gripping handle portion is more than 1.5 times the lancet thickness.

189. Iio also goes on to explain that "said disposal slot of the puncture needle cap has **an opening that is larger** than an opening of the protection slot" and also that the disposal slot (secondary sheath) has "a **larger aperture**." *Id.*, claim 21 (emphasis added), [0104] (emphasis added). These textual disclosures align with what is shown in Iio's figures, in particular Iio's Figures 8 and 9a-9c for Iio's second embodiment, which plainly depict what the text describes, i.e., that an opening of the disposal slot (secondary sheath) of the puncture needle cap

(gripping handle portion) is larger than an opening of the protection slot (primary sheath). A PHOSITA would have therefore appreciated that Iio's figures, in particular Figure 8 and 9a-c, accurately depict relative dimensions, including that the lateral span of the gripping handle portion is at least 1.5 times the lancet thickness.

190. I would further confirm this by the relative proportions of the size of the user's thumb depicted in Iio's Figure 9(a) as compared to the gripping handle portion and the lancet thickness. For example, the user's thumb appears to have a lateral span that is comparable to the lateral span of the gripping handle portion, whereas the lancet thickness appears to be very small in comparison to the size of the user's thumb. This further supports my opinion that a PHOSITA would have understood Iio to disclose a gripping handle portion with a lateral span and a length that is greater than 1.5 times the lancet thickness based on comparing of the size of the user's thumb to each of the lancet thickness, lateral span, and length of Iio's gripping handle portion.

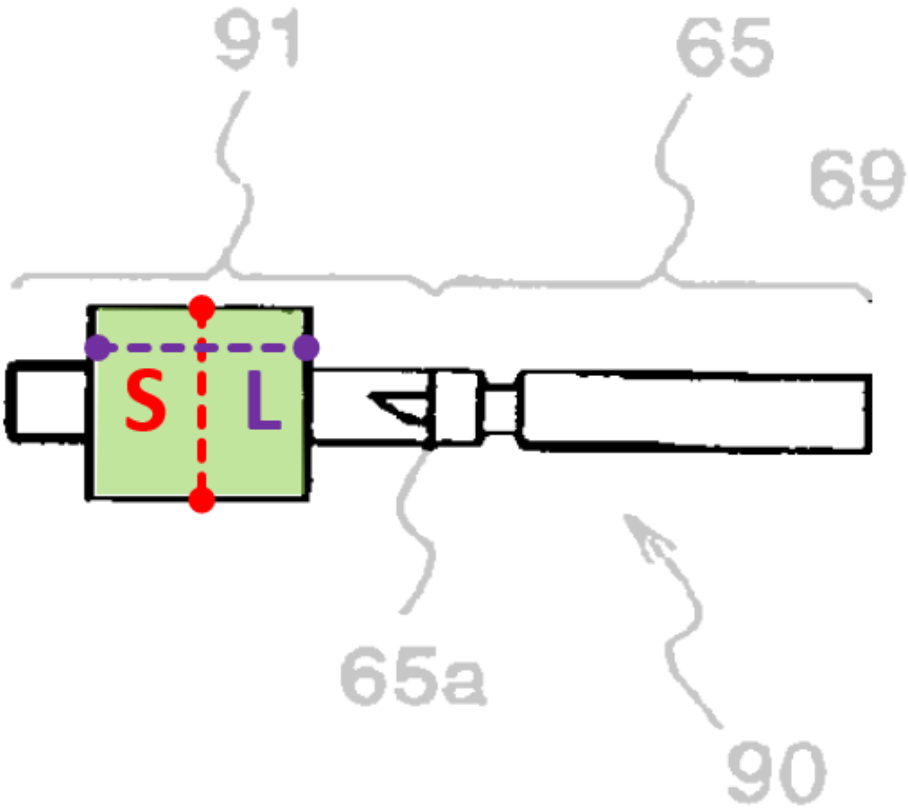
191. Beyond this, Iio textually describes a specific thickness for "a thin plastic film having a thickness of 0.1 mm or less in the puncture needle separation groove." Ex.1006, [0104]. Knowing this dimension, it is my view that a

PHOSITA could visually discern that the lancet thickness is around 5 times thicker than the depicted needle separate groove 65a (Figure 9(a)) and also that lateral span of the gripping handle portion is 20 or more times larger than the depicted thickness of the needle separation groove 65a. Considering these disclosures, in conjunction with all the other reasons offered above, a PHOSITA would have understood, in my opinion, that Iio's gripping handle portion has a lateral span of at least 1.5 times the lancet thickness.

192. I believe it is for at least the above reasons, claim 6 is anticipated.

F. Discussion of Claim 7

193. Iio discloses the protective sterility cap of claim 6 for the reasons I discussed in Section XII.E, incorporated here. Those same disclosures likewise inform my belief that the limitations of claim 7 are disclosed by showing that "the gripping handle portion defines a length at least equal to its lateral span," annotated below as "L" and "S," respectively.



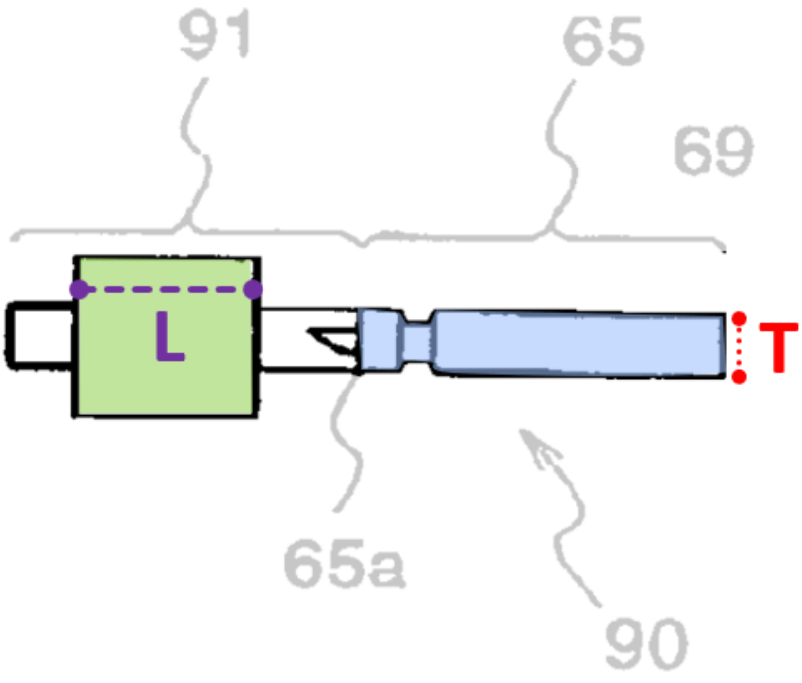
Iio, Fig. 9(a) (Colored and Annotated)

194. These depictions are also consistent with Iio's repeated descriptions of a "highly operable and safely handleable" puncture needle unit that may be "handled more safely" (*see, e.g.*, Ex.1006, [0029], [0030]). I understand a longer gripping handle portion, with a length at least equal to the lateral span helps to achieve these goals and ensure that users are able to safely handle the puncture needle unit.

195. In my opinion, claim 7 is thus anticipated.

G. Discussion of Claim 8

196. Iio discloses the protective sterility cap of claims 6 and 14 for the reasons I have outlined in Sections XII.E, XII.H, incorporated here. I believe those same disclosures likewise disclose the added limitations of claim 8, by showing that "the gripping handle portion defines a length at least equal to (including larger than, as shown in Iio) the lancet thickness," annotated below as "L" and "T," respectively.



Iio, Fig. 9(a) (Colored and Annotated)

197. Iio's visual depictions also show that Iio's gripping handle portion is larger than the outer diameter of the secondary sheath in Iio and the inner diameter of the secondary sheath is large enough to receive the entire thickness of the lancet body. Thus, because the length of Iio's gripping handle portion is at least equal to its lateral span (as I discussed above) and because the entire thickness of the lancet body fits within the inner diameter of the secondary sheath (which is smaller than both the length and lateral span of the gripping handle portion in Iio), these reasons inform my conclusion that the length of Iio's gripping handle portion is at least equal to the lancet thickness. In my opinion, claim 8 is anticipated.

H. Discussion of Claim 14

198. Claim 14 includes limitations analogous in scope to limitations 1[pre]-1[d], and those are disclosed by Iio for reasons I have explained above and incorporated here (*supra* Section XII.A.1-5). Claim 14 also includes limitations analogous in scope to those found in claim 6, and those are disclosed by Iio for reasons I explained above and incorporated here (*supra* Section XII.E).

I. Discussion of Claim 16

199. Claim 16 depends from claim 14, which is anticipated by Iio for reasons I have outlined above and incorporated here (*supra* Section XII.H). The

additional limitations of claim 16 correspond in scope to those found in claim 3, and those additional limitations are disclosed for the same reasons I explained previously (*supra* Section XII.C).

J. Discussion of Claims 17 and 18

200. Claims 17 and 18 depend from claim 14, which is anticipated by Saikley for reasons I explained above and incorporated here (supra Section XII.H). The additional limitations of claim 17 correspond in scope to those found in claim 7, and those additional limitations are disclosed for the same reasons (*supra* Section XII.F). The additional limitations of claim 18 correspond in scope to those found in claim 8, and those additional limitations are disclosed for the same reasons I have provided (*supra* Section XII.G).

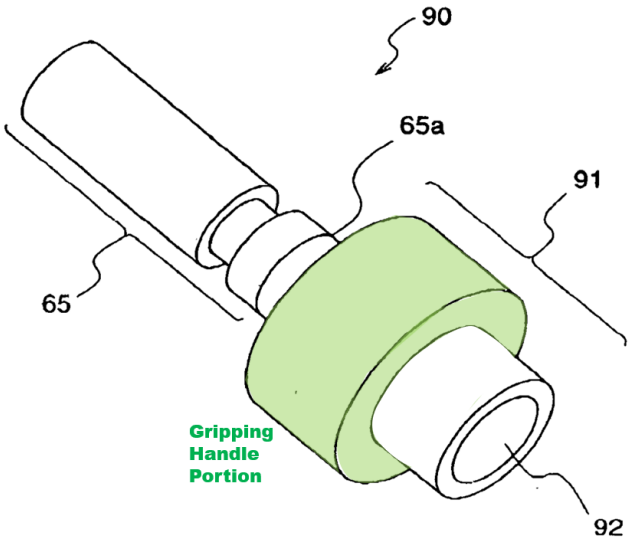
XIII GROUND #5: IIO IN VIEW OF PECKHAM RENDERS OBVIOUS CLAIMS 1-3, 5-8, 14, 16-18

201. For the reasons I set forth below, in my opinion, all of the limitations of claims 1-3, 5-8, 14, and 16-18 of the '635 Patent are disclosed by the combination of Iio and Peckham.

A. All Claims: "Gripping Handle Portion"

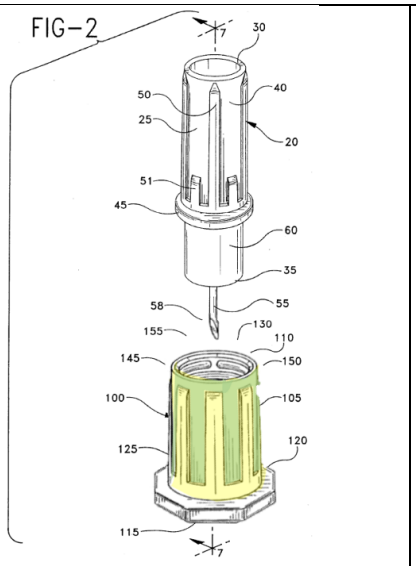
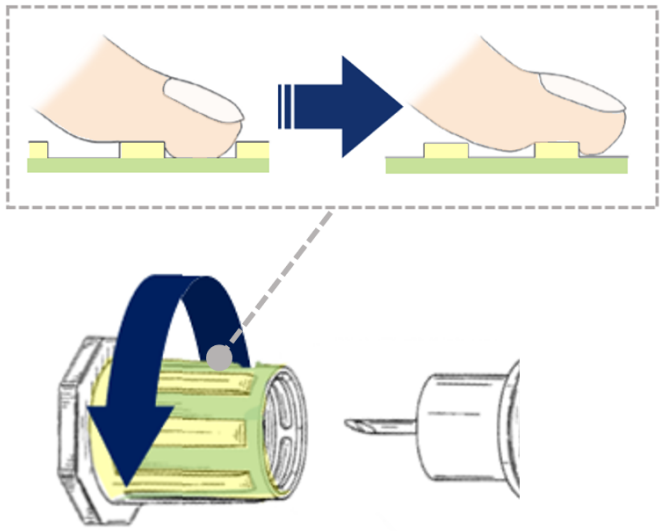
202. As I explained above in Section XII.A.4, incorporated here, Iio's puncture needle unit includes a "griping handle portion" and a PHOSITA would have recognized that the cylindrical handle (green below) provides the user with "excellent **usability** and **handleability.**" Ex.1006, [0005]. I believe a PHOSITA would have appreciated that this cylindrical handle has end stops that "safely set[] a puncture needle" at the same depth before every puncture. A PHOSITA would understand that this cylindrical handle has the size and proportions to make it easier to grasp and "***twist[]*** the puncture needle unit 90" until "the puncture needle 65 [is] separated from the puncture needle cap 91," to "pull[] out the lancet" and "discard it safely and easily without exposing the front end of the puncture needle." Ex.1006, ¶¶ [0005], [0023], [106].

FIG. 9(a)-9(c)

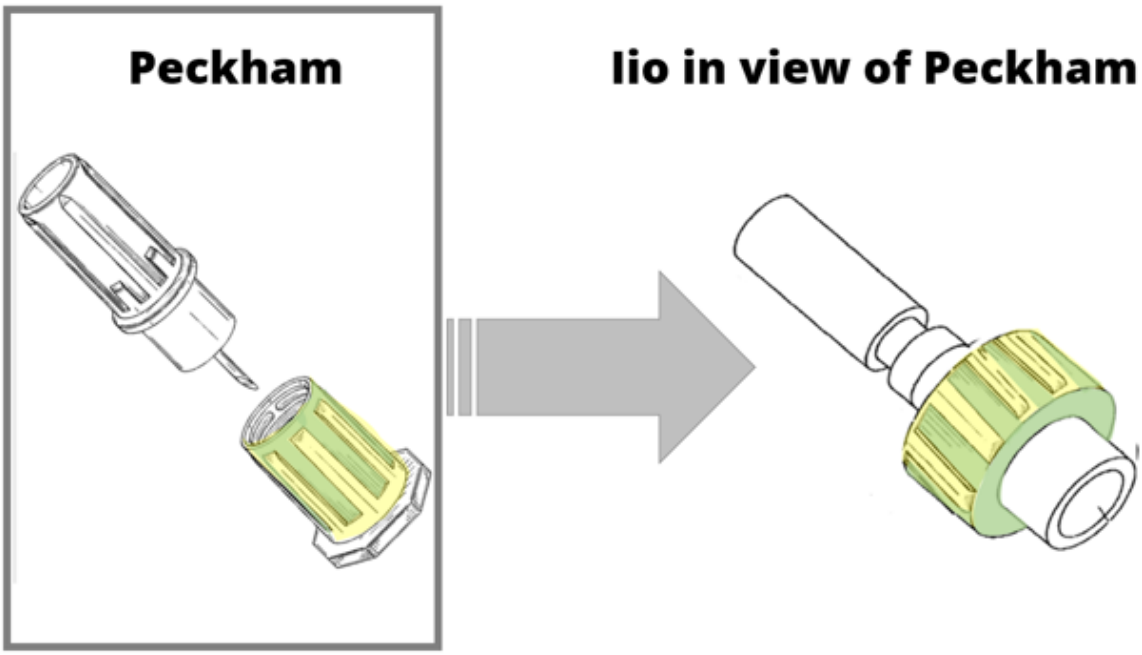


203. In my opinion, Iio also renders obvious the challenged claims in light of Peckham.

204. Peckham discloses a protective sterility cap 100 with a "cylindrical housing 105" that "includes a plurality of longitudinal ribs or splines 125 [*colored yellow in Fig. 2 below*] on housing 105 that extend from octagonal shaped flange 120 toward open end 110." Ex.1008, 3:11-13. In my review of Peckham, it expressly teaches that the "[r]ibs 125 provide a sufficient **textured surface to improve handling** and maneuverability of cap 100, when it is being removed from lancet assembly 20." Ex.1008, 3:13-15.

	
Peckham Fig. 2	**(Demonstrative)**

205. I believe there is abundant motivation for a PHOSITA to apply the ribbed design from Peckham's protective cap 100 to the cylindrical handle on IIo's puncture needle unit (in the manner graphically demonstrated below), and thereby "provide a sufficient textured surface to improve handling and maneuverability of [IIo's puncture needle unit]," particularly "when it is being removed from lancet assembly 20." Ex.1008, 3:13-15.



206. In my opinion, Iio in view of Peckham would anticipate the challenged claims.

B. Claims 6-8, 14, and 17-18: The "Length and "Lateral Span" of the Gripping Handle Portion

207. As I explained above (*supra* Sections XII.E-H, XII.J, incorporated here), Iio anticipates the relative dimensional aspects of these claims.

208. Regarding the relative dimensional aspects, they all would have also been obvious to try, as I explain below. As a threshold matter, the problem of inadvertent needle sticks was a well-recognized problem in the art caused by user's

inability to safely handle the lancet when the needle is exposed. Ex.1006, [0004] ("when attaching or detaching the puncture needle to/from the lancet, the needle is unprotected because it is not covered with the protection cap, and the puncture rod easily moves because it is held by only the spring, leading to puncture by mistake."). This well-recognized problem led to many sterility caps, including Iio's, being developed with both primary and secondary sheaths and gripping handles therebetween to facilitate ease of handling. A PHOSITA would have routinely experimented with the dimensions of the gripping handle portion (including both its lateral span and length) to try to optimize the sterility caps for mass-market use. A PHOSITA would recognize that there are only a finite number of potential dimensions for the gripping handle portion as compared to thickness of the lancet. And when provided with Iio's instruction to "ensure excellent usability and handleability with safety" (Ex.1006, [0005]), I understand a PHOSITA would have focused on designing larger gripping handle portions to achieve these handleability, usability, and safety goals.

209. In designing larger gripping handle portions, a PHOSITA would have routinely experimented with optimizing the size of the gripping handle including its lateral span and length. This would have included trying various relative

dimensions to ensure that the gripping handle portion was usable and handleable even by those with dexterity challenges, such as elderly users. In doing so, I believe a PHOSITA would have tried dimensions in which the gripping handle's lateral span was much more than 1.5 times the lancet thickness as this would have further improved a user's ability to safely handle a lancet both before and after use. And doing so would have been achieved with a reasonable expectation of success as the iterative process of testing various dimensions for a prototype product is a standard practice utilized in designing consumer products prior to arriving at a final product design, particularly in the medical device field where safety is critically important. In my opinion, the relative-dimensional aspects in claims 6 and 14 are, therefore, obvious.

210. Given the motivation and reasonable expectation of success discussed above to arrive at a lateral span of at least 1.5 times the lancet thickness for the modified Iio device, it similarly would have been obvious to have the gripping handle's length at least equal to its lateral span (recited in claims 7 and 17). In particular, the gripping handle portion in Iio is already cylindrically-shaped and designing such a cylindrical shape to have equal lateral span and length dimensions is commonplace. I believe a PHOSITA would be motivated to try

these relative dimensions to help achieve the handleability, usability, and safety goals articulated in Iio. Because the gripping handle portion would have needed to be easily held by a user's thumb and one of their digits, something that is more easily done with a longer handle than with a shorter handle that might slip out of the user's grip. Thus, in my opinion, having the length of that cylindrically-shaped gripping handle portion at least equal to its lateral span would have been a natural option that would have been achieved with a reasonable expectation of success.

211. Since there was a motivation and a reasonable-expectation of success in having the lateral span of Iio's gripping handle portion be at least 1.5 times the lancet thickness and also in having the length of Iio's gripping handle portion be at least equal to the lateral span, then I believe it also would have been a natural and obvious choice to modify Iio's device so that the gripping handle's length would be at least equal to the lancet thickness (as recited in claims 8 and 18).

212. For the above reasons, claims 6-8, 14, and 17-18 are obvious.[4]

[4] During prosecution, I understand the Examiner also argued that "[i]t 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." Ex.1003, 60. Patent Owner

213. Beyond the rationales articulated above, it also would have been obvious to add extra gripping features as taught by Peckham to Iio's sterility cap. This would have led a PHOSITA to increase the lateral span of the gripping handle portion even more (*i.e.*, further beyond 1.5 times the lancet thickness) because the ribs would have extended beyond an outer surface of Iio's cap, thereby extending the cap's lateral span. In particular, this would have furthered Peckham's goals of providing "good grip" for the user, and thus I believe these relative-dimensional limitations would have been satisfied by the combination of Iio and Peckham. In my opinion, once Peckham's gripping features were incorporated into Iio's device, this combination would have included all limitations of claims 6-8, 14, and 17-18.

C. Ample Motivation Existed to Combine with Peckham

214. In my opinion, a PHOSITA would have been motivated to combine Iio and Peckham for at least the following reasons.

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never rebutted this argument or provided any reason as to why the relative dimensional aspects has any patentable significance. I believe these features are anticipated or, at a minimum, obvious as I explained in view of the new prior art relied on herein.

215. First, a PHOSITA would have appreciated that Iio and Peckham are within **the same field of endeavor** and **address the same problem**. I understand the Technical Field of the '635 Patent to be directed to "lancets and lancing devices for blood sampling and testing." Ex.1001, 1:18-19. Both Iio and Peckham also relate to lancets for blood collection. Ex.1006, [0001]; Ex.1008, 1:5-8.

216. At a minimum, I believe Iio and Peckham to be reasonably pertinent to a problem identified in the '635 Patent. The '635 Patent provides for a "sterility cap or cover" for a lancet "with **a handle or grip portion for assisting**" in removal or replacement of the cap. Ex.1001, 1:66-2:2. Both Iio and Peckham also disclose solutions which assist patients with handling lancets. I understand the object of Iio is to provide for a lancet with "excellent **usability** and **handleability** with safety," while Peckham provides a "novel textured surface to **improve handling, maneuverability** and fit" when the lancet is mounted in a lancing device. Ex.1006, [0005]; Ex.1008, 2:67-3:2. I understand Iio also specifically teaches a lancet where its relative size, proportions, and shape make it easier to "twist[] the puncture needle unit 90" until the "puncture needle 65 [is] separated from the puncture needle cap 91." Ex.1006, [106]. Similarly, Peckham teaches a lancet with "ribs" on the outer wall of the lancet which "provide a sufficient

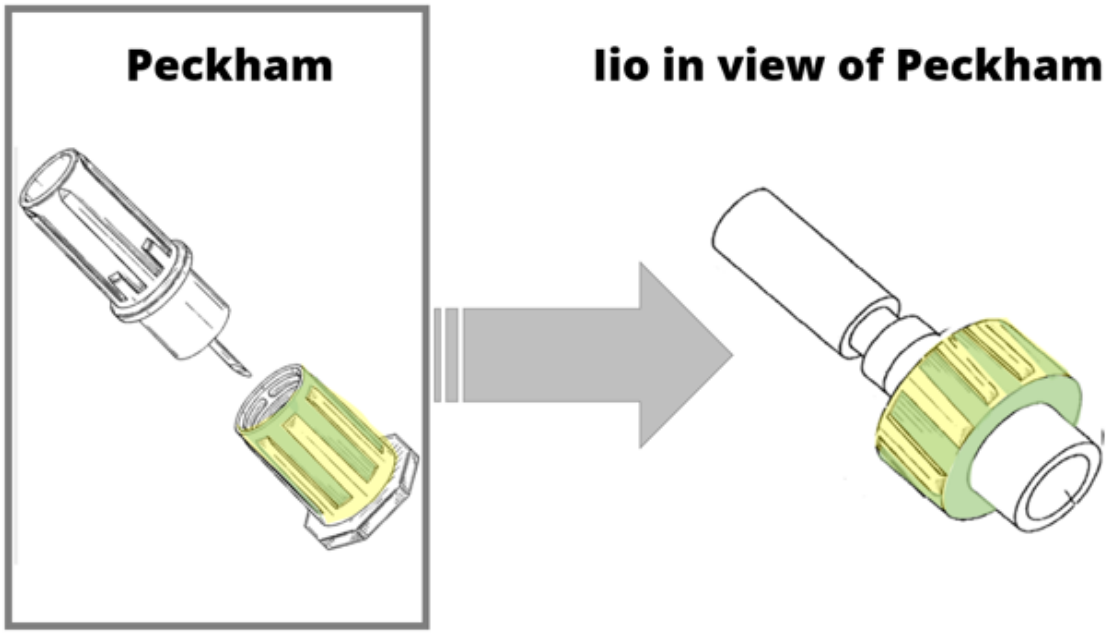
textured surface to improve handling and maneuverability of cap 100 [] when it is being removed from lancet assembly 20." Ex.1008, 3:13-15. In my opinion, Iio and Peckham disclose inventions in the same field of endeavor as the '635 Patent that also address one of the problems identified by the '635 Patent.

217. Iio also provides ample motivation for a PHOSITA to specifically modify the protective cap of the puncture needle unit 90. Iio expressly states that "[t]he shape of the puncture needle cap of the puncture needle unit 90 is not restricted to [the second embodiment] shown in FIG. 8." Ex.1006, [102].

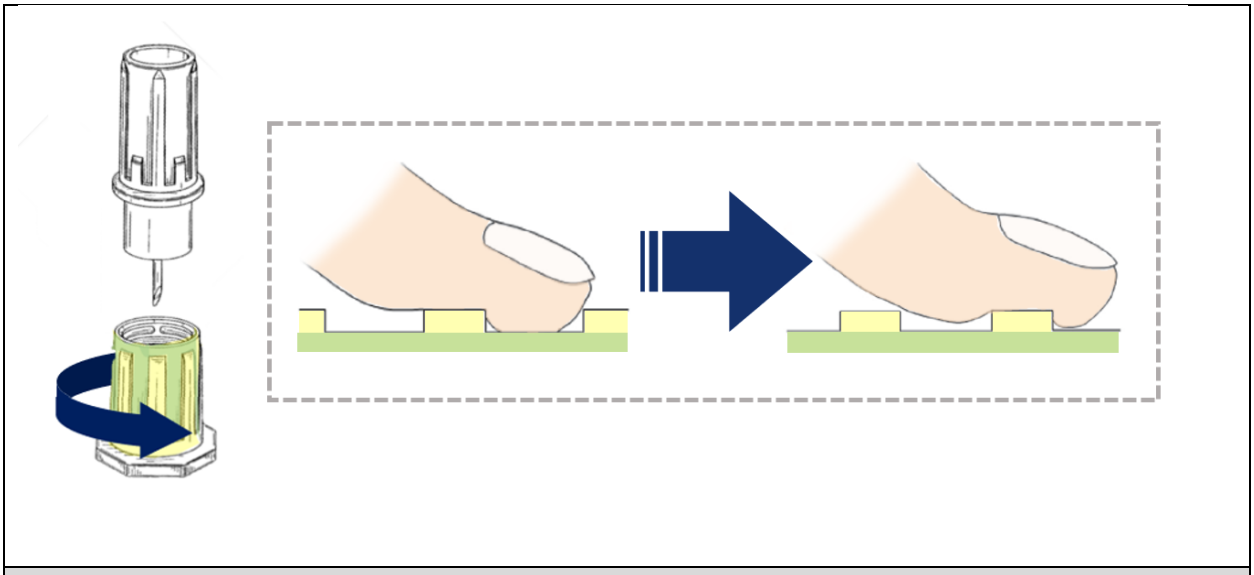
218. In my view, Iio also teaches that the "detailed description and specific embodiments described are provided only for illustration" and acknowledges that "various additions and modifications" to those embodiments "***will be apparent*** to those of skill in the art from the detailed description." Ex.1006, [0006]. It would have been apparent to a PHOSITA that Peckam's ribs are an addition or modification that could be made to improve the handling and maneuverability of Iio's cap.

219. In addition, I believe ample motivation existed for a PHOSITA to incorporate the longitudinal ribs (*highlighted yellow below*) from the cylindrical

grips or handle portion of Peckham's lancet cap into the cylindrical grips or handle portion of Iio's lancet cap, as illustrated below.



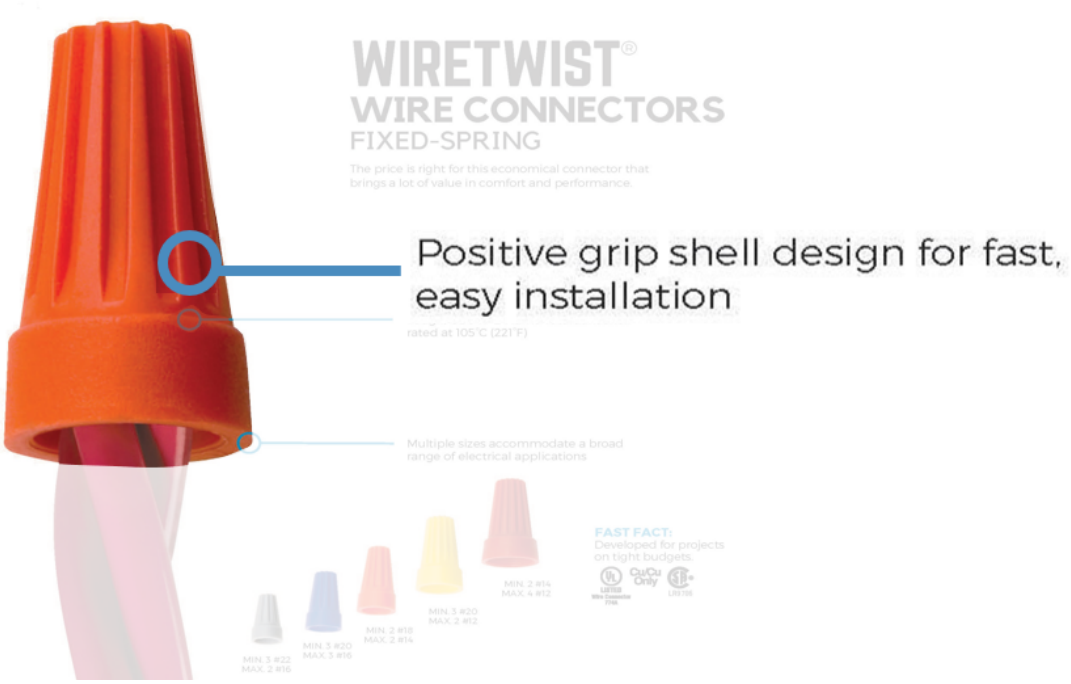
220. While Iio does not disclose the use of a textured surface to improve "useability and handleability" of a lancet, I believe a PHOSITA would have recognized that the invention in Iio could be improved by the addition of such a gripping texture. Industrial designers routinely use, ribbed patterns to increase finger friction and thereby improve grip. As illustrated below, when a user's finger moves over the ribbed surface, friction varies between the raised and recessed regions depending on the position of the user's finger. Friction will increase as the rib height increases or the width between ribs increases.



(Demonstratives)

221. A PHOSITA would have recognized that these common industrial design techniques had been applied to an analogous pull-top lancet in Peckham. Peckham teaches how having "molded-in longitudinal splines" on the "exterior of the [lancet] housing [makes] the housing easier to handle and manipulate." Ex.1008, 2:7-10. Peckham also explains that the "longitudinal ribs or splines" can be "alternate[d] around" the outer wall of the lancet "to provide a novel textured surface to improve handling, maneuverability and fit." *Id.*, 2:64-3:2. Both of Peckham's teachings are well-known industrial design concepts. Peckham specifically teaches such concepts as applied to a lancet. In my opinion, it would have been obvious to a PHOSITA to improve the grip of Iio's cylindrical handle by adding a ribbed surface texture.

222. Furthermore, I believe a PHOSITA would have combined Iio's cylindrical handle with Peckham's surface texture ribs to achieve predictable results. Ridges were a well-known and conventional structure for improving the grip on handles. A wide variety of products, such as toothpaste caps and the twist-on wire-nut seen below, implemented ridges as a surface texture to make the product easy to grip.



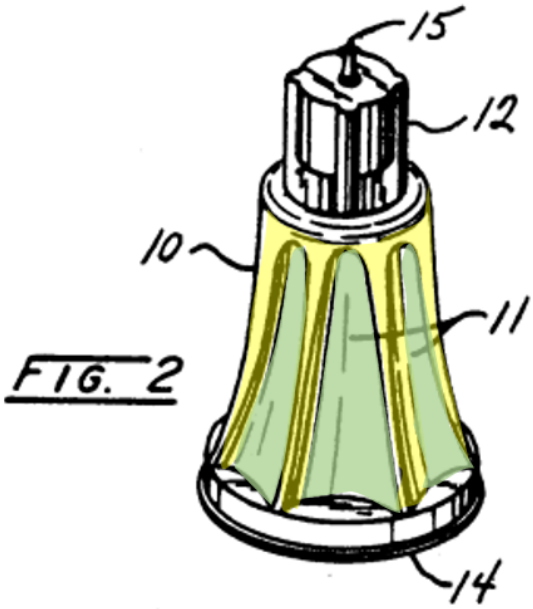
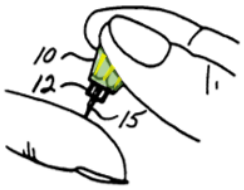
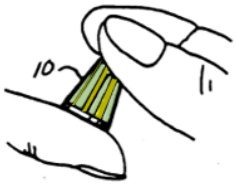
(Demonstrative: Ribs Improve Grip and Make Turning Easier)

223. In my view, the combination of adding Peckham's ribs to Iio's cylindrical handle, would have resulted in a lancet with an improved grip that would have been predictable to a PHOSITA.

224. It is also my understanding that a PHOSITA would have been further motivated to combine Iio and Peckham because such a combination would be commercially desirable. When designing a product, cost is a critical consideration. For disposable items like lancets, it is preferrable to keep material costs to a minimum. Ribs are an inexpensive and economical solution for adding surface texture and improving grip for small, disposable items. Thus, I believe a PHOSITA would have been further motivated to combine Iio and Peckham to economically achieve a more ergonomic product.

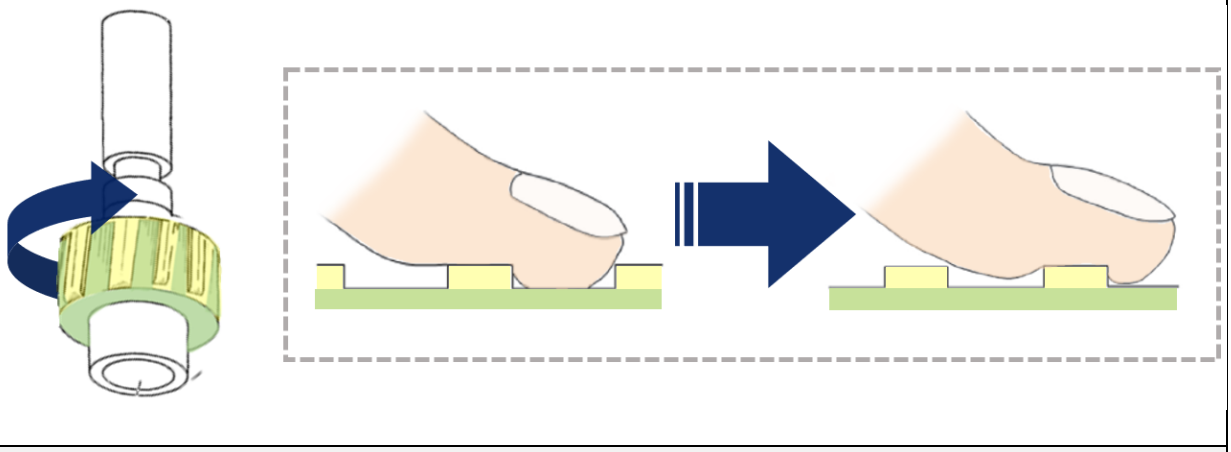
225. Lastly, I believe a PHOSITA would have had a reasonable expectation of success in combining the teachings of Iio and Peckham. The solution of such a combination was well-known at the time. During the relevant period, conventional lancets and lancing devices implemented ridges on surfaces meant to be gripped by users. For example, U.S. Patent No. 4,994,068 to Hufnagle discloses a lancet protective cap with a plurality of "depressed ***finger engaging*** portions 11—11" which "provid[e] a ***good grip for the user***" as seen highlighted in

yellow below. Ex.1024, 2:47-49. As such, I believe it would have been straightforward for a PHOSITA to improve the grip of Iio's cylindrical handle with Peckham's ribbed surface texture and know that such a combination would be feasible.

Conventional Lancet Cap Used Ribs to Improve Grip and Handleability
 FIG. 2  FIG. 7  FIG. 6

226. Such a combination would also not require undue experimentation. If a PHOSITA were to begin improving the grip on Iio's cylindrical handle, I believe the PHOSITA would first start with a design for high friction. A high friction design would require high and narrow ridges with large spaces between

ridges. However, because friction changes between raised and recessed surfaces, a PHOSITA would then have to know to keep the spacing narrow enough to maintain a more consistent frictional force. Narrowing the space between ridges would lower the friction, however, I believe a PHOSITA would have to exercise common sense to know that such a loss would be negligible due to the threshold friction needed to grip the lancet handle securely enough to remove the end cap. In my opinion, for Peckham, the rib pattern disclosed already balanced the interests of rib height and spacing in the context of lancet cap removal. A PHOSITA would readily recognize that Peckham's large ridges would be useful for Iio as the user could position their hand at the point of maximum friction, as seen below. The narrow size of the ridges would also allow the finger to deform more, thereby improving grip. In my opinion, a PHOSITA would therefore had a reasonable expectation of success in combining the teachings of Iio and Peckham without undue experimentation.

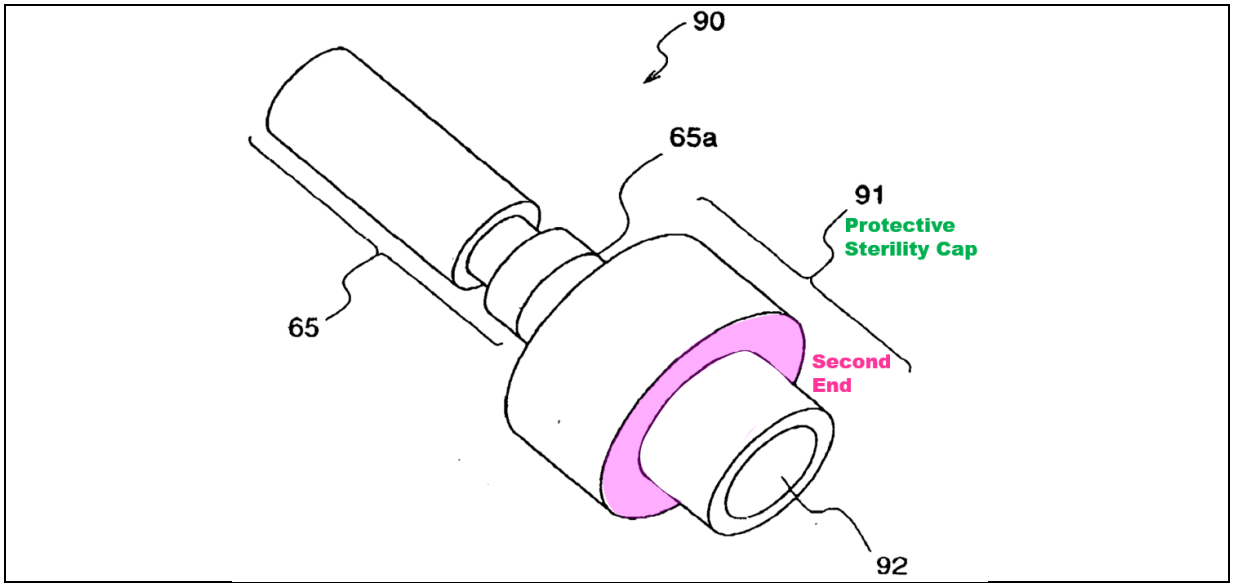


(Demonstrative: Ribs Generate Surface Friction

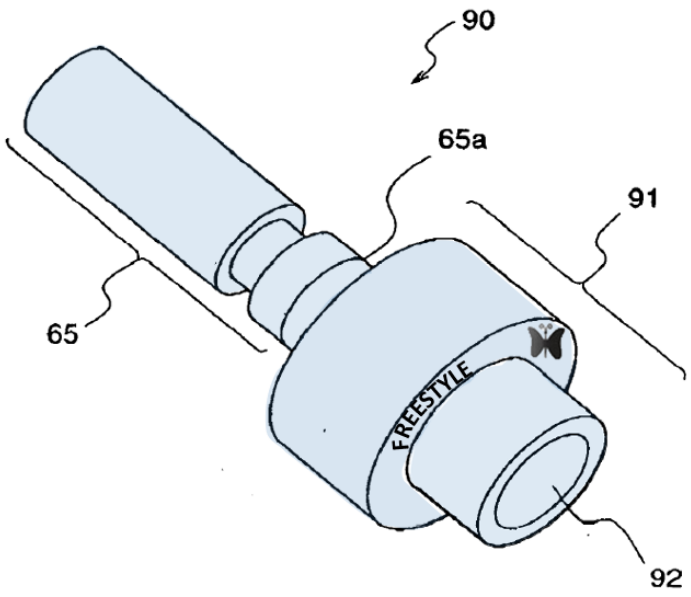
XIV GROUND #6: IIO IN VIEW OF THE FREESTYLE MANUAL RENDERS OBVIOUS CLAIMS 3 and 16

227. As I explained previously, Iio anticipates claims 3 and 16 by disclosing the flat surface of the cylindrical gripping handle (*colored magenta in Figure 8 below*) because the remainder of the limitation—*i.e.*, "for placement of branding indicia thereon"— I understand merely recites an intended use and is not entitled to patentable weight.

FIG. 8



228. In my opinion, the combination of Iio and FreeStyle discloses this limitation. The combination of these two references is straightforward, as FreeStyle expressly teaches using a flat display surface of a cap to display branding indicia (*i.e.,* the FreeStyle logo) as shown below. I believe this combination would be obvious for the same reasons set forth in Section XI (Ground 3).



(Demonstrative)

229. For these reasons, I believe Iio in view of FreeStyle renders claims 3 and 6 obvious.

XV CONCLUSION

230. For the reasons set forth above, in my opinion, all limitations of the challenged claims of the ’635 Patent are disclosed by the prior art (and combinations thereof) cited herein.

231. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the

knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or bother, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the results of these proceedings.

Executed on March 20, 2023 in Los Angeles, CA.



Joel Delman