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**

NOTICE OF COMMISSION DETERMINATION TO REVIEW THE FINAL INITIAL DETERMINATION IN ITS ENTIRETY; SCHEDULE FOR FILING WRITTEN SUBMISSIONS

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review the final initial determination ("final ID") issued by the presiding administrative law judge ("ALJ") on April 7, 2022, in its entirety. The Commission requests briefing from the parties on certain issues under review, as indicated in this notice. The Commission also requests briefing from the parties, interested government agencies, and interested persons on the issues of remedy, the public interest, and bonding.

FOR FURTHER INFORMATION CONTACT: Ronald A. Traud, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-3427. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at https://edis.usitc.gov. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its Internet server at *https://www.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on January 25, 2021, based on a complaint filed on behalf of Ventria Bioscience Inc. ("Ventria") of Junction City, Kansas. 86 FR 6916 (Jan. 25, 2021). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain plant-derived rHSA and products containing same by reason of infringement of certain claims of U.S. Patent Nos. 10,618,951 ("the '951 patent") and 8,609,416 ("the '416 patent"). *Id.* The complaint also alleged violations of section 337 based on the

importation into the United States, or in the sale of, certain plant-derived rHSA and products containing same by reason of false designation of origin, the threat or effect of which is to destroy or substantially injure an industry in the United States. *Id.* The notice of investigation named four respondents: Wuhan Healthgen Biotechnology Corp. of Wuhan, China ("Healthgen"); ScienCell Research Laboratories, Inc. of Carlsbad, California ("ScienCell"); Aspira Scientific, Inc. of Milpitas, California ("Aspira"); and eEnzyme LLC of Gaithersburg, Maryland ("eEnzyme") (collectively, the "Respondents"). *Id*. at 6917. The Office of Unfair Import Investigations ("OUII") was also named as a party in this investigation. *Id.*

Of the four Respondents named in the notice of investigation, only Healthgen participated in the investigation. ScienCell, Aspira, and eEnzyme were found in default. *See* Order No. 13 (July 28, 2021), *unreviewed by* Comm'n Notice (Aug. 18, 2021). ScienCell, Aspira, and eEnzyme are collectively referred to herein as the "Defaulting Respondents."

Prior to the issuance of the final ID, the investigation terminated as to all asserted claims of the '416 patent, claims 2 and 3 of the '951 patent, and the false designation of origin claims against Healthgen. *See* Order No. 12 (July 16, 2021), *unreviewed by* Comm'n Notice (Aug. 10, 2021); Order No. 29 (Nov. 3, 2021), *unreviewed by* Comm'n Notice (Nov. 29, 2021). The false designation of origin claims against the Defaulting Respondents were not terminated. *See* Order No. 12 at 1. Accordingly, at the time the final ID issued, only claims 1 and 11–13 of the '951 patent remained pending against Healthgen, and only claims 1 and 11–13 of the '951 patent and the false designation of origin (or Lanham Act) claims remained pending against the Defaulting Respondents.

On April 7, 2022, the ALJ issued the final ID, which found that Respondents violated section 337. The ALJ found a violation of section 337 by Healthgen and the Defaulting Respondents as to infringement of the '951 patent and found the requirements of section 337(g)(1) met as to the Lanham Act claim with respect to the Defaulting Respondents.

The final ID included the ALJ's recommendation on remedy, the public interest, and bonding (the "RD"). The RD recommended that, if the Commission finds a violation of section 337, the Commission should issue a limited exclusion order against Healthgen and the Defaulting Respondents, cease and desist orders against the Defaulting Respondents, and impose a 100% bond during the period of Presidential review.

On April 19, 2022, Healthgen filed a petition for review of the final ID. On April 22, 2022, OUII filed a response to Healthgen's petition, and on April 27, 2022, Ventria filed a response to Healthgen's petition.

On May 9, 2022, Ventria and Healthgen filed their public interest comments pursuant to Commission Rule 210.50(a)(4) (19 CFR 210.50(a)(4)). The Commission also received several submissions from third parties in response to the Commission's *Federal Register* notice seeking comment on the public interest. 87 FR 21923–24 (Apr. 13, 2022).

Having examined the record in this investigation, including the final ID, the petition for review, and the responses thereto, the Commission has determined to review the final ID in its entirety.

The parties are requested to brief their positions with reference to the applicable law and the evidentiary record regarding the questions provided below:

(1) Given the construction of aggregated albumin ("non-monomeric albumin (*e.g.*, albumin dimers)"), what distinguishes "non-monomeric albumin" from "monomeric albumin"? How can this distinction be determined from testing data, such as by electrophoresis or chromatographic testing data?

(2) Given the construction of aggregated albumin ("non-monomeric albumin (*e.g.*, albumin dimers)"), the applicable burdens of proof, and any other relevant considerations, which of the following should be considered within the scope of "aggregated albumin":

(a) fragments of native mammalian albumin;

(b) the combination of i) one or more recombinant albumins (*i.e.*, albumins heterologous or foreign to the transgenic plant producing it) which has the amino acid sequence of a native mammalian albumin or which is a variant, derivative, or fusion protein, and ii) one or more fragments of native mammalian albumin;

(c) the combination of two or more fragments of native mammalian albumin;

(d) any substance identified via electrophoresis or chromatographic techniques with a molecular weight greater than the molecular weight corresponding to the "main band" that is not a discrete, integer multiple of the molecular weight corresponding to that "main band;"

(e) non-covalently linked aggregated albumin; and

(f) "low molecular weight impurities," such as those included in the May 2021 reducing SDS-PAGE test results from SGS Life Science Services (JX-0129.0006–7).

(3) Given the '951 patent specification's identification of "aggregates at around 250 KDa" (*see* col. 72, ll. 51–54), explain:

(a) whether the molecular weight(s) of those "aggregates at around 250 KDa" are or are not discrete, integer multiple(s) of the molecular weight(s) of the main band(s) (*see* Figs. 9A and/or 9B); and

(b) whether the answer to subpart (a) above affects the result of any responses to (2)(a)–(f)?

(4) Does the parties' agreement that dimers are the simplest form of an aggregated albumin preclude any of the species in (2)(a)–(f) from contributing towards "aggregated albumin"?

(5) Does the resolution of whether any of (2)(a)–(f) are within the scope of "aggregated albumin" (or what constitutes "non-monomeric albumin") require further claim construction, or are these determinations purely factual? If further claim construction is required, should the Commission remand the investigation to the ALJ?

(6) If species identified in (2)(d) that are detected via an electrophoresis or chromatographic technique are within the scope "aggregated albumin," could an assay that does not use molecular weight markers or standards be able to determine whether or not a sample has "less than 2% aggregated albumin"?

(7) How can the Commission determine whether species detected via an electrophoresis, chromatographic, or other technique retain the biological or therapeutically beneficial activity of native mammalian albumin? If the Commission is unable to determine whether such a species retains that activity, how should that inability factor into determining whether a product satisfies the "less than 2% aggregated albumin" claim limitation, considering, for example, the burdens of proof?

(8) In instances where species detected in electrophoresis or chromatographic techniques are determined not to be within the scope of "aggregated albumin," how is the percentage of "aggregated albumin" calculated? Is the percentage of "aggregated albumin" calculated by dividing the sum total of "band volume" (or equivalent) of species within the scope of aggregated albumin by the sum total of the band volume of both "aggregated" and non-"aggregated" albumin?

(9) How should the Commission address the situation where the accused products or domestic industry products are found to satisfy the "less than 2% aggregated albumin" claim limitation under one testing methodology, but not under another?

(10) Assuming the reducing agents used in reducing SDS-PAGE convert aggregated albumin into "monomeric albumin," does the evidence show the extent that reducing agents do so? Please specify whether the evidence of conversion, if any, depends on the form of the product (for example, lyophilized/freeze dried powder versus liquid products).

(11) If Optibumin is found to be the only asserted product to satisfy the technical prong of the domestic industry requirement for the '951 patent and the scope of the products that can be considered in the economic prong analysis include only Optibumin, discuss whether (and why or why not) Complainant Ventria's investments and expenditures in the alleged domestic industry are significant and/or substantial within the meaning of 19 U.S.C. 1337(a)(3)(A), (B), and/or (C) with citations to record evidence.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia*, (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or are likely to do so. For background, *see Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843, Comm'n Op. at 7–10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on: (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

Please address the following questions relevant to the public interest considerations in this investigation, including evidence in support:

1) Please identify Healthgen's customers of the accused products and state the uses for

which these customers are using its products. Are Ventria's products substitutes for these products and uses?

2) Is there any vaccine or therapeutics research currently using Healthgen's accused products? If so, please describe.

3) For any current uses of the accused products, can Ventria's products be used as substitutes?

4) Can Ventria adequately supply U.S. demand for rHSA products?

5) Are there uses for which a pHSA product cannot substitute for a plant-based rHSA product? To what extent should pHSA products be considered when examining the question of available substitutes for the accused products?

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

WRITTEN SUBMISSIONS: The parties to the investigation are requested to file written submissions on the questions identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such initial written submissions should include views on the RD that issued on April 7, 2022.

Initial written submissions, limited to 80 pages, must be filed no later than the close of business on June 20, 2022. Complainants are requested to identify the form of the remedy sought and to submit proposed remedial orders for the Commission's consideration. Complainants are also requested to state the HTSUS subheadings under which the accused articles are imported, and to supply identification information for all known importers of the accused products. Reply submissions, limited to 50 pages, must be filed no later than the close of business on June 27, 2022. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (Mar. 19, 2020). Submissions should refer to the investigation number ("Inv. No. 337-TA-1238") in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary at (202) 205-2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on June 6, 2022.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR Part 210).

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(s) complete service for any party/parties without a method of electronic service noted on the attached Certificate of Service and shall file proof of service on the Electronic Document Information System (EDIS).

By order of the Commission.

Lisa R. Barton
Secretary to the Commission

Issued: June 6, 2022