

December 1, 2020

VIA ELECTRONIC FILING

The Honorable Lisa R. Barton
Secretary to the Commission
U.S. INTERNATIONAL TRADE
COMMISSION
500 E Street, S.W., Room 112-A
Washington, D.C. 20436

Re: *Certain Gabapentin Immunoassay Kits and Test Strips, Components Thereof, and Methods Therefor*, Inv. No. 337-TA-_____

Dear Secretary Barton:

Enclosed for filing on behalf of Complainant ARK Diagnostics, Inc. (“ARK”) are the following documents in support of ARK’s request that the Commission commence an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended:

1. One (1) electronic copy of the verified Non-Confidential Complaint and the Public Interest Statement. (19 C.F.R. §§ 210.8(a)(1)(i), 210.8(b));
2. One (1) electronic copy of ARK’s letter and certification requesting confidential treatment for the information contained in the Confidential Exhibits 5C and 106C. (19 C.F.R. §§ 210.5(d) and 201.6(b));
3. One (1) electronic copy of the non-confidential exhibits and public versions of the Confidential Exhibits (19 C.F.R. § 210.8(a)(1)(i))
4. One (1) electronic copy of the Confidential Exhibits 5C and 106C (19 C.F.R. §§ 210.8(a)(1)(ii) and 201.6(c));
5. One (1) electronic certified copy of United States Patent Nos. 8,828,665 (“the ’665 patent”) and United States Patent No. 10,203,345 (“the ’345 patent”); (collectively, the “Asserted Patents”) cited in the Complaint as Exhibits 1 and 2. (19 C.F.R. §§ 210.12(a)(9)(i));
6. One (1) electronic certified copy of each of the assignments for the Asserted Patents cited in the Complaint as Exhibits 3 and 4. (19 C.F.R. §§ 210.12(a)(9)(ii));

7. The original certified copies of the prosecution histories for the Asserted Patents included as Appendices 1 and 2 to the Complaint. (19.C.F.R. §§ 210.12(c)(1));
8. One (1) copy of patent and technical reference documents identified in each of the prosecution histories of the Asserted Patents, included in the Complaint as Appendices 3 and 4. (19.C.F.R. §§ 210.12(c)(2));

Please contact me with any questions regarding this submission. Thank you for your attention to this matter.

Sincerely,



Joshua A. Hartman

Paul M. Bartkowski
Joshua Hartman
Hayley Ostrin
ADDUCI, MASTRIANI & SCHAUMBERG, L.L.P.
1133 Connecticut Avenue, N.W.
Washington, DC 20036
Telephone: (202) 467-6300
Facsimile: (202) 466-2006

Counsel for Complainant ARK Diagnostics, Inc.

December 1, 2020

***REQUEST FOR CONFIDENTIAL TREATMENT & CERTIFICATION REGARDING
REQUEST FOR CONFIDENTIAL TREATMENT***

VIA ELECTRONIC FILING

The Honorable Lisa R. Barton
Secretary to the Commission
U.S. INTERNATIONAL TRADE
COMMISSION
500 E Street, S.W., Room 112-A
Washington, D.C. 20436

Re: *Certain Gabapentin Immunoassay Kits and Test Strips, Components Thereof, and
Methods Therefor, Inv. No. 337-TA-_____*

Dear Secretary Barton:

In accordance with Commission Rules 210.5(d) and 210.6(b)(1), 19 C.F.R. §§ 201.5 and 210.6, Complainant ARK Diagnostics, Inc. (“Complainant”) respectfully requests confidential treatment of the business information contained in Confidential Exhibits 5C and 106C to the Verified Confidential Complaint identified above. The information contained in Confidential Exhibits 5C and 106C qualifies as confidential business information pursuant to Commission Rule 201.6 because:

- a. It is not available to the public;
- b. Unauthorized disclosure of such information could cause substantial harm to Complainant’s and its contractual partner’s competitive positions; and
- c. Its disclosure could impair the Commission’s ability to obtain information necessary to perform its statutory function.

I certify that the proprietary commercial information, proprietary commercial relationships, and/or proprietary business information contained in Confidential Exhibits 5C and 106C is not reasonably available to the public, and thus warrants confidential treatment.

Thank you for your attention to this matter. Please contact me with any questions regarding this submission.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Joshua A. Hartman', with a long horizontal flourish extending to the right.

Joshua A. Hartman

Paul M. Bartkowski

Joshua Hartman

Hayley Ostrin

ADDUCI, MASTRIANI & SCHAUMBERG, L.L.P.

1133 Connecticut Avenue, N.W.

Washington, DC 20036

Telephone: (202) 467-6300

Facsimile: (202) 466-2006

Counsel for Complainant ARK Diagnostics, Inc.

**THE 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-_____

CERTIFICATION REGARDING REQUEST FOR CONFIDENTIAL TREATMENT

I, Joshua A. Hartman, counsel for Complainant ARK Diagnostics, Inc. (“Complainant”),
declare as follows:

1. I have reviewed Complainant’s Confidential Exhibits Nos. 5 and 106 to the above-captioned Verified Confidential Complaint (“the Confidential Exhibits”) filed concurrently with this Certification.
2. The Confidential Exhibits contain the following confidential business information of Complainant:
 - a. proprietary information not available to the public; and
 - b. confidential information related to the terms of agreements between Complainant and other parties regarding the Asserted Patents.
3. Disclosure of the confidential business information in the Confidential Exhibits to the public would cause substantial harm to Complainant, its contractual partner, and its competitive position.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 1st day of December 2020 in Alexandria, Virginia.

/s/ Joshua Hartman _____

Paul M. Bartkowski

Joshua Hartman

Hayley Ostrin

ADDUCI, MASTRIANI & SCHAUMBERG, L.L.P.

1133 Connecticut Avenue, N.W.

Washington, DC 20036

Telephone: (202) 467-6300

Facsimile: (202) 466-2006

Counsel for Complainant ARK Diagnostics, Inc.

**THE 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-_____

COMPLAINANT'S INITIAL STATEMENT ON THE PUBLIC INTEREST

Complainant ARK Diagnostics, Inc. (“ARK”) respectfully submits this Statement on the Public Interest regarding the requested remedial orders against the proposed respondents named in the accompanying complaint. ARK seeks a permanent limited exclusion order against the accused products—gabapentin immunoassay kits and test strips, and components of such kits and test strips, that infringe one or more claims of United States Patents No. 8,828,665 (“the ’665 Patent”) and No. 10,203,345 (“the ’345 Patent”) (collectively, “the Asserted Patents”). ARK also seeks permanent cease-and-desist orders that prohibit the Proposed Respondents, their subsidiaries, related companies, and agents from, among other things, importing, selling, offering for sale, licensing, leasing, marketing, and distributing the accused products, as well as from aiding and abetting others in the importation, sale for importation, or sale after importation of such products.

The relief requested by ARK poses no significant threat to the public interest. The Commission has acknowledged the importance of protecting domestic intellectual property rights against infringing imports and thus denies relief only in the exceptional circumstances of severe harm to the public interest.¹ Here, the requested remedies would serve the public interest by supporting American innovation and would not harm the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers. Consequently, the Commission should decline to delegate public interest to the Administrative Law Judge (“ALJ”) in an investigation initiated in response to ARK’s complaint.

¹ See, e.g., *Certain Powered Cover Plates*, Inv. No. 337-TA-1124, Comm’n Op. at 29-30 (Jul. 10, 2020) (citations omitted) (“[C]ompetition policy in the United States favors the protection of valid intellectual property rights.”); *Certain Toothbrushes & the Packaging Thereof*, Inv. No. 337-TA-391, USITC Pub. No. 3068, Comm’n Op. at 6 (Oct. 1997) (“[T]he public interest favors the protection of U.S. intellectual property rights . . .”).

I. ARK AND THE PROPOSED RESPONDENTS

ARK is an American company dedicated to developing *in vitro* diagnostic immunoassays for detecting and managing drug levels in patients. ARK's innovations include improved materials and processes for detecting gabapentin in biological samples that offer improved speed and accuracy over traditional detection methods. The U.S. Food and Drug Administration ("FDA") has approved ARK's gabapentin immunoassays and associated products for clinical use. (Ex. 63.) ARK has conducted its activities related to the Asserted Patents at its facility in Fremont, California. Further, ARK has partnered with Advin Biotech, Inc. ("Advin") for the exclusive U.S. distribution of rapid gabapentin tests that use ARK's gabapentin materials protected by the Asserted Patents. Advin has started manufacturing these rapid gabapentin tests in the U.S. and plans to increase production over the next few years.

The Proposed Respondents import, sell for importation, and/or sell after importation into the United States rapid gabapentin immunoassay kits and test strips, as well as components of such kits and test strips, that practice the Asserted Patents or are made under or by means of processes covered by the Asserted Patents.

II. USE OF THE PRODUCTS AT ISSUE IN THE UNITED STATES

Gabapentin is a chemical compound used as an anti-seizure and anti-convulsant medication. Doctors prescribe gabapentin with patient-specific dosages due to the varying rates at which patients metabolize the compound. Consequently, clinical use of gabapentin requires assaying patients' biological samples to confirm that their prescribed dosages are appropriate. ARK manufactures, markets, sells, and distributes a gabapentin immunoassay kit that allows for quantitative analysis of patients' samples using a clinical chemistry analyzer.

Aside from its clinical use, enforcement agencies have identified gabapentin as a drug of abuse, as users take it along with opioids to increase their potency.⁵ This recreational use has led

to the development of rapid tests for determining whether biological samples contain gabapentin. These rapid gabapentin tests, which include those offered by Advin and the Proposed Respondents, only identify whether an opioid user also consumed gabapentin. As such, they are appropriate for law enforcement and workplace settings, among others. Further, because rapid gabapentin tests do not provide actionable medical results, they are ill-suited for clinical use.

III. ARK’S REQUESTED REMEDIES DO NOT IMPLICATE PUBLIC INTEREST ISSUES

A. The Requested Remedies Do Not Raise Public Health, Safety, or Welfare Concerns

The relief requested by ARK does not raise any public health, safety, or welfare concerns. The Accused Products are rapid gabapentin immunoassay kits and test strips, unapproved for use in clinical settings. (*See supra*, Section II.) Because they cannot be used for medical purposes, they do not raise any health or welfare concern recognized by the Commission.²

B. Directly Competitive Articles from ARK, Advin, and Third Parties Could Replace any Excluded Articles

No public interest concerns exist when the U.S. demand for an Accused Product can be met by the complainant, its licensees, or other suppliers of competitive or substitute products. *See, e.g., Certain Lens-Fitted Film Packages*, Inv. No. 337-TA-406, Comm’n Op. at 18 (June 28, 1999). Here, ample non-accused sources of rapid gabapentin immunoassays kits and test strips are available to replace any products subject to remedial orders issued by the Commission in response to ARK’s complaint. As stated above, ARK’s exclusive distributor, Advin, manufactures rapid

² *See Certain Personal Data & Mobile Commc’ns Devices & Related Software*, Inv. No. 337-TA-710, Comm’n Op. at 73 (Dec. 29, 2011) (when assessing harm to public health and welfare, the Commission “has historically examined whether ‘an exclusion order would deprive the public of products necessary for some important health or welfare need: energy efficient automobiles, basic scientific research, or hospital equipment’”).

gabapentin tests that could replace the Accused Products. In addition, rapid gabapentin tests from manufacturers and distributors not named as Proposed Respondents also can help to meet demand for any products subject to the Commission's remedial orders.

C. Sufficient Capacity Exists to Replace any Excluded Articles in a Commercially Reasonable Time

There is sufficient capacity to produce gabapentin immunoassay kits and test strips to satisfy United States demand for such products. ARK estimates that United States demand for rapid gabapentin tests is currently one million tests per year and will increase to two million tests per year. ARK's capacity to supply the gabapentin materials used in Advin's rapid tests exceeds those amounts. Rapid gabapentin tests produced by non-respondent manufacturers also could help to satisfy the demand for excluded articles.

D. ARK's Requested Remedies Would Not Harm U.S. Consumers

Exclusion of the proposed respondents' accused products will not harm United States consumers. The FDA has not approved the proposed respondents' rapid gabapentin immunoassay kits or test strips for clinical use. The requested remedial orders thus would not impact patients or doctors. (*See supra*, Section II). Although the proposed respondents' accused products are marketed for use in drug testing facilities, law enforcement agencies, and places of work, commercially reasonable substitutes are readily available in sufficient supply, as discussed above. (*See supra*, Section IV). Therefore, such orders will not harm United States consumers.

IV. CONCLUSION

Issuing the requested remedial orders will advance the public interest by protecting valid intellectual property rights and promoting American innovation, with no adverse impacts on the public interest. Delegating public interest to the ALJ therefore is unnecessary.

Date: December 1, 2020

Respectfully submitted,

/s/ Joshua Hartman

Paul M. Bartkowski

Joshua Hartman

Hayley Ostrin

**ADDUCI, MASTRIANI & SCHAUMBERG
LLP**

1133 Connecticut Avenue, NW, 12th Floor
Washington, DC 20036

Telephone: (202) 467-6300

Facsimile: (202) 466-2006

E-Mail: ARK-001@adduci.com

*Counsel for Complainant ARK
Diagnostics, Inc.*

**THE 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-_____

**VERIFIED COMPLAINT UNDER SECTION 337 OF
THE TARIFF ACT OF 1933, AS AMENDED**

COMPLAINANT:

ARK DIAGNOSTICS, INC.
48089 Fremont Boulevard
Fremont, CA 94538
(877) 869-2320

COUNSEL FOR COMPLAINANT:

Paul M. Bartkowski
Joshua Hartman
Hayley Ostrin
ADDUCI, MASTRIANI & SCHAUMBERG LLP
1133 Connecticut Avenue, NW, 12th Floor
Washington, DC 20036
Telephone: (202) 467-6300
Facsimile: (202) 466-2006
E-Mail: ARK-001@adduci.com

PROPOSED RESPONDENTS:

HANGZHOU ALLTEST BIOTECH CO., LTD.
No. 550, Yin Hai Street
Hangzhou Economy and Technology
Development Area
Hangzhou, China 210018
Phone: 86-571-56267891

SHANGHAI CHEMTRON BIOTECH CO., LTD.
No. 518, Qingdai Rd.
International Medical Park, Pudong 201318
Shanghai, China
Phone: 86 21 68129988 ext. 203

CHEMTRON BIOTECH CO., LTD.
9425 Brown Deer Road, Suite B
San Diego, CA 92121
Phone: 86-21-68129666

**ZHEJIANG ORIENT GENE BIOTECH CO.,
LTD.**
#3787 East Yangguang Ave., Dipu St.
Anji 313300, Huzhou
Zhejiang, China
Phone: 86-572-5228781

HEALGEN SCIENTIFIC, LLC

3818 Fuqua Street
Houston, TX 77047
Phone: 713-773-8088

KAPPA CITY BIOTECH, SAS

32 Rue Danton
03100 Montlucon
France
Phone: 33-(0)4-70-08-08-80

12PANELMEDICAL, INC.

846 Wee Burn Street
Apt. E306
Sarasota, FL 34243
Phone: 561-409-5151

ACRO BIOTECH, INC.

9500 7th Street, Unit M
Rancho Cucamonga, CA 91730
Phone: 909-466-6892

ALCOPRO, INC.

2547 Sutherland Ave.
Knoxville, TN 37919
Phone: 800-227-9890

AMERICAN SCREENING, LLC

9742 St. Vincent Ave., Ste. 100
Shreveport, LA 71106
Phone: 318-798-3306

CONFIRM BIOSCIENCES, INC.

10123 Carroll Canyon Road
San Diego, CA 92131
Phone: 800-908-5603

MERCEDES MEDICAL, LLC

12210 Rangeland Parkway
Lakewood Ranch, FL 34211
Phone: 929-429-2716

TRANSMED CO., LLC

1887 McFarland Parkway
Alpharetta, GA 30005
Phone: 404-840-8900

	<p>TRANSMETRON, INC. 1476 S. Major Street (50 East) Salt Lake City, UT 84115 Phone: 801-596-2709</p>
--	---

TABLE OF SUPPORTING MATERIALS

Exhibit List	
Ex. No.	Description
1	Certified Copy of United States Patent No. 8,828,665
2	Certified Copy of United States Patent No. 10,203,345
3	Certified Copy of Assignment of United States Patent No. 8,828,665
4	Certified Copy of Assignment of United States Patent No. 10,203,345
5C	Licensing and Supply Agreement between Advin Biotech, Inc. and ARK Diagnostics, Inc.
6	Declaration of R. Singh
7	United States Patent No. 8,828,665 Patent Claim Chart for ARK Diagnostics, Inc.
8	United States Patent No. 10,203,345 Patent Claim Chart for ARK Diagnostics, Inc.
9	Package Insert for ARK Diagnostics, Inc.'s "ARK Gabapentin Assay"
10	Package Insert for ARK Diagnostics, Inc.'s "ARK Gabapentin Calibrator"
11	Package Insert for ARK Diagnostics, Inc.'s "ARK Gabapentin Control"
12	Photo of ARK Diagnostics, Inc.'s "ARK Gabapentin Assay"
13	Photo of ARK Diagnostics, Inc.'s "ARK Gabapentin Calibrator"
14	Photo of ARK Diagnostics, Inc.'s "ARK Gabapentin Control"
15	United States Patent No. 8,828,665 Patent Claim Chart for 12PanelMedical, Inc. & Kappa City Biotech, SAS
16	United States Patent No. 10,203,345 Patent Claim Chart for 12PanelMedical, Inc. & Kappa City Biotech, SAS
17	Product Page for 12PanelNow's "Gabapentin GAB Test Strips (25 pack)"
18	Product Page for 12PanelNow's Gabapentin Tests, with Image Expanded to Show "NarcoCheck" Markings
19	Product Page for 12PanelNow's Gabapentin Tests, with Image Expanded and Circled to Show "NarcoCheck" Markings
20	Package Insert for 12PanelNow's "Gabapentin GAB Test Strips"
21	Packing Slip for Confirm Biosciences, Inc.'s "Single Panel Gabapentin Urine Drug Test Dip Card"
22	United States Patent No. 10,203,345 Patent Claim Chart for Acro Biotech, Inc., Mercedes Medical LLC, and Hangzhou AllTest Biotech Co., Ltd.
23	Product Page for Acro Biotech, Inc. Drugs of Abuse Rapid Tests Product
24	Photo of Acro Biotech's Gabapentin Immunoassay (Sold by Mercedes Scientific)
25	Packing Slip for American Screening's "Precision Dx - 1 Panel Dip Card - Gabapentin"

Exhibit List	
Ex. No.	Description
26	United States Patent No. 10,203,345 Patent Claim Chart for AlcoPro, Inc., and Shanghai Chemtron Biotech Co., Ltd and Chemtron Biotech Co., Ltd.
27	United States Patent No. 8,828,665 Patent Claim Chart for AlcoPro, Inc., and Shanghai Chemtron Biotech Co., Ltd and Chemtron Biotech Co., Ltd.
28	Product Page for AlcoPro, Inc.'s "CheckPoint Instant Gabapentin Urine Dip Drug Test Box of 25"
29	Package Insert for AlcoPro, Inc.'s "Gabapentin (GAB) Dip Card Tests"
30	Photo of AlcoPro, Inc.'s "Gabapentin (GAB) Dip Card (Manufactured by Chemtron)"
31	Order Confirmation for American Screening's "Precision Dx - 1 Panel Dip Card - Gabapentin"
32	Packing Slip for Kappa City Biotech, SAS' "Gabapentin (Neurontoin) Test"
33	Product Page for Hangzhou AllTest Biotech Co., Ltd.'s "AllTest Gabapentin(GAB) Rapid Test – Urine"
34	Product Page for Hangzhou AllTest Biotech Co., Ltd.'s "JusCheck Gabapentin(GAB) Rapid Test – Urine"
35	Package Insert for Kappa City Biotech, SAS' "Gabapentin (Neurontoin) Test"
36	United States Patent No. 10,203,345 Patent Claim Chart for Healgen Scientific, LLC and Zhejiang Orient Gene Biotech Co., Ltd.
37	Product Page for American Drug Test's Gabapentin Dip Test Manufactured by Healgen
38	Package Insert for American Drug Test's "Gabapentin Dip Test" Manufactured by Healgen
39	Order Confirmation for American Drug Test's "Gabapentin Dip Test" Manufactured by Healgen
40	Photo of American Drug Test's "Gabapentin Dip Test" Manufactured by Healgen
41	Packing Slip for AlcoPro, Inc.'s "CheckPoint Instant Gabapentin Urine Dip Drug Test"
42	United States Patent No. 8,828,665 Patent Claim Chart for American Screening, LLC, and Shanghai Chemtron Biotech Co., Ltd and Chemtron Biotech Co., Ltd
43	United States Patent No. 10,203,345 Patent Claim Chart for American Screening, LLC, and Shanghai Chemtron Biotech Co., Ltd and Chemtron Biotech Co., Ltd
44	Product Page for American Screening, LLC's "Precision Dx – 1 Panel Dip Card – Gabapentin"
45	Package Insert for American Screening, LLC's "Precision Dx - 1 Panel Dip Card - Gabapentin"
46	Photo of American Screening, LLC's "Precision Dx – 1 Panel Dip Card – Gabapentin"

Exhibit List	
Ex. No.	Description
47	Order Confirmation for AlcoPro, Inc.'s "CheckPoint Instant Gabapentin Urine Dip Drug Test "
48	United States Patent No. 8,828,665 Patent Claim Chart for Confirm Biosciences, Inc., and Shanghai Chemtron Biotech Co., Ltd and Chemtron Biotech Co., Ltd
49	United States Patent No. 10,203,345 Patent Claim Chart for Confirm Biosciences, Inc., and Shanghai Chemtron Biotech Co., Ltd and Chemtron Biotech Co., Ltd
50	Product Page for Confirm Biosciences, Inc.'s "Single Panel Gabapentin Urine Drug Test Dip Card"
51	Product Page for Confirm Biosciences, Inc.'s "Gabapentin Urine Drug Test Dip Card – FAQ'S"
52	Product Page for Confirm Biosciences, Inc.'s "Gabapentin Urine Drug Test Dip Card – INSTRUCTIONS"
53	Product Page for Confirm Biosciences, Inc.'s "Gabapentin Urine Drug Test Dip Card – DETECTION CUT-OFFS & TIMES"
54	Product Page for Confirm Biosciences, Inc.'s "Gabapentin Urine Drug Test Dip Card – DESCRIPTION"
55	Product Page for Confirm Biosciences, Inc.'s "Gabapentin Urine Drug Test Dip Card – VIDEOS"
56	Package Insert for Confirm Biosciences, Inc.'s "Single Panel Gabapentin Urine Drug Test Dip Card"
57	Photo of Confirm Biosciences, Inc.'s "Single Panel Gabapentin Urine Drug Test Dip Card"
58	Packing Slip for Transmetron, Inc.'s "GAB Rapid Test Panel (Urine)"
59	Product Page for Kappa City's "GAB URINE TEST (GABAPENTIN NEURONTIN)" available on NarcoCheck.com
60	Product Page for Kappa City's "Gabapentin (Neurontin) urine test" available on PharmaDrugtest.com
61	Photo of Kappa City Biotech, SAS' "Gabapentin (Neurontin) Test"
62	Photo of 12PanelNow's "Gabapentin GAB Test Strips"
63	United States Food and Drug Administration 510(k) Premarket Notification for Gabapentin Assay
64	Product Page for Mercedes Scientific's "ACR DGAB 114-2000 Nanogram/ML, Urine, Gabapentin Rapid Test Panel (25 per Box)"
65	Package Insert for Mercedes Medical "GAB Rapid Test Panel (Urine)"
66	Mercedes Scientific Packing List for Order No. 2150554
67	United States Patent No. 8,828,665 Patent Claim Chart for TransMed Co., LLC, and Shanghai Chemtron Biotech Co., Ltd and Chemtron Biotech Co., Ltd

Exhibit List	
Ex. No.	Description
68	United States Patent No. 10,203,345 Patent Claim Chart for TransMed Co., LLC, and Shanghai Chemtron Biotech Co., Ltd and Chemtron Biotech Co., Ltd
69	Product Page for TransMed Co., LLC's "Gabapentin (GAB) Single Panel Dip Card 25/Box"
70	Package Insert for TransMed Co., LLC's "Gabapentin (GAB) Single Panel Dip Card 25/Box"
71	Photo of TransMed Co., LLC's "Gabapentin (GAB) Single Panel Dip Card 25/Box"
72	Unwrapped AcroBiotech "Gabapentin (GAB) Single Panel Dip Card" (SKU DGAB-114)
73	United States Patent No. 10,203,345 Patent Claim Chart for Transmetron, Inc., and Hangzhou AllTest Biotech Co., Ltd.
74	Product Page for Transmetron Inc.'s "GAB Rapid Test Panel (Urine)"
75	Package Insert for Transmetron Inc.'s "GAB Rapid Test Panel (Urine)"
76	Photo of Transmetron Inc.'s "GAB Rapid Test Panel (Urine)"
77	Receipt from Drug Testing for Less for "AllTest/AcroBiotech Gabapentin (GAB) Single Panel Dip Card" SKU DGAB-114
78	12PanelNow's "Gabapentin GAB Test Strips" as Received from Distributor
79	Order Confirmation for American Drug Test's "Gabapentin Dip Test "
80	Product Page for Shanghai Chemtron Biotech Co., Ltd.'s "DOA Multi-Drug Panel/Device/Cup"
81	Product Page for Shanghai Chemtron Biotech Co., Ltd.'s "DOA Single-Drug Strip/Device"
82	Chemtron Biotech, Inc. Drugs of Abuse Rapid Tests Product Listing Page
83	Google Maps Result for American Drug Test's Address
84	Product Page for Healgen Multi-Drug Test Cups
85	Product Page for Zhejiang Orient Gene Website's Multi-Drug Test Strips
86	Product Page for Zhejiang Orient Gene Website's Multi-Drug Test Cups
87	Drugtestingforless.com Search Result for "Gab"
88	Order Confirmation for Drug Testing for Less' Gabapentin Dip Test
89	Photo of Drug Testing for Less' Gabapentin Dip Test
90	Panjiva Importation Records for AllTest Biotech Co., Ltd.
91	Panjiva Importation Records for American Screening Corporation
92	Panjiva Importation Records for Confirm Biosciences, Inc.
93	Panjiva Importation Records for Healgen
94	Panjiva Importation Records for Mercedes Medical, LLC
95	Panjiva Importation Records for TransMed
96	Panjiva Importation Records for Zhejiang Orient Gene Biotech

Exhibit List	
Ex. No.	Description
97	United States Food and Drug Administration Establishment Registration & Device Listing Search Results for Shanghai Chemtron Biotech, Co., Ltd.
98	United States Food and Drug Administration Establishment Registration & Device Listing Company Information for Acro Biotech Co., Ltd.
99	United States Food and Drug Administration Establishment Registration & Device Listing Search Results for Acro Biotech, Inc.
100	United States Food and Drug Administration Establishment Registration & Device Listing Registration Information for Zhejiang Orient Gene Biotech
101	United States Food and Drug Administration Establishment Registration & Device Listing Search Results for Chemtron Biotech, Inc.
102	United States Food and Drug Administration Establishment Registration & Device Listing Search Results for “OTF” (Gabapentin Assay Product Code)
103	United States Food and Drug Administration Establishment Registration & Device Listing Search Results for “Gabapentin.”
104	United States Food and Drug Administration Establishment Registration & Device Listing Company Information for Hangzhou AllTest Biotech Co., Ltd.
105	United States Food and Drug Administration Establishment Registration & Device Listing Registration Information for Healgen
106C	Domestic Industry Statement

Appendices	
Appendix	Description
1	Certified Copy of Prosecution History for United States Patent No. 8,828,665
2	Certified Copy of Prosecution History for United States Patent No. 10,203,345
3	Copy of Reference Documents Identified in Prosecution History of United States Patent No. 8,828,665
4	Copy of Reference Documents Identified in Prosecution History of United States Patent No. 10,203,345

TABLE OF CONTENTS

I. INTRODUCTION 1

II. THE PARTIES..... 2

 A. The Complainants – ARK Diagnostics, Inc..... 2

 B. The Proposed Respondents 3

 1. Producer Respondents..... 4

 2. Distributor Respondents..... 6

III. THE ASSERTED PATENTS 8

 A. The '665 Patent 8

 1. Identification of the Patent and Ownership 8

 2. Non-Technical Description of the Patented Invention..... 9

 3. Foreign Counterparts 10

 B. The '345 Patent 10

 1. Identification of the Patent and Ownership 10

 2. Non-Technical Description of the Patented Invention..... 11

 3. Foreign Counterparts 11

 C. ARK’s Licensing and Supply Agreement with Advin Biotech 11

IV. THE PRODUCTS AND PROCESSES AT ISSUE..... 11

 A. Gabapentin Immunoassays 11

 B. ARK’s Gabapentin-Specific Antibodies, Gabapentin Conjugates,
 Gabapentin Immunoassays and Processes 13

 C. ARK’s Patented Methods for Testing for Gabapentin Are Used to
 Manufacture Competitive Assay Test Strips 16

 D. Commission Rule 210.10(b)(1) Statement 17

 E. Respondents’ Accused Products 17

V. UNLAWFUL AND UNFAIR ACTS OF PROPOSED RESPONDENTS 17

 A. Respondents’ Infringement of the '665 Patent 21

 1. Chemtron and Its Distributors..... 21

 2. Kappa City and Its Distributor 23

 B. Respondents’ Infringement of the '345 Patent 24

1.	AllTest and Its Distributors.....	24
2.	Chemtron and Its Distributors.....	26
3.	Healgen	28
4.	Kappa City and Its Distributor	28
VI.	RELATED LITIGATION	29
VII.	SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE	29
A.	AllTest and Its U.S. Distributors.....	30
1.	AllTest.....	30
2.	Acro.....	31
3.	Mercedes Scientific.....	32
4.	Transmetron	34
B.	Chemtron and Its U.S. Distributors.....	35
1.	AlcoPro	36
2.	ASC.....	37
3.	Confirm Biosciences.....	38
4.	TransMed	40
C.	The Healgen Respondents and Their U.S. Distributors	41
1.	Purchase of Healgen’s Gabapentin Single Panel Dip Card Drug Tests from American Drug Test	42
2.	Confirm Biosciences and TransMed.....	43
D.	Kappa City and Its U.S. Distributors	43
1.	12Panel.....	44
VIII.	CLASSIFICATION OF THE ACCUSED PRODUCTS UNDER THE HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES.....	45
IX.	THE DOMESTIC INDUSTRY	45
A.	Technical Prong	45
B.	Economic Prong.....	46
X.	REQUESTED RELIEF.....	46

I. INTRODUCTION

1. ARK Diagnostics, Inc. (“ARK” or “Complainant”) files this Complaint under Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 (“Section 337”), based on the unlawful sale for importation into the United States, importation into the United States, and sale within the United States after importation of gabapentin immunoassay kits and test strips, and components of such kits and test strips, that infringe ARK’s United States Patent No. 8,828,665 or that are made, produced, or processed under or by means of a process that infringes ARK’s United States Patent No. 10,203,345 (collectively, the “Asserted Patents”).

2. This Complaint names the following companies as Proposed Respondents: Hangzhou AllTest Biotech Co., Ltd., Acro Biotech, Inc., 12PanelMedical, Inc., AlcoPro, Inc., American Screening, L.L.C., Shanghai Chemtron Biotech Co. Ltd., Chemtron Biotech Co. Ltd., Confirm Biosciences, Inc., Healgen Scientific, LLC, Zhejiang Orient Gene Biotech Co., Ltd., Kappa City Biotech, SAS, Mercedes Medical, LLC, TransMed Co, LLC, and Transmetron, Inc. (together, the “Proposed Respondents”). On information and belief, the Proposed Respondents have violated Section 337(a)(1)(B) by unlawfully and without permission importing into the United States, selling for importation into the United States, or selling within the United States after importation the aforementioned gabapentin immunoassay kits, test strips, and components of such kits and tests (the “Accused Products”) that infringe or that were made, produced, or processed under or by means of a process covered by one or more claims of the Asserted Patents.

3. As required under Sections 337(a)(2)-(3), an industry exists in the United States relating to ARK’s gabapentin immunoassay products protected by the Asserted Patents (the “Domestic Industry Products”). ARK has made significant investments in plant and equipment and undertaken significant employment of labor and capital with respect to the Domestic Industry

Products, and it has made substantial investments in exploiting the Asserted Patents, including through research, development, and engineering of the Domestic Industry Products and of processes for making, processing, and producing them. Founded in 2003, ARK has conducted its research, design, development, engineering, manufacturing, quality assurance, and other activities related to its Domestic Industry Products exclusively in California.

4. ARK requests that the Commission investigate and remedy the Proposed Respondents' unfair acts. Under Section 337(d)(1), ARK seeks a permanent limited exclusion order ("LEO") barring from entry into the United States Accused Products that infringe the Asserted Patents and that are imported, sold for importation, or sold within the United States after importation by or on behalf of the Proposed Respondents in violation of Section 337. Further, under Section 337(f), ARK seeks permanent cease-and-desist orders ("CDO") against the Proposed Respondents that prohibit conducting any of the following activities in the United States: importing, selling, offering for sale, marketing, advertising, distributing, transferring (except for exportation), soliciting United States agents or distributors, and aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution Accused Products that infringe one or more claims of the Asserted Patents. Finally, under Section 337(j), ARK asks the Commission to impose a bond covering the importation, sale, or other transfer of infringing Accused Products during the 60-day Presidential review period to prevent further injury to ARK's domestic industry resulting from the Proposed Respondents' unfair acts.

II. THE PARTIES

A. The Complainants – ARK Diagnostics, Inc.

5. Complainant ARK Diagnostics, Inc. is a California corporation founded in 2003. ARK's principal place of business is located at 48089 Fremont Boulevard, Fremont, California

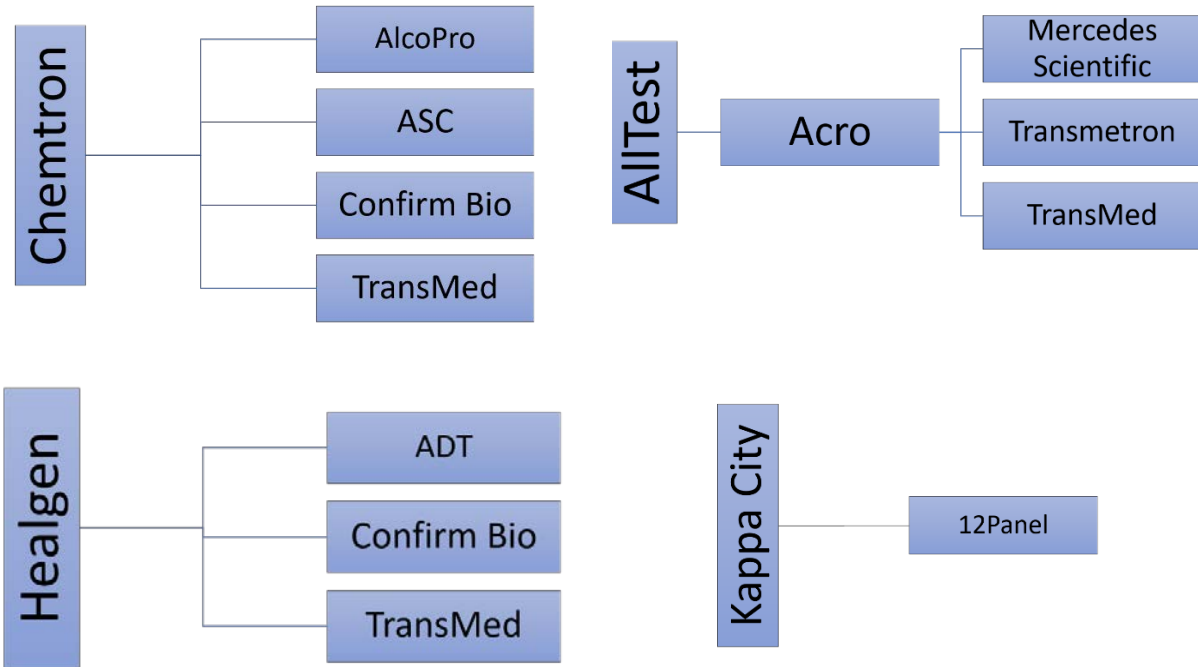
94538 (the “Fremont Facility”), where it conducts its research, design, development, manufacture, testing, marketing, sales, and support activities related to its Domestic Industry Products, including ARK’s gabapentin-specific antibodies and immunoassays, and its associated processes and techniques.

6. Since its incorporation on March 21, 2003, ARK’s mission has been improving health care through the design, research and development, manufacture, and distribution of *in vitro* diagnostic (“IVD”) immunoassays for therapeutic drug monitoring (“TDM”) and for urine drug testing (“UDT”). ARK is a pioneer in the *in vitro* TDM and UDT diagnostic markets, which include assays and tests to detect and monitor the presence of therapeutic and illicit drugs and other small molecules. ARK’s innovations include its homogeneous enzyme immunoassay technology, which it introduced for the next generation of clinical laboratory testing. This technology includes the ARK Gabapentin Assay, an immunoassay capable of rapidly detecting the presence of gabapentin, an entirely new field in the TDM and UDT markets. The Asserted Patents protect the ARK Gabapentin Assay. (*See infra* § IV.)

B. The Proposed Respondents

7. As discussed further below in Section VII, the Proposed Respondents include companies that manufacture gabapentin immunoassay kits or test strips or components of such kits or test strips that infringe or use methods protected by the Asserted Patents that they sell for importation, import, or sell after importation into the United States. The Proposed Respondents also include companies that import, market, sell, and distribute such imported kits, test strips, or

components in the United States. The following diagrams show the various supply relationships among the Proposed Respondents:¹



1. Producer Respondents

a) Hangzhou AllTest Biotech Co., Ltd.

8. Respondent Hangzhou AllTest Biotech Co., Ltd. (“AllTest”) is a company organized under the laws of the Peoples Republic of China maintaining its principal place of business at No. 550, Yinhai Street, Hangzhou Economy and Technology Development Area, Hangzhou, China, 310018.

¹ Based on distributor websites, and the differences between products advertised and products received, the evidence shows that distributors often import gabapentin strips from multiple suppliers.

9. AllTest's Accused Products are imported, sold for importation, or sold after importation by AllTest and Distributor Respondents, including at least Acro Biotech, Inc., Mercedes Medical LLC, and Transmetron Inc. (*See infra* § VII.A.)

b) Shanghai Chemtron Biotech Co. Ltd. and Chemtron Biotech Co. Ltd.

10. Respondent Shanghai Chemtron Biotech Co., Ltd. ("Shanghai Chemtron") is a company organized under the laws of the Peoples Republic of China maintaining its principal place of business at No.518, Qingdai Rd., International Medical Park, Pudong, 201318, Shanghai, P.R. China. Respondent Chemtron Biotech Co. Ltd. ("Chemtron Biotech") is a California corporation maintaining its principal place of business at 9425 Brown Deer Road, Suite B, San Diego, CA 92121. Shanghai Chemtron and Chemtron Biotech (collectively, "Chemtron") sell their testing kits under the "Chemtrue" Brand. (*See Exs. 80-81.*)

11. Chemtron's Accused Products are imported, sold for importation, or sold after importation by Chemtron and Distributor Respondents, including at least AlcoPro, Inc., American Screening, L.L.C., Confirm Biosciences, Inc. and TransMed Co., LLC. (*See infra* § VII.B.)

c) Zhejiang Orient Gene Biotech Co., Ltd. and Healgen Scientific, LLC (the "Healgen Respondents")

12. Respondent Zhejiang Orient Gene Biotech Co., Ltd. is a company organized under the laws of the Peoples Republic of China ("Orient Gene") and maintains its principal place of business at #3787, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China. Respondent Healgen Scientific, LLC ("Healgen Scientific") is a Texas corporation maintaining its principal place of business at 3818 Fuqua Street, Houston, TX 77047. Healgen Scientific is a wholly owned subsidiary of Orient Gene. (*See* www.healgen.com/about.)

13. Orient Gene and Healgen Scientific's (collectively, "Healgen") Accused Products are imported, sold for importation, or sold after importation by Healgen and Distributor Respondents, including at least Confirm Biosciences and TransMed Co., LLC. (*See infra* § VII.C.)

d) Kappa City Biotech, SAS

14. Respondent Kappa City Biotech, SAS ("Kappa City") is a company organized under the laws of France. Kappa City maintains its principal place of business at 32 Rue Danton 03100 Montlucon, France.

15. Kappa City's Accused Products are imported, sold for importation, or sold after importation by Kappa City and by Distributor Respondents, including at least 12PanelMedical, Inc. (*See infra* § VII.D.)

2. Distributor Respondents

a) 12PanelMedical, Inc.

16. Respondent 12PanelMedical, Inc., doing business as 12Panel Now ("12Panel"), is a Florida corporation. 12Panel registered its principal place of business at 846 Wee Burn Street, Apt. No. E306, Sarasota, Florida 34243. 12Panel's physical address is 1499 SW 30th Avenue, No. 19, Boynton Beach, FL 33426. (*See Ex. 17.*)

17. 12Panel imports or sells after importation Accused Products manufactured by Producer Respondents, including at least Kappa City. (*See infra* § VII.D.1.)

b) Acro Biotech, Inc.

18. Respondent Acro Biotech, Inc. ("Acro") is a California corporation. Acro maintains its principal place of business at 9500 7th Street, Unit M, Rancho Cucamonga, CA 91730.

19. Acro imports or sells after importation Accused Products manufactured by Producer Respondents, including at least AllTest. (*See infra* § VII.A.2.)

20. Acro sells Accused Products after importation to other distributor respondents, including at least Mercedes Medical. (*See infra* § VII.A.)

c) AlcoPro, Inc.

21. Respondent AlcoPro, Inc. (“AlcoPro”) is a Tennessee corporation. AlcoPro maintains its principal place of business at 2547 Sutherland Ave, Knoxville, TN 37919.

22. AlcoPro imports or sells after importation Accused Products manufactured by Producer Respondents, including at least Chemtron. (*See infra* § VII.B.1.)

d) American Screening, L.L.C.

23. Respondent American Screening, L.L.C., doing business as American Screening Corp. (“ASC”), is a Louisiana corporation. ASC maintains its principal place of business at 9742 St. Vincent Ave, Ste.100, Shreveport, LA 71106.

24. ASC imports or sells after importation Accused Products manufactured by Producer Respondents, including at least Chemtron. (*See infra* § VII.B.2.)

e) Confirm Biosciences, Inc.

25. Respondent Confirm Biosciences, Inc. (“Confirm Biosciences”) is a Delaware corporation. Confirm Biosciences maintains its principal place of business at 10123 Carroll Canyon Road, San Diego, CA 92131.

26. Confirm Biosciences imports or sells after importation Accused Products manufactured by Producer Respondents, including at least Chemtron and Healgen. (*See infra* §§ VII.B.3, VII.C.2)

f) Mercedes Medical, LLC (d/b/a Mercedes Scientific)

27. Respondent Mercedes Medical, LLC (d/b/a Mercedes Scientific) (“Mercedes Scientific”) is a Florida company. Mercedes Scientific maintains its principal place of business at 12210 Rangeland Parkway, Lakewood Ranch, FL 34211.

28. Mercedes Scientific imports or sells after importation Accused Products manufactured by Producer Respondents, including at least AllTest. (*See infra* § VII.A.3.)

g) TransMed Co, LLC

29. Respondent TransMed Co, LLC (“TransMed”) is a Georgia company. TransMed maintains its principal place of business at 1887 McFarland Parkway, Alpharetta, GA, 30005. Drug Testing For Less, a division of TransMed, is the online seller of TransMed’s products. (*See* <https://drugtestingforless.com/> (identifying “Drug Testing for Less” as “A Division of TransMed Co, LLC”).)

30. TransMed imports or sells after importation Accused Products manufactured by Producer Respondents, including at least AllTest, Chemtron, and Healgen. (*See infra* § VII.B.4.)

h) Transmetron, Inc.

31. Respondent Transmetron, Inc. (“Transmetron”) is a Utah company. Transmetron maintains its principal place of business at 1476 S. Major Street (50 East), Salt Lake City, UT 84115.

32. Transmetron imports or sells after importation, Accused Products manufactured by Producer Respondents, including at least AllTest. (*See infra* § VII.A.4.)

III. THE ASSERTED PATENTS

A. The ’665 Patent

1. Identification of the Patent and Ownership

33. United States Patent No 8,828,665, titled “Compounds and Methods for Use in Detecting Gabapentin,” issued on September 9, 2014 and expires on May 31, 2031. The patent is based on United States Application No. 12/032,528, filed February 15, 2008, and claims priority to Provisional Application No. 60/890,313, filed on February 16, 2007. The ’665 Patent has 36 claims, including 3 independent claims and 33 dependent claims. A certified copy of the

'665 Patent is attached to the Complaint as Exhibit 1. A certified copy of the '665 Patent's prosecution history is attached to the Complaint as Appendix 1.

34. The named inventors of the '665 Patent, Johnny Jose Valdez, Byung Sook Moon, Michael Kevin Helms, and Alejandro A. Orozco, assigned their rights to the '665 Patent to ARK on April 22, 2008. ARK owns by assignment all right, title, and interest in and to the '665 Patent. A certified copy of the '665 Patent's assignment records is attached to the Complaint as Exhibit 3.

2. Non-Technical Description of the Patented Invention²

35. The '665 Patent generally describes isolated antibodies that can be used to test for the presence of gabapentin in samples of interest, such as blood or urine samples. The antibodies described in the '665 patent specifically bind to free gabapentin and to gabapentin conjugates that include gabapentin linked to a moiety of interest at the gabapentin molecule's carboxyl group through a linker. This specificity improves the accuracy of gabapentin tests by decreasing the rates of failure and of false positives. Further, the claimed antibody, the target gabapentin molecule, or both are labeled with a detectable tag that allows the tester to determine whether the antibody detected gabapentin in the sample.

36. The antibodies described in the '665 Patent are generated by introducing gabapentin conjugated to an immunogenic carrier, a small molecule that will incite an immune response, to an animal host. In the conjugate, the gabapentin and the immunogenic carrier are linked at the gabapentin molecule's carboxyl group. After the animal host generates antibodies in response to the introduced gabapentin conjugate, its serum is harvested and screened to extract the claimed antibodies.

² These descriptions, and any other non-technical descriptions within this Complaint, are for illustrative purposes only. Nothing in this Complaint is intended to express, either implicitly or explicitly, any position regarding the proper construction of any claim of the '665 Patent.

3. Foreign Counterparts

37. The '665 Patent has one foreign counterpart patent application: App. No. PCT/US2008/002096; Pub. Nos. WO2008103319A2 and WO2008103319A3. The status of that application is abandoned. To the best of ARK's knowledge, information, and belief, there are no other foreign counterpart patents or patent applications related to the '665 Patent that have been denied, abandoned, or withdrawn.

B. The '345 Patent

1. Identification of the Patent and Ownership

38. United States Patent No. 10,203,345, titled "Compounds and Methods for Use in Detecting Gabapentin," issued on February 2, 2019 and expires on June 14, 2028. The patent is based on United States Application No. 15/349,832, filed November 11, 2016, which is a divisional of Application No. 14/447,179, filed July, 30, 2014, now issued as U.S. Patent No. 9,522,880, which is a divisional of Application No. 12/032,528, filed February 15, 2008, now issued as the '665 Patent, which claims the benefit of Provisional Application No. 60/890,313, filed February 16, 2007. The '345 Patent has 29 claims, including two independent claim and twenty-seven dependent claims. A certified copy of the '345 Patent is attached to the Complaint as Exhibit 2. A certified copy of the '345 Patent's prosecution history is attached to the Complaint as Exhibit Appendix 2.

39. The named inventors of the '345 Patent, Johnny Jose Valdez, Byung Sook Moon, Michael Kevin Helms, and Alejandro A. Orozco, assigned their rights to the '345 Patent to ARK on March 7, 2008. ARK owns by assignment all right, title, and interest in and to the '345 Patent. A certified copy of the '345 Patent's assignment records is attached to the Complaint as Exhibit 4.

2. Non-Technical Description of the Patented Invention

40. The '345 Patent generally describes a method of detecting gabapentin by combining a target sample, an anti-gabapentin antibody, and a gabapentin conjugate. In general, the target samples are quality-control samples or biological samples (such as urine samples) of humans suspected of consuming gabapentin. The anti-gabapentin antibody is capable of binding with gabapentin or gabapentin conjugates. Any free gabapentin in the sample will form complexes with the anti-gabapentin antibodies, making the antibodies unavailable to bind with the gabapentin conjugate when it is introduced into the sample. The output of the conjugated label is affected by the presence or absence of the antibody-gabapentin conjugate complex. This method detects the presence and concentration of gabapentin in the sample based on the label's output.

3. Foreign Counterparts

41. The '345 Patent has a single foreign counterpart patent application: App. No. PCT/US2008/002096; Pub. Nos. WO2008103319A2 and WO2008103319A3. The status of that application is abandoned. To the best of ARK's knowledge, information, and belief, there are no other foreign counterpart patents or patent applications related to the '345 Patent that have been denied, abandoned, or withdrawn.

C. ARK's Licensing and Supply Agreement with Advin Biotech

42. ARK has entered into a Licensing and Supply Agreement with Advin Biotech Inc. A copy of the Licensing and Supply Agreement is attached as Confidential Exhibit 5C.

IV. THE PRODUCTS AND PROCESSES AT ISSUE

A. Gabapentin Immunoassays

43. The products and processes at issue in this investigation relate to immunoassays for detecting the presence of gabapentin in a biological sample. Gabapentin (trade name Neurontin) is

a chemical compound used as an anti-seizure and anti-convulsant medication that has the following chemical structure:

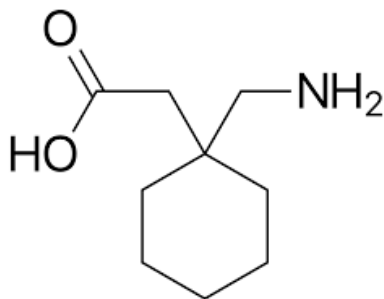


Fig. 1 – Chemical Structure of Gabapentin

44. Patients can metabolize gabapentin at different rates. As a result, two patients who receive the same dose of gabapentin may experience different levels of serum drug concentration, which will result in inconsistent therapeutic effects. (See Ex. 1 at 1:33-46.) Thus, monitoring a patient's concentration level of gabapentin is essential to determining the correct dosage to prescribe.

45. Apart from its therapeutic uses, gabapentin has become popular as a drug of abuse. Users often take gabapentin in tandem with opioids to increase their potency.³ When abused with opioids, gabapentin increases the risk of respiratory problems and fatal overdose.⁴ The growing abuse of gabapentin has led to demand for quick, accurate, and inexpensive methods for testing the presence of gabapentin in a test subject's biological sample.

³ See Alyssa M. Peckham et. al., *Gabapentin use, abuse, and the US opioid epidemic: the case for reclassification as a controlled substance and the need for pharmacovigilance*, 11 RISK MANAG. HEALTHCARE 11, 109, 110 (2018), www.ncbi.nlm.nih.gov/pmc/articles/PMC6103607/pdf/rmhp-11-109.pdf.

⁴ *Id.* at 109; *FDA warns about serious breathing problems with seizure and nerve pain medicines gabapentin (Neurontin, Gralise, Horizant) and pregabalin (Lyrica, Lyrica CR)*, FDA (last updated Jan. 30, 2020), www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-serious-breathing-problems-seizure-and-nerve-pain-medicines-gabapentin-neurontin.

B. ARK's Gabapentin-Specific Antibodies, Gabapentin Conjugates, Gabapentin Immunoassays and Processes

46. ARK researched, developed, and invented novel methods and compounds for assaying gabapentin that can be used to test for the presence of gabapentin quickly, accurately, and inexpensively. ARK's gabapentin immunoassay products use antibodies, enzymes, and a substrate to test for the presence of gabapentin and gabapentin conjugates in a biological sample. When gabapentin is absent in a sample, the gabapentin-specific antibody binds to the enzyme, preventing the enzyme from producing NADH. Conversely, when gabapentin is present, the antibody binds to the gabapentin, allowing the enzyme to bind to the substrate and produce NADH. NADH levels can then be measured and used to determine the presence and concentration of gabapentin. (*See Ex. 9*)

47. ARK's gabapentin immunoassay products include the ARK Gabapentin Assay, the ARK Gabapentin Calibrator, and the ARK Gabapentin Control. (*See Exs. 9-11.*) The ARK Gabapentin Assay is a homogenous enzyme immunoassay that can be used to quantitatively determine the presence and amount of gabapentin in biological samples. It contains two components, Reagent R1 – Antibody/Substrate; and Reagent R2 – Enzyme, that are used together. (*See Ex. 9.*) Reagent R1 contains rabbit polyclonal antibodies that specifically bind to gabapentin as well as nicotinamide adenine dinucleotide (“NAD”). Reagent R2 contains gabapentin conjugated at the carboxyl group to bacterial glucose-6-phosphate dehydrogenase (“G6PDH”). When G6PDH is active, it converts NAD to NADH, which changes the way the solution absorbs light. A spectrometer can measure this change in absorbance with enough specificity to allow users to determine appropriate dosage rates.

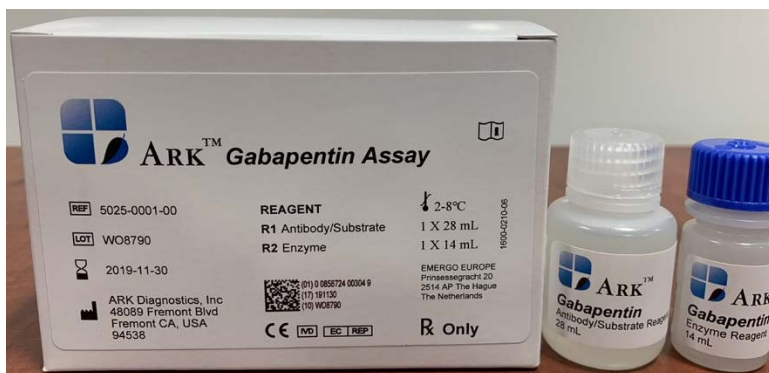


Fig. 2 - ARK Gabapentin Assay (Ex. 12)

48. ARK’s Gabapentin Assay can be used with clinical analyzers to test for the presence and concentration levels of gabapentin and gabapentin conjugates in a patient’s biological sample. To do so, a known quantity of Reagent R1 is mixed with the biological sample. If the sample contains gabapentin, Reagent R1’s antibodies will bind to the free gabapentin. When Reagent R2 is introduced, these bound antibodies will not be free to bind to the enzyme-tagged gabapentin. The unbound, the enzyme-tagged gabapentin will then convert NAD to NADH, creating a measurable change in absorbance proportional to the amount of free gabapentin in the biological sample. Conversely, if the sample does not contain gabapentin, Reagent R1’s antibodies will bind to Reagent R2’s enzyme-tagged gabapentin, in turn inhibiting production of NADH.

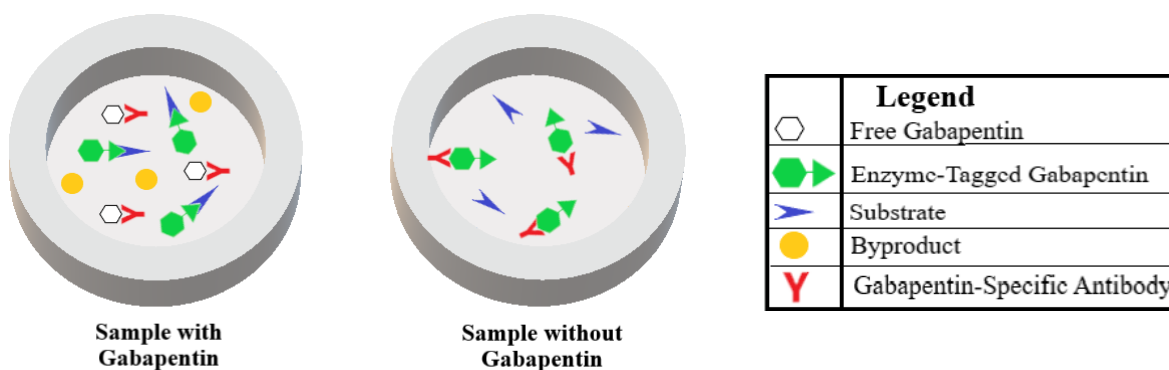


Fig. 3 - Diagram of ARK Gabapentin Assay’s Response to Different Samples

49. Sold separately, the ARK Gabapentin Calibrator and ARK Gabapentin Control are intended for use with the ARK Gabapentin Assay. They enable a full, 6-point calibration of

spectrometers to ensure accurate reading of the ARK Gabapentin Assay’s test results. This quality assurance procedure is vital for ensuring that the patients’ samples are accurately read and interpreted for accurate dosing.



Fig. 4 - Photo of ARK Calibrator (Ex. 13)



Fig. 5 - Photo of ARK Control (Ex. 14)

50. In addition to use with a clinical chemistry analyzer, ARK’s gabapentin-specific antibodies can be and are used in competitive lateral flow test strips in cups, dip-cards, and other test formats for performing rapid drug tests without using specialized equipment. Lateral flow tests include gabapentin antibodies deposited on the test’s “dip zone” that are designed to bind with gabapentin and specific gabapentin conjugates. In these lateral flow tests, the gabapentin antibodies are labeled with a marker, such as a gold microparticle, that becomes visible to the naked eye when antibodies concentrate in a small enough area. Gabapentin lateral flow tests also include a “test line” that includes unbound gabapentin molecules and a “control line” that includes gabapentin antibodies that bind with excess labeled antibody.

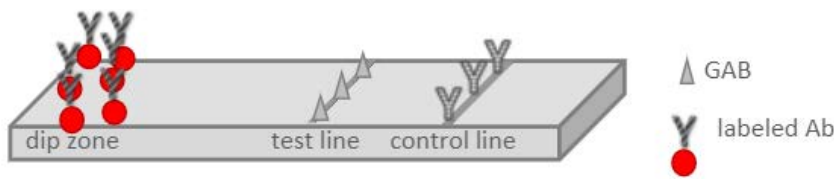


Fig. 6 - Diagram of Gabapentin Lateral Flow Test

51. When a biological sample, such as a blood or urine sample, is added to the dip zone, the sample diffuses along the strip, carrying the gabapentin antibodies. A properly functioning strip will carry the sample, including the gabapentin antibodies dispersed within it, all the way to

the control line. The antibodies bind to free gabapentin and specific gabapentin conjugates on a first-come, first-serve basis. Because the tagged antibodies are located at the test strip's dip zone, they interact with the biological sample before reaching the gabapentin on the test line. If the biological sample contains gabapentin, the tagged antibodies will bind to the sample's gabapentin and not to the gabapentin on the test line. All the tagged antibodies then flow to the control line, resulting in a single-line, positive test. If the sample contains little or no gabapentin, the tagged antibodies are free to bind to the gabapentin on the test line, at a concentration significant enough to make the test line visible. Excess tagged antibodies will flow to the control line, resulting in a double-line, negative test.

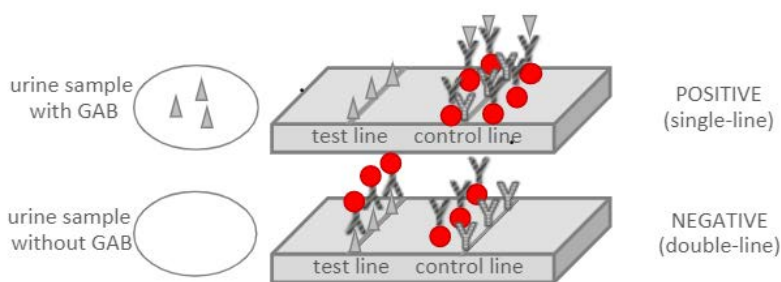


Fig. 7 - Diagram of Positive and Negative Gabapentin Lateral Flow Tests

C. ARK's Patented Methods for Testing for Gabapentin Are Used to Manufacture Competitive Assay Test Strips

52. Gabapentin lateral flow assays used in rapid drug tests are made, produced, and/or processed under or by means of the gabapentin testing methods claimed in the '345 Patent. During the initial phase of manufacturing such lateral flow assays, gabapentin-specific antibodies are produced by first inducing an immunogenic response in an animal host and then collecting the host's blood plasma. (*See* Ex. 6, R. Singh Decl. ¶¶8-13.) The serum collected from the host animal contains a multitude of antibodies, many of which do not target gabapentin. (*See id.*) Manufactures

then isolate the gabapentin-specific antibodies from this serum based on their weight, size, or specificity.

53. To determine whether the batch of isolated antibodies is sufficient for use in rapid drug test panels, a manufacturer must then use an assay that relies on a detectable label bound to gabapentin. (*See id.*) On information and belief, the assay manufacturers do this by combining in a reaction mixture samples suspected of containing gabapentin, a sample from the batch of isolated antibodies, and a gabapentin conjugate tagged with a detectable label and then analyze the mixture to detect whether the antibodies have formed complexes with the gabapentin. (*See id.*) By employing this method to assist with the making, production, and processing of accused test kits and strips by determining whether the batch of harvested antibodies is appropriate for use in such kits and strips, manufacturers practice the '345 Patent.

D. Commission Rule 210.10(b)(1) Statement

54. Pursuant to Commission Rule 210.10(b)(1), the Accused Products or categories of Accused Products that will be the subject of this Investigation are gabapentin-specific immunoassay 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.

E. Respondents' Accused Products

55. Pursuant to Commission Rule 210.12(a)(12), ARK plainly describes the Accused Products as 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.

V. UNLAWFUL AND UNFAIR ACTS OF PROPOSED RESPONDENTS

56. The following chart identifies the claims of the Asserted Patents that ARK asserts against each Respondent:

Respondent	The '665 Patent	The '345 Patent
12Panel	2, 3 or 6, 7, 9, 14, 17, 18, 20, 21	2, 7, 8, 11 or 12, 20, 26 or 27
Acro		2, 7, 8, 11 or 12, 19, 26 or 27
AlcoPro	2, 3 or 6, 7, 9, 14, 17, 18, 20, 21	2, 7, 8, 11 or 12, 20, 26 or 27
AllTest		2, 7, 8, 11 or 12, 19, 26 or 27
ASC	2, 3 or 6, 7, 9, 14, 17, 18, 20, 21	2, 7, 8, 11 or 12, 20, 26 or 27
Chemtron	2, 3 or 6, 7, 9, 14, 17, 18, 20, 21	2, 7, 8, 11 or 12, 20, 26 or 27
Confirm Bio	2, 3 or 6, 7, 9, 14, 17, 18, 20, 21	2, 7, 8, 11 or 12, 20, 26 or 27
The Healgen Respondents		2, 7, 8, 11 or 12, 19, 26 or 27
Kappa City	2, 3 or 6, 7, 9, 14, 17, 18, 20, 21	2, 7, 8, 11 or 12, 19 or 20, 26 or 27
Mercedes Medical		2, 7, 8, 11 or 12, 19, 26 or 27
TransMed	2, 3 or 6, 7, 9, 14, 17, 18, 20, 21	2, 7, 8, 11 or 12, 20, 26 or 27
Transmetron		2, 7, 8, 11 or 12, 19, 26 or 27

57. The evidence shows that the Proposed Respondents sell for importation, import, and/or sell within the United States after importation gabapentin immunoassay kits and test strips and/or components of such kits and test strips that infringe, or that were made, produced, or processed under or by means of methods covered by, one or more of claims of the Asserted Patents either literally or under the doctrine of equivalents. The Proposed Respondents infringe the Asserted Patents (i) directly, as discussed below; (ii) contributorily by selling products or components thereof that especially made or especially adapted for use in an infringement of the asserted claims without substantial noninfringing uses; and/or (iii) by inducement by exhibiting an affirmative intent to cause direct infringement of the asserted claims.

58. The Proposed Respondents will have received notice of their infringement by, among other things, the service of this Complaint.

59. The '665 Patent is directly infringed when the Proposed Respondents sell for importation, import, or sell after importation into the United States, gabapentin-specific kits and test strips that contain gabapentin-specific antibodies.

60. The '345 Patent is directly infringed when Proposed Respondents sell for importation, import, or sell after importation into the United States, gabapentin-specific kits and test strips that contain gabapentin-specific antibodies that are made, produced, or processed under, or by means of, the processes claimed by the '345 Patent.⁵ By using the Proposed Respondents' use of the '345 Patent's claimed processes to validate batches of antibodies that are incorporated into accused gabapentin immunoassay kits and test strips, or into components of such kits and test strips, has a close interdependence such kits and test strips imported into the United States. As discussed in the concurrently filed declaration of Dr. Raj Singh, manufacturers must perform this validation as part of the production of accused kits and test strips and of any components of such kits and test strips that contain gabapentin-specific antibodies. (*See* Ex. 6, R. Singh Decl. ¶¶ 14-18.)

61. On information and belief, Respondents induced, and continue to induce, others to infringe the asserted claims of the '665 Patent. With knowledge of infringement of the '665 Patent,

⁵ *See ClearCorrect Operating, LLC v. ITC*, 810 F.3d 1283, 1299 (Fed. Cir. 2015) (concluding that Section 337 has “perhaps a broader scope” than 35 U.S.C. § 271(g) because the statutory language of Section 337 covers articles that were “made, . . . produced, processed or mined . . .”); *Certain Sucralose, Sweeteners Containing Sucralose, and Related Intermediate Compounds Thereof*, Inv. No. 337-TA-604, Comm’n Op. at 34 (Apr. 29, 2009) (the Commission has authority to exclude articles that are made, produced, or processed under, or by means of, a patented process so long as the process has a “close interdependence” with the imported products); *see also id.* at 27 (observing that “cases indicat[ing] that further processing of a certain extent does not remove an article from the scope of section 337(a)(1)(B)(ii) . . . do not . . . necessarily represent the maximum further processing that may be performed on an article without removing it from the reach of the statute”).

Proposed Respondents have taken active steps to encourage and facilitate direct infringement by sellers, distributors, and users of the Accused Products. Proposed Respondents induce infringement of the '665 Patent by marketing the Accused Products in the United States, by contracting for the distribution of the Accused Products in the United States, and by creating or distributing product inserts, marketing materials, or similar materials that include instructions on how to use the accused gabapentin immunoassay kits and rapid drug tests. (*See, e.g.*, Exs. 17, 28, 44, 46, 50-55 (Proposed Respondent websites), Exs. 20, 29, 45, 56, 70 (package inserts).) Use of the Accused Products in their ordinary and customary fashion results in infringement of the asserted claims of the '665 Patent. (*See* Exs. 20, 29, 45, 56, 70.)

62. On information and belief, Respondents have contributorily infringed the asserted claims. Respondents have sold for importation into the United States, offered for sale within the United States, or imported into the United States gabapentin immunoassay kits and test strips that contain gabapentin-specific antibodies that practice the accused claims of the '665 Patent. These gabapentin-specific antibodies are a material part of the claimed inventions of the '665 Patent and are not staple articles or commodities suitable for substantial noninfringing use. The Respondents specially made or adapted the gabapentin-specific antibodies for use in an infringing manner. (*See* Exs. 20, 29, 45, 56, 70.)

63. In lieu of providing physical samples of the numerous, generally available, and prevalent devices, this complaint provides charts comparing claims of the Asserted Patents to exemplary products and photographs of the exemplary infringing devices. (*See, e.g.*, Exs. 15-16, 22, 26-27, 42-43.) These accused infringing devices were all purchased and delivered within the United States. (*See, e.g.*, Exs. 21, 25, 39, 41, 58.) The Accused Products infringe claims 1, 2, 3 or 6, 7, 9, 14, 17, 18, 20, and 21 of the '665 Patent and claims 1, 2, 7, 8, 11 or 12, 19 or 20, and 26 or

27 of the '345 Patent. Discovery may reveal that the Accused Products infringe additional claims of the Asserted Patents. Discovery may also reveal that additional products of the Proposed Respondents infringe the Asserted Patents, including unreleased products or versions of products that will become commercially available in the United States prior to the conclusion of this Investigation. Discovery may also reveal that Distributor Respondents source infringing products from manufacturers other than the Producer Respondents, and that Producer Respondents may distribute infringing products to distributors other than the Distributor Respondents.

A. Respondents' Infringement of the '665 Patent

64. As discussed further below, evidence shows that certain Proposed Respondents violate Section 337(a)(1)(B)(i) by selling for importation, importing, and/or selling after importation accused gabapentin immunoassay kits and test strips, or components of such kits and test strips, that directly infringe the Asserted '665 Patent.

1. Chemtron and Its Distributors

a) Chemtron

65. As discussed below, publicly available importation records show that Chemtron imports into the United States and/or sells within the United States after importation a gabapentin dip card test that infringes at least claims 1, 2, 3 or 6, 7, 9, 14, 17, 18, 20, and 21 of the '665 Patent, either literally or under the doctrine of equivalents. Attached as Exhibits 27, 42, 48, and 67 are representative claim charts that apply independent claims 1 and 20 of the '665 Patent to Chemtron's gabapentin dip card tests that are imported into or sold within the United States after importation by, at least, Distributor Respondents AlcoPro, ASC, Confirm Biosciences, and TransMed. (*See infra* § VII.B.)

b) AlcoPro

66. As discussed below, publicly available records show that AlcoPro imports into the United States and/or sells within the United States after importation a gabapentin dip card test that infringes at least claims 1, 2, 3 or 6, 7, 9, 14, 17, 18, 20, and 21 of the '665 Patent, either literally or under the doctrine of equivalents. Attached as Exhibit 27 is a representative claim chart that applies independent claims 1 and 20 of the '665 to AlcoPro's gabapentin dip card test that is manufactured for importation, imported, or sold after importation into the United States by, at least, Producer Respondent Chemtron. (*See infra* § VII.B.1.)

c) American Screening Corp.

67. As discussed below, publicly available records show that ASC imports into the United States and/or sells within the United States after importation a gabapentin dip card test that infringes at least claims 1, 2, 3 or 6, 7, 9, 14, 17, 18, 20, and 21 of the '665 Patent, either literally or under the doctrine of equivalents. Attached as Exhibit 42 is a representative claim chart that applies independent claims 1 and 20 of the '665 Patent to ASC's gabapentin dip card test that is manufactured for importation, imported, or sold after importation into the United States by, at least, Producer Respondent Chemtron. (*See infra* § VII.B.2.)

d) Confirm Biosciences

68. As discussed below, publicly available records show that Confirm Biosciences imports into the United States and/or sells within the United States after importation a gabapentin dip card test that infringes at least claims 1, 2, 3 or 6, 7, 9, 14, 17, 18, 20, and 21 of the '665 Patent, either literally or under the doctrine of equivalents. Attached as Exhibit 48 is a representative claim chart that applies independent claims 1 and 20 of the '665 Patent to Confirm Biosciences' gabapentin dip card test that is manufactured for importation, imported, or sold after importation into the United States by, at least, Producer Respondent Chemtron. (*See infra* § VII.B.3.)

e) TransMed

69. As discussed below, publicly available records show that TransMed imports into the United States and/or sells within the United States after importation a gabapentin dip card test that infringes at least claims 1, 2, 3 or 6, 7, 9, 14, 17, 18, 20, and 21 of the '665 Patent, either literally or under the doctrine of equivalents. Attached as Exhibit 67 is a representative claim chart that applies independent claims 1 and 20 of the '665 Patent to TransMed's gabapentin dip card test that is manufactured for importation, imported, or sold after importation into the United States by, at least, Producer Respondent Chemtron. (*See infra* § VII.B.4.)

2. Kappa City and Its Distributor

a) Kappa City

70. As discussed below, publicly available importation records show that Kappa City imports into the United States and/or sells within the United States after importation a gabapentin dip card test that infringes at least claims 1, 2, 3 or 6, 7, 9, 14, 17, 18, 19 or 20, and 21 of the '665 Patent, either literally or under the doctrine of equivalents. Attached as Exhibit 15 is a representative claim chart that applies independent claims 1 and 20 of the '665 Patent to Kappa City's gabapentin dip card test that is imported into or sold within the United States after importation by, at least, Distributor Respondent 12Panel. (*See infra* § VII.D.)

b) 12Panel

71. As discussed below, publicly available importation records show that 12Panel imports into the United States and/or sells within the United States after importation a gabapentin dip card test that infringes at least claims 1, 2, 3 or 6, 7, 9, 14, 17, 18, 20, and 21 of the '665 Patent, either literally or under the doctrine of equivalents. Attached as Exhibit 15 is the representative claim chart that applies independent claims 1 and 20 of the '665 Patent to 12Panel's gabapentin

dip card test that is manufactured for importation, imported, or sold after importation into the United States by, at least, Producer Respondent Kappa City. (*See infra* § VII.D.1.)

B. Respondents' Infringement of the '345 Patent

72. As discussed further below, the evidence shows that certain Proposed Respondents violate Section 337(a)(1)(B)(ii) by selling for importation, importing, and/or selling after importation accused gabapentin immunoassay kits and test strips, or components of such kits and test strips that are made, produced, or processed under a process covered by the Asserted '345 Patent. On information and belief, during manufacture of such accused products, the '345 Patent's claimed methods are employed to validate batches of isolated antibodies to determine whether the batches are appropriate for use in gabapentin immunoassay kits and test strips. This validation of antibody batches is a necessary step in the production of accused kits and test strips and of components of such kits and test strips. (*See* Ex. 6, R. Singh Decl. ¶¶ 14-18.)

1. AllTest and Its Distributors

a) AllTest

73. As discussed below, publicly available importation records show that AllTest imports into the United States and/or sells within the United States after importation a gabapentin dip card test that is made, produced, or processed under or by means of a process that is covered by at least claims 1, 2, 7, 8, 11 or 12, 19, and 26 or 27 of the '345 Patent, either literally or under the doctrine of equivalents. Attached as Exhibits 22 and 73 are representative claim charts that apply claim 1 of the '345 Patent to AllTest's gabapentin dip card tests that are imported into or sold within the United States after importation by, at least, Distributor Respondents Acro, Mercedes Medical, and Transmetron. (*See infra* § VII.A.)

b) Acro

74. As discussed below, publicly available importation records show that Acro imports into the United States and/or sells within the United States after importation a gabapentin dip card test that is made, produced, or processed under or by means of a process that is covered by at least claims 1, 2, 7, 8, 11 or 12, 19, and 26 or 27 of the '345 Patent, either literally or under the doctrine of equivalents. Attached as Exhibit 22 is a representative claim chart that applies claim 1 of the '345 Patent to Acro's gabapentin dip card test that is manufactured for importation, imported, or sold after importation into the United States by, at least, Producer Respondent AllTest. (*See infra* § VII.A.2.)

c) Mercedes Medical

75. As discussed below, publicly available importation records show that Mercedes Medical imports into the United States and/or sells within the United States after importation a gabapentin dip card test that is made, produced, or processed under or by means of a process that is covered by at least claims 1, 2, 7, 8, 11 or 12, 19, and 26 or 27 of the '345 Patent, either literally or under the doctrine of equivalents. Attached as Exhibit 22 is a representative claim chart that applies claim 1 of the '345 Patent to Mercedes Medical's gabapentin dip card that is manufactured for importation, imported, or sold after importation into the United States by, at least, Producer Respondent AllTest. (*See infra* § VII.A.3.)

d) Transmetron

76. As discussed below, publicly available importation records show that Transmetron imports into the United States and/or sells within the United States after importation a gabapentin dip card test that is made, produced, or processed under or by means of a process that is covered by at least claims 1, 2, 7, 8, 11 or 12, 19, and 26 or 27 of the '345 Patent, either literally or under the doctrine of equivalents. Attached as Exhibit 73 is a representative claim chart that applies claim

1 of the '345 Patent to Transmetron's gabapentin dip card test that is manufactured for importation, imported, or sold after importation into the United States by, at least, Producer Respondent AllTest. (*See infra* § VII.A.4.)

2. Chemtron and Its Distributors

a) Chemtron

77. As discussed below, publicly available importation records show that Chemtron imports into the United States and/or sells within the United States after importation a gabapentin dip card test that is made, produced, or processed under or by means of a process that is covered by at least claims 1, 2, 7, 8, 11 or 12, 20, and 26 or 27 of the '345 Patent, either literally or under the doctrine of equivalents. Attached as Exhibits 26, 43, 49, 68 are representative claim charts that apply independent claim 1 of the '345 Patent to Chemtron's gabapentin dip card tests that are imported into or sold within the United States after importation by, at least, Distributor Respondents AlcoPro, ASC, Confirm Biosciences, and TransMed. (*See infra* § VII.B.)

b) AlcoPro

78. As discussed below, publicly available importation records show that AlcoPro imports into the United States and/or sells within the United States after importation a gabapentin dip card test that is made, produced, or processed under or by means of a process that is covered by at least claims 1, 2, 7, 8, 11 or 12, 20, and 26 or 27 of the '345 Patent, either literally or under the doctrine of equivalents. Attached as Exhibit 26 is a representative claim chart that applies independent claim 1 of the '345 Patent, respectively, to AlcoPro's gabapentin dip card test that is manufactured for importation, imported, or sold after importation into the United States by, at least, Producer Respondent Chemtron. (*See infra* § VII.B.1.)

c) American Screening Corp.

79. As discussed below, publicly available importation records show that ASC imports into the United States and/or sells within the United States after importation a gabapentin dip card test that is made, produced, or processed under or by means of a process that is covered by at least claims 1, 2, 7, 8, 11 or 12, 20, and 26 or 27 of the '345 Patent, either literally or under the doctrine of equivalents. Attached as Exhibit 43 is a representative claim chart that applies independent claim 1 of the '345 Patent to ASC's gabapentin dip card test that that is manufactured for importation, imported, or sold after importation into the United States by, at least, Producer Respondent Chemtron. (*See infra* § VII.B.2.)

d) Confirm Biosciences

80. As discussed below, publicly available importation records show that Confirm Biosciences imports into the United States and/or sells within the United States after importation a gabapentin dip card test that is made, produced, or processed under or by means of a process that is covered by at least claims 1, 2, 7, 8, 11 or 12, 20, and 26 or 27 of the '345 Patent, either literally or under the doctrine of equivalents. Attached as Exhibit 49 is a representative claim chart that applies independent claim 1 of the '345 Patent to Confirm Biosciences' gabapentin dip card test that is manufactured for importation, imported, or sold after importation into the United States by, at least, Producer Respondent Chemtron. (*See infra* § VII.B.3.)

e) TransMed

81. As discussed below, publicly available importation records show that TransMed imports into the United States and/or sells within the United States after importation a gabapentin dip card test that is made, produced, or processed under or by means of a process that is covered by at least claims 1, 2, 7, 8, 11 or 12, 20, and 26 or 27 of the '345 Patent, either literally or under the doctrine of equivalents. Attached as Exhibit 68 is a representative claim chart that applies

independent claim 1 of the '345 Patent to TransMed's gabapentin dip card test that is manufactured for importation, imported, or sold after importation into the United States by, at least, Producer Respondent Chemtron. (*See infra* § VII.B.4.)

3. Healgen

82. As discussed below, publicly available importation records show that Healgen imports into the United States and/or sells within the United States after importation a gabapentin dip card test that is made, produced, or processed under or by means of a process that is covered by at least claims 1, 2, 7, 8, 11 or 12, 19, and 26 or 27 of the '345 Patent, either literally or under the doctrine of equivalents. Attached as Exhibit 36 is a representative claim chart that applies claim 1 of the '345 Patent to Healgen's gabapentin dip card test that is manufactured for importation, imported, and/or sold after importation into the United States. (*See infra* § VII.C.)

4. Kappa City and Its Distributor

a) Kappa City

83. As discussed below, publicly available importation records show that Kappa City imports into the United States and/or sells within the United States after importation a gabapentin dip card test that is made, produced, or processed under or by means of a process that is covered by at least claims 1, 2, 7, 8, 11 or 12, 19 or 20, and 26 or 27 of the '345 Patent, either literally or under the doctrine of equivalents. Attached as Exhibit 16 is a representative claim chart that applies independent claim 1 of the '345 Patent to Kappa City's gabapentin dip card test that is imported into or sold within the United States after importation by, at least, Distributor Respondent 12Panel. (*See infra* § VII.D.)

b) 12Panel

84. As discussed below, publicly available importation records show that 12Panel imports into the United States and/or sells within the United States after importation a gabapentin

dip card test that is made, produced, or processed under or by means of a process that is covered by at least claims 1, 2, 7, 8, 11 or 12, 20, and 26 or 27 of the '345 Patent, either literally or under the doctrine of equivalents. Attached as Exhibit 16 is a representative claim chart that applies independent claim 1 of the '345 Patent, respectively, to 12Panel's gabapentin dip card test that is manufactured for importation, imported, and/or sold after importation into the United States by, at least, Producer Respondent Kappa City. (*See* § VII.D.1.)

VI. RELATED LITIGATION

85. To the best of ARK's knowledge, information, and belief, there has been no litigation related to the Asserted Patents or to the Domestic Industry Products.

VII. SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE

86. Evidence demonstrates that the Proposed Respondents sell for importation, import, and/or sell in the United States after importation gabapentin immunoassay kits and test strips, and/or components of such kits and test strips, that infringe the Asserted '665 Patent or that were made, produced, or processed under or by means of methods covered by the Asserted '345 Patent.

87. Specific instances of sale for importation, importation, and/or sale within the United States after importation of gabapentin-specific antibodies,⁶ gabapentin immunoassays, and products including the same covered by the Asserted Patents by the Respondents are set forth below. These instances of importation and/or sale are exemplary in nature and are not intended to restrict the scope of any remedy the Commission may issue.

88. The nature of the products at issue allows manufacturers, suppliers, and distributors to mask the supply chain of the Accused Products by importing infringing immunoassays under a

⁶ The Commission assumes jurisdiction for Section 1337(a)(1)(B)(ii) allegations and must evaluate such allegations "on the merits." *Amgen v. ITC*, 902 F.2d 1532, 1537 (Fed. Cir. 1990).

high-level description (*e.g.*, “Diagnostic Test”) and omitting manufacturer information. Therefore, similarities between the branding of different test strips, the plastic shells used to encase the test strips, images used in operating directions, and the admissions of Proposed Respondents are used as the bases of the Complainant’s allegations.⁷

A. AllTest and Its U.S. Distributors

1. AllTest

89. As noted above, Respondent AllTest sells for importation and/or imports into the United States gabapentin immunoassays covered by the Asserted Patents. (*See supra* § V.) Publicly available evidence demonstrates that AllTest has imported gabapentin immunoassays into the United States and/or sold gabapentin immunoassays for importation into the United States.

90. AllTest operates a website at www.alltests.com.cn/ that is accessible to customers in the United States. AllTest’s website advertises and offers for sale a “JusCheck Gabapentin(GAB) Rapid Test – Urine” (*see* Ex. 34) and an “AllTest Gabapentin(GAB) Rapid Test – Urine” (*see* Ex. 33). The evidence shows that these rapid tests are gabapentin immunoassays covered by the Asserted Patents.

91. In addition, importation records obtained through Panjiva show that AllTest has imported into the United States gabapentin immunoassays covered by the Asserted Patents. (*See* Ex. 90.) Specifically, AllTest has sold for importation into the United States “DIAGNOSTIC TESTS” and “DIAGNOSTIC TESTS RAPID TEST FOR FORENSIC USE.” (*See* Ex. 90.) The evidence shows that these diagnostic tests and rapid tests include AllTest’s gabapentin test strips:

⁷ *See e.g., Certain Powered Cover Plates*, Inv. No. 337-TA-1124, Initial Determination at 7-8 (Jul. 10, 2019) not reviewed, Notice (Aug. 12, 2019); *see also, Certain Fish-Handling Pliers & Packaging Thereof*, Inv. No. 337-TA-1169 Unreviewed Part of Order No. 14 at 12-13 (Aug. 7, 2020) (relying on similarity of website photos and received products to show importation); *see also infra*, Section VII.A-C.



Fig. 8 – AllTest’s Gabapentin Immunoassays (Exs. 33-34)⁸

2. Acro

92. Publicly available evidence demonstrates that Acro has imported gabapentin immunoassays manufactured by AllTest into the United States and/or sold that gabapentin immunoassays for importation into the United States.

93. Panjiva records show that Acro imports “DIAGNOSTIC TESTS” from the Producer Respondent AllTest. (Ex. 90.) On information and belief, these diagnostic tests include gabapentin immunoassays, which Acro repackages, relabels, and resells AllTest’s products to users and to other distributors, such as Mercedes Scientific. (See Exs. 66, 77; see also *supra* Fig. 8.)

94. Acro is registered as a “Repackager” and “Relabeler” with the FDA, rather than as a manufacturer (Ex. 99), and it has registered a gabapentin assay that it intends to distribute in the United States with the FDA (*see* Exs. 98-99, 102-103). Acro’s Joseph Fan is registered as AllTest’s U.S. Agent for FDA communications. (*Compare* Ex. 98 with Ex. 104.)

95. Acro operates a website at www.acrobiotech.com that is accessible to customers in the United States. Acro’s website advertises and offers for sale a “Gabapentin(GAB) Rapid Test Cassette,” “Gabapentin(GAB) Rapid Test Panel,” and “Gabapentin(GAB) Rapid Test Dipstick.”

⁸ The images on AllTest’s website use a cotinine (COT) strip in its pictures.

(See Ex. 23.) A gabapentin rapid drug test purchased in the United States from a website that advertises a “AllTest/AcroBiotech” rapid drug test with the SKU number “DGAB-114” (Ex. 77) shows that the packaging of Acro’s gabapentin rapid drug test is identical to the packaging on AllTest’s website. (Compare Ex. 72 with Exs. 33-34.) As discussed above in Section V, these products are covered by the Asserted Patents.

3. Mercedes Scientific

96. Publicly available evidence demonstrates that Mercedes Medical has imported gabapentin immunoassays into the United States and/or sold gabapentin immunoassays for importation into the United States.

97. Mercedes Scientific operates a website at www.mercedesscientific.com that is accessible to customers in the United States. Mercedes Scientific’s website advertises and offers for sale a “ACR DGAB114 . . . Gabapentin Rapid Test Panel.” (See Ex. 64.) The evidence shows that this product is a gabapentin immunoassays covered by the Asserted Patents. In particular, importation records obtained through Panjiva show Mercedes Scientific has imported into the United States gabapentin immunoassays covered by the Asserted Patents. (See Ex. 94.) Specifically, they have imported several “DIAGNOSTIC TESTS.” (Ex. 94.) On information and belief, these diagnostic tests include Mercedes Scientific’s “Gabapentin Rapid Test Panel.”

98. A test purchased from Mercedes Scientific in the United States included a packing slip that listed “ACR DGAB114” as the item identifier. (Ex. 66.) The evidence shows that this is Acro Biotech’s Gabapentin Rapid Test Panel, which bears an identical item number of DGAB-114. (See Ex. 77) As discussed above, Panjiva records show that Acro imports several “DIAGNOSTIC TESTS” from AllTest (Ex. 90), and a visual comparison between the shells of

AllTest’s products⁹ and the Acro products distributed by Mercedes Medical shows that they are almost identical. (*See infra* Fig. 9.) Notably, the branding of the test strip used in the AllTest/Acro product distributed by Mercedes Medical matches Chemtron’s branding—a red background, white lettering, and spacing of the abbreviation “GAB” (*see* Ex. 30)—and not the strips shown on AllTest’s site (*see infra* Fig. 9). Consequently, it appears that AllTest sometimes obtains gabapentin strips from other suppliers, including Chemtron, and incorporates these third-party strips into its shells and packaging to assemble a final product, which is then imported into the United States. (*See infra* Fig. 9; *see also* Ex. 90.)



Fig. 9 - Chemtron’s Gabapentin Strip (Left, Ex. 30) physically matches the test strip in Acro’s gabapentin immunoassay sold by Mercedes Scientific (Right, Ex. 24), which matches the casing of AllTest’s gabapentin immunoassay (Middle, Ex. 33.)¹⁰

99. In addition to the similarities in packaging, Mercedes Scientific’s package inserts call the product “Gabapentin(GAB) Rapid Test Panel,” which is identical to the name that Acro

⁹ Note, the stock photos for AllTest’s products show a cotinine (COT) strip encased in AllTest’s rapid test shell, not a gabapentin strip (GAB).

¹⁰ The images on AllTest’s website use a cotinine (COT) strip in its pictures.

uses to describe this product on its website. (Exs. 23, 65.) Further, graphic directions in Mercedes Medical's package insert match diagrams on AllTest's website, further showing that Acro imports and distributes AllTest's gabapentin immunoassays to Mercedes Medical. (*Compare* Ex. 33, 65.)

4. Transmetron

100. As noted above, Respondent Transmetron sells for importation and/or imports into the United States gabapentin immunoassays covered by the Asserted Patents. (*See supra* § V.) Publicly available evidence demonstrates that Transmetron has imported gabapentin immunoassays into the United States and/or sold gabapentin immunoassays for importation into the United States.

101. Transmetron operates a website at <http://drug-test-store.com/> that is accessible to customers in the United States. Transmetron's website advertises and offers for sale "Gabapentin Dip Test" and "VistaFlow 20 Panel Drug Test Cup w/adulteration." (Ex. 74.) ARK purchased Transmetron's gabapentin dip test in the United States. (Ex. 112.) The evidence shows that these products are AllTest's gabapentin immunoassays, which are covered by the Asserted Patents, as stated above. (*See also infra* Fig. 10.) In particular, the Transmetron's products purchased in the United States are physically identical to products offered on AllTest's website. (Exs. 33-34, 76.) In addition, Transmetron's package inserts (Ex. 75) use images from AllTest's website (*see* Ex. 33.) The visual similarities between the branding of these products is sufficient to show importation.



Fig. 10 - AllTest's Gabapentin Immunoassay (Left, Ex. 33) is identical to Transmetron's Gabapentin Immunoassay (Right, Ex. 76.)

B. Chemtron and Its U.S. Distributors

102. As noted above, Respondent Chemtron sells for importation and/or imports into the United States gabapentin immunoassays covered by the Asserted Patents. (*See supra* § V.) Publicly available evidence demonstrates that Chemtron has imported gabapentin immunoassay into the United States and/or sold gabapentin immunoassays for importation into the United States.

103. Several of the Distributor Respondents sell Chemtron's "Gabapentin (GAB) Single Panel Dip Card 25/Box," listing Chemtron as the manufacturer. (*See, e.g.*, Ex. 29.) Chemtron operates two websites, one for its Chinese products (www.chemtronbio.com/product/index.htm) and one for its United States products (www.uschemtronbio.com/index.php/services/). Both websites are visible to customers in the United States. Chemtron's U.S. site lists 25 drug of abuse tests available from its United States facility; Chemtron USA's product list does not include gabapentin tests. (Ex. 82.) Chemtron's U.S. facility also registered itself as a manufacturer, contract manufacturer, and re-labeler with the FDA (Ex. 101), but neither entity has registered its gabapentin tests with the FDA (*see* Exs. 97, 101). Based on Chemtron USA's omission of

gabapentin immunoassays on its website and its failure to register the gabapentin immunoassay with the FDA, on information and belief, Chemtron’s gabapentin immunoassays are manufactured in China and imported into the United States.

104. Chemtron’s drug of abuse tests have distinct branding – the background of the strip has a solid color, and a three-letter abbreviation of the drug being tested is overlaid in white. Several Proposed Respondents use gabapentin strips with this same branding:

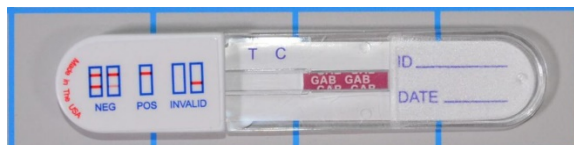


Fig. 11 – Chemtron’s Gabapentin Immunoassay, distributed by AlcoPro (Ex. 30)

1. AlcoPro

105. As noted above, Respondent AlcoPro sells for importation and/or imports into the United States gabapentin immunoassays covered by the Asserted Patents. (*See supra* § V.) Publicly available evidence demonstrates that AlcoPro has imported gabapentin immunoassays into the United States and/or sold gabapentin immunoassays for importation into the United States.

106. AlcoPro operates a website at www.alcopro.com/ that is accessible to customers in the United States. AlcoPro’s website advertises and offers for sale a “CheckPoint Instant Gabapentin Urine Dip Drug Test.” (Ex. 28.) Respondent Chemtron manufactures AlcoPro’s “CheckPoint Instant Gabapentin Urine Dip Drug Test.” (Ex. 29.) As discussed above in Section V, the “CheckPoint Instant Gabapentin Urine Dip Drug Test” is covered by the Asserted Patents.

107. AlcoPro’s gabapentin rapid drug tests were purchased in the United States. (Exs. 41, 47.) AlcoPro’s gabapentin immunoassays are labeled “Made in the USA,” and its package inserts identify Chemtron USA in the manufacturer contact information, but this likely refers to final assembly and not to the test strip included in the finished product. (*See* Ex. 29.) As discussed above, the evidence shows that Chemtron manufactures its gabapentin strips in China and imports

them into the United States, then performs final packaging and distribution from its United States facilities. (*See supra* § VII.B.)

108. As AlcoPro admits its strips are manufactured by Chemtron, the branding of the above test is used as a baseline for identifying other Chemtron products, as discussed below.

2. ASC

109. As noted above, Respondent ASC sells for importation and/or imports into the United States gabapentin immunoassays covered by the Asserted Patents. (*See supra* § V.) Publicly available evidence demonstrates that ASC has imported gabapentin immunoassays into the United States and/or sold gabapentin immunoassays for importation into the United States.

110. ASC operates a website at www.americanscreeningcorp.com/ that is accessible to customers in the United States. ASC's website advertises and offers for sale a "Precision Dx - 1 Panel Dip Card – Gabapentin." (*See Ex. 44.*) These rapid drug tests have been purchased within the United States. (*See Exs. 25, 31*) As seen below, the gabapentin strip in ASC's product matches the branding from Chemtron's strips. As discussed above, Chemtron's gabapentin immunoassay products are imported and covered by the Asserted Patents.

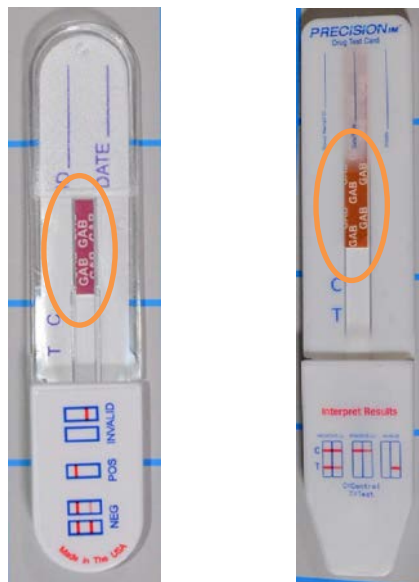


Fig. 12 - Comparing a known Chemtron strip (Left, Ex. 30), with ASC's Gabapentin Immunoassay (Right, Ex. 46)

111. Importation records obtained through Panjiva show ASC imports “RAPID DIAGNOSTIC TESTS” from several different suppliers. (Ex. 91.) On information and belief, these rapid diagnostic tests include ASC’s “Precision Dx - 1 Panel Dip Card – Gabapentin.”

3. Confirm Biosciences

112. As noted above, Respondent Confirm Biosciences sells for importation and/or imports into the United States gabapentin immunoassays covered by the Asserted Patents. (*See supra* § V.) Publicly available evidence demonstrates that Confirm Biosciences has imported that gabapentin immunoassays into the United States and/or sold that gabapentin immunoassays for importation into the United States.

113. Confirm Biosciences operates websites at www.confirmbiosciences.com and testcountry.com, both of which are accessible to customers in the United States. Confirm Biosciences’ website advertises and offers for sale a “Single Panel Gabapentin Urine Drug Test Dip Card.” (*See* Exs. 50-55.) Confirm Biosciences’ gabapentin rapid drug tests have been purchased within the United States. (*See* Ex. 21)

114. A visual inspection of Confirm Biosciences' test shows that the test strip bears the distinctive branding of the strips manufactured by Chemtron. (*See supra* § VII.B; *see also* Ex. 57.) In addition, the product insert included with Confirm Biosciences' immunoassay identifies Chemtron as the manufacturer. (*See* Ex. 56.)



Fig. 13 - Comparing a known Chemtron strip (Left, Ex. 30) with Confirm Bioscience's Gabapentin Immunoassay (Right, Ex. 57)

115. Confirm Biosciences' website states that these tests are "Made in the USA," but this likely refers to final assembly and not to the test strip included in the finished product. (*See* Ex. 29.) As discussed above, the evidence shows that Chemtron manufactures its gabapentin strips in China and imports them into the United States, then performs final packaging and distribution from its United States facilities. (*See supra* § VII.B.)

116. In addition to the test strips purchased from Chemtron, publicly available information shows that Confirm Biosciences purchases and imports diagnostic tests manufactured by Respondent Healgen manufactures several diagnostic tests. (*See* Ex. 92.) On information and belief, these imported diagnostic tests include Confirm Bioscience's Single Panel Gabapentin

Urine Drug Test Dip Card. (*See* § VII.C.) As discussed above, Healgen’s products are covered by the Asserted Patents.

4. TransMed

117. As noted above, Respondent TransMed sells for importation and/or imports into the United States gabapentin immunoassays covered by the Asserted Patents. (*See supra* § V.) Publicly available evidence demonstrates that TransMed has imported gabapentin immunoassays into the United States and/or sold gabapentin immunoassays for importation into the United States.

118. TransMed also operates a website at <https://drugtestingforless.com/> that is accessible to customers in the United States. TransMed’s website advertises and offers for sale at least three different gabapentin immunoassays, including Chemtron’s “Gabapentin (GAB) Single Panel Dip Card” (*see* Exs. 70, 87), AllTest/Acro’s “Gabapentin (GAB) Single Panel 2000 ng cut off,” and AllTest/Acro’s “17 Panel Drug Test Cup with ETG, K2, FEN, GAB, TRA with Adulterants” (Ex. 87). TransMed also operates the website www.transmedco.com, which offers a “Healgen Scientific . . . Gabapentin Drug Test Dip Card.” (Exs. 69.) As stated above, these products are covered by the Asserted Patents. (*See supra* § VII.A-B.)

119. Chemtron’s Gabapentin (GAB) Single Panel Dip Card was purchased from TransMed in the United States. (Exs. 70, 88.) The package insert provided with this product identifies Chemtron as the manufacturer and provides contact information for Chemtron’s domestic facility. (*See* Ex. 70.) As discussed above, the evidence shows that the immunoassays themselves are manufactured at Chemtron’s Chinese facility and imported into the United States.



Fig. 14 - Comparing a known Chemtron strip (Left, Ex. 30) with TransMed's Gabapentin Immunoassay (Right, Ex. 89)

120. In addition to purchasing and importing test strips from Chemtron, publicly available records available from Panjiva show that TransMed imports several “DIAGNOSTIC TEST[S]” on behalf of Healgen. (Ex. 95.) On information and belief, these diagnostic tests include Healgen’s gabapentin immunoassays covered by the Asserted Patents.

C. The Healgen Respondents and Their U.S. Distributors

121. As noted above, Respondent Healgen sells for importation and/or imports into the United States gabapentin immunoassays covered by the Asserted Patents. (*See supra* § V.) Publicly available evidence demonstrates that Healgen has imported gabapentin immunoassays into the United States and/or sold gabapentin immunoassays for importation into the United States.

122. Healgen operates websites at www.healgen.com/ and www.orientgene.com/asp-en/home/index.aspx that are accessible to customers in the United States. Healgen Scientific’s website advertises and offers for sale a “Multi-Drug Test Cup” and “Multi-Drug Test Dipcard” that are identical to the products offered on its Orient Gene’s site. (*Compare* Ex. 84 with Exs. 85, 86.) The evidence shows that Healgen Scientific does not manufacture products; it is a

“Specification Developer” for its manufacturer, Orient Gene. (Exs. 100, 105.) Orient Gene then manufactures and sells these products for importation into United States to Healgen Scientific and other importers. (*See* Exs. 100, 105.) As discussed above in Section V, these products include gabapentin immunoassays covered by the Asserted Patents.

123. In addition, publicly available importation records from Panjiva show Healgen imports many “DIAGNOSTIC TEST[S],” under the care and name of other entities, including some of the Proposed Respondents. (Exs. 92-93, 95-96.) On information and belief, these products include gabapentin immunoassays that practice the Asserted Patents.

1. Purchase of Healgen’s Gabapentin Single Panel Dip Card Drug Tests from American Drug Test

124. As noted above, Healgen’s drug tests are available for purchase domestically, and Healgen sells for importation and/or imports into the United States gabapentin immunoassays covered by the Asserted Patents. (*See supra* § V.) Publicly available evidence demonstrates that Healgen has imported gabapentin immunoassays into the United States and/or sold gabapentin immunoassays for importation into the United States.

125. For example, American Drug Test¹¹ (“ADT”) operates a website at <https://americandrugtest.com/> that is accessible to customers in the United States. ADT’s website advertises and offers for sale a “Gabapentin (Neurontin) Single Panel Dip Card Drug Test” and “Gabapentin (Neurontin) 2000 ng cut-off Single Panel Dip Card Drug Test.” (Ex. 37.) Healgen manufactures ADT’s “Gabapentin (Neurontin) Single Panel Dip Card Drug Test” and “Gabapentin (Neurontin) 2000 ng cut-off Single Panel Dip Card Drug Test.” (Ex. 38.) A “Gabapentin

¹¹ American Drug Test (“ADT”) is not named as a Proposed Respondent because of potential issues in serving this entity. ADT it is not registered as a business with any state and maintains its principal place of business at 3482 Keith Bridge Rd., Ste. 196, Cumming, GA 30041, a UPS Store. (*See* Ex. 83).

(Neurontin) Single Panel Dip Card Drug Test” test strip advertised as a Healgen product was ordered in the United States from ADT’s website. (Ex. 79) The package insert that comes with ADT’s test strips states that the gabapentin immunoassay is “[m]anufactured for Healgen.” (Ex. 38.) This is consistent with Orient Gene’s manufacture of the strips in China for importation by Healgen’s U.S. arm into the United States. (*See id.*; *see also supra* § VII.C.) As discussed above, Healgen’s products are covered by the Asserted Patents.

2. Confirm Biosciences and TransMed

126. As discussed above, the evidence suggests that Respondents Confirm Biosciences and TransMed source infringing gabapentin test strips from Healgen, in addition to sourcing them from Chemtron. (*See supra* §§ VII.B.3, VII.B.4.) In addition, the product insert listed on TransMed’s website, www.transmedco.com, is a link to a website belonging to American Drug Test, https://americandrugtest.com/content/Gabapentin_Package_Insert.pdf. (Exs. 69-70.)

D. Kappa City and Its U.S. Distributors

127. As noted above, Respondent Kappa City sells for importation and/or imports into the United States gabapentin immunoassays covered by the Asserted Patents. (*See supra* § V.) Publicly available evidence demonstrates that Kappa City has imported gabapentin immunoassays into the United States and/or sold gabapentin immunoassays for importation into the United States.

128. Kappa City operates websites at www.pharmadrugtest.com, www.narcocheck.com/en/, and www.kappa-city.fr/?lang=en, all of which are accessible to customers in the United States. These websites advertise and offer for sale Kappa City’s “Gabapentin (Neurontin) test,” which is manufactured in France. (Ex. 59 at 2; Ex. 60 at 4.)

129. Kappa City’s rapid drug test has been purchased in the United States. (*See* Ex. 32.) The packing slip (Ex. 32) and package inserts (Ex. 35) for orders of “Gabapentin (Neurontin) test”

state that Kappa City’s gabapentin rapid drug tests are as an import manufactured in France. As discussed above in Section V, this product is covered by the Asserted Patents.

130. The branding of Kappa City’s gabapentin strips is recognizable by its white background, and the spacing of the red “GAB” letters on the strip. (*See* Ex. 61.) The evidence shows that distributors of this product can be identified by this distinctive branding:

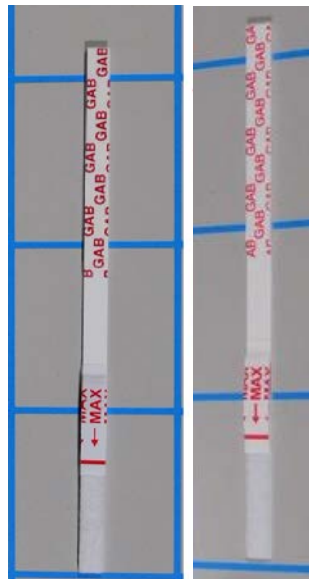


Fig. 15 - Comparing Kappa City’s Gabapentin Strip (Left, Ex. 61) with 12Panel’s Gabapentin Strips (Right, Ex. 62.)

1. 12Panel

131. As noted above, Respondent 12Panel sells for importation and/or imports into the United States gabapentin immunoassays covered by the Asserted Patents. (*See supra* § V.) Publicly available evidence demonstrates that 12Panel has imported gabapentin immunoassays into the United States and/or sold gabapentin immunoassays for importation into the United States.

132. 12Panel operates a website at <https://12panelnow.com/> that is accessible to customers in the United States. 12Panel’s website advertises and offers for sale a “Gabapentin GAB Test Strip.” (*Compare* Ex. 17 with Ex. 60.) 12Panel’s gabapentin rapid drug test has been purchased in the United States. (*See* Ex. 78.) As shown above, 12Panel’s gabapentin test strip bears

Kappa City's distinctive branding. (*See* Fig. 15; *see also* Ex. 17.) This evidence shows that 12Panel distributes Kappa City's gabapentin test strip, which is covered by the Asserted Patents. In addition, images on 12Panel's site show the test strips bear Kappa City's brand name, "NarcoCheck." (*See supra* § VII.D; *see also* Exs. 18, 19.)

VIII. CLASSIFICATION OF THE ACCUSED PRODUCTS UNDER THE HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES

133. The infringing Accused Products may be classified under at least the following heading and subheading of the Harmonized Tariff Schedule of the United States ("HTSUS"): 3002.12.00, 3002.15.00, 3002.19.00, and 3822.00.10. These classifications are intended for illustration only and are not intended to restrict the scope of any exclusion order or other remedy ordered by the Commission.

IX. THE DOMESTIC INDUSTRY

134. A domestic industry, as defined by 19 U.S.C. § 1337(a)(2)-(3), exists in the United States relating to the Asserted Patents based on ARK's significant investment in plant and equipment, significant employment of labor or capital, and substantial investment in exploiting the Asserted Patents (including through engineering, research, and development) in connection with ARK's gabapentin immunoassay products, including the ARK Gabapentin Assay, ARK Gabapentin Calibrator, and ARK Gabapentin Control.

A. Technical Prong

135. The Asserted Patents protect ARK's Domestic Industry Products, including the ARK Gabapentin Assay, ARK Gabapentin Calibrator, ARK Gabapentin Control, and gabapentin materials supplied to Advin. ARK's Domestic Industry Products practice or can be used to perform the claimed methods of the Asserted Patents, including claims 1-3, 4 or 6, 5, 7, 8, 17, 18, 20-30,

33, and 35 of the '665 Patent and claims 1–9, 11, 15, 16, 20, 22–25, and 26 or 27 of the '345 Patent.

136. Pursuant to Commission Rule 210.12(a)(9)(ix), attached to this Complaint as Exhibits 17 and 18 are claim charts applying exemplary claim 1 of each of the Asserted Patents to ARK's Domestic Industry Products.

B. Economic Prong

137. ARK has made and continues to make significant investments in connection with its gabapentin immunoassay products that practice the Asserted Patents and substantial investments in exploiting that patent. This includes significant investments related to facilities and equipment used in connection with its gabapentin immunoassay methods and products, significant employment of personnel and capital in connection with those methods and products, and substantial investments related to research, development, and engineering in connection with the invention described in the Asserted Patents. Confidential Exhibit 106C details these investments and employments.

X. REQUESTED RELIEF

138. WHEREFORE, by reason of the foregoing, ARK respectfully requests that the United States International Trade Commission:

A. Institute an immediate investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, into the violation of Section 337 based on the sale for importation into the United States, importation, and/or sale within the United States after importation of Respondents' Accused Products that infringe, or are made, produced and/or processed by means of a process covered by the Asserted Patents;

B. Schedule and conduct a hearing pursuant to Section 337(c), for purposes of receiving evidence and hearing argument concerning whether there has been a violation of

Section 337, and following the hearing to determine that there has been a violation of Section 337;

C. Issue a permanent limited exclusion order forbidding entry into the United States of Accused Products that are imported, sold for importation, or sold after importation by Respondents that infringe, or are made, produced and/or processed by means of a process covered by the Asserted Patents;

D. Issue permanent cease and desist orders, pursuant to Section 337(f), directing Respondents to cease and desist from the importation, sale, offer for sale, marketing, advertising, packaging, distribution, transfer, or solicitation of any sale by Respondents of gabapentin immunoassays that are made, produced and/or processed by means of a process covered by the Asserted Patents.

E. Impose a bond, pursuant to 19 U.S.C. §§ 1337(e), (j), upon Proposed Respondents' importation of the Accused Products that infringe, or are made, produced and/or processed by means of a process covered by the Asserted Patents during the 60-day Presidential review period to prevent further injury to ARK's domestic industry relating to the Asserted Patents; and

F. Grant all such other and further relief as it deems appropriate under the law, based upon the facts complained of herein and as determined by the investigation.

Date: December 1, 2020

/s/ Joshua Hartman

Paul M. Bartkowski

Joshua Hartman

Hayley Ostrin

ADDUCI, MASTRIANI & SCHAUMBERG, LLP

1133 Connecticut Avenue, NW, 12th Floor

Washington, DC 20036

Telephone: (202) 467-6300

Facsimile: (202) 466-2006

E-Mail: ARK-001@adduci.com

*Counsel for Complainant ARK Diagnostics,
Inc.*

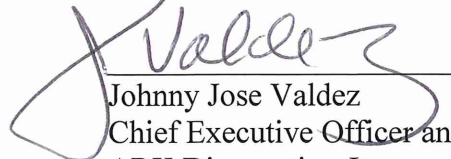
Verification of Complaint

I, Johnny Jose Valdez, in accordance with 19 CFR §§ 210.4 and 210.12(a), under penalty of perjury, that the following statements are true:

1. I am the Chief Executive Officer and President of ARK Diagnostics, Inc. and am duly authorized to verify this Complaint on behalf of the Complainant;
2. I have read the foregoing Complaint and am aware of its contents;
3. To the best of my knowledge, information, and belief, the foregoing Complaint is well-founded in fact and is warranted by existing law or by a non-frivolous argument for the extension, modification, or reversal of existing law or the establishment of new law;
4. The allegations and other factual contentions in the Complaint have evidentiary support or are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery; and
5. The foregoing Complaint is not being presented for an improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on November 25, 2020



Johnny Jose Valdez
Chief Executive Officer and President
ARK Diagnostics, Inc.