IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

LIFENET HEALTH,

Plaintiff,

v.

ZIMMER BIOMET HOLDINGS, INC. and EMBODY, INC.,

Defendants.

CASE NO. 2:23-CV-00479-AWA-RJK

JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT

Pursuant to Rule 15(a)(1)(B), Plaintiff LifeNet Health ("LifeNet") brings the following amended complaint against Zimmer Biomet Holdings, Inc. ("Zimmer") and Embody, Inc. ("Embody") (collectively, "Defendants"):

THE PARTIES

1. LifeNet is a nonstock corporation organized under the laws of the Commonwealth of Virginia, having a principal place of business at 1864 Concert Drive, Virginia Beach, Virginia 23453. LifeNet is a not-for-profit, tax-exempt corporation under Section 501(c)(3) of the Internal Revenue Code and is a federally designated Organ Procurement Organization and tissue recovery agency.

2. Embody is a for-profit corporation organized under the laws of the Commonwealth of Virginia, with its principal place of business at 4211 Monarch Way, Norfolk, Virginia 23508. Embody was founded as Embody LLC on April 11, 2014. Embody LLC was converted to Embody, Inc. on December 13, 2018. Embody is listed as a subsidiary of Zimmer.

3. Zimmer is a for-profit corporation organized under the laws of the state of Delaware, with its principal place of business at 345 East Main St., Warsaw, Indiana 46580. On January 5,

2023, Zimmer announced that it had reached an agreement to acquire Embody. Zimmer completed the acquisition of all outstanding shares of Embody on February 14, 2023.

JURISDICTION AND VENUE

4. This is an action for patent infringement of U.S. Patent Nos. 10,137,223 ("the '223 Patent") and 11,318,227 ("the '227 Patent") (collectively, "the LifeNet Patents") under the United States Patent Laws, 35 U.S.C. § 1, *et seq*. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338.

5. This Court also has supplemental jurisdiction over the asserted state law claim for tortious interference pursuant to 28 U.S.C. § 1367(a) because the federal and state law claims derive from a common nucleus of operative facts.

6. This Court has personal jurisdiction over Embody because Embody is a Virginia corporation, with its principal place of business in Norfolk, Virginia. Embody has done continuous and systematic business in this District and has committed acts of infringement in this District, including at least by making, using, offering to sell, and selling LifeNet's patented inventions in this District.

7. This Court has personal jurisdiction over Zimmer because Zimmer does continuous and systematic business and has committed acts of infringement in this District, including at least by substantively and directly operating Embody to make, use, offer to sell, and sell LifeNet's patented inventions in this District. Zimmer acquired Embody on January 5, 2023. On information and belief, since that date, Zimmer has substantively directed and controlled Embody, operating Embody not as an independent subsidiary but instead as part in parcel of Zimmer itself. By way of example, Ivan Tornos is the President and CEO of Zimmer, and is also the President of Embody according to the most recent information available on the Virginia State Corporation Commission

website. *See* Ex. P at 2. Similarly, Chad Phipps is the Senior Vice President and General Counsel of Zimmer, and is also the Secretary and Senior Vice President of Embody. *Id.* Similarly, Pradipto Bagchi is the Vice President and Treasurer of Zimmer, and is also the Treasurer of Embody. *Id.* Zimmer is effectively operating in Virginia through its acquisition of Embody. By virtue of its acquisition of Embody on January 5, 2023, as well as its direct management of Embody's operations, Zimmer does continuous and systematic business in this District and has committed acts of infringement in this District, including at least by making, using, offering to sell, and selling LifeNet's patented inventions in this District.

8. Zimmer also continues to sell and offer to sell LifeNet's patented inventions in this District. *See* https://www.zimmerbiomet.com/en/products-and-solutions/specialties/sports-medicine/activbraid.html#contact (offering ActivBraid suture) (last visited September 27, 2023); https://www.zimmerbiomet.com/content/dam/zb-corporate/en/support/coding-guides/4150.1-US-en-TAPESTRY-Biointegrative-Implant-Coding-Reference-Guide.pdf (offering TAPESTRY implant) (last visited September 27, 2023).

9. In addition to its acquisition and *de facto* operation of Embody and its direct sales and operations in the Commonwealth, this Court also has personal jurisdiction over Zimmer because Zimmer has multiple other regular and established places of business in this District, regularly does or solicits business in Virginia, and derives substantial revenue from goods used or consumed or services rendered in Virginia.

10. For example, Zimmer has multiple facilities and offices in Virginia, including at the following locations: (1) 12820 West Creek Parkway, Suite M, Richmond, VA; (2) 1308 B Plantation Road NE, Roanoke, VA; and (3) 113 Muskoka Court, Unit 115, Winchester, VA. *See* Exs. Q-R.

11. Zimmer also advertises multiple job openings for its business operations in this District. These include open positions for a Manufacturing Associate in Norfolk, a Manufacturing Associate Supervisor in Norfolk, a Development Principal Engineer in Norfolk, a Warehouse Driver in Richmond, and a Recruitment Marketing Manager in Richmond. Exs. S-T.

12. Further, Zimmer connects its customers with doctors based in Virginia who will provide treatments using Zimmer's goods and services. In the region within 25 miles of Norfolk, Zimmer's website provides contact information for ten different surgeons who will perform knee surgeries using Zimmer's goods and services. Ex. U. In the region within 25 miles of Richmond, Zimmer's website provides contact information for 11 surgeons who will perform knee surgeries using Zimmer's goods and services. Ex. V. In the region within 25 miles of Alexandria, Zimmer's website provides contact information for 24 surgeons who will perform knee surgeries using Zimmer's goods and services. Ex. W. These surgeons (and others) provide substantial revenue to Zimmer for goods used or consumed or services rendered in Virginia.

13. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400. Both Embody and LifeNet reside in this District. Zimmer, as described above, also has a regular and established place of business in this District by virtue of its direct operation of Embody. Also, as described above, Zimmer has multiple additional regular and established places of business located in this District, including facilities and offices in Winchester and Richmond, as well as engineering and manufacturing facilities in Norfolk. Zimmer also employs numerous individuals within this District at these locations. Zimmer also partners with and promotes dozens of surgeons and other medical professionals in this District who are authorized by Zimmer to provide treatments to patients using Zimmer's goods and services. Furthermore, Zimmer has committed multiple acts of infringement in this District by making, using, selling, and offering to sell the accused products

in this District.

FACTUAL BACKGROUND

A. LifeNet Developed Its Novel Electrospinning Technology over Many Years

14. Originally founded in 1982 as Eastern Virginia Tissue Bank, LifeNet is a non-profit, global leader in regenerative medicine and life sciences. LifeNet fulfills its life-changing mission by focusing its efforts in three core areas: (1) LifeNet Health's Organ Procurement Organization, which saves more than 600 lives annually through transplantation; (2) LifeNet Health Biologics, which provides nearly 1 million tissue implants globally each year for use in many different surgical disciplines; and (3) LifeNet Health LifeSciences, which offers innovative human cell- and tissue-based solutions for improved drug discovery and enabling biomedical researchers developing the next generation of therapies.

15. Beginning in 2010, researchers at LifeNet, led by Dr. Michael Francis, a Research and Development Scientist at LifeNet, began developing novel improvements to a process known as electrospinning. Electrospinning techniques are used to form particles and fibers as small as one nanometer in diameter. The phenomenon involves the formation of a droplet of polymer melt at an end of a needle (also called a spinneret), the electric charging of that droplet, and an expulsion of parts of the droplet because of the repulsive electric force due to the electric charges. In electrospinning, fibers are formed from the liquid as the parts are expelled.

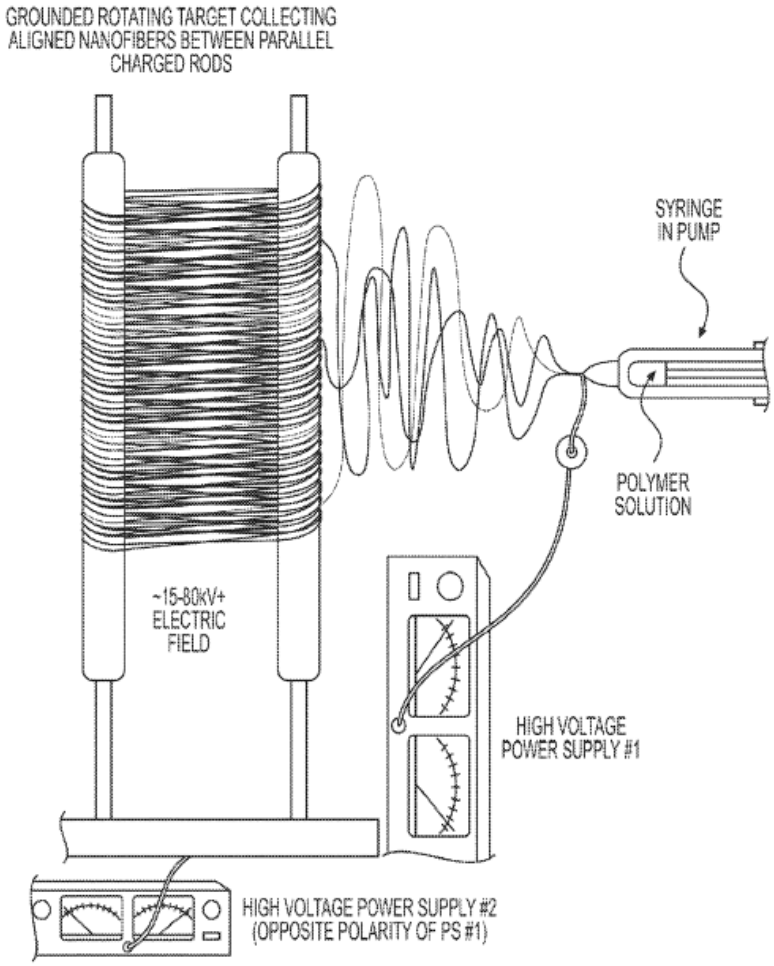
16. Once a sufficiently high voltage is introduced to the polymer solution to create a charge imbalance, the solution is then drawn towards a grounded collector through the static electric field. As the polymer solution erupts from the needle and the assembling polymer whips through space and rapidly thins into a fine stream, the solution assembles into fibers, leaving dry nano- to micro-scale fibers of tailorable physical attributes on the collector. Polymer solution

properties, polymer or co-polymer solution composition, surface tension, conductivity, viscosity, applied electrical potential, polymer molecular weight, polymer solution flow rate, distance between spinner and collector, ambient parameters (e.g. humidity, air velocity, temperature) and motion of the collecting target can be altered to form fibers of controlled fiber distribution, diameter and alignment via electrospinning.

17. Working with electrospinning techniques in connection with a collagen/synthetic co-polymer solution, LifeNet's researchers led by Dr. Francis found that when extruding a solution from an electrified tip of a spinneret and collecting the extruded solution on a portion of a collector comprising multiple charged vertical rods on a rotating platform, the electrospun fibers could be collected between the opposing metal rods in a highly aligned fashion.

18. As shown in the renderings above of an early prototype of LifeNet's electrospinning technology, the collector comprised at least two vertical rods mounted on a platform. The rods were made of an electrical conducting material and were configured to split an

electric field between them. The rods in the prototype above were configured to rotate about an axis passing through the center of the platform (as shown by the annotated red arrow above). Another embodiment of the electrospinning technology is shown in the following diagram:

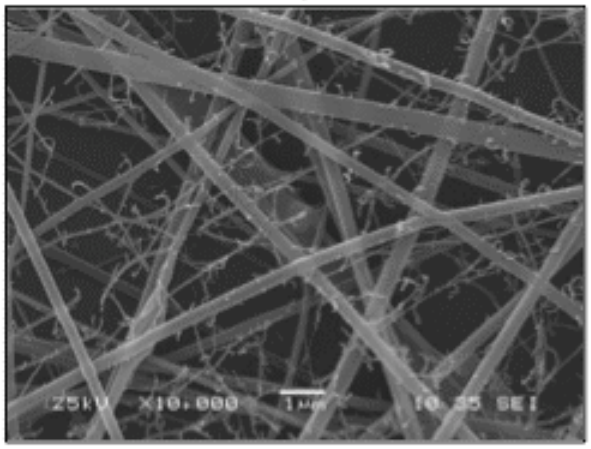
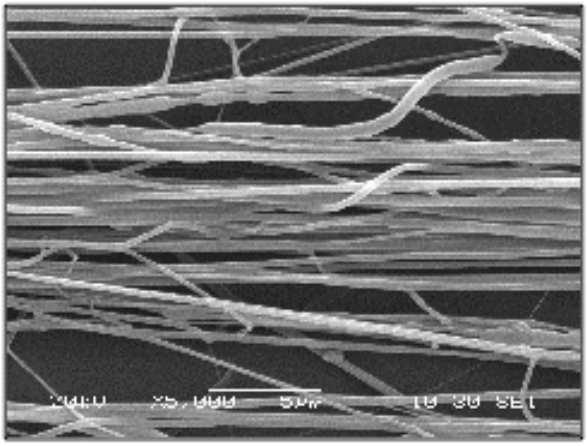


19. The diagram above shows another embodiment of LifeNet's electrospinning technology in operation. First, a syringe (or spinneret) is filled with a polymer solution (such as a collagen-based solution). The syringe is then subjected to a sufficiently high voltage to create a charge imbalance such that when the solution is ejected from the syringe and assembled into fibers it is drawn towards the charged rods on the collector. In the above embodiment, the rods are stationary and the fibers spin around the rods to form a highly aligned pattern. In some instances, the fibers may also move or jump from one rod to another rod. In other embodiments, the rods

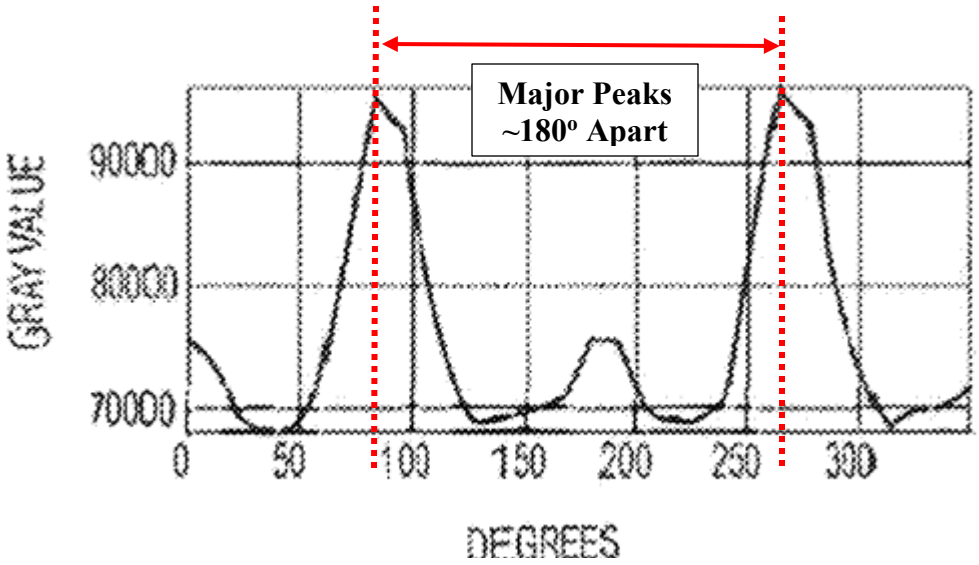
may rotate.

20. As the aligned fibers are collected, they can be coated on the surface of a biocompatible matrix (or scaffold) to form an elongated sheet. The aligned electrospun fibers on the matrix can be configured in a direction parallel to the length of the elongated sheet.

21. The figures below show a highly magnified comparison between a matrix of electrospun fibers using LifeNet's patented technology (shown on the right), with a matrix of randomly electrospun fibers (on the left). As shown on the right, the aligned fiber membrane generated by LifeNet's patented electrospinning techniques lead to highly aligned fibers when compared to the randomly patterned fibers generated by traditional electrospinning techniques.

Traditional Electrospun Fibers	**LifeNet's Patented Electrospun Fibers**
	

22. The degree of alignment of the fibers can be measured using a fast Fourier transform (FFT) analysis. When the results of the FFT analysis of the highly aligned fibers from LifeNet's patented technology are graphed on a frequency plot, they show major peaks on the y-axis that occur about every 180 degrees on the x-axis, as shown below. This indicates that the electrospun fibers are highly aligned.



23. This elongated sheet of aligned fibers can be applied as an implant on surgical sites of a soft-tissue injury (such as a damaged tendon) to aid in the recovery of the surgically-repaired tissue. By using an implant with electrospun fibers that are aligned in the same pattern as the naturally occurring fibers on the surgically repaired tissue, the recovery and tissue remodeling process is greatly enhanced and accelerated.

B. LifeNet Obtained U.S. Patents on Its Novel Electrospinning Technology

24. To protect its novel electrospinning technology and the resulting treatment applications, LifeNet prepared and filed Provisional Application No. 61/785,031 ("the '031 Provisional Application") with the United States Patent and Trademark Office (USPTO) on March 14, 2013. In the ensuing years, LifeNet prepared and filed several non-provisional patent applications based on the '031 Provisional Application.

25. On November 27, 2018, the USPTO duly and legally issued the '223 Patent. The '223 Patent is entitled "Aligned Fiber and Method of Use Thereof" and names as inventors Michael Francis and Roy Ogle. The '223 Patent claims priority back to the '031 Provisional Application filed on March 14, 2013. A true and correct copy of the '223 Patent is attached as Exhibit A.

26. On May 3, 2022, the USPTO duly and legally issued the '227 Patent. The '227 Patent is entitled "Aligned Fiber and Method of Use Thereof." The '227 Patent is a divisional of the '223 Patent, names the same inventors, and also claims priority back to the '031 Provisional Application. A true and correct copy of the '227 Patent is attached as Exhibit B.

27. LifeNet is the owner, by assignment registered in the USPTO, of the entire right, title, and interest in the LifeNet Patents.

28. The LifeNet Patents generally describe a scaffold comprising an aligned fiber. Ex. A ('223 Patent) at Abstract. The LifeNet Patents further describe "a scaffold comprising one or more electrospun fibers wherein a fast Fourier transform (FFT) analysis result of the fibers have adjacent major peaks with about 180° apart from each other." *Id.*

29. Certain embodiments of the LifeNet patents describe crosslinking the aligned fiber and/or electrospun fiber. *Id.* at 12:27-30; 14:60-61. In some embodiments, "the crosslinking may be performed by any conventional chemical crosslinking method (e.g. chemical reagent-promoted, chemically reactive linker-promoted and/or enzyme-promoted) and/or dehydrothermal crosslinking method (e.g. heat-promoted condensation), forming the covalently crosslinked electrospun fiber(s)." *Id.* at 12:30-36. "In additional embodiments, the crosslinking comprises applying a cross-linking agent to the polymer or oligomer solutions to be electrospun." *Id.* at 12:36-38.

30. The LifeNet Patents further describe "methods of promoting differentiation of stem cells into osteoblasts, chondrocytes, ligament or tendon, the method comprising culturing the cells on the scaffold or aligned fiber described herein in conditions suitable for the cell differentiation." *Id.* at 1:19-24. The resulting implantable biocompatible matrix of aligned fibers "may be prepared by combining a sheet or sheets to facilitate surgical implantation." *Id.* at 8:23-25. In some

embodiments, "the materials for each elongated sheet in the multiple layers of sheets may be different from each other." *Id.* at 15:14-16.

31. The resulting implant can be used for a variety of purposes, such as "for tissue augmentation, contouring, restoring physiological function, repairing or restoring tissues damaged by disease or trauma, and/or delivering therapeutic agents to normal, damaged or diseased organs and tissues." *Id.* at 15:61-65.

32. Claim 1 of the '223 Patent recites "[a] scaffold comprising one or more electrospun fibers comprising collagen, wherein a fast Fourier transform (FFT) analysis result of the fibers have adjacent major peaks with about 180° apart from each other." *Id.* at 23:6-9.

33. Claim 1 of the '227 Patent recites a method of treating a tissue defect in a subject comprising "implanting at the tissue defect a scaffold comprising crosslinked fibers comprising collagen, wherein a result of a fast Fourier transform (FFT) analysis of the fibers demonstrates that the fibers have major adjacent peaks that are about 180° apart from each other, and applying the scaffold to the tissue defect to repair a tendon, a ligament or a nerve defect." Ex. B at 23:31-37.

C. Dr. Francis and Mr. Kemper Were at All Relevant Times Subject to Their Employment Agreements with LifeNet

34. As a condition of his employment with LifeNet, Dr. Francis executed several agreements related to his employment. On May 2, 2012, as part of his promotion to the position of Research and Development Scientist, Dr. Francis executed an Employment Agreement ("Francis Employment Agreement"). A true and correct copy of the Francis Employment Agreement is attached as Exhibit C.

35. Section 4 of the Francis Employment Agreement includes the following provision governing any inventions that were created or developed by Dr. Francis in the course of his work for LifeNet:

> Employee acknowledges and agrees that LifeNet Health owns, and will own, whether as "works made for hire" or otherwise, any and all documents, designs, drawings, charts, computer program code, computer software, specifications, notes, inventions, improvements, discoveries, and other works of any kind (collectively, "Works") that Employee creates or develops, whether alone or with others, in the course of Employee's employment with LifeNet Health, regardless of whether any such Work is in printed, mechanical, electronic, or other form and regardless of whether any such Work may be subject to patent, copyright, trademark, domain name, trade secret, mask work, or other legal protection. To the extent, if any, that LifeNet Health does not by operation of law automatically own all right, title, and interest in and to all such Works, Employee agrees to assign, and hereby does assign, to LifeNet Health any and all of his or her right, title, and interest in and to all such Works.

Ex. C (Francis Employment Agreement) at 4-5.

36. Section 4 also included a provision stating: "Employee agrees never to exploit, challenge, seek to register, or assign or license to any third party, directly or indirectly anywhere in the world, any of the rights owned by, or assigned to, LifeNet Health hereunder." *Id.* at 5. According to Section 5.2 of the Francis Employment Agreement, Dr. Francis's obligations under Section 4 survived the termination of the agreement.

37. Another individual, Nathan Kemper, was hired by LifeNet in 2011 as a design engineer to be part of Dr. Francis' team. Mr. Kemper also executed a number of agreements as a condition of his employment with LifeNet. On March 7, 2014, Mr. Kemper signed a Confidentiality, Non-Competition, Non-Solicitation, and Intellectual Property Agreement ("Kemper IP Agreement"). A true and correct copy of the Kemper IP Agreement is attached as Exhibit D.

38. Section 7 of this agreement included the following provision governing any inventions that were created or developed by Mr. Kemper in the course of his work for LifeNet:

> Employee acknowledges and agrees that LifeNet owns, and will own, whether as "works made for hire" or otherwise, any and all documents, designs, drawings, charts, computer program code, computer software, specifications, notes, inventions, improvements, discoveries, and other works of any kind (collectively, "Works") that Employee creates or develops (or has created or developed), whether

> alone or with others, in the course of Employee's employment with LifeNet, regardless of whether any such Work is in printed, mechanical, electronic, or other fo1m and regardless of whether any such Work may be subject to patent copyright, trademark, domain name, trade secret, mask work, or other legal protection. To the extent, if any, that LifeNet does not by operation of law automatically own all right, title, and interest in and to all such Works, Employee agrees to assign, and hereby does assign, to LifeNet any and all of his/her right, title, and interest in and to all such Works.

Ex. D (Kemper IP Agreement) at 5.

39. Like the Francis Employment Agreement, Section 7 of the Kemper IP Agreement also included a provision stating: "Employee agrees never to exploit, challenge, seek to register, or assign or license to any third party, directly or indirectly anywhere in the world, any of the rights owned by, or assigned to, LifeNet hereunder." *Id.*

D. Embody Copied LifeNet's Patented Technology in Its Own Patent Filings

40. Embody was founded in 2014 in Norfolk Virginia, utilizing $22 million in federal grant money from the Defense Advanced Research Projects Agency (DARPA) to develop collagen-based implants for soft tissue repair and augmentation. Facing a severe knowledge and technology deficit while under pressure to justify the significant federal grant money it received, Embody almost immediately began poaching LifeNet's locally based research team to develop its own tissue implants using LifeNet's patented technology, unbeknownst to LifeNet.

41. In 2015, just a few years after LifeNet filed the '031 Provisional Application to protect its propriety technology, Embody secretly recruited and hired Dr. Francis, the co-inventor on the LifeNet Patents. When he left LifeNet in 2015, Dr. Francis informed his colleagues in the R&D department at LifeNet that he was planning to take a long sabbatical and move out of state. Dr. Francis, however, did no such thing. Instead, upon leaving LifeNet, Dr. Francis immediately joined Embody on a full-time basis. At no time did Dr. Francis ever inform LifeNet of his plans to work for Embody, and LifeNet was not aware of Dr. Francis's decision to move to Embody

until much later.

42. Dr. Francis first worked as Embody's Director of Research and Development, a role he held until September of 2016. Embody then promoted Dr. Francis to the role of Chief Scientific Officer, a position he maintained until he left Embody in 2021. Almost immediately after Dr. Francis joined Embody (and unbeknownst to LifeNet), Embody began utilizing LifeNet's patented electrospinning technology to develop its own implants for treating soft-tissue injuries. Dr. Francis served as the principal investigator for Embody on its electrospinning research. Over the ensuing years, Embody continued to poach employees from LifeNet as part of this development process, including Nathan Kemper, who left LifeNet to join Embody in 2015.

43. Beginning in 2017, Embody began filing its own patent applications on collagen-based products that incorporated LifeNet's patented technology. The evidence of Embody's knowledge and use of LifeNet's technology is found on the face of Embody's own patent filings. For example, U.S. Publication No. 2016/0022865 (the "'865 Publication"), which is the published version of the application that eventually issued as the '223 Patent,[1] was cited and discussed by Embody and the USPTO during the prosecution of several Embody patents, including U.S. Patent No. 10,617,787 (the "'787 Patent") (attached as Exhibit E), U.S. Patent No. 11,116,870 (the "'870 Patent") (attached as Exhibit F), and U.S. Patent No. 11,213,610 (the "'610 Patent") (attached as Exhibit G). The '787 Patent, the '870 Patent, and the '610 Patent all list Dr. Francis as a co-inventor, and all three cite the '865 Publication on their face. Mr. Kemper is listed as a co-inventor on the '787 and '870 Patents.[2]

[1] *See* Ex. A at Cover (listing "US 2016/0022865" under "Prior Publication Data").

[2] *See, e.g.,* Ex. E at page 2 (listing 2016/0022865 to Francis under "References Cited"); Ex. F at page 2 (same); Ex. G at page 2 (same).

44. Embody's representatives also extensively discussed LifeNet's patented inventions during the prosecution of Embody's own patent applications. For example, during the prosecution of the '787 Patent, Embody extensively discussed LifeNet's patented inventions in an office action response to the USPTO on March 15, 2019 (several months after the '223 Patent had issued). In that March 15, 2019 filing, Embody admitted that LifeNet's '865 Publication disclosed highly aligned fibers, which is a critical feature of LifeNet's patented inventions. Ex. H at 8. Embody again discussed LifeNet's patented inventions in another office action response on September 6, 2019, where Embody again acknowledged that the '865 Publication "teaches a scaffold having aligned fibers." Ex. I at 10.

45. During the prosecution of the '870 Patent, in an office action on July 28, 2020 (more than a year and a half after the '223 Patent issued), the USPTO discussed LifeNet's '865 Publication, stating that it "teaches a scaffold comprising an aligned fiber." Ex. J at 7. The USPTO further explained that the '865 Publication's "invention further relates to a scaffold comprising one or more **electrospun** fibers wherein a fast Fourier transform (FFT) analysis result of the fibers have adjacent major peaks with about 180? *[sic]* Apart from each other." *Id.* (emphasis in the original). The USPTO also highlighted that in the '865 Publication "the scaffold may be in the form of **one or more elongated sheets**," and "**includes fiber from collagen**." *Id.* (emphasis in the original). In its response on January 28, 2021, Embody submitted a sworn declaration from Dr. Francis, in which he stated that he was Embody's Chief Scientific Officer and acknowledged that he was also a "named inventor" on LifeNet's '865 Publication. Ex. K at ¶ 2. Dr. Francis also acknowledged that the '865 Publication, which disclosed the inventions claimed in the LifeNet Patents, was "assigned on its face to LifeNet Health." *Id.*

E. Embody Interfered with LifeNet's Business in November 2018 by Having Dr. Francis and Mr. Kemper Assign Their Rights in the Embody Patent Applications to Embody

46. On November 9, 2018, at Embody's request, Dr. Francis and Mr. Kemper assigned their interests in Patent Application No. 16/152,963 ("the '963 Application") to Embody LLC. Ex. L at REEL: 047486 FRAME: 0570. The '963 Application is the parent application for the '787 and '870 Patents. Ex. E at Cover (listing "Appl. No.: 16/152,963"). The '787 Patent describes inventions that were developed by Dr. Francis and Mr. Kemper while they were still LifeNet employees. For example, claim 1 of the '787 Patent recites "An implantable ligament and tendon repair device comprising an annealed biopolymer sheet ***having substantially aligned electrospun biopolymer fibers*** . . ." *Id.* at 14:2-5 (emphasis added). Yet Dr. Francis had already developed this same technology years earlier at LifeNet (and assigned it to LifeNet). *See* Ex. A ('223 Patent) at Abstract (describing "[a] scaffold comprising an aligned fiber. The invention further relates to a scaffold comprising one or more electrospun fibers wherein a fast Fourier transform (FFT) analysis result of the fibers have adjacent major peaks with about 180? apart from each other"). Similarly, the '870 Patent describes inventions that were developed by Dr. Francis and Mr. Kemper while they were still LifeNet employees. For example, claim 1 of the '870 Patent recites "[a]n implantable ligament and tendon repair device comprising an annealed biopolymer sheet ***having substantially aligned electrospun biopolymer fibers***." Ex. F at 14:2-4 (emphasis added).

47. Per the terms of the Francis Employment Agreement, Dr. Francis was contractually obligated to assign the inventions described in the '787 and '870 Patents to LifeNet, and was contractually prohibited from assigning those inventions to any third party (including Embody). Ex. C (Francis Employment Agreement) at 4-5. Similarly, per the terms of the Kemper IP Agreement, Mr. Kemper was contractually obligated to assign these inventions to LifeNet, and was contractually prohibited from assigning those inventions to any third party (including

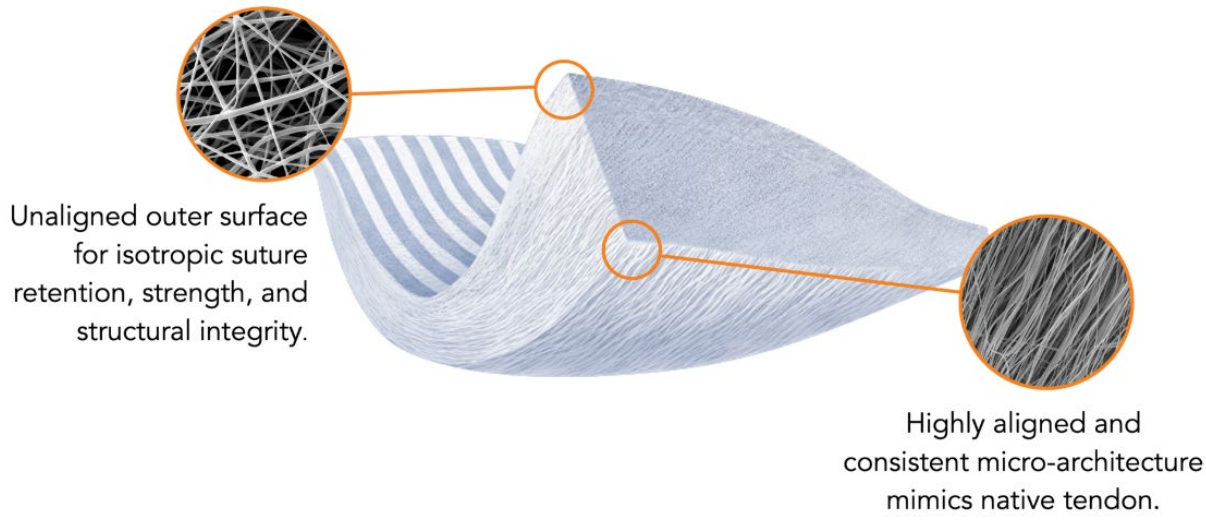
Embody). Ex. D (Kemper IP Agreement) at 5.

F. Embody Copied LifeNet's Patented Inventions in Its Products

48. By 2018, Embody's CEO Jeff Conroy was attending industry tradeshows and publicly touting Embody's allegedly new "scaffold" that was made up of "microfibers that are aligned in the same direction" as the fibers of the native cells at the surgical site.[3] Just like LifeNet's patented invention, Embody's "new" scaffold would stimulate new cells and new tissue to greatly improve the repair process at the surgical site.

49. On information and belief, by unlawfully using LifeNet's patented inventions, Embody ultimately arrived at the TAPESTRY Biointegrative Implant ("TAPESTRY"). According to Embody, TAPESTRY "is a bioengineered collagen implant with a highly aligned & highly porous architecture specifically designed to support tendon and ligament healing." Copying directly from LifeNet's patented electrospun fiber architecture, Defendants' promotional materials (shown below) highlight the way TAPESTRY's "highly aligned and consistent micro-architecture ***mimics native tendon***."

[3] *See* "Rick Horrow interviews Jeff Conroy" at https://rickhorrow.tumblr.com/post/173264380601/rick-horrow-interviews-jeff-conroy (last visited September 21, 2023)

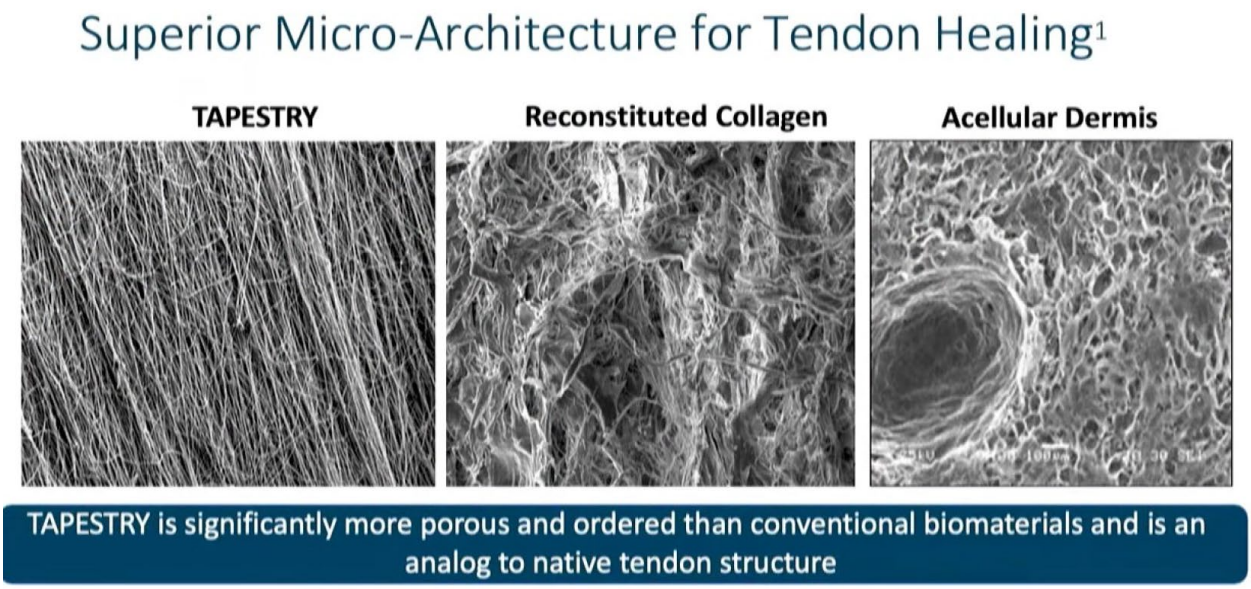


See https://embody-inc.com/tapestry/ (emphasis added) (last visited September 21, 2023); *see also* https://www.zimmerbiomet.com/content/dam/zb-corporate/en/support/coding-guides/4150.1-US-en-TAPESTRY-Biointegrative-Implant-Coding-Reference-Guide.pdf (last visited February 1, 2024) (providing TAPESTRY coding reference guide).

50. According to Defendants, TAPESTRY's "highly aligned collagen-based implant . . . gradually resorbs leaving new tendon-like tissue to augment the existing tendon." This "highly aligned" arrangement provides a "cell infiltration friendly microstructure." https://embody-inc.com/tapestry/; *see also* https://www.zimmerbiomet.com/content/dam/zb-corporate/en/support/coding-guides/4150.1-US-en-TAPESTRY-Biointegrative-Implant-Coding-Reference-Guide.pdf.

51. Borrowing directly from LifeNet's patented inventions, Zimmer and Embody have promoted TAPESTRY's "superior micro-architecture for tendon healing" based on the fact that it is "significantly more porous ***and ordered***" than conventional biomaterials. For example, during a presentation by Embody's CEO at the Emerging Medtech Summit in March 2022 (attached as

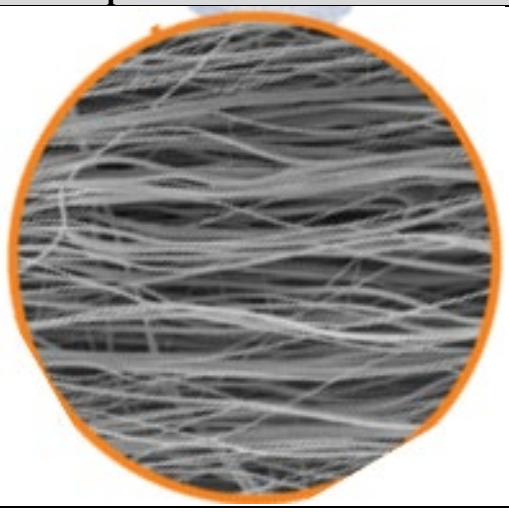
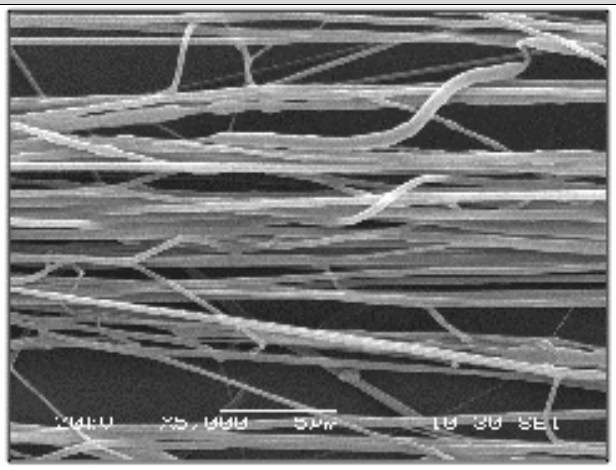
Exhibit M),[4] Embody touted the highly aligned electrospun fibers of the TAPESTRY implant compared to "conventional biomaterials":



Ex. M at 7.

52. Yet, as shown in the table below, TAPESTRY's "highly aligned" electrospun fiber architecture is nothing more than a repackaging of LifeNet's highly aligned electrospun fibers that are claimed in the LifeNet Patents.

[4] Mr. Conroy's presentation can be viewed at https://www.youtube.com/watch?v=WOhFPD8uUZg (last visited September 21, 2023).

Defendants' "Highly Aligned" Electrospun Fibers	LifeNet's Patented Electrospun Fibers
	

53. On October 9, 2020, Embody received FDA clearance for the TAPESTRY implant. According to Defendants, "[p]reclinical studies of TAPESTRY showed dense collagenous fibrous connective tissue ingrowth into and around the scaffolding."

54. In its March 2022 presentation, Embody made known its plans to use LifeNet's patented inventions in TAPESTRY to treat an "unparalleled" number of injuries, including rotator cuff injuries, ACL and LCL tears, Achilles tendon ruptures, and quadriceps injuries. Ex. M at 9.

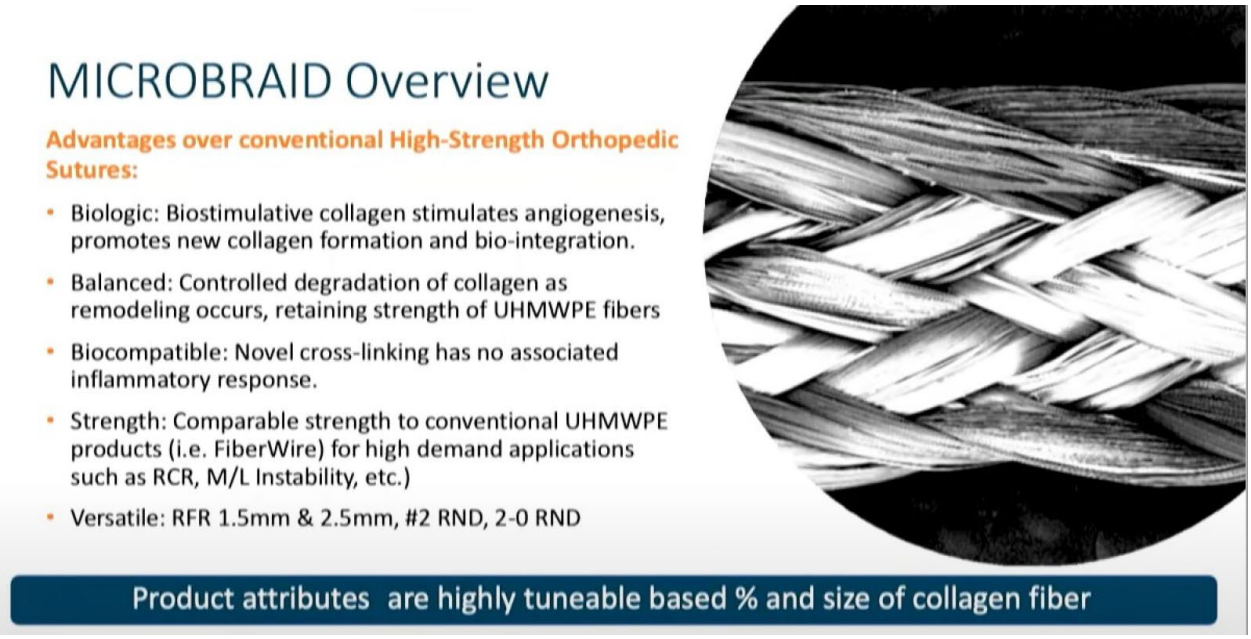
55. On information and belief, Embody began selling TAPESTRY in the United States in 2021.

56. In 2022, Embody launched the TAPESTRY RC, which is directed to rotator cuff repair and includes mechanisms for delivering and fixing the TAPESTRY implant at post-surgical sites in vivo:

Ex. M at 12.

57. Defendants provide videos on their website showing their customers how to use the TAPESTRY RC to practice the claimed inventions of the LifeNet Patents. *See* https://embody-inc.com/tapestryrc/ (last visited September 21, 2023); *see also* https://www.zimmerbiomet.com/content/dam/zb-corporate/en/support/coding-guides/4150.1-US-en-TAPESTRY-Biointegrative-Implant-Coding-Reference-Guide.pdf.

58. Not satisfied with using LifeNet's patented technology unlawfully in their TAPESTRY implant, Defendants also have been using LifeNet's patented technology in the ActivBraid Collagen Suture ("ActivBraid"). According to Defendants, ActivBraid uses a "novel cross-linking" that has "no associated inflammatory response."



Ex. M at 14.

59. Just as with LifeNet's '227 Patent, ActivBraid uses highly aligned, crosslinked collagen microfibers.[5]

60. On June 2, 2023, Defendants received FDA approval to market ActivBraid in the United States. Defendants have now begun advertising and selling ActivBraid in the United States. *See* https://www.zimmerbiomet.com/en/products-and-solutions/specialties/sports-medicine/activbraid.html#contact (last visited September 21, 2023).

G. Zimmer Acquired Embody for LifeNet's Patented Inventions

61. The value of LifeNet's patented inventions in Embody's products did not go unnoticed by the market. On January 5, 2023, Zimmer announced that it had reached a definitive agreement to acquire Embody for $155 million at closing, with up to an additional $120 million subject to achieving future regulatory and commercial milestones over a three-year period. In its

[5] Embody initially named the suture MICROBRAID during the R&D phase, but later abandoned that name in favor of ActivBraid.

press release announcing the acquisition, Zimmer touted "Embody's complete portfolio of collagen-based biointegrative solutions to support healing in the most challenging orthopedic soft tissue injuries – including the TAPESTRY® biointegrative implant for tendon healing and TAPESTRY® RC, one of the first arthroscopic implant systems for rotator cuff repair." Embody's then-CEO Jeff Conroy also stated "[w]e are excited for the potential to create value for patients and customers in new ways and believe the combination of Embody's innovative products and Zimmer Biomet's established portfolio will bring new solutions to the market that could redefine the standard of care." *See* https://investor.zimmerbiomet.com/news-and-events/news/2023/01-05-2023-120317843 (last visited September 21, 2023).

62. Zimmer's press release understates the value of LifeNet's patented inventions: "Embody's complete portfolio of collagen-based biointegrative solutions" consists of only two product lines (TAPESTRY and ActivBraid), and *both* of these products practice LifeNet's patented inventions. Zimmer therefore recognizes the growing market demand for the inventions in the LifeNet Patents.

63. According to its Form 10-Q for the first quarter of 2023, Zimmer completed the acquisition of all outstanding shares of Embody on February 14, 2023.

COUNT 1: PATENT INFRINGEMENT OF THE '223 PATENT

64. LifeNet realleges and incorporates by reference the allegations set forth in paragraphs 1-63 above.

65. Defendants made, used, offered for sale, and sold TAPESTRY, and Defendants continue to make, use, offer for sale, and sell TAPESTRY in the United States, including in the Commonwealth of Virginia through their facilities and offices.

66. As shown in the claim chart attached as Exhibit N, pursuant to 35 U.S.C. § 271(a),

Defendants have directly infringed at least claim 1 of the '223 Patent (either literally or under the doctrine of equivalents) by making, using, offering for sale, and/or selling the TAPESTRY implant in the United States, including in the Commonwealth of Virginia through their facilities and offices. Defendants' infringement is ongoing.

67. On information and belief, Defendants have been aware that the TAPESTRY implant infringes at least claim 1 of the '223 Patent since the date of the '223 Patent's issuance. Embody repeatedly and extensively discussed a number of the patented features of the '223 Patent during the prosecution of Embody's own later-filed patents. *Supra* ¶¶ 43-45. All of these discussions occurred well after the '223 Patent had issued.

68. Furthermore, Embody employed Dr. Francis—the co-inventor of the '223 Patent—for over seven years until 2021. In a declaration dated January 27, 2021, Dr. Francis admitted that the inventions in the '865 Publication (which are claimed in the LifeNet Patents) were "assigned . . . to LifeNet Health." Ex. K, ¶ 2. Dr. Francis co-founded Embody along with Jeff Conroy, served as Embody's Chief Scientific Officer and Vice President of R&D, and developed Embody's infringing TAPESTRY implant. *See* https://embody-inc.com/embody-competes-for-another-milestone-victory/ (last visited September 20, 2023). Defendants also employed Mr. Kemper as their Director of Engineering.[6] Mr. Kemper worked closely with Dr. Francis on LifeNet's novel electrospinning technology while they were both employed by LifeNet. Defendants are also aware that the TAPESTRY implant infringes at least claim 1 of the '223 Patent by virtue of the filing of LifeNet's complaint.

69. Defendants have manufactured, used, sold, and offered to sell the TAPESTRY in spite of their awareness of its infringement of the '223 Patent. Thus, Defendants' infringement of

[6] *See* https://embody-inc.com/img_6242/ (last visited September 25, 2023).

the ’223 Patent has been (and continues to be) willful and deliberate.

70. Defendants’ infringement of the ’223 Patent will continue unless enjoined by this Court.

71. As a direct and proximate cause of Defendants’ infringement of the ’223 Patent, LifeNet has suffered and will continue to suffer irreparable injury and damages in an amount not yet determined for which LifeNet is entitled to relief.

72. Because Defendants’ infringement of the ’223 Patent is willful and deliberate, LifeNet is entitled to enhanced damages under 35 U.S.C. § 284 and to attorneys’ fees and costs under 35 U.S.C. § 285.

COUNT 2: PATENT INFRINGEMENT OF THE ’227 PATENT

73. LifeNet realleges and incorporates by reference the allegations set forth in paragraphs 1-72 above.

74. On information and belief, Defendants have used ActivBraid, and continue to use ActivBraid in the United States, including in the Commonwealth of Virginia through their facilities and offices.

75. As shown in the claim chart attached as Exhibit O, Defendants’ use of the ActivBraid sutures for testing purposes infringed and continues to infringe at least claim 1 of the ’227 Patent pursuant to 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents.

76. Defendants also infringe at least claim 1 of the ’227 Patent with respect to ActivBraid sutures sold to customers inside the United States pursuant to 35 U.S.C. § 271(b). As shown in Exhibit O, such United States customers directly infringe at least claim 1 of the ’227 Patent pursuant to 35 U.S.C. § 271(a) when they use the ActivBraid suture. Defendants actively induce the infringement of their United States customers by encouraging their customers to use

the ActivBraid, as evidenced by Defendants' promotional materials for the ActivBraid on Defendants' website. *See* https://www.zimmerbiomet.com/en/products-and-solutions/specialties/sports-medicine/activbraid.html#contact (last visited September 21, 2023). Defendants encourage their customers to do so in spite of knowing that such use infringes at least claim 1 of the '227 Patent.

77. Defendants also infringe at least claim 1 of the '227 Patent with respect to their customers inside the United States pursuant to 35 U.S.C. § 271(c). Such United States customers directly infringe at least claim 1 of the '227 Patent pursuant to 35 U.S.C. § 271(a) when they use the ActivBraid. Defendants contribute to the infringement of their United States customers by selling the ActivBraid to their customers (including customers in the Commonwealth of Virginia), which includes the claimed features of claim 1 of the '227 Patent. As shown in Exhibit O, these features are a material part of the invention of at least claim 1 of the '227 Patent and are not a staple article or commodity of commerce suitable for substantial noninfringing use. There is no way to use the ActivBraid without infringing claim 1 of the '227 Patent, because ActivBraid must be implanted at a tissue defect and applied to the tissue defect in order to perform its intended function. Defendants sell the ActivBraid to their customers with the knowledge that the ActivBraid is especially made or especially adapted for use in infringing at least claim 1 of the '227 Patent, as evidenced by Defendants' promotional materials for the ActivBraid found on Defendants' website. *See* https://www.zimmerbiomet.com/en/products-and-solutions/specialties/sports-medicine/activbraid.html#contact (last visited September 21, 2023).

78. On information and belief, Defendants have been aware that the ActivBraid suture infringes at least claim 1 of the '227 Patent since the date of the '227 Patent's issuance. Embody repeatedly and extensively discussed a number of the patented features of the '227 Patent during

the prosecution of Embody's own later-filed patents. *Supra* ¶¶ 43-45.

79. Furthermore, Embody employed Dr. Francis—the co-inventor of the '227 Patent—for over seven years until 2021. In a declaration dated January 27, 2021, Dr. Francis admitted that the inventions in the '865 Publication (which are claimed in the LifeNet Patents) were "assigned . . . to LifeNet Health." Ex. K, ¶ 2. Dr. Francis co-founded Embody, served as Embody's Chief Scientific Officer and Vice President of R&D, and developed Embody's infringing ActivBraid suture. Defendants also employed Mr. Kemper as their Director of Engineering. Mr. Kemper worked closely with Dr. Francis on LifeNet's novel electrospinning technology while they were both employed by LifeNet. Defendants are also aware that the ActivBraid suture infringes at least claim 1 of the '227 Patent by virtue of the filing of LifeNet's complaint.

80. Defendants used and continue to use the ActivBraid suture despite their awareness of its infringement of the '227 Patent. Thus, Defendants' infringement of the '227 Patent has been (and continues to be) willful and deliberate.

81. Defendants' infringement of the '227 Patent will continue unless enjoined by this Court.

82. As a direct and proximate cause of Defendants' infringement of the '227 Patent, LifeNet has suffered and will continue to suffer irreparable injury and damages in an amount not yet determined for which LifeNet is entitled to relief.

83. Because Defendants' infringement of the '227 Patent is willful and deliberate, LifeNet is entitled to enhanced damages under 35 U.S.C. § 284 and to attorneys' fees and costs under 35 U.S.C. § 285.

COUNT 3: TORTIOUS INTERFERENCE WITH CONTRACT

84. LifeNet realleges and incorporates by reference the allegations set forth in

paragraphs 1-83 above.

85. LifeNet had valid and binding contractual relationships with Dr. Francis and Mr. Kemper, namely the Francis Employment Agreement and the Kemper IP Agreement, respectively.

86. Under the Francis Employment Agreement, Dr. Francis agreed "to assign, and hereby does assign, to LifeNet Health any and all of his or her right, title, and interest in and to all such Works." Ex. C (Francis Employment Agreement), § 4.

87. Dr. Francis further agreed "never to exploit, challenge, seek to register, or assign or license to any third party, directly or indirectly anywhere in the world, any of the rights owned by, or assigned to, LifeNet Health hereunder." *Id.*

88. Under the Kemper IP Agreement, Mr. Kemper agreed "to assign, and hereby does assign, to LifeNet Health any and all of his or her right, title, and interest in and to all such Works." Ex. D (Kemper IP Agreement), § 7.

89. Similarly, under the Kemper IP Agreement, Mr. Kemper agreed "never to exploit, challenge, seek to register, or assign or license to any third party, directly or indirectly anywhere in the world, any of the rights owned by, or assigned to, LifeNet hereunder." *Id.*

90. On information and belief, Embody was aware that Dr. Francis and Mr. Kemper were subject to these provisions in their agreements with LifeNet. Embody knew that Dr. Francis and Mr. Kemper had both worked for LifeNet in the exact same field related to collagen-based implants immediately before joining Embody. During prosecution of its own patents, Embody submitted a declaration from Dr. Francis acknowledging this fact. *See* Ex. K, ¶ 3 (Dr. Francis stating "prior to joining [Embody], I was the scientific lead at LifeNet health for orthobiologics, having invented and commercialized multiple collagen-based therapeutics for orthopedics indications.") Embody knew that it was common practice for employers like LifeNet to require

its employees performing scientific & engineering research to execute employment agreements containing provisions governing the ownership of intellectual property developed in the course of employment. Embody has reviewed employment agreements of other LifeNet employees and decided not to hire those LifeNet employees because of provisions in their agreements. Further, Dr. Francis co-founded Embody and was employed there until 2021, holding a variety of high-level positions before departing, including Chief Science Officer and Vice President of R&D. Mr. Kemper left LifeNet to join Embody in 2015 and was Embody's Director of Engineering prior to departing Embody.

91. Embody, through its predecessor-in-interest Embody LLC, intentionally interfered with the contractual relationship between Dr. Francis and LifeNet by inducing or causing Dr. Francis to breach the Francis Employment Agreement. More specifically, Embody (including but not limited to its then-president Jeff Conroy) induced Dr. Francis to breach Section 4 of the Francis Employment Agreement on November 9, 2018 by requiring Dr. Francis to assign his interests in the inventions of at least the '787 Patent and '870 Patent to Embody's predecessor in interest Embody LLC. This action breached Dr. Francis's contractual obligation never to "***assign or license*** to any third party, directly or indirectly anywhere in the world, any of the rights owned by, or assigned to, LifeNet Health" under the Francis Employment Agreement. Ex. C at 5 (emphasis added).

92. Embody was aware that the inventions described in the '787 and '870 Patents were developed by Dr. Francis while he was still a LifeNet employee, and thus under Section 4 of the Francis Employment Agreement, those inventions are owned by LifeNet, and Dr. Francis was contractually obligated to refrain from assigning those inventions to any third party (including Embody).

93. While LifeNet does not currently allege that Dr. Francis breached other provisions in the Francis Employment Agreement (or that Embody induced those breaches), to the extent Dr. Francis breached other provisions in Section 4 (or elsewhere) of the Francis Employment Agreement, LifeNet could not have reasonably discovered those breaches prior to 2018. Dr. Francis misled LifeNet about his future plans when he left LifeNet in 2015, and LifeNet was unaware that he intended to join Embody, or that he did in fact join Embody in 2015. Nor was LifeNet aware that Embody began utilizing LifeNet's patented technology when Dr. Francis joined Embody, because Embody concealed its actions for several years following its founding (since Embody was a startup and not required to file public disclosures).

94. Embody, through its predecessor-in-interest Embody LLC, intentionally interfered with the contractual relationship between Mr. Kemper and LifeNet by inducing or causing Mr. Kemper to breach the Kemper IP Agreement. More specifically, Embody (including but not limited to its then-president Jeff Conroy) induced Mr. Kemper to breach Section 7 of the Kemper IP Agreement on November 9, 2018 by requiring Mr. Kemper to assign his interests in the inventions of at least the '787 Patent and '870 Patent to Embody's predecessor in interest Embody LLC. This action breached Mr. Kemper's contractual obligation never to "***assign or license*** to any third party, directly or indirectly anywhere in the world, any of the rights owned by, or assigned to, LifeNet Health" under the Francis Employment Agreement. Ex. D at 5 (emphasis added).

95. Embody was aware that the inventions described in the '787 and '870 Patents were developed by Mr. Kemper while he was still a LifeNet employee, and thus under Section 7 of the Kemper IP Agreement, those inventions are owned by LifeNet, and Mr. Kemper was contractually obligated to refrain from assigning those inventions to any third party (including Embody).

96. Upon information and belief, all of these acts of tortious interference occurred

within the Commonwealth of Virginia.

97. As a result of Embody's tortious interference, LifeNet has suffered damages, including at least through the loss of the value of its intellectual property in at least the '787 and '870 Patents that was developed by Dr. Francis and Mr. Kemper while they were LifeNet employees, intellectual property to which LifeNet has ownership rights by virtue of the Francis Employment Agreement and the Kemper IP Agreement.

98. Although LifeNet is entitled to damages to compensate it for the harm is has already suffered, the damages will not provide an adequate remedy at law, as Defendants have profited from this interference by unlawfully exploiting inventions that rightfully belong to LifeNet. This harm cannot be adequately remedied by monetary damages, and LifeNet is entitled to an order transferring ownership of at least the '787 and '870 Patents (as well as any other Embody patents and patent applications describing inventions developed by Dr. Francis and Mr. Kemper while they were LifeNet employees) to LifeNet.

PRAYER FOR RELIEF

WHEREFORE, LifeNet requests that:

a) The Court enter judgment that Defendants have infringed one or more claims of the '223 Patent;

b) The Court enter judgment that Defendants have infringed one or more claims of the '227 Patent;

c) The Court enter an injunction restraining and enjoining Defendants, and their respective officers, agents, servants, employees, attorneys, and those persons in active concert or participation with Defendants who receive actual notice of the order by personal service or otherwise, from any further sales or use of their

infringing products and/or services and any other infringement of the LifeNet Patents, whether direct or indirect;

d) The Court enter an award of damages to compensate LifeNet for Defendants' infringement, including damages pursuant to 35 U.S.C. § 284, such as an award of LifeNet's lost profits on sales lost to Defendants and/or a reasonable royalty on Defendants' sales, not only of the TAPESTRY and ActivBraid, but also convoyed goods and services; prejudgment and post-judgment interest, and ongoing royalties in the absence of a permanent injunction;

e) The Court find that Defendants have willfully infringed and are willfully infringing one or more claims of the LifeNet Patents and award treble damages due to Defendants' deliberate and willful conduct;

f) The Court declare this case to be exceptional under 35 U.S.C. § 285 or otherwise, and award LifeNet its reasonable attorneys' fees, costs, and expenses incurred in bringing this action;

g) The Court enter judgment that Defendants have tortiously interfered with LifeNet's contractual relationships with Dr. Francis;

h) The Court enter judgment that Defendants have tortiously interfered with LifeNet's contractual relationships with Mr. Kemper;

i) The Court award LifeNet damages for past harm it has suffered from Embody's tortious interference in an amount to be determined at trial;

j) The Court enter an injunction transferring ownership of at least the '787 and '870 Patents to LifeNet, along with any other Embody patents and patent applications

describing inventions developed by Dr. Francis and Mr. Kemper while they were LifeNet employees; and

k) The Court grant such other and further relief as it deems to be just and proper.

JURY DEMAND

LifeNet hereby demands a trial by jury on all claims, issues and damages so triable.

Dated: February 2, 2024

Respectfully submitted,

/s/ Brian C. Riopelle

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LifeNet Health

CERTIFICATE OF SERVICE

I hereby certify that on February 2, 2024, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will automatically send notification of electronic filing to all counsel of record.

By: */s/ Brian C. Riopelle*
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