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DEXCOM, INC.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

DEXCOM, INC., Plaintiff, v. AGAMATRIX, INC., Defendant.	Case No. 16-cv-05947-SJO-AS **FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT** **DEMAND FOR JURY TRIAL**

Plaintiff DexCom, Inc. ("DexCom") files this First Amended Complaint and demand for jury trial seeking relief for patent infringement by Defendant AgaMatrix, Inc. ("AgaMatrix") pursuant to Fed. R. Civ. P. 15. AgaMatrix has not yet answered DexCom's original Complaint, which was filed on August 9, 2016 and served on AgaMatrix on August 11, 2016, and AgaMatrix's time to respond thereto has been extended to September 30, 2016. DexCom hereby alleges as follows:

THE PARTIES

1. DexCom is a corporation organized under the laws of the state of Delaware, having its principal place of business at 6340 Sequence Drive, San Diego, CA 92121. DexCom is a medical device company primarily focused on the design, development and commercialization of glucose monitoring systems for use by and for the treatment of patients suffering from diabetes. DexCom has advanced the accuracy of glucose monitoring through its patented inventions.

2. DexCom is a top diabetes care innovator. DexCom has spent more than $400 million in research and development since 2006, including over $130 million in 2015 alone. DexCom also has more than 700 pending and issued patents world-wide. Indeed, to date, the United States Patent Office has issued over 300 patents to DexCom.

3. A particular area of DexCom's innovation is advanced electrochemistry technology used to improve the accuracy of glucose monitoring. DexCom has been performing advanced electrochemistry research since as early as 2001 and presently employs a group of experts in the field of advanced electrochemistry to develop improved techniques that can be used in its glucose monitoring products. Some of DexCom's earlier innovations in advanced electrochemistry for use in glucose monitoring resulted in United States Patent No. 7,081,195 (the "'195 patent"),.

4. Upon information and belief, defendant AgaMatrix is a corporation organized under the laws of the state of Delaware, having its principal place of business at 7C Raymond Ave, Salem, NH 03079.

JURISDICTION AND VENUE

5. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 271 et seq.

6. This Court has subject matter jurisdiction over this action pursuant to 28. U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over AgaMatrix because, upon information and belief, AgaMatrix has knowingly and purposefully directed its wrongful acts to this forum, distributed, advertised and/or sold products embodying DexCom's patented inventions without authority in this forum, including but not limited to the AgaMatrix manufactured CVS Health™ Advanced Blood Glucose Meter available at CVS pharmacy at 210 W. Seventh Street, Los Angeles, CA 90014, actively solicited business in this forum, and utilized websites that permit residents of this forum to purchase products embodying DexCom's patented inventions over the internet and have these products shipped into this forum.

8. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

FACTS

9. The '195 patent, entitled "Systems and Methods for Improving Electrochemical Analyte Sensors," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on July 25, 2006 to DexCom. DexCom reduced to practice the invention claimed in the '195 patent by at least April 2003 and on December 8, 2003 filed a provisional patent application on its invention, which ultimately led to the '195 patent. The '195 was further subject to re-examination by the PTO at the request of a third-party. On April 24, 2012 an *Ex Parte* Reexamination Certificate for the '195 Patent was issued by the PTO. DexCom is the assignee and owner of the '195 patent. A true and correct copy of the '195 patent as re-examined is attached hereto as Exhibit A.

10. Upon information and belief, AgaMatrix was founded in 2001.

AgaMatrix represents it "receive[d] FDA approval for [its] first meter" with what AgaMatrix calls "Dynamic Electrochemistry®" in 2006. (Ex. B (9/30/2016 capture of http://agamatrix.com/about-us/).) AgaMatrix states that its Dynamic Electrochemistry Technology is "a sophisticated technology platform for sensing blood glucose, by improving the ability to detect the glucose signal and correct for common sources of interference." (Ex. C (9/30/2016 capture of http://agamatrix.com/technology/innovation/).)

11. Upon information and belief, "all of [AgaMatrix's] blood glucose meters feature its WaveSense™ technology, a proprietary suite of measurement techniques using [the] dynamic electrochemistry® [technology] to correct factors that can impact the accuracy of blood glucose measurements." (Ex. D (9/30/2016 capture of http://agamatrix.com/products/blood-glucose-monitors/).)

12. Upon information and belief, "[AgaMatrix's] WaveSense™ Technology uses Dynamic Electrochemistry® coupled with specific signal processing algorithms to correct for a number of errors that are common in self-monitoring blood glucose (SMBG) systems, resulting in more accurate measurements." (Ex. E. (AgaMatrix® White Paper: Performance of the AgaMatrix Presto® Advanced Blood Glucose Monitoring System, November/December 2007).) More specifically, upon information and belief, AgaMatrix's WaveSense™ technology uses "[a] time-varying input signal [that] induces an output signal . . . , which can then be exploited by sophisticated digital signal processing algorithms to give an accurate glucose reading." (*Id.*)

13. Upon information and belief, AgaMatrix actively solicits and does business throughout this Judicial District, including making, using, offering for use, selling, offering for sale, and/or importing its blood glucose meters.

14. Upon information and belief, AgaMatrix manufactures AgaMatrix-branded, private label, and co-developed blood glucose meters that use the WaveSense™ technology, including but not limited to the CVS Health™ Advanced

Blood Glucose Meter.

15. Upon information and belief, the AgaMatrix manufactured CVS Health™ Advanced Blood Glucose Meter is marked with U.S. Patent No. 7,517,439, among other patents. The "Summary of Invention" in U.S. Patent No. 7,517,439 describes "the present invention" as a determination of an analyte such as glucose in a blood sample through a series of steps (a) through (e) using an electrochemical test strip. Those steps include subjecting the test strip to two different potential settings and determining a drop in voltage from one setting to another to determine and generate an error message. "[T]he invention" also provides for a meter programmed to execute these steps. (Ex. F (U.S. Patent No. 7,517,439, col. 6, ll. 1-23, 53-63).)

16. U.S. Patent No. 7,517,439 has two independent claims, claims 1 and 7. Claim 1 reflects the steps (a) through (e) in the description of "the present invention" in the "Summary of the Invention" section of U.S. Patent No. 7,517,439. The scope of claim 7 is also supported by the description of "the present invention" in the "Summary of Invention" section of U.S. Patent No. 7,517,439.

17. Upon information and belief, according to the CVS Health™ Advanced Blood Glucose Meter packaging, the product practices the steps of claims 1 and 7 of U.S. Patent No. 7,517,439.

18. DexCom's '195 patented invention predates AgaMatrix's U.S. Patent No. 7,517,439.

19. Upon information and belief, the AgaMatrix manufactured blood glucose meters that use the WaveSense™ technology, including but not limited to the CVS Health™ Advanced Blood Glucose Meter, utilize the technology claimed and taught in the '195 patent.

COUNT 1 – INFRINGEMENT OF THE '195 PATENT

20. DexCom re-alleges and incorporates by reference the allegations in paragraphs 1 to 19 above.

21. AgaMatrix has directly infringed and is continuing to directly infringe

one or more claims of the '195 patent, either literally or under the doctrine of equivalents, by making, using, selling, offering for sale, and/or importing in the United States and in this Judicial District, products that use the WaveSense™ technology ("the Accused Products"), including but not limited to the AgaMatrix manufactured CVS Health™ Advanced Blood Glucose Meter (hereinafter "the CVS Meter") without authority, thereby violating 35 U.S.C. § 271.

22. The CVS Meter satisfies each and every element of one or more claims of the '195 patent, for example, and without limitation, claim 53 of the '195 patent.

23. Claim 53 of the '195 patent recites:

> A method for identifying a signal interference in an analyte-measuring device, the method comprising:
>
> providing at least one electrochemical sensor;
>
> measuring a first signal output obtained at a first bias potential setting;
>
> measuring a second signal output obtained at a second bias potential setting;
>
> comparing the first signal output with the second signal output to determine a differential measurement, thereby identifying an interference in the signal outputs; and
>
> deriving an analyte concentration from the first signal output and the second signal output to determine an analyte concentration,
>
> wherein the first bias potential setting is at a different bias voltage than the second bias potential setting.

24. To the extent the preamble is considered a limitation, upon information and belief, the CVS Meter satisfies the preamble of claim 53 of the '195 patent: "A method for identifying a signal interference in an analyte-measuring device." Upon information and belief, the CVS Meter "accurately detects the glucose signal by removing common sources of interference," including but not limited to hematocrit interference. (*See* Ex. C (9/30/2016 capture of

http://agamatrix.com/technology/innovation/).)

25. Upon information and belief, the CVS Meter satisfies the following limitation of claim 53 of the '195 patent: "providing at least one electrochemical sensor." Upon information and belief, the CVS Meter is designed to work with "an electrochemical test strip having working and counter electrodes." (Ex. F (U.S. Patent No. 7,517,439, claim 1(a) and claim 7, marked by AgaMatrix).)

26. Upon information and belief, the CVS Meter satisfies the following limitation of claim 53 of the '195 patent: "measuring a first signal output obtained at a first bias potential setting." Upon information and belief, the CVS Meter measures at least a voltage signal output at a first potential setting. (*See, e.g.*, Ex. F (U.S. Patent No. 7,517,439, claim 1(b) and claim 7, Fig 3 and col. 2, ll. 34-37, marked by AgaMatrix).)

27. Upon information and belief, the CVS Meter satisfies the following limitation of claim 53 of the '195 patent: "measuring a second signal output obtained at a second bias potential setting." Upon information and belief, the CVS Meter measures at least a second voltage signal output at a second potential setting. (*See, e.g.*, Ex. F (U.S. Patent No. 7,517,439, claim 1(c) and claim 7, Fig 3 and col. 2, ll. 34-37, marked by AgaMatrix).)

28. Upon information and belief, the CVS Meter satisfies the following limitation of claim 53 of the '195 patent: "comparing the first signal output with the second signal output to determine a differential measurement, thereby identifying an interference in the signal outputs." Upon information and belief, the CVS Meter performs the step of "determining the magnitude, V_{drop}, of a voltage drop occurring immediately after [switching off the applied potential]," Ex. F (U.S. Patent No. 7,517,439, claim 1(c) and claim 7, marked by AgaMatrix), which is based on a comparison of the first and second voltage signals, and "detect[s] and correct[s] for interferences," including but not limited to hematocrit interference, Ex. G (9/30/2016 capture of http://agamatrix.com/technology/accuracy).

29. The CVS Meter satisfies the following limitation of claim 53 of the '195 patent: "deriving an analyte concentration from the first signal output and the second signal output to determine an analyte concentration." Upon information and belief, the CVS Meter performs the steps of "checking the determined magnitude of V_{drop} against a predetermined range" and using the V_{drop} information derived from comparing the first and second voltage signals to determine whether the determined analyte concentration has errors and "proceeding to display or communicate the result from the determination of analyte," Ex. F (U.S. Patent No. 7,517,439, claim 1(d) and (e) and claim 7, marked by AgaMatrix), thereby "accurately detect[ing] the glucose signal by removing common sources of interference," Ex. C (9/30/2016 capture of http://agamatrix.com/technology/innovation/).

30. Upon information and belief, the CVS Meter satisfies the following limitation of claim 53 of the '195 patent: "wherein the first bias potential setting is at a different bias voltage than the second bias potential setting." Upon information and belief, the CVS Meter performs the steps of "applying a potential difference, V_{app}, between the electrodes of the test strip" and "switching off the applied potential . . . and determining the magnitude, V_{drop}, of a voltage drop occurring immediately [thereafter]." (Ex. F (U.S. Patent No. 7,517,439, claim 1(b) and 1(c) and claim 7, marked by AgaMatrix).)

31. Upon information and belief, AgaMatrix also induces infringement of the '195 patent as of the date of its earliest awareness of the '195 patent, which is no later than the date of service of DexCom's original Complaint. AgaMatrix's Accused Products as sold are specifically configured to infringe the '195 patent as described above. AgaMatrix actively instructs its customers on how to use its products, including through its product manuals, website, and advertising. For example, the CVS Meter's Quick Start Guide instructs its customers to 1) "[i]nsert the test strip into the meter," 2) "[l]ance test site," 3) "[e]xpress blood drop," 4) "[b]ring test strip to blood sample," 5) "[r]emove test strip from blood sample when you hear the

beep," and 6) "[f]inal steps: Your test result is displayed on the meter . . . ." (Ex. H (CVS Health$_{TM}$ Advanced Glucose Meter Quick Start Guide).) When used as instructed, AgaMatrix's customers use its products to practice the methods of the '195 patent. AgaMatrix's customers thereby directly infringe, either literally or under the doctrine of equivalents, the '195 patent. As of the date of its earliest awareness of the '195 patent, AgaMatrix knew of the '195 patent and knew that its customers' actions taken during the ordinary and intended use of the Accused Products would constitute infringement of the '195 patent. Alternatively, AgaMatrix understood that there is a high probability that its customers would infringe the '195 patent but remained willfully blind to the infringing nature of its customers' actions taken during the ordinary and intended use of the Accused Products.

32. On information and belief, AgaMatrix also contributes to infringement by its customers by offering to sell and/or selling within the U.S. products that contain components that constitute a material part of the invention claimed in the '195 patent. AgaMatrix's Accused Products are especially made or especially adapted for use in infringement of the '195 patent and are not a staple article or commodity of commerce suitable for substantial non-infringing use. For example, AgaMatrix's website states that "WaveSense extracts extensive data from the test strip and blood sample to detect and correct for interferences – providing accurate, reliable blood glucose readings." (Ex. G (9/30/2016 capture of http://agamatrix.com/technology/accuracy/).) AgaMatrix's customers thereby directly infringe, either literally or under the doctrine of equivalents, the '195 patent. No later than the date of service of DexCom's original Complaint, AgaMatrix knew of the '195 patent and knew or should have known that its products infringe the '195 patent during their ordinary and intended use.

33. On information and belief, AgaMatrix's infringement of the '195 patent, as of the date of its earliest awareness of the '195 patent, which is no later than the date of service of DexCom's original Complaint, is willful and intentional under 35

U.S.C. § 284, rendering this case exceptional under 35 U.S.C. § 285, and entitling DexCom to enhanced damages and attorneys' fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285. In committing these acts of infringement, AgaMatrix knew or should have known that its actions constituted an unreasonable risk of infringement of at least one valid and enforceable claim of the '195 patent.

34. Additional allegations regarding AgaMatrix's knowledge of the '195 patent and willful infringement likely will have evidentiary support after a reasonable opportunity for discovery.

35. By its actions, AgaMatrix has committed and continues to commit acts of infringement under 35 U.S.C. § 271.

PRAYER FOR RELIEF

WHEREFORE, DexCom prays that the Court enter judgment in its favor and against AgaMatrix as follows:

A. A judgment that AgaMatrix has infringed at least one claim of the '195 patent;

B. A judgment that the '195 patent is valid and enforceable;

C. An award to DexCom of damages adequate to compensate it for AgaMatrix's past infringement and any continuing or future infringement, including at minimum reasonable royalties, together with interest, costs, expenses and disbursements as justified under 35 U.S.C. § 284;

D. An award to DexCom an ongoing royalty for AgaMatrix's post-verdict infringement, payable on each product offered by AgaMatrix that is found to infringe one or more claims of the '195 patent, and on all future products that are not colorably different from those found to infringe;

E. An award to AgaMatrix all other damages permitted by 35 U.S.C. § 284, including enhanced damages up to three times the amount of compensatory damages found;

F. Permanently enjoining AgaMatrix, its officers, agents, servants,

employees, attorneys, all parent and subsidiary corporations and affiliates, its assigns and successors in interest, and those persons in active concert or participation with AgaMatrix who receive notice of the injunction, from continuing acts of infringement of the '195 patent.

G. Finding that this is an exceptional case and awarding to DexCom its reasonable attorneys fees and costs pursuant to 35 U.S.C. § 285;

H. Such other and further relief in law or equity as the Court deems just and appropriate.

Dated: September 30, 2016

SIDLEY AUSTIN LLP

By: /s/ Sona De
Sona De
Ching-Lee Fukuda
Bradford. J. Badke
Thomas A. Broughan
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Grace Chiang

Attorneys for Plaintiff
DEXCOM, INC.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury for each and every issue so permitted by law and statute.

Respectfully submitted,

Dated: September 30, 2016

SIDLEY AUSTIN LLP

By: /s/ Sona De
Sona De
Ching-Lee Fukuda
Bradford. J. Badke
Thomas A. Broughan
Erik J. Carlson
Grace Chiang

Attorneys for Plaintiff
DEXCOM, INC.

PROOF OF SERVICE

I hereby certify that on September 30, 2016, I had the First Amended Complaint for Patent Infringement with Exhibits A-H annexed thereto electronically filed using the CM/ECF system, which will automatically generate notification of such filing to all attorneys of record, and additionally had the aforementioned documents served by electronic mail upon Defendant's counsel, which method of service was agreed to by Defendant's counsel.

/s/ Sona De
Sona De