IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT DIABETES CARE INC. and ABBOTT DIABETES CARE LIMITED, Plaintiffs, v. DEXCOM, INC., Defendant.	))))))))))	C.A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT

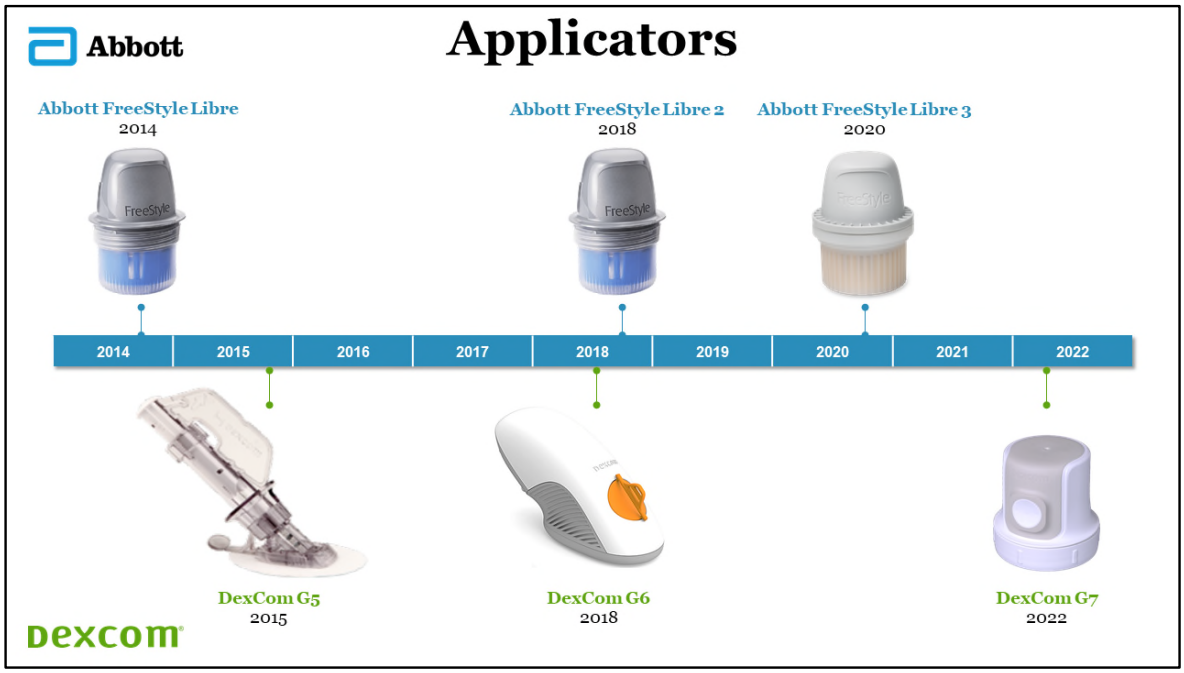
Plaintiffs Abbott Diabetes Care Inc. and Abbott Diabetes Care Limited (collectively, "Abbott") bring this action against DexCom, Inc. ("DexCom") for DexCom's ongoing, willful, and unauthorized use of Abbott's patented technologies in DexCom's G7 continuous glucose monitoring system ("G7").

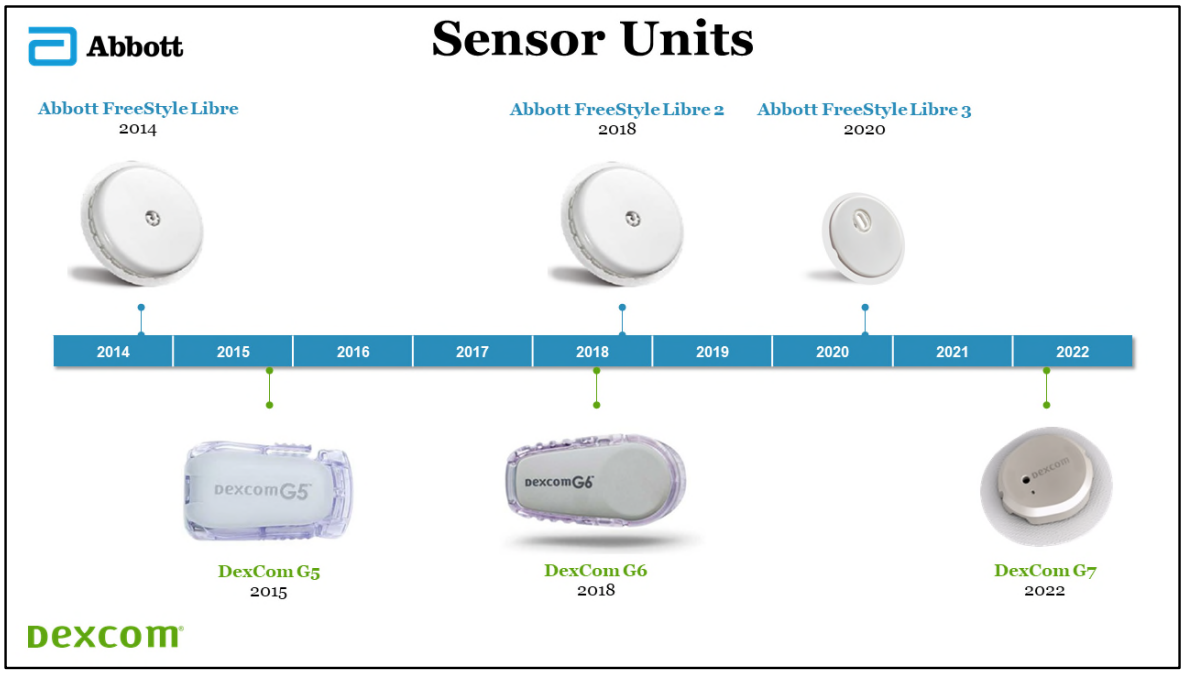
DexCom has had full notice of Abbott's patent rights and yet continues to engage in the theft of Abbott's valuable technology. DexCom has had over seven years to get its house in order while it enjoyed Abbott's agreement not to sue. But instead of using that time to steer its products clear of Abbott's patents, DexCom has continued to use more and more of Abbott's technology. Even after being put on clear notice of its infringement, DexCom persists. And it just launched its biggest knockoff yet: G7.

DexCom's infringement is willful and deliberate. It robs Abbott and the people who worked to develop and bring Abbott's award-winning FreeStyle Libre systems to market. It also robs the public because if companies like DexCom can simply copy others' innovations, they jeopardize the investments necessary to develop the innovations in the first place. DexCom's infringement must be stopped.

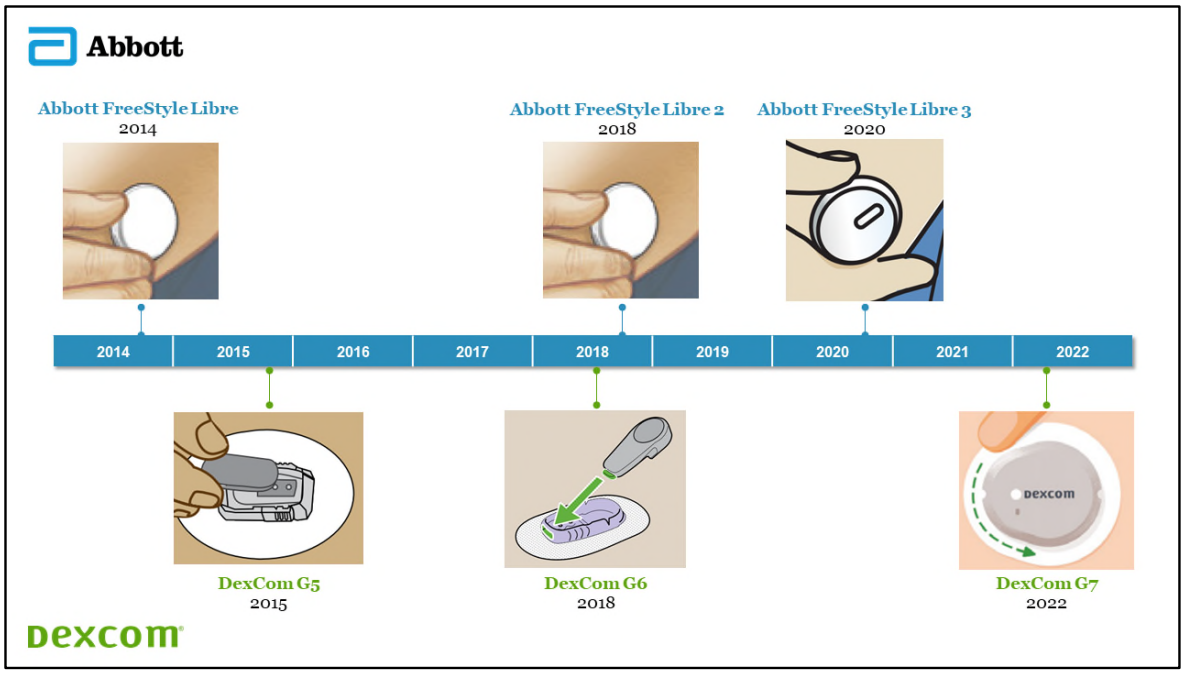
INTRODUCTION

1. DexCom's mimicking of Abbott's technology is striking. Having failed to independently develop a successful design for its own products for over a decade, DexCom has converged on Abbott's award-winning, worldwide market-leading products. DexCom's imitation of Abbott's technology is illustrated in the following timelines comparing the dates when each product received regulatory approval:





2. In its most recent product, the G7, DexCom has mimicked one of Abbott's flagship features: a patent-protected, all-in-one sensor unit with a sensor pre-connected to electronics and loaded in an applicator. After inserting the sensor into the user, the FreeStyle Libre systems are ready for use. Before G7, DexCom's G5 and G6 continuous glucose monitoring systems did not have this advantageous design. DexCom's users had to do more than Abbott's users after insertion, including manually attaching a reusable transmitter to the sensor pod. But now, as illustrated in the following timeline, DexCom has changed that by taking Abbott's innovative technology and promoting it as "G7":



BACKGROUND

3. The technology DexCom has been taking from Abbott is for continuous glucose monitors, or CGMs. CGMs continuously monitor blood sugar in the body, called glucose, and are relied upon by people with diabetes to manage their glucose levels. Diabetes results in 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, and CGMs, are so important for people with diabetes.

4. Historically, glucose 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 single test value. 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 diabetes treatments, diet, and exercise.[1] Often patients would not do all the fingersticks needed to adequately monitor their glucose levels and prevent the disease's progression and deadly effects.[2]

5. Blood sugar monitoring for diabetes improved with the introduction of CGMs. Early CGMs, however, were inaccessible and unrealistic for many people with diabetes. They were unaffordable for many, often were not covered by insurance, and required in-use calibration using the same problematic fingersticks they were meant to replace.[3] They were also bulky, complicated, required separate sensors and transmitters, had gaps in the glucose data they displayed, and required insertion with daunting applicators.

Abbott's FreeStyle Libre Systems

6. Unlike others, Abbott focused its designs on maximizing patient access and convenience. In 2014, it launched the FreeStyle Libre system, the first commercially available CGM that avoids fingersticks. The FreeStyle Libre system 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

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[1] *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.

[2] *See id.* at 2, 6.

[3] *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.

continuously monitors glucose levels and wirelessly transmits glucose data to digitally-connected devices, including smartphones and dedicated readers.

7. The FreeStyle Libre system's integrated electronics feature allows the sensor and transmitter to remain attached as one on-body unit so the user does not have to manually connect the two pieces after the sensor has been inserted. The simple insertion process requires only one step with an easy-to-use compact applicator. The FreeStyle Libre systems are 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, building, and expanding the market for its FreeStyle Libre systems. It is now the most accessible and top-selling glucose monitoring system in the world.

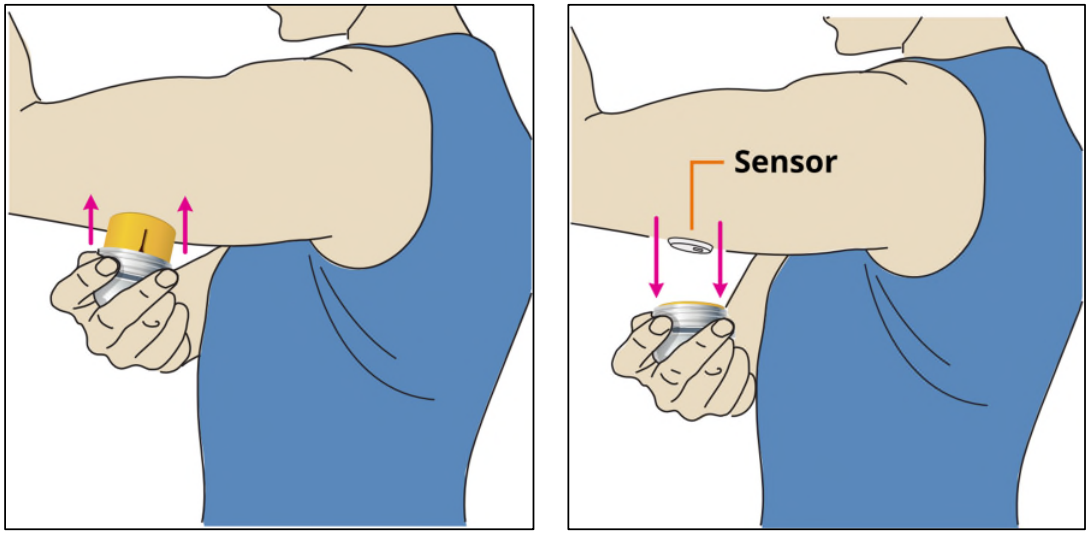
8. From the start and to this day, Abbott's FreeStyle Libre systems comprise: (1) an applicator (*i.e.*, insertion device), (2) a fully disposable on-body unit that is deployed from the applicator and consists of a factory-calibrated glucose sensor and a transmitter, and (3) a display device (such as a reader or smartphone) with proprietary software. This concept, which has remained consistent for many years, is responsible for FreeStyle Libre systems' affordability, accuracy, reliability, and its simple, effective handling (ease of use) for the patient. The following illustration shows the applicator, on-body unit, and smartphone display for the Freestyle Libre 3:[4]

[4] *FreeStyle Libre 3 System*, ABBOTT FREESTYLE, https://www.freestyle.abbott/eu-en/products/freestyle-libre-3.html.

Applicator (insertion device)	**On-body unit including sensor and transmitter**	**Display device (smartphone) with proprietary software**

9. In one step, a FreeStyle Libre user inserts a portion of the glucose sensor under the skin and attaches the on-body unit, containing the sensor and electronics, to the user's body using the applicator. Data from the on-body unit is wirelessly transmited to a display device where a current glucose value, a graph of the time series of past values, and other related information are shown.[5]

[5] *Freestyle Libre 3 Quick Start Guide*, ABBOTT, at 4-5, https://freestyleserver.com/Payloads /IFU/2022/q2/ART44255-001_rev-A.pdf.



10. Abbott's FreeStyle Libre systems overcame the significant drawbacks of earlier CGM products. For example, the FreeStyle Libre systems eliminated the need for fingerstick calibration to obtain accurate glucose measurements. Instead, the FreeStyle Libre systems are fully calibrated in the factory, so no fingerstick calibration is required.[6] Additionally, the Freestyle Libre systems are simple to use as an all-in-one disposable device with a quick, one-step process for application to the skin. The sensor and transmitter are integrated into a single unit, which can be disposed of at the end of the wear period.

11. Compared to earlier CGM products, FreeStyle Libre systems offered many other benefits, including:

- significantly lower cost;
- an improved applicator design;
- integrated, all-in-one electronics that allowed for the 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;

[6] Confirmatory fingersticks are required under certain circumstances for non-adjunctive use.

- greater ease-of-use;
- shorter warm-up times;
- more complete and accurate glucose data; and
- longer wear periods with accurate readings (up to 14 days of continuous use).

These advances made the Freestyle Libre systems accessible to many people who could not or would not otherwise use CGMs.

12. Researchers have acknowledged these 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."[7]

13. FreeStyle Libre system users have described how it changed the way they manage diabetes and improved their lives:

- The FreeStyle Libre "has been the easiest and single-most positive 'medical improvement' in my diabetic journey since being diagnosed [twenty-two years ago]."[8]
- "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!!"[9]
- "[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

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[7] 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.

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

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

> the next 3 months my A1C[10] 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!"[11]

14. In 2016, top senior business executives, academics, and innovation professionals selected the first-generation FreeStyle Libre to receive the Edison Award for the "best of the best" for patient care.[12] 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."[13] In April 2021, the FreeStyle Libre 2 received an Edison Award as "best of the best" for personal wellness technology.[14]

15. In 2019, Abbott received the prestigious *Prix Galien* award recognizing FreeStyle Libre systems as the Best Medical Technology approved by the Food and Drug Administration (FDA) in the preceding five years.[15] Abbott received another award from the Galien Foundation

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[10] *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).

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

[12] *2016 Edison Best New Product Awards™ Winners*, EDISON AWARDS, https://edisonawards.com/winners2016.php.

[13] *About the Edison Awards*, EDISON AWARDS, https://edisonawards.com/about.php.

[14] *2021 Edison Best New Product Awards™ Winners*, EDISON AWARDS, https://edisonawards.com/winners2021.php.

[15] *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).

in 2022, which named the Freestyle Libre systems as the "Best Medical Technology" of the last 50 years.[16] In 2022, Abbott's Freestyle Libre 3 also won the CES 2022 INNOVATION AWARD for Best of Innovation in Health & Wellness.[17]

16. Abbott's FreeStyle Libre systems are now the top selling CGM products in the world. They have helped more than 4.5 million people across 50 countries by providing breakthrough technology that is affordable, accurate, reliable, and simple to use.[18]

DexCom's History of Following Abbott's Lead

17. 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, DexCom's G4 and G5 CGM systems required fingersticks for calibration. Users needed to take frequent fingerstick blood glucose readings throughout the day and had to input those values into the receiver for the entire sensor wear life. DexCom's prior CGM generations also had shorter wear times and required inserting the needle diagonally under the skin using applicators described by its CEO as "kind of scary"[19] and likened to an

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[16] https://abbott.mediaroom.com/2022-10-28-Abbotts-FreeStyle-Libre-R-is-Named-Best-Medical-Technology-in-Last-50-Years-by-the-Galien-Foundation#:~:text=Award%20winners%20were%20chosen%20across,Award%20for%20Best%20Medical%20Technology.

[17] *CES 2022 Innovation Award Product*, CES, https://www.ces.tech/innovation-awards/honorees/2022/best-of/f/freestyle-libre-3-system.aspx.

[18] *Abbott's FreeStyle Libre® 3 Integrated with Automated Insulin Delivery System MyLife™ Loop in Germany*, https://abbott.mediaroom.com/2022-12-21-Abbotts-FreeStyle-Libre-R-3-Integrated-with-Automated-Insulin-Delivery-System-mylife-TM-Loop-in-Germany (Dec. 21, 2022).

[19] 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).

"intimidating" "harpoon."[20] The insertion process for the sensors required numerous steps, and included manually retracting the needle after the sensor had been inserted into the body.[21]

18. The on-body unit was also not designed as one piece, but as several pieces. The user had to first apply a transmitter holder including a glucose sensor onto their body with an adhesive patch. Then, a separate transmitter had to be snapped into the transmitter holder on the adhesive patch each time the sensor was replaced. This made DexCom's prior CGM generations[22] more complicated and more error-prone relative to the FreeStyle Libre systems, as illustrated below:[23]

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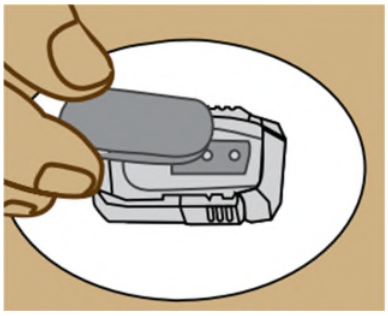
[20] *See, e.g.*, *DexCom User Guide for DexCom G5 Mobile Continuous Glucose Monitoring (CGM) System, LBL015014 Rev 009 MT24706*, DEXCOM.COM, at 42, https://s3-us-west-2.amazonaws.com/dexcompdf/G5-Mobile-Users-Guide-Touchscreen-Receiver.pdf (hereinafter, "G5 User Guide"); Jonah Comstock, *DexCom CEO Tells Investors Not to Fear New Competition 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/.

[21] The G5's cumbersome insertion process can be viewed at https://www.youtube.com/watch? v=9_8t_HSG-uE.

[22] *G5 User Guide*, *supra* note 20.

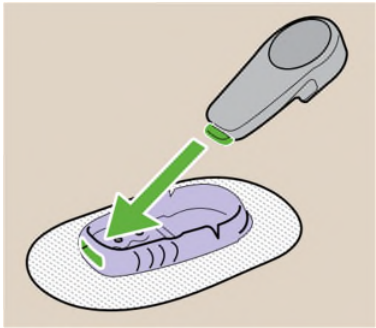
[23] *What Are the Components of the Freestyle Libre System?*, ABBOTT FREESTYLE LIBRE, https://www.freestyle.abbott/om-en/discover-freestyle-libre/why-freestyle-libre-/what-are-the-components-of-the-freestyle-libre-system.html; *FreeStyle Libre Sensor*, ABBOTT FREESTYLE LIBRE, https://www.freestyle.abbott/om-en/product/freestyle-libre-sensor.html; *Abbott Freestyle Libre 2 Get Started Guide*, at 5, https://www.freestyle.abbott/content/dam/adc/freestyle/countries /us-en/documents/get-started-guide.pdf; *FreeStyle Libre 2 Sensor*, ABBOTT FREESTYLE LIBRE, https://www.freestylelibre.co.uk/libre/products/FreeStyle-Libre-2-Sensor.html.

Abbott FreeStyle Libre/FreeStyle Libre 2 (same inserter/applicator design)	DexCom G5
	

19. In 2018, four years after Abbott first introduced the first FreeStyle Libre system, DexCom introduced its G6 continuous glucose monitoring product, followed by the G6 Pro in 2020.[24] DexCom's G6, its sixth-generation device, is a substantial departure from its fifth-

[24] Hereinafter "G6" includes the G6, G6 Pro, Pro Q, G6 Glucose Program, and DexCom ONE.

generation product (i.e., "G5") and earlier products.[25] The G6 incorporates many of Abbott's patented innovations in its design and operation.[26]

Abbott FreeStyle Libre/FreeStyle Libre 2 (same inserter/applicator design)	**DexCom G6**
	

[25] *Compare* https://www.youtube.com/watch?v=dBOgdsfeM-A (G6 insertion process) *with* https://www.youtube.com/watch?v=9_8t_HSG-uE (G5 insertion process).

[26] *DexCom G6 CGM System for Personal Use*, DEXCOM, https://provider.DexCom.com/products/DexCom-g6-personal-cgm-system; *G6 Overview*, DEXCOM, https://www.DexCom.com/en-us/g6-cgm-system.

20. In 2014, years before DexCom introduced G6, Abbott and DexCom had entered into an agreement under which Abbott agreed not to sue DexCom for infringement of certain patented technology for a period of approximately seven years. This agreement settled the prior litigation that Abbott had initiated in 2005 when DexCom first started infringing Abbott's technology. DexCom released G6 during the period when Abbott had agreed not to sue DexCom. Abbott upheld its end of that bargain. But Abbott's covenant not to sue expired in March 2021. Abbott brought an infringement suit against DexCom's G6 in this District in July 2021 (C.A. No. 21-977-KAJ) ("the G6 Action").

21. Before the covenant period expired, DexCom tried multiple times to convince Abbott to extend its agreement not to sue DexCom. It is clear why DexCom did that: DexCom was already using Abbott's patented technology in its on-market products and was preparing to take even more of Abbott's patented technology with its G7.

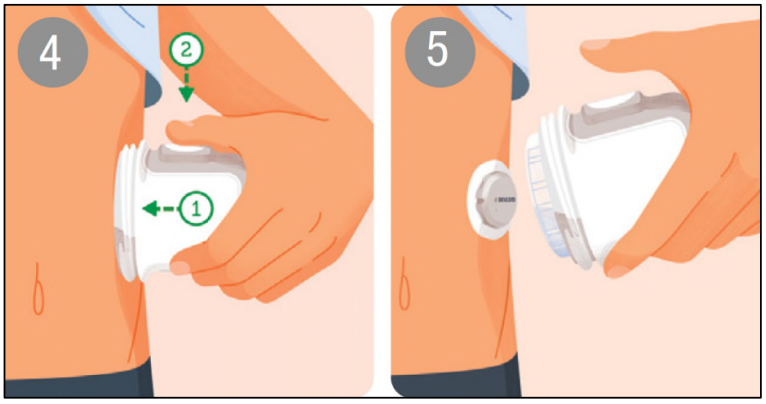
22. Abbott did not agree to DexCom's requests. DexCom should have stopped its copying. But DexCom did not stop, not even at that point. Despite DexCom's failure to obtain Abbott's agreement to extend the covenant not to sue, and despite DexCom having received clear notice of its unlawful conduct, DexCom deliberately chose to incorporate into G7 some of the same infringing features as the G6 plus additional features that infringe more of Abbott's patents.

Abbott FreeStyle Libre 3	DexCom G7

23. DexCom designed the G7 so that the applicator is placed perpendicularly to the skin and delivers an on-body sensor unit that includes an integrated glucose sensor and transmitter unit—just as patients have known for years from Abbott.[27]

> *All new components and app*
> Sensor and patch
> - Streamlined all-in-one sensor with built in disposable transmitter

[27] The G7 insertion process can be viewed at https://www.youtube.com/watch?v=KLbBidcY4lA; *Dexcom G7 User Guide*, Rev 001 MT00046-05, DEXCOM.COM, at 2, https://s3.us-west-2.amazonaws.com/dexcompdf/Downloads+and+Guides+Updates/AW00046-05+UG+G7+OUS+en+MMOL.pdf (hereinafter, "G7 User Guide"); *DexCom Inserting Sensor*, DEXCOM.COM, https://s3.us-west-2.amazonaws.com/dexcompdf/Downloads+and+Guides+Updates/AW00048-00+Insert+SX+Sheet+G7+OUS.pdf (hereinafter, "G7 Insert Guide").



24. Like Abbott's Freestyle Libre systems, DexCom's G7 now uses an all-in-one transmitter and sensor design that can be applied in a single step and is fully disposable.[28] To accomplish this—in a substantial departure from DexCom's previous devices—the G7 incorporates Abbott's patented applicator and all-in-one on-body unit with an integrated sensor and electronics, which are significant improvements over the complicated, not-user-friendly design of earlier DexCom products.

25. The 510(k) summary for G7's FDA approval confirms that G7's primary "improvement" over DexCom's earlier G6 system is attributable to Abbott's patent-protected technology: "[t]he G7 CGM System primarily improves upon the user experience of the predicate G6 CGM System by providing a fully enclosed miniaturized wearable with pre-connected sensor

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[28] *See, e.g.*, *G7 User Guide*, *supra* note 27, at 2; *DexCom G7 Release: These Are the Most Exciting New Features*, NOT JUST A PATCH, https://notjustapatch.com/DexCom-g7-release/#:~:text=The%20G7%20is%20supposedly%2060,loose%20while%20sweating%20and%20swimming; *What's Going on With the DexCom G7?*, DIABETES DAILY, https://www.diabetesdaily.com/blog/whats-going-on-with-the-DexCom-g7-695251/ (March 14, 2022); *DexCom G7 Receive CE Mark - Next-Generation Continuous Monitoring System to Revolutionize Diabetes Management*, DEXCOM, https://investors.dexcom.com/news/news-details/2022/Dexcom-G7-Receives-CE-Mark--Next-Generation-Continuous-Glucose-Monitoring-System-to-Revolutionize-Diabetes-Management/default.aspx (March 14, 2022); *DexCom CEO Kevin Sayer Says G7 Will Be 'Wonderful'*, DRUG DELIVERY BUSINESS NEWS, https://www.drugdeliverybusiness.com/DexCom-ceo-kevin-sayer-says-g7-will-be-wonderful/ (July 19, 2021).

that is applied to the body in a single button press."[29] DexCom's own press release about G7's FDA approval touts these same Abbott features:[30]

> **New features with Dexcom G7:**
> - 60% smaller, all-in-one, discreet† wearable, easier to use with fewer components

26. Below is just some of the feedback G7 has received since it incorporated Abbott's patented technology:

- "The biggest difference from the G6 system is that the G7 is a 1-piece sensor application. Patients will no longer have to remember to save the separate transmitter for 90 days when changing the sensor every 10 days. This new 1-piece sensor is also 60% smaller than the G6 version."[31]

- "The transmitter is included in every sensor (like the Freestyle Libre but shhh I never said that), so there is no need for the two-step process when applying to have it funded by the HSE."[32]

- Comparing the Freestyle Libre with DexCom CGMs: "And a smaller, single sensor unit is far more convenient."[33]

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[29] U.S. FOOD & DRUG ADMINISTRATION, *510(k) Summary*, FDA.gov, at 5, https://www.accessdata.fda.gov/cdrh_docs/pdf21/K213919.pdf (hereinafter, "FDA 510(k) Summary").

[30] *DexCom G7 Receives FDA Clearance: The Most Accurate Continuous Glucose Monitoring System Cleared in the U.S.*, DEXCOM (Dec. 8, 2022), https://investors.dexcom.com/news/news-details/2022/Dexcom-G7-Receives-FDA-Clearance-The-Most-Accurate-Continuous-Glucose-Monitoring-System-Cleared-in-the-U.S/default.aspx.

[31] *The Next Generation of Continuous Glucose Monitors: Freestyle Libre 3 vs DexCom G7*, PHARMACY TIMES, https://www.pharmacytimes.com/view/the-next-generation-of-continuous-glucose-monitors-freestyle-libre-3-vs-dexcom-g7.

[32] *DexCom G7 CGM Arrives In Ireland*, BLOOD SUGAR TRAMPOLINE, https://bloodsugartrampoline.com/blog/2022/10/16/dexcom-g7-cgm-arrives-in-ireland.

[33] *r/dexcom*, *Dexcom* CEO Kevin Sayer says G7 will be 'wonderful', REDDIT, https://www.reddit.com/r/dexcom/comments/oo6y4l/dexcom_ceo_kevin_sayer_says_g7_will_be_wonderful/.

- "The G7 should have some nice improvements too, mainly that it's one small piece - no more separate transmitter and sensor!"[34]
- "This requires a new insertion tool that looks more akin to the Freestyle Libre with a button on the side. The whole unit is disposable, no longer requiring the transmitter to be reused."[35]

27. DexCom is deliberately using Abbott's patented technologies in its products and is infringing Abbott's valuable patent rights. Abbott is entitled to injunctive relief and damages for DexCom's infringement.

NATURE OF THE ACTION

28. 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. 10,827,954 ("the '954 patent"), 11,202,591 ("the '591 patent"), 11,266,335 ("the '335 patent"), and 11,298,056 ("the '056 patent") (collectively, the "Asserted Patents").

29. This is an action for infringement of the Asserted Patents.

30. This action is based on the Patent Laws of the United States, 35 U.S.C. §§ 100, *et seq.*

PARTIES

31. 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.

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[34] *r/diabetes_t1*, Longer term CGM, REDDIT, https://www.reddit.com/r/diabetes_t1/comments/mve59a/longer_term_cgm/.

[35] Andrew O'Hara, *First Look: New DexCom G7 Glucose Monitor*, APPLEINSIDER.COM, https://appleinsider.com/articles/22/12/13/first-look-at-the-new-DexCom-g7-glucose-monitor.

32. 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.

33. 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

34. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) *et seq*.

35. This Court has personal jurisdiction over DexCom because, *inter alia*, it is incorporated in Delaware, and thus resides in this District.

36. 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.

ASSERTED PATENTS

37. Abbott has invested heavily in developing and maintaining a portfolio of patents protecting its inventions, including the Asserted Patents.

38. 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.

39. A true and correct copy of the '954 patent is attached as **Exhibit A**.

40. The '591 patent is titled "Analyte Sensor and Apparatus for Insertion of the Sensor," and was duly and legally issued on December 21, 2021.

41. A true and correct copy of the '591 patent is attached as **Exhibit B**.

42. The '335 patent is titled "Medical Device Inserters and Processes of Inserting and Using Medical Devices," and was duly and legally issued on March 8, 2022.

43. A true and correct copy of the ’335 patent is attached as **Exhibit C**.

44. The ’056 patent is titled “Methods and Systems for Early Signal Attenuation Detection and Processing,” and was duly and legally issued on April 12, 2022.

45. A true and correct copy of the ’056 patent is attached as **Exhibit D**.

DEXCOM’S INFRINGEMENT

46. DexCom’s G7 received CE mark approval in Europe in March 2022.[36] As of April 28, 2022, DexCom had initiated a limited launch of G7 in the United Kingdom that would expand across Europe throughout 2022.[37] On October 4, 2022, DexCom announced that the G7 was available in the United Kingdom, Germany, Austria, and Hong Kong.[38] And as of January 9, 2023, DexCom’s G7 was “fully launched in 6 markets: United Kingdom, Ireland, Germany, Austria, Hong Kong, and New Zealand.”[39] DexCom manufactures its products at its headquarters in San

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[36] *Dexcom G7 Receives CE Mark – Next-Generation Continuous Glucose Monitoring System to Revolutionize Diabetes Management*, DEXCOM, https://investors.dexcom.com/news/news-details/2022/Dexcom-G7-Receives-CE-Mark--Next-Generation-Continuous-Glucose-Monitoring-System-to-Revolutionize-Diabetes-Management/default.aspx.

[37] *Dexcom Reports First Quarter 2022 Financial Results*, DEXCOM, https://investors.dexcom.com /news/news-details/2022/Dexcom-Reports-First-Quarter-2022-Financial-Results/default.aspx (April 28, 2022).

[38] *Dexcom G7 Launches in the United Kingdom, Ireland, Germany, Austria and Hong Kong – Initiating Global Rollout of World’s Most Powerful Continuous Glucose Monitoring System*, DEXCOM, https://investors.dexcom.com/news/news-details/2022/Dexcom-G7-Launches-in-the-United-Kingdom-Ireland-Germany-Austria-and-Hong-Kong--Initiating-Global-Rollout-of-Worlds-Most-Powerful-Continuous-Glucose-Monitoring-System/default.aspx.

[39] *J.P. Morgan Healthcare Conference*, DEXCOM, at 14, https://s201.q4cdn.com/758408164/files /doc_presentation/2023/Investor-Presentation_JPM-2023_FINAL.pdf.

Diego, California and at its manufacturing facility in Mesa, Arizona.[40] As DexCom's Executive Vice President and Chief Operating Officer has acknowledged:

> So from a capacity perspective, we've been gearing up for this G7 launch for quite a while. So we've got G7 lines installed here in San Diego as well as in Mesa. And so we feel really good about our position to meet the needs of our full G7 U.S. launch as well as the international launches that will continue throughout the year.[41]

Accordingly, since at least as early as April 2022, DexCom has been manufacturing G7 in the Unites States for use, sale, and/or offer for sale in European and Asian markets.

47. Although DexCom began construction of a new, "future manufacturing facility" in Malaysia in 2020,[42] that facility is still under construction and is only expected to open "over the course of the year[.]"[43] Indeed, the facility is not expected to produce commercial products until at least mid-2023.[44] Thus, on information and belief, DexCom's manufacturing of the G7 currently takes place exclusively in the United States.

48. DexCom has also been manufacturing G7 for use, sale, and offer for sale in the United States. On January 19, 2023, in an interview with MedTech Dive, DexCom's CEO Kevin

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[40] *2021 Annual Report*, DEXCOM, at 13, https://s201.q4cdn.com/758408164/files/doc_financials/2021/ar/2021_Annual_Report.pdf (hereinafter, "2021 Annual Report"); *see also Dexcom's Jake Leach discusses preparations for G7 launch next year*, MEDTECHDIVE, https://www.medtechdive.com/news/Dexcom-DXCM-CGM-G7-launch-Insurance/638826/ (December 15, 2022).

[41] *DexCom (DXCM) Q3 2022 Earnings Call Transcript*, THE MOTLEY FOOL, https://www.fool.com/earnings/call-transcripts/2022/10/27/dexcom-dxcm-q3-2022-earnings-call-transcript/.

[42] *2021 Annual Report*, supra note 40 at 55.

[43] *J.P. Morgan Healthcare Conference*, DEXCOM, at 19, https://s201.q4cdn.com/758408164/files/doc_presentation/2023/Investor-Presentation_JPM-2023_FINAL.pdf.

[44] *DexCom (DXCM) Q3 2022 Earnings Call Transcript*, THE MOTLEY FOOL, https://www.fool.com/earnings/call-transcripts/2022/10/27/dexcom-dxcm-q3-2022-earnings-call-transcript/.

Sayer stated that the G7 "launch will roll out here in February."[45] And as DexCom geared up for its launch of G7, DexCom's CEO further stated that DexCom is currently "building inventory, we're getting our ducks in a row so we can get it out the door. And we'll continue to roll it out in [Europe]."[46] Since February 17, 2023 or earlier, DexCom has been selling and/or offering for sale the G7 in the United States.

49. DexCom's infringement of at least the '954 patent has been and continues to be willful, intentional, deliberate, and in conscious disregard of Abbott's rights. DexCom does not have, nor could it have had, a good-faith belief that making, selling, offering to sell, using, or importing the G7 does not infringe at least the '954 patent.

50. Indeed, DexCom became aware of the '954 patent at least as early as July 2, 2021, when DexCom was served with Abbott's original complaint in the G6 Action. (*See* C.A. No. 21-977-KAJ, D.I. 1.) In that complaint, Abbott alleged infringement of twelve patents, including the '954 patent, and provided a claim chart to illustrate examples of DexCom's infringement. Therefore, by no later than July 2, 2021, DexCom not only knew of the '954 patent, but also how the G6 and G7 infringe this patent.

51. In any event, this complaint not only provides DexCom with indisputable notice of the Asserted Patents, but also of its infringement of those patents.

52. As discussed in greater detail below, the conclusion that DexCom's infringement is knowing, willful, and deliberate for at least the '954 patent is supported by the available

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[45] *Dexcom CEO discusses 2023 plans, expanding to more patients with Type 2 diabetes*, MEDTECHDIVE, https://www.medtechdive.com/news/dexcom-ceo-2023-plans-diabetes-CGMs/640767/.

[46] *Diabetes Outlook: What Dexcom, Medtronic and Other Leaders Are Watching in 2023*, MEDTECHDIVE, https://www.medtechdive.com/news/diabetes-technology-leaders-medtronic-tandem-dexcom-abbott-MDT-DXCM-TNDM-ABT-2023/640864/ (January 20, 2023).

evidence, including that DexCom (1) copied inventions from Abbott's commercial products, patent specifications, and/or other publications describing Abbott's patented technology, (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.

53. 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.

DexCom Copied Inventions from Abbott's Commercial Products, Patent Specifications, and/or Other Publications Describing Abbott's Patented Technology

54. DexCom's newly launched G7 is designed to compete with Abbott's award-winning FreeStyle Libre technology. To better compete with Abbott's FreeStyle Libre systems, DexCom copied Abbott's innovations and incorporated them into G7, as explained below and illustrated in Exhibits E-H.

Accurate Glucose Measurements Without Requiring User Calibration During the Wear Life

55. Abbott's FreeStyle Libre systems 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).

56. 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" in sensor readings, calibrate again every twelve hours throughout the wear life for accurate glucose readings.[47]

57. 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."[48]

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.

58. To perform these calibrations, the user was required to draw a blood sample, typically by sticking or pricking a finger.[49] 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.[50]

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[47] *See G5 User Guide*, *supra* note 20, at 99. 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.

[48] *G5 User Guide*, *supra* note 20, at 21 (highlighting added).

[49] *See, e.g.*, *G5 User Guide*, *supra* note 20, at 107.

[50] 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.").

59. 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.[51] Attempting to compete, DexCom copied Abbott's innovations and incorporated them into DexCom's G6, which was DexCom's first CGM system that did not require fingerstick calibration. 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.[52]

60. Among other things, DexCom's G6 incorporates a "drift profile" programmed into memory. DexCom copied this feature (and other features) from Abbott's FreeStyle Libre and the disclosures in patents protecting Abbott's innovations, as well as publications describing Abbott's patented technology, as detailed in Abbott's Second Amended Complaint and associated claim charts, and infringement contentions, in the G6 Action.

61. In a 2019 article analyzing how the G6 is factory calibrated, the authors concluded that this feature was necessary to "remove the need for [fingerstick] calibrations":

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[51] 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, 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.").

[52] 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.").

> 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.[53]

62. DexCom was put on clear notice of its infringement of the '954 patent when Abbott filed the G6 Action. Despite this, DexCom deliberately chose to launch the G7 with the same infringing features as the G6 relating to the '954 patent.

63. Just as it did with the G6,[54] DexCom is also now promoting the G7 by touting the technology it copied from Abbott, including by repeatedly emphasizing that there is no need for painful fingerstick calibration measurements. For example, in the press release announcing that G7 had received FDA approval, DexCom promoted "[n]o fingersticks, scanning or calibration" as

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[53] 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 . . . .").

[54] *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."); *id*. ("The DexCom G6 is FDA-permitted to make diabetes treatment decisions without confirmatory fingersticks or calibration."); *Dexcom G6 Continuous Glucose Monitoring System User Guide, Rev 012 MT23976*, DEXCOM.COM, at 22, 40, 43, 44, 107, https://s3-us-west-2.amazonaws.com/dexcompdf/G6-CGM-Users-Guide.pdf (hereinafter, "G6 User Guide"); *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."); *G6 User Guide* at 38 (asserting that that factory calibration "can reduce the pain and burden of excessive fingersticks . . . and reduce potential errors due to inaccurate calibration."); *DexCom G6 Features and Benefits*, DEXCOM CONTINUOUS GLUCOSE MONITORING, https://www.DexCom.com /g6/features-and-benefits ("No need to calibrate with a blood glucose meter, eliminating the need for fingersticks."); *Discover the DexCom G6 CGM System*, DEXCOM CONTINUOUS GLUCOSE MONITORING, https://www.DexCom.com/g6/how-it-works (advertising no fingersticks as the "Best. News. Ever.").

a G6 feature that was included with the G7.[55] Similarly, on its website, DexCom notes that "no fingersticks [are] required" with the G7.[56]

64. Moreover, the G7 User Guide describes "Sparing your fingertips" as one of the benefits of using the G7.[57] The G7 User Guide goes on to note some of the advantages of "No Fingersticks":[58]

> *No fingersticks*
>
> You can use your sensor reading and trend arrow to make treatment decisions. Go to the Treatment Decisions chapter for more information. No calibration (with your BG meter) is needed. This reduces the pain and burden of excessive fingerstick and potential errors due to inaccurate calibration.

Applicator Technology For Delivery of An Integrated Sensor-Electronics Unit

65. Abbott's FreeStyle Libre products are applied by the user with an applicator that is simple to use and relatively pain free. In particular, Abbott's FreeStyle Libre products include a sensor and transmitter that are integrated into a single unit that allows for the application of the on-body unit by a user in a single, simple step. At the end of the wear period, the on-body unit can be easily removed and disposed of.

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[55] *Dexcom G7 Receives FDA Clearance: The Most Accurate Continuous Glucose Monitoring System Cleared in the U.S.*, DEXCOM CONTINUOUS GLUCOSE MONITORING, https://investors.dexcom.com/news/news-details/2022/Dexcom-G7-Receives-FDA-Clearance-The-Most-Accurate-Continuous-Glucose-Monitoring-System-Cleared-in-the-U.S/default.aspx.

[56] *FAQs, What is the DexCom G7 CGM System?*, DEXCOM CONTINUOUS GLUCOSE MONITORING, https://www.dexcom.com/en-us/g7-fda.

[57] *Dexcom G7 User Guide, Rev 001 MT00046-05*, DEXCOM.COM, at 1, https://s3.us-west-2.amazonaws.com/dexcompdf/Downloads+and+Guides+Updates/AW00046-05+UG+G7+OUS+en+MMOL.pdf (hereinafter, "G7 User Guide"); *see also id.* ("No more fingersticks: G7 allows you to make treatment decisions without fingersticks.").

[58] *Id.*

66. In contrast, Dexcom's G5 (and other predecessor products) and G6 include a transmitter holder and reusable transmitter. The transmitter must be attached to the transmitter holder by the user before use. At the end of the wear period, the transmitter has to be removed from the used transmitter holder before it can be reused with a new device. Moreover, before G6, DexCom's applicator technology was complicated and, in the words of its CEO, "scary looking" with "threatening steps."[59] Users of the G5 even compared the G5 applicator to a "harpoon."[60]

67. For the G6, DexCom completely overhauled its "scary" inserter design.[61] 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. As a result, Abbott filed the G6 Action. But this did not stop DexCom.

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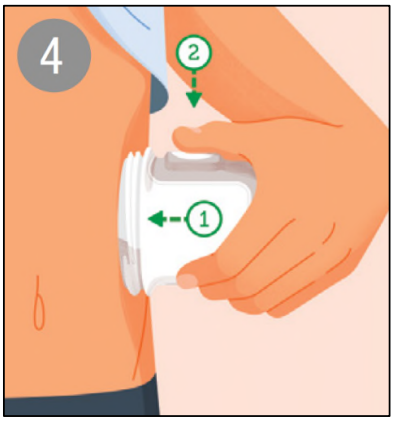
[59] Michelle Boise, *Interview with Dexcom CEO*, BEYOND TYPE 1, https://beyondtype1.org/Dexcom-ceo-kevin-sayer-explains-g6/ (Jul. 6, 2018); Steve Freed, *CGMs Changing Diabetes Management: Kevin Sayer, DIC Interview Transcript*, DIABETES IN CONTROL, https://www.diabetesincontrol.com/cgms-changing-diabetes-management-kevin-sayer-dic-interview-transcript/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

[60] *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); *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) (describing the G5 inserter during an investor call, by acknowledging that: "[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.").

[61] *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) ("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.").

68. Instead, with G7, DexCom has further converged its technology toward Abbott's patented designs by incorporating inventions from Abbott's patent disclosures and features from Abbott's commercial products. In particular, DexCom's G7 makes unauthorized use of Abbott's breakthrough technologies patented in the '591 and '335 patents, which provide important advantages, including a small, one-piece glucose sensor with integrated electronics and a simpler, easier-to-use, and safer CGM insertion assembly.

69. As explained in more detail above, with G7, DexCom has copied Abbott's flagship patented features: an applicator with an all-in-one on-body unit with integrated sensor and electronics that allows for application in a single step. G7 now uses essentially a one-step application process with the press of a button that applies an integrated on-body unit.[62]



4 Use Applicator to Insert Sensor

a. Relax any muscles near site
b. Press and hold applicator firmly against skin and then push button

70. According to the DexCom Start Here Guide and G7 User Guide, the G7 includes an applicator with a built-in sensor and transmitter.[63]

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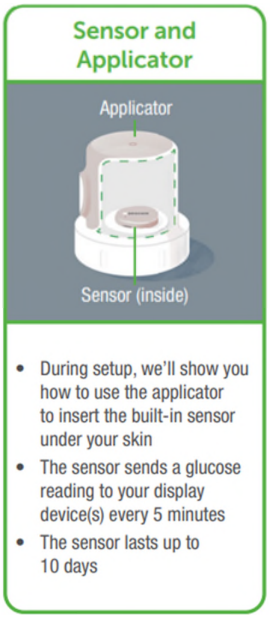
[62] *G7 Insert Guide: DexCom Inserting Sensor*, DEXCOM.COM, https://s3.us-west-2.amazonaws.com/dexcompdf/Downloads+and+Guides+Updates/AW00048-00+Insert+SX+Sheet+G7+OUS.pdf (hereinafter, "G7 Insert Guide").

[63] *G7 Start Here Guide: Dexcom G7 Start Here Guide, Rev 001 MT00047-05*, DEXCOM.COM, at 3, https://s3.us-west-2.amazonaws.com/dexcompdf/Downloads+and+Guides+Updates/AW00047-05+SHG+G7+OUS+en.pdf (hereinafter, "G7 Start Here Guide"); *G7 User Guide*, *supra* note 27, at 19-20.



Transmitter	Sends sensor readings to the display device. In G7, the transmitter is built into the sensor.

Sensor	Sends sensor readings to the display device. In G7, the transmitter and adhesive patch are built into the sensor.

71. In promoting the G7, DexCom touts the applicator with the one-piece on-body unit technologies enabled by the innovations copied from Abbott. For example, the press release announcing that G7 received FDA approval compared the G6 to the G7 by asserting that G7 is "60% smaller, all-in-one, discreet wearable, easier to use with fewer components."[64] In fact, this is one of the features that, according to DexCom, "helped Dexcom G7 earn recognition as a CES 2023 innovation awards honoree in the wearable technology, digital health category."[65] Similarly, on its website, Dexcom describes the G7 as its "smallest" and "easiest to use" system; "so comfortable, you'll forget you're wearing it."[66]

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[64] *Dexcom G7 Receives FDA Clearance: The Most Accurate Continuous Glucose Monitoring System Cleared in the U.S.*, DEXCOM CONTINUOUS GLUCOSE MONITORING, https://investors.dexcom.com/news/news-details/2022/Dexcom-G7-Receives-FDA-Clearance-The-Most-Accurate-Continuous-Glucose-Monitoring-System-Cleared-in-the-U.S/default.aspx.

[65] (*Id.*)

[66] *Dexcom G7 has received FDA clearance*, DEXCOM CONTINUOUS GLUCOSE MONITORING, https://www.dexcom.com/en-us/g7-fda.

72. In the G7 User Guide, DexCom again touts the benefits associated with the G7 applicator with an all-in-one wearable:[67]

New since G6

New features include:

- All new components and app
- New alert sounds and sound options
- Glucose summary reports on your display device

All new components and app

Sensor and patch

- Streamlined all-in-one sensor with built in disposable transmitter
- Shorter warmup — less than 30 minutes
- Extra 12-hour grace period at the end of the sensor session gives you flexibility to change your sensor at your convenience
- Smaller sensor and shorter sensor wire for your comfort
- Patch is smaller — half the size of G6
- Overpatch comes with each sensor and keeps the sensor on longer if needed

Applicator

- Smaller size — less plastic waste
- Fast and easy to insert sensor

73. Notably, DexCom's incorporation of Abbott's technology has been very-well received by the diabetes community. For example, during DexCom's Q2 2022 earnings call, its CEO noted that the G7 launch in the U.K. continued to "be met with significant enthusiasm" from customers who have provided "consistently positive feedback" on features such as "product size" and "ease of use." [68] Similarly, in an interview with Fierce Medtech during the American Diabetes Association's annual scientific sessions, DexCom's CEO explained that the limited launch of G7 in Europe "so far has validated all of Dexcom's assumptions that customers would appreciate the

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[67] *G7 User Guide*, *supra* note 27, at 15 (highlighting added).

[68] *Q2 2022 Earnings Call*, THE MOTLEY FOOL, https://www.fool.com/earnings/call-transcripts/2022/07/28/dexcom-dxcm-q2-2022-earnings-call-transcript/.

new sensor's smaller size, revamped app and improved ease of use."[69] Thomas Grace, MD, a primary care physician in Findlay, Ohio stated, "Dexcom G7 is so simple and easy to use that it should be prescribed to every person with Type 1 and Type 2 diabetes."[70]

74. Not surprisingly, the diabetes community has noticed DexCom's convergence on Abbott's systems. For example, a writer for AppleInsider recently noted:

> The biggest of the changes is the new [G7] design, which is 60 percent smaller than its predecessor. It's an all-in-one design that combines the previously-separate transmitter and sensor. This requires a new insertion tool that looks more akin to the Freestyle Libre with a button on the side. The whole unit is disposable, no longer requiring the transmitter to be reused. … We like the new insertion tool that is even easier to use than the G6 model.[71]

75. Similarly, a writer for Not Just a Patch opined:

> It is a complete overhaul for Dexcom with the G7. Moving in the direction of major competitor Abbott's FreeStyle Libre with a disposable system that is an all in one transmitter and sensor. Once done, just peel it off and dispose of it. Also now looking to compete with the Libre for size. Previously Libre had the measure of Dexcom with a more subtle and sleek design. The G7 is supposedly 60% smaller than the G6. … The Dexcom G7 catches up with the Abbott Freestyle Libre offering.[72]

76. DexCom is deliberately using Abbott's patented technologies in its products and is infringing Abbott's valuable patent rights in an attempt to compete with Abbott.

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[69] *ADA: Dexcom CEO Kevin Sayer on putting M&A on the back burner: 'We've been the organic growth story of the decade'*, FIERCE BIOTECH, https://www.fiercebiotech.com/medtech/ada-dexcom-ceo-kevin-sayer-putting-ma-back-burner-weve-been-organic-growth-story-decade.

[70] *Dexcom G7 Receives FDA Clearance: The Most Accurate Continuous Glucose Monitoring System Cleared in the U.S.*, DEXCOM CONTINUOUS GLUCOSE MONITORING, https://investors.dexcom.com/news/news-details/2022/Dexcom-G7-Receives-FDA-Clearance-The-Most-Accurate-Continuous-Glucose-Monitoring-System-Cleared-in-the-U.S/default.aspx.

[71] *First look: New Dexcom G7 glucose monitor*, APPLEINSIDER, https://forums.appleinsider.com/discussion/229958/first-look-new-dexcom-g7-glucose-monitor.

[72] *Dexcom G7 Release: These Are The Most Exciting New Features*, NOT JUST A PATCH, https://notjustapatch.com/dexcom-g7-release/.

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

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

78. 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.

79. 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 now into the G7, as described above.

80. 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.

81. Nevertheless, DexCom failed to take action to avoid infringement of the Asserted Patents now that the covenant has expired. Instead, DexCom has continued unabatedly to infringe Abbott's patents asserted in the G6 Action, as well as the Asserted Patents, even though DexCom had actual knowledge of the infringement, 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.

FIRST CAUSE OF ACTION

(Infringement of the '954 Patent)

82. Abbott repeats and re-alleges the allegations of paragraphs 1 through 81 above.

83. As shown in **Exhibit E**, DexCom's G7 meets each and every limitation of at least claim 1 of the '954 patent, either literally and/or under the doctrine of equivalents.

84. DexCom has directly infringed and continues to directly infringe at least claim 1 of the '954 patent under 35 U.S.C. § 271(a) by making, using, selling, and/or offering to sell the G7.

85. DexCom has infringed and continues to infringe at least claim 1 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 claim 1 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 supplies or causes to be supplied the G7 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 at least claim 1 of the '954 patent if such combination occurred within the United States.

86. For example, DexCom supplies or causes to be supplied the G7 and components thereof (*e.g.*, sensor units, receivers, apps, etc.) and provides materials, including for example, instructions for use and user guides, that instruct customers to combine the G7 and the components thereof with other components (*e.g.*, sensor units, receivers, smart devices, etc.) that, together, comprise the claimed inventions of at least claim 1 of the '954 patent.

87. DexCom has infringed and continues to infringe at least claim 1 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 claim 1 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 at least claim 1 of the ’954 patent if such combination occurred within the United States.

88. For example, DexCom supplies or causes to be supplied the G7 and components thereof (*e.g.*, sensor units, receivers, apps, etc.) and specifically intends for customers to combine them with other components (*e.g.*, sensor units, receivers, smart devices, etc.) that, together, DexCom knows comprise the claimed inventions of at least claim 1 of the ’954 patent.

89. To the extent DexCom alleges that it does not directly infringe claim 1 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(f)(1) and/or 271(f)(2) for sales outside of the United States.

90. DexCom has been and is engaging in willful and deliberate infringement of the ’954 patent. As detailed above, before Abbott filed 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. Indeed, DexCom is fully aware of its infringement of the ’954 patent from the G6 Action.

91. Despite that knowledge, DexCom continues to make, use, offer for sale and/or sell the G7 with 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.

92. 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.

93. 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.

SECOND CAUSE OF ACTION

(Infringement of the '591 Patent)

94. Abbott repeats and re-alleges the allegations of paragraphs 1 through 93 above.

95. As shown in **Exhibit F**, DexCom's G7 meets each and every limitation of at least claim 1 of the '591 patent, either literally and/or under the doctrine of equivalents.

96. DexCom has directly infringed and continues to directly infringe at least claim 1 of the '591 patent under 35 U.S.C. § 271(a) by making, using, selling, and/or offering to sell the G7.

97. DexCom has infringed and continues to infringe at least claim 1 of the '591 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 claim 1 of the '591 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 G7 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 at least claim 1 of the ’591 patent if such combination occurred within the United States.

98. For example, DexCom supplies or causes to be supplied the G7 and components thereof (*e.g.*, sensor units, receivers, apps, etc.) and provides materials, including for example, instructions for use and user guides, that instruct customers to combine the G7 and the components thereof with other components (*e.g.*, sensor units, receivers, smart devices, etc.) that, together, comprise the claimed inventions of at least claim 1 of the ’591 patent.

99. DexCom has infringed and continues to infringe at least claim 1 of the ’591 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 claim 1 of the ’591 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 at least claim 1 of the ’591 patent if such combination occurred within the United States.

100. For example, DexCom supplies or causes to be supplied the G7 and components thereof (*e.g.*, sensor units, receivers, apps, etc.) and specifically intends for customers to combine them with other components (*e.g.*, sensor units, receivers, smart devices, etc.) that, together, DexCom knows comprise the claimed inventions of at least claim 1 of the ’591 patent.

101. To the extent DexCom alleges that it does not directly infringe claim 1 of the ’591 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(f)(1) and/or 271(f)(2) for sales outside of the United States.

102. Unless enjoined by this Court, DexCom will continue to infringe the ’591 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.

103. Abbott has suffered and will continue to suffer damage as a direct and proximate result of DexCom’s infringement of the ’591 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 ’335 Patent)

104. Abbott repeats and re-alleges the allegations of paragraphs 1 through 103 above.

105. As shown in **Exhibit G**, DexCom’s G7 meets each and every limitation of at least claim 1 of the ’335 patent, either literally and/or under the doctrine of equivalents.

106. DexCom has directly infringed and continues to directly infringe at least claim 1 of the ’591 patent under 35 U.S.C. § 271(a) by making, using, selling, and/or offering to sell the G7.

107. DexCom has infringed and continues to infringe at least claim 1 of the ’335 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 claim 1 of the ’335 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 G7 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 at least claim 1 of the ’335 patent if such combination occurred within the United States.

108. For example, DexCom supplies or causes to be supplied the G7 and components thereof (*e.g.*, sensor units, receivers, apps, etc.) and provides materials, including for example, instructions for use and user guides, that instruct customers to combine the G7 and the components thereof with other components (*e.g.*, sensor units, receivers, smart devices, etc.) that, together, comprise the claimed inventions of at least claim 1 of the ’335 patent.

109. DexCom has infringed and continues to infringe at least claim 1 of the ’335 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 claim 1 of the ’335 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 at least claim 1 of the ’335 patent if such combination occurred within the United States.

110. For example, DexCom supplies or causes to be supplied the G7 and components thereof (*e.g.*, sensor units, receivers, apps, etc.) and specifically intends for customers to combine them with other components (*e.g.*, sensor units, receivers, smart devices, etc.) that, together, DexCom knows comprise the claimed inventions of at least claim 1 of the ’335 patent.

111. To the extent DexCom alleges that it does not directly infringe claim 1 of the ’335 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(f)(1) and/or 271(f)(2) for sales outside of the United States.

112. Unless enjoined by this Court, DexCom will continue to infringe the ’335 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.

113. Abbott has suffered and will continue to suffer damage as a direct and proximate result of DexCom’s infringement of the ’335 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 ’056 Patent)

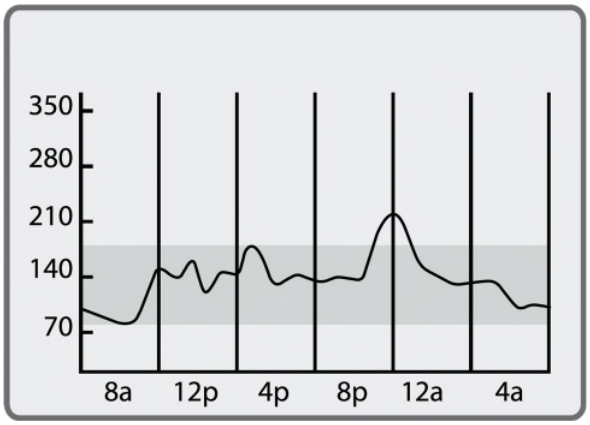
114. Abbott repeats and re-alleges the allegations of paragraphs 1 through 113 above.

115. The inventions claimed in the ’056 patent save lives by providing diabetes patients who use CGM systems with more complete and accurate information about their glucose levels, even after an adverse condition 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.

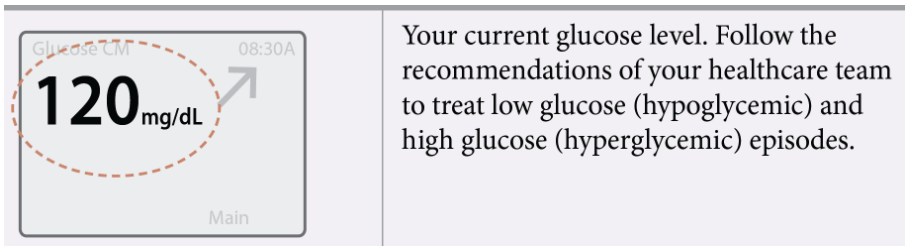
116. Before Abbott introduced factory calibration, commercial CGM systems typically required periodic calibration, such as every 12 to 24 hours. Using the fingerstick method, patients periodically determined their glucose levels and entered this information into the system. With this information, the 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.

117. 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



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

118. 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.

119. The named inventor of the ’056 patent, Wesley Scott Harper, recognized that in CGM systems there are instances when a patient’s glucose levels cannot be reported or accurately reported by the system, which could lead a patient to act on inaccurate or incomplete information. For example, the specification of the ’056 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.”[73] For the time period associated with the failed calibration event, there

[73] Ex. D, ’056 patent at 11:6-8.

can be "a gap in the output display during which the necessary calibration did not occur."[74] This is illustrated below in FIG. 7A of the '056 patent.

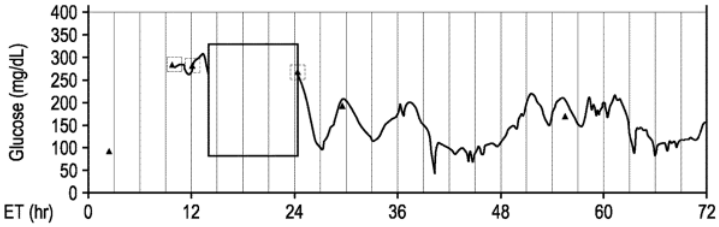


FIG. 7A

120. 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, 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.

121. 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."[75] When this occurs, "Glucose Data Gaps" appeared in the patient's glucose levels on the display device.[76]

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

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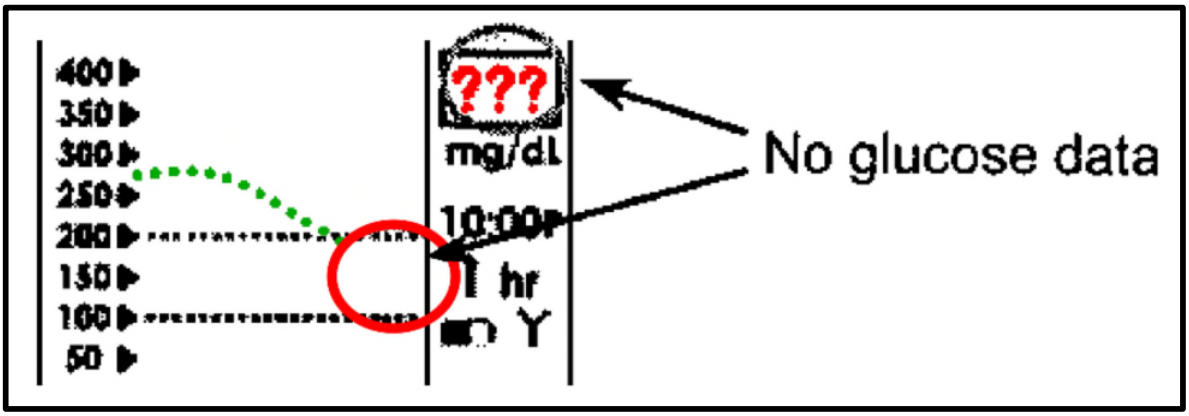
[74] *Id.* at 12:32-34.

[75] **Exhibit I**, STS-7 Continuous Glucose Monitoring System User's Guide (hereinafter, "STS-7 User's Guide") at 33.

[76] *Id.*



123. As depicted,[77] 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.

124. 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.[78] The STS-7 User's Guide explained that "[s]ometimes sensors fail to provide readings after calibration" and therefore the readings were simply "skipped."[79]

125. 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).[80]

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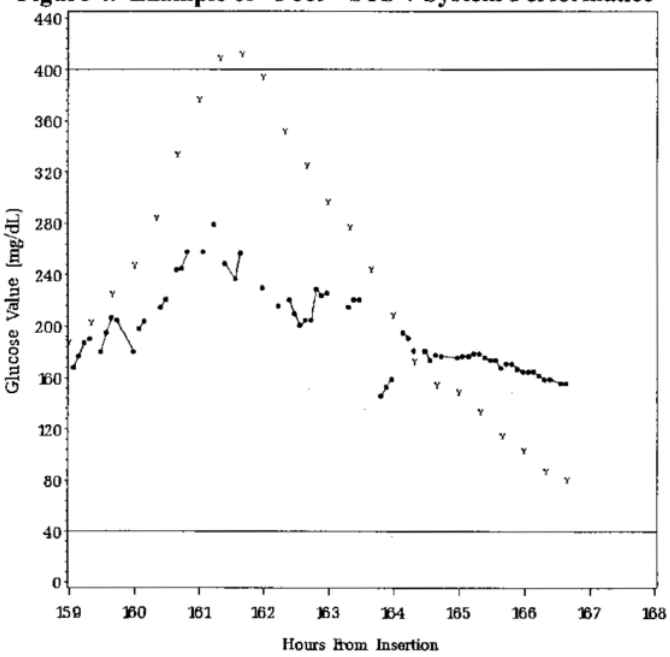
[77] Ex. I, STS-7 User's Guide at 34 (color added).

[78] *Id.* at 58.

[79] *Id.*

[80] *Id.* at 60.

Figure 4. Example of "Poor" STS-7 System Performance



YYY YSI Value ••• STS-7 Glucose Value

126. The inventor of the ’056 patent solved the data-gap problem unique to CGM systems by devising technological solutions that improved the functionality of the CGM systems themselves, increasing their accuracy and safety. For example, the ’056 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 ’056 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."[81] Thereafter, "the gap in [the] output display . . . may be filled."[82] Figure 7B of the '056 patent, reproduced below, shows the data gap backfilled with processed sensor data after the adverse condition was corrected.

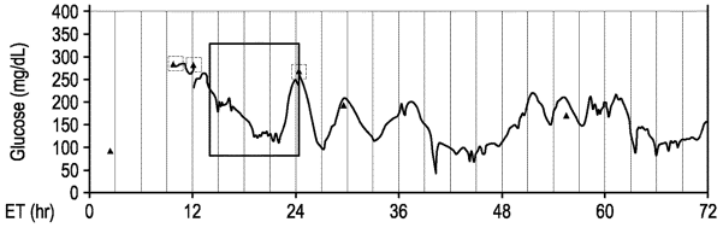


FIG. 7B

127. The inventor of the '056 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 '056 patent explains that an adverse 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."[83]

128. Such adverse conditions were issues that plagued CGM systems. For example, DexCom's STS-7 User's 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."[84]

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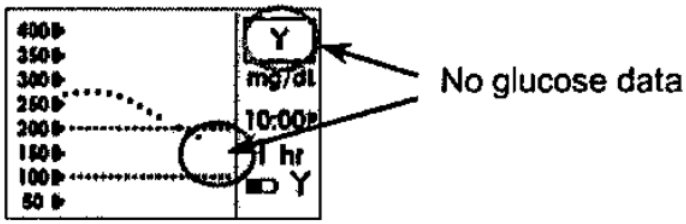
[81] Ex. D, '056 patent at 12:47-54.

[82] *Id.* at 12:59-61.

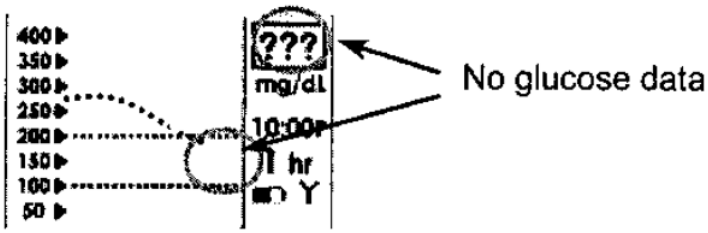
[83] *Id.* at 13:19-27.

[84] Ex. I, STS-7 User's Guide at 33.

129. In the STS-7 User's 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."[85] This will result in a sensor data gap output to the display device:



130. 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:[86]



131. The '056 patent solved these technological problems affecting CGM systems with inventions capable of recovering what would otherwise be lost data when there is an adverse condition in the system. The innovative technological solution is reflected in the claims of the '056 patent.

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[85] *Id.*

[86] *Id.*

132. For example, claim 1 of the ’056 patent is directed to a “glucose monitoring system for backfilling data gaps that occur while a user monitors glucose levels.”[87] The claimed glucose monitoring system comprises “a glucose sensor” and “a data processing and transmitter unit coupled to the glucose sensor.”[88] A portion of the glucose sensor is “configured to be positioned under skin of the user” and “sample a biological fluid of the user to provide sensor data.”[89] The data processing and transmitter unit comprises “a processor,” “memory,” and “a radio frequency transceiver.”[90] The claimed glucose monitoring system further comprises “a receiver unit,” which includes “a processor,” “memory,” “a radio frequency transceiver,” “an antenna,” and “a display.”[91]

133. In operation, the data processing and transmitter unit is configured to “receive the sensor data from the glucose sensor and store the sensor data in the memory of the data processing and transmitter unit.”[92] It is further configured to “process the sensor data using calibration data to provide processed sensor data, wherein the calibration data comprises data associated with a sensitivity of the glucose sensor, and wherein the processed sensor data is stored in the memory of the data processing and transmitter unit.”[93] The processed sensor data is transmitted “over a Bluetooth wireless communication link.”[94] The receiver unit, in turn, is configured to receive “the

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[87] Ex. D, ’056 patent at 15:25-62.

[88] *Id.* at 15:27-32.

[89] *Id.* at 15:27-30.

[90] *Id.* at 15:31-36.

[91] *Id.* at 15:52-54.

[92] *Id.* at 15:39-41.

[93] *Id.* at 15:42-47.

[94] *Id.* at 15:48-51.

processed sensor data over the Bluetooth wireless communication link," output to the display of the receiver unit "a numerical value representing the processed sensor data" and "a first line graph that is a substantially continuous depiction of the processed sensor data over time."[95]

134. As the user monitors their glucose levels, the claimed monitoring system is "configured to detect an adverse condition" that "results in the receiver unit displaying a data gap."[96] During this time period, "sensor data, processed sensor data, or both, are stored in the memory of the data processing and transmitter unit."[97] After the adverse condition is corrected, the receiver unit outputs the "processed sensor data for the time period corresponding to the adverse condition such that the data gap is backfilled"[98]

135. Thus, instead of merely "skipping" glucose readings during an adverse 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 adverse 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.

136. Claims 3-11 and 13-17 of the '056 patent, each of which depends from independent claim 1, claim systems capable of backfilling sensor data gaps resulting from a variety of adverse conditions, such as "sensor communication error," "signal error associated with the glucose

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[95] *Id.* at 15:56-64.

[96] *Id.* at 15:65 to 16:3.

[97] *Id.* at 16:4-7.

[98] *Id.* at 16:8-12.

sensor," "data processing and transmitter unit," or "receiver unit," "system malfunction," or "a calibration failure condition," to name a few.[99]

137. 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.[100] 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 an adverse 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."[101] As the specification explains, this "advantageously" provides "additional robustness . . . to the user and/or healthcare provider to improve therapy or health management decisions."[102]

138. Another advantage realized by the invention claimed in the '056 patent is that patients are protected from making uninformed or misinformed decisions about their glucose levels and trends. For example, claim 19 of the '056 patent recites that the system "wait[s] a predetermined period of time after the correction of the adverse condition before displaying the [backfilled data]."[103] As the specification explains, this is to "avoid possible unnecessary or incorrect action by a user in response to the backfilled processed sensor data."[104]

139. Unable to solve the data-gap problem, DexCom appropriated the inventions of the claims of the '056 patent into the G7. Further, DexCom now touts its infringing backfill feature as

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[99] *Id.* at 16:26 to 17:3.

[100] *Id.* at 12:54-61.

[101] *Id.* at 13:27-30.

[102] *Id.* at 13:39-42.

[103] *Id.* at 15:63-67, 16:54-59.

[104] *Id.* at 13:10-13.

a "Quality of Service" for G7. 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 24 hours) will be transmitted from the transmitter to the display device."[105]

140. As shown in **Exhibit H**, DexCom's G7 meets each and every limitation of at least claim 1 of the '056 patent, either literally and/or under the doctrine of equivalents.

141. DexCom has directly infringed and continues to directly infringe at least claim 1 of the '056 patent under 35 U.S.C. § 271(a) by making, using, selling, and/or offering to sell the G7.

142. DexCom has infringed and continues to infringe at least claim 1 of the '056 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 claim 1 of the '056 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 G7 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 at least claim 1 of the '056 patent if such combination occurred within the United States.

143. For example, DexCom supplies or causes to be supplied the G7 and components thereof (*e.g.*, sensor units, receivers, apps, etc.) and provides materials, including for example, instructions for use and user guides, that instruct customers to combine the G7 and the components thereof with other components (*e.g.*, sensor units, receivers, smart devices, etc.) that, together, comprise the claimed inventions of at least claim 1 of the '056 patent.

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[105] *G7 User Guide*, *supra* note 27, at 128.

144. DexCom has infringed and continues to infringe at least claim 1 of the ’056 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 claim 1 of the ’056 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 at least claim 1 of the ’056 patent if such combination occurred within the United States.

145. For example, DexCom supplies or causes to be supplied the G7 and components thereof (*e.g.*, sensor units, receivers, apps, etc.) and specifically intends for customers to combine them with other components (*e.g.*, sensor units, receivers, smart devices, etc.) that, together, DexCom knows comprise the claimed inventions of at least claim 1 of the ’056 patent.

146. To the extent DexCom alleges that it does not directly infringe claim 1 of the ’056 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(f)(1) and/or 271(f)(2) for sales outside of the United States.

147. Unless enjoined by this Court, DexCom will continue to infringe the ’056 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.

148. Abbott has suffered and will continue to suffer damage as a direct and proximate result of DexCom's infringement of the '056 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 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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