

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

WUHAN HEALTHGEN BIOTECHNOLOGY
CORPORATION, HEALTHGEN
BIOTECHNOLOGY CO., LTD.,

Plaintiffs,

v.

EXPRESSTEC LLC, VENTRIA BIOSCIENCE
INC., INVITRIA, INC.,

Defendants.

C.A. No. _____

JURY TRIAL DEMANDED

COMPLAINT

Plaintiffs Wuhan Healthgen Biotechnology Corporation and Healthgen Biotechnology Co., Ltd. (collectively, “Healthgen”) complain and allege as follows against Defendants ExpressTec LLC, Ventria Bioscience Inc., and InVitria, Inc. (collectively, “Ventria”):

NATURE OF THE ACTION

1. Healthgen brings this action to protect its proprietary technology enabling the production of highly pure recombinant human serum albumin (rHSA), a product with a wide variety of medical and clinical applications. When Healthgen began developing this technology, most albumin for clinical use was derived from human blood plasma, which had significant public health concerns and limited supply challenges.

2. Recombinant proteins are expressed in a host cell through the use of genetic engineering techniques. The protein expressed from the host cell must be purified to eliminate potential toxins and host-related impurities from the purified product. rHSA produced by animal cells, human cells, or bacteria also often contained trace amounts of impurities that could cause an adverse immune response in the human body. Conventional purification methods often failed

to achieve the high purity level of the extracted rHSA required for safe and effective clinical use. Healthgen's pioneering innovations in the field of molecular pharming—use of a host such as a plant for the large-scale production of commercially valuable recombinant proteins—have helped to develop an alternative method of producing, extracting, and purifying rHSA from rice grain for commercial and clinical use.

3. Healthgen's scientists not only discovered a transgenic rice model that leads to production of rHSA at a high yield, but also techniques to extract and purify rHSA in a cost-effective way for large-scale manufacturing. Healthgen's rHSA product was the first of its kind from China to be approved for human clinical applications in China and later in the U.S. by the FDA. The clinical trials demonstrated the safety and efficacy of Healthgen's rHSA products, validating Healthgen's technology. Healthgen's technology is the result of significant investment in resources and years of research and development effort by Healthgen scientists.

4. Ventria markets and sells plant-derived rHSA products for clinical and medical use. On information and belief, Ventria infringes Healthgen's United States Patent Nos. 9,951,100 (the "100 patent"), 10,183,984 (the "984 patent"), and 10,730,926 (the "926 patent"), collectively the "patents-in-suit." On information and belief, Ventria has already made millions of dollars in sales of an infringing product and has caused significant damages to Healthgen.

THE PARTIES

5. Plaintiff Healthgen Biotechnology Co., Ltd. is a corporation organized under the laws of the People's Republic of China, with a principal place of business at 268 Shendun 5th Road, East Lake High-Tech Development Zone, Wuhan, China 430070.

6. Plaintiff Wuhan Healthgen Biotechnology Corp. is a corporation organized under the laws of the People's Republic of China, with a principal place of business at 268 Shendun 5th Road, East Lake High-Tech Development Zone, Wuhan, China 430070.

7. Healthgen specializes in molecular pharmaceutical research and development, focusing on developing, manufacturing, and marketing products that can be used as cell culture media supplements, cosmetic additives, and large-scale biological reagents for use in biopharmaceuticals and scientific research. Healthgen was co-founded by Dr. Daichang Yang, who was a professor at Wuhan University and has spent decades on research to improve the safety and quality of plant-derived proteins such as rHSA for clinical and medical use.

8. Defendant Ventria Bioscience Inc. ("Ventria Bioscience") is a corporation organized under the laws of Delaware with its principal place of business at 2718 Industrial Drive, Junction City, Kansas 66441. Ventria Bioscience's other primary facility is at 12635 East Montview Boulevard, Aurora, Colorado 80045.

9. Defendant ExpressTec LLC ("ExpressTec") is a limited liability company formed under the laws of Delaware with its principal place of business at 2718 Industrial Drive, Junction City, Kansas 66441. On information and belief, ExpressTec acquired at least some of Ventria Bioscience in or around August 2023.

10. Defendant InVitria, Inc. ("InVitria") is a corporation organized under laws of Delaware with its principal place of business at 2718 Industrial Drive, Junction City, Kansas 66441. On information and belief, InVitria is a subsidiary of ExpressTec responsible for, among other things, ExpressTec's rHSA products.

11. On information and belief, Defendants Ventria Bioscience, ExpressTec, and InVitria hold themselves out to the public as a singular entity. For example, ExpressTec

maintains an Internet website that is copyrighted to “Ventria Bioscience Inc.” (Ex. 1.) As another example, ExpressTec maintains a LinkedIn profile and the URL identifies it as “Ventria Bioscience” as follows: <https://www.linkedin.com/company/ventria-bioscience/>. (Ex. 2.) As another example, ExpressTec markets its technology as “time-proven, with more than 10 years of experience manufacturing and marketing recombinant proteins for use in biotechnology applications through its subsidiary, InVitria.” (Ex. 3.) Moreover, all three Defendants use the exact same address as their principal place of business: 2718 Industrial Drive, Junction City, Kansas 66441. There is no public difference between “Ventria Bioscience Inc.,” “ExpressTec LLC,” and “InVitria.” The Defendants are collectively referred to in this complaint as “Ventria.”

JURISDICTION AND VENUE

12. This action arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

13. This Court has personal jurisdiction over Ventria Bioscience because Ventria Bioscience is incorporated in Delaware. Moreover, Ventria Bioscience has sufficient minimum contacts with the forum because it conducts business in Delaware. On information and belief, Ventria Bioscience—directly or through subsidiaries or intermediaries including distributors, retailers, and others—offers for sale, and sells, as well as distributes, advertises and markets products made by certain methods, including Optibumin, that infringe the ’100, ’984 and ’926 patents (“infringing products”) throughout Delaware. On information and belief, Ventria Bioscience acts in concert with others to purposefully and voluntarily place the infringing products in a distribution chain that foreseeably leads to the infringing products being offered for sale, sold, and used in Delaware and this district as a part of the ordinary stream of commerce. On information and belief, Ventria Bioscience has done so with the expectation that these

infringing products have been, and will continue to be, purchased in Delaware and this district, and that such purchases will be part of the ordinary stream of commerce.

14. This Court has personal jurisdiction over ExpressTec because ExpressTec is incorporated in Delaware. Moreover, ExpressTec has sufficient minimum contacts with the forum because it conducts business in Delaware. On information and belief, ExpressTec — directly or through subsidiaries or intermediaries including distributors, retailers, and others— offers for sale, and sells, as well as distributes, advertises and markets products made by certain methods, including Optibumin, that infringe the '100, '984 and '926 patents throughout Delaware. On information and belief, ExpressTec acts in concert with others to purposefully and voluntarily place the infringing products in a distribution chain that foreseeably leads to the infringing products being offered for sale, sold, and used in Delaware and this district as a part of the ordinary stream of commerce. On information and belief, ExpressTec has done so with the expectation that these infringing products have been, and will continue to be, purchased in Delaware and this district, and that such purchases will be part of the ordinary stream of commerce.

15. This Court has personal jurisdiction over InVitria because InVitria is incorporated in Delaware. Moreover, InVitria has sufficient minimum contacts with the forum because it conducts business in Delaware. On information and belief, InVitria—directly or through subsidiaries or intermediaries including distributors, retailers, and others—offers for sale, and sells, as well as distributes, advertises and markets products made by certain methods, including Optibumin, that infringe the '100, '984 and '926 patents throughout Delaware. On information and belief, InVitria acts in concert with others to purposefully and voluntarily place the infringing products in a distribution chain that foreseeably leads to the infringing products being

offered for sale, sold, and used in Delaware and this district as a part of the ordinary stream of commerce. On information and belief, InVitria has done so with the expectation that these infringing products have been, and will continue to be, purchased in Delaware and this district, and that such purchases will be part of the ordinary stream of commerce.

16. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1400(b) and 1391. Each of the Defendants is a Delaware corporation and may be sued in this district for patent infringement. Venue is also proper because each of the Defendants has committed acts of infringement in this district and has purposefully transacted business involving the infringing products in this district.

BACKGROUND

17. Human blood plasma, the liquid component of blood, is composed of many different biological molecules such as proteins. Among them, the most abundant protein is human serum albumin (HSA) that has a wide variety of functions in the body under normal physiological conditions. HSA is also utilized for numerous cell culture studies and pharmaceutical applications. It can be used clinically, for example, for treatment of blood loss, serious burn, or hemorrhagic shock, as well as for treatment of liver cirrhosis, hydronephrosis, and many others. In addition, it can also be used as an excipient in pharmaceutical formulations and in cell culture processes for manufacturing biopharmaceutical proteins.

18. Therapeutic HSA is primarily derived from donated human blood. Preparing HSA from human blood plasma for clinical applications, however, comes with many challenges, including the limited availability of donated blood supply to meet the high demand for HSA production and concerns over infectious pathogens that may be present in human plasma. Using modern genetic manipulation technologies, scientists have advanced this field to produce rHSA in different host organisms such as plants and bacteria. However, rHSA often includes

impurities, including color pigments, host cell proteins, and complex sugar molecules (*e.g.*, starch), requiring the rHSA to be highly purified before use. Further, the rHSA can form clumps (*e.g.*, aggregates) during the purification process. Therefore, technology for extracting and purifying rHSA to high purity remains crucial for large-scale production of rHSA. Healthgen's innovative manufacturing methods enabled the production of rHSA with extremely high purity and with minimal endotoxin levels from the rice grain on a commercial scale.

19. Recombinant proteins like rHSA expressed in a host cell (*e.g.*, rice grain) can be extracted and purified using various techniques that require analysis of a wide variety of parameters. For example, the conditions for extracting the rHSA from the rice grain may necessitate developing the composition of the extraction buffer for successfully extracting the desired target molecule.

20. After extraction, additional purification techniques are necessary to further reduce the endotoxin and impurity levels from the extracted rHSA. Chromatography, for example, refers to a set of techniques for the separation of mixtures and further purification. A positively charged resin can be used to bind negatively charged substances (referred to as "anion exchange chromatography"), and a negatively charged resin can be used to bind positively charged substances (referred to as "cation exchange chromatography"). Another example of a purification technique is a hydrophobic interaction chromatography ("HIC"), which relies on the tendency of hydrophobic (*i.e.*, water-fearing) substances to bind to each other.

21. In addition, other factors such as the sequence by which the chromatography steps are carried out, the design of the chromatography steps to include the rHSA in the flow-through or elution pool, the pH, the temperature, and the chemical solutions such as buffers used at various purification steps can impact the quality and purity level of the desired end product.

22. As part of Healthgen's dedication and commitment to improve the safety and availability of rHSA for medical and therapeutic applications, Healthgen scientists, including Dr. Yang, have pioneered technologies for extracting and purifying rHSA from rice grain at a high yield and high purity. Under Dr. Yang's guidance, a team of Healthgen researchers developed novel manufacturing processes to extract and purify rHSA from rice grain at commercial scale and in a cost-effective way without compromising the yield or quality of the extracted rHSA protein. Healthgen's investment and more than a decade of research yielded advancements in several key areas of manufacturing rHSA, such as extraction and purification methods to improve and maintain rHSA quality, consistency, safety, and effectiveness. Healthgen's work also led to the optimization of several additional parameters such as the temperature, pH, buffers, and resins used for purifying rHSA product that is of a high purity level and suitable for therapeutic applications. Healthgen obtained patent protection for many of these advancements, which are reflected in the patents-in-suit.

PATENTS-IN-SUIT

U.S. Patent No. 9,951,100

23. The United States Patent and Trademark Office (USPTO) duly and legally issued the '100 patent, titled "Method for isolating and purifying recombinant human serum albumin from transgenic rice grain," on April 24, 2018. The '100 patent claims priority to a Chinese patent application filed on December 24, 2010. Ventria has had notice of the '100 patent from at least as of March 1, 2024.

24. The '100 patent is assigned to Healthgen Biotechnology Co., Ltd. and Healthgen has the sole right to enforce it. The named inventors are Daichang Yang, Yang He, Guangfei Li, and Jingru Liu. A copy of the '100 patent is attached as Exhibit 4.

25. The '100 patent discloses and claims technologies associated with isolating and purifying rHSA from transgenic rice. Obtaining rHSA products at extremely high purity can eliminate potential risks to patients due to impurities in the rHSA products. The inventors invented a method for separating and purifying rHSA from transgenic rice grain that involves sequentially subjecting a crude extract of rHSA to cation exchange chromatography, followed by anion exchange chromatography, and finally a hydrophobic chromatography process whereby the rHSA does not adsorb to the resins of the hydrophobic chromatography to obtain purified rHSA that has a purity of more than about 99%. The inventors discovered that this method has significant advantages over conventional methods by reducing cost associated with purification process, maintaining consistency throughout various batches of the purified rHSA product, and obtaining a higher purity of rHSA.

26. Representative claim 1 of the '100 patent recites:

1. A method for isolating and purifying recombinant human serum albumin (rHSA) from transgenic rice grain, sequentially comprising the steps of:
 - 1) subjecting a crude extract from the transgenic rice grain containing the recombinant human serum albumin to cation exchange chromatography to obtain primary product I;
 - 2) subjecting the primary product I to anion exchange chromatography to obtain secondary product II that contains the recombinant human serum albumin, wherein the secondary product II further comprises ammonium sulfate at a concentration from about 0.1 M to about 1 M;
 - 3) subjecting the secondary product II to hydrophobic chromatography, under a condition that the rHSA does not adsorb to the resins of the hydrophobic chromatography; and
 - 4) recovering non-adsorbed flow-through fractions from the hydrophobic chromatography to obtain the purified recombinant human serum albumin having a purity of more than about 99% rHSA monomer plus dimer and polymer by HPLC.

U.S. Patent No. 10,183,984

27. The USPTO duly and legally issued the '984 patent, titled "Method for extracting recombinant human serum albumin from transgenic rice grain," on January 22, 2019. The '984

patent claims priority to a Chinese patent application filed on December 20, 2010. Ventria has had notice of the '984 patent from at least as of March 1, 2024.

28. The '984 patent is assigned to Healthgen Biotechnology Co., Ltd. and Healthgen has the sole right to enforce it. The named inventors are Daichang Yang, Yang He, and Guangfei Li. A copy of the '984 patent is attached as Exhibit 5.

29. The '984 patent discloses and claims technologies for extracting rHSA from transgenic rice. Developing rHSA products for clinical applications requires minimizing the presence of non-target species such as bacterial endotoxins in rHSA products. As the '984 patent reflects, the inventors invented a method to enhance the extraction efficiency by a combination of different pH and different salt concentrations. The patented method for extracting rHSA from transgenic rice grain involves grinding dehusked rice containing rHSA into milled rice grain that is mixed with an extraction buffer of a specific recipe that comprises a mixture of salts such as phosphate, sodium acetate, ammonium sulfate, and sodium caprylate for use during the extraction process under the right conditions. The inventors invented an extraction method that substantially increases the concentration of rHSA in the resulting extracted solution compared to conventional methods. At the same time, the use of the patented extraction method leads to a reduction of non-target proteins such as endotoxins, microbial contamination, and other impurities, which improves the quality of the rHSA products for clinical applications.

30. Representative claim 1 of the '984 patent recites:

1. A method for extracting recombinant human serum albumin from transgenic rice grain, comprising the steps of:

1) removing the hull of transgenic paddy rice containing recombinant human serum albumin, and grinding the dehusked rice grain;

2) mixing the transgenic milled rice grain with an extraction buffer and extracting with stirring to obtain mixture I,

wherein the extraction buffer has a pH of between about 6.5 and about 8, and comprises between about 10 mM and about 30 mM phosphate, between about 10 mM and about 20

mM sodium acetate, between about 10 mM and about 50 mM ammonium sulfate, and between about 5 mM and about 40 mM sodium caprylate;
3) adjusting pH of the mixture I of step 2) to between about 4.0 and about 4.5 and precipitating non-target proteins for between about 1 hour and about 12 hours to obtain mixture II; and
4) filtrating the mixture II of step 3) and collecting the filtrate to obtain a solution containing high concentration of recombinant human serum albumin.

U.S. Patent No. 10,730,926

31. The USPTO duly and legally issued the '926 patent, titled "Chromatographic method for isolating and purifying high-purity recombined human serum albumin," on August 4, 2020. The '926 patent claims priority to a Chinese patent application filed on December 21, 2012. Ventria has had notice of the '926 patent from at least as of March 1, 2024.

32. The '926 patent is assigned to Wuhan Healthgen Biotechnology Corp. and Healthgen has the sole right to enforce it. The named inventors are Daichang Yang, Bo Shi, Qianni Shi, Jiquan Ou, and Jingru Liu. A copy of the '926 patent is attached as Exhibit 6.

33. The '926 patent discloses and claims technologies for isolating and purifying rHSA from transgenic rice. Purification techniques that achieve a high purity of extracted rHSA product and eliminate endotoxin and contamination levels are critical for therapeutic applications. The inventors invented a method for isolating and purifying high-purity rHSA that comprises the steps of equilibrating a cation/hydrophobic composite resin for cation exchange chromatography with an equilibrium buffer comprising alcohol, loading the crude extract of rHSA to a cation/hydrophobic composite resin, re-equilibrating the cation/hydrophobic composite resin with an equilibrium buffer comprising alcohol, washing the cation/hydrophobic composite resin with a wash buffer, eluting the cation/hydrophobic composite resin to obtain a first rHSA product, subjecting the first product to anion exchange chromatography and then to hydrophobic chromatography to obtain high-purity rHSA. The patented methods significantly

improve the quality of the rHSA product to achieve a purity of more than 99.9999% and it has a content of an endotoxin that is less than 0.08 EU/mg.

34. Representative claim 1 of the '926 patent recites:

1. A method for isolating and purifying high-purity recombinant human serum albumin, sequentially comprising the steps of:

- 1) equilibrating a cation/hydrophobic composite resin for cation exchange chromatography with an equilibrium buffer I comprising about 0% to about 10% alcohol by volume;
- 2) loading a crude extract of recombinant human serum albumin to the cation/hydrophobic composite resin after step 1);
- 3) re-equilibrating the cation/hydrophobic composite resin after step 2) with an equilibrium buffer II comprising about 5% to about 15% alcohol by volume;
- 4) washing the cation/hydrophobic composite resin after step 3) with a wash buffer comprising 10% to 16% ethanol or isopropyl alcohol by volume;
- 5) eluting the cation/hydrophobic composite resin after step 4) to obtain a first product I comprising recombinant human serum albumin;
- 6) subjecting the first product I to anion exchange chromatography to obtain a second product II, wherein the anion exchange chromatography is performed on an anion/hydrophobic composite resin; and
- 7) subjecting the second product II to hydrophobic chromatography to obtain high-purity recombinant human serum albumin, wherein the recombinant human serum albumin obtained in step 7 has a purity of more than 99.9999% by HPLC, and the recombinant human serum albumin obtained in step 7) has a content of an endotoxin less than 0.08 EU/mg.

VENTRIA'S INFRINGEMENT

35. The patents-in-suit are enforceable and valid. The claims of the patents-in-suit are directed to technologies that enable extraction and purification of rHSA from rice grain at a high purity level.

36. On information and belief, Ventria develops, manufactures, and sells a line of rHSA products that are derived from rice grain—the same as Healthgen's patented technologies. According to Ventria's published websites, its "production process harnesses the humble rice plant's natural ability to use sunlight as an energy source and soil, water, and air as raw materials. Desired proteins are manufactured as the plant grows, and naturally become

concentrated within the rice-seed endosperm for easy harvest and purification.” A copy of the page from Ventria’s website is attached as Exhibit 1.

37. Among Ventria’s various rHSA products, it markets its Optibumin rHSA product on its website as the “highest purity albumin on the market” and with the “[l]owest product-related high molecular weight impurity.” Ventria further claims that its Optibumin rHSA product is manufactured using a “[h]ost manufacturing system [that] is of non-animal and non-human source” and that the “[c]omplete supply and manufacturing chain is owned and operated by InVitria.” A copy of the page from Ventria’s website is attached as Exhibit 7.

38. Ventria’s Certificate of Analysis for Optibumin states that the source of the product is “Recombinant DNA Origin” and the “product has been manufactured without use of an animal host cell and without animal components.” Further, it claims that the “Purity” of Optibumin is “100.0%” and the endotoxin level is “0.22 EU/mL.” A copy of the Certificate of Analysis for Optibumin dated February 3, 2023 is attached as Exhibit 8.

39. In addition, a publication authored by the Vice President of InVitria’s Product Development, titled “Albumin in Cell Culture Media – An examination of quality and function,” states that Optibumin has “100% monomer purity.” A copy of this publication is attached as Exhibit 9.

40. On information and belief, any one or all of Ventria’s uses of the extraction and purification methods to prepare its rHSA products, including Optibumin, with high purity and low endotoxin levels fall within the scope of the patent rights provided by the claims of the patents-in-suit.

41. On or about March 1, 2024, Healthgen gave Ventria notice of Healthgen’s patent rights and sought information from Ventria about its manufacturing and purification process for

its rHSA products. Ventria did not provide this information. To Healthgen's knowledge, the extraction and purification methods and protocol for Ventria's rHSA products, including Optibumin, cannot be reverse engineered using known methods.

COUNT I

(Infringement of U.S. Patent No. 9,951,100)

42. Healthgen hereby restates and re-alleges the allegations set forth in paragraphs 1 through 41 above and incorporates them by reference.

43. On information and belief, Ventria has been and is now directly infringing, contributing to infringement, and inducing others to infringe the '100 patent in this district and elsewhere in violation of 35 U.S.C. § 271 at least by making, using, selling, offering to sell, and importing into the United States rHSA products, including Optibumin, that meet the limitations of one or more claims of the '100 patent.

44. On information and belief, Ventria has committed infringing acts without the permission, consent, authorization, or license of Healthgen.

45. On information and belief, Ventria manufactures Optibumin using the claimed technologies of the '100 patent.

46. On information and belief, Ventria's infringement is literal or under the doctrine of equivalents, or both.

47. On information and belief, Ventria, in addition to its own direct infringement, is currently actively inducing and encouraging infringement of the '100 patent and will continue to actively induce and encourage infringement of the '100 patent. On information and belief, Ventria has known of the '100 patent at least since March 1, 2024. Ventria nevertheless actively encourages others to infringe the '100 patent such as by promoting and encouraging the use of

the infringing products, including Optibumin. On information and belief, Ventria knowingly induces infringement by others, including importers, manufacturers, sellers, and users of the infringing products, including Optibumin. These facts give rise to a reasonable inference that Ventria knowingly induces others, including importers, manufacturers, sellers, and users, to directly infringe the '100 patent, and that Ventria possesses a specific intent to cause such infringement. On information and belief, importers, manufacturers, sellers, and users of the infringing products directly infringe the '100 patent.

48. On information and belief, Ventria also contributes to infringement of the '100 patent by manufacturing, offering to sell, or selling within the United States or importing into the United States components of the infringing products, including Optibumin, while having knowledge of the '100 patent and knowledge that these components are specially made or specially adapted for use in products that infringe the '100 patent. These components are not staple articles or commodities of commerce suitable for substantial noninfringing uses. On information and belief, importers, manufacturers, sellers, and users of the infringing products including these components directly infringe the '100 patent.

49. On information and belief, Ventria's infringement has been willful. On information and belief, Ventria had knowledge of the '100 patent and its published claims, at least as of March 1, 2024. Ventria has proceeded to make, use, offer for sale, sell, and import the infringing products, including Optibumin, despite knowing that the products would infringe the '100 patent, and Ventria has continued to make, use, offer for sale, sell, and import the infringing products, including Optibumin. On information and belief, Ventria was also generally aware of Healthgen's technologies to make rHSA, and directly compared it to Ventria's infringing products, including Optibumin.

50. As a direct and proximate result of Ventria's infringement of the '100 patent, Healthgen has suffered, and will continue to suffer, damages, including lost profits.

COUNT II

(Infringement of U.S. Patent No. 10,183,984)

51. Healthgen hereby restates and re-alleges the allegations set forth in paragraphs 1 through 41 above and incorporates them by reference.

52. On information and belief, Ventria has been and is now directly infringing, contributing to infringement, and inducing others to infringe the '984 patent in this district and elsewhere in violation of 35 U.S.C. § 271 at least by making, using, selling, offering to sell, and importing into the United States rHSA products, including Optibumin, that meet the limitations of one or more claims of the '984 patent.

53. On information and belief, Ventria has committed infringing acts without the permission, consent, authorization, or license of Healthgen.

54. On information and belief, Ventria manufactures Optibumin using the claimed technologies of the '984 patent.

55. On information and belief, Ventria's infringement is literal or under the doctrine of equivalents, or both.

56. On information and belief, Ventria, in addition to its own direct infringement, is currently actively inducing and encouraging infringement of the '984 patent and will continue to actively induce and encourage infringement of the '984 patent. Ventria has known of the '984 patent at least since March 1, 2024. On information and belief, Ventria nevertheless actively encourages others to infringe the '984 patent such as by promoting and encouraging the use of the infringing products, including Optibumin. On information and belief, Ventria knowingly

induces infringement by others, including importers, manufacturers, sellers, and users of the infringing products, including Optibumin. These facts give rise to a reasonable inference that Ventria knowingly induces others, including importers, manufacturers, sellers, and users, to directly infringe the '984 patent, and that Ventria possesses a specific intent to cause such infringement. On information and belief, importers, manufacturers, sellers, and users of the infringing products directly infringe the '984 patent.

57. On information and belief, Ventria also contributes to infringement of the '984 patent by manufacturing, offering to sell, or selling within the United States or importing into the United States components of the infringing products, including Optibumin, while having knowledge of the '984 patent and knowledge that these components are specially made or specially adapted for use in products that infringe the '984 patent. These components are not staple articles or commodities of commerce suitable for substantial noninfringing uses. On information and belief, importers, manufacturers, sellers, and users of the infringing products including these components directly infringe the '984 patent.

58. On information and belief, Ventria's infringement has been willful. Ventria had knowledge of the '984 patent and its published claims, at least as of March 1, 2024. Ventria has proceeded to make, use, offer for sale, sell, and import the infringing products, including Optibumin, despite knowing that the products would infringe the '984 patent, and Ventria has continued to make, use, offer for sale, sell, and import the infringing products, including Optibumin. On information and belief, Ventria was also generally aware of Healthgen's technologies to make rHSA, and directly compared it to Ventria's infringing products, including Optibumin.

59. As a direct and proximate result of Ventria's infringement of the '984 patent, Healthgen has suffered, and will continue to suffer, damages, including lost profits.

COUNT III

(Infringement of U.S. Patent No. 10,730,926)

60. Healthgen hereby restates and re-alleges the allegations set forth in paragraphs 1 through 41 above and incorporates them by reference.

61. On information and belief, Ventria has been and is now directly infringing, contributing to infringement, and inducing others to infringe the '926 patent in this district and elsewhere in violation of 35 U.S.C. § 271 at least by making, using, selling, offering to sell, and importing into the United States rHSA products, including Optibumin, that meet the limitations of one or more claims of the '926 patent.

62. On information and belief, Ventria has committed infringing acts without the permission, consent, authorization, or license of Healthgen.

63. On information and belief, Ventria's infringement is literal or under the doctrine of equivalents, or both.

64. On information and belief, Ventria, in addition to its own direct infringement, is currently actively inducing and encouraging infringement of the '926 patent and will continue to actively induce and encourage infringement of the '926 patent. On information and belief, Ventria has known of the '926 patent at least since March 1, 2024. On information and belief, Ventria nevertheless actively encourages others to infringe the '926 patent such as by promoting and encouraging the use of the infringing products, including Optibumin. On information and belief, Ventria knowingly induces infringement by others, including importers, manufacturers, sellers, and users of the infringing products, including Optibumin. These facts give rise to a

reasonable inference that Ventria knowingly induces others, including importers, manufacturers, sellers, and users, to directly infringe the '926 patent, and that Ventria possesses a specific intent to cause such infringement. On information and belief, importers, manufacturers, sellers, and users of the infringing products directly infringe the '926 patent.

65. On information and belief, Ventria also contributes to infringement of the '926 patent by manufacturing, offering to sell, or selling within the United States or importing into the United States components of the infringing products, including Optibumin, while having knowledge of the '926 patent and knowledge that these components are specially made or specially adapted for use in products that infringe the '926 patent. These components are not staple articles or commodities of commerce suitable for substantial noninfringing uses. On information and belief, importers, manufacturers, sellers, and users of the infringing products including these components directly infringe the '926 patent.

66. On information and belief, Ventria's infringement has been willful. On information and belief, Ventria had knowledge of the '926 patent and its published claims, at least as of March 1, 2024. On information and belief, Ventria has proceeded to make, use, offer for sale, sell, and import the infringing products, including Optibumin, despite knowing that the products would infringe the '926 patent, and Ventria has continued to make, use, offer for sale, sell, and import the infringing products, including Optibumin. On information and belief, Ventria was also generally aware of Healthgen's technologies to make rHSA, and directly compared it to Ventria's infringing products, including Optibumin.

67. As a direct and proximate result of Ventria's infringement of the '926 patent, Healthgen has suffered, and will continue to suffer, damages, including lost profits.

PRAYER FOR RELIEF

WHEREFORE, Healthgen respectfully requests the following relief:

- A. Judgment in Healthgen's favor against Ventria that Ventria has infringed one or more valid and enforceable claims of the patents-in-suit;
- B. A finding that Ventria's infringement was willful;
- C. An award of damages to Healthgen in an amount to be proven at trial, including lost profits but in no event less than a reasonable royalty, as well as pre-judgment and post-judgment interest at the maximum rate permitted by law;
- D. A declaration that the manufacture, use, offer for sale, sale, and/or importation of Ventria's rHSA products, including Optibumin, has infringed or will infringe one or more claims of the patents-in-suit;
- E. A declaration that the patents-in-suit are valid and enforceable;
- F. An award of attorneys' fees and enhancement of any damages by virtue of the exceptional nature of this case under 35 U.S.C. § 285;
- G. A running royalty; and
- H. Such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Healthgen demands a trial by jury of all claims and issues so triable presented in this Complaint.

Dated: March 11, 2024

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