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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

VETSTEM, INC., Plaintiff, v. REGEN LABS LLC dba REGENERATIVE MEDICAL LA, Defendant.	CASE NO.: 2:24-02475 **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff VetStem, Inc. ("VetStem" or "Plaintiff") files this Original Complaint against Defendant Regen Labs LLC dba Regenerative Medical LA, alleging as follows:

THE PARTIES

1. VetStem is a corporation organized and existing under the laws of Delaware having a principal place of business at 14261 Danielson Court, Poway, California 92064.

2. Defendant Regen Labs LLC ("RMLA" or "Defendant") is a limited liability company organized and existing under the laws of California, having a principal place of business at 9201 W. Sunset Blvd. Suite 414, West Hollywood, California 90069. RMLA operates a clinic location at this address under the trade name "Regenerative Medicine LA." RMLA may be served with process through its registered agent Dr. Mark Ghalili at 9201 W. Sunset Blvd. Suite 414, West Hollywood, California 90069.

JURISDICTION AND VENUE

3. This is a patent infringement action under 35 U.S.C. § 271, *et seq*.

4. This Court has jurisdiction to hear these matters, as this Court has exclusive subject matter jurisdiction over patent infringement causes of action arising under 28 U.S.C. §§ 1331, 1338(a).

5. RMLA's sole office location is within this District at 9201 W. Sunset Blvd. Suite 414, West Hollywood, California 90069. RMLA offers for sale, sells, and performs the accused regenerative stem cell therapies from this location. VetStem's claims of patent infringement against RMLA arise from these infringing acts, each of which is performed within this District.

6. Personal jurisdiction exists and venue is proper in this Court under 28 U.S.C. §§ 1391(b), (c), and 1400(b).

BACKGROUND AND FACTS

7. Dr. Bob Harman, D.V.M., M.P.V.M., is a licensed veterinarian with over thirty years of experience as a chief executive officer and biotechnology entrepreneur. Dr. Harman has founded and managed several successful biotechnology businesses — including VetStem and Personalized Stem Cells, Inc. Dr. Harman has also overseen

the completion of more than 1,000 contract research projects for the development of veterinary and human biotechnology products. Among these research projects are studies directed to the effectiveness of cell populations comprising adipose-derived mesenchymal stem cells for the treatment of osteoarthritis in canines. The results of these studies, and others, have been published in peer-reviewed research publications dating as far back as 2007.

8. In 2002, Dr. Harman co-founded VetStem for the purpose of offering new hope for animals suffering from debilitating diseases and life-altering injuries. VetStem is veterinarian-led and is focused on exploring regenerative modalities including, by way of example, stem cell therapies. Dr. Harman serves as the Chief Executive Officer of VetStem. Since its founding, VetStem has performed stem cell treatments to treat over 16,000 animals, becoming the world-leader in regenerative veterinary medicine services. VetStem's laboratory services has delivered stem cell treatments to over 2,400 veterinarians across the United States.

9. Dr. Harman has also spearheaded innovative research into therapeutic uses of adipose-derived stem cells in human applications. In October 2018, Dr. Harman co-founded Personalized Stem Cells, Inc. ("PSC"), a Delaware corporation having its principal place of business in Poway, California. PSC is an affiliate of VetStem operating under license to the VetStem Patents. PSC conducts studies for the purpose of developing and studying therapeutic treatments of various afflictions in humans using adipose derived stem cells. VetStem has contracted with PSC to provide stem cell lab services for use in studies conducted by PSC.

10. Additionally, VetStem has established research relationships with other prominent veterinarians and research institutions. VetStem is the exclusive licensee of over 50 patents held by the University of Pittsburg, the University of California, and Artecel, Inc. relating to use of adipose-derived stem cells.

11. VetStem's extensive research into regenerative stem cell treatments employing adipose-derived stem cells has yielded three validly issued U.S. Patents, to date. Among these are VetStem's U.S. Pat. No. 9,453,202 ("the '202 Patent") and U.S. Pat. No. 11,129,855 ("the '855 Patent"). Each is entitled "Methods of Preparing

and Using Novel Stem Cell Compositions and Kits Comprising the Same." They disclose and claim, respectively, certain novel treatment methods utilizing cell populations comprising adipose-derived stem cells.

THE ASSERTED PATENTS AND TECHNOLOGY

12. On September 27, 2016, United States Patent No. 9,453,202 was duly and legally issued for "Methods of Preparing and Using Novel Stem Cell Compositions and Kits Comprising the Same." As of the filing of this Complaint, the '202 Patent remains in force. A true and correct copy of the '202 Patent is attached hereto as Exhibit A and made a part hereof.

13. The application issuing as the '202 Patent was originally filed on October 7, 2004. It claims priority to four earlier filed provisional patent applications, including Provisional Application Ser. No. 60/510,021, filed on Oct. 8, 2003, Provisional Application Ser. No. 60/510,022, filed on Oct. 8, 2003, Provisional Application Ser. No. 60/509,928, filed on Oct. 8, 2003, and Provisional Application Ser. No. 60/510,072, filed on Oct. 8, 2003. The '202 Patent issued on September 27, 2016 following lengthy prosecution that resulted in the term of the '202 Patent being extended by 1173 days under 35 USC 154(b).

14. The '855 Patent was duly and legally issued on September 28, 2021, and is entitled "Methods of Preparing and Using Novel Stem Cell Compositions and Kits Comprising the Same." As of the filing of this Complaint, the '855 Patent remains in force. A true and correct copy of the '855 Patent is attached hereto as Exhibit B and made a part hereof. The application issuing as the '855 Patent was originally filed on April 27, 2020. It claims priority to the application issuing as the '202 Patent, and to the four provisional patent applications filed on Oct. 8, 2003. The '855 Patent shares a common specification with the '202 Patent.

15. The '202 Patent and the '855 Patent are referred to collectively, herein, as the "Asserted Patents" or the "Patents-in-Suit."

16. VetStem is the owner of all rights, title, and interest in the Asserted Patents — including all rights to enforce, prosecute, and collect damages for infringement thereof. Accordingly, VetStem possesses the exclusive right and

standing to bring the present action for RMLA's infringement of claims of the Asserted Patents, detailed herein.

17. The '202 Patent discloses and claims methods of treating inflammation at the site of a musculoskeletal injury or disease in both human and veterinary settings. The treatments utilize a cell population comprising stem cells obtained from adipose tissue (fat) harvested from the person or animal to be treated. The adipose tissue is processed to release and separate the cell population comprising stem cells from surrounding adipose tissue. Although the '202 Patent discloses and claims several alternative processing steps for both releasing and separating the cell population from the adipose tissue, this processing is typically done via enzymatic digestion followed by centrifugation. Once released and separated, the cell population comprising adipose derived stem cells is not subjected to additional processing to further isolate the stem cells from other cells within the cell population. Rather, according to the methods claimed in the '202 Patent, the cell population is then reintroduced into the patient directly at the site of a musculoskeletal injury or disease to treat inflammation.

18. The streamlined processing methodology claimed in the '202 Patent, which does not involve subsequent processing to isolate, culture, or expand the stem cell component of the cell population, ran counter to the prevailing thought and practice in the industry at the time of the '202 Patent application filing. At that time, stem cell therapies utilized cell populations comprising expanded stem cell populations obtained through costly and time-consuming rounds of culturing. Dr. Harman discovered that treatment with cell populations that have not been subjected to these further expansion and culturing steps are therapeutically superior, far less costly, and obtainable in far less time.

19. VetStem offers, sells, and performs therapies practicing the inventions claimed in the '202 Patent on animals. Likewise, VetStem's affiliate PSC also offers, sells, and performs therapies practicing the inventions claimed in the '202 Patent on human.

20. Because the '855 Patent is within the same patent family as the '202 Patent and shares a common specification, it discloses identical subject matter to that

disclosed in the '202 Patent. The claims of the '855 Patent are more broadly addressed to treatment methods utilizing a cell population comprising stem cells obtained via processing steps to release and separate the cell population from surrounding adipose tissue. Again, as claimed in the '855 Patent, this processing is devoid of any further steps to further isolate the stem cells contained therein from other cells released and separated from the adipose tissue. This cell population is then provided to the patient to treat an injury or disease afflicting the patient.

21. Importantly, the '202 and '855 Patents comprise only method claims. Therefore, VetStem is under no obligation to "mark" its products and services practicing any claim of the Asserted Patents under 35 U.S.C. § 287, *et seq*. Further, licensees to the Asserted Patents are also not obligated to mark their licensed products and services.

22. The '202 Patent has been in force for the duration of RMLA's infringing activities over the past six years. Therefore, VetStem is entitled to damages for the entire period thereof.

RMLA'S INFRINGING STEM CELL THERAPIES

23. RMLA operates one clinic location from which it commercially offers for sale, sells, and performs regenerative therapies utilizing cell populations comprising adipose-derived stem cells. These stem cell therapies are offered, sold, and performed for the treatment of various ailments. More specifically, RMLA offers, sells, and performs "Stem Cell Therap[ies]" that are described as using "naturally regenerate tissues inside your body" that possess "the ability to regenerate and convert into differentiated cells, producing various types of tissues." See Exh. G.1

24. RMLA touts on its website that its primary physician, Dr. Mark Ghalili (the only named manager in RMLA's corporate filings), "is a cutting-edge stem cell doctor offering stem cell therapy and platelet-rich plasma to effectively heal many types of injuries and diseases." Exh. G. RMLA also describes itself as operating "in

[1] Exhibit G is a screen capture of a webpage from RMLA's website, available at URL: https://regenerativemedicinela.com/treatments/stem-cell-therapy/.

collaboration with The Cell Surgical Network [and] is proud to be a world-class facility offering Stem Cell treatment in Los Angeles for patients looking for cutting edge therapies to improve their lives." Exh. G (providing links to several datasheets presenting patient outcome data from stem cell treatments and noting that "the Cell Surgical Network has performed over 12,000 stem cell cases"). RMLA references CSN's stem cell treatment protocols, studies, and patient outcome statistics throughout its website.

25. RMLA's Stem Cell Therapies are promoted for treatment of several injuries and disorders because "the combined effect of stem cells results in accelerated wound healing and regeneration of damaged tissues." Exh. G. RMLA's Stem Cell Therapies are therapeutically effective to "replicate to produce diverse tissues such as bone, cartilage, tendons, ligaments, and muscles" and to "reduce inflammation and relieve pain." Exh. G. RMLA affirms that "Stem Cell Therapy is frequently used to treat musculoskeletal conditions, such as damaged cartilage; muscle, ligament, and tendon tears; and inflammatory joint conditions like arthritis and bursitis." Exh. G (noting that "Stem cells' ability to form bone and cartilage makes them potentially highly effective in the treatment of degenerative orthopedic conditions").

26. RMLA's Stem Cell Therapies involve injection of cell populations comprising adipose derived stem cells (a type of mesenchymal stem cell) directly "at the site of your injured tissues," including directly into a patient's joints, muscle, tendon, or ligament being treated. Exh. G ("When Dr. Ghalili injects a concentrated amount of stem cells at the site of your injured tissues, the injected cells jump into action, doing their natural job: triggering new cell growth to heal the area.").

27. RMLA's Stem Cell Therapies are also performed to treat other conditions are treated via direct injection and/or intravenous deployment, including multiple sclerosis, hair loss, autoimmune conditions and diseases, COPD, immunological conditions, and others.

28. RMLA harvests fat (adipose tissue) from the patient's body, from which a cell population comprising adipose derived stem cells is extracted via processing steps that include centrifugation following incubation of the fat in an enzyme. See,

Exhs. G, F2 (listing work experience at RMLA to include "provid[ing] services and treatments for Stem Cell harvesting from adipose tissue;" and identifying as "Medical Training" that Dr. Ghalili is "Certified in harvesting stem cells from adipose tissue through a mini liposuction procedure and providing stem cells through joint injections, facial injections, and IV infusion").

29. Processing of the adipose tissue releases and separates the desired cell population comprising adipose stem cells, growth factors, and other cells from the adipose tissue. This stem cell population is then reintroduced into the patient's body to effect treatment. RMLA provides the following, high-level description of the procedure:

> Stem Cells are extracted from a patient's adipose tissue or love handles, not only do you receive millions of your own body's stem cells at once, we also remove some of the fat, so it's a win-win situation. The flank portion of the back is numbed with cream and then lidocaine, all while you are awake, and is completely painless. Once you are numb, we suction 50cc of fat or less than 2 ounces and from there we centrifuge the stem cells from the remaining fat and blood through a proprietary process that is registered with the IRB and the FDA. Once the Stem Cells are completely separated through this tedious and careful process, they can be reintroduced right back into your body the same day.

Exh. G (annotations added).

30. RMLA is an Affiliate within the Cell Surgical Network ("CSN").[3] CSN is a corporation organized and existing under the laws of California. CSN purports to operate a "medical network" for "the investigational use of Adipose Derived Stem Cells (ADSC's) for clinical research and deployment." CSN's medical network comprises several "Affiliate" clinics that offer for sale, sell, and perform regenerative stem cell procedures promoted by CSN in accordance with specific protocols and equipment provided by CSN. The CSN protocol is marketed as the CSN Time Machine system. Exh. C at 1.

[2] Exhibit F is a true and correct copy of a document described as Dr. Mark Ghalili's CV available for download from Cell Surgical Network's ("CSN") website at URL: https://stemcellrevolution.com/dt_team/mark-m-ghalili/. Dr. Ghalili is referred to by CSN as an Affiliate, which accords with statements made throughout RMLA's website. See, Exh. G.

[3] RMLA admits to being an Affiliate of CSN on its website, as noted above in para. 24 of this Complaint. Additionally, Dr. Mark Ghalili is identified as an Affiliate physician of CSN on CSN's website and Dr. Ghalili's CV obtainable through CSN's website. Exh. F.

31. VetStem has alleged infringement of the claims of its '202 Patent through use of the CSN Time Machine system and protocol for treatment of musculoskeletal injuries and diseases in another, recently concluded litigation against another CSN Affiliate. In particular, VetStem alleged infringement of at least claim 1 of the '202 Patent by California Stem Cell Treatment Center, Inc. ("CSCTC") relating to CSCTC's selling and performing stem cell therapies in accordance with the CSN Time Machine system and protocol to treat musculoskeletal injuries and diseases.[4]

32. During the CSCTC Litigation, the District Court found, as a matter of law on summary judgment, that use of the CSN Time Machine system and treatment protocol for treatment of musculoskeletal injuries and diseases infringed claims of the '202 Patent. *See*, Exh. D (Plaintiff's Memorandum of Contentions of Fact and Law [Dkt. 229] submitted in the CSCTC Litigation). RMLA utilizes the same CSN Time Machine system and treatment protocol to perform its accused Stem Cell Treatments.

33. Aspects of CSN's infringing protocols are memorialized in the CSN study article, including a description of the equipment and processing steps for collecting adipose tissue from a patient and obtaining a cell population comprising adipose stem cells (referred to as "SVF" in CSN's documents). *See*, *generally*, Exh. C. Specifically, the article describes processing steps including enzymatic digestion of adipose tissue followed by centrifugation to separate the SVF cell population. In application for treatment of musculoskeletal conditions, such as arthritis of the knee, for example, the prepared SVF is injected directly to the site of the musculoskeletal injury or disease to reduce inflammation present at the site.

34. CSN Affiliate clinics and physicians are required to purchase CSN's Time Machine equipment and to adhere to CSN's protocols for operating the Time Machine to produce SVF and for therapeutic deployment of the SVF to treat patients.[5]

[4] VetStem, Inc. v. Cal. Stem Cell Treatment Center, Inc., Case No. 2:19-CV-4728-AB, filed in the Central District of California, Western Division ("the CSCTC Litigation").

[5] See Original Complaint at 5–6, United States v. Cal. Stem Cell Treatment Center, Inc., 624 F. Supp. 3d 1177 (C.D. Cal. 2022) (No. 5:18-CV-1005); see also Memorandum in Opposition to

35. Based on CSN's requirements in how Affiliates must operate the Time Machine equipment and processes, CSN's Affiliates have already been effectively adjudicated to infringe at least the '202 Patent based on their performance of CSN's instructions and treatment procedures. By way of example, the California Stem Cell Treatment Center, Inc. ("CSCTC") is an Affiliate clinic within CSN.

36. RMLA has commercially offered and performed regenerative adipose derived stem cell therapies in human patients from its clinic located within this District since at least 2017. Exhs. F, G. RMLA's principal physician and its lone corporate manager is Dr. Mark Ghalili, an Affiliate physician of CSN.

37. RMLA and Dr. Ghalili admit to working in collaboration with CSN as an Affiliate thereof, as indicated by the several statements on RMLA's website and on Dr. Ghalili's C.V., referenced herein.

38. Upon information and belief, therefore, RMLA utilizes the same, infringing regenerative stem cell therapy protocols that all CSN Affiliates are contractually obligated to use. These are the very same protocols that have been found to infringe VetStem's patent rights as a matter of law. Specifically, RMLA offers and performs regenerative stem cell therapies at its clinics, during which fat (adipose tissue) is harvested from a patient as lipoaspirate via a liposuction procedure. The lipoaspirate is then treated with an enzyme to effectuate enzymatic digestion, thereby releasing a cell population comprising adipose derived stem cells (sometimes referred to as "SVF"). This cell population is known to comprise a heterogeneous mixture of adult mesenchymal stem cells and several other types of cells and growth factors. Centrifugation is used to separate the desired cell population from the surrounding adipose tissue. Once separated, the cell population is injected directly into the site of the injury or disease being treated. For musculoskeletal conditions, injections are made directly to the site of the afflicted bone, joint, cartilage, ligament, tendon,

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Plaintiff's Motion for Summary Judgment at 29, United States v. Cal. Stem Cell Treatment Center, Inc., 624 F. Supp. 3d 1177 (C.D. Cal. 2022) (No. 5:18-CV-1005).

muscle, or the like to treat the inflammation at the site(s) of the musculoskeletal injury or disease.

39. The Abstract of the study article entitled "Safety of Stromal Vascular Fraction Cells Applications in Chronic Pain" provides the following description of the protocol employed by CSN Affiliates (including by RMLA) and the results achieved:

> Autologous stromal vascular fraction (SVF) can be ***enzymatically released from lipoaspirate*** obtained under local anesthesia. SVF is known to have regenerative, ***anti-inflammatory***, pain mitigating, and immune-modulatory properties. Our translational research network has been studying the safety and efficacy of SVF since 2012. Almost 100 related physician teams around the world are applying the same institutional review board-approved methods of SVF production, which use a surgically closed SVF isolation system. ***During the same outpatient surgical procedure, procured SVF is administered*** according to strict investigative protocols to mitigate diseases associated with chronic pain including arthritis, autoimmune disease, neurodegenerative disease, and various inflammatory conditions. The shared research collaborative online database contains safety and efficacy data on more than 3500 patients. ***Our processed SVF contains valuable cytokine growth factors in addition to both adult mesenchymal and hematopoietic stem cells targeting damaged, or inflamed tissue.*** SVF administration may potentially play a large role in the outpatient treatment of pain. In this article, we describe our protocol for the production and administration of SVF, and its safety and efficacy in the treatment of pain associated with chronic conditions.

See Landar, MD et al., Safety of Stromal Vascular Fraction Cells Applications in Chronic Pain (2016) (emphasis added) (attached hereto as Exh. E).

40. RMLA performance of this system and treatment protocol of CSN constitutes practice of the inventions claimed in one or more claims of the '202 and '885 Patents. Such performance constitutes a patented use of a composition of matter (e.g., claimed methods of obtaining and using a cell population comprising adipose derived stem cells to effect treatment). Such use directly causes a therapeutic effect, such as the treatment of inflammation occurring at a site of a musculoskeletal injury or disease of the patient.

41. As mentioned above, VetStem has asserted its patents against other CSN affiliates for practicing the same infringing protocols that RMLA practices. CSN and its founders, Drs. Berman and Lander, regularly communicate with its Affiliates with regard to the protocols it promotes, to include providing updates on litigations challenging the use of those protocols filed by the FDA and by VetStem. Therefore, upon information and belief, RMLA learned of the VetStem Patents, as well as the infringing nature of its own conduct, by way of CSN's inter-network communications, inter-network conferences, and/or word of mouth in relation to discussions of VetStem's enforcement actions against other CSN Affiliates. Accordingly, upon information and belief, RMLA and/or Dr. Ghalili have been aware of VetStem, its patent rights, and the infringement claims presented herein since at least May 30, 2019, the date on which VetStem filed its Complaint for infringement against CSCTC, if not earlier.

COUNT I

Infringement of U.S. Patent No. 9,453,202 by RMLA

42. VetStem repeats and realleges the preceding paragraphs as if fully set forth herein.

43. RMLA, without authority, consent, right or license, offers for sale, sells, and/or performs Stem Cell Therapies for the treatment of various conditions and diseases that practice the invention claimed in at least claim 1 of the '202 Patent.

44. RMLA's offering for sale, selling, and/or performing its Stem Cell Therapies to treat musculoskeletal injuries and diseases, including arthritis, knee pain, meniscus tears, muscle injuries, tendon injuries, and ligament injuries, among others, directly infringes at least claim 1 of the '202 Patent. RMLA is therefore liable for direct infringement, either literally or under the doctrine of equivalents, of the '202 Patent pursuant to 35 U.S.C. § 271(a) by at least following the procedures described by CSN's requirements of its Affiliates.

45. RMLA's physicians, personnel, representatives, affiliates, and/or agents perform its regenerative stem cell therapies to effect treatment on human patients.

46. More specifically, RMLA's physicians and/or personnel collect adipose tissue from the patient through tumescent liposuction, during which the adipose tissue is repeatedly scraped using a cannula to slice and cut away small pieces of adipose tissue for removal.

47. The harvested lipoaspirate comprising adipose tissue is further processed by RMLA's physicians and/or personnel to prepare cell population comprising stem cells from the adipose tissue.

48. The processing steps include, first, incubating the harvested adipose tissue with an enzyme resulting in enzymatic digestion of the adipose tissue to release the cell population therein, comprising stem cells and growth factors, from within the lipoaspirate.

49. Thereafter, the released cell population undergoes centrifugation to separate the cell population from the digested adipose tissue. The resulting cell population comprises stem cells and growth factors, among other cell types.

50. The cell population is loaded into one or more syringes for injection into the patient without any further processing being performed to further isolate the stem cells from the other cells separated from the adipose tissue.

51. For treatment of musculoskeletal conditions, the cell population is deployed via direct injection into the patient at the joint, bone, cartilage, ligament, tendon, bursa, or muscle at which the musculoskeletal condition or disease is present. These stem cell treatments are promoted by RMLA to reduce inflammation and relieve pain resulting from the musculoskeletal condition or disease at the injection site.

52. The performance of its Stem Cell Therapies to treat musculoskeletal injuries and diseases by RMLA in this manner constitutes direct infringement of at least claim 1 of the '202 Patent.

53. Such performance constitutes the practice of a patented use of a composition of matter in violation of at least claim 1 of the '202 Patent, which disclosed subject matter in the field of biotechnology.

54. RMLA's Stem Cell Therapies are offered commercially and for profit to patients, are paid for commercially by the patients, and are not solely for uses reasonably related to the development and submission of information for testing to obtain approval from the Food and Drug Administration.

55. VetStem expressly reserves the right to assert additional claims of the '202 Patent against RMLA.

56. VetStem has been damaged as a result of RMLA's infringing conduct. RMLA is, thus, liable to VetStem in an amount that adequately compensates for their infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

57. Upon information and belief, RMLA and/or Dr. Ghalili have been aware of VetStem, its patent rights, and the infringement claims presented herein since at least May 30, 2019, the date on which VetStem filed its Complaint for infringement against CSCTC, if not earlier.

58. Based on RMLA's actual knowledge of the '202 Patent and specific knowledge of VetStem's infringement claims presented herein, in addition to RMLA's objective recklessness in continuing to make, use, and sell its regenerative stem cell therapies thereafter, RMLA's infringement of the '202 Patent has been willful since at least May 30, 2019. Therefore, VetStem is further entitled to enhanced damages under 35 U.S.C. § 284.

COUNT II

Infringement of U.S. Patent No. 11,129,855 by RMLA

59. VetStem repeats and realleges the preceding paragraphs as if fully set forth herein.

60. RMLA, without authority, consent, right or license, offers for sale, sells, and/or performs Stem Cell Therapies for the treatment of various conditions and diseases that practice the invention claimed in at least claim 1 of the '855 Patent.

61. RMLA's offering for sale, selling, and/or performing its Stem Cell Therapies to treat musculoskeletal injuries and diseases, neurological conditions, autoimmune diseases, heart disease, urologic conditions, kidney and bladder

conditions, vascular disease, and lung diseases, among others, directly infringes at least claim 1 of the '855 Patent. RMLA is therefore liable for direct infringement, either literally or under the doctrine of equivalents, of the '855 Patent pursuant to 35 U.S.C. § 271(a) by at least following the procedures described by CSN's requirements of its Affiliates.

62. RMLA's physicians, personnel, representatives, affiliates, and/or agents perform its development of cell populations and its regenerative stem cell therapies to effect treatment on human patients.

63. More specifically, RMLA's physicians and/or personnel collect adipose tissue from the patient through tumescent liposuction, during which the adipose tissue is repeatedly scraped using a cannula to slice and cut away small pieces of adipose tissue for removal.

64. The harvested lipoaspirate comprising adipose tissue is further processed by RMLA's physicians and/or personnel to prepare cell population comprising stem cells from the adipose tissue, which RMLA (and CSN) refer to as "SVF."

65. The processing steps include, first, incubating the harvested adipose tissue with an enzyme resulting in enzymatic digestion of the adipose tissue to release the cell population therein, comprising stem cells and growth factors, from within the lipoaspirate.

66. Thereafter, the released cell population undergoes centrifugation to separate the cell population from the digested adipose tissue. The resulting cell population comprises stem cells and growth factors, among other cell types.

67. The cell population is loaded into one or more syringes for injection into the patient without any further processing being performed to further isolate the stem cells from the other cells separated from the adipose tissue.

68. RMLA's preparation and use of its regenerative stem cell therapies in this manner constitutes direct infringement of at least claim 1 of the '855 Patent.

69. Such performance constitutes the practice of a patented use of a composition of matter in violation of at least claim 1 of the '855 Patent, which is addressed to subject matter in the field of biotechnology.

70. RMLA's Stem Cell Therapies are offered commercially and for profit to patients, are paid for commercially by the patients, and are not solely for uses reasonably related to the development and submission of information for testing to obtain approval from the Food and Drug Administration.

71. VetStem expressly reserves the right to assert additional claims of the '855 Patent against RMLA.

72. VetStem has been damaged as a result of RMLA's infringing conduct. RMLA is, thus, liable to VetStem in an amount that adequately compensates for their infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

73. Upon information and belief, RMLA and/or Dr. Ghalili have been aware of VetStem, its patent rights, and the infringement claims presented herein since at least May 30, 2019, the date on which VetStem filed its Complaint for infringement against CSCTC, if not earlier.

74. Based on RMLA's actual knowledge of the '202 Patent and specific knowledge of VetStem's infringement claims presented herein, in addition to RMLA's objective recklessness in continuing to make, use, and sell its regenerative stem cell therapies thereafter, RMLA's infringement of the '855 Patent has been willful since issuance of the '855 Patent through to the present. Therefore, VetStem is further entitled to enhanced damages under 35 U.S.C. § 284.

PRAYER FOR RELIEF

VetStem requests that the Court find in its favor and against RMLA, and that the Court grant VetStem the following relief:

a. Judgment that one or more claims of the '202 and '855 Patents have been infringed, either literally and/or under the doctrine of equivalents, by RMLA;

b. Judgment that RMLA accounts for and pay to VetStem all damages to and costs incurred by VetStem because of RMLA's infringing activities;

c. Judgement that RMLA's infringement is willful from the time RMLA became aware of the infringing nature of its products and services and that the Court

award treble damages for the period of such willful infringement pursuant to 35 U.S.C. § 284;

d. That VetStem be granted pre-judgment and post-judgment interest on the damages caused by RMLA's infringing activities and other conduct complained of herein;

e. That the Court declare this an exceptional case and award VetStem its reasonable attorney's fees and costs in accordance with 35 U.S.C. § 285;

f. That RMLA, its officers, agents, servants and employees, and those persons in active concert and participation with any of them, be permanently enjoined from infringement of one or more claims of the '202 and '855 Patents by the acts complained of herein. In the alternative, if the Court finds that an injunction is not warranted, VetStem requests an award of post judgment royalty to compensate for future infringement; and

g. That VetStem be granted such other and further relief as the Court may deem just and proper under the circumstances.

JURY DEMAND

VetStem hereby requests a trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure.

DATED: March 26, 2024

Respectfully submitted,

/s/ Matthew L. Rollin
MATTHEW L. ROLLIN
SRIPLAW, P.A.

and

JONATHAN T. SUDER (*pro hac vice* to be filed)
GLENN S. ORMAN (*pro hac vice* to be filed)
RICHARD A. WOJCIO, JR. (*pro hac vice* to be filed)
FRIEDMAN, SUDER & COOKE

Counsel for Plaintiff VetStem, Inc.