## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

DED

### **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 that affects nearly half a billion people worldwide. Abbott's innovations make "[r]egular blood sugar monitoring,"

<sup>&</sup>lt;sup>1</sup> 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 Awards*<sup>TM</sup> *Winners*, EDISON AWARDS, https://edisonawards.com/winners2016.php; *2021 Edison Best New Product Awards*<sup>TM</sup> *Winners*, EDISON AWARDS, 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-galien-foundation-honors-2019-prix-galien-award-recipients-300945409.html (Oct. 25, 2019). "Worldwide, the Prix Galien is regarded as the equivalent of the Nobel Prize in biopharmaceutical and medical technology research." *Id.* 

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 Libre³ 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

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

<sup>&</sup>lt;sup>3</sup> 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.<sup>4</sup> Often patients would not do all the fingersticks needed to adequately monitor their glucose levels and prevent the disease's progression and deadly effects.<sup>5</sup>

- 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.<sup>6</sup> 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. Abbott invested enormous resources, including more than a billion dollars, into developing,

<sup>&</sup>lt;sup>4</sup> 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.

<sup>&</sup>lt;sup>5</sup> See id. at 2, 6.

<sup>&</sup>lt;sup>6</sup> 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.

building, and expanding the market for FreeStyle Libre. It is now the most accessible and topselling 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: 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

<sup>&</sup>lt;sup>7</sup> 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-ceotells-investors-not-fear-new-competition-abbotts-freestyle-libre (Nov. 8, 2017).

<sup>&</sup>lt;sup>8</sup> See, e.g., Dexcom User Guide for Dexcom G5 Mobile Continuous Glucose Monitoring (CGM) System, Rev 009 MT24706, DEXCOM.COM, https://s3-us-west-2.amazonaws.com/dexcompdf/G5-Mobile-Users-Guide-Touchscreen-Receiver.pdf; 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); Dana Howe, Comparing the Dexcom G6 to the G5, BEYOND TYPE 1, https://beyondtype1.org/comparing-the-dexcom-g6-to-the-g5/.

("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."<sup>12</sup>

### **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

<sup>&</sup>lt;sup>9</sup> International Diabetes Federation, *IDF Diabetes Atlas* (9th ed. 2019) https://www.diabetesatlas.org/upload/resources/material/20200302\_133351\_IDFATLAS9e-final-web.pdf.

<sup>&</sup>lt;sup>10</sup> Center for Disease Control and Prevention, *National Diabetes Statistics Report*, 2020, CDC.GOV, https://www.cdc.gov/diabetes/data/statistics-report/index.html.

<sup>&</sup>lt;sup>11</sup> Center for Disease Control and Prevention, *Monitoring Your Blood Sugar*, CDC.GOV, https://www.cdc.gov/diabetes/managing/managing-blood-sugar/bloodglucosemonitoring.html. <sup>12</sup> *Id*.

get more than a limited set" of data from these methods "due to the inconvenience and pain 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.

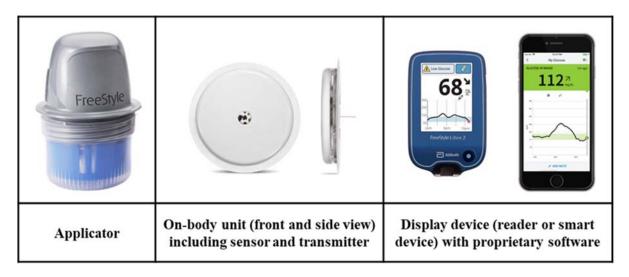
18. Various companies developed continuous glucose monitoring products as an alternative to traditional fingerstick measurements. But these products had significant drawbacks including high cost, short wear times, burdensome and painful insertion techniques, non-intuitive operation requiring significant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

<sup>&</sup>lt;sup>13</sup> 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.

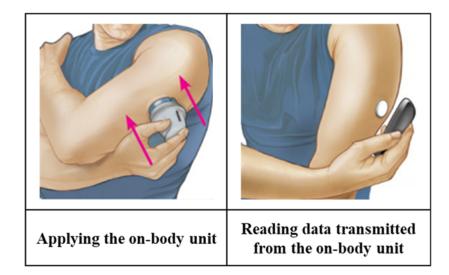
<sup>&</sup>lt;sup>14</sup> See, e.g., W. Gonzales, et al., The Progress of Glucose Monitoring—A Review of Invasive to Minimally and Non-Invasive Techniques, Devices and Sensors, SENSORS (BASEL), 2019;19(4):800 at 1 (Feb. 15, 2019) doi: 10.3390/s19040800; U. Hoss. & E. Budiman, Factory-Calibrated Continuous Glucose Sensors: The Science Behind the Technology, DIABETES TECHNOL THER, 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 THER., 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 CARE, 34 (Suppl. 2): S197–S201 (May 2011) doi: 10.2337/dc11-s219.

## 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 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 on-body 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."<sup>15</sup>
- 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 A1C<sup>16</sup> 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]." <sup>18</sup>

<sup>&</sup>lt;sup>15</sup> 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.

<sup>&</sup>lt;sup>16</sup> 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.

<sup>&</sup>lt;sup>18</sup> 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.<sup>20</sup> 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."<sup>21</sup> In April 2021, the FreeStyle Libre 2 received another Edison Award, as "best of the best" for personal wellness technology.<sup>22</sup>
- 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.<sup>23</sup>
- 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.

<sup>&</sup>lt;sup>19</sup> Terri Michelle, *Patient Stories*, FREESTYLE LIBRE, https://www.freestylelibre.us/patient-stories.html.

<sup>&</sup>lt;sup>20</sup> 2016 Edison Best New Product Awards<sup>TM</sup> Winners, EDISON AWARDS, https://edisonawards.com/winners2016.php.

<sup>&</sup>lt;sup>21</sup> About the Edison Awards, EDISON AWARDS, https://edisonawards.com/about.php.

<sup>&</sup>lt;sup>22</sup> 2021 Edison Best New Product Awards<sup>TM</sup> Winners, EDISON AWARDS, https://edisonawards.com/winners2021.php.

<sup>&</sup>lt;sup>23</sup> 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).

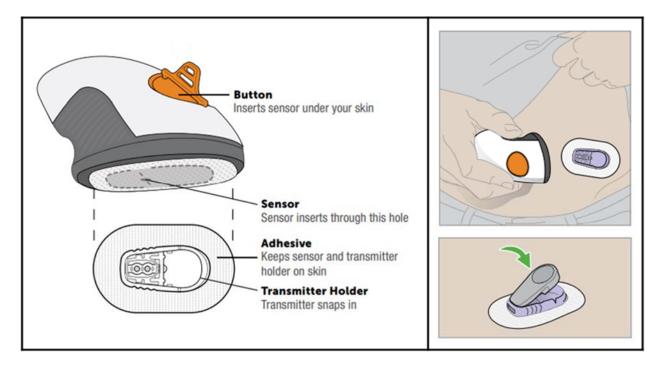
## Dexcom's Follow-On G6 Glucose Monitoring Product

- 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 attached infringement claim charts.
- 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
Applicator  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.
SOZEON •	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.<sup>24</sup>

<sup>&</sup>lt;sup>24</sup> 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.<sup>25</sup>
- 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 G6 product 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**.

<sup>&</sup>lt;sup>25</sup> *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.**

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

- 61. Abbott repeats and re-alleges the allegations of paragraphs 1 through 60 above.
- 62. As shown in the claim chart in **Exhibit M**, Dexcom's G6 meets each and every limitation of at least claim 14 of the '842 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '842 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.
- 63. 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.
- 64. 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)

- 65. Abbott repeats and re-alleges the allegations of paragraphs 1 through 64 above.
- 66. As shown in the claim chart in **Exhibit N**, Dexcom's G6 meets each and every limitation of at least claim 1 of the '954 patent, either literally and/or under the doctrine of

equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '954 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.

- 67. 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.
- 68. 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)

- 69. Abbott repeats and re-alleges the allegations of paragraphs 1 through 68 above.
- 70. As shown in the claim chart in **Exhibit O**, Dexcom's G6 meets each and every limitation of at least claim 23 of the '338 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '338 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.
- 71. 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.
- 72. 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)

- 73. Abbott repeats and re-alleges the allegations of paragraphs 1 through 72 above.
- 74. As shown in the claim chart in **Exhibit P**, Dexcom's G6 meets each and every limitation of at least claim 1 of the '341 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '341 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.
- 75. 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.
- 76. 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)

- 77. Abbott repeats and re-alleges the allegations of paragraphs 1 through 76 above.
- 78. As shown in the claim chart in **Exhibit Q**, Dexcom's G6 meets each and every limitation of at least claim 1 of the '647 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '647 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.

- 79. 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.
- 80. 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)

- 81. Abbott repeats and re-alleges the allegations of paragraphs 1 through 80 above.
- 82. As shown in the claim chart in **Exhibit R**, Dexcom's G6 meets each and every limitation of at least claim 1 of the '649 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '649 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.
- 83. 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.
- 84. 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)

- 85. Abbott repeats and re-alleges the allegations of paragraphs 1 through 84 above.
- 86. As shown in the claim chart in **Exhibit S**, Dexcom's G6 meets each and every limitation of at least claim 1 of the '653 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '653 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.
- 87. 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.
- 88. 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)

- 89. Abbott repeats and re-alleges the allegations of paragraphs 1 through 88 above.
- 90. As shown in the claim chart in **Exhibit T**, Dexcom's G6 meets each and every limitation of at least claim 1 of the '654 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '654 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.
- 91. 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.

92. 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)

- 93. Abbott repeats and re-alleges the allegations of paragraphs 1 through 92 above.
- 94. As shown in the claim chart in **Exhibit U**, Dexcom's G6 meets each and every limitation of at least claim 1 of the '644 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '644 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.
- 95. 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.
- 96. 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)

97. Abbott repeats and re-alleges the allegations of paragraphs 1 through 96 above.

- 98. As shown in the claim chart in **Exhibit V**, Dexcom's G6 meets each and every limitation of at least claim 13 of the '443 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '443 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.
- 99. 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.
- 100. 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)

- 101. Abbott repeats and re-alleges the allegations of paragraphs 1 through 100 above.
- 102. As shown in the claim chart in **Exhibit W**, Dexcom's G6 meets each and every limitation of at least claim 1 of the '216 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '216 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.
- 103. 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.

104. 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)

- 105. Abbott repeats and re-alleges the allegations of paragraphs 1 through 104 above.
- 106. As shown in the claim chart in **Exhibit X**, Dexcom's G6 meets each and every limitation of at least claim 1 of the '440 patent, either literally and/or under the doctrine of equivalents. Thus, Dexcom has infringed and continues to infringe one or more claims of the '440 patent by making, using, selling, and/or offering to sell G6 in the United States and in this District.
- 107. 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.
- 108. 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. an award of pre-judgment and post-judgment interest on the damages caused by Dexcom's infringing activities and other conduct complained of herein;
  - e. a finding that this case is an exceptional case under 35 U.S.C. § 285;
- f. a judgment awarding Abbott reasonable attorneys' fees and its costs and reimbursements in this action, as provided by 35 U.S.C. § 285;
- g. an accounting for infringing sales not presented at trial and an award by the Court of additional damages for any such infringing sales;
  - h. a compulsory future royalty; and
  - i. 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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## /s/Jack B. Blumenfeld

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