UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN PLANT-DERIVED RECOMBINANT HUMAN SERUM ALBUMINS ("rHSA") AND PRODUCTS CONTAINING SAME**	**Investigation No. 337-TA-1238**

LIMITED EXCLUSION ORDER

The United States International Trade Commission ("Commission") has determined that there is a violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), in the unlawful importation, sale for importation, or sale within the United States after importation by respondent Wuhan Healthgen Biotechnology Corp.[1] of Wuhan, China ("Healthgen") of certain plant-derived recombinant human serum albumins ("rHSA") and products containing the same (as defined in paragraph 2 below) that infringe one or more of claims 1 and 11–13 of U.S. Patent No. 10,618,951 ("Asserted Patent").

The Commission has also found respondents ScienCell Research Laboratories, Inc. of Carlsbad, California ("ScienCell"); Aspira Scientific, Inc. of Milpitas, California ("Aspira"); and eEnzyme LLC of Gaithersburg, Maryland ("eEnzyme") (collectively, the "Defaulting Respondents") in default. *See* Order No. 13 (July 28, 2021), *unreviewed by* Comm'n Notice (Aug. 18, 2021). The Complaint alleged: (1) a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the unlawful importation, sale for importation, or sale within the United States after importation of certain plant-derived recombinant human serum

[1] Also known as Healthgen Biotechnology, Co. Ltd; Healthgen Biotechnology Corp.; Wuhan Healthgen Biotechnology Corp.; and Healthgen Biotechnology Co.

albumins ("rHSA") and products containing the same that infringe one or more of claims 1 and 11–13 of the Asserted Patent; and (2) a violation of section 337 with respect to the importation into the United States or sale of certain plant-derived recombinant human serum albumins ("rHSA") and products containing the same by reason of a false designation of geographic origin the threat or effect of which is to substantially injure an industry in the United States. Because the conditions in 19 U.S.C. § 1337(g)(1)(A)–(E) have been satisfied, the Commission, upon the request of the complainant, issues a limited exclusion order, based on the violations alleged in the complaint that are presumed to be true as to the Defaulting Respondents.

Having reviewed the record in this investigation, including the written submissions of the parties, the Commission has made its determinations on the issues of remedy, the public interest, and bonding. The Commission has determined that the appropriate form of relief is a limited exclusion order prohibiting (1) the unlicensed entry of infringing plant-derived recombinant human serum albumins ("rHSA") and products containing the same manufactured by or on behalf of, or imported by or on behalf of, Healthgen or the Defaulting Respondents or any of their affiliated companies, parents, subsidiaries, agents, or other related business entities, or their successors or assigns; and (2) the entry of plant-derived recombinant human serum albumins ("rHSA") and products containing same that fail to accurately designate the country of origin, and which are manufactured abroad by or on behalf of, or imported by or on behalf of, the Defaulting Respondents or any of their affiliated companies, parents, subsidiaries, agents, or other related business entities, or their successors or assigns.

The Commission has also determined that the public interest factors enumerated in 19 U.S.C. §§ 1337(d)(1) and (g)(1) do not preclude the issuance of the limited exclusion order, and that the bond during the period of Presidential review shall be in the amount of one hundred

percent (100%) of the entered value of the entered value of the articles subject to this Order.

Accordingly, the Commission hereby **ORDERS** that:

1. Plant-derived recombinant human serum albumins ("rHSA") and products containing the same that infringe one or more of claims 1 and 11–13 of the Asserted Patent and are manufactured abroad by or on behalf of, or imported by or on behalf of, Healthgen or the Defaulting Respondents or any of their affiliated companies, parents, subsidiaries, agents, or other related business entities, or their successors or assigns, are excluded from entry for consumption into the United States, entry for consumption from a foreign-trade zone, or withdrawal from a warehouse for consumption, for the remaining terms of the Asserted Patent, except under license from, or with the permission of, the patent owner or as provided by law.

2. Plant-derived recombinant human serum albumins ("rHSA") and products containing the same that fail to accurately designate the country of origin, and which are manufactured abroad by or on behalf of, or imported by or on behalf of, the Defaulting Respondents or any of their affiliated companies, parents, subsidiaries, agents, or other related business entities, or their successors or assigns, are excluded from entry for consumption into the United States, entry for consumption from a foreign-trade zone, or withdrawal from a warehouse for consumption, or withdrawal from a warehouse for consumption, unless a printed label meeting the following requirements is attached thereto:

   a. the label, to the extent reasonably possible, shall be designed, made, and attached in a manner to inhibit any person except the ultimate purchaser in the United States from destroying, removing, altering, covering, or obliterating the label or its contents; and

   b. the label shall state legibly, permanently, and conspicuously, the English language

name of the country of origin.

3. The plant-derived recombinant human serum albumins ("rHSA") and products containing the same subject to this exclusion order (*i.e.*, "covered articles") are as follows: plant-derived recombinant human serum albumins ("rHSA") and products containing the same, such as lyophilized powders and liquid suspensions primarily containing rHSA along with naturally-occurring plant expression by-products, such as plant heat shock proteins and/or plant fatty acids, as well as cell culture media supplements formulated with such rHSA products.

4. Notwithstanding paragraphs 1 and 2 of this Order, covered articles are entitled to entry into the United States for consumption, entry for consumption from a foreign trade zone, or withdrawal from a warehouse for consumption, under bond in the amount of one hundred percent (100%) of their entered value, pursuant to subsection (j) of section 337 (19 U.S.C. § 1337(j)) and the Presidential Memorandum for the United States Trade Representative of July 21, 2005 (70 Fed. Reg. 43,251), from the day after this Order is received by the United States Trade Representative until such time as the United States Trade Representative notifies the Commission that this Order is approved or disapproved but, in any event, not later than sixty (60) days after the receipt of this Order. All entries of covered articles made pursuant to this paragraph are to be reported to U.S. Customs and Border Protection ("CBP"), in advance of the date of the entry, pursuant to procedures CBP establishes.

5. At the discretion of CBP and pursuant to the procedures it establishes, persons seeking to import articles are required to provide testing data using a methodology found acceptable in the accompanying Commission Opinion that demonstrates that the products to be imported do not infringe claims 1 and 11–13 of the Asserted Patent because they have 2% or more aggregated albumin, and they may be required to certify that they are familiar with the

terms of this Order, that they have made appropriate inquiry (including through the required testing), and thereupon state that, to the best of their knowledge and belief, the products being imported are not excluded from entry under paragraphs 1 or 2 of this Order. At its discretion, CBP may require persons who have provided the certification described in this paragraph to furnish such records or analyses as are necessary to substantiate the certification.

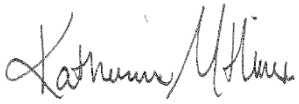
6. In accordance with 19 U.S.C. § 1337(l), the provisions of this Order shall not apply to covered articles that are imported by and for the use of the United States, or imported for and to be used for, the United States with the authorization or consent of the Government.

7. The Commission may modify this Order in accordance with the procedures described in Rule 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

8. The Secretary shall serve copies of this Order upon each party of record in this investigation that has retained counsel or otherwise provided a point of contact for electronic service and upon CBP. While temporary remote operating procedures are in place in response to COVID-19, the Office of the Secretary is not able to serve parties that have not retained counsel or otherwise provided a point of contact for electronic service. Accordingly, pursuant to Commission Rules 201.16(a) and 210.7(a)(1) (19 CFR §§ 201.16(a), 210.7(a)(1)), the Commission orders that the Complainant complete service of this Order for any party without a method of electronic service noted on the attached Certificate of Service and shall file proof of service on the Electronic Document Information System (EDIS).

9. Notice of this Order shall be published in the Federal Register.

By order of the Commission.



Katherine M. Hiner
Acting Secretary to the Commission

Issued: September 12, 2022

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN PLANT-DERIVED RECOMBINANT HUMAN SERUM ALBUMINS ("rHSA") AND PRODUCTS CONTAINING SAME**	**Investigation No. 337-TA-1238**

CEASE AND DESIST ORDER

IT IS HEREBY ORDERED THAT RESPONDENT Aspira Scientific, Inc. of Milpitas, California cease and desist from 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 of certain plant-derived recombinant human serum albumins ("rHSA") and products containing the same (as defined in Definition (G) below), in violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), (1) that infringe one or more of claims 1 and 11–13 of U.S. Patent No. 10,618,951 ("Asserted Patent"); or (2) that bear a false designation of origin.

I.
Definitions

As used in this order:

(A) "Commission" shall mean the United States International Trade Commission.

(B) "Complainant" shall mean Ventria Bioscience Inc. of Junction City, Kansas.

(C) "Respondent" shall mean Aspira Scientific, Inc. of Milpitas, California.

(D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than Respondent or its majority-owned or controlled subsidiaries, successors, or assigns.

(E) "United States" shall mean the fifty States, the District of Columbia, and Puerto Rico.

(F) The terms "import" and "importation" refer to importation for entry for consumption under the Customs laws of the United States.

(G) The term "covered products" shall mean certain plant-derived recombinant human serum albumins ("rHSA") and products containing the same that infringe one or more of claims 1 and 11–13 of U.S. Patent No. 10,618,951 (or, "Asserted Patent") and/or certain plant-derived recombinant human serum albumins ("rHSA") and products containing the same that fail to designate the country of origin. The plant-derived recombinant human serum albumins and products containing the same subject to this order are as follows: plant-derived recombinant human serum albumins ("rHSA") and products containing the same, such as lyophilized powders and liquid suspensions primarily containing rHSA along with naturally-occurring plant expression by-products, such as plant heat shock proteins and/or plant fatty acids, as well as cell culture media supplements formulated with such rHSA products. Products that could be considered "covered products" solely on the basis of infringing the Asserted Patent shall not be considered "covered products" where a provision of law or license avoids liability for infringement.

II.
Applicability

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by section III, *infra*, for, with, or otherwise on behalf of, Respondent.

III.
Conduct Prohibited

The following conduct of Respondent in the United States is prohibited by this Order.

1. For the remaining term of the Asserted Patent, and for so long as Respondent fails to properly designate the country of origin of covered products, Respondent shall not:

(A) import or sell for importation into the United States covered products;

(B) market, distribute, sell, offer to sell, or otherwise transfer (except for exportation) in the United States imported covered products;

(C) advertise imported covered products;

(D) solicit U.S. agents or distributors for imported covered products; or

(E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of covered products.

2. Respondent will not in the United States represent, or aid or encourage other persons to represent, explicitly or by implication, orally or in sales, advertising or promotional material for covered products, that such covered products were manufactured in a country other than the country where such covered products were originally manufactured.

IV.
Conduct Permitted

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this Order shall be permitted if:

(A) in a written instrument, the owner of the Asserted Patents licenses or authorizes such specific conduct; or

(B) such specific conduct is related to the importation or sale of covered products by or for the United States; or

(C) with respect to the importation or sale of covered products that is prohibited only because they failed to designate the country of origin, such products include a printed label meeting the following requirements:

(1) the label, to the extent reasonably possible, shall be designed, made, and attached in a manner to inhibit any person except the ultimate purchaser in the United States from destroying, removing, altering, covering, or obliterating the label or its contents; and

(2) the label shall state legibly, permanently, and conspicuously, the English language name of the country of origin.

V.
Reporting

For purposes of this requirement, the reporting periods shall commence on January 1 of each year and shall end on the subsequent December 31. The first report required under this section shall cover the period from the date of issuance of this order through December 31, 2022. This reporting requirement shall continue in force until such time as Respondent has truthfully

reported, in two consecutive timely filed reports, that it has no inventory (whether held in warehouses or at customer sites) of covered products in the United States.

Within thirty (30) days of the last day of the reporting period, Respondent shall report to the Commission: (a) the quantity in units and the value in dollars of covered products that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and (b) the quantity in units and value in dollars of reported covered products that remain in inventory in the United States at the end of the reporting period.

When filing written submissions, Respondent must file the original document electronically on or before the deadlines stated above. Submissions should refer to the investigation number ("Inv. No. 337-TA-1238") in a prominent place on the cover pages and/or the first page. *See* Handbook for Electronic Filing Procedures, http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf. Persons with questions regarding filing should contact the Secretary (202-205-2000). If Respondent desires to submit a document to the Commission in confidence, it must file the original and a public version of the original with the Office of the Secretary and must serve a copy of the confidential version on Complainant's counsel.[1]

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

[1] Complainant must file a letter with the Secretary identifying the attorney to receive reports and bond information associated with this Order. The designated attorney must be on the protective order entered in the investigation.

VI.
Record-Keeping and Inspection

(A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, marketing, or distribution in the United States of covered products, made and received in the usual and ordinary course of business, whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.

(B) For the purposes of determining or securing compliance with this Order and for no other purpose, subject to any privilege recognized by the federal courts of the United States, and upon reasonable written notice by the Commission or its staff, duly authorized representatives of the Commission shall be permitted access and the right to inspect and copy, in Respondent's principal offices during office hours, and in the presence of counsel or other representatives if Respondent so chooses, all books, ledgers, accounts, correspondence, memoranda, and other records and documents, in detail and in summary form, that must be retained under subparagraph VI(A) of this Order.

VII.
Service of Cease and Desist Order

The Secretary shall serve copies of this Order upon each party of record in this investigation that has retained counsel or otherwise provided a point of contact for electronic service and upon CBP. While temporary remote operating procedures are in place in response to COVID-19, the Office of the Secretary is not able to serve parties that have not retained counsel or otherwise provided a point of contact for electronic service. Accordingly, pursuant to Commission Rules 201.16(a) and 210.7(a)(1) (19 CFR 201.16(a), 210.7(a)(1)), the Commission

orders that the Complainant complete service of this Order for any party without a method of electronic service noted on the attached Certificate of Service and shall file proof of service on the Electronic Document Information System (EDIS).

Respondent is ordered and directed to:

(A) Serve, within fifteen (15) days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, transfer, or sale of imported covered products in the United States;

(B) Serve, within fifteen (15) days after the succession of any persons referred to in subparagraph VII(A) of this order, a copy of the Order upon each successor; and

(C) Maintain such records as will show the name, title, and address of each person upon whom the Order has been served, as described in subparagraphs VII(A) and VII(B) of this order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the expiration of the Asserted Patents.

VIII.
Confidentiality

Any request for confidential treatment of information obtained by the Commission pursuant to section VI of this order should be made in accordance with section 201.6 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 201.6). For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

IX.
Enforcement

Violation of this order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.75), including an action for civil penalties under section 337(f) of the Tariff Act of 1930 (19 U.S.C. § 1337(f)), as well as any other action that the Commission deems appropriate. In determining whether Respondent is in violation of this order, the Commission may infer facts adverse to Respondent if it fails to provide adequate or timely information.

X.
Modification

The Commission may amend this order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

XI.
Bonding

The conduct prohibited by section III of this order may be continued during the sixty (60) day period in which this Order is under review by the United States Trade Representative, as delegated by the President (70 Fed. Reg. 43,251 (Jul. 21, 2005)), subject to Respondent's posting of a bond in the amount of one hundred percent (100%) of their entered value. This bond provision does not apply to conduct that is otherwise permitted by section IV of this Order. Covered products imported on or after the date of issuance of this Order are subject to the entry bond as set forth in the exclusion order issued by the Commission, and are not subject to this bond provision.

The bond is to be posted in accordance with the procedures established by the Commission for the posting of bonds by complainants in connection with the issuance of

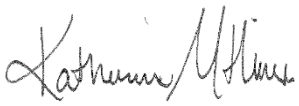
temporary exclusion orders. (*See* 19 C.F.R. § 210.68.) The bond and any accompanying documentation are to be provided to and approved by the Commission prior to the commencement of conduct that is otherwise prohibited by section III of this Order. Upon the Secretary's acceptance of the bond, (a) the Secretary will serve an acceptance letter on all parties, and (b) Respondent must serve a copy of the bond and accompanying documentation on Complainant's counsel.[2]

The bond is to be forfeited in the event that the United States Trade Representative approves this Order (or does not disapprove it within the review period), unless (i) the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and order as to Respondent on appeal, or (ii) Respondent exports or destroys the products subject to this bond and provides certification to that effect that is satisfactory to the Commission.

This bond is to be released in the event (i) the United States Trade Representative disapproves this Order and no subsequent order is issued by the Commission and approved (or not disapproved) by the United States Trade Representative, (ii) the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and order as to Respondent on appeal, or (iii) Respondent exports or destroys the products subject to this bond and provides certification to that effect that is satisfactory to the Commission, upon service on Respondent of an order issued by the Commission based upon application therefor made by Respondent to the Commission.

[2] *See* Footnote 1.

By order of the Commission.



Katherine M. Hiner
Acting Secretary to the Commission

Issued: September 12, 2022

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN PLANT-DERIVED RECOMBINANT HUMAN SERUM ALBUMINS ("rHSA") AND PRODUCTS CONTAINING SAME**	**Investigation No. 337-TA-1238**

CEASE AND DESIST ORDER

IT IS HEREBY ORDERED THAT RESPONDENT eEnzyme LLC of Gaithersburg, Maryland cease and desist from 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 of certain plant-derived recombinant human serum albumins ("rHSA") and products containing the same (as defined in Definition (G) below), in violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), (1) that infringe one or more of claims 1 and 11–13 of U.S. Patent No. 10,618,951 ("Asserted Patent"); or (2) that bear a false designation of origin.

I.
Definitions

As used in this order:

(A) "Commission" shall mean the United States International Trade Commission.

(B) "Complainant" shall mean Ventria Bioscience Inc. of Junction City, Kansas.

(C) "Respondent" shall mean eEnzyme LLC of Gaithersburg, Maryland.

(D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than Respondent or its majority-owned or controlled subsidiaries, successors, or assigns.

(E) "United States" shall mean the fifty States, the District of Columbia, and Puerto Rico.

(F) The terms "import" and "importation" refer to importation for entry for consumption under the Customs laws of the United States.

(G) The term "covered products" shall mean certain plant-derived recombinant human serum albumins ("rHSA") and products containing the same that infringe one or more of claims 1 and 11–13 of U.S. Patent No. 10,618,951 (or, "Asserted Patent") and/or certain plant-derived recombinant human serum albumins ("rHSA") and products containing the same that fail to designate the country of origin. The plant-derived recombinant human serum albumins and products containing the same subject to this order are as follows: plant-derived recombinant human serum albumins ("rHSA") and products containing the same, such as lyophilized powders and liquid suspensions primarily containing rHSA along with naturally-occurring plant expression by-products, such as plant heat shock proteins and/or plant fatty acids, as well as cell culture media supplements formulated with such rHSA products. Products that could be considered "covered products" solely on the basis of infringing the Asserted Patent shall not be considered "covered products" where a provision of law or license avoids liability for infringement.

II.
Applicability

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by section III, *infra*, for, with, or otherwise on behalf of, Respondent.

III.
Conduct Prohibited

The following conduct of Respondent in the United States is prohibited by this Order.

1. For the remaining term of the Asserted Patent, and for so long as Respondent fails to properly designate the country of origin of covered products, Respondent shall not:

(A) import or sell for importation into the United States covered products;

(B) market, distribute, sell, offer to sell, or otherwise transfer (except for exportation) in the United States imported covered products;

(C) advertise imported covered products;

(D) solicit U.S. agents or distributors for imported covered products; or

(E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of covered products.

2. Respondent will not in the United States represent, or aid or encourage other persons to represent, explicitly or by implication, orally or in sales, advertising or promotional material for covered products, that such covered products were manufactured in a country other than the country where such covered products were originally manufactured.

IV.
Conduct Permitted

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this Order shall be permitted if:

(A) in a written instrument, the owner of the Asserted Patents licenses or authorizes such specific conduct; or

(B) such specific conduct is related to the importation or sale of covered products by or for the United States; or

(C) with respect to the importation or sale of covered products that is prohibited only because they failed to designate the country of origin, such products include a printed label meeting the following requirements:

(1) the label, to the extent reasonably possible, shall be designed, made, and attached in a manner to inhibit any person except the ultimate purchaser in the United States from destroying, removing, altering, covering, or obliterating the label or its contents; and

(2) the label shall state legibly, permanently, and conspicuously, the English language name of the country of origin.

V.
Reporting

For purposes of this requirement, the reporting periods shall commence on January 1 of each year and shall end on the subsequent December 31. The first report required under this section shall cover the period from the date of issuance of this order through December 31, 2022. This reporting requirement shall continue in force until such time as Respondent has truthfully

reported, in two consecutive timely filed reports, that it has no inventory (whether held in warehouses or at customer sites) of covered products in the United States.

Within thirty (30) days of the last day of the reporting period, Respondent shall report to the Commission: (a) the quantity in units and the value in dollars of covered products that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and (b) the quantity in units and value in dollars of reported covered products that remain in inventory in the United States at the end of the reporting period.

When filing written submissions, Respondent must file the original document electronically on or before the deadlines stated above. Submissions should refer to the investigation number ("Inv. No. 337-TA-1238") in a prominent place on the cover pages and/or the first page. *See* Handbook for Electronic Filing Procedures, http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf. Persons with questions regarding filing should contact the Secretary (202-205-2000). If Respondent desires to submit a document to the Commission in confidence, it must file the original and a public version of the original with the Office of the Secretary and must serve a copy of the confidential version on Complainant's counsel.[1]

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

[1] Complainant must file a letter with the Secretary identifying the attorney to receive reports and bond information associated with this Order. The designated attorney must be on the protective order entered in the investigation.

VI.
Record-Keeping and Inspection

(A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, marketing, or distribution in the United States of covered products, made and received in the usual and ordinary course of business, whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.

(B) For the purposes of determining or securing compliance with this Order and for no other purpose, subject to any privilege recognized by the federal courts of the United States, and upon reasonable written notice by the Commission or its staff, duly authorized representatives of the Commission shall be permitted access and the right to inspect and copy, in Respondent's principal offices during office hours, and in the presence of counsel or other representatives if Respondent so chooses, all books, ledgers, accounts, correspondence, memoranda, and other records and documents, in detail and in summary form, that must be retained under subparagraph VI(A) of this Order.

VII.
Service of Cease and Desist Order

The Secretary shall serve copies of this Order upon each party of record in this investigation that has retained counsel or otherwise provided a point of contact for electronic service and upon CBP. While temporary remote operating procedures are in place in response to COVID-19, the Office of the Secretary is not able to serve parties that have not retained counsel or otherwise provided a point of contact for electronic service. Accordingly, pursuant to Commission Rules 201.16(a) and 210.7(a)(1) (19 CFR 201.16(a), 210.7(a)(1)), the Commission

orders that the Complainant complete service of this Order for any party without a method of electronic service noted on the attached Certificate of Service and shall file proof of service on the Electronic Document Information System (EDIS).

Respondent is ordered and directed to:

(A) Serve, within fifteen (15) days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, transfer, or sale of imported covered products in the United States;

(B) Serve, within fifteen (15) days after the succession of any persons referred to in subparagraph VII(A) of this order, a copy of the Order upon each successor; and

(C) Maintain such records as will show the name, title, and address of each person upon whom the Order has been served, as described in subparagraphs VII(A) and VII(B) of this order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the expiration of the Asserted Patents.

VIII.
Confidentiality

Any request for confidential treatment of information obtained by the Commission pursuant to section VI of this order should be made in accordance with section 201.6 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 201.6). For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

IX.
Enforcement

Violation of this order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.75), including an action for civil penalties under section 337(f) of the Tariff Act of 1930 (19 U.S.C. § 1337(f)), as well as any other action that the Commission deems appropriate. In determining whether Respondent is in violation of this order, the Commission may infer facts adverse to Respondent if it fails to provide adequate or timely information.

X.
Modification

The Commission may amend this order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

XI.
Bonding

The conduct prohibited by section III of this order may be continued during the sixty (60) day period in which this Order is under review by the United States Trade Representative, as delegated by the President (70 Fed. Reg. 43,251 (Jul. 21, 2005)), subject to Respondent's posting of a bond in the amount of one hundred percent (100%) of their entered value. This bond provision does not apply to conduct that is otherwise permitted by section IV of this Order. Covered products imported on or after the date of issuance of this Order are subject to the entry bond as set forth in the exclusion order issued by the Commission, and are not subject to this bond provision.

The bond is to be posted in accordance with the procedures established by the Commission for the posting of bonds by complainants in connection with the issuance of

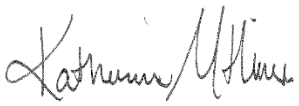
temporary exclusion orders. (*See* 19 C.F.R. § 210.68.) The bond and any accompanying documentation are to be provided to and approved by the Commission prior to the commencement of conduct that is otherwise prohibited by section III of this Order. Upon the Secretary's acceptance of the bond, (a) the Secretary will serve an acceptance letter on all parties, and (b) Respondent must serve a copy of the bond and accompanying documentation on Complainant's counsel.[2]

The bond is to be forfeited in the event that the United States Trade Representative approves this Order (or does not disapprove it within the review period), unless (i) the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and order as to Respondent on appeal, or (ii) Respondent exports or destroys the products subject to this bond and provides certification to that effect that is satisfactory to the Commission.

This bond is to be released in the event (i) the United States Trade Representative disapproves this Order and no subsequent order is issued by the Commission and approved (or not disapproved) by the United States Trade Representative, (ii) the U.S. Court of Appeals for the Federal Circuit, in a final judgment, reverses any Commission final determination and order as to Respondent on appeal, or (iii) Respondent exports or destroys the products subject to this bond and provides certification to that effect that is satisfactory to the Commission, upon service on Respondent of an order issued by the Commission based upon application therefor made by Respondent to the Commission.

[2] *See* Footnote 1.

By order of the Commission.



Katherine M. Hiner
Acting Secretary to the Commission

Issued: September 12, 2022

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **CERTAIN PLANT-DERIVED RECOMBINANT HUMAN SERUM ALBUMINS ("rHSA") AND PRODUCTS CONTAINING SAME**	**Investigation No. 337-TA-1238**

CEASE AND DESIST ORDER

IT IS HEREBY ORDERED THAT RESPONDENT ScienCell Research Laboratories, Inc. of Carlsbad, California cease and desist from 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 of certain plant-derived recombinant human serum albumins ("rHSA") and products containing the same (as defined in Definition (G) below), in violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), (1) that infringe one or more of claims 1 and 11–13 of U.S. Patent No. 10,618,951 ("Asserted Patent"); or (2) that bear a false designation of origin.

I.
Definitions

As used in this order:

(A) "Commission" shall mean the United States International Trade Commission.

(B) "Complainant" shall mean Ventria Bioscience Inc. of Junction City, Kansas.

(C) "Respondent" shall mean ScienCell Research Laboratories, Inc. of Carlsbad, California.

(D) "Person" shall mean an individual, or any non-governmental partnership, firm, association, corporation, or other legal or business entity other than Respondent or its majority-owned or controlled subsidiaries, successors, or assigns.

(E) "United States" shall mean the fifty States, the District of Columbia, and Puerto Rico.

(F) The terms "import" and "importation" refer to importation for entry for consumption under the Customs laws of the United States.

(G) The term "covered products" shall mean certain plant-derived recombinant human serum albumins ("rHSA") and products containing the same that infringe one or more of claims 1 and 11–13 of U.S. Patent No. 10,618,951 (or, "Asserted Patent") and/or certain plant-derived recombinant human serum albumins ("rHSA") and products containing the same that fail to designate the country of origin. The plant-derived recombinant human serum albumins and products containing the same subject to this order are as follows: plant-derived recombinant human serum albumins ("rHSA") and products containing the same, such as lyophilized powders and liquid suspensions primarily containing rHSA along with naturally-occurring plant expression by-products, such as plant heat shock proteins and/or plant fatty acids, as well as cell culture media supplements formulated with such rHSA products. Products that could be considered "covered products" solely on the basis of infringing the Asserted Patent shall not be considered "covered products" where a provision of law or license avoids liability for infringement.

II.
Applicability

The provisions of this Cease and Desist Order shall apply to Respondent and to any of its principals, stockholders, officers, directors, employees, agents, distributors, controlled (whether by stock ownership or otherwise) and majority-owned business entities, successors, and assigns, and to each of them, insofar as they are engaging in conduct prohibited by section III, *infra*, for, with, or otherwise on behalf of, Respondent.

III.
Conduct Prohibited

The following conduct of Respondent in the United States is prohibited by this Order.

1. For the remaining term of the Asserted Patent, and for so long as Respondent fails to properly designate the country of origin of covered products, Respondent shall not:

(A) import or sell for importation into the United States covered products;

(B) market, distribute, sell, offer to sell, or otherwise transfer (except for exportation) in the United States imported covered products;

(C) advertise imported covered products;

(D) solicit U.S. agents or distributors for imported covered products; or

(E) aid or abet other entities in the importation, sale for importation, sale after importation, transfer (except for exportation), or distribution of covered products.

2. Respondent will not in the United States represent, or aid or encourage other persons to represent, explicitly or by implication, orally or in sales, advertising or promotional material for covered products, that such covered products were manufactured in a country other than the country where such covered products were originally manufactured.

IV.
Conduct Permitted

Notwithstanding any other provision of this Order, specific conduct otherwise prohibited by the terms of this Order shall be permitted if:

(A) in a written instrument, the owner of the Asserted Patents licenses or authorizes such specific conduct; or

(B) such specific conduct is related to the importation or sale of covered products by or for the United States; or

(C) with respect to the importation or sale of covered products that is prohibited only because they failed to designate the country of origin, such products include a printed label meeting the following requirements:

(1) the label, to the extent reasonably possible, shall be designed, made, and attached in a manner to inhibit any person except the ultimate purchaser in the United States from destroying, removing, altering, covering, or obliterating the label or its contents; and

(2) the label shall state legibly, permanently, and conspicuously, the English language name of the country of origin.

V.
Reporting

For purposes of this requirement, the reporting periods shall commence on January 1 of each year and shall end on the subsequent December 31. The first report required under this section shall cover the period from the date of issuance of this order through December 31, 2022. This reporting requirement shall continue in force until such time as Respondent has truthfully

reported, in two consecutive timely filed reports, that it has no inventory (whether held in warehouses or at customer sites) of covered products in the United States.

Within thirty (30) days of the last day of the reporting period, Respondent shall report to the Commission: (a) the quantity in units and the value in dollars of covered products that it has (i) imported and/or (ii) sold in the United States after importation during the reporting period, and (b) the quantity in units and value in dollars of reported covered products that remain in inventory in the United States at the end of the reporting period.

When filing written submissions, Respondent must file the original document electronically on or before the deadlines stated above. Submissions should refer to the investigation number ("Inv. No. 337-TA-1238") in a prominent place on the cover pages and/or the first page. *See* Handbook for Electronic Filing Procedures, http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf. Persons with questions regarding filing should contact the Secretary (202-205-2000). If Respondent desires to submit a document to the Commission in confidence, it must file the original and a public version of the original with the Office of the Secretary and must serve a copy of the confidential version on Complainant's counsel.[1]

Any failure to make the required report or the filing of any false or inaccurate report shall constitute a violation of this Order, and the submission of a false or inaccurate report may be referred to the U.S. Department of Justice as a possible criminal violation of 18 U.S.C. § 1001.

[1] Complainant must file a letter with the Secretary identifying the attorney to receive reports and bond information associated with this Order. The designated attorney must be on the protective order entered in the investigation.

VI.
Record-Keeping and Inspection

(A) For the purpose of securing compliance with this Order, Respondent shall retain any and all records relating to the sale, marketing, or distribution in the United States of covered products, made and received in the usual and ordinary course of business, whether in detail or in summary form, for a period of three (3) years from the close of the fiscal year to which they pertain.

(B) For the purposes of determining or securing compliance with this Order and for no other purpose, subject to any privilege recognized by the federal courts of the United States, and upon reasonable written notice by the Commission or its staff, duly authorized representatives of the Commission shall be permitted access and the right to inspect and copy, in Respondent's principal offices during office hours, and in the presence of counsel or other representatives if Respondent so chooses, all books, ledgers, accounts, correspondence, memoranda, and other records and documents, in detail and in summary form, that must be retained under subparagraph VI(A) of this Order.

VII.
Service of Cease and Desist Order

The Secretary shall serve copies of this Order upon each party of record in this investigation that has retained counsel or otherwise provided a point of contact for electronic service and upon CBP. While temporary remote operating procedures are in place in response to COVID-19, the Office of the Secretary is not able to serve parties that have not retained counsel or otherwise provided a point of contact for electronic service. Accordingly, pursuant to Commission Rules 201.16(a) and 210.7(a)(1) (19 CFR 201.16(a), 210.7(a)(1)), the Commission

orders that the Complainant complete service of this Order for any party without a method of electronic service noted on the attached Certificate of Service and shall file proof of service on the Electronic Document Information System (EDIS).

Respondent is ordered and directed to:

(A) Serve, within fifteen (15) days after the effective date of this Order, a copy of this Order upon each of its respective officers, directors, managing agents, agents, and employees who have any responsibility for the importation, marketing, distribution, transfer, or sale of imported covered products in the United States;

(B) Serve, within fifteen (15) days after the succession of any persons referred to in subparagraph VII(A) of this order, a copy of the Order upon each successor; and

(C) Maintain such records as will show the name, title, and address of each person upon whom the Order has been served, as described in subparagraphs VII(A) and VII(B) of this order, together with the date on which service was made.

The obligations set forth in subparagraphs VII(B) and VII(C) shall remain in effect until the expiration of the Asserted Patents.

VIII.
Confidentiality

Any request for confidential treatment of information obtained by the Commission pursuant to section VI of this order should be made in accordance with section 201.6 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 201.6). For all reports for which confidential treatment is sought, Respondent must provide a public version of such report with confidential information redacted.

IX.
Enforcement

Violation of this order may result in any of the actions specified in section 210.75 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.75), including an action for civil penalties under section 337(f) of the Tariff Act of 1930 (19 U.S.C. § 1337(f)), as well as any other action that the Commission deems appropriate. In determining whether Respondent is in violation of this order, the Commission may infer facts adverse to Respondent if it fails to provide adequate or timely information.

X.
Modification

The Commission may amend this order on its own motion or in accordance with the procedure described in section 210.76 of the Commission's Rules of Practice and Procedure (19 C.F.R. § 210.76).

XI.
Bonding

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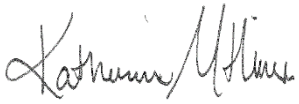

Katherine M. Hiner
Acting Secretary to the Commission

Issued: September 12, 2022