UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	
CERTAIN GABAPENTIN IMMUNOASSAY KITS AND TEST STRIPS, COMPONENTS THEREOF, AND METHODS THEREFOR	**Inv. No. 337-TA-1239**

NOTICE OF INSTITUTION OF INVESTIGATION

Institution of Investigation Pursuant to 19 U.S.C. 1337

AGENCY: U.S. International Trade Commission

ACTION: Notice

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on December 2, 2020, under section 337 of the Tariff Act of 1930, as amended, on behalf of ARK Diagnostics, Inc. of Fremont, California. A supplement to the complaint was filed on December 2, 2020 and an amended complaint was filed on December 23, 2020. The complaint, as amended, alleges 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 gabapentin immunoassay kits and test strips, components thereof, and methods therefor by reason of infringement of certain claims of U.S. Patent No. 8,828,665 ("the '665 patent") and U.S. Patent No. 10,203,345 ("the '345 patent"). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at https://edis.usitc.gov. For help accessing EDIS, please email EDIS3Help@usitc.gov. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205-2000. General information concerning the Commission may also be obtained by accessing its internet server at https://www.usitc.gov.

FOR FURTHER INFORMATION CONTACT: Katherine Hiner, Office of Docket Services, U.S. International Trade Commission, telephone (202) 205-1802.

SUPPLEMENTARY INFORMATION:

AUTHORITY: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.10 (2020).

SCOPE OF INVESTIGATION: Having considered the complaint, the U.S. International Trade Commission, on January 19, 2021, **ORDERED THAT** –

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether 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 products identified in paragraph (2) by reason of infringement of one or more of claims 1-3, 6, 7, 9, 14, 17, 18, 20, and 21 of the '665 patent; and claims 1, 2, 7, 8, 11, 12, 19, 20, 26, and 27 of the '345 patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is "gabapentin immunoassays kits, gabapentin-specific test strips, multi-drug test kits and strips that test for gabapentin among other drugs, and components of such kits and test strips";

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is:

ARK Diagnostics, Inc.
48089 Fremont Boulevard
Fremont, CA 94538

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Hangzhou AllTest Biotech Co., Ltd.
No. 550, Yinhai Street
Hangzhou Economy and Technology Development Area
Hangzhou, China 210018

Shanghai Chemtron Biotech Co., Ltd.
No. 518, Qingdai Rd.
International Medical Park, Pudong 201318
Shanghai, China

Chemtron Biotech Co., Ltd.
9425 Brown Deer Road, Suite B
San Diego, CA 92121

Zhejiang Orient Gene Biotech Co., Ltd.
#3787 East Yangguang Ave., Dipu St.
Anji 313300, Huzhou
Zhejiang, China

Healgen Scientific, LLC
3818 Fuqua Street
Houston, TX 77047

Kappa City Biotech, SAS
32 Rue Danton
03100 Montlucon
France

12PanelMedical, Inc.
846 Wee Burn Street
Apt. E306
Sarasota, FL 34243

Acro Biotech, Inc.
9500 7th Street, Unit M
Rancho Cucamonga, CA 91730

AlcoPro, Inc.
2547 Sutherland Ave.
Knoxville, TN 37919

American Screening, LLC
9742 St. Vincent Ave., Ste. 100
Shreveport, LA 71106

Confirm Biosciences, Inc.
10123 Carroll Canyon Road
San Diego, CA 92131

Mercedes Medical, LLC
12210 Rangeland Parkway
Lakewood Ranch, FL 34211

TransMed Co., LLC
1887 McFarland Parkway
Alpharetta, GA 30005

Transmetron, Inc.
1476 S. Major Street (50 East)
Salt Lake City, UT 84115

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not participate as a party in this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 C.F.R. 210.13. Pursuant to 19 C.F.R. 201.16(e) and 210.13(a), as amended in 85 Fed. Reg. 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainant of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: January 19, 2021