## UNITED STATES PATENT AND TRADEMARK OFFICE

\_\_\_\_\_

### BEFORE THE PATENT TRIAL AND APPEAL BOARD

\_\_\_\_\_

ABBOTT DIABETES CARE INC.,
Petitioner

v.

DEXCOM, INC., Patent Owner.

\_\_\_\_\_

Case: IPR2022-00917

Patent 10,980,452

\_\_\_\_\_

DECLARATION OF JOHN L. SMITH, PH.D. IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S. PAT. NO. 10,980,452



## TABLE OF CONTENTS

I.	INTRODUCTION		
II.	QUALIFICATIONS		
III.	UNDERSTANDING OF APPLICABLE LEGAL STANDARDS5		
IV.	TECHNOLOGY BACKGROUND		7
	A.	Background of Continuous Glucose Monitor Sensors	8
	B.	Electrochemistry Background	10
	C.	Calibration Background	12
V.	THE 452 PATENT		13
	A.	Calibration Using Reference Measurements	13
	B.	Priority Claims and Prosecution History	14
VI.	LEV	LEVEL OF ORDINARY SKILL IN THE ART14	
VII.	OTHER OPINIONS RELIED ON		
VIII.	PRIOR ART RELIED ON IN PETITION		
	A.	References Relied on by Mr. Leinsing	16
	B.	Gross (EX1024)	20
	C.	The Subject Prior Art Is Analogous	28
	D.	A POSITA's Knowledge of Using Predictive Relationships Betwee In Vitro and In Vivo Sensor Sensitivities to Calibrate Sensor Data Disclosed by Gross	as
IX.	CLA	CLAIM CONSTRUCTION	
X.	THE PREDICTIVE RELATIONSHIP ELEMENT OF DEPENDENT CLAIM 18 WOULD HAVE BEEN OBVIOUS TO A POSITA3		
	A.	Petitioned Grounds and Claim 18	31
	B.	Motivation to Combine with Gross	33
	C.	Gross Teaches the Predictive Relationship Element of Claim 18	36
XI.	SECONDARY CONSIDERATIONS41		
XII.	CONCLUSION41		



### I. INTRODUCTION

- 1. I submit this declaration in support of a Petition for *Inter Partes* Review of U.S. Patent No. 10,980,452 (the "452 Patent"), owned by DexCom, Inc. ("DexCom"). I have been retained in this matter by counsel for Abbott Diabetes Care Inc. ("Petitioner").
- 2. Although I am being compensated for my time at my customary rate of \$400 per hour in preparing this declaration, the opinions herein are my own, and I have no stake in the outcome of the review proceedings. My compensation does not depend in any way on the outcome of the Petition.
- 3. The materials I considered in forming my opinions herein have included at least the 452 Patent (Exhibit 1001) and its prosecution history (Exhibit 1002), as well as certain other exhibits submitted with IPR2022-00917, including the following:
  - Exhibit 1001: U.S. Patent No. 10,980,542 ("452 Patent")
  - Exhibit 1003: Declaration of Karl R. Leinsing, MSME, PE in Support of *Inter Partes* Review of U.S. Patent No. 10,980,452
  - Exhibit 1002: Prosecution File History of the 452 Patent
  - Exhibit 1024: U.S. Patent No. 6,275,717 ("Gross")
  - Exhibit 1030: Spichiger-Keller, Ursula E., CHEMICAL SENSORS AND BIOSENSORS FOR MEDICAL AND BIOLOGICAL APPLICATIONS, Chapter 20, *In vivo chemical sensors and biosensors in clinical medicine*, by Denzil J. Claremont and John C. Pickup (pp. 356-376) (1998) ("Spichiger-Keller")



4. I also relied on my considerable experience with glucose monitoring systems and devices.

## II. QUALIFICATIONS

- 5. I am a consultant in the areas of analytical chemistry, clinical chemistry, blood glucose monitoring, and non-invasive blood measurements. I hold a Bachelor of Science degree in chemistry from Butler University and a Ph.D. in analytical chemistry from the University of Illinois.
- 6. I have over 55 years of experience with electrochemical analytical instruments and systems; 34 of those years have been spent in the blood glucose monitoring field. My work includes development of novel electrochemical instrumentation, development of automated clinical laboratory instrumentation, research and development, including for blood glucose meters and test strips, development of transcutaneous intravascular glucose measurement systems, and development of noninvasive glucose measurement systems.
- 7. I have consulted for more than 50 companies in the field of blood glucose monitoring or their investors, including LifeScan, Inc., TheraSense, Insulet, Masimo Corporation, and Cercacor Laboratories.
- 8. At the LifeScan division of Johnson & Johnson, I was employed for twelve years in the positions of Vice President of Research, Development, and Engineering (R, D & E), Worldwide Vice President of R, D & E, and Chief Scientific



Officer. Prior to that time, I had been employed as a Senior Applications Chemist and Manager of Product Development for electrochemical instrumentation at Princeton Applied Research, and as a Staff Systems Engineer and Director of Decentralized Testing at Technicon Instruments Corporation. Throughout my career, I have worked closely with numerous technicians, engineers, and scientists employed at all levels by technical organizations and who were persons of ordinary skill in the art, as I explain below.

- 9. I hold seventeen issued United States patents (most with foreign counterparts) and five additional published United States patent applications. Eleven of the aforementioned issued patents relate to glucose monitoring, four relate to clinical laboratory instrumentation, and two relate to novel electrochemical instrumentation. I have authored publications in refereed journals and a manuscript entitled "The Pursuit of Noninvasive Glucose: Hunting the Deceitful Turkey," 8th Edition: Revised and Expanded, 2022.
- 10. The full details of my education, employment, and consulting history are in my curriculum vitae, attached hereto as Appendix A (also filed as Exhibit 1044).
- 11. As detailed in Appendix A, I have participated as an expert witness in patent infringement litigation, including consulting, expert reports, depositions and court testimony in *Markman* hearings, arbitrations, bench trials, and jury trials in



# DOCKET

# Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

# **Real-Time Litigation Alerts**



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## **Advanced Docket Research**



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## **Analytics At Your Fingertips**



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

#### API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

#### **LAW FIRMS**

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

#### **FINANCIAL INSTITUTIONS**

Litigation and bankruptcy checks for companies and debtors.

### **E-DISCOVERY AND LEGAL VENDORS**

Sync your system to PACER to automate legal marketing.

