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.