

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT DIABETES CARE INC. and	)	
ABBOTT DIABETES CARE LIMITED,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 21-977 (KAJ)
	)	
DEXCOM, INC.,	)	
	)	
Defendant.	)	
	)	

EXPERT DECLARATION OF MAJID SARRAFZADEH, Ph.D., IN SUPPORT OF
ABBOTT’S OPENING CLAIM CONSTRUCTION BRIEF

TABLE OF CONTENTS

I. INTRODUCTION 1

II. QUALIFICATIONS 1

III. SCOPE OF OPINIONS AND MATERIALS CONSIDERED 4

IV. BASIC LEGAL PRINCIPLES 6

V. QUALIFICATIONS OF ONE OF ORDINARY SKILL IN THE ART 7

VI. OPINIONS..... 8

 A. Background of the Inventions..... 8

 B. Constructions of the Disputed Claim Terms..... 16

 1. “processing . . . the sensor data,” “processing the sensor data,”
 “process the sensor data” (842 patent)..... 16

 2. “data indicative of the sensed glucose level” (653 patent) 19

 3. “failure mode condition” (842 and 653 patents)..... 20

VII. CONCLUSION..... 28

I. INTRODUCTION

I, Majid Sarrafzadeh, declare as follows:

1. My full name is Majid Sarrafzadeh, and I reside at 448 Isabella Terrace, Corona Del Mar, California, 92625.

2. I understand that Abbott Diabetes Care Inc. and Abbott Diabetes Care Limited (collectively, “Abbott”) sued DexCom, Inc. (“DexCom”) for patent infringement. Abbott retained me through their attorneys as a technical expert in this case.

3. I have been asked to provide my opinions regarding the interpretation of certain claim terms in U.S. Patent Nos. 10,820,842 (“842 patent”) and 10,952,653 (“653 patent”).

4. I am over the age of 18 and am competent to write this declaration. I have personal knowledge, or have developed knowledge, of the technologies in these patents based upon my education, training, or experience.

5. I am being compensated at my usual and customary rate of \$700 per hour, including reasonable expenses. My compensation in no way depends on the content of my opinions or on the outcome of this litigation, and I have no financial interest in this case.

II. QUALIFICATIONS

6. I have summarized in this section my educational background, career history, publications, and other relevant qualifications for forming the opinions expressed in this declaration. A more detailed account of my work experience, qualifications, and publications is included in my curriculum vitae, attached as Exhibit A to this declaration.

7. I am currently a Distinguished Professor of Computer Science & Electrical and Computer Engineering at UCLA and have been a Full Professor for the last twenty-three years. I am also the Director of the UCLA eHealth Research Laboratory (“ER Lab”), a co-founder of the

UCLA Center for SMART Health, a co-director of the BRITE Center on Minority Health Disparities, and a co-founder of UCLA Wireless Health Institute.

8. I earned Bachelor of Science, Master of Science, and Ph.D. degrees from the University of Illinois at Urbana-Champaign in Electrical and Computer Engineering in 1982, 1984, and 1987, respectively.

9. I became an Assistant Professor of Electrical and Computer Engineering at Northwestern University in 1987, earned tenure in 1993, and became a Full Professor in 1997.

10. In 2000, I joined the Computer Science Department at UCLA as a Full Professor. In 2008, I co-founded and became a director of the UCLA Wireless Health Institute. I currently teach two core undergraduate courses (involving implementing digital logic designs and advanced digital design techniques), a course on Algorithms and Complexity, and a series of graduate courses in the area of embedded systems and Digital Health. Digital health includes problems related to interactive medical systems and often requires wireless transmission and detection of signals.

11. I have experience as a system designer, circuit designer, and software designer. This experience includes positions as a design engineer at IBM and Motorola and a test engineer at Central Data Corporation. I was the main architect of an Electronic Design Automation (“EDA”) software tool for Monterey Design Systems, Inc. (“Monterey”). I co-founded and co-managed the technical team at Hierarchical Design, Inc. (“Hier Design”), an EDA company that specialized in reconfigurable Field-Programmable Gate Array (FPGA) systems. Hier Design was acquired by Xilinx in 2004. I have co-founded three companies in the area of digital health and remote health monitoring: MediSens Wireless, Bruin Biometrics, and WANDA Health.

12. I am a Fellow of the Institute of Electrical and Electronics Engineers, Inc. (“IEEE”). “IEEE Fellow is a distinction reserved for select IEEE members whose extraordinary accomplishments in any of the IEEE fields of interest are deemed fitting of this prestigious grade elevation.”

13. I received Time Magazine’s Best Inventions of 2020 award for the work related to interactive and non-invasive physiological monitoring.

14. I was elected as a fellow in the National Academy of Inventors. The fellow award states that I have “demonstrated a highly prolific spirit of innovation in creating or facilitating outstanding inventions that have made a tangible impact on the quality of life, economic development, and welfare of society.”

15. I have served on the technical program committees of numerous conferences in the area of system design. I co-founded the International Conference on Wireless Health and have served in various committees of this conference.

16. I have performed research in the area of wired and wireless physiological monitoring devices including handling of missing and corrupt data. More information can be found in the attached CV (Exhibit A).

17. I am a co-author of several books, including “*Synthesis Techniques and Optimizations for Reconfigurable Systems*” (2003 by Springer). I have published approximately 580 papers, and I am a named inventor on 25+ patents. Many of these articles and patents are related to interactive physiological monitoring systems and deal with wireless signal transmission and detection, such as:

- Rofouei et al., “*Your Phone or Mine? Fusing Body, Touch and Device Sensing for Multi-User Device-Display Interaction,*” CHI in the field of Human-Computer Interaction (HCI) (2012).

- Kachuee, et al., “*Generative Imputation and Stochastic Prediction*,” IEEE Transactions on Pattern Analysis and Machine Intelligence (TPAMI), 2020.
- Sarrafzadeh et al., “*Missing Data Imputation for Remote CHF Patient Monitoring Systems*,” 33rd Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC’11), Boston, MA, USA, (08/30/2011).
- Jafari et al., “*CustoMed: A Power Optimized Customizable and Mobile Medical Monitoring and Analysis System*,” Proceedings of the ACM HCI Challenges in Health Assessment Workshop in conjunction with Computer Human Interaction (CHI) Portland, OR (April 2005).
- Sarrafzadeh et al., “*Apparatus, Systems, and Methods for Tissue Oximetry and Perfusion Imaging*,” EP2665417A2 (2011).
- Hosseini, et al., “*Feasibility of a Secure Wireless Sensing Smartwatch Application for the Self-Management of Pediatric Asthma*,” Sensors (2017).
- Evangelista et al., “*Predicting Adherence to Use of Remote Health Monitoring Systems in a Cohort of Patients with Chronic Heart Failure*,” Technology and Health Care, 16-466-R (2016).
- Mortazavi et al., “*Context-Aware Data Processing to Enhance Quality of Measurements in Wireless Health Systems: An Application to MET Calculation of Exergaming Actions*,” IEEE Internet of Things Journal (2014).
- Nahapetian et al., “*Wireless Body Sensor Enhanced Tracking for Extended In-Home Care*,” Workshop on Wireless Sensor Networks for Health Care (WSNHC) (June 2007).
- Wang et al., “*A Wireless Biomedical Handheld Instrument for Evidence-Based Detection of Pressure Ulcers*,” Wireless Health (2011).

III. SCOPE OF OPINIONS AND MATERIALS CONSIDERED

18. I understand from counsel that Abbott asserts that DexCom infringes the following claims from the 842 and 653 patents:

Patent	Asserted Claims
842 patent:	claims 1, 2, 3, 6, 8, 10, 14, 15, 17, and 19
653 patent:	claims 1, 3, 5, 6, 7, 8, 11, 15, and 18

19. I understand that the following claim terms from these patents are in dispute:

Patent	Claim Term
842 patent:	<i>“processing . . . the sensor data”</i>
	<i>“processing the sensor data”</i>
	<i>“process the sensor data”</i>
653 patent:	<i>“data indicative of the sensed glucose level”</i>
842 & 653 patents:	<i>“failure mode condition”</i>

20. I have been asked to provide my opinions regarding the qualifications of persons of ordinary skill in the art (“POSITA”) for the 842 and 653 patents and how a POSITA would understand the disputed claim terms at the time of the invention.

21. I understand that the 653 patent is a continuation of the 842 patent, and that both patents claim priority to U.S. Provisional Application No. 61/173,600 (“600 Provisional”). I understand from counsel that Abbott contends the inventor of the 842 and 653 patents, Wesley Scott Harper, conceived the inventions disclosed and claimed in the 842 and 653 patents by August 14, 2007, and then diligently pursued the inventions until the 600 Provisional application was filed on April 29, 2009. Thus, I understand from counsel that Abbott contends the asserted claims are entitled to a priority date of August 14, 2007. I have presumed this date in my analysis, but my opinions would not change regardless of which priority date the patents are entitled to.

22. In forming my opinions, I considered:

- The 842 and 653 patents and their file histories;
- U.S. Provisional Application No. 61/173,600;
- The file histories for related patents, including U.S. Patent Nos. 8,483,967; 9,310,230; 10,194,844; 11,013,431; 11,116,431; and 11,298,056;
- The parties’ claim construction disclosures and Joint Claim Construction Chart; and
- Any other material or resource referenced in this declaration.

IV. BASIC LEGAL PRINCIPLES

23. I am neither a lawyer nor an expert in patent law. Instead, I have been informed by counsel of certain legal principles under U.S. patent law that govern claim construction. I have applied these principles in forming my opinions expressed herein.

24. I understand that claim construction is a process by which a court determines, as a matter of law, the scope and meaning of terms used in the claims of a patent. I understand that the goal of this process is to give claim terms their ordinary and customary meaning as would be understood by a POSITA at the time of the invention after reading the entire patent and its prosecution history.

25. I understand that courts primarily consider intrinsic evidence when determining the meaning of a claim term. I understand that intrinsic evidence includes the claims themselves, the specification, and the prosecution history of the patent, including prior art that was considered by the Patent Office examiner. I understand that intrinsic evidence also includes related patents and applications and their prosecution histories.

26. I understand that claims are to be construed as written, and should not be rewritten through interpretation. I understand that some claim terms may need no construction because the terms are easily understood by a POSITA. I understand that the knowledge, education, and experience of a POSITA are relevant to determining the scope and meaning of a patent claim.

27. I understand that a principal consideration of claim construction is the plain language of the claims. I understand that, even when an isolated term is disputed, the surrounding claim language and the full context of the claim must be considered. I understand that claim terms should not be construed to render claim language superfluous.

28. I understand that claims are to be read in light of the specification. I understand that the specification of a patent is the best guide to understanding disputed claim terms, beyond the

wording of the claims themselves. I understand that the use of a disputed term in the specification and in the claims of the patent can be informative because terms are normally used consistently throughout a patent. I understand that, unless an inventor shows a clear intent to limit their invention, particular examples or embodiments discussed in the specification are not to be read into the claims as limitations.

29. I understand that the prosecution history of a patent can inform the meaning of a claim term because it demonstrates how the inventor and the Patent Office examiner understood the claims during the course of prosecution.

30. I understand that there are two primary circumstances when a claim term may not be given its ordinary and customary meaning. I understand that one circumstance is when the inventor acts as a lexicographer by clearly and unambiguously setting forth a definition of a claim term that may differ from the ordinary and customary meaning it would otherwise have. I understand that another circumstance is when the inventor clearly and unmistakably disclaims or disavows claim scope during prosecution.

31. I understand that extrinsic evidence, which includes all evidence external to the intrinsic evidence such as expert and inventor testimony, dictionaries, textbooks, and learned treatises, may also be considered but may not be used to contradict or override the intrinsic evidence.

V. QUALIFICATIONS OF ONE OF ORDINARY SKILL IN THE ART

32. I understand that a hypothetical POSITA is considered to have the normal skills and knowledge of a person in a certain technical field, as of the time of the invention at issue. I understand that factors that may be considered in determining the level of ordinary skill in the art include: (1) the education level of the inventor; (2) the types of problems encountered in the art;

(3) the prior art solutions to those problems; (4) the rapidity with which innovations are made; (5) the sophistication of the technology; and (6) the education level of active workers in the field.

33. With respect to the 842 and 653 patents, in my opinion, a POSITA would have at least a bachelor's degree in biomedical engineering, electrical engineering, computer engineering, computer science or a related field, and 2 or more years of experience developing or designing wireless-based physiological monitoring systems. Less experience can be offset by a higher level of education and vice versa.

34. The POSITA may be part of an interdisciplinary team with others having relevant experience in the areas set forth above and/or with clinicians involved in diagnosis, treatment, and patient management relevant to the use of medical devices for measuring analyte levels, e.g., analyte sensors.

VI. OPINIONS

A. Background of the Inventions

35. The inventions of the 842 and 653 patents are generally related to analyte (e.g., glucose) monitoring systems that are able to provide patients with information about analyte concentrations even when there is a failure mode condition in the system.

36. The 842 patent was filed on July 18, 2020. The face of the patent indicates that it is a continuation of U.S. Patent No. 10,194,844, which is a continuation of U.S. Patent No. 9,310,230, which is a continuation of U.S. Patent No. 8,483,967. The 842 patent also makes a claim of priority to U.S. Provisional Application No. 61/173,600.

37. The 653 patent was filed on October 8, 2020. The face of the 653 patent indicates that it is a continuation of the 842 patent and the other patents mentioned above with respect to the 842 patent. The 653 patent also makes a claim of priority to U.S. Provisional Application No. 61/173,600.

98. DexCom's proposed construction is also puzzling because it does not specify what "disabl[es]" the output of sensor data. The claims recite several different components in the system, but do not use the words "disable" or "disabling." Therefore, it is unclear which component is doing the "disabling" under DexCom's construction.

99. Another reason why I find DexCom's proposed construction to be incorrect is because neither the claims nor the specification are limited to outputting a data gap only by "disabling the output of sensor data." The claims clearly do not call for this. Instead, they state that the failure mode condition "**causes** one or more sensor data gaps to be outputted to the display." While disabling the output of sensor data may be one manner in which a data gap can be displayed, there are other causes as well, such as when there is no sensor data to display in the first place.

100. This is provided for in the specification. For example, the specification explains that "gaps in monitored analyte levels" can be "due to" various conditions. (Ex. 8, 842 patent at 13:19-27.) This broad language makes it clear that various conditions can **cause** "gaps in monitored analyte levels." It does not require disabling the output of sensor data.

101. The specification further explains that the various conditions include "any other variables or parameters **that result in the inability** of the analyte monitoring system **to display or output** the real-time monitored analyte levels." The inability to display data does not require the system to actively disable the output of the data.

102. The specification provides another example in the context of a calibration failure. In such event, "the receiver unit may no longer display the monitored and processed glucose information." (Ex. 8, 842 patent at 11:16-18.)

103. Other examples also indicate why "disabling the output of sensor data" is not the only manner in which a data gap can appear. One example failure mode condition is "signal errors

associated with the sensor, transmitter unit, receiver unit, and the like.” (Ex. 8, 842 patent at 13:23-24.) Such errors can occur, for example, when the transmitter unit and the receiver unit are unable to communicate accurate data (e.g., out of range, environmental interference, etc.). During such a failure mode condition, the receiver unit would not have received the processed sensor data and would therefore be “unable” to display the data.

104. Therefore, in my opinion, DexCom’s proposed construction is also incorrect because it imposes limitations on the manner in which data gaps can be displayed (while leaving “failure mode condition” untouched), yet neither the specification nor the claims require such a limitation.

VII. CONCLUSION

105. I reserve the right to adjust or supplement my opinions in light of additional information that may be brought to my attention. I also reserve the right to adjust or supplement my analysis in light of any critique of my declaration or alternative opinions advanced by or behalf of DexCom.

Executed this 13th of July, 2022 at Corona Del Mar, CA.

A handwritten signature in black ink, appearing to read 'M. Sarrafzadeh', written in a cursive style.

Majid Sarrafzadeh, Ph.D.