

Filed on behalf of: Facet Technologies, LLC

Entered: June 28, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIFESCAN, INC.,
Petitioner,

v.

FACET TECHNOLOGIES, LLC,
Patent Owner.

IPR2023-00712, IPR2023-00713
Patent 8,840,635

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

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

I. Introduction

1. I am over the age of eighteen and competent to make this Declaration.
2. Unless stated otherwise, all facts stated herein are within my personal knowledge and are true and correct. If called upon, I would be willing to testify as set forth in this Declaration.
3. I have been retained by Facet Technologies, LLC (“Facet”) to provide my opinion concerning the validity of U.S. Patent No. 8,840,635 (“’635 Patent”).
4. I understand Petitioner LifeScan, Inc. (“LifeScan”) filed two Petitions for *Inter Partes* Review of U.S. Patent No. 8,840,635: (1) IPR2023-00712 (“’712 Petition” or “’712 Pet.”); and (2) IPR2023-00713 (“’713 Petition” or “’713 Pet.”) (collectively, “Petitions” or “Pets.”).
5. I understand LifeScan challenged claims 1-3, 5-8, 14, and 16-18 of the ’635 Patent in the ’712 Petition. I understand Facet then disclaimed claims 1-5 and 9-10. Thus I understand only claims 6-8, 14, and 16-18 remain at issue for the ’712 Petition.
6. I understand LifeScan challenged claims 1, 4, and 9-15 of the ’635 Patent in the ’713 Petition. I understand Facet then disclaimed claims 1-5 and 9-10. Thus I understand only claims 11-15 remain at issue for the ’713 Petition.

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

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

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

II. Summary of Opinions

10. It is my opinion that none of the Grounds in the Petitions anticipate or render obvious any of the challenged claims in the Petitions.

III. Qualifications

11. I have over 40 years of product design and product development expertise covering a wide range of industries and products, including consumer, industrial, and medical products and devices. Over that time, I have had a consistent focus on medical devices and technologies. I have been responsible for all aspects of a product's development, including defining the need in the market

as well as the requirements, user interface, overall look and feel (industrial design), construction (design for manufacturing, etc.), and performance/functionality validation. In addition to doing engineering work, including technology assessment and planning, my responsibilities have included assembling and managing teams to develop new products.

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

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

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

15. A recent example of the use of these platforms to support innovation is in CIMIT's work as the coordinating center for the National Institutes of Health's Rapid Acceleration of Diagnostics Technology ("RADx Tech") initiative. This

\$500M-plus initiative was highly successful in speeding innovation in the development and deployment of Point of Care (“POC”) testing technologies capable of testing millions of Americans for the presence of the SARS-CoV-2 virus. A paper describing the use of these platforms is available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8112669/>.

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

17. Prior to 2008, I held various positions at technology and product development companies. From 1982 to 1986, after receiving my M.S. degree at MIT, I worked at Booz, Allen & Hamilton, where I developed automotive, consumer, and industrial products. Examples include GE’s under-counter coffee maker, GM’s hydraulic systems for automotive anti-lock brakes, Engelhard’s

coating and drying system for catalytic converters, Rubbermaid's ergonomic table, and the Regina rug scrubber.

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

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

- Lancets;
- Minimally invasive surgical access (cutting) devices called trocars with automated safety covers as well as universal seals;
- Minimally invasive surgical devices including clip applicators, ligate & divide absorbable clip applicators (which collected, cut, and clipped tissue) and arthroscopic shaver blades;
- Intraosseous infusion needles;

- Blood and IV fluid warmers along with the associated containers;
- Chest drainage devices;
- Ambulatory infusion pumps;
- Neurological and vascular surgical navigation systems;
- Blood pressure monitors for high noise environments; and
- Scroll pumps for applications in blood handling, pulsed lavage in orthopedic surgery, irrigation/aspiration in ophthalmic microsurgery.

20. I am a named inventor on over 20 United States patents, in addition to foreign counterparts, on products and manufacturing processes. Many of these patents are directed to technologies relating to medical devices. A complete list of my patents is set forth in my curriculum vitae (Exs. 2002, 2102), which I incorporate here by reference.

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

IV. Summary of Materials Reviewed and Considered

22. All of the opinions contained in this Declaration are based on the documents I reviewed and my knowledge and professional judgment. In forming the opinions expressed in this Declaration, while drawing on my experience in the

field of medical devices and similar-type consumer products, I reviewed the following documents:

Exhibit	Description
1001	U.S. Patent No. 8,840,635 to Pusey et al. (the “’635 Patent”)
1002	Declaration of Expert Joel Delman
1003	File History of the ’635 Patent
1004	Claim Construction Order for <i>Facet Technologies, LLC v. LifeScan, Inc.</i> , Case No. 2:22-cv-1717-MCS-MAR, Dkt. 122 (C.D. Cal. Jan. 20, 2023)
1005	U.S. Patent Application Publication 2004/0138588 to Saikley (“Saikley”)
1006	U.S. Patent Application Publication to Iio 2005/0131441 (“Iio”)
1007	U.S. Patent No. 5,318,584 to Lange (“Lange”)
1008	U.S. Patent No. 5,569,286 to Peckham et al. (“Peckham”)
1009	U.S. Patent Application Publication 2005/0131440 (“Starnes”)
1010	Wayback Declaration and Reference: FreeStyle Owner’s Booklet, TheraSense, Inc. (2004)
1013	Stipulation
1014	U.S. Patent No. 3,358,689 to Higgins (“Higgins”)
1015	Therasense Trademark Registration and File History
1016	U.S. Provisional Application No. 60/424,414 to Saikley (“Provisional to Saikley”)
1017	U.S. Patent No. 6,283,982 to LeVaughn et al. (“LeVaughn”)
1018	U.S. Patent Application Publication 2006/0241669 to Stout (“Stout”)

Exhibit	Description
1019	International Pub. No. WO 2007-089930A2 (“Lathrop”)
1020	Wayback Declaration and Reference: One Touch Lancing Device User’s Instructions, Rev. 10/2006, LifeScan Inc., Milpitas California (2006)
1021	U.S. Patent No. 4,994,068 to Hufnagle (“Hufnagle”)
1022	Lengths, girths, and diameters of children’s fingers from 3 to 10 years of age, Annals of Anatomy (2010)
1023	3-D Finite-Element Models of Human and Monkey Fingertips to Investigate the Mechanics of Tactile Sense, Journal of Biomechanical Engineering (2003)
1024	CV of Joel Delman
1101	U.S. Patent No. 8,840,635 to Pusey et al. (the “’635 Patent”)
1102	File History of the ’635 Patent
1103	Declaration of Expert Joel Delman
1104	CV of Joel Delman
1105	District Court Order on Claim Construction
1106	U.S. Patent No. 5,207,699 to Coe (“Coe”)
1107	JP Patent App. No. 2005168634 to Sakata (“Sakata”)
1108	U.S. Patent App. Pub. No. 2007/0162064 (“Starnes”)
1109	Japanese Patent No. JPH05285127 (“Morita”)
1110	Wayback Declaration + One Touch Booklet: One Touch Basic Complete Diabetes Monitoring System Owner’s Booklet, Rev. 02/2004, LifeScan Inc., Milpitas, California (1999)
1111	Stipulation Not to Pursue in a Parallel Proceeding the Same Grounds or Any Grounds that could have Reasonably been Raised

Exhibit	Description
1112	U.S. Patent No. 5,385,571 (“Morita II”)
1113	U.S. Patent No. 8,920,454 (“Hyoue”)
1114	U.S. Patent App. No. 2007/0293883 (“Horie”)
1115	International Pub. No. WO2007089930 (“Lathrop”)
1116	U.S. Patent App. No. 2005/0131440 (“Starnes ‘440”)
1117	U.S. Patent App. No. 2003/0144608 (“Kojima”)
1118	U.S. Patent No. 3,358,689 (“Higgins”)
1119	U.S. Patent Application Publication No. 2006/0174592 (“Chan”)
1120	U.S. Patent No. 6,283,982 (“LeVaughn”)
1121	Dandekar et al., <i>3-D Finite-Element Models of Human and Monkey Fingertips to Investigate the Mechanics of Tactile Sense</i> , Journal of Biomedical Engineering (Oct. 2003, Vol. 125)
1122	Hohendorff et al., <i>Lengths, Girths, and Diameters of Children’s Fingers from 3 to 10 Years of Age</i> , Annals of Anatomy 192 (2010)
1123	Abbott Freestyle Freedom Manual
1124	Goyal et al., <i>Diabetic Hand: A Neglected Complication of Diabetes Mellitus</i> (June 9, 2018)
1125	D.C. Anderson et al., <i>Preventing Needlestick Injuries</i> (March 30, 1991)
2002	<i>Curriculum Vitae</i> of John M. Collins
2009	Memorandum of Points and Authorities in Support of LifeScan, Inc.’s Motion for Summary Judgment of Invalidity, <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal. May 29, 2023), ECF No. 190-1

Exhibit	Description
2010	Opening Expert Report of Joel Delman Regarding Invalidity of U.S. Patent No. 8,840,635, <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal. June 7, 2023)
2102	Curriculum Vitae of John M. Collins
2110	Opening Expert Report of Joel Delman Regarding Invalidity of U.S. Patent No. 8,840,635, <i>Facet Techs., LLC v. LifeScan, Inc.</i> , No. 2:22-cv-01717 (C.D. Cal. June 7, 2023)
2113	Merriam-Webster's Collegiate Dictionary (10th ed. 2001) (excerpts)
2115	McGraw-Hill Dictionary of Scientific and Technical Terms (6th ed. 2003) (excerpts)
2117	Collins English Dictionary, Complete & unabridged (7th ed. 2005) (excerpts)
2119	U.S. Patent No. 5,569,286 ("Peckham '286")

23. My opinions are additionally guided by my appreciation of how a person of ordinary skill in the art would have understood the claims of the '635 patent at the time of the alleged invention, which I have been asked to assume is July 29, 2008.

V. Background

A. The '635 Patent ('712 Pet. Ex.1001; '713 Pet. Ex.1101)

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

2014. It names the following individuals as inventors: Lauren Pusey, Brian Collins, Christopher Ruf, Nicholas Reaves, and Jonathan Sanders.

25. The '635 Patent claims priority to U.S. Provisional Application No. 61/084,456, which was filed on July 29, 2008.

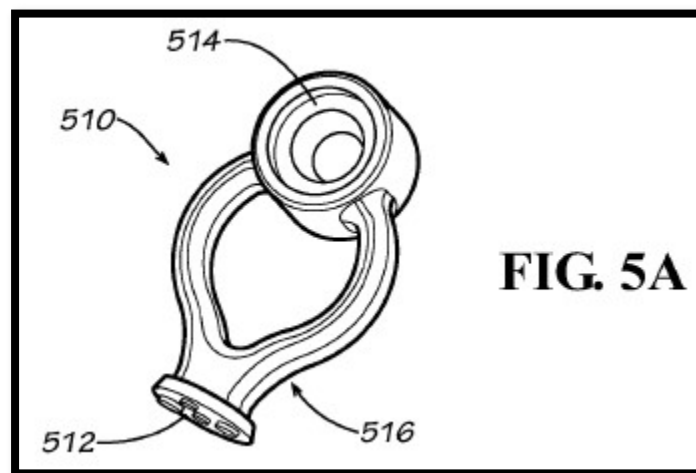
26. The '635 Patent relates to lancets with protective sterility caps and lancing devices. '635 Patent Abstract, 1:17-19. Lancets and lancing devices are used to penetrate the skin of a human subject to obtain a sample of blood for medical testing, such as blood sugar (glucose) testing. '635 Patent 1:17-19,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

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

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

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

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



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

B. Prosecution History

31. During almost two years of prosecution of the '635 Patent, the Examiner considered a wide variety of art from their own search and provided by the applicant. *See* '712 Pet. Ex.1003; '713 Pet. Ex.1102.

32. Facet responded to two sets of art rejections by first adding “a secondary sheath for receiving the sharp lancing tip of a used lancet” and moving a limitation that the gripping handle portion is “extending between the primary sheath and the secondary sheath” from an initially filed dependent claim, and then further by adding the limitation 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. '712 Pet. Ex.1003 48-60, 74-76, 187-89; '713 Pet. Ex.1102 48-60, 74-76, 187-89.

33. Facet argued the art did not teach these limitations in combination with the other claim limitations. '712 Pet. Ex.1003 51-53; '713 Pet. Ex.1102 48-60, 74-76, 187-89.

34. The Examiner agreed and allowed the claims. '712 Pet. Ex.1003 15-21; '713 Pet. Ex.1102 15-21.

C. Person of Ordinary Skill in the Art

35. I have reviewed the definition of a POSA provided by Joel Delman in his Declarations in Support of Petition for *Inter Partes* Review of All Claims of

U.S. Patent No. 8,840,635 ('712 Pet. Ex.1002 ¶¶34, 35; '713 Pet. Ex.1103 ¶¶34, 35) and I do not agree with it. For instance, I disagree that a person with a degree only in industrial design would be a POSITA. I also disagree that coursework in designing consumer products for mass markets is necessary. I also disagree that 4 to 6 years of experience is needed in addition to education.

36. It is my opinion that a POSA at the time of the invention would (1) have completed college-level coursework, and/or obtained a bachelor's degree, in engineering, such as mechanical engineering or biomechanical engineering, or another similar discipline, and (2) have had at least one year of experience researching, developing, and/or designing mechanical medical devices. Less work experience may be compensated by a higher level of education, such as a Master's Degree, and vice versa.

37. Although I disagree with Mr. Delman's definition of a POSA, my opinions do not change if I apply his definition.

38. Although I surpass both my definition of a POSA as well as Mr. Delman's definition of a POSA, I have conducted my analysis from the perspective of a POSITA as of July 29, 2008.

VI. Legal Principles

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

40. I understand that the claims of a patent define the patented invention.

41. I understand that a patent is presumed to be valid.

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

43. I understand the court issued an order regarding claim construction of terms in the '635 Patent ('712 Pet. Ex.1004; '713 Pet. Ex.1105). I apply those constructions from that order. I ascribe the plain and ordinary meaning to any claim term unconstrued by the court.

44. I understand that a claim directed to subject matter that is not novel based on a single prior art reference, product, or process is said to be anticipated by the prior art under 35 U.S.C. § 102.

45. I understand that for a claim to be anticipated by the prior art, every limitation of that claim must be found in a single prior art reference, product, or process as arranged in the claim.

46. I understand for anticipation, each limitation of a claim must be found explicitly or inherently in that prior art reference, product, or process. In other words, to determine whether a single prior art reference, product, or process anticipates a claim, one should consider not only what is expressly disclosed that prior art reference, product, or process, but also what inherently occurred as a natural result of the practice of the product or process disclosed in the prior art reference, product, or process.

47. I understand that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.

48. I understand that to establish inherency, the missing descriptive matter must be necessarily present in the prior art and that it would be so recognized by a person of ordinary skill in the art (POSA). I understand that inherency may be shown through extrinsic evidence. I understand a prior art reference may incorporate subject matter by reference to another document.

49. I understand a prior art reference, product, or process must enable a POSA to make the invention without undue experimentation. A POSA would combine the prior art reference, product, or process with his relevant knowledge derived from articles, publications, etc. to determine if it is enabled. I understand the prior art is presumed to be enabled. I understand that the full scope of a prior

art reference need not be enabled; rather, it is only required that the portion related to the claimed invention be enabled. Factors to consider in determining whether undue experimentation is needed are the quantity of experimentation, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, predictability of the art, and the breadth of the claims.

50. I understand that when a prior art reference discloses multiple embodiments of the subject matter, each disclosed embodiment can be the basis for an anticipatory disclosure. I understand a prior art reference is not limited to its stated preferred embodiments, but includes nonpreferred embodiments.

51. I understand that patent claims can be deemed invalid if the differences between the claimed subject matter and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the pertinent art. While such conclusions are often based on more than one piece of prior art only one is required. It is not sufficient that a collection of prior art references merely recites the various elements of a challenged patent claim. Rather, as I understand it, the prior art must present the elements in a manner that is consistent with their arrangement or use in the challenged claims. I understand that obviousness cannot be based on the hindsight combination of components selectively culled from the prior art.

52. I understand that a person having ordinary skill in the art (i.e., a POSA) is a hypothetical person who is presumed to have known the relevant art at the time the invention was made. I understand that the condition “at the time the invention was made” is imposed to rule out impermissible hindsight. I also understand that an expert is to analyze the prior art from the perspective of a person of ordinary skill in the art and not simply to provide his/her own personal conclusions.

53. I also understand that an obviousness determination includes several factual inquiries, including (1) determining the scope and content of the prior art; (2) ascertaining the differences between the claimed invention and the prior art; (3) resolving the level of ordinary skill in the pertinent art; and (4) taking into consideration any objective indicia of nonobviousness.

54. It is my understanding that obviousness must be determined as of the date of the invention (i.e., the effective filing date or priority date of the patent). Thus, in considering the reason or motivation to combine references, it is essential to avoid using hindsight. For example, the problem examined when considering obviousness is the general problem that confronted the inventor before the invention was made, not the specific problem solved by the invention. Defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness. Further, an overly narrow statement of the

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

55. I understand that a motivation to solve a problem (or issue) is not the same as a motivation to have combined references. I understand that whether a skilled artisan would be motivated to make a combination includes whether he/she would select particular references in order to combine their elements.

56. I am informed that the analysis of the motivation to combine should be explicit. Additionally, it must include articulated reasoning with rational underpinnings to support the conclusion of obviousness. Providing a full explanation of the motivation to combine the references and the reasonable expectation of success is a necessary component of the obviousness inquiry, as inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known. However, conclusory statements fail to adequately explain to a lay person why a person of ordinary skill would have a

motivation to combine the potential prior art references and therefore do not provide evidentiary value.

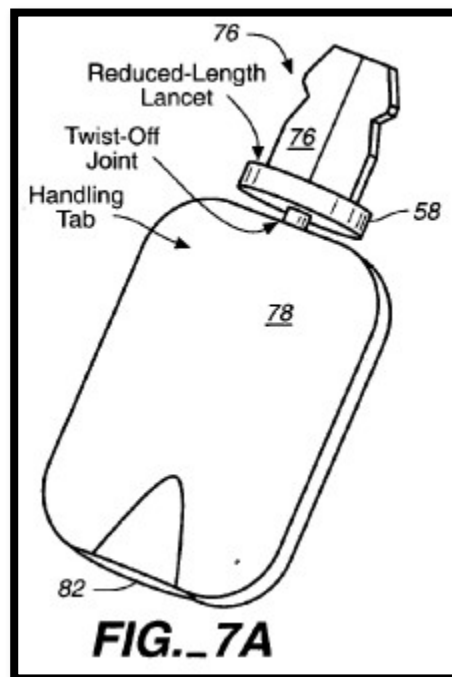
57. I understand that common sense, common wisdom, and common knowledge may be used to support a motivation to combine, so long as the use of common sense in the analysis is explained with sufficient reasoning. But, common sense can only be used to supply a limitation missing from the prior art where the technology is unusually simple and straightforward.

58. I also understand that evidence suggesting reasons to combine cannot be viewed apart from evidence suggesting reasons not to combine. In analyzing motivation, both advantages and disadvantages must be considered. Teaching away, for example, is a statement in the prior art that either (i) discourages one from following the path of the claimed invention, or (ii) encourages one to follow a path that diverges from the path of the claimed invention. The concept of teaching away bears directly on whether there was a reason to combine prior art. Known disadvantages in prior art technology or devices which would naturally discourage a search for new inventions may also be taken into account in determining obviousness.

VII. The Asserted References

A. Saikley ('712 Pet. Ex.1005)

59. U.S. Pat. App. Pub. No. 2004/0138588 (“Saikley,” ’712 Pet. Ex.1005) describes a shortened lancet and cap, in one Figure (Fig. 7A) and one paragraph (¶50):



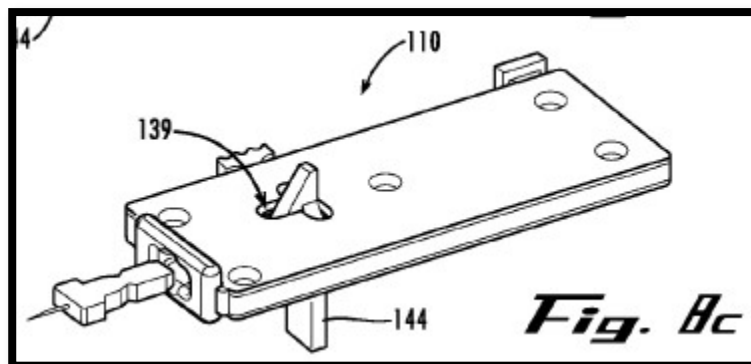
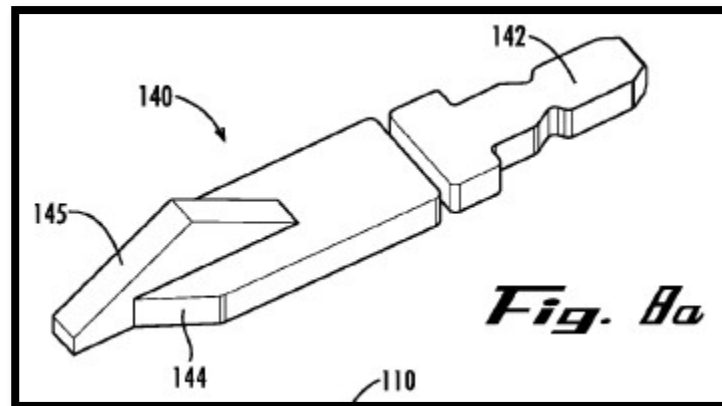
Saikley Fig. 7A.

60. The shortened lancet 76 has a main body 76, collar 58, and protective cap 78. Saikley ¶50, Fig. 7A. Saikley describes protective cap 78 as “an integrally molded, pull-off tab.” Saikley ¶50, Fig. 7A. Fig. 7A includes the words “Twist-Off Joint” with an arrow pointing to an interface of a cylindrical portion and rounded cuboid of protective cap 78. Saikley Fig. 7A. Saikley teaches the protective cap 78 is removed before use and “should be made much larger than usual to aid

handling.” Saikley ¶50, Fig. 7A. The protective cap 78 has a “hollow cup or solid ‘pin cushion’ type area 82” to “cover the sharp during removal from the device and disposal.” Saikley ¶50, Fig. 7A.

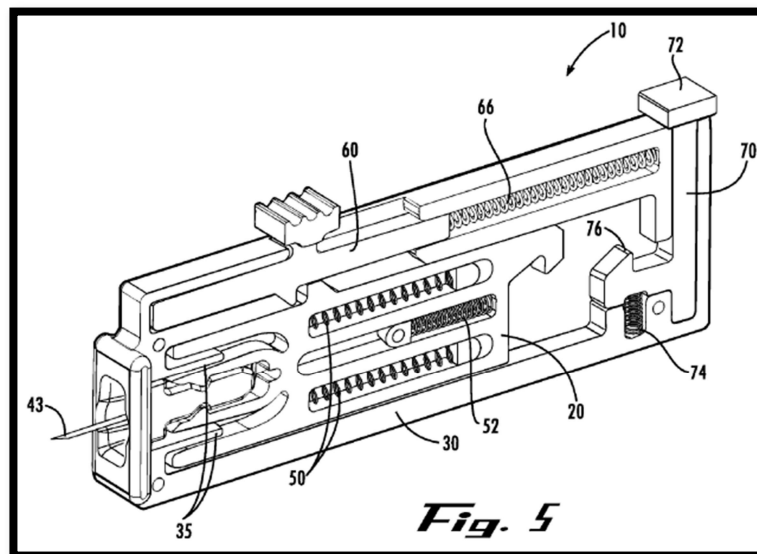
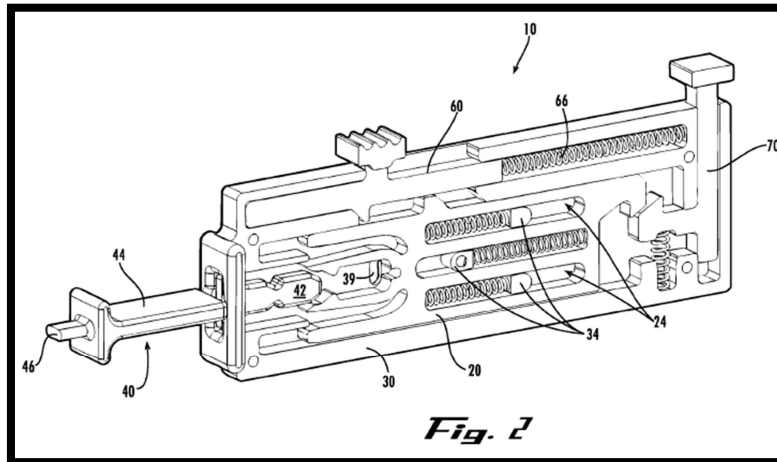
B. Stout ('712 Pet. Ex.1018)

61. U.S. Pat. App. Pub. No. 2006/0241669 (“Stout,” ’712 Pet. Ex.1018) describes a lancing device for medical sampling of blood or other body fluids that has a thin profile, for easy and convenient stowage. Stout ¶¶2, 6. The lancing device 110 receives a lancet 140, which includes a lancet body 142, sharp lancing tip, and endcap 144. Stout Figs. 8a-h, ¶41.



Stout Figs. 8a, 8c.

62. Stout discloses another embodiment of lancing device 10 that receives a lancet 40, which includes a lancet body 42, sharp lancing tip 43, and sterility cap 44. Stout Figs. 1-7, ¶35.



Stout Figs. 2, 5.

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

C. FreeStyle Manual ('712 Pet. Ex.1010)

64. Wayback Declaration and Reference: FreeStyle Owner's Booklet, TheraSense, Inc. (2004) ("FreeStyle Manual," '712 Pet. Ex.1010) describes a blood glucose monitoring system in the form of an "Owner's Booklet." FreeStyle include a picture labeled "Blood Glucose Testing Components." FreeStyle Manual 17.

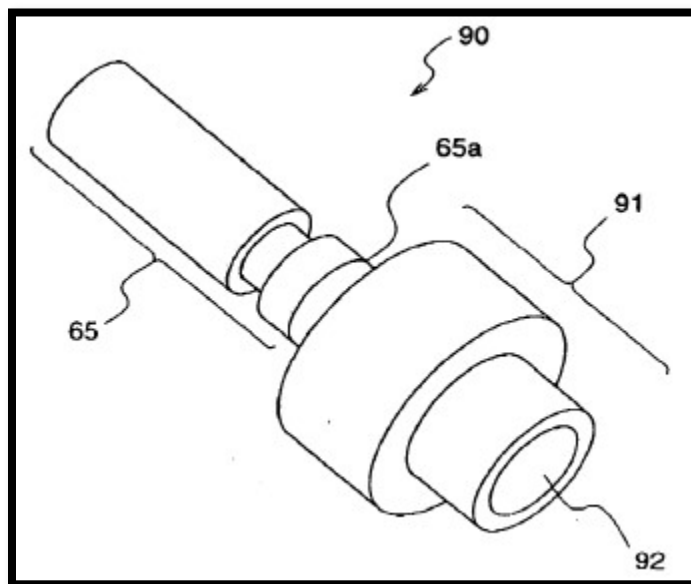


FreeStyle Manual 17.

65. One of the components in the picture is labelled "Lancet." FreeStyle Manual 17.

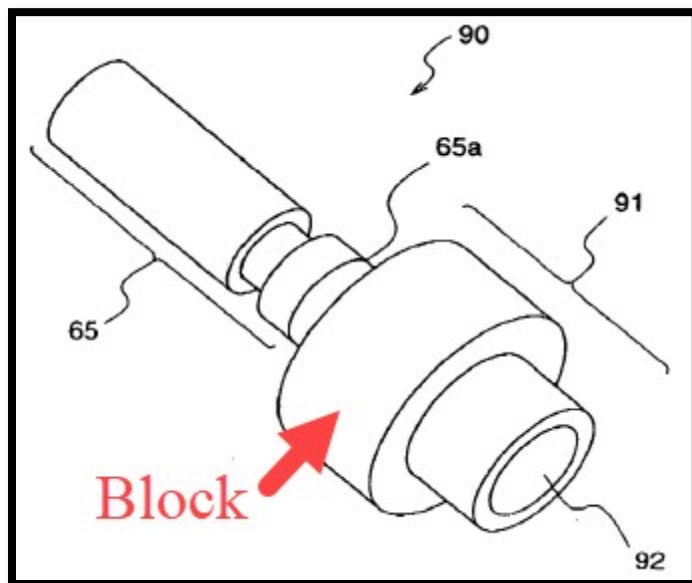
D. Iio ('712 Pet. Ex.1006)

66. U.S. Pat. App. Pub. No. 2005/0131441 ("Iio," '712 Pet. Ex.1006) describes a lancet for blood collection and a puncture needle unit. Iio ¶¶1, 5, Fig. 6. Iio discloses a puncture needle unit 90 that is divided into a puncture needle body 65 and a puncture needle cap 91 with a puncture needle separation groove 65a as boundary. Iio ¶104, Fig. 8.



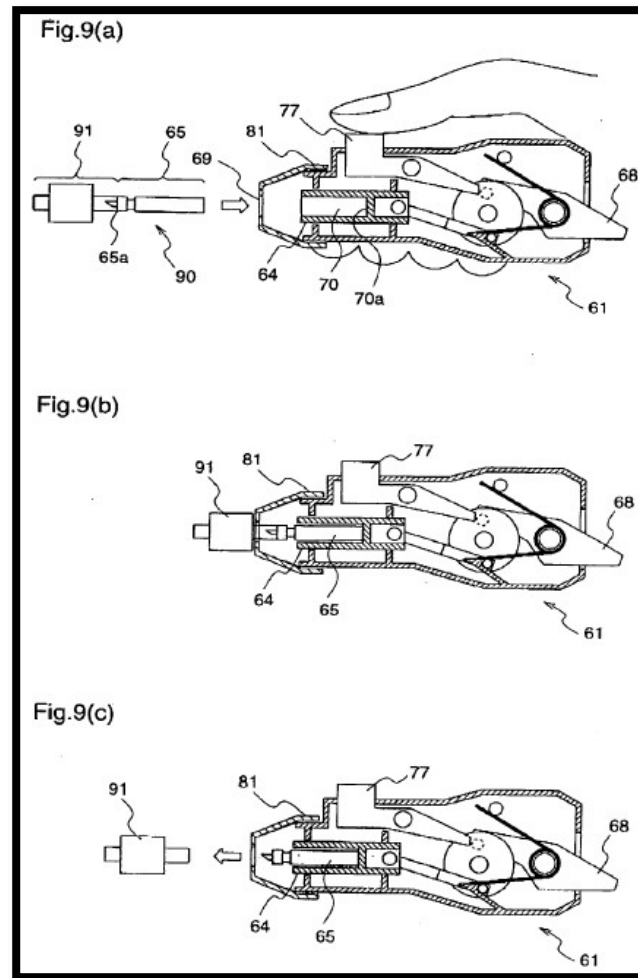
Iio Fig. 8.

67. Iio states, "The puncture needle body 65 is set in a state where it is embedded in the puncture needle cap 91, and a disposal slot 92 for pulling out the puncture needle 65 after puncture has been carried out is provided at an end of the puncture needle cap 91." Iio ¶104. The puncture needle cap 91 includes a block connected to the disposable slot 92 and portion that receives the puncture needle 65. Iio Fig. 8.



Iio Fig. 8 (annotated).

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

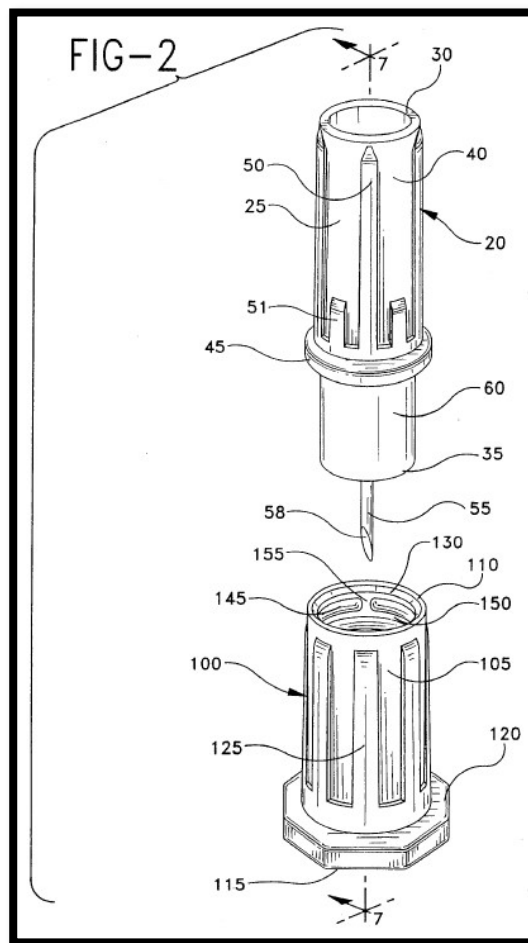


Iio Fig. 9.

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

E. Peckham ('712 Pet. Ex.1008)

70. U.S. Pat. No. 5,569,286 ("Peckham," '712 Pet. Ex.1008) describes a disposable lancet assembly for use in a blood sampling instrument. Peckham 1:65-2:4. Peckham discloses a shielded lancet assembly 10 with (a) a lancet assembly 20 containing a cylindrical housing 25 and stylet 55; and (b) a removable cap or shield 100. Peckham Fig. 2, 2:52-62.



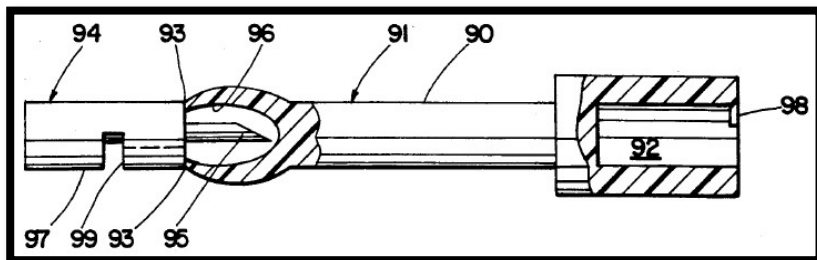
Peckham Fig. 2

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

The inside of cylindrical housing 105 includes three labyrinth rings to provide sterility. Peckham Fig. 2, 3:46-50. The outside cylindrical housing 105 includes ribs 125 extending from the octagonal shaped flange 120. Peckham Fig. 2, 3:11-14. Peckham discloses nothing about the sizes of either its cylindrical housing 105 or its lancet assembly.

F. Coe ('713 Pet. Ex.1106)

72. U.S. Pat. No. 5,569,286 ("Coe," '713 Pet. Ex.1106) discloses a lancet 94 and extractor 91. Coe Fig. 9, 5:22-24. The lancet 94 includes lancet hub 97 with slot 99 and sharp tip 95. Coe Fig. 9, 5:22-38. The extractor 91 includes an extractor cavity 92, handle portion 90, second cavity 96, and extractor tab 98. Coe Fig. 9, 5:22-38.



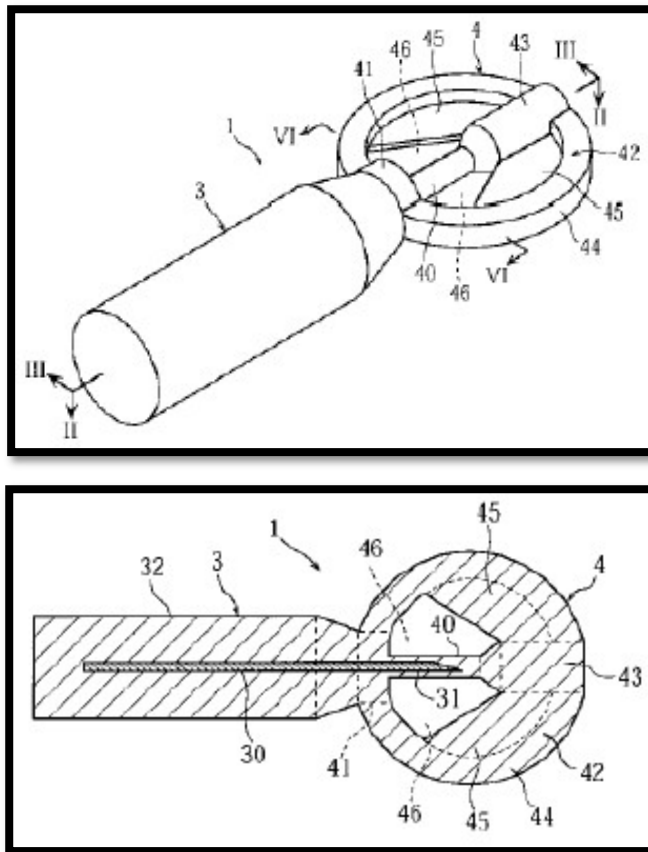
Coe Fig. 9.

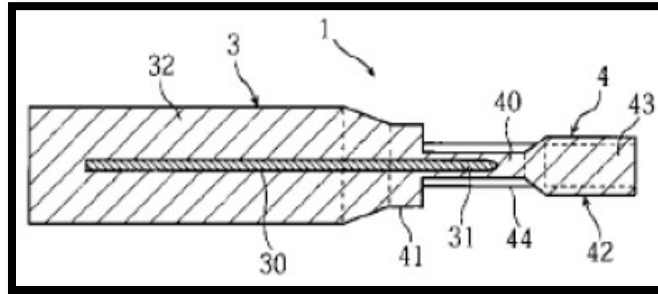
73. The lancet 94 and extractor 91 are connected through integral molding at breakaway points 93. Coe Fig. 9, 5:22-24, 5:28-30. The connections are broken by “gently twisting” while the lancet 94 is in a lancet device. Coe Fig. 9, 5:30-33. After the use, the lancet 94 “is inserted (point first) into the extractor cavity until

the extractor tab (98) engages the slot (99) in the lancet hub thereby locking the sharp lancet tip protectively within the extractor cavity for safe handling and disposal.” Coe Fig. 9, 5:33-38.

G. Sakata ('713 Pet. Ex.1107)

74. JP 2005-168634 (“Sakata,” ’713 Pet. Ex.1107) discloses a lancet 1. Sakata ¶¶8, 14. The lancet 1 includes a lancet body 3 and cap portion 4, which are separated by twisting them relative to each other. Sakata Figs. 1-3, ¶¶14, 20.





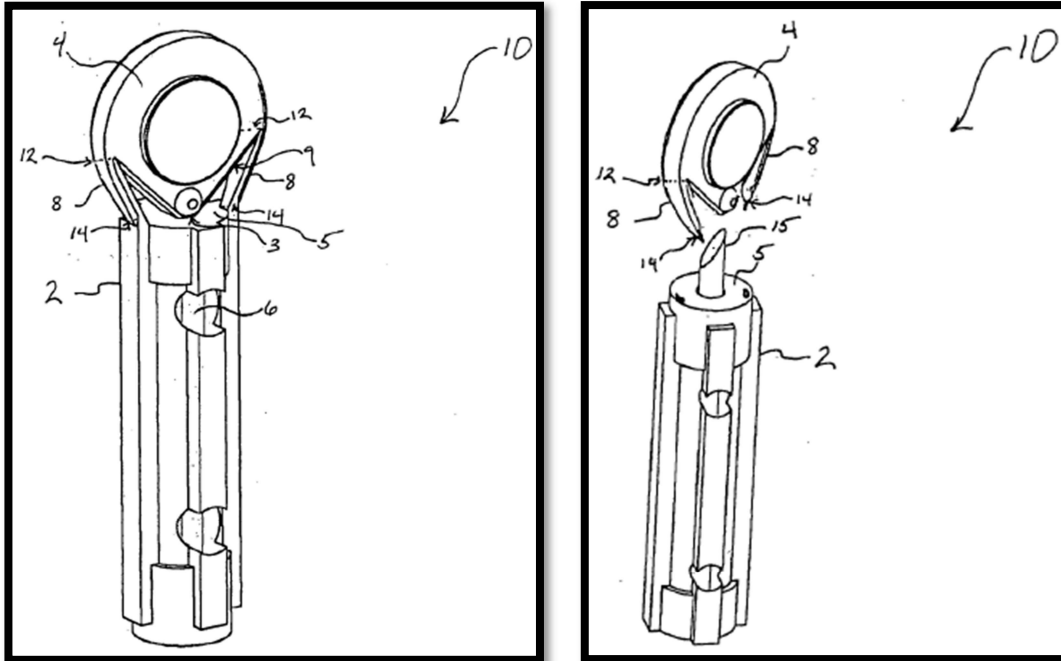
Sakata Figs. 1-3.

75. The lancet body 3 includes a holding portion 32 and puncture needle 30 with needle tip 31. Sakata ¶15, Figs. 2-3. The cap portion 4 includes small diameter covering portion 40, a large diameter covering portion 41, and an operating portion 42. Sakata ¶16, Figs. 1-3. The small diameter covering portion 40 covers needle tip 31. Sakata ¶17, Figs. 1-3. The large diameter covering portion 41 covers the root portion of the puncture needle 30. Sakata ¶18, Figs. 1-3. The operating portion 42 has a cylindrical portion 43, an arch portion 44, and a pair of thin-walled portions 45. Sakata ¶19, Figs. 1-3. There is a gap 46 interposed between the arch portion 44 and the small diameter covering portion 40. Sakata ¶19, Figs. 1-2. The cap portion 4 purportedly reduces the load applied to edge of blade's surface of the puncture needle when separating the cap portion 4 and does not significantly disturb the blade surface. Sakata ¶12.

H. Starnes ('713 Pet. Ex.1108)

76. U.S. Pat. App. Pub. No. 2007/0162064 ("Starnes," '713 Pet. Ex.1108) Starnes discloses a protective lancet. Starnes ¶¶3, 12. In a first embodiment

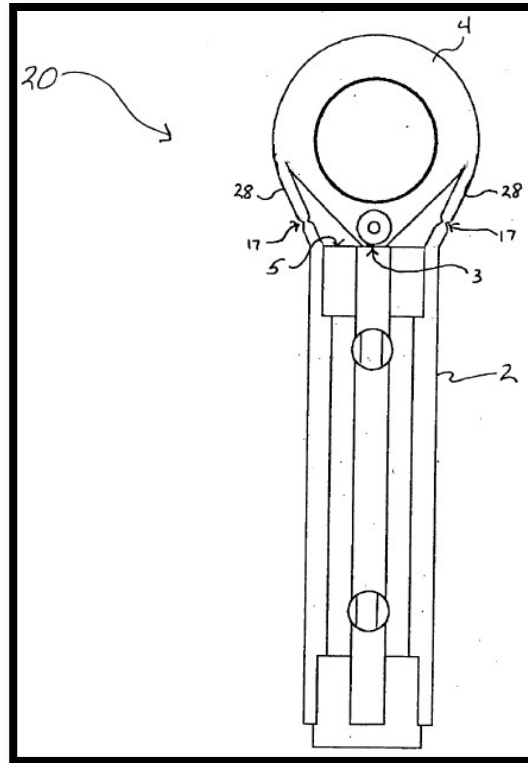
(Starnes Figs. 1-3), Starnes describes a lancet unit 10 including a cap member 4 and lancet body 2 with a pointed end section 15. Starnes ¶¶23-24.



Starnes Figs. 1, 2.

77. The cap member 4 covers the pointed end section 15 and connects to lancet body 2 by frangible junction 3 and narrower tear-away ends 14 of tab members 8. Starnes ¶¶26-27. The tab members 8 “provide a readily perceptible user indication of the status of whether or not the cap member has been re-attached or tampered with.” Starnes ¶12. The cap member 4 is separated from the lancet body 2 by “a twisting or pulling force.” Starnes ¶24. Upon twisting of cap member 4, the narrower tear-away ends 14 should disengage from an upper bearing surface 5 of lancet body 2, along with frangible junction 3. Starnes ¶27.

78. In a second embodiment (Starnes Fig. 4), Starnes describes a lancet unit 20 including a cap member 4 and lancet body 2. Starnes ¶35.



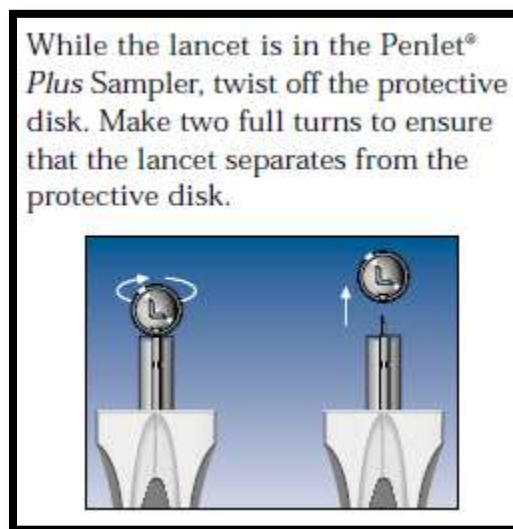
Starnes Fig. 4.

79. The cap member 4 connects to lancet body 2 by frangible junction 3 and tab members 28 with medial tear-away joints 17. Starnes ¶¶26-27. The tab members 28 “provide a readily perceptible user indication of the status of whether or not the cap member has been re-attached or tampered with.” Starnes ¶12. The cap member 4 is separated from the lancet body 2 by “a twisting or pulling force.” Starnes ¶35. When cap member 4 detaches from lancet body 2, the medial tear-away joints 17 should fracture such that a substantial appendage portion of tab

member 28 remains attached to cap member 4 and a visually perceptible stub remains on upper bearing surface 5 of lancet body 2., which provides “a readily perceptible indicator of de-attachment.” Starnes ¶35.

I. One Touch Owner’s Manual (’713 Pet. Ex.1110)

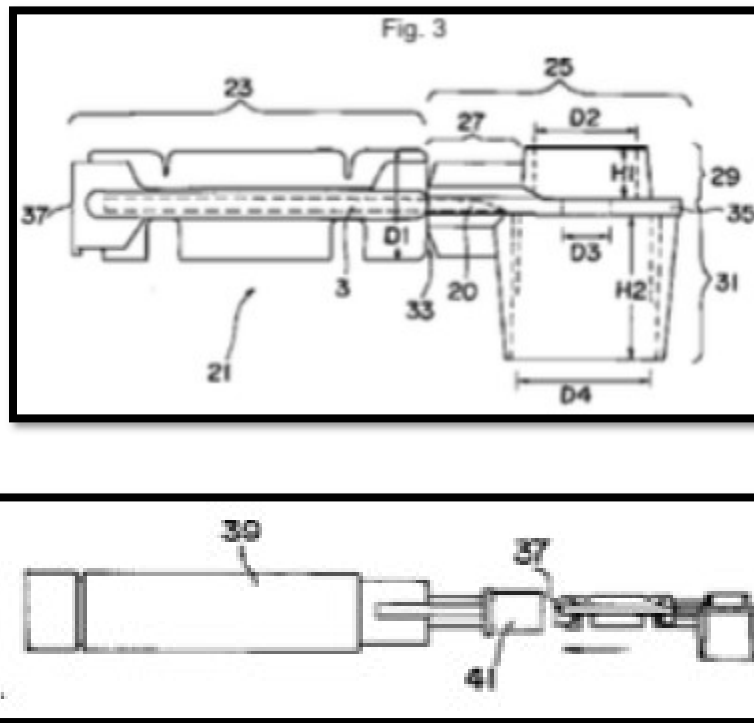
80. Wayback Declaration + One Touch Booklet: One Touch Basic Complete Diabetes Monitoring System Owner’s Booklet, Rev. 02/2004, LifeScan Inc., Milpitas, California (1999) (“One Touch Owner’s Manual,” ’713 Pet. Ex.1110) describes a blood glucose monitoring system in the form of an “Owner’s Booklet.” One Touch Owner’s Manual describes twisting off a protective disk of a lancet. One Touch Owner’s Manual 36.



One Touch Owner’s Manual 36.

J. Morita ('713 Pet. Ex.1109)

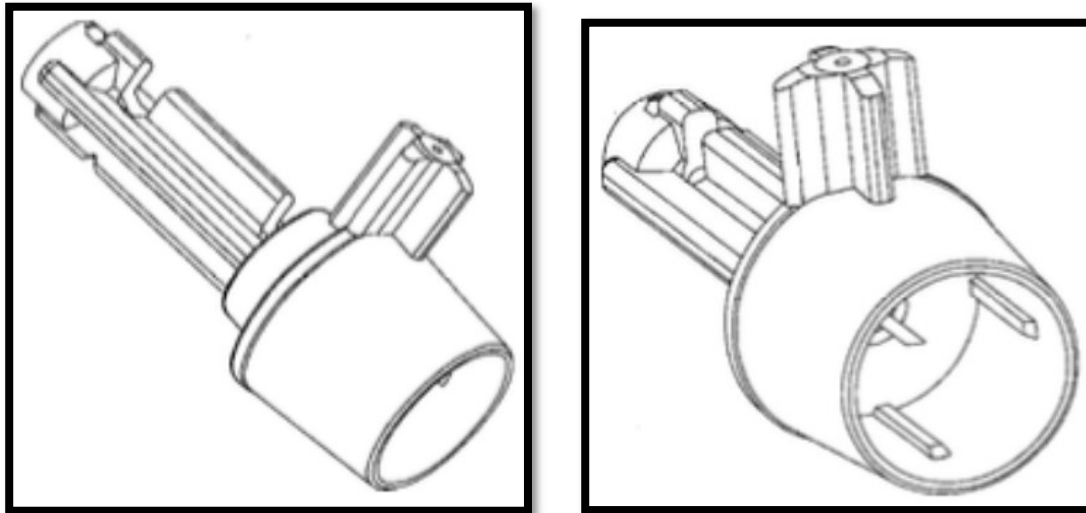
81. JP Pat. App. Pub. No. H5-285127 ("Morita," '713 Pet. Ex.1109) discloses a blood collection lancet. Morita ¶1. A device accepts a lancet 21 having a lancet body 23, needle part 3 (including needle tip part 20), and protective platform 25. Morita ¶¶29, 33, Figs. 3, 10.



Morita Figs. 3, 5.

82. Morita discloses processes for loading and discarding the lancet 21. Morita ¶¶33-35, 42, Figs. 5-13, 15-19. For loading, the lancet 21 through lancet body 23 is fixed to the device and the lancet body 23 and protective platform 25 are separated to expose needle tip part 20 from needle tip protection portion 27. Morita ¶33, Figs. 5-7. The detached protective platform 25 is then fitted onto the

end of the end cap 43 of the finger-pricking device (see Figure 8). The end cap 43 with a protective platform 27 is fitted onto the device with the lancet body attached. Morita ¶34. The combination is then placed on the user and triggered. Morita ¶34. The needle tip part 20 creates a wound for blood collection. Morita ¶34, Fig. 9. For discarding, the lancet body 23 with the needle tip part 20 is fitted into the platform part 29. Morita ¶35, Fig. 11. The device releases the lancet body 23. Morita ¶35, Fig. 12. The combination of the lancet 21 and protective platform 25 are discarded. Morita ¶35. The height of an end cap connection part 31 is sufficient that the needle tip does not protrude out and has an opening to connect with an end cap that is too small for a finger to enter. Morita ¶36, Figs. 3, 19.



Morita Figs. 18, 19.

VIII. All Grounds in the '712 Petition Do Anticipate or Render Obvious Any '712 Petition Challenged Claim

A. Ground 1: Saikley Does Not Anticipate Claims 6-8, 14, and 16-18

1. Saikley Does Not Disclose All Claim Limitations

a. Saikley Does Not Disclose “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness” (Claims 6, 14)

83. Claims 6 and 14 of the '635 Patent require “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.” In my opinion, Saikley does not disclose this limitation.

84. Saikley provides no dimensional information of shortened lancet 76 or cap 78. Accordingly, Saikley does not provide dimensional information of “a lateral span” of “a gripping handle portion” or “a lancet thickness” of “a lancet body.”

85. None of Saikley’s figures have a reference for scale. The written specification does not indicate any figure is to scale. Any exact dimensional information derived from the figures with this lack of information is unreliable and I understand, as noted above, is not proper in such situations.

86. Saikley discloses a “Large Lancet Cap for Handling” (Saikley ¶49) and cap 78 “should be made much larger than usual to aid handling” (Saikley ¶50). That disclosure provides no dimensional information of “a lateral span” of “a gripping handle portion” or “a lancet thickness” of “a lancet body.” Also, there is

no information of what cap 78 is larger than, i.e., usual dimensions of a protective cap, or how cap 78 is larger. For example, cap 78 may be larger in the thickness dimension. Even assuming cap 78 is “larger” in the span dimension, there is no reference point to know what the minimum span of cap 78 would be.

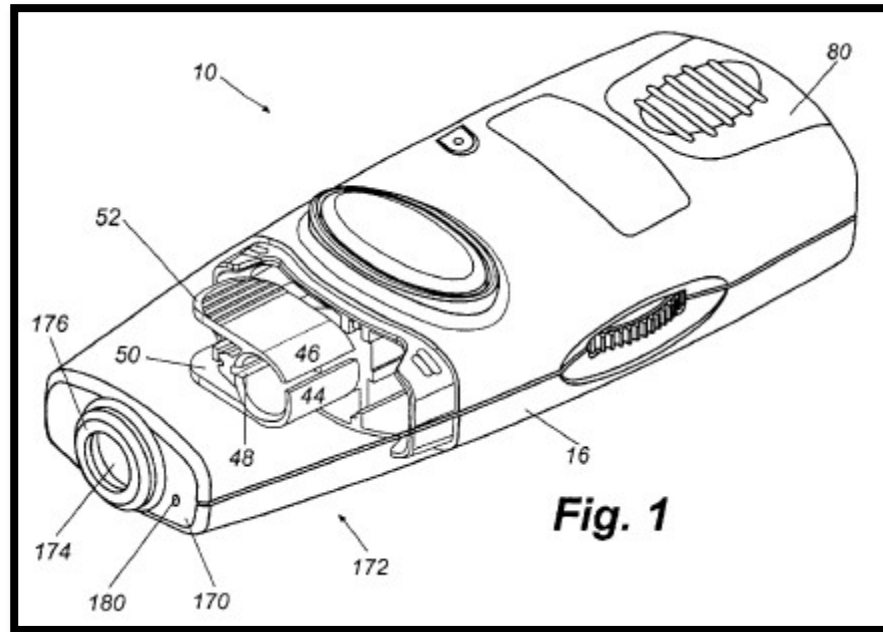
87. Saikley discloses a “short length” for shortened lancet 76. Saikley ¶50. That disclosure provides no dimensional information of “a lateral span” of “a gripping handle portion” or “a lancet thickness” of “a lancet body.”

88. In other words, Saikley provides no disclosure whatsoever about the relationship between the alleged gripping handle and the lancet’s thickness.

89. Saikley’s disclosure that cap 78 “should be made much larger than usual to aid handling” (Saikley ¶50) does not mean the span should, or necessarily, be larger than 16 mm (average width of a human thumb according to LifeScan). Many items are grabbed, manipulated, and twisted with a thumb and other digit that are less than 16 mm, e.g., pen and pen cap; eye liner pencil and cover.

90. According to LifeScan, a “standard lancet” may have a diameter of less than 6 mm. ’712 Pet. at 39. But there is no indication that a diameter of a “standard lancet” is applicable to shortened lancet 76. Saikley discloses the embodiment in Fig. 71 as not traditional. Saikley ¶50. Saikley discloses a “[t]raditional disposable lancets, such as shown in FIG. 3” to contrast its description of the lancet in Fig. 7A. Saikley ¶50.

91. LifeScan states Saikley’s alleged disclosure of this claim limitation “is consistent with incorporated-by-reference LeVaughn, which teaches that a ‘transverse ratio (W/t) of at least 3:2, and more preferably about 2:1, provides an easy to grip [lancing] device which resists twisting about the central axis.’” ’712 Pet. 40 (citing ’712 Pet. Ex.1017 5:15-18). LifeScan is incorrect. First, as shown above Saikley does not disclose this limitation. Second, LeVaughn (’712 Pet. Ex.1017) does not provide a ratio analogous to the claimed ratio. LeVaughn (’712 Pet. Ex.1017) discloses “the overall width W of the lancing device 10 is at least 1½ times, and more preferably about twice the overall thickness t,” which “provides an easy to grip device which resists twisting about the central axis.” ’712 Pet. Ex.1017 5:13-18. The ratio relates to lancing device 10, which is the device that receives a lancet—not the lancet itself. *See, e.g.*, ’712 Pet. Ex.1017 4:48-52, Fig. 1.



'712 Pet. Ex.1017 Fig. 1.

92. The lancing device 10 is distinct from a lancet. There is no basis to correlate the ratio of the lateral span of a gripping handle portion of a protective sterility cap or a lancet thickness with that of a lancing device. The lancing device 10 as seen in Fig. 1 includes many other components, such as an end cap 172 and housing 16. '712 Pet. Ex.1017 9:57-62, Fig. 1. The lancing device 10 may be of a variety of shapes and sizes to achieve desired design goals. The dimensions of device 10 are independent and do not need to correlate to other parts of a bodily fluid testing system, such as sterility cap or lancet thickness.

B. Ground 2: Saikley in View of Stout Do Not Render Obvious Claims 6-8, 14, and 16-18

1. Saikley in View of Stout Does Not Disclose All Claim Limitations

a. Saikley in View of Stout Does Not Disclose “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness” (Claims 6, 14)

93. Claims 6 and 14 of the '635 Patent require “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.” In my opinion, Saikley in view of Stout does not disclose this limitation.

2. Saikley does not disclose this limitation. Section Saikley Does Not Disclose All Claim Limitations

94. Saikley Does Not Disclose “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness” (Claims 6, 14)VIII.A.1.a.

95. Stout does not disclose this limitation.

96. LifeScan mismatches Stout’s disclosure of one embodiment (Stout Figs. 1-7, ¶32)—“The slotted opening 32 has a length considerably greater than its width, most preferably having a length at least twice its width”—with the embodiment primarily relied upon by LifeScan (Stout Figs. 8a-h, ¶41). '712 Pet. 53-54. Stout does not disclose dimensional information for the Figure 8 embodiment. Stout ¶41. Stout does not provide dimensional information of “a lateral span” of “a gripping handle portion” or “a lancet thickness” of “a lancet

body” for the Figure 8 embodiment. Stout ¶41. Stout does not indicate that the description or dimensional information from one embodiment is applicable to another embodiment in Stout.

97. Stout provides no dimensional information of end cap 144 or lancet 140. Accordingly, Stout does not provide dimensional information of “a lateral span” of “a gripping handle portion” or “a lancet thickness” of “a lancet body.”

98. None of Stout’s figures have a reference for scale. The written specification does not indicate any figure is to scale. Any exact dimensional information derived from the figures with this lack of information is unreliable and I understand, as noted above, is not proper in such situations.

3. A POSA Would Not Have Combined Saikley and Stout

99. A POSA would not have been motivated to combine Saikley and Stout.

100. LifeScan gives multiple purported motivations to combine Saikley and Stout. All fail.

101. **First**, LifeScan argues a POSA would have been motivated “to embed the lancet needle within the twist-off joint and adjoining portion of the handling tab of the protective cap 78 because it was well known that this would make the needle tip 50 more resistant to the non-axial cocking or pivoting movement of the endcap when it is twisted off by the user, which could bend or break the needle

tip.” ’712 Pet. 47. This is an alleged motivation related to embedding and not the dimensional ratio limitation. Embedment of a needle in a cap is separate from dimensional information, including what dimensions of what component to use in a ratio and the value of the ratio itself.

102. ***Second***, Saikley and Stout being in the “same field of endeavor” and addressing “the same problem” is not a sufficient motivation not combine them.

103. ***Third***, LifeScan argues it would be commercially desirable to have and obvious to try the combination of Saikley and Stout as Stout’s components could be used with an Abbott FreeStyle Flash Meter—a “system disclosed by Saikley.” ’712 Pet. 56. But the supposed teachings from Stout LifeScan wants to combine with Saikley—primary sheath embedding a sharp lance tip and gripping handle span to lancet thickness ratio limitations—has nothing to do with the compatibility of Stout working with another device. Compatibility has to do with mechanical connections components directly in contact with one another. Ratios of dimensions for a cap that does not directly interface with the device do not fall within that realm. There is no indication why Saikley and Stout being used with an Abbott FreeStyle Flash Meter would have anything to do with commercial desirability of the lancet and cap.

4. A POSA Would Not Have Adjusted a Lateral Span of a “gripping handle portion” to be at Least 1.5 Times a “lancet thickness” (Claims 6, 14)

104. A POSA would not have adjusted a lateral span of a “gripping handle portion” of Saikley to be at least 1.5 times a “lancet thickness.”

105. LifeScan cites no prior art that recognized the specific relationship claimed in claims 6 and 14—between the lateral span of the gripping handle and the lancet thickness, much less the specific ratio claimed therein. Indeed, I’m not aware of any.

106. Saikley’s disclosure that its cap 78 should be “larger than usual to aid handling,” does not provide a reason to size the span of its cap 78 in relation to the thickness of the lancet, as opposed to, for example, the length or width of the lancet or specific ranges of dimensions.

107. The ’635 Patent teaches why the ratio of at least 1.5 is important, and the prior art does not recognize this importance. ’635 Patent 3:52-56, 6:52-7:3 (“The provision of the elongate handle portion 516 [of at least 1.5 times span of the lancet thickness] 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”). These benefits are combined with the reduced pain enabled by the relatively small mass lancet body with a thickness less than 1.5 times the span.

108. A POSA would not have seen the claimed dimensional limitation as an obvious design choice. The prior art did not even recognize the importance of the claimed relationship. And even if it did, the prior art did not recognize at least 1.5 as the critical or important ratio of those two dimensions.

109. Contrary to LifeScan's assertion, it would not have been obvious try to a POSA to try or part of routine optimization of a POSA to determine a relationship between the span of the gripping handle portion of a sterility cap and the lancet thickness of a lancet body was important or arrive at the claimed ratio of at least 1.5 between the two dimensions.

110. LifeScan has not presented a finite number of known solutions to improve the use or maneuverability of a lancet for people.

111. A POSA could take multiple avenues to improve the use or maneuverability of a lancet for people.

112. For example, a POSA could add a cover to the areas of the cap gripped by a user (e.g., rubber, polymer, textured coating). This is done in other areas where gripping or maneuverability is important, such as pens, scissors, screwdrivers, baseball bats, and bike handles.

113. As another example, a POSA could add mechanical features to the areas of the cap gripped by a user (e.g., dimples). This is done in other areas where gripping or maneuverability is important, such as pop bottle caps.

114. As another example, a POSA could change dimensions of certain components. This is done in other areas where gripping or maneuverability is important, such as different sizes of golf clubs or other athletic equipment between adults and children.

115. Even pursuing only changing the dimensions of the area gripped by a user, there is still a vast number of options to choose from to make adjustments of dimensions in a lancing device system. There are at least three dimensions of the area gripped by a user: length, width, thickness. After selecting one of those three dimensions, one would have to choose what other component in the lancing device system to be ratioed with the selected dimension of the areas gripped by the user. A lancing device system may be composed of at least tens or hundreds of components. Then one would have to choose the dimension of the component in the lancing device to ratio with the selected dimension. Then one would have to decide if the ratio is larger, equal to, or less than one (larger/same/smaller) and then vary the magnitude of ratios to find the important relationship between the two.

116. In a simple lancing device system, the amount of possibilities to choose from would be high. For example, in a lancing device system with 10 components, there would be a 1 out of 270 (3 dimensions of the lancet body * 10 components from which to choose * 3 dimensions of each component * 3 choices for being larger/same/smaller) chances of choosing the ratios to be established and

then and then at least 10's or 100's of values to select, producing over 10's of thousands of options for the ratios in the claims.

117. All of these choices would have to be made in the backdrop of the prior art that gave no motivation to pursue this course of action nor indication of what component to start with, what dimension to choose, what component to ratio with, and what dimension to choose of the component.

C. Ground 3: Saikley in View of FreeStyle Manual Do Not Render Obvious Claim 16

1. Saikley in View of FreeStyle Does Not Disclose All Claim Limitations

a. Saikley in View of FreeStyle Manual Does Not Disclose “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness” (Claims 6, 14)

118. Claims 6 and 14 of the '635 Patent require “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.” In my opinion, Saikley in view of FreeStyle Manual does not disclose this limitation.

2. Saikley does not disclose this limitation. Section Saikley Does Not Disclose All Claim Limitations

119. Saikley Does Not Disclose “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness” (Claims 6, 14)VIII.A.1.a.

120. LifeScan does not rely on FreeStyle Manual to disclose this limitation. '712 Pet. 57-59. Indeed, FreeStyle Manual does not disclose this limitation,

including any dimensional information about a lateral span of a gripping handle portion (or cap) or thickness of a lancet body. *See, e.g.,* '712 Pet. Ex.1010 17.

D. Ground 4: Iio Does Not Anticipate Claims 6-8, 14, and 16-18

1. Iio Does Not Disclose All Claim Limitations

a. Iio Does Not Disclose “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness” (Claims 6, 14)

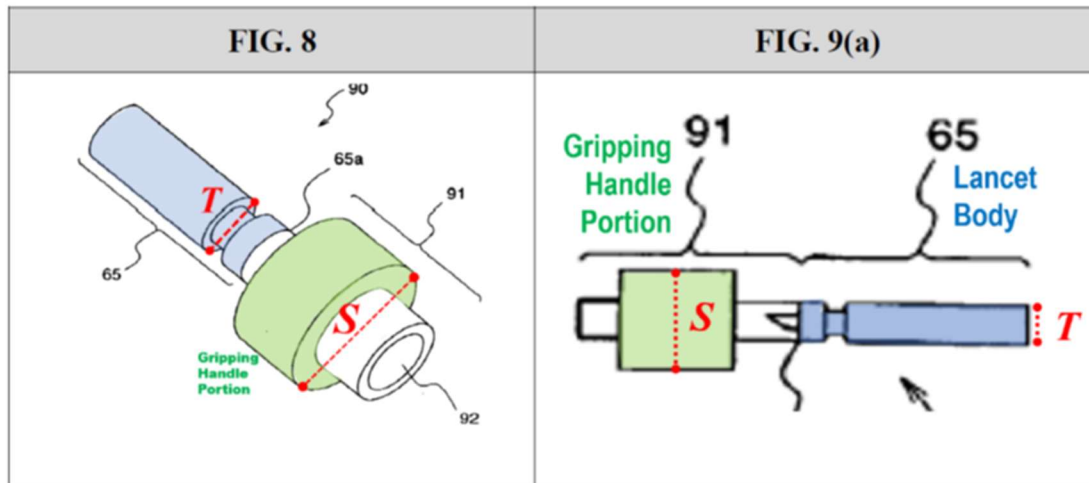
121. Claims 6 and 14 of the '635 Patent require “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.” In my opinion, Iio does not disclose this limitation.

122. Iio provides no dimensional information of puncture needle body 65 or the puncture needle cap 91. Accordingly, Iio does not provide dimensional information of “a lateral span” of “a gripping handle portion” or “a lancet thickness” of “a lancet body.”

123. None of Iio’s figures have a reference for scale. The written specification does not indicate any figure is to scale. Any exact dimensional information derived from the figures with this lack of information is unreliable and I understand, as noted above, is not proper in such situations.

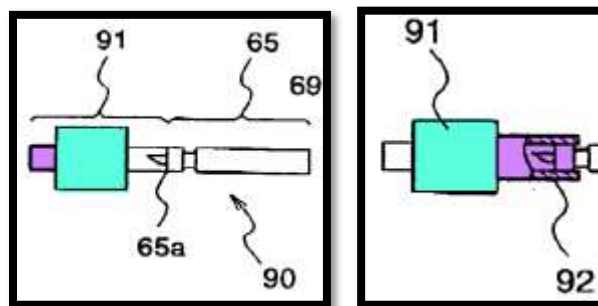
124. Iio’s figures are clearly not drawn to scale. For example, components in Iio’s figures change size across figures as shown by changes in relative sizes of the same components. For example, Figure 8 and Figure 9(a) annotated by LifeScan show different relevant sizes for the same components that LifeScan

marked as “S” and “T” and the block labeled “Gripping Handle Portion” in Fig. 8 (annotated) is has a diameter larger than it is long, while the diameter of same block in Fig. 9 (annotated) is smaller than it is long.



’712 Pet. 80.

125. As another example, Figure 9 and Figure 11 annotated below show different relevant sizes for the same components, i.e., disposal slot 92 (purple) and the block (teal). Fig 9a (on the left below) has a disposal slot 92 that is much shorter than the block, but Fig 11b (on the right below) shows that the two are about the same length—the disposal slot 92 also appears to double in diameter.



Iio Figs. 9(a), 11(a) (annotated).

126. Iio discloses that “fitting of the puncture needle to the disposal slot is easier than fitting of the puncture needle to the protection slot.” Iio ¶20. That disclosure provides no dimensional information of “a lateral span” of “a gripping handle portion” or “a lancet thickness” of “a lancet body.”

127. Figure 8, Figure 9, and Figure 11 may show that the block is broader than the disposal slot 92, but that does not mean it is “significantly broader” or that any dimensional information may be derived from them because the figures and written description provide no information about its scale, including whether things in the figures are scale to each other in the figure.

128. The thumb in Figure 9(a) provides no information that can be used to derive dimensional information of “a lateral span” of “a gripping handle portion” or “a lancet thickness” of “a lancet body.” Figure 9(a) is a side view of “a method for loading a puncture needle on the lancet according to the second embodiment.” Iio ¶45. Fig. 9(a) is like every other figure in Iio in that the figures and written description provide no information about its scale, including whether things in the figures are scaled to each other in the figure.

129. Iio discloses that “the body 65 and the cap 91 are connected to each other by a thin plastic film having a thickness of 0.1 mm or less in the puncture needle separation groove 65a.” Iio ¶104. There is no way to correlate the thin film

to either the thickness of the lancet or the lateral span of the block. This thin film is not even shown in Figs. 8 and 9(a) or any other figure. The written specification of Iio does not disclose that any figure includes the thin plastic film. Iio does not disclose any dimension of puncture needle unit 90 is connected to the thickness of the thin plastic film.

E. Ground 5: Iio in View of Peckham Do Not Render Obvious Claims 6-8, 14, 16-18

1. Iio in View of Peckham Does Not Disclose All Claim Limitations

a. A POSA Would Not Have Adjusted a Lateral Span of a “gripping handle portion” to be at Least 1.5 Times a “lancet thickness” (Claims 6, 14)

130. A POSA would not have adjusted a lateral span of a “gripping handle portion” of Iio in view of Peckham to be at least 1.5 times a “lancet thickness.”

131. LifeScan makes two arguments why this limitation is obvious. LifeScan argues that, (1) it would have been obvious to try to adjust any relative dimensions limitations of Iio; and (2) it would have been obvious to add Peckham’s ribs to the portion of Iio that LifeScan calls a handle (block), which would have allegedly increased the lateral span of Iio’s block even more. ’712 Pet. 90-91, 93. Both are wrong.

132. The obvious to try argument is wrong for the same reasons in Section VIII.B.3.

133. The added span argument from Peckham's rib argument is wrong as it is entirely speculative.

134. To "add" the ribs of Peckham to Iio, a POSA could just as easily remove material from Iio's block to create the ribs as "add" the ribs on top of Iio's block. When material is removed to create the ribs, the lateral span of Iio's block would remain constant, instead of increasing.

135. Putting aside that issue, Peckham, like Iio, provides no dimensional information about its shielded lancet assembly, including rib height. Accordingly, Peckham does not provide dimensional information of "a lateral span" of "a gripping handle portion" or "a lancet thickness" of "a lancet body."

136. None of Peckham's figures have a reference for scale. The written specification does not indicate any figure is to scale. Any exact dimensional information derived from the figures with this lack of information is unreliable and I understand, as noted above, is not proper in such situations.

137. Lastly, even putting all of the above issues aside, there is no disclosure in Iio or Peckham as to a lancet thickness of a lancet body. That dimension is needed to be able to calculate the claimed ratio. As neither disclose it and lancet body thicknesses may vary, the combination would not render this claim limitation obvious.

F. Ground 6: Iio in View of Freestyle Manual Do Not Render Obvious Claim 16

1. Iio in View of FreeStyle Manual Does Not Disclose “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness” (Claims 6, 14)

138. Claims 6 and 14 of the '635 Patent require “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.” In my opinion, Iio in view of FreeStyle Manual does not disclose this limitation.

2. Iio does not disclose this limitation. Section Saikley Does Not Disclose All Claim Limitations

139. Saikley Does Not Disclose “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness” (Claims 6, 14)VIII.D.1.a.

140. LifeScan does not rely on FreeStyle Manual to disclose this limitation. '712 Pet. 100-01. Indeed, FreeStyle Manual does not disclose this limitation, including any dimensional information about a lateral span of a gripping handle portion (or cap) or thickness of a lancet body. *See, e.g.*, '712 Pet. Ex.1010 17.

IX. All Grounds in the '713 Petition Do Anticipate or Render Obvious Any '713 Petition Challenged Claim

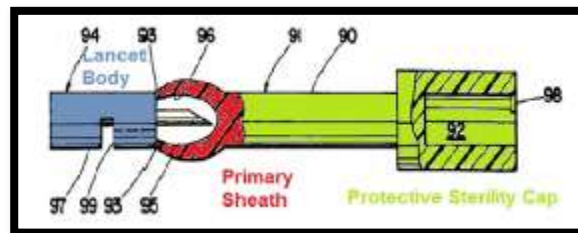
A. Ground 2: Coe in View of Sakata Does Not Render Obvious Claims 11-15¹

1. Coe in View of Sakata Does Not Disclose All Claim Limitations

a. Coe in View of Sakata Does Not Disclose “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein” (Claims 11, 14)

141. Claims 11 and 14 of the '635 Patent require “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein.” In my opinion, Coe in view of Sakata does not disclose this limitation.

142. LifeScan asserts the red portion below is the “primary sheath,” which includes second cavity 96:



¹ LifeScan asserted in Ground 1 of the '713 Petition that Coe anticipated only claim 1. '713 Pet. at 4. As Facet disclaimed claim 1, I understand that claim 1, and thus Ground 1, are not at issue in the '713 Petition. I further understand that LifeScan disclaimed claims 1-5 and 9-10 as well such that they may not form a basis for institution of an IPR. So I do not address them in this Declaration.

Pet. 11; *see also* Coe Fig. 9. The sharp lancet tip (which Coe labels as 95 in Fig. 9; LifeScan removed the leader line from 95 to the sharp lancet tip), as plainly seen, is not “embedded” within the second cavity 96.

143. A POSA would understand a sharp lancing tip is “embedded” when fixed firmly and deeply in a surrounding solid mass or surrounded closely. By way of example, the prior art teaches many examples of needles being insert molded with the proximal end of the needle (opposite the point) being embedded in the lancet body and the tip embedded in a cap.

144. An analogy would be to driving a railroad or tent spike into the ground, which would embed the spike in the earth.

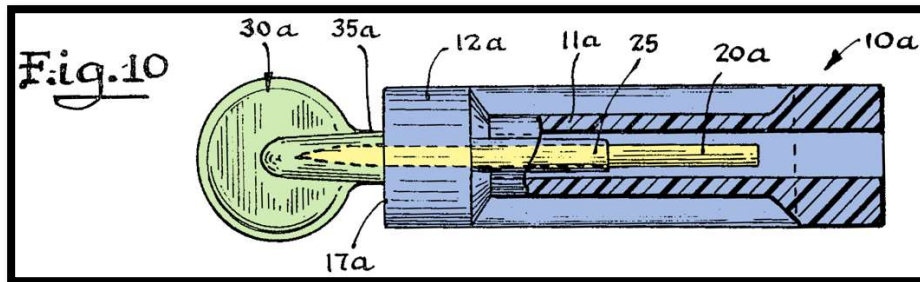
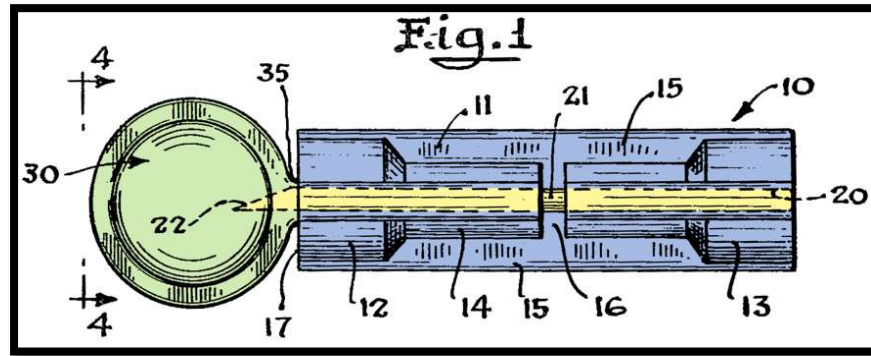
145. This understanding is supported by the dictionary definition of “embed” from near the time of filing of the patent application that became the ’635 Patent. Ex.2117 (Collins English Dictionary) (embed: “to fix or become fixed firmly and deeply in a surrounding solid mass”); Ex.2115 (McGraw-Hill Dictionary) (embed: “To closely surround”); Ex.2113 (Merriam-Webster Dictionary) (embed: “to enclose closely in or as if in a matrix;” “to surround closely”).

146. Coe’s sharp tip 95 is not fixed firmly and deeply in a surrounding solid mass or surrounded closely.

147. Coe recognizes that what LifeScan labels as the “primary sheath” in red does not embed a sharp lancing tip. Coe calls 96 a “second cavity.” A POSA would understand a “cavity” to mean an unfilled or hollow space. Ex.2117 (Collins English Dictionary) (cavity: “a hollow space”); Ex.2113 (Merriam-Webster Dictionary) (cavity: “an unfilled space within a mass”). There is nothing in the cavity of second cavity 96 of Coe. There is no mass for the sharp lancet tip 95 to go into in order to be embedded. It is a big empty space.

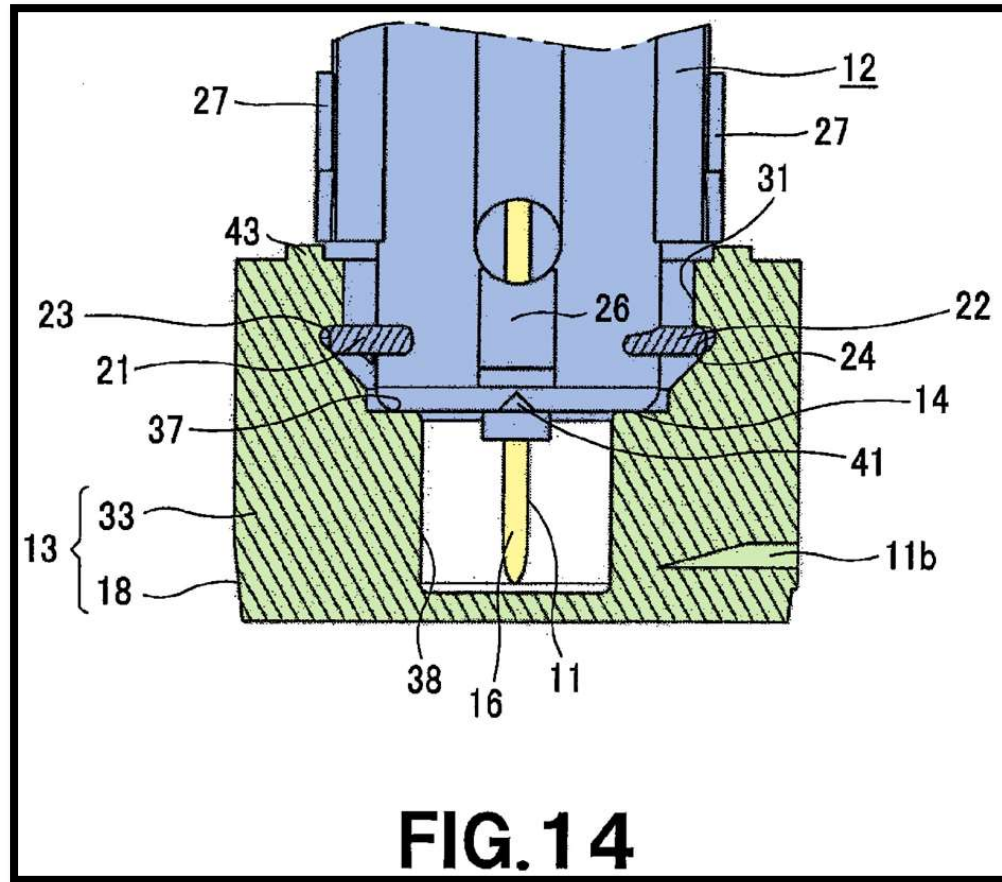
148. The art supports this reading of Coe that it does not embed a sharp lancing tip.

149. Starnes (Ex.1116) describes the art including U.S. Pat. No. 3,358,689 to Higgins (Ex.1118 – Higgins ’689 Patent). Ex.1116 ¶¶6-13. Starnes (Ex.1116) states Higgins teaches “a lancet needle is encased in an elongated plastic body with the needle tip *embedded* in a removable protective cap integrally molded with the plastic body to form a single integral unit prior to use.” Ex.1116 ¶8. Below is an embodiment of Higgins where the cap 30 or 30a and body section 11 or 11a are integrally molded and the cap 30 or 30a surrounds closely the needle tip:



Higgins Figs. 1 (annotated), 10 (annotated), 2:21-25, 4:5-11, 4:74-5:2. The cap 30 or 30a is a solid mass that the needle is present in. There is no space or cavity in the cap 20 or 30a.

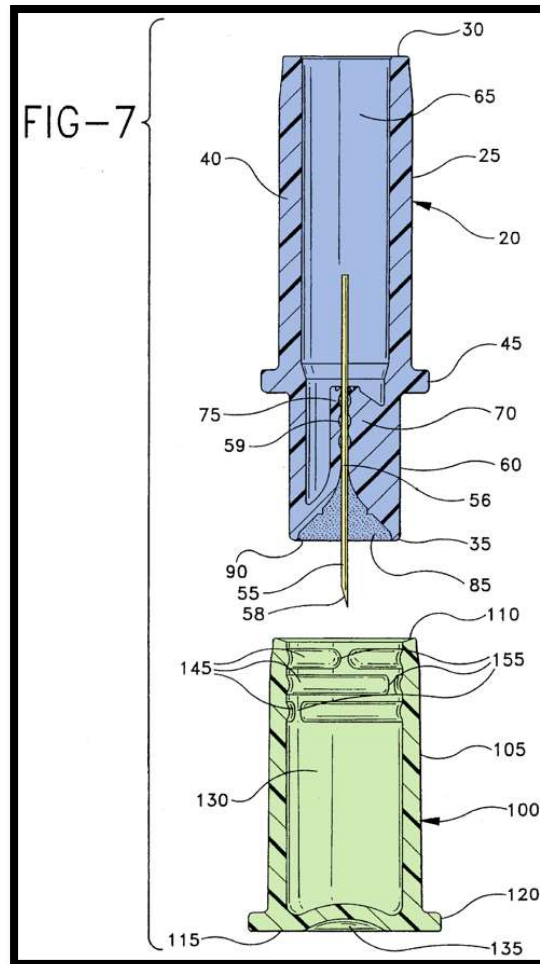
150. When the art describes a cap that does not have mass that fixes firmly and deeply a sharp lancing tip or surrounds the sharp lancing tip closely, the art does not describe the cap as “embedding” the sharp lancing tip. For example, Horie (Ex.1114) describes a distal end 11a of a needle 11 attached to pricking member body 12 being inserted into a needle protective cap 13 where there is an appreciable space between the needle 11 and the protective cap 13 (as seen below) “such as to isolate the distal end 11a from outside.”



Ex.1114 Fig. 14 (annotated), ¶81. Horie (Ex.1114) does not say that the needle 11 is “embedded” by the needle protective cap 13, but rather that it is “isolate[d].” *See* Ex.1114 ¶81. Figure 14 shows a gap (white space) of a cavity or void where the 11 is housed. This is similar to the drawing in Coe.

151. Peckham (Ex.2119) describes a shielded lancet assembly 10 with (a) a lancet assembly 20 containing a cylindrical housing 25 and stylet 55; and (b) a removable cap or shield 100. Ex.2119 - Peckham Figs. 2, 7, 2:52-62. When the lancet assembly 20 is inserted into removable cap or shield 100, the stylet 55 is “shield[ed]”—not “embedded,” especially as seen in the figure below where there

would be an appreciable distance between the stylet 55 and removable cap or shield 100 upon insertion.



Ex.2119 Fig. 7, 2:56-59, 3:4-8.

152. LifeScan relies solely on Coe to teach this limitation—not Sakata nor the proposed combination. '713 Pet. 31. To the extent LifeScan makes such assertions, I reserve the right to respond.

b. Coe in View of Sakata Does Not Disclose “the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness” (Claims 11, 14)

153. Claims 11 and 14 of the '635 Patent require “wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness.” In my opinion, Coe in view of Sakata does not disclose this limitation.

154. As described above, Coe does not disclose a primary sheath for initial embedment of a sharp lancing tip of an unused lancet. And, Sakata has no secondary sheath for receiving the sharp lancing tip of a used lancet. As such, neither can have a gripping handle portion that extends between a primary sheath and a secondary sheath as required by the claims.

155. Also, Sakata provides no dimensional information about dimensions of any component in the figures except the distance between puncture needle 30 and small diameter covering portion 40 *may be* between 0.1 and 3 mm. Sakata ¶¶10, 17. That dimension is not the “T” or “S” in LifeScan’s mapping to Sakata. There is no way to calculate the “T” or “S” based on that dimension either as “T” and “S” contain structures beyond the structures defining that dimension. Accordingly, Sakata does not provide dimensional information of “a lateral span” of “a gripping handle portion” or “a lancet thickness” of “a lancet body.”

156. None of Sakata’s figures have a reference for scale. The written specification does not indicate any figure is to scale. Any exact dimensional

information derived from the figures with this lack of information is unreliable and I understand, as noted above, is not proper in such situations.

157. I do not agree that the lateral span of cap portion 4 would need “to be much larger than the 16 mm diameter of an average human thumb to ensure that the handling goal was achieved.” Pet. 36. There are plenty of items maneuvered by hand that are less than the diameter of the average human thumb, including those where pieces are separated, such as a pen and pen cap and an eyeliner pencil and cap.

158. LifeScan assumes Sakata includes a “standard lancet” with a diameter of less than 6 mm as taught by LeVaughn (Ex. 1120). But Sakata says nothing about using a “standard lancet,” much less about the dimensions of such a standard lancet. In fact, Sakata distinguishes its purported lancet with a “conventional lancet.” Sakata ¶22.

2. A POSA Would Not Have Adjusted a Lateral Span of a “gripping handle portion” to be At Least 1.5 Times a “lancet thickness” (Claims 11, 14)

159. A POSA would not have adjusted a lateral span of a “gripping handle portion” of Coe in view of Sakata to be at least 1.5 times a “lancet thickness.”

160. LifeScan cites no prior art that recognized the specific relationship claimed in claims 11 and 14—between the lateral span of the gripping handle and

the lancet thickness, much less the specific ratio claimed therein. Indeed, I'm not aware of any.

161. Coe's object of its purported invention of "effectively minimiz[ing] hazards to medical personnel resulting from accidental lancet punctures" has nothing to do with dimensions of extractor 91 as Coe's object deals with covering the sharp tip of a disposable lancet via an extraction member—not the size or dimensions of the extractor 91. Coe 3:17-22, 3:33-36.

162. Sakata likewise provides no disclosure of the importance of certain dimensions of the lancet and cap and what is the critical or beneficial ratio.

163. The '635 Patent teaches why the ratio of at least 1.5 is important, and the prior art does not recognize this importance. '635 Patent 3:52-56, 6:52-7:3 ("The provision of the elongate handle portion 516 [of at least 1.5 times span of the lancet thickness] 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"). These benefits are combined with the reduced pain enabled by the relatively small mass lancet body with a thickness less than 1.5 times the span.

164. A POSA would not have seen the claimed dimensional limitation as an obvious design choice. The prior art did not even recognize the importance of

the claimed relationship. And even if it did, the prior art did not recognize at least 1.5 as the critical or important ratio of those two dimensions.

165. Contrary to LifeScan's assertion, it would not have been obvious try to a POSA to try or part of routine optimization of a POSA to determine a relationship between the span of the gripping handle portion of a sterility cap and the lancet thickness of a lancet body was important or arrive at the claimed ratio of at least 1.5 between the two dimensions.

166. LifeScan has not presented a finite number of known solutions to improve the use or maneuverability of a lancet for people.

167. A POSA could take multiple avenues to improve the use or maneuverability of a lancet for people.

168. For example, a POSA could add a cover to the areas of the cap gripped by a user (e.g., rubber, polymer, textured coating). This is done in other areas where gripping or maneuverability is important, such as pens, scissors, screwdrivers, baseball bats, and bike handles.

169. As another example, a POSA could add mechanical features to the areas of the cap gripped by a user (e.g., dimples). This is done in other areas where gripping or maneuverability is important, such as pop bottle caps.

170. As another example, a POSA could change dimensions of certain components. This is done in other areas where gripping or maneuverability is

important, such as different sizes of golf clubs or other athletic equipment between adults and children.

171. Even pursuing only changing the dimensions of the area gripped by a user, there is still a vast number of options to choose from to make adjustments of dimensions in a lancing device system. There are at least three dimensions of the area gripped by a user: length, width, thickness. After selecting one of those three dimensions, one would have to choose what other component in the lancing device system to be ratioed with the selected dimension of the areas gripped by the user. A lancing device system may be composed of at least tens or hundreds of components. Then one would have to choose the dimension of the component in the lancing device to ratio with the selected dimension. Then one would have to decide if the ratio is larger, equal to, or less than one (larger/same/smaller) and then vary the magnitude of ratios to find the important relationship between the two.

172. In a simple lancing device system, the amount of possibilities to choose from would be high. For example, in a lancing device system with 10 components, there would be a 1 out of 270 (3 dimensions of the lancet body * 10 components from which to choose * 3 dimensions of each component * 3 choices for being larger/same/smaller) chances of choosing the ratios to be established and then and then at least 10's or 100's of values to select, producing over 10's of thousands of options for the ratios in the claims.

173. All of these choices would have to be made in the backdrop of the prior art that gave no motivation to pursue this course of action nor indication of what component to start with, what dimension to choose, what component to ratio with, and what dimension to choose of the component.

3. A POSA Would Not Have Combined Coe and Sakata

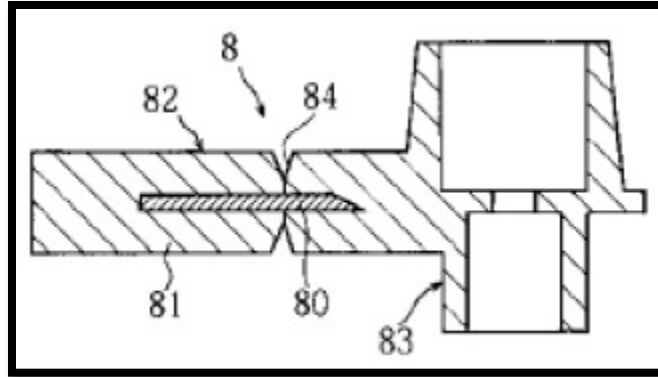
174. A POSA would not have been motivated to combine Coe and Sakata.

175. LifeScan gives multiple purported motivations to combine Saikley and Stout. All fail.

176. *First*, LifeScan asserts that POSA “would have been motivated to prevent damage to the lancet tip and pain to the user.” Pet. 26-28. LifeScan says that tips of lancets may be broken during transport and storage without a cap and Sakata solves a problem of damaging needle tips when removing a cap from the lancet. Pet. 26-28. But, Coe itself addresses this problem with the second cavity (96) protectively covering the sharp tip (95) of the lancet (94). Coe 5:26-28. In addition, protective caps for needle tips were already widely known in the art to solve this problem. ’635 Patent 1:47-50 (“The sharp tip of the lancet is commonly embedded in a removable plastic cap to maintain sterility and prevent inadvertent sticks prior to use.”).

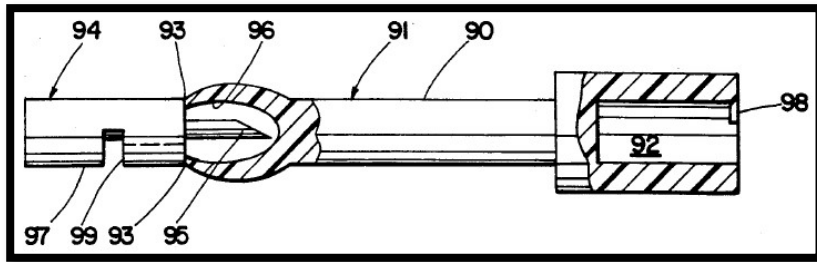
177. Moreover, the problem that Sakata supposedly solves is not present in Coe. Sakata describes a conventional lancet 8 with a cap portion 83 and a lancet

body 82 having a puncture needle 80 and cylindrical portion 81. Sakata Figs. 6, 7, ¶3.



Sakata Fig. 7. The puncture needle 80 is insert-molded into lancet body 82 and cap portion 83 and thus formed in close contact with the cap portion 83. Sakata Figs. 6, 7, ¶3. When the cap portion 83 is in close contact with puncture needle 80 and the diameter of the cavity covering it is large, the twisting of cap portion 83 puts relatively large stress acts on the blade surface of puncture needle 80 that may disrupt the blade surface. Sakata Figs. 6, 7, ¶4; Sakata purportedly solves this issue by reducing the thickness of the cover around portions of the needle and including an arch portion to concentrate stress away from the needle. Sakata ¶¶9, 10.

178. But Sakata's solution is inapplicable to Coe's Figure 9. Unlike Sakata's conventional lancet, as described above, the sharp tip 95 is initially not embedded in the cap. Instead, the needle and tip are in a void defined as the second cavity 96. Coe Fig. 9, 5:25-28.



Coe Fig. 9. shows that there is no contact between the sharp tip 95 and the structure that defines second cavity 96—let alone close contact. Coe Fig. 9, 5:25-28. This is one of the necessary conditions in Sakata for its purported problem of inducing stress and “disrupting” the needle during the twisting action of decapping and resulting in pain for the user. Sakata ¶4. And there is no indication in Coe that removing the extractor 91 from lancet hub 97 causes any damage to sharp tip 95. See Coe 5:22-38.

179. **Second**, Coe and Sakata being in the “same field of endeavor” and addressing “the same problem” is not a sufficient motivation not combine them.

180. **Third**, LifeScan asserts that POSA “would have been motivated to identify used or tampered with lancets.” Pet. 29-30. But Coe already provides a way to identify used or tampered lancets, so there is no need for POSA to look to Sakata. Coe describes extractor 91 is connected at breakaway points 93 at the outer edge of an upper bearing face of lancet hub 97. Coe Fig. 9, 5:22-38.² Once the

² For this motivation to combine, LifeScan bases its argument on an embodiment other than the one in Fig. 9, which it relies upon in Ground 1 and uses in the proposed combination with Sakata, with no explanation of why the argument

connection is broken, the extractor 91 will not be able to easily go back on top of the upper bearing surface of lancet hub 97, if at all. Coe does not disclose any way, mechanical or chemical, to reconnect the pieces. *See* Coe Fig. 9, 5:22-38. And placing the extractor 91 on top of lancet hub 97 after breaking the connection would be unstable and the extractor 92 would be prone to fall off given the interface between the pieces would be uneven with no component to bind the pieces and the center of gravity of the extractor would be relatively high above the interface. Once the lancet 97 is used, the extractor cavity is used for disposal of the used lancet 97. Coe 5:22-38.

181. Furthermore, Sakata does not teach a solution to the problem posited by LifeScan. Pet. 30. Sakata does not indicate that the “deformation” of the covering portions 40, 41 would prevent the puncture needle 30 and needle tip 31 from being reinserted in cap portion 4 such that a person could identify a used or tampered lancet. A person could still put the cap back on the needle and such prior removal of the cap may not be caught by another person.

would be applicable to the embodiment in Fig. 9. I understand this argument should be disregarded on that basis alone. I reserve the right to respond to this argument if it is allowed.

B. Ground 3: Coe in View of Starnes and One Touch Booklet Does Not Render Obvious Claims 11-15

1. Coe in View of Starnes and One Touch Booklet Does Not Disclose All Claim Limitations

a. Coe in View of Starnes and One Touch Booklet Does Not Disclose “a primary sheath for initial embedment of a sharp lancing tip of an unused lancet therein” (Claims 11, 14)

182. Coe does not disclose this limitation. Section IX.A.1.a.

183. LifeScan solely relies on Coe to teach this limitation—not Starnes, One Touch Book, nor the proposed combination. To the extent LifeScan makes such assertions, I reserve the right to respond.

2. A POSA Would Not Have Combined Coe and Starnes

184. A POSA would not have been motivated to combine Coe and Starnes.

185. LifeScan gives multiple purported motivations to combine Coe and Starnes. All fail.

186. The purported added function of the tab members 8 or 28 of Starnes is unnecessary or redundant of structures that already provide the same function in Coe. And adding the tab members 8 or 28 of Starnes would detrimentally interfere with operation of Coe.

187. *First*, LifeScan asserts a POSA would be motivated to combine Coe and Starnes as it “provides a solution to the problem of determining whether a lancet has been used.” Pet. 45. But Starnes solution of determining whether a lancet

has been used is not needed in Coe. Coe describes extractor 91 as being connected at breakaway points 93 at the outer edge of an upper bearing face of lancet hub 97. Coe Fig. 9, 5:22-38. Once the connection is broken, the extractor 91 will not be able to easily go back on top of the upper bearing surface of lancet hub 97, if at all. Coe does not disclose any way, mechanical or chemical, to reconnect the pieces. *See* Coe Fig. 9, 5:22-38. With pieces disconnected and no way to be put back together, Coe already provides a way to determine whether a lancet has been used.

188. ***Second***, Coe already discloses a structure that provides the purported added function of tab members 8 or 28 of Starnes, i.e., determining whether a lancet has been used, and thus making them redundant or unnecessary in Coe. As noted, Coe describes extractor 91 as being connected at breakaway points 93 at the outer edge of an upper bearing face of lancet hub 97. Coe Fig. 9, 5:22-38. The extractor 91 is removed from lancet hub 97 at those breakaway points. Coe 5:22-38. The extractor 91 will not be able to easily go back on top of the upper bearing surface of lancet hub 97, if at all. The breakaway points 93 tell a user whether a lancet has not been used or tampered with—if they are not broken, the lancet has not been used or tampered with and if they are broken, the lancet may have been used or tampered with. The tab members 8 or 28 of Starnes are not needed to provide this information as lancet 94 of Coe already provides the same information. Adding them would not be helpful or provide any additional benefit.

189. **Third**, adding the tab members 8 or 28 of Starnes would likely detrimentally interfere with operation of Coe such that a POSA would not combine them as proposed by LifeScan. Coe describes breakaway points 93 at the outer edge of an upper bearing face of lancet hub 97. Coe Fig. 9, 5:22-38. This means the tab members 8 or 28 of Starnes would have to be connected on the sides of lancet hub 97. When doing so, the tab members would leave a “visually perceptible stub” on lancet hub 97 upon disconnection. Starnes ¶35. The visually perceptible stub would likely interfere with, and potentially prevent, insertion of lancet hub 97 into extractor cavity 92 as it would hit the walls of extractor cavity 92, extractor tab 98, or the end face of the structure defining extractor cavity 92.

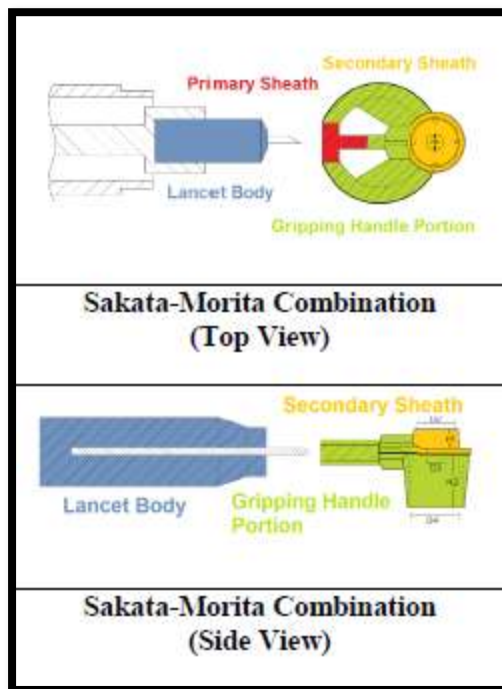
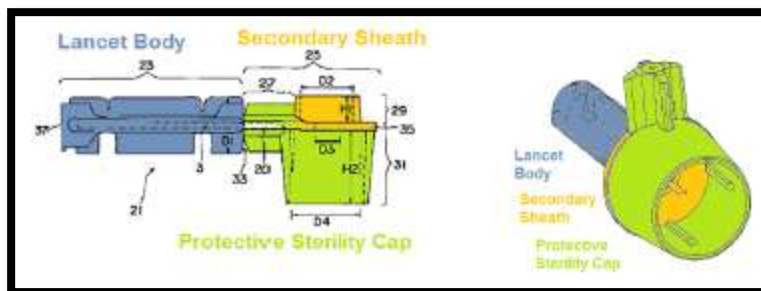
C. Ground 4: Sakata in View of Morita Does Not Render Obvious Claims 11-15

1. Sakata in View of Morita Does Not Disclose All Claim Limitations

a. Sakata in View of Morita Does Not Disclose “a secondary sheath for receiving the sharp lancing tip of a used lancet” (Claims 11, 14)

190. Claims 11 and 14 of the '635 Patent require “a secondary sheath for receiving the sharp lancing tip of a used lancet.” In my opinion, Sakata in view of Morita does not disclose this limitation.

191. To supposedly teach this limitation, LifeScan relies on Morita’s platform portion, more specifically only platform part 29 and connection part 35 highlighted in yellow:



Pet. 64.

192. As shown above, LifeScan does not include end cap connection part 31 in the components of Morita incorporated into Sakata that replaces cylindrical portion 43 of Sakata as part of the secondary sheath. However, neither platform part 29 nor connection part 35, alone nor combine, “receiv[es] the sharp lancing tip of a used lancet.”

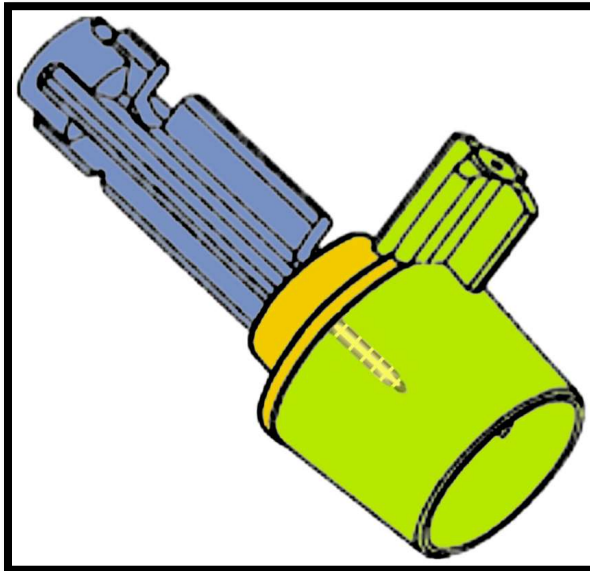
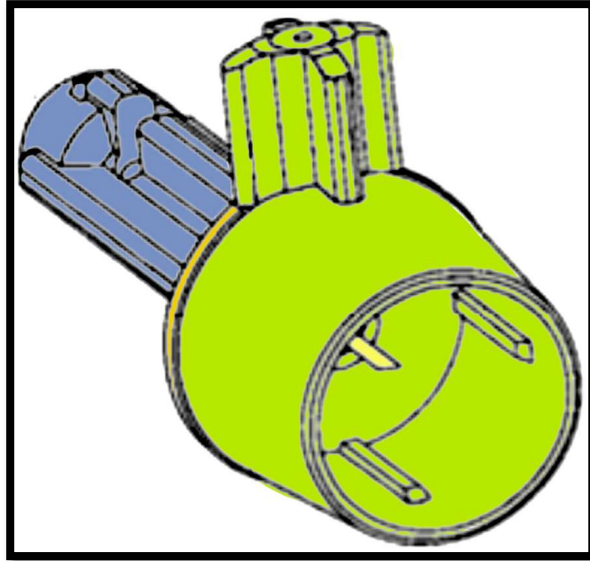
193. The district court construed this limitation to be “a secondary sheath for covering the sharp lancing tip a used lancet *by embedding or enclosing* the lancet tip.” Ex.1105 14.

194. Morita’s alleged secondary sheath (platform part 29 and connection part 35) alone or combined, do not “embed[],” meaning “fixed firmly and deeply in a surrounding solid mass or surrounded closely,” the lancet tip.

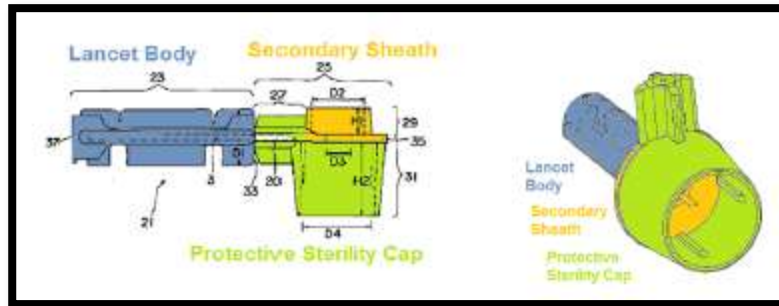
195. A POSA would understand the ordinary meaning of “enclosing” means “closing or surrounding on all sides.” Ex.2113 (Merriam-Webster Dictionary) (enclose: “to close in: surround”); Ex.2117 (Collins English Dictionary) (enclose: “to close; hem in; surround”).

196. Morita fails to disclose platform part 29 and connection part 35, alone or combined, either closely surrounds the lancet tip or closes or surrounds it on all sides.

197. After blood collection, Morita describes fitting the end of the lancet body 23 with the protruding needle part 3 into platform part 29 where the top of needle part 3 passes through platform part 29 (through D2) and connection part 35 (through D3). Morita Figs. 11, 18, 19, ¶¶20, 35. Once done, the sharp lancing tip sits in a cavity formed by platform part 29 and end cap connection part 31. Morita Figs. 11, 18, 19, ¶¶20, 29, 35; *see also* Morita ¶29.



Morita Figs. 18, 19 (annotated). The needle part 3 sits and extends through the platform part 29 and connection part 35, which LifeScan contends is the secondary sheath. Pet. 64.



Pet. 64.

198. A POSA would understand that such a configuration of the “secondary sheath” of Morita as defined by LifeScan as not embedding or enclosing a sharp lancing tip.

199. The sharp lancing tip (needle tip part 20) of needle part 3 is not fixed firmly and deeply in a surrounding solid mass or surrounded closely by the platform part 29 and connection part 35. In fact, the needle tip extends beyond the connection part 35. Even if it did not, there is no mass close to the needle part 3 at all. It sits in an open cavity beyond the purposed secondary sheath. The needle part 3 sticks through and out of connection part 35. Also, the claims require a “sharp lancing tip of a used lancet” to be received by the secondary sheath. So this claim limitation is not satisfied by the platform part 29 and connection part 35 holding or touching lancet body 25 with the shaft portion of needle part 3. The needle tip part 20 of needle part 3 is not within the lancet body 25. It is the needle tip (the end portion of the needle that is angled), which causes the “sticks” which puncture a user.

200. The sharp lancing tip (needle tip part 20) of needle part 3 is not closed or surrounded on all sides platform part 29 and connection part 35. The needle tip part 20 sticks out from connection part 35. Connection part 35 only emanates from the needle part 3 in a horizontal dimension. Neither it nor platform part 29 extend in a vertical direction such that either or both are even with the needle tip part 20.

201. That the end cap connection part 31 purportedly protects the needle after blood collection does not help LifeScan's position. LifeScan consistently maps platform part 31 as the "gripping handle portion" of the claims. *See, e.g.,* Pet. 64, 71. But claims 11 and 14 of the '635 Patent require *the secondary sheath* to receive the sharp lancing tip of a used lancet—not the gripping handle portion.

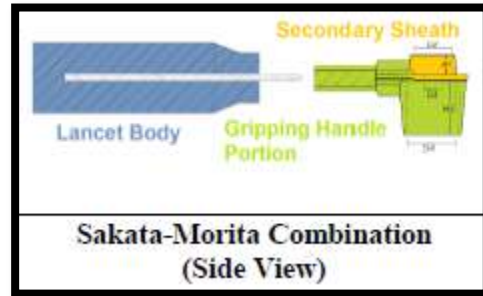
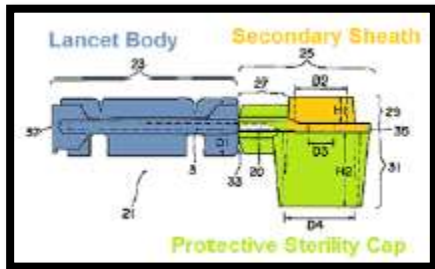
b. Sakata in View of Morita Does Not Disclose "the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness" (Claims 11, 14)

202. Claims 11 and 14 of the '635 Patent require "wherein the gripping handle portion defines a lateral span of at least 1.5 times the lancet thickness." In my opinion, Sakata in view of Morita does not disclose this limitation.

203. As described above, Sakata does not disclose a secondary sheath and Morita does not disclose a secondary sheath. As such, neither can disclose a gripping handle portion which extends between them.

204. LifeScan mapped the claim language in multiple ways for the Morita and/or the Sakata/Morita combination.

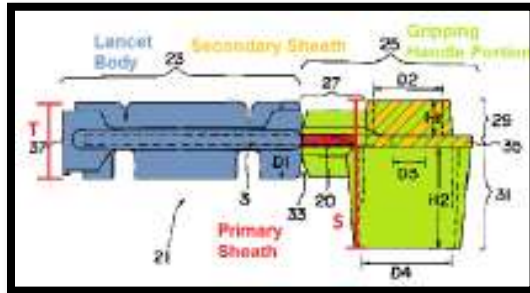
205. For a first claim mapping, LifeScan asserts that platform part 29 and connection part 35 highlighted in yellow are the secondary sheath and everything highlighted in green are the gripping handle portion in Morita and combination of Sakata and Morita.



Pet. 64.

206. A POSA would not understand that the portion highlighted in green in Morita would be a gripping handle portion. The claims of the '635 Patent require the gripping handle portion to “extend[] between the primary sheath and the secondary sheath.” '635 Patent cls. 1, 9, 14. If any exists at all, at most there is only a small volume between the Morita’s “primary sheath” (unhighlighted portion) and purported “secondary sheath” (platform part 29 and connection part 35 highlighted in yellow). A POSA would understand that the small volume is unlikely to be the place where one would grip Morita’s cap given the small area’s uneven topography and better locations on Morita’s cap for torque in order to twist the cap.

207. For a second claim mapping, LifeScan asserts that platform part 29 and connection part 35 are now part of the gripping handle portion in addition to being the secondary sheath.



Pet. 72.

208. Assuming LifeScan’s first claim mapping is correct, LifeScan does not provide a calculation of the span of the gripping handle portion and a POSA would not be able to calculate the span given the dimensions disclosed in Morita. Using LifeScan’s first claim mapping of Morita, the “span” of the gripping handle would be H2 plus the distance of H2 to the top of the ridge needle protection part 27. LifeScan does not calculate this span in its Petition. Pet. 72-73. Morita does disclose a range of H2 from 6-15 mm and preferably 9 mm. Morita ¶32. Morita does not disclose the length from H2 to the top of the ridge 27 and does not provide enough other dimensional information to do so. *See* Morita ¶32.

209. Assuming LifeScan’s second claim mapping is correct, LifeScan considers both platform part 29 and connection part 35 as both the “secondary sheath” and “gripping handle portion.” A POSA would not understand that a

“gripping handle portion” would be extending between the “primary sheath” and a “secondary sheath” as required by the claims because the “gripping handle portion” cannot extend between itself. Also, I understand that there is a presumption that two claimed separate components must be separate and distinct in the prior art. LifeScan does not point to two separate and distinct components in Morita under its second claim mapping. LifeScan has not tried to overcome the presumption.

210. Sakata’s figures cannot be relied on to disclose dimensional information. Section IX.A.1.a.

211. Similarly, Morita’s figures cannot be relied on to disclose dimensional information.

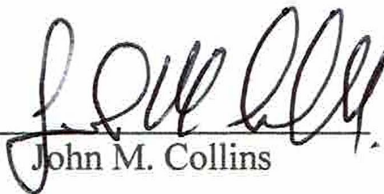
212. None of Morita’s figures have a reference for scale. The written specification does not indicate any figure is to scale. Any exact dimensional information derived from the figures with this lack of information is unreliable and I understand, as noted above, is not proper in such situations.

213. Morita does provide certain dimensional information (§32), but it does not disclose what dimensions are used in the figures.

X. Conclusion

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

Executed on June 25, 2023, in South Dartmouth, Mass.



John M. Collins