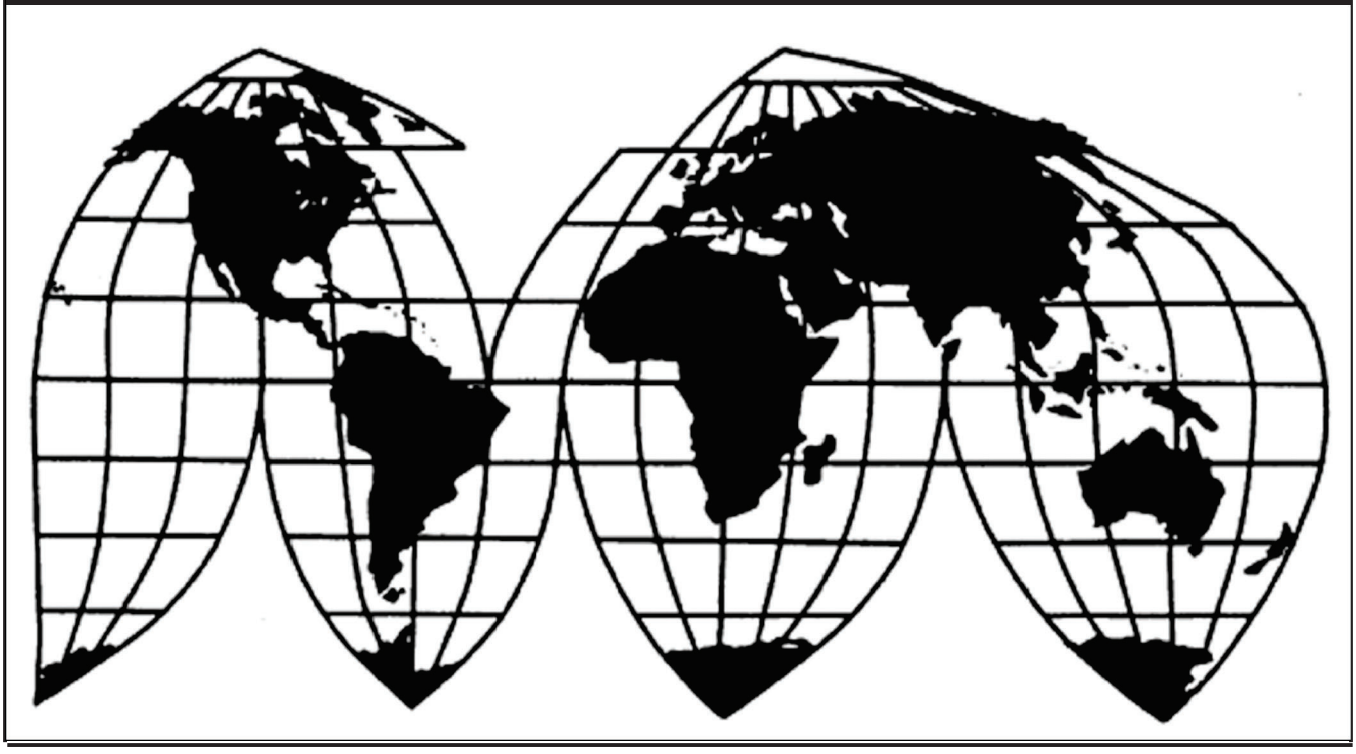
In the Matter of

CERTAIN BLOOD CHOLESTEROL TESTING STRIPS AND ASSOCIATED SYSTEMS CONTAINING THE SAME

Investigation No. 337-TA-1116

Publication 5252 **February 2022**

U.S. International Trade Commission



Washington, DC 20436

U.S. International Trade Commission

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In the Matter of

CERTAIN BLOOD CHOLESTEROL TESTING STRIPS AND ASSOCIATED SYSTEMS CONTAINING THE SAME

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN BLOOD CHOLESTEROL TESTING STRIPS AND ASSOCIATED SYSTEMS CONTAINING THE SAME**	**Investigation No. 337-TA-1116**

NOTICE OF THE COMMISSION'S FINAL DETERMINATION FINDING A VIOLATION OF SECTION 337; ISSUANCE OF A LIMITED EXCLUSION ORDER; TERMINATION OF THE INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has found a violation of section 337 of the Tariff Act of 1930, as amended, by ACON Biotech (Hangzhou) Co., Ltd. of Hangzhou, China, and ACON Laboratories, Inc., of San Diego, California, and has determined to issue a limited exclusion order. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Robert Needham, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 708-5468. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its Internet server (*https://www.usitc.gov*). Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on June 5, 2018, based on a complaint filed by Polymer Technology Systems, Inc. of Indianapolis, Indiana ("PTS"). 83 FR 26087-88. The complaint alleges violations of section 337 in the importation into the United States, the sale for importation, and the sale after importation within the United States after importation of certain blood cholesterol testing strips and associated systems containing the same by reason of infringement of one or more claims of U.S. Patent Nos. 7,087,397 ("the '397 patent"); 7,625,721 ("the '721 patent"); and 7,494,818 ("the '818 patent"). *Id*. at 26087. The notice of investigation named as respondents ACON Laboratories, Inc. of San Diego, California ("ACON Labs"), and ACON Biotech (Hangzhou) Co., Ltd. of Hangzhou, China ("ACON Bio") (collectively, "ACON"). The Office of Unfair Import Investigations is not a party

to the investigation. *Id.* at 26088.

The Commission subsequently terminated the investigation with respect to claims 10, 13, 14, and 20 of the '397 patent based on PTS's withdrawal of those allegations. *See* Order. No. 7 (Sept. 10, 2018), *not reviewed*, Notice (Sept. 25, 2018); Order No. 10 (Jan. 31, 2019), *not reviewed*, Notice (Feb. 21, 2019). The Commission also terminated the investigation for infringement purposes with respect to claim 17 of the '397 patent; claims 2, 3, 13, and 14 of the '721 patent; and claim 10 of the '818 patent based on PTS's withdrawal of allegations. Order No. 14 (Feb. 14, 2019), *not reviewed*, Notice (Mar. 5, 2019). Finally, the Commission terminated the investigation with respect to claims 1-3, 5, and 18 of the '397 patent and claims 5, 7, and 9 of the '721 patent based on PTS's withdrawal of allegations. Order No. 15 (Mar. 12, 2019), *not reviewed*, Notice (April 9, 2019). Accordingly, at the time of the Final ID, PTS asserted for infringement claim 19 of the '397 patent; claims 1, 4, 6, 8, and 15 of the '721 patent; and claims 8, 9, and 11 of the '818 patent. Final ID at 43.

On February 13, 2019, the presiding administrative law judge ("ALJ") issued an initial determination ("ID") granting a summary determination that PTS satisfied the economic prong of the domestic industry requirement for each of three asserted patents under section 337(a)(3)(A), (B), and (C). Order No. 13 (Feb. 13, 2019). No party petitioned for review of the ID, and the Commission declined to review the ID. Notice (Mar. 12, 2019).

On June 4, 2019, the ALJ issued a final ID finding a violation of section 337 with respect to the '397 and '721 patents, and no violation with respect to the '818 patent. The ALJ found that ACON infringed claim 19 of the '397 patent and claims 1, 4, 6, 7, and 15 of the '721 patent, but did not infringe claims 8, 9, and 11 of the '818 patent. The ALJ also found that PTS satisfies the domestic industry requirement with respect to all three asserted patents, and that no asserted claims were shown to be invalid by clear and convincing evidence.

On June 17, 2019, ACON petitioned for review of the final ID with respect to the '397 and '721 patents, and contingently petitioned for review of the final ID with respect to the '818 patent. PTS did not file a petition for review, and, on June 25, 2019, PTS filed a response to ACON's petition.

On August 13, 2019, the Commission determined to review the Final ID in part. Specifically, the Commission determined to review the following issues: (1) whether ACON Labs' use of the accused products in the United States constitutes a violation of 19 U.S.C. 1337(a)(1)(B)(i); (2) the final ID's construction of "reacting HDL . . . without precipitating said one or more non-selected analytes" in the '721 patent, as well as related findings on infringement, the domestic industry, and invalidity; and (3) the final ID's finding that all of the asserted claims of the '721 patent are not shown to be invalid for a lack of enablement. The Commission did not review any other findings presented in the final ID.

The Commission also sought briefing from the parties on four issues and on remedy, bonding, and public interest. On August 27, 2019, PTS and ACON filed their initial submissions in response to the Commission's request for briefing. On September 3, 2019, PTS and ACON filed their reply submissions in response to the Commission's request for briefing. No third-party submissions on remedy, bonding, or the public interest were received.

Having examined the record of this investigation, including the Final ID, the petition, response, and other submissions from the parties, the Commission has determined that PTS has shown a violation of section 337 by ACON Bio and ACON Labs with respect to the '397 and '721 patents. The Commission has also determined to construe the term "precipitating" to mean "separating a solid substance or material from a solution by a chemical reaction," and finds that, under this construction, PTS established infringement and the domestic industry requirement with respect to claims 1, 4, 6, 8 and 15 of the '721 patent, and that ACON failed to show that any claim is invalid by clear and convincing evidence. The Commission's determinations are explained more fully in the accompanying Opinion. All other findings in the ID under review that are consistent with the Commission's determinations are affirmed.

The Commission has determined that the appropriate form of relief in this investigation is a limited exclusion order with respect to ACON Bio and ACON Labs prohibiting the importation of imported blood cholesterol testing strips and associated systems containing the same that are covered by one or more of claim 19 of the '397 patent and claims 1, 4, 6, 8, and 15 of the '721 patent. The Commission has further determined that the public interest factors enumerated in subsection 337(d)(1) (19 U.S.C. 1337(d)(1)) do not preclude the issuance of the limited exclusion order. Finally, the Commission has determined that the bond for importation during the period of Presidential review shall be in the amount of zero percent of the entered value of such articles.

The Commission's notice, order, and opinion were delivered to the President and to the United States Trade Representative on the day of their issuance. The Commission has also notified the Secretary of the Treasury and Customs and Border Protection of the order. The investigation is hereby 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 CFR part 210).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: April 16, 2020

CERTAIN BLOOD CHOLESTEROL TESTING STRIPS AND ASSOCIATED SYSTEMS CONTAINING THE SAME **Inv. No. 337-TA- 1116**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served upon the following parties as indicated, on **April 16, 2020**.

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

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☒ Other: Email Notification of Availability for Download

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN BLOOD CHOLESTEROL TESTING STRIPS AND ASSOCIATED SYSTEMS CONTAINING THE SAME**	**Investigation No. 337-TA-1116**

LIMITED EXCLUSION ORDER

The Commission has determined that there is a violation of section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) in the unlawful importation into the United States, sale for importation into the United States, or sale within the United States after importation by Respondents ACON Biotech (Hangzhou) Co., Ltd. of Hangzhou, China, and ACON Laboratories, Inc., of San Diego, California (collectively, "Respondents"), of blood cholesterol testing strips and associated systems containing the same covered by one or more of claim 19 of U.S. Patent Nos. 7,087,397 ("the '397 patent") and claims 1, 4, 6, 8, and 15 of U.S. Patent No. 7,625,721 ("the '721 patent").

Having reviewed the record in this investigation, including the written submissions of the parties, the Commission has made its determination on the issues of remedy, the public interest, and bonding. The Commission has determined that the appropriate form of relief is a limited exclusion order prohibiting the unlicensed entry of covered blood cholesterol testing strips and associated systems containing the same, manufactured for or on behalf of, or imported by or on behalf of, Respondents or any of their affiliated companies, parents, subsidiaries, or other related business entities, or its successors or assigns.

The Commission has also determined that the public interest factors enumerated in 19 U.S.C. § 1337(d) do not preclude the issuance of the limited exclusion order, and that the

bond during the Presidential review period shall be in the amount of zero percent of the entered value of the articles in question.

Accordingly, the Commission hereby **ORDERS** that:

1. Blood cholesterol testing strips and associated systems containing the same covered by one or more of claim 19 of the '397 patent and claims 1, 4, 6, 8, and 15 of the '721 patent, that are manufactured abroad by or on behalf of, or are imported by or on behalf of Respondents, or any of their affiliated companies, parents, subsidiaries, or other related business entities, or its successors or assigns ("covered articles"), are excluded from entry for consumption into the United States, entry for consumption from a foreign-trade zone, or withdrawal from a warehouse for consumption, for the remaining term of each patent, except under license of the patent owner or as provided by law.

2. Notwithstanding paragraph 1 of this Order, the covered articles are entitled to entry into the United States for consumption, entry for consumption from a foreign trade zone, or withdrawal from a warehouse for consumption under bond in the amount of zero percent of the entered value of such articles pursuant to subsection (j) of Section 337 of the Tariff Act, as amended (19 U.S.C. § 1337(j)), and the Presidential Memorandum for the United States Trade Representative of July 21, 2005 (70 Fed. Reg. 43,251), from the day after this Order is received by the United States Representative, and until such time as the United States Trade Representative notifies the Commission that the Commission's determination is approved, disapproved, or if no action is taken but, in any event, not later than sixty (60) days after the date of receipt of this Order by the United States Trade Representative. All entries of covered articles made pursuant to this paragraph are to be reported to U.S. Customs and Border Protection ("CBP"), in advance of the date of the entry, pursuant to procedures CBP establishes.

3. At the discretion of CBP and pursuant to the procedures it establishes, persons seeking to import blood cholesterol testing strips and associated systems containing the same that are potentially subject to this Order may be required to certify that they are familiar with the terms of this Order, that they have made appropriate inquiry, and thereupon state that, to the best of their knowledge and belief, the products being imported are not excluded from entry under paragraph 1 of this Order. At its discretion, CBP may require persons who have provided the certification described in this paragraph to furnish such records or analyses as are necessary to substantiate this certification.

4. In accordance with 19 U.S.C. § 1337(l), the provisions of this Order shall not apply to covered articles that are imported by and for the use of the United States, or imported for and to be used for, the United States with the authorization or consent of the Government.

5. The Commission may modify this Order in accordance with the procedures described in section 210.76 of the Commission's Rules of Practice and Procedure, 19 C.F.R § 210.76.

6. The Secretary shall serve copies of this Order upon each party of record in this investigation and CBP.

7. Notice of this Order shall be published in the Federal Register.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: April 16, 2020

CERTAIN BLOOD CHOLESTEROL TESTING STRIPS AND ASSOCIATED SYSTEMS CONTAINING THE SAME **Inv. No. 337-TA- 1116**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **COMMISSION ORDER** has been served upon the following parties as indicated, on **April 16, 2020**.

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

On Behalf of Complainant Polymer Technology Systems, Inc.:

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☐ Via First Class Mail
☒ Other: Email Notification of Availability for Download

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	
CERTAIN BLOOD CHOLESTEROL TESTING STRIPS AND ASSOCIATED SYSTEMS CONTAINING THE SAME	**Investigation No. 337-TA-1116**

COMMISSION OPINION

The Commission has determined that there has been a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to claim 19 of U.S. Patent No. 7,087,397 ("the '397 patent") and claims 1, 4, 6, 8, and 15 of U.S. Patent No. 7,625,721 ("the '721 patent") on review of the final initial determination ("final ID") of the presiding administrative law judge's ("ALJ"). The Commission has determined to issue a limited exclusion order ("LEO") directed to infringing blood cholesterol testing strips and associated systems containing the same and to set the bond during the Presidential review period at zero percent. This opinion sets forth the Commission's reasoning in support of that determination. In addition, the Commission adopts the findings in the final ID that are not inconsistent with this opinion.

I. BACKGROUND

A. Procedural History

The Commission instituted this investigation on June 5, 2018, based on a complaint filed by Polymer Technology Systems, Inc. of Indianapolis, Indiana ("PTS"). 83 Fed. Reg. 26087-88 (June 5, 2018). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and the sale after importation within the United States of certain blood cholesterol testing strips

and associated systems containing the same by reason of infringement of one or more of claims 1-3, 5, 10, 13-14, and 17-20 of the '397 patent; claims 1-9 and 13-15 of the '721 patent; and claims 8-11 of U.S. Patent No. 7,494,818 ("the '818 patent"). *Id*. at 26087. The notice of investigation named as respondents ACON Laboratories, Inc. of San Diego, California ("ACON Labs") and ACON Biotech (Hangzhou) Co., Ltd. of Hangzhou, China ("ACON Bio") (collectively, "ACON"). *Id.* at 26087-88. The Office of Unfair Import Investigations is not a party to the investigation. *Id.* at 26088.

The Commission subsequently terminated the investigation with respect to certain claims based on PTS's withdrawal of those allegations. Specifically, the Commission terminated the investigation with respect to claims 1-3, 5, 10, 13, 14, 18, and 20 of the '397 patent and claims 5, 7, and 9 of the '721 patent. *See* Order. No. 7 (Sept. 10, 2018), *not reviewed*, Notice (Sept. 25, 2018); Order No. 10 (Jan. 31, 2019), *not reviewed*, Notice (Feb. 21, 2019); Order No. 15 (Mar. 12, 2019), *not reviewed*, Notice (Apr. 9, 2019). The Commission also terminated the investigation for infringement purposes with respect to claim 17 of the '397 patent; claims 2, 3, 13, and 14 of the '721 patent; and claim 10 of the '818 patent. Order No. 14 (Feb. 14, 2019), *not reviewed*, Notice (Mar. 5, 2019). Accordingly, at the time of the Final Initial Determination, the only remaining claims asserted were claim 19 of the '397 patent; claims 1, 4, 6, 8, and 15 of the '721 patent; and claims 8, 9, and 11 of the '818 patent.

On February 13, 2019, the presiding ALJ issued an ID granting a summary determination that PTS satisfied the economic prong of the domestic industry requirement for each of the three asserted patents under section 337(a)(3)(A), (B), and (C). Order No. 13 (Feb. 13, 2019). No party petitioned for review of the ID, and the Commission declined to review the ID. Notice (Mar. 12, 2019).

The ALJ held an evidentiary hearing on February 19-22 and 25, 2019. On June 4, 2019, the ALJ issued the final ID and found a violation of section 337 with respect to claim 19 of the '397 patent and claims 1, 4, 6, 8, and 15 of the '721 patent, and no violation of section 337 with respect to the '818 patent. Initial Determination on Violation of Section 337 (Final ID) and Recommended Determination on Remedy and Bond ("RD") (June 4, 2019). The final ID found that, *inter alia*: (1) PTS showed that the use of the accused products infringed claim 19 of the '397 patent and claims 1, 4, 6, 8, and 15 of the '721 patent, but failed to show that the accused products infringed claims 8, 9, or 11 of the '818 patent; (2) PTS showed that ACON Labs directly infringed claim 19 of the '397 patent and claims 1, 4, 6, 8, and 15 of the '721 patent, and ACON Bio is liable for contributory infringement with respect to those claims; (3) PTS showed that the domestic industry requirement is satisfied with respect to all three asserted patents; and (4) ACON failed to show that any asserted claim is invalid by clear and convincing evidence. *Id.* at 66-67, 98.

On June 17, 2019, ACON filed a petition for review of the final ID with respect to the findings on the '397 and '721 patents.[1] PTS did not file a petition for review. On June 25, 2019, PTS opposed ACON's petition for review.[2]

On August 13, 2019, the Commission determined to review the final ID and sought briefing with respect to the following issues:

> (1) whether ACON Laboratories, Inc.'s use of the accused products in the United States constitutes a violation of 19 U.S.C. 1337(a)(1)(B)(i);

[1] Respondents' Petition for Review of the Initial Determination on Violation of Section 337 and Recommended Determination on Remedy and Bond (Jun. 17, 2019) ("ACON Pet.").

[2] Complainant Polymer Technology Systems, Inc.'s Response to Respondents' Petition for Review of the Initial Determination (Jun. 25, 2019) ("PTS Pet. Resp.").

(2) the final ID's construction of "reacting HDL . . . without precipitating said one or more non-selected analytes" in the '721 patent, as well as related findings on infringement, the domestic industry, and invalidity; and

(3) the final ID's finding that all of the asserted claims of the '721 patent are not shown to be invalid for a lack of enablement.

Notice, 84 Fed. Reg. 42949-50 (Aug. 19, 2019). The Commission did not review any other issues, including the final ID's determination that PTS failed to show a violation of section 337 with respect to the '818 patent. *Id.* at 42949.

On August 27, 2019, PTS and ACON filed written submissions in response to the Commission's request for briefing, and on remedy, bonding, and the public interest. PTS filed separate submissions for its response to the briefing questions[3] and its response on remedy, bonding, and the public interest,[4] and Respondents filed a single submission on all issues.[5] On May 3, 2019, PTS[6] and ACON[7] filed reply submissions. No submissions from the public were received.

B. The '397 and '721 Patents

The '397 patent is entitled "Method for Determining HDL Concentration from Whole Blood or Plasma," and claims priority to December 21, 2001. JX-0001 ('397 patent). The '397

[3] Complainant Polymer Technology Systems, Inc.'s Initial Written Submission to the Commission (Aug. 27, 2019) ("PTS Init. Sub.").

[4] Complainant Polymer Technology Systems, Inc.'s Public Interest Submission (Aug. 27, 2019) ("PTS PI Sub.").

[5] Respondents' Initial Supplemental Submission in Response to Notice of Commission Determination to Review Final Initial Determination in Part (Apr. 26, 2019) ("Resp. Init. Sub.").

[6] Complainant Polymer Technology Systems, Inc.'s Reply Written Submission to the Commission (Sept. 3, 2019) ("PTS Rep. Sub.").

[7] Respondents' Reply to Complainants' Response to the Commission's Request for Additional Briefing (May 3, 2019) ("Resp. Rep. Sub.").

patent generally relates to a method of using a blood test strip to separate out red blood cells and non-high-density-lipoprotein ("HDL") cholesterol in order to test for a concentration of HDL cholesterol. *Id.* at Abstract. The only asserted claim of the '397 patent, claim 19, a method claim, reads as follows:

> 19. A method of determining concentration of HDL cholesterol in a whole blood sample, said method comprising:
>
> a) providing a layered stack comprising a dispersement layer, a red blood cell separation layer, a non-HDL separation chemistry layer, and an HDL reaction layer; said red blood cell separation layer not containing an agglutinin or a coagulant, said non-HDL cholesterol separation chemistry layer containing non-HDL cholesterol separation chemicals for separating the non-HDL blood components from the HDL blood components so that the non-HDL components do not participate in the reaction in said HDL reaction layer; said HDL reaction layer containing chemicals for reacting with said HDL; said layers arranged in a vertical stack with said dispersement layer at the top and said HDL reaction layer at the bottom;
>
> b) applying blood to said dispersement layer and permitting fluid from said blood to first flow laterally across said dispersement layer and then to flow vertically downward in said stack to said HDL reaction layer without substantial lateral migration of fluid below said dispersement layer,
>
> c) separating said red blood cells from a fluid portion of said blood in said red blood cell separation layer;
>
> d) separating said non-HDL cholesterol from said HDL cholesterol using said non-HDL cholesterol separation chemicals;
>
> e) reacting said HDL in said HDL reaction layer in a colorimetric reaction; and
>
> f) determining the HDL cholesterol concentration in said reaction layer by measuring the reflectance of said reaction layer after said colorimetric reaction.

JX-0001 ('397 patent) at 26:8-41. The only issue under review with respect to the '397 patent is whether ACON Labs' direct infringement of this method claim constitutes a violation of section

337. All other issues of claim construction, infringement, validity, and domestic industry were not reviewed with respect to the '397 patent and thus became the determination of the Commission. 84 Fed. Reg. at 42949.

The '721 patent is entitled "Non-Precipitating Bodily Fluid Analysis System," and claims priority to August 17, 2004. JX-0002 ('721 patent). The '721 patent generally relates to a method of using a dry test strip to test for a concentration of HDL cholesterol while avoiding precipitating undesired analytes. *Id.* at Abstract. The asserted claims of the '721 patent, claims 1, 4, 6, 8, and 15, which are all method claims, read as follows (including incorporated dependent claims 2, 5, and 7):

> 1. A method of determining a characteristic of high density lipoprotein (HDL) from a plurality of analytes in a bodily fluid, said method comprising:
>
> providing said bodily fluid containing HDL and one or more non-selected analytes;
>
> providing a dry test strip having a well with porous layers within said well that allow said analytes to pass creating a vertical column of said analytes having a defined volume;
>
> applying said bodily fluid to said well in said dry test strip; and
>
> **reacting HDL** in the bodily fluid with a reactant in said dry test strip to provide an indication of said characteristic while preventing said one or more non-selected analytes from participating in said reaction, **without precipitating said one or more non-selected analytes**.
>
> 2. A method as in claim 1 wherein said bodily fluid is blood.
>
> 4. A method as in claim 2 wherein said one or more non-selected analytes are selected from the group consisting of analytes, such as LDL (low density lipoproteins), VLDL (very low density lipoproteins), ILDL (intermediate density lipoproteins), and chylomicrons (big, tryglyceride-rich lipoproteins).

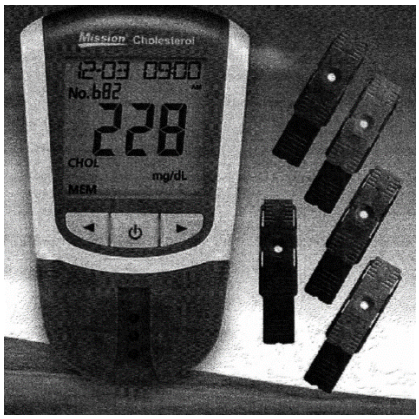
> 5. A method as in claim 1 wherein said indication is an optical indication.
>
> 6. A method as in claim 5 wherein said optical indication is a colorimetric indication.
>
> 7. A method as in claim 1 wherein said preventing comprises complexing said non-selected analyte so that it cannot participate in said reaction.
>
> 8. A method as in claim 7 wherein said complexing comprises interacting said non-selected analytes with a polyanion.
>
> 15. A method as in claim 7 wherein said complexing comprises exposing said non-selected analyte to a reagent comprising dextran sulphate and a divalent metal.

JX-0002 ('721 patent) at 16:54-18:17 (highlighting the claim construction term under review in bold). The issues under review with respect to the '721 patent are whether ACON Labs' direct infringement of this method claim constitutes a violation of section 337; the construction of "reacting HDL . . . without precipitating said one or more non-selected analytes" in the '721 patent, as well as related findings on infringement, the domestic industry, and invalidity; and whether the specification enabled the full scope of the asserted claims. 84 Fed. Reg. at 42949.

C. The Accused Products

The accused products in this investigation are the Mission® Cholesterol Meter and Mission® Cholesterol Test Devices 3-1 Lipid Panel (collectively, "the Accused Products" or the "ACON 3-1 Products"). Stipulations of the Parties at ¶ 14. ACON Bio manufactures the accused products in China, *id.* at ¶ 19, and ACON Labs imports the accused products into the United States, *id.* at ¶ 44. ACON Labs and its affiliate, Azure Institute, Inc., stipulated that they have used the accused products in the United States according to their Directions for Use (JX-0008). *Id.* at ¶ 5, 45-46. The Accused Products are imported and packaged as complete and ready to use for the analysis of blood or other bodily fluids to detect cholesterol or other target

analytes, and they are neither combined with other articles nor physically modified in any material way after importation. *Id.* at ¶¶ 106-58; *see also* ACON Post-Hearing Br. at 1 ("Even if ACON were found to infringe, every method step would occur entirely within or upon the test devices" and for the '397 patent "the ACON Meter would only infringe when used with the ACON 3-1 Devices."). An exemplary Accused Product is shown below:



RX-0409.

D. The Domestic Industry Products

The asserted domestic industry products are the CardioChek Plus, CardioChekPA, and CardioCheck Meters, and the HDL Cholesterol and CHOL+HDL test strips (collectively, "the Domestic Industry Products"). Stipulations of the Parties at ¶ 31. With respect to the '721 patent, the parties stipulated that a finding that the Accused Products infringe necessarily means that the alleged domestic industry products satisfy the domestic industry requirement. *See* Stipulations of the Parties at ¶ 54-55; Second Set of Stipulations of the Parties (Feb. 19, 2019) at ¶ 246, 250.

II. STANDARD

With respect to the issues under review, "the Commission may affirm, reverse, modify, set aside or remand for further proceedings, in whole or in part, the initial determination of the

administrative law judge." 19 C.F.R. § 210.45(c). The Commission also "may take no position on specific issues or portions of the initial determination," and "may make any finding or conclusions that in its judgment are proper based on the record in the proceeding." *Id.*

III. ANALYSIS

The Commission determines to make the findings, conclusions, and supporting analysis set forth below. Any findings, conclusions, and supporting analysis by the ALJ that are under review and are not inconsistent with our analysis and conclusions below are affirmed.

A. The "Precipitating" Limitation

For the reasons set forth below, with respect to the '721 patent, the Commission determines to construe "precipitating" to mean "separating a solid substance or material from a solution by a chemical reaction." Under that construction, for the reasons discussed *infra*, the Commission finds that PTS has established infringement and the domestic industry requirement with respect to claims 1, 4, 6, 8, and 15 of the '721 patent, and that ACON has failed to demonstrate that any asserted claim of the '721 patent is invalid by clear and convincing evidence.

1. Claim Construction

a. The Final ID

Each of the asserted claims of the '721 patent requires the limitation "reacting HDL . . . without precipitating said one or more non-selected analytes." JX-0002 ('721 patent) at 16:65-17:2. PTS argued to the ALJ that "precipitating" should be construed to mean "forming and separating a solid from a bodily fluid by chemical reaction without further intervention." Revised Joint Chart of Agreed and Disputed Claim Constructions at 2 (Aug. 17, 2018). ACON argued to the ALJ that "precipitating" should be construed to have its "plain and ordinary

meaning, which is bringing a substance out of solution to form a solid and/or an oil, and/or a colloid thereof." *Id.*

The final ID construed "reacting HDL . . . without precipitating said one or more non-selected analytes" to "cover a reaction that results in the formation of a complex of non-selected analytes." Final ID at 31-32. The final ID found that the parties' dispute was over the distinction between complexing and precipitating and found that the dispute was resolved by a construction that clarified that a reaction that results in the formation of a complex does not constitute "precipitating." *Id.* at 30-31. The final ID found that the specification taught that prior art systems created precipitates that could clog pores and reduce test accuracy, but the invention of the '721 patent created complexes to avoid the creation of precipitates. *Id.* at 29-30.

b. Petition and Response

In its petition for review, ACON argued that the ALJ's construction is erroneous because it fails to define the meaning of "precipitating" and is a violation of the Administrative Procedure Act ("APA") because the ALJ did not give advance notice of his construction. ACON Pet. at 52-55, 57. Instead, ACON argued that the ALJ should have adopted ACON's proposed construction, which is consistent with the testimony of its expert, Dr. Louis DeFilippi. *Id.* at 55-57.

In response, PTS contended that the ALJ's construction is appropriate. PTS Pet. Rep. at 42-48. PTS argued that the ALJ resolved the controversy between the parties and properly rejected ACON's proposed construction. *Id.* at 42-44, 45-48. PTS further argued that ACON was on notice of PTS's contention that creating a complex satisfied the limitation "without precipitating." *Id.* at 44-45.

The Commission determined to review the ALJ's construction. Notice, 84 Fed. Reg. at 42949. The Commission sought briefing on whether "precipitating" should be construed to mean "separating a substance or material from a solution," with the clarification that "complexing" does not constitute "precipitating" in the context of the '721 patent. *Id.* at 42950.

c. The Parties' Submissions

In its response to the Commission's request for briefing, ACON argues that the Commission's proposed construction of "precipitating" is erroneous because it does not require the formation of a "solid, oil, and/or colloid," does not require that the separation be a chemical reaction and includes an unsupported negative limitation regarding complexing. ACON Init. Sub. at 4-9. ACON also argues that the Commission's construction is an APA violation. *Id.* at 7-9. PTS argued that the Commission's proposed construction is appropriate and that no APA violation occurred. PTS Init. Sub. at 8-14; PTS Rep. Sub. at 4-8.

d. Analysis

The Commission addresses each of ACON's arguments in turn.

1) "Solid, Oil, and/or Colloid"

ACON contends that "precipitating" should be construed to state that the precipitate is "a solid, oil, and/or colloid." ACON Init. Sub. at 5-6. PTS argues that the construction should not state that a precipitate includes an "oil and/or colloid" because ACON has not shown that whether a precipitate is an "oil and/or colloid" is even relevant to any claim or defense in this investigation. PTS Rep. Sub. at 5.

The Commission has determined that it need not decide whether the construction of "precipitating" includes an "oil and/or colloid." Claim terms need only be construed if they "are in controversy, and only to the extent necessary to resolve the controversy." *Vivid Techs., Inc. v.*

Am. Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999). Here, as PTS argues, ACON has failed to demonstrate that the inclusion or exclusion of "oil and/or colloid" from the construction of "precipitating" has any impact on any issue in this investigation. Accordingly, that aspect of the construction is not in controversy, and the Commission declines to construe "precipitating" to include "oil and/or colloid."

Even if the "oil and/or colloid" aspect were in controversy, the Commission finds that the record does not support including those terms in the construction of "precipitating." A claim term is to be given the "meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Philips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (*en banc*). Here, the terms "oil" and "colloid" do not appear in the intrinsic record. Although ACON also relies on its expert Dr. DeFilippi's testimony, Dr. DeFilippi acknowledged that he did not look for the meaning of "precipitating" generally, but rather conducted Internet searches to specifically find mentions of "oily precipitate" and "crystalline precipitate."[8] But despite these results-oriented searches, Dr. DeFilippi found only a 1978 book and a 1996 paper referring to an "oily precipitate," and only a 1994 paper that refers to "a stable colloidal precipitate," none of which purport to define the term "precipitating" generally. Declaration of Louis DeFilippi at Ex. 3-6. The Commission finds that this evidence and testimony is insufficient to establish that a person of ordinary skill in the art would have considered "precipitating" to include "oil and/or colloids."[9]

[8] Complainant Polymer Technology Systems, Inc's Responsive Claim Construction Brief at Ex. E (Aug. 31, 2018), DeFilippi Depo. at 65:18-67:6 (Aug. 24, 2018).

[9] Additionally, PTS provided evidence that colloids are not precipitates. PTS's Responsive Claim Construction Br. at Ex. F.

The Commission, however, determines that the construction of "precipitating" requires the creation of a solid. No party disputes that the term "precipitating" covers the formation of a solid particle. *Compare* ACON's original proposal ("bringing a substance out of solution to form a **solid** and/or an oil and/or a colloid thereof") *with* PTS's original proposal ("forming and separating a **solid** from a bodily fluid by a chemical reaction without further intervention") (emphasis added).[10] Construing "precipitating" to require the formation of a solid is also consistent with the specification's teaching that "precipitates" clog filters, which suggests that "precipitating" creates solid particles that cannot pass through the filters.[11] The construction is also consistent with Federal Circuit precedent finding that precipitation involves the formation of a solid. *See, e.g., Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1328 (Fed. Cir. 2012) ("Taxanes, however, have low solubility in water and tend to **precipitate, i.e., form solid clumps**, and come out of solution.") (emphasis added).[12] In the context of the '721 patent, whether a process creates a solid can be determined by whether particles are large enough to clog the filter pores of the subject test strips. *See* JX-0002 ('721 patent) at 1:63-65 (stating that precipitates tend to block pores in filters); 14:38-45 (stating that "[p]recipitation creates particles of precipitate that would tend to clog pores").

[10] ACON Init. Sub. at 5 n.4, 5; *see also id.* at 6 ("precipitates are most commonly **solid** particles") (emphasis added).

[11] *See* JX-0002 ('721 patent) at 1:63-65 (stating that precipitates tend to block pores in filters); 14:38-45 (stating that "[p]recipitation creates particles of precipitate that would tend to clog pores").

[12] Although *Aventis* was not interpreting the meaning of the term "precipitating" in the '721 patent, the parties agreed that the '721 patent gave no special meaning to the term "precipitating." *See* Joint Claim Construction Chart at 2 (containing proposed constructions that all purport to explain the "plain and ordinary meaning" of "precipitating").

2) Separating

ACON contends that the Commission's proposed construction is erroneous because it does not specify that "precipitating" requires chemical separation and it could be viewed as covering physical separation. ACON Init. Sub. at 5-7. PTS argues that the Commission's proposed construction is appropriate, PTS Init. Sub. at 8, and contends that ACON failed to support its position with intrinsic evidence or explain why that difference matters to this investigation, PTS Rep. Sub. at 5.

The Commission determines that "precipitating" should be construed to require chemical separation. The specification refers to precipitation as a chemical reaction. JX-0002 ('721 patent) at 1:62 (stating that "other lipoproteins are reacted to form a precipitate"). The specification also disparages prior art systems that separate by filtering. *Id.* at 1:59-2:5 (disparaging systems that "depend on precipitation and/or filtration" because "such separation" causes accuracy problems due to clogged filters). Requiring chemical separation is also consistent with PTS's original proposed construction[13] and extrinsic evidence,[14] each of which state that "precipitating" requires a chemical reaction.

3) "Complexing"

ACON contends that the Commission's proposed construction erroneously states that "complexing" is not "precipitating" despite the lack of intrinsic evidence that "complexing" and "precipitating" are mutually exclusive. ACON Init. Sub. at 7-9. PTS contends that the

[13] *See* Revised Joint Chart of Agreed and Disputed Claim Constructions at 2 (construing "precipitating" as "forming and separating a solid from a bodily fluid **by a chemical reaction** without further intervention") (emphasis added).

[14] PTS's Opening Claim Construction Br. (Aug. 17, 2018) at Ex. C (defining "precipitate" as "to make a substance separate from a chemical compound and fall to the bottom of a liquid **during a chemical reaction**") (emphasis added).

Commission's proposed construction is correct in that "complexing" does not constitute "precipitating" in the context of the '721 patent. PTS Init. Sub. at 10-12; PTS Rep. Sub. at 6.

The Commission determines that the construction of "precipitating" should not contain a statement that "complexing" necessarily excludes "precipitating." The intrinsic evidence states that "complexing" is one method for preventing non-selected analytes from reacting without precipitating, but does not state that the formation of any quantity of any complex necessarily demonstrates that no precipitate was formed. *See* JX-0002 ('721 patent) at claim 7; Abstract; 1:59-2:15. Thus, although the '721 patent is directed to forming complexes to avoid precipitating, it is not appropriate to define whether a reaction constitutes "precipitating" based on whether or not a complex is formed.

4) APA Violation

ACON contends that the construction proposed in the Commission's notice of review is a violation of the APA. ACON Init. Sub. at 7-9. ACON argues that no party proposed that the term "precipitating" should be construed as not covering complexing, so both the ALJ's construction and the Commission's proposed construction violate the APA because ACON did not have notice and an opportunity to respond to such a construction. *Id.* PTS argues that ACON failed to cite any authority in support of its assertion of an APA violation, PTS Rep. Sub. at 8, and contends that ACON should not have been surprised by the construction considering that PTS had repeatedly argued that "precipitating" excludes "complexing," PTS Init. Sub. at 11-12.

The Commission finds that ACON has failed to demonstrate an APA violation. The APA requires that an administrative agency give parties notice of a hearing and provide an opportunity to submit facts and arguments. 5 U.S.C. § 554(b) and (c). Here, there is no dispute

that the construction of "precipitating" was an issue in controversy and that the parties each presented facts and arguments regarding the term's proper construction. Although the ALJ did not adopt either construction proposed by the parties, ACON cites no authority for the proposition that an agency is required to do so. *See* ACON Init. Sub. at 7-9 (citing no authority). Rather, precedent shows that a tribunal in an adversarial action may arrive at its own claim construction in compliance with the APA.[15]

Moreover, in addition to the notice and opportunity to respond during the proceedings before the ALJ, the Commission gave ACON additional notice and the opportunity to respond during the Commission petition process and in requested briefing. The Commission's notice of review specifically gave ACON notice and the opportunity to respond to the Commission's proposed construction, and the Commission incorporated ACON's proposals into the Commission's construction to the extent they were properly supported by record evidence. 84 Fed. Reg. at 42950. Indeed, the Commission removed the portion of the ALJ's construction that ACON complained violated the APA. Accordingly, ACON has had notice of numerous opportunities to provide evidence and argument on the proper construction of "precipitating," so the Commission did not violate the APA in arriving at its own construction of the term.

[15] *See Hamilton Beach Brands, Inc. v. f'real Foods, LLC*, 908 F.3d 1328, 1339-40 (Fed. Cir. 2018) (holding that it is not an APA violation for an agency to arrive at its own claim construction for a disputed term as long as the parties had the opportunity to argue the construction); *Intellectual Ventures II LLC v. Ericsson Inc.*, 686 Fed. Appx. 900, 905-06 (Fed. Cir. 2017) (same); *Genzyme Therapeutic Prods. Ltd. P'ship, v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1366-67 (Fed. Cir. 2016) (holding that, for an *inter partes* tribunal, "[t]here is no requirement … for the institution decision to anticipate and set forth every legal or factual issue that might arise in the course of trial").

5) Summary

For the reasons set forth above, the Commission finds that "precipitating" requires the formation of a solid and requires separation by a chemical reaction, and that the presence of "complexing" does not necessarily mean that no precipitation occurred. Accordingly, the Commission has determined to construe "precipitating" to mean "separating a solid substance or material from a solution by a chemical reaction."

2. ACON Labs' Use of the Accused Products Satisfies the "Without Precipitating" Limitation

The Commission must now assess how its construction of "precipitating" affects the issues of direct infringement, the domestic industry, and invalidity. Infringement requires "sufficient evidence to prove that the accused product or process contains, either literally or under the doctrine of equivalents, every limitation of the properly construed claim." *Seal-Flex, Inc. v. Athletic Track and Court Constr.*, 172 F.3d 836, 842 (Fed. Cir. 1999). Here, the ALJ found under his construction that PTS had shown that the Accused Products directly satisfied the "without precipitating" limitation because: (1) PTS's expert showed that the separation of non-HDL cholesterol was performed by complexing; (2) the accused products give accurate readings, which shows that the complex reaction is both preventing the non-HDL from reacting and avoiding the clogging of the pores; (3) PTS's expert performed a fluorescent microscopy test which demonstrated that the LDL cholesterol was not captured in the glass fiber pores but rather migrated to the reaction layer; and (4) PTS's expert performed a scanning electron microscope test that demonstrated that the pores in the test strip were not clogged with precipitate. Final ID at 52-57.

The Commission finds that PTS has demonstrated that ACON Labs' use of the Accused Products satisfies claims 1, 4, 6, 8, and 15 of the '721 patent under the Commission's

construction of "precipitating" for the reasons set forth in the final ID. *Id.* PTS's expert, Dr. Stephen Weber, showed that the Accused Products perform a reaction "without separating a solid substance or material from a solution by a chemical reaction" by demonstrating through fluorescent microscopy testing that the use of Accused Products did not cause precipitates to clog the pores of the glass fiber layers. Final ID at 54-55; CX-1004; CX-1005; RX-0747; Tr. 136:2-10, 145:3-150:2, 152:10-154:10, 277:15-17, 278:4-279:14, 282:20-284:24, 287:4-6, 314:14-316:2, 876:16-877:12. Additionally, Dr. Weber and fellow PTS expert, Dr. Adrienne Hoeglund, demonstrated through scanning electron microscopy that the use of the Accused Products did not create precipitates in any portion of the test strip. Final ID at 54, 56-57; CX-1004; CX-0795; Tr. 114:17-119:23, 120:6-22, 121:16-22, 123:11-24, 136:17-23, 162:3-164:13, 164:20-165:9. Although ACON provided testing showing precipitation, PTS persuasively demonstrated that ACON's testing was conducted in an environment that was substantially dissimilar from what occurs in the Accused Products. Specifically, ACON used a test tube instead of a test strip; ACON agitated the test tube instead of letting it rest; ACON used a reagent ten times more concentrated than the actual formulation of the Accused Products; and ACON used a duration of three minutes instead of the Accused Products' forty-five seconds to two minutes. Final ID at 86-87; Tr. 665:5-18, 667:18-668:8, 802:22-803:16. Based on the evidence above, the Commission finds that PTS has shown by the preponderance of the evidence that ACON Labs' use of the Accused Products practices the "without precipitating" limitation under the Commission's construction of "precipitating," and thus ACON Labs directly infringes claims 1, 4, 6, 8, and 15 of the '721 patent.

3. Domestic Industry

Section 337 requires "an industry in the United States, relating to the articles protected by the patent" that "exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). A part

of that analysis involves an examination of "whether the industry produces articles covered by the asserted claims," which "is essentially the same as that for infringement, *i.e.*, a comparison of the domestic products to the asserted claims." *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). Here, the parties stipulated that the ALJ's findings on whether the Accused Products practice the asserted claims for infringement also apply to whether the Domestic Industry Products practice the asserted claims. Final ID at 72; Stipulations of the Parties at ¶ 54-55; Second Set of Stipulations of the Parties (Feb. 19, 2019) at ¶ 246, 250. Accordingly, because the Commission finds that PTS showed that the Accused Products infringe claims 1, 4, 6, 8, and 15 of the '721 patent under the Commission's construction set forth above, the Commission also finds that PTS has shown based on the record evidence that the Domestic Industry Products practice claims 1, 4, 6, 8, and 15 of the '721 patent.

4. Invalidity

A patent is invalid by anticipation if the accused infringer shows by clear and convincing evidence that "a single prior art reference discloses each and every limitation of the claimed invention," which can include a "missing characteristic [that] is necessarily present, or inherent, in the single anticipating reference." *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). Anticipation by inherency, however, requires that the "prior art necessarily functions in accordance with, or includes, the claimed limitations," so "[t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 639 (Fed. Cir. 2011).

Here, ACON alleged that the asserted claims of the '721 patent are invalid because they are anticipated by U.S. Patent No. 5,460,974 ("Kozak") (RX-0016). Although ACON acknowledged that Kozak does not expressly teach a reaction "without precipitating," ACON argues that Kozak inherently teaches "without precipitating" by disclosing the use of dextran

sulfate. ACON Init. Sub. at 22-24. The ALJ found that, while PTS showed that dextran sulfate can react "without precipitating" in certain circumstances, such as in the Accused Products, neither PTS nor ACON showed that dextran sulfate necessarily reacts "without precipitating" in all instances, such as in that of Kozak. Final ID at 89. The ALJ also found that Kozak specifically referred to dextran sulfate as a "precipitating compound." *Id.* (citing RX-0016 at 15:5-16, 20:45-51).

The Commission finds that, under its construction of "precipitating," ACON failed to demonstrate by clear and convincing evidence that Kozak satisfies the "without precipitating" limitation for the same reasons set forth in the final ID. ACON failed to provide any evidence that Kozak inherently teaches a reaction that occurs "without precipitating" under any construction of "precipitating." Rather, Kozak teaches the opposite by disclosing the use of dextran sulfate as a "precipitating compound." RX-0016 at 15:5-16, 20:45-51; Tr. 925:17-926:8. Considering that there is no evidence that Kozak or the '721 patent gave a different meaning to the term "precipitating," the Commission finds that Kozak's express disclosure of precipitating fails to satisfy the "without precipitating" limitation by clear and convincing evidence. Accordingly, the Commission finds that ACON failed to show by clear and convincing evidence that Kozak anticipates any of the asserted claims of the '721 patent.

ACON also alleged that the asserted claims of the '721 patent are invalid because they are anticipated by U.S. Patent No. 5,215,886 ("Patel"). The final ID found that ACON failed to demonstrate that Patel disclosed the "dry test strip" limitation and the "without precipitating" limitation. Final ID at 90-92. The Commission's modification of the construction of "precipitating" does not affect the first ground, which is an issue that ACON did not petition for review and itself necessitates a finding that Patel does not anticipate any of the asserted claims.

With respect to the second ground, the Commission finds that ACON has failed to present any evidence that Patel discloses a reaction that occurs "without precipitating" under any construction of "precipitating." Rather, Patel teaches the opposite by disclosing the use of a "dextran sulfate solution" for "solution phase precipitation." RX-0018 at 8:65; Tr. 923:22-925:16; *see also* RX-0018 at 1:45-55; 3:41-46; 7:69-9:45. Accordingly, the Commission finds that, under its construction of "precipitating," ACON failed to demonstrate by clear and convincing evidence that Patel anticipates any of the asserted claims of the '721 patent.

B. Enablement

ACON made two enablement arguments. First, ACON alleged that the asserted claims of the '721 patent are invalid for lack of enablement because the disclosed invention created precipitates and thus did not function as claimed. The ALJ rejected ACON's argument because, although ACON showed that the use of dextran sulfate may create precipitates in certain circumstances, ACON failed to show that a person of ordinary skill in the art could not practice the claimed invention without undue experimentation. Final ID at 84-88. The Commission finds that changing the construction of "precipitating" does not change ACON's failure of proof, and thus finds that ACON failed to show by clear and convincing evidence that any asserted claim of the '721 patent is invalid for failing to enable the claimed invention. Second, ACON argued that the asserted claims of the '721 patent are invalid because the specification does not enable the full scope of the claimed invention. For the reasons set forth below, the Commission finds that ACON has failed to show by clear and convincing evidence that any asserted claim is invalid due to a lack of enablement for failing to enable the full scope of the claim.

1. Final ID

The final ID found that ACON failed to show by clear and convincing evidence that any asserted claim of the '721 patent is invalid for a lack of enablement. Final ID at 84-88. ACON

argued that the final ID erred in its enablement findings because the specification does not enable a person of ordinary skill in the art to practice the full scope of the claimed invention without undue experimentation. ACON Pet. at 66-68. The Commission determined to review that issue and sought briefing from the parties.

2. The Parties' Arguments

ACON argues that the specification does not enable a person of ordinary skill in the art to practice the full scope of the claimed invention without undue experimentation because the asserted claims cover broad categories of reagents, but the specification provides little guidance on how to select those reagents. ACON Init. Sub. at 26-28. PTS argues that, although ACON argued that the asserted claims were invalid for a lack of enablement because the claimed invention did not work as claimed, ACON waived its opportunity to argue that the asserted claims do not enable the full scope of the claimed invention by failing to present that argument to the ALJ. PTS Init. Sub. at 18-20. PTS further argues that the specification provides guidance on practicing the claims, and that ACON has not provided facts demonstrating that a person of ordinary skill in the art could not practice the invention without undue experimentation. *Id.* at 21-27; PTS Rep. Sub. at 21.

3. Analysis

The enablement requirement necessitates that the patentee disclose "the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . . ." 35 U.S.C. § 112 ¶ 1. The requirement "is met when at the time of filing the application one skilled in the art, having read the specification, could practice the invention without 'undue experimentation.'" *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1336 (Fed. Cir. 2013) (quoting *In re Wands*, 858 F.2d 731, 736-37 (Fed.

Cir. 1988)). Thus, the relevant inquiry is "whether, with [the patentee's] patent specification as an initial guide, the hypothetical skilled artisan's knowledge of the surrounding art and ability to modestly experiment would have been sufficient to enable him to make and use [the claimed invention]." *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003). Enablement is a question of law based on underlying factual findings and must be shown by clear and convincing evidence. *MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1380 (Fed. Cir. 2012).

The Commission finds that ACON failed to show by clear and convincing evidence that a person of ordinary skill in the art, using the specification and knowledge of the art, could not practice the full scope of the invention without undue experimentation. Although ACON briefly argued to the ALJ that the full scope of the asserted claims of the '721 patent was not enabled, ACON failed to address the knowledge of the skilled artisan and whether undue experimentation was required. ACON Pre-Hearing Br. at 263-64; ACON Post-Hearing Br. at 39, 41. Thus, even in response to the Commission's request for briefing, ACON has failed to identify any evidence or argument stating that undue experimentation would be required to use the full scope of the claimed invention. Moreover, although ACON cites a paper stating that the use of dextran sulfate and Mg^{2+} can cause precipitation in certain circumstances, that paper fails to demonstrate that a person of ordinary skill in the art would be unable to measure the HDL concentration without precipitating in the test strip method of the claimed invention. Accordingly, by failing to adequately address undue experimentation and the knowledge of the art, ACON failed to demonstrate a lack of enablement by clear and convincing evidence.

C. A Violation Based on ACON Labs' Direct Infringement of a Method Claim

This investigation presents the question whether ACON Labs is in violation of section 337(a)(1)(B)(i) based on its importation of the ACON 3-1 Products, *i.e.*, the Mission® Cholesterol Meters and the Mission® Cholesterol Test Devices 3-1 Lipid Panels, the domestic use of which by ACON Labs the Commission has previously found constitutes direct infringement of the asserted method claims (*see supra*). For the reasons set forth below, the Commission finds that the evidence indicates that the imported ACON test strips and ACON Meter perform the claimed methods when used according to ACON's Directions for Use (JX-0008); and that ACON Labs' importation and subsequent use of these "articles that infringe" violated section 337(a)(1)(B)(i).

1. Final ID

The ALJ found that ACON Labs is liable for direct infringement of the methods claimed in the '721 and '397 patents, that ACON Bio is liable for contributory infringement of these method claims, and that there is a violation of section 337. Final ID at 1, 66-68. The Commission determined to review the issue of whether ACON Labs' importation into the United States of the ACON test strips and ACON Meter that it subsequently used to practice the claimed methods constitutes a violation of section 337. Although no party petitioned for review of the final ID with respect to this issue, the Commission determined to review the issue on its own motion. 19 C.F.R. § 210.44.

2. The Parties' Arguments

The Commission sought briefing on whether it should find ACON Labs in violation of section 337 based on its direct infringement of the asserted method claims using the imported test strips and meter. 84 Fed. Reg. at 42950. ACON Bio and ACON Labs argue that the Commission should not find a violation with respect to ACON Labs because Commission

precedent states that a violation must be based on articles that infringe at the time of importation, but ACON Labs' direct infringement occurs only when the articles are used after importation. ACON Init. Sub. at 1-4 (citing *Certain Electronic Devices with Image Processing Systems, Components Thereof, and Associated Software*, Inv. No. 337-TA-724, USITC Pub. No. 4374, Comm'n Op. at 13-19 (Dec. 2, 2011) (public version) ("*Electronic Devices*")). ACON contends that the Commission's decision in *Electronic Devices* was unaffected by the Federal Circuit's holding in *Suprema, Inc. v. International Trade Commission*, 796 F.3d 1338 (Fed. Cir. 2015) (*en banc*). ACON Rep. Sub. at 1-3.

PTS argues that ACON Labs' direct infringement constitutes a violation of section 337 pursuant to the Federal Circuit's holding in *Suprema*, which stated that the Commission may base a violation on post-importation infringement. PTS Init. Sub. at 3-4 (citing *Suprema*); PTS Rep. Sub. 1. PTS further argues that the Commission should find a violation of section 337 because the subject products are non-staple articles that have no use other than to practice the asserted method claims. PTS Init. Sub. at 4-8; PTS Rep. Sub. at 1-3. Finally, PTS argues that both ACON Bio and ACON Labs should each be held liable for a violation of section 337 because they are co-owned corporate affiliates. PTS Init. Sub. at 8.

3. Analysis

For the reasons set forth below, the Commission holds that ACON Labs violated section 337 by importing the ACON 3-1 Products into the United States and using these articles to directly infringe the asserted method claims of the '721 and '397 patents.

ACON's argument that no violation exists because its products are not "articles that infringe" at the time of importation[16] has twice been rejected by the United States Court of

[16] ACON argues that its ACON 3-1 Products "do not meet every limitation of the asserted claims at the time of importation because the claims require applying a bodily fluid to the accused

Appeals for the Federal Circuit. Specifically, the Federal Circuit sitting *en banc* in *Suprema*, repudiated a time-of-importation requirement. *Suprema*, 796 F.3d at 1348-52. The Court again rejected the argument that section 337 does not apply to articles that infringe after importation in *Comcast Corp. v. International Trade Commission*, 951 F.3d 1301, 1308 (Fed. Cir. 2020) ("The Commission correctly held that Section 337 applies to articles that infringe after importation."). Thus, ACON's attempt to avoid a violation determination based on its time-of-importation argument is inconsistent with controlling Federal Circuit precedent.[17]

The Commission, therefore, turns to its controlling statute to determine whether a violation by ACON Labs has been established in this investigation. The statute sets forth the elements of an unlawful act based on patent infringement in section 337(a)(1)(B)(i) as follows:[18]

> **(a) Unlawful Activities; covered industries; definitions**
>
> (1) [T]he following are unlawful . . .:
>
> (B) The *importation into the United States*, the sale for importation, or the sale within the United States after importation *by the* owner, *importer*, or consignee, of *articles that —*
>
> (i) *infringe* a valid and enforceable United States patent. . .

products." ACON Init. Sub. at 2.

[17] To the extent the Commission's determinations in *Electronic Devices,* Inv. No. 337-TA-724, *Certain Gaming and Entertainment Consoles, Related Software, and Components Thereof*, Inv. No. 337-TA-752, Final Initial Remand Determination (Mar. 22, 2013), *not reviewed*, Notice (May 23, 2013), or any subsequent decision, have been interpreted to mean that there is a time of importation requirement in section 337, those determinations are effectively overruled by *Suprema, Comcast,* and by this decision of the Commission.

[18] An additional requirement for a violation is the existence of a domestic industry with respect to articles protected by the asserted patents. 19 U.S.C. § 1337(a)(2), (a)(3). The ALJ issued a summary determination that PTS satisfied the economic prong of the domestic industry requirement for each asserted patent, and no party petitioned for review of that determination. Order No. 13 (Feb. 13, 2019), *not reviewed,* Notice (Mar. 12, 2019). The Commission has also found that the domestic industry products practice the claims of the asserted patents. *See supra.*

19 U.S.C. § 1337(a)(1)(B)(i) (emphasis added).

As to the first requirement in the statute – "importation into the United States" – the parties stipulated that ACON Labs imported the ACON 3-1 Products into the United States. Stipulation of the Parties at ¶¶ 44-45. The phrase following the "importation" language, specifies the identity of the person who can be held liable for an unlawful act of "importation into the United States": "by the owner, importer, or consignee" of the subject articles. There is no dispute that ACON Labs is the "importer" of the ACON 3-1 Products. *Id.*

The last phrase in section 337(a)(1)(B)(i) applicable to a violation predicated upon patent infringement — "articles that infringe a valid and enforceable patent"[19] — is a phrase that the Federal Circuit concluded in *Suprema* lacks an understood meaning because 35 U.S.C. § 271 defines "infringe" in terms of *actions* that infringe, whereas section 337 refers to *articles* that infringe.[20] *Suprema*, 796 F.3d at 1346-47. The Federal Circuit found that Congress had not provided an unambiguous resolution to that uncertainty. *Id.* at 1347-49.

In both *Suprema* and *Comcast,* the Court opined on the meaning of "articles that infringe" in the context of induced infringement under section 271(b). The Federal Circuit concluded in *Suprema* that the Commission's interpretation of the phrase "articles that infringe" in section 337 to cover articles that were used by the seller to induce the importer to directly infringe the claimed method was reasonable and consistent with the statutory text, the text of

[19] As to the validity and enforceability of the patents at issue here, as noted above, ACON has failed to prove by clear and convincing evidence that the '397 patent and '721 patent claims are invalid. *See supra.*

[20] The Federal Circuit explained that "[b]y using the word 'infringe,' section 337 refers to 35 U.S.C. § 271, the statutory provision defining patent infringement." *Id*. at 1346. The Federal Circuit confirmed that the word "infringe" does not narrow section 337's scope to any particular subsections of section 271, and explained that the term encompasses direct infringement, induced infringement, and contributory infringement. *Suprema,* 796 F.3d at 1346.

section 337 as a whole, the legislative history, and the statutory policy, and as such, should not be overturned. *Suprema*, 796 F.3d at 1349-52. The Court reasoned that "[i]nduced infringement is one kind of infringement, and when it is accomplished by supplying an article, the article supplied can be an 'article that infringes' if the other requirements of inducement are met." *Suprema*, 796 F.3d at 1349. Similarly, the Court in *Comcast* upheld the Commission's determination that section 337 applies to products that were imported on behalf of a respondent and supplied to its customers with instructions to use the imported products with their mobile devices to directly infringe the asserted system claims. *Comcast,* 951 F.3d at 1308 ("It is undisputed that direct infringement of the '263 and '413 patents occurs when the imported X1 set-top boxes are fitted by or on behalf of Comcast and used with Comcast's customers' mobile devices. Reversible error has not been shown in the Commission's determinations that the X1 set-top boxes imported by and for Comcast for use by Comcast's customers are 'articles that infringe' in terms of Section 337.").[21]

Although the Court's rulings applied the term "articles that infringe" in the context of induced infringement, many of the holdings therein are relevant to the context of a violation predicated on an allegation of direct infringement by the respondent. First, similar to the analysis for induced infringement, "use" of a patented invention is a type of direct infringement under 35 U.S.C. § 271(a); one that Congress chose not to exclude from the types of

[21] *See also Suprema,* 796 F.3d at 1350-51 (affirming the reasonableness of the Commission's interpretation of section 337(a)(1)(B) to reach articles used to induce direct infringement in the United States consistent with Congressional intent to broadly empower the Commission to "'prevent *every type and form* of unfair practice ….'") (quoting S.Rep. No. 67-595, at 3 (1922) (emphasis added by Court); *TianRui Group Co. Ltd. v. Int'l Trade Comm'n*, 661 F.3d 1322, 1331-32 (Fed. Cir. 2011) (affirming the reasonableness of the Commission's construction of section 337 to reach imported articles involved in trade secret misappropriating conduct outside the United States in light of Congressional intent to broadly address unfair acts involving imported articles).

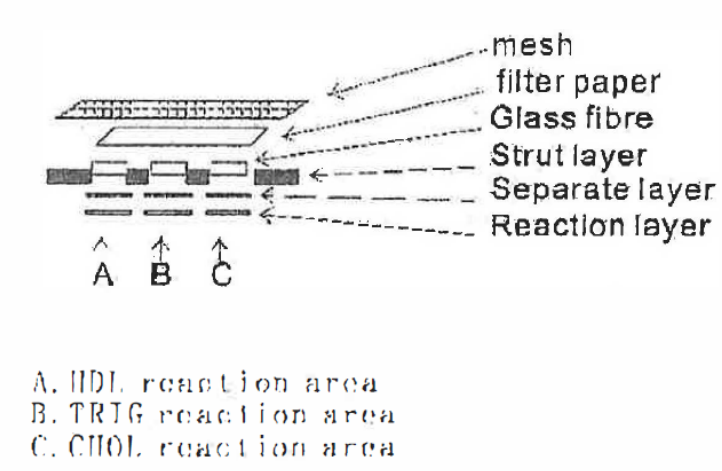
infringements actionable under section 337. *See* 35 U.S.C. § 271(a) ("[W]hoever without authority makes, uses, offers to sell, or sells any patented invention . . . or imports . . . any patented invention . . . infringes the patent."); *Suprema*, 796 F.3d at 1348 (Congress did not preclude section 337 from covering the ordinary case of post-importation use without post-importation sale.).[22] Pertinent to the facts in this investigation, to infringe a patented method by using it, a direct infringer must carry out all of the steps of the claimed method. *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 921 (2014). Second, the Court's reasoning in *Suprema* makes clear that the status of an article at the time of importation does not preclude a finding of violation based on direct infringement of a method claim. *Suprema,* 796 F.3d at 1348-52.

The facts here show that ACON Labs used the imported ACON 3-1 Products (test strips and meters) in the United States according to the ACON Directions for Use and that their use, with the application of a blood sample, carried out the steps of the claimed methods of the '271 and '397 patents. As such, the ACON 3-1 Products are "articles that infringe" under section 337 and ACON Labs is a direct infringer under section 271(a). As discussed above, the patent claims

[22] As the Court observed in *Suprema,* "There is no indication that Congress, in 1988, meant to contract the Commission's authority regarding patent infringement. To the contrary, Congress said it was expanding Commission authority." 796 F.3d at 1351. Even before the 1988 amendments to section 337, the Commission found an unfair act in the use of articles like the ACON 3-1 Products here. In *Certain Apparatus for the Production of Copper Rod*, Inv. No. 337-TA-52 ("*Copper Rod*"), the patent claims at issue (in U.S. Patent No. 3,317,994) covered "a method of hot-forming non-homogenized continuously cast copper" with a number of method steps recited. Respondent Krupp imported its copper casting and rolling systems, *Copper Rod*, Comm'n Op. at 18, and tested those systems in the United States after importation, *id.* at 15 ("[T]he installation and use of such a system by Krupp engineers during the start-up operations at Asarco's Amarillo, Texas, facility, constitutes infringement by the Krupp respondents of the claims [of] the '994 patent."). The Commission held that Krupp's importation was a violation of section 337. Congress has never indicated, before or after 1988, that the Commission's authority under section 337 does not extend to a respondent's use of imported articles to directly infringe a method claim as in *Copper Rod*.

are directed to methods of determining desired characteristics of blood (or in some cases, bodily fluid) by applying a blood sample onto the top surface of the dispersement layer of the test strips, and, after the fluid has worked through the claimed multi-layered vertically-stacked test strip structures and reacted with a reagent, obtaining a reading corresponding to the concentration of the desired analyte. JX-0001 ('397 patent) at 26:8-41; JX-0002 ('721 patent) at 16:54-18:17. The claim language reads on the structure and operation of the ACON 3-1 Products such that, as the evidence shows, ACON Labs' use of these products according to ACON's Directions for Use results in the performance of the claimed method steps upon applying a single blood sample to the test strip.[23] ID at 66-67; Stipulation of the Parties at ¶¶ 73-105.

The parties' stipulations describe and illustrate in detail the five-layered vertically-stacked structures of the test strips as well as the chemical and physical compositions of those layers. Stipulation of the Parties at ¶¶ 73-105. The test strip has a general structure shown in the following diagram:



[23] The ALJ found that the ACON 3-1 Products have no substantial non-infringing uses. ID at 67. This finding was not reviewed by the Commission. 84 Fed. Reg. at 42949.

Id. ¶ 82. The parties' stipulations describe with precision how the ACON 3-1 test strips and meter operate, according to ACON's Directions for Use (JX-0008), to determine one or more desired characteristics claimed in the '721 and '397 patents, such as the concentration of HDL cholesterol in the fluid sample. *Id.* at ¶¶ 106-158. To perform a test, ACON's Directions for Use instruct the user to insert an ACON 3-1 Test Device (*i.e.*, the test strip) into a slot on the front of the ACON Meter and apply a single blood (or serum or heparinized plasma) sample to the single application window. *Id.* ¶ 108; RX-0409 at AL00007808. The ACON 3-1 Products themselves then carry out the other steps of the asserted claims.[24] *Id.* ¶ 111-58. The ALJ found, and the Commission affirms herein, that using the ACON 3-1 Products in the manner directed by ACON satisfies all of the limitations of asserted method claim 19 of the '397 patent and claims 1, 4, 6, 8, and 15 of the '721 patent. ID at 66; *see also* PTS Init. Sub. at 4. ("ACON configured the ACON 3-1 Accused Products so that any use of the product – in accordance with ACON's own instructions – infringes.").

ACON Labs cannot avoid liability based on the application of fluid to the test strips in the United States. The record evidence, including the Directions of Use (JX-0008), the product manual (RX-0409), and the parties' stipulations (Stipulation of the Parties), show that ACON 3-1 Products are designed to process fluid after importation and here ACON Labs' employees admittedly put fluid on the test strips when they used the products according to ACON's instructions.

[24] ACON argues that its products are not non-staple items because they may be used in two non-infringing ways: (1) for demonstration or marketing purposes without applying blood; and (2) for testing that is exempt from the patent infringement laws (*e.g.*, 35 U.S.C. § 271(e)(1). ACON Rep. Sub. at 3. These arguments, however, have been waived, and in any event are unsupported by evidence in the record.

Finally, ACON Labs satisfies all other requirements necessary to find direct infringement. ACON Labs stipulated that its employees actually used the ACON 3-1 Products according to ACON's Directions of Use (JX-0008) after importation in the United States. Stipulation of the Parties at ¶¶ 44 & 45. Further, the Commission determined above that ACON Labs' use of these products satisfies the limitations of the asserted method claims, constituting direct infringement of those claims.

In conclusion, the Commission finds that applying the language of the statute, as explained by the Federal Circuit, to the facts here yields the conclusion that the ACON 3-1 Products, used according to ACON's instructions, perform the steps of the method claims; that ACON Labs' use of these products in the United States directly infringes claim 19 of the '397 patent and claims 1, 4, 6, 8, and 15 of the '721 patent under 35 U.S.C. § 271(a); and that ACON Labs' importation of these "articles that infringe" violates section 337(a)(1)(B)(i).[25]

We note that the Commission's current analysis and findings on this issue are specific to the facts in this investigation. They should not be read to limit "articles that infringe" to only analogous situations. In any future investigation in which the Commission is presented with this

[25] As discussed above, the foreign respondent in this investigation, ACON Bio, contributed to the infringement of the Asserted Claims by supplying the Accused Products to ACON Labs for its use in directly infringing the asserted claims after importation into the United States. ID at 66. As noted above, the ALJ found that the ACON 3-1 Products have no substantial non-infringing uses. *Id.* Thus, the ACON 3-1 Products are "articles that infringe" by virtue of ACON Bio's indirect infringement. ACON Labs' importation of the ACON 3-1 Products supplied by ACON Bio to directly infringe the asserted claims is, independently, a violation of section 337(a)(1)(B)(i). *See Suprema*, 796 F.3d at 1352-53.

issue, the Commission will consider and fully assess its controlling statute, Congressional intent, the applicable precedent from the Commission's reviewing courts, and the relevant facts.[26, 27]

IV. REMEDY, THE PUBLIC INTEREST, AND BONDING

A. Remedy

If the Commission finds a violation of section 337, the Commission shall issue an LEO and/or a cease-and-desist order ("CDO") against the infringing articles of the parties found in violation. 19 U.S.C. § 1337(d)(1), (f)(1). Here, the parties agree that the appropriate remedy is the issuance of an LEO. PTS Init. Sub. at 48 (arguing that an LEO is appropriate, and that a CDO is unnecessary); ACON Init. Sub. at 33 (same). Accordingly, the Commission has determined that the appropriate remedy is the issuance of an LEO against ACON Bio's and ACON Labs' products that infringe one or more of claim 19 of the '397 patent and claims 1, 4, 6, 8, and 15 of the '721 patent.

[26] Commissioner Kearns notes that, in any future investigations in which the Commission is presented with this issue (including in the context of imported components accused of infringing an apparatus claim), he is likely to consider such factors as the nature of the imported items and what additional activity occurs in the United States, including any combinations or modifications that are made with respect to the imported articles after importation, all in light of the limitations of the asserted claims.

[27] Commissioner Schmidtlein notes that in this investigation the imported Accused Products, together with the actions of ACON Labs in using the imported Accused Products, carry out all of the recited steps of each asserted method claim in satisfaction of section 271(a). In particular, although the Accused Products themselves do not "provide" any bodily fluid or "apply" such fluid or blood, the actions of ACON Labs in using the Accused Products satisfied that claim language. *See* '397 patent, claim 19 ("applying blood"); '721 patent, claim 1 ("providing said bodily fluid . . . applying said bodily fluid"). In addition, Commissioner Schmidtlein finds that the addition of the "blood" or "bodily fluid" does not constitute a substantial modification of the Accused Products from their status as imported. Commissioner Schmidtlein observes that for these reasons the imported Accused Products constitute "articles that – infringe." In any future investigations in which the Commission is presented with the issue of post-importation direct infringement by the respondent as the basis for the 337 violation, she believes it is appropriate to consider the extent, if any, to which the accused products are modified or combined with other non-accused articles after importation in order to satisfy all of the elements of the asserted claim.

B. The Public Interest

Subsection 337(d)(1) provides that before issuing an LEO upon finding a violation, the Commission must consider "the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers." 19 U.S.C. § 1337(d)(1). For the reasons set forth below, the Commission finds that these factors do not warrant denying a remedy against ACON.

1. Public Health and Welfare

The Commission has historically examined the effect of the remedy on the public health and welfare by looking to whether "an exclusion order would deprive the public of products necessary for some important health or welfare need[.]" *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1360 (Fed. Cir. 2010). ACON acknowledges that there are noninfringing alternatives to obtain blood cholesterol test results, but argues that these noninfringing alternatives are not as convenient as the testing provided by the Accused Products. ACON Init. Sub. at 34-36. PTS argues that there are numerous noninfringing alternatives to test blood cholesterol, and that PTS has the capacity to fulfill all demand for home cholesterol blood tests. PTS PI Sub. at 1-2; PTS Rep. Sub. at 23-24.

The Commission finds that this factor does not weigh against the issuance of a remedy. The relevant issue is not whether there is a public health and welfare benefit provided by blood cholesterol testing generally, but rather whether the exclusion of the Accused Products will negatively impact the public health and welfare. Here, the evidence does not suggest that an unfilled public health and welfare need exists in the home blood cholesterol testing provided by the Accused Products, particularly in light of the continued availability of noninfringing alternatives and the Domestic Industry Products.

2. Competitive Conditions in the United States Economy

With respect to the effect of the remedy on competitive conditions in the United States economy, ACON argues that PTS is attempting to monopolize the cholesterol testing industry to impose high prices on consumers. ACON Init. Sub. at 36. PTS argues that it does not have a monopoly because its market share in the United States blood cholesterol testing market is only approximately [ ], with third-party noninfringing products constituting the remaining approximately [ ] of the market. PTS PI Sub. at 2.

The Commission finds that this factor does not weigh against the issuance of a remedy. In support of its position, ACON points only to its unsubstantiated allegation that PTS is attempting to monopolize the blood cholesterol testing market. The Commission finds that the evidence does not indicate that PTS has a monopoly, particularly in light the undisputed assertion that third parties supply noninfringing products to approximately seventy percent of the market.

3. Production of Like or Directly Competitive Articles in the United States

The third public interest factor is the effect of the remedy on the production of like or directly competitive articles in the United States. Since the domestic industry articles as well as the infringing articles are produced abroad, there is no evidence that issuance of an LEO would adversely impact domestic production of these products. *Certain Personal Data and Mobile Communication Devices and Related Software*, Inv. No. 337-TA-710, USITC Pub. No. 4331, Comm'n Op. at 77 (Dec. 29, 2011). No party has argued that this factor weighs against a remedy. Accordingly, the Commission finds that this factor does not weigh against issuing an LEO against ACON's products.

4. United States Consumers

As to the effect of the remedy on United States consumers, ACON argues that the exclusion of the Accused Products will negatively impact United States consumers by raising prices on home cholesterol test kits and forcing consumers to use less convenient noninfringing alternatives. ACON Init. Sub. at 35-37. PTS argues that the exclusion of the Accused Products will have minimal impact on United States consumers because the Accused Products are not and never have been sold in the United States, and that United States consumers can continue to obtain blood cholesterol tests from PTS or third-party noninfringing alternatives. PTS DI Sub. at 2; PTS Rep. Sub. at 23-24.

The Commission finds that this factor does not weigh against the issuance of a remedy. The Commission finds that United States consumers will continue to have multiple options for blood cholesterol testing even if the Accused Products are excluded. Moreover, the Accused Products have never been sold in the United States, and ACON has failed to show that United States consumers have a compelling need for the availability of a product that they have never been able to purchase.

C. Bonding

During the 60-day period of Presidential review, imported articles that are subject to remedial orders are entitled to conditional entry under bond. 19 U.S.C. § 1337(j)(3). The amount of the bond is specified by the Commission and must be an amount sufficient to protect the complainant from any injury. *Id*; 19 C.F.R. § 210.50(a)(3). The complainant bears the burden of establishing the need for a bond. *See, e.g.*, *Certain Rubber Antidegradants, Components Thereof, and Prods. Containing Same,* Inv. No. 337-TA-533, Comm'n Op. at 39-40 (July 21, 2006). Here, PTS failed to present a reason why a bond is necessary and failed to present any methodology for calculating a bond. Accordingly, the Commission has determined

to set the bond during the period of Presidential review in the amount of zero percent of entered value.

V. CONCLUSION

For the foregoing reasons, the Commission determines that PTS has established a violation of section 337 by ACON Bio and ACON Labs with respect to claim 19 of the '397 patent and claims 1, 4, 6, 8, and 15 of the '721 patent. The Commission determines that the appropriate remedy is the issuance of an LEO against ACON's infringing products, and sets the bond during the period of Presidential review in the amount of zero percent of entered value.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: May 1, 2020

CERTAIN BLOOD CHOLESTEROL TESTING STRIPS AND ASSOCIATED SYSTEMS CONTAINING THE SAME **Inv. No. 337-TA- 1116**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **OPINION** has been served upon the following parties as indicated, on **May 1, 2020**.

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

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	
CERTAIN BLOOD CHOLESTEROL TESTING STRIPS AND ASSOCIATED SYSTEMS CONTAINING THE SAME	**Investigation No. 337-TA-1116**

NOTICE OF COMMISSION DETERMINATION TO REVIEW IN PART A FINAL INITIAL DETERMINATION FINDING A VIOLATION OF SECTION 337; SCHEDULE FOR FILING WRITTEN SUBMISSIONS ON THE ISSUES UNDER REVIEW AND ON REMEDY, THE PUBLIC INTEREST, AND BONDING; EXTENSION OF THE TARGET DATE

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part a final initial determination ("ID") issued by the presiding administrative law judge ("ALJ"), finding a violation of section 337 of the Tariff Act of 1930. The Commission requests briefing from the parties on certain issues under review, as indicated in this notice. The Commission also requests briefing from the parties, interested persons, and government agencies on the issues of remedy, the public interest, and bonding. The Commission has also determined to extend the target date for the completion of the above-captioned investigation to October 21, 2019.

FOR FURTHER INFORMATION CONTACT: Robert Needham, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW, Washington, D.C. 20436, telephone (202) 708-5468. 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, D.C. 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 June 5, 2018, based on a complaint filed by PTS. 83 FR 23087-88. The complaint alleges violations of section 337 in the importation into the United States, the sale for

importation, and the sale after importation within the United States after importation of certain blood cholesterol testing strips and associated systems containing the same by reason of infringement of one or more claims of U.S. Patent Nos. 7,625,721 ("the '721 patent"); 7,625,721 ("the '721 patent"); and 7,494,818 ("the '818 patent"). *Id.* at 26087. The notice of investigation named as respondents ACON Laboratories, Inc. of San Diego, California, and ACON Biotech (Hangzhou) Co., Ltd. of Hangzhou, China (collectively, "ACON"). The Office of Unfair Import Investigations is not a party to the investigation. *Id.* at 26088.

The Commission subsequently terminated the investigation with respect to claims 10, 13, 14, and 20 of the '397 patent based on PTS's withdrawal of those allegations. *See* Order. No. 7 (Sept. 10, 2018), *not reviewed*, Notice (Sept. 25, 2018); Order No. 10 (Jan. 31, 2019), *not reviewed*, Notice (Feb. 21, 2019). The Commission also terminated the investigation for infringement purposes with respect to claim 17 of the '397 patent; claims 2, 3, 13, and 14 of the '721 patent; and claim 10 of the '818 patent based on PTS's withdrawal of allegations. Order No. 14 (Feb. 14, 2019), *not reviewed*, Notice (Mar. 5, 2019). Finally, the Commission terminated the investigation with respect to claims 1-3, 5, and 18 of the '397 patent and claims 5, 7, and 9 of the '721 patent based on PTS's withdrawal of allegations. Order No. 15 (Mar. 12, 2019), *not reviewed*, Notice (April 9, 2019). Accordingly, at the time of the Final ID, PTS asserted for infringement claim 19 of the '397 patent; claims 1, 4, 6, 8, and 15 of the '721 patent; and claims 8, 9, and 11 of the '818 patent. Final ID at 43.

On February 13, 2019, the ALJ issued an initial determination granting a motion for summary determination that PTS established sufficient investments and activities with respect to the PTS articles protected by the asserted patents to satisfy the domestic industry requirement under section 337(a)(3)(A), (B), and (C) for each of three asserted patents. Order No. 13 (Feb. 13, 2019). No party petitioned for review of the ID, and the Commission declined to review the ID. Notice (Mar. 12, 2019).

On June 4, 2019, the ALJ issued a final ID finding a violation of section 337 with respect to the '397 and '721 patents, and no violation with respect to the '818 patent. The ID found that ACON infringed claim 19 of the '397 patent and claims 1, 4, 6, 7, and 15 of the '721 patent, but does not infringe claims 8, 9, and 11 of the '818 patent. The ID also found that PTS showed that its domestic industry articles practice certain claims of each of the three asserted patents, and that no asserted claims are shown to be invalid by clear and convincing evidence.

On June 17, 2019, ACON petitioned for review of the final ID with respect to the '397 and '721 patents, and contingently petitioned for review of the final ID with respect to the '818 patent. PTS did not file a petition for review, and, on June 25, 2019, PTS filed a response to ACON's petition.

Having examined the record of this investigation, including the final ID, the petition for review, and the responses thereto, the Commission has determined to review the final ID in part. Specifically, the Commission has determined to review the following

issues: (1) whether ACON Laboratories, Inc.'s use of the accused products in the United States constitutes a violation of 19 U.S.C. 1337(a)(1)(B)(i); (2) the final ID's construction of "reacting HDL . . . without precipitating said one or more non-selected analytes" in the '721 patent, as well as related findings on infringement, the domestic industry, and invalidity; and (3) the final ID's finding that all of the asserted claims of the '721 patent are not shown to be invalid for a lack of enablement. The Commission has determined not to review any other findings presented in the final ID.

The Commission has also determined to extend the target date for the completion of the investigation until October 21, 2019.

In connection with its review, the Commission is interested in briefing on following issues:

1. Please address whether ACON Laboratories, Inc.'s direct infringement through its use of the accused imported products in the United States is actionable under section 337(a)(1)(B)(i), regardless of any indirect infringement by ACON Biotech (Hangzhou) Co., Ltd. *See* PTS Post-Hearing Initial Br. at 2, n.2. and 4; *Suprema, Inc. v. Int'l Trade Comm'n*, 796 F.3d 1338 (Fed. Cir. 2015) (*en banc*); *Certain Electronic Devices with Image Processing Systems, Components Thereof, and Associated Software*, Inv. No. 337-TA-724, Comm'n Op. (Public Version) (Dec. 21, 2011).

2. Please explain whether it is appropriate to construe the claim term "precipitating" to mean "separating a substance or material from a solution," with the clarification that "complexing" does not constitute "precipitating" in the context of the '721 patent.

3. Please explain whether and how the adoption of the above proposed construction of "precipitating" would affect the issues of infringement, the domestic industry, and invalidity in this investigation.

4. Please explain whether the specification enables the full scope of claims 1, 4, 6, 8, and 15 of the '721 patent. In your discussion, please address and cite record evidence regarding whether a person of ordinary skill in the art at the time of filing of the application resulting in the '721 patent would be able to practice the claimed invention without undue experimentation using something other than dextran sulfate. Additionally, please explain whether ACON preserved before the ALJ its enablement argument regarding the enablement of the full scope of the claims.

The parties are invited to brief only the discrete issues described above, with reference to the applicable law and evidentiary record. The parties are not to brief other issues on review, which are adequately presented in the parties' existing filings.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue a cease and desist order that could result in the respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843, Comm'n Op. at 7-10 (December 1994).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or a cease and desist order would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

WRITTEN SUBMISSIONS: The Commission requests that the parties to the investigation file written submissions on the issues identified in this notice. The Commission encourages parties to the investigation, interested government agencies, and any other interested parties to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding, which issued on June 4, 2019. The Commission further requests that PTS submit proposed remedial orders, state the date when the '397 and '721 patents expire, provide the HTSUS numbers under which the subject articles are imported, and supply a list of known importers of the subject article. The written submissions, exclusive of any exhibits, must not exceed 50 pages, and must be filed no later than close of business on August 27, 2019. Reply submissions must not exceed 25 pages, and must be filed no later than the close of business on September 3, 2019. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR § 210.4(f)). Submissions should refer to the investigation number ("Inv. No. 337-TA-1116") in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf). Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 C.F.R. § 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel[1], solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

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 CFR part 210).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: August 13, 2019

[1] All contract personnel will sign appropriate nondisclosure agreements.

CERTAIN BLOOD CHOLESTEROL TESTING STRIPS AND ASSOCIATED SYSTEMS CONTAINING THE SAME **Inv. No. 337-TA- 1116**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served upon the following parties as indicated, on **August 13, 2019**.

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

On Behalf of Complainant Polymer Technology Systems, Inc.:

Kandis C. Gibson, Esq.
FOSTER, MURPHY, ALTMAN & NICKEL, PC
1150 18th Street. N.W., Suite 775
Washington, DC 20036

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

On Behalf of Respondents ACON Laboratories, Inc. and ACON Biotech (Hangzhou) Co., Ltd.:

Matthew H. Pope, Esq.
RIMON, PC
800 Oak Grove Avenue, Suite 250
Menlo Park, CA 94025

☐ 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 BLOOD CHOLESTEROL TESTING STRIPS AND ASSOCIATED SYSTEMS CONTAINING THE SAME**	**INV. NO. 337-TA-1116**

INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BOND

Administrative Law Judge Clark S. Cheney

(June 4, 2019)

Appearances:

For the Complainant Polymer Technology Systems, Inc.:

Kenneth G. Parker, Esq., and Jason T. Lao, Esq. of Haynes and Boone, LLP of Costa Mesa, CA

Robert P. Ziemian, Esq. of Haynes and Boone, LLP of Denver, CO

Charles M. Jones II, Esq., Michael D. Karson, Esq., and Tiffany M. Cooke, Esq. of Haynes and Boone, LLP of Dallas, TX

Yifang Zhao, Esq. of Haynes and Boone, LLP of Washington, DC

James B. Altman, Esq., Barbara A. Murphy, Esq., and Kandis C. Gibson, Esq. of Foster, Murphy, Altman & Nickel, PC of Washington, DC

For the Respondents ACON Laboratories, Inc. and ACON Biotech (Hangzhou) Co. Ltd.:

Matthew H. Poppe, Esq. of Rimon P.C. of Menlo Park, CA

Craig Kaufman, Esq. of TechKnowledge Law Group LLP of Redwood City, CA

Table of Contents

TABLE OF ABBREVIATIONS

CDX	Complainant's demonstrative exhibit
CIB	Complainant's initial post-hearing brief
CPB	Complainant's pre-hearing brief
CPX	Complainant's physical exhibit
CRB	Complainant's responsive post-hearing brief
CRRB	Complainant's reply post-hearing brief
CX	Complainant's exhibit
Dep.	Deposition
JX	Joint Exhibit
RDX	Respondents' demonstrative exhibit
RIB	Respondents' initial post-hearing brief
RPX	Respondents' physical exhibit
RPB	Respondents' Pre-hearing brief
RRB	Respondents' responsive post-hearing brief
RRRB	Respondents' reply post-hearing brief
RRX	Respondents' rebuttal exhibit
RX	Respondents' exhibit
Stip.	Stipulation of the parties
Tr.	Transcript

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of	
CERTAIN BLOOD CHOLESTEROL TESTING STRIPS AND ASSOCIATED SYSTEMS CONTAINING THE SAME	**INV. NO. 337-TA-1116**

INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BOND

Administrative Law Judge Clark S. Cheney

(June 4, 2019)

Pursuant to the Notice of Investigation, 83 Fed. Reg. 26087 (June 5, 2018), and 19 C.F.R. §§ 210.10(b), 210.42(a)(1)(i), this is the final Initial Determination in the matter of *Certain Blood Cholesterol Testing Strips and Associated Systems Containing the Same*, Investigation No. 337-TA-1116.

For the reasons stated herein, I have determined that a violation of section 337 of the Tariff Act, as amended, has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation, of certain blood cholesterol testing strips and associated systems containing the same that infringe asserted claim 19 of U.S. Patent No. 7,087,397 and asserted claims 1, 4, 6, 8, and 15 of the U.S. Patent No. 7,625,721. I have determined no violation of section 337 based on allegations of infringement of U.S. Patent No. 7,494,818.

I. INTRODUCTION

A. Procedural History

On April 30, 2018, complainant Polymer Technology Systems, Inc. ("PTS") filed a complaint alleging violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain blood cholesterol testing strips and associated systems containing the same by reason of infringement of one or more of U.S. Patent No. 7,087,397 ("the '397 patent"); U.S. Patent No. 7,625,721 ("the '721 patent"); and U.S. Patent No. 7,494,818 ("the '818 patent"). 83 Fed. Reg. 20095 (May 7, 2018).

On June 5, 2018, the Commission instituted this investigation to determine:

> [W]hether there is a violation of subsection (a)(1)(b) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain blood cholesterol testing strips and associated systems containing the same by reason of infringement of one or more claims 1-3, 5, 10, 13-14, and 17-20 of the '397 patent; claims 1-9 and 13-15 of the '721 patent; and claims 8-11 of the '818 patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337.

83 Fed. Reg. 26087 (June 5, 2018).

The named respondents are ACON Laboratories, Inc. of San Diego, California ("ACON Labs") and ACON Biotech (Hangzhou) Co., Ltd. of China ("ACON Biotech") (collectively, "ACON"). *Id.*

The Commission Investigative Staff is not a party to this investigation. *Id.*

On September 10, 2018, I granted an unopposed motion by PTS for termination of the investigation with respect to claim 10 of the '397 patent. Order No. 7, *aff'd*, Notice of Commission Determination Not to Review an Initial Determination Terminating the Investigation As to Claim 10 of U.S. Patent No. 7,087,397 (Sept. 25, 2019). On January 30, 2019, I granted an unopposed

motion by PTS for termination of the investigation with respect to claims 13, 14, and 20 of the '397 patent. Order No. 10, *aff'd*, Notice of a Commission Determination Not to Review an Initial Determination Terminating the Investigation As to Certain Claims of U.S. Patent No. 7,087,397 (Feb. 21, 2019). On February 14, 2019, I granted an unopposed motion by PTS for termination of the investigation with respect to claim 17 of the '397 patent; claims 2, 3, 13, and 14 of the '721 patent; and claim 10 of the '818 patent "for infringement purposes." Order No. 14, *aff'd*, Notice of Commission Determination Not to Review an Initial Determination Terminating the Investigation As to Certain Claims (Mar. 4, 2019). On March 12, 2019, I granted an unopposed motion by PTS for termination of the investigation with respect to claims 1-3, 5, and 18 of the '397 patent; and claims 5, 7, and 9 of the '721 patent for infringement purposes. Order No. 15, *aff'd*, Notice of Commission Determination Not to Review an Initial Determination Terminating the Investigation As to Certain Patent Claims (Apr. 9, 2019).

On February 13, 2019, I granted an unopposed motion by PTS for summary determination that it has satisfied the economic prong of the domestic industry requirement. Order No. 13, *aff'd*, Notice of Commission Determination Not to Review an Initial Determination That Complainant Has Satisfied the Economic Prong of the Domestic Industry Requirement (Mar. 11, 2019).

I held a prehearing conference on February 15, 2019, during which PTS confirmed that the asserted claims remaining at issue for purposes of infringement and domestic industry are claim 19 of the '397 patent; claims 8, 9, and 11 of the '818 patent; and claims 1, 4, 6, 8, and 15 of the '721 patent. Prehearing Tr. 17:17-18:4. The parties also entered into two sets of stipulations, which narrowed the issues for determination in this investigation. *See* Stipulations of the Parties (EDIS Doc. No. 667335) (Feb. 16, 2019); Second Set of Stipulations of the Parties (EDIS Doc. No. 667337) (Feb. 18, 2019) (collectively, "Stip.").

I convened an evidentiary hearing on February 19, 2019, to determine whether section 337 has been violated by reason of the importation into the United States, the sale for importation, or the sale within the United States after importation of allegedly blood cholesterol testing strips and associated systems containing the same. The evidentiary hearing concluded on February 25, 2019. *See* Tr. 1-992.

B. The Parties

1. Complainant Polymer Technology Systems, Inc.

PTS is a corporation organized and existing under the laws of Indiana, with its headquarters and principal place of business located at 7736 Zionsville Road, Indianapolis, Indiana 46268. Stip. ¶ 1. PTS is the owner by assignment of the asserted patents in this investigation. *See* Stip. ¶ 6; '397 patent at cover; '721 patent at cover; '818 patent at cover.

2. The ACON Respondents

Respondents ACON Labs and ACON Biotech are "sister" corporations owned by their founders, Jixun and Feng Lin. *See* RPB at 2-3; Stip. ¶ 5. The companies sell a range of medical products, including the blood cholesterol products at issue in this investigation. RPB at 2-3.

a) ACON Labs

ACON Labs is a California corporation with its principal place of business at 10125 Mesa Rim Road, San Diego, California 92121. Stip. ¶ 3.

b) ACON Biotech

ACON Biotech is a Chinese company with its principal place of business at No. 210 Zhengzhoong Road, West Lake Science and Technology Park, Hangzhou, 310030, China. Stip. ¶ 4.

C. The Asserted Patents

PTS asserts claims under three patents in this investigation: the '397 patent, the '721 patent, and the '818 patent. The asserted patents relate to test devices for determining concentrations of cholesterol and other analytes in blood and other bodily fluids.

U.S. Patent No. 7,087,397 is titled "Method for Determining HDL Concentration From Whole Blood or Plasma," issued on August 8, 2006, and names Sunil G. Anaokar, Gena Lynn Antonopoulos, and Alexandra N. Muchnik as inventors. JX-0001 ('397 patent) at cover page. The patent issued from Application Number 10/329,044, filed on December 23, 2002, and claims priority to provisional application No. 60/342,790, filed on December 21, 2001. *Id.* The patent, on its face, is assigned to PTS. *Id.* The asserted claim of the '397 patent is directed to a method for measuring the concentration of HDL cholesterol in whole blood using a multilayer test strip. *Id.* at Abstract.

U.S. Patent No. 7,625,721 is titled "Non-Precipitating Bodily Fluid Analysis System," issued on December 1, 2009, and names Gregory M. Lawrence and Meredith Knight as inventors. JX-0002 ('721 patent) at cover page. The patent issued from Application Number 11/206,893, filed on April 17, 2005. *Id.* It is a continuation-in-part of U.S. Patent No. 7,435,577, and claims priority to provisional application No. 60/541,681, filed on February 3, 2004, and provisional application No. 60/602,210 filed on August17, 2004. *Id.* The patent, on its face, is assigned to PTS. *Id.* The asserted claims of the '721 patent are directed to a method for analyzing bodily fluid using dry test strips designed to exclude non-desired analytes. *Id.* at Abstract.

U.S. Patent No. 7,494,818 is titled "Method for Determining Concentration of Multiple Analytes in a Single Fluid Sample," issued on February 24, 2009, and names Sunil G. Anaokar, Michele Jeanne Crispino, and Emmanuel Paul Crabtree as inventors. JX-0003 ('818 patent) at cover page. The patent issued from Application Number 10/334,043, filed on December 30, 2002,

and claims priority to provisional application No. 60/344,300, filed on December 28, 2001. *Id.* The patent, on its face, is assigned to PTS. *Id.* The asserted claims of the '818 patent are directed to methods for using a multilayer test strip to measure concentrations of multiple analytes from a single blood sample. *Id.* at Abstract.

D. The Technology at Issue

The level of cholesterol in blood is an indicator of risk of coronary heart disease. Stip. ¶ 66. "Total cholesterol" includes high-density lipoproteins ("HDL"), low-density lipoproteins ("LDL"), very low-density lipoproteins ("VLDL"), and chylomicrons (big, triglyceride-rich lipoproteins). Stip. ¶¶ 67, 72. There is a positive correlation between the levels of LDL and VLDL in blood and coronary heart disease. Consequently, LDL and VLDL are known as "bad cholesterol." Stip. ¶ 68. There is a negative correlation between the level of HDL in blood and coronary heart disease. Consequently, HDL is known as "good cholesterol." Stip. ¶ 69.

Blood also contains red blood cells, also known as erythrocytes. Red blood cells contain hemoglobin. Stip. ¶ 70. Blood, serum, and plasma are bodily fluids that, unless delipidized, contain HDL. Stip. ¶ 71. Blood, serum, and plasma, unless delipidized, also contain LDL, VLDL, intermediate density lipoproteins ("ILDL"), and chylomicrons. Stip. ¶ 72.

The technology at issue in this investigation relates to methods of analyzing blood to detect cholesterol and other analytes using multilayer test strips. *See, e.g.*, '818 patent at Abstract. The patents acknowledge that prior to the work of the inventors, many methods were known in the art for analyzing blood using dry test strips. *See* '721 patent at 1:18-2:7; '397 patent at 1:20-4:27; '818 patent at 1:50-3:27. The patents distinguish themselves from such prior art because that art had required precise timing or multiple additional steps after placing the blood to be analyzed on the dry test strip, or required multiple different test strips. *See* '818 patent at 1:50-57.

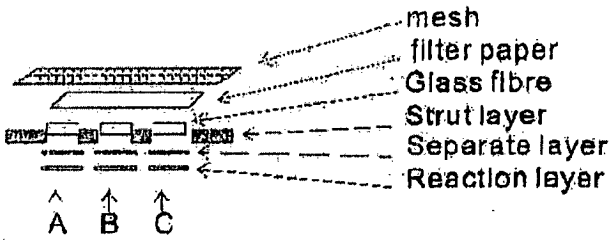
E. The Accused Products

The parties have stipulated that the accused products in this investigation are the Mission® Cholesterol Meter ("ACON Meter") and Mission® Cholesterol Test Devices 3-1 Lipid Panel ("ACON 3-1 Test Devices") (collectively, "ACON 3-1 Accused Products"). Stip. ¶ 14.

An ACON 3-1 Test Device includes a test strip in a plastic cartridge. The plastic cartridge serves as a test strip holder. Stip. ¶ 75. The plastic cartridge consists of an upper housing and a lower housing. Stip. ¶ 77. The upper housing of the ACON 3-1 Test Device is attached to the lower housing by inserting pegs in the upper housing into holes in the lower housing. Stip. ¶ 78.

The top of the test strip cartridge of the ACON 3-1 Test Device has a single circular window for application of a fluid sample. Stip. ¶ 79. The bottom of the test strip cartridge of the ACON 3-1 Test Device has three circular windows for reading test results. The window furthest from the test strip handle is for the HDL result, the middle window is for the triglycerides ("TRIG") result, and the window closest to the handle is for the total cholesterol ("CHOL") result. Stip. ¶ 80.

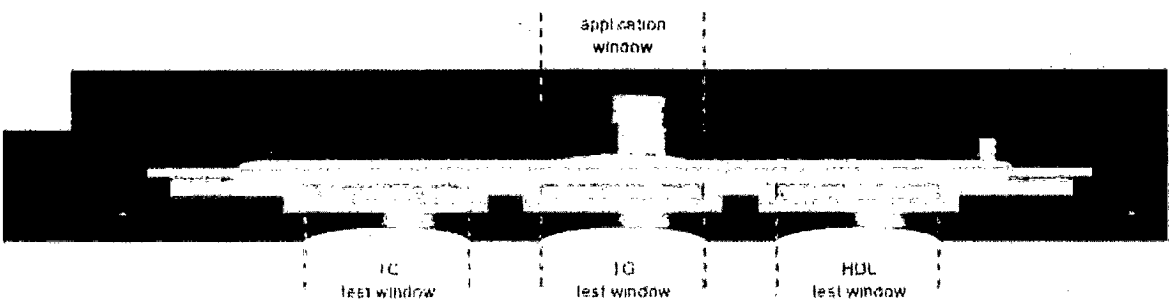
The ACON 3-1 Test Device comprises a test strip located in the test strip holder between the application window and the test reading windows. Stip. ¶ 81. Internally, ACON personnel describe the ACON 3-1 Test Device as including five tiers of material in the vertical direction (illustrated below). From the top down, they are (1) the "mesh" tier, (2) the "filter paper" tier, (3) the "glass fiber" tier, which includes three pieces, (4) the "separate" (also known as "separation") tier, which includes three pieces, and (5) the "reaction" tier (also known as "reagent" or "enzyme" tier), which includes three pieces. Stip. ¶ 83.



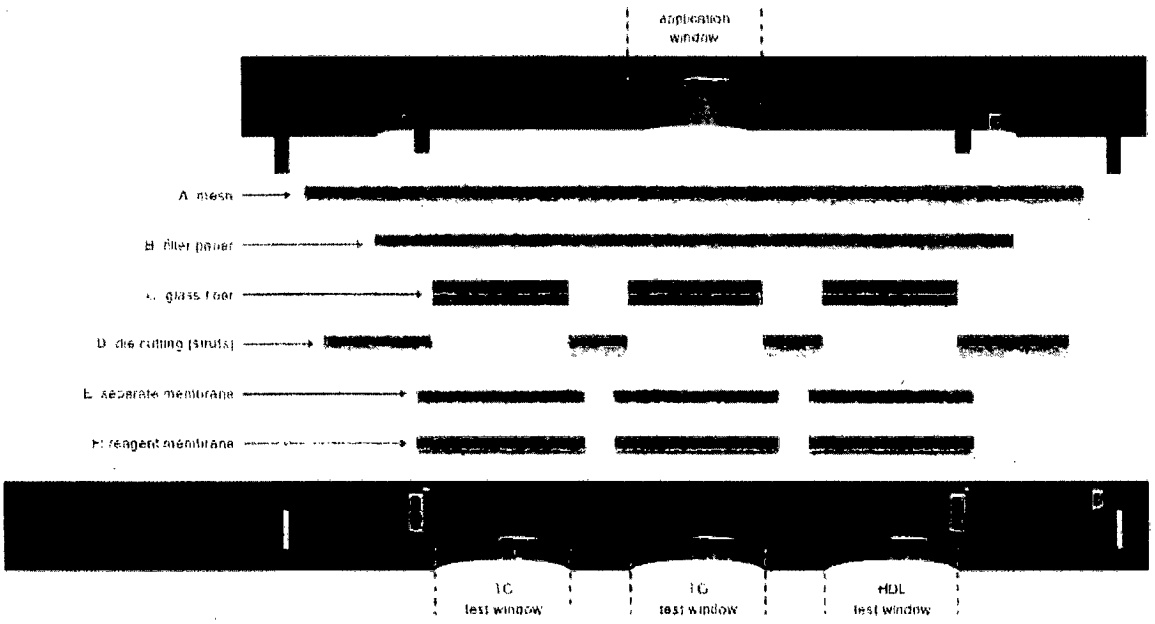
A. HDL reaction area
B. TRIG reaction area
C. CHOL reaction area

Stip. ¶ 82.

In the horizontal direction, the test strip of the ACON 3-1 Test Device is divided into three test stacks (illustrated in the demonstratives reproduced below), each comprising a glass fiber membrane, a separate membrane, and a reaction membrane. Stip. ¶ 87. Each of the three test stacks performs a different test, one for HDL, one for CHOL (TC in the illustration below), and one for TRIG (TG in the illustration below). *See* Stip. ¶ 88.



RDX-0006C.7.



RDX-0006C.8.

ACON instructs users about how to perform a test using the ACON 3-1 Accused Products. First, the user inserts a chip into an ACON Meter. The chip contains a code specific to a batch of ACON 3-1 test strips. The code chip includes equations used by the meter to calculate the HDL, CHOL, and TRIG concentrations for the specific batch of ACON 3-1 test strips. Stip. ¶ 107. The user then inserts an ACON 3-1 test strip into a slot on the front of the ACON Meter. Next the user applies a single blood sample to the single application window. Stip. ¶¶ 108, 110.

After blood fluid passes to the reaction membranes of the ACON 3-1 test strip, colorimetric reactions in each reaction layer produce a color that the ACON Meter reads with a reflectance photometer to determine the HDL, CHOL, and TRIG concentrations in the blood sample. Stip. ¶ 155. The ACON Meter reports results within one to two minutes after fluid is applied. Stip. ¶ 156.

F. The Domestic Industry Products

To satisfy the domestic industry requirement of section 337, PTS relies on the CardioChek Plus, CardioChekPA, and CardioChek Meters and four types of test strips: (1) HDL, (2) CHOL+HDL, (3) CHOL+HDL+GLU, and (4) Lipid Panel. Stip. ¶¶ 31-33. The "'379 DI Products" are the CardioChek Plus, CardioChekPA, and CardioChek Meters and the HDL and CHOL+HDL test strips. Stip. ¶ 31. The "'721 DI Products" are the CardioChek Plus, CardioChekPA, and CardioChek Meters and the HDL and CHOL+HDL test strips. Stip. ¶ 32. The "'818 DI Products" are the CardioChek Plus and CardioChekPA Meters and the CHOL+HDL+GLU and Lipid Panel test strips. Stip. ¶ 33.

The four varieties of PTS test strips at issue in this investigation have some similarities and some differences. As for similarities, all four varieties contain an HDL test stack. A reaction layer in the HDL test stack reacts HDL cholesterol in a body fluid sample using a colorimetric reaction. *See* Stip. ¶¶ 34-37, 166. A properly calibrated PTS meter can be used to determine the concentration of HDL cholesterol in a sample of whole blood based on the colorimetric reaction. *See* Stip. ¶¶ 159-60; *see also id.* at ¶ 257.

The four kinds of PTS test strips differ from each other in the various tests they perform. The PTS Lipid Panel test strip has three circular windows on the bottom for reading test results. The window farthest from the test strip handle is for the total cholesterol result, the middle window is for the HDL cholesterol result, and the window closest to the handle is for the triglycerides result. Stip. ¶ 258.

The PTS CHOL+HDL+GLU test strip also has three circular windows on the bottom for reading test results, but the window closest to the handle is for a glucose result instead of a triglycerides result. The window for the total cholesterol result and for the HDL cholesterol result are in the same positions as for the Lipid Panel test. Stip. ¶ 259.

The PTS CHOL+HDL test strip has two circular windows for reading test results. The window furthest from the test strip handle is for the total cholesterol result and the window closest to the handle is for the HDL cholesterol result. Stip. ¶ 260.

II. JURISDICTION & IMPORTATION

A. Subject Matter Jurisdiction

Section 337 confers subject matter jurisdiction on the Commission to investigate and, if appropriate, to provide a remedy for, unfair acts and unfair methods of competition in the importation, the sale for importation, or the sale after importation of articles into the United States. *See* 19 U.S.C. §§ 1337(a)(1)(B) and (a)(2). PTS filed a complaint alleging a violation of section 337(a) based on the importation, the sale for importation, or the sale after importation of infringing cholesterol test strips into the United States. Accordingly, the Commission has subject matter jurisdiction over this investigation under section 337 of the Tariff Act of 1930. *See Amgen, Inc. v. Int'l. Trade Comm'n*, 902 F.2d 1532, 1536 (Fed. Cir. 1990).

B. Personal Jurisdiction

ACON has appeared and participated in this investigation. The Commission therefore has personal jurisdiction over ACON. *See, e.g., Certain Optical Disk Controller Chips & Chipsets & Prods. Containing Same, Including DVD Players & PC Optical Storage Devices*, Inv. No. 337-TA-506, Initial Determination at 4-5 (May 16, 2005) (unreviewed in relevant part).

C. *In Rem* Jurisdiction

ACON has stipulated that ACON Labs has imported the ACON Meter and ACON 3-1 Test Devices into the United States. Stip. ¶ 44. Accordingly, the Commission has *in rem* jurisdiction over the accused ACON Meter and ACON 3-1 Test Devices. *See Sealed Air Corp. v. Int'l Trade Comm'n*, 645 F.2d 976, 985-86 (C.C.P.A. 1981) (noting the Commission has jurisdiction over imported goods).

D. Importation

As noted above, ACON has stipulated that ACON Labs has "imported into the United States samples of the ACON Meter and the ACON 3-1 Test Devices." Stip. ¶ 44. Accordingly, the importation requirement of section 337 is satisfied as to the accused ACON Meter and ACON 3-1 Test Devices.

E. Standing

The record evidence demonstrates that PTS has standing in this investigation via its ownership by assignment of the asserted patents. *See* '397 patent at Cover; '721 patent at Cover; '818 patent at Cover. ACON does not dispute PTS's ownership of the asserted patents. *See* Stip. ¶ 6.

III. LEGAL PRINCIPLES

A. Claim Construction

"An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*) (internal citations omitted), *aff'd*, 517 U.S. 370 (1996). Claim construction resolves legal disputes between the parties regarding claim scope. *See Eon Corp. IP Holdings v. Silver Spring Networks*, 815 F.3d at 1314, 1319 (Fed. Cir. 2016).

Evidence intrinsic to the application, prosecution, and issuance of a patent is the most significant source of the legally operative meaning of disputed claim language. *See Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001). The intrinsic evidence includes the claims themselves, the specification, and the prosecution history. *See Phillips v. AWH Corp*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (*en banc*); *see also Markman*, 52 F.3d at 979. As the Federal Circuit explained in *Phillips*, courts must analyze each of these

components to determine the "ordinary and customary meaning of a claim term" as understood by a person of ordinary skill in the art at the time of the invention. 415 F.3d at 1313.

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips*, 415 F.3d at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). "Quite apart from the written description and the prosecution history, the claims themselves provide substantial guidance as to the meaning of particular claim terms." *Id.* at 1314; *see Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) ("In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point[ ] out and distinctly claim[ ] the subject matter which the patentee regards as his invention.'"). The context in which a term is used in an asserted claim can be "highly instructive." *Phillips*, 415 F.3d at 1314. Additionally, other claims in the same patent, asserted or unasserted, may also provide guidance as to the meaning of a claim term. *Id.*

The specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Id.* at 1316. "In other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Id.* As a general rule, however, the particular examples or embodiments discussed in the specification are not to be read into the claims as limitations. *Id.* at 1323. In the end, "[t]he construction that stays true to the claim language and most naturally aligns with the

patent's description of the invention will be . . . the correct construction." *Id.* at 1316 (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

When the intrinsic evidence does not establish the meaning of a claim, then extrinsic evidence (*i.e.*, all evidence external to the patent and the prosecution history, including dictionaries, inventor testimony, expert testimony, and learned treatises) may be considered. *Id.* at 1317. Extrinsic evidence is generally viewed as less reliable than the patent itself and its prosecution history in determining how to define claim terms. *Id.* "The court may receive extrinsic evidence to educate itself about the invention and the relevant technology, but the court may not use extrinsic evidence to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence." *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 977 (Fed. Cir. 1999).

B. Infringement

In a section 337 investigation, the complainant bears the burden of proving infringement of the asserted patent claims by a preponderance of the evidence. *See Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1349 (Fed. Cir. 2010). This standard "requires proving that infringement was more likely than not to have occurred." *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1341 n.15 (Fed. Cir. 2005).

1. Literal Infringement

Literal infringement is a question of fact. *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1332 (Fed. Cir. 2008). "Literal infringement requires the patentee to prove that the accused device contains each limitation of the asserted claim(s). If any claim limitation is absent, there is no literal infringement as a matter of law." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000).

2. Indirect Infringement

Section 271 of the Patent Act defines both direct infringement and the two categories of indirect infringement—active inducement of infringement and contributory infringement. 35 U.S.C. § 271(a), (b), and (c). There can be no indirect infringement absent direct infringement. *See Limelight Networks, Inc. v. Akamai Technologies, Inc.*, 134 S. Ct. 2111, 2117 (2014); *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 365 U.S. 341 (1961); *see also Met-Coil Sys. Corp. v. Korners Unltd., Inc.*, 803 F.2d 684, 687 (Fed. Cir. 1986) ("Absent direct infringement of the patent claims, there can be neither contributory infringement . . . nor inducement of infringement.") (citations omitted).

a) Inducement of Infringement

Section 271(b) of the Patent Act prohibits inducement of infringement: "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). *See DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006) *(en banc)* ("To establish liability under section 271(b), a patent holder must prove that once the defendants knew of the patent, they actively and knowingly aided and abetted another's direct infringement.") (citations omitted). "The mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven." *Id.* (citations omitted). A violation of section 337 may arise from an act of induced infringement. *Suprema*, 796 F.3d at 1351-52 (*en banc* opinion).

b) Contributory Infringement

Section 271(c) of the Patent Act prohibits contributory infringement. *See* 35 U.S.C. § 27l(c). "Under 35 U.S.C. § 27l(c), a party who sells a component with knowledge that the component is especially designed for use in a patented invention, and is not a staple article of commerce suitable for substantial noninfringing use, is liable as a contributory infringer."

Wordtech Sys., Inc. v. Integrated Networks Solutions, Inc., 609 F.3d 1308, 1316 (Fed. Cir. 2010). To establish contributory infringement in a section 337 investigation, it must be shown that "(1) there is an act of direct infringement in violation of section 337; (2) the accused device has no substantial non-infringing uses; and (3) the accused infringer imported, sold for importation, or sold after importation within the United States, the accused components that contributed to another's direct infringement." *Spansion*, 629 F.3d at 1353.

C. Validity

A patent is presumed valid. *See* 35 U.S.C. § 282; *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011). A respondent who has raised patent invalidity as an affirmative defense has the burden of overcoming this presumption by clear and convincing evidence. *See Microsoft*, 131 S. Ct. at 2242.

1. Anticipation

Under 35 U.S.C. § 102, a claim is anticipated, and therefore invalid, when "the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000). To be considered anticipatory, the prior art reference must be enabling and describe the applicant's claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention. *See Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1346 (Fed. Cir. 2000).

2. Obviousness

Under 35 U.S.C. § 103, a patent may be found invalid as obvious if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). Because obviousness is determined at the time of invention, rather than the date of litigation, "[t]he great challenge of the obviousness judgment is proceeding without any hint of hindsight." *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1375 (Fed. Cir. 2011).

When a patent is challenged as obvious, the critical inquiry in determining the differences between the claimed invention and the prior art is whether there is an apparent reason to combine the known elements in the fashion claimed by the patent at issue. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 417-418 (2007). Thus, based on a combination of several prior art references, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007) (citations omitted).

Obviousness is a determination of law based on underlying determinations of fact. *Star Scientific*, 655 F.3d at 1374. The factual determinations behind a finding of obviousness include: (1) the scope and content of the prior art, (2) the level and content of the prior art, (3) the differences between the claimed invention and the prior art, and (4) secondary considerations of non-obviousness. *KSR*, 550 U.S. at 399 (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). These factual determinations are referred to collectively as the "*Graham* factors." Secondary considerations of non-obviousness include commercial success, long felt but unresolved need, and the failure of others. *Id.* When present, secondary considerations "give light to the circumstances surrounding the origin of the subject matter sought to be patented," but they are not dispositive on the issue of obviousness. *Geo. M. Martin Co. v. Alliance Mach. Sys. Int'l.*, 618 F.3d 1294, 1304-06

(Fed. Cir. 2010). For evidence of secondary considerations to be given substantial weight in the obviousness determination, its proponent must establish a nexus between the evidence and the merits of the claimed invention. *See W. Union Co. v. MoneyGram Payment Sys. Inc.*, 626 F.3d 1361, 1372-73 (Fed. Cir. 2010) (citing *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995)).

3. Written Description and Enablement

The issue of whether a patent is invalid for failure to meet the written description requirement of 35 U.S.C. § 112, ¶ 1 is a question of fact. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 670 F.3d 1171, 1188 (Fed. Cir. 2012). The hallmark of the written description requirement is the disclosure of the invention. *See Ariad Pharm., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*). The test for determining the sufficiency of the written description in a patent requires "an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Id.* "The level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Id.*

To satisfy the enablement requirement a patent specification must "contain a written description of the invention . . . to enable any person skilled in the art . . . to make and use the same." 35 U.S.C. §112, ¶ 1. The specification must enable a person of ordinary skill in the art to practice the claimed invention without undue experimentation. *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1305 (Fed. Cir. 2010). Although a specification need not disclose minor details that are well known in the art, this "rule" is "merely a rule of supplementation, not a substitute for a basic enabling disclosure." *Auto. Tech. Int'l Inc., v. BMW of N. Am.*, 501 F.3d 1274, 1283 (Fed. Cir. 2007) (*quoting Genentech, Inc. v. Novo Nordisk,*

A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997)). "It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement." *Auto. Tech.*, 501 F.3d at 1283.

Enablement is a question of law with underlying questions of fact regarding undue experimentation. *Transocean*, 617 F.3d at 1305. The factors weighed by a court in determining whether a disclosure requires undue experimentation include: (1) the quantity of experimentation necessary, (2) the amount of direction provided, (3) the presence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability of the art, and (8) the breadth of the claims. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

4. Indefiniteness

A claim must also be definite. Pursuant to 35 U.S.C. § 112, ¶ 2, a patent specification "shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2. Section 112, ¶ 2 requires "that a patent's claims, viewed in light of the specification and prosecution history inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc.* v. *Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). A patent claim that is indefinite is invalid. 35 U.S.C. § 282(b)(3)(A).

D. Domestic Industry

For a patent-based complaint, a violation of section 337 can be found "only if an industry in the United States, relating to the articles protected by the patent . . . concerned, exists or is in the process of being established." 19 U.S.C. § 1337(a)(2). The complainant bears the burden of establishing that the domestic industry requirement is satisfied. *See Certain Set-Top Boxes and Components Thereof*, Inv. No. 337-TA-454, ID at 294, 2002 WL 31556392 (June 21, 2002)

(unreviewed by Commission in relevant part). The domestic industry requirement of section 337 is often described as having an economic prong and a technical prong. *InterDigital Commc'ns, LLC v. Int'l Trade Comm'n*, 707 F.3d 1295, 1298 (Fed. Cir. 2013); *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 12-14, USITC Pub. No. 4120, 2009 WL 5134139 (Dec. 2009).

1. Economic Prong

Section 337(a)(3) sets forth the following economic criteria for determining the existence of a domestic industry in such 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 the statutory 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. *See Certain Variable Speed Wind Turbines and Components Thereof*, Inv. No. 337-TA-376, Comm'n Op. at 15, USITC Pub. 3003 (Nov. 1996).

2. Technical Prong

The technical prong of the domestic industry requirement is satisfied when the complainant in a patent-based section 337 investigation establishes that it is practicing or exploiting the patents at issue. *See* 19 U.S.C. § 1337(a)(2) and (3); *Certain Microsphere Adhesives, Process for Making Same and Prods. Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm'n Op. at 8, 1996 WL 1056095 (Jan. 16, 1996). "The test for satisfying the

'technical prong' of the industry requirement is essentially [the] same as that for infringement, *i.e.*, a comparison of domestic products to the asserted claims." *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). To prevail, the patentee must establish by a preponderance of the evidence that the domestic product practices one or more claims of the patent. It is sufficient to show that the products practice any claim of that patent, not necessarily an asserted claim of that patent. *See Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm'n Op. at 38 (Aug. 1, 2007).

IV. DISPUTED CLAIM CONSTRUCTIONS

Only those claim terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy. *Vanderlande Indus. Nederland BV v. Int'l Trade Comm.*, 366 F.3d 1311, 1323 (Fed. Cir. 2004); *Vivid Tech., Inc. v. American Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

The parties have identified eight claim terms as needing construction. *See* Revised Joint Chart of Agreed and Disputed Claim Constructions (EDIS Doc. No. 653245) (Aug. 17, 2018) ("Joint CC Chart"). Each term is addressed in turn below.

A. Level of Ordinary Skill in the Art

I must determine the meaning of the disputed claim terms as they would have been understood by a person of ordinary skill in the art at the time of the invention. *Phillips*, 415 F.3d at 1313. PTS and ACON both presented evidence about the level of skill possessed by an ordinary artisan in the field relevant to the asserted patents. PTS's expert Dr. Foley testified that a person of ordinary skill in the art would have a bachelor's degree in chemistry, biology, or other related discipline, plus two additional years of relevant work experience. Tr. 911:24-912:6. ACON's expert Dr. Henry testified that a person of ordinary skill in the art for the '397 and '818 patents would have a bachelor's degree in a field such as chemistry or biology plus five years of work

experience on test strips, or an advanced degree with somewhat less work experience. Tr. 491:20-492:3. ACON's expert Dr. DeFilippi testified that a person of ordinary skill in the art for the '721 patent would have a master's degree in a field such as biochemistry, chemistry, or separation science, plus three years of additional experience. Tr. 712:10-17.

Although the parties' experts proposed minor differences in the level of skill they believed an ordinary artisan would possess, no party presented any argument that the understanding of any claim term in this investigation turns on the level of skill of the artisan interpreting the term. Accordingly, any dispute about the appropriate level of skill is moot. Nevertheless, for the sake of thoroughness, I find that a person of ordinary skill in the art with respect to the asserted patents would have at least a bachelor's degree in chemistry, biology, or other related discipline, plus at least two years of work experience in a relevant field.

B. '397 Patent

1. "Red Blood Cell Separation Layer" (claim 19)

The claim term "red blood cell separation layer" is recited in asserted claim 19 of the '397 patent. Claim 19 is a method of determining concentration of HDL cholesterol in a whole blood sample. The claim requires a test strip having certain attributes as part of the method, and the claimed red blood cell separation layer is part of the test strip required for the method.

The parties have two main disputes about this term. First, the parties dispute whether the red blood cell separation layer must be distinct from other claimed layers such as the non-HDL separation chemistry layer and the HDL reaction layer. Second, the parties dispute how much red blood cell separation the layer must perform. PTS contends the claimed red blood cell separation layer can perform other functions and proposes a construction of a "layer whose purpose includes retaining most of the red blood cells from blood." Joint CC Chart at 3. PTS contends its construction is the plain and ordinary meaning of the term. *Id.* ACON proposes a construction of

"a single sheet of material that retains at least 80% of the red blood cells in a whole blood sample and is separate from the non-HDL separation chemistry layer and the HDL reaction layer." *Id.*

This is not the first dispute about whether different limitations in a claim must be distinct physical elements. When the Federal Circuit has considered similar disputes, it has looked to the claim language and the patent specification to determine the proper understanding of the claims. For example, in *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1304 (Fed. Cir. 2011), the court examined the claim language, the teachings of the specification, and the prosecution history to determine that a "needle holder" and "retainer member" need not be separately molded pieces. Similarly, in *Linear Tech. Corp. v. Int'l Trade Comm'n*, 566 F.3d 1049, 1055 (Fed. Cir. 2009), the court declined to construe "second circuit" and "third circuit" to require "entirely separate and distinct circuits" where "nothing in the claim language or specification" supported that construction and the specification disclosed that the circuits could share common circuit elements.

I will follow the same approach here and begin with an examination of the evidence intrinsic to the '397 patent. First, the language of claim 19 does not expressly require the red blood cell separation layer to be physically distinct from other claimed layers. Similarly, nothing in the '397 patent specification requires the claimed "red blood cell separation layer" be a single sheet of material. To the contrary, the patent discloses an embodiment comprising a two-stage blood separation mechanism, wherein a first glass fiber matrix "separates *most* of the blood cells and an adjacent, second matrix, also preferably containing glass fibers, separates *the remainder* of the blood cells." *Id.* at 4:43-47 (emphasis added); *see also id.* at 5:16-18 ("[T]he first glass fiber matrix does not provide complete separation of blood. Instead, *most* of the red blood cells are retained in the first glass fiber layer." (emphasis added)); *id.* at 10:17-19 ("The inventors have found that layer

38, by itself, does not retain 100% of the blood cells. Instead, it has been found that layer 40 also contributes to blood separation.").

Moreover, neither the claim language nor the specification requires that red blood cell separation layer have *only* the function of separating red blood cells, such that it is distinct from the claimed non-HDL separation chemistry layer. The claim language points to a contrary conclusion. Claim 19 states that the method includes "providing a layered stack *comprising* a dispersement layer, a red blood cell separation layer, a non-HDL separation chemistry-layer, and an HDL reaction layer." '397 patent at claim 19 (emphasis added). The term "comprising" is open-ended, meaning claim 19 embraces test strips that have features beyond those specifically recited in the claim. *See Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1371 (Fed. Cir. 2005) (a claim to "[a] safety razor blade unit comprising . . . a group of first, second, and third blades" covered a razor with four blades). Thus, a layer that performs blood separation along with another function, such as non-HDL separation, can be within the meaning of "red blood cell separation layer."

This interpretation is reinforced by evidence that the inventors knew how to place negative or exclusionary limitations on the red blood cell separation layer when they so intended. Specifically, claim 19 requires that the red blood cell separation layer "not contain[ ] an agglutinin or a coagulant." '397 patent at 19. If the inventors intended that the red blood cell separation *not* perform other functions, presumably they would have employed similar language to expressly indicate that fact.

The '397 patent specification also supports a conclusion that a red blood cell separation layer in accordance with the claimed invention can serve more than one purpose. For example, in one described embodiment, layer 40 retains non-HDLs ('397 patent at 10:10-12), but it "*also*

contributes to blood separation" (*id.* at 10:17-19 (emphasis added)). In that embodiment, therefore, layer 40 may function to separate remaining red blood cells *and* separate non-HDL cholesterol. *Id.* at 10:17-23, 10:59-65 ("separation of non-HDLs from HDLs can be achieved in . . . layer 40").

No party has cited evidence from the patent prosecution history that would limit the claimed red blood cell separation layer to a layer physically distinct from other claimed layers or a layer that performs functions in addition to red blood cell separation.

The evidence intrinsic to the '397 patent discussed above is consistent with PTS's proposed construction. PTS's construction does not restrict the red blood cell separation layer to a single material and does not specify a certain percentage of red blood cells that must be separated by that layer.

By contrast, ACON's proposed construction incorporates three limitations that are not supported by the intrinsic evidence. ACON's construction would require that the claimed red blood cell separation layer: (1) retain 80% of the red blood cells in a whole blood sample, (2) be a single sheet of material, and (3) be separate from the non-HDL separation chemistry layer and the HDL reaction layer.

With respect to ACON's first requirement, nothing in the '397 patent specification requires that 80% of the red blood cells be retained in the claimed red blood cell separation layer. One set of experimental data described in the specification did find "that about 80%-90% of red blood cells are retained within layer 38." '397 patent at 8:57-59. Yet, the inventors expressly noted that "[t]he percentage of blood cells retained in layer 38 can vary." *Id.* at 10:21-23. When discussing these results, the specification teaches: "[O]f course, the relative percentages just noted may vary from strip to strip and from sample to sample." *Id.* at 23:40-41. Importing an exemplary experimental finding of 80% separation into the construction of the disputed term is improper. *See Phillips*, 415

F.3d at 1323 (cautioning tribunals to "avoid importing limitations from the specification into the claims").

With respect to ACON's second contention—that the red blood cell separation layer be a single sheet of material—I note that the word "sheet" does not appear in the patent specification. To the extent that ACON intends the word sheet to limit the red blood cell separation layer to a layer physically distinct from other claimed layers, I have already explained why that would be improper. With respect to the third aspect of ACON's construction, I have explained above why excluding functions beyond red blood cell separation would be improper on this record.

In sum, I have determined to apply the plain and ordinary meaning of "red blood cell separation layer" in my infringement and validity analysis of the '397 patent. The plain and ordinary meaning of the term indicates that the "red blood cell separation layer" retains red blood cells from the whole blood sample applied to the test strip, and that the "red blood cell separation layer" does not have to be a single sheet separate from the "non-HDL separation chemistry layer" and/or the "the HDL reaction layer."

2. "Non-HDL Separation Chemistry Layer . . ." (claim 19)

Claim 19 of the '397 patent also recites "a non-HDL separation chemistry layer . . . containing non-HDL cholesterol separation chemicals for separating the non-HDL blood components from the HDL blood components so that the non-HDL components do not participate in the reaction in said HDL reaction layer." The parties' dispute over this term mirrors the dispute over "red blood cell separation layer." ACON contends that the non-HDL separation chemistry layer must be physically distinct from the other claimed layers. Specifically, ACON proposes a construction of "a single sheet of material that is impregnated with non-HDL cholesterol separation chemicals, retains substantially all of the non-HDL cholesterol in a whole blood sample, and is separate from the red blood cell separation layer and the HDL reaction layer." *Id.* PTS proposes

a construction of "material containing non-HDL cholesterol separation chemicals to separate substantially all of the non-HDL from a blood sample," which it asserts is the plain and ordinary meaning of the term. *See* Joint CC Chart at 2.

Again I start with the claim language itself. As noted above, claim 19 is a method of determining concentration of HDL cholesterol in a whole blood sample. The claim requires a test strip having certain attributes as part of the method, and the non-HDL separation chemistry layer is part of the test strip required for the method. The language of claim 19 does not expressly require the non-HDL separation chemistry layer to be physically distinct from other claimed layers.

The '397 specification also contains no requirement that the non-HDL separation chemistry layer be physically distinct from other layers. To the contrary, one of the examples of a non-HDL separation chemistry layer described in the '397 patent is also part of a blood separation mechanism. *See* '397 patent at 10:24-29. Specifically, the patent teaches a layer 40 that contains chemicals to separate out non-HDL cholesterol components so that they do not react in the reaction layer. *Id.* at 10:59-65, 11:26-12:15. The same layer 40 "also contributes to blood separation." *Id.* at 10:17-19. PTS's proposed construction is consistent with this intrinsic evidence.

On the other hand, ACON's proposed construction incorporates limitations that are not supported by the intrinsic evidence. ACON's construction would require that the claimed non-HDL separation chemistry layer: (1) be a single sheet of material, (2) retain substantially all of the non-HDL cholesterol in a whole blood sample, and (3) be separate from the red blood cell separation layer and the HDL reaction layer.

As with the red blood cell separation layer discussed above, the intrinsic evidence does not require that the claimed "non-HDL separation chemistry layer" be a single sheet of material. The word "sheet" does not appear in the patent specification.

The intrinsic evidence also does not require that the non-HDL separation chemistry layer "retain[ ] substantially all of the non-HDL cholesterol in a whole blood sample," as ACON proposes. It is true that the '397 patent teaches an example of a layer 40 in which "non-HDLs are precipitated and retained." '397 patent at 12:10-12. But the claim language does not include language expressly requiring retention of non-HDLs. Claim 19 describes the layer in question as a separation layer, and separation is different from retention. The '397 patent specification reiterates this distinction. The patent describes "multiple chemical and physical functions, viz., separation of blood, precipitation and retention of non-HDL cholesterol." *Id.* at 11:17-21. The implication of that teaching is that "retention" of non-HDL cholesterol is not synonymous with "separation" of non-HDL cholesterol. *See id.*; *see also id.* at 11:34-45. Importing a requirement of non-HDL retention from the specification is improper. *See Phillips*, 415 F.3d at 1323 (cautioning tribunals to "avoid importing limitations from the specification into the claims").

Additionally, the intrinsic evidence does not require that the claimed non-HDL separation chemistry layer have only one function or be separate from the other layers in the invention. Indeed, one described embodiment has a non-HDL separation chemistry layer that "also contributes to blood separation," thereby teaching that a layer can have multiple functions. '397 patent at 10:17-19. *See Retractable Techs., Inc.*, 653 F.3d at 1304 (claimed "needle holder" and "retainer member" need not be separately molded pieces); *Linear Tech. Corp.*, 566 F.3d at 1055 (claimed "second circuit" and "third circuit" did not require "entirely separate and distinct circuits").

ACON has cited no evidence from the patent prosecution history that would limit the claimed non-HDL separation layer in the manner it proposes.

Having reviewed the intrinsic evidence, I have determined to apply the plain and ordinary meaning of "a non-HDL separation chemistry layer . . . containing non-HDL cholesterol separation chemicals for separating the non-HDL blood components from the HDL blood components so that the non-HDL components do not participate in the reaction in said HDL reaction layer" in my infringement and validity analysis of the '397 patent. The plain and ordinary meaning of the term indicates that the "non-HDL separation chemistry layer" does not require a single sheet separate from the "red blood cell separation layer" and the "HDL reaction layer."

C. '721 Patent

1. "Precipitating" (claim 1)

The claim term "precipitating" is recited in asserted claim 1 of the '721 patent. Claim 1 is a method for measuring HDL in a bodily fluid. The last recited step of the method requires reacting HDL in the bodily fluid with a reactant without precipitating non-selected analytes, such as LDL (low density lipoproteins). *Compare* '721 patent at claim 1 *with id.* at claim 4. The parties dispute the scope of processes covered by "precipitating," and whether mechanical actions like filtering or agitation can be involved. Specifically, PTS proposes a construction of "forming and separating a solid from a bodily fluid by a chemical reaction without further intervention." Joint CC Chart at 2. ACON proposes a construction of "bringing a substance out of solution to form a solid and/or an oil, and/or a colloid thereof," which it asserts is the plain and ordinary meaning of the term. *See id.*

The opening paragraphs of the '721 patent specification contain an illuminating discussion about precipitation in the prior art, which informs my understanding of how the term is used in the claim 1. Prior art systems sought to separate an analyte under observation from other unwanted

analytes in a blood sample. For example, prior art test strips for measuring HDL in a blood sample would react other unwanted lipoproteins in the sample to form a precipitate. '721 patent at 1:59-63. The unwanted precipitate would then be filtered from the plasma using filter membranes. *Id.* However, the precipitates would tend to block the pores in the test strip and impede the flow the desired HDL analyte through the test strip. *Id.* at 1:63-37. The blockages reduced the amount of HDL observed at the outcome of the test, reducing the accuracy of the test. *Id.*

The invention described in the '721 patent overcomes the problem of pore blockage. It "reacts the unwanted components of the bodily fluid into complexes that do not participate in the test reaction. The complexes remain free to flow, and thus do not clog membranes or filters." '721 patent at 2:11-15. To transform the unwanted analytes into complexes, the invention uses "reagents that interact with the non-desired analytes." *Id.* at 4:49-52. The '721 patent describes parameters for controlling the interaction between the reagent and non-desired analytes. For example, in a test strip for measuring HDL, the complex comprises an anionic polymer, a divalent metal, and the non-desired lipoproteins. *Id.* at 7:52-54. By controlling the molecular weight, charge density, and branching of the anionic polymer, different reagents can be made "selective" for different non-desired analytes. *Id.* at 7:60-8:53. The reaction between a selective reagent and the undesired analytes in a sample "prevents the undesired analytes from participating" in the portion of the test designed to measure the HDL, leading to more accurate test results. *Id.* at 7:33-36. Importantly for the parties' dispute, the '721 patent teaches one of skill in the art to select certain molecular weights for the anionic polymer in the reagent so that it will "be selective without precipitation." *Id.* at 7:63-66.

The distinction between the process for forming a complex and that of precipitation is the key to resolving the parties' dispute over the meaning of "precipitating." Whatever the meaning

of "precipitating" in claim 1, it does not encompass the process of forming a complex described in the '721 patent specification. The inventors expressly distinguished complexes from precipitates, explaining that precipitation is detrimental to the claimed invention because it creates "particles of precipitate that would tend to clog pores in the test strip." *Id.* at 14:38-40; 12:59-61. This understanding is consistent with the language of claim 1. Claim 1 requires "reacting HDL in the bodily fluid with a reactant . . . without precipitating said one or more non-selected analytes." '721 at claim 1.

The intrinsic evidence surrounding the meaning of "precipitating" in the '721 patent is sufficiently clear that I need not rely on extrinsic evidence to resolve the parties' dispute. I note, however, that the record also contains extrinsic expert evidence consistent with the distinction noted above. PTS's expert Dr. Weber testified credibly about the difference between complexing and precipitation. *See, e.g.*, Tr. 152:24-153:25. He explained complexes are formed when particles stick together in a reversible way without chemically changing, such as when hemoglobin complexes with oxygen to carry oxygen throughout the body. Tr. 153:11-25. He testified that precipitation involves an irreversible chemical reaction, such as when oxygen and iron combine to form rust. Tr. 153:3-10. Dr. Weber's testimony that precipitation is distinct from the formation of a complex is consistent with the distinction drawn by the inventors within the teachings of the '721 patent. Similarly, these teachings are consistent with the testimony of Dr. Foley, who credibly explained that whether precipitation occurs is a function of many factors, including analyte concentration, pH, the solution's ionic strength, the agents used, and their molecular weight. Tr. 913:11-20.

In sum, for purposes of the infringement and validity analysis with respect to the '721 patent limitation, I construe the phrase "reacting HDL . . . without precipitating said one or more

non-selected analytes" to cover a reaction that results in the formation of a complex of non-selected analytes. This construction is sufficient to resolve the factual disputes in this investigation.

2. "Well" (claim 1)

Claim 1 of the '721 patent recites "a well with porous layers within said well that allow said analytes to pass creating a vertical column of said analytes having a defined volume." The dispute between the parties centers on how the boundaries of the claimed well should be defined. Essentially, ACON contends that if any fluid penetrates the sides or bottom of the space in question, it is not a well. Specifically, ACON proposes a construction of "a well with walls that tightly encircle porous layers of a test strip such that, when bodily fluid is added to the test strip, the analytes pass through the porous layers creating a vertical column with a volume defined by the well walls and a bottom feature that do not pass fluid." *Id.* PTS proposes a construction of "a well with boundaries and porous layers of a test strip such that, when bodily fluid is added to the test strip, the analytes pass through the porous layers creating a vertical column with a volume defined by the well," which it asserts is the plain and ordinary meaning of the term. *See* Joint CC Chart at 2.

The '721 specification describes several wells. For example, Figure 2 illustrates well 62, which itself is divided into an inner portion 64 and an outer portion 66 by retainer 90. '721 patent at 3:16-27. The patent also refers to inner portion 64 as a test strip well. *Id.* at 25. The patent additionally teaches "the structures of the invention create a sample container, . . . 480, the sidewalls and bottom of which essentially do not pass liquid." *Id.* at 13:9-12. The container 480, depicted in Figure 5, "results in a well-defined test volume of sample fluid." *Id.* at 13:14-15. These various disclosures indicate that the inventors used the term "well" broadly. The best understanding of what the inventors meant by the well limitation in claim 1 are the words of the

claim itself. Adopting a construction of different words than those used in the claim would likely lead to less, rather than more, clarity.

I decline to adopt ACON's proposed construction. It incorporates limitations that are not supported by the intrinsic evidence. For instance, the word "tightly" is not used in the '721 specification. Additionally, ACON's limitation of "walls and a bottom feature that do not pass fluid" narrows the scope of the claim beyond what is indicated by the teachings of the patent. In particular, the specification describes one embodiment where "the structures of the invention create a sample container . . . the sidewalls and bottom of which *essentially* do not pass liquid, and the top of which is open." '721 patent at 13:9-12 (emphasis added); *see also id.* at 14:20–23 ("the bottommost layer, such as 58 and 460, which forms the bottom of container 80, *preferably* does not pass liquid" (emphasis added). "[E]ssentially do not pass liquid" and "do not pass fluid" are not equivalent, and the latter phrase should not be imported into the claimed invention through claim interpretation.

Accordingly, it is my determination that this disputed claim term does not need construction, and that I will apply the plain and ordinary meaning of the term in the infringement and validity analysis of the '721 patent.

3. "Said Analytes" (claim 1)

The claim term "said analytes" is recited in asserted claim 1 of the '721 patent. The dispute between the parties is a question of antecedent basis. The dispute is best understood by looking at the claim as a whole, with relevant terms highlighted:

> 1. A method of determining a characteristic of high density lipoprotein (HDL) from ***a plurality of analytes*** in a bodily fluid, said method comprising:
>
> providing said bodily fluid containing ***HDL*** and ***one or more non-selected analytes***;

> providing a dry test strip having a well with porous layers within said well that allow ***said analytes*** to pass creating a vertical column of ***said analytes*** having a defined volume . . .

'721 patent at claim 1 (emphasis added).

ACON argues that "said analytes" in the second recited step of the method is "indefinite and thus not capable of construction." Joint CC Chart at 4. Specifically, ACON contends that "said analytes" could refer to (1) the "plurality of analytes" recited in the preamble of claim, which represents a combination of all biologically active materials in the blood serum; or (2) the "one or more non-selected analytes" found in the first claim step; or (3) the combination of HDL and the one or more non-selected analytes, since HDL is another analyte recited in the first step of claim 1.

PTS takes the position that this term is not indefinite for lack of an antecedent basis and does not need construction.

Under 35 U.S.C. § 112, ¶ 2, a patent must conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as the invention. A patent claim fails to satisfy this statutory requirement and, as a result, is invalid for indefiniteness if its language fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). "[T]he definiteness inquiry trains on the understanding of a skilled artisan at the time of the patent application, not that of a court viewing matters *post hoc*." *Id.* at 911. Indefiniteness is a question of law with factual underpinnings, and ACON has the burden to establish indefiniteness by clear and convincing evidence. *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1363 (Fed. Cir. 2018); *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1332 (Fed. Cir. 2010).

The fact that a definite article in a claim may not have a grammatically perfect antecedent basis does not automatically render a claim invalid as indefinite. In *Energizer Holdings, Inc. v. International Trade Commission*, for example, the "said zinc anode" limitation did not have an

explicit antecedent basis, but the Federal Circuit held that the "anode gel" was "by implication the antecedent basis." 435 F.3d 1366, 1370-71 (Fed. Cir. 2006). Likewise, in *Microprocessor Enhancement Corp. v. Texas Instruments Inc.*, the Federal Circuit held that the "condition code" limitation need not have a single antecedent basis in order to be definite because "the appropriate meaning of 'condition code' is readily apparent from each occurrence in context . . . the [asserted] patent used condition code to refer to a value or a storage location based on its context within the claims." 520 F.3d 1367, 1376 (Fed. Cir. 2008) (also noting "the well-settled rule that claims are not necessarily invalid for a lack of antecedent basis").

Here, the claim language in question describes "said analytes" passing through a well in a "vertical column" having "a defined volume." The claim language surrounding "said analytes," when read in light of the specification passages cited below, makes clear which analytes in claim 1 pass through the well.

The '721 patent clearly describes "analytes" as components of bodily fluid, including HDL, LDL, VLDL, ILDL, chylomicrons, triglycerides, and glucose, among others. *See, e.g.*, '721 patent at 1:24-35, 4:49-59, 7:24-36, 12:55-61, 15:56-62, 16:2627. The '721 patent specification describes a "well-defined test volume of sample fluid," echoing the requirements of claim 1. *Id.* at 13:14-16. The fluid is "bodily fluid" and "it flows to the bottom" of the well. *Id.* This "vertical flow of sample liquid" (*id.* at 12:48-50) includes "the non-selected bodily fluid components" (*id.* at 14:48-50) as well as the selected analyte, such as HDL (*id.* at 7:24-33). To drive home the point, the patent teaches that a "plurality of analytes" includes the "selected" analyte for measurement and one or more "non-selected" analytes also present in the body fluid sample. *See id.* at 2:16–24.

A person of ordinary skill in the art would understand from the structure of claim 1 and the teachings of the '721 patent specification that the "said analytes" in the second recited step of

claim 1 are HDL and one or more non-selected analytes in the bodily fluid being tested. Accordingly, I find ACON has not shown that the claim term "said analytes" is indefinite for lack of an antecedent basis.

D. '818 Patent

1. "Blank Layer" (claims 8 and 11)

The claim term "blank layer" is recited in asserted claims 8 and 11 of the '818 patent. The main dispute between the parties is whether this term is indefinite. The '818 patent specification expressly states, "For purposes of this specification, the term 'blank layer' refers to a layer such as layer 88 whose main purpose is to maintain all stacks at substantially the same thickness." '818 patent at 9:45-48. ACON contends the term "blank layer" is indefinite because the '818 specification provides no objective standard by which to determine what a layer's "main purpose" is. Alternatively, in the event this term is determined not to be indefinite, ACON proposes it be construed as "a single sheet of material that is not loaded with any reagents and whose main purpose is to maintain the stack at substantially the same thickness as one or more other stacks that do not have a blank layer at the corresponding position." Joint CC Chart at 3. PTS takes the position that this term is not indefinite and proposes a construction of "layer whose main purpose is to maintain all stacks at substantially the same thickness." *Id.*

The '818 specification first refers to the blank layer in a description of Figure 5, reproduced below:

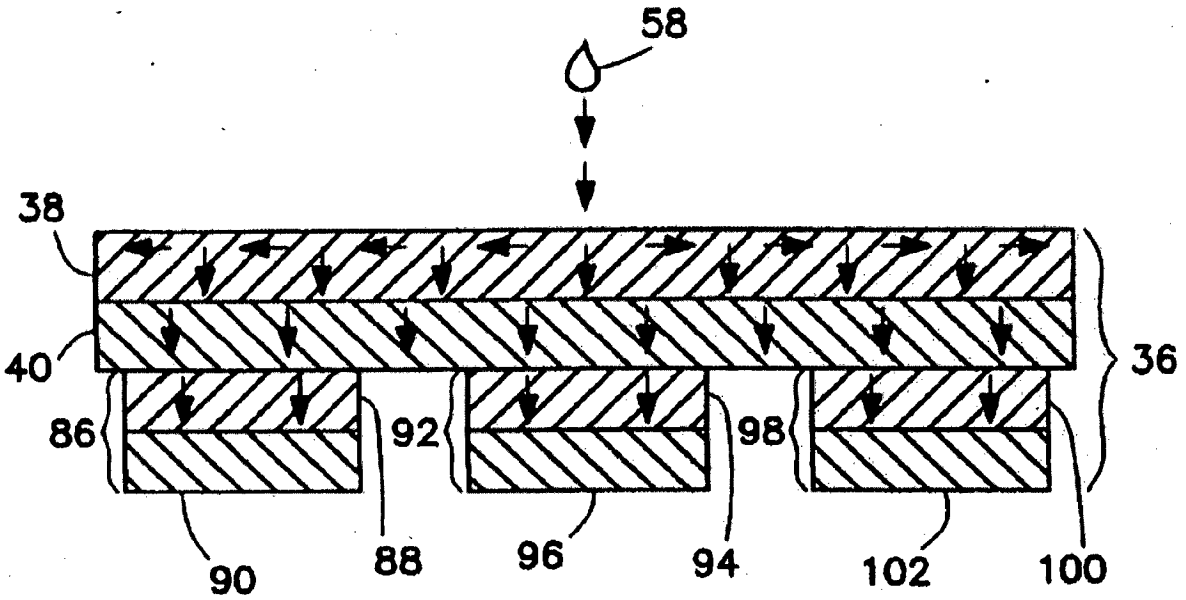


FIG. 5

The specification teaches:

> With further reference to FIG. 5, end stack 86 is spaced from middle stack 92 and is adjacent to and in fluid communication with layer 40. Stack 86 takes fluid from layer 40 and produces a colored response in reaction layer 90 that is proportional to the concentration of total cholesterol in sample 58. Stack 86 also includes a blank or spacer layer 88 whose main purpose is to maintain the relative thickness of all stacks approximately the same and, in so doing, improves overall compression exerted upon matrix 36 by top and bottom portions 26 and 30 of strip holder 22. Blank layer 88 also retains residual blood cells passed to it from layer 40. For purposes of this specification, the term "blank layer" refers to a layer such as layer 88 whose main purpose is to maintain all stacks at substantially the same thickness. Blank layer 40 is not loaded with any reagents, but may be impregnated with a wetting agent to improve fluid flow or may be impregnated with a chromogen in applications wherein two test membranes are employed.

'818 patent at 9:35-52.[1]

This language from the specification informs the meaning of "blank layer" to a person of skill in the art. In particular, the patent teaches that "blank layer" refers to "a layer . . . whose main

[1] The specification further states: "Stack 98 also includes a blank or spacer layer 100, that in this embodiment is the same as blank layer 88." '818 patent at 9:62-64.

purpose is to maintain all stacks at substantially the same thickness," and that a blank layer "is not loaded with any reagents, but may be impregnated with a wetting agent to improve fluid flow or may be impregnated with a chromogen in applications wherein two test membranes are employed." *Id.* at 9:46-52.

By stating the "main purpose" of a blank layer, the '818 patent specification is essentially stating the function of the blank layer. The inventors could have instead written, "For purposes of this specification, the term 'blank layer' refers to a layer for maintaining all stacks at substantially the same thickness," with the same effect. Such functional language does not necessarily render a claim indefinite. *Application of Swinehart*, 439 F.2d 210, 213 (C.C.P.A. 1971) ("[T]here is no support, either in the actual holdings of prior cases or in the statute, for the proposition, put forward here, that 'functional' language, in and of itself, renders a claim improper."); *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1366 (Fed. Cir. 2017) (even after *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S.Ct. 2120, 2124, (2014), "nothing in the law precludes, for indefiniteness, defining a particular claim term by its function" (internal quotations omitted)). The probative test is whether claim 1, viewed in light of the specification and prosecution history, informs those skilled in the art about the scope of the invention "with reasonable certainty." *Nautilus, Inc.* v. *Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014).

The '818 specification defines the function of the claimed "blank layer" as "maintain[ing] all stacks at substantially the same thickness." '818 patent at 9:45-48. The specification also defines functions and characteristics of the blank layer that are secondary to its "main purpose." *Id.* at 9:44-45 ("Blank layer 88 also retains residual blood cells passed to it from layer 40."), 9:48-52 ("Blank layer 40 is not loaded with any reagents, but may be impregnated with a wetting agent to improve fluid flow or may be impregnated with a chromogen in applications wherein two test

membranes are employed.").) The claim language and the teachings of the specification are broad enough to allow a "blank layer" to have more than one function within the claimed invention.

ACON argues that the inventor's statement about the "purpose" of the blank layer requires an inquiry into the subjective mental state of an alleged infringer when designing the blank layer. *See* RIB at 30-33; RRB at 13-15. ACON's argument is not persuasive, as the specification does in fact teach an objective test to determine infringement. Specifically, if a "blank layer" is removed from a stack that was originally substantially coplanar with the other two stacks, and if that stack from which the "blank layer" was removed is then of unequal height when compared to the other two stacks, then that "blank layer" maintains the stacks at substantially the same thickness.

Therefore, for purposes of the infringement and validity analysis with respect to the "blank layer" limitation, I will apply the definition of "blank layer" set forth in column 9 of the '818 specification. Specifically, a "blank layer" is a layer for maintaining stacks at substantially the same thickness and is not loaded with any reagents.

2. "Each of Said First, Second or Third Stacks Could Be of a Different Height" (claim 8)

Claim 8 of the '818 patent describes a method of determining concentrations of at least three different analytes from a single blood sample using three test stacks. Claim 8 states "each of said first, second or third stacks could be of a different height." The main dispute between the parties is whether this phrase is indefinite. ACON argues that this term is "indefinite and thus not capable of construction" because it is uses the modal verb "could." *See* Joint CC Chart at 4. Alternatively, in the event this phrase is determined not to be indefinite, ACON proposes it be construed as: "the combined layers that perform essential blood test functions (other than supporting compression) are a different height in each of the first, second, and third stacks" in the event this term is determined not to be indefinite. *Id.* PTS takes the position that this term is not

indefinite and proposes a construction of "prior to the inclusion of a blank layer, one or more of the first, second, or third stacks are a different height," which it asserts is the plain and ordinary meaning of this term. *Id.*

ACON argues that the words "could be" render the phrase indefinite because they do not "inform those skilled in the art about the scope of the invention with reasonable certainty." RIB at 34-35 (quoting *Nautilus*, 572 U.S. at 910). ACON's argument lacks merit. Claims are not fatally indefinite simply because they contain optional limitations. For example, in *In re Johnston*, 435 F.3d 1381, 1384 (Fed. Cir. 2006), the Federal Circuit reviewed a prior art rejection by the Patent Office of a claim stating that a certain pipe "wall *may* be smooth, corrugated, or profiled with increased dimensional proportions as pipe size is increased." The court noted, "As a matter of linguistic precision, optional elements do not narrow the claim because they can always be omitted." *Id.* at 1384. But there was no discussion of indefiniteness by either the Patent Office or the court. *See also Cybersettle, Inc. v. Nat'l Arbitration Forum, Inc.*, 243 F. App'x 603, 607 (Fed. Cir. 2007) (Bryson, J.) (unpublished) ("It is of course true that method steps may be contingent. If the condition for performing a contingent step is not satisfied, the performance recited by the step need not be carried out in order for the claimed method to be performed.").

The meaning of this disputed claim term can be readily understood from the plain language of claim 8:

> . . . wherein each of said first, second or third stacks could be of a different height and wherein a blank layer is introduced to any one of or combinations of stacks such that the height of said first, second or third stacks are substantially equal and coplanar . . .

'818 patent at claim 8. According to the claim, any of the three stacks could be a different height; that much is optional. But a blank layer must be introduced to one or more of stacks, and the

stacks must be substantially equal in height when one or more blank layers are added into one or more of the stacks.

This interpretation is supported by the patent specification, which describes the functional purpose of the blank layers as making the height or thickness of the stacks equal. Referring to Figure 5, the specification teaches the use of "blank or spacer layer 88 whose main purpose is to maintain the relative thickness of all stacks approximately the same." '818 patent at 9:40-42. The use of blank layers can make the stacks "have about the same thickness, such that the bottom surfaces of stacks 42 are substantially coplanar." *Id.* at 6:32-35.

In light of the intrinsic evidence, I have determined to apply the plain and ordinary meaning of the disputed phrase in my infringement and validity analysis of the '818 patent. The plain and ordinary meaning of the phrase indicates that any of the three stacks could be a different height; a blank layer must be introduced to one or more of stacks; and the stacks must be substantially equal in height when one or more blank layers are added into one or more of the stacks.

3. "An Elongate Disbursement Layer" (claim 8)

The claim term "an elongate disbursement layer" is recited in asserted claim 8 of the '818 patent.[2] Both parties agree that the '818 patent specification contains an express definition of "disbursement layer" and, based on that definition, that the claimed elongate disbursement layer "delivers a uniform blood sample across its entire length to its other side, delivering the uniform distribution of blood to a layer or layers adjacent to and in contact with its underside." Joint CC Chart at 4. The parties' dispute centers on how the blood sample spreads over the disbursement layer. ACON contends that the elongated layer be "made of a material such that, upon receiving

[2] Use of the word "disbursement" in the '818 patent appears to be a typographical error. The parties agree that the intended word is "dispersement." *See* CIB at 54 n.36. To be precise, the original spelling is used throughout this Initial Determination.

a blood sample on one side of the layer, *the material's physical properties* cause the sample to spread through and across the layer's entire length." *Id.* (emphasis added). PTS proposes a construction that does not expressly state that the "physical properties" of the material used to make the layer cause the blood sample to spread. *Id.*

The '818 specification defines "disbursement layer" as follows:

> A "disbursement layer" is an elongated layer that receives a blood sample on one side thereof, spreads the sample through and across its entire length, and delivers a uniform blood sample across its entire length to its other side, delivering the uniform distribution of blood to a layer or layers adjacent to and in contact with its underside.

'818 patent at 5:42-47. This definition squares directly with PTS's proposed construction.

ACON's proposed construction, however, adds a requirement that the material of which the claimed disbursement layer is made has "physical properties" that cause spreading of the received blood. It is unclear to which physical properties ACON refers. It is similarly unclear how adding language about undefined "physical properties" helps to clarify the meaning of the term. To the extent that ACON seeks to create a noninfringement argument with its claim construction, patent claims should not be construed "with an aim to include or exclude an accused product." *Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442 F.3d 1322, 1326 (Fed. Cir. 2006). I find no support in the record for adding a "physical properties" limitation to the inventors' express definition of "disbursement layer."

Therefore, for purposes of the infringement and validity analysis with respect to the "elongate disbursement layer" limitation, I will apply the definition of "disbursement layer" recited in the '818 specification and set forth above.

V. INFRINGEMENT

PTS asserts infringement of the following claims by ACON:[3]

'397 Patent	'721 Patent	'818 Patent
Claim **19**	Claims **1**, 4, 6, 8, 15	Claim **8**, 9, 11

Each asserted patent claim is addressed below.

A. '397 Patent

PTS asserts that ACON's cholesterol testing systems infringe independent claim 19 of the '397 patent, which reads:

> 19. A method of determining concentration of HDL cholesterol in a whole blood sample, said method comprising:
>
> a) providing a layered stack comprising a dispersement layer, a red blood cell separation layer, a non-HDL separation chemistry-layer, and an HDL reaction layer; said red blood cell separation layer not containing an agglutinin or a coagulant; said non-HDL cholesterol separation chemicals for separating the non-HDL blood components from the HDL blood components so that the non-HDL components do not participate in the reaction in said HDL reaction layer; said HDL reaction layer containing chemicals for reacting with said HDL; said layers arranged in a vertical stack with said dispersement layer at the top and said HDL reaction layer at the bottom;
>
> b) applying blood to said dispersement layer and permitting fluid from said blood to first flow laterally across said dispersement layer and then to flow vertically downward in said stack to said HDL reaction layer without substantial lateral migration of the fluid below said dispersement layer;
>
> c) separating said red blood cells from a fluid portion of said blood in said red blood cell separation layer;
>
> d) separating said non-HDL cholesterol from said HDL cholesterol using said non-HDL cholesterol separation chemicals;

[3] Independent claims are emphasized with boldface type.

> e) reacting said HDL in said HDL reaction layer in a colorimetric reaction; and
>
> f) determining the HDL cholesterol concentration in said reaction layer by measuring the reflectance of said reaction layer after said colorimetric reaction.

'397 patent at claim 19.

The parties have stipulated that use of the ACON 3-1 Accused Products according to ACON's Directions of Use (JX-0008) satisfies all limitations of claim 19 except for the following limitations, which the parties dispute:

> 1. "a layered stack comprising . . . a red blood cell separation layer [and] a non-HDL separation chemistry layer"
>
> 2. "said layers arranged in a vertical stack"
>
> 3. "said red blood cell separation layer not containing an agglutinin or a coagulant"
>
> 4. "without substantial lateral migration of fluid below said dispersement layer"

Stip. ¶ 47.

As discussed below, the record evidence demonstrates that the ACON 3-1 Test Devices satisfy all disputed claim limitations of asserted claim 19 of the '397 patent.[4]

1. "A Layered Stack Comprising . . . a Red Blood Cell Separation Layer" and "A Non-HDL Separation Chemistry Layer"

Claim 19 of the '397 patent requires "a layered stack comprising . . . a red blood cell separation layer [and] a non-HDL separation chemistry layer."[5] '397 patent at claim 1. The parties' dispute as to this claim limitation centers on whether the same layer in the "layered stack"

[4] ACON previously moved for summary determination of non-infringement of the asserted claims of the '397 and '721 patents. Motion Docket No. 1116-010. In view of my findings on infringement of the '397 and '721 patents herein, Motion No. 1116-010 is denied as moot.

[5] Claim 19 also requires the "layered stack" include a dispersement layer and an HDL reaction layer. Those limitations are not in dispute.

can be both the claimed "red blood cell separation layer" and the claimed "non-HDL separation chemistry layer." *See, e.g.*, Tr. 493.14-495:25. As discussed above with respect to claim construction, I have determined that the claimed "red blood cell separation layer" and "non-HDL separation chemistry layer" do not have to be separate physical layers.

The evidence shows that the ACON 3-1 Test Devices include a "layered stack" comprising a glass fiber layer, a separate layer, and a reaction layer, all within the HDL stack. CX-0018C; Tr. 206:1-8; *see* Stip. ¶ 87.

The evidence shows that the glass fiber layer of the HDL stack in the ACON 3-1 Test Devices satisfies the "red blood cell separation layer" claim limitation when applying the plain and ordinary meaning of the term, as discussed above in the section on claim construction.[6] Specifically, ACON's test results demonstrate that the glass fiber layer of the HDL stack retains approximately 72.3% of red blood cells. RX-0524C at PTS_001822859; Tr. 411:25-412:24. PTS's expert Dr. Weber also tested the ACON 3-1 Test Devices and found that the glass fiber layer of the HDL stack retained approximately 71% of red blood cells. CX-0793C; Tr. 216:22-218:20. I therefore find that the ACON 3-1 Test Devices have a "red blood cell separation layer."

The evidence shows that the glass fiber layer of the HDL stack in the ACON 3-1 Test Devices satisfies the "non-HDL separation chemistry layer" claim limitation when applying the plain and ordinary meaning of the term, as discussed above in the section on claim construction. The glass fiber layer contains non-HDL cholesterol separation chemicals, specifically dextran

[6] PTS also argues that the ACON 3-1 Test Devices satisfy this limitation under ACON's proposed construction under the doctrine of equivalents. CIB at 47-48. Because I have determined ACON's proposed construction is incorrect, I need not analyze ACON's doctrine of equivalents arguments.

sulfate and magnesium chloride. CX-0010C at 2; CX-0013C at 2; CX-0377C; Stip. ¶¶ 96-97. The dextran sulfate and magnesium form a complex with LDL (*i.e.*, non-HDL), thereby separating the LDL from the HDL blood components. Tr. 152:20-154:10, 164:10-165:4.

The parties have stipulated that non-HDL cholesterols are exposed to dextran sulfate and magnesium in the glass fiber layer, and that separating non-HDL cholesterol from HDL cholesterol occurs in the ACON 3-1 Test Devices. Stip. ¶¶ 133-34. The ACON 3-1 Test Devices generate accurate HDL measures when used, thereby demonstrating that this separation process separates substantially all of the non-HDL from a blood sample. *See* Tr. 222:3-20. I therefore find that the glass fiber layer in the ACON 3-1 Test Devices is a "non-HDL separation chemistry layer."

The ACON 3-1 Test Devices also include a dispersement layer and an HDL reaction layer, features not in dispute. CX-0018C; Tr. 207:13-208:4. I therefore find that the ACON 3-1 Test Devices have every element of the "layered stack" required by claim 19.

2. "Said Layers Arranged in a Vertical Stack"

Claim 19 requires that the layers in the layered stack are "arranged in a vertical stack." '397 patent at claim 19. The layers of the ACON 3-1 Test Devices that comprise the claimed layered stack, discussed above, are arranged in a vertical stack. Tr. 206:1-10. I therefore find that the ACON 3-1 Test Devices satisfy this claim limitation.

3. "Said Red Blood Cell Separation Layer Not Containing an Agglutinin or a Coagulant"

Claim 19 requires that the red blood cell separation layer discussed above "not contain[ ] an agglutinin or a coagulant." As discussed above, the glass fiber layer of the HDL stack of the ACON 3-1 Test Devices is the claimed "red blood cell separation layer." The record evidence shows that this glass fiber layer does not include an agglutinin or a coagulant. Tr. 222:22-225:7,

403:4-12; *see also* RRB at 9. I therefore find that the ACON 3-1 Test Devices satisfy this claim limitation.

4. "Without Substantial Lateral Migration of Fluid Below Said Dispersement Layer"

In the method of claim 19, the blood sample must "flow vertically downward in said stack to said HDL reaction layer without substantial lateral migration of fluid below said dispersement layer." '397 patent at claim 19. The parties have stipulated: "When used according to ACON's Directions for Use in JX-0008, the ACON 3-1 Test Devices permit some of the fluid in a blood sample to move downward through the three test stacks in a direction substantially normal to the plane defined by the test stacks." Stip. ¶ 127. Movement of the blood sample downward through the stack in a direction normal to the plane of the stack is the same as the "vertically downward" flow required by claim 19. The parties dispute, however, whether the ACON 3-1 Test Devices permit substantial lateral migration of the fluid.

ACON argues that the ACON 3-1 Test Devices do not practice this limitation because the separate layer in the ACON 3-1 Test Devices "is wider than the glass fiber layer immediately above it, resulting in lateral flow in a portion of the separate layer." *See* RRB at 11-13. This argument is not persuasive. At the hearing, Dr. Weber testified regarding a test he performed with the ACON 3-1 Test Devices. Dr. Weber created a time-lapse video of a DiI-infused LDL solution filling the well. CX-1005; Tr. 168:2-9. I watched the video at the hearing and questioned Dr. Weber about it. Tr. 169:15-170:5. The video showed flow of the fluid vertically downward in the test stack. I did not observe substantial lateral migration of the sample fluid in the video. Additionally, CX-0818 is a still image taken from the video created by Dr. Weber. The still image shows a side view of the HDL stack corresponding with stack "A" in CX-0018C. Tr. 167:5-20,

169:12-170:10. The still image does not show lateral movement of the fluid sample below the dispersement layer.

ACON also showed a video at the hearing. *See* RX-428C. In ACON's video, the ACON 3-1 Test Devices are overloaded with a quantity of fluid that exceeds ACON's own instructions for using the ACON 3-1 Test Devices. Tr. 515:12-516:15; *see* JX-0008; Stip. ¶ 106. I find that ACON's video and similar testing involving atypical fluid sample sizes are not probative of the question of whether a person following ACON's instructions for normal use of the ACON 3-1 Test Devices would infringe claim 19.

Other record evidence supports a conclusion that there is no substantial lateral migration of sample fluid in the ACON 3-1 Test Devices. The glass fiber layer in the ACON 3-1 Test Devices is approximately 4 millimeters wide, and the separate layer extends approximately 0.5 millimeters to either side of the glass fiber layer. Tr. 515:4-6. Any lateral migration of fluid into the outer edges of the separate layer from the glass fiber layer would be *de minimis* when compared with the width of the layers in question.

Additionally, any lateral migration of fluid in the separate layer of the accused devices would be *de minimis* when compared with the lateral flow of fluid taught in prior art devices. Specifically, the '397 patent distinguishes the insignificant lateral flow allowed in the claimed invention from the significant lateral flow in the prior art:

> Further, and quite remarkably, applicants' strip is designed such that precipitation and separation take place in a direction that is substantially normal to the plane established by layer 40. That is, while fluid movement occurs in all directions within layer 40, there is no significant net lateral migration of fluid from one side of layer 40 to the other. Indeed, quite unlike the prior art noted above, the present invention does not incorporate or rely on different migration rates of plasma and precipitated non-HDLs across layer 40. This is because fluid transport is through layer 40, not across it. Thus, it can be appreciated that blood separation and separation of precipitated non-HDLs both occur vertically, in a direction that is

> perpendicular to the plane of the vertically aligned test layers. This is a significant advantage, in that the test strip can be configured compactly in a vertically aligned stack of layers.

'397 patent at 10:66-11:14. This portion of the specification teaches that the "lateral migration of fluid" recited in claim 19 refers to the prior art practice of providing "a sample application point that is laterally offset (along the axis of the test strip) from the sample reading area of the test strip." *Id.* at 2:11-24 (discussing prior art "lateral flow devices"). By contrast, the invention claimed in the '397 patent involves a vertical flow of the applied blood sample through the layered stack.

Viewing the record evidence as a whole, I find that PTS has shown by a preponderance of the evidence that there is no substantial lateral migration of the blood sample with the ACON 3-1 Test Devices.

5. Conclusion

PTS has shown by a preponderance of the evidence that usage of the ACON 3-1 Test Devices, in the manner directed by ACON, results in performance of every step of the method in claim 19 of the '397 patent.

B. '721 Patent

PTS asserts that ACON's cholesterol testing systems infringe independent claim 1 and dependent claims 4,[7] 6,[8] 8,[9] and 15 of the '721 patent. The relevant claims, including the intervening dependent claims, read as follows:

> 1. A method of determining a characteristic of high density lipoprotein (HDL) from a plurality of analytes in a bodily fluid, said method comprising:

[7] Claim 4 depends from claim 2, which is no longer asserted in this investigation.

[8] Claim 6 depends from claim 5, which is no longer asserted in this investigation.

[9] Claims 8 and 15 depend from claim 7, which is no longer asserted in this investigation.

providing said bodily fluid containing HDL and one or more non-selected analytes;

providing a dry test strip having a well with porous layers within said well that allow said analytes to pass creating a vertical column of said analytes having a defined volume;

applying said bodily fluid to said well in said dry test strip; and

reacting HDL in the bodily fluid with a reactant in said dry test strip to provide an indication of said characteristic while preventing said one or more non-selected analytes from participating in said reaction, without precipitating said one or more non-selected analytes.

2. A method as in claim 1 wherein said bodily fluid is blood.

4. A method as in claim 2 wherein said one or more non-selected analytes are selected from the group consisting of analytes, such as LDL (low density lipoproteins), VLDL (very low density lipoproteins), ILDL (intermediate density lipoproteins), and chylomicrons (big, tryglyceride-rich lipoproteins).

5. A method as in claim 1 wherein said indication is an optical indication.

6. A method as in claim 5 wherein said optical indication is a colorimetric indication.

7. A method as in claim 1 wherein said preventing comprises complexing said non-selected analyte so that it cannot participate in said reaction.

8. A method as in claim 7 wherein said complexing comprises interacting said non-selected analytes with a polyanion.

15. A method as in claim 7 wherein said complexing comprises exposing said non-selected analyte to a reagent comprising dextran sulphate and a divalent metal.

'721 patent at claims 1, 4, 6, 8, 15.

The parties have stipulated that use of the ACON 3-1 Accused Products according to ACON's Directions of Use (JX-0008) satisfies all limitations of claims 1, 4, 6, 8, and 15 of the '721 patent except for the following limitations of claim 1, which the parties dispute:

1. "a well with porous layers within said well that allow said analytes to pass creating a vertical column of said analytes having a defined volume"

2. "preventing said one or more non-selected analytes from participating in said reaction, without precipitating said one or more non-selected analytes"

Stip. ¶¶ 48-49.

As discussed further below, the record evidence demonstrates that the ACON 3-1 Test Devices satisfy all disputed claim limitations of asserted independent claim 1 of the '721 patent. The ACON 3-1 Test Devices also satisfy all limitations of asserted dependent claims 4, 6, 8, and 15, which ultimately depend from claim 1.

1. "Well"

Claim 1 of the '721 patent requires "a well with porous layers within said well that allow said analytes to pass creating a vertical column of said analytes having a defined volume." In the claim construction analysis above, I determined that this phrase should be given its plain and ordinary meaning. Under that construction, the evidence shows that the ACON 3-1 Test Devices satisfy this claim limitation.

The ACON 3-1 Test Devices are illustrated in the exploded figure of CX-0018C. As shown in CX-0018C, the claimed "well" is formed by stack "A," which is the HDL stack. PTS's expert Dr. Weber testified that the HDL stack is comprised of porous layers that permit fluid from blood (including analytes) to pass, creating a vertical column of analytes. Tr. 167:3-8. Dr. Weber further testified that the edges of the fibrous materials form the stack's boundaries. Tr. 166:25-167:2. The parties have stipulated that the ACON 3-1 Test Devices permit "some of the fluid from blood to flow downward to the HDL reaction layer," and that they "permit some of the fluid in a blood sample to move downward through the three test stacks in a direction substantially normal to the plane defined by the test stacks." Stip. ¶¶ 126-27. Thus, the evidence demonstrates that the porous layers comprising the HDL stack permit fluid from blood to pass.

At the hearing, Dr. Weber testified regarding a test he performed to demonstrate the existence of the claimed "well." Dr. Weber shaved the edge off a test strip and created a time-lapse video of a DiI-infused LDL solution filling the well. CX-1005; Tr. 168:2-9. CX-0818 is a still image taken from that video, and shows a side view of the HDL stack corresponding with stack "A" in CX-0018C. Tr. 167:5-20; 169:12-170:10. Dr. Weber identified the boundaries of the well as the edges of the porous layers on the right and left in CX-0818. Tr. 169:2-14. As shown in still image CX-0818, there is a vertical column of analytes with a defined volume.

ACON argues that the well limitation is not met because (1) the edges of the stack's porous layers cannot constitute boundaries, (2) the air next to the porous layers cannot constitute boundaries, and (3) blood seeps out of the stack and out the bottom when the ACON 3-1 Test Devices are overloaded with blood. *See* RRB at 36-38. These arguments are not persuasive. As discussed above, the edges of the porous layers (as well as the air immediately bordering the edges) form a vertical column with a defined volume apparent to those skilled in the art. The bottom of the stack also forms a boundary of the defined volume. The fact that blood may seep from the edges and bottom of the stack if the test strip is overloaded with excessive fluid is not probative of the question of whether a person following ACON's instructions for normal use of the ACON 3-1 Test Devices, would infringe the method of claim 1. I find that the ACON 3-1 Test Devices satisfy this claim limitation because those devices have "a well with porous layers within said well that allow said analytes to pass creating a vertical column of said analytes having a defined volume."

2. "Without Precipitating"

The last recited step of the method of claim 1 requires reacting HDL in a bodily fluid with a reactant "without precipitating" non-selected analytes. *See* '721 patent at claim 1. As discussed in the above section regarding claim construction, I have construed the phrase "without precipitating" to allow for the formation of a complex of non-selected analytes. As discussed

below, the record evidence demonstrates that the ACON 3-1 Test Devices satisfy the claim limitation "preventing said one or more non-selected analytes from participating in said reaction, without precipitating said one or more non-selected analytes" when applying the adopted construction.

The evidence shows that the glass fiber material in the ACON 3-1 Test Devices is a glass-fiber membrane impregnated with dextran sulfate sodium salt, $MgCl_2$, [redacted]. Stip. ¶¶ 95, 97. The dextran sulfate is an anionic polymer with a molecular weight of [redacted]. Stip. ¶¶ 98-100. The parties have stipulated that, when used as directed, the ACON 3-1 Test Devices expose non-HDL cholesterol (*i.e.*, non-selected analytes) to dextran sulfate and divalent magnesium ions in the glass fiber membrane of the HDL test stack (identified as "C1" in CX-0018C). Stip. ¶¶ 133-34. There is no dispute that this separates non-HDL cholesterol from HDL cholesterol. *Id.*

PTS's expert Dr. Weber testified credibly that the separation of non-HDL cholesterol within the glass fiber membrane occurs through complexing, and not precipitation. *See, e.g.*, Tr. 152:24-25. As Dr. Weber explained, complexes are formed when particles stick together in a reversible way without chemically changing, such as when hemoglobin complexes with oxygen in the bloodstream to carry oxygen throughout the body. Tr. 153:11-25. Dr. Weber contrasted complexing with precipitation when he testified that precipitation involves an irreversible chemical reaction, such as when oxygen and iron combine to form rust. Tr. 153:3-10. This testimony supports a conclusion that the ACON 3-1 Test Devices react non-selected analytes "without precipitating" the non-selected analytes.

It is undisputed that the ACON 3-1 Test Devices give accurate readings of HDL in a test sample. Stip. ¶ 112. This fact informs what is going on inside the ACON 3-1 Test Devices. If

non-HDL makes its way to the HDL reaction layer and participates in the colorimetric reaction read by a meter, the results of the HDL test would be inflated. Tr. 151:1-152:9. The fact that HDL test results are *not inflated* in the ACON system is evidence that non-selected analytes have been reacted in a manner that prevents the non-selected analytes from interfering with the colorimetric reaction in the reaction layer. Additionally, the fact that HDL analytes are *not undercounted* in the ACON system is evidence that the pores of the HDL layered stack in the ACON 3-1 Test Devices have not been clogged with precipitants. *See* '721 patent at 2:63-67 ("precipitates tend to block the pores in the system and impede the flow the desired analytes also, which reduces the amount of the desired analytes that reach the reaction area, and thus reduces the accuracy of the test"). The evidence thus supports a conclusion that the dextran sulfate and divalent magnesium ions in the glass fiber membrane of the HDL test stack do not cause precipitation in the ACON 3-1 Test Devices.

Additionally, Dr. Weber testified that he relied on two independent tests to verify that (1) non-HDL cholesterol was prevented from participating in the HDL reaction layer and (2) the non-HDL cholesterol was not precipitated within the HDL test stack. Dr. Weber first conducted fluorescent microscopy testing. *See, e.g.*, Tr. 136:2-10, 145:3-148:6; CX-1004 at 2; CX-1005. Dr. Weber next analyzed and relied upon scanning electron microscopy ("SEM") imaging that Dr. Adrienne Hoeglund of Evans Analytical Group ("EAG") performed on the accused products. *See, e.g.*, Tr. 114:17-119:23, 136:17-23; CX-0795.

For the first test, fluorescent microscopy testing, Dr. Weber tagged LDL cholesterol in a solution with a fluorescent dye ("DiI") that has a high affinity for LDL. Tr. 145:10-146:21, 274:22-275:16; CX-1005; RX-0747. Dr. Weber added glycerol to the sample to emulate the viscosity of blood, then dosed four ACON 3-1 Test Devices with the DiI/LDL solution. CX-1005

§ 1.5; Tr. 277:15-17; CX-1004; Tr. 146:5-21, 149:24-150:2. After applying an appropriately sized sample of the DiI/LDL solution to a test strip, Dr. Weber waited two minutes, dissected the strip, placed the individual layers on microscope slides, took images, and "recorded the quantitative data for fluorescence in each of the pads . . . in those test strips." Tr. 145:3-147:9; CX-1005. Dr. Weber then compared the fluorescence measurements of the various glass fiber, separate, and reaction layers[10] in the HDL and CHOL stacks and translated the relative fluorescence values to percentages. CX-1004 at 2; Tr. 148:12-149:5; 282:20-284:20.

Dr. Weber testified: "In the HDL stack, which is not intended to measure non-HDL cholesterol, that is the LDL, we find a significant amount of the LDL in the reaction layer . . . indicating that the LDL make it to the reaction layer but don't react." Tr. 147:15-23; *see also* Tr. 287:4-6. Dr. Weber also testified that, if the LDL were "precipitating, they would form these particles, they would be hung up in the membrane below [the glass fiber layer], they would not make it to the reaction layer." Tr. 152:10-18. Therefore, the presence of LDL in the reaction layer of the HDL stack demonstrates that LDL was not precipitating and clogging the test strip, but rather complexing and flowing to the reaction layer. *See* Tr. 152:20-154:10.

ACON criticizes Dr. Weber's methodology because (1) Dr. Weber did not wash the LDL after the DiI tagging process to remove unreacted, free DiI and (2) LDL bound with DiI does not precipitate as well as unbound LDL. *See* RRB at 57-61. Neither critique is persuasive. Washing the LDL after tagging was not needed, as DiI is "intensely colored" and free DiI would have been visible in the clear, white solution. It was not visible. *See* Tr. 278:4-279:14, 876:16-877:12. Moreover, Dr. Weber testified credibly that DiI-tagged LDL particles behave in a manner similar

[10] Dr. Weber did not measure the mesh and filter paper layers for fluorescence because those images showed virtually zero fluorescence. Tr. 284:21-24.

to untagged LDL particles because of the charges of the particles involved in the relationship between LDL, magnesium, and dextran sulfate. Tr. 315:3-316:2; *see also* Tr. 314:17-315:2 (literature explaining that DiI-tagged LDL behaves like untagged LDL in biological environments).

For the second test, analysis of SEM imaging, Dr. Hoeglund applied fresh human blood to ACON 3-1 Test Devices, waited for two minutes, disassembled the strips, transported them to EAG wrapped in Parafilm, sputter coated the samples with gold, placed them in the SEM, and collected SEM images. Tr. 117:16-118:24, 120:6-14, 120:15-121:15, 121:16-22, 123:11-24; CX-0795 at PTS_002429642-48. The resulting images do not reveal clogged pores in the test strip, which would have resulted had there been precipitation. *See* Tr. 159:17-162:16, 164:9-13, 165:5-9. Dr. Weber testified that comparisons of the dry strips used as controls and those treated with blood showed no evidence of precipitation having occurred in any of the glass fiber, separate, or reaction layers. The fluorescence microscopy testing described above showed that 92% of the LDL in the HDL stack ended up in the glass fiber and separate layers combined. Tr. 161:4-11; CX-1004 at 2.. Accordingly, if precipitation occurred in the ACON 3-1 Test Devices, evidence of that precipitation should have been evident in the SEM images of the glass fiber and separate layers, but it was not. Tr. 162:3-163:15; CX-0795. There was also no evidence of precipitation in the reaction layer. Tr. 163:16-164:13; CX-0795.

The "dry control" and "with blood" SEM images of the HDL stack of the ACON 3-1 Test Devices appear substantially similar and do not reveal clogged pores. That evidence supports a conclusion that the ACON 3-1 Test Devices remove non-HDL cholesterol from the blood sample without precipitating. *See* Tr. 165:5-9. Moreover, the absence of visible particles in the SEM

images is consistent with very small, complexed (as opposed to precipitated) particles. Tr. 164:20-165:4.

Viewing the record evidence as a whole, I find that PTS has shown, by a preponderance of the evidence, that the ACON 3-1 Test Devices satisfy this claim limitation when used as directed.

3. Conclusion

PTS has shown by a preponderance of the evidence that usage of the ACON 3-1 Test Devices, in the manner directed by ACON, results in performance of every step of the methods in claims 1, 4, 6, 8, and 15 of the '721 patent.

C. '818 Patent

PTS asserts that ACON's cholesterol testing systems infringe independent claim 8 and dependent claims 9 and 11 of the '818 patent, which read as follows:

> 8. A method of determining concentrations of at least three different analytes from a single blood sample, placed in a single opening, said method comprising:
>
> (a) contacting the single blood sample with the top surface of an elongate disbursement layer and spreading the sample substantially throughout the entire length of the disbursement layer;
>
> (b) delivering the blood sample from the disbursement layer to a first stack, a second stack and a third stack, each of said first, second and third stacks positioned adjacent to and in constant contact with the disbursement layer, wherein each of said first, second or third stacks could be of a different height and wherein a blank layer is introduced to any one of or combinations of stacks such that the height of said first, second or third stacks are substantially equal and coplanar
>
> (c) moving the sample downward through said stacks and including through said blank layer in a direction substantially normal to the plane defined by the stacks; and
>
> (d) producing a colored response at the bottom of each of said three stacks, said colored response at the bottom of said first stack being proportional to the concentration of a first analyte in said blood sample, said colored response at the bottom of said second stack being proportional to the concentration of a second analyte in said blood

> sample, and said colored response at the bottom of said third stack being proportional to the concentration of a third analyte in said blood sample.
>
> 9. The method claim 8 wherein the first analyte is HDL cholesterol, the second analyte is total cholesterol, and the third analyte is selected from the group consisting of triglycerides, glucose, and ketones.
>
> 11. The method of claim 8 wherein none of the first, second, and third stacks share the blank layer.

'818 patent at claims 8, 9, 11.

The parties have stipulated that use of the ACON 3-1 Accused Products according to ACON's Directions of Use (JX-0008) satisfies all limitations of claims 8 and 9 of the '818 patent except the following limitations, which the parties dispute:

> 1. "blank layer"
>
> 2. "each of said first, second or third stacks could be of a different height"
>
> 3. "wherein a blank layer is introduced to any one of or combinations of stacks such that the height of said first, second or third stacks are substantially equal and coplanar "
>
> 4. "disbursement layer"
>
> 5. "each of said first, second and third stacks positioned adjacent to and in constant contact with the disbursement layer"

Stip. ¶¶ 50-51.

As discussed below, the record evidence demonstrates that the ACON 3-1 Test Devices do not satisfy all claim limitations of asserted independent claim 8 of the '818 patent. In particular, the ACON 3-1 Test Devices do not satisfy the claim 8 requirement that "each of said first, second and third stacks [are] positioned adjacent to and in constant contact with the disbursement layer." For the same reason, the ACON 3-1 Test Devices do not satisfy all limitations of asserted dependent claims 9 and 11, which depend from claim 8.

1. "Blank Layer" (claims 8 and 9)

Claim 8 requires that "a blank layer is introduced to any one of or combinations of stacks such that the height of said first, second or third stacks are substantially equal and coplanar." '818 patent at claim 1. The evidence shows that the ACON 3-1 Test Devices satisfy the "blank layer" limitation under the construction I have adopted above. In particular, PTS's expert Dr. Weber identified the blank layers as the separate layers in the triglycerides and total cholesterol stacks. Tr. 187:14-19. These layers are identified as "E2" and "E3" on the first page of CX-0018C. *Id.*

The HDL stack of the ACON 3-1 Test Device, identified by the handwritten box "A" on the first page of CX-0081C, is designed to measure HDL cholesterol only. That requires preventing non-HDL cholesterol from reacting in the HDL reaction layer (layer "F1" in CX-0081C). Tr. 186:19-187:13. To achieve this result, the glass fiber layer in the HDL stack (layer "C1" in CX-0081C) is impregnated with dextran sulfate and magnesium chloride. CX-0010C at 2; CX-0013C at 2; CX-0337C; Stip. ¶¶ 96-97. But because there is no need to prevent non-HDL from reaching the reaction layers in the TRIG ("C2") and CHOL ("C3") stacks, the glass fiber layers in these stacks are not similarly treated. CX-0010C at 2; CX-0013C at 2; CX-0337C.

The three separate layers in the ACON 3-1 Test Device ("E1," "E2," and "E3" in CX-0081C) are made of a [redacted] membrane treated with [redacted]. CX-0010C at 3; CX-0031C at 2; Tr. 189:20-190:16. Yet, their function differs from stack to stack because the non-HDL separation chemicals are only present on the glass fiber layer of the HDL stack. As Dr. Weber testified, the separate layer in the HDL stack performs an essential blood test function that the separate layers in the TRIG and CHOL stacks do not perform. *See* Tr. 187:20-188:10.

In accordance with the construction of "blank layer" I have adopted, the separate layers in the TRIG and CHOL stacks maintain those stacks at substantially the same thickness as the HDL stack; they do not serve to separate non-HDL from the blood sample. Tr. 186:13-190:23. As discussed above in the section on claim construction, the fact that the separate layers in the TRIG and CHOL stacks might have a secondary function of separating red blood cells from the sample does not detract from their function of maintaining the stacks at substantially equal height. *Cf.* RRB at 16-27 (arguing that the "main purpose" of the separate layers is to separate red blood cells). In addition, none of the separate layers is loaded with any reagents. Tr. 189:20-190:2; CX-0010C at 2-3; CX-0013C at 2; CX0337C at AB00000068. The [redacted] impregnated on the [redacted] membrane is [redacted], and not a reagent. Tr. 189:20-190:16.

I therefore find that the ACON 3-1 Test Devices satisfy this claim limitation.

2. "Each of Said First, Second or Third Stacks Could Be of a Different Height" (claims 8 and 9)

The parties' dispute regarding this claim limitation is an extension of the "blank layer" dispute, in that ACON argues that the ACON 3-1 Test Devices do not include blank layers that result in substantially equal and coplanar stacks. *See* CIB at 69; RRB at 30.

As explained above in the claim construction section, this phrase does not limit the claim because it is permissive rather than mandatory. *In re Johnston*, 435 F.3d at 1384; *Cybersettle, Inc.*, 243 F. App'x at 607. Nevertheless, I will evaluate the evidence relating to this claim term for thoroughness.

The evidence shows that the three stacks of the ACON 3-1 Test Device are substantially equal and coplanar. Tr. 192:9-193:9; CX-0018C at AB00000070; CX-0337C at AB00000067. In the absence of the blank layers, *i.e.*, the separate layers in the TRIG and CHOL stacks, the three stacks could and would be a different height from each other. Tr. 193:10-18. To the extent that

PTS has a burden to show this claim limitation in the accused device, I find that this evidence satisfies any such burden.

3. "Wherein a Blank Layer Is Introduced to Any One of or Combinations of Stacks Such That the Height of Said First, Second or Third Stacks Are Substantially Equal and Coplanar" (claims 8 and 9)

The parties' dispute regarding this claim limitation is an extension of the "blank layer" dispute, in that ACON argues that the ACON 3-1 Test Devices do not include blank layers that result in substantially equal and coplanar stacks. *See* CIB at 68; RRB at 27. I have previously found that the separate layers in the TRIG and CHOL stacks are the "blank layers" claimed in the '818 patent, and therefore find that the ACON 3-1 Test Devices satisfy this claim limitation as well. In particular, as discussed above, the separate layers in the TRIG and CHOL stacks have the effect of ensuring that the height of the first (HDL), second (TRIG), and (CHOL) stacks are substantially equal and coplanar.

ACON notes it has made changes to its manufacturing process after this dispute with PTS began. Although the ACON 3-1 Test Devices used to be made with [redacted] separate layer membranes in each stack, ACON contends that it has since changed its manufacturing process so that [redacted] membranes, each with a different thickness range, could be used for a stack's separate layer. RRB at 27-28 (citing Tr. 377:18-20, 378:23-379:9, 381:25-382:8; RX-0683C; RX-0684C; Tr. 369:4-371:17; RX-0487C at PTS_001822705 (English translation); Tr. 377:2-10; RX-0599C at AB00007471 ([redacted]); RX-0600C at AB00007191 ([redacted]); RX-0601C at AB00007188 ([redacted]); RX-0607C at AB00007565 ([redacted]); RX-0487C at PTS_001822705; Tr. 371:1-17).

ACON's argument focuses on the allegedly variable height of each individual separate layer, not on how these variations affect the height of the first, second, and third stacks as a whole. The evidence shows that, even in the most extreme scenario, the thickness difference between the

various separate layers could be less than [redacted] microns. Tr. 549:3-11. This results in a potential stack height difference of about [redacted] which I find is still substantially equal and coplanar. Thus, even changing to the alternate membranes for the separate layers described by ACON, this claim limitation is still met. *See* Tr. 621:4-622:21, 193:15-194:22.

Moreover, ACON has only approved the alternative separate layer membranes for devices sold outside the United States. RX-0683C at AB00005223; RX-0684C at AB00056023; Tr. 380:6-14. It is unclear whether these alternative separate layer membranes would be approved by the FDA for importation into and sale into the United States, and thus any findings made regarding these alternative layers would be speculative at best.

4. "An Elongate Disbursement Layer" (claims 8 and 9)

The evidence shows that the mesh layer in the ACON 3-1 Test Devices satisfies the "elongate disbursement layer" claim limitation when applying the definition of "disbursement layer" set forth in the specification of the '818 patent.[11] PTS's expert Dr. Weber identified the mesh layer in the ACON 3-1 Test Devices as the elongate disbursement layer during his testimony, and ACON's documents depict the mesh layer as elongated. Tr. 173:19-174:8; Stip. ¶¶ 82-83; CX-0018C at AB00000070. The parties have stipulated: "When an ACON 3-1 Test Device is used according to ACON's Directions for Use in JX-0008, a single blood sample is contacted with the top surface of the mesh layer of the ACON 3-1 Test Device." Stip. ¶ 125. The blood sample then spreads in the mesh layer, and the mesh layer delivers a uniform blood sample across its entire length to the other side. Tr. 174:3-8, 180:4-20; CX-1027C at 113:20-115:15.

[11] As discussed above in the section on claim construction, this definition reads: "A 'disbursement layer' is an elongated layer that receives a blood sample on one side thereof, spreads the sample through and across its entire length, and delivers a uniform blood sample across its entire length to its other side, delivering the uniform distribution of blood to a layer or layers adjacent to and in contact with its underside." '818 patent at 5:42-47.

ACON disputes that the mesh layer is the claimed disbursement layer, arguing that the mesh layer is not the structure that causes the blood to spread. *See* RRB at 33-34. According to ACON: "In the ACON products, blood spreads due to the channel in the underside of the upper housing, not the mesh layer's physical properties." *Id.* at 33. Yet, the result of tests performed by ACON's expert Dr. Henry contradict this argument.

Dr. Henry applied samples containing 150 mg/dL and 300 mg/dL of LDL to the ACON 3-1 Test Devices with and without the top cover. CX-1047C at 2; Tr. 627:6-628:1. As the test sample only included LDL cholesterol, Dr. Henry did not obtain test results in the HDL stack of the ACON 3-1 Test Devices, but he did obtain results in the CHOL stack, which is offset from the application window by the same distance as the HDL stack. Tr. 627:23-628:1, 626:9-630:13. Dr. Henry found no or only a very small "significant difference in the operation of the strips with the top on and the operation with the strips with the plastic top removed." Tr. 629:9-24. Dr. Henry's test results demonstrate that, even with the plastic top removed, fluid flowed through and across the mesh layer in a quantity sufficient for the CHOL stack test to function in the manner required by the asserted claims. *See* CX-1047C at 2; Tr. 626:9-630:13.

ACON's argument also fails because nothing in the claim language restricts how the spreading step of the method is performed. The disbursement layer may play a role in the spreading step, but other structures or actions may also be involved. Asserted claims 8, 9, and 11 all use the transition word "comprising," which indicates that the entire claim is open-ended. *See Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1371 (Fed. Cir. 2005). Thus, even though blood dispersement through the mesh layer of the ACON 3-1 Test Devices might be facilitated the structure of the top channel, "[t]he addition of elements not recited in the claim cannot defeat infringement." *Id.* at 1372.

I therefore find that the ACON 3-1 Test Devices satisfy this claim limitation.

5. "Each of Said First, Second and Third Stacks Positioned Adjacent to and in Constant Contact with the Disbursement Layer" (claims 8 and 9)

Claim 8 requires delivery of a blood sample "from the disbursement layer to a first stack, a second stack and a third stack, each of said first, second and third stacks positioned adjacent to and in constant contact with the disbursement layer . . . ." '818 patent at 18:1-5. The dispute between the parties is whether the disbursement layer in the ACON 3-1 Test Devices is positioned adjacent to and in constant contact with the stacks.

I determined above that the mesh layer near the top of the stacks in ACON 3-1 Test Devices corresponds to the claimed "disbursement layer." *See* Stip. ¶¶ 82-83, 91, 94. The question, therefore, is whether the stacks in ACON 3-1 Test Devices are in constant contact with the mesh layer. The record shows they are not. The ACON 3-1 Test Devices have a filter paper layer positioned between the stacks and the mesh disbursement layer. Stip. ¶¶ 82-83, 91, 94. The ACON 3-1 Test Devices thus do not have stacks "adjacent to" the disbursement layer as required by the claims.

When the term "adjacent" is used in the '818 specification, it refers to things that directly abut one another, in accordance with the word's ordinary meaning. *See* '818 patent at Abstract, 3:46, 3:53, 3:55, 5:47, 6:64, 8:34, 8:50, 9:36, 9:59, 10:17, 10:31, 17:19, 18:4, 18:52. Nevertheless, PTS argues that "adjacent" must have a broader meaning, else the claims would not cover the embodiment shown in Figure 5 (reproduced below). *See* CIB at 60-61. As in the ACON 3-1 Test Devices, Figure 5 has a layer 40 between the disbursement layer 38 and the stacks 86, 92, and 98:

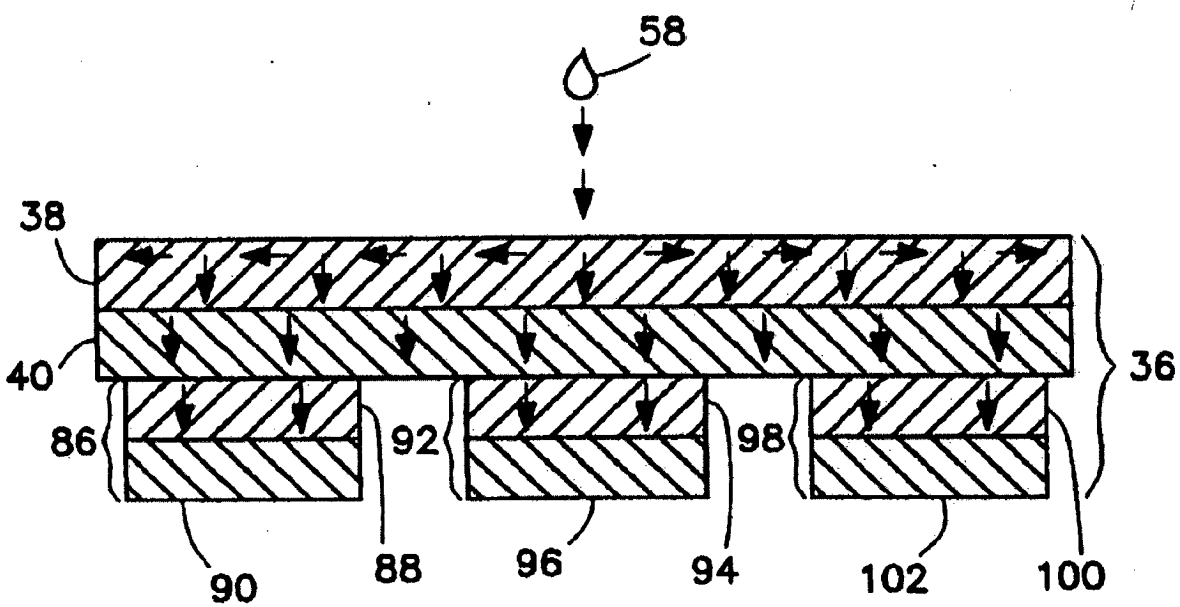


FIG. 5

PTS argues that the specification describes Figure 5 as "one embodiment of the present invention." CIB at 60-61 (citing '818 patent at 4:50-51). However, the original patent application included another independent claim that did cover Figure 5. Original claim 1 recited that the stacks were not adjacent to the disbursement layer, but were adjacent to "at least one blood separation layer." JX-0006 at PTS_000000749. This claim language matches Figure 5, in which the stacks are adjacent to layer 40, described in the specification as a "blood separation layer." '818 patent at 6:12. As to Figure 5, the specification describes blood separation layer 40, and not disbursement layer 38, as "adjacent to" the stacks. *Id.* at 8:49-51, 9:35-37, 9:58-60. The applicant cancelled original claim 1, leaving only claims that read on the Figure 6 embodiment. JX-0006 at PTS_000000855. Accordingly, Figure 6, and not Figure 5, depicts the embodiment of the claim. *See Baran v. Med. Device Techs., Inc.*, 616 F.3d 1309, 1316 (Fed. Cir. 2010) ("It is not necessary that each claim read on every embodiment.").

For the reasons above, I find that the ACON 3-1 Test Devices do not satisfy this claim limitation.

6. "None of the First, Second, and Third Stacks Share the Blank Layer" (claim 11)

Claim 11 adds an additional limitation to claim 8 and specifies that "none of the first, second, and third stacks share an identical blank layer." The evidence demonstrates that the ACON 3-1 Test Devices satisfy this limitation. I have previously found that the separate layers in the TRIG and CHOL stacks correspond to the claimed "blank layers." No stack shares a separate layer with another stack. Tr. 195:5-15; CX-0018C at AB00000070; CX-0337C at AB00000067. Accordingly, no stacks share a blank layer. I therefore find that the ACON 3-1 Test Devices satisfy this claim limitation.

D. Direct Infringement

The parties have stipulated that ACON Labs and Azure Institute, Inc. ("Azure") used the ACON 3-1 Accused Devices in the United States according to ACON's instructions set forth in JX-0008. Stip. ¶¶ 44-46, 106. I have determined that using the ACON 3-1 Accused Devices in the manner directed by ACON satisfies all limitations of asserted method claim 19 of the '397 patent and asserted method claims 1, 4, 6, 8, and 15 of the '721 patent. I therefore conclude that PTS has proven direct infringement of these claims as to the ACON 3-1 Accused Devices within the United States.[12]

[12] In the event the Commission determines that use of the ACON 3-1 Accused Products satisfies all limitations of the asserted '818 claims, the record also supports a finding of direct infringement of the '818 patent as to the ACON 3-1 Accused Devices within the United States.

E. Indirect Infringement

PTS argues that ACON Bio is liable for contributory infringement of the asserted patents. CIB at 4-6. As discussed above, the evidence demonstrates direct infringement of the '397 and '721 patents in the United States by ACON Labs and Azure.

In support of its indirect infringement position, PTS argues:

> - The ACON 3-1 Accused Products have no substantial non-infringing use. Use of them pursuant to the only method ACON's instructions (JX-0008) directly infringes;
>
> - ACON Bio has known of the Asserted Patents since 2010 (Stipulation Nos. 8-10);
>
> - ACON Bio never obtained an opinion of counsel, much less U.S. patent counsel, regarding infringement of the Asserted Patents. Despite knowing of PTS's patents since 2010, ACON Bio only had an employee with minimal training, Ms. Zhu, analyze two of the patents—the '397 and '721 Patents. (Tr. 440:5-471:16.) Ms. Zhu is not an attorney or U.S. patent agent and never reviewed PTS's Complaint or infringement charts. (Tr. 472:2-473:3, 473:13-476:1.) Worse, she performed her analysis using a design-stage test strip, not the final ACON 3-1 Test Device. (Tr. 476:2-7). Ms. Zhu admitted she has no opinion whether the ACON 3-1 Accused Products infringe because she never evaluated the final product. (Tr. 479:21-480:19.).

CIB at 5.

Based on the record evidence, I find PTS has demonstrated that ACON Bio is liable for contributory infringement of the '397 and '721 patents. Specifically, it has been shown that (1) ACON Labs and Azure performed acts of direct infringement within the United States, (2) the ACON 3-1 Accused Products have no substantial non-infringing use when operated in accordance with ACON's directions, and (3) ACON Bio imported, sold for importation, or sold after importation within the United States the ACON 3-1 Accused Products. *See* Stip. ¶¶ 19, 44, 106-54, 156-58.

ACON argues that ACON Bio is not liable for contributory infringement because "there is no basis to find the 'knowledge of infringement' required for indirect infringement." RRB at 2 (citing *Commil USA, LLC v. Cisco Systems, Inc.*, 135 S. Ct. 1920, 1926-28 (2015) (no knowledge where "the defendant reads the patent's claims differently from the plaintiff, and that reading is reasonable . . . ."). ACON further argues that "ACON Bio analyzed each of the Asserted Patents in 2010-2014 and determined that the accused product designs did not infringe for reasons consistent with ACON's reasonable non-infringement defenses." *Id.*

ACON's argument against a finding of contributory infringement on the part of ACON Bio is not persuasive, as the requisite knowledge for a finding of contributory infringement can be established with proof of (1) knowledge of the patent and (2) a lack of substantial noninfringing use on the part of the accused product. *See Spansion*, 629 F.3d at 1355 (citing *Metro–Goldwyn–Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913, 932 (2005) ("One who makes and sells articles which are only adapted to be used in a patented combination will be presumed to intend the natural consequences of his acts; he will be presumed to intend that they shall be used in the combination of the patent."). As ACON Bio has stipulated to knowledge of the asserted patents since 2010, I find that they have knowledge sufficient to establish liability for contributory infringement. *See* Stip. ¶¶ 8-10.

VI. DOMESTIC INDUSTRY – TECHNICAL PRONG

"The test for satisfying the 'technical prong' of the industry requirement is essentially [the] same as that for infringement, *i.e.*, a comparison of domestic products to the asserted claims." *Alloc, Inc.*, 342 F.3d at 1375. PTS contends its domestic industry products practice the following claims:[13]

[13] Independent claims are emphasized with boldface type.

'397 Patent	'721 Patent	'818 Patent
Claim **19**	Claims **1**, 4, 6, 8, 15	Claim **8**, 9, 11

Each patent claim is addressed below.

A. '397 Patent

The parties have stipulated that use of the PTS CardioChek Plus, CardioChek PA, and CardioChek Meters with the CHOL+HDL test strips satisfies all limitations of claim 19 of the '397 patent except for the following limitations, which the parties dispute:

1. "a layered stack comprising . . . a red blood cell separation layer [and] a non-HDL separation chemistry layer"

2. "said layers arranged in a vertical stack"

3. "without substantial lateral migration of fluid below said dispersement layer"

Stip. ¶ 52.

The parties' technical prong positions with respect to the PTS HDL cholesterol test strips are almost identical to their positions with respect to the PTS CHOL+HDL test strips. The parties apparently agree the CHOL+HDL test strips have a "red blood cell separation layer" in the layered stack, but they dispute other aspects of the layered stack and the question of lateral migration of fluid. Stip. ¶ 53. The parties have also stipulated that certain arguments raised in the infringement sections of their briefs apply equally to their technical prong arguments. *See, e.g.*, Stip. ¶¶ 247-249; 253. Those latter stipulations essentially make the parties' technical prong arguments about the CHOL+HDL test strips and the HDL test strips identical. I note any material differences between the two products in my analysis of the two products below.

As discussed below, the record evidence demonstrates that the '397 DI Products practice all limitations of claim 19 of the '397 patent.

1. "A Layered Stack"

The parties have stipulated that my infringement determination regarding this element will equally govern this limitation for domestic industry purposes. Stip. ¶ 247. For the same reasons explained in my determination that the ACON 3-1 Test Devices satisfy this limitation, I find that the '397 DI Products also satisfy this limitation.

2. "Said Layers Arranged in a Vertical Stack"

The parties have stipulated that my infringement determination regarding this element will equally govern this limitation for domestic industry purposes. Stip. ¶ 248. For the same reasons explained in my determination that the ACON 3-1 Test Devices satisfy this limitation, I find that the '397 DI Products also satisfy this limitation.

3. "A Red Blood Cell Separation Layer"

The parties have stipulated that my literal infringement determination regarding this limitation will equally govern this limitation for domestic industry purposes for literal practice of this limitation with the CHOL+HDL test strips.[14] Stip. ¶¶ 249, 253. Accordingly, in view of my determination that the ACON 3-1 Test Devices satisfy this limitation literally (in contrast to a finding that this limitation is satisfied under the doctrine of equivalents),[15] I find that the '397 DI Products also satisfy this limitation.

[14] This limitation is not disputed for the HDL Cholesterol test strips. Stip. ¶ 53.

[15] *See supra* note 6.

4. "A Non-HDL Separation Chemistry Layer . . ."

In the claim construction section, I determined that this claim limitation does not require the non-HDL separation chemistry layer to be physically separate from the red blood cell separation layer. Applying that construction, the evidence discussed below shows that the '397 DI Products satisfy this limitation.

Mr. Huffstodt, President and CEO of PTS, testified that PTS employees use PTS's Work Instruction documents to manufacture the CHOL+HDL test strip and the HDL cholesterol test strip. CX 0049C; Tr. 17:16-19:22, 25:5-16. PTS employees also use a Device Master Record ("DMR") to manufacture the CHOL+HDL test strip and HDL cholesterol test strip. CX-0044C; CX-0051C; Tr. 21:4-22:2, 25:5-16. These Work Instruction and DMR documents comprise evidence that the CHOL+HDL test strip and HDL cholesterol test strip each include an HDL Fractionation membrane in the HDL test stack. CX-0044C at 4; CX-0049C at PTS_001862223, PTS_001862226; CX-0051C at 4.

As with the glass fiber layer in the ACON 3-1 Test Devices, the HDL Fractionation membrane contains dextran sulfate and magnesium chloride. CX-0044C at 4; CX-0049C at PTS_001862223, PTS_001862226; CX-0051C at 4. Dr. Weber testified that dextran sulfate and magnesium chloride are non-HDL separation chemicals. Tr. 230:24-232:10. The parties do not dispute that separation of non-HDL occurs in the Fractionation membrane of the '397 DI Products. Stip. ¶ 163.

Dr. Weber further testified that dextran sulfate and magnesium chloride separate substantially all the non-HDL blood components from the HDL blood components such that the non-HDL components do not participate in the reaction in the HDL reaction layer. Tr. 232:15-18. If the non-HDL cholesterol had not been substantially separated from the whole blood sample, then the non-HDL cholesterol would have participated in the reaction and would have caused

inaccurate results. Tr. 147:10-148:6. The '397 DI Products generate accurate HDL measures when used, thereby demonstrating that this separation process separates substantially all of the non-HDL from a blood sample. *See id.* I have provided additional explanation of why this is so in my infringement analysis.

Viewing the record evidence as a whole, I find that PTS has satisfied its burden to show that the '397 DI Products satisfy this claim limitation.

5. "Without Substantial Lateral Migration of Fluid Below Said Dispersement Layer"

PTS's Work Instruction and DMR documents demonstrate that each of the '397 DI Products have a top mesh layer that comprises the claimed "dispersement layer." CX-0044C at 4; CX-0049C at PTS_001862223, PTS_001862226; CX-0051C at 4. Dr. Weber testified that the blood sample spread across the length of the top mesh layer and then flows vertically down into the stacks of the '397 DI Products. Tr. 235:1-11. The parties have also stipulated: "When each of the test strips in the '397 [DI Products] are used as directed and intended by PTS, the blood sample applied to the test strip does not flow laterally between test stacks." Stip. ¶ 188.

Because the mesh layer spreads the blood sample across its length and no lateral flow occurs between the stacks below that layer, I find that use of the '397 DI Products as directed and intended by PTS satisfies this claim limitation.

B. '721 Patent

PTS asserts that its CardioChek Plus, CardioChekPA, and CardioChek Meters, in combination with either its HDL Cholesterol test strips or its CHOL+HDL test strips, practice all elements of the asserted claims of the '721 patent. The parties have stipulated that my infringement determination regarding the disputed limitations in claims 1, 4, 6, 8, and 15 of the '721 patent would equally govern for domestic industry purposes. *See* Stip. §§ 54-55, 246, 250. In view of

my finding that use of the ACON 3-1 Test Devices according to ACON's Directions of Use (JX-0008) satisfies all limitations of the asserted claims of the '721 patent, I therefore also find that use of PTS's CardioChek Plus, CardioChekPA, and CardioChek Meters and HDL Cholesterol and CHOL+HDL test strips practice all elements of the asserted claims of the '721 patent.

C. '818 Patent

The parties have stipulated that use of the '818 DI Products satisfies all limitations of claims 8 and 9 of the '818 patent except for the "blank layer" limitation, which the parties dispute. Stip. ¶¶ 56-57.

As discussed below, the record evidence demonstrates that the '818 DI Products practice all limitations of claims 8 and 9 of the '818 patent. The '818 DI Products also practice the additional limitation related to the blank layer set forth in dependent claim 11 of the '818 patent.

1. "Blank Layer" (claims 8 and 9)

PTS's President and CEO, Mr. Huffstodt, testified that PTS employees use PTS's Work Instruction documents (CX-0054C) to manufacture both the CHOL+HDL+GLU and the Lipid Panel test strips. Tr. 17:16-25, 19:23-21:3, 25:5-16. He also testified that PTS employees use two DMRs (CX-0053C and CX-0060C) to manufacture the CHOL+HDL+GLU and the Lipid Panel test strips, respectively. Tr. 21:4-22:7, 25:5-16.

PTS's expert Dr. Weber testified that PTS CHOL+HDL+GLU and Lipid Panel test strips include a "blank layer" as that term has been construed above. Tr. 197:25-198:23. Dr. Weber also testified that the CHOL+HDL+GLU test strip (CPX-0048) and the Lipid Panel test strip (CPX-0047) are identical for purposes of evaluating this limitation. Tr. 197:5-15. Accordingly, my analysis below addresses only the Lipid Panel test strip, but the analysis applies equally to the CHOL+HDL+GLU test strip.

PTS's Work Instruction (CX-0054C) and DMR (CX-0060C) documents show that the Lipid Panel test strip includes test stacks for CHOL, HDL, and TRIG. CX-0060C; CX-0054C at PTS_001862049. The TRIG and CHOL stacks include a Cytosep 1660 Membrane, designated "BS-000628" in the PTS documents. *Id.* The Cytosep 1660 Membrane in the TRIG and CHOL stacks is a single sheet of material and is impregnated with deionized water and purified sorbitol, which are not reagents. Tr. 200:3-7, 201:12-202:14, 203:4-11; CX-0060C at 5; CX-0054C at PTS_001862049. Dr. Weber testified that no chemistry functions occur in the Cytosep 1660 Membrane of the TRIG or CHOL stacks. Tr. 200:3-7.

The Cytosep 1660 Membrane in the TRIG and CHOL stacks is at the same elevation as an HDL fractionation layer[16] in the HDL stack. Tr. 199:25-200:2. Without the Cytosep 1660 Membrane, the TRIG and CHOL stacks would be a different height than the HDL stack. *See* Tr. 192:9-193:18. Therefore, the Cytosep 1660 Membrane maintains the TRIG and CHOL stacks at substantially the same thickness as the HDL stack, and the Cytosep 1660 Membrane in the TRIG and CHOL stacks is therefore the claimed "blank layer."

I therefore find that the '818 DI Products comprise the "blank layer" required by claim 8.

2. "None of the First, Second, and Third Stacks Share the Blank Layer" (claim 11)

This additional limitation is recited in dependent claim 11 and requires that the relevant stacks each have their own blank layer, as opposed to a single elongated blank layer that extends across two or more stacks. *See* '818 patent at claim 11. Dr. Weber testified, and PTS's

[16] The evidence shows that the HDL Fractionation Membrane (designated "BS 000611" in PTS documents) in the HDL stack is not a "blank layer" as that term has been construed. CX-0060C at 5; CX-0054C at PTS_001862049. The HDL Fractionation Membrane is impregnated with separation chemicals (*i.e.*, reagents), including phosphotungstic acid and magnesium sulfate. CX-0060C at 5; CX-0054C at PTS_001862049. Dr. Weber testified that phosphotungstic acid and magnesium sulfate serve to separate non-HDL from HDL cholesterol. Tr. 203:12-204:1.

manufacturing documents confirm, that there are two separate Cytosep 1660 Membranes in the Lipid Panel test strip, one each in the TRIG and CHOL stacks. Tr. 204:8-13; CX-0060C at 5; CX 0054C at PTS_001862049. This arrangement of blank layers also holds true for the CHOL+HDL+GLU test strip; there is one blank layer in the glucose stack and a separate blank layer in the total cholesterol stack. Tr. 204:8-13; CX-0053C at 6; CX-0054C at PTS_001862050. None of the stacks in the '818 DI Products share a blank layer.

I therefore find that the '818 DI Products satisfy the additional limitation of claim 11.

The record evidence discussed above demonstrates that the '818 DI Products practice all limitations of claims 8, 9, and 11 of the '818 patent.

VII. VALIDITY

A. '397 Patent

1. Obviousness

ACON argues that claim 19 of the '397 patent is obvious based on the combination of U.S. Patent Nos. 5,426,030 ("Rittersdorf") (RX-0021) and 6,040,195 ("Carroll") (RX-0065). RIB at 1-18. The '397 patent has a priority date of December 21, 2001. Stip. ¶ 189. Rittersdorf and Carroll are each prior art under pre-AIA 35 U.S.C. §§ 102(a) & (b) and 103, having issued or been published more than one year before the '397 patent's priority date. Stip. ¶¶ 190, 200.

a) The Rittersdorf and Carroll Combination

The parties have stipulated to much of the scope and content of the Rittersdorf reference (Stip. ¶¶ 58, 190-199) and the Carroll reference (Stip. ¶¶ 59, 200-211). *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 15-17 (1966); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). Both Rittersdorf and Carroll disclose a test strip comprising layers arranged in a vertical stack. Stip. ¶¶ 196, 205. ACON admits that Rittersdorf does not teach a dispersement layer as

required by claim 19, but ACON asserts Carroll teaches such a layer. RIB at 3; Stip. ¶¶ 207-208.[17] The relevant layer disclosed in Carroll is called a spreading screen. *See, e.g.*, RX-0065 at 6:6-9. I must therefore determine "whether there was an apparent reason to combine" the spreading screen in Carroll with the test strip in Rittersdorf "in the fashion claimed by the patent at issue." *See KSR Int'l Co.*, 550 U.S. at 418.

ACON's argument for combining Carroll with Rittersdorf is based on Carroll's teaching that "uniform distribution is required to produce uniform color development," and "uneven distribution to the membrane" will "produce an unreliable reading." *See* RX-0065 at 6:20-25. From this disclosure, ACON contends a person of ordinary skill in the art would have been motivated to employ Carroll's spreading screen in "other test strips" to achieve "a more uniform distribution of blood, more uniform color development, and more reliable test results." RIB at 10.

There are several problems with ACON's cursory argument. First, ACON has not addressed the scope and content of Carroll as a whole; it has focused only on the spreading screen. "It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986).

An examination of Carroll as a whole raises significant questions about whether a skilled artisan would select the spreading screen from Carroll to combine with the HDL test stack of

[17] ACON also asserted the possible combination of Rittersdorf, Carroll, and a German published patent application DE-30-29-579-A1 ("Vogel") (RX 0072) should Rittersdorf's disclosure of the red blood cell separation layer required by claim 19 "be deemed insufficient." RIB at 3. ACON presented no argument that Vogel teaches a dispersement layer (*see* RIB at 4-8) and has thus forfeited any reliance on Vogel for disclosure of a dispersement layer. I need not further consider the combination involving Vogel because my analysis of the dispersement layer required by claim 19 is dispositive.

Rittersdorf and expect to arrive at the claimed invention. While Carroll makes passing reference to the possibility of detecting cholesterol, Carroll's "Summary of the Invention" states that the disclosure is "*tailored* to the receipt and testing of *glucose* analytes in a whole blood sample." RX-0065 at 2:23–26 (emphasis added). For example, the chemistry in Carroll is focused on separating and detecting glucose, not HDL. *Id.* Meanwhile, the Rittersdorf invention is "particularly advantageously used in methods for the quantitative determination of HDL cholesterol on test strips." RX-0021 at 4:19-21. This difference factored into to Dr. Foley's credible conclusion that a person of ordinary skill in the art would not have thought to combine Carroll and Rittersdorf. *See* Tr. 933:17-20.

Additionally, Carroll teaches that the screen 20 is "defined" by mesh openings that "momentarily *hold* the sample" and until "[*e*]*ventually* the sample passes through the screen mesh 20." RX-0065 at 6:14-18 (emphasis added). In contrast, Rittersdorf criticizes methods that are "too time consuming," stressing that "flow rates of the sample through the carrier are very important for the test performance." RX-0021 at 1:67-68, 3:35-37. Indeed, an object of Rittersdorf is "a more rapid and a simpler HDL cholesterol determination." *Id.* at 2:6-12. ACON has not demonstrated why a skilled artisan would find the screen of Carroll, which apparently slows the flow of the sample, suitable in the Rittersdorf invention, where flow rates "are very important."

As for ACON's supposed motivation of improving the accuracy of test results, Rittersdorf's teachings on that point are equivocal. While it is true that Rittersdorf points out that prior art methods of pipetting a supernatant to separate HDL by centrifugation "can lead to less precise measurements" (RX-0021 at 2:2-5), Rittersdorf is hardly clear that precise measurement of HDL is a priority. To the contrary, Rittersdorf seems content with only "a close approximation

the determination of the HDL," because approximations of HDL and total cholesterol are "sufficient for an assessment of risk." *Id.* at 1:22-25.

Even if a skilled artisan were motivated by Carroll to attempt to improve the accuracy of the HDL measurements in Rittersdorf, the record contains no credible evidence that a person would expect to successfully obtain a more accurate measure of HDL by using Carroll's spreading screen in the Rittersdorf test strip. The only testimony cited by ACON for this point is the entirely conclusory testimony of its expert Dr. Henry that a person of skill in the art "would readily understand this [combination] would work." RIB at 10 (citing Tr. 539:18-540:12). Dr. Henry said nothing about accuracy. ACON then cites passages and figures from Carroll describing Carroll's spreading screen before declaring, without explanation or record evidence, that Carroll's screen "would be expected to produce the same result in Rittersdorf." RIB at 10. The passages in Carroll say nothing about whether the spreading screen would produce the same result in Rittersdorf, which discloses different separation chemistry.

ACON contends that combining Carroll and Rittersdorf "requires only the simple step of placing Carroll's 'spreading layer' in the same position in the Rittersdorf stack as it occupies in the Carroll stack." RIB at 10. That conclusion is incorrect for at least two reasons. First, there is no evidence in the record that a skilled artisan would have a reason to place a spreading screen in any particular location in the Rittersdorf stack. Why not put the spreading screen at the bottom of the stack, just before detection, since Carroll teaches an advantage of uniform detection? The record contains no answer. Second, ACON's characterization of the combination as "simple" does little to aid the inquiry. Simplicity is not inimical to patentability. *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992). The combination ACON proposes only seems simple in retrospect, after its disclosure in the '397 patent and with the benefit hindsight. *See id.*

Then there is the problem of geometry. Dr. Foley credibly testified "it's difficult to discern exactly" the geometry of the Rittersdorf device, which "would cause some confusion for a person of ordinary skill in trying to figure out how to apply a [Carroll] spreading layer...into the Rittersdorf device." Tr. 933:13-934:2. Carroll provides a significant exposition of how the geometry of the spreading layer relates to the layers and structures specific to the Carroll device—structures not found in Rittersdorf. *See* RX-0065 at 5:27-37. For example, Carroll teaches "spreading screen 20 overextends beyond the separating layer 30 to allow the screen 20 to adhere to the glued surfaces of the support strips 35." *Id.* The record contains no evidence about support strips in Rittersdorf that would be suitable for gluing a spreading screen, or what the effect would be of a spreading screen "overextending beyond" the separation layer in Rittersdorf. The record also lacks evidence of how to secure the Carroll screen to the Rittersdorf device without disrupting the spreading function of the screen.

Before turning to secondary indicia of nonobviousness, I note that Rittersdorf and Carroll were all before USPTO during prosecution of the '397 patent. "[W]hether a reference was before the PTO goes to the weight of the evidence." *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1260 (Fed. Cir. 2012). Even though Patent Office consideration of a particular reference does not change ACON's burden, "it may be harder to meet the clear and convincing burden when the invalidity contention is based upon the same argument on the same reference that the PTO already considered." *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1260 (Fed. Cir. 2012). Here, the examiner specifically cited and discussed Rittersdorf and Carroll, and the applicants specifically responded to those arguments during prosecution. JX-0004 at PTS_000000252, PTS_000000279; *see id.* at PTS_000000270, PTS_000000294. I find ACON's arguments do not carry sufficient

weight to "overcom[e] the deference that is due to a qualified government agency presumed to have done its job." *Sciele Pharma*, 684 F.3d at 1258.

b) Secondary Considerations of Nonobviousness

A determination of whether a patent claim is invalid as obvious under § 103 requires consideration of all four *Graham* factors, and it is error to reach a conclusion of obviousness until all those factors are considered. *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc). The *Graham* factors include so-called secondary considerations of nonobviousness. *Graham*, 383 U.S. 1 at 17-18. Objective indicia of nonobviousness must be considered in every case where present. *Apple Inc.*, 839 F.3d at 1048. As discussed below, some secondary indicia of nonobviousness proffered by PTS supports a conclusion that claim 19 of the '397 patent is not obvious.

(1) Commercial Success

I have determined above that PTS's CardioChek products, including the HDL and CHOL+HDL test strips, embody claim 19 of the '397 patent. I also find that those products are commercially successful. PTS's CEO Mr. Huffstodt testified that the success of PTS's CardioChek products was due to the "strip architecture and chemistry." Tr. 29:20-30:4, 31:18-32:2. Documentary evidence establishes that [redacted] CX-0672C at cells C16 and C17. PTS also adduced evidence showing that it has a significant market share in the lipid testing market. CX-0083C.

Additionally, I previously granted PTS's unopposed motion for summary determination that it satisfies the economic prong of the domestic industry requirement, based in part on evidence of sales of the PTS products described in my technical prong analysis above. Order No. 13 (Initial Determination Granting Complainant's Motion For Summary Determination That Complainant Satisfies the Economic Prong of the Domestic Industry Requirement). My summary determination

found PTS's industry relating to the '397 patent to have been built on substantial investments. *Id.* That determination is now a final determination of the Commission.

ACON now presents attorney argument questioning the connection between PTS's sales and the invention of claim 19. RIB at 15. But ACON has marshalled no credible evidence that there is some other reason for PTS's commercial success. The evidence of commercial success presented by PTS, based on products embodying claim 19, is sufficient for me to give it some weight in my determination of nonobviousness. But even if I were to ignore any commercial success, as ACON requests, I would still reach the conclusion that claim 19 is not invalid for obviousness, for the reasons I have already described.

(2) Long-felt but Unresolved Need

Mr. Huffstodt testified that PTS's DI Products satisfied long-felt needs in the industry, such as the need for a small, portable, fast-acting, and multi-analyte cholesterol test. Tr. 28:20-29:19, 945:15, 946:4. Dr. Foley also testified that PTS's test strips met a "long-felt but unresolved need." Tr. 945:15-946:4. This evidence of a long-felt need, a need satisfied by PTS products embodying claim 19, is sufficient for me to give it some weight in my determination of nonobviousness. But even if I were to ignore it, as ACON requests, I would still reach the conclusion that claim 19 is not invalid for obviousness, for the reasons I have already described.

(3) Praise by Others

PTS's CardioChek products, which include the '397 DI Products, have received many awards, including from Popular Science, TechPoint, and Thermo Fisher. Tr. 30:5-32:2. Mr. Huffstodt testified that he "believed" these awards were specifically attributable to the inventions claimed in the asserted patents. Tr. 31:18-32:2.

ACON rebuts this evidence. RIB at 16-17. ACON contends that the Popular Science award from in 2006 was for a CardioChek meter, which allowed the user to "run five tests" including total cholesterol, triglycerides, and glucose. CX-00792; Tr. 33-20-34:11. ACON notes PTS's CEO admitted that "none of those assays are asserted to be covered by any of the patents in this suit." Tr. 34:12-14. ACON concedes PTS received three Mira awards and a Thermo Fisher award. Tr. 31:6-17, 40:11-41:18, 946:17-24. However, ACON notes PTS's CEO testified that the awards were given for the CardioChek the meter, not the HDL test strip or any component thereof. Tr. 31:6-17, 33:17-34:14. Another award cited by PTS related to a different test strip that PTS has discontinued due to [redacted]. Tr. 41:7-18. PTS has no real response to ACON's criticisms on these points. CRB at 28-29.

I find the evidence of alleged praise is not sufficiently relevant to the claimed invention to factor into my obviousness analysis. I therefore give it no weight.

(4) Copying

Mr. Huffstodt testified that PTS believes ACON and Infopia, another company in the same market space, copied PTS's product. Tr. 32:3-17. PTC filed a complaint with the Commission against Infopia, and the parties settled. *See id.* I find the evidence of alleged copying is not sufficiently relevant to the claimed invention to factor into my obviousness analysis. I therefore give it no weight.

(5) Unexpected Results

The '397 file history contains a declaration from James Sutor, a senior scientist at PTS, describing the "unexpectedly accurate" invention claimed in the '397 patent. JX-0004 at PTS_000000268; *see also id.* at PTS_000000284-87. The declaration was made under penalty of

perjury and identifies the basis for Mr. Sutor's personal knowledge of the statements made. *Id.* at PTS_000000284-87.

ACON criticizes this evidence because Mr. Sutor was never subjected to cross-examination. To the extent that fact is relevant, the critique sounds with ACON, not PTS. ACON should have examined Mr. Sutor if it thought his testimony was suspect.

I find Mr. Sutor's testimony about unexpected results is sufficient for me to give it some weight in my determination of nonobviousness. But even if I were to ignore it, as ACON requests, I would still reach the conclusion that claim 19 is not invalid for obviousness, for the reasons I have already described.

c) Conclusion

Weighing the record evidence as a whole, including secondary considerations of non-obviousness, I have determined that ACON has not presented clear and convincing evidence that claim 19 is invalid due to obviousness. I find deficient ACON's evidence and argument that a person of ordinary skill in the art would have a reason to combine the Carroll and Rittersdorf references with an expectation of success in arriving at the invention of claim 19. In particular, ACON has not shown that a method using the claimed a dispersement layer would have been obvious to a person of skill in the art at the time of the claimed invention.

2. Indefiniteness

ACON argues that the term "without substantial lateral migration" is indefinite and therefore renders claim 19 of the '397 invalid under 35 U.S.C. § 112. RIB at 18-20. ACON did not present evidence supporting this argument at the evidentiary hearing, and no expert testimony was adduced in support of ACON's position. In particular, the record evidence fails to demonstrate that a person of ordinary skill in the art would not have understood the term.

As discussed above in the section on infringement, the '397 patent distinguishes the invention of claim 19 from prior art that reacted analytes as they flowed along the lateral axis of the test strip. '397 patent at 2:11-24 (discussing prior art "lateral flow devices"); *see also id.* at 10:66-11:14. In contrast to those prior art devices, the invention in claim 19 requires vertical flow of the applied blood sample through the layered stack. The language of claim 19, viewed in light of the teachings in the '397 patent specification, would have informed a person of skill in the art about the scope of the invention in claim 19 with reasonable certainty. *See Nautilus*, 134 S. Ct. at 2129.

Accordingly, I find ACON has not presented clear and convincing evidence that claim 19 is invalid for indefiniteness based on the term "without substantial lateral migration."

B. '721 Patent

1. Enablement

ACON argues that claims 1, 4, 6, 8, and 15 of the '721 are not enabled and therefore invalid under 35 U.S.C. § 112:

> [T]he specification does not enable a POSITA to practice the claimed invention without undue experimentation. The '721 specification describes a well-known method for separating HDL from LDL and VLDL in blood – using dextran sulfate and Mg^{2+} – but proclaims that the invention is different from the art because the separation allegedly occurs without precipitation. JX-0002 at 1:59-2:24. That proclamation contradicts conventional wisdom about how the recited chemicals accomplish separation and is unsupported by evidence, either contemporaneous or current. The '721 patent offers no proof that separation actually occurs without precipitation, or guidance on how to achieve that result, much less to the full scope of the claims. A POSITA would therefore be unable to practice the full scope without undue experimentation.

RIB at 35-36; *see also id.* at 35-42.

ACON argues that evidence adduced at the hearing demonstrates that, as of the '721 filing date in 2004, "the combination of dextran sulfate and Mg^{2+} was a well-known separation chemistry

used in HDL blood assays, and was universally understood to result in precipitation of non-HDL cholesterol." RIB at 36. ACON specifically identifies testimony from its expert Dr. DeFilippi, peer-reviewed articles, patents pre-dating the '721 patent, and results from tests performed by its expert Dr. Phillips as support for its enablement critique. *Id.* (citing RX-0016; RX-0018; RX-0020; RX-0024; RX-0025; Tr. 739:1-743:8, 774:1-775:25, 787:11-788:16, 793:7-13, 795:10-18; RX-0025; RX-0046; Tr. 659:19-662:20).

The primary reference upon which Dr. DeFilippi relies for his opinion is a chemistry article published in 1982 ("Warnick") (RX-0025).[18] Tr. 800:23-801:19. Warnick describes using dextran sulfate and Mg^{2+} to separate HDL from LDL by precipitating the LDL. RX-0025. Dr. DeFilippi testified that Warnick tested the effectiveness of HDL separation over a range of dextran sulfate molecular weights and concluded that combining 50kDa dextran sulfate with Mg^{2+} provides "optimum precipitation of LDL and VLDL, without excessive precipitation of HDL." RX-0025 at 1379; Tr. 740:22-741:17. Dr. Phillips replicated the procedure taught in Warnick, and photographs of Dr. Phillips's results show precipitation forming in the test tubes. Tr. 660:11-662:12; RX-0046.

PTS distinguishes the teachings of Warnick and other prior art references from the test strips claimed in the '721 invention and argues that the precipitation seen in Warnick was achieved under circumstances not present in the claimed invention:

> Warnick involves extensive physical intervention, wait time, and additional chemical intervention if desired results are not achieved. (RX-0025 at AL00213856 (agitation, 10-minute wait, centrifugation, potential "ER method" (step 6A).) Burstein also describes an extended centrifugation process. (CX-0983 at 5 (right column).)

[18] The second reference Dr. DeFilippi relies upon is an article published in 1986 ("Bachorik") (RX-0024) that used the same test method as Warnick. Tr. 824:3-9. A third reference important to this discussion is an article published in 1970 ("Burstein") (CX-0983).

> Dr. DeFilippi admitted that agitating the tubes causes mixing and likely increases the precipitation rate over time. (Tr. 802:22-803:16.) Further, he admitted it is unlikely that the amount of precipitates decreases over time. (Tr. 804:3-11.) There is no dispute that the Warnick method is nothing like the chemical interaction that occurs in the ACON 3-I Test Devices. ACON emphasizes that Warnick was peer-reviewed but fails to explain how the Warnick test-tube test translates to the environment and timing of a dry test strip.

CRB at 2.

In addition to performing the tests described in Warnick, ACON's expert Dr. Phillips also tested whether the chemical formulations listed in Tables A and B of the '721 patent cause precipitation of LDL in plasma. '721 patent at 8:55-9:30; Tr. 667:5-668:15. Dr. Phillips took photographs of the test results after three minutes, and again after centrifugation. *See* RX-0022. Dr. DeFilippi testified that the photos show precipitation in the test tubes. Tr. 751:20-753:8.

With respect to Dr. Phillips's tests, PTS argues:

> Dr. Phillips' test-tube test of the '721 Patent formulations do not prove that the dry test strip process described in the '721 Patent does not work. The reactions at issue here do not occur in test tubes. . . . In every instance, he also "flicked the tube to agitate it, which increases aggregation and precipitation. (Tr. 667:18-668:8, 802:22-803:16.) Although Dr. Phillips claimed that the "flicking" was akin to the mixing due to capillary action in a test strip, he provided no analysis or data showing why or how that is so. (Tr. 667:18-668:8.) In addition, it appears Dr. [Phillips] used a reagent formulation ten times more concentrated than the actual formulations. (Tr. 665:5-18 (ten times strength for ACON formulation), 667:18-20 (experiment run the same way for '721 Patent and PTS formulations).) He said he wanted to "work with the concentration of reagents that would...develop in the devices." (Tr. 665:9-18.) But again, Dr. Phillips provided no analysis or logic showing how or why such a formula correlated with how the dry test strips described in the '721 Patent work.
>
> Finally, for the '721 Patent formulations, Dr. Phillips took picture of the test tubes after three minutes—as much as ***two minutes and fifteen seconds longer than a dry test strip embodying the '721 Patent requires***. . . . Given that the last step of the '721 Patent's claim 1 is "reacting HDL in the bodily fluid with a reactant in said dry test strip to provide an indication of said characteristic (JX-0002 at 16:65-66) and the indication is provided in 45 seconds to two minutes, three minutes is simply too long.

CRB at 3-4 (emphasis original).

With respect to the '721 patent specification, ACON argues:

> [A]lthough it includes working examples . . . the examples only show that HDL was successfully measured, not that the technique operated without precipitation of non-HDL cholesterol. . . . Dr. Weber, PTS's expert, confirmed that the '721 patent included no testing showing the absence of precipitation. Tr. 248:17-249:13. Thus, these working examples do not provide guidance permitting a POSITA to practice the claimed invention without undue experimentation. . . .
>
> Nor do the more general teachings in the '721 patent explain how to separate without precipitation, much less to the full scope of the asserted claims. The only guidance is:
>
> > The chemistry for an HDL test strip relies on a complex including a polyanion, a divalent metal, and the lipoproteins. Preferably, the polyanion is a negatively charged polymer. Preferably, the polymer is dextran sulphate...For this complex to be selective between the various lipoproteins, the molecular weight, charge density, and branching of the anionic polymer must all be considered. To be selective without precipitation, the molecular weight should preferably be between 50,000 and 8,000; more preferably between 25,000 and 10,000; and most preferably 18,000 and 12,000.
>
> JX-0002 at 7:52-66. None of the asserted claims are limited to these molecular weight ranges. *Id.* at claims 1, 4, 6, 8 and 15. Indeed, only claim 15 requires dextran sulfate. Moreover, the endpoint of one of the preferred weight ranges—50,000 Daltons (50kDa)—is the same as the molecular weight that provided "optimum" selective precipitation in Warnick. RX-25 at 1379.

RIB at 38-39.

ACON's argument with respect to the '721 specification is not persuasive, as the specification teaches two example formulas. *See* '721 patent at 8:55-10:38, 10:40-12:5. The specification also includes relevant test results in Figures 6 and 7. *See id.* at 10:31-38, 11:60-12:5.

Moreover, even if the laboratory testing performed by ACON's expert Dr. Phillips resulted in precipitate formation in a test tube environment, ACON has failed to demonstrate that a person of ordinary skill in the art, having read the '721 patent specification, would not have been able to

practice the claimed invention without undue experimentation. As discussed above with respect to infringement and the domestic industry technical prong, the evidence shows that the separation of non-HDL cholesterol in a test strip constructed in accordance with the claimed invention does not occur by precipitation. Specifically, the non-HDL cholesterol reacts to form a complex, and that complex remains free to flow through the test strip without clogging the strip's pores. PTS's expert Dr. Weber verified that this type of chemical reaction was taking place in the ACON 3-1 Test Devices using fluorescence microscopy testing and SEM imaging. The fact that the claimed invention has been implemented by both PTS and ACON further suggest that the asserted claims are enabled.

Having considered the record evidence and the arguments of the parties, I find that ACON has failed to prove by clear and convincing evidence that the asserted claims of the '721 patent are invalid for lack of enablement.

2. Kozak – Anticipation

ACON argues that all asserted claims of the '721 patent are invalid as anticipated by U.S. Patent No. 5,460,974 ("Kozak") (RX-0016). RIB at 42-44. The '721 patent has a priority date of August 17, 2004. Stip. ¶ 215. Kozak is prior art under pre-AIA 35 U.S.C. § 102(b), having issued on October 24, 1995. Stip. ¶¶ 215, 222.

The parties have stipulated that Kozak discloses every limitation of the '721 asserted claims except reacting HDL in a bodily fluid with a reactant "without precipitating said one or more non-selected analytes." Stip. ¶¶ 62-63, 226-30, 264-65. Kozak expressly teaches reacting non-selected analytes with dextran sulfate, which Kozak calls a precipitating compound. *See* RX-0016 at 15:5-16, 20:45-51. However, Kozak never expressly states precipitation occurs in its disclosed method. *See id.*

ACON argues that if dextran sulfate and magnesium can separate VLDL and LDL from HDL without precipitation, as PTS contends in its infringement argument, then Kozak's process anticipates the claimed invention. ACON contends the ability to separate analytes without precipitation must be an inherent property of a dextran sulfate/Mg^{2+} separation system. RIB at 43.

Anticipation by inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Cont'l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991) (quotation omitted). Rather, anticipation by inherency requires proof that the reference necessarily includes the unstated limitation and would be so recognized by a person of ordinary skill in the art. *Id.* at 1268.

Here, I find that Kozak refers to dextran sulfate as a "precipitating compound" but does not expressly disclose that non-selected analytes are actually precipitated using dextran sulfate. *Compare* RX-0016 at 15:5-16, 20:45-51 *with* '721 patent at claim 1. As I discussed in the claim construction section above, the '721 patent teaches that controlling the molecular weight, charge density, and branching of an anionic polymer such as dextran sulfate can make it "be selective without precipitation" ('721 patent at 7:63-66) and instead form a complex (*id.* at 7:60-8:53). These teachings are consistent with the testimony of Dr. Foley, who credibly explained that whether precipitation occurs is a function of many factors, including analyte concentration, pH, the solution's ionic strength, the agents used, and their molecular weight. Tr. 913:11-20. Kozak does not disclose specifics for any of these factors.

Because ACON has not shown whether the dextran sulfate in Kozak is controlled to cause complexing or to cause precipitation, ACON has not shown that Kozak inherently anticipates the claimed invention of the '721 patent. Accordingly, I find that the asserted claims of the '721 patent are not invalid as anticipated by Kozak.

3. Patel – Anticipation

ACON argues that all asserted claims of the '721 patent are invalid as anticipated by U.S. Patent No. 5,215,886 ("Patel") (RX-0018). RIB at 44-49. The '721 patent has a priority date of August 17, 2004. Stip. ¶ 215. Patel is prior art under pre-AIA 35 U.S.C. § 102(b), having issued on June 1, 1993. Stip. ¶¶ 215-16.

The parties have stipulated that Patel discloses all limitations of the asserted '721 claims except for the following, which the parties dispute:

> 1. "providing a dry test strip having a well with porous layers within said well that allow said analytes to pass creating a vertical column of said analytes having a defined volume"
>
> 2. "applying said bodily fluid to said well in said dry test strip"
>
> 3. "reacting HDL in the bodily fluid with a reactant in said dry test strip to provide an indication of said characteristic while preventing said one or more non-selected analytes from participating in said reaction, without precipitating said one or more non-selected analytes"

Stip. ¶¶ 60-61.

For the reasons discussed below, I find that the asserted claims of the '721 patent are not invalid as anticipated by Patel.

a) The "Well" Limitation

The language of claim 1 requires a "well" with boundaries and porous layers that creates a "vertical column of said analytes having a defined volume." '721 patent at claim 1. A review of Patel demonstrates that this reference teaches the "well" claimed in the '721 patent. Specifically, the "well with boundaries" requirement is met by the walls 12 shown in Figure 1A of Patel. RX-0018 at 6:41-55, Fig. 1A; *see* Tr. 778:3-8, 780:13-781:5. Patel also discloses porous layers arranged within the well. RX-0018 at 6:42-47, Fig. 1A; *see* Tr. 781:6-23. The blood sample is applied, and analytes pass through the porous layers creating a vertical column. RX-0018 at

6:49-55, Fig. 1A; Tr. 781:24-782:18 ("The VLDL, the very low-density lipoprotein, and the LDL, and the HDL, which is a thing you're wanting to measure, these are all the analytes, and they're passing through what is referred to as the membranes."). Patel's well also has boundaries that define a volume. RX-0018 at 6:7-16; *see* Tr. 783:10-21.

Accordingly, I find that Patel discloses a "well with porous layers within said well that allow said analytes to pass creating a vertical column of said analytes having a defined volume."

b) The "Dry Test Strip" Limitations

Although Patel teaches the "well" recited in claim 1 of the '721 patent, that well is not located in a dry test strip as required by claim 1. In particular, claim 1 recited the steps of "providing a dry test strip having a well" and applying bodily fluid to "said well in said dry test strip." '721 patent at claim 1. Patel's well, item 12 illustrated in Figure 1A, is not located in the dry test strip. *See* Tr. 831:17-832:1. By contrast, Patel's Figures 1B and 2 show a quantitation strip, which is the dry test strip. *See* Tr. 832:16-833:5, 835:23-836:17. In Patel, the user first adds the sample to the device shown in Figure 1A, then snaps the device into a portion above layer 24 in the strip shown in Figure 1B. RX-0018 at Fig. 2; *see* Tr. 833:6-9, 836:12-17. Thus, the structure containing the well is not part of the dry test strip. *See* Tr. 832:25-833:5.

Accordingly, I find that Patel does not teach "a dry test strip having a well . . ." or "applying said bodily fluid to said well in said dry test strip" as required by claim 1 of the '721 patent.

c) The "Without Precipitation" Element

Patel expressly describes a "dextran sulfate solution" prepared "[f]or solution phase precipitation." RX-0018 at 8:48-9:26. Patel also expressly states that "precipitation was also performed." *Id.*; *see* Tr. 924:3-8. Unlike the '721 patent, Patel does not disclose that any parameters were adjusted that would allow the user to achieve a complex using dextran sulfate instead of precipitation. *See* Tr. 925:3-16. Because "precipitation was . . . performed" in Patel, I

find Patel therefore does not disclose "reacting HDL . . . without precipitating said one or more non-selected analytes," as required by claim 1.

d) Conclusion

Patel does not disclose the "dry test strip" limitations or the "without precipitating" limitation. Because Patel does not disclose every element of any of the asserted claims of the '721 patent, it does not anticipate those claims. ACON therefore has not presented clear and convincing evidence that Patel renders the '721 patent claims invalid.

C. '818 Patent

1. Knappe – Anticipation

ACON argues that claims 8 and 11 of the '818 patent are anticipated by U.S. Patent No. 6,455,001 ("Knappe") (RX-0078). RIB at 20-26. The '818 patent has a priority date of December 28, 2001. Stip. ¶ 231. Knappe is prior art under pre-AIA 35 U.S.C. §§ 102(a) & (b) and 103, having issued more than one year before the '818 patent's priority date. Stip. ¶ 232.

The parties have stipulated that every element of claim 8 is present in Knappe except one: "wherein each of said first, second or third stacks could be of a different height and wherein a blank layer is introduced to any one of or combinations of stacks such that the height of said first, second or third stacks are substantially equal and coplanar." Stip. ¶¶ 233-37.

Knappe discloses test strips with stacks of equal height, but Knappe does not contemplate or discuss stacks of different height within the same test strip. This is illustrated in Figure 4 of Knappe, wherein the two test stacks are shown as equal in height. RX-0078 at Fig. 4. The other figures and embodiments in Knappe also show stacks of equal height. *See id.* The record evidence demonstrates that, ultimately, "[t]here's no information provided that the stacks could possibly be a different height." Tr. 941:2-9.

As Knappe only discloses test strips with stacks of equal height, there is no "blank layer" in Knappe functioning to achieve "substantially equal and coplanar" stack heights, as required by the claim.

Additionally, as explained above in claim construction, a blank layer is not loaded with any reagents. But Knappe describes the layers in its stack as "functional layers," *i.e.*, layers where the glucose detection reaction takes place. RX-0078 at 2:10-18 (equating "functional layers" with "test elements," "detection elements," etc.), 9:26-31 (describing layers 3-3c as "functional layers"). For at least these reasons, the evidence shows that Knappe does not disclose a "blank layer" as that term has been construed. *See* Tr. 940:14-18, 941:21-22.

I find that Knappe does not anticipate claim 8 of the '818 patent because Knappe does not teach the limitation "wherein each of said first, second or third stacks could be of a different height and wherein a blank layer is introduced to any one of or combinations of stacks such that the height of said first, second or third stacks are substantially equal and coplanar."

Claim 11 of the '818 patent depends from claim 8 and therefore also includes the same blank layer limitation. Claim 11 is not anticipated.

2. Knappe – Obviousness

ACON argues that claim 9 of the '818 patent is rendered obvious by Knappe in view of U.S. Patent No. 6,524,864 ("Decastro") (RX-0022). RIB at 26-29. Decastro is prior art under pre-AIA 35 U.S.C. §§ 102(e) and 103, having issued from an application filed before the '818 patent's priority date. Stip. ¶ 238.

As discussed above, Knappe does not teach the "different height" and "blank layer" limitations of claim 8. Decastro does not teach these elements either. Indeed, ACON argues that "Decastro merely contributes the idea of the CHOL/HDL/TRIG combination and the need for a different number of reaction layers to implement each test. Knappe teaches the architecture for

implementing the test strip." RIB at 29. As neither Knappe nor Decastro teach all limitations of claim 8, ACON's obviousness argument fails.

Moreover, ACON has not shown that a person of ordinary skill in the art would have a reason to combine Knappe, which focuses on glucose and never mentions cholesterol testing, with the cholesterol-testing device discussed in Decastro. As PTS's expert Dr. Foley testified, based on 30 years of experience as a separation scientist and analytical chemist, "When you're developing any kind of separation system, it's really analyte-dependent." Tr. 944:8-10. The record evidence shows that, because "the chemistries are going to be very different for detecting" glucose and HDL cholesterol, "[n]ot to mention the architectures of these devices . . . are very different from each other," a person of ordinary skill in the art would not be motivated to combine Knappe and Decastro to arrive at the invention claimed in the '818 patent. Tr. 943:14-20, 944:3-16.

a) Secondary Considerations of Nonobviousness

PTS contends that secondary considerations demonstrate that the invention described in claim 9 of the asserted '818 patent claims is not obvious. As explained above with respect to the '397 patent, I must consider PTS's evidence when evaluating obviousness. *Apple Inc.*, 839 F.3d at 1048.

(1) Commercial Success

PTS adduced evidence showing that sales of the HDL+CHOL+GLU test strip exceed [redacted] annually. CX-0672C. The evidence shows that PTS commands [redacted] of the physician's office laboratory and [redacted] of the health promotion market segments. CX-0083C.

I have determined above that PTS's CardioChek products, including the CHOL+HDL+GLU test strips, embody claims 8, 9, and 11 of the '818 patent. I here find those products are commercially successful as demonstrated by record evidence. Additionally, I

previously granted PTS's unopposed motion for summary determination that it satisfies the economic prong of the domestic industry requirement, based in part on evidence of sales of the PTS sales of the CHOL+HDL+GLU test strips. Order No. 13 (Initial Determination Granting Complainant's Motion For Summary Determination That Complainant Satisfies the Economic Prong of the Domestic Industry Requirement). My summary determination found PTS's industry relating to the '397 patent to have been built on substantial investments. *Id.* That determination is now a final determination of the Commission.

As with the '397 patent, ACON now presents attorney argument questioning the connection between PTS's sales and the invention claimed in claim 9 of the '818 patent. RIB at 29-30. But ACON has marshalled no credible evidence that there is some other reason for PTS's commercial success. The evidence of commercial success presented by PTS, based on products embodying claim 9 of the '818 patent, is sufficient for me to give it some weight in my determination of nonobviousness. But even if I were to ignore PTS's commercial success, as ACON requests, I would still reach the conclusion that claim 9 is not invalid for obviousness, for the reasons I have already described.

(2) Long-felt but Unresolved Need

PTS's CEO Mr. Huffstodt testified regarding the benefit of obtaining "multiple results from one dose of blood rather than having to run sequential values." Tr. 29:16-19. I find this testimony too vague to give any weight in my obviousness analysis.

b) Conclusion

Weighing the record evidence as a whole, including secondary considerations of non-obviousness, I have determined that ACON has not presented clear and convincing evidence that claim 9 is invalid due to obviousness. I find deficient ACON's evidence and argument that a

person of ordinary skill in the art would have a reason to combine the Knappe and Decastro references with an expectation of success in arriving at the invention of claim 9.

3. Indefiniteness

ACON argues that the terms "blank layer" and "each of said first, second or third stacks could be of a different height . . . ." are indefinite and therefore render claim 8 of the '818 patent invalid under 35 U.S.C. § 112. RIB at 30-33, 34-35. As discussed above in the section on claim construction, I have found these claims not indefinite.

4. Written Description

ACON argues that the "blank layer" element violates the written description requirement of 35 U.S.C. § 112:

> Because a blank layer might be introduced to "any . . . combinations of stacks," the claim covers embodiments with a blank layer in *every* stack. Yet nothing in the original application or claims indicates that such an embodiment was within the inventors' contemplation. Rather, the original application indicates the inventors only contemplated placing blank layers in *fewer* than all stacks to bring them to the same height as another stack. Claim 8 and all dependent claims thereof are therefore invalid.

RIB at 33; *see also id.* at 33-34.

ACON's argument is not persuasive. Whether a specification complies with the written description requirement is a question of fact judged from the perspective of a person of ordinary skill. *Falkner v. Inglis*, 448 F.3d 1357, 1363 (Fed. Cir. 2006). The law does not require the specification to contain embodiments "explicitly covering the full scope of the claim language." *Falkner*, 448 F.3d at 1366. "'[T]he written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice' may be sufficient if it 'identifies the claimed invention' and does so 'in a definite way.'" *Centrak, Inc. v. Sonitor Techs., Inc.*, 915 F.3d 1360, 1367 (Fed. Cir. 2019) (quoting *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) (en banc)). PTS is entitled to rely on the full scope of the

original disclosure, including the original claims, when determining whether the inventors had possession of the invention. *See Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373, 1380 (Fed. Cir. 2011).

As a factual matter, I find that a person of skill in the art at the time of the '818 invention would have understood from the original application disclosures that the invention could include blank layers in every stack. That conclusion would have been apparent from various examples in the original patent application and the original patent claims cited by ACON. The original disclosure taught that blank layers could be inserted into stacks to maintain all stacks at "substantially equal and coplanar" height, and it taught blank layers of differing heights. There is no disclaimer in the original disclosures that blank layers could not be used on each and every stack. A simple hypothetical, well within the grasp of a skilled artisan, illustrates how such a configuration achieves the inventors' object in adding blank layers. Assume a short stack A, a medium height stack B, and tall stack C, all without blank layers. A thick blank layer could be added to stack A, a medium thickness blank could be added to stack B, and a thin blank layer could be added to stack C. With properly selected blank layer thicknesses, the effect would make stack A, B, and C substantially equal in height. Such a hypothetical would be within the full scope of the claims in question and is reasonably suggested to a skilled artisan by the examples given in the original application disclosure.

Based on my review of the record, I find that claim 8 of the '818 patent satisfies the written description requirement of 35 U.S.C. § 112.

VIII. DOMESTIC INDUSTRY – ECONOMIC PRONG

I previously granted PTS's unopposed motion for summary determination that it satisfies the economic prong of the domestic industry requirement. Order No. 13 (Initial Determination Granting Complainant's Motion For Summary Determination That Complainant Satisfies the

Economic Prong of the Domestic Industry Requirement). The Commission did not review the initial determination granting PTS's motion, and the determination is now the Commission's final decision.

IX. CONCLUSIONS OF LAW

1. The Commission has subject matter, personal, and *in rem* jurisdiction in this investigation.
2. The ACON 3-1 Accused Products have been imported into the United States.
3. Use of the ACON 3-1 Accused Products infringes claim 19 of the '397 patent and claims 1, 4, 6, 8, and 15 of the '721 patent.
4. Use of the ACON 3-1 Accused Products does not infringe claims 8, 9, or 11 of the '818 patent.
5. The economic prong of the domestic industry requirement is satisfied.
6. The technical prong of the domestic industry requirement is satisfied with respect to the '397, '721, and '818 patents.
7. It has not been shown by clear and convincing evidence that any asserted claim is invalid.

X. RECOMMENDED DETERMINATION ON REMEDY & BOND

The Commission's Rules provide that the administrative law judge shall issue a recommended determination concerning the appropriate remedy in the event that the Commission finds a violation of section 337, and the amount of bond to be posted by respondents during Presidential review of the Commission action under section 337(j). *See* 19 C.F.R. § 210.42(a)(l)(ii).

A. Findings of Fact Relevant to Remedy and Bond

The Commission did not ask me to take public interest evidence or to provide findings and recommendations concerning the public interest. 83 Fed. Reg. 26087 (June 5, 2018). Thus, in accordance with the usual Commission practice and the applicable Commission Rule, only the Commission can determine the role that public interest factors may play in this investigation. See 19 C.F.R. § 210.50(b)(1).

B. Limited Exclusion Order

The Commission has broad discretion in selecting the form, scope, and extent of the remedy in a section 337 proceeding. *Viscofan, S.A. v. U.S. Int'l Trade Comm'n*, 787 F.2d 544, 548 (Fed. Cir. 1986). A limited exclusion order directed to a respondent's infringing products is among the remedies that the Commission may impose. *See* 19 U.S.C. § 1337(d).

PTS argues that the Commission should issue a limited exclusion order directed to infringing products in the event a violation of section 337 is found. *See* CIB at 85. ACON agrees that a limited exclusion order directed to infringing products is an appropriate remedy in the event a violation of section 337 is found. *See* RRB at 65.

Having considered the arguments of the parties, I recommend that, in the event the Commission determines that a violation of section 337 has occurred, and if consideration of the statutory public interest factors does not require that remedies be set aside or modified, the Commission should issue a limited exclusion order covering products found to infringe the asserted patents.

C. Cease and Desist Order

Section 337 provides that in addition to, or in lieu of, the issuance of an exclusion order, the Commission may issue a cease and desist order as a remedy for a violation of section 337. 19 U.S.C. § 1337(f)(1). The Commission may issue a cease and desist order when it has personal

jurisdiction over the party against whom the order is directed. *Gamut Trading Co. v. U.S. Int'l Trade Comm'n*, 200 F.3d 775, 784 (Fed. Cir. 1999).

The Commission "generally issues a cease and desist order only when a respondent maintains a commercially significant inventory of infringing products in the United States." *Certain Ground Fault Circuit Interrupters and Products Containing Same*, Inv. No. 337-TA-615, Comm'n Op. at 24 (Mar. 26, 2009). Cease and desist orders are usually issued "when there is a commercially significant amount of infringing imported product in the United States that could be sold so as to undercut the remedy provided by an exclusion order." *Certain Protective Cases and Components Thereof*, Inv. No. 337-TA-780, Comm'n Op. at 28 (Nov. 19, 2012) (quoting *Certain Laser Bar Code Scanners and Scan Engines, Components Thereof, and Products Containing Same*, Inv. No. 337-TA-551, Comm'n Op. (Pub. Version) at 22 (June 14, 2007)).

PTS does not seek a cease and desist order because ACON has represented that it has no inventory of ACON 3-1 Accused Products properly labelled for sale in the United States. CIB at 86. ACON agrees that "[n]o cease and desist order is necessary." RRB at 65.

Having considered the arguments of the parties, it is my recommendation that the Commission not issue a cease and desist order in the event it finds a violation of section 337 has occurred.

D. Bond During Presidential Review

Pursuant to section 337(j)(3), the administrative law judge and the Commission must determine the amount of bond to be required of a respondent, during the 60-day Presidential review period following the issuance of permanent relief, in the event that the Commission determines to issue a remedy. The purpose of the bond is to protect the complainant from any injury. 19 U.S.C. § 1337(j)(3); 19 C.F.R. §§ 210.42(a)(1)(ii), 210.50(a)(3).

When reliable price information is available, the Commission has often set bond by eliminating the differential in sales prices between the domestic product and the imported, infringing product. *Certain Microsphere Adhesives, Process for Making Same, and Products Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, USITC Pub. No. 2949, Comm'n Op. at 24 (1995). In other cases, the Commission has turned to alternative approaches, especially when the level of a reasonable royalty rate could be ascertained. *See Certain Integrated Circuit Telecommunication Chips and Products Containing Same, Including Dialing Apparatus*, Inv. No. 337-TA-337, USITC Pub. No. 2670, Comm'n Op. at 41-43 (1995). A 100 percent bond has been required when no effective alternative existed. *Certain Flash Memory Circuits and Products Containing Same*, Inv. No. 337-TA-382, USITC Pub. No. 3046, Comm'n Op. at 26-27 (July 1997) (a 100% bond imposed when price comparison was not practical because the parties sold products at different levels of commerce, and the proposed royalty rate appeared to be *de minimis* and without adequate support in the record).

With respect to bond, "PTS does not currently seek imposition of a bond because ACON has represented that it 'will not be importing any accused devices during the presidential review period' and that 'there is no risk of injury to PTS during that time.'" CIB at 86. Yet, "[i]f ACON withdraws its representation," PTS argues that the Commission "should impose a bond of 100% of the entered value of the infringing products to protect PTS from injury during the 60-day Presidential review period." *See id.* Specifically, PTS argues that "[it] is the only seller of the DI Products, and would be severely harmed by ACON's sales of the ACON 3-1 Accused Products." *Id.*

ACON argues that "PTS does not offer evidence sufficient to support any bond amount, let alone 100%." RRB at 65. ACON further argues that "PTS never made any effort to show that a bond could not be calculated," and that "[t]hus, the bond amount should be 0%." *Id.*

Having considered the arguments of the parties and the evidence of record, I find that PTS has not shown that its proposed bond amount of 100% is warranted under the circumstances of this investigation. In particular, PTS has not demonstrated that calculation of a price differential between domestic products and the imported accused products is not possible, or that a reasonable royalty could not be calculated. Accordingly, it is my recommendation that the Commission, in the event it finds a violation of section 337 has occurred, set a zero percent bond for any importations of infringing products during the Presidential review period.

XI. INITIAL DETERMINATION ON VIOLATION

For the reasons set forth above, it is my initial determination that a violation of section 337 of the Tariff Act, as amended, has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation, of certain blood cholesterol testing strips and associated systems containing the same that infringe asserted claim 19 of U.S. Patent No. 7,087,397 and asserted claims 1, 4, 6, 8, and 15 of the U.S. Patent No. 7,625,721. I have determined no violation of section 337 based on allegations of infringement of U.S. Patent No. 7,494,818.

I hereby certify to the Commission this Initial Determination and the Recommended Determination.

The Secretary shall serve the confidential version of this Initial Determination upon counsel who are signatories to the Protective Order (Order No. 1) issued in this investigation. A public version will be served at a later date upon all parties of record.

Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall become the determination of the Commission unless a party files a petition for review 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 therein.

XII. ORDER

Within seven days of the date of this document, the parties shall jointly submit a single proposed public version with any proposed redactions indicated in red. If the parties submit excessive redactions, they may be required to provide declarations from individuals with personal knowledge, justifying each proposed redaction and specifically explaining why the information sought to be redacted meets the definition for confidential business information set forth in 19 C.F.R. § 201.6(a). To the extent possible, the proposed redactions should be made electronically, in a single pdf file using the "Redact Tool" within Adobe Acrobat. The proposed redactions should be submitted as "marked" but not yet "applied." The proposed redactions should be submitted via email to Cheney337@usitc.gov and not filed on EDIS.

SO ORDERED.

Clark S. Cheney
Administrative Law Judge

CERTAIN BLOOD CHOLESTEROL TESTING STRIPS AND ASSOCIATED SYSTEMS CONTAINING THE SAME

Inv. No. 337-TA-1116

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **Initial Determination on Violation of Section 337 and Recommended Determination on Remedy and Bond** has been served by hand upon the following parties as indicated, on **July 5, 2019**.

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

On Behalf of Complainant: Polymer Technology Systems, Inc.:

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☐ Other:_____

On Behalf of Respondents: ACON Laboratories, Inc. and ACON Biotech (Hangzhou) Co. Ltd.

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	
CERTAIN BLOOD CHOLESTEROL TESTING STRIPS AND ASSOCIATED SYSTEMS CONTAINING THE SAME	**Investigation No. 337-TA-1116**

NOTICE OF COMMISSION DETERMINATION NOT TO REVIEW AN INITIAL 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 ("Commission") has determined not to review a February 13, 2019 initial determination ("ID") (Order No. 13) granting the complainant's unopposed motion for summary determination that it has satisfied the economic prong of the domestic industry requirement.

FOR FURTHER INFORMATION CONTACT: Ron Traud, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205-3427. 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 Information System ("EDIS") (*https://edis.usitc.gov*). Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone (202) 205-1810.

SUPPLEMENTARY INFORMATION: On June 5, 2018, the Commission instituted this investigation based on an amended complaint filed on behalf of Polymer Technology Systems, Inc. of Indianapolis, Indiana ("PTS"). 83 FR 26087 (June 5, 2018). 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 blood cholesterol testing strips and associated systems containing the same by reason of infringement of one or more of claims 1–3, 5, 10, 13–14, and 17–20 of U.S. Patent No. 7,087,397 ("the '397 patent"); claims 1–9 and 13–15 of U.S. Patent No. 7,625,721 ("the '721 patent"); and claims 8–11 of U.S. Patent No. 7,494,818 ("the '818 patent"). *Id.* The

Commission's Notice of Investigation named as respondents ACON Laboratories, Inc. of San Diego, California; and ACON Biotech (Hangzhou) Co., Ltd., of Hangzhou Zhejiang, China. *Id.* The Office of Unfair Import Investigations was not named as a party in this investigation. *Id.*

The Commission previously terminated the investigation as to claims 10, 13, 14, 17, and 20 of the '397 patent; claims 2, 3, 13, and 14 of the '721 patent; and claim 10 of the '818 patent. Order No. 14, *unreviewed*, Notice (Mar. 4, 2019); Order No. 10, *unreviewed*, Notice (Feb. 21, 2019); Order No. 7, *unreviewed*, Notice (Sept. 25, 2018).

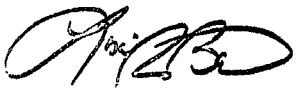
On December 19, 2018, PTS filed an unopposed motion for summary determination that it satisfied the economic prong of the domestic industry requirement.

On February 13, 2019, the presiding administrative law judge issued Order No. 13, the subject ID, granting the motion. No party petitioned for review of the ID.

The Commission has determined not to review 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 CFR part 210).

By order of the Commission.



Lisa R. Barton
Secretary to the Commission

Issued: March 11, 2019

CERTAIN BLOOD CHOLESTEROL TESTING STRIPS AND ASSOCIATED SYSTEMS CONTAINING THE SAME **Inv. No. 337-TA- 1116**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **NOTICE** has been served upon the following parties as indicated, on **March 12, 2019**.

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

On Behalf of Complainants Polymer Technology Systems, Inc.:

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On Behalf of Respondents ACON Laboratories, Inc. and ACON Biotech (Hangzhou) Co., Ltd.:

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PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of	
CERTAIN BLOODCHOLESTEROL TESTING STRIPS AND ASSOCIATED SYSTEMS CONTAINING THE SAME	**INV. NO. 337-TA-1116**

ORDER NO. 13: INITIAL DETERMINATION GRANTING COMPLAINANT'S MOTION FOR SUMMARY DETERMINATION THAT COMPLAINANT SATISFIES THE ECONOMIC PRONG OF THE DOMESTIC INDUSTRY REQUIREMENT

(February 13, 2019)

On December 19, 2018, complainant Polymer Technology Systems, Inc. ("PTS") moved (1116-009) for summary determination that it satisfies the economic prong of the domestic industry requirement of 19 U.S.C. § 1337(a) for each of U.S. Patent No. 7,087,397; U.S. Patent No. 7,625,721; and U.S. Patent No. 7,494,818 (collectively, "asserted patents"). Respondents ACON Laboratories, Inc. and ACON Biotech (Hangzhou) Co., Ltd. (collectively "ACON") indicated to PTS that they do not oppose the motion. Mot. at 2. While ACON did not file a response to the motion, ACON did indicate its position with respect to certain allegedly undisputed facts in the chart required by Ground Rule 5.5 entered in this investigation. ACON did not dispute any fact material to the disposition of this motion.

I have reviewed the pleadings and evidence submitted with the motion. As discussed below, I have concluded that it is appropriate to grant summary determination that PTS has satisfied the economic prong of the domestic industry requirement.

I. Legal Standards

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. 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) (citations omitted).

In a section 337 investigation based on patent infringement, the complainant has the burden of proving the existence of a domestic industry relating to articles protected by each of the patents at issue. *See* 19 U.S.C. § 1337(a)(2). Under Commission precedent, this domestic industry requirement may be viewed as comprising a technical prong and an economic prong. *Inter Digital Communications, LLC v. ITC*, 707 F.3d 1295, 1298 (Fed. Cir. 2013); *Certain Printing and Imaging Devices and Components Thereof*, Inv. No. 337-TA-690, Comm'n Op., 2011 WL 1303160 at *14 (U.S.I.T.C. Feb. 2000); *see also Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op., 2009 WL 5134139 at *10 (U.S.I.T.C. Dec. 2009). "The technical prong concerns whether complainant practices at least one claim of the asserted patents. The economic prong concerns domestic activities with respect to the patent or patented article." *Certain Printing and Imaging Devices*, 2011 WL 1303160 at *14.

Section 337(a)(3) sets forth the following economic criteria for determining whether the economic prong of the domestic industry requirement is satisfied in such investigations:

> [A]n 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. *See Certain Printing and Imaging Devices*, 2011 WL 1303160 at *14. Thus, a complainant will satisfy the economic prong of the domestic industry requirement upon establishing that the economic activities set forth in subsections (A), (B), or (C) have taken place or are taking place with respect to articles protected by the asserted patent(s).

Determining whether an activity is "significant" under sections (A) and (B) focuses on the nature of the activities with respect to the article protected by the patent, and is not measured subject to a rigid mathematical formula. *Id*. at *15. Activities can be shown to be "significant," for example, by demonstrating their importance to the articles protected by the patent in the context of the company's operations, the marketplace, or the relevant industry. *Id.; see also Certain Batteries and Electrochemical Devices Containing Composite Separators, Components Thereof, and Products Containing Same*, Notice of Commission Determination to Review, and on Review Affirm (Sep. 17, 2018) (affirming summary determination that the economic prong of the domestic industry had been satisfied.)

II. Alleged Domestic Industry Products

PTS makes blood cholesterol testing strips and handheld analyzers for analyzing those strips. PTS contends its products practice claims of the asserted patents as follows:

	'397 Patent	'721 Patent	'818 Patent
Analyzers	CardioChek®	CardioChek®	CardioChek® PA
	CardioChek® PA	CardioChek® PA	CardioChek® Plus
	CardioChek® Plus	CardioChek® Plus	
Test Strips	Lipid Panel Test Strips		Lipid Panel Test Strips
	HDL Cholesterol Test Strips	HDL Cholesterol Test Strips	
	CHOL+HDL Test Strips	CHOL+HDL Test Strips	
	CHOL+HDL+GLU Test Strips		CHOL+HDL+GLU Test Strips
	Metabolic Chemistry Panel Test Strips		Metabolic Chemistry Panel Test Strips

ACON disputes that the products listed above actually practice one or more claims of the asserted patents. However, all parties agree that issue is not before me in the present motion.

III. Undisputed Facts

PTS has submitted with its motion a declaration and certain deposition testimony of its President and CEO Robert S. Huffstodt. Mr. Huffstodt described the design, development, and manufacture of the alleged PTS domestic industry products. PTS also submitted leases and rent payments for its plants, a report on the net book value of its equipment, payroll reports showing labor expenses, and a report showing research and development expenditures. PTS additionally provided financial analyses showing the percentage of revenue attributed to each alleged domestic industry product. ACON does not dispute the authenticity or content of any of these documents.

From the evidence submitted, I have concluded the following facts are not disputed.

A. PTS's Investments in Plant and Equipment Under Section 337(a)(3)(A)

1. PTS's Manufacturing Facilities and Equipment

Since August 15, 2000, PTS has maintained its headquarters at 7736 Zionsville Road, Indianapolis, Indiana 46268. Ex. 1[1], Am. Huffstodt Decl. at ¶ 3.1. PTS designs, develops, and manufactures all of the alleged domestic industry test strips at PTS's Indianapolis headquarters. PTS also designs its CardioChek® series of handheld analyzers at its facility in Indianapolis, but those analyzers are manufactured by third-party suppliers in Wisconsin and Alabama. *Id*. at ¶¶ 3.1, 3.3 n.4.

PTS's headquarters houses [redacted] in equipment used primarily for the manufacturing and development of the alleged domestic industry products. *Id*. at ¶ 3.2; Ex. 3, PTS_000038584–609. PTS's headquarters also houses nearly all of PTS's business functions relating to the alleged domestic industry products. Ex. 1, Am. Huffstodt Decl. at ¶ 3.3. PTS pays [redacted] annually to lease its headquarters facility. *Id*. at ¶ 3.3; Ex. 4, PTS_000038563–66. As of March 1, 2018, the book value of PTS's leasehold improvements in its headquarters facility is approximately [redacted], net of depreciation. Ex. 1, Am. Huffstodt Decl. at ¶ 3.3. Approximately [redacted] square foot headquarters facility is used primarily to manufacture, produce, and test the alleged domestic industry products. *Id*. at ¶ 3.4.

2. PTS's Disaster Recovery and Overflow Facility

Since March 13, 2014, PTS has also maintained a disaster recovery and overflow site in Indianapolis. *Id*. at ¶ 3.3. The disaster recovery and overflow site functions as a backup facility from which operations relating to the alleged domestic industry products may continue in the event of a disaster or other event impacting use of the Indianapolis headquarters facility. *Id*. at ¶ 3.3.

[1] All citations to "Ex." refer to the exhibits submitted with PTS's motion for summary determination.

PTS currently pays [redacted] annually to lease its disaster recovery and overflow site. *Id*. at ¶ 3.3; Ex. 5, PTS_0000385686; Ex. 6, PTS_000038570–72; Ex. 7, PTS_000038574–77.

B. PTS's Deployment of Labor and Capital Under Section 337(a)(3)(B)

PTS employs [redacted] personnel in the United States. In 2017, approximately [redacted] of PTS's employees at its Indianapolis headquarters facility were involved in manufacturing, engineering, operations, and research and development of products, including the alleged domestic industry products. Ex. 1, Am. Huffstodt Decl. at ¶ 4.1; Ex. 9, PTS_000038610. In 2017, PTS expended approximately [redacted] in total payroll expenses. Ex. 1, Am. Huffstodt Decl. at ¶ 4.2; Ex. 12, PTS_000038573. As of March 31, 2018, PTS paid approximately total [redacted] in payroll expenses. Ex. 1, Am. Huffstodt Decl. at ¶ 4.2; Ex. 12, PTS_000038573.

PTS's capital investments in plant and equipment detailed above also constitute an employment of capital.

C. PTS's Research and Development Investments Under Section 337(a)(3)(C)

1. PTS's Engineering Activities

As of March 2018, [redacted] full-time employees conduct engineering in areas such as product design and research and development the Indianapolis headquarters facility. Ex. 1, Am. Huffstodt Decl. at ¶ 5.1; Ex. 9, PTS_000038610. PTS's 2018 payroll expenses for these research and development employees is approximately [redacted]. Ex. 1, Am. Huffstodt Decl. at ¶ 5.1; Ex. 9, PTS_000038610. The [redacted] research and development employees spend approximately [redacted] of their time on the alleged domestic industry products. Ex. 1, Am. Huffstodt Decl. at ¶ 5.1. Since 2015, PTS has paid approximately [redacted] on research and development expenses in Indianapolis. *Id*.; Ex. 10, PTS_000038581–83. This [redacted] includes expenses such as labor, fringe benefits, supplies, consulting fees, and testing materials. Ex. 1, Am. Huffstodt Decl. at ¶ 5.1; Ex. 10, PTS_000038581–83.

Based on PTS's estimate that at least [redacted] of its research and development expenses and payroll are attributable to the alleged domestic industry products, PTS has spent at least [redacted] on research and development since 2015 with respect to the Domestic Industry Products. Ex. 1, Am. Huffstodt Decl. at ¶ 5.1 n.6. Similarly, PTS anticipates spending at least [redacted] on research and development payroll in 2018. *Id.*

D. Summary of Expenses and Investments in the United States Contributing to the Domestic Industry Products

A summary of the expenses and investments detailed above, and allocations thereof to each of the asserted patents, is summarized below: [2]

[2] PTS also submitted evidence of certain other investments in support of its motion, including evidence that PTS [redacted], and evidence about quality control expenses. None of this evidence is disputed. Because PTS's investments discussed herein are sufficient to satisfy the economic prong of the domestic industry requirement, I need not consider the additional evidence submitted by PTS.

Description of Expenditure	Total Expenditure	'397 Patent Allocation	'721 Patent Allocation	'818 Patent Allocation
Annual rent for Indianapolis headquarters	[redacted]			
Book value of leasehold improvements as of March 1, 2018				
Annual rent for disaster recovery and overflow site				
PTS's annual payroll in 2017				
Current payroll paid out in 2018 as of March 31, 2018				
Projected payroll for full-time R&D employees in 2018				
Cumulative R&D expenses in Indianapolis since 2015				

IV. Conclusion

In view of the undisputed facts above, it is my initial determination that PTS has shown, with respect to products alleged to practice the asserted patents, a significant investment in plant and equipment and a significant employment of labor and capital. PTS has also shown a significant investment in the exploitation of the asserted patents through engineering and research and development.

PTS's motion (1116-009) for partial summary determination that it has satisfied the economic prong of the domestic industry requirement is granted. Of course, PTS must still show at the evidentiary hearing in this investigation that the products that PTS has relied upon to prove up its expenditures are products protected by the asserted patents.

This initial determination is hereby certified to the Commission. 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, each party shall submit a statement to Cheney337@ustic.gov stating whether or not it seeks to have any portion of this document redacted from the public version. Any party seeking to have any portion of this document redacted from the public version thereof shall attach a copy of this document with red brackets indicating any portion asserted to contain confidential business information.[3] The parties' submissions concerning the public version of this document should not be filed with the Commission Secretary.

SO ORDERED.

Clark S. Cheney
Administrative Law Judge

[3] If the parties submit excessive redactions, they may be required to provide an additional written statement, supported by declarations from individuals with personal knowledge, justifying each proposed redaction and specifically explaining why the information sought to be redacted meets the definition for confidential business information set forth in Commission Rule 201.6(a). *See* 19 C.F.R. § 201.6(a).

CERTAIN BLOOD CHOLESTEROL TESTING STRIPS AND ASSOCIATED SYSTEMS CONTAINING THE SAME **Inv. No. 337-TA- 1116**

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **INITIAL DETERMINATION** has been served upon the following parties as indicated, on **May 5, 2020**.

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

On Behalf of Complainant Polymer Technology Systems, Inc.:

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☐ Via First Class Mail
☒ Other: Email Notification of Availability for Download

On Behalf of Respondents ACON Laboratories, Inc. and ACON Biotech (Hangzhou) Co., Ltd.:

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☐ Via Hand Delivery
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