IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM; and TISSUEGEN, INC., *Plaintiffs,* *v.* ETHICON, INC. and ETHICON US, LLC, *Defendants.*	CASE NO. _____ JURY TRIAL DEMANDED

ORIGINAL COMPLAINT FOR PATENT INFRINGEMENT

1. Plaintiffs BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM ("UT") and TISSUEGEN, INC. ("TissueGen") (collectively, "Plaintiffs"), by and through their undersigned counsel, files this Original Complaint against Defendants ETHICON, INC. ("Ethicon Corp.") and ETHICON US, LLC ("Ethicon US") (collectively referred to as "Ethicon" or "Defendants") as follows:

I. THE PARTIES

2. UT is an agency of the State of Texas and is the assignee and owner of patents relating to drug-releasing biodegradable fibers used in the delivery of therapeutics, including U.S. Patent Nos. 6,596,296 (the "'296 Patent") and 7,033,603 (the "'603 Patent"). UT has its principal place of business at 201 West 7th Street, Austin, Texas 78701. For the avoidance of doubt, UT neither waives its sovereign immunity nor consents to any suit or proceeding filed separate from this action, including but not limited to any declaratory judgment action or inter partes review.

3. TissueGen is the developer of ELUTE® fiber and the exclusive licensee of the

'296 Patent and '603 Patent. ELUTE® fiber is a groundbreaking biodegradable fiber format for advanced drug delivery, nerve regeneration, and tissue engineering. TissueGen was established in 2000 by Dr. Kevin Nelson, while still faculty in Biomedical Engineering at The University of Texas at Arlington, following his research with Dr. George Smith at UT Southwestern Medical Center at Dallas. TissueGen is a Delaware corporation with a principal place of business at 2110 Research Row, Suite 330, Dallas, Texas 75235.

4. Defendant ETHICON, INC. ("Ethicon Corp.") is a New Jersey corporation with a regular and established place of business at 3348 Pulliam St., San Angelo, Texas 76905 and may be served through its registered agent, CT Corporation System, Inc., at 1999 Bryan St., Ste. 900, Dallas, Texas 75201 or wherever else it may be found.

5. Defendant ETHICON US, LLC ("Ethicon US") is a Texas corporation with a principal place of business at 1125 Bear Tavern Rd., Titusville, New Jersey 08560 and may be served through its registered agent, CT Corporation System, Inc., at 1999 Bryan St., Ste. 900, Dallas, Texas 75201 or wherever else it may be found.

II. JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. UT is an arm of the State of Texas, and has sovereign immunity. *See* TEX. EDUC. CODE § 61.003; TEX. GOV'T CODE § 441.101(3); *Tegic Comm'ns, Corp. v. Board of Regents of Univ. of Tex. Sys.,* 458 F.3d 1335, 1344-45 (Fed. Cir. 2006); *Xechem Int'l, Inc. v. Univ. of Tex. M.D. Anderson Cancer Ctr.*, 382 F.3d 1324, 1327–28 (Fed. Cir. 2004); *Northern Ins. Co. of N.Y. v. Chatham Cty., Ga.*, 547 U.S. 189, 193 (2006).

8. Venue is proper in the Western District of Texas because UT has sovereign

immunity and this Court has personal jurisdiction over Defendants.

9. This Court has personal jurisdiction over Ethicon Corp. and Ethicon US. First, Ethicon US is incorporated in Texas and is, therefore, subject to this Court's jurisdiction. Second, each Defendant has conducted and does conduct business within the State of Texas and the Western District of Texas. Ethicon Corp. is registered to conduct business in Texas with the Texas Secretary of State. Defendants have purposefully and voluntarily availed themselves of the privileges of conducting business in the United States, the State of Texas, and the Western District of Texas by continuously and systematically placing goods into the stream of commerce through an established distribution channel with the expectation that they will be purchased by consumers in Texas and this District.

10. Plaintiffs' causes of action arise directly from Defendants' business contacts and other activities in the State of Texas and this District. Upon information and belief, Defendants have committed acts of infringement in this District giving rise to this action and do business in this District, including making sales and/or providing service and support for their customers in this District. Defendants purposefully and voluntarily sold one or more of their infringing products with the expectation that they would be purchased by consumers in this District. These infringing products have been and continue to be purchased by consumers in this District. Defendants have committed acts of patent infringement within the United States, the State of Texas, and the Western District of Texas.

11. Ethicon US is incorporated in Texas. Ethicon US therefore resides in the Western District of Texas. *See TC Heartland LLC v. Kraft Food Grps. Brands LLC*, 137 S. Ct. 1514, 1521 (2017).

12. Ethicon Corp. maintains a regular and established place of business in the Western District of Texas, including a location at 3348 Pulliam St., San Angelo, Texas 76905. *See TC Heartland LLC v. Kraft Food Grps. Brands LLC*, 137 S. Ct. 1514, 1521 (2017). On information and belief, Ethicon Corp. owns the location at 3343 Pulliam St., San Angelo, Texas 76905. On its website, Ethicon US stated that Ethicon maintains in San Angelo, Texas (and other locations) "word-class manufacturing centers, where [Ethicon] produce[s] the world's most innovative surgical solutions and medical devices." *See* www.ethicon.com/corporate/our-commitment/locations (last visited Nov. 2, 2017).

13. Among other things, in San Angelo, Texas, Ethicon Corp. and/or Ethicon US maintain laboratories and manufacturing equipment and facilities, employ numerous employees, and perform various services relating to the products at issue in this case (e.g., VICRYL®-branded products). *See, e.g.*, https://jobs.jnj.com/jobs/0978170728/Laboratory+Supervisor?lang=en-US (last visited Nov. 2, 2017) (listing San Angelo, Texas-based laboratory supervisor position with "Ethicon Inc." responsible for "Manag[ing] the laboratory inventory to ensure safety stock of consumables and reagents to avoid business impact," among other things); http://jobs.jnj.com/jobs/3099171029/ASW+Operator+L1+(1+of+4)?lang=en-US (last visited Nov. 2, 2017) (listing San Angelo, Texas-based ASW Operator position with "Ethicon Inc." responsible for "processing VICRYL and VICRYL PLUS and possibly other products through the auto swaging and winding department," among other things).

14. Venue is proper in the Western District of Texas pursuant to 28 U.S.C. § 1400(b).

III. TISSUEGEN'S FOUNDATION

15. In the late 1990s, TissueGen's founder Dr. Kevin D. Nelson, while still faculty in Biomedical Engineering at The University of Texas at Arlington, was inspired to investigate delivering drugs directly from an extruded fiber while working to develop biodegradable vascular stents and microspheres for delivering non-toxic drugs to the inner ear.

16. Dr. Nelson's early work was followed by collaborations with Dr. George Smith at UT Southwestern Medical Center at Dallas, a leading researcher working on peripheral nerve regeneration, as well as Dr. Nadir Alikacem at the Callier Center, Texas Woman's University.

17. Working in peripheral nerve regeneration, Dr. Nelson and Dr. Smith showed fascicle formation in regenerated nerves with the aid of fibers, convincing Dr. Nelson that the fiber-based drug delivery technology had commercial viability.

18. The peripheral nerve regeneration work was the culmination of a long line of extremely successful experiments that demonstrated the benefit of drug delivery fibers in numerous applications.

19. With Dr. Alikacem, for example, Dr. Nelson demonstrated the ability to load a small pharmaceutical agent into a fiber to help stem the blindness that results from diabetes.

20. In 2000, Dr. Nelson embarked upon the path to commercialization by founding TissueGen, Inc. Dr. Nelson's work led to several issued patents, ultimately assigned to UT and licensed exclusively to TissueGen, including the '296 Patent and the '603 Patent.

21. Following relentless development efforts spanning more than a decade,

TissueGen has brought the scientific promise of implantable drug delivery via biodegradable fibers to commercial reality.

22. In 2013, TissueGen commercially released ELUTE® fiber, a groundbreaking biodegradable fiber format for advanced drug delivery, nerve regeneration, and tissue engineering.

23. ELUTE® fiber may directly replace standard fibers used in biodegradable textiles currently on the market and provide significantly improved clinical outcomes by delivering therapeutic agents directly at the site of the implant.

24. By delivering therapeutic agents including, but not limited to, pharmaceuticals and growth factors at the topical application or implant site, ELUTE® fiber may enable medical devices to aid the body's healing and regenerative processes.

IV. COUNT I: INFRINGEMENT OF U.S. PATENT NO. 6,596,296 B1

25. Plaintiffs repeat and re-allege each and every allegation of the prior paragraphs as though set forth fully herein.

26. On July 22, 2003, U.S. Patent No. 6,596,296 B1 (the "'296 Patent")—titled "Drug Releasing Biodegradable Fiber Implant"—was duly and legally issued by the United States Patent and Trademark Office to Board of Regents, The University of Texas System, as assignee of named inventors Kevin D. Nelson, Andres A. Romero-Sanchez, George M. Smith, Nadir Alikacem, Delia Radulescu, Paula Waggoner, and Zhibing Hu. A true and correct copy of the '296 Patent is attached hereto as **Exhibit A**.

27. UT is the owner of all right, title, and interest in and to the '296 Patent and has granted TissueGen an exclusive license "to manufacture, have manufactured, use, have used, and/or Sell or have Sold" products including inventions and discoveries covered by the '296 Patent and "to otherwise exploit" UT's rights in information or discoveries covered

by the '296 Patent.

28. The '296 Patent is directed to useful and novel compositions that provide for three-dimensional matrices for in vitro and in vivo use comprised of biodegradable polymer fibers capable of the controlled delivery of therapeutic agents.

29. Each and every claim of the '296 Patent is valid and enforceable and enjoys a statutory presumption of validity separate, apart, and in addition to the statutory presumption of validity enjoyed by every other of its claims. 35 U.S.C. § 282.

30. Upon information and belief, Defendants have been, and are currently, directly and/or indirectly infringing one or more claims of the '296 Patent in violation of 35 U.S.C. § 271, including as stated below.

31. Upon information and belief, Defendants have directly infringed, literally and/or under the doctrine of equivalents, and will continue to directly infringe claims of the '296 Patent by making, using, selling, offering to sell, and/or importing into the United States products that embody or practice the apparatus and/or method covered by one or more claims of the '296 Patent, including but not limited to the following products: Defendants' Coated VICRYL® Plus Antibacterial (polyglactin 910) Suture, including the following products: VCPB269H, VCPB726D, VCPB727D, VCPB416H, VCPB774D, VCPB864D, VCPB417H, VCPB944H, VCPB259H, VCPB739D, VCPB839D, VCPB945H, VCPB260H, VCPB340H, VCPB41D, VCPB740D, VCPB840D, VCPB946H, VCPPB31D, VCPB341H, VCPB741D, VCPB841D, VCPB947H, VCPB958H, D10083, D10084, VCPB724D, VCPB978H, VCPB725D, VCPB765D, VCPB977H, D10045, VCPB650G, VCP433H, VCP434H, VCP743D, D10082, VCP213H, VCP303H, VCP214H, VCP304H, VCP714D, VCP215H, VCP305H, VCP713D, VCP306H, D9973, D10081, VCP327H,

VCP328H, VCP329H, VCP218H, VCP310H, VCP771D, VCP219H, VCP311H, VCP772D, VCP232H, VCP332H, VCP269H, VCP333H, VCP726D, VCP270H, VCP334H, VCP727D, VCP335H, D9909, D9908, D9910, D9907, VCP789D, VCP315H, VCP415H, VCP773D, VCP316H, VCP416H, VCP774D, VCP784D, VCP864D, VCP527H, VCP317H, VCP417H, VCP775D, VCP785D, VCP418H, D9911, VCP801D, VCPP81D, VCPP80D, VCP258H, VCP338H, VCP344H, VCP738D, VCP838D, VCP944H, VCP259H, VCP339H, VCP345H, VCP739D, VCP839D, VCP945H, VCPP42D, VCP260H, VCP340H, VCP346H, VCP740D, VCP840D, VCP946H, VCPP31D, VCPP41D, VCP261H, VCP341H, VCP347H, VCP741D, VCP841D, VCP947H, VCPP40D, VCP322H, VCP323H, VCP700D, VCP436H, VCP701D, VCPP71D, VCP437H, VCP702D, VCP356H, VCP956H, VCP275H, VCP351H, VCP357H, VCP751D, VCP957H, VCP280H, VCP352H, VCP358H, VCP752D, VCP958H, VCP281H, VCP353H, VCP359H, VCP753D, VCP959H, VCP980H, VCP363H, VCP369H, VCP723D, VCP979H, VCP364H, VCP370H, VCP724D, VCP764D, VCP978H, VCP365H, VCP371H, VCP765D, VCP977H, D10035, VCP649G, VCP849G, VCP880T, VCP581G, VCP583G, D10006, VCP602H, VCP603H, VCP375H, VCP376H, D9922, D10042, D10046, VCP916H, VCP917H, VCP516H, VCP517H, VCP518H, VCP519H, VCP391H, VCP421H, VCP392H, VCP422H, VCP393H, VCP423H, VCP441H, VCP451H, VCP442H, VCP452H, VCP443H, VCP787D, VCP787Z, VCP588H, VCP589H, VCP502H, VCP596H, VCP706T, VCP748T, VCP694H, VCP749T, VCP695H, VCP708T, VCP458H, VCP460H, VCP790D, VCP459H, VCP761D, VCP868H, VCP762D, VCP869H, VCP870H, VCP871H, VCP265H, VCP266H, VCP466H, VCP472H, VCP267H, VCP467H, VCP268H, VCP468H, VCP474H, VCP533H, VCP710T, VCP750T, VCP534H, VCP711T, VCP754T, VCP535H, D10054, VCP478H, VCP197H, VCP196H, VCP480H,

VCP486H, VCP195H, VCP716T, VCP698H, VCP717T, VCP756T, VCP699H, VCP718T, VCP757T, VCP719T, VCP568H, VCP569H, D9957, VCP662H, VCP663H, VCP940H, VCP931H, VCP490G, VCP463G, VCP493G, VCP493H, VCP464G, VCP494G, VCP494H, VCP500G, VCP500H, VCP495G, VCP495H, VCP426H, VCP496G, VCP496H, VCP427H, VCP497G, VCP497H, VCP428H, VCP682G, VCP682H, VCP935H, VCP683G, VCP683H, VCP936H, VCP511G, VCP593G, VCP594G, VCP506G, VCP507G, VCP503G, VCP504G, VCP656G, VCP834G, VCP835G, VCP844G, VCP845G, VCP822G, VCP823G, VCP823H, VCP824G, VCP103G, VCP109G, VCP104G, VCP110G, VCP634T, VCP644H, VCP105G, VCP111G, VCP607H, VCP615H, VCP635T, VCP645T, VCP106G, VCP112G, VCP608H, VCP616H, VCP636T, VCP646T, VCP107G, VCP617H, VCP618H, D9906, D9905, VCP284G, VCP205G, VCP285G, VCP885G, VCP286G, VCP207G, VCP287G, VCP208G and any other products offered and/or sold under the Coated VICRYL® Plus Antibacterial (polyglactin 910) Suture name (the "Coated VICRYL® Plus Antibacterial Sutures"); Defendants' products within the scope of the Federal Drug Administration ("FDA") 510(k) Number K132580 (the "K132580 Products"); Defendants' MONOCRYL® Plus Antibacterial (poliglecaprone 25) Suture, including the following products: YB416, YB944, YB257, YB258, YB946, YB947, YB978, D8815, D9759, D9641, Y432H, Y433H, Y434H, D9891, D9555, Y213H, Y303H, Y214H, Y304H, Y215H, Y305H, D9842, D9543, D9213, D9158, D8291, Y218H, Y219H, Y872D, D8901, D9568, D8927, Y333H, Y762H, Y334H, Y335H, D8893, Y315H, Y415H, Y316H, Y416H, Y317H, Y417H, Y732H, Y318H, Y527H, D8694, Y801D, D8678, Y338H, Y344H, Y738D, Y944H, Y339H, Y345H, Y739D, Y945H, Y340H, Y346H, Y740D, Y946H, YY31G, Y341H, Y347H, Y947H, YY30G, D9912, D9270, Y227H,

D8721, Y701D, YY71G, YY70G, Y350H, Y351H, Y357H, Y352H, Y358H, Y353H, Y359H, Y397H, Y398H, Y399H, D9162, D9473, D8726, D8550, D9639, D9645, D9471, Y604H, Y605H, Y606H, D9503, D7611, D8592, Y377H, Y378H, D8752, D9765, Y817H, Y917H, D8955, Y266H, Y267H, D9372, D8655, Y523H, D9600, Y931H, Y932H, Y489G, Y490G, Y492G, Y463G, Y493G, Y464G, Y494G, Y495G, Y426H, Y496G, Y513G, Y427H, Y497G, D8786, Y682H, Y935H, Y936H, D8797, D7656, Y510G, D8839, D8762, D9418, D8539, D10051, Y833G, Y834G, Y835G, Y844G, Y845G, Y822G, Y823G, Y814G, D8633, D9491, Y908G, Y909G, Y910G, Y911G, D8477 and any other products offered and/or sold under the MONOCRYL® Plus Antibacterial (poliglecaprone 25) Suture name (the "MONOCRYL® Plus Antibacterial Sutures"); and Defendants' products within the scope of FDA 510(k) Number K050845 (the "K050845 Products") (collectively, the "'296 Accused Products").

32. On information and belief, Defendants indirectly infringe the '296 Patent by inducing others to infringe one or more claims of the '296 Patent through sale and/or use of the '296 Accused Products. On information and belief, at least as a result of the filing of this action, Defendants are aware of the '296 Patent; are aware that their actions with regards to distributors, resellers, and/or end users of the '296 Accused Products would induce infringement; and despite such awareness will continue to take active steps—such as, creating and disseminating the '296 Accused Products and product manuals, instructions, promotional and marketing materials, and/or technical materials to distributors, resellers, and end users—encouraging other's infringement of the '296 Patent with the specific intent to induce such infringement.

33. Plaintiffs adopt, and incorporate by reference, as if fully stated herein, the

attached claim chart for claim 1 of the '296 Patent, which is attached hereto as **Exhibit B**. The claim chart describes and demonstrates how Defendants infringe the '296 Patent. In addition, Plaintiffs allege that Defendants infringe one or more additional claims of the '296 Patent in a similar manner.

A. COATED VICRYL® PLUS ANTIBACTERIAL SUTURES

34. At least one of the Coated VICRYL® Plus Antibacterial Sutures includes a biodegradable polymer fiber. For example, at least one of the Coated VICRYL® Plus Antibacterial Sutures is composed of biodegradable copolymers.

35. The biodegradable polymer fiber included in at least one of the Coated VICRYL® Plus Antibacterial Sutures comprises a first phase and a second phase. For example, the biodegradable polymer fiber included in at least one of the Coated VICRYL® Plus Antibacterial Sutures comprises polymer structure and structure containing pharmacological agents.

36. The first phase and the second phase comprising the biodegradable polymer fiber included in at least one of the Coated VICRYL® Plus Antibacterial Sutures are immiscible. For example, the polymer structure and the structure containing pharmacological agents comprising the biodegradable polymer fiber included in at least one of the Coated VICRYL® Plus Antibacterial Sutures are immiscible.

37. The second phase comprising the biodegradable polymer fiber included in at least one of the Coated VICRYL® Plus Antibacterial Sutures includes at least one therapeutic agent. For example, at least one therapeutic agent (e.g., an antibacterial agent) is included in the structure containing pharmacological agents comprising the biodegradable polymer fiber included in at least one of the Coated VICRYL® Plus Antibacterial Sutures.

38. The second phase comprising the biodegradable polymer fiber included in at

least one of the Coated VICRYL® Plus Antibacterial Sutures is derived from an aqueous solution, a hydrogel, or a polymer.

39. The biodegradable polymer fiber included in at least one of the Coated VICRYL® Plus Antibacterial Sutures is woven, braided, or knitted in an assembly with other fibers.

40. The biodegradable polymer fiber included in at least one of in the Coated VICRYL® Plus Antibacterial Sutures is woven, braided, or knitted in an assembly with other fibers, and at least one fiber in the assembly comprises one or more therapeutic agents.

41. The therapeutic agent included in the second phase comprising the biodegradable polymer fiber included in at least one of the Coated VICRYL® Plus Antibacterial Sutures is a drug, a protein, an enzyme, a growth factor, an immunomodulator, a compound promoting angiogenesis, a compound inhibiting angiogenesis, an anti-inflammatory compound, an antibiotic, a cytokine, an anti-coagulation agent, a procoagulation agent, a chemotactic agent, an agent to promote apoptosis, an agent to inhibit apoptosis, or a mitogenic agent. For example, an antibacterial agent is included in the structure containing pharmacological agents comprising the biodegradable polymer fiber included in at least one of the Coated VICRYL® Plus Antibacterial Sutures.

42. The biodegradable polymer fiber included in at least one of the Coated VICRYL® Plus Antibacterial Sutures comprises a plurality of polymer layers, wherein an outer layer circumscribes an adjacent inner layer. For example, the biodegradable polymer fiber included in at least one of the Coated VICRYL® Plus Antibacterial Sutures comprises a polymer coated with another polymer.

B. K132580 PRODUCTS

43. At least one of the K132580 Products includes a biodegradable polymer fiber. For example, at least one of the K132580 Products is composed of biodegradable copolymers.

44. The biodegradable polymer fiber included in at least one of the K132580 Products comprises a first phase and a second phase. For example, the biodegradable polymer fiber included in at least one of the K132580 Products comprises polymer structure and structure containing pharmacological agents.

45. The first phase and the second phase comprising the biodegradable polymer fiber included in at least one of the K132580 Products are immiscible. For example, the polymer structure and the structure containing pharmacological agents comprising the biodegradable polymer fiber included in at least one of the K132580 Products are immiscible.

46. The second phase comprising the biodegradable polymer fiber included in at least one of the K132580 Products includes at least one therapeutic agent. For example, at least one therapeutic agent (e.g., an antibacterial agent) is included in the structure containing pharmacological agents comprising the biodegradable polymer fiber included in at least one of the K132580 Products.

47. The second phase comprising the biodegradable polymer fiber included in at least one of the K132580 Products is derived from an aqueous solution, a hydrogel, or a polymer.

48. The biodegradable polymer fiber included in at least one of the K132580 Products is woven, braided, or knitted in an assembly with other fibers.

49. The biodegradable polymer fiber included in at least one of in the K132580

Products is woven, braided, or knitted in an assembly with other fibers, and at least one fiber in the assembly comprises one or more therapeutic agents.

50. The therapeutic agent included in the second phase comprising the biodegradable polymer fiber included in at least one of the K132580 Products is a drug, a protein, an enzyme, a growth factor, an immunomodulator, a compound promoting angiogenesis, a compound inhibiting angiogenesis, an anti-inflammatory compound, an antibiotic, a cytokine, an anti-coagulation agent, a procoagulation agent, a chemotactic agent, an agent to promote apoptosis, an agent to inhibit apoptosis, or a mitogenic agent. For example, an antibacterial agent is included in the structure containing pharmacological agents comprising the biodegradable polymer fiber included in at least one of the K132580 Products.

51. The biodegradable polymer fiber included in at least one of the K132580 Products comprises a plurality of polymer layers, wherein an outer layer circumscribes an adjacent inner layer. For example, the biodegradable polymer fiber included in at least one of the K132580 Products comprises a polymer coated with another polymer.

C. MONOCRYL® PLUS ANTIBACTERIAL SUTURES

52. At least one of the MONOCRYL® Plus Antibacterial Sutures includes a biodegradable polymer fiber. For example, at least one of the MONOCRYL® Plus Antibacterial Sutures is composed of biodegradable copolymers.

53. The biodegradable polymer fiber included in at least one of the MONOCRYL® Plus Antibacterial Sutures comprises a first phase and a second phase. For example, the biodegradable polymer fiber included in at least one of the MONOCRYL® Plus Antibacterial Sutures comprises polymer structure and structure containing pharmacological agents.

54. The first phase and the second phase comprising the biodegradable polymer fiber included in at least one of the MONOCRYL® Plus Antibacterial Sutures are immiscible. For example, the polymer structure and the structure containing pharmacological agents comprising the biodegradable polymer fiber included in at least one of the MONOCRYL® Plus Antibacterial Sutures are immiscible.

55. The second phase comprising the biodegradable polymer fiber included in at least one of the MONOCRYL® Plus Antibacterial Sutures includes at least one therapeutic agent. For example, at least one therapeutic agent (e.g., an antibacterial agent) is included in the structure containing pharmacological agents comprising the biodegradable polymer fiber included in at least one of the MONOCRYL® Plus Antibacterial Sutures.

56. The second phase comprising the biodegradable polymer fiber included in at least one of the MONOCRYL® Plus Antibacterial Sutures is derived from an aqueous solution, a hydrogel, or a polymer.

57. The biodegradable polymer fiber included in at least one of the MONOCRYL® Plus Antibacterial Sutures is woven, braided, or knitted in an assembly with other fibers.

58. The biodegradable polymer fiber included in at least one of the MONOCRYL® Plus Antibacterial Sutures is woven, braided, or knitted in an assembly with other fibers, and at least one fiber in the assembly comprises one or more therapeutic agents.

59. The therapeutic agent included in the second phase comprising the biodegradable polymer fiber included in at least one of the MONOCRYL® Plus Antibacterial Sutures is a drug, a protein, an enzyme, a growth factor, an

immunomodulator, a compound promoting angiogenesis, a compound inhibiting angiogenesis, an anti-inflammatory compound, an antibiotic, a cytokine, an anti-coagulation agent, a procoagulation agent, a chemotactic agent, an agent to promote apoptosis, an agent to inhibit apoptosis, or a mitogenic agent. For example, an antibacterial agent is included in the structure containing pharmacological agents comprising the biodegradable polymer fiber included in at least one of the MONOCRYL® Plus Antibacterial Sutures.

60. The biodegradable polymer fiber included in at least one of the MONOCRYL® Plus Antibacterial Sutures comprises a plurality of polymer layers, wherein an outer layer circumscribes an adjacent inner layer. For example, the biodegradable polymer fiber included in at least one of the MONOCRYL® Plus Antibacterial Sutures comprises a polymer coated with another polymer.

D. K050845 PRODUCTS

61. At least one of the K050845 Products includes a biodegradable polymer fiber. For example, at least one of the K050845 Products is composed of biodegradable copolymers.

62. The biodegradable polymer fiber included in at least one of the K050845 Products comprises a first phase and a second phase. For example, the biodegradable polymer fiber included in at least one of the K050845 Products comprises polymer structure and structure containing pharmacological agents.

63. The first phase and the second phase comprising the biodegradable polymer fiber included in at least one of the K050845 Products are immiscible. For example, the polymer structure and the structure containing pharmacological agents comprising the biodegradable polymer fiber included in at least one of the K050845 Products are

immiscible.

64. The second phase comprising the biodegradable polymer fiber included in at least one of the K050845 Products includes at least one therapeutic agent. For example, at least one therapeutic agent (e.g., an antibacterial agent) is included in the structure containing pharmacological agents comprising the biodegradable polymer fiber included in at least one of the K050845 Products.

65. The second phase comprising the biodegradable polymer fiber included in at least one of the K050845 Products is derived from an aqueous solution, a hydrogel, or a polymer.

66. The biodegradable polymer fiber included in at least one of the K050845 Products is woven, braided, or knitted in an assembly with other fibers.

67. The biodegradable polymer fiber included in at least one of the K050845 Products is woven, braided, or knitted in an assembly with other fibers, and at least one fiber in the assembly comprises one or more therapeutic agents.

68. The therapeutic agent included in the second phase comprising the biodegradable polymer fiber included in at least one of the K050845 Products is a drug, a protein, an enzyme, a growth factor, an immunomodulator, a compound promoting angiogenesis, a compound inhibiting angiogenesis, an anti-inflammatory compound, an antibiotic, a cytokine, an anti-coagulation agent, a procoagulation agent, a chemotactic agent, an agent to promote apoptosis, an agent to inhibit apoptosis, or a mitogenic agent. For example, an antibacterial agent is included in the structure containing pharmacological agents comprising the biodegradable polymer fiber included in at least one of the K050845 Products.

69. The biodegradable polymer fiber included in at least one of the K050845 Products comprises a plurality of polymer layers, wherein an outer layer circumscribes an adjacent inner layer. For example, the biodegradable polymer fiber included in at least one of the K050845 Products comprises a polymer coated with another polymer.

70. Defendants' acts of infringement have caused and will continue to cause substantial and irreparable damage to Plaintiffs.

71. As a result of Defendants' infringement of the '296 Patent, Plaintiffs have been damaged. Plaintiffs are, therefore, entitled to damages pursuant to 35 U.S.C. § 284 in an amount that presently cannot be pled but that will be determined at trial.

V. COUNT II: INFRINGEMENT OF U.S. PATENT NO. 7,033,603 B2

72. Plaintiffs repeat and re-allege each and every allegation of the prior paragraphs as though set forth fully herein.

73. On April 25, 2006, U.S. Patent No. 7,033,603 B2 (the "'603 Patent")—titled "Drug Releasing Biodegradable Fiber for Delivery of Therapeutics"— was duly and legally issued by the United States Patent and Trademark Office on April 25, 2006 to Board of Regents, The University of Texas System, as assignee of named inventors Kevin D. Nelson and Brent B. Crow. A true and correct copy of the '603 Patent is attached hereto as **Exhibit C**.

74. UT is the owner of all right, title, and interest in and to the '603 Patent and has granted TissueGen an exclusive license "to manufacture, have manufactured, use, have used, and/or Sell or have Sold" products including inventions and discoveries covered by the '603 Patent and "to otherwise exploit" UT's rights in information or discoveries covered by the '603 Patent.

75. The '603 Patent is directed to useful and novel compositions that provide for

three-dimensional matrices for in vitro and in vivo use comprised of biodegradable polymer fibers capable of the controlled delivery of therapeutic agents.

76. Each and every claim of the '603 Patent is valid and enforceable and enjoys a statutory presumption of validity separate, apart, and in addition to the statutory presumption of validity enjoyed by every other of its claims. 35 U.S.C. § 282.

77. Upon information and belief, Defendants have been, and are currently, directly and/or indirectly infringing one or more claims of the '603 Patent in violation of 35 U.S.C. § 271, including as stated below.

78. Upon information and belief, Defendants have directly infringed, literally and/or under the doctrine of equivalents, and will continue to directly infringe claims of the '603 Patent by making, using, selling, offering to sell, and/or importing into the United States products that embody or practice the apparatus and/or method covered by one or more claims of the '603 Patent, including but not limited to the following products: Defendants' Coated VICRYL® Plus Antibacterial (polyglactin 910) Suture, including the following products: VCPB269H, VCPB726D, VCPB727D, VCPB416H, VCPB774D, VCPB864D, VCPB417H, VCPB944H, VCPB259H, VCPB739D, VCPB839D, VCPB945H, VCPB260H, VCPB340H, VCPB41D, VCPB740D, VCPB840D, VCPB946H, VCPPB31D, VCPB341H, VCPB741D, VCPB841D, VCPB947H, VCPB958H, D10083, D10084, VCPB724D, VCPB978H, VCPB725D, VCPB765D, VCPB977H, D10045, VCPB650G, VCP433H, VCP434H, VCP743D, D10082, VCP213H, VCP303H, VCP214H, VCP304H, VCP714D, VCP215H, VCP305H, VCP713D, VCP306H, D9973, D10081, VCP327H, VCP328H, VCP329H, VCP218H, VCP310H, VCP771D, VCP219H, VCP311H, VCP772D, VCP232H, VCP332H, VCP269H, VCP333H, VCP726D, VCP270H, VCP334H, VCP727D,

VCP335H, D9909, D9908, D9910, D9907, VCP789D, VCP315H, VCP415H, VCP773D, VCP316H, VCP416H, VCP774D, VCP784D, VCP864D, VCP527H, VCP317H, VCP417H, VCP775D, VCP785D, VCP418H, D9911, VCP801D, VCPP81D, VCPP80D, VCP258H, VCP338H, VCP344H, VCP738D, VCP838D, VCP944H, VCP259H, VCP339H, VCP345H, VCP739D, VCP839D, VCP945H, VCPP42D, VCP260H, VCP340H, VCP346H, VCP740D, VCP840D, VCP946H, VCPP31D, VCPP41D, VCP261H, VCP341H, VCP347H, VCP741D, VCP841D, VCP947H, VCPP40D, VCP322H, VCP323H, VCP700D, VCP436H, VCP701D, VCPP71D, VCP437H, VCP702D, VCP356H, VCP956H, VCP275H, VCP351H, VCP357H, VCP751D, VCP957H, VCP280H, VCP352H, VCP358H, VCP752D, VCP958H, VCP281H, VCP353H, VCP359H, VCP753D, VCP959H, VCP980H, VCP363H, VCP369H, VCP723D, VCP979H, VCP364H, VCP370H, VCP724D, VCP764D, VCP978H, VCP365H, VCP371H, VCP765D, VCP977H, D10035, VCP649G, VCP849G, VCP880T, VCP581G, VCP583G, D10006, VCP602H, VCP603H, VCP375H, VCP376H, D9922, D10042, D10046, VCP916H, VCP917H, VCP516H, VCP517H, VCP518H, VCP519H, VCP391H, VCP421H, VCP392H, VCP422H, VCP393H, VCP423H, VCP441H, VCP451H, VCP442H, VCP452H, VCP443H, VCP787D, VCP787Z, VCP588H, VCP589H, VCP502H, VCP596H, VCP706T, VCP748T, VCP694H, VCP749T, VCP695H, VCP708T, VCP458H, VCP460H, VCP790D, VCP459H, VCP761D, VCP868H, VCP762D, VCP869H, VCP870H, VCP871H, VCP265H, VCP266H, VCP466H, VCP472H, VCP267H, VCP467H, VCP268H, VCP468H, VCP474H, VCP533H, VCP710T, VCP750T, VCP534H, VCP711T, VCP754T, VCP535H, D10054, VCP478H, VCP197H, VCP196H, VCP480H, VCP486H, VCP195H, VCP716T, VCP698H, VCP717T, VCP756T, VCP699H, VCP718T, VCP757T, VCP719T, VCP568H, VCP569H, D9957, VCP662H, VCP663H, VCP940H,

VCP931H, VCP490G, VCP463G, VCP493G, VCP493H, VCP464G, VCP494G, VCP494H, VCP500G, VCP500H, VCP495G, VCP495H, VCP426H, VCP496G, VCP496H, VCP427H, VCP497G, VCP497H, VCP428H, VCP682G, VCP682H, VCP935H, VCP683G, VCP683H, VCP936H, VCP511G, VCP593G, VCP594G, VCP506G, VCP507G, VCP503G, VCP504G, VCP656G, VCP834G, VCP835G, VCP844G, VCP845G, VCP822G, VCP823G, VCP823H, VCP824G, VCP103G, VCP109G, VCP104G, VCP110G, VCP634T, VCP644H, VCP105G, VCP111G, VCP607H, VCP615H, VCP635T, VCP645T, VCP106G, VCP112G, VCP608H, VCP616H, VCP636T, VCP646T, VCP107G, VCP617H, VCP618H, D9906, D9905, VCP284G, VCP205G, VCP285G, VCP885G, VCP286G, VCP207G, VCP287G, VCP208G and any other products offered and/or sold under the Coated VICRYL® Plus Antibacterial (polyglactin 910) Suture name (the "Coated VICRYL® Plus Antibacterial Sutures"); Defendants' products within the scope of the Federal Drug Administration ("FDA") 510(k) Number K132580 (the "K132580 Products"); Defendants' MONOCRYL® Plus Antibacterial (poliglecaprone 25) Suture, including the following products: YB416, YB944, YB257, YB258, YB946, YB947, YB978, D8815, D9759, D9641, Y432H, Y433H, Y434H, D9891, D9555, Y213H, Y303H, Y214H, Y304H, Y215H, Y305H, D9842, D9543, D9213, D9158, D8291, Y218H, Y219H, Y872D, D8901, D9568, D8927, Y333H, Y762H, Y334H, Y335H, D8893, Y315H, Y415H, Y316H, Y416H, Y317H, Y417H, Y732H, Y318H, Y527H, D8694, Y801D, D8678, Y338H, Y344H, Y738D, Y944H, Y339H, Y345H, Y739D, Y945H, Y340H, Y346H, Y740D, Y946H, YY31G, Y341H, Y347H, Y947H, YY30G, D9912, D9270, Y227H, D8721, Y701D, YY71G, YY70G, Y350H, Y351H, Y357H, Y352H, Y358H, Y353H, Y359H, Y397H, Y398H, Y399H, D9162, D9473, D8726, D8550, D9639, D9645, D9471,

Y604H, Y605H, Y606H, D9503, D7611, D8592, Y377H, Y378H, D8752, D9765, Y817H, Y917H, D8955, Y266H, Y267H, D9372, D8655, Y523H, D9600, Y931H, Y932H, Y489G, Y490G, Y492G, Y463G, Y493G, Y464G, Y494G, Y495G, Y426H, Y496G, Y513G, Y427H, Y497G, D8786, Y682H, Y935H, Y936H, D8797, D7656, Y510G, D8839, D8762, D9418, D8539, D10051, Y833G, Y834G, Y835G, Y844G, Y845G, Y822G, Y823G, Y814G, D8633, D9491, Y908G, Y909G, Y910G, Y911G, D8477 and any other products offered and/or sold under the MONOCRYL® Plus Antibacterial (poliglecaprone 25) Suture name (the "MONOCRYL® Plus Antibacterial Sutures"); and Defendants' products within the scope of FDA 510(k) Number K050845 (the "K050845 Products") (collectively, the "'603 Accused Products").

79. On information and belief, Defendants indirectly infringe the '603 Patent by inducing others to infringe one or more claims of the '603 Patent through sale and/or use of the '603 Accused Products. On information and belief, at least as a result of the filing of this action, Defendants are aware of the '603 Patent; are aware that their actions with regards to distributors, resellers, and/or end users of the '603 Accused Products would induce infringement; and despite such awareness will continue to take active steps—such as, creating and disseminating the '603 Accused Products and product manuals, instructions, promotional and marketing materials, and/or technical materials to distributors, resellers, and end users—encouraging others' infringement of the '603 Patent with the specific intent to induce such infringement.

80. Plaintiffs adopt, and incorporate by reference, as if fully stated herein, the attached claim chart for claim 1 of the '603 Patent, which is attached hereto as **Exhibit D**. The claim chart describes and demonstrates how Defendants infringe the '603 Patent. In

addition, Plaintiffs allege that Defendants infringe one or more additional claims of the '603 Patent in a similar manner.

A. COATED VICRYL® PLUS ANTIBACTERIAL SUTURES

81. At least one of the Coated VICRYL® Plus Antibacterial Sutures includes a drug delivery composition.

82. The drug delivery composition included in at least one of the Coated VICRYL® Plus Antibacterial Sutures includes at least one fiber.

83. The fiber comprising the drug delivery composition included in at least one of the Coated VICRYL® Plus Antibacterial Sutures includes a bore and a wall.

84. The fiber comprising the drug delivery composition included in at least one of the Coated VICRYL® Plus Antibacterial Sutures includes a first component and a second component.

85. The first component comprising the fiber comprising the drug delivery composition included in at least one of the Coated VICRYL® Plus Antibacterial Sutures is a biodegradable fiber.

86. The first component comprising the fiber comprising the drug delivery composition included in at least one of the Coated VICRYL® Plus Antibacterial Sutures is present in the bore included in said fiber.

87. The second component comprising the fiber comprising the drug delivery composition included in at least one of the Coated VICRYL® Plus Antibacterial Sutures is a hydrogel or a colloidal system with at least two phases, one of which phases forms a continuous three-dimensional network that acts as an elastic solid.

88. The second component comprising the fiber comprising the drug delivery composition included in at least one of the Coated VICRYL® Plus Antibacterial Sutures is

present in the wall included in said fiber.

89. The second component comprising the fiber comprising the drug delivery composition included in at least one of the Coated VICRYL® Plus Antibacterial Sutures includes a therapeutic agent.

90. The therapeutic agent included in the second component comprising the fiber comprising the drug delivery composition included in at least one of the Coated VICRYL® Plus Antibacterial Sutures is a protein, an enzyme, a transcription factor, a signaling molecule, an internal messenger, a second messenger, a kinase, a protease, a cytokine, a chemokine, a structural protein, an interleukin, a hormone, an anti-coagulant, a pro-coagulant, an anti-inflammatory agent, an antibiotic, an agent that promotes angiogenesis, an agent that inhibits angiogenesis, a growth factor, an immunomodulator, a chemotactic agent, an agent that promotes apoptosis, an agent that inhibits apoptosis, or a mitogenic agent.

B. K132580 PRODUCTS

91. At least one of the K132580 Products includes a drug delivery composition.

92. The drug delivery composition included in at least one of the K132580 Products includes at least one fiber.

93. The fiber comprising the drug delivery composition included in at least one of the K132580 Products includes a bore and a wall.

94. The fiber comprising the drug delivery composition included in at least one of the K132580 Products includes a first component and a second component.

95. The first component comprising the fiber comprising the drug delivery composition included in at least one of the K132580 Products is a biodegradable fiber.

96. The first component comprising the fiber comprising the drug delivery

composition included in at least one of the K132580 Products is present in the bore included in said fiber.

97. The second component comprising the fiber comprising the drug delivery composition included in at least one of the K132580 Products is a hydrogel or a colloidal system with at least two phases, one of which phases forms a continuous three-dimensional network that acts as an elastic solid.

98. The second component comprising the fiber comprising the drug delivery composition included in at least one of the K132580 Products is present in the wall included in said fiber.

99. The second component comprising the fiber comprising the drug delivery composition included in at least one of the K132580 Products includes a therapeutic agent.

100. The therapeutic agent included in the second component comprising the fiber comprising the drug delivery composition included in at least one of the K132580 Products is a protein, an enzyme, a transcription factor, a signaling molecule, an internal messenger, a second messenger, a kinase, a protease, a cytokine, a chemokine, a structural protein, an interleukin, a hormone, an anti-coagulant, a pro-coagulant, an anti-inflammatory agent, an antibiotic, an agent that promotes angiogenesis, an agent that inhibits angiogenesis, a growth factor, an immunomodulator, a chemotactic agent, an agent that promotes apoptosis, an agent that inhibits apoptosis, or a mitogenic agent.

C. MONOCRYL® PLUS ANTIBACTERIAL SUTURES

101. At least one of the MONOCRYL® Plus Antibacterial Sutures includes a drug delivery composition.

102. The drug delivery composition included in at least one of the MONOCRYL® Plus Antibacterial Sutures includes at least one fiber.

103. The fiber comprising the drug delivery composition included in at least one of the MONOCRYL® Plus Antibacterial Sutures includes a bore and a wall.

104. The fiber comprising the drug delivery composition included in at least one of the MONOCRYL® Plus Antibacterial Sutures includes a first component and a second component.

105. The first component comprising the fiber comprising the drug delivery composition included in at least one of the MONOCRYL® Plus Antibacterial Sutures is a biodegradable fiber.

106. The first component comprising the fiber comprising the drug delivery composition included in at least one of the MONOCRYL® Plus Antibacterial Sutures is present in the bore included in said fiber.

107. The second component comprising the fiber comprising the drug delivery composition included in at least one of the MONOCRYL® Plus Antibacterial Sutures is a hydrogel or a colloidal system with at least two phases, one of which phases forms a continuous three-dimensional network that acts as an elastic solid.

108. The second component comprising the fiber comprising the drug delivery composition included in at least one of the MONOCRYL® Plus Antibacterial Sutures is present in the wall included in said fiber.

109. The second component comprising the fiber comprising the drug delivery composition included in at least one of the MONOCRYL® Plus Antibacterial Sutures includes a therapeutic agent.

110. The therapeutic agent included in the second component comprising the fiber comprising the drug delivery composition included in at least one of the MONOCRYL®

Plus Antibacterial Sutures is a protein, an enzyme, a transcription factor, a signaling molecule, an internal messenger, a second messenger, a kinase, a protease, a cytokine, a chemokine, a structural protein, an interleukin, a hormone, an anti-coagulant, a pro-coagulant, an anti-inflammatory agent, an antibiotic, an agent that promotes angiogenesis, an agent that inhibits angiogenesis, a growth factor, an immunomodulator, a chemotactic agent, an agent that promotes apoptosis, an agent that inhibits apoptosis, or a mitogenic agent.

D. K050845 PRODUCTS

111. At least one of the K050845 Products includes a drug delivery composition.

112. The drug delivery composition included in at least one of the K050845 Products includes at least one fiber.

113. The fiber comprising the drug delivery composition included in at least one of the K050845 Products includes a bore and a wall.

114. The fiber comprising the drug delivery composition included in at least one of the K050845 Products includes a first component and a second component.

115. The first component comprising the fiber comprising the drug delivery composition included in at least one of the K050845 Products is a biodegradable fiber.

116. The first component comprising the fiber comprising the drug delivery composition included in at least one of the K050845 Products is present in the bore included in said fiber.

117. The second component comprising the fiber comprising the drug delivery composition included in at least one of the K050845 Products is a hydrogel or a colloidal system with at least two phases, one of which phases forms a continuous three-dimensional network that acts as an elastic solid.

118. The second component comprising the fiber comprising the drug delivery composition included in at least one of the K050845 Products is present in the wall included in said fiber.

119. The second component comprising the fiber comprising the drug delivery composition included in at least one of the K050845 Products includes a therapeutic agent.

120. The therapeutic agent included in the second component comprising the fiber comprising the drug delivery composition included in at least one of the K050845 Products is a protein, an enzyme, a transcription factor, a signaling molecule, an internal messenger, a second messenger, a kinase, a protease, a cytokine, a chemokine, a structural protein, an interleukin, a hormone, an anti-coagulant, a pro-coagulant, an anti-inflammatory agent, an antibiotic, an agent that promotes angiogenesis, an agent that inhibits angiogenesis, a growth factor, an immunomodulator, a chemotactic agent, an agent that promotes apoptosis, an agent that inhibits apoptosis, or a mitogenic agent.

121. Defendants' acts of infringement have caused and will continue to cause substantial and irreparable damage to Plaintiffs.

122. As a result of Defendants' infringement of the '603 Patent, Plaintiffs have been damaged. Plaintiffs are, therefore, entitled to damages pursuant to 35 U.S.C. § 284 in an amount that presently cannot be pled but that will be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiffs pray for entry of judgment against Defendants as follows:

A. A judgment that Defendants have infringed and continue to infringe the '296 Patent and the '603 Patent, directly and/or indirectly, as alleged herein;

B. That Defendants provide to Plaintiffs an accounting of all gains, profits, and advantages derived by Defendants' infringement of the '296 Patent and the '603 Patent, and that Plaintiffs be awarded damages adequate to compensate them for the wrongful infringement by Defendants, in accordance with 35 U.S.C. § 284;

C. That Plaintiffs be awarded any other supplemental damages and interest on all damages, including, but not limited to, attorney fees available under 35 U.S.C. § 285;

D. That the Court permanently enjoin Defendants and all those in privity with Defendants from making, having made, selling, offering for sale, distributing, and/or using products that infringe the '296 Patent and the '603 Patent, including the '296 Accused Products and the '603 Accused Products, in the United States; and

E. That Plaintiffs be awarded such other and further relief and all remedies available at law.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury on all issues triable to a jury.

Dated: November 15, 2017

Respectfully submitted,

/s/ Alfonso G. Chan

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