

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

Case No. IPR2023-01409

U.S. Patent No. 11,202,591

PATENT OWNER'S RESPONSE

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PATENT OWNER'S EXHIBITS

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2001	PCT Publication No. WO 2005/046780
2002	Declaration of Karl Leinsing with Appendix A (curriculum vitae) and Appendix B (Claim Chart for U.S. Patent No. 11,202,591)
2003	Complaint with Exhibit F from <i>Abbott Diabetes Care, Inc. v. Dexcom, Inc.</i> , 1:23-cv-00239 (D. Del.), dated March 3, 2023
2004	“Abbott’s FreeStyle Libre® Is Named Best Medical Technology In Last 50 Years By The Galien Foundation,” dated October 28, 2022, printed from https://abbott.mediaroom.com/2022-10-28-Abbotts-FreeStyle-Libre-R-is-Named-Best-Medical-Technology-in-Last-50-Years-by-the-Galien-Foundation
2005	“The Galien Foundation is proud to announce the laureates of the best-of-the-best from the half century 1970-2020,” printed from https://www.galienfoundation.org/galien-golden-jubilee
2006	“FreeStyle Libre Honored by Prix Galien,” dated Oct. 25, 2019, printed from https://www.abbott.com/corpnewsroom/strategy-and-strength/freestyle-libre-honored-by-prix-galien.html
2007	Your FreeStyle Libre 14 day System, In-Service Guide, Rev. ADC-10385 v3.0 A (2021)
2008	Get Started, Your Guide To The FreeStyle Libre 2 System, Rev. ADC-29385 v5.0 (2023)
2009	Getting Started with the FreeStyle Libre 3 System, Rev. ADC-55381 (2023)
2010	FreeStyle Libre 3 Continuous Glucose Monitoring System User’s Manual, Rev. A (2023)
2011	Louisa van den Boom <i>et al</i> , <i>Changes In the Utilization of Blood Glucose Test Strips Among Patients Using Intermittent-Scanning Continuous Glucose Monitoring in Germany</i> , 22 DIABETES OBES. METAB. 6:922–28 (Jun. 2020)
2012	Jeroen Hermanides <i>et al</i> , <i>Current Application of Continuous Glucose Monitoring in the Treatment of Diabetes: Pros and Cons</i> , DIABETES CARE, Vol. 34 Supp. 2, S197–S201 (May 2011)

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2013	Wilbert Villena Gonzales <i>et al</i> , <i>The Progress of Glucose Monitoring—A Review of Invasive to Minimally and Non-Invasive Techniques, Devices and Sensors</i> , SENSORS 2019, vol. 19, Art. 800, pp. 1-45 (Feb. 15, 2019)
2014	Dexcom G5 Mobile Continuous Glucose Monitoring System Quick Start Guide, Rev. 005 MT23203 (2020)
2015	Dexcom G6 Start Here Guide, Rev. 001 MT-1000053-10 (2022)
2016	“Dexcom G7 CGM – Powerfully Simple Diabetes Management” printed from https://dexcom.com/g7-cgm-system
2017	Dexcom G7 User’s Guide, Rev. 003 MT-00078-10 (2024)
2018	Letter from FDA dated December 7, 2020, attaching 510(K) Summary for Dexcom G7 Continuous Glucose Monitoring (CGM) System, available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K213919
2019	“Real-World Data Show Abbott’s FreeStyle Libre® Systems and GLP-1 Medicines Work Better Together for People with Type 2 Diabetes,” dated March 6, 2024, printed from https://abbott.mediaroom.com/2024-03-06-Real-World-Data-Show-Abbotts-FreeStyle-Libre-R-Systems-and-GLP-1-Medicines-Work-Better-Together-for-People-with-Type-2-Diabetes
2020	“Abbott’s FreeStyle® Libre 2 iCGM Cleared in U.S. for Adults and Children with Diabetes, Achieving Highest Level of Accuracy and Performance Standards,” dated June 15, 2020, printed from https://abbott.mediaroom.com/2020-06-15-Abbotts-FreeStyle-R-Libre-2-iCGM-Cleared-in-U-S-for-Adults-and-Children-with-Diabetes-Achieving-Highest-Level-of-Accuracy-and-Performance-Standards
2021	“About the Edison Awards,” printed from https://edisonawards.com/about.php
2022	“2021 Edison Best New Product Awards™ Winners,” printed from https://edisonawards.com/winners2021.php
2023	“Edison Awards Announces 2016 Gold, Silver, and Bronze Awards Winners,” dated April 22, 2016, printed from https://www.prweb.com/releases/edison_awards_announces_2016_gold_silver_and_bronze_awards_winners/prweb13354037.htm

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2024	“2022 Winners – Edison Awards” printed from https://edisonawards.com/2022-winners/
2025	“27 Winners Announced at the 19 th Annual Medical Design Excellence Awards (MDEA) Award Ceremony,” dated June 13, 2017, printed from https://www.prnewswire.com/news-releases/27-winners-announced-at-the-19th-annual-medical-design-excellence-awards-mdea-award-ceremony-300473477.html
2026	“Abbott’s FreeStyle Libre Flash Glucose Monitoring System Wins the IMSTA Most Innovative Product Multi-National Awards,” dated September 29, 2017, printed from https://www.ie.abbott/media-center/news/abbotts-freestyle-libre-flash-glucose-monitoring-system-wins-the-imsta-award-2017.html
2027	Business Intelligence Group, “55 Chosen As Winners In Annual BIG Innovation Awards,” dated February 7, 2018, printed from https://www.bintelligence.com/posts/55-chosen-as-winners-in-annual-big-innovation-awards
2028	“Binaxnow, Freestyle Libre 2 Win BIG [Business Intelligence Group] Innovation Honors,” dated January 12, 2021, printed from https://www.abbott.com/corpnewsroom/strategy-and-strength/binaxnow-freestyle-libre-win-big-innovation-honors.html
2029	Chicago Innovation, “Abbott Laboratories,” referencing “Abbott’s FreeStyle Libre Flash Glucose Monitoring System, 2018” printed from https://chicagoinnovation.com/winners/abbott-laboratories/
2030	The Scientist, “2019 Top 10 Innovations,” dated December 1, 2019, printed from https://www.the-scientist.com/features/2019-top-10-innovations-66738
2031	German Innovation Award '20 Gold, “FreeStyle Libre 2” printed from https://www.german-innovation-award.de/en/winners/preis/gewinner/freestyle-libre-2-zucker-messen-ohne-stechen-per-sensor-und-app/
2032	2017 Good Design Award, “Glucose Monitoring Systems FreeStyle Libre” printed from https://www.g-mark.org/gallery/winners/9dda01a3-803d-11ed-af7e-0242ac130002

Exhibit No.	Description
2033	“How Big Are The Freestyle Libre Sensors? How Deeply Is It Inserted?,” printed from https://www.freestyle.abbott/uk-en/support/faq/question-answer.html?q=UKFaquestion-55
2034	Abbott 2023 Annual Report for the fiscal year ended December 31, 2023, printed from https://www.abbottinvestor.com/static-files/6cb09c09-2422-40e0-a24b-6545ffcf5267
2035	Consumer Technology Association CES 2022 Best of Innovation, “FreeStyle Libre 3 system,” printed from https://www.ces.tech/innovation-awards/honorees/2022/best-of/freestyle-libre-3-system.aspx
2036	Transcript of the Deposition of Dr. Gary Fletcher, dated June 26, 2024.
2037	“Abbott's Freestyle® Libre 14 Day Flash Glucose Monitoring System Now Approved In U.S.,” dated July 27, 2018, printed from https://abbott.mediaroom.com/2018-07-27-Abbotts-FreeStyle-R-Libre-14-Day-Flash-Glucose-Monitoring-System-Now-Approved-in-U-S
2038	“Abbott's Freestyle Libre® 3 Receives U.S. FDA Clearance - Features World's Smallest, Thinnest And Most Accurate 14-Day Glucose Sensor,” dated May 31, 2022, printed from https://abbott.mediaroom.com/2022-05-31-Abbotts-FreeStyle-Libre-R-3-Receives-U-S-FDA-Clearance-Features-Worlds-Smallest,-Thinnest-and-Most-Accurate-14-Day-Glucose-Sensor
2039	“Dexcom G7: These Are The Most Exciting Features,” printed from https://notjustapatch.com/dexcom-g7-features/
2040	“What’s Next For Dexcom? CEO, CTO Talk G6 For Inpatient Use, Expanding CGMs For Patients Without Diabetes,” dated June 19, 2020, printed from https://www.mobihealthnews.com/news/whats-next-dexcom-ceo-cto-talk-g6-inpatient-use-expanding-cgms-patients-without-diabetes
2041	“Product Review: Abbott FreeStyle Libre Flash Glucose Monitor” dated June 1, 2021, printed from https://www.healthline.com/diabetesmine/abbott-freestyle-libre-review

Exhibit No.	Description
2042	“Abbott’s Euro Approved Wearable Glucose Monitor Is Different Than Anything On The Market,” dated September 9, 2014, printed from https://www.imedicalapps.com/2014/09/abbotts-wearable-glucose-monitor/
2043	David Gough <i>et al</i> , <i>Development of the Implantable Glucose Sensor – What Are the Prospects and Why Is It Taking So Long?</i> , DIABETES, Vol. 44, 1005-1009 (Sept. 1995)
2044	Jeffrey Joseph <i>et al</i> , <i>Glucose Sensing in the Subcutaneous Tissue: Attempting to Correlate the Immune Response with Continuous Glucose Monitoring Accuracy</i> , DIABETES, TECHNOLOGY, & THERAPEUTICS, Vol. 22, No. 5, 321-324 (2018)

I. INTRODUCTION

Patent Owner Abbott Diabetes Care (“Abbott”) is a market leader in innovative solutions for diabetes management, including continuous glucose monitoring systems (“CGMs”). Abbott’s blockbuster FreeStyle Libre products (“Libre”) are covered by U.S. Patent No. 11,202,591 (“the 591 Patent”). Libre includes an easy-to-apply, ultra-low profile on-body unit (“OBU”) that includes sensor electronics pre-coupled with a glucose sensor. Libre revolutionized the market for diabetes care and won the prestigious Galien Golden Jubilee Award (likened to the Nobel Prize) for “Best Medical Technology” *in the last fifty years*.

Petitioner sold prior art designs for years until recently launching a new Libre-style product (the “G7”). Petitioner now asserts that the 591 inventions were obvious more than a decade earlier. Petitioner’s obviousness analysis is the epitome of hindsight. For each ground, Petitioner attempts to cobble together the 591 inventions by combining four, five, or more references and asserting missing limitations are “well-known”—all while ignoring that its own references demonstrate that POSAs would not be motivated to make Petitioner’s proposed combinations.

Petitioner’s grounds—all resting on a combination of Stafford and Cote—fail for multiple reasons, including because (1) the teachings of the primary reference (Stafford) conflict with Petitioner’s proposed combinations and (2) even if POSAs

ignored those teachings (contrary to the law), each combination lacks numerous claim limitations.

For each ground, Petitioner starts with Stafford's CGM, which includes an on-body unit ("OBU") that already includes an "introducer" needle and then adds Cote's infusion cannula inserter. But Stafford describes a "simple, easy to handle" design and teaches minimizing the cost and complexity of CGMs by "*reducing the number of components*," expressly stating that *a separate inserter is "not necessary."* EX1004, [0044]-[0045].¹ POSAs, starting with Stafford, would not be motivated to add *any* separate inserter, let alone Cote's cannula inserter. Indeed, Petitioner's proposed combinations eviscerate the express advantages of Stafford's minimalist design.

Moreover, Petitioner ignores that Cote's infusion cannula inserter is not suitable for a fragile glucose sensor where precision and stability are critical during sharp insertion and retraction. In this regard, the 591 claims all require the "distal end" of the inserter to be configured to be "removed [from the skin]...*after* automatic retraction of the sharp," ensuring stability and precision during the sensor-insertion and sharp-retraction process. But Cote teaches the opposite. Cote's cannula inserter only functions if its distal end is removed from the skin *before* retraction.

¹ Unless noted, all emphases and colored annotations to drawings are added.

Petitioner's combination therefore lacks this claim limitation.

Most claims additionally require that the distance between the proximal and distal positions of the OBU housing in the inserter be “**greater than** a maximum height of the [OBU] housing,” ensuring that the OBU is relocated away from the inserter's distal end. But, in Petitioner's combination using Stafford's OBU in Cote's inserter, the distance would be **less than**—not greater than—the claimed height (the opposite of what is claimed). Numerous other limitations are also not taught.

For these reasons and others, including ignoring objective indicia of non-obviousness, Petitioner has failed to show that the challenged claims are unpatentable.

II. BACKGROUND

A. Background Of The Inventions And Prior Art

1. Diabetes And The Advent Of CGMs

Diabetes is a chronic disease where the body does not properly utilize insulin in response to changing levels of blood glucose. Monitoring glucose levels is vitally important for diabetics because uncontrolled fluctuations can cause serious health problems. This led to the development of *in vivo* continuous glucose monitoring systems (CGMs) that use analyte sensor implanted under the skin to continuously monitor glucose levels. EX1001,1:35-2:10; EX2011, 923,926; EX2013, 1-2.

As Abbott's expert, Karl Leinsing explains, glucose monitoring improved with the introduction of CGMs, but early CGMs were unrealistic for many diabetics

and the designs suffered from numerous disadvantages. Products were unaffordable, bulky, complicated, required separate sensors and transmitters, and used daunting inserters. EX2002, ¶¶51-56; EX2012, S199; EX2013, 6. Moreover, because electrochemical sensors are fragile, ensuring that diabetics could accurately self-implant a sensor subcutaneously without causing tissue trauma and compromising the sensor's efficacy was challenging. EX2002, ¶¶57-58,160; *see infra*.

Notably, while the prior art described numerous ways to self-implant glucose sensors, none provided an all-in-one solution that was reliable and simple enough for medically untrained individuals to use while remaining cost-effective and accessible to the average user. EX2002, ¶¶58,405-407.

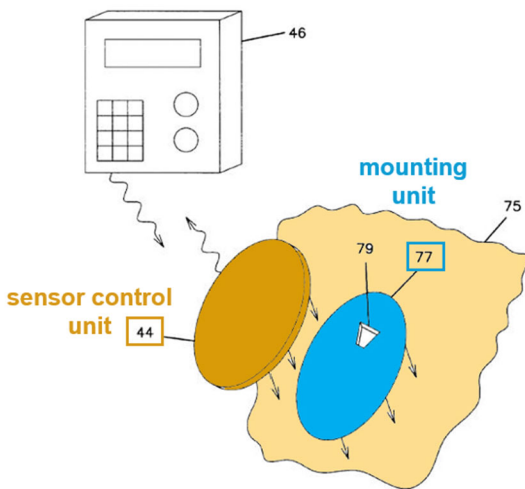
2. Prior Art Continuous Glucose Monitoring Systems

a) Say

U.S. Patent No. 6,175,752 (“Say”), considered by the PTO during prosecution, issued in 2001 to an Abbott predecessor. EX1008, abstract; EX1001, 5. Say generally describes a “two-part” CGM system. This means that the sensor is not coupled with the sensor electronics before sensor insertion; rather, the user separately inserts the sensor and then manually connects the electronics after insertion. EX1008, 3:6-16, 27:47-57,28:44-60; EX2002, ¶¶60-62; EX2036,77:3-8.

In one embodiment, a glucose sensor 42 is delivered via an “insertion gun” (e.g., 200). EX1008, 3:6-16, 28:44-60. The insertion gun includes an “insertion

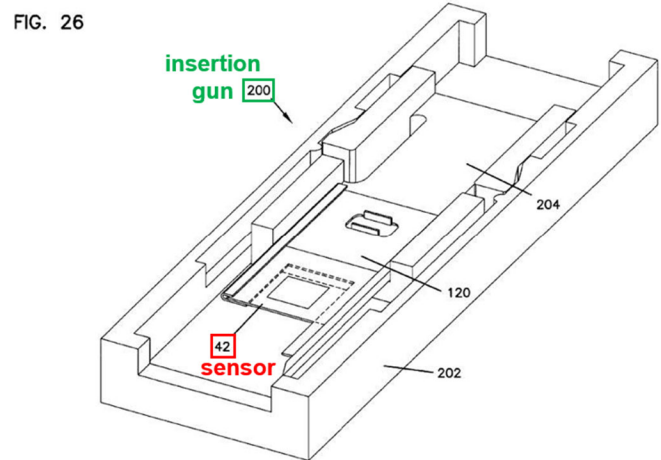
device” 120 (such as a sharp or needle) preloaded with the sensor and delivers the sensor via an opening in a mounting unit 77 attached to the user's skin. 27:42-51, 32:13-15, 32:53-59, 33:7-12, 34:5-15, 3:6-16. After the sensor is implanted, the sensor control unit is then attached to the top of the mounting unit. 32:6-14, 36:25-64, 3:6-16.



b) Shah

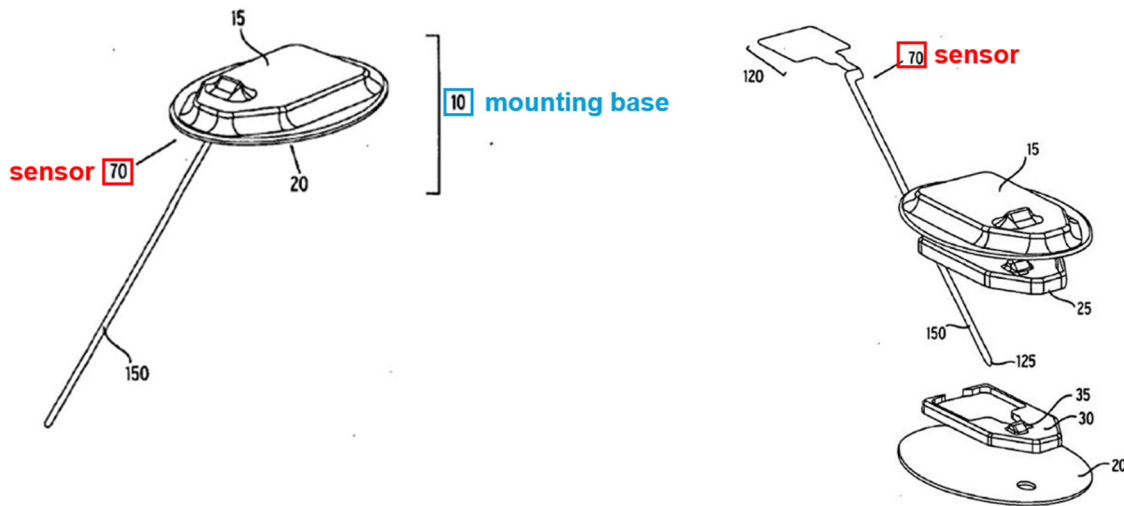
U.S. Publication No. 2007/0073129 (“Shah”) published in 2007 and was also before the PTO. EX1006; EX1001, 9. Shah describes CGMs in which the sensor is delivered by an inserter into a control unit attached to the skin. EX1006, [0007]; EX2002, ¶¶63-68.

Shah describes problems with existing CGMs including issues surrounding sharp stabilization. EX1006, [0005]. Shah acknowledges that, because “sensor systems utilize a component that is positioned transcutaneously, it is very important that the [placement] site *be stable*.” [0006]. Shah explains that “[m]any [prior]



glucose sensors generally utilize complex structures to mount and hold the sensor set in place on the patient's skin." *Id.* Shah's solution is "an improved sensor mounting base adapted to provide quick and easy transcutaneous placement of the film sensor on a patient comfortably *and with sufficient stability....*" [0007]; EX2002, ¶64.

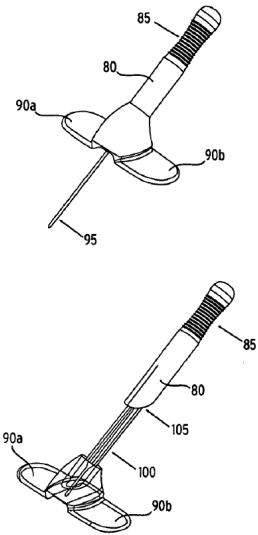
In one embodiment, "a subcutaneous insertion set" is used with a "flexible mounting base [10]" for placing the sensor [70] at a site within the body. [0012].



The mounting base 10 is pressed onto the user's skin. [0013]. The user employs an insertion set, which does not deliver any on-body unit, but rather

includes an insertion needle (e.g., 95 in Fig. 5A) that pierces the skin and places the sensor. *Id.* Addressing the concerns with needle stability, Shah describes mechanisms to “stabilize the needle and substantially ensure[] safe, stable entry and exit for the needle.” [0010], [0042]-[0044] (“wings [90a, 90b]...hold the...needle...stable after the needle tip...is inserted....”); EX2002, ¶¶65-66.

Fig. 5A



Other embodiments and needle safety features are also described. [0045],[0043]; EX2002, ¶¶67-68.

c) Brenneman

WO 2008/115409 (“Brenneman”) published in 2008 and was considered by the PTO. EX1001, 14; EX1040. Describing yet another CGM variation, Brenneman recognizes that, despite years of development, there were still significant problems surrounding existing CGMs. EX1040, [003].

Brenneman discusses “challenges” in “minimiz[ing] the number of acts to (a) attach the sensor/electronics to the skin and (b) insert the implantable sensor...” and was concerned with “control[ling] location (especially depth) of the sensor in the skin.” *Id.*; EX2002, ¶¶70-75. Brenneman explains that controlling sensor delivery “is especially important” for at-home users. [0040]; EX2002, ¶70.

Brenneman's solution employs an inserter that uses "simple rotary motion" to deliver a monitoring assembly 10 with a sensor 22 and sensor electronics. [0026], [0041], [0036], [0044]. A sharp-ended cannula 24 "assists in inserting the implantable sensor 22 into the body" and "in controlling the depth of the placement." [0036]; EX2002, ¶71.

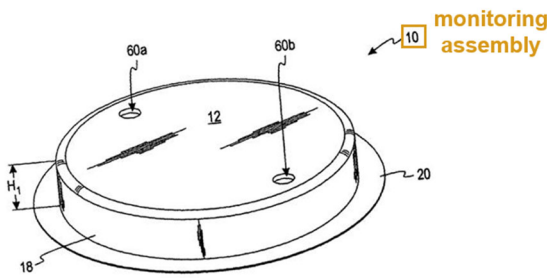


Fig. 1

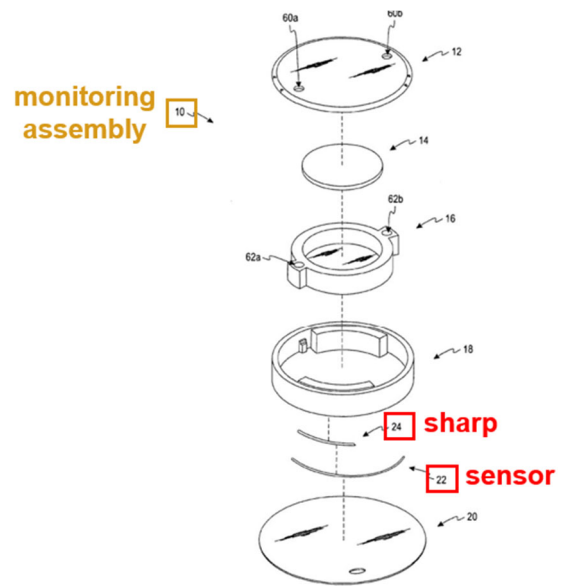
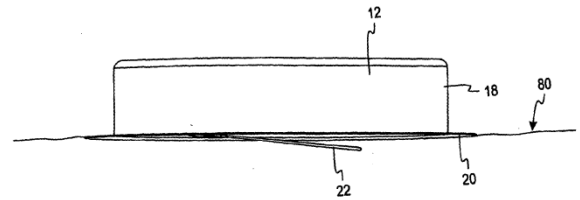
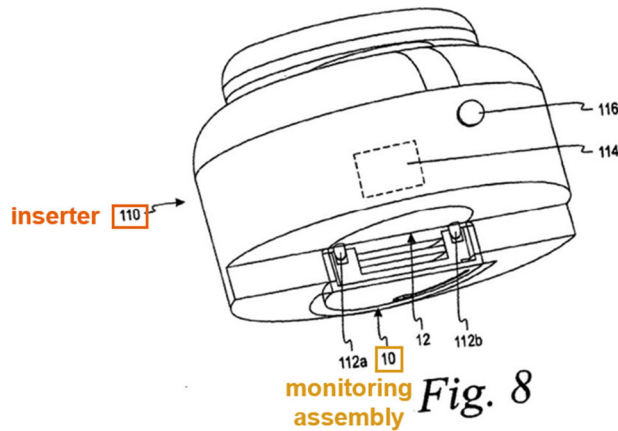


Fig. 3

Brenneman's inserter (110) is loaded with the monitoring assembly (10) at its distal end. [0041]-[0042]. The monitoring assembly is pressed against and rotated on to the skin, driving the sensor into the user at an angle. [0041],[0044]. The assembly does not advance from a proximal to a distal position; rather, it starts—and remains—at the inserter's distal end. Figure 7 depicts the assembly with sensor 22 implanted in the skin 80. [0017]; EX2002, ¶¶72-73.



Brenneman teaches that “[t]he rotary motion of the...assembly 10 is desirable because it results in a smaller footprint.” [0047]. Moreover, “rotary motion is desirable” because the angled insertion results “in improved depth control in the locating of the implantable sensor.” *Id.*; EX2002, ¶74.

As discussed *infra*, while Petitioner relies on certain arbitrary “openings” in Brenneman, Petitioner *never considers* Brenneman’s *inserter* (including its “desirable” features) for its combinations. EX2002, ¶75.

d) Stafford

As certain sensor delivery mechanisms became more complicated, others focused on *simplifying* the design. U.S. Publication No. 2008/0097246 (“Stafford”), an Abbott application published in 2008 and Petitioner’s primary reference, describes a simple, easy-to-use, eco-friendly, and low-cost CGM that was *specifically designed to reduce components and avoid the need for a separate inserter*. EX1004, [0044]-[0045]; EX2002, ¶¶76-83. Stafford was also before the PTO. EX1001, 10.

Stafford recognizes that the art often employed “a separate deployment mechanism such as a sensor inserter or introducer” to “substantially concurrently guide the sensor” through the skin. [0002]. But Stafford observes that the “inserter is typically used only during the sensor insertion process” and “the inserter and the introducer are [then] discarded.” [0004],[0003].

Recognizing potential wastefulness, Stafford’s solution is a “simple, easy to handle and accurate sensor introduction and retention mechanism” that “***minimizes the number of components***, and which also reduces the number of required steps to properly and accurately position the analyte sensor.” [0005],[0045]. Stafford’s invention is thus “an ***integrated*** analyte sensor delivery and data processing unit” with an “introducer removably coupled to the housing” that “provides simple, easy to use analyte sensor placement...and also, which may be easily performed without the use of both hands.” [0018], [0006]-[0007]; EX2002, ¶79. With those components, Stafford’s “simple” device is complete; there is no need for additional components.

The minimalist nature of Stafford's design is described in its five-page specification. The integrated assembly 100 includes a data processing unit 101, introducer 102 comprising a needle, and a sensor 106 housed within the needle. [0019], [0023]. A removable guard 104 covers the needle, preventing inadvertent needle sticks. [0022].

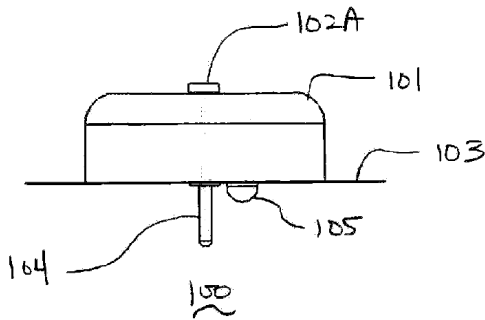


FIGURE 1

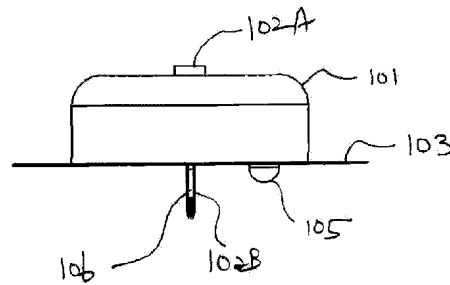


FIGURE 2

The user removes the needle guard, places the assembly on the skin, and applies force to unit 101 such that the introducer (portion 102B) pierces the skin. [0024]. The user then pulls the top of the introducer (102A) away and the device is ready for use. *Id.*; [0019]; EX2002, ¶¶80-81.

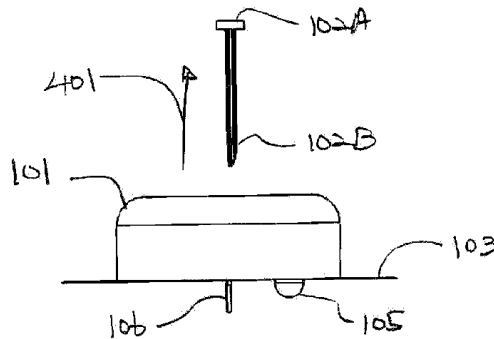


FIGURE 4A

A fundamental aspect of Stafford's design is that it is a simple *standalone device* that “*reduce[s]...components*” such that *a separate inserter is “not necessary”*:

[T]he integrated analyte sensor and data processing unit assembly is configured to integrate an analyte sensor, a sensor introducer mechanism, and a data processing device into a single disposable assembly which allows for simple and accurate sensor deployment Accordingly, *a separate sensor introducing device* such as a separate insertion gun or a separate sensor delivery mechanism is *not necessary*.

[0045],[0044],[0028].

In a paragraph ignored by Petitioner, Stafford emphasizes that its simplified design achieves numerous advantages:

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...other benefits such as *reduction in material cost, weight, packaging, and associated handling and disposal* may be achieved.

[0045]; EX2002, ¶¶82-83.

3. Cote's Reorientable Infusion Set And Cannula Delivery System

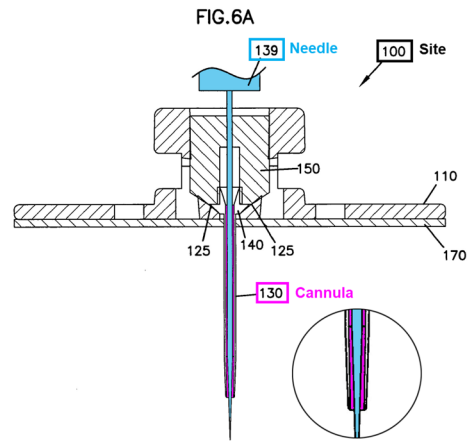
Petitioner relies on Cote (U.S. Publication 2005/0101932) as its secondary

reference for all grounds. Cote was published in 2005 and a counterpart was considered by the PTO. EX1005; Institution Decision, 11.

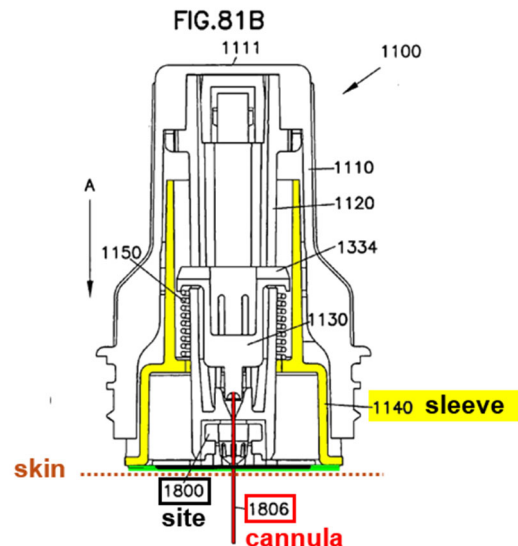
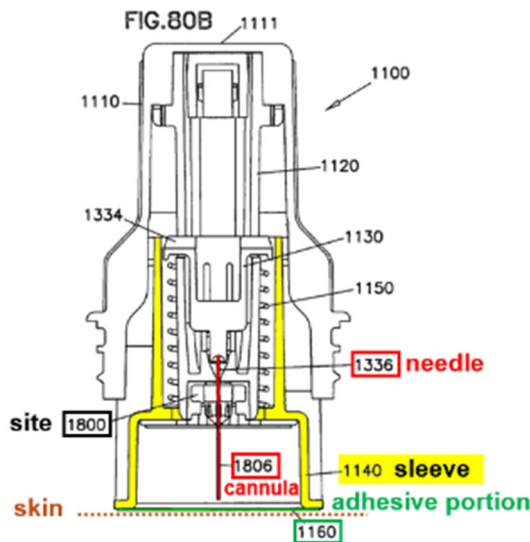
Cote relates to an *infusion system*; it says nothing about glucose sensors or challenges with sensor delivery. EX2002, ¶¶85, 177,57-58, 160, 171-172. Cote's infusion system uses a "device" to insert an infusion "site" that includes an infusion cannula into the patient's skin. Once the site is placed, an "infusion set" is attached to it, allowing medicament to be delivered through the cannula. EX1005, [Abstract],[0001]-[0002]; EX2002, ¶¶85-88,180-189.

Importantly, Cote focuses on problems with existing *infusion systems*, noting that "once the infusion device is placed..., there is typically no way to reorient [it]...or to remove the tubing...without removing the cannula from the skin." EX1005, [0003]. Cote also describes "difficulty loading the infusion device into the insertion device." [0006]. Cote's solution is a reconfigured device that includes "multiple rotational orientations with respect to the site" that can "be coupled and uncoupled with the site multiple times." [Abstract], [0010]; EX2002, ¶¶86,92-95.

Figure 6A depicts Cote's infusion site with the infusion cannula (pink) surrounding the sharp (blue). [0143]; [0134],[0184]. Diaphragm 150 functions as "septum," allowing for the delivery of medicament from the infusion device to the cannula. [0141],[0144]. Adhesive 170 allows the site to adhere to skin. [0134], [0150], Fig. 79A; EX2002, ¶87.

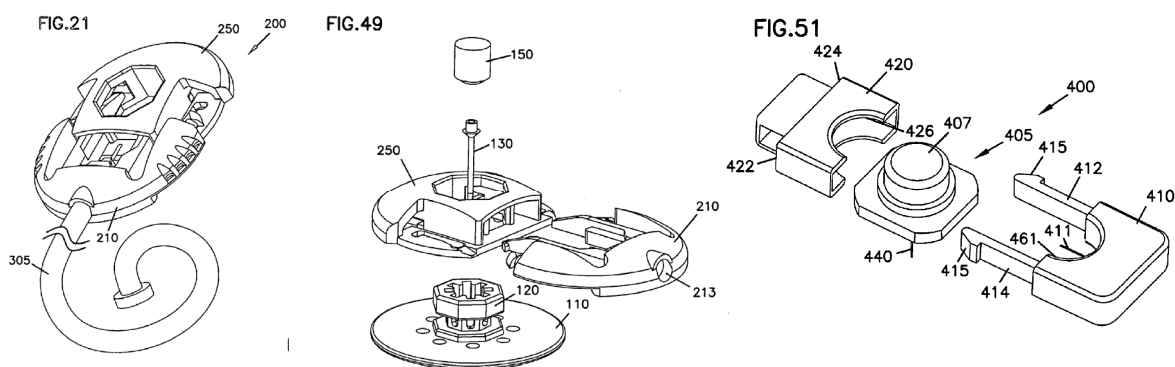


As shown below, the infusion cannula (1806) is inserted into the skin with an insertion "device" (e.g., 1100) in which the site (1800) is preloaded. [0179], [0202],[0205]; Figs. 80B,81B. The patient "applies pressure" to the upper housing of the device 1100 "to move the housing 1110 and associated structures...including

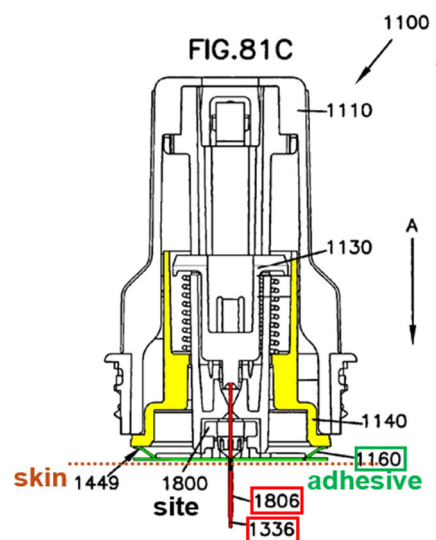


needle 1336 and site 1800[] in a direction A...toward the skin 1900.” [0207];
EX2002, ¶¶88, 180-183.

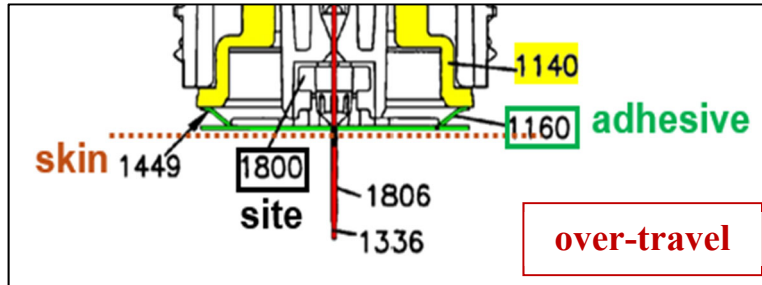
Once Cote’s infusion site is on the skin and the inserter is removed, the patient couples an infusion set (e.g., 200) to the site to deliver medicament into the cannula. [0153]. Using Cote’s redesigned infusion set and site configuration, patients can easily adjust and reorient the infusion set in numerous positions relative to the fixed-in-place site—a *benefit irrelevant to CGM systems*. [Abstract],[0154]-[0171]; EX2002, ¶¶92-95. Embodiments of Cote’s reorientable infusion sets are below.



As explained below (§VI.A.1.), *Cote's infusion cannula inserter is unlike the sensor inserter of the claimed invention*, which requires the distal end of the inserter to be positioned on the skin for sensor insertion and sharp retraction, Instead, Cote's infusion cannula inserter is specifically configured to have an "over-travel" feature that requires the distal end of the inserter to



move *away from* the skin after the cannula is delivered but *before* its sharp (1336) is retracted (see blow-up). Specifically, the “site 1800 travels slightly beyond...the



sleeve 1140 [yellow] as shown in Fig. 81C.” [0209]. Cote explains that “[t]his ‘over-travel’ assures that the adhesive portion 1160 [green] is properly sheared away from the....sleeve 1140” to couple the site to the adhesive. [0209]-[0210]. As Petitioner acknowledges (Pet. 63 n.9), the over-travel is also required to *initiate sharp retraction*. Thus, rather than having its sharp retract while the distal end of the inserter is *on* the skin, Cote is configured so that its sharp retracts while the distal end is *off* the skin. [0211], [0203]; EX2002, ¶¶89-91, 184-190.

B. Abbott's Innovations In The 591 Patent

1. The 591 Patent

While the industry spent years trying to develop CGMs that allowed for easy yet accurate self-deployment, by 2009, there was still no accessible, user-friendly, and simple all-in-one solution.

Abbott embarked on extensive efforts to develop CGM systems that maintained sensor accuracy while maximizing user access and convenience. The 591

Patent was a result, recognizing the “need for an easy-to-use, simple, insertion assembly which is reliable, minimizes pain, and is easy to use.” EX1001, 2:7-9. The specification describes numerous cost-effective, convenient, and reliable all-in-one solutions. EX2002, ¶98.

The 591 Patent describes and claims “an insertion assembly,” which includes an “on-body unit” (OBU 16) and an “inserter” to deliver it. 4:17-26, 14:54-57, 15:1-3, 16:30-19:40. The OBU has a

“reduced height” yet comprises an analyte sensor 14 and related electronics (processor, power source, analog interface, data storage unit, and wireless communication circuitry). 11:52-

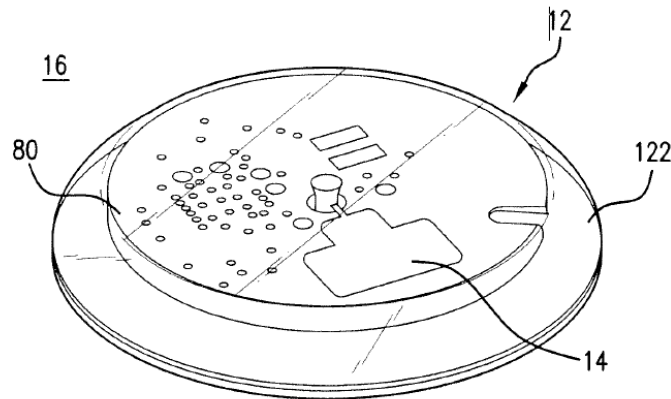
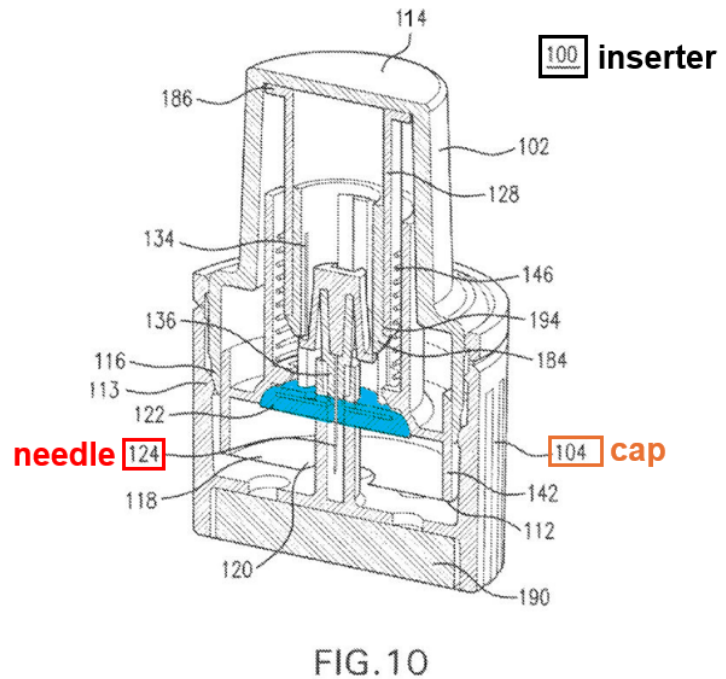


FIG. 7

62, 14:1-27, 17:59-63. Users do not need to insert the sensor and then manually connect the electronics (a departure from the two-part CGM systems that came before). Rather, the specification describes sensor electronics disposed in the OBU housing coupled with a glucose sensor. 2:34-36, 14:28-42. Numerous ways to construct this compact all-in-one OBU are described. 17:66-18:7, 12:34-13:2, 14:28-41; EX2002, ¶¶99-100.

The inserter (e.g., 100) allows users to accurately and safely deliver the OBU and its delicate sensor. 16:30-19:40, 3:51-60, 4:17-26, 15:1-6. The inserter includes an automatically retractable sharp (e.g., needle 124) that extends through the OBU (blue), with a portion of the sensor positioned within the needle. 19:16-19, 15:49-54, 17:20-22, 17:54-56, 12:31-34, Figs. 10, 22, 23. A removable cap 104 maintains a sterile environment, stabilizes the needle and sensor, and protects the user from the sharp. 16:31-37, 16:60-67; EX2002, ¶¶101-103.



In use, the distal end of the inserter is first positioned on the skin (S). 16:37-43, 17:1-4. The user then advances the OBU and sharp linearly from a first, proximal position within the inserter (e.g., Figure 29) to a second, distal position on the skin (e.g., Figure 30). 16:41-43, 19:1-22. While moving from the first to second position, the OBU housing travels a distance greater than its maximum height. *Id.*; EX2002, ¶104.

First Proximal Position

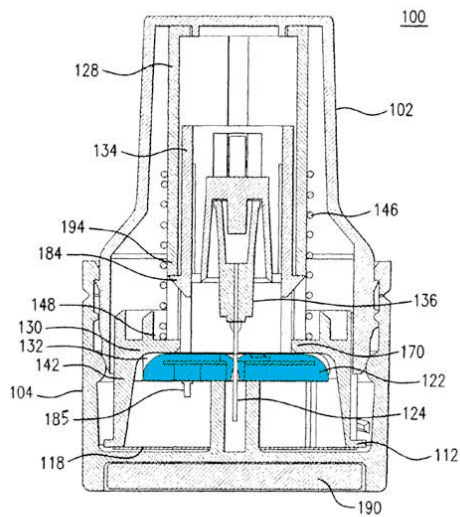


FIG. 29

Second Distal Position

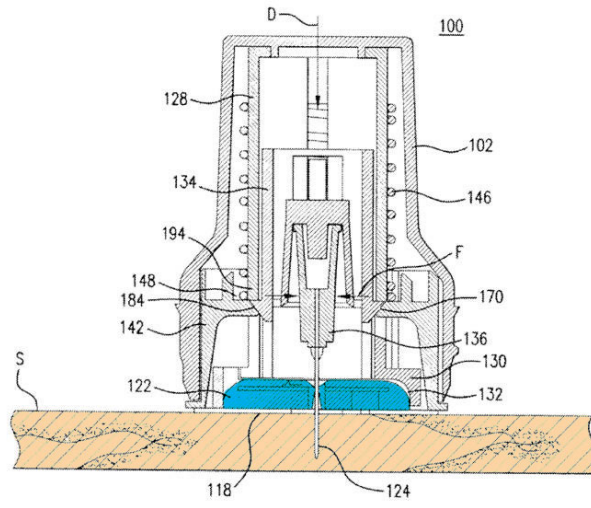


FIG. 30

After the OBU is advanced, the inserter then automatically retracts the sharp from within the user. 15:60-16:7, 16:20-28, 19:26-33. The inserter can then be removed from the skin, leaving the OBU securely on the skin and the sensor appropriately inserted in the user. 15:3-6, 19:16-33, Figs. 28-31; EX2002, ¶105.

The sensor electronics may be in a sleep or idle mode until activation, preserving battery life. 19:41-57. Many novel activation mechanisms are described. Figs. 32-43, 19:41-22:35. For example, a plunger switch (185) on the distal end of the OBU activates the electronics when the switch engages the user's skin. 19:58-20:14; Fig. 29; EX2002, ¶106.

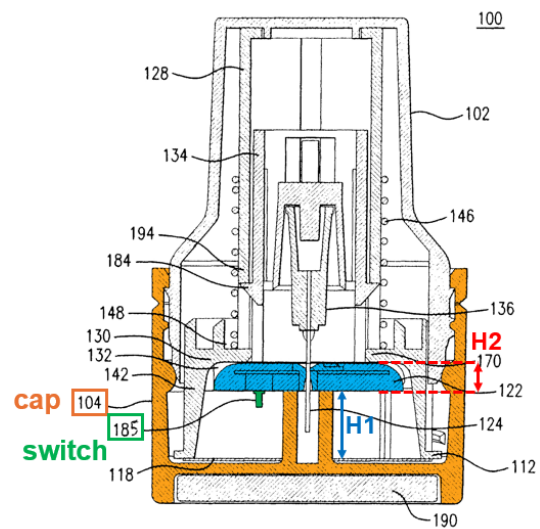


FIG. 29

The claims capture these novel features. EX2002, ¶107. Claims 1 and 19 are the independent claims with *all elements of Claim 1 being subsumed by Claim 19*, e.g.:²

[19.1]/[1.1] An insertion assembly, comprising:

[19.2]/[1.2] (a) *an on-body unit, comprising:...*

[19.3]/[1.3] a housing...wherein the top [housing] surface comprises an opening..., ...; ...

[19.5]/[1.5] *sensor electronics* disposed within the housing and *coupled with the glucose sensor*, [19.6] wherein the sensor electronics comprise a processor, a power source, an analog interface, a data storage unit, and wireless communication circuitry...; and

[19.7]/[1.6] (b) *an inserter*,...:...

[19.12]/[1.12] wherein the inserter is configured to advance the [OBU] and the sharp in a linear direction from a[the] first position to a second position such that the sharp pierces skin of a user and the housing of the [OBU] is secured to the skin of the user in the second position,

[19.13] wherein a distance between the housing when the [OBU] is in the first position and the housing when the [OBU] is in the second position is *greater than a maximum height of the housing*,

[19.14] wherein *a height profile of the housing is less than...10 millimeters*,...

[19.17] /[1.13] wherein *the distal end of the inserter* is configured to be *positioned on the skin* of the user before advancement of the [OBU] and

² Abbott utilizes Petitioner's limitation numbering.

the sharp,

[19.18]/[1.14] ...the inserter...automatically retract[s] the sharp ...and leave[s]...the...sensor in the skin..., and

[19.19]/[1.15] wherein *the distal end of the inserter* is further *configured to be removed* from the skin of the user *after* automatic *retraction* of the sharp from within the user.

Claims 2-18 and 20-30 depend on Claims 1 and 19, respectively. **Claims 4-17** further depend on Claim 3, which recites limitation 19.13.

Claims 22-30 each further depend on Claim 21, which (along with Claim 18) require a “second opening” in the top surface of the OBU housing.

Claims 7, 8, 25, and 26 further require “sleep mode” or “activation” features relating to the sensor electronics.

Claims 15 and 28 further comprise a “sensor hub.”

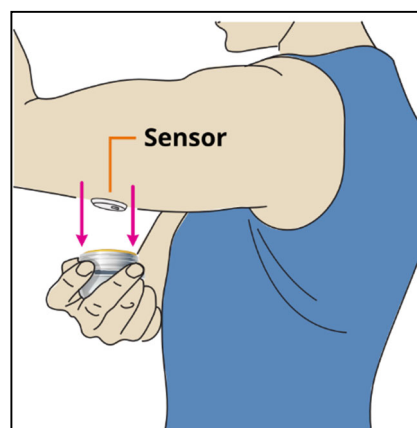
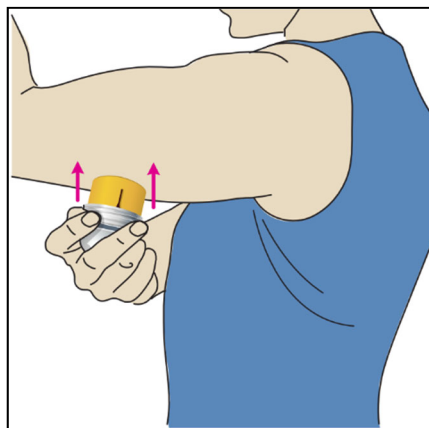
2. Abbott's Award-Winning FreeStyle Libre Products And Petitioner's G7 Products

In 2014, Abbott launched the FreeStyle Libre CGM system, which embodies the 591 invention. EX2033; EX2002, ¶¶373,390, App.B; EX2007-2010. Libre made continuous glucose monitoring simple, affordable, and accessible for a broad population. Abbott's FreeStyle Libre systems (across all iterations) were the first commercially-available CGMs that allowed the average person to use an easy-to-use inserter to deploy an all-in-one, ultra-low profile OBU that includes a glucose sensor connected to sensor electronics and reliably monitor their glucose levels. *Id.*;

EX2002, ¶¶375-382; EX2019; EX2011, 923-924; EX2037-EX2038; EX2007, 7; EX2008, 6-7; EX2009, 5; EX2010, 39.

	FreeStyle Libre	FreeStyle Libre 2	FreeStyle Libre 3
Insertion Device			
On-Body Unit			

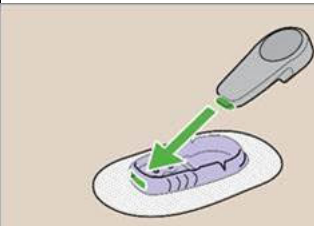
Libre's simple application is depicted below. EX2010, 39; EX2002, ¶¶383-4.



Libre is now the *most accessible and widely used CGM in the world*, helping more than 5.5 million people worldwide by providing technology that is affordable, accurate, reliable, and simple to use. EX2019, 1. As discussed in §XII, Libre has

been praised worldwide, received numerous prestigious awards including the Galien Golden Jubilee award for the “Best Medical Technology” *in the last fifty years*, and is commercially successful. EX2002, §XVIII.D; EX2004-EX2006; EX2022-2032; EX2035. The public waited decades for a cost-effective, user-friendly, all-in-one CGM. Libre finally provided the solution. The fundamental concepts embodied in the 591 Patent have contributed to Libre’s affordability, reliability, accessibility, and its simple, effective handling. EX2002, ¶414.

While Petitioner now asserts that the 591 inventions were obvious in 2009, Petitioner released generations of multi-component systems with complex angular inserters that required users to first insert the sensor and manually connect the sensor electronics (two-part CGM systems). EX2014, 20-22; EX2015, 14-16; EX2002, ¶¶397-399.

	Dexcom G5	Dexcom G6
Inserter		
On-Body Portions		

It was only *after* Abbott's patented Libre product was released that Petitioner released the "G7," which uses a Libre-style inserter to deploy an all-in-one single on-body unit. EX2003, 16-19, Ex.F; EX2002, ¶¶400-401.

	FreeStyle Libre	Dexcom G7
Inserter		
On-Body Unit		

Abbott has sued Petitioner, asserting that the G7 infringes the 591 Patent. EX2003, 37-39, Ex. F.

III. LEVEL OF ORDINARY SKILL

Abbott does not necessarily agree with Petitioner's proposed skill level, but it is not disputed for purposes of this IPR. *See* EX2002, ¶¶22-23.

IV. CLAIM CONSTRUCTION

Abbott contends the plain and ordinary meaning of the claim terms should apply with additional clarifications provided herein. While Petitioner purports to

apply the “plain and ordinary meaning” (Pet. 19), Petitioner’s application of the art to the claims demonstrate that it is not doing so.

V. ALL GROUNDS: POSAS WOULD NOT HAVE BEEN MOTIVATED TO COMBINE STAFFORD WITH COTE

All of Petitioner’s grounds hinge on combining Stafford and Cote. But the references fail to disclose numerous claim elements—even when combined with multiple additional references as Petitioner urges. EX2002, ¶¶40-49, 121-123, 163. Worse, Petitioner starts with the 591 Patent as a blueprint and then uses hindsight to reconstruct the patented inventions. Petitioner ignores plain evidence demonstrating that POSAs would *not* have been motivated to complicate Stafford’s streamlined CGM design by *adding* Cote’s complex infusion-site inserter. Stafford expressly teaches to *simplify* CGM designs and “*minimize...components*”—not add them.

Moreover, Petitioner never explains why POSAs would ignore the numerous existing inserters known for delivering *glucose sensors* (despite arguing that POSAs would rely on that same art for other limitations) and arbitrarily cherry-pick one embodiment of Cote’s *particular* inserter for an infusion cannula attached to a rotatable infusion set. Petitioner’s hindsight analysis is improper, and the claims are not unpatentable.

A. Stafford Teaches Simplifying CGM Design—Not Making It More Complex And Costly

“Determining whether a claimed combination would have been obvious to a skilled artisan requires consideration of all the facts....” *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1360 (Fed. Cir. 2017). “Evidence suggesting reasons to combine cannot be viewed in a vacuum apart from evidence suggesting reasons **not to combine**.” *Id.* at 1363. “The prior art, skill, and knowledge of [POSAs] may also provide reasons not to combine....” *Id.* Prior art teaches away when POSAs “would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path...taken by the applicant.” *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1305 (Fed. Cir. 2015).

Moreover, “[i]t is **impermissible** within the framework of section 103 **to pick and choose** from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests.” *In re Wesslau*, 353 F.2d 238, 250 (CCPA 1965). Indeed, assessing prior art excerpts in isolation from their full context is “improper hindsight analysis.” *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 448 (Fed. Cir. 1986).

Here, Petitioner impermissibly picks and chooses among the art, ignoring the teachings of its own references. Stafford teaches a “simple,” cost-effective, streamlined “single assembly” **without** a separate inserter. POSAs would not have

been motivated to add a complex “Cote-like inserter” to Stafford. Pet. 29. Doing so would gut the expressly-identified benefits of Stafford’s design. EX2002, ¶¶125-127,133.

As explained in §II.A.2.d., a critical aspect of Stafford’s design is that it “minimizes...components” and renders separate inserters **“not necessary.”** Stafford recognizes the wastefulness of “inserters and introducers” that are used once and “discarded” and explains how its “sensor introducer mechanism” allows for a “simple and accurate” system **without** costly and complex inserters:

[T]he integrated analyte sensor and data processing unit assembly is configured to integrate an analyte sensor, a sensor introducer mechanism, and a data processing device into a single disposable assembly which allows for simple and accurate sensor deployment Accordingly, **a separate sensor introducing device** such as a separate insertion gun or **a separate sensor delivery mechanism is not necessary.**

EX1004, [0044], [0007], [0003], [0021]-[0026]; EX2002, ¶¶128-133.

Petitioner argues that its combination “aligns with Stafford’s goal of ‘a single disposable assembly’” because Cote’s infusion site inserter is somehow not “separate” (apparently attempting to distinguish Say’s sensor “insertion gun”). Pet. 30. But Petitioner never explains why Cote’s inserter would not be a “separate inserter.” Pet. 30. Indeed, Petitioner’s combination relies on using both the Stafford OBU and its “introducer mechanism” (sensor-comprising sharp). Pet. 43, 40.

Petitioner then adds Cote's separate inserter *on top of* Stafford's complete device. Pet. 37-38; EX2002, ¶¶134-135.

Nevertheless, Petitioner tellingly ignores the next paragraph of Stafford, which emphasizes the numerous advantages offered by Stafford's streamlined design—*all of which are eliminated* by Petitioner's proposed combination:

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*...other benefits such as *reduction in material cost, weight, packaging, and associated handling and disposal* may be achieved.

EX1004, [0045], [0005].

Indeed, adding a Cote-like inserter as Petitioner urges results in *exactly what Stafford counsels against*—a larger profile, more packaging, increased manufacturing costs, more components, increased material cost, increased weight packaging, and additional handling and disposal. Even Petitioner's expert agreed. EX2036, 98:25-106:12. Thus, contrary to Petitioner's arguments, POSAs would *not* be motivated to make the combination as Stafford suggests the opposite. EX2002, ¶¶136-137.

Petitioner's sole argument is that adding a "Cote-like inserter" would "prevent[] accidental needle sticks." Pet. 29. Petitioner relatedly asserts that "a

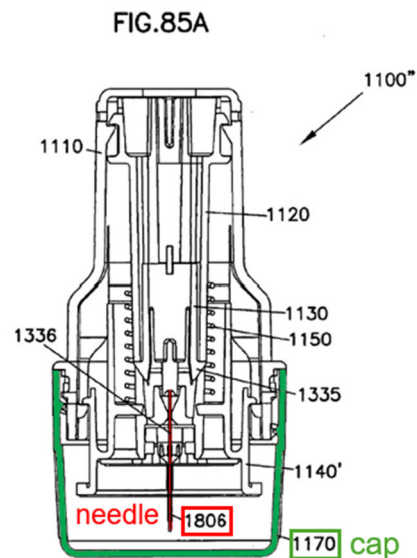
shrouded and automatically-retracting inserter” would minimize “pain and anxiety.”

Pet. 30. But Stafford already describes ways to prevent “accidental needle sticks:”

[G]uard segment 104 is configured to substantially cover the lower portion 102B of the introducer....[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....

EX1004,[0022]-[0024]. Petitioner ignores this disclosure, asserting that Stafford does not prevent sticks “after the guard is removed.” Pet. 29. But it is well understood that a needle guard can be replaced after use and/or the needle can be placed in a sharps container. EX2002, ¶¶138-140, 142-143. Indeed, Cote states as much. EX1005, [0213],[0219] (“the patient preferably reapplies the cap to the housing”).

Petitioner also never adequately explains why “a Cote-like inserter” would reduce “pain and anxiety” over Stafford’s “guard segment” design. Pet. 30. Petitioner’s references demonstrate that a needle guard/cover is an accepted design. EX2002, ¶142; EX1006, [0043]; EX1009, [0107]. ***Cote itself includes embodiments where the needle is covered just like Stafford***—never suggesting that this design causes “pain and anxiety” or



should be avoided. EX1005, Fig.85A, [0107], [0216] (“once the cap 1170 has been removed, needle 1336 is exposed”); [0219]; EX2002, ¶143. Moreover, in the embodiment selected by Petitioner, Cote relies on manual force to initiate the needle injection—***just like Stafford***, demonstrating that avoiding needle “pain and anxiety” was not Petitioner’s guiding concern. EX1005, [0207]; EX2002, ¶¶141,144,155; EX2036, 71:10-15.³

There is no motivation to arbitrarily alter Stafford to make the device more complex and costly (contrary to Stafford’s teachings)—to solve an alleged “problem” present in both references that neither reference endeavors to address. *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1369 (Fed. Cir. 2012) (“Because each device independently operates effectively, [POSAs] would have no reason to combine the features”); *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019) (no motivation to combine references with redundant capabilities); *St. Jude Med., Inc. v. Access Closure, Inc.*, 729 F.3d 1369, 1381 (Fed. Cir. 2013) (no motivation to combine when POSAs would view references “as substitutes to achieve the same...objective”). Moreover, any “pain and anxiety” reduction does not overcome Stafford’s ***explicit goal*** of eliminating

³ Cote discloses other embodiments with both automatic insertion ***and*** retraction. EX1005, [0220], [0236].

complex insertion mechanisms and reducing components and cost. EX2002, ¶¶145-146; *see, e.g., Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349-50 (Fed. Cir. 2000).⁴

Courts have found no motivation to combine under less compelling circumstances. *Arctic Cat*, 876 F.3d at 1363 (art discouraged the combination); *Henny*, 938 F.3d at 1331-32 (combining references would result in needless inefficiencies); *St. Jude Med., LLC v. Snyders Heart Valve LLC*, 977 F.3d 1232, 1242-43 (Fed. Cir. 2020) (no motivation to combine references in illogical way). Thus, Petitioner's combination of Stafford and Cote should be rejected, and all of Petitioner's grounds fail.

B. POSAs Would Not Employ Petitioner's Cherry-Picking Methodology

It is improper to use “naked parts of separate prior art references...as a mosaic to recreate a facsimile of the claimed invention.” *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1552-53 (Fed. Cir. 1983). But that is exactly what Petitioner does with its Stafford/Cote combination. Even if Petitioner's “needle” arguments

⁴ In asserting the combination is reasonably expected, Petitioner further ignores the challenges of converting Cote's infusion cannula inserter to an analyte sensor inserter, which requires significant considerations surrounding proper and stable placement of the fragile sensor. Pet. 31-32; EX2002, ¶¶159-161, 57-58, 170-173.

compelled a separate inserter despite Stafford's admonitions, Petitioner never explain why POSAs would turn to *Cote's infusion cannula* inserter rather than start with the numerous *sensor* inserters in the art, including many cited by Petitioner (e.g., Brenneman, Shah, another Stafford reference (EX1042)), which focus on solving *sensor delivery* problems. EX2002, ¶¶57-58, 147-150, 160,64,70.

Petitioner simply ignores those sensor inserter designs while selecting arbitrary disclosures from that art for other limitations. Pet. 76-79, 100-101. Indeed, Petitioner identifies *seven other references* that purportedly establish “inserter designs were interchangeably used” for inserting both sensors and cannulas, yet Petitioner relies on *none* of those inserters. Pet. 12. Petitioner likewise ignores the differently-configured automatic *cannula inserters* described in the very publications upon which it relies to establish needle “pain and anxiety.” Pet. 11, citing EX1036, [0004]-[0005]; EX1037, [0005]; EX2002, ¶¶151-152.

Petitioner cherry-picks one of *Cote's* inserter designs to solve purported “needle” issues though Cote does not discuss delivering analyte sensors, does not address challenges with sensor delivery, and teaches using shrouded needles. Indeed, Cote focuses on infusion system problems and provides embodiments that—*just like Stafford*—use needle caps. EX2002, ¶153; EX1005, [0198]; §II.A.3. Moreover, that Petitioner relies on Cote embodiments that employ *manual* (rather than *automatic*) needle insertion demonstrates Petitioner's goal is not minimizing “pain and anxiety”

but using hindsight to recreate the invention. EX2002, ¶155; EX1005, [0207], [0220],[0236]; EX2036, 71:10-15. Petitioner's combination is particularly curious given that Cote's inserter already has the same benefits as Stafford's "introducer" (e.g., single-handed operation) while offering no additional benefits in sensor handling or placement. Pet. 31; EX2002, ¶¶146,154.

POSAs would not employ Petitioner's selective and improper hindsight strategy. EX2002, ¶¶155-157; *see Monolithic Power Sys., Inc. v. Volterra Semiconductor*, IPR2020-01368, Paper 19 at 24 (PTAB Mar. 4, 2021) (petitioner inappropriately "cherry-picked among the teachings"); *Lyft, Inc. v. Quartz Auto Techs., LLC*, IPR2020-01450, Paper 7 at 18 (PTAB Mar. 4, 2021) (petitioner employed "'pick-and-choose' presentation of evidence").

VI. GROUND I: THE PETITION DOES NOT ESTABLISH OBVIOUSNESS BASED ON STAFFORD IN VIEW OF COTE

In Ground I, Petitioner alleges that Claims 1-6, 9-14, 16-24, 27, and 29-30 are unpatentable over Stafford and Cote. Pet. 20. "Motivation to combine is considered "only 'if all the elements of an invention are found in a combination of prior art references.'" *PAR Pharm. v. TWI Pharms.*, 773 F.3d 1186, 1194 (Fed. Cir. 2014). Here, even assuming (incorrectly) a POSA would combine Stafford and Cote, numerous limitations are still missing.

A. Independent Claims 1 And 19

1. The “Distal End Of [Cote’s] Inserter” Is Not “Configured” To Be Positioned On And Removed From The Skin As Claimed (Limitation [19.19]/[1.15] in All Claims)

All claims require “the distal end of the inserter [to be] configured to be positioned on the skin” before advancement of the OBU and sharp. And the distal end is “further configured to be removed from the skin of the user *after automatic retraction of the sharp* from within the user.” EX1001, 23:35-43, 25:37-48. This is described throughout the 591 Patent. *See, e.g.*, 16:30-41, 17:1-4, 3:51-60, 15:1-6, 4:17-26, Figs. 10, 14, 28-31; EX2002, ¶¶166-169,175.

These limitations cannot be ignored as they ensure that the inserter is stabilized on the skin before and during sensor insertion and placement to avoid undue tissue trauma and so that the sensor is precisely delivered without shifting or misplacement. These limitations also provide needed stability during sharp retraction and prevent inadvertent tilting or bending of the sharp and sensor, which could interfere with retraction, increase user pain, or cause tissue trauma or other user injury. EX2002, ¶¶170-173; EX2043, 1007-1008; 2044, 321-322.

Unlike the claimed invention, Cote does not describe placing the distal end of the inserter on the skin before the cannula/needle is advanced and then removing the distal end from that positioning *after* automatic retraction of the sharp. To the contrary, Cote’s cannula inserter is configured so that its distal end moves away from

the skin *before* its needle is retracted—*the opposite* of the claims. EX2002, ¶¶174,184-189.

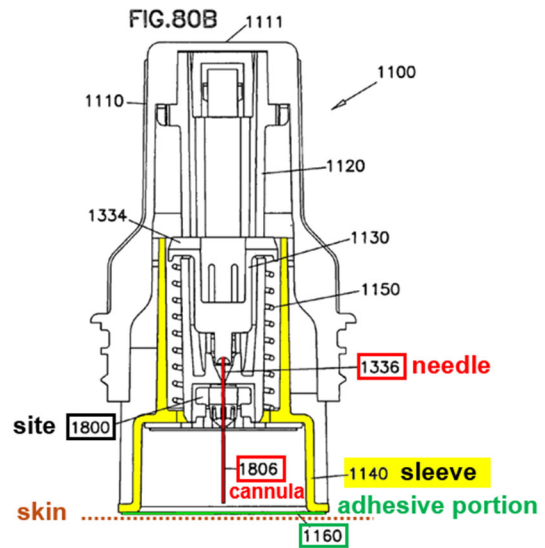
a) Cote's Infusion Cannula Inserter

For all grounds, Petitioner relies on Cote's inserter "device 1100" to satisfy the above-discussed limitations. Pet. 38, 48, 50; EX2036, 28:5-22, 29:19-30:18. Specifically, Petitioner repeatedly identifies the distal end of Cote's sleeve 1140 (yellow in images below) as the "distal end" of the inserter. Pet. 38, 48; EX2002, ¶178. But Cote focuses on delivering an infusion cannula—not an OBU comprising a fragile sensor from within a sharp. *See* §II.A.3; EX2002, ¶¶160,177, EX2036, 69:17-70:13. Cote is thus unconcerned about stability during placement of a fragile sensor. Accordingly, *unlike the claimed sensor inserter*, the distal end of Cote's inserter is specifically configured to be removed from the skin *before* its sharp is retracted. *Id.* While this is not a problem for Cote's infusion cannula, it could result in serious problems for CGM systems where, e.g., even a small degree of tissue trauma can adversely affect sensor performance. EX2002, ¶¶57-58,160.

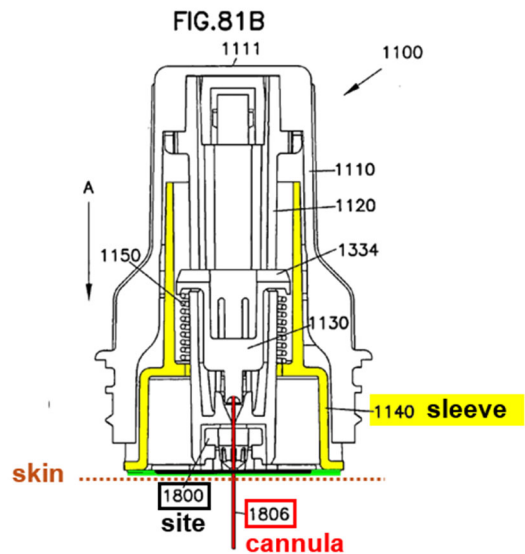
Specifically, Cote Figure 80B depicts device 1100 "in a delivery state ready to deliver the cannula of an infusion device into the skin." EX1005, [0203]. As

shown here, infusion site 1800 and sharp (needle 1336, red) are within the device.

An adhesive (green) that adheres the site 1800 to the skin is on the bottom of sleeve 1140 (separated from the site). [0180], [0190], Figs. 71-73. Cote states that “sleeve 1140...is positioned so that the adhesive...contacts the skin...” [0206], [0190]; EX2002, ¶¶180-181.⁵

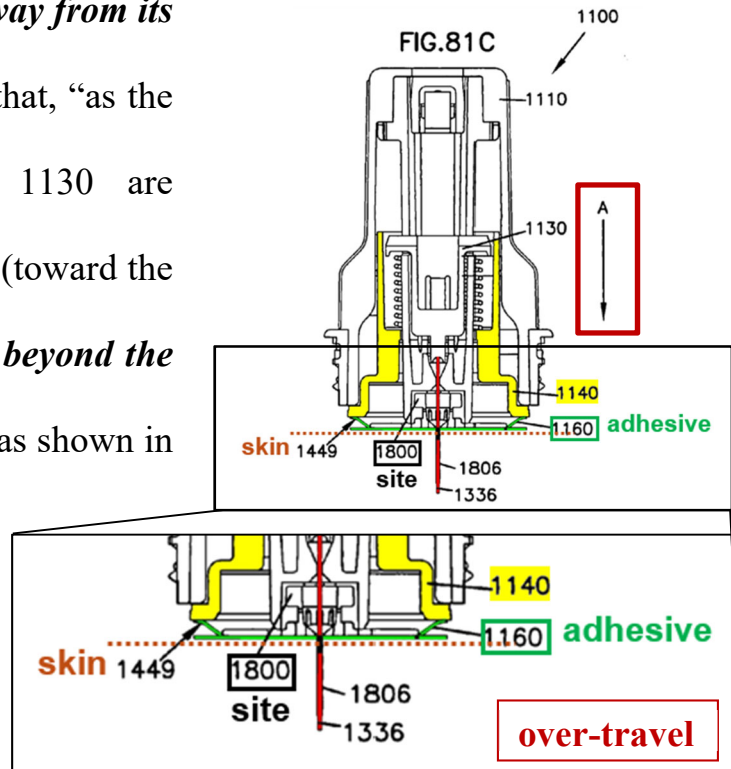


The user presses the upper housing of inserter 1100, moving needle 1336 and site 1800 “in a direction A...toward the skin” and inserting the infusion cannula (and needle within it) into the skin. [0207]-[0208]. Figure 81B depicts the device in a “trigger state” where the needle and cannula “have been fully inserted into” the skin. [0203], [0208]; EX2002, ¶¶182-183.



⁵ Petitioner relies on this statement to satisfy the limitation that the “distal end of the inserter is configured to be positioned on the skin...before advancement” of the OBU/sharp. Pet. 48.

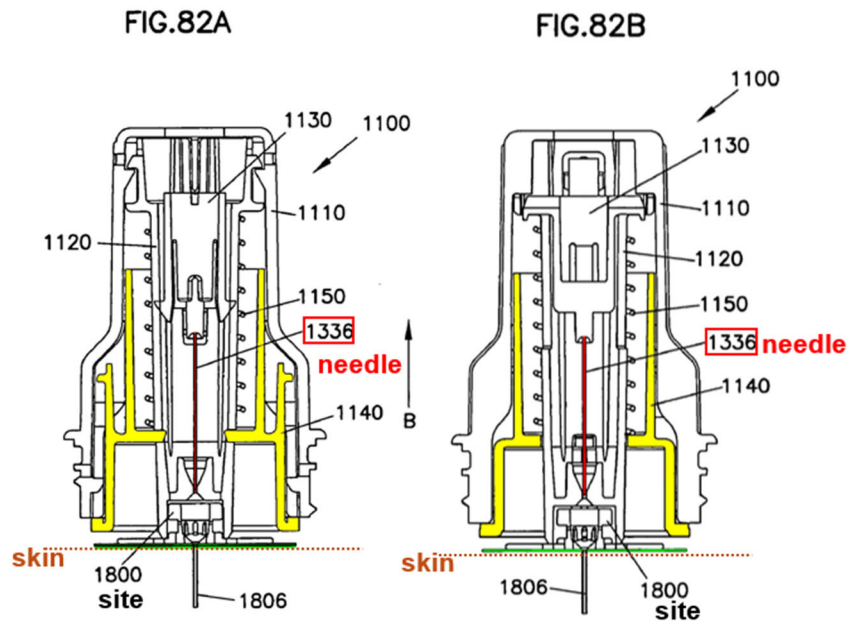
Importantly, *before the needle is retracted*, the distal end of Cote's cannula inserter is configured to be *moved away from its position on the skin*. Cote explains that, "as the housing 1110...and needle hub 1130 are displaced further in the direction A" (toward the skin), the "site 1800 travels slightly *beyond the second end 1442 of the sleeve 1140* as shown in Fig. 81C." [0209] As discussed (§II.A.3), Cote refers to this feature as the site "over-travel." [0209]. As can be seen, the "over-travel" results



in the distal end of the inserter moving away from the skin. "This 'over-travel' assures that the adhesive...is...sheared away from....sleeve 1140," coupling the adhesive to the site. [0209]-[0210]; EX2002, ¶¶184-185.

Cote's "over-travel" feature serves another purpose. As Petitioner's acknowledge (Pet. 53, n.9), Cote's inserter is configured so that the "over-travel" initiates sharp retraction. And this occurs while the distal end of the inserter is *removed from* the skin. [0211]. Specifically, Cote explains that "as the housing 1110...and needle hub...are displaced further in the direction A as described above [i.e., over-travel]," barbs holding the hub within the device are disengaged, allowing

the needle to retract. [0211]. Thus, the needle hub is “is free to move longitudinally within the passage....*in a direction B* opposite to...direction A.” *Id.* “[S]pring 1150...propels the needle hub 1130 and associated needle 1336 *in the direction B*,” “while the site 1800 and associated cannula 1806 are held on the skin..., as shown in Figs. 82A and 82B.” *Id.*; EX2002, ¶¶186-188.



Simply put, the needle is retracted while the site is “over-traveling,” i.e., while the distal end is removed from the skin, *the opposite of the 591 claims*. Figures 82A and 82B (above) show Cote’s inserter device in its “retracted state with the needle hub 1130 and associated needle 1336...retracted into the device” and with the distal end of the inserter *still removed from the skin*. [0203]; EX2002, ¶189.

Importantly, Petitioner and its expert admit that this over-travel—where the distal end of the inserter is moved away from the skin—is *necessary before* Cote’s

needle can retract:

POSITA[s] would understand that [Cote's] on-body unit [site 1800] ***must travel beyond the distal end of Cote's inserter*** to enable automatic retraction of the sharp.

Pet. 53 n.9; EX1003 ¶110 n.6; EX2002, ¶¶190-192.

b) “The Distal End Of The Inserter” Is Not “Configured To Be Removed...After Automatic Retraction of the Sharp”

All claims require “the ***distal end of the inserter*** [to be] configured to be positioned on the skin...before advancement of the [OBU]....” and that “distal end...is further configured to be removed from the skin of the user ***after*** automatic retraction of the sharp....” Thus, as described in the 591 Patent (and as Petitioner's expert agrees, EX2036, 95:15-96:2), the distal end of the claimed inserter is configured to be (1) positioned on the skin before OBU/sharp advancement and then (2) removed from that positioning ***after*** automatic retraction of the sharp from within the user. EX1001, 16:37-41,17:1-4, Figs.28-31; EX2002, ¶¶194, 175166-169, 176. As discussed, and as Petitioner's expert agrees, this configuration offers numerous advantages including, e.g., stabilizing the sensor and sharp during insertion and retraction, minimizing effects of wobble, and preventing tissue trauma. EX2002, ¶¶194, 170-173; EX2036, 116:15-117:7.

But Cote's infusion cannula inserter has the opposite configuration. Cote is configured such that, after the distal end of the inserter is positioned on the skin, the

distal end is removed from the skin *before* sharp retraction. Indeed, the deliberately-designed over-travel feature triggers retraction while the distal end is removed. Thus, the distal end of Cote's inserter is *not* configured to be removed from the skin *after* automatic retraction as claimed. §VI.A.1.a.; EX2002, ¶¶195-200; EX1005, [0209], Figs. 81C, 82B. Petitioner's own colored images confirm this. EX1003, ¶¶57,59; EX2002, ¶199.

This configuration is not happenstance—it is a *requirement* of Cote's design for delivery of its infusion cannula. Indeed, Petitioner admits that POSAs would know that the distal end “*must*” travel away from the skin “to enable” automatic sharp retraction. Pet. 53 n.9; EX1003, ¶110 n.6. EX2002, ¶201.

Petitioner's analysis of the claim limitation is a single conclusory sentence. Pet. 50. Ignoring Cote's “over-travel” feature (despite addressing it elsewhere, Pet. 53-54), Petitioner instead references a Cote sentence in Paragraph 213 that states: “[f]inally, the sleeve 1140 is removed from contact with the skin 1900....” Pet. 50, citing EX1005, [0213]. But that sentence has nothing to do with whether the distal end is “configured to be removed from the skin...after automatic retraction of the sharp” as claimed. The sentence does not address how and when *automatic retraction* of the sharp occurs whatsoever. Rather that sentence simply references the “final step” of removing the device from the skin after the cannula is inserted—an act that of course must occur with *any* inserter after insertion *regardless of the*

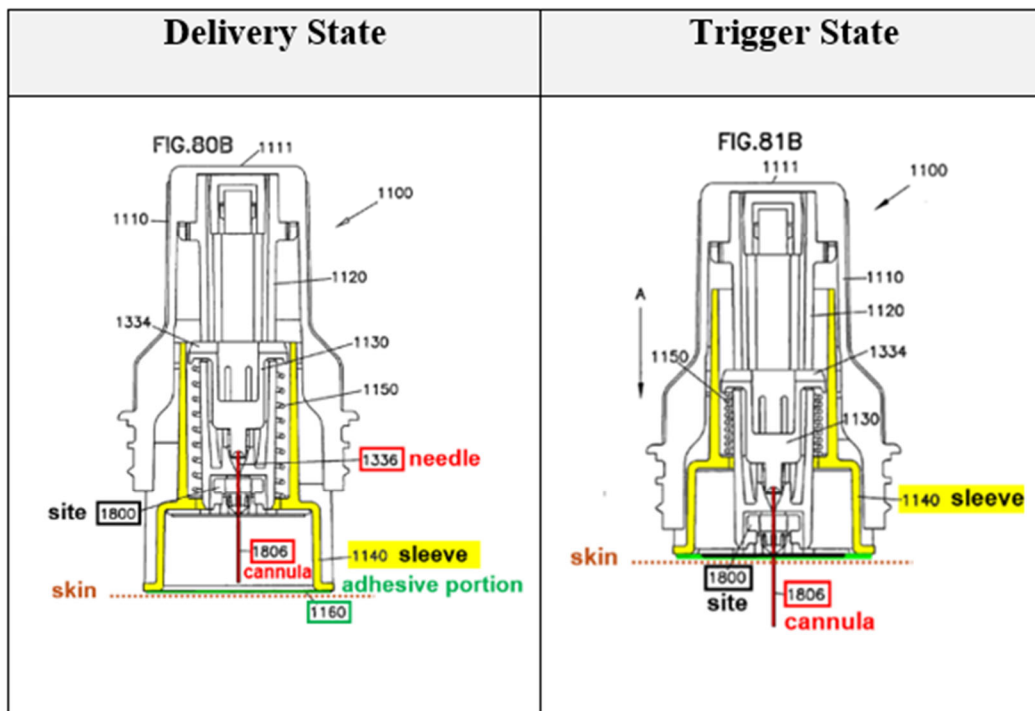
timing of sharp retraction (and the corollary advantages regarding stabilization during insertion/retraction). EX2002, ¶¶202-203, 170-172.

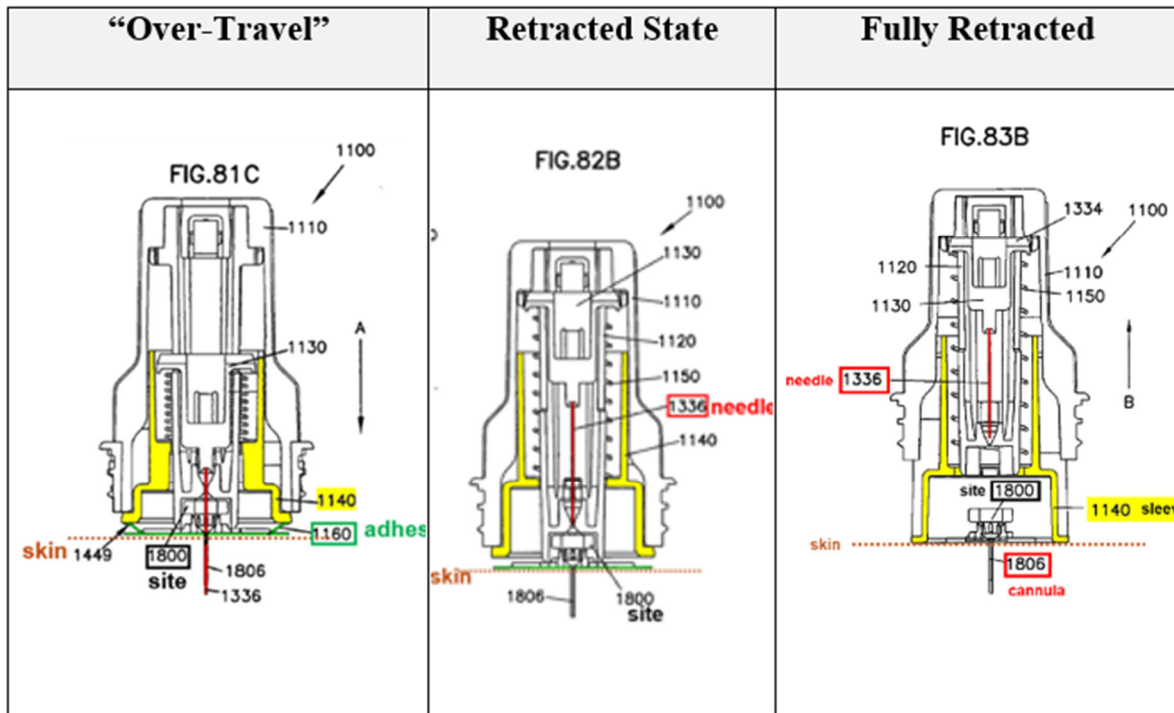
Petitioner has not (and cannot) argue that a device configured to be removed from the skin **before** sharp retraction satisfies the limitation that requires that removal **after** retraction (i.e., the opposite) as that would eviscerate the plain meaning of the claims and render the limitation meaningless, which is “highly disfavored.” *Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1288 n.10 (Fed. Cir. 2017); *Wireless Protocol Innovations, Inc. v. TCT Mobile, Inc.*, 771 F. App'x 1012, 1016-18 (Fed. Cir. 2019) (limitation reciting that a transition occurs “**after** a subsequent bandwidth grant is received” construed as “specifically require[d]...only at a particular time”—i.e., “after”). It also would defeat the purpose of the claim language because, as discussed, the configuration offers numerous advantages for placement of the delicate electronic sensor. EX2002, ¶¶204-206, 170-173; *KEYnetik, Inc. v. Samsung Elecs. Co.*, 837 F. App'x 786 (Fed. Cir. 2020) (declining to construe “after” in a way “incompatible with the purpose of the claimed invention”).

Additionally, when Cote refers to removing the sleeve from the skin in Paragraph 213, Cote is **not** referring to removing it from its initial position on the skin as the claims require (and as Petitioner's expert agrees, EX2036, 95:15-96:2). Instead, Cote is referring to removing the sleeve from a **later** positioning on the skin

that occurs *after* the site/sharp were advanced and the sharp retracted. EX2002, ¶207.

This later positioning is shown in Figure 83B (“fully retracted state”). [0212]. That “fully retracted state” occurs (1) after the distal end of the inserter (according to Petitioner’s expert, the sleeve) is positioned on the skin before site/sharp advancement ([0206], Fig. 80B/81B) *and* also after (2) the subsequent removal of the sleeve from that positioning on the skin due to over-travel *before* needle retraction (e.g., [0209], Fig. 81C/82B). This process is reflected in the progression of Figures 80B (delivery state, distal end positioned on the skin), 81B (trigger state, cannula and site delivered), 81C (over-travel, distal end removed from its positioning on the skin), 82B (retracted state, distal end remains off the skin), and 83B (fully retracted). EX2002, ¶¶208-209.





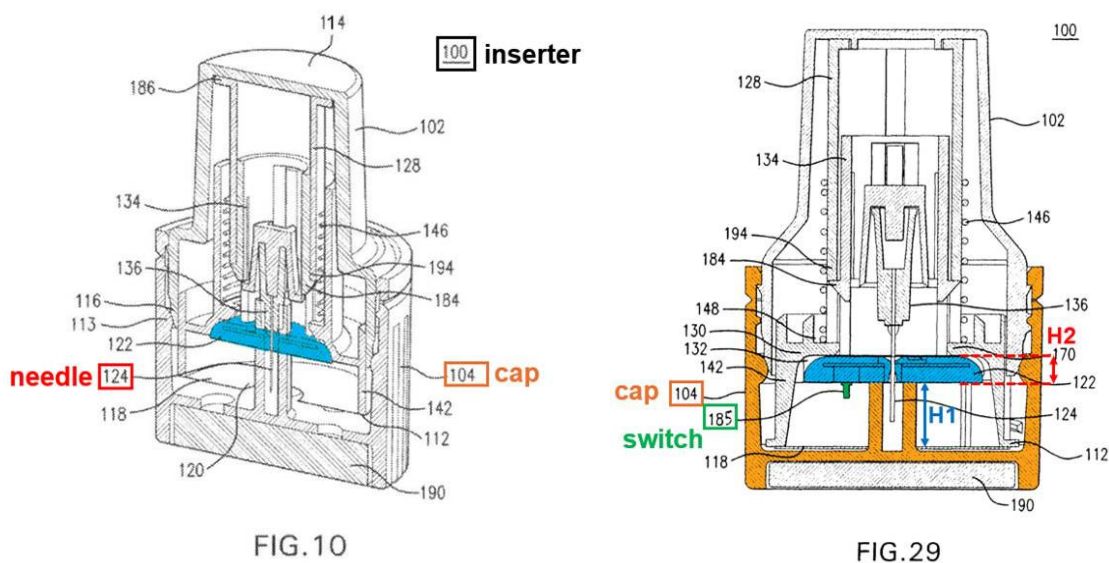
In short, the distal end is clearly not configured to be positioned on the skin before site/sharp advancement and then further configured to be removed from *that* skin positioning *after* automatic needle retraction from within the user (as the claims require and Petitioner's expert admits). EX2036, 95:15-96:2. EX2002, ¶¶210-211.

2. Petitioner Failed To Prove The OBU “Housing-Distance” Limitation (Limitation [19.13] in Claims 3-17 and 20-30)

All claims require the OBU and sharp to advance “from a first position to a second position such that the sharp pierces” the skin and secures the OBU in the second position. EX1001, 25:18-24. Independent Claim 19 and Dependent Claim 3 (and dependent claims 4-17 and 20-30) further require that the “*distance* between the [OBU] housing when the [OBU] is in the first position and the housing when [OBU] is in the second position *is greater than a maximum height of the housing*”

(the “housing-distance limitation”). Petitioner fails to establish this limitation.

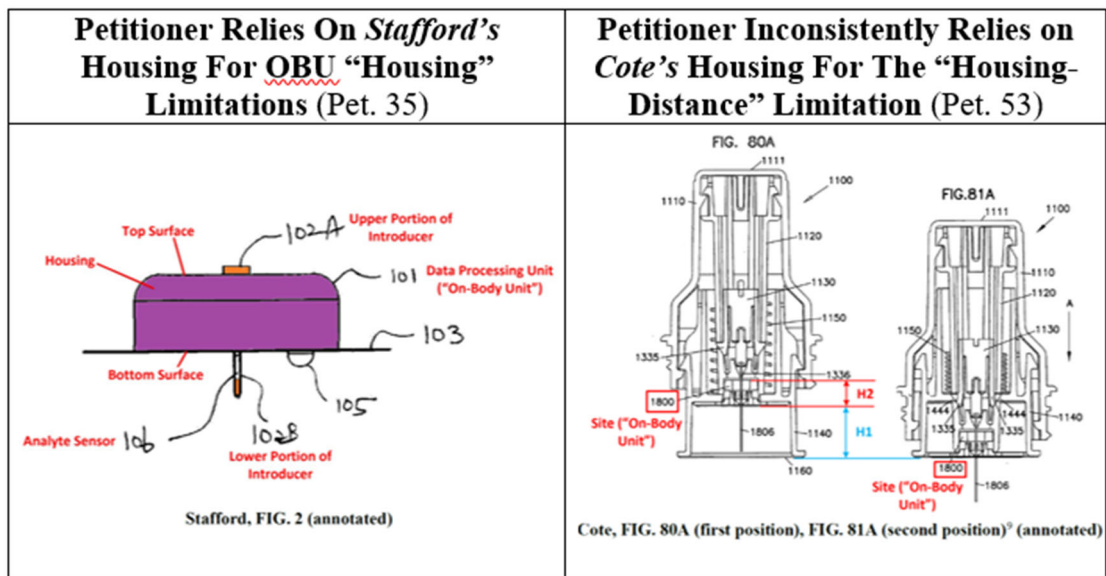
Figures 10 and 29 of the 591 Patent, showing the inserter with an OBU (blue) in the first position, illustrates the limitation. The limitation effectively requires that the OBU housing be located proximally within the inserter a distance (labelled “H1” by Petitioner, Pet. 52-55) that is greater than the OBU’s housing’s height (“H2”), ensuring that the OBU is relocated away from the distal end of the inserter. EX2002, ¶¶212-213.



In the context of the 591 Patent, this configuration results in several benefits including ensuring, e.g., that a mechanism that triggers activation of the smart OBU (e.g., plunger switch 185) is not accidentally engaged by the user. EX1001, 19:58-67. It also allows for a boss in the cap 104 (orange) that protects the sensor-comprising needle until it is ready for use. EX2002, ¶¶214-215; EX1001, 16:30-34, 16:52-54, Fig.13.

a) **Petitioner's Arguments About *Cote* Fail To Establish The Limitation Is Satisfied By *Stafford***

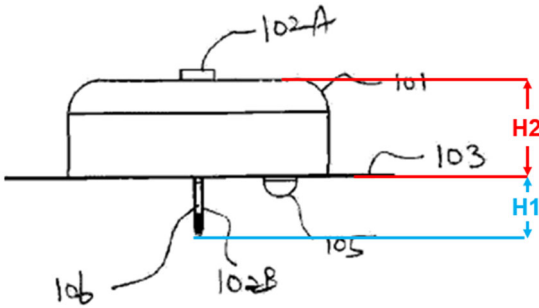
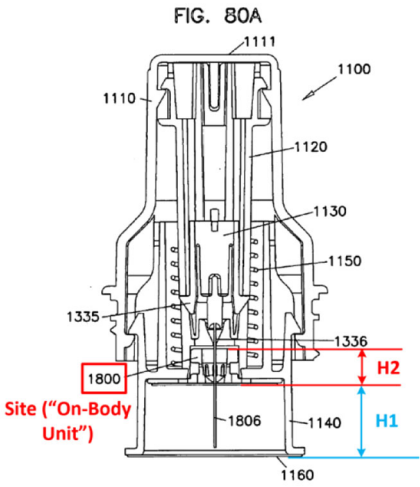
Petitioner's obviousness combination is that POSAs would have "implement[ed] a Cote-like inserter to deploy *Stafford's on-body unit* and sensor." Pet. 28-29. Petitioner repeatedly relied on *Stafford's* OBU (including *Stafford's* "housing") to satisfy the claims' OBU limitations. Pet. 28, 34-35. However, *for the housing-distance limitation only*, Petitioner improperly switched references and relied on *Cote's* infusion site housing as the "OBU" housing, contending that "*Cote* discloses this limitation." Pet. 53-54,57; EX2002, ¶¶217-219. Petitioner's analysis of this limitation fails.



First, "citation of two different sets of [prior art] teachings...for the same [limitation] represents a *fatal inconsistency*" in unpatentability arguments. See, e.g., *FedEx Corp. v. Intell. Ventures II LLC*, IPR2017-00743, Paper 7 at 13-14 (PTAB

July 25, 2017); *TeleSign Corp. v. Twilio Inc.*, IPR2017-01978, Paper 11 at 6-8 (PTAB Mar. 9, 2018) (petitioner improperly mapped a single term to two different prior art elements). Petitioner cannot vacillate between Stafford's OBU and Cote's OBU when the claim recites only one OBU. Because Petitioner relied on *Stafford* for the OBU housing and OBU-related limitations, it is *Stafford's* housing height that matters—*not Cote's*. Petitioner's analysis must fail for this reason alone.

Petitioner resorts to embodiment-shifting gymnastics because the limitation *is clearly not satisfied* by *Stafford*. Indeed, Petitioner never argued that Stafford satisfied the limitation. Pet. 52-58. That is because, as shown below, the portion of Stafford's sharp/sensor extending from the bottom of its OBU (H1) is *shorter than* Stafford's OBU housing height (H2)—*unlike* Cote's infusion site and its extending sharp/cannula. EX1004, Fig. 2; EX1005, Fig. 80A; EX2002, ¶223.

Stafford's Extending Sharp/Sensor Is <i>Shorter Than</i> Its OBU Housing Height ($H1 < H2$)	Cote's Extending Sharp/Cannula Is <i>Longer Than</i> Its Site Housing Height ($H1 > H2$)
 FIGURE 2	

Thus, if Stafford's OBU housing was used with Cote's inserter—*as required by Petitioner's combination*, the “distance between the housing when the [OBU] is in the first position and...second position” [H1] would be *less than—not “greater than* a maximum height of the housing [H2]” as required by the claims. EX2002, ¶224. Thus, the limitation is clearly not satisfied.

In any case, Petitioner's arguments regarding the comparative height of Cote's infusion site relative to its infusion cannula are irrelevant to the claims. The claim is clear that it is the height of *the sensor-comprising OBU housing* that is at issue. EX2002, ¶¶222-223.

b) Petitioner's Attempts To Recreate The Limitation Based On “Knowledge” Fail

Unable to show that its combination satisfies the limitation, Petitioner offers several theories to fabricate it—identifying no reference that actually discloses it.

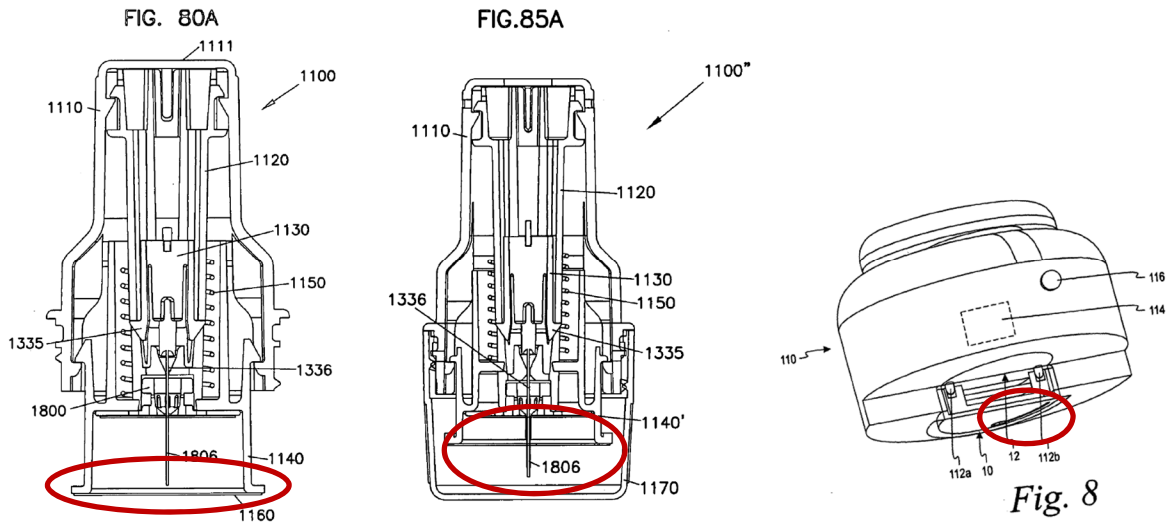
Petitioner first argues that POSAs “would have configured the travel distance of Stafford's [OBU]....to be greater than [its] height.” Pet. 54. Petitioner contends that POSAs find “low-profile [OBUs] desirable” and it would be “desirable for the needle to extend” beyond the sensor. Pet. 56. But, even if true, neither “desirable” feature necessarily results *in the claimed housing-distance limitation*. There is nothing in Stafford or Cote that would compel POSAs to arbitrarily redesign Stafford so that its extending sharp is *longer than* the height of its OBU housing. EX2002, ¶¶226-228. Indeed, Stafford stresses “hav[ing] a smaller profile” and “reduction in

material cost”—the opposite of what Petitioner suggests. EX1004, [0045].

Petitioner next raises numerous *other* references, contending that “well-known” concepts would lead to the claimed limitation. Pet. 55-57. Petitioner first states that three other references disclose “transcutaneous devices” with an “*in vivo* portion that was longer than the on-body portion was tall.” Pet. 56, citing EX1006, Fig. 1A, [0034], EX1018, Fig. 3, EX1038, FIGS.6-11. But none of these cursory, unexplained citations support Petitioner’s ultimate conclusion that this was “an obvious design choice” applicable *to Stafford*. For example, Petitioner references Shah, but Shah does not have an “on-body portion” comprising a sensor that moves distally; rather, the sensor is delivered to a mounting unit on the user. EX1006, [0045]-[0046]. And whether other references have *in vivo* “cannulas” and “sensors” that are longer than various “on-body portions” does not bear on whether POSAs would modify *Stafford* to include that feature. Petitioner never explains why POSAs would arbitrarily make its extending sharp/sensor longer than its OBU—particularly given Stafford’s concerns with minimizing the profile of the device. EX2002, ¶¶229-233.

Petitioner also argues it was “routine and desirable to position the sharp...well away from the distal end of the inserter[] to avoid needle sticks,” suggesting the sharp be moved proximally. Pet. 56-57, citing Cote. But Cote depicts the needle *at* or *beyond and outside* the distal end—not “well away” from it. EX1005, [0215],

Figs. 80A, 85A (device shown with cap 1170). Brenneman likewise shows the needle at the distal end of its inserter. EX1040, Fig. 8; EX2002, ¶¶234-235.



In any case, as discussed, inadvertent needle sticks are already avoided in Stafford (with the needle guard) and Cote (with the cap); thus “relocating” the needle is unnecessary. EX1004, [0022]; EX1005, [0219]; EX2002, ¶236, 238; §V.A.

Petitioner also argues that repositioning the needle “allows the needle to accelerate prior to hitting the skin,” citing a different Stafford publication describing “variable speed sensor insertion devices.” Pet. 56, citing EX1042, [0004]. This other Stafford reference shows that Stafford was aware of different complex inserters, but deliberately chose a simpler approach. EX2002, ¶¶78, 237.

In any case, even if one arbitrarily decided to move the needle proximally “away from” the inserter distal end, Petitioner still has not proposed a reason for why that would necessarily result in the *claimed* OBU housing-distance limitation.

EX2002, ¶239.

After presenting its litany of misplaced “needle” arguments, Petitioner next contends that “a travel distance H1 greater than the height of the housing H2” was “well-known” for “inserters devices”—citing *three more references*. Pet. 57, citing Pet. 13-17 (EX1009, EX1011, EX1020). But, again, Petitioner never explains why those configurations would impact how *Stafford's* OBU would operate with a Cote-like inserter. Pet. 13-14; EX2002, ¶240. In the end, Petitioner identifies nothing that would motivate POSAs to redesign *Stafford's* OBU or to otherwise move *Stafford's* housing proximally to the claimed relative distance. To the contrary, such a modification would seemingly increase wasted space within the design and increase the device profile, making the overall assembly larger and further undermining *Stafford's* goal of reducing size, material, and cost. EX2002, ¶241.

Finally, after discussing why the limitation was “obvious” due to its numerous advantages, Petitioner contends that the limitation can simply be ignored because “the claimed dimensions do not affect...performance.” Pet. 57. Petitioner fails to satisfy its “burden of proving that the claimed dimensional limitations had no effect on the performance....” *Waldemark Link GmbH v. Lima Corporate SpA*, IPR2020-00258, Paper 7 at 24 (PTAB June 23, 2020). Petitioner's own “obviousness” arguments proves its benefits. *ASM IP Holding B.V. v. Hitachi Kokusai Elec. Inc.*,

IPR2018-01561, Paper 11 at 17-18 (PTAB Feb. 25, 2019).⁶

As discussed, POSAs understand that the claimed design provides advantages in the context of the 591 Patent including, e.g., locating the OBU electronics activation switch away from the distal end to prevent inadvertent activation and allowing for a cap boss to protect the sensor and needle. EX2002, ¶¶242-243, 213-215. These advantages must be considered. *In re Chu*, 66 F.3d 292, 298-299 (Fed. Cir. 1995); *Knoll Pharm. Co. v. Teva Pharms. USA, Inc.*, 367 F.3d 1381, 1384-85 (Fed. Cir. 2004).

In the end, Petitioner identifies *no reference* where the “distance between the housing” of an OBU comprising a sensor pre-coupled to electronics in a proximal versus distal position is “greater than...[the] height of [its] housing.” Petitioner’s allegations of common knowledge “cannot be used as a wholesale substitute for reasoned analysis and evidentiary support, especially when dealing with a limitation

⁶ Petitioner’s case law is inapposite. *Gardner v. TEC Sys., Inc.*, 725 F.2d 1338, 1349 (Fed. Cir. 1984) (“performance was essentially the same”); *First Quality Baby Prods., LLC v. Kimberly-Clark Worldwide, Inc.*, IPR2014-01021, Paper 57 at *19-21 (PTAB Dec. 10, 2015) (expert admitted dimensions were well-known in the art); *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990) (applicant failed to provide evidence of functionality).

missing” from the art. *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1362 (Fed. Cir. 2016); *K/S Himpp v. Hear-Wear Techs., LLC*, 751 F.3d 1362, 1366 (Fed. Cir. 2014).

3. The References Do Not Teach The Claimed Data Storage Unit (Limitation [19.6] in Claims 4 and 19-30)

Independent Claim 19 and Dependent Claim 4 require the sensor electronics to comprise “a data storage unit.” EX1001, 25:5-10, 23:58-62.

Petitioner concedes that Stafford does not expressly disclose a “data storage unit,” but contends it is “require[d]” for “data processing” and transmission. Pet. 59. The Petition cites two other references—neither of which establishes any such “requirement” for CGMs, but instead simply describes generic data storage systems (EX1034, 509) or advantages of digital data filters (EX1035, 23-25). EX2002, ¶246.

Petitioner ultimately concedes data storage is “optional” and a “design choice,” citing Say. Pet. 60. However, as discussed, Say does not describe an OBU housing with sensor electronics pre-coupled to a sensor; rather, Say’s sensor is separately inserted with the electronics manually connected thereafter by the user (a two-part system). §II.A.2.a.; EX1008, 3:6-16. Thus, Say does not disclose the claimed “sensor electronics disposed within the housing coupled with the glucose sensor,...[and] compris[ing]...a data storage unit.” EX2002, ¶¶247-249. Petitioner’s generic assertions of “knowledge” cannot establish the claim limitation. *Himpp*, 751 F.3d at 1365-66.

4. The Cited References Do Not Teach The Claimed Height Profile (Limitation [19.14] in Claims 14 and 19-30)

Independent Claim 19 further requires the OBU housing, which includes the sensor electronics (“processor,” “power source,” “analog interface,” “data storage unit,” and “wireless communication circuitry”) coupled with the sensor, to have “a height profile...less than...10 millimeters.” Dependent Claim 14 includes the “10 millimeters” limitation.

Conceding that the limitation is not present in Stafford or Cote, Petitioner again relies on “general knowledge” to contend that it was obvious to reconfigure the housing to 10 mm or less because both teach “a low height profile.” Pet. 72-73. Petitioner’s analysis is flawed.

First, the height of Cote’s infusion site is irrelevant because it is not an OBU housing comprising a sensor or any electronics. EX1005, [0228]; EX2002, ¶¶251-252. And Stafford does not disclose an OBU with all the relevant electronics—much less with the claimed height profile. EX1004, [0045]; EX2002, ¶253. That Stafford references a “smaller profile” does not teach the dimensions claimed. *Id.*

Facing yet another missing limitation, Petitioner contends that the limitation “was well-known,” citing five other references. Pet. 72, citing Pet. 13. However, none of the cited references include an ***all-in-one OBU*** that has ***an analyte sensor pre-coupled to sensor electronics*** that is less than 10 mm. *See, e.g.*, EX2002, ¶¶254-255; EX1012, [0155], Fig.1 (disclosing two-part CGM system where the sensor and

the sensor electronics are manually connected after insertion); Ex. 1013, [0267], Fig.1 (same); EX1014, [0009], Figs.8, 12, 16 (two-part CGM system where sensor is coupled via port in mounting unit); EX1015, 2:24-33, Figs.14, 17, 33 (same); EX1016, 31:20-35, 33:23-34:8, Figs., 14,17 (same). Petitioner has once again failed to show that the height profile of the ***claimed*** OBU housing (including the claimed components therein) was “well-known.” *HIMPP*, 751 F.3d at 1365-66.

After extolling the benefits of low profile OBUs, Petitioner once again asserts that the limitation can simply be ignored because the claimed dimension does not affect device performance. Pet. 72-73. Petitioner again misconstrues the law. §VI.A.2.b. Achieving an ultra-low profile OBU housing where the sensor electronics were disposed within the housing and coupled with a sensor was an important achievement, resulting in a device that was more tolerable and convenient for the user. EX2002, ¶256; EX1001, 2:7-9; EX2037, 1; EX2038,1. Indeed, the 591 Patent describes numerous ways to configure the components so that they could be included within the compact housing. *Id.*; EX1001, 17:66-18:7, 12:34-12:2, 14:28-42.

Petitioner finally argues the limitation is not “critical” because “low-profile” is “well-known.” Pet. 73. But Petitioner never established that the height profile of the ***claimed*** OBU housing was “well-known.” And, Petitioner cannot simply ignore what it characterizes as “non-critical” claim limitations; its cited cases do not hold otherwise. EX2002, ¶¶257-259.

POSAs' desire for the claimed ultra-low profile OBU does not establish that actually designing one was obvious. There is a "clear distinction...between a patent challenger's burden to prove that [POSAs were] motivated to combine prior art references and the **additional** requirement that [Petitioner] also prove that [POSAs] would have had a reasonable expectation of successfully achieving the claimed invention...." *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1344 (Fed. Cir. 2021).

B. Dependent Claims

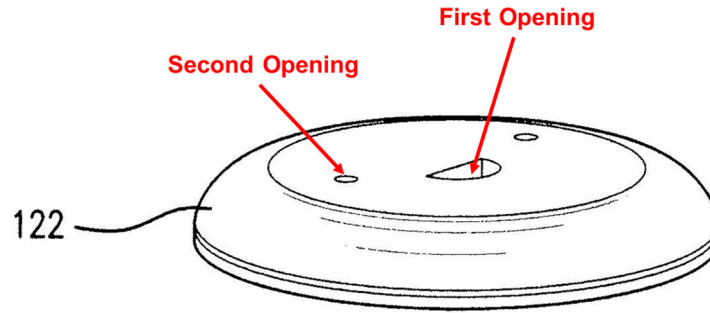
The dependent claims are not obvious at least for the reasons set forth for Independent Claims 1 and 19. Additional reasons are addressed below.

1. Claims 3-6, 9-14, and 16-17

Claims 3-17 incorporate the housing-distance limitation of Claim 19 (limitation 19.13) and are thus nonobvious. *See* §VI.A.2. Claim 4 is additionally nonobvious because it incorporates limitation 19.6. *See* §VI.A.3.

2. Petitioner's Combinations Do Not Render The "Second Opening" In The OBU Top Surface Obvious (Claims 18 And 21-30)

Claims 1 and 19 recite a first "opening of the top surface" of the OBU housing through which the sharp extends. Dependent Claims 18 and 21 further recite "a second opening of the [OBU housing] top surface" with a maximum width less than the first opening. Claims 22-30 depend on Claim 21 and also incorporate this limitation. This "second opening" feature is illustrated, for example, in Figure 23:



See also, e.g., Fig. 22. The second opening—as well as a third—serves as an alignment mechanism for the OBU during manufacturing. EX2022, ¶265.

Petitioner concedes that Stafford and Cote do not teach the “second opening” limitation. Pet. 76-80. Instead, Petitioner again relies on numerous “background” references. Petitioner’s arguments fail for multiple reasons.

a) Petitioner’s “OBU Securing” Argument Is Refuted By Petitioner’s Own Art And Admissions

Relying mainly on Brenneman, Petitioner argues that POSAs would add a second opening to the top surface of Stafford’s OBU housing “to secure the [OBU]...within the inserter” and “maintain the position of the [OBU] relative to the inserter.” Pet. 17, 80, 96-97. But Petitioner’s argument makes no sense.

As Petitioner admits, *Cote’s existing design—without a second OBU opening—already secures the infusion site to the inserter* and maintains the site’s positioning via friction fit with the needle. EX2002, ¶¶266-267

POSITA[s] reading Cote would understand that...*the frictional engagement between the needle and the diaphragm maintains the positioning of the site* relative to the needle prior to and during delivery.

EX1003, ¶¶54-56, 98, ¶93; Pet. 25-26; EX1005, [0205]; EX2002, ¶¶268-269.

Petitioner cites nothing that suggests that Cote's "securing" method is inadequate. Indeed, Petitioner acknowledges that Cote's securing method was commonly used in "other known inserter devices." EX1003, ¶56. Petitioner provides no legitimate reason to make Cote's complex assembly even more complex by adding a feature to achieve a function that Cote already provides. *See, e.g., In re Schweickert*, 676 F. App'x 988, 995 (Fed. Cir. 2017) (modification of prior art "unnecessary" and "add[s] unwanted cost and complexity"); *Sony Corp. v. Fujifilm Corp.*, IPR2018-01751, Paper 14 at 11 (PTAB Apr. 12, 2019) ("Petitioner does not explain adequately why modifying Ejiri...would have been an improvement....Ejiri already addresses the problem"). This is especially true given that Stafford emphasizes "cost reduction in manufacturing" and "reducing...components." EX1004, [0045]; EX2002, ¶270. Notably, the Board has rejected Petitioner's equivalent "securing" argument in IPR2023-01396 and IPR2023-10397 for the same reasons. IPR2023-10396, Paper 13 at 30-31; IPR2023-01397, Paper 13 at 31.

Adding a "second opening" is not only unnecessary, but it also conflicts with Stafford and Cote, which teach avoiding openings "where moisture or contaminant may compromise the functions and operations of the data processing unit." EX1004, [0027]; EX1005, [0165]; EX2002, ¶¶271-272. Petitioner's expert agrees. EX2036, 111:16-113:5.

Petitioner's passing reliance on Turner (EX1007) as "background art" further confirms that Petitioner's "second opening" combinations are pure hindsight. Pet. 78-79. Turner's cited openings (or recesses) are not for securing an OBU to an inserter, as Petitioner suggests. *As the Board already found in IPR2023-01396 and -01397*, they are not used for securing the OBU to anything. IPR2023-01396, Paper 13 at 48-51; IPR2023-01397, Paper 13 at 46-50. Rather, Turner's "optional" "openings" serve an entirely different purpose, *i.e.*, preventing rotation between Turner's needle hub and OBU. *See, e.g., id.*; EX1007, [0069]; EX2002, ¶273. Notably, Turner teaches securing its "body" to its needle-hub assembly by a different mechanism—a friction fit between the needle (coupled to the needle hub) and the septum 40 of the body (*just like Cote*). EX1007, [0099]; EX2002, ¶274.

Turning to Brenneman, the cited openings (*i.e.*, apertures 60a and 60b) correspond with "apertures 62a, 62b *of the printed circuit board housing*." EX1040, [0042], Fig. 3. But these are exactly the type of openings POSAs would *not* be motivated to add, *i.e.*, creating a risk of moisture/contamination ingress into the electronics. EX2002, ¶¶275-276.

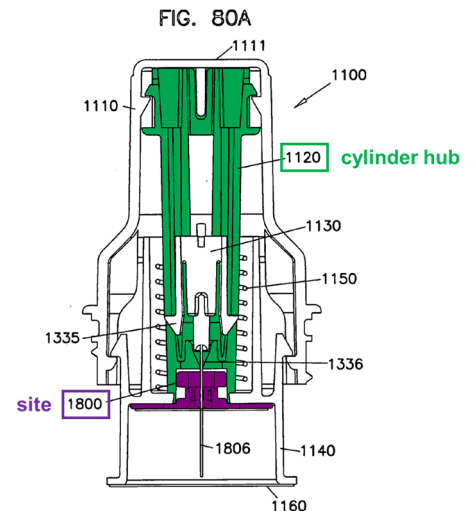
Moreover, that Petitioner cites Brenneman—but only for a "second opening"—confirms that Petitioner's proposed combinations are improper hindsight. Why wouldn't POSAs simply use Brenneman's inserter/OBU design instead of (1) starting with Stafford (which teaches against a separate inserter), (2)

then combining Stafford with Cote's infusion cannula inserter, and then (3) cherry-picking an unnecessary second opening from Brenneman's design? EX2002, ¶¶277-278.

b) Petitioner's "Anti-Rotation" Argument Lacks Merit

Petitioner next argues in passing that POSAs reading Brenneman and Turner would add a second top-surface opening to provide the alleged "benefit" of preventing OBU rotation. Pet. 78. This cursory argument fails.

First, Cote does not need a second top-surface opening to prevent rotation, as Petitioner admits. As shown in Cote's figures, the cylinder hub (green) pinches opposite sides of the site (purple), which would prevent rotation. EX1003, ¶55 (stating that Cote's friction fit "*maintains the positioning of the site relative to the needle*"); see also EX2002, ¶¶279-281, 285; EX1005, Figs. 79A, 80A, 81A.

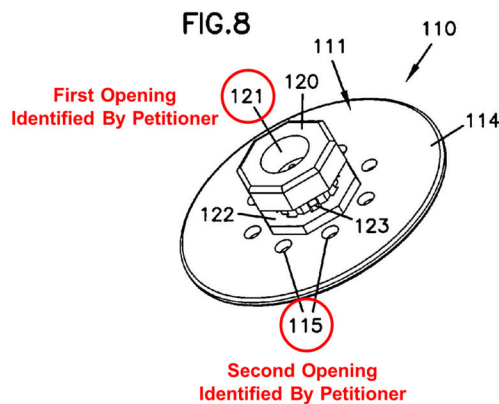


Second, rather than teaching preventing rotation, Brenneman teaches that OBU rotation is "*desirable*" and indeed necessary for its assembly to work. See, e.g., EX1040, [0047] ("rotary motion...is desirable"), [0046], [0044], [007]. Turner—not part of any ground—cannot override the contradictory teachings of expressly-cited

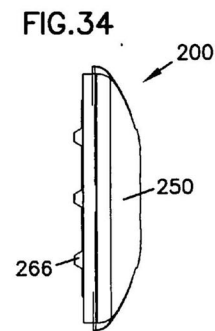
Brenneman.⁷ EX2002, ¶¶282-283.

c) Cote's "Openings" Do Not Satisfy the Claim Limitation

Petitioner next cites to "openings" in Cote. Pet. 79. But those openings are located in *the interior* of Cote's infusion device (on a *lower surface* of the bottom portion)—not the OBU top surface as claimed. EX1005, [0167], Fig. 8; EX2002, ¶¶286-287.



**Bottom Portion Of
Cote's Infusion Device**

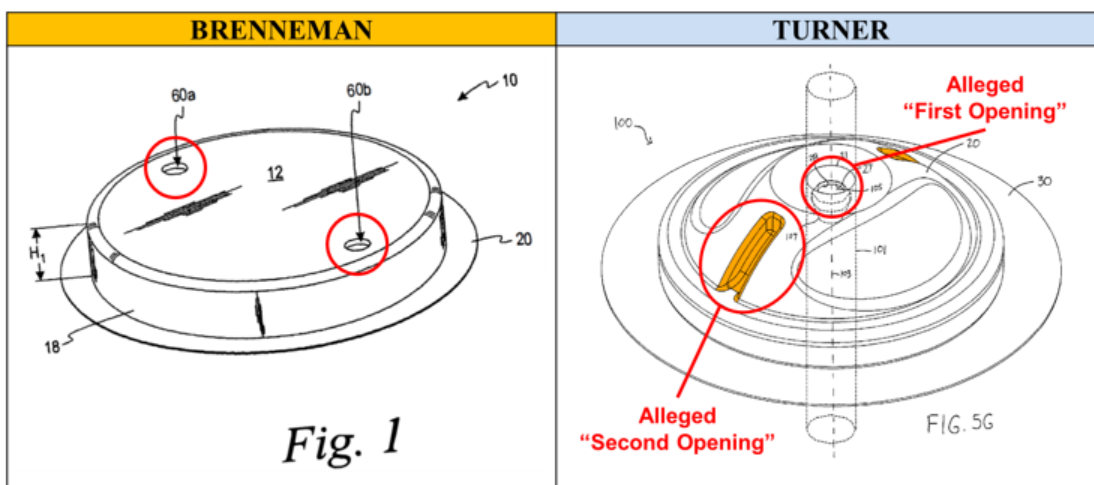


**Top Portion Of
Cote's Infusion Device**

⁷ Providing virtually no context, Petitioner alleges that Abbott made Turner-related "admissions" in a German proceeding involving an unrelated patent. Pet. 79-80. This erroneous assertion merely repeats Petitioner's unsuccessful argument in IPR2023-01396 and -0197. IPR2023-01396 (Paper 3 at 32-33); IPR2023-01397 (Paper 3 at 39-40); EX2002, ¶284.

d) Petitioner Fails To Substantively Address The Different Maximum Width Limitation

The claims further require that the “second opening” have a smaller maximum width than the first opening. Petitioner side-steps this limitation because Brenneman’s apertures 60a/60b are the same size and Turner teaches its alleged “second opening” has a *larger* maximum width than its “first:”



EX1040, Fig. 1; EX1007, Fig. 5G. Unable to satisfy the limitation, Petitioner instead points to irrelevant “openings” on an internal lower surface of Cote’s infusion device (Pet. 81-82) that are not even on the same surface as Petitioner’s identified “first opening” (as the claims require). EX2002, ¶¶288-291. That argument fails.

VII. GROUND 2: THE PETITION DOES NOT ESTABLISH OBVIOUSNESS BASED ON STAFFORD, COTE, AND SAY

In Ground 2, Petitioner alleges Claims 4, 7-8, 14-15, and 19-30 are obvious in view of Stafford and Cote in further view of Say. Pet. 84.

These claims depend on the independent claims and are not unpatentable as discussed (§§V.&VI.). All claims additionally depend on Claims 3/19 (housing-distance), and Claims 22-30 additionally depend on Claim 21 (second opening), thus numerous elements remain missing even with Say. §§VI.A.2.&B.2. The “data storage unit” limitations in Claims 4 and 19 are discussed in view of Say in §VI.A.3. EX2002, ¶¶293-300.

A. OBU Height Profile (Claims 14 and 19)

Claims 14 and 19 require the *claimed OBU* housing to have “a height profile...less than 10 mm.” Petitioner relies on Say (Pet. 87), but like the other references addressed in §VI.A.4., Say’s “OBU” is not *the claimed* OBU, e.g., one comprising sensor electronics coupled with a sensor. Again, Say discloses a two-part system where the sensor is not pre-coupled to the electronics. EX1008, 3:6-16; EX2002, ¶¶301-303.

B. Petitioner Fails To Establish That The “Sleep/Idle Mode” (Claims 7/25) And “Activation” Claims (8/26) Are Obvious

In addition to the limitations of Claims 1/3 and 19/21 (§§VI.A.&B.2.), Claims 7 and 25 further recite that the “sensor electronics are in a sleep mode or an idle mode when the [OBU] is in the first position” within the inserter. EX1001, 24:7-9, 26:24-26. Claims 8 and 26 require that the “sensor electronics are configured to be activated when the [OBU] is at or near the second position” on the skin. *Id.*, 24:11-13, 26:27-29.

These limitations relate to unique features of the claimed assembly—where the sensor and electronics are coupled within the inserter—to provide “cost optimization and prolong[ed] shelf life.” *Id.*, 19:44-51. As the 591 Patent explains, if the sensor and electronics are pre-coupled, “there may be a period of time” before the product is used. 19:41-44. Preferably, the electronics would initially be in a sleep mode to conserve battery power, but then activate when the OBU is on or near the skin. 19:41-51. The patent describes multiple solutions to this complex problem. *See, e.g.*, Figs. 32-43, 19:41-22:35; EX2002, ¶¶305-306.

In its two-page cursory analysis, Petitioner concedes that Stafford, Cote, Brenneman, and Shah do not teach the recited limitations and relies solely on Say. Pet. 4; EX2036, 89:22-90:2, 90:15-20, 91:10-15. Petitioner’s arguments fail for multiple reasons.⁸

Say’s OBU is fundamentally different—*especially with respect to the “sleep mode/activation” claims*. Say involves a separate electronics component that is

⁸ Petitioner wrongly suggests that electronics “activation” in Claims 8/26 is limited to activating the electronics from a no-power state. Pet. 88. The claims have no such restriction and the 591 specification teaches activating the electronics from a “sleep” or “idle” mode to “an active mode.” EX1001, 19:41-57; EX2036, 32:21-33:3; EX2002, ¶304,n.4.

manually connected to the sensor by the user after sensor insertion (sensor and electronics are not pre-coupled). Say's electronics are ***never*** disposed within an inserter (coupled or not), let alone advanced from a first position within an inserter to a second position on the skin where the electronics are activated when the OBU is at or near the second position. And Say's electronics are activated when the user manually connects the electronics to the sensor after insertion—***not*** when they are in specific positions in the inserter, as claimed. EX1008, 31:45-53, 36:34-39; EX2002, ¶¶307-309.

Combining Say with Stafford would not work because, unlike Say, Stafford's sensor and electronics are ***already coupled***. EX1004, [0006], [0018]. The Petition fails to describe how Say could possibly be combined with Stafford. While conserving battery power may be desirable (Pet. 89), Say does not explain how that could be done while the sensor is coupled with the electronics. Wanting to do it—versus teaching how to do it—are two different things. EX2002, ¶311; EX1001, Figs. 32-43, 19:41-22:35, 19:58-60 (describing “automatic activation of the electronics 80”); *see, e.g., Eli Lilly*, 8 F.4th at 1344. Indeed, unlike Say, the 591 Patent depicts and describes multiple ways to activate electronics that are ***coupled with the sensor*** within an inserter as claimed. *See, e.g.,* EX1001, Figs. 32-43, 19:41-22:35, 19:58-60; EX2002, ¶¶310-311.

Regarding the electronics “activation” claims (8/26), Petitioner quotes a

partial sentence from Stafford indicating that its data processing unit can send signals “after the completion of the initial power on procedure.” Pet. 88, citing EX1004, [0037]. But as Petitioner concedes, Stafford—including this partial sentence—does not disclose the limitation or render the claims obvious. Indeed, ***Petitioner specifically excludes these claims from grounds that include Stafford but not Say*** (i.e., Grounds 1, 3, 4, and 7). Pet. 4. That is not surprising because Stafford’s OBU is never within an inserter at all and Stafford never teaches activating its electronics when the OBU is at or near the second position as claimed. Moreover, reference to an “initial power on procedure” says nothing about how or when “power on” is initiated—much less how its unexplained “power on” could work if the OBU starts within an inserter. EX2002, ¶¶312-313.

Finally, in connection with the electronics “activation” claims, Petitioner passingly cites Pesach (EX1019) with no analysis. Pet. 89; EX1003, ¶169. Pesach is irrelevant. Pesach lacks an implantable glucose sensor, an OBU within an inserter, and electronics in a sleep or idle mode. Pesach involves a drug delivery device with a “tissue treatment element” coupled to a delivery device for “improv[ing] the drug’s pharmacokinetic...profile.” EX1019, [0010], Abstract, [0048], [0018], [0082-84], claims 1-3, Figs.4A-C,7A-C; EX2002, ¶¶314-317.

C. Petitioner Fails To Establish Obviousness Of The “Sensor Hub” Claims (Claims 15 and 28)

In addition to the requirements of Claims 1/3 and 19/21 (§§VI.A.&B.2.),

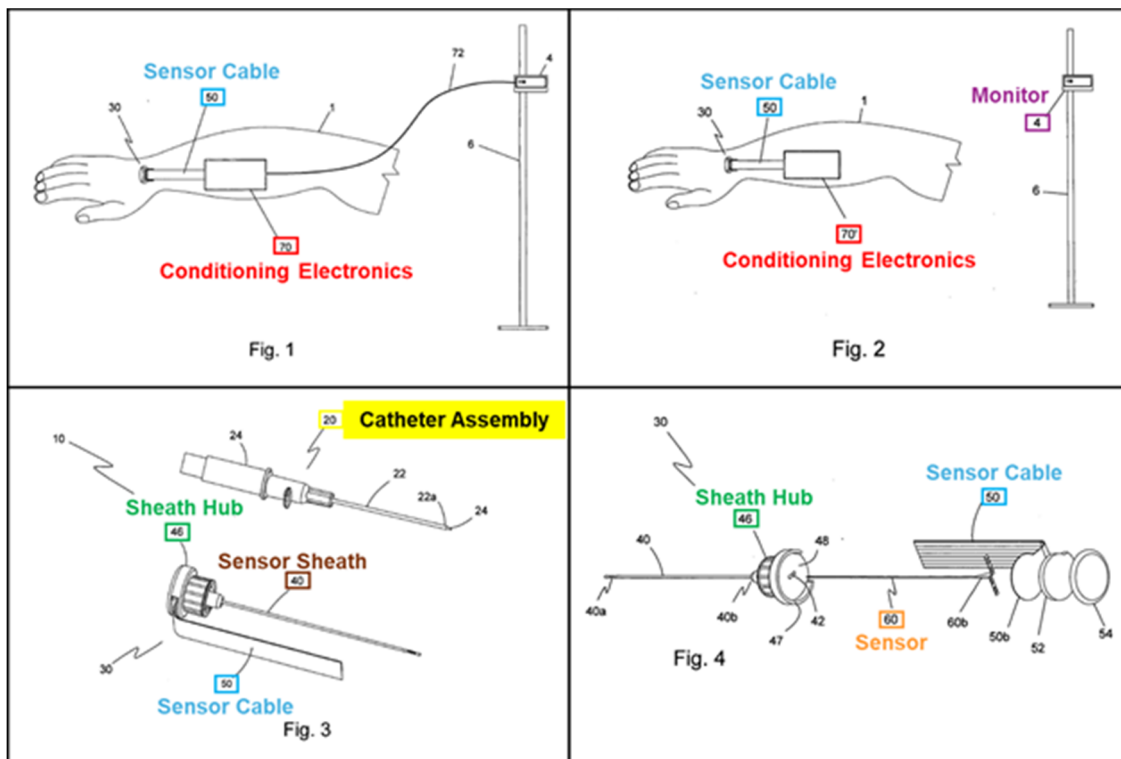
Claims 15 and 28 require a “sensor hub” engaged with a proximal portion of the sensor. According to Petitioner, the claimed “sensor hub” is a separate “support structure” or feature that “hold[s], support[s], and/or guide[s] the sensor...into the correct position” and “help[s] promote adequate electrical contact between” the sensor and electronics.⁹ Pet., 92-93, 85, 90-91; EX1003, ¶177.

Petitioner proposes modifying Stafford’s design by adding a sensor hub from Say. Pet. 89-91; EX2036, 89:10-15, 90:4-14. But, in Stafford, the sensor and electronics are connected *by the manufacturer*, as Petitioner admits. EX1004, [0018], Fig.7; Pet. 63-64; EX1003, ¶¶127-128. Thus, there is no risk of inadequate connection by the user. EX2002, ¶326. Nor is there any need to “guide the sensor [] into the correct position” as Petitioner urges (Pet. 92). Accordingly, POSAs would not be motivated to modify Stafford’s OBU with Say’s alleged sensor hub, which would only add material and complexity contrary to Stafford’s teachings. §VI.B.2.a. (citing *Schweickert* and *Sony*). That is particularly true since Say teaches that the feature is optional even in a design where the *user manually* makes the connection. §II.A.2.a; EX1008, 31:59-62, 33:38-42, 36:25-38; EX2002, ¶¶322-328; EX1006,

⁹ Petitioner suggests that the “sensor hub” must be “within” the OBU housing. Pet. 89-90; EX1003, ¶¶170, 172. But the claims require no such thing. The Board need not resolve that issue to address the “sensor hub” arguments.

Fig. 6, [0045]. Notably, of the five references cited in Petitioner's grounds, based on Petitioner's arguments, only two of them arguably disclose a sensor/electronics connection *by the manufacturer* (i.e., Stafford and Shah), and tellingly those references do not disclose a sensor hub (nor does Petitioner so allege). EX2002, ¶¶329-330.

Finally, Petitioner passingly cites Bickoff (EX1018) with no analysis. Pet. 93. Bickoff teaches a complicated and unwieldy design for hospital staff with an intravenous catheter, connection cable, and after-connected and remotely-located electronics (see figures below). EX1018, Abstract, [0004], [0009]-[0014], [0034]-[0036]; EX2002, ¶¶331-336. POSAs starting with Stafford's minimalist design



would not be motivated to combine with Bickoff, and Petitioner makes no attempt to argue otherwise.

VIII. GROUND 3: STAFFORD, COTE, AND BRENNEMAN

Petitioner alleges Claims 18, 21-24, 27, and 29-30 are obvious in view of Stafford, Cote, and Brenneman. Pet. 95.

These claims depend on Claims 1, 19, and 21 and are not unpatentable for the reasons discussed (§§V.&VI.).

Petitioner argues that, to satisfy the “second opening” limitations in Claims 18 and 21, it was obvious to further modify Stafford/Cote to include Brenneman’s “apertures.” Pet. 96-97. As explained (§§VI.B.2.&V.B.), Petitioner’s combinations with Brenneman fail. Moreover, Petitioner fails to adequately explain why POSAs would combine the three references as proposed. Indeed, Petitioner engages in the epitome of hindsight by cherry-picking irrelevant apertures from Brenneman while ignoring Brenneman’s differently-configured sensor *inserter assembly*. EX2002, ¶¶340-342.

IX. GROUND 4: STAFFORD, COTE, AND SHAH

Petitioner alleges Claims 9, 22-24, 27, and 29-30 are obvious in view of Stafford, Cote, and Shah. Pet. 98.

These claims depend on Claims 1, 3, 19, and 21 and are not unpatentable for the reasons discussed (§§V.&VI.).

Petitioner argues that, to satisfy Claims 9 and 22, it was obvious to further modify Stafford/Cote to include an aperture in the electronics based on Shah. Pet. 100-102. Petitioner fails to adequately explain why POSAs would combine Stafford, Cote, and Shah. For example, as explained (*e.g.*, §§V.B.), Petitioner again cherry-picks irrelevant apertures from Shah while ignoring Shah's differently-configured sensor *insertter*.

Moreover, Claim 9 additionally depends on Claim 3 (housing-distance), and the remaining claims additionally depend on Claim 21 (second opening), thus numerous limitations remain missing even with Shah. §§VI.A.2&VI.B.2; *see* EX2002, ¶¶345-348.

X. GROUNDS 5, 6, AND 7: PETITIONER'S FOUR-REFERENCE COMBINATIONS

In Ground 5, Petitioner alleges Claims 21-30 are obvious in view of Stafford, Cote, Say, and Brenneman, combining Grounds 1, 2, and 3. Pet. 103. In Ground 6, Petitioner alleges Claims 25-26 and 28 are obvious in view of Stafford, Cote, Say, and Shah, combining Grounds 1, 2, and 4. Pet. 104. In Ground 7, Petitioner alleges Claims 22-24, 27, and 29-30 are obvious in view of Stafford, Cote, Brenneman, and Shah, combining Grounds 1, 3, and 4. Pet. 105.

As explained (§§V.-IX.), Petitioner cannot establish that the combinations render these claims obvious. These claims depend on Claim 19 and are not unpatentable as discussed (§§V.&VI.).

Moreover, as explained in Grounds 1 and 2 (§§VI.&VII.), Petitioner cannot establish that Stafford, Cote, and Say render Claim 21-30 obvious. And, as explained in Grounds 3 and 4 (§§VI.2,VIII.,&IX.), Petitioner's addition of Brenneman for the "second opening" and Shah for an additional "aperture" is likewise misplaced. Moreover, in Ground 6, Petitioner fails to provide *any* evidentiary basis for the "second opening" limitation present in Claims 25-26 and 28.

Furthermore, Petitioner failed to explain why POSAs would have been motivated to combine *four* references to achieve the claimed combinations in the cherry-picking manner proposed. §§V.B.&VI.B.2.; EX2002, §§XIV.,XV.,XVI.

XI. GROUND 8: STAFFORD, COTE, SAY, BRENNEMAN, AND SHAH

In Ground 8, Petitioner alleges Claims 25-26 and 28 are obvious in view of *five* references. Pet. 105. As explained (Sections V.-X.), Petitioner cannot establish that the combinations render Claims 19, 21, and 22 obvious. Petitioner inadequately explained how Claims 25-26 and 28 are additionally obvious as explained. §§VII.C.&D. Petitioner also failed to explain why POSAs would have been motivated to combine *all five* references to achieve the claimed combinations in the cherry-picking manner proposed. §§V.B; EX2002, ¶¶368-369.

XII. OBJECTIVE INDICIA OF NONOBVIOUSNESS

Petitioner and its expert failed to consider evidence of objective indicia of nonobviousness—including known evidence in Abbott's litigation Complaint. *See*,

e.g., EX2003, 2-19; EX2036, 56:5-60:4. But objective evidence of nonobviousness “play[s] an important role as a guard against the statutorily proscribed hindsight reasoning in the obviousness analysis.” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016). Indeed, it “may often be the most probative and cogent evidence in the record” and “***must be considered in every case.***” *Id.* Importantly, “there is a ***presumption of nexus***...when the patentee shows that the asserted objective evidence is tied to a specific product and that product ‘is the invention disclosed and claimed in the patent.’” *Id.* at 1329.

Here, Petitioner acknowledges that the claimed ***combination*** was not known. Evidence of long-felt but unsolved need, failure of others, industry praise, and commercial success are linked to the claimed combination and demonstrate nonobviousness. EX2002, §XVIII; *Medtronic, Inc. v. Teleflex Innovations SARL*, 70 F.4th 1331, 1337-38 (Fed. Cir. 2023) (affirming PTAB findings on objective indicia where claimed ***combination*** was not disclosed in the art). Indeed, the relevant indicia show how the claimed combination, including as embodied in Abbott’s successful and award-winning FreeStyle Libre products, solved the long-felt problem of providing an easy-to-apply, user-friendly, and cost-effective CGM with an all-in-one, ultra-low profile on-body unit that was reliable and effective.

A. FreeStyle Libre

The FreeStyle Libre products are covered by the 591 patent. EX2002,

¶¶372,381-390, Appendix B; EX2007, 7; EX2008, 6-7; EX2009, 5; EX2010, 39; EX2033, 1. As discussed in §II.B.2, they are the ***most accessible and widely used CGM in the world***, helping more than 5.5 million people worldwide by providing technology that is affordable, accurate, reliable, and simple to use. EX2019, 1. Unlike earlier CGM products (including Petitioner's pre-existing devices), with Libre, the user no longer needed to insert the sensor separately or manually connect multiple CGM pieces after placing the OBU. EX2002, ¶391.

	FreeStyle Libre	FreeStyle Libre 2	FreeStyle Libre 3
Inserters			
On-Body Unit			

The all-in-one OBU is small and less obtrusive and also easier to accurately self-apply while remaining user-friendly. EX2041, 4 (recognizing Libre's "slimness and discreetness, simplicity of setup and use, and ease of sensor insertion");

EX2042, 4 (Libre “is less bulky by abandoning the wireless transmitter”). Libre is also more affordable, often selling for a fraction of the cost of other CGMs. EX2020, 1; EX2041, 2 (Libre is “more affordable...[as it] doesn’t include a separate (costly) transmitter that attaches to the sensor”). The fundamental concepts embodied in the claims of the 591 Patent have contributed to Libre’s affordability, reliability, accessibility, and its simple, effective handling. EX2002, ¶¶372, 378,391-396,414; EX2011, 923-24.

B. The Claimed Inventions Solved a Long-Felt, Unmet Need After Many Failures

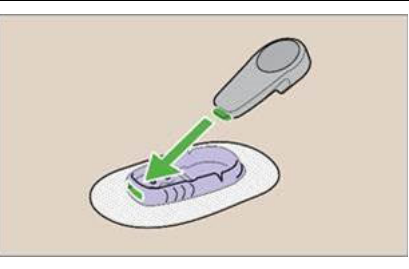
A long-felt but unresolved need and failure of others demonstrate nonobviousness because “the need would have not persisted had the solution been obvious.” *WBIP*, 829 F.3d at 1332; *In re Piasecki*, 745 F.2d 1468, 1475 (Fed. Cir. 1984).

As discussed above, while the prior art described numerous ways to self-implant glucose sensors, none provided an all-in-one, ultra-low profile solution that was reliable and simple while remaining cost-effective and accessible to the average person. *See, e.g.*, §§II.B.,VI.; EX2002, ¶¶405-408.

By the time of the invention, others repeatedly tried and failed to develop an all-in-one solution. *Id.* The 591 Patent recognized the ongoing “need for an easy-to-use, simple insertion assembly which is reliable, minimizes pain, and is easy to use.” EX1001, 2:8-2:9. Stafford reinforced these concerns, itself attempting to design a

device which “minimizes the number of components...and [] reduces the number of required steps to properly and accurately position the analyte sensor....” EX1004, [0005]. The prior art did not provide the needed solutions or lead to the claimed combination, however, as discussed extensively above.

Further, despite Petitioner's claims of obviousness, for years, Petitioner released numerous generations of multi-component systems with complex angular inserters that required the user to first insert the sensor and manually connect the sensor electronics (two-part systems). EX2014, 20-22; EX2015, 14-16; EX2002, ¶¶397-399, 402,408.

	Dexcom G5	Dexcom G6
Inserter		
On-Body Portions		

It was not until 2022—more than a decade after Petitioner contends that the prior art rendered the patented design “obvious”—when Petitioner finally released

its G7 product with its Libre-style applicator and on-body unit. EX2003, 16-19; EX2039, 1.

	FreeStyle Libre	Dexcom G7
Insertter		
On-Body Unit		

When releasing its G7, Petitioner did not assert its solution was “obvious”. Rather, Petitioner repeatedly touted its new device—including inventive aspects of the 591 combination. *See, e.g.*, EX2018, 6 (the G7 “provid[es] a fully enclosed miniaturized wearable with pre-connected sensor”); EX2017, 2-3 (“[s]treamlined all-in-one sensor with built in disposable transmitter” and “[f]ast and easy [applicator] to insert sensor”); EX2016, 6-7 (“most comfortable and discreet sensor yet”); EX2039, 11 (“complete overhaul for Dexcom with G7. Moving in the direction of...Abbott’s FreeStyle Libre with a disposable system that is an all in one transmitter and sensor.”); EX2040, 5 (“One of the benefits of G7 is its all-in-one CGM component. So the sensor is not separate from the electronics...”); EX2002, ¶¶400-401,410-412.

C. Industry Praise and Commercial Success of Libre

“Demonstrating that an invention...is commercially successful weighs in favor of its non-obviousness.” *WBIP*, 829 F.3d at 1337. Similarly, “[e]vidence that the industry praised a claimed invention or a product that embodies the patent claims weighs against an assertion” of obviousness. *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1053-54 (Fed. Cir. 2016).

The Libre products have been praised worldwide, received numerous prestigious awards, and are commercially successful, and these successes are tied to the contributions of the claimed combination. EX2004-2006; EX2022-2032; EX2034-2035; EX2037-2038; EX2041-2042; EX2002, §XVIII.D, ¶¶415-429; *see WBIP*, 829 F.3d at 1329. Libre’s all-in-one solution, which was reliable and simple while remaining cost-effective and accessible to the average diabetic, “revolutionized” diabetes care. EX2004, 1.

Libre has won numerous awards including the prestigious Galien Golden Jubilee Award (likened to the Nobel Prize) for “Best Medical Technology” *in the last fifty years*. EX2004-EX2005. Libre also won the 2016, 2021, and 2022 Edison Awards, awarded to the “best of the best” new products in the areas of patient care, personal wellness technology, and technology and tools. EX2021-EX2024. Other awards recognizing the value of Libre’s innovations include:

- 2020 Gold German Innovation Award, recognizing Libre for “provid[ing] a simple, safe, painless and discreet alternative...” that includes “a small sensor that is easy to apply and can be worn unobtrusively...provid[ing] an essentially more convenient and pain-free measurement method.” EX2031, 1.
- Consumer Technology Association’s 2022 CES Innovation Award, recognizing Libre for having the “world’s smallest, thinnest glucose sensor” “and delivering breakthrough technology that is accessible and affordable.” EX2035, 1.
- 2017 Good Design Award, recognizing Libre’s “ease of understanding, ease of use, and ease of storage.” EX2032, 6.
- 2017 Irish Medical & Surgical Trade Association MedTech Awards for “Most Innovative Product Multi-National,” recognizing Libre as a “painless[]” “groundbreaking monitoring system ...consist[ing] of a small, round sensor—approximately the size of a €2 coin.” EX2026, 1.

There are numerous other examples. *See, e.g., id.*; EX2025 (2017 Medical Design Excellence Award); EX2027-EX2028 (2018 and 2021 Business Intelligence Group (BIG) awards); EX2029 (2018 Chicago Innovation Award, recognizing Libre’s ultra-low profile); EX2030 (Scientist Magazine’s Top 10 Innovation of 2019);

EX2006 (2019 Prix Galien Award recognizing Libre for “Best Medical Technology”); EX2002, ¶¶390,381.

“[S]ales figures alone are also evidence of commercial success.” *Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353, 1361 (Fed. Cir. 1999). Abbott repeatedly touts the features of the claimed inventions in promoting the Libre products. EX2037, 1; EX2038, 1; EX2002, ¶¶376-378, 430. The Libre products are the most widely used CGM in the world and have reported sales of \$4.3 and \$5.3 billion in 2022 and 2023 alone. EX2034, 72; EX2019, 1. This tremendous success further demonstrates the nonobviousness of the claimed inventions. *Alcon Rsch., Ltd. v. Apotex, Inc.*, 687 F.3d 1362, 1371 (Fed. Cir. 2012); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1382 (Fed. Cir. 1986).

XIII. CONCLUSION

Petitioner failed to show that the Claims 1-30 are unpatentable.

Dated: July 19, 2024

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **Patent Owner's Response and Exhibits 2002 – 2044** were served on July 19, 2024 by electronic mail to the following:

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CERTIFICATE OF WORD COUNT

I hereby certify that this Response complies with the word count limit of 37 C.F.R. § 42.24(d). The argument sections of this Response (Sections I-XIII) have a total of 13,925 words, less than 14,000 words, as measured by Microsoft Word® word count tool.

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