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Attorneys for Plaintiff
ARBMETRICS, LLC

1 **IN THE UNITED STATES DISTRICT COURT**
2 **FOR THE SOUTHERN DISTRICT OF CALIFORNIA**

3 ARBMETRICS, LLC, an Ohio
4 limited liability company,

5 Plaintiff,

6 v.

7 DEXCOM INC., a Delaware
8 corporation,

9 Defendant.

Case No. 3:18-cv-00134-JLS-KSC

**PLAINTIFF'S SECOND AMENDED
COMPLAINT FOR PATENT
INFRINGEMENT**

Jury Trial Demanded

10 Plaintiff Arbmatics, LLC files this Second Amended Complaint against
11 Dexcom, Inc. ("Dexcom" or "Defendant") for infringement of U.S. Patent No.
12 6,343,225.

13 **THE PARTIES**

14 1. Arbmatics, LLC ("Arbmatics" or "Plaintiff") is an Ohio limited liability
15 company with a registered agent at 33 West First Street, Suite 600, Dayton, Ohio
16 45402. Arbmatics is the owner by assignment of U.S. Patent No. 6,343,225 ("the
17 '225 patent").

18 2. On information and belief, Dexcom, Inc. is a Delaware corporation
19 with its principal place of business at 6340 Sequence Drive, San Diego, California
20 92121. Dexcom does business in the State of California and in the Southern
21 District of California.

22 **JURISDICTION AND VENUE**

23 3. Arbmatics brings this action for patent infringement under the patent
24 laws of the United States, namely 35 U.S.C. §§ 271, 281, and 284-285, among
25 others. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and
26 1338.

27 4. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b)-(d) and
28

1 1400(b). On information and belief, Dexcom resides in this District, has committed acts of
2 infringement in this District, has purposely transacted business involving the accused
3 products in this District, and has a regular and established place of business in this District.

4 5. Dexcom is subject to this Court's specific and general personal
5 jurisdiction pursuant to due process and/or the California Long Arm Statute, due at
6 least to its substantial business in this State and judicial district, including: (A) at
7 least part of its infringing activities alleged herein; and (B) regularly doing or
8 soliciting business, engaging in other persistent conduct, and/or deriving
9 substantial revenue from goods sold and services provided to California residents.

10 **FACTUAL BACKGROUND**

11 6. On January 29, 2002, the United States Patent and Trademark Office
12 duly and legally issued the '225 patent, entitled, "Implantable Glucose Sensor." A
13 copy of the '225 patent is attached hereto as Exhibit 1. The '225 patent is assigned to
14 Arbmetrics.

15 7. The sole inventor of the '225 patent is Leland C. Clark, Jr.

16 8. Leland C. Clark, Jr. was an American biochemist whose career spanned
17 more than six decades. He is widely recognized as the "father of biosensors" for his
18 invention of the oxygen electrode in the 1950's, commonly referred to as the "Clark
19 electrode." *See* William R. Heineman, and William B. Jensen, *Leland C. Clark Jr.*
20 *(1918–2005)*, 21 *BIOSENSORS AND BIOELECTRONICS* 1403, 1403–1404 (2006). *See*
21 *also* Renneberg R., et al., *Frieder Scheller and the Short History of Biosensors*, in
22 *BIOSENSING FOR THE 21ST CENTURY* 1, 1-2 (Fred Lisdat ed., 2008). Clark is a named
23 inventor on more than thirty issued United States Patents.

24 9. According to an article by the National Academy of Engineering, the
25 awards and honors bestowed upon Clark during his lifetime include the NIH Research
26 Career Award (1962); Distinguished Lecturer Award, American College of Chest
27 Physicians (1975); Honorary Doctor of Science, University of Rochester School of
28 Medicine and Dentistry (1984); Horace Mann Award for Service to Humanity,

1 Antioch College (1984); Heyrovsky Award in Recognition of the Invention of the
2 Membrane-Covered Polarographic Oxygen Electrode (1985); American Association
3 for Clinical Chemistry Award for Outstanding Contributions to Clinical Chemistry
4 (1989); American Heart Association Samuel Kaplan Visionary Award (1991);
5 enshrinement into the Engineering and Science Hall of Fame (1991); Pharmacia
6 Biosensor's Sensational Contributions to the Advancement of Biosensor Technology
7 Award (1992); and the Daniel Drake Award for Outstanding Achievements in
8 Research, University of Cincinnati College of Medicine (1993). Clark was elected to
9 membership in the National Academy of Engineering (NAE) in 1995 and was
10 awarded the NAE Fritz J. and Dolores H. Russ Prize in 2005. His citation reads "For
11 bioengineering membrane-based sensors in medical, food, and environmental
12 applications." See Hardy W. Trolander, *Leland C. Clark Jr.*, in MEMORIAL TRIBUTES
13 VOLUME 11, 58, 61 (National Academy of Engineering, 2007).

14 10. The subject matter of the '225 patent relates to work completed later in
15 Clark's career, related to reducing the oxygen sensitivity of enzyme-based
16 polarographic electrodes for implantable biosensors.

17 11. Defendant Dexcom describes itself in its 10-Q SEC filings as "a medical
18 device company focused on the design, development and commercialization of
19 continuous glucose monitoring ('CGM') systems for ambulatory use by people with
20 diabetes and by healthcare providers for the treatment of people with diabetes." See
21 Dexcom 10-Q (filed Nov. 1, 2017), available at
22 [http://investor.shareholder.com/dexcom/secfiling.cfm?filingID=1093557-17-](http://investor.shareholder.com/dexcom/secfiling.cfm?filingID=1093557-17-221&CIK=1093557)
23 [221&CIK=1093557](http://investor.shareholder.com/dexcom/secfiling.cfm?filingID=1093557-17-221&CIK=1093557).

24 12. Dexcom has commercialized several implantable sensor products for the
25 measurement of glucose levels in diabetes patients. Such products include the
26 Dexcom Seven® Plus CGM Sensor, Dexcom G4® CGM Sensors, and the Dexcom
27 G5® Mobile CGM Sensor.

COUNT I

(Patent Infringement - U.S. Patent No. 6,343,225)

13. Arbmtrics incorporates paragraphs 1 through 12 herein by reference.

14. This cause of action arises under the patent laws of the United States, and in particular, 35 U.S.C. §§ 271, *et seq.*

15. Arbmtrics is the owner of the '225 patent, entitled "Implantable Glucose Sensor," with ownership of all substantial rights in the '225 patent, including the right to exclude others and to enforce, sue, and recover damages for past and future infringement.

16. The '225 patent is valid, enforceable and was duly issued in full compliance with Title 35 of the United States Code.

DIRECT INFRINGEMENT (35 U.S.C. § 271(a))

17. Defendant has directly infringed, and continues to directly infringe, one or more claims of the '225 patent in this judicial district and elsewhere in California and the United States.

18. Defendant has, and continues to, infringe the '225 patent, including at least claims 1, 2, 5, 7, and 8, by making, using, selling, and/or offering to sell, within the United States, and/or by importing into the United States, products, including but not limited to implantable glucose sensors for Continuous Glucose Monitoring ("CGM") (the "Accused Products") in violation of 35 U.S.C. § 271. The Accused Products include, but are not limited to, the Dexcom Seven® Plus CGM Sensor, Dexcom G4® PLATINUM CGM Sensor, and the Dexcom G5® Mobile CGM Sensor.

19. Claim 1 of the '225 patent claims:

An implantable sensor for sensing a concentration of an organic substrate, the sensor comprising:

a conductive electrode; and

a stabilized enzyme emulsion in contact with the electrode, the enzyme

1 emulsion comprising:

2 an oxidase enzyme that quantitatively oxidizes the organic substrate;

3 a water immiscible oxygen dissolving substance emulsified into intimate

4 contact with the enzyme to provide oxygen; and

5 a protein crosslinking agent to crosslink and insolubilize the enzyme

6 forming a stabilized gel comprising crosslinked protein and

7 particles of said oxygen dissolving substance.

8 *See* Exhibit 1, '225 patent, claim 1.

9 20. To the extent the preamble of claim 1 is found to be a limitation, the
10 Accused Products meet the preamble of claim 1.

11 21. The Accused Products are implantable sensors for sensing a
12 concentration of an organic substrate.

13 22. For example, Dexcom's literature describing the Accused Products refers
14 to them as "Small Sensor that measures glucose levels just underneath the skin.
15 Exhibit 2, Dexcom G4 Patient Brochure, pp. 5-7, 9; *see also* Exhibit 3, Dexcom G4
16 User Guide pp. 8, 13-15, 55-62; Exhibit 4, Dexcom G5 User Guide, pp. 13-14, 21, 25,
17 27-29, 54-62; Exhibit 5, Dexcom Seven Plus User Guide, pp. 5, 7, 16, 20, 46-51;
18 Exhibit 6, Dexcom Seven Plus Patient Brochure, pp. 5, 8-9.

19 23. As a further example, Dexcom's literature describing the Accused
20 Products states: The system includes the sensor, the transmitter, and the receiver. The
21 sensor is a disposable unit that you insert under the skin of your abdomen (belly) to
22 continuously monitor your glucose levels for up to 7 days." Exhibit 3, Dexcom G4
23 User Guide, pp. 13-15; *see also Id.* at pp. 8, 55-62; Exhibit 4, Dexcom G5 User Guide,
24 pp. 13-14, 21, 25, 27-29, 54-62; Exhibit 5, Dexcom Seven Plus User Guide, pp. 5, 7,
25 16, 20, 46-51; Exhibit 6, Dexcom Seven Plus Patient Brochure, pp. 5, 8-9.

26 24. The Accused Products include a conductive electrode and a stabilized
27 enzyme emulsion in contact with the electrode.

28 25. For example, Dexcom's literature describing the Accused Products

1 states: “The sensor wire is thin and flexible, and inserts just under the skin of your
2 belly. It is attached to the sensor pod, and is made of silver and platinum metal with
3 polymer membranes. Exhibit 3, Dexcom G4 User Guide, p. 15; *see also* Dexcom G4
4 Patient Brochure, p. 7; Exhibit 4; Dexcom G5 User Guide, pp. 28-29; Exhibit 6,
5 Dexcom Seven Plus Patient Brochure, p. 9.

6 26. In addition, as described in detail *infra* in paragraphs 27 to 37, the
7 Accused Products include a stabilized enzyme emulsion in contact with the electrode.

8 27. The enzyme emulsion of the Accused Products comprises an oxidase
9 enzyme that quantitatively oxidizes the organic substrate.

10 28. For example, a study funded by Dexcom indicates that the enzyme
11 emulsion of the Accused Products includes “glucose oxidase sensor technology” (*e.g.*,
12 an oxidase enzyme) that quantitatively oxidizes the organic substrate (*e.g.*, glucose).
13 Exhibit 7, Christiansen, Mark, et al. “*A New-Generation Continuous Glucose*
14 *Monitoring System: Improved Accuracy and Reliability Compared with a Previous-*
15 *Generation System*,” DIABETES TECHNOLOGY & THERAPEUTICS, VOL. 15, No. 10
16 (2013), at pp. 882, 886, 887.

17 29. In addition, U.S. Patent No. 8,255,030 is titled “Oxygen Enhancing
18 Membrane Systems for Implantable Devices” (“the ’030 patent”). Exhibit 8, U.S.
19 Patent No. 8,255,030.

20 30. Dexcom is the assignee of the ’030 patent.

21 31. On information and belief, the Accused Products are covered by the ’030
22 patent. *See* Exhibit 9, Dexcom Patents, *available at*
23 <https://www.dexcom.com/patents>; Exhibit 6, Seven Plus Patient Brochure, p. 11.

24 32. As another example that the enzyme emulsion of the Accused Products
25 includes an oxidase enzyme that quantitatively oxidizes the organic substrate, the ’030
26 patent states:

27 Enzyme Domain

28 An immobilized enzyme domain **46** is situated less distal from the

1 electrochemically reactive surfaces than the resistance domain **44**. In one
2 embodiment, the immobilized enzyme domain **46** comprises glucose
3 oxidase. In other embodiments, the immobilized enzyme domain **46** can
4 be impregnated with other oxidases, for example, galactose oxidase,
5 cholesterol oxidase, amino acid oxidase, alcohol oxidase, lactate oxidase,
6 or uricase. For example, for an enzyme-based electrochemical glucose
7 sensor to perform well, the sensor's response should neither be limited by
8 enzyme activity nor cofactor concentration.

9 Exhibit 8, '030 patent, 16:18-29.

10 33. On information and belief, the enzyme emulsion of the Accused Products
11 further comprises a water immiscible oxygen dissolving substance emulsified into
12 intimate contact with the enzyme to provide oxygen.

13 34. For example, Dexcom's '030 patent states:

14 The enzyme domain **44** (*sic*) is preferably formed from high oxygen
15 soluble materials such as polymers formed from silicone, fluorocarbons,
16 perfluorocarbons, or the like. In one embodiment, the enzyme domain is
17 formed from a silicone composition with a hydrophile such as such as
18 polyethylene glycol, propylene glycol, pyrrolidone, esters, amides,
19 carbonates, or polypropylene glycol covalently incorporated or grafted
20 therein.

21 ...

22 A variety of configurations are contemplated with the membrane
23 systems of the preferred embodiments, however the exemplary
24 configurations are not meant to be limiting and may be modified within
25 the scope of the preferred embodiments. In one embodiment, the enzyme
26 domain is formed from a material with a high oxygen solubility, which is
27 believed to optimize oxygen availability to the enzyme immobilized
28 therein. In another embodiment, all domains between the fluid supply

(for example, interstitial fluid) and the enzyme (up to and including the enzyme domain) are formed from a material with a high oxygen solubility, which is believed to dynamically retain a substantially continuous path of high oxygen availability to the enzyme and/or electroactive surfaces during local ischemic periods. In yet another embodiment, all domains of a membrane system are formed from high oxygen soluble materials; in this way, the membrane system transports and/or maintains high oxygen availability substantially continuously across the membrane system, from the interstitial fluid to the implantable device surface, providing increased oxygen availability to the implantable device, for example electroactive surfaces thereon or transplanted cells located therein. While not wishing to be bound by theory, it is believed that maintaining high oxygen availability at the interface of the implantable device improves device performance even during transient ischemia and other low oxygen situations.

Exhibit 8, '030 patent, 16:30-37; 18:47-19:5.

35. On information and belief, the enzyme emulsion of the Accused Products further comprises a protein crosslinking agent to crosslink and insolubilize the enzyme forming a stabilized gel comprising crosslinked protein and particles of said oxygen dissolving substance.

36. For example, at least one publication has described the Accused Products as including a "GOx layer consisting of polyurethane latex and glutaraldehyde as a cross linker." Exhibit 10, Ocvirk, Gregor, et al. "*Electrochemical Glucose Biosensors for Diabetes Care*," TRENDS IN BIOELECTROANALYSIS, pp. 58-59, Springer International Publishing (2017).

37. As another example, Dexcom's '030 patent describes the "enzyme domain 46" as "immobilized." Exhibit 8, '030, 16:18-22.

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38. Claim 2 of the '225 patent claims:

The implantable sensor of claim 1 further comprising a semipermeable membrane covering the electrode with the enzyme emulsion sandwiched between the membrane and the electrode.

See Exhibit 1, '225 patent, claim 2.

39. On information and belief, the implantable sensor of the Accused Products further comprises a semipermeable membrane covering the electrode with the enzyme emulsion sandwiched between the membrane and the electrode. *See e.g.*, Exhibit 8, '030 patent, 15:7-16-21, Fig. 4.

40. Claim 5 of the '225 patent claims:

The implantable sensor of claim 1, wherein the oxygen dissolving substance is selected from the group consisting of perfluorocarbons, silicone oils, fluorosilicone oils, aromatic and aliphatic hydrocarbon oils or solids, carotenoids and steroids.

See Exhibit 1, '225 patent, claim 5.

41. On information and belief, the oxygen dissolving substance of the Accused Products is selected from the group consisting of perfluorocarbons, silicone oils, fluorosilicone oils, aromatic and aliphatic hydrocarbon oils or solids, carotenoids and steroids. *See supra* ¶ 34 (quoting Exhibit 8, '030 patent, 16:30-37; 18:47-19:5).

42. Claim 7 of the '225 patent claims:

The implantable sensor of claim 1, wherein the crosslinking agent is selected from the group consisting of aldehydes, carbodiimides, imidoesters, pyrocarbonates, epoxides and N-hydroxysuccinimid esters.

See Exhibit 1, '225 patent, claim 7.

43. On information and belief, the crosslinking agent of the Accused Products is selected from the group consisting of aldehydes, carbodiimides, imidoesters, pyrocarbonates, epoxides and N-hydroxysuccinimid esters. *See supra* ¶

1 36.

2 44. Claim 8 of the '225 patent claims:

3 The implantable sensor of claim 1, wherein the oxidase enzyme is
4 selected from the group consisting of cholesterol oxidase, amino acid
5 oxidase, alcohol oxidase, lactic acid oxidase, oxygen oxidoreductase,
6 galactose oxidase, and glucose oxidase.

7 See Exhibit 1, '225 patent, claim 8.

8 45. The oxidase enzyme of the Accused Products is glucose oxidase. See
9 *supra* ¶¶ 28, 32.

10 46. Defendant is liable for these direct infringements pursuant to 35 U.S.C. §
11 271.

12 **INDIRECT INFRINGEMENT (INDUCEMENT - 35 U.S.C. § 271(b))**

13 47. Based on the information presently available to Plaintiff, and in the
14 alternative to direct infringement, Plaintiff contends that Defendant has, and continues
15 to, indirectly infringe one or more claims of the '225 patent by inducing direct
16 infringement by users of the Accused Products.

17 48. Defendant has had knowledge of the '225 patent since at least service of
18 this action. On information and belief, Defendant has had knowledge of the '225
19 patent for many years prior to the filing of this action.

20 49. Prior to the original filing of this action on January 19, 2018, Defendant
21 was aware of the '225 patent.

22 50. Dexcom's awareness of the '225 patent is evidenced by its patent
23 prosecution activities. On information and belief, Dexcom employs a substantial in-
24 house intellectual property staff, including a Vice President of Intellectual Property
25 and several intellectual property attorneys, patent agents, paraprofessionals, and
26 support staff.

27 51. On information and belief, Dexcom had knowledge of the '225 patent
28 since at least 2004.

1 52. Dexcom began disclosing the '225 patent to the United States Patent and
2 Trademark Office ("USPTO") on Information Disclosure Statements at least as early
3 as November 30, 2004. For example, an Information Disclosure Statement submitted
4 by Dexcom on November 30, 2004 in conjunction with its prosecution of U.S. Pat.
5 App. No. 10/632,537 identifies the '225 patent.

6 53. The '225 patent was cited by a USPTO patent examiner during
7 prosecution of Dexcom's U.S. Pat. App. No. 12/037,812 in an Office Action dated
8 July 24, 2009.

9 54. The '225 patent was cited by a USPTO patent examiner during
10 prosecution of Dexcom's U.S. Pat. App. No. 12/037,812 in an Office Action dated
11 July 24, 2009.

12 55. The '225 patent is cited on the face of at least 240 of Dexcom's issued
13 United States patents.

14 56. The '225 patent has been cited, referenced, or otherwise disclosed during
15 the prosecution of over 350 of Dexcom's United States patent applications.

16 57. On information and belief, despite having knowledge of the '225 patent,
17 Defendant has specifically intended for persons who acquire and use the Accused
18 Products, including Defendant's distributors, customers, and end consumers, to use,
19 sell, and/or offer to sell, within the United States, and/or import into the United States,
20 such devices in a manner that infringes the '225 patent, including at least claims 1, 2,
21 5, 7, and 8, and Defendant knew or should have known that its actions were inducing
22 infringement.

23 58. For example, Defendant instructs and encourages users to use the
24 Accused Products (*i.e.*, directly infringe the '225 patent). *See*
25 <http://www.dexcom.com/guides> (providing user guides that instruct and encourage
26 consumers to use Dexcom G4® and G5® CGM Sensors);
27 <https://www.manualslib.com/manual/1117336/Dexcom-Seven-Plus.html#manual>
28 (user guide for the Dexcom Seven® Plus CGM Sensor);

1 https://www.youtube.com/watch?v=9_8t_HSG-uE&t=2s (video uploaded to YouTube
 2 by Dexcom showing how to insert CGM sensors); *see generally* Exhibit 2, Dexcom
 3 G4 Patient Brochure; Exhibit 3, Dexcom G4 User Guide; Exhibit 4, Dexcom G5 User
 4 Guide; Exhibit 5, Dexcom Seven Plus User Guide; Exhibit 6, Dexcom Seven Plus
 5 Patient Brochure.

6 59. Arbmetrics has been damaged because of Defendant's infringing conduct
 7 described in this Count. Defendant is, thus, liable to Arbmetrics in an amount that
 8 adequately compensates Arbmetrics for Defendant's infringements, which, by law,
 9 cannot be less than a reasonable royalty, together with interest and costs as fixed by
 10 this Court under 35 U.S.C. § 284.

11 **PRAYER FOR RELIEF**

12 **WHEREFORE**, Arbmetrics asks that the Court find in its favor and against
 13 Defendant, and that the Court grant Arbmetrics the following relief:

- 14 a. Judgment that one or more claims of the '225 patent have been infringed,
 15 either literally and/or under the doctrine of equivalents, by Defendant;
- 16 b. Judgment that Defendant account for and pay to Arbmetrics all damages
 17 and costs incurred by Arbmetrics because of Defendant's infringing
 18 activities and other conduct complained of herein;
- 19 c. Judgment that Defendant account for and pay to Arbmetrics a reasonable,
 20 on-going, post judgment royalty because of Defendant's infringing
 21 activities and other conduct complained of herein;
- 22 d. That Arbmetrics be granted prejudgment and post judgment interest on
 23 the damages caused by Defendant's infringing activities and other
 24 conduct complained of herein;
- 25 e. That Arbmetrics be granted such other and further relief as the Court may
 26 deem just and proper under the circumstances.

1 Dated: August 7, 2019

FERNALD LAW GROUP

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