

**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