UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIFESCAN, INC.
Petitioner,

v.

FACET TECHNOLOGIES, LLC
Patent Owner.

Case No. IPR2023-00713
U.S. Patent No. 8,840,635

DECLARATION OF JOEL DELMAN IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 1, 4, AND 9-15 OF U.S. PATENT NO. 8,840,635

Exhibit 1103
Filed with Petition for IPR of
Claims 1, 4, and 9-15 of U.S. Patent No. 8,840,635

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PETITIONER'S EXHIBIT LIST

Exhibit	Description
Ex. 1101	U.S. Patent No. 8,840,635 to Pusey et al. (the "'635 Patent")
Ex. 1102	File History of the '635 Patent
Ex. 1103	Declaration of Expert Joel Delman
Ex. 1104	CV of Expert Joel Delman
Ex. 1105	District Court Order on Claim Construction
Ex. 1106	U.S. Patent No. 5,207,699 to Coe ("Coe")
Ex. 1107	JP Patent App. No. 2005168634 to Sakata ("Sakata")
Ex. 1108	U.S. Patent App. Pub. No. 2007/0162064 ("Starnes")
Ex. 1109	Japanese Patent No. JPH05285127 ("Morita")
Ex. 1110	Wayback Declaration + One Touch Booklet: One Touch Basic Complete Diabetes Monitoring System Owner's Booklet, Rev. 02/2004, LifeScan Inc., Milpitas, California (1999)
Ex. 1111	Stipulation Not to Pursue in a Parallel Proceeding the Same Grounds or Any Grounds that could have Reasonably been Raised
Ex. 1112	U.S. Patent No. 5,385,571 ("Morita II")
Ex. 1113	U.S. Patent No. 8,920,454 ("Hyoue")
Ex. 1114	U.S. Patent App. No. 2007/0293883 ("Horie")
Ex. 1115	International Pub. No. WO2007089930 ("Lathrop")
Ex. 1116	U.S. Patent App. No. 2005/0131440 ("Starnes '440")
Ex. 1117	U.S. Patent App. No. 2003/0144608 ("Kojima")
Ex. 1118	U.S. Patent No. 3,358,689 ("Higgins")
Ex. 1119	U.S. Patent Application Publication No. 2006/0174592 ("Chan")
Ex. 1120	U.S. Patent No. 6,283,982 ("LeVaughn")
Ex. 1121	Dandekar et al., *3-D Finite-Element Models of Human and Monkey Fingertips to Investigate the Mechanics of Tactile Sense*, Journal of Biomedical Engineering (Oct. 2003, Vol. 125)
Ex. 1122	Hohendorff et al., *Lengths, Girths, and Diameters of Children's Fingers from 3 to 10 Years of Age*, Annals of Anatomy 192 (2010)
Ex. 1123	Abbott Freestyle Freedom Manual
Ex. 1124	Goyal et al., *Diabetic Hand: A Neglected Complication of Diabetes Mellitus* (June 9, 2018)

Ex. 1125	D.C. Anderson et al., *Preventing Needlestick Injuries* (March 30, 1991)

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. 1101"). 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 the patentability of all claims (which I may refer to subsequently as the "Challenged Claims") 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 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) since 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 Art Center College of Design in Pasadena, California.

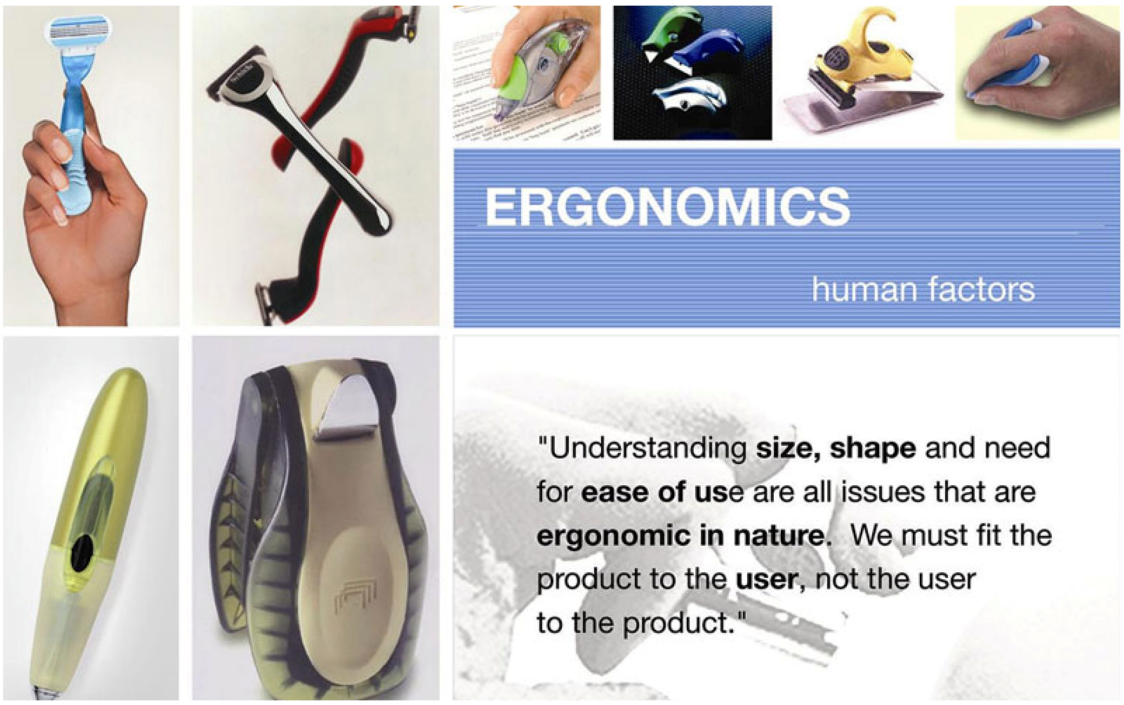
B. Industrial Design Work

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.

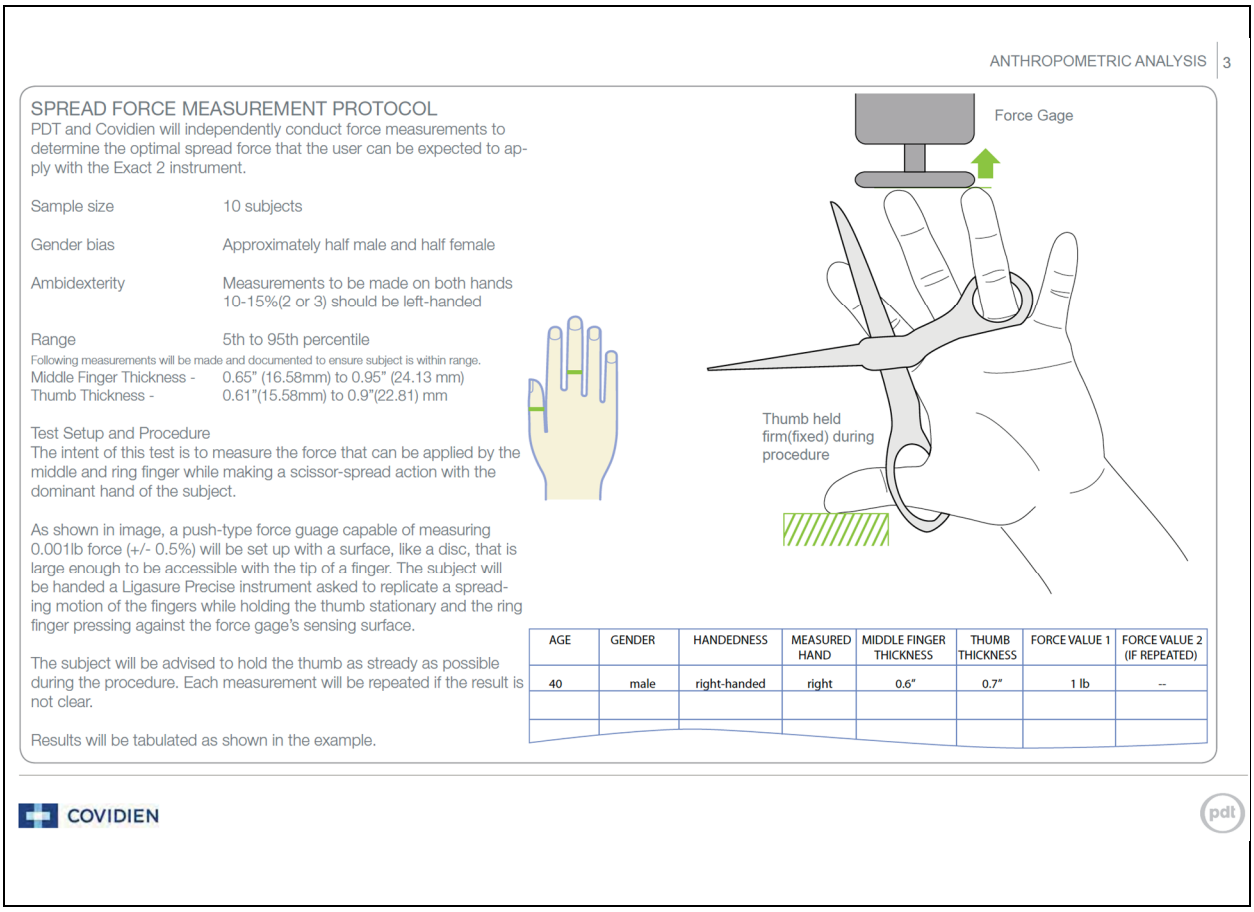
8. When designing handheld consumer items, understanding the **size**, **shape**, and need for **ease of use**, are all human factors considerations that are taken into account throughout the design process. Industrial designers must fit the product to the user, not the user to the product. Below are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

Demonstrative: Designing to Fit the Product to the User



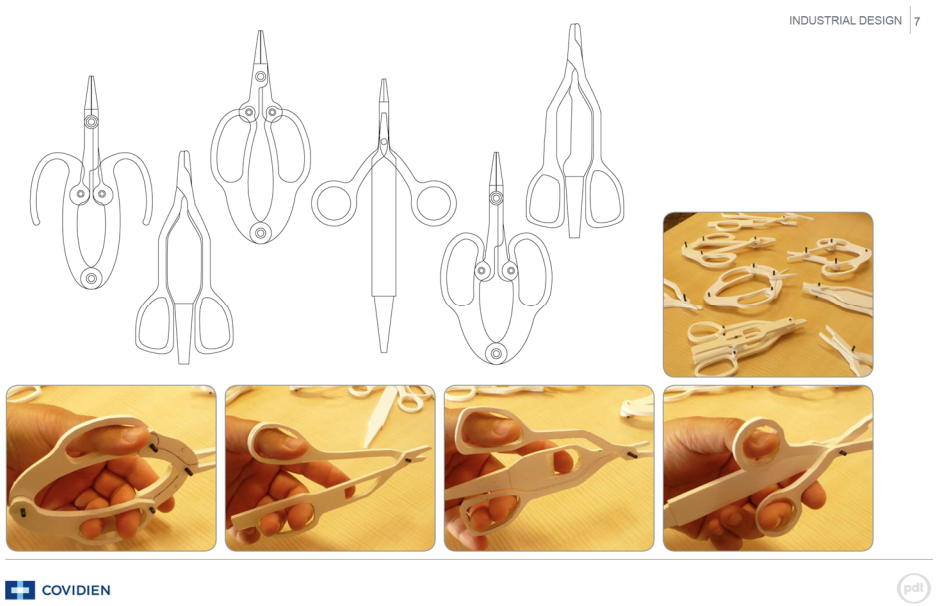
9. Ergonomic studies are critical in the design of certain products to ensure that they fit the product to the user. These studies serve to help designers gain an understanding of the particular use case and ergonomic challenges to be solved. Below is an example of research summarized for an ergonomic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

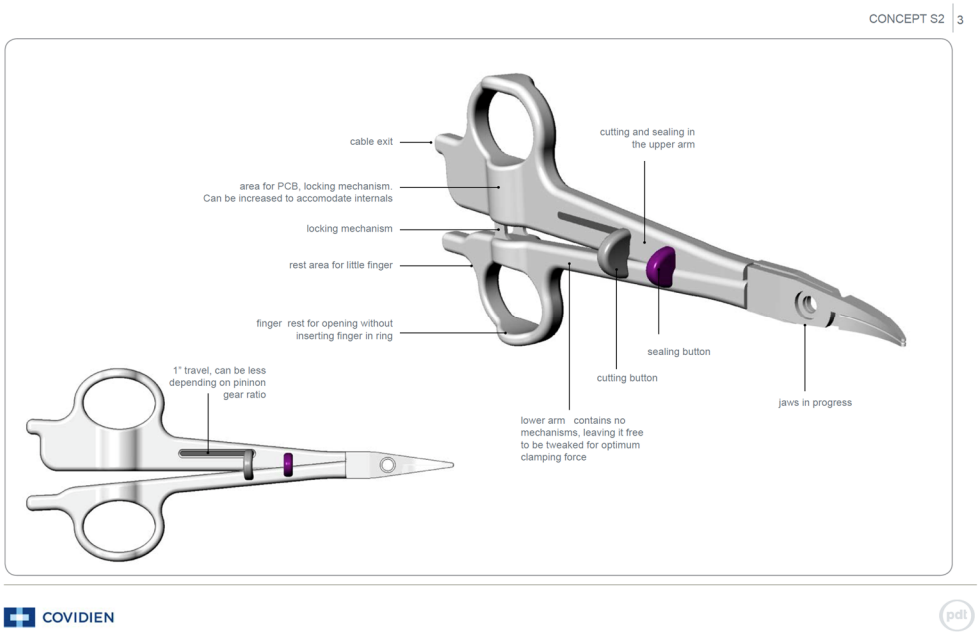
Demonstrative: Design Concept for Covidien



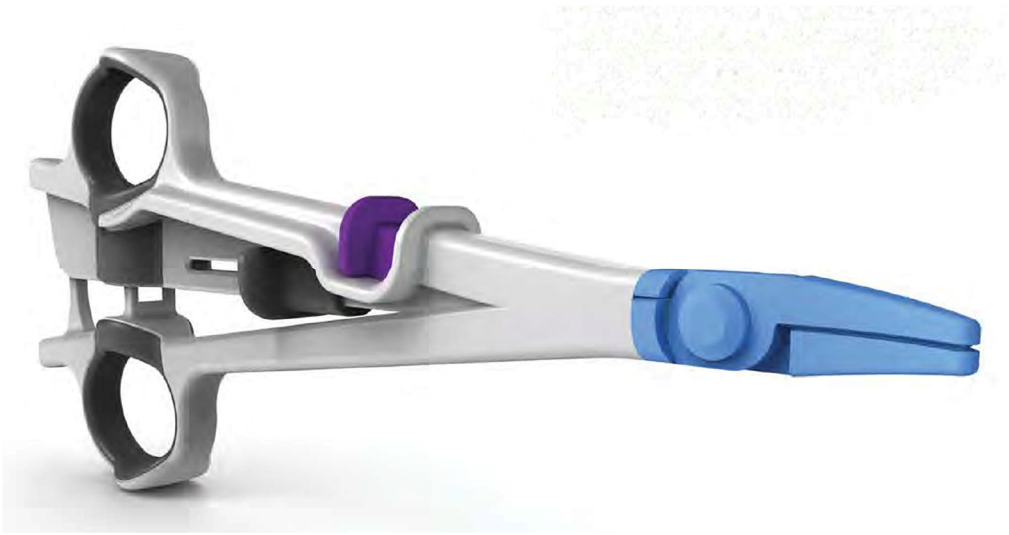
Demonstrative: Design Concept for Covidien



Demonstrative: Design Concept for Covidien

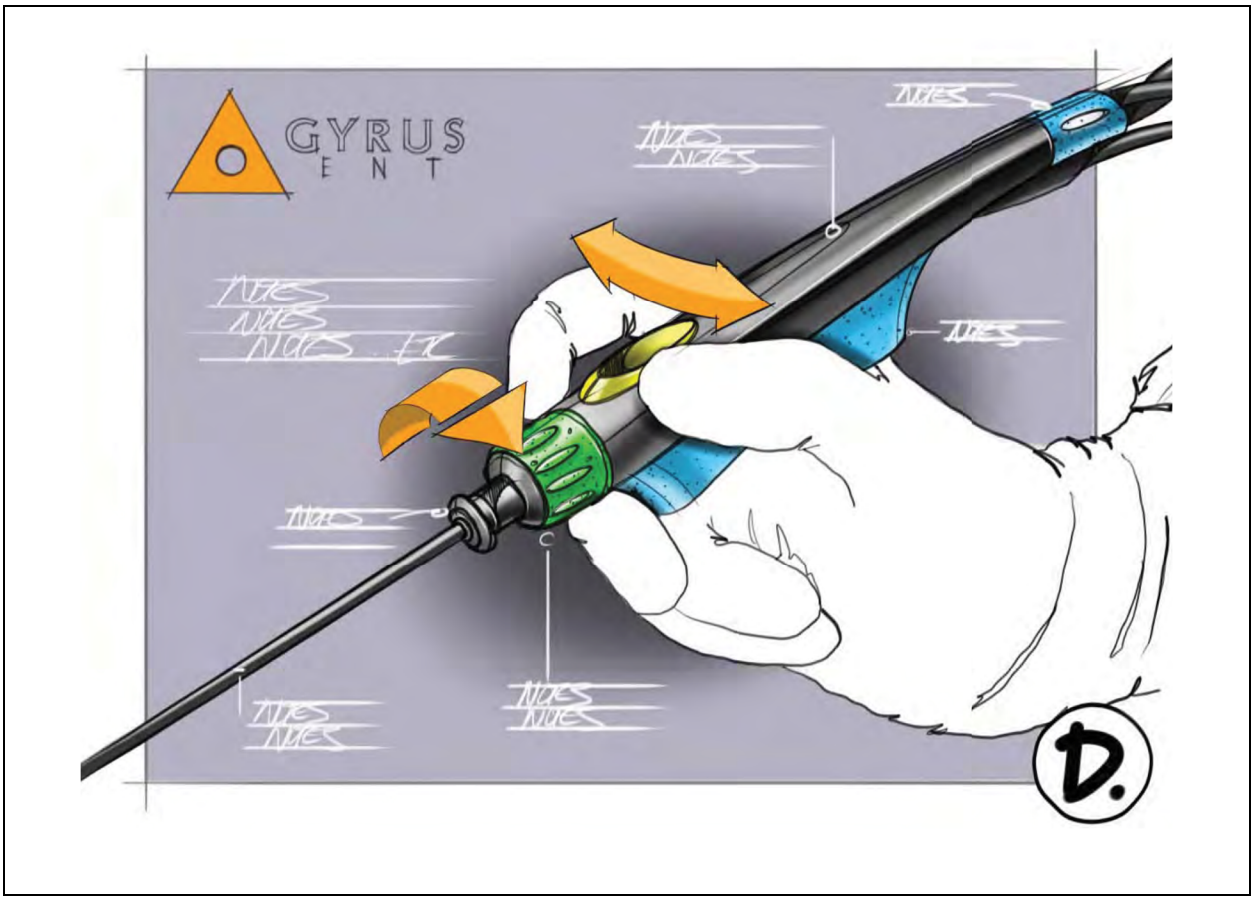


Demonstrative: Design Concept for Covidien



11. A design that I have implemented in handheld surgical tools is the abrupt "step." Below is a preliminary sketch 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 userbase 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 form abruptly 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 sweaty.

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

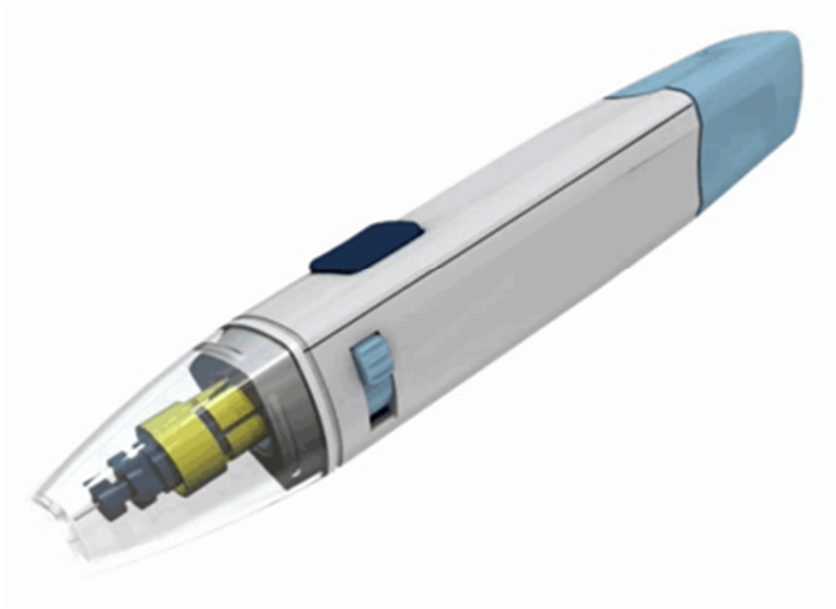
Demonstrative: Papermate Mechanical Pencils



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 Figure 9 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. 1123, 187.

Demonstrative: Understanding Lancing Devices



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.

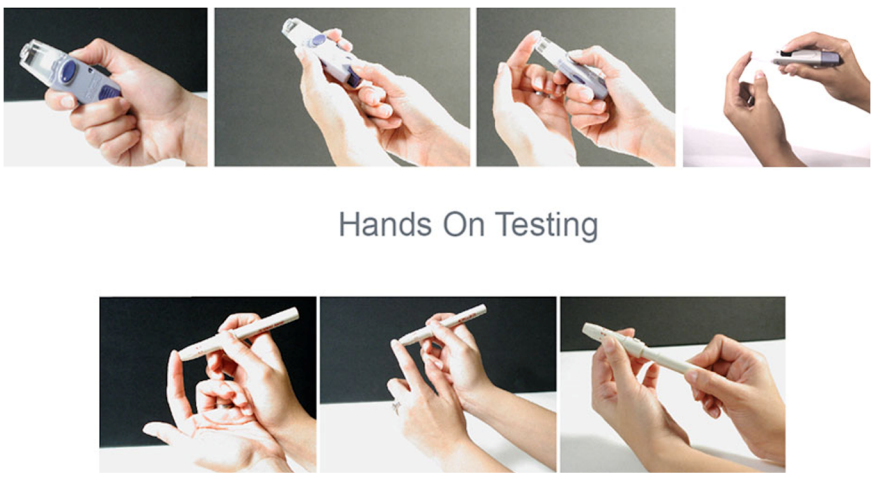
Demonstrative: Popular Lancing Devices Were Used as Comparisons



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. Ex. 1124, abstract. 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

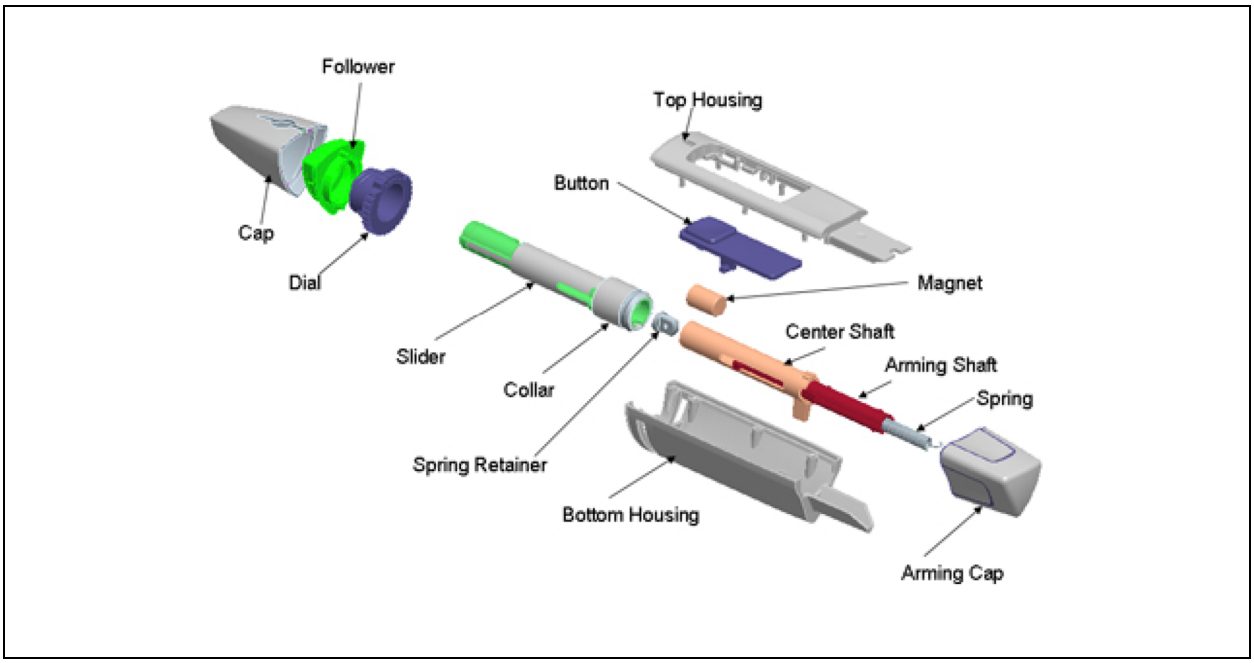


21. In addition to hands-on testing with patients of lancing devices, we engaged in validation testing of the newly developed magnetic lancing mechanism using a high-speed camera to show how the oscillation and vibration was significantly reduced in comparison to other devices. This testing also showed 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

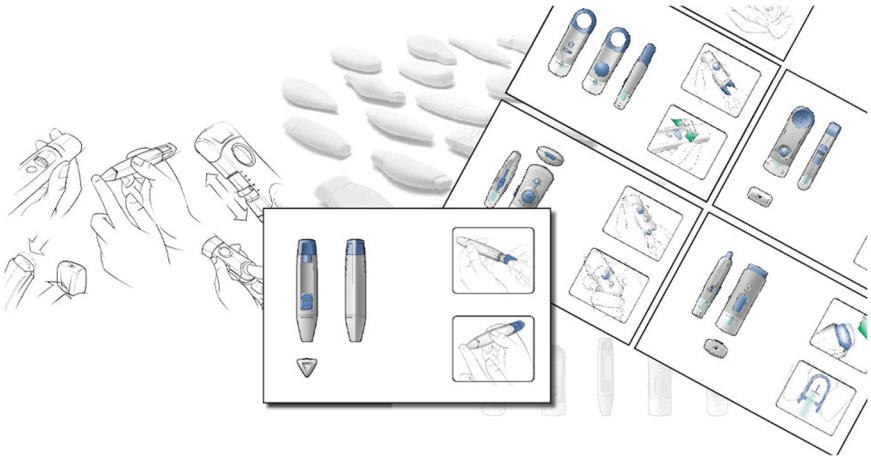


23. There were at least five factors which drove the design choices regarding the dimensions of the magnetic lancing device: (1) benchmarking against popular lancing devices; (2) the size of the lancets to be used; (3) the size and layout of the internal components; (4) human factor data; and (4) cost considerations. Addressing the first factor, it is often a smart move in industrial design to provide an innovative design with functional benefits that do 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 factor 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.1104.

27. I am experienced 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.1025.

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 4-6 years of experience designing consumer products to optimize overall system performance (including medical-device products), including 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.1101, 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 '683 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:

- Coe anticipates all limitations of claim 1;
- Coe, in view of Sakata, teaches the limitations of claims 4 and 9-15;
- Coe, in view of Starnes and the One Touch Booklet, teaches the limitations of claims 4 and 9-15.
- Sakata, in view of Morita, teaches the limitations of claims 1, 4, and 9-15.

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 have 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. 1105, 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.1105, 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 '635 PATENT

A. Prosecution History

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. 1102, 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. Ex. 1102, 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.

IX GROUND #1: COE DISCLOSES ALL LIMITATIONS OF CLAIM 1

51. For the reasons I set forth below, in my opinion, Coe discloses all of the limitations of claim 1 of the '635 Patent.

A. Discussion of Claim 1

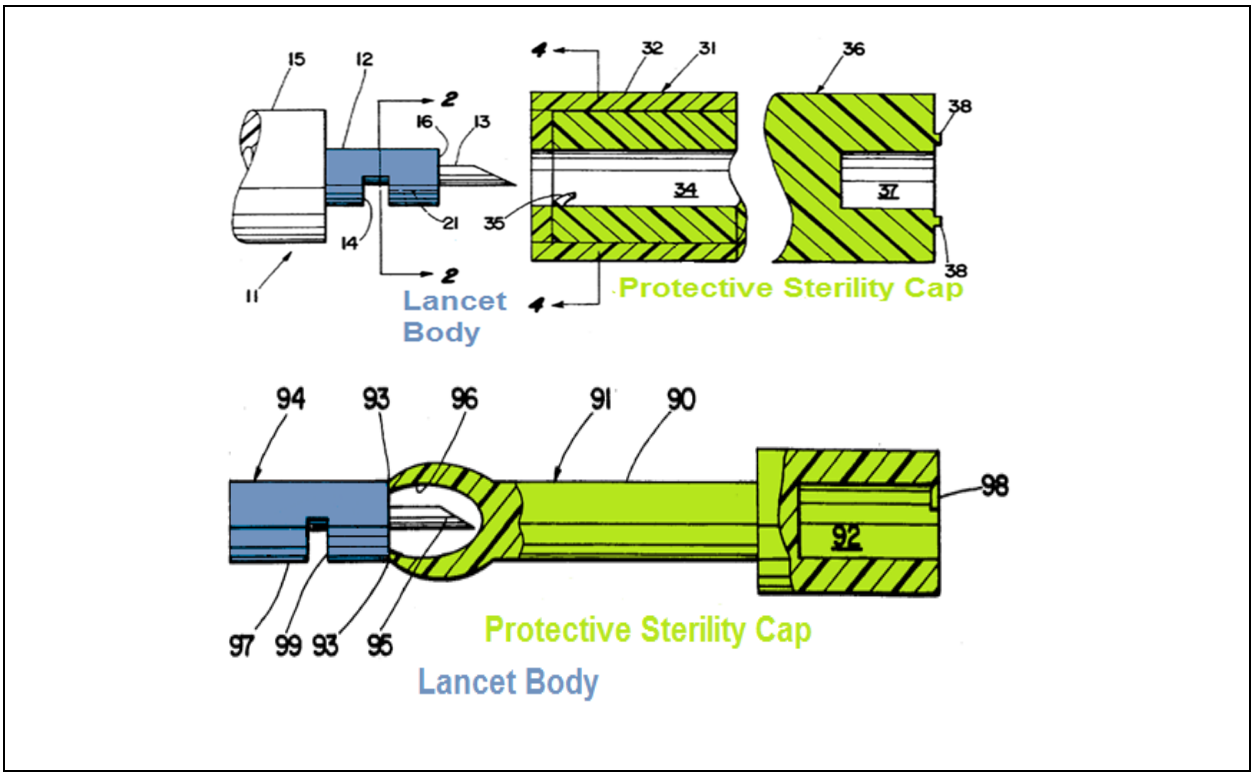
52. I discuss each limitation of claim 1 in turn below, in conjunction with the relevant disclosures of each claim limitation by Coe.

1. Coe Discloses 1[p] – "A protective sterility cap for a lancet"

53. I have been informed that claim preambles are generally not limiting. In any case, even if the preamble were limiting here, I believe that Coe discloses this preamble because Coe discloses "[a] lancet extraction and handling assembly adapted for protectively covering…a lancet…." Ex. 1106, abstract

54. Specifically, Coe discloses a "lancet extractor (91)" for "covering the sharp tip (95) of the lancet (94)," seen in the annotations to Figure 9 below. Ex.1106, 4:3-5 and 5:28-38 ("FIG. 9 is a perspective view of a lancet extractor integrally molded to a lancet to protect the lancet tip before use").

FIGS. 1, 3, and 9 of Coe

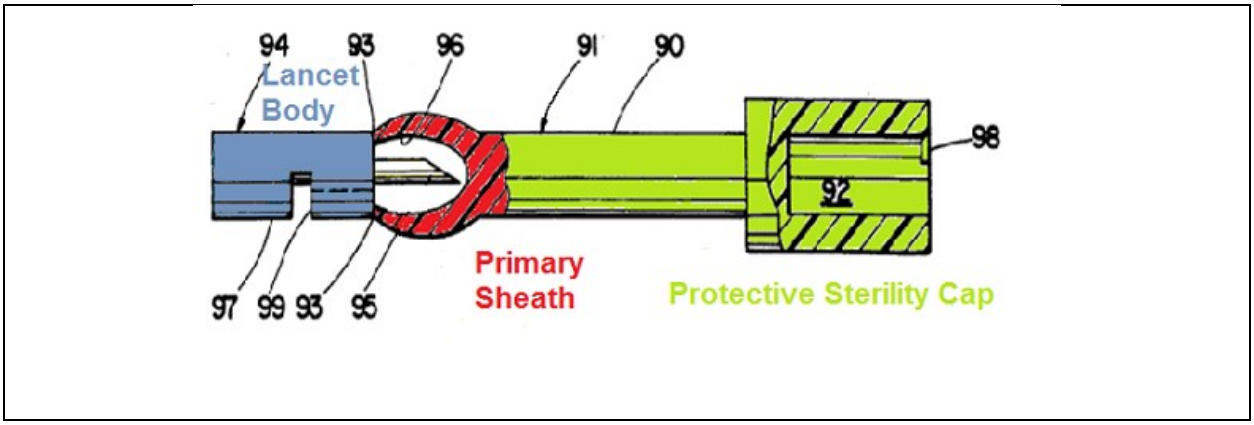


55. One observation to be made here is that Coe states that the extractor (91) may be "integrally molded to a lancet (94)." Ex. 1106, 5:22-38. The "sterile lancet tip" maintains sterility via protection provided by extractor 91.

56. It is therefore my opinion that Coe discloses "a protective sterility cap [*i.e.*, lancet extractor 91] for a lancet [*i.e.*, lancet 94]."

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

57. Looking at an annotated version of Figure 9 below, Coe discloses a primary sheath, or the "cavity (96)" [*colored red in Fig. 9 below*] below with the cavity "protectively covering the sharp tip (95) of the lancet (94)." [*blue with white sharp needle* tip] adjoining a portion of the "extractor (91)" [*green*] Ex.1106, 5:24-28, annotated Figure 9 below. The primary sheath is also molded to the lancet body at breakaway points 93. *Id.* at 4:3-5. The "sterile lancet tip" is released for use by separating the cap from the lancet by "gentle twisting" at "breakaway points" on the surface of the releasing cavity or primary sheath adjacent to the lancet.

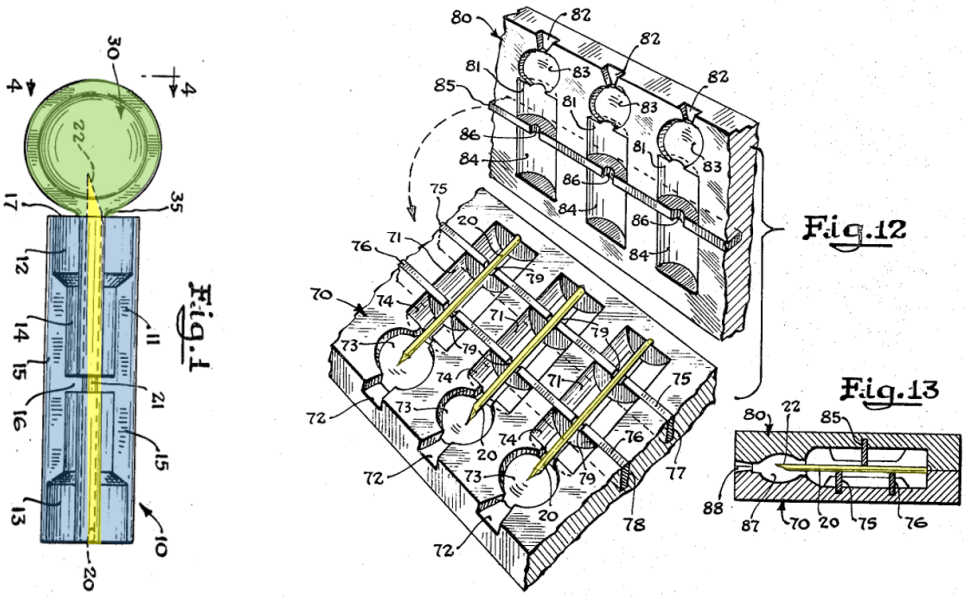


58. Coe does not use the term "embedment" as required by the claim. However, in my opinion, Coe discloses this claim limitation for a number of reasons.

59. *First*, Coe describes the extractor 91 of lancet 94 as "**integrally molded** to a lancet (94)," which a PHOSITA would understand to mean that the needle tip from the lancet body is **embedded** in the extractor because it is integrally molded with the plastic body to form a single integral unit prior to use. Ex. 1106, 1:32-35; 3:29-32 ("The extractor is preferably substantially rigid and may advantageously be molded from the same plastic resinous material as the lancet hub." As shown in the exemplary reference below, I understand that the "integrally molded" extractor described in Coe was likewise molded to the needle tip and joins the needle in a state where it is **embedded** (e.g., molded) in the puncture needle cap. A PHOSITA would understand that sharp tip 95 of the lancet 94 is embedded in the breakaway points 93 at the hub of the lancet 97, because Coe describes the cap as being "**integrally molded** to a lancet" and teaches that the extractor (i.e., cap) operates first by "bar[ing]...by breaking away the handle portion at the breakaway points by gently **twisting**" (not pulled) off of the lancet body to avoid potentially bending or damaging the lancet. Ex.1106, 5:31-33.

60. *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.1101, 1:47-50, 6:18-24. I observe this is also the case in Higgins (Ex.1118), Starnes ‘440 (Ex.1116), and other prior art patents and published applications cited on the face of the ’635 Patent (Ex. 1101, pgs. 1-2, “References Cited”). All of these references I note 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 cap is “molded integrally with [a lancet] and sealably embedding and enclosing [a sharp lancing tip] in the material thereof to prevent bacterial contamination.” Ex.1118, claim 1.

“Integrally-Molded” Cap as Undstood by a PHOSITA



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

61. *Third*, in my opinion, Figure 9 also discloses the sharp 95 of Coe's lancet 94 being embedded in the extractor because a PHOSITA would recognize the "breakaway points" as frangible junctions (*colored red below*) by which "the cap [] is integrally molded and joined to the lancet body" such that the "piercing tip [of the lancet] is **embedded** within cap [] and frangible junction []." Ex. 1116, ¶0028. As taught in Starnes '440, the protective cap "receives the distal end of piercing tip 32 in the pre-use, 'as manufactured' configuration." *Id*. Moreover, Coe's cap can be separated from the lancet body by "gentle twisting."

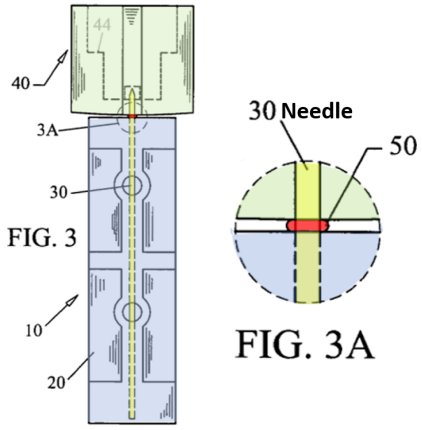
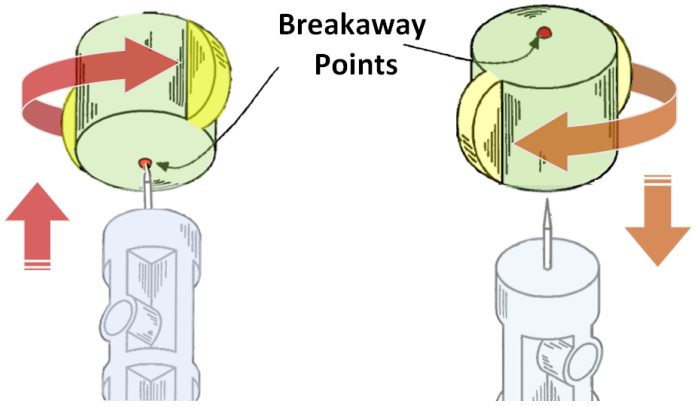
<table>
<tr><th colspan="2">“Breakaway Points” as understood by a PHOSITA</th></tr>
<tr><td> 

FIG. 3
FIG. 3A</td><td> 
</td></tr>
<tr><td>Starnes ‘440, Figs.3-3A

(Colored)</td><td>Demonstrative</td></tr>
</table>

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.*, breakaway points—“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.1101, 6:18-26. I understand

that because the breakaway points in Figure 9 are not broken, the needle has not yet been used for sampling or testing, and therefore, remains sterile.

62. *Fourth*, I am further informed by Coe's Figure 9 that the needle sharp 95 is embedded within extractor 91 and adjoining portion of the handle portion 90. Coe teaches that the extractor 91 may include "an extractor cavity (92)…[with] the extractor tab (98) engag[ing] the slot (99) in the lancet hub thereby locking the sharp lancet tip protectively within the extractor cavity for safe handling and disposal." Ex.1106, 5:33-38. By differentiating the "cavity (96)…attached to the hub of the lancet (97) by breakaway points (93)" from the "extractor cavity (92)" of Figure 9, I understand that the lancet sharp 95 within lancet 97 is embedded within the "integrally molded" extractor 91. Ex. 1106, 5:22-38.

63. In my opinion, Coe therefore discloses that the "sterility cap [*i.e.*, extractor 91] compris[es] a primary sheath [*i.e.*, cavity 96 and breakaway points 93] for initial embedment of a sharp lancing tip of an unused lancet therein [*i.e.*, sharp tip 95 of lancet 97]."

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

64. I observe that Coe's protective cap 91 also includes "an extractor cavity (92)," which serves as a "secondary sheath" for several reasons. See Figure 9, annotated below. Ex.1106, Figure 9.

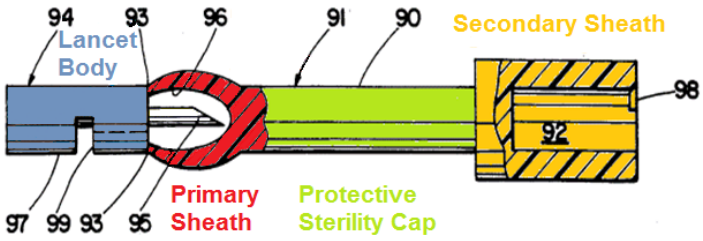


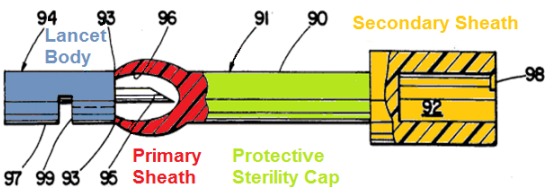
Fig. 9 (Annotated and Colored)

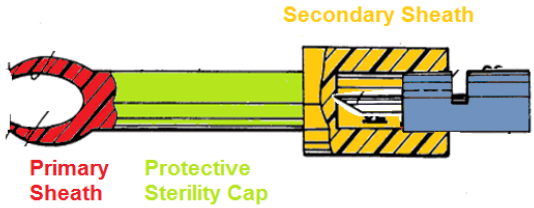
65. Coe teaches that "[a]fter use, the lancet is inserted (point first) into the extractor cavity…for safe handling and disposal." Ex. 1106, 5:33-38. I understand this to refer to pushing the lancet sharp 95 into a hollow cup-like sheath of the extractor 91. Ex.1106, 24-25.

66. Accidental needlesticks have been an art-recognized problem. Ex. 1125, pg. 1. 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.1110 (LifeScan One Touch); Ex. 1123 (Freestyle) (Freestyle Product Manual disclosing lancet with a secondary sheath including Petitioner's own prior art lancets 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 "extractor cavity" of Coe's protective cap 91 can also "be used for **receiving** [the] sharp ***after use*** and ***prior to disposal.***"

67. By positioning the secondary sheath on the opposite end of the handle portion away from the primary sheath and by using a hollow cavity for the secondary sheath that is visually and tactilely distinct from the primary sheath, Coe's protective cap 91 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 cavity 96 rather than into the wider cavity 92.





Ex.1106, Figure 9 (Demonstratives: Recapping Used Lancet)

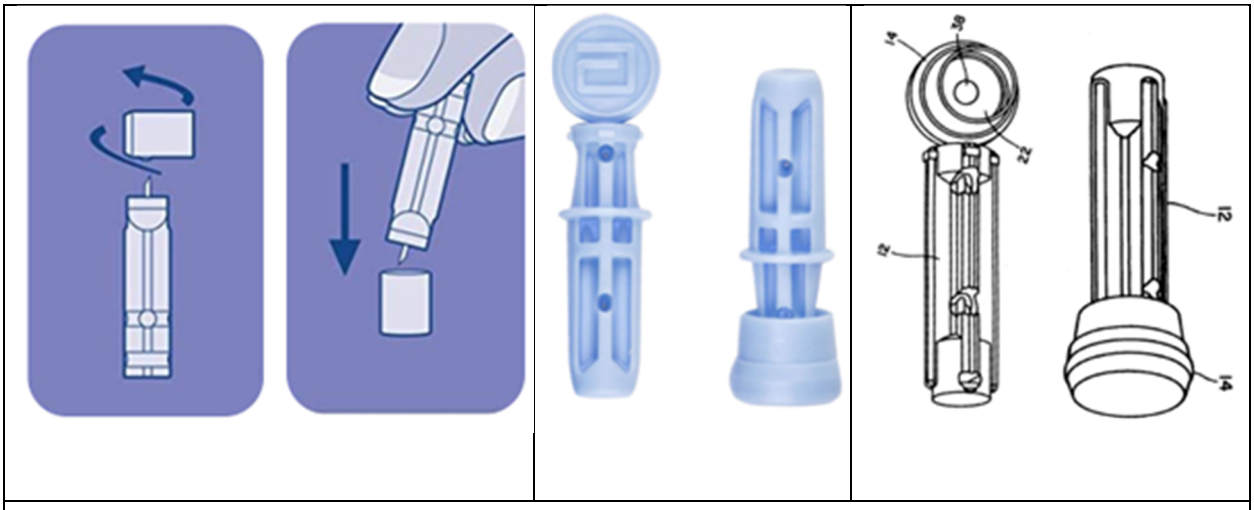
68. To prevent inadvertent needle sticks after use but prior to disposal, many conventional caps also include a hollow cup so the user can safely dispose the lancet after it has been used. The needle sharp remains encased within the hollow cup while the user finishes testing the blood sample and even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

69. The hollow cup/cavity is designed for "receiving" a used lancet because the sharp lancing tip is enclosed in the cavity rather than embedded in the cavity. 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.1105, 13:24-14:3. Like Coe, the '635 Patent uses

the term "receiving" to describe a lancet needle "enclosed" within a "hollow cup" Ex.1101, 6:1-5, 7:6-10; Ex.1101, Figs. 5A-5D

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 the lancet after it has been used.

Meaning of "Hollow Cup" to a PHOSITA

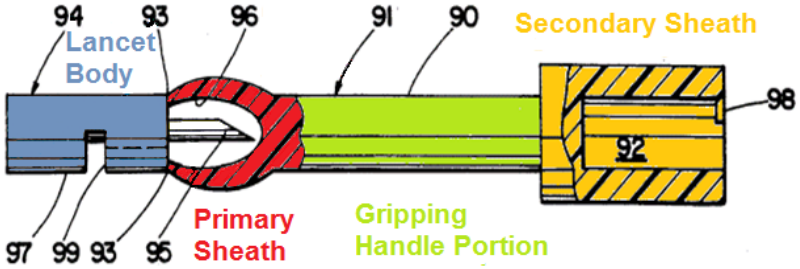


Demonstative: Recapping Used Lancet in a Hollow Cup

71. In my opinion, it is for at least these reasons, Coe discloses "a secondary sheath for receiving the sharp lancing tip of a used lancet [*i.e.*, for receiving the sharp 95 of the lancet 94 after it has been used to collect a blood sample].

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

72. Coe's protective cap 91 further includes a "handle portion 90" (*colored green below*) extending between the primary sheath (*colored red below*) and the secondary sheath—*i.e.*, the hollow "extractor cavity 92" (*orange*).



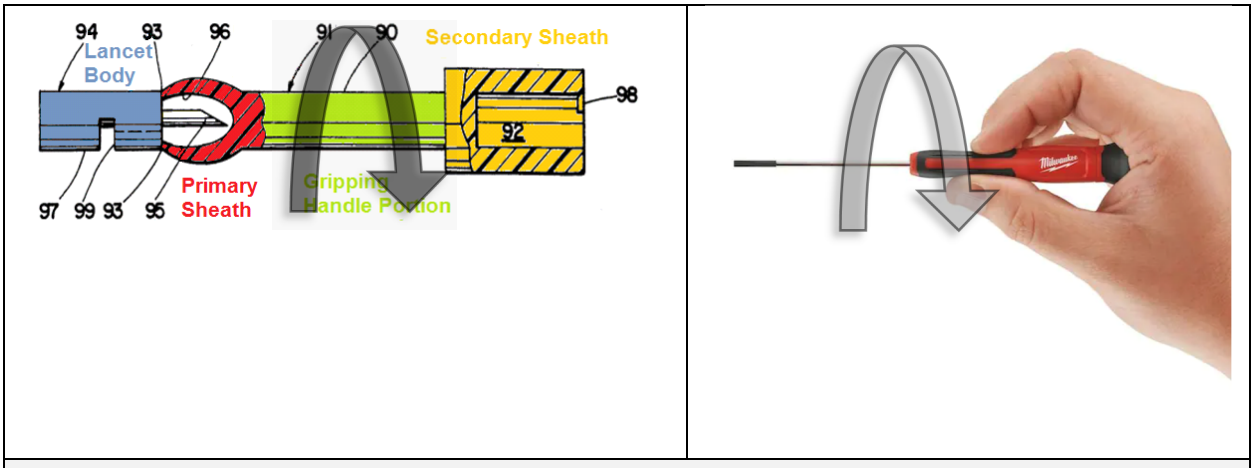
Ex.1106, FIG. 9 (Colored and Annotated)

73. Many individuals with diabetes have trouble seeing and collecting a blood sample or even just juggling all of the different pieces during a test. Coe incorporates a "**handle portion**" into the protective cap 91 to provide users with a handle for twisting (*i.e.*, gripping) away the cap at breakaway points 93 to bare the sharp tip of the lancet 95. Ex.1106, 5:24-27. 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.1105, 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.1101, 1:66-2:3, 6:5-9, 7:6-12, 8:17-22.

74. Like the ’635 patent, Coe recognizes an objective of “provid[ing] a lancet extraction assembly which will effectively minimize hazards…which will be simple to use and economical to adopt.” This is because users need to grip the lancet by the cap when inserting it into the lancing device, and need to remove the cap from the lancet prior to use and then re-insert it back into the cap after use.

75. And just like the ’635 patent, Coe teaches that “the present invention [is] to provide for disposal of used lancets in such a fashion as to minimize risk to housekeeping personnel.”

76. By having the handle portion 90 on the extractor 91between the primary sheath and secondary sheath, Coe’s protective cap provides the user with an elongated surface area, near the center of the extractor, so as to encourage and facilitate a user to **gently twist** off the extractor/cap from breakaway points 93.



(Demonstrative: Twisting Off Coe's Cap)

77. The elongated handle portion (*green above*) enables the user to apply torque when twisting the protective cap from the lancet. The surface of the handle portion allows the user to firmly grasp the protective cap with the thumb and index finger and exert pressure while twisting. Coe's handle portion functions much like a conventional handle of a screwdriver, wherein a user is able to controllably twist the screwdriver near its handle's center of gravity. Just like a screwdriver, Coe's handle portion provides a surface to provide a firm grip while turning.

78. Coe's handle portion 90 provides leverage for applying rotational force to effectively twist the cap, making it easier to remove the protective cap 90 from the lancet 94. A PHOSITA would appreciate that the increased leverage

provided by the handling portion better accommodates diabetic patients with limited dexterity by spreading the applied force efficiently across a longer contact area.

79. Coe's handle portion also allows the user to grip the lancet further away from the needle sharp, which helps "minimize the risk of accidental puncture wounds both during and after removal of the lancet from an automatic lancet device." Ex.1106, 3:11-14.

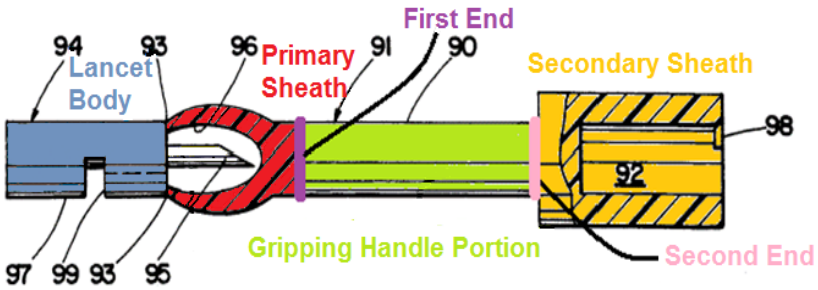
80. In my opinion, Coe therefore discloses "a gripping handle portion [i.e., handle portion] extending between the primary sheath [i.e., second cavity] and the secondary sheath" [*i.e.*, extractor cavity]."

5. Coe 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"

81. Coe's Figure 9 shows the primary and secondary sheaths attached to opposing ends of the handle portion (i.e., gripping handle portion) of the protective cap 78. Ex. 1106, Figure 9. Specifically, Coe 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 9 below.

FIG. 9 (Annotated)



82. The primary and secondary sheaths are attached at opposing ends of the handle portion "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 handle portion even after the user twists off the puncture cap 78 from the lancet needle to collect a blood sample. Nothing in Coe 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-type area 92 at the opposite end of cap 91 is made available opposite of the part of the cap embedding the sharp lancing tip. Ex.1106, 5:25-27.

83. In my opinion, Coe therefore discloses a "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.

X GROUND #2: COE RENDERS OBVIOUS CLAIMS 1, 4 AND 9-15 IN VIEW OF SAKATA

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

84. As I explained in Ground 1 above, Coe anticipates this limitation by disclosing that extractor may be "**integrally molded** to a lancet" 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(2).

85. It would have also been obvious to a PHOSITA to embed the lancet needle into Coe's cap/extractor to not only protect the integrity of the needle tip,

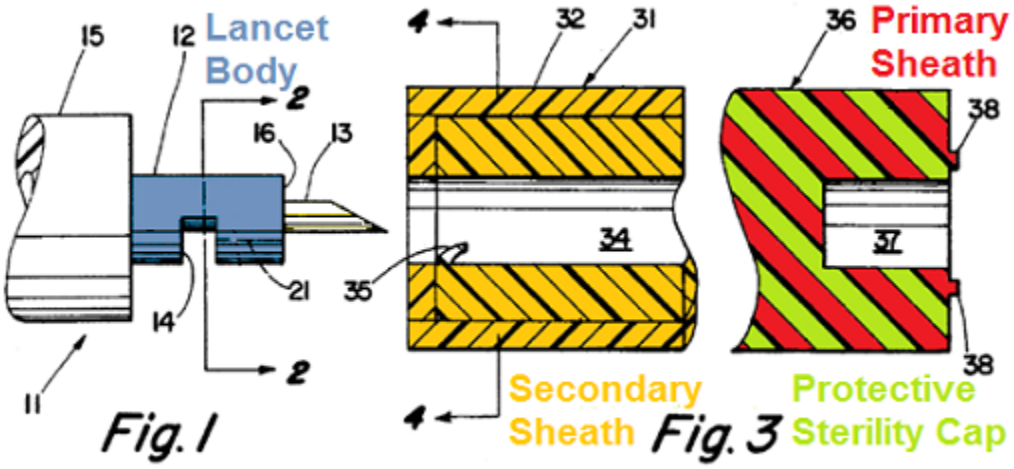
but also to protect the sterility of the needle and prevent contamination during post manufacturing packaging, shipping, and storage. To do so, a PHOSITA would not need to use anything other than traditional insert molding methods, for high-volume, low-cost manufacturing. Thus, modifying Coe's cap to 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.1108, ¶0008. Additionally, a PHOSITA would know that embedding the lancet needle within the breakaway points of the protective cap 91 makes the needle tip 95 more resistant to lateral forces from different sides or pivoting movements of the endcap when it is twisted off by the user, which could bend or break the needle tip. *Id*.

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

86. In my opinion, not only does Coe expressly disclose a secondary sheath 92, Coe 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 Coe's express teaching of secondary

sheath 92 fails to teach the claimed secondary sheath, it would have been obvious to modify Coe to have (i) a different type of secondary sheath (in addition to sheath 92) or (ii) to remove sheath 92 and to instead use a different type of secondary sheath.

87. Coe teaches the use of another embodiment of a secondary sheath, as illustrated in annotated figures 1 and 3 below.

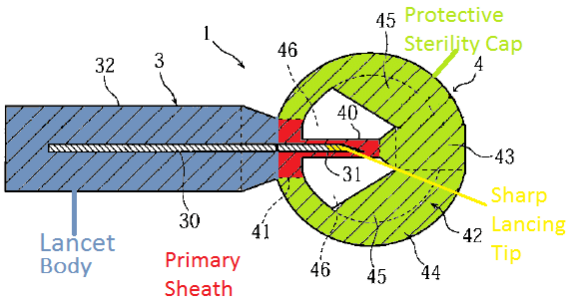


A PHOSITA would have been motivated to combine the features of Coe's Figure 3 and Figure 9 embodiments, because Coe describes advantages associated with the secondary sheath. Coe makes clear that the structure and function of secondary sheaths 34 and 92 are also identical. *Compare* Ex.1106 4:27-39 *with* 5:22-38.

C. Claims 4, 9, and 15: "wherein the gripping handle portion comprises at least one open loop"

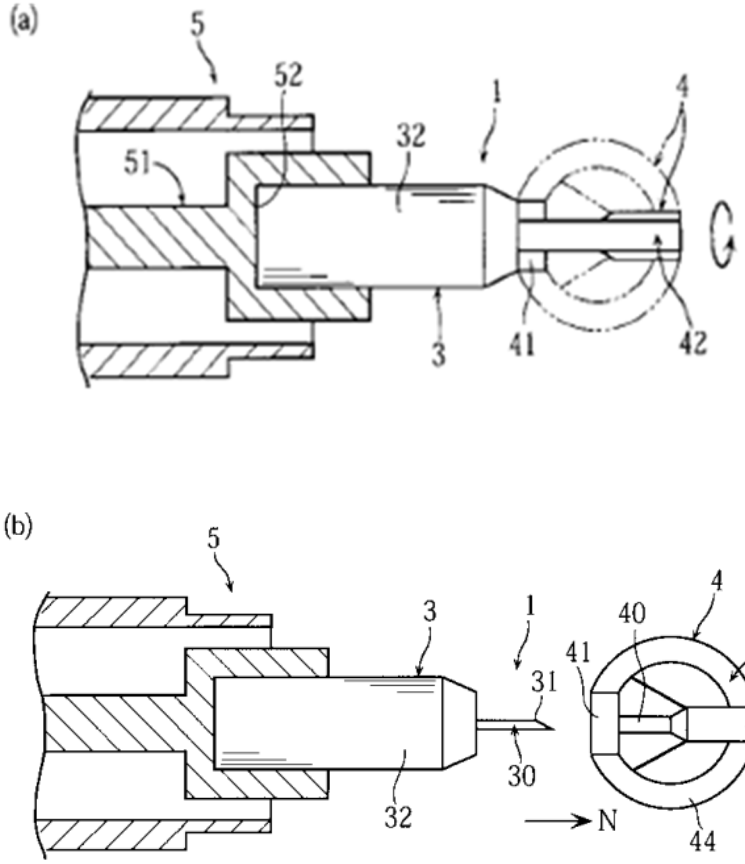
88. In my opinion, the recitation of "wherein the gripping handle portion comprises at least one open loop" is disclosed by a combination of Coe and Sakata. The combination of these two references is straightforward as Sakata expressly teaches an operating portion (i.e., a gripping handle portion of the cap) with "a gap 46 [that] is interposed between [an] arch portion 44 and [a] small diameter covering portion 40." Ex.1107, ¶0019, Figures 1 and 2 annotated below.





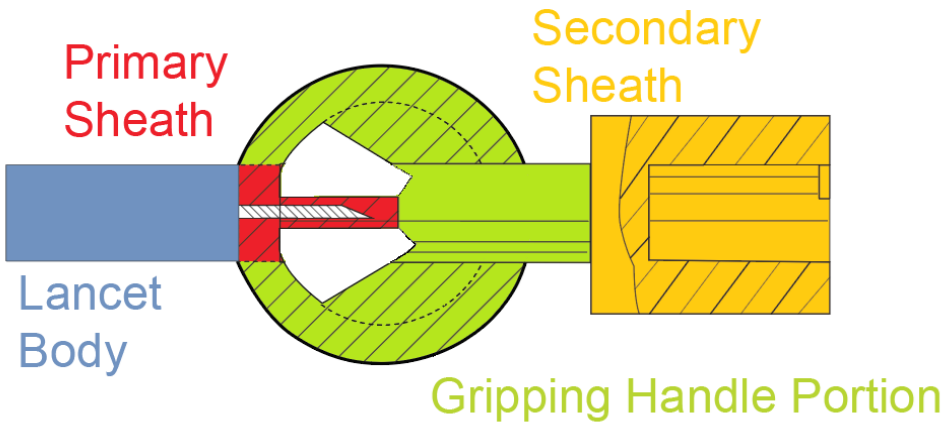
89. This combination would be obvious given that Sakata also discloses a protective sterility cap for a lancet, with the protective sterility cap having a gripping handle portion in the form of an "operating portion," wherein a "cap portion has a covering portion that adheres to the above needle tip and covers the

above needle tip portion." Ex. 1107, paragraph 0013. In my review of Sakata, Sakata expressly teaches a solution to the problem of rotational/twisting forces deforming a sharp lancet tip to the extent of "causing greater puncture pain when the puncture needle [] is pierced into the skin." *Id.*, ¶0004. That solution is the operating portion, which is designed in a loop shape so that "[w]hen the cap portion 4 is rotated, the **rotational force applied to the operating portion** 42 is concentrated on the cylindrical portion 43 and the large diameter covering portion 41 because the arch portion 44 connects the cylindrical portion 43 and the large diameter covering portion 41. As a result, the operating portion 42 is twisted and rotated at the boundary between the large diameter covering portion 41 and the holding portion 32. The small diameter covering portion 40 rotates relative to the needle tip 31 of the puncture needle 30, reducing the adhesiveness of the interface between the small diameter covering portion 40 and the needle tip 31, so that the cap portion 4 can be separated from the lancet body 3 by applying a force in the direction N of the arrow in the figure to the operating portion 42." Ex.1107, paragraph 0020; see Figures 5(a) and 5(b) below.



90. Both Coe and Sakata 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.1101, 1:17-19. Like the '635 Patent, both Coe and Sakata relate to skin lancing devices. Ex.1106, 1:11-18; Ex.1107, ¶0001.

91. I believe there is abundant motivation for a PHOSITA to apply the loop design from Sakata's protective cap 4 to the handle portion of Coe (in the manner graphically demonstrated below) so as to provide the solution of "when the cap portion is separated, the force applied to the operating [portion 42] is absorbed by the deformation of the covering [portion 41] …." Ex.1107, ¶[0012].



Demonstrative: Coe in view of Sakata

92. My review of Coe in view of Sakata also reveals how Sakata solves a problem contemplated by Coe. Coe discloses that a lancet's fine "tip easily breaks off during transport and storage. To make and protect a fine tip, the tip is surrounded by a plastic protective cap which is extruded in one piece with retaining attachment points and is twisted off before use of the lancet." Ex.1106,

1:32-35. It is therefore clear that the force applied to the large diameter of Coe's releasing cavity or primary sheath when twisting off the protective cap from the lancet can damage the fine tip of the lancet, as even transport and storage activities expose the cap and its needle to risks of damage. A damaged lancet tip can cause additional pain to the user when puncturing the user's skin, and thereby lower the quality of a lancet. Sakata's loop-shaped gripping handle solves this problem by minimizing lateral forces at the needle that may be imparted to the needle when a user twists the handle.

93. While preventing damage to the sharp needle tip, Sakata's loop-shaped cap also provides an intuitive surface for the user to handle and twist. An exemplary item akin to Sakata's open loop is a conventional corkscrew.





94. Thus, in my opinion a PHOSITA would have had a reasonable expectation of success in combining Coe with Sakata as such a combination would merely require replicating components that already existed in the art. So, Coe in view of Sakata would render unpatentable claims 4, 9 and 15 in terms of the "open loop" limitation.

95. Sakata clearly presents a protective sterility cap for a lancet having an open loop configuration. Sakata discloses an operating portion with "a gap 46 [that] is interposed between the arch portion 44 and the small diameter covering portion 40." Ex. 1107, paragraph 0019.

D. Claim 10: "at least one flat display surface for placement of branding indicia thereon"

96. As I explained previously, Coe in view of Sakata renders obvious claim 9.

97. As an initial matter, it is my understanding the limitation "for placement of branding indicia thereon" merely recites an intended use.

98. In my opinion, the recitation of "at least one flat display surface" is disclosed by a combination of Coe and Sakata. Sakata includes an "operating

portion 42 [that] has … a pair of thin-walled portions 45." These thin-walled portions not only serve as flat surfaces onto which branding indicia can be placed, but also as flat surfaces onto which a user's fingers may grip to twist Sakata's cap, as explicitly taught by Sakata. "The thin-walled portions 45 shown in Fig. 1 and 2 are intended to facilitate operation of the operating portion 42 and is formed so that it is not in direct contact with the small diameter covering portion 40 in the area defined by the arch portion 44."

99. In my opinion, Coe in view of Sakata would render unpatentable claim 10.

E. Claims 11-13: The "Length" and "Lateral Span" of the Gripping Handle Portion

100. In my opinion, it would have been obvious for a PHOSITA to try to render Coe's gripping handle portion to define a "lateral span of at least 1.5 times the lancet thickness"; "a length at least equal to its lateral span"; and "a length at least equal to the lancet thickness." There was an art-recognized problem of lancets being held by people with limited dexterity or other challenges (including the elderly and other individuals that might 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. (*See, e.g.,* Ex. 1125) Determining how to dimension the gripping handle portion (in both its lateral span and length) was also an aspect that a PHOSITA would have routinely experimented with in seeking to optimize the sterility caps for mass-market use, including having only a finite number of potential solutions for dimensioning the gripping handle portion as compared to thickness of the lancet. With this factual backdrop in mind, a discussion of the obviousness of each of the relative dimensional aspects is below.

101. As to the gripping handle's lateral span being at least 1.5 times the lancet thickness (recited in claims 11 and 14), it was already known that gripping handles on many sterility caps (Morita) were larger than the lancet thickness. Coe is one example of this, because 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 Coe's express instruction to create a cap that would "effectively minimize hazards to medical personnel resulting from accidental

lancet punctures." Ex.1106, 3:33-36. Both express statements in Coe 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 Coe. And, given the instruction to create a gripping handle portion that "minimize[s] risk to housekeeping personnel," a PHOSITA would have used dimensions for the cap 91 in Coe that allows a user to easily handle the cap 91 with their fingers, including creating a large enough cap 91 to at least be held between the average human fingerpad size of 10-14 mm. Ex. 1121, §4.1; Ex. 1122, abstract.

102. 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 handle portion in Coe, to ensure proper handleability for users with limited dexterity, such as the elderly. Having the length of that handle portion at least equal its lateral span would have been a natural option that would have been achieved with a reasonable expectation of success.

103. As to the gripping handle's length being at least equal to the lancet thickness (recited in claim 13), this again would have been a dimensional aspect

that a PHOSITA would have naturally chosen in exploring various sizing options for the gripping handle portion.

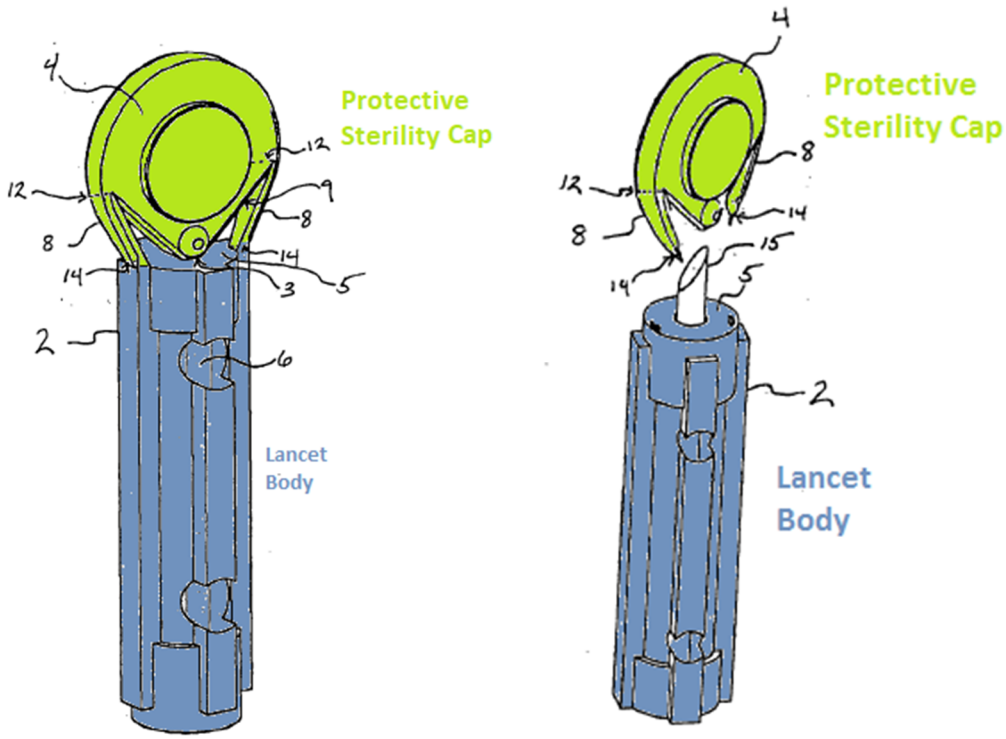
104. As to the gripping handle's length being at least equal to the lateral span (recited in claim 14), a PHOSITA would have tried various dimensions for the length and lateral span of the handle portion in Coe, to ensure proper handleability for users with limited dexterity, such as the elderly. Having the length of that handle portion at least equal its lateral span would have been a natural option that would have been achieved with a reasonable expectation of success.

XI GROUND #3: COE RENDERS CLAIMS 4, 9-10, AND 15 OBVIOUS IN VIEW OF STARNES AND ONE TOUCH OWNER'S MANUAL

A. Claims 4, 9, and 15: "wherein the gripping handle portion comprises at least one open loop"

105. In my opinion, the recitation of "wherein the gripping handle portion comprises at least one open loop" is disclosed by a combination of Coe and Starnes. The combination of these two references is straightforward, as Starnes expressly teaches a "lancet casing further include[ing] a cap integrally molded

about the pointed end of the lancet needle and joined to the lancet body by a narrow frangible junction on the upper bearing surface of the lancet body." Ex. 1108, abstract, Figures 1 and 2, annotated below.



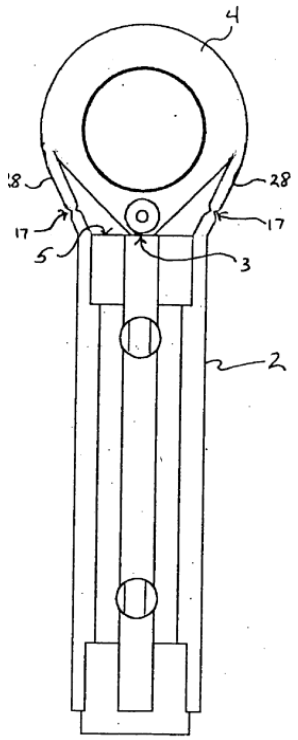
106. This combination would be obvious given that Starnes also discloses a protective sterility cap for a lancet, wherein "The top portion of lancet unit 10 comprises a cap member 4 that is integrally and sealably joined to lancet body 2 by

a frangible junction 3 that is preferably of a reduced diameter so that frangible junction 3 can be readily fractured to detach cap member 4 from an upper bearing surface 5 by exerting a twisting or pulling force, as by rotating cap member 4 relative to lancet body 2." Ex. 1108, ¶0024.

107. Starnes also illustrates a cap that is twisted off via a user's fingers, thereby rendering its cap to mostly comprise of a gripping handle portion. Ex. 1108, ¶0024 ("Furthermore, cap member 4 includes opposing face surfaces to provide a relatively flat or disc-like member that can be conveniently grasped between the ends of the thumb and forefinger when it is desired to rotatably detach cap member 4 relative to lancet body 2.").

108. In my review of Starnes, Starnes expressly teaches a solution to the problem of determining whether a lancet has been used, given that a used lancet would be at risk of contamination and therefore should be discarded upon notice. This problem is also highlighted in the '635 Patent. Ex. 1101, 1:50-52. The solution taught by Starnes includes designing the cap 4 to have an open loop defined by "a pair of integrally molded tab members 28 each having a medial tear-away joint 17 disposed between the points at which each of tab members 28

attaches to cap member 4 and lancet body 2." Ex. 1108, Figure 4, ¶0035. Starnes further teaches "tear-away joint 17 comprises a Substantially narrowed neck junction that will more readily fracture upon application of a twisting or pulling force applied between cap member 4 and lancet body 2. In this manner, when cap member 4 is detached from lancet body 2, a substantial appendage portion of the original tab member 8 remains attached to cap member 4 while a visually perceptible stub remains the upper bearing surface 5 of lancet body 2." The visually perceptive stub "provides a readily perceptible indicator of de-attachment while not unduly interfering with the surface contour of upper bearing surface 5." *Id;* see Figure 4 below.



109. My review of Starnes also shows how the gripping handle of Starnes provides a "detachment technique [that] is effective for the flat-faced, disk like cap member 4 by providing a well-suited lever for applying sufficient force to simultaneously detach the pair of tab members 8 from upper bearing surface 5 of the lancet body." Ex. 1108, ¶0031. The "tab members 8 disengage from lancet body 2 at or near the lower tear-away ends 14 such that a minimum amount of plastic molding residue remains which will not appreciably affect the shape or contour of lancet body 2 thus preventing any potential interference by such residue

with upper bearing surface 5 or with the fitting of the uncapped lancet into a lancing device." *Id.* Overall, gaps 19 also serve a purpose of directing twisting forces towards breakaway points in a manner that preserves the integrity of an attached lancet body.

110. Both Coe and Starnes are analogous art to the '635 Patent because they are both within the same field of endeavor with the '635 Patent. Ex.1101, 1:17-19. Like the '635 Patent, both Coe and Starnes relate to skin lancing devices. Ex.1106, 1:11-18; Ex.1108, ¶0003.

111. I believe there is abundant motivation for a PHOSITA to apply the loop design from Starnes' protective cap 4 to the handle portion of Coe (as an example, in the manner graphically demonstrated above of Coe in view of Sakata, which also employs an open loop) and have "[t]he relative width of tab base 12 ensures that responsive to a twisting removal action, tab member 8 will remain attached at its upper end to cap member 4 while the lower tear-away joint 14 will disengage from upper bearing surface 5 of lancet body 2 substantially simultaneously with fracturing of frangible junction 3." Ex.1108, ¶0012.

112. My review of Coe in view of Starnes also reveals how Starnes possesses an open loop at its gripping handle portion. Starnes teaches "such detachment is typically effectuated by a hand twisting motion in which the suitably disk shaped cap member 4 is grasped between a user's thumb and index finger while the lancet body 2 is grasped by the fingers of the user's other hand. In the depicted embodiment, this detachment technique is effective for the flat-faced, disk like cap member 4 by providing a well-suited lever for applying sufficient force to simultaneously detach the pair of tab members 8 from upper bearing surface 5 of the lancet body." *Id.* ¶0031.

113. Thus, in my opinion, a PHOSITA would have had a reasonable expectation of success in combining Coe with Starnes as such a combination would merely require replicating components that already existed in the art.

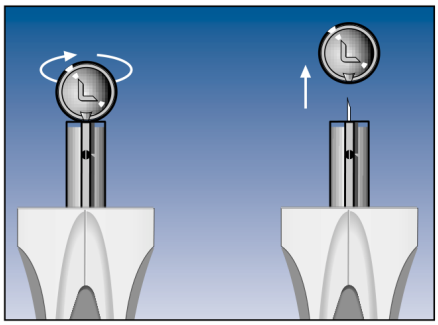
B. Claim 10: "at least one flat display surface for placement of branding indicia thereon"

114. As I explained previously, Coe in view of Starnes renders obvious claim 9.

115. As an initial matter, it is my understanding the limitation "for placement of branding indicia thereon" merely recites an intended use.

116. In my opinion, the recitation of "at least one flat display surface" is disclosed by a combination of Coe. Starmes. And LifeScan One Touch Booklet. The combination of these two references is straightforward as One Touch expressly teaches using a flat display surface of a cap to display branding indicia (the LifeScan logo) as shown below.

While the lancet is in the Penlet® *Plus* Sampler, twist off the protective disk. Make two full turns to ensure that the lancet separates from the protective disk.



117. Both Coe and One Touch are analogous art to the '635 Patent because they are both within the same field of endeavor. Like the '635 Patent, Coe relates to skin lancing devices while One Touch provides for the "One Touch Basic

Complete Diabetes Monitoring System" which is used for "in vitro diagnostic use for quantitative determination of glucose in whole blood as an aid in monitoring effectiveness of diabetes management in the home and in clinical settings." Ex.1106, 1:11-18; Ex.1110, pg. 2.

118. In addition, Coe and One Touch 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.1101, 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." *Id*., 5:28-29.

119. One Touch discloses the steps for testing blood glucose with the One Touch Basic Diabetes Monitoring System, including the steps for inserting a lancet into a lancing device. Ex.1110, pgs. 27-28. For these reasons, I believe Coe and One Touch are analogous art to the '635 Patent.

120. A PHOSITA would be further motivated to add the One Touch branding to the Coe cap because such a combination would be commercially desirable and to indicate a source of goods.

121. In addition, a PHOSITA would have been motivated to add the One Touch branding to the Coe cap because doing so would improve a patient's grip on the lancet. Industrial designers often incorporate embossed or debossed logos or symbols on the surface of an object to provide increased friction for users when handling small objects. As seen in the example above, having the logo molded onto the protective cap would provide areas where patients can grip the cap with higher friction.

122. Lastly, a PHOSITA would have had a reasonable expectation of success in combining Coe and One Touch branding because it would have only entailed a simple modification. Such a modification would have only involved adding an "indicia" from the One Touch manual to Coe's protective cap with little or no experimentation.

123. In my opinion, Coe in view of Starnes and One Touch would render unpatentable claim 10.

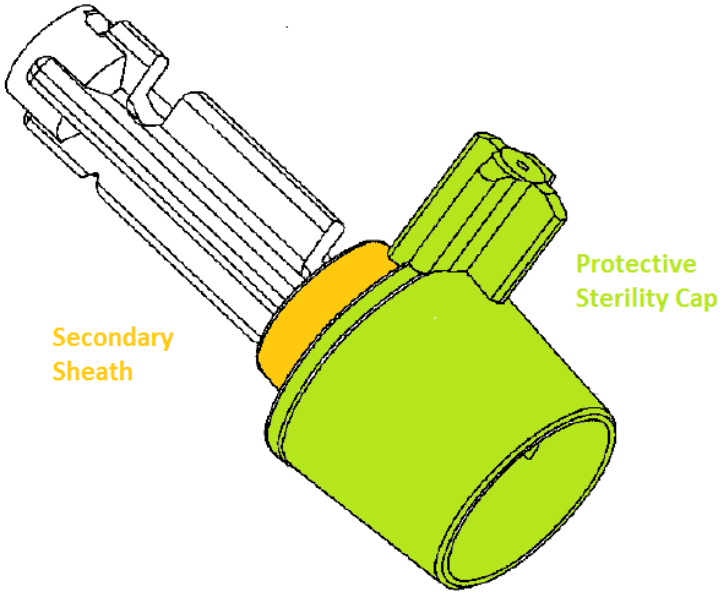
XII GROUND 4: SAKATA RENDERS CLAIMS 1, 4, AND 9-15 OBVIOUS IN VIEW OF MORITA.

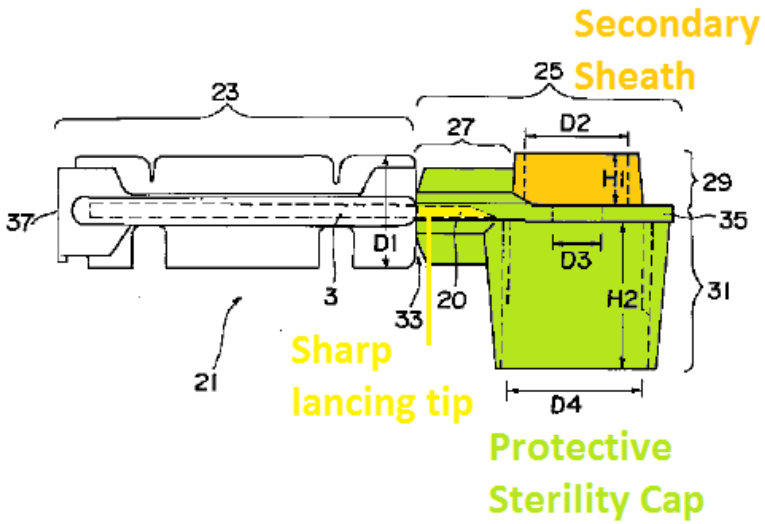
A. All Claims: "Primary Sheath for Initial Embedment"

124. Sakata discloses this limitation by disclosing that Sakata's cap may include "**integral molding [being] used,** [and] **the puncture needle can be embedded in the cap part by insert-molding, so the sterilization of the puncture needle can be achieved.**" Ex. 1109, ¶0013.

B. All Claims: "Secondary Sheath for Receiving"

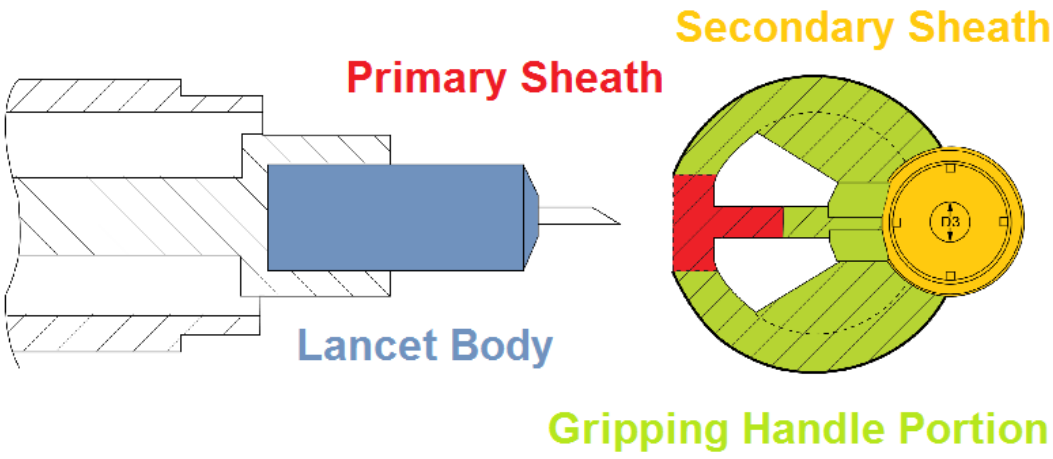
125. In my opinion, Morita teaches a secondary sheath, as "finger-pricking device as shown in Figure 2…, the end cap 15 is removed to expose the lancet body 5 after blood collection, and the lancet fixing means of the lancet attachment part 13 is released to remove the lancet body 5 by hand." See annotated figures 3 18 below.





126. A PHOSITA would have been motivated to combine the features of Sakata and Morita, because Morita describes advantages associated with the secondary sheath, including "disposal with the lancet body inserted into the

platform part does not pose a health and safety problem of infection." Ex.1109 ¶0020. An illustrative embodiment of Sakata in view of Morita is annotated below.

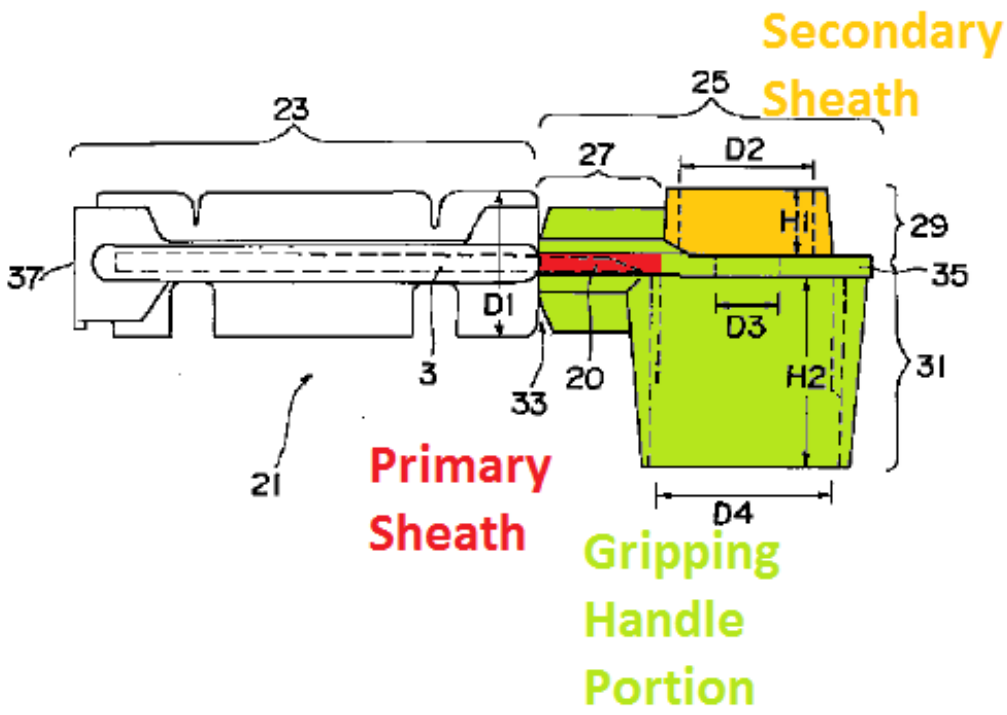


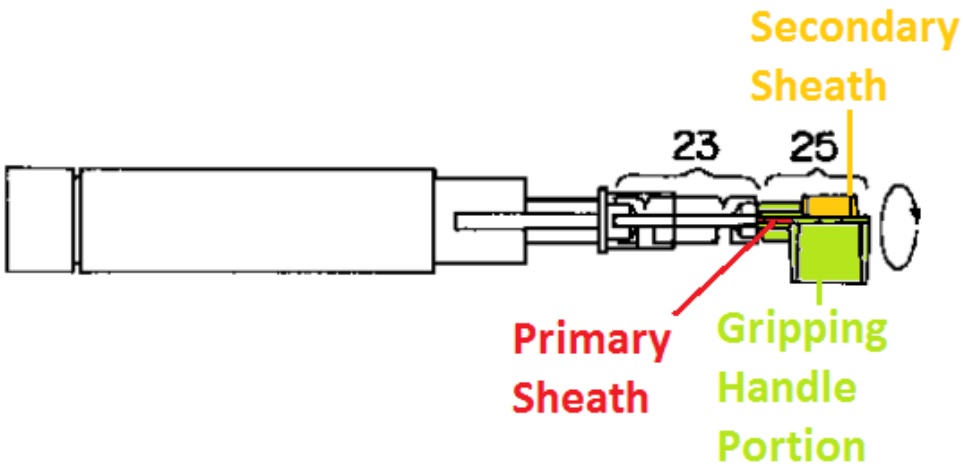
C. All Claims: Gripping Handle Portion

127. I explained Sakata disclosing the limitation of a "gripping handle portion" via its operating portion in section X(C) incorporated herein.

128. At least a majority of the cap of Morita is designed to be gripped, since "[a]s shown in the figures, the lancet body 23 is adjacent to the needle tip protection part 27 of the protection platform 25 and is preferably connected in a state which can be **separated by hand** 33, e.g., a state that enables a twist-off

separation." The Morita cap can be twisted off by grasping its bulb adjacent its secondary sheath. See annotated figures 3 and 6 below.





D. Claims 4, 9-10, and 15: "wherein the gripping handle portion comprises at least one open loop" and "flat surface for branding indicia"

129. The additional limitations of claims 4, 9-10, and 15 are disclosed by Sakata, as explained in section X(C).

E. Claims 11-13: The "Length" and "Lateral Span" of the Gripping Handle Portion

130. The gripping handle portion of Morita explicitly teaches the limitations of claims 11-13, as outlined below.

131. Morita teaches a PHOSITA that a sterility cap "can be molded into various dimensions, depending on the purpose of use, such as the volume of blood collected, the user, and the degree of penetration," and subsequently provides measurement examples. Ex.1109 ¶0032.

132. The lancet body has a **thickness between 4-7 millimeters**. This means, for claims 11-13, the lateral span of the gripping handle portion must be **at least between 6-10.5mm**; and the length of the gripping handle portion, by mathematical logic, has to be at least 6-10.5mm. *Id.*

133. The span of Morita's gripping handle portion is its widest dimension (rather than its longest or shortest dimension). The widest dimension is approximately the addition of variables H1 and H2. H1 is between 2-3.5mm, while H2 is between 6-15mm. This means that the span of Morita's gripping handle portion is between 8-18.5mm. This exceeds the boundaries of 6-10.5mm. *Id.*

134. The length of the gripping handle portion, by default, is at least 6-10.5mm, as its length is, by definition, at least larger than its width/span. *Id.*

135. In my opinion, Morita explicitly teaches the limitations of claims 11-13, and thereby, in combination with Sakata, renders all the challenged claims herein as unpatentable.

XIII CONCLUSION

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.

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, CALIFORNIA.



Joel Delman