

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Abbott Diabetes Care Inc.,
Petitioner,

v.

DexCom, Inc.,
Patent Owner.

Case No. IPR2024-00840
Patent No. 9,119,528

**PETITIONER'S UNOPPOSED MOTION TO CORRECT PETITION
UNDER 37 C.F.R. § 42.104(c)**

EXHIBIT LIST

Exhibit	Description
1001	U.S. Patent No. 9,119,528 (the “’528 patent”)
1002	File History for U.S. Patent No. 9,119,528
1003	Declaration of Dr. David Rodbard
1004	Curriculum Vitae of Dr. David Rodbard
1005	U.S. Patent Application Publication No. 2007/0208244 (“Brauker”)
1006	Stefania Guerra et al., <i>A Dynamic Risk Measure from Continuous Glucose Monitoring Data</i> , Diabetes Technology & Therapeutics, 13(8), 843-852 (Aug. 2011) (“Guerra”)
1007	Colleen S. Hughes et al., <i>Hypoglycemia Prevention via Pump Attenuation and Red-Yellow-Green “Traffic” Lights Using Continuous Glucose Monitoring and Insulin Pump Data</i> , Journal of Diabetes Science and Technology, 4(5), 1146-1155 (Sept. 2010) (“Hughes”)
1008	DexCom TM STS TM Continuous Glucose Monitoring System User’s Guide (“STS Guide”)
1009	U.S. Patent No. 6,565,509 (“Say”)
1010	FreeStyle Navigator Continuous Glucose Monitoring System User’s Guide (“Navigator Guide”)
1011	Giovanni Sparacino, et al., <i>Glucose Concentration Can Be Predicted Ahead in Time from Continuous Glucose Monitoring Sensor Time-Series</i> , IEEE Transactions on Biomedical Engineering, 54(5), 931-937 (May 2007) (“Sparacino”)
1012	U.S. Patent No. 10,702,215 (“’215 patent”)
1013	Paul G. Hayter et al., <i>Performance Standards for Continuous Glucose Monitors</i> , Diabetes Technology & Therapeutics, 7(5), 721-726 (2005) (“Hayter”)
1014	Andrea Facchinetti et al., <i>A New Index to Optimally Design and Compare Continuous Glucose Monitoring Glucose Prediction Algorithms</i> , Diabetes Technology & Therapeutics, 13(2), 111-119 (2011) (“Facchinetti”)
1015	Aaron J. Kowalski, <i>Can We Really Close the Loop and How Soon? Accelerating the Availability of an Artificial Pancreas: A Roadmap to Better Diabetes Outcomes</i> , Diabetes Technology & Therapeutics, 11(1), S-113-S-119 (Sept. 2009) (“Kowalski”)
1016	U.S. Patent No. 5,973,613

1017	Premarket Approval (PMA) Order, FreeStyle Navigator Continuous Glucose Monitoring System (Mar. 12, 2008), https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050020A.pdf
1018	Garry M. Steil et al., <i>Feasibility of Automating Insulin Delivery for the Treatment of Type 1 Diabetes</i> , Diabetes, 55, 3344-3350 (Dec. 2006)
1019	JPMorgan, North America Equity Research, Diabetes Care ADA 2006: Spotlight On Continuous Glucose Monitoring (June 11, 2006)
1020	Bruce Buckingham et al., <i>Prevention of Nocturnal Hypoglycemia Using Predictive Alarm Algorithms and Insulin Pump Suspension</i> , Diabetes Care, 33(5), 1013-1017 (May 2010)
1021	Eyal Dassau et al., <i>Real-Time Hypoglycemia Prediction Suite Using Continuous Glucose Monitoring</i> , Diabetes Care, 33(6), 1249-1254 (June 2010)
1022	Boris P. Kovatchev et al., <i>Symmetrization of the Blood Glucose Measurement Scale and Its Applications</i> , Diabetes Care, 20(11), 1655-1658 (Nov. 1997)
1023	David C. Klonoff et al., <i>Innovations in Technology for the Treatment of Diabetes: Clinical Development of the Artificial Pancreas (as Autonomous System)</i> , Journal of Diabetes Science and Technology, 5(3), 804-826 (May 2011)
1024	U.S. Patent No. 8,160,669
1025	B. Wayne Bequette, <i>Continuous Glucose Monitoring: Real-Time Algorithms for Calibration, Filtering, and Alarms</i> , Journal of Diabetes Science and Technology, 4(2), 404-418 (Mar. 2010)
1026	Cesar C. Palerm et al., <i>Hypoglycemia Prediction and Detection Using Optimal Estimation</i> , Diabetes Technology & Therapeutics, 7(1), 3-14 (2005)
1027	Declaration of Sylvia D. Hall-Ellis, Ph.D.
1028	Approved Judgment, In the High Court of Justice, Business and Property Courts of England and Wales, Intellectual Property List (ChD) Patents Court, [2024] EWHC 36 (Pat)
1029	European Patent No. 2,914,159
1030	<i>Abbott Diabetes Care Inc. et al v. DexCom, Inc.</i> , No. 1:23-cv-00239, Dkt. 54 (D. Del. Sept. 19, 2023) (“Scheduling Order”)
1031	Stuart A. Weinzimer et al., <i>Fully Automated Closed-Loop Insulin Delivery Versus Semiautomated Hybrid Control in Pediatric</i>

	<i>Patients With Type 1 Diabetes Using an Artificial Pancreas</i> , Diabetes Care, 31(5), 934-939 (May 2008)
1032	Helen R. Murphy et al., <i>Closed-Loop Insulin Delivery During Pregnancy Complicated by Type 1 Diabetes</i> , Diabetes Care, 34, 406-411 (Feb. 2011)

Petitioner Abbott Diabetes Care Inc. (“Abbott”) respectfully submits this unopposed motion under 37 C.F.R. § 42.104(c) to correct certain clerical errors in the Petition and the declaration by Sylvia D. Hall-Ellis, Ph.D. (Ex. 1027 (“Hall-Ellis Declaration”)).

Specifically, Abbott seeks to correct the following clerical errors: (1) in the body of the Petition, references to three cites to the Hall-Ellis Declaration (Ex. 1027) being mis-numbered by one paragraph; and (2) in the body of Hall-Ellis Declaration (Ex. 1027), two paragraph numbers being mis-numbered by three paragraphs. The accompanying Attachment A is a redline showing the corrections to the Petition. Attachment B is a July 6, 2024, declaration of Dr. Hall-Ellis regarding the correction of the two paragraph numbers in her declaration that is Ex. 1027.

Abbott respectfully requests the Board to grant its motion to file a revised Petition, along with the July 6 declaration of Dr. Hall-Ellis (Attachment B) as a new exhibit.

As the Board pointed out, Rule 42.104(c) preauthorizes a petitioner to file a motion to correct clerical or typographical errors; prior authorization from the Board is not required. Attachment C. Petitioner has met and conferred with Patent Owner, and Patent Owner does not oppose the motion.

Accordingly, the motion to correct the Petition and the Hall-Ellis Declaration should be granted.

Date: July 29, 2024

Respectfully submitted,

By: /Peter P. Chen/

Peter P. Chen

Registration No.: 39,631

COVINGTON & BURLING LLP

3000 El Camino Real

5 Palo Alto Square, 10th Floor

Palo Alto, CA 94306

Telephone: (650) 632-4700

Facsimile: (650) 632-4820

Counsel for Petitioner

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6, I hereby certify that the foregoing Petitioner's Motion to Correct Petition under 37 C.F.R. § 42.104(c) was served by electronic mail today on the following counsel of record for Patent Owner:

Richard F. Giunta,
RGiunta-PTAB@wolfgreenfield.com

Elisabeth H. Hunt,
EHunt-PTAB@wolfgreenfield.com

Anant K. Saraswat,
ASaraswat-PTAB@wolfgreenfield.com

WOLF GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, MA 02210

Date: July 29, 2024

/Peter P. Chen/
Peter P. Chen
Registration No. 39,631

ATTACHMENT A

Corrections to Petition in IPR2024-00840

user settable. *Id.*, [0010] (emphasis added). Second, Brauker teaches “the receiver comprises programming configured to estimate glucose data for a future time” and “the system *further comprises* an alarm configured to provide at least one of a visual signal, an audible signal, and a tactile signal *when the estimated glucose data for the future time is below a predetermined threshold.*” *Id.*, [0013]-[0015] (emphasis added). This is a predicted alarm because it is triggered based on “estimated glucose data for the future time.” *Id.*, [0015]; *see also* Ex-1003 ¶49. Further, unlike the user settable “lower glucose threshold,” the “predetermined threshold” (i.e., threshold pre-programmed at the factory) is not limited to being user settable. Ex-1003 ¶49.

Along with alarms, Brauker discloses providing therapy recommendations such as “consume carbohydrates” or “inject insulin.” Ex-1005, [0719]. Brauker further discloses customizing therapy recommendations depending on the “severity of medical condition.” *Id.*

B. Guerra (Ex-1006)

Guerra was published in Volume 13, Number 8 of the journal *Diabetes Technology & Therapeutics*, in an issue dated August 2011. Ex-1006. Guerra was publicly accessible at least by July 27, 2011. Ex-1027 ¶[7475](#). It is thus prior art under pre-AIA 35 U.S.C. §102(b). Guerra was cited in an IDS along with over 180 other references, but not relied upon or otherwise meaningfully addressed by the examiner during prosecution of the '528 patent.

Guerra teaches improving the method of measuring risk of low glucose for generation of alarms in CGM systems. Ex-1006, 843. In particular, Guerra discloses evaluating a *dynamic risk* that considers *the rate of change* of glucose as a threat factor. *Id.* (“A new *dynamic risk (DR)* is proposed to explicitly consider the rate of change of glucose as a threat factor for the patient.”) (emphasis added); see also Ex-1003 ¶¶ 52-53.

C. Hughes (Ex-1007)

Hughes was published in Volume 4, Issue 5 of the *Journal of Diabetes Science and Technology*, in an issue dated September 2010. It was publicly accessible at least by September 1, 2010. Ex-1027 ¶7475. It is prior art under 35 U.S.C. § 102(b). Hughes was not of record during prosecution of the '528 patent.

Hughes discloses a CGM system coupled with an insulin delivery device. Figure 3 depicts an example system from Hughes.

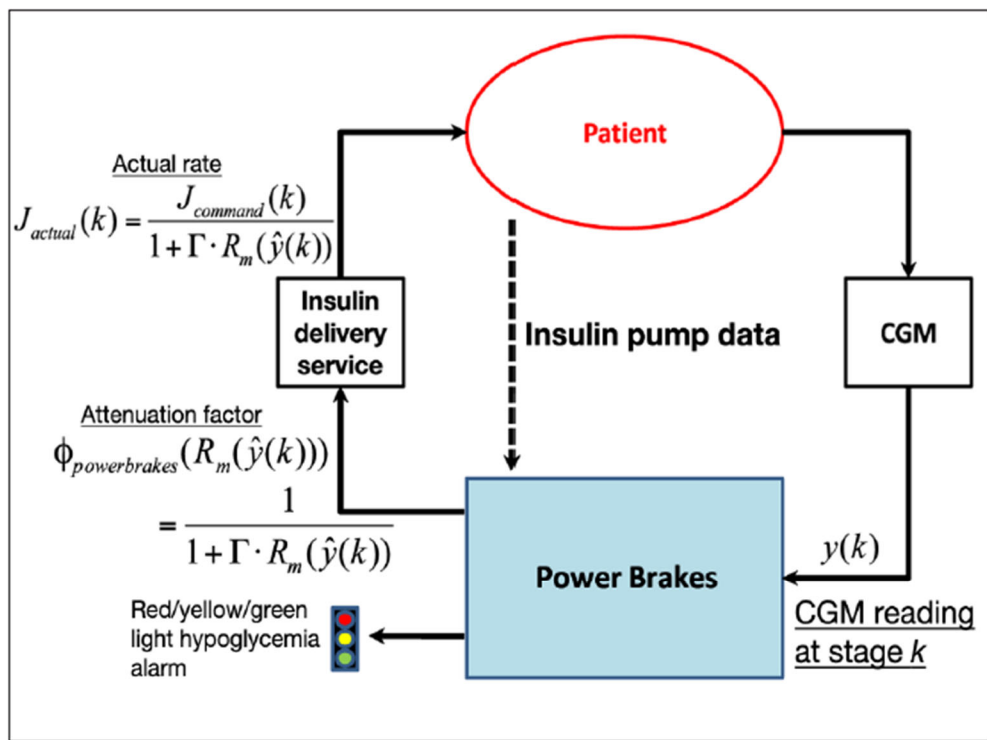


Figure 3. Schematic of Power Brakes.

Ex-1007, Fig. 3. Hughes discloses evaluating a risk of hypoglycemia using a dynamic risk function R_m of a predicted glucose value $\hat{y}(k)$. *Id.*, 1150-51; *see also* Ex-1003 ¶¶54-55. Hughes further discloses controlling insulin delivery, as well as providing red-yellow-green light alerts based on a dynamic risk function. Ex-1007, 1150-51; *see also id.*, 1147.

D. STS Guide (Ex-1008)

DexCom's STS Guide was published online and accessible to the public through its website at least as early as October 23, 2007. Ex-1027 ¶7475. It is thus prior art under 35 U.S.C. § 102(b). The Board previously found that STS Guide was

prior art to the '215 patent (a continuation of the '528 patent). IPR2022-00909, Paper 38 at 39-41 (P.T.A.B. Nov. 1, 2023).

DexCom published the STS Guide (Ex-1008), but failed to make the STS Guide of record during prosecution. It is the same “User’s Guide” based on which the Board found unpatentable all but two of the challenged claims of the '215 patent. IPR2022-00909, Paper 38 at 70-71 (P.T.A.B. Nov. 1, 2023).

STS Guide describes a CGM system with a sensor, a transmitter, and a receiver. Ex-1008, 9. The sensor is inserted through the skin of a host’s abdomen to continuously monitor glucose levels for up to 3 days. *Id.*, 10.



Ex-1008, 17.

The transmitter is installed on the sensor and wirelessly sends glucose information measured by the sensor to the receiver every 5 minutes:

ATTACHMENT B

UNITED STATES PATENT AND TRADEMARK OFFICE

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IPR2024-00840
Patent No. 9,119,528

DECLARATION OF SYLVIA D. HALL-ELLIS, PH.D.
REGARDING CORRECTION OF CLERICAL ERRORS

1. My name is Sylvia D. Hall-Ellis. On April 24, 2024, I signed a declaration for Abbott Diabetes Care Inc. ("April Declaration"). I am informed that my April Declaration was submitted as Ex. 1027 in an IPR petition (IPR2024-00840) regarding U.S. Patent No. 9,119,528. My April Declaration is attached as Exhibit A.

2. My April Declaration had two clerical errors on page 42. Paragraphs 73 and 74 should have been numbered 76 and 77, respectively.

3. After being informed of these errors on June 11, 2024, I provided a corrected page 42 with a new signature. The corrected page 42 is attached as Exhibit B.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

DATED: July 6, 2024

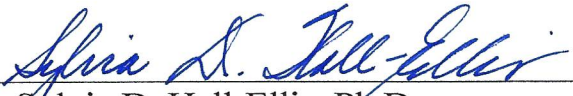
By: 
Sylvia D. Hall-Ellis, Ph.D.

Exhibit A

UNITED STATES PATENT AND TRADEMARK OFFICE

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IPR2024-00840
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DECLARATION OF SYLVIA D. HALL-ELLIS, PH.D.

I. INTRODUCTION

1. My name is Sylvia D. Hall-Ellis. I have been retained as an expert by Abbott Diabetes Care Inc. (“Abbott”).

2. I have written this report at the request of Abbott to provide my expert opinion regarding the authenticity and public accessibility of several journal publications, books, and documents. My report sets forth my opinions in detail and provides the basis for my opinions regarding the public accessibility of these publications.

3. I reserve the right to supplement or amend my opinions, and bases for them, in response to any additional evidence, testimony, discovery, argument, and/or other additional information that may be provided to me after the date of this report.

4. I am being compensated for my time spent working on this matter at my normal consulting rate of \$400 per hour, plus reimbursement for any additional reasonable expenses. My compensation is not in any way tied to the content of this report, the substance of my opinions, or the outcome of this litigation. I have no other interests in this proceeding or with any of the parties.

5. All of the materials that I considered are discussed explicitly in this declaration.

II. QUALIFICATIONS

6. I am currently an Adjunct Professor in the School of Information at San José State University. I obtained a Master of Library Science from the University of North Texas in 1972 and a Ph.D. in Library and Information Science from the University of Pittsburgh in 1985. Over the last fifty-five years, I have held various positions in the field of library and information resources. I was first employed as a librarian in 1966 and have been involved in the field of library sciences since, holding numerous positions.

7. I am a member of the American Library Association (ALA) and its Association for Library Collections & Technical Services (ALCTS) Division (now known as CORE), and I served on the Committee on Cataloging: Resource and Description (which wrote the new cataloging rules) and as the chair of the Committee for Education and Training of Catalogers and the Competencies and Education for a Career in Cataloging Interest Group. I also served as the Chair of the ALCTS Division's Task Force on Competencies and Education for a Career in Cataloging. Additionally, I have served as the Chair for the ALA Office of Diversity's Committee on Diversity, as a member of the national Board of Directors for REFORMA, as a member of the Editorial Board for the ALCTS premier cataloging journal, *Library Resources and Technical Services*, a member of the Membership Committee for the Library Research Round Table (LRRT) of

the American Library Association, and a member of the LRRT Nominating Committee. Currently I serve as a member of the CORE Margaret Mann Citation Committee.

8. I have also given over one hundred presentations in the field, including several on library cataloging systems and Machine-Readable Cataloging (“MARC”) standards. My current research interests include library cataloging systems, metadata, and organization of electronic resources.

9. My full curriculum vitae is attached hereto as Appendix A to this report.

III. LIBRARY CATALOGING PRACTICES

10. I am fully familiar with the library cataloging standard known as the MARC standard, which is an industry-wide standard method of storing and organizing library catalog information.¹ MARC was first developed in the 1960s by the Library of Congress. A MARC-compatible library is one that has a catalog consisting of individual MARC records for each of its items. Today, MARC is the primary communications protocol for the transfer and storage of bibliographic

¹ The full text of the standard is available from the Library of Congress at <http://www.loc.gov/marc/bibliographic/>

metadata in libraries.²

11. A MARC record comprises several fields, each of which contains specific data about the work. Each field is identified by a standardized, unique, three-digit code corresponding to the type of data that follow. For example, a work's title is recorded in field 245, the primary author of the work is recorded in field 100, an item's International Standard Book Number ("ISBN") is recorded in field 020, an item's International Standard Serial Number ("ISSN") is recorded in field 022, an item's Library of Congress call number is recorded in field 050, and the publication date is recorded in field 260 under the subfield "c." If a work is a periodical, then its publication frequency is recorded in field 310, and the publication dates (e.g., the first and last publication) are recorded in field 362, which is also referred to as the enumeration/chronology field.

² Almost every major library in the world is MARC-compatible. *See, e.g., MARC Frequently Asked Questions (FAQ)*, Library of Congress, <https://www.loc.gov/marc/faq.html> (last visited February 20, 2024) ("MARC is the acronym for MACHine-Readable Cataloging. It defines a data format that emerged from a Library of Congress-led initiative that began nearly fifty years ago. It provides the mechanism by which computers exchange, use, and interpret bibliographic information, and its data elements make up the foundation of most library catalogs used today."). MARC is the ANSI/NISO Z39.2-1994 (reaffirmed 2016) standard for Information Interchange Format.

12. The library that created the record is recorded in field 040 in subfield “a” with a unique library code. When viewing the MARC record online via Online Computer Library Center’s (“OCLC”) bibliographic database, hovering over this code with the mouse reveals the full name of the library. I used this method of “mousing over” the library codes in the OCLC database to identify the originating library for the MARC records discussed in this report. Where this “mouse over” option was not available, I consulted the Directory of OCLC Libraries to identify the institution that created the MARC record.³

13. MARC records also include several fields that include subject matter classification information. An overview of MARC record fields is available through the Library of Congress.⁴ For example, 6XX fields are termed “Subject Access Fields.”⁵ Among these, for example, is the 650 field; this is the “Subject Added Entry – Topical Term” field.⁶ The 650 field is a “[s]ubject added entry in which the entry element is a topical term.” These entries “are assigned to a bibliographic record to provide access according to generally accepted thesaurus-building rules (e.g., *Library of Congress Subject Headings* (LCSH), *Medical*

³ <https://www.oclc.org/en/contacts/libraries.html>

⁴ <http://www.loc.gov/marc/bibliographic/>

⁵ <http://www.loc.gov/marc/bibliographic/bd6xx.html>

⁶ <http://www.loc.gov/marc/bibliographic/bd650.html>

Subject Headings (MeSH)).” Further, MARC records include call numbers, which themselves include a classification number. For example, the 050 field is the “Library of Congress Call Number.”⁷ A defined portion of the Library of Congress Call Number is the classification number, and “source of the classification number is *Library of Congress Classification* and the *LC Classification-Additions and Changes*.” Thus, included in the 050 field is a subject matter classification. Each item in a library has a single classification number. A library selects a classification scheme (*e.g.*, the Library of Congress Classification scheme just described or a similar scheme such as the Dewey Decimal Classification scheme) and uses it consistently. When the Library of Congress assigns the classification number, it appears as part of the 050 field. If a local library assigns the classification number, it appears in a 090 field. In either scenario, the MARC record includes a classification number that represents a subject matter classification.

14. The OCLC was created “to establish, maintain and operate a computerized library network and to promote the evolution of library use, of libraries themselves, and of librarianship, and to provide processes and products for the benefit of library users and libraries, including such objectives as increasing

⁷ <http://www.loc.gov/marc/bibliographic/bd050.html>

availability of library resources to individual library patrons and reducing the rate of rise of library per-unit costs, all for the fundamental public purpose of furthering ease of access to and use of the ever-expanding body of worldwide scientific, literary and educational knowledge and information.”⁸ Among other services, OCLC and its members are responsible for maintaining the WorldCat database,⁹ used by independent and institutional libraries throughout the world.

15. OCLC also provides its members online access to MARC records through its OCLC bibliographic database. When an OCLC member institution acquires a work, it creates a MARC record for this work in its computer catalog system in the ordinary course of its business. MARC records created at the Library of Congress are directly uploaded or may be tape-loaded into the OCLC database through a subscription to MARC Distribution Services daily or weekly. Once the MARC record is created by a cataloger at an OCLC member institution or is tape-loaded from a participating institution, the MARC record is then made available to any other OCLC members online, and therefore made available to the public. Accordingly, once the MARC record is created by a cataloger at an OCLC member

⁸ Third Article, Amended Articles of Incorporation of OCLC Online Computer Library Center, Incorporated (available at <https://www.oclc.org/content/dam/oclc/membership/articles-of-incorporation.pdf>).

⁹ <http://www.worldcat.org/>

institution or is tape-loaded from the Library of Congress or another library anywhere in the world, any publication corresponding to the MARC record has been cataloged and indexed according to its subject matter such that a person interested in that subject matter could, with reasonable diligence, locate and access the publication through any library with access to the OCLC bibliographic database or through the Library of Congress.

16. When an OCLC member institution creates a new MARC record, OCLC automatically supplies the date of creation for that record. The date of creation for the MARC record appears in the fixed field (008), characters 00 through 05. The MARC record creation date reflects the date on which, or shortly after which, the item was first acquired or cataloged. Initially, field 005 of the MARC record is automatically populated with the date the MARC record was created in year, month, day format (YYYYMMDD) (some of the newer library catalog systems also include hour, minute, second (HHMMSS)). Thereafter, the library's computer system may automatically update the date in field 005 every time the library updates the MARC record (*e.g.*, to reflect that an item has been moved to a different shelving location within the library). Field 005 is visible when viewing a MARC record via an appropriate computerized interface, but when a MARC record is printed to hardcopy, no "005" label appears. The initial field 005 date (*i.e.*, the date the MARC record was created) does appear, however,

next to the label “Entered.”¹⁰ The date upon which the most recent update to field 005 occurred also appears, next to the label “Replaced.” Thus, when an item’s MARC record has been printed to hardcopy—as is the case with the exhibits to this report—the date reflected next to the label “Entered” is necessarily on or after the date the library first cataloged and indexed the underlying item.

17. Once one library has cataloged and indexed a publication by creating a MARC record for that publication, other libraries that receive the publication do not create additional MARC records—the other libraries instead rely on the original MARC record. They may update or revise the MARC record to ensure accuracy, but they do not replace or duplicate it. This practice does more than save libraries from duplicating labor. It also enhances the accuracy of MARC records. Further, it allows librarians around the world to know that a particular MARC record is authoritative (in contrast, a hypothetical system wherein duplicative records were created would result in confusion as to which record is authoritative).

18. The date of creation of the MARC record by a cataloger at an OCLC

¹⁰ In this report, I sometimes refer to the “Entered” entry as Field 008, characters 00-05. Field 005 is visible when viewing a MARC record via an appropriate computerized interface. But when a MARC record is printed directly to hardcopy from the OCLC database, the “005” label is not shown. The date in the 005 field instead appears next to the label “Replaced.”

member institution reflects when the underlying item is accessible to the public. Upwards of two-thirds to three-quarters of book sales to libraries come from a jobber or wholesaler for online and print resources. These resellers make it their business to provide books to their customers as fast as possible, often providing turnaround times of only a single day after publication. Libraries purchase a significant portion of the balance of their books directly from publishers themselves, which provide delivery on a similarly expedited schedule. In general, libraries make these purchases throughout the year as the books are published and shelve the books as soon thereafter as possible in order to make the books available to their patrons. Thus, books are generally available at libraries across the country within just a few days of publication.

19. Catalogers can create MARC records for all types of print, online, and digital resources. For example, MARC records cover serial publications, including both serially-published monographs and journals. OCLC hosts MARC records for more than 320 million serial publications. Serial publications are those publications that have the same collective title but are intended to be continued indefinitely with enumeration such as a volume or issue number (*e.g.*, magazines, journals, etc.). In the OCLC bibliographic database, the first issue or volume of the monographic serial is typically cataloged (*i.e.*, a corresponding MARC record is created), but the date is left open-ended with the use of a punctuation mark such

as a dash. MARC records for serial publications represent the entire run of the title. With knowledge of the first issue or volume published, future issues or volumes can be predicted based on the information provided in the MARC record, for example in field 362. In my extensive professional experience, is it highly unusual for a library to stop collecting and shelving a serial publication prior to the time of its cessation. If a subscription to a serial publication ends or is cancelled, the library will denote that it has stopped receiving new issues or volumes by filling in the end date in the MARC record.

20. The handling of printed journal subscriptions is shown on the covers of individual issues. As was the best practice among libraries, issues arrived at a central facility and were immediately received, verified as part of a subscription, checked in, and stamped with the institution's name and date. Determining that the issue was part of the library subscription ensured that the entire set of publications for the year had been received so that they could be professionally bound and retained. This process also verified that each of the published issues arrived so that the library staff did not have to request or claim an issue that did not arrive as expected. In large public libraries with branches and multi-campus libraries within academic institutions, the journals were sorted and delivered to the subscribing unit. The issues were frequently stamped again to acknowledge receipt. The new issue was placed in the public area; the older issue was stored so that it remained

available.

21. The foregoing process has been standard library practice longer than I have been working in the profession. I first learned the steps in the process in the late 1970s and later supervised it. Although the checking in process has become automated and now links electronically to holdings records for the MARC record for each serial title, the manual stamping and placing the issue in a public area has not changed for 50 years. Unless I note otherwise below in reference to a specific serial publication, it is my expert opinion that this standard protocol was followed for each of the serial publications discussed below.

22. In preparing this report, I used authoritative databases, such as the OCLC bibliographic database and the Library of Congress Online Catalog, to confirm citation details of the various publications discussed.

23. *Indexing.* A researcher may discover material relevant to his or her topic in a variety of ways. One common means of discovery is to search for relevant information in an index of periodical and other publications. Having found relevant material, the researcher will then normally obtain it online, look for it in libraries, or purchase it from the publisher, a bookstore, a document delivery service, or other provider. Sometimes, the date of a document's public accessibility will involve both indexing and library date information. However, date information for indexing entries is often unavailable. This is especially true

for online indices.

24. Indexing services use a wide variety of controlled vocabularies to provide subject access and other means of discovering the content of documents. The formats in which these access terms are presented vary from service to service.

25. Online indexing services commonly provide bibliographic information, abstracts, and full-text copies of the indexed publications, along with a list of the documents cited in the indexed publication. These services also often provide lists of publications that cite a given document. A citation of a document is evidence that the document was publicly accessible and in use by researchers no later than the publication date of the citing document.

26. Before the widespread development of online databases to index articles in journals, magazines, conference papers, and technical reports, libraries purchased printed volumes of indices. Graduate library school education mandated that students learn about the bibliographic control of disciplines, the prominent indexing volumes, and searching strategies required to use them effectively and efficiently. Half of the courses that I studied in library school were focused on the bibliography and resources in academic disciplines.

27. Librarians consulted with information seekers to verify citations, check availability in union catalogs, printed books catalogs, the OCLC database, and make formal requests for materials (e.g., books, conference proceedings,

journal articles). Requests were transmitted using Telex machines, rudimentary email systems, and the United States Postal Service. During my career, I have performed and supervised staff who handled these resource sharing tasks.

28. A major firm known for the breadth of subjects and comprehensive treatment in the preparation of index volumes, the H. W. Wilson Company offered these reference resources since the firm was founded in 1898. The *Reader's Guide to Periodical Literature* is one of the best-known titles available from H. W. Wilson. Each volume includes a comprehensive index for 300 of the most popular and important periodicals published in the United States and Canada. Information seekers have subject access expressed in plain language terminology, author access, and cross references to find the desired results from their searches. The family of index titles included *Science & Technology Index*, *Business Periodicals*, *Applied Science & Technology Index*, *Humanities Index*, *Biological & Agricultural Index*, and *Industrial Arts Index*. These printed indices have been superseded by digital database offerings available to information seekers through Ebsco.

29. Information seekers also used printed versions of *Chemical Abstracts* and *Index Medicus* to locate articles, scientific reports, and research papers. *Chemical Abstracts* began publication in 1907 and by 2007 its databases

“contained more than 27 million records of journal and patent literature.”¹¹ In 2010, *Chemical Abstracts* discontinued the print index. Access is now available through two electronic databases: *CAPLUS* and *Registry*.¹² *Index Medicus* is a bibliographic index to medical science information, started in 1879.¹³ Currently, *PubMed* includes the content that had been published as *Index Medicus*.¹⁴

30. Established in 1836 as part of the Surgeon General of the Army’s Office, the National Library of Medicine (NLM) has been instrumental in the

¹¹ Chemical Abstracts Service, “CAS History,” *available at* <https://www.cas.org/about/cas-history> (last accessed February 20, 2024); American Chemical Society, “Chemical Abstracts Service,” *available at* <https://www.acs.org/content/acs/en/education/whatischemistry/landmarks/cas.html> (last accessed February 20, 2024).

¹² American Chemical Society, “Chemical Abstracts Service,” *available at* <https://www.acs.org/content/acs/en/education/whatischemistry/landmarks/cas.html> (last accessed February 20, 2024).

¹³ Stephen Greenberg and Patricia Gallagher, “The great contribution: *Index Medicus*, *Index-Catalogue*, and *IndexCast*,” *Journal of Medical Library Association*, April 2009, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2670211/> (last accessed February 20, 2024).

¹⁴ U.S. National Library of Medicine, “List of All Journals Cited in PubMed®,” https://www.nlm.nih.gov/bsd/serfile_addedinfo.html (last accessed February 20, 2024).

development of access to medical books, journals, and research publications. In the 1970s, NLM introduced MEDLINE, followed by “the establishment of the National Center for Biotechnology Information in 1988, the introduction of free MEDLINE in 1997, the creation of consumer-friendly MedlinePlus in 1998, and the introduction of ClinicalTrials.gov in 2000.”¹⁵

31. Online indexing services such as *Google Scholar*¹⁶ or *ScienceDirect*¹⁷ commonly provide bibliographic information, abstracts, and full-text copies of the indexed publications, along with a list of the documents cited in the indexed publication. These services also often provide lists of publications that cite a given document. A citation of a document by another is evidence that the document was publicly accessible and in use no later than the publication date of the citing document.

32. *Internet Archive*. Founded in 1996, the Internet Archive, a 501(c)(3) non-profit, is building a digital library of Internet sites and other cultural artifacts in digital form.¹⁸ Like a paper library, the Internet Archive provides free access to

¹⁵ U.S. National Library of Medicine, “A Brief History of NLM,” available at <https://www.nlm.nih.gov/about/briefhistory.html>

¹⁶ <https://scholar.google.com/>

¹⁷ <https://www.sciencedirect.com/>

¹⁸ <https://archive.org/>

researchers, historians, scholars, the print disabled, and the members of the public. The organization's mission is to provide Universal Access to All Knowledge.

33. The Internet Archive features 20+ years of web history accessible through the Wayback Machine and more than 625 library and other partners through our Archive-It program to identify important web pages. As the Internet Archive grew, so did its commitment to provide digital versions of other published works. Currently, the Internet Archive includes 330 billion web pages, 20 million books and texts, 4.5 million audio recordings (including 180,000 live concerts), 4 million videos (including 1.6 million Television News programs), 3 million images, and 200,000 software programs.

34. The Internet Archive maintains an archive of webpages collected from the Internet using software called a crawler. Crawlers automatically create a snapshot of webpages as they existed at a certain point in time. The WayBack Machine is an application using a crawler created by the Internet Archive to search its archive of Web page URLs and to represent, graphically, the date of each crawler capture. The Internet Archive captures data that is publicly accessible. Some sites are "not archived because they were password protected, blocked by robots.txt, or otherwise inaccessible to our automated systems. Site owners might

have also requested that their sites be excluded from the WayBack Machine.”¹⁹ Many Internet Archive captures made by the WayBack Machine have a banner at the top with the capture date prominently displayed. Other dates when captures of the same URL have been made are indicated to the right and left of the date provided in the banner. Some captures may lack this banner. In any case, the URL for the capture begins with the identification of the Internet Archive page (e.g., <http://web.archive.org/web/>) followed by information that dates and time stamps the capture as follows: year in yyyy, month in mm, day in dd, time code in hh:mm:ss (e.g., 20071120082013, or November 20, 2007 at 8:20:13 a.m.). These elements are then followed by the URL of the original capture site. When links are active, the WayBack Machine is programmed to produce the archived file with the closest available date (not the closest available prior date) to the page upon which the link appeared and was clicked. I and other librarian professionals are familiar with the Internet Archive and the Wayback Machine.²⁰

IV. PRELIMINARIES

35. *Scope of this declaration.* I am not an attorney and will not offer opinions on the law. I am, however, rendering my expert opinion on the

¹⁹ <https://help.archive.org/help/using-the-wayback-machine/>.

²⁰ For more information about the Internet Archive see the WayBack Machine FAQ, https://archive.org/about/faqs.php#The_Wayback_Machine.

authenticity of the documents referenced herein and when and how each of these documents was disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, could have located the documents before October 30, 2012.

36. I am informed by counsel that a printed publication qualifies as publicly accessible as of the date it was disseminated or otherwise made available such that a person interested in and ordinarily skilled in the relevant subject matter could locate it through the exercise of ordinary diligence.

37. While I understand that the determination of public accessibility under the foregoing standard rests on a case-by-case analysis of the facts particular to an individual publication, I also understand that a printed publication is rendered “publicly accessible” if it is cataloged and indexed by a library such that a person interested in the relevant subject matter could locate it exercising reasonable diligence (*i.e.*, I understand that cataloging and indexing by a library in a manner that permits a person of ordinary skill in the relevant subject matter to locate the publication is sufficient, though there are other ways that a printed publication may qualify as publicly accessible). One manner of sufficient indexing is indexing according to subject matter category. I understand that the cataloging and indexing by a single library of a single instance of a particular printed publication is sufficient, even if the single library is in a foreign country. I understand that, even

if access to a library is restricted, a printed publication that has been cataloged and indexed therein is publicly accessible so long as a presumption is raised that the portion of the public concerned with the relevant subject matter would know of the printed publication. I also understand that the cataloging and indexing of information that would guide a person interested in the relevant subject matter to the printed publication, such as the cataloging and indexing of an abstract for the printed publication, is sufficient to render the printed publication publicly accessible.

38. I understand that routine business practices, such as general library cataloging and indexing practices, can be used to establish an approximate date on which a printed publication became publicly accessible.

39. *Persons of ordinary skill in the art.* I am told by counsel that the subject matter of this proceeding relates generally to researching and analyzing data from devices used to monitor glycemic levels and/or other analytes in biological fluids, or in the development of methods, devices, or algorithms to generate alarms for hypoglycemia, impending hypoglycemia, hyperglycemia, impending hyperglycemia, metabolites or analytes, or other findings relevant to care of people with diabetes and/or other medical conditions.

40. I have been informed by counsel that a “person of ordinary skill in the art at the time of the invention” (POSITA) is a hypothetical person who is

presumed to be familiar with the relevant field and its literature at the time of the inventions. This hypothetical person is also a person of ordinary creativity, capable of understanding the scientific principles applicable to the pertinent field.

41. I am told by counsel that persons of ordinary skill in this subject matter or art would have had a Bachelor's degree in biomedical engineering, mathematics, statistics, or computer science (or a related or equivalent field), and two or more years of experience researching, developing, designing and/or evaluating (or supervising the same) medical devices for measuring analyte levels, e.g., analyte sensors, including at least some experience in researching, developing, designing and/or evaluating (or supervising the same) methods, systems, or algorithms for providing indicators (e.g., alerts, alarms or other indicators) of analyte levels to users, or equivalent experience. A person with less or different education but more relevant practical experience, or vice versa, may also meet this standard. Each of these POSITAs may be part of an interdisciplinary team with others having the relevant experience set forth above and/or with clinicians involved in diagnosing, treatment and patient management relevant to the use of medical devices for measuring analyte levels, e.g., analyte sensors.

42. It is my opinion that such a person would have been engaged in research, learning through study and practice in the field and possibly through formal instruction the bibliographic resources relevant to his or her research.

Before October 30, 2012, such a person would have had access to a vast array of long-established print resources in development of methods, devices, or algorithms to generate alarms for hypoglycemia, impending hypoglycemia, hyperglycemia, impending hyperglycemia, metabolites or analytes as well as to a rich set of online resources providing indexing information, abstracts, and full text services for development of methods, devices, or algorithms to generate alarms for hypoglycemia, impending hypoglycemia, hyperglycemia, impending hyperglycemia, metabolites or analytes references.

43. Based on my experience working in research libraries with researchers having the qualifications described above, or even lesser qualifications, it is my opinion that such researchers would have been able to locate the material discussed herein on their own or with the assistance of a research librarian with relative ease using the tools and resources described herein.

V. PUBLICATIONS

A. Document 1: Exhibit 1006 (“Guerra”)

44. Exhibit 1006 is a copy of the journal article “A Dynamic Risk Measure from Continuous Glucose Monitoring Data” by Stefania Guerra, Giovanni Sparacino, Andrea Facchinetti, Machele Schiavon, Chiara Dalla Man, and Claudio Cobelli (hereafter “Guerra”). The Guerra article was published in Volume 13, Number 8 of the journal *Diabetes Technology & Therapeutics* and was

found in the Indiana University South Bend Libraries (South Bend, Indiana). The Guerra article appears beginning on page 843 of this issue dated August 2011. Exhibit 1006 is a true and correct copy of the Guerra article (pages 843-852). Specifically, the text of the article is complete; no pages are missing, and the text on each page appears to flow seamlessly from one page to the next; further, there are no visible alterations to the document. The Guerra article is also available in the National Library of Medicine,²¹ from the publisher, Mary Ann Liebert,²² and in the digital repositories *ResearchGate*²³ and *Semantic Scholar*.²⁴ Exhibit 1006 was found within the custody of a library – a place where an authentic copy of this journal would likely be. Exhibit 1006 is a true and correct copy in a condition that creates no suspicion about its authenticity.

45. Attached hereto as Attachment 1A is a true and correct copy of the

²¹ <https://pubmed.ncbi.nlm.nih.gov/21561370/>

²² https://www.liebertpub.com/doi/10.1089/dia.2011.0006?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

²³

https://www.researchgate.net/publication/51116323_A_Dynamic_Risk_Measure_from_Continuous_Glucose_Monitoring_Data

²⁴ <https://www.semanticscholar.org/paper/A-dynamic-risk-measure-from-continuous-glucose-Guerra-Sparacino/431b2aba36bc3a56ece95c1d3a5d4a8512465976>

MARC record for the journal *Diabetes Technology & Therapeutics* at the Indiana University South Bend Libraries online catalog. Library ownership is indicated by the presence of the library's code ("IULA") in field 049. The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 1A occurred on September 28, 2007, as shown in field 005 ("20070928"). I personally identified and retrieved the MARC record that is Attachment 1A.

46. Based on finding a print copy of Exhibit 1006 in the Indiana University South Bend Libraries and MARC record in its online library catalog attached as Attachment 1A, it is my opinion that the Guerra article published in the journal *Diabetes Technology & Therapeutics* was publicly accessible on or shortly after July 13, 2011, as shown on the publisher's website and July 27, 2011, as shown on the second page of Exhibit 1006. Attachment 1A also shows that Exhibit 1006 was catalogued with five descriptor terms reading "Diabetes \$v Periodicals" (see Attachment 1B, Library of Congress subject heading sh2009123299), "Medical technology \$v Periodicals" (see Attachment 1C, Library of Congress subject heading sh2010101256), "Diabetes Mellitus \$x therapy \$v periodicals" (see Attachment 1D, National Library of Medicine subject heading D003920), "Blood Glucose Self-Monitoring \$v periodicals" (see Attachment 1E, National Library of Medicine subject heading D015190), and "Equipment and Supplies \$v

periodicals” (see Attachment 1F, National Library of Medicine subject heading D004864) in the 650 fields.

47. As noted in the holdings information (362 field), the Indiana University South Bend Libraries has received the journal *Diabetes Technology & Therapeutics* since 1999 and continues to receive the publication. In view of the MARC record for Exhibit 1006, the Guerra article was publicly accessible on or shortly after July 27, 2011, because the serial title had been received, cataloged, and indexed at the Indiana University South Bend Libraries and made part of its online catalog database.

48. Attached hereto as Attachment 1G is a true and correct copy of the MARC record for the journal *Diabetes Technology & Therapeutics* obtained from the OCLC bibliographic database. As previously noted, the library that created the record is recorded in field 040 with a unique library code. For Attachment 1G, that library code is “NSD,” which means that the MARC record for this serial was cataloged as part of the National Serials Data Program at the Library of Congress. As can be seen in the “Entered” field in the MARC record for this exhibit, a cataloger at the Library of Congress created OCLC record number 39624503 on July 31, 1998, as shown in the “Entered” field (“19980731”). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 1G occurred

on November 22, 2018, as shown in the “Replaced” field (“20181122”). I personally identified and retrieved the MARC record that is Attachment 1G. The “BLvl” entry in Attachment 2b is “s,” which indicates that the journal *Diabetes Technology & Therapeutics* is a serial publication. Field 310 of Attachment 1G reads “Bimonthly, \$b 2002-.” Accordingly, the MARC record for Exhibit 1006 corresponds to the journal *Diabetes Technology & Therapeutics* from the time the serial title began and includes the date of the Guerra article.

49. Attachment 1G includes an entry in field 050 (“RC660.A1 \$b.D528”)—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system) and an entry in field 060 (“W1 \$b DI168D”), a subject matter consistent with the National Library of Medicine classification system. Attachment 1G further includes five descriptor terms reading “Diabetes \$v Periodicals” (see Attachment 1B, Library of Congress subject heading sh2009123299), “Medical technology \$v Periodicals” (see Attachment 1C, Library of Congress subject heading sh2010101256), “Diabetes Mellitus \$x therapy \$v periodicals” (see Attachment 1D, National Library of Medicine subject heading D003920), “Blood Glucose Self-Monitoring \$v periodicals” (see Attachment 1E, National Library of Medicine subject heading D015190), and “Equipment and Supplies \$v periodicals” (see Attachment 1F, National Library of Medicine subject

heading D004864) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 1G was indexed according to its subject matter by virtue of at least three independently sufficient classifications: the field 050 entry, the field 060 entry, and the field 650 entries. As of July 31, 1998, the MARC record attached hereto as Attachment 1G was accessible through any library with access to the OCLC bibliographic database or the online catalog at a library that subscribed to the serial, which means that the corresponding publication was publicly accessible on or before that same date through any library with access to the OCLC bibliographic database or through an individual library.

50. Attachment 1G indicates that the journal *Diabetes Technology & Therapeutics* as cataloged at the Library of Congress is currently available from 52 libraries. In view of the above, this issue of the journal *Diabetes Technology & Therapeutics* was publicly accessible on or shortly after July 27, 2011, because by that date it had been cataloged and indexed at the Library of Congress, made part of the OCLC bibliographic database, and received at the Indiana University South Bend Libraries. For these reasons, it is my opinion that Exhibit 1006 was published and accessible to the public on or shortly after July 27, 2011.

B. Document 2: Exhibit 1008 (“DexCom”)

51. Attached hereto as Exhibit 1008 is a digital book, *DexCom*TM *STS*TM

Continuous Glucose Monitoring System: User's Guide, (hereafter “DexCom”) and issued by the firm DexCom, Inc. The DexCom book is identified as document LBL 9548 REV 03. I obtained the DexCom document from the Wayback Machine²⁵ and made the copies which comprise Exhibit 1008.²⁶ Specifically, the text of the DexCom document is complete; no pages are missing, and the text on each page appears to flow seamlessly from one page to the next; further, there are no visible alterations to the document. Exhibit 1008 was found within the custody of the issuing corporate entity – a place where, if authentic, a copy of this document would likely be.

52. The declaration prepared by Duncan Hall, Records Request Processor at the Internet Archive, indicates that the website on which the DexCom document can be found was available on October 23, 2007, and has been captured four times (Attachment 2A).

53. Based on the date recorded in the document, it is my opinion that the

²⁵

https://web.archive.org/web/20071023024953/http://www.dexcom.com/html/supp_ort_user_manuals.html

²⁶

<https://web.archive.org/web/20071009014038/http://www.dexcom.com/pdf/LBL9548rev03UsersGuide.pdf>

digital book *DexCom™ STS™ Continuous Glucose Monitoring System: User's Guide* was available to the public on October 23, 2007, or shortly thereafter.

C. Document 3: Exhibit 1011 (“Sparacino”)

54. Exhibit 1011 is a copy of the journal article “Glucose Concentration can be Predicted Ahead in Time from Continuous Glucose Monitoring Sensor Time-Series” by Giovanni Sparacino, Francesca Zanderigo, Stefano Corazza, Alberto Maran, Andrea Facchinetti, and Claudio Cobelli (hereafter “Sparacino”). The Sparacino article was published in Volume 54, Number 5 of the journal *IEEE Transactions on Bio-medical Engineering* and was found in the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). The Sparacino article appears beginning on page 931 of this issue dated May 2007. Exhibit 1011 is a true and correct copy of the Sparacino article (pages 931-937). I obtained this copy of the article from the Linda Hall Library of Science, Engineering & Technology. Specifically, the text of the column is complete; no pages are missing, and the text on each page appears to flow seamlessly from one page to the next; further, there are no visible alterations to the document. Exhibit 1011 was found within the custody of a library – a place where, if authentic, a copy of this journal would likely be. Exhibit 1011 are true and correct copies in a condition that creates no suspicion about its authenticity.

55. The cover of the May 2007 issue of the journal *IEEE Transactions on*

Bio-medical Engineering has a stamp which shows that it was received, verified, and checked in on May 2, 2007. Therefore, in my experience, this issue of the journal *IEEE Transactions on Bio-medical Engineering* would have been available to users at the Linda Hall Library of Science, Engineering & Technology on that date.

56. Attached hereto as Attachment 3A is a true and correct copy of the MARC record for the journal *IEEE Transactions on Bio-medical Engineering* at the Linda Hall Library of Science, Engineering & Technology. Library ownership is indicated by the presence of the library's code ("LHL") in the 049 field. The most recent enhancement to Attachment 3A occurred on September 6, 2023, as shown in field 005 ("20230906"). I personally identified and retrieved the MARC record that is Attachment 3A. Attachment 3A also shows that Exhibit 1011 was catalogued with three descriptor terms reading "Biomedical engineering \$v Periodicals" (see Attachment 3B, Library of Congress subject heading sh2007102015), "Medical electronics \$v Periodicals" (see Attachment 3C, Library of Congress subject heading sh2010101221), and "Medical physics \$v Periodicals" (see Attachment 3D, Library of Congress subject heading sh85083001 and Attachment 3E, Library of Congress subject heading sh85099890) in the 650 fields.

57. Based on finding a print copy of Exhibit 1011 in the Linda Hall

Library of Science, Engineering & Technology and MARC record in its online library catalog attached as Attachment 3A, it is my opinion that the Sparacino article published in the journal *IEEE Transactions on Bio-Medical Engineering* was available at the Linda Hall Library of Science, Engineering & Technology on May 2, 2007.

58. As noted in the holdings information (field 362), the Linda Hall Library of Science, Engineering & Technology has received the journal *IEEE Transactions on Bio-Medical Engineering* since publication began under the current title in 1964 and continues to receive the publication.²⁷ In view of the MARC record for Exhibit 1011, the Sparacino article was publicly accessible in print on May 2, 2007, because the serial title had been received, cataloged, and indexed at the Linda Hall Library of Science, Engineering & Technology and made part of its catalog.

59. Attached hereto as Attachment 3F is a true and correct copy of the

²⁷ The publication began under the title *Transactions of the IRE Professional Group on Medical Electronics* in January 1953, changed the title to the *IRE Transactions on Bio-Medical Electronics* in January 1955, and adopted the current title, *IEEE Transactions on Bio-Medical Engineering*, in January 1964.²⁸

https://journals.sagepub.com/doi/10.1177/193229681000400513?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

MARC record for the journal *IEEE Transactions on Bio-Medical Engineering* obtained from the OCLC bibliographic database. I personally identified and retrieved the MARC record that is Attachment 3F. As previously noted, the library that created the record is recorded in field 040 with a unique library code. For Attachment 3F, that library code is “DLC,” which means that the MARC record for this serial was cataloged at the Library of Congress. As can be seen in the “Entered” field in the MARC record for this exhibit, a cataloger at the Library of Congress created OCLC record number 1752544 on November 1, 1995. The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 4f occurred on April 21, 2021, as shown in the “Replaced” field (“20210421”). The “BLvl” entry in Attachment 3F is “s,” which indicates that the journal *IEEE Transactions on Bio-Medical Engineering* was a serial publication. Field 310 of Attachment 3F reads “Monthly, \$b <Jan. 1979-.” Accordingly, the MARC record for Exhibit 1011 corresponds to those issues of the journal *IEEE Transactions on Bio-Medical Engineering* during the time that the Sparacino article was published.

60. Attachment 3F further includes an entry in field 050 (“R895.A1 \$b I25”)—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system). Attachment 3F further includes an entry in field 060 (“W1

\$b I223”)—as described above, this includes a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system). Attachment 3F further includes three descriptor terms reading “Biomedical engineering \$v Periodicals” (see Attachment 3B, Library of Congress subject heading sh2007102015), “Medical electronics \$v Periodicals” (see Attachment 3C, Library of Congress subject heading sh2010101221), and “Medical physics \$v Periodicals” (see Attachment 3D, Library of Congress subject heading sh85083001 and Attachment 3E, Library of Congress subject heading sh85099890) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 3F was indexed according to its subject matter by virtue of at least three independently sufficient classifications: the field 050 entry, the field 060 entry, and the field 650 entries. Further, as of November 1, 1975, the MARC record attached hereto as Attachment 3F was accessible through any library with access to the OCLC bibliographic database or the online catalog at a library that subscribed to the serial, which means that the corresponding publication was publicly accessible on or before that same date through any library with access to the OCLC bibliographic database or through an individual library. Therefore, the Sparacino article was publicly accessible in print as early as May 2, 2007, because by that time it had been received, cataloged, and indexed at the Linda Hall Library

of Science, Engineering & Technology.

61. Attachment 3F indicates that the journal *IEEE Transactions on Bio-Medical Engineering* as cataloged at the Library of Congress is currently available from 436 libraries. In view of the above, this issue of the journal *IEEE Transactions on Bio-Medical Engineering* was publicly accessible in print on May 2, 2007, because by that date it had been cataloged and indexed at the Library of Congress, made part of the OCLC bibliographic database, and received at the Linda Hall Library of Science, Engineering & Technology. For these reasons, it is my opinion that Exhibit 1011 was published and accessible to the public on May 2, 2007.

D. Document 4: Exhibit 1007 (“Hughes”)

62. Exhibit 1007 is a copy of the journal article “Hypoglycemia Prevention via Pump Attenuation and Red-Yellow-Green "Traffic" Lights Using Continuous Glucose Monitoring Abstract and Insulin Pump Data” by Colleen S. Hughes, Stephen D. Patek, Marc D. Breton, and Boris P. Kovatchev (hereafter “Hughes”). The Hughes article was published in Volume 4, Issue 5 of the open access *Journal of Diabetes Science and Technology* and was found in the National Library of Medicine (Bethesda, Maryland). The Hughes article appears beginning on page 1146 of this issue dated September 2010. Exhibit 1007 is a true and correct copy of the Hughes article (pages 1146-1155). I obtained this copy of the

article from the National Library of Medicine. Specifically, the text of the column is complete; no pages are missing, and the text on each page appears to flow seamlessly from one page to the next; further, there are no visible alterations to the document. Exhibit 1007 was found within the custody of a library – a place where, if authentic, a copy of this open access journal would likely be. Exhibit 1007 are true and correct copies in a condition that creates no suspicion about its authenticity.

63. Open access serials are published online and do not have traditional covers. Publishers indicate a publication date on their websites. Therefore, in my experience, this issue of the open access *Journal of Diabetes Science and Technology* would have been available to users at the National Library of Medicine on September 1, 2010, as indicated on the Sage Journals website.²⁸

64. The Hughes article is also available through the National Library of Medicine²⁹ and the digital repository *ResearchGate*.³⁰

²⁸

https://journals.sagepub.com/doi/10.1177/193229681000400513?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed

²⁹ <https://pubmed.ncbi.nlm.nih.gov/20920434/>

³⁰

https://www.researchgate.net/publication/47335649_Hypoglycemia_Prevention_vi

65. Attached hereto as Attachment 4A is a true and correct copy of the MARC record for the open access *Journal of Diabetes Science and Technology* at the National Library of Medicine. Library ownership is indicated by the presence of the library's code ("DNLM") in the 935 field. The most recent enhancement to Attachment 4A occurred on February 9, 2024, as shown in field 005 ("20240209"). I personally identified and retrieved the MARC record that is Attachment 4A. Attachment 4A also shows that Exhibit 1007 was catalogued with a descriptor term reading "Diabetes Mellitus x| therapy v| Periodicals" (see Attachment 1D, National Library of Medicine subject heading D003920) in the 650 field.

66. Based on finding a digital copy of Exhibit 1007 in the National Library of Medicine and MARC record in its online library catalog attached as Attachment 4A, it is my opinion that the Hughes article published in the open access *Journal of Diabetes Science and Technology* was available at the National Library of Medicine on September 1, 2010.

67. As noted in the holdings information (field 362), the National Library of Medicine has received the open access *Journal of Diabetes Science and Technology* since publication began in January 2007 and continues to receive the

[a Pump Attenuation and Red-Yellow-Green Traffic Lights Using Continuous Glucose Monitoring and Insulin Pump Data](#)

publication. In view of the MARC record for Exhibit 1007, the Hughes article was publicly accessible in digital form on September 1, 2010, because the serial title had been received, cataloged, and indexed at the National Library of Medicine and made part of its catalog.

68. Attached hereto as Attachment 4B is a true and correct copy of the MARC record for the open access *Journal of Diabetes Science and Technology* obtained from the OCLC bibliographic database. I personally identified and retrieved the MARC record that is Attachment 4B. As previously noted, the library that created the record is recorded in field 040 with a unique library code. For Attachment 4B, that library code is “NSD,” which means that the MARC record for this serial was cataloged as part of the National Serials Data Program at the Library of Congress. As can be seen in the “Entered” field in the MARC record for this exhibit, a cataloger at the Library of Congress created OCLC record number 70140637 on June 20, 2006. The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 4B occurred on January 15, 2024, as shown in the “Replaced” field (“20240115”). The “BLvl” entry in Attachment 4B is “s,” which indicates that the open access *Journal of Diabetes Science and Technology* was a serial publication. Field 310 of Attachment 4B reads “Bimonthly.” Accordingly, the MARC record for Exhibit 1007 corresponds to those issues of the

open access *Journal of Diabetes Science and Technology* during the time that the Hughes article was published.

69. Attachment 4B further includes an entry in field 050 (“RC60.A1”)—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 (“W1”)—as described above, this includes a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system), and an entry in field 082 (“616”)—as described above, this includes a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 4B further includes two descriptor terms reading “Diabetes \$v Periodicals” (see Attachment 1B, Library of Congress subject heading sh2009123299) and “Medical technology \$v Periodicals” (see Attachment 1C, Library of Congress subject heading sh2010101256) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 4B was indexed according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry, and the field 650 entries. Further, as of June 20, 2006, the MARC record attached hereto as Attachment 4B was accessible through any library with access to the OCLC bibliographic database or the online catalog at a

library that subscribed to the open access serial, which means that the corresponding publication was publicly accessible on or before that same date through any library with access to the OCLC bibliographic database or through an individual library. Therefore, the Hughes article was publicly accessible in digital form as early as September 1, 2010, because by that time it had been received, cataloged, and indexed at the National Library of Medicine.

70. Attachment 4B indicates that the open access *Journal of Diabetes Science and Technology* as cataloged at the Library of Congress is currently available from 655 libraries. In view of the above, this issue of the open access *Journal of Diabetes Science and Technology* was publicly accessible on September 1, 2010, because by that date it had been cataloged and indexed at the Library of Congress, made part of the OCLC bibliographic database, and received at the National Library of Medicine. For these reasons, it is my opinion that Exhibit 1007 was published and accessible to the public on September 1, 2010.

E. Document 5: Exhibit 1010 (“Navigator Guide”)

71. Attached hereto as Exhibit 1010 is a digital book, *FreeStyle Navigator® Guide Continuous Glucose Monitoring System User's Guide*, (hereafter “Navigator Guide”) and issued by the firm Abbott Diabetes Care, Inc. The Abbott book is identified as document ART 16072 Rev. A and a May 2008 date, which is printed on the back cover (“05/08”).

72. I downloaded the Abbott document from the Wayback Machine³¹ and made the copies which comprise Exhibit 1010. The WayBack Machine indicates that Navigator Guide was posted on December 16, 2010. Specifically, the text of Navigator Guide is complete; no pages are missing, and the text on each page appears to flow seamlessly from one page to the next; further, there are no visible alterations to the document. Exhibit 1010 was found within the custody of the issuing corporate entity – a place where, if authentic, a copy of this document would likely be.

73. Further supporting my opinion that the Navigator Guide was available to the public is an affidavit prepared by Nathaniel E. Frank-White, Records Request Processor for the Internet Archive (Attachment 5). Mr. Frank-White provides the URL for the Navigator Guide which was captured by the WayBack Machine on December 16, 2010, at 3:05:36 a.m. (Exhibit B, page 4). The information in his affidavit supports the description of the Internet Archive and the WayBack Machine (see ¶ 32-34).

74. Based on the date recorded in the document, it is my opinion that the digital book *FreeStyle Navigator® Guide Continuous Glucose Monitoring System*

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https://web.archive.org/web/20101216030536/http://freestylenavigator.com/static/cms_workspace/document/FSN-User-Guide-ART16072_Rev-A-Web.pdf

User's Guide was accessible to the public at least by December 16, 2010.

VI. SUMMARY OF OPINIONS

75. In view of the foregoing, it is my opinion that the publications described above were publicly accessible at least by the corresponding date listed in the table below:

Document	Publication	Publicly Accessible
Exhibit 1006	Guerra, Stefania, Giovanni Sparacino, Andrea Facchinetti, Machele Schiavon, Chiara Dalla Man, and Claudio Cobelli. "A Dynamic Risk Measure from Continuous Glucose Monitoring Data." <i>Diabetes Technology & Therapeutics</i> , vol. 13, no. 8 (August 2011): 843-852.	July 27, 2011
Exhibit 1008	DexCom, Inc. <i>DexCom™ STS™ Continuous Glucose Monitoring System: User's Guide. LBL 9548 REV 03</i> . San Diego, CA: DexCom, c2006.	October 23, 2007
Exhibit 1011	Sparacino, Giovanni, Francesca Zanderigo, Stefano Corazza, Alberto Maran, Andrea Facchinetti, and Claudio Cobelli. "Glucose Concentration can be Predicted Ahead in Time from Continuous Glucose Monitoring Sensor Time-Series." <i>IEEE Transactions on Biomedical Engineering</i> , vol. 54, no. 5 (May 2007): 931-937.	May 2, 2007
Exhibit 1007	Hughes, Colleen S., Stephen D. Patek, Marc D. Breton, and Boris P. Kovatchev. "Hypoglycemia Prevention via Pump Attenuation and Red-Yellow-Green "Traffic" Lights Using Continuous Glucose Monitoring Abstract and Insulin Pump Data." <i>Journal of Diabetes Science and Technology</i> , vol. 4, issue 5 (September 2010): 1146-1155.	September 1, 2010
Exhibit 1010	<i>FreeStyle Navigator Guide Continuous Glucose Monitoring System User's Guide. ART 16072 Rev. A</i> . Alameda, CA: Abbott Diabetes Care, Inc., c2008.	December 16, 2010

73. In signing this Declaration, I recognize that the Declaration will be filed as evidence in a case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in the case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

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

DATED: April 24, 2024

By: 
Sylvia D. Hall-Ellis, Ph.D.

Exhibit B

76. In signing this Declaration, I recognize that the Declaration will be filed as evidence in a case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in the case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

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

DATED: June 11, 2024

By:


Sylvia D. Hall-Ellis, Ph.D.

ATTACHMENT C

Byun, Hyun

From: Trials <Trials@USPTO.GOV>
Sent: Thursday, July 18, 2024 11:44 AM
To: Chen, Peter; Trials
Cc: Rich Giunta; Elisabeth.Hunt@WolfGreenfield.com; Weidenfeller, Scott; Garr, David
Subject: RE: IPR2024-00840

[EXTERNAL]

Counsel,

From the Board –

Rule 42.104(c) preauthorizes a petitioner to file a motion to correct clerical or typographical errors; prior authorization from the Board is not required. Although it may be possible to interpret Petitioner's e-mail as a motion under Rule 42.104, the email is not of record. Petitioner is directed to Rules 42.20 and 42.22, which govern the filing of motions for relief. Accordingly, Petitioner should file a motion as set forth under Rules 42.20, 42.22, and 42.104(c). In that motion Petitioner should expressly state whether Patent Owner opposes the motion.

Regards,

Esther Goldschlager
Supervisory Paralegal Specialist
Patent Trial & Appeal Board
U.S. Patent & Trademark Office

From: Chen, Peter <pchen@cov.com>
Sent: Tuesday, July 16, 2024 7:31 PM
To: Trials <Trials@USPTO.GOV>
Cc: Rich Giunta <Rich.Giunta@WolfGreenfield.com>; Elisabeth.Hunt@WolfGreenfield.com; Weidenfeller, Scott <SWeidenfeller@cov.com>; Garr, David <dgarr@cov.com>
Subject: IPR2024-00840

CAUTION: This email has originated from a source outside of USPTO. **PLEASE CONSIDER THE SOURCE** before responding, clicking on links, or opening attachments.

Dear Honorable Board:

Pursuant to 37 C.F.R. § 42.104(c), Petitioner Abbott Diabetes Care Inc. respectfully requests authorization to correct clerical errors in its petition for inter partes review without changing the filing date of the petition. Specifically, Petitioner has noted certain clerical (typographical) errors in its petition for inter partes review filed in IPR2024-00840 and in an accompanying declaration, and seeks to file revised papers correcting these errors under 37 C.F.R. § 42.104(c). Petitioner has met and conferred with Patent Owner, and Patent Owner does not oppose Petitioner's request.

In particular, in the Petition, references to three cites to the Hall-Ellis Declaration (Ex. 1027) were mis-numbered by one paragraph; and in the Hall-Ellis Declaration, two paragraph numbers were mis-numbered by three paragraphs. For the convenience of the Board, attached is a redline showing the corrections to the petition. Also attached is a July 6, 2024, declaration of Dr. Hall-Ellis regarding the correction of the two

paragraph numbers in her declaration that is Ex. 1027. Accordingly, Petitioner respectfully requests the Board to authorize Petitioner to file a revised petition, along with the July 6 declaration of Dr. Hall-Ellis as a new exhibit.

Thank you,

- Peter Chen
Lead Counsel for Petitioner

Peter Chen

Covington & Burling LLP
3000 El Camino Real, 5 Palo Alto Square, 10th Floor
Palo Alto, CA 94306-2112
T +1 650 632 4720 | pchen@cov.com
www.cov.com

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