

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION**

FACET TECHNOLOGIES, LLC,

Plaintiff,

v.

LIFESCAN, INC.,

Defendant.

CASE NO. 2:22-cv-01717-MCS-MARx

**OPENING EXPERT REPORT OF JOEL DELMAN REGARDING
INVALIDITY OF U.S. PATENT NO. 8,840,635**

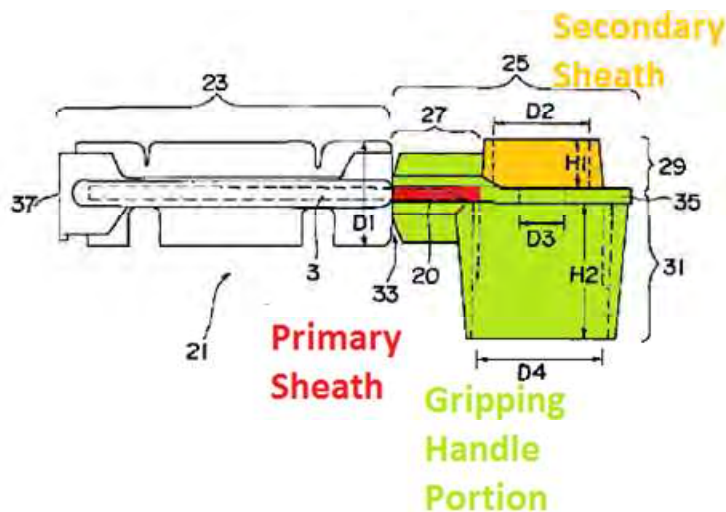
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58. I explained that both Coe and Morita each disclose these dimensional limitations. <i>See supra</i> [].	206
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I. INTRODUCTION

1. My name is Joel Delman. I have been retained to testify as an expert in this case on behalf of Defendant LifeScan, Inc. (“LifeScan”).

2. As part of this engagement, I have been asked to provide my analysis and opinions concerning U.S. Patent No. 8,840,635 (“the ’635 Patent” or the “Asserted Patent”). More specifically, I have been asked to provide my analysis and opinions concerning the validity of claims 6, 8, 14, and 18 of the ’635 Patent (“Asserted Claims”).

3. I am being compensated for my work on this case at my standard consulting rate of \$350 per hour. No part of my compensation is contingent upon the outcome of this litigation. I have no other interests in this litigation or with any of the parties.

4. I expect to be called to provide expert testimony regarding opinions formed based on my analysis of the issues considered in this report. I may also discuss my own work and publications in the field and knowledge of the state of the art in the relevant time period. I reserve the right to modify or supplement my opinions, as well as the basis for my opinions, based on the nature and content of the documentation, proof, and other evidence or testimony that Plaintiff, Facet Technologies, LLC (“Plaintiff” or “Facet”), or its expert(s) may present, or based on any additional discovery or other information provided to me or found by me in

this matter. All of the opinions stated in this report are based on my current personal knowledge and professional judgment, and if called as a witness during the trial in this matter, I am prepared to testify competently about them. I reserve the right to use and rely on certain demonstratives to do so. I also reserve the right to amend and/or supplement this report should additional information or developments that may affect my opinions become available.

5. It is my understanding that Plaintiff may submit an expert report responding to this report. I reserve the right to rebut any positions taken in that report.

II. SUMMARY OF OPINIONS

6. I understand that Facet is asserting claims 6, 8, 14 and 18 of the '635 Patent against LifeScan.

7. I have analyzed certain materials and formed an opinion on whether the asserted claims are invalid based on: (i) my analysis, (ii) my experience, and (iii) legal principles that counsel has provided to me. In my opinion, for the reasons I provide in this volume of my report:

- Every asserted claim is anticipated by and/or obvious based on prior art cited herein and they are therefore invalid (*see* Section XI)¹.

¹ To be clear, insofar as one or more limitations of an otherwise anticipatory reference is found not to be present in said reference, it is my opinion that one of skill in the art would find that limitation to be obvious either alone (*i.e.*, single reference obvious) or in view of other prior art.

III. QUALIFICATIONS

8. My *curriculum vitae* (“CV”) is provided at Exhibit 1, which includes a more detailed statement of my professional qualifications, including education, publications, honors and awards, professional activities, consulting engagements, and other relevant experience. While I incorporate Exhibit 1 by reference, below is a brief summary of my background, including my background and exemplary experience relevant to this case.

A. Education and Career History

9. 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.

10. 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

11. 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.

12. When designing handheld consumer items, understanding the size, shape, and need for ease of use are all human factors considerations which must be 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.



13. 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

ANTHROPOMETRIC ANALYSIS 3

SPREAD FORCE MEASUREMENT PROTOCOL

PDT and Covidien will independently conduct force measurements to determine the optimal spread force that the user can be expected to apply with the Exact 2 instrument.

Sample size - 10 subjects
 Gender bias - Approximately half male and half female
 Ambidexterity - Measurements to be made on both hands
 10-15% (2 or 3) should be left-handed
 Range - 5th to 95th percentiles
 Following measurements will be made and documented to ensure subject is within range.
 Middle Finger Thickness - 0.65" (16.59mm) to 0.95" (24.13 mm)
 Thumb Thickness - 0.61" (15.58mm) to 0.9" (22.81) mm

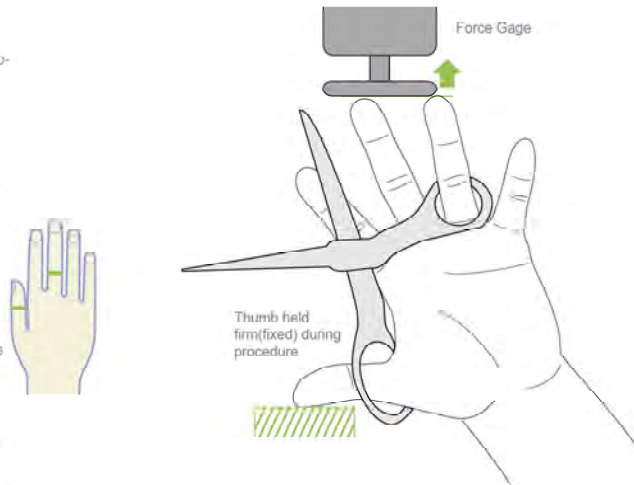
Test Setup and Procedure

The intent of this test is to measure the force that can be applied by the middle and ring finger while making a scissor-spread action with the dominant hand of the subject.

As shown in image, a push-type force gauge capable of measuring 0.001lb force (+/- 0.5%) will be set up with a surface, like a disc, that is large enough to be accessible with the tip of a finger. The subject will be handed a Ligasure Precise instrument asked to replicate a spreading motion of the fingers while holding the thumb stationary and the ring finger pressing against the force gage's sensing surface.

The subject will be advised to hold the thumb as steady as possible during the procedure. Each measurement will be repeated if the result is not clear.

Results will be tabulated as shown in the example.



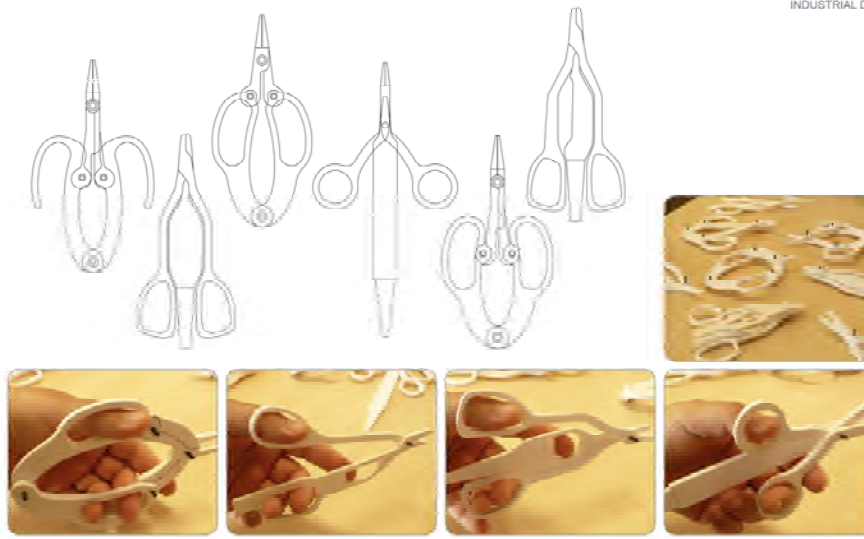
AGE	GENDER	HANDEDNESS	MEASURED HAND	MIDDLE FINGER THICKNESS	THUMB THICKNESS	FORCE VALUE 1	FORCE VALUE 2 (IF REPEATED)
40	male	right-handed	right	0.6"	0.7"	1 lb	---



14. 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

INDUSTRIAL DESIGN | 7



COVIDIEN

pdf

Demonstrative: Design Concept for Covidien

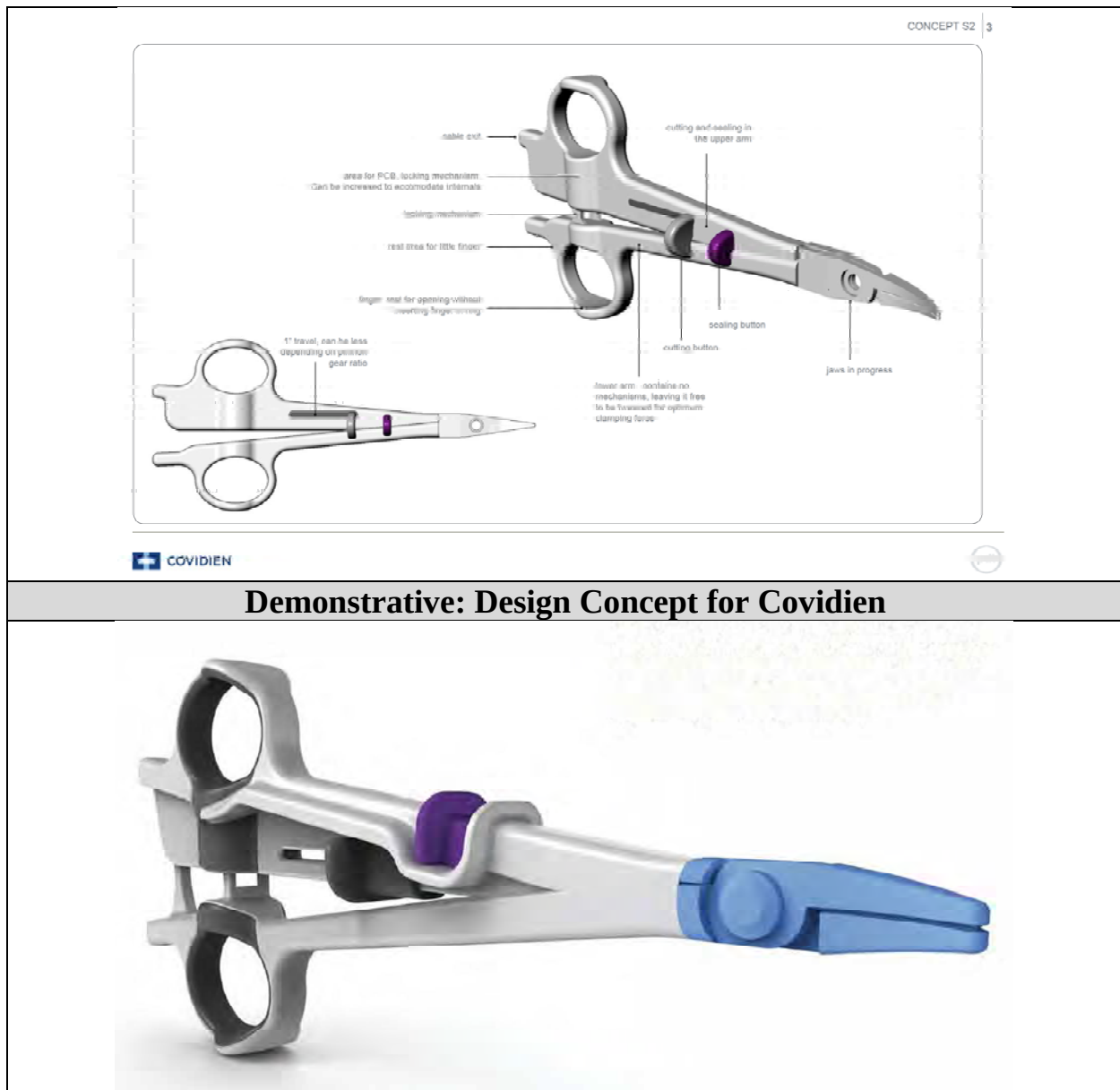
CONCEPT B | 4



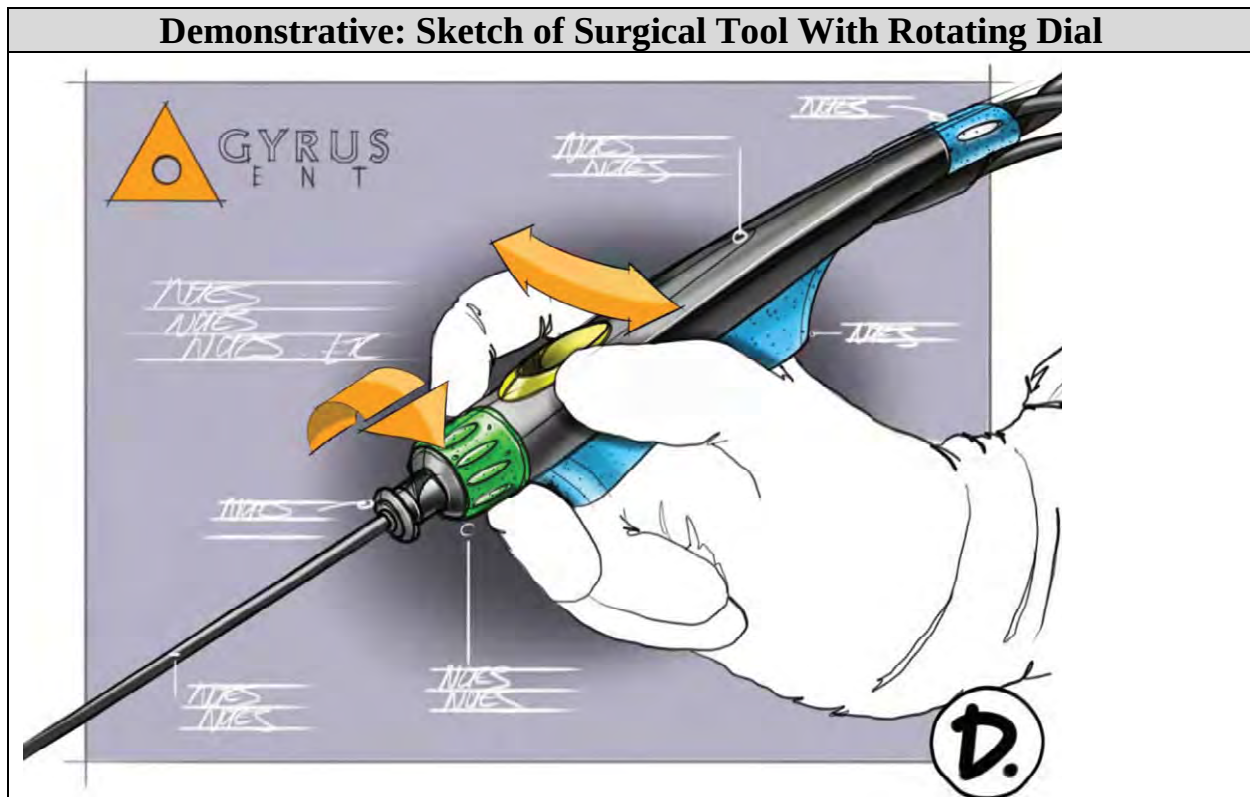
COVIDIEN

pdf

Demonstrative: Design Concept for Covidien



15. A design that was proposed to a client for a handheld surgical tool is shown in the preliminary sketch below, illustrating 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.



16. 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
	

17. 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.



18. I also assisted with the design of the handheld school supplies 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



19. 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

20. 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.



21. 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



22. 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.

Demonstrative: Understanding Lancing Devices



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

	Most Test Sites Available The FreeStyle Freedom System can be used to test your blood glucose from your forearm, upper arm, thigh, calf, hand, as well as fingers (for more information see your Owner's Booklet). Warning: If you are testing for hypoglycemia (low blood glucose), or if you suffer from hypoglycemia unawareness, we recommend that you test on your fingers or palm (at the base of the thumb). <i>FreeStyle Freedom Testing Areas</i>
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23. 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



24. 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.

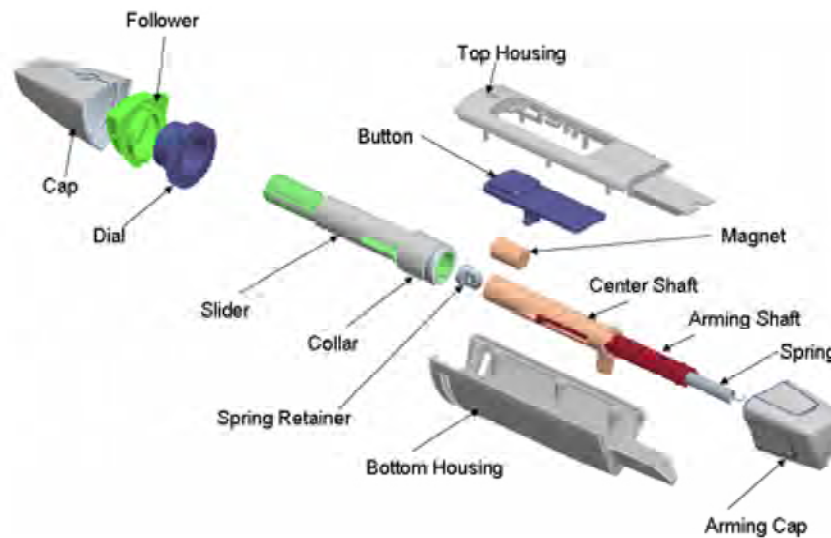


25. In addition to hands-on testing with patients of lancing devices, we engaged in validation testing of the newly developed magnetic lancing mechanism using a high-speed camera to show how the oscillation and vibration was significantly reduced in comparison to other devices. This testing also showed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

26. 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



27. 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.

28. 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 to the client as part of this project can be seen below.

Demonstrative: Examples of Alternative Lancing Device Designs



Demonstrative: Examples of Alternative Lancing Device Designs



29. 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.

30. 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 CV, which is provided as Exhibit 1.

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

32. Additional information regarding my background, qualifications, publications, and presentations is included as part of my CV, which is provided as Exhibit 1.

33. 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.

IV. MATERIALS CONSIDERED

34. To prepare this report and to develop the opinions expressed herein, I have reviewed the asserted '635 Patent, including its claims, specification and drawings. I also have reviewed the file history of the '635 Patent, including the prior art documents identified therein. I further have reviewed each prior art reference discussed in this report.

35. Although I may cite to particular evidence in this report, I do so to assist in understanding the various bases used to support my conclusions. I do not intend this report to contain an exhaustive citation of every piece of evidence that may support my opinions. Accordingly, I expressly reserve the right to affirm, update, or modify my opinions based on such other evidence as necessary.

36. I reserve the right to rely on any other documents and materials that come to light. To the extent necessary, I anticipate supplementing this report after the completion of any further deposition or after the receipt of any additional documents or materials produced in the future.

37. At trial, I may use some or all of the information listed, mentioned, or described in this report; I may use materials or demonstratives prepared based on such information as exhibits to explain the relevant technologies or to support or summarize my opinions. In addition, I may supplement these materials with other materials and charts to provide additional context, background, or information. If any additional information is provided to me, I reserve the right to modify or supplement my report and to testify regarding such information.

38. Additionally, at trial, I expect to prepare graphics or demonstratives to assist in the explanation of the opinions set forth in this report.

V. LEGAL STANDARDS

A. Introduction

39. In formulating my opinions, I have been instructed to apply certain legal standards that apply concerning patent invalidity. 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 opinions or testimony regarding

what the law is. My understanding of the law as it pertains to the invalidity of the asserted claims of the '635 Patent is described briefly as follows.

40. I understand that issued patents are presumed valid, but this presumption may be overcome by “clear and convincing evidence.” I understand that the “clear and convincing evidence” burden requires the presentation of less evidence than required to satisfy the “beyond a reasonable doubt” standard, but the presentation of more evidence than required to satisfy the “preponderance of the evidence” standard. I also understand that “clear and convincing evidence” means that the evidence presented by a party during the trial must be substantially more probable than not to be true.

41. I also understand that if the Patent Office did not previously consider a prior art reference, it may carry more weight than references that were previously considered by the Patent Office.

42. I understand that a patent claim is invalid if it is anticipated by, or rendered obvious over, prior art.

B. Legal Standard for Priority Date

43. I understand that the claimed “priority date” of a patent is the date on which it is filed, or the date on which an earlier-filed patent application is filed if the patentee claims the benefit of priority to that earlier-filed patent application. I understand that a particular claim is entitled to claim the priority date of an earlier-

filed application if the earlier-filed application provides written description of the full subject matter of that particular claim. I further understand that the priority date is significant because patents, systems, or documents that are public prior to the priority date may invalidate the claims.

44. I understand that a “critical date” for a patent is one year prior to its priority date. It is my understanding that this date is significant because patents, systems, or documents that are public prior to the critical date, if they disclose each and every limitation of the claims, will invalidate a patent.

C. Legal Standard for Prior Art

45. I understand that a patent or other publication must first qualify as prior art before it can be found to invalidate a patent claim.

46. I Understand that a U.S. or foreign patent qualifies as prior art to an asserted patent if the date of issuance of the patent is prior to the alleged invention of the asserted patent. I further understand that a printed publication, such as an article published in a magazine or trade publication, qualifies as prior art to an asserted patent if the date of publication is prior to the alleged invention of the asserted patent.

47. I understand that a U.S. or foreign patent qualifies as prior art to an asserted patent if the date of issuance of the patent is more than one year before the filing date of the asserted patent. I further understand that a printed publication,

such as an article published in a magazine or trade publication, constitutes prior art to an asserted patent if the publication occurs more than one year before the priority date of the asserted patent.

48. I understand that a U.S. patent qualifies as prior art to the asserted patent if the application for that patent was filed in the United States before the alleged invention of the asserted patent.

49. I understand that a system or device qualifies as prior art to the asserted patent if it was in “public use,” meaning it was accessible to the public or was commercially exploited, before the alleged invention of the asserted patent or more than one year before the priority date of the asserted patent.

50. I understand that subject matter an alleged inventor derives from a reference or system (regardless of whether that reference or system was otherwise public) qualifies as prior art to any claimed invention by that alleged inventor, both for purposes of anticipation and obviousness. Thus, a party cannot patent subject matter derived from another, and that party also cannot patent an obvious combination of other prior art combined with the subject matter derived from another.

51. I understand that to qualify as prior art, a reference must contain an enabling disclosure that allows one of ordinary skill to practice the claims without undue experimentation.

52. I understand that documents and materials that qualify as prior art may invalidate a patent claim as anticipated or obvious.

D. Legal Standard for Anticipation

53. I understand that, once the claims of a patent have been properly construed, determining anticipation of a patent claim requires a comparison of the properly construed claim language to the prior art on a limitation-by-limitation basis.

54. I understand that a prior art reference “anticipates” an asserted claim, and thus renders the claim invalid, if all elements of the claim are disclosed in that prior art reference, either explicitly or inherently (*i.e.*, necessarily present or implied). This requirement is not met if a single limitation of the claim is missing from the prior art reference. I further understand that a prior art reference can disclose claim elements either actually or inherently.

55. I understand that anticipation must be shown by clear and convincing evidence.

56. I understand that a prior art reference can actually disclose a particular claim element for anticipation purposes even if the reference does not explicitly identify that claim element. In particular, I understand that even if a prior art reference does not expressly disclose a limitation, it anticipates that claim

limitation if a POSITA would have understood the prior art to disclose the limitation.

57. I have also been informed that a prior art reference can inherently disclose a claim element if that limitation is necessarily present when practicing the teachings of the reference, regardless of whether a POSITA would have recognized the presence of that limitation in the prior art reference. I understand that inherency cannot be established by mere probabilities or possibilities.

58. I understand that the anticipation standard, as it applies to the application that led to the asserted patents, is set forth in pre-AIA 35 U.S.C. §§ 102(a), (b), and (e). The relevant sections are reproduced below:

59. 35 U.S.C. § 102 – A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or . . .

(e) the invention was described in – (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent.

E. Legal Standard for Obviousness

60. I understand that even if a patent is not anticipated, it is still invalid if the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person of ordinary skill in the pertinent art.

61. I have been informed and understand that the obviousness analysis requires a comparison of the properly construed claim language to the prior art on a limitation-by-limitation basis.

62. I understand that a person of ordinary skill in the art provides a reference point from which the prior art and claimed invention should be viewed. This reference point prevents one from using his or her own insight or hindsight in deciding whether a claim is obvious.

63. I also understand that an obviousness determination includes the consideration of various factors such as (1) the scope and content of the prior art, (2) the differences between the prior art and the asserted claims, (3) the level of ordinary skill in the pertinent art, and (4) the existence of secondary considerations or objective indicia of obviousness or non-obviousness.

64. I am informed that secondary considerations of non-obviousness may include (1) a long felt but unmet need in the prior art that was satisfied by the alleged invention of the patent; (2) commercial success or lack of commercial

success of processes covered by the patent; (3) unexpected results achieved by the alleged invention; (4) praise of the alleged invention by others skilled in the art; (5) taking of licenses under the patent by others; and (6) deliberate copying of the alleged invention. I also understand that there must be a relationship or nexus between any such secondary indicia and the alleged invention. I further understand that near simultaneous and independent invention by others is a secondary consideration supporting an obviousness determination.

65. I understand that a claim can be obvious in light of a single reference, without the need to combine references, if the elements of the claim that are not found explicitly or inherently in the reference are supplied by the common sense of one of skill in the art. I also understand that single-reference obviousness may occur based on a combination of techniques taught in that reference, such as based on a combination of embodiments.

66. I understand that a claim can be obvious in light of a combination of multiple prior art references. I understand that the prior art references themselves may provide a suggestion, motivation, or reason to combine, but other times the nexus linking two or more prior art references is standard knowledge and simple common sense.

67. I understand that if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve

similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.

68. I also understand that practical and common-sense considerations should guide a proper obviousness analysis, because familiar items may have obvious uses beyond their primary purposes. I understand that obviousness analysis therefore takes into account the inferences and creative steps that a person of ordinary skill in the art would employ under the circumstances.

69. I understand that a particular combination may be proven obvious merely by showing that it was obvious to try the combination. For example, when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp because the result is likely the product not of innovation, but of ordinary skill and common sense.

70. I understand that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, obviousness likely bars its patentability.

71. It is also my understanding that a proper obviousness analysis focuses on what was known or obvious to a person of ordinary skill in the art at the time of the alleged invention. Accordingly, I understand that any need or problem known in the field of endeavor at the time of alleged invention can provide a reason for combining the elements in the manner claimed.

72. I understand that in analyzing obviousness, one must consider common sense, common wisdom, and common knowledge. I understand that in an obviousness analysis, common sense may supply a missing claim limitation that is not expressly disclosed in a prior art reference. I understand it is appropriate to consider whether a skilled artisan would have used common sense to incorporate a claim limitation into a prior art reference or combination of references.

73. In sum, my understanding is that prior art teachings are properly combined where a person of ordinary skill in the art, having the understanding and knowledge reflected in the prior art and motivated by the general problem facing the inventor, would have been led to make the combination of elements recited in the claims.

F. Legal Standard on Claim Construction

74. I understand the words of a patent claim are generally given their ordinary and customary meaning. I understand the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of

ordinary skill in the art in question at the time of the invention. I understand that the ordinary and customary meaning is determined in the context of the entire patent, including the patent claims, specification, and prosecution history.

75. I understand that claim terms are interpreted as a POSITA would have interpreted them at the time of the invention.

76. I understand that the issued claims must be read and interpreted with reference to both the claims that were rejected during prosecution and the state of the prior art. Claims that have been narrowed in order to obtain the issuance of a patent by distinguishing the prior art cannot be construed to cover subject matter which was previously subject to limitation and eliminated from the patent.

77. I also understand that claim terms must be interpreted the same way, whether analyzed for invalidity or non-infringement. Essentially, one must be consistent and apply the same understanding of each claim element when determining (1) whether an accused product practices those claim elements and (2) whether a prior art reference discloses those claim elements.

VI. PERSON OF ORDINARY SKILL IN THE ART (POSITA)

78. 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.

79. 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.

80. 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.

81. In addition, a POSITA 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 recover the sharp lancet tip for safety and hygienic purposes.” ’635 Patent, 1:38-57.

82. 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 of ordinary skill in the art, 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.

VII. CLAIM CONSTRUCTION

83. 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.” Claim Construction Order, 13:26-14:3. I have applied the Court’s construction of secondary sheath in my analysis of the prior art below.

84. 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. Claim Construction Order, 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 POSITA 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. SUMMARY OF THE ASSERTED PATENT

85. The '635 Patent, titled “Lancets with Improved Coupling Features and Sterility Caps,” relates generally to the field of lancets and lancing devices for blood sampling and testing. *See* '635 Patent at 1:17-20. The '635 Patent is directed to “a lancet having a sterility cap or protective cover with a handle or grip portion for assisting in removal of the cap for use of the lancet and/or for replacement of the cap onto a used lancet for disposal.” *Id.* at 1:66-2:3.

A. Asserted Claims

86. I understand that Facet asserts claims 6, 8, 14, and 18 of the '635 Patent against LifeScan. Claim 6 depends from independent claim 1. Independent claim 14 includes limitations analogous in scope to the limitations in claims 1 and 6. Claim 8 depends from claim 6 and claim 18 corresponds to the limitations found in claim 8. The Asserted Claims are listed below with preamble and reference letters added:

1[preamble]: A protective sterility cap for a lancet, said sterility cap comprising

1[a]: a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein,

1[b]: a secondary sheath for receiving the sharp lancing tip of a used lancet,

1[c]: and a gripping handle portion extending between the primary sheath and the secondary sheath,

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.

6[a]: The protective sterility cap of claim 1, in combination with a lancet

6[b]: having a lancet body defining a lancet thickness, and

6[c]: a sharp lancet tip initially embedded in the primary sheath,

6[d]: wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.

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

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

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

B. Prosecution History of the '635 Patent

87. 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. '635 File History, 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.

88. 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.

89. 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.*

90. 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.

91. Although U.S. Patent No. 5,569,286 (“Peckham”) was cited by the Applicant in an information disclosure statement (’635 File History, 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. PRIORITY DATE

92. I understand that the '635 Patent claims priority to Provisional Application No. 61/084,456, filed on July 29, 2008.

93. I understand from counsel that claims in a U.S. patent are entitled to the priority date of the earliest filed U.S. application. I further understand that claims in a U.S. patent may be entitled to the priority date of an earlier filed foreign patent if each of the elements of the claim is disclosed in the earlier-filed foreign patent. I further understand from counsel that it is Plaintiff's burden to demonstrate the asserted claims of the '635 Patent are entitled to this earlier priority date.

94. Accordingly, I understand that the priority date of the '635 Patent is the filing date of the earliest filed U.S. application, *i.e.*, July 29, 2008. To the extent the Plaintiff is permitted to provide additional analysis or evidence demonstrating a different priority date, I reserve the right to supplement my opinion.

95. Regardless, I understand that each of the prior art references I address below qualify as prior art under the July 29, 2008 priority date.

X. PRIOR ART INVALIDITY

96. It is my opinion that the Asserted Claims are anticipated by and/or obvious at least based on prior art cited herein, and they are therefore invalid. To be clear, insofar as one or more limitations of an otherwise anticipatory reference is found not to be present in said reference, it is my opinion that one of skill in the art would find that limitation to be obvious either alone (*i.e.*, single reference obvious) or in view of other prior art.

XI. Facet's Own Prior Art Anticipates and/or Renders Obvious the Asserted '635 Patent Claims

A. All Asserted Claims Are Rendered Obvious By Lathrop

1. International Publication No. WO 2007/089930 to Lathrop ("Lathrop")

97. Lathrop published on August 9, 2007. Because Lathrop's publication date is prior to the Effective Filing Date, I understand Lathrop qualifies as prior art under at least pre-AIA § 102(e).

2. Discussion of Claim 6

98. I discuss each limitation of claim 6 in turn below, in conjunction with the relevant disclosures of each limitation by Lathrop. As I expand upon below, Lathrop discloses and renders obvious each limitation of claim 1, to which claim 6 depends.

(a) Lathrop discloses claim 1[p] – "A protective sterility cap for a lancet"

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

100. Lathrop discloses a “removable **endcap** may be provided to **maintain sterility** of the tip element and to protect against inadvertent sticks with the sharp tip element [of the lancet].” Lathrop, [0002].

101. Lathrop specifically discloses in annotations to Figure 2A that the “**endcap 116** preferably includes a cap-replacement sleeve portion 140, allowing the endcap to be replaced over the tip 114 after use.” Lathrop, [00030].

102. U.S. Provisional Application No. 60/763,671 (“Provisional to Lathrop”), which is incorporated by reference in Lathrop, discloses “a lancet having a body portion, sharp tip element, and a **removable endcap**.” Provisional to Lathrop, Claim 1.

103. It is therefore my opinion that Lathrop discloses “a protective sterility cap for a lancet.”

**(b)Lathrop discloses claim 1[a] – “a primary sheath for initial
embedment of a sharp lancing tip of an unused lancet therein”**

104. Lathrop discloses a primary sheath, or one or more “guidance fingers 122 [that] are preferably provided adjacent the interior free ends of the U-shaped

endcap member” which “are releasably engaged within corresponding guidance channels 120 of the lancet body, to axially guide the endcap and prevent damage of the lancet tip 114 during endcap removal.” Lathrop, [0030]. These “guidance fingers” are similar to the “spacer ribs or breakaway connections 518” which indicate an **unused lancet** in the ’635 Patent. ’635 Patent, 6:18-26.

105. Lathrop further provides that the endcap is typically “removed **prior to the lancing procedure**” and the “**endcap 16 is preferably removable** from the body portion 12 **to expose the sharp tip element** 14 for use, and replaceable thereon after use.” Lathrop, [0004], [0024].

106. Although Lathrop does not use embedded, it teaches that the user is to remove endcap 16 by **twisting the endcap** and “sever[ing] the connection between the endcap and an **integrally molded** body portion” to “break[] the seal between the endcap and the tip element” which allows for easier endcap removal. Lathrop, [0027].

107. Furthermore, the Provisional to Lathrop also provides for a “**conventional insert molded lancet with molded in sterility cap.**” Provisional to Lathrop, Figure 1A, Figure 2A.

108. As previously described with Saikley in Section XI.B.1(b), which I incorporate herein, a POSITA would have known that an integrally molded cap must be twisted in order to avoid potentially bending or damaging the lancet.

Where the seal has not been broken, the needle has not yet been used for sampling or testing, and therefore, remains sterile.

109. In my opinion, Lathrop therefore discloses that the “sterility cap comprises a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein.”

(c) Lathrop discloses claim 1[b] – “a secondary sheath for receiving the sharp lancing tip of a used lancet”

110. I observe that Lathrop’s endcap 16 includes a “cap-replacement sleeve 40” which is “**replaced over the tip** element 14 [of the lancet] after use.” Lathrop, [00029], Fig. 1C.

111. The cap-replacement sleeve portion 140, provided in Fig. 2A, also provides for the “endcap to be **replaced over the tip** 114 [of the lancet] after use” and “serve[s] as an indicator to distinguish a used lancet from a new lancet.” *Id.*, [0030], Fig. 2A.

112. The cap replacement sleeve is “replaced over the tip” of the lancet “after use”, which I understand covers the sharp lancing tip of the used lancet. 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.” Claim Construction Order, 13:24-14:3.

113. The Provisional to Lathrop provides that the “**cap snaps back onto lancet post use similar to conventional lancets.**” Provisional to Lathrop, Figures 1C, 2C.

114. In my opinion, Lathrop discloses “a secondary sheath (*i.e.*, cap-replacement sleeve 40) for receiving the sharp lancing tip of a used lancet (*i.e.*, for replac[ing] over the tip 114 after use and which serves as an indicator to distinguish a used lancet from a new lancet).”

(d)Lathrop discloses claim 1[c] – “and a gripping handle portion extending between the primary sheath and the secondary sheath”

115. Lathrop features an endcap 16 which further includes “one or more **gripping features to facilitate its removal.**” Lathrop, [0028], Fig. 2A. Lathrop describes that the “U-shaped [endcap] member preferably has flat side surfaces that **serve as gripping features**, and can optionally be provided with ridges or knurling **to assist the user in twisting and pulling the endcap.**” Lathrop, [0030].

116. Lathrop describes how many lancet users “suffer from reduced visual acuity and/or impaired manual dexterity” with many users finding it difficult “to remove and replace the endcaps.” *Id.*, [0008]-[0009]. Lathrop also describes that there is a need for “such improvements that **facilitate endcap removal and replacement, even by users with reduced visual acuity or manual dexterity.**” *Id.*

117. In my opinion, Lathrop’s “gripping features” are consistent with the plain and ordinary meaning of the claim term “gripping handle portion” which the district court considered. Claim Construction Order, 17:12-13. As the Court noted, it “[did] not make much of the modifier ‘gripping’ and finds the term merely restates the purpose of the handle.” *Id.* The ’635 Patent also refers to a “handle or grip” interchangeably. ’635 Patent, 1:66-2:3, 6:5-9, 7:6-12, 8:17-22.

118. Further, the Provisional to Lathrop discloses that the “endcap comprises at least one **gripping feature to facilitate removal.**” Provisional to Lathrop, Claim 3.

119. In my opinion, Lathrop therefore discloses “a gripping handle portion extending between the primary sheath and the secondary sheath.”

(e) Lathrop 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”

120. Lathrop’s Figure 1C and Figure 2C embodiments both show the primary and secondary sheaths attached to opposing ends of the “gripping features” of the endcap. Lathrop, Fig. 1C, Fig. 2C.

121. Lathrop also provides that the secondary sheath, or cap-replacement sleeve 40, is positioned on the endcap 10 at a location **remote** from the initial point of attachment of the endcap 16 to the body portion, so that a user can readily distinguish a used lancet from a new lancet.” *Id.*, [00029].

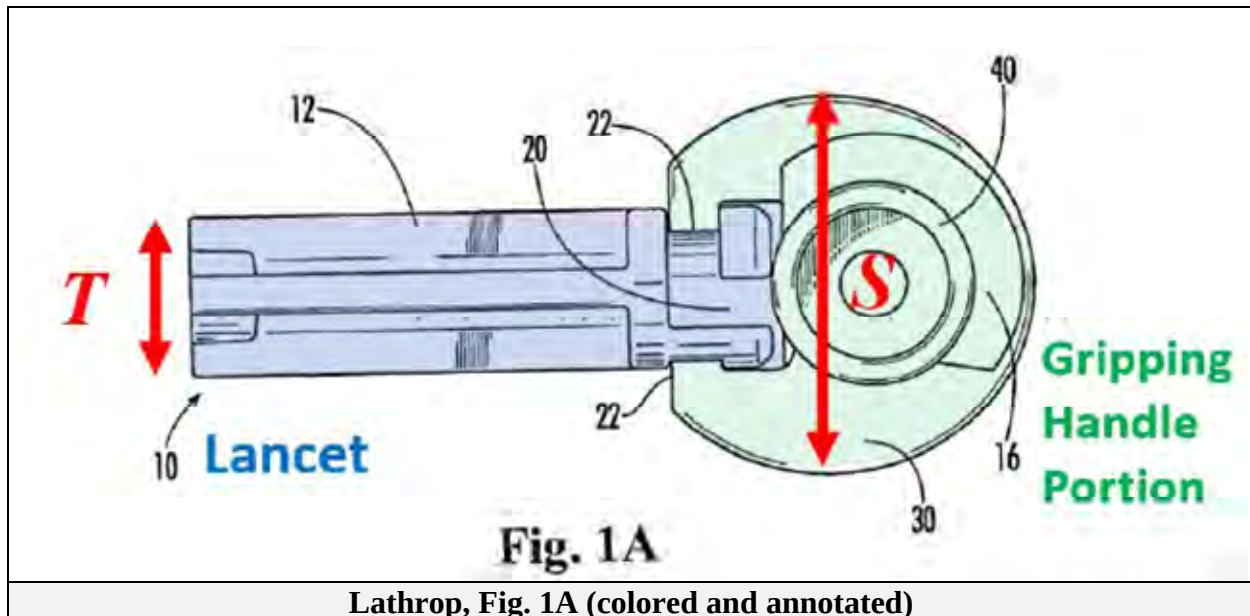
122. Based on Lathrop's figures and disclosures, in my opinion, Lathrop therefore discloses a "primary sheath attached at a first end of the gripping handle portion and the secondary sheath attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet."

(f) Lathrop discloses limitations 6[a]-6[d]

123. 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 Lathrop.

124. As to elements 6[a]-6[c], I believe Lathrop discloses its endcap which has "guidance fingers 22 [which] preferably remain engaged within the guidance channels 20 during the twisting step, and during the axial pulling step, until the endcap 16 releases from **contact with the [lancet] tip element 14**, thereby resisting non-axial cocking or pivoting movement of the endcap during removal, which could bend or break the tip element." Lathrop, [0027], Fig. 1C. Lathrop also teaches that the endcap is twisted relative to the "[lancet] **body** portion 12" from a first angular position to a second angular position. *Id.* The "endcap 16" is also described to be "preferably removable from the body portion 12 to expose the sharp tip element 14 for use." *Id.*, [0024].

125. As to element 6[d]’s limitation of “the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness,” Lathrop discloses this limitation, with the lateral span annotated “S” in Figure 1A below.



126. Visual inspection of the gripping handle portion’s lateral span (“S”) with the lancet’s thickness (“T”) shown in Lathrop’s figure confirms to my knowledge that the “gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.”

127. In my opinion, Lathrop renders claim 6 obvious.

3. Discussion of Claim 8

128. Claim 8 depends from claim 6, which Lathrop anticipates for the reasons I discussed above in Section XI.F.1, incorporated herein. Claim 8 adds “wherein the gripping handle portion defines a length at least equal to the lancet thickness.”

129. Because Lathrop discloses both that the gripping handle portion (cap 78) is at least 1.5 times the lancet thickness (*supra* Section XI.F.1, incorporated here), the length of Lathrop's gripping handle portion must also necessarily be at least equal to (including larger than, as Lathrop teaches) the lancet thickness.

4. Discussion of Claim 14

130. Claim 14 includes limitations analogous in scope to limitations 1[pre]-1[d], and those are disclosed by Lathrop for reasons I provided above and incorporated here (*supra* Section XI.F.1(a)-(e)). Claim 14 also includes limitations analogous in scope to those found in claim 6, and those are disclosed by Lathrop for reasons I provided above and incorporated here (*supra* Section XI.F.1(f)).

5. Discussion of Claim 18

131. Claim 18 depends from claim 14, which is anticipated by Lathrop for reasons I provided above and incorporated here (*supra* Section XI.F.3). 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 XI.F.2).

6. Claims 6, 8, 14, and 18: The “Length” and “Lateral Span” of the Gripping Handle Portion

132. As I note above, Lathrop discloses the dimensional limitations of the asserted claims. Even if these limitations were not disclosed or inherent in Lathrop, all of the relative-dimensional limitations would have been obvious for a

POSITA to apply to Lathrop. Lathrop explicitly recognizes that it was not uncommon for lancet users to “suffer from reduced visual acuity and/or impaired manual dexterity” and protecting against “inadvertent sticks” was needed. Lathrop, [0004], [0009].

133. Designing a gripping handle that had a lateral span at least 1.5 times the lancet thickness (as recited in claims 6 and 14) would have been pursued by a POSITA as a matter of routine optimization and with a reasonable expectation of success, particularly in view of Lathrop’s instruction that “one or more gripping features” be included in order to help “facilitate” removal of the endcap. *Id.*, [0028]. A POSITA would have utilized dimensions that would allow a user to easily handle the cap and provide for a more “ergonomic and user-friendly operation.” *Id.* A POSITA would have thus routinely designed an endcap that would have been at least 1.5 times the thickness of a standard lancet.

134. Regarding the gripping handle’s length being at least equal to the lancet thickness (as recited in claims 8 and 18), this would also be a natural choice for a POSITA who would have appreciated that users who have difficulty handling lancets would have a more “ergonomic and user-friendly” way to “facilitate” removal of the endcap if the gripping handle had a length at least equal to, or larger, than the lancet thickness.

135. In my opinion, Lathrop renders obvious claims 6, 8, 14, and 18.

A. All Asserted Claims Are Anticipated by Saikley

1. U.S. Patent App. Pub. No. 2004/0138588 to Saikley (“Saikley”)

136. Saikley published on July 15, 2004. Because Saikley’s publication date is more than 4 years before the Effective Filing Date, I understand Saikley qualifies as prior art under pre-AIA § 102(b).



137. I understand Facet designed the FreeStyle lancing device and lancet for Abbott.

2. Discussion of Claim 6

138. For the reasons I set forth below, in my opinion Saikley discloses all of the limitations of claims 6, 8, 14, and 18 of the '635 Patent.

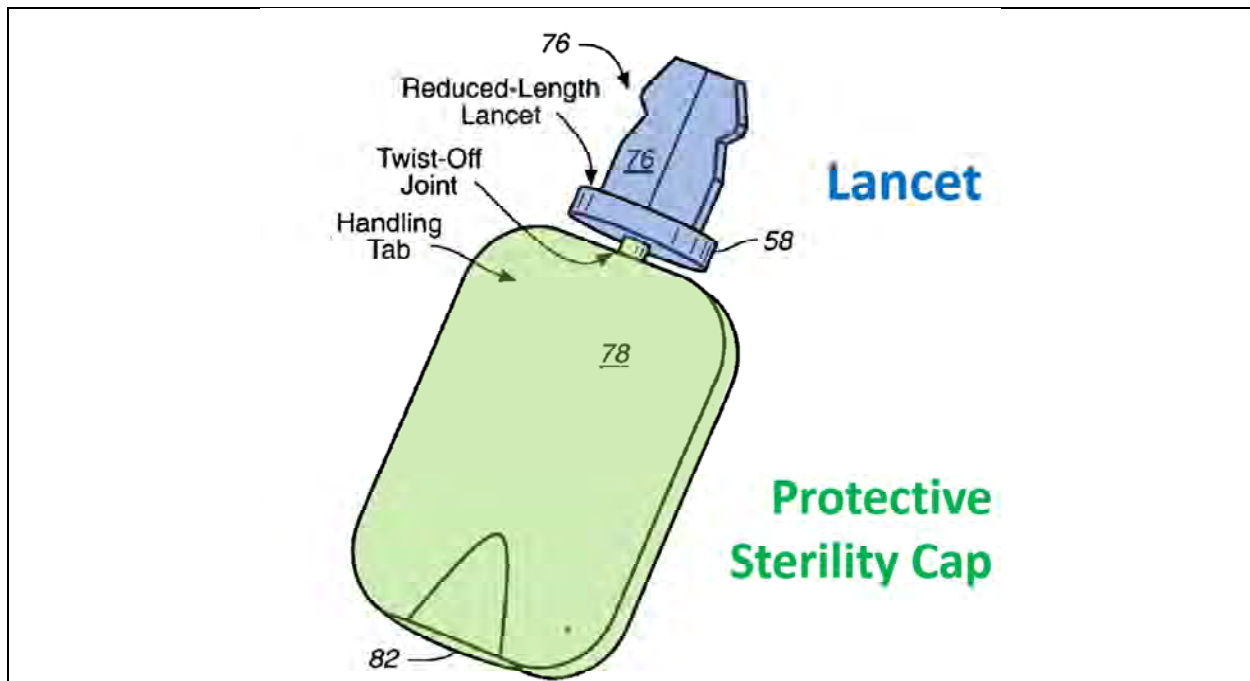
139. I discuss each limitation of claim 6 in turn below, in conjunction with the relevant disclosures of each claim limitation by Saikley. As I expand upon below, Saikley discloses each limitation of claim 1, to which claim 6 depends.

(a) Saikley discloses claim 1[p] – “A protective sterility cap for a lancet”

140. 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.”

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

FIG. 7a of Saikley



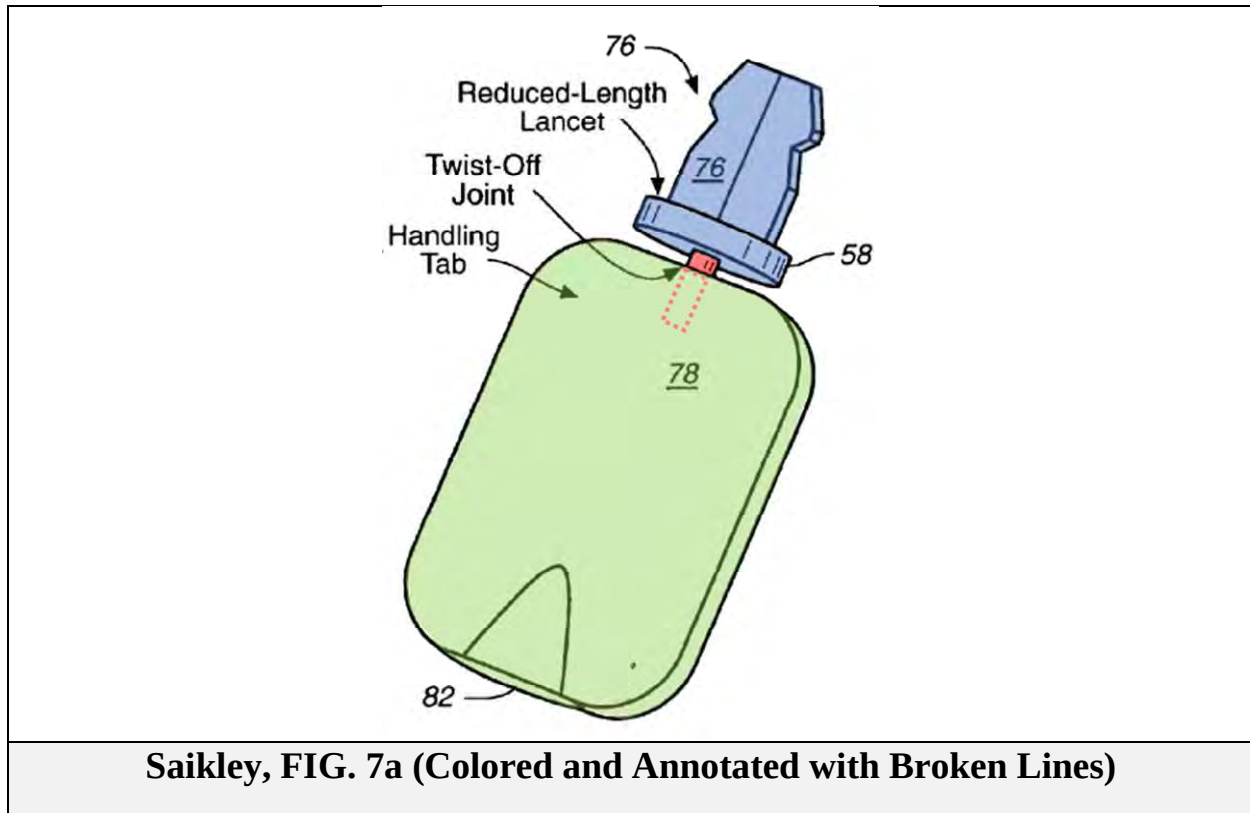
142. One observation to be made here is that Saikley states that the “cap 78 may be an integrally molded, pull-off tab, such as shown in FIG.7A.” *Id.*, [0050]. The sterility of “lancet sharp 50,” or the sharp lancing tip which projects from the lancet body, is maintained through Saikley’s “cap 78”.

143. 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].”

(b)Saikley discloses claim 1[a] – “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein”

144. 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*

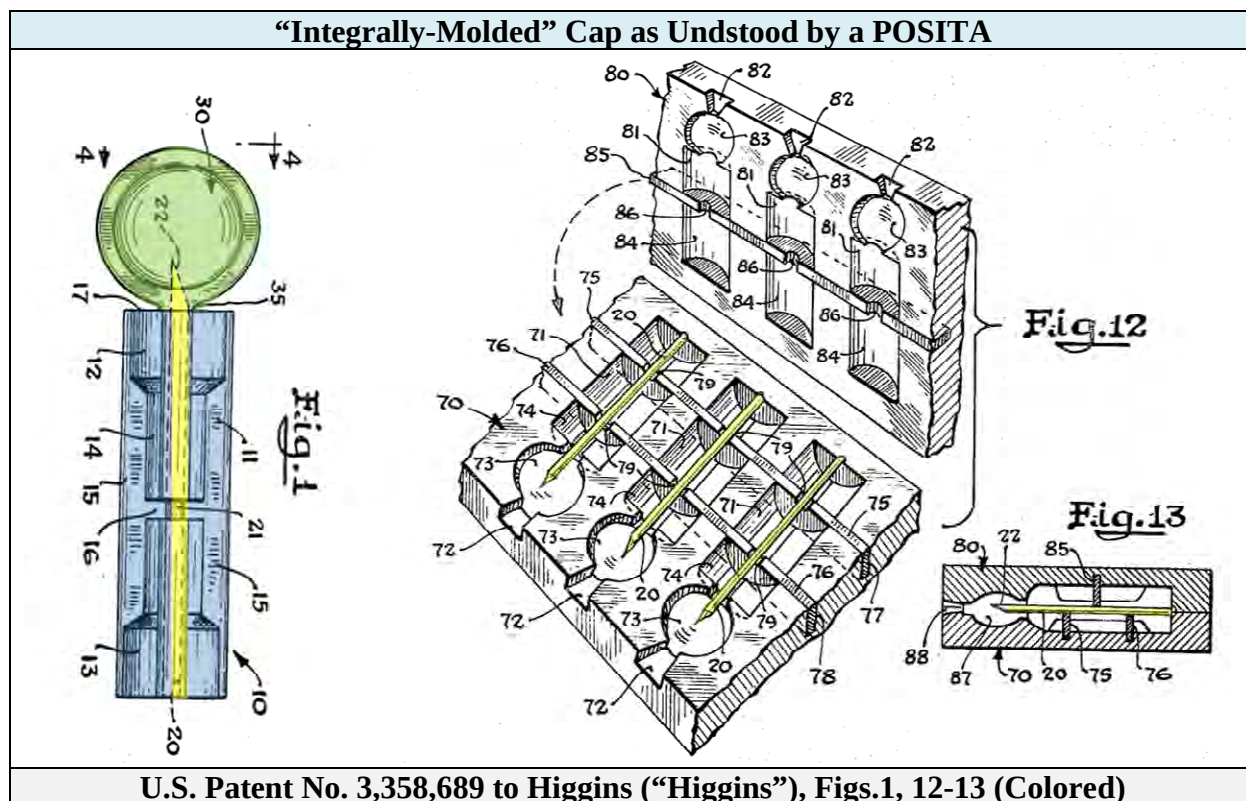
lines] that “covers the lancet sharp 50” of the “shortened lancet 76” [blue] prior to use. Saikley, ¶¶[0037], [0050-52], [0065].



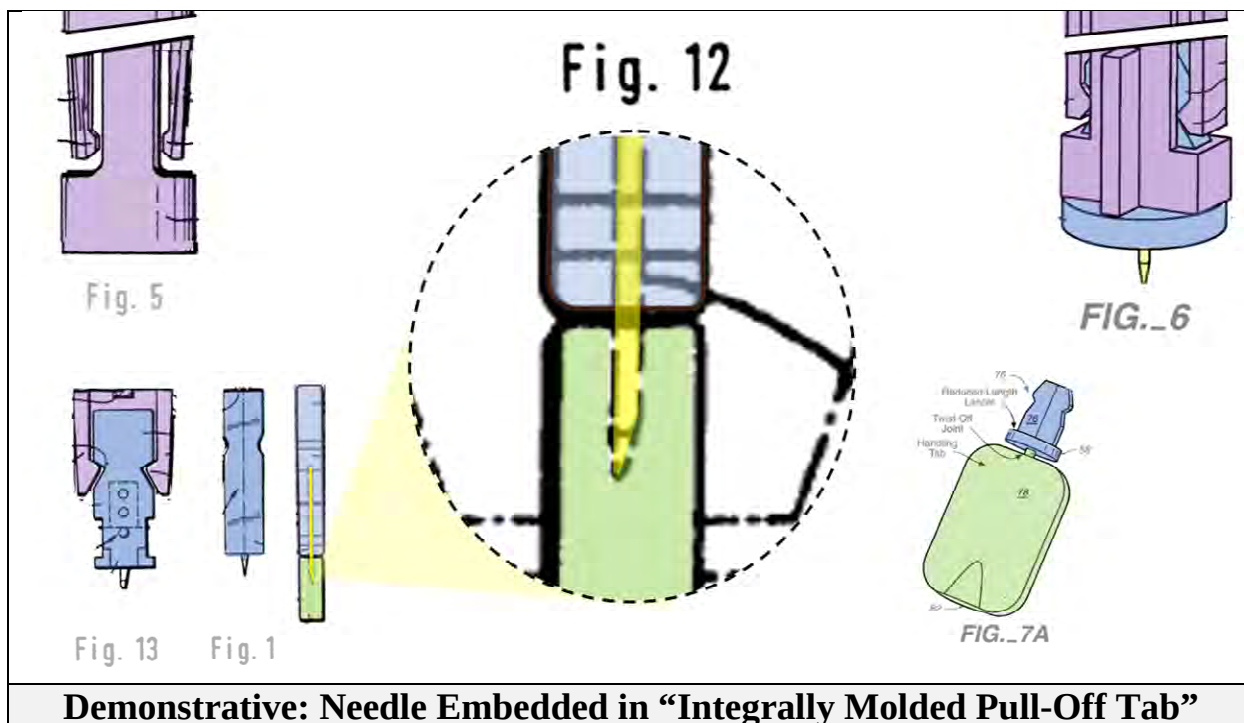
145. Saikley does not use the term “embedding” as required by the claim. However, in my opinion, Saikley otherwise discloses this claim limitation for a number of reasons.

146. *First*, Saikley describes and depicts the removable cap 78 of lancet 76 as an “**integrally molded** pull-off tab 78,” and a POSITA would this 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.” (Saikley,

[0050]; Starnes, [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 POSITA 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 POSITA, 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.” Lathrop, [00027] (“Lathrop”).



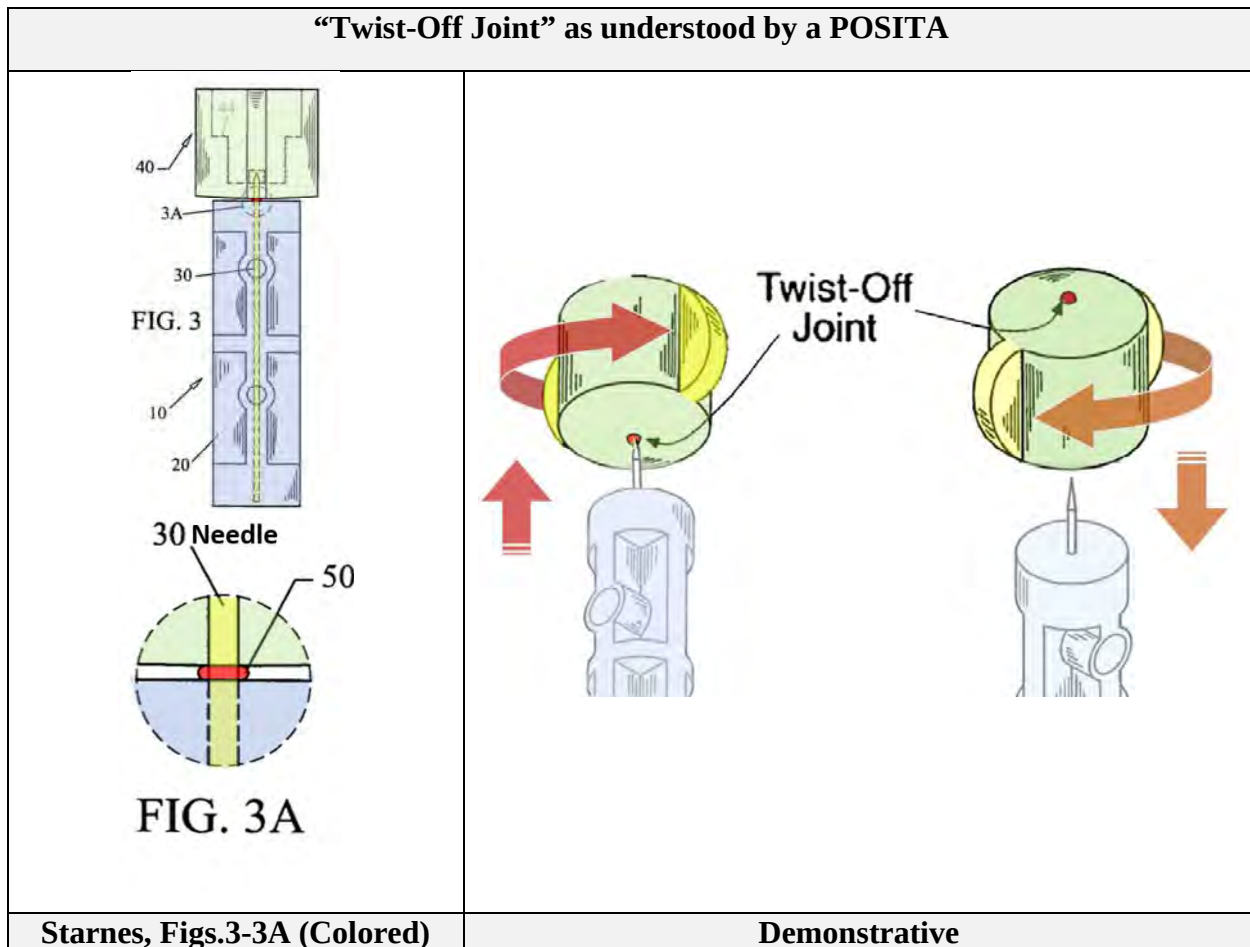
147. Furthermore, U.S. Patent No. 6,283,982 to LeVaughn (“LeVaughn”), which I understand to be incorporated by reference in its entirety in Saikley (Saikley, [0003]), discloses the “particular forms of body fluid sampling devices” from U.S. Patent No. 5,317,574 to Lange (“Lange”), including lancets having 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. Lange, Fig. 5, 11-13 (“Lange”).**



148. *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.” '635 Patent, 1:47-50, 6:18-24. I observe this is also the case in Higgins, Starnes, 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

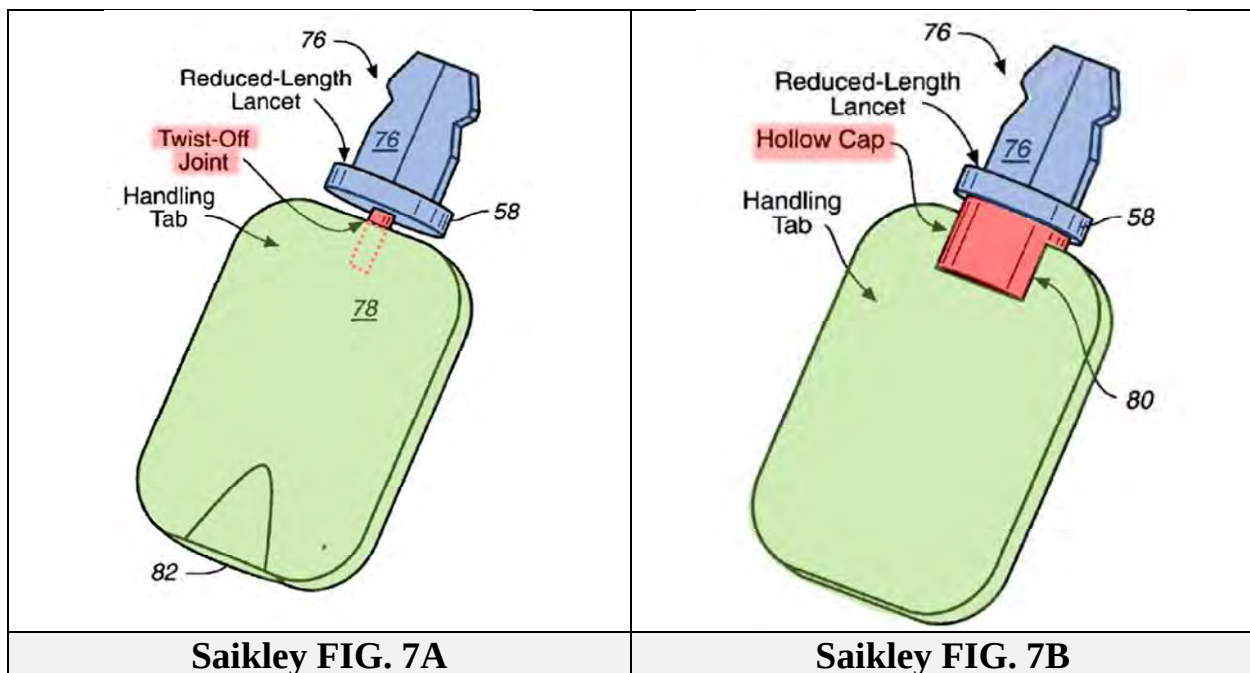
and exposed needle tip, such that “the needle tip [is] embedded in a removable protective cap integrally molded with the plastic body to form a single integral unit prior to use.” Starnes, [0008].

149. *Third*, in my opinion, Figure 7a also discloses the sharp 50 of Saikley’s lancet 76 embedded in the protective cap because a POSITA 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.” Starnes, [0028].



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.” '635 Patent, 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.

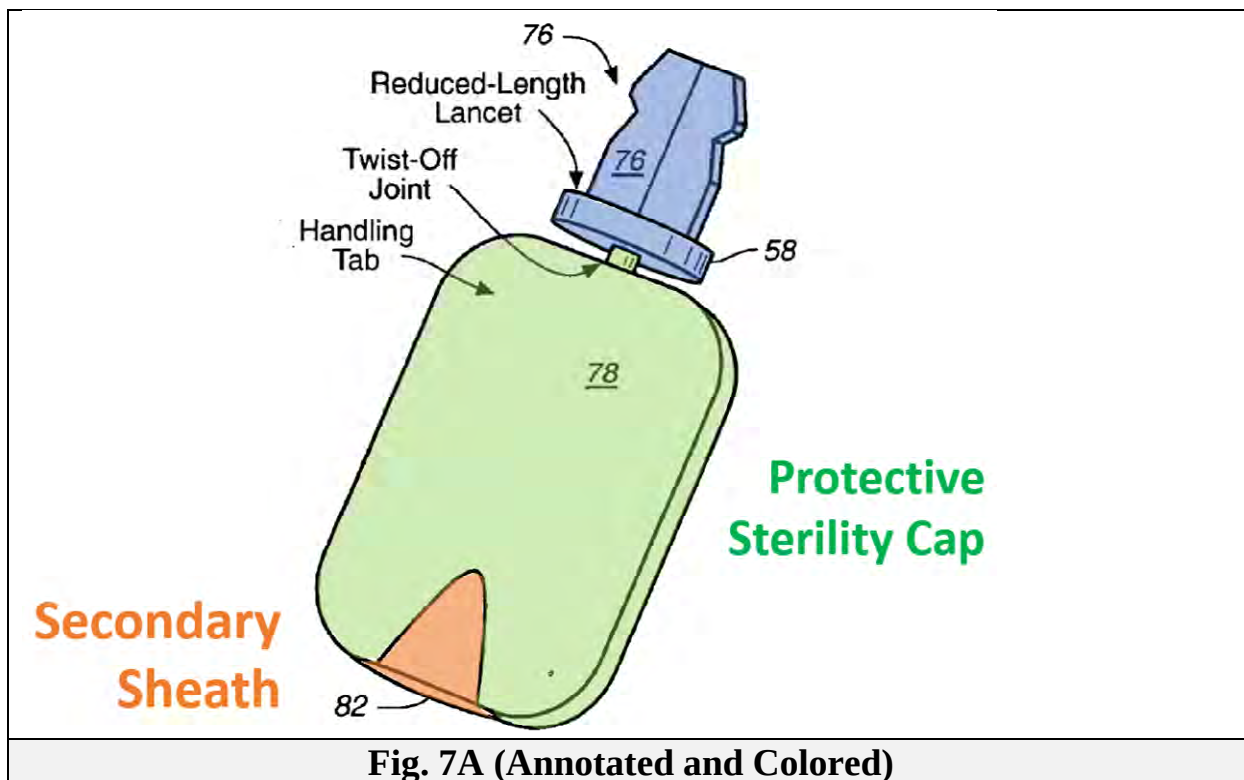
150. *Fourth*, I am further informed by the alternative embodiments disclosed by Saikley that the needle sharp 50 is embedded within the Twist-Off Joint and adjoining portion of the Handling Tab in the Figure 7a embodiment. Unlike the “integrally molded” protective cap 78 of the Figure 7a embodiment, 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.” Saikley, [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.



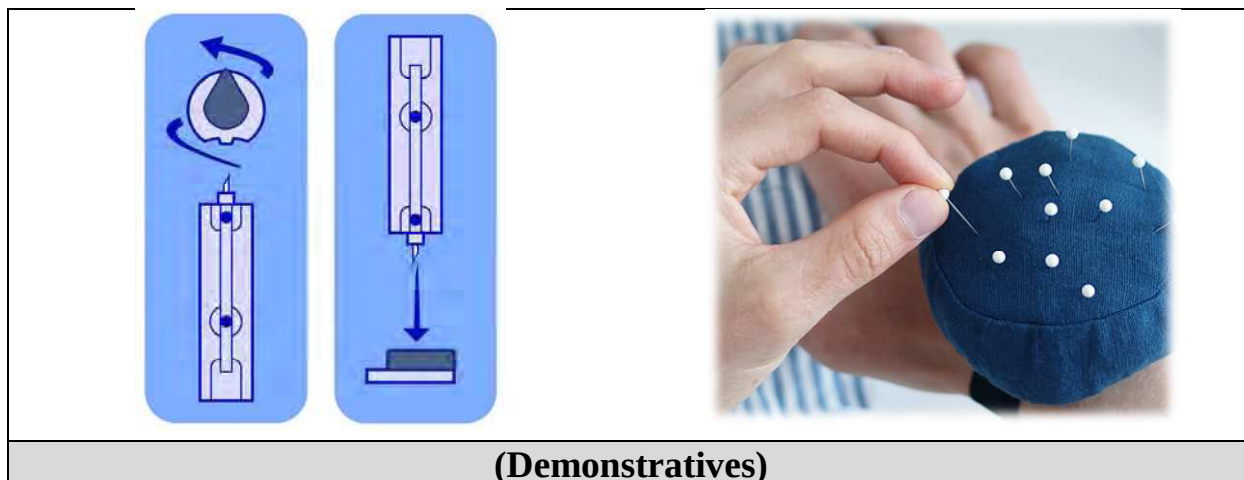
151. In my opinion, Saikley therefore discloses that the “sterility cap [*i.e.*, protective cap 78] compris[es] a primary sheath [*i.e.*, twist-off joint and] for initial embedment of a sharp lancing tip of an unused lancet therein [*i.e.*, needle point 50 of lancet 76].”

(c) Saikley discloses claim 1[b] – “a secondary sheath for receiving the sharp lancing tip of a used lancet”

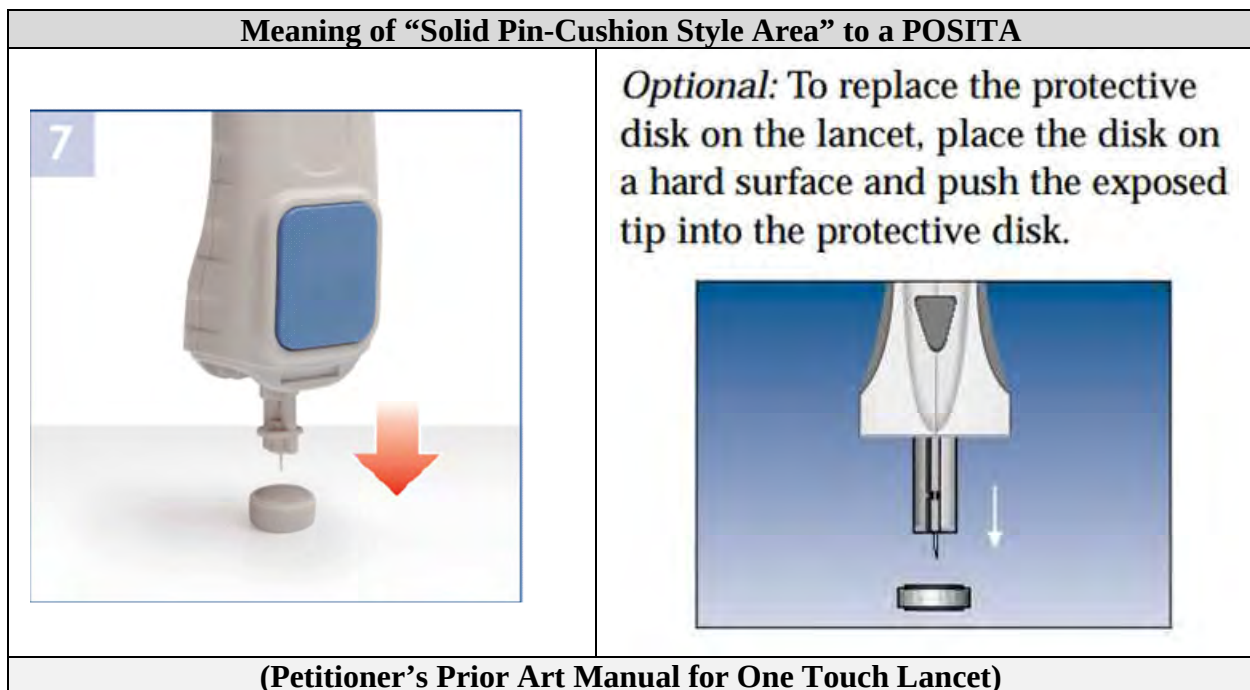
152. I observe that Saikley’s protective cap 78 also includes “[a] hollow cup or solid ‘pin cushion’ type area 82 at the opposite end of cap 78, as shown in FIG. 7A [*orange below*], to cover the sharp during **removal** from the [lancing] device and **disposal**” and safely handle the lancet after it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



153. 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.” Saikley, [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. Saikley, [0050-0052], [0064].

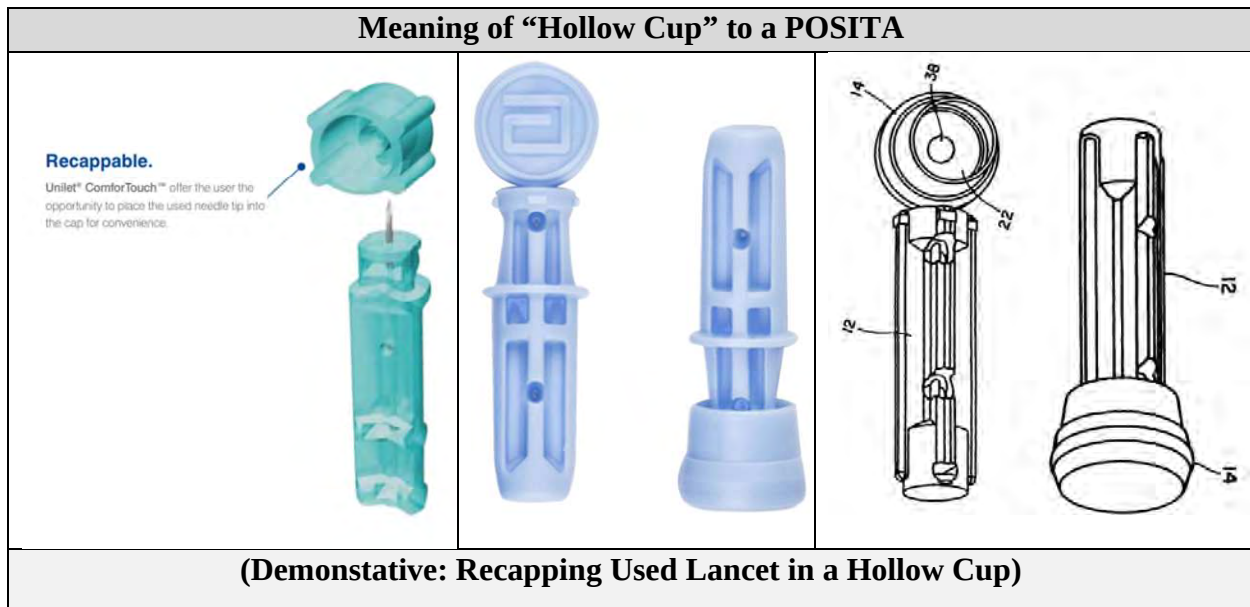


154. Accidental needlesticks have been an art-recognized problem. Thus, having a secondary sheath has been a well-known feature of disposable lancets by the critical date. Such secondary sheaths often resembled a “pincushion” or a “hollow cup.” Exhibit 2 (Wayback: LifeScan One Touch); Exhibit 3 (Wayback: 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 POSITA 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*.”

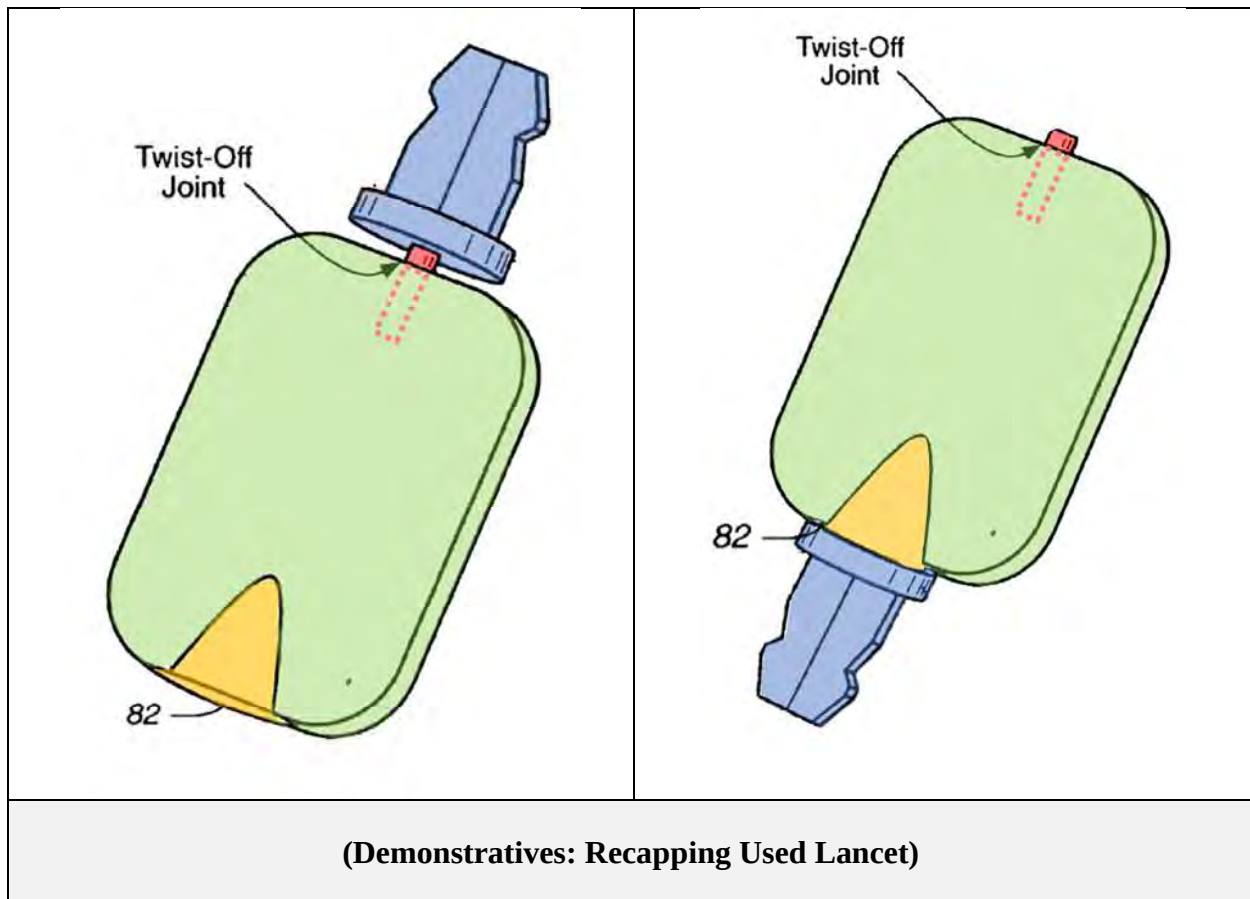


155. By positioning the secondary sheath on the opposite end of the handling tab away from the primary sheath and by using a “hollow cup or solid pin-cushion type area 82” for the secondary sheath that is visually and tactilely distinct from the primary sheath, Saikely’s protective cap 78 allows users 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.

156. 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.



157. 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.” Court’s Claim Construction Order, 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.” ’635 Patent, 6:1-5, 7:6-10; *compare* ’635 Patent, Figs. 5A-5D *with* Figs. 6A-6D.

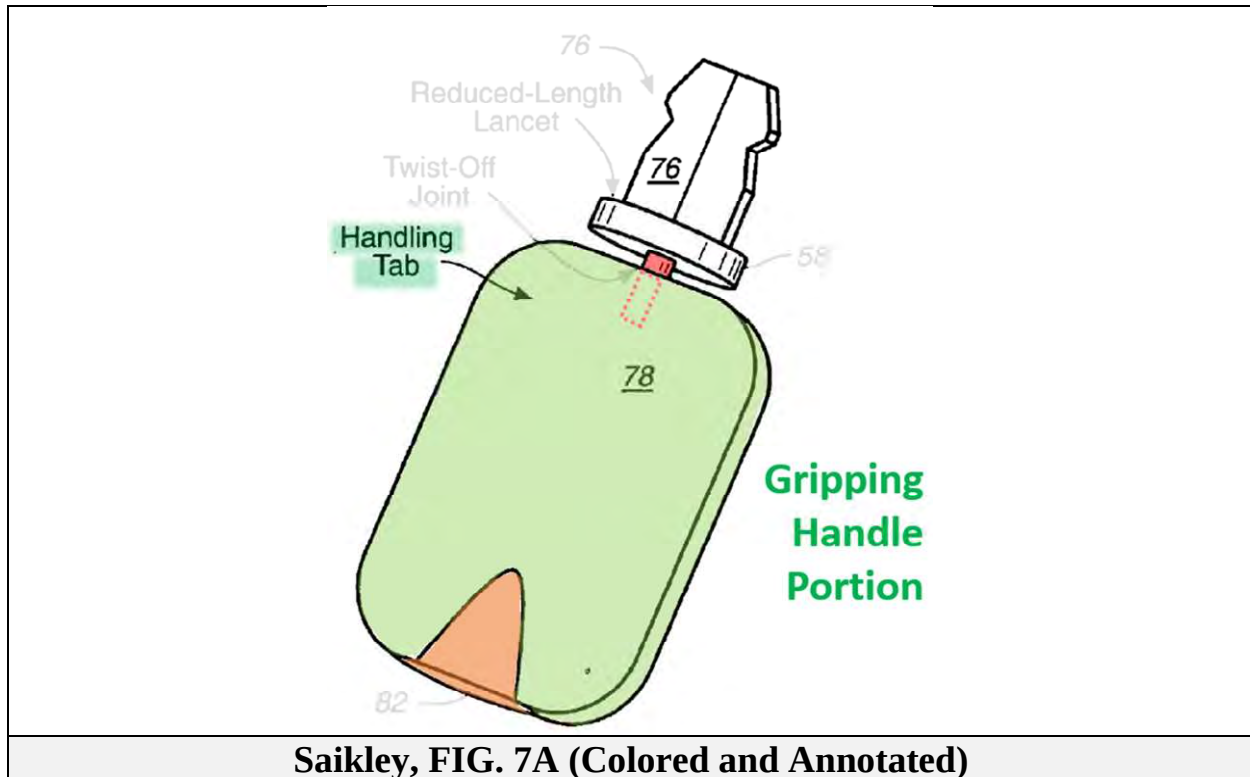


158. In my opinion, it is for at least these reasons, Saikley discloses “a secondary sheath (*i.e.*, hollow cup or pin-cushion type area 82) for receiving the sharp lancing tip of a used lancet [*i.e.*, for receiving the sharp 50 of the shortened lancet 76 after it has been used to collect a blood sample].

(d) Saikley discloses claim 1[c] - “and a gripping handle portion extending between the primary sheath and the secondary sheath”

159. 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).



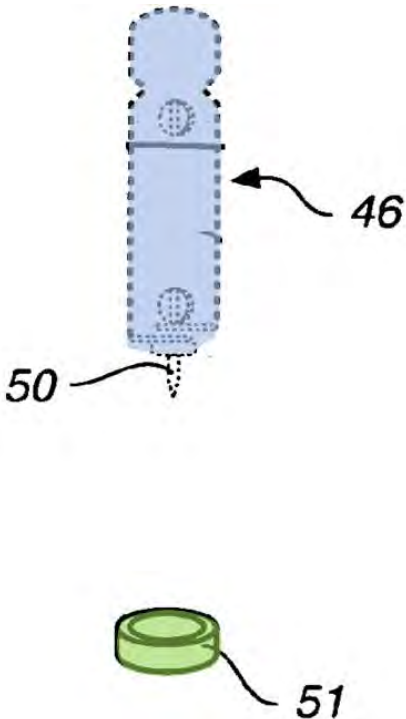
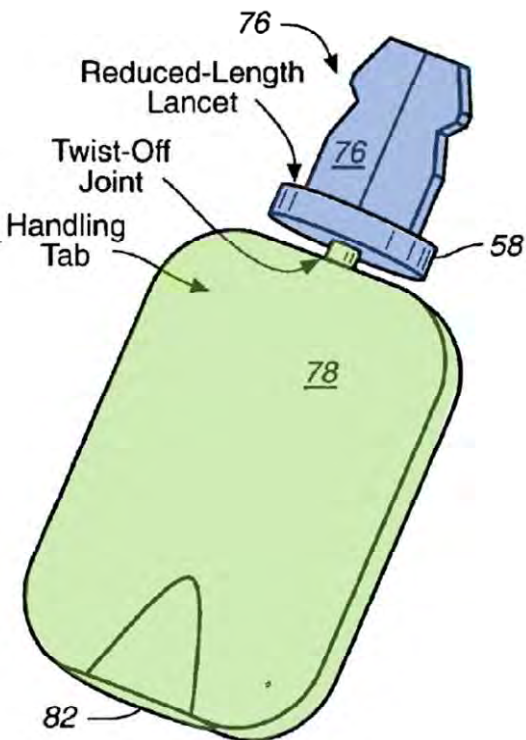
Saikley, FIG. 7A (Colored and Annotated)

160. 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). Saikley, [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.” Court’s Claim Construction Order, 17:12-13. Per the Court, “all handles are ‘gripping handles.’”

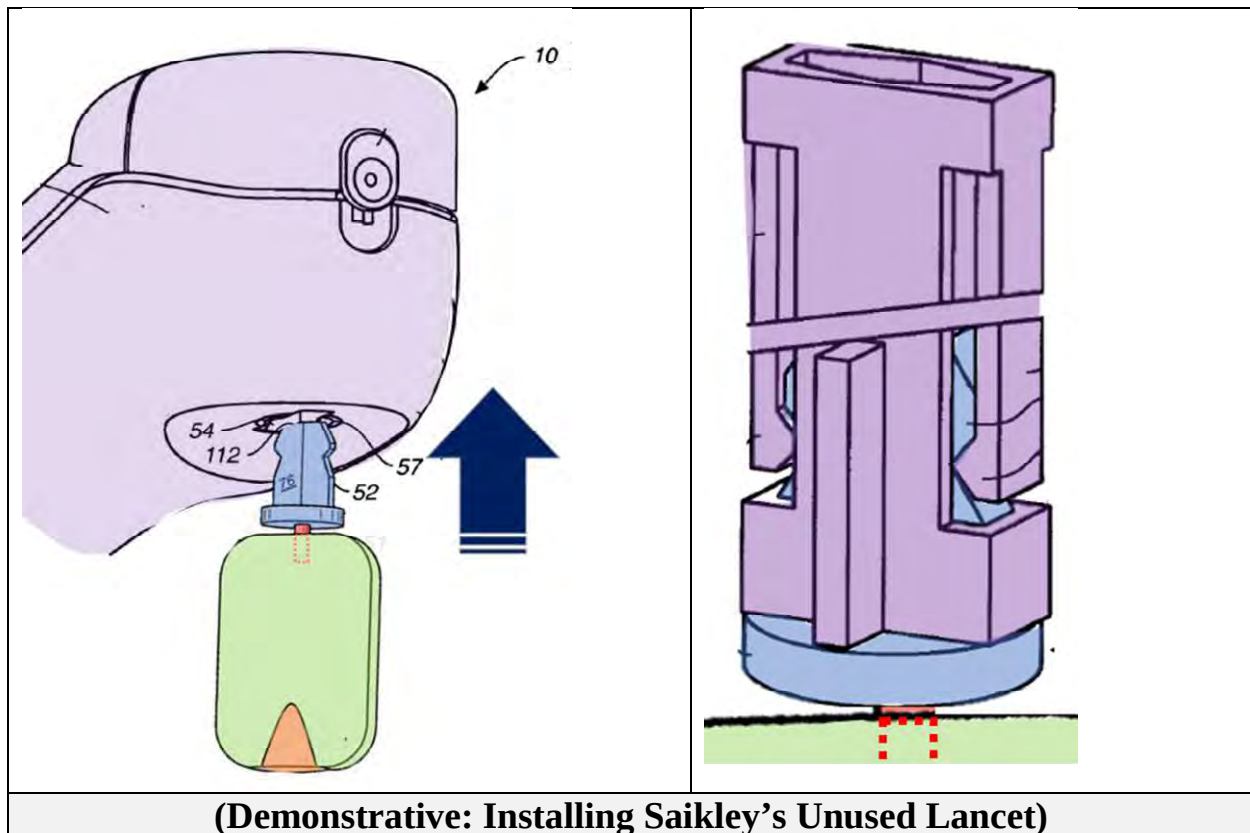
Id. The '635 patent likewise refers to a “handle or grip” interchangeably and describes a “handle” or “handle portion of the cap.” '635 Patent, 1:66-2:3, 6:5-9, 7:6-12, 8:17-22.

161. 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* Saikley, ¶¶ [0004], [0050] *with* '635 Patent, 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.

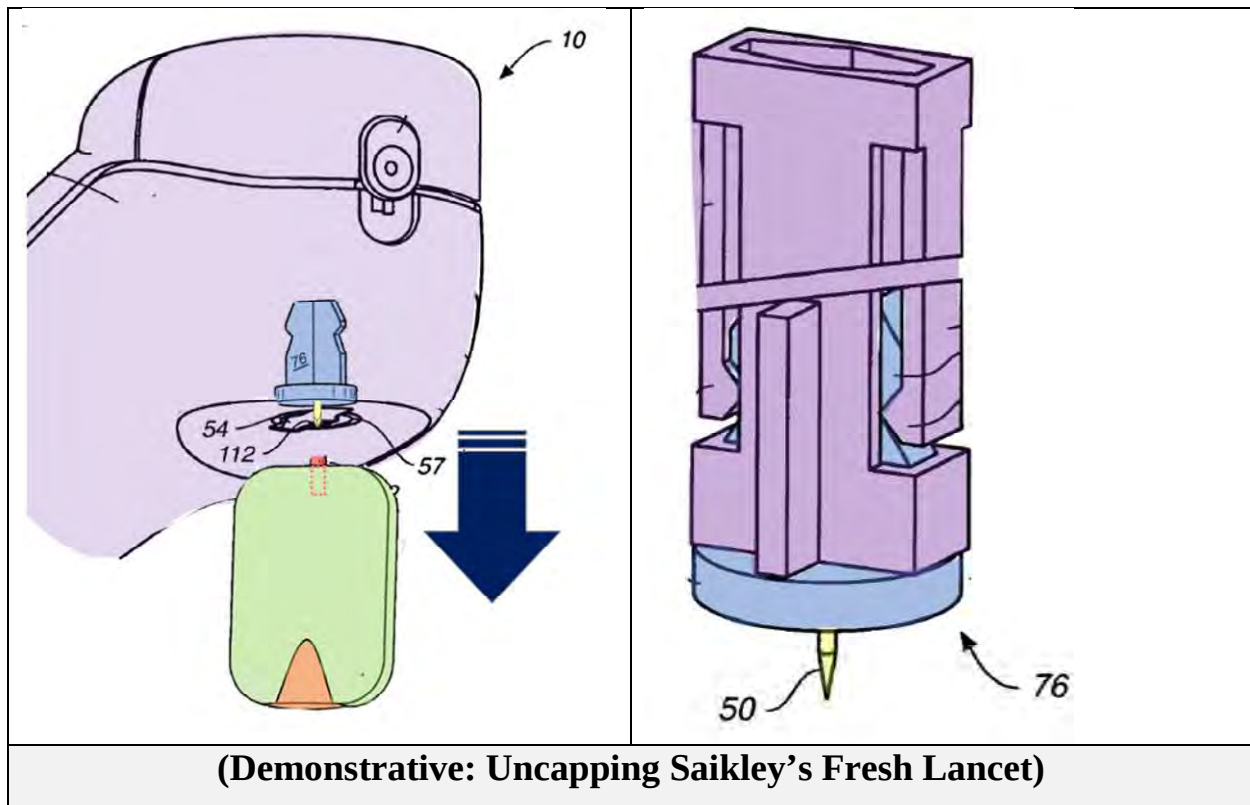
162. And just like the '635 patent, to address this problem, Saikley teaches that “the protective cap 78 (that is removed before use) should be made **much larger** than usual to **aid handling**.” *Compare* Saikley, ¶¶ [0004], [0050] *with* '635 Patent, 6:66-7:3 (“[T]he expanded dimensions of the endcap 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
	
Saikley, Fig. 3 (Colored and Showing Only the Lancet and Cap)	Saikley, Fig. 7A (Colored)

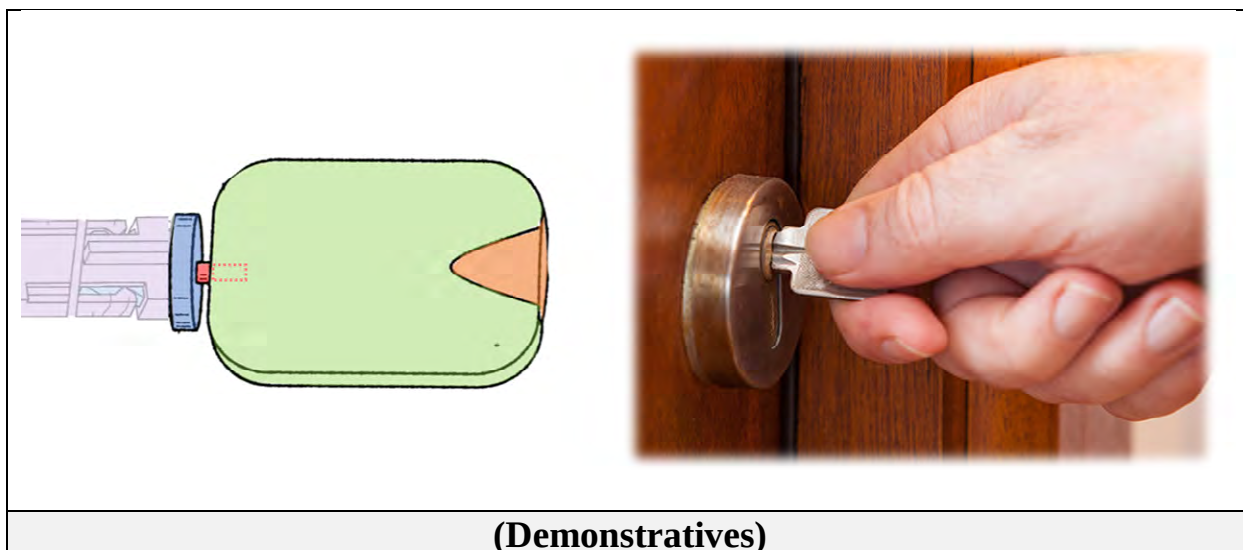
163. By extending the “much larger” “handling tab” between the primary sheath and secondary sheath, Saikley’s protective cap 78 provides the user with “a large protective cap for handling” the lancet prior to collecting a blood sample—or more specifically, when inserting a “fresh lancet into the lancet holder 68” of the lancing device 10. *Compare* Saikley, ¶¶ [0050], [0087] *with* ’635, 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:



164. 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* Saikley, [0050-52], [0087] *with* ’635 Patent, 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.”); ’635 Patent, 53-55 (disclosing a “handle with a greater width” for “allowing the user to more easily twist the endcap during removal from the lancet.”)



165. 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.



166. 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 POSITA 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.

167. 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.” Saikley, ¶¶[0050-52], [0064]; *Compare* Saikley, ¶¶[0050-52],[0064] *with* ’635 Patent, 6:61-66 (“The provision of the elongate handle portion 516 allows the user to grab the lancet further from the needle during

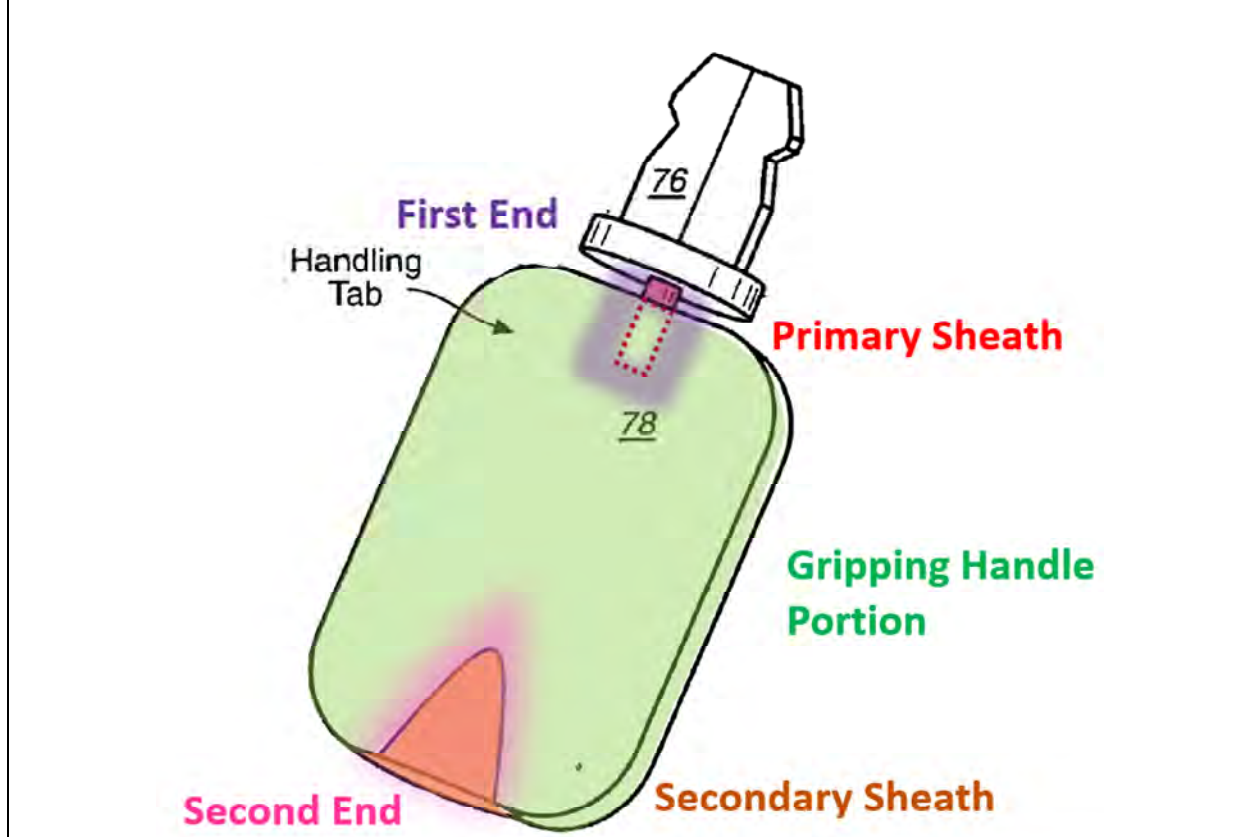
decapping and disposal, providing a larger safety margin from the needle tip, protecting the patient and other persons handling the lancet from accidental needle sticks.”).

168. 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].”

(e) 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”

169. 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. Saikley, 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)



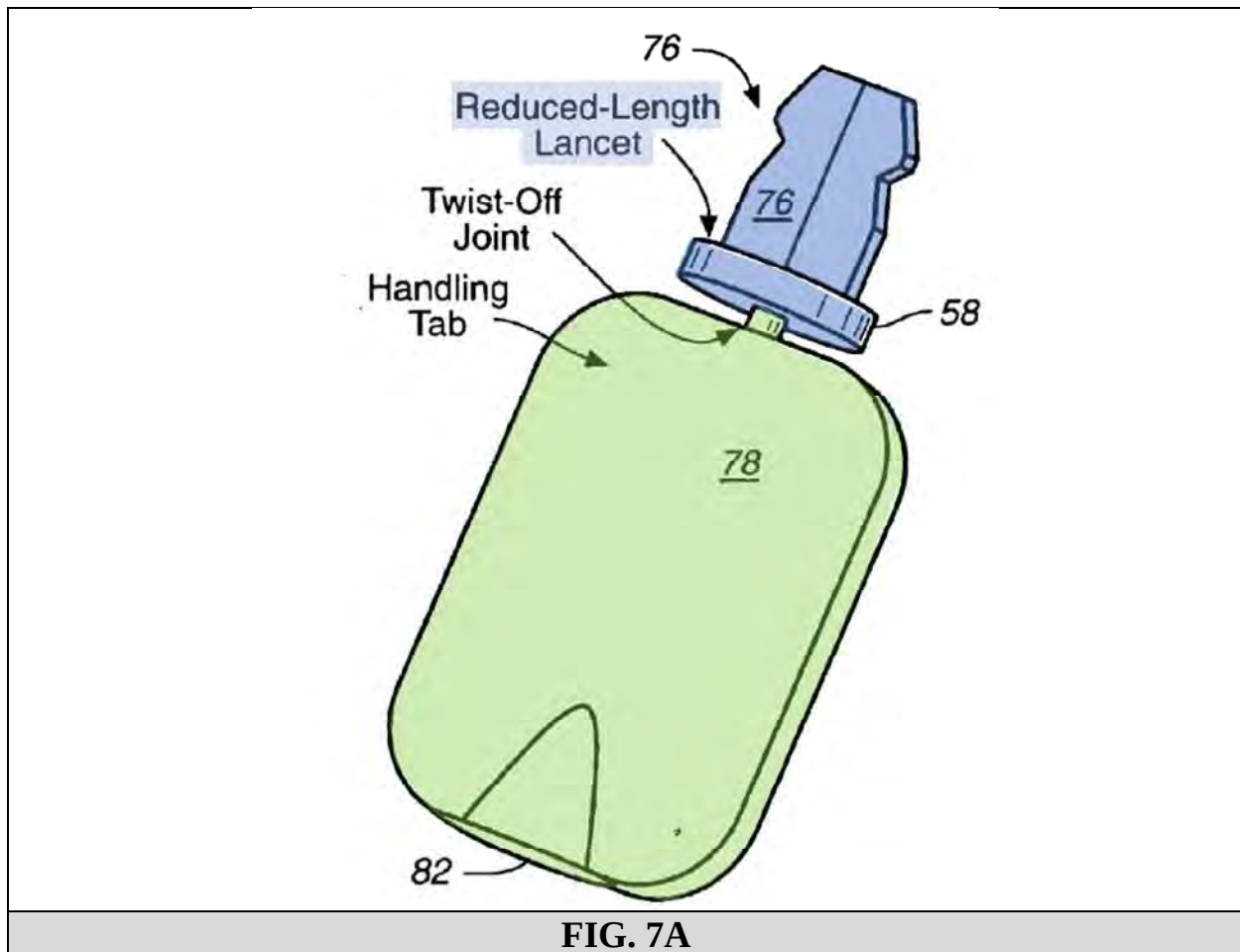
170. The primary and secondary sheaths are attached at opposing ends of the handling tab “when the protective sterility cap is removed from the lancet” and at all other times. Both sheaths are integrally molded to the protective cap so that they remain attached to the handling tab even after the user 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**.” Saikley, [0050].

171. 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.]”

(f) Saikley discloses claim 6[a] – “The protective sterility cap of claim 1, in combination with a lancet”

172. 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*].” Saikley, [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.”).



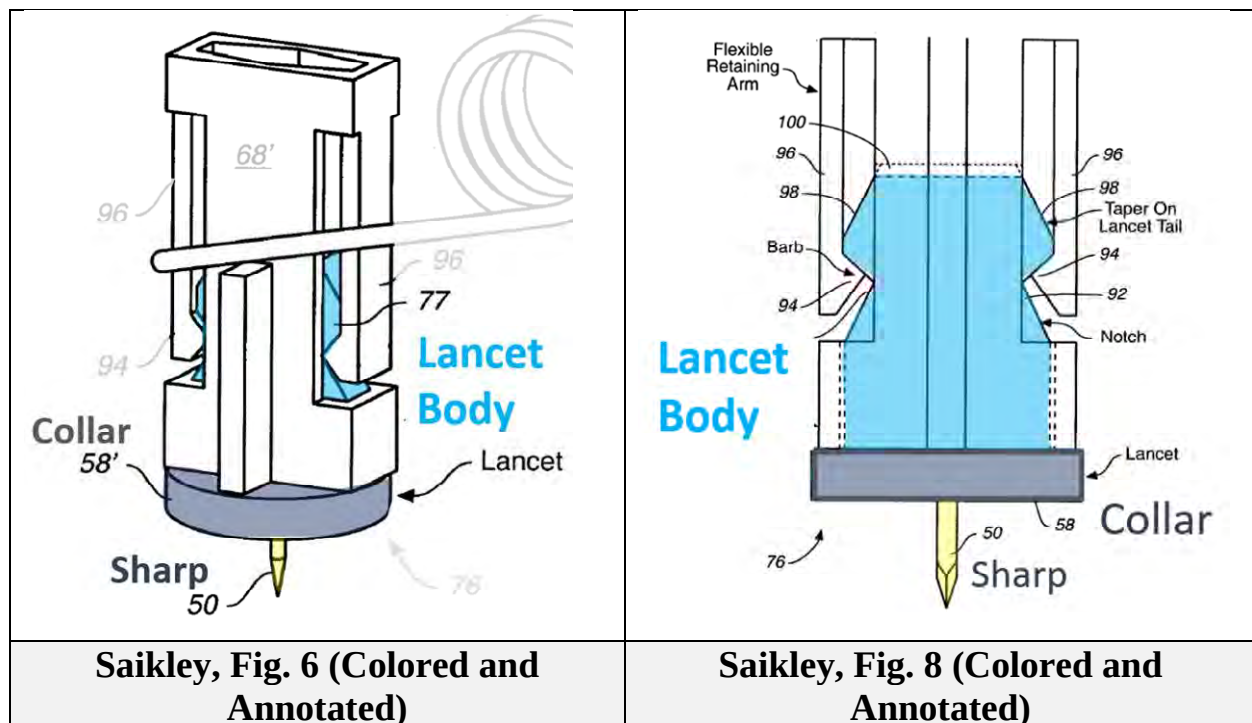
173. In my opinion, Saikley discloses “[t]he protective sterility cap of claim 1 [i.e., protective cap 78], in combination with a lancet [i.e., reduced-length lancet 76].”

(g) Saikley discloses claim 6[b] – “having a lancet body defining a lancet thickness, and”

174. 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

Saikley, ¶¶[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.”).

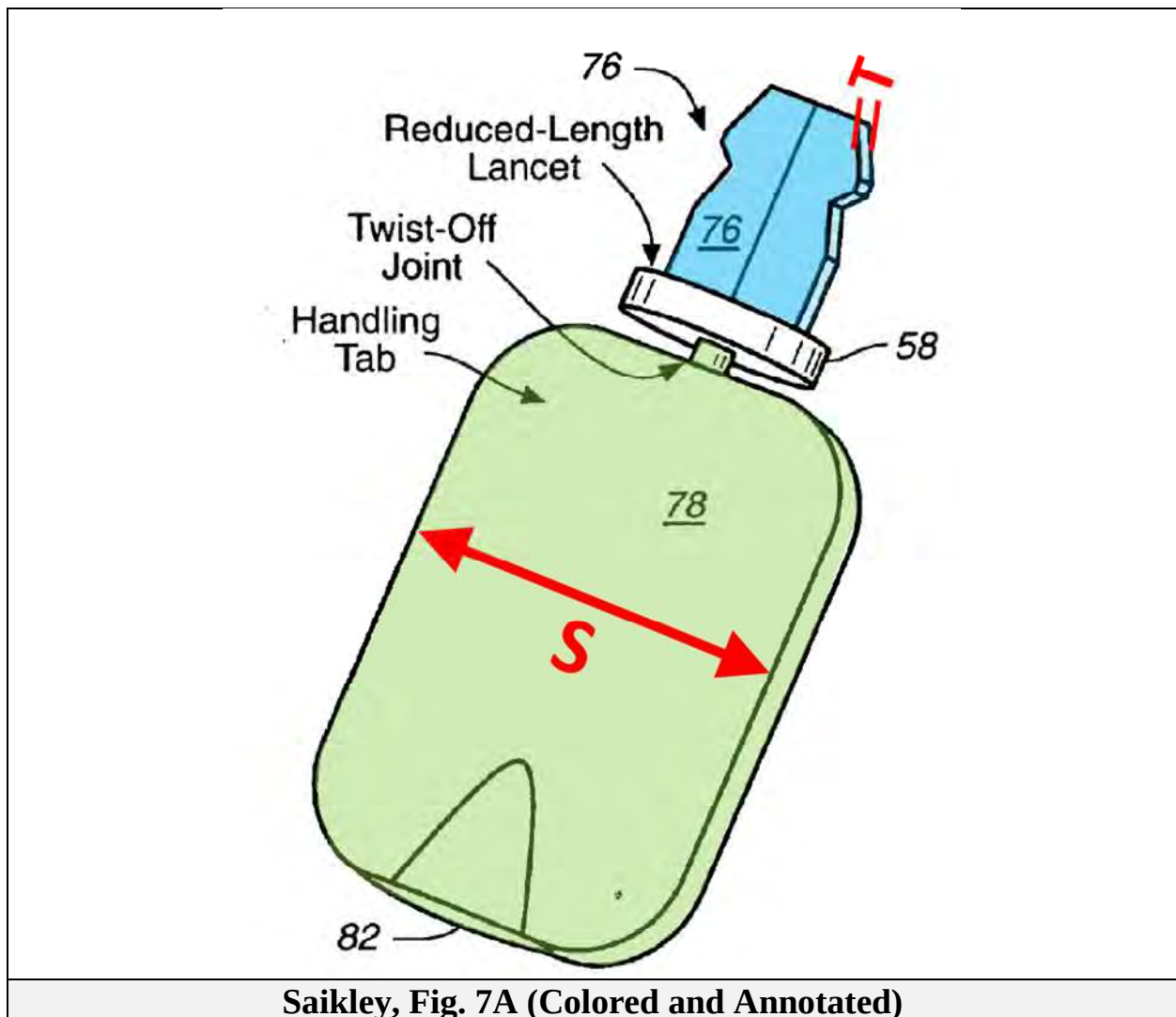


(h) Saikley discloses claim 6[c] – “a sharp lancet tip initially embedded in the primary sheath”

175. A POSITA 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 6[a] in Section XI.B(1)(f), incorporated herein.

(i) Saikley discloses claim 6[d] – “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness”

176. 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*).



177. 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 (Saikley,

[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 POSITA would have understood element 6[d] to be expressly or, at least inherently, disclosed.

178. 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 POSITA would have also appreciated that the average human thumb has a diameter of 16 mm in size. Exhibit 4 (Annals of Anatomy), 157. In light of this, a POSITA would have understood Saikley’s instruction to make its cap 78 “much larger than usual to aid handling” (Saikley, [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 (LeVaughn, 9:67-10:10, which I understand to be incorporated by reference in Saikley and referred to hereinafter as “incorporated-by-reference LeVaughn”), a POSITA 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.” LeVaughn, 5:15-18.

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

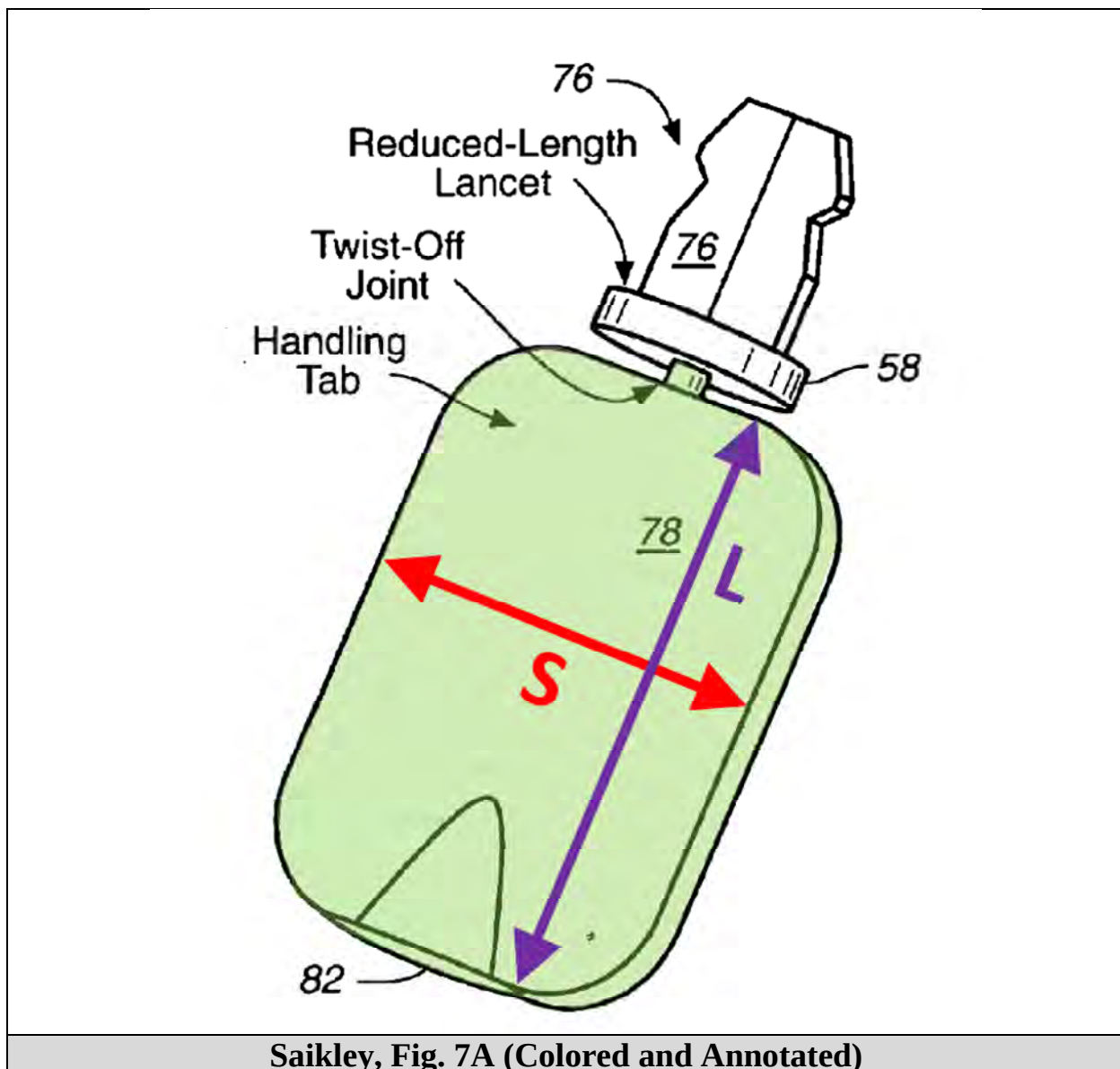
3. Discussion of Claim 8

180. Claim 8 depends from claim 6, which Saikely anticipates for the reasons I discussed above in Section XI.B(1), incorporated herein. Claim 8 adds “wherein the gripping handle portion defines a length at least equal to the lancet thickness.”

181. Because Saikley discloses both that the gripping handle portion (cap 78) is at least 1.5 times the lancet thickness (*supra* Section XI.B(1), 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.

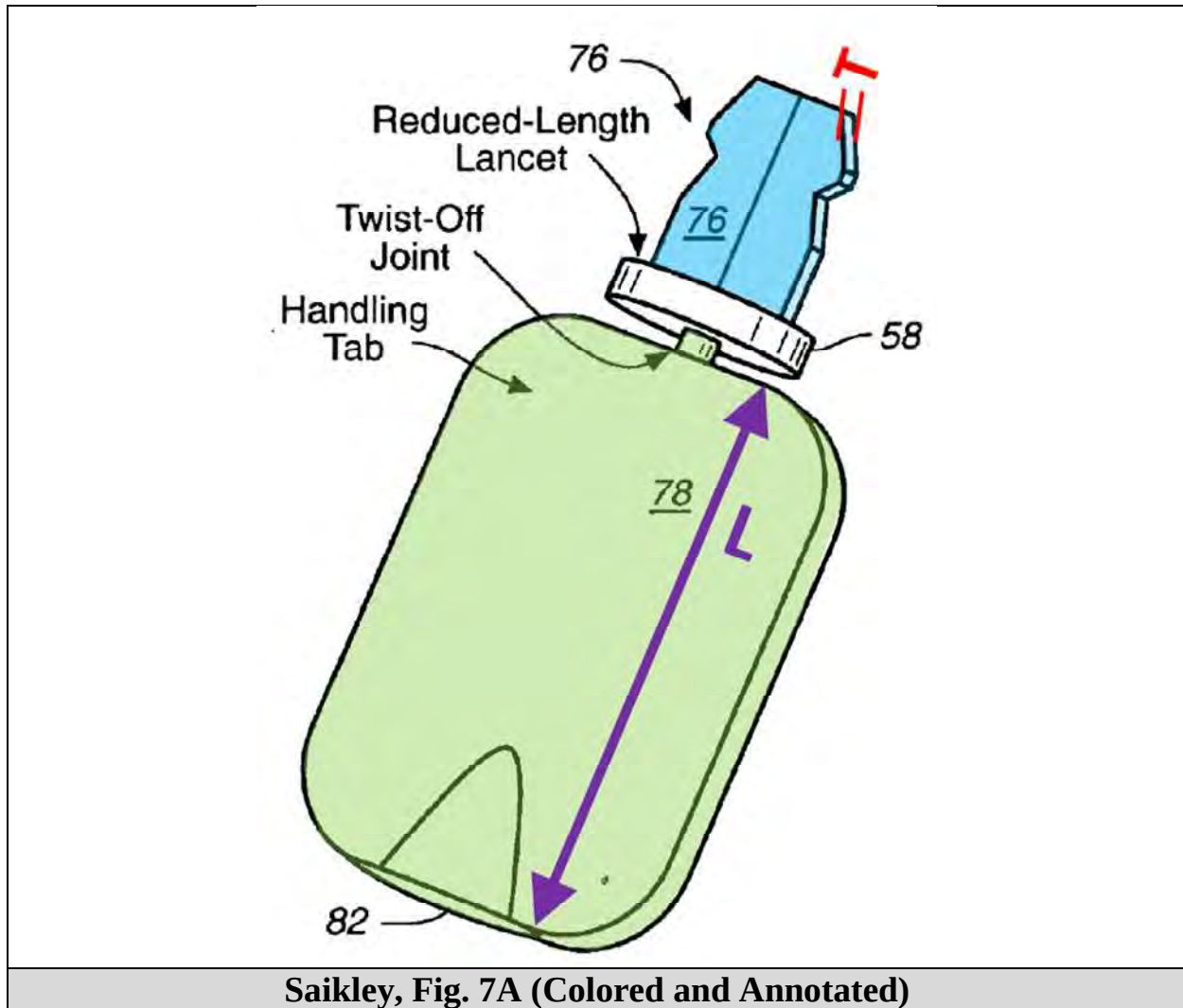
182. Saikley also discloses that the gripping handle portion has a length at least equal to its lateral span. A POSITA would have understood Saikley’s Figure 7A (in conjunction with the textual descriptions concerning larger lancet caps for handling) to plainly depict a gripping handle portion (cap 78) 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, the gripping handle must also be at least equal to its lateral span.



183. Because Saikley discloses both that the gripping handle portion (cap 78) is at least 1.5 times the lancet thickness and that the gripping handle portion's length is at least equal to the lateral span, 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.



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

4. Discussion of Claim 14

185. 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 XI.B.1(a)-(e)). 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 XI.B.1(f)-(i)).

5. Discussion of Claim 18

186. Claim 18 depends from claim 14, which is anticipated by Saikley for reasons I provided above and incorporated here (*supra* Section XI.B.3). 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 XI.B.2).

B. All Asserted Claims Are Rendered Obvious By Saikley in Further View of Stout

6. U.S. Patent Application Publication 2006/0241669 to Stout (“Stout”)

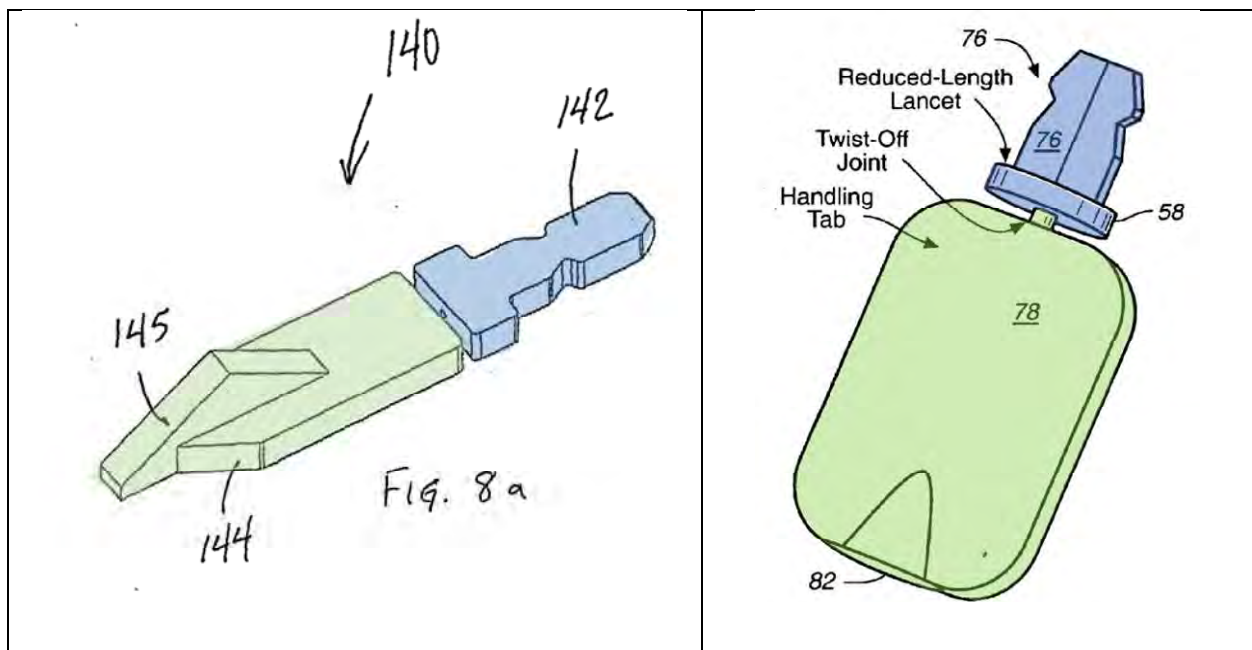
187. U.S. Patent Application Publication 2006/0241669 to Stout (“Stout”) published on October 26, 2006. Because Stout’s publication date is more than 1 year before the Effective Filing Date, Stout qualifies as prior art under pre-AIA § 102(b).

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

188. For the reasons I set forth below, in my opinion, Saikley discloses all of the limitations of claims 6, 8, 14, and 18 of the ’635 Patent and renders them obvious.

189. As I explained 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 POSITA 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 XI.B.1(b).

190. 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 POSITA in view of Stout, 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.” Stout, [0035].



Stout, Fig. 8a	Saikley, Fig. 9
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191. 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.”

Stout, [0035]. I believe a POSITA 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.

192. It would have also been obvious to a POSITA 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 POSITA 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.” Starnes, [0008]. Additionally, a POSITA 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.” Lathrop, [00027].

8. All Claims: “Secondary Sheath for Receiving.”

193. 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.

194. A POSITA 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.” Saikley, [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 POSITA 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 POSITA 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).

9. Claims 6, 8, 14, and 18: The “Length” and “Lateral Span” of the Gripping Handle Portion

195. As I explained above (*supra* Sections XI.B.1-4, incorporated here), Saikley anticipates the “length” and “lateral span” limitations. Because Saikley is being modified only by combining embodiments of Saikley and based on a POSITA’s general knowledge of primary and secondary sheaths, the modified Saikley here 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 lancet thickness (claims 8 and 18).

196. All of the relative-dimensional limitations taught in Saikley would have been obvious for a POSITA 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 POSITA 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.

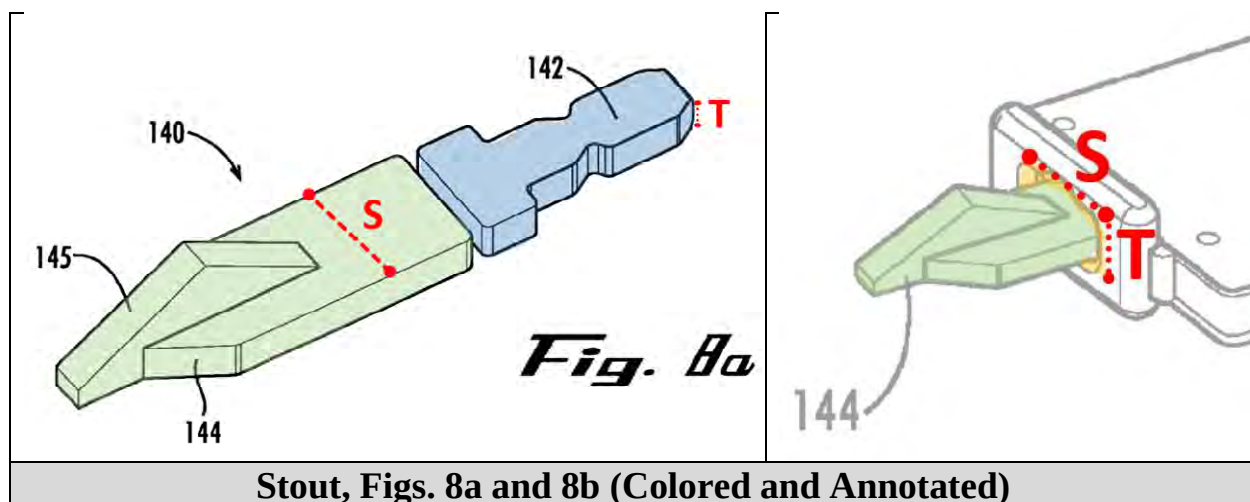
197. As to the gripping handle's lateral span being at least 1.5 times the lancet thickness (recited in claims 6 and 14), it was already known that gripping handles on many sterility caps were larger than the lancet thickness. Saikley is one example of this, because as is visually apparent from the depiction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

made much larger than usual to aid handling.” Saikley, [0050]. Designing a gripping handle’s lateral span to be at least 1.5 times the lancet thickness would have been pursued by a POSITA 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.” Saikley, [0050]. Both express statements in Saikley and the knowledge of those skilled in the art would have motivated a POSITA 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 POSITA 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. Exhibit 5 (3D Finger Tip Model Article), 685.

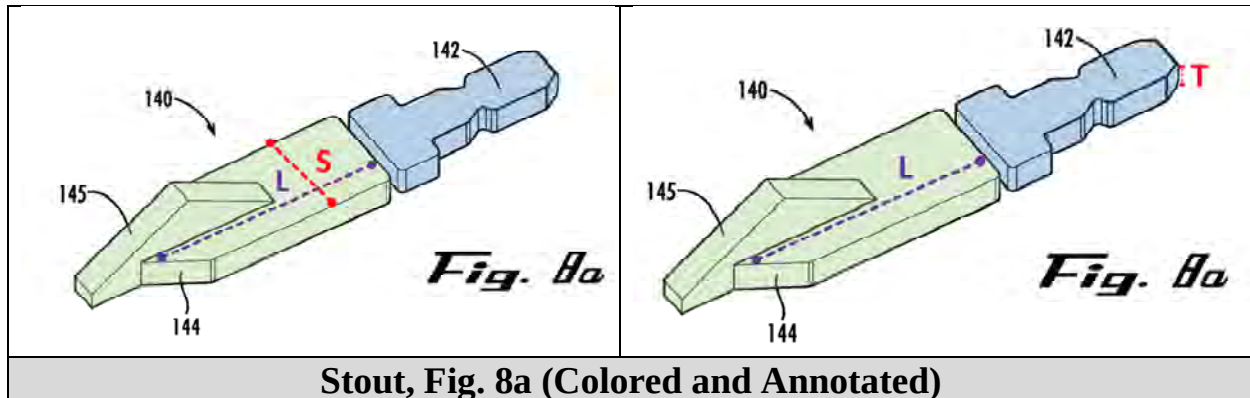
198. To my knowledge, Saikley incorporates by reference U.S. Patent No. 6,283,982, which indicates that an opening for receiving a lancet should be “less than about 6 mm in diameter, so that a standard lancet will not pass therethrough,” which means that “standard” lancets were less than 6 mm in diameter. LeVaughn, 10:3-6. Thus, in designing Saikley’s cap 78 to be held by the average human fingerpad, a POSITA would have routinely designed a cap 78 that would have been at least 1.5 times the thickness (diameter) of a standard lancet.

199. 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 POSITA 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.

200. 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].” Stout, [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”).



201. I believe a POSITA 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.



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

10. Ample Motivation Existed to Combine Saikley with Stout

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

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

205. *Second*, Saikley 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." '635 Patent, 1:17-19. Both Saikley and Stout relate to lancing

devices. Saikley, [0002]; Stout, [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.” ’635 Patent, 5:28-29. Saikley discloses a lancet where the “flat shape of lancet body 66 allows for such alignment and prevents misalignment.” Saikley, [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. Stout, [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.

206. In addition, I believe a POSITA 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. Stout, [00046]; Saikley, [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.” Stout, [0005]. A POSITA 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.” Stout, [0046].

207. *Finally*, the Saikley and Stout combination would be one that I believe a POSITA 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.” Saikley, [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.” Stout, [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.



208. I also examined the FreeStyle Lancets above as part of my analysis.

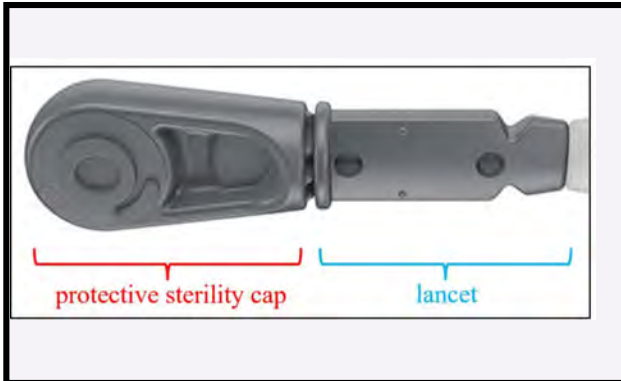
209. As such, I believe it would have been straightforward for a POSITA to improve of Saikley's protective cap 78 with Stout's sterility cap 44 and know that such a combination would be feasible.

C. The Roche Softclix Lancet Anticipates and/or Renders Obvious the Asserted Claims

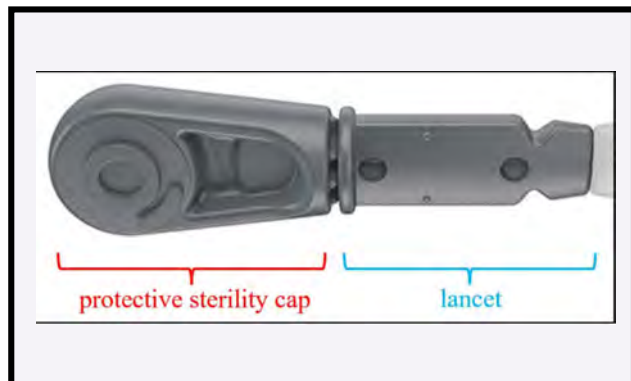
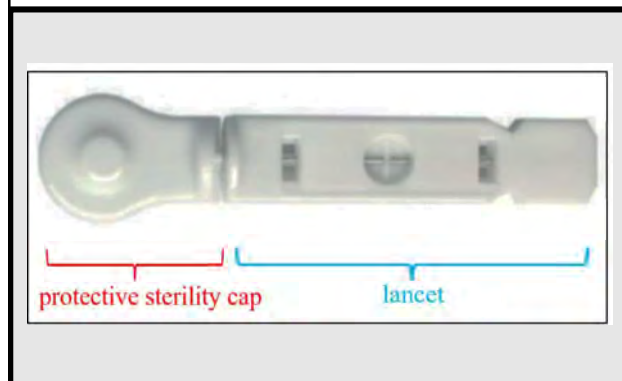
1. The Roche Softclix Lancet Anticipates and/or Renders Obvious the Asserted Claims

Facet's Infringement Contentions Broaden the Plain and Ordinary Meaning of "Gripping Handle" to mean any portion of the cap that extends between the two sheaths.

Excerpt, Facet's Infringement Contentions

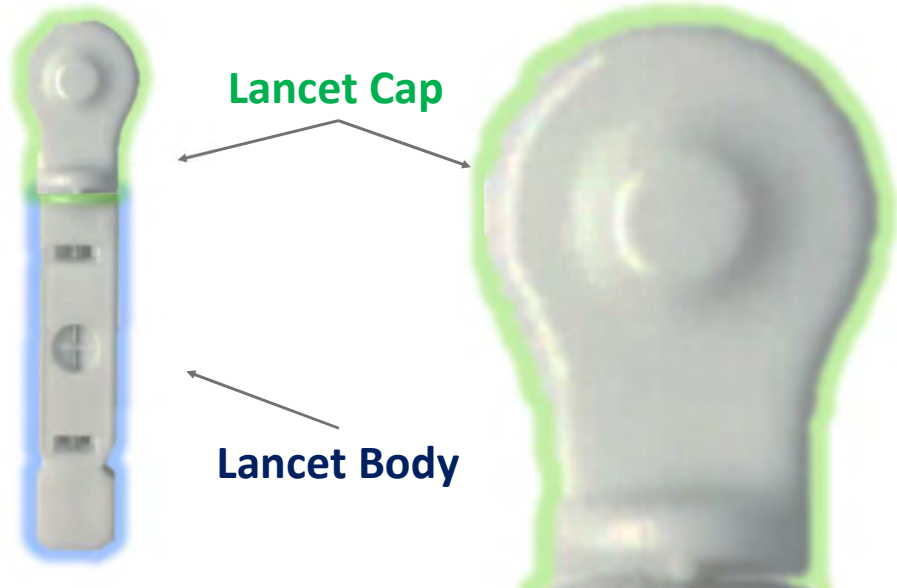


If the Broad P&O Meaning Advanced by Facet Is Adopted, then the Softclix Lancet Cap discloses the Gripping Handle and other claimed limitations.



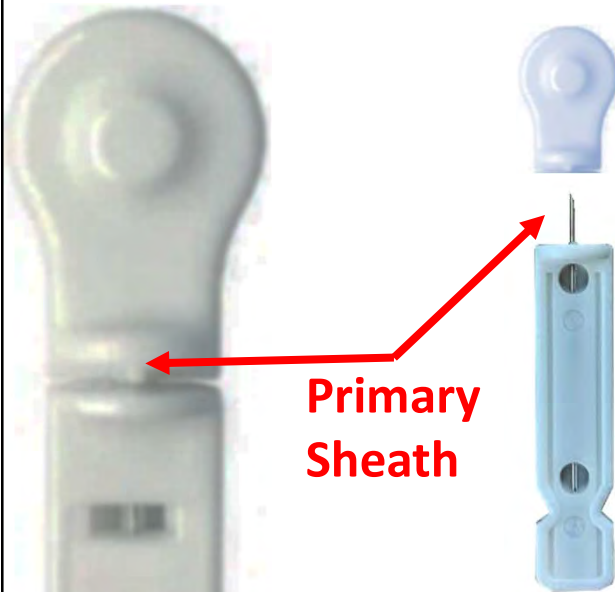
Product Prior Art

Roche | Accu-Chek | Softclix Lancets | 2007



Product Prior Art

Roche | Accu-Chek | Softclix Lancets | 2007



Softclix Instructional Video



Product Prior Art

Roche | Accu-Chek | Softclix Lancets | 2007



**Secondary
Sheath**

Softclix Uses a Pin Cushion Design for
Secondary Sheath



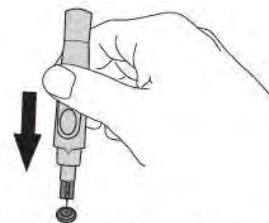
Product Prior Art

Roche | Accu-Chek | Softclix Lancets | 2007



**Secondary
Sheath**

Pin-Cushion Sheaths Were Well Known



9. Remove the lancet by twisting the cap off first. Safely dispose of the used lancet by placing the protective disk on a hard surface, and pushing the exposed tip into the disk.

Product Prior Art

Roche | Accu-Chek | Softclix Lancets | 2007

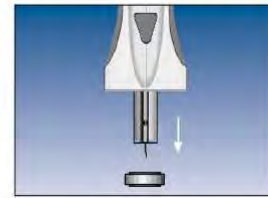


**Secondary
Sheath**

Pin-Cushion Sheaths Were Well Known



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.



Product Prior Art

Roche | Accu-Chek | Softclix Lancets | 2007

Even if P&O Meaning Applied by Facet Is Adopted, then the cap of the Softclix Lancet still has a Gripping Handle Portion that Extends Between the Primary and Secodnary Sheaths

Facet's Infringemoent Contentions



Product Prior Art

Roche | Accu-Chek | Softclix Lancets | 2007

Even if the Broad P&O Meaning Advanced by Facet Is Adopted, the Gripping Handle Portion of the Softclix Lancet Cap Still Has a Lateral Span of at least 1.5 times greater than the thickness of the lancet body.



Product Prior Art

Roche | Accu-Chek | Softclix Lancets | 2007

Even if the Broad P&O Meaning Advanced by Facet Is Adopted, the Gripping Handle Portion of the Softclix Lancet Cap Has a Length that is at least 1.5 times greater than body thickness.



D. All Asserted Claims Are Anticipated By Iio²

1. U.S. Patent Application Publication 2005/0131441 to Iio (“Iio”)

210. U.S. Patent Application Publication 2005/0131441 to Iio (“Iio”) published on June 16, 2005. Because Iio’s publication date is more than 3 years before the Effective Filing Date, Iio qualifies as prior art under pre-AIA § 102(b).

211. For the reasons I set forth below, in my opinion, Iio discloses all of the limitations of claims 6, 8, 14, and 18 of the ’635 Patent.

2. Discussion of Claim 6

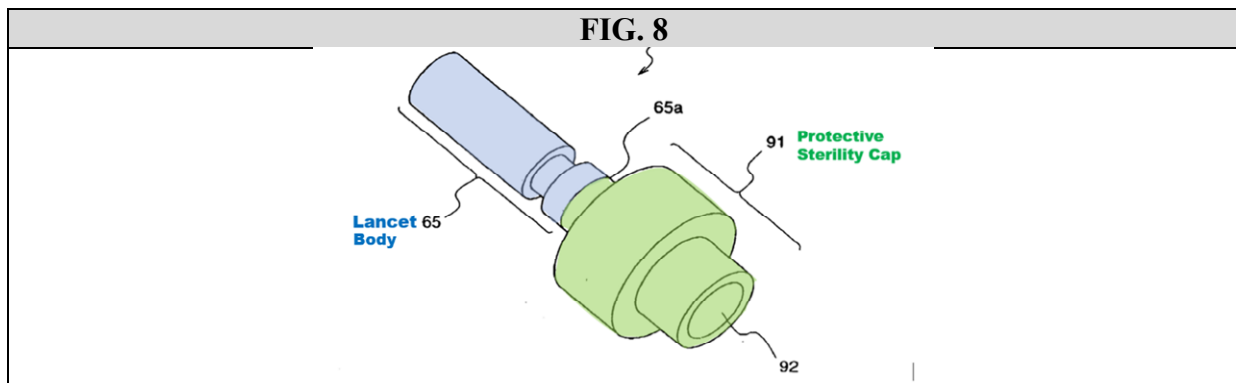
(a) Iio discloses claim 1[p] – “A protective sterility cap for a lancet”

212. It is my understanding that the preamble is not limiting. However, if it were, the second embodiment³ 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 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

² Iio discloses two embodiments depicted in Figures 1-5(b) and Figures 6-12, respectively. Iio, ¶¶[31-55], Figures 1-12. My analysis of Iio relies exclusively on the second embodiment to discuss why I believe the asserted claims are anticipated.

³ As I explained in Section XI.D 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. Iio, [0031-0055]. My analysis of Iio relies on the second embodiment of the lancet and sterility unit to anticipate the challenged claims.

separation groove 65a.” Iio, [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.”).

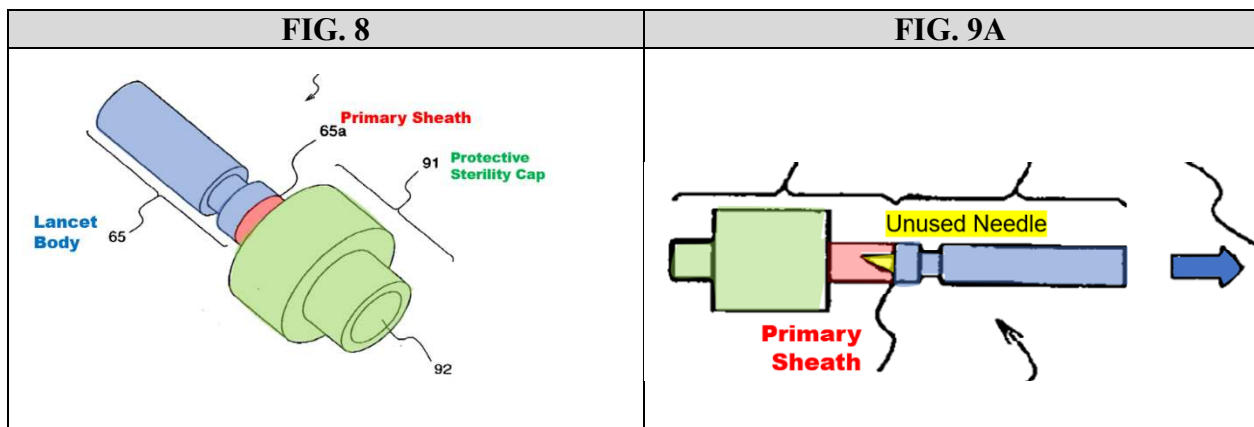


213. Iio teaches in its first embodiment that “the lancet and the puncture needle are used to collect a small amount of blood for such as measurement of blood sugar.” Iio, [0095]. To ensure that the lancet needle remains sterile before puncture, I understand Iio explains that “the puncture needle body 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].

214. 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).”

(b) Iio discloses claim 1[a] – “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein”

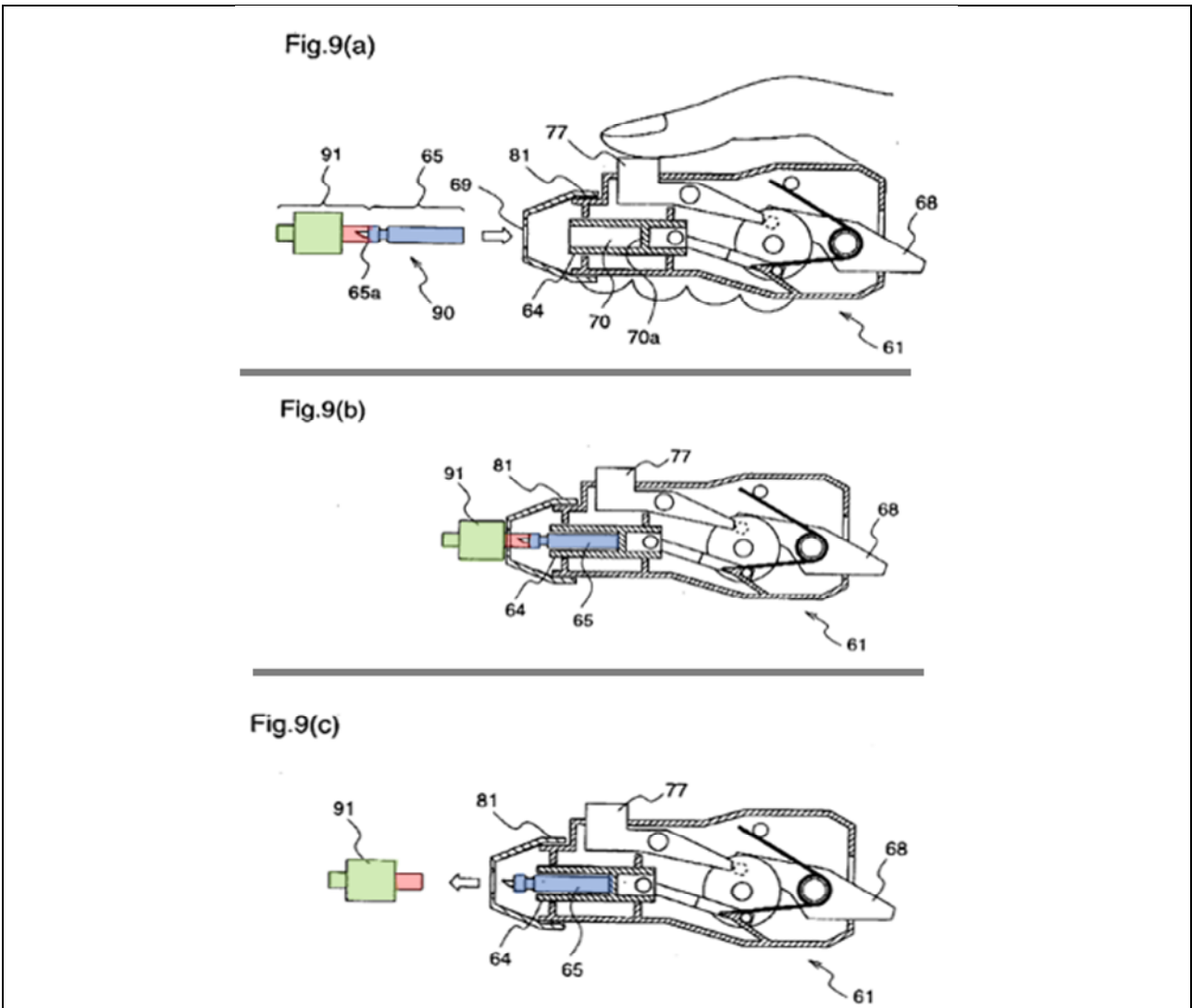
215. Iio’s puncture needle cap 91 includes a primary sheath at one “end” with a “puncture needle separation groove 65a,” a groove where “the body 65 and the cap 91” connect to each other “by a thin plastic film having a thickness of 0.1 mm or less.” Iio, [0104]. This primary sheath “cover[s] the front end of the puncture needle 65 before [it is] used.” Iio, [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].



216. 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.” Iio, [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.” Iio, [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)

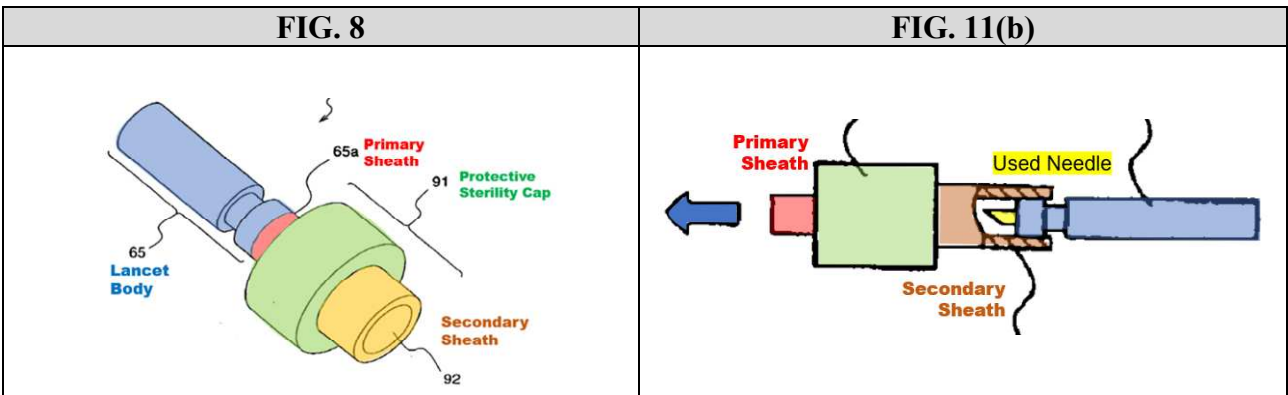


217. Based on these figures and my understanding of the descriptions in the specification, Iio teaches that “the puncture needle body 65 is set in a state where it is **embedded** in the puncture needle cap 91” that “cover[s] the front end of the puncture needle 65 **before** [it is] used.” *Id.*, ¶¶[0104],[0117].

218. 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.”

(c) Iio discloses claim 1[b] – “a secondary sheath for receiving the sharp lancing tip of a used lancet”

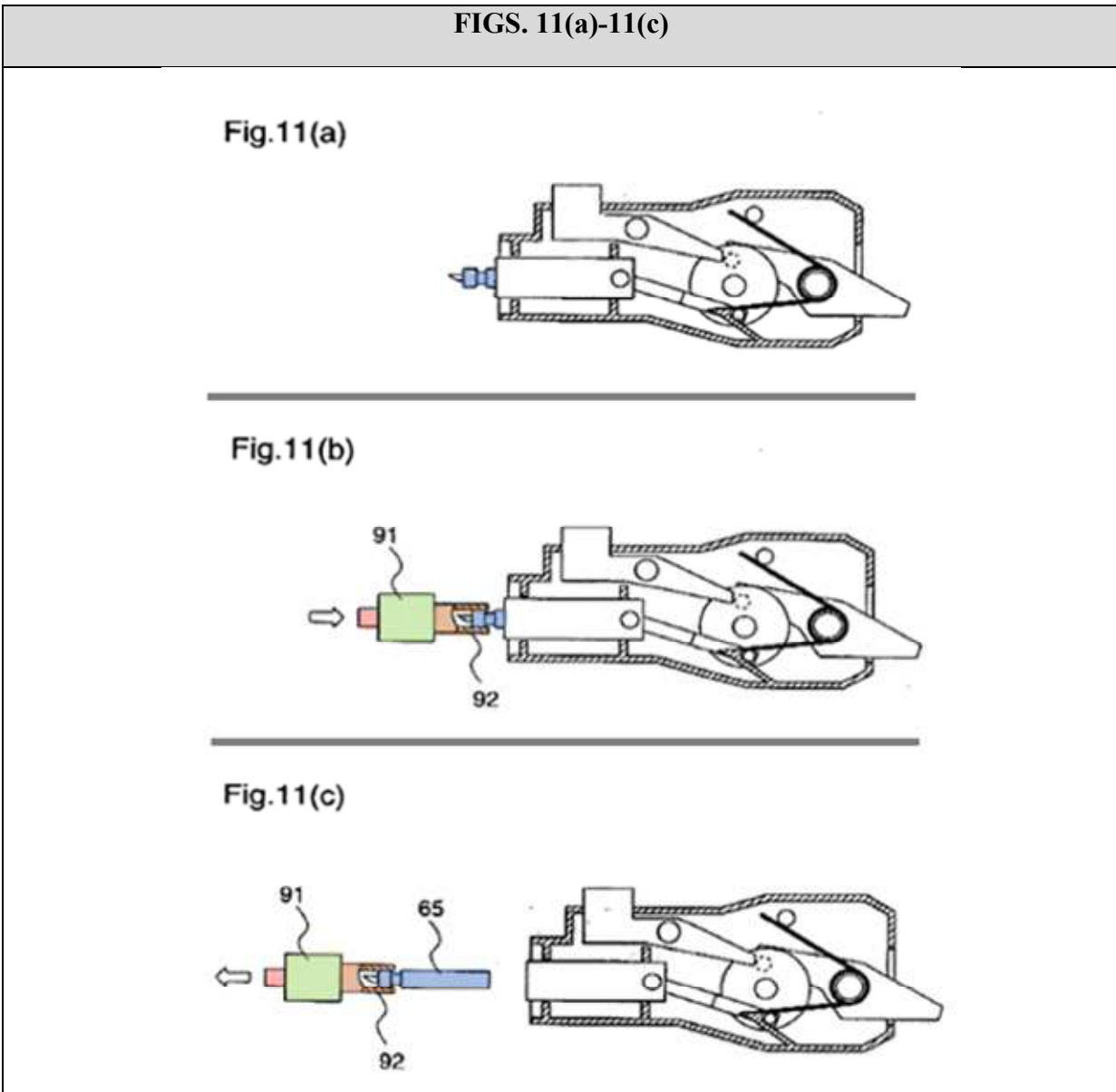
219. The other “end of the puncture needle cap 91” has “a disposal slot 92 [colored orange in Figure 8 below] for pulling out the puncture needle 65 after puncture has been carried out.” Iio, [0104] (explaining that while the “the shape of the puncture needle cap of the puncture needle unit 90 is not 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.”).



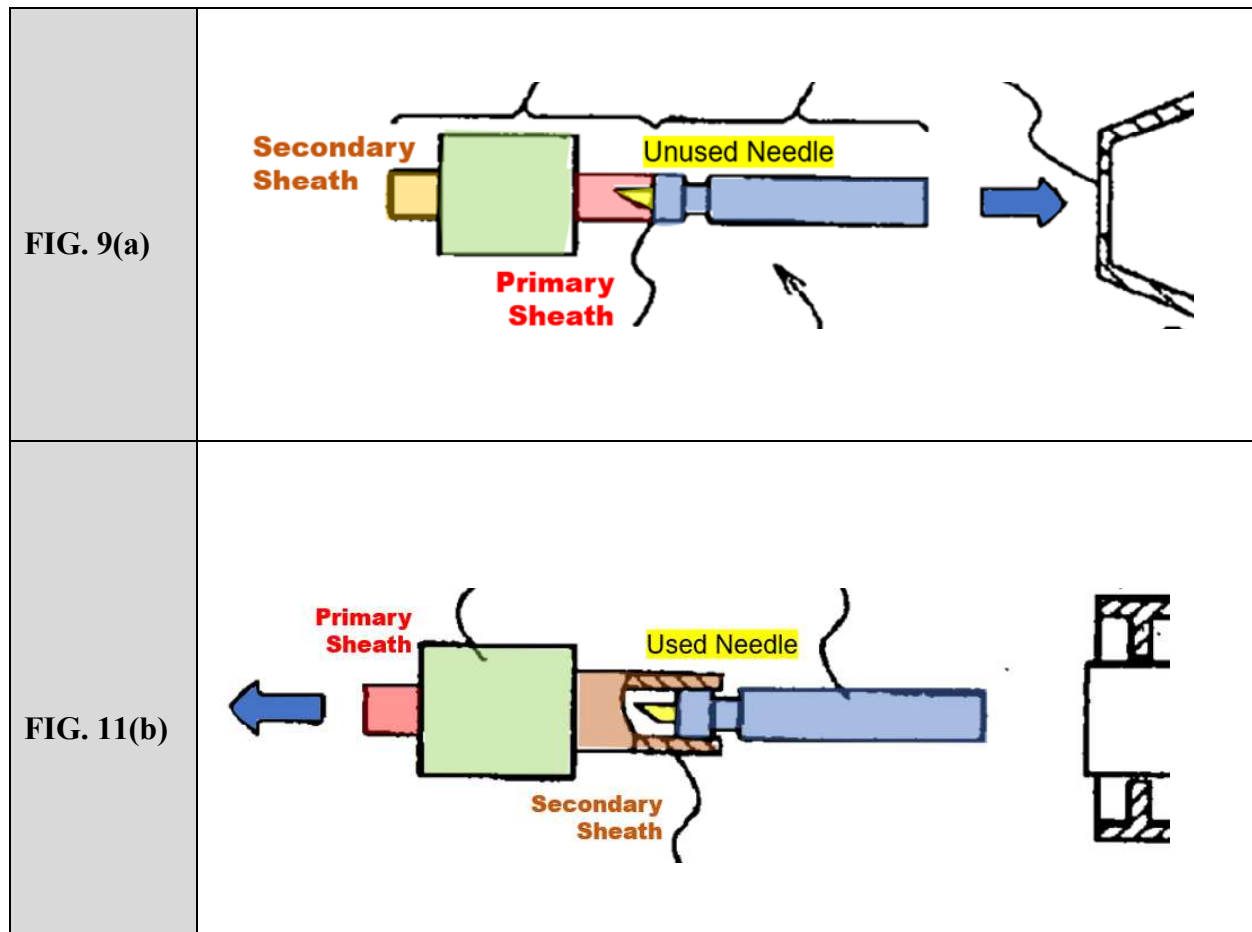
220. “[A]fter the puncture operation has been completed [and] the front end of the puncture needle 65 is exposed (FIG. 11(a)),” Iio teaches “discarding the puncture needle 65” by fitting “the shaft of the disposal slot 92 ... to the front end of the puncture needle 65,” and then pressing “the front end 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)).” Iio, [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.



221. 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).



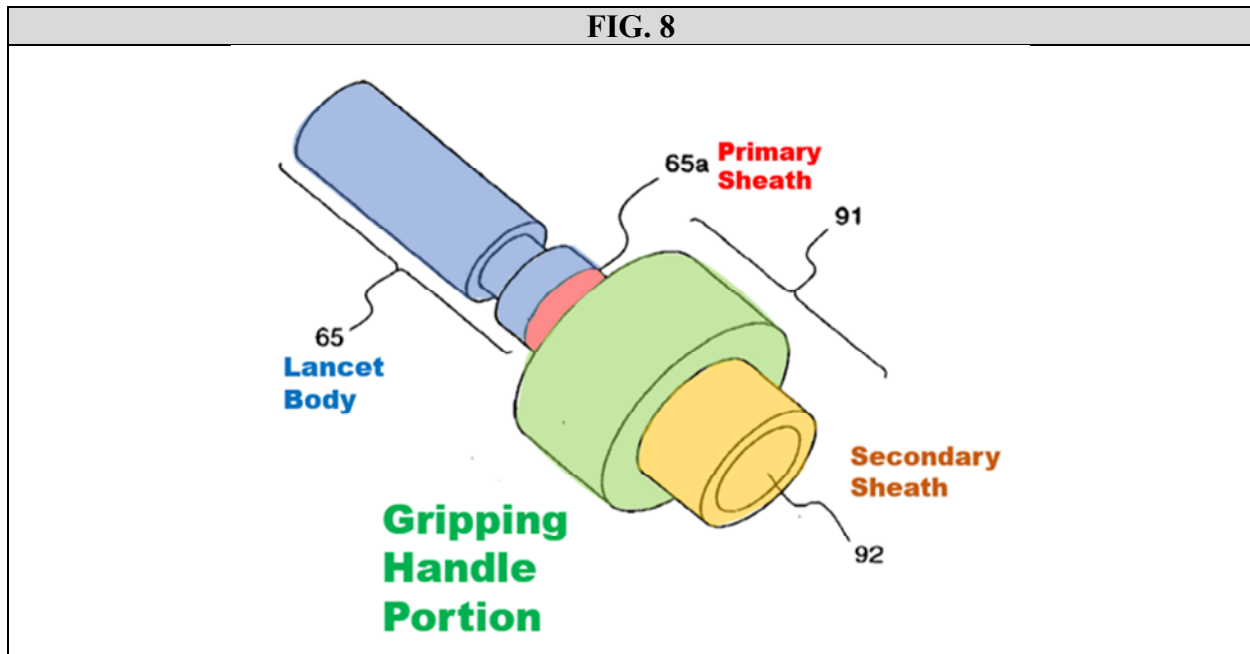
222. The hollow shaft is designed to receive a used lancet because the sharp lancing tip is ultimately “enclosed” within the hollow portion of the shaft. This meets the claim term “a secondary sheath for receiving,” which the district court broadly construed as “a secondary sheath for covering the sharp lancing tip

of a used lancet by embedding or enclosing the lancet tip.” Claim Construction Order, 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. ’635 Patent, 6:1-5, 7:6-10; *compare* ’635 Patent, Figs. 5A-5D *with* Figs. 6A-6D.

223. 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.”

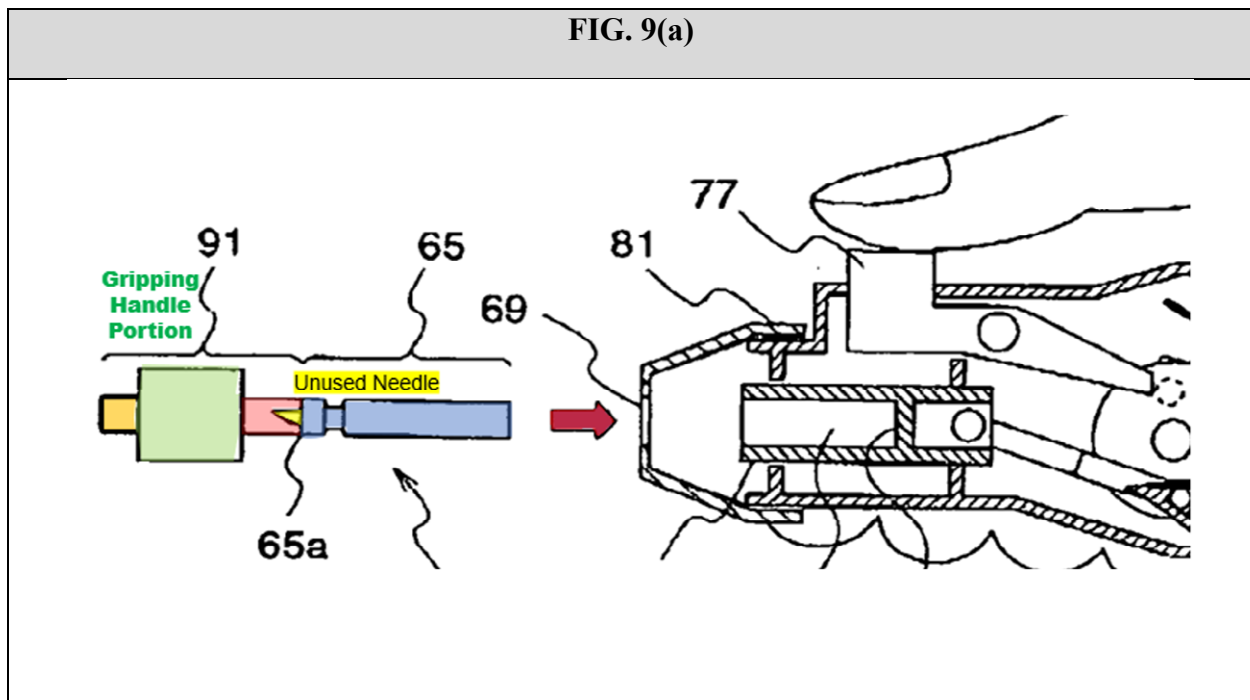
(d) Iio discloses claim 1[c] - “and a gripping handle portion extending between the primary sheath and the secondary sheath”

224. 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).



225. 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.

226. 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. Iio, [0106].

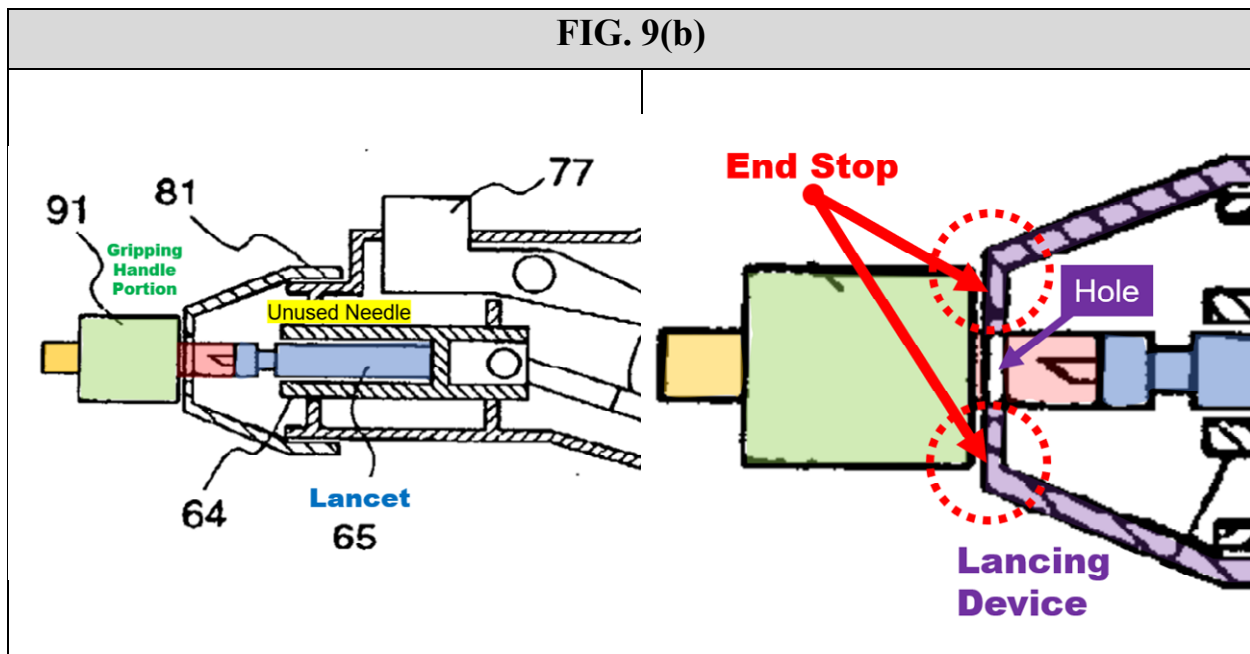


227. As illustrated above, the operator cannot grip the puncture needle 65 when pushing the puncture needle unit 90 into the lancing device because the

puncture needle 65 must be “snugly fitted to the inner wall of the puncture needle fixing hole 70 of the slider 64.” *Id.*

228. 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.” Iio, [0005].

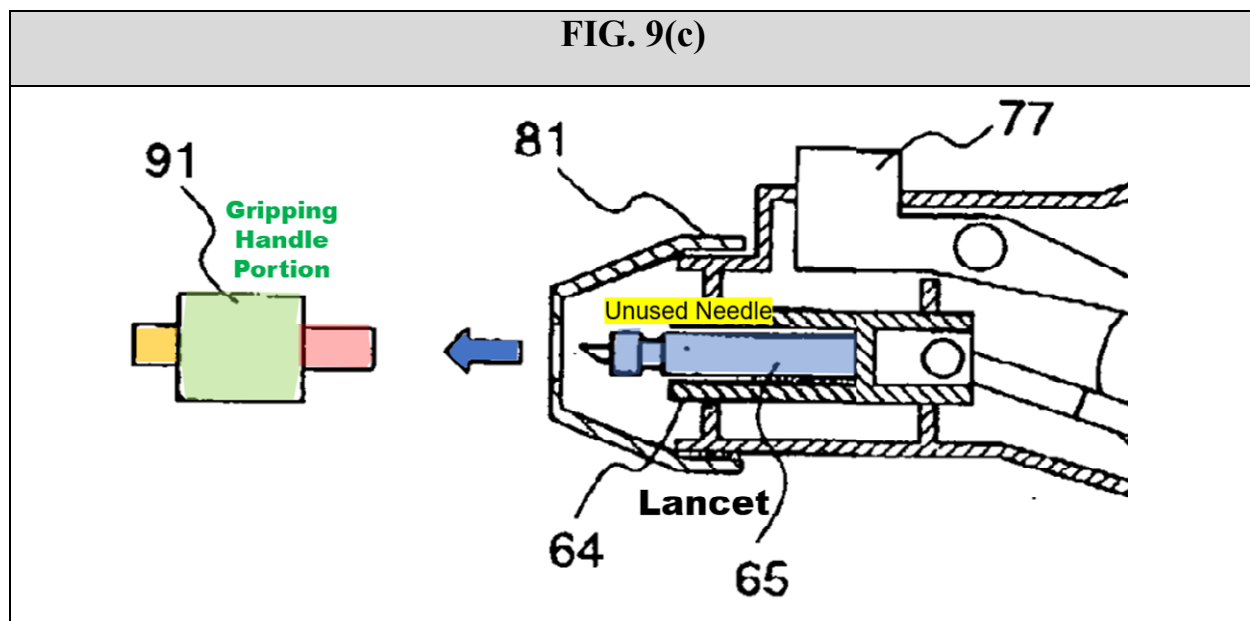
229. In addition, the larger diameter of the grip also acts as an end stop that “safely set[s] a puncture needle” at the same depth for every puncture, as shown in Figure 9(b) below. *Id.*, [0005], [0023].



230. To expose the sharp tip of the unused needle after it has been snugly 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.” Iio, [0106].

231. 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].



232. 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.” Iio, [0005], [0007] (explaining that “the puncture needle unit” is

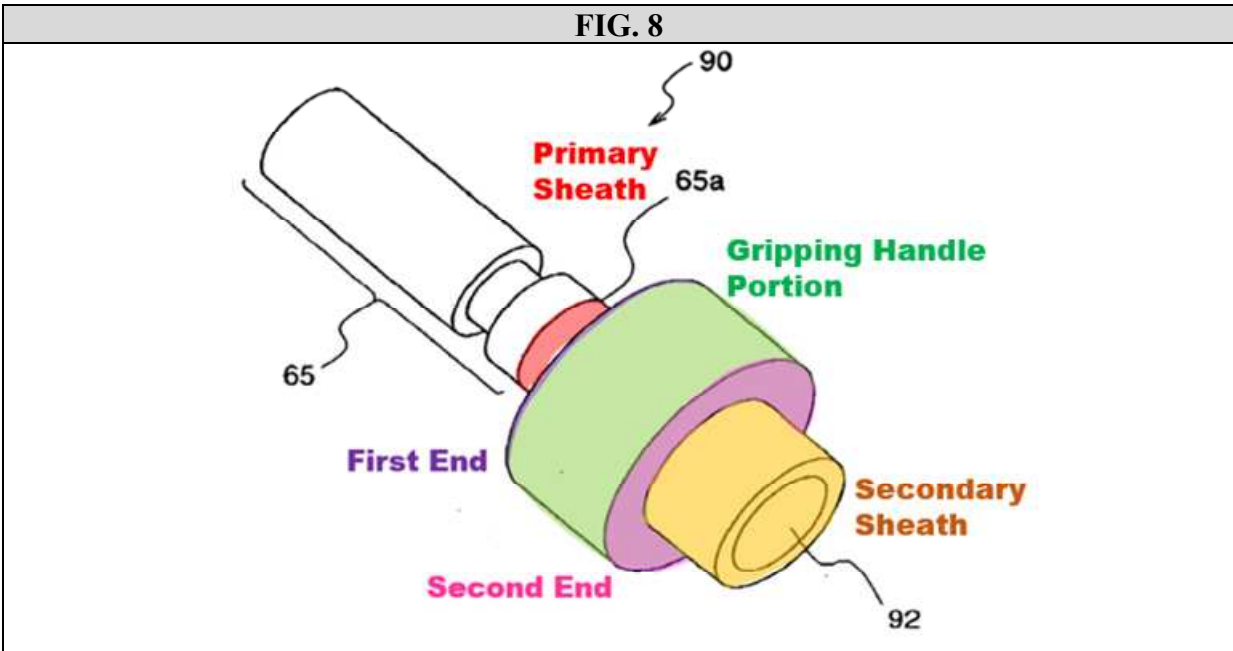
“highly operable and safely handleable.”). It is for this reason I believe a POSITA would understand that the cylindrical grip of Iio’s puncture needle cap 91, by design, is easy to grip and handle.

233. In my opinion, Iio therefore discloses “a gripping handle portion extending between the primary sheath and the secondary sheath.”

(e) 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”

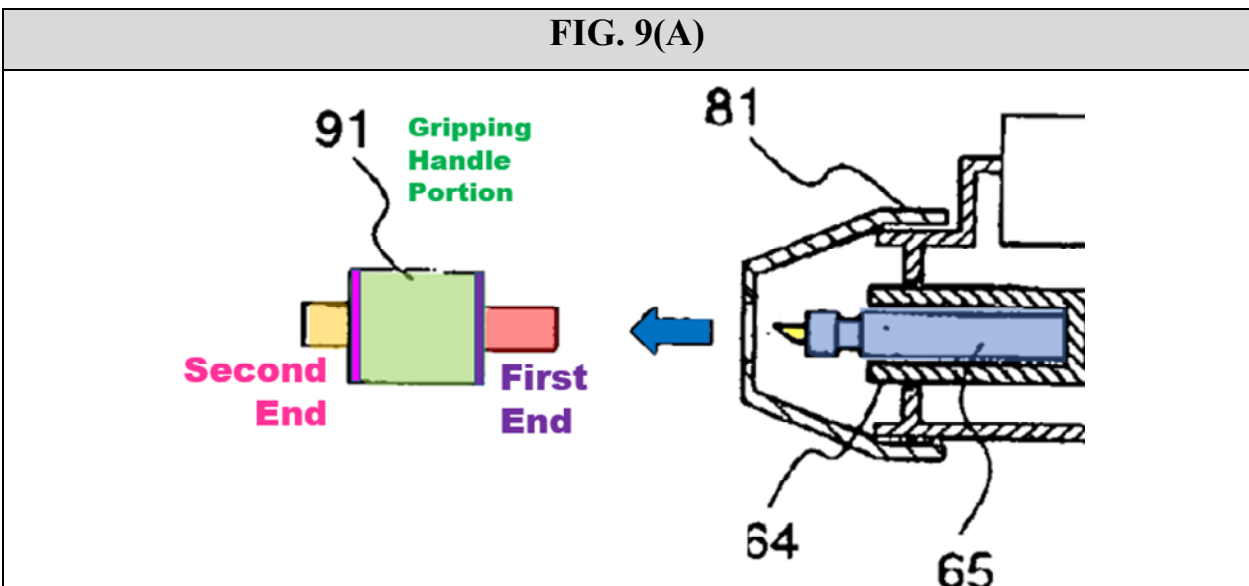
234. As illustrated in Figure 8 below, I believe Iio discloses that the primary sheath is attached to one end of the gripping handle (i.e., a first end, colored purple below) and the secondary sheath is attached to the other end of the gripping handle (i.e., a second end, colored magenta). Because the 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. Iio, 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 an end and the other end of the cylindrical shape**. Therefore, it is possible to safely discard a used puncture needle.”).

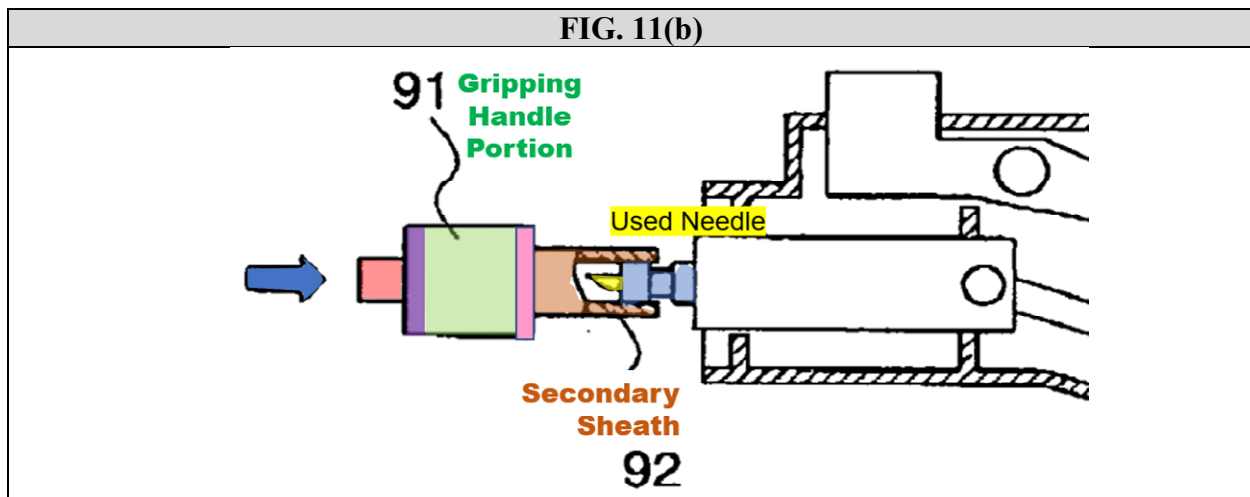


235. From my observations, even after the operator separates the puncture needle cap 91 from the puncture needle 65 to expose the unused needle tip for use in puncturing the skin, as shown in annotated Figure 9(a) below, the first and second ends of the gripping handle portion of the puncture needle cap 91 remain attached to the primary and secondary sheaths, respectively. Iio, ¶¶ [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)).”).

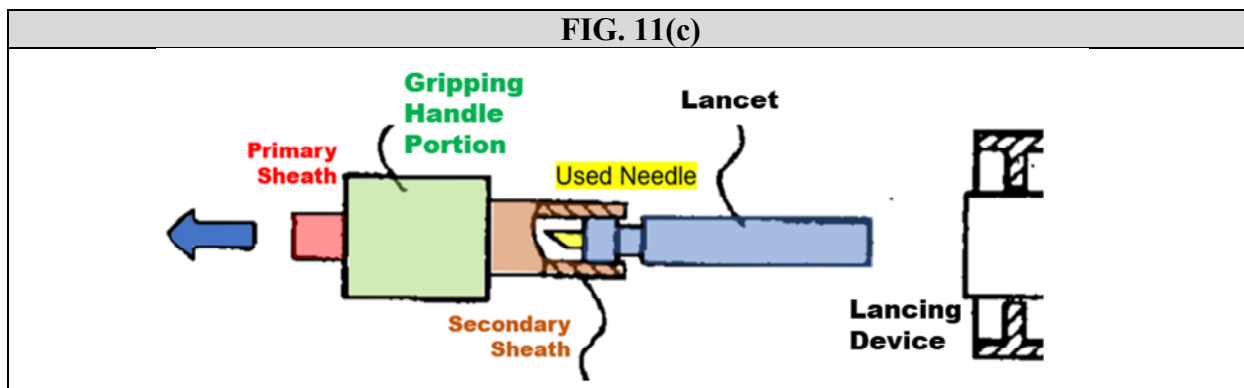
236. Because the puncture needle cap 91 is an integral structure, the location of these attachments remains the same before and after the puncture needle cap 91 is removed from the lancet. Nothing in Iio teaches or suggests reconfiguring the puncture needle cap 91 after removal, let alone removing either 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.” Iio, [0104].



237. The same is true for “discarding the puncture needle 65 after the puncture operation has been completed.” Iio 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].



238. 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.*

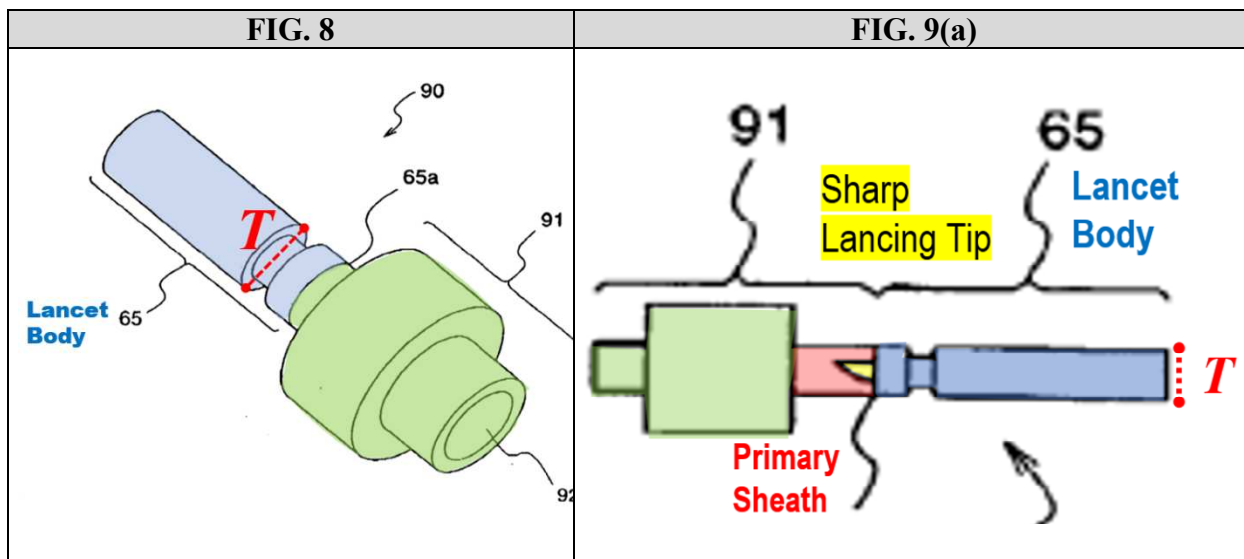


239. In my opinion, Iio therefore discloses that “the primary sheath [is] attached at a first end of the gripping handle portion and the secondary sheath [is] attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet.”

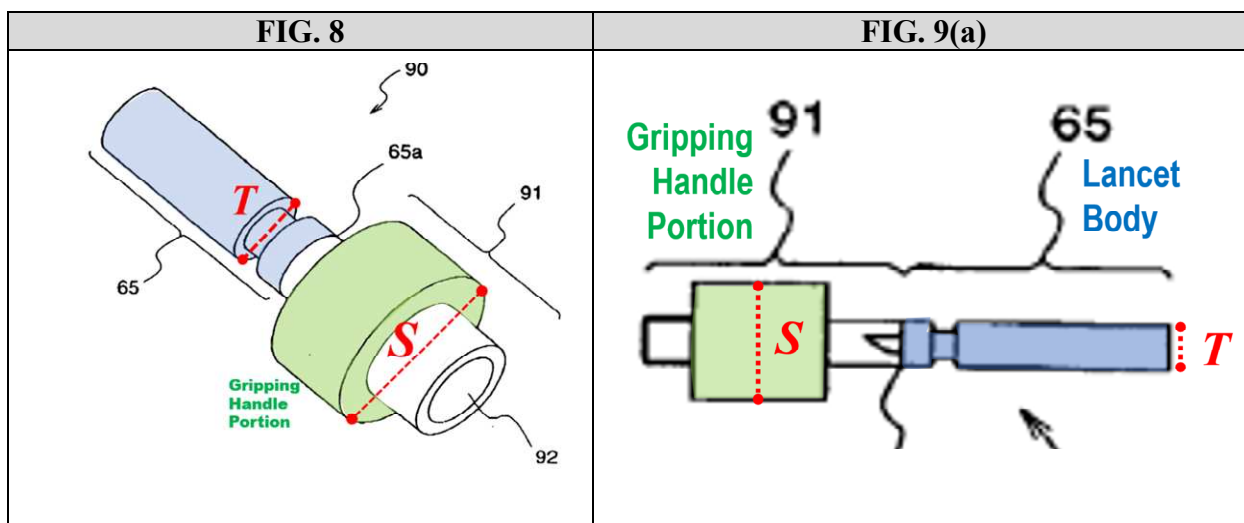
(f) Iio discloses claims 6[a] – 6[d]

240. 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.

241. 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.”



242. 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.⁴



⁴ Lateral span being measured as depicted above for Iio is consistent with how the ’635 Patent depicts lateral span in its Figure 5D.

243. 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 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]." Iio, 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.

244. 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 POSITA 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.

245. 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 POSITA 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.

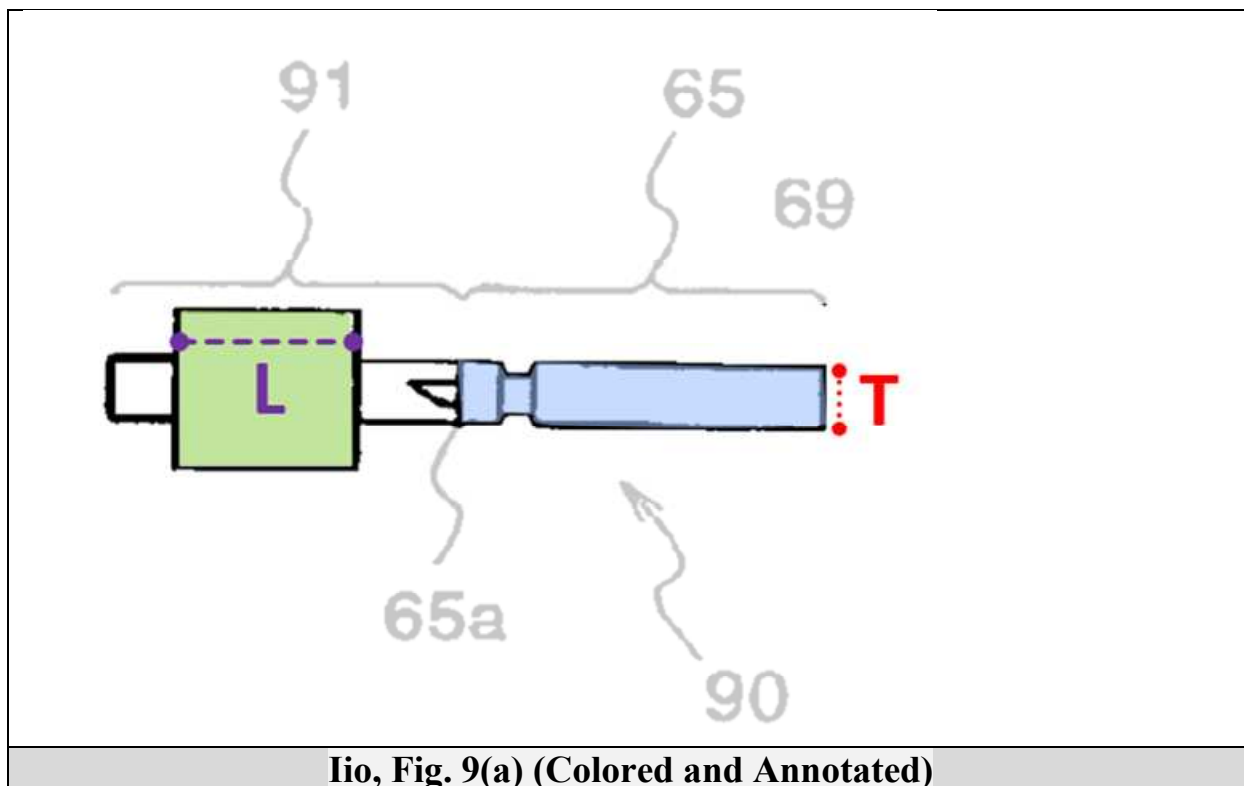
246. Beyond this, Iio textually describes a specific thickness for "a thin plastic film having a thickness of 0.1 mm or less in the puncture needle separation

groove.” Iio, [0104]. Knowing this dimension, it is my view that a POSITA 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 POSITA 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.

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

3. Discussion of Claim 8

248. Iio discloses the protective sterility cap of claims 6 and 14 for the reasons I have outlined in Sections XI.D.1, XI.D.3, 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.



249. 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.

4. Discussion of Claim 14

250. 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 XI.D.1(a)-(e)). 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.D.1(f)).

5. Discussion of Claim 18

251. Claim 18 depends from claim 14, which is anticipated by Saikley for reasons I explained above and incorporated here (*supra* Section XI.D.3). 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 XI.D.2).

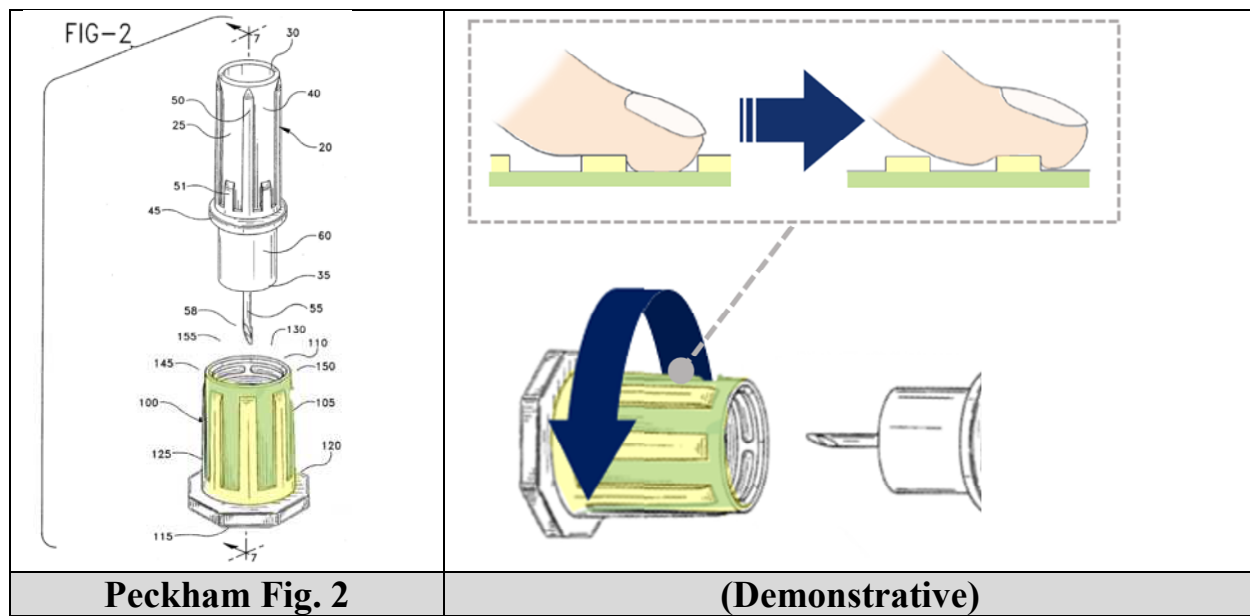
E. Iio in View of Peckham Renders Obvious Claims 6, 8, 14, and 18

252. For the reasons I set forth below, in my opinion, all of the limitations of claims 6, 8, 14, and 18 of the '635 Patent are disclosed by the combination of Iio and Peckham.

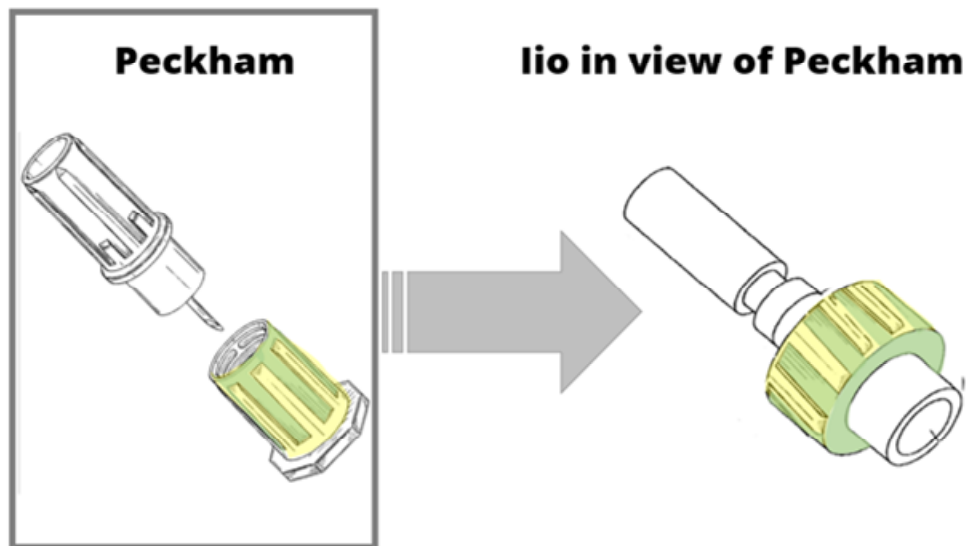
1. All Claims: “Gripping Handle Portion”

253. As I explained above in Section XI.D.1, incorporated here, Iio’s puncture needle unit includes a “gripping handle portion” and a POSITA would have recognized that the cylindrical handle (green below) provides the user with “excellent usability and handleability.” Iio, [0005]. I believe a POSITA would

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." Peckham, 3:13-15.



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



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

2. Claims 6, 8, 14, and 18: The “Length” and “Lateral Span” of the Gripping Handle Portion

258. As I explained above (*supra* Sections XI.D.1-4, incorporated here), Iio anticipates the relative dimensional aspects of these claims.

259. 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. Iio, [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 POSITA 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 POSITA 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” (Iio, [0005]), I understand a POSITA would have focused on designing larger gripping handle portions to achieve these handleability, usability, and safety goals.

260. In designing larger gripping handle portions, a POSITA 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 POSITA 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.

261. 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).

262. For the above reasons, claims 6, 8, 14, and 18 are obvious.⁵

263. 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 POSITA to increase the lateral span of the gripping handle

⁵ 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." '635 File History, 60. Patent Owner 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.

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 18.

3. Ample Motivation Existed to Combine with Peckham

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

265. First, a POSITA 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." '635 Patent, 1:18-19. Both Iio and Peckham also relate to lancets for blood collection. Iio, [0001]; Peckham, 1:5-8.

266. 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. '635 Patent, 1:66-2:2. Both Iio and Peckham also disclose solutions which assist patients with handling lancets. I understand the

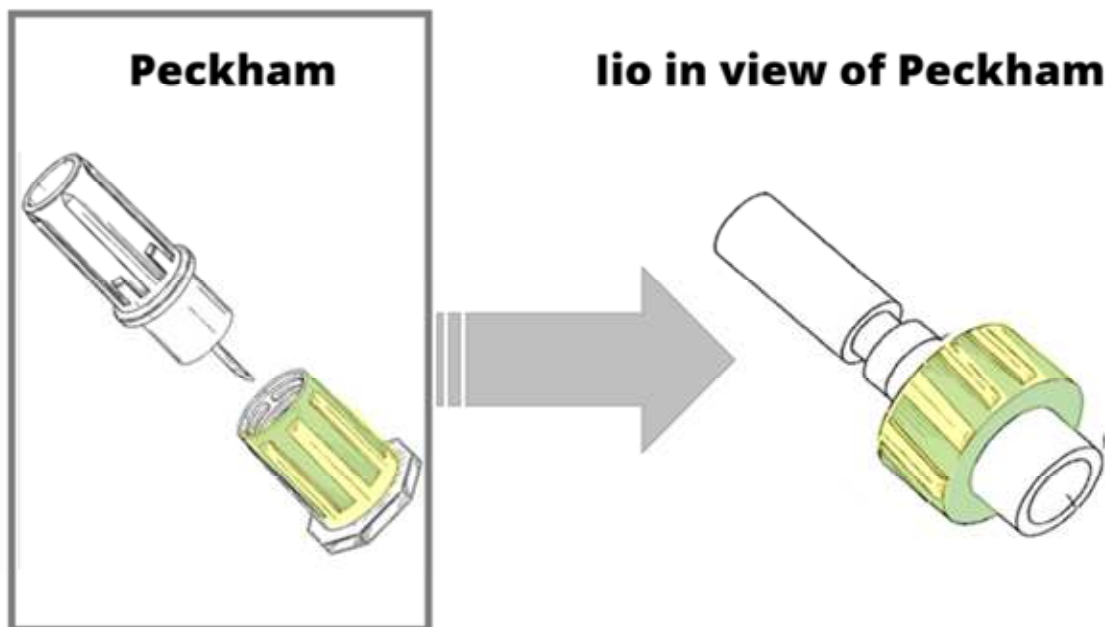
object of Iio is to provide for a lancet with “excellent usability and handleability with safety,” while Peckham provides a “novel textured surface to improve handling, maneuverability and fit” when the lancet is mounted in a lancing device. Iio, [0005]; Peckham, 2:67-3:2. I understand Iio also specifically 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.” Iio, [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.” Peckham, 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.

267. Iio also provides ample motivation for a POSITA 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.” Iio, [102].

268. 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.” Iio, [0006]. It would have

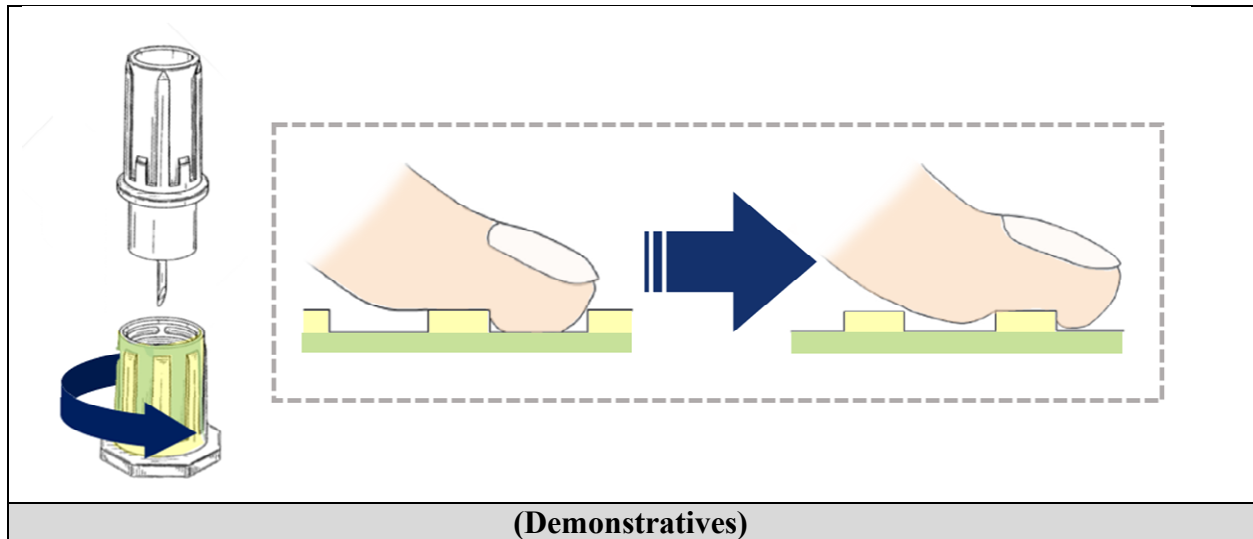
been apparent to a POSITA that Peckham's ribs are an addition or modification that could be made to improve the handling and maneuverability of Iio's cap.

269. In addition, I believe ample motivation existed for a POSITA 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.



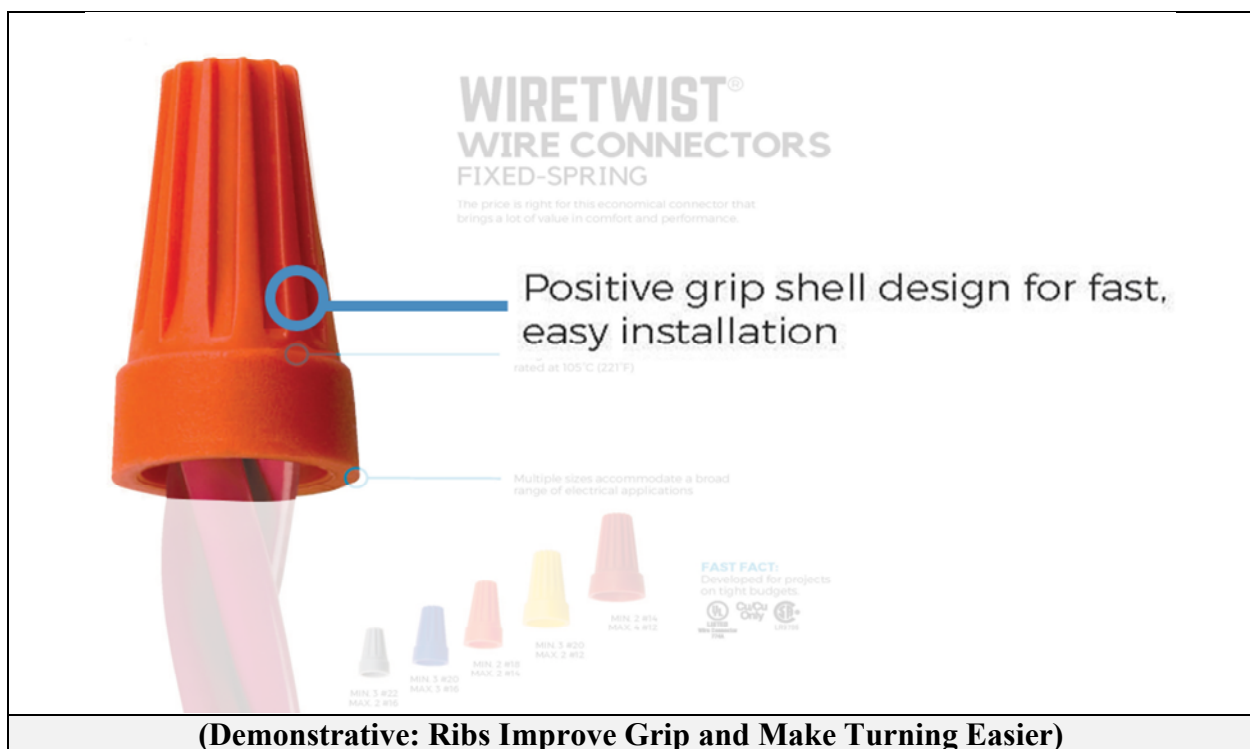
270. While Iio does not disclose the use of a textured surface to improve "useability and handleability" of a lancet, I believe a POSITA would have recognized that the invention in Iio could be improved by the addition of such a gripping texture. Industrial designers routinely use, ribbed patterns to 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.



271. A POSITA 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.” Peckham, 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 POSITA to improve the grip of Iio’s cylindrical handle by adding a ribbed surface texture.

272. Furthermore, I believe a POSITA 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.



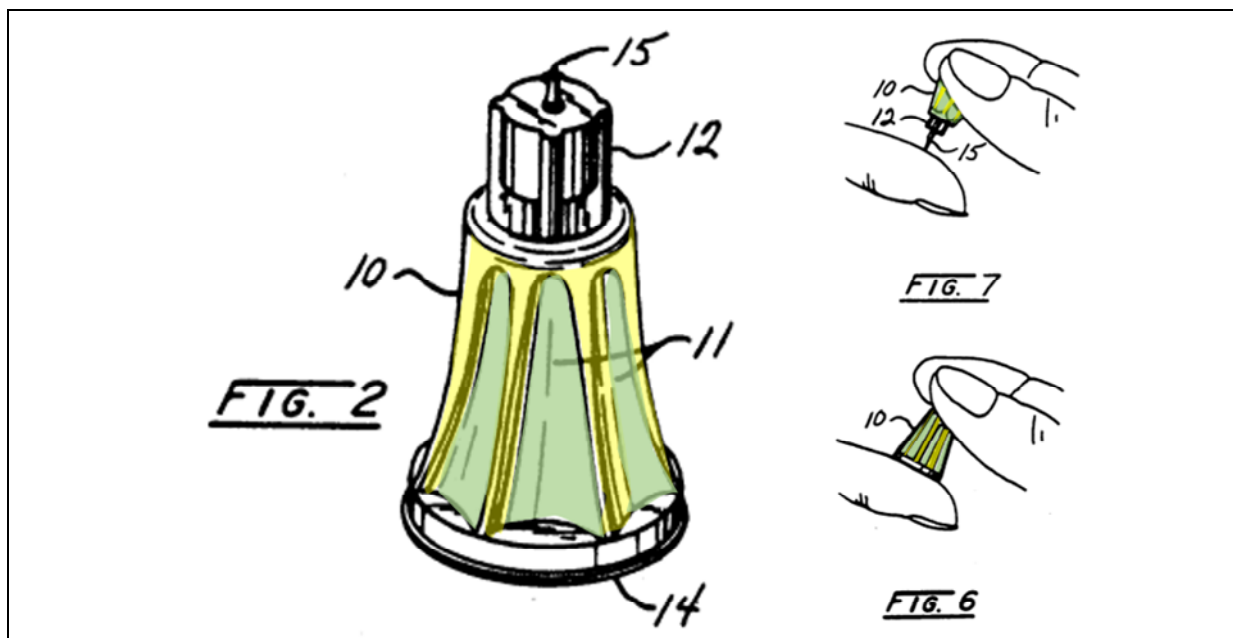
273. In my view, the combination of adding Peckham's ribs to Iio's cylindrical handle, would have resulted in a lancet with an improved grip that would have been predictable to a POSITA.

274. It is also my understanding that a POSITA 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 preferable 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 POSITA would have been further motivated to combine Iio and Peckham to economically achieve a more ergonomic product.

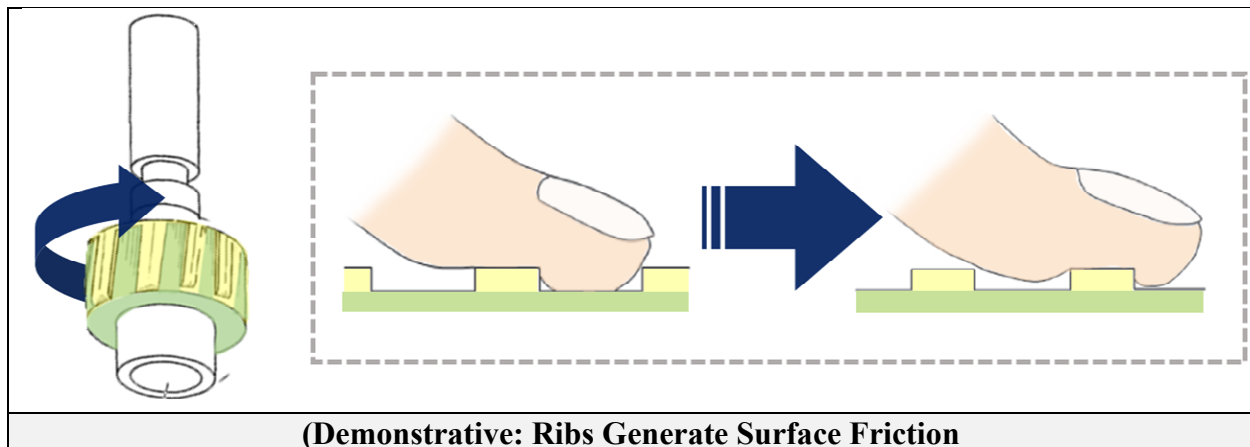
275. Lastly, I believe a POSITA would have had a reasonable expectation of success in combining the teachings of Iio and Peckham. The solution of such a combination was well-known at the time. During the relevant period, conventional lancets and lancing devices implemented ridges on surfaces meant to 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. Hufnagle, 2:47-49. As such, I believe it would have been straightforward for a POSITA 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
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276. Such a combination would also not require undue experimentation. If a POSITA were to begin improving the grip on Iio's cylindrical handle, I believe the POSITA 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 POSITA 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 POSITA 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 POSITA 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 POSITA would therefore have had a reasonable expectation of success in combining the teachings of Iio and Peckham without undue experimentation.



F. All Asserted Claims Are Rendered Obvious by Hyoue

1. U.S. Patent No. 8,920,454 to Hyoue ("Hyoue")

277. Hyoue published on February 19, 2007. Because it was filed more than the Effective Filing Date, I understand Hyoue qualifies as prior art under at least pre-AIA §102(e).

2. Discussion of Claim 6

278. I discuss each limitation of claim 6 in turn below, in conjunction with the relevant disclosures of each limitation by Hyoue. As I expand upon below, Hyoue discloses and renders obvious each limitation of claim 1, to which claim 6 depends.

(a) Hyoue discloses claim 1[p] – “A protective sterility cap for a lancet”

279. Hyoue discloses a “**cap** that houses and protects” the “distal end portion” of a lancet. Hyoue at 2:21-35. Hyoue also provides that “the lancet 100 of the present invention comprises the lancet body 102 and the **cap** 104.” *Id.* at 7:13-15.

280. It is therefore my opinion that Hyoue discloses “a protective sterility cap for a lancet.”

(b) Hyoue discloses claim 1[a] – “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein”

281. Hyoue teaches that the lancet is formed by “molding, particularly injection molding, more particularly insertion molding where the puncturing member is placed in a die in advance.” Hyoue, 6:57-67. A POSITA would understand that where the puncturing member is placed “in a die in advance,” and formed by using methods like “injection molding,” the needle is embedded in the protective cap. *See supra*, Section XI.B.1(b).

282. Hyoue also provides that the distal end 108 of the “puncturing member 106” is “housed” in cap 104. Hyoue, 7:13-15. The cap 104 “houses and protects the distal end portion of the puncturing member before use.” *Id.* at 2:21-35. In addition, cap 104 has “weakened portion 114 that surrounds a part of puncturing member 106.” *Id.* at 8:60-65.

283. In my opinion, Hyoue discloses that the “sterility cap (*i.e.*, cap 104) comprises a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein.”

(c) Hyoue discloses claim 1[b] – “a secondary sheath for receiving the sharp lancing tip of a used lancet”

284. Hyoue teaches that the cap may have a “space 200” that “**houses** the distal end portion of the puncturing member **after the lancet has been used.**”

Hyoue, 10:13-20. By “housing” the distal end portion of the puncturing member after the lancet is used, a POSITA would readily recognize that the lancet needle is covered by “space 200” in the cap. This conforms with the Court’s construction of the term “secondary sheath for receiving.” Claim Construction Order, 13:24-14:3.

285. Hyoue also describes the “space 200” as being “opposite” a closed end 204. *Id.* at 10:14-29. By having the “space 200” distinct from the primary sheath and opposite a closed end, a POSITA would recognize that Hyoue’s protective cap allows users to easily distinguish one end from the other after removing the cap and to also readily identify the sheath intended to dispose of the used lancet needle. Indeed, Hyoue provides that this configuration “makes it possible to **substantially separate** the distal end portion of the puncturing member after the lancet has been used.” *Id.* at 10:13-20.

286. In my opinion, Hyoue discloses “a secondary sheath for receiving the sharp lancing tip of a used lancet.”

(d) Hyoue discloses claim 1[c] – “and a gripping handle portion extending between the primary sheath and the secondary sheath”

287. Hyoue describes that when a lancet user is preparing the lancet for puncturing operation, the lancet body 102 and cap 104 are “twisted in directions opposite to each other around the puncturing member 106.” Hyoue at 7:19-30; 7:26-30; 4:37-34; 2:54-65. The lancet body and cap are then “brought away from each other along the longitudinal direction of the puncturing member 106” in order to expose the distal end portion of the puncturing member. *Id.*

288. By requiring that the lancet body and cap be twisted in “opposite directions” and then “brought away from each other along the longitudinal direction,” I believe a POSITA would recognize that the cap must have a gripping handle portion in order to facilitate twisting of the cap in an opposite direction from that of the lancet body. A POSITA would also have to recognize that there must be a gripping handle portion on the cap to assist a lancet user with effectively pulling the lancet in a longitudinal direction away from the lancet body in order to expose the lancet needle. A POSITA would know that the ridge along the cap 104 would provide a textured surface for a lancet user to have a better grip on the cap when twisting or pulling it in order to prepare for puncturing.

289. In my opinion, Hyoue thus discloses a “gripping handle portion extending between the primary sheath and the secondary sheath.”

(e) Hyoue 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”

290. Hyoue’s Figure 4 embodiment shows the primary sheath and secondary sheaths attached to opposing ends of the lancet cap. Hyoue, Fig. 4. First, I note that the lancet need or “puncturing member 106” has its distal end 108 “**housed**” in cap 104. *Id.* at 7:13-15. When a lancet user is preparing the lancet for puncturing use, Hyoue teaches that the lancet body 102 and cap 104 are “**twisted in directions opposite to each other**” around the puncturing member.” *Id.* at 7:19-30. From Hyoue’s description for preparation of the lancet need for puncturing, a POSITA would recognize there is nothing to suggest that the structure of the protective cap is changed or that the sheaths are detached.

291. Regarding the secondary sheath, or space 200, Hyoue specifically notes that it “**firmsly fits** with the front end portion of the lancet body where the distal end portion of the puncturing member protrudes” and after the lancet has been used, “houses the distal end portion of the puncturing member.” *Id.* at 10:13-20. A POSITA would know that the secondary sheath and space 200 must remain readily available to “house” the distal end portion of the puncturing member following use.

292. It is therefore my opinion that Hyoue discloses a “primary sheath attached at a first end of the gripping handle portion and the secondary sheath

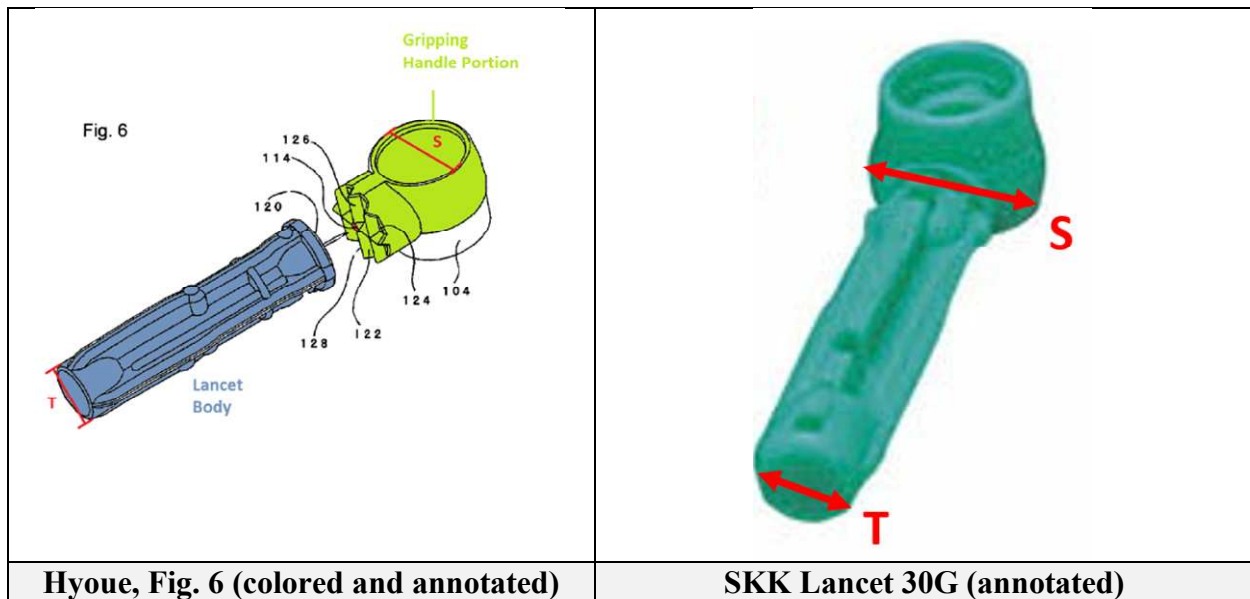
attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet.”

(f) Hyoue discloses limitations 6[a]-6[d]

293. 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 Hyoue.

294. As to elements 6[a]-6[c], I believe Hyoue discloses a “**lancet** that comprises a **lancet body** having a front end portion, from which a distal end portion of a puncturing member protrudes, and **a cap that houses and protects** the distal end portion of the puncturing member before use.” Hyoue at 2:21-35. Hyoue also discloses the sharp lancet tip initially embedded in the primary sheath, as I described previously in Section XI.G.1(b), which I incorporate herein.

295. As to element 6[d]’s limitation of “the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness,” a visual inspection of Figure 6 below with the lateral span annotated “S” would indicate that Hyoue discloses this limitation.



Additionally or alternatively, it is my opinion that a POSITA would recognize that having an endcap with a lateral span of at least 1.5 times the lancet thickness would provide a lancet user with the optimal rotational leverage to apply the twisting force on cap required to facilitate ease of disengagement of cap from the lancet body. A POSITA would understand that such a lateral span would allow the mold to more readily detach through minimal rotation of the cap, such that its disengagement from the lancet body would not bend or otherwise damage the needle sharp.

3. Discussion of Claim 8

296. Claim 8 depends from claim 6, which Hyoue anticipates for the reasons I discussed above in Section XI.G.1, incorporated herein. Claim 8 adds “wherein the gripping handle portion defines a length at least equal to the lancet thickness.”

297. Because Hyoue discloses both that the gripping handle portion (cap 78) is at least 1.5 times the lancet thickness (*supra* Section XI.G.1, incorporated here), the length of Hyoue's gripping handle portion must also necessarily be at least equal to (including larger than, as Hyoue teaches) the lancet thickness.

4. Discussion of Claim 14

298. Claim 14 includes limitations analogous in scope to limitations 1[pre]-1[d], and those are disclosed by Hyoue for reasons I provided above and incorporated here (*supra* Section XI.G.1(a)-(e)). Claim 14 also includes limitations analogous in scope to those found in claim 6, and those are disclosed by Hyoue for reasons I provided above and incorporated here (*supra* Section XI.G.1(f)).

5. Discussion of Claim 18

299. Claim 18 depends from claim 14, which is anticipated by Hyoue for reasons I provided above and incorporated here (*supra* Section XI.G.3). 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 XI.G.2).

6. Claims 6, 8, 14, and 18: Gripping Handle Portion

300. As I analyzed previously in Section XI.G.1(d), I believe Hyoue discloses a gripping handle portion. Even if Hyoue did not expressly or inherently

disclose a gripping handle portion, then it would have been obvious to modify Hyoue's cap to include a gripping handle portion.

301. A POSITA would understand that in order to effectuate Hyoue's goal of providing a lancet where the puncturing member does not easily bend when the weakened portion between the lancet body and the cap is broken, a lancet user must be able to efficiently twist both lancet body and cap in opposite directions. Hyoue, 2:13-17. To be able to twist the lancet body and cap in opposite directions and create a sliding motion while rotating around the longitudinal axis of the puncturing member, a POSITA would have been motivated to create a gripping handle portion in order to assist a lancet user facilitate this twisting motion.

302. It is for these reasons I believe it would have been obvious for a POSITA to include a gripping handle portion on Hyoue's cap.

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

303. All of the relative-dimensional limitations would have been obvious for a POSITA to apply to Hyoue. Designing a gripping handle that had a lateral span at least 1.5 times the lancet thickness (as recited in claims 6 and 14) would have been pursued by a POSITA as a matter of routine optimization and with a reasonable expectation of success, particularly in view of Hyoue's requirement that the lancet body and cap be "twisted in directions opposite to each other around the puncturing member" before being "brought away from each other along the

longitudinal direction of the puncturing member” in order to “prevent the puncturing member from bending at the front end of the portion of the lancet body.” Hyoue at 2:54-65, 4:37-44, 7:19-30. A POSITA would recognize that having an endcap with a lateral span at least 1.5 times the lancet thickness would help a lancet user twist both the cap and lancet body in opposite directions without breaking or bending the needle. A POSITA would have thus routinely designed an endcap that would have been at least 1.5 times the thickness of a standard lancet.

304. Regarding the gripping handle’s length being at least equal to the lancet thickness (as recited in claims 8 and 18), this would also be a natural choice for a POSITA who would have appreciated that users who have difficulty handling lancets would have an easier way to twist the lancet cap and body in opposite directions if the gripping handle’s length was at least equal to or greater than the lancet thickness.

305. In my opinion, Hyoue renders obvious claims 6, 8, 14, and 18.

G. All Asserted Claims are Rendered Obvious by Starnes

1. U.S. Patent App. Publication No. 2007/0162064 to Starnes (“Starnes”)

306. Starnes was published on July 12, 2007. Because it was published more than a year before the Effective Filing Date, I understand it qualifies as prior art under at least pre-AIA 102(b).

2. Discussion of Claim 6

307. I discuss each limitation of claim 6 in turn below, in conjunction with the relevant disclosures of each limitation by Starnes. As I expand upon below, Starnes discloses and renders obvious each limitation of claim 1, to which claim 6 depends.

(a) Starnes discloses claim 1[p] – “A protective sterility cap for a lancet”

308. Starnes discloses an invention that is in the general field of “medical **lancet** devices that utilize **protective caps** for user safety and security.” Starnes, [0003]. Starnes also notes that the invention relates to devices “capable of **covering** the lancet needle to **protect** from unintended puncturing” and to “maintain **sterility** prior to use.” *Id.*

309. It is therefore my opinion that Starnes discloses “a protective sterility cap for a lancet.”

(b) Starnes discloses claim 1[a] – “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein”

310. Starnes discloses that the lancet needle tip is typically “**embedded** in a protective cap that is **integrally molded** with a plastic body to form a single integral unit **prior to use**.” Starnes, [0005]. Specifically, Starnes directs that the protective sterility cap is “integrally molded about” the pointed end of the lancet needle. *Id.*, [0025], [0012], [0023], [0026]. The lancet needle is “**completely enclosed and sealed**” by cap member 4 which is formed integrally with lancet

body 2 and “sealably joined therewith so that the pointed end is protected from external sources of contamination **prior to use.**” *Id.*, [0026]. By describing the use of “injection molding manufacturing techniques” to have the lancet needle “completely enclosed and sealed” in the cap, a POSITA would recognize the cap provides a “primary sheath” where the unused lancet needle is “**embedded.**”

311. In my opinion, Starnes discloses a cap with a “primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein.

(c) Starnes discloses claim 1[b] – “a secondary sheath for receiving the sharp lancing tip of a used lancet”

312. Starnes teaches that due to the difficulty encountered in attempting to insert a used needle back into the cap’s miniscule extant cavity, the cap may be “forcibly impaled on the needle **at a different surface location.**” Starnes, [0009]. By “impaling” the cap on the needle, a POSITA would recognize that the needle would be enclosed or embedded in the cap, which comports with the Court’s construction of this term. Claim Construction Order, 13:24-14:3. In addition, Starnes specifically teaches that the cap is to be impaled on the needle, not via the primary sheath, but on a “different surface location” of the cap.

313. It is for these reasons I believe Starnes discloses “a secondary sheath for receiving the sharp lancing tip of a used lancet.”

(d) Starnes discloses claim 1[c] – “and a gripping handle portion extending between the primary sheath and the secondary sheath”

314. Starnes provides that its 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.” Starnes, [0024].

315. It is my understanding that Starnes teaches that in order to detach cap member 4 from the lancet body 2, “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 lancet body 2 is grasped by the fingers of the user’s other hand.” *Id.*, [0031]. The “twisting force on cap member 4” must also be multiplied in order to facilitate “ease of disengagement of tab members 8” from the lancet body. *Id.*

316. A POSITA would recognize that the “outer contour edge of cap member 4” also provides a textured surface for a lancet user to gain a better “grip” or “grasp” of the cap in order to create the necessary twisting force to disengage the tab members 8 from the lancet body. A POSITA would know that the cap member 4 has a gripping handle, as annotated below in Figures 1 and 2, in order to best facilitate the hand twisting motion needed to utilize the lancet disclosed in Starnes.

317. In my opinion, Starnes discloses a “gripping handle portion extending between the primary sheath and the secondary sheath.”

(e) Starnes 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”

318. As I noted previously, Starnes provides that the secondary sheath is located on a different surface location of the cap than the primary sheath. *See supra*, Section XI.H.1(b). Starnes also does not teach or disclose anything that would suggest either sheath structurally changes when the cap is removed from the lancet.

319. It is therefore my opinion that Starnes 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.”

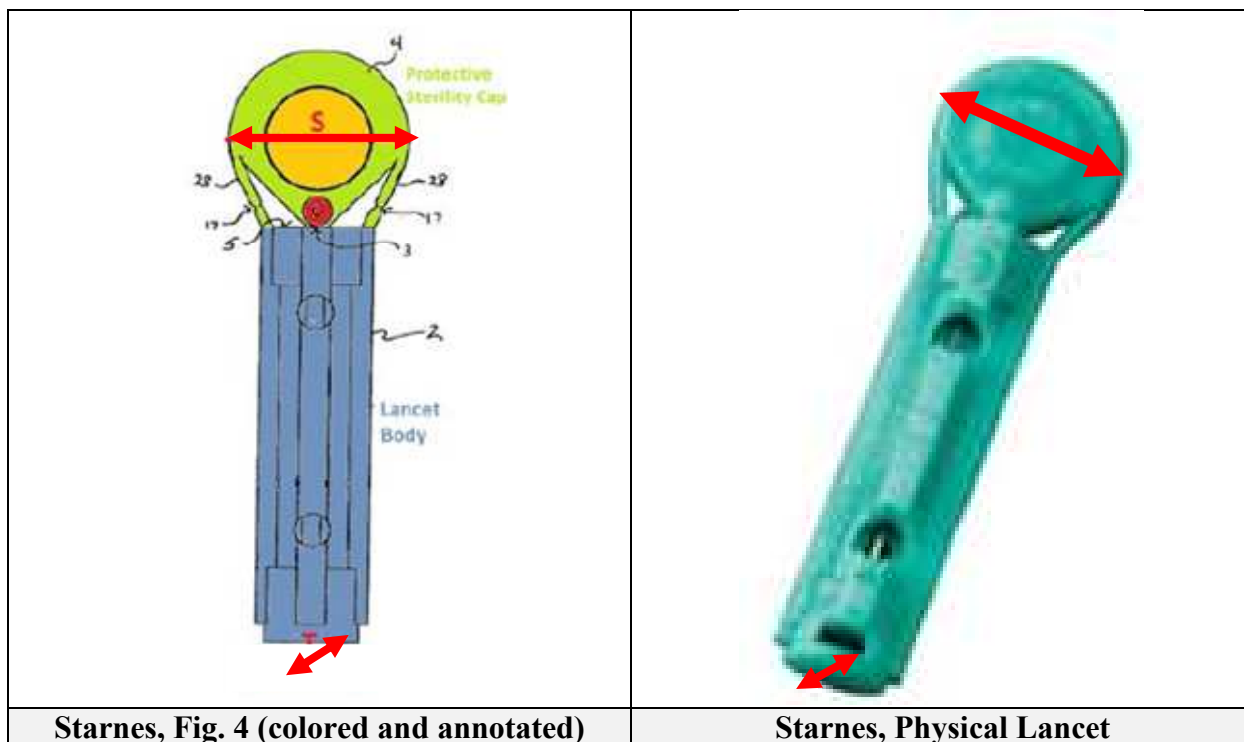
(f) Starnes discloses limitations 6[a]-6[d]

320. 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 Starnes.

321. As to elements 6[a]-6[c] Starnes discloses an improved “protective lancet” with a lancet casing which includes 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.” Starnes, [0012]. Starnes also discloses the sharp lancet tip initially embedded in the primary sheath, as I described previously in Section XI.H.1(b), which I incorporate herein.

322. As to element 6[d]’s limitation of “the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness,” a visual inspection of Figure 4 below with the lateral span annotated “S” would indicate that Starnes discloses this limitation. To be sure, I measured and examined the lateral span and thickness of the prior art lancet commercialized by Starnes and confirmed that lancet base thickness was more than 1.5 times the lateral span of the gripping handle portion.



Additionally or alternatively, it is my opinion that a POSITA would recognize that having an endcap with a lateral span of at least 1.5 times the lancet thickness would provide a lancet user with the optimal rotational leverage to apply the “twisting force on cap member 4” required to facilitate “ease of disengagement of tab members 8” from the lancet body. A POSITA would understand that such a lateral span would allow these tab members to break more readily through minimal rotation of the cap, such that their disengagement would more effectively serve to indicate that the lancet blade has potentially been bent.

3. Discussion of Claim 8

323. Claim 8 depends from claim 6, which Starnes anticipates for the reasons I discussed above in Section XI.H.1, incorporated herein. Claim 8 adds “wherein the gripping handle portion defines a length at least equal to the lancet thickness.”

324. Because Starnes discloses both that the gripping handle portion (cap 78) is at least 1.5 times the lancet thickness (*supra* Section XI.H.1, incorporated here), the length of Starnes’s gripping handle portion must also necessarily be at least equal to (including larger than, as Starnes teaches) the lancet thickness.

4. Discussion of Claim 14

325. Claim 14 includes limitations analogous in scope to limitations 1[pre]-1[d], and those are disclosed by Starnes for reasons I provided above and

incorporated here (*supra* Section XI.H.1(a)-(e)). Claim 14 also includes limitations analogous in scope to those found in claim 6, and those are disclosed by Starnes for reasons I provided above and incorporated here (*supra* Section XI.H.1(f)).

5. Discussion of Claim 18

326. Claim 18 depends from claim 14, which is anticipated by Starnes for reasons I provided above and incorporated here (*supra* Section XI.H.3). 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 XI.H.2).

6. Claims 6, 8, 14, and 18: The “Length” and “Lateral” Span of the Gripping Handle Portion

327. As I discussed above, the length and lateral span limitations of the asserted claims are disclosed by Starnes. Even if they are not explicitly or inherently disclosed, all of the relative-dimensional limitations would have been obvious for a POSITA to apply to Starnes. Designing a gripping handle that had a lateral span at least 1.5 times the lancet thickness (as recited in claims 6 and 14) would have been pursued by a POSITA as a matter of routine optimization and with a reasonable expectation of success, particularly in view of Starnes’s requirement that the “twisting force on cap member 4 is multiplied” in order to “facilitate ease of disengagement of tab members 8” from the lancet body. Starnes,

[0029]. A POSITA would recognize that having an endcap with a lateral span at least 1.5 times the lancet thickness would help a lancet user twist with enough force to “fracture frangible junction 3” and “breaking the molded joint between tear-away end 14 and upper bearing surface 5.” *Id.*, [0024], [0027], [0029], [0031]. A POSITA would have thus routinely designed an endcap that would have been at least 1.5 times the thickness of a standard lancet.

328. Regarding the gripping handle’s length being at least equal to the lancet thickness (as recited in claims 8 and 18), this would also be a natural choice for a POSITA who would have appreciated that users who have difficulty handling lancets would have an easier way to twist the lancet cap with enough force to easily disengage tab members 8 from the lancet body.

329. In my opinion, Starnes renders obvious claims 6, 8, 14, and 18.

H. All Asserted Claims Are Rendered Obvious By Kim

1. U.S. Patent No. 8,647,356 to Kim (“Kim”)

330. Kim was filed on July 21, 2008, claiming priority to U.S. Provisional Application No. 60/961,411. Because Kim’s filing date is prior to the Effective Filing Date, I understand Kim qualifies as prior art under at least pre-AIA § 102(e).

2. Discussion of Claim 6

331. I discuss each limitation of claim 6 in turn below, in conjunction with the relevant disclosures of each limitation by Kim. As I expand upon below, Kim discloses and renders obvious each limitation of claim 1, to which claim 6 depends.

(a) Kim discloses claim 1[p] – “A protective sterility cap for a lancet”

332. Kim discloses a “**lancing system**” which comprises a “**safety cap**” for “receiving the needle(s) of the **lancet**.” Kim, 2:26-31.

333. It is therefore my opinion that Kim discloses “a protective sterility cap for a lancet.”

(b) Kim discloses claim 1[a] – “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein”

334. Kim provides in Figure 9 that the flange 130 can be “**integrally molded**” with the needle bearing portion 30. Kim, 12:28-34. Kim further provides that removal of the safety cap from the needle requires the “safety cap 100 [be] preferably **twisted**.” A POSITA would recognize that where the needle is “integrally molded” with the cap and where the lancet user needs to twist the cap to break the connection between flange and needle, the lancet needle is “embedded” in the lancet cap. *See supra* Section XI.B.1(b).

335. Thus, because the needle is integrally molded with the lancet cap in Kim, Kim discloses the “primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein.”

(c) Kim discloses claim 1[b] – “a secondary sheath for receiving the sharp lancing tip of a used lancet”

336. Kim discloses two chambers in its cap 100: a “first opening for enclosing and protecting the needle prior to use” and a “**second chamber 120** having a **second opening 122** into which the needle of a **used lancet** can be placed.” Kim, 8:49-53. Kim also provides that the second chamber of safety cap 100 also has a mechanism for securing the needle of the lancet in the second chamber in order to “hold the cap in place when the safety cap 100 is covering a used lancet.” *Id.* at 10:20-24. Kim’s disclosure for the “second chamber” or secondary sheath comports with the Court’s construction for a “secondary sheath for receiving.” Claim Construction Order, 13:24-14:3. The Court construed “a secondary sheath for receiving” to be a “secondary sheath for covering the sharp lancing tip of a used lancet by *embedding* or *enclosing* the lancet tip.” *Id.* Kim also provides a definition for “chamber” as used in its disclosures as an “enclosed or partially enclosed space” with the cap including one or more changes for “receiving needle(s) and/or the needle bearing portion of the present lancet.” Kim, 4:12-15.

337. In my opinion, Kim thus discloses a “secondary sheath for receiving the sharp lancing tip of a used lancet.”

(d) Kim discloses claim 1[c] – “and a gripping handle portion extending between the primary sheath and the secondary sheath”

338. Kim describes that when a lancet user removes the safety cap 100 from the lancet 10, it is removed by a “twisting motion to the safety cap 100 by a user.” Kim, 11:12-22. Twisting the safety cap 100 is required in order to “break[] the connection between the flange 130 and the needle bearing portion 30.” *Id.* at 12:30-34.

339. By requiring that the cap be twisted from the lancet in order to be removed, I believe a POSITA would recognize that the cap must have a gripping handle portion to facilitate twisting of the cap for removal. The gripping handle portion, annotated green below, provides the user with a place to grasp and twist the cap for efficient removal. A POSITA would understand that by using the green gripping handle portion, a lancet user is able to grasp the cap and create the leverage needed to twist and remove it from the lancet.

340. In my opinion, Kim discloses a “gripping handle portion extending between the primary sheath and secondary sheath.”

(e) Kim 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”

341. Kim discloses a cap with two chambers, with the cap potentially “hav[ing] an indicator to distinguish “the **second end** (*i.e.*, the secondary sheath) from the **first end** (*i.e.*, the primary sheath” of the lancet cap. Kim, 2:52-55. Kim also describes an embodiment where the “**first and second compartments** can be

located at **opposed ends** of the safety cap.” Kim, 2:45-48. As annotated in Figure 9 below, the primary sheath and secondary sheath of the lancet cap in Kim are located at a first and second end of the green gripping handle portion of the lancet cap.

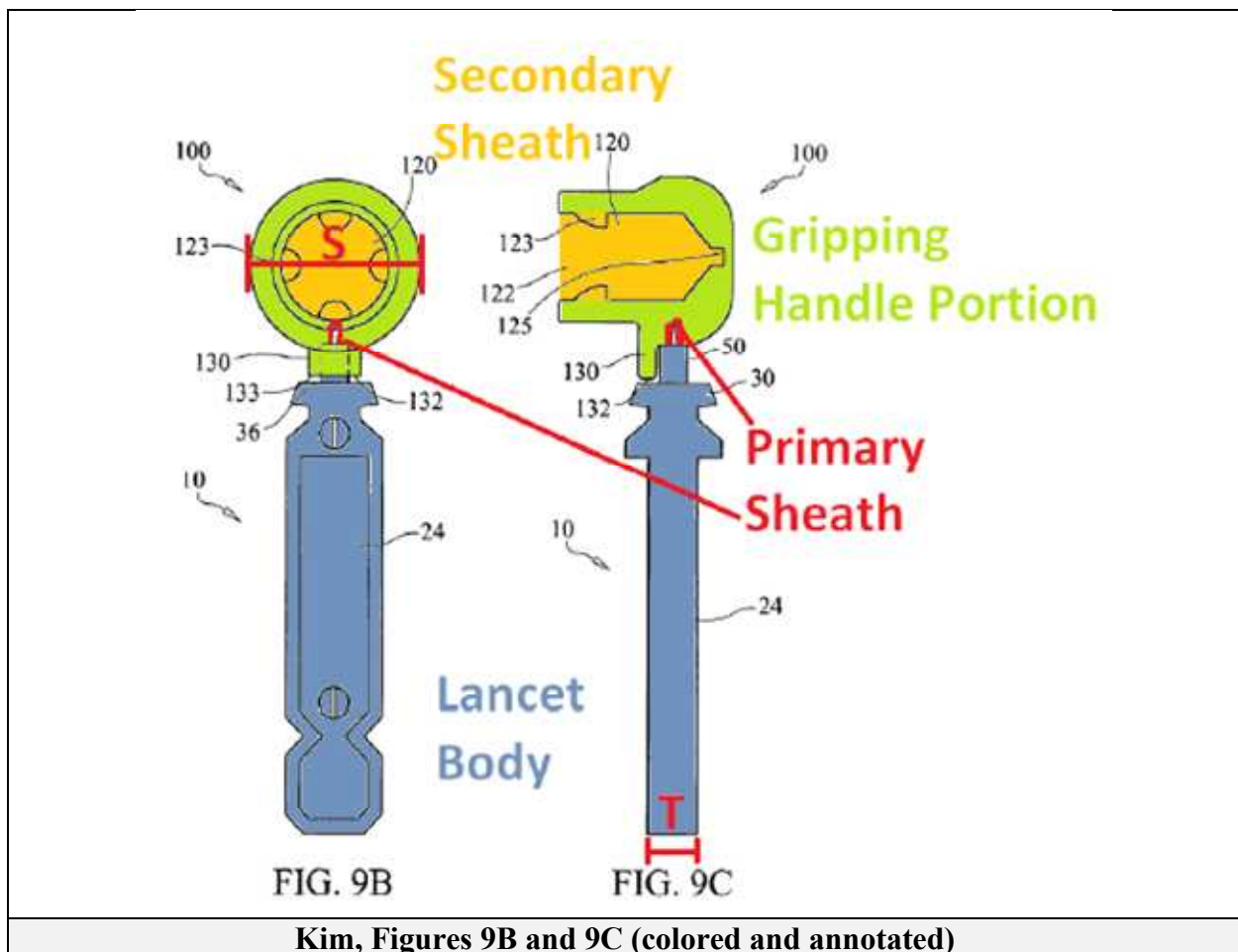
342. It is therefore my opinion that Kim discloses a “primary sheath attached at a first end of the gripping handle portion and the secondary sheath attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet.

(f) Kim discloses limitations 6[a]-6[d]

343. 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 Kim.

344. As to elements 6[a]-6[c], I believe Kim discloses a “**safety cap 10**” “**molded together** with the **lancet 10**” with the first chamber 110 (*i.e.*, primary sheath) sized so as to fit around the flanges provided on “**lancet body 20**.” Kim, 11:12-22. Kim also discloses the sharp lancet tip initially embedded in the primary sheath, as I described previously in Section XI.I.1(b), which I incorporate herein.

345. As to element 6[d]’s limitation of “the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness,” from a cursory review of Figures 9B and 9C, with the lateral span annotated “S” below, I believe the lateral span of the lancet cap is at least 1.5 times, if not more, larger than the lancet thickness.



346. In addition, Kim discloses exemplary measurements for the pedestal 50, as seen in Figure 9C. Kim provides that the pedestal can have a diameter of 1.75 mm and a length of 2 mm. Kim, 14:35-38. In my opinion, based on Kim’s disclosure of the diameter of the pedestal 50, the lancet thickness looks to be 1.5 to

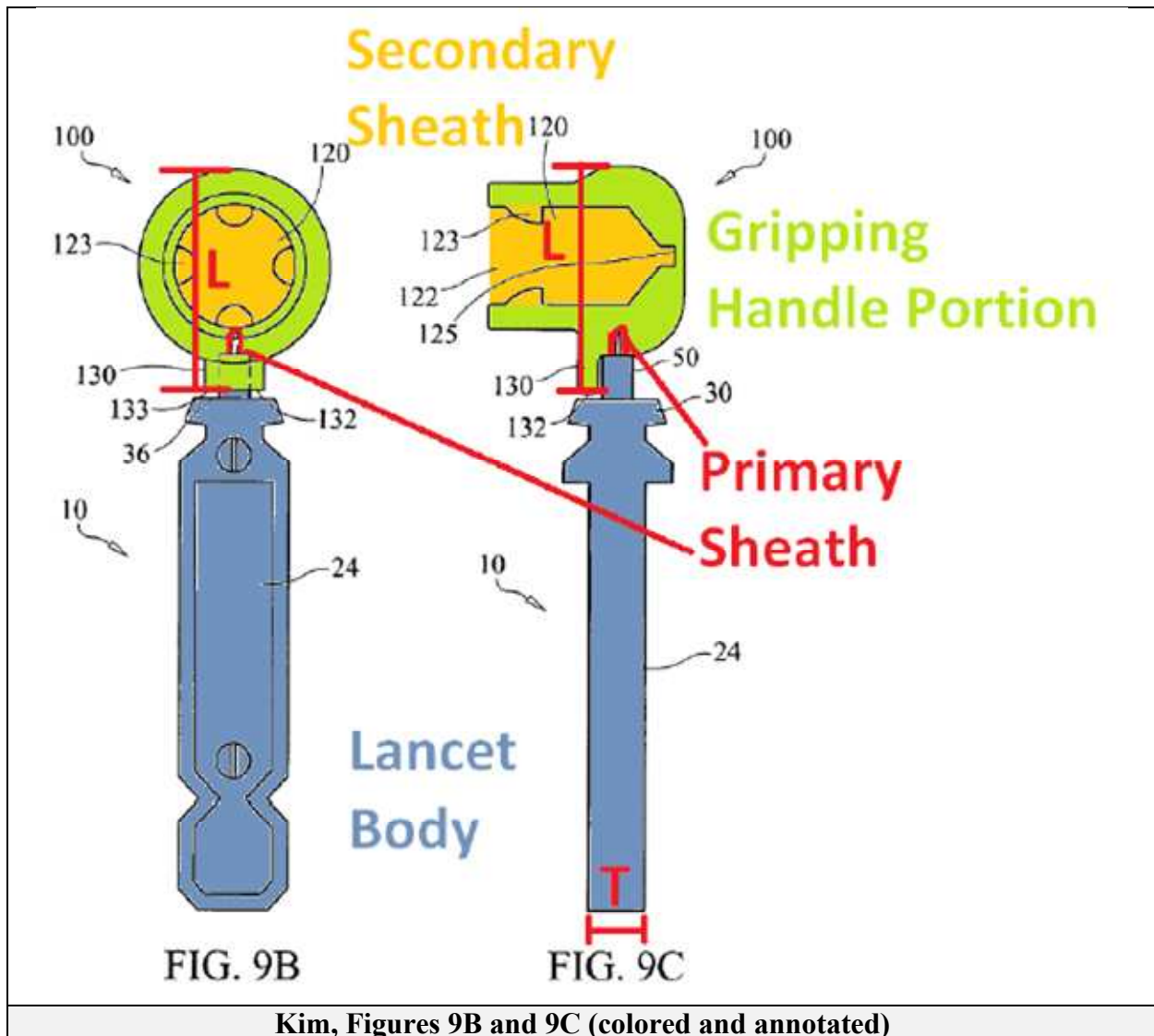
2 times the diameter of the pedestal while the lateral span of the gripping handle portion looks to be at least 4-5 times the diameter of the pedestal.

347. Based on these measurements provided in Kim, I believe Kim discloses that the “gripping handle portion of the lateral span is at least 1.5 times the lancet thickness.”

3. Discussion of Claim 8

348. Claim 8 depends from claim 6, which Kim anticipates for the reasons I discussed above in Section XI.I.1, incorporated herein. Claim 8 adds “wherein the gripping handle portion defines a length at least equal to the lancet thickness.”

349. Because Kim discloses both that the gripping handle portion is at least 1.5 times the lancet thickness (*supra* Section XI.I.1, incorporated here), the length of Kim’s gripping handle portion must also necessarily be at least equal to (including larger than, as Kim teaches) the lancet thickness.



4. Discussion of Claim 14

350. Claim 14 includes limitations analogous in scope to limitations 1[pre]-1[d], and those are disclosed by Kim for reasons I provided above and incorporated here (*supra* Section XI.I.1(a)-(e)). Claim 14 also includes limitations analogous in scope to those found in claim 6, and those are disclosed by Kim for reasons I provided above and incorporated here (*supra* Section XI.I.1(f)).

5. Discussion of Claim 18

351. Claim 18 depends from claim 14, which is anticipated by Hyoue for reasons I provided above and incorporated here (*supra* Section XI.G.3). 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 XI.I.2).

6. Claims 6, 8, 14, and 18: Gripping Handle Portion

352. As I analyzed previously in Section XI.I.1(d), I believe Kim discloses a gripping handle portion. Even if Kim did not expressly or inherently disclose a gripping handle portion, then it would have been obvious to modify Kim's cap to include a gripping handle portion.

353. A POSITA would understand that in order to remove the safety cap 100 by twisting and breaking the connection between the flange 130 and the needle bearing portion 30, the lancet user would have to be able to effectively grip the safety cap and twist with enough force to break the flange. Kim, 12:30-34. A POSITA would have been motivated to create a gripping handle portion on the safety cap 100 in Kim in order to provide lancet users with a better means to twist off the cap and utilize the lancet to draw blood.

354. It is for these reasons I believe it would have been obvious for a POSITA to include a gripping handle portion on Kim's cap.

I. All Asserted Claims Are Rendered Obvious By Kojima

1. U.S. Patent Publication No. 2003/0144608 to Kojima (“Kojima”)

355. Kojima was published on July 31, 2003. Because it has a publication date more than one year before the Effective Filing Date, I understand it qualifies as prior art under at least pre-AIA § 102(b).

2. Discussion of Claim 6

356. I discuss each limitation of claim 6 in turn below, in conjunction with the relevant disclosures of each limitation by Kojima. As I expand upon below, Kojima discloses and renders obvious each limitation of claim 1, to which claim 6 depends.

(a) Kojima discloses claim 1[p] – “A protective sterility cap for a lancet”

357. Kojima discloses a “protective cover 3” which protects the needle tip of lancet 2. Kojima, [0168].

358. A POSITA would understand that the “protective cover 3” disclosed in Kojima would maintain the sterility of the needle tip of lancet 2.

359. It is therefore my opinion that Kojima discloses “a protective sterility cap for a lancet.”

(b) Kojima discloses claim 1[a] – “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein”

360. Looking at an annotated version of Figure 6(a) below, Kojima discloses a primary sheath where the protection cover 3 of the device in Kojima is **fitted** over the lancet needle tip. Kojima, Fig. 6(a), [0141]. The needle tip is also described as being “housed” in the protection cover with the protective cover 3 being removed during the skin lancing operation and measurement of a patient’s blood sugar. *Id.*; [0168]; claim 15. Kojima also describes the protection cover as having a “tube part” for housing the needle tip in. *See id.* at [0050]; claim 15.

361. Although Kojima does not use the word “embedded,” a POSITA would recognize that in order for the protective cover 3 to be **fitted** over the lancet needle tip, it must be embedded over the unused lancet.

362. In my opinion, Kojima thus discloses a “primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein.”

(c) Kojima discloses claim 1[b] – “a secondary sheath for receiving the sharp lancing tip of a used lancet”

363. Kojima’s Figure 6(b) discloses a “state where the protection cover is fitted to a front end of the sensor when the needle tip is housed.” Kojima, [0141].

364. Kojima further discloses that in order to “prevent injury and infectious disease more reliably,” there is a “semi-circular space that conforms to the shape of the front end of the lancet-integrated sensor 1” which is formed on a side part of the grip part 3. *Id.* at [0196]. Following lancet use, the lancet-integrated sensor

“may be ejected with the sensor 1 being covered with the protection cover 3 as seen in Fig. 6(b).” *Id.*

365. From Kojima’s disclosures and Figure 6(b), annotated and colored below, a POSITA would understand that the lancet needle is enclosed and embedded in the semi-circular space or secondary sheath of the protective cover 3. In order for the used lancet-integrated sensor needle to be covered with protection cover 3, a POSITA would recognize that the lancet needle is enclosed in the space provided by the protective cover. In my opinion, this understanding of the semi-circular space on the protective cover as the secondary sheath of this invention comports with the Court’s broad construction of the term “secondary sheath for receiving” as a “secondary sheath for covering the sharp lancing tip of a used lancet by embedding or enclosing the lancet tip.” Claim Construction Order, 13:24-14:3.

366. Therefore, it is my opinion that Kojima discloses a “secondary sheath for receiving the sharp lancing tip of a used lancet.”

(d) Kojima discloses claim 1[c] - “and a gripping handle portion extending between the primary sheath and the secondary sheath”

367. Kojima discloses the protective cover has a “wide grip part for **facilitating removal** of the protection cover from the lancet.” Kojima, [050]. When utilizing the device in Kojima, the patient is instructed to “**grip** a **wide grip part 3a** of the **protection cover 3**” and the grip part is described as an

“approximately-square-shaped grip part 3a” which is identified as a separate part of the protection cover 3. *Id.* at [0187], [0196], [0215].

368. A POSITA would readily recognize based on Figure 6(a) and the disclosures in Kojima that the protective cover 3 has a gripping handle portion. In the Court’s Claim Construction Order, the Court noted that it “did not make much of the modifier ‘gripping’” and “all handles are ‘gripping handles.’” Claim Construction Order, 17:12-13. In addition, the ’635 Patent refers to “a handle or grip” interchangeably. ’635 Patent, at 1:66-2:3.

369. It is for these reasons I believe that the “wide grip part 3a” of protection cover 3 in Kojima is “a gripping handle portion extending between the primary sheath and the secondary sheath.”

(e) Kojima 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”

370. Figures 6(a) and 6(b), annotated below, in Kojima illustrate that the protection cover 3 is fitted by the primary sheath when the needle tip protrudes and by the secondary sheath or semi-circular space when the lancet-integrated sensor is ejected. Kojima, Figure 6(a), Figure 6(b).

371. Kojima also provides that the “protection cover is **fitted to a front end**” in Figure 6(b) when housed and the semi-circular space or secondary sheath is described as being on a **“side of the grip part 3a of protection cover 3”**. *Id.* at

[0196]. Kojima does not disclose that either the primary sheath or secondary sheath change when the protective cover is removed from the lancet-integrated sensor. Both are located on separate sides of protective cover 3. In addition, a POSITA would know that the “semi-circular space” or secondary sheath must be readily available to cover the lancet needle when ejected in order to “prevent injury and infectious disease more reliably.” *Id.*

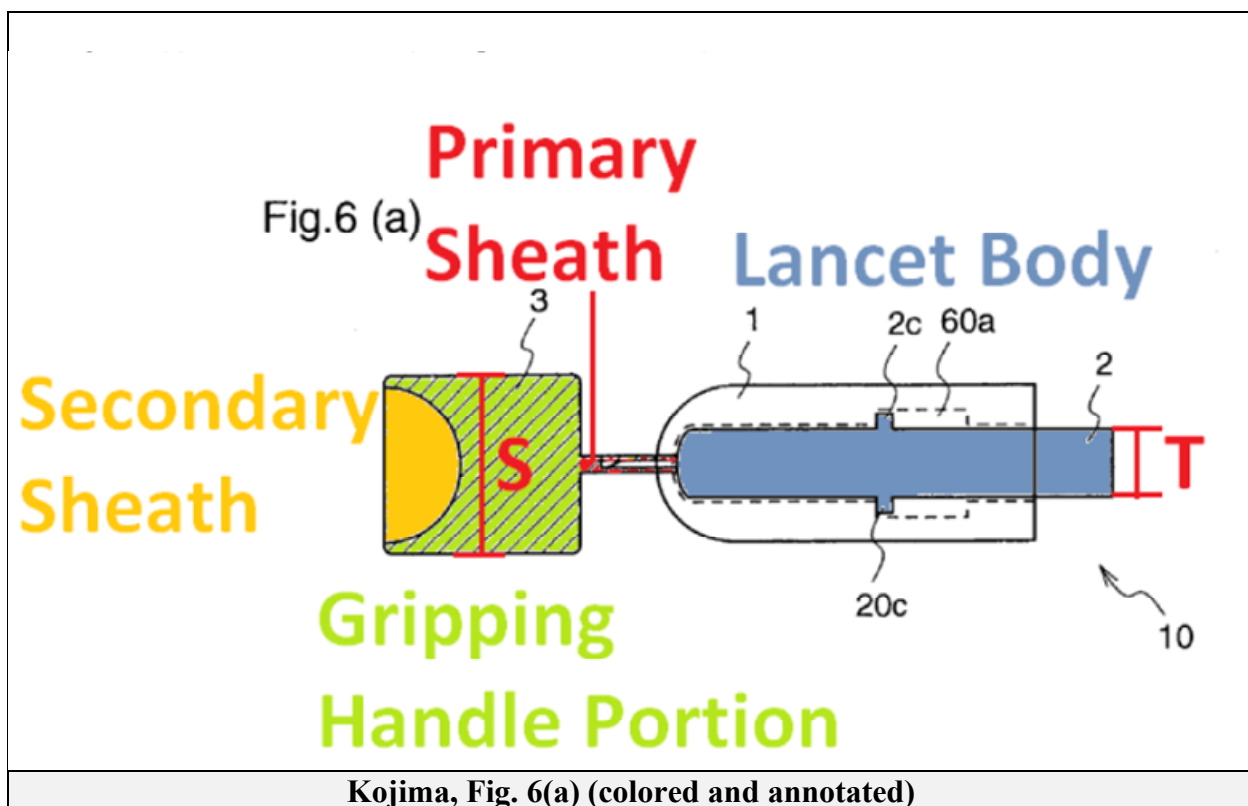
372. It is therefore my opinion that Kojima discloses a “primary sheath attached at a first end of the gripping handle portion and the secondary sheath attached at a second end of the gripping handle portion when the protective sterility cap is removed from the lancet.”

(f) Kojima discloses limitations 6[a]-6[d]

373. 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 Kojima.

374. As to elements 6[a]-6[c], I believe Kojima discloses a “lancet 2” with a needle tip pressed into protection cover 3. Kojima at [0168], Figure 6(a). Kojima also discloses the sharp lancet tip initially embedded in the primary sheath, as I described previously in Section XI.J.1(b), which I incorporate herein.

375. As to element 6[d]’s limitation of “the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness,” a visual inspection of Figure 6(a), annotated below with “S” being the lateral span and “T” being the thickness, would indicate that the lateral span of the gripping handle portion is at least 1.5 times the lancet thickness. A POSITA would also recognize and be motivated to modify the gripping handle portion or “wide grip part” to be more than 1.5 times the lancet thickness in order to help patients with “removal of the protection cover from the lancet.”



3. Discussion of Claim 8

376. Claim 8 depends from claim 6, which Kojima anticipates for the reasons I discussed above in Section XI.J.1, incorporated herein. Claim 8 adds “wherein the gripping handle portion defines a length at least equal to the lancet thickness.”

377. Because Kojima discloses both that the gripping handle portion or “wide grip part” is at least 1.5 times the lancet thickness (*supra* Section XI.J.1, incorporated here), the length of Kojima’s gripping handle portion must also necessarily be at least equal to (including larger than, as Kojima teaches) the lancet thickness.

4. Discussion of Claim 14

378. Because Kojima discloses both that the gripping handle portion (cap 78) is at least 1.5 times the lancet thickness (*supra* Section XI.J.1, incorporated here), the length of Kojima’s gripping handle portion must also necessarily be at least equal to (including larger than, as Kojima teaches) the lancet thickness.

5. Discussion of Claim 18

379. Claim 18 depends from claim 14, which is anticipated by Kojima for reasons I provided above and incorporated here (*supra* Section XI.J.3). 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 XI.J.2).

6. Claims 6, 8, 14, and 18: The “Length” and “Lateral” Span of the Gripping Handle Portion

380. As I discussed above, the length and lateral span limitations of the asserted claims are disclosed by Kojima. Even if they are not explicitly or inherently disclosed, all of the relative-dimensional limitations would have been obvious for a POSITA to apply to Kojima. Designing a gripping handle that had a lateral span at least 1.5 times the lancet thickness (as recited in claims 6 and 14) would have been pursued by a POSITA as a matter of routine optimization and with a reasonable expectation of success, particularly in view of Kojima’s disclosure that the gripping handle portion be a “**wide grip part** for facilitating removal of the protection cover from the lancet.” Kojima, [0050]. A POSITA would recognize that having a wide, protective cover with a lateral span at least 1.5 times the lancet thickness would help a lancet user “facilitate removal” of the protective cover. A POSITA would have thus routinely designed an endcap that would have been at least 1.5 times the thickness of a standard lancet.

381. Regarding the gripping handle’s length being at least equal to the lancet thickness (as recited in claims 8 and 18), this would also be a natural choice for a POSITA who would have appreciated that users who have difficulty handling lancets would have an easier way to remove the protection cover from the lancet body.

382. In my opinion, Starnes renders obvious claims 6, 8, 14, and 18.

J. All Asserted Claims Are Rendered Obvious By Marshall In View of the Unilet ComforTouch Lancets

1. U.S. Design Patent No. D562,980 to Marshall (“Marshall”)

383. Marshall was filed on May 8, 2006 and published on February 26, 2008. Because its publication date is prior to the Effective Filing Date, I understand it is prior art under at least pre-AIA 102(e).

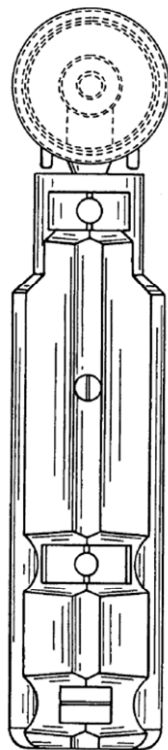
2. Discussion of Claim 6

384. I discuss each limitation of claim 6 in turn below, in conjunction with the relevant disclosures of each limitation by Marshall and the Unilet ComforTouch Lancets. As I expand upon below, Marshall in view of the Unilet ComforTouch Lancets (the “Combination”) disclose and render obvious each limitation of claim 1, to which claim 6 depends.

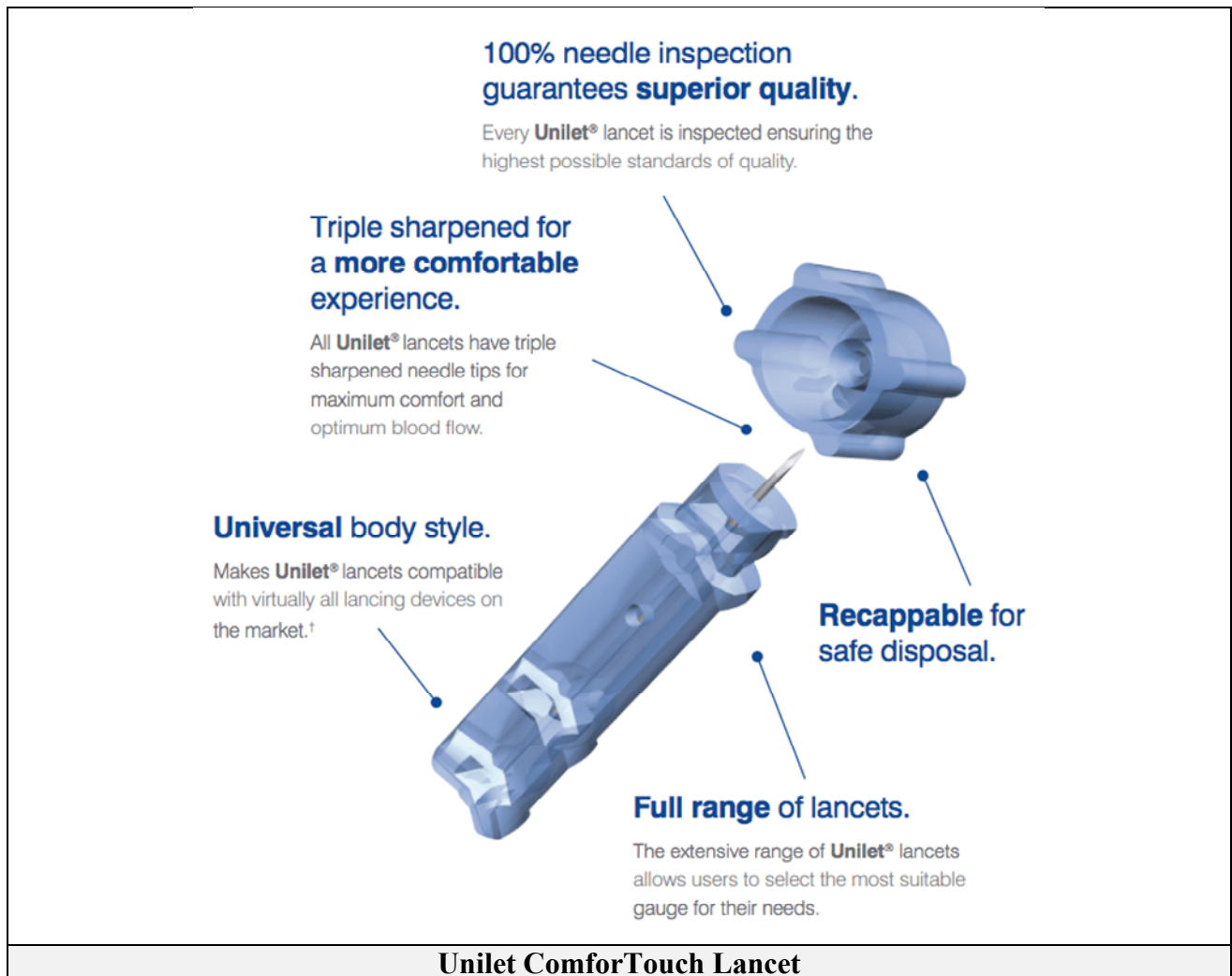
(a) The Combination discloses claim 1[p] – “A protective sterility cap for a lancet”

385. The Combination discloses “a protective sterility cap for a lancet.” As can be seen in the below diagrams, Marshall and the Unilet ComforTouch Lancets both have a protective cap for a lancet. A POSITA would understand observing both that a protective sterility cap for a lancet is disclosed.

Fig. 2

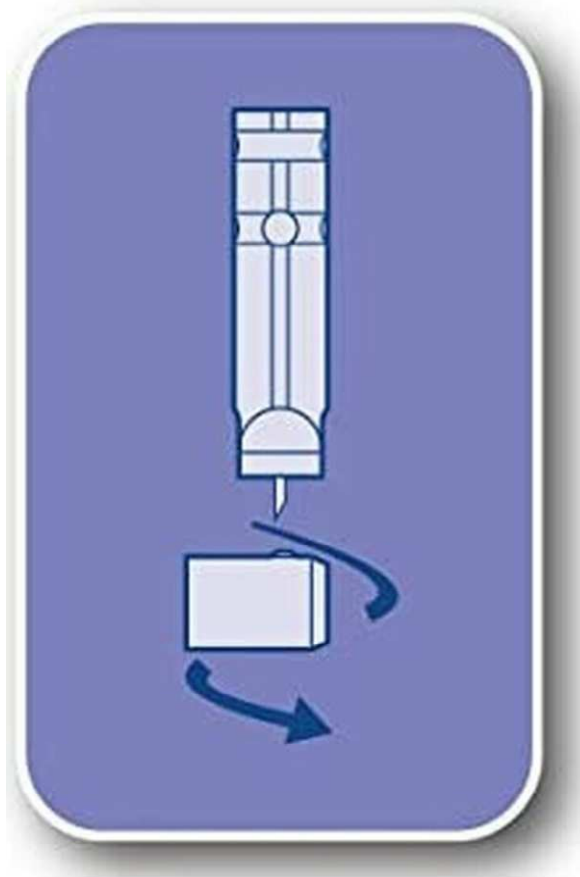


Marshall, Figure 2



(b) The Combination discloses claim 1[a] – “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein”

386. In order to utilize the Unilet ComforTouch Lancet, a patient must first twist the cap to remove it from the lancet body and reveal the lancet needle. This step can be seen from the bottom diagram.



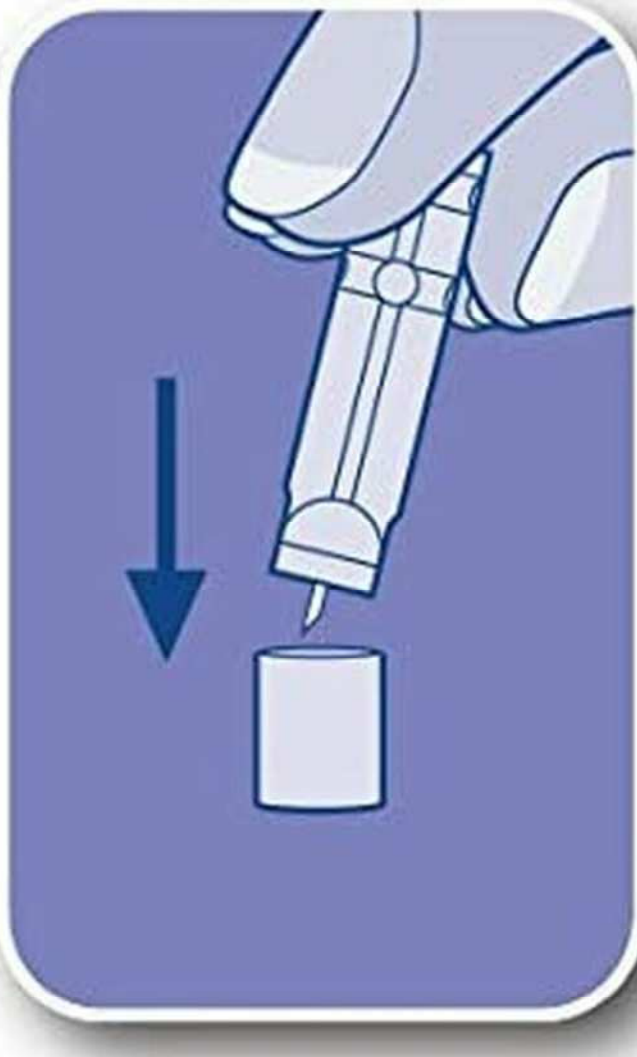
The cap of the Unilet ComforTouch Lancet must be twisted off in order to reveal the lancet needle

387. Because the Unilet ComforTouch Lancet requires using a twisting motion to remove the cap, a POSITA would recognize that the lancet needle is likely “integrally molded” and embedded within the cap. *See supra* Section XI.B.1(b). A POSITA would also recognize that twisting the cap would avoid potentially bending or damaging the needle prior to use.

388. Thus, it is my opinion that the Combination discloses the “primary sheath for initial embedment of a sharp lancing tip of an unused needle.”

(c) The Combination discloses claim 1[b] – “a secondary sheath for receiving the sharp lancing tip of a used lancet”

389. The Unilet ComforTouch lancet provides that the used lancet tip can be placed into the cap for convenience. This can be observed in the following diagrams.

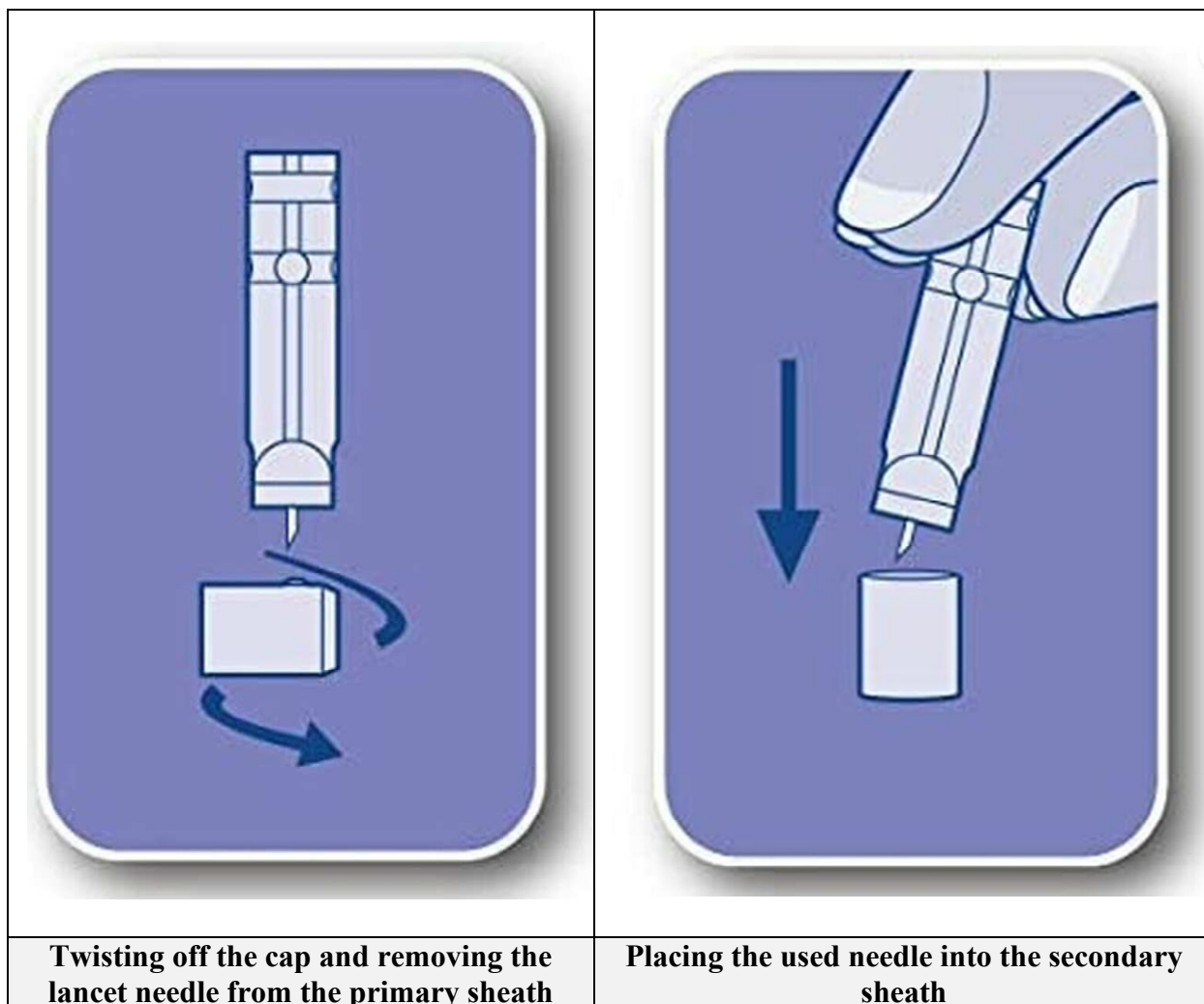
 A diagram showing a hand holding a lancet. A large blue arrow points downwards towards a small white cylindrical container, indicating the direction to place the used needle tip.	 Recappable. Unilet® ComforTouch™ offer the user the opportunity to place the used needle tip into the cap for convenience.
Placing the used needle into the secondary sheath	“Recappable” – the Unilet ComforTouch lancet offers users the opportunity to place the used needle tip into the cap for convenience

390. In my opinion, these disclosures associated with the Unilet ComforTouch lancet align with the Court’s construction of “secondary sheath for receiving.” Per the Court, the secondary sheath was construed to mean “a secondary sheath for covering the sharp lancing tip of a used lancet by embedding or enclosing the lancet tip.” Claim Construction Order, 13:24-14:3. A POSITA would understand that by placing the used needle back into the “secondary sheath” of the Unilet ComforTouch lancet, the lancet user would be “embedding” or “enclosing” the lancet tip within the cap.

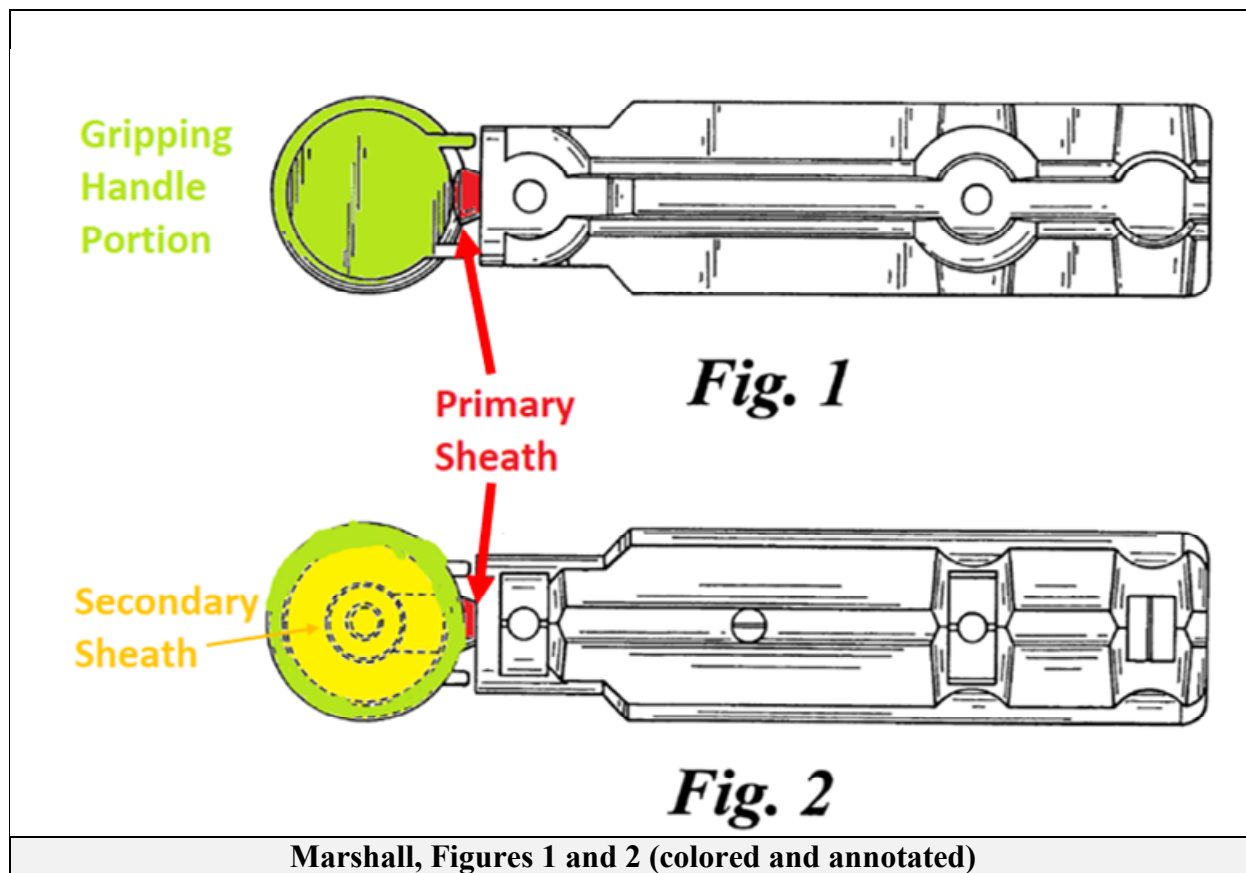
391. It is for these reasons I believe this Combination discloses a “secondary sheath for receiving the sharp lancing tip of a used lancet.”

(d) The Combination discloses claim 1[c] – “and a gripping handle portion extending between the primary sheath and the secondary sheath”

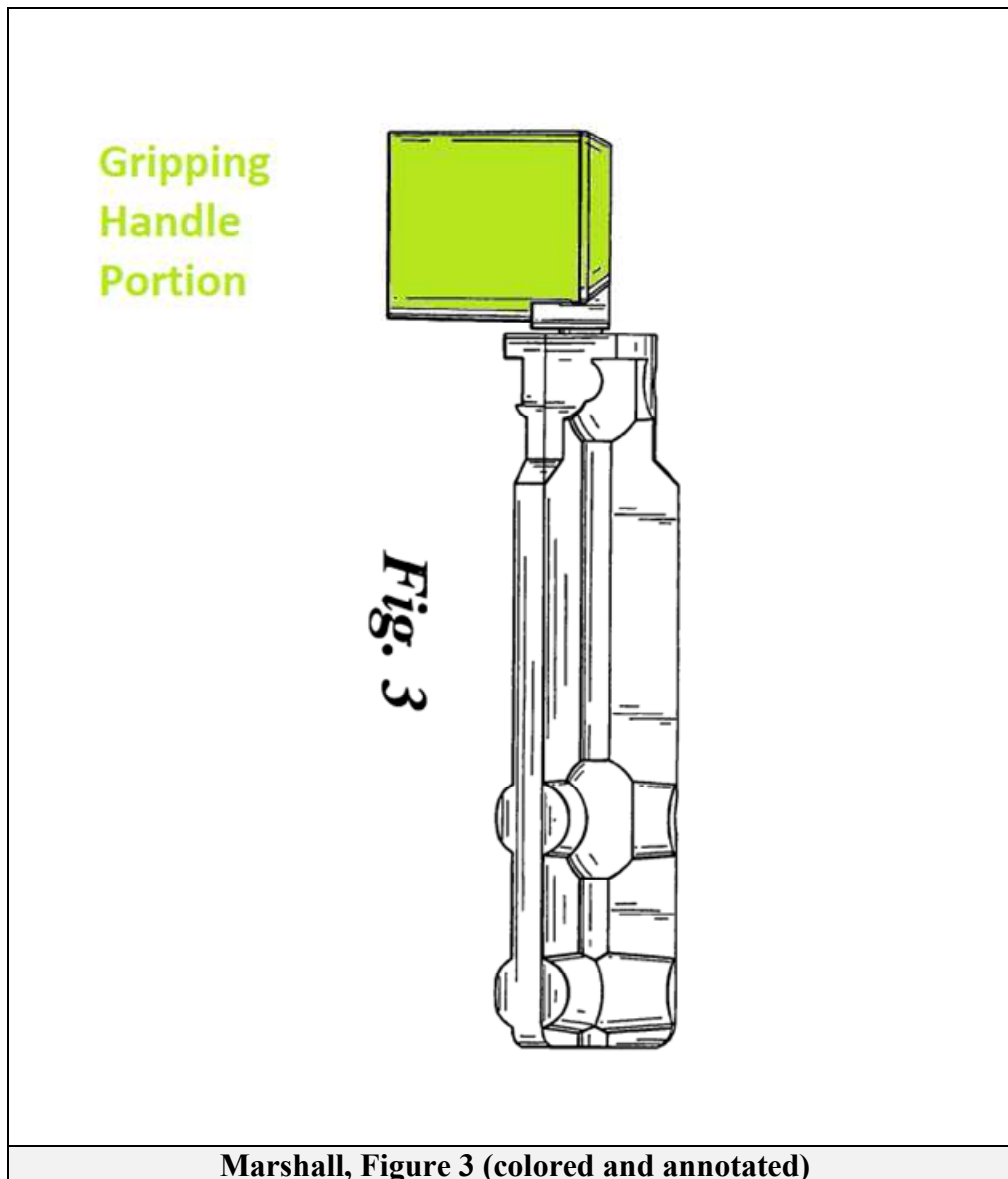
392. Both Marshall and the Unilet ComforTouch lancet disclose a gripping handle extending between the primary sheath and the secondary sheath. First, a POSITA would recognize that the Unilet ComforTouch lancet discloses both a primary sheath and secondary sheath, as seen in the instructional diagram below.



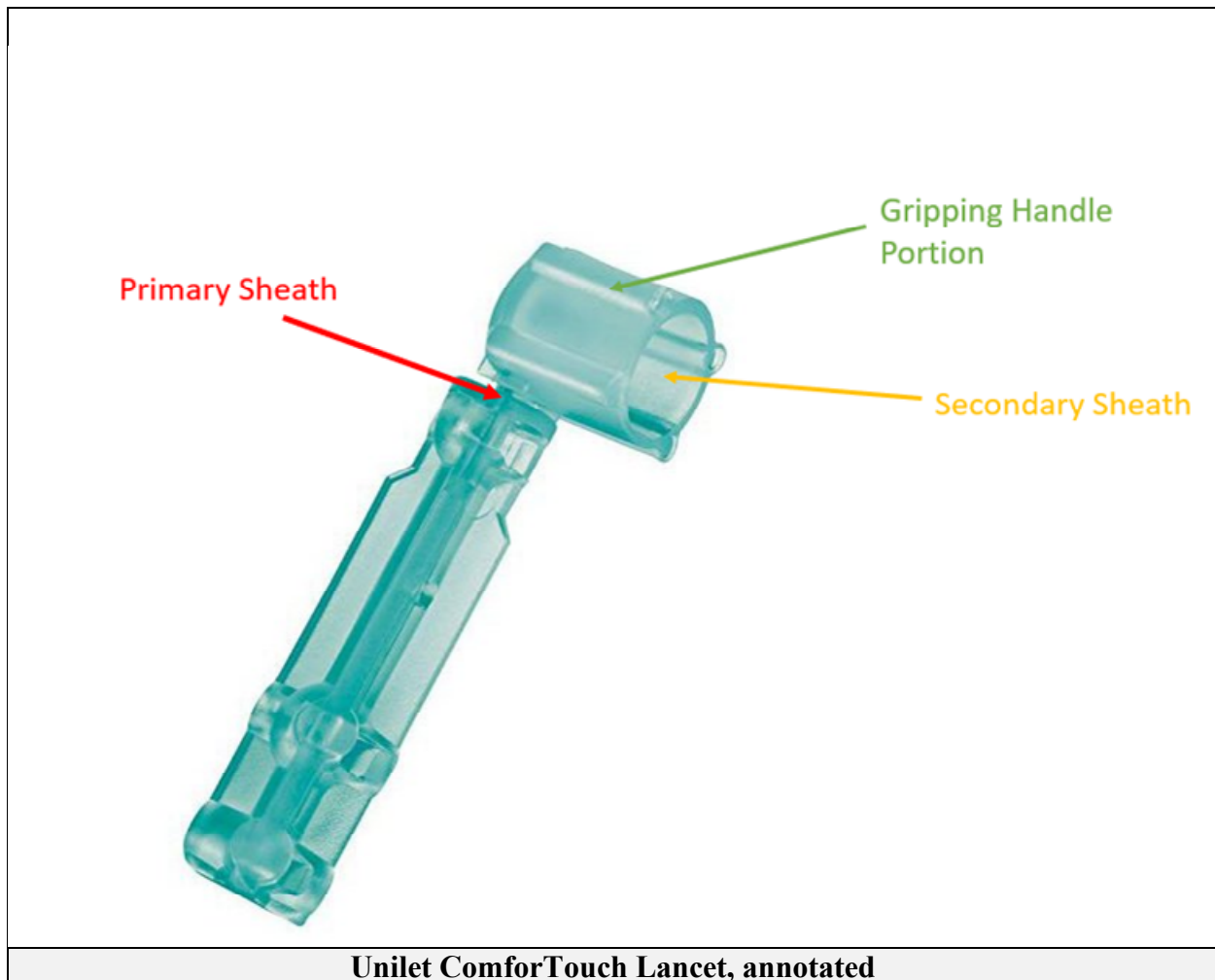
393. Secondly, I believe a POSITA would understand that in order to be able to twist the cap and remove it from the primary sheath, the cap must have a gripping handle portion in order to facilitate the twisting motion. The gripping handle portion, in addition to the primary and secondary sheaths, as disclosed in Marshall are annotated below. Marshall, Figures 1 and 2.



394. A POSITA would recognize that the cap in Marshall provides the lancet user with enough surface area to grasp and twist the lancet when removing the cap and exposing the lancet needle.



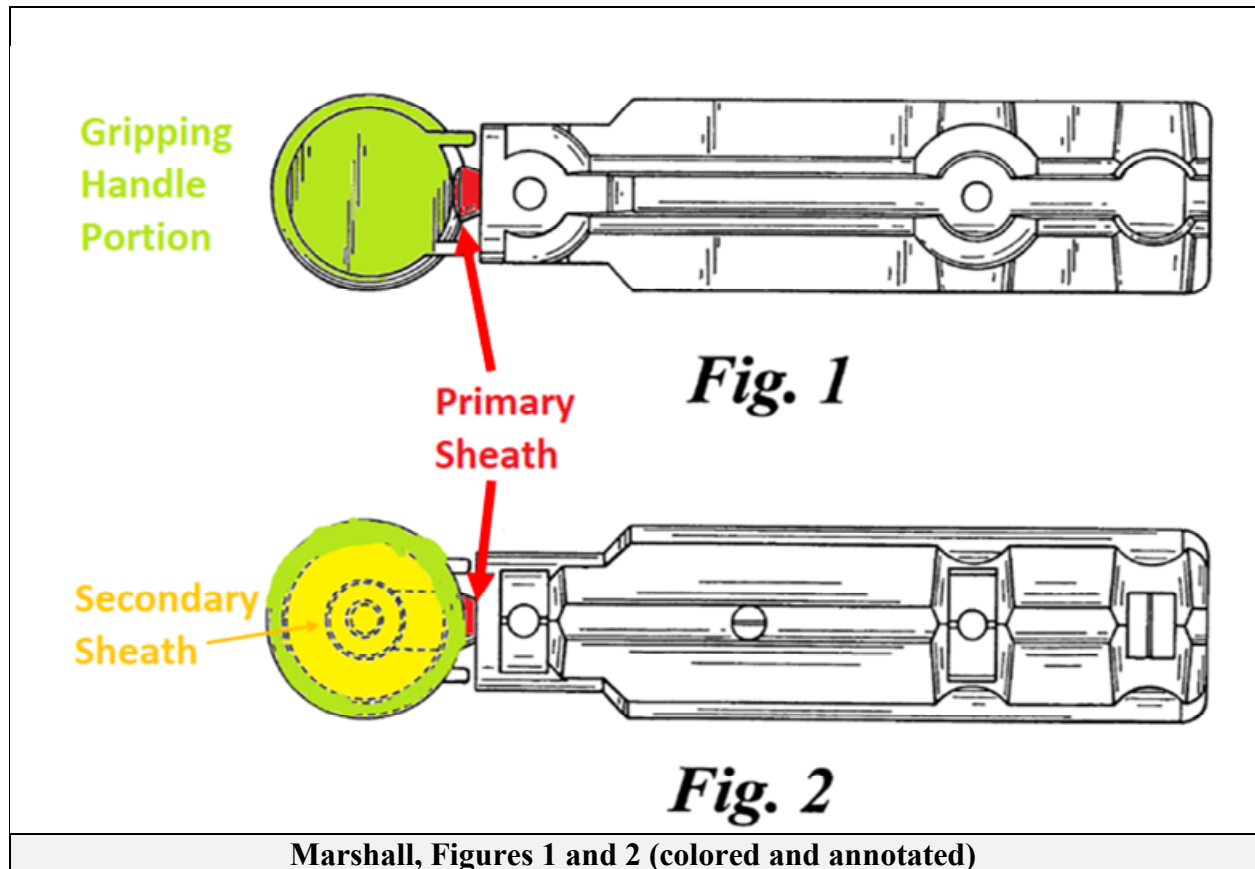
395. The same can be seen with the cap of the Unilet ComforTouch lancet.

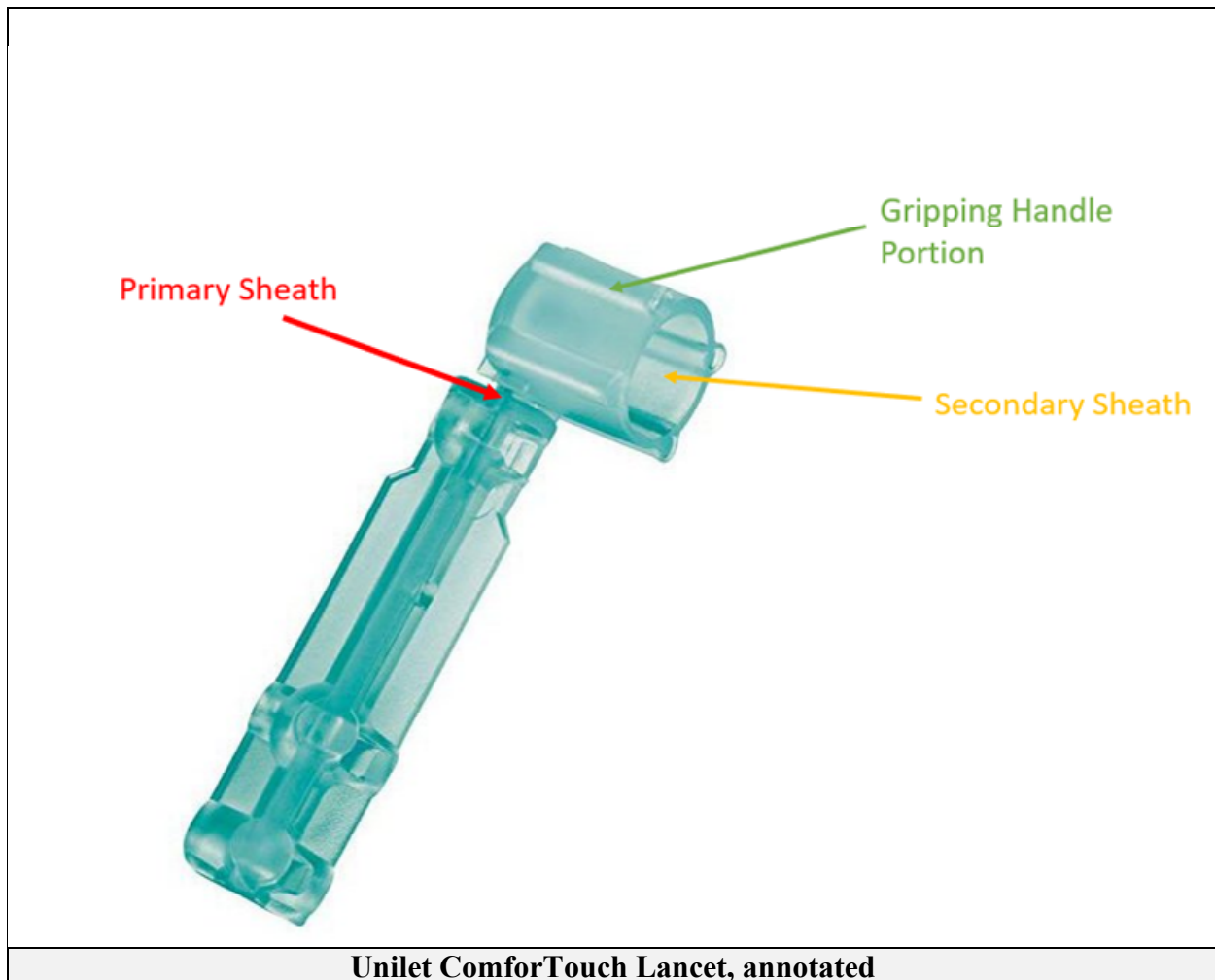


396. It is therefore my opinion that the Combination discloses the “gripping handle portion extending between the primary sheath and the secondary sheath.”

- (e) The Combination 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”

397. As seen in the annotated figures below, both Marshall and the Unilet ComforTouch Lancet disclose the primary sheath and secondary sheath attached at different ends of the gripping handle portion.





398. A POSITA would recognize based on the disclosures from this combination that the primary and secondary sheaths do not change when the lancet cap is removed from the lancet body.

399. It is therefore my opinion that the Combination discloses “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.”

(e) The Combination discloses 6[a]-6[c]

400. 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, elements 6[a] through 6[c] is disclosed by this Combination.

I COE DISCLOSES ALL LIMITATIONS OF CLAIM 1

1. 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

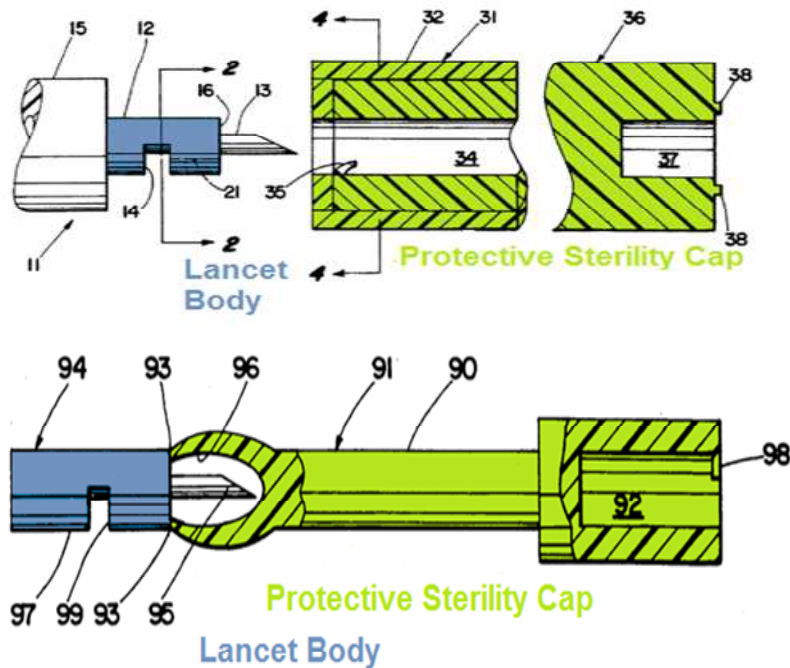
2. I discuss each limitation of claim 1 in turn below, in conjunction with the relevant disclosures of each claim limitation by Coe.

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

3. 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

4. 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



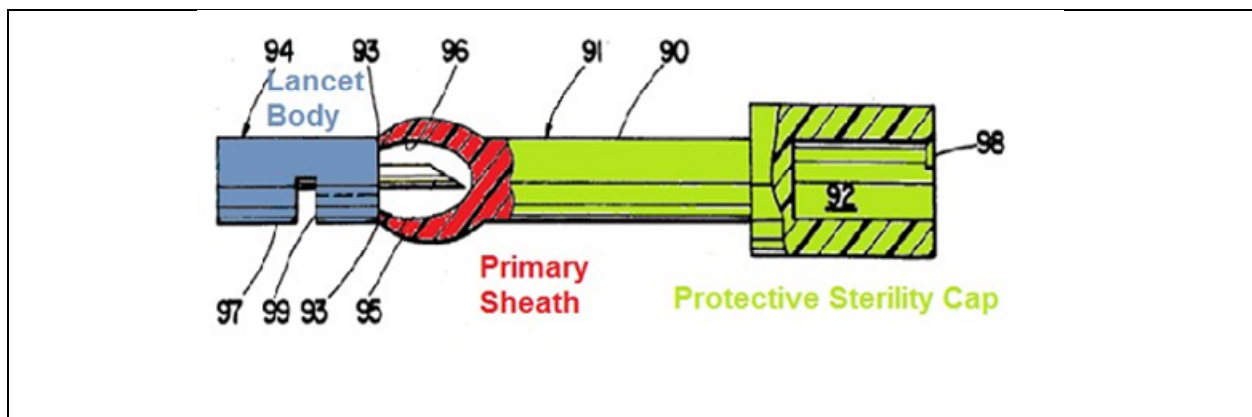
5. One observation to be made here is that Coe states that the extractor (91) may be “integrally molded to a lancet (94).” Ex. 1106, 5:22-38. The “sterile lancet tip” maintains sterility via protection provided by extractor 91.

6. 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”

7. 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.



8. Coe does not use the term “embedment” as required by the claim.

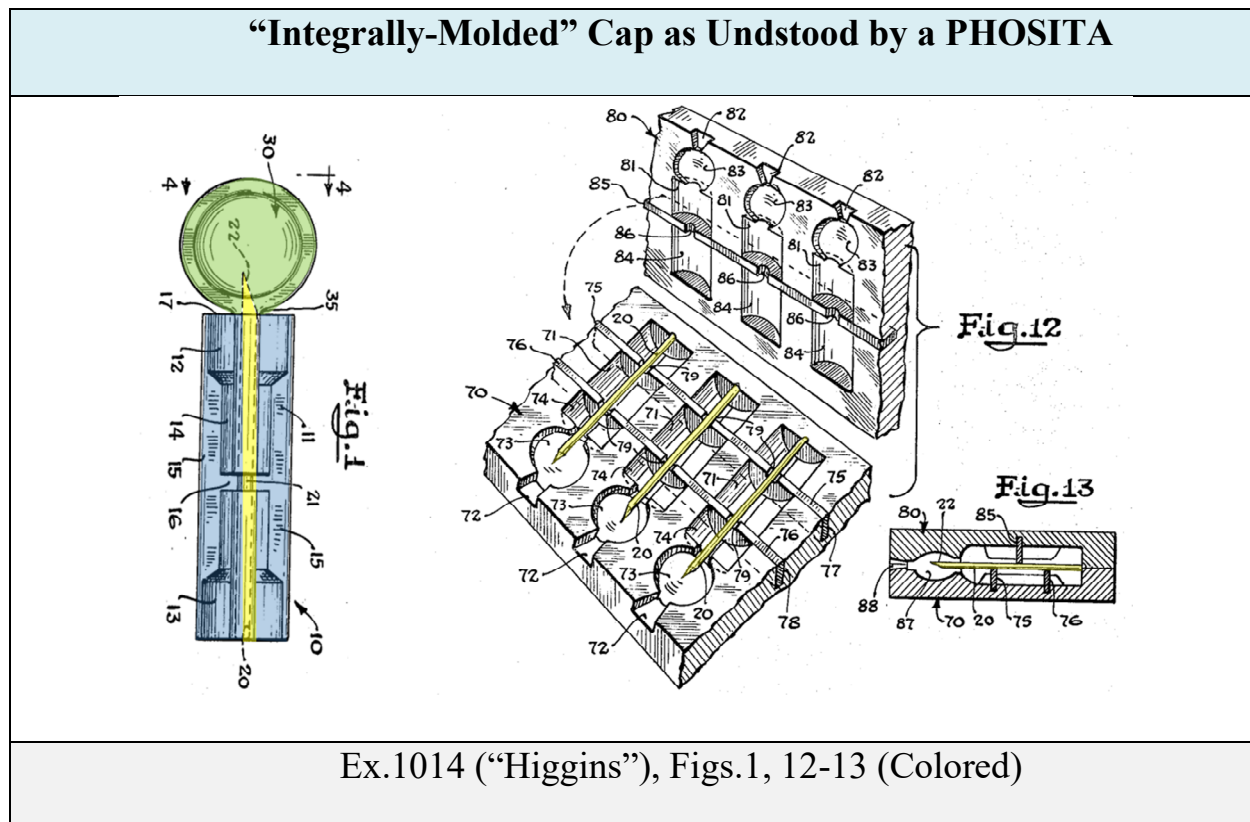
However, in my opinion, Coe discloses this claim limitation for a number of reasons.

9. *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.

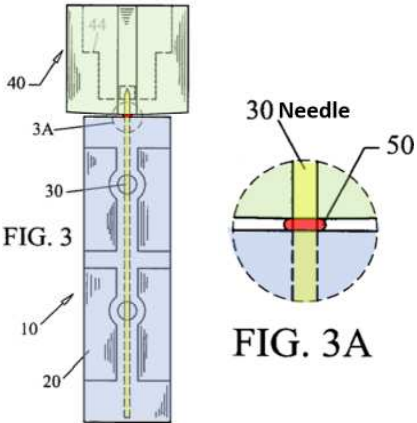
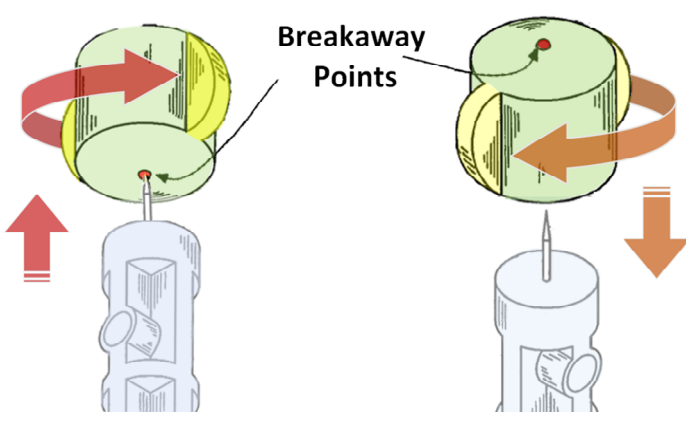
10. *Second*, the '635 Patent itself admits that the “sharp tip of [a conventional] lancet is commonly **embedded** in a removable plastic cap to maintain sterility and prevent inadvertent sticks prior to use,” and even describes the “primary sheath” as the “flange or ring at one **end of the sterility 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.



11. *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.”

“Breakaway Points” as understood by a PHOSITA	
 FIG. 3 is a side cross-sectional view of a lancet assembly. It shows a lancet body (10) with a needle (30) inside. A cap (40) is shown above the needle. A spacer rib (3A) is located between the needle and the body. A breakaway point (50) is indicated at the junction of the cap and the body. FIG. 3A is a top-down view of the cap (50) showing the needle (30) passing through it.	 The diagram illustrates the breakaway points of the cap. It shows two views of the cap (50) being twisted relative to the lancet body (10). Red arrows indicate the direction of twisting. The label "Breakaway Points" points to the junction between the cap and the body, where the cap is designed to detach.
Starnes '440, 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.*, 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

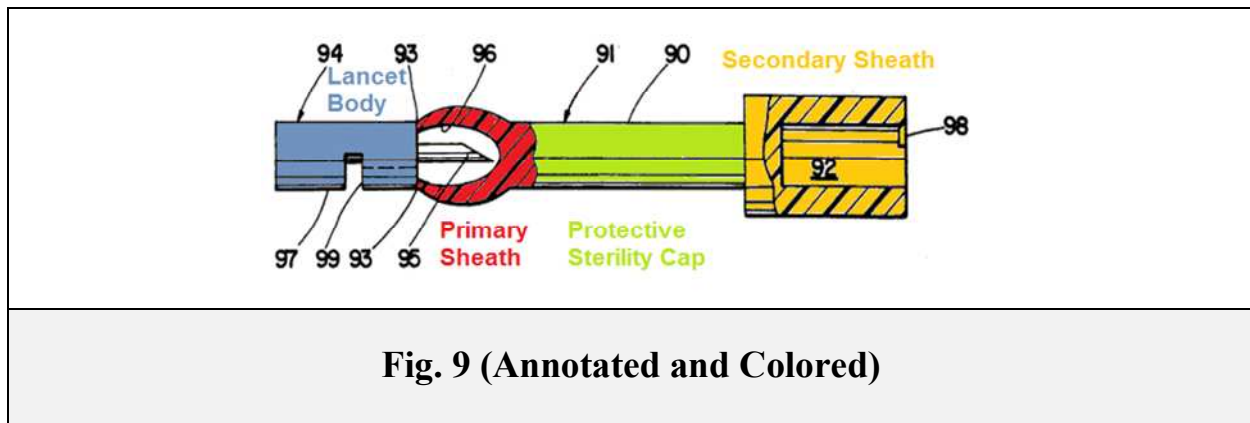
that because the breakaway points in Figure 9 are not broken, the needle has not yet been used for sampling or testing, and therefore, remains sterile.

12. *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.

13. 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”

14. 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.

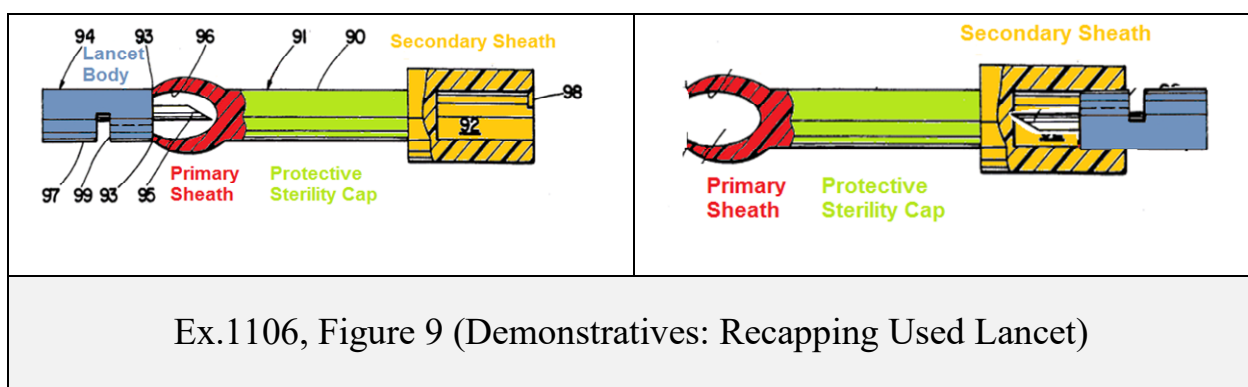


15. Coe teaches that “[a]fter use, the lancet is inserted (point first) into the extractor cavity...for safe handling and disposal.” Ex. 1106, 5:33-38. I understand this to refer to pushing the lancet sharp 95 into a hollow cup-like sheath of the extractor 91. Ex.1106, 24-25.

16. 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*.”

17. 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.

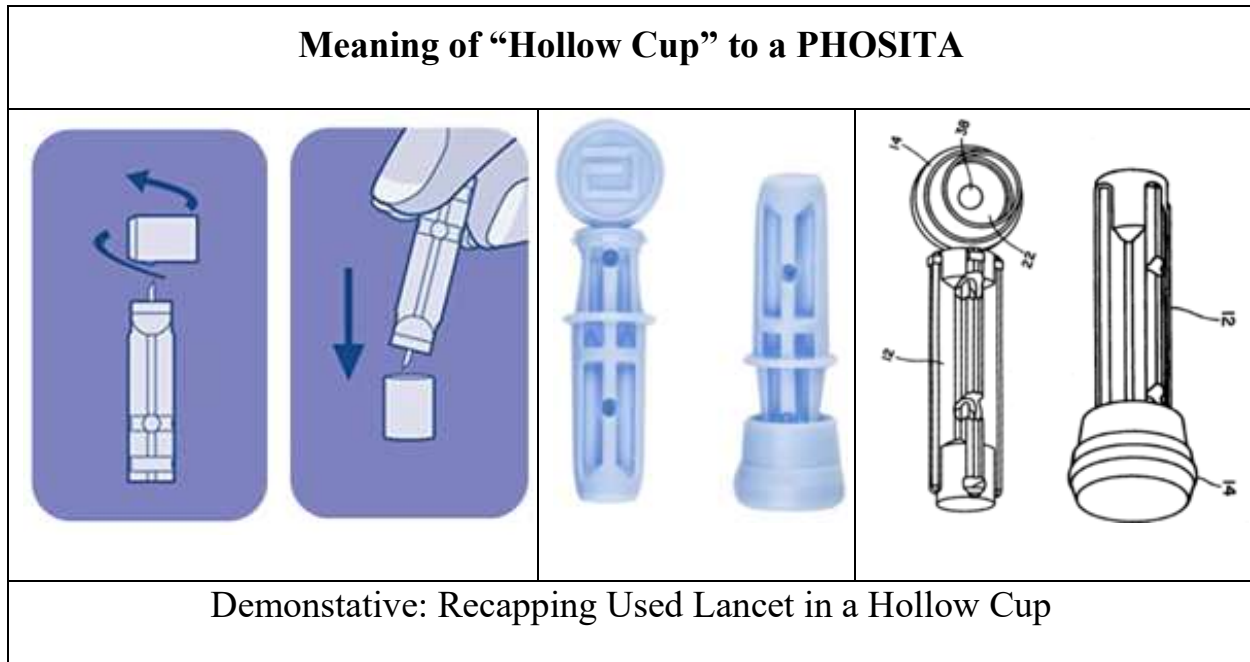


18. To prevent inadvertent needle sticks after use but prior to disposal, many conventional caps also include a hollow cup so the user can safely dispose the lancet after it has been used. The needle sharp remains encased within the

hollow cup while the user finishes testing the blood sample and even after the lancet has been discarded.

19. 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

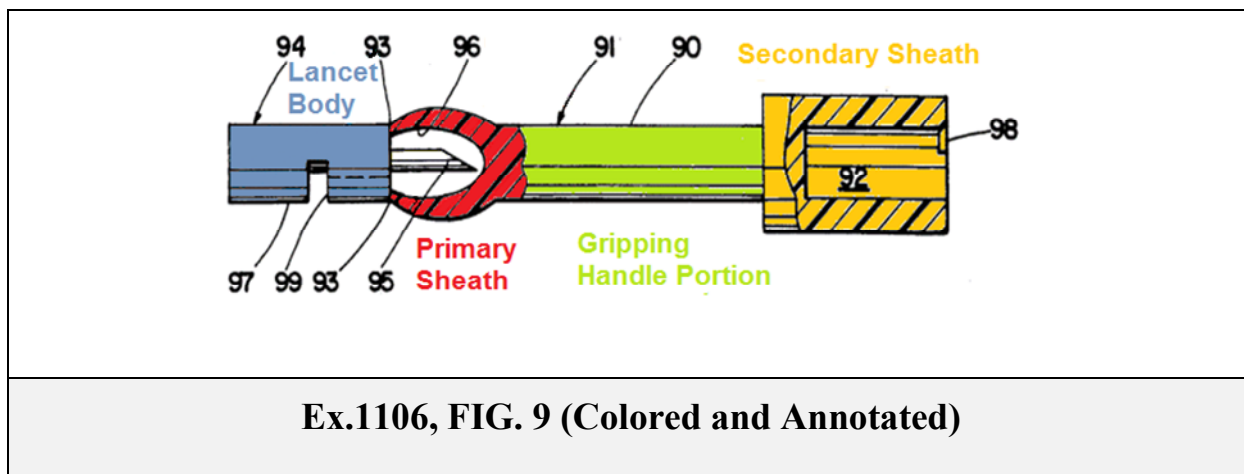
20. To prevent inadvertent needle sticks after use but prior to disposal, many conventional caps also include a hollow cup so the user can safely dispose the lancet after it has been used.



21. 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”

22. 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*).



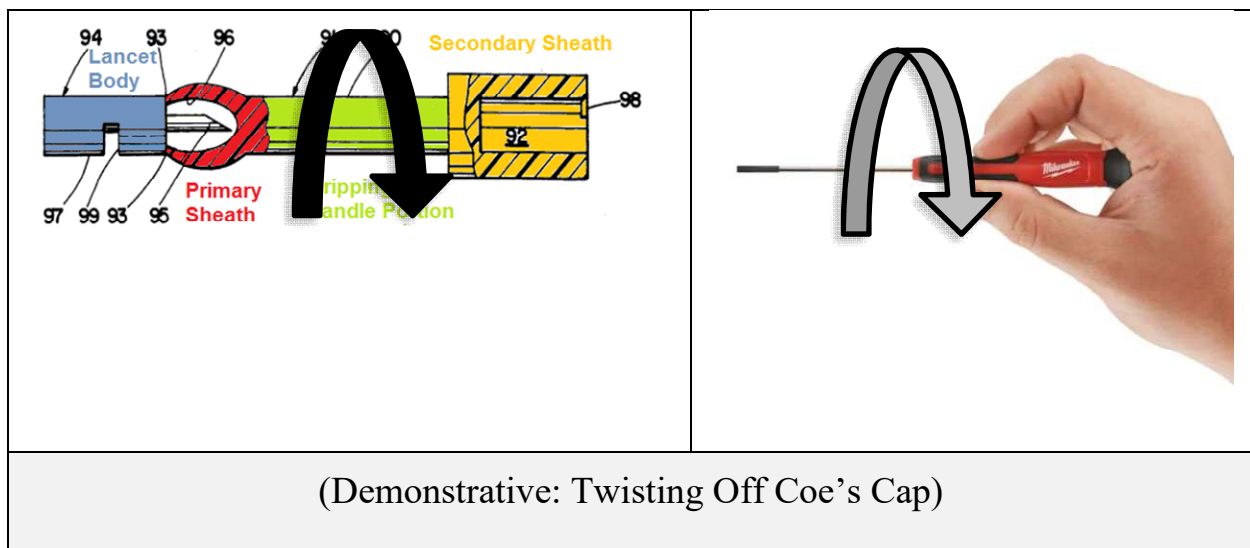
23. Many individuals with diabetes have trouble seeing and collecting a blood sample or even just juggling all of the different pieces during a test. Coe incorporates a “**handle portion**” into the protective cap 91 to provide users with a handle for twisting (*i.e.*, gripping) away the cap at breakaway 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.

24. 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.

25. 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.”

26. By having the handle portion 90 on the extractor 91 between 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.



27. 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.

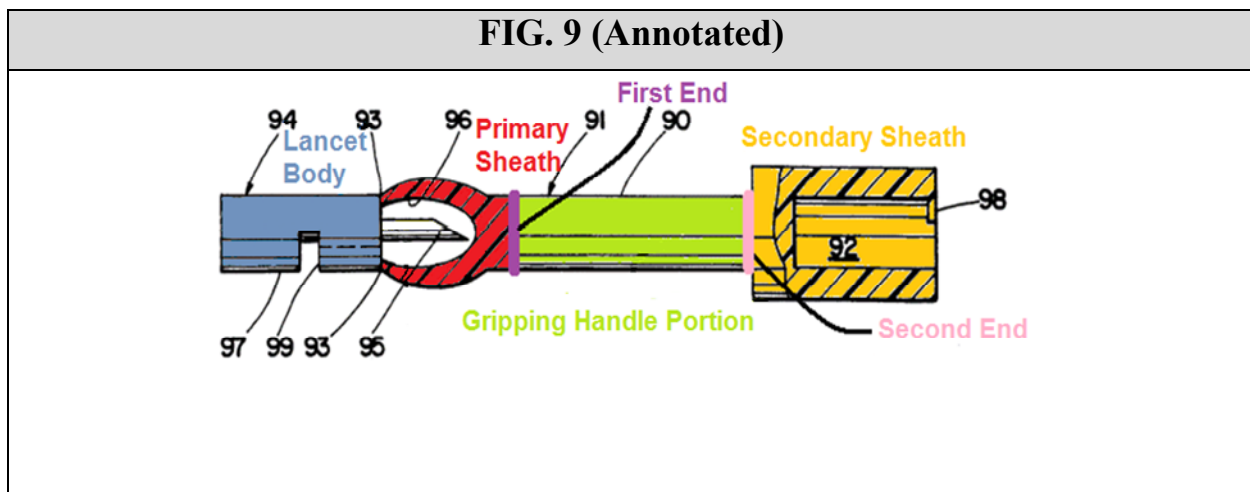
28. Coe's handle portion 90 provides leverage for applying rotational force to effectively twist the cap, making it easier to remove the protective cap 90 from the lancet 94. A PHOSITA would appreciate that the increased leverage provided by the handling portion better accommodates diabetic patients with limited dexterity by spreading the applied force efficiently across a longer contact area.

29. 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.

30. 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”

31. 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.



32. 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.

33. 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.

II COE RENDERS OBVIOUS CLAIMS 1, 6, 8, 14, and 18 IN VIEW OF SAKATA

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

34. 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).

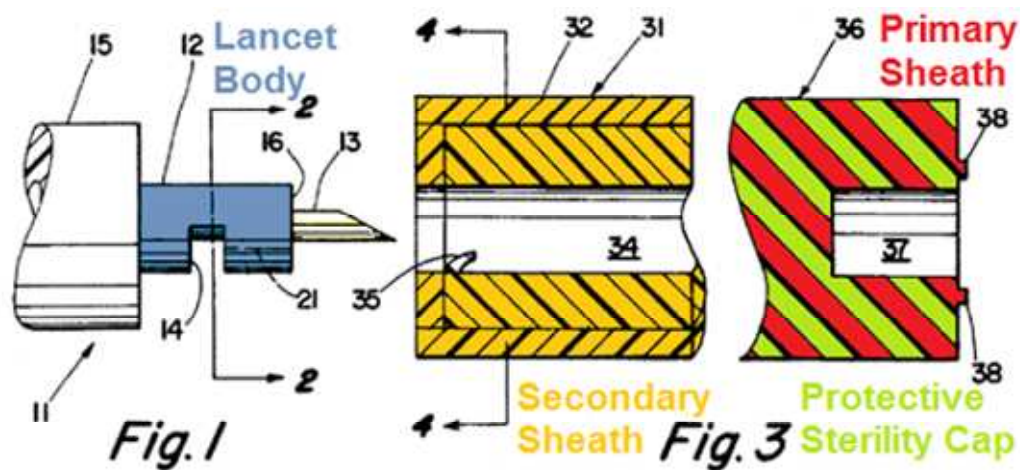
35. It would have also been obvious to a PHOSITA to embed the lancet needle into Coe's cap/extractor to not only protect the integrity of the needle tip, but also to protect the sterility of the needle and prevent contamination during post manufacturing packaging, shipping, and storage. To do so, a PHOSITA 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."

36. 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.

37. 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 6, 8, 14, and 18: The “Length” and “Lateral Span” of the Gripping Handle Portion

38. 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.

39. 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 (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.

40. 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.

41. 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.

42. 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.

III SAKATA RENDERS CLAIMS 1, 6, 8, 14, and 18 OBVIOUS IN VIEW OF MORITA.

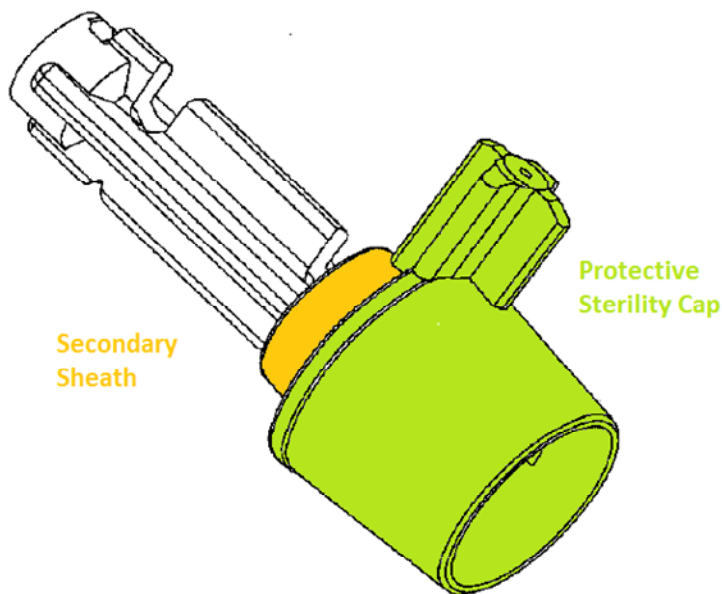
A. All Claims: "Primary Sheath for Initial Embedment"

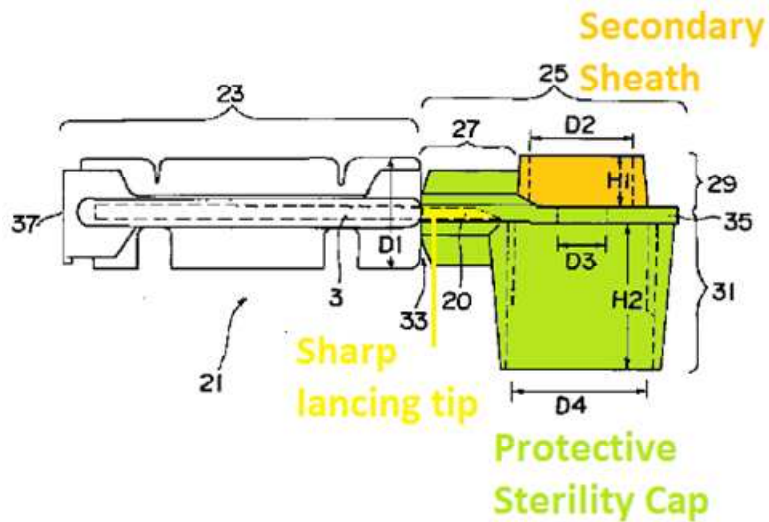
43. Sakata discloses this limitation by disclosing that Sakata's cap may include **"integral molding [being] used, [and] the puncture needle can be**

embedded in the cap part by insert-molding, so the sterilization of the puncture needle can be achieved.” Ex. 1107, ¶0013.

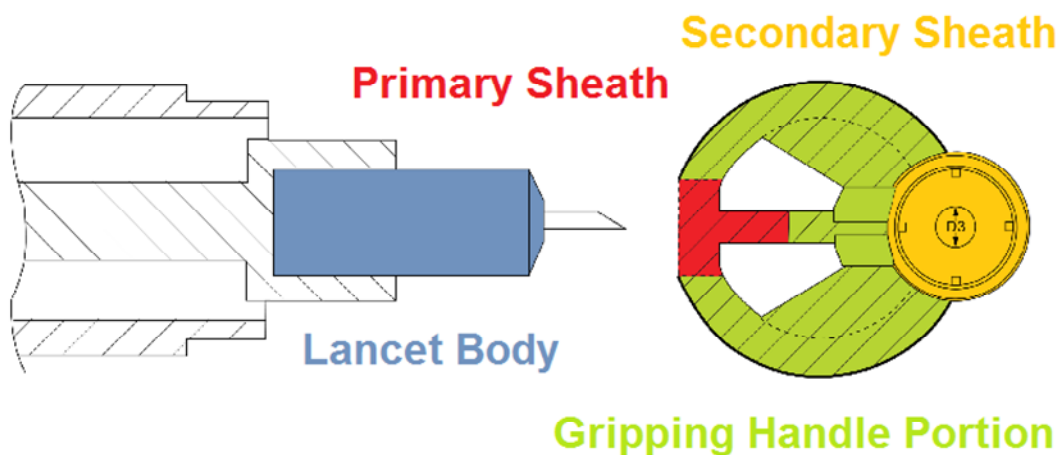
B. All Claims: “Secondary Sheath for Receiving”

44. 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.





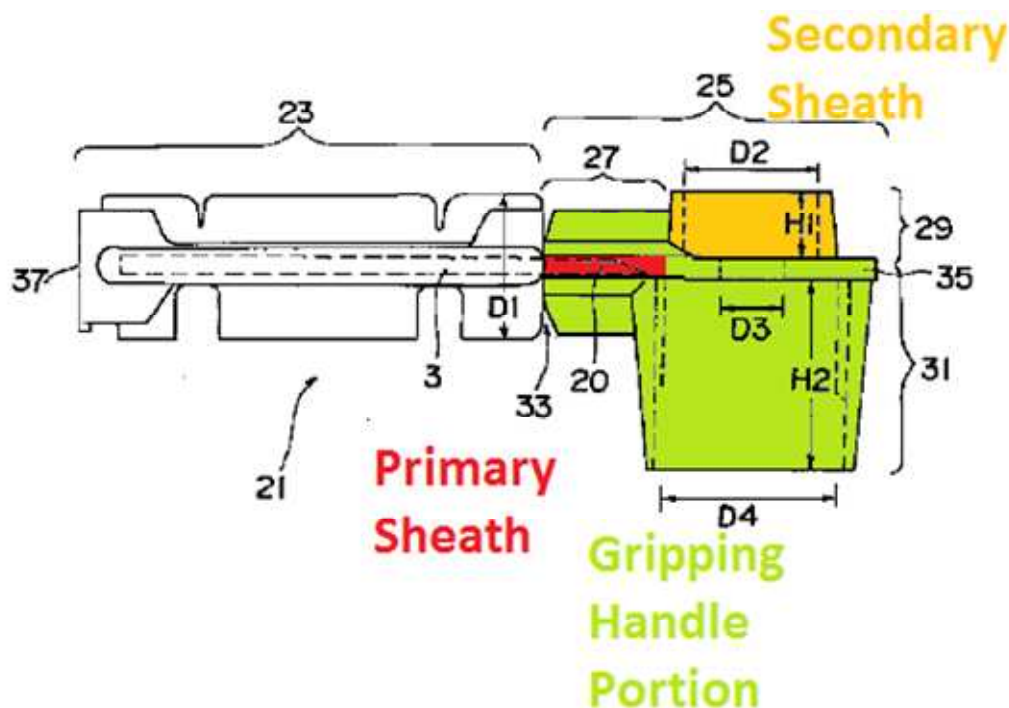
45. A PHOSITA would have been motivated to combine the features of Sakata and Morita, because Morita describes advantages associated with the secondary sheath, including “disposal with the lancet body inserted into the platform part does not pose a health and safety problem of infection.” Ex.1109 ¶0020. An illustrative embodiment of Sakata in view of Morita is annotated below.

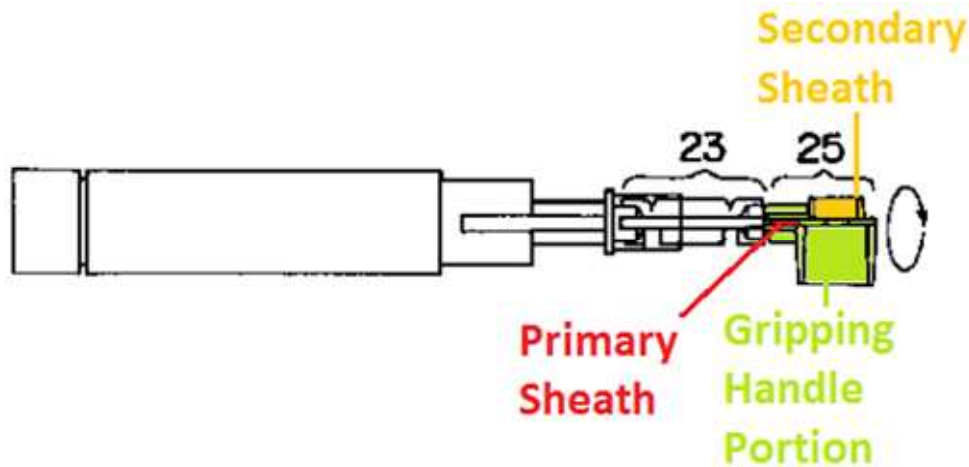


C. **All Claims: Gripping Handle Portion**

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

47. 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 6, 8, 14, and 18: The “Length” and “Lateral Span” of the Gripping Handle Portion

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

49. 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.

50. 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.*

51. 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.*

52. 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.*

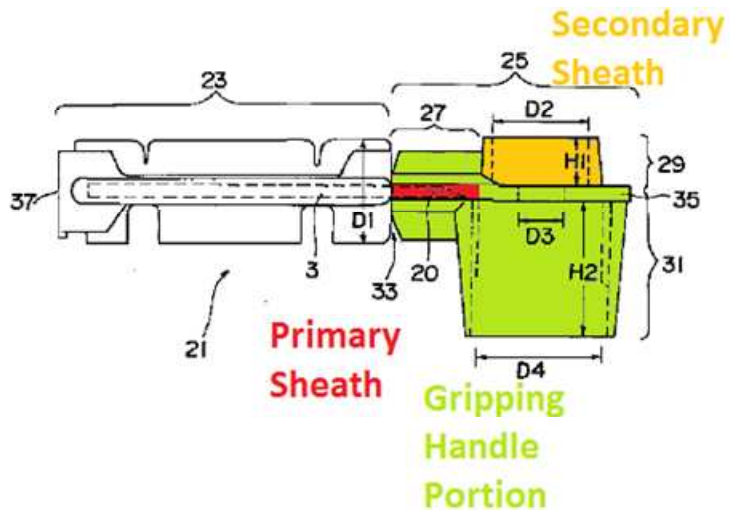
53. In my opinion, Morita explicitly teaches the limitations of claims 11-13, and thereby, in combination with Sakata, renders all the challenged claims herein as unpatentable.

IV COE RENDERS CLAIMS 6, 8, 14, and 18 OBVIOUS IN VIEW OF MORITA.

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

54. 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).

55. Morita also anticipates this limitation by disclosing a needle tip protective part having the structure and function of a primary sheath. Ex. [], Figures 3 and 5, ¶0016.



B. All Claims: “Secondary Sheath for Receiving”

56. As described above, both Coe and Morita each disclose secondary sheaths. *See supra* [].

C. All Claims: Gripping Handle Portion

57. I explained that both Coe and Morita each disclose the limitation of a “gripping handle portion” in sections [] above.

D. Claims 6, 8, 14, and 18: The “Length” and “Lateral Span” of the Gripping Handle Portion

58. I explained that both Coe and Morita each disclose these dimensional limitations. *See supra* [].

V SAKATA RENDERS CLAIMS 6, 8, 14, and 18 OBVIOUS.

401. In my opinion, it would have been obvious for a PHOSITA to try to render Sakata’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.

59. 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 (Morita, which is discussed in the Sakata reference) were larger than the lancet thickness. Sakata 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 Sakata 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 Sakata. Given Sakata's disclosure of a large diameter portion, and Sakata's objective of preventing deformation and damage to the sharp lancing tip, particular instructions to a PHOSITA are provided for dimensional limitations.

60. 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 dimensional

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

61. In section [], I explained how Morita modifies Sakata to meet the dimensional limitations of claims 6, 8, 14, and 18. For the same reasons, Iio, as modified by Morita, would meet the limitations of the dimensional claims.

XII. CONCLUSION

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

403. 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 both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the results of this trial.

A handwritten signature in purple ink, consisting of stylized initials followed by a long horizontal line.

Dated: June 7, 2023