IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

LIFENET HEALTH, a Virginia Corporation, Plaintiff, v. TISSUE REGENIX GROUP PLC, a British Corporation, and TISSUE REGENIX WOUND CARE INC., a Delaware Corporation, and COMMUNITY TISSUE SERVICES, an Ohio Corporation, Defendants.	Civil Action No. 1:17-cv-00533 **JURY TRIAL DEMANDED** Hon. Liam O'Grady

FIRST AMENDED COMPLAINT

LifeNet Health ("LifeNet"), by and through its undersigned counsel, states as follows for its complaint against the defendants Tissue Regenix Group PLC ("TRx Group"), Tissue Regenix Wound Care Inc. ("TRx Wound Care") (collectively, "Tissue Regenix"), and Community Tissue Services (collectively with Tissue Regenix, "Defendants"):

THE PARTIES

LifeNet Health

1. LifeNet is a nonprofit corporation organized under 26 U.S.C. § 501(c)(3), existing under the laws of the Commonwealth of Virginia and having a principal place of business in this judicial district at 1864 Concert Drive, Virginia Beach, Virginia 23453.

2. LifeNet's mission statement is "Saving Lives, Restoring Health and Giving Hope." Founded in 1982 as the Eastern Virginia Tissue Bank, LifeNet is one of the world's most trusted providers of transplant solutions, from organ and tissue procurement to innovative bio-implant technologies and cellular therapies.

3. Each year, LifeNet facilitates the transplantation of over 400 organs in the United States and distributes over 500,000 allograft bio-implants to meet the needs of hospitals and patients in the United States. An allograft is human donor tissue, such as skin, bone, tendon, and cardiovascular tissue, intended for transplantation in a human recipient.

4. LifeNet is also extensively involved in promoting and facilitating tissue-donation and bio-implant tissues. For example, LifeNet's Tissue Services Division is dedicated to training, educating, and maintaining relationships with more than 50 partners to promote tissue donation in their respective communities.

5. LifeNet also established its Plastic & Reconstructive Surgical Specialties franchise to ensure the processing and delivery of skin/dermal allograft bio-implants for U.S. trauma and burn centers.

6. In addition, LifeNet's Bio-Implants Division has pioneered technologies related to all aspects of the allograft bio-implant production process, including disinfection, decellularization (*i.e.*, the removal of cellular elements from an allograft bio-implant), preservation, and sterilization.

7. LifeNet is also a member of several organizations related to tissue donation. For example, LifeNet is an accredited member of the American Association of Tissue Banks, and also a member organization of Donate Life America, a not-for-profit alliance of national organizations across the United States committed to increasing organ, eye, and tissue donation.

8. The patent asserted by LifeNet in this Complaint, U.S. Patent No. 6,569,200 ("the '200 Patent"), is a result of LifeNet's extensive research and development in the field of tissue and bio-implant technology. A copy of the '200 Patent is attached as **Exhibit A**.

TRx Group

9. Upon information and belief, TRx Group is a corporation organized and existing under the laws of the country of the United Kingdom and has a principle place of business at Unit 1 & 2, Astley Way, Astley Lane Industrial Estate, Swillington, Leeds LS26, United Kingdom.

10. TRx Group is in the business of manufacturing, using, selling, and/or offering for sale various medical products, including skin/dermal products under the brand names DermaPure® Decellularized Dermal Allograft ("DermaPure") and SurgiPure™ XD Reconstructive Tissue Matrix ("SurgiPure") (collectively the "Infringing Products").

11. Upon information and belief, in November 2012 TRx Group set up a wholly owned subsidiary company in the United States, TRx Wound Care, as part of its commercialization strategy for manufacturing, using, selling, and/or offering for sale at least the Infringing Products in the United States.

TRx Wound Care

12. Upon information and belief, TRx Wound Care is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 2611 North Loop 1604 West, Suite 201, San Antonio, Texas 78258.

13. TRx Wound Care is in the business of manufacturing, using, selling, and/or offering for sale various medical products, including skin/dermal products under the brand names DermaPure and SurgiPure.

14. Upon information and belief, in 2013 TRx Wound Care began a partnership with

Community Tissue Services as part of the Tissue Regenix commercialization strategy for manufacturing, using, selling, and/or offering for sale DermaPure in the United States.

Community Tissue Services

15. Upon information and belief, Community Tissue Services is a nonprofit corporation organized under 26 U.S.C. § 501(c)(3), existing under the laws of the State of Ohio, and has a principal place of business at 33 West First Street, Suite 600, Dayton, Ohio 45402.

16. Community Tissue Services is in the business of manufacturing, using, selling, and/or offering for sale various medical products, including skin/dermal products under the brand name DermaPure.

JURISDICTION AND VENUE

17. This action is a claim for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 271, *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201(a) and 2202.

18. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1332, 1338(a), 2201(a), and 2202.

19. This Court has personal jurisdiction over Defendants at least because they have substantial, continuing, and ongoing contacts within the Commonwealth of Virginia and this judicial district, and Defendants have sold and continue to offer for sale and sell DermaPure in this Commonwealth and judicial district and intend to offer for sale and sell SurgiPure in this Commonwealth and judicial district.

20. Upon information and belief, Defendants utilize a "hybrid model" of direct sales and distributors. *See* TRx Group, PowerPoint Presentation (attached as **Exhibit B**) at 17. Upon information and belief, Defendants maintain a sales force in the Commonwealth, at least including

an "agent distributor" located in the Commonwealth. *Id.* The Commonwealth is located within one of three sales regions [East] for Defendants and "[e]ach of these regions is responsible for recruiting and development of direct sales people and distributors." *Id*.

21. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and 1400(b) because acts of patent infringement have occurred, are occurring, and are expected to occur within this judicial district, and Defendants have regular and established place(s) of business in this judicial district.

FACTS

U.S. Patent No. 6,569,200

22. On June 5, 2001, Lloyd Wolfinbarger, Jr., Robert K. O'Leary, and Billy G. Anderson (collectively, "the Inventors"), filed U.S. Patent Application No. 09/874,862 ("the '862 Application"). The '862 Application is a division of U.S. Patent Application No. 09/107,459, filed June 30, 1998, now U.S. Patent No. 6,293,970.

23. On August 29, 2002, the '862 application published as U.S. Publication No. 2002/0120345. On May 27, 2003, the U.S. Patent and Trademark Office ("USPTO") issued the '862 Application as the '200 Patent.

24. LifeNet is the assignee of all right, title, and interest in and to the '200 Patent and possesses all rights of recovery under the '200 Patent.

25. The '200 Patent is directed to, inter alia, "plasticized dehydrated or freeze-dried bone and/or soft tissue product[s] that do[] not require special conditions of storage," and methods for producing the same. *See* Exhibit A, '200 Patent Abstract.

26. In 2007, LifeNet introduced Preservon® technology, its proprietary bio-implant tissue-preservation technology based on the '200 Patent family. It is an ambient temperature

(room temperature) preservation method that simplifies the tissue-preparation and product distribution processes and storage, saves valuable time in the operating room, and allows allograft tissue to retain its physical and biomechanical properties.

27. Starting in 2010 with the launch of its Oracell® dermal implant, LifeNet has marked its products incorporating the Preservon® technology with the '200 Patent number.

28. In September 2013, LifeNet filed suit in this Court asserting infringement of the '200 Patent against LifeCell Corporation. *See* D.I. 1, Civil Action No. 2:13-cv-00486, September 6, 2013 (E.D. Va.).

29. After a ten-day trial, the jury found that the '200 Patent was valid and infringed by LifeCell's allograft and xenograft tissue products sold under the brand names AlloDerm® RTM Ready to Use, Strattice™ Reconstructive Tissue Matrix, GraftJacket® Regenerative Tissue Matrix, and Conexa™ Reconstructive Tissue Matrix. *Id.*, D.I. 369. The Court of Appeals for the Federal Circuit upheld the decision on appeal. *LifeNet Health v. LifeCell Corp.*, 837 F.3d 1316 (Fed. Cir. 2016).

Defendants' Infringing Products

30. Upon information and belief, Defendants have been manufacturing, using, selling, and offering for sale a tissue product under the brand name DermaPure.

31. Defendants market DermaPure as a Human Cells, Tissues, and Cellular and Tissue-Based Product ("HCT/P"). Under 21 C.F.R. § 1271.10(a), HCT/Ps need not be approved by the U.S. Food and Drug Administration ("FDA") if, among other requirements, they are minimally manipulated and intended solely for homologous use.

32. Defendants make the following claims about DermaPure:

- "DermaPure is a new decellularized human dermis product from Tissue Regenix. The product concept replaces human dermis with human dermis, to most closely approximate the structure and function of the native tissue it is replacing." Community Tissue Services Allograft Offerings Brochure (attached as **Exhibit C**), page 26.

- "DermaPure is produced using dCELL Technology, a patented proprietary process that maintains the essential structure of the native extracellular matrix, [and] preserves a high degree of the natural tissue's biomechanical properties . . . ." *Id.*; DermaPure Product Page, Tissue Regenix Wound Care Inc. (attached as **Exhibit D**).

- "DermaPure requires no thawing, no rehydrating, no special storage." Exhibit C at 27; Exhibit D.

- "DermaPure is stored at ambient temperature and comes hydrated, with only a simple rinse required prior to use." *Id.*

33. Upon information and belief, DermaPure is a plasticized soft tissue graft, as set forth in at least claims 1-3, 7, and 8 of the '200 Patent. *See, e.g.*, Exhibit C, pages 26–27; Exhibit D; Tissue Regenix Group Corporate Overview Presentation (June 7, 2016) (attached as **Exhibit E**), page 14; Tissue Regenix Website, dCell Technology (attached as **Exhibit F**).

34. Upon information and belief, DermaPure is suitable for transplantation into a human, as set forth in claims 1-3, 7, and 8 of the '200 Patent. *See, e.g.*, Exhibit C and D; Exhibit E, pages 14–16; DermaPure Instructions for Use QC-605-F-24-Rev 03 (attached as **Exhibit G**); June 4, 2015.

35. Upon information and belief, DermaPure is a cleaned soft tissue graft, as set forth in claims 1-3, 7, and 8 of the '200 Patent. *See, e.g.*, Exhibits C, D, E, F, and G.

36. Upon information and belief, DermaPure has an internal matrix, as set forth in claims 1-3, 7, and 8 of the '200 Patent. *See, e.g.*, *id*.

37. Upon information and belief, DermaPure has one or more plasticizers contained in the internal matrix, as set forth in claims 1-3, 7, and 8 of the ’200 Patent. *See, e.g.*, Exhibit C, page 27; Exhibits D, E, G.

38. Upon information and belief, in DermaPure one or more plasticizers are not removed from the internal matrix of the plasticized soft tissue graft prior to transplantation into a human, as set forth in claims 1-3, 7, and 8 of the ’200 Patent. *See, e.g.*, Exhibit G.

39. Upon information and belief, Defendants are preparing to commercialize a tissue product under the brand name SurgiPure in the United States in the second half of 2017.

40. TRx Group obtained marketing clearance for SurgiPure through FDA’s substantial equivalence pathway for medical devices, Section 510(k) of the Food, Drug, and Cosmetic Act (“FDCA”). *See* SurgiPure 510(k) Clearance letter, Mar. 8, 2016 (attached as **Exhibit H**).

41. TRx Group represented to the FDA that SurgiPure is substantially equivalent to LifeCell Corporation’s Strattice™ Reconstructive Tissue Matrix (LTM Surgical Mesh, K070560) (“Strattice”). In doing so, TRx Group represented that SurgiPure has the same intended uses and the same or similar indications, technological characteristics, and principles of operation as Strattice, and that TRx Group has performance data that demonstrates that SurgiPure functions equivalently to Strattice. *See id*.

42. Upon information and belief, SurgiPure is substantially equivalent to Strattice, a product already found to infringe the ’200 Patent.

43. Upon information and belief, SurgiPure is a plasticized soft tissue graft, as set forth in at least claims 1-3, 7, and 8 of the ’200 Patent. *See*, *e.g.*, *id*.; Exhibit E, pages 5 and 17.

44. Upon information and belief, SurgiPure is suitable for transplantation into a human, as set forth in claims 1-3, 7, and 8 of the ’200 Patent. *See*, *e.g.*, Exhibit E, pages 5 and 17; Exhibit H.

45. Upon information and belief, SurgiPure is a cleaned soft tissue graft, as set forth in claims 1-3, 7, and 8 of the ’200 Patent. *See*, *e.g.*, Exhibit E, pages 5 and 17; Exhibits F and H.

46. Upon information and belief, SurgiPure has an internal matrix, as set forth in claims 1-3, 7, and 8 of the ’200 Patent. *See*, *e.g.*, *id*.

47. Upon information and belief, SurgiPure has one or more plasticizers contained in the internal matrix, as set forth in claims 1-3, 7, and 8 of the ’200 Patent. *See*, *e.g.*, Exhibit E, page 17; Exhibit H.

48. Upon information and belief, in SurgiPure, one or more plasticizers are not removed from the internal matrix of the plasticized soft tissue graft prior to transplantation into a human, as set forth in claims 1-3, 7, and 8 of the ’200 Patent. *See*, *e.g.*, *id*.

49. Defendants have sold and/or offered for sale, and will continue to sell and/or offer for sale at least DermaPure in this Commonwealth and this District, including but not limited to hospitals and other surgical centers.

50. Defendants intend to offer for sale and/or sell at least SurgiPure in this Commonwealth and this District, including but not limited to hospitals and other surgical centers.

Defendants’ Knowledge of the ’200 Patent

51. Defendants have had knowledge of the ’200 Patent since at least 2016.

52. Tissue Regenix compares DermaPure to LifeNet’s plasticized soft tissue graft, DermACELL, in a “dCell Technology Information Card,” available on the TRx Group’s and TRx Wound Care’s website(s) and copyrighted 2016 (attached as **Exhibit I**). In doing so, Tissue

Regenix cites to a LifeNet Health publication: Moore, Mark A. Decellularization of human dermis using matrecell technology: process, preclinical studies, and medical applications; LifeNet Health 2011 (hereinafter, "the Moore Paper," attached as **Exhibit J**). Exhibit I at 2.

53. The Moore Paper specifically identifies the '200 Patent as a proprietary bio-implant preservation method, explaining that "[t]he bio-implant is also treated to remove and replace the water volume with glycerol prior to final packaging in order to allow room temperature storage and rapid preparation time." Exhibit J at 4 n.49.

54. Defendants' advertising of DermaPure touts these same features. *See e.g.*, Exhibits C and D ("DermaPure requires no thawing, rehydrating, no special storage. DermaPure is stored at ambient temperature and comes hydrated, with only a simple rinse required prior to use.").

55. On or about May 9, 2017, LifeNet sent a letter to Defendants advising them of LifeNet's ownership of the '200 Patent and requesting that Defendants compare the claims of the '200 Patent to the Infringing Products. The letter also advised Defendants that Strattice, the predicate device relied upon for FDA clearance of SurgiPure, had been found to infringe the '200 Patent.

COUNT I
INFRINGEMENT OF THE ' 200 PATENT

56. Plaintiff LifeNet realleges and incorporates by reference paragraphs 1 through 55 of this First Amended Complaint as though fully set forth herein.

57. Defendants TRx Group, TRx Wound Care, and Community Tissue Services have infringed and continue to infringe at least claims 1-3, 7, and 8 of the '200 Patent by, without LifeNet's authority, manufacturing, causing to be manufactured, using, offering for sale, and selling in the United States at least DermaPure, pursuant to 35 U.S.C. § 271(a).

58. Defendants have been aware of the '200 Patent since at least as early as 2016 and

have compared DermaPure to products which incorporate the invention disclosed and claimed in the ’200 Patent.

59. In light of their knowledge of the ’200 Patent, and their knowledge that DermaPure infringes the ’200 Patent, Defendants actions demonstrate intentional and egregious infringement.

60. LifeNet has suffered, and will continue to suffer, monetary and other damages by reason of Defendants’ infringement of the ’200 Patent.

COUNT II
DECLARATION OF INFRINGEMENT OF THE ’200 PATENT

61. Plaintiff LifeNet realleges and incorporates by reference paragraphs 1 through 60 of this First Amended Complaint as though fully set forth herein.

62. Plaintiff LifeNet is entitled to a judicial declaration that Defendants’ manufacture, use, offer for sale, and/or sale of SurgiPure will infringe at least claims 1-3, 7 and 8 of the ’200 Patent by, without LifeNet’s authority, manufacturing, causing to be manufactured, using, offering for sale, and/or selling in the United States of at least SurgiPure, pursuant to 35 U.S.C. § 271(a).

63. The dispute is real and immediate. TRx Group obtained FDA marketing clearance for SurgiPure in March 2016 and, upon information and belief, Defendants plan to commercially launch SurgiPure product in the United States in the second half of 2017.

64. Defendants have been aware of the ’200 Patent since at least as early as 2016 and have compared SurgiPure to products which incorporate the invention disclosed and claimed in the ’200 Patent.

65. In light of their knowledge of the ’200 Patent, and their knowledge that SurgiPure infringes the ’200 Patent, Defendants’ actions demonstrate intentional and egregious intent to infringe.

66. LifeNet will suffer monetary and other damages by reason of Defendants’

infringement of the '200 Patent with SurgiPure.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff LifeNet requests relief against Defendants TRx Group, TRx Wound Care, and Community Tissue Services as follows:

(a) A judgment that Defendants have infringed the '200 Patent;

(b) A declaration that Defendants will infringe the '200 Patent upon commercial launch of SurgiPure in the United States;

(c) A judgment that Defendants' infringement has been willful;

(d) A judgment and order requiring Defendants to pay damages under 35 U.S.C. § 284, including treble damages for willful infringement, together with costs and prejudgment and post-judgment interest;

(e) A finding that this case is an exceptional case, and an order awarding Plaintiff its costs and reasonable attorney fees under 35 U.S.C. § 285; and

(f) Any and all such other and further relief as the Court may deem appropriate.

JURY DEMAND

LifeNet hereby demands a trial by jury on all issues triable to a jury.

Dated: June 29, 2017

Respectfully submitted,

/s/ Stephen E. Noona

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