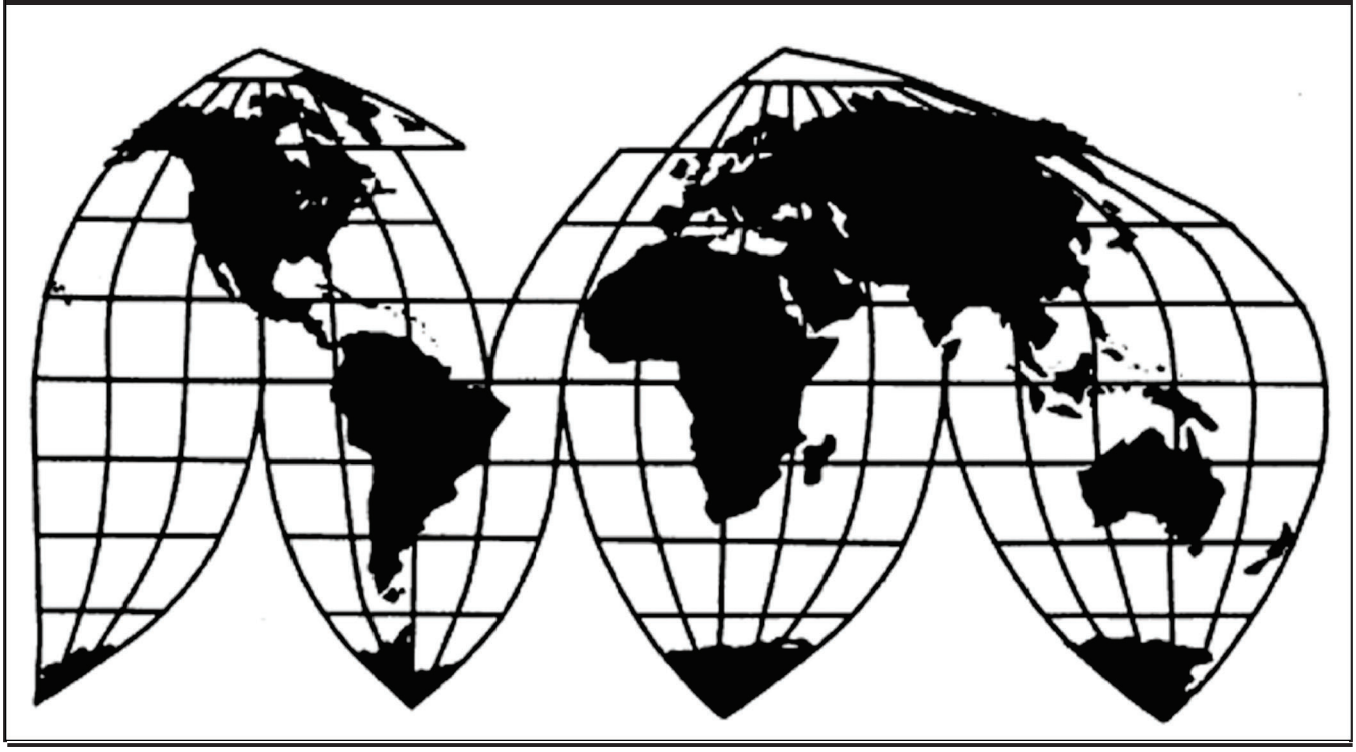
In the Matter of

CERTAIN ELECTROCHEMICAL GLUCOSE MONITORING SYSTEMS AND COMPONENTS THEREOF

Investigation No. 337-TA-1075

Publication 4983 **September 2019**

U.S. International Trade Commission



Washington, DC 20436

U.S. International Trade Commission

COMMISSIONERS

David Johanson, Chairman
Irving Williamson, Commissioner
Meredith Broadbent, Commissioner
Rhonda Schmidtlein, Commissioner
Jason Kearns, Commissioner

Address all communications to
Secretary to the Commission
United States International Trade Commission
Washington, DC 20436

U.S. International Trade Commission

Washington, DC 20436
www.usitc.gov

In the Matter of

CERTAIN ELECTROCHEMICAL GLUCOSE MONITORING SYSTEMS AND COMPONENTS THEREOF

Investigation No. 337-TA-1075

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September 2019

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC

In the Matter of **CERTAIN ELECTROCHEMICAL GLUCOSE MONITORING SYSTEMS AND COMPONENTS THEREOF**	**Investigation No. 337-TA-1075**

NOTICE OF COMMISSION DETERMINATION TO AFFIRM AN INITIAL DETERMINATION GRANTING A MOTION FOR SUMMARY DETERMINATION OF NON-INFRINGEMENT OF THE ASSERTED PATENTS; TERMINATION OF INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to affirm an initial determination (Order No. 33) granting a motion for summary determination of non-infringement of the asserted patents and the presiding administrative law judge's ("ALJ") underlying orders. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Megan M. Valentine, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW, Washington, DC 20436, telephone 202-708-2301. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW, Washington, DC 20436, telephone 202-205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (https://www.usitc.gov). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at https://edis.usitc.gov. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on October 25, 2017, based on a complaint filed on September 18, 2017, on behalf of Dexcom, Inc. of San Diego, California ("Dexcom"). 82 Fed. Reg. 49420 (Oct. 25, 2017). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain electrochemical glucose monitoring systems and components thereof by reason of infringement of one or more of claims of U.S. Patent Nos. 9,724,045 and 9,750,460. The notice of investigation named as a respondent AgaMatrix, Inc. of Salem, New Hampshire ("AgaMatrix"). The Office of Unfair Import Investigations was not

named as a party in the investigation.

On May 10, 2018, the ALJ issued Order No. 26, granting-in-part a motion by AgaMatrix to strike portions of Dexcom's expert reports. Order No. 26 struck, in relevant part, certain portions of an expert report relating to whether the accused products meet the "film" term of the "enzyme-containing film" limitation of the asserted claims and precluded Dexcom from relying on the arguments and theories described in the struck portions of the expert report during the investigation.

On May 17, 2018, AgaMatrix filed a motion for summary determination of non-infringement of the asserted patents on the basis that Dexcom cannot prove that the accused products directly or indirectly infringe any of the asserted claims. On May 29, 2018, Dexcom opposed the motion. On June 1, 2018, AgaMatrix moved for leave to file a reply in support of its motion. On June 6, 2018, Dexcom opposed the motion for leave.

On June 7, 2018, the ALJ issued the subject initial determination ("ID") (Order No. 33), granting AgaMatrix's motion for summary determination of non-infringement with respect to direct infringement but denying the motion with respect to indirect infringement. The ID also denied AgaMatrix's motion for leave to file a reply in support of its motion and stayed the procedural schedule pending review of the ID.

On June 18, 2018, Dexcom filed a petition for review of the ID's findings on direct infringement and Order No. 26. On June 25, 2018, AgaMatrix filed its opposition.

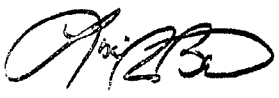
On July 23, 2018, the Commission determined to review the subject ID in its entirety, as well as the underlying orders. Notice (July 23, 2018).

Having reviewed the record in this investigation, including the subject ID, the petition for review, and response thereto, the Commission has determined to affirm Order No. 33's summary determination of non-infringement and the ALJ's underlying orders. Commissioner Schmidtlein dissents from the majority's decision. Her views have been filed on EDIS.

The investigation is terminated.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 C.F.R. Part 210).

By order of the Commission.



Lisa R. Barton
Secretary to the Commission

Issued: April 4, 2019

CERTAIN ELECTROCHEMICAL GLUCOSE MONITORING SYSTEMS AND COMPONENTS THEREOF **Inv. No. 337-TA-1075**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served to the following parties as indicated, on April 4, 2019.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants Dexcom, Inc.:

Kirk R. Ruthenberg, Esq.
DENTON US LLP
1900 K Street, NW
Washington, DC 20006

☐ Via Hand Delivery
☒ Via Express Delivery
☐ Via First Class Mail
☐ Other:_____

On Behalf of Respondents AgaMatrix, Inc.:

Ira Jay Levy
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue, 25th Floor
New York, NY 10018

☐ Via Hand Delivery
☒ Via Express Delivery
☐ Via First Class Mail
☐ Other:_____

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC

In the Matter of	
CERTAIN ELECTROCHEMICAL GLUCOSE MONITORING SYSTEMS AND COMPONENTS THEREOF	Investigation No. 337-TA-1075

NOTICE OF COMMISSION DETERMINATION TO REVIEW AN INITIAL DETERMINATION GRANTING A MOTION FOR SUMMARY DETERMINATION OF NON-INFRINGEMENT OF THE ASSERTED PATENTS AND THE UNDERLYING ORDERS

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review an initial determination (Order No. 33), granting a motion for summary determination of non-infringement of the asserted patents, and the underlying orders.

FOR FURTHER INFORMATION CONTACT: Lucy Grace D. Noyola, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW, Washington, DC 20436, telephone 202-205-3438. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW, Washington, DC 20436, telephone 202-205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (https://www.usitc.gov). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at https://edis.usitc.gov. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on October 25, 2017, based on a complaint filed on September 18, 2017, on behalf of Dexcom, Inc. of San Diego, California ("Dexcom"). 82 FR 49420 (Oct. 25, 2017). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain electrochemical glucose monitoring systems and components thereof by reason of infringement of one or more of claims of U.S. Patent Nos. 9,724,045 and 9,750,460. The notice of investigation named as a respondent AgaMatrix, Inc. of Salem, New Hampshire ("AgaMatrix"). The Office of Unfair Import Investigations was not named as a party in the investigation.

On May 10, 2018, the presiding administrative law judge ("ALJ") issued Order No. 26, granting a motion by AgaMatrix to strike portions of Dexcom's expert reports. Order No. 26 struck, among other things, certain portions of an expert report relating to whether the accused products meet the "film" portion of the "enzyme-containing film" limitation of the asserted claims and precluded Dexcom from relying on the arguments and theories described in the struck portions of the expert report during the investigation.

On May 17, 2018, AgaMatrix filed a motion for summary determination of non-infringement of the asserted patents on the basis that Dexcom cannot prove that the accused products directly or indirectly infringe any of the asserted claims. On May 29, 2018, Dexcom opposed the motion. On June 1, 2018, AgaMatrix moved for leave to file a reply in support of its motion. On June 6, 2018, Dexcom opposed the motion for leave.

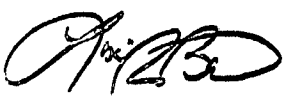
On June 7, 2018, the ALJ issued the subject initial determination ("ID") (Order No. 33), granting AgaMatrix's motion for summary determination of non-infringement with respect to direct infringement but denying the motion with respect to indirect infringement. The ID also denied AgaMatrix's motion for leave to file a reply in support of its motion and stayed the procedural schedule pending review of the ID.

On June 18, 2018, Dexcom filed a petition for review of the ID's findings on direct infringement and Order No. 26. On June 25, 2018, AgaMatrix filed its opposition.

The Commission has determined to review the subject ID in its entirety, as well as the underlying orders.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 C.F.R. part 210).

By order of the Commission.



Lisa R. Barton
Secretary to the Commission

Issued: July 23, 2018

CERTAIN ELECTROCHEMICAL GLUCOSE MONITORING SYSTEMS AND COMPONENTS THEREOF **Inv. No. 337-TA-1075**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served to the following parties as indicated, on July 23, 2018.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants Dexcom, Inc.:

Kirk R. Ruthenberg, Esq.
DENTON US LLP
1900 K Street, NW
Washington, DC 20006

☐ Via Hand Delivery
☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

On Behalf of Respondents AgaMatrix, Inc.:

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☐ Via Hand Delivery
☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of	
CERTAIN ELECTROCHEMICAL GLUCOSE MONITORING SYSTEMS AND COMPONENTS THEREOF	Inv. No. 337-TA-1075

ORDER NO. 33: INITIAL DETERMINATION GRANTING-IN-PART RESPONDENT'S MOTION FOR SUMMARY DETERMINATION OF NON-INFRINGEMENT OF U.S. PATENT NOS. 9,724,045 AND 9,750,460 AND STAYING THE PROCEDURAL SCHEDULE

(June 7, 2018)

On May 17, 2018, Respondent AgaMatrix, Inc. ("AgaMatrix") moved (1075-021) for "summary determination of non-infringement because Complainant Dexcom, Inc. ("Dexcom") has not proven, and will not be able to prove at the evidentiary hearing, that the accused AgaMatrix products directly or indirectly infringe any of the asserted claims of U.S. Patent No. 9,724,045 ("the '045 Patent") and 9,750,460 ("the '460 patent')." (Mot. at 1.) On May 29, 2018, Dexcom opposed the motion. On June 1, 2018, AgaMatrix moved for leave (1075-023) to file a reply in support of their motion. On June 6, 2018, Dexcom opposed the motion for leave. The motion for leave (1075-0023) is hereby denied.

AgaMatrix argues that summary determination is appropriate on two grounds. First, AgaMatrix asserts that Dexcom cannot prove that the "enzyme-containing film" limitation is met, in light of the fact that evidence related to this limitation was struck in Order No. 26. (*Id.*) Second, AgaMatrix argues that Dexcom failed to disclose evidence of indirect infringement in its

infringement contentions[1]. (*Id.*) As such, AgaMatrix argues that "Dexcom has effectively waived all arguments on indirect infringement and summary judgment is appropriate." (*Id.*)

Summary determination is appropriate when there is no genuine issue as to any material fact and the moving party is entitled to a determination as a matter of law. *See* 19 C.F.R. § 210.18(b). In determining whether there is a genuine issue of material fact, "the evidence must be viewed in the light most favorable to the party opposing the motion with doubts resolved in favor of the non-movant." *Crown Operations Int'l, Ltd. v. Solutia, Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002) (citation omitted).

I. "Enzyme-Containing Film" Limitation

AgaMatrix explains that "[e]very asserted claim of the patents at issue . . . requires the presence of an 'enzyme-containing film.'" (Mem. at 1.) AgaMatrix notes that the undersigned previously found that "Dexcom's infringement contentions 'did not make any disclosure regarding how the Accused Products meet the 'film' limitation." (*Id.* (quoting Order No. 26 at 4.) As a result, AgaMatrix explains that "Dexcom will be unable to establish a necessary element of all of the asserted claims, and consequently unable to establish infringement." (*Id.*)

Dexcom argues that "AgaMatrix's motion is based on improperly stretching Order No. 26 beyond its holding and an erroneous contention that Dexcom's entire infringement case for the 'enzyme-containing film' is contained within the stricken paragraphs of the expert report of Dexcom's expert, Dr. Richard Mihran." (Opp. at 3.) Dexcom explains: "Separate from the paragraphs stricken from Dr. Mihran's expert report, Dexcom has provided extensive evidence and argument that the Accused Products contain an 'enzyme containing film' as claimed in the

[1] For purposes of this Order, "responses to contention interrogatories" and "infringement contentions" are used interchangeably.

Asserted Patents." (*Id.*) Specifically, Dexcom asserts that this information is contained in Dexcom's infringement contentions and in unstruck paragraphs of Dr. Mihran's report. (*Id.*)

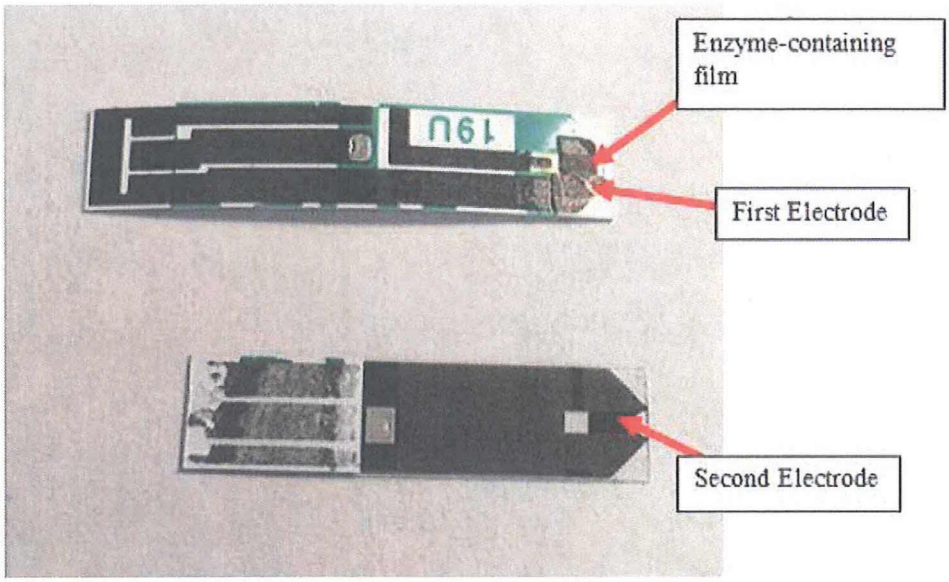
A. Background

On April 23, 2018, AgaMatrix moved to strike portions of the Initial Expert Report of Richard T. Mihran on the grounds that his opinions violated Ground Rule 4.4.3. (Respondent's Motion to Strike Portions of Complainant Dexcom, Inc.'s Expert Report ("Motion to Strike"), 1075-016, at 1.) Specifically, AgaMatrix sought to strike opinions related to "the argument that the application of a reagent solution in liquid form to the working electrode would dry to form a 'film.'" (Motion to Strike at 2.)

In the Motion to Strike, AgaMatrix explained that Dexcom did not include any information about how the "film" limitation was met in its infringement contentions. AgaMatrix explained that, with respect to "film," Dexcom's contentions included only the following statement:

> The [Accused Product] utilizes an electrochemical glucose sensor ([Accused Product] Test Strips) that is configured to be in contact with a biological fluid (i.e. blood) to obtain a glucose measurement. The [Accused Product] Test Strips are configured to be used in connection with sensor electronics to quantify a glucose concentration and utilize a first electrode including an electrode surface, a second electrode, and an enzyme-containing film.

(Motion to Strike at 10 (citing Attachment D, Exhibit 1A at 83-85, Exhibit 2A at 86-88, Exhibit 3A at 87-89).) AgaMatrix further explained that "[t]his language was followed by an image of the relevant Accused Product test strip with an arrow indicating where Dexcom alleged the required enzyme-containing 'film' was to be found":



(*Id.* (citing Attachment D, Exhibit 2A at 88).) According to AgaMatrix, "[t]his response was conclusory, and was the *only* response Dexcom provided in its contentions regarding how Dexcom contended the Accused Products met the asserted claims which require an 'enzyme-containing film.'" (*Id.* (emphasis in original).) AgaMatrix continued: "No explanation or analysis of how an enzyme containing film was applied or formed was provided in any of Dexcom's infringement contentions." (*Id.* at 10-11.) AgaMatrix argued that Dexcom instead focused on how the "enzyme-containing" part of the claim element was met, rather than on how the "film" limitation was met. (*Id.* at 11.) AgaMatrix noted: "In fact, it appears that Dexcom never even considered the possibility that the 'enzyme-containing' material in the accused products might be in a structure other than a 'film.'" (*Id.*)

In its opposition to the Motion to Strike, Dexcom disagreed that it failed to disclose how the "film" limitation was met. (Complainant's Opposition to Respondent's Motion to Strike Portions of Complainant's Expert Reports ("Opposition to Motion to Strike") at 24.) Dexcom argued that it "identified the component that was accused of meeting the 'enzyme-containing

film' limitation in its infringement contentions and had disclosed its theory of infringement at that time." (*Id.*) Dexcom did not cite to its infringement contentions in support of this statement or provide any further explanation as to where the disclosure was made.[2]

Dexcom instead focused on *why* it did not include evidence as to how the "film" limitation was met in its responses to contention interrogatories. Dexcom explained that the opinions in Dr. Mihran's report were based on the testimony of AgaMatrix's corporate witness, David Olson, Ph.D. (*Id.*) Dexcom stated that "it did not discuss the testimony of Dr. Olson in its infringement contentions because the deposition of David Olson occurred after the contention interrogatory responses were due." (*Id.*) Dexcom argued that "[t]he concept that the enzyme dried in a film layer was not available to Dexcom before this time." (*Id.* at 25.) Dexcom stated: "It cannot be the case that the party is barred from using evidence it is likely to obtain only during depositions for not having disclosed such evidence earlier in the Investigation." (*Id.* at 26.)

Ground Rule 4.4.3 states: "Parties are expected to respond to contentions interrogatories by the date set forth in the Procedural Schedule. A party may not introduce evidence at the hearing that is outside of the scope of its responses to contention interrogatories." This Ground Rule was specifically added in October 2017[3] to apprise the parties of their obligations at the outset of the Investigation and to avoid any surprise when information outside of the scope of the responses is struck.

In ruling on AgaMatrix's Motion to Strike, the undersigned wrote:

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[2] In contrast, in opposing AgaMatrix's motion to strike with respect to other opinions in expert reports, Dexcom included lengthy discussions with numerous citations to its infringement contentions. (*See* Opp. at 12-21 (discussing Dexcom's disclosure of the role of the ASIC as part of the processor), *id.* at 27-29 (discussing Dr. Mihran's opinions related to partial fill).) The fact that these portions of the opposition included detailed discussions of Dexcom's responses to contention interrogatories, while the portion related to "enzyme-containing film" did not, suggests that there was not, in fact, support of the "film" limitation in its responses to contention interrogatories.

[3] Although the undersigned has amended the Ground Rules several times throughout the Investigation, Rule 4.4.3 was included in the initial Ground Rules issued as part of Order No. 2 on October 26, 2017.

> Ground Rule 4.3.3 does not require that the parties disclose every detail with respect to their contentions in their contention interrogatory responses. It does, however, require the parties to make *some* disclosure regarding each contention. Here, the undersigned finds that Dexcom did not make any disclosure regarding how the Accused Products meet the "film" limitation.

(Order No. 26 at 4.) The undersigned further noted:

> Dexcom essentially concedes this when it argues that it did not obtain the relevant evidence until a deposition of AgaMatrix's corporate witness taken *after* its final responses were due. (*See id.* at 24-26 (explaining that "[d]uring the deposition of David Olson on March 27, 2018, Dexcom learned additional detail as to how the enzyme-containing film is formed in the Accused Products").) Dexcom writes: "The concept that the enzyme dried in a film layer was not available to Dexcom before this time." (*Id.* at 25.) These statements show that the specific details related to "film" were not included in Dexcom's final contention interrogatory responses.

(*Id.*) Finally, the undersigned wrote:

> Dexcom's arguments also make clear that Dr. Mihran's opinions related to "film" were not within the *scope* of its previously disclosed infringement contentions either. AgaMatrix suggests that "Dexcom never even considered the possibility that the 'enzyme-containing' material in the accused products might be in a structure other than a 'film.'" (Mem. at 11.) Dexcom's opposition demonstrates that this was indeed the case. Dexcom writes that discovery produced by AgaMatrix's did not discuss "how a film is formed or applied" and that "Dexcom had no indication that such process occurred and would later be disclosed in interrogatories." (Opp. at 11.) It appears, therefore, that Dexcom assumed that the question of whether the "film" limitation was met would not be in dispute.

(*Id.*)

The undersigned also addressed Dexcom's arguments that it should be permitted to use evidence obtained after the deadline for infringement contentions. The undersigned wrote:

> Dexcom is correct, but the Ground Rules provide a clear mechanism for dealing with such situations. Ground Rule 4.3.3 provides: "Amendment or supplementation of responses to contention interrogatories after the deadlines set forth in the Procedural Schedule may be made only with leave of the Court and shall be entered only upon a showing of good cause." Dexcom clearly had good cause to amend its infringement contentions but chose to seek forgiveness, instead

> of ask for permission. The undersigned has previously made it clear that such tactics will not be tolerated.

(*Id.* at 5.)

For those reasons, the undersigned granted AgaMatrix's motion to strike and stated: "Dexcom is also precluded from further relying on the arguments and theories described in these sections during the course of this Investigation." (*Id.* at 10.)

B. Effect of Order No. 26

In its opposition, Dexcom states: "Order No. 26 did not preclude Dexcom from offering evidence and arguments of infringement that were previously disclosed to AgaMatrix (or independent of the struck paragraphs.) (Opp. at 10.) Dexcom's understanding is incorrect. As noted above, in Order No. 26, the undersigned found that "Dexcom did not make any disclosure regarding how the Accused Products meet the "film" limitation" in its responses to contention interrogatories. (Order No. 26 at 4.) As such, the undersigned precluded any arguments related to whether the "film" limitation is met. (*Id.* at 10.) Thus, all evidence[4] to establish that the "film" limitation is met is precluded by Order No. 26.

C. Dexcom's Arguments that Order No. 26 Was Incorrect

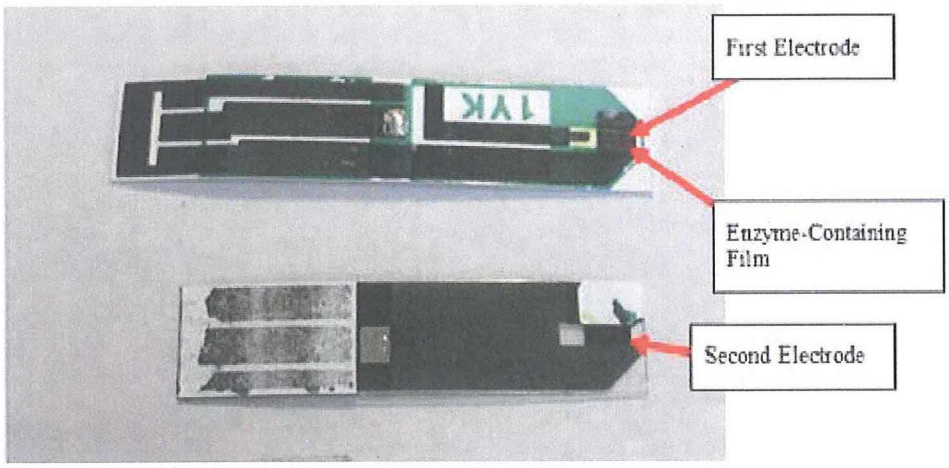
In its opposition, Dexcom argues that it did, in fact, disclose the film limitation in its responses to contention interrogatories. (Opp. at 12-13.) Such information is irrelevant. Dexcom did not point to any such evidence in its Opposition to AgaMatrix's Motion to Strike and should not be provided with a second bite at the apple to cite to such evidence now. Parties are not permitted to "re-brief" issues once they have lost their motions. Rather, it has long been the

[4] Some of the evidence on which Dexcom intends to reply was the subject of a recent motion for leave (1075-022), which was pending at the time of Dexcom's opposition. On May 31, 2018, the undersigned denied Dexcom leave to supplement its responses to contention interrogatories and expert reports. (Order No. 30 at 6.) In doing so, the undersigned found that the factual premise underlying Dexcom's motion was incorrect. (*Id.* at 2.) Although Dexcom had argued that AgaMatrix's expert had changed his position on claim construction, a review of the record revealed that the expert had not changed his position and had been consistent with his opinions throughout the Investigation. (*Id.* at 2-5.)

policy in ITC Investigations that reconsideration of orders is permitted only in limited circumstances: (1) an intervening change in controlling law, (2) the availability of new evidence, or (3) the need to correct a clear error of law or fact or to prevent manifest injustice. *See Certain Digital Cameras and Component Parts Thereof*, Inv. No. 337-TA-593, Order No. 8 at 3 (Aug. 16, 2007) (citing *Certain Network Interface Cards and Access Points for Use in Direct Sequence Spread Spectrum Wireless Local Area Networks and Prods. Containing Same*, Inv. 337-TA-455, Order No. 69 at 2-3 (Jan. 17, 2002)). Dexcom did not seek reconsideration and its arguments do not reveal any reason why reconsideration would be appropriate.

Dexcom's opposition instead includes arguments it could have made in its Opposition to the Motion to Strike. Additionally, these arguments do not persuade the undersigned that the "film" limitation was disclosed in the responses to contention interrogatories.

First, a portion of the new evidence that Dexcom points to was already noted in AgaMatrix's motion. Specifically, Dexcom cites to a picture of the Accused Products with a label of "enzyme-containing film":



(Opp. at 12; Statement of Material Facts Warranting Denial of Summary Determination ("Statement of Material Facts") at ¶ 14; *see also id.* at ¶ 17 (depicting similar picture).) Dexcom

also asserts that its "infringement charts . . . include evidence that the test strip film included a glucose oxidase enzyme" and points to the following statement:

> The AgaMatrix CVS Health Glucose Meter System utilizes an electrochemical glucose sensor ("CVS Health Advanced Glucose Meter Test Strips") that is configured to be in contact with a biological fluid (e.g. blood) to obtain a glucose measurement. The CVS Health Advanced Glucose Meter Test Strips are configured to be used in connection with sensor electronics to quantify a glucose concentration and utilize a first electrode including an electrode surface, a second electrode, and an enzyme-containing film.

(Statement of Material Facts at ¶¶ 15, 16; *see also* Opp. at 12-13.) Both the picture[5] and the statement were discussed by AgaMatrix in the Motion to Strike. (*See* discussion, *supra* at 3-4.) AgaMatrix argued that this evidence was conclusory and failed to provide an explanation or analysis as to how an enzyme-containing film was applied or formed. (*See* Motion to Strike at 10-11.) The undersigned agrees. Because Ground Rule 4.4.3[6] does not permit parties to rest on conclusory statements, this evidence would be insufficient to compel a finding that the "film" limitation was disclosed. Additionally, Dexcom did not include any explicit statement that this evidence demonstrated that the "film" limitation is met as opposed to the "enzyme-containing" part of the claim element.

Dexcom next cites to various other statements that mention the word "film." (Opp. at 13 (citing Statement of Material Facts at ¶¶ 18-20.) Dexcom offers no explanation, however, as to how these citations to the responses to contention interrogatories disclose that the Accused Products contain a "film." The first citation includes a reference to "reagent":

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[5] The Statement of Material Facts includes two pictures, which are each different than the one in the Motion to Strike. (Statement of Material Facts at ¶¶ 14, 17; Motion to Strike at 10.) Each of these pictures depicts an image of a different Accused Product test strip. (*See* Motion to Strike at 10.) The differences are therefore irrelevant to the issues involved in the summary determination.

[6] Ground Rule 4.4.3 provides: "Conclusory statements in responses to contention interrogatories are insufficient. For example, if a party simply states: 'There is also infringement under the doctrine of equivalents,' the party is prohibited from later introducing evidence regarding the details of such infringement."

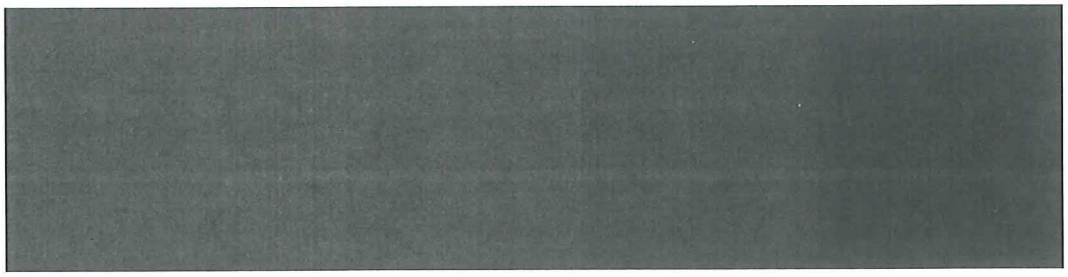
Various terms are used to refer to the sample chamber electrodes, and the circuit connections to the electrodes. For clarity, this document uses the terms Electrode A and Electrode B. The mapping of these terms to other terms used is as follows:

Term used in this document	Other terms used
Electrode A	Working Electrode, W_ELECTRODE, Reagent Electrode, Stimulus Signal, connected to V2
Electrode B	Counter/Reference Electrode, C_ELECTRODE, Non reagent Electrode, Sensing Signal, Current Sensing Electrode, connected to V1

(Statement of Material Facts at ¶¶ 18-19.) In its Statement of Material Facts, Dexcom explains that "[t]he reagent is a layer provided on the working electrode that includes an enzyme (glucose oxidase) and a mediator (hexaamineruthentium)." (*Id.* at ¶ 19.) Dexcom next states that it "provided additional evidence in its responses to contention interrogatories that the film included a glucose oxidase enzyme":

TEST PRINCIPLE
The test strip contains glucose oxidase enzyme with a redox chemical mediator that produces an electrochemical signal in proportion to the glucose concentration in the blood sample. The blood glucose meter measures this signal, using dynamic electrochemistry to correct for common analytical interferences such as hematocrit.

AgaMatrix CVS Health Glucose Meter Test Strips package insert (Doc. No. 8100-10106 Rev. B).



AGAITC042990, Source Control Specification, Test Strip, Alpha Analytical Platform (Doc. No. 8300-02942)

(Statement of Material Facts at ¶ 20.) Again, it is unclear how this evidence demonstrates that Dexcom previously disclosed how the film limitation has been met. The evidence appears, instead, to relate to how the "enzyme-containing" part of the claim element is met.

Thus, even if Dexcom had included the above evidence in its Opposition to the Motion to Strike, the outcome would be the same. Dexcom did not disclose in its responses to contention interrogatories that that the "film" limitation was met by the Accused Products.

D. Conclusion

For the reasons stated above, because Dexcom did not disclose in its responses to contention interrogatories that the film limitation is met, Dexcom cannot introduce evidence of infringement of this claim element at the hearing. Accordingly, the undersigned finds that there is no genuine issue of material fact relating to non-infringement of the claim limitation "wherein the electrochemical glucose sensor comprises a first electrode, a second electrode, and an enzyme-containing film." Because this limitation is found in all of the asserted claims, the undersigned finds that summary determination of non-infringement is appropriate.

II. Indirect Infringement

AgaMatrix argues that "[e]ach asserted claim requires both "an electrochemical glucose sensor" and "sensor electronics comprising a processor for executing a computer program code stored in a memory to cause the sensor electronics to [perform various functions]." (Mem. at 8.) "Since the 'electrochemical glucose sensor' (allegedly met by AgaMatrix test strips) is not the only element of the claimed 'glucose sensor system,'" an AgaMatrix test strip, by itself, could only infringe the Asserted Patents, if at all, under a theory of indirect infringement (*i.e.*, contributory infringement or induced infringement)." (*Id.*) AgaMatrix argues that Dexcom "only disclosed its arguments and theories concerning direct infringement" and "did not disclose any contentions concerning any indirect infringement by AgaMatrix test strips *per se*." (*Id.*)

Dexcom asserts that it "disclosed extensive evidence of AgaMatrix's indirect infringement in its infringement contentions and Dr. Mihran extensively discussed each of the

elements of induced infringement and contributory infringement by AgaMatrix's test strips." (Opp. at 19.)

"Absent direct infringement of the claims of a patent, there can be neither contributory infringement nor inducement of infringement." *Carborundum Co. v. Molten Metal Equip. Innovations, Inc.*, 72 F.3d 872, 876 n.4 (Fed. Cir. 1995); *see also RF Delaware, Inc. v. Pacific Keystone Techs, Inc.*, 326 F.3d 1255, 1268 (Fed. Cir. 2003). In light of the finding above, Dexcom cannot show indirect infringement. However, should the Commission decide that Dexcom can introduce evidence that the film limitation is met, the undersigned, after reviewing the parties' motions and accompanying exhibits, finds that a genuine dispute of material exists with respect to indirect infringement. As such, this portion of the motion is denied.

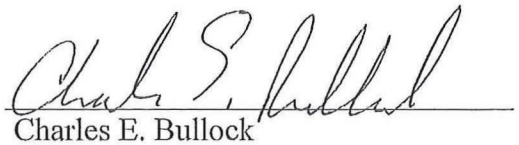
Accordingly, Respondents' motion (1075-021) for summary determination of non-infringement is hereby granted-in-part. In light of this finding, the procedural schedule in this Investigation is hereby stayed, pending review of this Initial Determination.

Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall be the determination of the Commission unless a party files a petition for review of the Initial Determination pursuant to 19 C.F.R. § 210.43(a), or the Commission, pursuant to 19 C.F.R. § 210.44, orders, on its own motion, a review of the Initial Determination or certain issues herein.

Within seven days of the date of this document, the parties shall submit to the Office of the Administrative Law Judges a joint statement as to whether or not they seek to have any portion of this document deleted from the public version. If the parties do seek to have portions of this document deleted from the public version, they must submit to this office a copy of this document with red brackets indicating the portion or portions asserted to contain confidential

business information. The submission may be made by email and/or hard copy by the aforementioned date and need not be filed with the Commission Secretary.

SO ORDERED.



Charles E. Bullock
Chief Administrative Law Judge

CERTAIN ELECTROCHEMICAL GLUCOSE MONITORING SYSTEMS AND COMPONENTS THEREOF

Inv. No. 337-TA-1075

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that **PUBLIC VERSION ORDER NO. 33** has been served upon the following parties as indicated, on **6/22/2018**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street SW, Room 112
Washington, DC 20436

On Behalf of Complainant Dexcom, Inc.:

Kirk R. Ruthenberg, Esq.
DENTON US LLP
1900 K Street, NW
Washington, DC 20006

☐ Via Hand Delivery
☑ Via Express Delivery
☐ Via First Class Mail
☐ Other:_____

On Behalf of Respondent AgaMatrix, Inc.:

Ira Jay Levy, Esq.
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue, 25th Floor
New York, NY 10018

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☑ Via Express Delivery
☐ Via First Class Mail
☐ Other:_____

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC

In the Matter of	
CERTAIN ELECTROCHEMICAL GLUCOSE MONITORING SYSTEMS AND COMPONENTS THEREOF	Investigation No. 337-TA-1075

NOTICE OF COMMISSION DETERMINATION TO REVIEW AND, ON REVIEW, AFFIRM WITH MODIFICATIONS AN INITIAL DETERMINATION GRANTING AN UNOPPOSED MOTION FOR SUMMARY DETERMINATION THAT COMPLAINANT SATISFIED THE ECONOMIC PRONG OF THE DOMESTIC INDUSTRY REQUIREMENT

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review and, on review, affirm with modifications an initial determination (Order No. 32) granting an unopposed motion for summary determination that the complainant satisfied the economic prong of the domestic industry requirement.

FOR FURTHER INFORMATION CONTACT: Lucy Grace D. Noyola, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW, Washington, DC 20436, telephone 202-205-3438. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW, Washington, DC 20436, telephone 202-205-2000. General information concerning the Commission may also be obtained by accessing its Internet server (https://www.usitc.gov). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at https://edis.usitc.gov. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on October 25, 2017, based on a complaint filed on September 18, 2017, on behalf of Dexcom, Inc. of San Diego, California ("Dexcom"). 82 Fed. Reg. 49420 (Oct. 25, 2017). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain electrochemical glucose monitoring systems and components thereof by reason of infringement of one or more of claims of U.S. Patent Nos. 9,724,045 and 9,750,460. The notice of investigation named as a respondent AgaMatrix, Inc. of

Salem, New Hampshire ("AgaMatrix"). The Office of Unfair Import Investigations was not named as a party in the investigation.

On May 17, 2018, Dexcom filed a motion for summary determination that Dexcom satisfies the economic prong of the domestic industry requirement under 19 U.S.C. § 1337(a)(3)(A) and (B). On May 29, 2018, AgaMatrix filed a response stating that it did not oppose Dexcom's motion that it satisfies the economic prong of the domestic industry requirement as of the time of the filing of the complaint.

On June 6, 2018, the presiding administrative law judge ("ALJ") issued an initial determination ("ID") (Order No. 32), granting Dexcom's motion. The ID found that the undisputed facts demonstrate that the economic prong of the domestic industry requirement has been satisfied. No petitions for review of the ID were filed.

The Commission has determined to review the subject ID and, on review, affirm the ID with modifications. Specifically, the Commission vacates the ID's statement on page 4 referring to Dexcom's post-complaint lease obligations and the ID's statements on page 8 referring to Dexcom's costs of goods sold. The Commission affirms the remainder of the ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 C.F.R. Part 210).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: July 5, 2018

CERTAIN ELECTROCHEMICAL GLUCOSE MONITORING SYSTEMS AND COMPONENTS THEREOF **Inv. No. 337-TA-1075**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served to the following parties as indicated, on July 5, 2018.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants Dexcom, Inc.:

Kirk R. Ruthenberg, Esq.
DENTON US LLP
1900 K Street, NW
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☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

On Behalf of Respondents AgaMatrix, Inc.:

Ira Jay Levy
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☐ Via Express Delivery
☒ Via First Class Mail
☐ Other:_____

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of	
CERTAIN ELECTROCHEMICAL GLUCOSE MONITORING SYSTEMS AND COMPONENTS THEREOF	**Inv. No. 337-TA-1075**

ORDER NO. 32: INITIAL DETERMINATION GRANTING DEXCOM, INC.'S MOTION FOR SUMMARY DETERMINATION THAT IT SATISFIES THE ECONOMIC PRONG OF DOMESTIC INDUSTRY REQUIREMENT

(June 6, 2018)

On May 17, 2018, Complainant Dexcom, Inc. ("Dexcom") moved (1075-020) for summary determination that Dexcom satisfies the economic prong of the domestic industry requirement under 19 U.S.C. §§ 1337(a)(3)(A) and (B). (Mot. at 1.) On May 29, 2018, Respondent AgaMatrix, Inc.'s ("AgaMatrix") filed a response indicating that it does not dispute any of the facts presented in Dexcom's Statement of Undisputed Material Facts.[1] (*See* Response at 2 ("AgaMatrix does not oppose Dexcom's contention that (if it meets the technical prong) it satisfied the economic prong of the domestic industry requirement under 19 U.S.C. §§ 1337(a)(3)(A) and (B) . . . as of the time of the complaint.")

Summary determination is appropriate when there is no genuine issue as to any material fact and the moving party is entitled to a determination as a matter of law. *See* 19 C.F.R. § 210.18(b). In determining whether there is a genuine issue of material fact, "the evidence must be viewed in the light most favorable to the party opposing the motion with doubts resolved in

[1] AgaMatrix's response emphasizes that it continues to contest that the technical prong of the domestic industry requirement has been met. (Response at 1-2.) AgaMatrix also explains that Dexcom [redacted] (*Id.* at 2.) AgaMatrix argues that [redacted] would constitute "a significant and unusual development" that would impact the assessment of a domestic industry. (*Id.* at 2-3.) Accordingly, AgaMatrix states that it "reserves its rights to oppose the existence of a continuing domestic industry in the event that 'a significant and unusual development' arises." (*Id.* at 3.)

favor of the non-movant." *Crown Operations Int'l, Ltd. v. Solutia, Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002) (citation omitted).

Section 337(a)(3) sets forth the following economic criteria for determining the existence of a domestic industry in Section 337 investigations:

> (3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned –
>
> (A) significant investment in plant and equipment;
> (B) significant employment of labor or capital; or
> (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

Given that these criteria are listed in the disjunctive, satisfaction of any one of them will be sufficient to meet the economic prong of the domestic industry requirement. *Certain Integrated Circuit Chipsets and Prods. Containing Same*, Inv. No. 337-TA-428, Order No. 10, Initial Determination (unreviewed) (May 4, 2000).

Having reviewed the pleadings and arguments contained therein, the undersigned finds the undisputed facts to show that the economic prong of the domestic industry requirement has been satisfied.

A. Significant Investment in Plant and Equipment

The undisputed facts show that Dexcom has made significant investments in plant and equipment with respect to the domestic industry requirements. The evidence shows that Dexcom utilizes approximately [redacted] dedicated to the manufacturing, R&D, testing, sales, marketing, legal, and operations of the G4 Platinum Continuous Glucose Monitoring Systems ("G4") and G5 Mobile Continuous Glucose Monitoring Systems ("G5") (collectively, the "Domestic Industry Products") in the United States. (Statement of Undisputed Material Facts at

¶¶ 13, 16-17.) All of manufacturing, R&D, and testing operations are in the United States. (*Id.* at ¶¶ 13-17.) Of that square footage, approximately [redacted] is dedicated to manufacturing the Domestic Industry Products. (*Id.* at ¶ 21.) Between 2015 and March 2018, the only products Dexcom manufactured were the Domestic Industry Products, thus during this time frame each of Dexcom's facilities were dedicated entirely to the support of the Domestic Industry Products. (*Id.* at ¶ 5.)

The evidence shows that Dexcom manufactures all of the Domestic Industry Products at its facilities in San Diego, California. (*Id.* at ¶ 3.) Dexcom's San Diego facilities also contain activities relating to the R&D, testing, sales, marketing, legal, and operations associated with the Domestic Industry Products, located at 6310 Sequence Dr., 6340 Sequence Dr., 6350 Sequence Dr., and 6290 Sequence Dr. These four facilities total [redacted] (*Id.* at ¶ 13.) Dexcom also has a warehouse facility in San Diego relating to the shipping of the Domestic Industry Products located at 5883 Pacific Dr., with [redacted] (*Id.* at ¶ 14.) Thus, the total square footage of Dexcom facilities in San Diego, California supporting the Domestic Industry Products is [redacted] (*Id.* at ¶ 15.)

The evidence shows that Dexcom also has U.S. facilities in Oregon, Florida and Arizona that support the Domestic Industry Products. (*Id.* at ¶ 16.) Specifically, Dexcom has approximately [redacted] at 308 SW 2nd Avenue, in Portland, Oregon, [redacted] at 5555 Anglers Avenue in Dania Beach, Florida and [redacted] at 232 and 318 South Dobson Road in Mesa, Arizona. The facilities in Portland, Oregon and Dania Beach, Florida contain research and development activities relating to the Domestic Industry Products. Beginning in 2018, Dexcom also plans to [redacted] (*Id.*) Thus, Dexcom has continued to invest in the building and expansion of its U.S. facilities, including

facilities intended to be used for U.S. manufacturing. The Mesa, Arizona facility currently contains customer service activities relating to the Domestic Industry Products. (*Id.*)

The evidence shows that, in total, Dexcom utilizes [redacted] in the United States to support the Domestic Industry Products. (*Id.* at ¶ 17.) This is in comparison to the approximate [redacted] (or approximately [redacted] of Dexcom's facilities abroad. (*Id.* at ¶¶ 28-29.) Thus, all of Dexcom's manufacturing and the vast majority (approx. [redacted] of operations relating to the support of the Domestic Industry Products occurs in its facilities in the United States demonstrating a significant domestic investment in facilities in the United States.

With respect to manufacturing of the Domestic Industry Products, the evidence shows that approximately [redacted] of the San Diego, California facilities are used to manufacture the Domestic Industry Products. (*Id.* at ¶ 21.) Each of the Domestic Industry Products consists of a sensor, receiver and transmitter. Approximately [redacted] is used for the manufacture of the sensors for both the G4 and the G5 systems, approximately [redacted] is used for the manufacture of the G4 transmitters, approximately [redacted] is used for the manufacture of the G4 receivers, approximately [redacted] is used for the manufacture of the G5 transmitters, and approximately [redacted] is used for the manufacture of the G5 receivers. (*Id.*) Dexcom does not manufacture outside of the United States. (*Id.*)

The evidence shows that the value of Dexcom's U.S. facilities as they pertain to the Domestic Industry Products is also significant. The evidence shows that Dexcom's outstanding lease obligations, from 2016 through 2028, in the United States are approximately [redacted] (*Id.* at ¶ 18.) And, from 2012-June 30, 2017, Dexcom spent approximately [redacted] on

paying leases, acquiring new facilities, and purchasing machinery and equipment in the United States to support the Domestic Industry Products. (*Id.* at ¶ 19.)

In 2017, the evidence shows Dexcom spent approximately [redacted] on facilities in the U.S. associated with the manufacture of the Domestic Industry Products. (*Id.* at ¶ 22.) In 2017, Dexcom spent approximately [redacted] on facilities in the U.S. associated with the manufacture of the G4 and G5 sensors. (*Id.* at ¶ 23.) In 2017, Dexcom spent approximately [redacted] on facilities associated with the manufacture of the G4 transmitters. (*Id.* at ¶ 24.) In 2017, Dexcom spent approximately [redacted] on facilities associated with the manufacture of the G4 receivers. (*Id.* at ¶ 25.) In 2017, Dexcom spent approximately [redacted] on facilities associated with the manufacture of the G5 transmitters. (*Id.* at ¶ 26.) Finally, Dexcom spent approximately [redacted] on facilities associated with the manufacture of the G5 receivers in 2017. (*Id.* at ¶ 27.)

Given the facilities described above are used in the domestic manufacturing, research/development, and operations of Dexcom's Domestic Industry Products, the undisputed facts demonstrate that Dexcom has made significant investments towards plant and equipment in the United States related to both of the Domestic Industry Products under 19 U.S.C. § 1337(a)(3)(A) to meet the economic prong.

B. Significant Employment of Labor or Capital

The undisputed facts show that Dexcom has made significant employment of labor or capital with respect to the domestic industry requirements. The evidence shows that, between 2015 and March 2018, the only products Dexcom manufactured and sold were the Domestic Industry Products, thus during this time frame each Dexcom employee was necessarily dedicated to the support of the Domestic Industry Products. (*Id.* at ¶ 5.) Approximately [redacted] of Dexcom's

employees are located in the United States. (*Id.* at ¶ 30.) Thus, Dexcom has employed a significant amount of domestic labor directed to both the G4 and G5 systems.

In 2017, the evidence shows Dexcom employed approximately [redacted] in the United States. (*Id.* at ¶ 31.) Each of the Domestic Industry Products consists of a sensor, receiver and transmitter. Of the [redacted] employed in the United States, approximately [redacted] are involved in the manufacture of the G4 and G5 within the United States broken down as follows: approximately [redacted] are dedicated to the manufacture of the G4/G5 sensors; approximately [redacted] are dedicated to the manufacture of the transmitters; approximately [redacted] are dedicated to the manufacture of the receivers; approximately [redacted] split their time [redacted] approximately [redacted] split their time [redacted] approximately [redacted] split their time [redacted] approximately [redacted] split their time [redacted] and approximately [redacted] split their time [redacted] (*Id.* at ¶ 41.)

Of the people who manufacture the transmitters and receivers, their work is broken down to approximately [redacted] spent on manufacturing the G5 components. The remaining [redacted] of the work is related to manufacturing the G4 components. Because the sensors are used with both G4 and G5 systems, the employees who manufacture the sensors support both the G4 and G5. (*Id.* at ¶ 42.)

The evidence shows Dexcom's capital investments in labor dedicated to the Domestic Industry Products have also been significant. From 2012 through June 2017, Dexcom spent over [redacted] in the United States on salaries, wages, and other compensation relating to the Domestic Industry Products. (*Id.* at ¶¶ 34-40.) In 2017, Dexcom spent approximately [redacted] on employee compensation in the United States relating to the support of the Domestic Industry Products. (*Id.* at ¶ 40.) And, for a reasonable allocation in 2017, [redacted] was spent as direct labor costs on sensors, [redacted] was spent as direct labor costs on transmitters, and [redacted] was spent as direct labor costs on receivers. (*Id.* at ¶ 43.)

These investments in labor can be further allocated based on the Domestic Industry Product. Approximately [redacted] of the direct labor costs on sensors is attributed to sensors used with the G5 systems and the remaining [redacted] is attributed to sensors used with the G4 systems. (*Id.* at ¶ 44.) In 2017, approximately [redacted] was spent as direct labor costs on G4 transmitters. (*Id.* at ¶ 45.) In 2017, approximately [redacted] was spent as direct labor costs on G4 receivers. (*Id.* at ¶ 46.) In 2017, approximately [redacted] was spent as direct labor costs on G5 transmitters. (*Id.* at ¶ 47.) In 2017, approximately [redacted] was spent as direct labor costs on G5 receivers. (*Id.* at ¶ 48.)

In addition to the labor expenditures in the United States, Dexcom has also made other significant capital expenditures in the United States associated with the Domestic Industry Products. Specifically, in 2017, Dexcom spent over [redacted] on raw material associated with the manufacture, processing, and packaging of the G4 and G5 in the United States. (*Id.* at ¶ 49.) And, Dexcom spent an additional [redacted] on material overhead costs associated with procuring materials and handling and storing materials of the G4 and G5 in the

United States. (*Id.*) Further, Dexcom spent [redacted] on outside processing costs associated with sterilization of the G4 and G5 in the United States. (*Id.*)

For 2017, Dexcom spent [redacted] on raw material costs associated with the sensors, [redacted] on material overhead on sensors, and [redacted] on outside processing associated the sensors. (*Id.* at ¶ 50.) In 2017, Dexcom spent approximately [redacted] on raw material costs associated with G4 transmitters, and spent [redacted] on material overhead on G4 transmitters. In 2017, Dexcom spent approximately [redacted] on raw material costs associated with G4 receivers, and spent [redacted] on material overhead on G4 receivers. In 2017, Dexcom spent approximately [redacted] on raw material costs associated with G5 transmitters and spent [redacted] on material overhead on G5 transmitters. In 2017, Dexcom spent approximately [redacted] on raw material costs associated with G5 receivers, and spent [redacted] on material overhead on G5 receivers. (*Id.*)

Additionally, from 2015 through 2017 all of Dexcom's costs of goods sold supported the Domestic Industry Products in the United States. In 2017, the cost of goods sold for the G4 and G5 was [redacted] (*Id.* at ¶ 51.) In 2016, the cost of goods sold for the G4 and G5 systems was [redacted] (*Id.*) In 2015, the cost of goods sold for the G4 and G5 systems was [redacted] (*Id.*)

Given the labor and capital expenditures described above, the undisputed facts demonstrate that Dexcom has made significant investments towards labor and capital in the United States related to both of the Domestic Industry Products under 19 U.S.C. § 1337(a)(3)(B) to meet the economic prong.

No genuine issue of material fact therefore remains and a summary determination that the economic prong of the domestic industry requirement has been satisfied is appropriate.

Accordingly, Respondents' motion (1075-020) for summary determination of the economic prong of the domestic industry requirement is granted.

Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall be the determination of the Commission unless a party files a petition for review of the Initial Determination pursuant to 19 C.F.R. § 210.43(a), or the Commission, pursuant to 19 C.F.R. § 210.44, orders, on its own motion, a review of the Initial Determination or certain issues herein.

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SO ORDERED.

Charles E. Bullock
Chief Administrative Law Judge

CERTAIN ELECTROCHEMICAL GLUCOSE MONITORING SYSTEMS AND COMPONENTS THEREOF

Inv. No. 337-TA-1075

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that **PUBLIC VERSION ORDER NO. 32** has been served upon the following parties as indicated, on **6/22/2018**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street SW, Room 112
Washington, DC 20436

On Behalf of Complainant Dexcom, Inc.:

Kirk R. Ruthenberg, Esq.
DENTON US LLP
1900 K Street, NW
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On Behalf of Respondent AgaMatrix, Inc.:

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