

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

IPR2023-01409
U.S. Patent No. 11,202,591

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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EXHIBIT LIST

LIST OF NEWLY FILED EXHIBITS

Exhibits concurrently filed with Petitioner's Reply:

No.	Description
1044	Transcript of Deposition of Karl R. Leinsing, dated October 17, 2024
1045	Second Declaration of Gary D. Fletcher, Ph.D., dated October 25, 2024
1046	Abbott FreeStyle Navigator Continuous Glucose Monitoring System User's Guide dated May 2008
1047	Neil T. Clancy, <i>et al.</i> , <i>A New Device for Assessing Changes in Skin Viscoelasticity Using Indentation and Optical Measurement</i> , Skin Research and Technology (2010) (" Clancy ")
1048	Alvin H. Sacks, Ph.D., <i>et al.</i> , <i>Skin Blood Flow Changes and Tissue Deformations Produced by Cylindrical Indentors</i> , Journal of Rehabilitation Research and Development Vol. 22 No. 3 (July 1985) (" Sacks ")
1049	<i>intentionally left blank</i>
1050	Cleo90 Infusion Set Training Guide (from Wayback Machine)
1051	Food and Drug Administration approval of Cleo90 Infusion Set dated October 7, 2004
1052	"Diabetes Patents," printed on October 21, 2024 from https://www.abbott.com/patents/diabetes-patents.html
1053	Photographs showing patent marking on CLEO90 device
1054	DexCom STS Continuous Glucose Monitoring System User's Guide (from Wayback Machine)

No.	Description
1055	Declaration of Mung Conway, Paralegal, dated October 25, 2024
1056	Medtronic Guardian REAL-Time Features and Components, from Wayback Machine, available at https://web.archive.org/web/20071025084715/http://www.medtronicdiabetes.com/products/guardian/features.html , https://web.archive.org/web/20071013095355/http://www.medtronicdiabetes.com/products/guardian/components.html
1057	U.S. Publication No. 2004/0186365 (“ Jin ”)
1058	U.S. Patent No. 7,731,691 (“ Cote Patent ”)
1059	Amendment and Response filed January 7, 2008, from Cote File History for U.S. Patent No. 7,731,691
1060	U.S. Patent No. 10,827,954 (“ 954 patent ”)
1061	U.S. Patent No. 11,298,056 (“ 056 patent ”)
1062	“Answers to Frequently Asked Questions,” Freestyle Navigator System, from Wayback Machine, available at https://web.archive.org/web/20080917183534/http://www.freestylenavigator.com/ab_nav/url/content/en_US/30.10.10:10/general_content/General_Content_0000004.htm (“ Navigator FAQ ”)
1063	U.S. Patent No. 7,585,287 (“ Bresina Patent ”)
1064	U.S. Publication No. 2005/0283114 (“ Bresina ”)
1065	Code of Federal Regulations (2007) 29 C.F.R. § 1910.1030, Bloodborne pathogens
1066	FDA 510(k) Premarket Notification page for CLEO90

No.	Description
1067	Smiths Medical Cleo90 Infusion Set Product Literature, available at https://web.archive.org/web/20220816002119/https://www.smiths-medical.com/-/media/M/Smiths-medical_com/Files/Import-Files/Product-Literature/IN193873GB-092019_LR.pdf

LIST OF PREVIOUSLY FILED EXHIBITS

Petitioner previously filed the following exhibits:

No.	Description
1001	U.S. Patent No. 11,202,591 (“ 591 patent ” or “ 591 ”)
1002	File History of U.S. Patent No. 11,202,591
1003	Declaration of Dr. Gary D. Fletcher, dated October 10, 2023 (“ Fletcher Decl. ”)
1004	U.S. Publication No. 2008/0097246 (“ Stafford ”)
1005	U.S. Publication No. 2005/0101932 (“ Cote ”)
1006	U.S. Publication No. 2007/0073129 (“ Shah ”)
1007	U.S. Publication No. 2007/0135774 (“ Turner ”)
1008	U.S. Patent No. 6,175,752 (“ Say ”)
1009	U.S. Publication No. 2009/0124979 (“ Raymond ”)
1010	U.S. Publication No. 2006/0095014 (“ Ethelfeld ”)
1011	PCT Publication No. WO2008/155377 (“ Hasted ”)
1012	U.S. Publication No. 2009/0076360 (“ Brister-360 ”)
1013	U.S. Publication No. 2006/0155180 (“ Brister-180 ”)
1014	U.S. Publication No. 2004/0133164 (“ Funderburk-164 ”)
1015	U.S. Patent No. 6,560,471 (“ Heller ”)
1016	U.S. Patent No. 6,579,690 (“ Bonnecaze ”)

No.	Description
1017	U.S. Publication No. 2003/0225373 (“ Bobroff-373 ”)
1018	U.S. Publication No. 2009/0240121 (“ Bickoff ”)
1019	PCT Publication No. WO2008/114223 (“ Pesach ”)
1020	U.S. Publication No. 2004/0002682 (“ Kovelman ”)
1021	U.S. Patent No. 7,381,184 (“ Funderburk ”)
1022–1024	<i>intentionally left blank</i>
1025	U.S. Publication No. 2008/0319414 (“ Yodfat-414 ”)
1026	U.S. Patent No. 7,207,974 (“ Safabash ”)
1027	U.S. Publication No. 2004/0204687 (“ Mogensen-687 ”)
1028	U.S. Publication No. 2002/0022855 (“ Bobroff-855 ”)
1029	U.S. Patent No. 9,566,384 (“ Gyrn ”)
1030	U.S. Patent No. 8,747,363 (“ Nielsen ”)
1031	U.S. Publication No. 2007/0093754 (“ Mogensen-754 ”)
1032–1033	<i>intentionally left blank</i>
1034	Steven W. Smith, <i>The Scientist and Engineer’s Guide to Digital Signal Processing</i> (2nd ed. 1999) (excerpted)
1035	B.A. Sheno, <i>Introduction to Digital Signal Processing and Filter Design</i> (2006) (excerpted)
1036	U.S. Publication No. 2009/0099521 (“ Gravesen ”)
1037	U.S. Publication No. 2009/0216215 (“ Thalmann ”)
1038	U.S. Publication No. 2008/0255440 (“ Eilersen ”)
1039	Scheduling Order, <i>Abbott Diabetes Care Inc. v. DexCom Inc.</i> , No. 1-23-cv-00239 (D. Del. filed Mar. 3, 2023)
1040	PCT Publication No. WO2008/115409 (“ Brenneman ”)

No.	Description
1041	Statement of Defense (Counterclaim), <i>Dexcom Inc. v. Abbott Diabetes Care Inc.</i> , Case No. 21 O 6562/23 (Munich D. Ct. I), Sept. 1, 2023
1042	U.S. Publication No. 2008/0114280 (“ Stafford-280 ”)
1043	Transcript of Telephone Conference Call dated February 2, 2024

I. INTRODUCTION

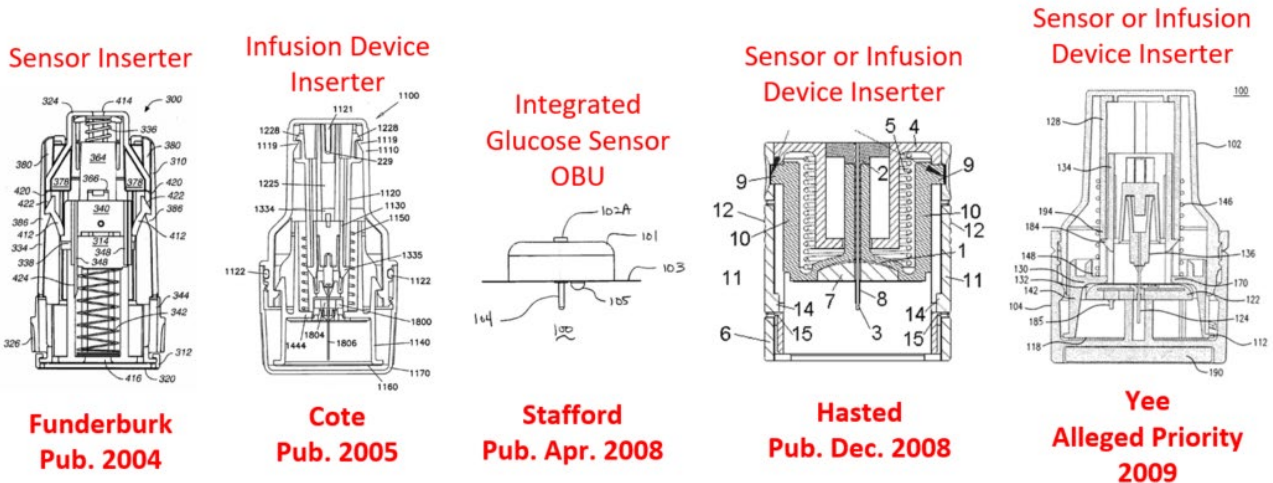
Patent Owner's Response (Paper 18, "POR") fails to rebut Petitioner's obviousness showing. Patent Owner ("PO") relies on unsupported arguments and expert assertions contradicted by evidence. PO recasts the alleged invention in various ways, e.g., "an all-in-one, ultra-low profile solution," POR, 73. But that is untethered from the claims of the '591 patent ("'591") and was not new.

An "all-in-one, ultra-low profile" on-body unit ("OBU") was known. Shah disclosed an OBU smaller than a penny, noting a "slim shape provides more comfort while being less conspicuous" (EX1006, [0011]); Say disclosed making the height profile of the wearable 0.7cm (thinner than challenged claims require); and Stafford's "all-in-one" OBU (with no expressly disclosed dimensions) would be understood in the context of the prior art (and common sense) as preferably low-profile.

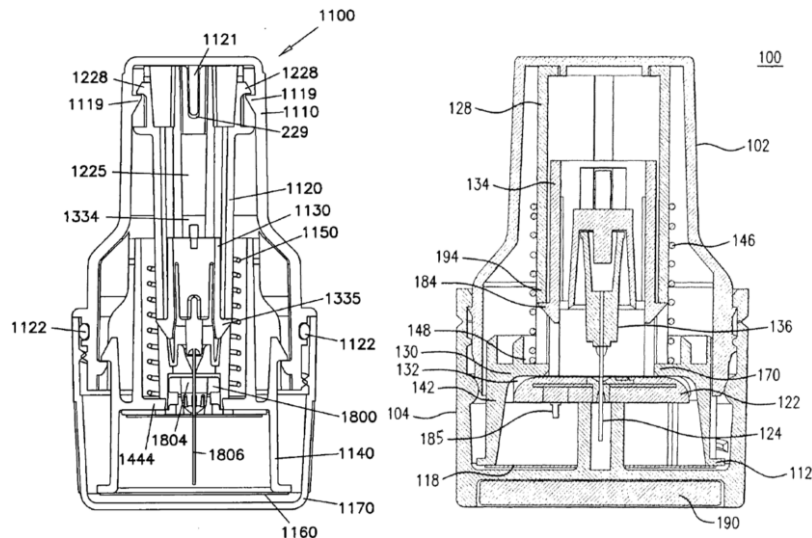
The idea of a disposable-automatic-sensor-inserter was also a well-known option within the state of the art in sensor and infusion device inserters to provide features and benefits different than the manual needle insertion/retraction disclosed in Stafford and Shah. *See generally* EX1011; EX1014; EX1046.

Cote, Stafford itself, and a POSITA's background knowledge all provided teachings and motivation to replace Stafford's manual needle/sensor insertion with a Cote-like disposable-automatic-sensor-inserter to improve user experience/safety.

EX1045, ¶¶14-21. Suggestion to do so also is found in the overlap of prior sensor/infusion insertion technology, such as Hasted, disclosing a similar disposable-automatic-sensor-insertion for sensor or infusion devices.



No patentable invention follows from the '591's applicants taking the teaching-suggestion-motivation in the art to effectively copy Cote¹ for use with sensor/infusion devices. EX1001, 14:57-59; Pet., 28-33. *Compare:*



Cote, FIG. 79A (left); '591, FIG. 29 (right)

¹ As PO noted, a Cote “equivalent” was cited during prosecution. EX2001.

II. OBVIOUS STAFFORD+COTE COMBINATION

Stafford teaches an all-in-one OBU like the one claimed; Cote teaches an automatic inserter like the one claimed. A POSITA would have found it obvious to combine those complementary teachings to make the claimed “insertion assembly,” with a reasonable expectation of success. Pet., 28-33. PO improperly relies on select disclosures of individual references, failing to meaningfully challenge the motivation to combine well-known elements and/or reasonable expectation of success to make the claimed “insertion assembly.” EX1045, ¶¶8-9.

A. Cote’s Simple-To-Use Inserter Complements Stafford, Solving Problems Stafford Identified

A POSITA would have recognized advantages of Stafford’s “all-in-one” OBU design, but also recognized at least two disadvantages of Stafford’s inserter: (1) the exposed introducer/needle (causing anxiety and risking needlesticks) and (2) manual retraction of the introducer/needle (increasing pain/discomfort). A Cote-like inserter addressed both, by reducing anxiety and mitigating risk of needlesticks (via shrouding the needle), and by reducing pain (via automatic retraction). Pet., 28-33.

PO argues non-obviousness, alleging complexity and cost of a Cote-like inserter would “eviscerate the express advantages of Stafford’s minimalist design” (POR, 2) outweighing any benefits provided by Stafford+Cote. POR, 26-27. This misstates the obviousness analysis, where “it is a commonplace fact that design

decisions entail making tradeoffs among multiple objectives.” *Corephotonics, Ltd. v. Apple Inc.*, No. 2020-1961, 2021 WL 4944471, at *6 (Fed. Cir. Oct. 25, 2021).

A Cote-like inserter complements and improves upon Stafford’s teachings by addressing problems Stafford identified, improving user experience even if increasing manufacturing complexity. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (“[S]imultaneous advantages and disadvantages...do[] not necessarily obviate motivation to combine.”).

Stafford notes that discarding the inserter “requires a level of care” as it “may damage other parts of the patient’s skin if not properly handled,” and that disposal of the inserter must include “particular precautions” as it has contacted biological fluids. EX1004, [0003]. Cote addresses these problems by guarding the needle not only prior to and during insertion (EX1005, [0235]), but also after insertion via automatic retraction of the needle into the inserter. *Id.*, Abstract, [0236]. This protects against contact with the needle and biological fluids in ways Stafford alone would not. A POSITA would be motivated to avoid Stafford’s shortcomings, and would deem impractical PO’s suggestion of recapping Stafford’s needle, for safety and regulatory reasons. EX1045, ¶¶10-15; *compare* EX2002, ¶140.

PO alleges that Petitioner “never adequately explains why a ‘Cote-like inserter’ would reduce ‘pain and anxiety’ over Stafford’s...design.” POR, 29. Cote teaches reducing pain and anxiety based on (1) ***needle shrouding*** (via the cap *and*

via sleeve 1140) and (2) *automatic retraction* of the needle. Pet., 29-30; EX1005, [0005] (recognizing that “patients may react adversely to viewing the needle prior to insertion and may...be reluctant to place the needle into the skin”), [0235]-[0236]; *see also* EX1020, [0005]. Unlike Stafford, a Cote-like inserter shrouds the needle with sleeve 1140 prior to, during, and after use, reducing needle anxiety. EX1005, [0235]-[0236]. Cote also includes automatic needle retraction “limit[ing] the dwell time of the needle in the patient, increasing comfort for the patient.” *Id.*, [0236].

PO’s contention that Stafford+Cote has the same benefits as Stafford “(e.g., single-handed operation) while offering no additional benefits...” (POR, 33) ignores these stated advantages of a Cote-like inserter. Pet., 28-33; EX1045, ¶¶16-21.

1. PO’s “Separate Sensor Introducing Device” Point Fails

PO argues that Stafford teaches away from using a “separate sensor introducing device.” POR, 27. The Cote-like inserter of Stafford+Cote is no more a separate introducer than Stafford’s own introducer. In both cases, the OBU/introducer are provided as a unit, and the introducer is later removed and discarded. If, as PO implies, Stafford’s goal of a “single disposable assembly” (*id.*) requires no separable components, Stafford does not achieve it. EX1045, ¶¶22-23.

2. Interchangeability Of Cannula And Sensor inserter Technology Was Well-Known

PO contends: “Cote’s infusion cannula inserter is not suitable for a fragile glucose sensor where precision and stability are critical during sharp insertion and

retraction.” POR, 2, 31 n.4. This unsubstantiated statement runs contrary to the accepted knowledge in the art regarding interchangeability of cannula and sensor inserters. Pet., 12-13. The ’591 itself reiterates cannula/sensor interchangeability for the claimed inserter. EX1001, 14:54-59.

PO further argues lack of interchangeability due to a need for stability of the inserter on the skin during sensor insertion that it alleges Cote does not provide. POR, 2; EX2002, ¶¶170-172. However, this argument relies on PO’s misinterpretation of both how Cote’s inserter functions and the ’591 claims. *See infra* §III.A; EX1045, ¶¶24-28.

B. Alternative Designs Would Also Be Obvious, But That Does Not Undermine Obviousness Of The Combination

PO accuses Petitioner of “cherry-picking” prior art to combine an “*infusion cannula* inserter” with Stafford’s sensor inserter. POR, 31-32 (emphasis original). But the Petition explained the well-known interchangeability of cannula/sensor inserters, and specific benefits Cote’s design adds to Stafford. Pet., 12-13, 28-33.

PO argues that Petitioner “cherry-picks” one of Cote’s inserter designs when Cote provides others and despite other known automatic sensor inserters. POR, 32. However, “[i]t’s not necessary to show that a combination is the *best* option, only that it be a *suitable* option.” *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 800 (Fed. Cir. 2021) (emphasis original, internal quotes omitted).

A POSITA would have been motivated to implement Cote’s teachings to reduce pain/anxiety and inadvertent needlesticks to complement Stafford’s goals and provide an all-in-one insertion assembly, pre-loaded with a Stafford-like OBU. Pet., 28-33; EX1005, [0005]-[0006], [0235]-[0239]; EX1004, [0044]-[0045]; EX1045, ¶¶29-30. That there were other obvious solutions is irrelevant.

III. THE COMBINATIONS RENDER THE CLAIMS OBVIOUS

A. Stafford+Cote Provides An Inserter “Configured To Be Removed From The Skin Of The User After Automatic Retraction Of The Sharp...”

PO argues: “the distal end of Cote’s inserter is specifically configured to be removed from the skin *before* its sharp is retracted.” POR, 35 (emphasis original). PO is wrong on the facts—Cote’s inserter is removed only after retraction, not before—and PO’s alleged factual distinctions are irrelevant under the correct claim interpretation. EX1045, ¶31.

1. Cote Expressly Teaches Removing The Inserter From The Skin As The Final Step *After* Needle Retraction

After describing needle retraction (¶[0211]), Cote states: “***Finally***, the sleeve 1140 is removed from contact with the skin 1900....” EX1005, [0213].² PO argues that “Cote is referring to removing the sleeve from a *later* positioning on the skin” occurring after sharp retraction. POR, 41-42 (emphasis original). PO offers no

² Emphases added throughout, unless otherwise indicated.

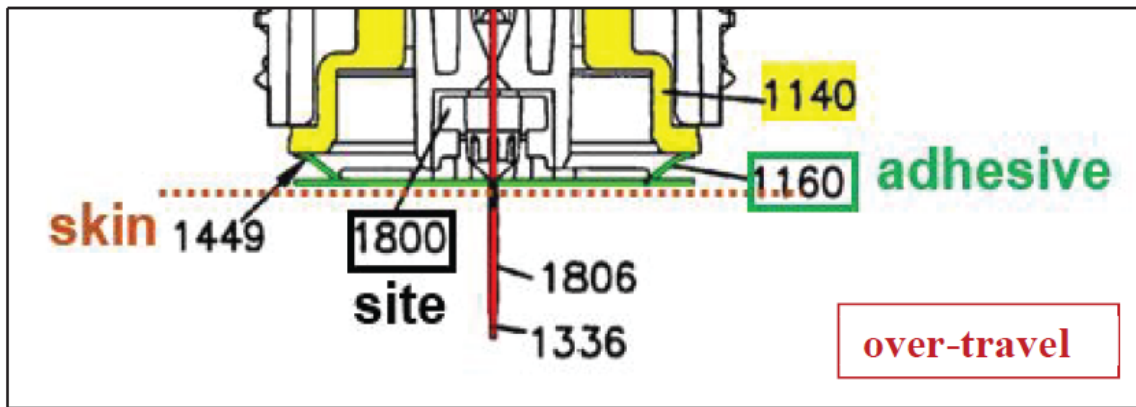
credible evidence supporting this contention, relying instead on a fanciful re-interpretation of Cote's figures.

Cote nowhere describes the inserter being removed from the skin, repositioned, then removed again, as PO alleges "must" occur. POR, 40. To the contrary, Cote's disclosure is clear, and corroborated by its issued claims (published in the file history in 2008): "automatically moving the needle...to the retracted position" occurs "while leaving the [inserter] sleeve in contact with the skin of the patient." EX1058, claim 1; EX1059, 2; EX1045, ¶¶32-37.

2. PO's Annotated Figures Contradict Cote's Clear Disclosure

PO offers annotated figures purporting to show relative positioning of Cote's inserter to the skin throughout insertion/retraction. EX2002, ¶¶209-211. But these Cote figures were never intended to illustrate skin position. When Cote wanted to illustrate the skin's position, it did so. *See* EX1005, FIGS. 77-78.

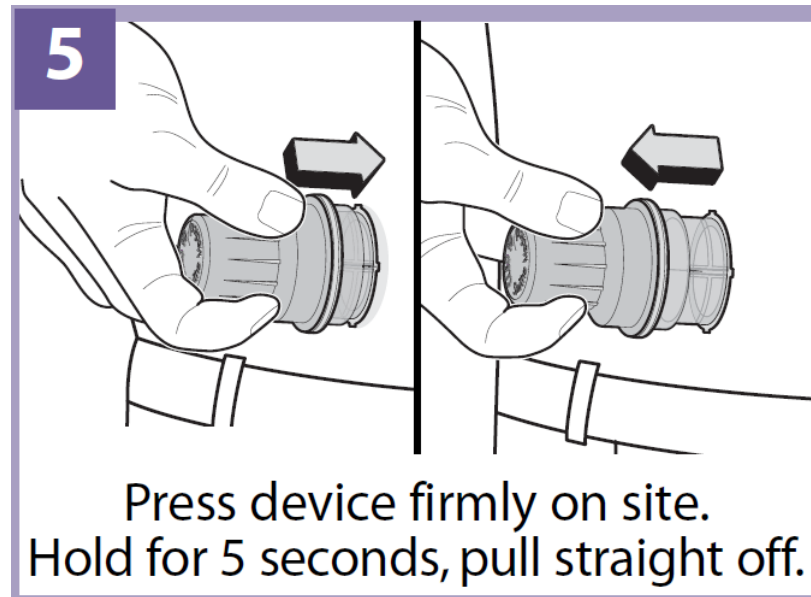
PO's annotations are wrong. Annotated FIG. 81C, below, for example, purports to show separation between sleeve 1140 and PO's fictional skin surface where none would exist. PO's reliance on this annotated figure as allegedly showing separation of the sleeve from the skin during over-travel is misplaced. EX1045, ¶¶38-40.



Cote, FIG. 81C (as incorrectly annotated by PO, EX2002, ¶184)

These annotations are contrary to Cote’s express disclosure of its trigger state in FIG. 78 (which PO ignores), showing the sleeve 1140 remains on the skin 1900 during the trigger state. Cote’s trigger state is *also* “shown in FIG[.]...**81C**” (EX1005, [0203]) on which PO relies. Cote’s disclosure is clear: sleeve 1140 maintains contact with the skin during needle retraction, as needle retraction automatically occurs before “the patient removes pressure...” (*id.*, [0211]-[0212]), and before the inserter “sleeve 1140 is removed from contact with the skin” (*id.*, [0213]). Moreover, like FIG. 81C, FIGS. 82A-82B show the housing 1110 fully compressed against sleeve 1140 by patient pressure, holding the inserter on the skin throughout needle retraction. *Id.*, [0211]-[0213]; EX1045, ¶¶41-47, *see also id.*, ¶¶63-67.

That POSITAs would understand Cote-like inserters to work this way is confirmed by background references, including the instructions for Cote’s 2005 commercial embodiment, Cleo90, which included instructions to “press...firmly” and “[h]old for 5 seconds”:



Excerpt from 2005-dated Cleo90 instructions (EX1050)

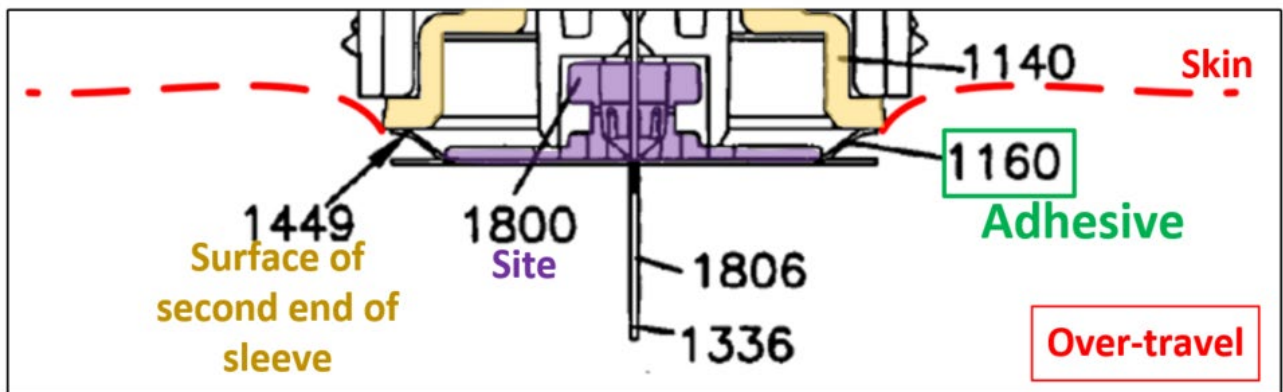
A POSITA would have understood that automatic needle retraction occurs in a fraction of a second, so these instructions further support that the needle would retract before the user removes the inserter from the skin. EX1045, ¶¶61-67; *see also id.*, ¶¶57-60.

Finally, the “over-travel” on which PO relies is optional in “preferred embodiments” of Cote’s inserter 1100 (EX1005, [0209]-[0210]), making PO’s argument irrelevant to Cote embodiments without “over-travel,” which a POSITA would know to use when appropriate. EX1045, ¶¶48, 68-69.

Simply put, Cote consistently teaches that the inserter is removed from the skin surface only *after* automatic needle retraction completes and Cote-like inserters would be implemented (with or without over-travel) with a reasonable expectation of success in Stafford+Cote. EX1005, [0211]-[0213]; EX1045, ¶¶26, 66-68.

3. PO's Annotated Figures Are At Odds With Anatomy

PO's annotated figures, at odds with Cote, also fail to consider that skin is elastic, not rigid and flat as drawn. EX1045, ¶¶49-54. *See generally*, EX1047; EX1048. A POSITA would understand that downward force applied to Cote's site 1800 and sleeve 1140 during over-travel (if any) would deform/indent the skin surface, maintaining skin contact with the sleeve throughout insertion and retraction. EX1005, [0209]-[0211].



Cote, FIG. 81C (partial, annotated)

EX1045, ¶¶55-60; *see also id.*, ¶¶61-69.

4. PO's Position Rewrites The Claims, Adding Limitations

No credible evidence supports PO's theory that over-travel causes the inserter to momentarily lose contact with the skin before the inserter is "finally" removed. But even were PO correct in hypothesizing that Cote's over-travel would cause the inserter to "jump" off the skin (it is not), the claims do not require the distal end of the inserter to remain on the skin at all times prior to needle retraction. And, Cote's

inserter is indisputably ultimately removed from the skin after needle retraction, (POR, 41-42; EX1045, ¶¶70-76), thus satisfying the '591 claims.

B. Stafford+Cote Teaches The Height Limitations

1. Stafford+Cote Teaches Or Suggests ≤ 10 mm OBU Height

Claims 14/19 require an OBU housing height “less than or equal to approximately 10 millimeters.” Both Stafford and Cote discuss desirability of a “smaller profile” OBU. EX1004, [0045]; EX1005, [0228]. PO dismisses Cote’s and Stafford’s disclosures as allegedly lacking “relevant electronics.” POR, 53. However, both are OBUs; a POSITA would have wanted to make any OBU as low-profile as possible to maximize patient comfort, as was well-known. Pet., 13; EX1006, [0010]-[0011]; EX1045, ¶¶77-78.

Stafford references Say (EX1004, [0043]), which teaches an OBU height of “preferably 0.7 cm [7mm] or less.” EX1008, 29:45-47. Pet., 85, 87. PO neither presents evidence of a relevant difference between an “all-in-one” OBU and a multi-part OBU, nor explains why the height of an assembled OBU, such as Say’s, should be ignored. Indeed, a POSITA would understand that an “all-in-one” unit, requiring no separate mount, would be as small or smaller than a multi-part unit. Further, Say includes OBU embodiments including electronics as part of the housing. EX1008, 30:19-22. PO offers no reason that a POSITA would consider making the OBU any

taller than the “approximately” $\leq 10\text{mm}$ heights previously used in background references in the CGM field. EX1045, ¶¶79-84; *see also id.*, ¶¶97-100.

Given Stafford’s and Cote’s teachings, a POSITA would have found it obvious to implement an OBU with a height $\leq 10\text{mm}$. Say and other background references confirm that a lower-profile OBU than the claims require was known, conventional, and preferred.³ *Id.*, ¶85, *see also id.*, ¶¶97-100.

Further, PO provides no evidence of alleged criticality of the claimed $\leq 10\text{ mm}$ height range: the ’591 gives a wide range of OBU heights, ranging from less than to greater than 10mm (EX1001, 14:5-7), as does the prior art. Accordingly, OBU height selection was within a POSITA’s skillset, and it would have been obvious to implement Stafford+Cote with an OBU height $\leq 10\text{mm}$, with a reasonable expectation of success. EX1045, ¶¶86-87, *see also id.*, ¶114.

2. Stafford+Cote Teaches The Relative Heights Limitation

Petitioner did not “switch[] references” to rely on Cote’s rather than Stafford’s OBU for the “housing-distance limitation.” POR, 43-45. Petitioner combined Cote’s and Stafford’s teachings, but relies on a Stafford-like OBU, properly relying on “what the combined teachings of the references would have suggested to those of ordinary skill in the art.” *In re Keller*, 642 F.2d 413, 425 (C.C.P.A. 1981). Pet., 54

³ Say reflects state of the art here; Grounds 2/6/8 rely on Say’s express teachings.

(“Based on Cote’s teachings, a POSITA would have configured the travel distance of *Stafford’s [OBU]* (‘H1’) to be greater than the height of the [OBU]’s housing (‘H2’).”); EX1045, ¶88; *see also id.*, ¶¶105-109.

a) **H1≠Sharp/Sensor Length**

PO misstates the $H1 > H2$ claim limitation: H1 does **not** measure the “portion of Stafford’s sharp/sensor extending from the bottom of its OBU....” POR, 46. It is “a distance between the housing when the [OBU] is in the first position and the housing when the [OBU] is in the second position.” EX1001, claims 3/19; Pet., 14. PO illustrated this correctly:

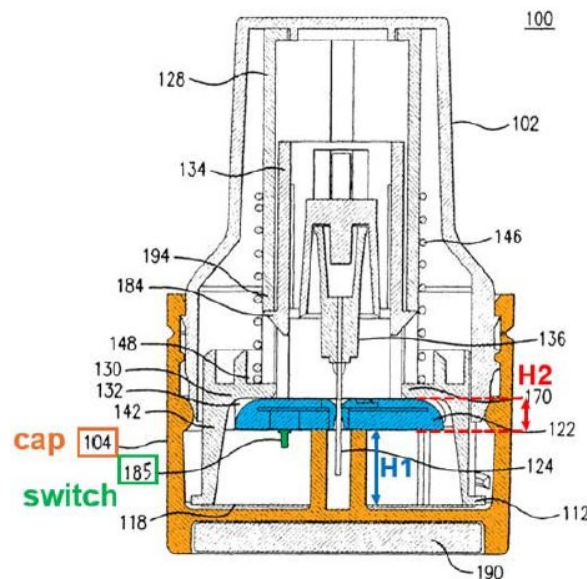


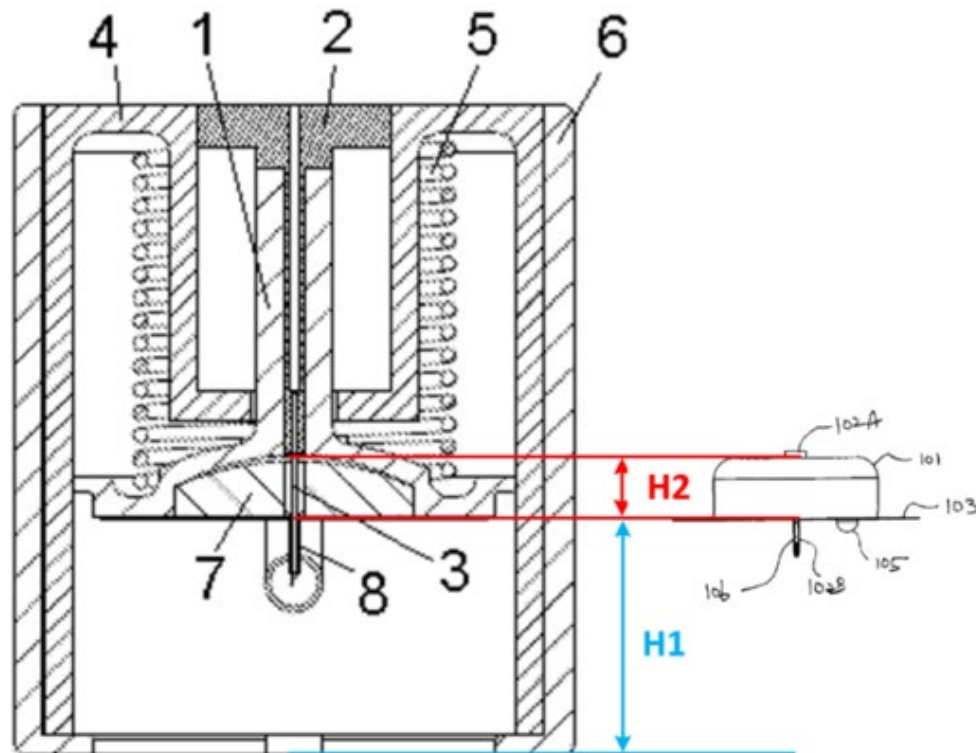
FIG. 29

POR, 44.

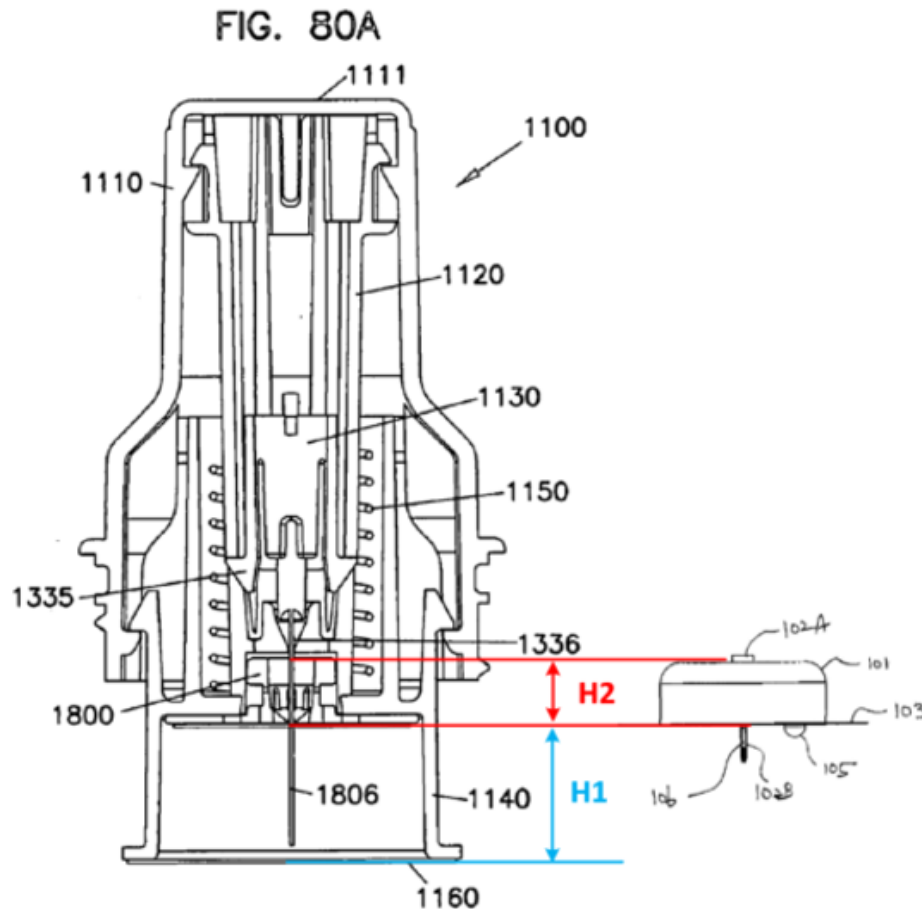
POSITAs knew that H1 preferably should be greater than the OBU’s sharp/sensor length. Otherwise, the sharp would not be shrouded by the inserter before use, risking premature/inadvertent needlesticks. EX1045, ¶¶89-94.

b) $H1 > H2$ Was Not Only Obvious, But Effectively Required For Known Ranges Of Needle/Insertion Depth And OBU Heights

As Dr. Fletcher illustrates, $H1 > H2$ was used in conventional designs, e.g., Hasted where the “medical device used with the inserter device can be...a sensor device” (EX1011, 4:6-7) and in Cote; $H1 > H2$ would be used in combining conventional inserter designs with Stafford’s OBU with a reasonable expectation of success:



**Comparison of Hasted FIG. 1
and Stafford FIG. 2 (annotated)**



**Comparison of Cote FIG. 80A
and Stafford FIG. 2 (annotated)**

EX1045, ¶¶90-96.

PO complains that Petitioner relies on references not expressly forming part of a combination to establish a POSITA's knowledge. POR, 53. But "referenc[ing] the knowledge of a person of ordinary skill in the art" as the basis for a separate ground is not necessary because the obviousness analysis "must consider knowledge generally available to one of ordinary skill in the art." *New World Med., Inc. v. Microsurgical Tech., Inc.*, IPR2021-00065, 2022 WL 945580, at *5 (P.T.A.B. Mar. 11, 2022).

POSITAs well understood that OBU height (H2) should be minimized for patient comfort and that travel distance (H1) should exceed the depth of sensor/cannula insertion, to avoid inadvertent needlesticks and needle anxiety from the sharp/needle extending out of the inserter before use. EX1045, ¶¶97; *see also id.*, ¶¶78, 82-83, 89, 91, 94. To accomplish that, H1 effectively must be greater than H2 where, as was known in the art, the OBU height is less than the needle/sensor insertion depth. Pet., 13-17, 56; EX1045, ¶¶97-98.

POSITAs also well understood that for CGM systems the ranges of (a) insertion depths (should be $<H1$) included 2mm-12.5mm, and (b) OBU heights (H2) included 1.5mm-11mm (preferably ≤ 7 mm). $H1 > H2$ is therefore derived from:

- known ranges of sensor/needle/depth (e.g., 8mm-12.5mm), which dictates *minimum* travel distance H1 if one is going to shroud the needle and avoid inadvertent/premature needlesticks, and
- OBU height (H2, preferably ≤ 7 mm).

Simply, $H1(8\text{mm to } 12.5\text{mm}) > H2(7\text{mm})$. EX1045, ¶¶99-101.

Hence, “there is a presumption of obviousness” that cannot be rebutted here as there is no evidence that “the prior art taught away” or that the claimed $H1 > H2$ provided “new and unexpected results.” *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004); *New World Med.*, 2022 WL 945580, at *17

(finding claimed “result-effective, optimizable” size range obvious, absent “persuasive evidence of teaching away from the claimed range,” unexpected results).

Further, the ’591’s description of wide ranges of sensor lengths and housing heights (EX1001, 14:1-7, 17:30-32)—without describing any benefit to any of them or the claimed $H1 > H2$ relationship—indicates that a POSITA knew to select whatever length needle/sensor (and travel distance) was appropriate. EX1045, ¶102. *See In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994) (failure to provide detail lacking in prior art references supports “Board’s finding that [a POSITA] would have known how to implement the features...”).

Finally, because Cote FIGS. 79A-80B show $H1 > H2$ for an OBU/inserter, it would have been obvious to a POSITA to try that configuration. Pet., 52-58; EX1045, ¶¶103-108. Moreover, as illustrated above, a Stafford-like OBU would be scaled to fit into a Cote-like inserter without changing the ratio of sharp/sensor length to OBU height as drawn in Stafford, thereby meeting the $H1 > H2$ limitations. *Id.*, ¶¶94-98.

Stafford+Cote, the knowledge of a POSITA, and ranges of known needle/OBU sizes in CGM systems all teach and suggest positioning the OBU within the inserter such that $H1 > H2$. And, in any event, $H1 > H2$ would have been obvious to try in Stafford+Cote, as a simple design choice. *Id.*, ¶¶99-109, 115.

**c) PO's Alleged Benefits Are Not Tied
To The Relative Heights Limitation**

PO argues: “Petitioner fails to satisfy its burden of proving that the claimed dimensional limitations had no effect on the performance.” POR, 50 (citation omitted). PO misstates the required showing, namely whether the limitation imparts patentability in that the device “performed and operated any differently from the prior art.” *Gardner v. TEC Sys. Inc.*, 725 F.2d 1338, 1349 (Fed Cir. 1984); *see also Ex Parte Puthillath*, No. Appeal 2023-001346, 2024 WL 3179788, at *4 (P.T.A.B. Mar. 26, 2024) (failing to “explain how or why the particular dimension...imparts patentability...supports a logical conclusion that using a larger...component is largely a matter of design choice”).

PO lists two advantages allegedly provided by the '591 inserter's design: (1) preventing inadvertent activation of the OBU electronics and (2) “allowing for a cap boss.” POR, 51. However, the '591 never discusses the claimed $H1 > H2$ relationship, much less describes it as providing these advantages. PO's *post hoc* alleged advantages are not necessarily provided by—and do not require—the claimed $H1 > H2$ relationship. EX1045, ¶¶110-113.

PO simply does not show that an inserter having the claimed $H1 > H2$ would perform differently than the prior art. *See Ex Parte Frerichs*, No. Appeal 2023-000813, 2023 WL 6285157, at *4 (P.T.A.B. Sept. 25, 2023) (where “a device having

the claimed relative dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct”); *In re Rose*, 220 F.2d 459, 463 (C.C.P.A. 1955) (“size...is not ordinarily a matter of invention”). This should be determinative here, even disregarding that Stafford+Cote teaches or suggests the “housing-distance limitation,” as shown above. EX1045, ¶¶114-115.

C. Stafford+Cote Teaches The Claimed “Data Storage Unit”

Given Stafford’s teaching that data is processed by the OBU’s data processing unit (DPU) and transmitted by the DPU in one-minute intervals (EX1004, [0036]-[0037]), a POSITA would have found it obvious to include a data storage unit to store the data before/during processing and/or to allow for a lag between data collection and transmission. Pet., 59-60. Further, Stafford (¶[0043]) teaches that additional details of its DPU are disclosed in both: (a) Say, which expressly teaches a “data storage unit” (EX1008, 36:40-43, 44:54-45:7), and (b) Jin, which similarly teaches that “the transmitter processor 204 also includes a memory.” EX1057, [0042]. Moreover, it was well-known in the art for analyte sensor OBU’s to optionally include a data storage unit. *See, e.g.*, EX1012, [0315]; EX1013, [0469]; EX1014, [0007]; EX1015, 2:28-32; EX1021, 2:35-39; EX1016, 37:48-51; EX1030, 30:45-48; EX1040, [0053]. This made it an obvious choice to include a data storage unit. EX1045, ¶¶116-118.

D. Stafford+Cote Renders The “Second Opening” Claims Obvious

1. A Second Opening Was Obvious, To Prevent Unintended Movement Between OBU And Inserter

PO incorrectly asserts that Petitioner “concedes” Stafford+Cote lacks a second opening. POR, 56. Cote teaches a second opening in a top surface of its OBU and Stafford’s OBU has only one top surface on which to place a “second opening.” Pet., 78-80; EX1005, [0135-0137], [0168], FIGS. 8, 34; EX1045, ¶124.

PO also asserts that including a second opening (claims 18/21) was non-obvious because “Cote’s existing design...already secures the infusion site to the inserter.” POR, 56. This ignores that while Cote’s diaphragm/needle friction fit holds the OBU within the inserter, it does not prevent rotation or tipping of the OBU within the inserter as a second opening would. Mr. Leinsing states that “proper placement [of sensors] requires care and precision.” EX2002, ¶160. Knowing this, a POSITA would be motivated to ensure the OBU does not tip/tilt within the inserter. Further, a POSITA would have had a reasonable expectation of success in including a second opening. Not only was it known in the art (EX1040, [0042]; EX1007, [0069]), but as previously stated, Cote also teaches it. EX1045, ¶¶124-128.

PO argues that the Board “rejected Petitioner’s equivalent ‘securing’ argument in IPR2023-01396...for the same reasons.” POR, 57. Petitioner’s arguments here are not equivalent. The “second opening” prevents undesired

rotation (the purpose discussed in Turner (Pet., 78), tipping/tilting, *and* aids in maintaining the OBU within the inserter. Pet., 76-80; EX1045, ¶¶127-129.

The Board’s further reasoning (POR, 58), was that “Turner’s rotation-resisting recesses 77 are not located on the peripheral edge of its body 20.” IPR2023-01396, Paper 13, 48-49. Because the ’591 claims do not require a peripheral “second opening,” the Board’s prior reasoning is inapplicable.

PO’s further position that Cote’s “cylinder hub (green) pinches opposite sides of the site (purple), which would prevent rotation” (POR, 59) is unsupported by Cote’s disclosure and is inapposite to Stafford+Cote, with its round Stafford-like OBU rather than the octagonal-shaped Cote OBU. EX1045, ¶¶130-133. If anything, PO’s argument confirms that one implementing a Cote-like inserter would want to avoid rotation of the OBU relative to the inserter, thus supporting the motivation to use a second opening on a round OBU.

PO’s argument that Brenneman does not teach preventing rotation (POR, 59-60) also fails. To function, Brenneman must prevent inadvertent rotation between portions of the OBU and the inserter to allow them both to rotate together to effect needle insertion. EX1040, [0044]-[0046]; EX1045, ¶134.

A POSITA would further recognize that the “second opening” need not expose electronics or the sensor (POR, 58) to provide the functions discussed above, thus not “creating a risk of moisture/contamination ingress.” EX1045, ¶¶135-136.

**2. “Second Opening” Limitations
Entitled To Little Or No Weight**

Common sense and the law dictate that if prior art discloses a “first opening” (which serves a purpose in Stafford) and a “second opening” (which serves a purpose in Brenneman), then a second opening having a smaller diameter (serving no purpose in the ’591) provides no patentable distinction. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (“If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.”). A POSITA would have found it an obvious design choice and one of a finite number of solutions to configure a second opening with a smaller maximum width than Stafford’s aperture (“first opening”) when logically only three possibilities exist—smaller, bigger, or the same. Pet., 81-83; EX1004, [0027], FIG. 2; EX1045, ¶¶125-126.

The ’591 associates no function or utility with a “second opening” in the top surface of a housing—indeed the ’591 never mentions such an opening. The “second opening” claims should thus be accorded little or no patentable weight in the obviousness inquiry because there is no clear disclosure of a “second opening” and no purpose ascribed to it or required by the claims. Indeed, a purely ornamental feature would meet the claim requirement. EX1045, ¶¶119-123. *In re Guldenaar Holding*, 911 F.3d 1157, 1161 (Fed. Cir. 2018) (finding dice markings have no

patentable weight where they “do not cause the die itself to become a manufacture with new functionality”); *cf.* 35 U.S.C. § 101.

**E. Stafford+Cote+Say Renders
 Obvious Claims 4, 7-8, 14-15, And 19-30**

1. Stafford+Cote+Say Teaches The Claimed Height Profile

As discussed in §III.B.1, *supra*, the height of Say’s two-part OBU (referenced in Stafford) is relevant here. Further, Say includes embodiments wherein the electronics are formed as part of the housing. Given Say’s teachings, a POSITA would have been motivated and able to implement a Stafford-like OBU to have a height $\leq 7\text{mm}$ and there is simply no reason an “all-in-one” OBU would be made any taller. EX1045, ¶137.

**2. Stafford+Cote+Say Teaches And
 Renders Obvious Sleep/Idle/Activation Claims**

Say (referenced in Stafford) teaches a sleep mode for conserving battery power in a two-part OBU (EX1008, 31:45-47; Pet., 87-88) and for the same reasons a POSITA would have used a sleep mode in an “all-in-one” OBU. Indeed, Stafford also teaches using a sleep mode for the OBU by referring a POSITA to Jin for details about the electronics (EX1004, [0043]), and Jin teaches a “post-manufacture sleep mode” to increase shelf-life. EX1057, [0044].

Further, Say teaches the OBU “detects that it is being used and activates itself...through a number of mechanisms” that a POSITA knew, including “a

switch” or “change in resistance.” EX1008, 31:47-52. A POSITA would be motivated to similarly activate an “all-in-one” OBU when deployed, to awaken and turn “on.” It was well-known in the art to design OBUs to activate when positioned on the skin. *See, e.g.*, EX1019, [0084]-[0087]; EX1045, ¶¶138-140.

3. Stafford+Cote+Say Teaches A Sensor Hub

PO did not dispute that a “sensor hub” is a feature supporting the sensor and promoting electrical contact with OBU electronics. POR, 66. A POSITA understood that an OBU requires adequate contact between the sensor and electronics. Stafford refers to Say, which provides one example of how to implement such a support structure. EX1008, 34:59-61; Pet., 92-93.

Supporting the sensor “to promote adequate contact between the...sensor 42 and the [electronics]” as taught by Say (EX1008, 34:59-61) would have motivated a POSITA to implement a sensor hub in a Stafford-like OBU. Say’s and Stafford’s sensors have similar shapes, and it would have been obvious to support each in a similar fashion with a reasonable expectation of success. A support structure/sensor hub was a well-known, conventional feature for maintaining electrical contact between the sensor and electronics, and a POSITA knew a Stafford-like OBU would require a way to hold the sensor and maintain electrical contact. Pet., 92-93; *see* EX1018, [0034], [0035], FIG. 4; EX1013, FIG. 4A; EX1021, FIGS. 29-32; EX1045, ¶¶141-143.

F. Grounds 3-8

1. Grounds 3-4: “Opening” Arguments

PO alleges: Petitioner “cherry-pick[s]” Brenneman and Shah’s “irrelevant apertures.” POR, 68-69. Labeling Brenneman and Shah’s apertures “irrelevant” is baseless when the ’591 itself neither describes the “second opening” or the “opening of the sensor electronics,” nor their purpose or function. Brenneman (EX1040) and Shah (EX1006) are analogous transcutaneous medical device art teaching the claimed openings. Such openings show obviousness. *See* EX1045, ¶¶144-145.

2. Grounds 5-8

PO takes issue with Grounds 5-8 combining four or five references. Reliance on a larger number of references (let alone four or five) does not weigh against obviousness. *In re Gorman*, 933 F.2d 982 (Fed. Cir. 1991) (affirming rejection based on *thirteen* references).

Regarding Ground 6, PO argues Petitioner provides no evidentiary basis mapping the “second opening” limitation in claims 25-26 and 28. POR, 70. That mapping is incorporated via Ground 1’s “second opening” (claims 18/21) mapping (Pet., 76-83), incorporated into Grounds 2/6. *Id.*, 94, 104 (incorporating prior grounds); *see also supra*, §III.D.

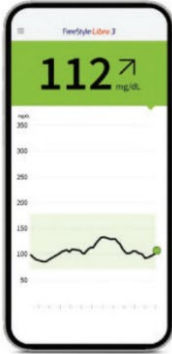
IV. NO OBJECTIVE INDICIA

PO’s objective indicia arguments (POR, 70-78) fail.

A. No Presumed Nexus

“A patent claim is not coextensive [and therefore not entitled to a presumption of nexus] with a product that includes a ‘critical’ unclaimed feature...claimed by a different patent....” *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1375 (Fed. Cir. 2019). This inquiry looks at “whether unclaimed features are ‘insignificant,’ period.” *Campbell Soup Co. v. Gamon Plus, Inc.*, 10 F.4th 1268, 1277 (Fed. Cir. 2021) (citing *Fox Factory*, 944 F.3d at 1374).

Even assuming, *arguendo*, that the Libre products embody some of the claims, they are not coextensive with them. PO itself alleges that Libre products include critical features unclaimed in the '591, including, e.g., factory calibration and a separate display device:

		
Applicator (insertion device)	On-body unit including sensor and transmitter	Display device (smartphone) with proprietary software

EX2003, ¶8 (showing unclaimed display device).

There is no presumed nexus because PO contends unclaimed features are, in part, “responsible for FreeStyle Libre systems’ affordability, accuracy, reliability, and its simple, effective handling (ease of use) for the patient.” *Id.*

Such allegedly critical features are claimed in other patents. In the same case alleging infringement of the ’591, PO alleged infringement of U.S. Patent Nos. 10,827,954 (EX1060, claim 1, reciting a “drift profile”) and 11,298,056 (EX1061, claim 1, reciting “backfilling data gaps” on “a receiver unit comprising...a display”). EX2003, ¶¶82-93, 114-148. PO contends: “[t]he inventions claimed in the ’056 patent save lives....” *Id.*, ¶115. These features are not claimed in the ’591, but are claimed by other patents PO contends cover Libre products. Both the ’954 and ’056 patents are marked on PO’s website for Libre 3, which lists 80 or more marked patents each for Libre, Libre 2, and Libre 3. EX1052, 1, 3, 5.

PO’s contentions regarding importance of unclaimed features and marking dozens of disparate patents on its Libre products disprove nexus here. *See Fox Factory*, 944 F.3d at 1377 (“Where a product embodies claims from two patents, a presumption of nexus can be appropriate only if the claims of both patents generally cover the same invention.”).

Further, PO has not established that Dexcom products infringe the challenged claims (EX2002, ¶414, App. B), and PO’s expert testimony on this issue should be given no weight as it is not based on sufficient facts. 37 C.F.R. § 42.65(a).

B. Alleged Objective Indicia Are Not The Direct Result Of Unique Characteristics Of The Claimed Invention

Absent a presumption, a patent owner may prove nexus “by showing that the evidence of secondary considerations is the direct result of the unique characteristics of the claimed invention.” *Fox Factory*, 944 F.3d at 1373-74. However, PO’s own evidence allegedly showing nexus between Libre’s “praise and commercial success” (POR, 76) and the ’591 instead demonstrates the opposite: any purported “success” or “praise” relates either to features not claimed in the ’591 (e.g., eliminating fingersticks), and/or reflect general statements that PO does not tie to ’591 claim elements supposedly distinguishing the prior art (e.g., the OBU is “less bulky”). *See* EX2004, EX2006, EX2020, EX2022, EX2026, EX2028, EX2029, EX2032, EX2037, EX2038, EX2041, EX2042 (mentioning accuracy, eliminating fingersticks, affordability or the like, none of which has any connection to the ’591 claims); EX2020, EX2024, EX2031, EX2033, EX2041 (citing “small,” “slimness,” “thinnest” or “less bulky,” features known in the prior art and/or not specific to the claims); *see generally* POR, 72-73.

Moreover, the characteristics PO highlights were not new or unique to the claimed subject matter. Stafford already included an OBU integrating a wireless transmitter and described as being “smaller profile.” EX1004, [0045]. And, PO identified no criticality of its claimed OBU being ≤ 10 mm tall (claims 14/19), where

the '591 specification lists wide ranges of sizes, and prior art touted lower profiles. *See supra*, §III.B.1. Finally, PO does not tie features it alleges the prior art lacks (e.g., removing inserter after needle retraction, data storage, or $H1 > H2$) to praise or commercial success.

C. Alleged Long-Felt Need, Failure Unsupported

PO's "evidence" of alleged long-felt need should be given no weight because it relies on an implicit allegation that G7 practices the patent and in so doing solved an existing need in the prior art. PO compares G7 to G6, but does not establish that G7 practices the '591 or that G6 does not. The '591 did not satisfy a "long felt need."

PO makes a passing reference to alleged failure (POR, 73), but no "evidence" shows "failure."

V. CONCLUSION

All challenged claims are unpatentable as obvious.

Respectfully submitted,

Dated: October 25, 2024

By: /Andrew M. Mason/

Andrew M. Mason, Reg. No. 64,034
andrew.mason@klarquist.com
KLARQUIST SPARKMAN, LLP
Tel: 503-595-5300

Counsel for Petitioner

**CERTIFICATE OF COMPLIANCE WITH
TYPE-VOLUME LIMITATION PURSUANT TO 37 C.F.R. § 42.24**

This brief complies with the type-volume limitation of 37 C.F.R. § 42.24(a)(1)(i).

The brief has been prepared in a proportionally spaced typeface using Microsoft Word® in a 14-point Times New Roman font.

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Dated: October 25, 2024

By: /Andrew M. Mason/
Andrew M. Mason, Reg. No. 64,034
andrew.mason@klarquist.com
KLARQUIST SPARKMAN, LLP
Tel: 503-595-5300

Counsel for Petitioner

**CERTIFICATE OF SERVICE
IN COMPLIANCE WITH 37 C.F.R. §42.6(e)(4)**

The undersigned certifies that on October 25, 2024, a complete copy of the **PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE and EXHIBITS 1044-1048, 1050-1067** were served on counsel for Patent Owner via electronic mail as follows:

Peter J. McAndrews
Sandra A. Frantzen
James M. Hafertepe
Leland G. Hansen
Dorien J. Clark
Michael J. Carrozza
David Z. Petty
McAndrews, Held & Malloy, Ltd.
500 W. Madison Street, 34th Floor
Chicago, IL 60661
Email: pmcandrews@mcandrews-ip.com
sfrantzen@mcandrews-ip.com
jhafertepe@mcandrews-ip.com
lhansen@mcandrews-ip.com
dclark@mcandrews-ip.com
mcarrozza@mcandrews-ip.com
dpetty@mcandrews-ip.com
IPR2023-01409@mcandrews-ip.com

By: /Andrew M. Mason/
Andrew M. Mason, Reg. No. 64,034
andrew.mason@klarquist.com
KLARQUIST SPARKMAN, LLP
Tel: 503-595-5300

Counsel for Petitioner