UNITED STATES DISTRICT COURT
DISTRICT OF KANSAS

VETSTEM BIOPHARMA, INC., Plaintiff, vs. ENSO DISCOVERIES LLC; KANSAS REGENERATIVE MEDICINE CENTER LLC; PATRICK FARLEY, individually; and, JAMES COREY ORAVA, D.V.M., individually, Defendants.	CASE NO.: **JURY TRIAL DEMANDED**

ORIGINAL COMPLAINT

Plaintiff VetStem Biopharma, Inc. ("VetStem" or "Plaintiff") files this Original Complaint against Defendants Enso Discoveries LLC, Kansas Regenerative Medicine Center LLC, Patrick Farley, and James Corey Orava, D.V.M. alleging as follows:

THE PARTIES

1. VetStem is a corporation organized and existing under the laws of the California having a principal place of business at 12860 Danielson Court, Suite B, Poway, California 92064.

2. Defendant Enso Discoveries LLC ("Enso") is a limited liability company organized and existing under the laws of Kansas, having a principal place of business at 2017 Vanesta Place, Suite 118, Manhattan, Kansas 66503. Enso may be served with process through its registered agent Kenneth Woods at 4114 Will Kent Drive, Manhattan, Kansas 66502.

3. Enso was originally formed and operated under the name Veterinary Regenerative Products LLC ("VRP"). VRP was founded as a Kansas limited liability company having its principal place of business at 4114 Will Kent Drive, Manhattan, Kansas, in April 2014. Filings with the Kansas Secretary of State show Farwood Holdings, LLC of 4809 Vue De Lac Place,

Suite 101, Manhattan, Kansas 66503 as the owner of VRP. Farwood Holdings, LLC was incorporated in Kansas in December 2014. Its first Annual Report filing with the Kansas Secretary of State shows its ownership group as comprising Defendant Patrick Farley along with John W. Farley and Kenneth Woods. VRP was renamed Enso Discoveries LLC in June 2016 and is now owned by Farwood Holdings, LLC and Patrick Farley, individually. The ownership group of Farwood Holdings, LLC additionally includes Katelyn Farley of 2223 Alta Drive, Manhattan, Kansas 66502 as of April 2018 along with the original ownership group.

4. Defendant Kansas Regenerative Medicine Center LLC ("KRMC") is a limited liability company organized and existing under the laws of Kansas, having a principal place of business at 4809 Vue Du Lac Place, Suite 101, Manhattan, Kansas 66503. KRMC may be served with process through its registered agent Ken Woods at 4114 Will Kent Drive, Manhattan, Kansas 66502.

5. KRMC was incorporated on November 22, 2013. KRMC's first Annual Report filing with the Kansas Secretary of State shows its ownership group as comprising Defendant Patrick Farley, John W. Farley, and Kenneth A. Woods, Jr. As of April 2018, KRMC's ownership comprises Farwood Holdings, LLC and Patrick Farley, individually. Likewise, KRMC's website at URL: https://kansasrmc.com/about lists Defendant Patrick Farley, John Farley, and Ken Woods as founders of KRMC.

6. Upon information and belief, Defendant Patrick Farley ("Farley") is an individual residing in the City of Manhattan within Riley County, Kansas since at least 2015. At the time of filing of the present Complaint, Farley serves as the President and Chief Executive Officer of Enso and is a founder and an owner of both Enso and KRMC.

7. Upon information and belief, Defendant James Corey Orava, D.V.M., ("Orava") is an individual residing in the City of Manchester within Bennington County, Vermont at all times relevant to the claims and allegations presented herein. Orava currently serves as the Chief Scientific Officer of Enso.

8. Enso, KRMC, Patrick Farley, and James Corey Orava are sometimes referred to collectively herein as "Defendants."

JURISDICTION AND VENUE

9. This is an action alleging multiple causes of action, including patent infringement under 35 U.S.C. §§ 271, *et seq.*, and breach of contract under common law of the State of California.

10. This Court has jurisdiction to hear these matters. This Court has exclusive subject matter jurisdiction over the patent infringement causes of action under 28 U.S.C. §§1331, 1338(a). This Court has supplemental jurisdiction over the non-patent causes of action pursuant to 28 U.S.C. § 1367. These non-patent causes of action are so related to Plaintiff's patent infringement claims that they each form part of the same case or controversy because, at a minimum, determination of whether Defendants practice the subject matter claimed in the Asserted Patent bear upon whether Defendants Farley and Orava have breached the no-compete clauses of their respective employment agreements with Plaintiff. Additionally, or alternatively, this Court has jurisdiction over the non-patent causes of action pursuant to 28 U.S.C. § 1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.

11. Defendants each reside in Kansas and/or have sufficient minimum contacts with the District of Kansas such that this venue is fair and reasonable. Defendants have committed such purposeful acts and/or transactions in this District that each reasonably should know and expect that they could be hailed into this Court as a consequence of such activity. Defendants have transacted and, at the time of the filing of this Complaint, continue to transact business within the District of Kansas. Defendants, respectively, make, use, and/or sell products and services that are the subject of the patent infringement claims made herein in the District of Kansas.

12. Enso maintains its principal place of business at 2017 Vanesta Place, Suite 118, Manhattan, Kansas 66503, within this District. Upon information and belief, Enso makes, uses,

and sells its accused regenerative therapy products and services at this location. Enso markets and sells these products and services through its website at URL: https://ensodiscoveries.com.

13. KRMC maintains its principal place of business at principal place of business at 4809 Vue Du Lac Place, Suite 101, Manhattan, Kansas 66503. Upon information and belief, KRMC makes, uses, and sells its accused regenerative therapy products and services at this location. KRMC markets and sells these products and services through its website at URL: https://kansasrmc.com/.

14. Upon information and belief, Defendant Farley is a permanent resident of the state of Kansas. This court, therefore, has personal jurisdiction over Defendant Farley. Additionally, or alternatively, Defendant Farley is a founder, owner, and officer of both Enso and KRMC, both of which are organized and exist under the laws of Kansas. Through both Enso and KRMC, Defendant Farley regularly transacts business within this District.

15. Defendant Orava has availed himself of the jurisdiction of this Court through his substantial, continuing, and ongoing contacts with the state of Kansas such that facing suit in Kansas is fair and reasonable. Orava has availed himself of the protections and laws of Kansas through at least his employment with Enso (f/k/a VRP) as its Chief Scientific Officer responsible for "developing and validating medical products and devices for both the human and veterinary fields." The development, use, and sale of such products and devices by Enso forms at least part of the basis for the causes of actions presented herein. Through Enso, therefore, Orava regularly transacts business within this District.

16. For these reasons, personal jurisdiction exists and venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b), respectively.

17. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b), because Defendants reside in or maintain their respective principal places of business, where applicable, within this District. It is from these locations that Defendants, respectively, have engaged in conduct forming the bases for the claims of patent infringement and breach of contract.

BACKGROUND AND FACTS

18. Dr. Bob Harman, D.V.M., M.P.V.M., is a licensed veterinarian with nearly 30 years of experience as a chief executive officer and biotechnology entrepreneur. Dr. Harman has founded and managed several successful biotechnology businesses, including VetStem. Additionally, Dr. Harman has overseen the completion of more than 1,000 contract research projects in his career for the development of veterinary and human biotechnology products. Among these are three studies directed to the effectiveness of adipose-derived mesenchymal stem cells for the treatment of osteoarthritis in canines published in peer-reviewed research publications dating as far back as 2007.

19. In 2002, Dr. Harman co-founded VetStem for the purpose of offering new hope for animals suffering from debilitating diseases, life-altering injuries, fractures, joint damage, or degenerative disease. VetStem is veterinarian-led and focused on exploring regenerative modalities including stem cell therapies in veterinary applications. Dr. Harman serves as the Chief Executive Officer of VetStem.

20. 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 Asserted Patent to conduct studies and develop human stem cell therapies practicing the claims of the Asserted Patent. VetStem has contracted with PSC to provide stem cell lab services for use in studies conducted by PSC.

21. VetStem's has established research relationships with other prominent veterinarians and research institutions and is the exclusive licensee of over 50 issued patents covering the use of adipose-derived stem cells held by the University of Pittsburgh, the University of California, and Artecel, Inc. Additionally, VetStem's own pioneering research into regenerative treatments employing adipose-derived stem cells resulted in the development of patented treatment methods owned by VetStem, including those disclosed and claimed in U.S. Patent No. 9,453,202 B2.

22. VetStem is the current world leader in providing regenerative veterinary medicine services, having assisted in the treatment of over 12,000 animals since 2002 and is a pioneer in the field of adult stem cell therapy options for veterinary medicine. VetStem's lab services are used by over 2,000 practicing veterinarians throughout the United States.

23. VetStem has developed confidential information and valuable trade secrets relating to VetStem's business operations, lab and treatment procedures, validation procedures, research plans and results, lists of clients and veterinary affiliates, financial information, and product production and distribution. VetStem has employed reasonable steps to ensure the secrecy of its confidential information and trade secrets through at least its regular practice of entering into Confidentiality Agreements prior to any disclosure thereof, inclusion of specific provisions requiring maintenance of confidentiality and non-use of its confidential trade secret information in Employment Agreements, and requiring the return of all VetStem materials by former employees upon termination of their employment.

24. Beginning on August 28, 2006, Defendant Orava was employed at will by VetStem as its Eastern Equine Veterinary Services Manager under the terms of an Employment Agreement executed on August 14, 2006 ("Orava Employment Agreement") and a Confidential Disclosure Agreement executed on July 10, 2006 ("Orava CDA"). The Orava Employment Agreement is attached hereto as Exhibit A and the Orava CDA is attached hereto as Exhibit B.

25. As part of his employment with VetStem and in furtherance of performance of his job duties, Orava was provided access to VetStem's confidential business information relating to VetStem's business operations, lab and treatment procedures, research plans and results, lists of clients and veterinary affiliates, financial information, and product production and distribution.

26. The Orava Employment Agreement provides that Orava's duties to VetStem precluded Orava from "provid[ing] employee or consulting services or other business or scientific services to any other party, without the prior written consent of [VetStem]…" at Section 2.

27. The Orava Employment Agreement includes an acknowledgement by Orava of VetStem's "proprietary interest [] in any Trade Secrets…" at Section 6.3.1.

28. The Orava Employment Agreement includes a covenant by Orava not to divulge the trade secrets of VetStem, requiring that Orava "at all times during the term of the employment by [VetStem] and thereafter to hold in strictest confidence, and not to use, disclose or allow to be disclosed to any person, firm, or corporation, Trade Secrets of [VetStem]…" at Section 6.3.2.

29. The Orava Employment Agreement includes a "No Adverse Use" precluding use of VetStem's trade secrets at any time that in any manner directly or indirectly adverse to VetStem's business at Section 6.4.

30. The Orava Employment Agreement includes a "Covenant Not to Compete" clause prohibiting Orava from directly or indirectly competing with VetStem in any business in which VetStem was engaged in or which is involved in a related technology thereto at Section 7.

31. The Orava Employment Agreement provides for the award of attorney's fees in favor of the prevailing party for any enforcement action arising from a breach of its terms at Section 8.1.

32. The Orava Employment Agreement is to be interpreted and enforced in accordance with the laws of California pursuant to Section 8.7 of the Agreement.

33. Orava was placed on unpaid leave on March 31, 2015 for knowingly submitting false expense reports in connection with Orava's work for VetStem in November 2014 and February 2015 in violation of the VetStem's expense policies and for behavior that was not considered ethical for an employee, and was subsequently terminated for cause pursuant to Section 4.3 of the Orava Employment Agreement.

34. At the time, VetStem had no knowledge or suspicion that Orava was otherwise violating the provision of the Orava Employment Agreement. However, upon first learning of Enso by viewing its website in or around January 2018 and subsequently receiving emailed

marketing of Enso's fee schedule for stem cell services in or around April 2018, VetStem began to investigate Enso and Orava further.

35. Subsequent inspection of Orava's work computer revealed that Orava had been planning and preparing to leave VetStem to join VRP (later renamed Enso), a direct competitor of VetStem, during his employment at VetStem and was using VetStem confidential and trade secret information for prohibited purposes. For example, Orava's work computer contained emails between Orava and Defendant Patrick Farley, John Farley, and Dr. Chanran Ganta from January and February 2015 – all of whom were then involved with the KRMC and/or VRP, and with the Kansas State University Veterinary Diagnostic Laboratory ("KSVDL") (to which VRP was partnered). The emails regarded a "horse blood draw," "the current stem cell study at K State," "many papers that discuss the cryopreservation of mesenchymal stem cells," and "future opportunities." Also found in the folder "SERVER-FS1\Marketing\Corey's Docs\KRMC" was a document titled "Revenue streams Kansas Properties" which detailed short term, mid-range, and long term revenue goals and analysis for various stem cell services to be offered by KRMC and VRP and in partnership with KSVDL, as well as Orava's roles in the development and provision of those services. One of Orava's anticipated roles was "to validate the SVF kits in horses, dogs and cats and to create a plan for implementing sales based upon the extensive contacts I have in this market." Additionally, upon information and belief, Orava copied internal VetStem documents and procedures and contacted several VetStem customers in anticipation of his leaving VetStem to join VRP.

36. VRP was formed in Kansas in April 2014, nearly a year before Orava was terminated by VetStem. VRP's website describes the company as "Veterinarians and partnering staff who have been involved with regenerative medicine (stem cells and platelet-rich plasma) …" at URL: http://vetrp.com/about-us/. VRP's website shows Orava as its Chief Scientific Officer, the position Orava continues to hold at Enso.

37. Orava's biographical information on the Enso website confirms this timeline of events, stating:

> First introduced to stem cell treatment and regenerative medicine in the early 2000s, Dr. Orava was so impressed and inspired by the transformative therapy that he left his position as an equine veterinarian at a progressive sports horse practice to pursue full-time work with a California-based company that focused on regenerative medicine. In 2015, Dr. Orava joined a start-up company based in Manhattan, Kansas, that focused on developing innovative regenerative medicine products for the veterinary field. That company has evolved into Enso Discoveries.

This information is available on Enso's website at URL: https://ensodiscoveries.com/about-2/management-team/.

38. Defendant Patrick Farley was likewise employed at will at VetStem under the terms of an Employment Agreement ("Farley Employment Agreement"), serving as VetStem's Vice President of Sales and Marketing from January 21, 2013 through January 3, 2014. The Farley Employment Agreement, attached hereto as Exhibit C, includes substantially identical provisions to those of the Orava Employment Agreement, namely Sections 6.3.1, 6.3.2, 6.4, 7, 8.1, and 8.7, discussed above.

39. Defendant Farley co-founded and formed KRMC in November 2013 while still employed at VetStem in direct violation of the Farley Employment Agreement. Documents filed with the Kansas Secretary of State list Defendant Farley and Farwood Holdings LLC as the owners of KRMC. Farwood Holdings, LLC filings with the Kansas Secretary of State list Defendant Farley, along with John Farley and Kenneth Woods as owners of Farwood Holdings LLC. Additionally, Defendant Farley is shown on the KRMC website as a Founder of the company. Farley's LinkedIn page also shows that he served as President of the KRMC from January 2014 through April 2016.

40. Farley also co-founded VRP (later Enso) three months after leaving VetStem, also in direct violation of the Farley Employment Agreement. Documents filed with the Kansas Secretary of State list Defendant Farley and Farwood Holdings LLC as the owners of Enso. Farwood Holdings, LLC filings with the Kansas Secretary of State list Defendant Farley, along with John W. Farley and Kenneth Woods as owners of Farwood Holdings LLC. The Enso and

VRP websites describe Defendant Farley as the company founder and President and CEO at URL: https://ensodiscoveries.com/about-2/management-team/ and at vetrp.com.

41. Farley is shown on the Enso website as its President and Chief Executive Officer. His biographical information confirms the timeline laid out herein, stating:

> Patrick has been involved in the world of regenerative medicine for several years. He was Vice President of marketing and sales for a well-established company on the veterinary side and was President and co-founder of a human regenerative medicine clinic which is one of the largest and most successful standalone stem cell clinics in the world today.

This information is available on Enso's website at URL: https://ensodiscoveries.com/about-2/management-team/.

42. Enso (f/k/a VRP) offers stem cell therapy products and services for veterinary applications for treating musculoskeletal conditions, such as osteoarthritis, among others. More specifically, Enso commercially uses and sells its Adipose Derived Stem Cell Lab services in connection with regenerative therapies performed by veterinarians. These services accommodate administration of adipose derived stem cell therapies by veterinarians to treat musculoskeletal conditions and inflammation relating thereto. For example, Enso describes the regenerative therapies accommodated as providing anti-inflammatory and analgesic effects at the injury site and as being usable to treat at least the following musculoskeletal injuries/diseases in animals: tendon and ligament injuries; joint injuries and degenerative joint disease (osteoarthritis); osteochondrosis; meniscal tears; stifle ligament injuries; fractures; and Cervical Facet Joint Osteoarthritis.

43. These therapies are performed by veterinarians in accordance with procedures developed and provided by Enso using cell populations prepared by Enso which comprise stromal vascular fraction ("SVF") pre-loaded by Enso into vials for injection at the site of the musculoskeletal injury or disease by veterinarians. Enso describes the SVF cell populations it provides as comprising "a heterogeneous mixture of cells which include adipose stem cells" and notes that "intra-articular regenerative cells may provide long-term anti-inflammatory effects,

decrease pain, initiate healing in acute and chronic tendon/ligament injuries and stimulate regeneration of cells."

44. Enso provides lab services to veterinarians to prepare these SVF cell populations from adipose tissue collected from an animal patient. The source tissues is "easily harvested from the [animal's] own adipose (fat) tissue" from which "[l]arge numbers of stem cells, and other regenerative cells are obtained." Enso instructs vets to aseptically collect adipose tissue from an animal patient and send the collected tissue to Enso via the "Validated Enso Shipping System." Upon receipt, lab technicians at Enso' lab in Manhattan, Kansas process the adipose tissue to release and separate the SVF from the adipose tissue. The separated SVF cell population is loaded into syringes and shipped back to the vet. ("Enso isolates the regenerative cells and returns them in a sterile vial for the veterinarian to inject/apply as necessary.") The processing is done on the same day as receipt of the adipose tissue and the SVF loaded syringes are "returned in 48 hours after collection" from Enso's lab. Vets are instructed to inject the SVF into the animal patient "into each affected joint." Enso even provides instructional videos showing proper injection locations for treating musculoskeletal conditions affecting the animal's elbow, strifle, or shoulder.

45. Enso touts its lab services and the adipose derived stem cell therapies accommodated thereby as providing "a higher quantity of viable cells than other tissues and it's a minimally invasive procedure." Enso also states that "[t]he advantage of using adipose-derived regenerative stem cells is that culturing to increase cell numbers is not necessary."

46. Upon information and belief, Enso does not provide its Stem Cell Lab services providing SVF cell populations in connection with any clinical study or trial relating to development of a corresponding medical procedure in humans. Rather, Enso offers its Stem Cell Lab services providing SVF cell populations commercially for profit.

47. KRMC offers stem cell therapy products and services for human applications for treating musculoskeletal conditions, such as osteoarthritis, among others from its two Kansas clinic locations – one in Manhattan, Kansas and the other in Kansas City, Kansas. KRMC

markets itself as "one of the largest stem cell treatment centers in the country that focuses solely on stem cell therapy" and claims to be "the Midwest leader in adult stem cell therapy, treating over 1,000 patients to date for orthopedics, osteoarthritis, back, neck, and spine, neurological, and some autoimmune diseases."

48. KRMC's stem cell therapies involve use of adipose derived stem cells which are harvested via liposuction. KRMC's website notes:

> At KRMC, we never use embryonic stem cells. We use your own naturally occurring Mesenchymal 'adult' stem cells. These remarkable cells are able to differentiate into a variety of cell types, including bone, cartilage, muscle and fat cells, that can promote healing and reduce pain and inflammation.
>
> In a single 2-4 hour session, our physicians can collect, concentrate and deploy your own stem cells to affected areas in your body. We use a nearly pain-free collection of stem cells from your own natural fatty deposits or bone marrow, depending on your specific condition and overall health.
>
> Adult adipose stem cells from naturally occurring fatty deposits are abundant in quantities. The abundance of these stem cells allows for multiple treatments on the same day.

49. KRMC's stem cell therapies involve processing the lipoaspirate obtained via liposuction to prepare a cell population comprising adipose derived stem cells. The processing comprises enzymatic digestion of the lipoaspirate to release the stem cells and growth factors therein. KRMC's website describes this processing step:

> Personal cell therapy around the world has illuminated the benefits of adipose (fat) derived stem cells (ADSCs). These cells are easy to obtain and are generally robust. Adipose fat is an abundant and reliable source of stem cells. The best quality adipose cells are derived from the enzymatic digestion of liposuctioned fat which can be performed in a nearly painless, outpatient procedure.

50. Following enzymatic digestion, centrifugation is used to separate the released cells to prepare an SVF cell population comprising stem cells. KRMC follows Cell Surgical Network's protocols for preparing SVF cell populations. This protocol is discussed in an article

authored by physicians at Cell Surgical Network available at URL: https://dx.doi.org/10.1053/j.trap.2016.09.002. The protocol described therein is consistent with those presented here.

51. The prepared SVF cell population is then injected into the patient's body at the site of the musculoskeletal injury or disease being treated. For example, KRMC's knee treatment involves "separate[ing] the adipose (fat) cells from the regenerative cells and inject[ing] them cells directly into your knee. This helps your body speed the healing process, alleviate pain and even allows for the regeneration of new tissue." KRMC's stem cell therapies effect a reduction of pain and inflammation in the affected areas.

52. KRMC's stem cell therapies take about four hours to complete, with the processing of lipoaspirate to prepare the SVF cell population taking approximately 90 minutes. The SVF cell population comprising stem cells is not obtained using further isolating techniques, such as culturing, therefore.

53. KRMC conducts informational seminars describing the applications and advantages of its stem cell therapies which practice one or more inventions claimed in the '202 Patent of VetStem. These seminars are advertised through KRMC's website. KRMC advises potential patients that its stem cell therapies allow for "[u]sing your own cells to treat arthritis, joint injuries, and spine pain." The seminar description states:

> During our one-hour interactive seminar, we share our expertise in using your own fat-derived stem cells to treat a variety of medical conditions - potentially avoiding traditional invasive surgery and/or reducing/eliminating common medications - with little to no downtime.
>
> What you will learn at the Kansas Regenerative Seminar:
> The science of stem cells and how they do what they do
> Why using YOUR OWN stem cells is the safest source of cells
> Explain how Adipose (fat) is richer in stem cells than any other source
> Share case studies and KRMC patient success stories

54. KRMC offers its stem cell therapies to patients commercially for profit. These services are not offered as part of any formal study or for the purpose of developing or seeking

approval of a new medical drug or procedure. Additionally, KRMC's stem cell therapies implicate practicing the inventions claimed in one or more claims of the' 202 Patent with respect to use of a composition of matter (i.e. the obtained SVF cell population). The use of the obtained SVF cell population in KRMC's stem cell therapies directly contributes to the treating of inflammation at a site of a musculoskeletal injury or disease of the patient.

55. Through its counsel VetStem sent correspondence to each of the Defendants on June 28, 2018 to provide actual notice to each of VetStem's claims of patent infringement and breach of contract, among others, and inviting each to engage VetStem in discussions on how to amicably resolve the present dispute. The June 28, 2018 correspondence detailed the many claims VetStem has against Defendants and are substantially the same as those presented herein, including a claim chart directed specifically to the Accused Products of Enso described above, mapping them to claim 1 of the '202 Patent. The parties then engaged in discussions over the course of a number of months, but the discussions eventually stalled in late 2018, forcing VetStem to file the present lawsuit.

THE ASSERTED PATENT AND TECHNOLOGY

56. On September 27, 2016, United States Patent No. 9,453,202 B2 ("the '202 Patent") 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 D and made a part hereof.

57. VetStem is the owner of all right, title, and interest of the '202 Patent, including all rights to enforce and prosecute actions for infringement of the '202 Patent and to collect damages for all relevant times against infringers of the '202 Patent. Accordingly, VetStem possesses the exclusive right and standing to prosecute the present action for infringement of the '202 Patent by Defendants.

58. 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 that is 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, typically via enzymatic digestion followed by centrifugation, although the '202 Patent discloses and claims several other alternative processing methods for releasing and separating the cell population from the adipose tissue. Once separated, the cell population is not processed further to isolate the stem cells from other cells within the cell population. Rather, the cell population is then reintroduced into the patient directly to the site of the musculoskeletal injury or disease to treat inflammation.

59. According to certain embodiments disclosed and claimed in the '202 Patent, the cell population is purified through separation from the adipose tissue from which it is derived without expansion or culturing. This streamlined processing methodology ran counter to the prevailing thinking relating to stem cell therapy at the time of filing for the application issuing as the '202 Patent. 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 comprising stem cells that were not subjected to these further expanding and culturing steps are therapeutically superior, far less costly, and obtained in far less time. VetStem has offered and sold and continues to offer and sell products and therapies practicing the inventions claimed in the '202 Patent.

COUNT I

Infringement of U.S. Patent No. 9,453,202 B2 by Enso

60. VetStem repeats and realleges the preceding paragraphs as though fully set forth herein.

61. Enso, without authority, consent, right, or license, and in both direct and indirect infringement of the '202 Patent, makes, uses, sells, offers to sell, and/or imports products and services for use in practicing the inventions claimed in at least claim 1 of the '202 Patent.

62. Enso has had actual knowledge of the '202 Patent since at least June 28, 2018, the date that VetStem's notice letter and claim chart detailing the infringement allegations made

herein were received by Farley, Orava, and Enso, respectively, and there have been continued discussions between VetStem and Enso regarding VetStem's allegations since that time.

63. Enso sells, offers to sell, and performs stem cell services, including its Adipose Derived Stem Cell Services, to administer adipose derived stem cells for treatment of animals suffering from musculoskeletal injuries and conditions or to accommodate the administration of adipose derived stem cell therapies by veterinarians ("Accused Enso Services"). Enso also makes, sells, offers to sell, and imports kits to sell or otherwise provide to veterinarians for use performing the same services which it refers to as Enso's Validated Shipping System ("Accused Enso Products").

64. Enso's Accused Products and Services are offered commercially for sale and paid for commercially 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 ("FDA").

65. Enso actively induces infringement of at least claim 1 of the '202 Patent of its veterinarian customers and end users of the Accused Enso Products and Services pursuant to 35 U.S.C. § 271(b).

66. Enso's makes, uses, sells, and offers to sell the Accused Enso Products and Services to veterinarians and end users to effect treatment of animal patients, including horses, dogs, and other mammal species.

67. Enso's veterinarian customers and end users are instructed to schedule stem cell submissions through Enso's website and to aseptically collect adipose tissue from the animal patient and ship the collected tissue to Enso using Enso's Validated Shipping System for processing.

68. Upon receipt, lab technicians at Enso process the adipose tissue to release and separate cells from the fat into a population of cells including adipose stem cells. This cell population is referred to as a stromal vascular fraction ("SVF"), which Enso describes as comprising "a heterogeneous mixture of cells which include adipose stem cells" which "works

better than in individual treatment of cells." Upon information or belief, Enso treats the adipose tissue with an enzyme to facilitate the release of cells and separates the cells uses centrifugation to separate the stem cells from the fat layer to prepare the SVF. The cell population is placed in sterile vials and shipped back to the veterinarian or end user.

69. Enso instructs the veterinarian or end user to inject the cell population into the animal patient into each injury site or affected joint for treatment of tendon and ligament injuries, joint injuries, degenerative joint disease (osteoarthritis), osteochondrosis, meniscal tears and stifle ligament injuries, fractures, cervical facet joint osteoarthritis and osteochondrosis. Enso even provides instructions and videos showing proper injection locations for treating musculoskeletal conditions affecting the animal's elbow, stifle, or shoulder. Enso states that the treatment with adipose derived stem cells will provide long-term anti-inflammatory effects and decrease pain.

70. Through Enso's marketing literature soliciting use of the Accused Enso Products and Services in the manner described herein and through Enso's providing protocols, equipment, training, customer support, and laboratory processing services to effect treatment of animals in the manner claimed. Enso therefore intentionally and knowingly directs and encourages veterinarian and end users to use the Accused Products and Services to perform a method of treatment in a manner that infringes at least the method of claim 1 of the '202 Patent.

71. Enso therefore actively induces the direct infringement of at least claim 1 of the '202 Patent by veterinarians and end users and is liable for induced infringement under 35 U.S.C. § 271(b).

72. Enso contributes to the infringement of at least claim 1 of the '202 Patent by its veterinarian customers and end users of the Accused Enso Products pursuant to 35 U.S.C. § 271(c).

73. Enso's makes, uses, sells, and offers to sell the Accused Enso Products and Services to veterinarians and end users which use the Accused Enso Products and Services to effect treatment of animal patients.

74. These veterinarian customers and affiliates are instructed to schedule stem cell submissions through Enso's website, to collect adipose tissue from the animal patient and ship to Enso using Enso's Validated Shipping System for processing, and to inject the processed cell populations into the patient animal via intraarticular injection at the site of the musculoskeletal injury as shown in the injection videos provided by Enso.

75. As described above, Enso instructs the veterinarian or end user to schedule stem cell submissions through Enso's website and to collect the adipose tissue to ship back to Enso within the Validated Enso Shipping System. Enso provides these veterinarians and end users instructions for collecting adipose tissue and shipping materials for submitting the collected adipose tissue to Enso. Upon receipt, Enso processes the adipose tissue to release and separate cells from the fat into a population of cells including adipose stem cells and returns the processed cell population to the veterinarian customers in vials. Enso then, and instructs veterinarian or end user on injection of the cell population into the patient mammal at the site(s) of the musculoskeletal injury or disease to be treated.

76. Enso provides instructions and procedure protocols for using its Accused Enso Products and Services in ways that infringe claims of the '202 Patent. Enso additionally provides online content, video demonstrations, and live customer support available through Enso's website and product literature. Instructions are provided for collecting adipose tissue from the patient animal, shipping it to Enso for processing, and for intraarticular injection at the site of the musculoskeletal condition, typically osteoarthritis, of the patient animal. For example, the Enso provides a procedural overview at URL https://ensodiscoveries.com/adipose-process/ and provides video demonstrations showing how to inject animal joints with the processed cell population comprising stem cells at URL https://ensodiscoveries.com/how-to-inject-joints/.

77. Use by veterinarian customers and affiliates of the Accused Enso Products and Services in this manner as proscribed by Enso on its website and product literature constitutes direct infringement of at least claim 1 of the '202 Patent.

78. Use of the Accused Enso Products and Services in the manner proscribed by Enso results in a treatment procedure that is especially suited for infringing at least the method of claim 1 of the '202 Patent.

79. This use comprises the typical use of the Accused Enso Products and Services. The Accused Enso Products and Services are not staple articles of commerce as they have no substantial non-infringing uses. They are marketed and shown by Enso for use only in manners that infringe one or more claims of the '202 Patent.

80. Enso therefore contributes to the direct infringement of at least claim 1 of the '202 Patent by veterinarian end users and affiliates of Enso and is liable for contributory infringement under 35 U.S.C. § 271(c).

81. Enso's using, selling, and offering to sell the Accused Enso Products and Services directly infringe at least Claim 1 of the '202 Patent, and Enso 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).

82. Enso veterinarians, representatives, affiliates, and/or agents use the Accused Enso Products and Services to treat animal patients and for product testing, studies, and demonstrations in the manner described above, as evidenced by at least the videos uploaded by Enso to its website and YouTube channel demonstrating use of the Accused Enso Products. For example, the video at URL https://ensodiscoveries.com/dr-corey-orava-visits-equine-center-in-cave-creek-az/ documents use of the Accused Enso Products in the field to treat a horse suffering from navicular disease – a musculoskeletal condition causing inflammation or degeneration of the navicular bone – directly infringing at least claim 1 of the '202 Patent. This video was uploaded to Enso's YouTube channel on April 9, 2018.

83. VetStem expressly reserves the right to assert additional claims of the '202 Patent against Enso.

84. VetStem has been damaged as a result of Enso's infringing conduct. Enso 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.

85. Based on Enso's actual knowledge of the '202 Patent and specific knowledge of VetStem's infringement claims presented herein since at least June 28, 2018, if not earlier, as well as Enso's objective recklessness in continuing to make, use, and sell the Accused Enso Products since that time, Enso's infringement of the '202 Patent has been willful since at least June 28, 2018. Therefore, VetStem is further entitled to enhanced damages under 35 U.S.C. § 284.

COUNT II

Infringement of U.S. Patent No. 9,453,202 B2 by KRMC

86. VetStem repeats and realleges the preceding paragraphs as though fully set forth herein.

87. KRMC, without authority, consent, right, or license, and in infringement of the '202 Patent, makes, uses, sells, and/or offers to sell the Accused Services practicing the inventions claimed in at least claim 1 of the '202 Patent.

88. KRMC's making, using, selling, and/or offering to sell the Accused KRMC Services directly infringes at least Claim 1 of the '202 Patent, and KRMC 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).

89. KRMC physicians, personnel, representatives, affiliates, and/or agents use the Accused KRMC Services to effect treatment on human patients, which are mammals.

90. KRMC physicians 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. This harvested lipoaspirate comprising adipose tissue is further processed by KRMC personnel to prepare an SVF cell population comprising stem cells from the adipose tissue. Upon information or belief, this further processing to release the desired SVF cell population from adipose tissue involves

treating the lipoaspirate with an enzyme to facilitate the release of stem cells and growth factors within the lipoaspirate. Centrifugation is used to then separate the SVF from the fat layer. The resulting SVF cell population is loaded into one or more syringes for injection into the patient at the site of a musculoskeletal conditions to reduce corresponding inflammation.

91. Use by KRMC of the Accused KRMC Services in this manner constitutes direct infringement of at least claim 1 of the '202 Patent.

92. Use by KRMC of the Accused KRMC Services in this manner constitutes the practice of a patented use of a composition of matter in violation of claim 1 of the '202 Patent.

93. The Accused KRMC are offered commercially for sale 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 FDA.

94. VetStem expressly reserves the right to assert additional claims of the '202 Patent against KRMC.

95. VetStem has been damaged as a result of KRMC's infringing conduct. KRMC 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.

96. KRMC has had actual knowledge of the '202 Patent since at least June 28, 2018, the date that VetStem's notice letter and claim chart detailing the infringement allegations made herein were received by Farley and KRMC, respectively, and there have been continued discussions between VetStem and KRMC regarding VetStem's allegations since that time.

97. Based on KRMC's actual knowledge of the '202 Patent and specific knowledge of VetStem's infringement claims presented herein, as well as KRMC's objective recklessness in continuing to make, use, and sell the Accused KRMC Services since that time, KRMC's infringement of the '202 Patent has been willful since at least June 28, 2018. Therefore, VetStem is further entitled to enhanced damages under 35 U.S.C. § 284.

COUNT III

Breach of Contract by Patrick Farley

98. VetStem repeats and realleges all preceding paragraphs of this Complaint as though fully set forth herein.

99. The Farley Employment Agreement was executed by VetStem and Farley on January 21, 2013, and is a valid, enforceable contract. Farley's conduct as described herein constitutes a breach of the provisions of the Farley Employment Agreement.

100. VetStem is the owner via assignment of all rights, remedies, obligations and liabilities to the Farley Employment Agreement and to all right, title, and interest to VetStem's Trade Secrets and Confidential Information relating to its regenerative stem cell treatments and related business operations, including all rights to enforce, prosecute actions, and collect damages for any past, present and future breach of the Farley Employment Agreement. Accordingly, VetStem possesses the exclusive right and standing to prosecute the present action for breach of the Farley Employment Agreement by Farley resulting from his breach of at least the covenants not to divulge or use VetStem's Trade Secret and Confidential Information and covenant to not compete with VetStem for at least three years after leaving VetStem's employ.

101. VetStem performed any and all terms, conditions, promises, and obligations required by the Farley Employment Agreement.

102. Farley was permitted access to and obtained VetStem's Trade Secret and Confidential Information during the time of his employment with VetStem pursuant to the terms of the executed Farley Employment Agreement.

103. VetStem took all reasonable steps to maintain the secrecy of its Trade Secret and Confidential Information, including only disclosing the Trade Secret and Confidential Information under the protections of provisions of the Farley Employment Agreement prohibiting unauthorized use or disclosure of VetStem's Trade Secret and Confidential Information.

104. Upon information and belief, Defendants has breached the Farley Employment Agreement through the use and continued use of VetStem's Trade Secret and Confidential Information to improperly gain a head start in entering the market with products and gaining market share through at least Farley's Enso business which directly competes with VetStem and was formed shortly after Farley's employment at VetStem. The founding and managing of Enso itself constitutes a breach of the Covenant Not to Compete of the Farley Employment Agreement.

105. All of Farley's use of VetStem's valuable Trade Secret and Confidential Information has been done without permission from VetStem and is therefore unauthorized and improper.

106. As a result of Farley's conduct, VetStem has been damaged in an amount beyond the jurisdictional minimum of this Court and is entitled to compensation.

107. Farley's conduct has caused, is causing, and will continue to cause irreparable harm to VetStem for which there is no adequate remedy at law. Therefore, VetStem seeks the award of a permanent injunction against Farley, Enso, and KRMC, pursuant to Cal. Civil Code §§ 3420 - 3424 and Sections 6.6 and 8.7 of the Farley Employment Agreement, prohibiting any and all further uses of the Trade Secret and Confidential Information at issue to stop all activities connected to Farley's breaches of the Farley Employment Agreement.

COUNT IV

Breach of Contract by Dr. James Corey Orava

108. VetStem repeats and realleges all preceding paragraphs of this Complaint as though fully set forth herein.

109. The Orava Employment Agreement was executed by VetStem and Orava on August 14, 2006, and is a valid, enforceable contract. Orava's conduct as described herein constitutes a breach of the provisions of the Orava Employment Agreement.

110. VetStem is the owner via assignment of all rights, remedies, obligations and liabilities to the Orava Employment Agreement and to all right, title, and interest to VetStem's

Trade Secrets and Confidential Information relating to its regenerative stem cell treatments and related business operations, including all rights to enforce, prosecute actions, and collect damages for any past, present and future breach of the Orava Employment Agreement. Accordingly, VetStem possesses the exclusive right and standing to prosecute the present action for breach of the Orava Employment Agreement by Orava resulting from his breach of at least the covenants not to divulge or use VetStem's Trade Secret and Confidential Information and covenant to not compete with VetStem for at least three years after leaving VetStem's employ.

111. VetStem performed any and all terms, conditions, promises, and obligations required by the Orava Employment Agreement.

112. Orava was permitted access to and obtained VetStem's Trade Secret and Confidential Information during the time of his employment with VetStem pursuant to the terms of the executed Orava Employment Agreement.

113. VetStem took all reasonable steps to maintain the secrecy of its Trade Secret and Confidential Information, including only disclosing the Trade Secret and Confidential Information under the protections of provisions of the Orava Employment Agreement prohibiting unauthorized use or disclosure of VetStem's Trade Secret and Confidential Information.

114. Upon information and belief, Defendants has breached the Orava Employment Agreement through the use and continued use of VetStem's Trade Secret and Confidential Information to improperly gain a head start in entering the market and gaining market share with Enso products and services. Enso directly competes with VetStem. Orava's immediate commencement of work at Enso following his termination from VetStem constitutes a breach of the Covenant Not to Compete of the Orava Employment Agreement.

115. All of Orava's use of VetStem's valuable Trade Secret and Confidential Information has been done without permission from VetStem and is therefore unauthorized and improper.

116. As a result of Orava's conduct, VetStem has been damaged in an amount beyond the jurisdictional minimum of this Court and is entitled to compensation.

117. Orava's conduct has caused, is causing, and will continue to cause irreparable harm to VetStem for which there is no adequate remedy at law. Therefore, VetStem seeks the award of a permanent injunction against Orava and Enso pursuant to Cal. Civil Code §§ 3420 - 3424 and Sections 6.6 and 8.7 of the Orava Employment Agreement, prohibiting any and all further uses of the Trade Secret and Confidential Information at issue to stop all activities connected to Orava's breaches of the Orava Employment Agreement.

PRAYER FOR RELIEF

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

a. Judgment that one or more claims of the '202 Patent has been infringed, either literally and/or under the doctrine of equivalents, by Defendants, or judgment that one or more of the claims of the '202 Patent has been directly infringed by others and indirectly infringed by Defendants, to the extent Defendants contributed to or induced such direct infringement by others;

b. Judgment that Defendants account for and pay to VetStem all damages to and costs incurred by VetStem because of Defendants' infringing activities and other conduct complained of herein;

c. Judgement that Defendants' infringement is willful from the time each respective Defendant 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 Plaintiff be granted pre-judgment and post-judgment interest on the damages caused by Defendants' infringing activities and other conduct complained of herein;

e. Judgment that Defendants' conduct complained of herein constitutes breach of the one or more terms of the respective Employment Agreements and/or Confidential Disclosure Agreements entered into between certain Defendants and VetStem;

f. Judgment that VetStem be awarded actual damages associated with and resulting from Defendants' respective breaches of the respective Employment Agreements and/or Confidential Disclosure Agreements;

g. That the Court declare this an exceptional case and award Plaintiff its reasonable attorney's fees and costs in accordance with 35 U.S.C. § 285 and/or any other basis provided for under applicable federal or state law; and

h. That each of Defendants, 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 Patent, and breach of the respective Employment Agreements 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

i. 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.

DESIGNATION OF PLACE OF TRIAL

PLAINTIFF HEREBY DESIGNATES KANSAS CITY, KANSAS, AS THE CITY WHERE PLAINTIFF DESIRES THE TRIAL HEREIN TO BE HELD, PURSUANT TO LOCAL RULE 40.2(a).

DATED: May 30, 2019

Respectfully Submitted,

*/s/ James D. Myers*_____

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