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)
DEVICE A NAC	
DEXCOM, INC.,) JURY TRIAL DEMANDED
)
Defendant.)

SECOND AMENDED COMPLAINT

Plaintiffs Abbott Diabetes Care Inc. and Abbott Diabetes Care Limited (collectively "Abbott"), for their Complaint against Defendant Dexcom, Inc. ("Dexcom"), allege as follows:

INTRODUCTION

1. Abbott brings this action to stop Dexcom from infringing multiple Abbott patents protecting Abbott's award-winning FreeStyle Libre technology, a "life changing" "advance in the management of diabetes." Diabetes is a chronic condition and global epidemic

L. Leelarathna & E.G. Wilmot, Flash forward: a review of flash glucose monitoring, DIABET. MED., 35(4), 472–482 (2018) (describing FreeStyle Libre as "a watershed moment in the history of diabetes care" and a "significant advance in the management of diabetes" and noting that "[m]any users describe it as 'life changing'"). FreeStyle Libre has received several awards. These have included the Edison Award as the "best of the best" for "Patient Care" for the first generation FreeStyle Libre system in 2016, and as the "best of the best" for "Personal Wellness Technology" for the second-generation FreeStyle Libre 2 in 2021. 2016 Edison Best New Product AwardsTM Winners, EDISON AWARDS, https://edisonawards.com/winners2016.php; 2021 Edison New **Product** Awards TM Winners. **EDISON** Best https://edisonawards.com/winners2021.php. In addition, in 2019, FreeStyle Libre was awarded the Prix Galien for "Best Medical Technology." The Galien Foundation Honors 2019 Prix Galien Award Recipients, CISION PR NEWSWIRE https://www.prnewswire.com/news-releases/the-galienfoundation-honors-2019-prix-galien-award-recipients-300945409.html (Oct. "Worldwide, the Prix Galien is regarded as the equivalent of the Nobel Prize in biopharmaceutical and medical technology research." Id.

that affects nearly half a billion people worldwide. Abbott's innovations make "[r]egular blood sugar monitoring," which is "the most important thing you can do to manage ... diabetes," accessible to the world. Were it not for the protections of inventions in the United States Constitution and patent laws, medical technologies that save and improve lives like FreeStyle Libre would be unavailable to people who need them. Dexcom's infringing misconduct is exactly what these laws were designed to protect against, and must be stopped.

2. Diabetes results in blood sugar (glucose) levels that can cause severe health problems such as heart attack, stroke, kidney disease, blindness, amputation, and death. That is why regular blood sugar monitoring is so important for people with diabetes. Historically, monitoring involved "fingerstick" measurements. These required pricking and drawing blood from a finger, putting the blood on a test strip, inserting it into a monitor, and waiting for a test. That method was painful and invasive, and had to be repeated frequently. It also did not show the continuous data that people needed to make more accurate and timely decisions about their

² Center for Disease Control and Prevention, *Monitoring Your Blood Sugar*, CDC.GOV https://www.cdc.gov/diabetes/managing/managing-blood-sugar/bloodglucosemonitoring.html.

See, e.g., D. Pintus, et al., Freestyle Libre Flash Glucose Monitoring Improves Patient Quality of Life Measures in Children With Type 1 Diabetes Mellitus (T1DM) With Appropriate Provision of Education and Support by Healthcare Professionals, DIABETES METAB SYNDR, 13(5), 2923-2926 (Jul. 30, 2019); M. Fokkert, et al., Improved well-being and decreased disease burden after 1-year use of flash glucose monitoring, BMJ OPEN DIABETES RESEARCH AND CARE, 2019;7:e000809, doi: 10.1136/bmjdrc-2019-000809 (2019); S. Charleer, et al., Quality of Life and Glucose Control After 1 Year of Nationwide Reimbursement of Intermittently Scanned Continuous Glucose Monitoring in Adults Living With Type 1 Diabetes (FUTURE): A Prospective Observational Real-World Cohort Study. DIABETES CARE, 43(2):389–397 doi: 10.2337/dc19-1610 (Feb. 2020).

diabetes treatments, diet, and exercise.⁴ Often patients would not do all the fingersticks needed to adequately monitor their glucose levels and prevent the disease's progression and deadly effects.⁵

- 3. Blood sugar monitoring for diabetes improved with the introduction of continuous glucose monitors. Early continuous glucose monitoring devices, however, were inaccessible and unrealistic for many people with diabetes. They were unaffordable for many, often were not covered by insurance, and required calibration using the same problematic fingersticks they were meant to replace.⁶ They were also bulky, complicated, required separate sensors and transmitters, had gaps in the glucose data they displayed, and required insertion with daunting applicators.
- 4. Unlike others, Abbott focused its designs on maximizing patient access and convenience, and launched the FreeStyle Libre continuous glucose monitoring system, the first commercially available continuous glucose monitor that avoids fingersticks. FreeStyle Libre made continuous glucose monitoring simple and accessible for a broad population of people with diabetes. Its tiny glucose sensor with integrated electronics is easy to insert, can be discreetly worn for 14 days, and reliably and continuously monitors glucose levels and transmits glucose data to digitally connected devices, including smartphones and dedicated readers. FreeStyle Libre is also much more affordable, often selling for a fraction of the cost of other continuous glucose monitors.

⁴ See W. Gonzales, et al., The Progress of Glucose Monitoring—A Review of Invasive to Minimally and Non-Invasive Techniques, Devices and Sensors, SENSORS, 19(4):800 doi:10.3390/s19040800 (Feb. 15, 2019) at 1, 5.

⁵ See id. at 2, 6.

See id. at 6; see also U. Hoss. & E. Budiman, Factory-Calibrated Continuous Glucose Sensors: The Science Behind the Technology, DIABETES TECHNOL. & THER., 19 Supp. 2, S44–S50 (May 1, 2017) doi: 10.1089/dia.2017.0025; D. Rodbard, Continuous Glucose Monitoring: A Review of Successes, Challenges, and Opportunities, DIABETES TECHNOL. & THER., 18 Supp. 2, S3–S13 (Feb. 2016) doi: 10.1089/dia.2015.0417; J. Hermanides, et al., Current Application of Continuous Glucose Monitoring in the Treatment of Diabetes, DIABETES CARE, 34 Supp. 2, S197–S201 (May 2011) doi: 10.2337/dc11-s219.

Abbott invested enormous resources, including more than a billion dollars, into developing, building, and expanding the market for FreeStyle Libre. It is now the most accessible and top-selling glucose monitoring system in the world.

5. Dexcom's prior efforts in this space resulted in complex, expensive, and cumbersome devices that failed to achieve the substantial benefits that Abbott's transformative innovations provide. For example, prior generations of Dexcom's CGM devices (including G5) required fingersticks for calibration, had shorter wear times, and required insertion using applicators described by its CEO as "kind of scary" and likened to an "intimidating" "harpoon." Now, in its current G6 product, Dexcom has adopted Abbott's patented technologies, including technologies that avoid fingersticks and enable easy insertion, longer wear times, and reliable and continuous transmission of glucose readings to digitally connected devices. But the law does not allow Dexcom to incorporate Abbott's patented technology without authorization and improperly reap the benefits of Abbott's investments.

NATURE OF THE ACTION

6. The Patent Office has awarded Abbott an extensive patent portfolio that protects Abbott's inventions relating to continuous glucose monitoring, including the following:

Jonah Comstock, *Dexcom CEO Tells Investors Not to Fear New Competition From Abbott's Freestyle Libre*, MOBI HEALTH NEWS, https://www.mobihealthnews.com/content/dexcom-ceo-tells-investors-not-fear-new-competition-abbotts-freestyle-libre (Nov. 8, 2017).

See, e.g., Dexcom User Guide for Dexcom G5 Mobile Continuous Glucose Monitoring (CGM)Rev 009 DEXCOM.COM, https://s3-us-west-System, MT24706, 2.amazonaws.com/dexcompdf/G5-Mobile-Users-Guide-Touchscreen-Receiver.pdf (hereinafter, "G5 User Guide"); Jonah Comstock, Dexcom CEO Tells Investors Not to Fear New Competition Abbott's Freestyle Libre, Мові From HEALTH https://www.mobihealthnews.com/content/dexcom-ceo-tells-investors-not-fear-new-competitionabbotts-freestyle-libre (Nov. 8, 2017); Dana Howe, Comparing the Dexcom G6 to the G5, BEYOND TYPE 1, https://beyondtype1.org/comparing-the-dexcom-g6-to-the-g5/.

United States Patent Nos. 10,820,842 ("the '842 patent"), 10,827,954 ("the '954 patent"), 10,874,338 ("the '338 patent"), 10,881,341 ("the '341 patent"), 10,945,647 ("the '647 patent"), 10,945,649 ("the '649 patent"), 10,952,653 ("the '653 patent"), 10,959,654 ("the '654 patent"), 10,966,644 ("the '644 patent"), 10,973,443 ("the '443 patent"), 11,000,216 ("the '216 patent"), and 11,013,440 ("the '440 patent") (collectively, the "Asserted Patents").

- 7. This is an action for infringement of the Asserted Patents.
- 8. This action is based on the Patent Laws of the United States, 35 U.S.C. §§ 100, et seq.

PARTIES

- 9. Abbott Diabetes Care Inc. ("ADC Inc.") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business in Alameda, California. ADC Inc. holds legal title to the Asserted Patents as the assignee.
- 10. Abbott Diabetes Care Limited ("ADC Ltd.") is a company organized under the laws of the United Kingdom, having its principal place of business in Witney, United Kingdom. ADC Ltd. has an exclusive license from ADC Inc. under the Asserted Patents.
- 11. Dexcom, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business in San Diego, California.

JURISDICTION AND VENUE

- 12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) *et seq*.
- 13. This Court has personal jurisdiction over Dexcom because, *inter alia*, it is incorporated in Delaware, and thus resides in this District.
- 14. Venue is proper in this District under 28 U.S.C. § 1400(b) because, *inter alia*, Dexcom is incorporated in Delaware, and thus resides in this District.

BACKGROUND

Diabetes

- 15. Diabetes is a global epidemic. An estimated 460 million people worldwide have diabetes. By 2045 that number is expected to rise to 700 million. According to the CDC, in 2020, 26.9 million people were diagnosed with diabetes in the US. Diabetes results in low or high glucose (sugar) levels in the body that can cause severe health problems such as heart attacks, strokes, kidney failure, limb loss, vision loss, and skin ulcers, and can lead to death.
- 16. According to the CDC, "[r]egular blood sugar monitoring is the most important thing you can do to manage ... diabetes. You'll be able to see what makes your numbers go up or down, such as eating different foods, taking your medicine, or being physically active. With this information, you can work with your health care team to make decisions about your best diabetes care plan."¹²

Prior Blood Glucose Monitoring Methods

17. Traditionally, diabetes patients and healthcare providers monitored blood glucose levels using "fingerstick" methods, often referred to as "self blood glucose monitoring" ("SBGM"), that involved pricking a finger to obtain blood, placing blood on a test strip, and inserting that test strip into a monitor that would give a glucose value. But "[i]t is challenging to get more than a limited set" of data from these methods "due to the inconvenience and pain

⁹ International Diabetes Federation, *IDF Diabetes Atlas* (9th ed. 2019) https://www.diabetesatlas.org/upload/resources/material/20200302_133351_IDFATLAS9e-final-web.pdf.

Center for Disease Control and Prevention, *National Diabetes Statistics Report*, 2020, CDC.GOV, https://www.cdc.gov/diabetes/data/statistics-report/index.html.

¹¹ Center for Disease Control and Prevention, *Monitoring Your Blood Sugar*, CDC.GOV, https://www.cdc.gov/diabetes/managing/managing-blood-sugar/bloodglucosemonitoring.html.

¹² *Id*.

associated with fingersticks, ... and unforgiving requirements for specific timing. Even in the best of circumstances, SBGM data can be challenging to interpret." With these traditional methods, patients and providers must frequently extrapolate from a single blood glucose value or from glucose values at scattershot time points without clear temporal relationships to the food, exercise, medication, or other things that affect blood glucose levels — temporal relationships that provide needed context. Further, the fingerstick methods suffered from low compliance, because many patients were so put off by the painful fingersticks that they simply would not test.

18. Various companies developed continuous glucose monitoring products as an alternative to traditional fingerstick measurements. But these products had significant drawbacks including high cost, short wear times, burdensome and painful insertion techniques, non-intuitive operation requiring significant training, and calibration methods requiring regular fingersticks — the painful and invasive sampling that continuous glucose monitor technologies were designed to avoid.¹⁴

Abbott's FreeStyle Libre Continuous Glucose Monitoring Products

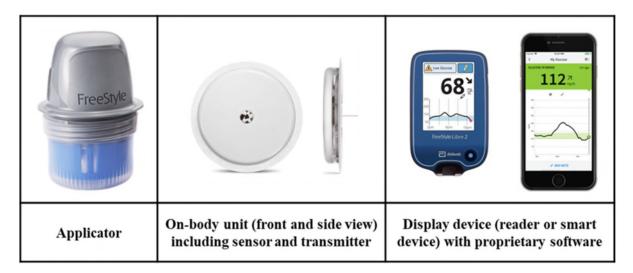
19. In 2014, Abbott introduced the FreeStyle Libre line of continuous glucose monitoring products, which brought new and more accessible technology to the market and

T. Kompala, et. al, *A New Era: Increasing Continuous Glucose Monitoring Use in Type 2 Diabetes*, AM J. MANG. CARE, 25(4), SP123-SP126 (2019) doi: 10.1111/dme.13149.

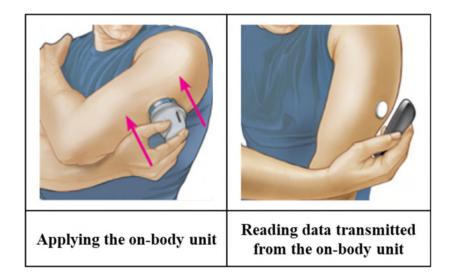
See, e.g., W. Gonzales, et al., The Progress of Glucose Monitoring—A Review of Invasive to Minimally and Non-Invasive Techniques, Devices and Sensors, Sensors (Basel), 2019;19(4):800 at 1 (Feb. 15, 2019) doi: 10.3390/s19040800; U. Hoss. & E. Budiman, Factory-Calibrated Continuous Glucose Sensors: The Science Behind the Technology, Diabetes Technol There, 19 Supp. 2, S-44-50 (May 1, 2017) doi: 10.1089/dia.2017.0025; D. Rodbard, Continuous Glucose Monitoring: A Review of Successes, Challenges, and Opportunities, Diabetes Technol There, 1; 18 (Suppl 2) S2-3-S2-13 (Feb. 2016) doi: 10.1089/dia.2015.0417; J. Hermanides, M. Phillip & H. DeVries, Current Application of Continuous Glucose Monitoring in the Treatment of Diabetes, Diabetes, 24 (Suppl. 2): S197-S201 (May 2011) doi: 10.2337/dc11-s219.

addressed problems with prior diabetes and glucose management methods. The original FreeStyle Libre product was first approved for use in Europe in 2014, and in the United States in 2017. Continuing to innovate, Abbott built on these product launches with the FreeStyle Libre 2, which was approved for use in Europe in 2018 and in the United States in 2020, and the FreeStyle Libre 3, which was approved for use in Europe in 2020. These products are referred to herein collectively as the "FreeStyle Libre."

20. Abbott's FreeStyle Libre includes an applicator, an integrated on-body unit that includes a glucose sensor and a transmitter, and a display device (such as a reader or smart device) with proprietary software (see example below).



21. In a single step, the applicator is used to insert a portion of the glucose sensor under the skin and attach the on-body unit to the user's body with an adhesive patch. Data from the on-body unit is transmitted to a display device where a glucose value and related information are provided to the user.



- 22. Abbott's FreeStyle Libre overcame significant drawbacks associated with earlier continuous glucose monitoring products. In stark contrast to other glucose monitors in the marketplace, Abbott's FreeStyle Libre eliminated the need for fingerstick calibration by the user to obtain accurate glucose measurements. The FreeStyle Libre is calibrated in the factory, and no fingersticks (or any user-initiated action) are required for calibration.
- 23. Further, compared to earlier continuous glucose monitoring products, Abbott's FreeStyle Libre offered many other benefits, including:
 - significantly lower cost;
 - an improved applicator design and process allowing for application of the onbody unit by a user in a single, simple step;
 - smaller and less obtrusive device to be positioned on the user's body;
 - greater ease-of-use;
 - more complete and accurate glucose data; and
 - longer wear periods with accurate readings (up to 14 days of continuous use).

These advancements made continuous glucose monitoring products accessible to many people who could not or would not use them previously.

- 24. Describing FreeStyle Libre, researchers have acknowledged some important advantages: "the [FreeStyle Libre] system is a very easy, painless and user-friendly way of monitoring glucose values without the need for blood. A small sensor is inserted under the skin of one arm and remains there for 14 days. The patient can insert the sensor himself/herself and can replace it with a new sensor when the current one has expired. ... This can be done as often as the patient wishes and in any situation, and is very discreet and fast."¹⁵
- 25. Users of FreeStyle Libre often describe how it has changed the way they manage diabetes and improved their lives.
 - "[During the first two weeks using FreeStyle Libre,] I learned more about my diabetes and myself ... than I had learned in the previous 15 years. I suddenly had a clearer picture of how my decisions impacted me. I continued to use the product ... and over the next 3 months my A1C¹⁶ dropped from 8.6 to 5.7! The data you get and the ease of getting it makes this an indispensable tool for anyone living with diabetes. I know it changed my life!"¹⁷
 - The FreeStyle Libre "has been the easiest and single-most positive 'medical improvement' in my diabetic journey since being diagnosed [twenty-two years ago]."¹⁸

L. van den Boom & K. Kostev, Changes In the Utilization of Blood Glucose Test Strips Among Patients Using Intermittent-Scanning Continuous Glucose Monitoring in Germany, 22 DIABETES OBES. METAB. 6:922–28 (Jun. 2020) doi: 10.1111/dom.13977.

A1C Test, MAYO CLINIC, https://www.mayoclinic.org/tests-procedures/a1c-test/about/pac-20384643 (The A1C test (also known as the hemoglobin A1C or HbA1c test) is a common blood test used to diagnose diabetes. An A1C test result reflects average blood glucose level for the past two to three months. A1C test results are reported as a percentage. A higher A1C percentage corresponds to higher average blood glucose levels: below 5.7% is normal, 5.7% to 6.4% indicates prediabetes, and 6.5% or higher indicates diabetes. For most adults living with diabetes, an A1C level of less than 7% is a common treatment target).

William M., *Patient Stories*, FREESTYLE LIBRE, https://www.freestylelibre.us/patient-stories.html.

NG, *Patient Stories*, FREESTYLE LIBRE, https://www.freestylelibre.us/patient-stories.html.

- "I love it and it helps me better understand how and what affects my glucose levels. ... It's the best thing I could have ever done for my diabetes!!! And the best part—NO MORE PAIN OF FINGER PRICKS!!" 19
- 26. In 2016, the first-generation FreeStyle Libre was chosen by top senior business executives, academics, and innovation professionals to receive the Edison Award as the "best of the best" for patient care.²⁰ The Edison Awards "recognize[] and honor[] some of the most innovative products ... in the world and [are] among the most prestigious accolades honoring excellence in new product and service development, marketing, design and innovation." In April 2021, the FreeStyle Libre 2 received another Edison Award, as "best of the best" for personal wellness technology.²²
- 27. In 2019, Abbott received the prestigious *Prix Galien* award (the equivalent of the Nobel Prize in biopharmaceutical research), recognizing FreeStyle Libre as the Best Medical Technology approved by the Food and Drug Administration in the prior five years.²³
- 28. Abbott's FreeStyle Libre is now the top selling continuous glucose monitoring product in the world. It has helped more than 3 million people across 50 countries by providing breakthrough technology that is affordable, accurate, reliable, and simple to use.

Terri Michelle, *Patient Stories*, FREESTYLE LIBRE, https://www.freestylelibre.us/patient-stories.html.

²⁰ 2016 Edison Best New Product AwardsTM Winners, EDISON AWARDS, https://edisonawards.com/winners2016.php.

²¹ About the Edison Awards, EDISON AWARDS, https://edisonawards.com/about.php.

²² 2021 Edison Best New Product AwardsTM Winners, EDISON AWARDS, https://edisonawards.com/winners2021.php.

The Galien Foundation Honors 2019 Prix Galien Award Recipients, CISION PR NEWSWIRE, https://www.prnewswire.com/news-releases/the-galien-foundation-honors-2019-prix-galien-award-recipients-300945409.html. (Oct. 25, 2019).

Dexcom's Follow-On G6 Glucose Monitoring Product

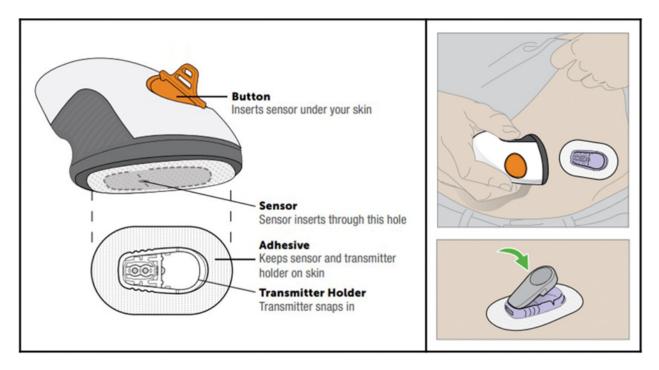
- 29. In 2018, four years after Abbott first introduced FreeStyle Libre, Dexcom introduced its G6 continuous glucose monitoring product, followed by the G6 Pro in 2020 (collectively the "G6"). Dexcom's G6, its sixth generation device, is a substantial departure from its fifth generation product (*i.e.*, "G5") and earlier products. The G6 incorporates many of Abbott's patented innovations in its design and operation, as illustrated in the infringement claim charts referenced below.
- 30. As described by Dexcom in the G6 user guide, the G6 includes three components: an applicator with a sensor, a transmitter, and a display device (receiver or smart device).

What you see	What it's called	What it does
Sensor (inside)	Applicator with built-in sensor	Applicator helps you insert the sensor wire under your skin. Sensor gets your glucose information.
	Transmitter	Transmitter sends your glucose information from the sensor to the display device.
SCHOOL &	Display Device(s): Receiver Your smart device	Display device(s) shows your glucose information. Receiver is required for Medicare.

(G6 User Guide at 47.) As part of G6, Dexcom provides software (e.g., G6 App) for the display devices.

31. As described by Dexcom, the G6 applicator is used, in a single step, to insert a portion of the sensor under the skin and to apply a transmitter holder with an adhesive patch.

After the transmitter holder is applied to the skin, the transmitter is snapped into the holder.



(*G6 User Guide* at 77, 80, 83.)

- 32. With G6, Dexcom is using Abbott's breakthrough patented technologies.
- 33. For example, to obtain accurate readings, all of Dexcom's earlier products required the user to calibrate the product with frequent fingerstick measurements throughout the sensor wear life. But, like Abbott's FreeStyle Libre products, Dexcom's G6 adopts factory calibration, including drift correction to allow for a longer wear period (10 days for G6 versus 7 days for G5), moving away from requiring fingerstick measurements for calibration. Dexcom heavily promotes this feature of its G6 products.²⁴

See, e.g., Better manage your Type 1 or Type 2 diabetes with the Dexcom G6 CGM System, DEXCOM CONTINUOUS GLUCOSE MONITORING, https://www.dexcom.com/g6-cgm-system (The Dexcom G6 "lets you see your glucose and where it's heading without fingersticks.").

- 34. Likewise, moving away from Dexcom's "intimidating" and complicated G5 applicator design, the G6 incorporates Abbott's patented applicator and insertion technologies. Dexcom also promotes these features of its G6 product adopted or resulting from Abbott's patented technologies.²⁵
- 35. As evidenced by the substantial departures from the technology in Dexcom's earlier products, Dexcom is deliberately using Abbott's patented technology in its products and is infringing Abbott's valuable patent rights. Abbott is entitled to injunctive relief and to recover damages for such infringement.

ASSERTED PATENTS

- 36. Abbott has invested heavily in developing and maintaining a portfolio of patents protecting its inventions, including the Asserted Patents.
- 37. The '842 patent is titled "Methods and Systems for Early Signal Attenuation Detection and Processing," and was duly and legally issued on November 3, 2020.
 - 38. A true and correct copy of the '842 patent is attached as **Exhibit A**.
- 39. The '954 patent is titled "Continuous Analyte Measurement Systems and Systems and Methods for Implanting Them," and was duly and legally issued on November 10, 2020.
 - 40. A true and correct copy of the '954 patent is attached as **Exhibit B**.
- 41. The '338 patent is titled "Devices, Systems and Methods for On-Skin or On-Body Mounting of Medical Devices," and was duly and legally issued on December 29, 2020.
 - 42. A true and correct copy of the '338 patent is attached as **Exhibit C**.

 $^{^{25}}$ *Id.* ("Simple auto-applicator – a one-touch applicator easily inserts a small sensor just beneath the skin."); *id.* ("The Dexcom G6 features a 10-day wear sensor that is ... easy to insert with an auto-applicator.").

- 43. The '341 patent is titled "Medical Device Inserters and Processes of Inserting and Using Medical Devices," and was duly and legally issued on January 5, 2021.
 - 44. A true and correct copy of the '341 patent is attached as **Exhibit D**.
- 45. The '647 patent is titled "Analyte Sensor Transmitter Unit Configuration for a Data Monitoring and Management System," and was duly and legally issued on March 16, 2021.
 - 46. A true and correct copy of the '647 patent is attached as **Exhibit E**.
- 47. The '649 patent is titled "Medical Device Inserters and Processes of Inserting and Using Medical Devices," and was duly and legally issued on March 16, 2021.
 - 48. A true and correct copy of the '649 patent is attached as **Exhibit F**.
- 49. The '653 patent is titled "Methods and Systems for Early Signal Attenuation Detection and Processing," and was duly and legally issued on March 23, 2021.
 - 50. A true and correct copy of the '653 patent is attached as **Exhibit G**.
- 51. The '654 patent is titled "Medical Device Inserters and Processes of Inserting and Using Medical Devices," and was duly and legally issued on March 30, 2021.
 - 52. A true and correct copy of the '654 patent is attached as **Exhibit H**.
- 53. The '644 patent is titled "Devices, Systems and Methods for On-Skin or On-Body Mounting of Medical Devices," and was duly and legally issued on April 6, 2021.
 - 54. A true and correct copy of the '644 patent is attached as **Exhibit I**.
- 55. The '443 patent is titled "Sensor Inserter Assembly," and was duly and legally issued on April 13, 2021.
 - 56. A true and correct copy of the '443 patent is attached as **Exhibit J**.

- 57. The '216 patent is titled "Medical Device Inserters and Processes of Inserting and Using Medical Devices," and was duly and legally issued on May 11, 2021.
 - 58. A true and correct copy of the '216 patent is attached as **Exhibit K**.
- 59. The '440 patent is titled "Medical Device Inserters and Processes of Inserting and Using Medical Devices," and was duly and legally issued on May 25, 2021.
 - 60. A true and correct copy of the '440 patent is attached as **Exhibit L**.

ASSERTED CLAIMS

61. Dexcom has infringed and continues to infringe at least the following claims (collectively, the "Asserted Claims"), which Abbott previously identified in Plaintiffs' Initial Claim Charts ("Initial Claim Charts") (served on March 31, 2022):

Patent	Claims
'842 patent	1-3, 6, 8, 10, 14-15, 17, 19
'954 patent	1, 7, 15-17
'338 patent	1, 3, 5, 10-11, 14-15, 17, 22-23, 26
'341 patent	1, 4, 13, 16, 18, 26-27, 29
'647 patent	1-3, 11-14
'649 patent	1, 6, 8, 10, 17-18, 25, 28
'653 patent	1, 3, 5-8, 11, 15, 18
'654 patent	1, 8, 10, 15, 20, 22, 26
'644 patent	1-3, 5, 8-11, 15
'443 patent	1, 13-14, 18, 20-21, 23
'216 patent	1-4, 6, 11, 13, 16-17, 19, 23-26, 28-29
'440 patent	1, 7, 10-11, 17, 24-25

ACCUSED PRODUCTS

62. Abbott previously identified the "Accused Products" in Plaintiffs' Initial Identification of Accused Products, Asserted Patents, and Damages Model (served on December 10, 2021). The Accused Products, including accused methods and systems, are: Dexcom G6 Continuous Glucose Monitoring System and variations thereof, including Dexcom Pro Q Continuous Glucose Monitoring System, Dexcom G6 Pro Continuous Glucose Monitoring System, Dexcom G6 Glucose Program Continuous Glucose Monitoring System, and the Dexcom ONE Continuous Glucose Monitoring System (collectively, the "Accused Products"). The Accused Products include all components, features, and variations thereof (including any receivers and/or smart devices with compatible software/apps).

DEXCOM'S DIRECT, INDIRECT, AND WILLFUL INFRINGEMENT

- 63. In violation of 35 U.S.C. § 271(a), Dexcom has directly infringed and continues to directly infringe at least the Asserted Claims by making, using, offering for sale, selling, and/or importing the Accused Products.
- 64. Appendices A-L of Abbott's Initial Claim Charts, which are incorporated herein by reference, show how each element of the Asserted Claims is met by the Accused Products.
- 65. To the extent any claim element is not literally met, the Accused Products include a corresponding equivalent feature, structure, instrumentality, function, step, process, or method that is insubstantially different from the asserted claim element and/or performs substantially the same function, in substantially the same way, to achieve substantially the same result of the asserted claim element. These corresponding equivalent features, structures, instrumentalities, functions, steps, processes, and methods at least include those identified in the Initial Claim Charts.

- 66. In violation of 35 U.S.C. § 271(b), Dexcom has been actively and knowingly, and with specific intent, inducing others (*e.g.*, patients, physicians, etc.) to commit acts that Dexcom knows constitute direct infringement of the Asserted Patents.
- 67. In violation of 35 U.S.C. § 271(c), Dexcom has been knowingly contributing to the infringement of the Asserted Patents by offering to sell, selling, and/or importing Accused Products (including components thereof), for use in practicing the claimed inventions of the Asserted Patents, knowing they are material to practicing the claimed inventions of the Asserted Patents, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are especially made or especially adapted for use in an infringement.
- 68. Dexcom continues to directly infringe and to induce and contribute to the infringement of the Asserted Patents. Dexcom's infringement of the Asserted Patents, direct and indirect, has been and continues to be willful, intentional, deliberate, and in conscious disregard of Abbott's rights under the Asserted Patents. Dexcom does not have, nor could it have had, a goodfaith belief that making, selling, offering to sell, using, or importing the Accused Products does not infringe the Asserted Patents.
- 69. Dexcom knew about the Asserted Patents before Abbott filed its original Complaint. (*See* DexCom's Response to Plaintiffs' First Set of Interrogatories at Interrogatory No. 1 ("DexCom became aware of the [Asserted Patents] on or shortly after the dates on which they issued.").)
- 70. Indeed, on information and belief, Dexcom actively monitors the patent activity of Abbott and knew about the inventions disclosed in the Asserted Patents and the allowed claims in the Asserted Patents, even before the Asserted Patents issued. This belief is supported by multiple considerations, including that Dexcom (1) knew when the Asserted Patents issued,

- (2) views itself as a "fierce rival" of Abbott (*see* D.I. 58 at 1) in a market where Abbott is a known pioneer with whom Dexcom has great familiarity, and (3) regularly challenges Abbott's patents (*e.g.*, in EPO oppositions).
- 71. Dexcom knew or should have known it was infringing the Asserted Patents, directly and indirectly, at least as early as the date it became aware of each patent. Dexcom possessed the technical expertise to understand the scope and content of the Asserted Patents. Dexcom also knows how its own Accused Products were designed, how they function, and how Dexcom encourages and instructs others to use the Accused Products. Accordingly, even before Abbott filed its original Complaint, Dexcom had actual knowledge that the Accused Products infringe the Asserted Patents, or chose to be willfully blind to the infringement by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.
- 72. Moreover, Dexcom was put on notice of its infringement of the Asserted Patents when Dexcom was served with the original Complaint in this action on July 2, 2021. (*See* D.I. 1.) Despite this knowledge, Dexcom has been infringing and continues to infringe the Asserted Patents, directly and indirectly.
- 73. As discussed in greater detail below and illustrated in the Initial Claim Charts, the conclusion that Dexcom's infringement (direct and indirect) is knowing, willful, and deliberate is supported by the available evidence, including that Dexcom (1) copied inventions from Abbott's patent disclosures and commercial products, (2) continued unabatedly after unsuccessfully seeking an extension of a prior covenant-not-to-sue, and (3) lacked any license rights to the Asserted Patents.

Dexcom Copied Inventions from Abbott's Patent Disclosures and Commercial Products

74. Dexcom first introduced the Accused Products in 2018 with the introduction of the G6. Dexcom designed the G6 to compete with Abbott's award-winning FreeStyle Libre technology. To compete with FreeStyle Libre, Dexcom copied Abbott's innovations and incorporated them into G6 and the other Accused Products, as explained below and illustrated in the Initial Claim Charts.

Accurate Glucose Measurements Without Requiring User Calibration During the Wear Life

- 75. FreeStyle Libre products are calibrated in the factory. They provide accurate glucose measurements for up to 14 days without any calibration by the user (or other post-factory calibration).
- 76. In contrast, before G6, Dexcom's glucose monitoring systems required frequent calibration by the user. For example, for Dexcom's G5, the user was required to calibrate the device twice during the first two hours of use and then, to account for "drift," calibrate again every twelve hours throughout the wear life. ²⁶ (G5 User Guide at 99.)
- 77. Dexcom specifically cautioned users not to "use the Dexcom G5 Mobile for diabetes treatment decisions unless you have followed the prompts from the device and calibrated every 12 hours after the initial calibration."

Dexcom contends that it invented "factory calibration." This is not correct. Dexcom did not introduce the G6 with factory calibration until 2018, four years after Abbott introduced the FreeStyle Libre products with factory calibration.

Calibrate on Schedule

What is calibrating and why it is important? Calibration is the process of making sure your sensor continues to be accurate. Your sensor doesn't automatically know what your glucose levels are—you have to teach your system what a given BG value is by entering in a KNOWN glucose value from your BG meter.

Calibrate the Dexcom G5 Mobile at least once every 12 hours. The Dexcom G5 Mobile needs to be calibrated in order to provide accurate readings. Do not use the Dexcom G5 Mobile for diabetes treatment decisions unless you have followed the prompts from the device and calibrated every 12 hours after the initial calibration.

(G5 User Guide at 21 (highlighting added).)

- 78. To perform these calibrations, the user was required to draw a blood sample, typically by sticking or pricking a finger.²⁷ This was not only painful but also could affect the accuracy of the device if it was not done on time or if it was done incorrectly.²⁸
- 79. With the FreeStyle Libre, Abbott was the first to introduce a CGM with accurate readings throughout the wear life using factory calibration without post-insertion calibration by the user.²⁹ Attempting to compete, Dexcom copied Abbott's innovations and

²⁷ See, e.g., G5 User Guide at 107.

Michelle D. Lundholm et al., Applications and Pitfalls of Hemoglobin A1C and Alternative Methods of Glycemic Monitoring, J. OF DIABETES AND ITS COMPLICATIONS, at 7 (Apr. 23, 2020) ("Another barrier to CGM use is that many patients feel burdened by the discomfort of wearing a sensor or calibrating regularly . . . "); Ramzi A Ajjan et al., Accuracy of Flash Glucose Monitoring and Continuous Glucose Monitoring Technologies: Implications for Clinical Practice, DIABETES AND VASCULAR DISEASE RES., 15(3), 175, 176 (Feb. 15, 2018) ("A key difference between the two systems is the need to calibrate Dexcom G5 twice daily, whereas Abbott FreeStyle Libre is factory calibrated. Infrequent or incorrect calibration by patients can potentially reduce the accuracy of Dexcom G5, an issue that does not affect FreeStyle Libre.").

Giacomo Cappon et al., Continuous Glucose Monitor-ing Sensors for Diabetes Management: A Review of Technologies and Applications, DIABETES METABOLISM J., 43(4), 383, 385 (Jul. 25, 2019) ("[The FreeStyle Libre] CGM system is the first that required no fingerstick testing during wear."); Isabelle Paris et al., The New FreeStyle Libre Flash Glucose Monitoring System Improves the Glycemic Control in a Cohort of People with Type 1 Diabetes Followed in Real-Life Conditions over a Period of One Year, ENDOCRINOLOGY, DIABETES & METABOLISM,

incorporated them into Dexcom's G6, as demonstrated in Appendix B of the Initial Claim Charts.

When G6 was introduced, Dexcom's CEO admitted:

From a practical use perspective, the thing that would be the most important to me is that the system is engineered for no calibration. So, once you put that G6 on and get it set up and paired with your phone, no calibration is required.³⁰

- 80. Among other things, Dexcom's G6 incorporates a "drift profile" programmed into memory. (*See* Appendix B of Initial Claim Charts.) Dexcom copied this feature (and other features) from Abbott's FreeStyle Libre and the disclosures in patents protecting Abbott's innovations.
- 81. In a 2019 article by a group of Dexcom collaborators, the authors acknowledged that this feature was necessary to "remove the need for [fingerstick] calibrations":

To remove the need for [fingerstick] calibrations, the G6 uses a calibration function, which corrects for sensor drift over the 10-day wear period by keeping track of the day since insertion and adjusting the calibration function, which converts interstitial current to glucose, based on the day. The adjustments are hardcoded and based on how much an "average" sensor would drift.³¹

at 2 (Jun. 17, 2018) ("Few major problems though still hamper the use of CGM for glucose management on a large scale, that is, the need of daily finger-stick BGM for device calibration, the short sensor lifetime and the price. An alternative technology, the FreeStyle Libre . . . recently made available by Abbott Diabetes Care, overcome[s] these pitfalls.").

Zach Hall, An Interview with Kevin Sayer, President and CEO of Dexcom, About the New Dexcom G6, C. DIABETES NETWORK (Apr. 4, 2018); see also Michelle Boise, Interview with Dexcom CEO, BEYOND TYPE 1, https://beyondtype1.org/Dexcom-ceo-kevin-sayer-explains-g6/ (Jul. 6, 2018) (Dexcom's CEO further stating that factory calibration is "something everybody has asked for forever.").

Gregory P. Forlenza et al., Factory-Calibrated Continuous Glucose Monitoring: How and Why It Works, and the Dangers of Reuse Beyond Approved Duration of Wear, DIABETES TECH. & THERAPEUTICS, 21(4), 222, 224 (Mar. 30, 2019); see also id. ("Removing the necessity of [fingerstick] calibrations provides a large benefit to the patient in terms of ease of use and cost").

82. To promote the Accused Products, Dexcom touts the technology it copied from Abbott.³² In marketing materials comparing G6 to G5, Dexcom asserts that G6 requires "0 fingerpricks":

EXCON	1 G6 & DEXCO	M G5 MOBILI
ONTINUOUS GLU	COSE MONITORING (CGM) SYST	EMS
	Dexcom G5 Mobile	Dexcom G6

(Dexcom G6 & Dexcom G5 Mobile Continuous Glucose Monitoring (CGM) Systems, AMSL DIABETES, https://amsldiabetes.com.au/wp-content/uploads/2020/06/PR-100-378-Dexcom-G5-Mobile-Dexcom-G6-Comparison-Flyer-1.pdf.)

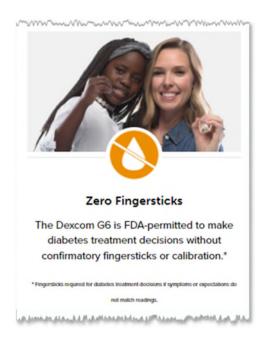
- 83. Further, in the G6 User Guide, Dexcom repeatedly emphasizes that there is no need for painful fingerstick calibration measurements.³³
- 84. The G6 User Guide also asserts that factory calibration "can reduce the pain and burden of excessive fingersticks . . . and reduce potential errors due to inaccurate calibration."

See, e.g., Better manage your Type 1 or Type 2 diabetes with the Dexcom G6 CGM System, DEXCOM CONTINUOUS GLUCOSE MONITORING, https://www.dexcom.com/g6-cgm-system ("The Dexcom G6 CGM System lets you see your glucose and where it's heading without fingersticks.").

G6 User Guide at 22, 40, 43, 44, 107; see also Better manage your Type 1 or Type 2 diabetes with the Dexcom G6 CGM System, DEXCOM CONTINUOUS GLUCOSE MONITORING, https://www.dexcom.com/g6-cgm-system ("The Dexcom G6 CGM System lets you see your glucose and where it's heading without fingersticks.").

³⁴ G6 User Guide at 38.

85. Similarly, on its website, Dexcom again repeatedly emphasizes that no fingerstick calibration is required:



(Better manage your Type 1 or Type 2 diabetes with the Dexcom G6 CGM System, DEXCOM CONTINUOUS GLUCOSE MONITORING, https://www.dexcom.com/g6-cgm-system.)



(*Dexcom G6 Features and Benefits*, DEXCOM CONTINUOUS GLUCOSE MONITORING, https://www.dexcom.com/g6/features-and-benefits.)

86. Indeed, Dexcom advertises no fingersticks as the "Best. News. Ever."

No Fingersticks! Best. News. Ever.

The Dexcom G6 eliminates fingersticks for calibration and diabetes treatment decisions.*

* It your glucose alerts and readings from the G6 do not match symptoms or expectations, use a blood glucose meter to make diabetes

(*Discover the Dexcom G6 CGM System*, DEXCOM CONTINUOUS GLUCOSE MONITORING, https://www.dexcom.com/g6/how-it-works.)

Applicator Technology That Is Simple To Use And Relatively Pain Free

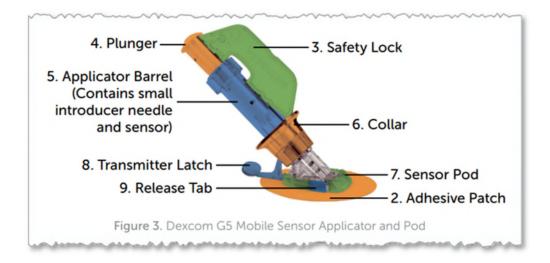
87. For the '443, '341, '654, '216, '649 and '440 patents, the unique combinations of elements in the Asserted Claims, incorporated by Dexcom in the Accused Products, provide important advantages. For example, the inventions of the Asserted Claims of the '443 patent provide the user with an easier-to-use and safer CGM insertion assembly that also enhances the accuracy of sensor placement. By coupling the mount to the end of the inserter, the number of components that the user must handle is reduced (e.g., instead of having to first separately and manually apply a mount to the skin).

88. Also, with automated insertion and retraction with a simple push of a button, the claimed devices are easier to use and simplify the steps the user must perform (which also helps reduce the potential for errors). Automatic retraction ensures the timely, quick, and safe retraction of the needle from within the user. By adhering the mount – coupled to the inserter – to the skin before inserting the sensor, the users ensure they have securely placed the mount at precisely the desired location before the sensor is "fired" into the skin.

- 89. The '341, '654, and '216 patents provide, for example, a more compact, automated CGM system and inserter assembly design that is easier for a user to handle and carry, including by having various insertion assembly components move along multiple different axes.
- 90. And the '649 and '440 patents allow, for example, for a convenient, easy-to-use, compact, automated CGM system and inserter assembly, including a torsion spring, providing a consistent, rapid, and less painful needle insertion.
- 91. Abbott's FreeStyle Libre products are applied by the user with an inserter that is simple and relatively pain free. In contrast, before G6, Dexcom's applicator technology was complicated and, in the words of its CEO, "scary looking" with "threatening steps." Users of the G5 even compared the G5 applicator to a "harpoon." 36
- 92. To compete with FreeStyle Libre, Dexcom copied Abbott's innovations and incorporated them into the G6. Notably, before G6, the G5 inserter technology had at least 9 components and involved twelve complicated steps:

Michelle Boise, *Interview with Dexcom CEO*, BEYOND TYPE 1, https://beyondtype1.org/Dexcom-ceo-kevin-sayer-explains-g6/ (Jul. 6, 2018); Steve Freed, *CGMs Changing Diabetes Management: Kevin Sayer, DIC Interview Transcript*, DIABETES IN CONTROL, https://www.diabetesincontrol.com/cgms-changing-diabetes-management-kevin-sayer-dic-interview-transcript/ (May 7, 2019).

See, e.g., Dana Howe, Comparing the Dexcom G6 to the G5, BEYOND TYPE 1, https://beyondtype1.org/comparing-the-dexcom-g6-to-the-g5/ (Sept. 15, 2021).



Order of Use Name What it does Sterilized for your protection. 1 Sensor Pack Open to remove applicator and sensor. Holds the sensor/transmitter in place on your 2 Adhesive Patch skin. Prevents plunger from inserting sensor until 3 Safety Lock you are ready. 4 Plunger Inserts sensor wire into your body. Contains small insertion needle and sensor wire. 5 **Applicator Barrel** Disposable, for single use only. Collar removes insertion needle. Collar 6 Helps remove applicator barrel once sensor

wire is inserted.

Holds transmitter.

sensor pod.

Holds sensor wire in place under skin.

Locks transmitter into sensor pod.

Allows you to remove applicator barrel from

Applicator Components

7

8

9

Sensor Pod

Release Tab

Transmitter Latch

(G5 User Guide at 75-76; see also id. at 79-82 (outlining the twelve complicated steps required to insert the G5 sensor).)

93. Describing the G5 inserter during an investor call, Dexcom's CEO acknowledged:

[N]ew patients, patients foreign to DexCom and who haven't used it before, when they went into a physician's office and saw the DexCom insertion device, I can tell you there's some trepidation, because that looks like another great big needle that you're going to stick in me.³⁷

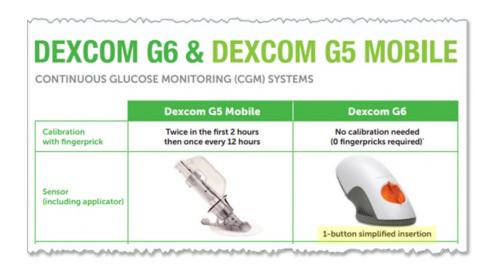
94. For the G6, Dexcom completely overhauled its "scary" inserter design. In another investor call, Dexcom's CEO explained:

When we switch to the new insertion system, we're changing everything we do. We've used the current insertion system since we started way back when. That's been our insertion system since our first product was launched. . . . We're going to have to change our manufacturing assembly processes and everything. This is the biggest change operation we've ever undertaken.³⁸

- 95. In a rush to compete with Abbott's FreeStyle Libre products, Dexcom did not develop its own technology but rather incorporated inventions from Abbott's patent disclosures and commercial products. In particular, Dexcom incorporated the inventions of the Asserted Claims of the '341, '654, '216, '649, '440, and '443 patents. (*See* Appendices D, F, H, J, K, and L of the Initial Claim Charts.)
- 96. In promoting the Accused Products, Dexcom touts the inserter technologies enabled by the innovations copied from Abbott. For example, in marketing materials comparing the G6 to the G5, Dexcom asserts that G6 has a "1-button simplified insertion[.]"

DexCom (DXCM) Q1 2018 Results – Earnings Call Transcript, SEEKING ALPHA, https://seekingalpha.com/article/4168949-dexcom-dxcm-q1-2018-results-earnings-call-transcript (May 2, 2018).

DexCom (DXCM) Kevin Ronald Sayer on Q4 2015 Results – Earnings Call Transcript, SEEKING ALPHA, https://seekingalpha.com/article/3922776-dexcom-dxcm-kevin-ronald-sayer-on-q4-2015-results-earnings-call-transcript (Feb. 23, 2016).



(Dexcom G6 & Dexcom G5 Mobile Continuous Glucose Monitoring (CGM) Systems, AMSL DIABETES, https://amsldiabetes.com.au/wp-content/uploads/2020/06/PR-100-378-Dexcom-G5-Mobile-Dexcom-G6-Comparison-Flyer-1.pdf (highlighting added).)

97. Similarly, on its website, Dexcom highlights in multiple instances that the Accused Products include a "simple auto-applicator" / "one-touch applicator" that "easily inserts" the sensor:



(*Discover the Dexcom G6 CGM System*, DEXCOM CONTINUOUS GLUCOSE MONITORING, https://www.dexcom.com/g6/how-it-works.)

98. In the "Features and Benefits" section of its website, Dexcom again touts the benefits associated with the G6 inserter:



(Dexcom G6 Features and Benefits, DEXCOM CONTINUOUS GLUCOSE MONITORING, https://www.dexcom.com/g6/features-and-benefits.)

- 99. In addition, Dexcom's G6 User Guide acknowledges that "[t]he automatic applicator was designed to provide more consistent sensor insertions." 39
- 100. Further, Dexcom asserts that the "redesigned sensor applicator allows [the user] to insert a sensor with just one hand."⁴⁰
- 101. And Dexcom touts the G6 "automatic applicator," which incorporates Abbott's patented technology, by reporting that 84% of subjects enrolled in a study to assess the comfort and ease of use of the G6 "automatic applicator" reported "painless" application.⁴¹
- 102. Notably, according to Dexcom, "[a]ll reported subjects (100%) found that the automatic applicator was easy to use and the IFU [(instruction for use)] was easy to

G6 User Guide at 322; see also Is it painful to insert a Dexcom G6 sensor?, DEXCOM CONTINUOUS GLUCOSE MONITORING, https://www.dexcom.com/faqs/is-it-painful-to-insert-a-dexcom-g6-sensor ("The Dexcom G6 auto applicator was designed for easier, more consistent sensor insertions.").

⁴⁰ *G6 User Guide* at 46.

⁴¹ *Id.* at 323.

understand."⁴² Moreover, Dexcom describes as "overwhelming" the positive feedback received about the copied inserter technology.⁴³

103. Further, Dexcom asserts that the "simple and comfortable sensor insertion" process has resulted in "amazing outcomes" for patients:



(*Discover the Dexcom G6 CGM System*, DEXCOM CONTINUOUS GLUCOSE MONITORING, https://www.dexcom.com/g6/how-it-works.)

Easier And Safer Transmitter Removal

- 104. Dexcom's G5 and G6 both include a reusable transmitter that must be removed from a used device before it can be reused in a new device.
- 105. For the G5, the removal process was complicated and could result in damage to the transmitter with potentially dangerous consequences for the user.

⁴² *Id*.

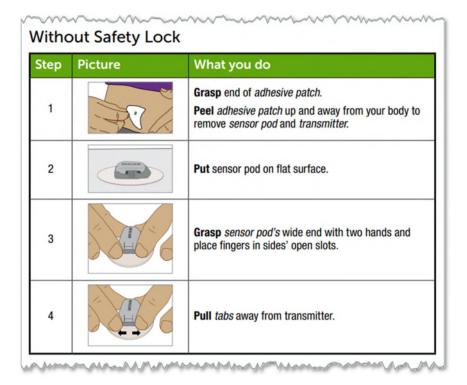
Steve Freed, CGMs Changing Diabetes Management: Kevin Sayer, DIC Interview Transcript, DIABETES IN CONTROL, https://www.diabetesincontrol.com/cgms-changing-diabetesmanagement-kevin-sayer-dic-interview-transcript/ (May 7, 2019).

- 106. For the G6, Dexcom copied Abbott's innovations and incorporated them into the G6, as demonstrated in Appendices C and I of the Initial Claim Charts. These innovations allow users to easily remove and reuse a transmitter device for a new sensor session.
- 107. In particular, the G5 transmitter could be removed for re-use in one of two ways. (G5 User Guide at 134.) The first method involved using a safety lock tool that the user had to remove from the applicator barrel during insertion and store and save until the end of the sensor session. (Id.) Per the G5 User Guide, the method involved the following four steps:

itep	Picture	What you do
1		Grasp end of adhesive patch. Peel adhesive patch up and away from your body to remove sensor pod and transmitter.
2		Put sensor pod on flat surface.
3		Place safety latch's jagged edge: Over transmitter's wide edge In between open slots on sensor pod's sides
4		Lift up safety latch.

(*Id*.)

108. Alternatively, if the user lost the safety lock, the user could "[m]anually spread out tabs holding [the] transmitter" in the transmitter mount. (*Id.*) This process also required four steps, as follows:



(*Id.* at 135.) These removal methods were not only complicated, but could also result in damage to important components of the system, including the transmitter itself.

- 109. For the G6, Dexcom addressed these problems by copying Abbott's innovations. Now, Dexcom promotes the sale and use of the Accused Product by touting its infringing "Streamlined Transmitter Holder and Transmitter."⁴⁴
- 110. Dexcom also copied inventions covered by the Asserted Claims of the '842 and '653 patents as explained in paragraphs 125–168 and 270–292 below.

Dexcom Continued Unabatedly After Unsuccessfully Seeking An Extension Of A Prior Covenant-Not-To-Sue

111. Starting nearly two decades ago, Abbott and Dexcom engaged in litigation lasting approximately nine years. This prior litigation saw three separate patent infringement

G6 User Guide at 46 ("With the transmitter holder's new breakaway feature, when your sensor session is done, the transmitter snaps out for easy removal.").

lawsuits brought by ADC Inc. against Dexcom and Dexcom challenging ADC Inc.'s patents through serial reexaminations before the United States Patent and Trademark Office (all of which failed to invalidate even a single ADC Inc. patent).

- 112. Ultimately, Dexcom sought to settle the prior litigation rather than risking an infringement finding at trial, and ADC Inc. and Dexcom entered into a Settlement and License Agreement ("SLA") in July 2014.
- 113. As a part of the SLA, the parties entered a covenant-not-to-sue that expired on March 31, 2021. Dexcom used the covenant-not-to-sue as an opportunity to incorporate Abbott's inventions into the G6 and other Accused Products, as described above.
- 114. As the expiration date approached, Dexcom reached out to Abbott on multiple occasions to request an extension of the covenant. Abbott did not agree to extend the covenant.
- Asserted Patents after the covenant expired. Instead, Dexcom has continued unabatedly to infringe the Asserted Patents, directly and indirectly, even though Dexcom had actual knowledge that the Accused Products infringe the Asserted Patents, or chose to be willfully blind to the infringement by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.

Induced Infringement

- 116. Dexcom has been and is inducing infringement of the Asserted Patents by actively and knowingly, and with specific intent, inducing others (*e.g.*, patients, physicians, etc.) to commit acts that it knows constitute direct infringement of the Asserted Patents.
- 117. Dexcom knows that the Accused Products infringe the Asserted Patents, but has continued to aid, abet, direct, encourage, and instruct others to infringe the Asserted Patents.

118. As explained in further detail below, examples of Dexcom's inducing acts include, but are not limited to: (1) publishing and providing product documentation and educational materials (*e.g.*, user guides and other materials located on its website at, *e.g.*, https://www.dexcom.com/guides or elsewhere provided) that instruct and encourage others to use the Accused Products in an infringing manner, (2) marketing and advertising the Accused Products for use in a manner Dexcom knows infringes the Asserted Patents and highlighting infringing features, and (3) manufacturing and selling Accused Products designed and configured in a manner such that others will necessarily infringe when using the Accused Products for their intended purposes.

Contributory Infringement

- Asserted Patents by making, selling, offering to sell, and/or importing Accused Products (including components thereof), for use in practicing the Asserted Claims, knowing that the same are material to practicing the claimed inventions, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are especially made or especially adapted for use in an infringement. By continuing to provide the Accused Products (including components thereof), Dexcom has been and is contributorily infringing the Asserted Patents with specific intent.
- 120. Dexcom does not have, nor could it have had, a good-faith belief that the infringement by Dexcom and/or others using the Accused Products is non-infringing. Moreover, Dexcom's acts of willful infringement of the Asserted Patents, as discussed below, further demonstrate Dexcom's induced and contributory infringement. Dexcom is therefore liable for contributory infringement of the Asserted Patents.

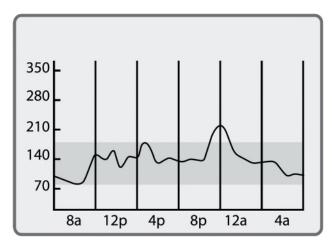
Willful Infringement

- 121. Dexcom has been and is engaging in willful and deliberate infringement of the Asserted Patents. As detailed above, before Abbott filed the original Complaint in this action, Dexcom knew about the Asserted Patents and knew that it was infringing the Asserted Patents, or chose to be willfully blind to the fact that it is infringing the Asserted Patents by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.
- 122. Despite that knowledge, Dexcom continues to make, use, offer for sale, sell, and/or import Accused Products in willful disregard of the Asserted Patents, with the intent to infringe the Asserted Patents, and without any reasonable basis for believing that it had or has a right to engage in the infringing conduct. Therefore, Dexcom's infringement of the Asserted Patents has been, is, and will continue to be willful, intentional, deliberate, and in conscious disregard of Abbott's rights under the Asserted Patents.
- 123. In addition, Abbott believes that documents and other evidence that support a finding of willful infringement are in Dexcom's custody and control and that, after a reasonable opportunity for additional investigation and discovery, it is likely that such evidence will further show that Dexcom's infringement has been, and continues to be, willful.
- 124. Additional allegations of direct, indirect, and willful infringement of each Asserted Patent are set forth below in several causes of action.

FIRST CAUSE OF ACTION (Infringement of the '842 Patent)

125. Abbott repeats and re-alleges the allegations of paragraphs 1 through 124 above.

- 126. The inventions claimed in the '842 patent save lives by providing diabetes patients who use CGM systems with more complete and accurate information about their glucose levels, even after a failure in the system. The claimed inventions thus address a problem unique to the CGM field by describing and claiming technological solutions that improve the functioning of the CGM systems themselves.
- 127. Before Abbott introduced factory calibration, commercial CGM systems typically required periodic calibration, such as every 12 to 24 hours. Using the fingerstick method, patients periodically determined their glucose levels and entered this information into the system. With this information, the CGM system determined (or updated) a conversion function to convert uncalibrated data received from the glucose sensor to estimated glucose levels. The estimated glucose levels were then output to the patient's display device, for example.
- 128. The display device could convey information about the patient's glucose levels in different ways. For one, a graph could be provided depicting glucose levels over time. From the graph, patients could determine their current glucose levels, how their levels fluctuated in the recent past, whether the patient's glucose levels were stable or trending toward dangerous levels and how their levels were impacted by food, medicine, and physical activity. The display device also could provide a numerical value of the patient's current glucose level and a trend arrow indicating the direction of the patient's glucose levels and the rate at which the levels were changing. Examples of this information from Abbott's FreeStyle Navigator product is provided below.



Graph Depicting Glucose Levels Over Time



Your current glucose level. Follow the recommendations of your healthcare team to treat low glucose (hypoglycemic) and high glucose (hyperglycemic) episodes.

Current Glucose Level in Numerical Form



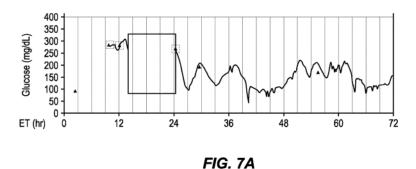
The directional glucose trend arrow tells you the direction that your glucose levels are trending and how fast (see Step 4). The system uses 15 minutes of continuous glucose data to display the arrow. Occasionally, the arrow may not be displayed temporarily. Refer to the Line Graph for recent glucose history.

Trend Arrow

129. The continuity and accuracy of information received from CGM systems is critical for patients to manage their diabetes. Falling outside of a target glucose range can have adverse consequences on the patient, including reduced brain function that can lead to confusion and an inability to reason, remember, or react. Some diabetic patients also use medication, such as insulin, to regulate their glucose levels. Having more complete and accurate information about

glucose levels is important for patients to optimize their glycemic control and minimize the frequency and severity of hypo- or hyperglycemic conditions.

that in CGM systems there are instances when a patient's glucose levels cannot be accurately reported by the system, which could lead a patient to act on inaccurate or incomplete information. For example, the specification of the '842 patent explains that "[t]here are time periods when the sensor characteristics or the user's physiological condition renders the condition unsuitable for a sensor calibration event." (Ex. A, '842 patent at 11:6-8.) For the time period associated with the failed calibration event, there can be "a gap in the output display during which the necessary calibration did not occur." (*Id.* at 12:32-34.) This is illustrated below in FIG. 7A of the '842 patent.

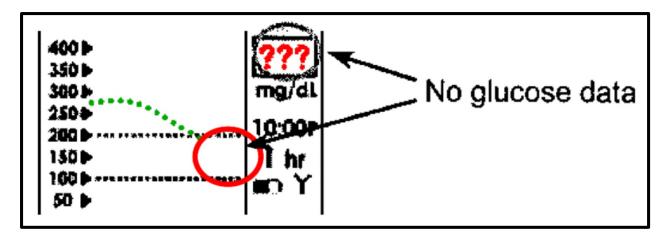


(*Id.* at FIG. 7A.)

- 131. Data gaps in a patient's estimated glucose levels was a known issue that plagued CGM systems, as the patient could not recover the lost data. For example, before G6, Dexcom knew for years about the "data-gap" problem with its products, warned patients about it, and had every incentive to address it, but was unable to resolve it.
- 132. Dexcom's prior STS-7 CGM System is an example. A user guide for Dexcom's STS-7 CGM system explained that "[a]t times [the] STS-7 System will not display glucose information or provide alerts," which can happen when the system "needs another [blood glucose] fingerstick reading[] for calibration because the STS-7 Sensor readings do not match [the

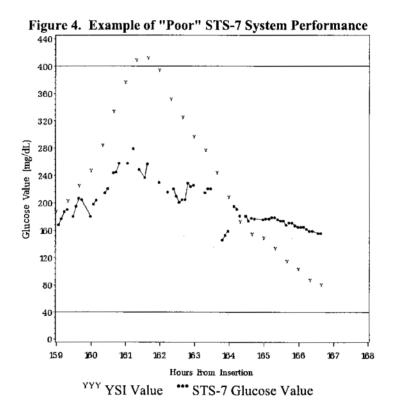
patient's] blood glucose meter readings." (Ex. M, STS-7 Continuous Glucose Monitoring System User's Guide [hereinafter, "STS-7 User Guide"] at 33.) When this occurs, "Glucose Data Gaps" appeared in the patient's glucose levels on the display device. (*Id.*)

133. In the STS-7 User Guide, Dexcom could only caution patients about data gaps (see below) but offered no option to recover the lost data.



(Ex. M at 34 (color added).)

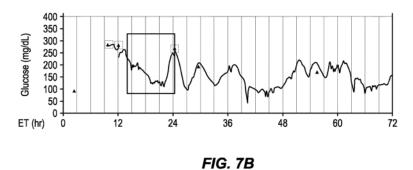
- 134. As depicted, Dexcom's STS-7 display shows continuous glucose readings (green dots) followed by a data gap (red circle), and provides an alert ("???" (in red)) indicating that "No glucose data" is available.
- 135. During a clinical study involving 72 participants who wore the Dexcom STS-7 CGM System for seven days, more than 25% of the data was lost for 31% of the systems and more than 50% of the data was lost for 18% of the systems. (*Id.* at 58.) The STS-7 User Guide explained that "[s]ometimes sensors fail to provide readings after calibration" and therefore the readings were simply "skipped." (*Id.*)
- 136. An illustration of "'Poor' STS-7 System Performance" with numerous data gaps is provided below, showing how the glucose concentration measured with the STS-7 system (y-axis) failed to track the actual glucose concentration measured with a YSI analyzer (x-axis).



(Ex. M, STS-7 User Guide at 60.)

systems by devising technological solutions that improved the functionality of the CGM systems themselves, increasing their accuracy and safety. For example, the '842 patent describes a system where the data gap associated with a calibration failure could be filled by storing the unprocessed sensor data during the calibration failure and then processing the data after a subsequent and successful calibration event. Specifically, the '842 patent explains that, "based on the parameters associated with the successful calibration, the previously unprocessed data during the display time out period [that caused the sensor data gap] may be retrieved . . . and processed using calibration data, such as the sensitivity ratio for conversion of the [glucose] related sensor data to [glucose] levels." (Ex. A, '842 patent at 12:47-54.) Thereafter, "the gap in [the] output display . . . may be

filled." (*Id.* at 12:59-61.) Figure 7B of the '842 patent, reproduced below, shows the sensor data gap backfilled with processed sensor data after the failure mode condition was corrected.

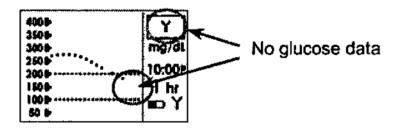


(Ex. A, '842 patent at FIG. 7B.)

138. The inventor of the '842 patent further recognized that a failed calibration was only one type of error that could interrupt a patient's glucose monitoring and cause data gaps. The '842 patent explains that a failure mode condition can result from "an inability to promptly calibrate the sensor, system malfunction, sensor dislodging, signal errors associated with the sensor, transmitter unit, receiver unit, and the like, or other variables or parameters that result in the inability of the [glucose] monitoring system to display or output the real-time monitored [glucose] level." (Ex. A, '842 patent at 13:19-27.)

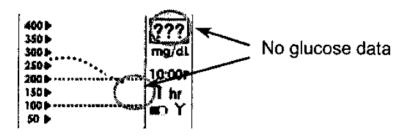
139. Such failure mode conditions were issues that plagued CGM systems. For example, Dexcom's STS-7 User Guide explains that, in addition to calibration failures, the "STS-7 System will not display glucose information or provide alerts" when "[t]he Transmitter and Receiver are out of range" or when "[t]he STS Receiver does not understand the STS-7 Sensor signal." (Ex. Y, STS-7 User Guide at 33.)

140. In the STS-7 User Guide, Dexcom advised users that "[a]nytime [they] see the Antenna Icon 'Y' in the Status Box instead of a glucose reading the STS Receiver has 'missed' the last glucose reading sent by the Transmitter to the Receiver." (*Id.*) This will result in a sensor data gap output to the display device:



(*Id*.)

141. Also, "[d]uring continuous glucose monitoring [the] STS® System may get a reading that it does not understand." (*Id.* at 34.) "When this occurs [the patient] will see 3 question marks (???) in the STS Receiver Status Box" along with sensor data gaps output to the display device:



(*Id*.)

- 142. The '842 patent solved these technological problems plaguing CGM systems with inventions capable of recovering what would otherwise be lost data when there is a failure mode condition in the system. The innovative technological solution is reflected in the claims of the '842 patent.
- 143. For example, claim 14 of the '842 patent is directed to an "analyte monitoring system." (Ex. A, '842 patent at 16:29-41.) As explained in the specification, glucose is one such analyte. (*Id.* at 4:35-55.) The claimed analyte monitoring system comprises "an analyte sensor," "one or more processors," and "a memory device." (*Id.* at 16:30-32.) The memory device stores "instructions which, when executed by the one or more processors, causes the one or more processors to: detect a failure mode condition, wherein the failure mode condition causes one or

more sensor data gaps to be outputted to a display of the analyte monitoring system." (*Id.* at 16:32-38.) The claimed system detects that a failure mode condition has occurred that is causing a gap in the data displayed to the patient. To resolve the data gap, the instructions, "when executed by the one or more processors," further "cause[] the one or more processors to . . . store sensor data received from the analyte sensor for at least a portion of a time period associated with the failure mode condition," "process the sensor data for the at least a portion of the time period associated with the failure mode condition," and "in response to a correction of the failure mode condition, output the processed stored sensor data to the display of the analyte monitoring system such that the one or more sensor data gaps are at least partially filled by the processed stored sensor data." (*Id.* at 16:39-49.) Thus, instead of merely "skipping" glucose readings during a failure mode condition as in Dexcom's STS-7, the improved monitoring system of claim 14 is able to recover glucose data from the time period associated with the failure mode condition, thereby providing the patient with a more complete and accurate record of their glucose levels. As illustrated by this example, the claimed system is a technological improvement over prior art CGM systems.

- 144. Claims 3 and 25 of the '842 patent, which depend from independent claims 1 and 23, respectively, claim methods and systems for backfilling sensor data gaps resulting from "an inability to calibrate the sensor." (*Id.* at 15:46-48, 18:8-11.) The system detects when the sensor cannot be calibrated, which will cause "one or more sensor data gaps" to be output to a display, stores and processes the sensor data from that time period, then outputs the processed sensor data (*e.g.*, glucose levels) after the failure mode condition is corrected.
- 145. Dependent claims 2, 4, 13, 15, and 22, which depend from independent claims 1 and 14, respectively, recite other failure mode conditions that can be detected and from which the system can recover otherwise lost data. For example, claims 2 and 15 recite that "the

failure mode condition comprises signal errors associated with a transmitter unit of the analyte monitoring system or a receiver unit of the analyte monitoring system." (*Id.* at 15:42-45, 16:50-53.) Claim 4 recites that the failure mode comprises "one or more of a sensor data value being outside a predetermined sensor data value range, a rate of change of one or more sensor data values being above a predetermined rate-of-change threshold, or a temperature measurement outside a predetermined temperature range." (*Id.* at 15:49-54.) Claims 13 and 22 recite that the failure mode condition "comprises an inability of the analyte monitoring system to display or output the sensor data." (*Id.* at 16:26-28; 17:25-27.)

- 146. Thus, using a specific combination of components, the '842 patent is directed to an improved glucose monitoring system capable of detecting if and when a failure mode condition occurs and recovering what would otherwise be lost glucose data—something that no previous system was able to achieve.
- 147. Several advantages are realized from these technological improvements. An important advantage is that a diabetes patient is provided with a more complete and accurate record of their glucose levels. (Ex. A, '842 patent at 12:54-61.) This includes having a continuous glucose graph, trend data, and current glucose levels output to the display device. Gaps in the patient's glucose data caused by a failure mode condition can be "retrospectively filled or reprocessed so that the data gap is closed" and "the continuously monitored [glucose] level does not have any or substantially [any] missing data." (*Id.* at 13:27-30.) As the specification explains, this "advantageously" provides "additional robustness . . . to the user and/or healthcare provider to improve therapy or health management decisions." (*Id.* at 13:39-42.)
- 148. Another advantage realized by the invention claimed in the '842 patent is that patients are protected from making uninformed or misinformed decisions about their glucose

levels and trends. For example, claims 7 and 16 of the '842 patent recite that the system "wait[s] a predetermined period of time before outputting . . . the processed stored sensor data to the display." (*Id.* at 15:63-67, 16:54-59.) As the specification explains, this is to "avoid possible unnecessary or incorrect action by a user in response to the backfilled processed sensor data." (*Id.* at 13:10-13.)

- 149. Unable to solve the data-gap problem, Dexcom appropriated the inventions of the Asserted Claims of the '842 patent into the G6. Further, Dexcom now touts its infringing backfill feature as a "Quality of Service" for G6. For example, Dexcom assures its users that "[i]f connection is lost between the transmitter and display device, upon re-connection any missed packets (up to 3 hours) will be transmitted from the transmitter to the display device."⁴⁵
- 150. As shown in **Appendix A** of the Initial Claim Charts, the Accused Products meet each and every limitation of the Asserted Claims of the '842 patent, either literally and/or under the doctrine of equivalents.
- 151. Dexcom has directly infringed and continues to directly infringe the Asserted Claims of the '842 patent under 35 U.S.C. § 271(a) by making, using, selling, and/or offering to sell the Accused Products.
- 152. Dexcom has induced infringement and continues to induce infringement of the Asserted Claims of the '842 patent under 35 U.S.C. § 271(b). As illustrated in Appendix A of the Initial Claim Charts, Dexcom's customers (e.g., patients and physicians) have directly infringed and continue to directly infringe the Asserted Claims of the '842 patent by making (e.g., completing the systems) and/or using the Accused Products. Dexcom actively and knowingly

⁴⁵ *G6 User Guide* at 326.

induces such infringement with specific intent through activities relating to instructions for use, marketing, advertising, promotion, support, and distribution of the Accused Products.

- 153. The Accused Products are designed and configured in a manner such that others will necessarily infringe when using the Accused Products for their intended purposes and as instructed in Dexcom's user guides. As shown in the Initial Claim Charts, Dexcom provides materials, including, for example, its user guides, that instruct others to use the system to recover missed data in a manner that directly infringes the Asserted Claims of the '842 patent.
- 154. According to the G6 User Guide, data gaps can be caused by, for example, "a temporary shutdown, Signal Loss, or similar issue."
 - When the receiver and transmitter reconnect after a temporary shutdown, Signal Loss, or similar issue, up to 3 hours of missed G6 readings can fill in on the graph.

(*G6 User Guide* at 246.)

155. The G6 can backfill these data gaps:

When the transmitter reconnects with the display device after a Signal Loss or similar issue, up to 3 hours of missed G6 readings can fill in on the graph.

(*Id.* at 115.)

- 156. Dexcom has acted and continues to act with specific intent to induce others to infringe the Asserted Claims of the '842 patent, or has chosen to be willfully blind to the fact that it is inducing infringement by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.
- 157. Dexcom has infringed and continues to infringe the Asserted Claims of the '842 patent under 35 U.S.C. § 271(f)(1). Dexcom supplies or causes to be supplied in or from the

United States all or a substantial portion of the components of the inventions claimed in the Asserted Claims of the '842 patent, where such components are uncombined in whole or in part with other components, which together comprise the claimed inventions. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof, and with specific intent, instructs its customers to combine them outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '842 patent if such combination occurred within the United States.

- Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and provides materials, including for example, instructions for use and user guides, that instruct customers to combine the Accused Products and/or components thereof with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, comprise the claimed inventions of the Asserted Claims of the '842 patent.
- Asserted Claims of the '842 patent under 35 U.S.C. § 271(c) by selling, offering to sell, and/or importing the Accused Products and components thereof for use in practicing the Asserted Claims of the '842 patent. Dexcom knows that the same are material to practicing the claimed inventions, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are especially made or especially adapted for use in an infringement.
- 160. For example, Dexcom sells, offers to sell, and/or imports the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) that customers use and/or combine with other components (*e.g.*, sensors, transmitters, smart devices, etc.) to practice the Asserted Claims of the '842 patent. By continuing to provide the Accused Products and

components thereof, Dexcom has been and is contributorily infringing the '842 patent with specific intent.

- 161. Dexcom does not have, nor could it have had, a good-faith belief that the infringement by Dexcom and/or others using the Accused Products is non-infringing. Moreover, Dexcom's acts of willful infringement of the '842 patent further demonstrate Dexcom's induced and contributory infringement. Dexcom is therefore liable for contributory infringement of the '842 patent.
- 162. Dexcom has infringed and continues to infringe the Asserted Claims of the '842 patent under 35 U.S.C. § 271(f)(2). Dexcom supplies or causes to be supplied in or from the United States components of the inventions claimed in the Asserted Claims of the '842 patent that Dexcom knows are especially made or especially adapted for use in the claimed inventions. Such components are not staple articles or commodities of commerce suitable for substantial non-infringing use. Dexcom supplies or causes to be supplied such components uncombined with other components, and knows that such components are so made or adapted, and with specific intent, intends for such components to be combined with other components outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '842 patent if such combination occurred within the United States.
- 163. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and specifically intends for customers to combine them with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, Dexcom knows comprise the claimed inventions of the Asserted Claims of the '842 patent.

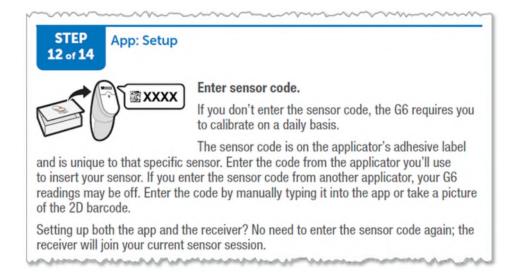
- Claim of the '842 patent (*e.g.*, because the claim recites an element that Dexcom does not sell (*e.g.*, smart device) or that Dexcom sells separately from other components), Dexcom nevertheless infringes such claim under 35 U.S.C. §§ 271(b) and/or 271(c) for sales within the United States and 35 U.S.C. §§ 271(f)(1) and/or 271(f)(2) for sales outside of the United States.
- 165. Dexcom has been and is engaging in willful and deliberate infringement of the '842 patent. As detailed above, before Abbott filed the original Complaint in this action, Dexcom knew about the '842 patent and knew that it was infringing the '842 patent, or chose to be willfully blind to the fact that it is infringing the '842 patent by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.
- 166. Despite that knowledge, Dexcom continues to make, use, offer for sale, sell, and/or import the Accused Products in willful disregard of the '842 patent, with the intent to infringe the '842 patent, and without any reasonable basis for believing that it had or has a right to engage in the infringing conduct. Therefore, Dexcom's infringement of the '842 patent has been, is, and will continue to be willful, intentional, deliberate, and in conscious disregard of Abbott's rights under the '842 patent.
- 167. Unless enjoined by this Court, Dexcom will continue to infringe the '842 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.
- 168. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '842 patent. Thus, in addition to injunctive

relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

SECOND CAUSE OF ACTION (Infringement of the '954 Patent)

- 169. Abbott repeats and re-alleges the allegations of paragraphs 1 through 168 above.
- 170. As shown in **Appendix B** of the Initial Claim Charts, the Accused Products meet each and every limitation of the Asserted Claims of the '954 patent, either literally and/or under the doctrine of equivalents.
- 171. Dexcom has directly infringed and continues to directly infringe the Asserted Claims of the '954 patent under 35 U.S.C. § 271(a) by making, using, selling, and/or offering to sell the Accused Products.
- 172. Dexcom has induced infringement and continues to induce infringement of the Asserted Claims of the '954 patent under 35 U.S.C. § 271(b). As illustrated in Appendix B of the Initial Claim Charts, Dexcom's customers (e.g., patients and physicians) have directly infringed and continue to directly infringe the Asserted Claims of the '954 patent by making (e.g., completing the systems) and/or using the Accused Products. Dexcom actively and knowingly induces such infringement with specific intent through activities relating to instructions for use, marketing, advertising, promotion, support, and distribution of the Accused Products.
- 173. The Accused Products are designed and configured in a manner such that others will necessarily infringe when using the Accused Products for their intended purposes and as instructed in Dexcom's user guides. As shown in the Initial Claim Charts, Dexcom provides materials, including, for example, its user guides, that instruct others to use the Accused Products in a manner that directly infringes the Asserted Claims of the '954 patent.

174. The G6 User Guide explains that "[c]alibration is not required if users enter a sensor code." Specifically, users are told to "enter a code into [the] display device to use the G6 without fingerstick calibrations." 47



(G6 User Guide at 61.)

175. Dexcom has acted and continues to act with specific intent to induce others to infringe the Asserted Claims of the '954 patent, or has chosen to be willfully blind to the fact that it is inducing infringement by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.

176. Dexcom has infringed and continues to infringe the Asserted Claims of the '954 patent under 35 U.S.C. § 271(f)(1). Dexcom supplies or causes to be supplied in or from the United States all or a substantial portion of the components of the inventions claimed in the Asserted Claims of the '954 patent, where such components are uncombined in whole or in part with other components, which together comprise the claimed inventions. For example, Dexcom

⁴⁶ G6 User Guide at 22.

⁴⁷ *Id*.

supplies or causes to be supplied the Accused Products and components thereof, and with specific intent, instructs its customers to combine them outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '954 patent if such combination occurred within the United States.

- 177. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and provides materials, including for example, instructions for use and user guides, that instruct customers to combine the Accused Products and/or components thereof with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, comprise the claimed inventions of the Asserted Claims of the '954 patent.
- Asserted Claims of the '954 patent under 35 U.S.C. § 271(c) by selling, offering to sell, and/or importing the Accused Products and components thereof for use in practicing the Asserted Claims of the '954 patent. Dexcom knows that the same are material to practicing the claimed inventions, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are especially made or especially adapted for use in an infringement.
- 179. For example, Dexcom sells, offers to sell, and/or imports the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) that customers use and/or combine with other components (e.g., sensors, transmitters, smart devices, etc.) to practice the Asserted Claims of the '954 patent. By continuing to provide the Accused Products and components thereof, Dexcom has been and is contributorily infringing the '954 patent with specific intent.

- 180. Dexcom does not have, nor could it have had, a good-faith belief that the infringement by Dexcom and/or others using the Accused Products is non-infringing. Moreover, Dexcom's acts of willful infringement of the '954 patent further demonstrate Dexcom's induced and contributory infringement. Dexcom is therefore liable for contributory infringement of the '954 patent.
- 181. Dexcom has infringed and continues to infringe the Asserted Claims of the '954 patent under 35 U.S.C. § 271(f)(2). Dexcom supplies or causes to be supplied in or from the United States components of the inventions claimed in the Asserted Claims of the '954 patent that Dexcom knows are especially made or especially adapted for use in the claimed inventions. Such components are not staple articles or commodities of commerce suitable for substantial non-infringing use. Dexcom supplies or causes to be supplied such components uncombined with other components, and knows that such components are so made or adapted, and with specific intent, intends for such components to be combined with other components outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '954 patent if such combination occurred within the United States.
- 182. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and specifically intends for customers to combine them with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, Dexcom knows comprise the claimed inventions of the Asserted Claims of the '954 patent.
- 183. To the extent Dexcom alleges that it does not directly infringe an Asserted Claim of the '954 patent (*e.g.*, because the claim recites an element that Dexcom does not sell (*e.g.*, smart device) or that Dexcom sells separately from other components), Dexcom nevertheless

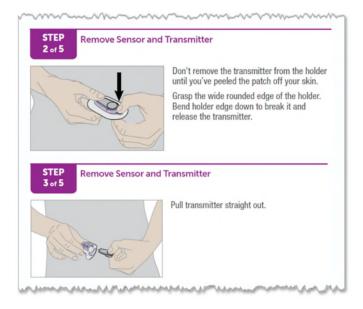
infringes such claim under 35 U.S.C. §§ 271(b) and/or 271(c) for sales within the United States and 35 U.S.C. §§ 271(f)(1) and/or 271(f)(2) for sales outside of the United States.

- 184. Dexcom has been and is engaging in willful and deliberate infringement of the '954 patent. As detailed above, before Abbott filed the original Complaint in this action, Dexcom knew about the '954 patent and knew that it was infringing the '954 patent, or chose to be willfully blind to the fact that it is infringing the '954 patent by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.
- 185. Despite that knowledge, Dexcom continues to make, use, offer for sale, sell, and/or import Accused Products in willful disregard of the '954 patent, with the intent to infringe the '954 patent, and without any reasonable basis for believing that it had or has a right to engage in the infringing conduct. Therefore, Dexcom's infringement of the '954 patent has been, is, and will continue to be willful, intentional, deliberate, and in conscious disregard of Abbott's rights under the '954 patent.
- 186. Unless enjoined by this Court, Dexcom will continue to infringe the '954 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.
- 187. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '954 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

THIRD CAUSE OF ACTION (Infringement of the '338 Patent)

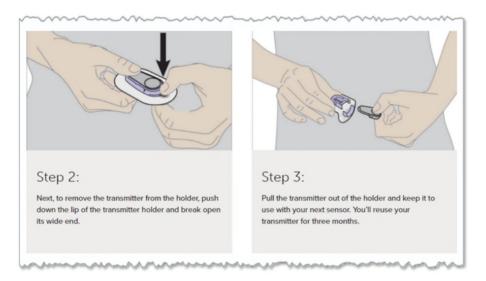
- 188. Abbott repeats and re-alleges the allegations of paragraphs 1 through 187 above.
- 189. As shown in **Appendix C** of the Initial Claim Charts, the Accused Products meet each and every limitation of the Asserted Claims of the '338 patent, either literally and/or under the doctrine of equivalents.
- 190. Dexcom has directly infringed and continues to directly infringe the Asserted Claims of the '338 patent under 35 U.S.C. § 271(a) by making, using, selling, and/or offering to sell the Accused Products.
- 191. Dexcom has induced infringement and continues to induce infringement of the Asserted Claims of the '338 patent under 35 U.S.C. § 271(b). As illustrated in Appendix C of the Initial Claim Charts, Dexcom's customers (e.g., patients and physicians) have directly infringed and continue to directly infringe the Asserted Claims of the '338 patent by making (e.g., completing the systems) and/or using the Accused Products. Dexcom actively and knowingly induces such infringement with specific intent through activities relating to instructions for use, marketing, advertising, promotion, support, and distribution of the Accused Products.
- 192. The Accused Products are designed and configured in a manner such that others will necessarily infringe when using the Accused Products for their intended purposes and as instructed in Dexcom's user guides. As shown in the Initial Claim Charts, Dexcom provides materials, including, for example, its user guides, that instruct others to remove the sensor and transmitter in a manner that directly infringes the Asserted Claims of the '338 patent.
- 193. Specifically, Dexcom's G6 User Guide instructs users to "[g]rasp the wide rounded edge of the [transmitter] holder" and "[b]end [the transmitter] holder edge down to break

it and release the transmitter."⁴⁸ After that, the user simply has to "[p]ull the transmitter straight out."⁴⁹



(*G6 User Guide* at 211-12.)

194. Similarly, on its website, Dexcom instructs users to remove the transmitter by "push[ing] down the lip of the transmitter holder and break[ing] open its wide end."



⁴⁸ *G6 User Guide* at 211.

⁴⁹ *Id.* at 211-12.

(Ending Your Sensor Session, DEXCOM CONTINUOUS GLUCOSE MONITORING, https://www.dexcom.com/training-videos/removing-your-sensor-and-transmitter.)

- 195. Dexcom has acted and continues to act with specific intent to induce others to infringe the Asserted Claims of the '338 patent, or has chosen to be willfully blind to the fact that it is inducing infringement by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.
- 196. Dexcom has infringed and continues to infringe the Asserted Claims of the '338 patent under 35 U.S.C. § 271(f)(1). Dexcom supplies or causes to be supplied in or from the United States all or a substantial portion of the components of the inventions claimed in the Asserted Claims of the '338 patent, where such components are uncombined in whole or in part with other components, which together comprise the claimed inventions. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof, and with specific intent, instructs its customers to combine them outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '338 patent if such combination occurred within the United States.
- 197. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and provides materials, including for example, instructions for use and user guides, that instruct customers to combine the Accused Products and/or components thereof with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, comprise the claimed inventions of the Asserted Claims of the '338 patent.
- 198. Dexcom has been and is knowingly contributing to the infringement of the Asserted Claims of the '338 patent under 35 U.S.C. § 271(c) by selling, offering to sell, and/or

importing the Accused Products and components thereof for use in practicing the Asserted Claims of the '338 patent. Dexcom knows that the same are material to practicing the claimed inventions, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are especially made or especially adapted for use in an infringement.

- 199. For example, Dexcom sells, offers to sell, and/or imports the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) that customers use and/or combine with other components (*e.g.*, sensors, transmitters, smart devices, etc.) to practice the Asserted Claims of the '338 patent. By continuing to provide the Accused Products and components thereof, Dexcom has been and is contributorily infringing the '338 patent with specific intent.
- 200. Dexcom does not have, nor could it have had, a good-faith belief that the infringement by Dexcom and/or others using the Accused Products is non-infringing. Moreover, Dexcom's acts of willful infringement of the '338 patent further demonstrate Dexcom's induced and contributory infringement. Dexcom is therefore liable for contributory infringement of the '338 patent.
- 201. Dexcom has infringed and continues to infringe the Asserted Claims of the '338 patent under 35 U.S.C. § 271(f)(2). Dexcom supplies or causes to be supplied in or from the United States components of the inventions claimed in the Asserted Claims of the '338 patent that Dexcom knows are especially made or especially adapted for use in the claimed inventions. Such components are not staple articles or commodities of commerce suitable for substantial non-infringing use. Dexcom supplies or causes to be supplied such components uncombined with other components, and knows that such components are so made or adapted, and with specific intent, intends for such components to be combined with other components outside of the United States

in a manner that Dexcom knows would infringe the Asserted Claims of the '338 patent if such combination occurred within the United States.

- 202. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and specifically intends for customers to combine them with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, Dexcom knows comprise the claimed inventions of the Asserted Claims of the '338 patent.
- 203. To the extent Dexcom alleges that is does not directly infringe an Asserted Claim of the '338 patent (*e.g.*, because the claim recites an element that Dexcom does not sell (*e.g.*, smart device) or that Dexcom sells separately from other components), Dexcom nevertheless infringes such claim under 35 U.S.C. §§ 271(b) and/or 271(c) for sales within the United States and 35 U.S.C. §§ 271(f)(1) and/or 271(f)(2) for sales outside of the United States.
- 204. Dexcom has been and is engaging in willful and deliberate infringement of the '338 patent. As detailed above, before Abbott filed the original Complaint in this action, Dexcom knew about the '338 patent and knew that it was infringing the '338 patent, or chose to be willfully blind to the fact that it is infringing the '338 patent by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.
- 205. Despite that knowledge, Dexcom continues to make, use, offer for sale, sell, and/or import the Accused Products in willful disregard of the '338 patent, with the intent to infringe the '338 patent, and without any reasonable basis for believing that it had or has a right to engage in the infringing conduct. Therefore, Dexcom's infringement of the '338 patent has been, is, and will continue to be willful, intentional, deliberate, and in conscious disregard of Abbott's rights under the '338 patent.

206. Unless enjoined by this Court, Dexcom will continue to infringe the '338 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

207. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '338 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

FOURTH CAUSE OF ACTION (Infringement of the '341 Patent)

- 208. Abbott repeats and re-alleges the allegations of paragraphs 1 through 207 above.
- 209. As shown in **Appendix D** of the Initial Claim Charts, the Accused Products meet each and every limitation of the Asserted Claims of the '341 patent, either literally and/or under the doctrine of equivalents.
- 210. Dexcom has directly infringed and continues to directly infringe the Asserted Claims of the '341 patent under 35 U.S.C. § 271(a) by making, using, selling, and/or offering to sell the Accused Products.
- 211. Dexcom has induced infringement and continues to induce infringement of the Asserted Claims of the '341 patent under 35 U.S.C. § 271(b). As illustrated in Appendix D of the Initial Claim Charts, Dexcom's customers (*e.g.*, patients and physicians) have directly infringed and continue to directly infringe the Asserted Claims of the '341 patent by making (*e.g.*, completing the systems) and/or using the Accused Products. Dexcom actively and knowingly

induces such infringement with specific intent through activities relating to instructions for use, marketing, advertising, promotion, support, and distribution of the Accused Products.

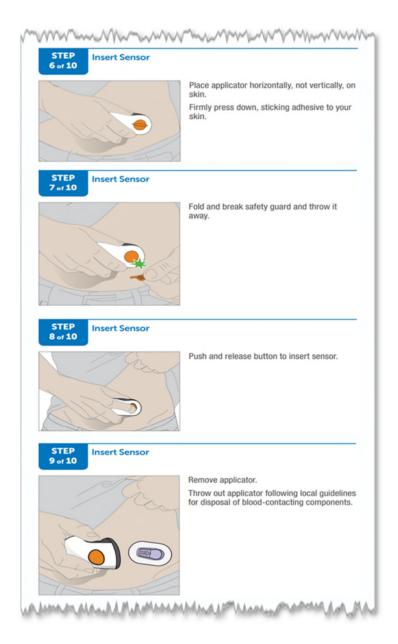
212. The Accused Products are designed and configured in a manner such that others will necessarily infringe when using the Accused Products for their intended purposes and as instructed in Dexcom's user guides. As shown in the Initial Claim Charts, Dexcom provides materials, including, for example, its user guides, that instruct others to use the applicator in a manner that directly infringes the Asserted Claims of the '341 patent.

213. For example, the G6 User Guide instructs users to "[p]lace the applicator . . . on [the] skin" and "[f]irmly press down, sticking [the] adhesive to [the] skin." After removing the safety guard on the applicator, the user is instructed to "[p]ush and release [the] button to insert [the] sensor." The user is then instructed to "[r]emove [the] applicator." 52

⁵⁰ *G6 User Guide* at 78.

⁵¹ *Id.* at 79.

⁵² *Id.* at 80.



(*G6 User Guide* at 78-80.)

214. To attach the transmitter, the user is directed to "[s]lide the transmitter tab into the slot at the narrow end of the [transmitter] holder" and "[p]ress the wide end of the transmitter until it clicks into the [transmitter] holder."⁵³

⁵³ *G6 User Guide* at 82-83.

- 215. Dexcom has acted and continues to act with specific intent to induce others to infringe the Asserted Claims of the '341 patent, or has chosen to be willfully blind to the fact that it is inducing infringement by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.
- 216. Dexcom has infringed and continues to infringe the Asserted Claims of the '341 patent under 35 U.S.C. § 271(f)(1). Dexcom supplies or causes to be supplied in or from the United States all or a substantial portion of the components of the inventions claimed in the Asserted Claims of the '341 patent, where such components are uncombined in whole or in part with other components, which together comprise the claimed inventions. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof, and with specific intent, instructs its customers to combine them outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '341 patent if such combination occurred within the United States.
- 217. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and provides materials, including for example, instructions for use and user guides, that instruct customers to combine the Accused Products and/or components thereof with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, comprise the claimed inventions of the Asserted Claims of the '341 patent.
- 218. Dexcom has been and is knowingly contributing to the infringement of the Asserted Claims of the '341 patent under 35 U.S.C. § 271(c) by selling, offering to sell, and/or importing the Accused Products and components thereof for use in practicing the Asserted Claims of the '341 patent. Dexcom knows that the same are material to practicing the claimed inventions,

are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are especially made or especially adapted for use in an infringement.

- 219. For example, Dexcom sells, offers to sell, and/or imports the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) that customers use and/or combine with other components (*e.g.*, sensors, transmitters, smart devices, etc.) to practice the Asserted Claims of the '341 patent. By continuing to provide the Accused Products and components thereof, Dexcom has been and is contributorily infringing the '341 patent with specific intent.
- 220. Dexcom does not have, nor could it have had, a good-faith belief that the infringement by Dexcom and/or others using the Accused Products is non-infringing. Moreover, Dexcom's acts of willful infringement of the '341 patent further demonstrate Dexcom's induced and contributory infringement. Dexcom is therefore liable for contributory infringement of the '341 patent.
- 221. Dexcom has infringed and continues to infringe the Asserted Claims of the '341 patent under 35 U.S.C. § 271(f)(2). Dexcom supplies or causes to be supplied in or from the United States components of the inventions claimed in the Asserted Claims of the '341 patent that Dexcom knows are especially made or especially adapted for use in the claimed inventions. Such components are not staple articles or commodities of commerce suitable for substantial non-infringing use. Dexcom supplies or causes to be supplied such components uncombined with other components, and knows that such components are so made or adapted, and with specific intent, intends for such components to be combined with other components outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '341 patent if such combination occurred within the United States.

- 222. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and specifically intends for customers to combine them with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, Dexcom knows comprise the claimed inventions of the Asserted Claims of the '341 patent.
- 223. To the extent Dexcom alleges that is does not directly infringe an Asserted Claim of the '341 patent (*e.g.*, because the claim recites an element that Dexcom does not sell (*e.g.*, smart device) or that Dexcom sells separately from other components), Dexcom nevertheless infringes such claim under 35 U.S.C. §§ 271(b) and/or 271(c) for sales within the United States and 35 U.S.C. §§ 271(f)(1) and/or 271(f)(2) for sales outside of the United States.
- 224. Dexcom has been and is engaging in willful and deliberate infringement of the '341 patent. As detailed above, before Abbott filed the original Complaint in this action, Dexcom knew about the '341 patent and knew that it was infringing the '341 patent, or chose to be willfully blind to the fact that it is infringing the '341 patent by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.
- 225. Despite that knowledge, Dexcom continues to make, use, offer for sale, sell, and/or import the Accused Products in willful disregard of the '341 patent, with the intent to infringe the '341 patent, and without any reasonable basis for believing that it had or has a right to engage in the infringing conduct. Therefore, Dexcom's infringement of the '341 patent has been, is, and will continue to be willful, intentional, deliberate, and in conscious disregard of Abbott's rights under the '341 patent.
- 226. Unless enjoined by this Court, Dexcom will continue to infringe the '341 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for

which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

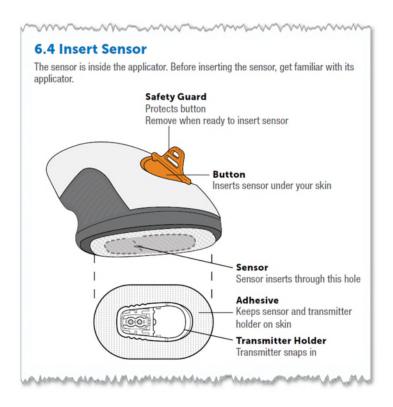
227. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '341 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

FIFTH CAUSE OF ACTION (Infringement of the '647 Patent)

- 228. Abbott repeats and re-alleges the allegations of paragraphs 1 through 227 above.
- 229. As shown in **Appendix E** of the Initial Claim Charts, the Accused Products meet each and every limitation of the Asserted Claims of the '647 patent, either literally and/or under the doctrine of equivalents.
- 230. Dexcom has directly infringed and continues to directly infringe the Asserted Claims of the '647 patent under 35 U.S.C. § 271(a) by making, using, selling, and/or offering to sell the Accused Products.
- 231. To improve sensor insertion, placement, and connectivity, Dexcom copied the inventions of the Asserted Claims of the '647 patent.
- 232. Dexcom has induced infringement and continues to induce infringement of the Asserted Claims of the '647 patent under 35 U.S.C. § 271(b). As illustrated in Appendix E of the Initial Claim Charts, Dexcom's customers (*e.g.*, patients and physicians) have directly infringed and continue to directly infringe the Asserted Claims of the '647 patent by making (*e.g.*, completing the systems) and/or using the Accused Products. Dexcom actively and knowingly

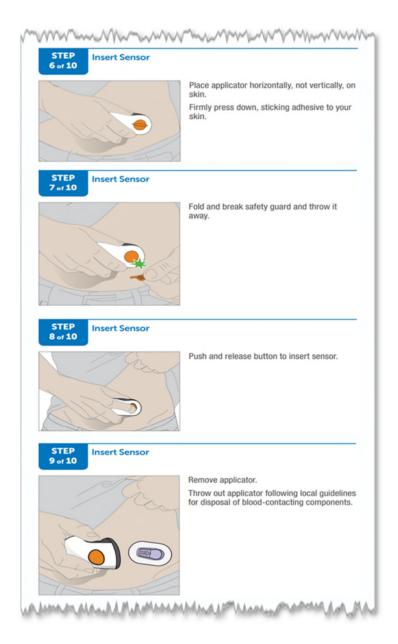
induces such infringement with specific intent through activities relating to instructions for use, marketing, advertising, promotion, support, and distribution of the Accused Products.

- 233. The Accused Products are designed and configured in a manner such that others will necessarily infringe when using the Accused Products for their intended purposes and as instructed in Dexcom's user guides. As shown in the Initial Claim Charts, Dexcom provides materials, including, for example, its user guides, that instruct others to use the Accused Products in a manner that directly infringes the Asserted Claims of the '647 patent.
- 234. The Accused Products include a transmitter mount that comprises a base and a locking mechanism:



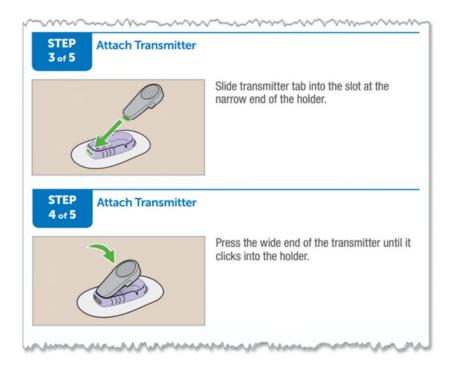
(G6 User Guide at 75.)

235. Further, as shown in Appendix E of the Initial Claim Charts, Dexcom's G6 User Guide instructs users to insert the sensor in a manner that results in a locking mechanism engaging the sensor subassembly:



(G6 User Guide at 78-80.)

236. And the G6 User Guide instructs users to attach the transmitter such that the transmitter mount receives the transmitter after the locking mechanism is engaged:



(*G6 User Guide* at 82-83.)

237. Dexcom has acted and continues to act with specific intent to induce others to infringe the Asserted Claims of the '647 patent, or has chosen to be willfully blind to the fact that it is inducing infringement by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.

238. Dexcom has infringed and continues to infringe the Asserted Claims of the '647 patent under 35 U.S.C. § 271(f)(1). Dexcom supplies or causes to be supplied in or from the United States all or a substantial portion of the components of the inventions claimed in the Asserted Claims of the '647 patent, where such components are uncombined in whole or in part with other components, which together comprise the claimed inventions. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof, and with specific intent, instructs its customers to combine them outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '647 patent if such combination occurred within the United States.

- 239. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and provides materials, including for example, instructions for use and user guides, that instruct customers to combine the Accused Products and/or components thereof with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, comprise the claimed inventions of the Asserted Claims of the '647 patent.
- 240. Dexcom has been and is knowingly contributing to the infringement of the Asserted Claims of the '647 patent under 35 U.S.C. § 271(c) by selling, offering to sell, and/or importing the Accused Products and components thereof for use in practicing the Asserted Claims of the '647 patent. Dexcom knows that the same are material to practicing the claimed inventions, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are especially made or especially adapted for use in an infringement.
- 241. For example, Dexcom sells, offers to sell, and/or imports the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) that customers use and/or combine with other components (*e.g.*, sensors, transmitters, smart devices, etc.) to practice the Asserted Claims of the '647 patent. By continuing to provide the Accused Products and components thereof, Dexcom has been and is contributorily infringing the '647 patent with specific intent.
- 242. Dexcom does not have, nor could it have had, a good-faith belief that the infringement by Dexcom and/or others using the Accused Products is non-infringing. Moreover, Dexcom's acts of willful infringement of the '647 patent further demonstrate Dexcom's induced and contributory infringement. Dexcom is therefore liable for contributory infringement of the '647 patent.

- 243. Dexcom has infringed and continues to infringe the Asserted Claims of the '647 patent under 35 U.S.C. § 271(f)(2). Dexcom supplies or causes to be supplied in or from the United States components of the inventions claimed in the Asserted Claims of the '647 patent that Dexcom knows are especially made or especially adapted for use in the claimed inventions. Such components are not staple articles or commodities of commerce suitable for substantial non-infringing use. Dexcom supplies or causes to be supplied such components uncombined with other components, and knows that such components are so made or adapted, and with specific intent, intends for such components to be combined with other components outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '647 patent if such combination occurred within the United States.
- 244. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and specifically intends for customers to combine them with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, Dexcom knows comprise the claimed inventions of the Asserted Claims of the '647 patent.
- 245. To the extent Dexcom alleges that is does not directly infringe an Asserted Claim of the '647 patent (*e.g.*, because the claim recites an element that Dexcom does not sell (*e.g.*, smart device) or that Dexcom sells separately from other components), Dexcom nevertheless infringes such claim under 35 U.S.C. §§ 271(b) and/or 271(c) for sales within the United States and 35 U.S.C. §§ 271(f)(1) and/or 271(f)(2) for sales outside of the United States.
- 246. Dexcom has been and is engaging in willful and deliberate infringement of the '647 patent. As detailed above, before Abbott filed the original Complaint in this action, Dexcom knew about the '647 patent and knew that it was infringing the '647 patent, or chose to

be willfully blind to the fact that it is infringing the '647 patent by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.

- 247. Despite that knowledge, Dexcom continues to make, use, offer for sale, sell, and/or import the Accused Products in willful disregard of the '647 patent, with the intent to infringe the '647 patent, and without any reasonable basis for believing that it had or has a right to engage in the infringing conduct. Therefore, Dexcom's infringement of the '647 patent has been, is, and will continue to be willful, intentional, deliberate, and in conscious disregard of Abbott's rights under the '647 patent.
- 248. Unless enjoined by this Court, Dexcom will continue to infringe the '647 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.
- 249. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '647 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

SIXTH CAUSE OF ACTION (Infringement of the '649 Patent)

- 250. Abbott repeats and re-alleges the allegations of paragraphs 1 through 249 above.
- 251. As shown in **Appendix F** of the Initial Claim Charts, the Accused Products meet each and every limitation of the Asserted Claims of the '649 patent, either literally and/or under the doctrine of equivalents.

252. Dexcom has directly infringed and continues to directly infringe the Asserted Claims of the '649 patent under 35 U.S.C. § 271(a) by making, using, selling, and/or offering to sell the Accused Products.

253. Dexcom has induced infringement and continues to induce infringement of the Asserted Claims of the '649 patent under 35 U.S.C. § 271(b). As illustrated in Appendix F of the Initial Claim Charts, Dexcom's customers (e.g., patients and physicians) have directly infringed and continue to directly infringe the Asserted Claims of the '649 patent by making (e.g., completing the systems) and/or using the Accused Products. Dexcom actively and knowingly induces such infringement with specific intent through activities relating to instructions for use, marketing, advertising, promotion, support, and distribution of the Accused Products.

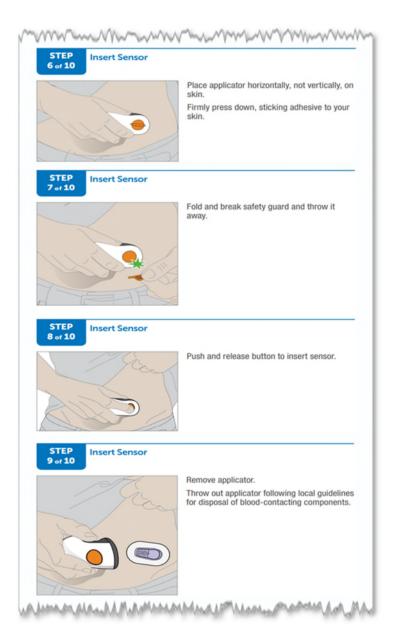
254. The Accused Products are designed and configured in a manner such that others will necessarily infringe when using the Accused Products for their intended purposes and as instructed in Dexcom's user guides. As shown in the Initial Claim Charts, Dexcom provides materials, including, for example, its user guides, that instruct others to use the applicator in a manner that directly infringes the Asserted Claims of the '649 patent.

255. For example, the G6 User Guide instructs users to "[p]lace the applicator... on [the] skin" and "[f]irmly press down, sticking [the] adhesive to [the] skin." After removing the safety guard on the applicator, the user is instructed to "[p]ush and release [the] button to insert [the] sensor." The user is then instructed to "[r]emove [the] applicator." 56

⁵⁴ *G6 User Guide* at 78.

⁵⁵ *Id.* at 79.

⁵⁶ *Id.* at 80.



(*G6 User Guide* at 78-80.)

256. To attach the transmitter, the user is directed to "[s]lide the transmitter tab into the slot at the narrow end of the [transmitter] holder" and "[p]ress the wide end of the transmitter until it clicks into the [transmitter] holder."⁵⁷

⁵⁷ *G6 User Guide* at 82-83.

- 257. Dexcom has acted and continues to act with specific intent to induce others to infringe the Asserted Claims of the '649 patent, or has chosen to be willfully blind to the fact that it is inducing infringement by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.
- 258. Dexcom has infringed and continues to infringe the Asserted Claims of the '649 patent under 35 U.S.C. § 271(f)(1). Dexcom supplies or causes to be supplied in or from the United States all or a substantial portion of the components of the inventions claimed in the Asserted Claims of the '649 patent, where such components are uncombined in whole or in part with other components, which together comprise the claimed inventions. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof, and with specific intent, instructs its customers to combine them outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '649 patent if such combination occurred within the United States.
- 259. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and provides materials, including for example, instructions for use and user guides, that instruct customers to combine the Accused Products and/or components thereof with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, comprise the claimed inventions of the Asserted Claims of the '649 patent.
- 260. Dexcom has been and is knowingly contributing to the infringement of the Asserted Claims of the '649 patent under 35 U.S.C. § 271(c) by selling, offering to sell, and/or importing the Accused Products and components thereof for use in practicing the Asserted Claims of the '649 patent. Dexcom knows that the same are material to practicing the claimed inventions,

are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are especially made or especially adapted for use in an infringement.

- 261. For example, Dexcom sells, offers to sell, and/or imports the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) that customers use and/or combine with other components (*e.g.*, sensors, transmitters, smart devices, etc.) to practice the Asserted Claims of the '649 patent. By continuing to provide the Accused Products and components thereof, Dexcom has been and is contributorily infringing the '649 patent with specific intent.
- 262. Dexcom does not have, nor could it have had, a good-faith belief that the infringement by Dexcom and/or others using the Accused Products is non-infringing. Moreover, Dexcom's acts of willful infringement of the '649 patent further demonstrate Dexcom's induced and contributory infringement. Dexcom is therefore liable for contributory infringement of the '649 patent.
- 263. Dexcom has infringed and continues to infringe the Asserted Claims of the '649 patent under 35 U.S.C. § 271(f)(2). Dexcom supplies or causes to be supplied in or from the United States components of the inventions claimed in the Asserted Claims of the '649 patent that Dexcom knows are especially made or especially adapted for use in the claimed inventions. Such components are not staple articles or commodities of commerce suitable for substantial non-infringing use. Dexcom supplies or causes to be supplied such components uncombined with other components, and knows that such components are so made or adapted, and with specific intent, intends for such components to be combined with other components outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '649 patent if such combination occurred within the United States.

- 264. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and specifically intends for customers to combine them with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, Dexcom knows comprise the claimed inventions of the Asserted Claims of the '649 patent.
- 265. To the extent Dexcom alleges that is does not directly infringe an Asserted Claim of the '649 patent (*e.g.*, because the claim recites an element that Dexcom does not sell (*e.g.*, smart device) or that Dexcom sells separately from other components), Dexcom nevertheless infringes such claim under 35 U.S.C. §§ 271(b) and/or 271(c) for sales within the United States and 35 U.S.C. §§ 271(f)(1) and/or 271(f)(2) for sales outside of the United States.
- 266. Dexcom has been and is engaging in willful and deliberate infringement of the '649 patent. As detailed above, before Abbott filed the original Complaint in this action, Dexcom knew about the '649 patent and knew that it was infringing the '649 patent, or chose to be willfully blind to the fact that it is infringing the '649 patent by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.
- 267. Despite that knowledge, Dexcom continues to make, use, offer for sale, sell, and/or import the Accused Products in willful disregard of the '649 patent, with the intent to infringe the '649 patent, and without any reasonable basis for believing that it had or has a right to engage in the infringing conduct. Therefore, Dexcom's infringement of the '649 patent has been, is, and will continue to be willful, intentional, deliberate, and in conscious disregard of Abbott's rights under the '649 patent.
- 268. Unless enjoined by this Court, Dexcom will continue to infringe the '649 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for

which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

269. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '649 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

SEVENTH CAUSE OF ACTION (Infringement of the '653 Patent)

- above. In particular, the allegations of paragraphs 125–168 concerning the unique problem of sensor data gaps resulting from failure mode conditions, and the technological solutions described and claimed in the '842 patent, are specifically repeated and re-alleged here, as the '653 patent is a continuation of the '842 patent and shares a common specification. In particular, the descriptions of the technological problems plaguing prior art CGM systems, the evidence of those technological problems, the inventor's creative, technological solution that solved these problems and enabled recovering what would otherwise be lost glucose data in CGM systems, the benefits and advantages gained from the solution, and Dexcom's copying and incorporation of Abbott's patented backfilling technology, as alleged in paragraphs 125–168, apply as well to the '653 patent.
- 271. As with the '842 patent, these technological solutions are reflected in the claims of the '653 patent. For example, claim 1 of the '653 patent is directed to a "glucose monitoring system." (Ex. G, '653 patent at 15:25-62.) The claimed glucose monitoring system comprises "an on body unit," "a glucose sensor," "a data processing and transmitter unit," "memory," and "a receiver unit." (*Id.* at 15:27-62.) The memory of the data processing and transmitter unit stores "instructions that, when executed by the processor, cause the processor to:

store, in the memory of the data processing and transmitter unit, at least a portion of the data indicative of the sensed glucose level corresponding to a time period associated with a failure mode condition, and cause wireless transmission of the at least a portion of the data indicative of the sensed glucose level to a receiver unit after the failure mode condition is corrected." (Id. at 15:47-49.) The claimed system detects that a failure mode condition has occurred that is causing a gap in the data displayed to the patient (as recited in dependent claim 2). Moreover, the memory device of the receiver unit stores instructions that, "when executed by the one or more processors, cause the one or more processors to output the at least a portion of the data indicative of the sensed glucose level to a display of the receiver unit after the failure mode condition is corrected." (Id. at 15:53-59.) As a result, "the one or more sensor data gaps are at least partially filled" as recited in dependent claim 3. (Id. at 15:66 to 16:3.) Thus, instead of merely "skipping" glucose readings during a failure mode condition as in Dexcom's STS-7, the improved monitoring system of claim 1 is able to recover glucose data from the time period associated with the failure mode condition, thereby providing the patient with a more complete and accurate record of their glucose levels. As illustrated by this example, the claimed system is a technological improvement over prior art CGM systems.

- 272. Claim 4 of the '653 patent, which depends from independent claim 1, claims systems capable of backfilling sensor data gaps resulting from "a sensor communication error." (*Id.* at 16:4-6.) The system detects the communication error, stores and processes the sensor data from that time period, then outputs the processed sensor data (*e.g.*, glucose levels) after the failure mode condition is corrected.
- 273. Dependent claims 5-10, which also depend from independent claim 1, recite other failure mode conditions that can be detected and from which the system can recover

otherwise lost data, such as a "signal error," "system malfunction," "sensor dislodgment," or an "inability of the receiver unit to output the data indicative of the sensed glucose level to the display (*Id.* at 16:7-24.)

- 274. As shown in **Appendix G** of the Initial Claim Charts, the Accused Products meet each and every limitation of the Asserted Claims of the '653 patent, either literally and/or under the doctrine of equivalents.
- 275. Dexcom has directly infringed and continues to directly infringe the Asserted Claims of the '653 patent under 35 U.S.C. § 271(a) by making, using, selling, and/or offering to sell the Accused Products.
- 276. Dexcom has induced infringement and continues to induce infringement of the Asserted Claims of the '653 patent under 35 U.S.C. § 271(b). As illustrated in Appendix G of the Initial Claim Charts, Dexcom's customers (*e.g.*, patients and physicians) have directly infringed and continue to directly infringe the Asserted Claims of the '653 patent by making (*e.g.*, completing the systems) and/or using the Accused Products. Dexcom actively and knowingly induces such infringement with specific intent through activities relating to instructions for use, marketing, advertising, promotion, support, and distribution of the Accused Products.
- 277. The Accused Products are designed and configured in a manner such that others will necessarily infringe when using the Accused Products for their intended purposes and as instructed in Dexcom's user guides. As shown in the Initial Claim Charts, Dexcom provides materials, including, for example, its user guides, that instruct others to use the system to recover missed data in a manner that directly infringes the Asserted Claims of the '653 patent.
- 278. According to the G6 User Guide, data gaps can be caused by, for example, "a temporary shutdown, Signal Loss, or similar issue."

 When the receiver and transmitter reconnect after a temporary shutdown, Signal Loss, or similar issue, up to 3 hours of missed G6 readings can fill in on the graph.

(G6 User Guide at 246.)

279. The G6 can backfill these data gaps:

When the transmitter reconnects with the display device after a Signal Loss or similar issue, up to 3 hours of missed G6 readings can fill in on the graph.

(*Id.* at 115.)

- 280. Dexcom has acted and continues to act with specific intent to induce others to infringe the Asserted Claims of the '653 patent, or has chosen to be willfully blind to the fact that it is inducing infringement by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.
- 281. Dexcom has infringed and continues to infringe the Asserted Claims of the '653 patent under 35 U.S.C. § 271(f)(1). Dexcom supplies or causes to be supplied in or from the United States all or a substantial portion of the components of the inventions claimed in the Asserted Claims of the '653 patent, where such components are uncombined in whole or in part with other components, which together comprise the claimed inventions. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof, and with specific intent, instructs its customers to combine them outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '653 patent if such combination occurred within the United States.
- 282. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and provides materials,

including for example, instructions for use and user guides, that instruct customers to combine the Accused Products and/or components thereof with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, comprise the claimed inventions of the Asserted Claims of the '653 patent.

- 283. Dexcom has been and is knowingly contributing to the infringement of the Asserted Claims of the '653 patent under 35 U.S.C. § 271(c) by selling, offering to sell, and/or importing the Accused Products and components thereof for use in practicing the Asserted Claims of the '653 patent. Dexcom knows that the same are material to practicing the claimed inventions, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are especially made or especially adapted for use in an infringement.
- 284. For example, Dexcom sells, offers to sell, and/or imports the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) that customers use and/or combine with other components (*e.g.*, sensors, transmitters, smart devices, etc.) to practice the Asserted Claims of the '653 patent. By continuing to provide the Accused Products and components thereof, Dexcom has been and is contributorily infringing the '653 patent with specific intent.
- 285. Dexcom does not have, nor could it have had, a good-faith belief that the infringement by Dexcom and/or others using the Accused Products is non-infringing. Moreover, Dexcom's acts of willful infringement of the '653 patent further demonstrate Dexcom's induced and contributory infringement. Dexcom is therefore liable for contributory infringement of the '653 patent.
- 286. Dexcom has infringed and continues to infringe the Asserted Claims of the '653 patent under 35 U.S.C. § 271(f)(2). Dexcom supplies or causes to be supplied in or from the

United States components of the inventions claimed in the Asserted Claims of the '653 patent that Dexcom knows are especially made or especially adapted for use in the claimed inventions. Such components are not staple articles or commodities of commerce suitable for substantial non-infringing use. Dexcom supplies or causes to be supplied such components uncombined with other components, and knows that such components are so made or adapted, and with specific intent, intends for such components to be combined with other components outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '653 patent if such combination occurred within the United States.

- 287. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and specifically intends for customers to combine them with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, Dexcom knows comprise the claimed inventions of the Asserted Claims of the '653 patent.
- 288. To the extent Dexcom alleges that is does not directly infringe an Asserted Claim of the '653 patent (*e.g.*, because the claim recites an element that Dexcom does not sell (*e.g.*, smart device) or that Dexcom sells separately from other components), Dexcom nevertheless infringes such claim under 35 U.S.C. §§ 271(b) and/or 271(c) for sales within the United States and 35 U.S.C. §§ 271(f)(1) and/or 271(f)(2) for sales outside of the United States.
- 289. Dexcom has been and is engaging in willful and deliberate infringement of the '653 patent. As detailed above, before Abbott filed the original Complaint in this action, Dexcom knew about the '653 patent and knew that it was infringing the '653 patent, or chose to be willfully blind to the fact that it is infringing the '653 patent by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.

- 290. Despite that knowledge, Dexcom continues to make, use, offer for sale, sell, and/or import the Accused Products in willful disregard of the '653 patent, with the intent to infringe the '653 patent, and without any reasonable basis for believing that it had or has a right to engage in the infringing conduct. Therefore, Dexcom's infringement of the '653 patent has been, is, and will continue to be willful, intentional, deliberate, and in conscious disregard of Abbott's rights under the '653 patent.
- 291. Unless enjoined by this Court, Dexcom will continue to infringe the '653 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.
- 292. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '653 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

EIGHTH CAUSE OF ACTION (Infringement of the '654 Patent)

- 293. Abbott repeats and re-alleges the allegations of paragraphs 1 through 292 above.
- 294. As shown in **Appendix H** of the Initial Claim Charts, the Accused Products meet each and every limitation of the Asserted Claims of the '654 patent, either literally and/or under the doctrine of equivalents.
- 295. Dexcom has directly infringed and continues to directly infringe the Asserted Claims of the '654 patent under 35 U.S.C. § 271(a) by making, using, selling, and/or offering to sell the Accused Products.

296. Dexcom has induced infringement and continues to induce infringement of the Asserted Claims of the '654 patent under 35 U.S.C. § 271(b). As illustrated in Appendix H of the Initial Claim Charts, Dexcom's customers (*e.g.*, patients and physicians) have directly infringed and continue to directly infringe the Asserted Claims of the '654 patent by making (*e.g.*, completing the systems) and/or using the Accused Products. Dexcom actively and knowingly induces such infringement with specific intent through activities relating to instructions for use, marketing, advertising, promotion, support, and distribution of the Accused Products.

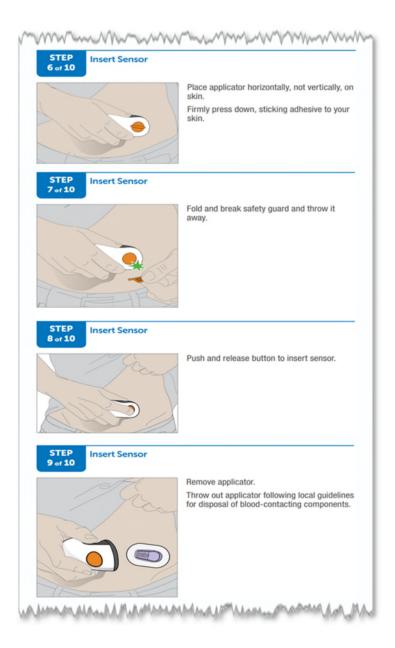
297. The Accused Products are designed and configured in a manner such that others will necessarily infringe when using the Accused Products for their intended purposes and as instructed in Dexcom's user guides. As shown in the Initial Claim Charts, Dexcom provides materials, including, for example, its user guides, that instruct others to use the applicator in a manner that directly infringes the Asserted Claims of the '654 patent.

298. For example, the G6 User Guide instructs users to "[p]lace the applicator... on [the] skin" and "[f]irmly press down, sticking [the] adhesive to [the] skin." After removing the safety guard on the applicator, the user is instructed to "[p]ush and release [the] button to insert [the] sensor." The user is then instructed to "[r]emove [the] applicator." 60

⁵⁸ *G6 User Guide* at 78.

⁵⁹ *Id.* at 79.

⁶⁰ *Id.* at 80.



(*G6 User Guide* at 78-80.)

299. To attach the transmitter, the user is directed to "[s]lide the transmitter tab into the slot at the narrow end of the [transmitter] holder" and "[p]ress the wide end of the transmitter until it clicks into the [transmitter] holder."

⁶¹ *G6 User Guide* at 82-83.

- 300. Dexcom has acted and continues to act with specific intent to induce others to infringe the Asserted Claims of the '654 patent, or has chosen to be willfully blind to the fact that it is inducing infringement by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.
- 301. Dexcom has infringed and continues to infringe the Asserted Claims of the '654 patent under 35 U.S.C. § 271(f)(1). Dexcom supplies or causes to be supplied in or from the United States all or a substantial portion of the components of the inventions claimed in the Asserted Claims of the '654 patent, where such components are uncombined in whole or in part with other components, which together comprise the claimed inventions. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof, and with specific intent, instructs its customers to combine them outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '654 patent if such combination occurred within the United States.
- 302. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and provides materials, including for example, instructions for use and user guides, that instruct customers to combine the Accused Products and/or components thereof with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, comprise the claimed inventions of the Asserted Claims of the '654 patent.
- 303. Dexcom has been and is knowingly contributing to the infringement of the Asserted Claims of the '654 patent under 35 U.S.C. § 271(c) by selling, offering to sell, and/or importing the Accused Products and components thereof for use in practicing the Asserted Claims of the '654 patent. Dexcom knows that the same are material to practicing the claimed inventions,

are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are especially made or especially adapted for use in an infringement.

304. For example, Dexcom sells, offers to sell, and/or imports the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) that customers use and/or combine with other components (*e.g.*, sensors, transmitters, smart devices, etc.) to practice the Asserted Claims of the '654 patent. By continuing to provide the Accused Products and components thereof, Dexcom has been and is contributorily infringing the '654 patent with specific intent.

305. Dexcom does not have, nor could it have had, a good-faith belief that the infringement by Dexcom and/or others using the Accused Products is non-infringing. Moreover, Dexcom's acts of willful infringement of the '654 patent further demonstrate Dexcom's induced and contributory infringement. Dexcom is therefore liable for contributory infringement of the '654 patent.

306. Dexcom has infringed and continues to infringe the Asserted Claims of the '654 patent under 35 U.S.C. § 271(f)(2). Dexcom supplies or causes to be supplied in or from the United States components of the inventions claimed in the Asserted Claims of the '654 patent that Dexcom knows are especially made or especially adapted for use in the claimed inventions. Such components are not staple articles or commodities of commerce suitable for substantial non-infringing use. Dexcom supplies or causes to be supplied such components uncombined with other components, and knows that such components are so made or adapted, and with specific intent, intends for such components to be combined with other components outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '654 patent if such combination occurred within the United States.

- 307. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and specifically intends for customers to combine them with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, Dexcom knows comprise the claimed inventions of the Asserted Claims of the '654 patent.
- 308. To the extent Dexcom alleges that is does not directly infringe an Asserted Claim of the '654 patent (*e.g.*, because the claim recites an element that Dexcom does not sell (*e.g.*, smart device) or that Dexcom sells separately from other components), Dexcom nevertheless infringes such claim under 35 U.S.C. §§ 271(b) and/or 271(c) for sales within the United States and 35 U.S.C. §§ 271(f)(1) and/or 271(f)(2) for sales outside of the United States.
- 309. Dexcom has been and is engaging in willful and deliberate infringement of the '654 patent. As detailed above, before Abbott filed the original Complaint in this action, Dexcom knew about the '654 patent and knew that it was infringing the '654 patent, or chose to be willfully blind to the fact that it is infringing the '654 patent by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.
- 310. Despite that knowledge, Dexcom continues to make, use, offer for sale, sell, and/or import the Accused Products in willful disregard of the '654 patent, with the intent to infringe the '654 patent, and without any reasonable basis for believing that it had or has a right to engage in the infringing conduct. Therefore, Dexcom's infringement of the '654 patent has been, is, and will continue to be willful, intentional, deliberate, and in conscious disregard of Abbott's rights under the '654 patent.
- 311. Unless enjoined by this Court, Dexcom will continue to infringe the '654 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for

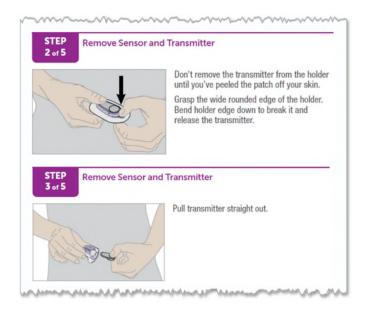
which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

312. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '654 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

NINTH CAUSE OF ACTION (Infringement of the '644 Patent)

- 313. Abbott repeats and re-alleges the allegations of paragraphs 1 through 312 above.
- 314. As shown in **Appendix I** of the Initial Claim Charts, the Accused Products meet each and every limitation of the Asserted Claims of the '644 patent, either literally and/or under the doctrine of equivalents.
- 315. Dexcom has directly infringed and continues to directly infringe the Asserted Claims of the '644 patent under 35 U.S.C. § 271(a) by making, using, selling, and/or offering to sell the Accused Products.
- 316. Dexcom has induced infringement and continues to induce infringement of the Asserted Claims of the '644 patent under 35 U.S.C. § 271(b). As illustrated in Appendix I of the Initial Claim Charts, Dexcom's customers (e.g., patients and physicians) have directly infringed and continue to directly infringe the Asserted Claims of the '644 patent by making (e.g., completing the systems) and/or using the Accused Products. Dexcom actively and knowingly induces such infringement with specific intent through activities relating to instructions for use, marketing, advertising, promotion, support, and distribution of the Accused Products.

- 317. The Accused Products are designed and configured in a manner such that others will necessarily infringe when using the Accused Products for their intended purposes and as instructed in Dexcom's user guides. As shown in the Initial Claim Charts, Dexcom provides materials, including, for example, its user guides, that instruct others to remove the sensor and transmitter in a manner that directly infringes the Asserted Claims of the '644 patent.
- 318. Specifically, Dexcom's G6 User Guide instructs users to "[g]rasp the wide rounded edge of the [transmitter] holder" and "[b]end [the transmitter] holder edge down to break it and release the transmitter." After that, the user simply has to "[p]ull the transmitter straight out." 63

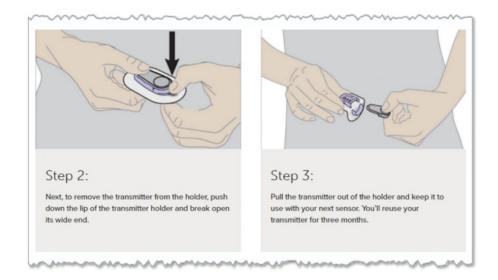


(*G6 User Guide* at 211-12.)

319. Similarly, on its website, Dexcom instructs users to remove the transmitter by "push[ing] down the lip of the transmitter holder and break[ing] open its wide end."

⁶² *G6 User Guide* at 211.

⁶³ *Id.* at 211-12.



(*Ending Your Sensor Session*, DEXCOM CONTINUOUS GLUCOSE MONITORING, https://www.dexcom.com/training-videos/removing-your-sensor-and-transmitter.)

- 320. Dexcom has acted and continues to act with specific intent to induce others to infringe the Asserted Claims of the '644 patent, or has chosen to be willfully blind to the fact that it is inducing infringement by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.
- 321. Dexcom has infringed and continues to infringe the Asserted Claims of the '644 patent under 35 U.S.C. § 271(f)(1). Dexcom supplies or causes to be supplied in or from the United States all or a substantial portion of the components of the inventions claimed in the Asserted Claims of the '644 patent, where such components are uncombined in whole or in part with other components, which together comprise the claimed inventions. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof, and with specific intent, instructs its customers to combine them outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '644 patent if such combination occurred within the United States.

- 322. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and provides materials, including for example, instructions for use and user guides, that instruct customers to combine the Accused Products and/or components thereof with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, comprise the claimed inventions of the Asserted Claims of the '644 patent.
- 323. Dexcom has been and is knowingly contributing to the infringement of the Asserted Claims of the '644 patent under 35 U.S.C. § 271(c) by selling, offering to sell, and/or importing the Accused Products and components thereof for use in practicing the Asserted Claims of the '644 patent. Dexcom knows that the same are material to practicing the claimed inventions, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are especially made or especially adapted for use in an infringement.
- 324. For example, Dexcom sells, offers to sell, and/or imports the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) that customers use and/or combine with other components (*e.g.*, sensors, transmitters, smart devices, etc.) to practice the Asserted Claims of the '644 patent. By continuing to provide the Accused Products and components thereof, Dexcom has been and is contributorily infringing the '644 patent with specific intent.
- 325. Dexcom does not have, nor could it have had, a good-faith belief that the infringement by Dexcom and/or others using the Accused Products is non-infringing. Moreover, Dexcom's acts of willful infringement of the '644 patent further demonstrate Dexcom's induced and contributory infringement. Dexcom is therefore liable for contributory infringement of the '644 patent.

- 326. Dexcom has infringed and continues to infringe the Asserted Claims of the '644 patent under 35 U.S.C. § 271(f)(2). Dexcom supplies or causes to be supplied in or from the United States components of the inventions claimed in the Asserted Claims of the '644 patent that Dexcom knows are especially made or especially adapted for use in the claimed inventions. Such components are not staple articles or commodities of commerce suitable for substantial non-infringing use. Dexcom supplies or causes to be supplied such components uncombined with other components, and knows that such components are so made or adapted, and with specific intent, intends for such components to be combined with other components outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '644 patent if such combination occurred within the United States.
- 327. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and specifically intends for customers to combine them with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, Dexcom knows comprise the claimed inventions of the Asserted Claims of the '644 patent.
- 328. To the extent Dexcom alleges that is does not directly infringe an Asserted Claim of the '644 patent (*e.g.*, because the claim recites an element that Dexcom does not sell (*e.g.*, smart device) or that Dexcom sells separately from other components), Dexcom nevertheless infringes such claim under 35 U.S.C. §§ 271(b) and/or 271(c) for sales within the United States and 35 U.S.C. §§ 271(f)(1) and/or 271(f)(2) for sales outside of the United States.
- 329. Dexcom has been and is engaging in willful and deliberate infringement of the '644 patent. As detailed above, before Abbott filed the original Complaint in this action, Dexcom knew about the '644 patent and knew that it was infringing the '644 patent, or chose to

be willfully blind to the fact that it is infringing the '644 patent by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.

- 330. Despite that knowledge, Dexcom continues to make, use, offer for sale, sell, and/or import the Accused Products in willful disregard of the '644 patent, with the intent to infringe the '644 patent, and without any reasonable basis for believing that it had or has a right to engage in the infringing conduct. Therefore, Dexcom's infringement of the '644 patent has been, is, and will continue to be willful, intentional, deliberate, and in conscious disregard of Abbott's rights under the '644 patent.
- 331. Unless enjoined by this Court, Dexcom will continue to infringe the '644 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.
- 332. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '644 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

TENTH CAUSE OF ACTION (Infringement of the '443 Patent)

- 333. Abbott repeats and re-alleges the allegations of paragraphs 1 through 332 above.
- 334. As shown in **Appendix J** of the Initial Claim Charts, the Accused Products meet each and every limitation of the Asserted Claims of the '443 patent, either literally and/or under the doctrine of equivalents.

335. Dexcom has directly infringed and continues to directly infringe the Asserted Claims of the '443 patent under 35 U.S.C. § 271(a) by making, using, selling, and/or offering to sell the Accused Products.

336. Dexcom has induced infringement and continues to induce infringement of the Asserted Claims of the '443 patent under 35 U.S.C. § 271(b). As illustrated in Appendix J of the Initial Claim Charts, Dexcom's customers (e.g., patients and physicians) have directly infringed and continue to directly infringe the Asserted Claims of the '443 patent by making (e.g., completing the systems) and/or using the Accused Products. Dexcom actively and knowingly induces such infringement with specific intent through activities relating to instructions for use, marketing, advertising, promotion, support, and distribution of the Accused Products.

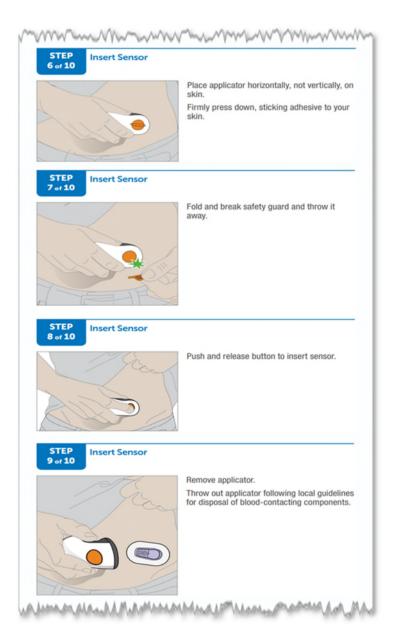
337. The Accused Products are designed and configured in a manner such that others will necessarily infringe when using the Accused Products for their intended purposes and as instructed in Dexcom's user guides. As shown in the Initial Claim Charts, Dexcom provides materials, including, for example, its user guides, that instruct others to use the applicator in a manner that directly infringes the Asserted Claims of the '443 patent.

338. For example, the G6 User Guide instructs users to "[p]lace the applicator... on [the] skin" and "[f]irmly press down, sticking [the] adhesive to [the] skin." After removing the safety guard on the applicator, the user is instructed to "[p]ush and release [the] button to insert [the] sensor." The user is then instructed to "[r]emove [the] applicator."

⁶⁴ G6 User Guide at 78.

⁶⁵ *Id.* at 79.

⁶⁶ *Id.* at 80.



(*G6 User Guide* at 78-80.)

339. To attach the transmitter, the user is directed to "[s]lide the transmitter tab into the slot at the narrow end of the [transmitter] holder" and "[p]ress the wide end of the transmitter until it clicks into the [transmitter] holder."

⁶⁷ *G6 User Guide* at 82-83.

- 340. Dexcom has acted and continues to act with specific intent to induce others to infringe the Asserted Claims of the '443 patent, or has chosen to be willfully blind to the fact that it is inducing infringement by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.
- 341. Dexcom has infringed and continues to infringe the Asserted Claims of the '443 patent under 35 U.S.C. § 271(f)(1). Dexcom supplies or causes to be supplied in or from the United States all or a substantial portion of the components of the inventions claimed in the Asserted Claims of the '443 patent, where such components are uncombined in whole or in part with other components, which together comprise the claimed inventions. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof, and with specific intent, instructs its customers to combine them outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '443 patent if such combination occurred within the United States.
- 342. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and provides materials, including for example, instructions for use and user guides, that instruct customers to combine the Accused Products and/or components thereof with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, comprise the claimed inventions of the Asserted Claims of the '443 patent.
- 343. Dexcom has been and is knowingly contributing to the infringement of the Asserted Claims of the '443 patent under 35 U.S.C. § 271(c) by selling, offering to sell, and/or importing the Accused Products and components thereof for use in practicing the Asserted Claims of the '443 patent. Dexcom knows that the same are material to practicing the claimed inventions,

are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are especially made or especially adapted for use in an infringement.

- 344. For example, Dexcom sells, offers to sell, and/or imports the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) that customers use and/or combine with other components (*e.g.*, sensors, transmitters, smart devices, etc.) to practice the Asserted Claims of the '443 patent. By continuing to provide the Accused Products and components thereof, Dexcom has been and is contributorily infringing the '443 patent with specific intent.
- 345. Dexcom does not have, nor could it have had, a good-faith belief that the infringement by Dexcom and/or others using the Accused Products is non-infringing. Moreover, Dexcom's acts of willful infringement of the '443 patent further demonstrate Dexcom's induced and contributory infringement. Dexcom is therefore liable for contributory infringement of the '443 patent.
- 346. Dexcom has infringed and continues to infringe the Asserted Claims of the '443 patent under 35 U.S.C. § 271(f)(2). Dexcom supplies or causes to be supplied in or from the United States components of the inventions claimed in the Asserted Claims of the '443 patent that Dexcom knows are especially made or especially adapted for use in the claimed inventions. Such components are not staple articles or commodities of commerce suitable for substantial non-infringing use. Dexcom supplies or causes to be supplied such components uncombined with other components, and knows that such components are so made or adapted, and with specific intent, intends for such components to be combined with other components outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '443 patent if such combination occurred within the United States.

- 347. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and specifically intends for customers to combine them with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, Dexcom knows comprise the claimed inventions of the Asserted Claims of the '443 patent.
- 348. To the extent Dexcom alleges that is does not directly infringe an Asserted Claim of the '443 patent (*e.g.*, because the claim recites an element that Dexcom does not sell (*e.g.*, smart device) or that Dexcom sells separately from other components), Dexcom nevertheless infringes such claim under 35 U.S.C. §§ 271(b) and/or 271(c) for sales within the United States and 35 U.S.C. §§ 271(f)(1) and/or 271(f)(2) for sales outside of the United States.
- 349. Dexcom has been and is engaging in willful and deliberate infringement of the '443 patent. As detailed above, before Abbott filed the original Complaint in this action, Dexcom knew about the '443 patent and knew that it was infringing the '443 patent, or chose to be willfully blind to the fact that it is infringing the '443 patent by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.
- 350. Despite that knowledge, Dexcom continues to make, use, offer for sale, sell, and/or import the Accused Products in willful disregard of the '443 patent, with the intent to infringe the '443 patent, and without any reasonable basis for believing that it had or has a right to engage in the infringing conduct. Therefore, Dexcom's infringement of the '443 patent has been, is, and will continue to be willful, intentional, deliberate, and in conscious disregard of Abbott's rights under the '443 patent.
- 351. Unless enjoined by this Court, Dexcom will continue to infringe the '443 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for

which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

352. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '443 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

ELEVENTH CAUSE OF ACTION (Infringement of the '216 Patent)

- 353. Abbott repeats and re-alleges the allegations of paragraphs 1 through 352 above.
- 354. As shown in **Appendix K** of the Initial Claim Charts, the Accused Products meet each and every limitation of the Asserted Claims of the '216 patent, either literally and/or under the doctrine of equivalents.
- 355. Dexcom has directly infringed and continues to directly infringe the Asserted Claims of the '216 patent under 35 U.S.C. § 271(a) by making, using, selling, and/or offering to sell the Accused Products.
- 356. Dexcom has induced infringement and continues to induce infringement of the Asserted Claims of the '216 patent under 35 U.S.C. § 271(b). As illustrated in Appendix K of the Initial Claim Charts, Dexcom's customers (*e.g.*, patients and physicians) have directly infringed and continue to directly infringe the Asserted Claims of the '216 patent by making (*e.g.*, completing the systems) and/or using the Accused Products. Dexcom actively and knowingly induces such infringement with specific intent through activities relating to instructions for use, marketing, advertising, promotion, support, and distribution of the Accused Products.

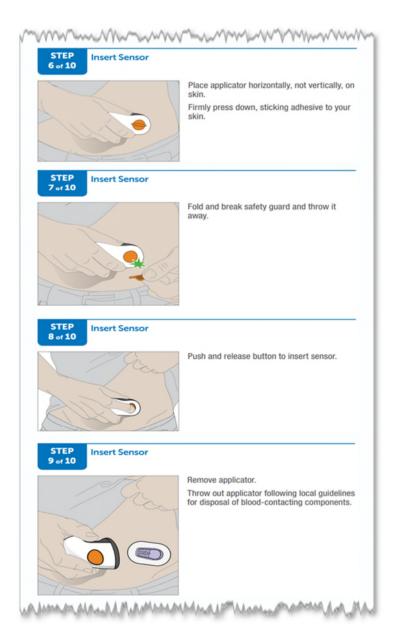
357. The Accused Products are designed and configured in a manner such that others will necessarily infringe when using the Accused Products for their intended purposes and as instructed in Dexcom's user guides. As shown in the Initial Claim Charts, Dexcom provides materials, including, for example, its user guides, that instruct others to use the applicator in a manner that directly infringes the Asserted Claims of the '216 patent.

358. For example, the G6 User Guide instructs users to "[p]lace the applicator... on [the] skin" and "[f]irmly press down, sticking [the] adhesive to [the] skin." After removing the safety guard on the applicator, the user is instructed to "[p]ush and release [the] button to insert [the] sensor." The user is then instructed to "[r]emove [the] applicator."

⁶⁸ *G6 User Guide* at 78.

⁶⁹ *Id.* at 79.

⁷⁰ *Id.* at 80.



(*G6 User Guide* at 78-80.)

359. To attach the transmitter, the user is directed to "[s]lide the transmitter tab into the slot at the narrow end of the [transmitter] holder" and "[p]ress the wide end of the transmitter until it clicks into the [transmitter] holder."

⁷¹ *G6 User Guide* at 82-83.

- 360. Dexcom has acted and continues to act with specific intent to induce others to infringe the Asserted Claims of the '216 patent, or has chosen to be willfully blind to the fact that it is inducing infringement by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.
- 361. Dexcom has infringed and continues to infringe the Asserted Claims of the '216 patent under 35 U.S.C. § 271(f)(1). Dexcom supplies or causes to be supplied in or from the United States all or a substantial portion of the components of the inventions claimed in the Asserted Claims of the '216 patent, where such components are uncombined in whole or in part with other components, which together comprise the claimed inventions. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof, and with specific intent, instructs its customers to combine them outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '216 patent if such combination occurred within the United States.
- 362. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and provides materials, including for example, instructions for use and user guides, that instruct customers to combine the Accused Products and/or components thereof with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, comprise the claimed inventions of the Asserted Claims of the '216 patent.
- 363. Dexcom has been and is knowingly contributing to the infringement of the Asserted Claims of the '216 patent under 35 U.S.C. § 271(c) by selling, offering to sell, and/or importing the Accused Products and components thereof for use in practicing the Asserted Claims of the '216 patent. Dexcom knows that the same are material to practicing the claimed inventions,

are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are especially made or especially adapted for use in an infringement.

364. For example, Dexcom sells, offers to sell, and/or imports the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) that customers use and/or combine with other components (*e.g.*, sensors, transmitters, smart devices, etc.) to practice the Asserted Claims of the '216 patent. By continuing to provide the Accused Products and components thereof, Dexcom has been and is contributorily infringing the '216 patent with specific intent.

365. Dexcom does not have, nor could it have had, a good-faith belief that the infringement by Dexcom and/or others using the Accused Products is non-infringing. Moreover, Dexcom's acts of willful infringement of the '216 patent further demonstrate Dexcom's induced and contributory infringement. Dexcom is therefore liable for contributory infringement of the '216 patent.

366. Dexcom has infringed and continues to infringe the Asserted Claims of the '216 patent under 35 U.S.C. § 271(f)(2). Dexcom supplies or causes to be supplied in or from the United States components of the inventions claimed in the Asserted Claims of the '216 patent that Dexcom knows are especially made or especially adapted for use in the claimed inventions. Such components are not staple articles or commodities of commerce suitable for substantial non-infringing use. Dexcom supplies or causes to be supplied such components uncombined with other components, and knows that such components are so made or adapted, and with specific intent, intends for such components to be combined with other components outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '216 patent if such combination occurred within the United States.

- 367. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and specifically intends for customers to combine them with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, Dexcom knows comprise the claimed inventions of the Asserted Claims of the '216 patent.
- 368. To the extent Dexcom alleges that is does not directly infringe an Asserted Claim of the '216 patent (*e.g.*, because the claim recites an element that Dexcom does not sell (*e.g.*, smart device) or that Dexcom sells separately from other components), Dexcom nevertheless infringes such claim under 35 U.S.C. §§ 271(b) and/or 271(c) for sales within the United States and 35 U.S.C. §§ 271(f)(1) and/or 271(f)(2) for sales outside of the United States.
- 369. Dexcom has been and is engaging in willful and deliberate infringement of the '216 patent. As detailed above, before Abbott filed the original Complaint in this action, Dexcom knew about the '216 patent and knew that it was infringing the '216 patent, or chose to be willfully blind to the fact that it is infringing the '216 patent by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.
- 370. Despite that knowledge, Dexcom continues to make, use, offer for sale, sell, and/or import the Accused Products in willful disregard of the '216 patent, with the intent to infringe the '216 patent, and without any reasonable basis for believing that it had or has a right to engage in the infringing conduct. Therefore, Dexcom's infringement of the '216 patent has been, is, and will continue to be willful, intentional, deliberate, and in conscious disregard of Abbott's rights under the '216 patent.
- 371. Unless enjoined by this Court, Dexcom will continue to infringe the '216 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for

which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

372. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '216 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

TWELFTH CAUSE OF ACTION (Infringement of the '440 Patent)

- 373. Abbott repeats and re-alleges the allegations of paragraphs 1 through 372 above.
- 374. As shown in **Appendix L** of the Initial Claim Charts, the Accused Products meet each and every limitation of the Asserted Claims of the '440 patent, either literally and/or under the doctrine of equivalents.
- 375. Dexcom has directly infringed and continues to directly infringe the Asserted Claims of the '440 patent under 35 U.S.C. § 271(a) by making, using, selling, and/or offering to sell the Accused Products.
- 376. Dexcom has induced infringement and continues to induce infringement of the Asserted Claims of the '440 patent under 35 U.S.C. § 271(b). As illustrated in Appendix L of the Initial Claim Charts, Dexcom's customers (e.g., patients and physicians) have directly infringed and continue to directly infringe the Asserted Claims of the '440 patent by making (e.g., completing the systems) and/or using the Accused Products. Dexcom actively and knowingly induces such infringement with specific intent through activities relating to instructions for use, marketing, advertising, promotion, support, and distribution of the Accused Products.

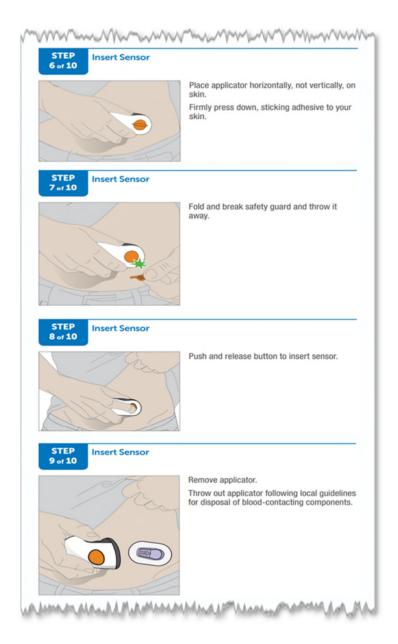
377. The Accused Products are designed and configured in a manner such that others will necessarily infringe when using the Accused Products for their intended purposes and as instructed in Dexcom's user guides. As shown in the Initial Claim Charts, Dexcom provides materials, including, for example, its user guides, that instruct others to use the applicator in a manner that directly infringes the Asserted Claims of the '440 patent.

378. For example, the G6 User Guide instructs users to "[p]lace the applicator... on [the] skin" and "[f]irmly press down, sticking [the] adhesive to [the] skin." After removing the safety guard on the applicator, the user is instructed to "[p]ush and release [the] button to insert [the] sensor." The user is then instructed to "[r]emove [the] applicator."

⁷² *G6 User Guide* at 78.

⁷³ *Id.* at 79.

⁷⁴ *Id.* at 80.



(*G6 User Guide* at 78-80.)

379. To attach the transmitter, the user is directed to "[s]lide the transmitter tab into the slot at the narrow end of the [transmitter] holder" and "[p]ress the wide end of the transmitter until it clicks into the [transmitter] holder."⁷⁵

⁷⁵ *G6 User Guide* at 82-83.

- 380. Dexcom has acted and continues to act with specific intent to induce others to infringe the Asserted Claims of the '440 patent, or has chosen to be willfully blind to the fact that it is inducing infringement by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.
- 381. Dexcom has infringed and continues to infringe the Asserted Claims of the '440 patent under 35 U.S.C. § 271(f)(1). Dexcom supplies or causes to be supplied in or from the United States all or a substantial portion of the components of the inventions claimed in the Asserted Claims of the '440 patent, where such components are uncombined in whole or in part with other components, which together comprise the claimed inventions. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof, and with specific intent, instructs its customers to combine them outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '440 patent if such combination occurred within the United States.
- 382. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and provides materials, including for example, instructions for use and user guides, that instruct customers to combine the Accused Products and/or components thereof with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, comprise the claimed inventions of the Asserted Claims of the '440 patent.
- 383. Dexcom has been and is knowingly contributing to the infringement of the Asserted Claims of the '440 patent under 35 U.S.C. § 271(c) by selling, offering to sell, and/or importing the Accused Products and components thereof for use in practicing the Asserted Claims of the '440 patent. Dexcom knows that the same are material to practicing the claimed inventions,

are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are especially made or especially adapted for use in an infringement.

384. For example, Dexcom sells, offers to sell, and/or imports the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) that customers use and/or combine with other components (*e.g.*, sensors, transmitters, smart devices, etc.) to practice the Asserted Claims of the '440 patent. By continuing to provide the Accused Products and components thereof, Dexcom has been and is contributorily infringing the '440 patent with specific intent.

385. Dexcom does not have, nor could it have had, a good-faith belief that the infringement by Dexcom and/or others using the Accused Products is non-infringing. Moreover, Dexcom's acts of willful infringement of the '440 patent further demonstrate Dexcom's induced and contributory infringement. Dexcom is therefore liable for contributory infringement of the '440 patent.

386. Dexcom has infringed and continues to infringe the Asserted Claims of the '440 patent under 35 U.S.C. § 271(f)(2). Dexcom supplies or causes to be supplied in or from the United States components of the inventions claimed in the Asserted Claims of the '440 patent that Dexcom knows are especially made or especially adapted for use in the claimed inventions. Such components are not staple articles or commodities of commerce suitable for substantial non-infringing use. Dexcom supplies or causes to be supplied such components uncombined with other components, and knows that such components are so made or adapted, and with specific intent, intends for such components to be combined with other components outside of the United States in a manner that Dexcom knows would infringe the Asserted Claims of the '440 patent if such combination occurred within the United States.

- 387. For example, Dexcom supplies or causes to be supplied the Accused Products and components thereof (*e.g.*, sensors, transmitters, apps, etc.) and specifically intends for customers to combine them with other components (*e.g.*, sensors, transmitters, smart devices, etc.) that, together, Dexcom knows comprise the claimed inventions of the Asserted Claims of the '440 patent.
- 388. To the extent Dexcom alleges that is does not directly infringe an Asserted Claim of the '440 patent (*e.g.*, because the claim recites an element that Dexcom does not sell (*e.g.*, smart device) or that Dexcom sells separately from other components), Dexcom nevertheless infringes such claim under 35 U.S.C. §§ 271(b) and/or 271(c) for sales within the United States and 35 U.S.C. §§ 271(f)(1) and/or 271(f)(2) for sales outside of the United States.
- 389. Dexcom has been and is engaging in willful and deliberate infringement of the '440 patent. As detailed above, before Abbott filed the original Complaint in this action, Dexcom knew about the '440 patent and knew that it was infringing the '440 patent, or chose to be willfully blind to the fact that it is infringing the '440 patent by knowing there was a high probability of infringement, but taking deliberate actions to avoid confirming that infringement.
- 390. Despite that knowledge, Dexcom continues to make, use, offer for sale, sell, and/or import the Accused Products in willful disregard of the '440 patent, with the intent to infringe the '440 patent, and without any reasonable basis for believing that it had or has a right to engage in the infringing conduct. Therefore, Dexcom's infringement of the '440 patent has been, is, and will continue to be willful, intentional, deliberate, and in conscious disregard of Abbott's rights under the '440 patent.
- 391. Unless enjoined by this Court, Dexcom will continue to infringe the '440 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for

which there is no adequate remedy at law. Accordingly, Abbott is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

392. Abbott has suffered and will continue to suffer damage as a direct and proximate result of Dexcom's infringement of the '440 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Abbott prays for the following relief:

- a. a judgment that Dexcom has infringed and is infringing each of the Asserted Patents;
- b. an order permanently enjoining Dexcom, its officers, agents, servants, employees and attorneys, all parent, subsidiary, and affiliate corporations and other related business entities, and all other persons or entities acting in concert, participation or in privity with one or more of them, and their successors and assigns, from infringing the Asserted Patents;
- c. a judgment against Dexcom for money damages sustained as a result of Dexcom's infringement of the Asserted Patents in an amount to be determined at trial as provided under 35 U.S.C. § 284;
- d. a judgment awarding Abbott enhanced damages as provided by 35 U.S.C § 284;
- e. an award of pre-judgment and post-judgment interest on the damages caused by Dexcom's infringing activities and other conduct complained of herein;
 - f. a finding that this case is an exceptional case under 35 U.S.C. § 285;
- g. a judgment awarding Abbott reasonable attorneys' fees and its costs and reimbursements in this action, as provided by 35 U.S.C. § 285;

- h. an accounting for infringing sales not presented at trial and an award by the Court of additional damages for any such infringing sales;
 - i. a compulsory future royalty; and
 - j. any and all other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Abbott hereby respectfully requests trial by jury under Rule 38 of the Federal Rules of Civil Procedure of all issues in this action so triable.

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