

**UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.**

In the Matter of

**CERTAIN GABAPENTIN
IMMUNOASSAY KITS AND TEST
STRIPS, COMPONENTS THEREOF, AND
METHODS THEREFOR**

Investigation No. 337-TA-1239

**NOTICE OF COMMISSION DETERMINATION NOT TO REVIEW
AN INITIAL DETERMINATION TERMINATING A FINAL RESPONDENT BASED
ON SETTLEMENT; REQUEST FOR WRITTEN SUBMISSIONS ON REMEDY, THE
PUBLIC INTEREST, AND BONDING**

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (“ID”) (Order No. 29) terminating the final, non-defaulting respondent, Shanghai Chemtron Biotech Co. Ltd., in the above-captioned investigation based on settlement. The Commission has further determined to find that the complainants’ declaration seeking immediate relief against a respondent previously found to be in default is moot. The Commission also requests written submissions from the parties, interested government agencies, and interested persons on remedy, the public interest, and bonding concerning the defaulted respondent.

FOR FURTHER INFORMATION CONTACT: Lynde Herzbach, Office of the General Counsel, U.S. International Trade Commission, 500 E Street S.W., Washington, D.C. 20436, telephone (202) 205-3228. 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 at <https://www.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: On January 25, 2021, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (“section 337”), based on a complaint filed by ARK Diagnostics, Inc. of Fremont, California (“ARK”). See 86 FR 6918-19. The complaint, as supplemented, alleges a violation of

section 337 based upon the importation into the United States, sale for importation, or sale after importation into the United States of certain gabapentin immunoassay kits and test strips, components thereof, and methods therefor by reason of infringement of certain claims of U.S. Patent Nos. 8,828,665 and 10,203,345. *Id.* The complaint further alleges that a domestic industry exists. *Id.* The notice of investigation names fourteen respondents, including Shanghai Chemtron Biotech Co., Ltd. of Shanghai, China (“Shanghai Chemtron”) and Kappa City Biotech, SAS of Montlucon, France (“Kappa City”). *See id.* The complaint and notice of investigation were later amended to add two respondents. Order No. 8 (March 9, 2021), *unreviewed by* 86 FR 16640-41 (March 30, 2021).

The Commission previously terminated six respondents based on consent orders. Order Nos. 11 and 12 (Mar. 31, 2021), *unreviewed by* Comm’n Notice (Apr. 15, 2021); Order No. 14 (April 9, 2021), *unreviewed by* Comm’n Notice (Apr. 22, 2021); Order No. 15 (April 12, 2021), *unreviewed by* Comm’n Notice (May 12, 2021). The Commission also previously terminated three respondents based on settlement agreements. Order No. 13 (Apr. 5, 2021), *unreviewed by* Comm’n Notice (Apr. 19, 2021); Order No. 17 (May 5, 2021), *unreviewed by* Comm’n Notice (May 18, 2021); Order No. 18 (May 20, 2021), *unreviewed by* Comm’n Notice (June 21, 2021). The Commission also terminated five respondents based on partial withdrawal of the complaint. Order No. 20 (June 4, 2021), *unreviewed by* Comm’n Notice (June 28, 2021); Order No. 21 (June 14, 2021), *unreviewed by* Comm’n Notice (July 1, 2021).

On May 18, 2021, the Commission determined not to review an initial determination (Order No. 16) finding Kappa City in default. Order No. 16 (Apr. 30, 2021), *unreviewed by* Comm’n Notice (May 18, 2021).

On December 7, 2021, ARK filed a declaration seeking immediate entry of a limited exclusion order and cease and desist order against Kappa City.

On January 20, 2022, ARK filed a motion to terminate this investigation with respect to Shanghai Chemtron based on a settlement.

On January 31, 2022, the presiding administrative law judge issued the subject ID granting the motion to terminate Shanghai Chemtron based on settlement. *See* Order No. 29 (Jan. 31, 2022). The subject ID finds that the motion complies with Commission Rule 210.21(b)(1) (19 CFR 210.21(b)) and that no extraordinary circumstances prevent denying the motion. The subject ID further finds that termination of Shanghai Chemtron based on settlement would not be contrary to the public interest.

No party petitioned for review of the subject ID.

The Commission has determined not to review the subject ID (Order No. 29). Shanghai Chemtron is terminated from the investigation.

The Commission has further determined that ARK’s declaration is now moot given the termination of the final remaining non-defaulting respondent in this investigation. The

Commission has also determined to request briefing on the issues of remedy, bonding, and the public interest.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia*, (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) 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 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and 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, disapprove, or take no action on the Commission's determination. 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: Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding.

ARK is requested to submit proposed remedial orders for the Commission's consideration. ARK is further requested to state the dates that the Asserted Patents expire, to provide the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. The initial written submissions and proposed remedial orders must be filed no later than close of business on **March 8, 2022**. Reply submissions must be filed no later than the close of business on **March 15, 2022**. 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. The Commission's paper filing requirements in

19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (Inv. No. 337-TA-1239) in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, https://www.usitc.gov/documents/handbook_on_filing_procedures.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 by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. 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, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on February 22, 2022.

While temporary remote operating procedures are in place in response to COVID-19, the Office of the Secretary is not able to serve parties that have not retained counsel or otherwise provided a point of contact for electronic service. Accordingly, pursuant to Commission Rules 201.16(a) and 210.7(a)(1) (19 CFR 201.16(a), 210.7(a)(1)), the Commission orders that the complainant complete service for any party/parties without a method of electronic service noted on the attached Certificate of Service and shall file proof of service on the Electronic Document Information System (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: February 22, 2022