

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 SUR-REPLY

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PATENT OWNER'S EXHIBITS

Exhibit No.	Description
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)

Exhibit No.	Description
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

Exhibit No.	Description
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)
2045	Transcript of the Deposition of Dr. Gary Fletcher, dated December 4, 2024.
2046-2055	NOT USED
2056	Fletcher Deposition Exhibit 2056, colorized image
2057-2061	NOTUSED
2062	Fletcher Deposition Exhibit 2062, colorized image
2063	Fletcher Deposition Exhibit 2063, colorized image

I. INTRODUCTION

On Reply, Petitioner fails to substantively respond to Abbott's POR while resorting to untimely new theories that do not salvage its Petition.

Petitioner starts with Stafford, which describes a deliberately streamlined CGM device. EX1004, [0005], [0044]-[0045]. The Stafford design is complete without a separate inserter. [0044] (A "separate sensor delivery mechanism is not necessary").¹ Ignoring Stafford's express teachings, Petitioner contends that POSAs would have added a *cannula* inserter (from Cote) to Stafford's *sensor*-comprising OBU with its own introducer needle. Petitioner's motivation arguments fail. In the end, Petitioner's combinations arise from hindsight.

Even with hindsight, Petitioner's combinations lack important limitations. As one example, all claims require that the inserter distal end be configured to be "removed from the skin...*after* automatic retraction of the sharp," ensuring stability and precision during sharp/sensor-insertion and sharp-retraction. But Cote teaches an inserter that only functions if its distal end separates from the skin *before* retraction. Petitioner's new arguments contradict Cote and if implemented would render Petitioner's Cote inserter inoperable.

For these and many other reasons, Petitioner failed to prove unpatentability.

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

II. PETITIONER RELIES ON A LENGTHY REPLY DECLARATION TO SKIRT WORD LIMITS

Petitioner proffers a new declaration from Dr. Fletcher with new exhibits and lengthy new arguments, many of which are never mentioned in the Reply or are only referenced with conclusory statements. *See, e.g.*, Rep. 9-12. Constrained by word limits, Abbott cannot respond to all the new arguments (and exhibits) buried in the declaration. They should not be considered. 37 C.F.R. §42.6(a)(3); *Cisco Systems v. C-Cation Techs.*, IPR2014-00454, Paper 12 at 10 (PTAB Aug. 29, 2014); *Consolidated Trial Practice Guide* 35-36 (Nov. 2019).

III. POSAS WOULD NOT HAVE UNDERTAKEN PETITIONER'S PROBLEMATIC COMBINATION

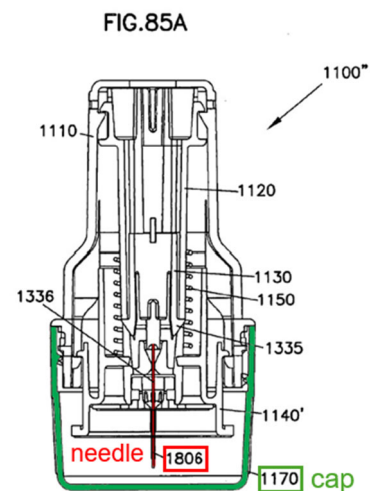
Stafford enumerates many advantages of its simplified design—all of which would be eviscerated by Petitioner's combination. POR 26-31; EX1004, [0044]-[0045]; EX2002, ¶¶128-133, 136-137. Petitioner never explains why POSAs would add a separate inserter² *when Stafford counsels against it*. Petitioner asserts that “design decisions entail...tradeoffs.” Rep. 3-4. But “[e]vidence suggesting reasons to combine cannot be viewed in a vacuum apart from evidence suggesting reasons

² Petitioner contends that Cote's inserter is somehow not “separate.” Rep. 5. But Petitioner's combinations specifically require *adding* Cote's redundant inserter to Stafford's already complete design. Pet. 28,39-40; EX2002, ¶¶134-135.

not to combine.” *Arctic Cat v. Bombardier Recreational Prods.*, 876 F.3d 1350, 1363 (Fed. Cir. 2017); *In re Wesslau*, 353 F.2d 238, 241 (CCPA 1965).

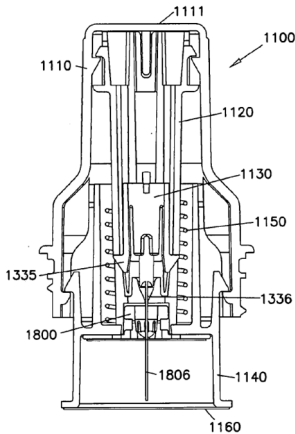
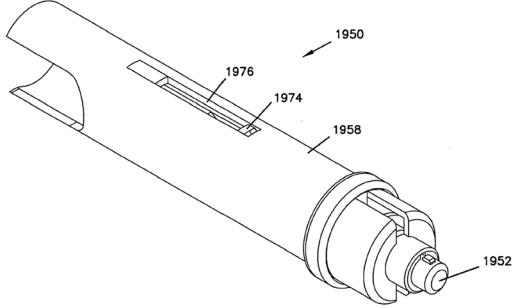
Petitioner ignores many reasons why POSAs would **not** select Cote’s cannula inserter, including to avoid tissue trauma that adversely affects CGM sensor performance. POR 34, 39; EX2002, ¶¶170-173. Petitioner’s expert admitted that POSAs would consider these factors in evaluating Petitioner’s Stafford+Cote combination, but he deemed them not relevant to obviousness because they were not “explicitly listed” in the 591 claims, which is not the law. EX2045, 70:25-72:9; *Arctic Cat*, 876 F.3d at 1359-60. Petitioner relies on generic statements about “cannula/sensor interchangeability” (Rep. 5-6), but identifies no **evidence** that POSAs knew how to use **Cote’s** cannula inserter to deploy an all-in-one CGM OBU with pre-coupled sensor and electronics.

Regarding “needle anxiety” and potential needlesticks, Petitioner summarily dismisses Stafford’s solution (the well-understood use of a guard or cap), yet never explains why such an allegedly “impractical” solution is repeatedly employed by **Cote** and others. Rep. 4; POR 29-30; EX2002, ¶¶139-143. Indeed, Cote utilizes caps and includes embodiments, like Stafford’s solution, where the needle is not shrouded by a sleeve (shown).



EX1005, Fig.85A, [0107],[0216].

Regarding “pain/discomfort” from **manual** needle retraction, Petitioner never explains why that same “concern” would not lead POSAs to select Cote’s **automatic insertion** as well. Rep. 3-5. Instead, Petitioner cherry-picks Cote’s embodiment requiring **manual** insertion (*like Stafford*) rather than Cote’s embodiments with automatic insertion/retraction. Compare EX1005, [0207] with [0220],[0236]; EX2002, ¶¶144, 155; EX2036, 71:10-15.

Cote Embodiment Selected By Petitioner (Manual Insertion, Automatic Retraction)	Cote Embodiment Ignored by Petitioner (Automatic Insertion/Retraction)
FIG. 80A 	FIG.97 

Petitioner also never explains why it selects Cote’s inserter 1100 while ignoring other inserters (including inserters in Petitioner’s cited references) that address needle anxiety, needlesticks, and discomfort associated with manual insertion (Petitioner’s alleged motivations). POR 32; EX2002, ¶¶148-153. Petitioner excuses its hindsight, contending it need only pick a “suitable” option—not the

“best” one. Rep. 6. But the question is not whether other options are better, but rather why POSAs would ignore those options and instead select *one* particular *cannula* inserter with *manual insertion*. POR 31-33; EX2002, ¶¶147-156. Hindsight is the only explanation.

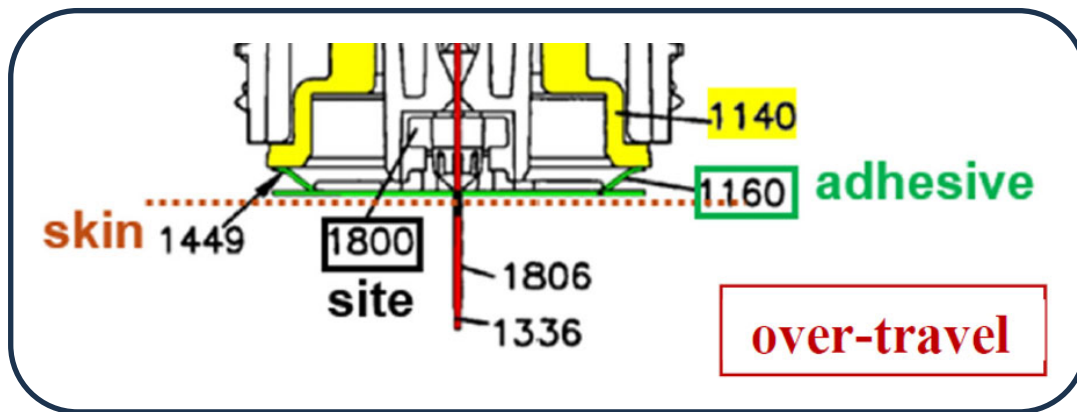
IV. THERE CAN BE NO OBVIOUSNESS WHEN LIMITATIONS ARE MISSING FROM THE ART

A. Inserter “Distal End” Limitations (All Claims)

All claims require that the distal end of the inserter (1) “is *configured* to be positioned on the skin...before advancement” of the OBU/sharp and then (2) “*further configured* to be removed from the skin of the user *after* automatic retraction of the sharp from within the user.” So configured, the inserter distal end is positioned on the skin before OBU/sharp advancement and then removed *from that positioning after* automatic sharp retraction, as both experts agreed. It is undisputed that POSAs would understand that this feature ensures that the inserter is stable during insertion-retraction, thereby avoiding damage to the fragile sensor, minimizing tissue trauma, and providing accurate sensor placement. POR 34,39; EX2002, ¶¶170-173,194.

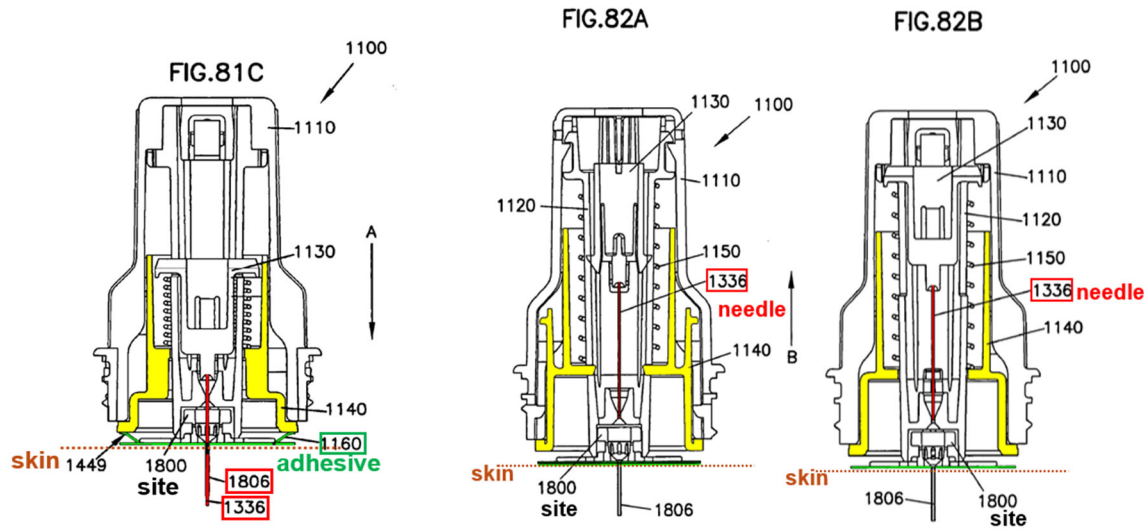
Petitioner's main Reply argument is that the distal end of Cote's inserter (distal end of sleeve 1140) is only removed from the skin *after* needle retraction. Rep. 7-10 (“Cote's inserter is removed only after retraction, not before”); EX1045, ¶¶32,37,47,65,67. Petitioner is wrong.

There is no dispute that one fundamental purpose of Cote's "over-travel" feature—as depicted in Figure 81C—is to "assure[] that the adhesive portion 1160 is properly sheared away from the [bottom surface] of the sleeve 1140" *before* needle retraction:



EX1005, Fig.81C, [0209],[0101]; EX2002, ¶¶89-91,184-185. As the POR explained, this shearing would be *impossible* if the adhesive remained trapped between the sleeve and the skin. POR 15-16,37; EX1044, 114:13-115:23 (removal from skin required to shear adhesive). This should be dispositive and is not disputed in the Reply.

Further, Cote's figures plainly show a gap between the sleeve and infusion site 1800, both before (Figure 81C) and during (Figures 82A-B) needle retraction:



Because site 1800 is on the skin in these figures, *Cote's inserter sleeve is not*. EX1005, [0209]-[0211]; EX2002, ¶¶89-91, 184-185, 188-189.

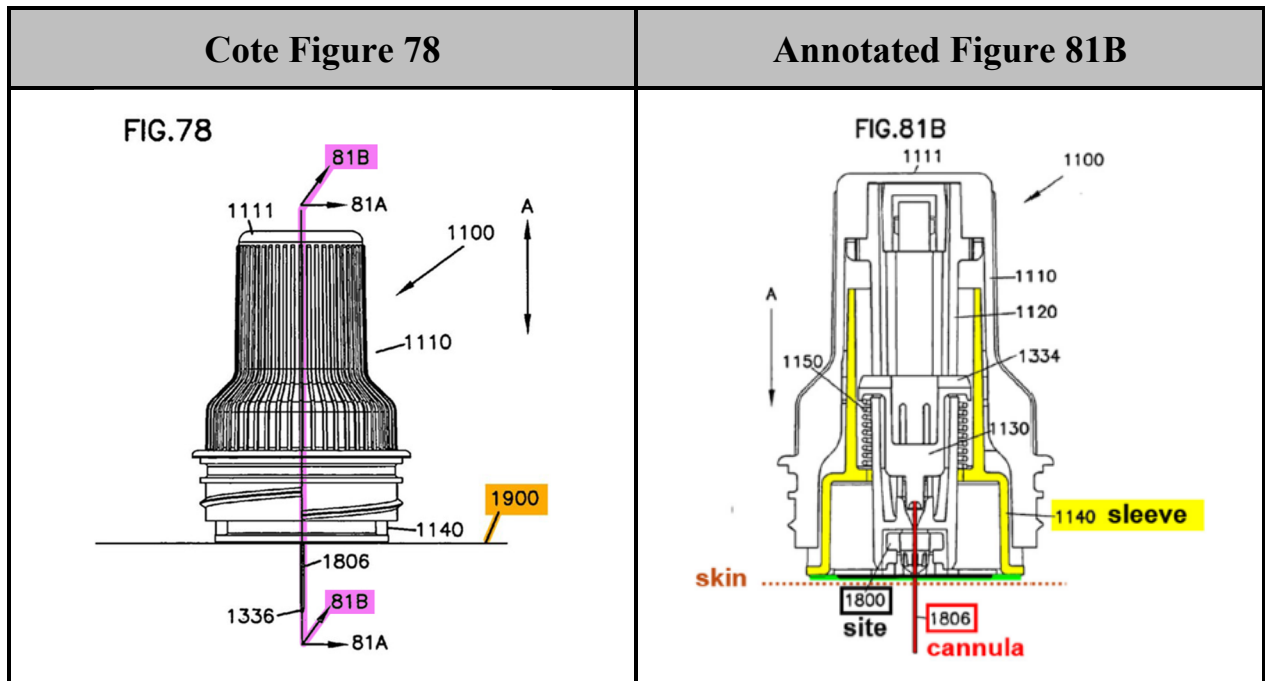
1. Petitioner's New Skin Argument

Trying to explain away these figures, Petitioner now argues that the skin would deform to remain in contact with the sleeve end. Petitioner's theory cannot be correct. Even assuming the skin would deform to some extent, the adhesive *could not shear off* if it were sandwiched between the sleeve and the skin.

a) Nothing In Cote Supports Petitioner's Skin Deformation Argument

Petitioner advances its new argument by first criticizing Abbott's depiction of the skin in annotated Figures 80A-81C. Rep. 8-9. But Abbott's annotations are consistent with Cote. Petitioner's annotations are not. For example, in Figure 78, the line depicting the skin 1900 is flat. Figure 81B is a cross-section of Figure 78.

EX1005, [0099]-[0100]; EX2045, 107:11-23. Accordingly, Abbott annotated Figure 81B with a flat skin line, just like Cote in corresponding Figure 78. POR 14, 36.



The same applies to Figure 77 (flat skin line) and corresponding Figure 80B (annotated with the same flat reference line at POR 14). EX1005, [0097]-[0098]; EX2045, 106:9-15, 108:13-17.

Importantly, flat skin or not, Figures 82A-B show during needle retraction the inserter sleeve is separated from the adhesive, which is on the skin—not contacting the skin as Petitioner now contends. EX2002, ¶¶184-189, 197-200. And, consistent with Cote's plain figures, Cote states only that the site and cannula—not the sleeve—are held on the skin in Figures 82A-B. [0211]. Additionally, Cote states that, before needle retraction, site 1800 travels “*beyond the second end 1442 of the sleeve 1140*

as shown in FIG. 81C” (*i.e.*, “over-travel”). [0209]. If the site is distal of the sleeve, and the site is on the skin, then the sleeve is not on the skin. Nothing in Cote teaches or suggests the sleeve would remain on the skin, whether or not the skin deformed.

b) Dr. Fletcher's New Opinions Are Unfounded And Unreliable

Petitioner relies on Dr. Fletcher who in turn relies on a commercial product (Cleo90), a different Cote patent (Cote 691) allegedly covering Cleo90, and two articles about technology for testing skin deformation. Rep. 8-11; EX1045, ¶¶49-50, 57-60.

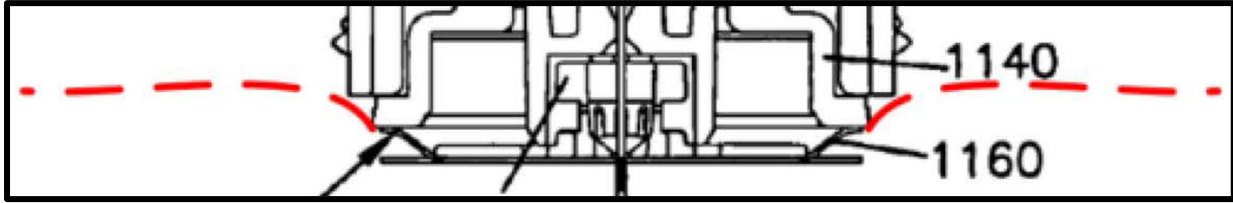
But Dr. Fletcher never analyzed Cleo90 using that technology (or any other technology). EX2045, 11:16-13:6, 20:3-21:17, 29:17-30:14. He does not know whether or to what extent Cleo90 functions like Cote's inserter 1100. 13:2-6. He never compared any Cote 691 claims to Cleo90 or Cote's inserter 1100. 16:2-19. Indeed, he did not understand the Cote 691 claims on which he purports to rely. 84:6-86:1 (testifying he has no understanding of 691 claim terms like “retracted position” and “extended position”).³

³ Petitioner's “Cleo90” evidence should be rejected as untimely and unauthenticated. *Henny Penny v. Frymaster*, 938 F.3d 1324, 1330-31 (Fed. Cir. 2019); *Neste Oil Oyj v. Reg Synthetic Fuels*, IPR2013-00578, Paper 53 at 4 (PTAB Mar. 12, 2015); *First Solar v. Rovshan Sade*, IPR2023-00827, Paper 13 at 18 (PTAB Nov. 16, 2023).

The extent of Dr. Fletcher's analysis was "playing" with an unknown version of Cleo90, which requires no expertise. EX2045, 11:21-12:15. His opinions about skin deformation, which are the basis for Petitioner's new argument, are unfounded and unreliable and therefore not entitled to any weight. *Xerox v. Bytemark*, IPR2022-00624, Paper 9 at 15-16 (PTAB Aug. 24, 2022) (precedential); *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993).

Dr. Fletcher's skin-deformation opinions are the epitome of hindsight using the patent claims as a template to form his opinions. Even assuming the skin would deform to some extent, he articulated no scientific basis for his opinion that the skin would deform to touch (barely) the edge of the sleeve (to arbitrarily satisfy the claims), as illustrated below (excerpted from figure in Fletcher's second declaration). EX1045, ¶52; EX2063; EX2045, 29:23-30:3, 116:7-14.

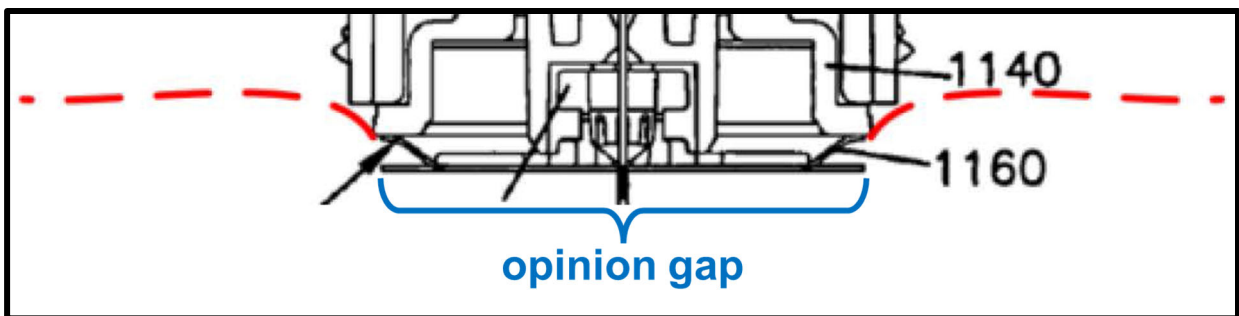
Moreover, how a **product** operates has no bearing on what a **reference** discloses. *Shenzhen Buxiang Network Tech. v. Sun Pleasure*, IPR2021-00080, Paper 43 at 25-26 (PTAB Apr. 11, 2022) (existence of product features does not mean reference "has to disclose the same structure"). And "Petitioner cannot combine the teachings of a printed publication with ... an actual system...." *Red Hat v. Elec. & Telecomm. Res. Inst.*, IPR2019-00465, Paper 15 at 23 (PTAB June 13, 2019).



And Dr. Fletcher articulated no scientific basis why the skin would not deform in some other way—without contacting the sleeve as depicted below. *Id.*



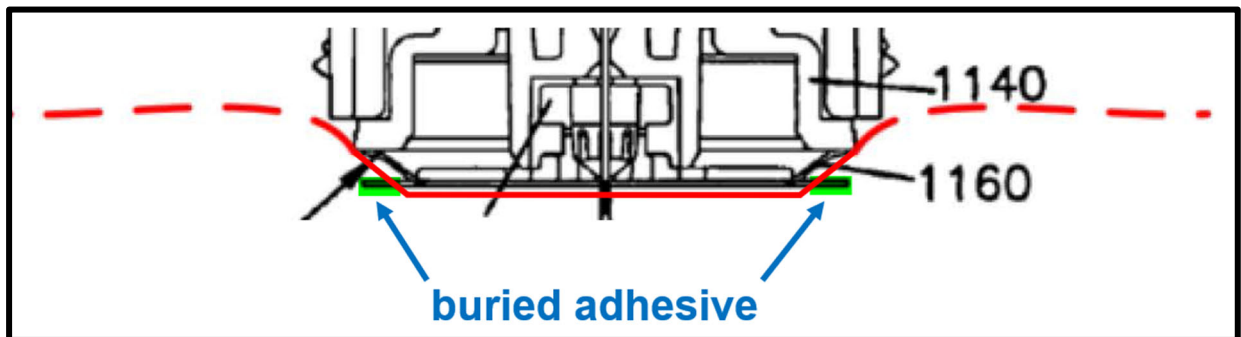
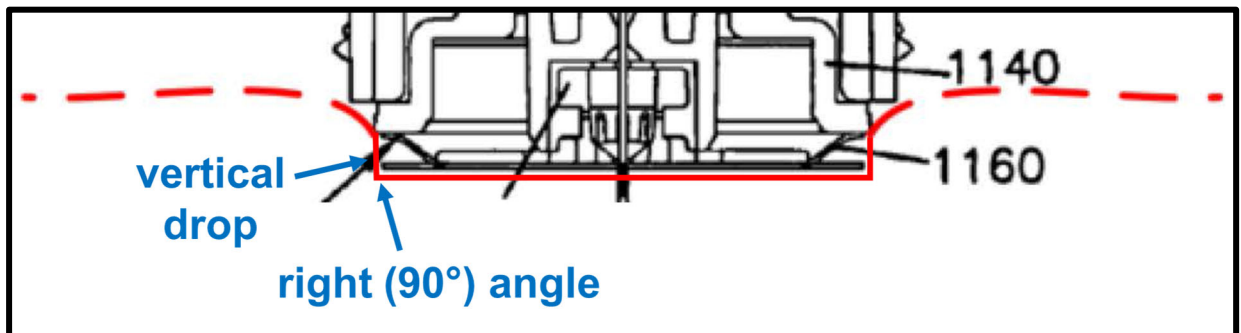
Perhaps most critically, Dr. Fletcher concedes unexplained gaps in his skin-deformation opinions. He was cross-examined about a figure illustrating his opinion. Rep. 11; EX2045, 109:18-114:6; EX2062. Dr. Fletcher (and Petitioner's counsel) insisted he only has an opinion about skin deformation on either side of the device, not under it. EX2045, 110:12-114:6.



Further, Dr. Fletcher testified that, for Cote inserter 1100 in Figure 81C (depicting over-travel), he had no understanding of the very regions where he contends the skin would touch the sleeve during over-travel. EX2045, 91:1-93:8;

EX2056. But Figure 81C is clear. The layers of adhesive portion 1160 are separating as they shear away from sleeve end 1442 during over-travel. EX1005, [0190] (describing multi-layer adhesive portion), [0209] (describing adhesive shearing during over-travel).

Why the unexplained gaps in Dr. Fletcher's understanding of alleged skin-deformation and adhesive-shearing during over-travel? If the skin deformed as he says (barely touching the sleeve end), the skin in the regions of Figure 81C that he does not understand would have to deform at impossible angles (e.g., vertical drop followed by a right angle) to pass under the adhesive, or some of the adhesive would be buried under the skin.



Constrained by using the claims as a template for his opinions, Dr. Fletcher took a position that results in absurdities he cannot explain, despite his alleged expertise.

2. Petitioner's New "Optional" Argument

Petitioner raises another new argument—Cote's "over-travel" is "optional." Rep. 10. But Petitioner and its expert previously admitted the opposite, acknowledging that over-travel was *necessary* before needle retraction for the Cote embodiment that it selected for the Petition. Pet. 53 n.9 (OBU "*must* travel beyond the distal end of Cote's inserter to enable automatic [sharp] retraction"); EX1003, ¶110 n.6; EX1045, ¶107 (Cote inserter 1100 is "the one relied upon"). Petitioner cannot reverse course on Reply. Moreover, Petitioner never explains how the adhesive would shear off or how the needle would retract without this "preferred" feature.

3. Petitioner's New Claim Construction

Petitioner concludes by raising a new conclusory claim construction argument without addressing Abbott's POR. Petitioner argues that "the claims do not require the distal end of the inserter to remain on the skin at all times prior to needle retraction." Rep. 11. Petitioner's new argument is wrong and improper.⁴

⁴ A new claim construction on Reply is improper. *Cisco v. Oyster Optics*, IPR2017-01719, Paper 31 at 24-25 (PTAB Jan. 24, 2019) ("[P]etitioner providing its

The claims require that the inserter distal end is (a) “configured to be positioned on the skin...before advancement” of the OBU/sharp and (b) “further configured to be removed from the skin...after” automatic sharp retraction. So configured, the inserter distal end is positioned on the skin before OBU/sharp advancement and then removed from *that positioning* after automatic sharp retraction.

As discussed in the POR, this is plain at least because:

- the claim language is clear (e.g., the “configured to” and “further configured to” clauses);
- the “remov[al] from the skin” clause must refer to the earlier “position[ing] on the skin” clause—the original positioning on the skin is the antecedent basis for the later removal;
- the above-described operation of the claimed inserter comports with the embodiments depicted and described in the 591 Patent;
- the 591 Patent nowhere contemplates removing the inserter distal end before or during automatic sharp retraction;

explanation based on its claim construction, for the first time, in its Reply is improper and not acceptable.”).

- construing the claims to allow for removal of the inserter distal end *before* needle retraction would eviscerate the advantages of the claimed configuration; and
- construing the claims to allow for removal of the distal end *before* needle retraction—when the claims require “*after*”—would be contrary to precedent.

POR 34, 39-41; EX2002, ¶¶166-173.

Notably, Petitioner's expert agreed with Abbott's expert on this issue:

Q: Under claim one of the 591 patent, the distal end of the inserter is configured to be positioned on the skin before the advancement of the OBU and the sharp; is that fair?

A: Yes.

Q: And then under claim one of the 591 patent, the distal end of the inserter is further configured to be removed *from that positioning* on the skin *after* automatic retraction of the sharp from within the user?

A: *That's the way that that claim element reads, yes.*

EX2036, 95:15-96:2.

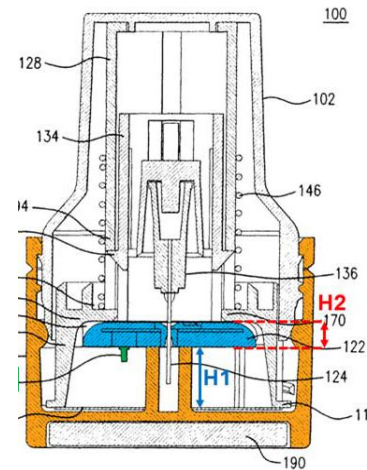
On Reply, Petitioner does not refute any of the intrinsic and extrinsic evidence, nor does Petitioner refute Abbott's cited law. And Petitioner does not dispute that important advantages, including stabilizing the sensor/sharp for accurate placement and minimizing tissue trauma, arise from maintaining the distal inserter

end on the skin throughout the insertion-retraction process. EX2002, ¶¶194,170-173,204-206; EX2036, 116:15-117:7. Yet, Petitioner's new construction—that allows the distal end to be removed from the skin *before and during* needle retraction—would eviscerate those advantages and render the limitation meaningless. *KEYnetik v. Samsung*, 837 F. App'x 786, 792-93 (Fed. Cir. 2020); *Wireless Protocol Innovations, v. TCT Mobile*, 771 F. App'x 1012, 1016-18 (Fed. Cir. 2019); POR. 41.

Indeed, in applying its new claim construction, Petitioner relies on Cote's "fully retracted state," which involves retraction of the housing and the cylinder hub (not the needle), and final removal and discarding of the inserter. Rep. 11-12. But, as discussed, neither disclosure is connected to the removal of the distal end relative to the timing of *needle retraction* (as claimed) and thus they have no bearing on the limitation. POR 40-41; EX2002, ¶¶203, 207-208.

B. “Housing-Distance” Limitation (Claims 3-17, 19-30)

Most claims effectively recite that the distance that the sensor-comprising OBU travels within the inserter from the proximal to distal position (H1) is greater than the OBU housing height (H2). The POR explained how Petitioner never proved that *any* art—much less the claimed combination—teaches this limitation. POR 45-47, 51-52. Petitioner's flawed and untimely new theories on Reply cannot change that dispositive fact.



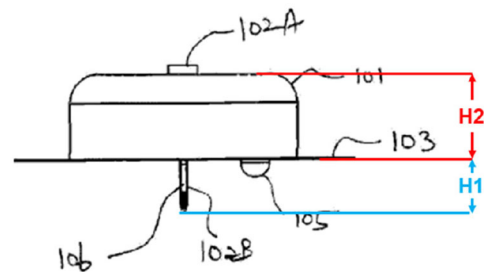
1. Petitioner's Failure To Address *Stafford's* OBU

Petitioner concedes that “citation of two different sets of...teachings...for the same [limitation] represents a *fatal inconsistency*.” *FedEx v. Intell. Ventures II*, IPR2017-00743, Paper 7 at 13-14 (PTAB July 25, 2017). Yet, as explained, while Petitioner relied on *Stafford's* OBU for the “housing” in the housing limitations, Petitioner relied on *Cote's* site/cannula for the “housing” in the housing-distance limitation. POR 45-47; Pet. 52-54.

On Reply, Petitioner pretends that it did not make this “fatal” error, contending it argued that POSAs “*would have configured* the travel distance of *Stafford's* [OBU]” as claimed. Rep. 13-14. But that is an obviousness *argument*—not a statement that *Stafford* discloses the limitation.

Improperly citing pages of its expert declaration, Petitioner newly argues that it would be “obvious to...try” modifying Stafford’s OBU so it is “scaled to fit” Cote’s inserter, depicting miniaturized Stafford OBUs next to Hasted and Cote inserters. Rep. 15-16,18. But, beyond those new simplistic comparisons, the Reply never explains how to implement its new combination of unrelated references with uncorrelated dimensions. *Id.*

In any case, Petitioner’s new substitution still does not satisfy the limitation because $H1 < H2$ in Stafford (POR 46-47; EX2002, ¶¶223-224), and the Petition *never argued* the contrary. Pet. 52-58. Again, the relative dimensions of Cote’s *infusion site/cannula* (where the cannula is relatively long and the infusion site is relatively thin) still have no applicability to Stafford’s *CGM OBU/needle*. POR 46-47; EX2002, ¶222.



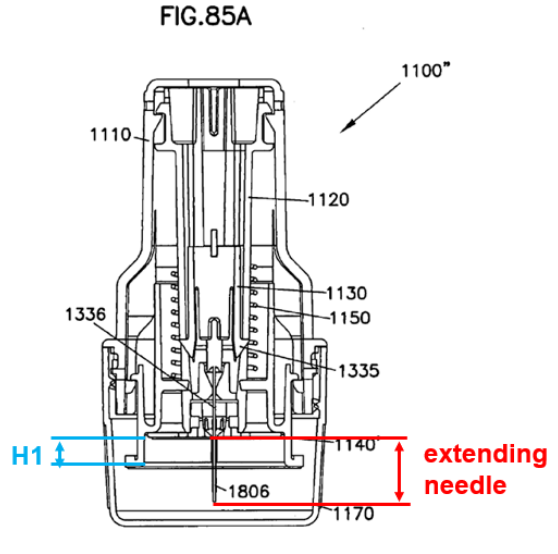
2. Petitioner Undermines Its Stafford+Cote Combination

To recreate the limitation, Petitioner next argues for yet another modification. Petitioner contends that POSAs would move Stafford’s sensor-comprising needle proximally from the inserter’s end by some unspecified distance (identifying no CGM reference that does so). Petitioner argues that POSAs “knew that H1 [the OBU travel distance] preferably should be greater than the OBU’s sharp/sensor length”

because of the “risk[] [of] premature/inadvertent needlesticks” and needle “anxiety.” Rep. 14,17.⁵ But Petitioner’s argument undermines its core obviousness position.

Petitioner’s obviousness position hinges on its contention that POSAs would combine Stafford’s OBU/introducer *with Cote’s inserter 1100* to prevent “needlesticks” and reduce “anxiety.” Pet. 29-30. Thus, for the housing-distance limitation, Petitioner contends that inserter 1100 is inadequate to avoid anxiety and needlesticks and must be modified. That is because Cote discloses *neither* (1) H1 as “greater than the OBU’s sharp/sensor length” *or* (2) the needle moved proximally away from the end of the inserter. To the contrary, Cote depicts *the opposite*: (1) H1 is *less than* the sharp length; and (2) the needle is flush with (or extends past) the distal end:

⁵ Petitioner contends that Abbott “misstates” the limitation because “H1 does *not* measure the ‘portion of Stafford’s sharp/sensor extending from’” its OBU. Rep. 14 (original emphasis). But it was *Petitioner* that *originally* argued it was obvious “to implement the sensor with an *in vivo* length longer than the [OBU] is tall.” Pet. 56.



POR 48-49; EX1005, [0215], Figs. 80A,85A. If Petitioner's Stafford+Cote combination would solve the needlestick/anxiety issues—as Petitioner repeatedly asserts, there would be no reason for POSAs to further adjust the location of the needle.

3. Petitioner's New Insertion Depth Arguments

Petitioner now argues that $H1 > H2$ can somehow be mathematically derived from allegedly-known sensor “insertion depths” (purportedly related to $H1$) and housing heights ($H2$). Rep. 17. But Petitioner’s “calculations” are nonsensical. Petitioner *mixes and matches* arbitrarily-selected insertion depths and housing heights in *unrelated* CGMs (none of which use an inserter to deliver a sensor-comprising OBU) while ignoring unfavorable data. *Id.*, citing EX1045, ¶¶99-101. For example, relying on Abbott’s Navigator measurements alone, $H1$ (5 mm insertion) *is less than* $H2$ (11 mm OBU height). EX1045, ¶99. And, while

Petitioner's Reply relies on insertion depths **>8mm** (Rep. 17) to recreate the limitation, its cited references *prefer* shallower depths (<7 mm) that are *less than* the preferred OBU heights ($H1 < H2$)—thus contradicting its arguments. EX1008, 29:7-9; EX1014, [0069]; EX1012, [0290]; EX1013, [0438]; EX1015, 29:24-26; EX1016, 29:61-62.

4. Petitioner Identified No On-Point Disclosure Of The Limitation

Petitioner still identifies *no reference* with the claimed limitation, e.g., where an *OBU comprising a sensor* travels from a proximal to distal position a distance greater than the OBU housing height. POR 51-52. All “examples” either: (1) do not involve inserters to deliver *any* OBU; or (2) involve infusion cannulas (with differently-dimensioned sites/cannulas and without many components of the claimed CGM OBU) that lack sensor sensitivity issues. POR 48, 50-52; EX2002, ¶¶230-234, 237,240-241. The Reply implies Hasted Figure 1 discloses the limitation. Rep. 15. But that figure depicts a “port-device” and “carrier body...for a medical device to be inserted”—not an inserter delivering an OBU with a fragile and sensitive sensor. EX1011, 4:15-23. That Hasted generically references sensors is immaterial.

The lack of disclosure in the art is dispositive, particularly given the challenges surrounding sensor insertion. Common knowledge “cannot be used as a wholesale substitute for reasoned analysis and evidentiary support, especially when

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

Moreover, Petitioner still provides no motivation to arbitrarily redesign *Stafford's* OBU, extend its sharp, or adjust Stafford's housing location proximally. Such modifications would increase the assembly's profile, size, materials, and cost (in contravention of Stafford's directive). POR 50; EX2002, ¶¶226-228,241. And Petitioner still never explains how such modifications would necessarily result in the *claimed* distance ($H1 > H2$). POR 49.

Faced with this failure of proof, Petitioner concludes with its oft-repeated strategy—ignore the limitation. Rep. 19-20. It was *Petitioner's* “burden of proving that the claimed limitations had *no effect* on the performance,” and Petitioner's own “obviousness” arguments prove the opposite. *Waldemark Link v. Lima Corporate SpA*, IPR2020-00258, Paper 7 at 24 (PTAB June 23, 2020). Petitioner's attempt to dismiss the identified advantages is misguided. Rep. 19; EX2002, ¶¶213-215, 242-243. The specification is not required to describe advantages, and advantages known to POSAs must be considered. *In re Chu*, 66 F.3d 292, 298-299 (Fed. Cir. 1995).

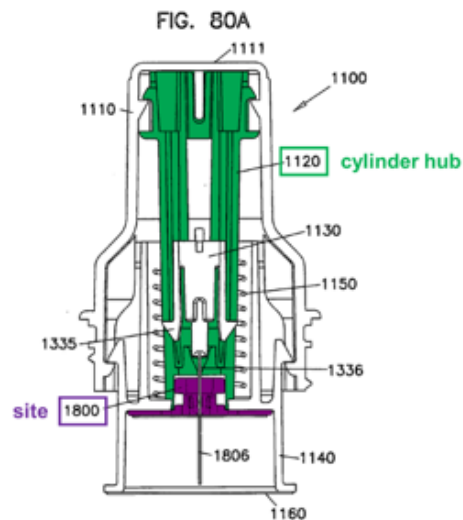
C. “Second Opening” Of OBU Housing Top Surface (Claims 18, 21-30)

Petitioner's primary Petition argument was that POSAs would add a second top-surface opening to secure the OBU to the inserter. Pet. 76-77. Petitioner now

abandons that argument, acknowledging that Cote's design already secures the OBU. Rep. 21 ("Cote's diaphragm/needle friction fit holds the OBU within the inserter"); EX1045, ¶129.

Instead, Petitioner's Reply expands on its cursory secondary argument that POSAs would add the second opening to prevent OBU rotation/tilting. This argument likewise fails.

First, as demonstrated, Cote already prevents rotation/tilting because its cylinder hub pinches opposite sides of the octagon-shaped site top:



POR 59. Cote consistently depicts this in figures cut along the same cross-section (79A, 80A, 81A, 82A). Petitioner's only Reply response—without explanation—is that Abbott's contention "is unsupported by Cote's disclosure." Rep. 22. That non-response should be dispositive.

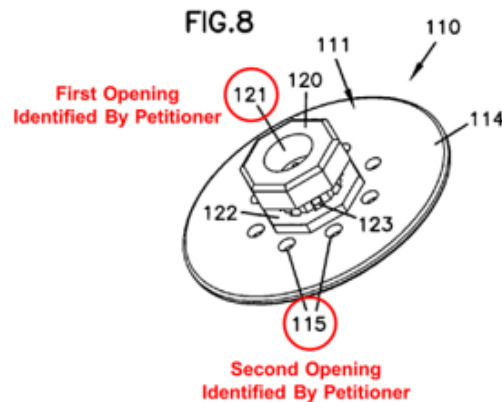
Instead of substantively responding in its Reply, Petitioner cites multiple paragraphs of its Reply declaration. Setting that tactic aside, Petitioner's expert is wrong. Dr. Fletcher hedgingly states that Cote's cylinder hub "does not necessarily frictionally engage its OBU," but cites a figure cut along a **different** cross-section. Ex. 1045, ¶131 (Figure 80B). Notably, Petitioner never contests that pinching at some OBU locations would prevent rotation/tilting. And beyond Cote's pinching, Cote's needle-septum friction fit would inhibit rotation/tilting. EX1005, [0205]; EX1003, ¶¶54-56; EX2002, ¶¶280-281.

Second, Petitioner argues its combination would differ because Stafford's OBU is round. Rep. 22. But it is Petitioner's burden to show how Cote could/would be modified. Petitioner did not. Even assuming a round OBU, POSAs logically would use Cote's **existing** approaches that prevent rotation/tilting: needle-septum friction fit and fitting the OBU within Cote's cylinder hub such that the hub pinches around the OBU. Petitioner nowhere explains why POSAs would unnecessarily adopt a new, more complex approach utilizing a second top-surface opening (presumably with a new complementary protrusion on some unidentified component).

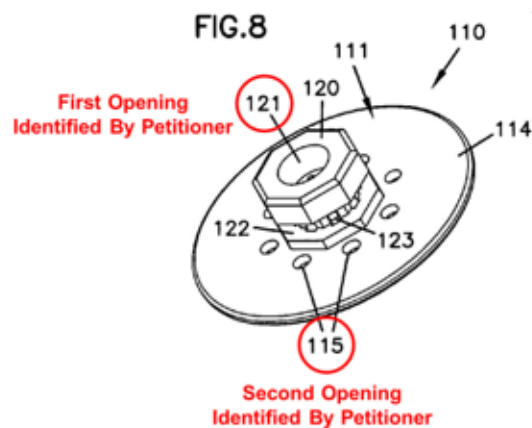
Third, Petitioner cites no reference satisfying the 591 claims where the same OBU-housing-top surface comprises two openings where (1) the sharp extends through the first opening and (2) the second opening has a smaller maximum width

than the first (let alone where the second opening prevents rotation/tilting). Indeed, Petitioner's "second opening" references (Cote, Brenneman, Turner) contradict Petitioner's arguments.

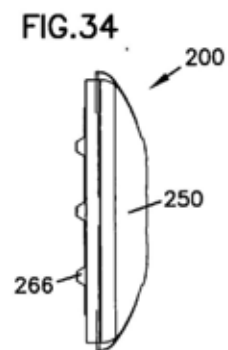
As for Cote, Petitioner's identified first/second openings are not on the same surface:



Pet. 79. Further, Cote's "second opening" is on a *lower surface* of *the interior* of Cote's infusion device—not the OBU housing top surface:



Bottom Portion Of
Cote's Infusion Device



Top Portion Of
Cote's Infusion Device

Lastly, Cote's "second opening" does not prevent rotation/tilting between the OBU and inserter (Petitioner's purported motivation).

As for Brenneman, its equal-width "openings" are for securing the OBU to the inserter, not preventing OBU rotation/tilting. EX1040, [0042]. Indeed, they *must allow for rotation* for Brenneman to work. Specifically, Brenneman's "openings" 60a/b are in the "reusable assembly 50" part of the OBU:

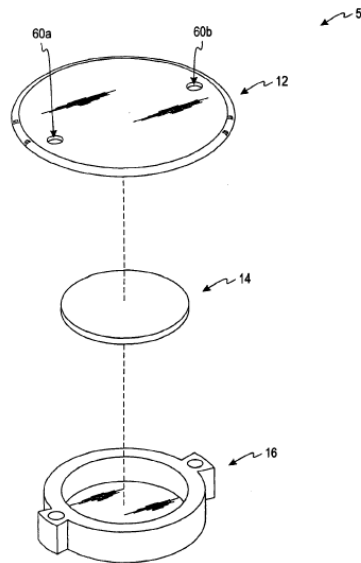


Fig. 5a

Per Brenneman, "assembly [5]0...including the cover 12...*are rotated*" upon inserter activation. [0044]. Petitioner alleges that Brenneman's openings "prevent inadvertent rotation" (Rep. 22), but Brenneman utilizes "safety button 116"—not the openings—to prevent inadvertent activation. EX1040, [0045]. Additionally, Brenneman's sharp never extends through either opening as claimed. Lastly, as

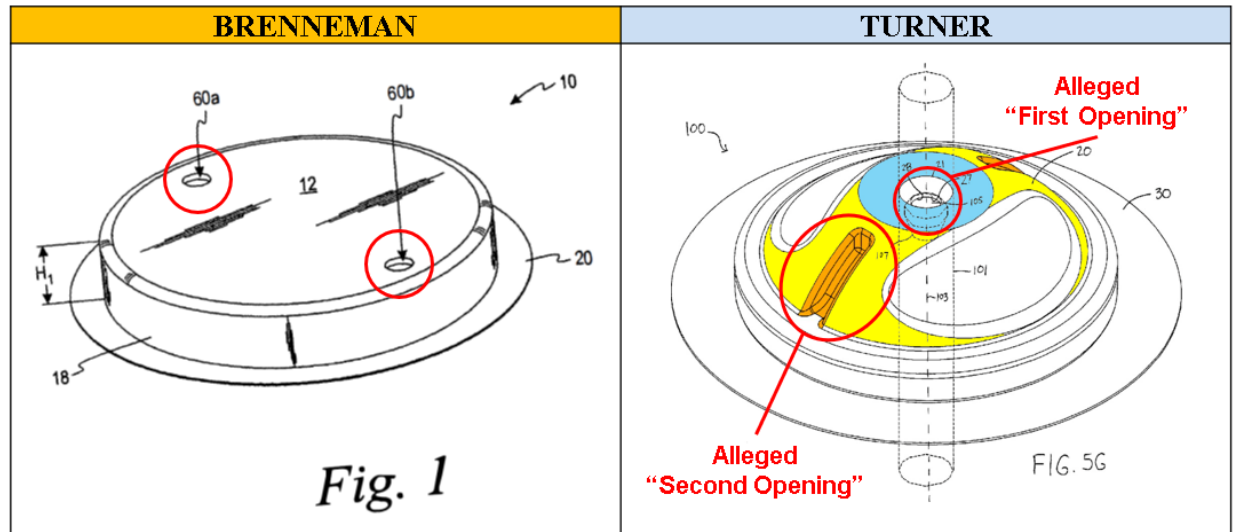
explained, the fact that Petitioner cites Brenneman only for a “second opening”—rather than its complete CGM system—confirms hindsight. POR 58-59; EX2002, ¶¶277-278.

As for Turner, it's not part of any ground and the Petition correspondingly provided no Turner combination analysis. Moreover, Turner cannot override the contradictory teachings of expressly-cited Brenneman. Further, Turner's optional design couldn't work with Cote. EX2002, ¶¶283-284. Finally, looking to Turner makes no sense given Dr. Fletcher's admission that Cote's existing design already “maintains the positioning of the site relative to the needle.” EX1003, ¶55.

Fourth, Petitioner newly argues that the “second opening” claims generally (not just the “maximum width” sub-parts) have “no patentable weight” because the specification text does not ascribe utility to the second opening. Rep. 23-24. This argument is untimely and legally incorrect. *Chu*, 66 F.3d at 299. For example, limitations can be based on figures alone. *In re Wolfensperger*, 302 F.2d 950, 955 (CCPA 1962). Nevertheless, the second opening has utility (manufacturing alignment), as Abbott explained and the Reply does not contest. POR 56; EX2002, ¶265 (Figs. 22-23); EX1001, 18:8-16. Indeed, Petitioner's expert admits that POSAs “understood that alignment...could be useful.” EX1045, ¶126.

Finally, Petitioner still never substantively addresses the requirement that the “second opening” have a smaller maximum width than the first. That's because

Petitioner's art with openings on upper surfaces teaches otherwise (indeed, Turner teaches the opposite which the Reply does not contest):



POR 61. Petitioner merely argues “obvious design choice.” Rep. 23. But as explained, POSAs would not add a second opening in the first place. POR 57. Moreover, it’s hardly an obvious choice when Petitioner cites no art that teaches it (while citing art teaching the opposite). The Board rejected Petitioner’s “obvious-design-choice” argument in IPR2023-01396 for the same reason. Paper 15, 6-7, n.3.

D. OBU Housing Height Profile (Claims 14, 19-30)

Claims 14 and 19-30 require the OBU housing to have “a height profile...less than...10 millimeters.” The limitation is not in Stafford or Cote. Petitioner again relies on Say’s multi-part system, contending that an “assembled” and “all-in-one” OBU are the same. Rep. 12. But Petitioner again ignores the challenges in designing the claimed ultra-low profile, “all-in-one” OBU. EX2002, ¶¶254-256.

Independent claim 19 requires the ultra low-profile OBU to include sensor electronics (“processor,” “power source,” “analog interface,” “data storage unit,” “wireless...circuitry”) coupled with the sensor. Petitioner’s generic assertions that it was obvious to construct the claimed low-profile OBU is the epitome of hindsight given that Petitioner failed to rely on *any* art that achieved this innovation. *Himpp*, 751 F.3d at 1365-66. There is a “clear distinction...between a patent challenger’s burden to prove that [POSAs were] motivated...and the *additional* requirement that...[POSAs] would...successfully achiev[e] the...invention...” *Eli Lilly v. Teva Pharms.*, 8 F.4th 1331, 1344 (Fed. Cir. 2021).

E. OBU With Data Storage (Claims 4, 19-30)

Petitioner concedes that Stafford does not expressly disclose the “data storage unit.” Rep. 20. The Petition originally relied on Say for obviousness (Pet. 60), but Say does not describe an OBU housing with the *claimed* sensor electronics (including the data storage unit) pre-coupled to a sensor as claimed. POR 52; EX2002, ¶¶247-249.

Petitioner now cites a new reference (Jin) and eight others to fill the gaps, but it is far too late to raise *nine* new prior art references. Rep. 20; *Koninklijke Philips v. Google*, 948 F.3d 1330, 1336-37 (Fed. Cir. 2020). Regardless, none of the new references discloses an OBU housing with the *claimed* sensor electronics pre-coupled to a sensor. EX1057, Fig. 1, [0031]; EX1012-1013, Fig.1; EX1014&1021,

Figs. 8,12,16; EX1015, Figs. 14,17,33; EX1016, Figs. 14,17; EX1030, Fig. 28; EX1040, [0053]. Generic assertions of “knowledge” are not sufficient. *Himpp*, 751 F.3d at 1365-66.

F. Sleep/Idle/Activation Claims (Claims 7-8, 25-26)

In two paragraphs, Petitioner repeats its Say-based arguments without addressing the POR and resorts to new evidence (EX1057) and related argument. Rep. 24-25.

Petitioner admits Say is directed only to “two-part” OBUs where the user manually connects the electronics to the sensor after sensor insertion. *Id.* 24. Cropping language out of context, Petitioner suggests Say teaches how to activate electronics in an all-in-one OBU. *Id.* 24-25. Not true. Read fully, Say clearly states “activation” is achieved *when the user manually connects the electronics* (e.g., causing a change in resistance across contacts). EX1008, 31:47-53 (describing activation “upon mating the [electronics] with a mounting unit”), 36:34-39 (same). As explained, such teachings couldn’t work with the 591 claims because the sensor and electronics are pre-coupled within the inserter. POR 63-64. Again, it’s one thing for POSAs to “want” to activate an all-in-one OBU upon deployment, *but another to teach how*. *Id.* 64; *Eli*, 8 F.4th at 1344. Say does not (unlike 591’s extensive teachings). EX1001, Figs. 32-43, 19:41-22:35.

In a conclusory sentence, Petitioner argues that activating an all-in-one OBU was “well-known.” Rep. 25. Petitioner again cites Pesach—directed to improving a drug’s pharmacokinetic profile—which is not part of any ground. As Abbott previously explained—and unrefuted on Reply—Pesach is irrelevant. POR 65.

G. “Sensor Hub” Claims (Claims 15 and 28)

On Reply, Petitioner merely repeats its Petition and does not contest the following dispositive facts raised in the POR:

- Petitioner’s “sensor hub” arguments are based on Say where *the user* must manually connect the electronics and sensor;
- Accordingly, Say understandably teaches a feature to help ensure *the user* properly makes that connection;
- Even in that *user-dependent* context, Say teaches that its alleged “sensor hub” is optional;
- In Stafford, the sensor-electronics connection is made *by the manufacturer*. Thus, there is no need to add an optional feature to ensure a proper *user* connection, especially since Stafford emphasizes reducing components, cost, complexity, waste, etc.

POR 66; Rep. 25. Petitioner’s art confirms Abbott’s position. As explained, based on Petitioner’s arguments, Petitioner cites two references where the manufacturer pre-connects the sensor/electronics (Stafford and Shah) and, tellingly, Petitioner never alleges either utilizes a sensor hub. POR 67.

Petitioner rotely asserts that the limitation was “well-known.” Rep. 25. Petitioner cites Bickoff, which Abbott showed was inapposite (and the Reply does not dispute). POR 67-68. Given Bickoff’s deficiencies, Petitioner resorts to two new references (EX1013, EX1021) for its assertion. Rep. 25. They should be disregarded. And neither discloses using a sensor hub where the manufacturer pre-couples the sensor and electronics.

V. OBJECTIVE INDICIA

Regarding praise and commercial success, Petitioner argues that nexus is not proved. But Petitioner ignores that “there is a presumption of nexus...when the...objective evidence is tied to a specific product and that product is the invention...claimed....” *WBIP v. Kohler*, 829 F.3d 1317, 1329 (Fed. Cir. 2016). It is undisputed that FreeStyle Libre is covered by the 591 Patent. Abbott provided significant *evidence* of praise and commercial success and explained how it is directly tied to patented features. POR 70-78; EX2002, ¶¶372, 376-378, 381-396, 413-431.

A “patent challenger cannot successfully rebut the presumption with argument alone—it must present evidence.” *WBIP*, 829 F.3d at 1329. Petitioner did not dispute Abbott’s evidence, but simply *argued* that there are “critical features” of Libre not claimed. Rep. 27-28. Attorney argument without evidence is insufficient. *WBIP*, *supra*. Petitioner likewise argues Libre practices additional patents (Rep. 28), but

without explanation, that cannot defeat nexus. *Apple v. ITC*, 725 F.3d 1356, 1365-66 (Fed. Cir. 2013).

Petitioner finally contends that nexus must be tied to “features...the prior art lacks.” Rep. 29-30. But “it is the claimed combination *as a whole* that serves as a nexus for the objective evidence; proof of nexus is not limited to only when objective evidence is tied to the supposedly ‘new’ feature(s).” *WBIP*, 829 F.3d at 1330.

Petitioner similarly ignores Abbott’s evidence of long-felt need and failure of others. POR 73-75. Petitioner claims they are based on “an implicit allegation that G7” infringes (Rep. 30), but Abbott addressed more than Petitioner’s CGMs (POR 73-74). And Petitioner’s *prior* devices demonstrate how the art lacked the claimed combination.

VI. CONCLUSION

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

Dated: December 10, 2024

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **Patent Owner's Sur-Reply and Exhibits 2045, 2056, 2062, and 2063** in connection with *Inter Partes* Review IPR2023-01409 were served on December 10, 2024 by electronic mail to the following:

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CUSTOMER NUMBER: 23446

CERTIFICATE OF WORD COUNT

I hereby certify that this Sur-Reply complies with the word count limit of 37 C.F.R. § 42.24(d). The argument sections of this Sur-Reply (Sections I-VI) have a total of 5563 words, less than 5,600 words, as measured by Microsoft Word® word count tool.

Dated: December 10, 2024

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