CHAIRMAN

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C. 20436

September 12, 2022

The Honorable Katherine Tai
United States Trade Representative
Washington, D.C. 20508

Dear Ambassador Tai:

In accordance with subsection (j) of Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337) ("Section 337"), and the July 21, 2005, Memorandum for the United States Trade Representative (70 Fed. Reg. 43251), I am transmitting to you and the President copies of the Commission's limited exclusion order and cease and desist orders, as described below, and the record upon which the Commission based its determination.

On September 12, 2022, the United States International Trade Commission issued a limited exclusion order and three cease and desist orders pursuant to Section 337 in USITC Investigation No. 337-TA-1238, *Certain Plant-Derived Recombinant Serum Albumins ("rHSA") and Products Containing Same*. The limited exclusion order prohibits 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") from importing into the United States certain plant-derived recombinant serum albumins and products containing the same that infringe one or more of 1 and 11–13 of United States Patent No. 10,618,951. The limited exclusion order also prohibits respondents ScienCell, Aspira, and eEnzyme from importing into the United States certain plant-derived recombinant serum albumins and products containing the same that include a false designation of origin. The cease and desist orders prohibit respondents ScienCell, Aspira, and eEnzyme from further importing, selling, and distributing the covered products and products that include a false designation of origin in the United States.

The Commission concluded that the statutory public interest factors in subsections (d)(1); (f)(1); and (g)(1) of Section 337 do not preclude the issuance of this remedy. The Commission also determined that, during the period of Presidential review, the covered products described

above may be imported and sold in the United States with the posting of a bond in the amount of one hundred percent (100%) of their entered value.

Sincerely,

David S. Johanson
Chairman

Enclosures

cc: Shannon M. Nestor, Esq.
Office of the General Counsel
Office of the United States Trade Representative

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 THE COMMISSION'S FINAL DETERMINATION FINDING A VIOLATION OF SECTION 337; ISSUANCE OF A LIMITED EXCLUSION ORDER AND CEASE AND DESIST ORDERS; TERMINATION OF THE INVESTIGATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has found a violation of section 337 in the above-captioned investigation. The Commission has determined to issue: (1) a limited exclusion order ("LEO") prohibiting the unlicensed entry of infringing plant-derived recombinant human serum albumins ("rHSA") and products containing the same covered by certain claims of U.S. Patent No. 10,618,951 that are manufactured by or on behalf of, or imported by or on behalf of, respondents Wuhan Healthgen Biotechnology Corp. ("Healthgen"); ScienCell Research Laboratories, Inc. ("ScienCell"); Aspira Scientific, Inc. ("Aspira"); and eEnzyme LLC ("eEnzyme") or any of their affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns; and the entry of plant-derived rHSAs and products containing the same that include a false designation of origin that are manufactured by or on behalf of, or imported by or on behalf of, ScienCell, Aspira, or eEnzyme or any of their affiliated companies, parents, subsidiaries, agents, or other related business entities, or their successors or assigns; and (2) cease and desist orders ("CDOs") directed against ScienCell, Aspira, and eEnzyme, and any of their affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns. This investigation is terminated.

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 the 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 the 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: Healthgen of Wuhan, China; ScienCell of Carlsbad, California; Aspira of Milpitas, California; and eEnzyme of Gaithersburg, Maryland (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 under section 337(a)(1)(B) by Healthgen as to infringement of the '951 patent and found the requirements of section 337(g)(1) met as to infringement of the '951 patent and 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 bond of one hundred percent (100%) of entered value 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).

On June 6, 2022, after considering the petition and responses thereto, the Commission determined to review the final ID in its entirety. 87 FR 35570–72 (June 10, 2022). The Commission requested briefing on the issues under review and on remedy, the public interest, and bonding. *Id.*

On review, and as explained in the simultaneously-issued Commission opinion, the Commission has determined that there has been a violation of section 337 with respect to the Asserted Patent by respondent Wuhan Healthgen Biotechnology Corp. ("Healthgen") and that the requirements of section 337(g)(1) are met as to the defaulting respondents based on a violation of section 337 alleged in the complaint with respect to both the Asserted Patent claims and the Lanham Act claim. As to Ventria's allegations of a section 337 violation based on infringement of the '951 patent, Ventria has shown such a violation only as to the clinical grade products. (Commissioner Stayin does not join the Commission's determination as to medium grade products and would find a violation as to all accused products.)

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 determined to issue cease and desist orders against respondents ScienCell, Aspira, and eEnzyme.

The Commission has further determined that the public interest factors enumerated in subsections (d)(l) and (g)(1) (19 U.S.C. 1337(d)(l), (g)(1)) do not preclude issuance of the above-referenced remedial orders. Additionally, the Commission has determined to impose a bond of one hundred percent (100%) of the entered value of the covered products during the period of Presidential review (19 U.S.C. 1337(j)).

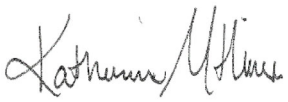
The investigation is hereby terminated in its entirety.

The Commission vote for this determination took place on September 12, 2022.

While temporary remote operating procedures are in place in response to COVID-19, the

Office of the Secretary is not able to serve parties that have not retained counsel or otherwise provided a point of contact for electronic service. Accordingly, pursuant to Commission Rules 201.16(a) and 210.7(a)(1) (19 CFR 201.16(a), 210.7(a)(1)), the Commission orders that the Complainant(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.



Katherine M. Hiner
Acting Secretary to the Commission

Issued: September 12, 2022