IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ACERA SURGICAL, INC, RETECTIX, LLC, and WASHINGTON UNIVERSITY, Plaintiffs, v. NANOFIBER SOLUTIONS, LLC, PARAGEN TECHNOLOGIES LLC, ATREON ORTHOPEDICS LLC, and RENOVODERM LLC, Defendants.	)	C.A. No. 20-980-CFC **DEMAND FOR JURY TRIAL**

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs ACERA SURGICAL, INC ("Acera"), RETECTIX, LLC ("Retectix") and WASHINGTON UNIVERSITY ("WashU") (collectively, "Plaintiffs") hereby complain of Defendants NANOFIBER SOLUTIONS, LLC, PARAGEN TECHNOLOGIES LLC, RENOVODERM LLC, and ATREON ORTHOPEDICS LLC (collectively, "Defendants") and allege as follows:

PARTIES

1. Plaintiff Acera is a corporation incorporated under the laws of Delaware and has its principal place of business at 10880 Baur Blvd., St. Louis, Missouri 63132.

2. Acera is a St. Louis based medical device company specializing in the development of innovative solutions for assisting wound healing. Much of their work is the product of the pioneering research and development of Dr. Matthew MacEwan, Acera's Chief Technology Officer. In 2008, while an MD/Ph.D. student at WashU, Dr. MacEwan began investigating the use of polymer nanofibers and their potential use in the medical field, ultimately leading to the founding of Acera. Following successful product tests, Acera developed Cerafix® Dura Substitute, a nanofiber dural repair matrix and received FDA clearance for Cerafix® in 2016.Acera also offers a product called Restrata® Wound Matrix, a fully resorbable nanofiber soft-tissue repair. Acera's products are based on the groundbreaking nanofiber technology Dr. MacEwan and his colleagues developed and brought to market. Acera's technology enables the engineering of matrices closely resembling the structure and architecture of the native human extracellular matrix. The nanofiber matrix is engineered from intricately designed fibers to create a fully resorbable regenerative scaffold. Native cells rapidly migrate into the scaffold, and then proliferate and differentiate to form new tissue. Gradual and defined resorption of the nanofiber scaffold is designed to occur at a similar rate to cellular in growth and new tissue formation. As the scaffold resorbs, the porosity of the matrix gradually increases to support continued tissue integration and neovascularization, while eliciting a minimal inflammatory response.

3. Plaintiff Retectix is an LLC formed under the laws of Missouri and located in St. Louis, MO. Dr. Matthew MacEwan is the Founder and President of Retectix.

4. Plaintiff WashU is a corporation established by special act of the Missouri General Assembly approved February 22, 1853 and acts amendatory thereto, having its principal place of business at 1 Brookings Dr., St. Louis, MO 63130.

5. WashU is a world-renowned research institution located St. Louis, Missouri. In addition to educating tens of thousands of students each year, WashU also funds nearly a billion dollars of research into numerous cutting edge and innovative fields. The developments of WashU research programs have led to breakthroughs in the areas of environmental and energy research, medical devices, and agriculture. To support such endeavors, WashU maintains a robust patent portfolio.

6. Upon information and belief, Defendant Nanofiber Solutions, LLC ("Nanofiber") is a Delaware corporation having its principal place of business at 4389 Weaver Court North, Hilliard, Ohio 43026. Nanofiber represents (at least by including its name on labeling) that one of the products at issue—the Phoenix Wound Matrix—is a Nanofiber product. Nanofiber is the listed applicant for the 510(k) premarket notification submission to the FDA for the Phoenix Wound Matrix,

which is marketed as RenovoDerm's product. Nanofiber's name, physical address, and website address are listed on the packaging for RenovoDerm's Phoenix Wound Matrix. Nanofiber is also the listed applicant for the 510(k) premarket notification submission to the FDA for another accused product, Atreon's Rotium Bioresorbable Wick product. Nanofiber lists both "Phoenix Would Matrix" and "Rotium" as "Products" in the drop down menu that appears when you scroll over the "Products" tab on Nanofiber's website.

7. Upon information and belief, Defendant Paragen Technologies LLC ("Paragen") is a Delaware corporation having its principal place of business at 1330 Kinnear Rd., Suite 100, Columbus, OH 43212. On its website, Paragen represents that scaffolds comprised of nanofibers (such as that utilized by the Phoenix Wound Matrix and the Rotium Bioresorbable Wick) are "Our Technology." https://www.paragentechnologies.com/. Additionally, while incorporated separately, on information and belief, Paragen is controlled and directed by Nanofiber.

8. Upon information and belief, Defendant RenovoDerm LLC ("RenovoDerm") is a Delaware corporation having its principal place of business at 1330 Kinnear Rd., Suite 100, Columbus, Ohio 43212. On information and belief, although RenovoDerm is incorporated separately, it is controlled and directed by Nanofiber and Paragen.

9. Upon information and belief, Defendant Atreon Orthopedics LLC ("Atreon") is a Delaware corporation having its Principal place of business at 1330 Kinnear Rd. Suite 200, Columbus, OH 43212. On information and belief, although Atreon is incorporated separately, it is controlled and directed by Nanofiber and Paragen.

10. On information and belief, Nanofiber publicly represents and states that Paragen, RenovoDerm, and Atreon are subsidiaries of Nanofiber. On information and belief, Paragen, RenovoDerm, and Atreon publicly state that they are controlled by Nanofiber. Atreon and RenovoDerm both represent that they are subsidiaries of Paragen. RenovoDerm's website states that Nanofiber is "the technical parent company" of RenovoDerm. RenovoDerm's website's "about-us" page contains no information on RenovoDerm but instead provides information on Nanofiber and Paragen. Paragen's, RenovoDerm's, and Atreon's websites also state they are "[c]reated in partnership with" Nanofiber. The contact entity listed on RenovoDerm's and Atreon's Registration of Foreign For-Profit LLC with the Secretary of State of Ohio is Paragen. In at least some filings with the U.S. Patent and Trademark Office, Atreon provides its address as Nanofiber's principal place of business--4389 Weaver Ct. N. Hillard, OH 43026.

11. On information and belief Nanofiber, Paragen, RenovoDerm, and Atreon identify the same individuals as making up their leadership teams. All four

entities identify Ross Kayuha as their Chief Executive Officer. All four entities identify Ronald Bracken as their Chief Operating Officer. All four entities identify Dr. Jed Johnson as their Chief Technology Officer. Thus, on information and belief, the decision-making apparatus of all three companies is identical. Moreover, on information and belief, the employees responsible for the development, sale, use and commercialization of the Phoenix Wound Matrix, the Rotium Bioresorbable Wick and other nanofiber scaffold products report to the leadership team of Nanofiber and Paragen.

12. Paragen has publicly stated that it has raised funding to support the commercialization of RenovoDerm's product, the Phoenix Wound Matrix. https://www.prnewswire.com/news-releases/paragen-technologies-closes-3m-bridge-funding-round-300757376.html.

13. Publicity for the Defendants is also often cross-branded. Posters and presentations for RenovoDerm's products often include Nanofiber or Paragen branding as well. Paragen also regularly promotes the activities of both RenovoDerm and Atreon on its website and has put out press releases on behalf of RenovoDerm and Atreon. https://www.prnewswire.com/news-releases/atreon-orthopedics-received-fda-clearance-for-rotator-cuff-regeneration-product-300814430.html; https://www.paragentechnologies.com/news

14. With specific respect to Defendant's Phoenix Wound Matrix, on

information and belief, despite being advertised as RenovoDerm product the packaging includes the Nanofiber name and address rather than RenovoDerm's.

15. On information and belief, as explained above, Defendants share a unified governance, interest, and ownership in connection with the infringing acts discussed below. On information and belief, Defendants jointly control and direct the manufacture and sale of the accused products and their own properties without regard to corporate formalities, such that the entities providing the accused products/services are alter egos and/or in a principal agency relationship with each other. For example, in a press release by Atreon, Ross Kayuha is identified as the CEO of Atreon, but refers to the approval of Defendants' Rotium Bioresorbable Wick and the approval of Defendants' Phoenix Wound Matrix as being achieved by the same company stating: "To receive the second FDA clearance in a year, in two different clinical areas, tells us we are on the right track in developing our regeneration technology platform." **Exhibit 11**.

16. Accordingly, all of the accused infringing activities and products are directed and controlled by Nanofiber and/or Paragen, and operated as a joint enterprise directed and controlled by Nanofiber and/or Paragen such that the dispute set forth in this Complaint should be entirely resolved in this case by this Court.

JURISDICTION AND VENUE

17. Plaintiffs reallege and reincorporate by reference the allegations set

forth in Paragraphs 1 through 16 of this Complaint.

18. Plaintiffs assert claims for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., more particularly, 35 U.S.C § 271. This Court has subject matter jurisdiction of these claims under 28 U.S.C. §§ 1331 and 1338(a).

19. On information and belief, Defendants are engaged in the business of manufacturing, selling, offering for sale, and/or importing the Phoenix Wound Matrix, the Rotium Bioresorbable Wick and/or other nanofiber scaffold products in the United States, including within this District, and are incorporated in this District, and accordingly are subject to personal jurisdiction in this District.

20. Venue is proper in this District pursuant to 28 U.S.C. § 1400(b), because Defendants reside in this District.

THE PATENTS-IN-SUIT

21. The patents-in-suit belong to three different patent families.

22. Together, Retectix and Acera are the exclusive licensee with the right of enforcement of U.S. Patent No. 10,617,512 entitled "Biomedical Patches with Aligned Fibers" ("the '512 patent") which the United States Patent and Trademark Office lawfully and duly issued on April 14, 2020. WashU is the owner by assignment of the '512 patent. Acera and Retectix are licensees of the '512 patent. A true and correct copy of the '512 patent is attached hereto as **Exhibit 1**. The '512

patent is a member of the first family of patents.

23. Together, Retectix and Acera are the exclusive licensee with the right of enforcement of U.S. Patent No. 10,888,409 entitled "Biomedical Patches with Aligned Fibers" ("the '409 patent") which the United States Patent and Trademark Office lawfully and duly issued on January 12, 2021. WashU is the owner by assignment of the '409 patent. Acera and Retectix are licensees of the '409 patent. A true and correct copy of the '409 patent is attached hereto as **Exhibit 12**. The '409 patent is a member of the first family of patents.

24. Together, Retectix and Acera are the exclusive licensee with the right of enforcement of U.S. Patent No. 10,080,687 entitled "Biomedical Patches with Spatially Arranged Fibers" ("the '687 patent") which the United States Patent and Trademark Office lawfully and duly issued on September 25, 2018. WashU is the owner by assignment of the '687 patent. Acera and Retectix are licensees of the '687 patent. A true and correct copy of the '687 patent is attached hereto as **Exhibit 2**. The '687 patent is a member of the second family of patents.

25. Together, Retectix and Acera are the exclusive licensee with the right of enforcement of U.S. Patent No. 10,682,444 entitled "Biomedical Patches with Spatially Arranged Fibers" ("the '444 patent") which the United States Patent and Trademark Office lawfully and duly issued on June 16, 2020. WashU is the owner by assignment of the '444 patent. Acera and Retectix are licensees of the '444 patent.

A true and correct copy of the ’444 patent is attached hereto as **Exhibit 3**. The ’444 patent is a member of a second family of patents.

26. Acera is the assignee of all rights including the right of enforcement of U.S. Patent No. 10,632,228 entitled “Tissue Substitute Materials and Methods for Tissue Repair” (“the ’228 patent”) which the United States Patent and Trademark Office lawfully and duly issued on April 28, 2020. A true and correct copy of the ’228 patent is attached hereto as **Exhibit 4**. The ’228 patent is a member of a third family of patents.

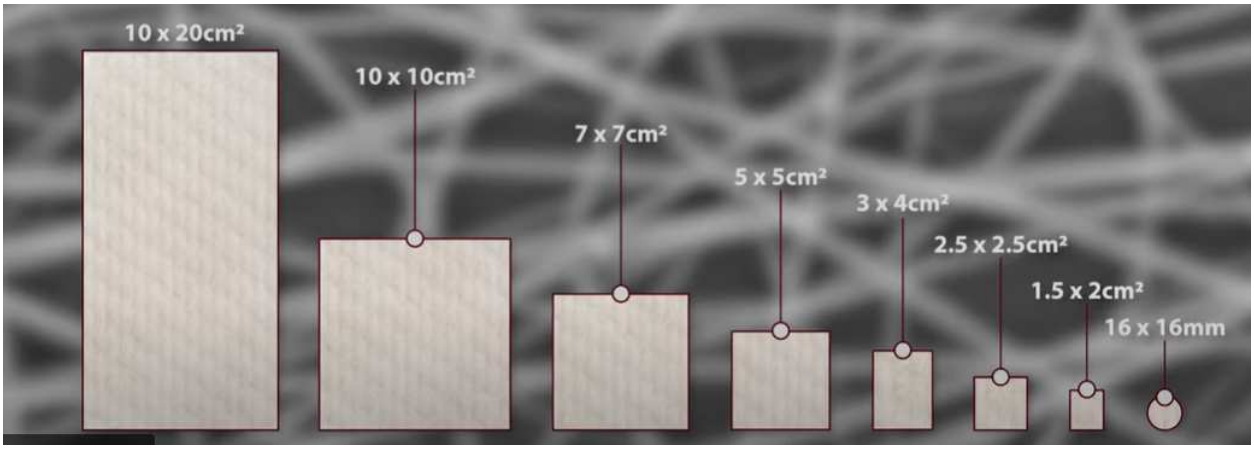
DEFENDANTS’ ACTIVITES

27. Defendants have made, used, offered to sell, and/or sold within the United States, and/or have imported into the United States, products made from electrospun, non-woven, matrices made of poly(lactide-co-caprolactone) and poly(glycolic acid), including the Phoenix Wound Matrix and Rotium Bioresorbable Wick.

28. The Phoenix Wound Matrix is marketed and sold by RenovoDerm and Nanofiber Solutions. On information and belief, Defendants manufacture the Phoenix Would Matrix in the United States. Information regarding the Phoenix Wound Matrix is available on RenovoDerm’s website. The Phoenix Wound Matrix’s instructions state it “is a sterile, single use device intended for the management of wounds. The Phoenix Wound Matrix is a conformable, non-woven,

fibrous, three-dimensional matrix. The Phoenix Wound Matrix is made from two types of polymer fibers: Poly(lactide-co-caprolactone) and Polyglycolic acid, which are bioabsorbed after degrading via hydrolysis." **Exhibit 5**. The Phoenix Wound Matrix is sold under a variety of sizes under the following reference numbers: FG-0001 (20cm x 10cm); FG-0002 (10cm x 10cm); FG-0003 (5cm x 5cm); FG-0004 (2.5cm x 2.5cm); FG-0005 (7cm x 7cm); FG-0006 (4cm x 3cm); FG-0013 (2cm x 1.5cm); FG-0014 (1.6 cm diameter disc). *Id*. The instructions indicate that the Phoenix Wound Matrix will completely degrade via hydrolysis within 14-21 days. *Id*.

29. The RenovoDerm website links to a video containing the below image of the different available sizes of the Phoenix Wound Matrix.



30. On information and belief, the Rotium Bioresorbable Wick is made of substantially the same material as the Phoenix Wound Matrix. Both 510K submissions for the product states that the "wick is an electrospun, non-woven,

microporous, microfiber matrix. The wick is made from two types of polymer fibers: Poly(lactide-co-caprolactone) (PLCL) and Polyglycolic acid (PGA)." See Nanofiber's March 2019 510(k) filing for the Rotium Bioresorbable Wick attached as **Exhibits 8** and Nanofiber's June 2020 510(k) filing for the Rotium Bioresorbable Wisk attached as **Exhibit 9**. The Rotium Bioresorbable Wick is also bioresorbable. The Rotium Bioresorbable Wick is advertised on Atreon's website. https://www.atreonortho.com/Products/. On information and belief, Defendants manufacture and sell the Rotium Bioresorbable Wick in the United States.

CLAIMS FOR PATENT INFRINGEMENT

FIRST CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 10,617,512)

31. Plaintiffs reallege and reincorporate the allegations set forth in Paragraphs 1 through 30.

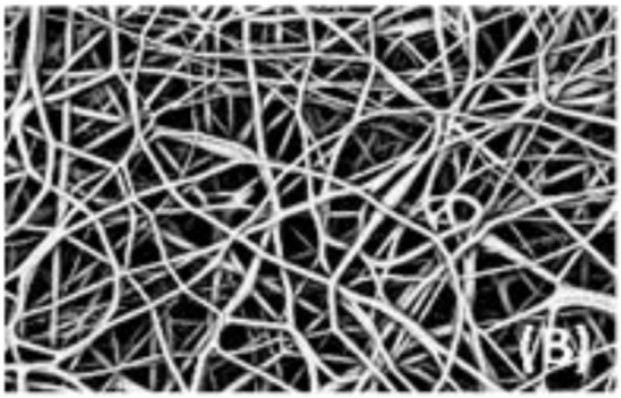
32. Upon information and belief, the Phoenix Wound Matrix and the Rotium Bioresorbable Wick, infringe at least Claim 1 of '512 patent under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents.

33. Upon information and belief, Defendants have directly infringed one or more of the claims of the '512 patent through manufacture, use, offering for sale, and/or selling within the United States, and/or importation into the United States, of electrospun, non-woven, wound matrices including the Phoenix Wound Matrix and

the Rotium Bioresorbable Wick in violation of 35 U.S.C. § 271(a).

34. For example, based upon a thorough analysis of Defendants' filings with the FDA (see IFU for the Phoenix Wound Matrix attached as **Exhibit 5**, Defendants' 510(k) disclosure attached as **Exhibit 6**) in addition to RenovoDerm's and Nanofiber's marketing materials (see RenovoDerm's website advertising the product: https://www.renovoderm.tech/Phoenix-Wound-Matrix/Learn-More/ and a poster discussing the Phoenix Wound Matrix attached as **Exhibit 7**) Defendants' Phoenix Wound Matrix includes all of the limitations of Claim 1 of the '512 patent.

35. Specifically, the Phoenix Wound Matrix includes a multi-laminar electrospun nanofiber scaffold for use in repairing a defect in a tissue substrate. The nanofiber scaffold of the Phoenix Wound Matrix is illustrated by the following Scanning Electron Microscope ("SEM") image from Defendants' own publications.



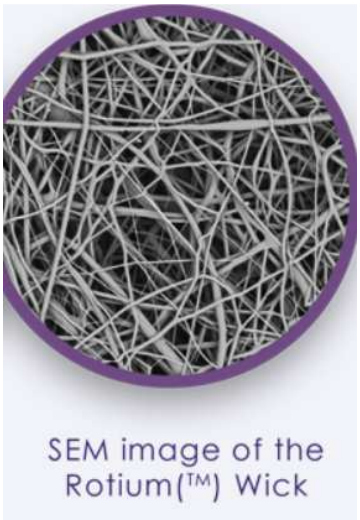
PHOENIX Wound Matrix

36. The multi-laminar electrospun nanofiber scaffold includes multiple layers of fibers including a first layer formed by a first plurality of deposited

electrospun polymeric fibers; and a second layer formed by a second plurality of deposited electrospun polymeric fibers, wherein the second layer is combined with the first layer. On information and belief, the multi-laminar electrospun nanofiber scaffold further includes at least a first portion of a higher density than a second portion of the multi-laminar electrospun nanofiber scaffold. On information and belief, the first portion also has a higher tensile strength than the second portion. The Phoenix Wound Matrix is also advertised as being configured to degrade via hydrolysis after 14-21 days, which is at least one of a predetermined time or an environmental condition. The Phoenix Would Matrix is and configured to be applied to the tissue substrate containing the defect. Finally, the multi-laminar electrospun nanofiber scaffold making of the Phoenix Wound Matrix includes varying density to be sufficiently flexible to facilitate application of the multi-laminar electrospun nanofiber scaffold to uneven surfaces of the tissue substrate and to enable movement of the multi-laminar electrospun nanofiber scaffold by the tissue substrate. These acts by Defendants constitute infringement of the ’512 patent in violation of 35 U.S.C. § 271(a).

37. On information and belief, and based on a detailed review of publicly available information on Atreon’s website and the 510K filing for the product (see Nanofiber’s March 2019 510(k) filing for the Rotium Bioresorbable Wick attached as **Exhibits 8**, Nanofiber’s June 2020 510(k) filing for the Rotium Bioresorbable

Wick attached as **Exhibit 9**, and a brochure discussing results of animal studies for the Rotium Bioresorbable Wick attached as **Exhibit 10**), for relevant features to the '512 patent, the Rotium Bioresorbable Wick, has substantially the same structure as the Phoenix Wound Matrix. The nanofiber scaffold of the Rotium Bioresorbable Wick is illustrated by the following Scanning Electron Microscope ("SEM") image from Atreon's website:



Promotional material regarding the Rotium Bioresorbable Wick from Atreon's website (https://www.atreonortho.com/Media/Atreon-Rotium-Animal-Studies-Brochure.pdf) also shows SEM images of the product.

38. The multi-laminar electrospun nanofiber scaffold includes multiple layers of fibers including a first layer formed by a first plurality of deposited electrospun polymeric fibers; and a second layer formed by a second plurality of deposited electrospun polymeric fibers, wherein the second layer is combined with the first layer. On information and belief, the multi-laminar electrospun nanofiber

scaffold further includes at least a first portion of a higher density than a second portion of the multi-laminar electrospun nanofiber scaffold. On information and belief, the first portion also has a higher tensile strength than the second portion. The Rotium Bioresorbable Wick is designed to be fully absorbed by 3-4 months, which is at least one of a predetermined time or an environmental condition. The Rotium Bioresorbable Wick is configured to be applied to the tissue substrate containing the defect. Finally, the multi-laminar electrospun nanofiber scaffold making of the Rotium Bioresorbable Wick includes varying density to be sufficiently flexible to facilitate application of the multi-laminar electrospun nanofiber scaffold to uneven surfaces of the tissue substrate and to enable movement of the multi-laminar electrospun nanofiber scaffold by the tissue substrate. These acts by Defendants constitute infringement of the ’512 patent in violation of 35 U.S.C. § 271(a).

COUNT TWO

(Infringement of U.S. Patent No. 10,080,687)

39. Plaintiffs reallege and reincorporate the allegations set forth in Paragraphs 1 through 38.

40. Upon information and belief, Defendants’ products, including the Phoenix Wound Matrix and Rotium Bioresorbable Wick, infringe at least Claim 1 of ’687 patent under 35 U.S.C. § 271(a) either literally or under the doctrine of

equivalents.

41. Upon information and belief, Defendants have directly infringed one or more of the claims of the ’687 patent through manufacture, use, offering for sale, and/or selling within the United States, and/or importation into the United States, of nanofiber scaffolds including the Phoenix Wound Matrix and Rotium Bioresorbable Wick in violation of 35 U.S.C. § 271(a).

42. For example, based upon a thorough analysis of Defendants’ filings with the FDA (see IFU for the Phoenix Wound Matrix attached as **Exhibit 5**, Defendants’ 510(k) disclosure attached as **Exhibit 6**) in addition to RenovoDerm’s and Nanofiber’s marketing materials (see RenovoDerm’s website advertising the product: https://www.renovoderm.tech/Phoenix-Wound-Matrix/Learn-More/ and a poster discussing the Phoenix Wound Matrix attached as **Exhibit 7**) Defendants’ Phoenix Wound Matrix includes all of the limitations of Claim 1 of the ’687 patent.

43. Specifically, Defendants’ Phoenix Wound Matrix includes a structure for repairing a defect in a substrate. On information and belief, the structure includes a first layer formed by a plurality of polymeric fibers and a second layer formed by a second plurality of polymeric fibers. On information and belief, the second layer is coupled to the first layer using a first coupling process. On information and belief, the second layer of the structure has a plurality of densities formed by the second plurality of polymeric fibers. The first and second layers of the structure are

configured to degrade via hydrolysis after 14-21 days, which means they are configured to separate after a predetermined time and/or environmental condition arises. Finally, the structure is configured to be applied to the substrate containing the defect. These acts by Defendants constitute infringement of the '687 patent in violation of 35 U.S.C. § 271(a).

44. On information and belief, and based on a detailed review of publicly available information on Atreon's website and the 510K filing for the product (see Nanofiber's March 2019 510(k) filing for the Rotium Bioresorbable Wick attached as **Exhibits 8**, Nanofiber's June 2020 510(k) filing for the Rotium Bioresorbable Wick attached as **Exhibit 9**, and a brochure discussing results of animal studies for the Rotium Bioresorbable Wick attached as **Exhibit 10**), for relevant features to the '687 patent, the Rotium Bioresorbable Wick, has substantially the same structure as the Phoenix Wound Matrix. The Rotium Bioresorbable Wick includes a structure for repairing a defect in a substrate. On information and belief, the structure includes a first layer formed by a plurality of polymeric fibers and a second layer formed by a second plurality of polymeric fibers. On information and belief, the second layer is coupled to the first layer using a first coupling process. On information and belief, the second layer of the structure has a plurality of densities formed by the second plurality of polymeric fibers. The first and second layers of the structure are configured to absorb after 3-4 months, which means they are configured to separate

after a predetermined time and/or environmental condition arises. Finally, the structure is configured to be applied to the substrate containing the defect. These acts by Defendants constitute infringement of the '687 patent in violation of 35 U.S.C. § 271(a).

COUNT THREE

(Infringement of U.S. Patent No. 10,682,444)

45. Plaintiffs reallege and reincorporate the allegations set forth in Paragraphs 1 through 44.

46. Upon information and belief, Defendants' products, including the Phoenix Wound Matrix, infringe at least Claim 1 of the '444 patent under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents.

47. Upon information and belief, Defendants have directly infringed one or more of the claims of the '444 patent through manufacture, use, offering for sale, and/or selling within the United States, and/or importation into the United States, of nanofiber scaffolds including the Phoenix Wound Matrix in violation of 35 U.S.C. § 271(a).

48. For example, based upon a thorough analysis of Defendants' filings with the FDA (see IFU for the Phoenix Wound Matrix attached as **Exhibit 5**, Defendants' 510(k) disclosure attached as **Exhibit 6**) in addition to RenovoDerm's and Nanofiber's marketing materials (see RenovoDerm's website advertising the

product: https://www.renovoderm.tech/Phoenix-Wound-Matrix/Learn-More/ and a poster discussing the Phoenix Wound Matrix attached as **Exhibit 7**) Defendants' Phoenix Wound Matrix includes all of the limitations of Claim 1 of the '444 patent.

49. Specifically, Defendants' Phoenix Wound Matrix includes a three-dimensional electrospun nanofiber scaffold that is used in repairing a defect in tissue substrate. The scaffold includes a first plurality of electrospun polymeric nanofibers having a diameter of 1-3000 nanometers and second plurality of deposited electrospun polymeric nanofibers. The second plurality of deposited electrospun polymeric nanofibers being coupled to the first plurality of electrospun polymeric nanofibers. The second plurality of electrospun polymeric nanofibers forms one or more regions within the three-dimensional electrospun nanofiber scaffold. On information and belief, one or more of the regions comprise a density different from one or more other regions of the three-dimensional electrospun polymeric nanofiber scaffold. On information and belief, the one or more regions are overlaid on a first portion of the first plurality of electrospun polymeric nanofibers and are not overlaid on a second portion of the first plurality of electrospun polymeric nanofibers. The three-dimensional electrospun nanofiber scaffold of Defendants' Phoenix Wound Matrix is further configured to be applied to the tissue substrate that contains the defect and comprises a controlled separation rate of less than 30 days. Within 30 days after application to the tissue substrate containing the defect the first plurality

of electrospun polymeric nanofibers and the second plurality of deposited electrospun nanofibers are adapted to separate via hydrolysis. These acts by Defendants constitute infringement of the '444 patent in violation of 35 U.S.C. § 271(a).

COUNT FOUR

(INFRINGEMENT OF U.S. PATENT NO. 10,632,228)

50. Plaintiffs reallege and reincorporate the allegations set forth in Paragraphs 1 through 49.

51. To the extent Defendants' products, including the Phoenix Wound Matrix and the Rotium Bioresorbable Wick are found not to include more than a single layer, upon information and belief, Defendants' products, including the Phoenix Wound Matrix and the Rotium Bioresorbable Wick, infringe at least Claim 1 of '228 patent under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents.

52. Upon information and belief, Defendants have directly infringed one or more of the claims of the '228 patent through manufacture, use, offering for sale, and/or selling within the United States, and/or importation into the United States, of nanofiber scaffolds including the Phoenix Wound Matrix and the Rotium Bioresorbable Wick in violation of 35 U.S.C. § 271(a).

53. For example, based upon a thorough analysis of Defendants' filings

with the FDA (see IFU for the Phoenix Wound Matrix attached as **Exhibit 5**, Defendants' 510(k) disclosure attached as **Exhibit 6**) in addition to RenovoDerm's and Nanofiber's marketing materials (see RenovoDerm's website advertising the product: https://www.renovoderm.tech/Phoenix-Wound-Matrix/Learn-More/ and a poster discussing the Phoenix Wound Matrix attached as **Exhibit 7**) Defendants' Phoenix Wound Matrix includes all of the limitations of Claim 1 of the '228 patent if the product does not have multiple layers.

54. Specifically, Defendants' Phoenix Wound Matrix includes a resorbable non-woven graft material consisting of a single layer. The single layer of the non-woven graft material includes a first electrospun non-woven fiber composition made from poly(glycolic acid). The single layer of the non-woven graft material also includes a second electrospun non-woven fiber composition made from poly(lactide-co-caprolactone). The first and second electrospun non-woven fiber compositions comprise different polymers, and are comingled throughout the thickness of the non-woven graft material. These acts by Defendants constitute infringement of the '228 patent in violation of 35 U.S.C. § 271(a).

55. On information and belief, and based on a detailed review of publicly available information on Atreon's website and the 510K filing for the product (see Nanofiber's March 2019 510(k) filing for the Rotium Bioresorbable Wick attached as **Exhibits 8**, Nanofiber's June 2020 510(k) filing for the Rotium Bioresorbable

Wick attached as **Exhibit 9**, and a brochure discussing results of animal studies for the Rotium Bioresorbable Wick attached as **Exhibit 10**), for relevant features to the '228 patent, the Rotium Bioresorbable Wick, has substantially the same structure as the Phoenix Wound Matrix. The Rotium Bioresorbable Wick includes a resorbable non-woven graft material consisting of a single layer. The single layer of the non-woven graft material includes a first electrospun non-woven fiber composition made from poly(glycolic acid). The single layer of the non-woven graft material also includes a second electrospun non-woven fiber composition made from poly(lactide-co-caprolactone). The first and second electrospun non-woven fiber compositions comprise different polymers, and are comingled throughout the thickness of the non-woven graft material. These acts by Defendants constitute infringement of the '228 patent in violation of 35 U.S.C. § 271(a).

COUNT FIVE

(INFRINGEMENT OF U.S. PATENT NO. 10,888,409)

56. Plaintiffs reallege and reincorporate the allegations set forth in Paragraphs 1 through 55.

57. Upon information and belief, Defendants' products, including the Phoenix Wound Matrix, infringe at least Claim 44 of the '409 patent under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents.

58. Upon information and belief, Defendants have directly infringed one or

more of the claims of the ’409 patent through manufacture, use, offering for sale, and/or selling within the United States, and/or importation into the United States, of nanofiber scaffolds including the Phoenix Wound Matrix in violation of 35 U.S.C. § 271(a).

59. For example, based upon a thorough analysis of Defendants’ filings with the FDA (see IFU for the Phoenix Wound Matrix attached as **Exhibit 5**, Defendants’ 510(k) disclosure attached as **Exhibit 6**) in addition to RenovoDerm’s and Nanofiber’s marketing materials (see RenovoDerm’s website advertising the product: https://www.renovoderm.tech/Phoenix-Wound-Matrix/Learn-More/, a poster discussing the Phoenix Wound Matrix attached as **Exhibit 7**, and a brochure discussing the Phoenix Wound Matrix attached as **Exhibit 13**) Defendants’ Phoenix Wound Matrix includes all of the limitations of Claim 1 of the ’409 patent.

60. Specifically, Defendants’ Phoenix Wound Matrix includes a three-dimensional electrospun skin substitute for use in repairing tissue. The product contains a flexible electrospun fiber network with a first set of electrospun fibers comprising a first bioresorbable polymer (poly(glycolic acid)) and a second set of electrospun fibers comprising a second bioresorbable polymer made out of a different composition than the first(poly(lactide-co-caprolactone)). On information and belief, and as shown in Defendants’ documents, the flexible electrospun fiber network includes a surface comprising a repeating surface pattern.

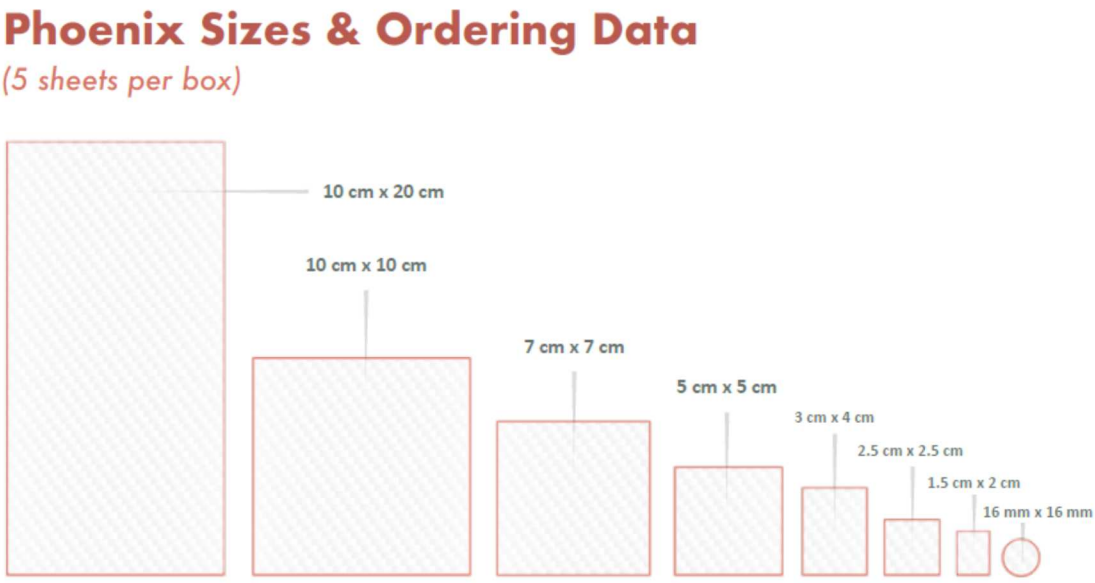


Exhibit 13, pg. 10. On information and belief, a first portion of the flexible electrospun fiber network of a particular size comprises a first spatial variation between fibers that is lower than a second spatial variation between fibers in a second portion of the flexible electrospun fiber network of the particular size and the first and second portion form a part of the surface of the flexible electrospun fiber network. As reflected in Defendants' documents, the first set and second set of electrospun fibers are configured to degrade after application to the tissue. These acts by Defendants constitute infringement of the '409 patent in violation of 35 U.S.C. § 271(a).

JURY DEMAND

61. Plaintiffs demand a jury trial on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request judgment and seek relief as follows:

A. A judgment that Defendants and its officers, agents, servants, employees, attorneys, and all others in active concert and/or participation with Defendants have directly infringed one or more claims of each of the ’512, ’444, ’687, ’409, and/or ’228 patents;

B. A ruling that this case is exceptional under 35 U.S.C. § 285, and an award of reasonable attorneys’ fees and non-taxable costs;

C. An injunction enjoining Defendants and their officers, agents, servants, employees, attorneys, and all others in active concert and/or participation with Defendants, from infringing any and all of the ’512, ’444, ’687, ’409 and/or ’228 patents through the manufacture, use, importation, offer for sale, and/or sale of infringing products, and/or any of the other acts prohibited by 35 U.S.C. § 271;

D. An award of monetary damages compensating Plaintiffs for the infringement of the ’512, ’444, ’687, ’409 and/or ’228 patents by Defendants through payment of not less than a reasonable royalty on sales of infringing products by Defendants;

E. An assessment of prejudgment and post-judgment interest and costs against Defendants, together with an award of such interest and costs, pursuant to 35 U.S.C. § 284;

F. Any and all further necessary relief as the Court may deem just and proper.

/s/ Karen E. Keller

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