

**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

**REBUTTAL EXPERT REPORT OF PAUL HATCH REGARDING NON-  
INFRINGEMENT OF U.S. PATENT NO. 8,840,635**

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## **I. INTRODUCTION**

1. My name is Paul Hatch. 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 give my opinion regarding certain patent infringement allegations asserted against LifeScan as provided in the Expert Report of John M. Collins (“Collins Report”) that is dated June 7, 2023. The Collins Report asserts that the Delica Plus Lancet Cap (the “Accused Product”) infringes claims 6, 8, 14, and 18 of U.S. Patent No. 8,840,635 (the “’635 Patent”).

3. I am being compensated for my work on this case at my standard consulting rate of \$450 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. 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. In addition, I expect that there may be additional exhibits that I create to illustrate and help explain the matters on which I will testify, including but not limited to annotated versions of figures in this report. 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. If I am asked to address any additional matters by the attorneys working on this matter, I will do so as appropriate. I also may offer explanations or descriptions of technology or devices related to those used in the patented technology.

## II. QUALIFICATIONS

6. My *curriculum vitae* (“CV”) is provided at **Appendix A**, 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 **Appendix A** by reference, below is a brief summary of my background.

7. I am the recently retired CEO of TEAMS Design USA, a global product design consultancy. I have over 25 years of product and industrial design

experience and have designed many healthcare and dentistry products, such as operation tools, MRI and CTA equipment, patient recovery chairs, IV poles, and tools for dental care. I designed many products for global companies such as Bosch, Siemens, Stryker, Dentsply, United imaging, Honeywell, Johnson Controls, Intel, and Bissell. I have also designed many mass-produced products that center around ergonomics and visual communication for ease of use (see examples below). In my company, I was actively involved in all phases of the development process, including the user research, idea conceptualization, styling, visual brand language, development, engineering and overseeing the final production stages.

8. I reside in Chicago, Illinois. I hold a Bachelor of Arts degree with honors (BA (Hons)) in Industrial Design from the University of Northumbria at Newcastle, United Kingdom. While studying to obtain my honors degree in Industrial Design, I took courses covering subjects including technical drawing, computer aided drawing, ergonomics, product styling and brand language, product evaluation, usability testing, production techniques, prototyping, mechanical engineering, and production techniques. I am currently a candidate for a doctorate degree in the Learning Sciences and have recently created and taught a graduate course on visual perception and cognitive psychology called ‘Perceptual Design’.

9. In the course of my work as a designer and managing teams of designers, I have gained an understanding of the training, knowledge, skills, and

abilities of a person skilled in the art of industrial design and mechanical engineering. Through this work, I have also gained an understanding of how a designer perceives and appreciates the functional merits of a product's design, and I use this understanding to opine on how a person of ordinary skill in the art ("POSITA") would answer questions raised in the examination of patent claims. Through user research of various types, I have also gained a good understanding of how consumers view, choose, and purchase products related to the fields I have designed in, including garden products.

10. I am the named inventor of over 50 design and utility patents.

11. I was recently nominated into the prestigious IDSA Academy of Fellows. I have also been awarded many design awards, including the "Design of the Decade Award" from Business Week. In 2016 I was elected to the board of IDSA as Director-at-Large. I have previously provided expert testimony in many other patent-related matters, a detailed list of cases for which I have provided expert testimony is attached at **Appendix B**.

#### **A. Industrial Design Work**

12. After completing my industrial design degree in the UK, I worked for Slany Design GmbH in Germany, which later changed its name to TEAMS Design GmbH. My design work there included many ergonomic studies for Robert Bosch power tools, which led to many innovative breakthrough features on power tools

and garden tools. I also designed handheld dentistry tools for market leading Durr Dental and designed many kitchen gadgets and tools for Leifheit and Silit, both well-known European companies respected for their quality innovative products. In 1998 I opened the company's first branch office, in Chicago, and our success there inspired the opening of three more branches across the world. While our work was wide-ranging, two aspects became common threads in our work and helped establish our reputation that lasts today; *ergonomics* and *visual brand language*.

### **1. Ergonomics at TEAMS**

13. The original founder of the company, Hans-Erich Slany is considered one of the twelve founding fathers of ergonomics in Europe. In the 1950s and 1960s he conducted detailed research into how people used tools on assembly lines and uncovered new insights on the effect of how tools are handled can have on blood flow and cramping, and can have knock-on effects across the entire body. He provided guidelines to Bosch on how engineers and designers should design touchpoints such as handles and knobs and wrote a book specifically on the design of hand-held objects. These same principles are still used by Bosch today, and are certainly at the heart of why Bosch tools are known for their good ergonomics and handling.

**Table 1: Hans-Erich Slany based Bosch's successful debut into the power tool market in 1956 using his own ergonomic principles.**

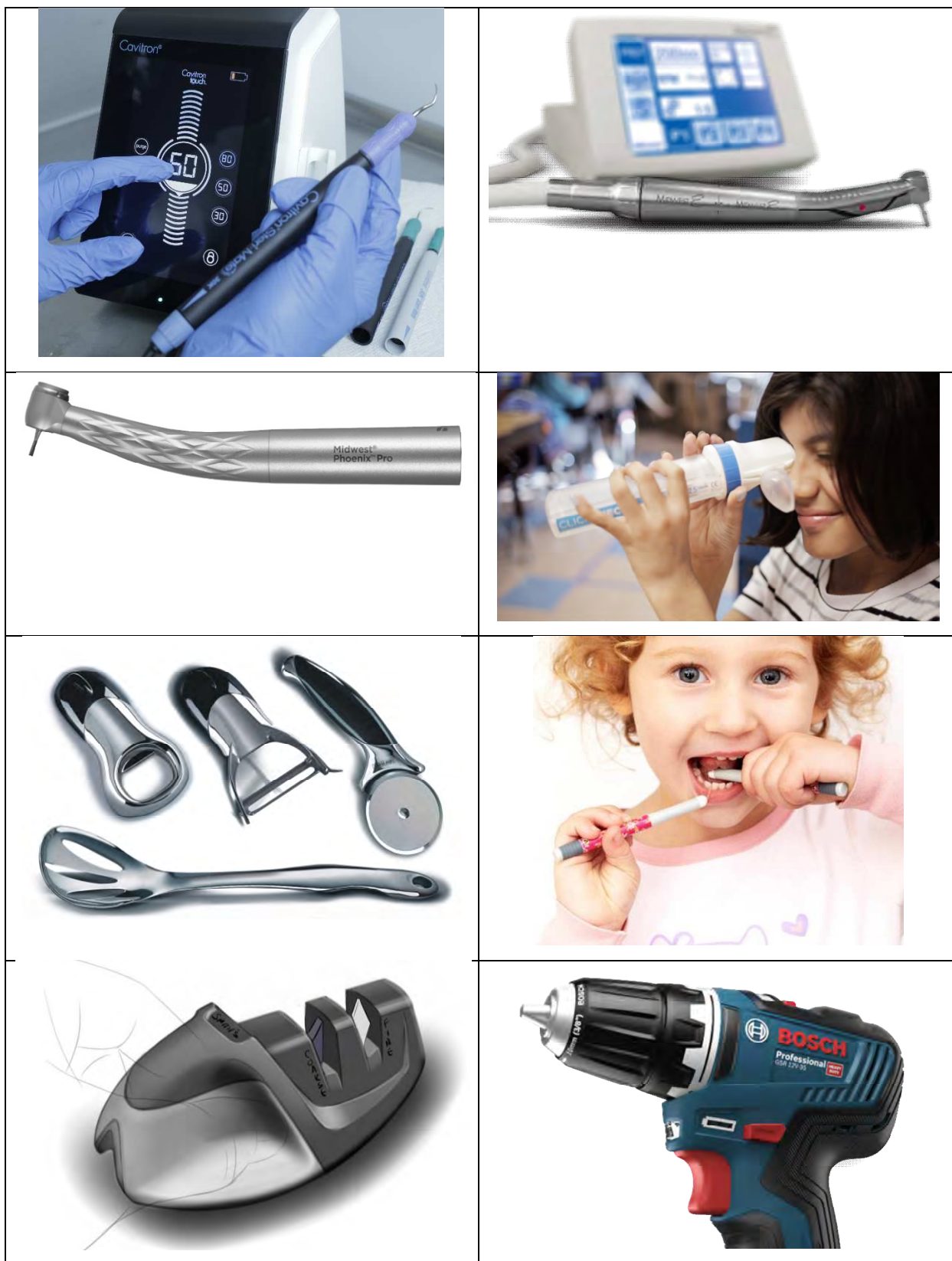


14. Mr. Slany's focus on ergonomics became an essential aspect of every design for every client we designed for, principles that are continued at TEAMS Design today. Sometimes the improved ergonomics are the main feature of a new product, but often they simply become an invisible but essential part of a design—something the user wouldn't notice unless it wasn't there.

15. I had already studied ergonomics as part of my industrial design degree, and some of my early student work and internship work already featured close attention to how the object conforms to the hand. My very first produced object, for example, was a cheese knife for WMF that featured an ergonomically

sculpted handle. However, what I learned from Mr. Slany went well beyond anything I had learned before and makes a great difference to ergonomic quality of my work even today. He taught that ergonomics exists in three separate domains; visual ergonomics, short term comfort and long term comfort. For example, short term comfort relates to how a handle feels in the hand, what positions it allows and what surfaces, edges and contours it has to guide the user. Long term comfort relates to providing angles and shapes that avoid hindering blood flow or providing enough space for the hand to move or re-grip as the muscles tire. **‘Visual ergonomics’** was even more helpful – Mr. Slany would claim that up to 50% of perceived comfort would rely upon the way something looked. For example, if a handle *looks* like it will be comfortable to grab, or a dial easy to turn, the user will expect it to feel that way even before trying it. Thus, it was essential that the visual language of touchpoints communicated to the user how the user expects to feel when using them.

|                                                                                    |
|------------------------------------------------------------------------------------|
| <b>Table 2: Good handling and ergonomics is a key attribute of most of my work</b> |
|------------------------------------------------------------------------------------|





16. This application of visual ergonomics to touch points is usually accompanied with design details that also communicate *how* to grip or move a handle, button, or lever. In industrial design this is called ‘**design semantics**’ or ‘**affordances**’. For example, if a circular dial is to be turned, the designer can communicate this affordance by putting gripping ribs or grooves around the outer perimeter. These physical details have two roles; first to communicate that the dial should be turned, and second to help provide grip. Often however, the physical

ribs or grooves are too small to actually provide friction to improve the grip but are still essential because of their role in visually communicating how the user should interact with the object. Some examples of my work below show a range of such design details that communicate and/or provide grip.

**Table 3: Design details help communicate how to interact with touchpoints.**

|                                                                                                                                                                                            |                                                                                                                                                                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  <p>The protruding ribs show where and how the user should open or close the jaws of these calipers.</p> |  <p>The grooves on the volume dial on these headphones show that this can be turned.</p>                     |
|  <p>The protruding ribs on this dial also communicate that this can easily be turned.</p>               |  <p>The spacing and size of ribs or grooves can vary, but still communicate a turning ‘design semantic’</p> |



Here in a non-rotational shape, the protruding ribs signify where to push.



The ribs/grooves on this chuck are very broad to allow for maximum surface contact with the hand, while offering substantial grip, compared with if it were smooth.



We were not able to make large protrusions on this dental device, so these thin ribs still provide visual communication and some amount of friction.



The watch features ribs and grooves on both touchpoints, providing not only ergonomic advantages but also adding to the look and feel of the product as a whole.



The fine ribs on the sides of this shaver clearly show a hand gripping area, and do not signify a push or twist semantic.



Designed by Hans-Erich Slany, this 1959 Zeiss camera also demonstrate the use of 'grippy' ribs to communicate a turnable dial.

17. In one such project for World Kitchen, we were tasked to find a “unique approach” to kitchen knives for their Chicago Cutlery line. Among other research, we attended a ‘cutting class’ at a local Cooking School where we found that professionals are trained to grip the knife further forward of the handle—essentially on the blade itself. Doing so gave the user more control and cutting force, making cutting remarkably easier. We aimed to find a way for the design of the handle to encourage the user to position their hand further forward but without feeling like they are grabbing the blade. This guidance would have to be done by the look and feel of the knife handle alone, as we could not rely on retraining the user through advertising or a printed manual. After much experimentation we found a shape that felt quite natural to grab in the ‘pro position’ but also

comfortable to hold in a traditional manner. We removed the traditional bolster that puts a wall between the blade and the handle, and made the handle and blade seemingly merge. We also added some design details to visually communicate the primary ‘pinch point’ area for the fingers to grab. We tested the prototypes against traditional knives by having users cut vegetables with each and asked only which knives had the sharpest blades (where the blades were identical). We found users naturally grabbed the knives in the pro position for most tasks, and 98% remarked that the knives with the new design had much sharper blades. The knives went into production and, despite a higher cost, became one of the brand’s all-time bestselling products.

**Table 4: Ergonomics was the key breakthrough in these Chicago Cutlery kitchen knives**



We explored initial ideas with many simple prototypes.



Very small changes made great differences in the feel. Here, we see several stages of detailed refinements as we increased the fidelity of the prototype material.





## **2. Visual Brand Language at TEAMS**

18. TEAMS Design was also well-known for creating the look and feel for entire products lines. This is commonly known as Visual Brand Language (“VBL”), where products within a brand will share many visual characteristics and therefore be intuitively recognizable as being from that brand and create a sense of trust with potential purchasers. A good VBL will not just share a color and graphic scheme across its products, but also use common forms (such as being generally geometric or rounded) and use common visual details (such as how to communicate touch points, styling lines or air vents). Because a new VBL sets a brand’s styling direction for the entire product line, it is vital that this new look is clearly visually differentiated from competitors. Therefore, another consideration in the design exploration and eventual strategy definition was on how much ‘elbow

room’ the new language would have—that is how different the forms and details are to existing competitors.

19. For example, in 2005 Robert Bosch power tools asked us to revitalize their entire product line through a new VBL, a new styling guideline that would define the look of all new products over the next decade. This new language should be inherently recognizable across objects of different materials, sizes, and in differing markets. To do so, we first analyzed which aspects consumers already related to Bosch, and which functional /performance aspects they most valued in each tool type (irrespective of brand). We then found five common ‘attributes’ (such as ‘durable’ or ‘trustworthy’) that would both fit Bosch’s existing reputation and align to consumers’ needs. We then explored how these attributes could be communicated by visual aspects of the form and design details by designing several optional designs of each of their key products. We built these as prototypes and tested them with users, and chose the design direction that most evoked users to describe it in words similar to the attributes we used. We then created designs of each of Bosch’s key products, thus creating an example for the design of each tool, as the existing ones gradually were replaced.

20. We applied a similar VBL strategy to whole product lines of several other firms, as can be seen below in the table. Some were to refresh an existing

line (such as Bosch or Bissell), whereas other VBL projects were to debut a new category for an existing brand (such as Fiskars or Pyrex).

**Table 5: Finding the right visual differentiator is the key to creating a successful VBL.**



Although the shape and usage may vary, the VBL helps ensure each product gives the same impression of “Bosch-ness.”



The new VBL for Bissell.



Pyrex extended their product range into kitchen tools and gadgets. This was a new VBL that aimed to capture the approachability and trust of their existing bakeware products.



Fiskars ventured into DIY products and needed the VBL to reflect on their existing reputation from office products and garden products while being completely unique.



Mr. Coffee needed a VBL to elevate their reputation from being a low-cost option to being able to sell high-end coffeemakers and espresso makers.



This VBL for Sunbeam echoed how their users considered them to be a friendly company that has simple but reliable products.

### III. SUMMARY OF OPINIONS

21. It is my opinion that, for the reasons stated below, the Delica Plus Cap does not infringe the asserted claims of U.S. Patent No. 8,840,635.

### IV. MATERIALS CONSIDERED

22. To prepare this report and to develop the opinions expressed herein, I have reviewed the asserted '635 Patent, including its claims, specification, drawings, and prosecution history.

23. Moreover, I have considered key pleadings in the case, documents filed, and documents produced by Facet, LifeScan, and the Court throughout this litigation. I have considered Plaintiff's infringement contentions. I have also considered several decisions and orders of the Court, including the Court's Order Regarding Claim Construction published on January 20, 2023.

24. 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.

25. 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.

26. 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.

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

28. A list of all of the documents, testimony, and things I have considered is included in **Appendix C**.

## **V. LEGAL STANDARDS**

### **A. Introduction**

29. In formulating my opinions, I have been instructed to apply certain legal standards that apply concerning non-infringement. I am not an attorney and I do not expect to offer any opinions or testimony regarding what the law is.

30. All of the opinions that I provide herein are provided through the lens of a POSITA. Based on my knowledge, experience, and review of the '635 Patent, it is my opinion that a POSITA 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.

31. My understanding of the law as it pertains to non-infringement of the asserted claims of the '635 Patent is described briefly as follows.

### **B. Legal Standard for Infringement**

32. I have been informed that patent infringement under 35 U.S.C. § 271(a) requires making, using, offering to sell, or selling a patented invention within the United States, or importing a patented invention into the United States, without authorization. I understand that determining whether an accused product constitutes the “patented invention” involves two steps: First, each claim must be construed to determine its proper scope and meaning to one of ordinary skill in the art; and second, to find infringement by an accused product or method, the patentee must show the presence of every element of a given claim (literal infringement) or its equivalent (infringement under the doctrine of equivalents or “DOE”) in the accused product.

33. I have also been informed that a system that does not infringe a patent claim literally may still infringe under the DOE if each and every claim limitation is at least equivalently present. A claim limitation is equivalently satisfied by an accused device if there exists only insubstantial differences between the claim

limitation and the accused aspect of the device. I understand that a method for determining whether infringement under the DOE occurs if the element or step in the accused device performs substantially the same function, in substantially the same way, to obtain substantially the same result as the claim limitation. I also understand that I cannot ignore any claim limitations.

34. I also understand that the doctrine of equivalents can be limited by prosecution history estoppel, prior art, and disclosure in the patent itself that was not explicitly claimed.

35. I was informed that if a theory of equivalents would entirely vitiate a particular claim element, then application of the doctrine of equivalents is improper.

36. I understand that if there is no infringement of an independent claim, there can be no infringement of a claim dependent thereupon, since a dependent claim incorporates all of the limitations of the base independent claim.

37. I understand that infringement can be “direct” or “indirect.” A party directly infringes a patent if it makes, uses, sells, or offers to sell a product or method that meets all the limitations of a patent claim. Direct infringement requires that the party accused of infringement actually performs or controls the infringing acts.

38. Indirect infringement occurs when a party “contributes to” or “induces” the direct infringement of another. I understand that a party can only be a contributory infringer only if (1) someone other than the indirect infringer directly infringes a patent’s claim; (2) the accused contributory infringer sold, offered for sale, or imported a component of an infringing product or product used in an infringing method; (3) the component or product is not a staple article or commodity capable of substantial non-infringing use; (4) the component or product is a material part of the claimed invention; and (5) the accused contributory infringer knew that the component or product was especially made or adapted for use in an infringing product or method.

39. I understand that a party can only be liable for inducing the infringement of another under 35 U.S.C. § 271(b) if (1) the alleged inducer aided, instructed, or acted with the intent to cause acts of another that constitute direct infringement; (2) the alleged inducer knew of the patent; (3) the alleged inducer knew that the actions of the direct infringer would cause direct infringement; and (4) a direct infringer actually infringed a patent claim.

40. I also understand that, where an alleged inducer instructs end users to use a product in a non-infringing manner and does not instruct end users to use a product in an infringing manner, there can be no liability for inducement.

41. I understand that patent infringement under 35 U.S.C. § 271(c) consists of an offer to sell, or sale within the United States or the importation into the United States of “a component of a patented machine, manufacture, combination, or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use.”

### **C. Legal Standard for Lost Profits and Non-Infringing Alternatives**

42. I have also been asked to consider and expect to testify about potential non-infringing alternatives and certain aspects of their design.

43. I understand that non-infringing alternatives are relevant to a calculation of a reasonable royalty rate and lost profits for patent infringement. I understand that for an alternative to be “commercially acceptable” it (i) must produce the same degree and type of benefits for the defendant as the infringing apparatus, (ii) must not generate any substantial additional costs, and (iii) must use a technology that was available and proven as of the date of a hypothetical negotiation between the patent holder and the infringer.

### **D. Legal Standard for Willfulness**

44. I understand that infringement is willful when the infringer was aware of the asserted patent, but nonetheless acted despite an objectively high likelihood that its actions constituted infringement of a valid patent.

#### **E. Legal Standard on Claim Construction**

45. 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.

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

47. 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.

48. 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. THE '635 PATENT**

### **A. Overview**

49. The '635 Patent, titled “Lancets with Improved Coupling Features and Sterility Caps,” relates generally to the field of medical devices, and more specifically, to lancets and lancing devices for sampling and testing. *See* '635 Patent at 1:17-20.

50. The '635 Patent describes multiple lancet and protective lancet endcap configurations. In particular, the '635 Patent provides for “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.” '635 Patent at 1:66-2:3.

51. The '635 Patent also claims a “protective sterility cap for a lancet, the sterility cap comprising a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein, and a gripping handle portion extending from the primary sheath.” *Id.* at 2:21-25.

52. Figures 5A-5E of the '635 Patent show a protective sterility cap or cover or a lancet according to an example form of the invention claimed. *Id.* at 5:66-6:1; *id.* at Figs. 5A-5E.

**Figures 5A – 5E of the '635 Patent Showing Example Protective Sterility Cap of Invention**

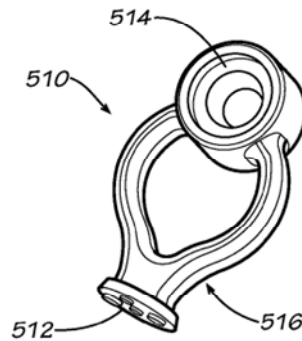


**FIG. 5A**

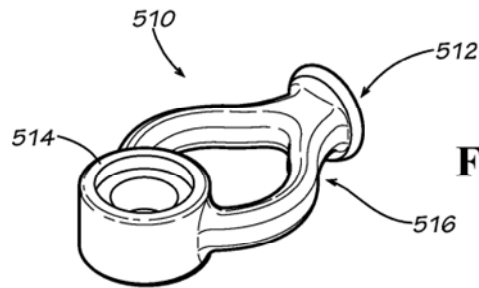


**FIG. 5B**

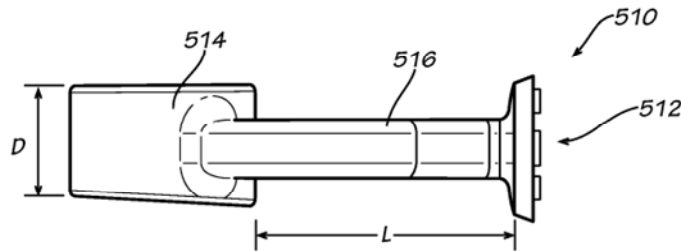


**FIG. 5C**

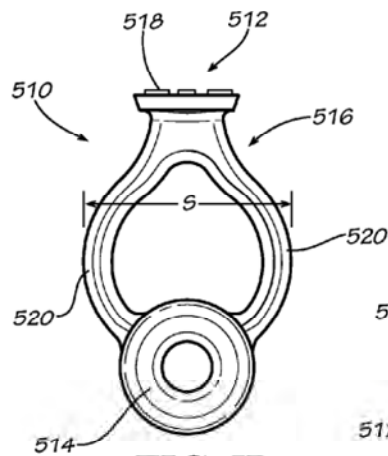


**FIG. 5D**

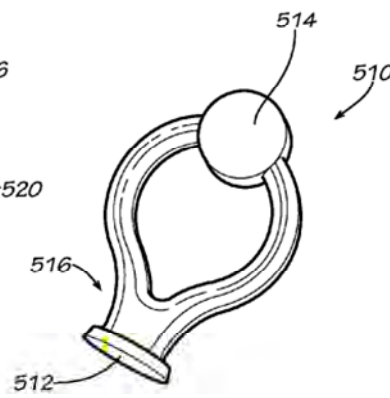


**FIG. 5E**

53. The '635 Patent describes that the “expanded dimensions of the endcap allows for easier use by persons with limited dexterity or vision, and permit the use of smaller lancets with lower mass and/or finer gauge needles, which may reduce pain.” *Id.* at 6:66-7:3.

54. Regarding the benefits of the '635 Patent, the specification provides:

The protective/sterility cap or cover provides an intuitive modality for users to grab when handling a lancet. Additionally, the 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.

*Id.* at 7:26-33.

#### **B. Provisional Application No. 61/084,456**

55. The '635 patent claims priority to Provisional Application No. 61/084,456, (“the provisional application”, or the “'456 application”) filed July 29, 2008.

56. The provisional application includes multiple lancet and protective lancet endcap configurations. The figures of the protective sterility cap (figures 2a-2c) in the provisional application lack any reference numerals, reference letters, and reference dimensions.

57. The provisional application’s cover sheet lists the same inventors as the listed inventors of the '635 patent.

### **C. Non-Provisional Application No. 12/510,701**

58. The '635 Patent also claims priority to Non-Provisional Application No. 12/510,701, ("the '701 application") filed July 28, 2009.

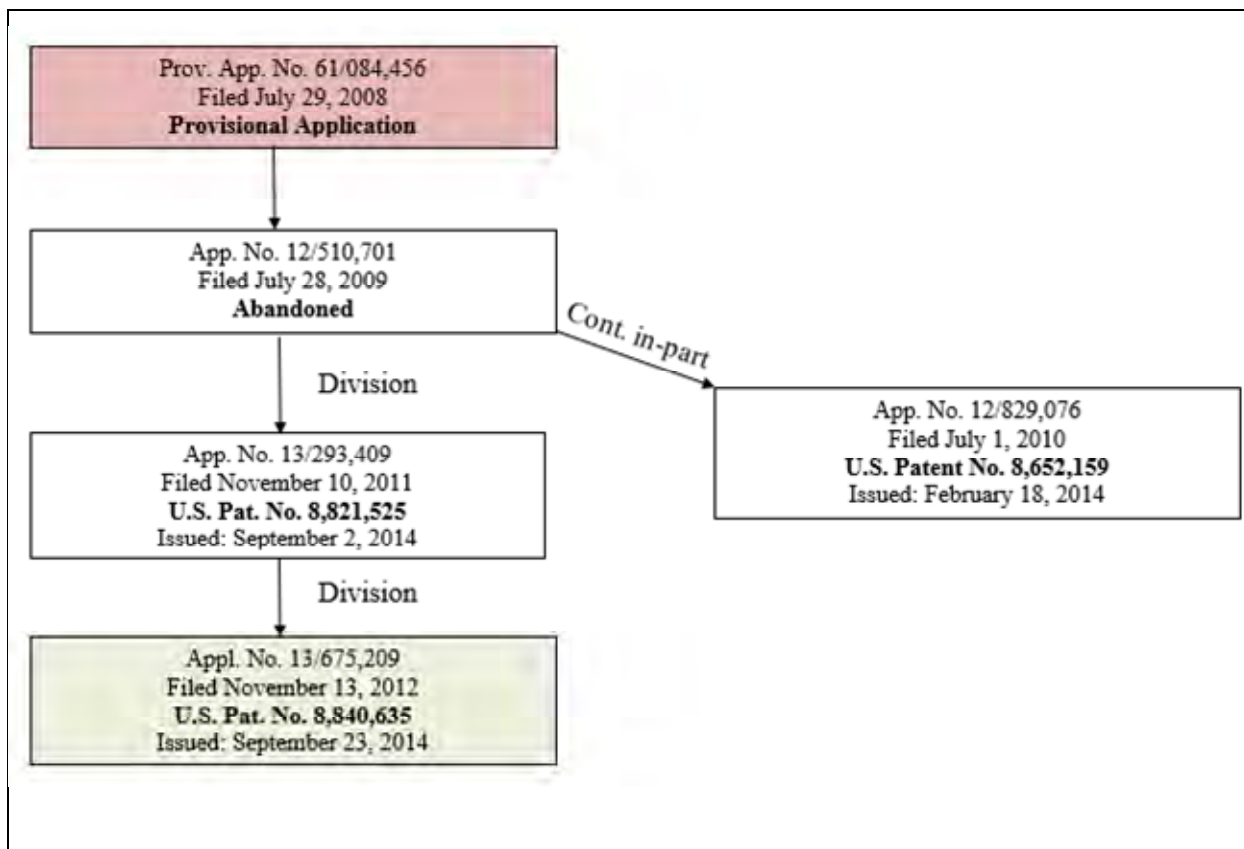
59. The listed inventors of the non-provisional application are the same inventors as the listed inventors of the '635 Patent.

60. The non-provisional application first had 35 claims, with claims 12 and 18-20 possessing common limitations with the '635 Patent's claims 1, 6, 8, 14, and 18.

61. The '701 application was abandoned for failure to respond to an office action on June 15, 2012.

62. The '635 Patent is a division of U.S. Application No. 13/293,409, filed November 10, 2011 and issued as U.S. Patent No. 8,821,525 on September 2, 2014. U.S. Patent No. 8,821,525, is also a division of the '701 application. U.S. Patent No. 8,652,159 is a continuation-in-part of the '701 application.

|                                    |
|------------------------------------|
| <b>Priority of the '635 Patent</b> |
|------------------------------------|



#### D. Prosecution History of the '635 Patent

63. 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 (FACET\_002203) at 1. The applicant claimed priority to the July 29, 2008 filing date of Provisional Application No. 61/084,456. *Id.* at 46. 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.* at 73-77.

64. I understand that 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.* at 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.* at 94-97. The Applicant then amended claim 1, canceled claim 3, and added 10 claims. *Id.*, 73-79.

65. 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.* Regarding the claims involving the “gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness,” the Examiner indicated 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, 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.*

66. 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.

## **E. Claim Construction**

67. I understand that on January 20, 2023, Judge Mark C. Scarsi of the Central District of California issued an Order Regarding Claim Construction for certain terms of the '635 Patent. I understand that both parties submitted competing claim constructions to the Court before the January 20, 2023 Order was issued. Below I have summarized my understanding of the parties' proposed constructions and the Court's ultimate decision regarding the construction of certain terms in the '635 Patent. I have accepted the Court's constructions in reaching my opinions regarding non-infringement of the '635 Patent.

68. I understand that the parties agreed that the claim term, "attached at a[n] . . . end of the gripping handle portion" of claims 1 and 14, was to be given its plain and ordinary meaning.

69. I understand that the parties proposed different constructions for the term "a secondary sheath for receiving" from claims 1 and 14, with each party providing the below constructions:

| Each Party's Proposed Construction for "a secondary sheath for receiving"                                                                                                                                                                                          |                                                                                                                                                                                     |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Facet's Proposed Construction                                                                                                                                                                                                                                      | LifeScan's Proposed Construction                                                                                                                                                    |
| Plain and ordinary meaning.<br><br>To the extent the Court elects to state the meaning explicitly, it should do so in context, as follows: "a cover separate from the primary sheath, the cover being configured to encase the sharp lancing tip of a used lancet" | Indefinite.<br><br>Alternatively, this claim should be construed as: "a hollow receptable with an interior chamber, the hollow receptable being configured to encase a used lancet" |

70. I understand Facet provided the following argument for its proposed construction of “a secondary sheath for receiving”:

Facet argues the specification defines “a secondary sheath for receiving” in relation to “a primary sheath,” “a gripping handle portion,” and the functions of the primary and secondary sheaths. FOB at 11; *see also* ’635 Patent, Claims 1 and 14. As disclosed in the specification, the sharp tip of a used lancet is received by the secondary sheath. ’635 Patent at 6:1-9. Facet argues the way in which the secondary sheath receives the used lancet tip depends on the structure of the secondary sheath. FOB at 12. In some embodiments, the specification describes the secondary sheath generally as a “protective cover” or “for placement over” a used lancet tip. *See id.* at 1:66-2:8 and 2:30-35. In one embodiment, the secondary sheath has a cup with “a hollow interior chamber” into which the lancet tip is received. *Id.* at 6:35-40. In another embodiment, the specification discloses embedding the sharp into the secondary sheath. *Id.* at 7:12-14 and 8:24-27. Thus, the secondary sheath may receive a used lancet tip by either embedding or enclosing the tip. Facet argues that LifeScan’s construction is too narrow because it is limited to the “hollow interior chamber” embodiment and exclude the embedding embodiment. FOB at 13. Facet further argues that the dictionary definition for “receive” does not warrant such a limited construction. *Id.* at 14.

Claim Construction Order at 7:22-8:9.

71. I understand LifeScan provided the following argument for its proposed construction of “a secondary sheath for receiving”:

LifeScan also argues that Facet disavowed an embedding function of the secondary sheath during prosecution of the ’635 Patent. LSOB at 9. For instance, in response to a non-final office action, Facet distinguished the Morita reference by arguing the “lancet body 46 is not disclosed or suggested to provide for receiving the sharp lancing tip of a used lancet.” “File History,” ECF No. 96-2 at 15. LifeScan argues that Facet’s statement is a disavowal because the lancet body of the Morita reference can be used to embed the tip of a used lancet. LSOB at 9. In response to a final office action, Facet distinguished the Gorbahn reference by arguing it “discloses a sheath 4 for protecting the hypodermic needle 3 prior to its use, but does not

disclose or suggest protecting the needle after its use.” File History at 7. LifeScan argues that Facet’s statements admit the “sheath 4” is a hollow receptacle. LSOB at 10. LifeScan also points to two other Facet patents in the same family as the ’635 Patent as supporting the “hollow receptacle” construction. LSOB at 11–12. LifeScan argues the teachings of these patents are relevant to claim construction here because they claim aspects of the commercial embodiment of the ’635 Patent. *Id.* Finally, LifeScan argues dictionary definitions for “sheath” and “embed” support its construction. *Id.* at 12–13.

Claim Construction Order at 8:20-9:7.

72. I understand that for its proposed construction of “a secondary sheath for receiving,” LifeScan argued in the alternative that the term “sheath” would be indefinite if construed to have a broader scope than supported by the specification as the specification “consistently and exclusively discloses the secondary sheath as a hollow cavity.” *Id.* at 9:8-11.

73. I understand in response to LifeScan’s argument, Facet argued:

Facet reiterates that LifeScan’s construction is too narrow because the specification describes two embodiments (the “hollow cup” embodiment and the “flat panels” embodiment) for the secondary sheath. FRB at 8; *see also* ’635 Patent at 8:24–27. The fact that the claims use the term “embedding” with respect to the primary sheath and “receiving” with respect to the secondary sheath does not indicate that the secondary sheath cannot embed a used lancet tip. FRB at 8–9. Rather, the broader term “receiving” indicates that “the secondary sheath may come in a variety of forms.” *Id.* at 9. With respect to LifeScan’s prosecution history disclaimer arguments, Facet argues that it did not disclaim an embedding function of the secondary sheath. *Id.* at 10. Rather, Facet argued that each of the identified references entirely lacked a secondary sheath for protecting a needle *after* use. *Id.* Facet asks the Court to reject LifeScan’s arguments regarding the commercial embodiments disclosed in the related ’159 and ’664 Patents because the intrinsic evidence does not limit “secondary sheath” to a “hollow receptacle.” *Id.* at 11–12. Facet also offers a dictionary definition for

“receive” and expert testimony in support of its construction. *Id.* at 13. Finally, Facet argues its construction would not render “secondary sheath” indefinite because the specification teaches that the secondary sheath can “cover the sharp lancet tip by embedding or enclosing” it. ’635 Patent at 8:24–27. Facet also argues that LifeScan does not apply the correct legal test for indefiniteness. FRB at 14.

Claim Construction Order at 9:15-10:4.

74. I understand that LifeScan also responded as below:

LifeScan responds that Facet relies on an unclaimed embodiment to support inclusion of the “embedding” function. Specifically, LifeScan argues the “flat panels” embodiment “dissuades [] use as a secondary sheath” and is not related to the “receiving” language used in the claims. LSRB at 9. LifeScan also expands on its prosecution history disclaimer argument with respect to Morita. LSRB at 10. Facet amended Claim 1 to include the language “a secondary sheath for receiving the sharp lancing tip of a used lancet” to overcome Morita. *Id.* at 11. LifeScan argues Morita discloses a lancet body including a flat surface which can be used to embed to the tip of a used lancet. *Id.* at 12. Accordingly, the amended claim language should not be construed to include the embedding function. *Id.* LifeScan also reiterates its arguments regarding the related Facet patents and dictionary definitions. *Id.* at 13–14.

Claim Construction Order at 10:5-15.

75. I understand that the Court analyzed the construction of the term “a secondary sheath for receiving” as below:

First, the Court addresses whether the claims and written description of the ’635 Patent limit the “secondary sheath” to a “hollow receptacle.” The language of claims 1 and 14 provide no basis to limit construction to a “hollow receptacle.” Claims 1 and 14 use the terms “initial embedment” in relation to the primary sheath and “receiving” in relation to the secondary sheath, respectively. ’635 Patent, Claims 1 and 14. Thus, there is a presumption that the terms “for initial embedment” and “for receiving” are not synonyms. *See Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 93 F.3d 1572, 1579 (Fed. Cir. 1996). However, “receiving” could mean

something entirely different than embedding, as LifeScan contends, or it could encompass embedding and other functions, as Facet contends. In either scenario, “receiving” and “initial embedment” would have different meanings. Therefore, the Court turns to the remainder of the intrinsic evidence to resolve this dispute. . .

The best guide to determine the meaning of “receiving” within the context of the ’635 Patent is the specification. *Phillips*, 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582). To summarize the invention and embodiments, the written description of the ’635 Patent explains that “[a]fter use, the endcap may be replaced to cover the sharp lancet tip by embedding or enclosing the lancet tip into the secondary shroud or sheath portion of the endcap.” ’635 Patent at 8:24–27. The specification describes two embodiments, one directed to enclosing (the “hollow cup” embodiment) and one directed to embedding (the “flat panels” embodiment) in detail. *See id.* at 6:35–40 and 7:4–19, respectively. The “receiving” language appears in connection with each of these embodiments. *Id.* Accordingly, LifeScan’s construction is too narrow because it eliminates the “flat panels” embodiment. *See Vitronics*, 90 F.3d at 1583.

Next, the Court considers LifeScan’s prosecution history disclaimer arguments. The portions of the prosecution history LifeScan identified do not show any disclaimer of the “flat panels” embodiment. Instead, as Facet argues, the cited statements distinguish the prior art by pointing out that a separate, secondary sheath receives a used lancet tip. With respect to the Gorbahn reference, Applicant successfully argued:

In fact, Gorbahn does not disclose or suggest any type of sheath for containing the needle 3 after its use. Indeed, Gorbahn discloses sheath 4 for protecting the hypodermic needle 3 prior to its use, but does not disclose or suggest protecting the needle after its use.

File History at 7. With respect to the Morita reference, Applicant amended Claim 1 to include the limitations of dependent claim 3 (cancelled) and successfully argued:

“[T]he lancet body 46 is not disclosed or suggested to provide for receiving the sharp lancing tip of a used lancet. Morita

instead discloses that the convex portion 86 and the lancet body 46 (comprising the concave portion 88) are provided for interengagement therebetween, which provides for mounting the resin portion 82 (embedding the pricking member 44) to the lancet member 40 (*see* Morita, col. 10, lines 6-14). In fact, if the Examiner chooses to compare Morita to the presently claimed invention, the Applicant points to the resin cover 82, which comprises non-slip member 124 that is grasped and pulled to expose the pricking member 44 (*see* Morita, col. 8, lines 60-67, col. 9, lines 1-7). But, Morita does not disclose or suggest that the resin cover 82 comprises any secondary sheath for receiving the sharp lancing tip of a used lancet.”

File History at 15. Therefore, LifeScan has not established any disclaimer of claim scope with respect to the “flat panels” embodiment.

Next, the Court turns to the related ’159 and ’664 Patents. The ’159 and ’635 Patents claim priority to a common provisional application. Additionally, the ’635 Patent is a divisional of U.S. Patent App. No. 13/293,409, which in turn is a divisional of U.S. Patent App. No. 12/751,701 (the “’701 App”) (now abandoned). The ’159 Patent is a continuation-in-part (“CIP”) of U.S. App. No. 12/641,684 (the “’684 App”) which in turn is a CIP of the ’701 App. The ’684 App issued as the ’664 Patent. Thus, the patents are related, though the relationship is attenuated. More importantly, though, the specification of the ’635 Patent explains what the term “secondary sheath for receiving” means and describes the function of the secondary sheath in detail with respect to two embodiments. Therefore, the Court need not and should not rely on this extrinsic evidence in support of a construction that contradicts the teachings of the ’635 Patent. LifeScan’s arguments with respect to the ’159 and ’664 Patents are not persuasive for at least this reason.

Both parties also raise dictionary definitions in support of their respective constructions. While district courts may consider such extrinsic evidence, the intrinsic record takes precedence. *See Phillips*, 415 F.3d at 1317. For instance, Facet argues “receive” means “to take or hold (a substance, commodity, or certain amount).” FRB at 13. LifeScan argues “embed” means “to fix or become fixed firmly and deeply in a surrounding solid mass and “sheath” means “any similar close-fitting case.” LSOB at 12-13. The Court does not find any of these general definitions particularly helpful in construing “secondary sheath for receiving” in the context of

lancets and protective covers, as taught by the '635 Patent. Instead, the Court finds the written description of the '635 Patent adequately defines “secondary sheath for receiving” with respect to the two embodiments, discussed above, and the summary statement, “[a]fter use, the endcap may be replaced to cover the sharp lancet tip by embedding or enclosing the lancet tip into the secondary shroud or sheath portion of the endcap.” '635 Patent at 8:24–27. Though the '635 Patent does not explicitly define the term at issue, the above cited material expresses a clear understanding of the term “secondary sheath for receiving” that is slightly more specific than a general understanding of the individual terms. Accordingly, the Court construes the term “secondary sheath for receiving, as indicated below.

Finally, the Court addresses LifeScan’s indefiniteness argument. A party must prove indefiniteness by clear and convincing evidence. Here, LifeScan argues that a broad construction for “receiving” would render the claim term indefinite because the specification supports only the “hollow receptacle” embodiment. However, LifeScan is incorrect because, as discussed above, the specification also supports “receiving” by embedding a used lancet tip. The specification adequately supports the Court’s construction, provided below. Thus, the term is not indefinite. The *Graver Tank* decision is inapposite because the Court’s construction is consistent with and adequately supported by the written description.

Claim Construction Order at 10:16-13:23.

76. I understand that the Court construed the term “a secondary sheath for receiving the sharp lancing tip of a used lancet” as “a secondary sheath for covering the sharp lancing tip of a used lancet by embedding or enclosing the lancet tip.” Claim Construction Order at 13:24-14:3.

77. I understand that the parties proposed different constructions for the term “a gripping handle portion extending between” from claims 1 and 14, with each party providing the below constructions:

| Each Party's Proposed Construction for "a gripping handle portion extending between"                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Facet's Proposed Construction                                                                                                                                                                                                                                                                           | LifeScan' Proposed Construction                                                                                                                                                                                                                                             |
| <p>Plain and ordinary meaning.</p> <p>To the extent the Court elects to state the meaning explicitly, it should do so in context, as follows: "a portion of the protective sterility cap occupying the distance between the primary sheath and the secondary sheath, and forming a gripping handle"</p> | <p>Indefinite.</p> <p>Alternatively, this claim should be construed as "a portion of the protective sterility cap positioned between the primary sheath and the secondary sheath and forming a handle that is gripped separately from the primary and secondary sheath"</p> |

78. I understand the parties disputed (1) whether the term "gripping handle portion" is indefinite and (2) if not indefinite, whether the "gripping handle portion" must be gripped in a particular manner. Claim Construction Order at 14:14-16.

79. I understand Facet provided the following argument for its proposed construction of "a gripping handle portion extending between":

Facet argues that the specification and claims define "gripping handle portion" relative to "primary sheath" and "secondary sheath." FOB at 15; '635 Patent at Claims 1 and 14 (teaching 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"). The specification also explains that the purpose of the gripping handle portion is to "assist[] in removal of the cap for use of the lancet and/or for replacement of the cap onto a used lancet for disposal." '635 Patent at 1:66-2-3. The gripping handle portion makes the lancet easier and safer to use. *Id.* at 6:9-11, 6:61-7:3, and 7:26-33. Facet also argues that LifeScan's introduction of the language "gripped separately from" introduces an improper and unsupported functional limitation. *Id.* at 18.

Claim Construction Order at 14:17-15:5.

80. I understand LifeScan provided the following argument for its proposed construction of “a gripping handle portion extending between”:

LifeScan argues that “gripping handle portion” is a “coined term” with no plain and ordinary meaning to a POSITA. LSOB at 15–16. Therefore, because “gripping handle portion” is not defined in the specification, LifeScan argues the term is indefinite. *Id.* at 16. LifeScan argues the term “gripping handle portion” appears in the specification only once, the specification does not individually define “gripping,” “handle,” or “portion,” and that, at most, the figures depict only “three possible” forms of the handle which “do not sufficiently inform a POSITA of the boundaries of the claim term.” *Id.* at 17 (emphasis in original). LifeScan also argues that the written description fails to explain which features make the “gripping handle portion” more “intuitive for users to grab” than prior art devices. *Id.* at 18. LifeScan argues that the claim term is indefinite because the specification identifies advantages offered by a “gripping handle portion” but does not explain how the gripping handle offers those advantages. *Id.* at 19. LifeScan further argues adopting a functional construction for “gripping handle portion” would render the term indefinite because the claim scope would depend on the subjective view of the user. *Id.* at 19–20.

Claim Construction Order at 15:6-20.

81. I understand that LifeScan also argued in the alternative that:

[I]f the term “gripping handle portion” is not indefinite, then it must be construed to require independent gripping of the gripping handle portion versus the primary and secondary sheaths. *Id.* at 21. In support, LifeScan argues the gripping handle must provide “an intuitive modality for users to grab when handling a lancet” and that the only way to provide such a modality is to require independent gripping of the handle and sheaths. ’635 Patent at 6:61–7:3 and 7:26–33. Per LifeScan, any other gripping configuration would increase the risk of accidental needle sticks. *Id.* at 21–22.

Claim Construction Order at 15:21-16:4.

82. I understand that in response to LifeScan’s argument, Facet argued:

In response, Facet argues LifeScan applies an improper indefiniteness standard. FRB at 15. Facet further argues that the specification provides adequate support for the term “gripping handle portion.” *Id.* at 16 (citing ’635 Patent at 1:66–2:8, 2:21–25, 2:30–35, 6:1–11, 6:52–54, 6:61–7:3, 7:6–12, 7:20–33, 8:17–22, Figs. 5A–5E, 6A–6D, and 7). Facet also argues that the term “gripping handle portion” is structural not functional. *Id.* at 17. Therefore, LifeScan’s arguments regarding functionality and indefiniteness are inapplicable here. *Id.* Finally, Facet argues that LifeScan’s proposed alternative construction is improper because nothing in the specification requires a user to grip the “gripping handle portion” in a particular way. *Id.* at 18. In fact, importing functional limitations into a structural claim term is not proper. *Id.* (citing *Schwing GmbH v. Putzmeister Aktiengesellschaft*, 305 F.3d 1318, 1324 (Fed. Cir. 2002)).

Claim Construction Order at 16:5-15.

83. I understand that LifeScan also responded as below:

LifeScan reiterates the arguments from its opening brief and primarily argues the term is indefinite because the specification does not explain “what structure(s) or function(s) are needed to qualify as a “gripping handle portion.” LSRB at 16. In support of its position that “gripping handle portions” were not known in the art, LifeScan discusses several references having sheaths but, purportedly, not having “gripping handle portions.” *Id.* at 19–20. In support of its alternative construction, LifeScan argues the “separate gripping” requirement is consistent with other Facet patents. *Id.* at 21.

Claim Construction Order at 16:16-22.

84. I understand the Court analyzed the construction of the term “a gripping handle portion extending between” as below:

Here, the Court is not convinced that “gripping handle portion” is a coined term absent any plain and ordinary meaning. “In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases

involves little more than the application of the widely accepted meaning of commonly understood words.” *Phillips*, 415 F.3d at 1314. “In such circumstances, general purpose dictionaries may be helpful.” *Id.* General purpose dictionaries provide that a “handle” is “a part that is designed especially to be grasped by the hand” and “grip” means “to seize or hold firmly.” Portion, as indicated by the claim language, “a sterility cap comprising . . . ,” merely indicates that the gripping handle is a portion of the claimed sterility cap. ’635 Patent, Claims 1 and 14. The Court does not make much of the modifier “gripping” and finds the term merely restates the purpose of the handle. In other words, all handles are “gripping handles.” The specification supports this interpretation. For instance, the specification refers to “a handle or grip” interchangeable and later describes a “gripping handle portion of the handle.” ’635 patent at 1:66–2:3 and 7:15–19.

Further, the specification provides adequate support to inform a POSITA of the meaning of “gripping handle portion.” ’635 Patent at 6:5–9 (describing “a ‘handle’ or extension arm portion 516 extending between the primary and secondary shrouds for assisting in removal of the cap from the lancet, and/or for replacement of the cap onto a used lancet for disposal”); 6:49–54 (“The handle or extension arm portion 516 defines a forked or split configuration having first and second arms 520 transversely spaced apart from one another, with an open center portion therebetween. This forked arrangement provides the handle with a greater width, allowing the user to more easily twist the endcap during removal from the lancet.”); 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.”); and 7:15–19 (“Optionally, the disc having tapered flat panels serves as a gripping portion of the handle and/or as a display surface only, and not as a shroud or sheath for the needle, in which case the needle is replaced into the first or primary shroud or sheath portion after use.”) The specification also labels and depicts a handle portion in FIGS. 5A–5E, 6A–6C, and 7 (516 (handle portion), 616 (a “handle” or extension arm portion), 720 (second arms of the handle portion)).

In light of the commonly understood meaning of the word “handle,” the above cited portions of the specification, and the clear language of claims 1 and 14, the Court finds construction of the term “gripping handle portion” unnecessary. The Court also does not find any support for the

“separate gripping” requirement LifeScan proposes. First, a handle is a structural element. Therefore, it is improper to import unclaimed functional requirements, i.e. requirements that the handle be used for a certain purpose or in a certain way. *See Schwing GmbH v. Putzmeister Aktiengesellschaft*, 305 F.3d 1318, 1324 (Fed. Cir. 2002). Further, the specification does not require that the handle be gripped in any particular manner.

Claim Construction Order at 17:2-18:18.

85. I understand that the Court concluded no construction was necessary for the term “gripping handle portion.” *Id.* at 18:20-21.

86. I understand the parties proposed different constructions for the term “lancet thickness” from claims 6, 8, 14, and 18, with each party proposing the below constructions:

| Each Party’s Proposed Construction for “lancet thickness”                                                                                                                              |                                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| Facet’s Proposed Construction                                                                                                                                                          | LifeScan’s Proposed Construction                         |
| Plain and ordinary meaning<br><br>To the extent the Court elects to state the meaning explicitly, it should do so in context, as follows: “the height (i.e. depth) of the lancet body” | “the longest axis through the thickest part of a lancet” |

87. I understand the parties agreed that “lancet thickness” is a dimension of the lancet body, but there was dispute whether “thickness” refers to a “longer” or “shorter” diameter of an oval shape. Claim Construction Order at 19:7-9.

88. I understand Facet provided the following argument for its proposed construction of “lancet thickness”:

Facet argues both claims 6 and 14 disclose “a lancet body having a lancet thickness.” FOB at 19; ’635 Patent, Claims 6 and 14. Thus, “lancet thickness” is clearly a dimension of the lancet body. *Id.* FIG. 1B depicts a labeled diagram of the lancet body with thickness (T):

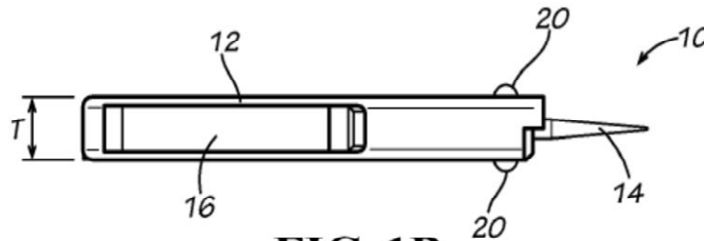


**FIG. 1B**

’635 Patent, FIG. 1B. The figure comports with the ordinary understanding of the term thickness, so the term does not require construction. *Id.* at 19–20. Facet argues LifeScan’s construction is improper because it focuses on the lancet as a whole instead of the lancet body. *Id.* at 20.

Claim Construction Order at 19:15-20:1.

89. I understand LifeScan provided the following argument for its proposed construction of “lancet thickness”:

LifeScan argues that its construction is correct because, “for a lancet body having an elliptic-shaped base, the lancet thickness must be the longest axis or major diameter, of the elliptic-shaped base.” LOB at 24. LifeScan argues FIG. 1B only shows a rectangular lancet body, so it would be unclear how to determine the thickness of an elliptical lancet body without an affirmative construction. *Id.* LifeScan argues that the specification refers to the “diameter” of an oval-shaped lancet body but does not explain which diameter since oval shapes have a longer and a shorter diameter. *Id.* at 25. Per LifeScan, a proper construction needs to clarify that, in the context of an oval-shaped lancet body, the “thickness” is the longer diameter. *Id.* at 25.

Claim Construction Order at 20:2-10.

90. I understand that in response to LifeScan’s argument, Facet responded as below:

Facet responds that LifeScan’s argument regarding an oval-shaped lancet body is not applicable here because the accused product includes an oval-shaped lancet but the ’635 Patent is not directed to an oval-shaped lancet body. FRB at 21. Thus, this is an infringement issue, not a claim construction issue. Facet further argues that even if the lancet body is oval-shaped, the “thickness” must be the shorter diameter. See ’635 Patent at 7:45–49.

Claim Construction Order at 20:11-16.

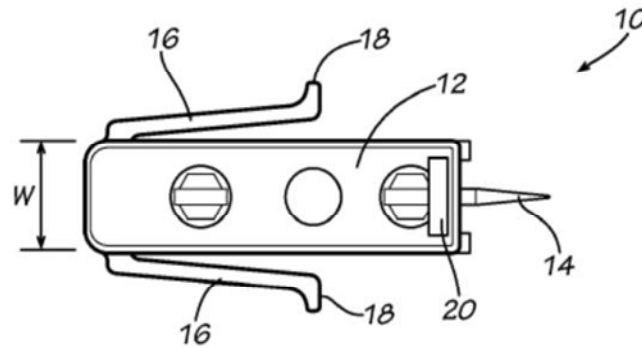
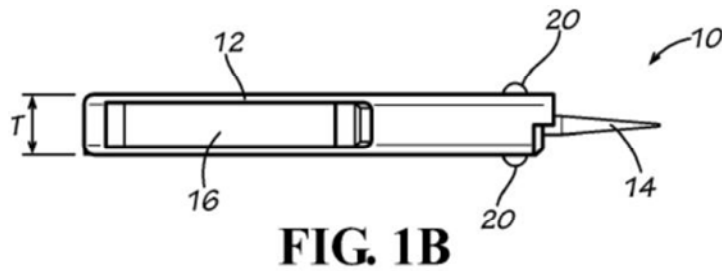
91. I understand that LifeScan, in turn, responded as below:

LifeScan reiterates the arguments from its opening brief and responds that the portion of the specification Facet cites is not applicable because it is directed to a nonelected invention. LRB at 29. LifeScan also argues that using the shorter diameter as the thickness would frustrate one purpose of the invention because it would not make the sterility cap easier to handle. *Id.* at 29–30. LifeScan also refers to measurements on an accused product that Facet included in the original complaint but did not include in the first amended complaint. *Id.*

Claim Construction Order at 20:17-23.

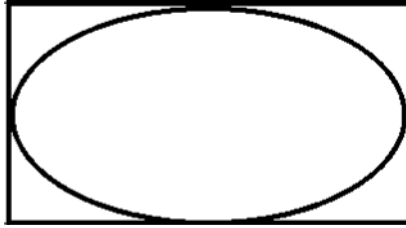
92. I understand the Court analyzed the construction of the term “lancet thickness” as below:

The parties agree that “lancet thickness” is a dimension of the lancet body however they disagree regarding whether the term refers to a “shorter” or “longer” dimension if the lancet body is oval-shaped. LifeScan argues that an oval-shape features two dimensions, a longer diameter and a shorter diameter. Because the ’635 Patent does not specify which dimension is the “lancet thickness,” LifeScan argues the term is not clear and requires construction. However, LifeScan neglects to mention that a rectangle also features two dimensions. FIGS. 1B and 1C of the ’635 Patent clarify that here, the shorter dimension (labeled T) is the “lancet thickness” and the longer dimension (labeled W) is the width:



'635 Patent, FIGS. 1B and 1C. This understanding is consistent with the specification, which provides "[t]he lancet body has a thickness T and a width W, with the width W preferably being at least about 1.5 times, and more preferably at least about twice the thickness T, thereby reducing potential twisting and misalignment of the lancet within the receiver of the lancing device during installation" and "the lancet body is optionally generally flattened, having a width that is substantially greater than its thickness, in example forms having an aspect ratio of the width relative to the thickness of at least about 3:2." '635 Patent at 3:51–56 and 7:45–49.

Consistent with the specification, a POSITA would understand that if the lancet body were oval-shaped, the "lancet thickness" would be the shorter dimension of the oval. A POSITA would also understand, based on the discussion of "lancet thickness" with respect to rectangle, how to determine the "lancet thickness" of an oval-shaped lancet body. For example, a POSITA may compare an oval and rectangle as show below to determine the relationship between the dimensions:



Thus, the Court finds that the term “lancet thickness” would be sufficiently understandable to a POSITA based on the claims, disclosure, and ordinary meaning of “thickness.” The term does not require construction. Further, the parties’ proposed constructions are needlessly confusing and inaccurate. For instance, Facet’s proposed construction introduces the additional terms height and depth, which are not helpful because the “thickness” dimension is clearly labeled and described. LifeScan’s construction introduces the language “the longest axis through the thickest part” which appears to contradict the specification.

Moreover, the Court finds LifeScan’s arguments regarding non-elected inventions unpersuasive. The applicant did withdraw original claims 10–18, which were directed to a lancet system. However, the claims at issue are directed to “a lancet body defining a lancet thickness.” The portion of the specification that LifeScan contends discusses a non-elected invention discusses a lancet body having a lancet thickness and is presumably relevant to claim construction.

Claim Construction Order at 21:1-23:10.

93. I understand that based on its analysis, the Court declined to construe the term “lancet thickness.”

94. I understand the parties proposed different constructions for the term “lateral span” from claims 6 and 14, with each party proposing the below constructions:

|                                                              |
|--------------------------------------------------------------|
| <b>Each Party’s Proposed Construction for “lateral span”</b> |
|--------------------------------------------------------------|

| Facet's Proposed Construction                                                                                                                                                                                                                                                                           | LifeScan's Proposed Construction                                                                                               |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|
| <p>Plain and ordinary meaning.</p> <p>To the extent the Court elects to state that meaning explicitly, it should do so in context, as follows: “the width of the gripping handle portion as measured from one side of the gripping handle portion to the other side of the gripping handle portion”</p> | <p>“the longest measurement from one side of the gripping handle portion to the other side of the gripping handle portion”</p> |

95. I understand the parties disputed whether “lateral span” must specifically be the “longest measurement from one side to the other” or “a width.”

96. I understand Facet provided the following argument in support of its proposed construction of “lateral span”:

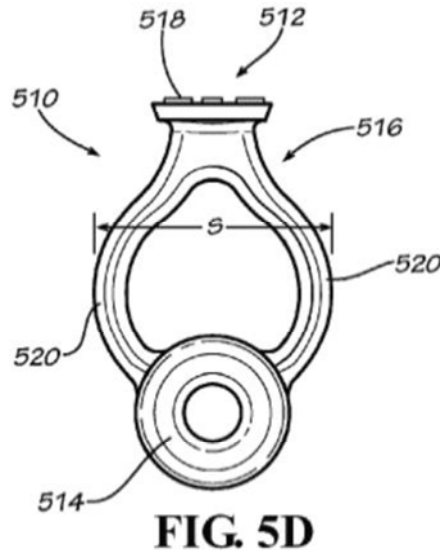
Facet argues the claims define “lateral span” relative to the “gripping handle portion.” FOB at 22. Facet further argues that the specification shows “the lateral or transverse span S” of the gripping handle in FIG. 5D and that the term “lateral span,” as shown and described, is consistent with ordinary usage. *Id.* at 22–23. Facet argues, alternatively, that if the term requires construction, lateral span should be construed to mean “width” because the ’635 Patent uses the terms “lateral span” and “width” interchangeably. *Id.* at 23.

Claim Construction Order at 24:4-10.

97. I understand LifeScan provided the following argument in support of its proposed construction of “lateral span”:

LifeScan argues the term “lateral span” appears only in the ’635 Patent claims with the exception of the following disclosure: “[i]n example forms, the lateral or transverse span S of the forked handle portion 516 is at least

about 1.5 times, and more preferably at least about 2 times the diameter or thickness of the lancet body.” LSOB at 22–23; ’635 Patent at 6:54–58. FIG. 5D also shows the labeled lateral span (S):



’635 Patent, FIG. 5D. LifeScan argues Facet’s construction is improper because it is inconsistent with FIG. 5D and because it would allow measurement of the distance between any two points of the gripping handle portion. LSOB at 23.

Claim Construction Order at 24:11-25:1.

98. I understand that Facet responded to LifeScan’s propose construction by arguing it was “needlessly confusing and would include ‘the diagonal length of the gripping handle portion,’ which is inconsistent with FIG. 5D. FRB at 19.”

Claim Construction Order at 25:2-4.

99. I understand that LifeScan, in turn, responded that “Facet’s construction is inadequate because it is imprecise, reiterating that ‘width’ could mean any measurement between any two points on the gripping handle portion.

LSRB at 30.” Claim Construction Order at 25:4-6.

100. I understand the Court analyzed its construction for the term “lateral span” as below:

The parties agree that FIG. 5D accurately depicts the claimed “lateral span.” LifeScan is concerned that Facet’s construction would include narrower horizontal measurements separating any portions of the gripping handle. Facet is concerned that LifeScan’s construction would allow a diagonal measurement. The plain meaning of the claim language precludes both of these readings. Lateral means “side-to-side.” Span clearly refers to a maximum distance. Accordingly, “lateral span” can only mean the maximum side-to-side (or horizontal distance) separating the gripping handle portion. A POSITA would understand that this is the meaning of “lateral span.” Reference to FIG. 5D would immediately confirm that understanding. See ’635 Patent at FIG. 5D (depicting a horizontal line extending the maximum distance between one side of the gripping handle and the other side of the gripping handle). This term is not indefinite and does not require any construction.

Claim Construction Order at 25:8-20.

101. I understand that based on its analysis, the Court declined to construe the term “lateral span.”

102. I understand the parties proposed different constructions for the term “length” from claims 8 and 18, with each party proposing the below constructions:

| <b>Each Party’s Proposed Construction for “length”</b> |                                                                                                                       |
|--------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| <b>Facet’s Proposed Construction</b>                   | <b>LifeScan’s Proposed Construction</b>                                                                               |
| Plain and ordinary meaning                             | “the longest measurement from one end of the gripping handle portion to the other end of the gripping handle portion” |

103. I understand the parties agreed that “length refers to an end-to-end measurement of the gripping handle portion but disagree regarding the language ‘the longest measurement’.” Claim Construction Order at 26:5-6.

104. I understand Facet provided the following argument in support of its proposed construction:

Facet argues the claims define “length” relative to the “gripping handle portion.” FOB at 23–24. Facet further argues that claims 1 and 14 disclose a “gripping handle portion extending between the primary sheath and the secondary sheath” and specify 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.” ’635 Patent, Claims 1 and 14. Therefore, the “length” is the end-to-end distance that the gripping handle portion extends between the primary and secondary sheaths and construction is unnecessary. FOB at 24. Facet further argues that FIG. 5C depicts the length (L) in accordance with this understanding. *Id.*

Claim Construction Order at 26:11-19.

105. I understand LifeScan provided the following argument in support of its proposed construction:

LifeScan argues the term “length” appears only in the ’635 Patent claims with the exception of the following disclosure: “[i]n example forms, the length L of the handle portion is at least equal to the span S, and/or is greater than the depth D of the secondary shroud 514, and/or is greater than the diameter or thickness of the lancet body.” LSOB at 26; ’635 Patent at 6:58–61. FIG. 5C also shows the labeled length (L):

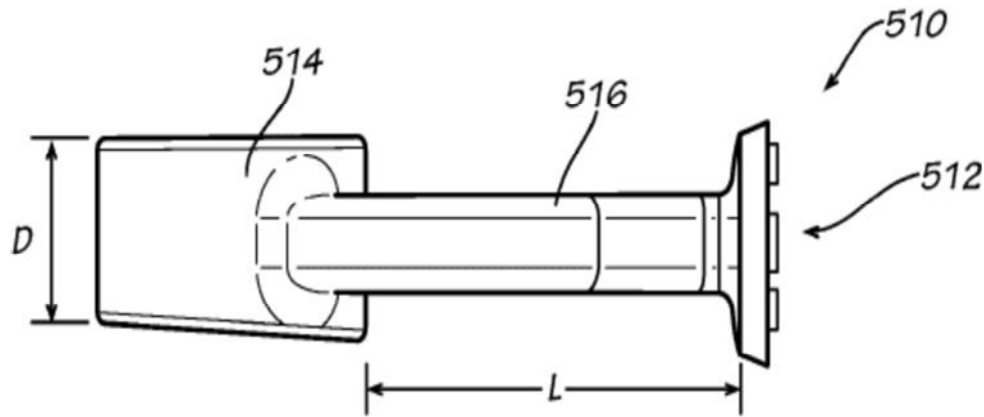


**FIG. 5C**

'635 Patent, FIG. 5C. LifeScan argues that, as shown by FIG. 5C, the length does not necessarily encompass the entire length of the structure between the primary and secondary sheaths, so plain and ordinary meaning should not apply. LSOB at 27–28.

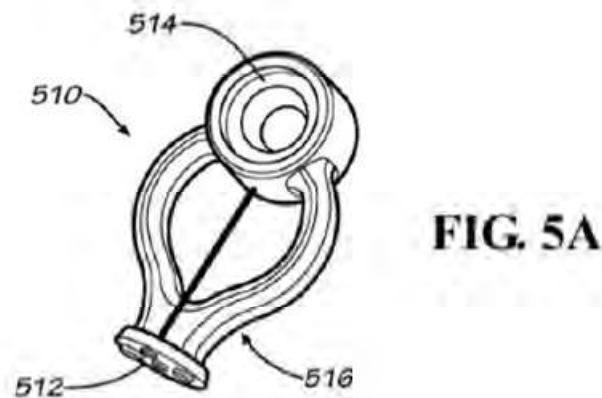
Claim Construction Order at 26:20-27:12.

106. I understand Facet responded to LifeScan's proposed construction of "length" by arguing "the construction of 'length' should not be limited to the embodiment shown in FIG. 5C and that the specification does not provide a clear, alternative definition for 'length' that would differ from the plain and ordinary meaning. FRB at 24-25." Claim Construction Order at 27:13-16.

107. I understand LifeScan, in turn, responded that: "'Figure 5C illustrates length as *excluding* the portions of the arms curling towards and ultimately connection with the secondary sheath,' which is inconsistent with the plain and ordinary meaning of length. LSRB at 31. LifeScan further argues 'length' is ambiguous because it is not clear whether it refers to the chord or the arc since the gripping handle portion is curved. *Id.*" Claim Construction Order at 27:16-20.

108. I understand the Court provided the following analysis for its construction of the term “length”:

FIG. 5C accurately depicts the claimed “length.” It shows a straight line, labeled “L” spanning the distance between the primary sheath and the secondary sheath. A POSITA would understand that the appropriate definition of “length” here is a “dimensional measure of [a] three-dimensional [] object[].”<sup>13</sup> It is a “magnitude[] representing the “size” of an object.” *Id.* “Length is the size of a line segment.” Thus, as LifeScan puts it, “length” is a chord. FIG. 5C shows the “length” L as a line segment that terminates at each respective end of the gripping handle portion, where the primary and secondary sheaths begin. For instance, if the length “L” were labeled in FIG. 5A it would be depicted as shown:



'635 Patent, FIG. 5A (annotated to show length “L”). “Length,” as shown and described, does not include the curling portions of the arms. The term “length” is not ambiguous or indefinite. LifeScan’s construction, which specifies that the length must be “the longest measurement” could actually suggest that the entire curvature is the length. This is not what a POSITA would understand “length” to mean and is not what the '635 Patent shows, describes, and claims.

Claim Construction Order at 27:22-28:20.

109. I understand that, based on its analysis, the Court declined to construe the term “length.”

110. For the claim terms the Court declined to construe, 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 these terms their plain and ordinary meaning in my analysis throughout this report.

#### **F. Asserted Claims**

111. I understand that Facet asserts only claims 6, 8, 14, and 18 of the ’635 Patent against LifeScan. The ’635 Patent contains 18 claims. Claims 6, 7, and 8 depend directly or indirectly from independent claim 1. Claim 18 depends from independent claim 14. I have read claims 1, 6, 8, 14, and 18 of the ’635 Patent, which are reproduced below:

| <b>Table 1: Claims 1, 6, 8, 14, and 18 of the ’635 Patent</b> |                                                                                                                                                                                                                              |
|---------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1.a</b>                                                    | A protective sterility cap for a lancet                                                                                                                                                                                      |
| <b>1.b</b>                                                    | said sterility cap comprising a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein                                                                                                      |
| <b>1.c</b>                                                    | a secondary sheath for receiving the sharp lancing tip of a used lancet                                                                                                                                                      |
| <b>1.d</b>                                                    | and a gripping handle portion extending between the primary sheath and the secondary sheath                                                                                                                                  |
| <b>1.e</b>                                                    | 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 |
| <b>6.a</b>                                                    | The protective sterility cap of claim 1                                                                                                                                                                                      |

|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>6.b</b> | in combination with a lancet having a lancet body defining a lancet thickness                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>6.c</b> | and a sharp lancet tip initially embedded in the primary sheath                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>6.d</b> | wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>8.a</b> | The protective sterility cap of claim 6,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>8.b</b> | wherein the gripping handle portion defines a length at least equal to the lancet thickness                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>14</b>  | 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. |
| <b>18</b>  | The protective sterility cap of claim 14, wherein the gripping handle portion defines a length at least equal to the lancet thickness.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

112. I understand the claim limitations of claim 6 are analogous in scope to claim 14. I also understand that Claim 14 includes limitations analogous to the limitations of claims 1 and 6.

| Claim limitations of claims 1, 6, and 14                                                                                                                                      |                                                                                                                                                                                    |                                                                                                                                                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Claim 1                                                                                                                                                                       | Claim 6                                                                                                                                                                            | Claim 14                                                                                                                                                                       |
| <b>1.</b> 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 | <b>6.</b> The protective sterility cap of claim 1, in combination with a lancet having a lancet body defining a lancet thickness, and a sharp lancet tip initially embedded in the | <b>14.</b> 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 |

|                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>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.</p> | <p>primary sheath, wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.</p> | <p>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.</p> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

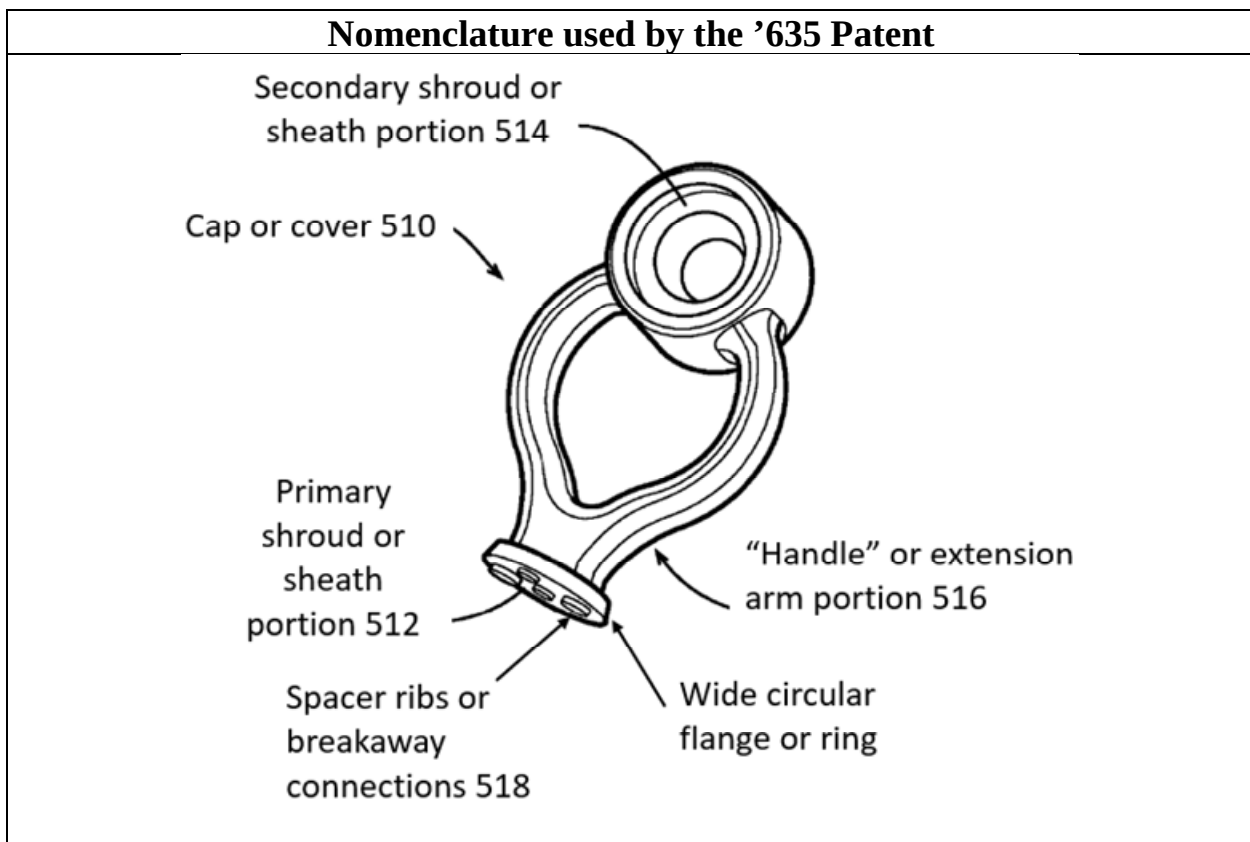
113. I understand claim 8 depends from claim 6. I also understand claim 18 depends from claim 14. I understand the additional limitations of claim 18 correspond in scope to those found in claim 8.

| Claim limitations of claims 8 and 18 |          |
|--------------------------------------|----------|
| Claim 8                              | Claim 18 |

|                                                                                                                                                               |                                                                                                                                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>8.</b> The protective sterility cap of claim <b>6</b>, wherein the gripping handle portion defines a length at least equal to the lancet thickness.</p> | <p><b>18.</b> The protective sterility cap of claim <b>14</b>, wherein the gripping handle portion defines a length at least equal to the lancet thickness.</p> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|

### G. Nomenclature of the '635 Patent

114. For clarity of this report, I have included below a nomenclature chart that shows the names used in the patent to refer to specific portions of the invention. For simplicity, I have used only one of the embodiments provided in the '635 Patent, but these names are also used in connection with other embodiments. This chart does not include all of the named parts of the patent, but rather it focuses only on those that may be referred to in this report.



## H. Gripping Handle

### 1. The design and role of touchpoints and handles

115. In my over 25 years of designing mass produced products, I have designed many thousands of touchpoints and hundreds of handles.

116. ‘Touchpoints’ are known to a designer as the part of a product that the user should touch, actuate or physically interact with typically using their hand or finger. Touchpoints include buttons on an electronic device, the trigger on a drill, or simply an area that is visually or physically designed to accommodate the finger or hand. Essentially, touchpoints are used by the designer to signal and/or accommodate an area of physical interaction.

|                                                                                                                 |
|-----------------------------------------------------------------------------------------------------------------|
| <b>Table 5: Touchpoints are visually and physically designed to encourage the user to touch or actuate them</b> |
|                                                                                                                 |



The patterned ribbing on this dental tool provides a visual cue as to where to grip, and aids the physical grip.



The red touchpoints on this drill, such as the trigger, direction switch and speed switch are made very visible and their shape and surroundings communicate how to actuate them. The black touchpoints such as the chuck and clutch-ring and the handle soft-grip also visually communicate how they should be gripped, and their form and materials help them be gripped.

|                                                                                                                                                                                                           |                                                                                                                                                                                                                                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  <p>The buttons and dials on this electronic device each use their shape to communicate how they should be actuated.</p> |  <p>This safety lancet uses color to bring attention to the two main touchpoints, which are also shaped to communicate how they should be handled.</p> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

117. Broadly speaking, a handle is generally understood by a POSITA to include some form of touchpoint as it provides for touching and physically interacting, but a POSITA would also appreciate that a handle is a distinct structure that the user can grab or grip, by holding or grasping the structure, rather than just interacting with such as button for pressing or pushing. Often a handle may have touchpoints on or around it, facilitating how and where the user should place their fingers or activate functions.

**Table 6: Many products have both handles and touchpoints**



118. In my experience, touchpoints and handles have two things in common; they are designed to (i) physically fit or accommodate the users' hand and or fingers, and (ii) to provide a physical advantage to use. Typically, both of these physical attributes would be visually communicated to the user using visual cues.

i. Physical Accommodation

119. The touchpoint or handle is typically shaped and sized to fit the contour of the hand or finger. POSITAs sometimes use anthropometric references<sup>1</sup> to check for statistically typical hand sizes, angles, or how much room they may need around a touchpoint or handle for movement. POSITAS may also reference other ergonomic data that provides information on comfort and performance of specific types of grips, such as for a clench grip, pinch grip, or twisting pinch grip. The size and shape of a touchpoint or handle is also highly contextual. In my experience, anthropometric and force data only provides a baseline for the design, and achieving a more optimal result requires prototyping and testing. Designers often make prototypes of handles and touchpoints to physically check their assumptions on fit and shape.

120. For example, a handle may be smaller than the hand it needs to accommodate because a large protruding handle on a small product may become cumbersome and create disadvantages to the usability of the product as a whole, or a handle may be much longer than is needed by one hand as the user may need to reposition their hand while using the product to accommodate different angles of use or relieve cramping.

**The shape and size of a handle or touchpoint is designed to accommodate the human scale and the context in which it is used**

---

<sup>1</sup> Mechanical engineers and designers often refer to the Dreyfuss ‘The Measure of Man and Woman: Human Factors in Design’ or its associated templates or editions.



The 'secondary handle' at the front of this saw is relatively short, because if it were longer it would restrict certain angled cuts and users the line of sight.



The rear handles on the rear patient recovery chair are extended to allow for comfortable reach from different angles and provide optional positions for lifting or pushing grips.



Fitting the hand for optimal use often requires making and testing many prototypes.



Often fitting the hand comfortably for use in different positions requires adding bulk to the product's shape.

ii. Physical advantage

121. A touchpoint or handle will also be positioned and shaped to provide the user with the ability to hold or operate the product in a way that is improved over how they would use it without the touchpoint or handle. That is, the handle may be positioned in the user's hand in the center of gravity or positioned or shaped to advantageously apply force. For instance, if a part needs to be pushed in a specific direction, the handle or surface would be positioned laterally to the direction of required force, giving the user more surface area to push against and avoid slipping.

122. The touchpoint or handle may also provide advantage to the user by increasing tactility and grip such as by using rougher surfaces, conforming or flexible materials, protrusions, or indentations. These can increase the user's heft or grip of the touchpoint or handle, thus reducing the physical effort required to maintain a grip or prevent from slipping.

**Touchpoints and handles are typically positioned and shaped to provide a physical advantage to the user**



The center of gravity of this knife was deliberately positioned to be under the user's hand, giving them more control and better balance.



Ribs, grooves, and texture often increase the user's ability to grip a surface. Soft, flexing materials can also help.



Both of these safety lancets use physical bumps and ribs to act as visual cues about where and how to handle the product.

123. While touchpoints and handles may be designed to accommodate the human scale and provide physical advantages, it is also important that the structure conveys to the user how to engage with it, to facilitate correct and prevent incorrect usage. A designer would understand to provide ‘visual cues’ to communicate where the user should touch or grip, and how they should do so. The visual cue may also communicate a desirable trait about the touchpoint or handle, such as comfort or ease of use. If there are very few options for where and how the user can touch or grab the product, the visual cues may be very subtle, but often the designer needs to use a combination of color, material, and shape to encourage the user’s correct interaction with the product.

## **2. The gripping handles of the ’635 Patent**

124. A POSITA would understand the use of the term in the ‘635 Patent ‘gripping handle’ by its plain and ordinary meaning. I also agree with the Court’s observation that the specification refers to ‘a handle or grip’ interchangeably and describes a ‘gripping portion of the handle’ (’635 Patent at 1:66–2:3 and 7:15–19).

125. In Figures 5A through 5E of the ’635 Patent, the patent identifies the “handle” or “extension arm” portion as being part **516**. ’635 Patent at 6:5-12. The handle of the cap is noted to “extend between the primary and secondary shrouds for assisting in removal of the cap from the lancet, and/or for replacement of the cap onto a used lancet for disposal.” *Id.* The “handles” also “allow for the body of

the lancet to be smaller than a Regular Version (RV) lancet, allowing the corresponding lancing devices to be smaller.” *Id.*

126. The configuration of the “handle or extension arm portion **516**” also is noted to be:

[A] forked or split configuration having first and second arms **520** transversely spaced apart from one another, with an open center portion therebetween. This forked arrangement provides the handle with a greater width, allowing the user to more easily twist the endcap during removal from the lancet. In example forms, the lateral or transverse span *S* of the forked handle portion 516 is at least about 1.5 times, and more preferably at least about 2 times the diameter or thickness of the lancet body. In example forms, the length *L* of the handle portion is at least equal to the span *S*, and/or is greater than the depth *D* of the secondary shroud 514, and/or is greater than the diameter or thickness of the lancet body. 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. Additionally, the expanded dimensions of the endcap allow for easier use by persons with limited dexterity or vision, and permit the use of smaller lancets with lower mass and/or finer gauge needles, which may reduce pain.

*Id.* at 6:52-7:3.

127. The specification does not require that the handle be gripped in any particular manner. The specification does however list the following *purposes* for the gripping handle:

128. **For gripping when installing the lancet into the lancing device.**

The POSITA would understand that the user needs to grip the lancet by the cap to apply a push force toward the device mouth. The POSITA would also understand that the elongated, wide span handles described in the patent would both communicate their use as gripping

handles and have the right shape and access to be used for this purpose. Because the user needs to push against the device, the POSITA would know that surfaces that are outwardly angled and /or have texturing or ribbing, provide better gripping surfaces. (See Table below)

**129. For gripping to twist the cap to remove it from the lancet.**

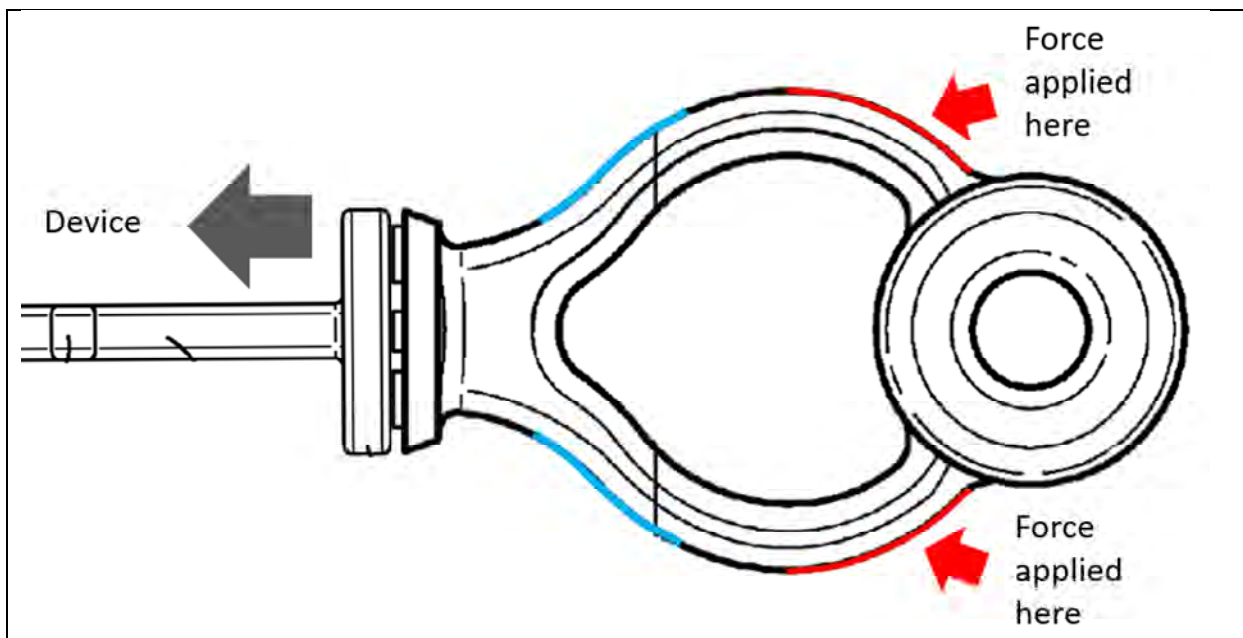
The POSITA would understand that the user needs to grip the lancet by the cap to apply a turning force to break the breakaway connections, thereby allowing the cap to come away from the lancet. The POSITA would also understand that the elongated, wide span handles described in the patent would both communicate their use as gripping handles and have the right shape and access to be used for this purpose. Because the user needs to apply a twisting motion, the POSITA would know that surfaces that are wider from the center would increase the amount of torque the user can apply for the same amount of effort, thus a wider grip is easier to turn<sup>2</sup>. The specification of the '635 Patent also discusses an embodiment, "This forked arrangement provides the handle with a greater width, allowing the user to more easily twist the endcap during removal from the lancet." '635 Patent at 6:52.

130. The '635 Patent also describes that the elongated gripping handle portion allows the user to grab the lancet further away from the needle during decapping and disposal, thus protecting from accidental needle sticks. '635 Patent at 6:61-66.

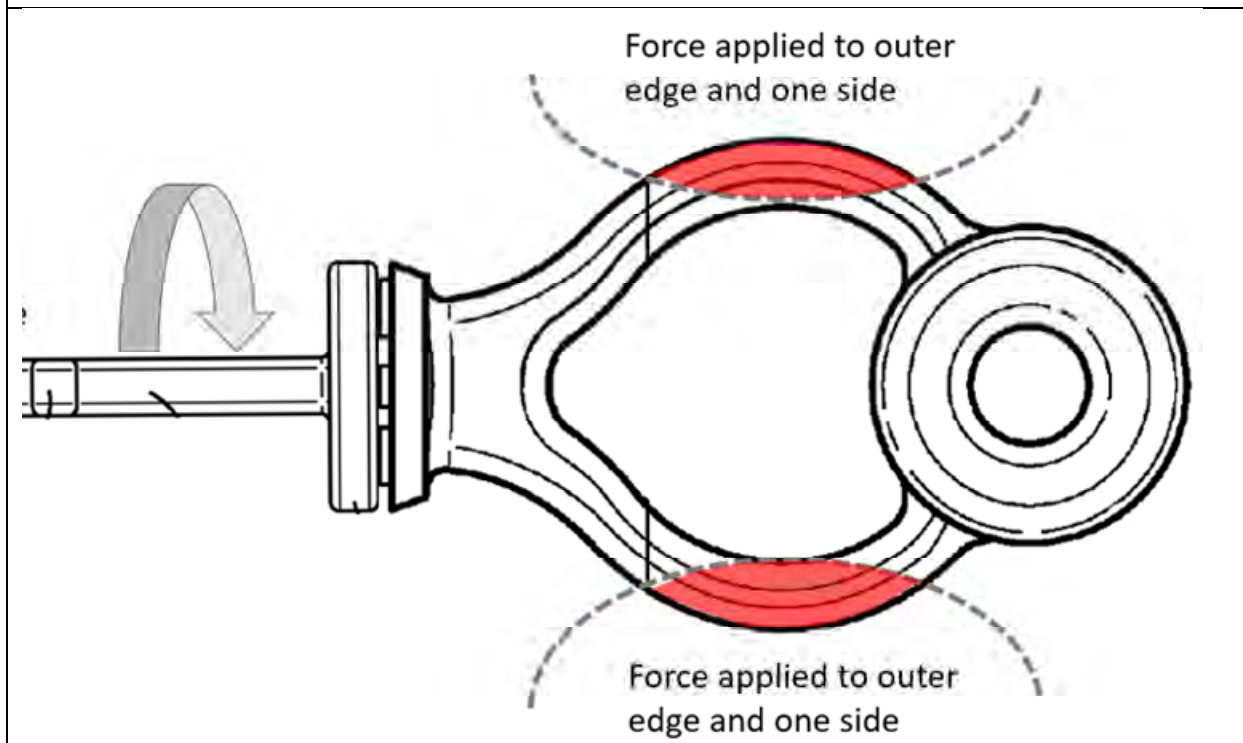
|                                                                            |
|----------------------------------------------------------------------------|
| <b>The patent describes the gripping handles are used in two main ways</b> |
|----------------------------------------------------------------------------|

---

<sup>2</sup> This assumes that the shape and size of the tunable object is suitable for handling in a comfortable manner.



Because the user needs to push against the device, the POSITA would know that surfaces that the user would apply force to surfaces that are outwardly angled, such as the ones highlighted in red above. The areas marked in blue would have the opposite effect and make the user's hand slip forward when applying a push force.



Because the user needs to apply a twisting motion, the POSITA would know that surfaces that are wider from the center would increase the amount of torque the user can apply for the same amount of effort, thus a wider grip is easier to turn. If

|                                                                                                                                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>the gripping handles are used, the user would grab the outermost areas of the handle and apply additional force to one side in a twisting motion.</p> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|

131. The POSITA would also recognize the benefit described in the specification that the expanded dimensions of the endcap allow for easier use by persons with limited dexterity or vision, as it would be easier to see, grip, pick off the table, and the increased width would make it easier to turn.

132. Further, the '635 Patent also says the gripping handles would aid in “replacement of the cap onto a used lancet for disposal” (2:2-3) and that the gripping handles would make it easier to hold when recapping the lancet, keeping the fingers at a distance away from the needle (6:62-66). The patent also says that “The larger surface area provided by the protective/sterility cap [because of the extended gripping handle], as compared to previously known designs, makes it easier to locate” (7:27-33)

133. The gripping handle is a structural element for which the specification explicitly provides examples of the *form and position* of the gripping handle:

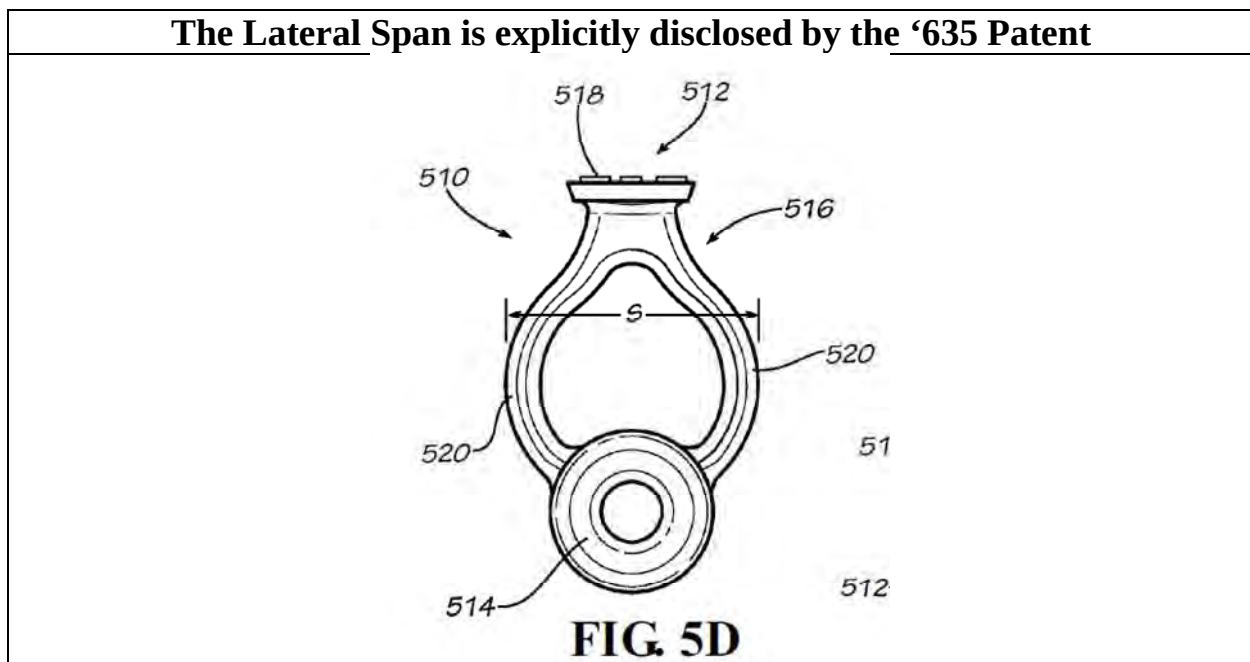
134. The gripping handle portion extends from the primary shroud portion to the secondary shroud portion. '635 Patent at 2:24-25, 2:34-35.

135. The length “L” of the gripping handle is described in a similar manner, and the position from which to measurement it is shown in Figure 5C of the '635 Patent.

136. One embodiment describes a forked shape handle, “with a greater width, allowing the user to more easily twist the endcap during removal from the lancet”. ’635 Patent at 6:49-54.

### **I. Lateral Span**

137. The ’635 Patent explicitly describes the lateral span as being the linear distance between the outermost points of the sides of the handle. A POSITA would understand ‘lateral span’ by its plain and ordinary definition, and this is reflected by the dimension ‘S’ shown in figure 5D.



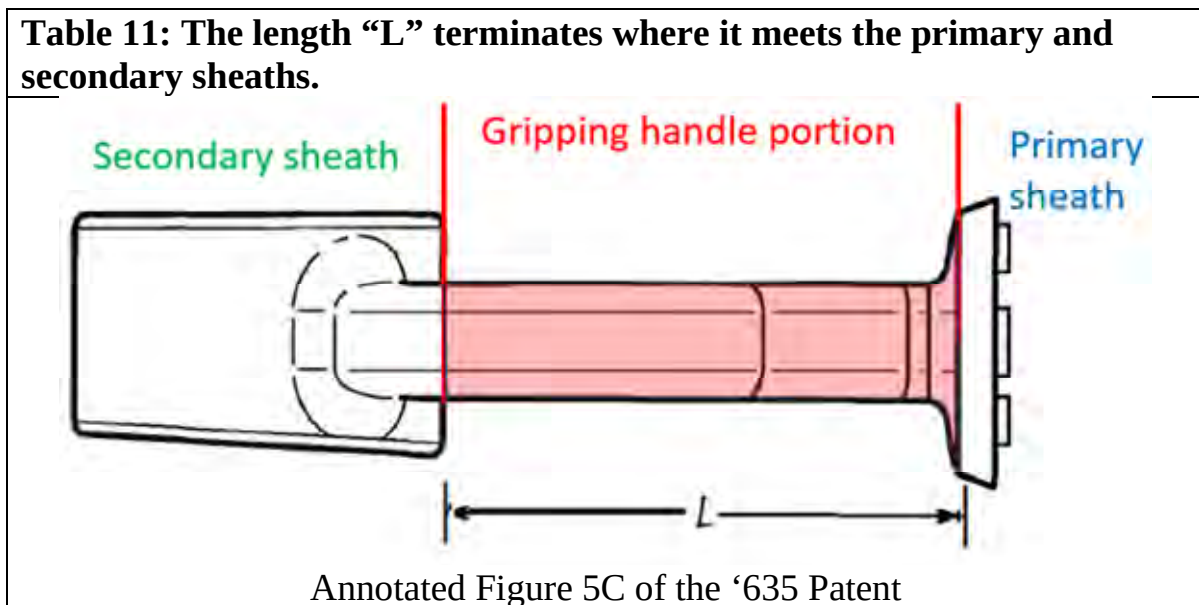
138. The ’635 Patent provides:

In example forms, the lateral or transverse span S of the forked handle portion 516 is at least about 1.5 times, and more preferably at least about 2 times the diameter or thickness of the lancet body. In example forms, the length L of the handle portion is at least equal to the span S, and/or is greater than the depth D of the secondary shroud 514, and/or is greater than the diameter or thickness of the lancet body.

*Id.* at 6:54-61.

## J. Length

139. As the Court has laid out in its Claim Construction Order, the term “length” would be understood by a POSITA in its plain and ordinary meaning and does not require construing. Claim Construction Order at 27:22-28:20. I agree that Figure 5C shows the length of the gripping handle “L” as a line segment that terminates at each respective end of the gripping handle portion, between the primary and secondary sheaths. The ’635 Patent identifies the length of the lancet cap, labeled *L*, in Figure 5C below. ’635 Patent at Figure 5C.



140. The Court has also identified the length of the lancet cap in its own annotation of Figure 5A in its Claim Construction Order. Claim Construction Order at 28:3-20.

**The Court Identified the Length of the Lancet Cap in the '635 Patent**

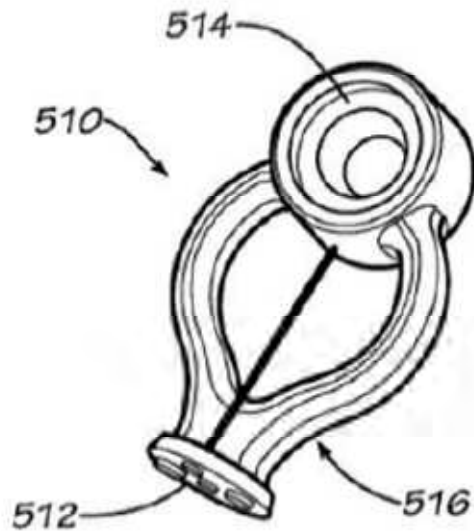


**FIG. 5A**

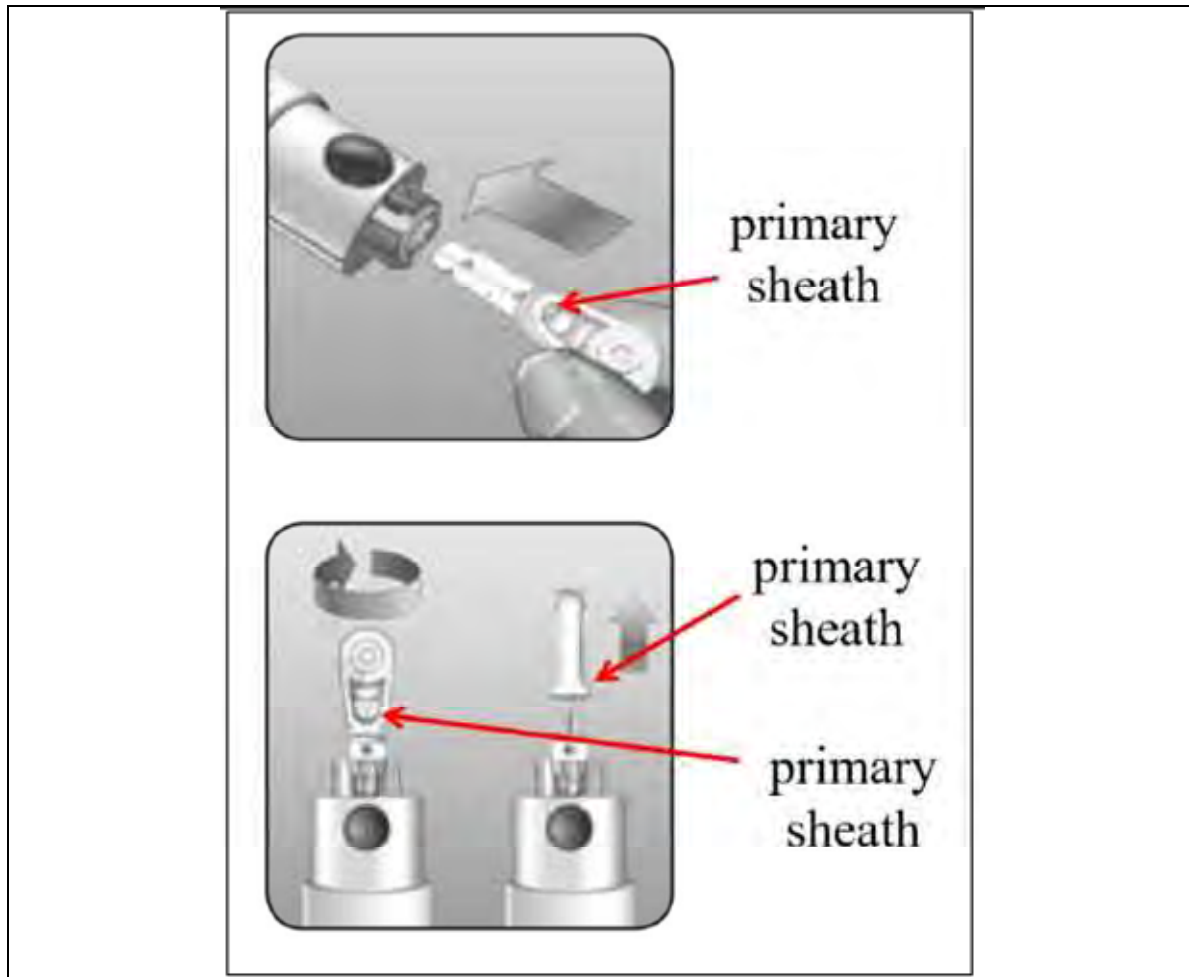
141. Regarding the “length” of the lancet cap, the Court noted that the “length” as shown and described in the '635 Patent, does not include the curling portions of the arms. Claim Construction Order at 28:3-16.

**K. Infringement Contentions**

142. I understand that Facet served its Preliminary Infringement Contentions on July 25, 2022.

143. I understand that for claims **1[a]** and **14[a]**, Facet used the following image to identify where it claims the primary sheath of the Delica Plus lancet cap to be:

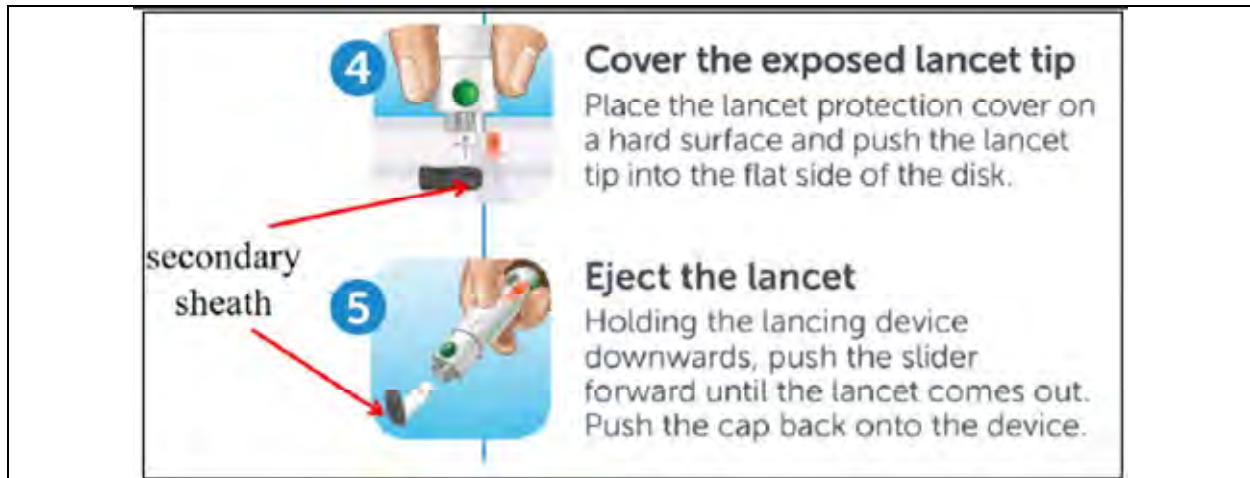
**Primary Sheath Identified by Facet**



Preliminary Infringement Contentions at 11.

144. I understand that for claims **1[b]** and **14[b]**, Facet used the following image to identify where it claims the secondary sheath of the Delica Plus lancet cap is:

**Secondary Sheath Identified by Facet**



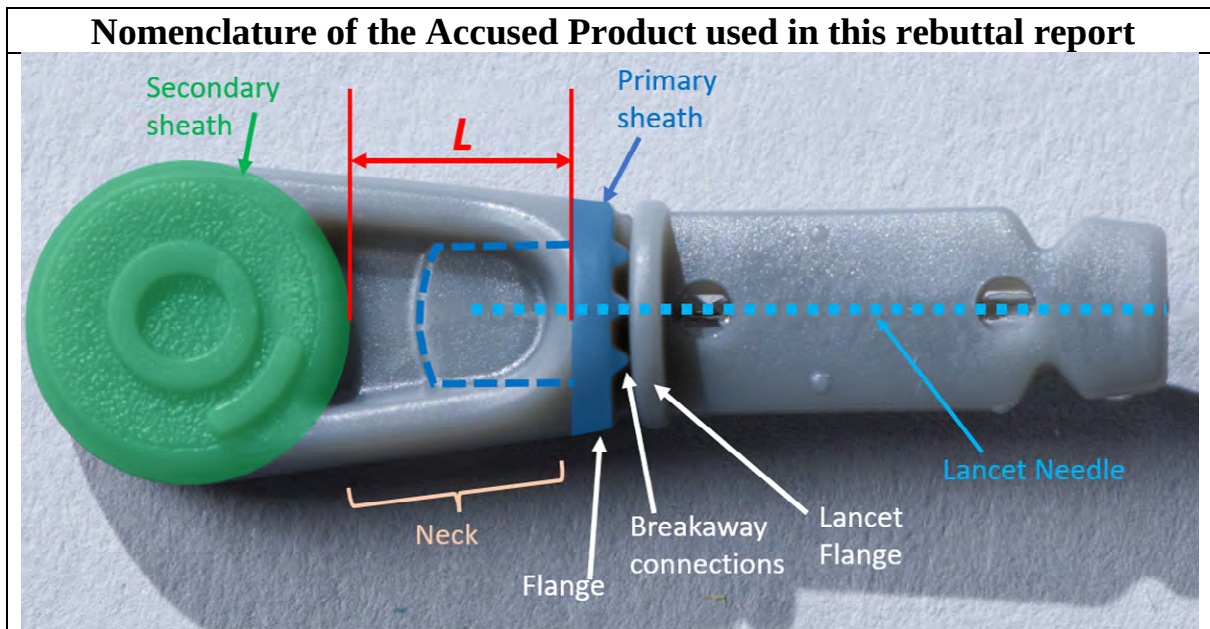
145. For claims **1[c]** and **14[c]**, Facet used the following image to identify where it claims the gripping handle portion of the Delica Plus lancet cap is:



#### **L. The Accused Product**

146. I have been informed that the accused product in this case is the protective sterility cap of the Delica Plus lancet.

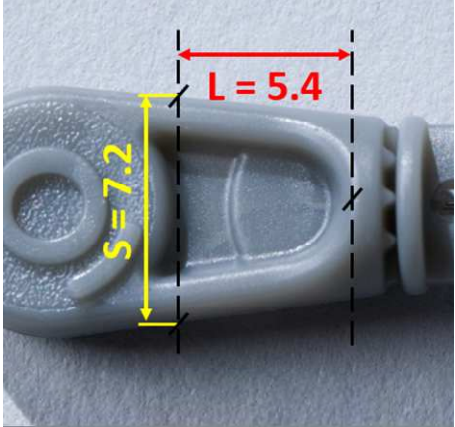
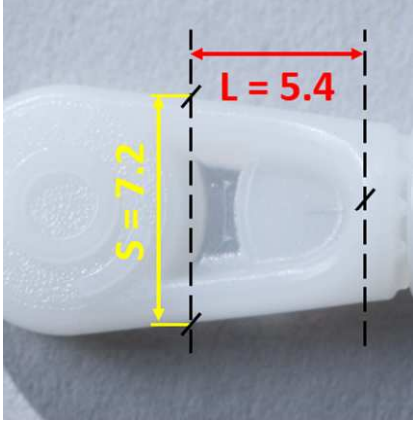
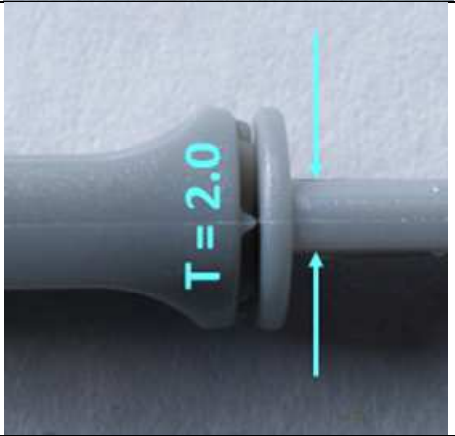
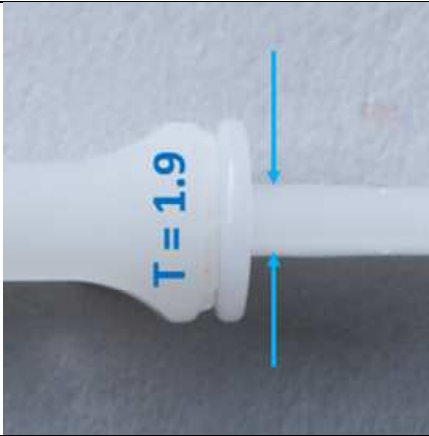
147. I have been informed that Asahi Polyslider Company Ltd. (“Asahi”), a Japanese company, developed the lancet used in the Delica Plus lancing system. I have also been informed that Asahi manufactures the Delica Plus lancet for LifeScan.



148. I measured the accused products using a digital caliper. I focused on the aspects salient to the patent, such as span, length, etc., paying strict attention to measure to the start and end positions described by the patent as a POSITA would understand them to be, and as confirmed by the court. (See above sections on Span and Length).

| <b>Measurements of the Accused Products<sup>3</sup></b> |                 |                         |
|---------------------------------------------------------|-----------------|-------------------------|
|                                                         | Delica Plus 30G | Delica Plus 33G [white] |

<sup>3</sup> I selected 10 samples and measured the length, span and thickness of each. The measurements between same SKUS varied only within 0.09mm. The measurements shown in the table represent the average dimension of the measurements rounded to the nearest 0.1mm.

|                                          |                                                                                    |                                                                                     |
|------------------------------------------|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| <p>“L” and Span “S” (at top of “L”)</p>  |   |   |
| <p>Thickness “T” (w/o lancet flange)</p> |  |  |

## VII. REBUTTAL OF THE COLLINS REPORT

149. In this section, I will provide my opinion on the opinions expressed in the Collins Report.

### A. The Collins Report Lacks Crucial Analysis and Expert Opinion

150. In my understanding, an expert opinion is sought in IP infringement cases, such as these, to provide substantiated opinions based on the evidence of the case. To form these opinions, the expert witness undertakes analysis of specific aspects of the case, therefore the report should provide this analysis and thereby

underscore any resulting opinions or conclusions. Without which, the opinions may seem baseless and conclusory.

151. The Collins Report does not provide adequate reasoning or analysis to support the concluding opinions and is missing many opinions on salient aspects of this case.

152. I understand that Mr. Collins was trained as a mechanical engineer and has been involved in many mechanical engineering tasks through many decades. However, Mr. Collin does not apply this expertise in his analysis of the patent and accused products but often relies only on selected pieces of extrinsic evidence and the aspects already identified by Plaintiff's counsel. This lack of applying expert opinion and analysis may undermine the credibility of his conclusions as an independent expert witness.

153. Further, much of the Collins Report does not center on providing an expert infringement analysis but on a rebuttal of the defendant's arguments in the materials submitted by the defendants, such as the deposition testimony, discovery responses and contentions.

154. It is my understanding that it is the burden of the plaintiffs to provide an infringement analysis. As the Collins Report leaves much of this analysis untouched, I will provide my infringement analysis in a later section.

#### **B. Mr. Collins Does Not Use the Viewpoint of the POSITA**

155. It is my understanding that the infringement analysis should be conducted between the Patent-In-Suit and the Accused Products, through the viewpoint of the POSITA.

156. The Collins Report acknowledges this process in the ‘Legal Understandings’ section (Collins Report ¶ 33) and provides an opinion that a POSITA at the time of the invention would have a bachelor’s degree in mechanical engineering, biomechanical engineering or similar, and have had at least one year of experience researching, developing and/or designing mechanical medical devices. Mr. Collins also suggests that less work experience could be compensated for by a higher level of education.

157. First, I disagree with the type of experience Mr. Collins suggests. The high complexity in the injection molding processes involved in products such as these would require a working knowledge and understanding of mold flow, tooling tolerances and molding issues related to very small injection molded parts. While these general topics may be taught in mechanical engineering courses, I would consider at least 2 years’ experience in designing very small injection molded parts to be a requirement for the POSITA in this case.

158. I have worked with many toolmakers and manufacturers of complex, mechanical parts, and have seen a great deal of variation in the skillsets of their mechanical designers, which appears to correlate with the molding quality of the

end product. Small injection molded products that demand high precision, reliable manufacture need a mechanical engineer with real-world designing experience in dealing with those particular constraints. For that reason, I know that an ‘average’ mechanical engineer with just one years’ experience researching and/or developing mechanical medical devices would not be sufficient experience.

159. Second, for the reasons stated above, I disagree that a lack of working experience could be compensated by a higher-level academic degree alone. A master’s degree in a related field would possibly provide further in-depth theory but would not provide the working knowledge necessary for designing such high precision plastic parts, as described above.

160. I surpass the requirement of a POSITA in this case. My degree was in a related field, industrial design, and I have worked for many years designing intricate parts for injection molding, within the medical field and in other fields.

161. Importantly, despite having provided a definition for the POSITA, Mr. Collins does not apply the viewpoint of the POSITA to his analysis. Outside of the Legal Understandings section, POSITA is mentioned only once, and only when quoting the Court’s Claim Construction order. (Collins Report ¶ 91).

### **C. The Collins Report Imports Purported Benefits Not Provided by the ‘635 Patent**

162. Mr. Collins suggests that the “dimensional limitations [of the patent claims] provide for a thinner and smaller lancet body, via the lancet thickness.” (Collins Report ¶ 49).

163. He suggests that the expanded dimensions of the endcap permits the use of finer gauge lancet needles (Collins ¶ 52). However, this defies logic, and would not be understood this way by a POSITA.

164. I understand that a finer lancet needle may contribute to reducing the pain experienced by the user. I have also been informed that most consumer/retail lancets from major brands are already considerably thinner than those used by professionals, and thus cause less pain if administered correctly.

165. However, the POSITA would understand that expanding the dimensions of the endcap does not aid in reducing the thickness of the lancet needle. The thickness of the lancet needle does however influence the thickness of the lancet body. For example, if the desired lancet needle thickness is 0.25mm (30 gauge), the lancet body thickness would need to be at least 0.25mm plus twice the minimum wall thickness of plastic<sup>4</sup>, which might result in a lancet thickness of 2mm. The cap, that is also molded around the needle to safely embed it, could have a width (or span) that is equal to this, 2mm. In fact, whether the span of the

---

<sup>4</sup> The minimum wall thickness would depend on the type of plastic used, the strength needed at that area, and the shape of the surrounding form.

cap is 2mm, 3mm or 5mm, it does not affect the thickness of the lancet needle. An increased width cap may have a slight effect on how easily the user can turn the cap, but this also does not affect the thickness of the lancet needle.

166. Mr. Collins also suggests a longer handle means “the user has **more room to maneuver** and hold the lancet and cap” (emphasis added) (Collins Report ¶ 53).

167. First, this does not align with the patent, which only suggests the advantage of the additional length is to bring the users’ fingers further away from the needle in order to better protect from accidental needle sticks (’635 Patent at 6:61-66).

168. Second, the provision of “more room to maneuver” is not Mr. Collins’ own opinion but appears to be the opinion of Mr. Seifert (Collins Report ¶¶ 53-54).

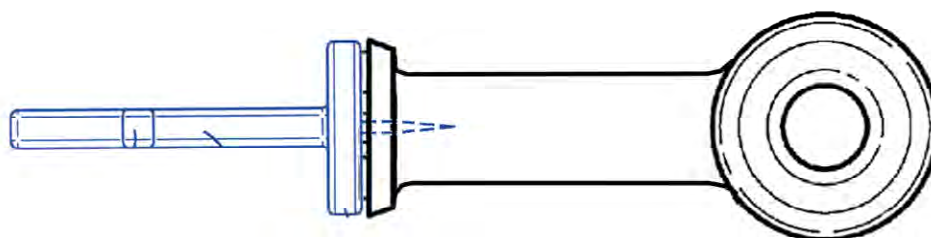
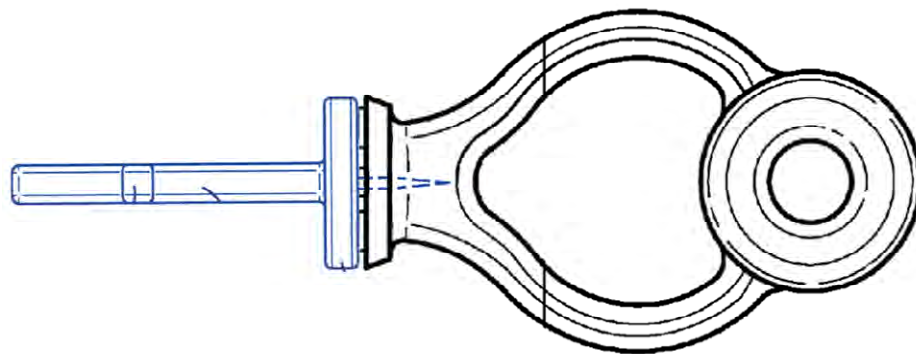
169. However, the POSITA would understand that an extended length of the cap could have adverse effects on the needle. Specifically, if the cap is overly long the user is more likely to accidentally apply a leverage force on the cap thus bending the end of the needle. The POSITA would understand that a shorter cap would reduce the risk of this accidental leverage and bending of the lancet needle.

170. I also note that an instructional video on how to handle the Delica Lancet echoed this observation: “You don’t want to hold it up here [on the secondary sheath] because the lancets [needle] so fine you can bend it so it’s best

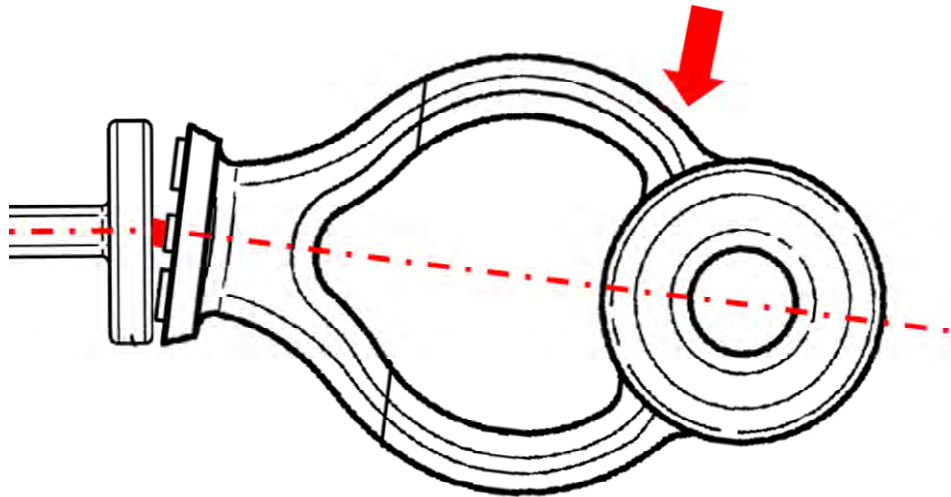
you just hold it in the middle and push.” (“One Touch Verio” youtube video at <https://www.youtube.com/watch?v=OVSrbH25oo0>).



**The span of the cap does not directly affect the width of the needle.**



The span of the gripping handle does not affect the width of the needle. In the example at the top based figure 3D and 5D of the '635 Patent, the gripping handle portion has very wide span, whereas the midsection of the hypothetical design below it is much thinner. The smaller span of the hypothetical version does not require a thicker needle.



However, if the gripping handles are overly long the user is more likely to accidentally apply a leverage force on the cap thus bending the end of the needle.

171. I do not agree with Mr. Collins that a wider, elongated gripping handle enables an overall reduction of size in the lancet, including the lancet body (Collins Report ¶ 53). The POSITA would understand from the patent, and based on their knowledge, that the wider, longer gripping handle of the patent may make the cap easier to grip and slightly easier to turn. They would also know from their own knowledge that a longer handle may cause accidental leverage thus damaging the needle, particularly one of relative thinness. With this in mind, the POSITA would likely consider *reducing*-not elongating- the length of the handle if they want to reduce the thickness of the needle.

172. To summarize, the thickness of the needle is not decreased by having a longer, wider cap. Having a dimensional “limitation” for a  $\geq 1.5$  ratio between the cap gripping handle lateral span and the lancet thickness does not reduce user pain, as Mr. Collins suggests.

**D. The Collins Report Fails to Provide Expert Opinions Regarding Infringement by Relying Only on Extrinsic Information**

173. While I understand that extrinsic evidence may help corroborate an expert’s opinion, it is expected that the expert draw upon their expertise for their own independent analysis. Mr. Collins does not base his infringement analysis on his knowledge of mechanical engineering or of the POSITA. Mr. Collins relies chiefly upon information extrinsic to the patent and to the accused products.

174. For example, instead of opining based on his expertise whether the Accused Products have a ‘protective sterility cap for a lancet’ – which would be apparent to the POSITA in view of the patent – Mr. Collins refers only to LifeScan’s ‘Specification Document’, a deposition of Mr. Knapp, the ‘Purchase Part Specification’, an email from Ms. Spellman, a deposition of Mr. Morrison, the One Touch Delica Plus Lancing Device Instructions For Use, and the ‘final specification documents’.

175. This approach is repeated for almost all of the claim elements, thus the Collins Report misses many crucial expert opinions that would otherwise support his conclusions.

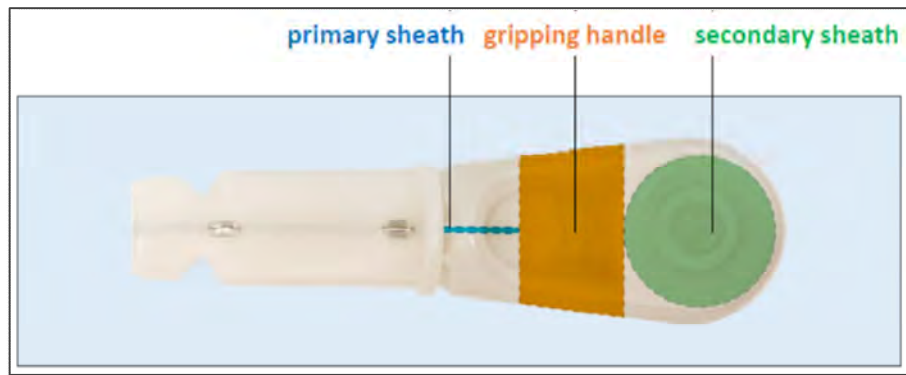
### **E. Mr. Collins Provides Different Opinions on Where the Primary Sheath Ends**

176. In one image Mr. Collins marks a line where the needle ends and the gripping handle begins (Collins Report ¶ 68). While I agree that the gripping handle is distinct from the primary sheath and starts where the sheath ends, I do not agree that the patent teaches that the sheath ends at the very tip of the lancet needle. Mr. Collins does not provide a reason why this particular point would be correct.

177. In another image, Mr. Collins shows a cross-section of the Accused Product (Collins Report ¶ 71) which shows the plastic surrounding the needle continues much further than the tip of the needle. However, Mr. Collins does not clarify if he understands that this contradicts his previous position or whether he suggests it as an alternative.

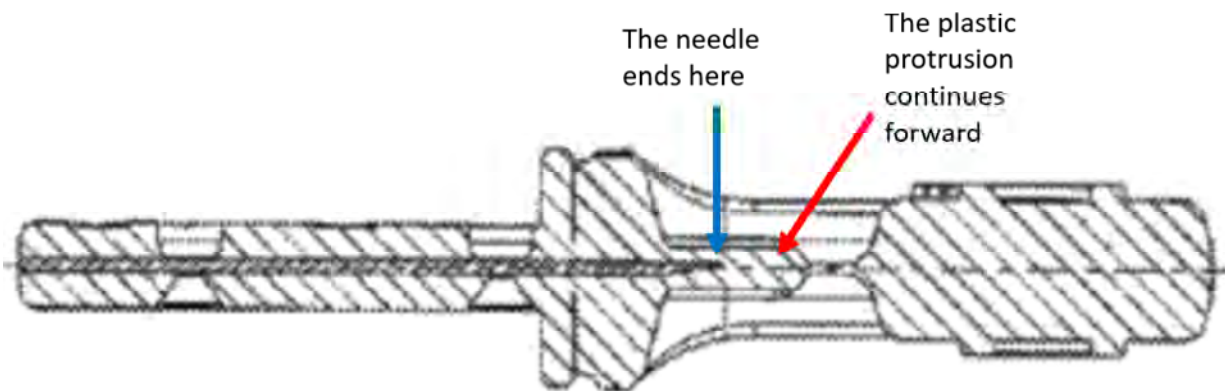
178. It is therefore not clear if Mr. Collins considers the primary sheath to be the flange, the forward protruding plastic part, or terminating at the very tip of the lancet needle.

|                                                                                    |
|------------------------------------------------------------------------------------|
| <b>Mr. Collins shows different, arbitrary places to mark the end of the sheath</b> |
|------------------------------------------------------------------------------------|



Collins Report ¶ 68 (cropped for clarity)

Here, Mr. Collins shows the tip of the (blue) needle marks the end of the sheath and the start of the gripping handle.



Collins Report ¶ 71 (annotated with my notes)

179. Mr. Collins' understanding of where the sheath ends is also left ambiguous in his later paragraphs on Claim 6, where he only states that a sharp lancet is initially embedded in the primary sheath, and provides a diagram that does not annotate or reveal the portion considered to be the primary sheath. (Collins Report ¶ 164).

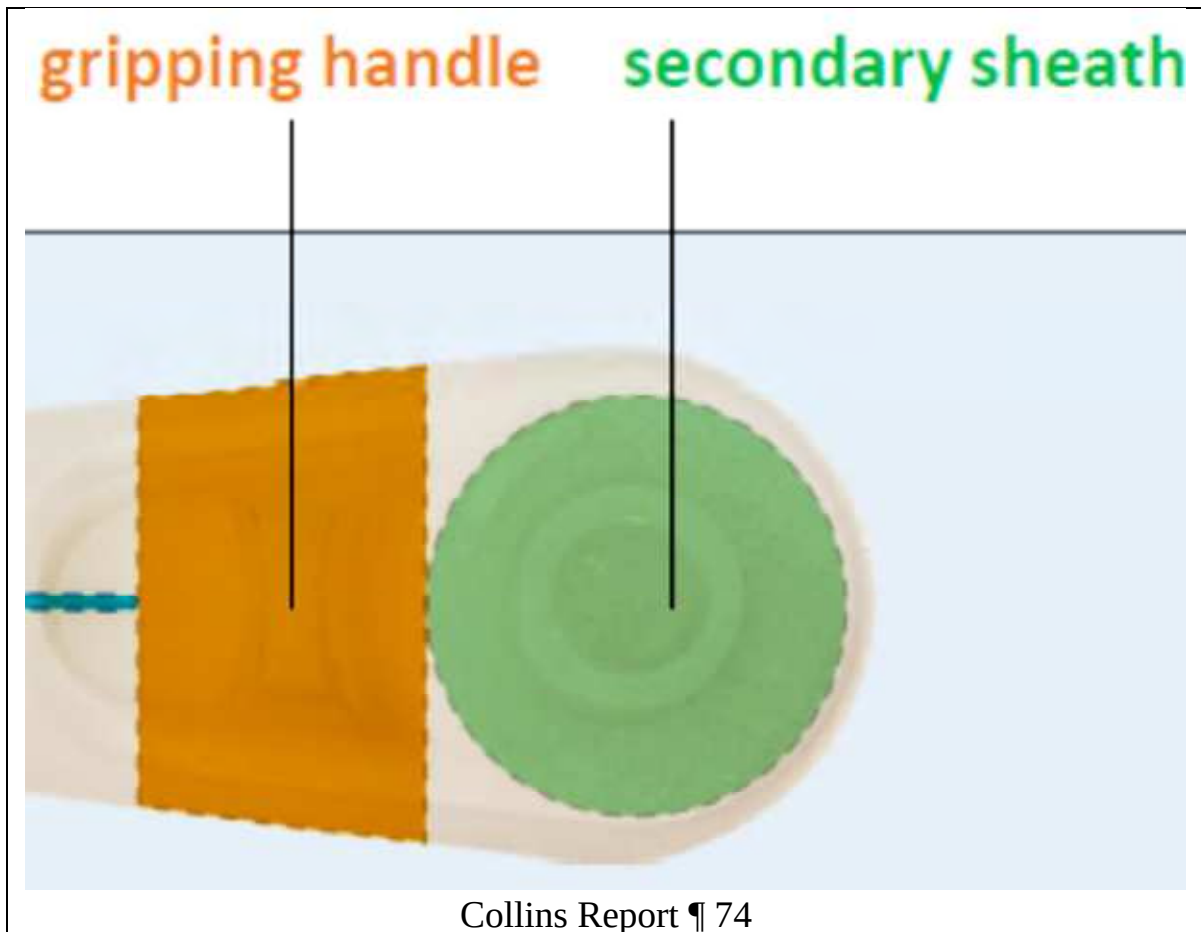
#### F. Mr. Collins Does Not Rely on the Patent to Identify the Secondary Sheath

180. Mr. Collins suggests the secondary sheath of the Accused Product is a circular area inset from the outer edge. However, Mr. Collins does not explain why this particular shape and this particular position – that does not align to any visible markings – would represent the secondary sheath, and the areas outside of this would not.

181. Further, the leftmost edge of this purported secondary sheath boundary does not correlate to the position shown in Figure 5C of the '635 Patent, and is therefore also arbitrary.

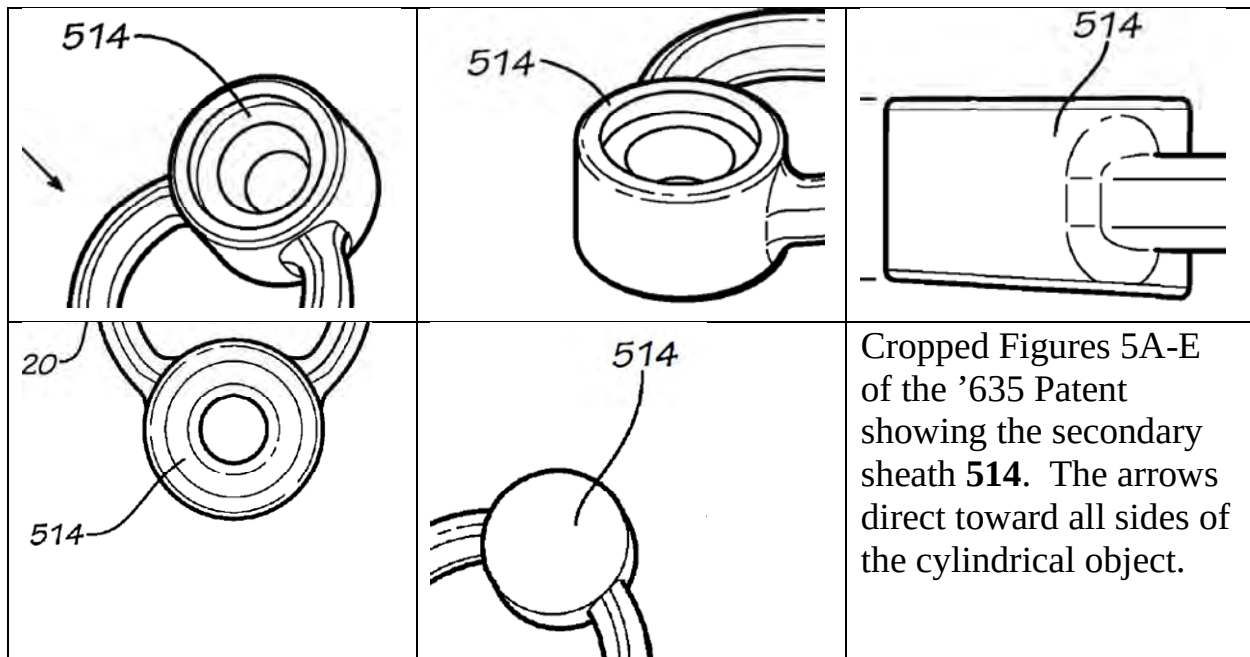
182. Furthermore, Mr. Collins does not measure to this location when providing measurements using digital calipers.

|                                                                                                                    |
|--------------------------------------------------------------------------------------------------------------------|
| <b>Mr. Collins chose an arbitrary position (and shape) to demark the sheath that is not informed by the patent</b> |
|--------------------------------------------------------------------------------------------------------------------|



183. Contrary to Mr. Collin’s position, the patent does label the inner and outer parts of the circular form as the ‘secondary shroud or sheath 514’ and that the embodiment in 5A-E ‘comprises a cup having an outer rim and hollow interior chamber’. ’635 Patent at 6:35-36. Therefore, the POSITA in view of the patent would know that the secondary sheath encompasses the entire circular structure and not an arbitrary circular portion.

**Figures 5A-E of the ‘635 Patent clearly demark the secondary sheath**



184. Again, rather than providing an opinion on what and where the POSITA would understand the secondary sheath to be on the Accused Product, or referring to the patent, Mr. Collins defers opinion to extrinsic information including Lifescan’s starter guide, deposition from Mr. Knapp, the ‘OneTouch Delica Plus Lancing Device Instructions For Use’, the deposition transcript of Ms. Voyten, and the “Getting Started” video.

185. Mr. Collins also suggests that the Court’s construction of the term “secondary sheath for receiving” would include sheaths that would expose the end tip of the lancet needle after the lancet has been positioned in it (Collins Report ¶ 77). I disagree.

186. I understand the Court construed the term to be “a secondary sheath for covering the sharp lancing tip of a used lancet by embedding or enclosing the

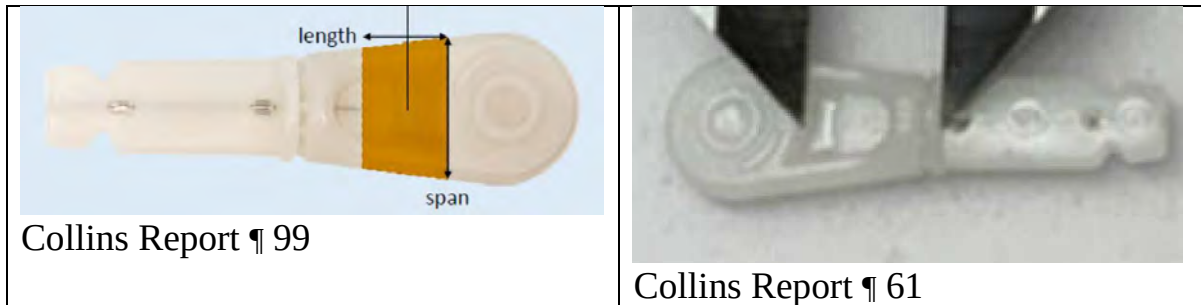
lancet tip”. I understand this to mean that the very tip of the lancet should not remain exposed but covered, or enclosed. The patent too, describes the secondary sheath to “re-cover the sharp lancet for safety and hygienic purposes.” ’635 Patent at 1:50-52. Therefore, the POSITA would understand from the patent that the secondary sheath should enclose or re-cover the sharp lancing tip to protect the user from inadvertent contact.

**G. The Collins Report Uses Several Different Start and End Locations for the Gripping Handle Length “L”**

187. I agree that the patent teaches that the primary sheath attaches to a first end of the gripping handle and the secondary sheath is attached at a second end of the gripping handle portion. The POSITA would also understand that the length “L” of the handle portion is a relative measurement as disclosed on one embodiment in Figure 5C, based on the distance between the top outer edge of the flange and the closest point of the secondary sheath.

188. Mr. Collins is inconsistent with his own definition of where these locations are within the report. In paragraph 81, Mr. Collins considers the gripping handle to be from the very tip of the embedded lancet needle, to a location just inside the cylindrical shape (see table below). However, in the photographs showing his measuring of the Delica Plus, he measures to a different location.

|                                                                          |
|--------------------------------------------------------------------------|
| <b>Mr. Collins uses different start and end locations for length “L”</b> |
|--------------------------------------------------------------------------|



189. Furthermore, Mr. Collins suggests the dimension of “L’ is **2.81mm** and **2.49mm** for the 30G and 33G versions (Collins Report ¶ 99). This dimension is considerably shorter than the portion shown by the orange zone in his accompanying illustration. Specifically, the orange zone is almost exactly 1/6<sup>th</sup> of the total length of the accused product, which would be **4.66mm**.

190. Moreover, Mr. Collins measured quite different “L” lengths for the two products, whereas my measurements showed that they were identical in that regard.<sup>5</sup> This further shows the arbitrary nature of the measurements provided in the Collins Report.

191. Additionally, the start and end positions Mr. Collins employs to measure the length “L” correlate with the patent, and contradict the court’s understanding of that dimension. The court did not construe the term ‘length’ but confirmed that figure 5C of the ‘635 Patent provides a clear definition, and also provided a corresponding annotation on figure 5A of the ‘635 Patent.

---

<sup>5</sup> The exposed length of the needles between the 30G and 33G products were also near identical, thus the difference between Mr. Collins own measurements was not due to a differing needle length.

192. Mr. Collins explains that he measured “L” by measuring from the secondary sheath to the far side of the lancet flange, then measured from that flange to the tip of the needle and subtracted the difference. I understand this was to calculate the minimum distance between the primary and secondary sheaths, but it is unclear why Mr. Collins did not measure from secondary sheath to the upper top of the flange as the patent describes “L” to be.

193. The POSITA would understand that the true length measurement of the gripping handle portion of the cap starts at the top of the flange and continues to the very underside of the secondary sheath.

**The patent and the court provide clear guidance on where to measure length “L”**

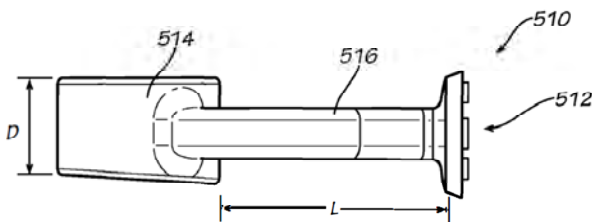


**FIG. 5C**

Figure 5C of the '635 Patent showing the length “L”.

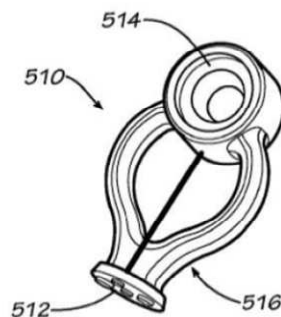
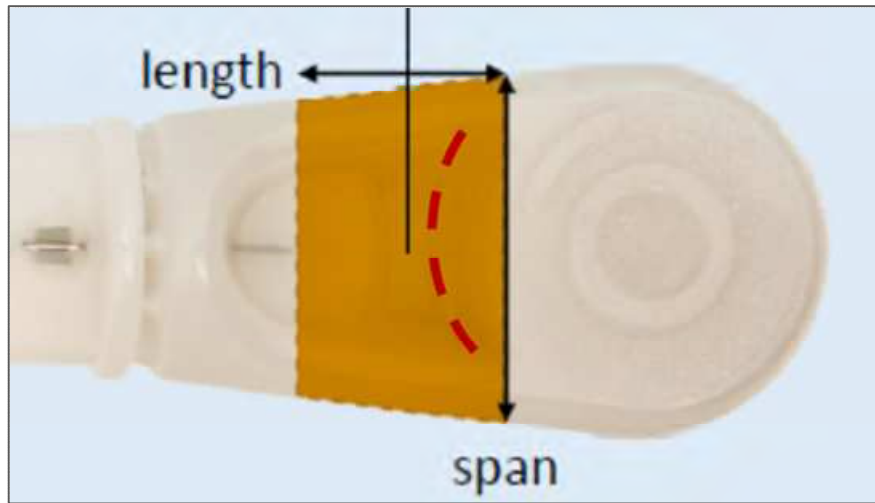


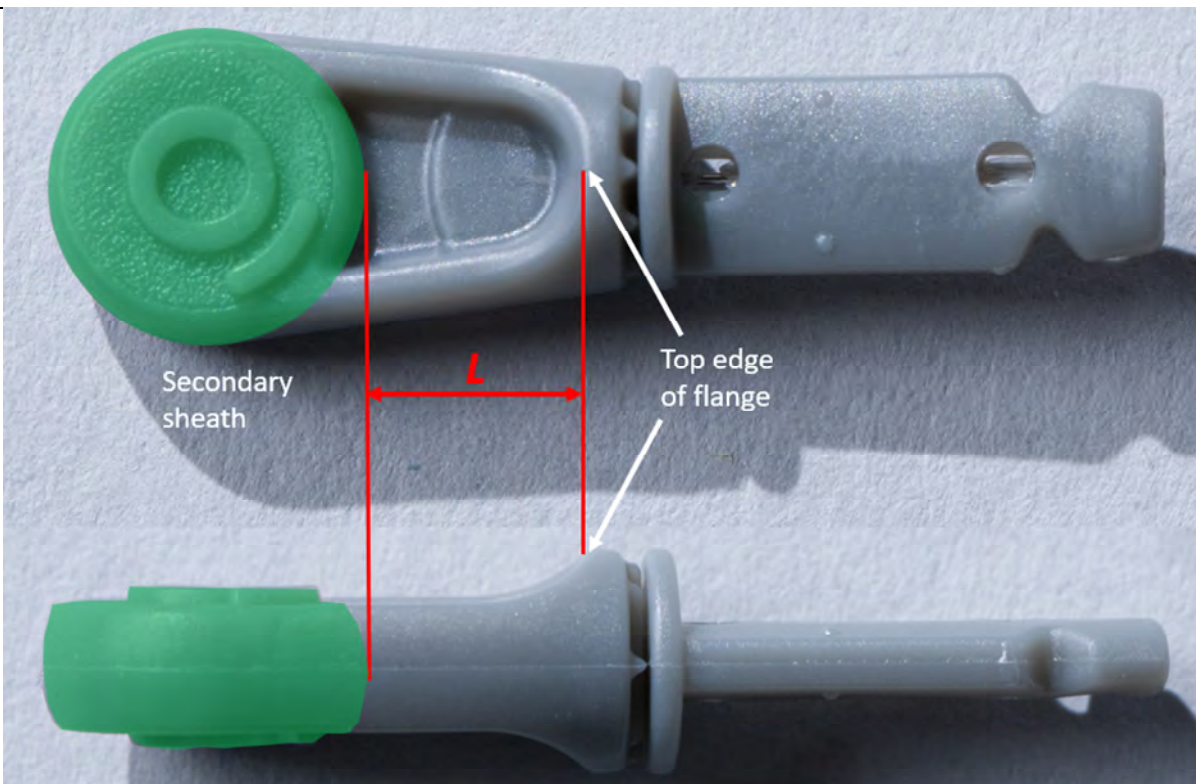
**FIG. 5A**

The court’s annotation of Fig 5A of the '635 Patent to show the length “L”



Collins Report ¶ 92 (annotated)

I added the dotted red line to show the approximate location of the rest of the secondary sheath. It is unclear why the length “L” would overlap the secondary sheath, which contradicts the patent.



Photograph of the 30G Accused Product, with annotation showing the length “L” as described by the patent and by the court.

194. Further, I note Mr. Collins measures the lancet body thickness to be 1.74-1.75 mm, (Collins Report ¶ 99) whereas I measure them to be considerably thicker, 1.98-2.02 mm. I was only able to recreate Mr. Collins's 1.75 mm by applying considerable force on the calipers to squeeze into the plastic, which would not be the typical method to measure an object.

195. Mr. Collins's incorrect measurements were the basis for his resulting conclusions that the Accused Product meet the requirements of the claims, thus his faulty analysis may undermine the strength of his conclusions.

#### **H. Mr. Collins Misappropriates the Accused Product's Neck to Be Gripping Handles**

196. Mr. Collins argues that the *Accused Product* has a gripping handle extending between the primary sheath and the secondary sheath. He confirmed through his examination that the Accused Product includes the gripping handle as shown in the below figures. I did not see an explanation describing Mr. Collins's own reasons for his depiction of a gripping handle to be this trapezoidal boundary. Mr. Collins's subsequently stated that since the sterility cap is designed to be gripped by hand, the trapezoidal boundary is a gripping handle portion. He then states that he confirmed this through his examination of the Accused Products and that LifeScan's own documents demonstrate this trapezoidal-shaped gripping handle portion. It is unclear what specifically in his examination independently convinced him that the trapezoidal area is a gripping handle portion.

197. Rather than referring to how the POSITA may understand the gripping handle portion, Mr. Collins defers his opinion to the Lifescan Instruction Manual which depicts a user “grasping what I have identified as the gripping handle portion” (Collins Report ¶ 85) and to a video of a user “inserting the lancet by holding the gripping handle portion and removing the cap by holding the same” (Collins Report ¶ 86). I disagree.

198. First, the fingers in both the images he provides show they are centered on the secondary sheath and are not *gripping* the portion he describes as the gripping handle. In looking closely, I note that the fingers may be touching some of the gripping handle zone identified by Mr. Collins, but the force of the *grip* applied by the fingers would be upon the secondary sheath and not on the adjacent, inward sloping neck area.

199. Second, the POSITA would not rely on these to understand where to grip the accused product, as the product itself makes it clear to the POSITA where to hold the cap for insertion into the device and for twisting to release it from the lancet body.

200. Furthermore, as I will explain in further detail in my infringement analysis, the POSITA would not consider the Accused Product to have gripping handles located in the portion of the cap between the primary and secondary sheaths. The POSITA would consider this to be the ‘neck’ of the product, thus not

designed to have the physical space or affordances of the gripping handle of the '635 Patent.

**I. The Collins Report relies upon inaccurate measurements of the Lateral Span**

201. Mr. Collins suggests the gripping handle lateral span “S” of the Accused Products is 6.88mm and 6.81mm for the 30G and 33G products respectively. (Collins Report ¶ 94). His measurements correspond to a position on the product much further down from even the position Mr. Collins marked as the uppermost edge of the gripping handles in his earlier diagram.

202. The POSITA would not consider the Accused Products necks to be ‘gripping handles’. Nevertheless, even if the neck would be considered to be gripping handles, the measurements provided by Mr. Collins are still inaccurate.

**VIII. INFRINGEMENT ANALYSIS**

**A. The Delica Plus Cap Does Not Infringe the '635 Patent**

203. Having analyzed the '635 Patent, its filing history and the Accused Product, it is my opinion that the POSITA would not find the Accused Product includes all of the elements of Claims 1, 6, 8, 14, and 18.

204. As Mr. Collins has not provided the necessary analysis nor provided his own expert opinion of all the claims from the viewpoint of the POSITA, I will provide an outline of my analysis below. For brevity I will not repeat in full the arguments laid out in the rebuttal section, but they are equally applicable here.

1. The Delica Plus cap does not infringe claim 1.

205. First, a POSITA would not understand the Accused Product to have a gripping handle between the primary and secondary sheaths.

206. The Accused Product has no portion that qualifies as a “gripping handle”. Under the court’s construction, the Delica Plus has two sheaths, and the plastic between the sheaths, the neck, is not designed as a grip, a gripping handle, nor is it designed as a touchpoint.

207. As discussed in section VII.H.1 above, touchpoints or handles are designed to (i) physically fit or accommodate the users’ hand and or fingers, and (ii) to provide a physical advantage to use. These physical attributes are also usually visibly communicated to the user, that is their shape, color or details provide visual cues that they are a touchpoint or handle.

208. The neck is not designed to physically fit or accommodate the users’ hand or fingers. The user *can* touch it, but being only approximately 5 mm in length and not in a prominent position for access, it is clearly not designed for a user’s finger to grasp, grip or hold in the way the Patent discloses a gripping handle.

209. The neck also does not provide a physical advantage to use. The patent describes two main purposes for the gripping handle where the handle may offer physical advantages; (1) to grip when pushing the lancet into the device, and

(2) to grip when twisting. The pushing movement would be facilitated by an outwardly tapering surface that would provide the user with something to push against. The twisting movement would be facilitated by a gripping handle that offers surfaces that are relatively far from the center of the product, thus increasing the torque and providing for easier twisting. The POSITA would understand how a gripping handle or touchpoint would be designed to provide these physical advantages, and would not consider them to be present in the neck of the Accused Products.

210. The neck of the Accused Products is short, narrow, and tapers inward, thus not providing a surface to push against, nor does it provide surfaces that are far from the center to provide easier twisting. A POSITA would not consider the neck to offer these physical advantages, especially as other parts of the product facilitate these physical attributes much better.

211. Further, these physical advantages are not visually communicated by the design of the neck, that is, the neck is devoid of the typical visual cues that a designer would use to communicate to the user to touch or interact specifically with that portion.

212. The POSITA would understand a user would treat the secondary sheath area as the main gripping point, as it has much better physical accommodations, and physical advantages for gripping, pushing, and turning.

213. First, its shape is designed to accommodate the fingers; it is relatively flat, round and offers gripping like the head of a key. There are also no constraining objects or edges nearby that would limit access to it.

214. Second, the secondary sheath provides outwardly oriented surfaces against which the user can push, when inserting the lancet into the device. It also provides the widest part of the product, thus providing the best point from which to twist. The two major faces of the secondary sheath also include raised ribs that provide tactility, thus improving grip.

215. The ribs on the major faces of the secondary sheath also act as visual cues to communicate to the user that this area is for gripping.

216. All of the above-mentioned attributes of the secondary sheath are either devoid or considerably lesser in the neck portion, thus greatly surpassing the neck as a potential touch point or gripping handle.

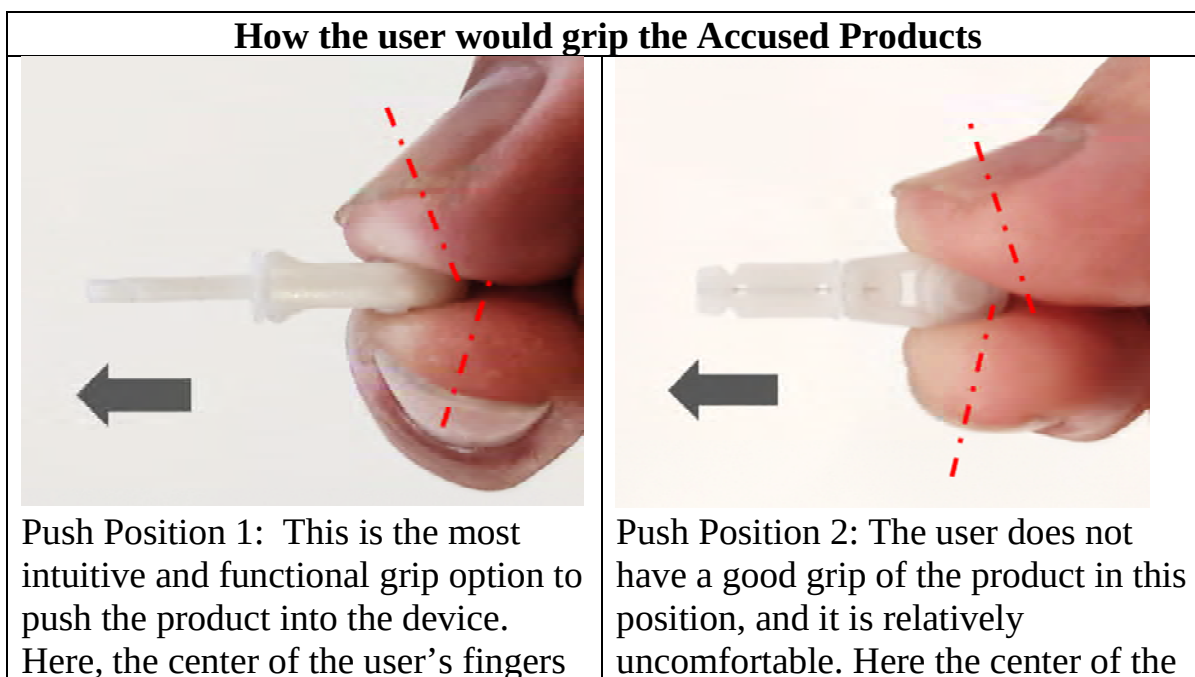
217. For at least these reasons, the POSITA would understand that the secondary sheath portion is designed to be the touchpoint or gripping area of the Accused Products and that a user would also consider it so.

218. As discussed earlier, designers use measurements, statistics and anthropometric data as a basis for a design, but the most crucial evaluation typically happens with hands-on prototypes. Therefore, I also analyzed the Accused Products as a designer would evaluate the ergonomics of a prototype, and

something I have done as a designer of hundreds of products. Here, I held the product in four different positions for the **‘push’ action** that a user would do when pushing it into a device, and then four positions for the **twist action** where the user removes the cap from the lancet body.

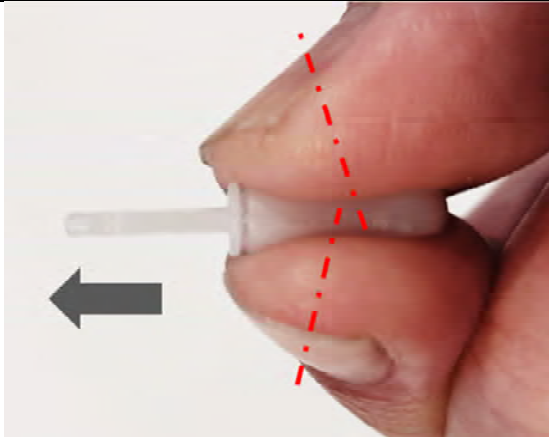
219. I noted how it felt, pressure points, and how much I could maintain my grip on the cap when actuating the respective force.

220. One observation of note is that when twisting the cap from the lancet, the cap needs to be turned more than a user can do in one twist. After twisting about 180 degrees, the cap does not come away, so the user then releases their grip, twists the hand back and then regrips to twist the cap a further 180 degrees. This happens intuitively and without thought, but it highlights that the user will need an easy and accessible surface to quickly regrip to.

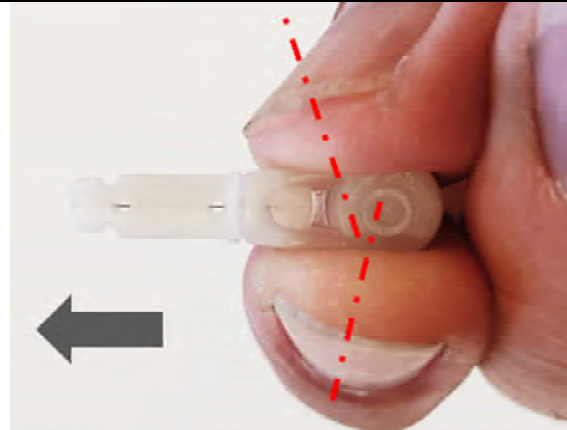


are slightly behind the center of the secondary sheath, allowing them to grip firmly while applying a pushing force.

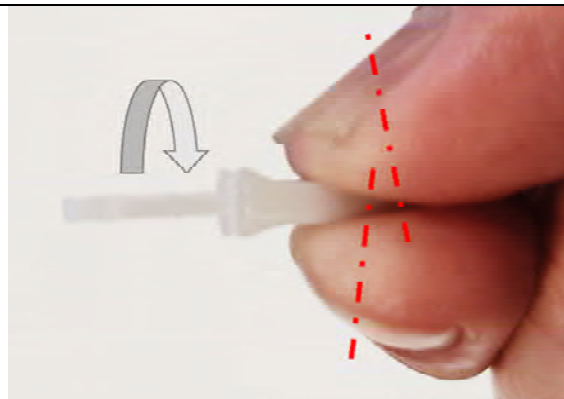
fingers is near the center of the secondary sheath, but the cap is held on the sides. Because the sides are taller than they are wide, the device is prone to rotate 90 degrees in the user's fingers.



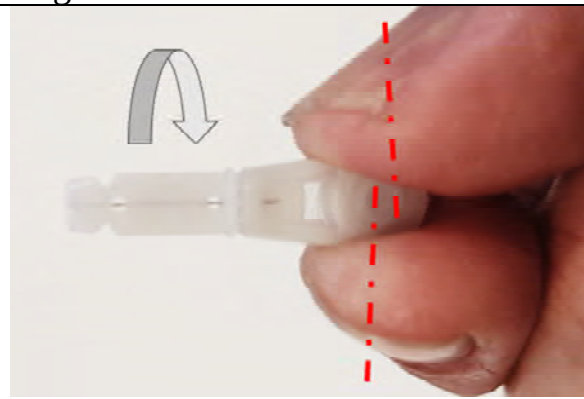
Push position 3: The user does not have a safe position on the product in this position. If the user's fingers grip the cap forward of the secondary sheath, the main surface the fingers use to push against is the flange, but touching this means the fingers also overlap the front and therefore get in the way of the device.



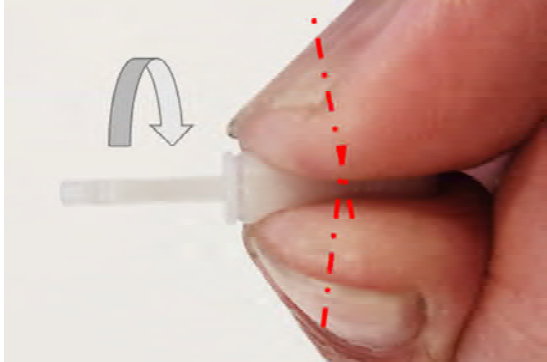
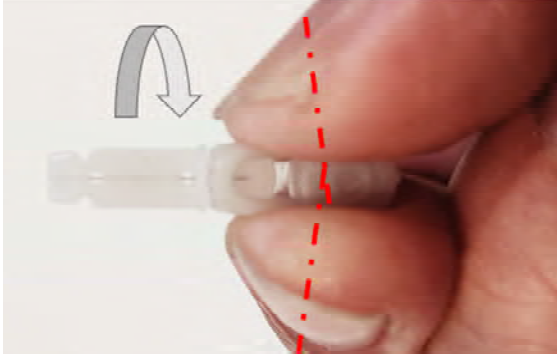
Push Position 4: The user does not have a good grip on the product in this position. Here the center of the user's fingers are closer to the neck portion. Because this area is sloping inward, the user has no surface to push. Additionally due to the shape being taller than it is wide, it is also prone to rotating 90 degrees in the user's fingers.



Twist Position 1: The user is able to firmly grip the cap in this position and apply a substantial twisting force to separate it from the lancet. The



Twist Position 2: The user does not have a good grip of the product in this position, and it is relatively uncomfortable. Here the center of the

|                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>fingers are centered over the middle of the secondary sheath, and the ribs help provide further grip. After twisting about 180 degrees and regripping, the flats of the secondary sheath are easy and quick to find and grip.</p>                                                                                                                                                                                                               | <p>fingers is near the center of the secondary sheath, but the cap is held on the sides. Because the sides are taller than they are wide, it is very difficult to stop it from flipping 90 degrees in the user's fingers when trying to twist. After which, the cap sits flat, and can be twisted like in twist position1.</p>                                                                                                                                                               |
|  <p>Twist Position 3: The user does not have a safe position on the product in this position. If the user's fingers grip the cap forward of the secondary sheath, the main surface the fingers use to push against is the flange, but touching this means the fingers also overlap the front and maybe be exposed to the tip of the lancet when it come free.</p> |  <p>Twist Position 4: The user does not have a good grip on the product in this position. Here the center of the user's fingers are close to the neck portion. Because the sides are taller than they are wide, it is very difficult to stop it from flipping 90 degrees in the user's fingers when trying to twist. After which, the cap sits flat, and can be twisted like in twist position 1 or 3.</p> |

221. The above analysis studied how a user would grip the Accused Product when conducting what the patent describes as the main features of the gripping handles; for gripping when installing the lancet into the lancing device and for gripping to twist the cap to remove it from the lancet (See above). The

‘635 Patent described other benefits of its gripping handles which I will briefly address below.

222. The elongated gripping handles of the ‘635 Patent encourage the user to grab the cap further away from the needle. In contrast, the short neck of the Accused Product does not provide this benefit. As shown in the ergonomic test, the shape of the Accused Product’s cap drives the user to position the center of their fingers on the flat sides of the secondary sheath, as positioning the fingers on the neck or generally closer to the needle are uncomfortable, lack grip and are unsafe.

223. The ‘635 Patent also touts the gripping handles aiding grabbing the cap further from the needle when recapping. On the Accused Products, there is very little space between even the endmost part of the cap, the flange and the secondary sheath where the needle will be disposed, and the (short) neck does not provide a gripping surface suitable for keeping the fingers at a safe distance.

224. The ‘635 Patent also explains further benefits of the gripping handles, that they allow for easier use by persons with limited dexterity or vision, as it would be easier to see, grip, pick off the table, and the increased width would make it easier to turn. The short neck of the Accused Products does not provide these benefits.

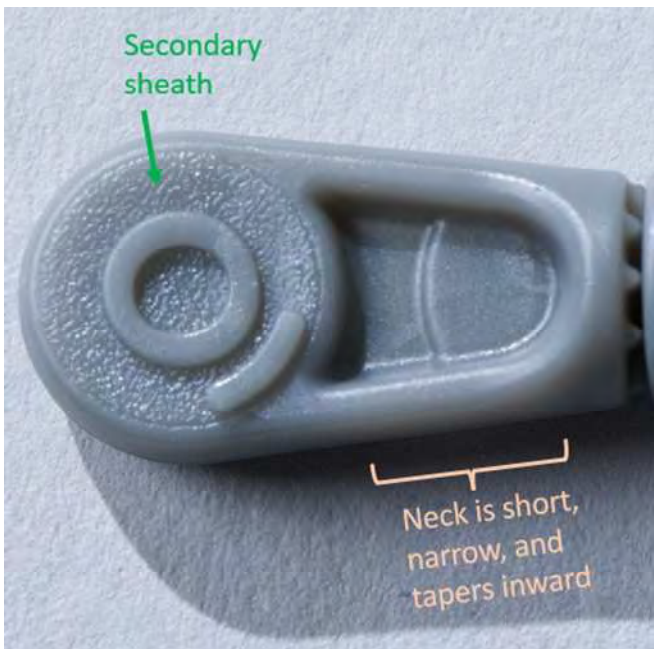
225. The POSITA would also recognize that these and many other benefits described in the specification about the gripping handles are not met by the neck of the Accused Products.

226. These are non-limiting benefits of the '635 Patent but help the POSITA's understanding of what the inventor intends such an elongated gripping handle to facilitate. They further support the POSITA's understanding that the neck of the Accused Product is not a gripping handle as it would not meet these additional benefits.

227. To summarize, the POSITA would not understand the neck of the Accused Products to be a gripping handle or touchpoint but would consider the secondary sheath as a touchpoint.

**2. The Delica Plus Cap does not infringe claims 6, 8, 14, or 18.**

| <b>Infringement Claim Chart comparing Claims 1, 6-8 with the Accused Products</b> |                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1.d</b>                                                                        | a gripping handle portion extending between the primary sheath and the secondary sheath, | <b>No.</b> The POSITA would not understand the Accused Product to have a gripping handle between the primary and secondary sheaths.<br><br>The POSITA would understand the gripping area of the Accused Products is the cylindrical secondary sheath portion, which has visual and physical affordances for gripping and turning. The neck portion however, is very short, narrow, and tapers inward, thus not visually cueing or providing the necessary grip for pushing the lancet into the device or for twisting the cap off the lancet body. |

|            |                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            |                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>1.e</b> | 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 | <b>No.</b> For the same reasons provided to claim element 1.d, the POSITA would not understand the Accused Product to have a gripping handle between the primary and secondary sheaths.                                                                                                                                                                                                                                                                                                   |
| <b>6.a</b> | The protective sterility cap of claim 1                                                                                                                                                                                      | <b>No.</b> The Accused Products are at least missing claim elements 1.d and 1.e as explained above.                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>6.d</b> | wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness                                                                                                                        | <b>No.</b> The POSITA would not understand the Accused Product to have the gripping handle of the patent, as there is only a neck, not a grip ‘extending between the primary shroud portion and the secondary shroud portion’. The POSITA would understand the gripping area of the Accused Products is the cylindrical secondary sheath portion, which has visual and physical affordances for gripping and turning. The neck portion, however, is very <i>short, narrow, and tapers</i> |

|            |                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            |                                                                                                                                                                                                                                                                                                                                                                                     | <i>inward</i> , thus not visually cueing or providing the necessary grip for pushing the lancet into the device or for twisting the cap off the lancet body.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>8.a</b> | The protective sterility cap of claim 6                                                                                                                                                                                                                                                                                                                                             | <b>No.</b> The Accused Products are at least missing claim elements 1.d, 1.e, and 6.d as explained above.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>8.b</b> | wherein the gripping handle portion defines a length at least equal to the lancet thickness                                                                                                                                                                                                                                                                                         | <b>No.</b> The POSITA would not understand the Accused Product to have the gripping handle of the patent, as there is only a neck, not a grip ‘extending between the primary shroud portion and the secondary shroud portion’. The POSITA would understand the gripping area of the Accused Products is the cylindrical secondary sheath portion, which has visual and physical affordances for gripping and turning. The neck portion, however, is very <i>short, narrow, and tapers inward</i> , thus not visually cueing or providing the necessary grip for pushing the lancet into the device or for twisting the cap off the lancet body. |
| <b>14</b>  | 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 | <p><b>No.</b> The Accused Products are at least missing claim elements 1.d, 1.e, and 6.d as explained above.</p> <p>Claim 14 includes limitations analogous in scope to limitations 1a – 1e, and a POSITA would understand whether or not the Accused Product meets the limitations of Claim 14 for the same reasons. Claim 14 also includes limitations analogous in scope to those found in claim 6, and a POSITA would understand whether or not the Accused Product meets the limitations of Claim 14 for the same reasons as well.</p>                                                                                                     |

|           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|           | <p>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.</p> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>18</b> | <p>The protective sterility cap of claim 14, wherein the gripping handle portion defines a length at least equal to the lancet thickness.</p>                                                                                                                                                                                                                                                                                                                                       | <p><b>No.</b> The Accused Products are at least missing claim elements 1.d, 1.e, 6.d and 8.d as explained above.</p> <p>Claim 18 depends from claim 14, which I have explained above how a POSITA would understand whether or not the Accused Product meets the limitations of that claim. The additional limitations of claim 18 correspond in scope to those found in claim 8, and for the same reasons I discussed above, a POSITA would not understand the Accused Product to meet these additional limitations.</p> |

228. My opinion is consistent with the file history of the ‘635 patent, and the manner in which Patent Examiner Victor Nguyen applied the term “gripping handle portion” during the prosecution of the ‘635 patent. In the December 6,

2013 Final Office Action, for example, Examiner Nguyen found that the cylindrical portion of the hypodermic needle (including the protrusions 2 and 13) disclosed by U.S. 3,680,559 to Gorbahn were a gripping handle portion that extended between a primary and secondary sheath. Notably, the cylindrical portion of Gorahn's syringe that the Examiner identified as a gripping handle has the same affordances and visual design cues as those found on the safety lancet body, as well as the extended tab of the safety lancet cap. Rather than dispute the Examiner's application of that claim term, the Applicant overcame the rejection by amending the claims. Because Gorbahn's cylindrical handle detached from the primary sheath prior to puncture, the Applicant overcame that prior art reference by amending the claims to require that the primary and secondary sheaths remain attached at each end of the handle when the cap is removed.

## Patent Examiner's Application of the term "Gripping Handle"

Gripping Handle Portion

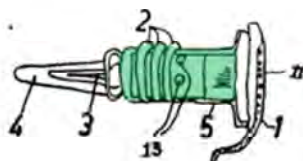
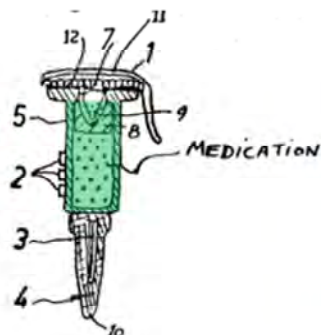


Fig. 2

Gripping Handle (Lancet Body)

Gripping Handle (Lancet Cap)



Intuitive top push button activation, contoured design to fit thumb shape, button permanently depresses after use (activation indicator to distinguish between used and non-used device)

V-shape body for convenient finger recess and stable grip within user's hand

Closed body assumes that needle stays safely inside the device before and after the puncture which fully protects both patient and user

Reliable sterility protector completely covers the needle until just few seconds before test. Ergonomic shape guarantees easy twist & pull while preparing for the test

## Patent Examiner's Application of the term "Gripping Handle"

Gripping Handle Portion

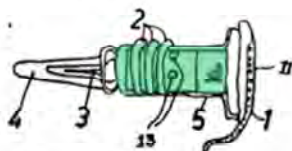
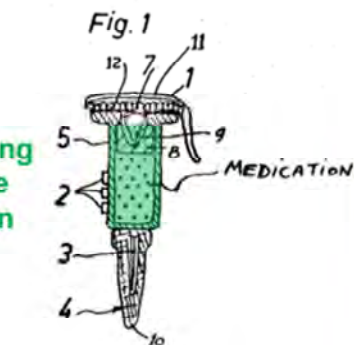


Fig. 2

Gripping Handle (on Body)

Gripping Handle (on Cap)



## B. Non-Infringing Alternatives

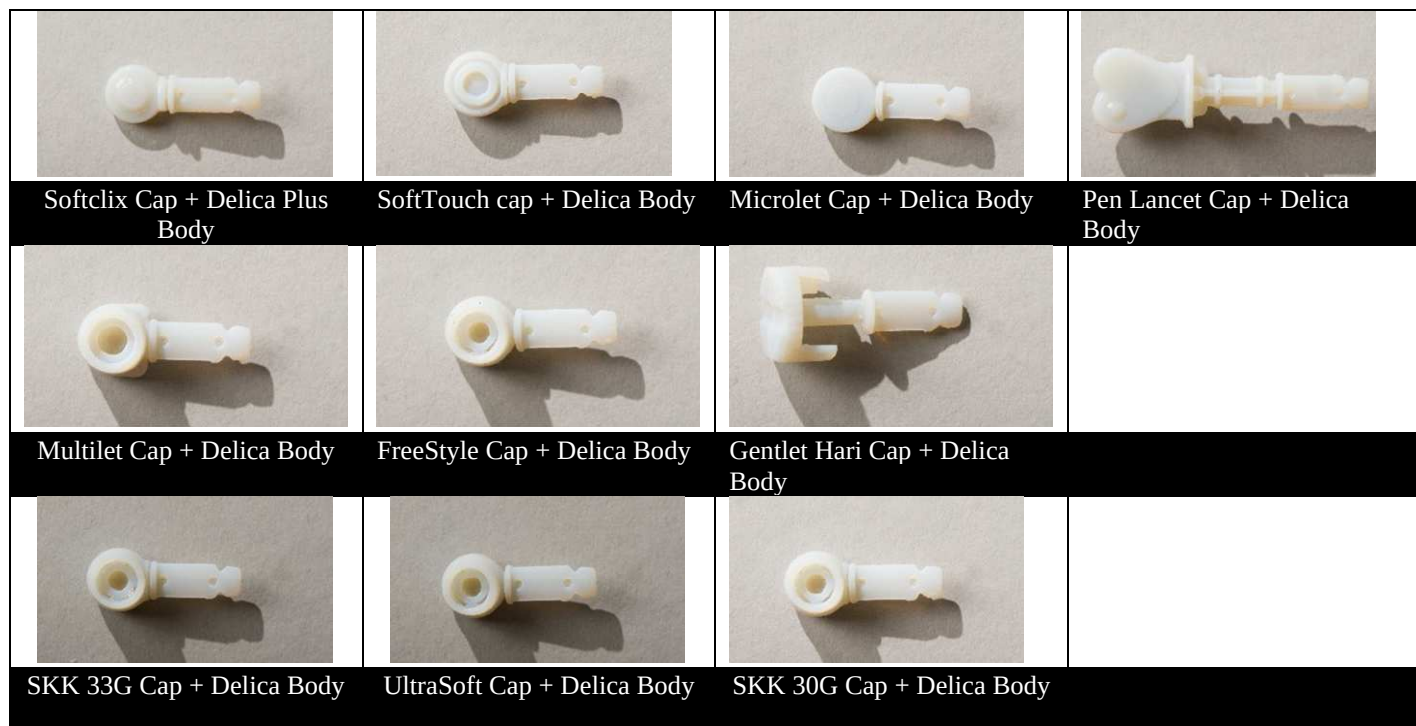
229. I understand that Facet contends it would be difficult to create non-infringing alternatives to the Delica Plus. I disagree.

230. In my opinion, the following eleven lancets made by Asahi would be acceptable and readily available non-infringing alternatives to the Delica Plus if the protective cap of the Delica Plus were found to infringe the Asserted '635 Patent Claims (“Alternative Asahi Lancets”):

|                                                                                     |                                                                                     |                                                                                      |                                                                                     |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
|    |    |    |  |
| Roche Accu-chek Softclix                                                            | Roche Accu-chek SoftTouch                                                           | Ascensia Microlet                                                                    | LifeScan OneTcouh Pen Lancet                                                        |
|  |  |  |                                                                                     |
| Arkray Multilet Super Soft                                                          | Abbott FreeStyle                                                                    | SKK Gentlet Hari                                                                     |                                                                                     |
|  |  |  |                                                                                     |
| SKK Blood Lancet 33G                                                                | LifeScan OneTouch UltraSoft                                                         | SKK Blood Lancet 30G                                                                 |                                                                                     |

231. Even if the acceptability of a lancet’s **cap** were dependent on the compatibility of that lancet’s **body** with the lancing **device**, as Facet contends, or on the pain experience from firing that lancet’s **base** from a lancing **device**, as Facet also contends, then it is also opinion that the protective cap from the same

eleven Alternative Asahi Lancets would still be acceptable and readily available non-infringing alternatives to the Delica Plus once molded to the lancet body of the Delica Plus (“Alternative Delica Plus Lancets”).

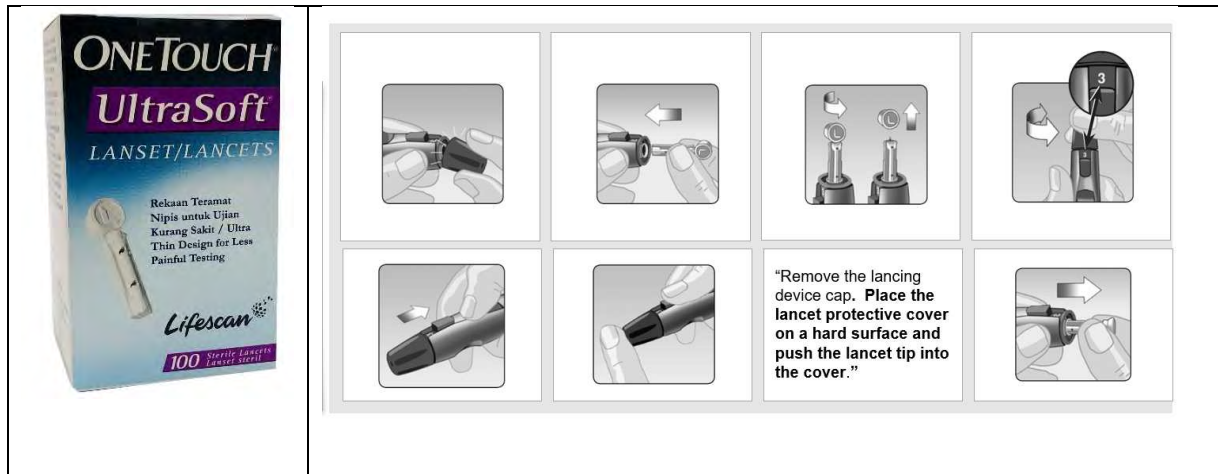


232. Additionally and alternatively, it is also my opinion that the protective cap of the Reli-on, Saikely, and Iio lancets would be an acceptable and readily available non-infringing alternative to the Delica Plus if the protective cap of the Delica Plus were found to infringe the Asserted '635 Patent Claims (“Alternative Asahi Lancets”):



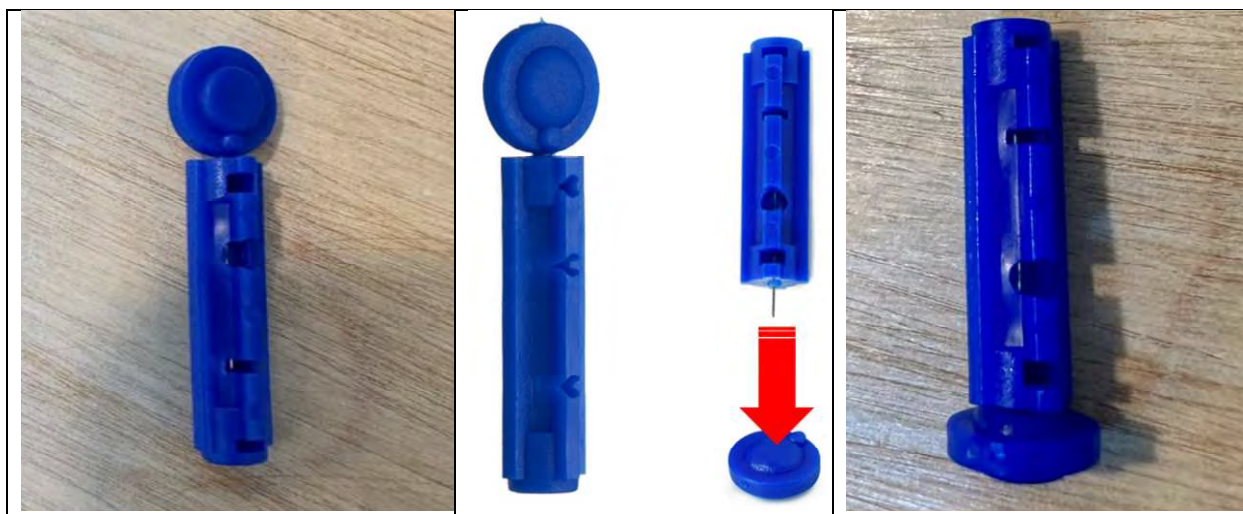
### **1. The Alternatives Do Not Infringe the '635 Patent.**

233. I have been informed by counsel that a product that was made, sold, and/or commercialized before the priority date of a patent is prior art to the patent, and therefore, cannot infringe that patent. I understand that Asahi has manufactured single-use, disposable lancets with protective caps for over 30 years, and began doing so well before the earliest priority claim of the '635 patent (2008). Based on my conversations with Asahi engineers, I understand that all of the Alternative Asahi lancets were made, supplied, and/or commercialized by Asahi well before 2008. I independently corroborated this through the Wayback Archives that I have compiled in Appendix D. For example, I confirmed through Wayback Archives that the OneTouch Ultrasoft lancet was commercialized and sold before 2008, and that the UltraSoft lancet that was sold in 2008 incorporated the cap shown below.

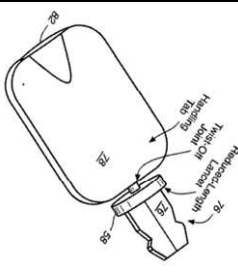


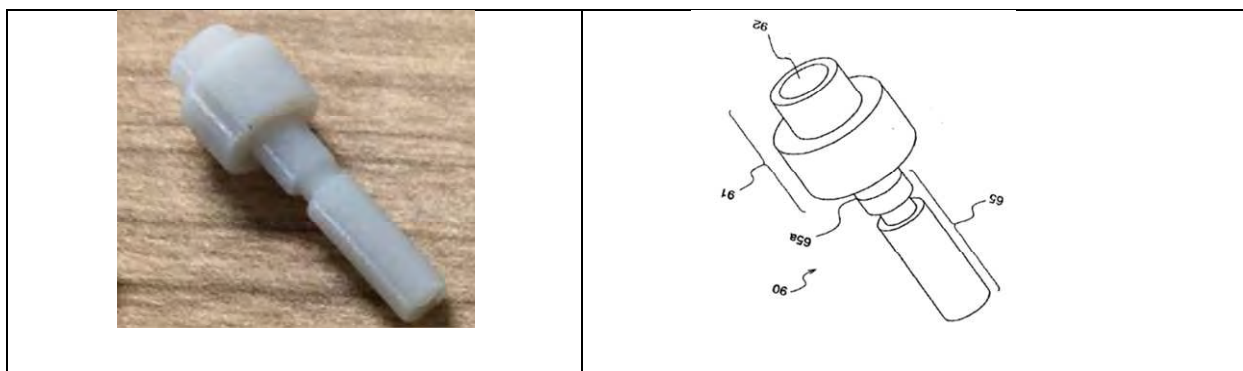
234. It is therefore my opinion that the protective cap from each of the Alternative Asahi Lancets is a non-infringing alternative. Additionally, because the Alternative Delica Plus Lancets incorporate the same protective caps from the prior art Alternative Asahi Lancets, it is also my opinion that the same eleven Alternative Asahi Lancets likewise are also non-infringing alternatives to the Delica Plus lancet.

235. Moreover, it is my opinion that the Relion Lancet does not infringe the '635 patent because even if the neck of the Delica Plus were found to qualify as a gripping handle portion, the ReliOn cap does not have **any** structure extending between the primary and secondary sheaths; rather, as shown below, the primary and secondary sheath on the Relion protective cap are part of the same structure. It is therefore my opinion that the Relion Lancet is a non-infringing alternative.



236. Finally, it is my opinion that neither the Saikely nor the Iio Lancets infringe the '635 patent. As explained above, Asahi created these lancets at my direction based solely on the disclosures of the prior art Saikley and Iio patent publications (US 2004/0138588 and US 2005/0131441, respectively), as shown below:

| 237. Physical Lancet                                                                | 238. Prior Art Patent                                                                |
|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
|  |  |



239. Accordingly, because the Saikley and Iio Lancets incorporate the protective cap disclosed by the prior art Saikley and Iio patents, it is also my opinion that the Saikley and Iio Lancets are also non-infringing alternatives to the Delica Plus lancet.

### **The Alternatives Are Either Available or Readily Available**

240. Based on my conversations with Asahi engineers, it is my understanding that Asahi currently manufactures and supplies the Alternative Asahi lancets, and as such, already possesses the molds, tooling, and supplies needed to manufacture these prior art lancets. I have seen the actual molds used by Asahi to manufacture the Alternative Asahi lancets. [Paul to Expand]. Accordingly, it is my opinion that the Alternative Asahi lancets are readily available alternatives to the Delica Plus lancets.

## **2. The Alternatives Are Acceptable**

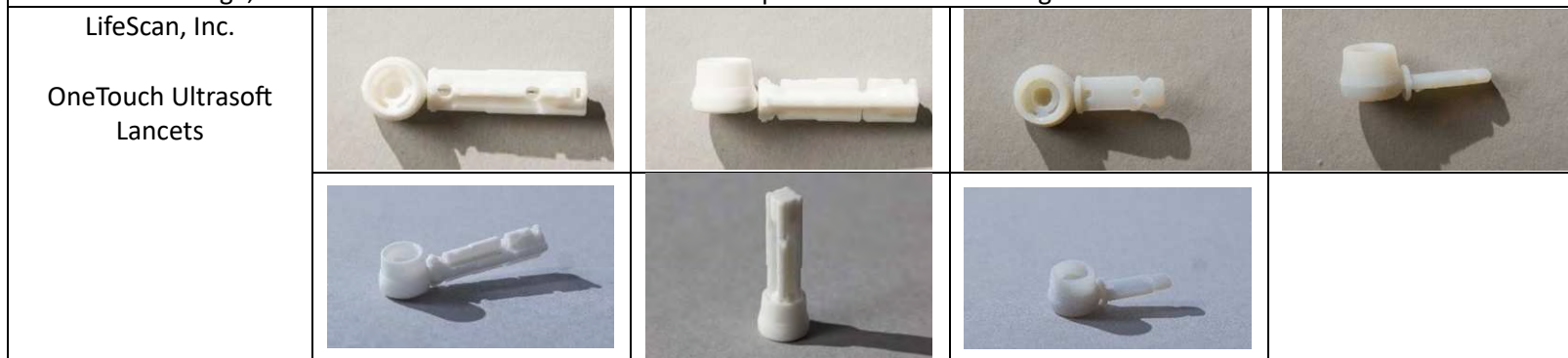
241. The purpose of the protective cap is the same for every lancet: it must protect and maintain the sterility of the needle from manufacture through transport

and up to the point it is used by the patient to draw a blood sample for testing. To draw such a sample, the patient must remove the cap to expose the needle sharp, and for this reason, the proactive cap design must also be easily removed without damaging the needle sharp. For the reasons set forth in the table below, it is my opinion that the Alternative Asahi Lancets, the Alternative Delica Plus Lancets, as well as the Relion Saikley, and Iio lancets, satisfy both of these objectives, and as such, are acceptable alternatives to the Delica Plus.

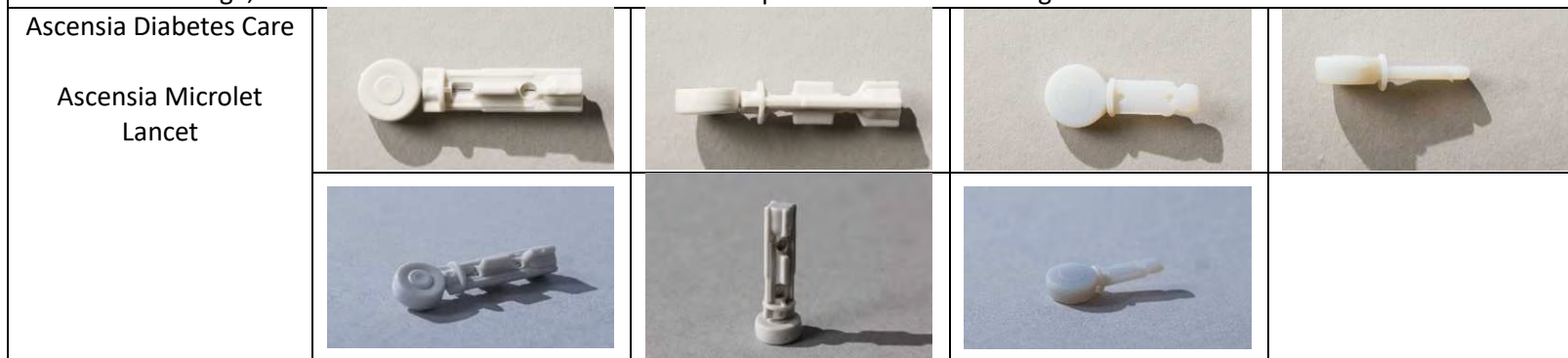
| Non-Infringing Alternatives                                                                                                                                                                                                                                                                                                                         |                                                                                     |                                                                                      |                                                                                       |                                                                                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Lancet                                                                                                                                                                                                                                                                                                                                              | Production Sample                                                                   |                                                                                      | Sample with compatible lancet                                                         |                                                                                       |
| Roche<br>Accu-chek Softclix                                                                                                                                                                                                                                                                                                                         |    |    |    |    |
|                                                                                                                                                                                                                                                                                                                                                     |    |    |    |                                                                                       |
| This is acceptable as a non-infringing alternative. I inspected it and it maintains sterility as the needle is fully enclosed in the cap, which was attached securely. The cap is also easily removed by twisting and the proximity of the two flanges helps reduce the risk of bending the needle when removing the cap.                           |                                                                                     |                                                                                      |                                                                                       |                                                                                       |
| Arkray Inc.<br>Multilet Super Soft                                                                                                                                                                                                                                                                                                                  |    |    |    |    |
|                                                                                                                                                                                                                                                                                                                                                     |   |   |   |                                                                                       |
| This is acceptable as a non-infringing alternative. I inspected it and it maintains sterility as the needle is fully enclosed in the cap, which was attached securely. The cap is also easily removed by twisting and the proximity of the lancet flange to the flat of the head helps reduce the risk of bending the needle when removing the cap. |                                                                                     |                                                                                      |                                                                                       |                                                                                       |
| Sanwa Kagaku<br>Kenkyusho Co., Ltd<br><br>SKK                                                                                                                                                                                                                                                                                                       |  |  |  |  |

|                                                                                                                                                                                                                                                                                                                                                     |                                                                                     |                                                                                      |                                                                                       |                                                                                      |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| Blood Lancet 33G                                                                                                                                                                                                                                                                                                                                    |    |    |    |                                                                                      |
| This is acceptable as a non-infringing alternative. I inspected it and it maintains sterility as the needle is fully enclosed in the cap, which was attached securely. The cap is also easily removed by twisting and the breakaway teeth that connect to the lancet flange help reduce the risk of bending the needle when removing the cap.       |                                                                                     |                                                                                      |                                                                                       |                                                                                      |
| Roche Diabetes Care<br>Accu-chek SoftTouch                                                                                                                                                                                                                                                                                                          |    |    |    |   |
|                                                                                                                                                                                                                                                                                                                                                     |    |    |    |                                                                                      |
| This is acceptable as a non-infringing alternative. I inspected it and it maintains sterility as the needle is fully enclosed in the cap, which was attached securely. The cap is also easily removed by twisting and the proximity of the lancet flange to the flat of the head helps reduce the risk of bending the needle when removing the cap. |                                                                                     |                                                                                      |                                                                                       |                                                                                      |
| Abbott Diabetes Care<br>FreeStyle Lancets                                                                                                                                                                                                                                                                                                           |   |   |   |  |
|                                                                                                                                                                                                                                                                                                                                                     |  |  |  |                                                                                      |

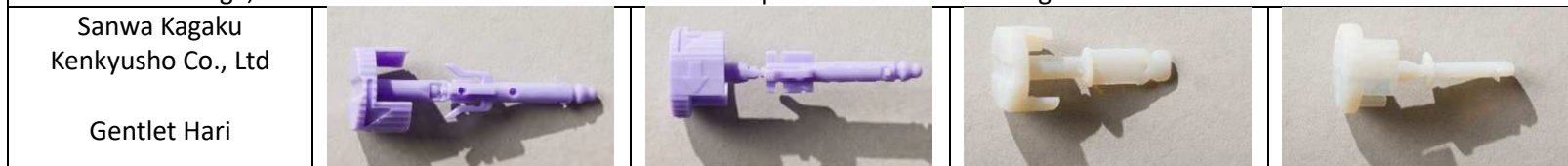
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|                                                                                                                                                                                                                                                                                                                                                                          |                                                                                     |                                                                                      |                                                                                       |                                                                                      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                          |    |    |    |                                                                                      |
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| Sanwa Kagaku<br>Kenkyusho Co., Ltd<br><br>SKK<br>Blood Lancet 30G                                                                                                                                                                                                                                                                                                        |    |    |    |   |
|                                                                                                                                                                                                                                                                                                                                                                          |    |    |    |                                                                                      |
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| OneTouch<br>Pen Lancet                                                                                                                                                                                                                                                                                                                                                   |   |   |   |  |
|                                                                                                                                                                                                                                                                                                                                                                          |  |  |  |                                                                                      |

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242. To the extent that the acceptability of a lancet's **cap** depends on the compatibility of that lancet's **body** with the lancing **device**, as Facet contends, or on the pain experience from firing that lancet's **base** from a lancing **device**, as Facet also contends, then it is my opinion that the Alternative Delica Plus Lancets would still be acceptable alternatives to the Delica Plus because, as I explain below, compatibility and pain are both dictated by the lancet's **body**, not cap, and the Alternative Delica Plus Lancets incorporate the same lancet base as the Delica Plus.

243. The acceptability of a cap is not dependent on the compatibility of a lancet's body with the lancing device. Many proprietary lancets are designed for the lancet **body** to fit into the lancing device they are meant for. Having a proprietary lancet system provides benefits which include seamless integration between glucose meters and lancets, quality control, differentiation and branding, and streamlining the process of quality control and regulatory compliance.

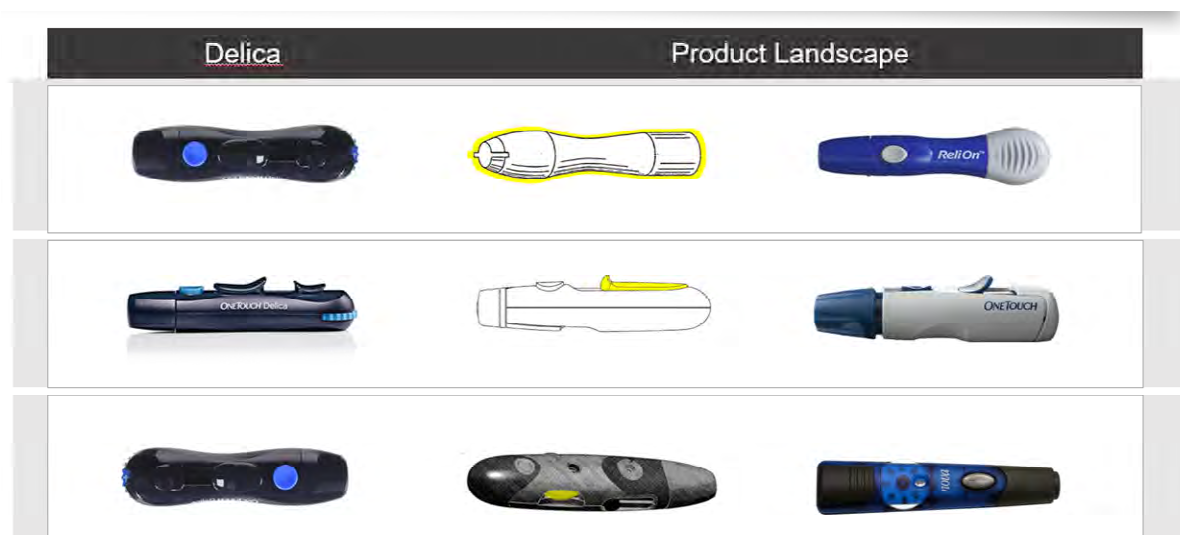
244. While the lancet **body** may not be compatible with every lancing device, such is not the case for the lancet **cap**. Any cap would fit the lancing device.

245. If there was any doubt, my analysis of the Alternative Delica Plus Lancets above indicate that the alternatives are acceptable.

246. As to pain, any benefits as to pain when using a lancet goes to the lancing device. See LSI0000020192, FACET\_002172, <https://journals.sagepub.com/doi/pdf/10.1177/193229681000400420>. Lancet launching and retracting varies depending on the lancing device and the lancet.

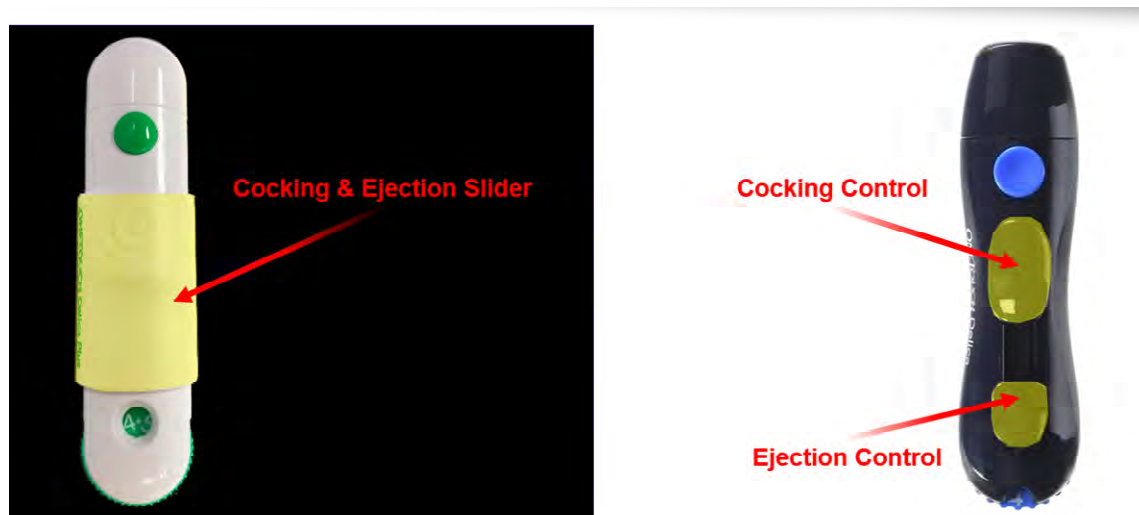
247. Note that the lancing device has the mechanisms for launching and retracting, not the lancet itself. In other words, the lancing device controls at least half of the factors of lancing system function and pain (e.g., lancet penetration depth, lancet speed, lancet movement, and skin fixation).

248. Some disposable lancets are designed to work with Lancing devices that are handheld devices that permit users to draw blood for testing and diagnostic purposes. These lancing devices commonly include a housing with a piercing aperture, a lancet, and a firing mechanism.



249. The firing mechanism typically includes a spring or other biasing means which can be cocked either by insertion of the lancet or, for example, by

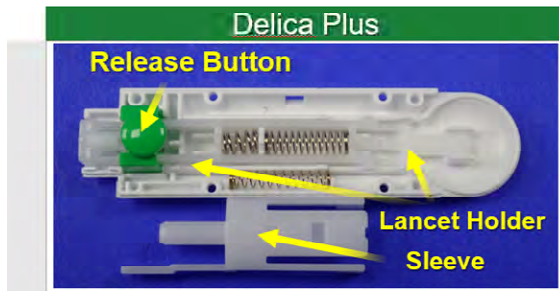
pulling a cocking handle. Once the lancing device is cocked, it is placed against the user's skin, often the fingertip. The user can then press a trigger to actuate the firing mechanism, which momentarily drives the sharp tip of lancet through the piercing aperture to puncture the user's skin and draw blood.



250. When the lancing operation is complete, the user can press a second actuator to eject the lancet for removal and disposal. A consideration in the design of both lancets and lancing devices is the benefits of minimizing the number of parts and thus simplifying assembly and reducing the cost of production.

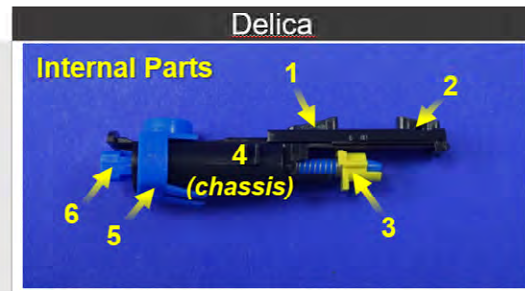
#### 8 parts- Thinner profile

- 1 external slider
- 4 springs
- **3 internal parts** guided by linear tracks in the body
- Cocking: 4 moving parts
- Ejection: 2 moving parts (same)
- Ejection control returns automatically



#### 10 parts- Thicker profile

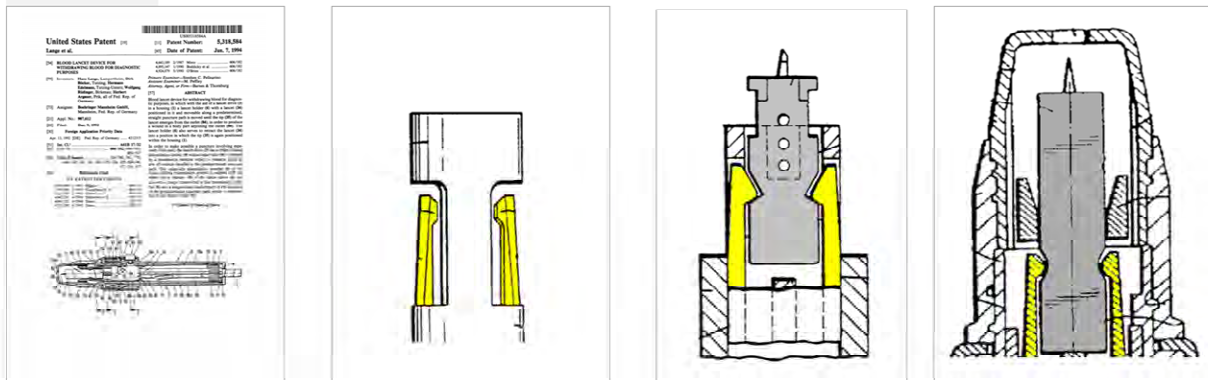
- 2 external controls (buttons)
- 2 springs
- **6 internal parts**, including a chassis that guides the other parts
- Cocking: 5 moving parts
- Ejection: 2 moving parts (distinct)
- Ejection control must be returned manually



251. Another consideration in the design of lancets is to minimize the discomfort experienced by users during the lancing process. To this end, some lancing devices include mechanisms to adjust the distance that the lancet sharp protrudes through the piercing aperture, thus regulating the depth that the lancet penetrates the user's skin. In some cases, these depth adjustment mechanisms include adjustable stops that limit the forward movement of the lancet during firing. In other cases, a lancet holder is moved axially within a lancing device housing to move the needle closer to or farther away from the piercing aperture, thus adjusting penetration depth.

Lancing devices include a lancet holder with a pair of resilient arms. The arms interface with features on the lancet to grip it like “a pair of tongs” to secure the lancet during handling and firing.

Date: 1992

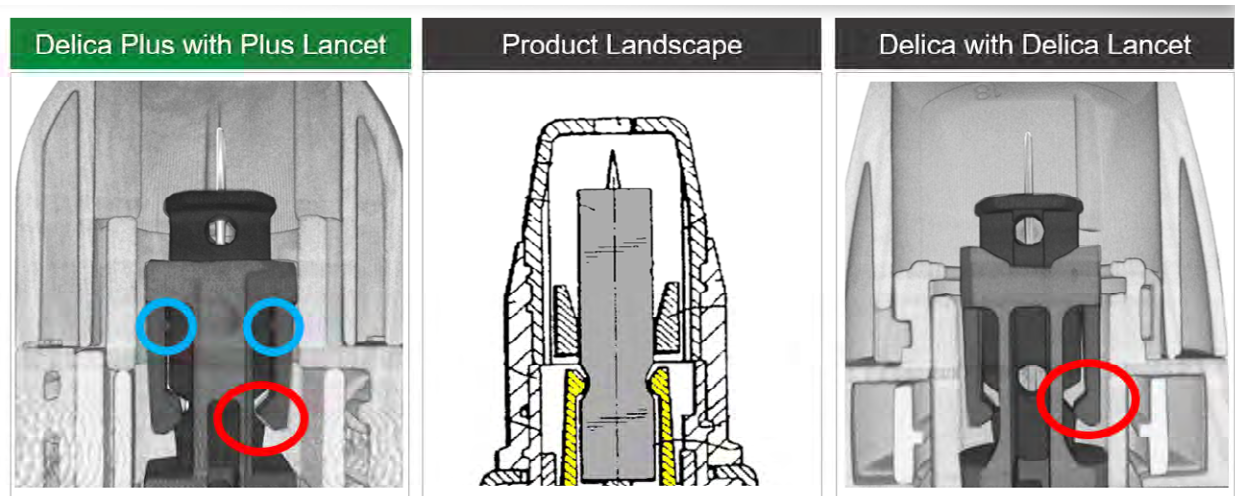


252. Lancing devices can draw blood from a user's fingertip or other body part. A fingertip is a good testing site because it contains a large number of blood vessels and it is therefore easy to draw an adequate quantity of blood from the fingertip. However, fingertips are also sensitive and users who must frequently draw blood samples may experience discomfort from repeated sampling of the fingertips. Therefore, some users also perform lancing operations on other parts of the body, and this is known as alternate site testing or alternate site incision, also known as “AST.”

253. To effectively draw blood from an alternate site, it is helpful to have the needle penetrate the skin more deeply. It is also helpful to have a relatively wide piercing aperture. A wider piercing aperture acts as an expression ring by allowing the skin to pucker into the aperture's opening and by compressing a wider

area of skin around the incision. When skin protrudes through the aperture into the housing, it is also more deeply penetrated by the lancet.

254. Another consideration in the design of lancing devices is the goal of avoiding accidental needle pricks when inserting and removing lancets from the lancing device. To this end, lancets include safety features such as frangible tabs which cover the needle sharp prior to insertion in the lancing device. Once the lancet is inserted, the user can break off and remove the frangible tab. Some lancets also include sleeves coaxially mounted to the main body of the lancet. The sleeve can be positioned so that it protectively encloses the needle sharp. During the lancing operation, the main body of the lancet slides through the sleeve to expose the lancet sharp. After removal of the lancet, however, the sleeve can be locked in its protective position, reducing the likelihood that a person handling the use lancet will prick himself or herself.



255. Another consideration in the design of lancing systems is the ease with which a lancet can be inserted into the lancing device. It is known that when a lancet is inserted into a lancing device, the force of the insertion can be used to cock the device. However, if the device is already cocked, and a lancet was to be inserted, there is some risk that the device would discharge during the insertion process and the user would be accidentally pricked. It is also known to insert the lancet into the lancet device when the cap of the device is removed.

256. The lateral movement of the driving mechanism in the lancing device affects how painful a blood draw will be. Minimizing the amount of lateral movement through the design of the lancing device's internal mechanism drives whether or not a patient will have a painless experience.

### **C. Willfulness**

257. In his report, Mr. Collins relies in his analysis on a Freedom to Operate Opinion Letter from Carter Ledyard & Milburn LLP to Yasuhiko Matsuda titled "Facet Patent Analysis," dated May 17, 2017. Collins Report ¶ 127. I disagree with Mr. Collins's analysis because it is erroneous, incomplete, and neglects other evidence relating to the non-infringement opinion that LifeScan received from Carter Ledyard & Milburn LLP.

258. It is my understanding that counsel for Asahi rendered a non-infringement opinion that was expressed to LifeScan in a series of opinion letters

that combined to form Asahi's Freedom to Operate analysis. During LifeScan's Rule 30(b)(6) deposition, Mr. Knapp testified that Asahi's Freedom to Operate analysis reached the conclusion that the accused Delica Plus lancets do not satisfy the claim limitations reciting a "handle" or "secondary sheath":

Q. Okay. In addition -- so, setting aside the handle that you've identified and the secondary sheath or the protective embedment on the second end, are there any other reasons why you believe that that -- or that LifeScan believes that the Delica Plus product does not infringe any of the claims of the '635 patent?

A. The primary component is that Asahi and their Freedom to Operate said that it did not infringe. That's the basis of LifeScan's, I'll call it point of view associated with any type of patent component.

...

Q. The only two factual assertions that you're saying don't meet the limitations are the handle and that secondary protective cover. Is that correct?

A. THE WITNESS: From a LifeScan perspective ... we have not relied on ourselves. We rely on Asahi to, you know, ultimately provide their point of view from counsel on, you know, Freedom to Operate and as LifeScan has reviewed the Freedom to Operate, the Freedom to Operate says that we do not infringe and we don't believe that there's an infringement associated with it because there is no handle and there is no secondary sheath.

Knapp Rule 30(b)(6) Depo. at 12:17-14:5 (objections omitted).

259. The Asahi Freedom to Operate opinion directed to the '635 patent was expressed in two letters: one dated May 17, 2017 (LSI0000275498) and the other dated August 23, 2017 (LSI0000079467). The willfulness assertions in the Collins Report are incomplete and erroneous because they focus only upon the first letter

without considering the combined Freedom to Operate opinion that is expressed in both.

260. Specifically, the August 23, 2017 letter begins by noting that it is a continuation of the non-infringement opinions set forth in the May 17, 2017 letter. LSI0000079467 (“We previously rendered our opinion on whether the Asahi mi-lancets (Mod 3 and 4) infringed the ’635 patent (May 17, 2017 letter to Mr. Masuda) and concluded that there was no infringement.”). The August 23, 2017 opinion goes on to identify additional bases for non-infringement as set forth below:

After further examination of the Asahi mi-lancets, and additional information provided by Asahi at a meeting on July 18, 2018, we have now concluded that the Asahi mi-lancets do not infringe the ’635 patent even if any portion of the mi-lancets could be considered a “secondary sheath” with “a depth greater than the length of the exposed portion of the lancet tip extending beyond the body.” This conclusion is based on our opinion that the Asahi mi-lancets do not include a “gripping handle portion” and should Facet (the owner of the ’635 patent) so assert the ’635 patent would be invalid as explained below.

(LSI0000079468). The letter goes on to explain that:

[I]f Facet attempted to claim infringement by asserting that Asahi’s mi-lancet had a gripping handle it could not deny that the Roche Softclix also has a gripping handle and therefore would also infringe. However the Roche Softclix lancet was sold more than a year before the earliest filing date of the ’635 patent so if the Softclix lancet allegedly infringed it would render the ’635 patent invalid.

(LSI0000079469).

261. I agree with this analysis and believe that it provides a sound reason to conclude the Delica Plus lancets do not infringe. Indeed, both the Delica Plus Lancets and the Softclix lancet have a “neck” portion extending between the primary and secondary sheaths. For all the reasons I discuss in this report, a POSITA would not consider this “neck” to be the claimed “gripping handle portion.” To the extent the claims were stretched and distorted so that the “gripping handle portion” limitation encompassed even such a “neck,” then this would render the claim invalid as anticipated by the Roche Softclix. In other words, there is no way to apply the claims as covering Delica Plus Lancets without also invaliding the claims in light of the Roche Softclix.

262. Accordingly, it is my opinion that these non-infringement opinions are reasonable and consistent with the opinions that I have expressed earlier in this report that the accused Delica Plus lancets do not satisfy the “gripping handle portion” limitations that are recited in the asserted claims. The willfulness assertions in the Collins Report are erroneous at least because they fail to consider the Freedom to Operate analysis set forth in the August 23, 2017 letter.

263. With respect to the May 17, 2017, I note that it cites to column 6, lines 35-48 of the '635 patent's specification, which teaches: “The secondary shroud or sheath portion 514 comprises a cup having an outer rim and a hollow interior chamber. When sharp lancet tip of the lancet is placed into the secondary shroud or

sheath portion 514 after use of the lancet, the lancet tip is received within the hollow interior chamber of the cup, and protected from inadvertent contact by the outer rim.” It is my understanding that during claim construction, LifeScan advanced a proposed construction of “secondary sheath” that was consistent with these disclosures in the ‘635 patent and that would have meant that the Delica Plus does not infringe for the additional reason that it would not have a secondary sheath under this proposed construction. Since I understand that the Court did not adopt LifeScan’s proposed construction for “secondary sheath,” I have not applied that construction in conducting the analysis that led to my non-infringement opinion discussed in this report.

## **IX. CONCLUSION**

264. In my opinion, the Delica Plus Cap does not infringe the asserted claims of the ‘635 Patent.

Dated: June 20, 2023

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Hatch", written over a horizontal line.

Paul Hatch