

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

**CERTAIN PLANT-DERIVED
RECOMBINANT SERUM ALBUMINS
("rHSA") AND PRODUCTS
CONTAINING SAME**

Investigation No. 337-TA-1238

COMMISSION OPINION

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I. INTRODUCTION

On June 6, 2022, the Commission determined to review in its entirety the final initial determination (“ID”) issued by the presiding administrative law judge (“ALJ”) on April 7, 2022. 87 Fed. Reg. 35570–72 (June 10, 2022). The final ID found a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, with respect to the alleged importation into the United States, the sale for importation, or the sale within the United States after importation of certain plant-derived recombinant human serum albumins (“rHSA”) and products containing the same that infringe certain claims of U.S. Patent No. 10,618,951 (“the ’951 patent” or “the Asserted Patent”). The final ID also found the requirements of section 337(g)(1) met as to the defaulting respondents based on a violation of section 337 alleged in the complaint as to infringement of certain claims of the ’951 patent and as to complainant’s false designation of origin claim (also referred to herein as the “Lanham Act claim”).

On review, 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. The Commission has determined to affirm with modifications the final ID’s findings that Healthgen’s clinical grade accused products infringe the asserted claims of the Asserted Patent. The Commission has also determined to reverse the final ID’s finding that Healthgen’s medium grade accused products infringe the asserted claims of the Asserted Patent. The Commission finds that the domestic industry requirement is satisfied based on the domestic industry product that the parties do not dispute practices the Asserted Patent, but has further determined to take no position as to whether

certain other domestic industry products practice the Asserted Patent. The Commission has determined to affirm the remainder of the final ID.

Accordingly, the Commission finds a violation under section 337(a)(1)(B) by Healthgen as to the patent-based allegations, and finds that the requirements of section 337(g)(1) are met with respect to the violations by the defaulting respondents alleged in the complaint as to both the patent-based allegations and the Lanham Act claim, which are presumed to be true. As a remedy, the Commission has determined to issue a limited exclusion order (“LEO”) to Healthgen and the defaulting respondents and cease and desist orders (“CDOs”) to the defaulting respondents. The Commission has found that the public interest factors do not preclude the issuance of this remedy. The Commission has further determined to set the bond at one hundred percent (100%) of the entered value of articles imported during the period of Presidential Review. This opinion sets forth the Commission’s reasoning in support of these determinations. The Commission affirms and adopts the ID’s findings, conclusions, and supporting analysis that are not inconsistent with the Commission’s opinion.

II. BACKGROUND

A. Procedural History

The Commission instituted this investigation on January 25, 2021, based on a complaint¹ filed on behalf of Ventria Bioscience Inc. (“Ventria”) of Junction City, Kansas. 86 Fed. Reg. 6916 (Jan. 25, 2021). The complaint, as supplemented, alleged violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain plant-derived rHSA and products

¹ Verified Complaint Under Section 337 of the Tariff Act of 1930, as Amended, EDIS Doc. ID. 728108 (Dec. 16, 2020) (“Complaint” or “Compl.”).

containing same by reason of infringement of certain claims of the '951 patent and U.S. Patent No. 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 ("ScienCell"); Aspira of Milpitas, California ("Aspira"); and eEnzyme of Gaithersburg, Maryland ("eEnzyme") (collectively, the "Respondents").² *Id.* at 6917. The Office of Unfair Import Investigations ("OUII") was also named as a party in this investigation. *Id.*

On February 23, 2021, Healthgen filed a response to the complaint and notice of investigation.³

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

The ALJ received briefing on claim construction,⁴ held a *Markman* hearing on May 18, 2021, and issued a *Markman* Order (Order No. 14) on August 23, 2021.

² Two additional entities were named as proposed respondents in the original Complaint: Antibodiesonline, Inc. and United States Biological Corporation. Compl. at ¶ 3. Ventria withdrew the allegations against both entities prior to institution of the investigation. EDIS Doc. ID Nos. 729967 (Jan. 8, 2021), 730236 (Jan. 11, 2021).

³ Response of Wuhan Healthgen Biotechnology Corp. to the Complaint and Notice of Investigation, EDIS Doc. ID 734917 (Feb. 23, 2021) ("Response" or "Resp.").

⁴ Ventria Bioscience Inc.'s Opening Claim Construction Brief, EDIS Doc. ID 740842 (Apr. 23, 2021); Ventria Bioscience Inc.'s Responsive Claim Construction Brief, EDIS Doc. ID 741957

On September 2, 2021, OUII filed a Notice of Partial Participation, stating that it would only participate on issues relating to remedy, the public interest, and bonding. EDIS Doc. ID 750820 (Sept. 2, 2021).

An evidentiary hearing was held on November 4–5 and 8–10, 2021. On December 2, 2021, the parties filed their opening post-hearing briefs,⁵ and on December 13, 2021, the parties filed their reply post-hearing briefs.⁶

Prior to the issuance of the final ID, the investigation was 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 of the final ID, claims 1 and 11–13 of the '951 patent remained pending against Healthgen, and claims 1 and 11–13 of the '951 patent and the

(May 7, 2021); Respondent Wuhan Healthgen Biotechnology Corporation's Opening Brief in Support of Claim Construction, EDIS Doc. ID 740826 (Apr. 23, 2021); Respondent Wuhan Healthgen Biotechnology Corporation's Responsive Brief in Support of Claim Construction, EDIS Doc. ID 741950 (May 7, 2021); The Commission Investigative Staff's Initial Claim Construction Brief, EDIS Doc. ID 741038 (Apr. 27, 2021); The Commission Investigative Staff's Responsive Claim Construction Brief, EDIS Doc. ID 741947 (May 7, 2021).

⁵ Complainant's Initial Post-Hearing Brief, EDIS Doc. ID 757800 (Dec. 2, 2021) ("CPHBr."); Respondent's Initial Post-Hearing Brief, EDIS Doc. ID 757795 (Dec. 2, 2021); The Commission Investigative Staff's Initial Post-Hearing Brief, EDIS Doc. ID 758044 (Dec. 2, 2021).

⁶ Complainant's Post-Hearing Reply Brief, EDIS Doc. ID 758475 (Dec. 13, 2021); Respondent's Reply Post-Hearing Brief, EDIS Doc. ID 758472 (Dec. 13, 2021) ("RPHBr. (Reply)"); Commission Investigative Staff's Reply Post-Hearing Brief, EDIS Doc. ID 758731 (Dec. 13, 2021).

false designation of origin (or Lanham Act) claim remained pending against the Defaulting Respondents.

On April 7, 2022, the ALJ issued the final ID, which found a violation under section 337 by Healthgen and found the requirements of section 337(g)(1) met with respect to the Defaulting Respondents based on a violation of section 337 alleged in the complaint. More particularly, the final ID found, in part:

1. The importation requirement of section 337 has been satisfied as to Healthgen;
2. Claims 1 and 11–13 of the '951 are not invalid and have been found to be practiced by Healthgen's and the Defaulting Respondents' Accused Products;
3. At least one of Ventria's domestic industry products practices one or more claims of the '951 patent;
4. Ventria's domestic research and development activities with respect to its domestic industry products have been found to satisfy the economic prong of the domestic industry requirement under 19 U.S.C. §§ 1337(a)(3)(A), (B), and (C);
5. Healthgen has violated section 337 by importing into the United States, selling for importation, or selling within the United States after importation certain plant-derived rHSAs that infringe claims 1 and 11–13 of the '951 patent;
6. Each of the Defaulting Respondents has violated section 337 by importing into the United States, selling for importation, or selling within the United States after importation certain plant-derived rHSAs that infringe claims 1 and 11–13 of the '951 patent; and
7. Each of the Defaulting Respondents has violated section 337 by violating the Lanham Act under 15 U.S.C. § 1125 by advertising, promoting and/or selling imported plant-derived rHSA without identifying the foreign country of origin of such products.

See Final ID at 8–9, 127–28.⁷

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 enter a 100% bond during the period of Presidential review. RD at 128. While Ventria requested a general exclusion order as to the patent claims, the RD declined to recommend one. *Id.* at 113–21. The Commission had not instructed the ALJ to make findings concerning the public interest. *See* 86 Fed. Reg. 6916.

On April 19, 2022, respondent Healthgen filed a petition for review of the final ID.⁸ On April 22, 2022, OUII filed a response to Healthgen’s petition for review.⁹ On April 27, 2022, Ventria filed a response to Healthgen’s petition for review.¹⁰

⁷ With respect to the final ID’s findings reflected in items 6 and 7 above, the Commission notes that it does not read corresponding items 7 and 8 of the final ID’s Conclusions of Fact or Law, Final ID at 128, as referring to a finding under section 337(d)(1), but rather as a finding under section 337(g)(1) as to the defaulting respondents that permits entry of a remedy under that subsection based on the allegations of a violation in the complaint.

⁸ Respondent Healthgen’s Petition for Review of the Final Initial Determination, EDIS Doc. ID 768709 (Apr. 19, 2022) (“RPet.”); Respondent Healthgen’s Summary of Issues Raised in its Petition for Review of the Final Initial Determination, EDIS Doc. ID 768708 (Apr. 19, 2022).

⁹ The Office of Unfair Import Investigation’s Response to Respondent Healthgen’s Petition for Review of the Final Initial Determination, EDIS Doc. ID 768977 (Apr. 22, 2022) (“OUIIResp.”).

¹⁰ Complainant Ventria’s Response to Healthgen’s Petition for Review, EDIS Doc. ID 769346 (Apr. 27, 2022); Summary of Complainant’s Response to Respondent Healthgen’s Petition for Review of the Final Initial Determination on Violation of Section 337, EDIS Doc. ID 769350 (Apr. 27, 2022).

PUBLIC VERSION

On May 9, 2022, Ventria and Healthgen filed their public interest statements.¹¹ The Commission also received several public interest submissions from third parties in response to the Commission's April 13, 2022, Federal Register notice.¹² *See* 87 Fed. Reg. 21923–24 (Apr. 13, 2022).

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

On June 21, 2022, the parties filed their written submissions on the issues under review and on remedy, the public interest, and bonding,¹³ and on June 27, 2022, the parties filed their

¹¹ Complainant's Submission on the Public Interest, EDIS Doc. ID 770241 (May 9, 2022) ("CStmt."); Respondent Healthgen's Submission on the Public Interest, EDIS Doc. ID 770281 (May 9, 2022) ("RStmt.").

¹² Kansas Attorney General Letter to US International Trade Commission regarding Ventria Biosciences Inc., EDIS Doc. ID 770135 (May 6, 2022); Kansas Chamber of Commerce Letter to USITC regarding Public Interest, EDIS Doc. ID 770160 (May 9, 2022); Public Interest Letter to Chairman Kearns and Commissioners from Senator Jerry Moran, EDIS Doc. ID 770162 (May 9, 2022); Letter from BioKansas to International Trade Commission in Support of Remedies, EDIS Doc. ID 770163 (May 9, 2022); Comments from the Office of Governor Jared Polis regarding Support for Remedies, EDIS Doc. ID 770164 (May 9, 2022); Letter regarding Public Interest to the United States International Trade Commission, EDIS Doc. ID 770166 (May 9, 2022) (filed on behalf of the Colorado BioScience Association); Letter of Support from the Office of Governor Laura Kelly to the ITC, EDIS Doc. ID 770167 (May 9, 2022); Letter from Members of the House of Representatives to the USITC regarding Investigation Remedies, EDIS Doc. ID 770168 (May 9, 2022) (filed on behalf of U.S. Representatives Ron Estes, Tracey Mann, and Jake LaTurner); CFPA Letter to ITC regarding Comments in Response to Commission Notice, EDIS Doc. ID 770169 (May 9, 2022); Public Interest Letter to the USITC regarding Investigation, EDIS Doc. ID 770170 (May 9, 2022) (filed on behalf of U.S. Representative Sharice Davids); Senators Bennet and Hickenlooper to ITC regarding Ventria Bioscience, EDIS Doc. ID 770171 (May 9, 2022).

¹³ Complainant's Initial Submission in Response to the Commission's Notice of Determination to Review the Final Initial Determination, EDIS Doc ID 773581 (June 21, 2022) ("CBr."); Respondent Healthgen's Brief in Response to Commission Notice and on Remedy, Bond, and Public Interest, EDIS Doc ID 773565 (June 21, 2022) ("RBr."); Response of the Office of

reply submissions.¹⁴ Ventria’s initial written submission included a Complainant’s Rule 210.16(c)(1) Declaration in Support of Relief Against Defaulting Respondents. *See* CBr. at Exh. J. The Commission did not receive additional comments on the public interest from non-parties in response to its June 6, 2022, notice.

B. The Parties

1. Complainant Ventria Bioscience Inc.

Ventria is a corporation organized under the laws of Delaware with its principal place of business in Junction City, Kansas. *See* Transcript (Deeter¹⁵) at 142:18–19, 144:18–45:1 (“Tr.”); Compl. at ¶ 48. Ventria also operates another facility in Aurora, Colorado. *See* Tr. (Deeter) at 142:18–19, 144:18–45:1; Compl. at ¶ 48.¹⁶

Unfair Import Investigations to the Commission’s Request for Written Submissions on Remedy, the Public Interest, and Bonding, EDIS Doc ID 773529 (June 21, 2022) (“OUIIBr.”).

¹⁴ Complainant’s Reply Submission in Response to the Commission’s Notice of Determination to Review the Final Initial Determination, EDIS Doc ID 774024 (June 27, 2022) (“CBr. (Reply)”); Respondent Healthgen’s Responsive Submission Concerning Commission Notice and on Remedy, Bond, and Public Interest, EDIS Doc ID 773996 (June 27, 2022) (“RBr. (Reply)”); Reply of the Office of Unfair Import Investigations to the Private Parties’ Submissions on Remedy, the Public Interest, and Bonding, EDIS Doc ID 773983 (June 27, 2022) (“OUIIBr. (Reply)”).

¹⁵ At the time he provided his testimony on November 4, 2021, Mr. Scott Deeter was the President and CEO of Ventria. *See* Final ID at 5 n.10. Ventria identified Mr. Deeter as a fact witness to testify about the Asserted Patent; the background of Ventria’s business, technology, and domestic industry products; the Accused Products and Healthgen’s targeting of United States customers; Ventria’s domestic industry; and other matters related to Ventria and the Asserted Patent. *Id.*

¹⁶ Ventria asserted that its “InVitria is a division and brand of Ventria responsible for, among other things, Ventria’s rHSA products. Because InVitria is not a separately registered or incorporated legal entity, it is not a named party to this case.” Compl. at ¶ 50. Ventria also declared that “‘Ventria’ as used [in the complaint] generally refers to both Ventria and InVitria.” *Id.*

2. Respondent Healthgen

Healthgen is a Chinese corporation based in Wuhan, China. *See* Resp. at ¶ 54.

Healthgen was co-founded by Dr. Daichang Yang, who previously worked at Ventria. *See id.* at ¶ 55. Healthgen manufactures abroad and sells for importation into the United States products containing rice-derived rHSA, including the product commercially branded as “OsrHSA.” *See id.* at ¶ 2.

3. ScienCell, Aspira, and eEnzyme—the Defaulting Respondents

According to the Complaint, ScienCell is a corporation organized under the laws of California with its principal place of business in Carlsbad, California, *see* Compl. at ¶ 68; Aspira is a corporation organized under the laws of Delaware with its principal place of business in Milpitas, California, *see* Compl. at ¶ 70; and eEnzyme is a limited liability company organized under the laws of Maryland with a principal place of business in Gaithersburg, Maryland, *see* Compl. at ¶ 74. Ventria presented evidence showing that each Defaulting Respondent is or has been a distributor of Healthgen’s rice-derived albumin products. *See, e.g.,* Final ID at 7.

On August 18, 2021, the Commission found the Defaulting Respondents (ScienCell, Aspira, and eEnzyme) in default. Order No. 13, *unreviewed by* Comm’n Notice (Aug. 18, 2021).

C. U.S. Patent No. 10,618,951

The ’951 patent, titled “Cell Culture Media Containing Combinations of Proteins,” was issued on April 14, 2020, from U.S. Patent Application Serial No. 15/188,478 (“the ’478 application”), filed on June 21, 2016. JX-0001 (’951 Patent) at 0002 (coversheet information boxes (10), (21), (22), (45), (54) (72)). The ’951 patent names Steven Clyde Pettit, Mary Ann Michelle Fernandez Santos, and Ning Huang as inventors. *Id.* at (10), (45), (72).

The '951 patent relates to compositions for use in cell culture. *See, e.g., id.* at Abstract. “Cell culture” is the growth of cells in an artificial environment (*e.g.*, a petri dish) under conditions that promote cell survival and/or proliferation. Joint Technology Stipulation, EDIS Doc. ID 741045, at 1 (Apr. 27, 2021) (“Joint Tech. Stip.”). One component of the artificial environment is the cell culture media, which is a composition that contains nutrients (*e.g.*, vitamins, carbohydrates, minerals, amino acids, etc.) that the cells need to stay alive and grow in the culture. *Id.* at 2. Additionally, the cell culture media contains various compounds that maintain other important conditions of the culture, such as pH and salt balance (osmolality). *Id.*

Complete media contains all the essential components needed to culture a particular cell type. *Id.* A cell culture media supplement is designed to be combined with other media components or with a base media formulation for a particular cell type. *Id.* Different types of cells have different media requirements. *Id.* Moreover, cells can be grown in different types of media depending upon the purpose of the culture. *Id.*

Blood serum and serum-derived albumin have been used as components of cell culture media. Joint Tech. Stip. at 2. Albumin is a protein that is naturally present in animal serum, including human serum. *Id.* Serum derived from animals is an important source of cell growth and adhesion factors, hormones, lipids, and minerals for cell cultures. *Id.* Although albumin derived from animal serum can be used in cell cultures, there are concerns regarding potential contamination as well as ethical concerns. *See id.* As a result, alternative cell culture media have been developed that do not rely on serum or animal-derived components. Recombinant albumin has been used in cell culture media instead of native proteins and animal-derived components. *Id.* at 2–3.

The Asserted Patent concerns, in part, recombinant proteins such as recombinant albumin. *See, e.g.*, JX-0001 ('951 Patent) at cl. 1. Recombinant technology involves the introduction of foreign genetic material (transgenes) into a host cell, where the foreign genetic material can be used to produce proteins that would not normally be present in that host cell (*e.g.*, recombinant albumin). Joint Tech. Stip. at 3. For instance, the DNA of a plant cell can be engineered to include DNA that is foreign to that plant cell. *Id.* When expressed by the plant cell's native machinery, this foreign DNA can produce a recombinant protein that the cell would not normally produce. *Id.*

The asserted claims of the '951 patent generally relate to media supplements or complete media compositions for the growth of cells in cell culture. *See, e.g.*, JX-0001 ('951 Patent) at 2:66–3:3. The recited media supplements or complete media compositions comprise a recombinant mammalian albumin that is produced in a transgenic plant. *See id.* at cl. 1. All the claims require that the recombinant mammalian albumin have less than 1 EU (endotoxin unit) of endotoxin per mg of albumin. *Id.* Endotoxins are toxins that can associate with cell culture components and cause cell death. *See id.* at 30:47–53. The claims also require that the recombinant mammalian albumin have less than 2% aggregated albumin (*i.e.*, non-monomeric albumin) by weight. *Id.* at cl. 1.

D. The Accused Products

Ventria alleged that Healthgen's rHSA product sold under the brand name OsrHSA infringes claims 1 and 11–13 of the '951 patent. *See* CPHBr. at 14–15. Healthgen's OsrHSA is supplied as both: (i) a powder “medium grade” or “culture grade” rHSA product; and (ii) a powder and a liquid “clinical grade” rHSA product (collectively, “Accused Products” or “OsrHSA Products”). *See, e.g.*, JX-0021C at 0001–4; CX-0053C at 0005; CX-0924 at 0001–3. Healthgen refers to the clinical grade Accused Products by their internal catalog numbers

HYC001C01, HYC001C02, and HYC002C01. *See, e.g.*, CX-0923; CX-0924 at 0003; JX-0032C at 0001–03. The HYC002C01 product is a clinical grade lyophilized powder. *See, e.g., id.* Healthgen’s medium grade Accused Products have internal catalog numbers HYC002M01, HYC002M02, and HYC002M03. *See, e.g.*, CX-0924 at 0001–3; JX-0032C at 0004–6; CX-0053C at 0007.

The Defaulting Respondents are accused of importing Healthgen’s products, described above.

E. Ventria’s Domestic Industry Products

Ventria asserted that the following Ventria products practice one or more claims of the Asserted Patent: (i) Cellastim[®] S (“Cellastim”); (ii) Exbumin[®] (“Exbumin”); (iii) Optibumin[®] (“Optibumin”); (iv) OptiPEAK[®] (“OptiPEAK”); (v) OptiVERO[®] (“OptiVERO”); and (vi) ITSE[™]+A (“ITSE+A,” and with Cellastim, Exbumin, Optibumin, OptiPEAK, and OptiVERO, “Domestic Industry Products”). *See, e.g.*, CPHBr. at 15–16; Compl. at ¶¶ 81–84. A description of each of the Domestic Industry Products can be found in the final ID at pages 31–32. OptiPEAK, OptiVERO, and ITSE+A [REDACTED]. *See, e.g.*, Final ID at 71. Healthgen does not dispute that Optibumin practices the Asserted Patent, but does dispute that the other five products practice that patent.

III. COMMISSION REVIEW OF THE FINAL INITIAL DETERMINATION

When the Commission reviews an initial determination, in whole or in part, it reviews the determination *de novo*. *Certain Soft-Edged Trampolines & Components Thereof*, Inv. No. 337-TA-908, Comm’n Op. at 4 (May 1, 2015). Upon review, the “Commission has ‘all the powers which it would have in making the initial determination,’ except where the issues are limited on notice or by rule.” *Certain Flash Memory Circuits & Prods. Containing Same*, Inv. No. 337-TA-382, USITC Pub. No. 3046, Comm’n Op. at 9–10 (July 1997) (quoting *Certain*

Acid-Washed Denim Garments & Accessories, Inv. No. 337-TA-324, Comm’n Op. at 5 (Nov. 1992)). With respect to the issues under review, “the Commission may affirm, reverse, modify, set aside or remand for further proceedings, in whole or in part, the initial determination of the administrative law judge.” 19 C.F.R. § 210.45(c). The Commission also “may take no position on specific issues or portions of the initial determination,” and “may make any finding or conclusions that in its judgment are proper based on the record in the proceeding.” *Id.*; *see also* *Beloit Corp. v. Valmet Oy*, 742 F.2d 1421, 1423 (Fed. Cir. 1984).

IV. INFRINGEMENT

A. The Applicable Law

Section 337 prohibits “the importation into the United States, the sale for importation, or the sale within the United States after importation . . . of articles that infringe a valid and enforceable United States patent.” 19 U.S.C. § 1337(a)(1)(B). Direct infringement includes making, using, offering to sell, or selling a patented invention or importing a patented invention into the United States, without consent of the patent owner. 35 U.S.C. § 271(a).

To prove direct infringement, the plaintiff must establish by a preponderance of the evidence that one or more claims of the asserted patent read on the accused product or process, either literally or under the doctrine of equivalents. *Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, 261 F.3d 1329, 1336 (Fed. Cir. 2001). Each limitation in a patent claim is considered material and essential to an infringement determination. *See London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991). “Literal infringement of a claim exists when each of the claim limitations reads on, or in other words is found in, the accused device.” *Allen Eng. Corp. v. Bartell Indus.*, 299 F.3d 1336, 1345 (Fed. Cir. 2002). If any claim limitation is found to be absent from the accused product or process, then there is no literal infringement. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 141, 1247 (Fed. Cir. 2000).

B. The Asserted Claims and the Claim Constructions

Claim 1 is reproduced below as representative of the asserted claims:

1. A cell culture media supplement or complete media composition for improving the growth of a cell in cell culture comprising:
a recombinant mammalian albumin wherein said albumin is:
 - i) produced in a transgenic plant;
 - ii) has less than 1 EU of endotoxin/mg of albumin; and
 - iii) less than 2% aggregated albumin.

The terms “recombinant mammalian albumin” and “aggregated albumin” were construed by the ALJ as follows:

“Recombinant mammalian albumin”: recombinant albumin (*i.e.*, albumin 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, fusion protein, or fragment of native mammalian albumin (provided the fragment retains the biological or therapeutically beneficial activity of the native mammalian albumin);

“Aggregated albumin”: Non-monomeric albumin (*e.g.*, albumin dimers).

See Order 14, Appx. at 1–3. The parties agreed on the construction of “aggregated albumin,” but disputed the construction of “recombinant mammalian albumin.” The ALJ largely agreed with Healthgen’s construction. *See id.*, Appx. at 2–9.

The private parties now agree that the claims require no further construction beyond the claim construction order, and that the issue of whether the products at issue meet the claims’ requirements is purely factual. *See* CBr. at 32–33; RBr. at 40–41. The private parties only dispute the claim limitation “less than 2% aggregated albumin,” as applied to both the Accused Products and certain of the Domestic Industry products.

C. Analytical Testing Methods for Determining Whether the Products at Issue Satisfy the “Less than 2% Aggregated Albumin” Claim Limitation

1. Size Exclusion Chromatography-High Pressure Liquid Chromatography (“SEC-HPLC”)

The parties agree that size exclusion chromatography (“SEC-HPLC”) can determine the amount of non-monomeric albumin in the products at issue. *See, e.g.*, CBr. at 15–17; RBr. at 9–13. In SEC-HPLC, smaller species and larger species pass through and exit a separation column at different speeds, with smaller species moving more slowly through the column and therefore exiting later. *See, e.g.*, Tr. (Wilken¹⁷) at 420:1–9; JX-0032 at 0008; CBr. at 15–16; RBr. at 9–10. The amount of time spent in the column is referred to as the “retention time” (and is on the x-axis in SEC-HPLC data plots). *See* CBr. at 15–16. Smaller species have a higher retention time because they are in the column longer. *See, e.g.*, Tr. (Wilken) at 420:1–9; Tr. (DeFilippi) at 1224:4–17. SEC-HPLC is recited in the Asserted Patent as a method for assessing purity and the specification states it was used to detect the presence of albumin dimers. *See* JX-0001 (’951 Patent) at 71:54–72:27. The final ID credited SEC-HPLC analyses. *See, e.g.*, Final ID at 40.

The final ID found that “the peer-reviewed literature recognizes unequivocally that SEC HPLC has its . . . limitations when it comes to quantifying aggregates.” Final ID at 20. The final ID also found that, in at least some circumstances, SDS-PAGE (discussed below, although not specifically reducing SDS-PAGE) and SEC-HPLC provide equivalent results. *Id.* at 24.

¹⁷ When she testified during the hearing, Dr. Lisa Wilken was an Associate Professor in the Department of Biological and Agriculture Engineering at Kansas State University. Final ID at 10 n.12. Ventria identified Dr. Wilken as an expert to testify about the technical background of the Asserted Patent; the Accused Products; the Domestic Industry Products; the knowledge of a person of ordinary skill in the art; claim construction; and other issues in connection with infringement, validity, the technical prong of the domestic industry requirement, enforceability, and/or any other technical issue that may arise. *Id.*

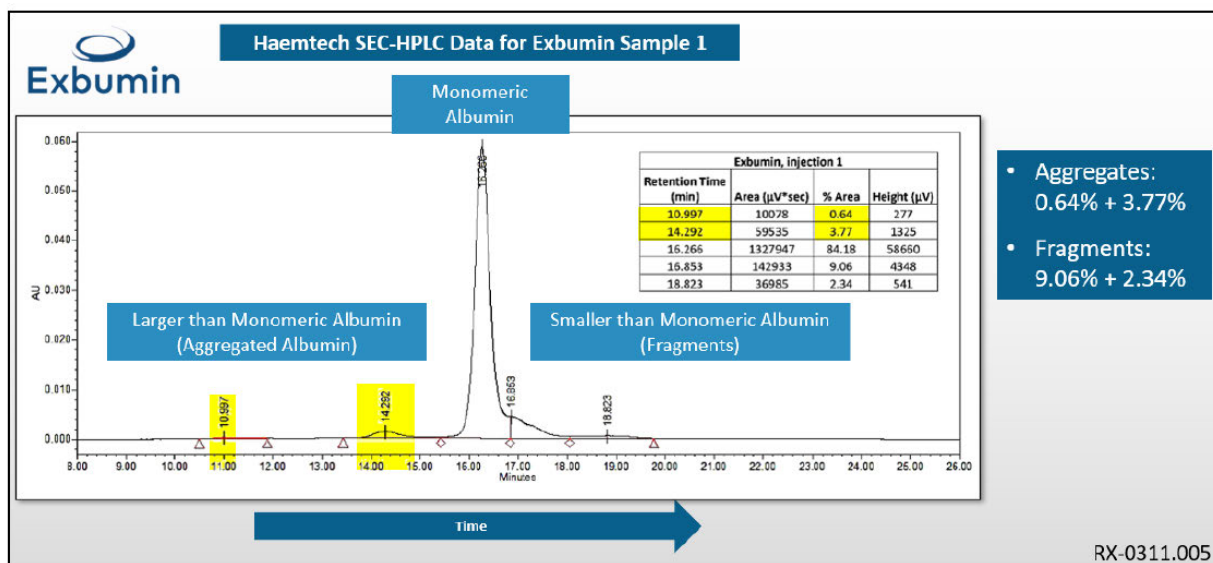
The final ID credited certain SEC-HPLC evidence in determining amounts of aggregated albumins in product samples. *See, e.g., id.* at 43. The final ID additionally noted that Dr. DeFilippi, Healthgen's expert, acknowledged that SEC-HPLC is a reliable technique to quantify aggregated albumin. *Id.*

We affirm the final ID's findings above that SEC-HPLC is generally a reliable technique and find that it is appropriate to credit SEC-HPLC testing data. However, we do not interpret all of the SEC-HPLC evidence the same as the final ID does. In particular, the Commission does not agree with the final ID's interpretation of the SEC-HPLC data in Healthgen's customer communications regarding the medium grade Accused Products as indicating that those products have [REDACTED] aggregated albumin.¹⁸ *See* Final ID at 52–54. Rather, we interpret those results (as discussed below in Section IV.D.3) as showing that the sample is [REDACTED] monomers, dimers, and aggregates combined. We affirm the final ID's finding that an SEC-HPLC data analysis shows that a Healthgen rHSA [REDACTED] has less than [REDACTED] aggregated albumin. *See id.* at 40. We also affirm the final ID's finding that an SEC-HPLC data analysis shows that a Healthgen clinical grade Accused Product had at most [REDACTED] aggregated albumin. *See id.* at 43. We also affirm the final ID's finding that, in some circumstances, SDS-PAGE and SEC-HPLC provide equivalent results for a particular product sample. *See id.* at 24.

The parties generally agree that, at least for the products at issue in this investigation, the percentage of aggregated albumin determined from an SEC-HPLC analysis is the sum total of the areas of the peaks corresponding to aggregated albumin in the sample, in relation to (*i.e.*,

¹⁸ As discussed *infra*, note 34, Commissioner Stayin does not join the Commission's determination as to the medium grade Accused Products.

divided by) the sum total of the areas of the peaks corresponding to all albumin species (including aggregated and non-aggregated) in the sample, multiplied by 100. *See* CBr. at 45–46; CBr. (Reply) at 30–31; RBr. at 45–46; RBr. (Reply) at 35. For example, in the data plot below, if the species with retention times of 10.997 minutes and 14.292 minutes were both considered aggregated albumin, the sample would include 4.41% aggregated albumin (0.64% + 3.77%):



RDX-0002C (DeFilippi Demonstrative Exhibit) at 75; RX-0311 at 005. According to the parties, species with a retention time greater than monomeric albumin (*i.e.*, species smaller than monomeric albumin) would not be considered aggregated albumin. *See, e.g.*, CBr. at 18–19, 28, 45–46; RBr. at 23–24, 33, 45–46.

2. Polyacrylamide Gel Electrophoresis (“PAGE”)

The final ID found that an analytical technique called “polyacrylamide gel electrophoresis” (“PAGE”), including “reducing SDS-PAGE,” can also quantify the amount of aggregated albumin in the products at issue. *See* Final ID at 16–26. PAGE separates the albumin species of an albumin mixture by size, where each differently-sized albumin species

accumulates in a separate “band.” *See, e.g.*, Tr. (Wilken) at 347:1–10, 372:5–13. A staining technique is used to quantify the amount of each albumin species present at each band. *See, e.g., id.* PAGE that uses the surfactant sodium dodecyl sulfate is called “SDS-PAGE.” *See, e.g.*, RBr. at 14. SDS-PAGE that uses a reducing agent is called “reducing SDS-PAGE,” and SDS-PAGE that does not use a reducing agent is called “non-reducing SDS-PAGE.” PAGE that uses neither a reducing agent nor a surfactant is called “Native-PAGE.” *See id.* at 15–16.

The private parties agree that, at least under some conditions, PAGE can be used to distinguish monomeric and non-monomeric albumin (*i.e.*, “aggregated albumin”). *See, e.g.*, CBr. at 12–15; RBr. at 13–17. However, respondent Healthgen argues that reducing SDS-PAGE is not a reliable technique for quantifying total aggregated albumin. *See, e.g.*, RPet. at 38–45. Healthgen asserts that the surfactant used in the method (SDS) can artificially decrease the amount of measured aggregated albumin by converting non-covalently linked aggregates into monomeric albumin. *See, e.g.*, RBr. at 14. Healthgen further asserts that the reducing agent used in the method can break “the bonds of aggregated albumin thereby artificially decreasing the percent of aggregated albumin.” *See, e.g.*, RPet. at 27.

The Commission modifies and affirms the final ID’s finding that “reducing SDS-PAGE” is an appropriate technique to measure and quantify “aggregated albumin.”¹⁹ First, the Asserted Patent explains that reducing SDS-PAGE can be used to quantify and compare percentages of proteins and protein complexes in samples of rice-expressed rHSA. *See* JX-0001 (’951 Patent) at 70:17–49 (describing the experimental preparation of rHSA samples, including rice-

¹⁹ The Commission does not adopt the reasons on pages 22–27 of the final ID for finding that reducing SDS-PAGE is an appropriate technique to measure and quantify “aggregated albumin.” The Commission instead finds this technique is appropriate for each of the following independently-sufficient reasons.

expressed rHSA, for analysis by reducing SDS-PAGE); *see also id.* at 70:22–23 (“The sample was mixed 1:1 with . . . buffer . . . containing reducing agent . . .”); *id.* at 70:43–47 (“The percent of each contaminating protein in each band was calculated . . .”). The Asserted Patent then proceeds to describe, under a heading titled “Results & Discussion” (*id.* at 71:54), the results from the reducing SDS-PAGE experiments described at JX-0001 (’951 Patent) at 70:17–49. *See id.* at 72:34–57. Specifically, the Asserted Patent states:

Visual inspection of the gel shows that the new process which meets more rigorous specifications is more consistent among the 3 lots tested. (FIG. 9B, lane 2, 3, 4 vs. lane 6, 7, 8). The banding pattern is significantly different among the three samples from the previous process as compared to the new process. *Importantly, the new process samples have significantly less aggregates at around 250 KDa than the old process samples have. (Average greater than 2% for the old process, and average less than 1% for the new process).*

Id. at 72:46–53 (emphasis added). The Asserted Patent thus discloses that reducing SDS-PAGE was used to quantify the percent of aggregated albumin in numerous samples of rice-produced rHSA, including Ventria’s Domestic Industry Product, Cellastim. *Id.* Dr. DeFilippi,²⁰ Healthgen’s expert witness, acknowledged under cross-examination that the Asserted Patent reports aggregate quantification by reducing SDS-PAGE. Tr. (DeFilippi) at 1250:23–1251:4; *see also id.* at 1246:11–13 (“Q. The ’951 patent does contain a description for testing of albumin with reducing SDS PAGE, doesn’t it? A. Yes.”).

²⁰ When he testified during the hearing, Dr. Louis DeFilippi was an independent consultant and the President of Louis DeFilippi, LLC. Final ID at 13 n.16. Healthgen identified Dr. DeFilippi as an expert to testify about the Asserted Patent, including the technical background and the relevant prior art, the level of knowledge of a person of ordinary skill in the art, invalidity of the Asserted Patent, the noninfringement of Healthgen’s Accused Products, and the technical prong of the Commission’s domestic industry requirement. *Id.*

Second, the peer-reviewed literature of record discloses that reducing SDS-PAGE is a suitable, and recommended, analytical technique for quantifying aggregated albumin. For example, den Engelsman²¹ (JX-0132) concludes, after reviewing many analytical techniques in detail:

SEC²² and -PAGE//CE-SDS²³ are methods that are robust enough for reproducible quantification of aggregates and that allow routine use with sufficient sample throughput . . . Below we list recommendations regarding the assessment of protein aggregates in biotech product development: Employ robust, quantifiable methods for QC testing: SEC (quantification of covalent and non-covalent aggregates, but not low-affinity aggregates and larger aggregates); SDS-PAGE and/or CE-SDS (covalent aggregates).

JX-0132 (den Engelsman) at 0013 (emphases added); *see also id.* at 0005, 0007, 0009 (describing both reducing and non-reducing SDS-PAGE as suitable for quantification of aggregates); JX-0060 (Mahler²⁴) at 0006; Tr. (Wilken) at 312:2–13, 347:14–21, 351:2–352:1. After describing in detail the advantages and disadvantages of numerous techniques for quantification and analysis of aggregates, the authors concluded that “*no single method covers the analysis of all aspects of aggregates. As each method covers different aggregate characteristics, the results obtained with a particular method are strictly linked to that method.*” JX-0132 at 0012 (den Engelsman) (emphases added).

Healthgen’s preferred peer-reviewed literature on the subject, Mahler (JX-0060), arrived at similar conclusions to den Engelsman. *See, e.g.,* JX-0060 (Mahler) at 0001 at Abstract (“A

²¹ den Engelsman, John, *et al.*, *Strategies for the Assessment of Protein Aggregates in Pharmaceutical Biotech Product Development*, Pharm. Res., Vol. 28, p. 920 (2011).

²² “SEC” refers to “size exclusion chromatography,” such as SEC-HPLC.

²³ “CE-SDS” appears to refer to “capillary electrophoresis-SDS.”

²⁴ Mahler, Hanns-Christian, *et. al.*, *Protein Aggregation: Pathways, Induction Factors and Analysis*, J. of Pharms. Sci., Vol. 98, p. 2909 (2009).

major challenge for the analysis of protein aggregates is that no single analytical method exists to cover the entire size range or type of aggregates which may appear. Each analytical method not only shows its specific advantages but also has its limitations.”); JX-0132 (den Engelsman) at 0004–6; *see also* JX-0060 (Mahler) at 0018; Tr. (Wilken) at 352:25–353:9, 458:6–11; JX-0060 (Mahler) at 0007–8 (discussing reducing SDS-PAGE and aggregate quantification using same); JX-0060 (Mahler) at 0006, Table 1 (table listing “Frequently Used Methods for Analysis of Protein Aggregation” with “SDS-PAGE” categorized as a “Quantification and/or size estimation” method).

Third, Healthgen’s expert, Dr. DeFilippi, relied on reducing SDS-PAGE results to argue both invalidity and non-infringement. During the Hearing, Dr. DeFilippi confirmed that paragraph 150 of his opening report as to invalidity indicates that Van Urk²⁵ evaluated its rHSA using SDS-PAGE with a reducing agent. Tr. (DeFilippi) at 962:21–24. And Dr. DeFilippi admitted during cross-examination that he was willing to accept Van Urk’s use of reducing SDS-PAGE in arriving at some of his opinions. *Id.* at 959:6–960:3. With respect to non-infringement, Dr. DeFilippi relied on data from reducing SDS-PAGE to quantify what he believes is the amount of aggregated albumin in the Accused Products. *See, e.g.*, Tr. (DeFilippi) at 1169:16–1170:15.

Fourth, at least for the Accused Products, the use of analytical techniques measuring aggregated albumin that use a surfactant and a reducing agent provide largely similar results as techniques that do not use those reagents. For example, Healthgen acknowledges that the analytical results for its medium grade Accused Products from both reducing SDS-PAGE and

²⁵ International Publication Number WO 00/44772 (Aug. 3, 2000) (JX-0030). Healthgen asserted Van Urk as prior art against the asserted claims.

Native-Page are largely the same. *See* RPet. at 6 n.3 (“The results for the samples tested by Native-PAGE contain from 5.5% to 9.3% aggregated albumin, while the samples tested by Reducing SDS-PAGE contain 6.8% to 9.7% aggregated albumin.”); *see also* RBr. at 56–57. And, while Healthgen argues that its clinical grade products show an artificially low aggregated albumin percentage when tested via reducing SDS-PAGE, *see, e.g.*, RBr. at 55–56, the data shows otherwise. An analysis of a sample using SEC-HPLC, a technique that does not use a surfactant or a reducing agent, showed that a sample of the clinical grade Accused Product had [REDACTED] aggregated albumin. *See* CX-0450 at 0002; *see also* CBr. at 55–57. Two additional tests using reducing SDS-PAGE on the same exact sample showed at most 0.64% and 1.81% aggregated albumin. *See* JX-0129 at 0006–7; CX-0904 at 0006–7.²⁶ The SEC-HPLC test result is not significantly different than either reducing SDS-PAGE result. *See* Final ID at 51. Also, the SEC-HPLC test result is in between the two SDS-PAGE test results, *i.e.*, at most 0.64% aggregated albumin and 1.81% aggregated albumin. Moreover, the SEC-HPLC test result does not show the highest amount of aggregated albumin of the three tests. Based on Healthgen’s concession and this testing data, we are not persuaded by Healthgen’s argument that reducing SDS-PAGE is an unreliable technique for measuring total aggregated albumin in the Accused Products.

The parties generally agree that, at least for the products at issue in this investigation, the percentage of aggregated albumin determined from an SDS-PAGE analysis is the sum total of the band volumes of the bands corresponding to aggregated albumin species in the sample, in

²⁶ A discussion of these SEC-HPLC and reducing SDS-PAGE test results is provided below in the discussion of whether the clinical grade Accused Products infringe the asserted claims of the Asserted Patent.

relation to (*i.e.*, divided by) the sum total of the band volumes corresponding to all albumin species (including aggregated and non-aggregated) in the sample, multiplied by 100. *See* CBr. at 45–46; CBr. (Reply) at 30–31; RBr. at 45–46; RBr. (Reply) at 35. For example, in the data below, if the species with a molecular weight of 134 kDa was the only species considered “aggregated albumin,” the sample would include 1.29% aggregated albumin:

Sample	Band	Molecular weight kDa	Band volume	% band	% purity
VEN00326	HMW impurities	134	702864	1.29	86
		128	296793	0.54	
		106	213094	0.39	
	Main band	68	47134589	86.21	
	LMW impurities	59	2282714	4.18	
		57	1493716	2.73	
		46	1873232	3.43	
		33	678065	1.24	
	Sum		54675067	100.00	

CBr. at 45. According to the parties, species with a molecular weight less than that of the main band would not be considered aggregated albumin. *See, e.g.*, CBr. at 18–19, 28, 45–46; RBr. at 23–24, 33, 45–46.

D. Whether Healthgen’s Accused Products Infringe the Asserted Patent

The Commission affirms with modifications the final ID’s finding that Ventria has shown that Healthgen’s clinical grade Accused Products infringe the asserted claims of the Asserted Patent. The Commission reverses the final ID’s finding that Ventria has shown that Healthgen’s medium grade Accused Products infringe those claims.

Before the ALJ, the parties disputed which albumin species fall within the ALJ’s construction of “aggregated albumin.” *See, e.g.*, Final ID at 64–65. Ventria generally argued that, for a species to be “aggregated albumin,” the species must be a complex or assembly of two or more “recombinant mammalian albumin” units as claimed, and therefore “aggregated albumin” must have a molecular weight that is a minimum of approximately twice the

molecular weight of monomeric recombinant mammalian albumin. *See, e.g., id.*; CBr. at 12. Healthgen, on the other hand, argued that any detected albumin species having a molecular weight greater than that of monomeric recombinant mammalian albumin should be considered “aggregated albumin.” *See, e.g.,* Final ID at 65; RBr. at 30–31.

Relatedly, and given Ventria’s asserted molecular weight minimum for determining whether a species is “aggregated albumin,” the parties disputed whether the molecular weights of albumin species identified in analytical testing, such as PAGE or SEC-HPLC, must be known in order to identify the species as an “aggregated albumin” species. *See, e.g.,* CBr. at 35–41; RBr. at 41–42. The signal in an analytical test corresponding to monomeric albumin can be easily determined because that species will have the strongest or most intense signal. Tr. (DeFilippi) at 1164:22–25. The molecular weight of monomeric albumin and other albumin species in the sample can be determined using molecular weight markers, ladders, or standards. *See, e.g.,* Tr. (Wilken) at 371:1–14, 371:20–372:4, 373:5–16. However, no standards are needed to determine if a given species has a molecular weight that is greater or less than the molecular weight of monomeric albumin. *See, e.g.,* Tr. (DeFilippi) 1162:9–1169:15 (discussing how to identify species larger than monomeric albumin using Native-PAGE); RX-0366C at 050 (test report for [REDACTED] identifying dimers and larger aggregates by SEC-HPLC with no molecular weight markers or standards). Ventria argued that such molecular weight markers, ladders, or standards are required for analytical testing data to be probative. *See, e.g.,* CBr. at 35–41. Healthgen argued to the contrary, asserting that it was sufficient to determine infringement by analyzing the amount of signal provided by species that were heavier than monomeric albumin, and that analysis does not require knowing the precise molecular weights of those heavier species. *See, e.g.,* RBr. at 41–42.

The final ID agreed with Ventria regarding both above disputes. *See, e.g.*, Final ID at 25–26, 64–65. The Commission takes no position on these disputes, as resolution is not necessary to determine whether the Accused Products (and Ventria’s Optibumin Domestic Industry Product) practice the asserted claims. Even accepting Healthgen’s positions, the evidence supports the Commission’s infringement and technical prong findings below. Likewise, accepting Ventria’s arguments also would not change these findings.

1. **Healthgen’s Accused Products** [REDACTED]

The final ID found that Healthgen’s Accused Products [REDACTED]
[REDACTED]. *See* Final ID at 37–41. The final ID found that the final clinical grade Accused Products and medium grade Accused Products [REDACTED]
[REDACTED]. *See id.* The Commission affirms this finding. The Commission clarifies, however, that the final forms of the clinical grade Accused Products and medium grade Accused Products may have different amounts of aggregated albumin, as shown by the test results discussed in the sections of this Opinion below, and therefore while the Commission agrees with the final ID that Healthgen’s clinical grade Accused Products meet the “less than 2% aggregated albumin” limitation, its medium grade Accused Products do not.

2. **Ventria has Shown that Healthgen’s Clinical Grade Accused Products Infringe the Asserted Patent**

The final ID, relying on certificates of analysis and testing data of the clinical grade Accused Products, found that the clinical grade Accused Products infringe the asserted claims of the Asserted Patent. The Commission affirms the final ID’s finding, but with modified and supplemented reasoning as discussed below.

a. **Ventria’s Arguments**

Before the ALJ, Ventria argued that the clinical grade Accused Products met the “less than 2% aggregated albumin” limitation based on a certificate of analysis (“COA”) of a sample of clinical grade product that was manufactured on September 14, 2020, which showed at most [REDACTED] aggregated albumin using the SEC-HPLC test, and that the satisfaction of the disputed limitation was further corroborated by two subsequent reducing SDS-PAGE tests from that exact same sample (tests performed in or around May 2021 and June 2021 by non-party SGS Life Sciences Services (“SGS”)). *See* CPHBr. at 46–51.

b. **Healthgen’s Arguments**

Healthgen did not present test data that rebutted the showing of infringement. *See generally* RPHBr. (Reply) at 29–43. Rather, Healthgen primarily argued that Ventria improperly sought to rely on (1) “test data from a fresh sample one day after manufacture in China where the percentage of aggregation is at its lowest—data collected at the wrong time”; and (2) “test data generated in the U.S. after treating the sample with a reducing/bond-breaking agent to artificially decrease the percent of aggregated albumin—data collected using the wrong test.” *Id.* at 29–30; *see also, e.g.*, RPet. at 27–37.

As to the SEC-HPLC test results, Healthgen reasoned that aggregated albumin concentration can increase over time, such as during shipping, and therefore testing soon after manufacture is not representative of the aggregated albumin concentration at the time of importation. *See, e.g.*, RPHBr. (Reply) (citing, *e.g.*, JX-0132 (den Engelsman) at 0002; JX-0060 (Mahler) at 0003–0004; Tr. (DeFilippi) 1197:11–18; Tr. (Wilken) 455:11–21). Healthgen further pointed out that the COA’s acceptance criteria allows for up to 4% aggregated albumin. *See, e.g., id.* at 34.

As to the reducing SDS-PAGE test results from non-party SGS on the same sample, Healthgen argued that reducing SDS-PAGE can decrease the amount of aggregated albumin measured to “half or even a fourth of the level observed by SEC-HPLC.” *Id.* (citing RX-0311 at 002, 5–8; RDX-0002C at 54; Tr. (DeFilippi) 1206:4–11). Relatedly, Healthgen argued that the alleged dramatically different test results in the September 2020 COA and the May 2021 and June 2021 test reports demonstrate the unreliability of reducing SDS-PAGE. *See, e.g., id.* at 31, 37. Healthgen further asserted that Ventria allegedly argued that the June 2021 “Reducing SDS-PAGE report should not be considered,” *id.* at 35–38; that Ventria incorrectly implied that the data shown in that report was for a sample that was treated with salt and heat stressors, *id.* at 35; and that Ventria’s reasoning for the absence of low molecular weight impurities in those results “is factually unsupported and makes no sense,” *id.* at 36.

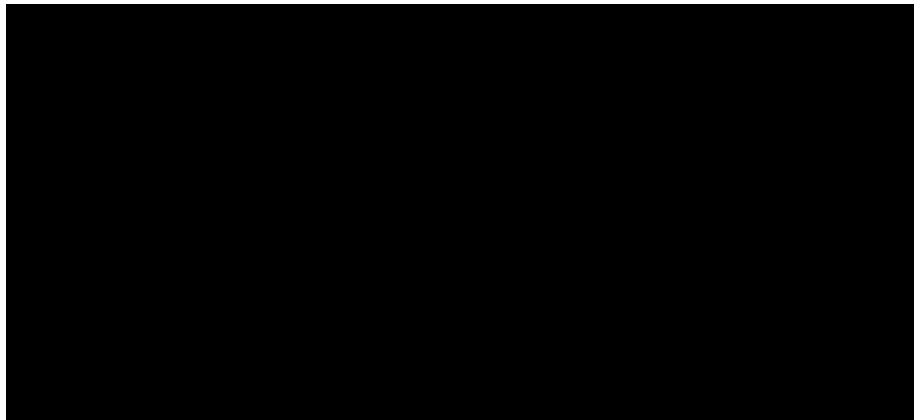
In its petition for review, Healthgen argued that the final ID neglected to consider some of its arguments. *See* RPet. at 45–47. Healthgen points to certain arguments related to its lyophilized powder products. *See id.* at 45–46 (citing RPHBr. (Reply) at 43–45). Healthgen asserted that the final ID also did not discuss Ventria’s own prelitigation testing or “documents evidencing Healthgen’s ‘purity’ calculations.” *See id.* Healthgen further asserted that the final ID disregarded evidence that lyophilization (freeze drying) can increase aggregation. *Id.* at 46 (citing Final ID at 56–57; JX-0060 (Mahler) at 0003).

c. Analysis

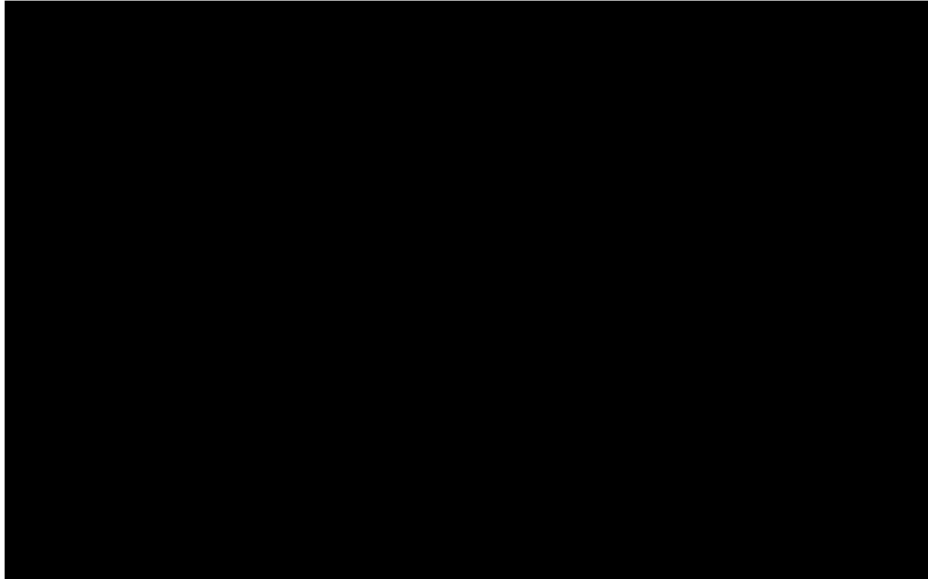
The Commission finds that Ventria has shown by a preponderance of the evidence that the clinical grade Accused Products infringe the asserted claims. The Commission does not adopt the analysis of the final ID regarding the August 14, 2019, email from Healthgen’s employee, Ms. Jung Cao, to [REDACTED] and related correspondence regarding the approval of clinical trials from the United States Food and Drug Administration. *See* Final ID at 47–49.

The Commission affirms the remainder of the final ID on this issue and supplements the final ID's reasoning.²⁷

The COA and SEC-HPLC data upon which Ventry relies show that the clinical grade products have less than 2% aggregated albumin at least as of one day after manufacture. *See* CX-0450 at 0002 (showing that a clinical grade product has at most [REDACTED] aggregated albumin (sum of polymer ([REDACTED]) and dimer ([REDACTED])). The COA includes, *inter alia*, the date of manufacture of the batch of the sample, an analysis date, an expiration date, the acceptance criteria, and analysis results of more than twenty “test items.” One such COA is reproduced in part below:



²⁷ Commissioner Stayin would affirm the entirety of the final ID's analysis on this point.



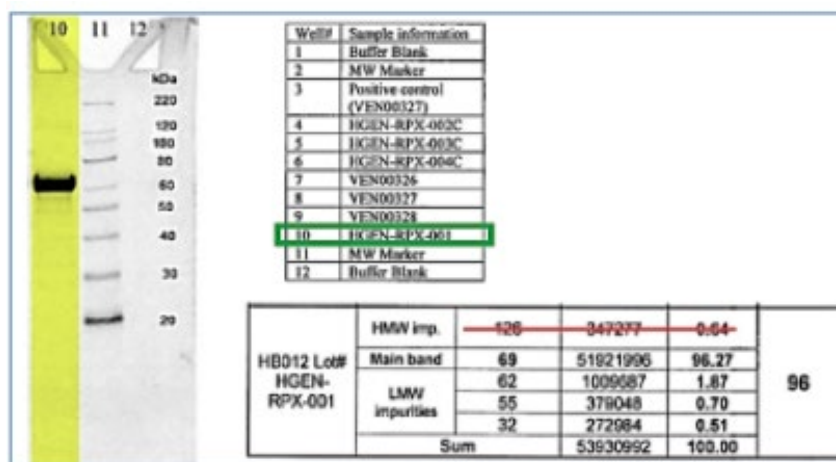
CX-0450 (COA) at 0001–2; JX-0032C (COA) at 0001–2 (same); CDX-0001 at 0047; Final ID at 42, Tr. (DeFilippi) at 1277:10–25 (Dr. DeFilippi confirming same); *see also, e.g.*, JX-0015C (COA) at 0001–2 (clinical grade Accused Product COA that shows less than 2% aggregated albumin as measured by SEC-HPLC).

The above COA shows that, under the parties’ agreed-upon method of calculating aggregated albumin, this sample of clinical grade product includes at most [REDACTED] aggregated albumin,²⁸ which is within the scope of the claims’ “less than 2% aggregated albumin” limitation. The COA includes acceptance criteria of greater than or equal to [REDACTED] monomer, of less than or equal to [REDACTED] polymer, and less than or equal to [REDACTED] dimer. CX-0450 (COA) at

²⁸ The [REDACTED] aggregated albumin is the sum of [REDACTED] polymer and [REDACTED] dimer. The parties agree that the [REDACTED] fragments do not count as “aggregated albumin.” *See* CBr. at 18–19; RBr. at 23–24. The parties also agree that the only relevant quantification is the total percent of “aggregated albumin” in the products at issue. *See* CBr. at 45–46; RBr. at 45–46. Ventria would appear to require knowledge of the molecular weight species comprising the “polymer” before it would agree that those species are “aggregated albumin.” *See* CPHBr. at 48 (“[E]ven when using Healthgen’s incorrect interpretation of what is encompassed by ‘aggregated albumin,’ as claimed, CX-0450-0002 confirms the maximum amount of aggregated albumin in Healthgen’s OsrHSA clinical grade is only [REDACTED].”).

0002. The COA states that the sample has an expiration date of September 13, 2024 (four years from manufacture). *See* CX-0450 (COA) at 0001.

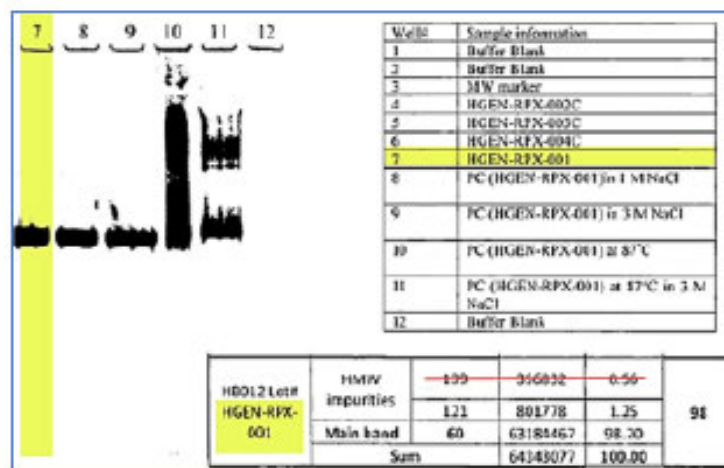
The COA and SEC-HPLC data are sufficient for Ventria to have met its burden of proof as to infringement of the clinical grade Accused Products. That Ventria satisfied its burden of proof is further corroborated by Ventria's reducing SDS-PAGE data, which (in this context) also independently shows by a preponderance of the evidence that the clinical grade products satisfy the only disputed limitation of the claim. Ventria presented May and June 2021 SGS reducing SDS-PAGE testing reports analyzing the amount of aggregated albumin in the same sample that was tested via SEC-HPLC above. *See* CPHBr. at 49–51; Tr. (Wilken) at 369:21–25; RX-0190C at 0001; Final ID at 44–46. SGS memorialized the results of the testing in study reports dated May 19, 2021 (JX-0129), and June 29, 2021 (CX-0904), respectively. Dr. Wilken testified that she found SGS's testing and protocols acceptable. Tr. (Wilken) at 370:17–24. Dr. DeFilippi did not offer any testimony criticizing or disputing SGS's testing conditions or protocols. The May 2021 testing results are reproduced below:



JX-0129 (test report) at 0006–7 (annotated, copied from CPHBr. at 50); *see also* Tr. (Wilken) at 413:1–414:3; Tr (DeFilippi) at 1198:13–1199:2 (confirming same); Final ID at 45. As the final ID found, the above data shows that, under the parties' agreed-upon method of calculating

aggregated albumin, the sample of clinical grade product includes at most 0.64% aggregated albumin, which is within the scope of the claims’ “less than 2% aggregated albumin” limitation.^{29, 30} Final ID at 44–45.

The June 2021 test results are reproduced below:



²⁹ The 0.64% aggregated albumin value corresponds to the 126 kDa species. This species includes a red strikethrough because Dr. Wilken testified that the species may not be properly considered “aggregated albumin” because the molecular weight of the species did not align with what she expected the molecular weight of a dimer to be. *See* Tr. (Wilken) at 413:1–414:3. As indicated above, *see supra* Section IV.D., the Commission takes no position on this issue, as its resolution is not necessary to determine whether the Accused Products infringe the Asserted Patent. As for the “LMW impurities” (or “low molecular weight impurities”), the parties agree that these species are not “aggregated albumin.” *See, e.g.*, CBr. at 18–19, 28, 45–46; RBr. at 23–24, 33, 45–46.

³⁰ The final ID found:

The May 2021 testing showed that Healthgen’s OsrHSA clinical grade has less than 2% aggregated albumin. As shown in the annotated collection of images below, all of which are taken from JX-0129, Healthgen’s OsrHSA clinical grade sample RPX-001 (*i.e.*, HYC001C02) had no more than 0.64% aggregated albumin, *i.e.*, less than 2% aggregated albumin.

Id. The Commission affirms this finding.

CX-0904 (test report) at 0006–7 (annotated, copied from CPHBr. at 51); *see also* Tr. (Wilken) at 539:11–540:12; Tr (DeFilippi) at 1199:7–12 (confirming same); Final ID at 45. The above data shows that, under the parties’ agreed-upon method of calculating aggregated albumin (*see* CBr. at 18–19, 45–46; RBr. at 23–24, 45–46), the sample of clinical grade product includes at most 1.81% aggregated albumin (0.56%^{31, 32} plus 1.25%), within the scope of the claims’ “less than 2% aggregated albumin” limitation. Final ID at 45–46.

Dr. Wilken testified that she found SGS’s testing and protocols acceptable. Tr. (Wilken) at 370:17–24. Dr. DeFilippi did not offer any testimony criticizing or disputing SGS’s testing conditions or protocols. In fact, Dr. DeFilippi agreed during cross-examination that “three test results on the same batch” of OsrHSA clinical grade product “showed results of less than 2 percent aggregated albumin.” Tr. (DeFilippi) at 1279:4–1282:14 (“Q. Okay. *All three showed results of less than 2 percent aggregated albumin[?]* A. By their particular—*by the particular analytical techniques, yes.*”) (emphases added); *see also* Final ID at 46.

While Healthgen argues that reducing SDS-PAGE measures an artificially low aggregated albumin measurement, Healthgen has not shown this to be the case for its own

³¹ The 0.56% aggregated albumin value corresponds to a species at 139 kDa. This species includes a red strikethrough because Dr. Wilken testified that the species should not be considered “aggregated albumin.” *See* Tr. (Wilken) at 540:8–12. However, this data shows infringement whether or not that species is considered to be aggregated albumin.

³² The final ID found:

The June 2021 testing also showed that Healthgen’s OsrHSA clinical grade has less than 2% aggregated albumin. As shown in the annotated collection of images below, all of which are taken from CX-0904, Healthgen’s OsrHSA clinical grade sample RPX-001 (*i.e.*, HYC001C02) had no more than 1.81% aggregated albumin, *i.e.*, less than 2% aggregated albumin.

Id. The Commission affirms this finding.

products.³³ In fact, Healthgen acknowledged that its medium grade products did not show a significant decrease in aggregates from reducing SDS-PAGE. *See* RBr. at 53–57. And, as to the clinical grade products, the measured aggregated albumin in the undisputed SEC-HPLC test ([REDACTED]) fits squarely within the results of the two reducing SDS-PAGE tests (May 2021: at most 0.64%; June 2021: at most 1.81%). Also, the SEC-HPLC test result is not significantly different than either reducing SDS-PAGE result, and the SEC-HPLC test result does not show the highest amount of aggregated albumin of the three tests. Moreover, as discussed above, the Commission agrees with the final ID that reducing SDS-PAGE is an acceptable technique for quantifying the amount of aggregated albumin in the products at issue.

Healthgen further argues that the alleged dramatically different test results in the September 2020, May 2021, and June 2021 reports demonstrate the unreliability of reducing SDS-PAGE. *See, e.g.*, RPHBr. (Reply) at 31, 37. The evidence does not support this assertion. Although the May 2021 and June 2021 tests were both performed using reducing SDS-PAGE, each of their testing conditions were markedly different. Specifically, the May 2021 and June 2021 tests: (1) used different reducing agents; (2) had different load volumes; (3) used different gels; (4) used different running buffers; and (5) used different electrophoresis conditions. *Compare* JX-0129 (test report) at 0005; *with* CX-0904 (test report) at 0005. Nevertheless, in both cases, the SGS testing showed that the clinical grade Accused Product had less than 2% aggregated albumin, with which Dr. DeFilippi agreed. Tr. (DeFilippi) at 1282:11–14 (“Q.

³³ Healthgen has presented evidence that tends to show reducing SDS-PAGE may reduce the amount of measured aggregated albumin in Ventria’s domestic industry products, but it did not do so for its own products. *Compare* RPet. at 47–48 (citing RX-0311 at 002, 5–8) *with* RPet. at 5–46.

Okay. All three showed results of less than 2 percent aggregated albumin[?] A. By their particular—by the particular analytical techniques, yes.”); *see also id.* at 1279:4–1282:14.

Healthgen also argued that Ventria allegedly argued that the June 2021 “Reducing SDS-PAGE report should not be considered.” RPHBr. (Reply) at 35; *see also id.* at 36–38. Again, the evidence does not support this assertion. Ventria advocated for the June 2021 report to be considered. *See, e.g.*, CPHBr. at 50 (“The June 2021 testing also revealed that Healthgen’s OsrHSA clinical grade has less than 2% aggregated albumin.”). Relatedly, Healthgen asserts that Ventria incorrectly implied that the data shown in that report was for a sample that was treated with salt and heat stressors, *id.* at 35, and that Ventria’s reasoning for the absence of low molecular weight impurities in those results “is factually unsupported and makes no sense,” *id.* at 36. However, the Commission is relying on the unsalted, unheated sample (not the salted, heated sample) from the dataset that Ventria cites.

With regard to Healthgen’s remaining arguments, while Healthgen argues that aggregated albumin accumulates over time, such as after production but before importation, the evidence of record undermines this assertion. Multiple communications from Healthgen to its customers provide representations as to the stability of the rHSA protein over time periods up to [REDACTED]. Healthgen stated to its customer [REDACTED] that long-term testing [REDACTED].” CX-0391C at 0013 (emphasis added); *see also id.* at 0006–07. Likewise, Healthgen shared similar stability data with its customer [REDACTED] in a December 13, 2018 Memorandum, which concluded that stability testing of OsrHSA “[REDACTED] [REDACTED].” CX-0456 at 0001–2 (emphasis added); *see also* CX-0470C at 0001 (email from Ms. Cao stating in relevant part: [REDACTED]).

[REDACTED]; CX-0474C at 0006 ([REDACTED])

); CX-0476C (same); CX-0478C (same).

Additionally, Healthgen tends to ship its products shortly after manufacture and under conditions that ensure the stability of the protein [REDACTED]. *See, e.g.*, CX-0474C at 0004 (March 28, 2019, email from Ms. Cao (who goes by “Abby”) to customer [REDACTED] [REDACTED]).

); *id.* at 0001–02

(email exchanges between Ms. Cao and

[REDACTED]; CX-0017C at 0001-06

(OsrHSA manufactured on

(January 8, 2020)); CX-0476C at 0002 (October 25, 2019, email from Ms. Cao indicating that

"); CX-0470C.0001 (email from Ms. Cao stating that “

_____”).

Moreover, Dr. DeFilippi (whose testimony Healthgen relies on for its argument) acknowledged during cross-examination that he had no knowledge as to the way Healthgen ships or maintains the stability of its products, Tr. (DeFilippi) at 1282:21–1283:3, and he also failed to review Healthgen customer communications, *id.* at 1273:23–1274:6, which describe, *inter alia*, how Healthgen ships its products and include its assurances about the stability of its products. Additionally, Healthgen has provided no specific evidence regarding the rate at which any aggregates would accumulate over time under the recommended storage conditions of [REDACTED], under which it appears to store and ship its products, *see, e.g.*, CX-0470C at 0001.

Lastly, Healthgen argues that the final ID neglected to consider certain of its arguments. *See* RPet. at 45–47. None of these allegedly-ignored arguments have any merit, however. First, Healthgen asserts that the final ID did not discuss “Ventria’s prelitigation testing or the documents evidencing Healthgen’s ‘purity’ calculations, as detailed above.” *Id.* at 45–46 (citing RPHBr. (Reply) at 43–45). However, the cited pages of Healthgen’s briefing that Healthgen contends were ignored by the ALJ refer generally to pre-litigation testing of its powder products. *See* RPHBr. (Reply) at 43–45. The only powder clinical grade Accused Product has the internal catalog number HYC002C01. *See, e.g.,* CX-0923; CX-0924.0003; JX-0032C.0001–03. And the argument to which Healthgen refers on pages 43–45 of that post-hearing reply brief shows internal catalog number HYC002M01, a medium grade Accused Product. *See* RDX-0002C.13–19. Healthgen’s Petition for Review fails to make a discernible argument that the final ID ignored any argument as to the clinical grade Accused Products on those pages. Accordingly, to the extent Healthgen opaquely raised such an argument in its brief before the ALJ, the Commission considers it waived. *Hazani v. U.S. Int’l Trade Comm’n*, 126 F.3d 1473, 1476–77 (Fed. Cir. 1977).

Further, Healthgen asserts that the final ID misconstrued its arguments regarding its [REDACTED] samples. RPet. at 46. Healthgen asserts that “Dr. DeFilippi explained [that] Healthgen [REDACTED] [REDACTED] [REDACTED].” *Id.* (quoting Tr. (DeFilippi) at 1175:4–14). But regardless of whether Healthgen is correct, the Commission is relying on testing data of the actual samples, which is far more probative and persuasive than testimony and argument

regarding inferences about the relative purity of two different kinds of products. *See* CX-0904 (test report) at 0006–7.

Next, Healthgen relatedly argues that the final ID disregarded the undisputed evidence that “lyophilization (freeze drying) can increase aggregation,” and that Mahler declares that “[a]ggregation can be induced by a wide variety of conditions, including . . . pumping, freezing, and/or thawing [the] formulation,’ *e.g.*, freeze drying/lyophilization.” *Id.* (quoting JX-0060 (Mahler) 0003) (citation to final ID omitted). However, Healthgen cites no evidence that “pumping, freezing, and/or thawing the formulation” is the same as “freeze drying/lyophilization.” Healthgen’s assertion in this investigation is at odds with its representations to U.S. customer, [REDACTED], that the clinical grade powder and liquid products are “completely consistent,” without mentioning any differences in aggregated albumin. *See* CX-0196C at 0007; Final ID at 56. Healthgen further assured [REDACTED] that the powder rHSA can be used in the same manner as the liquid. *See* CX-0196C at 0007; Final ID at 56. Ms. Cao’s representation on behalf of Healthgen implied that Healthgen’s powder clinical grade has near-identical characteristics as the liquid version of the product, *i.e.*, less than 2% aggregated albumin. *See* CX-0196C at 0007; *see also* Final ID at 56; CX-0923; CX-0924 at 0003; JX-0032C at 0001–03.

3. Ventria has Not Shown that Healthgen’s Medium Grade Accused Products Infringe the Asserted Patent

The final ID found that the medium grade Accused Products infringe the asserted claims of the Asserted Patent. *See* Final ID at 52–56. The Commission reverses this finding and determines that Ventria has not met its burden of proof on this issue.³⁴ In summary, the final ID

³⁴ Commissioner Stayin would affirm the final ID’s findings as to Healthgen’s medium grade product. In his view, the interpretation of the documents in the record is inextricably

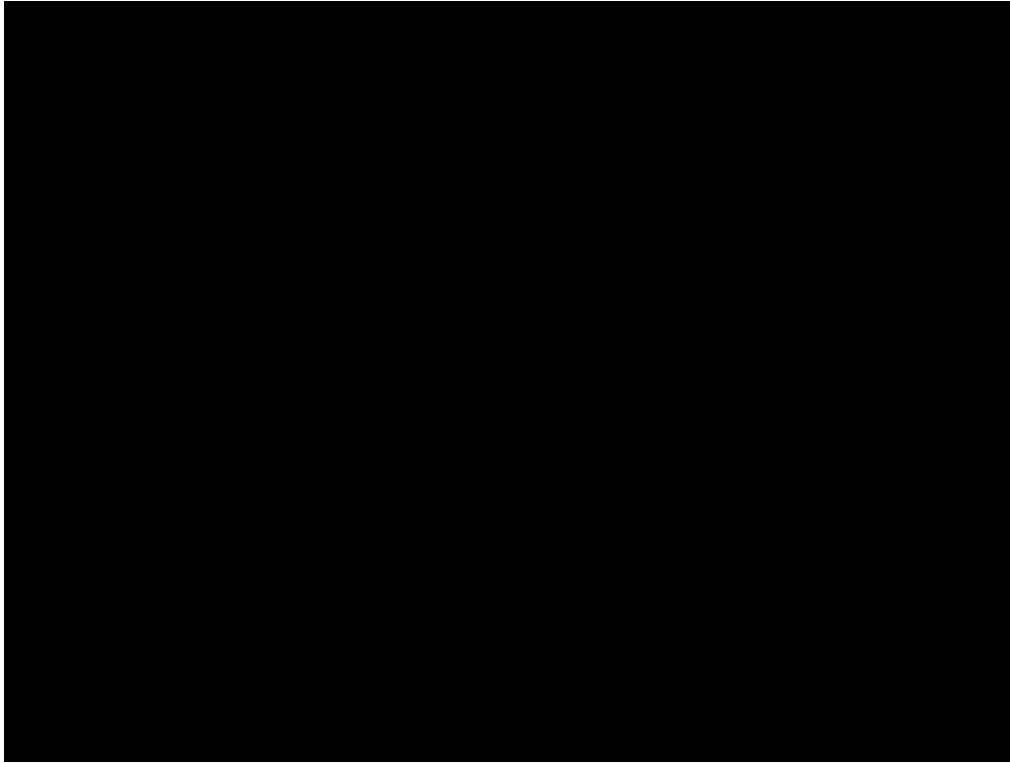
misconstrued customer communications that it mistakenly found declared that the medium grade Accused Products are at most [REDACTED] aggregated albumin. *See* Final ID at 52–54. The other evidence relied upon by the final ID on this issue, regarding Healthgen’s manufacturing and purification processes, is too weak and circumstantial to outweigh evidence from testing of the actual medium grade Accused Products.

a. **Ventria’s Argument**

Ventria’s primary evidence at trial was Healthgen’s communications to customers that allegedly stated that Healthgen’s medium grade Accused Products were [REDACTED] monomeric albumin, and thus, according to Ventria, contained only [REDACTED] aggregated albumin (*i.e.*, less than 2% aggregated albumin). *See, e.g.*, CPHBr. 59–63. Representative of the communications on which Ventria relies is a response to [REDACTED] inquiries about “OsrHSA for Use in Serum Free Medium.” *See* CX-0052C at 0001.³⁵ Along with that response, Healthgen provided a document to [REDACTED] that stated the following:

intertwined with expert testimony and credibility determinations the ALJ was in the best position to make. The record indicates that Healthgen uses critical terms (including “purity” and “aggregates”) in different ways in similar documents, and Healthgen itself argued that testing can result in dramatically different results. Ventria offered credible testimony to show infringement and to distinguish the counter-evidence introduced by Healthgen, and the final ID reasonably weighed the totality of the evidence in finding the medium grade products infringe. Commissioner Stayin believes the Commission is improperly substituting its judgment for that of qualified experts as credited by the ALJ, and is treating similar evidence inconsistently for the medium versus clinical grade products. Commissioner Stayin also believes the Commission misconstrues the final ID’s analysis, including as to the relevance of the fact [REDACTED]. The Commission even goes so far as to rely on its own “eye-ball” analysis of data that lacks any quantitative markers necessary to measure aggregate albumin (under either party’s approach) to find infringement of a claim with a specific quantitative threshold. With no clear error in the final ID’s thorough and credible analysis, Commissioner Stayin would affirm final ID’s finding of infringement, and therefore does not join the Commission’s reversal as to the medium grade Accused Products.

³⁵ Ventria cites other similar communications to [REDACTED] and similar communications with other customers, such as [REDACTED]. *See* CPHBr. at



See CX-0052C at 0003. [REDACTED] a 2011 Healthgen publication in an academic journal.³⁶ See JX-0022 (He). Ventria argued that Healthgen arrived at a purity of “>99.999%” by running its “OsrHSA culture grade through SEC-HPLC to generate a chromatogram like the one shown above, then ‘calculated the purity by ratio of [the] area of [the rHSA] monomer peak’ to ‘all detected peaks.’” CPHBr. at 60. Ventria then asserted that this means that the rHSA monomer peak is “99.999 percent of the total protein species present in samples of OsrHSA culture grade measured by SEC-HPLC, and the percent area of all other non-monomeric peaks combined is 0.001 percent of the total protein species

61–62 (citing, *e.g.*, CX-0002; CX-0005C; CX-0053C; CX-0360C; CX-0385C; CX-0387C; CX-0412C; JX-0019C). These communications are discussed in the analysis below.

³⁶ He, Yang, *et al.*, Large-scale production of functional human serum albumin from transgenic rice seeds, PNAS, vol. 108, no. 47, p. 19078 (Nov. 22, 2011). Details about the how the data was obtained, and the meaning thereof are included in a separate “Supporting Information,” exhibit CX-0252 (“He Supporting Information”).

present in samples of OsrHSA culture grade measured by SEC-HPLC.” *Id.* Thus, according to Ventria, the medium grade product has less than 2% aggregated albumin, which allegedly

“[REDACTED]

[REDACTED]” *Id.*

Ventria additionally argued:

The foregoing evidence, in combination with (i) Healthgen's SEC HPLC data and its characterization of the same in customer communications; (ii) the properties of Healthgen's [REDACTED] and Bo Shi's³⁷ testimony; and (iii) Dr. Yang et al.'s characterization of Healthgen's purification process in peer-reviewed literature (JX-0023-0014) establish by a preponderance of the evidence that OsrHSA culture grade has less than 2% aggregated albumin and therefore infringes Claim 1 of the '951 Patent.

CPHBr. at 62–63 (certain citations omitted).

b. Healthgen's Argument

Healthgen presented Ventria's own pre-litigation testing data, including reducing SDS-PAGE and Native-PAGE testing data, of Healthgen's medium grade Accused Products from tests conducted both by Ventria and by Ventria's independent lab. RPHBr. (Reply) at 44–46. All nine of the tests showed that the medium grade Accused Products had more than 2% aggregated albumin. RPet. at 6.

Healthgen also asserted that Ventria mischaracterized Healthgen's purity representations in its customer communications:

Ventria improperly attempts to conflate—as they did at trial—“purity” of total albumin (all albumin species including monomer, dimer, and all

³⁷ Mr. Bo Shi, Healthgen's Vice President of Operations, was designated as Healthgen's corporate representative to testify about, *inter alia*, the details of the manufacturing, production, purification, testing, and assembly of the Accused Products. See Tr. (DeFilippi) at 1289:5–23, 1289:24–1290:1; see also CX-1081C (Shi Dep. Tr.) at 21:11–15, 23:3–18; 24:9–16, 25:2–11, 142:7–143:5.

other aggregates) versus non-albumin impurities with the percent monomeric albumin (versus total albumin). [CPHBr. at] 59–62. But “purity” in Healthgen’s documents does not reflect the percent of monomeric albumin. *E.g.*, Wilken Tr. 531:6–11 (Dr. Wilken admitting that total albumin purity means monomeric albumin plus all non-monomeric albumin); *see also id.*, 1208:18–22 (Dr. DeFilippi explaining that “Healthgen calculated the purity [as] all forms of albumin, including monomer, dimer, and polymer.”).

Id. at 51–52.

c. Analysis

The Commission finds that the final ID misconstrued the primary evidence upon which it relies, customer communications that it mistakenly found declared that the medium grade Accused Products are at most [REDACTED] aggregated albumin. *See* Final ID at 52–54. Those communications addressed purity in terms of “albumin” generally, not in terms of “aggregated albumin,” as discussed below. The final ID also failed to recognize that the communications were outdated and included data from nearly a decade before the Asserted Patent issued (*see* Tr. (DeFilippi) at 1214:7–12 (explaining that data from 2011 is “out-of-date”)), and it also failed to make any finding that the data included in those communications was representative of an importation of any Accused Product after the Asserted Patent issued.

The other evidence relied upon by the final ID on this issue was Mr. Bo Shi’s testimony

[REDACTED]

[REDACTED]

[REDACTED]. *See* Final ID at 37–39. The final ID further relied on evidence that Healthgen has a purification process for its rHSA products and characterizations of that process. *See id.* at 55. However, this evidence is too weak and circumstantial to outweigh evidence from testing of the actual medium grade Accused Products (and Ventria’s own testing no less).

For example, the final ID relied on Dr. Yang's characterization of Healthgen's purification process in the peer-reviewed literature. *See* Final ID at 55; CPHBr. at 62. However, neither Ventría nor the final ID explain how the characterization of the purification process shows that Healthgen's medium grade Accused Products must have an aggregated albumin content of less than 2%. And, the evidence shows that, even if Healthgen has a purification process, it does not remove all aggregated albumin. *See, e.g.*, Final ID at 41–46; CX-0450 (COA) at 0001–0002 (showing as much as [REDACTED] aggregated albumin), JX-0129 (test report) at 0006–0007 (showing as much as 0.64% aggregated albumin); CX-0904 (test report) at 0006–0007 (showing as much as 1.81% aggregated albumin); JX-0129 (test report) at 0007 (showing that samples of medium grade Accused Products indisputably have *at least* 3.55%, 2.74%, 4.03%, counting only the species closest to the expected molecular weight of the expected dimer, consistent with Dr. Wilken's testimony); Final ID at 55 (finding that testing of samples of the medium grade Accused Products showed more than 2% aggregated albumin). Thus, we do not adopt the final ID's reliance on this evidence to show that the medium grade Accused Products have less than 2% aggregated albumin.

Moreover, testing data of Healthgen's products undermines the final ID's reasoning that the two categories of products should have the same amounts of aggregated albumin [REDACTED] [REDACTED]. The testing data of the final medium grade and clinical grade Accused Products have dramatically different amounts of aggregated albumin. For example, the final ID found that clinical grade Accused Products have tested as having at most 0.64%, [REDACTED], and 1.81% aggregated albumin, *see* Final ID at 41–46; CX-0450 (COA) at 0001–0002, JX-0129 (test report) at 0006–0007; CX-0904 (test report) at 0006–0007), and recent testing data from three medium grade Accused Product samples show that those samples have

at least 3.55%, 2.74%, 4.03% aggregated albumin, *see* JX-0129 at 0007 (counting only the species closest to the expected molecular weight of the expected dimer, consistent with Dr. Wilken’s testimony, which would be 138kDa, as the Commission is not taking a position on whether the other albumin species would be “aggregated albumin”). Moreover, the final ID’s finding that the medium grade Accused Products and clinical grade Accused Products should have the same aggregated albumin [REDACTED] cannot be squared with the final ID’s findings that the medium grade Accused Products tend to have [REDACTED] aggregated albumin and the clinical grade Accused Products have as much as 0.64%, [REDACTED], and 1.81% aggregated albumin, *see* CX-0450 (COA) at 0001–0002, JX-0129 (test report) at 0006–0007; CX-0904 (test report) at 0006–0007); Final ID at 41–46. Under the final ID’s reasoning, the clinical grade Accused Products would also be expected to have approximately [REDACTED] aggregated albumin. It was thus clear error to rely on an implication that the medium grade Accused Products and clinical grade Accused Products would have the same amount of aggregated albumin [REDACTED].

In any event, testing data of actual medium grade Accused Products produced after the issuance of the Asserted Patent is far more probative than customer communications including data from nearly ten years prior to the issuance of the Asserted Patent. Dismissing this data as being mere “outliers” is clear error. Thus, the Commission finds that the final ID erred and that Ventria has not met its burden of proof of showing that the medium grade Accused Products infringe the asserted claims of the Asserted Patent, as further explained below.

i. Healthgen’s Customer Communications Are Not Probative of Infringement

First, Healthgen’s communications to its customers are not probative of whether the medium grade Accused Products meet the claim limitation “less than 2% aggregated albumin”

because the quantification Ventria points to in those communications addresses total albumin content, not aggregated albumin. *See* RPet. at 12–19. A representative customer communication declared:

[REDACTED]

[REDACTED]

CX-0052C at 0003 (emphasis added).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *Id.* [REDACTED]

[REDACTED] Tr. (DeFilippi) at 1217:11–1218:2. [REDACTED]

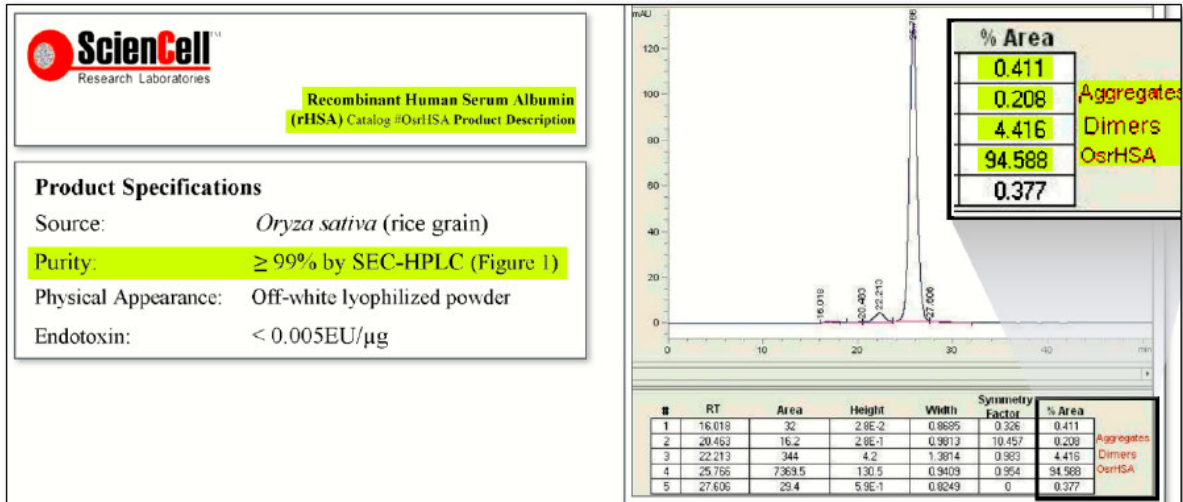
[REDACTED]

[REDACTED] *Id.*

The above reading is consistent with and corroborated by the source of the data and accompanying information. *See* JX-0022 (He); CX-0252 (He Supporting Information). The data images and supplemental information are provided below:

The images in He, which also appear in the He Supporting Information and other customer communications, are shown above on the left. The He Supporting Information explains that the purity values of, *e.g.*, 99.45%, were calculated as “TSP %,” which means “total soluble protein.” Tr. (DeFilippi) at 1215:13–15. And it is undisputed that the total soluble proteins include soluble albumin aggregates, including albumin dimers. *Id.* at 1215:5–25.³⁸

³⁸ Dr. Wilken’s contrary testimony that “purity” was calculated with respect to “aggregated albumin” was based on a flawed recollection of the He Supporting Information. *See* CX-0252 (He Supporting Information) at 0007; Tr. (Wilken) at 560:3–18; RPet. at 14–15.

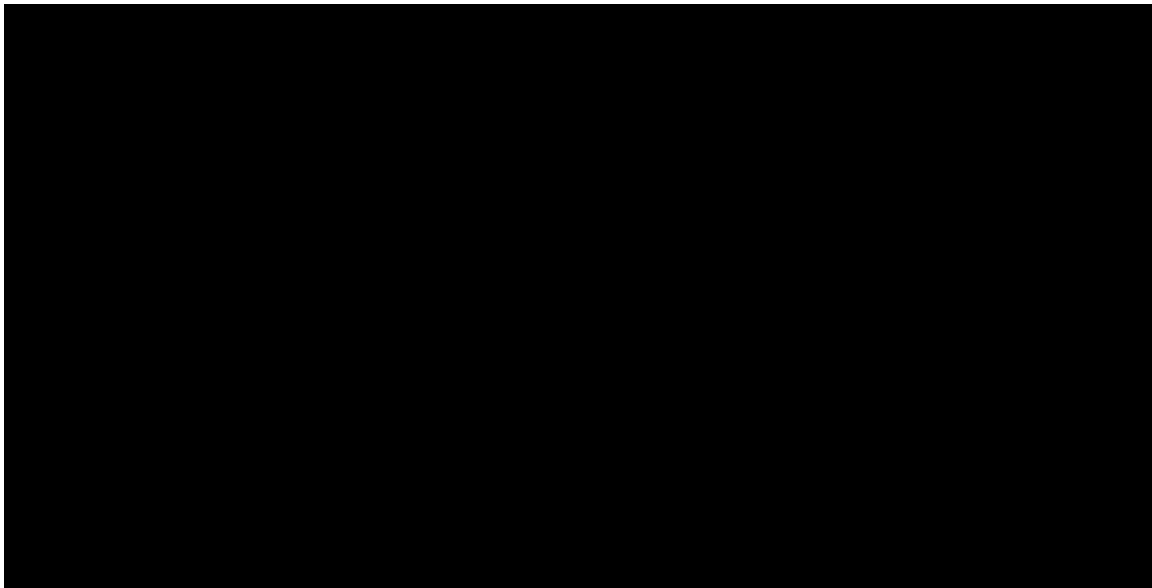


JX-0018C at 0001, 0002 (highlighting added by Healthgen, red text in original). To reach a purity of greater than 99% by SEC-HPLC, albumin monomers, dimers, and larger aggregates must be added together. *Id.* If “purity” by SEC-HPLC were simply the percent of monomeric albumin, then purity would be reported as 94.588% purity.

Similarly, Healthgen’s COAs report total albumin purity levels by [REDACTED]

[REDACTED].” E.g.,

RX-0366C at 003, 012. This statement is shown below, alongside the accompanying SDS-PAGE gel data:



RX-0366C at 003, 012.

Ventria also cites several additional customer communications that allegedly show that Healthgen's medium grade Accused Products contain less than 2% aggregated albumin:

- CX-0053C at 0007 refers to [REDACTED]

- CX-0053C at 0008 states that the [REDACTED]

See also CX-0005C at 0001 (same). [REDACTED]

- CX-0412C is a COA dated [REDACTED]. Similarly, CX-0387C at 0010 contains a [REDACTED]

- CX-0360C at 0003 is an email [REDACTED]

• CX-0002 at 0006 is a brochure stating that Aspira's rHSA is "a single protein at 66.4 kDa." However, the cited passage concerns distinguishing albumin from its "glycosylated or alkylated" forms, not the level of aggregation.

- JX-0019C at 0001 states that [REDACTED]

and JX-0064C at 0005 similarly states [REDACTED]

[REDACTED]. *See JX-0001 ('951 patent) at 72:20–22 ("[I]t is noticeable that the Cellastim dimer peak is significantly smaller than the plasma derived albumin."); see also JX-0009C at 00032–33 [REDACTED]*

- CX-0385C at 0012 notes [REDACTED]

³⁹ "pHSA" stands for "plasma-derived HSA."

ii. Weighing of the Remaining Evidence

Beyond the communications noted above, Ventria pointed to the following evidence:

“(i) Healthgen’s SEC HPLC data and its characterization of the same in customer communications;⁴⁰ (ii) the properties of Healthgen’s [REDACTED] and Bo Shi’s testimony;⁴¹ and (iii) Dr. Yang et al.’s characterization of Healthgen’s purification process in peer-reviewed literature.” CPHBr. at 62–63 (citations omitted).

In contrast to the weighty pre-litigation testing evidence, Ventria’s evidence is weak and circumstantial. Ventria points to Healthgen’s SEC HPLC data and its characterization of the same in customer communications. *See* CPHBr. at 62. However, that data and characterization relate to the clinical grade Accused Products. *See* CX-0450 (COA) at 0002 (data addressing product code HYC001C02); CX-0923 (identifying HYC001C02 as a clinical grade product).

Ventria further points to the properties of Healthgen’s [REDACTED] [REDACTED] and Bo Shi’s testimony. However, the evidence of record does not indicate that the properties of Healthgen’s [REDACTED] [REDACTED]. Testing data of the final medium grade Accused Products, on the other hand, are probative of whether the disputed limitation is met and show (as discussed below) that the medium grade Accused Products have more than 2% aggregated albumin. *See* JX-0080C; JX-0129 at 0007. Lastly, Ventria points to Dr. Yang’s characterization of Healthgen’s purification process in the peer-reviewed literature. *See* CPHBr.

⁴⁰ We interpret Ventria’s argument as referring to the SEC-HPLC data contained in Healthgen’s COA for the clinical grade Accused Products (discussed above). *See* CX-0450 (COA) at 0002.

⁴¹ Ventria alleges that a [REDACTED] [REDACTED]. *See* CPHBr. at 43–44 (citing, *e.g.*, JX-0047C at 0094–95; Tr. (Wilken) at 398:6–402:14).

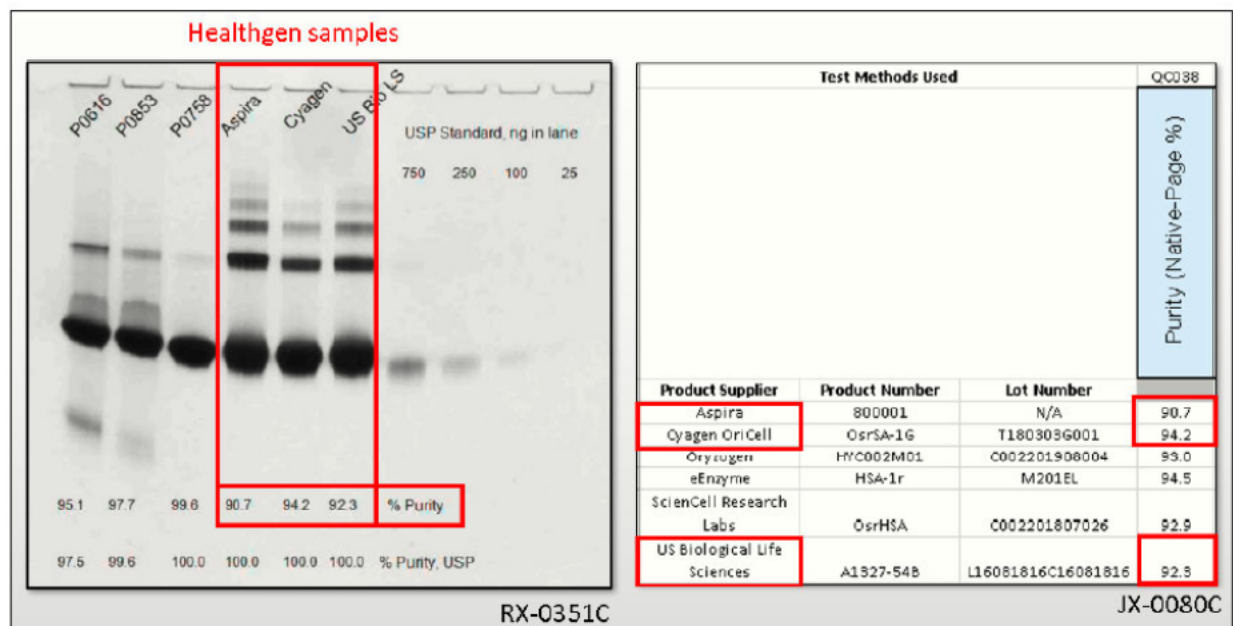
at 62. However, Ventria does not explain how the characterization of the purification process shows that Healthgen's medium grade Accused Products must have an aggregated albumin content of less than 2%. Moreover, any such characterizations are less weighty than testing data on the actual products, which show that the medium grade Accused Products have more than 2% aggregated albumin.

Healthgen, on the other hand, pointed to Ventria's pre-litigation testing of nine medium grade Accused Products using Native-PAGE and reducing SDS-PAGE. Those testing results are presented below and all show that the amount of aggregated albumin is greater than 2%:

Grade of product	Aggregated Albumin	Monomeric Albumin	Assay (Party Responsible for Testing)	Citation
medium	9.3%	90.7%	Native-Page (Ventria)	JX-0080C
medium	5.8%	94.2%	Native-Page (Ventria)	JX-0080C
medium	7.0%	93.0%	Native-Page (Ventria)	JX-0080C
medium	5.5%	94.5%	Native-Page (Ventria)	JX-0080C
medium	7.1%	92.9%	Native-Page (Ventria)	JX-0080C
medium	7.7%	92.3%	Native-Page (Ventria)	JX-0080C
medium	9.67%	86.20%	Reducing SDS-PAGE (Ventria)	JX-0129.0007
medium	6.82%	90.36%	Reducing SDS-PAGE (Ventria)	JX-0129.0007
medium	7.27%	86.28%	Reducing SDS-PAGE (Ventria)	JX-0129.0007

RPet. at 6. Ventria does not dispute that the reducing SDS-PAGE test results show non-infringement, but instead dismisses them as outliers that are outweighed by the other evidence of infringement. *See, e.g.*, CPHBr. at 64. In addition, Ventria asserts that the Native-PAGE test results are “meaningless” because the underlying testing did not use molecular weight standards to determine the molecular weights of the species that are included in calculating the aggregate albumin percentage. *See, e.g.*, CBr. at 39. Ventria reasons that the molecular weight of those species is necessary to determine if the species can be properly considered “aggregated albumin.” *See, e.g., id.* at 36–39.

Considering the evidence as a whole, the Commission finds that Ventria has not established by a preponderance of the evidence that the medium grade Accused Products infringe the asserted claims of the Asserted Patent. Ventria's own pre-litigation testing data weighs heavily against Ventria's argument that it is more likely than not that the medium grade Accused Products meet the "less than 2% aggregated albumin" limitation. This is so regardless of whether the Native-PAGE data are considered. Moreover, even if molecular weight markers or standards are needed to quantify which species are properly considered "aggregated albumin," the Native-PAGE data would still corroborate the reducing SDS-PAGE data because even a visual inspection of the Native-PAGE data shows that the medium grade Accused Products are very impure:



RX-0351C (Ventria's Native-PAGE gel, annotated); JX-0080C (report of Ventria's pre-litigation testing, annotated). The above test results show the presence of a significant amount of albumin species above the main band.

In sum, the weight of the evidence is that Ventria has not shown that the medium grade Accused Products infringe the asserted claims of the Asserted Patent. This conclusion would not change even if the customer communications Ventria points to concern “aggregated albumin,” as opposed to “total albumin.” The customer communications and related data are from 2013 and 2011, respectively, and therefore prior to the issuance of the Asserted Patent. Ventria’s testing data is much more recent and is more representative of Healthgen’s Accused Products after the issuance of the patent.⁴² The final ID is reversed on this issue.

V. THE DOMESTIC INDUSTRY REQUIREMENT

A. The Applicable Law

When a section 337 investigation is based on allegations of patent infringement, the complainant must show that “an industry in the United States, relating to the articles protected by the patent . . . exists or is in the process of being established.” 19 U.S.C. § 1337(a)(2).

[A]n industry is considered to exist if there is in the United States, with respect to the articles protected by the patent . . . concerned –

(A) significant investment in plant and equipment;

(B) significant employment of labor or capital; or

(C) substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3).

⁴² Ventria argues that the data in He and the He Supporting Information were shared “as recently as 2018.” CPHBr. at 63 (citing CDX-0007C at 6). CDX-0007C is a demonstrative exhibit that refers to JX-0023 (Yang), which appears to be a chapter in a textbook titled “Transgenic Rice for the Production of Recombinant Pharmaceutical Proteins: A Case Study of Human Serum Albumin,” authored by Dr. Yang. However, the chapter is credited to Yang, not Healthgen, and does not include representations about how Healthgen’s medium grade Accused Products in particular were manufactured at or around that time. Moreover, Yang does not include a date on which any manuscript was submitted for publication.

The “domestic industry requirement” consists of a so-called “technical prong” and a so-called “economic prong.” A complainant satisfies the technical prong by showing it is practicing, licensing, or otherwise exploiting the patents at issue. *Certain Microsphere Adhesives, Process for Making Same and Products Containing Same, Including Self-Stick Repositionable Notes*, Inv. No. 337-TA-366, Comm’n Op. at 8 (Jan. 16, 1996). The test for “practicing” a patent is essentially the same as it is for infringement, only it involves comparing the complainant’s own “domestic industry products” to one or more claims of the patent. *Alloc, Inc. v. Int’l Trade Comm’n*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). It is sufficient that the domestic industry product practices at least one claim of each patent that serves as a basis for relief; it is not necessary for the complainant to practice the same claims it is asserting against the respondent. *Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm’n Op. at 38 (Aug. 1, 2007).

B. Ventria’s Optibumin Satisfies the Domestic Industry Requirement

Healthgen concedes that Ventria’s Optibumin product satisfies the technical prong of the domestic industry requirement. *See, e.g.*, Final ID at 58; Tr. (DeFilippi) at 1243:22–1244:5. However, Healthgen contests that Ventria’s Cellastim, Exbumin, OptiPEAK, OptiVERO, or ITSE+A practice the asserted claims of the Asserted Patent. *See, e.g.*, Final ID at 58. The final ID found that Ventria satisfies the economic prong of the domestic industry requirement if all six Domestic Industry Products practice the Asserted Patent, *see id.* at 100–07; and, also alternatively, if Optibumin is the only product that practices the Asserted Patent, *see id.* at 107–111.

The Commission affirms and adopts the final ID’s finding that Ventria has satisfied the domestic industry requirement (both technical and economic prongs) based on Optibumin alone. The Commission takes no position on the final ID’s finding that Cellastim, Exbumin,

OptiPEAK, OptiVERO, or ITSE+A practice the Asserted Patent and the final ID’s finding that the economic prong of the domestic industry requirement is satisfied based on all six Domestic Industry Products practicing the Asserted Patent. *See Beloit*, 742 F.2d at 1423.

VI. REMEDY, BONDING, AND THE PUBLIC INTEREST

A. Remedy

The Commission has “broad discretion in selecting the form, scope, and extent of the remedy.” *Viscofan, S.A. v. US. Int’l Trade Comm’n*, 787 F.2d 544, 548 (Fed. Cir. 1986).

1. General Exclusion Order

In this investigation, three respondents defaulted without appearing, but respondent Healthgen appeared and participated in the investigation. Therefore, section 337(d)(2) provides the correct legal framework to analyze whether a general exclusion order (“GEO”) is an appropriate remedy. *See Certain Water Filters & Components Thereof*, Inv. No. 337-TA-1126, Comm’n Op. at 5–6 (Nov. 15, 2019). Section 337(d)(2) provides that “[t]he authority of the Commission to order an exclusion from entry of articles shall be limited to persons determined by the Commission to be violating this section unless the Commission determines that—(A) a general exclusion from entry of articles is necessary to prevent circumvention of an exclusion order limited to products of named persons; or (B) there is a pattern of violation of this section and it is difficult to identify the source of infringing products.” 19 U.S.C. § 1337(d)(2); *see also* 19 C.F.R. § 210.50(c). The RD recommended that a GEO not issue. The Commission has determined that a GEO is not warranted under either 19 U.S.C. §§ 1337(d)(2)(A) or (B).

a. 19 U.S.C. § 1337(d)(2)(A)

To determine whether a GEO is appropriate under section 337(d)(2)(A), the Commission considers whether the “general exclusion of entry of articles is necessary to prevent circumvention of an exclusion order limited to products of named persons.” 19 U.S.C.

§ 1337(d)(2)(A). The Commission has previously considered “(1) whether conditions are ripe for circumvention, and (2) the appearance of circumvention.” *Certain Lighting Control Devices Including Dimmer Switches & Parts Thereof (IV)*, Inv. No. 337-TA-776, Comm’n Op. at 8 (Nov. 8, 2012). In determining whether conditions are “ripe” for circumvention, the Commission has considered a variety of factors in determining whether a GEO is necessary to prevent circumvention, in particular examining whether there are conditions that would allow or facilitate circumvention. *See, e.g., Certain Lighting Control Devices Including Dimmer Switches & Parts Thereof (IV)*, Inv. No. 337-TA-776, Comm’n Op. at 8, 23–25 (Nov. 8, 2012); *Certain Inkjet Ink Supplies & Components Thereof*, Inv. No. 337-TA-730, Comm’n Op. at 4–5 (Feb. 24, 2012). In this case, the record does not show that the conditions are such that a GEO is necessary to prevent circumvention.

Initially, the record shows that Ventria and Healthgen are the only manufacturers of the products within the scope of the investigation. *See* Tr. (Deeter) at 276:22–277:9 (confirming that Healthgen and Ventria are the only manufacturers of rice-derived rHSA products); Tr. (Curl⁴³) at 639:2–10 (“I believe I’ve seen Orybio in the past as a potential manufacturer, but today, you know, based on my research, Wuhan Healthgen, Oryzogen, is the only rice-derived recombinant human serum albumin manufacturer other than Ventria Bioscience”); Tr. (LaMotta⁴⁴) at 769:25–770:7 (“I’m only aware of Ventria and Healthgen that manufacture a rice-derived rHSA at all.”). Ventria presented evidence demonstrating that foreign non-party

⁴³ Mr. Marcus Hofer-Curl, a fact witness for Ventria, is the Director of Product Applications at Ventria and has worked there about three and a half years. Tr. (Curl) at 579:25–580:9.

⁴⁴ Mr. Ryan LaMotta is Ventria’s expert witness on domestic industry, remedy, and bonding. Tr. (LaMotta) at 647:15–24. He has a BBA and MBA from Baylor University, is a Director of ASQ Consulting Group, and has experience in accounting and financial analysis. *Id.* at 645:24–647:18.

imported or sold for importation a limited amount of the Accused Products to United States non-party [REDACTED]. *See* CPHBr. at 102; CX-0217C; CX-1080C (Cao Dep. Tr.) at 23:16–24:9. However, even in that instance, the ultimate source of the rHSA product was Healthgen. Tr. (LaMotta) at 772:16–23. That Ventria and Healthgen are the only manufacturers of Accused Products strongly suggests that an LEO directed to Healthgen will be sufficient to exclude infringing goods from the United States.

Similarly, there is no evidence of a widespread marketing and distribution network with multiple intermediaries. Rather, the evidence indicates that the Accused Products are generally sold for importation into the United States by Healthgen and imported into the United States by its United States distributors. The evidence showed that Healthgen generally ships its products

[REDACTED]. See CX-1080C (Cao Dep. Tr.) at 49:18–
50:9, 53:3–16. For two customers, eEnzyme and ScienCell, the products are shipped [REDACTED]

[REDACTED]. *Id.* at 54:10–55:1. In either case, the chain of distribution into the United States appears relatively clear.

Ventria points out that third party [REDACTED] imported the Accused Products into the United States from third party [REDACTED] and argues that this importation, which involved only third parties, shows that a LEO could be circumvented. *See* CBr. at 68–69. However, this evidence includes invoices, but not shipping documents or packaging, so it is difficult to assess whether the imported packages identified Healthgen as the original manufacturer. *See* CX-0218C ([REDACTED]). [REDACTED] asserted in a letter that it was not aware that the products came from Healthgen until it contacted [REDACTED] to ask. *See*

CX-0217C. The invoices from [REDACTED], however, do identify the brand name of the Accused Products, “OsrHSA.” *See* CX-0218C ([REDACTED]). Ventria’s expert, Mr. LaMotta, thus agreed that the invoices show that, while [REDACTED] may not have known whether the products were coming from Healthgen, it was clear that they were buying OsrHSA, and Healthgen is the only company that makes OsrHSA. *See* Tr. (LaMotta) at 772:16–23. Moreover, while the presence of many foreign distributors might evidence that conditions are ripe for circumvention, here the evidence showed only a limited number of sales by a single foreign entity, and modest amounts at that. *See* CX-0217C (indicating that non-party [REDACTED] [REDACTED]).⁴⁵ Further, an LEO would extend to products manufactured and sold for importation by Healthgen but imported by a third party, and thus would extend to future sales by entities such as [REDACTED].

There is also little evidence of an increase in demand for the Accused Products that would suggest that circumvention of an LEO is likely. Healthgen’s sales data shows that Healthgen had approximately twenty United States customers total for 2017–2021, and on the order of approximately a dozen customers per year. CX-0019C; CX-0033C. The data does not show any rapid increase in demand for Healthgen’s Accused Products.

Furthermore, there are not low barriers to entry into this market, and the infringing products do not appear to be extremely profitable. Ventria’s expert, Mr. LaMotta, testified that if Ventria sold its products at the same price that Healthgen sold its products, Ventria would incur a loss because of the large investment necessary to develop rice-derived rHSA products. Tr. (LaMotta) at 773:4–20. Mr. LaMotta also testified that developing rice-derived rHSA

⁴⁵ By comparison, Healthgen itself sold a total of nearly [REDACTED] [REDACTED]. RX-0300C.

products requires a long lead time and substantial investments in time, employees, equipment, and land. *Id.* at 773:21–774:1. This evidence demonstrates that the barriers to entry into this market are quite high. This is also consistent with the fact that there are only two sources of the products within the scope of this Investigation: if the barriers were low, it would be reasonable to expect that more than just two companies (*i.e.*, Ventria and Healthgen) would be making and selling the products. Thus, the evidence weighs against finding that conditions are ripe for circumvention.

Furthermore, the evidence does not show that it will be difficult for United States Customs and Border Protection (“CBP”) to identify the source of infringing goods. Healthgen’s corporate witness, Ms. Cao, testified that it is standard practice for Healthgen to include a sales contract, commercial invoice, packing list, certificate of analysis, and FedEx label with all shipments to United States customers. *See* CX-1080C (Cao Dep. Tr.) at 186:14–187:7; JX-0034C. A FedEx label that Healthgen provided to one of its customers identifies that the package is from “Wuhan Healthgen Biotechnology” and contains “Recombinant Human Serum Albumin (OsrHSA).” *Id.* Hearing testimony confirmed that the brand name “OsrHSA” is unique to Healthgen, which further identifies that the source of the goods in the package are from Healthgen. Tr. (Deeter) at 279:18–280:1 (testifying that Healthgen is the only company that sells rice-derived rHSA products branded as OsrHSA); Tr. (Curl) at 639:2–10 (same); Tr. (LaMotta) at 769:25–770:7 (same). Thus, the evidence does not show that conditions are ripe for circumvention.

Ventria argues that Healthgen does business under several different names, implying that the name changes would assist Healthgen in circumventing an LEO. CBr. at 69. However, because there is only a single manufacturer of the Accused Products (*i.e.*, Healthgen), it is

unlikely that Healthgen would change its corporate name to avoid an LEO and remain undetected in doing so. Turning to the names themselves, most of the different names (Healthgen Biotechnology, Co. Ltd; Healthgen Biotechnology Corp.; Wuhan Healthgen Biotechnology Corp.; and Healthgen Biotechnology Co.) are all slight variations involving the same name “Healthgen Biotechnology” and thus do not suggest the names were changed for evasion purposes. CDX-0002C at 57 (annotated).

Ventria also argues that Healthgen is “known to operate under the name ‘Oryzogen’ and previously under ‘OryBio.’” CBr. at 69. But “Oryzogen” appears to be a brand name or trade name that Healthgen does business under, and Ventria’s fact and expert witnesses confirmed that it was a name uniquely associated with Healthgen. *E.g.*, Tr. (Deeter) at 279:5–12, (identifying the Oryzogen brand name on a label shown on CX-0840), 280:14–17 (testifying that he was not aware of any manufacturers other than Healthgen that make an rHSA product under the brand name Oryzogen).

Ventria also argues that “(former) distributors of Healthgen testified they did not know the exact, official name of the company.” CBr. at 69. But the deposition testimony of Mr. Hiddemann of Antibodies-Online and Mr. Shore of US Biological⁴⁶ show that Healthgen’s names have not changed in a way that would allow it to evade an LEO. Rather, both witnesses testified that they understood the slight variations to refer to the same entity. *See* RX-0008C (Hiddemann Dep. Tr.) at 15:3–16; RX-0009C (Shore Dep. Tr.) at 17:13–21, 35:8–12. Mr. Shore from US Biological also testified that [REDACTED]

[REDACTED]

⁴⁶ These are the “(former) distributors of Healthgen” on whose testimony Ventria relies. *See* CBr. at 69.

[REDACTED]

[REDACTED] See RX-0009C (Shore Dep. Tr.) at 64:11–65:9. The evidence in the record from Antibodies-Online and US Biological, including invoices, purchase orders, and shipping labels, also appear to consistently identify Healthgen, Oryzogen, and/or OsrHSA. CX-0008C (invoice and shipping label); CX-0068C (invoice); CX-0079C (invoices, purchase orders, and shipping labels).

Ventria further argues that “importation of the Accused Products is not conducted by Healthgen,” which allegedly means that an LEO directed to Healthgen could be circumvented. CBr. at 69–70. This argument is not persuasive for at least two reasons. First, the Commission’s LEO includes a direction to CBP that Accused Products that infringe the asserted claims that are manufactured abroad by or on behalf of, or imported by or on behalf of, the Respondents, are excluded from entry for consumption into the United States. Moreover, the Commission’s LEO includes language stating that the order applies to “affiliated companies, parents, subsidiaries, or other related business entities” of the named Respondents. Second, although Healthgen’s terms of sale generally [REDACTED]

[REDACTED]

[REDACTED], the evidence showed that the FedEx shipping labels provided by Healthgen still identify the sender as Healthgen. See JX-0033C–JX-0038C (shipping invoices and labels); CX-0023C (CBP Form 7501 identifying Healthgen in Box 13 with manufacturer ID “CNWUHHEA666WUH”). This evidence thus shows that CBP would be able to identify that the source of an imported product was Healthgen, and thus, that the product was subject to an LEO.

Ventria finally argues that “sales of the accused products often lack any identification of the Chinese origin of such articles, which could further lead to circumvention.” CBr. at 70.

However, Ventria’s evidence showed at best that (some) United States distributors obscure the manufacturer or country of origin after importation, which would not have any impact on CBP’s ability to enforce an exclusion order at the time of importation. *See* Tr. (Curl) at 607:2–609:15; Compl., Ex. 18; RX-0009C (Shore Dep. Tr.) at 24:19–24, 30:22–31:21, 67:7–25; CX-0080C.

In sum, the record does not show that a GEO is necessary to prevent circumvention of an LEO. The Commission therefore declines to issue a GEO under section 337(d)(2)(A).

b. 19 U.S.C. § 1337(d)(2)(B)

As to section 337(d)(2)(B), the evidence does not show the existence of a pattern of violation or difficulty identifying the source of Accused Products. First, there is only a single source of the Accused Products: Healthgen. *See, e.g.*, Tr. (Deeter) at 276:22–277:9; Tr. (Curl) at 639:2–10; Tr. (LaMotta) at 769:25–770:7. The evidence indicates that all of the companies identified as buying or importing the Accused Products are buying and importing those products from Healthgen. There is no pattern of violation to support a GEO where the “Respondents accounted for all of the infringing imported products” and the “Complainants have failed to identify a single act of importation that is unrelated to one of the Respondents.” *Certain Self-Cleaning Litter Boxes & Components Thereof*, Inv. No. 337-TA-625, Comm’n Op. at 56 (Apr. 28, 2009). Here, like in *Self-Cleaning Litter Boxes*, every act of importation (but one)⁴⁷ is related to one of the Respondents, *i.e.*, Healthgen.

⁴⁷ As noted above, Ventria presented evidence demonstrating that foreign non-party [REDACTED] imported or sold for importation a limited amount of the Accused Products to United States non-party [REDACTED]. However, even in that instance, the ultimate source of the Accused Products was identifiable as Healthgen. Tr. (LaMotta) at 772:16–23.

Second, it is not difficult to identify the source of the Accused Products because there is only one foreign source. *See Certain Cast Steel Rwy. Wheels, Certain Processes for Mfg. or Relating to Same & Certain Prods. Containing Same*, Inv. No. 337-TA-655, RD at 6 n.4 (Mar. 9, 2010), *adopted in relevant part on review* (noting that complainant had not attempted to show that there would be difficulty identifying the source of infringing goods, and explaining that “one would not expect it to be difficult to identify the source of a finished product such as a railway wheel in view of the relatively small number of manufacturers that complainant has referred to in the record”). Ventria’s products are produced domestically and are not imported. Thus, the only known source of imported rice-derived rHSA products is Healthgen.

Moreover, the record shows that the Accused Products are shipped in packages that identify Healthgen, if not by company name, then at least by brand name, *i.e.*, OsrHSA. *See* JX-0033C–JX-0038C; CX-0008C (shipping labels and invoices); RX-0009 (Shore Dep. Tr.) at 47:12–20, 66:12–16. The same evidence also reflects that the source of infringing goods is readily identifiable. *See Self-Cleaning Litter Boxes*, Comm’n Op. at 56–57 (explaining that “the ‘source’ of the infringing products” was not difficult to identify because it was “undisputed that all of the[] imported products are the Respondents” and “each Respondent is clearly identified on its products and the products’ packaging”). Accordingly, the evidence does not show that it would be difficult to identify the source of infringing goods, and a GEO under section 337(d)(2)(B) is not warranted in this investigation.

2. Limited Exclusion Order

Section 337(d)(1) provides that “[i]f the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded

from entry into the United States, unless, after considering the [public interest], it finds that such articles should not be excluded from entry.” 19 U.S.C. § 1337(d)(1).

Section 337(g)(1) provides:

(1) If—

(A) a complaint is filed against a person under this section;

(B) the complaint and a notice of investigation are served on the person;

(C) the person fails to respond to the complaint and notice or otherwise fails to appear to answer the complaint and notice;

(D) the person fails to show good cause why the person should not be found in default; and

(E) the complainant seeks relief limited solely to that person;

the Commission shall presume the facts alleged in the complaint to be true and shall, upon request, issue an exclusion from entry or a [CDO], or both, limited to that person unless, after considering the effect of such exclusion or order upon [the public interest], the Commission finds that such exclusion or order should not be issued.

19 U.S.C. § 1337(g)(1).

Ventria requests that the Commission issue an LEO to Healthgen and the Defaulting Respondents if the Commission does not issue a GEO. The Commission has determined to issue an LEO to Healthgen under section 337(d)(1) regarding Ventria’s patent-based allegations and to the Defaulting Respondents under section 337(g)(1) for both Ventria’s patent-based allegations and the false designation of origin allegations. *See* 19 U.S.C. § 1337(d)(1); 19 U.S.C. § 1337(g)(1); *Laerdal Med. Corp. v. Int’l Trade Comm’n*, 910 F.3d 1207, 1215 (Fed. Cir. 2018).

The issued LEO includes a certification provision, consistent with the Commission’s now general practice for exclusion orders, as requested by CBP. *See Certain Road*

Construction Machines & Components Thereof, Inv. No. 337-TA-1088, Comm’n Op. at 50 (July 15, 2019). The Commission disagrees with Ventria’s assertion that a certification provision would “invite foul play,” *see* CBr. at 71, because the provision can only be used for products that have been explicitly adjudicated as non-infringing, *Certain Composite Aerogel Insulation Materials and Methods for Manufacturing the Same*, Inv. No. 337-TA-1003, Comm’n Op. at 62 (Feb. 22, 2018) (declaring that CBP “only accepts a certification that the goods have been previously determined by CBP or the Commission not to violate the exclusion order”). Additionally, “[c]ertification provisions aid [CBP] in enforcing Commission orders but do not mandate that CBP accept certification as proof that the articles in question are not covered by the [LEO].” *See, e.g., Certain Robotic Vacuum Cleaning Devices & Components Thereof Such as Spare Parts*, Inv. No. 337-TA-1057, Comm’n Op., 2019 WL 1292948, at *36 (Feb. 1, 2019) (internal quotation marks omitted). The certification provision requires Healthgen to substantiate its certification with testing data using a methodology found acceptable by this Commission Opinion that demonstrates that the products to be imported do not have less than 2% aggregated albumin. Such substantiation may be in the form of a COA, such as the one in the record at CX-0450. While the medium grade Accused Products that were tested in this investigation were found to be non-infringing, Respondents’ future entries of imports must each be shown to be non-infringing (*i.e.*, have 2% or more aggregated albumin) through appropriate testing presented to CBP upon importation, regardless of whether the imports are labeled as “medium grade” or “culture grade.” The Commission notes that the nomenclature of the product is not necessarily indicative of the amount of aggregated albumin that will be present in future imports.

The LEO is not directed to the specific products found to infringe the asserted claims of the Asserted Patent, but is rather more generally directed to all products covered by the patent claims as to which a violation has been found. *See, e.g., Certain Optical Disk Controller Chips & Chipsets & Prods. Containing Same, Including DVD Players & PC Optical Storage Devices*, Inv. No. 337-TA-506, Comm’n Op. at 56–57 (Aug. 7, 2006). Healthgen argues that the LEO should include an exception allowing the Accused Products to be used for experimental purposes. RBr. at 63–64. However, Healthgen cites no evidence showing that such an exemption is warranted.

Healthgen argues that “no separate remedial order(s) should issue based on unproven and unsupported Lanham Act allegations.” RBr. at 69; *see also id.* at 69–71. Healthgen asserts that 19 U.S.C. § 1337(g)(1) does not apply here because one condition of section 337(g)(1) is not met, namely that “the complainant seeks relief solely limited to that person.” RBr. at 69. Healthgen reasons that Ventria also sought relief against Healthgen, and therefore it does not seek relief solely limited to the Defaulting Respondents. *Id.* at 70–71. According to Healthgen, “[b]ecause Ventria also seeks relief against Healthgen, a different statutory provision governs: 19 U.S.C. § 1337(d)(1),” and that, under that statute, Ventria was required to, but did not, prove a violation of section 337 arising out of the Lanham Act claim. *Id.* at 71.

First, Healthgen waived this argument by not presenting it to the ALJ. Second, the Commission finds that the conditions of 19 U.S.C. § 1337(g)(1) are met with regard to each Defaulting Respondent, and therefore, the Commission is required to “presume the facts alleged in the complaint to be true and shall, upon request, issue an exclusion from entry or a [CDO], or both, limited to that person,” subject only to consideration of the public interest factors. 19 U.S.C. § 1337(g)(1); *Laerdal*, 910 F.3d at 1212. Healthgen’s view to the contrary is

inconsistent with the plain language of the statute, as well as past Commission practice interpreting the statute.

For a party that defaults, section 337(g)(1) does not require a violation to be proven based on substantial, reliable, and probative evidence. Here, the conditions in 337(g)(1)(A)–(E) are met. Specifically, with respect to subsection 337(g)(1)(E), Complainant has requested, in part, an LEO (and not a GEO) with respect to each of the Defaulting Respondents. An LEO is, by definition, limited to each such respondent, and each Defaulting Respondent was named in the complaint and notice of investigation as allegedly violating section 337. Because the conditions in subsections 337(g)(1)(A)–(E) are met, the Commission presumes the facts alleged in the complaint to be true as to a violation of section 337 with respect to the infringement claim and the false designation of origin claim, and is issuing an LEO based upon Ventria’s request that an LEO be directed to the named defaulting parties.

The Commission has consistently interpreted section 337 in this manner, both before and after the 1988 amendments to section 337. *See, e.g., Certain Elec. Skin Care Devices, Brushes & Chargers Therefor, & Kits Containing the Same*, Inv. No. 337-TA-959, Comm’n Op. at 20, (Feb. 13, 2017); *Certain Agric. Vehicles & Components*, Inv. No. 337-TA-487, Comm’n Op. at 2–3 (Sep. 24, 2004); *Certain Airtight Cast-Iron Stoves*, Inv. No. 337-TA-69, Comm’n Op. at 15–16 (Dec. 31, 1980).

3. Cease and Desist Orders

Section 337(f)(1) provides that in addition to, or instead of, the issuance of an exclusion order, the Commission may issue a CDO as a remedy for violation of section 337. *See* 19 U.S.C. § 1337(f)(1). Relatedly, section 337(g)(1) provides that when the requirements of subparts (A)–(E) are met, subject to public interest considerations, the Commission “shall presume the facts alleged in the complaint to be true and shall, upon request, issue an exclusion

from entry or a cease and desist order, or both, limited to that person.” 19 U.S.C. § 1337(g)(1). CDOs are generally issued when, with respect to the imported infringing products, respondents maintain commercially significant inventories in the United States or have significant domestic operations that could undercut the remedy provided by an exclusion order.⁴⁸ *See, e.g., Certain Table Saws Incorporating Active Injury Mitigation Tech. & Components Thereof*, Inv. No. 337-TA-965, Comm’n Op. at 4–6 (Feb. 1, 2017); *Certain Protective Cases & Components Thereof*, Inv. No. 337-TA-780, USITC Pub. No. 4405, Comm’n Op. at 28 (Nov. 19, 2012) (citing *Certain Laser Bar Code Scanners & Scan Engines, Components Thereof & Prods. Containing Same*, Inv. No. 337-TA-551, Comm’n Op. at 22 (June 24, 2007)). For CDOs under section 337(f)(1), Complainants bear the burden of proof on this issue. “A complainant seeking a CDO must demonstrate, based on the record, that this remedy is necessary to address the violation found in the investigation so as to not undercut the relief provided by the exclusion order.” *Table Saws*, Comm’n Op. at 5 (citing *Certain Integrated Repeaters, Switches, Transceivers, & Prods. Containing Same*, Inv. No. 337-TA-435, USITC Pub. No. 3547 (Oct. 2002), Comm’n Op. at 27 (Aug. 16, 2002); *see also* H.R. REP. No. 100-40, at 160 (1987)). In the case of named respondents in the United States who have been found in default or who have not participated in the investigation, the Commission has inferred commercially significant domestic inventories or significant domestic operations with respect to the infringing articles. *See, e.g., Certain Elec.*

⁴⁸ When the presence of infringing domestic inventory or domestic operations is asserted as the basis for a CDO under section 337(f)(1), Commissioner Schmidtlein does not adopt the view that the inventory or domestic operations needs to be “commercially significant” in order to issue the CDO. *See, e.g., Certain Magnetic Tape Cartridges & Components Thereof*, Inv. No. 337-TA-1058, Comm’n Op. at 65 n.24 (Apr. 9, 2019); *Table Saws*, Comm’n Op. at 6 n.2 (Feb. 1, 2017). In Commissioner Schmidtlein’s view, the presence of some infringing domestic inventory or domestic operations, regardless of its commercial significance, provides a basis to issue a CDO.

Nicotine Delivery Sys. & Components Thereof, Inv. No. 337-TA-1139, Comm’n Op. at 14–15 (May 5, 2020); *Certain Earpiece Devices & Components Thereof*, Inv. No. 337-TA-1121, Comm’n Op. at 41–42 (Nov. 8, 2019); *Certain Hand Dryers & Housing for Hand Dryers*, Inv. No. 337-TA-1015, Comm’n Op. at 24 (Oct. 30, 2017); *Certain Mobile Device Holders & Components Thereof*, Inv. No. 337-TA-1028, Comm’n Op. at 27 (Mar. 22, 2018); *Certain Agric. Tractors, Lawn Tractors, Riding Lawnmowers, & Components Thereof*, Inv. No. 337-TA-486, Comm’n Op. at 18 (Aug. 19, 2003); *Certain Rare-Earth Magnets & Magnetic Materials & Articles Containing Same*, Inv. No. 337-TA-413, USITC Pub. No. 3307, Comm’n Op. at 17–18 (May 2000).

The evidence does not support issuing a CDO to Healthgen, a foreign entity, under section 337(f)(1). Healthgen does not hold a commercially significant inventory in the United States and has no significant domestic operations.⁴⁹ Ventria’s expert, Mr. LaMotta, testified that he was not aware of any Healthgen employees or facilities in the United States, or any domestic operations beyond selling the products into the United States. Tr. (LaMotta) at 767:25–768:11. Healthgen’s expert, Mr. Reed,⁵⁰ confirmed that Healthgen has no United States inventory or operations. Tr. (Reed) at 1327:3–8. Moreover, Healthgen ships most of its products “[REDACTED],” CX-1080C (Cao Dep. Tr.) at 49:18–50:9, 53:3–16, which shows that Healthgen does not need to maintain inventory in the United States because [REDACTED]

⁴⁹ Commissioner Schmidlein agrees the evidence does not support issuing a CDO as to Healthgen in this case. *See supra* note 48.

⁵⁰ When he testified on November 10, 2021, Mr. Brett Reed was the co-founder and Director of Competition Economics LLC. RD at 122 n.43. Healthgen identified Mr. Reed as an expert to testify about domestic industry, remedy, and bond. *Id.*

However, the Commission has determined to issue CDOs to the Defaulting Respondents as to both infringement of the Asserted Patent and the false designation of origin claims under section 337(g)(1). Each of the Defaulting Respondents is a domestic entity, and thus is presumed to hold commercially significant inventory in the United States.⁵¹ *See Certain Stainless Steel Prods., Certain Process for Mfg. or Relating to Same, & Certain Prods. Containing Same*, Inv. No. 337-TA-933, Comm’n Op. at 41 (June 9, 2016).

B. Public Interest

Section 337 requires the Commission, upon finding a violation of section 337, to issue an LEO “unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.” 19 U.S.C. §§ 1337(d)(1) & (g)(1). Similarly, the Commission must consider these public interest factors before issuing a CDO. 19 U.S.C. §§ 1337(f)(1) & (g)(1).

⁵¹ Commissioners Schmidlein and Karpel agree that section 337(g)(1) is the appropriate authority for the issuance of the requested CDOs but their reasoning differs from the Majority. Specifically, they support issuance of the CDOs against the Defaulting Respondents because the criteria for issuance of CDOs under subsection 337(g)(1)(A)–(E) are met as to these respondents. 19 U.S.C. § 1337(g)(1)(A)–(E). Here, Ventria has requested CDOs as to the Defaulting Respondents (*see, e.g.*, CBr. at 68 and n.27, 71–72), and the Commission has determined the conditions of subsections 337(g)(1)(A) through (D) have been satisfied. *See supra* Section VI.A.2. Given that subsections 337(g)(1)(A)–(E) are satisfied, the statute directs the Commission to issue the requested CDOs, subject to consideration of the public interest. The public interest factors as detailed in Section VI.B. *infra* do not support a finding that CDOs directed to the Defaulting Respondents would be contrary to the public interest. Accordingly, Commissioners Schmidlein and Karpel support issuance of the CDOs under section 337(g)(1) for the reasons provided in this footnote.

Under appropriate facts and circumstances, the Commission may determine that no remedy should issue because of the adverse impacts on the public interest. *See, e.g., Certain Fluidized Supporting Apparatus & Components Thereof*, Inv. Nos. 337-TA-182/188, USITC Pub. 1667, Comm’n Op. at 1–2, 23–25 (Oct. 1984) (finding that the public interest warranted denying the complainant’s requested relief). Moreover, when the circumstances of a particular investigation require, the Commission has tailored its relief in light of the statutory public interest factors. *E.g., Certain Microfluidic Devices*, Inv. No. 337-TA-1068, Comm’n Op. at 1, 22–48, 53–54.

The statute requires the Commission to consider and make findings on the public interest in every case in which a violation is found regardless of the quality or quantity of public interest information supplied by the parties. 19 U.S.C. §§ 1337(d)(1), (f)(1), and (g)(1). Thus, the Commission publishes a notice inviting the parties as well as interested members of the public and interested government agencies to gather and present evidence on the public interest at multiple junctures in the proceeding. *See* 19 U.S.C. §§ 1337(d)(1), (f)(1), and (g)(1). The Commission’s solicitation of public interest comments following the ALJ’s RD resulted in several submissions from third parties.⁵² The Commission did not receive any comments from

⁵² These third parties support Ventria’s request for relief, noting that the U.S. biotechnology industry should be protected from unfair competition from foreign actors and that Ventria is fully prepared to replace excluded products with its domestically-manufactured rHSA. *See* Kansas Attorney General Letter to US International Trade Commission regarding Ventria Biosciences Inc., EDIS Doc. ID 770135 (May 6, 2022); Kansas Chamber of Commerce Letter to USITC regarding Public Interest, EDIS Doc. ID 770160 (May 9, 2022); Public Interest Letter to Chairman Kearns and Commissioners from Senator Jerry Moran, EDIS Doc. ID 770162 (May 9, 2022); Letter from BioKansas to International Trade Commission in Support of Remedies, EDIS Doc. ID 770163 (May 9, 2022); Comments from the Office of Governor Jared Polis regarding Support for Remedies, EDIS Doc. ID 770164 (May 9, 2022); Letter regarding Public Interest to the United States International Trade Commission, EDIS Doc. ID 770166 (May 9, 2022) (filed on behalf of the Colorado BioScience Association); Letter of Support from

the public in response to the Commission's notice of review of the final ID, which also invited public interest comments from interested government agencies and interested persons.

The parties filed submissions on the public interest pursuant to Rule 210.50(a)(4)(i), 19 C.F.R. § 210.50(a)(4)(i), on May 9, 2022. Ventria states that exclusion of Healthgen's infringing rHSA will not impact the public interest factors particularly as alternative sources, including its own domestically-manufactured rHSA, are widely available. CStmt. at 3–4. Healthgen states that “excluding Healthgen's clinical grade rHSA products risks cutting short important academic and biomedical research and development of potential treatment.” RStmt. at 3. Healthgen also questions Ventria's ability to meet demand.

As reviewed below, the Commission finds that the public interest would not be adversely affected by the Commission's remedy.

1. The Public Health and Welfare

Healthgen argues that human serum albumin (HSA) “is a valuable biologic, which has been widely used clinically to treat numerous diseases, including hypovolemia, shock, burns, surgical blood loss, trauma, hemorrhage, cardiopulmonary bypass, acute respiratory distress syndrome, hemodialysis, acute liver failure, chronic liver disease, nutrition support, resuscitation, and hypoalbuminemia for decades.” RStmt. at 1; RBr. at 74. Healthgen additionally states that HSA is used as “an unreplaceable excipient for vaccines, therapeutic

the Office of Governor Laura Kelly to the ITC, EDIS Doc. ID 770167 (May 9, 2022); Letter from Members of the House of Representatives to the USITC regarding Investigation Remedies, EDIS Doc. ID 770168 (May 9, 2022) (filed on behalf of U.S. Representatives Ron Estes, Tracey Mann, and Jake LaTurner); CFPA Letter to ITC regarding Comments in Response to Commission Notice, EDIS Doc. ID 770169 (May 9, 2022); Public Interest Letter to the USITC regarding Investigation, EDIS Doc. ID 770170 (May 9, 2022) (filed on behalf of U.S. Representative Sharice Davids); Senators Bennet and Hickenlooper to ITC regarding Ventria Bioscience, EDIS Doc. ID 770171 (May 9, 2022).

proteins, and medical devices” and is “commonly used to promote cell growth and viability in cell culture media and widely used in academic and biomedical research.” RStmt at 1–2; RBr. at 74.

However, there is no specific evidence showing that the LEO and CDOs would harm the public health and welfare. Healthgen argues that its “rHSA products are a new generation of HSA products,” and that, “[a]mong other therapeutic uses, Healthgen’s clinical grade rHSA product is currently in Phase II trials for patients with cirrhosis and acute deterioration of liver function.” RBr. at 75. However, Healthgen does not dispute that the alleged Phase II trial takes place in China, and thus would not be affected by the Commission’s remedy. *See A Phase II, Multicenter, Randomized, Positive-Controlled, and Multi-Cohort Study of OsrHSA in Patients With Decompensated Cirrhotic Ascites*, ClinicalTrials.gov Identifier NCT04835480, (last updated Nov. 19, 2021), available at <https://www.clinicaltrials.gov/ct2/show/NCT04835480> (last visited July 22, 2022); *see also* CBr. at 78.

Plant-derived rHSA is “an alternative to traditional sources of commercial proteins—such as albumin expressed from animal, human and other natural hosts.” CStmt. at 4. Ventria notes that “Healthgen’s infringing rHSA is primarily applied in research and food/beverage contexts. While rHSA can be used in vaccines and therapeutics, nothing in the record indicates that Healthgen’s infringing rHSA is actively being used in this manner, much less in the United States.” *Id* at 3. Healthgen provides no evidence to substantiate its assertion that Healthgen’s clinical grade rHSA is used in “important academic and biomedical research and development of potential treatments” in the United States and thus that an LEO “risks cutting short” that research. RStmt. at 3; RBr. at 75. To the contrary, Healthgen claims it has “limited” knowledge as to its U.S. customers’ use of its rHSA. RBr. at 75 (“Healthgen is aware of the

general uses of rHSA, as discussed above; however, Healthgen's specific knowledge of the uses by individual customers is very limited.").

Ventria believes that most of Healthgen's customers are "in the cell-culture research space, and there is no evidence that any of them have used Healthgen's rHSA in the actual development of medicines or therapeutics." CBr. at 76. [REDACTED], Healthgen's largest customer, accounts for [REDACTED] of Healthgen's rHSA imported into the United States. Final ID at 126; Tr. (Reed) at 1328:18–1329:9. Ventria states that, based on [REDACTED]

[REDACTED]. CBr. at 76. [REDACTED], however, purchases only Healthgen's cell culture (medium) grade rHSA, which is not covered by the LEO. CX-1080C (Cao Dep.) at 82:13–20. Moreover, as discussed below, Ventria's products can substitute for Healthgen's infringing clinical grade Accused Products such that any health and welfare need for such products can be met by substituting Ventria's products or other traditional HSA products.

2. Competitive Conditions in the United States Economy

The evidence of record as to competitive conditions in the United States economy does not weigh against the Commission's remedy. There is no dispute that Ventria produces competitive articles in the United States. Moreover, the evidence shows that Ventria's products can substitute for the Accused Products. Healthgen's largest customer ([REDACTED]), which has purchased only medium grade rHSA, previously used Ventria's products and Mr. Curl of Ventria also confirmed that many of Ventria's and Healthgen's customers consider the Accused Products and the domestic industry products to be "identical" (other than with respect to the price). Tr. (Deeter) at 177:12–178:5; Tr. (Curl) at 635:17–24. As noted above, there are other sources of HSA available in the United States, including from traditional sources. And the

evidence further suggests that pHSA products are interchangeable with rHSA for some applications. *See, e.g.*, Tr. (DeFilippi) at 864:8–14; Tr. (Deeter) at 235:23–236:15; RX-0032; RX-0056C; Eswarappa, Veda, and Sujata K. Bhatia, *Biomaterial & Therapeutic Applications, Naturally Based Biomaterials and Therapeutics: The Case of India*, at 27–79 (Jul. 21, 2012), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7122290> (last visited July 25, 2022); He, Yang, *et al.*, *Large-scale production of functional human serum albumin from transgenic rice seeds*, *Proceedings of the National Academy of Sciences*, vol. 108, at 47 (2011), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3223471> (last visited July 25, 2022).

Healthgen questions Ventria’s ability to meet market demand. RStmt. at 3–4. However, because the Commission finds infringement only as to Healthgen’s clinical grade rHSA, Ventria has sufficient capacity to replace the volume of Healthgen clinical grade products imported into the United States. As noted, [REDACTED], which purchased [REDACTED] [REDACTED]. RX-300C; Tr. (Reed) at 1348:17–1349:3. Even if the remaining [REDACTED], it appears Ventria would have sufficient capacity to replace this volume. RX-301C at 1 (showing that Ventria sold [REDACTED]). This is particularly evident since Ventria has recently *doubled* its manufacturing capabilities. *See Ventria Bioscience has doubled biomanufacturing capacity for cell culture products* (May 3, 2022), available at <https://ventria.com/ventria-bioscience-has-doubled-biomanufacturing-capacity-for-cell-culture-products/> (last visited July 22, 2022).

Healthgen also argues that the public interest would be impacted because the domestic industry products are more expensive than the Accused Products. *See* RBr. at 75–76. However, Healthgen has provided no evidence to substantiate its position that the price difference between its products and those of Ventria would rise to the level of a public interest concern. Additionally, Healthgen cites no authority for the proposition that exclusion of infringing imports offered at lower prices in the United States would adversely impact competitive conditions in the U.S. economy sufficient to give rise to a cognizable public interest concern, nor does it offer facts to substantiate such an argument.

3. Production of Like or Directly Competitive Articles in the United States

The evidence indicates there would be no adverse impact of exclusion on the production of like or directly competitive articles in the United States. Ventria is the only U.S. producer of rice-derived rHSA products in the United States and its production would not be harmed by remedial relief. There is no evidence on the record that traditional suppliers of HSA products would be negatively impacted by remedial relief.

4. United States Consumers

The Commission finds that U.S. consumers would not be harmed by the exclusion of Healthgen’s infringing clinical grade Accused Products because Healthgen’s products do not fill a particular niche that Ventria’s products could not satisfy. Healthgen offers two arguments as to how exclusion could impact U.S. consumers: lower pricing of infringing imports and Ventria’s alleged inability to supply the market. *See* RBr. at 75–76. As noted above, Healthgen has provided no evidence to substantiate its position that the price difference between its products and those of Ventria would rise to the level of a public interest concern. We also note that the Commission has rejected such arguments in the past, explaining that “the protection of

intellectual property rights generally outweighs the right of consumers to the price advantages of infringing imports.” *Agric. Vehicles*, Comm’n Op. at 17.

As to the second argument, the evidence discussed above establishes that Ventria can adequately fill any void felt by United States consumers created by the exclusion of the infringing Healthgen clinical grade rHSA products, which comprise [REDACTED] of Healthgen’s U.S. sales during the most recent period for which data are available in the record. And, as discussed above, Ventria recently increased its production capacity. As Ventria’s witness, Mr. Curl, who is responsible for Ventria’s sales of its rHSA products testified, Healthgen principally competes with Ventria in the medium grade products. Tr. at 635:12–14 (“In my experience, it’s primarily—it’s the powder products from Oryzogen Healthgen that are competing with our products.”). Accordingly, the public interest factors do not warrant any change to the Commission’s remedy.

C. Bonding

If the Commission enters an exclusion order or a CDO, a respondent may continue to import and sell its products during the 60-day period of Presidential review under a bond in an amount determined by the Commission to be “sufficient to protect the complainant from any injury.” 19 U.S.C. § 1337(j)(3); *see also* 19 C.F.R. § 210.50(a)(3). When reliable price information is available in the record, the Commission has often set the bond in an amount that would eliminate the price differential between the domestic product and the imported, infringing product. *See Microsphere Adhesives*, Comm’n Op. at 24. The Commission also has used a reasonable royalty rate to set the bond amount where a reasonable royalty rate could be ascertained from the evidence in the record. *See, e.g., Certain Audio Digital-to-Analog Converters & Prods. Containing Same*, Inv. No. 337-TA-499, Comm’n Op. at 25 (Mar. 3, 2005). Where the record establishes that the calculation of a price differential is impractical or

there is insufficient evidence in the record to determine a reasonable royalty, the Commission has imposed a one hundred percent (100%) bond. *See, e.g., Certain Liquid Crystal Display Modules, Prods. Containing Same, & Methods Using the Same*, Inv. No. 337-TA-634, Comm'n Op. at 6–7 (Nov. 24, 2009). The complainant, however, bears the burden of establishing the need for a bond. *Certain Rubber Antidegradants, Components Thereof & Prods. Containing Same*, Inv. No. 337-TA-533, USITC Pub. No. 3975, Comm'n Op. at 40 (July 21, 2006).

The Commission has determined to set the bond during the period of Presidential review at one hundred percent (100%) of entered value. The bond applies to Healthgen and the Defaulting Respondents. It is undisputed that the private parties directly compete in the United States market for rice-derived rHSA. Ventria's economic expert, Mr. LaMotta, conducted an analysis studying pricing and competition through multiple lenses. *See* Tr. (LaMotta) at 704:9–25. That analysis showed that Healthgen is selling the Accused Products at a price that is [REDACTED] [REDACTED] lower than Ventria's prices for the Domestic Industry Products. *Id.* at 704:7–705:3, 705:4–706:1; CX-0019C (Healthgen sales data); CX-0888C (Ventria sales data); JX-0131C (Ventria sales data); CDX-0002 at 55–56. According to Mr. LaMotta, a 100% bond would provide a sufficient buffer for the actual price differential results (*i.e.*, [REDACTED] [REDACTED]). Tr. (LaMotta) at 717:2–7.

Healthgen argues that, if Ventria's domestic industry is limited only to Optibumin and/or only Healthgen's clinical grade Accused Product is found to infringe, then Ventria failed to present evidence comparing the prices of only the clinical grade Accused Products; and that the price differential analysis performed by its expert Mr. Reed supports only a bond amount between [REDACTED]. RPHBr. (Reply) at 80–81. We disagree. The evidence shows (as discussed in this paragraph) that the price difference between the liquid forms of the Accused

Product (which are now all clinical grade Accused Products) and Optibumin (which competes with Healthgen's products) supports a bond amount of at least 100%. Ms. Cao's deposition testimony confirms that Healthgen [REDACTED] [REDACTED]. CX-1080C (Cao Dep. Tr.) at 83:1–14, 99:8–100:12, 102:1–5, 102:14–16; CX-0050 at 0002; CX-0019C/CPX-0019C. According to Mr. Reed's Healthgen U.S. Sales data, the price per gram for the sales of Healthgen's liquid products to customers [REDACTED]. RX-0300C; *see also* RD at 125–26; CX-0019C/CPX-0019C; CX-1080C (Cao Dep. Tr.) at 99:8–100:12, 102:1–5, 14–16. And the sales price of Ventria's Optibumin is approximately [REDACTED]. CX-0888C at 0011–12. Thus, a comparison of the respective price per gram of the clinical grade Accused Products and Optibumin shows that Optibumin is [REDACTED] [REDACTED], which suggests that a bond amount between [REDACTED] [REDACTED] could be appropriate and thus that a bond of at least 100% is appropriate. Therefore, we disagree that if Ventria's domestic industry is limited only to Optibumin and/or only Healthgen's clinical grade product is found to infringe, that Ventria failed to present evidence comparing the prices of only the clinical grade Accused Products.

In its briefing before the Commission, Healthgen presents a new argument, that the bond should be set to zero because, during this investigation, Ventria allegedly [REDACTED] [REDACTED]. *See* RBr. at 72–73. Healthgen reasons that, [REDACTED], [REDACTED].” *Id.* at 73. However, this argument is waived because Ventria did not present it to the ALJ. Second, the

Commission is not the forum for adjudicating this alleged [REDACTED] between Healthgen and Ventria, and even if there was a [REDACTED], it would be irrelevant to the appropriate amount of the bond under section 337.

VII. CONCLUSION

For the reasons detailed above, the Commission affirms with modifications the final ID's finding of violation of section 337. We reverse the final ID's findings that the medium grade Accused Products infringe the asserted claims of the Asserted Patent, but affirm with modifications the final ID's finding that the clinical grade Accused Products infringe those claims. The Commission takes no position as to whether certain Domestic Industry Products practice the Asserted Patent, but finds that the domestic industry requirement is satisfied based on Ventria's Optibumin Domestic Industry Product. Because the Commission does not reach the technical prong for the remainder of the Domestic Industry Products, the Commission vacates the final ID's finding that the domestic industry requirement is satisfied when all of the alleged Domestic Industry Products are found to practice the Asserted Patent. The Commission affirms the remainder of the final ID.

The Commission thus finds that Healthgen is in violation of section 337 as to Ventria's patent-based allegations, and that the requirements of section 337(g)(1) are met for the Defaulting Respondents with respect to the patent-based allegations and the false designation of origin claim. The Commission has issued an LEO and three CDOs, but the CDOs are issued only to the Defaulting Respondents. The Commission finds that the public interest factors do not preclude the issuance of this remedy. The Commission has further set bond at one hundred percent (100%) of the entered value during the period of Presidential Review.

PUBLIC VERSION

By order of the Commission.

A handwritten signature in dark ink, appearing to read "Katherine M. Hiner". The signature is fluid and cursive, with the first name being the most prominent.

Katherine M. Hiner
Acting Secretary to the Commission

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