

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

VEDANTA BIOSCIENCES INC., and  
THE UNIVERSITY OF TOKYO,

*Plaintiffs,*

v.

SERES THERAPEUTICS INC., NESTLÉ S.A.,  
SOCIÉTÉ DES PRODUITS NESTLÉ S.A.,  
NESTLÉ HEALTH SCIENCE S.A., and  
NESTLÉ HEALTH SCIENCE US  
HOLDINGS, INC.,

*Defendants.*

C.A. No. \_\_\_\_\_

**JURY TRIAL DEMANDED**

**PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Vedanta Biosciences Inc. and the University of Tokyo (collectively, "Plaintiffs"), by their undersigned attorneys bring this action against Defendants Seres Therapeutics, Inc., Nestlé S.A., Société des Produits Nestlé S.A., Nestlé Health Science S.A., and Nestlé Health Science US Holdings, Inc. (collectively, "Defendants"), and hereby allege as follows:

**NATURE OF THE ACTION**

1. This is an action for infringement of United States Patent Nos. 9,433,652 (the "652 patent"), 9,662,381 (the "381 patent"), 9,808,519 (the "519 patent"), 10,555,978 (the "978 patent"), and 11,090,343 (the "343 patent") (collectively, the "Asserted Patents") under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, including §§ 271(a) and (b), arising from Defendants' unauthorized development, manufacturing, importation, commercial marketing, promotion, distribution, offers for sale, sales, and/or use of fecal microbiota spores, live-brpk ("API") and/or Vowst® (fecal microbiota spores, live-brpk capsules), and/or Defendants' active

inducement of others to commit such infringing acts, as detailed herein. True and correct copies of the Asserted Patents are attached as Exhibits A-E.

### **THE PARTIES**

2. Plaintiff the University of Tokyo is a Japanese university having an address at UCR Plaza, 7-3-1 Hongo, Bunkyo-Ku, Tokyo, Japan 113-0033.

3. The University of Tokyo is the owner and assignee of the Asserted Patents and exclusively licensed the Asserted Patents to Vedanta.

4. Plaintiff Vedanta Biosciences Inc. (“Vedanta”) is a Delaware corporation, having its principal place of business at 19 Blackstone St., Cambridge, MA 02139.

5. Vedanta has an exclusive license to the Asserted Patents, including the right to sue for infringement.

6. Vedanta is in the business of, *inter alia*, developing pharmaceutical products.

7. Upon information and belief, Defendant Seres Therapeutics Inc. (“Seres”) is a Delaware corporation, having its principal place of business at 101 Cambridgepark Dr., Cambridge, MA 02140.

8. Upon information and belief, Seres is a pharmaceutical company in the business of, among other activities, developing, manufacturing, and/or commercializing microbiome therapeutics.

9. Upon information and belief, Seres has developed the drug product fecal microbiota spores, live-brpk, capsules for oral administration, and commercially manufactures, distributes, markets, offers for sale and/or sells it under the name Vowst® in the United States.

10. Upon information and belief, Defendant Nestlé S.A. (“Nestlé SA”) is a Swiss company having a principal place of business at 55 Avenue Nestlé, 1800 Vevey, Switzerland.

11. Upon information and belief, Defendant Société des Produits Nestlé S.A. (“SPN”) is a Swiss company having a principal place of business at 55 Avenue Nestlé, 1800 Vevey, Switzerland.

12. Upon information and belief, Defendant Nestlé Health Science S.A. (“NHS SA”) is a Swiss company having a principal place of business at 55 Avenue Nestlé, 1800 Vevey, Switzerland.

13. Upon information and belief, Defendant Nestlé Health Science US Holdings, Inc. (“NHS US”) is a company organized and existing under the laws of the State of Delaware. NHS US may be served via its registered agent, the Corporation Trust Company, which has an address at Corporate Trust Center 1209 Orange St., Wilmington DE 19801.

14. Upon information and belief, Nestlé SA is the ultimate parent company of SPN, NHS SA, and NHS US.

15. Upon information and belief, Defendants Nestlé SA, SPN, NHS SA, and NHS US (collectively, “Nestlé”) are in the business of, among other activities, commercializing microbiome therapeutics.

16. Upon information and belief, Seres licenses Vowst® to Nestlé for the commercial marketing, distribution, and sales of Vowst® to residents throughout the United States, including in this district.

17. Upon information and belief, Nestlé distributes, markets, offers for sale, and/or sells Vowst® in the United States.

### **JURISDICTION AND VENUE**

18. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 100 et seq., including §§ 271(a) and 271(b).

19. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1332 and 1338(a).

20. This Court has personal jurisdiction over Seres.

21. Upon information and belief, this Court has personal jurisdiction over Seres, subject to this Court's specific and general personal jurisdiction pursuant to due process and/or the Delaware Long Arm Statute, due at least to its substantial business in this State and judicial district, including: (A) at least part of its infringing activities alleged herein; and (B) regularly doing or soliciting business, engaging in other persistent conduct, and/or deriving substantial revenue from infringing goods offered for sale, sold, and imported and services provided to Delaware residents vicariously through and/or in concert with its intermediaries, distributors, importers, customers and/or subsidiaries. Upon further information and belief, Seres commercially markets, distributes, offers for sale, and sells Vowst® to residents throughout the United States, including in Delaware. Upon further information and belief, Seres has established, and will continue to maintain, minimum contacts with this forum such that the exercise of jurisdiction over Seres would not offend traditional notions of fair play and substantial justice.

22. This Court has personal jurisdiction over Nestlé.

23. Upon information and belief, this Court has personal jurisdiction over Nestlé, directly and through intermediaries, distributors, importers, customers, and/or subsidiaries. Both by itself and through the direction and control of its subsidiaries, Nestlé has committed acts of direct and indirect patent infringement within Delaware, and elsewhere within the United States, giving rise to this Action and/or has established minimum contacts with Delaware such that personal jurisdiction over Nestlé would not offend traditional notions of fair play and substantial justice.

24. Upon further information and belief, Venue is proper in this judicial district as to Defendant Seres under 28 U.S.C. § § 1391 and 1400(b) at least because, upon information and belief, Seres has committed acts of infringement and has a regular and established place of business in this Judicial District. Upon further information and belief, Seres is a corporation organized and existing under the laws of Delaware.

25. Upon further information and belief, Venue is proper in this judicial district as to Nestlé under 28 U.S.C. § § 1391 and 1400(b). SPN and NHS SA are foreign companies not residing in any United States district and may be sued in any judicial district that has personal jurisdiction, including this district. NHS US is a Delaware company and thus resides in this this judicial district for the purpose of venue under § 1400(b).

## **FACTUAL BACKGROUND**

### **Background of the Invention**

26. Inventors Kenya Honda, Koji Atarashi, Kikuji Itoh, and Takeshi Tanoue and Plaintiff, the University of Tokyo, invested substantial resources in researching, identifying, and developing new compounds for the treatment of disease. One such composition includes live bacteria from a spore-forming fraction of a human fecal sample. The novel composition can be used for treating an individual whose resistance to the infectious diseases is impaired. (Ex. B, col. 2, ll. 22-24.) The live bacteria from a spore-forming fraction of a human fecal sample were used because the inventors discovered that specific bacteria induce proliferation or accumulation of regulatory T cells.

27. Inducement of proliferation or accumulation of regulatory T cells is significant because regulatory T cells are responsible for maintaining homeostasis of the immune system. (Ex. B, col. 15, ll. 1-5.) The inventors were motivated to discover a mechanism to induce the

proliferation or accumulation of regulatory T cells. The presence of certain species of intestinal microbiota exerts a major influence on the differentiation of regulatory T cells. (Ex. B, col. 2, ll. 20-24.)

28. Through the inventors' efforts and research, they discovered that bacteria belonging to the genus *Clostridium* induce proliferation or accumulation of regulatory T cells in the colon. (Ex. B, col. 3, ll. 42-45.) The inventors isolated and purified the live bacteria from a spore-forming fraction of a human fecal sample. (Ex. B, col. 12, ll. 55-60.) The isolated and purified bacteria became the active ingredient of the inventors' novel composition.

29. The inventors' discovery enabled them to create compositions comprised of the identified intestinal commensal bacteria to induce the proliferation or accumulation of regulatory T cells in the human utilizing the composition. (*See* Ex. B, col. 3, ll. 24-33).

#### **Novelty and Advantages of the Invention**

30. At the time of the invention, it was known that the presence of intestinal bacteria enhances mucosal immune systems, providing immune responses against pathogenic microbes invading a host. It was theorized that the presence of certain intestinal microbiota may exert an influence on the differentiation of regulatory T cells. However, it was unknown which, if any, species of commensal bacterial flora exert this influence on the induction of regulatory T cells. (Ex. B, col. 2, ll. 44-49.)

31. The inventors of the Asserted Patents found that certain spore-forming bacteria found in fecal matter, such as those in the genus *Clostridium*, induce this previously theorized accumulation of regulatory T cells in the colon. The T cells induced from bacterial mixtures identified in the Asserted Patents were also found to suppress proliferation of effector T cells to provide an immunosuppressive effect. (Ex. B, col. 3, ll. 37-51.) These spore forming bacteria may

be isolated from fecal matter through chemical treatments that result in a combination of spore forming bacteria that, when administered to a human patient, provide an improvement to the patient's immune function via the induction of T cells. (Ex. B, col. 3, ll. 52-57.)

32. The novel compositions and methods claimed in the Asserted Patents provide an enhancement to the immune function of a living organism through the administration of these bacteria in a pharmaceutical product. (Ex. B, col. 6, ll. 59-62.) These products may increase the accumulation of T cells and therefore can be used to treat certain diseases, disorders, or conditions that may benefit from immune system enhancement. For example, the compositions of the Asserted patents can be used to treat humans having infectious pathogens that impair maintenance or homeostasis of a host. (Ex. B col. 15, ll. 1-5.) The inventors discovered that humans infected with pathogens such as *Clostridium difficile*, which may induce immunopathological tissue damage resulting in impaired homeostasis, may be treated by administration of the claimed compositions, and claimed methods associated therewith.

### **The Asserted Patents**

33. The University of Tokyo is the owner and assignee of the Asserted Patents.

34. The University of Tokyo licensed its patent rights in International Patent Application Nos. PCT/JP2010/71746 and PCT/JP2011/063302 to Vedanta on November 14<sup>th</sup>, 2011, including any foreign counterparts, divisionals, continuations, continuation-in-part applications, continued prosecution applications, or any other application claiming priority to PCT/JP2010/71746 and PCT/JP2011/063302.

35. PCT/JP2011/063302 entered the U.S. national stage on June 3, 2011 as U.S. Patent Application No. 13/701,467.

36. Each of the Asserted Patents is issued from a continuation of U.S. Patent

Application No. 13/701,467.

37. Vedanta is the exclusive licensee of the Asserted Patents. Vedanta possesses the right to sue for infringement of the Asserted Patents.

**A. U.S. Patent 9,433,652**

38. The '652 Patent is titled "Composition for inducing proliferation or accumulation of regulatory T cells." The '652 Patent was duly and legally issued on September 6, 2016, from U.S. Patent Application No. 14/492,850, a continuation of U.S. Patent Application No. 13/701,467, the National Stage Entry of PCT/JP2011/063302. The '652 Patent lists inventors Kenya Honda, Koji Atarashi, Kikuji Itoh, and Takeshi Tanoue.

39. The '652 Patent describes, *inter alia*, a method for treating a disease comprising administering a pharmaceutical composition comprising a purified bacterial mixture of at least two live bacterial strains belonging to Clostridium clusters IV and/or XIVa, to a human subject, where the bacterial strains are spore-forming bacteria and are isolated from a human. (*See e.g.*, Ex. A, claim 1).

40. The claims of the '652 Patent are presumed valid and enforceable.

41. The '652 Patent will expire no earlier than June 3, 2031.

42. Vedanta, the exclusive licensee of the '652 Patent, possesses the right to sue for infringement of the '652 Patent.

**B. U.S. Patent 9,662,381**

43. The '381 Patent is titled "Composition for inducing proliferation or accumulation of regulatory T cells." The '381 Patent was duly and legally issued on May 30, 2017, from U.S. Patent Application No. 15/374,693, a continuation of U.S. Patent Application No. 15/216,015, a continuation of U.S. Patent Application No. 14/492,850, a continuation of U.S. Patent Application



No. 13/701,467, the National Stage Entry of PCT/JP2011/063302. The '381 Patent lists inventors Kenya Honda, Koji Atarashi, Kikuji Itoh, and Takeshi Tanoue.

44. The '381 Patent describes, *inter alia*, a method of treatment with oral administration of a pharmaceutical composition comprising a spore-forming fraction of human fecal matter, where the composition induces proliferation and/or accumulation of regulatory T cells. (*See e.g.*, Ex. B, claim 1.)

45. The claims of the '381 Patent are presumed valid and enforceable.

46. The '381 Patent will expire no earlier than June 3, 2031.

47. Vedanta, the exclusive licensee of the '381 Patent, possesses the right to sue for infringement of the '381 Patent.

### **C. U.S. Patent 9,808,519**

48. The '519 Patent is titled "Composition for inducing proliferation or accumulation of regulatory T cells." The '519 Patent was duly and legally issued on November 7, 2017, from U.S. Patent Application No. 15/590,257, a continuation of U.S. Patent Application No. 15/216,015, a continuation of U.S. Patent Application No. 14/492,850, a continuation of U.S. Patent Application No. 13/701,467, the National Stage Entry of PCT/JP2011/063302. The '519 Patent lists inventors Kenya Honda, Koji Atarashi, Kikuji Itoh, and Takeshi Tanoue.

49. The '519 Patent describes, *inter alia*, an orally administered pharmaceutical composition comprising a spore-forming fraction of human fecal matter formulated for delivery to the intestine that induces the proliferation and/or accumulation of regulatory T cells. (*See e.g.*, Ex. C, claim 17.)

50. The claims of the '519 Patent are presumed valid and enforceable.

51. The '519 Patent will expire no earlier than June 3, 2031.

52. Vedanta, the exclusive licensee of the '519 Patent, possesses the right to sue for infringement of the '519 Patent.

**D. U.S. Patent 10,555,978**

53. The '978 Patent is titled, "Composition for inducing proliferation or accumulation of regulatory T cells." The '978 Patent was duly and legally issued on February 11, 2020 from U.S. Patent Application No. 16/425,030, a continuation of U.S. Patent No. 16/389,380, a continuation of U.S. Patent No. 16/171,558, a continuation of U.S. Patent No. 16/117,054, a continuation of U.S. Patent No. 15/730,203, a continuation of U.S. Patent No. 5/216,015, a continuation of U.S. Patent Application No. 14/492,850, a continuation of U.S. Patent Application No. 13/701,467, the National Stage Entry of PCT/JP2011/063302. The '978 Patent lists inventors Kenya Honda, Koji Atarashi, Kikuji Itoh, and Takeshi Tanoue.

54. The '978 Patent describes, *inter alia*, a pharmaceutical composition formulated for delivery to the intestine and method of use thereof, comprising one or more purified live bacterial strains belonging to Clostridium clusters IV or XIVa, where the one or more bacterial strains are isolated from a human and induce proliferation and/or accumulation of regulatory T-cells. (*See e.g.*, Ex. D, claims 1 and 16.)

55. The claims of the '978 Patent are presumed valid and enforceable.

56. The '978 Patent will expire no earlier than June 3, 2031.

57. Vedanta, the exclusive licensee of the '978 Patent, possesses the right to sue for infringement of the '978 Patent.

**E. U.S. Patent 11,090,343**

58. The '343 Patent is titled, "Composition for inducing proliferation or accumulation of regulatory T cells." The '343 Patent was duly and legally issued on August 17, 2020, from U.S.

Patent Application No. 16/425,030, a continuation of U.S. Patent Application No. 16/425,030, a continuation of U.S. Patent No. 16/389,380, a continuation of U.S. Patent No. 16/171,558, a continuation of U.S. Patent No. 16/117,054, a continuation of U.S. Patent No. 15/730,203, a continuation of U.S. Patent No. 5/216,015, a continuation of U.S. Patent Application No. 14/492,850, a continuation of U.S. Patent Application No. 13/701,467, the National Stage Entry of PCT/JP2011/063302. The '343 Patent lists inventors Kenya Honda, Koji Atarashi, Kikuji Itoh, and Takeshi Tanoue.

59. The '343 Patent describes, *inter alia*, a pharmaceutical composition formulated for delivery to the intestine and method of use thereof, comprising one or more purified live bacterial strains belonging to Clostridium clusters IV or XIVa, where the one or more bacterial strains are human commensal bacteria and induce proliferation and/or accumulation of regulatory T-cells. (*See e.g.*, Ex. E, claims 1 and 16.)

60. The claims of the '343 Patent are presumed valid and enforceable.

61. The '343 Patent will expire no earlier than June 3, 2031.

62. Vedanta, the exclusive licensee of the '343 Patent, possesses the right to sue for infringement of the '343 Patent.

### **The Vowst® Product**

63. Upon information and belief, Seres is the owner of U.S. License No. 2262 under section 351(a) of the Public Health Services Act controlling manufacture and sale of biological products, specifically to manufacture the product fecal microbiota spores, live-brpk. Upon further information and belief, U.S. License No. 2262 was granted after FDA approval of Biologics License Application (“BLA”) No. 125757. (*See* Ex. F.)

64. Upon information and belief, Seres is the owner of BLA No. 125757 for Vowst®

which the FDA approved on April 26, 2023. Upon information and belief, the FDA's Purple Book lists Seres Therapeutics, Inc. as the owner of BLA No. 125757. (*See* Ex. F.)

65. Upon information and belief, Vowst® is a pharmaceutical composition approved for human patients.

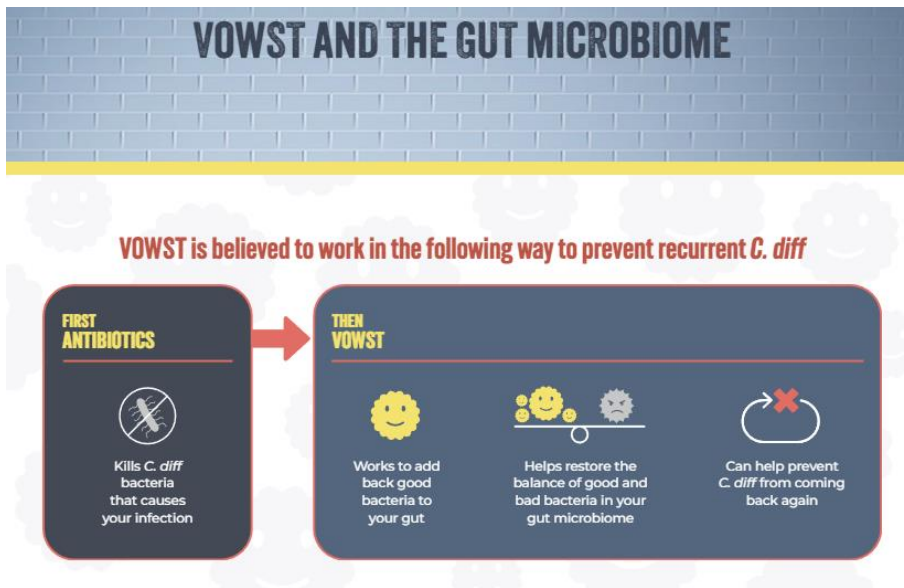
66. Upon information and belief, Vowst® is indicated for prevention of the recurrence of *Clostridioides difficile* infection. Upon further information and belief, Vowst® is indicated to treat a human suffering from an infectious disease.

67. Upon information and belief, Vowst® is administered orally. *See* Vowst® Prescribing Information, Dosage and Administration:

- DOSAGE AND ADMINISTRATION-----**
- For oral administration only. (2)**
- Prior to taking the first dose:
    - Complete antibacterial treatment for rCDI 2 to 4 days before initiating treatment with VOWST. (2.1)
    - Drink 296 mL (10 oz) of magnesium citrate on the day before and at least 8 hours prior to taking the first dose of VOWST. In clinical studies, participants with impaired kidney function received polyethylene glycol electrolyte solution (250 mL GoLYTELY, not approved for this use). (2.1)
  - The dosage of VOWST is 4 capsules taken orally once daily for 3 consecutive days. (2.2)
  - Take each dose (4 capsules) on an empty stomach prior to the first meal of the day. (2.2)

(Ex. G)

68. Upon information and belief, Vowst® works to add bacteria into the intestine. The following image from the Vowst® website explains that Vowst® targets the intestine.



<https://www.vowst.com/how-vowst-works>; (See also Ex. H.)

69. Upon information and belief, the code “SER-109” is an internal Seres code for the active ingredient, fecal microbiota spores, live-brpk.

70. Upon information and belief, Vowst® contains live bacterial strains. Upon further information and belief, the live bacterial strains are isolated from humans, and more specifically, from human fecal matter. See Ex. G, Vowst® Prescribing Information §11:

**11 DESCRIPTION**

VOWST (fecal microbiota spores, live-brpk) is a bacterial spore suspension in capsules for oral administration. VOWST is manufactured from human fecal matter sourced from qualified donors. Human fecal matter donations are routinely tested for a panel of transmissible pathogens. Donors do not have dietary restrictions with respect to potential food allergens. The spore suspension is generated by treating fecal matter with ethanol to kill organisms that are not spores, followed by filtration steps to remove solids and residual ethanol. Each capsule of VOWST contains between 1x10<sup>6</sup> and 3x10<sup>7</sup> Firmicutes spore colony forming units in 92 ± 4% (w/w) glycerol in saline.

71. Upon information and belief, the live bacterial strains in Vowst® are strains of human commensal bacteria.

72. Upon information and belief, the live bacterial strains in Vowst® are spore-forming bacteria. Section 11 of the Prescribing Information states, “[e]ach capsule of VOWST contains

between  $1 \times 10^6$  and  $3 \times 10^7$  Firmicutes spore colony forming units.” (Ex. G.)

73. Upon information and belief, live bacterial strains in Vowst® belong to the clostridium genus. Upon further information and belief, at least some of the live bacterial strains in Vowst® belong to Clostridium clusters IV and/or XIVa. The Table below is a portion of Table S3 from the Supplementary Appendix to the article, *SER-109, an oral microbiome therapy for recurrent Clostridioides difficile infection* published in the New England Journal of Medicine. (Ex. I.) The Table lists the organism genera present in Vowst®.

**Table S3. Taxonomic composition of organisms identified in SER-109**

Phylum	Class	Order	Family	Genus
Firmicutes	Bacilli	Bacillales	Bacillaceae	Bacillaceae novel genus
				Bacillus
				Caldibacillus
	Clostridia	Clostridiales	Christensenellaceae	Christensenellaceae novel genera
			Clostridiaceae	Clostridiaceae novel genera
				Clostridium
			Clostridiales novel family	Clostridiales novel genus
			Eubacteriaceae	<i>Anaerofustis</i>
				<i>Eubacterium</i> _
			Lachnospiraceae	<i>Acetatifactor</i>
				<i>Anaerobutyricum</i>

(Ex. I, Table S3.)

74. Upon information and belief, the live bacterial strains in Vowst® induce proliferation and/or accumulation of regulatory T cells in the human administered Vowst®. Upon information and belief, butyrate supports proliferation and/or accumulation of regulatory T-cells. (See e.g., Ex. J, p. 4.) Upon further information and belief, Vowst® increases butyrate levels. (See Ex. H.)

**Infringing Actions**

75. Upon information and belief, Defendants have willfully infringed the Asserted Patents.

76. Upon information and belief, Seres manufactures Vowst®.

77. Upon information and belief, Seres gained FDA approval to market Vowst® in April 2023. (Ex. F.)

78. Upon information and belief, Defendants first launched Vowst® in June 2023. (*See* Ex. K.) Upon further information and belief, Defendants continue to commercially market Vowst®.

79. Upon information and belief, Seres commercially markets, distributes, uses, offers for sale, and/or sells Vowst® throughout the United States. (*See id.*)

80. Upon further information and belief, Nestlé licenses Vowst® from Seres for commercial marketing, distribution, and sales of Vowst® in the United States. Seres' November 2023 10-Q describes the nature of the license agreement between Seres and Nestlé. (Ex. L, p. 20; *see also* Ex. M, p. 12.).

## **12. Revenue from Contracts with Customers**

### ***License Agreement with NHSc Rx License GmbH (Nestlé)***

#### *Summary of Agreement*

In July 2021, the Company entered into the 2021 License Agreement with NHSc Pharma Partners, succeeded by NHSc Rx License GmbH (together with Société des Produits Nestlé S.A., their affiliates, and their subsidiaries, "Nestlé") (the "2021 License Agreement"). Under the terms of the 2021 License Agreement, the Company granted Nestlé a co-exclusive, sublicensable (under certain circumstances) license to develop, commercialize and conduct medical affairs activities for (i) therapeutic products based on the Company's microbiome technology (including VOWST, previously the Company's SER-109 product candidate) that are developed by the Company or on the Company's behalf for the treatment of CDI and recurrent CDI, as well as any other indications pursued for the products upon mutual agreement of the parties (the "2021 Field") in the United States and Canada (the "2021 Licensed Territory"), and (ii) VOWST and any improvements and modifications thereto developed pursuant to the terms of the 2021 License Agreement (the "2021 Collaboration Products") for any indications in the 2021 Licensed Territory. The Company was responsible for completing development of the first 2021 Collaboration Product, which is VOWST, in the 2021 Field in the United States until first regulatory approval, which was obtained on April 26, 2023.

(Ex. L, p. 20.)

81. Upon information and belief, a slide (below) from the VOWST™ FDA Approval Conference Call on April 27, 2023, highlights the license and co-commercialization relationship between Seres and Nestlé.



**SERES**  
THERAPEUTICS



**Nestlé**  
HealthScience®

Co-commercializing VOWST in the United States with 50/50 profit sharing per July 2021 agreement, extending our global strategic collaboration

(Ex. N slide 5; *see also* Ex. M, p. 7.)

82. Upon further information and belief, Nestlé commercially markets, distributes, offers for sale, sells, and/or uses the Vowst® product throughout the United States in the same form in which it is manufactured by Seres.

83. Upon information and belief, Seres intentionally and knowingly induced Nestlé to infringe the Asserted Patents.

84. Defendants have specific intent that healthcare providers and patients use Vowst® to treat infection, according to the methods of the Asserted Patents.

85. As a result, Defendants are liable under 35 U.S.C. § 271(b) for intentionally inducing infringement of the Asserted Patents by healthcare professionals and patients who use Vowst®.

86. Upon information and belief, Seres actively monitors and analyzes patents relevant to their product line. (Ex. M, p. 55-58.) For example, in its 2023 10-K filed with the U.S. SEC, Seres admitted that it was “aware of third-party patent families that include issued and allowed patents, including in the United States, including claims that, if valid and enforceable, could be construed to cover Vowst®, some of our product candidates or their methods of use.” (*Id.* at 57.) Upon information and belief, Seres is aware that the University of Tokyo owns patents related to Vowst®. In the 2023 10-K, Seres also states, “on April 25, 2017, we filed a notice of opposition



in the European Patent Office challenging the validity of a patent issued to The University of Tokyo and requesting that it be revoked in its entirety for the reasons set forth in our opposition.” (*Id.* At 57.) The proceeding concerned a patent entitled, “Composition for inducing proliferation or accumulation of regulatory T cells,” and which is the EPO entry of PCT/JP2011/063302, the application to which all of the Asserted Patents claim priority. Upon information and belief, Defendants have specific knowledge of the Asserted Patents. Upon information and belief, Defendants have had specific knowledge of the Asserted Patents since before the first commercial marketing of Vowst.

87. Plaintiffs have been and are being damaged by Defendants’ infringement of the Asserted Patents. Plaintiffs have a right to recover from Defendants the damages sustained by Plaintiffs as a result of Defendants’ harmful acts.

88. Plaintiffs have no adequate remedy at law to redress Defendants’ infringement of the Asserted Patents.

## **COUNT I**

### **(Infringement of the ’652 Patent)**

89. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

90. Upon information and belief, Defendants’ actions have induced infringement of, and will continue to induce others to infringe, the ’652 Patent under 35 U.S.C. § 271(b).

91. Upon information and belief, the method of treating human adults who have *Clostridioides difficile* infection, according to the full prescribing information for Vowst®, is covered by one or more claims of the ’652 Patent.

92. The ’652 patent claims a method of treating a human subject with an infectious disease, autoimmune disease, or an allergic disease.

93. The novel method of treatment invented by the University of Tokyo and exclusively licensed by Vedanta is reflected in exemplary claim 1 of the '652 Patent which recites:

1. A method of treating a human subject having an infectious disease, an autoimmune disease, or an allergic disease, the method comprising administering a pharmaceutical composition comprising a purified bacterial mixture of at least two live bacterial strains belonging to Clostridium clusters IV and/or XIVa to the human subject, wherein the bacterial strains are spore-forming bacteria and are isolated from a human.

(Ex. A, claim 1.)

94. Upon information and belief, Defendants have actual knowledge of the '652 Patent.

95. Upon information and belief, Defendants have specific intent that healthcare providers and patients use Vowst® to treat infection, according to the methods of the '652 Patent.

96. Upon information and belief, Defendants' actions have induced infringement of and will continue to induce others to infringe the '652 Patent under 35 U.S.C. § 271(b).

97. Upon information and belief, Defendants have acted with full knowledge of the '652 Patent, with knowledge that physician and patients will infringe the '652 patent when using Vowst® according to the approved label, and without a reasonable basis for believing that they would not be liable for infringement of the '652 Patent.

98. Upon information and belief, Defendants' acts of infringement of the '652 Patent have been and will continue to be willful and deliberate.

99. Plaintiffs have suffered and continue to suffer damages as a result of Defendants' willful infringement of the '652 Patent in an amount to be determined at trial.

100. Plaintiffs are entitled to injunctive relief and damages in accordance with 35 U.S.C. §§ 271, 281, 283 and 284.

**COUNT II**

**(Infringement of the '381 Patent)**

101. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

102. Upon information and belief, Defendants' actions have induced infringement of, and will continue to induce others to infringe, the '381 Patent under 35 U.S.C. § 271(b).

103. Upon information and belief, the method of treating human adults who have Clostridioides difficile infection, according to the full prescribing information for Vowst®, is covered by one or more claims of the '381 Patent.

104. The novel method of treatment invented by the University of Tokyo and exclusively licensed by Vedanta is reflected in exemplary claim 1 of the '381 Patent which recites:

1. A method of treating a human subject having an infectious disease, an autoimmune disease or an allergic disease, the method comprising administering to the subject a pharmaceutical composition comprising a spore-forming fraction of human fecal matter, wherein the composition induces proliferation and/or accumulation of regulatory T cells, and wherein the composition is formulated for oral administration.

(Ex. B, claim 1.)

105. Upon information and belief, Defendants have actual knowledge of the '381 Patent.

106. Upon information and belief, Defendants have specific intent that healthcare providers and patients use Vowst® to treat infection, according to the methods of the '381 Patent.

107. Upon information and belief, Defendants' actions have induced infringement, and continue to induce infringement, of one or more claims of the '381 Patent under 35 U.S.C. § 271(b).

108. Upon information and belief, Defendants have acted with full knowledge of the '381 Patent, with knowledge that physician and patients will infringe the '381 patent when using

Vowst® according to the approved label, and without a reasonable basis for believing that they would not be liable for infringement of the '381 Patent.

109. Upon information and belief, Defendants' infringement of the '381 Patent has been and continues to be knowing, intentional, and willful.

110. Plaintiffs have suffered and continue to suffer damages as a result of Defendants' willful infringement of the '381 Patent in an amount to be determined at trial.

111. Plaintiffs are entitled to injunctive relief and damages in accordance with 35 U.S.C. §§ 271, 281, 283 and 284.

### **COUNT III**

#### **(Infringement of the '519 Patent)**

112. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

113. Upon information and belief, Defendants' actions have infringed, and will continue to infringe, the '519 Patent under 35 U.S.C. § 271(a).

114. Upon information and belief, Defendants' actions have induced infringement of, and will continue to induce others to infringe, the '519 Patent under 35 U.S.C. § 271(b).

115. Upon information and belief, the pharmaceutical composition of Vowst® is covered by one or more claims of the '519 Patent.

116. Upon information and belief, the method of treating human adults who have Clostridioides difficile infection, according to the full prescribing information for Vowst®, is covered by one or more claims of the '519 Patent.

117. The novel pharmaceutical composition invented by the University of Tokyo and exclusively licensed by Vedanta is reflected in exemplary claim 17 of the '519 Patent which recites:

17. A pharmaceutical composition comprising an active ingredient, wherein the active ingredient consists of a spore-forming fraction of human fecal matter, wherein the composition is formulated for delivery to the intestine, wherein the composition induces proliferation and/or accumulation of regulatory T cells, and wherein the composition is formulated for oral administration.

(Ex. C, claim 17.)

118. Upon information and belief, Defendants have actual knowledge of the '519 Patent.

119. Upon information and belief, when Seres makes, uses, and/or sells Vowst®, a pharmaceutical capsule containing spore-forming fraction of human fecal matter, Seres infringes one or more claims of the '519 Patent.

120. Upon information and belief, Seres induced Nestlé to infringe one or more claims of the '519 Patent when Seres entered into a license with Nestlé, such that Nestlé began to make, use, and/or sell Vowst®.

121. Upon information and belief, Nestlé infringed one or more claims of the '519 Patent when Nestlé began to make, use, and/or sell Vowst®.

122. Upon information and belief, Defendants' actions have infringed, induced infringement, continue to infringe, and continue to induce infringement, of one or more claims of the '519 Patent under 35 U.S.C. § 271(b).

123. Upon information and belief, Defendants have acted with full knowledge of the '519 Patent and without a reasonable basis for believing that they would not be liable for infringement of the '519 Patent.

124. Upon information and belief, Defendants' infringement of the '519 Patent has been and continues to be knowing, intentional, and willful.

125. Plaintiffs have suffered and continue to suffer damages as a result of Defendants' willful infringement of the '519 Patent in an amount to be determined at trial.

126. Plaintiffs are entitled to injunctive relief and damages in accordance with 35 U.S.C. §§ 271, 281, 283 and 284.

**COUNT IV**

**(Infringement of the '978 Patent)**

127. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

128. Upon information and belief, Defendants' actions have infringed, and will continue to infringe, the '519 Patent under 35 U.S.C. § 271(a).

129. Upon information and belief, Defendants' actions have induced infringement of, and will continue to induce others to infringe, the '978 Patent under 35 U.S.C. § 271(b).

130. Upon information and belief, the pharmaceutical composition of Vowst® is covered by one or more claims of the '978 Patent.

131. Upon information and belief, the method of treating human adults who have Clostridioides difficile infection, according to the full prescribing information for Vowst®, is covered by one or more claims of the '978 Patent.

132. The novel pharmaceutical composition invented by the University of Tokyo and exclusively licensed by Vedanta is reflected in exemplary claim 1 of the '978 Patent which recites:

1. A pharmaceutical composition, comprising one or more purified live bacterial strains belonging to Clostridium clusters IV or XIVa, wherein the one or more bacterial strains induces proliferation and/or accumulation of regulatory T cells, wherein the one or more bacterial strains are isolated from a human, and wherein the pharmaceutical composition is formulated for delivery to the intestine.

(Ex. D, claim 1.)

133. The novel method of treatment invented by the University of Tokyo and exclusively licensed by Vedanta is reflected in exemplary claim 16 of the '978 Patent which recites:

16. A method of treating a human subject having an infectious disease, the method comprising administering to the human subject the composition of claim 1.

(Ex. D, Claim 16.)

134. Upon information and belief, Defendants have actual knowledge of the '978 Patent.

135. Upon information and belief, when Seres, makes, uses, and/or sells Vowst®, a pharmaceutical capsule containing spore-forming fraction of human fecal matter, Seres infringes one or more claims of the '978 Patent.

136. Upon information and belief, Seres induced Nestlé to infringe one or more claims of the '978 Patent when Seres entered into a license with Nestlé, such that Nestlé began to make, use, and/or sell Vowst®.

137. Upon information and belief, when Nestlé makes, uses, and/or sells Vowst®, a pharmaceutical capsule containing spore-forming fraction of human fecal matter, Nestlé infringes one or more claims of the '978 Patent.

138. Upon information and belief, Defendants have specific intent that healthcare providers and patients use Vowst® to treat infection, according to the methods of the '978 Patent.

139. Upon information and belief, Defendants' actions have infringed, induced infringement, continue to infringe, and continue to induce infringement, of one or more claims of the '978 Patent under 35 U.S.C. § 271(b).

140. Upon information and belief, Defendants have acted with full knowledge of the '978 Patent, with knowledge that physician and patients will infringe the '978 patent when using Vowst® according the approved label, and without a reasonable basis for believing that they would not be liable for infringement of the '978 Patent.

141. Upon information and belief, Defendants' infringement of the '978 Patent has been and continues to be knowing, intentional, and willful.

142. Plaintiffs have suffered and continue to suffer damages as a result of Defendants' willful infringement of the '978 Patent in an amount to be determined at trial.

143. Plaintiffs are entitled to injunctive relief and damages in accordance with 35 U.S.C. §§ 271, 281, 283 and 284.

### **COUNT V**

#### **(Infringement of the '343 Patent)**

144. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

145. Upon information and belief, Defendants' actions have infringed, and will continue to infringe, the '343 Patent under 35 U.S.C. § 271(a).

146. Upon information and belief, Defendants' actions have induced infringement of, and will continue to induce others to infringe, the '343 Patent under 35 U.S.C. § 271(b).

147. Upon information and belief, the pharmaceutical composition of Vowst® is covered by one or more claims of the '343 Patent.

148. Upon information and belief, the method of treating human adults who have Clostridioides difficile infection, according to the full prescribing information for Vowst®, is covered by one or more claims of the '343 Patent.

149. The novel pharmaceutical composition invented by the University of Tokyo and exclusively licensed by Vedanta is reflected in exemplary claim 1 of the '343 Patent which recites:

1. A pharmaceutical composition, comprising one or more purified live bacterial strains belonging to Clostridium clusters IV or XIVa, wherein the one or more bacterial strains induces proliferation and/or accumulation of regulatory T cells, wherein the one or more bacterial strains are human commensal bacteria, and wherein the



pharmaceutical composition is formulated for delivery to the intestine.

(Ex. E, Claim 1.)

150. The novel method of treatment invented by the University of Tokyo and exclusively licensed by Vedanta is reflected in exemplary claim 16 of the '343 Patent which recites:

16. A method of treating a human subject having an infectious disease, the method comprising administering to the human subject the composition of claim 1.

(Ex. E, Claim 16.)

151. Upon information and belief, Defendants have actual knowledge of the '343 Patent.

152. Upon information and belief, when Seres makes, uses, and/or sells Vowst®, a pharmaceutical capsule containing spore-forming fraction of human fecal matter, Seres infringes one or more claims of the '343 Patent.

153. Upon information and belief, Seres induced Nestlé to infringe one or more claims of the '343 Patent when Seres entered into a license with Nestlé, such that Nestlé began to make, use, and sell Vowst®.

154. Upon information and belief, when Nestlé makes, uses, and/or sells Vowst®, a pharmaceutical capsule containing spore-forming fraction of human fecal matter, Nestlé infringes one or more claims of the '343 Patent.

155. Upon information and belief, Defendants have specific intent that healthcare providers and patients use Vowst® to treat infection, according to the methods of the '343 Patent.

156. Upon information and belief, Defendants' actions have infringed, induced infringement, continue to infringe, and continue to induce infringement, of one or more claims of the '343 Patent under 35 U.S.C. § 271(b).

157. Upon information and belief, Defendants have acted with full knowledge of the '343 Patent and without a reasonable basis for believing that they would not be liable for infringement of the '343 Patent.

158. Upon information and belief, Defendants' infringement of the '343 Patent has been and continues to be knowing, intentional, and willful.

159. Plaintiffs have suffered and continue to suffer damages as a result of Defendants' willful infringement of the '343 Patent in an amount to be determined at trial.

160. Plaintiffs are entitled to injunctive relief and damages in accordance with 35 U.S.C. §§ 271, 281, 283 and 284.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs Vedanta and the University of Tokyo request that the Court enter judgment for Plaintiffs against Defendants as follows:

A. A judgment that Defendants infringe the Asserted Patents under 35 U.S.C. § 271(a) or (b).

B. A permanent injunction restraining and enjoining Defendants, and their officers, agents, servants, and employees and those persons in active concert or participation with them, and their successors and assigns, from commercially manufacturing, marketing, distributing, using, offering to sell, or selling Vowst® or its API within the United States, or importing Vowst® or its API into the United States, or actively inducing others to do the same, prior to the expiration of the Asserted Patents;

C. That Plaintiffs be awarded damages adequate to compensate them for Defendants' past, present, and/or future infringement of the Asserted Patents, said damages being no less than

a reasonable royalty and/or lost profits together with any prejudgment and post-judgment interest as allowed by law, costs, and other damages permitted by 35 U.S.C. § 284;

D. A judgment finding that Defendants' infringement of the Asserted Patents was deliberate and willful, and an award of treble damages to Plaintiffs pursuant to 35 U.S.C. § 284;

E. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

F. An award of costs and expenses in this action; and

G. Such other and further relief as the Court may deem just and proper.

Date: August 20, 2024

**GREENBERG TRAUIG, LLP**

*Of Counsel:*

Scott J. Bornstein  
Jonathan D. Ball  
Greenberg Traurig, LLP  
One Vanderbilt Avenue  
New York, NY 10017  
(212) 801-9200  
bornsteins@gtlaw.com  
ballj@gtlaw.com

/s/ Benjamin J. Schladweiler  
Benjamin J. Schladweiler (#4601)  
222 Delaware Ave., Suite 1600  
Wilmington, DE 19801  
(302) 661-7352  
schladweilerb@gtlaw.com

*Attorneys for Plaintiffs Vedanta Biosciences,  
Inc. and The University of Tokyo*