

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

IPR2023-01409
U.S. Patent No. 11,202,591

DECLARATION OF MUNG CONWAY

DEXCOM EXHIBIT 1055 <i>Dexcom v. Abbott Diabetes</i> IPR2023-01409
--

I, Mung Conway, hereby declare:

1. I am a paralegal with the law firm of Klarquist Sparkman, LLP (“Klarquist”), counsel for Petitioner DexCom, Inc. This declaration relates to evidence served with Petitioner’s Reply to Patent Owner’s Response in IPR2023-01409.

2. I have personal knowledge of the matters described herein unless otherwise indicated, and if called to testify, I could and would testify competently thereto.

3. The facts set forth in this declaration are known to me personally or are based upon the information I obtained on the websites referenced below, which are facts I believe to be true.

4. EX1046 filed concurrently herewith is a true and correct copy of the Abbott FreeStyle Navigator Continuous Glucose Monitoring System User’s Guide dated 05/08.

5. EX1047 filed concurrently herewith is a true and correct copy of an article titled *A new device for assessing changes in skin viscoelasticity using indentation and optical measurement* by Neil T. Clancy, Gert E. Nilsson, Chris D. Anderson, and Martin J. Leahy from *Skin Research and Technology* (2010), Vol. 16, Issue 2, pp. 210-228 that I accessed and downloaded from Washington State University Library’s electronic databases on October 21, 2024 at

https://searchit.libraries.wsu.edu/discovery/fulldisplay?docid=cdi_swepub_primary_oai_DiVA_org_liu_55048&context=PC&vid=01ALLIANCE_WSU:WSUV&lang=en&search_scope=WSU_everything&adaptor=Primo%20Central.

6. EX1048 filed concurrently herewith is a true and correct copy of an article titled *Skin blood flow changes and tissue deformations produced by cylindrical indentors* by Alvin H. Sacks, Ph.D., Hugh O'Neill, B.S., and Inder Perakash, M.D. from the *Journal of Rehabilitation Research and Development* (1985), Vol. 22, No. 3, BPR 10-42, pp. 1-6 that I accessed and downloaded from Washington State University Library's electronic databases on October 22, 2024 at

https://searchit.libraries.wsu.edu/discovery/fulldisplay?docid=cdi_proquest_miscellaneous_76649438&context=PC&vid=01ALLIANCE_WSU:WSUV&lang=en&search_scope=WSU_everything&adaptor=Primo%20Central&tab=default_tab&query=any,contains,%22Skin%20blood%20flow%20changes%20and%20tissue%20deformations%20produced%20by%20cylindrical%20indentors%22&offset=0, also available at <https://www.rehab.research.va.gov/jour/85/22/3/pdf/sacks.pdf>.

7. EX1050 filed concurrently herewith is a true and correct copy of Cleo™90 Infusion Set Training Guide ©2005 as captured by the Wayback Machine on May 10, 2006, which I accessed and downloaded on October 21, 2024, from

<https://web.archive.org/web/20060510201801/http://www.cleoinfusionsets.com/fileUpload/19742.pdf>.

8. EX1051 filed concurrently herewith is a true and correct copy of pages excerpted from the FDA file for the Cleo 90 Infusion Set that I downloaded from the fda.gov website on October 3, 2024, available at https://www.accessdata.fda.gov/cdrh_docs/pdf4/K042172.pdf.

9. EX1052 filed concurrently herewith is a true and correct copy of Abbott's Diabetes Patents listed for FreeStyle Libre® Glucose Monitoring System, FreeStyle Libre® 2 Glucose Monitoring System, and FreeStyle Libre® 3 Glucose Monitoring System that I accessed and downloaded from the abbott.com website on October 21, 2024 and is available at <https://www.abbott.com/patents/diabetes-patents.html>.

10. EX1053 filed concurrently herewith contains true and accurate photographs of a sample of a Smiths Medical CLEO 90 device.

11. EX1054 filed concurrently herewith is a true and correct copy of a DexCom STS Continuous Glucose Monitoring System User's Guide as captured by the Wayback Machine on December 18, 2007, which I accessed and downloaded on October 21, 2024, from <https://web.archive.org/web/20071218213923/http://www.dexcom.com/pdf/LBL9548STSUserGuideRev03.pdf>.

12. EX1056 filed concurrently herewith is a true and correct copy of archived webpage captures from www.medtronicdiabetes.com titled *Features that fit your diabetes management lifestyle*, as captured by the Wayback Machine on October 25, 2007 and *Components*, as captured by the Wayback Machine on October 13, 2007, which I accessed and downloaded on October 21, 2024, from <https://web.archive.org/web/20071025084715/http://www.medtronicdiabetes.com/products/guardian/features.html>

and

<https://web.archive.org/web/20071013095355/http://www.medtronicdiabetes.com/products/guardian/components.html>.

13. EX1059 filed concurrently herewith is a true and correct copy of the Amendment and Response dated January 7, 2008 excerpted from the file history of U.S. Patent Application No. 10/705,719 that I accessed and downloaded from the USPTO Patent Center website and is available at <https://patentcenter.uspto.gov/applications/10705719/ifw/docs?application=>.

14. EX1062 filed concurrently herewith is a true and correct copy of an archived webpage capture from www.freestylenavigator.com titled *Answers to Frequently Asked Questions* as captured by the Wayback Machine on September 17, 2008, which I accessed and downloaded on October 21, 2024, from <https://web.archive.org/web/20080917183534/http://www.freestylenavigator.com>

[/ab_nav/url/content/en_US/30.10.10:10/general_content/General_Content_000004.htm#](http://www.freestylenavigator.com/ab_nav/url/content/en_US/30.10.10:10/general_content/General_Content_000004.htm#):

https://web.archive.org/web/20080917183534/http://www.freestylenavigator.com/ab_nav/url/content/en_US/30.10.10:10/general_content/General_Content_000004.htm# October 21, 2024 at 2:17 PM PDT

http://www.freestylenavigator.com/ab_nav/url/content/en_US/30.10.10:10/general_content/General_Content_000004.htm# Go AUG SEP NOV 17 2007 2008 2009 About this capture

19 captures 17 Sep 2008 - 23 Sep 2010

FreeStyle Navigator (R) Continuous Glucose Monitoring System

Abbott: A Promise for Life

Site Map | Contact Us

Enter Search go

Home
FreeStyle Navigator®
Virtual FreeStyle Navigator™
Product Literature
Customer Support
FAQs
▶ The Freestyle Navigator System
How does the FreeStyle Navigator system work?
How can I get a FreeStyle Navigator system?
For Healthcare Professionals
Contact Us
Purchase
Abbott Global
Abbott Diabetes Care

Answers to Frequently Asked Questions

What is the FreeStyle Navigator® system?

- ▶ What is the FreeStyle Navigator Continuous Glucose Monitoring System?
- ▶ How is continuous glucose monitoring different from traditional blood glucose monitoring?
- ▶ How does the FreeStyle Navigator system work? What are its components?
- ▶ How do you separate the transmitter from the sensor support mount?
- ▶ How do the features of the FreeStyle Navigator system compared to other continuous glucose monitoring systems?
- ▶ What is a TRU™ Directional Arrow?

How does the FreeStyle Navigator system work?
How can I get a FreeStyle Navigator system?
Additional Information for Healthcare Professionals

What is the FreeStyle Navigator system?

What is the FreeStyle Navigator® Continuous Glucose Monitoring System?
The FreeStyle Navigator® Continuous Glucose Monitoring System is a glucose monitoring device that continuously measures, displays, and records the glucose levels in the fluid found between the cells under the skin (interstitial fluid). It provides you with a glucose reading once every minute. It does this by using a small, thin, plastic sensor that is inserted about 5 mm (one-fifth of an inch) under your skin. A transmitter that is attached to the sensor sends the glucose data through wireless communication to a compact handheld display unit called the receiver.

↑ Top

How is continuous glucose monitoring different from traditional blood glucose monitoring?
Traditional blood glucose monitoring provides you with glucose readings that represent distinct points in time when you perform a finger-stick test. You do not get comprehensive information regarding how your glucose levels have been changing, nor do you get information about where your glucose levels are headed. Without such information, even people who check their glucose levels often miss significant glucose fluctuations – the ups and downs.

Continuous glucose monitoring provides a more complete picture of your glucose fluctuations by providing glucose values each minute. Understanding how your glucose levels have been changing makes it possible for you and your healthcare team to take appropriate actions and make therapy adjustments that are tailored to you.

A reusable *wireless transmitter* that attaches to the sensor and sends the glucose readings to the receiver anywhere within a 10-foot range. The transmitter is suitable for everyday activities including exercise, bathing, and swimming. The size of the transmitter is 2.05" x 1.23" x 0.43".

A compact *handheld receiver* that receives the glucose readings from the transmitter and displays them on

(Screenshot from

<https://web.archive.org/web/20080917183534/http://www.freestylenavigator.com>

[/ab_nav/url/content/en_US/30.10.10:10/general_content/General_Content_000004.htm#](#) with Internet Archive header dated September 17, 2008)

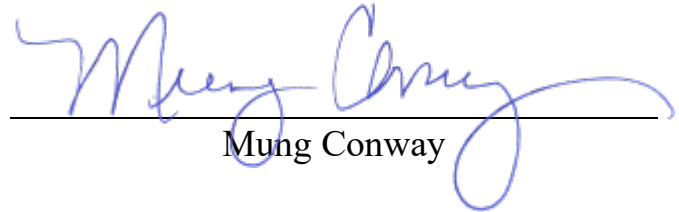
15. EX1065 filed concurrently herewith is a true and correct copy of pages excerpted from the Code of Federal Regulations, Title 29 Labor (July 1, 2007) that I accessed and downloaded from www.govinfo.gov at <https://www.govinfo.gov/content/pkg/CFR-2008-title29-vol6/pdf/CFR-2008-title29-vol6.pdf>.

16. EX1066 filed concurrently herewith is a true and correct copy of an FDA 510(k) Premarket Notification webpage for the CLEO 90 INFUSION SET that I accessed and downloaded on October 21, 2024, from <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K042172>.

17. EX1067 filed concurrently herewith is a true and correct copy of product literature for the Smiths Medical Cleo® 90 Infusion Set as captured by the Wayback Machine on August 16, 2022, which I accessed and downloaded on October 21, 2024, from https://web.archive.org/web/20220816002119/https://www.smiths-medical.com/-/media/M/Smiths-medical_com/Files/Import-Files/Product-Literature/IN193873GB-092019_LR.pdf.

I declare under penalty of perjury that the foregoing is true to the best of my information, knowledge and belief.

Executed this 25^h day of October, 2024 at Ridgefield, Washington.



Mung Conway