

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. IPR2023-01251

U.S. Patent No. 11,298,056

PATENT OWNER'S SURREPLY TO PETITIONER'S REPLY

TABLE OF CONTENTS

I.	Introduction.....	1
II.	Claim 1: Petitioner’s Reply Arguments Do Not Bridge The Gaps In The Prior Art.....	2
A.	Ground 1:.....	2
1.	Petitioner’s evidence does not disclose limitation [1.K]	2
2.	Petitioner’s new exhibits and arguments do not disclose limitation [1.L].	3
B.	Ground 3: Petitioner failed to rebut Abbott’s arguments for elements [1.I] and [1.K]/[1.L].	7
1.	Petitioner’s Reply does not rebut Dr. Wright’s testimony relating to [1.I].	7
2.	Petitioner’s new arguments for elements [1.K] and [1.L] should be ignored and do not meet its burden.	7
III.	Claim 21: Petitioner’s New Arguments Fail to Rebut Abbott’s Response	10
A.	Ground 1: Petitioner’s new arguments do not show a single integrated housing in Patel-2009.....	11
B.	Ground 3: Petitioner failed to rebut Abbott’s arguments and its new arguments do not show a single integrated housing.....	16
1.	Petitioner does not rebut Abbott’s arguments on Mastrototaro.	16
2.	Petitioner’s new arguments based on Patel-2008 are similarly deficient and should be ignored.....	17
IV.	Petitioner’s Reply Does Not Cure The Petition’s Lack Of Any Motivation To Combine Patel-2008 With The Other Ground 3 References.....	19
V.	Claims 5-7 Are Patentable For Additional Reasons.....	21

A.	Claims 5 and 6	21
B.	Claim 7	22
VI.	Conclusion	22

TABLE OF AUTHORITIES

CASES

<i>Abbott Diabetes Care Inc. et al. v. Dexcom, Inc.</i> , C.A. No. 21-977-KAJ, D.I. 143 (D. Del. Aug. 3, 2022)	22
<i>Arendi S.A.R.L. v. Apple Inc.</i> , 832 F.3d 1355 (Fed. Cir. 2016)	7, 9
<i>Ascend Perf. Materials Ops. LLC v. Samsung SDI Co.</i> , IPR2020-00349, Paper 53 (P.T.A.B. Jul 15, 2021)	vii
<i>Cisco Sys., Inc. v. C-Cation Techs., LLC</i> , IPR2014-00454, Paper 12 (P.T.A.B. Aug. 29, 2014)	22
<i>DSS Tech. Mgmt., Inc. v. Apple Inc.</i> , 885 F.3d 1367 (Fed. Cir. 2018)	7
<i>Equipmentsshare.com Inc., v. Ahern Rentals, Inc.</i> , IPR2021-00834, Paper 33 (P.T.A.B. Nov. 10, 2022)	5, 6, 9
<i>In re Magnum Oil Tools Int’l, Ltd.</i> , 829 F.3d 1364 (Fed. Cir. 2016)	14, 21, 22
<i>In re Stepan Co.</i> , 868 F.3d 1342 (Fed. Cir. 2017)	20
<i>Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.</i> , 821 F.3d 1359 (Fed. Cir. 2016)	11, 18
<i>InTouch Techs., Inc. v. VGO Comm’cns, Inc.</i> , 751 F.3d 1327 (Fed. Cir. 2014)	21
<i>Intuitive Surgical, Inc. v. Ethicon LLC</i> , IPR2018-01248, Paper 34 (P.T.A.B. Feb. 6, 2020)	19
<i>KSR Int’l Co. v. Teleflex, Inc.</i> , 550 U.S. 398 (2007)	8
<i>Motorola Mobility LLC v. Maxell, Ltd.</i> , IPR2022-01348, Paper 7 (P.T.A.B. Feb. 24, 2023)	5

<i>Nat’l Environmental Prods. v. Dri-Steem,</i> IPR2014-01502, Paper 13 (P.T.A.B. Apr. 3, 2015)	20
<i>Perfect Web Techs., Inc. v. InfoUSA, Inc.,</i> 587 F.3d 1324 (Fed. Cir. 2009)	5
<i>Regents of the Univ. of Minn. v. AT&T Mobility LLC,</i> 2024 WL 758541 (D. Minn. Feb. 23, 2024).....	20
<i>ResMed, Inc. v. NY Univ.,</i> IPR2022-00992, Paper 67 (P.T.A.B. Dec. 7, 2023)	20
<i>Ruiz v. A.B. Chance Co.,</i> 234 F.3d 654 (Fed. Cir. 2000)	20
<i>Xerox Corp. v. Bytemark, Inc.,</i> IPR2022-00624, Paper 9 (P.T.A.B. Aug. 24, 2022).....	5

OTHER AUTHORITIES

<i>Consolidated Trial Practice Guide</i> (2019)	9, 11, 18
---	-----------

TABLE OF EXHIBITS¹

Exhibit No.	Description
2001	STS-7 User's Guide
2002	DexCom G4 Platinum Continuous Glucose Monitoring System User's Guide
2003	FDA Premarket Approval (PMA) for DexCom G5 Mobile Continuous Glucose Monitoring System
2004	U.S. Patent No. 6,809,653
2005	U.S. Patent No. 7,098,803
2006	U.S. Patent No. 7,324,012
2007	CareLink™ Personal Getting Started Guide
2008	Declaration of Nathaniel E Frank-White (Internet Archive)
2009	FCC Frequency Table
2010	Bluetooth Basics
2011	LinkedIn Summary of Brian Gross
2012	U.S. Patent No. 9,577,934
2013	Declaration of Eugene E. Wright, Jr. MD
2014	Curriculum Vitae of Eugene E. Wright, Jr. MD
2015	Declaration of Aaron Striegel, Ph.D.
2016	Cappon et al., <i>Continuous Glucose Monitoring Sensors for Diabetes Management: A Review of Technologies and Applications</i> , J. Diab. Metab. 43:383-397 (2019)
2017	American Diabetes Association, <i>Role of Continuous Glucose Monitoring in Diabetes Treatment</i> (2018), available at https://pubmed.ncbi.nlm.nih.gov/30958664/
2018	The MiniMed Paradigm® REAL-Time Insulin Pump User Guide
2019	DexCom STS-7 Continuous Glucose Monitoring System User's Guide Submitted Under FCC ID PH29402

¹ Exhibits 2001-2010 were filed with PO's Preliminary Response. (Paper 7.)

Exhibits 2011-2034 were filed with PO's Response. (Paper 20.)

Exhibit No.	Description
2020	DexCom G6 Continuous Glucose Monitoring System User Guide
2021	Abbott FreeStyle Navigator Continuous Glucose Monitoring System User's Guide
2022	Abbott FreeStyle Libre 3 Continuous Glucose Monitoring System User's Manual
2023	U.S. Patent No. 10,085,640
2024	U.S. Patent No. 9,996,668
2025	Das et al., <i>Review—Electrochemistry and Other Emerging Technologies for Continuous Glucose Monitoring Devices</i> , ECS Sensors Plus (2022)
2026	Almurashi et al., <i>Emerging Diabetes Technologies: Continuous Glucose Monitors/Artificial Pancreases</i> , J. Indian Inst. Sci. (2023)
2027	Deposition Transcript of Brian Gross (May 2, 2024)
2028	Centers for Disease Control and Prevention—National Diabetes Statistics Report, <i>available at</i> https://www.cdc.gov/diabetes/data/statistics-report/diagnosed-undiagnosed-diabetes.html .
2029	Garg et al., <i>Flash Glucose Monitoring: The Future Is Here</i> , Diabetes Tech. & Therapeutics 19.S2 (2017)
2030	DexCom SEVEN Plus Users Guide
2031	DexCom G5 Mobile CGM System User Guide
2032	DexCom's Initial Proposed Claim Constructions in C.A. No. 23-239-KAJ (Feb. 28, 2024)
2033	Atmel Product Guide (Winter 2008), <i>available at</i> https://media.digikey.com/pdf/Data%20Sheets/Atmel%20PDFs/Products%20Select%20Guide.pdf
2034	Atmel - ATmega169P Datasheet, <i>available at</i> https://ww1.microchip.com/downloads/en/DeviceDoc/doc8018.pdf

TABLE OF ADDITIONAL EXHIBITS²

Exhibit No.	Description
2035	American Diabetes Association (ADA) Standards of Medical Care in Diabetes—2007, <i>available at</i> https://diabetesjournals.org/care/article/30/suppl_1/S4/24065/Standards-of-Medical-Care-in-Diabetes-2007
2036	American Diabetes Association (ADA) Standards of Medical Care in Diabetes—2006, <i>available at</i> https://diabetesjournals.org/care/article/29/suppl_1/s4/23327/Standards-of-Medical-Care-in-Diabetes-2006
2037	American Diabetes Association (ADA) Standards of Medical Care in Diabetes—2005, <i>available at</i> https://diabetesjournals.org/care/article/28/suppl_1/s4/22560/Standards-of-Medical-Care-in-Diabetes
2038	(withdrawn at deposition)
2039	Bergenstal, Ahmann et al., <i>Recommendations for Standardizing Glucose Reporting and Analysis to Optimize Clinical Decision Making in Diabetes: The Ambulatory Glucose Profile (AGP)</i> , J. Diabetes Tech. & Therapeutics 15(3), 198-211 (2013)
2040	Deposition Transcript of Brian Gross (October 10, 2024)
2041	Deposition Transcript of Andrew Ahmann (October 11, 2024)

² Exhibits 2035-2037 and 2039 were used at the deposition of Dr. Andrew Ahmann on October 11, 2024 (see Ex. 2041) “for the purposes of testing the witness’ testimony” and are submitted herewith to provide the Board with “the full context available in order to evaluate the testimony.” *Ascend Perf. Materials Ops. LLC v. Samsung SDI Co.*, IPR2020-00349, Paper 53 at 12 (P.T.A.B. Jul 15, 2021).

TABLE OF ABBREVIATIONS

Abbreviation	Reference
Pet.	Petition for <i>Inter Partes</i> Review (Paper 3)
ID	Institution Decision (Paper 11)
POR	Patent Owner's Response (Paper 20)
Reply	Petitioner's Reply to Patent Owner's Response (Paper 25)

I. Introduction

Petitioner has failed to prove that any claim of the '056 patent is unpatentable. Abbott's POR showed that two key elements of claim 1 ([1.L] and [1.K]) are not disclosed in the prior art, and that Petitioner relied on incorrect inferences and conclusory expert testimony to try to fill that gap. In Reply, Petitioner adds more hindsight-based argument in attempts to try to salvage its argument that the art discloses [1.L] and [1.K]. But the objective evidence shows that these claim features were not obvious at the time of the invention. Indeed, Petitioner's expert admitted on cross-examination that he couldn't point to "any evidence" that the word "report" used in the Paradigm Documentation referred to a graphical display as required by [1.L].

Petitioner has also not met its burden for the dependent claims. For example, Abbott showed that Grounds 1 and 3 do not disclose or render obvious that (1) the data processing and transmitter unit, and (2) at least a portion of the glucose sensor, are disposed within a "single integrated housing" as recited in claim 21. Apparently recognizing the weakness of the Petition for claim 21, Petitioner tries to introduce several new arguments in its Reply, but these should be rejected as improperly late. Even so, Petitioner's new arguments do not salvage these Grounds because the prior art indisputably teaches the opposite of a "single integrated housing"—disclosing

instead separate housings for the glucose sensor and data processing and transmitter unit.

The Board should find that Petitioner did not meet its burden here and find all claims patentable.

II. Claim 1: Petitioner’s Reply Arguments Do Not Bridge The Gaps In The Prior Art

There is no disclosure, in any reference of record, of backfilling gaps in a trend graph on the display of a glucose monitoring system as required by element [1.L]. Petitioner’s attempts to reconstruct the prior art and gap-fill with expert testimony and conclusory arguments fail. Thus, Petitioner has not met its burden, and the Board should find claim 1 patentable over Grounds 1 and 3.

A. Ground 1:

1. Petitioner’s evidence does not disclose limitation [1.K]

Abbott showed that references in the Paradigm Documentation to “reports” and “historical reports” refer to reports generated by stand-alone software, such as CareLink, after data is downloaded from the pump, and was never used to refer to graphical displays on the pump, let alone to trend graphs displayed on the pump. *Id.* at 12; *see also* Ex. 2007. Petitioner could not rebut this argument. In fact, Petitioner’s own evidence shows that reports are generated from downloaded data by computer software, and are not graphs on a user display. *See* Ex. 1030 at 6:35-40; Ex. 1039 at 294; Ex. 1040 at 300; Ex. 1050 at S45; Ex. 1059 at 10; Ex. 1014 at

49. For example, historical data stored on the Paradigm REAL-Time pump was downloaded for “comprehensive trend analyses and customizable treatment reports.” Ex. 1052 at 16-17; *see also id.* at 27; POR 17-36.

Petitioner’s Reply also argues that real-time data is so critical that a POSITA, reading the Paradigm Documentation, would conclude that the Paradigm REAL-Time system necessarily would have backfilled data gaps on the pump display. Reply 5-6, 17-18. But that is hindsight, ungrounded in the relevant timeframe. The evidence shows the opposite. When the Paradigm REAL-Time system was approved by the FDA in 2006, the Standards of Care in Diabetes promulgated by the American Diabetes Association (ADA) did not recommend CGMs for managing glucose levels in any setting, whether at home or in a hospital. Ex. 2041 76:3-78:8, 14:20-15:3. By the time Paradigm Documentation was created in October 2007, the Standards of Care still did not recommend using CGMs at home to manage glucose levels, and provided that it was premature to use CGMs in a hospital setting, except for research purposes only. Ex. 2041 74:8-76:2. Thus, no one was relying on CGM data to make treatment decisions. Petitioner’s arguments of criticality are therefore based on impermissible hindsight and are not grounded in the Paradigm Documentation.

2. Petitioner’s new exhibits and arguments do not disclose limitation [1.L].

In the Institution Decision, the Board agreed with Abbott that the supposed re-populated data gap identified in the Petition was in fact based on two unrelated

figures, and not on figures showing any backfilling. ID 32-33. Abbott’s POR reinforced the Board on that score, and also showed that other portions of the prior art cannot be cobbled together to form a hindsight reinterpretation of the reference in view of the ’056 patent. POR 17-36. For example, although the Paradigm REAL-Time pump could store up to 90 days of CGM data (Ex. 1011 at 26), only “up to 31 days” of the user’s “personal history” could be viewed on the “pump screen” (*Id.*, ID at 28)—and only in tabular form, **not** in trend graphs. POR at 21-23; Ex. 2018 at 124-126. Petitioner does not dispute these facts. Reply at 8-9.

In its Reply—faced with the truth that the Petition’s argument for [1.L] is demonstrably wrong—Petitioner tries to justify a piecemeal disclosure of this limitation from its discussion of other claim elements. It also invokes “common sense,” arguing in effect, that real-time data is so critical that a POSITA, reading the Paradigm Documentation, would conclude that the Paradigm REAL-Time system necessarily would have backfilled data gaps on the pump display. Reply at 5-6, 17-18.

But Petitioner’s “evidence” is rooted in hindsight and is not how a POSITA would have understood the references. To begin, Petitioner’s new piecemeal reliance on elements [1.H], [1.I], and [1.K] for [1.L] fails because the prior art does not disclose elements [1.H], [1.I], and [1.K]. *See* POR at 17-33.

But even if element [1.K.] were disclosed, disclosure of these other elements is not enough to show disclosure of [1.L]. Petitioner’s cases are not on point. In *Motorola*, the Board found the disputed limitation, “the digital content,” was met by the disclosure of preceding limitations: “input digital content,” “reproduced digital content” and “outputted digital content.” *Motorola Mobility LLC v. Maxell, Ltd.*, IPR2022-01348, Paper 7 at 35-36 (P.T.A.B. Feb. 24, 2023). Unlike that case, here there is no antecedent basis dictating that [1.L] is met if other elements of claim 1 are met. In *Perfect Web*, the disputed step was obvious because it merely recited repeating three previous steps until a threshold was met. *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1330 (Fed. Cir. 2009) (“Thus, this last step, and the claim as a whole, simply recites repetition of a known procedure until success is achieved.”). There is nothing analogous in Challenged Claim 1.

Further, Petitioner’s new piecemeal approach is unsupported by opinion from a skilled artisan. Mr. Gross’s original declaration, Petitioner’s only source of opinion evidence for [1.L], merely repeated Petitioner’s debunked theory relying on two unrelated figures. *Compare* Pet. at 46-48, *with* Ex. 1008 at ¶¶114-115; *Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15 (P.T.A.B. Aug. 24, 2022) (precedential); *Equipmentsshare.com Inc., v. Ahern Rentals, Inc.*, IPR2021-00834, Paper 33 at 35-37 (P.T.A.B. Nov. 10, 2022).

Petitioner’s attempt to cure its [1.L] analysis on Reply fails on the merits too. Petitioner cites no disclosure or depiction of backfilling of trend graphs. As discussed in the POR, the re-population of data within the CGM does not teach or suggest outputting a second line graph in the manner recited in element [1.L]. POR at 33-36; *see also id.* at 17-31. Nor is such output somehow implicit in the Paradigm Documentation. Indeed, Petitioner’s own expert, Dr. Ahmann, acknowledged on cross-examination that, in an article he co-authored with leading practitioners in the field, they used “**report**,” by consensus, to refer to retrospective historical reports, not graphs on a user display. Ex. 2041 at 126:18-130:11. Further, Dr. Ahmann admitted that he had cited no evidence that “uses the word ‘report’ to refer to a graphical display on the user display.” *Id.* at 131:12-20.

Dr. Ahmann also admitted that it would be beneficial to display backfilled data differently than non-backfilled data. Ex. 2041 at 95:23-96:8; 97:8-98:23. Abbott has thus offered ample evidence that, even assuming re-populated data was displayed, it could have and would have been displayed differently (i.e., not as a second line graph as recited in [1.L]) to distinguish it from real-time or non-backfill data. POR 29-31.

Petitioner tries to invoke “common sense” to fill missing elements in Petitioner’s obviousness position. Reply at 1. But courts have permitted “common sense to fill in a *missing* limitation only when ‘the limitation in question was

unusually simple and the technology particularly straightforward.” *DSS Tech. Mgmt., Inc. v. Apple Inc.*, 885 F.3d 1367, 1374 (Fed. Cir. 2018). Petitioner has made no such showing here. The lack of express disclosure is particularly important here, where the limitation at issue “plays a major role in the subject matter claimed.” *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1362 (Fed. Cir. 2016).

B. Ground 3: Petitioner failed to rebut Abbott’s arguments for elements [1.I] and [1.K]/[1.L].

1. Petitioner’s Reply does not rebut Dr. Wright’s testimony relating to [1.I].

As explained in the POR, whether taken alone or in combination, Petitioner’s cited art neither teaches nor suggests “*detect[ing] an adverse condition*” that “results in the receiver unit displaying a data gap” as recited in [1.I]. POR at 48-50. Dr. Wright explained why Petitioner and Mr. Gross misinterpret the disclosure they cite from Patel-2008, Shahmirian, and Causey. Ex. 2013 ¶¶233-54; POR 48-50. Petitioner’s experts do not rebut his testimony. *See generally* Exs. 1055, 1057. Petitioner also does not counter Patent Owner’s arguments and merely summarizes the Petition. Reply at 21. Thus, Petitioner has not met its burden on element [1.I] for the reasons previously explained. POR at 48-50.

2. Petitioner’s new arguments for elements [1.K] and [1.L] should be ignored and do not meet its burden.

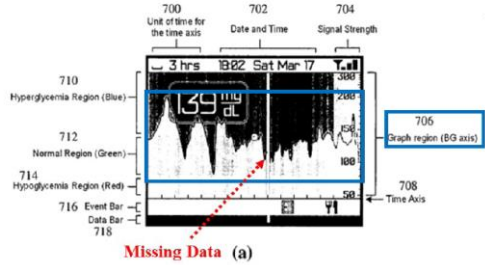
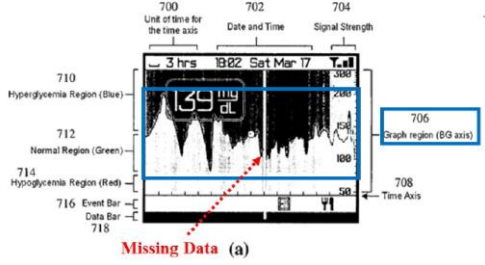
Patent Owner showed that Petitioner misinterprets Shahmirian and Causey, and that the combination would not lead to [1.K]. POR at 51-55; Ex. 2013 ¶¶255-

275. As Dr. Wright explained, if Shahmirian’s alternative embodiments were combined, then the “additional sensor data” received would not be displayed because Shahmirian says that only “the most recent sensor measurement” is displayed. POR at 52; Ex. 2013 ¶263. The “most recent sensor measurement,” or real-time data, is the opposite of historical backfilled data. *Id.* Petitioner’s experts do not rebut Dr. Wright’s testimony. Instead, Petitioner makes a new argument in its Reply, asserting for the first time that the combination of Shahmirian’s paragraph [0103] and Causey’s disclosure allegedly meets [1.K]. *Compare* Pet. at 101, *with* Reply at 21-22. Instead, the Petition cited disclosure from each reference without explaining the relevance, how the disclosures could or would be combined, or how or why the combination allegedly meets element [1.K]. Pet. at 101. Petitioner provided no “articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007).

Focusing on element [1.L], Petitioner tacitly concedes that it relies on Mr. Gross to supply this element, not the asserted prior art. Reply at 22 (Heading: **“POSITAs Would Find It Obvious To Graph Missing Data As A Line”**). In its Reply, Petitioner belatedly attempts to fill the gap for Ground 3 by referring to Ground 1 (Reply at 22), but the Petition never referenced Ground 1. Pet. at 102. The Petition also referenced no other claim elements. *Id.* Instead, the Petition simply

pointed to a data gap in Patel-2008 and then relied exclusively on Mr. Gross’s declaration. But Mr. Gross’s conclusory opinions are not a substitute for prior art. *Arendi*, 832 F.3d 1361-62; *supra* **Error! Reference source not found..2.**

In any event, the three paragraphs of Mr. Gross’s declaration that the Petition cites (*i.e.*, 217, 218, 60) do not establish disclosure or obviousness of element [1.L]. Paragraphs 217 and 218, for example, are substantively identical to the Petition and do not explain why [1.L] is obvious:

<i>Patel-2008</i> discloses a glucose line graph with a missing data gap:  EX1015, [0057], Fig. 7(a) (annotated in red, blue). EX1008, ¶217. POSITAs would have found it obvious to display missing data on the same graph when retransmitted or newly calibrated. EX1008, ¶¶60, 218. (Pet. at 102)	217. <i>Patel-2008</i> discloses a glucose line graph with a missing data gap:  (Ex1015, [0057], Fig. 7(a) (annotated in red and blue).) 218. POSITAs would have found it obvious to display missing data on the same graph when retransmitted or newly calibrated. (<i>See</i> Paragraphs 60, 217 above.) (Ex. 1008 ¶¶217-18)
---	---

Paragraph 60, for its part, does not even mention how backfilled data should be displayed let alone why it would be obvious to display it exactly as recited in element [1.L]. Petitioner thus failed to meet its burden for [1.L]. *Equipmentshare.com*, IPR2021-00834, Paper 33 at 35-37.

Petitioner makes three more new arguments in its Reply (Reply at 22-23) that the Board should disregard as untimely. *See Consolidated Trial Practice Guide* at 73 (2019) (“CTPG”) (“Petitioner may not submit new evidence or argument in reply

that it could have presented earlier, e.g., to make out a prima facie case of unpatentability.”); *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369-70 (Fed. Cir. 2016). First, Petitioner argues that the Board should consider other claim elements despite never referencing them in the Petition. Reply at 22-23. But satisfying other elements does not satisfy [1.L]. *Supra* **Error! Reference source not found..2**. Second, Petitioner argues that “POSITAs would have ‘display[ed] [glucose] information to the patient’ according to Patel-2008’s normal line graph operation.” Reply at 22-23. But Petitioner provides no evidentiary support for this bald assertion. Moreover, as discussed above and in the POR, the evidence shows why a POSITA would *not* have displayed backfilled data in the manner claimed in element [1.L], including for the user’s benefit and safety as understood then. *Supra* **Error! Reference source not found..2**. There is simply no disclosure in Patel-2008 to support a contrary finding. Third, Petitioner argues that POSITAs “would have at least found it obvious to try.” Reply 22-23. This conclusory argument also lacks evidentiary support, as there is no evidence of a limited number of options to try.

III. Claim 21: Petitioner’s New Arguments Fail to Rebut Abbott’s Response

Abbott’s Response identified critical deficiencies in Grounds 1 and 3 with respect to dependent claim 21, which requires that “the data processing and transmitter unit and at least a portion of the *glucose sensor* are disposed within a

single integrated housing.” In Reply, Petitioner strays from its Petition, now citing to different passages of Patel-2009 and relying for the first time on Patel-2008. Reply at 26-27. Even so, the references all contain the same deficiency and do not teach or suggest a “single integrated housing.”

A. Ground 1: Petitioner’s new arguments do not show a single integrated housing in Patel-2009.

The *only* argument offered by Petitioner in the Petition on claim 21 under Ground 1 was that Patel-2009’s disclosure of a transceiver that “fits directly onto and is supported by the sensor set” teaches the “single integrated housing” of claim 21. Petition at 56-57. In response, Abbott showed that the transceiver 100 and sensor set 10 of Patel-2009 are separate units in separate housings that the user can attach to each other “after the sensor set has been placed into” the user’s body. POR 63-68 (quoting Ex. 1012 at [0056]. This two-step connection process undisputedly means that there cannot be a “single integrated housing.”

In Reply, Petitioner pivots to an entirely new argument, that Figure 1 of Patel-2009 “demonstrate[s] that a portion of the glucose sensor is disposed within the transmitter’s housing.” Reply 26. Petitioner’s new arguments should be disregarded as improperly late and not part of the Petition. See *CTPG* at 73; *Intelligent Bio-Sys*, 821 F.3d at 1369-70. Regardless, not only is Petitioner’s argument factually incorrect, even if it were accurate it still fails to show a single integrated housing.

Figure 1 of Patel-2009, reproduced below, does not show a “portion of the glucose sensor [] disposed within the transmitter’s housing,” as Petitioner contends. To the contrary, Petitioner **modifies** Figure 1 with annotations **extending** the sensor into the transmitter’s housing.

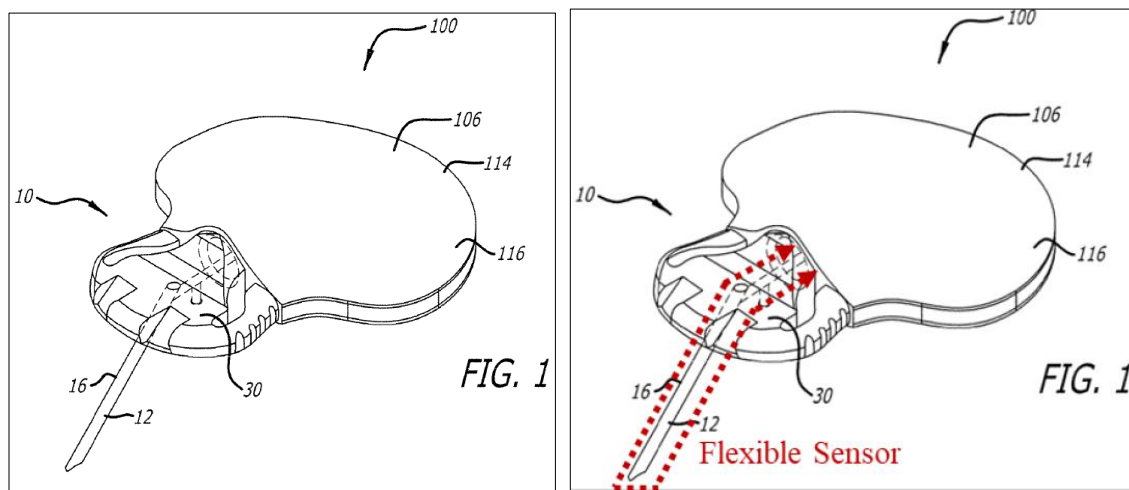
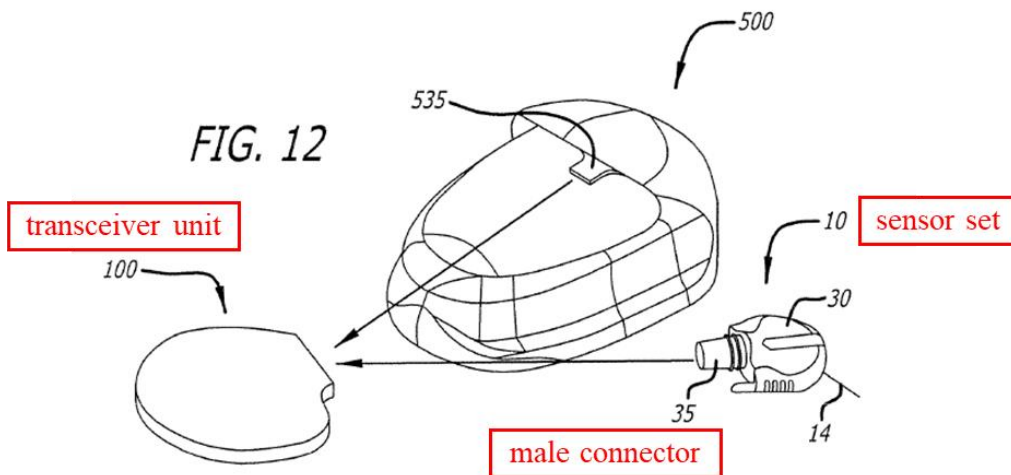


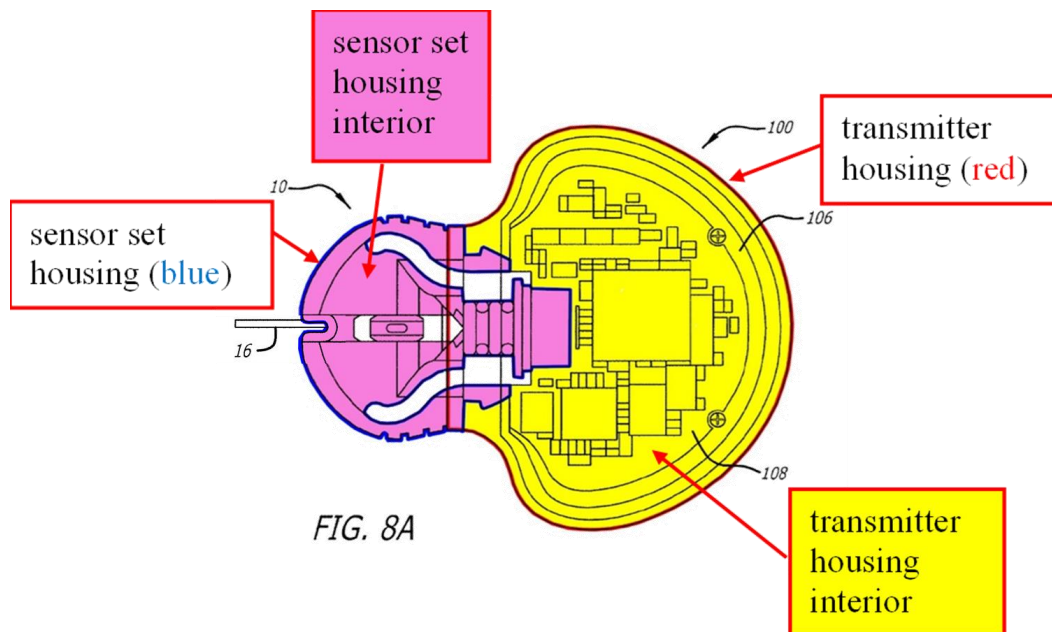
Figure 1 of Patel-2009, original (left) and with Petitioner’s annotations (right)
Petitioner has zero support for its arbitrary red annotation—not even a cite to its experts.

Contrary to Petitioner’s terse, conclusory argument, Patel-2009’s transceiver unit and sensor set are **separate** components with **separate** housings. (Ex. 1012 at FIG. 12.) The sensor and transmitter are always contained within the boundaries of their respective housings. These separate components (with separate housings) are “coupled” together with a “male/female connection scheme.” *Id.* ¶56 (describing FIG. 12). For example, Figure 12 shows the sensor set’s male connector 35. *Id.* The proximal end of the sensor does not extend outside the sensor set housing.



(Id. at FIG. 12 (annotations added).)

As another example, Figure 8A of Patel-2009, reproduced below with annotations, shows a system with the transceiver unit (housing annotated in red and housing interior annotated in yellow) connected to the sensor set housing (housing annotated in blue and housing interior annotated in pink) via the male/female connection.



Id. at Fig. 8A (annotated). The sensor is mounted on a “mounting base” within the sensor set housing. *Id.* ¶53. The transceiver is “electrically connected with the sensor set 10 via the mounting base 30 when the transceiver 100 is plugged into the mounting base 30.” *Id.* ¶60.

The Patel-2009 system is the ***opposite*** of the claimed “single integrated housing,” as the sensor, on the one hand, and the transmitter, on the other, (whether attached or detached) remain at all times within separate housings. No portion of the sensor is disposed within the transmitter housing in any figure of Patel-2009. Notably, the transmitter “is coupled to the sensor set after the sensor set has been placed into body ...of the user.” *Id.* ¶56. Tellingly, Petitioner does not offer any expert testimony supporting its strained interpretation of Figure 1. Reply at 26-27. That dooms this new argument. *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016) (“To satisfy its burden of proving obviousness, a petitioner cannot employ mere conclusory statements.”). Notably, the transmitter “is coupled to the sensor set after the sensor set has been placed into body ... of the user.” *Id.* ¶56. Under Petitioner’s apparent argument in which the transmitter housing covers a portion of the sensor, before the transmitter is connected, a proximal portion of the fragile sensor would be exposed and unprotected outside the sensor set housing. This is not shown or described in Patel-2009 (and it would be a very poor design).

Petitioner next cites Figure 8B of Patel-2009, and specifically to a connection between the sensor interface 122 and the sensor set 10. Reply 26 (citing Ex. 1012 [0060]). But Figure 8B is merely a block diagram and does not illustrate any housing, let alone a “single integrated housing.” And in any event the sensor interface 122 is a functional block of the printed circuit board 108 of transceiver 100, and is not part of the sensor set. Ex. 1012 [0060]; see Reply 26 (Sensor interface 122 is “part of printed circuit board 108 inside the transceiver housing” that connects to the sensor set 10.).

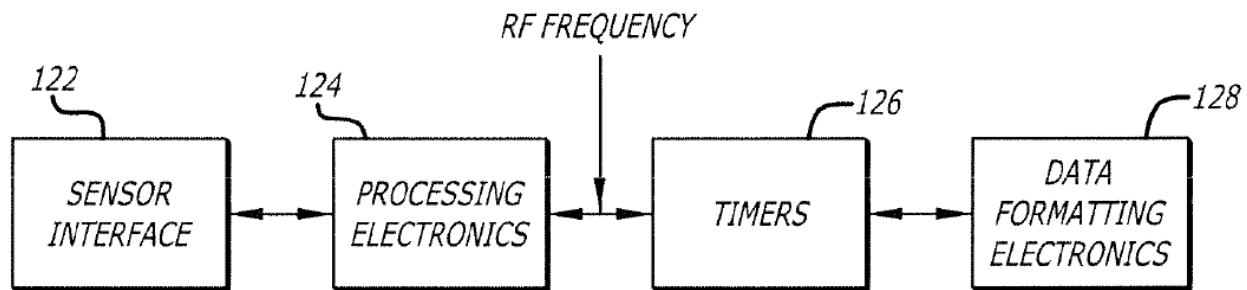


FIG. 8B

Petitioner also quotes Patel-2009 as stating the sensor interface may be “permanently connected to sensor set 10,” but omits that this electrical connection occurs “when the transceiver 100 is **plugged into the mounting base 30.**” Ex. 1012 [0060]. In other words, the transmitter unit, which includes the sensor interface, and sensor set are separate components with separate housings that need to be plugged together. This does not disclose or suggest “the data processing and transmitter unit

and at least a portion of the glucose sensor are disposed within a single integrated housing.”

Unlike claim 21, Patel-2009’s transmitter unit and sensor set have separate housings that are not connected until after the sensor set has been positioned on the body, unlike the integrated housing disclosed and claimed in the ’056 patent. Any connection of these separate components does not form a “single integrated housing.” POR 63-66. An example of a CGM with a “single integrated housing” in which the sensor and transmitter are disposed within one housing is Abbott’s Freestyle Libre 3. Ex. 2022 at 45. In contrast, Patel-2009’s two separate housings are not a “single integrated housing.” Ex. 1001 at 5:54-58. Connecting those separate housings together does not transform them into a “single” or “integrated” housing.

B. Ground 3: Petitioner failed to rebut Abbott’s arguments and its new arguments do not show a single integrated housing.

1. Petitioner does not rebut Abbott’s arguments on Mastrototaro.

For Ground 3, the Petition relied solely on Mastrototaro for claim 21. Pet. at 110. Petitioner makes the same arguments as for Patel-2009 discussed above, contending that Mastrototaro and Patel-2009 have “much of the same disclosure.” Reply at 26; *compare* Ex. 1012, FIGS. 1-2, 8A-8D, 12-13, *with* Ex. 1019, FIGS. 15-20. Accordingly, Ground 3 (based on Mastrototaro) fails for the same reasons as Ground 1 (based on Patel-2009).

Like Patel-2009 discussed above, Petitioner asserts that the sensor set and transmitter unit are “directly connected,” but then fails to explain or support how this meets the “single integrated housing” limitation of claim 21. To the contrary, like Patel-2009, Mastrototaro discloses a system where the transmitter unit and the sensor set are separate components with separate housings. Ex. 1019 at FIGS. 15-20; *see supra* III.A. The same male/female connection scheme from Patel-2009 is disclosed. *Id.* ¶50. Like Patel-2009, the proximal end of Mastrototaro’s sensor does not extend outside the sensor set housing (or into the transmitter housing). *Id.* Rather, “[t]he proximal part of the sensor 12 is mounted in a mounting base 30” inside the sensor set housing. *Id.* ¶47. Moreover, like Patel-2009, Mastrototaro does not disclose an ***integrated*** housing because the transmitter unit and sensor set have separate housings that are not connected until after the sensor set has been positioned on the body, unlike the integrated housing disclosed and claimed in the ’056 patent.

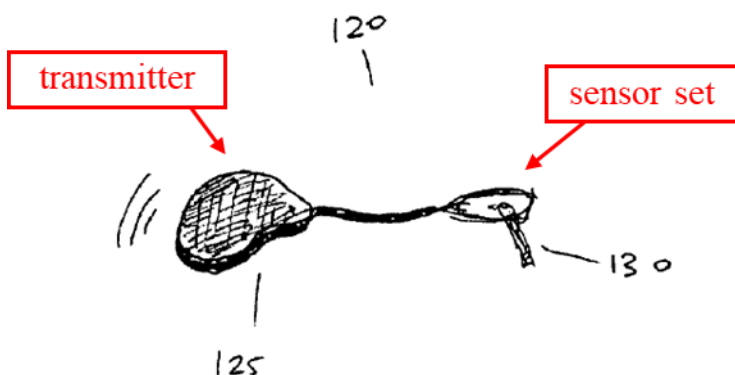
2. Petitioner’s new arguments based on Patel-2008 are similarly deficient and should be ignored.

In Ground 3, the Petition relied on Patel-2008 for claim 1 but did not rely on it with respect to the additional limitations of claim 21. Pet. at 110. Nor did the Petition mention Patel-2008 with respect to claim 21 under Ground 1. Pet. at 56-57. The same is true of Mr. Gross’s declaration. Ex. 1008 ¶¶132, 250.

But in the Reply, Petitioner now relies on Patel-2008 for claim 21 for the first time. Reply at 27. Further, Petitioner now asserts that its expert’s opinions are

supported by the disclosure of Patel-2008, even though its expert never mentions Patel-2008 with respect to claim 21 in his declaration. Ex. 1008 ¶¶132, 250. Petitioner’s new arguments based on Patel-2008 are untimely and should be disregarded. *CTPG* at 73; *Intelligent Bio-Sys.*, 821 F.3d at 1369-70.

At any rate, Patel-2008 does not disclose a “single integrated housing.” Like Patel-2009 and Mastrototaro discussed above, the transmitter unit and sensor set in Patel-2008 are separate components with separate housings and are not connected before the sensor set is positioned on the body.



Ex. 1015 at FIG. 1, ¶33; *see also id.*, FIG. 3, ¶40. Citing Patel-2008, Petitioner asserts that “the glucose sensor and glucose transmitter are fused into one device having a small profile.” Reply at 27. But Petitioner fails to explain or support the suggestion that this somehow translates into a “single integrated housing” wherein both the transmitter unit and a portion of the sensor are disposed, as required by claim 21. Petitioner’s new arguments based on Patel-2008 suffer from the same flaws as its arguments (old and new) based on Patel-2009 and Mastrototaro.

IV. Petitioner’s Reply Does Not Cure The Petition’s Lack Of Any Motivation To Combine Patel-2008 With The Other Ground 3 References.

Abbott’s Response showed that the alleged motivations to combine Patel-2008 with Mastrototaro, Shahmirian, and Causey were wrong. In Reply, Petitioner does nothing to cure these deficiencies, but reiterates its faulty arguments relying on incorporation by reference. But as explained in the POR, incorporation by reference does not replace the requirement of a reason to combine. *Intuitive Surgical, Inc. v. Ethicon LLC*, IPR2018-01248, Paper 34 at 47 (P.T.A.B. Feb. 6, 2020). In *Intuitive Surgical*, Petitioner’s primary art (Prisco) incorporated by reference Petitioner’s secondary art (Cooper). *Id.* at 25. Petitioner argued a POSITA would be motivated to combine them because (i) Prisco incorporated Cooper by reference and (ii) both were assigned to Petitioner. *Id.* at 47. The Board rejected these arguments and held that “Petitioner must, nevertheless, explain why a [POSITA] would have been motivated to incorporate Cooper’s [subject matter] into Prisco’s surgical tool.” *Id.* The Petition here fails for the same reason.

Indeed, if Mastrototaro, Shahmirian, and Causey are “effectively part of [Patel-2008]” as Petitioner argues, then Patel-2008 is a single reference with dozens of embodiments. When multiple embodiments in a single reference are relied upon for obviousness, a patent challenger must still explain why a POSITA would combine specific features from the embodiments to arrive at the claimed invention.

In re Stepan Co., 868 F.3d 1342, 1346 n.1 (Fed. Cir. 2017); *Nat’l Environmental Prods. v. Dri-Steem*, IPR2014-01502, Paper 13 at 12 (P.T.A.B. Apr. 3, 2015). The Petition did not. Pet. at 82.

In Reply, Petitioner cites *Ruiz* and *ResMed* to defend its lack of a motivation to combine (Reply at 20), but neither is on point. In *Ruiz*, the judgment was vacated because there was ***no evidence*** of a motivation to combine. *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 660, 6x64-65 (Fed. Cir. 2000). In *ResMed*, the Petitioner presented “the ***rare case*** where the combination [wa]s described explicitly in one of the references itself.” *ResMed, Inc. v. NY Univ.*, IPR2022-00992, Paper 67 at 58 (P.T.A.B. Dec. 7, 2023). Petitioner points to no comparable statement in *Patel-2008* that presents a “rare case.” Petitioner also cites *Regents of the Univ. of Minnesota v. AT&T Mobility* to excuse its lack of reasoning for why a POSITA would select Mastrototaro from among other references identified for the same subject matter. Reply at 20. That case is irrelevant because it examined whether incorporated documents provided support for claims in a reissue patent under the “original patent rule.” *Regents of the Univ. of Minn. v. AT&T Mobility LLC*, 2024 WL 758541, at *7 (D. Minn. Feb. 23, 2024). The case did not involve obviousness or a motivation to combine, and there are no parallels.

Accordingly, Ground 3 fails against all claims for this fundamental reason. *InTouch Techs., Inc. v. VGO Comm'cns, Inc.*, 751 F.3d 1327, 1351 (Fed. Cir. 2014); POR at 37-47.

V. Claims 5-7 Are Patentable For Additional Reasons

A. Claims 5 and 6

Petitioner has failed to meet its burden. The Petition did not identify any “signal error,” provide evidence or argument explaining how “communication failures” are relevant, and rested on conclusory statements that POSITAs would have simply found claims 5 and 6 obvious. Pet. at 49-50, 103-04; POR at 59-61. Even in its Reply, Petitioner provides no expert testimony to explain the Petition’s perfunctory and deficient analyses.

Patent Owner’s arguments about similar concepts in a different proceeding are irrelevant since Petitioner failed to meet its burden. *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1375 (Fed. Cir. 2016). It is also surprising that Petitioner would raise pleadings from a previous litigation since Petitioner’s responsive briefing in that case made the exact ***opposite arguments*** Petitioner made in the Petition and in its Reply:

[T]here is no reason to believe a “signal error” is the same thing as a signal loss, or that a “system malfunction” in the context of the specification has anything to do with loss of wireless connectivity. Going out of range of a receiving device does not create a “signal error.”

(Defendant’s Answering Claim Construction Brief, *Abbott Diabetes Care Inc. et al. v. Dexcom, Inc.*, C.A. No. 21-977-KAJ, D.I. 143 at 40 (D. Del. Aug. 3, 2022).)

B. Claim 7

The Petition’s analysis for claim 7 is deficient. For both Grounds 1 and 3, the Petition makes only conclusory statements based on Mr. Gross’s opinions. Pet. at 50, 104; POR at 61-63. The Petition cites no other evidence and does not explain the arguments in any detail, nor does it incorporate any purported explanation from Mr. Gross’s declaration. *Cisco Sys., Inc. v. C-Cation Techs., LLC*, IPR2014-00454, Paper 12 at 10 (P.T.A.B. Aug. 29, 2014) (precedential).

In its Reply, Petitioner deflects and criticizes Patent Owner for not “disproving” obviousness. Reply at 25. Petitioner has the law backwards. *In re Magnum*, 829 F.3d at 1375 (reversing where the burden was improperly shifted to Patent Owner to disprove obviousness).

VI. Conclusion

For the reasons set forth above and in the POR, the Board should uphold the patentability of the Challenged Claims.

Date: October 21, 2024

Respectfully submitted,

/Leland G. Hansen/

Leland G. Hansen
Registration No. 50,731
McANDREWS, HELD & MALLOY
500 West Madison St., Suite 3400
Chicago, IL 60661

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing **Patent Owner's Sur-reply to Petitioner's Reply** in connection with *Inter Partes* Review IPR2023-01251 was served on October 21, 2024 by electronic mail to the following:

Lead Counsel	Back-Up Counsel
Andrew M. Mason KLARQUIST SPARKMAN, LLP 121 SW Salmon Street, Suite 1600 Portland, Oregon, 97204 503-595-5300 (phone) 503-595-5301 (fax) andrew.mason@klarquist.com	Amy Haspel KLARQUIST SPARKMAN, LLP 121 SW Salmon Street, Suite 1600 Portland, Oregon, 97204 503-595-5300 (phone) 503-595-5301 (fax) amy.haspel@klarquist.com
	Tucker T. Mottl KLARQUIST SPARKMAN, LLP 121 SW Salmon Street, Suite 1600 Portland, Oregon, 97204 503-595-5300 (phone) 503-595-5301 (fax) tucker.mottl@klarquist.com
	John D. Vandenberg KLARQUIST SPARKMAN, LLP 121 SW Salmon Street, Suite 1600 Portland, Oregon, 97204 503-595-5300 (phone) 503-595-5301 (fax) john.vandenberg@klarquist.com

Dated: October 21, 2024

/Leland G. Hansen/

Leland G. Hansen, Reg. No. 50,731

CUSTOMER NUMBER: 23446

CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), the undersigned attorney for Patent Owner declares that this Patent Owner's Sur-reply to Petitioner's Reply has a total of 4,793 words, according to Microsoft Word® word count tool, excluding the parts of the Response exempted by 37 C.F.R. § 42.24(a)(1).

Dated: October 21, 2024

/Leland G. Hansen/
Leland G. Hansen
Registration No. 50,731
McANDREWS, HELD & MALLOY
500 West Madison St., Suite 3400
Chicago, IL 60661
Telephone: (312) 775-8000