

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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DEXCOM, INC.,  
Petitioner,

v.

ABBOTT DIABETES CARE INC.,  
Patent Owner.

U.S. Patent No.: 11,266,335  
Issued: March 8, 2022  
Application No.: 17/019,110  
Filed: September 11, 2020

Title: MEDICAL DEVICE INSERTERS AND PROCESSES OF  
INSERTING AND USING MEDICAL DEVICES

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**DECLARATION OF GARY D. FLETCHER, Ph.D.**

DEXCOM  
EXHIBIT 1003

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I, Gary D. Fletcher, Ph.D., do hereby declare as follows:

**I. INTRODUCTION AND ENGAGEMENT**

1. I have been retained as an independent expert on behalf of Dexcom, Inc. in connection with the above-captioned Petition for Inter Partes Review (“IPR”) to provide my analyses and opinions on certain technical issues related to U.S. Patent No. 11,266,335 (hereinafter “the ’335 patent”).

2. I am being compensated at my usual and customary rate for the time I spent in connection with this IPR. My compensation is not affected by the outcome of this IPR.

3. Specifically, I have been asked to provide my opinions regarding whether claims 1-4, 8-9, 11-27 (each a “challenged claim” and collectively the “challenged claims”) of the ’335 patent would have been obvious to a person having ordinary skill in the art (“POSITA”), as defined below, as of March 2010. My opinions herein would be the same if it is determined that the pertinent date of the alleged invention is November 2010 or March 2011, as the level of skill in the art did not change between March 2010 and March 2011. It is my opinion that each challenged claim would have been obvious to a POSITA after reviewing the prior art discussed herein.

## **II. BACKGROUND AND QUALIFICATIONS**

4. I am Founder and Principal Consultant at RnDDx Solutions LLC, a consulting firm founded in 2015, focused on industrial mechanical engineering, and research and product development, in medical devices, diagnostics, optical devices, point-of-care blood sample testing, and on expert witness patent litigation, including subject matter expertise in medical device mechanical engineering, and subject matter expertise in medical devices for blood collection and blood sample processing for diagnostics and therapeutics. I have particular expertise in mechanical engineering design and development of non-invasive and minimally invasive biomedical diagnostics systems, blood collection and stabilization, blood separation, and blood and cell preparation for both diagnostic and therapeutic applications. I have expertise in the development of sample collection devices, including needles and lancets. A complete list of my patents, publications, professional activities, and honors that I have received is set forth in my curriculum vitae, attached hereto as Appendix A.

5. I am also co-Founder of a startup biotech company, Raven Biomaterials, developing novel patented immunomagnetic blood cell separation technology, with both diagnostic and cell therapy manufacturing applications.

6. I received my Bachelor of Arts degree in Physics and Mathematics from DePauw University, Greencastle, Indiana, in 1976, my Master of Philosophy degree

in Physics from Yale University in 1978, and my Doctor of Philosophy degree in Physics, also from Yale University, in 1983. My doctoral research was in experimental atomic physics, where I gained experience in mechanical, electrical, and software engineering, optical physics, and vacuum engineering, developing and maintaining the experimental apparatus used in my research. I conducted postdoctoral research in experimental atomic and laser physics as a Postdoctoral Research Associate in Physics and Assistant Professor of Physics at the University of Virginia. At Lawrence Livermore National Laboratory I expanded my expertise in mechanical and optical engineering by developing x-ray spectroscopic and imaging instruments to measure x-rays emitted from laser-produced high-temperature plasmas. I have 23 years of senior industrial executive experience building new products and new businesses in the healthcare, life sciences, material sciences, medical device, imaging, and diagnostics space. That experience includes leading R&D and product development engineering teams of mechanical, electrical, optical, and software engineers. Among the positions described in my curriculum vitae, my industry experience includes engineering leadership role in 1996 in a company attempting to develop a noninvasive glucose measurement sensor. From 1996 to 2001, I led Engineering and Advanced Technology, including teams of optical, mechanical, electrical, software imaging, and clinical laboratory engineers, developing a noninvasive human complete blood count diagnostic device and

diagnostic blood perfusion assessment tool, for a medical diagnostic startup company. As technical manager at Sarnoff Corporation from 2001 to 2004 I led a team developing and licensing a painless minimally invasive blood glucose monitor. While at Becton Dickinson (“BD”), from 2004 to 2014, I developed blood collection devices for point of care diagnostic testing.

7. I am co-inventor on thirteen issued US Patents and ten issued European patents for devices and methods in the area of blood collection and processing including lancing devices and blood separation for diagnostic testing. A complete list of my patents is set forth in my curriculum vitae, attached hereto as Appendix A.

### **III. MATERIALS CONSIDERED AND INFORMATION RELIED UPON REGARDING '335 PATENT**

8. In preparing this declaration, I have reviewed the following materials bearing Exhibit Nos. that I understand are being referenced in the IPR which this declaration accompanies:

#### **LIST OF EXHIBITS**

| <b>No.</b> | <b>Description</b>                                                  |
|------------|---------------------------------------------------------------------|
| 1001       | U.S. Patent No. 11,266,335 (“ <b>335 Patent</b> ”)                  |
| 1002       | File History of U.S. Patent No. 11,266,335 (“ <b>335 FH</b> ”)      |
| 1004       | U.S. Provisional Application No. 61/411,262, Filed November 8, 2010 |
| 1005       | U.S. Patent Application No. 13/071,461, filed March 24, 2011        |
| 1006       | U.S. Provisional Application No. 61/317,243, filed March 24, 2010   |

|      |                                                                                                              |
|------|--------------------------------------------------------------------------------------------------------------|
| 1007 | U.S. Provisional Application No. 61/345,562, filed May 17, 2010                                              |
| 1008 | U.S. Provisional Application No. 61/361,374, filed July 2, 2010                                              |
| 1009 | U.S. Publication No. 2008/0097246 (“ <b>Stafford</b> ”)                                                      |
| 1010 | U.S. Publication No. 2009/0124979 (“ <b>Raymond</b> ”)                                                       |
| 1011 | U.S. Publication No. 2007/0135774 (“ <b>Turner</b> ”)                                                        |
| 1012 | U.S. Patent No. 6,175,752 (“ <b>Say</b> ”)                                                                   |
| 1013 | U.S. Publication No. 2009/0240121 (“ <b>Bickoff</b> ”)                                                       |
| 1014 | U.S. Publication No. 2007/0073129 (“ <b>Shah</b> ”)                                                          |
| 1015 | U.S. Publication No. 2006/0095014 (“ <b>Ethelfeld</b> ”)                                                     |
| 1017 | PCT Publication No. WO2008/155377 (“ <b>Hasted</b> ”)                                                        |
| 1018 | U.S. Publication No. 2004/0002682 (“ <b>Kovelman</b> ”)                                                      |
| 1023 | U.S. Publication No. 2008/0294024 (“ <b>Cosentino</b> ”)                                                     |
| 1028 | U.S. Patent No. 7,381,184 (“ <b>Funderburk</b> ”)                                                            |
| 1030 | U.S. Publication No. 2007/0093754 (“ <b>Mogensen</b> ”)                                                      |
| 1035 | Sybil P. Parker (ed.), <i>McGraw-Hill Dictionary of Mechanical and Design Engineering</i> , 1984 (excerpted) |
| 1037 | U.S. Publication No. 2009/0099521 (“ <b>Gravesen</b> ”)                                                      |
| 1039 | U.S. Publication No. 2008/0319414 (“ <b>Yodfat</b> ”)                                                        |
| 1040 | U.S. Patent No. 7,207,974 (“ <b>Safabash</b> ”)                                                              |
| 1041 | U.S. Publication No. 2004/0204687 (“ <b>Mogensen</b> ”)                                                      |
| 1042 | U.S. Publication No. 2002/0022855 (“ <b>Bobroff</b> ”)                                                       |
| 1043 | U.S. Patent No. 9,566,384 (“ <b>Gyrn</b> ”)                                                                  |
| 1044 | U.S. Patent No. 8,747,363 (“ <b>Nielsen</b> ”)                                                               |
| 1056 | U.S. Publication No. 2009/0216215 (“ <b>Thalmann</b> ”)                                                      |
| 1057 | U.S. Publication No. 2005/0131346 (“ <b>Douglas</b> ”)                                                       |
| 1059 | U.S. Publication No. 2008/0146904 (“ <b>Hunn</b> ”)                                                          |

|      |                                                                                                                                                                                                                                                                 |
|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1060 | V. Poitout, et al., <i>A glucose monitoring system for on line estimation in man of blood glucose concentration using a miniaturized glucose sensor implanted in the subcutaneous tissue and a wearable control unit</i> , Diabetologia, Vol. 36, Issue 7, 1993 |
| 1061 | Steven W. Smith, <i>The Scientist and Engineer's Guide to Digital Signal Processing</i> , 2 <sup>nd</sup> ed., 1999 (excerpted)                                                                                                                                 |
| 1062 | B. A. Shenoi, <i>Introduction to Digital Signal Processing and Filter Design</i> , 2006 (excerpted)                                                                                                                                                             |
| 1063 | Marc D. Breton, et al., <i>Optimum Subcutaneous Glucose Sampling and Fourier Analysis of Continuous Glucose Monitors</i> , Journal of Diabetes Science and Technology, Vol. 2, Issue 3, May 3, 2008                                                             |
| 1064 | Antonios E. Panteleon, et al., <i>The Role of the Independent Variable to Glucose Sensor Calibration</i> , Diabetes Technology & Therapeutics, Vol. 5, Number 3, 2003                                                                                           |

#### IV. UNDERSTANDING OF PATENT LAW

9. I am not an attorney. For the purposes of this declaration, I have been informed about certain aspects of the law that are relevant to my opinions. My understanding of the law was provided to me by the Petitioner's attorneys.

10. I understand that when considering the scope of the claims of a patent that the patent claim terms should generally be given the ordinary meaning that the terms would have to a person of ordinary skill in the art in question after reading the patent at the time of the invention.

11. I understand that the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the term appears, but in the context of the entire patent, including the specification. I further

understand that the principal considerations regarding the scope and meaning of the claims are the plain language of the claim (including the surrounding claim language and context), the patent specification, and the prosecution history. I understand that while a claim is to be read in light of the specification, one must generally avoid importing limitations into the claim from the specification. I am also informed that the prosecution history can often inform the meaning of the claim by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be. I applied these understandings when considering the scope and meaning of the claims of the '335 patent.

12. I understand that a claim is unpatentable if it would have been obvious. I understand that a patent claim is rendered obvious if the claimed subject matter as a whole would have been obvious to a person of ordinary skill in the art as of the date of invention. I understand that this determination is made after weighing the following factors: (1) the scope and content of the prior art; (2) the differences between the prior art as a whole and the claim at issue; (3) the level of ordinary skill in the pertinent art; and (4) as appropriate, secondary considerations of non-obviousness.

13. I understand that the knowledge of a person of ordinary skill in the art at the time of the alleged invention provides a reference point from which the prior

art and claimed invention should be viewed. This reference point safeguards against use of improper hindsight in evaluating whether a claim is obvious. However, if a person of ordinary skill in the art could have implemented the claimed invention as a predictable variation of a known product, then the claim may be rendered obvious. I further understand that a person of ordinary skill in the art is presumed to have knowledge of relevant prior art at the time of the claimed invention, which includes any prior art that was reasonably pertinent to the particular problems the inventor faced.

14. I understand that an obviousness evaluation can be made on a single reference or a combination of multiple prior art references. I understand that a proper obviousness analysis as to two or more references generally requires a reason that would have prompted a person of ordinary skill in the art to combine the elements of multiple prior art references in the way the claimed invention does. I understand that the prior art references themselves may provide a teaching, suggestion, motivation, or reason to combine, but that at other times such combinations can be based on simple common sense. I further understand that an obviousness analysis recognizes that market demand, rather than scientific literature, often drives innovation, and that a motivation to combine references may be supplied by the direction of the marketplace. I understand that prior art references used in obviousness analyses should be analogous to the claimed invention, which I

understand to mean (1) the reference is from the same field of endeavor as the claimed invention (even if it addresses a different problem); or (2) the reference is reasonably pertinent to the problem faced by the inventor (even if it is not in the same field of endeavor as the claimed invention).

15. I understand that a particular combination may be proven obvious merely by showing that it was obvious to try the combination. For example, when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within that person's technical grasp because the result is likely the product not of innovation but of ordinary skill and common sense. I further understand that a proper obviousness analysis focuses on what was known or obvious to a person of ordinary skill in the art, and not just to the patentee. Accordingly, I understand that any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.

16. In sum, my understanding is that prior art teachings are properly combined where a person of ordinary skill in the art, having the knowledge reflected in the prior art and motivated by the general problem addressed by the patent in question, would have been led to make the combination of elements recited in the claims. Under this analysis, the prior art references themselves, or any need or

problem known in the field of endeavor at the time of the invention, can provide a reason for combining the elements of multiple prior art references in the claimed manner. I understand that at least the following rationales may support a finding of obviousness:

- Combining prior art elements according to known methods to yield predictable results;
- Simple substitution of one known element for another to obtain predictable results;
- Use of a known technique to improve similar devices (methods, or products) in the same way;
- Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- Choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success (“obvious to try”);
- Predictable variation of work in the same or a different field of endeavor if a person of ordinary skill would be able to implement the variation;
- Existence of a known problem for which there was an obvious solution encompassed by the patent’s claims;
- Known work in one field of endeavor that may prompt variations of it for use in either the same or a different field based on design incentives or other

market forces if the variations would have been predictable to one of ordinary skill in the art; and

- Any teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

I further understand that an obviousness analysis includes considering whether a POSITA would have a “reasonable expectation of success”—not an “absolute predictability” of success—in achieving the claimed invention by combining prior art references.

17. I have been informed and understand that secondary considerations of nonobviousness may include: (1) whether the invention proceeded in a direction contrary to accepted wisdom in the field; (2) whether there was a long felt but unresolved need in the art that was satisfied by the invention; (3) whether others had tried but failed to make the invention; (4) whether others copied the invention; (5) whether the invention achieved unexpected results; (6) whether the invention was praised by others; (7) whether others have taken licenses to use the invention; (8) whether experts or those skilled in the art at the making of the invention expressed surprise or disbelief regarding the invention; (9) whether products incorporating the invention have achieved commercial success that is attributable to the invention and (10) whether or not others having ordinary skill in the field independently made the

claimed invention at about the same time the inventor made the invention. I understand that for evidence of secondary considerations to be accorded substantial weight, there must be an established nexus between the evidence and the merits of the claimed invention.

18. I am not aware of any allegations by the named inventors of the '335 patent or any assignee of the '335 patent that any secondary considerations tend to rebut the obviousness of any challenged claim of the '335 patent.

19. I understand that other challenges to the patentability of a patent, including patent ineligibility, enablement, written description, and definiteness or clarity of claim language, cannot be raised in IPR proceedings before the Board. However, I also understand that it is Patent Owner's burden to show written description and other support in earlier applications if it wishes to rely on the filing date of those earlier applications. In this vein, I understand that a priority application's disclosure must clearly allow a POSITA to recognize that the inventor invented what is claimed, such that the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.

20. I understand that Petitioner has the burden of proving unpatentability by a preponderance of evidence, which means that the claims are more likely than not unpatentable.

21. The analysis in this declaration is in accordance with the above-stated legal principles.

**V. THE '335 PATENT**

22. The challenged claims relate to (1) an inserter that includes a sharp configured to insert a portion of a glucose sensor into a subject, and (2) an on body electronics unit that includes a housing comprising a plurality of recesses on its periphery, on body electronics, and the glucose sensor. EX1001, 48:53-49:11. The inserter is configured to first advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position, then retract the sharp from the distal position to a retracted position entirely within the inserter. *Id.*

23. Representative embodiments pertinent to the challenged claims appear to be inserters 3700 and 3700', illustrated in FIGS. 109-140. *Id.*, 41:12-45:56, 45:57-46:23.

**VI. LEVEL OF SKILL IN THE ART, AND STATE OF THE ART**

**A. Person Of Ordinary Skill In The Art ("POSITA")**

24. A POSITA would have had a bachelor's degree in bioengineering, mechanical engineering, electrical engineering, or a related subject, and one or more years of experience researching, developing, and/or designing insertable medical devices, including, *e.g.*, systems for implanting wearable medical devices such as

cannulas, infusion sets, and analyte sensors, or equivalent experience.<sup>1</sup> Less work experience would have been compensated by a higher level of education, such as a master's degree, and vice versa.

**B. State Of The Art**

25. The concepts claimed in the '335 patent—namely, inserters configured to secure an on body unit therein, a retractable sharp to insert a transcutaneous medical device (*e.g.*, a glucose sensor, a cannula) into a subject, and wearable on body units—were known before 2010. *See, e.g.*, EX1010, [0126]-[0127] (“The base-retaining arms 1226 can spread outwardly when the sleeve-engagement surfaces 1233 of the shuttle 1116 clear the cam surface 1180 of the sleeve 1106. The base-retaining feet 1227 can move away from the base 122 as the base-retaining arms 1126 spread outwardly such that the base 122 can be released from the shuttle 1116. As the shuttle 1116 approaches or arrives at the end of its range of travel within the sleeve 1106, the needle-hub engaging arms 1210 can clear the cam surface 1180 of the sleeve 1106 to allow the needle-hub-engaging arms 1210 to move away from the needle hub 1110. Once the needle hub 1110 is released by the needle-hub-engaging

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<sup>1</sup> Regardless of whether the pertinent date of alleged invention is March 2010 (the date of the first provisional), March 2011 (the date of the first non-provisional), or somewhere in between, the pertinent level of skill in the art would not differ.

arms 1210, the retraction spring 1114 can push the needle hub 1110 away from the shuttle 1116 to draw the needle 1112 within the insertion device 1100.”); EX1018, [0011] (“The plunger head includes a safety lock mechanism .... In one preferred form, the safety lock mechanism comprises ... preferably a pair of safety lock arms for engaging and retaining the insertion set when the plunger is retracted from a fully advanced position. Each safety lock arm includes a cam lobe for engaging an appropriately shaped recess on the insertion set”), [0119] (“As shown in FIG. 7, the safety lock arms 94 and their associated lock fingers 100 have a size and shape so that the fingers 100 can engage and retain the hub 18 of the insertion set 14.”); EX1040, 2:45-57 (“The plunger head includes a safety lock mechanism .... In one preferred form, the safety lock mechanism comprises ... preferably a pair of safety lock arms for engaging and retaining the insertion set .... Each safety lock arm includes a cam lobe for engaging an appropriately shaped recess on the insertion set”), 3:59-4:5 (“[T]he insertion set is a transcutaneous insertion set, a subcutaneous insertion set, an infusion set, sensor set or the like. In still other embodiments, the insertion set rests mainly on the surface of the skin after insertion or the insertion set is implanted in the skin of the patient. In preferred embodiments, the at least one piercing member is a needle.”); EX1042, [0010] (“The plunger head includes a safety lock mechanism .... In one preferred form, the safety lock mechanism comprises at least one and preferably a pair of safety lock arms for engaging and

retaining the insertion set when the plunger is retracted from a fully advanced position. Each safety lock arm includes a cam lobe for engaging an appropriately shaped recess on the insertion set”); EX1057, [0015] (“[T]he safety lock mechanism comprises at least one safety lock arm(s) for engaging and retaining the insertion set when the plunger is retracted from a fully advanced position. Each safety lock arm may optionally include a cam lobe for engaging an appropriately shaped recess on the insertion set”).

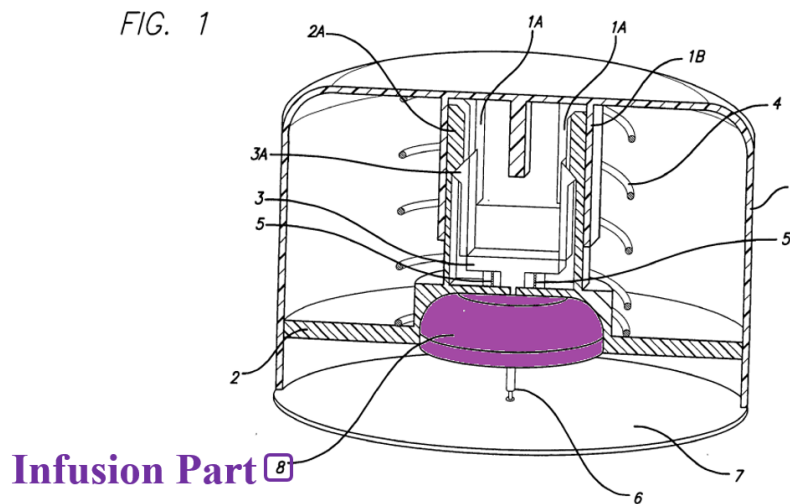
# **1. Inserters For Transcutaneous Medical Devices Were Known**

26. Inserters for inserting transcutaneous medical devices (*e.g.*, cannulas and glucose sensors) into subjects were known in the prior art. *See, e.g.*, EX1010, [0109] (“an insertion device 1100 for an infusion device”); EX1015, [0020]-[0023] (“[I]t is an object of the present invention to provide an insertion means for a transcutaneous access device (in the following also termed a transcutaneous device) which would allow for easy and swift, automatic insertion of the transcutaneous device,” “[t]he transcutaneous device may be in the form of a pointed hollow infusion needle, a micro needle array, a pointed needle sensor, or a combination of a relatively flexible per se blunt cannula or sensor device with a pointed insertion needle”); EX1017, 1:25-3:9 (“The object of the invention is to provide a simple, non-expensive inserter for an infusion device,” “[t]he medical device used with the inserter device can be *e.g.* an infusion part for administering medication or a sensor

device for measuring values e.g. of the blood or a simple port/gateway for administering medication by a syringe or the like.”); EX1018, [0015]-[0016] (“In other embodiments of the present invention, an insertion device for inserting at least a portion of at least one piercing member of an insertion set through the skin of a patient,” “the insertion set is a transcutaneous insertion set, a subcutaneous insertion set, an infusion set, sensor set or the like.”); EX1030, FIGS. 1-5, [0008] (“The object of the invention is to provide a simple, non-expensive inserter for an infusion device which inserter would be easy and safe for the user to handle during use and safe to dispose of after use.”). For example, as shown below, in an application published in 2007, Mogensen (EX1030) describes an inserter for inserting a transcutaneous cannula of an infusion part (purple).<sup>2</sup> EX1030, FIG. 1, [0005] (“The inserter device moves the infusion device towards the skin of the patient thereby inserting the needle and the cannula of the infusion device.”), [0008] (“The object of the invention is to provide a simple, non-expensive inserter for an infusion device”).

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<sup>2</sup> Parenthetical references to colors refer to highlighting in corresponding figures.



**Mogensen, FIG. 1 (annotated)**

27. It was known that inserter-based insertion methods caused subjects to experience comparatively less pain and anxiety than the manual insertion of needles, *e.g.*, by providing for faster needle puncturing and/or retraction. *See, e.g.*, EX1037, [0004] (“When performed manually, the penetration of the catheter-carrying needle into the body, however, may be considered uncomfortable for a patient, or may cause some other anxiety. Also, the subsequent manual withdrawal of the needle is often regarded by some patients as painful.”), [0007] (“[O]ne advantage of the invention is to increase the comfort of a patient during the insertion and withdrawal of a catheter or cannula. This benefit may be achieved with a device for the insertion of a cannula of the type described herein, wherein the needle, after reaching its extended state, can be withdrawn quickly and automatically by a retraction apparatus.”), [0008] (“[D]ue to aid from the retraction apparatus, the needle is

quickly with drawn from the body tissue and simultaneously, the inserted cannula remains within the body tissue. In this way, since the needle is relatively quickly withdrawn from the body tissue, a much more comfortable sensation is experienced than that associated with a slower insertion and withdrawal.”), [0011] (“[T]he movement of a needle within the body tissue can be uncomfortable, it is helpful if the displacement of the needle can be accelerated so that it can be removed from the tissue in a minimal amount of time.”); EX1056, [0004]-[0005] (“[A] sensor arrangement, for example, is placed on the patient's body and, with a puncturing tip of a suitable sensor, passes through the skin and into the patient's body .... In outpatient treatment, for example in the case of diabetics, this is often done by the patients themselves and, on account of the introduction of the infusion cannula or of the puncturing tip into the skin, is associated with a certain amount of pain. It is therefore important that such infusion sets, ports or sensor arrangements can be applied easily and safely, which is why many manufacturers have started designing their products as insertion heads for special insertion devices with the aid of which the insertion heads can be applied to the patient's body. Application is made easier in this way, and the pain occasioned by the application is reduced to a minimum, thanks to the quick and targeted puncturing procedure.”). Indeed, by 2007 “many manufacturers” used inserters to reduce the amount of pain felt by subjects during the insertion of transcutaneous medical devices. EX1056, [0005] (“[M]any

manufacturers have started designing their products as insertion heads for special insertion devices with the aid of which the insertion heads can be applied to the patient's body. Application is made easier in this way, and the pain occasioned by the application is reduced to a minimum, thanks to the quick and targeted puncturing procedure.”).

28. It was known to pre-load or pre-assemble transcutaneous medical devices and inserters, thereby eliminating the need for users to load the devices into inserters before use. *See, e.g.*, EX1010, [0100] (“The insertion device 100 and infusion device 102 can be packaged together and transported in the assembled state”), [0109] (“The insertion device 1100 is similar in many respects to the insertion device 100.”).

## **2. The Interchangeability Of Infusion Device Inserters And Glucose Sensor Inserters Was Known**

29. Inserters were known to be interchangeably configurable to insert glucose sensors and cannulas. It was known to configure a cannula-insertion inserter to insert a glucose sensor, *e.g.*, by substituting the cannula insertion needle with a sensor insertion needle, as needed, along with other changes that were within a POSITA’s skill. *See, e.g.*, EX1039, Abstract (“An insertion apparatus and a method for use with a device for delivery of a therapeutic fluid into a body of a patient and/or for sensing of a bodily analyte are disclosed.”); EX1040, 1-33:40 (“[I]nsertion needles are employed for transcutaneous placement of a soft and relatively flexible

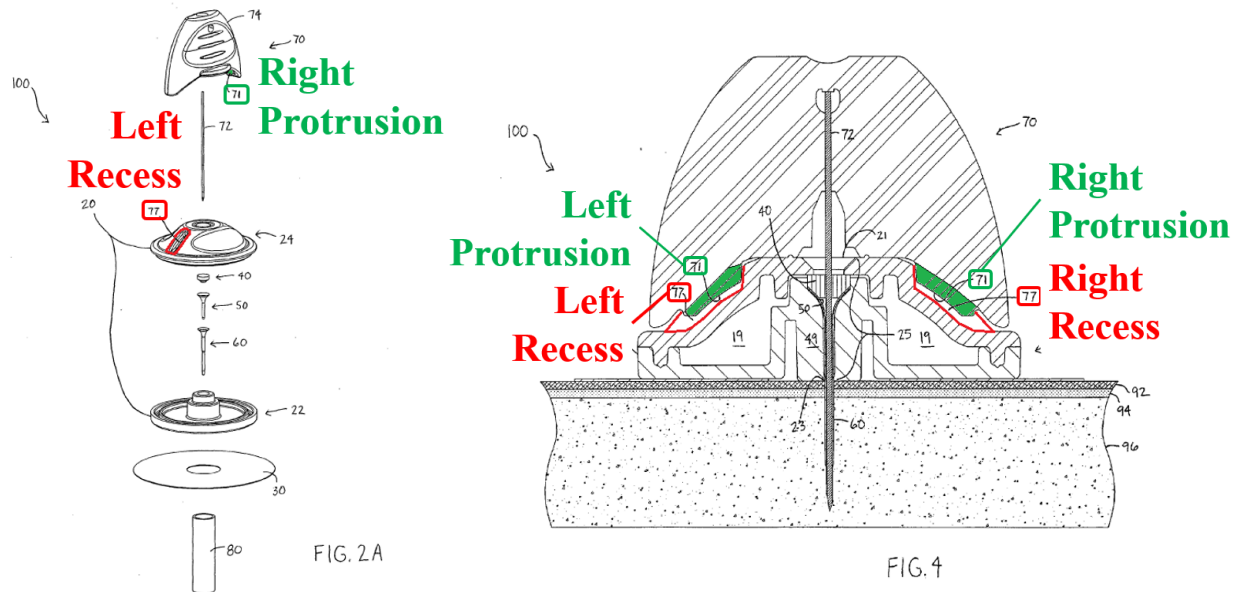
tubular cannula, followed by insertion needle removal and subsequent infusion of medical fluid to the patient through the cannula. More recently, insertion needles have also been used for transcutaneously placing other medical devices such as a subcutaneous sensor for monitoring specified patient parameters, such as blood glucose level.”); EX1041, [0079] (“[T]he injector device, provided with an insertion needle or not, is not exclusively suited for placing an infusion set but may also be used for placing a transcutaneous glucose sensor.”); EX1042, [0019] (“In additional embodiments, the insertion set is a transcutaneous insertion set, a subcutaneous insertion set, an infusion set, sensor set or the like.”); EX1043, 2:23-26 (“The current invention provides an insertion device for subcutaneously introduction of a penetrating member, where a ‘penetrating member’ is understood to be a needle, a cannula, a sensor or the like.”); EX1044, 13:12-16 (“The embodiment shown in FIG. 1 comprises a patch unit provided with an insertable steel needle, however, the embodiment is exemplary of how to use a patch unit with an insertable transcutaneous device, e.g. needle, cannula or sensor.”).

### **3. Using Plural Recesses For Securing Transcutaneous Medical Devices To An Inserter Was Known**

30. When designing inserter devices for transcutaneous medical devices, it was known to implement an on-body unit with plural recesses configured to engage corresponding features (*e.g.*, protrusions or arms) on the inserter, to secure the on

body unit of the transcutaneous medical device in a particular position relative to the inserter. EX1011, [0069]; EX1018, [0011] (“[T]he safety lock mechanism comprises ... preferably a pair of safety lock arms .... Each safety lock arm includes a cam lobe for engaging an appropriately shaped recess on the insertion set”); EX1040, 2:45-57 (same); EX1042, [0010] (same); EX1057, [0015] (“[T]he safety lock mechanism comprises at least one safety lock arm(s) .... Each safety lock arm may optionally include a cam lobe for engaging an appropriately shaped recess on the insertion set”). For example, as shown below, Turner (EX1011) discloses using plural rotation-restricting recesses (red) formed on the left and right sides of an on body infusion device to engage corresponding rotation-restricting protrusions (green) of an insertion device, thereby ensuring that the on body infusion device remains in a particular position relative to the insertion device. EX1011, [0069] (“Body 20 and insertion device 70 may be configured such that insertion device 70 cannot rotate with respect to body 20 when fully inserted in body 20. One manner of achieving this configuration comprises providing hub 74 with rotation-restricting protrusions 71, which extend in a downstream or downward direction from the main portion of insertion device hub 74, and by providing cap element 24 of body 20 with rotation-restricting recesses 77. When insertion device 70 is fully inserted in body 20, as shown in FIG. 3, at least a portion of each protrusion 71 extends into each recess 77 such that the recess side walls interfere with the protrusions to prevent rotation of

the insertion device relative to body 20. Although the embodiment shown includes two protrusions and two recesses, other embodiments may include fewer or greater numbers of each.”).



Turner, FIGS. 2A and 4 (annotated)

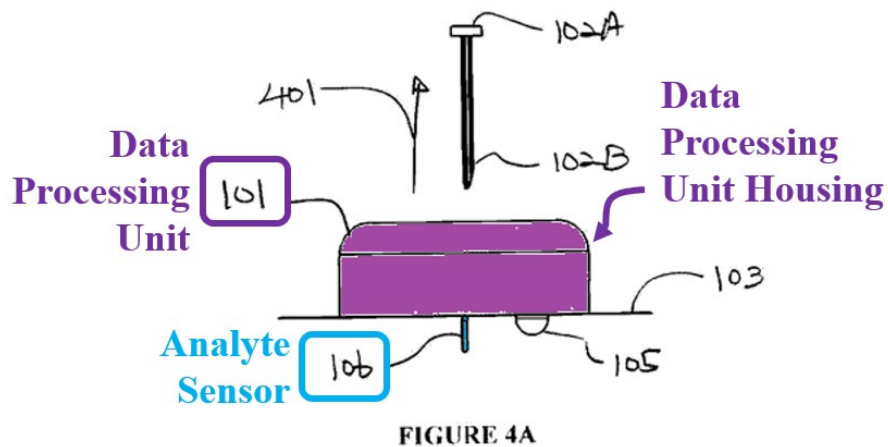
**VII. GROUNDS 1 & 2: CLAIMS 1-4, 8-9, 11-15, AND 17-27 ARE OBVIOUS OVER STAFFORD AND RAYMOND (GROUND 1), AND FURTHER IN VIEW OF TURNER (GROUND 2)**

31. As explained below, claims 1-4, 8-9, and 11-15, and 17-27 are obvious over Stafford and Raymond (Ground 1), and further in view of Turner (Ground 2).

**A. Stafford**

32. U.S. Publication No. 2008/0097246 (“Stafford,” EX1009) was published April 24, 2008, from an application filed September 10, 2006.

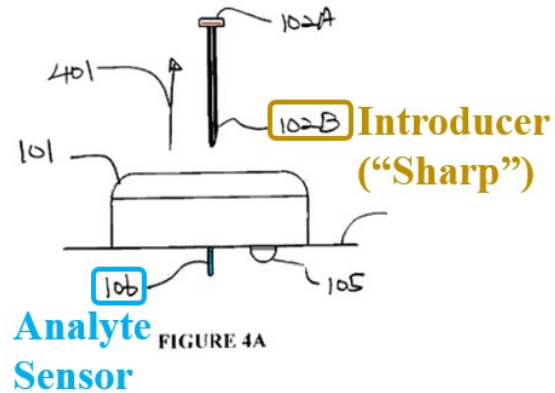
33. As shown below, Stafford describes an integrated assembly that includes an analyte sensor (blue) and a data processing unit (purple) coupled thereto for processing analyte level measurements therefrom. *See, e.g.*, EX1009, [0006] (“An integrated assembly in accordance with one embodiment of the present invention includes a housing, a data processing unit substantially disposed within the housing, ... and an analyte sensor coupled to the housing”). The data processing unit is disposed within a data processing unit housing (purple). *See, e.g.*, EX1009, FIG. 4A, [0006] (“a data processing unit substantially disposed within the housing”), [0020] (“housing of the data processing unit 101”), [0027], [0053] (“An integrated assembly ... includes a housing, a data processing unit substantially disposed within the housing”).



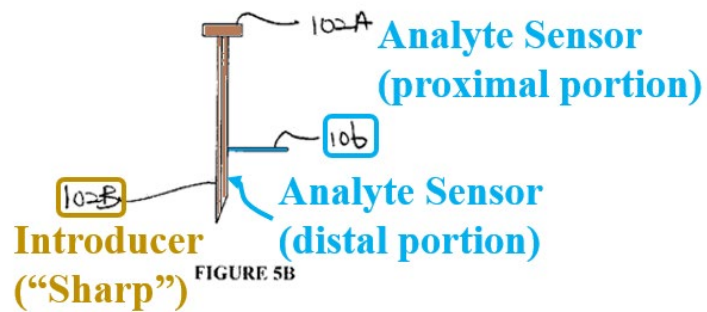
**Stafford, FIG. 4A (annotated)**

34. Stafford describes a glucose sensor (referred to herein as “Stafford’s sensor”). *Id.*, [0051] (“The analyte sensor may include a glucose sensor.”). As

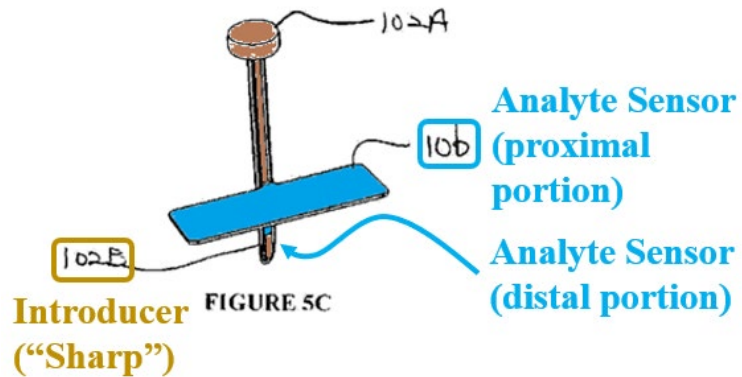
shown below, Stafford's sensor (blue) includes a distal portion perpendicular to the subject's skin and a proximal portion parallel to the subject's skin. *Id.*, FIGS. 4A, 5B-5C.



Stafford, FIG. 4A (annotated)



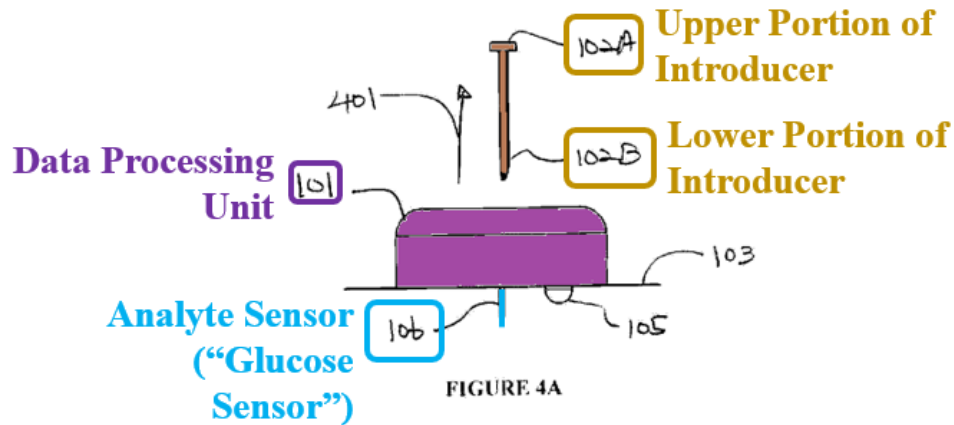
Stafford, 5B (annotated)



**Stafford, FIG. 5C (annotated)**

35. As shown below, the lower portion of Stafford's introducer (brown) has a sharp tip that pierces the subject's skin to deliver the sensor (blue) thereunder. EX1009, FIG. 4A, 5B-5C, [0021] ("[T]he lower portion 102B of the introducer is configured with a sharp tip to facilitate puncturing or piercing through the surface of the subject such as the skin of the patient."), [0024] ("[The user] places the entire analyte sensor delivery and data processing unit assembly 100 on the surface of the subject such as the skin layer of the patient with sufficient force applied on the upper surface of the data processing unit 101 such that the lower portion 102B of the introducer is pierced through the skin layer of the patient. Thereafter, the introducer may be removed to detach or decouple from the data processing unit 101 by, for example, pulling at the upper portion 102A of the introducer, thereby withdrawing the introducer from the patient and separating from the data processing unit 101,

while retaining the analyte sensor 106 (FIG. 2) in position in fluid contact with the patient's analyte.”).



**Stafford, FIG. 4A (annotated)**

36. As shown below, Stafford’s data processing unit includes electronics (pink), *e.g.*, a processor, a power supply, and an RF transceiver for wirelessly transmitting sensor data. EX1009, FIG. 7, [0040] (“[A]n RF transceiver 706 ... [is] operatively coupled to the processor 704. Moreover, a power supply 707 such as a battery is also provided in the data processing unit 101 to provide the necessary power for the components in the data processing unit 101”), [0052] (“The data processing unit in one embodiment may include a data transmission unit configured to receive one or more signals associated with an analyte level of the subject from the analyte sensor, where the data transmission unit may be configured to wirelessly transmit data associated with the one or more signals received from the analyte sensor, where the data transmission unit may include an RF data transmission unit.”).

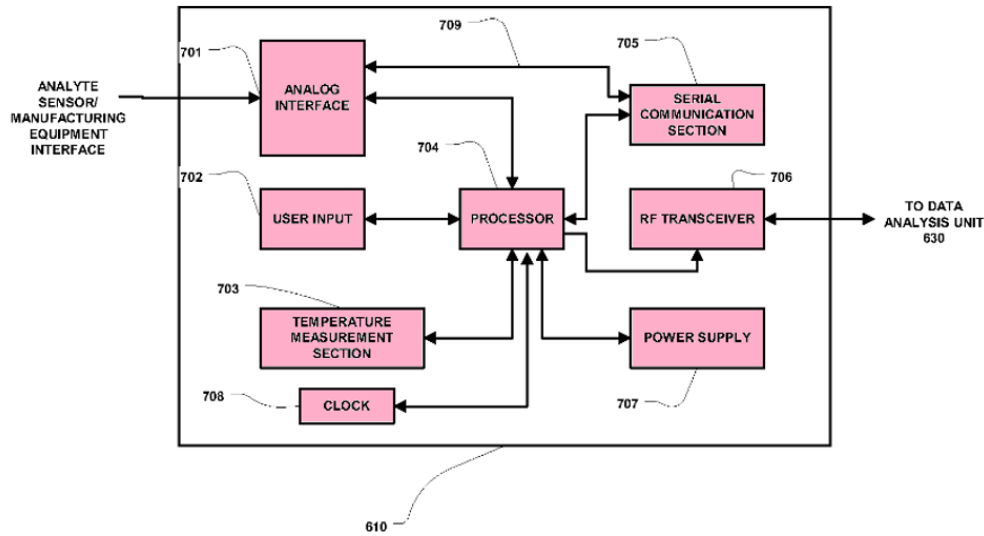


FIGURE 7

**Stafford, FIG. 7 (annotated)**

37. Stafford's data processing unit is initially powered off and can be powered on. EX1009, [0037] (“[T]he data processing unit 101 may be configured to transmit the encoded sampled data signals at a fixed rate (*e.g.*, at one minute intervals) *after the completion of the initial power on procedure.*”).<sup>3</sup>

38. Stafford explains that withdrawing the introducer “requires a level of care” to avoid injury from the introducer’s sharp tip and that “particular precautions” should be taken to avoid contact with the tip (*e.g.*, lower portion), after contact with the subject’s biological fluids. EX1009, [0003] (“[T]he inserter and the introducer are discarded [after use]. This requires a level of care as the inserter is sharp and may damage other parts of the patient's skin if not properly handled. Further, since the tip

<sup>3</sup> Emphasis added unless otherwise indicated.

of the inserter has come into fluid contact with the patient's biological fluids, it is important to take particular precautions in the handling of the inserter.”), [0022] (discussing “potential injury from the sharp edge of the [lower] portion 102B of the introducer.”). Although Stafford proposes a guard segment for preventing pre-insertion needlesticks, Stafford provides no solution for preventing post-insertion needlesticks. *Id.*, [0022] (“[T]here is provided a guard segment 104 in the integrated analyte sensor and data processing unit assembly 100 such that the guard segment 104 is configured to substantially cover the lower portion 102B of the introducer. In one embodiment, the guard segment 104 is configured as a protective needle guard so as to maintain the lower portion 102B of the introducer in a substantially sterile environment *prior to subcutaneous placement* through the surface of the subject such as the skin of the patient.”). As such, Stafford recognizes a need—but does not itself articulate a solution—for preventing needlesticks after the introducer’s lower portion has been withdrawn from the subject.

**B. Raymond**

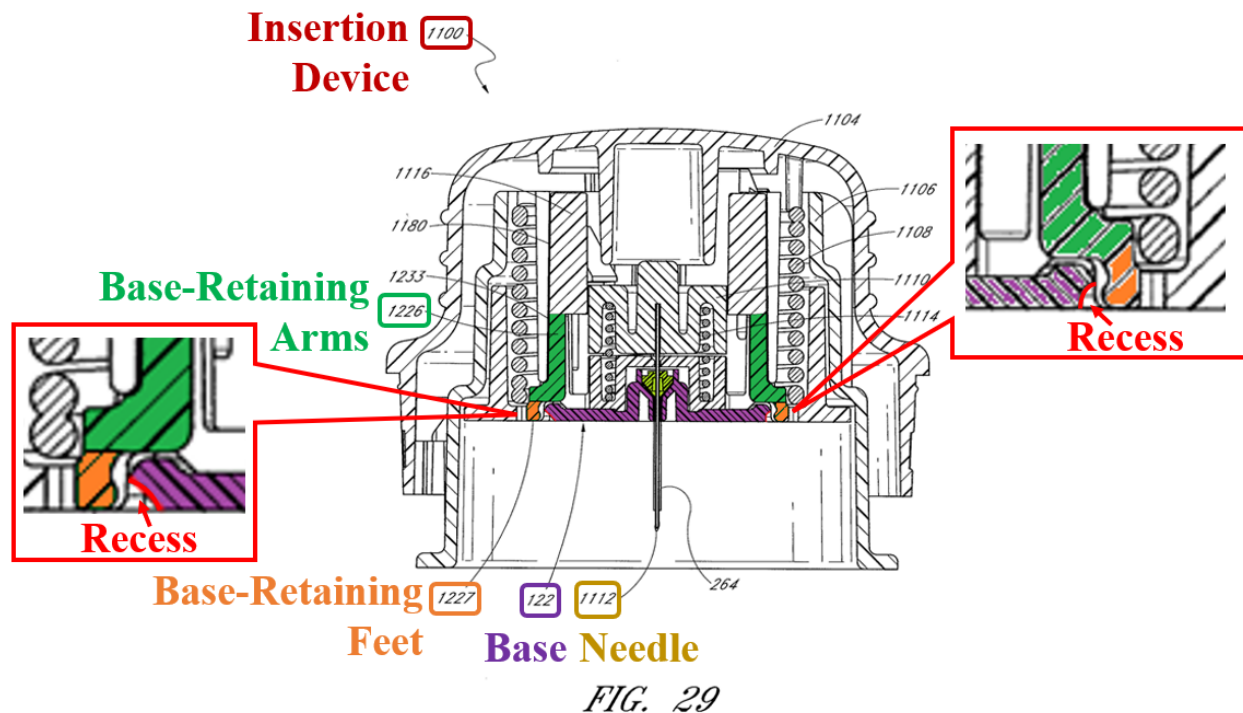
39. U.S. Publication No. 2009/0124979 (“Raymond,” EX1010), was published May 14, 2009, from an application filed September 10, 2008.

40. Raymond describes an insertion device that inserts a transcutaneous infusion device “quickly, safely, and conveniently.” EX1010, [0008] (“[I]t can be advantageous for an insertion device to insert an infusion device, such as an infusion

set, quickly, safely, and conveniently.”), [0109] (“FIG. 18 illustrates an embodiment of an insertion device 1100 for an infusion device, such as the infusion device 102.”). The infusion device includes a base housing at least a portion of an infusion set therein. EX1010, FIGS. 29-30. The infusion device delivers insulin. *Id.*, [0005] (“[I]njection ports include a component that extends through the skin and may remain in place for several days. Currently, a major application of such injection ports is to provide continuous delivery of medication, such as insulin”).

41. The insertion device includes an actuator, a sleeve, a needle, a shuttle, and a protective cap. EX1010, [0109] (“the insertion device 1100 can comprise an actuator 1104, a sleeve 1106, an insertion spring 1108, a needle hub 1110, a needle 1112, a retraction spring 1114, a shuttle 1116, [and] a protective cap 1118 .... In some embodiments, the infusion device 102 can be pack aged within the insertion device 1100.”). The shuttle includes plural base-retaining arms extending therefrom, each of which includes a base-retaining foot at a tip portion thereof for securing the infusion device within the insertion device. EX1010, [0123] (“[T]he shuttle 1116 can comprise one or more base-retaining arms 1226 ... to engage the infusion device 102 .... The arms 1226 can include base-retaining feet 1227, to clamp, grasp, or otherwise engage the base 122 [of infusion device 102] and secure it to the shuttle 1116”).

42. As shown below, Raymond's infusion device is in a proximal position within the insertion device before insertion, such that Raymond's infusion device and needle (brown) are disposed entirely within the insertion device. EX1010, FIG. 29. In this proximal position, Raymond's left and right base-retaining arms (green) with associated base-retaining feet (orange) detachably engage recesses (red) on the periphery of the infusion device's base (purple). *Id.*, [0123] (“[T]he shuttle 1116 can comprise one or more base-retaining arms 1226, such as those illustrated in FIGS. 25-28, to engage the infusion device 102.”). Each base-retaining foot is located at a tip portion of a corresponding base-retaining arm (green). *Id.*, FIG. 29.



**Raymond, FIG. 29 (annotated)**

43. As shown below, when the insertion device advances the infusion device to a distal position during insertion, the insertion device's outwardly-biased base-retaining feet disengage the infusion device's base such that the feet disengage the base's recesses by the time the infusion device reaches the distal position. EX1010, [0126] ("The base-retaining arms 1226 can spread outwardly when the sleeve-engagement surfaces 1233 of the shuttle 1116 clear the cam surface 1180 of the sleeve 1106. The base-retaining feet 1227 can move away from the base 122 as the base-retaining arms 1126 spread outwardly such that the base 122 can be released from the shuttle 1116."). Furthermore, a retraction spring (blue) retracts the needle (brown) from the distal position to a retracted position entirely within the insertion device. EX1010, [0127] ("[T]he retraction spring 1114 can ... draw the needle 1112 within the insertion device 1100").

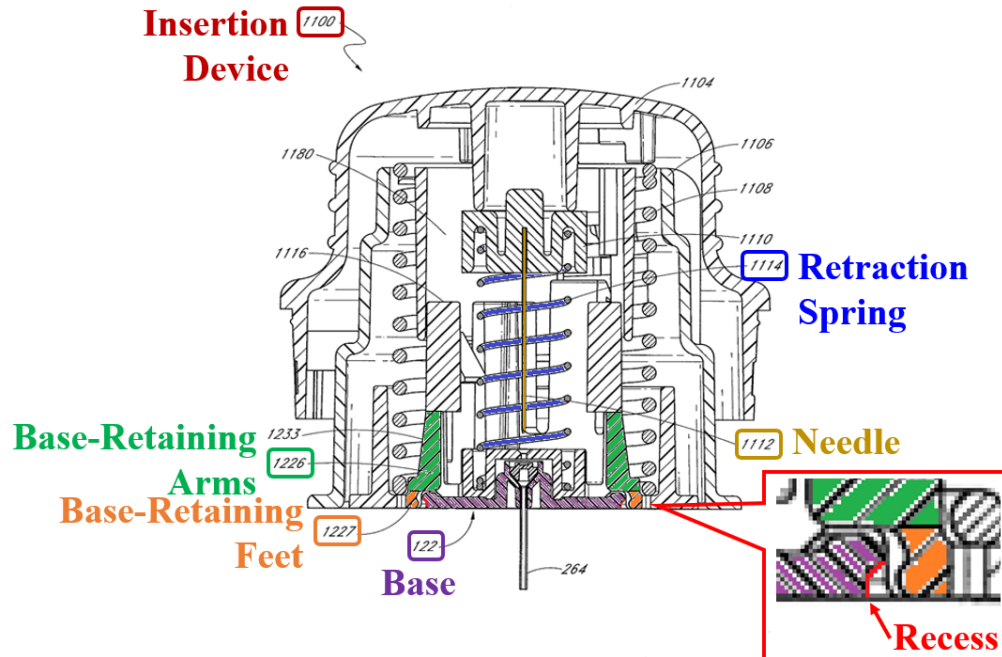


FIG. 30

**Raymond, FIG. 30 (annotated)**

44. Raymond describes several advantages of using its insertion device over prior insertion devices, such as positioning the needle within the insertion device before insertion and retracting the needle within the insertion device after insertion to prevent accidental needlesticks. EX1010, [0008] (“[I]t can be beneficial for an insertion device for an infusion device to require a minimum number of operational steps while providing safe operation and disposal. Such an insertion device may advantageously minimize the possibility of accidental needle sticks and/or premature activation of the insertion device.”), [0127] (“Once the needle hub 1110 is released by the needle-hub-engaging arms 1210, the retraction spring 1114 can push the needle hub 1110 away from the shuttle 1116 to draw the needle 1112

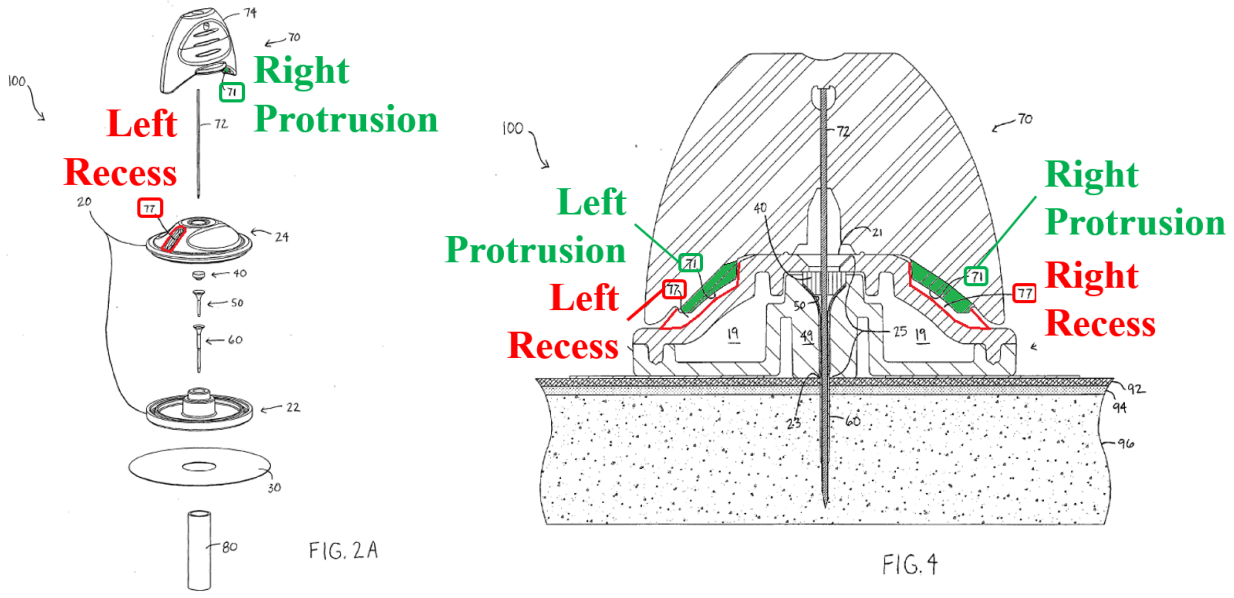
within the insertion device 1100 .... Thus, the needle 1112 can be protected both before and after insertion of the base 122 to prevent accidental needle sticks. This automatic retraction feature can ensure that the needle 1212 is only exposed while the infusion device 102 is being inserted.”); *see also id.*, [0104] (“Thus, the needle 112 can be protected both before and after insertion of the base 122 to prevent accidental needlesticks. This automatic retraction feature can ensure that the needle 212 is only exposed while the infusion device 102 is being inserted. In some embodiments, the insertion device 100 can be configured to be used only a single time such that the insertion device 100 can be discarded with the needle safely retained therein.”), [0109] (“The insertion device 1100 is similar in many respects to the insertion device 100.”).

**C. Turner**

45. U.S. Publication No. 2007/0135774 (“Turner,” EX1011) was published June 14, 2007, from an application filed November 3, 2006.

46. Turner describes an insertion device for delivering a fluid delivery device for the treatment of diabetes. EX1011, [0008] (“The devices also may include an insertion device that is coupled to the body and that may be used to aid in insertion of the device”), [0064] (“[S]ome embodiments of the present fluid delivery devices may be used to deliver insulin to the subcutaneous tissue of a person with diabetes.”).

47. As shown below, Turner discloses an insertion device that includes a plurality of rotation-restricting protrusions (green). EX1011, [0069] (“Body 20 and insertion device 70 may be configured such that insertion device 70 cannot rotate with respect to body 20 when fully inserted in body 20. One manner of achieving this configuration comprises providing hub 74 with rotation-restricting protrusions 71, which extend in a downstream or downward direction from the main portion of insertion device hub 74, and by providing cap element 24 of body 20 with rotation-restricting recesses 77. When insertion device 70 is fully inserted in body 20, as shown in FIG. 3, at least a portion of each protrusion 71 extends into each recess 77 such that the recess side walls interfere with the protrusions to prevent rotation of the insertion device relative to body 20. Although the embodiment shown includes two protrusions and two recesses, other embodiments may include fewer or greater numbers of each.”). Each protrusion is configured to engage a corresponding one of a plurality of rotation-restricting recesses disposed on the periphery of the fluid delivery device’s body. *Id.* The protrusions and recesses are configured to secure the fluid delivery device in a particular position relative to the insertion device. *Id.*; see *supra* Section VI.B.3.



**Turner, FIGS. 2A and 4 (annotated)**

#### D. The Stafford+Raymond Combination

48. The combination of Stafford and Raymond (“Stafford+Raymond”) applied herein combines teachings from Stafford and Raymond, namely Stafford’s teachings related to a glucose sensor, introducer (“sharp”), integrated assembly (“on-body electronics unit”), and housing (“on body electronics unit housing”) and Raymond’s teachings related to an insertion device (“inserter”) with base-retaining arms (“gripping arms”). Stafford+Raymond combines these respective teachings into an improved design featuring the benefits from each reference, with minor adjustments as needed for them to cooperate and function together for the intended function of insertion, as discussed below. Stafford+Raymond also includes plural recesses on the on-body electronics unit housing’s periphery to detachably engage

the inserter's gripping arms, as taught by Raymond. The resulting combination includes the following elements cooperating as follows:

- an insertion device as taught by Raymond, adjusted to accommodate and engage a housing as taught by Stafford, and to use a needle/introducer to insert a portion of a glucose sensor like that taught in Stafford beneath the skin of a subject; and
- an integrated assembly as taught by Stafford, including:
  - a housing adjusted to include spaced-apart recesses disposed on a periphery of the housing, with the recesses detachably engageable with the insertion device as taught by Raymond;
  - a glucose sensor; and
  - electronics coupled to the glucose sensor, wherein the electronics include a memory, processor, power supply, and RF transceiver for wirelessly communicating glucose level data;
- the insertion device is configured to advance the integrated assembly and needle/introducer from a proximal position entirely within the insertion device to a distal position, and
- wherein the insertion device is further configured to retract the needle/introducer from the distal position to a retracted position entirely within the insertion device.

49. Like the '335 patent, Stafford and Raymond are each directed to the insertion of transcutaneous medical devices for diabetes treatments. EX1001, Abstract (“An apparatus for insertion of a medical device in the skin of a subject”); EX1009, [0018] (“[A]n integrated analyte sensor delivery and data processing unit for subcutaneous placement of an analyte sensor”); EX1010, [0009] (“[A] device for inserting an infusion device through skin for subcutaneous infusion”); *see supra* Sections V, VII.A-B. Thus, Stafford and Raymond are analogous art to the claimed invention of the '335 patent.

**1. A POSITA Would Have Been  
Motivated To Combine Stafford And Raymond**

50. A POSITA would have been motivated to combine Stafford and Raymond for the following reasons.

51. Raymond improves upon an aspect of insertion identified by Stafford, namely, to prevent accidental needlesticks when withdrawing the needle from a subject. EX1009, [0003] (“[T]he inserter and the introducer are discarded ... [requiring] a level of care as the inserter is sharp and may damage other parts of the patient's skin if not properly handled. Further, since the tip of the inserter has come into fluid contact with the patient's biological fluids, it is important to take particular precautions in the handling of the inserter.”), [0022] (discussing “potential injury from the sharp edge of the [lower] portion 102B of the introducer.”); EX1010, [0008] (“[A]n insertion device may advantageously minimize the possibility of accidental

needle sticks and/or premature activation of the insertion device. Accordingly, it can be advantageous for an insertion device to insert an infusion device, such as an infusion set, quickly, safely, and conveniently.”), [0127] (Thus, the needle 1112 can be protected both before and after insertion of the base 122 to prevent accidental needle sticks. This automatic retraction feature can ensure that the needle 1212 is only exposed while the infusion device 102 is being inserted.”); *see also id.*, [0104] (“Thus, the needle 112 can be protected both before and after insertion of the base 122 to prevent accidental needlesticks. This automatic retraction feature can ensure that the needle 212 is only exposed while the infusion device 102 is being inserted. In some embodiments, the insertion device 100 can be configured to be used only a single time such that the insertion device 100 can be discarded with the needle safely retained therein.”), [0109] (“The insertion device 1100 is similar in many respects to the insertion device 100.”). Stafford describes a glucose sensor introducer with a “sharp tip” and a desire to prevent both pre-insertion and post-insertion needlesticks, but only proposes a guard segment for preventing pre-insertion needlesticks. EX1009, [0002] (describing introducer with “sharp needle shaped inserter”), [0003] (“[T]he inserter and the introducer are discarded ... [requiring] a level of care as the inserter is sharp and may damage other parts of the patient's skin if not properly handled. Further, since the tip of the inserter has come into fluid contact with the patient's biological fluids, it is important to take particular precautions in the

handling of the inserter.”), [0021] (“[T]he introducer is configured with a sharp tip to facilitate puncturing or piercing through the surface of the subject such as the skin of the patient”), [0022] (“[T]he guard segment 104 is configured to protect the sharp edge of the lower portion 102B of the introducer from inadvertent contact with the subject, for example, *prior to the subcutaneous deployment* of the analyte sensor to avoid, for example, ... potential injury from the sharp edge of the [lower] portion 102B of the introducer.”), [0049] (“[T]he first portion of the introducer may include a sharp tip for piercing through the skin layer of the subject, wherein when the sharp tip is pierced through the skin layer, the first portion of the analyte sensor is transcutaneously placed under the skin layer of the subject so as to be in fluid contact with the interstitial fluid of the subject.”). Raymond describes a needle-based insertion device designed to “minimize the possibility of accidental needle sticks” and “provid[e] safe operation and disposal” by ensuring that the needle is only exposed during insertion. EX1010, [0008] (noting the advantage of inserting a transcutaneous medical device “quickly, safely, and conveniently”), [0127] (Thus, the needle 1112 can be protected both before and after insertion of the base 122 to prevent accidental needle sticks. This automatic retraction feature can ensure that the needle 1212 is only exposed while the infusion device 102 is being inserted.”); *see also id.*, [0104] (“Thus, the needle 112 can be protected both before and after insertion of the base 122 to prevent accidental needlesticks. This automatic retraction

feature can ensure that the needle 212 is only exposed while the infusion device 102 is being inserted. In some embodiments, the insertion device 100 can be configured to be used only a single time such that the insertion device 100 can be discarded with the needle safely retained therein.”), [0109] (“The insertion device 1100 is similar in many respects to the insertion device 100.”). A POSITA implementing Stafford would have not only recognized that Stafford’s and Raymond’s teachings to prevent needlesticks are complementary but would have further understood that, as compared to Stafford’s solution that only prevents pre-insertion needlesticks, Raymond’s improved solution prevents against both pre-insertion and post-insertion needlesticks. Thus, a POSITA would have been motivated to implement Raymond’s teachings to cure the deficiencies of Stafford’s introducer.

52. Raymond also improves upon the insertion process as taught by Stafford by reducing pain and anxiety caused by exposed insertion needles. A POSITA would have understood that Stafford’s manual insertion needle’s exposed sharp tip causes a patient pain and anxiety. *See supra* Section VI.B.1. A POSITA would have understood that using an insertion device as taught by Raymond lessens the subject’s pain and anxiety by maintaining the introducer’s sharp tip within an enclosed structure before and after insertion. *See, e.g.,* EX1010, [0127] (Thus, the needle 1112 can be protected both before and after insertion of the base 122 to prevent accidental needle sticks. This automatic retraction feature can ensure that

the needle 1212 is only exposed while the infusion device 102 is being inserted.”); EX1037, [0004] (“When performed manually, the penetration of the catheter-carrying needle into the body, however, may be considered uncomfortable for a patient, or may cause some other anxiety. Also, the subsequent manual withdrawal of the needle is often regarded by some patients as painful.”), [0007] (“[O]ne advantage of the invention is to increase the comfort of a patient during the insertion and withdrawal of a catheter or cannula. This benefit may be achieved with a device for the insertion of a cannula of the type described herein, wherein the needle, after reaching its extended state, can be withdrawn quickly and automatically by a retraction apparatus.”), [0008] (“[D]ue to aid from the retraction apparatus, the needle is quickly withdrawn from the body tissue and simultaneously, the inserted cannula remains within the body tissue. In this way, since the needle is relatively quickly withdrawn from the body tissue, a much more comfortable sensation is experienced than that associated with a slower insertion and withdrawal.”), [0011] (“[T]he movement of a needle within the body tissue can be uncomfortable, it is helpful if the displacement of the needle can be accelerated so that it can be removed from the tissue in a minimal amount of time.”); *supra* Section VI.B.1.

53. A POSITA would have recognized the complementary nature of Stafford and Raymond. For example, each reference teaches the benefits of an inserter with an easily graspable assembly. EX1009, [0007] (“The integrated analyte

sensor and data processing unit assembly ... allows for simple and accurate sensor deployment to the desired subcutaneous position, and that may be easily operated using one hand by the user or the patient.”); EX1010, [0008] (“It can be advantageous for an insertion device for an infusion device to be easily grasped and operated by diabetics suffering from diabetic neuropathy.”). Additionally, as discussed later at [1.5] (¶¶70-87), a POSITA would have recognized that the arms as taught by Raymond work with the housing’s recesses to keep the on body electronics unit (and its sensor) as taught by Stafford aligned with the inserter as taught by Raymond during insertion. Thus, a POSITA would have understood that Stafford’s and Raymond’s teachings are complementary.

54. Raymond, with its pre-assembled inserter/device configuration, also comports with Stafford’s teaching that “a *separate* sensor introducing device such as a *separate* insertion gun ... is not necessary.” EX1009, [0044]. Unlike systems that rely on a separate insertion gun, *e.g.*, Say (EX1012, 36:18-39), Raymond’s pre-assembled insertion device and on body unit obviates the need for the user to manually align and apply a separate insertion gun. EX1009, [0028] (“[T]he integrated analyte sensor delivery and data processing unit 100 in one embodiment may be pre-assembled as a single integrated unit ... where a portion of the analyte sensor 106 is disposed within the lower portion 102B of the introducer”); EX1010, [0100] (“The insertion device 100 and infusion device 102 can be packaged together

and transported in the assembled state”), [0109] (“The insertion device 1100 is similar in many respects to the insertion device 100.”); *see supra* Section VI.B.1.

55. Thus, a POSITA would have been motivated to combine the teachings of Stafford and Raymond.

**2. A POSITA Would Have Had A Reasonable Expectation Of Success In Combining Stafford And Raymond**

56. A POSITA would have had a reasonable expectation of success in combining Stafford and Raymond for the following reasons.

57. Given the known interchangeability of insertion devices for cannulas and sensors, a POSITA would have easily adapted the inserter taught by Raymond for use with the Stafford housing, *e.g.*, by using a needle-like introducer that accommodated the sensor, as taught by Stafford. *See supra* Section VI.B.2. Indeed, the '335 patent itself states that its “inserter can be configured to insert various medical devices into the subject, such as for example, an analyte sensor, an infusion set, or a cannula” (EX1001, 22:27-29), yet provides no meaningful guidance on how to configure or adapt the inserter for the various types of devices. This confirms the known interchangeability of inserter devices between infusion sets and analyte sensors and similar devices. Similarly, a POSITA would have easily implemented the on-body unit with recesses that engagingly mated with the gripping arms, as

taught by Raymond. *See supra* Section VI.B.3. These adaptations required only basic skill and knowledge, possessed by a POSITA.

58. Thus, a POSITA would have had a reasonable expectation of success in combining the teachings of Stafford and Raymond.

**E. The Stafford+Raymond+Turner Combination**

59. The Petition relies on Turner with respect to the “plural recesses” recited in Element 1.5. For Ground 1, Turner serves as background art reflecting the knowledge and skill of a POSITA, confirming the obviousness of the recited recesses. Ground 2 relies expressly on Turner as a secondary reference for its teachings on use of recesses and protrusions to avoid rotational movement. Turner (directed to the insertion of transcutaneous medical devices for diabetes treatments) is analogous art to the claimed invention of the ’335 patent and, furthermore, is analogous art to Stafford and Raymond. EX1011, [0008] (“The devices also may include an insertion device that is coupled to the body and that may be used to aid in insertion of the device”), [0064] (“[S]ome embodiments of the present fluid delivery devices may be used to deliver insulin to the subcutaneous tissue of a person with diabetes.”); *see supra* Sections VII.C (characterizing Turner), VII.D (characterizing the ’335 patent, Stafford, and Raymond as analogous art).

60. To the extent Patent Owner argues that “plural recesses” were not at least obvious over Stafford+Raymond alone, Turner confirms the obviousness of

adding plural recesses to the periphery of the housing to beneficially prevent relative rotational movement between the housing and the inserter. EX1011, [0069] (“Body 20 and insertion device 70 may be configured such that insertion device 70 cannot rotate with respect to body 20 when fully inserted in body 20. One manner of achieving this configuration comprises providing hub 74 with rotation-restricting protrusions 71, which extend in a downstream or downward direction from the main portion of insertion device hub 74, and by providing cap element 24 of body 20 with rotation-restricting recesses 77. When insertion device 70 is fully inserted in body 20, as shown in FIG. 3, at least a portion of each protrusion 71 extends into each recess 77 such that the recess side walls interfere with the protrusions to prevent rotation of the insertion device relative to body 20.”). Turner provides express teachings on the use of “rotation-restricting recesses” that “prevent rotation of the insertion device relative to [the on-body unit],” thus confirming a benefit of this type of feature. *Id.*, [0069]. Given the motivation to avoid relative movement between the housing and the inserter (further discussed at [1.5] (§§70-87)), and Turner’s express teachings of plural recesses, a POSITA would have naturally implemented the Stafford+Raymond housing with plural recesses that engage corresponding portions of the inserter. *See supra* Sections VI.B.3, VII.C; *infra* Section VII.F. As Raymond already teaches an inserter with base-retaining feet (similar to Turner’s protrusions) at the tip portion of each base-retaining arm, a POSITA would have simply ensured

that the on-body electronics unit housing included spaced-apart recesses (in line with Turner’s teachings) that were engageable with the engagement bosses (similar to Raymond’s base-retaining feet) on the tip portions of the inserter’s gripping arms (similar to Raymond’s base-retaining arms). *See supra* Sections VI.B.3, VII.B-C, VII.D.1. As with Stafford+Raymond alone, the POSITA would have had a reasonable expectation of success in implementing such simple mechanical features as at least two recesses.

**F. Claim 1**

[1.1]<sup>4</sup> A glucose monitoring assembly, the assembly comprising:

61. Stafford discloses a glucose sensor. *See, e.g.*, EX1009, [0051] (“The analyte sensor may include a glucose sensor.”).

62. As previously discussed, a POSITA would have been motivated to combine the teachings of Stafford and Raymond (and Turner), for example, by configuring an inserter as taught by Raymond to advance an on body electronics unit as taught by Stafford and insert the glucose sensor as taught by Stafford. *See supra* Sections VII.D.1, VII.E.

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<sup>4</sup> Reference numbers in the format of [claim#.element#] are added throughout for ease of reference.

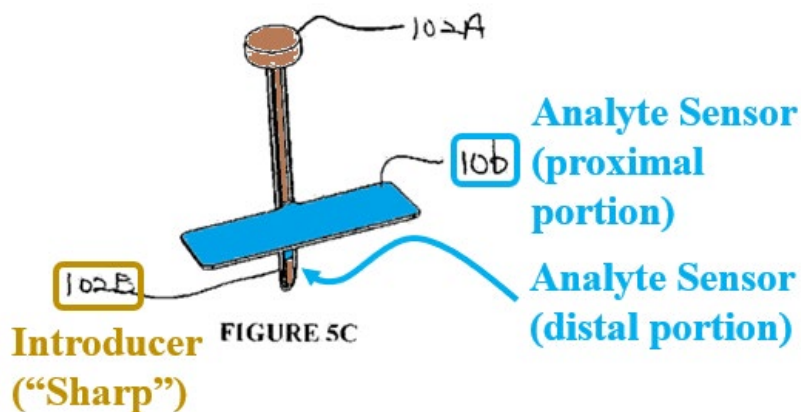
63. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “a glucose monitoring assembly.” *See* Sections VII.D, VII.E.

[1.2] (1) an inserter comprising:

64. As discussed at [1.1] (§¶61-63), Stafford+Raymond (and Stafford+Raymond+Turner) includes “an inserter.” *See* Sections VII.D, VII.E.

[1.3] a sharp configured to insert a portion of a glucose sensor into a subject; and

65. As shown below, Stafford discloses an introducer (“sharp,” brown) including a lower portion for inserting Stafford’s sensor. EX1009, FIG. 5C, [0028] (“[A] portion of the analyte sensor 106 is disposed within the lower portion 102B of the introducer such that, the user or patient may easily, and accurately position the analyte sensor 106 under the skin layer to establish fluid contact with the patient’s analyte”).



Stafford, FIG. 5C (annotated)

66. As shown below, Raymond's insertion device ("inserter," red) includes a needle ("sharp," brown) for inserting a cannula. EX1010, FIGS. 29-30, [0109] ("[T]he insertion device 1100 can comprise ... a needle 1112").

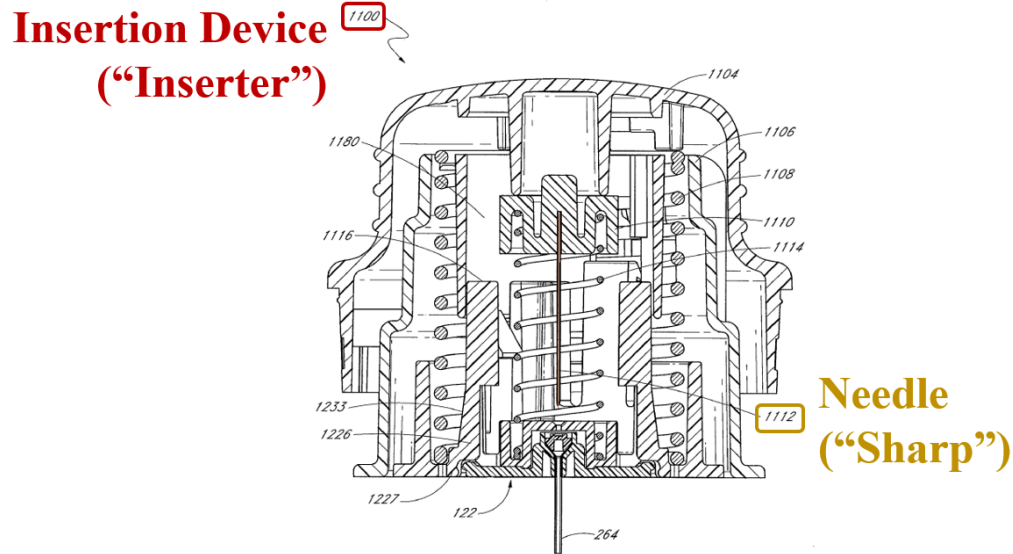


FIG. 30

### Raymond, FIG. 29 (annotated)

67. A POSITA would have employed a sharp like that disclosed in Stafford for compatibility with the sensor as taught by Stafford and would have had a reasonable expectation of success of doing so. *See supra* Sections VI.B.2, VII.D.1-2.

68. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes "a sharp configured to insert a portion of a glucose sensor into a subject." *See* Sections VII.D, VII.E.

[1.4] (2) an on body electronics unit, comprising:

69. As discussed below at [1.5] (§§70-87), Stafford+Raymond (and Stafford+Raymond+Turner) includes an “on body electronics unit.” *See* Sections VII.D, VII.E.

[1.5] an on body electronics unit housing comprising a plurality of recesses disposed on a periphery of the on body electronics unit housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is detachably engaged with the inserter;

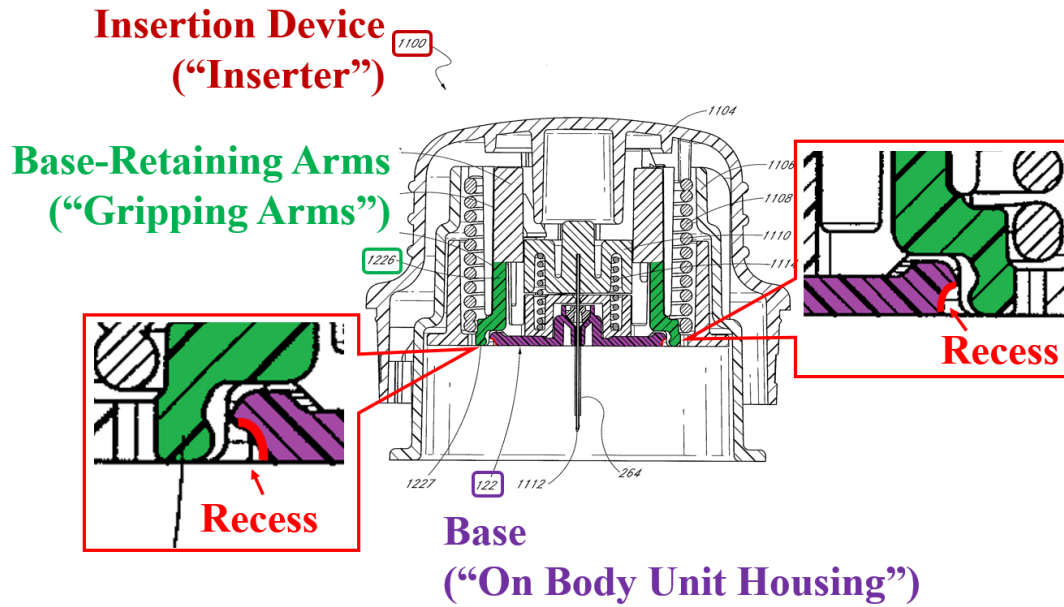
70. Stafford+Raymond includes an assembly (“on body electronics unit”) that includes a housing (“on body electronics unit housing”) configured to be adhered to a subject’s body, as taught by Stafford. EX1009, [0019] (“The adhesive patch 103 in one embodiment is provided with an adhesive material ... that is configured to securely attach the adhesive patch 103 and the data processing unit 101 on a surface of a subject such as the skin of a patient.”).

71. Stafford teaches that its on body electronics unit includes electronics (“on body electronics”) located within a housing. EX1009, FIG. 7; [0040] (“Further shown in FIG. 7 are a transmitter serial communication section 705 and an RF transceiver 706, each of which is also operatively coupled to the processor 704. Moreover, a power supply 707 such as a battery is also provided in the data processing unit 101 to provide the necessary power for the components in the data processing unit 101. Additionally, as can be seen from the Figure, clock 708 is

provided to, among others, supply real time information to the processor 704.”), [0052] (“[A]n RF transceiver 706 ... [is] operatively coupled to the processor 704. Moreover, a power supply 707 such as a battery is also provided in the data processing unit 101 to provide the necessary power for the components in the data processing unit 101,” “[t]he data processing unit in one embodiment may include a data transmission unit configured to receive one or more signals associated with an analyte level of the subject from the analyte sensor, where the data transmission unit may be configured to wirelessly transmit data associated with the one or more signals received from the analyte sensor, where the data transmission unit may include an RF data transmission unit.”). Since Stafford’s integrated assembly (which includes Stafford’s data processing unit) includes electronics and is securely attached to the subject’s skin (a portion of the subject’s body), a POSITA would have understood that Stafford’s integrated assembly is an “on body electronics unit.”

72. As shown below, Raymond teaches an insertion device with “base-retaining arms” that “engage” the on-body unit. EX1010, [0123] (“The arms 1226 can include base-retaining feet 1227, to clamp, grasp, or otherwise engage the base 122 and secure it to the shuttle 1116.”). More specifically, Raymond teaches arms with inward protrusions, called “base-retaining feet,” that “engage the base” of the on-body unit “and secure it” to the insertion device. *Id.* Raymond’s FIG. 29 shows how each of these feet/protrusions on the arms (green) detachably engages recesses

(red) disposed on opposite sides of the base (“on body unit housing,” purple). EX1010, FIGS. 29-30, [0126] (describing disengagement of the base-retaining feet), [0127]-[0128].



**Raymond, FIG. 29 (annotated)**

73. While the text of Raymond does not describe these recesses in narrative, based on the figures of Raymond a POSITA would have at least found it obvious to implement an on-body unit with recesses to engage the feet/protrusions of the retaining arms.

74. A POSITA knew that feet/protrusions like those taught by Raymond (EX1010, [0123]) were regularly designed to engage corresponding recesses or notches on associated components, in order to retain the components in relative position to one another. *See, e.g.,* EX1018, [0011] (describing inserter with a

plurality of safety lock arms, wherein each safety lock arm includes “a cam lobe for engaging an appropriately shaped recess on the insertion set”); EX1040, 2:45-57 (same); EX1042, [0010] (same); EX1057, [0015] (same). Indeed, Raymond itself elsewhere employs a similar basic feature, describing a bounded recess on one component that engages a foot/protrusion on another component “to prevent unintentional rotation.” EX1010, [0074] (“Referring to FIG. 7, the sleeve 106 can comprise a recess 170 in which the one or more feet 136 of the actuator 134 may move. The recess 170 can be bounded on one side by a shoulder 172 that is configured to engage the one or more feet 136 of the actuator 104. The shoulder 172 can comprise a protrusion 174 to prevent unintentional rotation of the actuator 104 with respect to sleeve”); *see also id.*, [0095] (describing recess that “receives a portion” of a corresponding component so that it “can be held securely”). As one purpose of the feet is to “secure” the on-body unit to the insertion device prior to insertion, a POSITA thus would have been motivated with a reasonable expectation of success to provide recesses on the on body electronics unit housing in order to securely engage the on body electronics unit to the inserter. EX1010, [0123] (“The arms 1226 can include base-retaining feet 1227, to clamp, grasp, or otherwise engage the base 122 and secure it to the shuttle 1116.”).

75. Even if Raymond taught only a single annular recess, it would have been an obvious design choice to implement two spaced-apart plural recesses on the

housing—one to engage the protrusions on each of the two arms taught by Raymond. *See also* EX1010, FIGS. 18, 25-27 (illustrating two arms); *see, e.g., id.*, FIGS. 29-30 (illustrating two recesses for engaging the two arms). A POSITA would have recognized that there were only two possibilities for a system having arms with protrusions that engage some type of recess: either the two arms engage different points of a single annular recess *or* each arm engages its own independent recess. As explained in the preceding paragraphs, a recess for each arm provided a more secure fit between the inserter and on-body unit, and FIGS. 29-30 show a recess for each arm, thus making it the better choice.

76. Thus, a POSITA would have implemented Stafford+Raymond with an on-body unit housing containing electronics, as taught by Stafford, and having recesses to engage each of the feet on the two base-retaining arms, as taught by Raymond.

77. Turner, which reflects the knowledge and skill of a POSITA, further confirms the obviousness of implementing spaced-apart plural recesses on the housing taught by Stafford to engage the inserter taught by Raymond. For example, as discussed at Section VII.C, Turner teaches the utility and desirability of a plurality of rotation-restricting recesses configured to engage a corresponding one of a plurality of rotation-restricting protrusions. EX1011, [0069] (“Body 20 and insertion device 70 may be configured such that insertion device 70 cannot rotate with respect

to body 20 when fully inserted in body 20. One manner of achieving this configuration comprises providing hub 74 with rotation-restricting protrusions 71, which extend in a downstream or downward direction from the main portion of insertion device hub 74, and by providing cap element 24 of body 20 with rotation-restricting recesses 77. When insertion device 70 is fully inserted in body 20, as shown in FIG. 3, at least a portion of each protrusion 71 extends into each recess 77 such that the recess side walls interfere with the protrusions to prevent rotation of the insertion device relative to body 20. Although the embodiment shown includes two protrusions and two recesses, other embodiments may include fewer or greater numbers of each.”). Thus, as expressly reflected by Turner, a POSITA would have been motivated to implement similar plural rotation-restricting recesses on the periphery of the housing as taught by Stafford to prevent rotation between the housing as taught by Stafford and the inserter as taught by Raymond.

78. Given the known interchangeability of sensor/cannula inserters, and the relative simplicity of adding recesses to any devices, the POSITA would have had a reasonable expectation of success in implementing Stafford+Raymond with two recesses on the on-body unit, one to engage or mate with each of the protrusions on the arms. Below I provide some exemplary steps a POSITA would have taken in doing so. Given the known interchangeability of sensor/cannula inserters, a POSITA would have made any necessary adjustments to an inserter like Raymond’s and/or

integrated assembly like Stafford's in implementing a physically compatible assembly, with a reasonable expectation of success in performing the claimed functions. *See* Section VII.D.1-2, *supra*. For example, a POSITA would have adjusted the dimensions of the recess ("recess 1220") of the shuttle of the inserter as taught by Raymond. If the housing as taught by Stafford was deemed wider than the recess of the shuttle as taught by Raymond,<sup>5</sup> a POSITA would have easily widened the recess of the shuttle such that the housing fits within the shuttle's recess.

79. A POSITA would have also known to adjust the size of the retraction spring and retraction spring recess ("recess 1208") as taught by Raymond. For example, if the housing as taught by Stafford were deemed taller than the recess in the shuttle as taught by Raymond,<sup>6</sup> a POSITA would have lengthened the recess within which the on body electronics unit as taught by Stafford is secured and would have correspondingly shortened the retraction spring recess. A POSITA would have

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<sup>5</sup> Although the housing illustrated in Stafford appears to be wider than the recess illustrated in Raymond in a side-by-side comparison, it should be noted that there is no indication Stafford's and Raymond's figures are drawn to scale.

<sup>6</sup> Although the housing illustrated in Stafford appears to be taller than the recess illustrated in Raymond in a side-by-side comparison, it should be noted that there is no indication Stafford's and Raymond's figures are drawn to scale.

accounted for the shortened retraction spring recess by increasing the stiffness of the retraction spring such that the spring in Stafford+Raymond exerts the same force on the needle hub as taught by Raymond during retraction as the unmodified spring in Raymond.

80. In another exemplary adjustment, a POSITA would have moved the tip portions of the gripping arms as taught by Raymond radially inwards to engage the periphery of the housing as taught by Stafford in the proximal position. Since the housing lacks the flanges that extend in the radially outwards direction from Raymond's base, a POSITA would have known to move the tip portions of the gripping arms radially inwards to contact the housing.

81. In another exemplary adjustment, a POSITA would have understood how to adjust the dimensions of the housing as taught by Stafford to fit within the recess of the shuttle of the inserter as taught by Raymond. For example, a POSITA would have understood that one of the largest components of the electronics as taught by Stafford disposed within the housing would be the power supply. *See, e.g.*, EX1012, 37:52-54 ("The battery is often one of the largest components in the on-skin control unit 44, so it is often desirable to minimize the size of the battery."). A POSITA would have further understood that the on body electronics' power requirements would vary based on the on body electronics' operating conditions (*e.g.*, sample rate, transit rate, transmit distance) and that power supplies come in a

variety of sizes depending in part on their power capacities. Thus, a POSITA would have understood how to reduce the size of the on body electronics as taught by Stafford to fit within a smaller housing by selecting lower-power electronics and a correspondingly lower-capacity power supply, such that the on body electronics unit both accomplishes the claimed functions and is compatible with the inserter as taught by Raymond. *See* Sections VI.B.1-2, VII.D.2.

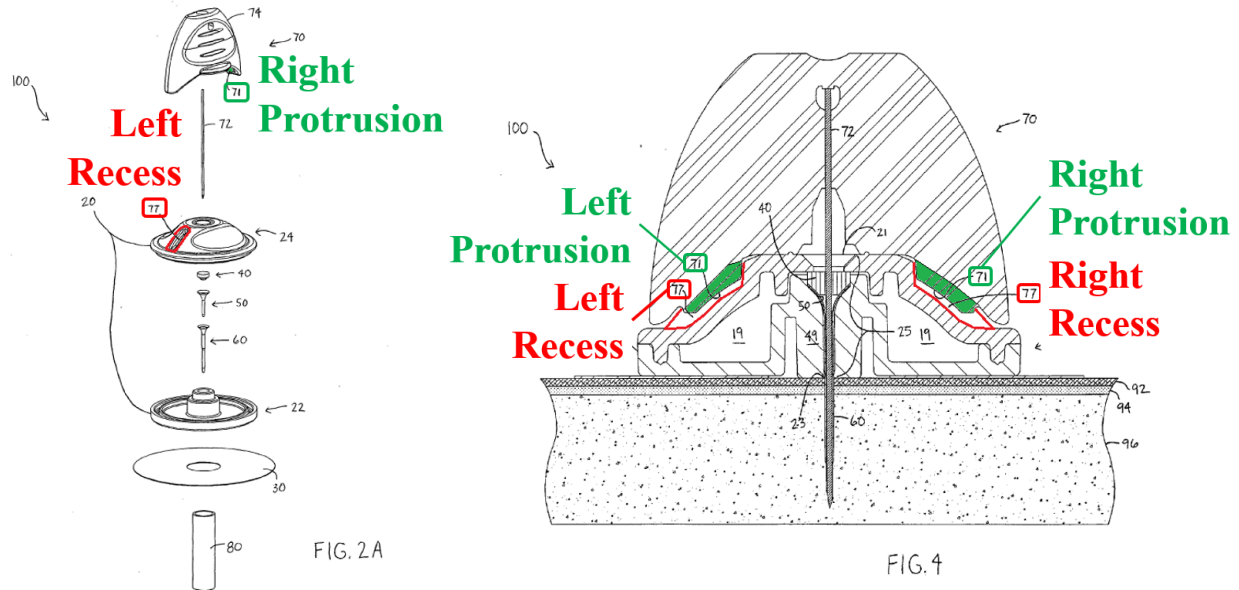
82. Since any changes to the housing and the inserter constitute routine design choices, there is neither evidence of any unexpected result associated with the plural recesses nor evidence that a POSITA would not have had a reasonable likelihood of success in using plural recesses to engage the corresponding plural gripping arms of the inserter. *See supra* Section VII.D.2.

83. Thus, Stafford+Raymond includes “an on body electronics unit housing comprising a plurality of recesses disposed on a periphery of the on body electronics unit housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is detachably engaged with the inserter.” *See* Section VII.D.

## **GROUND 2**

84. *Alternatively*, claims 1-4, 8-9, 11-15, and 17-27 are obvious over Stafford and Raymond, further in view of Turner (EX1011).

85. As shown below, Turner discloses plural rotation-restricting recesses (red) disposed on an infusion device's housing, wherein the plural recesses include a first recess in a spaced relation to a second recess, and wherein the plural recesses are detachably engaged with rotation-restricting protrusions (green) disposed on an insertion device ("inserter"). EX1011, [0069] ("Body 20 and insertion device 70 may be configured such that insertion device 70 cannot rotate with respect to body 20 when fully inserted in body 20. One manner of achieving this configuration comprises providing hub 74 with rotation-restricting protrusions 71, which extend in a downstream or downward direction from the main portion of insertion device hub 74, and by providing cap element 24 of body 20 with rotation-restricting recesses 77. When insertion device 70 is fully inserted in body 20, as shown in FIG. 3, at least a portion of each protrusion 71 extends into each recess 77 such that the recess side walls interfere with the protrusions to prevent rotation of the insertion device relative to body 20."); *see supra* Section VI.B.3.



**Turner, FIGS. 2A and 4 (annotated)**

86. As previously discussed, Turner’s teachings further confirm that a POSITA would have been motivated, with a reasonable expectation of success, to implement Stafford+Raymond with a housing having plural recesses spaced apart from one another so as to be engageable with the inserter, and specifically the corresponding engagement bosses on the tip portions of the gripping arms as taught by Raymond. *See supra* Section VII.E.

87. Thus, Stafford+Raymond+Turner includes “an on body electronics unit housing comprising a plurality of recesses disposed on a periphery of the on body electronics unit housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is detachably engaged with the inserter.” *See* Section VII.E.

[1.6] the glucose sensor; and

88. As discussed at [1.1] (¶¶61-63), Stafford+Raymond (and Stafford+Raymond+Turner) includes “a glucose sensor.” *See* Sections VII.D, VII.E.

[1.7] on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level,

89. As shown below, Stafford’s electronics (pink) include a processor, a power supply, and an RF transceiver (“wireless communication circuitry”) for wirelessly communicating glucose level data. EX1009, FIG. 7, [0040] (“[A]n RF transceiver 706 ... [is] operatively coupled to the processor 704. Moreover, a power supply 707 such as a battery is also provided in the data processing unit 101 to provide the necessary power for the components in the data processing unit 101”), [0052] (“The data processing unit in one embodiment may include a data transmission unit configured to receive one or more signals associated with an analyte level of the subject from the analyte sensor, where the data transmission unit may be configured to wirelessly transmit data associated with the one or more signals received from the analyte sensor, where the data transmission unit may include an RF data transmission unit.”). Stafford’s electronics are coupled with Stafford’s sensor. EX1003, ¶89, EX1009, [0028] (“[T]he analyte sensor 106 [is] in electrical contact with the data processing unit 101”), [0039] (“[T]he data processing unit 101

(FIG. 1) in one embodiment includes an analog interface 701 configured to communicate with the sensor 106 (FIG. 2)').

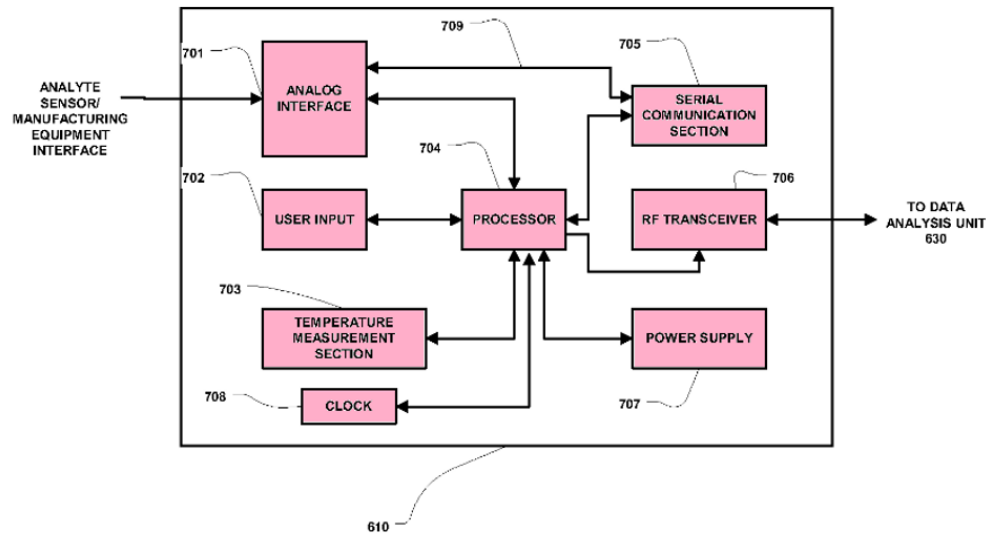
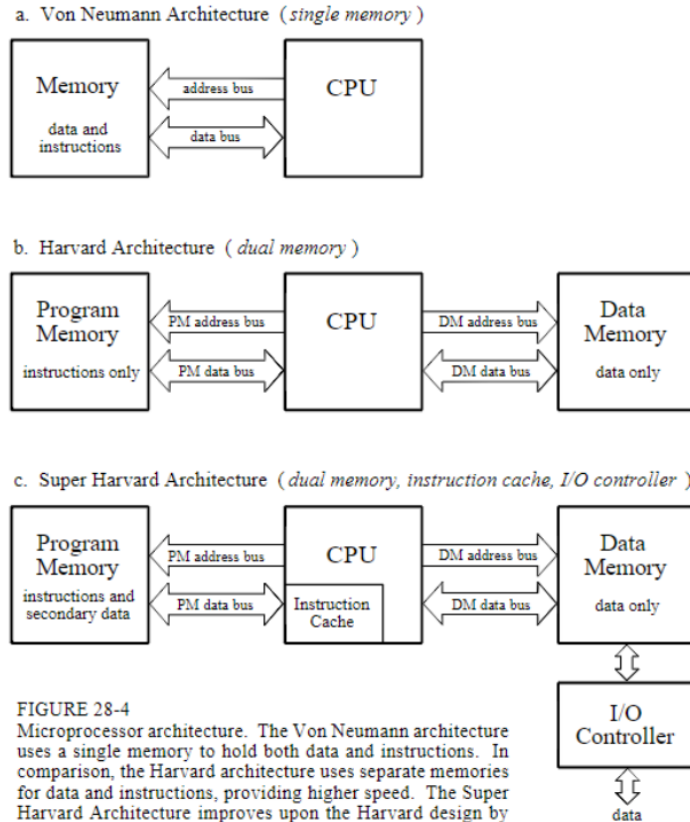


FIGURE 7

### Stafford, FIG. 7 (annotated)

90. Because Stafford discloses a processor and wireless communication circuitry, a POSITA would have found it at least obvious to implement Stafford's on body electronics with a memory in order to store the data processed by the processor and transmitted by the wireless communication circuitry. Both Say (EX1012) and Shah (EX1014), referenced in subsequent grounds presented herein, disclose glucose monitoring electronics that include memories configured to store information. EX1012, 44:54-45:7 ("The on-skin sensor control unit 44 may include an optional data storage unit 102 .... The data storage unit 102 typically includes a readable/writeable memory storage device."); *see* EX1014, [0045] ("[A]ll of the

circuitry that reads sensor information, digitizes the information, filters the data, calculates glucose, transmits information to the display, stores information, and so forth may be housed on the flexible circuit”). Furthermore, as discussed by Steven W. Smith, it was known no later than 1997 that memory was used in conjunction with a processor to process data. EX1061, 509 (“One of the biggest bottlenecks in executing DSP [Digital Signal Processing] algorithms is transferring information to and from memory. This includes *data*, such as samples from the input signal and the filter coefficients, as well as *program instructions*, the binary codes that go into the program sequencer. For example, suppose we need to multiply two numbers that reside somewhere in memory. To do this, we must fetch three binary values from memory, the numbers to be multiplied, plus the program instruction describing what to do.”) (emphasis original). Furthermore, as shown below, Smith illustrates several example processor architectures that each include a memory for storing data to be processed.



### Smith, FIG. 28-4, 511

91. Furthermore, as discussed by B.A. Shenoi, it was known no later than 2006 that digital signal processors stored input signal values in memory EX1062, 23 (“[T]he sample values of the input signal can be stored in the memory of the digital filter hardware.”). Additionally, Shenoi discloses that digital signal processing were used in biomedical systems. *Id.*, 2 (“The variety of machines used in hospitals and biomedical applications is staggering.”).

92. The use of digital signal processors to process glucose level data was also known long before 2010. For example, as discussed by Poitout et al., it was known no later than 1993 that electronics for processing glucose sensor electrical

current values included memories to store these values. EX1060, 659, 661-62 (“A glucose monitoring system must consist of two parts: a glucose sensor and an electronic device .... T[he functions of such a unit are multiple: controlling the potential of the working electrode, sampling, filtering, storing and processing the current, and transforming the current generated by the sensor into an estimation of a glucose concentration.”). Furthermore, as discussed by Breton et al., it was known no later than 2008 that glucose sensor values processed by electronics would be filtered, averaged, and sampled data for longer than five minutes and optimally eighteen minutes. EX1063, 497-99 (“This article focuses on the difference between BG and IG and on the ways of using Fourier decomposition to determine minimal sampling periods and/or maximum information to be expected from a specific sampling schedule of the interstitial fluid, ” “18 minutes of sampling (or 15 minutes for ease of use) was the maximum sampling frequency needed to fully register the fluctuations of interstitial glucose.”). A POSITA would have recognized that glucose level data collected over a period of time would need to be stored in memory in order for this data to be processed (*e.g.*, filtered, averaged, and sampled). Specifically, as discussed by Panteleon et al., it was known no later than 2003 that electronics for glucose monitoring systems store average glucose sensor values in memory at regular intervals (*e.g.*, every minute). EX1064, 403 (“The sensor connects to a Holter-style continuous glucose monitoring system (CGMS) via a cable where the

current data are stored for later calibration and evaluation by the physician. Sensor signals are sent to the monitor every 10s, with the average value stored in memory every minute.”). Also, as discussed by Hunn (EX1059), it was known no later than 2008 that electronics coupled to a glucose sensor used a memory in conjunction with a transmitter (“wireless communication circuitry”) to transmit data collected by the glucose sensor. EX1059, [0019] (“To enable data to be relayed wirelessly, such a signal means may be equipped with a transmitter, *e.g.*[,] a radio transmitter. To relay the signals received, the signal means can also feature a signal memory, *e.g.*[,] a digital data memory.”), [0025] (“The device of the exemplary embodiment serves to continuously monitor the glucose concentration in the subcutaneous tissue.”). Thus, a POSITA would have at least found it obvious to implement Stafford’s on body electronics with a memory.

93. Stafford+Raymond (and Stafford+Raymond+Turner) includes the processor, memory, power supply, and wireless communication circuitry as taught by Stafford disposed within the housing as taught by Stafford. The electronics as taught by Stafford are coupled with the sensor as taught by Stafford. *See also* Sections VII.D, VII.E.

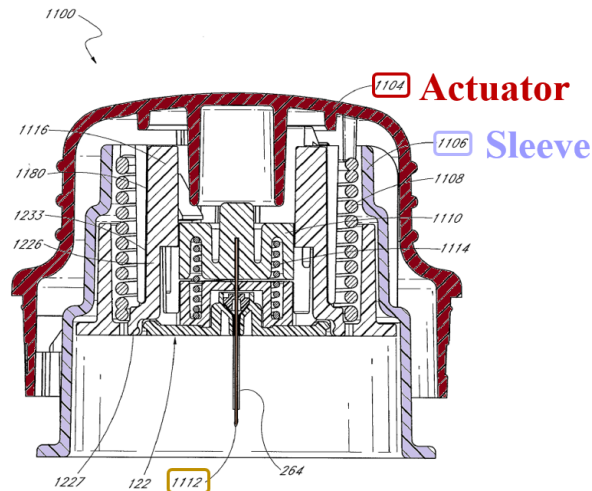
94. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the

on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level.” *See* Sections VII.D, VII.E.

[1.8] wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position, and

95. A lower portion of Stafford’s introducer (“sharp”) inserts Stafford’s sensor. EX1009, [0024] (“[T]he lower portion 102B of the introducer is pierced through the skin layer of the patient. Thereafter, the introducer may be removed to detach or decouple from the data processing unit 101 by, for example, pulling at the upper portion 102A of the introducer, thereby withdrawing the introducer from the patient and separating from the data processing unit 101, while retaining the analyte sensor 106 (FIG. 2) in position in fluid contact with the patient’s analyte.”).

96. As shown below, Raymond’s needle (“sharp,” brown) is entirely within an actuator (red) and a sleeve (light purple) of Raymond’s insertion device (“inserter”) when Raymond’s sharp is in a proximal position to protect the user from needlesticks. EX1010, FIG. 29, [0127] (“[T]he needle 1112 can be protected both before and after insertion of the base 122 to prevent accidental needle sticks. This automatic retraction feature can ensure that the needle 1212 is only exposed while the infusion device 102 is being inserted.”).



**Needle at Proximal Position  
("Sharp at Proximal Position")**

**Raymond, FIG. 29 (annotated)**

97. As discussed at [1.3] (§§65-68), Stafford+Raymond (and Stafford+Raymond+Turner) uses the inserter as taught by Raymond in combination with the sharp like that disclosed in Stafford to advance the on body electronics unit as taught by Stafford and insert the sensor as taught by Stafford. Since Stafford and Raymond teach that sharps should be covered to prevent needlesticks, a POSITA would have configured the sharp to be disposed entirely within the inserter (e.g., within the actuator and sleeve of the inserter as taught by Raymond) in the proximal position. EX1009, [0003] ("[T]he inserter and the introducer are discarded [after use]. This requires a level of care as the inserter is sharp and may damage other parts of the patient's skin if not properly handled."), [0022] (discussing "potential injury from the sharp edge of the [lower] portion 102B of the introducer."); EX1010, [0127] ("[T]he needle 1112 can be protected both before and after insertion of the base 122

to prevent accidental needle sticks”); *see also id.*, [0104] (“Thus, the needle 112 can be protected both before and after insertion of the base 122 to prevent accidental needlesticks. This automatic retraction feature can ensure that the needle 212 is only exposed while the infusion device 102 is being inserted. In some embodiments, the insertion device 100 can be configured to be used only a single time such that the insertion device 100 can be discarded with the needle safely retained therein.”), [0109] (“The insertion device 1100 is similar in many respects to the insertion device 100.”). Since the sensor is a part of the on body electronics unit, a POSITA would have configured the inserter to advance the on body electronics unit and the sharp in unison from a position entirely within the inserter to a distal (insertion) position in which the distal surface of the on body electronics unit is aligned with the distal end of the inserter and contacts the subject’s skin.

98. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the inserter ... configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position.” *See* Sections VII.D, VII.E.

[1.9] wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.

99. The lower portion of Stafford’s introducer is a sharp. EX1009, [0021] (“[T]he lower portion 102B of the introducer is configured with a sharp tip to

facilitate puncturing or piercing through the surface of the subject such as the skin of the patient.”).

100. As shown below, Raymond’s insertion device (“inserter”) retracts Raymond’s needle (“sharp,” brown) from a distal position to a retracted position entirely within the actuator (red) and the sleeve (light purple) of Raymond’s inserter. EX1010, FIG. 30, [0127].

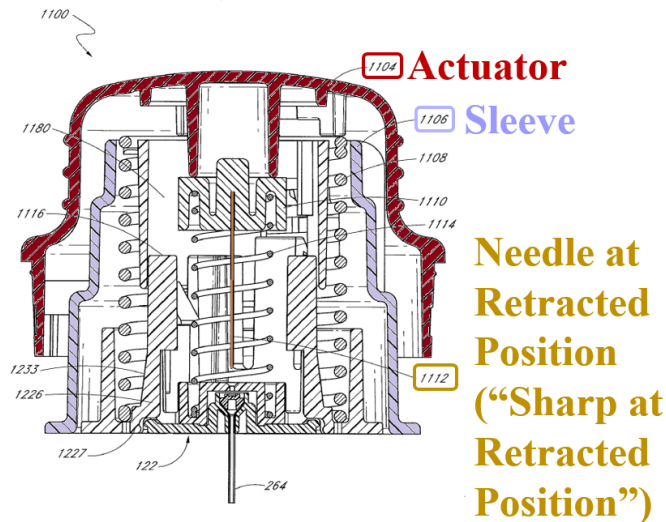


FIG. 30

### Raymond, FIG. 30 (annotated)

101. Stafford+Raymond (and Stafford+Raymond+Turner) includes the inserter as taught by Raymond and a sharp like that disclosed in Stafford. Based on Stafford’s and Raymond’s teachings, the sharp is retracted entirely within the inserter to cover the sharp. *See* EX1009, [0003] (“[T]he inserter and the introducer are discarded ... [requiring] a level of care as the inserter is sharp and may damage

other parts of the patient's skin if not properly handled. Further, since the tip of the inserter has come into fluid contact with the patient's biological fluids, it is important to take particular precautions in the handling of the inserter.”), [0022] (discussing “potential injury from the sharp edge of the [lower] portion 102B of the introducer.”); EX1010, [0127] (Thus, the needle 1112 can be protected both before and after insertion of the base 122 to prevent accidental needle sticks. This automatic retraction feature can ensure that the needle 1212 is only exposed while the infusion device 102 is being inserted.”); *see also id.*, [0104] (“Thus, the needle 112 can be protected both before and after insertion of the base 122 to prevent accidental needlesticks. This automatic retraction feature can ensure that the needle 212 is only exposed while the infusion device 102 is being inserted. In some embodiments, the insertion device 100 can be configured to be used only a single time such that the insertion device 100 can be discarded with the needle safely retained therein.”), [0109] (“The insertion device 1100 is similar in many respects to the insertion device 100.”).

102. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the inserter ... configured to retract the sharp from the distal position to a retracted position entirely within the inserter.” *See* Sections VII.D, VII.E.

103. Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 1's limitations, claim 1 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner).

**G. Claim 2**

2. The glucose monitoring assembly of claim 1, wherein the inserter further comprises a plurality of gripping arms.

104. As discussed at [1.5] (§§70-87) and [3.1] (§§106-07), Stafford+Raymond (and Stafford+Raymond+Turner) includes “the inserter ... [comprising] a plurality of gripping arms.” *See supra* Section VII.F; *see infra* Section VII.H.

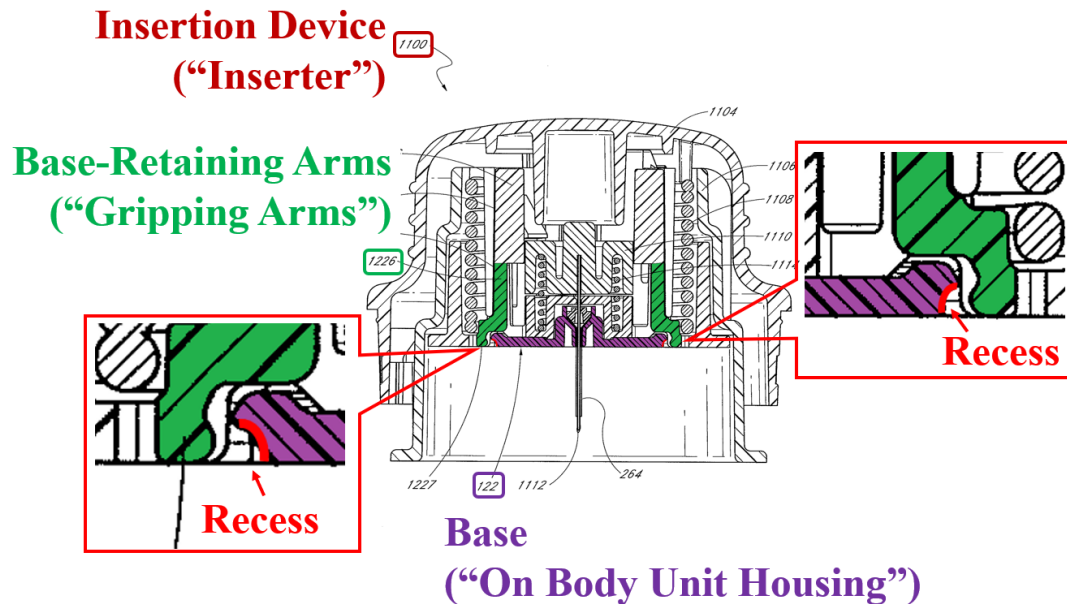
105. Thus, since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 2's limitations, claim 2 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner).

**H. Claim 3**

[3.1] The glucose monitoring assembly of claim 2, wherein each gripping arm of the plurality of gripping arms is configured to be engaged with a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

106. As discussed at [1.5] (§§70-87), Raymond discloses two gripping arms, each engaging a corresponding recess of the on body unit housing, or at least renders these recesses obvious. EX1010, FIG. 29, [0123] (“In some embodiments, the shuttle 1116 can comprise one or more base-retaining arms 1226, such as those illustrated

in FIGS. 25-28, to engage the infusion device 102.”); *supra* Section VII.F. As shown below, Raymond illustrates how, with the unit in its position proximal to the user, a left base-retaining arm (“gripping arm,” green) engages a left recess (red) and a right gripping arm (green) engages a right recess (red).

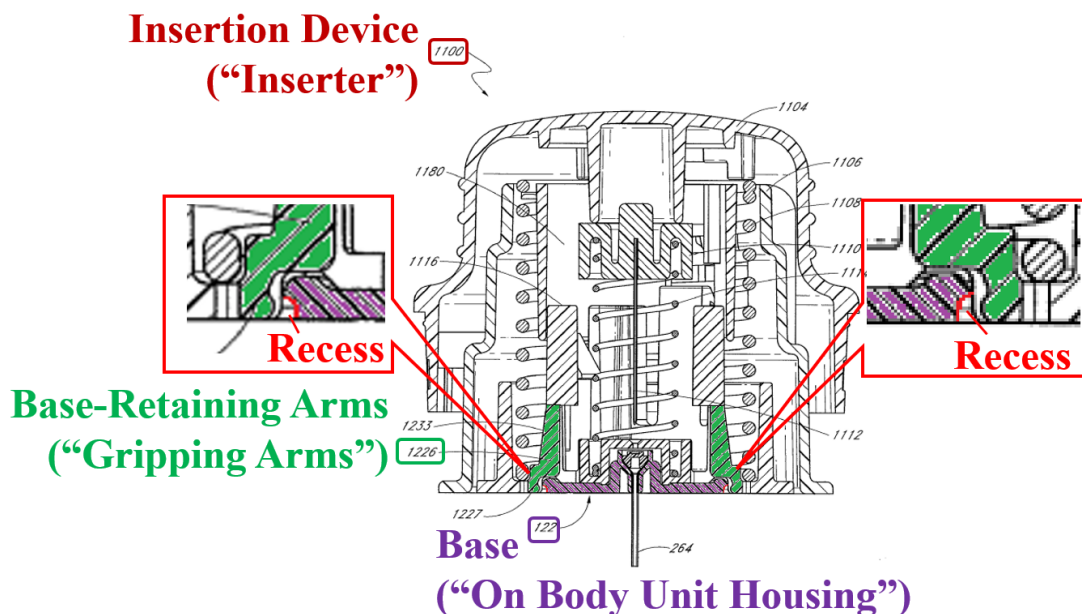


**Raymond, FIG. 29 (annotated)**

107. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the plurality of gripping arms ... [each] configured to be engaged with a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.” *Supra* Section VII.F.

[3.2] wherein the each gripping arm of the plurality of gripping arms is further configured to be disengaged from the corresponding recess of the plurality of recesses when the on body electronics unit is in the distal position.

108. As shown below, each of Raymond's base-retaining arms ("gripping arms," green) clears a cam surface and spreads radially outwardly to be disengaged with Raymond's base's ("on body unit housing," purple) recesses by the time the base reaches the distal position. EX1010, FIGS. 29-30, [0126] ("The base-retaining arms 1226 can spread outwardly when the sleeve-engagement surfaces 1233 of the shuttle 1116 clear the cam surface 1180 of the sleeve 1106. The base-retaining feet 1227 can move away from the base 122 as the base-retaining arms 1126 spread outwardly such that the base 122 can be released from the shuttle 1116."). Thus, each of Raymond's gripping arms are disengaged with a corresponding recess (red) of Raymond's housing when Raymond's on body unit is in the distal position. *Id.*



Raymond, FIG. 30 (annotated)

109. As discussed at [1.5] (§§70-87) and [3.1] (§§106-07), Stafford+Raymond (and Stafford+Raymond+Turner) includes plural recesses formed on the periphery of the on body electronics unit housing as taught by Stafford, wherein each of the arms as taught by Raymond (specifically, the base-retaining foot at the tip portion of each one of the arms as taught by Raymond) engage a corresponding recess. *Supra* Section VII.F. A POSITA would have also understood that each of the gripping arms disengages a corresponding recess on the housing when the housing is in the distal position. *Id.*

110. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the plurality of gripping arms ... [each] configured to be disengaged from the corresponding recess of the plurality of recesses when the on body electronics unit is in the distal position.”

111. Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 3’s limitations, claim 3 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner).

#### **I. Claim 4**

4. The glucose monitoring assembly of claim 2, wherein each gripping arm of the plurality of gripping arms is biased in a radially outward direction.

112. As discussed at [3.2] (§§108-11), Raymond discloses that each base-retaining arm (“gripping arm”) spreads radially outwards when unconstrained by the

sleeve. EX1010, FIGS. 29-30, [0126] (“The base-retaining arms 1226 can spread outwardly when the sleeve-engagement surfaces 1233 of the shuttle 1116 clear the cam surface 1180 of the sleeve 1106”); *supra* Section VII.H. Stafford+Raymond (and Stafford+Raymond+Turner) includes the inserter and gripping arms as taught by Raymond.

113. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the plurality of gripping arms ... [each] biased in a radially outward direction.”

114. Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 4’s limitations, claim 4 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner).

## **J. Claim 8**

8. The glucose monitoring assembly of claim 2, wherein each gripping arm of the plurality of gripping arms comprises an engagement boss configured to engage with a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.

115. The ’335 patent does not define “engagement boss” other than to explain that it is the portion of a gripping arm that is “configured to engage with corresponding recesses 3766 provided on the side walls of the on body housing 322.” EX1001, 44:9-12, 45:61-64. Thus, in view of the term’s plain and ordinary meaning read in light of the specification, an “engagement boss” is understood to encompass a “protrusion.” EX1035, 44 (defining a “boss” as a “[p]rotuberance”).

116. As shown below, Raymond discloses a foot (“engagement boss,” orange) on a tip of each base-retaining arm (“gripping arm,” green). EX1010, FIGS. 29-30, [0123] (“The arms 1226 can include base-retaining feet 1227, to clamp, grasp, or otherwise engage the base 122 and secure it to the shuttle 1116.”). As discussed at [1.5] (§§70-87), a POSITA would have understood Raymond to suggest that each boss engages a corresponding one of the plural recesses when Raymond’s on body unit is in a proximal position. *Id.*; *supra* Section VII.F.

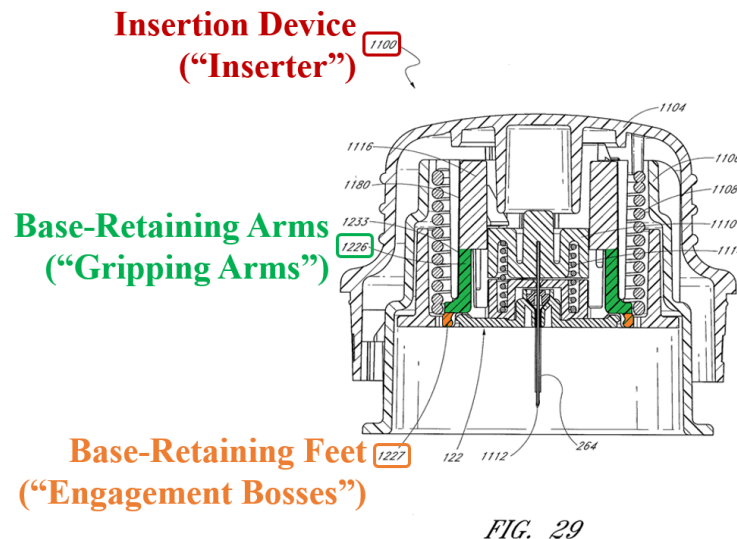


FIG. 29

### Raymond, FIG. 29 (annotated)

117. As discussed at [1.5] (§§70-87), it was at least obvious to implement Stafford+Raymond (and Stafford+Raymond+Turner) with plural recesses on an on body electronics unit housing to engage bosses on the tip portions of corresponding ones of gripping arms. *See supra* Section VII.F.

118. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the plurality of gripping arms [each comprising] an engagement boss configured to engage with a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.”

119. Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 8’s limitations, claim 8 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner).

**K. Claim 9**

9. The glucose monitoring assembly of claim 8, wherein the engagement boss is disposed on a tip portion of the gripping arm.

120. Claim 9 is the only place “tip portion” is recited in reference to the gripping arms. Although the ’335 patent recites “first-angled tip portion” (EX1001, 26:8, 27:4) and “steep-angled tip portion” (*id.*, 26:9, 27:5), these refer to the tip of the sharp. Thus, since the term “tip portion” is only used with respect to the gripping arms in claim 9, a POSITA would have understood this term to refer to the “end portion of the gripping arm.”

121. As shown below, Raymond discloses a foot (“engagement boss,” orange) on an end portion or tip portion of each base-retaining arm (“gripping arm,” green). EX1010, FIGS. 26-27, 29-30; *see id.*, [0123] (“The arms 1226 can include

base-retaining feet 1227”). As discussed at claim 8 (¶¶115-19), Stafford+Raymond (and Stafford+Raymond+Turner) includes the engagement bosses and gripping arms as taught by Raymond. *See supra* Section VII.J.

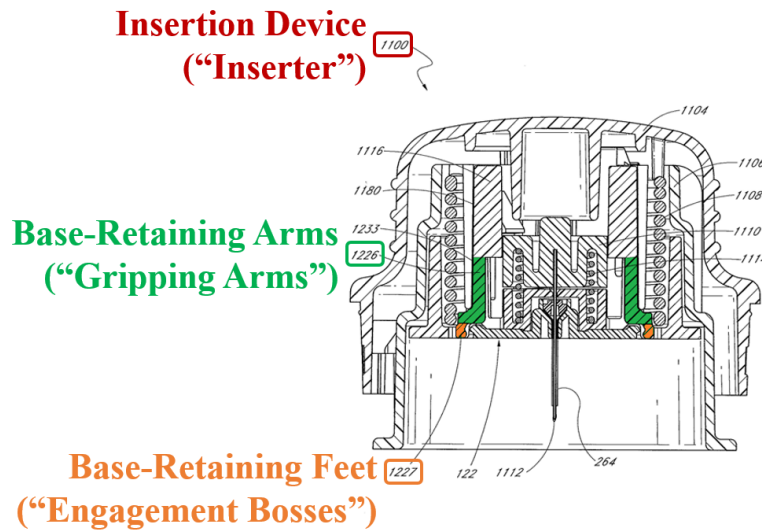


FIG. 29

### Raymond, FIG. 29 (annotated)

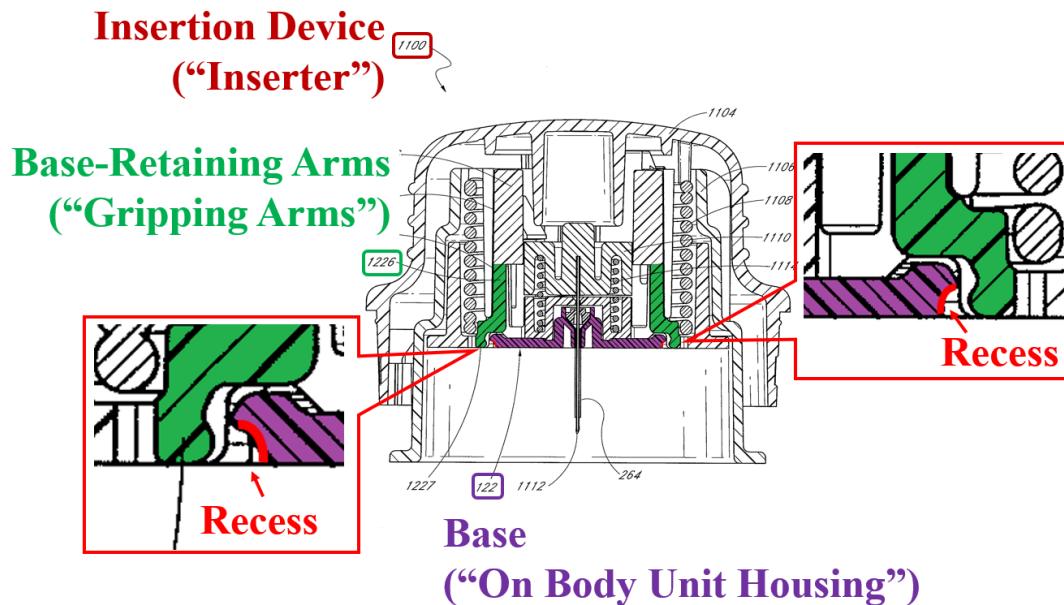
122. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes an “engagement boss ... disposed on a tip portion of the gripping arm.”

123. Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 9’s limitations, claim 9 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner).

### L. Claim 11

11. The glucose monitoring assembly of claim 1, wherein each recess of the plurality of recesses comprises a concave portion.

124. As shown below, Raymond illustrates concave left and right recesses (red). As discussed at [1.5] (§§70-87), a POSITA would have found it at least obvious to form such recesses on the housing as taught by Stafford. *Supra* Section VII.F.



**Raymond, FIG. 30 (annotated)**

125. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the plurality of recesses [each comprising] a concave portion.”

126. Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 11’s limitations, claim 11 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner).

**M. Claim 12**

12. The glucose monitoring assembly of claim 1, wherein each recess of the plurality of recesses is disposed on a side wall of the on body electronics unit housing.

127. Stafford discloses a housing (“on body electronics unit housing”).

*Supra* Section VII.A.

128. As illustrated in the figures at [1.5] (¶¶70-87), Raymond discloses recesses disposed on the sidewall of a base (“on body unit housing”). EX1010, FIGS. 29-30; *supra* Section VII.F.

129. As discussed at [1.5] (¶¶70-87), a POSITA would have found it at least obvious to form plural recesses on the on body electronics unit housing as taught by Stafford. *Supra* Section VII.F. A POSITA would have been motivated by Raymond’s disclosure to form the recesses on the sidewalls of the housing. *See supra* Section VII.B. For example, a POSITA would have been motivated to form the recesses on the sidewalls of the housing instead of the bottom surface of the housing to prevent the gripping arms as taught by Raymond from interfering with the adhesive patch (“adhesive portion”) coupled to the bottom surface as taught by Stafford. *See* EX1009, FIG. 1, [0019] (“[A] data processing unit 101 provided on an upper surface of an adhesive patch 103”). Stafford+Raymond (and Stafford+Raymond+Turner) includes the housing as taught by Stafford and the plural recesses on the sidewall thereof as taught by Raymond.

130. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the plurality of recesses ... [each] disposed on a side wall of the on body electronics unit housing.”

131. Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 12’s limitations, claim 12 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner).

**N. Claim 13**

13. The glucose monitoring assembly of claim 1, wherein the inserter further comprises a driver disposed in the inserter, wherein the driver is configured to apply a force that retracts the sharp after the sharp reaches the distal position.

132. As discussed at [1.3] (¶¶65-68), Stafford discloses a lower portion of an introducer (“sharp”) for inserting Stafford’s sensor. *Supra* Section VII.F.

133. Raymond’s retraction spring (“driver”) retracts a needle (“sharp”) after the needle reaches the distal position. EX1010, FIG. 30, [0127] (“Once the needle hub 1110 is released by the needle-hub-engaging arms 1210, the retraction spring 1114 can push the needle hub 1110 away from the shuttle 1116 to draw the needle 1112 within the insertion device 1100.”).

134. Stafford+Raymond (and Stafford+Raymond+Turner) includes the driver as taught by Raymond, which applies a force to retract a sharp like that disclosed in Stafford after the sharp reaches the distal position.

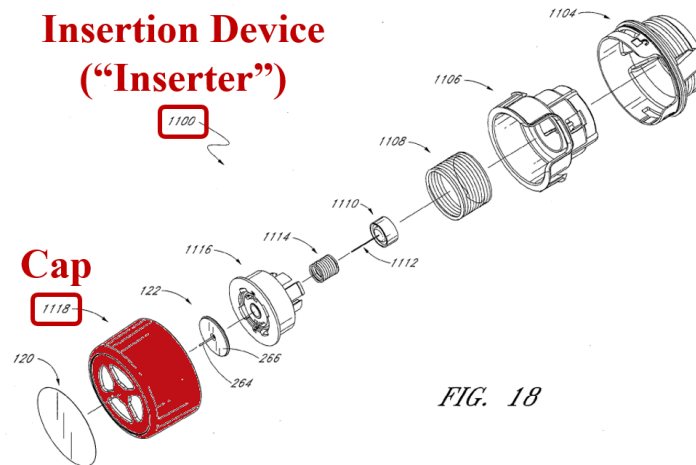
135. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the inserter ... [comprising] a driver disposed in the inserter, wherein the driver is configured to apply a force that retracts the sharp after the sharp reaches the distal position.”

136. Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 13’s limitations, claim 13 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner).

**O. Claim 14**

14. The glucose monitoring assembly of claim 1, further comprising a cap removably attached to a distal portion of the inserter.

137. As shown below, Raymond’s cap (red) is removably attached to the distal portion of Raymond’s insertion device (“inserter”). EX1010, FIG. 18, [0101] (“Once the protective cap 118 is removed from the actuator 104 ....”), [0109] (“The insertion device 1100 is similar in many respects to the insertion device 100. Therefore, similar components of the insertion device 1100 are referenced by the same reference numeral as the corresponding component in the insertion device 100 incremented by one thousand. As with the insertion device 100, the insertion device 1100 can comprise ... a protective cap 1118”). Stafford+Raymond (and Stafford+Raymond+Turner) includes the inserter and cap as taught by Raymond.



**Raymond, FIG. 18 (annotated)**

138. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “a cap removably attached to a distal portion of the inserter.”

139. Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 14’s limitations, claim 14 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner).

#### **P. Claim 15**

[15.1] The glucose monitoring assembly of claim 1, wherein the inserter further comprises an inserter housing and a sheath, and wherein the inserter housing is configured to move in a downward direction towards a skin surface relative to the sheath in response to an application of force on the inserter housing, and

140. As shown below, Raymond’s actuator (“housing, red”) moves downward relative to a sleeve (“sheath, light purple”) placed on the subject’s skin. EX1010, FIGS. 29-30 (illustrating “sleeve 1106” placed against the subject’s skin before and after actuation), [0124] (“[A] lower surface 1176 of the sleeve 1106 can

be placed on the skin at the injection site”), [0125] (“The actuator 1104 can be advanced toward the skin”). Stafford+Raymond (and Stafford+Raymond+Turner) includes the inserter, housing, and sheath as taught by Raymond.

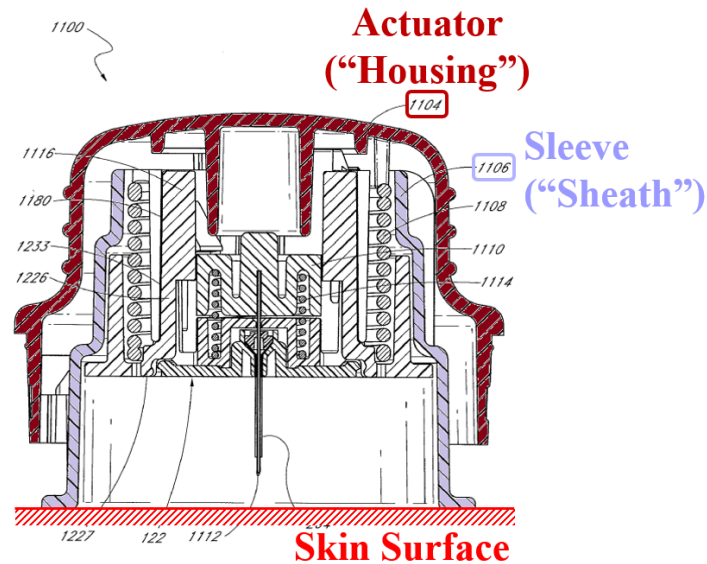


FIG. 29

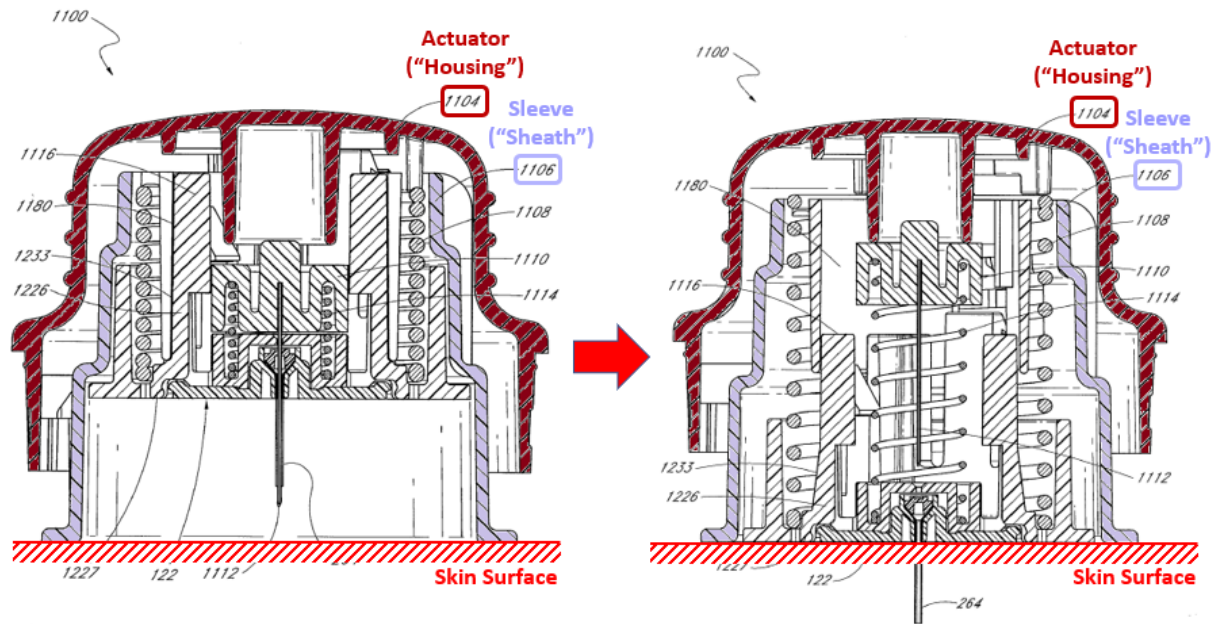
**Raymond, FIG. 29 (annotated)**

141. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “an inserter housing and a sheath ... wherein the inserter housing is configured to move in a downward direction towards a skin surface relative to the sheath in response to an application of force on the inserter housing.”

[15.2] wherein the sheath is configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing.

142. As shown below, Raymond’s sleeve (“sheath,” light purple) is pressed against the subject’s skin both before and after force is applied to the actuator

(“housing,” red). EX1010, FIGS. 29-30 (illustrating “sleeve 1106” placed against the subject’s skin before and after actuation), [0124] (“[A] lower surface 1176 of the sleeve 1106 can be placed on the skin at the injection site”). As discussed at [15.1] (¶¶140-41), Stafford+Raymond (and Stafford+Raymond+Turner) includes the sheath and housing as taught by Raymond.



**Raymond, FIGS. 29-30 (annotated)**

143. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the sheath ... configured to remain stationary relative to the skin surface in response to the application of force on the inserter housing.”

144. Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 15’s limitations, claim 15 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner).

**Q. Claim 17**

17. The glucose monitoring assembly of claim 1, wherein the on body electronics comprises an aperture, and wherein the sharp extends through the aperture of the on body electronics.

145. As shown below, Stafford's integrated assembly ("on body electronics unit" includes a lower portion of an introducer ("sharp," brown) extending through a housing ("on body electronics unit housing," purple"). *See, e.g.*, EX1009, FIG. 2; *see supra* Section VII.A. As discussed at [1.4] (§69), Stafford includes on body electronics disposed within the housing. *Supra* Section VII.F.

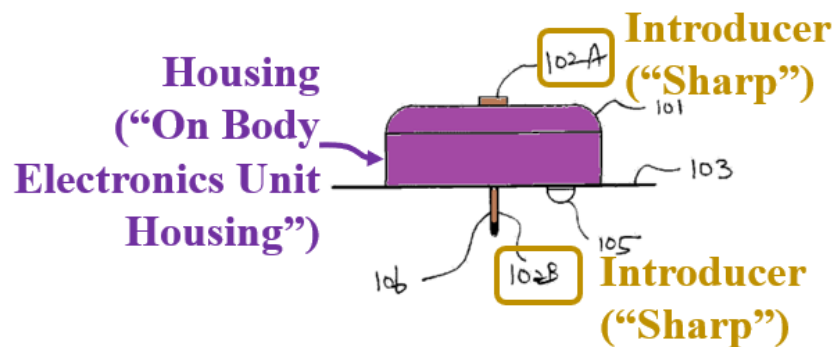


FIGURE 2

**Stafford, FIG. 2 (annotated)**

146. A POSITA would have found it at least obvious to form the first aperture in the electronics as taught by Stafford.

147. For example, Stafford discloses that the housing (and, consequently, the electronics disposed within the housing) desirably has a "small profile." EX1009, [0045]; *see supra* Section VII.F. A POSITA implementing a "small profile" on body

electronics unit would have made the electronics as large as possible relative to the housing to minimize empty space within the housing. Since relatively large electronics would have naturally occupied a center portion of the housing, and Stafford illustrates the sharp extending through the center portion, a POSITA would have formed the first aperture in the electronics for the sharp to extend therethrough.

148. *Thus*, Stafford+Raymond (and Stafford+Raymond+Turner) includes “an aperture, and wherein the sharp extends through the aperture of the on body electronics.”

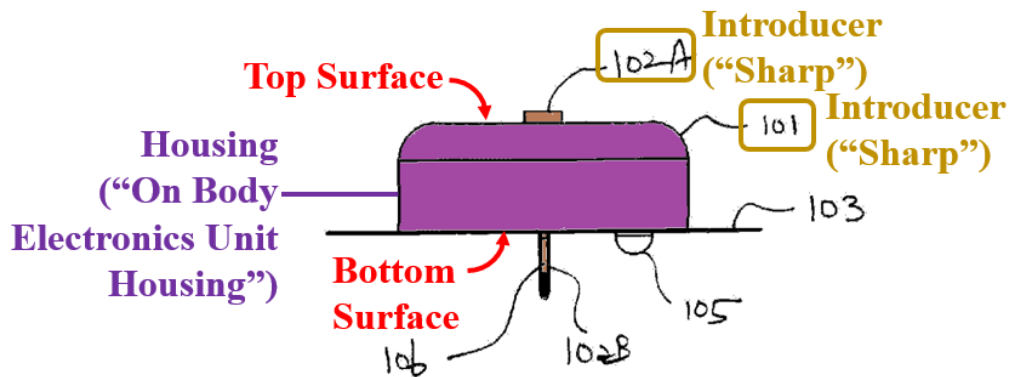
149. Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 17’s limitations, claim 17 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner).

**R. Claim 18**

18. The glucose monitoring assembly of claim 17, wherein the aperture of the on body electronics is a first aperture, wherein the on body electronics unit housing further comprises a top surface and a bottom surface, wherein the top surface comprises a second aperture, wherein the bottom surface comprises a third aperture, and wherein the sharp extends through the first aperture, the second aperture, and the third aperture when the on body electronics unit is in the proximal position.

150. As discussed at claim 17 (¶¶145-49), Stafford teaches a first aperture in Stafford’s electronics. *See supra* Section VII.Q. Stafford’s sharp extends through the first aperture before insertion. *Id.*

151. As shown below, Stafford's introducer ("sharp," brown) extends through top and bottom surfaces (red) of a housing ("on body electronics unit housing," purple). EX1009, FIG. 2. Since Stafford's sharp is unable to extend through these surfaces without apertures therein, a POSITA would have understood that Stafford at least suggests second and third apertures in the top and bottom surfaces of the housing.



**Stafford, FIG. 2 (annotated)**

152. A POSITA would have found it at least obvious to form the first aperture in the on body electronics as taught by Stafford and the second and third apertures in the top and bottom surfaces of the housing as taught by Stafford. A sharp like that disclosed in Stafford extends through the first, second, and third apertures before insertion. As discussed at [1.8] (§§95-98), the housing is in the proximal position within the inserter as taught by Raymond before insertion. *Supra* Section VII.F.

153. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the [first] aperture of the on body electronics ... the on body electronics unit housing further [comprising] a top surface and a bottom surface, wherein the top surface comprises a second aperture, wherein the bottom surface comprises a third aperture, and wherein the sharp extends through the first aperture, the second aperture, and the third aperture when the on body electronics unit is in the proximal position.”

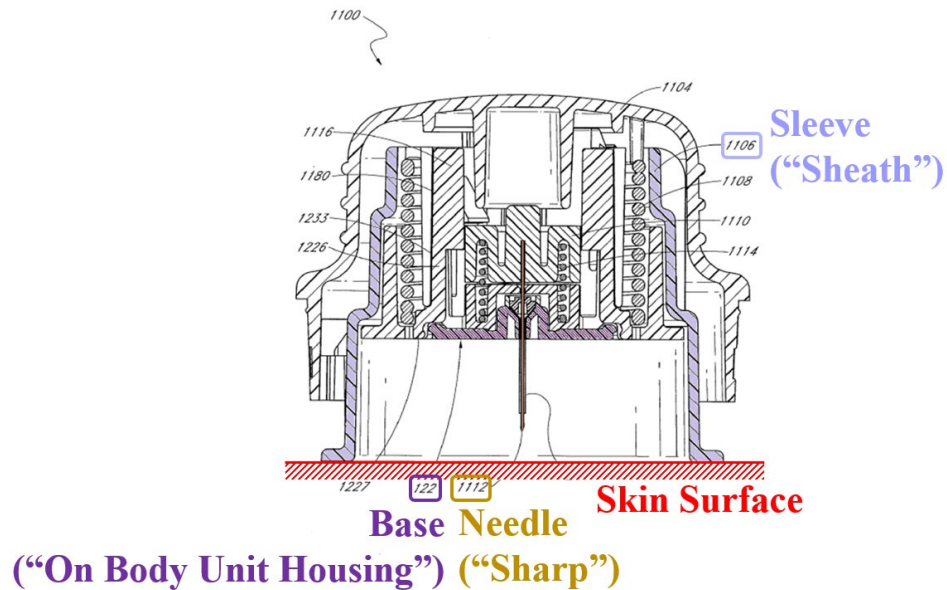
154. Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 18’s limitations, claim 18 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner).

**S. Claim 19**

19. The glucose monitoring assembly of claim 1, wherein the inserter further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit and the sharp.

155. Stafford discloses an integrated assembly (“on body electronics unit”) and an introducer (“sharp”). *Supra* Section VII.A.

156. As shown below, Raymond’s insertion device (“inserter”) includes a distal end (*e.g.*, a distal end of sleeve 1106, light purple) placed on the subject’s skin before the advancement of Raymond’s infusion device (“on body unit,” purple) and needle (“sharp,” brown). EX1010, [0124] (“[A] lower surface 1176 of the sleeve 1106 can be placed on the skin”).



**Raymond, FIG. 29 (annotated)**

157. Stafford+Raymond (and Stafford+Raymond+Turner) includes the on body electronics unit as taught by Stafford, a sharp like that disclosed in Stafford, and the distal end of the inserter as taught by Raymond.

158. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “a distal end [of an inserter] configured to be placed on a skin surface of the subject before advancement of the on body electronics unit and the sharp.”

159. Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 19’s limitations, claim 19 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner).

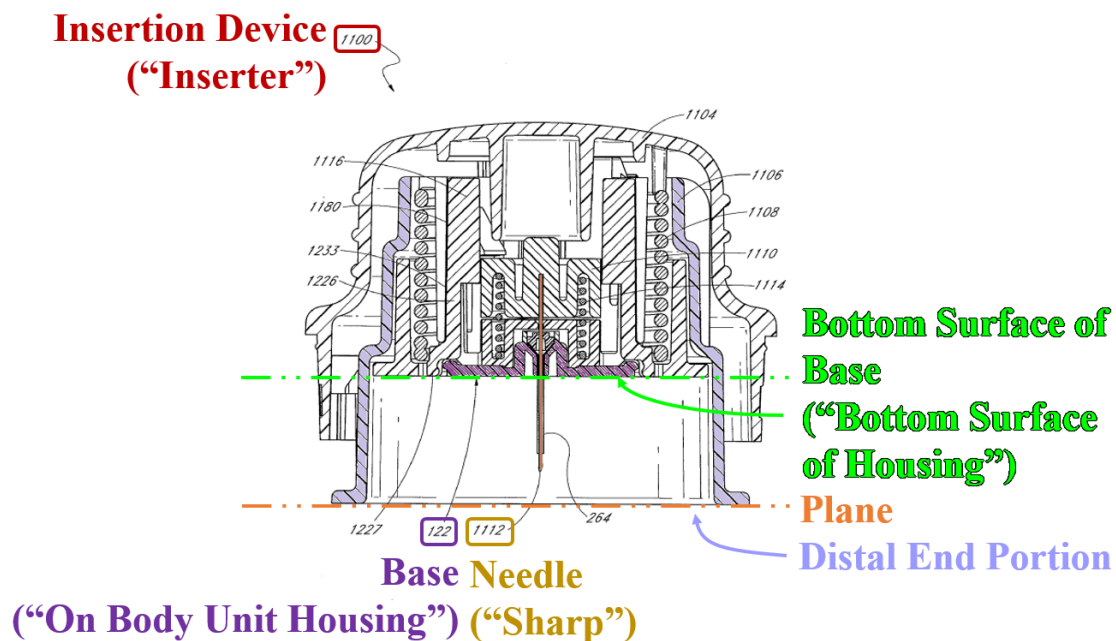
## **T. Claim 20**

20. The glucose monitoring assembly of claim 19, wherein the distal end of the inserter defines a plane, and wherein a bottom surface of the on body electronics

unit housing is parallel to the plane when the on body electronics unit and the sharp are in the proximal position.

160. As discussed at claim 18 (§§150-54), Stafford's housing ("on body electronics unit housing") includes a bottom surface. *Supra* Section VII.R. As discussed at [1.3] (§§65-68), Stafford discloses a sharp. *Supra* Section VII.F.

161. As shown below, Raymond's insertion device ("inserter") includes a distal end defining a plane (orange). Furthermore, Raymond's base ("on body unit housing," purple) includes a bottom surface parallel (as shown by the green line) to the first plane when the housing and a needle ("sharp," brown) are in a proximal position.



**Raymond, FIG. 29 (annotated)**

162. Stafford+Raymond (and Stafford+Raymond+Turner) includes the distal end of the inserter as taught by Raymond, a sharp like that disclosed in

Stafford, and the on body electronics unit housing as taught by Stafford. The distal end of the inserter defines a plane parallel to the bottom of Stafford's housing when Stafford's sharp and housing are in the proximal position.

163. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes "the distal end of the inserter [defining] a plane, and wherein a bottom surface of the on body electronics unit housing is parallel to the plane when the on body electronics unit and the sharp are in the proximal position."

164. Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 20's limitations, claim 20 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner).

**U. Claim 21**

21. The glucose monitoring assembly of claim 1, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit is in the proximal position.

165. The '335 patent discloses a "no power state" and "inactive mode" as examples of the claimed "low power state." EX1001, 11:45-49 ("[A]nother portion of the components in the on body electronics may be in powered down or maintained in a low power state including no power state, inactive mode, or all components may be in an inactive, powered down mode.")

166. Stafford discloses an integrated assembly ("on body electronics unit") that includes a data processing unit that is powered off before use. EX1009, [0037]

(“[T]he data processing unit 101 may be configured to transmit the encoded sampled data signals at a fixed rate (e.g., at one minute intervals) *after the completion of the initial power on procedure.*”). Since Stafford’s “powered off” state is a “no power state” as well as an “inactive mode,” Stafford also discloses a “low power state.”

167. Even without Stafford’s express disclosure, a POSITA would have found it obvious to place on body electronics in a low power state before use to conserve battery power. For example, Say discloses an on-skin sensor control unit that enters a “sleep mode” (in which a portion of the electronics are not activated) before use to conserve battery power. EX1012, 31:41-62 (“The on-skin sensor control unit 44 optionally remains in a sleep mode prior to use to conserve the battery's power”). Additionally, Cosentino (EX1023) discloses a glucose meter communication system that is initially powered off. *See* EX1023, [0240] (“The system 2800 is initiated by a start module 2802. In a power module 2804, a user, such as a patient, powers on the system 2800.”).

168. As discussed at [1.8] (¶¶95-98), Stafford+Raymond (and Stafford+Raymond+Turner) includes the on body electronics unit as taught by Stafford retained in the proximal position within the inserter as taught by Raymond. *Supra* Section VII.F.

169. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “at least a portion of the on body electronics ... in a low power state when the on body electronics unit is in the proximal position.”

170. Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 21’s limitations, claim 21 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner).

## V. Claim 22

22. The glucose monitoring assembly of claim 1, further comprising an adhesive portion configured to secure the on body electronics unit housing to a skin surface of the subject.

171. Stafford discloses an adhesive patch (“adhesive portion”). EX1009, [0019] (“[A]n integrated analyte sensor delivery and data processing unit assembly 100 includes ...an adhesive patch 103 .... [T]he adhesive patch 103 and the data processing unit 101 [securely attach] on a surface of a subject such as the skin of a patient.”). Stafford+Raymond (and Stafford+Raymond+Turner) includes the adhesive portion as taught by Stafford.

172. Thus, Stafford+Raymond includes “an adhesive portion configured to secure the on body electronics unit housing to a skin surface of the subject.”

173. Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 22’s limitations, claim 22 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner).

**W. Claim 23**

23. The glucose monitoring assembly of claim 1, wherein at least a portion of the on body electronics is in a no power state when the on body electronics unit is in the proximal position.

174. The “no power state” of claim 23 would have been obvious for the reasons discussed at claim 21 (§§165-70). *See supra* Section VII.U.

175. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “at least a portion of the on body electronics ... in a no power state when the on body electronics unit is in the proximal position.”

176. Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 23’s limitations, claim 23 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner).

**X. Claim 24**

24. The glucose monitoring assembly of claim 1, wherein at least a portion of the on body electronics is in an inactive mode when the on body electronics unit is in the proximal position.

177. The “inactive mode” of claim 24 would have been obvious for the reasons discussed at claim 21 (§§165-70). *See supra* Section VII.U.

178. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “at least a portion of the on body electronics ... in an inactive mode when the on body electronics unit is in the proximal position.”

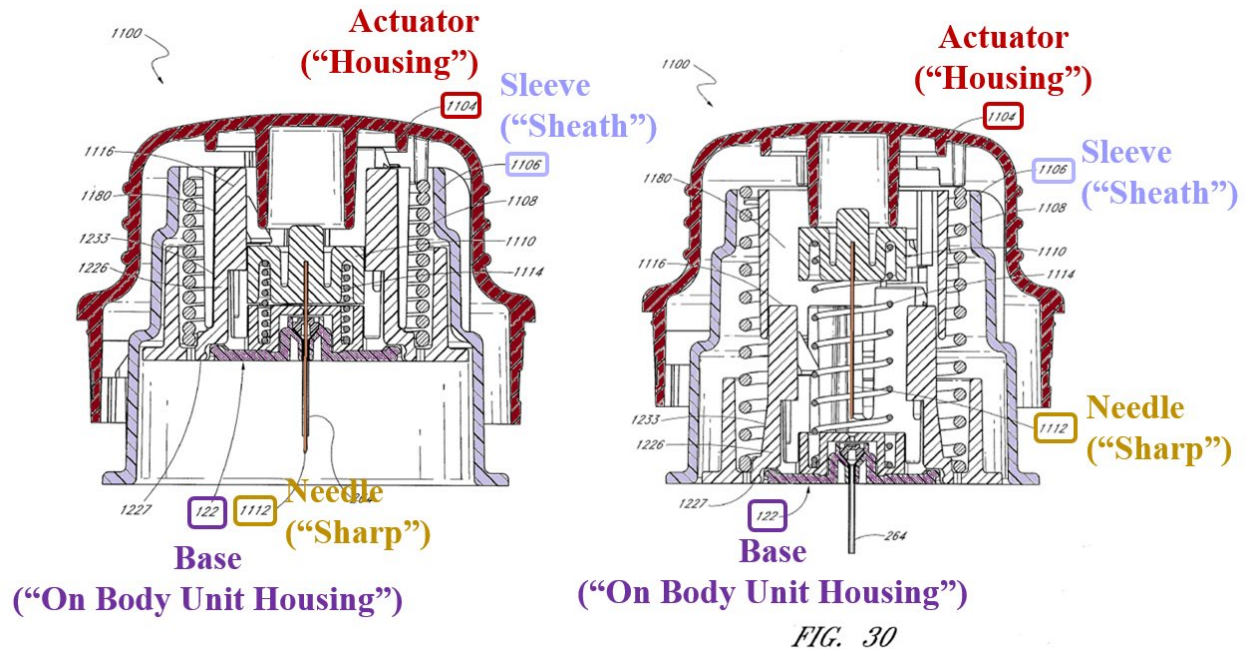
179. Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 24's limitations, claim 24 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner).

**Y. Claim 25**

25. The glucose monitoring assembly of claim 1, wherein the on body electronics unit and the sharp are configured to advance in a linear direction when advancing from the proximal position within the inserter to the distal position.

180. Stafford discloses an integrated assembly ("on body electronics unit") and an introducer ("sharp"). EX1009, [0006] ("An integrated assembly ... includes ... an introducer removably coupled to the housing"), [0021] ("[T]he introducer is configured with a sharp tip").

181. As shown below, Raymond discloses an infusion set ("on body unit," purple) and a needle ("sharp," brown), both of which linearly advance from a proximal position (FIG. 29) within an actuator (red) and sleeve (light purple) of Raymond's insertion device ("inserter") to a distal position (FIG. 30). EX1010, FIGS. 29-30.



### Raymond, FIGS. 29-30 (annotated)

182. In Stafford+Raymond (and Stafford+Raymond+Turner), the inserter as taught by Raymond linearly advances the on body electronics unit as taught by Stafford and a sharp like that disclosed in Stafford between proximal and distal positions.

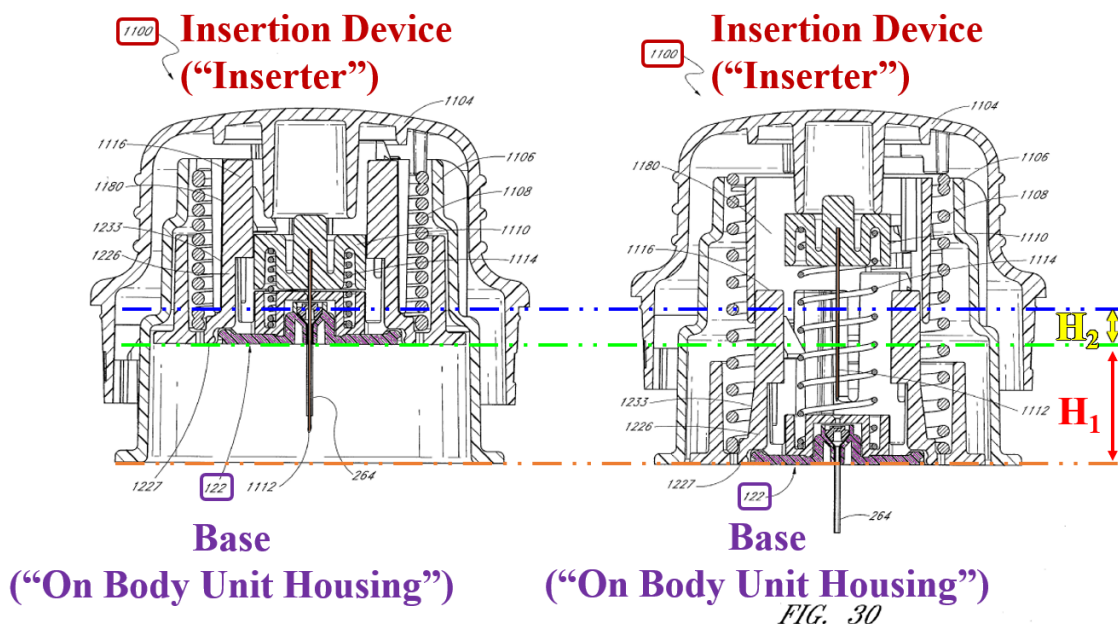
183. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the on body electronics unit and the sharp ... configured to advance in a linear direction when advancing from the proximal position within the inserter to the distal position.”

184. Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 25’s limitations, claim 25 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner).

**Z. Claim 26**

26. The glucose monitoring assembly of claim 1, wherein a distance between the on body electronics unit housing when the on body electronics unit is in the proximal position and the on body electronics unit housing when the on body electronics unit is in the distal position is greater than a maximum height of the on body electronics unit housing.

185. As shown below, Raymond discloses that a distance (“H<sub>1</sub>,” red, between the green and orange lines) between an infusion device’s base (“on body unit housing,” purple) in a proximal position (FIG. 29) and the base in a distal position (FIG. 30) is greater than a maximum height (“H<sub>2</sub>,” yellow, between the blue and green lines) of the base. EX1010, FIGS. 29-30. Based on Raymond’s teachings, a POSITA would have configured the travel distance of the on body electronics unit as taught by Stafford to be greater than the height of the on body electronics unit housing as taught by Stafford.



**Raymond, FIGS. 29-30 (annotated)**

186. Raymond's disclosure of these relative dimensions is at least equivalent to what is described in the '335 patent. *Compare*, EX1001, FIGS. 123-125 with EX1010, FIGS. 29-30. In particular, the '335 patent's specification neither describes a distance between the housing when the on body electronics unit is in a proximal position and when the on body electronics unit is in a distal position nor that this distance of travel is greater than the housing's height. Rather, to the extent that the '335 patent supports claim 26, any disclosure appears to come exclusively from its figures.

187. Even without Raymond's express teachings, it was an obvious design choice to configure Stafford+Raymond (and Stafford+Raymond+Turner) such that the on body electronics unit's travel distance is greater than the housing's height. A POSITA would have formed the housing to have a small profile to reduce packaging and cost as taught by Stafford. EX1009, [0045] ("Furthermore, by integrating the analyte sensor, the introducer as well as the data processing unit into a single assembly, it is possible to have a smaller profile, simpler use application with less packaging thereby achieving cost reduction in manufacturing. Indeed, by reducing the number of components needed for sensor placement, within the scope of the present invention, other benefits such as reduction in material cost, weight, packaging, and associated handling and disposal may be achieved"). It was also

known to implement glucose sensors with *in vivo* sensor portions longer than the housing's height. *See, e.g.*, EX1014, FIG. 1A, [0034] (“In some embodiments, the entire mounting base 10 with the flexible sensor 70 is approximately 0.06 inches thick, including the adhesive layer 20, not to exceed past 0.1 inches.”); EX1028, 8:53-55 (“For example, in some embodiments, the on-skin sensor control unit 44 has a height of 1.3 cm [0.51 inches] or less, and preferably 0.7 cm [0.27 inches] or less.”), 16:3-5 (“Tail 424 of introducer sharp 340 provides rigidity and a skin piercing edge 430 for allowing the flexible tail 431 of sensor 314 to be implanted in the patient's skin.”), 17:11-12 (“The length and width of introducer tail 424 are 0.354 and 0.036 inches [0.899 cm and 0.091 cm], respectively”). A POSITA would have understood that a longer sensor would also ensure contact with sub-dermal fluids and provide better glucose readings. Thus, it was a natural design choice to implement a sensor with a subcutaneous portion at least as long as the height of the housing.

188. Furthermore, a POSITA would have been motivated to configure the *in vivo* portion of the sharp to have a length greater than the length of the glucose sensor's *in vivo* portion to ensure sufficient protection of the sensor during insertion. Additionally, as taught by Raymond, a POSITA would have configured the travel distance of the *in vivo* portion of the sharp and the housing fixedly coupled thereto to be greater than the length of the corresponding portion of the sharp to ensure that the sharp is protected before insertion to prevent against needlesticks. EX1010,

[0127] (Thus, the needle 1112 can be protected both before and after insertion of the base 122 to prevent accidental needle sticks. This automatic retraction feature can ensure that the needle 1212 is only exposed while the infusion device 102 is being inserted.”); *see also id.*, [0104] (“Thus, the needle 112 can be protected both before and after insertion of the base 122 to prevent accidental needlesticks. This automatic retraction feature can ensure that the needle 212 is only exposed while the infusion device 102 is being inserted. In some embodiments, the insertion device 100 can be configured to be used only a single time such that the insertion device 100 can be discarded with the needle safely retained therein.”), [0109] (“The insertion device 1100 is similar in many respects to the insertion device 100.”).

189. This obvious implementation of the on-body electronics unit (with the length of the *in vivo* sensor portion greater than the height of the low-profile housing) and the inserter device (with the needle extending past the end of the sensor and the needle point withdrawn from the edge of the inserter prior to insertion) would result in a travel distance  $H_1$  greater than the height of the housing  $H_2$ .

190. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “a distance between the on body electronics unit housing when the on body electronics unit is in the proximal position and the on body electronics unit housing when the on body electronics unit is in the distal position is greater than a maximum height of the on body electronics unit housing.”



193. Thus, Stafford+Raymond (and Stafford+Raymond+Turner) includes “the sharp ... further configured to pierce a skin surface of the subject at an angle substantially perpendicular to the skin surface of the subject.”

194. Since Stafford+Raymond (and Stafford+Raymond+Turner) discloses each one of claim 27’s limitations, claim 27 is therefore obvious in view of Stafford+Raymond (and Stafford+Raymond+Turner).

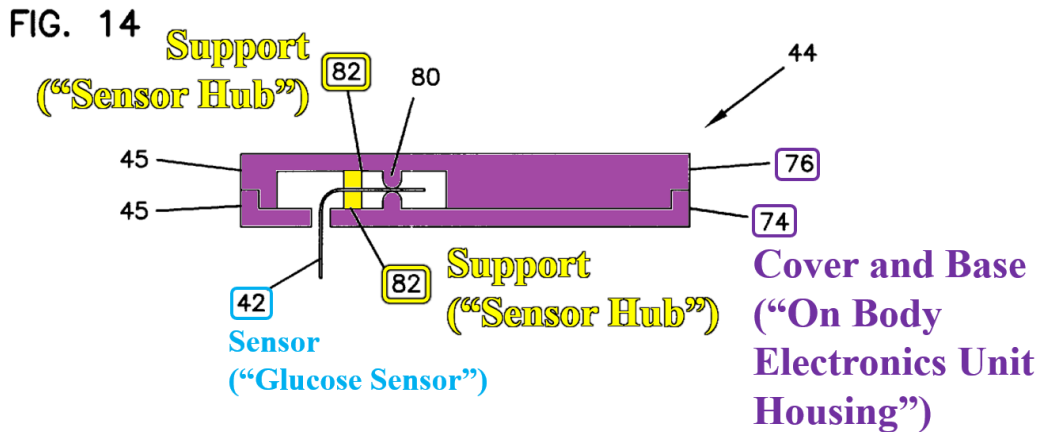
**VIII. GROUNDS 3 & 4: CLAIM 16 IS OBVIOUS  
OVER STAFFORD, RAYMOND, AND SAY (GROUND 3),  
AND FURTHER IN VIEW OF TURNER (GROUND 4)**

195. As explained below, claim 16 is obvious over Stafford+Raymond and further in view of Say (and Turner).

**A. Say**

196. U.S. Patent No. 6,175,752 (EX1012, “Say”), entitled “Analyte Monitoring Device and Methods of Use,” was issued January 16, 2001.

197. As shown below, Say discloses that a support (yellow) can be disposed within a housing (purple) of a sensor control unit to promote adequate contact between an analyte sensor (blue) and the electrical contacts of corresponding sensor electronics. EX1012, 34:53-35:5 (“In one embodiment, the conductive contacts 80 are pins 84 .... A support 82 may be provided under the sensor 42 to promote adequate contact between the contact pads 49 on the sensor 42 and the pins 84.”).



Say, FIG. 14 (annotated)

**B. The Stafford+Raymond+Say  
(And Stafford+Raymond+Turner+Say) Combination**

198. The combinations of Stafford, Raymond, and Say ("Stafford+Raymond+Say") and Stafford, Raymond, Turner, and Say ("Stafford+Raymond+Turner+Say") applied herein further combine teachings from Stafford+Raymond and Stafford+Raymond+Turner with teachings from Say related to the combination an on body electronics unit with Say's support. In addition to the aforementioned elements of Stafford+Raymond, Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) further include the following elements.

- Stafford's integrated assembly comprising Say's support.

199. Say (disclosing a transcutaneous medical device for diabetes treatments) is analogous art to the claimed invention of the '335 patent and is further analogous art to Stafford, Raymond, and Turner. EX1012, 3:8-11 ("An insertion gun is aligned with a port on the mounting unit. The electrochemical sensor is disposed

within the insertion gun and then the electrochemical sensor is inserted into the skin of the patient using the insertion gun.”), 54: 32-34 (“As an example, a glucose sensor could be used to control and adjust the administration of insulin.”); *see supra* Sections VII.D-E (characterizing the ’335 patent, Stafford, Raymond, and Turner as analogous art).

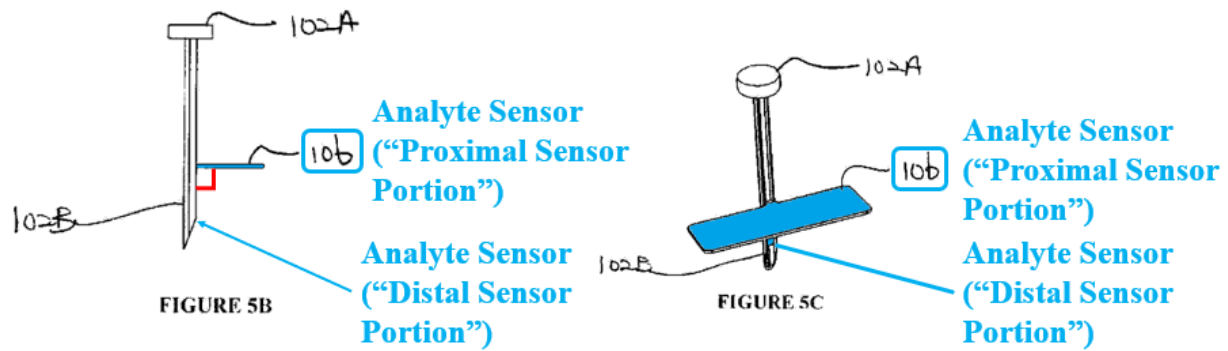
**1. A POSITA Would Have Been Motivated To Combine Stafford, Raymond, And Say (And Turner)**

200. A POSITA would have understood that it is desirable to promote adequate contact between a sensor and its associated electronics. A POSITA understanding such goals and reading Say would have been motivated to add a support as taught by Say to electronics as taught by Stafford to ensure adequate electrical contact between the sensor and electronics.

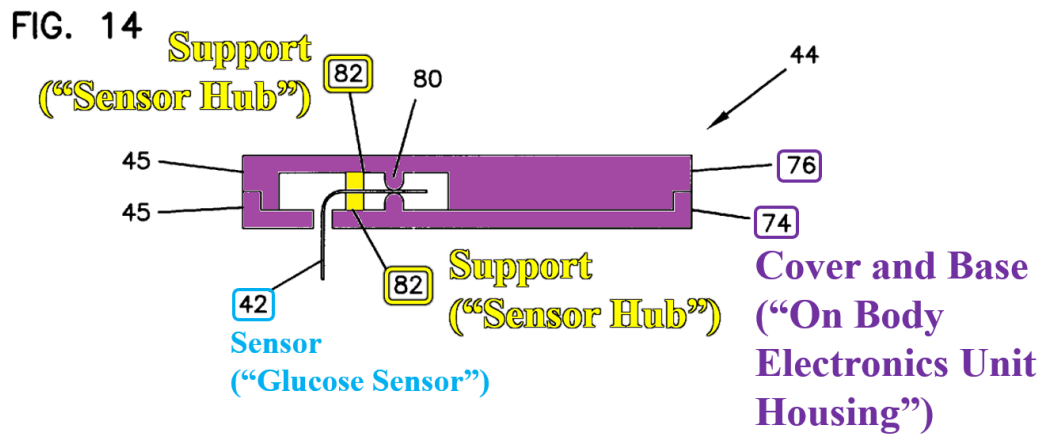
201. Thus, a POSITA would have been motivated to combine teachings from Stafford+Raymond with teachings from Say (and Turner).

**2. A POSITA Would Have Had A Reasonable Expectation Of Success In Combining Raymond, Stafford And Say (And Turner)**

202. A POSITA would have had a reasonable expectation of success of adding the support as taught by Say to the electronics as taught by Stafford because Say’s sensor and Stafford’s sensor have similar shapes and are supported in a similar fashion. *Compare, e.g., EX1009, FIGS. 5B-5C with EX1012, FIG. 14.*



Stafford, FIGS. 5B-5C (annotated)



Say, FIG. 14 (annotated)

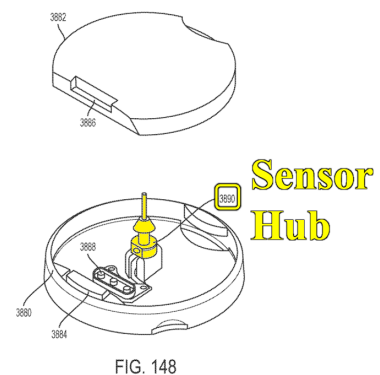
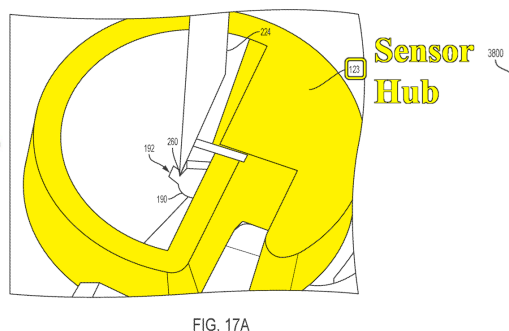
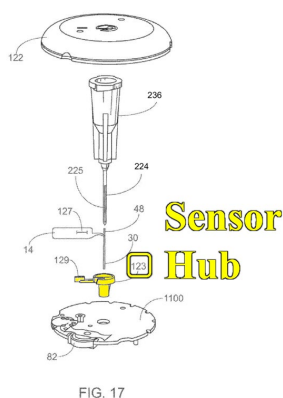
203. A POSITA would have only required ordinary skill to combine teachings from Stafford+Raymond with teachings from Say (and Turner).

204. Thus, a POSITA would have had a reasonable expectation of success in combining the teachings of Stafford, Raymond, and Say (and Turner).

### C. Claim 16

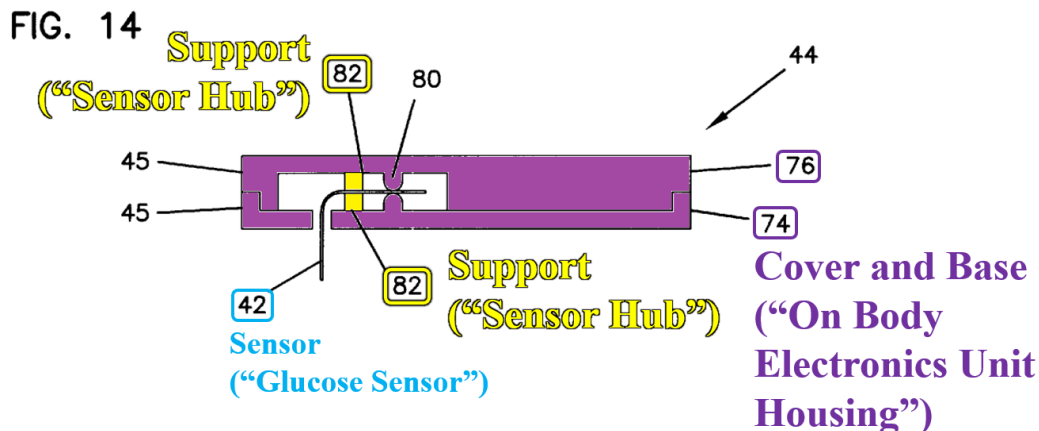
[16.1] The glucose monitoring assembly of claim 1, wherein the on body electronics unit further comprises a sensor hub,

205. The '335 patent provides several examples of a sensor hub, all of which encompass a structure positioned within the housing of the on-body unit that supports the portion of the sensor electrically coupled to electrical contacts. *See, e.g.*, EX1001, FIGS. 17, 17A, 148; *id.*, 27:41-49 (“[S]ensor hub 123 ... includes an aperture 190 through which sharp 224 and sensor 14 are configured to pass through.”), 46:65-47:4 (“The sensor hub 3890 stores at least a portion of the sensor which is electrically coupled to the contacts 3888.”), 47:18-49 (“In some embodiments, the sensor is at least partially positioned within the sensor hub 4022 and the distal insertion portion extends out of the sensor hub 4022. The sensor hub 4022 is contained in the inserter, and the housing unit 4020 is positioned in the inserter 3700. Electrical contact is made between the housing unit 4020 and the sensor in order to transfer the analyte readings from the sensor to the housing unit 4020.”).



**'335 Patent, FIG. 17-17A and 148 (annotated)**

206. As shown below, Say discloses an on-skin sensor control unit (an “on body electronics unit” functionally similar to Stafford’s data processing unit) including a support (“sensor hub,” yellow) disposed under an analyte sensor (“glucose sensor,” blue). EX1012, FIG. 14, 34:53-35:5 (“In one embodiment, the conductive contacts 80 are pins 84 .... A support 82 may be provided under the sensor 42 to promote adequate contact between the contact pads 49 on the sensor 42 and the pins 84.”). Say’s sensor hub is disposed within a housing (“on body electronics unit housing,” purple). *Id.* Thus, Say discloses an on body electronics unit comprising a “sensor hub.”



**Say, FIG. 14 (annotated)**

207. The most natural understanding of Say’s support structure is a separate structure that satisfies the claimed “sensor hub” limitation.

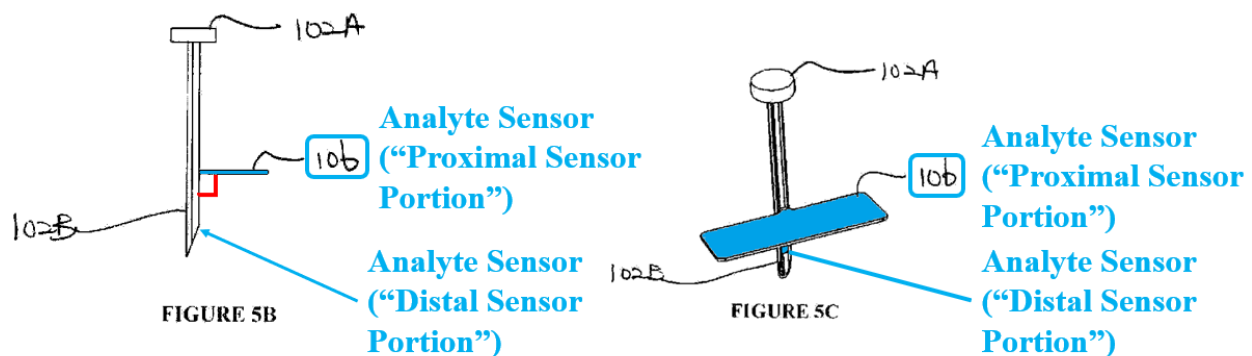
208. Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) includes the sensor as taught by Stafford and the support as taught by Say supporting

a proximal portion of the sensor (*e.g.*, the proximal portion of the sensor coupled to the electronics at the analog interface). A POSITA would have been motivated to add the support with a reasonable expectation of success. *See supra* Sections VIII.B.1-2.

209. Thus, Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) includes “the on body electronics unit further [comprising] a sensor hub.”

[16.2] wherein the glucose sensor comprises a distal sensor portion and a proximal sensor portion,

210. As shown below, Stafford’s sensor has proximal and distal sensor portions. EX1009, FIGS. 5B-5C; *see supra* Section VII.A. As discussed in Grounds 1-2, Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) includes the sensor as taught by Stafford. *See supra* Section VII.F.



**Stafford, FIG. 5B–5C (annotated)**

211. Thus, Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) includes “the glucose sensor [comprising] a distal sensor portion and a proximal sensor portion.”

[16.3] wherein the distal sensor portion is configured to sense the glucose level of the subject,

212. Stafford's glucose sensor includes a distal sensor portion configured to sense the glucose level of the subject. EX1009, [0028] ("[A] portion of the analyte sensor 106 is disposed within the lower portion 102B of the introducer such that, the user or patient may easily, and accurately position the analyte sensor 106 under the skin layer to establish fluid contact with the patient's analyte, and thereafter, to provide the detected analyte levels from the analyte sensor 106 to the data processing unit 101."); [0051] ("The analyte sensor may include a glucose sensor."). As discussed in Grounds 1-2, Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) includes Stafford's sensor. *See supra* Section VII.F.

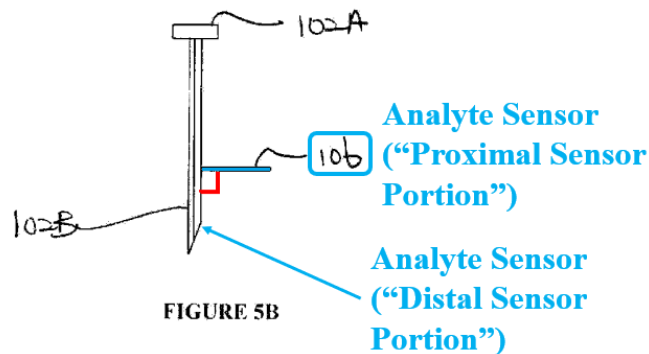
213. Thus, Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) includes "the distal sensor portion ... configured to sense the glucose level of the subject."

[16.4] wherein the proximal sensor portion is engaged with the sensor hub, and

214. As discussed at [16.1] (§§205-09), Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) teaches this element.

[16.5] wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

215. As shown below, the distal portion of Stafford's sensor (blue) is orthogonal (as indicated in red) to Stafford's sensor's proximal portion. EX1009, FIG. 5B; *see supra* Section VII.A. As discussed in Grounds 1-2, Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) includes Stafford's sensor. *See supra* Section VII.F.



**Stafford, FIG. 5B (annotated)**

216. Thus, Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) includes “the distal sensor portion ... substantially orthogonal to the proximal sensor portion.”

217. Since Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) discloses each one of claim 16's limitations, claim 16 is therefore obvious in view of Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say).

**IX. GROUND 5 & 6: CLAIM 16 IS OBVIOUS OVER STAFFORD, RAYMOND, AND BICKOFF (GROUND 5), AND FURTHER IN VIEW OF TURNER (GROUND 6)**

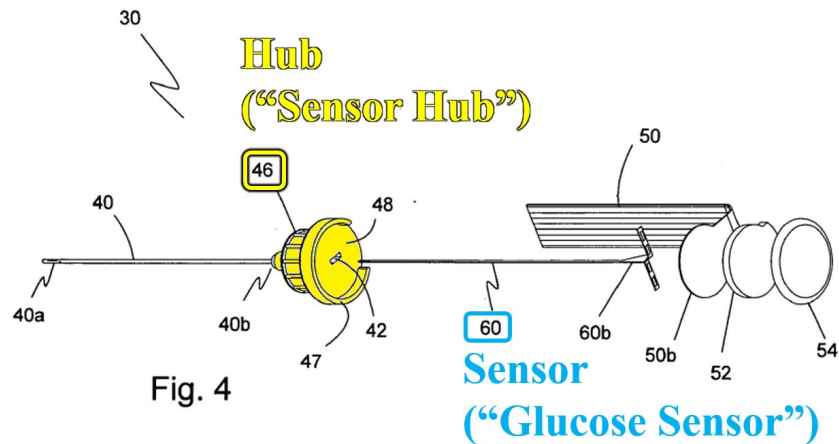
218. As explained below, if claim 16 is deemed non-obvious over Stafford+Raymond (and Turner), this claim is obvious over Stafford in view of Raymond and further in view of Bickoff (and Turner).

**A. Bickoff**

219. U.S. Publication No. 2009/0240121 (“Bickoff,” EX1013), entitled “INTRAVASCULAR SENSOR AND INSERTION SET COMBINATION,” was published September 24, 2009, from an application filed March 21, 2008.

220. As shown below, Bickoff discloses a hub (yellow) that receives a proximal portion of a sensor (blue). EX1013, [0034] (“Sensor assembly 30 includes a sensor sheath 40 sealingly connected to a sensor hub 46 from which sensor cable 50 extends.”), [0035] (“Sensor 60 has a shank proximal end 60b that is received within hub 46 against a hub surface 48 along with a sensor cable proximal end 50b. Sensor 60 and cable proximal end 50b are fixedly retained within hub 46 by a pressure applying component 52 and a pressure cap 54.”). The hub helps retain the sensor to maintain good electrical contact between the sensor and sensor electronics. *Id.*, [0038] (“As shown, cable proximal end 50b is preferably shaped to be captured within perimeter wall 47 of hub 46. As previously disclosed, pressure applying component 52 (not shown) is positioned on top of cable proximal end 50b ....

[P]ressure cap 54, when installed, pushes pressure applying component 53 against cable proximal end 50b in order to maintain good electrical contact between electrical contacts 65 of contact ears 64 and the corresponding portions of exposed electrical conductors 51 at cable proximal end 50b.”).



**Bickoff, FIG. 4 (annotated)**

**B. The Stafford+Raymond+Bickoff  
(And Stafford+Raymond+Turner+Bickoff) Combination**

221. The combination of Stafford, Raymond, and Bickoff (“Stafford+Raymond+Bickoff”) applied herein further combines teachings from Stafford and Raymond with teachings from Bickoff related to the combination an on body electronics unit (*e.g.*, Stafford’s integrated assembly) with Bickoff’s hub. The combination of Stafford, Raymond, Turner, and Bickoff (“Stafford+Raymond+Turner+Bickoff”) applied herein further combines teachings from Stafford+Raymond+Turner with these teachings from Bickoff. In addition to

the aforementioned elements of Stafford+Raymond, Stafford+Raymond+Bickoff (and Stafford+Raymond+Turner+Bickoff) further includes the following elements:

- Stafford's integrated assembly comprising Bickoff's hub.

222. Bickoff (disclosing a transcutaneous medical device for diabetes treatments) is analogous art to the '335 patent and, furthermore, is analogous art to Stafford, Raymond, and Turner. EX1013, [0011] ("The present invention achieves these and other objectives by providing an intravascular sensor and insertion set combination and method for the placement of an indwelling sensor within an inserted intravenous catheter."), [0013] ("[A monitor] processes the sensor signals and displays analytical values, trends and other patient related data for the measured analyte. A typical analyte is blood glucose."); *see supra* Sections VII.D-E (characterizing the '335 patent, Stafford, Raymond, and Turner as analogous art).

**1. A POSITA Would Have Been Motivated To Combine Stafford, Raymond, And Bickoff (And Turner)**

223. A POSITA would have understood the importance of maintaining electrical contact between a sensor and electronics coupled thereto. A POSITA understanding such a problem and reading Bickoff would have been motivated to add Bickoff's hub to ensure good electrical contact between Stafford's data processing unit and sensor within Stafford+Raymond's on body electronics unit.

224. Thus, a POSITA would have been motivated to combine teachings from Stafford+Raymond with teachings from Bickoff (and Turner).

**2. A POSITA Would Have Had A Reasonable Expectation Of Success In Combining Raymond, Stafford And Bickoff (And Turner)**

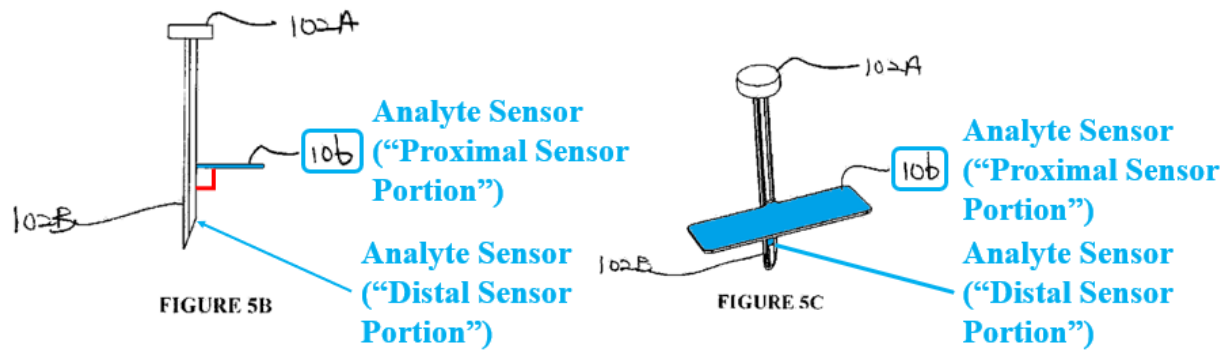
225. Stafford+Raymond+Bickoff (and Stafford+Raymond+Turner+Bickoff) is a simple combination of known elements that achieves the predictable result of maintaining a sensor's position relative to sensor electronics and which a POSITA would have only required ordinary skill to implement.

226. Thus, a POSITA would have had a reasonable expectation of success in combining the teachings of Stafford, Raymond, and Bickoff (and Turner).

**C. Claim 16**

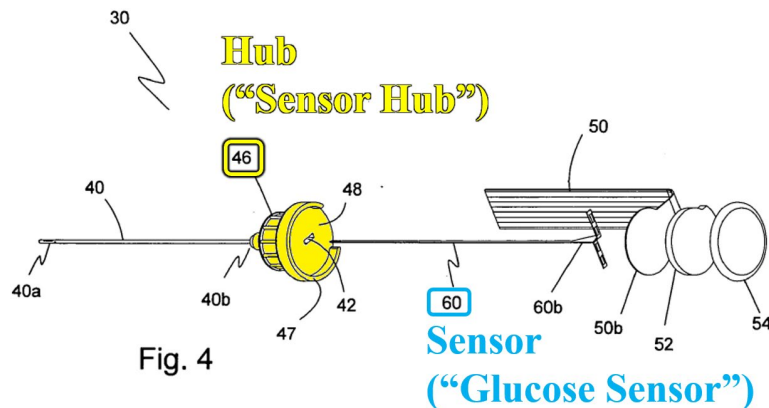
[16.1] The glucose monitoring assembly of claim 1, wherein the on body electronics unit further comprises a sensor hub,

227. As shown below, Stafford discloses a glucose sensor (blue) in electrical contact with on body electronics (*e.g.*, at an analog interface). EX1009, [0039] (“[T]he data processing unit 101 (FIG. 1) in one embodiment includes an analog interface 701 configured to communicate with the sensor 106 (FIG. 2)”).



**Stafford, FIG. 5B–5C (annotated)**

228. Bickoff discloses a hub (“sensor hub,” yellow) configured to receive a proximal portion of a sensor (“glucose sensor,” blue) therein. EX1013, [0034] (“Sensor assembly 30 includes a sensor sheath 40 sealingly connected to a sensor hub 46 from which sensor cable 50 extends.”), [0035] (“Sensor 60 and cable proximal end 50b are fixedly retained within hub 46”).



**Bickoff, FIG. 4 (annotated)**

229. Stafford+Raymond+Bickoff (and Stafford+Raymond+Turner+Bickoff) includes the on body electronics and glucose

sensor as taught by Stafford and the sensor hub as taught by Bickoff disposed therebetween.

230. A POSITA would have been motivated to augment Stafford+Raymond (and Stafford+Raymond+Turner) to include the sensor hub as taught by Bickoff with reasonable expectation of success. *Supra* Sections IX.B.1-2.

231. Thus, Stafford+Raymond+Bickoff (and Stafford+Raymond+Turner+Bickoff) includes “the on body electronics unit further [comprising] a sensor hub.”

[16.2] wherein the glucose sensor comprises a distal sensor portion and a proximal sensor portion,

232. As discussed in Grounds 3-4 (¶¶210-11), Stafford discloses [16.2]. *See supra* Section IX.C. Thus, Stafford+Raymond+Bickoff (and Stafford+Raymond+Turner+Bickoff) teaches this limitation.

[16.3] wherein the distal sensor portion is configured to sense the glucose level of the subject,

233. As discussed in Grounds 3-4 (¶¶212-13), Stafford discloses [16.3]. *See supra* Section VIII.C. Thus, Stafford+Raymond+Bickoff (and Stafford+Raymond+Turner+Bickoff) teaches this limitation.

[16.4] wherein the proximal sensor portion is engaged with the sensor hub, and

234. As discussed at [16.1] (¶¶227-231), Stafford+Raymond+Bickoff (and Stafford+Raymond+Turner+Bickoff) teaches this limitation.

[16.5] wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

235. As discussed in Grounds 3-4 (§§215-16), Stafford discloses [16.5]. *See supra* Section VIII.C. Thus, Stafford+Raymond+Bickoff (and Stafford+Raymond+Turner+Bickoff) teaches this limitation.

236. Since Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say) discloses each one of claim 27's limitations, claim 27 is therefore obvious in view of Stafford+Raymond+Say (and Stafford+Raymond+Turner+Say).

237. Since Stafford+Raymond+Bickoff (and Stafford+Raymond+Turner+Bickoff) discloses each one of claim 16's limitations, claim 16 is therefore obvious in view of Stafford+Raymond+Bickoff (and Stafford+Raymond+Turner+Bickoff).

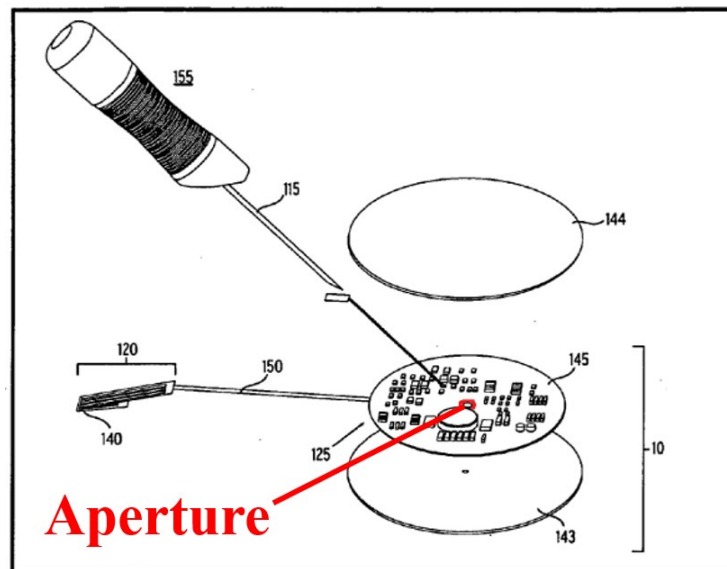
**X. GROUND 7 & 8: CLAIMS 17-18 ARE OBVIOUS OVER STAFFORD, RAYMOND, AND SHAH (GROUND 7), AND FURTHER IN VIEW OF TURNER (GROUND 8)**

238. As explained below, if claims 17-18 are deemed non-obvious over Stafford+Raymond (and Turner), claims 17-18 are obvious over Stafford+Raymond and further in view of Shah (and Turner).

**A. Shah**

239. U.S. Publication No. 2007/0073129 ("Shah," EX1014) was published March 29, 2007.

240. Shah discloses a transcutaneous analyte sensor coupled to a flexible partial circuit with an aperture through which a sensor and insertion needle pass. EX1014, Abstract, FIG. 6, [0045] (“[A] subcutaneous insertion set is provided with the flexible mounting base for placing the sensor at a selected site within the body of a patient. As shown in FIG. 6, the insertion set 155 comprises an insertion needle 115. The insertion needle 115 is adapted to extend through the partially shown flexible mounting base 10 adapted for seated mounting onto the patient's skin.”).



Shah, FIG. 6 (annotated)

**B. The Stafford+Raymond+Shah  
(And Stafford+Raymond+Turner+Shah) Combination**

241. The combinations of Stafford, Raymond, and Shah (“Stafford+Raymond+Shah”) and Stafford, Raymond, Turner, and Shah (“Stafford+Raymond+Turner+Shah”) applied herein further combine teachings

from Stafford+Raymond and Stafford+Raymond+Turner with teachings from Shah related to the combination of on body electronics and an aperture extending therethrough. In addition to the aforementioned elements of Stafford+Raymond, Stafford+Raymond+Shah and Stafford+Raymond+Turner+Shah further include the following elements cooperating as follows:

- on body electronics as taught by Stafford comprising an aperture as taught by Shah, wherein a sharp like that disclosed in Stafford extends through the aperture of the on body electronics.

242. Shah (disclosing a transcutaneous medical device for diabetes treatments) is analogous art to the claimed invention of the '335 patent and is further analogous to Stafford, Raymond, and Turner. EX1014, Abstract (“A flexible mounting base to hold a sensor at an infusion site, the sensor being a removable in vivo sensor for monitoring analyte concentration level in a patient, such as blood glucose (BG) level.”); *see supra* Sections VII.A-D (characterizing Stafford, Raymond, and Turner).

**1. A POSITA Would Have Been Motivated To Combine Stafford, Raymond, And Shah (And Turner)**

243. A POSITA would have been motivated to implement Shah’s teachings in Stafford+Raymond (and Stafford+Raymond+Turner) to form a first aperture in Stafford’s on body electronics. Stafford discloses a data processing unit including electronics and an introducer extending through a central portion of the data

processing unit. *See supra* Sections VII.Q-R. Likewise, Shah teaches a flexible mounting base (functionally similar to Stafford's data processing unit) including a flexible partial circuit having an aperture and a needle extending partially through a central portion of the base. EX1014, Abstract, FIG. 6, [0045] ("The insertion needle 115 is adapted to extend through the partially shown flexible mounting base 10 adapted for seated mounting onto the patient's skin."). Although Stafford does not explicitly show electronics within the data processing unit, a POSITA would have been motivated to form Shah's aperture in Stafford's electronics to maximize the electronics space and minimize empty space within Stafford's housing and create the smallest-profile on body unit (as taught by Stafford) and, consequently, would have needed an aperture for Stafford's introducer to extend through.

244. Thus, particularly in view of Shah, it would have been obvious to implement the electronics as taught by Stafford in a circular shape with an aperture in a central portion thereof, wherein the sharp extends through the aperture.

245. Thus, a POSITA would have been motivated to combine teachings from Stafford+Raymond with teachings from Shah (and Turner).

**2. A POSITA Would Have Had A Reasonable Expectation Of Success In Combining Raymond, Stafford And Shah (And Turner)**

246. A POSITA would have only required ordinary skill to combine teachings from Stafford+Raymond with teachings from Shah (and Turner). For

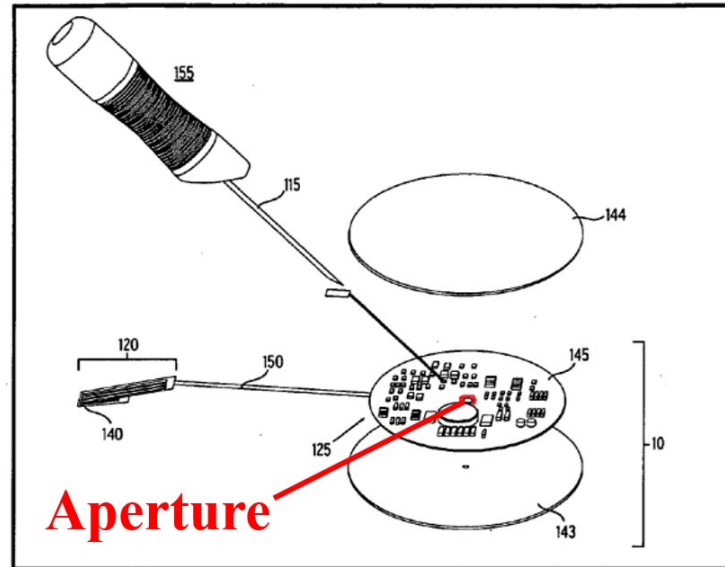
example, a POSITA would have formed the aperture as taught by Shah—a simple hole—in the on body electronics as taught by Stafford with a reasonable expectation of success.

247. Thus, a POSITA would have had a reasonable expectation of success in combining teachings from Stafford+Raymond with teachings from Shah (and Turner).

**C. Claim 17**

17. The glucose monitoring assembly of claim 1, wherein the on body electronics comprises an aperture, and wherein the sharp extends through the aperture of the on body electronics.

248. As shown below, Shah discloses a flexible mounting base with a flexible partial circuit having an aperture (red) and an insertion needle configured to extend partially through the aperture. EX1014, Abstract, FIG. 6, [0045] (“The insertion needle 115 is adapted to extend through the partially shown flexible mounting base 10 adapted for seated mounting onto the patient's skin.”).



**Shah, FIG. 6 (annotated)**

249. A POSITA would have been motivated to form Shah's aperture in Stafford's on body electronics with a reasonable expectation of success. *See supra* Sections X.B.1-2.

250. Thus, Stafford+Raymond+Shah (and Stafford+Raymond+Turner+Shah) includes "the on body electronics [comprising] an aperture, and ... the sharp [extending] through the aperture of the on body electronics."

251. Since Stafford+Raymond+Shah (and Stafford+Raymond+Turner+Shah) discloses each one of claim 17's limitations, claim 17 is therefore obvious in view of Stafford+Raymond+Shah (and Stafford+Raymond+Turner+Shah).

**D. Claim 18**

18. The glucose monitoring assembly of claim 17, wherein the aperture of the on body electronics is a first aperture, wherein the on body electronics unit housing further comprises a top surface and a bottom surface, wherein the top surface comprises a second aperture, wherein the bottom surface comprises a third aperture, and wherein the sharp extends through the first aperture, the second aperture, and the third aperture when the on body electronics unit is in the proximal position.

252. As discussed at claim 17 (¶¶145-49), a POSITA would have found it obvious to form the aperture as taught by Shah (a “first aperture”) in the on body electronics as taught by Stafford. *See supra* Section X.C.

253. As discussed in Grounds 1-2, a POSITA would have understood that Stafford teaches second and third apertures in the top and bottom surfaces of Stafford’s housing. *See supra* Section VII.R.

254. Stafford+Raymond+Shah (and Stafford+Raymond+Turner+Shah) includes the first aperture as taught by Shah in the on body electronics and the second and third apertures in the top and bottom surfaces of the housing as taught by Stafford. A sharp like that disclosed in Stafford extends through the first, second, and third apertures before insertion. *See supra* Section VII.R. As discussed at [1.8] (¶¶95-98), the housing is in the proximal position within the inserter as taught by Raymond before insertion. *See supra* Sections VII.F, VII.R.

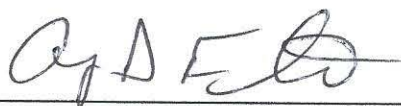
255. Thus, Stafford+Raymond+Shah (and Stafford+Raymond+Turner+Shah) includes “the aperture of the on body electronics

[defining] a first aperture, ... [and] the on body electronics unit housing further [comprising] a top surface and a bottom surface, wherein the top surface comprises a second aperture, wherein the bottom surface comprises a third aperture, and ... the sharp extends through the first aperture, the second aperture, and the third aperture when the on body electronics unit is in the proximal position.”

256. Since Stafford+Raymond+Shah (and Stafford+Raymond+Turner+Shah) discloses each one of claim 18’s limitations, claim 18 is therefore obvious in view of Stafford+Raymond+Shah (and Stafford+Raymond+Turner+Shah).

I, Gary D. Fletcher, Ph.D., do hereby declare and state, that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: October 6, 2023

  
Signature

# APPENDIX A

## **GARY D. FLETCHER, Ph.D.**

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<https://www.linkedin.com/in/garyfletcher>

### **R&D ENGINEERING PRODUCT DEVELOPMENT EXECUTIVE | IP EXPERT WITNESS**

Entrepreneurial executive with expanding R&D roles in business, technology, and new product development leadership and execution, building and guiding teams in both Fortune 500 and startup companies. Yale Ph.D. in physics with proven record of leadership in creating innovative new businesses and products in healthcare, medical devices, diagnostics, life, materials, and optical sciences.

- **New Product Development and R&D Leadership** - Managing, planning, budgeting, financing, recruiting, and leading internal and external research and product development programs in medical device, diagnostics, optical devices, point-of-care and blood sample testing; championing technology development and product development stage-gate process implementation.
- **New Business and Technology Due Diligence** - Strategic assessment, customer discovery, ideation, product design, usability, technology assessment, business development, and marketing of new products and business opportunities.
- **Strategic Innovation** – Building and communicating business strategy and technology cases; identifying industry trends, technology trends, market trends, translating into business development, technology roadmaps, implementing product portfolio management.
- **IP Assessment & Development** - Defining intellectual property strategy, conducting due diligence, implementing a major IP portfolio in start-up new technology company, negotiating licensing agreements, Expert Witness, 23 issued patents and 25 patent applications.

### **PROFESSIONAL EXPERIENCE**

#### **RAVEN BIOMATERIALS LLC, Pennington, NJ (2020 – present)**

**Founder & COO** -- biotech startup developing greatly improved cell separation / enrichment processes for cell therapy manufacturing, cell-based diagnostics, protein and vaccine manufacturing.

- Conducted customer discovery, built business models and case, developed investor presentations, performed due diligence, set up laboratory and operations, conducted proof of feasibility experiments, developed patent strategy.

#### **RnDDx SOLUTIONS LLC, Media, PA (2015 – present)**

**Founder & Principal – Expert Witness in Patent Litigation | Medical Device Business & Product Development Consultant**

- Expert Witness in patent litigation involving blood collection, blood separation, and blood preparation for clinical diagnostics, and cell and platelet therapy.
  - Successfully represented respondents as Expert Witness in International Trade Commission, Inv. No. 337-TA-1147, providing expert opinion on infringement, validity, and enforceability of US patent; included two declarations for Markman hearing, expert witness

report, rebuttal expert report, 9-hour deposition, expert witness statement and rebuttal statement. The technical case was so strong that Complainant withdrew complaint and requested stay of hearing. (2019)

- Retained as Expert Witness for the defendant in a patent dispute before the USDC in Delaware, involving four patents in the area of blood collection and processing. I reviewed drafts of the Petition for IPR, involving two of the four patents, informing defendant's counsel that I believed the arguments presented in the draft IPR Petition were not strong. I was not asked to prepare an IPR Expert Declaration, nor did I review the final IPR Petition. (2020)
- Retained as Expert Witness for the defendant in a patent infringement case before USDC in Delaware, involving two patents in the area of medical diagnostic testing fluidic systems and methods of sample processing, and point-of-care diagnostic fluidic systems and uses. I reviewed prior art, and the plaintiff dismissed their suit. (2020)
- Retained as Expert Witness for the defendant in a patent infringement case before USDC in Western District of Texas, involving two patents in the area of preparing blood samples for analysis of circulating nucleic acids using chemical agents that inhibit blood cell lysis. I prepared a declaration supporting defendant's responsive claim construction brief, and I was deposed by plaintiff regarding the declaration. (2021)
- Retained as Expert Consultant for counsel developing patent litigation strategy for client in glucose monitoring space, assisting in preparation of five (5) IPR Petitions. (2021)
- Expert video commentary for episode of Advancements TV with Ted Danson, discussing engineering challenges in developing comprehensive point-of-care testing systems, for point-of-care testing diagnostic company.
- Consultant to startup medical device company, providing product development and product optimization of chemical attributes of blood separation devices.
- Consultant and advisor to startup medical device company, providing business development, competitive analysis, and product development expertise in blood separation devices for point-of-care testing.
- Consultant to startup medical diagnostics company, providing technical due diligence, product design, development, and testing of blood sampling methods.
- Consultant to startup medical device company developing blood microcollection device and diagnostics, providing expertise in the field of blood diagnostic products and services.
- Consultant to startup medical device company developing blood collection device, providing project management and product advisory services.
- Consultant to Fortune 100 Healthcare Provider, delivered Point-of-Care-Testing Growth Opportunity Assessment and Emerging Technology Landscape, with actionable targets.
- Lean Startup Coach within Program Management Office of Fortune 1000 data analytics company, developing repeatable Lean Startup process around Customer Discovery and Validation, training materials for workshops.
- Mentored four early stage companies, building business models, plans, and funding presentations.
- Guided technology companies through Lean Startup, Business Model Canvas, and national NSF I-Corps business development efforts.
- Conducted customer discovery, built business models and case, developed investor presentations, performed due diligence, set up operations, and initiated licensing negotiations with academic inventors, for U. of Pennsylvania life sciences startup developing super-resolution fluorescent microscopy for cell analysis.
- Maven consultations
  - Phone consultation for confidential entity regarding emerging companies and technologies in in vitro diagnostics and point-of-care diagnostics and needs for outsourced contract design, development, and manufacturing.
- Guidepoint consultations
  - Phone consultation for confidential entity regarding remote blood collection devices.
  - Phone consultation for confidential entity regarding biospecimen users and purchasers.

- Phone consultation for confidential entity regarding remote blood collection space.
- Phone consultations for confidential entity regarding medical device supply chain and product development.
- Phone consultation for confidential entity regarding microfluidics and medical devices.
- Phone consultation for confidential entity regarding healthcare in vitro diagnostics.
- Survey for confidential entity regarding medical technology OEMs.
- Gerson Lehrman Group consultations
  - Completed survey on MedTech Services for confidential entity
- Reviewer for NSF SBIR/STTR Phase I and Phase II proposals

**BECTON DICKINSON, Franklin Lakes, NJ (2004 – 2014)**

BD is a global medical technology company with products in drug delivery, life sciences tools, and disease management in diabetes, women's health and cancer, and infection control.

**Leader, Technology Innovation, R&D (2010 – 9/2014)**

Responsible for identifying adjacent business opportunities, building compelling business cases, and leading product development in new business spaces. Moved into this role to address critical need to identify higher growth business opportunities for low-single-digit growth business.

- Developed and executed two adjacent market business plans and technology strategies, achieving \$2M internal investment for medical device technology development, in: 1) Tissue collection and preservation for improved cancer diagnostics; and 2) Point of care blood collection and diagnostic testing, managing consultants and partnerships in microfluidics technologies.
- Led product development of first tissue collection product to manufacturing release.
- Initiated customer discovery, developed Key Opinion Leader relationships with surgical and clinical pathologists and Point of Care Coordinators to understand cancer diagnostic and blood testing needs. Set up expert focus group panels at international conferences.

**Technology Leader, Advanced Technology, R&D (2006 – 2010)**

Moved into new innovation strategy role; charged with identifying and leading technology and product development of new-to-business concepts to reinvigorate core business.

- Developed business unit technology and innovation strategy.
- Developed and led technology scouting, due diligence, and innovation processes for new medical devices.
- Completed “deep dive” technology assessment in blood fractionation technologies, leveraging and contracting academic experts in materials and fluidics; led development effort assessing primary blood separation technologies. Effort to develop rapid noncentrifugal blood separation challenging and continues to present.

**Director, Core Technologies, R&D (2004 – 2006)**

Based on interest and experience in medical device product development, hired at Director level into Preanalytical [Vacutainer] business at BD to bring innovative new product development leadership and vision to legacy business.

- Reporting to VP R&D, led 5-member technology development group, executing technology strategy to support medical device blood specimen collection and preservation business.

- Built team key technical capabilities to support innovation of current and next generation products; interfacing R&D with clinical affairs, regulatory, Program Management Office.
- Led R&D teams resolving manufacturing problems in core plastic blood collection products, identified and solved vendor plastic materials changes, material coatings changes, manufacturing process changes.
- Led Business Unit R&D rollout of Technology Development stage-gate process, initiated prior to formal New Product Development stage-gate process, to reduce technology risk in New Product Development.
- Taught, on ongoing basis, 2-day BD University course on “Managing for Performance Excellence” to managers.

#### **SARNOFF CORPORATION, Princeton, NJ (2001 – 2004)**

Sarnoff [previously RCA Laboratories, now part of SRI] was a contract research laboratory executing both government and commercial research and new product development contracts in hardware, software, image analysis, and market analysis. Hired to expand Sarnoff's commercial medical device and diagnostic product development contract business, and to create patentable internal product development capabilities which could be licensed or spun-out as startup companies.

#### **Technical Manager, Healthcare Products (2001 – 2004)**

- Reporting to Technical Director, directed 12-member multidisciplinary group as product development program manager of new painless minimally invasive blood glucose monitor; achieved successful spinout as medical device startup. Managed 8-month, \$2M budget.
- Functionally manage 7-member scientific and engineering staff involved in multiple medical device product development contracts.
- As Co-Principal Investigator, prepared successful Department of Homeland Security research grant funding product development for rapid detection of airborne biological weapons, based on electrostatic particle collection and Raman spectroscopy detection.

#### **CYTOMETRICS, INC., Philadelphia, PA (1996 – 2001)**

Cytometrics was a medical imaging and diagnostic startup commercializing a platform miniature optical reflectance microscope for human in vivo assessment of circulation perfusion and noninvasive measurement of whole blood count parameters, using hemoglobin optical absorption spectroscopy.

#### **Vice President, Advanced Technology (1998 – 2001)**

Asked to lead innovative team developing additional clinical applications for the platform optical imaging instrument in circulation perfusion assessment.

- Reporting to CEO, led team of five scientists evaluating technical feasibility of new product concepts, identified new applications of core technology, and assessed competitive technology.
- Managed the development of a novel noninvasive technology platform, achieving product introduction 18 months after concept definition.
- Led research, medical imaging analysis, and clinical groups, demonstrating clinical efficacy of noninvasive blood analysis and microcirculation imaging instrument, generating \$41M in capital for continued development.
- Managed company intellectual property portfolio, resulting in filing of 14 major patent applications.
- Developed corporate R&D strategy. Negotiated external university research contracts and funding, resulting in 10 study reports and 8 manuscripts submitted for publication. Directed technical consultants.
- Collaborated in the ISO implementation and manufacturing start-up.

#### **Vice President, Engineering (1996 – 1998)**

Hired as employee #6 to lead product development and build the product development team for the core noninvasive WBC [whole blood count] application.

- Reporting to CEO, led optical, mechanical, electrical, software image analysis, and clinical team, and developed product prototypes.
- Built a high-performance team of scientists and engineers with a driven-to-execute innovation culture
- Led research, development, and clinical testing of 4 generations of prototype video reflectance microscopes for noninvasive blood analysis, resulting in performance improvements and sensor miniaturization, which generated \$10M in angel investment for continued development.

#### **BIOCONTROL TECHNOLOGY, INC.**, Indiana, PA (1996)

Biocontrol Technology was established medical device company developing noninvasive glucose measurement based in near infrared skin reflectance spectroscopy. Hired to lead product development.

#### **Manager, Engineering (1996)**

- Reporting to President, managed 25 electrical, mechanical, optical, and software engineers developing noninvasive glucose sensor utilizing diffuse reflectance near-infrared spectroscopy.
- Led cross-functional teams to refocus technical effort, resulting in greater interaction between engineering, research, data analysis, clinical, and manufacturing departments and faster sensor performance improvements.

#### **ANDROS, INC.**, Berkeley, CA (1993-1996)

Andros, Inc. was an OEM supplier of gas analysis instruments based on infrared absorption spectroscopy to the automotive and medical device markets. I was hired to expand development of new anesthetic and respiratory gas analyzers.

#### **Senior Physicist and Manager, Advanced R&D (1993-1996)**

- Reporting to VP Engineering, managed development of nondispersive infrared [NDIR] absorption anesthetic and respiratory gas analyzers, resulting in new OEM agreements with medical patient monitoring companies.
- Assessed and tested biomedical and automotive sensor technologies, including low cost gas analyzer based on quenching of fluorescent radiation excited by blue LEDs, and portable gas analyzer based on solid-state IR sources and nonimaging IR optics.

#### **MEASUREX CORPORATION**, Cupertino, CA (1991-1993)

Measurex Corporation provided process control sensors and instrumentation for the pulp and paper, and plastics industries. I was hired to develop and commercialize new infrared and x-ray sensor technology.

#### **Staff Physicist (1991-1993)**

- Reporting to Manager of Sensor Engineering, developed, field tested, and released to manufacturing new IR moisture sensor for paper industry use, requiring fewer calibrations and generating greater customer acceptance.
- Researched and led customer acceptance tests of 10 and 30 keV x-ray sensors as thickness monitors, generating new sales in aluminum industry.

#### **LAWRENCE LIVERMORE NATIONAL LABORATORY**, Livermore, CA (1986-1991)

LLNL is a Department of Energy national lab dedicated to research and development of energy, weapons, laser, defense, and biological technologies. I was hired into the Physics Department to understand and develop rapid laser and x-ray technologies.

#### **Physicist (1986-1991)**

- Designed and fielded subnanosecond time-resolving crystal x-ray spectrometers to measure temperature and density of laser-produced plasmas, which provided data for modeling and development of x-ray lasers.
- Formulated new nuclear test experiment, involving 2-dimensional x-ray imaging.

**UNIVERSITY OF VIRGINIA, Charlottesville, VA (1983-1986)**

**Assistant Professor of Physics and Research Associate in Physics (1983-1986)**

- Reporting to Prof. Daniel Larson, mentored seven graduate students, resulting in 6 peer-reviewed publications.
- Designed and executed precision measurements in high field nuclear magnetic resonance spectroscopy of laser optically pumped atomic rubidium and laser photodetachment studies of atomic negative ions confined in Penning trap, discovering new effects.
- Taught undergraduate introductory physics laboratory course.

**YALE UNIVERSITY, New Haven, CT (1976-1983)**

**Research Assistant in Physics (1976-1983)**

- Under the direction of Prof. Vernon Hughes and Prof. Michael Lubell, upgraded experimental lab, measured spin dependence in electron-hydrogen atom collisions, wrote dissertation and 4 peer-reviewed publications.

**EDUCATION**

**Doctor of Philosophy in Physics**, Yale University, New Haven, CT

**Bachelor of Arts in Physics and Mathematics**, DePauw University, Greencastle, IN

**HONORS**

1999 -- Cytometrics Founders' Award, "for outstanding contributions to the furtherance of Cytometrics' mission."

1975 -- Elected to Phi Beta Kappa, with 4.0 GPA

**PROFESSIONAL ACTIVITIES**

Member, American Association for Clinical Chemistry (AACC)

Member, American Chemical Society (ACS)

**PUBLICATIONS**

1. G.D. Fletcher et al., "Measurement of Spin-Exchange Effects in Electron-Hydrogen Collisions: 90° Elastic Scattering from 4 to 30 eV," Phys. Rev. Lett. **48**, 1671, (1982).
2. T. J. Gay, G. D. Fletcher, M. J. Alguard, V. W. Hughes, P. F. Wainwright, and M. S. Lubell, "Measurement of spin-exchange effects in electron-hydrogen collisions: Further studies of impact ionization," Phys. Rev. **A 26**, 3664 (1982).
3. G.D. Fletcher et al., "Experimental study of spin-exchange effects in elastic and ionizing collisions of polarized electrons with polarized hydrogen atoms," Phys. Rev. **A 31**, 2854 (1985).
4. G. D. Fletcher, T. J. Gay, and M. S. Lubell, "New insights into Mott-scattering electron polarimetry," Phys. Rev. **A 34**, 911 (1986).

5. S.J. Lipson, G.D. Fletcher, and D.J. Larson, "Observation of Quadrupole and Dipole Diamagnetic Shifts in Atomic Ground State Hyperfine Structure, Phys. Rev. Lett. **57**, 567 (1986).
6. R.E. Elmquist, C.J. Edge, G.D. Fletcher, and D.J. Larson, "Observation of Resolved Zeeman Thresholds in Photodetachment in a Magnetic Field," Phys. Rev. Lett. **58**, 333 (1987).
7. G.D. Fletcher, S.J. Lipson, and D.J. Larson, "Observation of a Magnetic Field Dependent g-Factor Ratio," Phys. Rev. Lett. **58**, 2535 (1987).
8. R. Trainham, G.D. Fletcher, N.B. Mansour, and D.J. Larson, "Photodetachment Threshold Shift in a Strong Laser Field," Phys. Rev. Lett. **59**, 2291 (1987).
9. N. B. Mansour, G. D. Fletcher, and D. J. Larson, "Laser photodetachment spectroscopy of S—near the D1 threshold," Phys. Rev. A **35**, 2321 (1987).
10. R Trainham, G D Fletcher and D J Larson, "One- and two-photon detachment of the negative chlorine ion," Journal of Physics B **20**, L777 (1987).

## CONFERENCE ORGANIZER

- **D2H2 [Distributed Diagnosis and Home Healthcare] Conference**, Program Committee, Session Organizer and Session Chair, Chair—Home Devices, April 2006.
- **NIST Cross-Industry Issues in Nanomanufacturing**. Workshop Organizer, Plenary Speaker, and Report Co-author; Organized and chaired session – "Surfaces, Interfaces, and Non-bonded Interactions of Nanomaterials." Plenary Speaker – "Pharmaceuticals and Medical Devices." May 2008. [http://www.nist.gov/mml/upload/nano\\_small\\_web-4.pdf](http://www.nist.gov/mml/upload/nano_small_web-4.pdf)

## CONFERENCE PROCEEDINGS

1. Rusty Trainham, G. D. Fletcher and D. J. Larson, "Laser photodetachment spectroscopy of the negative chlorine ion," AIP Conf. Proc. **146**, 385 (1986); <http://dx.doi.org/10.1063/1.35750>
2. O. Genzel-Boroviczeny, A. G. Harris, G. D. Fletcher, and F. Christ, "Non-invasive determination of hemoglobin in neonates with orthogonal polarization spectral (ops) imaging," Pediatric Research **47**(4), 332A–332A (2000). Part 2 Suppl. S.

## GRANTED PATENTS

|             |                                                                                              |
|-------------|----------------------------------------------------------------------------------------------|
| EP1983891B1 | System and method for blood collection devices                                               |
| EP2986220B1 | Biological fluid collection device and biological fluid collection and testing system        |
| EP2986221B1 | Biological fluid sampling device                                                             |
| EP2986222B1 | Biological fluid sampling transfer device and biological fluid separation and testing system |
| EP2986223B1 | Blood sampling transfer device                                                               |
| EP2986383B1 | Biological fluid separation device and biological fluid separation and testing system        |
| EP2986384B1 | Biological fluid sampling transfer device and biological fluid separation and testing system |
| EP3169236B1 | Lancet device with first-drop removal                                                        |
| EP3513727B1 | Biological fluid sampling device                                                             |

|               |                                                                                              |
|---------------|----------------------------------------------------------------------------------------------|
| EP3598944B1   | Lancet device with first-drop removal                                                        |
| US 9,380,972  | Biological Fluid Collection Device and Biological Fluid Collection and Testing System        |
| US 9,380,973  | Biological Fluid Sampling Transfer Device and Biological Fluid Separation and Testing System |
| US 9,408,568  | Biological Fluid Sampling Device                                                             |
| US 9,549,700  | Biological Fluid Sampling Transfer Device and Biological Fluid Separation and Testing System |
| US 9,724,690  | Blood Collection Device, Method, and System for Using the Same                               |
| US 9,743,876  | Lancet Device with First-Drop Removal                                                        |
| US 9,808,192  | Biological fluid sampling transfer device and biological fluid separation and testing system |
| US 10,154,808 | Biological fluid separation device and biological fluid separation and testing system        |
| US 10,194,851 | Blood sampling transfer device and blood separation and testing system                       |
| US 10,342,471 | Biological fluid transfer device and biological fluid sampling system                        |
| US 10,682,085 | Lancet Device with First-Drop Removal                                                        |
| US 10,791,975 | Biological fluid transfer device and biological fluid sampling system                        |
| US 10,925,530 | Blood Sampling Transfer Device                                                               |

#### **PATENT APPLICATIONS**

|                 |                                                                                                                      |
|-----------------|----------------------------------------------------------------------------------------------------------------------|
| US20040058311A1 | Method and apparatus for measuring the hemoglobin concentration and/or hematocrit in whole blood using diffuse light |
| WO2004091693A2  | Body fluid sampling constructions and techniques                                                                     |
| US20050070819A1 | Body fluid sampling constructions and techniques                                                                     |
| WO2007092585A2  | Biological specimen collection and storage devices                                                                   |
| WO2007092586A2  | Blood collection device, method, and system for using the same                                                       |
| WO2007092587A2  | Improved label processor and method relating thereto                                                                 |
| US20090130646A1 | BLOOD COLLECTION DEVICE, METHOD, AND SYSTEM FOR USING THE SAME                                                       |
| US20100217155A1 | BODY FLUID SAMPLING CONSTRUCTIONS AND TECHNIQUES                                                                     |
| US20100279397A1 | Biological specimen collection and storage devices                                                                   |
| US20140305197A1 | Biological Fluid Separation Device and Biological Fluid Separation and Testing System                                |
| US20140305823A1 | Blood Sampling Transfer Device                                                                                       |
| US20140308164A1 | Biological Fluid Transfer Device and Biological Fluid Sampling System                                                |
| US20140308166A1 | Blood Sampling Transfer Device and Blood Separation and Testing System                                               |
| US20140308167A1 | Biological Fluid Sampling Transfer Device and Biological Fluid Separation and Testing System                         |
| US20140309556A1 | Biological Fluid Collection Device and Biological Fluid Collection and Testing System                                |
| US20140309557A1 | Biological Fluid Sampling Transfer Device and Biological Fluid Separation and Testing System                         |
| US20140309558A1 | Biological Fluid Sampling Device                                                                                     |
| US20140328734A1 | Biological Specimen Collection and Storage Devices                                                                   |
| US20160015305A1 | Lancet Device with First-Drop Removal                                                                                |

|                 |                                                                                              |
|-----------------|----------------------------------------------------------------------------------------------|
| US20170095191A1 | Biological Fluid Sampling Transfer Device and Biological Fluid Separation and Testing System |
| US 62/302,296   | Biological Fluid Separation Device                                                           |
| US20170319120A1 | Lancet Device with First-Drop Removal                                                        |
| US20190274609   | Biological Fluid Transfer Device and Biological Fluid Sampling System                        |
| US20200397359   | Biological Fluid Transfer Device and Biological Fluid Sampling System                        |
| US20210137434   | Blood Sampling Transfer Device                                                               |